IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, AMERICAN COLLEGE OF PHYSICIANS, INC., AMERICAN PUBLIC HEALTH ASSOCIATION, INFECTIOUS DISEASES SOCIETY OF AMERICA, MASSACHUSETTS PUBLIC HEALTH ASSOCIATION D/B/A MASSACHUSETTS PUBLIC HEALTH ALLIANCE, SOCIETY FOR MATERNAL-FETAL MEDICINE, THE MASSACHUSETTS CHAPTER OF THE AMERICAN ACADEMY OF PEDIATRICS, JANE DOE 1, JANE DOE 2, and JANE DOE 3,

Plaintiffs,

vs.

ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; JIM O'NEILL, in his official capacity as Acting Director of Centers for Disease Control and Prevention; CENTERS FOR DISEASE CONTROL AND PREVENTION; and DOES 1–50, inclusive,

Defendants.

Case No. 1:25-cv-11916

PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE THIRD AMENDED COMPLAINT

District Judge: Hon. Brian E. Murphy
Magistrate Judge: Hon. M. Page Kelley

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I. INTRODUCTION

The federal immunization recommendation framework, which produces the evidence-based immunization schedules published on the website of the Centers for Disease Control and Prevention ("CDC"), is a structured, scientific, data-driven process that stakeholders in the vaccine ecosystem have relied on for decades as the nation's authoritative mechanism for evaluating and implementing vaccine safety, effectiveness, and population-level use. Under this framework, the Advisory Committee on Immunization Practices ("ACIP") conducts a systematic evidence review of vaccines using the GRADE (Grading of Recommendations Assessment, Development and Evaluation) methodology and the Evidence-to-Recommendation ("EtR") framework.[1] CDC then publishes the scientific, evidence-based rationale for the ACIP's vaccine recommendations in the Morbidity and Mortality Weekly Report ("MMWR"). This process (hereafter, the "ACIP recommendation process" or "ACIP framework") creates a transparent and nationally uniform evidentiary foundation for the CDC immunization schedules that physicians, medical practices, hospitals, patients, insurers, public health organizations, medical societies, and legislatures have grown to trust through the years.[2] Indeed, trust in the ACIP-recommendation process *was* so great that Congress and state legislatures explicitly incorporated ACIP recommendations into many laws such as the Affordable Care Act, the Vaccines for Children Program, Medicare Part D, and state school entry immunization requirements. *See* Third Amended Complaint ("TAC"), ECF 139, ¶¶ 31-37.

Defendant Robert F. Kennedy, Jr., Secretary of the United States Department of Health and Human Services (the "Secretary"), however, is waging an undeclared war against this long-

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[1] *See* Grace Lee, et al., *Updated Framework for Development of Evidence-Based Recommendations by the Advisory Committee on Immunization Practices,* 67 MORBIDITY & MORTALITY WKLY. REP. 1271 (Nov. 16, 2018), https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6745a4-H.pdf [https://perma.cc/BW7J-B48U].

[2] *Id.*

standing ACIP framework contrary to the United States' statutorily-mandated "goal of increasing rates of vaccination across all ages … to reduce and eliminate vaccine-preventable diseases." 42 U.S.C. § 245(a). Since taking office, the Secretary has repeatedly made statements and taken action that demonstrate that he is pursuing a policy to decrease access to vaccines and rates of vaccination and increase rates of vaccine skepticism, hesitancy, and denialism in the U.S. population writ large. *See, e.g.*, TAC, ¶¶ 38-43, 46-49, 51-58 (detailing the Secretary's actions to undermine trust in vaccines and his unlawful appointments to the ACIP). The Secretary has not, however, made a public pronouncement that explicitly states that these are his policy goals, but instead has made a myriad of ambiguous, inconsistent, or conflicting statements about what his vaccine policy is. On the other hand, one of his recent appointees to the ACIP, Robert Malone, recently stated publicly that "*[a]t the specific direction of the … Secretary*, major changes in public health and vaccine policies are being made by Secretary Kennedy's team with the assistance of the reconstituted and redirected ACIP. From ending universal COVID shots to uncovering manipulated RSV data, *the Secretary's team is reshaping the foundation of U.S. vaccine policy*."[3]

Assuming the truth of Malone's statement, all the Plaintiffs ask in this case is for the Secretary to be honest and transparent about his intentions—*i.e.*, *explain himself in good faith*. Plaintiffs are not, contrary to the assertion in Defendants' Motion to Dismiss ("MTD" or "ECF 145"), "requesting that the Court implement [Plaintiffs'] policy preferences." *See* ECF 145, p. 1. Instead, Plaintiffs ask three basic questions under the Administrative Procedure Act, 5 U.S.C. §§ 551, *et seq.* ("APA"): (i) are you changing United States policy on vaccines, (ii) are you following the proper procedure to do so, and (iii) if so, explain why. The APA requires the Secretary to provide "reasonable explanation" for a drastic change in vaccine policy. *See Dep't of Com. v. New*

[3] Robert Malone, *Malone News*, Substack, https://www.malone.news/ [https://perma.cc/8JC4-GQPX] (last visited Dec. 13, 2025) (emphasis added) (attached as Exhibit 1).

York, 588 U.S. 752, 785 (2019). If he fails to provide a reasonable explanation, then the actions challenged here must be set aside under the APA. Plaintiffs have stated plausible claims of violations of the APA, and the MTD should be denied in its entirety.[4]

II. FACTUAL BACKGROUND

A. Designation of the Covid-19 Vaccine as SCDM on the Childhood and Adult Immunization Schedules.

1. The Directive's Change to the Childhood and Adult Schedules

On May 27, 2025, the Secretary posted a video on social media platform X announcing that he had instructed the CDC to remove from its schedules the recommendation that pregnant women and children receive the Covid-19 vaccine. *See* TAC, ¶ 6. That same day, a written Secretarial Directive dated May 19 (the "Directive") was released that ordered the CDC to remove the Covid-19 vaccine from both the childhood and adult immunization schedules. *Id.* ¶ 6, 62. These actions sent shock waves through the vaccine ecosystem. *Id*. Curiously, even though the video and Directive unequivocally instructed the CDC to "remove" the Covid-19 vaccine from both schedules, the Covid-19 vaccine on the CDC's childhood and adolescent immunization schedule ("childhood schedule") was shortly thereafter changed to a "Shared Clinical Decision Making" ("SCDM") designation, not removed. *Id*. ¶ 64. No explanation was given for why the instruction to remove the Covid-19 vaccine from the childhood schedule was not followed. *Id*. ¶ 6. The Covid-19 vaccine recommendation with respect to pregnant women, however, was removed from the adult immunization schedule ("adult schedule"), *i.e*., changed to "No Guidance/Not Applicable." *Id*.

2. The ACIP's September 19 Vote that Changed the Adult Schedule

[4] Plaintiffs concurrently file with this Opposition the declarations of the individual party plaintiffs (Jane Does 1–3), the association plaintiffs, and members of those associations as Exhibits 2-39. These declarations provide further factual support for the harms alleged in the Third Amended Complaint and are incorporated into this Opposition in full.

On September 19, 2025, the Secretary's new ACIP voted that vaccination with the Covid-19 vaccine for individuals six months to 65 years of age should be "based on individual-based decision-making." *See id*. ¶ 7. This vote resulted in no change to the childhood schedule, because the Covid-19 vaccine was already designated as SCDM pursuant to the Directive. *Id*. ¶ 6. This vote, however, changed the adult schedule from a routine recommendation to a SCDM designation for Covid boosters. *Id*. ¶ 7. Before casting this vote, the ACIP did not apply the GRADE criteria or the EtR framework as prior ACIPs had done in the past when voting on the Covid-19 or any other vaccine. *See id*. ¶¶ 59–61. Nor did the CDC issue guidance on how to engage in SCDM discussions with patients as it had done in the four—and only four—times that the ACIP had previously voted to designate a vaccine as SCDM limited to very specific age groups. *See id*. ¶ 7; *see also* Ex. 17 (Goldman Decl.) ¶ 10.

3. Harm To Plaintiffs Caused by Changes to Both Schedules

Both the Directive, which resulted in the change of the Covid-19 vaccine to SCDM on the childhood schedule, and the ACIP's September 19 vote to change the routine recommendation of the Covid-19 vaccine to SCDM on the adult schedule, have harmed the individual Plaintiffs, physician members of the Plaintiff Organizations, and the Plaintiff Organizations.

i. The Directive

The Directive caused harm to the individual Plaintiffs. Both Jane Doe 1 and Jane Doe 2 were expecting their first child this past summer and wanted to get the Covid shot during the third trimester of pregnancy to protect the child during the first six months after birth; due to the confusion that the Directive created at pharmacies, they could not receive the vaccine despite repeated attempts. *See* TAC, ¶¶ 19, 20, 83, 84. Although both eventually were able to receive boosters before delivery, the stress and anxiety of becoming a first-time mother were exacerbated by the fear of not being able to receive a Covid booster that would protect their fetus and newborn

and by the aggravation of driving to and calling multiple pharmacies to ask if the pharmacy would administer to them what had previously been a routine vaccine for pregnant women. *Id*. The fear, anxiety, and aggravation manifested in loss of sleep, headaches, fatigue, and exacerbation of anxiety disorder, prenatal depression, clinically significant sleep disturbances, and teeth grinding. *Id*. Jane Doe 3's son suffered a panic attack at his second attempt to get a Covid booster before school started in the Fall after the pharmacist at the first attempt refused to give him the vaccine because of the Directive. *Id*. ¶ 21. The son's panic attack before the second attempt would not have happened but for the Directive. These are all cognizable injuries that occurred after the Directive was issued but before the ACIP vote on September 19.

Plaintiff Organizations were forced to divert resources to counter the confusion that the Directive created throughout the vaccine ecosystem. *Id*. ¶ 86. For example, over the summer, Plaintiff American Academy of Pediatrics ("AAP") diverted significant resources to guide its 67,000 members on the implications of the Directive, including updating guidance documents for pediatric practices, fielding additional calls and emails from AAP members seeking clarification about the implications of the Directive, holding webinars on navigating the implications of the Directive, developing a new policy statement "Recommendations for COVID-19 Vaccines in Infants, Children, and Adolescents" that was published online on August 19, and developing a new AAP immunization schedule. *See* Ex. 15 (Del Monte Decl.) ¶¶ 4–9.

Plaintiff American Public Health Association ("APHA"), too, was forced to divert substantial staff time and resources to work with public health administrators to reconcile the Secretary's Directive and the new CDC immunization schedule with the longstanding, evidence-based schedule that had previously guided Covid-19 vaccination practices and determined how APHA advised their communities. *See* Ex. 19 (Benjamin Decl.) ¶ 27. APHA member and Health

Officer for the Snohomish County Health Department in Washington state, Dr. James Lewis, has had to divert his attention from other duties to work on changing state and local laws to no longer defer to CDC guidance or ACIP recommendations because the "Directive and other actions by the Secretary … undermine trust in vaccines." *See* Ex. 21 (Lewis Decl.) ¶ 6.

The Directive's change to the childhood schedule harmed individual physician members of Plaintiff Organizations. For example, Dr. Molly O'Shea, who owns two pediatric practices in Michigan and is an AAP member, attested that, "[s]ince the Directive, fewer parents are getting their children vaccinated for anything, including Covid-19, than was the case before the Directive. *See* Ex. 38 (O'Shea Decl.) ¶ 11. The vaccine conversations are much longer and more difficult. The change in vaccine uptake and more time with each family is already resulting in financial harm to my practice that can be directly tied to the Directive because I typically am not able to bill for and therefore am not paid for the extra counseling time that the Directive has forced me to engage in. The Directive is making me provide extra counseling on the Covid-19 vaccine for free," which then cuts into her ability to see other patients. *See id*. ¶ 11.

Dr. Mary-Cassie Shaw, a pediatrician in North Carolina and AAP member, has seen families disengage with the healthcare system "because of their mistrust of the COVID-19 and other vaccines. The Directive . . . has caused financial harm to my practice by contributing to patients dropping out of my practice." *See* Ex. 16 (Shaw Decl.) ¶ 9.

Dr. Suzanne Berman, a pediatrician in Tennessee and AAP member, operates the only pediatric practice in her county and surrounding counties. *See* Ex. 11 (Berman Decl.) ¶ 11. Dr. Berman stocks the Covid-19 vaccine, and because only the Moderna Covid vaccine is authorized for children six months to 11 years old, she must order the Moderna vaccine for this age group at a cost of $847.10 per dose. *See id*. ¶ 16. The Directive, however, has led to "an increasing number

of parents starting with the presumption or default that their child should not get the Covid-19 vaccine," and has led to a decreasing number of parents consenting to their child getting the Covid-19 vaccine, citing the change to the CDC's immunization schedule as a reason. *Id.* ¶ 17. "The Directive's flipping of the recommendation to SCDM has and will result in continuing financial loss to my clinic" in uncompensated time spent on SCDM counseling and on being unable to return unused doses. *See id*. ¶¶ 17-18.

ii. The September 19 ACIP Vote

The ACIP's vote on September 19 that resulted in changing the adult schedule to SCDM for the Covid-19 vaccine has harmed physician members of Plaintiff Organizations. Dr. David Wheeler, member of Plaintiff Infectious Diseases Society of America ("IDSA") and American College of Physicians ("ACP"), attests:

> The recent ACIP recommendation, adopted by the CDC, which shifts the recommendation for Covid-19 vaccines to SCDM for adults under the age of 65, has caused me to spend more time during patient visits discussing the Covid-19 vaccine. There is no billable code that I can use to compensate me for the additional time now spent counseling patients who are resistant to vaccination. Due to this new uncertainty or confusion, on average, I spend about five minutes counseling each patient who is reluctant to receive a vaccine and I may see up to four such patients in a day, so this adds up to 20 minutes per day spent on non-reimbursable vaccine counseling. This is a significant opportunity cost because I could use this time to see an additional patient and get reimbursed for that time.

See Ex. 27 (Wheeler Decl.) ¶ 13. Dr. Sindhu Srinivas, President of the Society for Maternal-Fetal Medicine ("SMFM"), attests:

> SMFM members report that counseling patients about Covid-19 vaccination now requires an additional 10–20 minutes per patient, because patients arrive with confusion created by the Directive and ACIP's recent change to the CDC immunization schedule for Covid-19 vaccines to SCDM. The lack of clarity by the ACIP and CDC on what SCDM means for Covid-19 vaccines for pregnant women and the conflict with the Directive has increased consultation time and many SMFM members report not being able to be reimbursed for this increased consultation time, resulting in direct financial losses to SMFM members and their practices. These are quantifiable harms that did not exist prior to the Secretary's Directive, the recommendations approved by the reconstituted ACIP, and the

> CDC's recent changes to the CDC immunization schedule for Covid-19 vaccination for pregnant women.

See Ex. 34 (Srinivas Decl.) ¶ 13.

Furthermore, the Directive, the ACIP, and the CDC's "unexplained changes to the CDC immunization schedule for Covid-19 vaccination for pregnant individual[s] … has shifted the burden entirely to individual physicians to defend their medical advice on vaccination …. The deterioration of trust that SMFM physician members are experiencing right now in the exam room with their patients is a direct result of these recent actions by the Secretary, ACIP and CDC." *See* Ex. 34 (Srinivas Decl.) ¶ 15.[5]

The Directive and the ACIP's September 19 vote has also forced Plaintiff Organizations to divert resources to respond to the confusion caused by the policy shift for Covid-19 and other vaccines. SMFM has been "forced to divert substantial time, personnel, and resources away from its regular educational and policy initiatives described above in order to respond to the confusion caused by the policy shift. These efforts have included developing public communications, answering questions from members, correcting misinformation, and coordinating with other national medical associations to reaffirm the evidence-based guidance on Covid-19 vaccination

[5] The declarations submitted by the Plaintiff Organizations and their members (Exs. 2–39) uniformly confirm that the SCDM designation inflicts concrete harm on physicians and public health organizations. *See, e.g.*, Ex. 31 (Bornstein Decl.) ¶¶ 13, 22 ("A question about Covid-19 vaccines might once have taken a few minutes now routinely expands into a 10-minute discussion dominated by the conflict that now exists between my recommendation for Covid-19 vaccination and … the downgrade … to SCDM. These extended counseling sessions are not compensated…."); Ex. 24 (Pavia Decl.) ¶ 28 ("IDSA physicians report … they have been required to spend significantly more unbillable time counseling patients and answering questions from primary care physicians regarding Covid-19 vaccinations. Not only is this time unbillable, but it also infringes on the ability of IDSA physician members to see additional patients and receive reimbursement for that time."); Ex. 19 (Benjamin Decl.) ¶ 21; Ex 12, (Berman Decl.) ¶ 14 ("[M]y colleagues and I are spending increasingly more time counseling patients and their parents and performing work that is uncompensated as a result of the change to SCDM."); Ex 33 (Jaeger Decl.) ¶¶ 6, 8-9 ("SCDM … has shifted responsibility onto parents for understanding the relative risks and benefits of the Covid vaccine … the time necessary to adequately prepare a parent to make a medically sound decision far exceeds what is feasible in a typical 20-minute well child visit … This increased time burden directly harms my ability to provide complete, evidence-based pediatric care."); Ex 26 (Jhaveri Decl.) ¶¶ 11-15 ("The confusion and problems caused by downgrading to SCDM are further compounded by the fact that there is no shared or common understanding of what constitutes 'SCDM' … [and] the cumulative effect of engaging in SCDM with multiple patients every day results in more time spent engaging in work that is not compensable and that detracts from other pressing work.")

during pregnancy. These efforts are essential to mitigate ongoing harm, and they represent a significant and unplanned burden for SMFM." *See* Ex. 34 (Srinivas Decl.) ¶ 17; *see also* Ex. 19, (Benjamin Decl.) ¶¶ 17–29 (detailing harm to both members of the American Public Health Association and to the organization itself due to the Directive and the September 19 vote).[6]

B. The Secretary's Reconstitution of the ACIP

The Secretary sent further shockwaves through the vaccine ecosystem when he fired all 17 members of the ACIP in a *Wall Street Journal* commentary posted online on June 9, 2025. He justified the terminations with accusations that ACIP members had "persistent conflicts of interest," were "little more than a rubber stamp for any vaccine," and were "directly working for the vaccine industry." *See* TAC, ¶ 49. While his commentary cited reports of conflicts of interest from 1997, 2000, and 2009, none of the 17 terminated members were on the ACIP during those years. *Id* ¶ 50. Moreover, recent research on ACIP conflicts of interest indicated that conflicts were "at historic lows" and "had been virtually eliminated" among recent ACIP membership. *Id*. The Secretary promised that "[b]efore starting work on ACIP, the new members' ethics agreements will be made public." *Id*. To date, the Secretary has not fulfilled his promise.

The ACIP is required by law to have a charter. 5 U.S.C. § 9(c). The ACIP's Charter requires ACIP members to "be 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

[6] Dr. Benjamin further explains that APHA has ben compelled to divert substantial organizational resources to revise its flagship infectious-disease publications, which are core references relied on my members, including health departments, epidemiologists, and public health practitioners nationwide. *See* Ex. 19 (Benjamin Decl.) ¶¶ 28–29. APHA must now "reconvene editorial contributors, reassess affected chapters, and update guidance to reconcile the scientific evidence with the new CDC immunization schedule recommendations on Covid-19 vaccines," redirecting staff away from ongoing public health priorities. *Id.* The Secretary, ACIP, and CDC's break from the evidence-based process for vaccine recommendations has also weakened APHA's reputation as a reliable conduit of guidance, requiring APHA to expend additional resources to restore confidence in its communications. *See id*.

in assessment of vaccine efficacy and safety." *Id.* ¶ 45. Current ACIP members, however, include a gynecologist, a doctor who has studied myocardial inflammation, a neuroscientist, a professor of operations management, an emergency medicine physician, and a liver transplant doctor. *Id.* ¶ 54. The Federal Advisory Committee Act, 5 U.S.C. §§ 1001, *et seq*. ("FACA"), requires the ACIP to be "fairly balanced" and forbids "inappropriate[] influence[]" by the Secretary. *Id.* ¶ 8. Eight of the Secretary's appointments to the ACIP have publicly stated anti-vaccine views that align with the Secretary's. *See id.* ¶ 55.

III. ARGUMENT

A. The Challenge to the Directive Is Not Moot.

A case becomes moot only when "it is impossible for a court to grant any effectual relief whatever to the prevailing party." *Knox v. Serv. Emps. Int' Union, Loc. 1000*, 567 U.S. 298, 307 (2012) (citation modified). As long as any Plaintiff has a concrete interest, "however small, in the outcome of the litigation, the case is not moot." *Id.*; *see also Chafin v. Chafin*, 568 U.S. 165, 172 (2013); *Campbell-Ewald Co. v. Gomez*, 577 U.S. 153, 161 (2016).

In the MTD, Defendants mischaracterize the September 19, 2025 ACIP vote on the Covid-19 vaccine as replacing the Directive. *See* ECF 145, p. 9 ("on October 6, 2025, CDC replaced the immunization schedules from this summer, which had implemented the Directive"). The September 19 ACIP vote did not replace the Directive with respect to the *childhood* schedule, let alone withdraw or rescind the Directive. Only the *adult* schedule changed as a result of that vote, not the childhood schedule. Moreover, even if the Directive were replaced, withdrawn, or rescinded by the September 19 ACIP vote, voluntary cessation of a challenged practice does not deprive a federal court of its power to determine the legality of the practice. *Knox*, 567 U.S. at 307 ("The voluntary cessation of challenged conduct does not ordinarily render a case moot because a dismissal for mootness would permit a resumption of the challenged conduct as soon as the case

is dismissed."); *see also Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc*., 528 U.S. 167, 189 (2000).

In order for a case to be moot, intervening events must "have completely and irrevocably eradicated the effects of the parties' conduct in order for a case to be deemed moot." *Town of Barnstable v. O' Connor,* 786 F.3d 130, 142 (1st Cir. 2015) (citation modified) (quoting *County of Los Angeles v. Davis*, 440 U.S. 625, 631 (1979)). Before the September 19 ACIP vote, only the childhood schedule, which is applicable to those six months to 17 years old, designated the Covid-19 vaccine as SCDM per the Directive. The September 19 vote expanded the population of those covered by the SCDM designation for the Covid-19 vaccine from those under 18 to everyone under the age of 65. Plaintiffs have submitted scores of declarations attesting to the harm that the change from a routine recommendation to SCDM caused the Plaintiffs. Thus, far from eradicating the effects of the Directive, the September 19 ACIP vote to designate the Covid-19 vaccine as SCDM for everyone under 65 perpetuated and increased the harm that the Directive caused during the preceding four months. Moreover, neither the ACIP nor CDC have explained whether the September 19 vote superseded the Directive's command to the CDC to remove the recommendation that pregnant women receive the Covid-19 vaccine or whether the Directive's instruction regarding pregnant women remains in force. *See* Ex. 34 (Srinivas Decl.) ¶ 13 (noting that the SCDM designation for individuals six months through age 64 "conflict[s] with the Directive."). The Defendants' mootness argument is wholly without merit.

B. The Plaintiff Medical and Public Health Associations Have Established Organizational Standing.

Organizational standing exists when the challenged conduct causes "'concrete and demonstrable injury to the organization's activities' together with a 'consequent drain on the organization's resources' that is 'more than simply a setback to the organizations' abstract social

interests.'" *Am. Ass'n of Univ. Professors v. Rubio*, 780 F.Supp.3d 350, 379 (D. Mass. 2025) (quoting *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982)). In the First Circuit, "[i]t is a bedrock proposition that a relatively small economic loss – even an identifiable trifle – is enough to confer standing." *Massachusetts v. U.S. Dep't of Health and Hum. Servs.*, 923 F.3d 209, 222 (1st Cir. 2019) (citation modified). Thus, if a plaintiff's core service is "perceptibly impaired by the defendant's actions," organizational standing is satisfied. *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982). In *Havens*, as described by the Supreme Court in *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367, 395 (2024), the "[defendant] gave [plaintiff's] employees false information, … [which] directly affected and interfered with [plaintiff's] core business activities." Thus, in *Havens*, the plaintiff established standing because of the direct interference with the plaintiff's core business activities, whereas in *Hippocratic Medicine*, plaintiffs did not establish organizational standing because they did not allege "any similar impediment" to their core business activities. *Havens*, 455 U.S. at 379; *Hippocratic Medicine*, 602 U.S. at 395.

This case aligns squarely with *Havens*, whereas *Hippocratic Medicine* is clearly distinguishable.[7] While each of the Plaintiff Organizations in this case serve different populations, a mission common to all of the Plaintiff Organizations in this case is to enhance the quality and effectiveness of health care services in this country and to assist and support their members' delivery of health care services consistent with the applicable standard of care. The actions

[7] In *Hippocratic Medicine*, 602 U.S. at 372-73, anti-abortion doctors and their medical associations challenged the FDA's relaxing of restrictions on the prescribing of mifepristone, a drug used to terminate pregnancies up to seven weeks. The plaintiff doctors and medical associations themselves did not prescribe mifepristone, and federal conscience laws protected them from being forced to do so. *Id.* at 387. Thus, their objection to the FDA's action was an objection to mifepristone being prescribed *by others*. *Id.* at 388-89. The Supreme Court held that the plaintiff medical associations could not establish organizational standing simply because they incurred costs to object to an action that they objected to on ideological grounds but that did not impair their core business activities. *Id.* at 395 (an organization "cannot spend its way into standing simply by expending money to gather information and advocate against the defendant's action" based on moral objections to an action that did not impose "any similar impediment to the medical associations' advocacy business.").

challenged here—the Directive, the packing of the ACIP with vaccine skeptics and deniers, and the ACIP's September 19 vote to designate the Covid-19 vaccine SCDM for everyone under 65—all fundamentally and directly interfere with this mission. As Dr. Srinivas, President of SMFM declares, the "Directive has directly impacted SMFM physician members' ability to provide the optimal standard of care," because Directive the overrides "their clinical judgment, which is rooted in years of medical training, board certification in maternal-fetal medicine, and reliance on data from peer-reviewed literature and prior CDC/ACIP recommendations ...." *See* Ex. 34 (Srinivas Decl.) ¶ 11. Dr. Benjamin, Executive Director of the APHA, declares that the challenged actions have eroded public trust in APHA members and led to the questioning of APHA members' professional competence and integrity, which "directly impair the APHA members' ability to protect their communities—one of their core professional duties." *See* Ex. 19 (Benjamin Decl.) ¶ 20. Because of the direct impact the challenged actions have had on AAP's core mission, Plaintiff AAP has been "forced [at] all levels of the AAP to divert significant time away from other tasks and initiatives related to child health … to attempt to clear up the confusion and diminish the chaos the Directive has, unfortunately and unnecessarily, generated." *See* Ex 15 (Del Monte Decl.) ¶ 9.[8]

The initiatives that Plaintiff Organizations have had to take to address the fallout from the challenged actions are not, as Defendants mischaracterize, "a continuation of [the organizations'] 'ongoing activities.'" Indeed, Plaintiff Organizations would not be undertaking these new activities and initiatives to combat Covid-19 vaccine and other misinformation but for the Secretary's actions challenged here. There is no legitimate question that Plaintiffs have organizational standing. *See Diamond Alt. Energy, LLC v. EPA*, 606 U.S. 100, 113 (2025).

[8] Indeed, each Plaintiff Organization and its members have been forced to redirect considerable time and resources to responding to the confusion and disruption stemming from the SCDM recommendation for the Covid-19 vaccine. *See* Ex. 17 (Goldman Decl.) ¶ 11; Ex. 19 (Benjamin Decl.) ¶¶ 25-30; Ex. 24 (Pavia Decl.) ¶¶ 22-24, 26, 28; Ex. 25 (LaRocque Decl.) ¶¶ 16-19; Ex. 32 (Pavlos Decl.) ¶¶ 17, 20-23; Ex. 34 (Srinivas Decl.) ¶¶ 10, 16-18, 22.

C. The Plaintiff Medical and Public Health Associations Have Established Associational Standing.

Associational standing is established here because the doctors who have submitted declarations in this case unquestionably could sue in their own right. First, the doctor-declarants have suffered financial injury, including engaging in SCDM conversations without compensation, absorbing the full cost of purchasing vaccine doses that go unused due to the Directive's suppression of vaccine uptake, and being able to see fewer patients per day due to the increased amount of time spent with patients discussing vaccines.[9] These financial losses are more than a trifle, and "a relatively small economic loss – even an identifiable trifle – is enough to confer standing." *Massachusetts v. U.S. Dep't of Health and Hum. Servs.*, 923 F.3d 209, 222 (1st Cir. 2019) (citation modified). Second, the final agency actions challenged here have interfered with physicians and their practice's ability to do their jobs, which alone is sufficient to establish standing.[10] *See Havens,* 455 U.S. at 379 (where defendants' racially discriminatory steering

[9] *See, e.g.*, Ex. 6 (O'Shea Decl.) ¶¶ 8, 10–11 ("I have had to dedicate time and resources to developing a plan for complying with the SCDM requirement … [t]his has caused a direct financial impact on my practices, as none of that time I've spent developing these plans and protocols is reimbursable or billable…My practices have also had to forego our annual flu and Covid-19 vaccination clinics as a result of the CDC's downgrade of the Covid-19 vaccine recommendation for children…to SCDM."); Ex. 8 (Scott-Vernaglia Decl.) ¶¶ 17, Ex. 10 (Boyce Decl.) ¶ 13; Ex. 11 (Berman Decl.) ¶¶ 15–16, 19 (likely not to be reimbursed or to be able to return vaccine doses that cost $104.54/dose or $847/dose); Ex. 12 (Berman Supp. Decl.) ¶¶ 14–16; Ex. 13 (Andreae Decl.) ¶ 14 ("losing about $150/day" in uncompensated time because of "vaccine refusal rates tied to the Directive"); Ex. 14 (Andrae Supp. Decl.) ¶ 18 ("SCDM conversations forces me and my colleagues to devote substantial work time after office hours to complete documentation or other tasks not completed during or between wellness visits … SCDM is causing more and more work to be performed without compensation resulting in … lost earnings."); Ex. 7 (Shaw Decl.) ¶¶ 7–8; Ex. 17 (Goldman Decl.) ¶ 11; Ex. 18 (Hopkins Decl.) ¶¶ 25, 36 ("There is no payment for vaccine counseling which does not result in a vaccine being administered, which accounts for approximately 20–25% of the SCDM conversations in my practice."); Ex. 24 (Pavia Decl.) ¶¶ 26, 28; Ex. 25 (LaRocque Decl.) ¶ 17; Ex. 26 (Jhaveri Decl.) ¶¶ 13, 15 ("SCDM discussion that takes 10 or even 20 minutes is 10 or 20 minutes of time that is not reimbursed and that accumulates into hours additional work…."); Ex. 27 (Wheeler Decl.) ¶¶ 11–15; Ex. 28 (Chen Decl.) ¶ 20; Ex. 31 (Bornstein Decl.) ¶¶ 13–14; 24–25; Ex. 33 (Jaeger Decl.) ¶¶ 8–9; Ex. 36 (Ramsey Decl.) ¶¶ 7, 10, 12–17.

[10] *See, e.g.*, Ex. 10 (Boyce Decl.) ¶ 9; Ex. 14 (Andreae Supp. Decl.) ¶ 19; Ex. 7 (Shaw Decl.) ¶ 7; Ex. 24 (Pavia Decl.) ¶ 23; Ex. 25 (LaRocque Decl.) ¶ 18; Ex. 26 (Jhaveri Decl.) ¶¶ 11, 14–15 ("[T]he quality and quantity of time spent on issues at the core of the wellness visit suffer because of the downgrading of the Covid-19 vaccine from routinely recommended to SCDM."); Ex. 27 (Wheeler Decl.) ¶¶ 8–9, 11, 14, 16 ("ACIP, supported by the CDC staff—function as the brain of the system … [and] [c]ommunity infectious disease physicians like me serve as the arms and fingers of that system. Our role as physicians is to take … evidence-based recommendations from ACIP and the CDC and implement them in the real world …. ACIP did not provide me with the guidance I need to understand the change and apply it. This has further complicated my counseling process with patients and providers who ask me

practices "have perceptibly impaired [plaintiff's] ability to provide counseling and referral services for low- and moderate-income homeseekers, there can be no question that the [plaintiff] has suffered injury in fact"). Third, the Secretary's threat of legal liability for administering vaccines contrary to CDC guidance also demonstrates sufficient harm.[11] *See 303 Creative LLC v. Elenis*, 600 U.S. 570, 597 (2023) (wedding website designer who preemptively proclaimed she would not design a website for a same-sex couple had standing even though no same-sex couple had tried to engage her services because a credible threat of legal consequences existed).[12]

To answer Justice Scalia's famous question—"What's it to you?"—doctors in this case have a "personal stake" in not suffering financial loss, in being able to practice medicine consistent with their applicable standard of care,[13] in not being sued, and in keeping their license to practice medicine, all of which are directly affected by the change of the Covid-19 vaccine routine recommendation to an SCDM designation. Contrary to Defendants' assertions, these injuries are not too attenuated from the challenged actions or too speculative to be actionable but instead are directly in the causal chain from action to injury.

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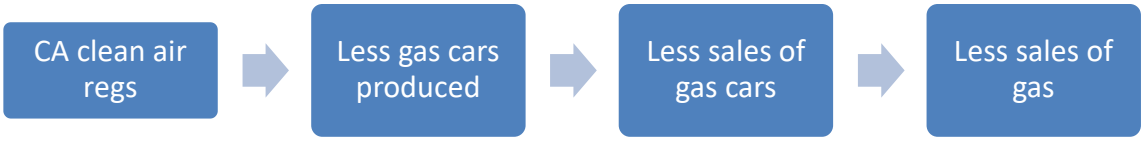
for guidance on the Covid-19 vaccine…."); Ex. 28 (Chen Decl.) ¶¶ 18–22 ("SCDM is like adding a ten-page consent form to a ferris wheel ride that has always been safe, creating doubt and uncertainty where none previously existed, which adds time to the physician-patient counseling discussions to overcome new mistrust."); Ex. 30 (Pring Decl.) ¶ 25; Ex. 31(Bornstein Decl.) ¶¶ 10, 12, 20–23; Ex. 33 (Jaeger Decl.) ¶¶ 7, 14 ("The Directive and recent actions by the ACIP and CDC are interfering with my ability to provide the standard of care…."); Ex. 35 (Rouse Decl.) ¶¶ 11; Ex. 36 (Ramsey Decl.) ¶ 10–14, 17.

[11] On the same day that the AAP issued its own evidence-based immunization schedule, the Secretary posted on X that "AAP today released its own list of corporate-friendly vaccine recommendations … AAP should also be candid with doctors and hospitals that recommendations that diverge from the CDC's official list are not shielded from liability under the 1986 Vaccine Injury Act." *See* TAC, ¶ 86.

[12] Physicians also report that the Secretary, ACIP, and CDC's changes to the CDC immunization schedule for Covid-19 vaccination expose them to liability. *See, e.g.*, Ex. 14 (Andreae Decl.) ¶ 20; Ex. 33 (Jaeger Decl.) ¶ 14 ("[B]y following … professional guidelines I know that I am now potentially placing myself at odds with the federal directive. I am exposing myself to malpractice liability, jeopardizing my medical license, and facing disciplinary action ….")

[13] *See Cain v. Niemela*, 2020 WL 4249161, at *6 (Mich. Ct. App. July 23, 2020) ("A plaintiff in a medical malpractice action must establish, among other elements, the applicable standard of care governing the defendant doctor's actions and that the defendant doctor breached that standard." (citation modified) (quoting *Elher v. Misra*, 878 N.W.2d 790, 795 (Mich. 2016)); *Palandjian v. Foster*, 842 N.E.2d 916, 920 (Mass. 2006) ("To prevail on a claim of medical malpractice, a plaintiff must establish the applicable standard of care and demonstrate both that a defendant physician breached that standard, and that this breach caused the patient's harm.").

The Supreme Court's recent *Diamond Alternative Energy* decision is on all fours with this case. There, the plaintiffs, gasoline producers, alleged the following chain of causation from California clear air regulations aimed at reducing carbon emissions to their injury:



See Diamond Alt. Energy, 606 U.S. at 105. The gas producers' theory of causation and redress thus depended on the actions of multiple third parties, *i.e.*, "without California's regulations in effect, manufacturers would likely make more cars powered by gasoline and other liquid fuels, thereby increasing purchases of those fuels and redressing the fuel producers' injury." *Id*. The Supreme Court held this chain of causation sufficient to confer standing because "a court must conclude that third parties will likely react to the government regulation … in predictable ways that will likely cause (or redress) the plaintiff's injury." *Id.* at 112 (citation modified); *see also Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 155 (2010) (FDA's deregulation of genetically-engineered alfalfa seed created a "reasonable probability" of contamination of organic or conventional alfalfa crops that, in turn, created a need for organic farmers to test their crops for contamination, an expense they previously had not incurred. "Such harms, which respondents will suffer even if their crops are not actually infected with the [genetically-engineered] gene, are sufficiently concrete to satisfy the injury-in-fact prong of the constitutional standing analysis" and were "readily attributable to [the] deregulation decision.").

Here, as in *Diamond Alternative Energy* and *Monsanto,* patients have indeed reacted predictably to the false information that the Secretary has spread about the Covid-19 vaccine—they have believed or credited the statements of this country's highest-ranking health official—which has impaired the ability of doctors to practice medicine consistent with the standard of care

and has caused them financial loss. This is injury in fact, and the Plaintiffs have established associational standing.

D. The Individual Plaintiffs Have Standing

All three individual plaintiffs have suffered concrete injuries traceable to the Directive and related changes to the CDC vaccination schedule, which are redressable by this Court. These injuries include loss of access to the Covid vaccine, physical harms, financial harms, and lost time spent navigating the confusion that directly resulted from these policy changes. *See TransUnion, LLC v. Ramirez*, 594 U.S. 413, 425 (2021) ("[C]ertain harms readily qualify as concrete injuries under Article III. … If a defendant has caused physical or monetary injury to the plaintiff, the plaintiff has suffered a concrete injury in fact under Article III."); *Tignor v. Dollar Energy Fund, Inc.*, 745 F.Supp.3d 189, 201 (W.D. Pa. 2024) (fear, anxiety, and stress were sufficient, concrete injuries).

E. Count II States a Plausible Claim for Relief Under the Administrative Procedure Act.

The First Circuit's decision in *Union of Concerned Scientists v. Wheeler*, 954 F.3d 11, 20 (1st Cir. 2020) is dispositive of Defendants' 12(b)(6) motion on this count. There, the First Circuit reversed the district court's dismissal of the plaintiffs' claims that an EPA federal advisory committee was not fairly balanced and was inappropriately influenced by the appointing official in violation of FACA. The First Circuit noted that while FACA contains no private right of action, the APA "generally provides a vehicle for reviewing agency decisions that are alleged to violate federal law." *Union of Concerned Scientists*, 954 F.3d at 17. The court then held that:

> FACA requires EPA to maintain a fair balance on its committees and to avoid inappropriate influences by both the appointing authority and any special interest. Plaintiffs allege that the directive skewed the composition of EPA committees in favor of regulated industries. They further allege that the EPA offered no rational reason for finding that any benefits of the policy justified the alteration of balance and influence on the committees. Indeed, the allegation is that the EPA did not even

> acknowledge that the directive had such an effect.[14] These allegations plausibly state claims for judicial review under the APA.

Id.

Union of Concerned Scientists compels the denial of Defendants' 12(b)(6) motion to dismiss Count II. Count II states a plausible claim that the Secretary violated FACA with his appointments of the current members of the ACIP and that he has inappropriately influenced the current ACIP. *See* TAC, ¶¶ 46–56, 73–82. The following undisputed sequence of events indicates that the Secretary rigged the ACIP in violation of FACA and the APA to further his vaccine policy goals:

June 9, 2025	Secretary fires all 17 members of the ACIP.[15]
June 11, 2025	Secretary announces the appointment of eight new members to the ACIP.[16]
August 27, 2025	Secretary fires Susan Monarez, CDC Director.[17]
August 29, 2025	Secretary appoints Jim O'Neill Acting CDC Director.[18]
September 11, 2025	Secretary announces the appointment of four new ACIP members.[19]
September 17, 2025	Monarez testifies before the Senate Finance Committee that the Secretary "directed me to commit in advance to approving every ACIP recommendation, regardless of the scientific evidence."[20]
September 19, 2025	ACIP votes in favor of SCDM for the Covid-19 vaccine for everyone under 65.[21]

[14] The directive at issue in *Union of Concerned Scientists* was one that "disqualifie[d] thousands of scientists [who were grant recipients] affiliated with academic and not-for-profit institutions. And precisely because those scientists … tend to be leaders in their fields, the directive is said to target many of the most knowledgeable scientists who are not affiliated with industry. … As a result, the plaintiffs allege that the directive has quickly and materially increased the participation of industry-affiliated scientists on EPA committees." *Union of Concerned Scientists*, 954 F.3d at 15.

[15] *See* TAC ¶¶ 46–48.

[16] *Id.* ¶ 53.

[17] *Id.* ¶ 72.

[18] *See* Emily Anthes, *Who Is the New Acting C.D.C. Director?*, N.Y. TIMES (Aug. 29, 2025), https://www.nytimes.com/2025/08/29/health/james-oneill-cdc.html? [https://perma.cc/W48U-TDGE] ("The pick leaves the nation's premier public health agency under the leadership of an official without medical or scientific training.").

[19] *See* TAC ¶¶ 53–54.

[20] *See Restoring Trust Through Radical Transparency: Reviewing Recent Events at the Centers for Disease Control and Prevention and Implications for Children's Health*, Senate HELP Committee Hearing (Sept. 17, 2025), https://www.help.senate.gov/imo/media/doc/e7a31f2a-d31c-42bb-1a9538e6abef8195/Monarez%20Testimony.pdf

[21] *See* TAC ¶¶ 73–75.

October 6, 2025	O'Neill endorses the ACIP's September 19 vote.[22]

These facts state a plausible claim that the Secretary's reconstitution of the ACIP violated FACA's "fairly balanced" and "inappropriately influence" provisions and, therefore, violated the APA. Plaintiffs should be allowed to move forward on this claim. *See Union of Concerned Scientists*, 954 F.3d at 22 (allowing plaintiffs to move forward on their claim that "the challenged EPA action was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law precisely because the EPA failed to rationally consider and explain the effects of the directive under FACA's standards.").

The First Circuit also blessed the type of relief that Plaintiffs seek here. The court noted that if plaintiffs "are successful and the EPA is forced to abandon the directive, grant recipients will again be permitted to sit on the EPA's committees. So long as there is some concrete interest, however small, in the outcome … the case is not moot." *Union of Concerned Scientists*, 954 F.3d at 22-23 (citation modified); *see also Nat'l Ass'n of Consumer Advocs., et al. v. Uejio,* 521 F.Supp.3d 130, 144–46 (D. Mass. 2021) (plaintiffs had standing to challenge composition of Federal Consumer Financial Law Taskforce, and if plaintiffs proved on the merits that Taskforce violated FACA requirements, then plaintiffs were entitled to a declaration that Taskforce and all of its actions could be set aside and Taskforce could be enjoined from meeting or conducting any business).

IV. CONCLUSION

Based on the foregoing facts, arguments, and authorities, Defendants' Motion to Dismiss should be denied in its entirety.

[22] *See id.* ¶ 7.

Dated: December 3, 2025

Respectfully submitted,

By: *James J. Oh*

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CERTIFICATE OF SERVICE

I hereby certify that this document was filed through the the Court's CM/ECF System on this 3rd day of December 2025 which will send notification to the following parties:

Robert F. Kennedy, Jr., in his official capacity as Secretary of Health and Human Services

Jim O'Neill, in his official capacity as Acting Director of the Centers for Disease Control and Prevention

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EXHIBIT 1

The MAHA and MEHA Movements- A View from Across the Atlantic

Invited address at the European Parliament in Brussels by Dr. Robert Malone

DR. ROBERT W. MALONE
OCT 16, 2025

304 56 38 Share



I have been in Brussels at the European Union to deliver the keynote speech for the "Make Europe Healthy Again" organization and conference, hosted by the Patriots for Europe. This movement is growing throughout Europe - almost every seat in the auditorium was filled!

Below is the full video that Jill made of the speech (the angle is off - but it was the best she could do), followed by the text:



The MAHA and MEHA Movements- A View from Across the Atlantic

For members of the press or others unfamiliar with my qualifications, I am a US Licensed Physician, and a well-qualified medical scientist trained at the University of California, the Salk Institute and both Northwestern and Harvard Medical Schools. I have experience and expertise in vaccine development, immunology, biochemistry, molecular biology, clinical research, and regulatory affairs. I was the original inventor of manufacturing, delivering and using synthetic mRNA as a drug including for vaccination purposes. I currently serve as a medical advisor to MAHA action, and as co-chairperson to the CDC Advisory Committee on Immunization Practices.

My primary purpose is to brief this meeting about "Make America Healthy Again" initiatives including the ongoing reforms at the US Centers for Disease Control and Prevention, and in particular the CDC Advisory Committee on Immunization Practices. I am not here to advise or even to pretend to fully understand European politics or the "Make Europe Healthy Again" movement. My hope is that the progress being made by the grass roots bipartisan MAHA movement in the United States can provide examples which may be useful to the MEHA movement in Europe.

The opinions expressed here are my own, and do not necessarily represent those of the US Government, the US Centers for Disease Control and Prevention, or the CDC Advisory Committee on Immunization Practices.

Medical Ethics and the Principle of Subsidiarity

I hope and trust that you share my strong support for both individual informed consent (as defined in the Nuremberg accords and Helsinki Agreement) as well as the Principle of Subsidiarity enshrined in Article 5(3) of the Treaty on European Union (TEU).

In my opinion, in medical treatment matters, the patient is the lowest effective level of governance, for, if we are not allowed to govern our own bodies and what medical treatments we accept, then there is no personal freedom and there can be no proportionality.

The cornerstone of this ethical structure is the principles of patient Informed Consent, which were widely violated during COVID. In a free society, citizens must have the freedom to decide what medical procedures they wish to accept for themselves and their children. They must be provided complete, transparent access to the full spectrum of information concerning risks and benefits of a procedure, including vaccination. And they must be allowed to choose whether to accept a medical procedure – whether or not it is experimental- without being subjected to coercion, compulsion, or enticement. The interests of the collective society should not outweigh the rights of the individual to bodily autonomy.

The principle of subsidiarity was introduced in the Maastricht Treaty of 1992 and reinforced in the 2009 Lisbon Treaty to balance EU integration with national sovereignty due to ongoing bureaucratic "competence creep," which is very similar to the "mission creep" seen with the CDC and many other US Federal agencies. More about that later.

As a reminder, this brilliant foundational component of the Treaty on European Unity in article 5, section 3 states that;

> "*Under the principle of subsidiarity, in areas which do not fall within its exclusive competence, the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level.*
>
> *The institutions of the Union shall apply the principle of subsidiarity as laid down in the Protocol on the application of the principles of subsidiarity and proportionality. National Parliaments ensure effective implementation of the principle of subsidiarity through the procedure set out in that Protocol.*"

In my opinion, the current European Council appears to be routinely violating this central European treaty principle. The bizarrely counterproductive decisions centrally

made and then forced on EU member states and citizens in the name of "public health" during COVID illustrate the consequences of permitting routine violations to Article 5 Section 3.

The toll in economic and social damage, sickness, death and loss of faith and legitimacy for public health and the healing professions is profound, and cannot be easily repaired.

Consequent to this heavy handed mismanagement, we now face a similar crisis of confidence in public health and medical caregiver legitimacy in the United States. The big difference in the political climate and affairs between the US and the European Union is the outcome of the recent leadership elections. You have Ursula von der Leyen and we have Donald Trump- and his close ally Robert F. Kennedy Junior.

President Trump and Secretary Kennedy share a deep, longstanding commitment to the overall health of the citizens that they serve, and in particular to America's children. With all of the rhetoric and weaponized hate currently deployed against both of these transformational leaders, what is often overlooked is that they are unified in their commitment to a better future for our children.

It is long past time for this political, social, and governmental commitment. As President Trump has often pointed out, data demonstrate that if nothing is done, America's children will live shorter, sicker lives than those of their parents.



The MAHA Commission

To understand and fix this situation, President Trump has launched an all-of-government response, in some ways similar to what he did for COVID with Operation Warp Speed, and has put Secretary Kennedy in charge of this new initiative. It is called the MAHA Commission.

The Presidential Make America Healthy Again (MAHA) Commission was established by Executive Order on February 13, 2025, shortly after Robert F. Kennedy Jr.'s confirmation as HHS Secretary. Chaired by Kennedy, the 14-member commission includes leaders from HHS, USDA, EPA, NIH, FDA, and other agencies. Its mission focuses on addressing the childhood chronic disease epidemic (e.g., obesity, diabetes, autism, mental health disorders) by identifying root causes like poor diet, environmental toxins, overmedicalization, and inactivity.

There has never been such a candid and comprehensive response to a public health crisis in the history of the United States.

So far, the commission has released two key reports:

The first was essentially a threat assessment. On May 22, 2025, the "Make Our Children Healthy Again: Assessment" was published – a 72-page analysis identifying a wide range of factors driving the decline in children's health such as ultra-processed foods, chemical exposures, chronic stress, and unnecessary medications. It outlined 10 initial research initiatives and called for federal restructuring.

The second was an action plan. On September 9, 2025: "Make Our Children Healthy Again: Strategy" was published. This is a comprehensive plan of action with over 120 initiatives, emphasizing executive actions to promote nutrition, reduce toxins, enhance transparency, and realign incentives. To guide implementation of these actions, it proposed creating a new agency within the US HHS called the *Administration for a Healthy America (AHA)*.

The strategy organizes initiatives into four pillars: advancing science, realigning incentives, raising awareness, and fostering collaboration. Many aspects of this plan may appear quite radical to Europeans. I will briefly summarize the key Pillars of this plan;

In the area of Nutrition & Food Policy-

· Revamp Dietary Guidelines for Americans to prioritize whole foods, limit ultra-processed items, and ban synthetic dyes.

· Remove restrictions on whole milk in schools; encourage states to waive SNAP benefits for sugary drinks/candy.

· Define/label ultra-processed foods; improve school/military meal standards (e.g., more fresh produce).

· Promote low-carb/whole-food diets in guidelines and education.

For the Environmental Toxins & Chemicals Pillar-

· Phase out petroleum-based synthetic food dyes; review GRAS status (generally recognized as safe) for food additives.

· Assess/reduce pesticide exposure (e.g., glyphosate, atrazine) via EPA reviews, though these policies have been softened from initial proposals.

· Remove fluoride from water supplies; study electromagnetic radiation and heavy metals in soil/water.

· Link soil health to human health through farmer support programs and research.

Regarding Physical Activity & Lifestyle-

· Re-establish Presidential Fitness Test in schools; fund afterschool activity programs.

· Partner with President's Council on Sports, Fitness, and Nutrition to combat child inactivity.

· Integrate nutrition/lifestyle education into medical schools and public awareness campaigns.

Medications & Overmedicalization is a particular focus-

· Review over-prescription of SSRIs, antipsychotics, stimulants, and weight-loss drugs for children.

· Ensure "most-favored-nation" drug pricing; ban direct-to-consumer pharma ads.

· Phase out animal testing for drugs/chemicals; lift bans on Category 2 peptides.

· Full transparency on vaccine data; reconstitute ACIP to eliminate conflicts of interest.

For the Research & Transparency Pillar-

· Fund $50M for autism/chronic disease research; close data gaps on root causes.

· Eliminate industry influence via ethics frameworks and transparency rules.

· Hold public hearings/roundtables; evaluate federal programs for effectiveness.

And the Final Pillar, Institutional Reforms-

· Create Administration for a Healthy America (AHA) to coordinate chronic disease efforts.

· Fire/replace conflicted CDC/NIH officials; cut $500M from mRNA projects.

· Align 30+ states with MAHA policies; prosecute misuse of public health funds.

Are these just words, or has there been progress?

· Under Secretary Kennedy's leadership, HHS has already advanced special nutrition program waivers, dietary reforms, and ACIP reconstitution. To date, the strategy emphasizes private-sector partnerships (e.g., with farmers) and public engagement.

· However, there have been setbacks. Agriculture lobbies have influenced pesticide language, drawing criticism from environmental groups and the general public – particularly in alternative media. Broader reforms face budget hurdles and congressional obstructionism.

· Broader, long term goals include reducing childhood obesity (from 20% to under 10% by 2030), cutting chronic disease rates, and reorienting the entire medical system from a focus on treating illness to promoting health, thereby saving trillions in healthcare costs through disease prevention.

Changes at CDC and ACIP

To illustrate how these plans are being translated into action and policy, I will now focus on the ongoing reforms at the US Centers for Disease Control and Prevention (CDC). There are multiple factors driving these changes.

In the United States, we have more protections in place to insure patient level data privacy than exist throughout much of Europe. This creates obstacles to implementing emerging big data technologies and solutions. One consequence of this is that it is more difficult to gather and analyze data necessary to guide public health policy decisions, and when gathering and assessing these data there is much more opportunity to introduce a variety of biases including confirmation bias.

Conflicting Mandates of "promotion versus protection"

Like many US Federal agencies, the CDC suffers from conflicting mandates. In the case of vaccines, it is tasked with gathering information on the safety and effectiveness of vaccines, but also tasked with promoting vaccines and vaccination. This creates an intrinsic conflict of interest within the agency that remains unresolved. There has been more emphasis and budget for promoting vaccination, which has driven development of a cult-like focus on maximizing vaccine uptake. This has pervaded the entire medical services sector, to the point that any attempt to objectively and rigorously evaluate vaccine safety and efficacy is regarded as a systemic cultural threat to public health. The interests and culture of public health and those of the vaccine industry have become inseparable, and are not allowed to be questioned.

The Overton window of acceptable public discourse concerning vaccines is functionally closed, with layers of gatekeepers in corporate media, academia, medical guilds, industry marketing, scientific journals and political parties all focused on preventing any objective scientific evaluation of vaccine risks and benefits. This is justified based on the thesis that any information concerning vaccine risks will lead to "vaccine hesitancy", which will then cost lives.

The CDC has become the primary governmental enforcer of this logic, to the point of sponsoring social media gang stalking campaigns targeting dissenters. During the Biden administration, the Federal Security Apparatus and Intelligence Community cooperated with the CDC to monitor and censor all who challenged or violated this cult-like belief system. The accepted official position became that any who questioned any aspect of promoted vaccine safety and effectiveness narratives was killing people. Those who transgress were literally or figuratively accused of being mass murderers by press as well as CDC-sponsored and facilitated activists. Those seeking to take my medical license during COVID literally accused me of being a mass murderer for publicly discussing the risks of the mRNA products.

Here is one example illustrating the perverse logic that has enabled this cult of vaccination. According to evidence based medicine, the "best available evidence" should guide clinical decisions. Retrospective studies have emerged showing vaccinated kids are much sicker, but these studies are always dismissed by the "vaccine experts" and the mainstream media for not being "well-controlled." However, since placebo trials on vaccines are never done for "ethical" reasons, by the rules of evidence based medicine, the retrospective studies we have are the "best available evidence" and their conclusions about vaccine harm cannot be dismissed unless better (placebo controlled trials) are conducted to corroborate or refute them.

The alternative vaccine safety advocate community's perspective is that the actual reason those placebo trials are never done is because they would immediately show how dangerous the vaccines are - hence why the vaccine industry has to constantly make excuses for not doing them while simultaneously claiming if done they would show vaccines are harmless.

In short, anytime someone critiques a retrospective study comparing vaccinated to unvaccinated as "invalid" it's critical to remember those studies are the gold standard because "better" ones will never be done due to promoted, contrived, and tenuous ethical considerations that can never be questioned.

And the profitability of the vaccine industry soared to new heights.

But all drugs, including vaccines, have risks and benefits. All drugs should be judiciously prescribed for those that are more likely to benefit from treatment than to be harmed. And free citizens have the right to understand those risks and benefits, and to determine if the potential benefits outweigh the risks for them as individuals. This is particularly true with prophylactic vaccines, which are administered to otherwise healthy persons with the intention of preventing an unpredictable event (infection and subsequent disease) at some point in the future.

To probe how far this has gone within American culture, I recently posted two simple questions on "X", both of which were read by over 200,000 people and provoked thousands of comments. **About a third of those comments were attacks that would meet European standards for hate speech**. These were the two posts:

"Can we at least agree that it would be good to have safer and more effective vaccines that are rigorously tested according to established modern regulatory standards?",

and

"I look forward to the day when it is no longer acceptable to censor and ridicule parents of vaccine injured children."

This hate speech appears to originate from a combination of left leaning political partisans, fake accounts (bots), and avid members of the cult that aggressively advocates that all vaccines are "safe and effective".

As has happened in the EU, CDC has suffered from bureaucratic mission creep, exacerbated by this cult-like culture of unquestioning vaccine advocacy, combined

with a perverse utilitarian bioethical framework based on the thesis that the ends justify the means, and this is requiring broad-based reorganization.

State Department is now Assuming a Greater Role in Global Health Policy

Major restructuring of the US Government Health enterprise is in progress. Together with USAID, the CDC has traditionally led many aspects of US International public health initiatives. Under President Trump, this is now changing. USAID has been decommissioned, and the US is withdrawing from the World Health Organization.

The State Department will now be playing a much larger role in guiding US International Health Policy. Under Secretary Rubio, Thomas DiNanno acting as Under Secretary of State for Arms Control & International Security will be assuming an active role in guiding International Health Security. This comes in the form of a new "*America First Global Health Strategy*" built on three pillars: making Americans safer, stronger and more prosperous.

The State Department argues U.S. global health programs have become "*inefficient and wasteful*," leading to a "*culture of dependency among recipient countries*."

The State Department has developed a plan to migrate from global health aid to fostering the self-reliance of countries the U.S. has supported in prior years. The U.S. will focus on working directly with nations, requiring them to co-invest in global health initiatives in order to tackle diseases such as tuberculosis, polio and HIV/AIDS as part of a new strategy from President Trump's administration. As part of co-investments, recipient governments will have to meet "*performance benchmarks*" in order for more U.S. foreign health assistance to be released.

The U.S. is looking to complete bilateral deals with countries getting the majority of the health foreign aid by the end of this year, with the goal of ushering in the new agreements by April 2026. According to the State Department,

> "*Our global health foreign assistance program is not just aid – it is a strategic mechanism to further our bilateral interests around the world. Moving forward, we will utilize our health foreign assistance to advance U.S. priorities and move countries toward resilient and durable local health systems. We will do this by entering multi-year bilateral agreements with recipient countries that lay out clear goals and action plans.*"
>
> "*These bilateral agreements will ensure that both 100 percent of frontline commodity purchases and frontline healthcare workers will continue to be funded during the agreement period. We will partner with each country to ensure there are data systems in place that can both monitor potential outbreaks and broader health outcomes," the State Department said. "We will also work to rapidly transition technical assistance to support governments in taking over key functions rather than individual clinical sites.*"

The rollout of the new plan comes after the administration effectively dismantled the United States Agency for International Development earlier this year, as the U.S. drew back disbursement of international aid. The position of the State Department is that

> *"When there is an outbreak, we will be prepared to work with local governments to respond promptly."*
>
> *"When necessary, we will be prepared to surge resources to ensure the outbreak is contained, travelers are appropriately screened, and – to the maximum extent possible – the outbreak does not reach American shores or harm Americans living abroad.*"

Changes in CDC and ACIP Structure and Policy

At the CDC, the consequences of years of absentee leadership are being corrected. Until recently, the bureaucracy has been allowed to run itself without significant oversight or peer review. Secretary Kennedy observed that his efforts to direct 50M$ in funding to support Texas efforts to address the Measles outbreak were blocked by the bureaucrats that had been running the CDC. These same bureaucrats also blocked access and external review of vaccine safety data bases. They are no longer employed by the Federal Government. The weekly MMWR publication, which has served as a non-peer reviewed mouthpiece for the bureaucracy, is also being operationally scaled back.

Perhaps most consequentially, the Advisory Committee on Immunization Practices (ACIP), which had been completely captured by the CDC bureaucracy and medical practice guilds, has been reconstituted and tasked with reevaluation of the scientific and medical underpinnings of the CDC childhood vaccine recommendations. The ACIP was originally intended to serve as an independent advisory board to the Director of the CDC, and operates under a congressional mandate provided by the Federal Advisory Committee Act. Over time, mission creep lead to the ACIP functioning as an unelected board determining federal vaccine policy, and thereby state vaccine policy.

Akin to the EU Principle of Subsidiarity, in the US the States have the authority to regulate the practice of medicine. But also like in the EU, bureaucratic mission creep has gradually eroded this to the point where the federal government, akin to your European Council, has assumed control of public health policy making. Under President Trump and Secretary Kennedy, the proper constitutional balance of power is now returning.

At the specific direction of both the President and Secretary, major changes in public health and vaccine policies are being made by Secretary Kennedy's team with the assistance of the reconstituted and redirected ACIP.

From **ending universal COVID shots to uncovering manipulated RSV data**, the Secretary's team is reshaping the foundation of U.S. vaccine policy. Even the CDC's childhood schedule—once considered untouchable—is now under review for safety, sequencing, and transparency. It marks the biggest shift in vaccine oversight in a generation—and it is all grounded on one principle: informed consent.

Health Secretary Robert F. Kennedy Jr. and officials at the Department of Health and Human Services have changed recommendations and policies for multiple vaccines, including shots against COVID-19 and measles.

In May of this year, under orders from Kennedy, the **CDC stopped recommending COVID-19 vaccines for healthy children and pregnant women**. The Food and Drug Administration later revoked emergency authorizations for the vaccines. The FDA also approved four shots for narrower populations: those younger than 65 who have an underlying condition and all those 65 years of age and older. After acceptance of recommendations from the ACIP, he CDC now calls for individuals to speak with a health care provider about risks and benefits before receiving a COVID-19 vaccine, a change approved on Oct. 6. The specifics involve a shift from COVID-19 vaccines being "recommended" to requiring "shared decision making". The ACIP has also called for improved disclosure of risks and benefits of these products in the CDC-produced "vaccine information sheets" (VIS). Kennedy wrote on X that the move amounted to "restoring informed consent." Unlike here in Europe, where the official advertising for the COVID injections has increased, the CDC and US Government are no longer advertising in favor of COVID vaccination.

Regarding the **Measles, Mumps, Rubella Vaccine**, President Donald Trump recently encouraged people to take separate vaccines against measles, mumps, and rubella. Stand-alone options, though, are not currently available in the United States. Acting CDC Director O'Neill on Oct. 6 backed Trump and called on manufacturers to produce monovalent vaccines against the diseases.

The United States in 2025 has recorded the most cases of measles since 1992, although these levels are still below typical measles case numbers for the European region. Secretary Kennedy has urged parents to stop the spread of measles and that people should get it. He also raised concerns about side effects, which can include seizures. Officials in Texas, the state that has recorded the bulk of the cases, announced on Aug. 18 that the measles outbreak there is over.

Regarding **Varicella Vaccine & MMRV**, accepting the advice of the ACIP, the CDC in an October update endorsed stand-alone varicella vaccinations for younger children because they face an elevated risk of febrile seizures if they receive the measles, mumps, rubella, and varicella combination vaccine. The CDC's immunization schedule lists a first dose against measles and varicella at about the time of a child's first birthday. It is recommended that children get a second dose when they are 4, 5, or 6 years of age. These recommendations are now being reviewed by the ACIP.

The CDC previously recommended both the MMR and MMRV vaccine options. It still recommends MMRV vaccination for a child's second dose, because the higher seizure risk has not been apparent for older children.

Regarding the **Hepatitis B Vaccine**, the ACIP had been prepared to vote on advising the CDC to delay the first dose of the hepatitis B vaccine from shortly after birth to at least 1 month of age, but advisers ended up tabling the motion on my recommendation, in which I stated that "*We need to postpone that decision because we need to really have the data to address whether or not hepatitis B vaccine should be administered to children at all*". Many other countries start the hepatitis B vaccine regimen at 2 or 3 months of age, if they have a regimen at all.

Trump said in remarks about vaccines that he thinks that children should not receive the hepatitis B vaccine until they are adolescents, as an Independent Women's Forum report recommends. Some other groups, including the American Academy of Pediatrics, support the current schedule. After additional internal study, this issue will be the subject of a following ACIP meeting and advisory recommendation

Regarding **Annual Influenza Vaccines**, the ACIP recommended that the government keep in place its recommendation that people at least 6 months of age receive an influenza vaccine each year. Advisers also said officials should stop backing influenza vaccines containing thimerosal, a mercury-based preservative, because of concerns over cumulative mercury exposure. Over the summer, with no CDC director in place, Kennedy signed off on both recommendations. I serve as chairperson for the Influenza Vaccine working group of the ACIP, and an HHS-approved scope of work for that working group should be published soon by the CDC.

RSV Vaccines and Antibodies. In August, then-CDC Director Susan Monarez approved another recommendation from the advisory committee. It recommended that infants receive an antibody for RSV during their first respiratory virus season. The season starts in the fall. The product, clesrovimab, provides an alternative to Beyfortus, an antibody that is already approved and recommended. One of the advisers (myself) later said the data the panel heard appeared to be manipulated, and Monarez was later fired. Over the summer, Secretary Kennedy also approved the panel's advice to expand the recommendation for RSV vaccination from individuals aged 60 to 74 who face an increased risk of severe disease to people aged 50 to 74 who face an increased risk.

The vaccines continue to be recommended for adults 75 years of age and older, regardless of health.

In the case of the **HPV vaccine**, the former ACIP had been scheduled to vote in June on whether to expand the recommendation for the human papillomavirus vaccine to children ages 9 and 10. The vaccine is currently recommended for children ages 11 and 12. The vote was removed from the meeting agenda after Kennedy replaced the panel's members, due to documented conflicts of interest. In meetings of the reformed committee, members have neither been presented with information about the human papillomavirus vaccine nor voted on altering the recommendation.

Regarding the **Chikungunya Vaccine**, the Food and Drug Administration in August suspended one chikungunya vaccine because, regulators said, data indicated that it was no longer safe. The data included reports of serious adverse events, such as cardiac problems, and even death following vaccination. Another vaccine against chikungunya virus is still available in the United States.

Concerning the **overall vaccine schedule**, the ACIP is studying the childhood immunization schedule, which has gone from having five vaccines in 1995 to about a dozen currently.

ACIP co-Chairman Martin Kulldorff said on Sept. 18 that *"The work includes looking] at interaction effects, or if it's best to do one vaccine before another..."*.

The CDC states on its website, "[The| CDC's recommended immunization schedule is safe and effective at protecting your baby." But The CDC is now facing a lawsuit over the schedule, with doctors alleging that the agency has not adequately tested vaccine-vaccine interactions.

Regarding the **potential association between childhood vaccines and autism**, this issue is still under review, but based on peer-reviewed studies, known concerns about the mechanism of action. and extensive data analysis, the President and Secretary have warned parents and pregnant mothers to avoid the use of acetaminophen, if at all possible, during pregnancy and when treating infant fever.

Regarding the **administration of vaccines during pregnancy**, an ACIP workgroup is examining vaccines for pregnant women. "*We always have to be very, very careful and considerate with not just vaccines but with drugs, or anything that we give to a pregnant mother, because of risk of, for example, birth defects*," Kulldorff said in the September meeting. The CDC has not recommended COVID-19 vaccines for pregnant women since May. No other vaccine recommendations during pregnancy have changed. The CDC currently recommends whooping cough, influenza, and RSV vaccination for pregnant women.

As you can see from this brief summary, under guidance from Secretary Kennedy as well as Secretary Rubio, President Trump and his team are making unprecedented strides towards reinvigorating scientific and medical integrity in Public Health. These actions are triggering an amazing amount of controversy, but at their core are commitments to both fundamental medical ethics, the rights of the individual patient, and a bipartisan commitment to improving the health of all Americans and particularly American children.

In the end, it is hard to refute or oppose a commitment to Making America Healthy Again. And, I suspect, equally hard to oppose the new grassroots movement to Make Europe Healthy Again.

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At the conclusion of the conference, I was grateful to honored and grateful to receive the **Mut und Menschlichkeit Award** (translated as "Courage and Humanity Award")





The Mut und Menschlichkeit Award (translated as "Courage and Humanity Award") is a recognition established by the Swiss association Leben und leben lassen (meaning "Live and Let Live"), a group of entrepreneurs and artists primarily from the canton of Aargau in Switzerland. The award honors individuals who demonstrate exceptional courage, humanity, and commitment to addressing societal challenges, often in politically or socially sensitive areas such as criticism of government policies, advocacy for freedom of speech, and opposition to perceived elite-driven agendas (e.g., the "Great Reset").

Key Details:

- Purpose: It aims to celebrate people who go beyond ordinary efforts to highlight injustices, stand with the public, and exhibit moral integrity amid global issues like pandemic restrictions and restrictions on civil liberties.
- Founded By: The association Leben und leben lassen, led by figures like chairman Peter Villiger, an international security consultant.

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Garry Blankenship Oct 16

Liked by Dr. Robert W. Malone

Another congratulations for a well warned reward. Graduates of our challenging medical and scientific training system that are courageous enough and willing to question that system are both desperately needed and rare. The best of health to you and yours.

LIKE (37) REPLY SHARE

James Goodrich Oct 16 *Edited*

There have been recent studies showing unvaccinated children are far less likely to have developmental delays, asthma, ear infections and gastrointestinal problems. These outcomes were shown because this is specifically what the tests were looking at. I saw a reporter ask Michigan congresswoman Debbie Dingell about vaccines and RFK Jr.'s position as HHS secretary and the woman went off the rails. She said Kennedy should not be in this position he's not a scientist and vaccines have made our kids and country extremely healthy. She basically called Kennedy an idiot and that he should be removed. This is what we're dealing with. 1 in 33 kids get autism up from 1 in 40,000 back in my day and she refuses to acknowledge this catastrophic problem. Ray Charles could see this blatant problem and he's dead, but Debbie Dingell gets her checks, big checks from big Pharma, so she's being paid to allow children's lives to be destroyed all for money! DISGUSTING!!! There are hundreds of representative, house and senate taking tens of thousands of dollars from pharmaceutical companies that won't allow themselves to see what is blatantly obvious also, because of money. It should be made illegal for all representatives to take money from Big Pharma period. J.Goodrich

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EXHIBIT 2

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 District Judge: Hon. Brian E. Murphy Magistrate Judge: Hon. M. Page Kelley

DECLARATION OF JANE DOE, MD

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

1. In October 2025, I gave birth to a full-term baby.

2. I talked with my obstetrician about my interest in receiving a covid-19 vaccine during my pregnancy to protect me and Baby Doe. My obstetrician strongly endorsed my decision to get a covid-19 vaccine and instructed me to wait until I was at least 34 weeks pregnant to ensure the best chance of maximally protecting Baby Doe from the upcoming respiratory season, especially because Baby Doe will be ineligible to get a covid-19 vaccine for her first respiratory season.

3. My physician counseled me that, because of the Secretary's May 28, 2025 Directive rescinding the recommendation that healthy children and pregnant women receive routine covid-19 vaccines, there has been such confusion in the medical community about who is eligible for the

covid-19 vaccine and, as a result, her patients have been having difficulty getting the vaccine at the point in their pregnancies that afforded them maximal protection. In July 2025, my obstetrician told me that because of the uncertainty about whether I would be able to actually access the covid-19 vaccine at the point in my pregnancy that would be maximally beneficial for my baby, she was deviating from her recommendation that I follow the standard of care and recommended, instead, I could consider trying to get a version of the covid-19 vaccine that was developed for the 2024–2025 respiratory season earlier than she would normally recommend.

4. My obstetrician counseled me that even if I could access a 2024–2025 covid-19 vaccine and my insurance agreed to cover me getting that covid-19 vaccine before my pregnancy progressed to 34 weeks, if I wanted to get a 2025–2026 covid-19 vaccine when it came out in the fall of 2025 when I would be at least 34-weeks pregnant, my insurance carrier would likely deny my insurance claim on an updated 2025–2026 covid-19 vaccine because I will have received some form of covid-19 vaccine too recently.

5. My reasonable belief that I will encounter difficulty accessing a covid-19 vaccine as a pregnant individual once I am 34 weeks pregnant is based on the information provided to me by my obstetrician. My obstetrician openly told me that the medical advice she gave me this summer is different advice than she would have given me without the Secretary's Directive.

6. Once the Directive rescinded the recommendation that healthy pregnant women receive the covid-19 vaccine, it forced me to gamble with my baby's life and my family's finances insofar as I was faced with the decision whether to try to get a 2024–2025 vaccine and risk jeopardizing the protection to my baby girl or waiting with hope that we can get a 2025–2026 vaccine to better protect her with the knowledge that if we wait, we may not be able to get any protection. I am not a betting person, and Mr. Kennedy demanded that I bet my firstborn child.

7. The magnitude of the dilemma the Secretary's Directive puts me in is augmented by the fact that, under the Secretary's Directive, my daughter will not be able to receive a covid-19 vaccine at all until she is at least six months old—after her first respiratory viral season—and she will be unable to receive a covid-19 vaccine as a routine matter after she is born until she becomes an adult.

8. I needed to try to give her the maximum protection while she was still in the safest place for her: my womb. The Secretary's Directive forced me to risk my baby's health and deprived me of my fundamental right as her mother to make the best decisions for my daughter, and my fundamental right to direct my personal medical decisions.

9. I have lost many hours of sleep worrying for my daughter's health and specifically about what decision I should have made once I was faced with the decision to either accept suboptimally timed old vaccine which, paying out of pocket for a second updated vaccine, or waiting and risking my baby losing her only best chance to be protected against this deadly virus.

10. My health suffered as a result of the stress of this decision; specifically, I lost sleep and suffered headaches and fatigue. I was fatigued and getting headaches at work because of the stress of the barriers to accessing the vaccine the Directive has caused, and my fatigue and headaches were negatively affecting my productivity at work.

11. Agonizing over the decision whether to wait to get the 2025–2026 vaccine or accept the suboptimally timed old vaccine, I actually contracted the covid-19 virus on September 1, 2025.

12. Even though I actually contracted the covid-19 virus during my pregnancy, my obstetrician has counseled me that the covid-19 vaccine was still the best way to protect my baby so I sought to be vaccinated.

13. I learned of pregnant women being denied the covid-19 vaccine because of the Directive, and as a result of learning that, I called several pharmacies and my employer's employee health resources to try to figure out if I could get a covid-19 vaccine during my pregnancy to protect myself and my baby. I spent significant time sorting out their various answers which ranged from being unable to tell me if I am eligible for the vaccine as a pregnant woman based on the Directive, and that I *should* be able to get it if I made an appointment, but the pharmacies I called could not make any guarantees that I would be able to get the vaccine there during my pregnancy. I reviewed news articles to try to get some insight where I might have been successful in getting a covid-19 vaccine, so I could best plan my attempt to get a vaccine for the highest chance of success. Today.com has reported that, even if pregnancy did not render me ineligible for the new 2025–2026 covid-19 vaccine categorically, I wouldn't be able to get the new 2025–2026 covid-19 vaccine in Massachusetts where I work, and I'd need a prescription in Connecticut where I live. *Are the New COVID Vaccines Available, and Can You Get One? It Depends, Experts Say.* TODAY.COM (Sept. 10, 2025) https://www.today.com/health/coronavirus/covid-vaccine-2025-2026-rcna228529.

14. I made calls to doctor's offices, pharmacies, and other individuals in my quest to get a covid-19 vaccine in between patient appointments, at times when I would otherwise would have been putting my efforts to profitable use.

15. I was far from sure that my insurance will pay for it. I had heard of insurance carriers rescinding coverage for the covid-19 vaccine for pregnant women based on the Secretary's Directive. Because I am not privy to the internal workings of my insurer, I was not guaranteed advance notice of insurance changes regarding coverage for the covid-19 vaccine.

16. My husband and I have significant educational debt, and on a medical trainee's salary with a baby on the way, I cannot afford to pay out-of-pocket for whatever the pharmacy wants to charge for a covid-19 vaccine. Some pharmacies in my area are charging more than two hundred dollars for a single covid-19 vaccine out of pocket. *See Immunizations*, CVS (last accessed Sept. 15, 2025) *https://www.cvs.com/immunizations/covid-19-vaccine*.

17. I ruminated over whether the covid-19 vaccine will be actually or functionally available to me to protect myself and my baby and it caused significant stress to myself and my baby by proxy. As a result of the stress, I felt about not being able to get a covid-19 vaccine because of the barriers the Directive has caused, I lost sleep and suffering stress-induced headaches and fatigue. I am sure that these symptoms and the underlying stress induced by the Directive caused compromised my immune system and left me more susceptible to contracting covid-19 when I did.

18. After much planning and preparation, I did receive a covid-19 vaccine during my pregnancy; however, the physical symptoms of the stress I was under leading up to the vaccine appointment were a burden on me and my baby and are negatively affecting my productivity at work, which was already reduced by the burden of coordinating with pharmacies and doctor's offices. I would not have suffered of these symptoms if not for the Directive.

19. Now that I am a mother, I am responsible for making the best choices for my child. The CDC's actions to subject covid-19 vaccination recommendations to shared clinical decision making for pediatric patients will impose obstacles to my child being able to get covid-19 vaccines when she becomes eligible in five months. I will inevitably have to spend additional time and resources coordinating vaccinating Baby Doe when she becomes eligible to receive the vaccine at

six-months of age. I will have to divert time away from productively working toward coordinating getting her a covid-19 vaccine.

20. The stress I feel knowing that I will have to fight for my child to access basic, scientifically-backed healthcare resources is causing me continued physical symptoms including contributing to continued sleep loss, headaches, and fatigue.

21. Additionally, I am likely to become pregnant in the future and I reasonably expect that I will have to navigate similar obstacles to obtaining the covid-19 vaccine to protect myself and any future children. The prospect of needing to navigate the hurdle of obtaining appropriate vaccinations, such as the covid-19 vaccine in connection with a future pregnancy is exhausting and has contributed to my current fatigue, headaches, and sleep loss.

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

Executed on December 2, 2025

/s/ Jane Doe I

Jane Doe, M.D.

EXHIBIT 3

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 District Judge: Hon. William G. Young Magistrate Judge: Hon. M. Page Kelley

DECLARATION OF JANE DOE 2

I, Jane Doe 2, declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I am over 18 years old.

2. I reside in Massachusetts.

3. I had planned to receive a Covid booster in Summer 2025.

4. I gave birth to a full-term baby in October 2025.

5. I saw the announcement that the Secretary of the Department of Health and Human Services ("Secretary") made on X on May 27, 2025, rescinding the recommendation that healthy pregnant individuals and children ages 6 months–17 years get the Covid vaccine.

6. I have been vaccinated against Covid and have received Covid vaccine boosters. However, as a pregnant woman, I was at greater risk for morbidity and mortality and severe illness if I contract Covid. If I contracted Covid while pregnant, that would put my unborn child at risk

for preterm birth and other complications, up to and including stillbirth or death. The Secretary's change to the Covid immunization schedule significantly raised my level of anxiety, and my inability to locate a health care practitioner able to administer the vaccine to me caused great distress. I joined this lawsuit because reversing the Secretary's directive would personally benefit me, as well as all other individuals who were also expecting and who were parents of minor children.

7. On May 30, 2025, following news of the Secretary's removal of the recommendation for the Covid vaccine for pregnant women, I attended a pre-scheduled, routine 20-week prenatal checkup. At this time, I asked my OB/GYN about the CDC recommendations for the Covid booster. She recommended that I be vaccinated against Covid and wrote a prescription for me which she sent to a chain pharmacy. She also documented this interaction in my prenatal report, which states, "Unclear where new CDC guidelines are coming from, unclear if data based. At this time, pregnancy still considered [high risk] for Covid infection and complications and vaccine recommended."[1]

8. On June 4, 2025 I scheduled a vaccination appointment with a chain pharmacy specifically for the Covid vaccine.

9. On June 4, 2025, I drove 6.5 miles in my 2018 Honda CR-V to a national chain pharmacy in the middle of my workday to my local pharmacy.

10. However, upon arrival at the pharmacy, as I was filling out my paperwork to receive the vaccine, the pharmacist on staff asked me whether I was pregnant. After I confirmed that I was, she refused to administer the Covid vaccine to me. The pharmacist stated that she could no longer

[1] A true and correct redacted copy of the May 30, 2025 prenatal report is attached hereto as **Exhibit A**.

administer the Covid vaccine due to the new CDC recommendations. She said that she could lose her license, even though she acknowledged the prescription for the Covid vaccine sent by my provider on May 30, 2025.

11. After being denied the covid-19 vaccine, I drove another 6.5 miles back to my home in my 2018 Honda CR-V.

12. My 2018 Honda CR-V gets approximately 31 miles per gallon. *2018 Honda CR-V*, UNITED STATES DEPARTMENT OF ENERGY (Last visited Sept. 16, 2025) https://www.fueleconomy.gov/feg/PowerSearch.do?action=noform&path=1&year1=2018&year2=2018&make=Honda&baseModel=CR-V&srchtyp=ymm&pageno=1&rowLimit=50.

13. A gallon of regular gasoline cost on average $3.11 in Massachusetts the first week of June 2025. *Weekly Massachusetts All Grades All Formulations Retail Gasoline Prices*, U.S. ENERGY INFORMATION ADMINISTRATION (last visited Sept. 16, 2025) https://www.eia.gov/dnav/pet/hist/LeafHandler.ashx?n=pet&s=emm_epm0_pte_sma_dpg&f=w.

14. Based on my 13-mile drive to and from the pharmacy on June 4, 2025 in my 2018 Honda CR-V which gets 31 miles to the gallon, and that gas prices in my area were $3.11 that week, I burned $1.30 in gas going to and returning from the pharmacy on June 4, 2025. My only purpose in going to the pharmacy that day was to be vaccinated against covid-19.

15. If I did not go to the pharmacy for my covid-19 vaccine on June 4, 2025, I would have devoted that time to my work.

16. Upon being denied the covid-19 vaccine on June 4, 2025, I immediately contacted my OB/GYN's office where I spoke with the on-call nurse to alert them that the chain pharmacy was not able to provide me with the vaccine—this caught them off-guard. The nurse reviewed the conflicting guidance between CDC and the American College of Obstetricians and Gynecologists

(ACOG) and determined that they could not administer the vaccine to me either, also citing concerns that their medical license could be at jeopardy. I also looked at the CDC website for guidance, and it stated that pregnant women should receive the Covid vaccine. I sent a message to my OB/GYN via the practice's medical portal with this information to get confirmation that this was indeed accurate.[2]

17. On June 11, 2025, having received no response to my June 4, 2025 portal message, I called my OB/GYN's office because their lack of responsiveness was uncharacteristically slow. The on-call nurse said that my portal message was sent to the Chair of Maternal Health for the practice who then spoke to the Chief Medical Officer (CMO) for the practice. The nurse explained to me that the CMO said that the guidance is not to administer the Covid vaccine right now and that they would revisit this next season. The nurse suggested I follow up with an urgent care and further stated that "it's a dead end with us" because the practice no longer carries the Covid vaccine and would no longer administer it.

18. A few minutes after this phone call, the on-call nurse sent me a message via the practice's medical portal which included an email from the Medical Director and CMO of the hospital regarding the current Covid vaccine status.[3] The CMO's email states:

> There's probably a lot of education that needs to take place this season. The CDC no longer recommends [the Covid vaccine] for children or pregnant women but there is no prohibition against giving it. The CDC now admits to the use of the word may. I can ask if perhaps the urgent cares can keep U.S. stock. But the new vaccine strain is not yet out.

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[2] A true and correct redacted copy of my June 4, 2025, portal message to my OB/GYN practice is attached hereto as **Exhibit B.**

[3] A true and correct redacted copy of the June 11, 2025, portal message from my OB/GYN practice is attached hereto as **Exhibit C.**

19. On June 11, 2025, immediately following this phone call and portal message, I called a local urgent care clinic. This clinic informed me they do not stock the vaccine and did not know if they would be ordering more stock. They also stated that it had been a while since anyone asked for the Covid vaccine.

20. On June 13, 2025, my OB/GYN called and left a voicemail following up on the portal messages from June 4, 2025 and June 11, 2025. She communicated that as an office practice, the practice was looking into the concerning reality that my experience at the chain pharmacy had unveiled: that there are now conflicting guidelines and, therefore, conflicting practices being followed by community pharmacies. She also shared that the practice follows materials from ACOG which strongly supports Covid vaccination during pregnancy.

21. On June 25, 2025, I had my 24-week checkup where I saw a nurse midwife. When I asked again about the Covid vaccine, she said that the practice "supports" me getting the vaccine but does not administer or carry it themselves. She said that the practice had no plans to order the vaccine and to check with the in-house pharmacy.

22. Following this appointment, I called the in-house pharmacy and was told that they also do not stock the Covid vaccine. I followed up with my OB/GYN practice to let them know the situation. [4]

[4] A true and correct redacted copy of my June 25, 2025, portal message to my OB/GYN practice is attached hereto as **Exhibit D**.

23. On June 26, 2025, I received a message via the practice's medical portal from a certified nurse midwife stating that she had called another location of the chain pharmacy which confirmed that they had the Covid vaccine in stock and sent a prescription directly to them.[5]

24. On July 6, 2025, I followed up with the other chain pharmacy location identified by the nurse midwife. My conversation with the pharmacist was confusing. She stated that certain "flexible" pharmacists would administer the Covid vaccine while others would not. When I asked whether it was the chain pharmacy's policy to allow individual pharmacists to determine which vaccines they could administer, she said that normally all pharmacists are on the same page regarding vaccine recommendations but that this is the first time a recommendation did not come from the Advisory Committee on Immunization Practices (ACIP) and, therefore, this is "a grey area." She said to schedule an appointment when a more "flexible" pharmacist, who would be willing to risk their license to vaccinate me, is on staff on July 23. I have scheduled an appointment with this pharmacist for July 23 and hope to receive the vaccine that day. However, I am nervous that should the pharmacist staffing schedule change, I will not be able to receive the vaccine yet again.

25. On July 7, 2025, I learned that a close acquaintance tested positive for Covid earlier that day. This acquaintance had stayed in my home from July 3 until July 6 to celebrate Independence Day, meaning that I and my unborn baby were unknowingly exposed to this deadly illness.

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[5] A true and correct redacted copy of the June 26, 2025, portal message from my OB/GYN practice is attached hereto as **Exhibit E.**

26. The stress of being vulnerable to covid-19 and having unknowingly exposed by unborn baby to covid-19 because the Directive blocked my ability to be vaccinated in June of 2025 exacerbated my underlying anxiety disorder and prenatal depression. I have suffered clinically-significant sleep disturbances as a result of this stress, and I required a dental intervention to address stress-induced tooth-grinding because I am so stressed about having access to covid-19 vaccines and being vulnerable to the disease personally and for my baby. I still suffer from anxiety, depression, and clinically-significant sleep disturbances as a result of being denied the covid-19 vaccine between June 2025 and July 2025.

27. On July 23, 2025, I finally received a COVID-19 vaccination at a national chain pharmacy. The scheduling process was conducted over the phone. I was told I would be seen during a time when a "flexible" pharmacist was on duty.

28. When I arrived at the pharmacy on July 23, 2025, the pharmacist presented me with an attestation form that I was required to sign in order to receive the Covid-19 vaccine. The form included the following statement: "If I am receiving a COVID-19 vaccine dose, I attest I am eligible for that dose according to current recommendations from the CDC."[6] I was confused by this statement because, on the one hand, pharmacists and my own doctor's office had refused to give me the vaccine because it was supposedly against current recommendations from the CDC and what Secretary Kennedy said in his announcement on X on May 27. On the other hand, I am aware that on the same day that I went to the flexible pharmacist who gave me the Covid shot, the CDC website states:

> "If you are pregnant or were recently pregnant, you are:

[6] A true and correct copy of the attestation form is attached hereto as **Exhibit F.**

- More likely to get very sick from COVID-19 compared to those who are not pregnant.
- More likely to need hospitalization, intensive care, or the use of a ventilator or special equipment to breathe if you do get sick from COVID-19. Severe COVID-19 illness can lead to death.
- At increased risk of complications that can affect your pregnancy and baby including, preterm birth or stillbirth.

COVID-19 vaccination remains the best protection against COVID-19-related hospitalization and death for you and your baby. CDC recommendations align with those from professional medical organizations including the American College of Obstetricians and Gynecologists, Society for Maternal Fetal Medicine, and American Society for Reproductive Medicine."

But then, the CDC website also has a prominently displayed banner stating: "COVID recommendations have recently been updated for some populations. This page will be updated to align with the updated immunization schedule."[7]

29. Since the CDC's current eligibility guidelines conflict with the Secretary's directive, I had to ask the pharmacist during my visit for clarification on that section of the attestation. The pharmacist agreed that the guidelines were unclear. He told me that, in cases like this, he personally chooses to follow the guidance of obstetric and pediatric professional organizations. Relying on his assurance, I signed the attestation and received the vaccine.

30. I am surprised that a major pharmacy chain permits this level of ambiguity and discretion among its pharmacists regarding federal vaccination guidelines.

31. During the two-month period from May 30, 2025 until July 23, 2025, I have personally experienced and witnessed the chaos, confusion, and stress that the Secretary's directive has caused for me, doctors and pharmacists as to whether the Covid vaccine can be given to

[7] A true and correct copy of the CDC website as of July 24, 2025 is attached hereto as **Exhibit G.**

pregnant individuals like me. I am grateful that I was finally able to find a "flexible" pharmacist who gave me the vaccine when others would not. I am very concerned for other pregnant individuals who are all in the same position as I have been—receiving conflicting and inconsistent guidance from the country's top public health official, from the CDC website, from my own doctor's office, and from the multiple pharmacists from whom I attempted to get the vaccine. It is clear to me that the Secretary's directive is the direct cause of this chaos and confusion. I sincerely hope for all pregnant individuals in this country that this situation gets fixed and clarified so that women who are pregnant do not have to experience what I experienced. That is why I submit this declaration and joined this lawsuit.

32. As a mother, I am very concerned that the CDC's actions to revise the childhood vaccination schedule to recommend shared clinical decision making as to the covid-19 vaccine for patients aged six months through seventeen years, will impose similar obstacles to those which Jane Doe 3's children have encountered to my own child's ability to obtain a covid-19 vaccine when she becomes eligible in five months.

33. All of the facts set forth in this declaration are based on my personal knowledge.

34. If called upon to testify as to the facts stated herein as a witness, I could and would competently testify under oath.

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

Executed on December 1, 2025.

Jane Doe 2

/s/

JANE DOE 2

EXHIBIT A

Docusign Envelope ID: 83DA0F03-65DF-4779-B10E-AADF48E20D68

OB/GYN Prenatal Report

Notes

Visit Date: 05/30/25 Last Updated by: [redacted]

35yo G2P0 at 20w1d for routine prenatal care.

No vaginal bleeding, leaking, discharge, dysuria or abdominal pain.

Endorses fetal flutters.

Prenatal chart and labs reviewed.

Level II reviewed, limited anatomy, otherwise normal EFW 22%tile. Needs 4 week f/u, scheduled for 6/27.

Rash in inferior abdominal fold, not c/w yeast. Advised to keep dry and use topical hydrocortisone. Given ABD pads.

Patient inquiring about Covid vaccine booster. Discussed recent CDC recommendations against Covid vaccination in health kids and pregnant women.

Unclear where new CDC guidelines are coming from, unclear if data based. At this time, pregnancy still considered HR for Covid infection and complications and vaccine recommended.

Increased daily water intake and PNVs encouraged.

PTL/SAB precautions reviewed.

FU in 4 weeks

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EXHIBIT B

Docusign Envelope ID: 83DA0F03-65DF-4779-B10E-AADF48E20D68

1:44 pm ***

Hi Dr. [redacted],
Unfortunately today I was refused a vaccination for the Covid vaccine, with the pharmacist citing their license would be in jeopardy, and insisting they had to follow CDC guidelines.

I spoke to [redacted] and the care team and [redacted] and it sounds like I'm the first person to experience this, but she reiterated they can't write a letter or administer the vaccine either for the same reasons- licenses would be in jeopardy.

Can you confirm this is all accurate and do you have any advice on how I can access the vaccine both you & ACOG recommend? The CDC website doesn't actually look like it's been updated, it still states pregnant women should get vaccinated against COVID.

Thanks,
[redacted]

EXHIBIT C

Docusign Envelope ID: 83DA0F03-65DF-4779-B10E-AADF

9:32 am

COVID vaccine

From [redacted] on
June 11, 2025 at 9:32 am

Hi [redacted],

Here is the most recent email from our medical director anf hospital CMO regarding the current COVID vaccine status:

His response "There's probably a lot of education that needs to take place this season. The CDC no longer recommends COVID for children or pregnant women but there is no prohibition against giving it. The CDC now admits to the use of the word may. I can ask if perhaps the urgent cares can keep U.S. stock. But the new vaccine strain is not yet out."

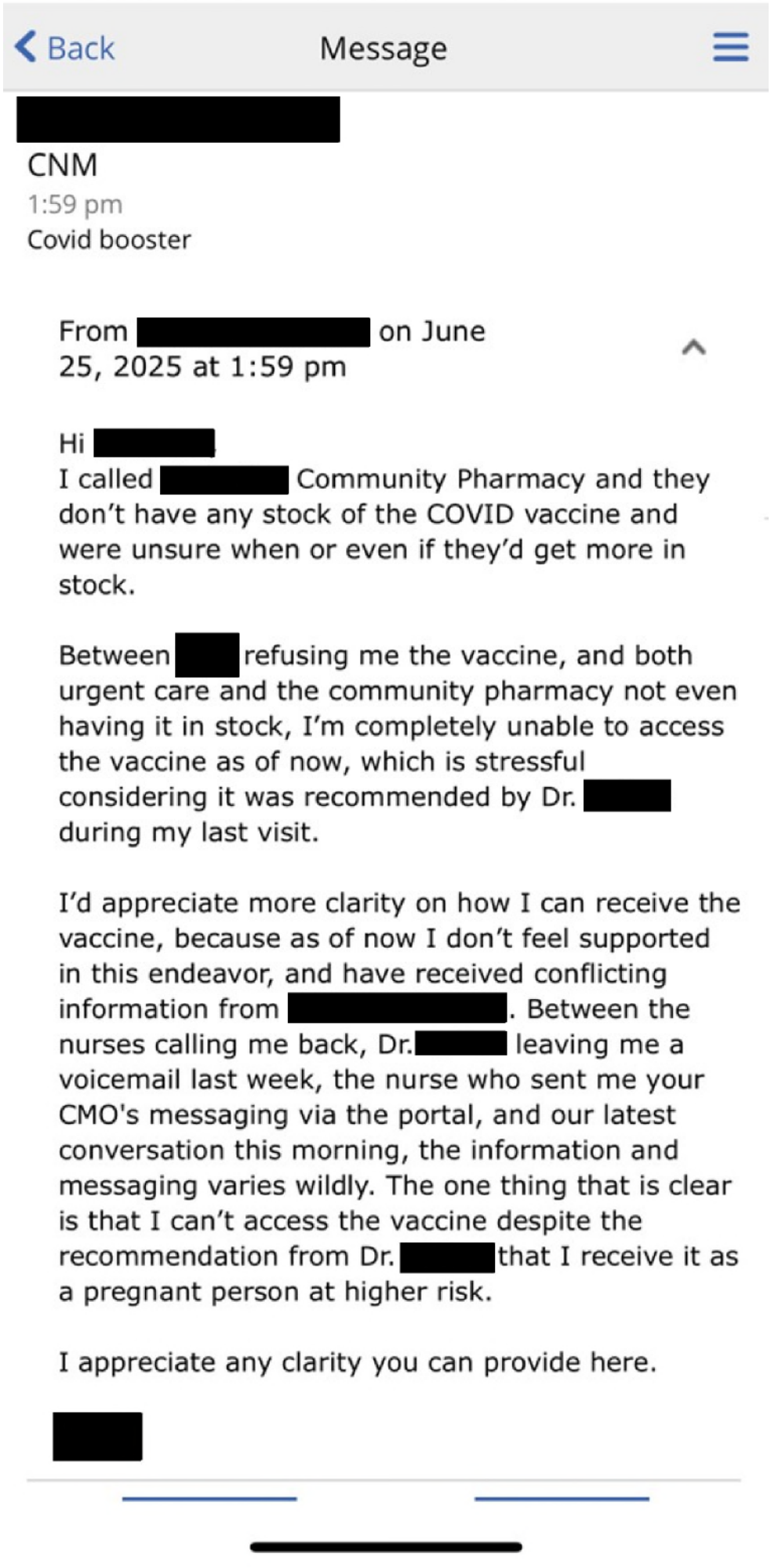
So, with that being said I would hold off for now until we get back to URI season and we have a better plan in place to help our patients access vaccination if it is desired.

Thank you,

[redacted]

EXHIBIT D

Docusign Envelope ID: 83DA0F03-65DF-4779-B1(



Back Message

[redacted]

CNM

1:59 pm

Covid booster

From [redacted] on June 25, 2025 at 1:59 pm

Hi [redacted]

I called [redacted] Community Pharmacy and they don't have any stock of the COVID vaccine and were unsure when or even if they'd get more in stock.

Between [redacted] refusing me the vaccine, and both urgent care and the community pharmacy not even having it in stock, I'm completely unable to access the vaccine as of now, which is stressful considering it was recommended by Dr. [redacted] during my last visit.

I'd appreciate more clarity on how I can receive the vaccine, because as of now I don't feel supported in this endeavor, and have received conflicting information from [redacted]. Between the nurses calling me back, Dr.[redacted] leaving me a voicemail last week, the nurse who sent me your CMO's messaging via the portal, and our latest conversation this morning, the information and messaging varies wildly. The one thing that is clear is that I can't access the vaccine despite the recommendation from Dr. [redacted] that I receive it as a pregnant person at higher risk.

I appreciate any clarity you can provide here.

[redacted]

EXHIBIT E

Docusign Envelope ID: 83DA0F03-65DF-4779-B

Back Message

[redacted] CNM
10:00 am
Covid booster

From [redacted], CNM on
June 26, 2025 at 10:00 am

Hi [redacted],

I just called [redacted] on [redacted] - the pharmacy tech that I spoke with said that they have the COVID vaccine in stock and they do not require any special documentation to administer the COVID vaccine in pregnancy. Just in case, I have also ordered the vaccine to the [redacted] pharmacy.

Our in-house pharmacy advised that there is a website that can help you identify alternative local vaccine access locations - vaxassist.com.

Please feel free to reach out with any questions or concerns.

[redacted] CNM

*** From [redacted] on June 25, 2025 at 1:59 pm ***

Hi [redacted],
I called [redacted] Community Pharmacy and they don't have any stock of the COVID vaccine and were unsure when or even if they'd get more in stock.

Between [redacted] refusing me the vaccine, and both urgent care and the community pharmacy not even having it in stock, I'm completely unable to access the vaccine as of now, which is stressful

EXHIBIT F

CONSENT FOR SERVICES: I have received/read (or had read to me) the Vaccine Information Statement(s), Vaccine Information Fact Sheet(s) and/or Patient Fact Sheet(s) regarding the vaccine(s). I understand the benefits/risks of vaccination. I voluntarily assume full responsibility for any reactions/consequences that may result. I understand I should remain in the vaccine administration area for 15 minutes, or longer if directed, after vaccination to be monitored for potential adverse reactions. In the event of side effects, I understand I should call the pharmacy, my doctor, or 911. I certify the information provided regarding eligibility for the vaccine is accurate and request the vaccine be given to me/the person previously named for whom I am authorized to make this request. If I am signing on behalf of another individual (including a minor), I attest I have the authority to do so. The following must have consent of a parent or guardian: Patients in Alabama/Nebraska under 19 yrs old; patients in South Carolina under 16 yrs old; and patients under 18 yrs old in all other states. If I am receiving a COVID-19 vaccine dose, I attest I am eligible for that dose according to current recommendations from the CDC. State of Georgia only: I verify a pharmacist asked for my health history and whether I had a physical exam in the past year. Health care providers did not identify conditions(s) that would mean I should not receive vaccine(s)

AUTHORIZATION TO REQUEST PAYMENT: I authorize [redacted] to release information to Medicare, Medicaid or any other third party payer as needed and to request payment of authorized benefits to be made on my behalf to [redacted], I certify the information provided about my Medicare, Medicaid or other coverage is correct

ACCEPTANCE OF FINANCIAL RESPONSIBILITY: Notwithstanding anything previously set forth, I agree I am responsible for and will promptly pay on demand any and all obligations to [redacted] Pharmacy including all self-pay balances as well as charges for services not covered or disallowed by my insurance carrier (for non-COVID-19 vaccines)

DISCLOSURE OF RECORDS: I understand [redacted] may be required to or may voluntarily disclose my health information with respect to this vaccine to my healthcare providers, my insurance plan, health systems and hospitals, and/or state or federal registries. I understand [redacted] will use and disclose my health information as set forth in the [redacted] Notice of Privacy Practices (copy is available in-store, online or by requesting a paper copy from the pharmacy team). State of California only: I agree to have the California Immunization Registry (CAIR) share my immunization data with the health care providers, agencies or schools State of Florida only: Students 18-23 may opt out of the immunization registry by notifying pharmacy prior to administration

Date: _____

X _____

Signature of patient to receive vaccine or person authorized to make the request (parent/guardian)

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EXHIBIT G

COVID-19

COVID-19 Vaccination for Women Who Are Pregnant or Breastfeeding

For Everyone
SEPT. 10, 2024 •

COVID-19 VACCINE RECOMMENDATIONS

COVID-19 vaccine recommendations have recently been updated for some populations. This page will be updated to align with the updated immunization schedule. Learn more.

WHAT TO KNOW

- Everyone ages 6 months and older is recommended to get the updated COVID-19 vaccine, including if you are pregnant, breastfeeding a baby, trying to get pregnant now, or might become pregnant in the future.
- COVID-19 vaccination during pregnancy is safe and effective.
- COVID-19 vaccines are not associated with fertility problems in women or men.
- Infants ages 6 months and older are recommended to get the updated COVID-19 vaccine even if born to mothers who were vaccinated or had COVID-19 before or during pregnancy.
- If you are pregnant or were recently pregnant, you are more likely to get very sick from COVID-19, compared to those who are not pregnant. Additionally, if you have COVID-19 during pregnancy, you are at increased risk of complications that can affect your pregnancy and your baby from serious illness from COVID-19.



Recommendations during and after pregnancy

If you are pregnant or were recently pregnant, you are:

- More likely to get very sick from COVID-19 compared to those who are not pregnant.
- More likely to need hospitalization, intensive care, or the use of a ventilator or special equipment to breathe if you do get sick from COVID-19. Severe COVID-19 illness can lead to death.
- At increased risk of complications that can affect your pregnancy and baby including, preterm birth or stillbirth.

COVID-19 vaccination remains the best protection against COVID-19-related hospitalization and death for you and your baby. CDC recommendations align with those from professional medical organizations including the American College of Obstetricians and Gynecologists, Society for Maternal Fetal Medicine, and American Society for Reproductive Medicine.

Pregnant and have questions about COVID-19 vaccine?

If you would like to speak to someone about the COVID-19 vaccination during pregnancy, you can talk to your healthcare provider. You can also contact MotherToBaby, whose experts can answer questions in English or Spanish. This service is free and confidential.

To reach MotherToBaby:

- **Call:** 1-866-626-6847
- **Text:** 1-855-999-3525 (standard messaging rates may apply)

Safety and effectiveness of COVID-19 vaccination during pregnancy

Studies including hundreds of thousands of people around the world show that COVID-19 vaccination before and during pregnancy is safe, effective, and beneficial to both the pregnant woman and the baby. The benefits of receiving a COVID-19 vaccine outweigh any potential risks of vaccination during pregnancy. Data show:

- **COVID-19 vaccines do not cause COVID-19, including in pregnant women or their babies.** None of the COVID-19 vaccines contain live virus. They cannot make anyone sick with COVID-19, including pregnant women or their babies. Learn more about how vaccines work.
- **It is safe to receive an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech), before and during pregnancy.** Both vaccines show no increased risk for complications like miscarriage, preterm delivery, stillbirth, or birth defects [1] [2].
- **mRNA COVID-19 vaccines during pregnancy are effective.** They reduce the risk of severe illness and other health effects from COVID-19. COVID-19 vaccination might help prevent stillbirths and preterm delivery [1] [2] [3] [4].
- **COVID-19 vaccination during pregnancy builds antibodies that can help protect the baby.** [4] [5]
- **Receiving mRNA COVID-19 vaccines during pregnancy can help protect babies younger than age 6 months from hospitalization due to COVID-19.** [6] [7] [8]
- Most babies hospitalized with COVID-19 were born to pregnant women who were not vaccinated during pregnancy [6] [7] [8].

Recommendations if you are breastfeeding

CDC recommends that women who are breastfeeding a baby, and infants 6 months of age and older, get vaccinated and stay up to date with their COVID-19 vaccines.

Vaccines are safe and effective at preventing COVID-19 in women who are breastfeeding a baby. Available data on the safety of COVID-19 vaccination while breastfeeding indicate no severe reactions after vaccination in the breastfeeding mother or the breastfed child. [9] There has been no evidence to suggest that COVID-19 vaccines are harmful to either women who have received a vaccine and are breastfeeding or to their babies. [10]

Studies have shown that mothers who are breastfeeding a baby and have received mRNA COVID-19 vaccines have antibodies in their breast milk, which could help protect their babies. [9] [10]

CDC also recommends COVID-19 vaccines for children aged 6 months and older.

Possible side effects

Pregnant women have not reported different side effects from women who are not pregnant after vaccination with mRNA COVID-19 vaccines (Moderna and Pfizer-BioNTech vaccines) [1] [2].

- Fever during pregnancy, for any reason, has been associated with adverse pregnancy outcomes.
- Fever in pregnancy may be treated with acetaminophen as needed, in moderation, and in consultation with a healthcare provider.
- Learn more about possible side effects and rare severe allergic reactions after receiving a COVID-19 vaccine.

Recommendations if you would like to have a baby in the future

CDC recommends that women who are trying to get pregnant now or might become pregnant in the future, as well as their partners, stay up to date and get the updated COVID-19 vaccine. COVID-19 vaccines are not associated with fertility problems in women or men.

Common questions

Expand All

What are the long-term effects on the baby if I get a COVID-19 vaccine during pregnancy?

Scientific studies to date have shown no safety concerns for babies born to mothers who were vaccinated against COVID-19 during pregnancy. Based on how these vaccines work in the body, experts believe they are unlikely to pose a risk for long-term health effects. CDC continues to monitor, analyze, and disseminate information from women vaccinated during all trimesters of pregnancy to better understand effects on pregnancy and babies.

When should I get the updated COVID-19 vaccine during pregnancy?

CDC and professional medical organizations, including the American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine, recommend COVID-19 vaccination at any point in pregnancy. COVID-19 vaccination can protect you from getting very sick from COVID-19. Keeping yourself as healthy as possible during pregnancy is important for the health of your baby.

Which COVID-19 vaccine should I receive if I am pregnant?

You can choose which updated COVID-19 vaccine to get.

Can I get a COVID-19 vaccine at the same time as other vaccines?

Children, teens, and adults, including pregnant women, may get a COVID-19 vaccine and other vaccines, including a flu vaccine, at the same time.

Resources

For Healthcare and Public Health

- Considerations for the Use of COVID-19 Vaccines in the United States
- Management of Anaphylaxis after COVID-19 Vaccination
- COVID-19 Clinical and Professional Resources
- Clinic Poster: Protect yourself and your baby from COVID-19 PDF

SOURCES

CONTENT SOURCE:
National Center for Immunization and Respiratory Diseases; Coronavirus and Other Respiratory Viruses Division

REFERENCES

1. Fleming-Dutra KE, Zauche LH, Roper LE, Ellington SR, Olson CK, Sharma AJ, Woodworth KR, Tepper N, Havers F, Oliver SE, Twentyman E, Jatlaoui TC. Safety and Effectiveness of Maternal COVID-19 Vaccines Among Pregnant People and Infants. Obstet Gynecol Clin North Am. 2023 Jun;50(2):279-297. Safety and Effectiveness of Maternal COVID-19 Vaccines Among Pregnant People and Infants - ScienceDirect
2. Prasad, S., Kalafat, E., Blakeway, H. et al. Systematic review and meta-analysis of the effectiveness and perinatal outcomes of COVID-19 vaccination in pregnancy. Nat Commun 13, 2414 (2022). Systematic review and meta-analysis of the effectiveness and perinatal outcomes of COVID-19 vaccination in pregnancy | Nature Communications
3. Schrag SJ, Verani JR, Dixon BE, et al. Estimation of COVID-19 mRNA Vaccine Effectiveness Against Medically Attended COVID-19 in Pregnancy During Periods of Delta and Omicron Variant Predominance in the United States. JAMA Netw Open. 2022;5(9):e2233273. doi:10.1001/jamanetworkopen.2022.33273
4. Piekos SN, Price ND, Hood L, Hadlock JJ. The impact of maternal SARS-CoV-2 infection and COVID-19 vaccination on maternal-fetal outcomes. Reprod Toxicol. 2022;114:33-43. The impact of maternal SARS-CoV-2 infection and COVID-19 vaccination on maternal-fetal outcomes - ScienceDirect
5. Yang YJ, Murphy EA, Singh S, et al. Association of Gestational Age at Coronavirus Disease 2019 (COVID-19) Vaccination, History of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Infection, and a Vaccine Booster Dose With Maternal and Umbilical Cord Antibody Levels at Delivery. Obstetrics & Gynecology: 2021. DOI: https://doi.org/10.1097/AOG.0000000000004693
6. Halasa NB, Olson SM, Staat MA, et al. Maternal Vaccination and Risk of Hospitalization for Covid-19 among Infants. N Engl J Med. 2022;387(2):109-119. doi:10.1056/NEJMoa2204399

7. Hamid S, Woodworth K, Pham H, et al. COVID-19–Associated Hospitalizations Among U.S. Infants Aged <6 Months — COVID-NET, 13 States, June 2021–August 2022. MMWR Morb Mortal Wkly Rep 2022;71:1442–1448. DOI: http://dx.doi.org/10.15585/mmwr.mm7145a3
8. Simeone RM, Zambrano LD, Halasa NB, et al. Effectiveness of Maternal mRNA COVID-19 Vaccination During Pregnancy Against COVID-19–Associated Hospitalizations in Infants Aged <6 Months During SARS-CoV-2 Omicron Predominance — 20 States, March 9, 2022–May 31, 2023. MMWR Morb Mortal Wkly Rep 2023;72:1057–1064. DOI: http://dx.doi.org/10.15585/mmwr.mm7239a3
9. Muyldermans J, De Weerdt L, De Brabandere L, Maertens K, Tommelein E. The Effects of COVID-19 Vaccination on Lactating Women: A Systematic Review of the Literature. Front Immunol. 2022;13:852928. Published 2022 Apr 8. doi:10.3389/fimmu.2022.852928
10. Drugs and Lactation Database (LactMed) [Internet]. Bethesda (MD): National Library of Medicine (US); 2006-. COVID-19 Vaccines. [Updated 2022 Sep 19]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK565969/

SOURCES

- National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases

EXHIBIT 4

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 District Judge: William G. Young Magistrate Judge: M. Page Kelley

DECLARATION OF JANE DOE 3

I, Jane Doe 3, declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I am over 18 years old.

2. I reside in the state of Washington.

3. I am immunocompromised, which places me at a substantially increased risk of severe illness, hospitalization, or death if I contract Covid.

4. I am the mother of two minor children, sons ages 16 (Jimmy) and 13 (Timmy).

5. Both of my sons are neurodivergent.

6. Jimmy and Timmy both have anxiety disorders and attention deficit hyperactivity disorder ("ADHD") and Jimmy also has autism.

7. In addition to his underlying anxiety and ADHD, Timmy Doe has a severe needle phobia.

8. I hold a Master's degree in Public Health and Epidemiology and a Bachelor of Science (major in biology and minors in chemistry and mathematics).

9. My children and I have followed public health guidance throughout the Covid pandemic, including receiving recommended vaccinations. This year, both my sons again wanted to receive the Covid booster before school starts on August 27, 2025, so they would be fully protected at the start of the school year.

10. I saw the announcement that the Secretary of the Department of Health and Human Services ("Secretary") made on X on May 27, 2025, ordering the Centers for Disease Control and Prevention ("CDC") to remove from its immunization schedules the recommendation that healthy pregnant individuals and children ages 6 months–17 years get the Covid vaccine (the "Directive"). As an immunocompromised parent, this decision alarmed me and my children. They do not want to contract Covid or risk passing it to me, and they expressly wanted the vaccine before school began.

11. On August 8, 2025, I personally received a Covid vaccine from a national pharmacy chain. I scheduled that appointment online and was vaccinated without issue that day.

12. I used the same pharmacy's online scheduling system to book Covid vaccination appointments for both of my sons for August 14, 2025. The system accepted their birthdates and allowed me to select the Covid vaccine for each child.

13. On the night of August 13, 2025, anticipating his vaccine appointment, Timmy Doe suffered an anxiety attack.

14. Before entering the pharmacy on August 14, 2025, Timmy Doe had a panic attack including hyperventilating, crying, clenching his teeth, shaking, and other physical symptoms of his anxiety and needle phobia.

15. I drove my electric vehicle to the chain pharmacy on August 14, 2025 with my two sons at the time of their scheduled vaccine appointment. I checked in with pharmacy technician at the pharmacy counter, and my children sat in the seats behind me. After checking in with the pharmacy technician, she got the pharmacist (a female with short dark hair) who came to the counter to speak with me.

a. The pharmacist stated that the new vaccine is coming out in September and I said, we don't know that. The pharmacist then asked if my children previously received the vaccine, and I said yes. The pharmacist responded, "then why do you need it?" I explained to the pharmacist that "I wanted my children protected before school started, and as it takes up to two weeks to obtain the full effect of the Covid vaccine, I wanted them to receive the vaccine now."

b. The pharmacist then took out her phone and started scrolling through something on her screen. The pharmacist then looked up from her phone and told me, "I cannot give them the Covid vaccine because they are not in the eligible age group." When I asked, "what is the eligible age group?," the pharmacist replied, "either over 60 or 65 is the eligible age group." The pharmacist then ended the conversation by stating that she would not vaccinate my sons because they are not in the eligible age group.

16. As a result of being turned away by the pharmacist, my children remained unvaccinated until September 12, 2025. Until they could be vaccinated, both boys were deeply upset—they were fearful of catching what they call the new Covid strain's "razor-blade throat" and even more fearful of infecting me given my compromised immune system.

17. I have experienced firsthand the confusion, anxiety, and disruption caused by the Secretary's Directive. Before the Directive, my children were eligible for and received the Covid vaccine. I encountered absolutely no issues getting my children the Covid vaccine last year. After

the Directive, my children were refused vaccination at a national pharmacy chain, leaving them and me more vulnerable to the virus.

18. The denial of vaccination for my children is a direct consequence of the Directive. Vacating that Directive would immediately benefit me and my children by restoring their ability to receive the vaccine and reduce our risk of severe illness. I am joining this lawsuit because I and my children have suffered, and continue to suffer, personal harm as a result of the Directive. I therefore urgently seek relief that will protect my children and me from the ongoing threat of Covid.

19. I made a second appointment for Jimmy and Timmy to be vaccinated against covid-19 at a local national chain pharmacy for September 12, 2025. I told my sons about their appointment the night before on September 11, 2025.

20. On September 11, 2025, anticipating his vaccine appointment for the following day, Timmy Doe had another anxiety attack.

21. Routine is very important to Timmy as a neurodivergent individual and it is critical to the success of his coping mechanisms for his mental health struggles. When we were denied the covid-19 vaccine because of the Directive, his routine around vaccinations was disrupted, and now he cannot readily rely on clear expectations what a vaccine appointment will look like, which exacerbates his anxiety and phobia symptoms, and contributed to triggering and exacerbating the severity of his anxiety attack on September 11, 2025.

22. Timmy Doe's anxiety attack on September 11, 2025 was caused, at least in part, by the disruption of his expectations about what a vaccine appointment entails because we were denied the vaccine during the August 14, 2025 appointment.

23. School started for Timmy Doe on August 27, 2025. Because the pharmacist denied him the covid-19 vaccine on August 14, 2025 due to the Directive, he was not vaccinated when school started. One of his classes had a celebrating involving food, and Timmy, fearing contracting covid-19 and giving it to his immunocompromised mother, did not feel comfortable taking his mask off to enjoy the class treat. As a result, he was unable to participate fully in the celebration and suffered an element of social ostracism. Had he received the vaccine on August 14, 2025 as planned, he would have participated in the class event and avoided the social ostracism.

24. All of the facts set forth in this declaration are based on my personal knowledge. If called upon to testify as to the facts stated herein as a witness, I could and would competently testify under oath to the truth of these facts.

25. Prior to driving my electric vehicle to the pharmacy on August 14, 2025, I charged my electric vehicle at my home. My electric bill is higher than it would have been had I not driven to the pharmacy and back on August 14, 2025 for my sons' vaccine appointment. The only reason I went to the pharmacy that day was to get my sons vaccinated against covid-19.

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

Executed on September 9/23/2025, 2025 in the state of Washington.

/s/ Jane Doe 3

Jane Doe 3

EXHIBIT 5

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

SUPPLEMENTAL DECLARATION OF SUSAN J. KRESSLY, M.D., FAAP

I, Susan J. Kressly, M.D., FAAP, 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 am board certified in Pediatrics and Clinical Informatics and a Fellow of the American Academy of Pediatrics.

3. I have over 30 years of clinical experience in general pediatrics, during which I founded Kressly Pediatrics, an independent general pediatrics practice located in Bucks County, Pennsylvania and served as the school physician for Central Bucks School District for over a decade. I also served as the Medical Director of Office Practicum (OP), a pediatric-specific Certified Electronic Health Record Technology (CEHRT) for over a decade.

4. I received my medical degree from Temple University School of Medicine and served my residency at St. Christopher's Hospital for Children, located in Philadelphia, Pennsylvania, where I stayed on for an additional year as Chief Pediatric Resident.

5. I am the current President of the American Academy of Pediatrics (AAP). In this role, I lead and manage all of the AAP's relationships with our members, operations of AAP, and the standards that our members follow to provide the highest level of care to their patients. I also play a crucial role in developing the AAP's public policies. As such, I have in-depth knowledge of the operations of AAP, its members, the standard of care for our physician members, and the facts and circumstances set forth herein.

6. The AAP was founded in 1930 to serve as an independent forum for addressing children's health and continues to operate with the mission to attain optimal physical, mental, and social health and well-being for all infants, children, adolescents and young adults.

7. The AAP's membership includes over 67,000 pediatricians nationwide, many of whom are currently providing direct care to infants, children, adolescents, and young adults in both hospital and outpatient settings.

8. The AAP's mission is to attain optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults. To accomplish this, the AAP operates to support the professional needs of its members through the publication of evidence-driven, nonpartisan, rigorously reviewed policies on a broad range of topics that impact the health and wellbeing of infants, children, adolescents, and young adults. This includes the maintenance and publication of the AAP Red Book, which is used across pediatric practices nationwide. Central to the AAP Red Book is the AAP's immunization recommendations.

9. The AAP's members have suffered and will continue to suffer greatly at the hands of the Secretary's changes to COVID-19 vaccine recommendations, which have injected chaos, confusion, and disruption into the practice and care that AAP physician members deliver to

patients. If called upon to testify as to the facts stated herein as a witness, I could and would competently testify under oath.

10. I am aware of and disagree with the "Secretarial Directive on Pediatric COVID-19 Vaccines for Children Less than 18 years of Age and Pregnant Women" (the "Secretarial Directive") issued by Secretary of Health and Human Services Robert F. Kennedy, Jr. (the "Secretary") on May 27, 2025 designating the COVID-19 vaccine for children as Shared Clinical Decision Making ("SCDM") and removing the recommendation for the COVID-19 for pregnant individuals. The Directive was arbitrary and not supported by the evidence. In fact, no data presented by the COVID-19 Vaccines Work Group for the Advisory Committee on Immunization Practices ("ACIP")—before or after the issuance of the Directive—has suggested that the COVID-19 vaccine should not be routinely recommended for children ages six months to 17 years old.

11. I am aware of and disagree with the recommendation issued by the ACIP in September 2025 and subsequently adopted by the acting director of the Centers for Disease Control and Prevention ("CDC") in October 2025, changing the COVID-19 vaccine recommendation for all individuals under the age of 65 from routine to SCDM. This change by the ACIP and the CDC was made without the usual transparent presentation of GRADE tables or Evidence to Recommendation (EtR) framework for evaluating the quality of evidence, nor was this change accompanied by a clear, contemporaneous explanation in the MMWR. This change to the CDC immunization schedule for COVID-19 vaccines has significantly disrupted the prior harmonious system and created multiple layers of confusion and harm.

12. The AAP has adopted clinical practice guidelines that are considered the standard of care for our physician members and are in place to optimize and protect the care provided to our members' patients. Clinical practice guidelines are informed by a systematic review of peer-

reviewed research and evidence, and an assessment of the benefits and harms of alternative care options. Clinical practice guidelines follow a sound, transparent methodology to translate best evidence into clinical practice for improved patient outcomes. They are a key component of patient-centered care.

13. As part of its evidence-based clinical practice guidelines, the AAP reviews and has historically endorsed the Child and Adolescent Immunization Schedule, as set forth by the CDC.

14. Until the recent issuance of the Directive, the AAP has consistently recommended the COVID-19 vaccine for infants and children in alignment with the recommendations of the U.S. Food and Drug Administration (FDA), the ACIP, and the CDC for the COVID-19 vaccine as these recommendations were made based on the engagement in rigorous analyses and extensive reviews of safety and efficacy data for specific age groups to determine whether to recommend administration of the COVID-19 vaccine to children.

15. On June 18, 2022, after years of carefully analyzing the safety and effectiveness data and evaluating the balance of the risks of the COVID-19 vaccine compared to the severity of the disease across all age brackets, the FDA, the ACIP, and the CDC unwaveringly recommended that the COVID-19 vaccine be administered to children ages six months to 17 years old.[1] That same day, the AAP released an updated policy statement recommending that all eligible infants, children and adolescents without contraindications get vaccinated.[2]

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[1] A true and correct copy of the 71 Morbidity & Mortality Weekly Rep. 26 (July 1, 2022) is attached hereto as **Exhibit A**.

[2] *See* AAP, *CDC approves COVID-19 vaccines for children under 5; vaccinations could begin this week*, AAP News (June 18, 2022). A true and correct copy of this news report is attached to this declaration as **Exhibit B**.

16. However, due to the confusion and lack of evidence-based data supporting the SCDM recommendation for COVID-19 vaccinations for children ages six months to 17 years old, the AAP ceased its endorsement of the CDC's current Child and Adolescent Schedule, and instead published and endorsed the CDC Child and Adolescent Immunization Schedule in effect prior to the issuance of the Directive. On November 21, 2025, the AAP published an updated Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, which lists the COVID-19 vaccine as a routine vaccination.[3]

17. The CDC immunization schedule change for children regarding the COVID-19 vaccine from "routine" to "SCDM" is a downgrading of the CDC's recommendation and sends a message to patients discouraging COVID-19 vaccine. Designating a vaccine as "routine" signals to patients an unequivocal recommendation from the CDC that a vaccine is recommended to protect patients. A "SCDM" recommendation, however, is the lowest-strength option available to ACIP, and instead signals to patients that "individuals may benefit from vaccination, but broad vaccination of people in that group is unlikely to have population-level impacts."[4]

18. In the past, when the CDC has issued a SCDM recommendation for a vaccine, the supporting data was published in the CDC's Morbidity and Mortality Weekly Report ("MMWR") in addition to the SCDM recommendation. This data is critical for physician use in consulting with and discussing the risk and benefits of a vaccine categorized as SCDM and, normally, provides clinicians with the evidence base to guide patient counseling. No such data or guidance

[3] A true and correct copy of the AAP's Recommended Child and Adolescent Immunization Schedule dated November 21, 2025 is attached hereto as **Exhibit C**.

[4] *ACIP Shared Clinical Decision-Making Recommendations*, CDC (Jan. 7, 2025), https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html, attached hereto as **Exhibit D**.

accompanied the CDC immunization schedule change for children for COVID-19 vaccines from "routine" to "SCDM," leaving AAP physician members without clear guidance regarding what to discuss with patients and their families or how to counsel them regarding the risks and benefits of the COVID-19 vaccine. This lack of clarity and guidance inherently increases the amount of time AAP physician members spend on unbillable counseling time with patients regarding the COVID-19 vaccine.

19. SCDM should be reserved for situations where there are multiple reasonable options and the best choice depends on individual medical factors, which is not the case for administration of the COVID-19 vaccine. When engaging in the SCDM process, a physician's first step is considering whether the medical decision includes more than one medically reasonable option that is consistent with the standard of care. If there are *not* more than one medically reasonable options available that are consistent with the standard of care, then shared decision making is not appropriate. Thus, SCDM is not the proper framework for routine vaccinations for which the safety and effectiveness data have already been established and for which alternate options do not exist, such as the COVID-19 vaccine.

20. The acting director of the CDC has also improperly conflated SCDM with informed consent.[5] Informed consent is always performed before the administration of any medical

[5] *CDC Immunization Schedule Adopts Individual-Based Decision-Making for COVID-19 and Standalone Vaccination for Chickenpox in Toddlers*, CDC (Oct. 6, 2025) ("'Informed consent is back,' said Deputy Secretary O'Neill. 'CDC's 2022 blanket recommendation for perpetual COVID-19 boosters deterred health care providers from talking about the risks and benefits of vaccination for the individual patient or parent. That changes today. I commend the doctors and public health experts of ACIP for educating Americans about important vaccine safety signals. I also thank President Trump for his leadership in making sure we protect children from unintended side effects during routine immunization.'"), https://www.cdc.gov/media/releases/2025/cdc-immunization-schedule-adopts-individual-based-decision.html, attached hereto as **Exhibit E**.

treatment to ensure a patient is aware of the risks and benefits of a treatment or procedure before agreeing to receive that treatment or procedure. Providers have always been required to obtain informed consent before administering any vaccine. SCDM builds upon informed consent through a collaborative process between a provider and a patient when there are multiple medically reasonable options that are consistent with the standard of care for the patient to consider. SCDM is a discussion process used to enable a patient to weigh and decide which medically reasonable option is best for their individual situation.

21. AAP physician members have informed me that this lack of clarity and lack of guidance regarding the SCDM COVID-19 vaccine recommendation has left them without a path for employing shared clinical decision-making in practice, including whether it requires face-to-face time with a healthcare provider or if it allows for consultation with pharmacists.

22. The CDC's downgrade of the recommendation of the COVID-19 vaccine for children to SCDM has created significant barriers for patients seeking to get a COVID-19 vaccine. For example, in order for a patient's parents to engage in SCDM with a physician, they must schedule a physician appointment, incur copay costs, and potentially take time off work and/or take their child out of school to attend the appointment. Further, limited healthcare provider availability remains a significant obstacle for parents seeking access to the COVID-19 vaccine for their children.

23. The downgrading of the recommendation of the COVID-19 vaccine for children to SCDM also requires AAP physician members to spend more time counseling parents about the safety and effectiveness of the COVID-19 vaccine for their children. Before the new ACIP recommendation was issued, when the COVID-19 vaccine was a routine recommendation for children, AAP members spent very little time counseling parents regarding the COVID-19 vaccine

because people generally trusted the well-supported, evidence-based recommendations published by the CDC. Although studies establishing the safety and effectiveness of the COVID-19 vaccine and the risk-benefit analysis of receiving the COVID-19 vaccination has not changed, the new SCDM recommendation has created significant confusion and distrust about the COVID-19 vaccine. This confusion and distrust require AAP members to spend significantly more time counseling parents in order to dispel the misinformation the Secretary and the CDC have spread about the COVID-19 vaccine.

24. The COVID-19 vaccine hesitancy that the CDC and the Secretary have unnecessarily created requires AAP physician members to spend more time counseling parents regarding the effectiveness of the COVID-19 vaccine when administered to children, which adds up to time and resources diverted from AAP physician members' other patients. If there is another severe COVID-19 outbreak, it would overwhelm AAP members' practices.

25. Peer-reviewed studies and clinical literature show that administration of the COVID-19 vaccine lowers hospitalization rates and deaths due to COVID-19 infections in child and adult populations.[6] Further, children who receive the COVID-19 vaccine and stay up to date on their boosters are less likely to develop long COVID, which can cause brain fog, shortness of breath, gastrointestinal issues, generalized pain or fatigue, and other long-term, debilitating symptoms.[7]

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[6] *See, e.g.*, Sarah K. Wood, et al., *Vaccination of Children in the United States against COVID-19: An Ounce of Prevention*, 115 Southern Medical Journal 347, 347–48 (2022) ("Although the absolute risks of hospitalizations and deaths in children are low, the relative risks are highest in those US states with rates of vaccinations that are lower than the national average and mainly among people who are not vaccinated."). A true and correct copy of this study is attached to this declaration as **Exhibit F**.

[7] *See* AAP, *Study: Vaccines help prevent long COVID in children, adolescents*, AAP News (Jan. 16, 2024). A true and correct copy of this study is attached to this declaration as **Exhibit G**.

26. AAP physician members have informed me that the change in the COVID-19 vaccine's classification from routine to one requiring shared clinical decision-making and the CDC's and the Secretary's associated messaging has left their patients' parents confused and concerned regarding the vaccine's efficacy and safeness. Parents are seeking clarity from AAP physician members regarding why this change is necessary and what additional risks have been identified necessitating the change, while providers are left without answers because there are no studies or data indicating that this change was necessary. As a result, the change in the COVID-19 vaccine recommendation from "routine" to "SCDM" has created a sense of chaos and instilled a lack of confidence among patients' families regarding a vaccine that is proven to be safe and effective at preventing the spread of COVID-19.

27. AAP physician members use Current Procedural Terminology ("CPT") codes to bill for the professional services that they provide to their patients. Each code is tied to a patient care service and is used to document and receive reimbursement for medical encounters. Vaccine administration has its own family of CPT codes, with the codes tying compensation of doctors to actual administration of the vaccine during a patient visit. AAP physicians report that, as a result of the shift in the COVID-19 vaccine recommendation from "routine" to "SCDM" for children, they have been required to spend significantly more unbillable time counseling families regarding COVID-19 vaccinations. Not only is this time unbillable, but it also infringes on the ability of AAP physician members to see additional patients and receive reimbursement for that time.

28. Members of the AAP have reported that the CDC's change in the COVID-19 vaccine recommendation from "routine" to "SCDM" for children has completely frustrated their ability to effectively counsel patients and their families regarding the effectiveness of the COVID-

19 vaccine at preventing serious illness and death, and that this change is compromising the standard of care by inciting patient delays or refusals to receive the COVID-19 vaccine.

29. AAP members have also reported that the removal of the COVID-19 vaccine from the routine vaccination recommendations for children has eroded some families' faith and trust in all vaccines, causing them to refuse a myriad of routine vaccinations and creating an even more imminent and severe risk of serious illness, hospitalization, and death.

30. COVID-19 infections typically rise during the respiratory illness season, which began in October. The Secretary's and the CDC's dangerous and unsupported decisions regarding the COVID-19 vaccines are causing preventable suffering and death to Americans, which will continue to escalate as the respiratory illness season progresses.

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

Executed on: 11/24/2025

Susan J. Kressly, MD, FAAP

Susan J. Kressly, M.D., FAAP
On behalf of the American Academy of Pediatrics

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EXHIBIT A

Docusign Envelope ID: C35AB490-BBE1-4EAA-939E-218EDC3D35DE Case 1:25-cv-11916-BEM Document 146-5 Filed 12/03/25 Page 13 of 58

Interim Recommendations of the Advisory Committee on Immunization Practices for Use of Moderna and Pfizer-BioNTech COVID-19 Vaccines in Children Aged 6 Months–5 Years — United States, June 2022

Katherine E. Fleming-Dutra, MD[1]; Megan Wallace, DrPH[1]; Danielle L. Moulia, MPH[1]; Evelyn Twentyman, MD[1]; Lauren E. Roper, MPH[1]; Elisha Hall, PhD[1]; Ruth Link-Gelles, PhD[1]; Monica Godfrey, MPH[1]; Kate R. Woodworth, MD[1]; Tara C. Anderson, DVM, PhD[1]; Amy B. Rubis, MPH[1]; Edwin Shanley III, MPH[1]; Jefferson M. Jones, MD[1]; Rebecca L. Morgan, PhD[2]; Oliver Brooks, MD[3]; H. Keipp Talbot, MD[4]; Grace M. Lee, MD[5]; Beth P. Bell, MD[6]; Matthew Daley, MD[7]; Sarah Meyer, MD[1]; Sara E. Oliver, MD[1]

On June 28, 2022, this report was posted as an MMWR *Early Release on the* MMWR *website (https://www.cdc.gov/mmwr).*

On June 17, 2022, the Food and Drug Administration (FDA) issued Emergency Use Authorization (EUA) amendments for the mRNA-1273 (Moderna) COVID-19 vaccine for use in children aged 6 months–5 years, administered as 2 doses (25 μg [0.25 mL] each), 4 weeks apart, and BNT162b2 (Pfizer-BioNTech) COVID-19 vaccine for use in children aged 6 months–4 years, administered as 3 doses (3 μg [0.2 mL] each), at intervals of 3 weeks between doses 1 and 2 and ≥8 weeks between doses 2 and 3. On June 18, 2022, the Advisory Committee on Immunization Practices (ACIP) issued separate interim recommendations for use of the Moderna COVID-19 vaccine in children aged 6 months–5 years and the Pfizer-BioNTech COVID-19 vaccine in children aged 6 months–4 years for the prevention of COVID-19.* Both the Moderna and Pfizer-BioNTech COVID-19 vaccines met the criteria for immunobridging, which is the comparison of neutralizing antibody levels postvaccination in young children with those in young adults in whom efficacy had been demonstrated. Descriptive efficacy analyses were also conducted for both Moderna and Pfizer-BioNTech COVID-19 vaccines during the period when the Omicron variant of SARS-CoV-2 (the virus that causes COVID-19) predominated. No specific safety concerns were identified among recipients of either vaccine. ACIP recommendations for the use of the Moderna COVID-19 vaccine and the Pfizer-BioNTech COVID-19 vaccine in children aged 6 months–5 years and 6 months–4 years, respectively, are interim and will be updated as additional information becomes available. Vaccination is important for protecting children aged 6 months–5 years against COVID-19.

The Moderna and Pfizer-BioNTech COVID-19 vaccines are lipid nanoparticle–formulated, nucleoside-modified mRNA vaccines encoding the prefusion spike glycoprotein of SARS-CoV-2. On January 31, 2022, FDA approved a Biologics License Application (BLA) for use of the Moderna COVID-19 vaccine (Spikevax, ModernaTX, Inc.) in persons aged ≥18 years, and the Moderna COVID-19 vaccine is also recommended under EUA for children and adolescents aged 6–17 years (*1*). On August 23, 2021, FDA approved a BLA for use of the Pfizer-BioNTech COVID-19 vaccine (Comirnaty, Pfizer, Inc.) in persons aged ≥16 years, and the Pfizer-BioNTech COVID-19 vaccine is also recommended under EUA for children and adolescents aged 5–15 years (*2*). Recommendations regarding products, dosing intervals, and booster doses and for persons who are moderately to severely immunocompromised, which differ from recommendations for persons without immunocompromising conditions, are available at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html. As of June 17, 2022, among persons aged ≥18 years, 223 million doses of the Moderna COVID-19 vaccine have been administered in the United States, and among persons aged ≥5 years, 349 million doses of the Pfizer-BioNTech COVID-19 vaccine have been administered (*3*).

Since June 2020, ACIP has convened 28 public meetings to review data relevant to the epidemiology of COVID-19 and considerations for the use of COVID-19 vaccines, including the Moderna and Pfizer-BioNTech COVID-19 vaccines.† The ACIP COVID-19 Vaccines Work Group (Work Group), comprising experts in pediatrics, infectious diseases, vaccinology, vaccine safety, public health, and ethics, has held weekly meetings to review COVID-19 surveillance data; evidence for vaccine efficacy, postauthorization effectiveness, and safety; and implementation considerations for COVID-19 vaccines. To guide its deliberations regarding recommendations for use of these vaccines, ACIP used the Evidence to Recommendation (EtR) Framework§ and incorporated a Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach.¶ Within the EtR Framework, ACIP considered the importance of COVID-19 as a public health problem, as well as parents' values and preferences, acceptability, feasibility, resource use, and equity regarding use of mRNA COVID-19 vaccines among children aged 6 months–5 years. Consistent with the age groups for each

* On June 18, 2022, ACIP voted 12 to 0 (three members absent) in favor of the interim recommendation for the use of the Moderna COVID-19 vaccine for children aged 6 months–5 years. ACIP voted 12 to 0 (three members absent) in favor of the interim recommendation for the use of the Pfizer-BioNTech COVID-19 vaccine for children aged 6 months–4 years.

† https://www.cdc.gov/vaccines/acip/meetings/index.html

§ https://www.cdc.gov/vaccines/acip/recs/grade/downloads/acip-evidence-recs-framework.pdf

¶ https://www.cdc.gov/vaccines/acip/recs/grade/about-grade.html

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vaccine included under EUA, ACIP also considered, within the EtR Framework, the benefits and harms of using each vaccine (i.e., the Moderna COVID-19 vaccine among children aged 6 months–5 years and the Pfizer-BioNTech COVID-19 vaccine among children aged 6 months–4 years), independently compared with no vaccine. After conducting systematic reviews of published and unpublished evidence for benefits and harms, the Work Group used the GRADE approach to independently assess the certainty of evidence for outcomes related to the Moderna and Pfizer-BioNTech COVID-19 vaccines, rated on a scale of type 1 (high certainty) to type 4 (very low certainty).** Work Group conclusions regarding evidence for the use of Moderna COVID-19 vaccine among children aged 6 months–5 years and Pfizer-BioNTech COVID-19 vaccine among children aged 6 months–4 years were presented to ACIP at a public meeting during June 17–18, 2022.

Summary of Evidence for Use of the Moderna COVID-19 Vaccine in Children Aged 6 Months–5 Years

The body of evidence regarding immunogenicity, efficacy, and safety of the Moderna COVID-19 vaccine among children aged 6 months–5 years was guided by one randomized, double-blind, placebo-controlled phase II/III clinical trial in which 6,388 participants aged 6 months–5 years were enrolled and randomized 3:1 to receive either 2 doses of vaccine (25 μg) or saline placebo, separated by an interval of 28 days (*4*). Interim findings from this clinical trial were based on data from participants with a median blinded follow-up after dose 2 of 68 days for children aged 6–23 months and 71 days for children aged 2–5 years. Vaccine efficacy against symptomatic, laboratory-confirmed COVID-19 was supported by two types of evidence: 1) direct efficacy of 2 doses against symptomatic COVID-19, and 2) immunobridging (i.e., comparing neutralizing antibody levels in one population [e.g., young children] with antibody levels in another population [e.g., young adults] with demonstrated efficacy). Vaccine efficacy ≥14 days after dose 2 was 37.8% (95% CI = 20.9%–51.1%) in preventing symptomatic, laboratory-confirmed COVID-19†† in children aged 6 months–5 years with or without evidence of previous SARS-CoV-2 infection.§§ This estimate was based on symptomatic illness in 181 vaccine recipients and 97 placebo recipients, none of whom were hospitalized. Vaccine efficacy against symptomatic COVID-19 was also inferred based on immunobridging criteria. The measure of immune response to 2 doses (25 μg each) of the Moderna COVID-19 vaccine in children aged 6–23 months and 2–5 years without evidence of previous SARS-CoV-2 infection was at least as high as the response observed in young adults aged 18–25 years after 2 doses (100 μg each) of the Moderna COVID-19 vaccine, with a geometric mean ratio (GMR) for 50% neutralizing antibody titer of 1.28 (95% CI = 1.12–1.47) for children aged 6–23 months and 1.01 (95% CI = 0.88–1.17) for children aged 2–5 years, satisfying the noninferiority criteria¶¶ for both age groups. In addition, vaccine efficacy against asymptomatic, laboratory-confirmed SARS-CoV-2 infection*** was 16.0% (95% CI = −18.5%–40.5%) among children aged 6 months–5 years with or without evidence of previous SARS-CoV-2 infection, based on asymptomatic infection in 111 vaccine recipients and 44 placebo recipients.

Among vaccine recipients aged 6 months–5 years, reactogenicity, defined as solicited local and systemic adverse reactions during the 7 days after vaccination, were reported frequently. After dose 2, 66.1% of caregivers reported any local reaction among the child vaccine recipients after vaccination, and 65.9% reported any systemic reaction; most reactions were mild to moderate with symptom onset 1–2 days after vaccination and resolving after 2–3 days. Reactogenicity was usually less frequent in children aged 6 months–5 years than in those aged 6–11 years. Among children aged 6 months–5 years, severe local and systemic adverse reactions (grade 3 or higher, defined as interfering with daily activity) occurred in 7.7% of vaccine recipients, more commonly after dose 2, and in 4.1% of placebo recipients. The most common grade 3 or higher local symptom reported by vaccine recipients after dose 2 was pain at the injection site (0.4%). The most commonly reported reactions of grade 3 or higher after dose 2 were fever (2.6%) and irritability or crying (1.2%) among vaccine recipients aged 6–36 months and fever (3.1%) and fatigue (2.3%) among those aged 37 months–5 years. Serious adverse events††† were

** https://www.cdc.gov/vaccines/acip/recs/grade

†† In the Moderna COVID-19 vaccine clinical trial, symptomatic, laboratory-confirmed COVID-19 was defined based on the CDC case definition, which required at least one clinical symptom (fever ≥100.4°F [≥38°C], chills, fatigue, headache, myalgia, nasal congestion or rhinorrhea, new loss of taste or smell, sore throat, abdominal pain, diarrhea, nausea or vomiting, poor appetite or poor feeding, cough, or shortness of breath or difficulty breathing), and a positive COVID-19 test result using reverse transcription–PCR (RT-PCR).

§§ In the Moderna COVID-19 vaccine clinical trial, approximately 10% of children aged 6 months–5 years were seropositive, indicating previous SARS-CoV-2 infection, at baseline.

¶¶ Noninferiority is declared if the lower bound of the 2-sided 95% CI for the GMR is >0.67 and the point estimate of GMR is ≥0.8.

*** In the Moderna COVID-19 vaccine clinical trial, asymptomatic SARS-CoV-2 infection was identified by absence of symptoms and at least one of the following conditions: 1) binding antibody level against SARS-CoV-2 nucleocapsid protein negative at baseline (or day 1) that became positive post-baseline (testing performed only on the immunogenicity subset [494]), or 2) a positive COVID-19 test result using RT-PCR post-baseline at a scheduled (29 days after dose 2) or unscheduled visit.

††† Serious adverse event is defined as any untoward medical occurrence that results in death, is life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent disability or incapacity, or is a congenital anomaly or birth defect. Serious adverse events occurring after dose 1 or dose 2 were reported.

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uncommon and occurred with similar frequency among vaccine (0.5%) and placebo (0.2%) recipients, with no statistically significant difference in frequency. Two serious adverse events in one participant were determined to be potentially related to vaccination.[§§§] No specific safety concerns were identified among vaccine recipients aged 6 months–5 years. A detailed summary of safety data, including information on reactogenicity, is available at https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/reactogenicity.html.

From the GRADE evidence assessment, the level of certainty for the benefits of Moderna COVID-19 vaccination among children aged 6 months–5 years was type 1 (high certainty) for the prevention of symptomatic laboratory-confirmed COVID-19 assessed using direct efficacy and type 2 (moderate certainty) assessed using immunobridging, because of serious concerns for indirectness, because immunogenicity is a surrogate measure of efficacy. The level of certainty for prevention of asymptomatic SARS-CoV-2 infection was type 3 (low certainty) because of serious concerns of indirectness, because serial SARS-CoV-2 polymerase chain reaction (PCR) testing was not performed, and serology was only performed for a subset of participants[¶¶¶]; serious concerns of imprecision were also noted because of the width of the 95% CI. Regarding potential harms after vaccination, evidence was type 4 (very low certainty) for serious adverse events because of short follow-up time (median = 68 and 71 days after dose 2 for children aged 6–23 months and 2–5 years, respectively), study size, and the width of the 95% CI. Evidence was type 1 (high certainty) for reactogenicity. No data were available to assess the other GRADE benefits, including prevention of COVID-19–associated hospitalization or multisystem inflammatory syndrome in children (MIS-C).

Summary of Evidence for Use of the Pfizer-BioNTech COVID-19 Vaccine in Children Aged 6 Months–4 Years

The body of evidence regarding immunogenicity, efficacy, and safety of the Pfizer-BioNTech COVID-19 vaccine among children aged 6 months–4 years was composed of data from one randomized, double-blind, placebo-controlled phase II/III clinical trial in which 4,526 participants aged 6 months–4 years were enrolled and randomized 2:1 to receive either vaccine or saline placebo (5). The protocol initially specified 2 doses of vaccine (3 μg) or saline placebo separated by an interval of 3 weeks. Per protocol, participants were unblinded 6 months after dose 2 or at age 5 years (whichever occurred first). Based on an interim analysis where the predefined criteria for immunobridging and efficacy of the trial were not met after 2 doses, a protocol amendment was implemented on February 1, 2022, to include a third dose of either vaccine (3 μg) or saline placebo, administered ≥56 days after dose 2. Dose 3 was offered to blinded and unblinded participants in the vaccine arm, and blinded participants in the placebo arm were offered a third dose of placebo. Among trial participants, 1,456 (32.2%) received a blinded third dose and were included in a 3-dose efficacy analysis (992 in the vaccine arm and 464 in the placebo arm). The median interval between doses 2 and 3 was 16 weeks among children aged 6–23 months and 11 weeks among children aged 2–4 years. Safety analyses included blinded participants and assessed outcomes starting at dose 1. Interim findings from this clinical trial were based on data from participants with a median blinded follow-up of 35 days after dose 3 for children aged 6–23 months and 40 days for children aged 2–4 years.

Vaccine efficacy was supported by two types of evidence: 1) direct efficacy of 3 doses against symptomatic laboratory-confirmed COVID-19[****] and 2) immunobridging data. Vaccine efficacy ≥7 days after dose 3 was 80.0% (95% CI = 22.8%–94.8%)[††††] in preventing symptomatic, laboratory-confirmed COVID-19 in children aged 6 months–4 years with and without evidence of previous SARS-CoV-2 infection,[§§§§] based on infection in three vaccine recipients and seven placebo recipients, none of whom were hospitalized. In the immunobridging analysis, the measure of immune response to 3 doses (3 μg each) of the Pfizer-BioNTech COVID-19 vaccine in children aged 6 months–4 years without evidence of previous SARS-CoV-2 infection was at least as high as the response observed in persons aged 16–25 years who had received 2 doses (30 μg each) of the Pfizer-BioNTech COVID-19 vaccine, with a GMR for 50% neutralizing

[§§§] One recipient in the Moderna COVID-19 vaccine clinical trial experienced two serious adverse events (i.e., fever and febrile seizure) that the investigator and FDA determined to be potentially related to the vaccine.

[¶¶¶] The definition of asymptomatic SARS-CoV-2 infection specified for GRADE: SARS-CoV-2 infection with no reported symptoms identified through 1) serial RT-PCR testing, or 2) testing of binding antibody level against SARS-CoV-2 nucleocapsid protein, on the entire cohort or a representative sample.

[****] In the Pfizer-BioNTech COVID-19 vaccine clinical trial, symptomatic laboratory-confirmed COVID-19 was defined based on the CDC case definition, which required at least one clinical symptom (fever, new or increased cough, new or increased shortness of breath, chills, new or increased muscle pain, new loss of taste or smell, sore throat, diarrhea, vomiting, and inability to eat or poor feeding), and a positive SARS-CoV-2 nucleic acid amplification test result within 4 days of the symptomatic period.

[††††] For GRADE, relative risks (RR) were calculated from numerators and denominators available in the body of evidence. Vaccine efficacy estimates were defined as 100% x (1–RR). Manufacturer vaccine efficacy estimates were calculated using incident rate ratios. Based on the Pfizer-BioNTech COVID-19 vaccine clinical trial analysis, the vaccine efficacy against symptomatic SARS-CoV-2 infection was 80.3% (95% CI = 13.9%–96.7%).

[§§§§] In the Pfizer-BioNTech COVID-19 vaccine clinical trial, approximately 30% of children aged 6 months–4 years were seropositive, indicating a previous SARS-CoV-2 infection, before dose 3.

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antibody titer of 1.19 (95% CI = 1.00–1.43) for children aged 6–23 months and 1.30 (95% CI = 1.13–1.50) for children aged 2–4 years, satisfying the noninferiority criteria[¶¶¶¶] for both age groups.

Among vaccine recipients aged 6 months–4 years, reactogenicity, defined as solicited local injection site or systemic signs or symptoms during the 7 days after vaccination, were common (47.8% reported any local reaction, and 63.8% reported any systemic reaction); most reactions were mild to moderate. Local and systemic reactogenicity symptoms were usually less frequent in children aged 6 months–4 years (63.8%) than in children aged 5–11 years (86.2%) (*6*). Severe local and systemic adverse reactions (grade 3 or higher, defined as interfering with daily activity) occurred in 4.3% and 3.6% of vaccine recipients and placebo recipients, respectively. The most commonly reported reactions of grade 3 or higher among vaccine recipients aged 6–23 months were fever (4.0%) and irritability (1.3%), and among recipients aged 2–4 years, were fatigue (0.8%) and fever (2.2%). Overall, reactions of grade 3 or higher were also more commonly reported after the second dose than after the first or third dose. Serious adverse events[*****] were uncommon and occurred with similar frequency among recipients of vaccine (1.0%) and placebo (1.5%), with no statistically significant difference in frequency. Two serious adverse events in one participant in the vaccinated group were determined to be potentially related to vaccination.[†††††] No specific safety concerns were identified among vaccine recipients aged 6 months–4 years. A detailed summary of safety data, including information on reactogenicity, is available at https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/reactogenicity.html.

From the GRADE evidence assessment, the level of certainty for the benefits of Pfizer-BioNTech COVID-19 vaccination among children aged 6 months–4 years was type 4 (very low certainty) for the prevention of symptomatic laboratory-confirmed COVID-19 assessed using direct efficacy because of serious concern about the short duration of follow-up (median = 35 and 40 days for children aged 6–23 months and 2–4 years, respectively) and very serious concerns about imprecision because of case accrual and study size. For the prevention of symptomatic, laboratory-confirmed COVID-19 assessed using immunobridging, the evidence was type 2 (moderate certainty) because of serious concerns for indirectness, because immunogenicity is a surrogate measure of efficacy. Regarding potential harms after vaccination, the evidence was type 4 (very low certainty) for serious adverse events because of very serious concerns for indirectness because of the short duration of follow-up of 1 month after dose 3 and because only 31% of trial participants received dose 3, limiting the ability to detect serious adverse events that might occur at a higher rate after dose 3, and serious concern of imprecision because of the study size. For reactogenicity, the evidence was type 2 (moderate certainty) because of serious concern for indirectness, as only 31% of trial participants received dose 3, limiting the ability to detect severe reactogenicity that might occur specifically after dose 3. No data were available to assess the other GRADE benefits, specifically prevention of COVID-19–associated hospitalization, MIS-C, or asymptomatic SARS-CoV-2 infection.

[¶¶¶¶] Noninferiority is declared if the lower bound of the 2-sided 95% CI for the GMR >0.67 and the point estimate of GMR is ≥0.8.

[*****] Serious adverse event is defined as any untoward medical occurrence that results in death, is life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent disability or incapacity, or is a congenital anomaly or birth defect. Serious adverse events occurring after dose 1, dose 2, or dose 3 were reported.

[†††††] One recipient in the Pfizer-BioNTech COVID-19 vaccine clinical trial had two serious adverse events (i.e., fever and pain in extremity requiring hospitalization) that the investigator and FDA determined to be potentially related to the vaccine. FDA noted that the events were also consistent with viral myositis.

Recommendations for the Use of the Moderna COVID-19 Vaccine in Children Aged 6 Months–5 Years and the Pfizer-BioNTech COVID-19 Vaccine in Children Aged 6 Months–4 Years

Data reviewed with the EtR Framework supported the use of COVID-19 vaccine in children aged 6 months–5 years. COVID-19 is a major public health problem among young children. As of June 12, 2022, approximately 2 million COVID-19 cases, 20,000 hospitalizations, and 200 deaths from COVID-19 have been reported among U.S. children aged 6 months–4 years (*7*,*8*). The SARS-CoV-2 Omicron variant emerged in the United States in December 2021 and led to the highest COVID-19 incidence, rates of COVID-19–associated emergency department visits and COVID-19–associated hospitalization among children aged 6 months–4 years yet seen during the pandemic (*9*). Approximately one half (51%–54%) of children aged 6 months–4 years with a COVID-19–associated hospitalization had no underlying health conditions, highlighting the risk for severe COVID-19 even among young children without underlying health conditions (*9*). During the period of Omicron predominance, illness among children aged 6 months–4 years with COVID-19–associated hospitalizations was as severe or more severe than that among children and adolescents aged 5–17 years, who were eligible for COVID-19 vaccination during that period (*9*). Furthermore, COVID-19 hospitalization rates among children aged 6 months–4 years during October 2021–April 2022 were as high or higher than were influenza-associated hospitalization rates during the 2017–18, 2018–19, and 2019–20 influenza seasons (*10*).

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SARS-CoV-2 can also lead to complications after acute infection. MIS-C is a severe illness in persons aged <21 years that occurs 2–6 weeks after SARS-CoV-2 infection and is characterized by fever, multisystem organ involvement, and laboratory evidence of inflammation (*11*). As of May 31, 2022, CDC has received 8,525 reports of cases of MIS-C in the United States, including 69 deaths (*12*); children aged 6 months–4 years account for 1,990 (23%) of these cases and 9 (13%) of the deaths among MIS-C cases (*9*). Post–COVID-19 conditions, which include a range of new, returning, or ongoing, health problems occurring ≥4 weeks after acute SARS-CoV-2 infection, also occur in children, including those aged <5 years (*13–15*). However, evidence regarding the prevalence and spectrum of these conditions in children, especially young children, is limited by the inability of younger children to verbalize symptoms, few studies that include children, lack of appropriate control groups, and because symptoms similar to those seen in post–COVID-19 conditions are frequently reported among children without known SARS-CoV-2 infection (*13*,*14*,*16*).

The pandemic has also had additional indirect effects on children and families, including missed routine childhood immunizations and health care visits; worsening of children's social, emotional, and mental well-being; and disruptions in early child care and education programs (*17–19*). In a survey conducted during July 15–August 2, 2021, 39% of parents reported that an adult in their household either left a job or changed work schedules to care for children during the past year; parents of a child aged <5 years, Black and African American parents, Hispanic or Latino parents, and parents with an annual household income of <$40,000 were most likely to report household job disruptions (*20*). COVID-19 vaccination in this age group may provide parents with increased confidence to return to prepandemic activities, improving social interactions in young children.

Implementation of these recommendations will require educating vaccine providers about the correct age-appropriate product (Table 1) and vaccination schedule (Table 2) for each vaccine, to avoid vaccine administration errors. ACIP determined that use of the Moderna and Pfizer-BioNTech COVID-19 vaccines among children is a reasonable and efficient allocation of resources. To expand COVID-19 vaccine access, additional considerations should be given to demographic groups that have experienced disproportionate COVID-19 morbidity and mortality, as well as those with barriers to routine health care (e.g., members of certain racial and ethnic groups and those living in a rural area, experiencing homelessness, or lacking health insurance). Children from racial and ethnic minority groups have experienced a disproportionately high incidence of COVID-19, associated hospitalization, and MIS-C (*7*,*12*,*21*). Pediatricians and health care providers remain the most trusted source among parents for information about COVID-19 vaccines for children (*22*). Based on the National Immunization Survey-Child COVID Module interviews conducted in May 2022, 33.5% of parents said they would definitely vaccinate their child aged 6 months–4 years for COVID-19, once eligible, and 19.6% said they would probably vaccinate their child aged 6 months–4 years (*7*). Thus, pediatricians and other primary care providers who care for children will be critical to increasing COVID-19 vaccine confidence among parents and coverage with COVID-19 vaccine among young children.

ACIP reviewed the balance of known and potential benefits and risks regarding the use of the Moderna COVID-19 vaccine in children aged 6 months–5 years and Pfizer-BioNTech COVID-19 vaccine in children aged 6 months–4 years, each compared with no vaccine. Both vaccines demonstrated ability to prevent COVID-19 and met noninferiority criteria based on immunobridging data. Although both the Moderna and Pfizer-BioNTech COVID-19 vaccine trials were conducted when Omicron was the predominant circulating SARS-CoV-2 variant, case accrual after the final dose occurred in different months, resulting in differences in COVID-19 incidence across the trials. Thus, efficacy estimates cannot be directly compared between these two vaccines. Moreover, vaccine efficacy from these trials should be interpreted in the context of what is known about vaccine effectiveness against Omicron infection. Postauthorization observational studies in persons aged ≥5 years have demonstrated that the vaccine effectiveness against Omicron infection is lower than that observed against earlier SARS-CoV-2 variants (*23*,*24*). However, postauthorization observational data also indicate that mRNA vaccine effectiveness is higher, even during Omicron predominance, against hospitalization (68% a median of 37 days after the second dose in children aged 5–11 years) than against infection (40% during the 2 months after the second dose in children aged 5–11 years) (*25*). Importantly, during Omicron predominance, mRNA vaccine effectiveness against MIS-C remained high (78%) among children aged 5–11 years (*25*). The clinical trials were not powered to detect efficacy against severe disease in young children, but similar patterns are expected in this age group to what has been observed in persons aged ≥5 years.

ACIP also considered evidence from known and potential harms from COVID-19 vaccines. Myocarditis and pericarditis are rare adverse events that have been reported after receipt of mRNA COVID-19 vaccines (*26*,*27*). Among vaccine recipients aged ≥5 years, the observed risk for myocarditis is highest among males aged 12–39 years (*26*,*28*,*29*). Cases of myocarditis among children aged 5–11 years after Pfizer-BioNTech COVID-19 vaccination have been rarely reported, primarily in boys and after dose 2 (*28*,*29*). To date, monitoring in CDC's

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TABLE 1. COVID-19 vaccines approved or authorized by the Food and Drug Administration for children aged 6 months–17 years — United States, June 2022

Vaccine manufacturer	Age group at vaccination	Vial cap color	Label border color	Concentration of mRNA per primary dose	Injection volume per primary dose	Diluent volume	Primary doses per vial
Moderna	6 mos–5 yrs	Dark blue	Magenta	25 μg	0.25 mL	None	10
	6–11 yrs	Dark blue	Purple*	50 μg	0.5 mL	None	5
	6–11 yrs	Dark blue	Teal*	50 μg	0.5 mL	None	5
	12–17 yrs	Red	Light blue	100 μg	0.5 mL	None	10–11
Pfizer-BioNTech	6 mos–4 yrs	Maroon	Maroon	3 μg	0.2 mL	2.2 mL	10†
	5–11 yrs	Orange	Orange	10 μg	0.2 mL	1.3 mL	10†
	12–17 yrs	Gray	Gray	30 μg	0.3 mL	None	6

Abbreviation: FDA = Food and Drug Administration.
* Moderna COVID-19 vaccine supplied in a vial with a dark blue cap and a label with a teal border stating "Age 6y through 11y" is currently not available. Moderna COVID-19 vaccine supplied in a vial with a dark blue cap and a label with a purple border stating "BOOSTER DOSES ONLY" is FDA-authorized for use in children aged 6–11 years to provide primary series doses.
† After dilution with 0.9% sodium chloride (normal saline, preservative-free).

Vaccine Safety Datalink have not detected an increased risk for myocarditis and pericarditis in children aged 5–11 years (*29*). No cases of myocarditis occurred among 7,804 children aged 6 months–5 years in the Moderna and Pfizer-BioNTech COVID-19 vaccine clinical trials who received an mRNA vaccine and had ≥7 days of follow-up, although the trials were not adequately powered to detect rare adverse events. Postauthorization safety monitoring, including monitoring for myocarditis and pericarditis after mRNA COVID-19 vaccination, is conducted through multiple national safety surveillance systems.

ACIP determined that the benefits of COVID-19 vaccination outweigh the known and potential risks, even in the setting of high seroprevalence among young children; by April 2022, in a national sample of children aged 6 months–4 years, 71% had infection-induced SARS-CoV-2 antibodies (*9*). Past infection with SARS-CoV-2 provides some protection against reinfection, but the immune response to infection can vary, especially by disease severity, and might not provide broad protection against all SARS-CoV-2 variants (*30*). The Omicron-wave surges of pediatric COVID-19 hospitalizations occurred even in the setting of high seroprevalence, suggesting this alone is not sufficient to provide broad population-level protection. Vaccination in previously infected persons enhances protection against reinfection (*30–32*) and COVID-19–associated hospitalization, including infections and hospitalizations due to the Omicron variant (*32*,*33*). No concerns have been identified in postauthorization safety surveillance associated with vaccination of seropositive persons aged ≥5 years. After assessing the balance of benefits and risks for COVID-19 vaccination, ACIP made an interim recommendation for vaccination with the Moderna COVID-19 vaccine for children aged 6 months–5 years as a 2-dose primary series as authorized under the EUA and an interim recommendation for vaccination with the Pfizer-BioNTech COVID-19 vaccine for children aged 6 months–4 years as a 3-dose primary series as authorized under the EUA. ACIP does not state a product preference between the two recommended vaccines for children aged 6 months–5 years; children may receive any ACIP-recommended COVID-19 vaccine and are encouraged to receive the earliest vaccine available to them. Once a primary series is started, the same mRNA vaccine product should be used for all doses in the series.

The GRADE evidence profiles, which provide details on the identification and assessment of relevant evidence, are available for the Moderna COVID-19 vaccine at https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-moderna-vaccine-6-months-5-years.html and for the Pfizer-BioNTech COVID-19 vaccine at https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-pfizer-biontech-vaccine-6-months-4-years.html. The EtR supporting evidence for both the Moderna COVID-19 vaccine and the Pfizer-BioNTech COVID-19 vaccine is available at https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-moderna-pfizer-children-vaccine-etr.html. Additional clinical considerations, including recommendations for children who are moderately or severely immunocompromised, are available at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.

These interim recommendations and clinical considerations are based on use of the Moderna COVID-19 vaccine under an EUA and on the Pfizer-BioNTech COVID-19 vaccine under an EUA and might change as more evidence becomes available. COVID-19 vaccines must be administered according to applicable state and territorial vaccination laws. Before vaccination, the EUA Fact Sheet (available at https://www.fda.gov/media/159309/download for the Moderna COVID-19 vaccine and https://www.fda.gov/media/159313/download for the Pfizer-BioNTech COVID-19 vaccine) should be provided to parents or guardians. ACIP will continue to review additional data as they become available; updates to recommendations or clinical considerations will be posted on the ACIP website (https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html).

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TABLE 2. Interim COVID-19 immunization schedule for children aged 6 months–17 years — United States, June 2022

Vaccine manufacturer*	Age group at vaccination	Immunocompromise status: Not moderately or severely immunocompromised† — Primary series§	Not moderately or severely immunocompromised† — Booster dose	Moderately or severely immunocompromised† — Primary series	Moderately or severely immunocompromised† — Booster doses
Moderna	6 mos–5 yrs	2 doses 4–8 weeks between doses 1 and 2	Not authorized	3 doses 4 weeks between doses 1 and 2; ≥4 weeks between doses 2 and 3	Not authorized
	6–11 yrs	2 doses 4–8 weeks between doses 1 and 2	Not authorized	3 doses 4 weeks between doses 1 and 2; ≥4 weeks between doses 2 and 3	Not authorized
	12–17 yrs	2 doses 4–8 weeks between doses 1 and 2	Not authorized	3 doses 4 weeks between doses 1 and 2; ≥4 weeks between doses 2 and 3	Not authorized
Pfizer-BioNTech	6 mos–4 yrs	3 doses 3–8 weeks between doses 1 and 2; ≥8 weeks between doses 2 and 3	Not authorized	3 doses 3 weeks between doses 1 and 2; ≥8 weeks between doses 2 and 3	Not authorized
	5–11 yrs	2 doses 3–8 weeks between doses 1 and 2	≥5 mos after primary series	3 doses 3 weeks between doses 1 and 2; ≥4 weeks between doses 2 and 3	≥3 mos after primary series
	12–17 yrs	2 doses 3–8 weeks between doses 1 and 2	≥5 mos after primary series	3 doses 3 weeks between doses 1 and 2; ≥4 weeks between doses 2 and 3	2 booster doses First: ≥3 mos after primary series Second: ≥4 mos after first booster

Abbreviation: FDA = Food and Drug Administration.

* More information on product and dosage is available at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html.

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

§ mRNA COVID-19 vaccines are FDA-approved or FDA-authorized for a 3-week (Pfizer-BioNTech vaccine) or 4-week (Moderna vaccine) interval between the first and second dose. CDC recommends that an 8-week interval might be optimal for some persons aged 6 months–64 years, especially for males aged 12–39 years because it might reduce the small risk of myocarditis or pericarditis associated with mRNA COVID-19 vaccines. A shorter interval (3 weeks for Pfizer-BioNTech and 4 weeks for Moderna) between the first and second doses remains the recommended interval for persons who are moderately or severely immunocompromised, adults aged ≥65 years, and those in situations in which there is increased concern about COVID-19 community levels or a person's higher risk for severe disease.

Reporting of Vaccine Adverse Events

FDA requires that vaccination providers report vaccination administration errors, serious adverse events, multisystem inflammatory syndrome cases, and COVID-19 cases that result in hospitalization or death after administration of COVID-19 vaccine under an EUA. Adverse events that occur after receipt of any COVID-19 vaccine should be reported to the Vaccine Adverse Events Reporting System (VAERS). Information on how to submit a report to VAERS is available at https://vaers.hhs.gov/index.html or 1-800-822-7967. Any person who administers or receives a COVID-19 vaccine (or their parent or guardian) is encouraged to report any clinically significant adverse event, whether it is clear that a vaccine caused the adverse event. In addition, CDC has developed a voluntary smartphone-based online tool (v-safe) that uses text messaging and online surveys to provide near real-time health check-ins after receipt of a COVID-19 vaccine. Parents or guardians can register their children in v-safe and complete

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Summary

What is already known about this topic?

On June 17, 2022, the Food and Drug Administration granted Emergency Use Authorization for the Moderna and Pfizer-BioNTech COVID-19 vaccines for children aged 6 months–5 years and 6 months–4 years, respectively.

What is added by this report?

On June 18, 2022, the Advisory Committee on Immunization Practices (ACIP) issued interim recommendations for the use of the Moderna COVID-19 vaccine for children aged 6 months–5 years and for the Pfizer-BioNTech COVID-19 vaccine for children aged 6 months–4 years in the United States for prevention of COVID-19. ACIP determined that the benefits of vaccination outweigh risks for this population.

What are the implications for public health practice?

Vaccination is important for protecting children aged 6 months–5 years against COVID-19.

the health surveys on their behalf. CDC's v-safe call center follows up on reports to v-safe that include possible medically significant health events to collect additional information for completion of a VAERS report. Information about v-safe is available at https://www.cdc.gov/vsafe.

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References

1. Food and Drug Administration. Spikevax and Moderna COVID-19 vaccine. Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2022. https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/spikevax-and-moderna-covid-19-vaccine
2. Food and Drug Administration. Comirnaty and Pfizer-BioNTech COVID-19 vaccine. Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2021. https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine
3. CDC. COVID data tracker. COVID-19 vaccinations in the United States. Atlanta, GA: US Department of Health and Human Services, CDC; 2022. Accessed June 17, 2022. https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-onedose-pop-5yr
4. Food and Drug Administration, Vaccines and Related Biological Products Advisory Committee. FDA briefing document: EUA amendment request for use of the Moderna COVID-19 vaccine in children 6 months through 17 years of age. Vaccines and Related Biological Products Advisory Committee meeting; June 14–15, 2022; Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2022. https://www.fda.gov/media/159189/download
5. Food and Drug Administration, Vaccines and Related Biological Products Advisory Committee. FDA briefing document: EUA amendment request for Pfizer-BioNTech COVID-19 vaccine for use in children 6 months through 4 years of age. Vaccines and Related Biological Products Advisory Committee meeting; June 15, 2022; Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2022. https://www.fda.gov/media/159195/download
6. Woodworth KR, Moulia D, Collins JP, et al. The Advisory Committee on Immunization Practices' interim recommendation for use of Pfizer-BioNTech COVID-19 vaccine in children aged 5–11 years—United States, November 2021. MMWR Morb Mortal Wkly Rep 2021;70:1579–83. PMID:34758012 https://doi.org/10.15585/mmwr.mm7045e1
7. Oliver SE. Evidence to recommendation framework: Moderna COVID-19 vaccine in children ages 6 months–5 years & Pfizer-BioNTech COVID-19 vaccine in children ages 6 months–4 years. Atlanta, GA: US Department of Health and Human Services, CDC; 2022. https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-06-17-18/03-COVID-Oliver-508.pdf
8. National Center for Health Statistics. Provisional COVID-19 death counts by age in years, 2020–2022. Hyattsville, MD: US Department of Health and Human Services, CDC; 2022. Accessed May 14, 2022. https://data.cdc.gov/d/3apk-4u4f
9. Fleming-Dutra KE. COVID-19 epidemiology in children ages 6 months–4 years. Atlanta, GA: US Department of Health and Human Services, CDC; 2022. https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-06-17-18/02-COVID-Fleming-Dutra-508.pdf
10. Delahoy MJ, Ujamaa D, Taylor CA, et al. Comparison of influenza and COVID-19-associated hospitalizations among children <18 years old in the United States—FluSurv-NET (October–April 2017–2021) and COVID-NET (October 2020–September 2021). Clin Infect Dis 2022;ciac388. PMID:35594564 https://doi.org/10.1093/cid/ciac388
11. CDC. Information for healthcare providers about multisystem inflammatory syndrome in children (MIS-C). Atlanta, GA: US Department of Health and Human Services, CDC; 2022. Accessed June 16, 2022. https://www.cdc.gov/mis/mis-c/hcp/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fmis%2Fhcp%2Findex.html
12. CDC. COVID data tracker. Health department-reported cases of multisystem inflammatory syndrome in children (MIS-C) in the United States. Atlanta, GA: US Department of Health and Human Services, CDC; 2022. Accessed June 15, 2022. https://covid.cdc.gov/covid-data-tracker/#mis-national-surveillance
13. Rao S, Lee GM, Razzaghi H, et al. Clinical features and burden of post-acute sequelae of SARS-CoV-2 infection in children and adolescents: an exploratory EHR-based cohort study from the RECOVER program. medRxiv [Preprint posted online May 25, 2022]. https://www.medrxiv.org/content/10.1101/2022.05.24.22275544v1
14. Borch L, Holm M, Knudsen M, Ellermann-Eriksen S, Hagstroem S. Long COVID symptoms and duration in SARS-CoV-2 positive children - a nationwide cohort study. Eur J Pediatr 2022;181:1597–607. PMID:35000003 https://doi.org/10.1007/s00431-021-04345-z
15. CDC. COVID-19. Post-COVID conditions: CDC Science. Atlanta, GA: US Department of Health and Human Services, CDC; 2022. Accessed June 15, 2022. https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/post-covid-science.html
16. Zimmermann P, Pittet LF, Curtis N. The challenge of studying long COVID: an updated review. Pediatr Infect Dis J 2022;41:424–6. PMID:35213866 https://doi.org/10.1097/INF.0000000000003502
17. Patel Murthy B, Zell E, Kirtland K, et al. Impact of the COVID-19 pandemic on administration of selected routine childhood and adolescent vaccinations—10 U.S. jurisdictions, March–September 2020. MMWR Morb Mortal Wkly Rep 2021;70:840–5. PMID:34111058 https://doi.org/10.15585/mmwr.mm7023a2
18. Schweiberger K, Patel SY, Mehrotra A, Ray KN. Trends in pediatric primary care visits during the coronavirus disease of 2019 pandemic. Acad Pediatr 2021;21:1426–33. PMID:33984496 https://doi.org/10.1016/j.acap.2021.04.031
19. CDC. COVID-19 parental resources kit—early childhood. Atlanta, GA: US Department of Health and Human Services, CDC; 2022. Accessed June 15, 2022. https://www.cdc.gov/mentalhealth/stress-coping/parental-resources/early-childhood/index.html
20. Lopes L, Kirzinger A, Hamel L, et al. KFF COVID-19 vaccine monitor: the impact of the coronavirus pandemic on the wellbeing of parents and children. San Francisco, CA: Kaiser Family Foundation; 2021. https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-the-impact-of-the-coronavirus-pandemic-on-the-wellbeing-of-parents-and-children/
21. Marks KJ, Whitaker M, Agathis NT, et al.; COVID-NET Surveillance Team. Hospitalization of infants and children aged 0–4 years with laboratory-confirmed COVID-19—COVID-NET, 14 states, March 2020–February 2022. MMWR Morb Mortal Wkly Rep 2022;71:429–36. PMID:35298458 https://doi.org/10.15585/mmwr.mm7111e2
22. Sparks G, Hamel L, Kirzinger A, Stokes M, Brodie M. KFF COVID-19 vaccine monitor: differences in vaccine attitudes between rural, suburban, and urban areas. San Francisco, CA: Kaiser Family Foundation; 2021. https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-vaccine-attitudes-rural-suburban-urban/
23. Accorsi EK, Britton A, Fleming-Dutra KE, et al. Association between 3 doses of mRNA COVID-19 vaccine and symptomatic infection caused by the SARS-CoV-2 Omicron and Delta variants. JAMA 2022;327:639–51. PMID:35060999 https://doi.org/10.1001/jama.2022.0470
24. Klein NP, Stockwell MS, Demarco M, et al. Effectiveness of COVID-19 Pfizer-BioNTech BNT162b2 mRNA vaccination in preventing COVID-19–associated emergency department and urgent care encounters and hospitalizations among nonimmunocompromised children and adolescents aged 5–17 years—VISION network, 10 states, April 2021–January 2022. MMWR Morb Mortal Wkly Rep 2022;71:352–8. PMID:35239634 https://doi.org/10.15585/mmwr.mm7109e3
25. Link-Gelles R. COVID-19 vaccine coverage & effectiveness during Omicron for children and adolescents. Atlanta, GA: US Department of Health and Human Services, CDC; 2022. https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-06-17-18/03-COVID-Link-Gelles-508.pdf

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26. Block JP, Boehmer TK, Forrest CB, et al. Cardiac complications after SARS-CoV-2 infection and mRNA COVID-19 vaccination—PCORnet, United States, January 2021–January 2022. MMWR Morb Mortal Wkly Rep 2022;71:517–23. PMID:35389977 https://doi.org/10.15585/mmwr.mm7114e1
27. Oster ME, Shay DK, Su JR, et al. Myocarditis cases reported after mRNA-based COVID-19 vaccination in the US from December 2020 to August 2021. JAMA 2022;327:331–40. PMID:35076665 https://doi.org/10.1001/jama.2021.24110
28. Hause AM, Shay DK, Klein NP, et al. Safety of COVID-19 vaccination in US children ages 5–11 years. Pediatrics 2022. PMID:35581698 https://doi.org/10.1542/peds.2022-057313
29. Shimabukuro T. Update on myocarditis following mRNA COVID-19 vaccination. Atlanta, GA: US Department of Health and Human Services, CDC; 2022. https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-06-22-23/03-COVID-Shimabukuro-508.pdf
30. CDC. Science brief: SARS-CoV-2 infection-induced and vaccine-induced immunity. Atlanta, GA: US Department of Health and Human Services, CDC; 2021. Accessed June 15, 2022. https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/vaccine-induced-immunity.html
31. Hall V, Foulkes S, Insalata F, et al.; SIREN Study Group. Protection against SARS-CoV-2 after Covid-19 vaccination and previous infection. N Engl J Med 2022;386:1207–20. PMID:35172051 https://doi.org/10.1056/NEJMoa2118691
32. Carazo S, Skowronski DM, Brisson M, et al. Protection against Omicron re-infection conferred by prior heterologous SARS-CoV-2 infection, with and without mRNA vaccination. medRxiv [Preprint posted online May 3, 2022]. https://www.medrxiv.org/content/10.1101/2022.04.29.22274455v2
33. Plumb ID, Feldstein LR, Barkley E, et al. Effectiveness of COVID-19 mRNA vaccination in preventing COVID-19–associated hospitalization among adults with previous SARS-CoV-2 infection—United States, June 2021–February 2022. MMWR Morb Mortal Wkly Rep 2022;71:549–55. PMID:35421077 https://doi.org/10.15585/mmwr.mm7115e2

EXHIBIT B

AAP News™



CDC approves COVID-19 vaccines for children under 5; vaccinations could begin this week

June 18, 2022

Steve Schering, Staff Writer

Article type: News

Topics: COVID-19, Infectious Diseases, Vaccine/Immunization

***Editor's note**: For the latest news on COVID-19, visit* http://bit.ly/AAPNewsCOVID19.

About 20 million U.S. children under 5 years old are eligible to receive a COVID-19 vaccine as early as next week following approval from the Centers for Disease Control and Prevention (CDC) Saturday afternoon.

The CDC's Advisory Committee on Immunization Practices (ACIP) voted 12-0 to recommend Moderna COVID-19 vaccine for children ages 6 months through 5 years and Pfizer-BioNTech vaccine for children ages 6 months through 4 years.

Shortly afterward, CDC Director Rochelle P. Walensky, M.D., M.P.H., gave final approval for both vaccines, which were granted emergency use authorization from the Food and Drug Administration Friday.

The AAP released an updated policy statement Saturday recommending that all eligible infants, children and adolescents without contraindications get vaccinated.

"Pediatricians know the power of vaccines to protect infants, children, adolescents and entire communities against deadly and debilitating infectious diseases," Yvonne "Bonnie" A. Maldonado, M.D., FAAP, chair of the AAP Committee on Infectious Diseases, said during the ACIP meeting. "We've successfully immunized millions of children and adolescents to protect them from COVID-19. Families with infants and toddlers need and deserve the same chance to protect their children against the virus."

Vaccine administration

The Moderna vaccine will be available to children ages 6 months through 5 years as a primary series of two 25-microgram (µg) doses administered four to eight weeks apart. Children who are moderately or severely immunocompromised can receive three doses, each given four weeks apart.

The Pfizer-BioNTech vaccine will be available to children ages 6 months through 4 years as a primary series of three 3-µg doses. Dose 1 and dose 2 should be administered three to eight weeks apart, while the third dose should be given at least eight weeks after the second dose. Immunocompromised children should receive a second dose four weeks after the first dose, and dose 3 should be given at least four weeks after dose 2.

Among children, COVID-19 vaccine induces a broader neutralizing antibody response when compared with infection-induced immunity. In contrast with SARS-CoV-2 infection, children vaccinated with two doses demonstrated higher titers against alpha, beta, gamma, delta and omicron variants. Officials say the data show the importance of vaccinating children with prior infection to prevent both severe disease and future infections.

Vaccine rollout

Children should receive the age-appropriate vaccine formulation and follow the schedule based on their age on the day of vaccination, regardless of their size or weight. Children who move from the younger age group to an older age group during the primary series or between the primary series and receipt of the booster dose(s) should receive the vaccine dosage for the older age group for all subsequent doses.

The same mRNA vaccine product should be used for all primary series doses. In accordance with general best practices from ACIP, routine administration of all age-appropriate vaccines simultaneously is recommended for children for whom no specific contraindications exist at the time of the health care visit.

While some children over 5 years old were vaccinated at school and community clinics, experts said physicians are likely to be the leaders in vaccinating children under 5.

The Moderna vaccine for children ages 6 months through 5 years will ship with a magenta label, contains a new National Drug Code and does not require diluent.

The Pfizer-BioNTech vaccine will ship with a maroon cap, with a new National Drug Code and a different amount of diluent added (2.2 milliliters vs. 1.3 milliliters for doses given to children ages 5-11 years). While the vaccine label says “Age 2y to < 5y,” officials said the vaccine can be used in children as young as 6 months. The label also states the vaccine must be discarded six hours after dilution, but officials said the vaccine may be discarded 12 hours after dilution.

Both products come in cartons containing 10 vials that each have 10 doses (100 doses total) with a minimum order quantity of 100 doses per product. While providers may be hesitant to open new vials, officials said getting as many children vaccinated as possible is the priority, noting no opportunity should be missed.

“It’s extremely important that we get this vaccine now and there will be waste, we understand that, but it’s important to get shots in the arms and take advantage of every opportunity. Don’t feel guilty about having to open a vial to administer two doses or one dose,” said José R. Romero, M.D., FAAP, director of the CDC’s National Center for Immunization and Respiratory Diseases.

Clinical trials

Moderna's clinical trial was conducted from December 2021 through February 2022 and involved 6,400 children. No deaths occurred among trial participants, and no cases of myocarditis/pericarditis or vaccine-associated anaphylaxis were reported.

Pfizer-BioNTech's vaccine clinical trial included 3,000 children and was conducted from June 2021 through April 2022. Initially, it involved review of a two-dose series, but the company soon began studying a three-dose primary series.

No deaths were reported in any trial participants, and serious adverse events (SAEs) were rare overall. SAEs occurred in 1% of vaccine recipients and 1.5% of placebo receipts. No cases of myocarditis/pericarditis or vaccine-associated anaphylaxis were reported.

COVID-19 in children

Between March 1, 2020, and April 30, 2022, 269 children younger than 1 year and 134 children ages 1-4 years died as a result of COVID-19.

More than 2 million cases of COVID-19 have been reported among children ages 6 months through 4 years. Children in this age group are at risk of severe illness from COVID-19, and more than half of all hospitalized children ages 6 months through 4 years had no underlying conditions.

Resources

- CDC's Pediatric COVID-19 Vaccination Operational Planning Guide
- AAP COVID vaccination resources
- CDC clinical considerations for administering COVID-19 vaccines
- Information from HealthyChildren.org: What Should Parents Know About the COVID Vaccine for Kids Under 5?
- CDC information on U.S. COVID-19 products

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EXHIBIT C

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Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger

United States 2025

American Academy of Pediatrics
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Vaccines and Other Immunizing Agents in the Child and Adolescent Immunization Schedule*

Monoclonal antibody	Abbreviation(s)	Trade name(s)
Respiratory syncytial virus monoclonal antibody	RSV-mAb	Beyfortus Enflonsia
Vaccine	**Abbreviation(s)**	**Trade name(s)**
COVID-19 vaccine	1vCOV-mRNA	Comirnaty mNEXSPIKE Spikevax
	1vCOV-aPS	Nuvaxovid
Dengue vaccine	DEN4CYD	Dengvaxia
Diphtheria, tetanus, and acellular pertussis vaccine	DTaP	Daptacel Infanrix
Haemophilus influenzae type b vaccine	Hib (PRP-T)	ActHIB Hiberix
	Hib (PRP-OMP)	PedvaxHIB
Hepatitis A vaccine	HepA	Havrix Vaqta
Hepatitis B vaccine	HepB	Engerix-B Recombivax HB
Human papillomavirus vaccine	HPV	Gardasil 9
Influenza vaccine (inactivated: egg-based)	IIV3	Multiple
Influenza vaccine (inactivated: cell-culture)	ccIIV3	Flucelvax
Influenza vaccine (recombinant)	RIV3	Flublok
Influenza vaccine (live, attenuated)	LAIV3	FluMist
Measles, mumps, and rubella vaccine	MMR	M-M-R II Priorix
Meningococcal serogroups A, C, W, Y vaccine	MenACWY-CRM	Menveo
	MenACWY-TT	MenQuadfi
Meningococcal serogroup B vaccine	MenB-4C	Bexsero
	MenB-FHbp	Trumenba
Meningococcal serogroup A, B, C, W, Y vaccine	MenACWY-TT/MenB-FHbp	Penbraya
	MenACWY-CRM/MenB-4C	Penmenvy
Mpox vaccine	Mpox	JYNNEOS
Pneumococcal conjugate vaccine	PCV15	Vaxneuvance
	PCV20	Prevnar 20
Pneumococcal polysaccharide vaccine	PPSV23	Pneumovax 23
Poliovirus vaccine (inactivated)	IPV	Ipol
Respiratory syncytial virus vaccine	RSV	Abrysvo
Rotavirus vaccine	RV1	Rotarix
	RV5	RotaTeq
Tetanus, diphtheria, and acellular pertussis vaccine	Tdap	Adacel Boostrix
Tetanus and diphtheria vaccine	Td	Tenivac Tdvax
Varicella vaccine	VAR	Varivax
Combination vaccines (use combination vaccines instead of separate injections when appropriate)		
DTaP, hepatitis B, and inactivated poliovirus vaccine	DTaP-HepB-IPV	Pediarix
DTaP, inactivated poliovirus, and *Haemophilus influenzae* type b vaccine	DTaP-IPV/Hib	Pentacel
DTaP and inactivated poliovirus vaccine	DTaP-IPV	Kinrix Quadracel
DTaP, inactivated poliovirus, *Haemophilus influenzae* type b, and hepatitis B vaccine	DTaP-IPV-Hib-HepB	Vaxelis
Measles, mumps, rubella, and varicella vaccine	MMRV	ProQuad

*Administer recommended vaccines if immunization history is incomplete or unknown. Do not restart or add doses to vaccine series for extended intervals between doses. When a vaccine is not administered at the recommended age, administer at a subsequent visit when indicated. The use of trade names is for identification purposes only and does not imply endorsement by the AAP.

Updated November 21, 2025

How to use the child and adolescent immunization schedule

1. Determine recommended vaccine by age (**Table 1**)
2. Determine recommended interval for catch-up vaccination (**Table 2**)
3. Assess need for additional recommended vaccines by medical condition or other indication (**Table 3**)
4. Review vaccine types, frequencies, intervals, and considerations for special situations (**Notes**)
5. Review contraindications and precautions for vaccine types (**Appendix**)
6. Review new or updated American Academy of Pediatrics (AAP) guidance (**Addendum**)

Report

- Suspected cases of reportable vaccine-preventable diseases or outbreaks to your state or local health department
- Clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov (Accessed August 11, 2025) or 800-822-7967
- For RSV-mAb products, clinically significant adverse events to MedWatch Adverse Event Report Program at www.accessdata.fda.gov/scripts/medwatch/index.cfm (Accessed August 11, 2025). If co-administered with other products, then report to VAERS.

Questions or comments

Submit a question or comment to www.aap.org/en/forms/immunization-schedule-questions.

Helpful information

- **Best practices for immunization (including contraindications and precautions):** www.aap.org/immunization and www.immunize.org
- ***Red Book: 2024–2027 Report of the Committee on Infectious Diseases* (33rd Edition):** www.aapRedBook.org
- **Vaccine information statements:** www.immunize.org/vaccines/vis/about-vis

For the most up-to-date version, visit AAP.org/ImmunizationSchedule

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Table 1 Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025

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These recommendations must be read with the Notes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the outlined purple bars. To determine minimum intervals between doses, see the catch-up schedule (Table 2).

Vaccine and other immunizing agents	Birth	1 mos	2 mos	4 mos	6 mos	8 mos	9 mos	12 mos	15 mos	18 mos	19–23 mos	2–3 yrs	4–6 yrs	7–10 yrs	11–12 yrs	13–15 yrs	16 yrs	17–18 yrs
Respiratory syncytial virus (RSV-mAb [nirsevimab, clesrovimab])	1 dose during RSV season depending on maternal RSV vaccination status (See Notes)					1 dose nirsevimab during RSV season (See Notes)												
Hepatitis B (HepB)	1st dose	2nd dose			3rd dose													
Rotavirus (RV): RV1 (2-dose series), RV5 (3-dose series)			1st dose	2nd dose	See Notes													
Diphtheria, tetanus, and acellular pertussis (DTaP <7 yrs)			1st dose	2nd dose	3rd dose				4th dose				5th dose					
Haemophilus influenzae type b (Hib)			1st dose	2nd dose	See Notes			3rd or 4th dose (See Notes)										
Pneumococcal conjugate (PCV15, PCV20)			1st dose	2nd dose	3rd dose			4th dose										
Inactivated poliovirus (IPV)			1st dose	2nd dose	3rd dose								4th dose					See Notes
COVID-19 (1vCOV-mRNA, 1vCOV-aPS)					1 or more doses of 2025–2026 vaccine (See Notes)							1 dose of 2025–2026 vaccine (See Notes)						
												1 dose of 2025–2026 vaccine (See Notes)						
Influenza					1 or 2 doses annually (See Notes)										1 dose annually (See Notes)			
Measles, mumps, and rubella (MMR)					See Notes			1st dose					2nd dose					
Varicella (VAR)								1st dose					2nd dose					
Hepatitis A (HepA)					See Notes			2-dose series (See Notes)										
Tetanus, diphtheria, and acellular pertussis (Tdap ≥7 yrs)															1st dose			
Human papillomavirus (HPV)															2-dose series	See Notes		
Meningococcal (MenACWY-CRM ≥2 mos, MenACWY-TT ≥2years)			See Notes												1st dose		2nd dose	
Meningococcal B (MenB-4C, MenB-FHbp)															See Notes			
Respiratory syncytial virus vaccine (RSV [Abrysvo])															Seasonal administration during pregnancy if not previously vaccinated			
Dengue (DEN4CYD: 9–16 yrs)															Seropositive in areas with endemic dengue (See Notes)			
Mpox																		

Range of recommended ages for all children
Range of recommended ages for catch-up vaccination
Range of recommended ages for certain high-risk groups or populations
Recommended vaccination for those who desire protection
Recommended vaccination based on shared clinical decision-making

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Table 2 Recommended Catch-up Immunization Schedule for Children and Adolescents Who Start Late or Who Are More than 1 Month Behind, United States, 2025

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The table below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age. **Always use this table in conjunction with Table 1 and the Notes that follow.**

Vaccine	Minimum Age for Dose 1	Minimum Interval Between Doses			
		Dose 1 to Dose 2	Dose 2 to Dose 3	Dose 3 to Dose 4	Dose 4 to Dose 5
Children age 4 months through 6 years					
Hepatitis B	Birth	**4 weeks**	**8 weeks *and* at least 16 weeks after first dose:** minimum age for the final dose is 24 weeks		
Rotavirus	6 weeks: Maximum age for first dose is 14 weeks, 6 days.	**4 weeks**	**4 weeks:** maximum age for final dose is 8 months, 0 days		
Diphtheria, tetanus, and acellular pertussis	6 weeks	**4 weeks**	**4 weeks**	**6 months**	**6 months:** A fifth dose is not necessary if the fourth dose was administered at age 4 years or older ***and*** at least 6 months after dose 3
Haemophilus influenzae type b	6 weeks	**No further doses needed** if first dose was administered at age 15 months or older **4 weeks** if first dose was administered before the 1st birthday **8 weeks (as final dose)** if first dose was administered at age 12 through 14 months	**No further doses needed** if previous dose was administered at age 15 months or older **4 weeks** if current age is younger than 12 months and first dose was administered at younger than age 7 months ***and*** at least 1 previous dose was PRP-T (ActHib, Pentacel, Hiberix), Vaxelis, or unknown **8 weeks and age 12 through 59 months (as final dose)** if current age is younger than 12 months ***and*** first dose was administered at age 7 through 11 months; **OR** if current age is 12 through 59 months ***and*** first dose was administered before the 1st birthday ***and*** second dose was administered at younger than 15 months; **OR** if both doses were PedvaxHIB and were administered before the 1st birthday	**8 weeks (as final dose):** This dose only necessary for children age 12 through 59 months who received 3 doses before the 1st birthday	
Pneumococcal conjugate	6 weeks	**No further doses needed** for healthy children if first dose was administered at age 24 months or older **4 weeks** if first dose was administered before the 1st birthday **8 weeks (as final dose for healthy children)** if first dose was administered at the 1st birthday or after	**No further doses needed** for healthy children if previous dose was administered at age 24 months or older **4 weeks:** if current age is younger than 12 months ***and*** previous dose was administered at <7 months old **8 weeks (as final dose for healthy children)** if previous dose was administered between 7–11 months (wait until at least 12 months old); **OR** if current age is 12 months or older ***and*** at least 1 dose was administered before age 12 months	**8 weeks (as final dose):** This dose is only necessary for children age 12 through 59 months regardless of risk, or age 60 through 71 months with any risk, who received 3 doses before age 12 months	
Inactivated poliovirus	6 weeks	**4 weeks**	**4 weeks** if current age is <4 years **6 months (as final dose)** if current age is 4 years or older	**6 months (minimum age 4 years for final dose)**	
Measles, mumps, and rubella	12 months	**4 weeks**			
Varicella	12 months	**3 months**			
Hepatitis A	12 months	**6 months**			
Meningococcal ACWY	2 months MenACWY-CRM 2 years MenACWY-TT	**8 weeks**	See Notes	See Notes	
Children and adolescents age 7 through 18 years					
Meningococcal ACWY	Not applicable (N/A)	**8 weeks**			
Tetanus, diphtheria; tetanus, diphtheria, and acellular pertussis	7 years	**4 weeks**	**4 weeks:** if first dose of DTaP/DT was administered before the 1st birthday **6 months (as final dose):** if first dose of DTaP/DT or Tdap/Td was administered at or after the 1st birthday	**6 months:** if first dose of DTaP/DT was administered before the 1st birthday	
Human papillomavirus	9 years	**Routine dosing intervals are recommended**			
Hepatitis A	N/A	**6 months**			
Hepatitis B	N/A	**4 weeks**	**8 weeks *and* at least 16 weeks after first dose**		
Inactivated poliovirus	N/A	**4 weeks**	**6 months:** A fourth dose is not necessary if the third dose was administered at age 4 years or older ***and*** at least 6 months after the previous dose	A fourth dose of IPV is indicated if all previous doses were administered at <4 years **OR** if the third dose was administered <6 months after the second dose	
Measles, mumps, and rubella	N/A	**4 weeks**			
Varicella	N/A	**3 months** if younger than age 13 years. **4 weeks** if age 13 years or older			
Dengue	9 years	**6 months**	6 months		

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Table 3 Recommended Child and Adolescent Immunization Schedule by Medical Indication, United States, 2025

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Always use this table in conjunction with Table 1 and the Notes that follow. Medical conditions are often not mutually exclusive. If multiple conditions are present, refer to guidance in all relevant columns. See Notes for medical conditions not listed.

Vaccine and other immunizing agents	Pregnancy	Immunocompromised (excluding HIV infection)[a]	HIV infection CD4 percentage and count[a]		CSF leak or cochlear implant	Asplenia or persistent complement component deficiencies	Heart disease or chronic lung disease (CLD)	Kidney failure, End-stage renal disease or on dialysis	Chronic liver disease	Diabetes
			<15% or <200/mm³	≥15% and <200/mm³						
RSV-mAb (nirsevimab, clesrovimab)		1 dose clesrovimab or nirsevimab during 1st RSV season depending on maternal RSV vaccination status (See Notes)								
		1 dose nirsevimab 2nd RSV season (See Notes)					1 dose nirsevimab 2nd RSV season for CLD (See Notes)			
Hepatitis B										
Rotavirus		SCID[b]								
DTaP/Tdap	DTaP: not applicable Tdap: 1 dose each pregnancy									
Hib		HCT[c]: 3 doses	See Notes			See Notes				
Pneumococcal										
IPV										
COVID-19	*	See Notes								
Influenza inactivated, recombinant		Solid organ transplant: 18 yrs (See Notes)								
LAIV3							Asthma, wheezing: 2–4 years[d]			
MMR	**									
VAR	**									
Hepatitis A										
HPV	**	3-dose series (See Notes)								
MenACWY										
MenB										
RSV (Abrysvo)	Seasonal administration (See Notes)									
Dengue										
Mpox	See Notes									

*For more information, refer to https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/covid-19-vaccination-considerations-for-obstetric-gynecologic-care

- Recommended for all age-eligible children who lack documentation of a complete vaccination series
- Not recommended for all children, but recommended for some children based on increased risk for or severe outcomes from disease
- Recommended for all age-eligible children, and additional doses may be necessary based on medical condition or other indications. See Notes.
- Precaution: Might be indicated if benefit of protection outweighs risk of adverse reaction
- Contraindicated or not recommended. **Vaccinate after pregnancy, if indicated

a. For additional information regarding immunization in immunocompromised children, see https://publications.aap.org/redbook/book/755/chapter/14074446/Immunization-and-Other-Considerations-in
b. Severe combined immunodeficiency
c. Hematopoietic cell transplantation
d. LAIV3 contraindicated for children 2–4 years of age with asthma or wheezing during the preceding 12 months

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Notes

Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025

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Additional information

- For calculating intervals between doses, 4 weeks = 28 days. Intervals of ≥4 months are determined by calendar months.
- Within a number range (eg, 12–18), a dash (–) should be read as "through."
- Vaccine doses administered ≤4 days before the minimum age or interval are considered valid. Doses of any vaccine administered ≥5 days earlier than the minimum age or minimum interval should not be counted as valid and should be repeated as age appropriate. **The repeat dose should be spaced after the invalid dose by the recommended minimum interval.** For further details, see https://publications.aap.org/redbook/book/755/chapter/14074243/Immunization-Schedule-and-Timing-of-Vaccines.
- Information on travel vaccination requirements and recommendations is available at https://publications.aap.org/redbook/book/755/chapter/14074567/International-Travel.
- For vaccination of persons with immunodeficiencies, see https://publications.aap.org/redbook/book/755/chapter/14074446/Immunization-and-Other-Considerations-in.
- For information about vaccination in the setting of a vaccine-preventable disease outbreak, contact your state or local health department.
- The National Vaccine Injury Compensation Program (VICP) is a no-fault alternative to the traditional legal system for resolving vaccine injury claims. All vaccines included in the child and adolescent vaccine schedule are covered by VICP except dengue, PPSV23, RSV, Mpox and COVID-19 vaccines. Mpox and COVID-19 vaccines are covered by the Countermeasures Injury Compensation Program (CICP). For more information, see www.hrsa.gov/vaccinecompensation (Accessed August 11, 2025) or www.hrsa.gov/cicp (Accessed August 11, 2025).

COVID-19 vaccination
(minimum age: 6 months [Moderna Spikevax], 5 years [Pfizer-BioNTech Comirnaty], 12 years [Novavax Nuvaxovid, Moderna mNEXSPIKE])

Refer to the AAP's COVID-19 Vaccine Dosing for a visual quick reference guide, www.aap.org/CovidVaccineGuide.

Trade names are used for Moderna because there is more than 1 Moderna product available.

Routine vaccination

Everyone age 6–23 months

- **Unvaccinated** (ie, never received any COVID-19 vaccine doses):
  - 2 doses Moderna Spikevax 0, 4–8 weeks
- **Incomplete initial vaccination series:**
  - **1 dose Moderna:** complete initial series with 1 dose 4–8 weeks after most recent dose of Spikevax
  - **1 dose Pfizer-BioNTech:** complete initial series with 2 doses Moderna Spikevax at least 4 weeks apart (administer dose 1 3–8 weeks after most recent dose)
  - **2 doses Pfizer-BioNTech:** complete initial series with 1 dose Moderna Spikevax at least 8 weeks after the most recent dose
- **Completed initial vaccination series:**
  - **1 dose Moderna Spikevax** at least 8 weeks after the most recent dose

Special situations

Age 2–18 years in the following risk groups*: persons at high risk of severe COVID-19, residents of long-term care facilities or other congregate settings, persons who have never been vaccinated against COVID-19, persons whose household contacts are at high risk for severe COVID-19

- **Ages 2–4 years:** 1 dose of Moderna Spikevax regardless of previous vaccination status at least 8 weeks after the most recent dose
- **Ages 5-11 years:** 1 dose of Moderna Spikevax or Pfizer-BioNTech Comirnaty regardless of previous vaccination status at least 8 weeks after the most recent dose
- **Ages 12–18 years:**
  - 1 dose of Moderna Spikevax, Pfizer-BioNTech Comirnaty, or Novavax Nuvaxovid regardless of previous vaccination status at least 8 weeks after the most recent dose
  - 1 dose of Moderna mNEXSPIKE regardless of previous vaccination status at least 12 weeks after the last dose was received

Children 2 through 18 years of age not included in the risk groups above whose parent or guardian desires their protection from COVID-19 should be offered a single dose of age-appropriate COVID-19 vaccine.

Use any available COVID-19 vaccine appropriate by age and health status that is approved by the FDA through a biologics license application. The most updated version of the COVID-19 vaccine that is available should be used.

*Refer to the AAP's COVID-19 Vaccine Policy Statement for more information on risk groups, https://doi.org/10.1542/peds.2025-073924.

Persons who are moderately or severely immunocompromised. People eligible for additional doses include those who are receiving active cancer treatment for tumors or cancers of the blood, those who received an organ transplant and are taking medicine to suppress the immune system, those who received a hematopoietic cell transplant within the last 2 years or are taking medicine to suppress the immune system, those with moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome), those with advanced or untreated HIV infection, and those with active treatment with high-dose corticosteroids or other drugs that may suppress an immune response. For revaccination guidance for children with hematologic malignancy post-hematopoietic cell transplant or CAR T-cell therapy, refer to: https://doi.org/10.1111/tid.14109.

Age 6 months–4 years moderately or severely immunocompromised

- **Unvaccinated:**
  - 4 doses (**3-dose initial series Moderna Spikevax** at 0, 4 weeks, and at least 4 weeks after dose 2, followed by 1 dose Moderna Spikevax 6 months later [minimum interval 2 months]). May administer additional doses.**
- **Incomplete initial 3-dose vaccination series:**
  - **Previous vaccination with Moderna**
    - **1 dose Moderna:** complete initial series with 2 doses Moderna Spikevax at least 4 weeks apart (administer dose 1 Moderna Spikevax 4 weeks after most recent dose), followed by 1 dose Moderna Spikevax 6 months later (minimum interval 2 months). May administer additional doses of Moderna Spikevax.**
    - **2 doses Moderna:** complete initial series with 1 dose Moderna Spikevax at least 4 weeks after most recent dose, followed by 1 dose Moderna Spikevax 6 months later (minimum interval 2 months). May administer additional doses of Moderna Spikevax.**

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COVID-19 vaccination—*continued*

- **Previous vaccination with Pfizer-BioNTech**
  - **1 dose Pfizer-BioNTech:** complete initial series with 2 doses Moderna Spikevax at least 4 weeks apart (administer dose 1 Moderna Spikevax 3 weeks after most recent dose), followed by 1 dose Moderna Spikevax 6 months later (minimum interval 2 months). May administer additional doses of Moderna Spikevax.**
  - **2 doses Pfizer-BioNTech:** complete initial series with 1 dose Moderna Spikevax at least 8 weeks after most recent dose, followed by 1 dose Moderna Spikevax 6 months later (minimum interval 2 months).
- **Previously completed initial 3-dose vaccination series with:**
  - **3 or more doses Moderna:** 2 doses Moderna Spikevax 6 months apart (minimum interval 2 months). Administer dose 1 at least 8 weeks after the most recent dose. May administer additional doses of Moderna Spikevax.**
  - **3 or more doses Pfizer-BioNTech:** 2 doses Moderna Spikevax 6 months apart (minimum interval 2 months). Administer dose 1 at least 8 weeks after the most recent dose. May administer additional doses of Moderna Spikevax.**

Age 5–11 years moderately or severely immunocompromised

Use vaccine from the same manufacturer for all doses in the initial vaccination series.

- **Unvaccinated:**
  - 4 doses (**3-dose initial series Moderna Spikevax** at 0, 4 weeks, and at least 4 weeks after dose 2, followed by 1 dose Moderna Spikevax or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses.**
  - 4 doses (**3-dose initial series Pfizer-BioNTech** at 0, 3 weeks, and at least 4 weeks after dose 2, followed by 1 dose Moderna Spikevax or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses.**
- **Incomplete initial 3-dose vaccination series:**
  - **Previous vaccination with Moderna**
    - **1 dose Moderna Spikevax:** complete initial series with 2 doses Moderna a Spikevax t least 4 weeks apart (administer dose 1 Moderna Spikevax 4 weeks after most recent dose), followed by 1 dose Moderna Spikevax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna Spikevax or Pfizer-BioNTech.**
    - **2 doses Moderna Spikevax:** complete initial series with 1 dose Moderna Spikevax at least 4 weeks after most recent dose, followed by 1 dose Moderna Spikevax or Pfizer BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna Spikevax or Pfizer-BioNTech.**
  - **Previous vaccination with Pfizer-BioNTech**
    - **1 dose Pfizer-BioNTech:** complete initial series with 2 doses Pfizer-BioNTech at least 4 weeks apart (administer dose 1 Pfizer-BioNTech 3 weeks after most recent dose), followed by 1 dose Moderna Spikevax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Pfizer-BioNTech.**
    - **2 doses Pfizer-BioNTech:** complete initial series with 1 dose Pfizer-BioNTech at least 4 weeks after most recent dose, followed by 1 dose Moderna Spikevax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna Spikevax or Pfizer-BioNTech.**
- **Completed initial 3-dose vaccination series with:**
  - **3 or more doses Moderna or 3 or more doses Pfizer-BioNTech:** 2 doses Moderna or Pfizer-BioNTech 6 months apart (minimum interval 2 months). Administer dose 1 at least 8 weeks after the most recent dose. May administer additional doses of Moderna or Pfizer-BioNTech.**

Age 12–18 years moderately or severely immunocompromised

Use vaccine from the same manufacturer for all doses in the initial vaccination series. Either Moderna product (Spikevax or mNEXSPIKE) can be used unless otherwise specified.

- **Unvaccinated:**
  - 4 doses (**3-dose initial series Moderna** at 0, 4 weeks, and at least 4 weeks after dose 2, followed by 1 dose Moderna or Novavax or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.**
  - 4 doses (**3-dose initial series Pfizer-BioNTech** at 0, 3 weeks, and at least 4 weeks after dose 2, followed by 1 dose Moderna or Novavax or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.**
  - 3 doses (**2-dose initial series Novavax** at 0, 3 weeks, followed by 1 dose Moderna or Novavax or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.**
- **Incomplete initial vaccination series:**
  - **Previous vaccination with Moderna**
    - **1 dose Moderna:** complete initial series with 2 doses Moderna at least 4 weeks apart (administer dose 1 Moderna 4 weeks after most recent dose), followed by 1 dose Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.**
    - **2 doses Moderna:** complete initial series with 1 dose Moderna at least 4 weeks after most recent dose, followed by 1 dose Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.**
  - **Previous vaccination with Pfizer-BioNTech**
    - **1 dose Pfizer-BioNTech:** complete initial series with 2 doses Pfizer-BioNTech at least 4 weeks apart (administer dose 1 Pfizer-BioNTech 3 weeks after most recent dose), followed by 1 dose Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.**
    - **2 doses Pfizer-BioNTech:** complete initial series with 1 dose Pfizer-BioNTech at least 4 weeks after most recent dose, followed by 1 dose Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.**
  - **Previous vaccination with Novavax**
    - **1 dose Novavax:** complete initial series with 1 dose Novavax at least 3 weeks after most recent dose, followed by 1 dose Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.**

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COVID-19 vaccination—*continued*

- **Completed initial 3-dose vaccination series with:**
  - **3 or more doses Moderna or 3 or more doses Pfizer-BioNTech:** 2 doses Moderna or Novavax or Pfizer-BioNTech 6 months apart (minimum interval 2 months). Administer dose 1 at least 8 weeks after the most recent dose. May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.**
  - **2 or more doses Novavax:** 2 doses Moderna or Novavax or Pfizer-BioNTech 6 months apart (minimum interval 2 months). Administer dose 1 at least 8 weeks after the most recent dose. May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.**

****Additional doses of COVID-19 vaccine for moderately or severely immunocompromised:** based on shared clinical decision making and administered at least 2 months after the most recent dose.

Dengue vaccination (minimum age: 9 years)

Routine vaccination

- Age 9–16 years living in areas with endemic dengue **AND** have laboratory confirmation of previous dengue infection
  - 3-dose series administered at 0, 6, and 12 months
- Endemic areas include Puerto Rico, American Samoa, US Virgin Islands, Federated States of Micronesia, Republic of Marshall Islands, and the Republic of Palau. For updated guidance on dengue endemic areas and pre-vaccination laboratory testing see www.cdc.gov/mmwr/volumes/70/rr/rr7006a1.htm?s_cid=rr7006a1_w (Accessed August 11, 2025).
- Dengue vaccine should not be administered to children traveling to or visiting endemic dengue areas.

Diphtheria, tetanus, and acellular pertussis (DTaP) vaccination (minimum age: 6 weeks [4 years for Kinrix or Quadracel])

Routine vaccination

- 5-dose series (3-dose primary series at age 2, 4, and 6 months, followed by booster doses at ages 15–18 months and 4–6 years)
  - **Prospectively:** Dose 4 may be administered as early as age 12 months if at least 6 months have elapsed since dose 3.
  - **Retrospectively:** A 4th dose that was inadvertently administered as early as age 12 months may be counted if at least 4 months have elapsed since dose 3.

Catch-up vaccination

- Dose 5 is not necessary if dose 4 was administered at age 4 years or older and at least 6 months after dose 3.
- For other catch-up guidance, see Table 2.

Special situations

- **Children younger than age 7 years with a contraindication specific to the pertussis component of DTaP:** May administer Td for all recommended remaining doses in place of DTaP. Encephalopathy within 7 days of vaccination when not attributable to another identifiable cause is the only contraindication specific to the pertussis component of DTaP. For additional information, see https://publications.aap.org/redbook/book/755/chapter/14076838/Diphtheria.
- **Wound management in children younger than age 7 years with history of 3 or more doses of tetanus toxoid-containing vaccine:** For all wounds except clean and minor wounds, administer DTaP if more than 5 years since last dose of tetanus toxoid-containing vaccine. For detailed information, see www.cdc.gov/mmwr/volumes/67/rr/rr6702a1.htm (Accessed August 11, 2025).

Haemophilus influenzae type b (Hib) vaccination (minimum age: 6 weeks)

Routine vaccination

- **ActHIB, Hiberix, Pentacel, or Vaxelis:** 4-dose series (3-dose primary series at age 2, 4, and 6 months, followed by a booster dose* at age 12–15 months)
  - *Vaxelis is not recommended for use as a booster dose. A different Hib-containing vaccine should be used for the booster dose.
- **PedvaxHIB:** 3-dose series (2-dose primary series at age 2 and 4 months, followed by a booster dose at age 12–15 months)
- **American Indian and Alaska Native infants:** Vaxelis and PedvaxHIB preferred over other Hib vaccines for the primary series.

Catch-up vaccination

- **Dose 1 at age 7–11 months:** Administer dose 2 at least 4 weeks later and dose 3 (final dose) at age 12–15 months or 8 weeks after dose 2 (whichever is later).
- **Dose 1 at age 12–14 months:** Administer dose 2 (final dose) at least 8 weeks after dose 1.
- **Dose 1 before age 12 months and dose 2 before age 15 months:** Administer dose 3 (final dose) at least 8 weeks after dose 2.
- **2 doses of PedvaxHIB before age 12 months:** Administer dose 3 (final dose) at age 12–59 months and at least 8 weeks after dose 2.
- **1 dose administered at age 15 months or older:** No further doses needed
- **Unvaccinated at age 15–59 months:** Administer 1 dose.
- **Previously unvaccinated children age 60 months or older who are not considered high risk:** Catch-up vaccination not required.

For other catch-up guidance, see Table 2. Vaxelis can be used for catch-up vaccination in children younger than age 5 years. Follow the catch-up schedule even if Vaxelis is used for one or more doses. For detailed information on use of Vaxelis, see www.cdc.gov/mmwr/volumes/69/wr/mm6905a5.htm (Accessed August 11, 2025).

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Haemophilus influenzae type b (Hib) vaccination—*continued*

Special situations

- **Chemotherapy or radiation treatment:**
  - **Age 12–59 months**
    - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
    - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

Doses administered within 14 days of starting therapy or during therapy should be repeated at least 3 months after therapy completion.

- **Hematopoietic cell transplant (HCT):**
  - 3-dose series 4 weeks apart starting 6 to 12 months after successful transplant, regardless of Hib vaccination history
- **Anatomic or functional asplenia (including sickle cell disease):**
  - **Age 12–59 months**
    - **Unvaccinated or only 1 dose before age 12 months:** 2 doses, 8 weeks apart
    - **2 or more doses before age 12 months:** 1 dose at least 8 weeks after previous dose
  - *Unvaccinated* persons age 5 years or older*
    - 1 dose
- **Elective splenectomy:**
  - *Unvaccinated* persons age 15 months or older*
    - 1 dose (preferably at least 14 days before procedure)
- **HIV infection:**
  - *Age 12–59 months*
    - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
    - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose
  - *Unvaccinated* persons age 5–18 years*
    - 1 dose
- **Immunoglobulin deficiency, early component complement deficiency, or early component complement inhibitor use:**
  - *Age 12–59 months*
    - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
    - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

Unvaccinated* = Less than routine series (through age 14 months) **or no doses (age 15 months or older)

Hepatitis A (HepA) vaccination (minimum age: 12 months for routine vaccination)

Routine vaccination

- **2-dose series** (minimum interval: 6 months) at age 12–23 months

Catch-up vaccination

- **Unvaccinated persons through age 18 years should complete a 2-dose series** (minimum interval: 6 months).
- Persons who previously received 1 dose at age 12 months or older should receive dose 2 at least 6 months after dose 1.
- Adolescents age 18 years or older may receive HepA-HepB (Twinrix) as a 3-dose series (0, 1, and 6 months) or 4-dose series (3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months).

International travel

- Persons traveling to or working in countries with high or intermediate endemic hepatitis A (https://publications.aap.org/redbook/book/755/chapter/14074567/International-Travel):
  - Infants age 6–11 months: 1 dose before departure; revaccinate with 2 doses (separated by at least 6 months) between age 12–23 months.
  - Unvaccinated age 12 months or older: Administer dose 1 as soon as travel is considered.

Hepatitis B (HepB) vaccination (minimum age: birth)

Routine vaccination

- **Mother is HBsAg-negative**
  - 3-dose series at age 0, 1–2, 6–18 months **(use monovalent HepB vaccine for doses administered before age 6 weeks)**
    - Birth weight ≥2000 grams: 1 dose within 24 hours of birth if medically stable
    - Birth weight <2000 grams: 1 dose at chronological age 1 month or hospital discharge (whichever is earlier and even if weight is still <2000 grams)
  - Infants who did not receive a birth dose should begin the series as soon as possible (see Table 2 for minimum intervals).
  - Administration of 4 doses is permitted when a combination vaccine containing HepB is used after the birth dose.
  - **Minimum intervals (see Table 2):** when 4 doses are administered, substitute "dose 4" for "dose 3" in these calculations.
  - **Final (3rd or 4th) dose:** age 6–18 months **(minimum age 24 weeks)**
- **Mother is HBsAg-positive**
  - **Birth dose (monovalent HepB vaccine only):** administer **HepB vaccine** and **hepatitis B immune globulin (HBIG)** in separate limbs within 12 hours of birth, regardless of birth weight.
  - **Birth weight <2000 grams:** administer 3 additional doses of HepB vaccine beginning at age 1 month (total of 4 doses).
  - **Final (3rd or 4th) dose:** administer at age 6 months **(minimum age 24 weeks).**
  - Test for HBsAg and anti-HBs at age 9–12 months. If HepB series is delayed, test 1–2 months after final dose. Do not test before age 9 months.

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Hepatitis B (HepB) vaccination—*continued*

- **Mother is HBsAg-unknown**
  If other evidence suggestive of maternal hepatitis B infection exists (eg, presence of HBV DNA, HBeAg-positive, or mother known to have chronic hepatitis B infection), manage infant as if mother is HBsAg-positive.
  - **Birth dose (monovalent HepB vaccine only):**
    - Birth weight ≥2000 grams: administer **HepB vaccine** within 12 hours of birth. Determine mother's HBsAg status as soon as possible. If mother is determined to be HBsAg-positive, administer **HBIG** as soon as possible (in separate limb), but no later than 7 days of age.
    - Birth weight <2000 grams: administer **HepB vaccine** and **HBIG** (in separate limbs) within 12 hours of birth. Administer 3 additional doses of **HepB vaccine** beginning at age 1 month (total of 4 doses).
  - **Final (3rd or 4th) dose:** administer at age 6 months **(minimum age 24 weeks)**.
  - If mother is determined to be HBsAg-positive or if status remains unknown, test for HBsAg and anti-HBs at age 9–12 months. If HepB series is delayed, test 1–2 months after final dose. Do not test before age 9 months.

Catch-up vaccination

- Unvaccinated persons should complete a 3-dose series at 0, 1–2, 6 months. See Table 2 for minimum intervals.
- Adolescents age 11–15 years may use an alternative 2-dose schedule with at least 4 months between doses (adult formulation Recombivax HB only).
- Adolescents age 18 years may receive:
  - **Heplisav-B:** 2-dose series at least 4 weeks apart.
  - **HepA-HepB (Twinrix):** 3-dose series (0, 1, and 6 months) or4-dose series (3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months).

Special situations

- Revaccination is generally not recommended for persons with a normal immune status who were vaccinated as infants, children, adolescents, or adults.
- **Post-vaccination serology testing and revaccination**(if anti-HBs <10mIU/mL) is recommended for certain populations, including:
  - Infants born to HBsAg-positive mothers
  - Persons who are predialysis or on maintenance dialysis
  - Other immunocompromised persons
  - For detailed revaccination recommendations, see http://dx.doi.org/10.15585/mmwr.rr6701a1 (Accessed August 11, 2025).

Human papillomavirus (HPV) vaccination (minimum age: 9 years)

Routine and catch-up vaccination

- The AAP recommends starting the series **between the ages of 9 and 12 years**, at an age the pediatric health care professional deems optimal for acceptance and completion of the vaccination series.
- Catch-up HPV vaccination recommended for all persons through age 18 years if not adequately vaccinated.
- 2- or 3-dose series depending on age at initial vaccination:
  - **Age 9–14 years at initial vaccination:** 2-dose series at 0,6–12 months (minimum interval: 5 months; repeat dose if administered too soon)
  - **Age 15 years or older at initial vaccination:** 3-dose series at 0, 1–2 months, 6 months (minimum intervals: dose 1 to dose 2 = 4 weeks; dose 2 to dose 3 = 12 weeks; dose 1 to dose 3 = 5 months; repeat dose if administered too soon)
- No additional dose recommended when any HPV vaccine series **of any valency** has been completed using recommended dosing intervals.

Special situations

- **Immunocompromising conditions, including HIV infection:** 3-dose series, even for those who initiate vaccination at age 9 through 14 years.
- **History of sexual abuse or assault:** Start at age 9 years.
- **Pregnancy:** Pregnancy testing not needed before vaccination; HPV vaccination not recommended until after pregnancy; no intervention needed if vaccinated while pregnant.

Influenza vaccination (minimum age: 6 months [IIV3], 2 years [LAIV3], 9 years [recombinant influenza vaccine, RIV3])

Routine vaccination

- Use any influenza vaccine appropriate for age and health status annually:
  - **Age 6 months–8 years** who have received fewer than 2 influenza vaccine doses before July 1, 2025, or whose influenza vaccination history is unknown: 2 doses, separated by at least 4 weeks. Administer dose 2 even if the child turns 9 years between receipt of dose 1 and dose 2.
  - **Age 6 months–8 years** who have received at least 2 influenza vaccine doses before July 1, 2025: 1 dose.
  - **Age 9 years or older:** 1 dose.
  - **Age 18 years solid organ transplant recipients receiving immunosuppressive medications:** high-dose inactivated (HD-IIV3) and adjuvanted inactivated (aIIV3) influenza vaccines are acceptable options. No preference over other age-appropriate IIV3 or RIV3.
- For the 2025–2026 season, see the AAP recommendations at https://doi.org/10.1542/peds.2025-073620.

Special situations

- **Close contacts (eg, household contacts) of severely immunosuppressed persons who require a protected environment:** should not receive LAIV3. If LAIV3 is given, they should avoid contact with, or caring for such immunosuppressed persons for 7 days after vaccination.

Note: Persons with an egg allergy can receive any influenza vaccine (egg-based or non-egg based) appropriate for age and health status.

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Notes

Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025

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Measles, mumps, and rubella (MMR) vaccination (minimum age: 12 months for routine vaccination)

Routine vaccination

- 2-dose series at age 12–15 months, age 4–6 years
- MMR or measles, mumps, rubella, and varicella (MMRV)* may be administered

Note: The AAP expresses no preference between MMR plus monovalent varicella vaccine or MMRV for toddlers receiving their first immunization of this kind. Parents should be counseled about the rare possibility of their child developing a febrile seizure 1 to 2 weeks after immunization with MMRV for the 1st immunizing dose. For the 2nd dose at 4–6 years, MMRV generally is preferred over MMR plus monovalent varicella to minimize the number of injections.

Catch-up vaccination

- **Unvaccinated children and adolescents:** 2-dose series at least 4 weeks apart*
- The maximum age for use of MMRV* is 12 years.

Special situations

- **International travel**
  - **Infants age 6–11 months:** 1 dose at least 2 weeks before departure; revaccinate with 2-dose series at age 12–15 months (12 months for children in high-risk areas) and dose 2 as early as 4 weeks later.*
  - **Children age 12 months or older:**
    - Unvaccinated: 2-dose series (separated by at least 4 weeks*) with the 2nd dose given at least 2 weeks before departure
    - Previously received 1 dose: administer dose 2 at least 4 weeks after dose 1*
- In mumps outbreak settings, for information about additional doses of MMR (including 3rd dose of MMR), see www.cdc.gov/mmwr/volumes/67/wr/mm6701a7.htm (Accessed August 11, 2025).

***Note:** If MMRV is used, the minimum interval between MMRV doses is 3 months.

Meningococcal serogroup A, C, W, Y (MenACWY) vaccination (minimum age: 2 months [MenACWY-CRM, Menveo], 2 years [MenACWY-TT, MenQuadfi]), 10 years [MenACWY-TT/MenB-FHbp, Penbraya; MenACWY-CRM/MenB-4C, Penmenvy])

Routine vaccination

- 2-dose series at age 11–12 years; 16 years

Catch-up vaccination

- **Age 13–15 years:** 1 dose now and booster at age 16–18 years (minimum interval: 8 weeks)
- **Age 16–18 years:** 1 dose

Special situations

Anatomic or functional asplenia (including sickle cell disease), HIV infection, persistent complement component deficiency, complement inhibitor (eg, eculizumab, ravulizumab) use:

- **Menveo****
  - Dose 1 at age 2 months: 4-dose series (additional 3 doses at age 4, 6, and 12 months)
  - Dose 1 at age 3–6 months: 3- or 4-dose series (dose 2 [and dose 3 if applicable] at least 8 weeks after previous dose until a dose is received at age 7 months or older, followed by an additional dose at least 12 weeks later and after age 12 months)
  - Dose 1 at age 7–23 months: 2-dose series (dose 2 at least 12 weeks after dose 1 and after age 12 months)
  - Dose 1 at age 24 months or older: 2-dose series at least 8 weeks apart
- **MenQuadfi**
  - Dose 1 at age 24 months or older: 2-dose series at least 8 weeks apart

Travel to countries with hyperendemic or epidemic meningococcal disease, including countries in the African meningitis belt or during the Hajj (www.cdc.gov/travel/):

- **Children younger than age 24 months:**
  - **Menveo** (age 2–23 months)**
    - Dose 1 at age 2 months: 4-dose series (additional 3 doses at age 4, 6, and 12 months)
    - Dose 1 at age 3–6 months: 3- or 4-dose series (dose 2 [and dose 3 if applicable] at least 8 weeks after previous dose until a dose is received at age 7 months or older, followed by an additional dose at least 12 weeks later and after age 12 months)
    - Dose 1 at age 7–23 months: 2-dose series (dose 2 at least 12 weeks after dose 1 and after age 12 months)
- **Children age 2 years or older:** 1 dose Menveo** or MenQuadfi

First-year college students who live in residential housing (if not previously vaccinated at age 16 years or older) or military recruits: 1 dose Menveo** or MenQuadfi

Adolescent vaccination of children who received MenACWY prior to age 10 years:

- **Children for whom boosters are recommended because of an ongoing increased risk of meningococcal disease** (eg, those with complement component deficiency, HIV, or asplenia): Follow the booster schedule for persons at increased risk.
- **Children for whom boosters are not recommended** (eg, a healthy child who received a single dose for travel to a country where meningococcal disease is endemic): Administer MenACWY according to the recommended adolescent schedule with dose 1 at age 11–12 years and dose 2 at age 16 years.

***Menveo has 2 formulations: lyophilized and liquid. The liquid formulation should not be used before age 10 years. See https://www.menveohcp.com/dosing.*

Note: For MenACWY **booster dose recommendations** for groups listed under "Special situations" and in an outbreak setting and additional meningococcal vaccination information, see www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm (Accessed August 11, 2025).

Children age 10 years or older may receive a single dose of Penbraya or Penmenvy as an alternative to separate administration of MenACWY and MenB when both vaccines would be given on the same clinic day (see "Meningococcal serogroup B vaccination" section below for more information).

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Notes

Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025

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Meningococcal serogroup B (MenB) vaccination (minimum age: 10 years [MenB-4C, Bexsero; MenB-FHbp, Trumenba; MenACWY-TT/MenB-FHbp, Penbraya; MenACWY-CRM/MenB-4C, Penmenvy])

Shared clinical decision making

- **Adolescents not at increased risk age 16–23 years (preferred age 16–18 years)* based on shared clinical decision making.**
  - **Bexsero or Trumenba (use same brand for all doses):** 2-dose series at least 6 months apart (if dose 2 is administered earlier than 6 months, administer dose 3 at least 4 months after dose 2)

*To optimize rapid protection (eg, for students starting college in less than 6 months), a 3-dose series (0, 1–2, 6 months) may be administered.

For additional information on shared clinical decision making for MenB, see https://www.immunize.org/ask-experts/topic/menb.

Special situations

Anatomic or functional asplenia (including sickle cell disease), persistent complement component deficiency, complement inhibitor (eg, eculizumab, ravulizumab) use.

- **Bexsero or Trumenba (use same brand for all doses including booster doses)** 3-dose series at 0, 1–2, 6 months (if dose 2 was administered at least 6 months after dose 1, dose 3 not needed; if dose 3 is administered earlier than 4 months after dose 2, a 4th dose should be administered at least 4 months after dose 3).

For MenB **booster dose recommendations** for groups listed under "Special situations" and in an outbreak setting and additional meningococcal vaccination information, see www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm (Accessed August 11, 2025).

Note: MenB vaccines may be administered simultaneously with MenACWY vaccines if indicated, but at a different anatomic site, if feasible.

- Children aged 10 years or older may receive a dose of Penbraya (MenACWY–TT/MenB–FHbp) or Penmenvy (MenACWY-CRM/MenB-4C) as an alternative to separate administration of MenACWY and MenB when both vaccines would be given on the same clinic day.
- For age-eligible children not at increased risk: if Penbraya is used for dose 1, MenB, MenB-FHbp (Trumenba) should be administered for dose 2 of MenB. If Penmenvy is used for dose 1, MenB, MenB-4C (Bexsero) should be administered for dose 2 of MenB. Meningococcal vaccine products from different manufacturers are not interchangeable.
- For age-eligible children at increased risk: Penbraya or Penmenvy may be used for additional MenACWY and MenB doses (including booster doses) if both would be given on the same clinic day and at least 6 months have passed since most recent Penbraya or Penmenvy dose. As above, patients must receive a vaccine product from the same manufacturer for all doses, including booster doses.

Mpox vaccination (minimum age: 18 years [JYNNEOS])

Special situations

- Age 18 years and at risk for mpox infection: complete 2-dose series, 28 days apart.

  Risk factors for mpox infection include:
  - Persons who are gay, bisexual, and other man who has sex with men (MSM), transgender, or nonbinary people who in the past 6 months have had:
    - A new diagnosis of at least 1 sexually transmitted infection
    - More than 1 sex partner
    - Sex at a commercial sex venue
    - Sex in association with a large public event in a geographic area where mpox transmission is occurring
  - Persons who are sexual partners of the persons described above
  - Persons who anticipate experiencing any of the situations described above
- **Pregnancy:** There is currently no recommendation for JYNNEOS use in pregnancy because of lack of safety data in pregnant women. Pregnant women with any risk factor described above may receive JYNNEOS.

For detailed information, see https://publications.aap.org/redbook/book/755/chapter/14079669/Mpox.

Pneumococcal vaccination (minimum age: 6 weeks [PCV15], [PCV 20]; 2 years [PPSV23])

Routine vaccination with PCV

- 4-dose series at 2, 4, 6, 12–15 months

Catch-up vaccination with PCV

- Healthy children ages 2–4 years with any incomplete** PCV series: 1 dose PCV
- For other catch-up guidance, see Table 2.

Note: For children **without** risk conditions, PCV20 is not indicated if they have received 4 doses of PCV13 or PCV15 or another age appropriate complete PCV series.

Special situations

Children and adolescents with cerebrospinal fluid leak, chronic heart disease, chronic kidney disease (excluding maintenance dialysis and nephrotic syndrome), chronic liver disease, chronic lung disease (including moderate persistent or severe persistent asthma), cochlear implant, or diabetes mellitus:

Age 2–5 years

- Any incomplete** PCV series with:
  - 3 PCV doses: 1 dose PCV (at least 8 weeks after the most recent PCV dose)
  - Less than 3 PCV doses: 2 doses PCV (at least 8 weeks after the most recent dose and administered at least 8 weeks apart)
- Completed recommended PCV series but have not received PPSV23.
  - Previously received at least 1 dose of PCV20: no further PCV or PPSV23 doses needed
  - Not previously received PCV20: administer 1 dose PCV20 or 1 dose PPSV23 administered at least 8 weeks after the most recent PCV dose

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Pneumococcal vaccination—*continued*

Age 6–18 years

- Not previously received any dose of PCV13, PCV15, or PCV20: administer 1 dose of PCV15 or PCV20. If PCV15 is used and no previous receipt of PPSV23, administer 1 dose of PPSV23 at least 8 weeks after the PCV15 dose.†
- Received PCV before age 6 years but have not received PPSV23:
  - Previously received at least 1 dose of PCV20: no further PCV or PPSV23 doses needed
  - Not previously received PCV20: 1 dose PCV20 or 1 dose PPSV23 administered at least 8 weeks after the most recent PCV dose.
- Received PCV13 only at or after age 6 years: administer 1 dose PCV20 or 1 dose PPSV23 at least 8 weeks after the most recent PCV13 dose.
- Received 1 dose PCV13 and 1 dose PPSV23 at or after age 6 years: no further doses of any PCV or PPSV23 indicated.

Children and adolescents on maintenance dialysis, or with immunocompromising conditions such as nephrotic syndrome; congenital or acquired asplenia or splenic dysfunction; congenital or acquired immunodeficiencies; diseases and conditions treated with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas, Hodgkin disease, and solid organ transplant; HIV infection; or sickle cell disease or other hemoglobinopathies:

Age 2–5 years

- Any incomplete** PCV series:
  - 3 PCV doses: 1 dose PCV (at least 8 weeks after the most recent PCV dose)
  - Less than 3 PCV doses: 2 doses PCV (at least 8 weeks after the most recent dose and administered at least 8 weeks apart)
- Completed recommended PCV series but have not received PPSV23
  - Previously received at least 1 dose of PCV20: no further PCV or PPSV23 doses needed
  - Not previously received PCV20: administer 1 dose PCV20 or 1 dose PPSV23 at least 8 weeks after the most recent PCV dose. If PPSV23 is used, administer 1 dose of PCV20 or dose 2 PPSV23 at least 5 years after dose 1 PPSV23.

Age 6–18 years

- Not previously received any dose of PCV13, PCV15, or PCV20: administer 1 dose of PCV15 or 1 dose of PCV20. If PCV15 is used and no previous receipt of PPSV23, administer 1 dose of PPSV23 at least 8 weeks after the PCV15 dose.†
- Received PCV before age 6 years but have not received PPSV23:
  - Previously received at least 1 dose of PCV20: no additional dose of PCV or PPSV23
  - Not previously received PCV20: administer 1 dose PCV20 or 1 dose PPSV23 at least 8 weeks after the most recent PCV dose. If PPSV23 is used, administer either PCV20 or dose 2 PPSV23 at least 5 years after dose 1 PPSV23.
- Received PCV13 only at or after age 6 years: administer 1 dose PCV20 or 1 dose PPSV23 at least 8 weeks after the most recent PCV13 dose. If PPSV23 is used, administer 1 dose of PCV20 or dose 2 PPSV23 at least 5 years after dose 1 PPSV23.
- Received 1 dose PCV13 and 1 dose PPSV23 at or after age 6 years: administer 1 dose PCV20 or 1 dose PPSV23 at least 8 weeks after the most recent PCV13 dose and at least 5 years after dose 1 PPSV23.

Pregnancy: no recommendation for PCV or PPSV23 because of limited data. Summary of existing data on pneumococcal vaccination during pregnancy can be found at www.cdc.gov/mmwr/volumes/72/rr/rr7203a1.htm (Accessed August 11, 2025).

***Incomplete series = Not having received all doses in either the recommended series or an age-appropriate catch-up series. See Table 2 in ACIP pneumococcal recommendations at stacks.cdc.gov/view/cdc/133252 (Accessed August 11, 2025).*

†When both PCV15 and PPSV23 are indicated, administer all doses of PCV15 first. PCV15 and PPSV23 should not be administered during the same visit.

Poliovirus vaccination (minimum age: 6 weeks)

Routine vaccination

- 4-dose series at ages 2, 4, 6–18 months, 4–6 years; administer the final dose on or after age 4 years and at least 6 months after the previous dose.
- 4 or more doses of IPV can be administered before age 4 years when a combination vaccine containing IPV is used. However, a dose is still recommended on or after age 4 years and at least 6 months after the previous dose.

Catch-up vaccination

- In the first 6 months of life, use minimum ages and intervals only for travel to a polio-endemic region or during an outbreak.
- **Adolescents age 18 years known or suspected to be unvaccinated or incompletely vaccinated:** administer remaining doses (1, 2, or 3 IPV doses) to complete a 3-dose primary series.†† Unless there are specific reasons to believe they were not vaccinated, most persons aged 18 years or older born and raised in the United States can assume they were vaccinated against polio as children.

Series containing oral poliovirus vaccine (OPV), either mixed OPV-IPV or OPV-only series:

- Total number of doses needed to complete the series is the same as that recommended for the US IPV schedule. See www.cdc.gov/mmwr/volumes/66/wr/mm6601a6.htm?s_%20cid=mm6601a6_w (Accessed August 11, 2025).
- Only trivalent OPV (tOPV) counts toward the US vaccination requirements.
- Doses of OPV administered before April 1, 2016, should be counted (unless specifically noted as administered during a campaign).
  - Doses of OPV administered on or after April 1, 2016, should not be counted.
  - For guidance to assess doses documented as "OPV," see www.cdc.gov/mmwr/volumes/66/wr/mm6606a7.htm?s_cid=mm6606a7_w (Accessed August 11, 2025).
- For other catch-up guidance, see Table 2.

Special situations

- **Adolescents aged 18 years at increased risk of exposure to poliovirus and completed primary series††:** may administer one lifetime IPV booster.

††**Note:** Complete primary series consists of at least 3 doses of IPV or trivalent oral poliovirus vaccine (tOPV) in any combination.

For detailed information, see: https://publications.aap.org/redbook/book/755/chapter/14080623/Poliovirus-Infections

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Respiratory syncytial virus (RSV) immunization (minimum age: birth [nirsevimab, RSV-mAb, Beyfortus; clesrovimab, RSV-mAb, Eflonsia])

Routine vaccination

- **Infants < 8 months of age born during or entering their first RSV season***
  - Mother did not receive RSV vaccine or mother's RSV vaccination status is unknown or mother received RSV vaccine in previous pregnancy: administer 1 dose nirsevimab or clesrovimab within 1 week of birth—ideally during the birth hospitalization.
  - Mother received RSV vaccine **less than 14 days** prior to delivery: administer 1 dose nirsevimab or clesrovimab within 1 week of birth—ideally during the birth hospitalization.
  - Mother received RSV vaccine **at least 14 days** prior to delivery: nirsevimab/clesrovimab not needed but can be considered in rare circumstances at the discretion of health care providers.

Infants with prolonged birth hospitalization (eg, for prematurity) discharged October through March should be immunized shortly before or promptly after discharge.

Special situations

- **Ages 8–19 months with chronic lung disease of prematurity requiring medical support (eg, chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the 6-month period before the start of the second RSV season; severe immunocompromise; cystic fibrosis with either weight for length <10th percentile or manifestation of severe lung disease (eg, previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable).****
  - 1 dose nirsevimab shortly before start of second RSV season.*
- **Ages 8–19 months who are American Indian or Alaska Native:** 1 dose nirsevimab shortly before start of second RSV season.* American Indian and Alaska Native Children are included in the high-risk category, because they experience significantly higher rates of severe RSV disease and hospitalization associated with social drivers of health, with children living in rural and reservation communities most impacted.
- **Age-eligible and undergoing cardiac surgery with cardiopulmonary bypass**:** 1 additional dose of nirsevimab or clesrovimab after surgery. See https://products.sanofi.us/beyfortus/beyfortus.pdf and www.merck.com/product/usa/pi_circulars/e/enflonsia/enflonsia_pi.pdf.

***Note:** While the timing of the onset and duration of RSV season may vary, administration of RSV immunization is recommended October through March in most of the continental United States (optimally October through November or within 1 week of birth). Providers in jurisdictions with RSV seasonality that differs from most of the continental United States (eg, Alaska, jurisdiction with tropical climate) should follow guidance from public health authorities (eg, CDC, health departments) or regional medical centers on timing of administration based on local RSV seasonality.

For further guidance, see https://publications.aap.org/redbook/book/755/chapter/14080939/Respiratory-Syncytial-Virus and www.aap.org/en/patient-care/respiratory-syncytial-virus-rsv-prevention/nirsevimab-frequently-asked-questions.

Respiratory syncytial virus (RSV) vaccination (RSV [Abrysvo])

Routine vaccination

- **Pregnant at 32 weeks 0 days through 36 weeks and 6 days gestation from September through January in most of the continental United States and have not received RSV vaccine in previous pregnancy**:** 1 dose Abrysvo. Administer RSV vaccine regardless of previous RSV infection.
  - Either maternal RSV vaccination with Abrysvo or infant immunization with nirsevimab or clesrovimab is recommended to prevent severe RSV disease in infants.
- **All other pregnant women:** RSV vaccine not recommended.
- **Subsequent pregnancies:** Additional doses not recommended. No data are available to inform whether additional doses are needed in subsequent pregnancies. Infants born to pregnant women who received RSV vaccine during a previous pregnancy should receive nirsevimab or clesrovimab.

****Note:** Providers in jurisdictions with RSV seasonality that differs from most of the continental United States (eg, Alaska,jurisdictions with tropical climate) should follow guidance from public health authorities (eg, CDC, health departments) or regional medical centers on timing of administration based on local RSV seasonality.

Rotavirus vaccination (minimum age: 6 weeks)

Routine vaccination

- **Rotarix:** 2-dose series at age 2 and 4 months
- **RotaTeq:** 3-dose series at age 2, 4, and 6 months
- If any dose in the series is either **RotaTeq** or unknown, default to 3-dose series.

Catch-up vaccination

- Do not start the series on or after age 15 weeks, 0 days.
- The maximum age for the final dose is 8 months, 0 days.
- For other catch-up guidance, see Table 2.

Notes

Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025

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Tetanus, diphtheria, and acellular pertussis (Tdap) vaccination (minimum age: 11 years for routine vaccination, 7 years for catch-up vaccination)

Routine vaccination

- **Age 11–12 years:** 1 dose Tdap (adolescent booster).
- **Pregnancy:** 1 dose Tdap during each pregnancy, preferably in early part of gestational weeks 27–36.

Note: Tdap may be administered regardless of the interval since the last tetanus and diphtheria toxoid-containing vaccine.

Catch-up vaccination

- **Age 13–18 years who have not received Tdap:** 1 dose Tdap (adolescent booster).
- **Age 7–18 years not fully vaccinated* with DTaP:** 1 dose Tdap as part of the catch-up series (preferably the first dose); if additional doses are needed, use Td or Tdap.
- **Tdap administered at age 7–10 years:**
  - **Age 7–9 years** who receive Tdap should receive the adolescent Tdap booster dose at age 11–12 years.
  - **Age 10 years** who receive Tdap do not need the adolescent Tdap booster dose at age 11–12 years.
- **DTaP inadvertently administered on or after age 7 years:**
  - **Age 7–9 years:** DTaP may count as part of catch-up series. Administer adolescent Tdap booster dose at age 11–12 years.
  - **Age 10–18 years:** Count dose of DTaP as the adolescent Tdap booster dose.
- For other catch-up guidance, see Table 2.

Special situations

- **Wound management** in persons age 7 years or older with history of 3 or more doses of tetanus toxoid-containing vaccine: For clean and minor wounds, administer Tdap or Td if more than 10 years since last dose of tetanus toxoid-containing vaccine; for all other wounds, administer Tdap or Td if more than 5 years since last dose of tetanus toxoid-containing vaccine. Tdap is preferred for persons age 11 years or older who have not previously received Tdap or whose Tdap history is unknown. If a tetanus toxoid-containing vaccine is indicated for a pregnant adolescent, use Tdap.
- For detailed information, see www.cdc.gov/mmwr/volumes/69/wr/mm6903a5.htm (Accessed August 11, 2025).

*_**Fully vaccinated**_ = 5 valid doses of DTaP or 4 valid doses of DTaP if dose 4 was administered at age 4 years or older

Varicella (VAR) vaccination (minimum age: 12 months)

Routine vaccination

- 2-dose series at age 12–15 months, 4–6 years.
- VAR or MMRV may be administered.**
- Dose 2 may be administered as early as 3 months after dose 1 (a dose inadvertently administered after at least 4 weeks may be counted as valid).

****Note:** The AAP expresses no preference between MMR plus monovalent varicella vaccine or MMRV for toddlers receiving their first immunization of this kind. Parents should be counseled about the rare possibility of their child developing a febrile seizure 1 to 2 weeks after immunization with MMRV for the 1st immunizing dose. For the 2nd dose at 4–6 years, MMRV generally is preferred over MMR plus monovalent varicella to minimize the number of injections.

Catch-up vaccination

- Ensure persons age 7–18 years without evidence of immunity (see www.cdc.gov/mmwr/pdf/rr/rr5604.pdf [Accessed August 11, 2025]) have a 2-dose series:
  - **Age 7–12 years:** Routine interval: 3 months (a dose inadvertently administered after at least 4 weeks may be counted as valid).
  - **Age 13 years and older:** Routine interval: 4–8 weeks (minimum interval: 4 weeks)
  - The maximum age for use of MMRV is 12 years.

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Appendix Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025

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Guide to Contraindications and Precautions to Commonly Used Vaccines

Vaccines and other Immunizing Agents	Contraindicated or Not Recommended[1]	Precautions[2]
COVID-19 mRNA vaccines [Pfizer-BioNTech, Moderna]	• Severe allergic reaction (eg, anaphylaxis) after a previous dose or to a component of an mRNA COVID-19 vaccine[3]	• Diagnosed nonsevere allergy (eg, urticaria beyond the injection site) to a component of an mRNA COVID-19 vaccine[3]; or nonsevere, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of an mRNA COVID-19 vaccine • Myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine • Multisystem inflammatory syndrome in children (MIS-C) or multisystem inflammatory syndrome in adults (MIS-A) • Moderate or severe acute illness, with or without fever
COVID-19 protein subunit vaccine [Novavax]	• Severe allergic reaction (eg, anaphylaxis) after a previous dose or to a component of a Novavax COVID-19 vaccine[3]	• Diagnosed nonsevere allergy (eg, urticaria beyond the injection site) to a component of Novavax COVID-19 vaccine[3]; or nonsevere, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of a Novavax COVID-19 vaccine • Myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine • Multisystem inflammatory syndrome in children (MIS-C) or multisystem inflammatory syndrome in adults (MIS-A) • Moderate or severe acute illness, with or without fever
Influenza, egg-based, inactivated injectable (IIV3)	• Severe allergic reaction (eg, anaphylaxis) after previous dose of any influenza vaccine (ie, any egg-based IIV, ccIIV, RIV, or LAIV of any valency) • Severe allergic reaction (eg, anaphylaxis) to any vaccine component[4] (excluding egg)	• Guillain-Barré syndrome within 6 weeks after a previous dose of any type of influenza vaccine • Moderate or severe acute illness with or without fever
Influenza, cell culture-based inactivated injectable (ccIIV3) [Flucelvax]	• Severe allergic reaction (eg, anaphylaxis) to any ccIIV of any valency, or to any component[4] of ccIIV3	• Guillain-Barré syndrome within 6 weeks after a previous dose of any type of influenza vaccine • Persons with a history of severe allergic reaction (eg, anaphylaxis) after a previous dose of any egg-based IIV, RIV, or LAIV of any valency. If using ccIIV3, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions. May consult an allergist. • Moderate or severe acute illness with or without fever
Influenza, recombinant injectable (RIV3) [Flublok]	• Severe allergic reaction (eg, anaphylaxis) to any RIV of any valency, or to any component[4] of RIV3	• Guillain-Barré syndrome within 6 weeks after a previous dose of any type of influenza vaccine • Persons with a history of severe allergic reaction (eg, anaphylaxis) after a previous dose of any egg-based IIV, ccIIV, or LAIV of any valency. If using RIV3, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions. May consult an allergist. • Moderate or severe acute illness with or without fever
Influenza, live attenuated (LAIV3) [Flumist]	• Severe allergic reaction (eg, anaphylaxis) after previous dose of any influenza vaccine (ie, any egg-based IIV, ccIIV, RIV, or LAIV of any valency) • Severe allergic reaction (eg, anaphylaxis) to any vaccine component[4] (excluding egg) • Children age 2–4 years with a history of asthma or wheezing • Anatomic or functional asplenia • Immunocompromised from any cause including, but not limited to, medications and HIV infection • Close contacts or caregivers of severely immunosuppressed persons who require a protected environment • Pregnancy • Cochlear implant • Active communication between the cerebrospinal fluid (CSF) and the oropharynx, nasopharynx, nose, ear or any other cranial CSF leak • Children and adolescents receiving aspirin or salicylate-containing medications • Received influenza antiviral medications oseltamivir or zanamivir within the previous 48 hours, peramivir within the previous 5 days, or baloxavir within the previous 17 days	• Guillain-Barré syndrome within 6 weeks after a previous dose of any type of influenza vaccine • Asthma in persons age 5 years old or older • Persons with underlying medical conditions other than those listed under contraindications that might predispose to complications after wild-type influenza virus infection, eg, chronic pulmonary, cardiovascular (except isolated hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus) • Moderate or severe acute illness with or without fever

1. When a contraindication is present, a vaccine should **NOT** be administered.
2. When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction.
3. See package inserts for a full list of vaccine ingredients. mRNA COVID-19 vaccines contain polyethylene glycol (PEG) www.fda.gov/vaccines-blood-biologics/approved-products/vaccines-licensed-use-united-states (Accessed August 11, 2025).
4. Vaccination providers should check FDA-approved prescribing information for the most complete and updated information, including contraindications, warnings, and precautions. See Package inserts for US-licensed vaccines (Accessed August 11, 2025).

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Appendix Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025

American Academy of Pediatrics
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Vaccines and other Immunizing Agents	Contraindicated or Not Recommended[1]	Precautions[2]
Dengue (DEN4CYD)	• Severe allergic reaction (eg, anaphylaxis) after a previous dose or to a vaccine component[3] • Severe immunodeficiency (eg, hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Lack of laboratory confirmation of a previous dengue infection	• Pregnancy • HIV infection without evidence of severe immunosuppression • Moderate or severe acute illness with or without fever
Diphtheria, tetanus, pertussis (DTaP)	• Severe allergic reaction (eg, anaphylaxis) after a previous dose or to a vaccine component[3] • Encephalopathy (eg, coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days of administration of previous dose of DTP or DTaP	• Guillain-Barré syndrome within 6 weeks after previous dose of tetanus toxoid-containing vaccine • History of Arthus-type hypersensitivity reactions after a previous dose of diphtheria toxoid-containing or tetanus toxoid-containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus toxoid-containing vaccine • For DTaP only: Progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, progressive encephalopathy; defer DTaP until neurologic status clarified and stabilized • Moderate or severe acute illness with or without fever
Haemophilus influenzae type b (Hib)	• Severe allergic reaction (eg, anaphylaxis) after a previous dose or to a vaccine component[3] • Younger than age 6 weeks	• Moderate or severe acute illness with or without fever
Hepatitis A (HepA)	• Severe allergic reaction (eg, anaphylaxis) after a previous dose or to a vaccine component[3] including neomycin	• Moderate or severe acute illness with or without fever
Hepatitis B (HepB)	• Severe allergic reaction (eg, anaphylaxis) after a previous dose or to a vaccine component[3] including yeast	• Moderate or severe acute illness with or without fever
Hepatitis A-Hepatitis B vaccine (HepA-HepB) [Twinrix]	• Severe allergic reaction (eg, anaphylaxis) after a previous dose or to a vaccine component[3] including neomycin and yeast	• Moderate or severe acute illness with or without fever
Human papillomavirus (HPV)	• Severe allergic reaction (eg, anaphylaxis) after a previous dose or to a vaccine component[3] • Pregnancy: HPV vaccination not recommended.	• Moderate or severe acute illness with or without fever
Measles, mumps, and rubella (MMR) Measles, mumps, rubella, and varicella (MMRV)	• Severe allergic reaction (eg, anaphylaxis) after a previous dose or to a vaccine component[3] • Severe immunodeficiency (eg, hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Pregnancy • Family history of altered immunocompetence, unless verified clinically or by laboratory testing as immunocompetent • For MMRV only: HIV infection of any severity	• Recent (≤11 months) receipt of antibody-containing blood product (specific interval depends on product) • History of thrombocytopenia or thrombocytopenic purpura • Need for tuberculin skin testing or interferon-gamma release assay (IGRA) testing • Moderate or severe acute illness with or without fever • For MMRV only: Personal or family (ie, sibling or parent) history of seizures of any etiology • If using MMRV, see Varicella/MMRV for additional precautions
Meningococcal ACWY (MenACWY) MenACWY-CRM [Menveo] MenACWY-TT [MenQuadfi]	• Severe allergic reaction (eg, anaphylaxis) after a previous dose or to a vaccine component[3] • For Men ACWY-CRM only: severe allergic reaction to any diphtheria toxoid— or CRM197—containing vaccine • For MenACWY-TT only: severe allergic reaction to a tetanus toxoid-containing vaccine	• For MenACWY-CRM only: Preterm birth if younger than age 9 months • Moderate or severe acute illness with or without fever
Meningococcal B (MenB) MenB-4C [Bexsero] MenB-FHbp [Trumenba]	• Severe allergic reaction (eg, anaphylaxis) after a previous dose or to a vaccine component[3]	• Pregnancy • For MenB-4C only: Latex sensitivity • Moderate or severe acute illness with or without fever
Meningococcal ABCWY (MenACWY-TT/MenB-FHbp) [Penbraya] (MenACWY-CRM/MenB-4C) [Penmenvy]	• Severe allergic reaction (eg, anaphylaxis) after a previous dose or to a vaccine component[3] • Severe allergic reaction to a tetanus toxoid-containing vaccine	• Moderate or severe acute illness with or without fever
Mpox [JYNNEOS]	• Severe allergic reaction (eg, anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness with or without fever
Pneumococcal conjugate (PCV)	• Severe allergic reaction (eg, anaphylaxis) after a previous dose or to a vaccine component[3] • Severe allergic reaction (eg, anaphylaxis) to any diphtheria toxoid-containing vaccine or its component[3]	• Moderate or severe acute illness with or without fever
Pneumococcal polysaccharide (PPSV23)	• Severe allergic reaction (eg, anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness with or without fever

1. When a contraindication is present, a vaccine should **NOT** be administered.
2. When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction.
3. Vaccination providers should check FDA-approved prescribing information for the most complete and updated information, including contraindications, warnings, and precautions. Package inserts for US-licensed vaccines are available at www.fda.gov/vaccines-blood-biologics/approved-products/vaccines-licensed-use-united-states (Accessed August 11, 2025).

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Appendix Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

Vaccines and other Immunizing Agents	Contraindicated or Not Recommended[1]	Precautions[2]
Poliovirus vaccine, inactivated (IPV)	• Severe allergic reaction (eg, anaphylaxis) after a previous dose or to a vaccine component[3]	• Pregnancy • Moderate or severe acute illness with or without fever
RSV monoclonal antibody (RSV-mAb)	• Severe allergic reaction (eg, anaphylaxis) after a previous dose or to a vaccine component[4]	• Moderate or severe acute illness with or without fever
Respiratory syncytial virus vaccine (RSV)	• Severe allergic reaction (eg, anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness with or without fever
Rotavirus (RV) RV1 [Rotarix] RV5 [RotaTeq]	• Severe allergic reaction (eg, anaphylaxis) after a previous dose or to a vaccine component[3] • Severe combined immunodeficiency (SCID) • History of intussusception	• Altered immunocompetence other than SCID • Chronic gastrointestinal disease • RV1 only: Spina bifida or bladder exstrophy • Moderate or severe acute illness with or without fever
Tetanus, diphtheria, and acellular pertussis (Tdap) Tetanus, diphtheria (Td)	• Severe allergic reaction (eg, anaphylaxis) after a previous dose or to a vaccine component[3] • For Tdap only: Encephalopathy (eg, coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days of administration of previous dose of DTP, DTaP, or Tdap	• Guillain-Barré syndrome within 6 weeks after a previous dose of tetanus toxoid-containing vaccine • History of Arthus-type hypersensitivity reactions after a previous dose of diphtheria toxoid-containing or tetanus toxoid-containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus toxoid-containing vaccine • For Tdap only: Progressive or unstable neurological disorder, uncontrolled seizures, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized • Moderate or severe acute illness with or without fever
Varicella (VAR) Measles, mumps, rubella, and varicella (MMRV)	• Severe allergic reaction (eg, anaphylaxis) after a previous dose or to a vaccine component[3] • Severe immunodeficiency (eg, hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Pregnancy • Family history of altered immunocompetence, unless verified clinically or by laboratory testing as immunocompetent • For MMRV only: HIV infection of any severity	• Recent (≤11 months) receipt of antibody-containing blood product (specific interval depends on product) • Receipt of specific antiviral drugs (acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination (avoid use of these antiviral drugs for 14 days after vaccination) • Use of aspirin or aspirin-containing products • Moderate or severe acute illness with or without fever • If using MMRV, see MMR/MMRV for additional precautions

1. When a contraindication is present, a vaccine should **NOT** be administered.
2. When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction.
3. Vaccination providers should check FDA-approved prescribing information for the most complete and updated information, including contraindications, warnings, and precautions. Package inserts for US-licensed vaccines are available at www.fda.gov/vaccines-blood-biologics/approved-products/vaccines-licensed-use-united-states (Accessed August 11, 2025).
4. Full prescribing information for BEYFORTUS (nirsevimab-alip) www.accessdata.fda.gov/drugsatfda_docs/label/2023/761328s000lbl.pdf (Accessed August 11, 2025) and EFLONSIA (clesrovimab-cfor) www.accessdata.fda.gov/drugsatfda_docs/label/2025/761432s000lbl.pdf (Accessed August 11, 2025).

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Addendum

Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

The AAP has made the following changes since publication of the AAP Immunization Schedule on August 20, 2025.

November 21, 2025

COVID-19 vaccination notes

Corrections noted in bold to algin with new dosing guidance that takes into account the efficacy of the primary series for patients 6–23 months old:

- Page 5, For 6–23 month old who has previously received 1 dose prior formulation of Pfizer-BioNTech vaccine, complete the initial series with 2 doses Moderna Spikevax at least ~~8~~ **4** weeks apart (administer dose 1 ~~4~~**3**–8 weeks after most recent dose)
- Page 6, For age 6 months–4 years moderately or severely immunocompromised who has previously received 1 dose prior formulation of Pfizer-BioNTech vaccine, complete initial series with 2 doses Moderna Spikevax at least ~~8~~ **4** weeks apart (administer dose 1 Moderna Spikevax ~~4~~ **3** weeks after most recent dose), followed by 1 dose Moderna Spikevax 6 months later (minimum interval 2 months). May administer additional doses of Moderna Spikevax.**

September 17, 2025

Page 10, MMR vaccination note

- Correction made to align with AAP Red Book policy expressing no preference between administering MMR plus monovalent varicella vaccine or MMRV for toddlers age 12–15 months of age receiving their first immunization of this kind.

Page 14, Varicella vaccination note

- Correction made to align with AAP Red Book policy expressing no preference between administering MMR plus monovalent varicella vaccine or MMRV for toddlers age 12–15 months of age receiving their first immunization of this kind.

September 9, 2025

Page 1: List of Vaccines

- COVID-19: Typo under Trade name(s) column corrected — "Nuvaxavoid" to "Nuvaxovid"

Page 4, Table 3

- RSV-mAb Immunization: Added a blue bar to clarify all eligible children with the conditions listed should receive RSV-mAb in the 1st RSV season
- RSV-mAb Immunization: Added "nirsevimab" in purple bars to clarify only nirsevimab recommended for 2nd RSV season
- COVID-19 Vaccine: Updated "*Referring to the Immunization Schedule endorsed by AAP in November 2024; will update as needed when the American College of Obstetricians and Gynecologists releases 2025–2026 guidance" to "*For more information, refer to https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/covid-19-vaccination-considerations-for-obstetric-gynecologic-care".

Page 5, COVID-19 vaccination notes

- Updated minimum age for Pfizer-BioNTech Comirnaty to 5 years
- Revised all COVID-19 vaccination notes to reflect the change in FDA approval of Pfizer-BioNTech Comirnaty from children 6 months of age and older to children 5 years of age and older.
- Removed Moderna mNEXSPIKE indication "for people who have previously received a COVID-19 vaccine" per the updated package insert.
- Replaced "These recommendations for the use of 2025-2026 COVID-19 vaccine are contingent upon the approval by the US Food and Drug Administration of updated COVID-19 vaccine products" with "Refer to the AAP's COVID-19 Vaccine Dosing for a visual quick reference guide, www.aap.org/CovidVaccineGuide. *Trade names are used for Moderna because there is more than 1 Moderna product available.*"
- Removed mention of emergency use authorization "Use any available COVID-19 vaccine appropriate by age and health status that is approved by the FDA through a biologics license application ~~or authorized through emergency use authorization~~."
- Paragraph on Persons who are moderately or severely immunocompromised — Added "For revaccination guidance for children with hematologic malignancy post-hematopoietic cell transplant or CAR T-cell therapy, refer to: https://doi.org/10.1111/tid.14109."
- Section on Age 12–18 years moderately or severely immunocompromised added the statement "Either Moderna product (Spikevax or mNEXSPIKE) can be used unless otherwise specified."

Vaccines	Recommendations	Effective Date of Recommendation
No new vaccines or vaccine recommendations to report		

EXHIBIT D

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Advisory Committee on Immunization Practices (ACIP)

ACIP Shared Clinical Decision-Making Recommendations

For Everyone
JANUARY 7, 2025

AT A GLANCE

- Unlike routine, catch-up, and risk-based recommendations, shared clinical decision-making vaccinations are individually based and informed by a decision process between the health care provider and the patient or parent/guardian.
- These frequently asked questions provide clarity on the ACIP's shared clinical decision-making recommendations, guidance, and implementation considerations.

Introduction

These frequently asked questions (FAQs) address the Advisory Committee on Immunization Practices' (ACIP) shared clinical decision-making recommendations and guidance and implementation considerations.

Frequently Asked Questions

Collapse All

What are ACIP's current shared clinical decision-making recommendations?

ACIP has five recommendations for vaccination based on shared clinical decision-making and these are shown in the adult and child/adolescent the immunization schedules.

- Meningococcal B (MenB) vaccination for adolescents and young adults aged 16–23 years
- Hepatitis B (HepB) vaccination for adults aged 60 years and older with diabetes mellitus
- Human papillomavirus (HPV) vaccination for adults aged 27–45 years
- Pneumococcal conjugate vaccination (PCV20 or PCV21) for adults aged 65 years and older who have completed the recommended vaccine series with both PCV13 (at any age) and PPSV23 (which was administered at age ≥65 years)
- Additional doses of COVID-19 vaccination for people who are moderately or severely immunocompromised

How do shared clinical decision-making recommendations differ from routine, catch-up, and risk-based immunization recommendations?

Unlike routine, catch-up, and risk-based recommendations, shared clinical decision-making vaccinations are not recommended for everyone in a particular age group or everyone in an identifiable risk group. Rather, shared clinical decision-making recommendations are individually based and informed by a decision process between the health care provider and the patient or parent/guardian.

The key distinction between routine, catch-up, and risk-based recommendations and shared clinical decision-making recommendations is the default decision to vaccinate. For routine, catch-up, and risk-based recommendations, the default decision should be to vaccinate the patient based on age group or other indication, unless contraindicated. For shared clinical decision-making recommendations, there is no default—the decision about whether or not to vaccinate may be informed by the best available evidence of who may benefit from vaccination; the individual's characteristics, values, and preferences; the health care provider's clinical discretion; and the characteristics of the vaccine being considered. There is not a prescribed set of considerations or decision points in the decision-making process.

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When does ACIP make shared clinical decision-making recommendations?

Generally, ACIP makes shared clinical decision-making recommendations when individuals may benefit from vaccination, but broad vaccination of people in that group is unlikely to have population-level impacts.

For example, in June 2019, ACIP recommended shared clinical decision-making for HPV vaccination of adults aged 27–45 years. HPV acquisition generally occurs soon after first sexual activity. Vaccine effectiveness is lower in older age groups because of prior infections and lower risk of exposure (for example, among persons who are in a long-term, mutually monogamous sexual partnership). ACIP recommended shared clinical decision-making rather than catch-up vaccination because most adults in this age group would have no or minimal benefits from vaccination. However, some individuals who are not already immune to HPV through vaccination or natural infection (e.g., a previously unvaccinated person who has never had sex) and who might be at risk for acquiring a new HPV infection in the future (e.g., plans to have sex with a new partner in the future) might benefit from vaccination.

Who is considered a health care provider with regard to shared clinical decision-making recommendations?

In this context, CDC defines a health care provider as anyone who provides or administers vaccines: primary care physicians, specialists, physician assistants, nurse practitioners, registered nurses, and pharmacists.

Which patients should providers discuss shared clinical decision-making recommendations with?

It's up to the provider. Some health care providers may choose to discuss immunizations recommended for shared clinical decision-making with all or most of their patients who could receive it, while some providers may be more selective when discussing these immunizations with their patients. Health care providers should also be receptive to patient-initiated conversations about these immunizations.

What resources are available for providers who want to implement these recommendations?

ACIP and CDC provide resources to help providers implement these recommendations.

ACIP recommendations

Health care providers can find information on ACIP's recommendations on the *ACIP Vaccine Recommendations and Guidelines* page.

For every ACIP recommendation, CDC publishes a policy note in the Morbidity and Mortality Weekly Report (MMWR), which provides background and considerations on each recommendation.

CDC resources for shared clinical decision-making

CDC will also develop vaccine-specific guidance to help clinicians understand and apply shared clinical decision-making recommendations.

Meningococcal B Vaccination PDF

Hepatitis B Vaccination

HPV Vaccination for Adults Aged 27-45 Years PDF

Pneumococcal Vaccination for Adults 65 Years or Older PDF

Additional Doses of COVID-19 Vaccination for People who are Moderately or Severely Immunocompromised

Are shared clinical decision-making recommendations covered by private insurers?

Under the Affordable Care Act and its implementing regulations, ACIP recommendations that have been adopted by CDC "with respect to the individual involved" and are "listed on the Immunization Schedules of the Centers for Disease Control and Prevention" generally are required to be covered by group health plans and health insurance issuers offering group or individual health insurance coverage without imposing any cost-sharing requirements (such as a copayment, coinsurance, or deductible).[A] This coverage requirement includes shared clinical decision-making recommendations when they have been adopted by CDC and are listed on the immunization schedules.

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SOURCES

CONTENT SOURCE:
National Center for Immunization and Respiratory Diseases (NCIRD)

FOOTNOTES

A. Section 2713(a)(2) of the Public Health Service Act, as added by section 1001 of the Affordable Care Act, implemented at 26 CFR 54.9815-2713(a)(1)(ii), 29 CFR 2590.715-2713(a)(1)(ii), and 45 CFR 147.130(a)(1)(ii). This requirement does not apply to grandfathered health plan coverage under section 1251 of the Affordable Care Act, implemented at 26 CFR 54.9815-1251, 29 CFR 2590.715-1272, and 45 CFR 147.140.

EXHIBIT E

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CDC Newsroom

CDC Immunization Schedule Adopts Individual-Based Decision-Making for COVID-19 and Standalone Vaccination for Chickenpox in Toddlers

RELEASE

For immediate release: October 6, 2025

CDC Media Relations
(404) 639-3286
https://www.cdc.gov/media/

The Centers for Disease Control and Prevention (CDC) today updated its adult and child immunization schedules to apply individual-based decision-making to COVID-19 vaccination and recommend that toddlers receive protection from varicella (chickenpox) as a standalone immunization rather than in combination with measles, mumps, and rubella vaccination.

The immunization schedules adopt recent recommendations by the CDC Advisory Committee on Immunization Practices (ACIP), which were approved last week by Acting Director of the CDC and Deputy Secretary of Health and Human Services Jim O'Neill. The schedules will be updated on CDC.gov by October 7, 2025.

"Informed consent is **back," said Deputy Secretary O'Neill.** "CDC's 2022 blanket recommendation for perpetual COVID-19 boosters deterred health care providers from talking about the risks and benefits of vaccination for the individual patient or parent. That changes today.

"I commend the doctors and public health experts of ACIP for educating Americans about important vaccine safety signals. I also thank President Trump for his leadership in making sure we protect children from unintended side effects during routine immunization."

Unlike the COVID-19 primary series vaccination pioneered by Operation Warp Speed (OWS) that reached a estimated nearly 85% of the U.S. adult population, just 23% of adults followed the CDC's most recent seasonal booster recommendation according to its National Immunization Survey. The booster shots prompted widespread risk-benefit concerns about their safety and efficacy as the COVID-19 virus became endemic following population-wide immunity acquired during the pandemic and OWS.

ACIP's recommendation emphasized that the risk-benefit of vaccination in individuals under age 65 is most favorable for those who are at an increased risk for severe COVID-19 and lowest for individuals who are not at an increased risk, according to the CDC list of COVID-19 risk factors. The U.S. Food and Drug Administration has approved marketing authorization for COVID-19 vaccines for individuals who have one or more of these risk factors, as well as for individuals age 65 and older.

Individual-based decision-making is referred to on the CDC's immunization schedules as vaccination based on shared clinical decision-making, which references providers including physicians, nurses, and pharmacists. It means that the clinical decision to vaccinate should be based on patient characteristics that unlike age are difficult to incorporate in recommendations, including risk factors for the underlying disease as well as the characteristics of the vaccine itself and the best available evidence of who may benefit from vaccination.

Like routine recommendations, individual-based-decision-making allows for immunization coverage through all payment mechanisms including entitlement programs such as the Medicare, Medicaid, Children's Health Insurance Program, and the Vaccines for Children Program, as well as insurance plans regulated by the Affordable Care Act.

The CDC child and adolescent immunization schedule's new recommendation of standalone chickenpox vaccination for toddlers through age three follows evidence presented PDF to ACIP by the CDC Immunization Safety Office's that healthy 12–23 months old toddlers have increased risk of febrile seizure seven to 10 days after vaccination for the combined measles, mumps, rubella, and varicella vaccine compared to those given immunization for chickenpox separately. The combination vaccine doubles the risk of febrile seizures without conferring additional protection from varicella compared to standalone vaccination.

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Whether diseases start at home or abroad, are curable or preventable, chronic or acute, or from human activity or deliberate attack, CDC's world-leading experts protect lives and livelihoods, national security and the U.S. economy by providing timely, commonsense information, and rapidly identifying and responding to diseases, including outbreaks and illnesses. CDC drives science, public health research, and data innovation in communities across the country by investing in local initiatives to protect everyone's health.

SOURCES

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CONTENT SOURCE:
Office of Communications (OC)

EXHIBIT F

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Perspective

Vaccination of Children in the United States against COVID-19: An Ounce of Prevention

Sarah K. Wood, MD, Dennis G. Maki, MD, and Charles H. Hennekens, MD

As of October 28, 2021, the United States was the epicenter of the coronavirus disease 2019 (COVID-19) pandemic. The United States accounts for >45.6 million of the >244 million cases of COVID-19 worldwide, or 18.5% in a population of <5% of the world. Accounting for deaths, >940,000 of the >4.95 million deaths worldwide have occurred in the United States since February 2020, a death rate that exceeds that of the "Spanish" flu in 1918 to 1919. As such, deaths in the United States account for approximately 15% of all deaths from COVID-19. At present, >1 in 500 Americans have died from COVID-19.[1] Although cases and hospitalizations are decreasing, on August 15, 2021, Arkansas, Florida, Louisiana, and Mississippi were each recording >500,000 new cases per week.[2,3]

Approximately 54% of the US public are fully vaccinated—the highest rates among older adults at 85% and lowest among children at 32%.[4] Furthermore, 85% trust their healthcare providers, more than 95% of whom are vaccinated.[4] In this perspective, we provide our scientific rationale to support the urgent plea to vaccinate children and young adults who make up 27% of cases, virtually all of them among unvaccinated people, compared with 3% in 2020.[5]

Primary healthcare providers and pediatricians play major roles in the prevention and treatment of illness in US children. These circumstances have increased since January 19, 2020, when the first cases of COVID-19 were introduced into the United States by travelers from Wuhan, China, the initial epicenter of the subsequent pandemic.[6] In the United States, mitigation strategies were not performed promptly and containment strategies varied based on the responses of individual states.[7]

Primary healthcare providers and pediatricians are in a unique position to use their effective, knowledgeable, and trusted voices to educate patients and their families to increase rates of vaccination. Primary healthcare providers and pediatricians routinely administer and patients and their families routinely accept. These include vaccines against polio (92.6%), measles, mumps, and rubella (90.8%), hepatitis B (90.6%), and varicella (90.2%).[8]

Primary care providers and pediatricians should emphasize to the parents and families of children that the COVID-19 vaccines have better safety and efficacy profiles than all of the routinely administered vaccines. With respect to safety, serious adverse effects of the COVID-19 vaccine occur at an extremely low rate. In the largest and most recently published real-world study of COVID-19 vaccine safety, the authors concluded that "in contrast to the relatively small number of adverse effects associated with the vaccine, high rates of multiple serious adverse events were associated with coronavirus infection among unvaccinated patients." For example, with respect to myocarditis, the number of nonvaccinees who developed COVID-19 were 11 excess cases per 100,000 population. In contrast, vaccinees experienced 2.7 excess cases of myocarditis per 100,000, a fourfold difference. Furthermore, the rates of myocarditis were highest among men aged 20 to 34 years. The database was large, but the lower limit of age was 16. In addition, the findings may be restricted in generalizability because the patients were Israeli and the vaccine was manufactured by Pfizer.[9]

In regard to the efficacy of COVID-19 vaccines, the rates exceed 95% compared with approximately 50% of that for influenza. In addition, the mortality rate from COVID-19 is 30-fold higher, and a positive patient will transmit COVID-19 to approximately 5 to 6 other individuals compared with 1 to 2 for influenza.[10] This situation is exacerbated by the prevalence of the Delta and Omicron variants, which have even greater infectivity and virulence than the conventional strain of COVID-19. Although vaccinated patients may become positive when exposed, it is important to note that the majority of breakthrough infections are asymptomatic positive tests.

Collaborations among academicians, industry, and government previously led to vaccines for COVID-19 in adults to be developed, approved, and distributed in record time throughout the United States under emergency use authorizations by the US Food and Drug Administration (FDA). In addition, both the FDA and the Centers for Disease Control and Prevention granted full and permanent approval of the Pfizer vaccine. Moderna was launched later and was approved by the FDA on January 31, 2022.

At present, primary healthcare providers and pediatricians should emphasize to parents and other family members that among those who develop symptoms, they are less likely to experience severe infection and the virus is less transmissible to others. In addition, parents and family should be made aware that COVID-19 vaccines offer almost complete protection against hospitalization and death. Finally, they should emphasize that in randomized trials among 300 children, there were no reported cases of myocarditis.[9]

From the Charles E. Schmidt College of Medicine, Florida Atlantic University, Boca Raton, and the University of Wisconsin School of Medicine and Public Health, Madison.

Correspondence to Sarah K. Wood, MD, FAAP, Charles E. Schmidt College of Medicine, Florida Atlantic University, 777 Glades Rd BC-71, Boca Raton, FL 33431. E-mail: swood31@health.fau.edu. To purchase a single copy of this article, visit sma.org/smj. To purchase larger reprint quantities, please contact Reprintsolutions@wolterskluwer.com.

S.K.W. has received compensation from Florida International University, the Texas Higher Education Coordinating Board and Amgen. D.G.M. did not report any financial relationships or conflicts of interest. C.H.H. has received compensation from Amgen, the British Heart Foundation, Cadila, the Canadian Institutes of Health Research, the Collaborative Institutional Training Initiative DalCor, the Food and Drug Administration, Pfizer, Regeneron, and UpToDate. He receives royalties for authorship or editorship of 3 textbooks and as co-inventor on patents for inflammatory markers and cardiovascular disease that are held by Brigham and Women's Hospital. He has an investment management relationship with the West-Bacon Group within Truist Investment Services.

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On October 26, 2021, the FDA Vaccine Advisory Committee[11] and on November 2, 2021, the Centers for Disease Control and Prevention[10] recommended approval of the Pfizer vaccine for use in children 5 to 11 years of age. Although children are less likely to develop serious illnesses, among those 5 to 11 years of age, there have been >1.9 million infections, >8300 hospitalizations, and > 1500 inflammatory disorders.[10]

In the United States, the epidemic in 2021 was occurring mainly among unvaccinated individuals and in 2020 mainly among those who did not practice masking, social distancing, crowd avoidance, and frequent handwashing.[12] Primary care providers and pediatricians may wish to explain efficacy and safety to parents and families and to reinforce the possibilities for school-based efforts. For children younger than 5 years of age, randomized data on efficacy and safety are beginning to emerge suggesting that the benefit to risk ratio may not be favorable.[11] In the meantime, it is our perspective that there is a need for primary health education of parents of unvaccinated children to attempt to restrict their surroundings to vaccinated individuals who are masked.

For US children aged 5 to 18 years old, we believe that primary care providers and pediatricians face clear and achievable clinical challenges. Specifically, there is an urgent need to achieve higher vaccination rates against COVID-19 in United States children as soon as possible. The urgency derives, in part, because during the summer of 2021 pediatric hospitalizations in the United States were at their highest level at the time that generally corresponds to the nadir of the respiratory virus season. The omicron surge that occurred in the late fall of 2021 implies that herd immunity has been achieved through vaccinations and the high infection rates. Thus, continued replication of the virus will sooner or later lead to the emergence of a vaccine-resistant strain. Primary care providers and pediatricians also can educate and influence entire families at a critical moment that will decrease morbidity and mortality.

The large racial inequalities in deaths from COVID-19 have been decreasing, not because deaths in Blacks are decreasing, but because deaths in largely unvaccinated Whites are increasing, especially in children and younger adults.[13] Although the absolute risks of hospitalizations and deaths in children are low, the relative risks are highest in those US states with rates of vaccinations that are lower than the national average and mainly among people who are not vaccinated.[11]

Approximately 30% of vaccine-hesitant parents reported that they were awaiting full FDA approval before accepting vaccinations.[8] As such, it is our belief that this is an important moment for primary health providers and pediatricians to discuss with all of their patients and families the efficacy and safety of the COVID-19 vaccines. They may also wish to emphasize that in the United States >550 million doses have been administered and globally >10 billion.[13,14]

It is also our perspective to do the most good for the most patients rather than following a strategy of risk avoidance. Based on the available evidence, the benefits of COVID-19 vaccination of children aged 5 to 18 years of age outweigh the risks. Furthermore, we believe that increasing vaccination rates among children eligible to receive the COVID-19 vaccine would have major clinical and public health benefits by reducing hospitalizations and deaths. We are fortunate to live in a country where COVID-19 vaccines are so readily available and accessible and applaud the recent actions by the US government to protect our children. We hope that US primary healthcare providers and pediatricians will agree and act on this perspective, as there is a real and impending threat of increasing cases and deaths unless more children and young adults are vaccinated. Last but not least, our perspective to primary health care providers and pediatricians is to apply to parents and families of children the Benjamin Franklin axiom that "an ounce of prevention is worth a pound of cure" by increasing the vaccination rates of US children against COVID-19.

References

1. Johns Hopkins University Coronavirus Resource Center. Tracking. https://coronavirus.jhu.edu/data. Accessed October 28, 2021.
2. Keith M. Southern US states face dire surges in COVID-19 cases and hospitalizations. https://www.insider.com/southern-us-states-surges-in-covid-19-2021-8. Published August 15, 2021. Accessed February 20, 2022.
3. Smith-Schoenwalder C. CDC data: coronavirus vaccine coverage lowest among 12-15-year-olds. https://www.usnews.com/news/health-news/articles/2021-07-14/cdc-data-coronavirus-vaccine-coverage-lowest-among-12-15-year-olds. Published July 14, 2021. Accessed February 20, 2022.
4. Hamel L, Kirzinger A, Muñana C, et al. KFF COVID-19 Vaccine Monitor December 2020. https://www.kff.org/coronavirus-covid-19/report/kff-covid-19-vaccine-monitor-december-2020. Published December 15, 2020. Accessed September 20, 2021.
5. McEvoy J. Child covid hospitalizations hit new pandemic peak—experts are bracing for worse. https://www.forbes.com/sites/jemimamcevoy/2021/08/26/child-covid-hospitalizations-hit-new-pandemic-peak-experts-are-bracing-for-worse/?sh=46fd25b4fc47. Published August 26, 2021. Accessed February 20, 2022.
6. Hennekens CH, George S, Adirim TA, et al. The emerging pandemic of coronavirus and the urgent need for public health leadership. *Am J Med* 2020;133:648–650.
7. Solano J, Maki DG, Adirim TA, et al. Public health strategies contain and mitigate COVID-19: a tale of two democracies. *Am J Med* 2020;133:1365–1366.
8. Maki DG, Hennekens CH. Health care workers need COVID-19 vaccination: clinical, public health, and ethical considerations. *Am J Med* 2021;134:1437–1439.
9. Barda N, Dagan N, Ben-Schlomo Y, et al. Safety of the BNT162b2 mRNA Covid-19 vaccine in a nationwide setting, *N Engl J Med* 2021;385:1078–1090.
10. Centers for Disease Control and Prevention. CDC recommends pediatric COVID019 vaccine for children 5 to 11 years. https://www.cdc.gov/media/releases/2021/s1102-PediatricCOVID-19Vaccine.html#:~:text=CDC%20Recommends%20Pediatric%20COVID%2D19%20Vaccine%20for%20Children%205%20to%2011%20Years,-Media%20Statement&text=Today%2C%20CDC%20Director%20Rochelle%20P,the%20Pfizer%2DBioNTech%20pediatric%20vaccine. Published November 2, 2021. Accessed February 20, 2022.
11. Ramirez-Feldman L. FDA advisory panel authorizes Pfizer's vaccine for children 5-11. https://www.aol.com/news/fda-advisory-panel-authorizes-pfizers-vaccine-for-children-5-11-232110554.html. Published October 26, 2021. Accessed February 20, 2022.
12. Hennekens CH, Drowos J, Levine RS, et al. The crucial and urgent role of family physicians in increasing COVID-19 vaccinations. *South Med J* 2022;115:280–281.
13. Levine RS, Johnson HM, Maki DG, et al. Racial inequalities in mortality from coronavirus: the tip of the iceberg. *Am J Med* 2020;133:1151–1153
14. Bloomberg News. More than 10.5 billion shots given: COVID-19 tracker. https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution. Published and accessed February 20, 2022.

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EXHIBIT G

AAP News™



Study: Vaccines help prevent long COVID in children, adolescents

January 16, 2024

Melissa Jenco, News Content Editor

Article type: News

Topics: COVID-19, Infectious Diseases, Vaccine/Immunization

Editor's note: *For the latest news on COVID-19, visit http://bit.ly/AAPNewsCOVID19.*

COVID-19 vaccines are about 35% effective in preventing long COVID in children for a year, according to a new study.

"This study provides us with important data showing the protective effects of the vaccine against long-haul COVID and suggests that this protection is mostly from preventing visible infections," senior study author Charles Bailey, M.D., Ph.D, an academic investigator in clinical informatics at Children's Hospital Philadelphia, said in a press release. "We hope this means that as vaccines are improved to be more effective against current strains of SARS-CoV-2, their protection against long COVID will get better, too."

Experts are still trying to understand post-COVID conditions, also known as long COVID. People with long COVID may experience brain fog, shortness of breath, gastrointestinal issues, generalized pain or fatigue. The study, "Vaccine Effectiveness Against Long COVID in Children" (Razzaghi H, et al. *Pediatrics*. Jan. 16, 2024), was part of the National Institutes of Health's Researching COVID to Enhance Recovery initiative.

Researchers analyzed electronic health record data on more than 1 million children ages 5-17 years to determine how effective COVID vaccines are preventing long COVID. Just over half had received at least one vaccine dose.

Long COVID was classified as "diagnosed" if the child had two or more health care visits with diagnosis codes for long COVID. Cases were "probable" if they only had one diagnosis code, or they had two

diagnoses similar to long COVID within 6 months after a COVID infection.

About 4.5% of the cohort had probable long COVID while just under 1% had a long COVID diagnosis.

The team calculated adjusted vaccine effectiveness (VE) of 35.4% against probable or diagnosed long COVID within 12 months. Vaccine effectiveness against diagnosed long COVID was 41.7%.

Adolescents had a higher vaccine effectiveness against probable or diagnosed long COVID (50.3%) compared to children ages 5-11 years (23.8%). The adolescents were studied during both the delta and omicron era while data on younger child is only from omicron period.

Data also showed effectiveness to be higher at 6 months (61.4%) than at 12 months (35.4%) or 18 months (10.6%) post vaccine.

“Evaluations of VE over time are needed to address whether these waning effects can be overcome through booster or annual vaccine doses,” authors wrote.

A mediation analysis found the protection vaccines provide against long COVID is largely tied to preventing children from getting a COVID infection.

“These retrospective data provide guidance for additional research into the ways long COVID develops, and how we can better protect children and adolescents,” Dr. Bailey said.

The AAP and Centers for Disease Control and Prevention (CDC) recommend everyone 6 months and older get vaccinated. However, just 8% of children and 21.4% of adults have received the updated 2023-’24 vaccine, according to the CDC.

COVID hospitalizations rose 3.2% and deaths rose 14.3% during the week ending Jan. 6, 2024, compared to the previous week, according to CDC data. Wastewater testing also has found increasing viral activity.

The current vaccines, tests and treatments work against JN.1, which has become the most widely circulating COVID variant, according to the CDC. There is no evidence it causes more severe disease than other circulating variants.

Resources

- CDC webinar “Evaluating and Supporting Children and Adolescents Presenting with Post-COVID Conditions”
- American Academy of Physical Medicine and Rehabilitation guidance on diagnosis and treatment of long COVID in children and adolescents
- Information from the AAP on COVID-19 vaccines, including a dosing guide and information on payment
- *AAP News* story “Battling long COVID: Pediatricians talk strategies, prevention measures for children with lingering symptoms”
- CDC interim clinical guidance on COVID-19 vaccines
- COVID-19 vaccine checklist for children from HealthyChildren.org

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EXHIBIT 6

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

SUPPLEMENTAL DECLARATION OF MOLLY O'SHEA, MD

I, Molly O'Shea, M.D., (aka Mary Doherty-O'Shea Gallucci) declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I am a graduate of the University of Michigan Medical School and completed residency at Children's Hospital of Michigan. I am a board-certified pediatrician and the owner of two pediatric practices in Michigan with locations in Bloomfield Hills (Oakland County) and Washington Township (Macomb County). I have practiced pediatrics for over 30 years. I care for children from birth through adolescence, including newborns.

2. I am a member of the American Academy of Pediatrics (AAP).

3. I am aware of the "Secretarial Directive on Pediatric COVID-19 Vaccines for Children Less than 18 years of Age and Pregnant Women" (the "Secretarial Directive") issued by Secretary of Health and Human Services Robert F. Kennedy, Jr. (the "Secretary") on May 27, 2025 designating the COVID-19 vaccine for children as Shared Clinical Decision Making ("SCDM") and removing the recommendation for the COVID-19 for pregnant individuals. I am also aware that on or about May 30, 2025, the CDC changed its immunization guidance with regard

to children and the COVID-19 vaccine from routine vaccination for all children to "Shared Clinical Decision Making" ("SCDM") without explanation.

4. I am aware of the recommendation issued by the Advisory Committee on Immunization Practices ("ACIP") in September 2025 and subsequently adopted by the acting director of the Centers for Disease Control and Prevention ("CDC") in October 2025, changing the COVID-19 vaccine recommendation for all individuals under the age of 65 from routine to SCDM.

5. As a board-certified pediatrician who has been practicing for more than 30 years, I wholeheartedly and vehemently disagree with the SCDM recommendation for the administration of the COVID-19 vaccine to children. Covid illness is currently on the rise, but this change to SCDM will, unfortunately and very likely, lead to more illness and death.

6. I and other providers at my practices are confused by the CDC's decision to list the COVID-19 vaccine for children as SCDM without explanation or guidance and view this to be an effort by the CDC and the Secretary to discourage parents and caregivers from giving their children the COVID-19 vaccine. When the CDC categorizes a vaccine on its immunization schedule as "routine," not only does it mean that the group of people in the category *should* get the vaccine, but in any health care setting the default decision is to vaccinate. In the past, when the CDC has issued a SCDM recommendation for a vaccine, the supporting data was published in the CDC's Morbidity and Mortality Weekly Report ("MMWR") in addition to the SCDM recommendation. This data is critical for physician use in consulting with and discussing the risk and benefits of a vaccine categorized as SCDM and, normally, provides clinicians with the evidence base to guide patient counseling. For example, after the ACIP recommended SCDM for the Meningococcal B

vaccine, the CDC published guidance on how providers could engage in SCDM with patients.[1] No such data or guidance accompanied the CDC immunization schedule change for children for COVID-19 vaccines from "routine" to "SCDM," leaving us without clear guidance regarding what to discuss with parents and caregivers or how to counsel them regarding the risks and benefits of the COVID-19 vaccine. This lack of clarity and guidance inherently increases the amount of time we spend on unbillable counseling time with patients regarding the COVID-19 vaccine.

7. The change to a SCDM recommendation for the COVID-19 vaccine and the associated messaging from the CDC has injected chaos, confusion, and disruption into the practice and care that I and other providers in my practices provide, and has led to parents and caregivers doubting the safety and efficacy of all vaccinations in general. Designating a vaccine as "routine" signals an unequivocal recommendation from the CDC that a vaccine is recommended to protect patients. A "SCDM" recommendation, however, is the lowest-strength option available to ACIP, and instead signals to parents and caregivers that their children *may* benefit from the COVID-19 vaccine.

8. I have already seen the impact of the downgrade of the recommendation for the COVID-19 vaccine for children from routine to SCDM. This lack of clarity and lack of guidance regarding the SCDM recommendation for the COVID-19 vaccine has left me and my colleagues without a path for employing shared clinical decision-making in practice. As a result, I have had to dedicate time and resources to developing a plan for complying with the SCDM requirement while ensuring we are able to vaccinate as many patients as possible. This has caused a direct

[1] *See Shared Clinical Decision Making Meningococcal B Vaccination*, CDC (Dec. 9, 2024), attached hereto as **Exhibit A**.

financial impact on my practices, as none of that time I've spent developing these plans and protocols is reimbursable or billable.

9. The CDC's downgrade of the recommendation of the COVID-19 vaccine for children to SCDM has also created significant barriers for patients seeking to get a COVID-19 vaccine. Now, in order to engage in SCDM, families must schedule a physician appointment and take time off from work and/or take their child out of school to attend the appointment. Parents and caregivers are also frustrated and strained by the additional co-pay cost required for these visits, which weren't required when the COVID-19 vaccine was recommended as a routine vaccination for children.

10. I and my colleagues use Current Procedural Terminology ("CPT") codes to bill for the professional services that we provide to our patients. Each code is tied to a patient care service and is used to document and receive reimbursement for medical encounters. Vaccine administration has its own family of CPT codes, with the codes tying compensation of doctors to actual counseling and administration of the vaccine during a patient visit—but the time spent meeting with patients in order to satisfy the SCDM requirement far exceeds the typical time counseling for vaccine administration normally takes. By putting COVID-19 vaccine in a different class than other vaccines we routinely give, even parents who accept vaccines willingly are more concerned. As a result of the shift in the COVID-19 vaccine recommendation from "routine" to "SCDM" for children, I and other providers at my practices have been required to spend significantly more unbillable time counseling families regarding the effectiveness of the COVID-19 vaccine when administered to children and dispelling misinformation regarding all vaccines administered to children. Not only is this time unbillable, but it also infringes on our ability to see additional patients and receive reimbursement for that time, too.

11. My practices have also had to forego our annual flu and COVID-19 vaccination clinics as a result of the CDC's downgrade of the COVID-19 vaccine recommendation for children from "routine" to "SCDM." In years past, I arranged for a flu and COVID-19 vaccination clinic to be held outside of normal office hours at my practices in order to give families the opportunity to obtain these vaccinations quickly and without having to miss school and work. When the flu and COVID-19 vaccinations were both listed as "routine" on the CDC's immunization schedule for children, we were able to quickly and efficiently administer the flu vaccine and/or the COVID-19 vaccine to hundreds of patients at a time that was convenient for the patients and their families. Approximately half of the parents and caregivers who have their child receive a flu vaccine also have their child receive a COVID-19 vaccine; these patients are now receiving the flu vaccine when they set up a SCDM appointment to receive the COVID-19 vaccine. Since the expected participation in a flu-only clinic is approximately halved, my practices were unable to justify the financial burden of holding a flu-only vaccine clinic. Instead, patients must schedule a regular appointment to receive the flu vaccine at my practices, which has led to a significant decline in the number of patients receiving the flu vaccine this year.

12. The removal of the COVID-19 vaccine from the routine vaccination recommendations for children has eroded some families' faith and trust in other vaccines, causing them to refuse or significantly delay a myriad of routine vaccinations. Some families have gone so far as to reject all vaccines now. As a result, fewer parents are getting their children vaccinated on time for anything, including COVID-19, than was the case before the change to a SCDM recommendation for the administration of the COVID-19 vaccine to children, creating an even more imminent and severe risk of serious illness, hospitalization, and death.

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

Executed on: 11/25/2025

Dr. Molly O'Shea

Molly O'Shea, M.D.

EXHIBIT A

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Shared Clinical Decision-Making

Meningococcal B Vaccination

All adolescents and young adults who are at increased risk for serogroup B meningococcal disease should receive Meningococcal B (MenB) vaccine. This includes patients with anatomic or functional asplenia (including sickle cell disease), persistent complement component deficiency, or complement inhibitor use.

Shared clinical decision-making (SCDM) is recommended regarding MenB vaccination for healthy people 16–23 years of age. SCDM recommendations are meant to be flexible and informed by the characteristics, values, and preferences of the individual patient and the clinical discretion of the health care provider.

When you decide to discuss MenB vaccination with people 16–23 years of age:

Remember:



- MenB vaccine is not routinely recommended for all people in this age group.
- The vaccine series provides short-term protection against most strains of serogroup B meningococcal bacteria circulating in the United States.

Consider:



- Serogroup B meningococcal disease is an uncommon but deadly disease. In recent years, between 20 and 50 cases occurred each year in 16- through 23-year-old people in the United States.
- A low risk of exposure or infection does not mean a person cannot get a MenB vaccine. It is just one potentially important consideration in SCDM.
- Serogroup B meningococcal disease cases most commonly affect young adults who attend a four-year university, are freshmen, live in on-campus housing, or participate in sororities or fraternities.
- MenB vaccines are safe and effective, but they only offer short-term protection (1 to 2 years) to those who get vaccinated.

How to vaccinate:



- If you and your patient decide MenB vaccination is appropriate, administer a 2-dose series of a MenB vaccine, one each at month 0 (the first vaccine appointment) and 6 months later.
  - To optimize rapid protection (e.g., for students starting college in less than 6 months), a 3-dose series (0, 1–2, 6 months) may be administered.
- MenB-4C and MenB-FHbp are not interchangeable.
- MenB vaccines should not be administered to a person who has had a severe allergic reaction (e.g., anaphylaxis) to a:
  - Previous dose of MenB vaccine
  - Component of the vaccine
- In pregnant women, delay vaccination until after pregnancy unless the patient is at increased risk and the benefits of vaccination outweigh the potential risks.

Additional information:

CDC Child and Adolescent Immunization Schedule by Age:
www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html

CDC Adult Immunization Schedule by Age:
www.cdc.gov/vaccines/hcp/imz-schedules/adult-age.html

CDC Meningococcal Vaccine Recommendations:
www.cdc.gov/meningococcal/hcp/vaccine-recommendations/index.html

EXHIBIT 7

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., *et al.*, *Defendants.*	Case No. 1:25-cv-11916

DECLARATION OF JAMES D. CAMPBELL, MD, MS

I, James D. Campbell, MD, MS declare pursuant to 28 U.S.C. § 1746 under penalty of perjury that the following is true and correct and within my personal knowledge.

1. I am a pediatrician and pediatric infectious disease physician.

2. I am Interim Division Head of Pediatric Infectious Disease and Tropical Pediatrics and Professor of Pediatrics at the University of Maryland School of Medicine in Baltimore, Maryland.

3. I am a member of the American Academy of Pediatrics (the "AAP"), and I serve as Vice Chair of AAP's Committee on Infectious Diseases.

4. Building my medical career took persistent dedication and personal sacrifice. I dedicated years of my life to learn my craft.

5. I prepared for medical school by studying biology and theology, earning a Bachelor of Science degree from Georgetown University College of Arts and Sciences, *magna cum laude*, in 1987.

6. I spent four years in medical school studying as part of the Health Professions Scholarship Program through the United States Navy, graduating from Columbia University College of Physicians and Surgeons in 1991.

7. While in medical school, I was awarded membership in the Alpha Omega Alpha Honor Medical Society, the William Perry Watson Prize for Outstanding Student in Pediatrics, and the Marie Nercessian Memorial Award for Outstanding Student in the Compassionate Care of Patients.

8. I completed a three-year pediatrics residency at the National Naval Medical Center (now known as the Walter Reed National Military Medical Center) in Bethesda, Maryland, in 1994.

9. In 1994, I obtained initial board certification in general pediatrics, a certification that I held and maintained until 2008.

10. From 1994 through 1998, I worked as a general pediatrician in the United States Navy in the ranks of Lieutenant through Lieutenant Commander in Bethesda, Maryland, and on the Island of Guam in the Micronesian Islands.

11. In 1998, I was awarded a Navy Commendation Medal for my accomplishments as Director of the General Pediatric Ambulatory Care Clinic, as author of the General Pediatrics curriculum, and other duties at the National Naval Medical Center.

12. Between 1998 and 2001, in addition to my position as a Reserve Officer in the United States Navy, I was also a research fellow at the University of Maryland School of Medicine studying pediatric infectious diseases and completed my fellowship there in 2001.

13. In 2001, I obtained board certification in infectious diseases and maintained that certification until 2008.

14. I returned to school to study epidemiology and biostatistics, earning a Master of Science in those fields in 2006 from the University of Maryland School of Medicine.

15. In 2006, I received an honorable discharge from my position as Commander in the United States Naval Reserves.

16. Since completing my medical training, I have dedicated my career to the welfare of my patients and my nation. Duty called me to work for the U.S. Centers for Disease Control and Prevention (the "CDC") from 2007 to 2012 on their HIV treatment and prevention missions in Uganda.

17. Due to the demands of my role with and my work for the CDC in Uganda, maintaining my board certifications in general pediatrics and infectious diseases was difficult, and both expired in 2008. I remain board eligible, but did not seek recertification in either field.

18. When I returned to the United States in 2012, I resumed my faculty position as Professor of Pediatrics at the University of Maryland School of Medicine.

19. In connection with my faculty appointment at the University of Maryland School of Medicine, I have been involved in several research endeavors including projects evaluating the use of a Group B Streptococcus vaccine in pregnant women; describing vaccine coverage rates among Ethiopian children in three representative districts; evaluating infant investigational vaccines against RSV, pneumococcus, and meningococcus; evaluating vaccines against COVID-19 in adults, teens, and children; and evaluating new generation anthrax vaccines.

20. The patients I treat on the Pediatric Infectious Diseases service at the University of Maryland Children's Hospital are often some of the sickest patients in the hospital and some require multiple invasive life-saving medical interventions and extensive treatments in the pediatric intensive care unit.

21. The May 19, 2025, decision of Secretary of Health and Human Services ("HHS"), Robert F. Kennedy, Jr. (the "Secretary") to rescind the CDC's recommendations for COVID-19 vaccinations for pregnant individuals and children has harmed and will continue to harm my patients and my practice.

22. Over the course of my practice, I have provided treatment to children who were not vaccinated for COVID-19. These patients ranged in age from infancy to their teenage years and suffered severe adverse medical outcomes, including the need for intubation and placement on a ventilator in order to breathe. One patient, a college athlete, suffered such severe lung damage from COVID-19 that he completely lost function of one of his lungs. The decision to rescind the COVID-19 recommendations for pregnant persons and children has harmed my patients because they functionally are being deprived of access to the COVID-19 vaccine and will face similar adverse medical outcomes.

23. Because of these adverse outcomes, my practice has been and will be harmed because there will be higher numbers and incident cases of severe COVID-19 that require treatment by my practice. These patients will be more numerous and will present with more complex and severe needs. In turn, this will put strain on my practice and the resources I rely on to provide medical care. This will ultimately deprive me of the opportunity to dedicate time and attention to patients, forcing me and my practice to increasingly stretch our time and resources across more and more patients, as was the case before children could be vaccinated for COVID-19.

[Signature on following page]

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

Executed on July 10, 2025, in Baltimore, Maryland.

James D. Campbell

JAMES D. CAMPBELL, MD, MS

EXHIBIT 8

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 SHANNON SCOTT-VERNAGLIA, M.D.

I, Shannon E. Scott-Vernaglia, M.D., declare pursuant to 28 U.S.C. § 1746 under penalty of perjury that the foregoing is true and correct and within my personal knowledge.

1. My name is Shannon E. Scott-Vernaglia. I am physician and Board Certified in Pediatrics and I am current a Fellow of the American Academy of Pediatrics. I submit this declaration in support of Plaintiffs' Third Amended Complaint because the May 19, 2025 Directive issued by the U.S. Department of Health and Human Services ("HHS") under Robert F. Kennedy Jr., designating the Covid-19 vaccine for children as Shared Clinical Decision-Making ("SCDM") and recent unexplained changes to the CDC immunization schedule by the Advisory Committee on Immunization Practices ("ACIP") (in September 2025) and the Centers for Disease Control and Prevention ("CDC") (in October 2025) for Covid-19 vaccinations, harms my patients and is interfering with my ability to practice pediatric medicine in accordance with the accepted standard of care.

2. I graduated from Harvard University in 1994 with a Bachelor's Degree in Earth and Planetary Science.

3. I went to medical school at the School of Medicine at Stony Brook University Medical School where I graduated in 1999.

4. I completed a residency in Pediatrics at Massachusetts General Hospital where I also was selected to serve as Chief Resident in Pediatrics.

5. I practice medicine and teach at an academic hospital in Boston, Massachusetts.

6. As part of my clinical practice as a pediatrician, I treat pediatric patients on an outpatient basis in a general pediatrics clinic (the "Clinic").

7. As part of my clinical practice, I routinely recommend that children be vaccinated against vaccine-preventable diseases such as measles, mumps, polio, whooping cough, rubella, tetanus, influenza, and COVID-19, among others.

8. I know that recommending routine vaccination of children ages 6 months–17 years against COVID-19 is appropriate evidence-based medicine and is the standard of care for healthy children.

9. Prior to May 19, 2025, the Clinic stocked COVID-19 vaccines to give to patients ages 6 months–17 years in accordance with the FDA's approval and CDC recommendations.

10. Since the May 19, 2025 directive (the "Directive") of the Secretary of the Department of Health and Human Services ("HHS") to rescind previous recommendations that healthy children ages 6 months–17 years be routinely immunized against COVID-19 and, instead, implement shared clinical decision-making ("SCDM"), the Clinic through which I practice medicine has experienced disruptions due to uncertainty about vaccine availability.

11. In general, the Clinic receives most childhood vaccines, including COVID-19 immunizations, through the Vaccines for Children ("VFC") Program. Shortly before the Directive, we were transitioning to buy COVID-19 vaccines through our central pharmacy.

12. The Clinic prioritizes vaccinating children against COVID-19 for their primary series, which are the doses of vaccine needed to provide initial immunity (as compared with later vaccines that boost immunity and provide better coverage for more recent circulating strains of COVID-19 virus ("Boosters")). Thus, we were planning to stock Boosters updated for the next season when available for older children to provide the best protection for them during the winter respiratory season.

13. When the Directive from HHS came out, we were due to order COVID-19 vaccines for children under the age of 12 to ensure that we could provide primary series vaccines, but had to pause as there was uncertainty about whether the vaccine would be reimbursed by insurance companies due to the Directive. Thus, for a period of just under two weeks, the Clinic did not have any COVID-19 immunizations eligible to be given to healthy patients.

14. On June 11, 2025, one of my patients who is between the ages of 6 months–17 years came to the Clinic for a wellness appointment with a plan to receive the first dose of COVID-19 immunization primary series. Our clinic did not have a stock of COVID-19 immunizations available. When we again had vaccine available, I had to reach out to the patient family and the patient was required to come back on a different day get the COVID-19 immunization. As a result, the patient and the patient's family incurred the significant expense of arranging to be at the Clinic on a separate day and traveling to the Clinic, and I and my staff had to spend additional time caring for the patient through messaging, scheduling, and having the patient return for a second visit.

15. For many of my patients' families, coming to the Clinic to attend a vaccine appointment is logistically difficult. Many of my patients require their parents or caregivers to take time off from work to bring them to the Clinic, and transportation to the Clinic can be costly because there is no free parking near the Clinic. The Clinic is designed to incorporate vaccine administration into our routine care of children coming for their wellness visits. Coming to the Clinic for a separate, additional appointment when the Clinic has insufficient stock of COVID-19 vaccines is a hardship for my patients that they cannot afford.

16. Before the Directive and the change to SCDM, I recommended that some of my healthy Clinic patients being seen in spring months receive their next COVID-19 Booster, but offered that they might wait to do so until the fall to help ensure maximum protection against COVID-19 during respiratory virus season that occurs in the winter months. When I made that recommendation, the availability of COVID-19 vaccines, updated seasonal Boosters, and whether they would be covered by major insurers was not in question.

17. The Directive has limited the Clinic's ability to consistently stock COVID-19 immunizations for healthy children ages 6 months–17 years. My pediatric patients who chose to wait to receive their COVID-19 Booster until the fall of 2025 may not be able to access it at that time, and they are being put at risk by the Directive. I lose sleep at night thinking about those children and their family members.

18. Given the uncertainty caused by the Advisory Committee on Immunization Practices ("ACIP") and Food and Drug Administration ("FDA"), as derived out of the Directive, my Clinic experienced a delay in vaccine shipments by approximately four to six weeks. Children who were seen in those weeks were unable to receive the COVID-19 vaccine. As a result, children

who would have received the COVID-19 vaccine must either return to the Clinic, seek it elsewhere, or have been lost to follow-up.

19. There is clear scientific evidence that missed opportunities for vaccination during regular office visits leads to a greater risk of future under-immunization status for children. Having irregular or uncertain vaccine availability due to the Directive therefore puts my patients at risk of remaining under-vaccinated in the future and increases their vulnerability to illness and hospitalization.

20. The Directive undermines my ability to professionally serve my patients. The Directive and SCDM recommendation is not the result of evidence-based medicine, and it conflicts with the established standard of care to routinely immunize children ages 6 months–17 years against COVID-19 and to provide annual Boosters in the fall. Statements from governmental authorities such as the Directive and the shift to SCDM dismantles public trust in science and medical-infrastructure, including my physician-patient relationships.

21. Since the Directive, I have had to spend more time counseling patients and family members regarding vaccine recommendations, the safety and efficacy of vaccines, including the COVID-19 vaccine, and correcting misinformation about the COVID-19 vaccine. For example, patients and their family members often have only a vague understanding of changes to the recommendation for COVID-19 vaccines and many believe the vaccine is no longer available to children. This increased time is compounded by the increasing number of patients who require longer and longer discussions to address vaccine misinformation. In my practice I have seen an increased number of families express mistrust in vaccines generally, as a result of both the Directive and persistent misinformation. Even for those vaccines that have retained routine recommendation status, I am often required to spend extra time counseling patients and their

families. Additionally, I spend increased time answering concerned parents' questions about the future availability of other vaccines, such as the MMR.

22. For well-child visits, which are regular appointments with pediatric patients in which vaccines are typically administered, I bill as an inclusive visit code. This means that if the visit exceeds the allocated time I am not compensated for that time.

23. Additionally, I lose out on time that I could be spending treating more patients having protracted discussions about misinformation and concerns about the implications for other vaccine availability.

24. There is a well-established shortage of primary care medical providers, including general pediatricians in the country and in Massachusetts. Additionally, there has been a significant drop in the percentage of medical school graduates pursuing Pediatrics as a specialty. HHS directives like the Directive and the SCDM recommendation cause more confusion about appropriate medical recommendations, and erode the relationship between the pediatric physician and patient family exacerbate the difference in the demand and availability of medical resources for children.

25. The Directive and recent actions by the ACIP and CDC downgrading the recommendation for Covid-19 vaccinations to SCDM also puts me at increased risk for contracting COVID-19 by increasing the risk that my patients will be infected with COVID-19 and seek treatment for COVID-19 at the Clinic. My mother is an immunocompromised older adult, and I fear that if I contract COVID-19, I could give it to her and either she or I, or both could suffer devastating long-term consequences from COVID-19. The heightened risk of COVID-19 transmission and infection is a direct result of the Secretary's Directive and the recent actions by ACIP and the CDC, which prevents my patients from being immunized against COVID-19.

26. I am a Fellow of the American Academy of Pediatrics.

27. I make this declaration in my personal capacity and in my capacity as a Fellow of the American Academy of Pediatrics.

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

Executed on November 27, 2025, in Boston, Massachusetts.

Shannon E. Scott-Vernaglia, MD

Shannon E. Scott-Vernaglia, M.D.

EXHIBIT 9

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 District Judge: William G. Young Magistrate Judge: M. Page Kelley

DECLARATION OF DR. SHETAL SHAH

I, Dr. Shetal Shah, declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I am at least 18 years of age.

2. I reside in New York.

3. I am a board-certified neonatologist. I specialize in the care of critically ill newborns, both premature and full-term, including those with congenital abnormalities such as cardiac and gastrointestinal defects.

4. I am employed by a physician practice group that contracts with Maria Fareri Children's Hospital, located in Valhalla, New York. The majority of my clinical work takes place within that hospital.

5. I graduated from medical school at Cornell University School of Medicine in 2000. I completed my residency at Duke University Children's Hospital in 2003 and completed my Fellowship at New York University Children's Hospital in 2006.

6. I am a member of the American Academy of Pediatrics.

7. The views expressed in this declaration are my own and do not reflect the views of New York Medical College, Westchester, Medical Center, Boston Children's Health Physicians or their affiliates.

8. The hospital orders its own vaccines and begins to order its influenza vaccines in late summer in hopes of having them by September or October to provide to eligible patients, caregivers and healthcare workers.

9. As part of my clinical responsibilities, I routinely provide prenatal consultations at the request of obstetric colleagues. These consults are designed to prepare families whose newborns are expected to require immediate or intensive care after delivery. During these sessions, I explain the anticipated neonatal care and emphasize the importance of maternal immunization during pregnancy.

10. I counsel families on all relevant vaccines recommended during pregnancy, including Tdap, influenza (in season), RSV (if eligible), and Covid. My counseling is designed to reinforce established obstetric recommendations and help parents make informed decisions to protect their infant's health.

11. I have a longstanding academic interest in vaccination and maternal immunization. I have delivered national lectures on antenatal immunization, including presentations at the Pediatric Academic Societies meeting.

12. Based on my clinical experience and data from the Centers for Disease Control and Prevention for the 2023-24 season, the acceptance rate for Tdap and influenza vaccines among pregnant patients is significantly higher than for the Covid vaccine. I have encountered a wide range of reasons for Covid vaccine refusal, including misinformation about fertility, conspiracy

theories, and concerns about long-term effects. Covid vaccine hesitancy remains markedly higher than for other recommended vaccines.

13. Prior to May 27, 2025, I would counsel my patients that the Covid vaccine is recommended by the Advisory Committee on Immunization Practices (ACIP) using the same rigorous scientific data as the Tdap or influenza vaccine. However, in light of changes to CDC guidance and greater skepticism about the Covid vaccine, I no longer cite the CDC explicitly during counseling for the Covid vaccine. Instead, I state that "your neonatologist recommends these vaccines" and emphasize that I have personally received them. I also use parent-centered communication strategies developed by American Academy of Pediatrics (AAP).

14. If I conduct a prenatal consultation, I document it in the maternal medical record. Postnatally, I document any relevant discussions in the infant's chart. If a parent refuses standard vaccinations for their newborn (e.g., the routine 2-month series), we ask them to sign an "informed refusal" form, which is placed in the infant's medical record.

15. Over the past five years, I have cared for newborns born to mothers with Covid infections. Some of these mothers were severely ill, and some were not. The incidence of severe, symptomatic Covid disease is two times higher in pregnant individuals compared to those who are not pregnant. Vaccinated individuals are less likely to contract the Covid virus, and if they do, they are less likely to have severe, symptomatic Covid disease.[1] Those who become pregnant within 12 months after receiving a Covid vaccine experience fewer adverse birth outcomes, such as very preterm birth and small for gestational age, than pregnant women who are unvaccinated.[2] This

[1] *See* Sonja A. Rasmussen & Denise J. Jamieson., *COVID-19 and Pregnancy*, 36 Infectious Disease Clinics of North America 423, at 427 (Jan. 31, 2022), https://pmc.ncbi.nlm.nih.gov/articles/PMC8802611/pdf/main.pdf.
[2] *See* Arun K. Suseeladevi., *COVID-19 vaccination and birth outcomes of 186,990 women vaccinated before pregnancy: an England-wide cohort study*, 45 The Lancet 1, at 5 (Aug. 13, 2024), https://www.thelancet.com/action/showPdf?pii=S2666-7762%2824%2900192-3.

matters because pregnant individuals with Covid, particularly severe Covid, have higher risk of preterm birth, and if preterm birth does occur, the infants are more likely to face serious complications than infants born at term gestation.[3]

16. In collaboration with Dr. Mark L. Hudak, I recently analyzed data from a multi-center Covid neonatal registry. We presented these findings at the Pediatric Academic Societies meeting in April 2025.[4]

17. The data show that infants born preterm to mothers with symptomatic Covid infection exhibit 1.4 times higher odds for requiring resuscitation, including the need for supplemental oxygen or positive pressure ventilation at birth compared to preterm infants born to mothers with asymptomatic infection. In other words, preterm infants born to mothers with severe, symptomatic Covid disease are at significantly higher risk for requiring advanced resuscitation at birth compared to preterm infants born to mothers with asymptomatic infection.

18. Preterm infants and infants requiring interventions such as mechanical ventilation and resuscitation must stay for extended periods in the Neonatal Intensive Care Unit (NICU) and require significantly more care and hospital resources than healthy infants born at term.

19. Preterm infants born to mothers who test positive for Covid must be put in isolation so as not to increase risk of transmission of the infection to other patients in the NICU until they are tested.

20. The removal of the Covid vaccine from the CDC immunization schedule for pregnant women, despite the continued risk of symptomatic disease and associated neonatal complications, is deeply concerning to me as a neonatologist. Increasing rates of unvaccinated

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[3] *See* Sonja A. Rasmussen & Denise J. Jamieson., *COVID-19 and Pregnancy*, 36 Infectious Disease Clinics of North America 423, at 425 (Jan. 31, 2022), https://pmc.ncbi.nlm.nih.gov/articles/PMC8802611/pdf/main.pdf.

[4] A true and correct copy of the poster presented to the Pediatric Academic Societies meeting in April 2025 is attached hereto as **Exhibit A**.

pregnant patients will lead to increased rates of symptomatic maternal Covid, more preterm births, more acutely ill newborns, and higher demands on NICU resources.

21. Vaccination during pregnancy is one of the most effective tools we have to reduce these risks. The Secretary's directive directly undermines efforts to protect maternal and neonatal health.

22. I submit this declaration in support of efforts to ensure that Covid vaccination remains strongly recommended for pregnant individuals. In my clinical judgment, supported by data and frontline experience, maternal Covid vaccination reduces the risk of preterm birth, lowers neonatal morbidity, and improves public health outcomes.

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

Executed on July 28, 2025 in Valhalla, New York.

Dr. Shetal Shah

Shetal Shah, MD

EXHIBIT A

The Impact of Symptomatic Maternal SARS-CoV-2 Symptoms and Treatment on the Need for Delivery Room Resuscitation in Preterm Infants

WMC Health | Maria Fareri Children's Hospital, Westchester Medical Center Health Network

Shetal Shah MD[1], Trace R. Getzlaff BS CS[2], Kimberly Barnette RRT[2], Shiva Gautam PhD[2], Mark L. Hudak MD[2]

(1) Pediatrics Department, Division of Neonatology, Maria Fareri Children's Hospital at Westchester Medical Center (2) Division of Neonatology, Department of Pediatrics, University of Florida College of Medicine-Jacksonville, Jacksonville, Florida

UF College of Medicine – Jacksonville, University of Florida

BACKGROUND

- SARS-CoV-2 infection during pregnancy increases the risk of maternal hospitalization & mortality.
- Treatment of mothers with symptomatic SARS-CoV-2 (COVID-19) improves maternal outcomes, but does not affect need for resuscitative measures in full-term infants.
- Yet, the role of treatment of maternal COVID-19 on newborn resuscitative interventions in preterm infants is unclear.

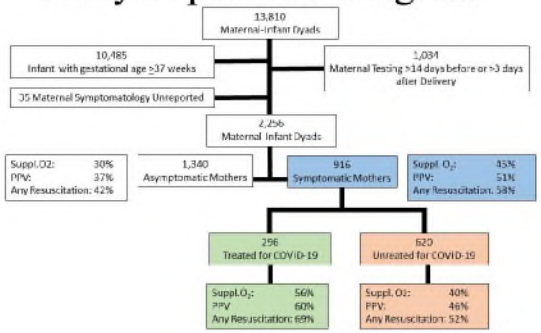
OBJECTIVE

To compare the need for resuscitation between preterm infants (<37 weeks' gestation) born to mothers with/without COVID-19-specific treatment.

METHODS

- Analysis of AAP Section on Neonatal Perinatal Medicine COVID Registry of maternal-infant dyads born <37 weeks.
- Symptomatic mothers: COVID-related hospitalization/outpatient symptoms of fever, any respiratory symptoms, myalgia or anosmia).
- Treatment: Remdesivir, or other COVID antiviral prior to delivery.
- Resuscitative outcomes: need for supplemental oxygen (O_2), positive pressure ventilation (PPV) or resuscitation (any O_2, PPV, intubation, chest compressions, epinephrine/volume expansion) at delivery.

Study Population Diagram



RESULTS

Demographics Comparing Differences in Symptom Status in Mothers with SARS-CoV-2 Infection Who Delivered Preterm

	ASYMPTOMATIC MOTHERS WITH COVID INFECTION (N=1340)		SYMPTOMATIC MOTHERS WITH COVID INFECTION (N=916)	
	N		N	
Maternal Age (years)**	**1340**	**29.0**	**916**	**30.1**
Gestational Age (weeks)**	1340	33.4	916	33.1
Maternal Betamethasone Receipt**	**1099**	**514 (47%)**	**678**	**295 (44%)**
Maternal Hispanic Race*	**1289**	**478 (37%)**	**892**	**288 (32%)**
Birthweight (grams)	1340	2202	916	2208
C-Section**	**1331**	**675 (51%)**	**914**	**633 (69%)**
OUTCOMES				
Supplemental Oxygen use in Infant at Delivery**	**1340**	**403 (30%)**	**916**	**411 (45%)**
Positive Pressure use in Infant at Delivery**	**1340**	**501 (37%)**	**916**	**464 (51%)**
Resuscitation (any O2, PPV, intubation, chest compressions, epinephrine or volume expansion) at Delivery**	**1340**	**560 (42%)**	**916**	**530 (58%)**

BOLD* p<0.05; Bold ** p<0.001

Demographics Comparing Differences in Treatment Status in Symptomatic Mothers with SARS-CoV-2 Infection Who Delivered Preterm

	N	Symptomatic & Untreated (N=2,082)	N	Symptomatic & Treated (N=235)
Maternal Age (years)**	**296**	**30.2**	**620**	**30.1**
Gestational Age (weeks)*	**296**	**32.6**	**620**	**33.3**
Maternal Betamethasone Receipt**	**210**	**111 (38%)**	**468**	**184 (30%)**
Maternal Hispanic Race	285	90 (32%)	607	198 (33%)
Birthweight (grams)**	**296**	**2136**	**620**	**2243**
C-Section**	**295**	**241 (82%)**	**619**	**392 (63%)**
OUTCOMES				
Supplemental Oxygen use in Infant at Delivery**	**296**	**165 (56%)**	**620**	**246 (40%)**
Positive Pressure use in Infant at Delivery296**	**296**	**178 (60%)**	**620**	**286 (46%)**
Resuscitation (any O2, PPV, intubation, chest compressions, epinephrine or volume expansion) at Delivery**	**296**	**205 (69%)**	**620**	**325 (52%)**

Adjusted Models for Resuscitative Outcomes in Infants with Mothers with Symptomatic SARS-CoV-2 Infection

Outcome	Odds Ratio	95% Confidence Intervals	C-Statistic
Oxygen	1.4*	(1.1-1.8)	0.76
Positive Pressure Ventilation	1.3*	(1.0-1.6)	0.78
Resuscitation	1.4*	(1.1-1.8)	0.80

*REFERENCE CATEGORY: Mothers with Asymptomatic COVID-19 Infection..

Models Adjusted for: Maternal Age, Receipt of Betamethasone, Prolonged Rupture of Membranes, Ethnicity, Delivery Mode, Gestational Age, 5-minute Apgar Score < 7, Gender and Multiple Gestation.

Adjusted Models for Resuscitative Outcomes in Infants with Mothers Treated for Symptomatic SARS-CoV-2 Infection

Outcome	Odds Ratio	95% Confidence Intervals	C-Statistic
Oxygen	1.3	(0.9-1.9)	0.76
Positive Pressure Ventilation	1.3	(0.8-1.9)	0.76
Resuscitation	1.4	(0.9-2.1)	0.79

*REFERENCE CATEGORY: Untreated Mothers with Symptomatic COVID-19 Infection.

CONCLUSIONS

- In mothers with SARS-CoV-2 infection who deliver preterm, presence of maternal symptoms increases odds of newborn resuscitation.
- Odds of neonatal resuscitation was not impacted by maternal SARS-CoV-2-specific drug therapy in symptomatic mothers who deliver preterm.
- We conclude the need for newborn resuscitation in infants born to mothers with symptomatic SARS-CoV-2 is driven by maternal illness & fetal factors and is not reduced by maternal SARS-CoV-2-specific drug therapy.
- We speculate low rates of prenatal vertical transmission of SARS-CoV-2 to the fetus may underlie these findings.

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EXHIBIT 10

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 DR. THOMAS BOYCE, M.D.

I, Dr. Thomas Boyce, M.D., 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 and not under any disability. All of the facts set forth in this declaration are based on my personal knowledge. I submit this declaration in support of Plaintiffs' requests for relief in this litigation.

2. I reside in Wisconsin and currently practice as a pediatric infectious disease specialist in a large, rural healthcare system, which has 60 locations in 32 counties in Wisconsin and serves about 310,000 patients, including 46,500 children.

3. I completed medical school at the University of Michigan in 1990. I completed my residency in pediatrics at University of Wisconsin in 1993. I then completed my fellowship in pediatric infectious diseases at Vanderbilt University Medical Center in 1999.

4. I am board-certified in pediatric infectious diseases and pediatrics.

5. I am a member of the Infectious Diseases Society of America ("IDSA") and the Pediatric Infectious Diseases Society ("PIDS").

6. As a pediatric infectious disease physician, my primary duty is to consult with providers and patients about infectious diseases and with parents of pediatric patients.

7. In the past, when the CDC classified a vaccine as routinely recommended, that meant that the patient should get the vaccine. A routine recommendation meant that the vaccine has proven over the years to be highly effective at preventing disease and saving lives with minimal risk to the patient and, therefore, should be administered as a standard part of medical care for children. In short, a routine recommendation indicates that unless there is a specific contraindication to administering that vaccine, the patient should receive the vaccine.

8. During my more than three decades of practice as an infectious disease specialist, I have, until this year, trusted the process that has resulted in vaccines being listed on the CDC immunization schedules as routinely recommended. Up until this year, the CDC's Advisory Committee on Immunization Practices ("ACIP") has likewise been a trustworthy source of non-partisan expertise backed by science and evidence. Based on the trustworthiness of these processes, I had no hesitation in advising providers and patients that a child should receive a vaccine that is a "routine" recommendation on the CDC schedules, including the Covid vaccine.

9. I am familiar with the recent ACIP recommendation that the Covid-19 vaccine be downgraded from routinely administered to one obtained through shared clinical decision making ("SCDM") for individuals under 65 years old and pregnant persons. This approach directly contradicts the standard of care as I know and understand it for safe and quality treatment of patients. This change undermines the patient-provider relationship, just as prior actions by the Secretary did in the Spring of 2025. This change also exposes me and other clinicians to unnecessary health and legal risks given the sound scientific evidence regarding Covid-19 vaccination and safety.

10. Based on my experience, there is no single definition for "SCDM." Rather, this term can mean different things to different people. In my practice and as it pertains here, SCDM means briefly discussing the benefits of a vaccine that I recommend the patient receive and risks of not being vaccinated. I am not aware of any uniform standard meaning of SCDM for any of the organizations to which I am a member, thus further emphasizing that it is an individual approach that varies from physician to physician.

11. These SCDM conversations are folded into the existing patient exam where there usually are other pressing items to cover and discuss. This means time is reallocated addressing vaccine related concerns. This makes a time pressed examination even more challenging as I do not have an infinite amount of time to spend with any one patient.

12. In addition to patient consults, I am also increasingly being called upon by other providers to assist or guide them in how to interpret the new SCDM framework. Providers have come to me with various questions about how and when a child might qualify for vaccination and whether it would be covered by insurance. Similar to my patient interactions, these consults take time and detract from other pressing work.

13. The time spent engaging in SCDM and counseling colleagues is not separately reimbursable. As a result, I am being called upon and forced to spend more and more time addressing issues caused by the changes to the recommendation of the Covid vaccine. It is not realistic to expect me or other physicians like me to dedicate countless amounts of time to these issues as doing so will detract from other work that must be done. It also deprives me of earnings and forces me to perform uncompensated work since this time is not separately reimbursable.

14. I do not believe the "SCDM" designation is appropriate for the Covid vaccine. Although there is no generally accepted definition of SCDM, in my experience most parents

interpret it as a less than full recommendation. This erodes trust in vaccine delivery and immunology, fosters vaccine hesitancy, and spreads misinformation and disinformation. Returning to the previous status quo will help alleviate the harms and adverse impacts I've described above.

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

Executed on November 30, 2025 in Marshfield, Wisconsin.

/s/ Dr. Thomas G. Boyce

Dr. Thomas Boyce

EXHIBIT 11

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 District Judge: William G. Young Magistrate Judge: M. Page Kelley

DECLARATION OF DR. SUZANNE BERMAN

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

1. I am over 18 years old, reside in Tennessee, and currently co-own Plateau Pediatrics, located in Crossville, Tennessee. I primarily manage the business and compliance aspects of the practice.

2. I completed medical school at the University of Tennessee, Memphis in 1998. I completed my residency in pediatrics at Southern Illinois University in 2001.

3. I am board-certified in pediatrics.

4. I am member of the American Academy of Pediatrics (AAP).

5. Ten clinicians, including physicians and nurse practitioners, currently practice at Plateau Pediatrics.

6. Many of the children we treat are medically complex or fragile, including former premature infants, children with G-tubes, and children requiring ventilators. These children require specialty care that family practitioners often cannot provide.

7. Given our large population of Medicaid patients, Plateau Pediatrics has long participated in the Vaccines for Children ("VFC") program, which requires us to stock both federally supplied vaccines and private stock vaccine formulations. We are therefore required to purchase and maintain private stock of Covid-19 vaccines.

8. When the Centers for Disease Control and Prevention ("CDC") classifies a vaccine as routine, that means that the patient should get the vaccine. In other words, when a vaccine is classified as routine, the default is to get the vaccine, or, put another way, it is assumed or presumed that the patient will get the vaccine as a matter of following the ordinary standard of care for the patient. I have been comfortable with recommending that my patients receive a vaccine recommended as routine because credible doctors, scientists, and other subject-matter experts on vaccines, infectious diseases, epidemiology, and public health have done thorough, comprehensive analysis of the evidence on the vaccine and concluded with a high degree of confidence that the vaccine is highly effective at preventing disease and saving lives with minimal risk to the patient.

9. I have viewed the video that the Secretary of Health and Human Services, Robert F. Kennedy, Jr. (the "Secretary") posted on X on May 27, 2025, and have read the related May 19 "Secretarial Directive" ("Directive") confirming what the Secretary said in the video. Although I understood the Secretary to be instructing the CDC in that video to remove the recommendation entirely that healthy children receive the Covid-19 vaccine, I learned that the Covid-19 recommendation was not entirely removed from the CDC immunization schedule but was changed to a "Shared Clinical Decision Making" recommendation, or SCDM. I and my colleagues

considered this change from "routine" to "SCDM" to be a downgrading of the CDC's recommendation and discouraging parents to permit the vaccine for their children.

10. The downgrading to SCDM has the downstream effect of discouraging parents to agree to vaccinate their children with the Covid vaccine, which will cause financial harm to my practice. Plateau Pediatrics serves approximately 8,800 active patients. The practice is located in a rural area of Western Appalachia, and roughly 75% of our patients are enrolled in Medicaid or CHIP (Children's Health Insurance Program).

11. We are the only pediatric practice in our county, which has a population of approximately 60,000 to 70,000 people. While some family medicine physicians in the county see children, we are the only pediatricians. Several neighboring counties have no pediatric practices. As a result, our practice provides essential pediatric care for families across multiple counties in Tennessee.

12. Our practice does not require patients to be vaccinated in order to remain in our care because the practice serves a population with a high level of skepticism of vaccines. If my practice were to require patients to be vaccinated, these families would have no alternative options for pediatric care. Yet, I and my colleagues nonetheless still try to convince parents to vaccinate their children. If we are successful in convincing a skeptical parent to give the Covid-19 vaccine to their child, Plateau Pediatrics must have the Covid-19 vaccine in stock when parents decide to vaccinate their child so that the vaccine can be administered immediately, before the parent leaves the practice and possibly changes his or her mind.

13. Covid-19 vaccination counseling is reimbursed only if the vaccine is actually administered to the patient. Medicaid reimbursement rates for Covid-19 vaccine administration range from as low as $15 per dose to approximately $40 per dose, depending on the payer.

Commercial payers typically reimburse in the same range. These payments do not cover the full cost of time and overhead involved.

14. Additionally, under the VFC program, our practice receives no payment for the vaccine product. We are only permitted to bill for the administration of the vaccine, which typically results in reimbursement of $15 to $40 depending on the Medicaid plan.

15. In August, our practice made a substantial investment in the Covid-19 vaccine when we bought 10 doses of the Pfizer vaccine at a cost of $1,045.37. We have ordered more doses, but they have not yet arrived. It is unclear whether we will be able to return any or all of the unused Pfizer vaccine. We cannot expect that vaccine manufacturers will allow full return of unused vaccine. For example, the 2025-2026 flu vaccine return policy only permits a credit for <=15% of unused doses, down from 30% in previous years.

16. Because only the Moderna Covid vaccine is authorized for children six months to 11 years old, we can only order the Moderna vaccine for this age group at a cost of $847.10 per dose. However, because we are not existing Moderna customers, there is no guarantee that we can return any unused or expired doses for a credit. The likelihood of my practice losing money on the Moderna vaccine is substantial because the likelihood that my practice will have unused 2025-2026 Moderna vaccine is high.

17. Counseling patients and families regarding the Covid-19 vaccine has become increasingly difficult in our practice because of the Secretary's Directive to the CDC to downgrade the recommendation of the Covid-19 vaccine from routine to SCDM. What the Directive practically did was to flip a switch from on to off. Before the Directive, the switch was set to on in that the presumption or default was that everyone should (not must) get the Covid-19 vaccine for their children. The Directive flipped the switch to off by downgrading the Covid-19 vaccine to

SCDM, which has led to an increasing number of parents starting with the presumption or default that their child should not get the Covid-19 vaccine. The vaccination numbers at my clinic this year show this flip of the switch. In the four and a half months before the Directive, my practice administered 44 vaccines to patients. Since May 2025, our practice has administered only seven Covid-19 vaccinations to pediatric patients. Many of the parents who declined the vaccine for their children have cited the change in the CDC's immunization schedule and/or other misinformation they heard from the Secretary.

18. The Directive's flipping of the recommendation to SCDM has and will result in continuing financial loss to my clinic. Shared decision making requires more time spent on counseling between physician and parent on the individual circumstances of the patient's health, medical history, family situation, and environmental/epidemiological milieu. As this year's Covid-19 vaccine uptake numbers at my clinic show, after the Directive, an increasing number of these discussions have resulted in refusal of the vaccine. In such cases, we are not reimbursed for the time spent counseling the parents or for the vaccine product that we had purchased.

19. My practice is likely to have unused 2025-2026 vaccine doses that we will be unable to return to the manufacturer and get our money back. The Directive has increased the financial risk of stocking Covid-19 vaccines because it has discouraged uptake of the vaccine. Nonetheless, my practice continues to stock the vaccine. We believe it is important to try to protect our patients, staff, and community from Covid as much as possible, even if my practice ends up eating some of the cost of stocking the vaccine.

20. Financial loss to the clinic affects me personally because I am a co-owner of Plateau Pediatrics.

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 September 22, 2025 in Crossville, Tennessee.

/s/ Suzanne Berman, MD, FAAP

Dr. Suzanne Berman

EXHIBIT 12

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 DR. 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 am over the age of 18 years old and not under any disability. All of the facts set forth in this declaration are based on my personal knowledge. I submit this declaration in support of Plaintiffs' requests for relief in this litigation.

2. I reside in Tennessee and currently co-own Plateau Pediatrics, located in Crossville, Tennessee. I primarily manage the business and compliance aspects of the practice.

3. I completed medical school at the University of Tennessee, Memphis in 1998. I completed my residency in pediatrics at southern Illinois University in 2001.

4. I am board-certified in pediatrics.

5. I am a member of the American Academy of Pediatrics ("AAP").

6. Ten clinicians, including physicians and nurse practitioners, currently practice at Plateau Pediatrics.

7. Many of the children we treat are medically complex or fragile, including former premature infants, children with G-tubes, and children requiring ventilators. These children require specialty care that family practitioners often cannot provide.

8. In my professional experience and judgment, the Covid vaccine is the standard of care for our patients. Our practice here at Plateau Pediatrics recommends that patients be vaccinated against Covid to avoid infection or adverse health outcomes connected to Covid.

9. I am familiar with the recent ACIP recommendation that the Covid-19 vaccine be downgraded from routinely administered to one obtained through shared clinical decision making ("SCDM") for individuals under 65 years old and pregnant persons. This approach directly contradicts the standard of care and clinical guidance that I and other members of our practice rely on to deliver safe and effective care to our patients. This change undermines the patient-provider relationship, just as prior actions by the Secretary did in the Spring of 2025. This change also exposes me and other clinicians to unnecessary health and legal risks given the sound scientific evidence regarding Covid-19 vaccination and safety.

10. Based on my training and experience, there is no universal definition or common understanding for what constitutes "SCDM." I similarly am not aware of any definitive guidance on or authoritative definition of SCDM issued by any of the organizations of which I am a member specific to Covid vaccination.

11. In the context of my own practice, SCDM means discussing the vaccine with parent[s.] This usually begins with an initial determination of whether the patient's parent[s] is/are willing to discuss the topic of the vaccine. Many do not wish to even engage in a discussion, so this first step is necessary. Assuming a discussion is possible, I proceed to discuss the benefits of

vaccination and risks of not being vaccinated. The final decision ultimately rests with the patient's parent[s].

12. Usually, these SCDM discussions last anywhere from 7–10 minutes, though some do run longer, especially if the family has several questions. In my experience, however, most parents have already made up their minds prior to their child's wellness visit, and no amount of discussion will change their mind.

13. As a result of this vaccine hesitancy, I am increasingly spending more and more time addressing misinformation and disinformation expressed by my patients. This takes away from time that could and should be spent during wellness exams on other, more pertinent details. This vaccine hesitancy is even spilling over beyond Covid as I see more families expressing hesitancy on getting the flu vaccine, as well. Some parents have –wrongly—claimed they do not want their children to be vaccinated against influenza because they believe that the flu vaccine also included the Covid vaccine.

14. The time spent engaging in SCDM is not separately reimbursable, and SCDM counseling cannot be reimbursed 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 change to SCDM. This extra time aggregates and amounts to significant time for which my colleagues and I do not receive compensation.

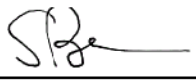
15. In addition to the added uncompensated time my colleagues and I must not invest in SCDM discussions and guidance, our practice has also been materially impacted by the change to SCDM in other ways. For example, because of the lack of a universal definition for SCDM, the practice had to discuss this 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.

16. Our practice has also been adversely impacted with respect to ordering and receiving vaccines. The change to SCDM caused a period of confusion where we were not sure how to proceed and thus could not order or even offer the vaccine until we knew the exact impact and consequences of the SCDM framework. 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 proved very disruptive to our practice and our ability to provide care, vaccinations, and treatment to our patients. Reversal to the status quo before these changes will alleviate these negative impacts.

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 November 30, 2025 in Crossville, Tennessee.

/s/ 

Dr. Suzanne Berman

EXHIBIT 13

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 District Judge: William G. Young Magistrate Judge: M. Page Kelley

DECLARATION OF DR. MARGIE ANDREAE

I, Dr. Margie Andreae, declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I am over 18 years old, reside in Michigan, and currently practice part time at the Pediatric Clinic of the Canton Health Center, located in Canton, Michigan.

2. I am the Professor Emerita of Pediatrics and former Chief Medical Officer for Revenue Cycle and Billing Compliance for the University of Michigan Medical Center.

3. I completed medical school at the University of Michigan Medical School in 1991. I completed my residency in pediatrics at William Beaumont Hospital in 1995.

4. I am board-certified in pediatrics.

5. I am fellow of the American Academy of Pediatrics ("AAP").

6. When the Centers for Disease Control and Prevention ("CDC") classifies a vaccine as routine, that means that the patient should get the vaccine. A routine recommendation means that the vaccine has proven over the years to be highly effective at preventing disease and saving

lives with minimal risk to the patient and, therefore, should be administered as a standard part of medical care for children. In short, a routine recommendation indicates that unless there is a specific contraindication to administering that vaccine, the patient should receive the vaccine.

7. During my more than three decades of taking care of children, I have paid close attention to the CDC's childhood immunization schedule, the process that is followed by the Food and Drug Administration ("FDA") to authorize a vaccine for use in the United States, and the process that the Advisory Committee on Immunization Practices ("ACIP") and the CDC follow to arrive at recommendations as to how vaccines should be used by different population groups in the United States. Up until this year, I have trusted the process that has resulted in vaccines being listed on the CDC's childhood immunization schedule. Up until this year, the FDA's Center for Biologics Evaluation and Research ("CBER") has been staffed with highly-qualified, non-partisan experts who have followed the science and made trustworthy, evidence-based decisions on whether to authorize a vaccine for use in the United States. Up until this year, the ACIP has likewise been staffed with highly-qualified, non-partisan experts who have followed the science and voted, based on the evidence, on how vaccines should be recommended for use for different population groups in the United States. Both CBER and the ACIP operated without undue influence from political appointees at either FDA or CDC before this year. Based on the trustworthy process that used to exist, I have had no hesitation in advising providers and patients that a child should receive a vaccine that is a "routine" recommendation on the CDC schedules, including receiving the Covid-19 vaccine. And most parents of my patients did not hesitate to get their children the Covid-19 vaccine, which is an outlier considering that pediatric uptake of Covid vaccines is waning.

8. I have viewed the video that the Secretary of Health and Human Services, Robert F. Kennedy, Jr. (the "Secretary") posted on X on May 27, 2025. I also learned that the Secretary issued a written "Secretarial Directive" ("Directive") that instructed the CDC to remove the recommendation that children ages six months to 17 years receive the Covid-19 vaccines from the CDC's childhood immunization schedule. I was very concerned when I learned this, especially because the Secretary has not identified any evidence or data that he relied upon to issue the Directive.

9. Although I understood the Secretary to be instructing the CDC to remove the recommendation entirely that children receive the Covid-19 vaccine, I learned that the Covid-19 recommendation was not removed from the CDC immunization schedule but instead was changed to a "Shared Clinical Decision Making" recommendation, or SCDM. I and my colleagues considered this change from "routine" to "SCDM" to be a downgrading of the CDC's recommendation and sending a message to parents discouraging them to vaccinate their children with the Covid-19 vaccine.

10. The effect of downgrading the recommendation of the Covid-19 vaccine for children to SCDM is to require me and my colleagues to spend more time counseling patients about the safety and effectiveness of the Covid-19 vaccine. Counseling is, of course, part of a doctor's job, but we usually are paid for it. Before the Directive was issued, when the Covid-19 vaccine was a routine recommendation, I spent very little time counseling on the Covid-19 vaccine because there was very little to debate about the safety and effectiveness of the Covid-19 vaccine. However, the Directive has contributed to the confusion and distrust about the Covid-19 vaccine. This confusion and distrust requires me to spend more time building trust with my patients and

telling them the truth about the Covid-19 vaccine to correct the misinformation the Secretary has spread about the Covid-19 vaccine, as in his video on X.

11. In pediatric practice, patients rarely come in solely for vaccines. Most vaccinations occur during scheduled well visits. For infants and toddlers, there are multiple well visits each year; for older children, there is typically an annual visit.

12. A standard well visit averages about twenty minutes, covering a wide range of preventive care tasks. No additional reimbursement is available for the extra time we are now spending on vaccine-specific counseling during these visits.

13. Health care providers like myself bill payers for their professional services using Current Procedural Terminology (CPT) codes. Each code is tied to a patient care service and are used to document and receive reimbursement for medical encounters.

14. Vaccine administration has its own family of CPT codes, with the codes tying compensation of doctors to actual administration of the vaccine during a well visit. The Directive has caused me to spend more time during well visits discussing the Covid-19 vaccine with parents, who are increasingly declining the Covid-19 vaccine for their children. There is no billable code that I can use to compensate me for the additional time now spent counseling parents who refuse the vaccine. While no billable code existed before the Directive for such encounters, the difference now is that the Directive has caused me to spend significantly more time in unbillable counseling on the Covid-19 vaccine. On average, I spend about five minutes counseling each patient who refuses a vaccine, and I see about three such patients per day. This adds up to 15 minutes per day spent on non-reimbursable vaccine counseling. This is a significant opportunity cost because I could use this time to see an additional patient which could be reimbursed $150. In other words, due to increased vaccine refusal rates tied to the Directive, I am losing about $150/day.

15. Unlike other vaccines subject to shared decision-making, such as the MenB vaccine, the COVID-19 directive was issued without publication of supporting data in the CDC's Morbidity and Mortality Weekly Report (MMWR). Normally, MMWR provides clinicians with the evidence base to guide patient counseling and serves as the trigger for payer coverage. No such data or guidance accompanied this change, leaving physicians without a clear basis to counsel patients, which also contributes to the increased amount of time spent on unbillable counseling time on the Covid-19 vaccine.

16. The lack of evidence to support the Directive has also caused a shift of the burden to physicians to research and interpret data that was previously synthesized and communicated by ACIP. In other words, the ACIP did the deep work to synthesize, analyze, and interpret the data to arrive at sound recommendations with regard to vaccines. Before the current ACIP, I trusted the recommendations that came out of the ACIP. Now, I do not trust the Directive or, for that matter, recommendations from the current ACIP. This has further complicated the counseling process.

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

Executed on September 23, 2025 in Canton, MI.

Dr. Margie Andreae

/s/ Dr. Margie Andreae

EXHIBIT 14

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 MARGIE ANDREAE, M.D.

I, Margie Andreae, M.D., 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 and not under any disability. All of the facts set forth in this declaration are based on my personal knowledge. I submit this declaration in support of Plaintiffs' Third Amended Complaint in the above-captioned action.

2. I reside in Michigan and currently practice part-time at the Pediatric Clinic of the Canton Health Center, located in Canton, Michigan.

3. I am the Professor Emerita of Pediatrics and former Chief Medical Officer for Revenue Cycle and Billing Compliance for the University of Michigan Medical Center.

4. I completed medical school at the University of Michigan Medical School in 1991. I completed my residency in pediatrics at William Beaumont Hospital in 1995.

5. I am board-certified in pediatrics.

6. I am a fellow of the American Academy of Pediatrics ("AAP").

7. When the Centers for Disease Control and Prevention ("CDC") classifies a vaccine as routine, that means that the patient should get the vaccine. A routine recommendation means that the vaccine has proven over the years to be highly effective at preventing disease and saying lives with minimal risk to the patient and, therefore, should be administered as a standard part of medical care for children. In short, a routine recommendation indicates that unless there is a specific contraindication to administering that vaccine, the patient should receive the vaccine.

8. During my more than three decades of caring for children, I have paid close attention to the CDC's childhood immunization schedule, the process that is followed by the Food and Drug Administration ("FDA") to authorize a vaccine for use in the United States, and the process that the Advisory Committee on Immunization Practices ("ACIP") and the CDC follow to arrive at recommendations as to how vaccines should be used by different population groups in the United States.

9. I am familiar with the CDC's adoption of new Covid-19 vaccine recommendations in October 2025, which reclassified the Covid-19 vaccine to "Shared Clinical Decision Making" ("SCDM"), a downgrade from the prior recommendation of "routine."

10. In my clinical judgment, this downgrading to SCDM is without justification and is causing confusion and vaccine hesitancy and is undermining public health as well as the public trust in vaccines and the physicians who recommend them. It is additionally causing confusion and strain within the health care field as I see more and more of my colleagues uncertain of how to navigate these changes, practice medicine, and properly engage with patients.

11. In my experience, there is no universal definition for the term "SCDM," and each physician approaches SCDM encounters differently according to how they understand that term. I

am similarly unaware of any universal guidance on SCDM issued by the AAP either in general or as it relates to the Covid-19 vaccine, specifically.

12. I understand SCDM to be a distinct concept from the term "informed consent." As a pediatrician, it is rare to encounter a situation where informed consent is needed. This is because the concept of informed consent – i.e., a process whereby a physician thoroughly discusses and explores the risks and benefits with the patient – is confined mostly to treatments or medical interventions that are new, novel, and/or that present a high risk.

13. SCDM, by contrast, involves discussing options when the standard of care allows for more than one option, and does not focus on the in-depth discussion of the risks and benefits of a single recommended treatment. In an SCDM encounter, a physician shares their knowledge and expertise regarding the options available and considers the concerns and interests expressed by a patient or a patient's parent. Together, the physician and the patient or patient's parent then reach a common or shared decision on the option that best fit with that patient's needs. Furthermore, because the risk of complication from the Covid vaccine is so low, there is little need, if any, to engage in the kind of discussion that constitutes "informed consent." This is the process by which I generally engage in SCDM with my patients.

14. Specific to SCDM for the Covid-19 vaccine, I find the CDC recommendation perplexing because there is only one medically reasonable option that is consistent with the standard of care, and that would be to vaccinate all children. I typically begin my SCDM encounters by referencing the topic of the Covid vaccine and my recommendation that patients receive it. I then solicit the patient or patient's parent for their perspective and engage in a conversation based on what is communicated.

15. Since the downgrade to SCDM, I have observed that fewer patients are electing to receive the Covid-19 vaccine. I have similarly observed that patients or their parents are increasingly coming to wellness visits with preconceived ideas or notions about the Covid vaccine that are usually based on misinformation or disinformation, such as linking the vaccine to autism. Patients or their parents seem to know that the Covid vaccine is no longer routinely recommended and are increasingly concluding that there is little clinical advantage or reason to be vaccinated as a result. This stands in contrast to vaccines that are still routinely recommended, which patients and their parents continue to receive without the same level of skepticism or preconceived notions.

16. These episodes have become much more common since the CDC's adoption of SCDM for the Covid vaccine. Patients or their parents increasingly exhibit incredulity in response to my recommendation that they receive the vaccine and insist—incorrectly—that Covid is no longer a health concern and that it does not affect children. This then compels me to counsel against that misinformation to the best of my ability to ensure that patients and their parents receive the best care possible. On average, these SCDM conversations last approximately 5 minutes, which are folded into the wellness visit with the patient. This means time is taken away from other areas of concern to address issues relating to the Covid vaccine and to provide patients and their parents with the correct information, oftentimes to no avail.

17. To date, I have not had a single pediatric patient receive the Covid vaccine during this season (*i.e.*, in Fall 2025). This is a major departure from this time last year, when roughly 40% of my patients elected to receive the Covid-19 vaccine.

18. Time spent counseling patients on the Covid-19 vaccine is not reimbursable if the patient declines to receive the vaccine. As a result, time spent counseling patients who decline vaccination is time that goes uncompensated because there is no dedicated Current Procedural

Terminology (CPT) billing code that can be used for SCDM counseling alone on the Covid vaccine. Because these episodes are becoming more common, my colleagues and I are increasingly spending more and more time combatting misinformation, which ultimately increases workload. This increased volume and length of SCDM conversations forces me and my colleagues to devote substantial work time after office hours to complete documentation or other tasks not completed during or between wellness visits. In short, the shift to SCDM is causing more and more work to be performed without compensation, resulting in financial harm in the form of lost earnings.

19. The CDC's recent adoption of SCDM has also left me and others in the dark and unsure of how to proceed with counseling patients or their parents who express concerns over the Covid vaccine. I frequently wonder if I have the latest and most reliable data and information to respond to the misinformed or incorrect statements patients or their parents express. This leaves me feeling unsure of how to engage with patients or their parents, especially those who so strenuously cite misinformation or disinformation and who fervently hold to misconceptions about the Covid-19 vaccine because of the lack of reliable or verifiable scientific or medical support for the decisions being made by the CDC, ACIP, and other federal public health entities. Consequently, my ability to provide reliable care consistent with the established standard is compromised.

20. These strident positions by CDC and ACIP place me and my peers at potential risk of liability. As a trained medical professional, I know the standard of care and know that Covid infection still poses a risk to children and that children may face serious health complications as a result of not being vaccinated. As a result, I worry that patients or their parents might come forward in the future and blame or hold me and my colleagues responsible for any adverse health conditions resulting from the lack of vaccination.

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

Executed on November 30, 2025 in Canton, Michigan.

/s/ Dr. Margie Andreae

Dr. Margie Andreae

EXHIBIT 15

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-WGY District Judge: William G. Young Magistrate Judge: M. Page Kelley

DECLARATION OF MARK DEL MONTE

I, Mark Del Monte, declare, pursuant to 28 U.S.C. § 1746, that the following is true and correct and within my personal knowledge.

1. I am over 18 years old, reside in Illinois, and currently am the Chief Executive Officer/Executive Vice President of the American Academy of Pediatrics ("AAP"), a position that I have held since September 2019. I have been an employee of AAP since 2005.

2. I completed my law degree from the University of California, Berkeley – School of Law in 1997.

3. I saw the video that United States Secretary of Health and Human Services, Robert F. Kennedy, Jr. (the "Secretary"), posted on X on May 27, 2025 announcing that he had directed the Centers for Disease Control and Prevention ("CDC") to remove from its immunization schedules the recommendations that pregnant individuals and children receive the Covid-19 vaccine. Since 2005 when I started at AAP, I have never seen a Secretary of Health and Human Services make a unilateral decision to change the CDC's immunization schedules, let alone ignore

the Advisory Committee on Immunization Practices ("ACIP") process of first studying and analyzing the data and evidence about the vaccine, then debating whether to change the CDC schedule at ACIP meetings open to the public, and then voting on changes to CDC schedules in an open meeting of the ACIP. In the May 27 video, and in the "Secretarial Directive" dated May 19, 2025 (the "Directive") that purported to document the decision, the Secretary cited no evidence that warranted a change to the CDC schedules with regard to the Covid vaccine, and he has released no supporting evidence for the Directive since.

4. Since the release of the Directive, AAP has had to divert significant resources to navigate and guide its 67,000 members on the implications of the Directive. The additional activities that the Directive has required AAP to engage in have included, but are not limited to, the following:

- Updating Frequently Asked Questions (FAQs) and guidance documents for pediatric practices.
- Fielding additional calls and emails from AAP members seeking clarification about the implications of the Directive.
- Holding two impromptu webinars focused on navigating the Directive and its implications for pediatricians and infants, children, adolescents, and young adults, including children with complex health care needs.
- Publishing additional guidance in the AAP Section on Administration and Practice Management ("SOAPM") online platform.
- Holding cross-team meetings to align advocacy, clinical, and communications efforts.
- Holding an SOAPM webinar on Countering Vaccine Hesitancy and Misinformation.
- Convening a meeting to address Covid concerns that six staff and 17 volunteer members attended.
- Holding multiple meetings to discuss the implications of the AAP's own immunization (IZ) schedule diverging from that of the CDC, which at least eight staff attended.

- Convening a meeting to discuss the AAP's COVID vaccine recommendations that seven staff and 50 volunteer members attended.
- Editing and finalizing the recommendations for the IZ schedule, including the Covid recommendations, involving multiple staff members and many hours.
- Developing a new policy statement, "Recommendations for COVID-19 Vaccines in Infants, Children, and Adolescents," which was pre-published online on August 19, 2025. At least ten staff members spent a significant amount of time developing this new policy statement.
- Developing a new AAP IZ schedule that was published online on August 19, 2025. At least twelve staff members spent many hours developing the new schedule in light of the Directive.
- Conducting a webinar hosted by four staff and four volunteer members on September 11, 2025 to discuss the Covid recommendation confusion that the Directive has created. The hosts of the webinar spent approximately 36 hours preparing for the webinar.
- Holding a meeting of four staff and 22 volunteer members to discuss which Covid vaccines were approved and recommended for use for different population groups.

5. Multiple different teams within AAP have had to divert their attention from other urgent matters related to child health to contend with the impact of the Directive, including staff at all levels on the Senior Leadership Team, the Pediatric Practice and Health Care Delivery Team, the Quality Team, the Finance and Payment Strategy Team, the Public Affairs Team, the Communications Team, the Publishing Team, and the Information Technology Team.

6. The Directive has generated, nearly on a daily basis, outreach from members communicated through phone calls, text messages, and emails. One Senior Vice President at AAP estimates that the volume of text, instant, and email messages in her inbox, and the number of meetings, has doubled due to the Directive and other statements and actions of the Secretary.

7. The Directive has forced multiple staff members to advocate to payers to continue to cover the Covid-19 vaccine to maintain immunization access for infants, children, adolescents, and young adults, regardless of the type of recommendation listed on the CDC schedules.

8. AAP has received outreach from other professional medical and public health societies that also have concerns about the public health impact and the impact to their members of the Directive. This has led to multiple meetings with other professional societies to try to achieve alignment and consensus on how to address the fallout from the Directive.

9. In short, the Directive has significantly affected the operations of the AAP and forced all levels of the AAP to divert significant time away from other tasks and initiatives related to child health. In my opinion, this diversion of AAP resources has been totally unnecessary because the evidence and the science strongly indicate that any changes to the CDC's immunization schedules' recommendations with regard to the Covid-19 vaccine could have been conducted with credible scientific evidence and established process through the ACIP. The impact of the Secretary's unilateral action has predictably sown confusion and chaos in this country's health care system. The AAP has had to expend significant time and resources to attempt to clear up the confusion and diminish the chaos that the Directive has, unfortunately and unnecessarily, generated. I respectfully implore the Court to right this wrong and vacate the Directive.

I declare under penalty of perjury and laws of the United States, including 28 U.S.C. § 1746, and the laws of [state in which sign], that the foregoing is true and correct.

Executed on September 23, 2025 in Itasca, Illinois.

Mark Del Monte

/s/ Mark Del Monte

EXHIBIT 16

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 MARY-CASSIE SHAW, MD, FAAP

I, Mary-Cassie Shaw, declare, pursuant to 28 U.S.C. § 1746, that the following is true and correct and within my personal knowledge.

1. I am over 18 years old and reside in Raleigh, North Carolina. I am not under any disability. I submit this declaration in support of Plaintiffs' Third Amended Complaint in the above captioned matter.

2. I earned a Doctor of Medicine degree from the East Carolina University Brody School of Medicine.

3. I am a Fellow of the American Academy of Pediatrics ("AAP") and a member of the North Carolina Pediatric Society.

4. I have been a practicing pediatrician at Oberlin Pediatrics in Raleigh, North Carolina since 2003.

5. I have viewed the video that the Secretary of Health and Human Services, Robert F. Kennedy, Jr. (the "Secretary") posted on X on May 27, 2025, and have read the related May 19, 2025 "Secretarial Directive" (the "Directive") confirming what the Secretary said in the video. I

disagree with the decisions announced in the May 27 video and in the Directive to remove recommendations from the Centers for Disease Control and Prevention's (the "CDC's") immunization schedules that pregnant women and children receive the COVID-19 vaccine.

6. I have reviewed the Advisory Committee on Immunization Practices' (the "ACIP's") new recommendation released in September 2025 to change the Covid-19 vaccine recommendation for adults under the age of 65 from routine to shared clinical decision making ("SCDM"). The CDC adopted this recommendation and then improperly conflated SCDM with informed consent. ACIP's recommendation and CDC's adoption of the recommendations provides no guidance to me on how to apply the new recommendations and the lack of guidance to support the change has caused disruption and confusion to me and my practice.

7. These actions (i.e. the Directive and recent actions by ACIP and CDC related Covid-19 vaccines) have personally affected my job and caused disruption to my practice. The Directive has caused chaos and confusion at my practice as to whether we can administer the COVID-19 vaccine to children and has caused confusion and delay as to whether and when we can get the vaccine. This has resulted in me and my colleagues at the practice, including providers and staff, having to spend time that we did not spend before calling drug stores, the health department, other pediatric offices, and hospitals to see if we could get the COVID-19 vaccine from them. This has also caused me and my colleagues to have to spend time doing our own research on the COVID-19 vaccine because the ACIP is not providing us with adequate recommendations and reasonings. Pediatricians and primary care physicians are meant to be foot soldiers who can rely on the researched recommendations and findings of the ACIP, and instead we are having to fulfill the roles of researchers ourselves. This time is not time we can bill and be paid for.

8. As a result of the Directive and recent ACIP recommendation for Covid-19 vaccines for my pediatric patients, I have had to have longer, more in-depth conversations with parents about the safety and effectiveness of the COVID-19 vaccine, conversations that we did not have to have before the Directive. These conversations take 2–3 extra minutes per visit, and I see 20–25 patients per day. I am not being compensated for this extra time, which results in an hour per day of unpaid time. The cumulative effect between the other providers in my practice is multiple hours a day of unpaid time. Many of these conversations have been about dispelling disinformation that the Secretary and others at the Department of Health and Human Services have spread about the COVID-19 and other vaccines. For example, I have had to tell patients that any trace amount of aluminum in vaccines is not dangerous and that there is ten times more aluminum in breast milk than there is in a dose of a vaccine. I have also had to spend considerable time equating the safety and efficacy of the COVID-19 vaccine and the flu vaccine. Ninety-nine percent of these discussions about vaccines are in preventative visits for which there is no CPT or HCPCS code that I can use to bill this time. The Directive and recent ACIP recommendation for SCDM for Covid-19 vaccines for my pediatric patients, are causing me to work this additional time for free.

9. The Directive and recent ACIP recommendation for Covid-19 vaccines for my pediatric patients has also contributed to patients dropping out of my practice. I treated a mother with eight children, all of whom I have seen since they were born. She came in with her husband and both expressed concern about aluminum in vaccines. These patients have since disappeared and not brought any of their children into my practice when they were due for their next preventative visits. They have not transferred practices, because if they had, we would have received a request for the children's medical records. This is not the only example of which I am

aware of families simply dropping out of the healthcare system because of their mistrust of the COVID-19 and other vaccines. The Directive and recent ACIP recommendation for SCDM for Covid-19 vaccines for my pediatric patients has caused financial harm to my practice by contributing to patients dropping out of my practice.

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

Executed on December 1, 2025, in Raleigh, North Carolina.

Dr. Mary-Cassie Shaw

/s/

Mary-Cassie Shaw, MD, FAAP

EXHIBIT 17

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 District Judge: Brian E. Murphy Magistrate Judge: M. Page Kelley

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"), representing internal medicine physicians, related subspecialists, and medical students.

4. I previously served as Governor of ACP's Florida Chapter from 2016 through 2020. I served as Chair of ACP's Medical Practice Quality Committee, and I currently serve on ACP's Immunization Committee.

5. 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.

6. 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 across the country, 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.

7. ACP's mission is to enhance the quality and effectiveness of health care by fostering excellence and professionalism in the practice of medicine. ACP embraces health equity and is committed to stopping and preventing the spread of medical misinformation and disinformation.

8. In 2020, I joined the Advisory Committee on Immunization Practice's ("ACIP") COVID-19 Vaccines Work Group as a liaison member representing the ACP. I served as the ACP's liaison member to the COVID-19 Vaccines 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 because liaison organizations allegedly were "special interest groups and therefore are expected to have a 'bias.'" From my service on the COVID-19 Vaccines Work Group, I am well-versed in the process and procedure that the COVID-19 Vaccines 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 what population groups in the United States should receive the Covid-19 vaccine, when, and in what dose.

9. I have read the government's Motion to Dismiss filed on November 19, 2025. On page 16, the government asserts that "a shared clinical decision-making recommendation does not plausibly mean the vaccine is 'suspect'—just that the patients should consult with healthcare providers." I disagree with this assertion. First, the designation of the Covid-19 vaccine as SCDM is not a "recommendation" at all. Attached hereto is the current color-coded Recommended Adult Immunization Schedule by Age Group, United States, 2025 ("Adult Schedule") that appears on the CDC's website as of the date of my signature to this Declaration. The Adult Schedule color codes in yellow vaccines that are "*Recommended* vaccination for adults who meet age requirement, lack documentation of evidence, or lack evidence of immunity." (Emphasis added). The Adult Schedule color codes in purple vaccines that are "*Recommended* vaccination for adults with an additional risk factor or another indication." (Emphasis added). The Adult Schedule color codes in blue those vaccines for which "Vaccination is based on shared clinical decision-making." The Adult Schedule does not use the words "Recommended" or "Recommendation" when describing what SCDM is. Second, the Secretary and others at HHS publicly expressing skepticism and doubt about vaccines has led to an increase in the number of my patients expressing suspicion about vaccines and refusing to get vaccinated after engaging in a discussion with me or my colleagues about the benefits and risks of vaccination. Designating the Covid-19 vaccine as SCDM thus has had the effect of increasing doubt about the vaccine and reducing the rate of vaccination – *i.e.*, it has been my experience that the SCDM designation contributes to patients believing vaccines are "suspect."

10. Before this year, the ACIP previously voted to designate a vaccine as SCDM only four times when the evidence has indicated that some individuals, but not everyone, can benefit from receipt of the vaccine. For example, when the ACIP considered expanding the HPV (human papillomavirus) vaccine use to adults between 27 to 45 years of age, the EtR framework indicated uncertainties related to the public health problem and acceptability in this age group, variable individual benefits, and high costs associated with use of resources if the recommendation was routine. Accordingly, the HPV vaccine was designated as SCDM for adults between 27 to 45 years of age. The only other times before this year that the ACIP voted to designate a vaccine as SCDM were for the MenB (meningococcal B) vaccination for adolescents and young adults aged 16-23 years, the HepB (hepatitis B) vaccination for adults aged 60 years and older with diabetes mellitus, and the PCV20 or PCV21 (pneumococcal conjugate vaccination) for adults aged 65 years and older who have completed the recommended vaccine series with both PCV13 (at any age) and PPSV23 (which was administered at age $\geq$ 65 years). Thus, the SCDM designation has previously been applied narrowly and only to specific age groups with certain risk characteristics.

11. On page 15, the government asserts that members of the ACP have not been financially injured because the Covid-19 vaccine is now designated as "Shared Clinical Decision Making" ("SCDM") on the CDC's immunization schedules. The government asserts that "insurers generally must cover COVID-19 vaccines administered through shared clinical decision-making. See 42 U.S.C. § 300gg-13; 26 C.F.R. § 54.9815-2713(a)(1)(ii); 45 C.F.R. § 147.130(a)(1)(ii); … And any harm from contrary action is traceable to the insurer's independent decision about what to reimburse, not to CDC's recommendation." Based on my many years of experience dealing with health insurance companies on reimbursement issues and my decades as a practicing primary care physician, I find these assertions in the government's motion to be highly problematic. The

government's motion to dismiss implies that all insurers in fact reimburse or cover vaccines that are designated as SCDM. That is simply not true. I have personal knowledge of two large health insurers in Florida where I practice who will not cover the Covid-19 vaccine now that it is designated as SCDM. In fact, my staff recently utilized an online Patient Cost Estimator tool to check whether either of these insurers would cover the Covid-19 vaccine if my practice administered the vaccine to a healthy adult under 65. The answer from both insurance companies was that the Covid-19 vaccine would not be covered. This contrasts with a vaccine that has a "routine" recommendation – *i.e.*, is color-coded as yellow or purple on the Adult Schedule. Vaccines that are yellow or purple on the CDC's Adult Schedule are covered by insurance. Therefore, the change of the Covid-19 vaccine from a "routine" recommendation to an SCDM designation is a direct cause of financial harm to primary care physicians in Florida because there are insurers who will not cover or reimburse for a vaccine that is designated as SCDM on the CDC's Adult Schedule.

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

Executed on December 2, 2025 in Coral Springs, Florida

Jason M. Goldman, MD, MACP
President, American College of Physicians

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Recommended Adult Immunization Schedule for Ages 19 Years or Older

UNITED STATES 2025

Vaccines in the Adult Immunization Schedule*

Vaccine	Abbreviation(s)	Trade name(s)
COVID–19 vaccine	1vCOV–mRNA	Comirnaty, mNexspike, Spikevax
	1vCOV–aPS	Nuvaxovid
Haemophilus influenzae type b vaccine	Hib	ActHIB, Hiberix, PedvaxHIB
Hepatitis A vaccine	HepA	Havrix, Vaqta
Hepatitis A and hepatitis B vaccine	HepA–HepB	Twinrix
Hepatitis B vaccine	HepB	Engerix–B, Heplisav–B, PreHevbrio, Recombivax HB
Human papillomavirus vaccine	HPV	Gardasil 9
Influenza vaccine (inactivated, egg-based)	IIV3	Multiple
	aIIV3	Fluad
	HD–IIV3	Fluzone High–Dose
Influenza vaccine (inactivated, cell–culture)	ccIIV3	Flucelvax
Influenza vaccine (recombinant)	RIV3	Flublok
Influenza vaccine (live, attenuated)	LAIV3	FluMist
Measles, mumps, and rubella vaccine	MMR	M–M–R II, Priorix
Meningococcal serogroups A, C, W, Y vaccine	MenACWY–CRM	Menveo
	MenACWY–TT	MenQuadfi
Meningococcal serogroup B vaccine	MenB–4C	Bexsero
	MenB–FHbp	Trumenba
Meningococcal serogroup A, B, C, W, Y vaccine	MenACWY–TT/ MenB–FHbp	Penbraya
Monkeypox vaccine	Mpox	Jynneos
Pneumococcal conjugate vaccine	PCV15	Vaxneuvance
	PCV20	Prevnar 20
	PCV21	Capvaxive
Pneumococcal polysaccharide vaccine	PPSV23	Pneumovax 23
Poliovirus vaccine (inactivated)	IPV	Ipol
Respiratory syncytial virus vaccine	RSV	Abrysvo, Arexvy, mResvia
Tetanus and diphtheria vaccine	Td	Tenivac
Tetanus, diphtheria, and acellular pertussis vaccine	Tdap	Adacel, Boostrix
Varicella vaccine	VAR	Varivax
Zoster vaccine, recombinant	RZV	Shingrix

*Administer recommended vaccines if vaccination history is incomplete or unknown.
Do not restart or add doses to vaccine series if there are extended intervals between doses.
The use of trade names is for identification purposes only and does not imply endorsement by ACIP or CDC.

Revised October 07, 2025

How to use the adult immunization schedule

1. Determine recommended vaccinations by age **(Table 1)**
2. Assess need for additional recommended vaccinations by medical condition or other indication **(Table 2)**
3. Review vaccine types, dosing frequencies and intervals, and considerations for special situations **(Notes)**
4. Review contraindications and precautions for vaccine types **(Appendix)**
5. Review new or updated ACIP guidance **(Addendum)**

Report

- Suspected cases of reportable vaccine–preventable diseases or outbreaks to the local or state health department
- Clinically significant adverse events to the Vaccine Adverse Event Reporting System at www.vaers.hhs.gov or 800-822-7967

Questions or comments

Contact www.cdc.gov/cdc-info or 800-CDC-INFO (800-232-4636), in English or Spanish, 8 a.m.–8 p.m. ET, Monday through Friday, excluding holidays.

Download the CDC Vaccine Schedules app for providers at www.cdc.gov/vaccines/hcp/imz-schedules/app.html.

Helpful information

- Complete Advisory Committee on Immunization Practices (ACIP) recommendations: www.cdc.gov/acip-recs/hcp/vaccine-specific/
- ACIP Shared Clinical Decision–Making Recommendations: www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html
- General Best Practice Guidelines for Immunization www.cdc.gov/vaccines/hcp/imz-best-practices/index.html
- Vaccine information statements: www.cdc.gov/vaccines/hcp/vis/index.html
- Manual for the Surveillance of Vaccine–Preventable Diseases (including case identification and outbreak response): www.cdc.gov/surv-manual/php/index.html

U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION

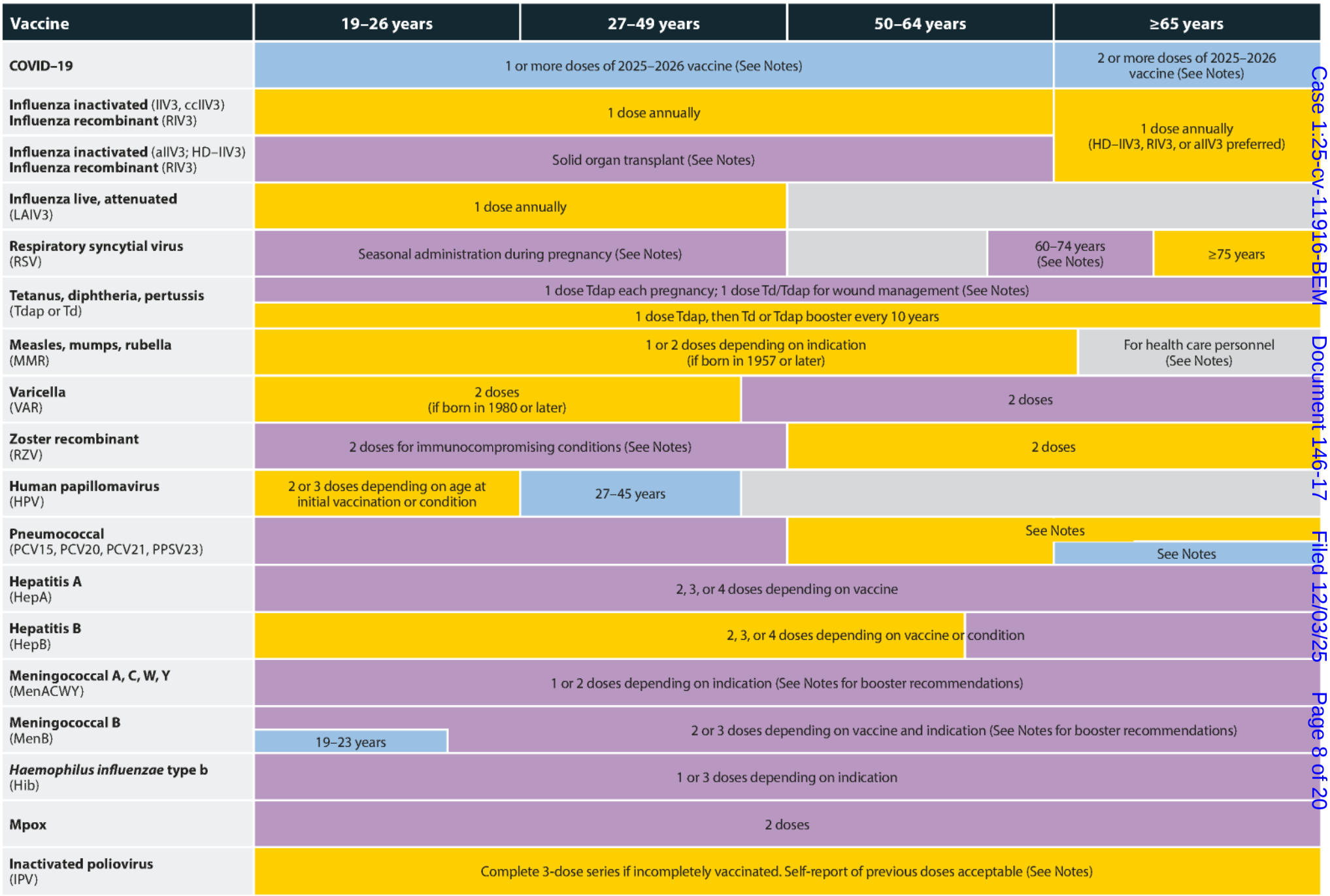
Scan QR code for access to online schedule

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Table 1 Recommended Adult Immunization Schedule by Age Group, United States, 2025



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Table 2 Recommended Adult Immunization Schedule by Medical Condition or Other Indication, United States, 2025

Always use this table in conjunction with Table 1 and the Notes that follow. Medical conditions or indications are often not mutually exclusive. If multiple medical conditions or indications are present, refer to guidance in all relevant columns. See Notes for medical conditions or indications not listed.

VACCINE	Pregnancy	Immunocompromised (excluding HIV infection)	HIV infection CD4 percentage and count: <15% or <200/mm³	HIV infection CD4 percentage and count: ≥15% and ≥200/mm³	Men who have sex with men	Asplenia, complement deficiency	Heart or lung disease	Kidney failure, End–stage renal disease or on dialysis	Chronic liver disease; alcoholism[a]	Diabetes	Health care Personnel[b]
COVID–19	See Notes	Additional doses may be necessary (See Notes)		See Notes							
Influenza inactivated Influenza recombinant		Solid organ transplant (See Notes)	1 dose annually								
LAIV3					1 dose annually if age 19–49 years		1 dose annually if age 19–49 years				
RSV	Seasonal administration (See Notes)	See Notes				See Notes			Liver disease (See Notes)	See Notes	
Tdap or Td	Tdap: 1 dose each pregnancy	1 dose Tdap, then Td or Tdap booster every 10 years									
MMR	*										
VAR	*			See Notes							
RZV		See Notes									
HPV	*	3-dose series if indicated									
Pneumococcal											
HepA											
Hep B	See Notes									Age ≥ 60 years	
MenACWY											
MenB											
Hib		HSCT: 3 doses[c]				Asplenia: 1 dose					
Mpox	See Notes				See Notes						See Notes
IPV		Complete 3-dose series if incompletely vaccinated. Self–report of previous doses acceptable (See Notes)									

- Recommended for all adults who lack documentation of vaccination, **OR** lack evidence of immunity
- Not recommended for all adults, but recommended for some adults based on either age **OR** increased risk for or severe outcomes from disease
- Vaccination is based on shared clinical decision-making
- Additional doses may be necessary based on medical condition or other indications. See Notes.
- Precaution: Might be indicated if benefit of protection outweighs risk of adverse reaction
- Contraindicated or not recommended *Vaccinate after pregnancy, if indicated
- No Guidance/ Not Applicable

a. Precaution for LAIV3 does not apply to alcoholism.

b. See Notes for influenza; hepatitis B; measles, mumps, and rubella; and varicella vaccinations.

c. Hematopoietic stem cell transplant.

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Notes Recommended Adult Immunization Schedule for Ages 19 Years or Older, United States, 2025

For vaccination recommendations for persons ages 18 years or younger, see the Recommended Child and Adolescent Immunization Schedule, 2025: www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html

Additional Information

- For calculating intervals between doses, 4 weeks = 28 days. Intervals of ≥4 months are determined by calendar months.
- Within a number range (e.g., 12–18), a dash (–) should be read as "through."
- Vaccine doses administered ≤4 days before the minimum age or interval are considered valid. Doses of any vaccine administered ≥5 days earlier than the minimum age or minimum interval should not be counted as valid and should be repeated. **The repeat dose should be spaced after the invalid dose by the recommended minimum interval.** For further details, see Table 3–2, Recommended and minimum ages and intervals between vaccine doses, in General Best Practice Guidelines for Immunization at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html.
- Information on travel vaccination requirements and recommendations is available at www.cdc.gov/travel/.
- For vaccination of persons with immunodeficiencies, see Table 8–1, Vaccination of persons with primary and secondary immunodeficiencies, in General Best Practice Guidelines for Immunization at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html
- For information about vaccination in the setting of a vaccine–preventable disease outbreak, contact your state or local health department.
- The National Vaccine Injury Compensation Program (VICP) is a no–fault alternative to the traditional legal system for resolving vaccine injury claims. All vaccines included in the adult immunization schedule except PPSV23, RSV, RZV, Mpox, and COVID–19 vaccines are covered by the National Vaccine Injury Compensation Program (VICP). Mpox and COVID–19 vaccines are covered by the Countermeasures Injury Compensation Program (CICP). For more information, see www.hrsa.gov/vaccinecompensation or www.hrsa.gov/cicp.

COVID–19 vaccination

Shared clinical decision-making

Vaccination based on individual-based decision-making—with an emphasis that the risk-benefit of vaccination is most favorable for individuals who are at an increased risk for severe COVID-19 disease and lowest for individuals who are not at an increased risk according to the CDC list of COVID-19 risk factors (see www.cdc.gov/covid/hcp/clinical-care/underlying-conditions.html). For additional information on shared clinical decision-making, see www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html

Current COVID-19 schedule and dosage formulation available at www.cdc.gov/covidschedule.

Administer an age-appropriate COVID-19 vaccine product for each dose. There is no preferential recommendation for the use of one COVID-19 vaccine over another when more than one recommended age-appropriate vaccine is available.

Haemophilus influenzae type b vaccination

Special situations

- **Anatomical or functional asplenia (including sickle cell disease):** 1 dose if previously did not receive Hib vaccine
  - **Elective splenectomy:** 1 dose preferably at least 14 days before splenectomy
- **Hematopoietic stem cell transplant (HSCT):** 3-dose series 4 weeks apart starting 6–12 months after successful transplant, regardless of Hib vaccination history

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Notes Recommended Adult Immunization Schedule for Ages 19 Years or Older, United States, 2025

Hepatitis A vaccination

Routine vaccination

- **Any person who is not fully vaccinated and requests vaccination** (identification of risk factor not required): complete 2-dose series HepA (Havrix 6–12 months apart or Vaqta 6–18 months apart [minimum interval: 6 months]) or 3-dose series HepA–HepB (Twinrix at 0, 1, 6 months [minimum intervals: dose 1 to dose 2 = 4 weeks; dose 2 to dose 3 = 5 months])

Special situations

- **Any person who is not fully vaccinated and who is at risk for hepatitis A virus infection or severe disease from hepatitis A virus infection:** complete 2-dose series HepA or 3-dose series HepA–HepB as above. Risk factors include:
  - **Chronic liver disease** including persons with hepatitis B, hepatitis C, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, alanine aminotransferase (ALT) or aspartate aminotransferase (AST) level greater than twice the upper limit of normal.
  - **HIV infection**
  - **Men who have sex with men**
  - **Injection or noninjection drug use**
  - **Persons experiencing homelessness**
  - **Work with hepatitis A virus** in research laboratory or with nonhuman primates with hepatitis A virus infection
  - **Travel in countries with high or intermediate endemic hepatitis A:** HepA–HepB (Twinrix) may be administered on an accelerated schedule of 3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months.
  - **Close, personal contact with international adoptee** (e.g., household or regular babysitting) in first 60 days after arrival from country with high or intermediate endemic hepatitis A: dose 1 as soon as adoption is planned; preferably at least 2 weeks before adoptee's arrival.
  - **Pregnancy** if at risk for infection or severe outcome from infection during pregnancy
  - **Settings for exposure,** including health care setting serving persons who use injection or noninjection drugs, or group homes and nonresidential day care facilities for developmentally disabled persons (individual risk factor screening not required)

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Hepatitis B vaccination

Routine vaccination

- **Age 19–59 years:** complete a 2- or 3- or 4-dose series
  - 2-dose series only applies when 2 doses of Heplisav–B are used at least 4 weeks apart
  - 3-dose series Engerix–B, PreHevbrio*, or Recombivax HB at 0, 1, 6 months (minimum intervals: dose 1 to dose 2 = 4 weeks; dose 2 to dose 3 = 8 weeks; dose 1 to dose 3 = 16 weeks)
  - 3-dose series HepA–HepB (Twinrix) at 0, 1, 6 months (minimum intervals: dose 1 to dose 2 = 4 weeks; dose 2 to dose 3 = 5 months)
  - 4-dose series HepA–HepB (Twinrix) accelerated schedule of 3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months

***Note:** PreHevbrio is not recommended in pregnancy due to lack of safety data in pregnant women.

- **Age 60 years or older without** known risk factors for hepatitis B virus infection **may** receive a HepB vaccine series.
- **Age 60 years or older with** known risk factors for hepatitis B virus infection **should** receive a HepB vaccine series.
- **Any adult age 60 years of age or older** who requests HepB vaccination **should** receive a HepB vaccine series.
  - **Risk factors for hepatitis B virus infection include:**
    - **Chronic liver disease** including persons with hepatitis C, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, alanine aminotransferase (ALT) or aspartate aminotransferase (AST) level greater than twice the upper limit of normal.
    - **HIV infection**
    - **Sexual exposure risk** e.g., sex partners of hepatitis B surface antigen (HBsAg)–positive persons, sexually active persons not in mutually monogamous relationships, persons seeking evaluation or treatment for a sexually transmitted infection, men who have sex with men

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Hepatitis B vaccination - *continued*

- **Current or recent injection drug use**
- **Percutaneous or mucosal risk for exposure to blood** e.g., household contacts of HBsAg–positive persons, residents and staff of facilities for developmentally disabled persons, health care and public safety personnel with reasonably anticipated risk for exposure to blood or blood–contaminated body fluids, persons on maintenance dialysis (including in–center or home hemodialysis and peritoneal dialysis), persons who are predialysis, and patients with diabetes**
- **Incarceration**
- **Travel in countries with high or intermediate endemic hepatitis B**

****Age 60 years or older with diabetes:** Based on shared clinical decision making, 2-, 3-, or 4-dose series as above.

Special situations

- **Patients on dialysis:** complete a 3- or 4-dose series
  - 3-dose series Recombivax HB at 0, 1, 6 months (Note: Use Dialysis Formulation 1 mL = 40 mcg)
  - 4-dose series Engerix–B at 0, 1, 2, and 6 months (Note: Use 2 mL dose instead of the normal adult dose of 1 mL)
- **Age 20 years or older with an immunocompromising condition:** complete a 2- or 3- or 4-dose series.
  - 3-dose series Recombivax HB at 0,1, 6 months (Note: Use Dialysis Formulation 1ml = 40 mcg)
  - 4-dose series Engerix–B at 0,1,2, and 6 months (Note: Use 2mL dose instead of the normal adult dose of 1mL)
  - 2-doses series Heplisav–B at 0, 1 months
  - 3-dose series PreHevbrio* at 0,1, 6 months

Human papillomavirus vaccination

Routine vaccination

- **All persons through age 26 years:** complete 2– or 3-dose series depending on age at initial vaccination or condition.
  - **Age 9–14 years at initial vaccination and received 1 dose or 2 doses less than 5 months apart:** 1 additional dose
  - **Age 9–14 years at initial vaccination and received 2 doses at least 5 months apart:** HPV vaccination series complete, no additional dose needed
  - **Age 15 years or older at initial vaccination:** 3-dose series at 0, 1–2 months, 6 months (minimum intervals: dose 1 to dose 2 = 4 weeks; dose 2 to dose 3 = 12 weeks; dose 1 to dose 3 = 5 months; repeat dose if administered too soon)
- No additional dose recommended when any HPV vaccine series of any valency has been completed using the recommended dosing intervals.

Shared clinical decision–making

- **Adults age 27–45 years:** Based on shared clinical decision–making, complete a 2-dose series (if initiated age 9–14 years) or 3-dose series (if initiated ≥15 years).

For additional information on shared clinical decision–making for HPV; see www.cdc.gov/vaccines/hcp/admin/downloads/isd–job–aid–scdm–hpv–shared–clinical–decision–making–hpv.pdf

Special situations

- **Age ranges recommended above for routine and catch–up vaccination or shared clinical decision–making also apply in special situations**
  - **Immunocompromising conditions, including HIV infection**: complete 3-dose series, even for those who initiate vaccination at age 9–14 years.
  - **Pregnancy**: Pregnancy testing is not needed before vaccination. HPV vaccination is not recommended until after pregnancy. No intervention needed if inadvertently vaccinated while pregnant.

Influenza vaccination

Routine vaccination

- **Age 19 years or older:** 1 dose any influenza vaccine appropriate for age and health status annually
  - **Solid organ transplant recipients aged 19–64 years receiving immunosuppressive medications:** HD–IIV3 and aIIV3 are acceptable options. No preference over other age–appropriate IIV3 or RIV3.
  - **Age 65 years or older:** Any one of HD-IIV3, RIV3, or aIIV3 is preferred. If none of these three vaccines is available, then any other age–appropriate influenza vaccine should be used.
- For the 2024–25 season, see www.cdc.gov/mmwr/volumes/73/rr/rr7305a1.htm
- For the 2025–26 season, see the 2025–26 ACIP influenza vaccine recommendations.

Special situations

- **Close contacts (e.g., caregivers, healthcare workers) of severely immunosuppressed persons who require a protected environment:** should not receive LAIV3. If LAIV3 is given, they should avoid contact with/caring for such immunosuppressed persons for 7 days after vaccination.

Note: Persons with an egg allergy can receive any influenza vaccine (egg-based or non–egg based) appropriate for age and health status.

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Notes Recommended Adult Immunization Schedule for Ages 19 Years or Older, United States, 2025

Measles, mumps, and rubella vaccination

Routine vaccination

- **No evidence of immunity to measles, mumps, or rubella:** 1 dose
  - **Evidence of immunity:** Born before 1957 (except for health care personnel, see below), documentation of receipt of MMR vaccine, laboratory evidence of immunity or disease (diagnosis of disease without laboratory confirmation is not evidence of immunity)

Special situations

- **Pregnancy with no evidence of immunity to rubella:** MMR contraindicated during pregnancy; after pregnancy (before discharge from health care facility): 1 dose
- **Nonpregnant women of childbearing age with no evidence of immunity to rubella:** 1 dose
- **HIV infection with CD4 percentages ≥15% and CD4 count ≥200 cells/mm^3 for at least 6 months and no evidence of immunity to measles, mumps, or rubella:** complete 2-dose series at least 4 weeks apart; MMR contraindicated for HIV infection with CD4 percentage <15% or CD4 count <200 cells/mm^3
- **Severe immunocompromising conditions:** MMR contraindicated
- **Students in postsecondary educational institutions, international travelers, and household or close, personal contacts of immunocompromised persons with no evidence of immunity to measles, mumps, or rubella:** complete 2-dose series at least 4 weeks apart if previously did not receive any doses of MMR or 1 dose if previously received 1 dose MMR
- **In mumps outbreak settings,** for information about additional doses of MMR (including 3rd dose of MMR), see www.cdc.gov/mmwr/volumes/67/wr/mm6701a7.htm
- **Health care personnel:**
  - **Born before 1957 with no evidence of immunity to measles, mumps, or rubella:** Consider 2-dose series at least 4 weeks apart for protection against measles or mumps or 1 dose for protection against rubella.
  - **Born in 1957 or later with no evidence of immunity to measles, mumps, or rubella:** complete 2-dose series at least 4 weeks apart for protection against measles or mumps or at least 1 dose for protection against rubella.

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Meningococcal vaccination

Special situations for MenACWY

- **Anatomical or functional asplenia (including sickle cell disease), HIV infection, persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use:** 2-dose primary series Menveo or MenQuadfi at least 8 weeks apart; 1 booster dose 5 years after primary series and every 5 years if risk remains
- **Travel in countries with hyperendemic or epidemic meningococcal disease, or for microbiologists routinely exposed to *Neisseria meningitidis*:** 1 dose Menveo or MenQuadfi; 1 booster dose 5 years after primary series and every 5 years if risk remains
- **First–year college students who live in residential housing (if not previously vaccinated at age 16 years or older) or military recruits:** 1 dose Menveo or MenQuadfi

For MenACWY recommendations **in outbreak setting** (e.g., in community or organizational settings, or among men who have sex with men) and **additional meningococcal vaccination** information, see www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm

Shared clinical decision–making for MenB

- **Adolescents and young adults age 16–23 years (age 16–18 years preferred)* not at increased risk for meningococcal disease:** based on shared clinical decision–making
  - **Bexsero or Trumenba (use same brand for all doses):** 2-dose series at least 6 months apart (if dose 2 is administered earlier than 6 months, administer dose 3 at least 4 months after dose 2)

*To optimize rapid protection (e.g., for students starting college in less than 6 months), a 3-dose series (0, 1–2, 6 months) may be administered.

For additional information on shared clinical decision–making for MenB, see www.cdc.gov/vaccines/media/pdfs/2025/03/2024-isd-job-aid-scdm-menb-508-remediated.pdf

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Meningococcal vaccination - *continued*

Special situations for MenB

- **Anatomical or functional asplenia (including sickle cell disease), persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use, or microbiologists routinely exposed to *Neisseria meningitidis*.**
  - **Bexsero or Trumenba (use same brand for all doses including booster doses):** 3-dose primary series at 0, 1–2, 6 months (if dose 2 was administered at least 6 months after dose 1, dose 3 not needed; if dose 3 is administered earlier than 4 months after dose 2, a 4th dose should be administered at least 4 months after dose 3).
  - **Booster doses:** 1 booster dose one year after primary series and every 2–3 years if risk remains
- **Pregnancy:** Delay MenB until after pregnancy due to lack of safety data in pregnant women. May administer if at increased risk and vaccination benefits outweigh potential risks.

For MenB recommendations **in outbreak setting** (e.g., in community or organizational settings, or among men who have sex with men) and **additional meningococcal vaccination** information, see ww.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm.

Note: MenB vaccines may be administered simultaneously with MenACWY vaccines if indicated, but at a different anatomic site, if feasible.

Adults may receive a single dose of Penbraya (MenACWY–TT/MenB–FHbp) as an alternative to separate administration of MenACWY and MenB when both vaccines would be given on the same clinic day. For adults not at increased risk, if Penbraya is used for dose 1 MenB, then MenB–FHbp (Trumenba) should be administered for dose 2 MenB. For adults at increased risk of meningococcal disease, Penbraya may be used for additional MenACWY and MenB doses (including booster doses) if both would be given on the same clinic day **and** at least 6 months have elapsed since most recent Penbraya dose.

Monkeypox virus vaccination

Special situations

- **Any person at risk for monkeypox infection:** complete 2-dose series, 28 days apart.

  Risk factors for monkeypox infection include:
  - Gay, bisexual, or other MSM, or a person who has sex with gay, bisexual, or other MSM who in the past 6 months have had one of the following:
    - A new diagnosis of at least 1 sexually transmitted disease
    - More than 1 sex partner
    - Sex at a commercial sex venue
    - Sex in association with a large public event in a geographic area where monkeypox virus transmission is occurring
  - Persons who are sexual partners of the persons described above
  - Persons who anticipate experiencing any of the situations described above
- **Pregnancy:** There is currently no ACIP recommendation for Jynneos use in pregnancy due to lack of safety data in pregnant women. Pregnant women with any risk factor described above may receive Jynneos.
- **Health care personnel:** Vaccination to protect against occupational risk in healthcare settings is not routinely recommended.

For detailed information, see www.cdc.gov/mpox/hcp/vaccine-considerations/vaccination-overview.html.

Pneumococcal vaccination

Routine vaccination

- **Age 50 years or older who have:**
  - **Not previously received a dose of PCV13, PCV15, PCV20, or PCV21 or whose previous vaccination history is unknown:** 1 dose PCV15 or 1 dose PCV20 or 1 dose PCV21
    - If PCV15 is used, administer 1 dose PPSV23 at least 1 year after the PCV15 dose (may use minimum interval of 8 weeks for adults with an immunocompromising condition,* cochlear implant, or cerebrospinal fluid leak).
  - **Previously received only PCV7:** follow the recommendation above.
  - **Previously received only PCV13:** 1 dose PCV20 or 1 dose PCV21 at least 1 year after the last PCV13 dose.
  - **Previously received only PPSV23:** 1 dose PCV15 or 1 dose PCV20 or 1 dose PCV21, at least 1 year after the last PPSV23 dose.
    - If PCV15 is used, no additional PPSV23 doses are recommended.
  - **Previously received both PCV13 and PPSV23 but NO PPSV23 was received at age 65 years or older:** 1 dose PCV20 or 1 dose PCV21 at least 5 years after the last pneumococcal vaccine dose.
  - **Previously received both PCV13 and PPSV23, AND PPSV23 was received at age 65 years or older:** Based on shared clinical decision–making, 1 dose of PCV20 or 1 dose of PCV21 at least 5 years after the last pneumococcal vaccine dose.

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Pneumococcal vaccination - *continued*

Special situations

- **Age 19–49 years with certain underlying medical conditions or other risk factors** who have:**
  - **Not previously received a PCV13, PCV15, PCV20, or PCV21 or whose previous vaccination history is unknown:** 1 dose PCV15 or 1 dose PCV20 or 1 dose PCV21
    - If PCV15 is used, administer 1 dose PPSV23 at least 1 year after the PCV15 dose (may use minimum interval of 8 weeks for adults with an immunocompromising condition,* cochlear implant, or cerebrospinal fluid leak).
  - **Previously received only PCV7:** follow the recommendation above.
  - **Previously received only PCV13:** 1 dose PCV20 or 1 dose PCV21 at least 1 year after the last PCV13 dose
  - **Previously received only PPSV23:** 1 dose PCV15 or 1 dose PCV20 or 1 dose PCV21, at least 1 year after the last PPSV23 dose.
    - If PCV15 is used, no additional PPSV23 doses are recommended.
  - **Previously received PCV13 and 1 dose of PPSV23:**
    - Cochlear implant, cerebrospinal fluid leak, or an immunocompromising condition*: 1 dose PCV20 or 1 dose PCV21 at least 5 years after the last pneumococcal vaccine dose.
    - Alcoholism, chronic heart/liver/lung disease, cigarette smoking, or diabetes mellitus: no additional PCV or PPSV23 doses recommended at this time. Review pneumococcal recommendations when age 50 years or older.

Adults aged 19 years and older who have received PCV20 or PCV21: no additional pneumococcal vaccine dose recommended.

Pregnancy: no recommendation for PCV or PPSV23 due to limited data. Summary of existing data on pneumococcal vaccination during pregnancy can be found at www.cdc.gov/mmwr/volumes/72/rr/rr7203a1.htm.

PPSV23 not available: adults aged 19 years or older who received PCV15 but have not yet completed PPSV23 series, can complete the series with either 1 dose of PCV20 or 1 dose of PCV21 if they no longer have access to PPSV23.

For guidance on determining which pneumococcal vaccines a patient needs and when, please refer to the mobile app which can be downloaded here: www.cdc.gov/pneumococcal/hcp/vaccine-recommendations/app.html.

***Note:** Immunocompromising conditions include chronic renal failure, nephrotic syndrome, immunodeficiencies, iatrogenic immunosuppression, generalized malignancy, HIV infection, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplant, congenital or acquired asplenia, or sickle cell disease or other hemoglobinopathies.

****Note:** Underlying medical conditions or other risk factors include alcoholism, chronic heart/liver/lung disease, chronic renal failure, cigarette smoking, cochlear implant, congenital or acquired asplenia, CSF leak, diabetes mellitus, generalized malignancy, HIV infection, Hodgkin disease, immunodeficiencies, iatrogenic immunosuppression, leukemia, lymphoma, multiple myeloma, nephrotic syndrome, solid organ transplant, or sickle cell disease or other hemoglobinopathies.

Poliovirus vaccination

Routine vaccination

- **Adults known or suspected to be unvaccinated or incompletely vaccinated:** administer remaining doses (1, 2, or 3 IPV doses) to complete a 3-dose primary series.* Unless there are specific reasons to believe they were not vaccinated, most adults who were born and raised in the United States can assume they were vaccinated against polio as children.

Special situations

- **Adults at increased risk for exposure to poliovirus who completed primary series*:** may administer one lifetime IPV booster.

***Note:** Complete primary series consists of at least 3 doses of IPV or trivalent oral poliovirus vaccine (tOPV) in any combination.

For detailed information, see www.cdc.gov/vaccines/vpd/polio/hcp/recommendations.html

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Respiratory syncytial virus vaccination

Routine vaccination

- **Pregnant women of any age:**
  - **Pregnant at 32 weeks 0 days through 36 weeks and 6 days gestation from September through January in most of the continental United States*:** 1 dose **Abrysvo**. Administer RSV vaccine regardless of previous RSV infection.
  - Either maternal RSV vaccination with Abrysvo or infant immunization with nirsevimab (RSV monoclonal antibody) is recommended to prevent severe respiratory syncytial virus disease in infants.
  - **All other pregnant women:** RSV vaccine not recommended
  - **Subsequent pregnancies:** additional doses not recommended. No data are available to inform whether additional doses are needed in subsequent pregnancies. Infants born to pregnant women who received RSV vaccine during a previous pregnancy should receive nirsevimab.

***Note:** Providers in jurisdictions with RSV seasonality that differs from most of the continental United States (e.g., Alaska, jurisdictions with tropical climate) should follow guidance from public health authorities on timing of administration. Refer to the 2025 Child and Adolescent Immunization Schedule for considerations regarding nirsevimab administration to infants.

Age 75 years or older

- **Unvaccinated:** 1 dose (Arexvy or Abrysvo or mResvia). Additional doses not recommended
- **Previously vaccinated:** additional doses not recommended. No data are available to inform whether additional doses are needed.

Special situations

- **Age 60–74 years:**
  - **Unvaccinated and at increased risk of severe RSV disease**:** 1 dose (Arexvy or Abrysvo or mResvia). Additional doses not recommended.
  - **Previously vaccinated:** additional doses not recommended. No data are available to inform whether additional doses are needed.

Persons 60 years and older can get RSV vaccine at any time but it is best to administer in late summer and early fall before RSV spreads in communities—ideally August through October in most of continental United States. For further guidance, see www.cdc.gov/mmwr/volumes/73/wr/mm7332e1.htm.

****Note:** ***People can self–attest to the presence of a risk factor.*** **The following medical and other conditions increase the risk of severe RSV disease:**

- Chronic cardiovascular disease e.g., heart failure, coronary artery disease, congenital heart disease. Excludes isolated hypertension.
- Chronic lung or respiratory disease e.g., chronic obstructive pulmonary disease, emphysema, asthma, interstitial lung disease, cystic fibrosis
- End stage renal disease or dependence on hemodialysis or other renal replacement therapy
- Diabetes mellitus complicated by chronic kidney disease, neuropathy, retinopathy, or other end–organ damage
- Diabetes mellitus requiring treatment with insulin or sodium–glucose cotransporter 2 (SGLT2) inhibitor
- Neurologic or neuromuscular conditions causing impaired airway clearance or respiratory muscle weakness e.g., post–stroke dysphagia, amyotrophic lateral sclerosis, muscular dystrophy. Excludes history of stroke without impaired airway clearance.
- Chronic liver disease e.g., cirrhosis
- Chronic hematologic conditions e.g., sickle cell disease, thalassemia
- Severe obesity (body mass index ≥ 40 kg/m2)
- Moderate or severe immune compromise
- Residence in a nursing home
- Other chronic medical conditions or risk factors that a health care provider determines would increase the risk of severe disease due to viral respiratory infection e.g., frailty, concern for presence of undiagnosed chronic medical conditions, residence in a remote or rural community where escalation of medical care is challenging.

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Notes Recommended Adult Immunization Schedule for Ages 19 Years or Older, United States, 2025

Tetanus, diphtheria, and pertussis vaccination

Routine vaccination

- **Completed primary series and received at least 1 dose Tdap at age 10 years or older:** Td or Tdap every 10 years thereafter
- **Completed primary series and did NOT receive Tdap at age 10 years or older:** 1 dose Tdap, then Td or Tdap every 10 years thereafter
- **Unvaccinated or incomplete primary vaccination series for tetanus, diphtheria, or pertussis:** administer remaining doses (1, 2, or 3 doses) to complete 3-dose primary series. 1 dose Tdap followed by 1 dose Td or Tdap at least 4 weeks later, and a third dose of Td or Tdap 6–12 months later (Tdap is preferred as first dose and can be substituted for any Td dose), then Td or Tdap every 10 years thereafter.

Special situations

- **Pregnancy:** 1 dose Tdap during each pregnancy, preferably in early part of gestational weeks 27–36
- **Wound management:** Persons with 3 or more doses of tetanus–toxoid–containing vaccine: For clean and minor wounds, administer Tdap or Td if more than 10 years since last dose of tetanus–toxoid–containing vaccine; for all other wounds, administer Tdap or Td if more than 5 years since last dose of tetanus–toxoid–containing vaccine. Tdap is preferred for persons who have not previously received Tdap or whose Tdap history is unknown. If a tetanus–toxoid–containing vaccine is indicated for a pregnant woman, use Tdap. For detailed information, see www.cdc.gov/mmwr/volumes/69/wr/mm6903a5.htm

Varicella vaccination

Routine vaccination

- **No evidence of immunity to varicella:** 2-dose series 4–8 weeks apart if previously did not receive varicella–containing vaccine (VAR or MMRV [measles–mumps–rubella–varicella vaccine] for children); if previously received 1 dose varicella–containing vaccine, 1 dose at least 4 weeks after first dose.
  - **Evidence of immunity:** U.S.–born before 1980 (except for pregnant women and health care personnel [see below]), documentation of 2 doses varicella–containing vaccine at least 4 weeks apart, diagnosis or verification of history of varicella or herpes zoster by a health care provider, laboratory evidence of immunity or disease.

Special situations

- **Pregnancy with no evidence of immunity to varicella:** VAR contraindicated during pregnancy; after pregnancy (before discharge from health care facility), 1 dose if previously received 1 dose varicella–containing vaccine or dose 1 of 2-dose series (dose 2: 4–8 weeks later) if previously did not receive any varicella–containing vaccine, regardless of whether U.S.–born before 1980.
- **Health care personnel with no evidence of immunity to varicella:** 1 dose if previously received 1 dose varicella–containing vaccine; 2-dose series 4–8 weeks apart if previously did not receive any varicella–containing vaccine, regardless of whether U.S.–born before 1980.
- **HIV infection with CD4 percentages ≥15% and CD4 count ≥200 cells/mm³ with no evidence of immunity:** Vaccination may be considered (2 doses 3 months apart); VAR contraindicated for HIV infection with CD4 percentage <15% or CD4 count <200 cells/mm³.
- **Severe immunocompromising conditions:** VAR contraindicated

Zoster vaccination

Routine vaccination

- **Age 50 years or older*:** 2-dose series recombinant zoster vaccine (RZV, Shingrix) 2–6 months apart (minimum interval: 4 weeks; repeat dose if administered too soon), regardless of previous herpes zoster or history of zoster vaccine live (ZVL, Zostavax) vaccination.

***Note:** Serologic evidence of prior varicella is not necessary for zoster vaccination. However, if serologic evidence of varicella susceptibility becomes available, providers should follow ACIP guidelines for varicella vaccination first. RZV is not indicated for the prevention of varicella, and there are limited data on the use of RZV in persons without a history of varicella or varicella vaccination.

Special situations

- **Pregnancy:** There is currently no ACIP recommendation for RZV use in pregnancy. Consider delaying RZV until after pregnancy.
- **Immunocompromising conditions (including persons with HIV regardless of CD4 count)**:** 2-dose series recombinant zoster vaccine (RZV, Shingrix) 2–6 months apart (minimum interval: 4 weeks; repeat dose if administered too soon). For detailed information, see www.cdc.gov/shingles/hcp/vaccine-considerations/immunocompromised-adults.html

****Note:** If there is no documented history of varicella, varicella vaccination, or herpes zoster, providers should refer to the clinical considerations for use of RZV in immunocompromised adults aged ≥19 years and the ACIP varicella vaccine recommendations for further guidance: www.cdc.gov/mmwr/volumes/71/wr/mm7103a2.htm

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Appendix Recommended Adult Immunization Schedule for Ages 19 Years or Older, United States, 2025

Contraindications and Precautions to Commonly Used Vaccines

Adapted from Table 4–1 in Advisory Committee on Immunization Practices (ACIP) General Best Practice Guidelines for Immunization: Contraindication and Precautions, Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices—United States, 2024–25 Influenza Season | MMWR (cdc.gov), *and* Contraindications and Precautions for COVID–19 Vaccination

Vaccines and Other Immunizing Agents	Contraindicated or Not Recommended[1]	Precautions[2]
COVID–19 mRNA vaccines [Comirnaty, mNexspike, Spikevax]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of an mRNA COVID–19 vaccine[3]	• Diagnosed non–severe allergy (e.g., urticaria beyond the injection site) to a component of an mRNA COVID–19 vaccine[3]; or non–severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of an mRNA COVID–19 vaccine • Myocarditis or pericarditis within 3 weeks after a dose of any COVID–19 vaccine • Multisystem inflammatory syndrome in children (MIS–C) or multisystem inflammatory syndrome in adults (MIS–A) • Moderate or severe acute illness, with or without fever
COVID–19 protein subunit vaccine [Nuvaxovid]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of a Nuvaxovid[3]	• Diagnosed non–severe allergy (e.g., urticaria beyond the injection site) to a component of Nuvaxovid[3]; or non–severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of Nuvaxovid • Myocarditis or pericarditis within 3 weeks after a dose of any COVID–19 vaccine • Multisystem inflammatory syndrome in children (MIS–C) or multisystem inflammatory syndrome in adults (MIS–A) • Moderate or severe acute illness, with or without fever
Influenza, egg-based, inactivated injectable (IIV3)	• Severe allergic reaction (e.g., anaphylaxis) after previous dose of any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV of any valency) • Severe allergic reaction (e.g., anaphylaxis) to any vaccine component[3] (excluding egg)	• Guillain–Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Moderate or severe acute illness with or without fever
Influenza, cell culture–based inactivated injectable (ccIIV3) [Flucelvax]	• Severe allergic reaction (e.g., anaphylaxis) to any ccIIV of any valency, or to any component[3] of ccIIV3	• Guillain–Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Persons with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any egg-based IIV, RIV, or LAIV of any valency. If using ccIIV3, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions. May consult an allergist. • Moderate or severe acute illness with or without fever
Influenza, recombinant injectable (RIV3) [Flublok]	• Severe allergic reaction (e.g., anaphylaxis) to any RIV of any valency, or to any component[3] of RIV3	• Guillain–Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Persons with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any egg-based IIV, ccIIV, or LAIV of any valency. If using RIV3, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions. May consult an allergist. • Moderate or severe acute illness with or without fever
Influenza, live attenuated (LAIV3) [Flumist]	• Severe allergic reaction (e.g., anaphylaxis) after previous dose of any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV of any valency) • Severe allergic reaction (e.g., anaphylaxis) to any vaccine component[3] (excluding egg) • Anatomic or functional asplenia • Immunocompromised due to any cause including, but not limited to, medications and HIV infection • Close contacts or caregivers of severely immunosuppressed persons who require a protected environment • Pregnancy • Cochlear implant • Active communication between the cerebrospinal fluid (CSF) and the oropharynx, nasopharynx, nose, ear, or any other cranial CSF leak • Received influenza antiviral medications oseltamivir or zanamivir within the previous 48 hours, peramivir within the previous 5 days, or baloxavir within the previous 17 days.	• Guillain–Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Asthma in persons aged 5 years or older • Persons with underlying medical conditions (other than those listed under contraindications) that might predispose to complications after wild–type influenza virus infection [e.g., chronic pulmonary, cardiovascular (except isolated hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus)] • Moderate or severe acute illness with or without fever

1. When a contraindication is present, a vaccine should NOT be administered. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization.
2. When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization.
3. Vaccination providers should check FDA–approved prescribing information for the most complete and updated information, including contraindications, warnings, and precautions. See Package inserts for U.S.–licensed vaccines.

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Vaccine	Contraindicated or Not Recommended[1]	Precautions[2]
Haemophilus influenzae type b (Hib)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness with or without fever
Hepatitis A (HepA)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including neomycin	• Moderate or severe acute illness with or without fever
Hepatitis B (HepB)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including yeast • Pregnancy: PreHevbrio is not recommended due to lack of safety data in pregnant women. Use other hepatitis B vaccines if HepB is indicated[4]	• Moderate or severe acute illness with or without fever
Hepatitis A–Hepatitis B vaccine (HepA–HepB) [Twinrix]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including neomycin and yeast	• Moderate or severe acute illness with or without fever
Human papillomavirus (HPV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • *Pregnancy: HPV vaccination not recommended*	• Moderate or severe acute illness with or without fever
Measles, mumps, rubella (MMR)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Pregnancy • Family history of altered immunocompetence, unless verified clinically or by laboratory testing as immunocompetent	• Recent (≤11 months) receipt of antibody-containing blood product (specific interval depends on product) • History of thrombocytopenia or thrombocytopenic purpura • Need for tuberculin skin testing or interferon-gamma release assay (IGRA) testing • Moderate or severe acute illness with or without fever
Meningococcal ACWY (MenACWY) (MenACWY-CRM) [Menveo] (MenACWY-TT) [MenQuadfi]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • For MenACWY-CRM only: severe allergic reaction to any diphtheria toxoid– or CRM197–containing vaccine • For MenACWY-TT only: severe allergic reaction to a tetanus toxoid–containing vaccine	• Moderate or severe acute illness with or without fever
Meningococcal B (MenB) MenB-4C [Bexsero] MenB-FHbp [Trumenba]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Pregnancy • For MenB-4C only: Latex sensitivity • Moderate or severe acute illness with or without fever
Meningococcal ABCWY (MenACWY-TT/MenB-FHbp) [Penbraya]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe allergic reaction to a tetanus toxoid–containing vaccine	• Moderate or severe acute illness, with or without fever
Mpox [Jynneos]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness, with or without fever
Pneumococcal conjugate (PCV15, PCV20, PCV21)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe allergic reaction (e.g., anaphylaxis) to any diphtheria–toxoid–containing vaccine or to its vaccine component[3]	• Moderate or severe acute illness with or without fever
Pneumococcal polysaccharide (PPSV23)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness with or without fever
Poliovirus vaccine, inactivated (IPV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Pregnancy • Moderate or severe acute illness with or without fever
Respiratory syncytial virus vaccine (RSV)	• Severe allergic reaction (e.g., anaphylaxis) to a vaccine component	• Moderate or severe acute illness with or without fever
Tetanus, diphtheria, and acellular pertussis (Tdap) Tetanus, diphtheria (Td)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • For Tdap only: Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures), not attributable to another identifiable cause, within 7 days of administration of previous dose of DTP, DTaP, or Tdap	• Guillain–Barré syndrome (GBS) within 6 weeks after a previous dose of tetanus–toxoid–containing vaccine • History of Arthus–type hypersensitivity reactions after a previous dose of diphtheria–toxoid containing or tetanus–toxoid–containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus–toxoid–containing vaccine • Moderate or severe acute illness with or without fever • For Tdap only: Progressive or unstable neurological disorder, uncontrolled seizures, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized
Varicella (VAR)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Pregnancy • Family history of altered immunocompetence, unless verified clinically or by laboratory testing as immunocompetent	• Recent (≤11 months) receipt of antibody–containing blood product (specific interval depends on product) • Receipt of specific antiviral drugs (acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination (avoid use of these antiviral drugs for 14 days after vaccination) • Use of aspirin or aspirin–containing products • Moderate or severe acute illness with or without fever
Zoster recombinant vaccine (RZV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness with or without fever • Current episode of herpes zoster

1. When a contraindication is present, a vaccine should NOT be administered. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.
2. When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.
3. Vaccination providers should check FDA-approved prescribing information for the most complete and updated information, including contraindications, warnings, and precautions. Package inserts for U.S.-licensed vaccines are available at www.fda.gov/vaccines-blood-biologics/approved-products/vaccines-licensed-use-united-states.
4. For information on the pregnancy exposure registry for persons who were inadvertently vaccinated with PreHevbrio while pregnant, please visit www.prehevbrio.com/#safety.

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Addendum Recommended Adult Immunization Schedule for Ages 19 Years or Older, United States, 2025

In addition to the recommendations presented in the previous sections of this immunization schedule, ACIP has approved the following recommendations by majority vote since October 24, 2024.

Vaccines	Recommendations	Effective Date of Recommendation*
Meningococcal (MenACWY-CRM/MenB-4C, Penmenvy)	MenABCWY vaccine may be used when both MenACWY and MenB are indicated at the same visit in: 1. healthy persons aged 16–23 years (routine schedule) when shared clinical decision-making favors administration of MenB vaccine and 2. persons aged = 10 years who are at increased risk for meningococcal disease (e.g., because of persistent complement deficiencies, complement inhibitor use, or functional or anatomic asplenia)	June 25, 2025
RSV (Abrysvo, Arexvy, mResvia)	Adults 50–59 years of age who are at increased risk of severe RSV disease[a] may receive a single dose of RSV vaccine[b,c]. a. CDC will publish Clinical Considerations that describe chronic medical conditions and other risk factors for severe RSV disease for use in this risk-based recommendation. b. At this time, RSV vaccination is recommended as a single dose only. Persons who have already received RSV vaccination are NOT recommended to receive another dose. c. RSV vaccine can be administered with any product licensed in this age group. As of March 27, 2025, that includes GSK's Arexvy and Pfizer's Abrysvo. There is no preferential recommendation for any licensed product over another.	June 25, 2025
Influenza	ACIP reaffirms the recommendations for routine annual influenza vaccination of all persons aged = 6 months who do not have contraindications for the 2025–2026 season	July 22, 2025
Influenza	ACIP recommends only single-dose formulations of annual influenza vaccines that are free of thimerosal as a preservative for three populations: - Children 18 years or younger - Pregnant women - All adults	July 22, 2025
Note: As of May 29, 2025, the schedule incorporates the HHS directive regarding COVID-19 vaccine recommendations. (Changes were made to tables and notes for COVID-19 vaccines in pregnant women).		

*The effective date is the date when the recommendation was adopted and became official.

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EXHIBIT 18

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 ROBERT H. HOPKINS, JR., MD, MACP, FAAP

I, Robert H. Hopkins, Jr., MD, MACP, declare pursuant to 28 U.S.C. § 1746, that the following is true and correct and within my personal knowledge.

1. Based on my over 30-year career as an Internal Medicine and Pediatrics physician, the recent arbitrary and unsupported decisions regarding COVID-19 vaccines by the Secretary of Health and Human Services Robert F. Kennedy, Jr., the Advisory Committee on Immunization Practices ("ACIP"), and the Centers for Disease Control and Prevention ("CDC") are harming me as a practicing physician and causing preventable suffering and death to Americans.

2. I am a board-certified Internal Medicine physician with an active clinical practice as Professor and immediate-past Chief of the Division of General Internal Medicine at the University of Arkansas for Medical Sciences College of Medicine, which is our state medical school in Little Rock, Arkansas.

3. I conduct clinical care for both pediatric and adult patients, including pregnant persons.

4. From 2020–2022, I served as medical director for COVID testing and vaccination at the University of Arkansas for Medicinal Sciences.

5. I spend a significant part of my day counseling patients, trainees, and residents about vaccines, and I would consider myself the go-to person in my clinical setting for questions about vaccination.

6. I am an active member of the American College of Physicians ("ACP") and the current chair of the ACP Immunization Committee.

7. I am also actively involved with the Advisory Committee on Immunization Practices ("ACIP") of the Centers for Disease Control and Prevention ("CDC") as I served on several vaccine work groups, such as the COVID-19 Vaccines Work Group, Pneumococcal Vaccines Work Group, the Influenza Vaccines Work Group, and the Combined Schedule Work Group.

8. On May 19, 2025, the Secretary of Health and Human Services Robert F. Kennedy, Jr. (the "Secretary") issued a "Secretarial Directive on Pediatric COVID-19 Vaccines for Children Less than 18 years of Age and Pregnant Women" (the "May 19 Secretarial Directive"). The Secretary stated, "I have determined that the known risks associated with the use of COVID-19 vaccines in healthy U.S. children ages six months to 17 years do not outweigh the purported benefits of the vaccine." *See* Ex. A. The May 19 Secretarial Directive directed the CDC to "remove COVID-19 vaccines from the recommended Child and Adolescent Immunization Schedule by Age and recommended vaccines during pregnancy." In September 2025, ACIP recommended the downgrade of the COVID-19 vaccine to shared clinical decision making ("SCDM") for essentially all children and adults and in October 2025 the CDC improperly conflated this recommendation with "informed consent".

9. The May 19 Secretarial Directive and recent actions by ACIP and the CDC were taken in contravention to the robust data compiled and presented by the COVID-19 Vaccines Work Group for years regarding the effectiveness of the COVID-19 vaccines, particularly for pregnant persons and children.

10. On June 9, 2025, the Secretary terminated all 17 voting members of ACIP. Because each work group must include at least two voting members of ACIP, all work groups were automatically terminated as a result.

11. The Secretary appointed new ACIP members ahead of the June 25–26, 2025 ACIP meeting, but only the COVID-19 Vaccines Work Group has met since then. The Influenza Vaccine Work Group and the other work groups that I have participated in have not met since the Secretary's termination of the ACIP members on June 9, 2025, and therefore have not reviewed any new data or studies on COVID-19 vaccinations that would support the downgrade to SCDM.

12. Non-governmental organizations, including the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists, typically appoint liaison members to ACIP Work Groups, such as the COVID-19 Work Group and the Influenza Vaccine Work Group. These liaison members are experts in clinical medicine, vaccinology, pharmacy, and other fields involved in vaccine research and delivery to patients. The role of the liaison is to represent their organization and advise ACIP on clinical and scientific issues relevant to vaccines and vaccinations. Many liaison members have served as external experts informing ACIP for a decade or more, and some are former ACIP voting members.

13. Typically, for prior ACIP meetings that I attended as a Work Group Liaison, I would receive an invitation to participate at the meeting along with documents and presentations

that would be discussed at the ACIP meeting. This usual format was not followed prior to the June 25–26, 2025 ACIP meeting.

14. I received an invitation for the June 25, 2025 ACIP meeting the night before.

15. On the morning of June 25, 2025, after having issues with the Zoom link provided by the CDC, I was eventually able to join the call, but I was unable to access my video and microphone functions. As a result, I was unable to participate in the usual roll call of liaison members that takes place at the beginning of each ACIP meeting. The inability for liaison members to participate was blamed on "technical difficulties."

16. It took several hours for the "technical difficulties" to be resolved, so liaisons were unable to participate for most of the ACIP meeting on June 25, 2025. Generally, liaison members are able to speak at any point during an ACIP meeting as recognized by the Chair.

17. On the afternoon of June 25, 2025, I was able to access the audio function for the ACIP meeting, although I did not participate unless I was called upon by the ACIP Chair.

18. On June 26, 2025, there was a presentation at the ACIP meeting regarding thimerosal-containing influenza vaccines followed by three votes on the subject, which was a complete deviation from the normal practice that I have observed and participated in as an ACIP Liaison member.

19. Previously, in the Influenza Work Group, which I was a member of for 4 years and a Liaison for 1.5 years, we would have robust discussions and presentations regarding the epidemiology of the influenza disease. We would examine data regarding the effectiveness of the influenza vaccines during the current season and at the end of the season. We would also discuss vaccine safety and hear presentations from manufacturers about any changes in the

vaccines. The Influenza Vaccines Work Group would then discuss implementation challenges, opportunities, and changes in vaccine strains for the upcoming flu season.

20. Whenever there is a change in recommendation for a vaccine, it goes through a certain process which is laid out in the Evidence to Recommendation ("EtR") framework that is published in the Mortality and Morbidity Weekly Report published by the CDC. The EtR framework is a structured, evidence-based process of review of vaccine evidence which is meant to allow the ACIP to consider vaccine safety, efficacy, access and availability, equity, and acceptability to the public. None of these processes were followed for the decision to remove thimerosal from seasonal influenza vaccines. Indeed, a retired nurse without a robust scientific background presented a non-peer-reviewed presentation with questionable assertions of data that contradicted standard practice, without quality evidence, without a work group-created evidence-recommended framework, and used junk data regarding thimerosal-containing vaccines that has been thoroughly studied and debunked. *See* Ex. B Thimerosal as a Vaccine Preservative, CDC ACIP Meeting (June 25, 2025) https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/05-influenza-redwood-508.pdf (presented by Lyn Redwood RN, MSN, FP (Retired)).

21. Following this presentation, there was a discussion during which Dr. Meissner and several liaison members raised valid concerns about the presentation. Several public commenters also raised concerns about the presentation and the upcoming vote. However, the ACIP voting members then rushed into a series of votes and voted "yes" on removing thimerosal-containing influenza vaccines for children, pregnant women, and all adults, which was not supported by the evidence.

22. I did virtually attend the September 2025 ACIP meeting. There were no technology issues as in the June 2025 meeting, and all liaisons were able to sign on virtually and

make comments for most of the meeting. The ACIP voting members, without presenting any robust analysis of evidence in support of their recommendation, including GRADE tables, and without following the EtR framework for evaluating the quality of evidence, voted against the advice of the liaisons and changed the COVID-19 immunization schedule to SCDM. This was only the second time in my years as serving as a Work Group Liaison that the EtR framework was not followed for a vaccine recommendation—the first being at the June 2025 ACIP meeting.

23. The Secretary's May 19, 2025 decision and recent actions by the ACIP and CDC to downgrade the CDC immunization schedule recommendation for COVID-19 vaccination to SCDM for essentially all adults and children has harmed and will continue to harm my patients.

24. Despite the Secretary's May 19, 2025 Directive and recent ACIP recommendation on COVID-19 vaccinations, I continue to counsel patients on the COVID-19 vaccination based on the evidence—that it is beneficial for pregnant women and children because it prevents severe illness and death.

25. The Secretary's May 19, 2025 Directive and recent ACIP vote on COVID-19 vaccinations now require that I spend more time counseling patients, specifically pregnant persons and parents of children, regarding the safety of the COVID-19 vaccine. Approximately half of the patients I see in a given day require counseling on COVID-19 vaccines. These meetings can be anywhere from 2–5 minutes long for patients who have previously gotten the COVID-19 vaccine or a booster shot, and up to 10 minutes long for patients who have never had a COVID-19 vaccine or booster shot. The SCDM discussion is expected to be paid for by the vaccine administration fee, which is billed for vaccines which have been administered. There is no payment for vaccine counseling which does not result in a vaccine being administered, which accounts for approximately 20–25% of the SCDM conversations in my practice.

26. After these discussions, several patients, such as parents of young children, have refused to get the COVID-19 vaccine for their child due to vaccine skepticism that has increased since the Secretary's May 19, 2025 Directive.

27. Despite the Secretary's May 19, 2025 Directive, my practice is to provide the most optimal care possible for my patients, which includes giving the COVID-19 vaccine to pregnant persons and children in accordance with the science.

28. Indeed, at the April 15–16, 2025 ACIP meeting, which I attended in my capacity as a Liaison for the National Foundation for Infectious Diseases ("NFID") and a Work Group member, the COVID-19 Vaccines Work Group presented five different presentations regarding the COVID-19 vaccines and ended with the Work Group's considerations for use of the 2025–2026 COVID-19 vaccines. *See* Ex. C, *ACIP COVID-19 Vaccines Work Group*, CDC ACIP Meeting (April 15, 2025) https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/01-Schechter-COVID-508.pdf (presented by Robert Schechter, MD, MSc); Ex. D *Use of 2025–2026 COVID-19 Vaccines: Work Group Considerations*, CDC ACIP Meeting (April 15, 2025) https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/05-Panagiotakopoulos-COVID-508.pdf (presented by Lakshmi Panagiotakopoulos, MD, MPH).

29. At the April 15–16, 2025 ACIP meeting, the COVID-19 Vaccines Work Group presented policy options for 2025–2026 COVID-19 vaccines based on the evidence gathered from our meetings concerning a multi-dose initial series for persons ages 6 months to 4 years and those who are immunocompromised. *See* Ex. D at 8. The COVID-19 Vaccines Work Group also presented policy options regarding annual COVID-19 vaccine doses and semi-annual COVID-19 vaccine doses. *Id*. at 9–10. These "policy options" were a precursor to an anticipated vote at the June 2025 ACIP meeting, where the COVID-19 Vaccines Work Group

would present more data and analyses before an anticipated vote on the 2025–2026 COVID-19 vaccines.

30. No data was presented by the COVID-19 Vaccines Work Group at the April 15–16, 2025 ACIP meeting to suggest that COVID-19 vaccines should not be recommended for pregnant persons or children. In fact, it was discussed that pregnancy and recent pregnancy were risk factors for severe illness of COVID-19.

31. There was no vote scheduled at the April 15–16, 2025 ACIP meeting regarding COVID-19 vaccine recommendations, meaning that ACIP committee members did not vote on changing the COVID-19 vaccine schedule for pregnant persons or children at that meeting. Indeed, the vote on the 2025–2026 COVID-19 vaccine recommendations was slated for the June 25–26, 2025 ACIP meeting. *See* Ex. E, *CDC ACIP Meeting Agenda*, April 15–16, 2025; Ex. D at 3.

32. I am currently unaware as of the date of this declaration whether a patient's insurance has denied COVID-19 vaccinations, but if it did, I would attempt to appeal it immediately because of this conflict between the Secretary's May 19 Directive and the well-established scientific evidence as well as the fact that the COVID-19 vaccine is FDA-approved. I am aware that some patients have received questions back from their insurers regarding their receipt of the COVID-19 vaccine. I have personally spoken to several major insurers regarding their COVID-19 vaccine reimbursement policies.

33. If insurance companies stop covering the COVID-19 vaccine for my patients, I will add that to my counseling on getting the vaccine, although I expect few patients to get vaccinated if they must pay out of pocket. Approximately 50% of my patients are covered by

Medicare or Medicaid. The COVID-19 reimbursement rate is $155 for Medicare, $147 for Medicaid, $90 for pediatric patients, and between $140 to $150 for other insured adults.

34. The Vaccines for Children ("VFC") program is a critical safety net that provides free vaccines, including COVID-19 vaccines, to eligible children who might not otherwise have access. However, access gaps remain for certain vulnerable populations, especially in light of recent policy changes. From May 19, 2025 (the date of the Secretary's Directive) until the September 2025 ACIP vote, I was unable to order the COVID-19 vaccine for children eligible through the VFC program. During that time, I saw a patient who typically receives their vaccinations through the VFC program. I informed the patient and their parent that the COVID-19 vaccine was currently not available through the VFC portal, and that the vaccine we had on hand was ordered outside of the VFC program and would require out-of-pocket payment. The patient's parent stated that they would decline the vaccine, as they were unable to afford the out-of-pocket cost.

35. My patients who deny the COVID-19 vaccine even after counseling because of skepticism due to the Secretary's May 19 Directive face increased risk of hospitalization and death from COVID-19, as well as higher risk of transmitting the disease to immunocompromised individuals or unvaccinated pregnant persons and children who are unable to get the vaccine from other providers.

36. Further, vaccine counseling and then refusal by the patient has financial ramifications for my practice as I do not bill for that time, and it also takes time away from other patients or training residents. For example, when a resident is treating a patient and engaging in SCDM regarding the COVID-19 vaccine, and the patient refuses the vaccine, then the resident will request that I or another attending physician see the patient and repeat the SCDM

conversation with the patient. There is no code to be reimbursed for these conversations when no vaccine is administered, and we are often having two SCDM conversations with a single patient.

37. If COVID-19 spreads more easily due to lower vaccination rates, my patients, including pregnant persons and children, will face increased illness, which will overwhelm my practice as I will spend more time treating patients with this vaccine-preventable illness. Indeed, when vaccinated patients get COVID-19, it is less severe. Consequently, if patients are not getting vaccinated and then get COVID-19, they will have much more severe illness which requires more of my time and resources to treat.

38. Finally, the Secretary's May 19, 2025 decision to rescind the COVID-19 recommendations for pregnant persons and children and the recent ACIP recommendation to change the CDC immunization schedule to SCDM directly puts me at risk of contracting COVID-19 as I encounter more patients with vaccine-preventable illnesses. If I become sick, I cannot see patients while I am ill.

39. Unless the unsupported May 19 Secretarial Directive and the downgrading of the COVID-19 vaccine for pregnant women, children, and essentially all adults under the age of 65 are vacated, it is reasonably foreseeable that my patients will face preventable illness, suffering, and in some cases death.

40. I am over the age of 18 years old. All of the facts set forth in this declaration are based on my personal knowledge. I submit this declaration in support of Plaintiffs' Opposition to the Motion to Dismiss in my role as a physician, healthcare professional, and member of the American College of Physicians. I do not speak for or represent my employer (the University of Arkansas for Medical Sciences).

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

Executed on December 1, 2025, in Little Rock, Arkansas.



Robert H. Hopkins, Jr., MD, MACP
Member, American College of Physicians

EXHIBIT A

SECRETARIAL DIRECTIVE ON PEDIATRIC COVID-19 VACCINES FOR CHILDREN LESS THAN 18 YEARS OF AGE AND PREGNANT WOMEN

May 19, 2025

The Department of Health and Human Services (HHS) continually considers and evaluates available science and evidence related to the safety and effectiveness of all currently available Food and Drug Administration (FDA) approved or authorized vaccines, and any risks of severe disease, hospitalization, and death to certain populations.

By Secretarial Directive on June 18, 2022, HHS ratified the Centers of Disease Control and Prevention (CDC) recommendations concerning use of Pfizer- BioNTech and the Moderna COVID-19 vaccines in the U.S. population for children ages six months through five years, consistent with the parameters of the Emergency Use Authorizations (EUAs) issued by FDA, for the Pfizer- BioNTech and the Moderna COVID-19 vaccines.[1]

By Secretarial Directive on June 24, 2022, HHS ratified the Centers of Disease Control and Prevention (CDC) recommendations concerning use of COVID-19 vaccines in the U.S. population for children ages six through 17 years, consistent with the parameters of EUAs issued by FDA.

The CDC also currently recommends the COVID-19 vaccine during pregnancy.[2]

Based on a review of the recommendation of the FDA and National Institutes of Health (NIH), I have determined that the known risks associated with use of COVID-19 vaccines in healthy U.S. children ages six months to 17 years do not outweigh the purported benefits of the vaccine. Accordingly, the HHS Secretarial Directives ratifying CDC recommendations for use of COVID-19 vaccines for children ages six months to 17 years and are rescinded.

Based on a review of the recommendation of the FDA, I have similarly determined that the lack of high-quality data demonstrating safety of the mRNA vaccines during pregnancy combined with the uncertainty of the benefits of vaccination pose potential risks to the mother and developing baby. Therefore, the CDC recommendation that pregnant women receive the COVID-19 vaccine is rescinded.

Accordingly, the CDC is directed to remove COVID-19 vaccines from the recommended Child and Adolescent Immunization Schedule by Age and recommended vaccines during pregnancy, as noted above.

Robert F. Kennedy, Jr.
Secretary

[1] The Pfizer and Moderna vaccines are currently approved by the FDA for children 12 years of age and older.
[2] https://www.cdc.gov/vaccines-pregnancy/recommended-vaccines/index.html.

EXHIBIT B

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ACIP 2025

Thimerosal as a Vaccine Preservative

Prepared for the Advisory Committee for Immunization Practices

Lyn Redwood RN, MSN, FP (Retired)

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The Food and Drug Administration Modernization Act of 1997

- Compiled list of drugs and foods that contained intentionally introduced mercury compounds
- Provided quantitative and qualitative analysis of mercury compounds
- Report included 219 products which included 11 biologics and immunoglobulin therapies

Ref: U.S. Congress. (1997, November 21). Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296.

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1999 Joint Statement by US Public Health Service (PHS) and American Academy of Pediatrics (AAP)

- On July 9th, 1999, a joint statement issued by PHS and AAP called for the immediate reduction and elimination of the mercury based preservative thimerosal from infant vaccines based on the findings that infants and children who received vaccines preserved with thimerosal **could be exposed to mercury in excess of federal safety guidelines.**

- "because any potential risk is of concern, the Public Health Service (PHS), the American Academy of Pediatrics (AAP), and vaccine manufacturers agree that thimerosal-containing vaccines should be removed as soon as possible."

Thimerosal in Vaccines: A Joint Statement of the American Academy of Pediatrics and the Public Health Service. MMWR Weekly. July 09, 1999 / 48(26);563-565.

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Institute of Medicine
Immunization Safety Review of Thimerosal Containing Vaccines and Neurodevelopmental Disorders (October 2001)

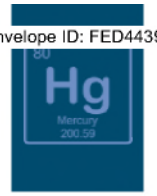
- The committee "supported prior decisions made by the ACIP and AAP to call for the removal of thimerosal from vaccines that are part of the recommended childhood immunization schedule." But they noted that "vaccines that are not part of the recommended childhood immunization schedule still contain thimerosal as a preservative and may be given to some children" and a lingering concern that there remains "on the shelf" an unknown quantity of thimerosal-containing Hib, hepatitis B, and DTaP vaccines.

- Recommended: "the use of thimerosal free DTaP, HiB and Hepatitis B vaccines despite the fact that there might be remaining supplies available" and "full consideration be given by appropriate professional societies and government agencies to removing thimerosal from vaccines administered to infants, children or pregnant women in the united States."

Institute of Medicine (US) Immunization Safety Review Committee; Stratton K, Gable A, McCormick MC, editors. Immunization Safety Review: Thimerosal-Containing Vaccines and Neurodevelopmental Disorders. Washington (DC): National Academies Press (US); 2001. Immunization Safety Review, Thimerosal-Containing Vaccines and Neurodevelopmental Disorders. Available from: https://www.ncbi.nlm.nih.gov/books/NBK223724/

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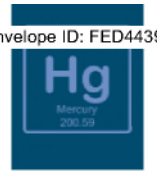
Safety Studies
Prior to Marketing Thimerosal as Vaccine Preservative

- In 1997, FDA Modernization Act prompted assessment of thimerosal use in vaccines.
- FDA was unable to find any clinical studies formally evaluating the use of thimerosal before its initial marketing in 1930's. (1)
- Single study published in 1931 where thimerosal administered to individuals suffering from meningitis. (2)
  - Not designed to specifically examine toxicity and no clinical assessments or laboratory studies reported.
- FDA grandfathered in the use of thimerosal and did not require the typical animal safety data for finished biological products, including active and inactive ingredients. (3)

(1) Ball LK, Ball R, Pratt RD. An assessment of thimerosal use in childhood vaccines Pediatrics. 2001;(107)5:1147-1153.
(2) Powell HM, Jamieson WA. Merthiolate as a germicide. Am J. Hyg. 1931;(13):296-310.
(3) Department of Health and Human Services. 21 Code of Federal Regulations: 601.25. 1985

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Thimerosal use in vaccines

- Thimerosal was first introduced as a preservative in vaccines in the 1930's after being developed and patented in 1927 and subsequently marketed by Eli Lilly under the trade name "Merthiolate" in 1928.

- After a deadly incident of bacterial contamination of vaccines in Australia where 12 children died from staphylococcal-contaminated diphtheria vaccine, the FDA began enforcing safety standards which led to regulations requiring that all multidose vaccines contain a preservative to prevent contamination.

- Thimerosal was used during the manufacturing process and in multi-dose vials to prevent bacterial and fungal contamination. By the 1930's thimerosal became widely used as a preservative in vaccines and other medical products.

Ref: 1. Ball LK, Ball R, Pratt RD. An assessment of thimerosal use in childhood vaccines Pediatrics. 2001;(107)5:1147-1153.
2. Powell HM, Jamieson WA. Merthiolate as a germicide. Am J. Hyg. 1931;(13):296-310.
3. Department of Health and Human Services. 21 Code of Federal Regulations: 601.25. 1985

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Thimerosal Not Generally Recognized as Safe and Effective (GRASE) in OTC Drugs

- In 1975, FDA convened panel of experts to evaluate the use of mercury-containing over-the-counter (OTC). The panel found evidence that thimerosal was "35.3 times more toxic for embryonic chick heart tissue than for Staphylococcus aureus" and "was no better than water in protecting mice from potential fatal streptococcal infections."

- The FDA issued a report of the panel's findings in the Federal Register in 1982 which concluded that "thimerosal was not safe for OTC topical use because of its potential for cell damage if applied to broken skin and its allergy potential, not effective "because bacteriostatic action could be reversed."

- In response to the expert panels report, the FDA published final rules in the Federal Register in 1998 that concluded **the use of thimerosal in over-the-counter products is not "generally recognized as safe or effective." (GRASE)**

Ref: Federal Register, Department of Health and Human Services, Food and Drug Administration. *Mercury-Containing Drug Products for Topical Antimicrobial Over-the-Counter Human Use; Establishment of a Monograph.* (January 5, 1982);47(2):436-442. 47 FR 436 [Docket No. 75N-0183(1) Federal Register, Department of Health and Human Services, Food and Drug Administration. Status of Certain Additional Over-the-Counter Drug Category II and III Active Ingredients. (April 22, 1998);63(77):19799-19802. 21 CFR Part 310 [Docket No. 75N-183F, 75N-183D, and 80N-0280.

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Evidence of Thimerosal Ineffectiveness as a Preservative

- In 1982, clusters of disease from Group A streptococcus infections were traced back to multi-dose vials of diphtheria toxoid, pertussis, and tetanus toxoid (DPT) vaccine which were contaminated after being opened. Thimerosal was present in acceptable limits in unopen vials of vaccine from the same lot. The authors concluded that **"Preservatives in multidose vials do not prevent short term bacterial contamination**" and the **"only feasible and cost-effective preventative measure now available is careful attention to sterile technique when administering vaccines from multidose vials."**

- In 2004, a Chiron plant that manufactured Fluvirin vaccine preserved with thimerosal was forced to close because its vaccine was contaminated with Serratia marcescens. The closure created shortages in the vaccine supply and caused concern among providers and patients. In this case and others, thimerosal failed to prevent bacterial growth.

Stetler HC, Garbe PL, Dwyer DM, Facklam RR, Orenstein WA, West GR, Dudley KJ, Bloch AB. Outbreaks of group A streptococcal abscesses following diphtheria-tetanus toxoid-pertussis vaccination. Pediatrics. 1985 Feb;75(2):299-303. PMID: 3881728.
Smith S. Safety fears cut vaccine for flu. Priority urged for the aged, frail. *Boston Globe*. (October 6, 2004).
http://www.boston.com/news/globe/health_science/articles/2004/10/06/safety_fears_cut_vaccine_for_flu?mode=PF

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Current Research
Thimerosal safety and effectiveness

- A more current in vitro investigation into the cytotoxic effects and antimicrobial activity of thimerosal was published in 2023. The authors reported that thimerosal **should be present in culture media at 100 µg/ml** concentration to achieve effective antimicrobial activity. **But all tested cell lines lost viability completely at 4.6 µg/mL.**

- "Overall, our study revealed **Thimerosal was 333-fold more cytotoxic to human and animal cells as compared to bacterial and fungal cells**. Our results promote more study on Thimerosal toxicity and its antimicrobial effectiveness to obtain more safe concentrations in biopharmaceuticals."

Rahimian A, Lakzaei M, Askari H, Dostdari S, Khafri A, Aminian M. In vitro assessment of Thimerosal cytotoxicity and antimicrobial activity. J Trace Elem Med Biol. 2023 May;77:127129. doi: 10.1016/j.jtemb.2023.127129. Epub 2023 Jan 4. PMID: 36630761.

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Evidence of Thimerosal
Developmental Neurotoxicity

- In 1987 the Commission of the European Communities initiated a research project on 10 known or suspected spindle poisons. Thimerosal was found to cause significant interference with microtubule polymerization destabilizing the spindle machinery that ensures accurate chromosome separation during cell division.
- This mechanistic disruption suggests direct mutagenic potential via structural chromosomal abnormalities, which is a known pathway to carcinogenesis or congenital defects.
- By affecting fundamental cellular structures at the molecular level, thimerosal revealed **“strong mechanistic evidence for mutagenicity and developmental toxicity”.**

Wallin, M. (1993). Effects of potential aneuploidy-inducing agents on microtubule assembly in vitro.
Mutation Research. Fundamental and Molecular Mechanisms of Mutagenesis, 287(1), 17–22. https://doi.org/10.1016/0027-5107(93)90141-2

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CALIFORNIA EPA Proposition - 65

- California's Proposition 65, requires identification of chemicals known to cause cancer, birth defects or other reproductive harm, and to ensure public warnings when people might be exposed to them. Thimerosal has been on the Prop-65 list since 1990.

- In 2003 a petition was filed on behalf of the Bayer Corporation "for reconsideration of the determination that mercury and mercury compounds (thimerosal) as reproductive toxicants."

- The CA EPA responded that "The scientific evidence that thimerosal cause reproductive toxicity is clear and voluminous. Thimerosal dissociates in the body to ethyl mercury. **The evidence for its reproductive toxicity includes severe mental retardation or malformations in human offspring who were poisoned when their mothers were exposed to ethyl mercury or thimerosal while pregnant,** studies in animals demonstrating developmental toxicity after exposure to either ethyl mercury or thimerosal, and data showing interconversion to other forms of mercury that also clearly cause reproductive toxicity."

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Evidence From Human Research (1)

- A study published in Pediatrics in 2000 measured blood mercury levels in preterm and term infants after administration of the Hepatitis B vaccine containing 12.5 µg ethyl mercury.
- The investigation documented elevated post-immunization concentrations relative to pre-immunization levels in all neonates studied. Levels of blood mercury after exposure in low-birth-weight infants were 7.36 (± 4.99) µg/L.
- One infant was found to have developed a mercury level of 23.6 µg/L, thus meeting the CDC criteria as a case of chemical poisoning from mercury 10µg /L. The study subjects had measurable blood Hg concentrations prior to immunization, indicating that risk assessment must include background mercury levels from other sources.

Stajich GV, Lopez GP, Harry SW, Sexson WR. Iatrogenic exposure to mercury after Hepatitis B vaccination in preterm infants. J.Pediatrics. 2000;136 (5):679-81.
Centers for Disease Control and Prevention. (2005, January 14). Case Definitions for Chemical Poisoning. MMWR Recommendations and Reports, 54(RR-1), 1–24. Retrieved from https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5401a1.htm

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Evidence From Human Research (2)

- Experts contend that there are “windows of vulnerability” which occur during neurological development and that specific types of developmental outcomes may have separate windows of vulnerability. These critical periods of development have not been established and may be relatively short in duration.

- The fact that thimerosal from vaccines has been documented to raise blood mercury levels over known thresholds where developmental effects have been documented to occur during the first few months of life, means that particular "windows of vulnerability" may have been breached. Even minor neurological impairment can have profound societal effects when amortized across the entire population and life span.

Rice D, Barone S Jr. Critical periods of vulnerability for the developing nervous system: evidence from humans and animal models. Environ Health Perspect. 2000;108 Suppl 3:511-33.

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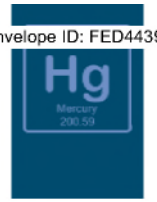
Exposure To Vaccine Level Thimerosal Crosses the Blood Brain Barrier and Results in Significant Deposition of Mercury in the Brain

- A 2005 study funded by NIH compared brain mercury levels in infant *Macaca fascicularis* primates exposed to: 1) injected ethyl mercury (thimerosal) and 2) equal amounts of ingested methylmercury.
- Ethyl mercury more rapidly converted to inorganic mercury in the brains of the primates which resulted in increasing levels of inorganic mercury.
- Primates exposed to ethyl mercury retained much higher levels of inorganic mercury in their brains, up to 71% vs. 10% compared to primates exposed to methyl mercury.
- Once organic mercury compounds reach the brain tissue and dealkylate, Hg2+ (toxic inorganic mercury) the mercury cannot cross the blood brain barrier and becomes trapped, resulting in neuroinflammation.

Burbacher TM, Shen DD, Liberato N, Grant KS, Cernichiari E, and Clarkson T. Comparison of blood and brain mercury levels I infant monkeys exposed to methylmercury or vaccines containing thimerosal. Environmental Health Perspectives. 2005;113(8):1015-1021.

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Inorganic Mercury and the Developing Brain

- A recent review outlined evidence from human and animal studies which estimated the inorganic mercury half-life in human brains of at least five to 27 years. (1)

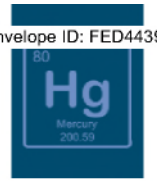
- The impact of mercury exposure to the developing brain interferes with neuronal proliferation, migration, differentiation, synaptogenesis, tightly regulated apoptosis, and other processes vital to the formation and functioning of the nervous system which can result in lifelong neurodevelopmental impacts.

- Exposure during the first trimester of pregnancy may result in deficits or defects very different from those developed by someone who is exposed during the third trimester of pregnancy. **"There may never be a safe level of mercury exposure, especially for an unborn child." (2)**

1.Rooney JP. The retention time of inorganic mercury in the brain--a systematic review of the evidence. Toxicol Appl Pharmacol. 2014 Feb 1;274(3):425-35.
2. Pletz J, Sánchez-Bayo F, Tennekes HA. Dose-response analysis indicating time-dependent neurotoxicity caused by organic and inorganic mercury-Implications for toxic effects in the developing brain. Toxicology. 2016 Mar 10;347-349:1-5. doi: 10.1016/j.tox.2016.02.006. Epub 2016 Mar 2. PMID: 26945727.

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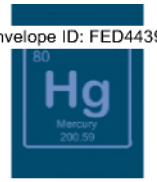


Mercury Content In Thimerosal-containing Flu Vaccines

- Thimerosal is ~49.6% mercury by weight with a concentration of 0.01% thimerosal in vaccines. This equates to 100 µg/mL of thimerosal and 50 µg/mL of ethyl mercury per ml.
- The EPA's Toxicity Characteristic Leaching Procedure (TCLP) determines whether a substance is considered hazardous waste based on its potential to leach toxic chemicals into groundwater.
- According to EPA TCLP Mercury Threshold (40 CFR § 261.24) the regulatory threshold for mercury (D009) under TCLP is: 0.2 mg/L (200 parts per billion, or 200 µg/L).
- Flu vaccine mercury concentration (~50,000 µg/L) is 250 times greater than the TCLP limit. **Therefore, thimerosal-containing vaccines exceed the TCLP threshold by orders of magnitude and are classified as D009 Hazardous Waste**

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Vaccine Mercury: Disposal Guidelines

PHARMECOLOGY® WM

PharmEcology® Provides Disposal Guidelines for the 2024-2025 Flu Season

PharmEcology Services, a division of WM Sustainability Services, is pleased to publish a summary of the proper flu vaccine disposal guidelines for the 2024-2025 flu season as a public service to the healthcare community. Please also see additional information regarding this year's vaccines following the table below.

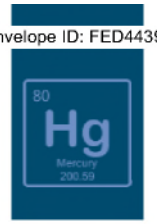
Flu vaccine summary table:

The table below summarizes the waste categorizations of the specific products available this season. Applying EPA's federal regulations to the flu vaccines, the vaccines meet the toxicity characteristic when the concentration of mercury is equal to or greater than 0.2mg/liter as a result of performing a test known as the toxicity characteristic leaching procedure (TCLP).

While we do not have results for such tests for vaccines, a calculation of the concentration of mercury in vaccines in which thimerosal is present as a preservative would cause the waste vaccine to fail the TCLP. Unless a manufacturer provides actual TCLP data indicating the mercury level to be below 0.2mg/liter or a healthcare facility has the test performed and the waste does not fail the TCLP, any vaccine waste containing thimerosal as a preservative should be managed as a toxic hazardous waste. As a result, all full or partially used multi-dose vials of the seasonal flu vaccine should be disposed of as federally hazardous waste, waste code D009 for mercury.

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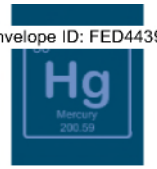


Susceptible Populations

Population	Susceptibility Factors
Fetus / Developing Infant	Rapid neurodevelopment, immature blood-brain barrier, low glutathione, high brain accumulation
Pregnant Women	Placental transfer, fetal susceptibility, breast milk transfer
Young Children	Higher exposure per kg, immature detoxification systems
Older Adults	Reduced renal clearance, pre-existing neurodegenerative conditions
Genetically Susceptible	Impaired detox (e.g., GST, MTHFR, APOE4), mitochondrial dysfunction
High Fish Consumers	Bioaccumulation through predatory fish, dietary exposure
Occupationally Exposed Workers	Inhalation exposure, chronic accumulation (e.g., dentists, miners)

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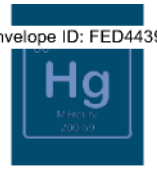


Summary (1)

- Mercury is the third most toxic element on earth, behind polonium and plutonium, and has no physiological role in the human body.
- Thimerosal was grandfathered for use without adequate safety testing by the FDA.
- Thimerosal is not “generally recognized as safe or effective” (GRASE) by the FDA OTC Division since 1998.
- There is evidence that thimerosal is not an effective preservative at vaccine levels.
- Thimerosal can cross the placenta and blood brain barriers and converts to inorganic mercury in the brain at higher levels that methyl mercury.
- Studies have identified infants with blood levels after exposure to thimerosal that breach CDC guidelines for a case of mercury chemical poisoning.

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Summary (2)

- Thimerosal is recognized as a developmental and reproductive toxicant and is listed as a chemical on the California Proposition 65 list since 1990.
- Unused doses of thimerosal preserved flu shots must be disposed of as hazardous waste.
- Tremendous progress has been made in removing thimerosal, but more than 60,000 pregnant mothers receiving Medicaid in the 2019-2020 flu season received TCVs.
- We currently have enough thimerosal free flu vaccines to recommend that all pregnant women, infants and children receive only thimerosal free vaccines.
- After a critical appraisal of this issue almost 25 years ago, the prestigious Institute of Medicine made this same recommendation.
- Removing a known neurotoxin from being injected into our most vulnerable populations is a good place to start with Making America Healthy Again.

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EXHIBIT C

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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

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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

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2024–2025 COVID-19 vaccine recommendations

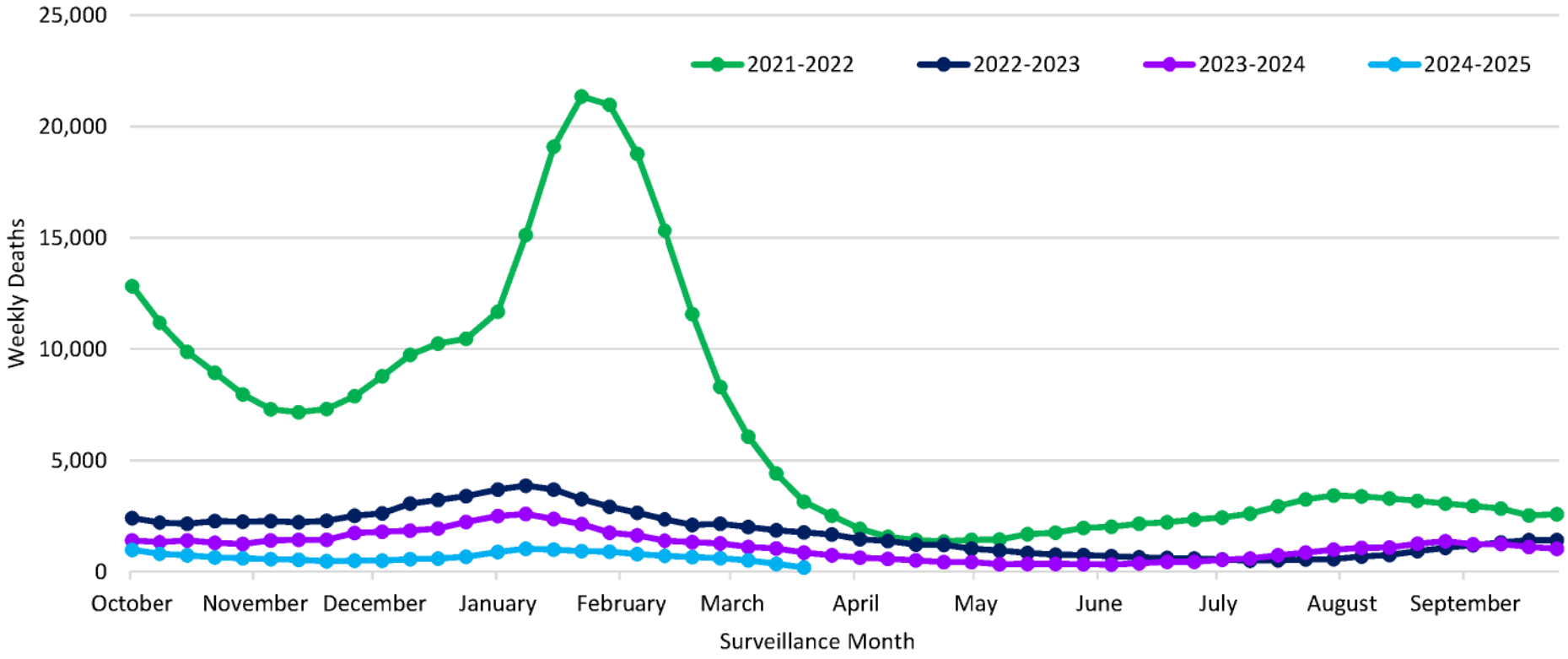
- Everyone aged ≥6 months should receive 2024–2025 COVID-19 vaccination
  - Children aged 6 months–4 years need multiple doses of COVID-19 vaccines to be up to date, including at least 1 dose of 2024–2025 COVID-19 vaccine
  - People aged 5-64 years should get 1 dose[1] of 2024-2025 COVID-19 vaccine
  - 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.

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

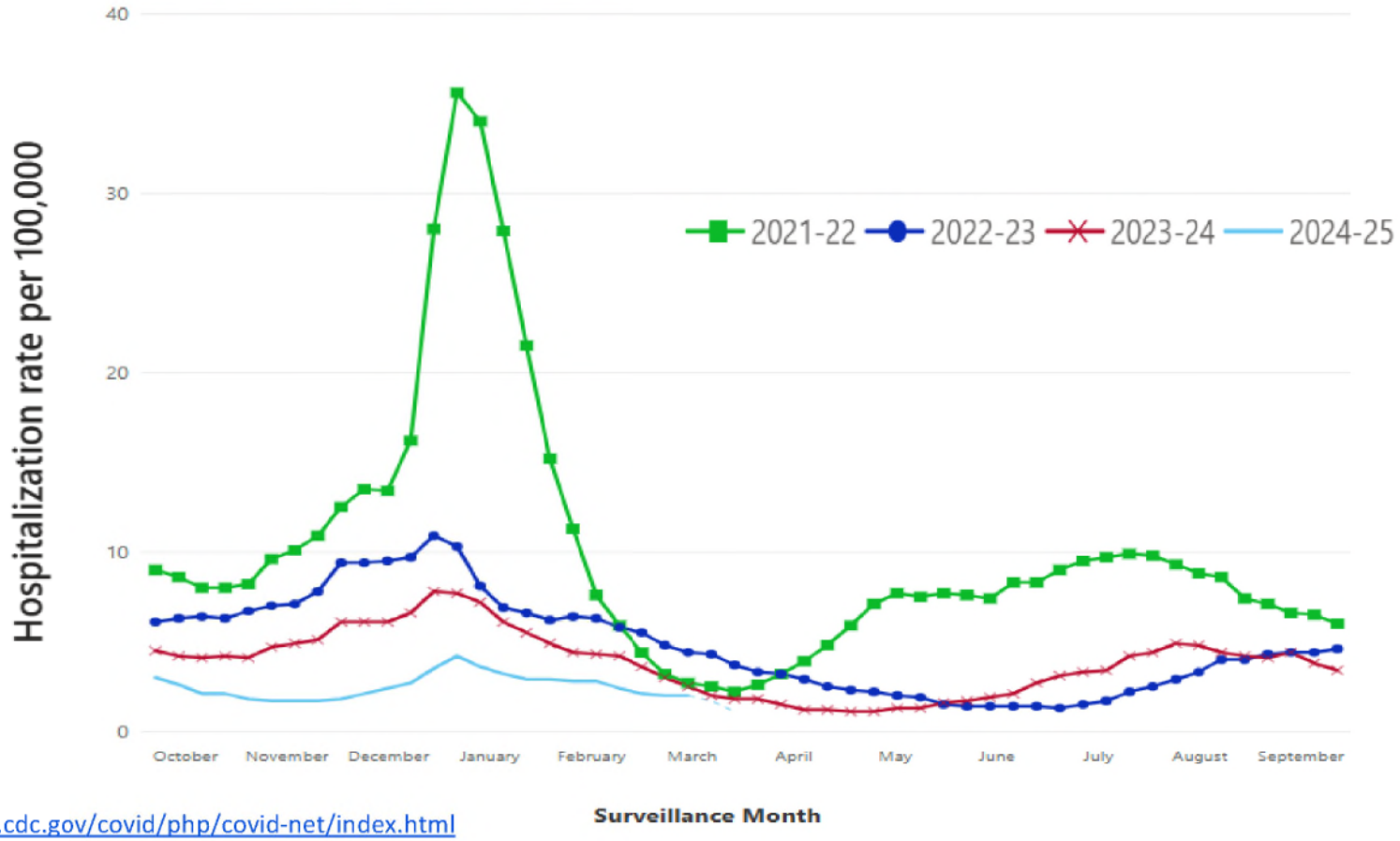


https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00
Accessed April 4, 2025

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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

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

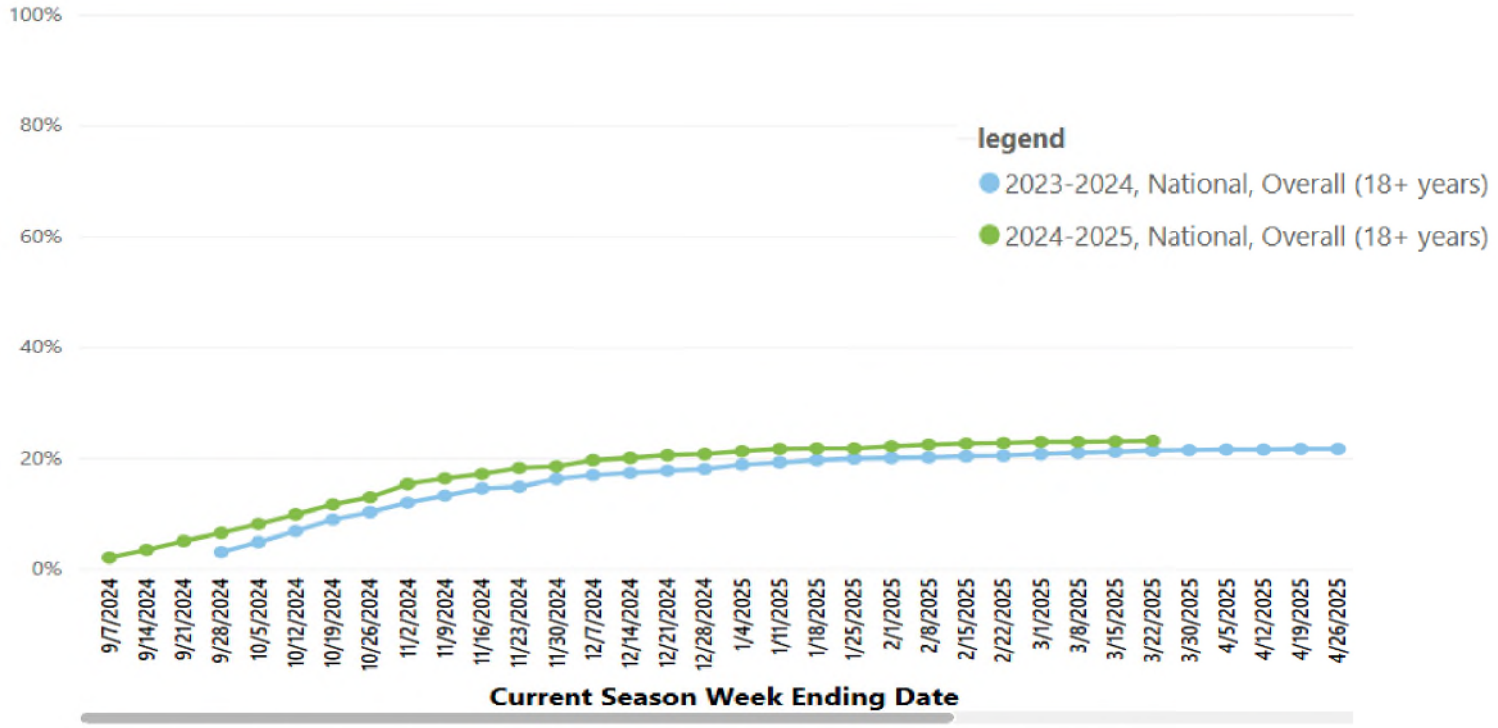
Disease	Illnesses	Outpatient Visits	Hospitalizations	Deaths
COVID-19[1]	7.7 – 13.5 Million	1.9 – 3.2 Million	220,000 – 370,000	26,000 – 43,000
Influenza[2]	44 – 76 Million	20 – 34 Million	580,000 – 1.2 Million	25,000 – 120,000

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

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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

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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

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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**

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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

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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

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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

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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.

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EXHIBIT D

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

Lakshmi Panagiotakopoulos, MD, MPH

Advisory Committee on Immunization Practices

April 15, 2025

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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

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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)**

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Review of 2024–2025 COVID-19 vaccine policy

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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

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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

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

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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

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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.

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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

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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?

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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

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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
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  - 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

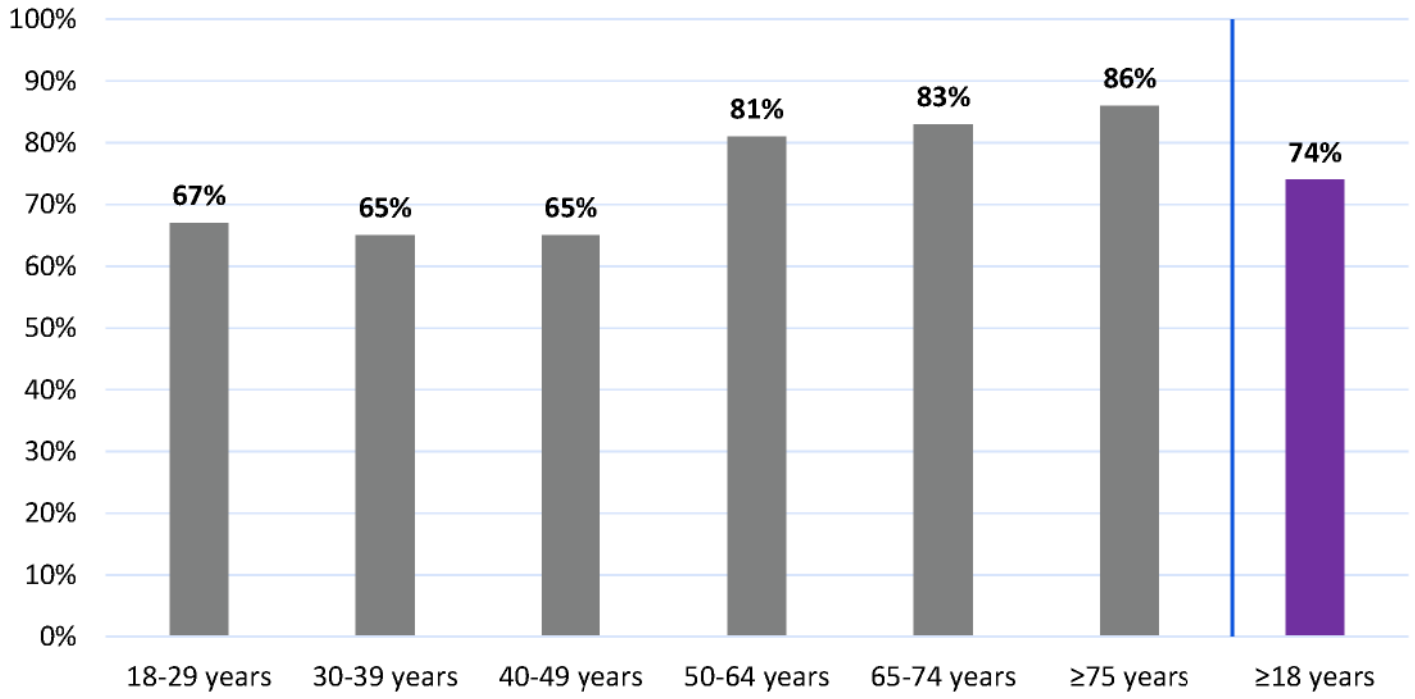
Bolded conditions were included in analysis on prevalence of risk conditions by the Center for Forecasting Analytics (unpublished data); those highlighted by the red boxes were not included

https://www.cdc.gov/covid/hcp/clinical-care/underlying-conditions.html

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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

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Summary of supporting evidence

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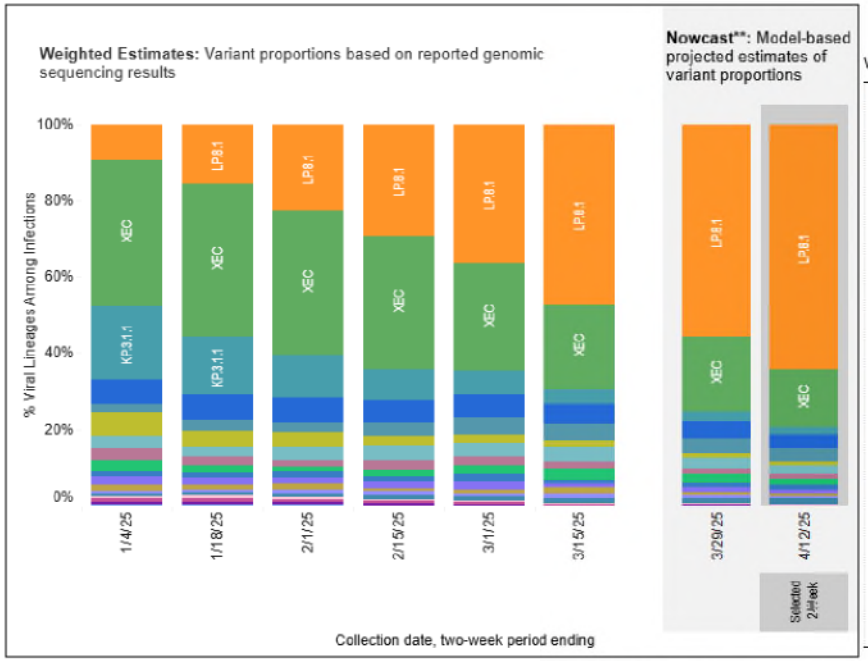
COVID-19 Epidemiology

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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

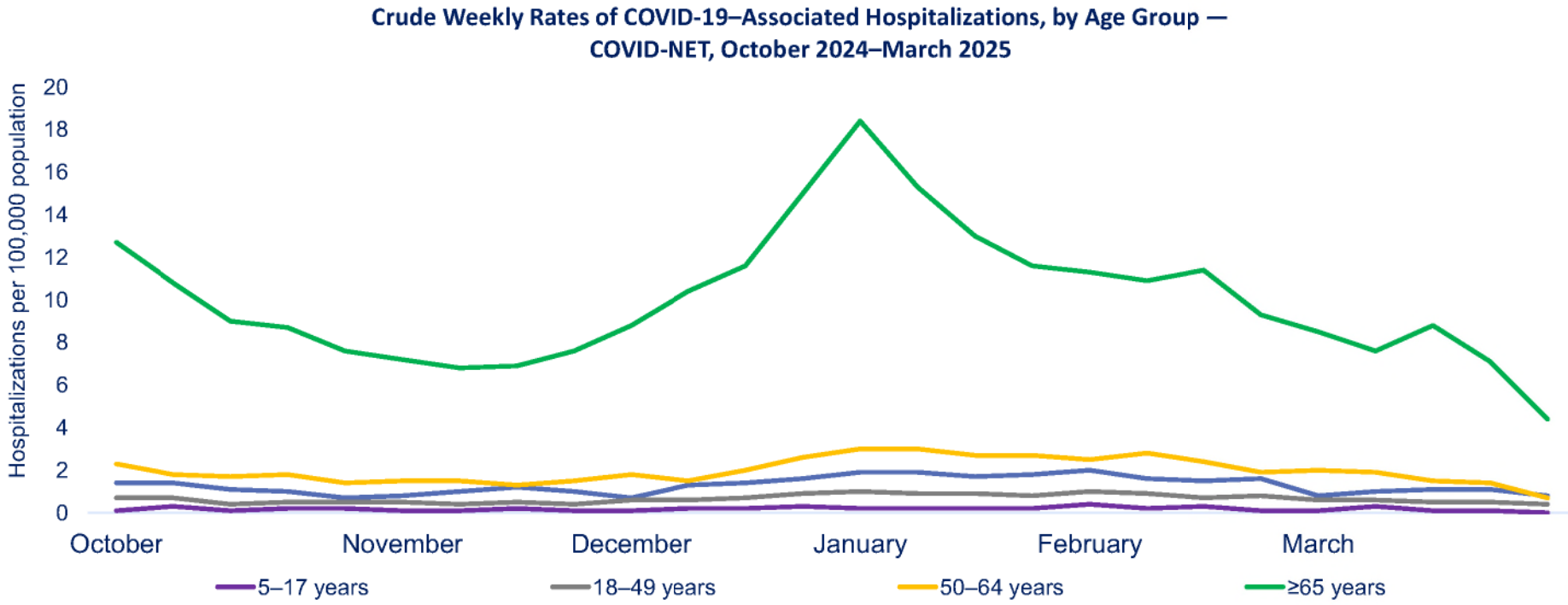
** These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates
# Enumerated lineages are US VOC and lineages circulating above 1% nationally in at least one 2-week period. "Other" represents the aggregation of lineages which are 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

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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.

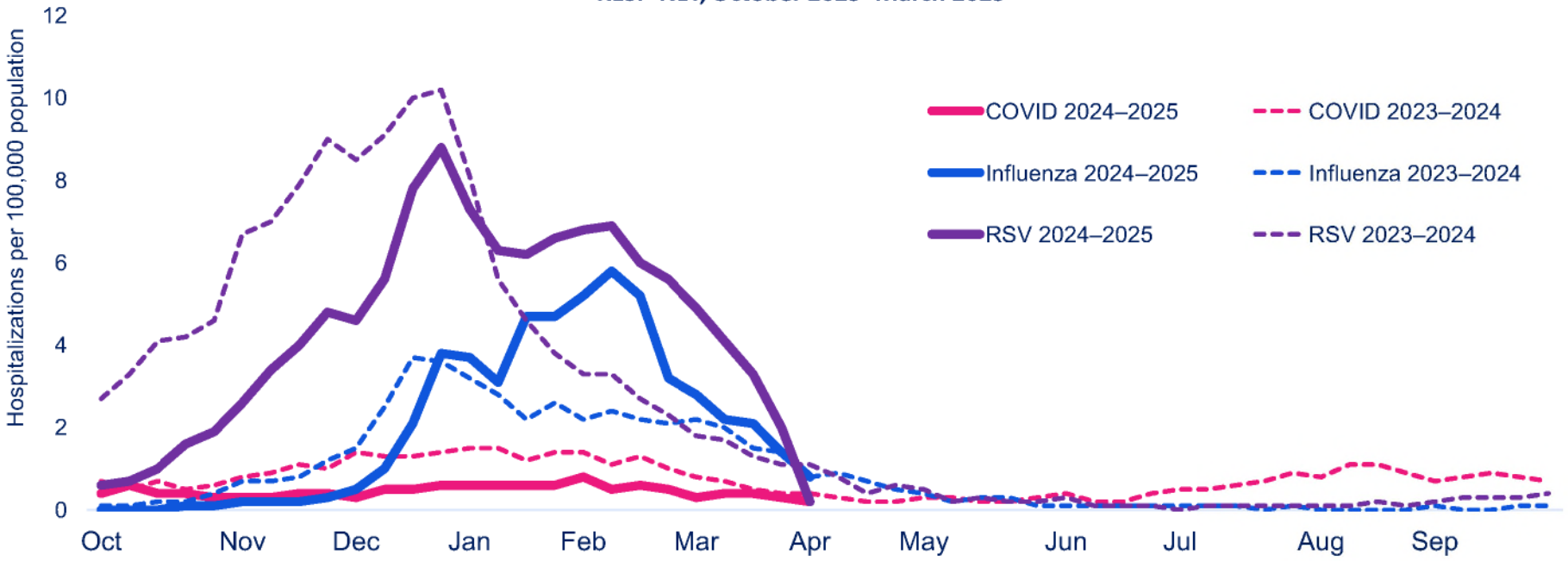
Data source: https://www.cdc.gov/resp-net/dashboard/ Accessed April 7, 2025

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

Crude Weekly Rates of COVID-19–, Influenza, and RSV-Associated Hospitalizations, by Surveillance Season* — RESP-NET, October 2023–March 2025



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

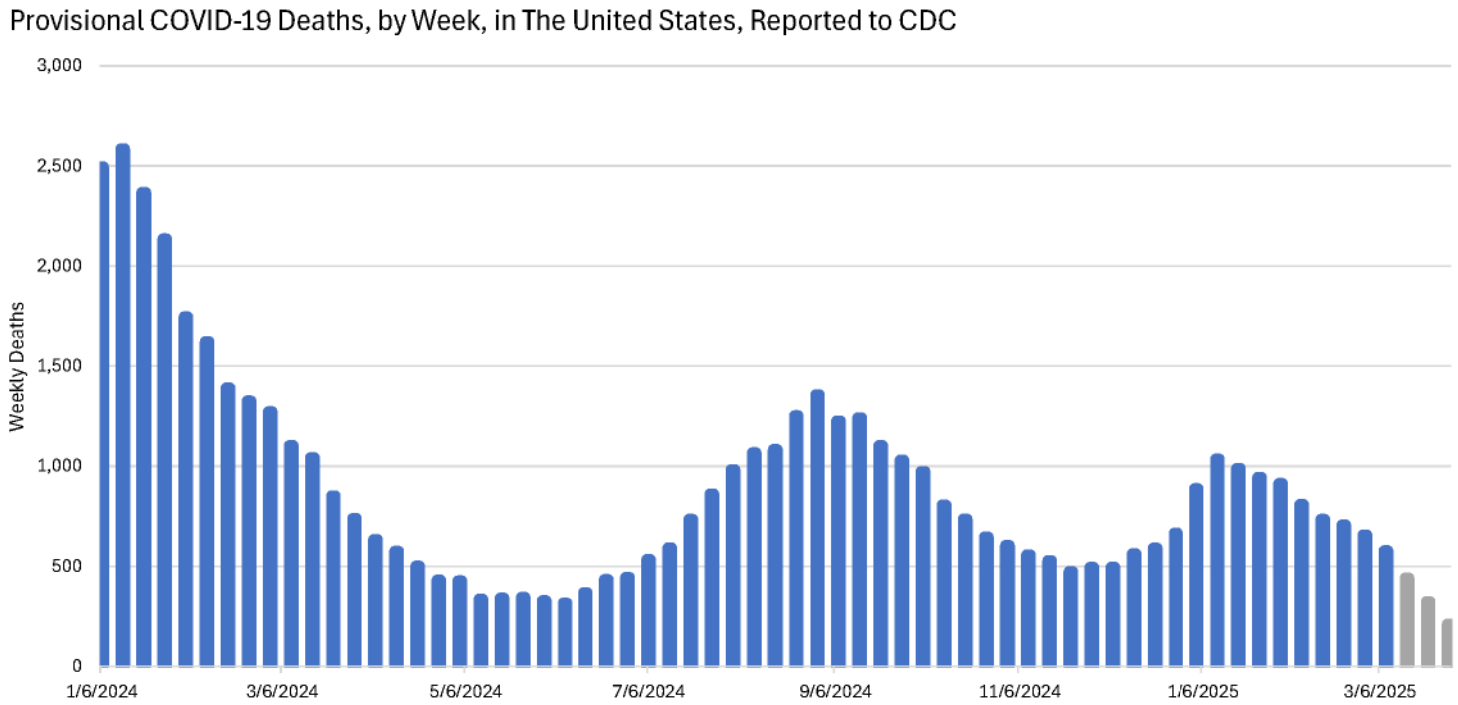
Note that rates are not adjusted for testing or limited to admissions where the respiratory infection is the likely primary reason for admission.

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

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

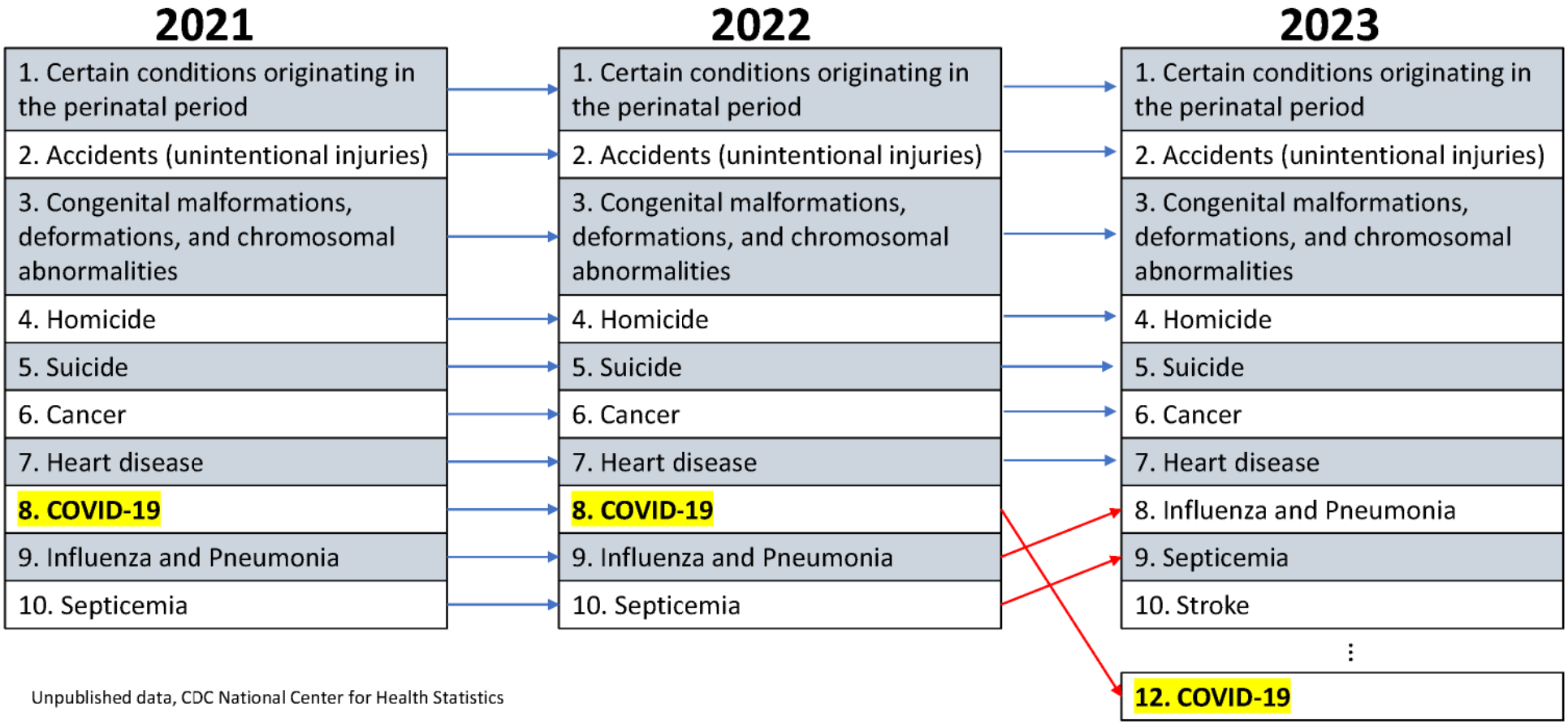


The most recent 3 weeks of mortality counts are shaded grey because NVSS reporting is <95% during this period.
Provisional data are non-final counts of deaths based on reported mortality data in NVSS. Deaths include those with COVID-19, coded as ICD–10 code U07.1, on the death certificate. Death data 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

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

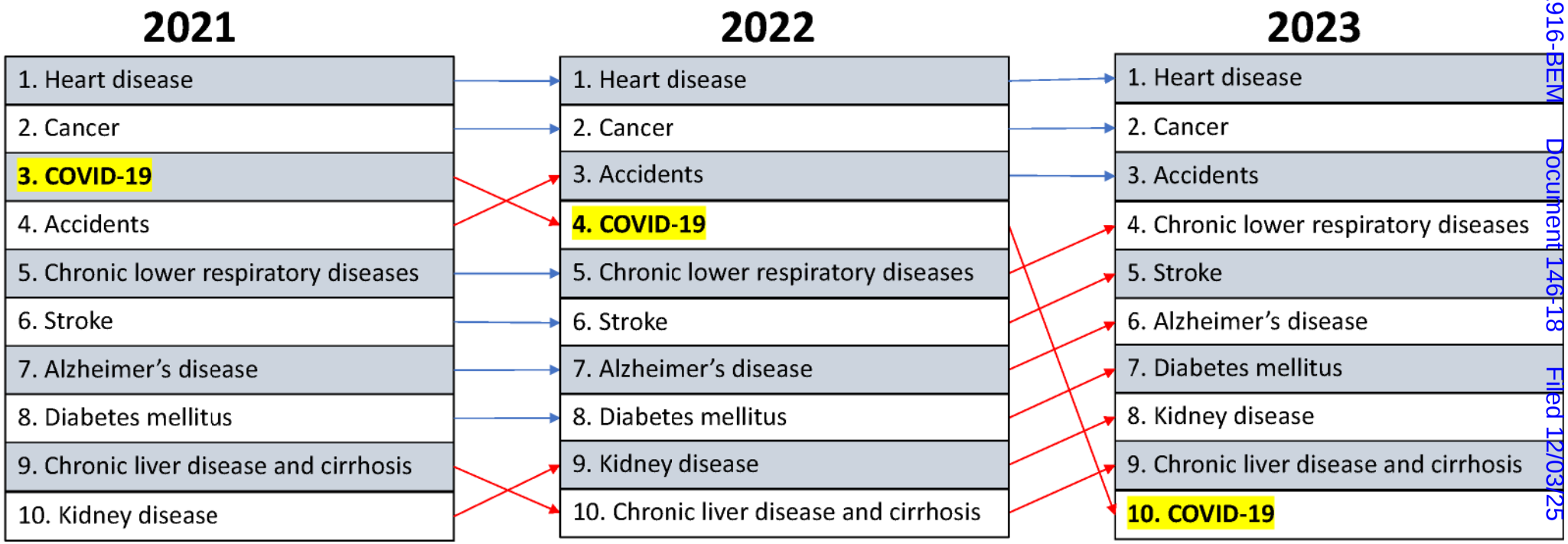


Unpublished data, CDC National Center for Health Statistics

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

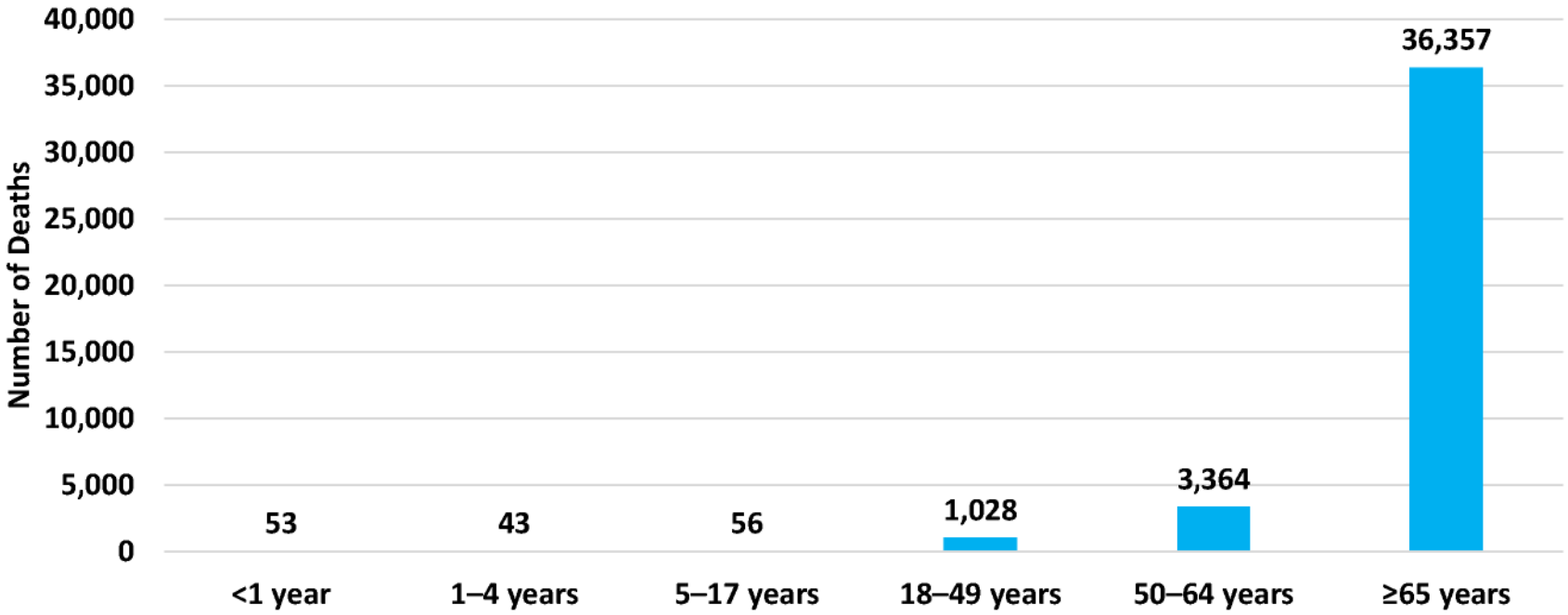


Influenza and pneumonia was ranked 9th pre-pandemic in 2019; ranked 13th in 2023
Unpublished data, CDC National Center for Health Statistics

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

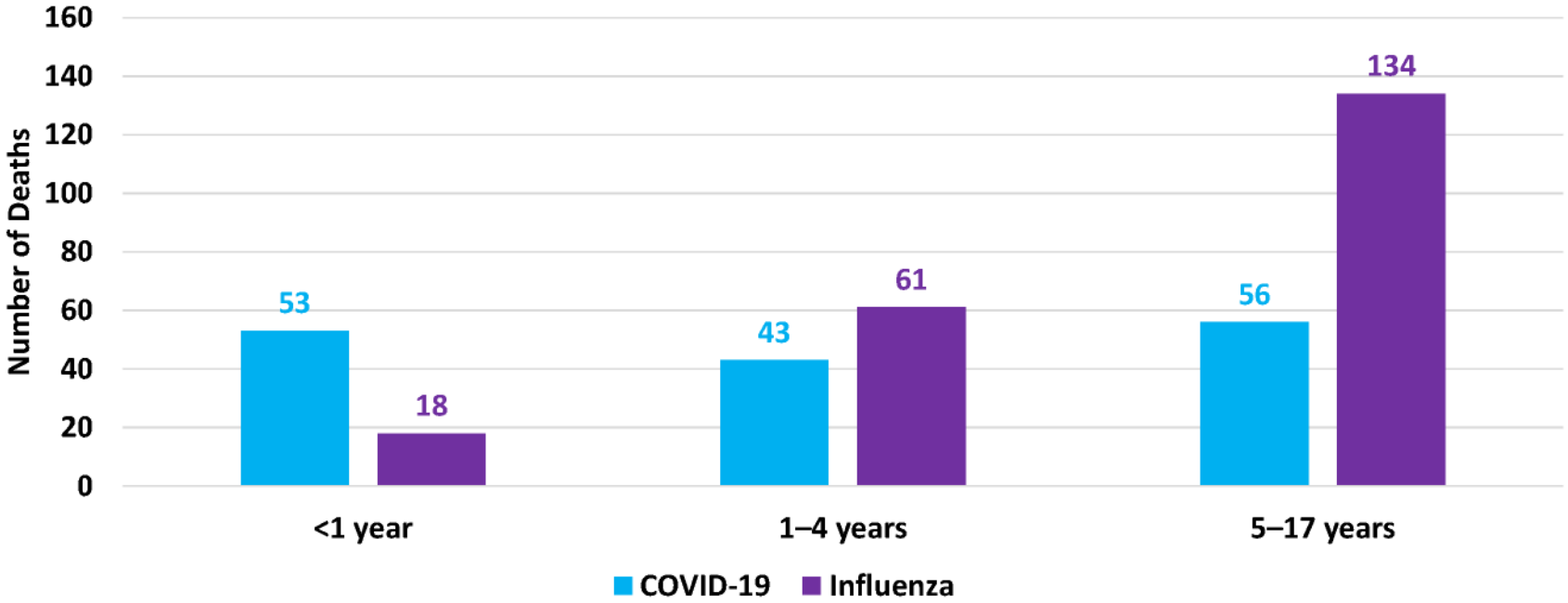


1. Provisional data
2. Underlying cause of death Source: Centers for Disease Control and Prevention, National Center for Health Statistics. National Vital Statistics System, Provisional Mortality on CDC WONDER Online Database. Data are from the final Underlying Cause of Death Files, 2018-2023, and from 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

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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.

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

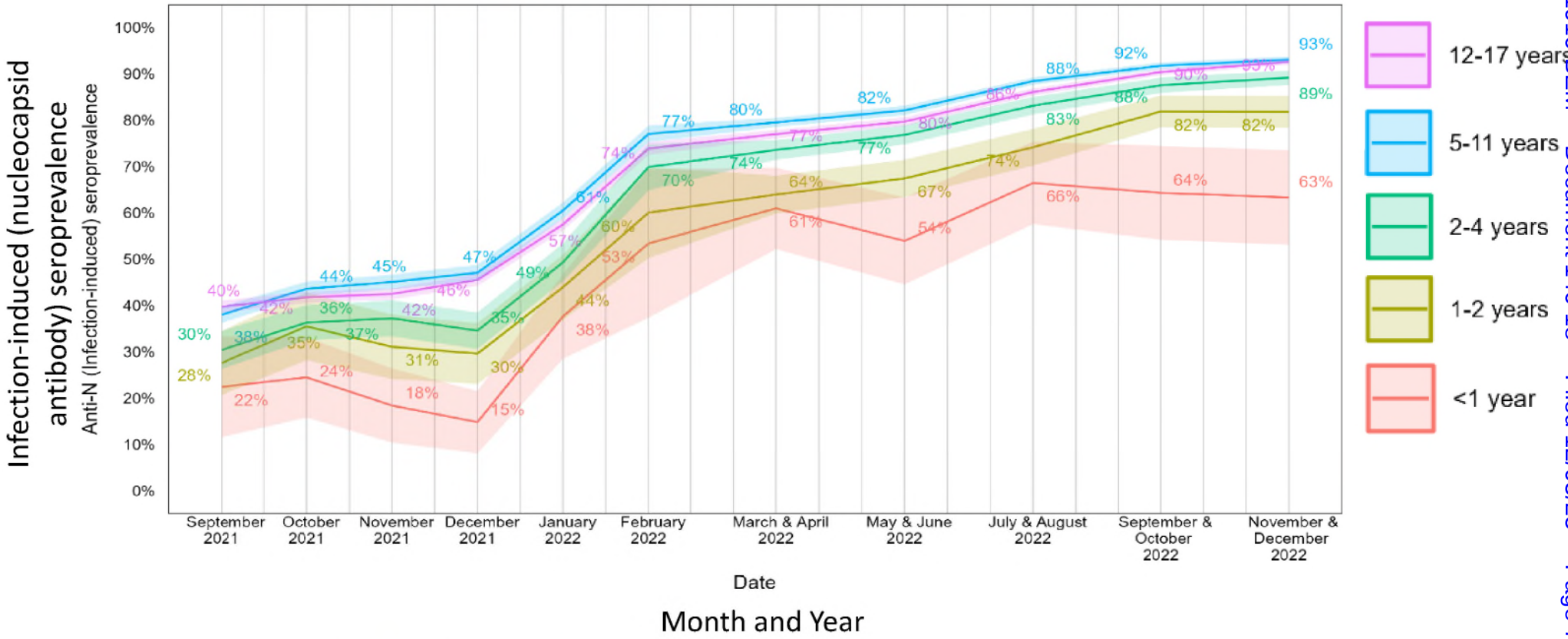
	2023–2024	2024–2025	Difference
Routine vaccine recommendation	6 months and older 65 and older: 2 doses	6 months and older 65 and older: 2 doses	No change
Vaccine coverage <18 years[1]	13.8% (13.4–14.3) (3/23/2024)	12.8% (12.2–13.4) (3/22/2025)	Similar
Vaccine coverage ≥18 years[2]	21.3% (21.0–21.5) (3/23/2024)	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

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

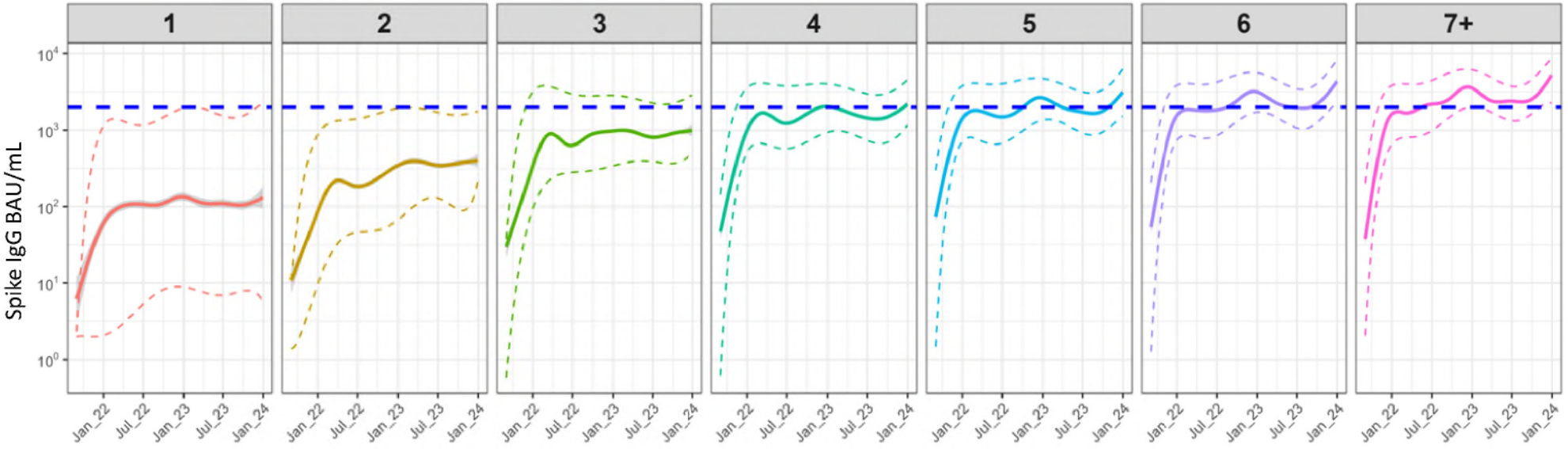


Shaded ranges depict 95% confidence intervals for the estimated seroprevalence shown by the dark line in the corresponding color.
Source: https://covid.cdc.gov/covid-data-tracker/#pediatric-seroprevalence
Accessed: March 20, 2025

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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

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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.

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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

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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

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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

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COVID-19 Vaccine and Myocarditis

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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.

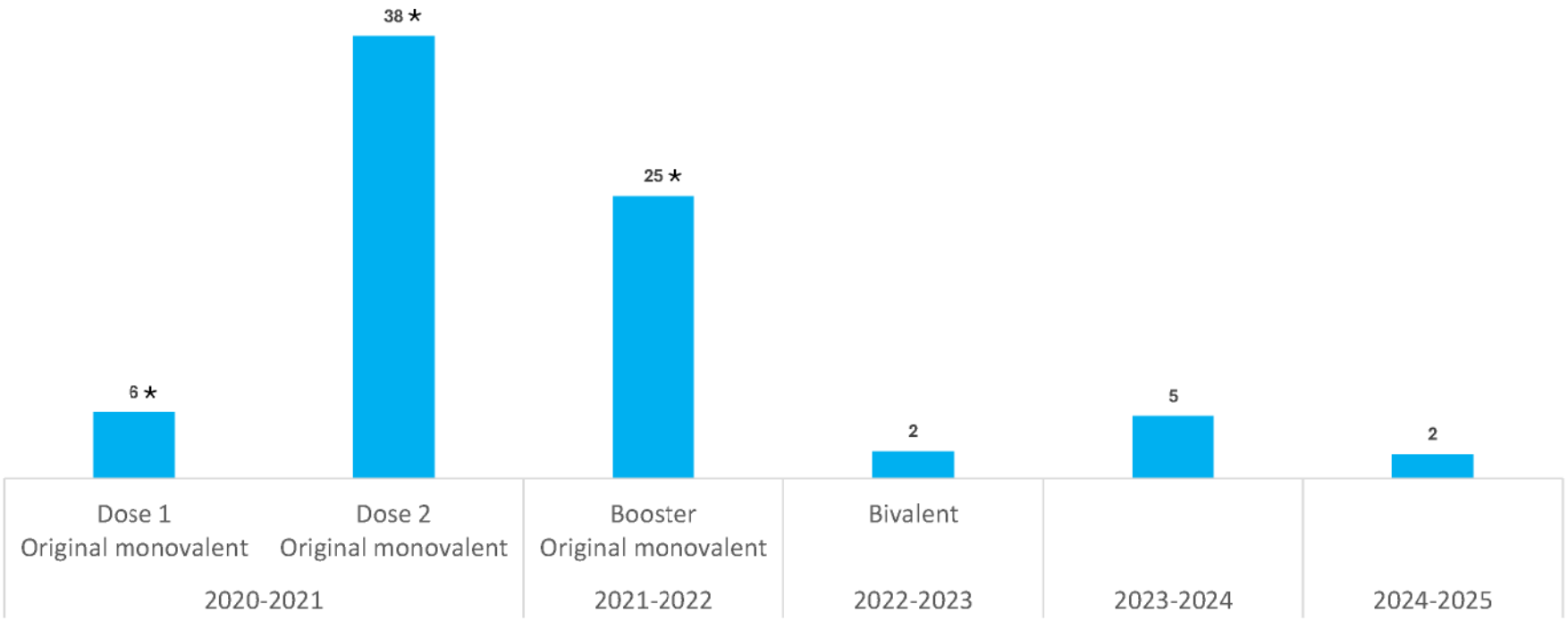
https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines-2024-2025

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Docusign Envelope ID: FED4439D-7C01-49D5-8DDA-EF8BFB3F493E

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

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Docusign Envelope ID: FED4439D-7C01-49D5-8DDA-EF8BFB3F493E

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

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Docusign Envelope ID: FED4439D-7C01-49D5-8DDA-EF8BFB3F493E

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

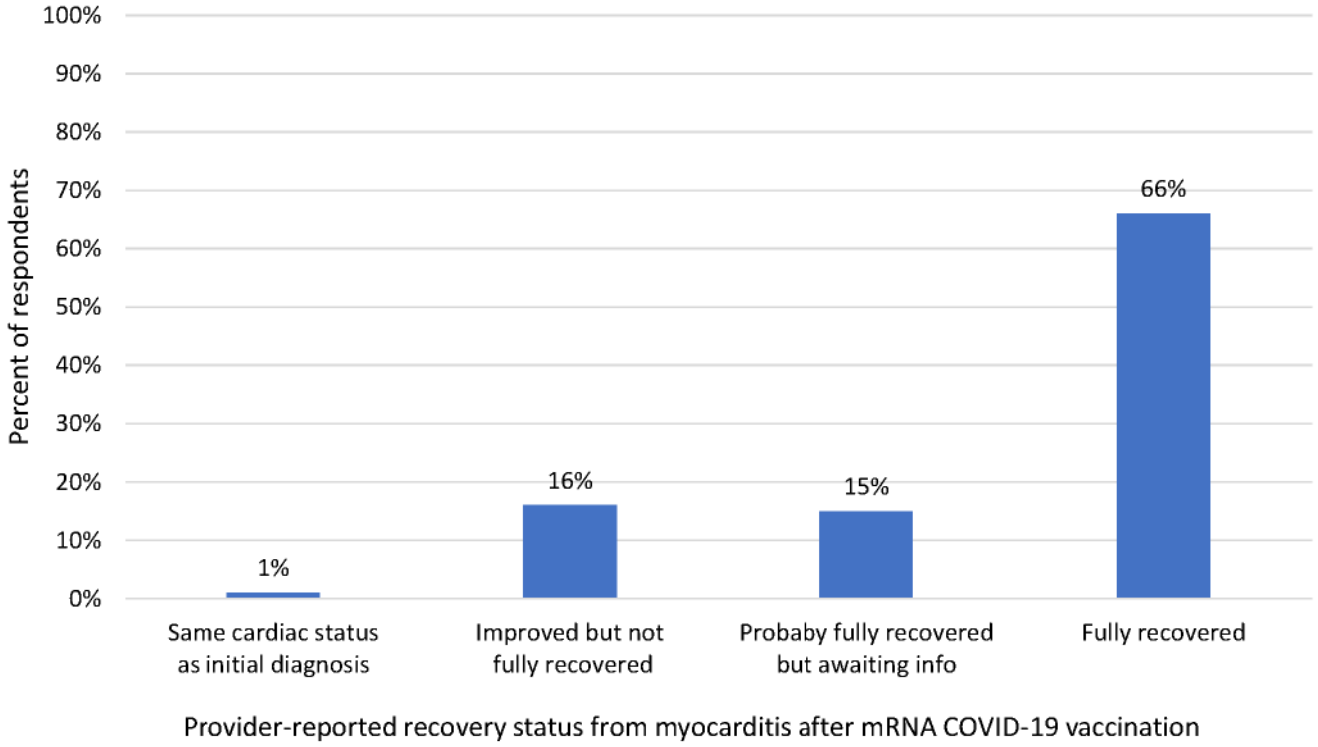
- **The reporting rates are similar to the expected background rates of <2 cases per million doses**

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

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Docusign Envelope ID: FED4439D-7C01-49D5-8DDA-EF8BFB3F493E

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



Provider-reported recovery status from myocarditis after mRNA COVID-19 vaccination

- **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

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Docusign Envelope ID: FED4439D-7C01-49D5-8DDA-EF8BFB3F493E

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.

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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

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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

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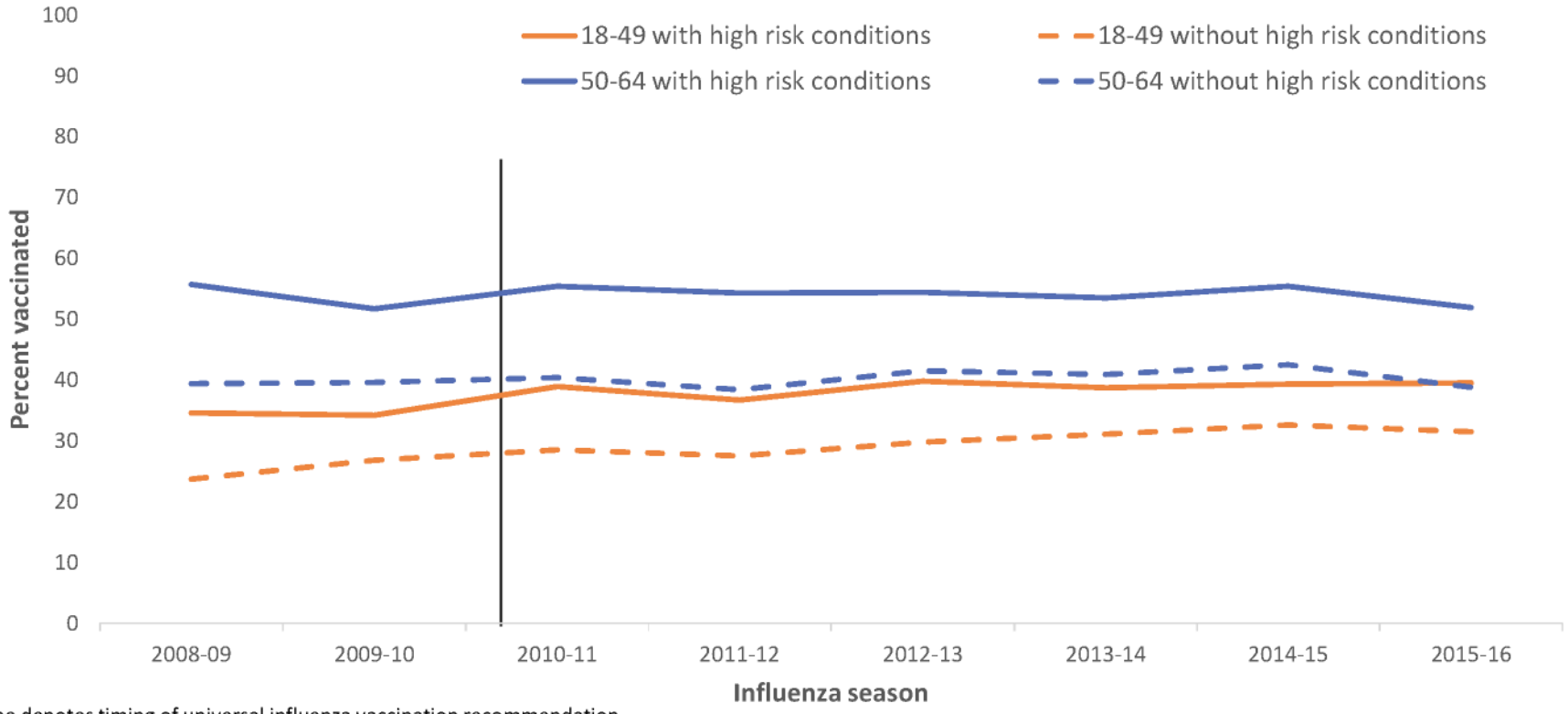
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Risk-based v. universal vaccine recommendations and vaccine coverage

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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

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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

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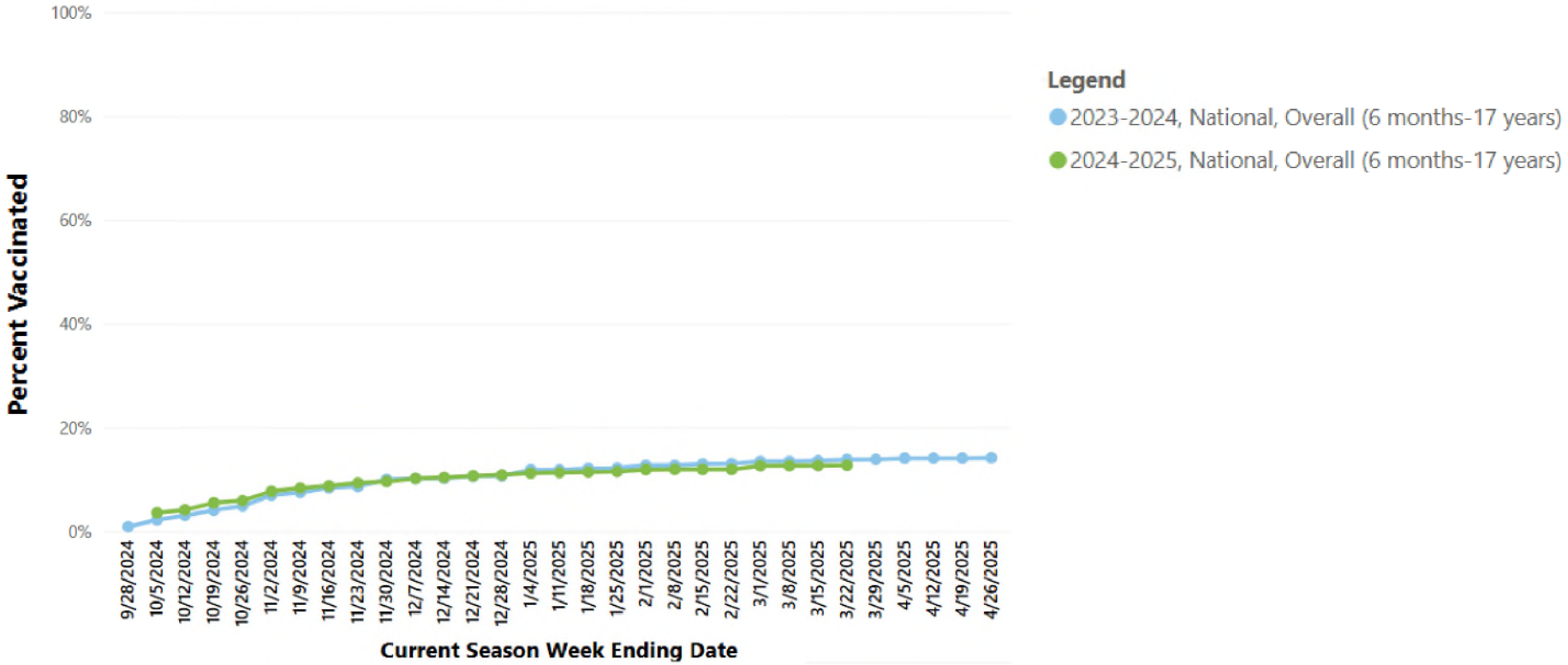
Parental vaccine confidence

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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

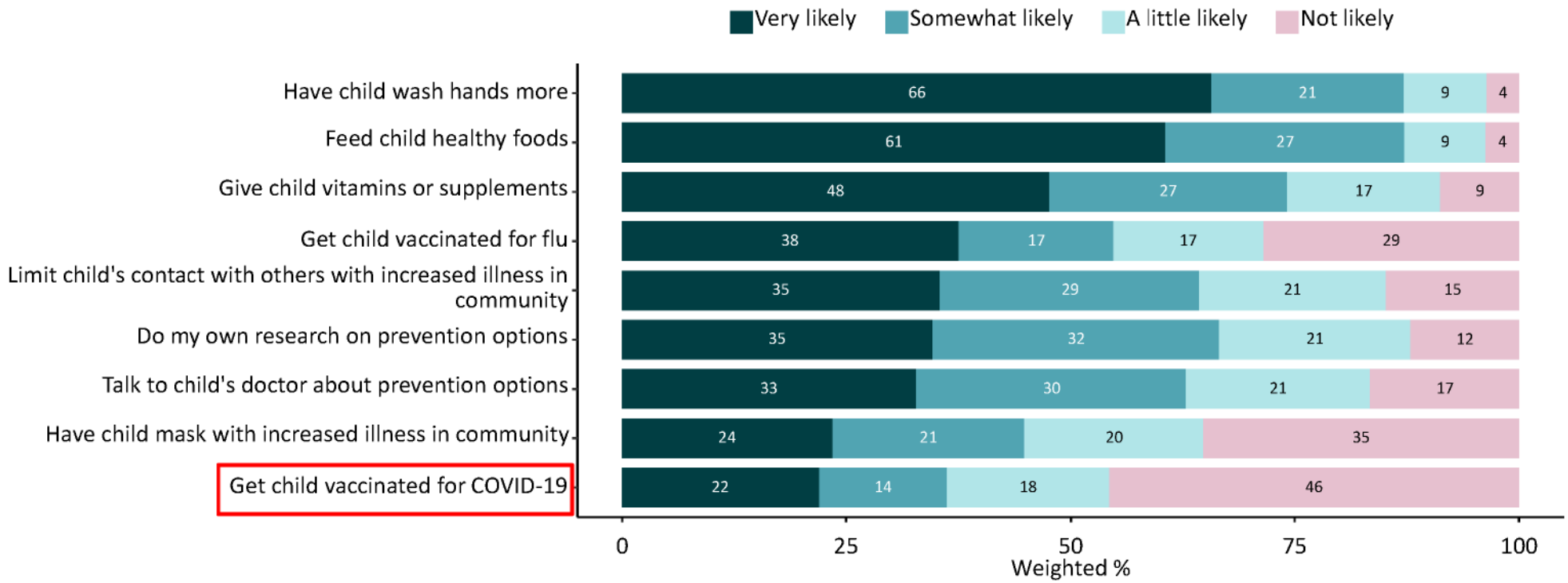
Data source: National immunization survey – Flu https://www.cdc.gov/covidvaxview/weekly-dashboard/child-coverage-vaccination.html

Accessed April 7, 2025

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"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)

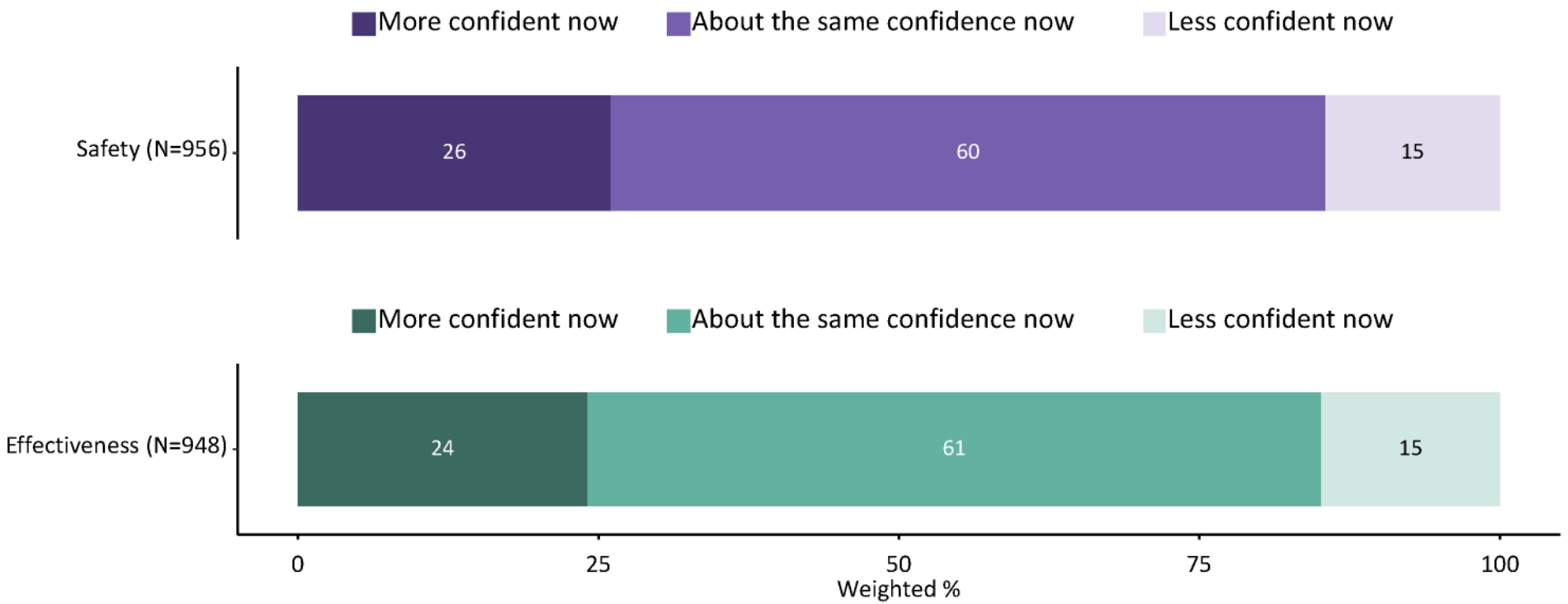


Omnibus Surveys: Data for this analysis were collected through the Ipsos KnowledgePanel and NORC AmeriSpeak Omnibus Surveys, which use probability-based panels to survey a nationally representative sample of U.S. adults ages 18 years and older. CDC fields questions about vaccination status, intent, knowledge, 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.

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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 Received at Least 1 Dose of a COVID-19 Vaccine, Omnibus Surveys, December 5, 2024–January 27, 2025

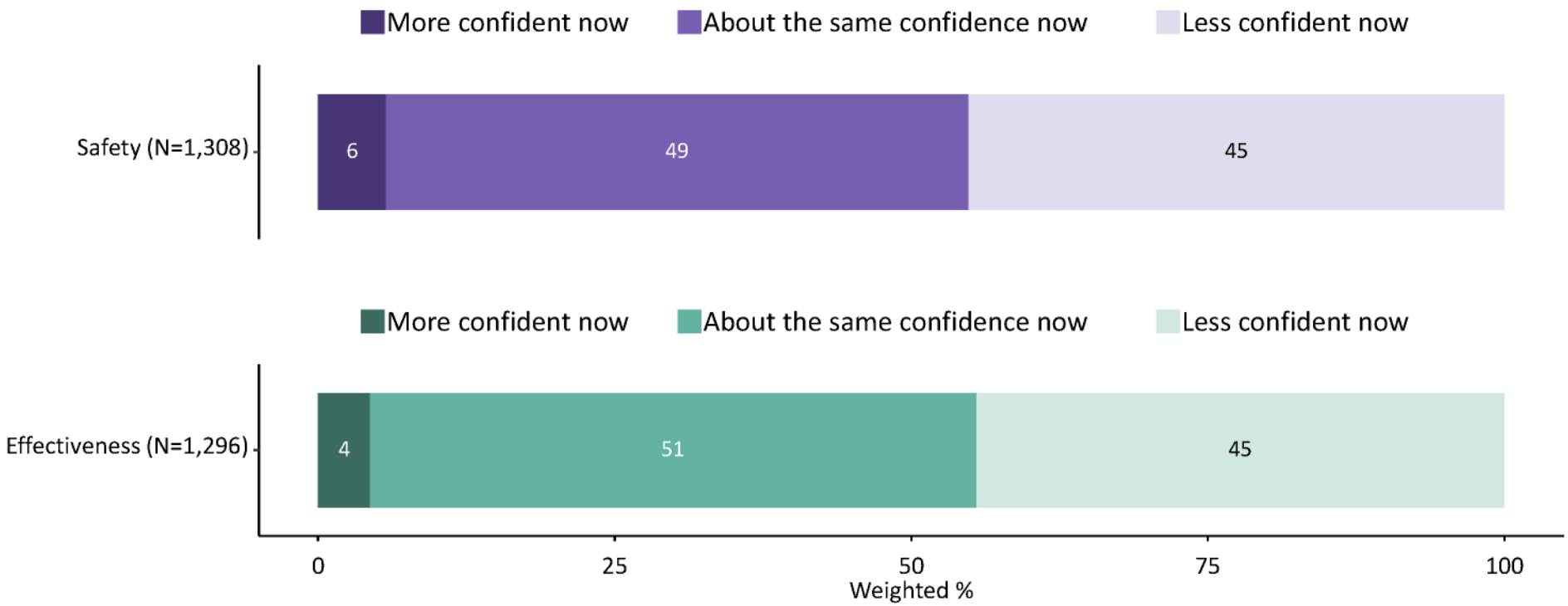


Omnibus Surveys: Data for this analysis were collected through the Ipsos KnowledgePanel and NORC AmeriSpeak Omnibus Surveys, which use probability-based panels to survey a nationally representative sample of U.S. adults ages 18 years and older. CDC fields questions about vaccination status, intent, knowledge, 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 December 2024 & January 2025 (N=8,536). Data were weighted to represent the non-institutionalized U.S. population and mitigate possible non-response bias. All responses are self-reported.

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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

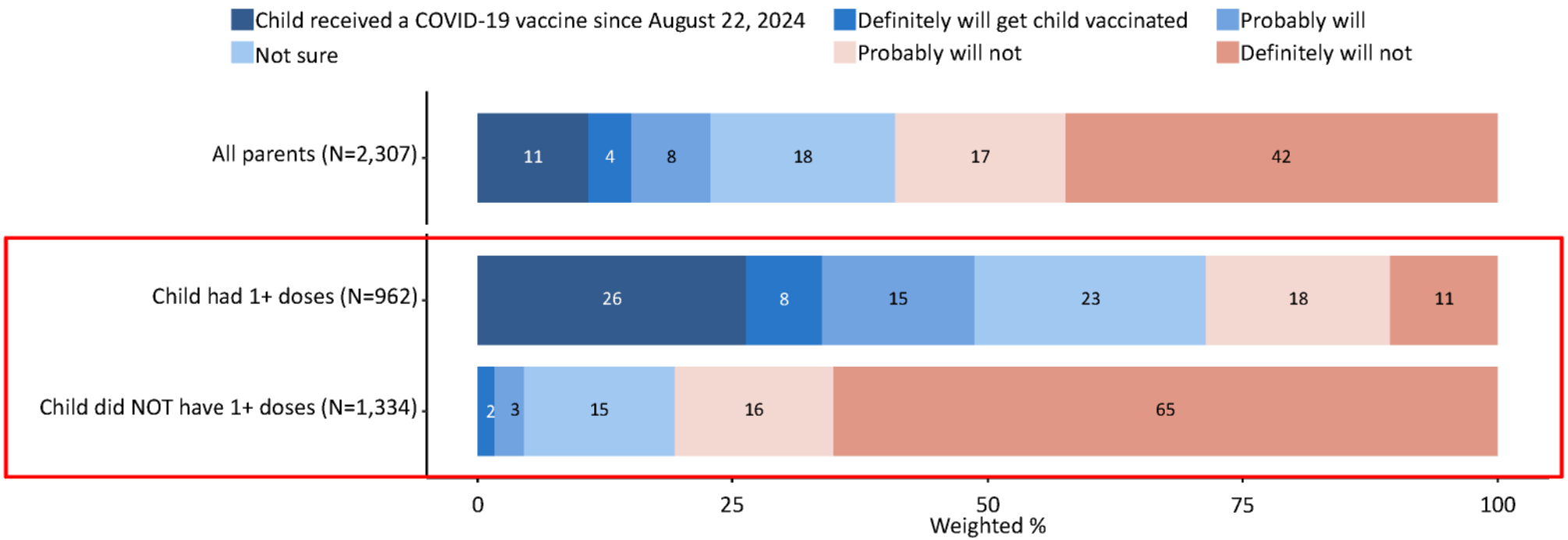


Omnibus Surveys: Data for this analysis were collected through the Ipsos KnowledgePanel and NORC AmeriSpeak Omnibus Surveys, which use probability-based panels to survey a nationally representative sample of U.S. adults ages 18 years and older. CDC fields questions about vaccination status, intent, knowledge, 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 December 2024 & January 2025 (N=8,536). Data were weighted to represent the non-institutionalized U.S. population and mitigate possible non-response bias. All responses are self-reported.

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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)

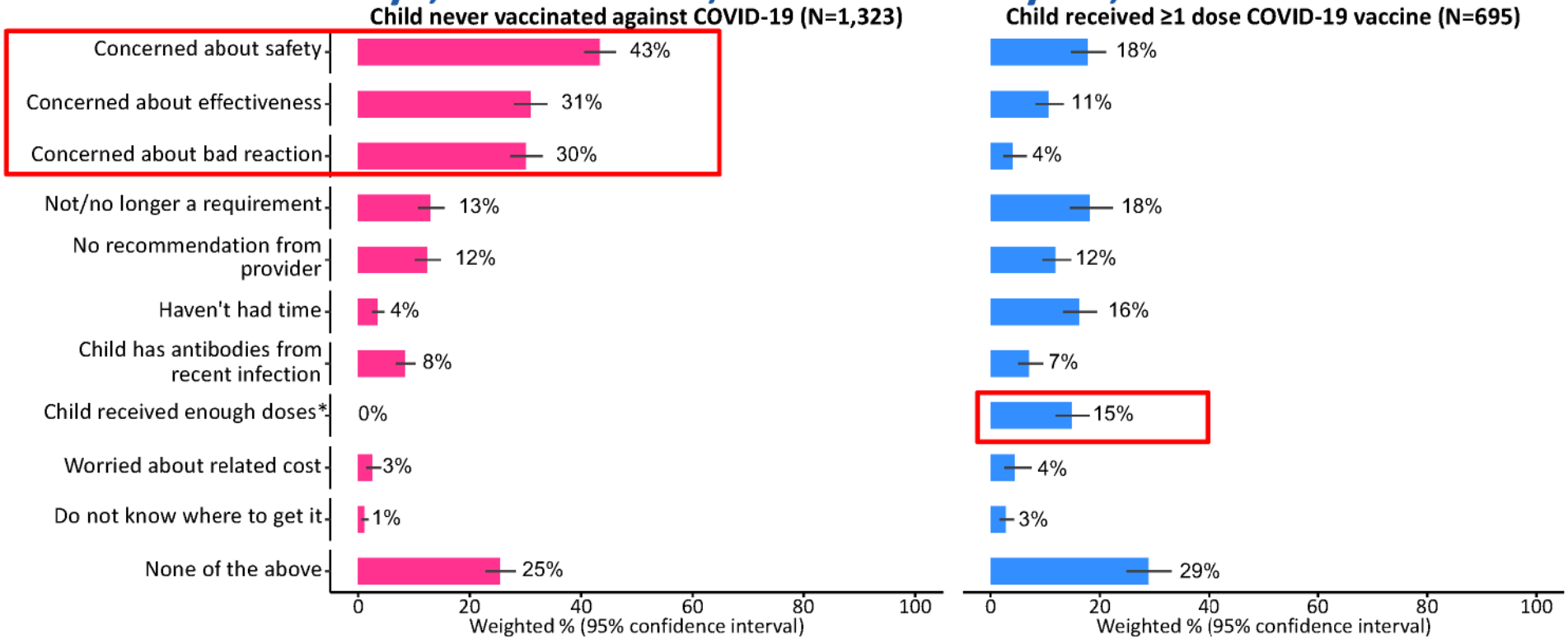


Omnibus Surveys: Data for this analysis were collected through the Ipsos KnowledgePanel and NORC AmeriSpeak Omnibus Surveys, which use probability-based panels to survey a nationally representative sample of U.S. adults ages 18 years and older. CDC fields questions about vaccination status, intent, knowledge, 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 December 2024 & January 2025 (N=8,536). Data were weighted to represent the non-institutionalized U.S. population and mitigate possible non-response bias. All responses are self-reported.

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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.

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 December 2024 & January 2025 (N=8,536). Data were weighted to represent the non-institutionalized U.S. population and mitigate possible non-response bias. All responses are self-reported.

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Recommendations in other countries

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Summary of international COVID-19 booster* recommendations

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** 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

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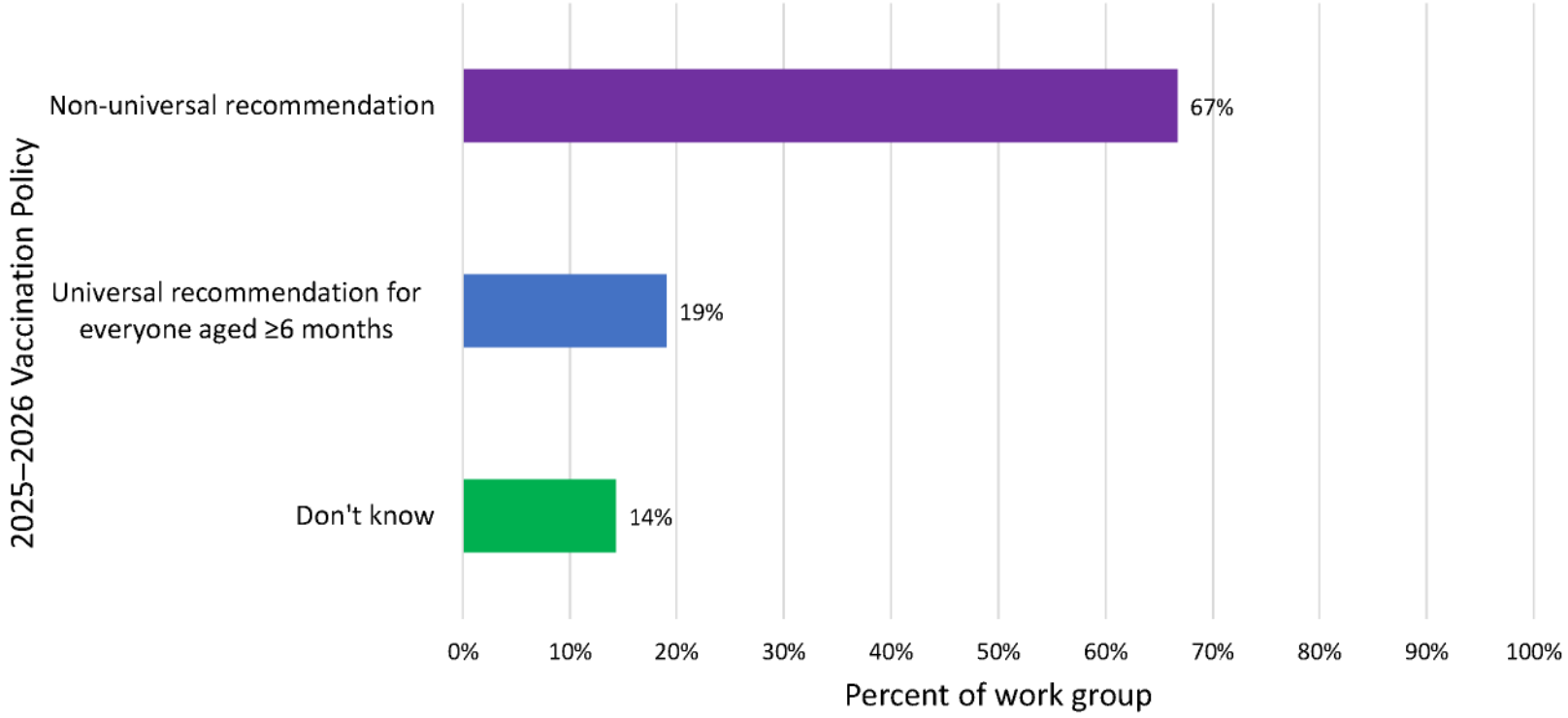
Initial Work Group interpretations

- 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.

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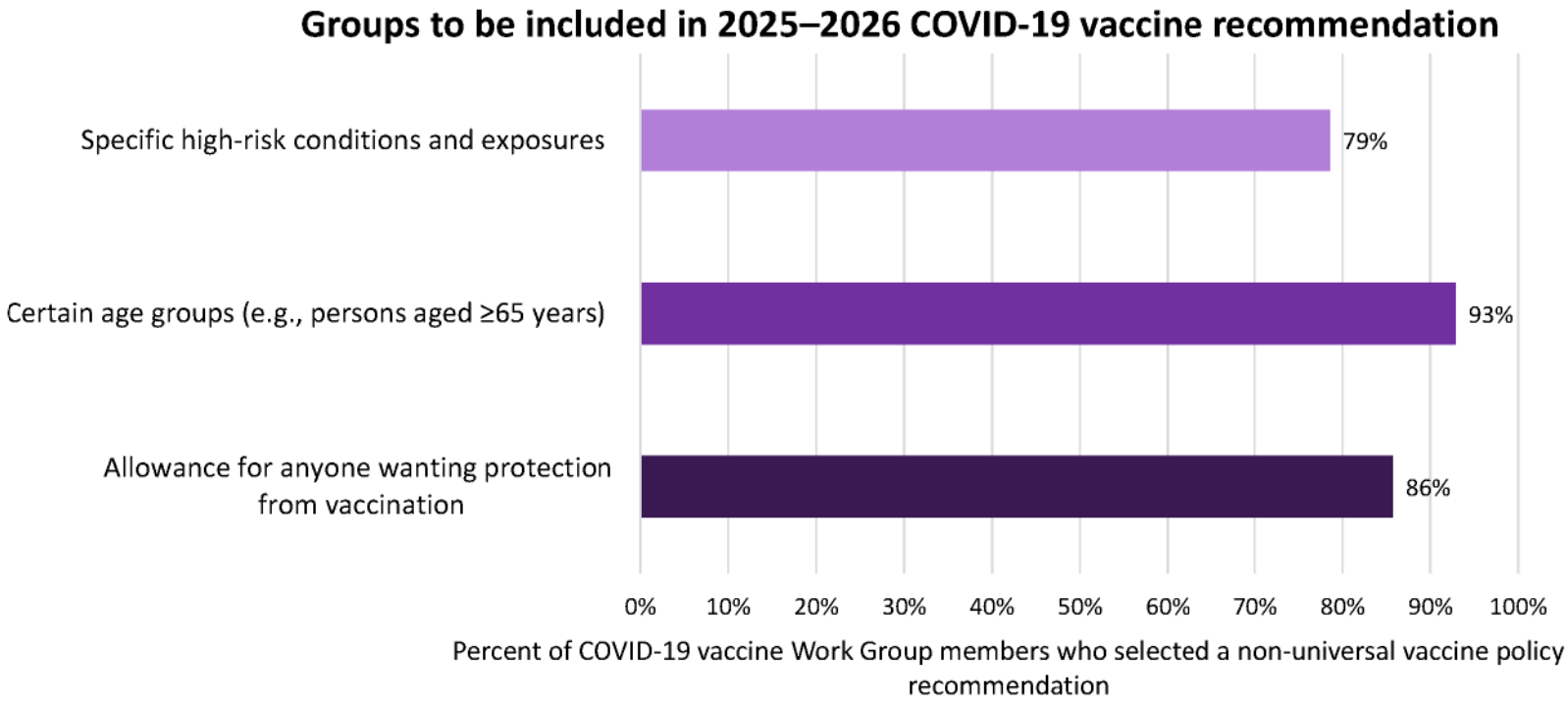
When polled on February 13, 2025, the majority of the work group supported a non-universal (risk-based) recommendation for 2025–2026 COVID-19 vaccination



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



* More than one response option could be selected.

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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)

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

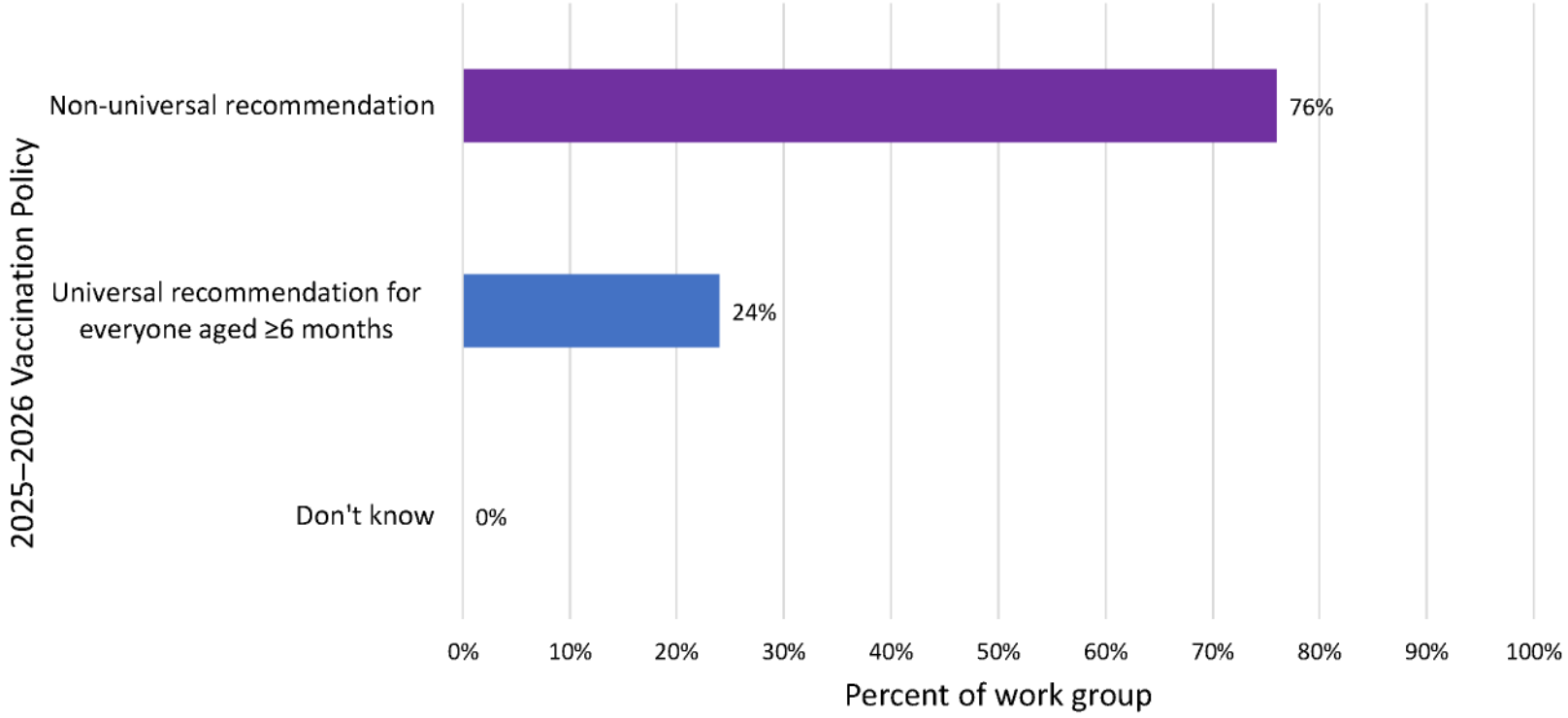
- American Academy of Family Physicians (AAFP)
- American Academy of Pediatrics (AAP)
- Association of Immunization Managers (AIM)
- American College of Physicians (ACP)
- American Pharmacists Association (APhA)
- American College of Obstetricians and Gynecologists (ACOG)

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

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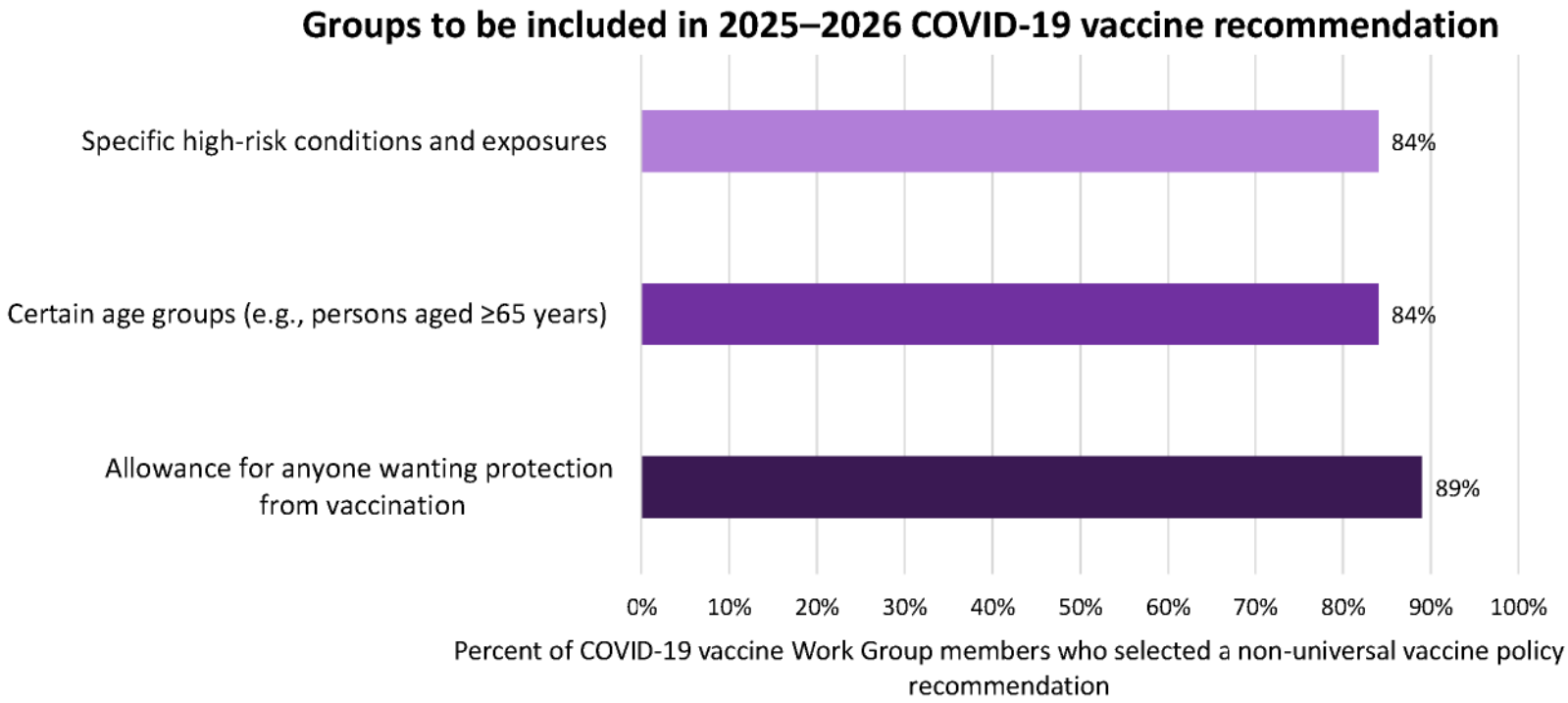
When polled on April 3, 2025, the majority of the work group continued to support a non-universal (risk-based) recommendation for 2025–2026 COVID-19 vaccination



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When polled on April 3, 2025, the Work Group continued to support all non-universal policy options*

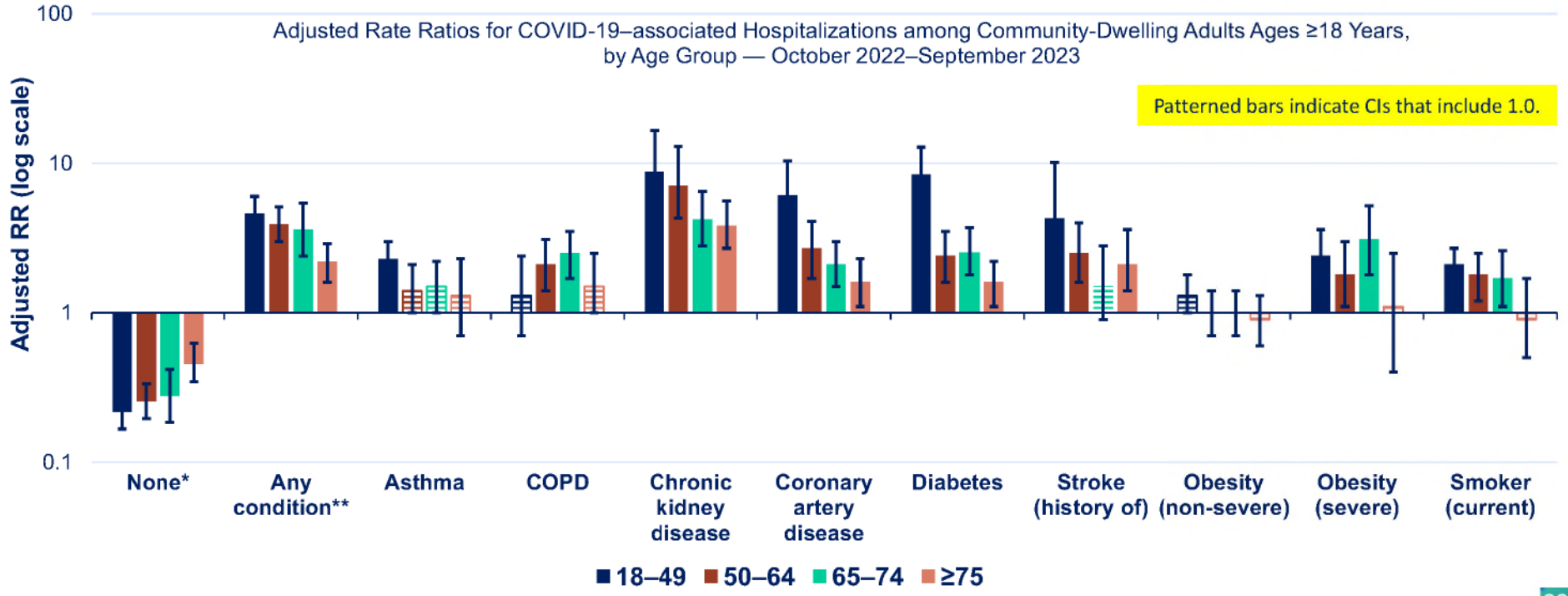


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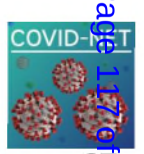
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Risk for COVID-19–associated hospitalization is increased among community-dwelling adults ages ≥18 years with underlying medical conditions.



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.



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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?

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Acknowledgements

- Lauren Roper
- Farida Ahmad
- Carla Black
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- 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
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- COVID-NET Team
- Immunization Safety Office
- Immunization Services Division
- National Center for Immunization and Respiratory Diseases

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EXHIBIT E

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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**	

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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**	

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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 19

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 GEORGES C. BENJAMIN, M.D.

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 am the Executive Director of the American Public Health Association ("APHA"). I have served in that role since December 2002. I make this statement based on personal knowledge and if called as a witness could and would testify competently thereto. I submit this supplemental declaration in support of APHA's participation as a plaintiff in this matter and in support of Plaintiffs' Third Amended Complaint. I am over the age of 18 and make this declaration based on my personal knowledge and in my official capacity as Executive Director of APHA

2. The actions of the Department of Health and Human Services that include (i) the Directive issued by Secretary of Health and Human Services Robert F. Kennedy, Jr. (the "Secretary") on May 19, 2025 designating the Covid-19 vaccine for children as Shared Clinical Decision-Making ("SCDM") and removing the recommendation for the Covid-19 vaccine for

pregnant women, and (ii) the Advisory Committee on Immunization Practices ("ACIP") new recommendation in September of this year to change the Covid-19 vaccine recommendation for adults under the age of 65 from routine to SCDM, which the Centers for Disease Control and Prevention ("CDC") later improperly conflated with informed consent, has injected chaos, confusion, and disruption into public health and care delivered by APHA members and has caused APHA to expend resources and time to address these conflicting, unfounded actions by the Secretary, ACIP, and CDC.

3. I am a graduate of the Illinois Institute of Technology and the University of Illinois College of Medicine. I am licensed to practice medicine in Maryland and the District of Columbia.

4. I am board-certified in internal medicine and a Master of the American College of Physicians, a fellow of the National Academy of Public Administration, a fellow emeritus of the American College of Emergency Physicians, an elected member of the National Academy of Medicine (formally the Institute of Medicine) of the National Academies of Sciences, Engineering and Medicine, an honorary fellow of the Faculty of Public Health, and an honorary fellow of the Royal Society of Public Health.

5. Following graduation from medical school, I entered active duty in the Army where I completed a residency in internal medicine at the Brooke Army Medical Center in San Antonio, Texas. Upon completion of my residency in 1981, I was assigned to Madigan Army Medical Center in Tacoma, Washington and served as faculty and staff in the Department of Emergency Medicine. At Madigan Army Medical Center, I managed a 72,000-patient per year ambulatory care service as chief of the Acute Illness Clinic and was an attending physician within the Department of Emergency Medicine. I was reassigned in 1983 and from then until the spring of 1987, I served as Chief of Emergency Medicine at the Walter Reed Army Medical Center.

6. Following my discharge from the United States Army in 1987, I was appointed as Chair of the Department of Community Health and Ambulatory Care at the District of Columbia General Hospital, serving in that post until December of 1990. From January 1990 to the fall of 1991, I was the Acting Commissioner for Public Health for the District of Columbia, and the Acting Director of the Emergency Ambulance Bureau in the District of Columbia Fire Department. I returned to serve as the Interim Director of the Emergency Ambulance Bureau from the fall of 1994 to the spring of 1995.

7. I served as the Secretary of the Maryland Department of Health and Mental Hygiene from April 1999 to December 2002, following four years as its Deputy Secretary for Public Health Services.

8. In April 2016, I was appointed by President Obama to the National Infrastructure Advisory Council. In that role, I helped advise the President on how best to assure the security of the nation's critical infrastructure. I served in this capacity until December 2020.

9. The APHA was founded in 1872, at a time when scientific advances were helping to reveal the causes of communicable diseases. These discoveries laid the foundation for the public health profession and for the infrastructure to support APHA' s work. From its inception, APHA has been dedicated to improving the health of all U.S. residents. From its early days, two of APHA's most important functions have been advocacy for adoption by the government of the most current scientific advances relevant to public health, and professional and public education on how to improve community health.

10. APHA's mission is to: "Build public health capacity and promote effective policy and practice." APHA members include more than 23,000 individual public health professional members, as well as state and local health departments, organizations interested in health, and

health-related businesses. APHA also coordinates with state and regional APHA affiliates across the nation. APHA members work in every discipline of public health, in every state, and in countries across the globe.

11. APHA has recommended, supported and adopted clinical and public health practice guidelines that are considered the standard of care for our clinician and non-clinician members who practice public health. These guidelines are in place to optimize and protect the health of our members' patients as well as the broader population that they have an obligation to protect. Clinical and public health guidelines are informed by a systematic review of peer-reviewed research and other public health evidence, the professional judgment of our members, and an assessment of the benefits and harms of alternative therapeutic and non-therapeutic options. Clinical and public health guidelines follow a sound, transparent methodology to translate the best evidence into clinical and public health practice for improved outcomes of individuals and population health.

12. APHA has published widely to share information relevant to its members and the broader health community related to Covid-19 and to lead policy engagement to support Covid-19 vaccination during initial development and administration of the vaccines.

13. Vaccines are a significant health and health equity issue, and nationwide, evidence-based vaccination guidelines has therefore been a priority issue for APHA and our members since the inception of APHA. The federal immunization recommendation framework, which produces the evidence-based Centers for Disease Control and Prevention ("CDC") immunization schedule, is a structured, scientific, data-driven process that has been relied on for decades by APHA and APHA members as the nations' authoritative mechanism for evaluating vaccine safety, effectiveness, and population-level need. Under this framework, ACIP conducts a systematic evidence review using the GRADE methodology and the Evidence-to-Recommendation ("EtR")

framework. CDC then publishes ACIP's scientific rationale in the MMWR, creating a transparent and nationally uniform evidentiary foundation that physicians, medical practices, insurers, public health systems, local public health departments, and professional societies rely on to determine the standard of care. Because this framework anchors clinical practice, the standard of care, malpractice expectations, public health infrastructure, and vaccine coverage and reimbursement, changes to the CDC or ACIP recommendations for the CDC immunizations schedule alter the entire medical, legal, public health, and operational infrastructure surrounding vaccination. APHA and APHA members cannot disregard changes to the CDC immunization schedule, as deviating from the CDC immunization schedule triggers heightened documentation demands, increased malpractice and liability exposure, coverage and reimbursement disruptions, and patient confusion. For this reason, the CDC immunization schedule is not an optional reference point for APHA and APHA members, it is a central benchmark that governs vaccine practice across the United States.

14. The CDC immunization framework is incorporated into public health systems at every level, and national consistency is essential in immunization practice. Preventing vaccine-preventable diseases, including Covid-19, requires population-level coordination. Because viruses and other infectious diseases spread across state borders, a uniform national benchmark that can then be implemented by public health administrators and health care providers across the country, is crucial for ensuring that individuals receive vaccinations at evidence-based ages and intervals regardless of where they live. This consistency is critical for protecting public health infrastructure nationwide and from preventable outbreaks and is engrained in the care APHA members provide to their patients and the public. APHA and APHA members have relied on the scientific, evidence-based CDC immunization schedule as the national benchmark for vaccinations for decades.

15. With respect to Covid-19 vaccines, APHA has invested time and resources to keep the population and our members informed on these issues since the Covid-19 vaccines were first developed. Our members, especially those working in local health departments and community health centers, are on the front lines of the public health infrastructure. They rely on clear and science-based guidance from federal public health authorities, including the CDC immunization schedule and recommendations, to inform and carry out their work.

16. Over many years, APHA and APHA members have depended on the CDC's immunization schedule and ACIP's Evidence-to-Recommendations ("EtR") framework. ACIP's transparent, systematic use of GRADE tables and evidence reviews has been the backbone of vaccine policy that APHA members rely upon to provide consistent, trusted, evidence-based guidance to their communities. Since the authorization of Covid-19 vaccines, APHA and its members consistently recommended vaccination for pregnant individuals, children, and adults under age 65—following ACIP and CDC recommendations grounded in rigorous evidence review.

17. However, the Secretary's May 2025 Directive and ACIP's September 2025 downgrade of the recommendation for Covid-19 vaccination for essentially all adults to shared clinical decision-making ("SCDM") represent a historic break from established federal practice. These abrupt changes were issued: without a systematic evidence review, without GRADE tables, without use of the EtR framework, and without an explanatory Morbidity and Mortality Weekly Report ("MMWR"), which is normally published to explain SCDM recommendations. CDC then improperly conflated "shared clinical decision-making" with "informed consent" adding further contusion and signaling to the public that Covid-19 vaccination may no longer be recommended or may be unsafe, despite no evidence supporting such a conclusion. APHA members who rely on clear, evidence-based federal vaccine recommendations were left without any scientific or

operational guidance explaining this extraordinary shift. These actions have injected confusion directly into public health administration and exam rooms, which is harming APHA and APHA members.

18. The recent dangerous and unsupported actions by the Secretary, ACIP, and CDC regarding the Covid-19 vaccine are harming APHA, APHA members, and causing preventable suffering, illness, and death to Americans. The public and patients are now questioning APHA and APHA members' judgment, doubting long-established vaccines, and expressing mistrust rooted in the Secretary, ACIP, and CDC recent contradictory and unexplained actions on Covid-19 vaccinations. APHA members who previously practiced with the support of consistent ACIP and CDC recommendations are now forced to navigate a confusing landscape with no authoritative guidance, spending significant time defending evidence-based care against these federal actions that lack clarity, methodology, and scientific rationale. The erosion of trust and the collapse of a unified standard of care for Covid-19 vaccination has materially harmed APHA members' ability to provide public health guidance on Covid-19 vaccination and safely and effectively care for patients and protect communities from Covid-19 outbreaks.

19. APHA members report that the Secretary, ACIP, and CDC's changes to the CDC immunization schedule for Covid-19 vaccines to SCDM have directly interfered with the ability to practice evidence-based public health and medicine. Specifically, APHA members report that these actions have: compromised the standard of care for Covid-19 vaccination for pregnant women, children, and adults under 65; forced members to choose between following best available science and following federal directives that lack evidentiary grounding, which undermines their clinical judgment and puts their licenses and professional credibility at risk; frustrated routine patient counseling, particularly regarding pregnancy, pediatric vaccination, and prevention of

severe disease in adults; and, increased the risk of preventable infection, hospitalization, and death among the populations they serve.

20. APHA members also report an erosion in public trust in APHA members and the vaccines they administer as a result of the Directive and ACIP and CDC's recent actions changing the CDC immunization schedule recommendation for Covid-19 vaccines to SCDM. APHA members report: patients now questioning their professional competence and integrity; families delaying or refusing Covid-19 vaccination solely because of the federal recommendation was downgraded; and, mistrust spilling over into hesitancy about routine childhood vaccines, threating broader immunization programs. These harms directly impair APHA members' ability to protect their communities—one of their core professional duties.

21. Since the Directive and recent actions by ACIP and the CDC changing the CDC immunization schedule recommendation for Covid-19 vaccines to SCDM, APHA members are now required to spend substantially more time: correcting misconceptions created by the Secretary's Directive and ACIP and CDC actions; explaining the safety and effectiveness of Covid-19 vaccines without the support of a transparent EtR framework; and, walking families through individualized risk assessments that did not exist prior to the Directive and ACIP and CDC recent changes to the CDC immunization schedule for Covid-19 vaccines. This additional counseling time is unreimbursed and diverts time away from APHA members' essential public health duties, including outbreak response, routine vaccinations, and chronic disease management.

22. APHA members also report that Covid-19 vaccination rates have dropped following the Directive and ACIP and CDC's actions downgrading the recommendation for Covid-19 vaccines to SCDM. Because vaccination rates have dropped following these actions, APHA members warn of increased likelihood of severe Covid-19 outbreaks, higher burdens on

local health departments, and greater risk to infants under 6 months and pregnant individuals, both of whom rely heavily on vaccination for protection. These harms are not speculative—they are already materializing.

23. A systematic review of the literature and studies show that Covid-19 infections during pregnancy poses increased risks of poor health outcomes including preterm birth and stillbirth. Therefore, vaccination against Covid-19 is necessary for pregnant women to prevent negative health outcomes including severe illness and death. In addition, vaccination of pregnant women against Covid-19 is necessary to transfer the antibodies the fetus to the prevent severe disease in infants less than 6 months. No data to date has shown that there are any serious safety concerns for Covid-19 vaccination during pregnancy. Additional peer-reviewed studies and literature show that Covid-19 vaccination prevents severe illness and death in children and adults as well. Severe illness and long Covid-19 in children also decreased significantly after vaccines were approved for that population. Therefore, the Directive and recent actions by ACIP and CDC downgrading the recommendation for Covid-19 vaccines, creates an increased health risk for pregnant women, children, and adults.

24. Since the Secretarial Directive and recent changes by ACIP to the CDC immunization schedule for Covid-19 vaccination to SCDM, APHA members have also informed me that they are faced with an untenable conflict between counseling patients and their communities on what the CDC recommends, and the optimal standard of care that members have been following since the Covid-19 vaccines were approved. Indeed, APHA members are either being forced to provide an inferior standard of care to pregnant women, children, and now healthy adults that increases the risk of preventable illness, hospitalization and death, or risk losing their medical or other professional license. For public health administrators, this creates a professional

conflict with the standard of public health practice required to control a disease outbreak in their community and the non-evidence-based Secretarial Directive and September 2025 ACIP recommendation to downgrade Covid-19 vaccination to SCDM.

25. Moreover, APHA clinician and public health professional members' ability to consult with individuals and their families or advise those communities regarding the effectiveness of the Covid-19 vaccine at preventing serious illness and death has been completely frustrated by the Directive and recent actions by ACIP and the CDC downgrading the recommendation for Covid-19 vaccines to SCDM for essentially all adults. APHA members report spending additional time consulting with patients and members of the public who now distrust Covid-19 vaccinations because of the Directive and recent changes by ACIP and the CDC, which is time that is not reimbursed. APHA members also report having to expend additional resources to now regain the public's trust in Covid-19 vaccinations, which has been diminished by the Secretary, ACIP, and CDC recent unfounded, conflicting, and unexplained changes to the CDC immunization schedule for Covid-19 vaccinations.

26. Because of vaccine hesitancy and loss of trust caused by the Secretarial Directive and recent actions by ACIP and CDC, APHA members are required to spend more time correcting misinformation with individuals and families regarding the effectiveness of the Covid-19 vaccines, which diverts time and resources away from other important health care or public health duties. If there is another severe Covid-19 outbreak, unvaccinated individuals create a risk to themselves as well as the rest of the community. Covid-19 is still a public health threat in our communities so being up to date on one's vaccination status is still a sound public health recommendation.

27. The Secretary's Directive, followed by ACIP's and the CDC's unfounded downgrade of Covid-19 vaccine recommendations to SCDM has caused APHA itself to suffer

significant injuries, including the diversion of resources and impairment of APHA's effectiveness. APHA has been forced to divert substantial time, personnel, and resources away from its core mission activities and policy initiatives in order to address to the confusion created by the Directive and recent actions taken by ACIP and the CDC downgrading the recommendation for Covid-19 vaccines for essentially all adults to SCDM. These efforts have included APHA staff developing public communications and educational materials to counter the widespread confusion. APHA staff are also fielding large volumes of inquiries from members seeking guidance on how to navigate these conflicting and unexplained federal actions by the Secretary, ACIP, and CDC, correcting misinformation, and coordinating with other public health administrators throughout the country to reaffirm the evidence-based guidance on Covid-19 vaccination. These efforts are essential to mitigate ongoing harm, and they represent a significant and unplanned burden for APHA. APHA has had to substantial divert resources to publish materials and statements to APHA members and the public on the safety and efficacy of Covid-19 vaccination to combat the mistrust in Covid-19 vaccines and misinformation on the safety and efficacy of the vaccine that has resulted from the Secretary, ACIP, and CDC's recent unfounded change to the CDC immunization schedule Covid-19 vaccine recommendation to SCDM.

28. As a direct result of the Secretary's Directive and ACIP's abrupt change to the Covid-19 vaccine recommendation to SCDM, APHA is now required to divert substantial organizational resources to revise 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 physicians) nationwide and their content is built around the evidence-based

immunization framework historically produced through the CDC and ACIP process. Because the Secretary, ACIP, and CDC's actions departed from the established GRADE and EtR evidence framework and created new confusion about the basis for Covid-19 vaccination recommendations, APHA must now reconvene its editorial contributors, reassess affected chapters, and update the guidance to reconcile the scientific evidence with the Secretary, ACIP, and CDC's new unfounded position. This work requires the reallocation of staff time, editorial oversight, and expert contributors away from other public health priorities that APHA would otherwise be pursing. These are compelled and concrete diversion of resources that APHA would not have undertaken but for these challenged actions by the Secretary, ACIP, and CDC.

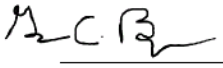
29. APHA's long-standing role as a reliable disseminator of evidence-based public health guidance has been undermined by the Secretary, ACIP, and CDC's unexplained reversals for Covid-19 vaccination to SCDM. APHA's ability to carry out its mission depends on the trust placed in it by public health professionals, policymakers, and the communities they serve. For decades, APHA's recommendations and educational materials have been grounded in the transparent, evidence-based federal vaccine framework established by ACIP and the CDC. The Secretary's Directive and ACIP and CDC's abrupt departure from that scientific process 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 that contradict these sudden, unexplained federal actions. The new doubt in APHA guidance caused by the Secretary, ACIP, and CDC unfounded changes to the CDC immunization schedule for Covid-19 vaccination erodes APHA's standing in the public health community, weakens perceived reliability of its communications, and diminishes the effectiveness of its educational initiatives. APHA has had to

expend additional resources to rebuild credibility with members and the public—resources that would otherwise be directed toward advancing 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.

30. In short, the Secretary's Directive, followed by ACIP's and the CDC's unfounded downgrade of the Covid-19 vaccine recommendation for essentially all adults to SCDM has destabilized the evidence-based public health framework that APHA and its members have relied upon. These actions contradict the robust scientific evidence demonstrating the safety and effectiveness of Covid-19 vaccines and have caused significant harm to APHA and APHA members' ability to protect their communities. APHA members now face increased demands to address preventable Covid-19 infections, hospitalizations, deaths; repair the public's rapidly eroding trust in Covid-19 vaccination; and, navigate conflicting guidance on Covid-19 vaccination that impedes their ability to protect communities. Without Court intervention, these harms are certain to escalate and will continue to impede APHA's mission and day-today-work of its members across the country.

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 December 2, 2025 in Washington, D.C.



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

EXHIBIT 20

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, AMERICAN COLLEGE OF PHYSICIANS, *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. _____

DECLARATION OF J. EDWARD JOHNSON

I, J. Edward Johnson, declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. My name is J. Edward Johnson. I am over 18 years old. I am of sound mind and am fully competent to make this declaration. This declaration contains only information about which I have personal knowledge.

2. I am the Assistant Health Commissioner for External Affairs at the Columbus Department of Public Health ("Columbus Public Health"). I have dedicated my professional life to Columbus Public Health for over the last seven years.

3. As Assistant Public Health Commission for External Affairs, I assist the Health Commission in protecting the health and improving the lives of the residents of Columbus.

4. Before my tenure with Columbus Public Health, I worked as a Legislative Aide and the Director of Legislative Affairs for the Columbus City Council.

5. I hold a Bachelor of Arts degree from Xavier University in Philosophy, and Politics and Economics.

6. I also hold a Master of Science degree in International Business, Trade, and Commerce from Valparaiso University.

7. Public health is important to me, and I volunteer my time to several health-related nonprofit organizations.

8. Since September 2022, I have served as the Vice Chair of OneOhio Recovery Foundation Region 1 Board of Directors to help distribute funds to combat and prevent opioid misuse.

9. Since May 2023, I have been devoting my free time to volunteering for the Health Equity Advisory Board at the Ohio State University Wexner Medical Center.

10. Columbus Public Health is a member of the American Public Health Association ("APHA").

11. Columbus Public Health is committed to APHA's mission: "Build public health capacity and promote effective policy and practice."

12. Columbus Public Health shares AHPA's vision: "Optimal, equitable health an well-being for all."

13. Columbus Public Health's stated values: "Innovation; Customer Focus; Accountability; Research/Scienced Based; and Equity & Fairness" mirror APHA's values: "Community; Science- and evidence-based decisionmaking; Health equity and justice; Prevention and wellness; Measurable progress in improving health; and Fortitude to persevere."

14. As part of its mission to build public health capacity, Columbus Public Health operates more than 90 different public health programs and services.

15. For instance, Columbus Public Health endeavors to curb transmission of and infection by vaccine-preventable illnesses by operating an immunization clinic.

16. The Columbus Public Health Vaccine Preventable Disease Clinic and Program offers children and adults immunizations for many illnesses including RSV, COVID-19, Tdap, Varicella, Influenza, HPV, Hepatitis A, Hepatitis B, among others.

17. The Columbus Public Health Vaccine Preventable Disease Clinic and Program stocks more than 45 different immunizations, from eight manufacturers, in more than five forms.

18. The Columbus Public Health Vaccine Preventable Disease Clinic and Program also offers education for children and adults regarding vaccine efficacy and safety.

19. The Columbus Public Health Vaccine Preventable Disease Clinic and Program has recommended the COVID-19 immunization for children 6 months–18 years and pregnant women as soon as the Federal Drug Administration ("FDA") approved COVID-19 immunizations generally.

20. Historically, Columbus Public Health adhered to the vaccine schedules recommended by the Centers for Disease Control and Prevention's ("CDC") Advisory Committee on Immunization Practices ("ACIP") and did not provide immunizations on an off-label basis.

21. On May 19, 2025, Department of Health and Human Services ("HHS") Secretary Robert F. Kennedy, Jr. issued a directive rescinding the recommendation that pregnant women and children 6 months–18 years receive COVID-19 immunizations.

22. Secretary Kennedy publicized his May 19, 2025 directive by posting it through social media platform, X, on May 27, 2025.

23. Since Secretary Kennedy issued his May 19, 2025 directive, Columbus Public Health Vaccine Preventable Disease Clinic and Program staff can no longer advise pregnant

women to receive a COVID-19 immunization, which is completely at odds with the mission, vision, and values of Columbus Public Health, and the standard of care Columbus Public Health holds itself to.

24. Because of Secretary Kennedy's May 19, 2025 directive, Columbus Public Health Vaccine Preventable Disease Clinic and Program staff are unable to provide adequate counseling about the safety and efficacy of COVID-19 immunizations to pregnant individuals and parents of children 6 months–18 years old, which is destroying the bedrock of the patient-provider relationship.

25. The Columbus Public Health Vaccine Preventable Disease Clinic and Program staff nurses specifically to administer immunizations; as a direct result of Secretary Kennedy's May 19, 2025 directive removing pregnant individuals and children ages 6 months–18 years from its patient population, the Immunization Clinic will see a decrease in the number of patients it can immunize. Accordingly, to preserve its resources, Columbus Public Health Immunization Clinic will be forced to reassign or relieve its immunization nurses.

26. As a result of Secretary Kennedy's May 1, 2025 directive which prevents pregnant individuals and children ages 6 months–18 years from getting the COVID-19 immunization, COVID-19 transmission and infection will rise in the community Columbus Public Health serves.

27. HHS recently cancelled Columbus Public Health's Enhanced Operation Grant, which funded its Disease Intervention Specialists. The Disease Intervention Specialists tracked transmission data to help fight contagion. Accordingly, Columbus Public Health is unable to implement programs to prevent an outbreak of COVID-19 in an unvaccinated public.

28. When more Columbus residents inevitably contract COVID-19 as a result of fewer being able to get the COVID-19 immunization, Columbus Public Health will need to either reroute

funding from other programs to address COVID-19 outbreaks, to the detriment of those initiatives, or else let the COVID-19 outbreak go unaddressed—either of which undermine the public's trust in Columbus Public Health's ability to address public health concerns in the community and erode its ability to meaningfully carryout its purpose to protect public health.

29. As a Department of the City of Columbus, Columbus Public Health is obligated to carry out its mission to protect health in service of the People of Columbus. Accordingly, the Secretary's May 19, 2025 directive is an existential threat to Columbus Public Health, and the City of Columbus.

30. The Columbus Public Health Vaccine Preventable Disease Clinic and Program purchases the immunizations it stocks at a "super low price," which is a small fraction of the market price for the same immunizations. The "super low price" is available only for immunizations that have been approved by the FDA and recommended by the CDC.

31. The Columbus Public Health Vaccine Preventable Disease Clinic and Program cannot purchase the immunizations it stocks except at the "super low price."

32. Despite having offered the COVID-19 immunization for several years, decisions that have increased the cost and/or removed eligible groups from the recommendation to be immunized have resulted in Columbus Public Health's Vaccine Preventable Disease Clinic and Program to cease stocking all COVID-19 immunizations, and impact our ability to serve all residents in preferred and convenient ways.

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

Executed on July 7, 2025, in Columbus, Ohio.



J. Edward Johnson

EXHIBIT 21

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

SUPPLEMENTAL DECLARATION OF JAMES LEWIS, MD, MPH

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

1. I am over 18 years old and reside in Everett, Washington. I am under no mental or legal disability, and am competent to testify as to the matters set forth herein. I make this declaration in support of the Third Amended Complaint and the statements made in my declaration are based on my personal knowledge.

2. I earned a Master of Public Health degree from the University of North Carolina and a Doctor of Medicine degree from the University of Arkansas for Medical Sciences. I am board certified in Internal Medicine, Infectious Diseases, and Preventive Medicine. I am an adjunct Clinical Assistant Professor at the University of Washington in the Division of Allergy and Infectious Diseases.

3. I am the Health Officer for the Snohomish County Health Department in Washington State.

4. I am a member of the American Public Health Association ("APHA").

5. I have viewed the video that the Secretary of Health and Human Services, Robert F. Kennedy, Jr. (the "Secretary") posted on X on May 27, 2025, and have read the related May 19 "Secretarial Directive" ("Directive") confirming what the Secretary said in the video.

6. I am aware that on June 9, 2025, all sitting Advisory Committee on Immunization Practices ("ACIP") were terminated and slowly replaced with non-experts.

7. I am aware that this newly reconstituted ACIP met from September 18 and 19 and that at this meeting the Committee discussed recommending the COVID-19 vaccine through Shared Clinical Decision Making ("SCDM") for essentially all patients.

8. I am aware that Centers for Disease Control and Prevention's ("CDC") adopted the new ACIP's recommendation for SCDM for essentially all patients under the age of 65 for COVID-19 vaccinations. I have also reviewed the CDC's immunization schedule, which was revised to reflect ACIP's SCDM recommendation for the COVID-19 vaccine across for all individuals older than 6 months, including pregnant women, even though COVID-19 vaccination during pregnancy was not discussed in the meeting.

9. I disagree with the decisions announced in the May 27 video, the Directive to remove recommendations from the CDC's immunization schedules that pregnant women and children receive the COVID-19 vaccine, the ACIP's SCDM recommendation for all individuals older than 6 months, and the current CDC immunization schedule. These decisions have personally affected my job and caused me to divert a significant amount of my time and attention on attempting to mitigate the damage that the Directive and newly reconstituted ACIP has had on public health in my county. This diversion of resources has adversely impacted the ability of the

Snohomish County Health Department to carry out its other public health responsibilities and initiatives.

10. One initiative that I worked on because of the Directive and other actions by the Secretary that undermine trust in vaccines is an initiative to change local and state laws that have tied vaccine recommendations to the ACIP and CDC guidance. I, along with colleagues with whom I am working on this initiative, no longer trust the new ACIP, its recommendations, or CDC guidance and immunization schedules. Accordingly, we are now forced to change state and local laws to no longer defer to CDC guidance or ACIP recommendations.

11. Every county in Washington State participates in a health officer group known as the Health Officer Committee for the State of Washington. As a result of the Directive and ACIP's actions, this Committee drafted educational materials recommending that the State Legislature enact a law ensuring that any statute that defers to ACIP also defers to other evidence-based bodies, including professional societies such as the American Academy of Pediatrics ("AAP"). The development of these materials required multiple rounds of drafting and review. The materials also had to be presented to the State Medical Association. This has required a significant investment of time and effort without any changes to our budget or staff.

12. I am also preparing for extensive advocacy work that will take place during the upcoming legislative session in the Spring, with the goal of securing passage of the bill. My work for this initiative includes reviewing data, assisting with the development of bill language, speaking with health care providers, gathering their feedback, and confirming that the proposed language meets their needs and reflects what they believe is in the best interest of patients. I have had internal discussions regarding this effort, as well as external discussions with organizations involved in patient care.

13. The net impact is that I, along with colleagues, am performing work that ACIP typically carries out through the Evidence to Recommendations ("EtR") framework. I would not need to take on this workload if ACIP were functioning as it had for many years and had not issued an unsupported SCDM recommendation for the COVID-19 vaccine. This, in turn, has diverted my ability to work on other tasks and initiatives that serve the residents of Snohomish County.

14. Neither the Snohomish County Health Department nor the Health Officer Committee for the State of Washington receives additional funding for these initiatives. Instead, to meet these new demands, we have been required to shift resources away from other public health efforts. These other public health efforts have slowed significantly, and in some cases have been paused, because the department has had to redirect resources to respond to the SCDM recommendation for COVID-19 issued by ACIP.

15. As part of my duties as Health Officer, I have spoken directly with providers and patients who are trying to navigate the confusion created by ACIP's SCDM recommendation for the COVID-19 vaccine. Patients have reported to me that some providers have refused to administer the COVID-19 vaccine to them because they are concerned about lack of reimbursement or potential liability. Providers have told me that they are considering not stocking the vaccine for the same reason, as they do not want to take on the financial risk of administering a vaccine when they may not be reimbursed through health plans. This work represents new unfunded demands on the time and resources of the Snohomish County Health Department.

16. Providers have also expressed their concerns to me about their personal liability. That are concerned about and do not want to take on the risk that if a patient experiences an adverse event after receiving a COVID-19 vaccine, the patient could assert that the provider did not follow the proper SCDM process. ACIP has not provided any supporting materials for its SCDM

recommendation for the COVID-19 vaccine, and it has offered neither guidelines published in the CDC's Morbidity and Mortality Weekly Report ("MMWR") nor any guidance describing a standard SCDM process for COVID-19 vaccination. As a result, providers across Washington State lack a baseline for how SCDM should be conducted or documented. Although Washington State has issued a standing order to help mitigate liability risks, providers are expending significant resources to meticulously document their SCDM conversations. These efforts include changing patient note templates, revising intake forms, and modifying electronic medical record systems to include prompts related to SCDM. Again, this work represents new unfunded demands on the time and resources of the Snohomish County Health Department.

17. Another initiative that I am working on because of the Directive and the Secretary's other actions is to revise internal Snohomish County policies so that they no longer defer to ACIP recommendations and CDC guidance.

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

Executed on November 14, 2025 in Everett, Washington.

/s/ James Lewis, MD, MPH

EXHIBIT 22

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

SUPPLEMENTAL DECLARATION OF AMIE LOEHR MD FAAFP

I, Jamie Loehr, MD, FAAFP, 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 supplemental declaration are based on my personal knowledge. I submit this supplemental declaration in support of Plaintiffs' Third Amended Complaint filed in the above-captioned action.

2. I am a board-certified family physician. I have been a physician for 35 years. I am the founder and owner of Cayuga Family Medicine, located in Ithaca, NY, where I have practiced family medicine since 2000.

3. I graduated from Cornell University in 1985 and then Baylor College of Medicine in 1990. I completed my residency in family medicine at the University of Rochester, Highland Hospital, in Rochester, NY in 1993.

4. I began my service on the Advisory Committee on Immunization Practices ("ACIP") in July 2011 as an American Academy of Family Physicians ("AAFP") liaison member.

5. In addition to voting and ex-officio members, ACIP is also comprised of 31 liaison members, primarily from professional organizations. Appointments of liaison members are based on written requests from the professional organizations. Liaison members represent organizations that have broad immunization interests and represent large constituencies. I served as the AAFP liaison member for four years and also on the Influenza Vaccines Work Group. After four years as a liaison member, I continued my service to the ACIP as a subject matter expert on the Influenza Vaccines Work Group. I then became a voting member of the ACIP in September 2021, until my termination from ACIP on June 9, 2025.

6. I applied to be a voting member of ACIP in 2015. The application process required me to submit a current curriculum vitae, two letters of recommendation, and a cover letter. I applied to be a voting member of the ACIP several times over the next few years.

7. In 2020, I was nominated to be a voting member of ACIP. Generally, ACIP submits the names of their nominated members to the Department of Health and Human Services (HHS) for approval. Nominations are not always approved, but once they are approved, nominations have always been confirmed. My nomination was confirmed, and I was supposed to begin my term as a voting member of ACIP on July 1, 2020. However, I was subsequently told that the White House rejected my nomination. I was also told that had never happened before and no reason was given to me for this rejection. As a result, I did not start as a voting member on ACIP in 2020.

8. Later in 2020, I put my name forward again. My nomination was accepted in late July 2021 and I began as a voting member with ACIP in September 2021. My initial term was supposed to run from July 1, 2021 until June 30, 2025, in accordance with the four-year term of ACIP voting members.

9. I was appointed to be Chair of ACIP starting July 1, 2025 until June 30, 2028, in accordance with the three-year term for the Chair of ACIP.

10. I saw the May 27, 2025 announcement on the X social media platform by Secretary of Health and Human Services Robert F. Kennedy, Jr. that he was rescinding prior ACIP recommendations that pregnant women and healthy children ages six months to 17 years old be routinely immunized against COVID-19. I was shocked by his announcement, especially because the Secretary changed the recommendations without consulting with the ACIP or without the ACIP voting to take this action. This decision was contrary to the longstanding practice and policy of vaccines being put on or taken off of the CDC's immunization schedules only after thorough review and a vote by the ACIP. This announcement came to the entire ACIP totally without warning. COVID-19 vaccines were not up for a vote at the prior ACIP meeting on April 15-16, 2025, and no data was presented at the April 15-16 meeting suggesting that COVID-19 vaccines should not be recommended for pregnant persons or children. In fact, there was discussion at the April 15-16, 2025 meeting that pregnancy was a risk factor for severe illness from COVID-19.

11. On June 9, 2025, at around 4 p.m., the Wall Street Journal published an opinion commentary ("June 9 Op-Ed") authored by Secretary Kennedy entitled "HHS Moves to Restore Public Trust in Vaccines."[1] The article read:

> Today, we are taking a bold step in restoring public trust by totally reconstituting the Advisory Committee for Immunization Practices (ACIP). We are retiring the 17 current members of the committee, some of whom were last-minute appointees of the Biden administration. Without removing the current members, the current Trump administration would not have been able to appoint a majority of new members until 2028.

[1] A true and correct copy of the June 9 Op-Ed is attached hereto as **E hibit A.**

12. Later that day, on June 9, 2025, at 6:06 p.m., I received formal communication of my removal from CDC.[2] The email read:

> Per the June 9, 2025, directive from the Secretary of the U.S. Department of Health and Human Services, this email serves as formal notice of your immediate termination as a member of the Advisory Committee on Immunization Practices (ACIP).
>
> We appreciate your prior service and commitment.

13. After receiving this email, I later learned that all seventeen (17) voting members of ACIP ("Former ACIP") were informed of their terminations in this manner.

14. I have not been told any other reason for termination of the entire Former ACIP other than the statements included in the June 9 Op-Ed.

15. Secretary Kennedy stated in the June 9 Op-Ed that the necessity for reconstituting ACIP arose from a need to "avoid conflicts of interest." Secretary Kennedy also asserted that the Former ACIP "has been plagued with persistent conflicts and has become little more than a rubber stamp for any vaccine." The June 9 Op-Ed cited conflicts of interests from an investigation into the Vaccines and Related Biological Products Advisory Committee in 2000; potential conflict of interests with the Rotashield vaccine in 1997; and an HHS inspector general report from 2009.

16. I was not on the Committee in 1997, 2000, or 2009. To the best of my knowledge, no one of the 17 terminated Former ACIP members were on the ACIP in 1997, 2000, or 2009.

17. ACIP members are required to disclose any conflicts of interest. Generally, this means that the member must disclose if they have any financial interactions or ongoing contact with a pharma company. Conflict is generally defined as participating in a study, on the public safety data review committee, or being on the speaking committee for a pharma company.

[2] A true and correct copy of the June 9, 2025 email is attached hereto as **E hibit B.**

18. As part of the application process, I was required to complete and file several forms including OGE Form 450 (Confidential Financial Disclosure Report), Foreign Activities Questionnaire, Special Government Employee Annual Certifications, and Special Government Employee Supplemental Report: Research Support/Project Funding. On these forms I was required to disclose, for example, how my salary was paid, whether I participated on any boards, all my assets (including stocks and bonds), and several other activities. I know that ACIP members were required to disclose whether they were working on a study or safety monitoring board

19. As part of the application process, I disclosed that my wife owned stock in Johnson & Johnson ("J&J"). She was required to divest from these stocks before I was allowed to participate in ACIP meetings. As a result, I missed the August 2021 ACIP meetings and did not attend my first meeting until September 22, 2021.

20. As part of the application process, I was required to review Ethics Training materials provided to me and also available at https://cdc.gov/faca/ethics/index.html.

21. Former ACIP members erred on the side of being overly transparent when disclosing conflicts of interest. Members would recuse themselves from votes if they previously worked at a company whose vaccine is up for a vote or if they worked on that vaccine previously. I did not need to disclose my wife's prior ownership of J&J stock because she divested her ownership of J&J stock before I began service on the Former ACIP as a voting member.

22. Whenever there was a question about what qualified as a conflict, I went to ACIP leadership, primarily Melinda Wharton, M.D., M.P.H. for clarity. For example, when I realized that I, as an owner of a physician practice that purchases vaccines, may have a transactional relationship with vaccine manufacturers, I disclosed my concerns to Melinda Wharton directly

who assured me that this was an "arm's length" transaction that did not qualify as a conflict for purposes of ACIP.

23. I have found my fellow Former ACIP members to be of the highest integrity and character. I have never witnessed or believed that any of my fellow Former ACIP voting members acted or voted unethically or without the best interests of the public health of Americans in mind. We have performed our duties on the ACIP with diligence, with integrity, and ethically. The accusations in the Secretary's Op-Ed against me and my fellow Former ACIP members are simply untrue.

24. Two days after my termination from the ACIP, on June 11, 2025, Secretary Kennedy appointed eight (8) new voting members to the ACIP ("Current ACIP"). Given that there were only two days between my termination and the announcement of the new members, I find it very hard to believe that these new ACIP members went through the rigorous, lengthy application process that I went through, and I know that other ACIP members went through, to become voting members of the ACIP. I also find it hard to believe that every Current ACIP member managed to finish all the required forms, go through the conflict checks, and review the ethics training materials in such a short time.

25. Prior to June 11, 2025 Former ACIP members were experts in their fields. For example, the Former ACIP included people who have done research into vaccine preventable diseases, run large public health departments, are knowledgeable about statistics, or knowledgeable about public health. It is my opinion that the vast majority of the Current ACIP members are not experts in any of these areas and lack credibility because they do not have these important experiences. The vast majority of the Current ACIP members do not have a depth of experience in vaccines, the ACIP process, public policy, nor how their decisions affect the world.

26. I have observed during meetings held by the Current ACIP that they were not familiar with the Vaccines for Children ("VFC") Program or the way the Affordable Care Act affect vaccine reimbursement. In fact, during an ACIP meeting, one Current ACIP member stated "I don't know what we just voted on," after the vote was completed.

27. In my view, the Current ACIP is not fulfilling the responsibility laid out in its charter, which calls for giving the CDC Director advice on how vaccines should be used to control vaccine-preventable diseases across the civilian population and to conduct a thorough, evidence-based review of the data to support an ACIP recommendation on COVID-19 vaccines. It seems to me that the committee is approaching vaccines as if the focus were individual patient care rather than public health. This comes through when members rely on personal stories about adverse events to argue that vaccines are causing broad harm during ACIP meetings. This was made clear to me when, during the public ACIP meeting, Current ACIP members used anecdotal evidence about adverse events to support claims of widespread harm being caused by vaccines.

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

Executed on November 21, 2025 in Ithaca, NY.

Jamie Loehr

Dr. Jamie Loehr, MD, FAAFP

EXHIBIT A

From: **FACM Policy and Oversight Team (CDC)** <facmpo@cdc.gov>
Date: Mon, Jun 9, 2025 at 6:06 PM
Subject: Advisory Committee on Immunization Practices Notice
To: JamieACIP@Gmail.com <JamieACIP@gmail.com>, jamie@cayugafamilymedicine.com <jamie@cayugafamilymedicine.com>

To: Jamie Loehr

Per the June 9, 2025 directive from the Secretary of the U.S. Department of Health and Human Services, this email serves as formal notice of your immediate termination as a member of the Advisory Committee on Immunization Practices (ACIP).

We appreciate your prior service and commitment.

EXHIBIT B

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https://www.wsj.com/opinion/rfk-jr-hhs-moves-to-restore-public-trust-in-vaccines-45495112

OPINION COMMENTARY Follow

RFK Jr.: HHS Moves to Restore Public Trust in Vaccines

We're reconstituting an advisory committee to avoid conflicts of interest.

By Robert F. Kennedy Jr.

June 9, 2025 4:00 pm ET



A nurse holds a Pfizer-BioNTech Covid-19 vaccine in Miami, May 29. PHOTO: JOE RAEDLE/GETTY IMAGES

Vaccines have become a divisive issue in American politics, but there is one thing all parties can agree on: The U.S. faces a crisis of public trust. Whether toward health agencies, pharmaceutical companies or vaccines themselves, public confidence is waning.

Some would try to explain this away by blaming misinformation or antiscience attitudes. To do so, however, ignores a history of conflicts of interest, persecution of dissidents, a lack of curiosity, and skewed science that has plagued the vaccine regulatory apparatus for decades.

That is why, under my direction, the U.S. Department of Health and Human Services is putting the restoration of public trust above any pro- or antivaccine agenda. The public must know that unbiased science guides the recommendations from our health agencies. This will ensure the American people receive the safest vaccines possible.

Today, we are taking a bold step in restoring public trust by totally reconstituting the Advisory Committee for Immunization Practices (ACIP). We are retiring the 17 current members of the committee, some of whom were last-minute appointees of the Biden administration. Without removing the current members, the current Trump administration would not have been able to appoint a majority of new members until 2028.

ACIP evaluates the safety, efficacy and clinical need of the nation's vaccines and passes its findings on to the Centers for Disease Control and Prevention. The committee has been plagued with persistent conflicts of interest and has become little more than a rubber stamp for any vaccine. It has never recommended against a vaccine—even those later withdrawn for safety reasons. It has failed to scrutinize vaccine products given to babies and pregnant women. To make matters worse, the groups that inform ACIP meet behind closed doors, violating the legal and ethical principle of transparency crucial to maintaining public trust.

In 2000 the House issued the results of an investigation of ACIP and another vaccine advisory committee under the U.S. Food and Drug Administration—the Vaccines and Related Biological Products Advisory Committee. It found that enforcement of its conflict-of-interest rules was weak to nonexistent. Committee members regularly participated in deliberations and advocated products in which they had a financial stake. The CDC issued conflict-of-interest waivers to every committee member. Four out of eight ACIP members who voted in 1997 on guidelines for the Rotashield vaccine, subsequently withdrawn because of severe adverse events, had financial ties to pharmaceutical companies developing other rotavirus vaccines. A 2009 HHS inspector-general report echoed these findings. Few committee members completed full conflict-of-interest forms—97% of them had omissions. The CDC took no significant action to remedy the omissions.

These conflicts of interest persist. Most of ACIP's members have received substantial funding from pharmaceutical companies, including those marketing vaccines. The problem isn't necessarily that ACIP members are corrupt. Most likely aim to serve the public interest as they understand it. The problem is their immersion in a system of industry-aligned incentives and paradigms that enforce a narrow pro-industry orthodoxy. The new members won't directly work for the vaccine industry. They will

exercise independent judgment, refuse to serve as a rubber stamp, and foster a culture of critical inquiry—unafraid to ask hard questions.

A clean sweep is needed to re-establish public confidence in vaccine science. In the 1960s, the world sought guidance from America's health regulators, who had a reputation for integrity, scientific impartiality and zealous defense of patient welfare. Public trust has since collapsed, but we will earn it back.

Mr. Kennedy is secretary of health and human services.

Further Reading

HHS to Stop Recommending Routine Covid Shots for Children, Pregnant Women

How RFK Jr. Is Boosting 'Food Babe' and Other MAHA Acolytes

Trump's FDA Sends a Bullish Signal to Biotech

OPINION **RFK Jr. Is Already Vindicating His Critics**

Videos

EXHIBIT 23

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

SUPPLEMENTAL DECLARATION OF CHARLOTTE MOSER, M.S.

I, Charlotte Moser, M.S., 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. I submit this declaration in support of Plaintiffs' Third Amended Complaint filed in the above-captioned action.

2. I work at the Children's Hospital of Philadelphia ("CHOP"), which is a non-profit. At CHOP, I am the co-director at the Vaccine Education Center, an outreach program that provides accurate and up-to-date information on vaccinations. I helped establish and expand the Vaccine Education Center for two and a half decades.

3. At CHOP, I am also the co-creator of the Vaccine Update program, where I assist in the development of programming for healthcare providers involved with vaccinations; these programs include a webinar series, a monthly e-newsletter, and resources for use at point of care and in professional development activities.

4. At CHOP, I am also the creator of the Parents PACK (Possessing, Accessing and Communicating Knowledge about vaccines), which is a program that helps develop a dialogue with families about vaccines, provides vaccine information more regularly than doctor visits, and establishes a place for parents to get up-to-date information and answers to vaccine questions.

5. I have a bachelor's degree in biology from Wilkes University and a master's degree in communication from Drexel University. I have done bench research studying the immunology of rotavirus.

6. I began service as a voting member of the Advisory Committee on Immunization Practices (ACIP) on July 1, 2024 as the consumer representative until I was summarily terminated on June 9, 2025.

7. The consumer representative position on the ACIP is a voting member position "held by a technically qualified person knowledgeable about consumer perspectives and/or social and community aspects of immunization programs."[1] My experience as co-director of the Vaccine Education Center at CHOP as well as with Parents PACK program at CHOP made me knowledgeable about consumer perspectives and social and community aspects of immunization programs. Just prior to my appointment to the ACIP, the consumer representative was a mother who lost their child to a vaccine-preventable illness.

8. I saw a call for applications to be an ACIP member and, based on my prior experience, thought I would like to do it. I spoke with Dr. Paul Offit, the Director of the Vaccine Education Center at CHOP, before applying and he said it was a great idea. I applied to be a voting member of ACIP on June 20, 2022. The application process required me to submit a current

[1] CDC, *Apply for ACIP Membership* (December 20, 2024), https://www.cdc.gov/acip/apply-for-membership/index.html, attached hereto as **Exhibit A.**

curriculum vitae, two letters of recommendation, and a cover letter. I submitted three letters of recommendation, including one from Dr. Paul Offit.

9. During the process, I was also required to complete an interview with the ACIP Secretariat and a CDC staff member. I received an invitation email for ACIP membership on May 14, 2024. The entire process took almost 2 years. Once invited, I submitted a signed letter accepting the invitation as well as completing onboarding paperwork and orientation before the start of my term.

10. My term on ACIP began on July 1, 2024. My initial term was supposed to run from July 1, 2024 until June 30, 2028, in accordance with the four-year term of ACIP voting members.

11. I saw Secretary of Health and Human Services Robert F. Kennedy, Jr.'s May 27, 2025 announcement on X that he was rescinding prior ACIP recommendations that pregnant women and healthy children ages six months to 17 years old be routinely immunized against COVID-19. I was surprised by his announcement because he did so without consulting with the ACIP or without the ACIP voting to take this action. This decision was contrary to the longstanding practice and policy of vaccines being put on or taken off of the CDC's immunization schedules only after thorough review and a vote by the ACIP. This announcement came without warning.

12. COVID-19 vaccines were on the agenda without a vote at the prior ACIP meeting on April 15-16, 2025, and no data presented at the April 15-16 meeting suggested that the COVID-19 vaccine recommendations for pregnant persons should be removed. In fact, a slide shown during the April meeting listed "pregnancy and recent pregnancy" as a condition that places one at higher risk for severe COVID-19. There was a discussion at the April 15-16, 2025 meeting that we would be evaluating the recommendations for 2025-2026 COVID-19 vaccines during the June 2025 meeting.

13. On June 5, 2025, at 10:01 a.m., I received an email from CDC Office of Human Resources, Client Services Operations, with the subject line "[External]CDC-Termination SF50."[2] Generally, a Standard Form 50 (SF-50) documents a change in employment status at a federal agency. Attached was a SF-50 form which listed "EXP of APPT," which I interpreted to be an "expiration of appointment" and that I was terminated. However, a conversation with the ACIP Secretariat suggested that this may have been in error, and they were looking into it with Human Resources.

14. On June 9, 2025, at 11:41 a.m., I received an email from Isaac Anderson, Director, Client Services Operations at CDC which stated that my current term had "not yet been extended" and that "[r]enewal by Department of Health and Human Services (HHS) is pending."[3] That email also stated that that "the system automatically generated a termination notice. This was an internal HR administrative process unrelated to your standing in the Committee. We sincerely apologize for the oversight and thank you for your service." I interpreted this email to mean that I had not been terminated from the ACIP.

15. On June 9, 2025, at exactly 4 p.m., the Wall Street Journal published an opinion commentary ("June 9 Op-Ed") authored by Secretary Kennedy entitled "HHS Moves to Restore Public Trust in Vaccines."[4] The article read:

> Today, we are taking a bold step in restoring public trust by totally reconstituting the Advisory Committee for Immunization Practices (ACIP). We are retiring the 17 current members of the committee, some of whom were last-minute appointees of the Biden administration. Without removing the current members, the current Trump administration would not have been able to appoint a majority of new members until 2028.

[2] A true and correct copy of the June 5, 2025 10:01 a.m. email is attached hereto as **Exhibit B.**

[3] A true and correct copy of the June 9, 2025 11:41 a.m. email is attached hereto as **Exhibit C.**

[4] A true and correct copy of the June 9 Op-Ed is attached hereto as **Exhibit D.**

16. Later that day, on June 9, 2025, at 5:51 p.m., I received formal communication of my removal from CDC.[5] The email read:

> Per the June 9, 2025, directive from the Secretary of the U.S. Department of Health and Human Services, this email serves as formal notice of your immediate termination as a member of the Advisory Committee on Immunization Practices (ACIP).
>
> We appreciate your prior service and commitment.

17. I learned that all seventeen (17) voting members of ACIP ("Former ACIP") were informed of their terminations in this manner.

18. I have not been told any other reason for termination of the entire Former ACIP other than the statements included in the June 9 Op-Ed.

19. Secretary Kennedy stated in the June 9 Op-Ed that the necessity for reconstituting ACIP arose from a need to "avoid conflicts of interest." Secretary Kennedy also asserted that the Former ACIP "has been plagued with persistent conflicts and has become little more than a rubber stamp for any vaccine." The June 9 Op-Ed cited conflicts of interest from an investigation into ACIP and the Vaccines and Related Biological Products Advisory Committee in 2000; potential conflict of interests with the Rotashield vaccine in 1997; and an HHS inspector general report from 2009.

20. I was not on the Committee in 1997, 2000, or 2009. To the best of my knowledge, none of the 17 terminated ACIP members were on the ACIP in 1997, 2000, or 2009.

[5] A true and correct copy of the June 9, 2025 5:51 p.m. email is attached hereto as **Exhibit E.**

21. I have no conflicts of interest and have never received money from pharmaceutical companies. Any such information about me would have been disclosed during the application process had it existed.

22. Two days after my termination from the ACIP, on June 11, 2025, Secretary Kennedy appointed eight (8) new voting members to the ACIP ("Current ACIP"). Given that there were only two days between my termination and the announcement of the new members, there is no way that these new ACIP members endured the same lengthy application process that I went through or that I understand other Former ACIP members went through to become members of the ACIP.

23. The current consumer representative, Vicky Pebsworth, has been part of an anti-vaccine group for many years.

24. I am aware that the Current ACIP met on June 25-26, 2025 and included COVID-19 vaccination in their discussions. I am also aware that the Current ACIP met September 18-19, 2025 and that at this meeting the Committee discussed recommending the COVID-19 vaccine through Shared Clinical Decision Making ("SCDM") for essentially all patients. During the September meeting, unvetted material and unsupported claims about the COVID-19 vaccine were presented. Some committee members relied on personal anecdotes or brought their own "studies" to the public discussion, expressed misunderstandings of basic biological concepts, and were at times confrontational toward CDC staff and vaccine manufacturers while discussing COVID-19 vaccines. I have also observed that during these meetings the Current ACIP members expressed a particular bias against COVID-19 vaccines.

25. I believe that the use of Current ACIP members' individual experiences in this setting is inconsistent with the ACIP's stated purpose to provide population-level guidance. The

purpose of public health is to provide a broad runway, so that when it comes down to individualized medicine, providers have a choice for their patients. In contrast, the Current ACIP tried to justify their limitation on COVID-19 vaccine access by framing it as "individual decision making" and treating that as the same as SCDM. To me, this illustrates a shift toward individualized medicine rather than the population-based work the ACIP is supposed to do. In my view, this was an attempt to use the committee to address individual medical concerns instead of public health concerns. When public health policy is used this way, it can undermine access to vaccines and weaken disease control.

26. Prior to September 2025, SCDM recommendations were used in situations where a general recommendation was not practical for the entire population, but from which some individuals could still benefit, as in the case where the vaccine was too costly for population-based administration to prevent a single case (cost per case) or offered limited protection, as with the meningococcal B vaccine. However, Former ACIP members believed that SCDM was not being well understood by providers and that it was creating substantial confusion and hindering vaccine use. It is my understanding that, prior to their termination, the Former ACIP had been deliberating doing away with the SCDM option. Therefore, the Current ACIP's decision to implement "individual decision making" and conflate it with the already-confusing SCDM recommendation is, in my experience, a step in the wrong direction.

27. I also believe the conflation of "informed consent" with SCDM is worsening the confusion that already surrounds the SCDM recommendation. In his October 6 endorsement of ACIP's SCDM recommendation, the Deputy Secretary of Health and Human Services, who is also the acting director of the CDC, said that "Informed consent is back." Informed consent is always part of medical care, but SCDM itself is not a mechanism to ensure that informed consent is

happening. This type of statement from CDC demonstrates that ACIP is focused on individual health care decision making rather than working within the scope of what they are charged with doing, which is to "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."

28. Decisions coming from ACIP, including the SCDM recommendation for the COVID-19 vaccine, are not improving clarity. As a result, our team at the CHOP Vaccine Education Center spent hours writing an article for our newsletter to help explain to providers what the recommendation actually means. Between September and November 2025, almost 25% of the inquiries sent to our website have been related to the COVID-19 vaccine. These questions come from both families and clinicians. We have also received inquiries about the Current ACIP's other talking points like use of placebo-controlled trials, the ability to sue manufacturers, changes to the CDC Immunization Schedule, autism, and even questions about germ theory. This has caused us to shift resources away from other educational initiatives intended to explain science and promote public health as described above.

29. Some patients who generally support vaccination now have concerns because they worry that ACIP is no longer relying on the strongest science. For example, they are uncertain whether the U.S. flu vaccine will be reliable because they believe the usual strain-selection process was not followed.

30. I have seen firsthand how the SCDM recommendation is hindering access to the COVID-19 vaccine. Because their children's own pediatricians are not offering the COVID-19 vaccine this year, parents have contacted the CHOP Vaccine Education Center looking for a place to have their infants vaccinated, even though we are not part of CHOP's clinical services.. We

often have to explain that they need to reach out to CHOP primary care or other vaccination sources, such as local health departments or pharmacies, to check availability. Providers may not be willing to vaccinate patients who do not regularly see them because they have only ordered quantities they anticipate needing for their own patients. In addition, some pharmacies may not be willing to vaccinate children with the COVID-19 vaccine.

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

Executed on November 24, 2025, in Bensalem, PA

Charlotte A Moser

/s/ Charlotte Moser, MS

EXHIBIT A

Advisory Committee on Immunization Practices (ACIP)

Apply for ACIP Membership

For Everyone
DECEMBER 20, 2024

AT A GLANCE

- The Centers for Disease Control and Prevention (CDC) regularly solicits applications and nominations of candidates to fill upcoming vacancies on the Advisory Committee on Immunization Practices (ACIP).
- Seats become vacant as members rotate off the committee.
- This page provides information about member roles and responsibilities as well as instructions to apply for membership on the committee.

What to know

Collapse All

Categories of membership: medical professional members and consumer representative member

Medical Professional Members

ACIP includes up to 18 voting members representing clinical medical fields (e.g., physician, nurse, nurse practitioner) and/or public health professionals (e.g., state health department, epidemiologist). These positions are held by technically qualified people trained in a clinical medical field and possessing in-depth knowledge of vaccines and immunization.

Qualifications of the medical or public health professional include the following:

- Advanced medical degree (e.g., MD, RN)
- Board certification in area(s) of specialization
- Scientific knowledge of vaccines, immunization, and/or immunization programs
- Ability to interact actively and respectfully with other ACIP voting members, as well as ACIP *ex officio* members and liaison representatives, all of whom attend each ACIP meeting
- Willingness to take part in three regularly scheduled meetings per year, and any additional meetings that may be called
- Individuals must demonstrate expertise, comfort, and facility with active participation in deliberations of the ACIP during public meetings
- Willingness to participate actively in at least two ACIP work groups
- Willingness to review and give input on ACIP recommendation statements

Lay Member: Consumer Representative

ACIP must include a consumer representative as one of the voting members of the committee. This position is held by a technically qualified person knowledgeable about consumer perspectives and/or social and community aspects of immunization programs.

Qualifications of the consumer representative include the following:

- Lay knowledge of vaccines, immunizations, and/or immunization programs
- Ability to interact actively and respectfully with other ACIP voting members, as well as ACIP *ex officio* members and liaison representatives, all of whom attend each ACIP meeting

- Willingness to take part in three regularly scheduled meetings per year, and any additional meetings that may be called
- Individuals must demonstrate expertise, comfort, and facility with active participation in deliberations of the ACIP during public meetings
- Willingness to participate actively in at least two ACIP work groups
- Willingness to review and give input to ACIP recommendation statements

Membership qualifications

ACIP members are acknowledged experts with an outstanding record of achievement in their own field and an understanding of the immunization issues covered by ACIP. They have a responsibility to provide CDC with high quality, well-considered advice and recommendations on matters described in the ACIP Charter.

Qualities required for ACIP members

Below are the criteria that will be applied when assessing candidates. To be considered, you must be able to demonstrate that you have the qualities, skills and experience to meet all the criteria.

Candidates must have:

- An understanding of the vaccination and immunization issues covered by the ACIP;
- An understanding of immunization issues in the U.S., including the routine domestic immunization program and vaccines used for special circumstances, e.g. "travel" vaccines;
- An outstanding record of achievement and personal credibility within their own field;
- Experience of operating at a strategic level in the public or other sectors;
- Experience of working effectively in high level advisory committees;
- Excellent interpersonal and communication skills to support effective discussion with a range of stakeholders;
- Ability to evaluate complex issues and weigh conflicting opinions;
- Ability to influence at a senior level;
- A broad range of expertise and interest in vaccines and immunization.

Member roles and responsibilities

The Chair and members of the committee play a critical role in ensuring ACIP's continued standing as a nationally and internationally recognized leading body in the field of immunization and that it continues to observe the highest standards of impartiality, integrity and objectivity in its deliberations and that its recommendations are driven by available scientific evidence. Members of ACIP will:

- Be committed to continued development and improvement in this important area of public health;
- Bring relevant experience to the committee;
- Contribute to the provision of high quality and considered public health advice to the CDC and DHHS;
- Be expected to make a full and considered contribution to the work of the committee and to contribute fully to the debate and to the decision-making processes;
- Provide expert guidance when an issue that falls within your particular area of expertise is under discussion;
- Contribute to the debate in the capacity of a well-informed health professional when the issue does not fall within your expertise;
- Take into account the need for and impact of vaccines, the quality and safety of vaccines and strategies to ensure that the greatest benefit can be obtained from the most appropriate use of vaccines;
- Be prepared to respond quickly to interaction by e-mail;
- Be prepared, as requested by the Secretariat, to attend and contribute to the work of one or more of the ACIP work groups, which report to the ACIP;
- Be committed to declare all relevant interests. Any reported interest that could be perceived as a potential conflict of interest will be disclosed during public ACIP meetings and in written meeting minutes, which are posted on the ACIP website.

All members serve in their personal capacity and should refrain from promoting the policies and views and products of the organization/institution for which they work.

Compensation

Appointments are not remunerated. However, members are compensated for expenses incurred by attendance at meetings. Such compensation, which includes the issuance of airline tickets, per diem to cover lodging, meals and incidental expenses will be in accordance with DHHS/CDC travel rules. An optional honorarium of $250/day for each day that a member attends an ACIP meeting is offered to voting members, who are designated as Special Government Employees during their tenure on the committee.

Location of meetings and time commitment

ACIP meets three times annually for a two- to three-day meeting at CDC in Atlanta, GA. The meetings take place usually during the third or fourth week in the months of February, June, and October, and meeting dates are posted on the ACIP website. Some preparation time for meetings will be required, which may involve weekends. In addition, members will be asked to participate in at least two ACIP work groups, which usually hold virtual one- to two-hour meetings, once or twice per month. Overall, including meeting and travel time, participation in virtual meetings, e-mail interaction, and participation in work groups, one can expect approximately a three-week commitment spread over the year.

Appointments and tenure

- Members will be appointed for a term of four years, which typically begins on July 1 in the year of appointment.
- In general, a member's term may not be extended beyond four years, and appointment to a second term is not allowed.
- The Chair shall be appointed for a term of up to three years. The Chair is selected and appointed by the HHS Secretary from among voting ACIP members with at least two years of experience serving on ACIP, that have demonstrated the ability both to lead the work of similar bodies and to work effectively with CDC.

Orientation and education

Orientation for new members is provided to enable members to fully understand the work and functioning of the ACIP, including participation in ACIP work groups. This is typically offered as a two-hour virtual meeting within one month of appointment of new members. The Secretariat will further arrange briefings and meetings with CDC staff and any other training in order to facilitate the full engagement of new members in the work of the ACIP.

The ACIP Secretariat also arranges educational sessions on topics such as the role of health economics in development of ACIP recommendations, immunization safety monitoring and procedures used in development of evidence-based recommendations. These sessions are sometimes held at the CDC on the day before an ACIP meeting.

Conflicts of interest

ACIP members are required to declare any potential conflicts of interest that arise in the course of ACIP tenure and any relevant business interests, positions of authority or other connections with organizations relevant to the work of the ACIP. Upon appointment, each voting member is required to file an Office of Government Ethics 450 form (OGE450), a Confidential Financial Disclosure Report, which is reviewed by the ACIP Secretariat, the Federal Advisory Committee Management Branch and the Office of General Counsel at CDC. Confidential Financial Disclosure must be updated annually during a member's term. At every ACIP meeting, the Chair calls for conflict of interest disclosure from each voting member at the opening of the meeting and prior to any vote taken by the ACIP.

Any actual or perceived conflict of interests will be explored fully by the Secretariat, CDC's Federal Advisory Committee Management Branch, and CDC legal counsel if necessary.

Members with declared interests will be asked to recuse themselves from participating in the discussion and decision-making of the issues relating to that interest. A member who has any doubt as to whether they have an interest that should be declared, or whether they should take part in the proceedings, should ask the Secretariat for guidance.

Application information

The ACIP Secretariat receives applications at any time of the year for candidates to fill upcoming vacancies on the ACIP. Selection of members is based on candidates' qualifications to contribute to the accomplishment of ACIP objectives.

The U.S. Department of Health and Human Services policy stipulates that committee membership be balanced in terms of professional training and background, points of view represented, and the committee's function. Consideration is given to a broad representation of geographic areas within the U.S., with equitable representation of the sexes, ethnic and racial minorities, and the handicapped. Preference is given to candidates who are U.S. citizens.

Candidates should submit the following items:

- Current ***curriculum vitae,***
- Two letters of recommendation from professional colleagues familiar with your work. A maximum of four letters of recommendation will be accepted.
  - Letters of recommendation should not come from current ACIP members.
  - At least one letter of recommendation must come from a professional colleague who is not employed by the U.S. Department of Health and Human Services (e.g., NIH, FDA, etc.). CDC employees should not provide letters of recommendation.
- A cover letter that includes a statement of interest in serving on the ACIP, qualifications and expertise, and written evidence to support all of the relevant criteria, which are identified in the "Membership Qualifications" section of this page.

The CV should include candidates' education, training, board certification and career history and list main areas of employment or other relevant activity and public appointments, if any. Include details of any relevant academic or professional qualifications.

A review of all applications will be conducted by the ACIP Steering Committee, with final selection of the candidates to be made by the Secretary, Department of Health and Human Services. Successful candidates will be notified of their appointment and those candidates not accepted will be informed in writing. Unsuccessful applicants are encouraged to re-apply in subsequent years. The need for various kinds of expertise varies from year to year and a candidate who is not selected in one year may be appointed in a subsequent year.

Complete online application

Access the online application. All candidates are required to submit their materials through the online application system. You must re-apply through the online application each year you would like to be considered for membership.

If you have previously submitted an application through our online system you may review and update your application. You must click the submit button to reapply every year, even if no new documents are submitted.

If you have any questions regarding these procedures, please email the ACIP Secretariat at ACIP@cdc.gov.

SOURCES

CONTENT SOURCE:
National Center for Immunization and Respiratory Diseases (NCIRD)

EXHIBIT B

From: Oden, DeChaka (CDC/OCOO/OHR)
To: Moser, Charlotte A
Subject: [External]CDC-Termination SF50
Date: Thursday, June 5, 2025 10:01:56 AM
Attachments: Moser, Charlotte SF50.pdf

You don't often get email from xvn4@cdc.gov. Learn why this is important

Greetings,

Please find your SF50 attached.

Thank you,
CDC, Office of Human Resources

Restricted Use/Recipients Only

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EXHIBIT C

From: OHRseparations (CDC)
To: Moser, Charlotte A
Subject: [External]Committee Member - Dr. Moser
Date: Monday, June 9, 2025 11:41:01 AM
Attachments: image001.png

You don't often get email from ohrseparations@cdc.gov. Learn why this is important

Distinguished Committee Member

Dear Dr. Moser,

We would like to add clarity to the email you received on June 5, 2025, from the CDC Office of Human Resources (OHR), Client Services Operations, team in reference to your Committee Member appointment. Your current term has not yet been extended. Renewal by Department of Health and Human Services (HHS) is pending.

Please note that our personnel data system only allows extensions in one-year increments and the system automatically generated a termination notice. This was an internal HR administrative process unrelated to your standing in the Committee. We sincerely apologize for the oversight and thank you for your service.

Isaac Anderson
Director, Client Services Operations
Office of the Chief Operating Officer (OCOO)
Office of Human Resources (OHR)
404-718-4073 (office); 210-863-9832 (cell)
fxd2@cdc.gov

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EXHIBIT D

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https://www.wsj.com/opinion/rfk-jr-hhs-moves-to-restore-public-trust-in-vaccines-45495112

OPINION COMMENTARY Follow

RFK Jr.: HHS Moves to Restore Public Trust in Vaccines

We're reconstituting an advisory committee to avoid conflicts of interest.

By Robert F. Kennedy Jr.

June 9, 2025 4:00 pm ET



A nurse holds a Pfizer-BioNTech Covid-19 vaccine in Miami, May 29. PHOTO: JOE RAEDLE/GETTY IMAGES

Vaccines have become a divisive issue in American politics, but there is one thing all parties can agree on: The U.S. faces a crisis of public trust. Whether toward health agencies, pharmaceutical companies or vaccines themselves, public confidence is waning.

Some would try to explain this away by blaming misinformation or antiscience attitudes. To do so, however, ignores a history of conflicts of interest, persecution of dissidents, a lack of curiosity, and skewed science that has plagued the vaccine regulatory apparatus for decades.

That is why, under my direction, the U.S. Department of Health and Human Services is putting the restoration of public trust above any pro- or antivaccine agenda. The public must know that unbiased science guides the recommendations from our health agencies. This will ensure the American people receive the safest vaccines possible.

Today, we are taking a bold step in restoring public trust by totally reconstituting the Advisory Committee for Immunization Practices (ACIP). We are retiring the 17 current members of the committee, some of whom were last-minute appointees of the Biden administration. Without removing the current members, the current Trump administration would not have been able to appoint a majority of new members until 2028.

ACIP evaluates the safety, efficacy and clinical need of the nation's vaccines and passes its findings on to the Centers for Disease Control and Prevention. The committee has been plagued with persistent conflicts of interest and has become little more than a rubber stamp for any vaccine. It has never recommended against a vaccine—even those later withdrawn for safety reasons. It has failed to scrutinize vaccine products given to babies and pregnant women. To make matters worse, the groups that inform ACIP meet behind closed doors, violating the legal and ethical principle of transparency crucial to maintaining public trust.

In 2000 the House issued the results of an investigation of ACIP and another vaccine advisory committee under the U.S. Food and Drug Administration—the Vaccines and Related Biological Products Advisory Committee. It found that enforcement of its conflict-of-interest rules was weak to nonexistent. Committee members regularly participated in deliberations and advocated products in which they had a financial stake. The CDC issued conflict-of-interest waivers to every committee member. Four out of eight ACIP members who voted in 1997 on guidelines for the Rotashield vaccine, subsequently withdrawn because of severe adverse events, had financial ties to pharmaceutical companies developing other rotavirus vaccines. A 2009 HHS inspector-general report echoed these findings. Few committee members completed full conflict-of-interest forms—97% of them had omissions. The CDC took no significant action to remedy the omissions.

These conflicts of interest persist. Most of ACIP's members have received substantial funding from pharmaceutical companies, including those marketing vaccines. The problem isn't necessarily that ACIP members are corrupt. Most likely aim to serve the public interest as they understand it. The problem is their immersion in a system of industry-aligned incentives and paradigms that enforce a narrow pro-industry orthodoxy. The new members won't directly work for the vaccine industry. They will

exercise independent judgment, refuse to serve as a rubber stamp, and foster a culture of critical inquiry—unafraid to ask hard questions.

A clean sweep is needed to re-establish public confidence in vaccine science. In the 1960s, the world sought guidance from America's health regulators, who had a reputation for integrity, scientific impartiality and zealous defense of patient welfare. Public trust has since collapsed, but we will earn it back.

Mr. Kennedy is secretary of health and human services.

Further Reading

HHS to Stop Recommending Routine Covid Shots for Children, Pregnant Women

How RFK Jr. Is Boosting 'Food Babe' and Other MAHA Acolytes

Trump's FDA Sends a Bullish Signal to Biotech

OPINION **RFK Jr. Is Already Vindicating His Critics**

Videos

EXHIBIT E

From: FACM Policy and Oversight Team (CDC)
To: Moser, Charlotte A
Subject: [External]Advisory Committee on Immunization Practices Notice
Date: Monday, June 9, 2025 5:51:07 PM

You don't often get email from facmpo@cdc.gov. Learn why this is important

To Charlotte Moser:

Per the June 9, 2025 directive from the Secretary of the U.S. Department of Health and Human Services, this email serves as formal notice of your immediate termination as a member of the Advisory Committee on Immunization Practices (ACIP).

We appreciate your prior service and commitment.

** This email originated from an EXTERNAL sender to CHOP. Proceed with caution when replying, opening attachments, or clicking links. Do not disclose your CHOP credentials, employee information, or protected health information to a potential hacker**.

EXHIBIT 24

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

SUPPLEMENTAL DECLARATION OF
ANDREW T. PAVIA, MD, FAAP, FACP, FIDSA

I, Andrew T. Pavia, MD, FAAP, FACP, FIDSA, declare pursuant to 28 U.S.C. § 1746, that the following is true and correct and within my personal knowledge.

1. Based on my over-30-year career as an infectious disease expert, the Secretary of Health and Human Services Robert F. Kennedy, Jr.'s dangerous and unsupported decisions regarding COVID-19 vaccines are causing preventable suffering and death to Americans.

2. I received my medical degree at Brown University. I trained in internal medicine at Dartmouth Hitchcock Medical Center and served as chief resident.

3. At the Centers for Disease Control and Prevention, I was trained in Public Health Epidemiology as an Epidemic Intelligence Service officer and a Preventive Medicine Resident.

4. I completed a fellowship in pediatric and adult infectious diseases at the University of Utah, and joined the faculty at the University of Utah in 1991. I later became the George and Esther Gross Presidential Professor and Chief of the Division of Pediatric Infectious Diseases.

5. I also currently serve as Director of Hospital Epidemiology at Primary Children's Hospital and Associate Director of Antimicrobial Stewardship.

6. I am a member of the Society for Pediatric Research, and a Fellow of the American Academy of Pediatrics, the American College of Physicians, the Infectious Diseases Society of America, and the Society for Healthcare Epidemiology of America. I have served as a member of the National Vaccine Advisory Committee and the National Biodefense Science Committee.

7. I have also been a member of the Advisory Committee on Immunization Practices ("ACIP") working group on Anthrax and a consultant to CDC on several expert groups.

8. I served as a member of the Board of Directors for the Infectious Diseases Society of America ("IDSA") from 2009 to 2012 and was the IDSA's past chair of the Pandemic Influenza Task Force, past Chair of the National and Global Public Policy Committee and past Chair of the IDWeek Program Committee. I am still an active member of IDSA as the Chair of the Avian Influenza Task Force and co-Chair of the IDSA Influenza Treatment Guidelines Committee.

9. IDSA was formed in 1970 in Washington, DC with the goal to cultivate the growing knowledge of infectious diseases, endorsing scientific programs, and retaining a membership of persons whose work showed significant contributions to the field.

10. IDSA is currently the leading medical society representing more than 13,000 infectious disease physicians, scientists, and other health professionals devoted to patient care, prevention, public health, education, and research in infectious diseases.

11. IDSA's mission is to bring together the curiosity, compassion, and knowledge of our members to strengthen the field of infectious diseases, advance science, and advocate for health equity.

12. IDSA offers robust training, education, and resources regarding immunization, which is one of the most important things people can do to protect their families and communities from infectious diseases, such as COVID-19, measles, polio, whooping cough, bacterial meningitis, and cervical cancer.

13. Our membership includes infectious disease physicians nationwide, many of whom are currently providing direct care to adults under the age of 65, pregnant patients, newborns, and children in both hospital and outpatient settings.

14. IDSA has adopted clinical practice guidelines that are considered the standard of care for our physician members and are in place to optimize and protect the care provided to our members' patients. Clinical practice guidelines are informed by a systematic review and quality assessment of peer-reviewed research and evidence; the professional judgment of our members and relevant experts from other specialties; and an assessment of the benefits and harms of alternative care options. Clinical practice guidelines follow a sound, transparent methodology to translate best evidence into clinical practice for improved patient outcomes. They are a key component of patient-centered care.

15. IDSA maintains regular guidance for clinicians regarding COVID-19, including related to the treatment and management of patients with COVID-19, infection prevention for health care personnel, and various diagnostic testing methodologies.

16. The recent actions of the Department of Health and Human Services related to the COVID-19 vaccine have injected chaos, confusion, and disruption into the practice and care that I and other IDSA physician members deliver to patients.

17. I am aware of and disagree with the "Secretarial Directive on Pediatric COVID-19 Vaccines for Children Less than 18 years of Age and Pregnant Women" (the "Secretarial

Directive") issued by Secretary of Health and Human Services Robert F. Kennedy, Jr. (the "Secretary") on May 27, 2025 designating the COVID-19 vaccine for children as Shared Clinical Decision Making ("SCDM") and removing the recommendation for the COVID-19 for pregnant individuals. The Directive was arbitrary and not supported by the evidence. In fact, no data presented by the COVID-19 Vaccines Work Group for the ACIP—before or after the issuance of the Directive—has suggested that vaccines should not be routinely recommended for pregnant persons or children. Indeed, pregnancy and recent pregnancy are considered risk factors for severe illness of COVID-19.

18. I am aware of and disagree with the recommendation issued by the newly reconstituted ACIP in September 2025 and subsequently adopted by the acting director of the Centers for Disease Control and Prevention ("CDC") in October 2025, changing the COVID-19 vaccine recommendation for adults under the age of 65 from routine to SCDM. This change by the ACIP and the CDC was made without the usual transparent presentation of GRADE tables or Evidence to Recommendation (EtR) framework for evaluating the quality of evidence, nor was this change accompanied by a clear, contemporaneous explanation in the MMWR. In my practice and in conversations with IDSA physician members, this change to the CDC immunization schedule for COVID-19 vaccines for adults has significantly disrupted the prior harmonious system and created multiple layers of confusion and harm.

19. IDSA has historically endorsed the ACIP's COVID-19 vaccine recommendations. That is no longer the case. The ACIP appointed by the Secretary has abandoned the careful, comprehensive, and transparent review historically undertaken by the ACIP that weighs all the factors that go into developing and issuing a vaccine recommendation. In reaching the decision to change the COVID-19 vaccine recommendation from "routine" to "SCDM," the ACIP appointed

by the Secretary excluded the opinions of liaison groups who care for patients and who have relevant expertise necessary to develop an effective, reliable vaccine recommendation; included minimal participation in deliberations from CDC experts; and failed to consider peer-reviewed, evidence-based data.

20. When the CDC classifies a vaccine as routine, that signals to patients that there is no ambiguity about the effectiveness and safety of a vaccine and enables providers to administer the vaccine with the backing of an unequivocal recommendation from the CDC and that the vaccine is recommended in order to protect their patients' health. That is because a routine recommendation means that the vaccine has proven over the years to be highly effective at preventing disease and saving lives with minimal risk to the patient and, therefore, should be administered as a standard part of medical care for the patient. A routine recommendation indicates that unless there is a specific contraindication to administering that vaccine, the patient should receive the vaccine. Routine recommendations do not in any way compel or mandate that the patient receive the vaccine. Rather, they provide clear, evidence-based medical advice and patients can discuss any questions they may have with providers.

21. The CDC immunization schedule change for adults for the 2025-2026 COVID-19 vaccines from "routine" to "SCDM" is a downgrading of the CDC's recommendation and sends a message to patients discouraging COVID-19 vaccine. As a recent article published by several distinguished IDSA physician members succinctly explained, "In contrast to an explicit recommendation to vaccinate is SCDM, which is the lowest-strength option available to ACIP. Rather than a recommendation, it is a 'perhaps.'"[1]

[1] Thomas R. Frieden, MD, MPH, et al., *CDC's Failure to Recommend COVID-19 Vaccination—"Shared Clinical Decision-Making" Is Abdication of Responsibility*, JAMA (November 13, 2025). A true and correct copy of this article is attached to this declaration as **Exhibit A.**

22. In the past, when the CDC has issued a SCDM recommendation for a vaccine, the supporting data was published in the CDC's Morbidity and Mortality Weekly Report ("MMWR") in addition to the SCDM recommendation. This data is critical for physician use in consulting with and discussing the risk and benefits of a vaccine categorized as SCDM and, normally, provides clinicians with the evidence base to guide patient counseling. No such data or guidance accompanied the CDC immunization schedule change for adults for the 2025-2026 COVID-19 vaccines from "routine" to "SCDM," leaving me and other IDSA physician members without clear guidance regarding what to discuss with patients or how to counsel them regarding the risks and benefits of the COVID-19 vaccine. This lack of clarity and guidance inherently increases the amount of time I and other IDSA physician members spend on unbillable counseling time with patients regarding the COVID-19 vaccine.

23. IDSA physician members have informed me that this lack of clarity and lack of guidance regarding the SCDM COVID-19 vaccine recommendation has left them without a path for employing shared clinical decision-making in practice, including whether it requires face-to-face time with a healthcare provider or if it allows for consultation with pharmacists.

24. This lack of standardized recommendations and practices has required states to fill in the gaps and determine how the SCDM recommendation for the COVID-19 vaccine fits within their state's laws. Consequently, states have had to hastily convene committees to interpret and develop guidance and regulations founded on evidence-based vaccine recommendations. As a result, instead of a single, trusted voice providing vaccine recommendations—as was the case prior to the Secretary's reconstitution of the ACIP—the public is receiving messages and recommendations regarding the COVID-19 vaccine that vary significantly on a state-by-state basis. As a resource for physicians on all issues and considerations related to vaccines, the IDSA

has had to devote significant time and resources to keeping up with the rapidly-changing patchwork of state requirements and laws related to the administration of the COVID-19 vaccine in order to address the influx of inquiries received from IDSA physician members following the downgrading of the CDC immunization schedule change for adults for the 2025-2026 COVID-19 vaccines from "routine" to "SCDM."

25. The CDC's downgrade of the recommendation of the COVID-19 vaccine for adults under age 65 to SCDM has created significant barriers for patients seeking to get a COVID-19 vaccine. For example, in order for a patient to engage in SCDM with a physician, a patient must schedule a physician appointment, incur copay costs, and potentially take time off work. Further, limited healthcare provider availability remains a significant obstacle for patients seeking access to the COVID-19 vaccine.

26. The downgrading of the recommendation of the COVID-19 vaccine for adults under age 65 to SCDM also requires me and other IDSA physician members to spend more time counseling patients about the safety and effectiveness of the COVID-19 vaccine. Before the new ACIP recommendation was issued, when the COVID-19 vaccine was a routine recommendation for adults under 65, I spent very little time counseling my patients regarding the COVID-19 vaccine because patients generally trusted the well-supported, evidence-based recommendations published by the CDC. Although studies establishing the safety and effectiveness of the COVID-19 vaccine and the risk-benefit analysis of receiving the COVID-19 vaccination has not changed, the new ACIP recommendation, adopted by the CDC, has created significant confusion and distrust about the COVID-19 vaccine among patients. This confusion and distrust requires me to spend significantly more time counseling patients in order to dispel the misinformation the Secretary has spread about the COVID-19 vaccine.

27. IDSA physician members have informed me that the change in the COVID-19 vaccine's classification from routine to one requiring shared clinical decision-making and the CDC's and the Secretary's associated messaging has left their patients confused and concerned regarding the vaccine's efficacy and safeness. Patients are seeking clarity from IDSA physician members regarding why this change is necessary and what additional risks have been identified necessitating the change, while providers are left without answers because there are no studies or data indicating that this change was necessary. As a result, the change in the COVID-19 vaccine recommendation from "routine" to "SCDM" has created a sense of chaos and instilled a lack of confidence among patients regarding a vaccine that is proven to be safe and effective at preventing the spread of COVID-19.

28. IDSA physician members use Current Procedural Terminology ("CPT") codes to bill for the professional services that they provide to their patients. Each code is tied to a patient care service and is used to document and receive reimbursement for medical encounters. Vaccine administration has its own family of CPT codes, with the codes tying compensation of doctors to actual administration of the vaccine during a patient visit. IDSA physicians report that, as a result of the recent ACIP recommendation, adopted by the CDC, which shifts the recommendation for COVID-19 vaccines to SCDM for adults under the age of 65, they have been required to spend significantly more unbillable time counseling patients and answering questions from primary care physicians regarding COVID-19 vaccinations. Not only is this time unbillable, but it also infringes on the ability of IDSA physician members to see additional patients and receive reimbursement for that time.

29. Peer-reviewed and evidence-based studies consistently show that the COVID-19 vaccine provides substantial protection against severe illness, long COVID-19, hospitalization,

and death for adults under the age of 65. Unless the COVID-19 vaccine is given to children and adults under the age of 65, including pregnant patients, then vaccination rates will fall and the risks of severe illness, hospitalization, and mortality will increase for these patient populations and their families. Moreover, increased rates of infection among adults under 65 and children who care for elderly and immunocompromised patients will increase the risk of COVID-19 related morbidity and mortality in these highly vulnerable patients.

30. I am over the age of 18 years old. All of the facts set forth in this declaration are based on my personal knowledge. If called upon to testify as to the facts stated herein as a witness, I could and would competently testify under oath.

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

Executed on: 11/19/2025

Dr. Andrew T. Pavia

Andrew T. Pavia, MD, FAAP, FACP, FIDSA
On behalf of Infectious Disease Society of America

EXHIBIT A

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VIEWPOINT

CDC's Failure to Recommend COVID-19 Vaccination—"Shared Clinical Decision-Making" Is Abdication of Responsibility

Thomas R. Frieden, MD, MPH; William Schaffner, MD; Joshua M. Sharfstein, MD

The acting Centers for Disease Control and Prevention (CDC) director recently endorsed making COVID-19 vaccination of older adults and other high-risk individuals a matter of so-called shared clinical decision-making (SCDM) rather than a definitive recommendation. This difference has important implications for clinicians and patients and will have unfortunate consequences for health in the US. The new direction, based on a proposal from the reconstituted Advisory Committee on Immunization Practices (ACIP), may foreshadow a new and troubling era of vaccine policy.

Guidance from ACIP forms the backbone of US immunization efforts. When evidence is clear that a vaccine's benefits exceed its risks, ACIP has historically issued—and the CDC director has endorsed—an explicit recommendation to vaccinate. A recommendation from CDC is not a vaccine mandate, nor does it keep patients from asking questions about vaccines or declining vaccination; all vaccines are given only after informed consent. A recommendation is a statement, based on evidence, that for individuals in the designated group, vaccination's benefits exceed the risks and will reduce the risk of serious illness.

For clinicians, an unequivocal CDC recommendation makes it possible to tell patients, "This vaccine is recommended to protect you." For patients, there is no ambiguity about the actions likely to protect their health. For policymakers, a CDC recommendation creates momentum to improve vaccine access, including coverage by health care payers.

In contrast to an explicit recommendation to vaccinate is SCDM, which is the lowest-strength option available to ACIP. Rather than a recommendation, it is a "perhaps." SCDM calls for patients to consult with their physicians about the risks and benefits of a vaccine in their individual circumstances before making a decision. CDC has stated that SCDM is appropriate "when individuals may benefit from vaccination, but broad vaccination of people in that group is unlikely to have population-level impacts" and when benefits and risks may be different based on "the individual's characteristics, values, and preferences; the health care provider's clinical discretion; and the characteristics of the vaccine being considered."[1]

The concept of SCDM originates from areas of medical practice where there are judgment calls that require careful discussions about risks and benefits of treatment. For example, for men aged 50 to 69 years, deciding whether to have a prostate-specific antigen test balances a small chance of reducing prostate cancer death against the risk of false-positive results and overtreatment. Similarly, for adults with borderline cardiovascular risk, starting a statin weighs modest prevention benefits against the burden and potential adverse effects of daily medication. A key criterion for the use of this approach is equipoise, meaning that there is no evidence-based best choice of action.[2]

Historically, CDC has used SCDM in certain situations, including hepatitis B vaccination for adults aged 60 years or older and human papillomavirus vaccination for adults aged 27 to 45 years, in which the benefits are uncertain or small. But this ambiguity does not exist for COVID-19 vaccination for individuals at the highest risk of serious illness or death, for whom the benefits are substantial and the risks minimal.

The benefits of COVID-19 vaccination, analogous to those of influenza vaccination, are likely to vary from year to year but have been substantial in recent seasons. High-risk individuals are less likely to be hospitalized and to die if they receive updated COVID-19 vaccinations. The most recent finding, during the 2024 to 2025 season, was a 39% reduction (95% CI, 22%-55%) in COVID-19–related hospitalization and 64% reduction (95% CI, 23%-86%) in COVID-19–related death among more than 160 000 veterans with a mean age of 71 years (SD, 11 years). The benefit of vaccination was even greater among veterans with cardiovascular disease, cerebrovascular disease, chronic kidney disease, chronic lung disease, and immunocompromised status.[3]

Adverse events from COVID-19 vaccination are rare, as documented by clinical trials, high-quality research reports, and large clinical studies. For example, in a 2024 study of more than 170 000 older adults from the Canadian National Vaccine Safety Network, the rate of serious health events, defined as emergency department visits or hospitalizations within 7 days of vaccination, was less than 0.3% across all messenger RNA vaccine products and doses and was not higher than in unvaccinated control participants; most symptoms were mild and self-limited.[4]

When a vaccine is routinely recommended, systems align: standing orders, pharmacy practices, payer rules, nursing home protocols, and outreach all reinforce uptake. By contrast, a switch to SCDM confuses patients and physicians about whether the underlying rationale for vaccination has changed and increases friction and inefficiency at each stage of the vaccination process.

If fewer clinicians make clear, strong recommendations for COVID-19 vaccination to people at high risk for illness, fewer patients will be vaccinated, which is a particular concern among older adults.[5] Although the absolute death rate from COVID-19 is declining, Loo and colleagues[6] projected for the 2024-2025 respiratory season that COVID-19 vaccination of high-risk individuals at current rates would prevent 70 000 COVID-19 hospitalizations and more than 7000 deaths; even 10% less vaccination of this group would lead to thousands more hospitalizations and hundreds more deaths.

SCDM for COVID-19 vaccination of high-risk individuals may seem to encourage patient autonomy, but it actually misinforms and does not support informed decision-making. As examples, clinicians

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do not use SCDM when they recommend tetanus vaccination after a dirty wound, folic acid for women who could become pregnant, or vitamin K for newborns because the benefits are well established and, as with vaccination against COVID-19, the risks are minimal. Instead, they give crisp and strong recommendations, providing the clarity that patients deserve.

Patients deserve this clarity about COVID-19 vaccination, too. A definitive CDC recommendation to vaccinate would support the consent process and the patient-clinician relationship; an agency recommendation is not equivalent to a clinical conversation. Rather, it is an essential resource to support such discussions. For vaccines whose benefits far exceed the risks, CDC failure to provide an unambiguous, strong recommendation abdicates the responsibility to share with clinicians and US families what they can do to avoid unnecessary illness and death.

CDC's endorsement of SCDM also assumes that patients have equal access to clinicians who can spend time to discuss vaccination. Yet those most at risk—people with limited access to care, lower health literacy, or other priorities—may not have regular sources of care. An explicit recommendation encourages clinicians to make special efforts to reach such patients, thereby promoting higher vaccination rates and better health protection in all groups.

In recent weeks, major professional associations have moved to fill the vacuum left by CDC. In September 2025, the American Academy of Family Physicians issued recommendations for COVID-19 vaccination of individuals, especially those aged 65 years and older and at higher risk for severe disease.[7] The American College of Obstetricians and Gynecologists recommends COVID-19 vaccination during pregnancy, and the American Academy of Pediatrics has issued its own recommendations for children at higher risk of serious illness from COVID-19. For many clinicians and patients, it is now possible to rely on these recommendations rather than CDC's guidance, and many US states and insurers are using these alternative recommendations to set policy, including for insurance coverage. Doing so may reduce unnecessary preventable hospitalizations and death.[6]

Yet these actions are not a full substitute for a clear and direct CDC recommendation. Making vaccination contingent on SCDM for people at high risk for serious illness from COVID-19 is the opposite path from making the US healthier. The administration may now be tempted to apply SCDM to other important vaccinations, including childhood vaccinations. If CDC proceeds in this direction, professional societies, state health departments, and clinicians should continue to respect patient autonomy by providing unambiguous recommendations for vaccination where the benefit far exceeds risk.

A better path would be for the administration to rethink its abandonment of a critical tool for public health communication and restore straightforward recommendations for people who would benefit from the COVID-19 vaccine.

ARTICLE INFORMATION

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Conflict of Interest Disclosures: None reported.

REFERENCES

1. Centers for Disease Control and Prevention. ACIP shared clinical decision-making recommendations. Published January 7, 2025. Accessed October 22, 2025. https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html

2. van der Horst DEM, Garvelink MM, Bos WJW, Stiggelbout AM, Pieterse AH. For which decisions is shared decision making considered appropriate? a systematic review. *Patient Educ Couns*. 2023;106:3-16. doi:10.1016/j.pec.2022.09.015

3. Cai M, Xie Y, Al-Aly Z. Association of 2024-2025 Covid-19 vaccine with Covid-19 outcomes in US veterans. *N Engl J Med*. 2025;393(16):1612-1623. doi:10.1056/NEJMoa2510226

4. Soe P, Wong H, Naus M, et al; Canadian Immunization Research Network. mRNA COVID-19 vaccine safety among older adults from the Canadian National Vaccine Safety Network. *Vaccine*. 2024;42(18):3819-3829. doi:10.1016/j.vaccine.2024.04.096

5. Veronese N, Saccaro C, Demurtas J, et al. Prevalence of unwillingness and uncertainty to vaccinate against COVID-19 in older people: a systematic review and meta-analysis. *Ageing Res Rev*. 2021;72:101489. doi:10.1016/j.arr.2021.101489

6. Loo SL, Jung SM, Contamin L, et al. Scenario projections of COVID-19 burden in the US, 2024-2025. *JAMA Netw Open*. 2025;8(9):e2532469. doi:10.1001/jamanetworkopen.2025.32469

7. American Academy of Family Physicians. COVID-19 vaccine: fall 2025-26 vaccine recommendations. Accessed October 22, 2025. https://www.aafp.org/family-physician/patient-care/public-health-emergencies/recent-outbreaks/covid-19/covid-19-vaccine.html

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EXHIBIT 25

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

SUPPLEMENTAL DECLARATION OF REGINA LAROCQUE, MD, MPH, FIDSA

I, Regina LaRocque, MD, 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 a physician and Board Certified in Internal Medicine and Infectious Diseases.

2. I received my Doctor of Medicine degree from Duke University School of Medicine in 1998.

3. I also earned a master's degree in public health from the Harvard School of Public Health (now known as the Harvard T.H. Chan School of Public Health) at Harvard University in 1998.

4. I completed a residency in Internal Medicine at Brigham and Women's Hospital and a fellowship in infectious diseases in the combined program at Brigham and Women's Hospital/Massachusetts General Hospital.

5. I am a physician and researcher at an academic hospital in Boston Massachusetts, specializing in infectious diseases.

6. I am a member and a Fellow of the Infectious Disease Society of America ("IDSA").

7. Based on my over-20-year career as an infectious disease expert, the precipitous and unsupported decisions of the Secretary of Health and Human Services Robert F. Kennedy, Jr. (the "Secretary") regarding COVID-19 vaccinations will cause preventable suffering and death to Americans.

8. As part of my clinical practice as an infectious disease specialist, I treat adult inpatients with known or suspected infectious diseases, and I care for adults and children as outpatients in a traveler's advice and immunization clinic (the "Clinic"). In the Clinic, I advise pediatric and adult patients, including pregnant individuals and women of child-bearing age, on how to protect themselves from infectious diseases when travelling outside of the United States, including through vaccination. I review patients' full immunization history and make evidence-based, personalized recommendations regarding routine and travel-related immunizations.

9. I recommend to my Clinic patients, which includes patients over and under the age of 65 years old and pregnant individuals, to be up to date on COVID-19 immunization. This recommendation is based on my professional training and experience, and on the published peer-reviewed research in infectious diseases.

10. I am aware of the "Secretarial Directive on Pediatric COVID-19 Vaccines for Children Less than 18 years of Age and Pregnant Women" (the "Secretarial Directive") issued by the Secretary on May 27, 2025 designating the COVID-19 vaccine for children as Shared Clinical Decision Making ("SCDM") and removing the recommendation for the COVID-19 for pregnant individuals. I am also aware that on or about May 30, 2025, the CDC changed its immunization

guidance with regard to children and the COVID-19 vaccine from routine vaccination for all children to "Shared Clinical Decision Making" ("SCDM") without explanation.

11. I am aware of the recommendation issued by the Advisory Committee on Immunization Practices ("ACIP") in September 2025, and subsequently adopted by the acting director of the Centers for Disease Control and Prevention ("CDC") in October 2025, changing the COVID-19 vaccine recommendation for all individuals under the age of 65 from "routine" to "SCDM."

12. In my practice and in conversations with colleagues, the change in the COVID-19 vaccine recommendation from "routine" to "SCDM" has created a sense of chaos and instilled a lack of confidence among patients regarding a vaccine that is proven to be safe and effective at preventing the spread of COVID-19.

13. The change in the CDC's recommendation for the COVID-19 vaccine from "routine" to "SCDM" is a downgrading of the CDC's recommendation, which sends a message to patients discouraging this vaccine. When the CDC classifies a vaccine as routine, that means that the patient should be offered the vaccine. A routine recommendation means that the vaccine has proven over the years to be highly effective at preventing disease and saving lives with minimal risk to the patient. A routine recommendation also indicates that unless there is a specific contraindication to administering that vaccine, the patient should receive it.

14. Informed consent is always performed before the administration of any vaccine to ensure a patient is aware of the risks and benefits of a vaccination before agreeing to receive that vaccine. Providers have always been required to obtain informed consent before administering any vaccine.

15. SCDM is reserved for situations where there are multiple reasonable options and the best choice depends on individual medical factors, which is not the case for administration of the COVID-19 vaccine. When engaging in the SCDM process, a physician engages in a back-and-forth conversation with a patient regarding the patient's medical history and clearly identified risk factors to determine an appropriate recommendation and plan of action with the patient. For example, because there is a known risk for serious adverse events after yellow fever vaccination, I engage in SCDM when consulting patients who plan to visit a location where they will potentially be exposed to yellow fever before recommending or administering the yellow fever vaccine. In doing so, I ask the patient questions to determine whether the patient has any known contradictions to the yellow fever vaccine and whether the patient's risk of exposure to the yellow fever virus outweighs the vaccination risk.

16. SCDM is not the proper framework for routine vaccinations for which the safety and effectiveness data have been established and for which there is no risk of serious adverse events, such as the COVID-19 vaccination. There is simply no investigation or personalized, intensive analysis that can be conducted to determine whether a patient should or should not receive the COVID-19 vaccine as no such information makes it more or less likely that recommending COVID-19 vaccination is appropriate for a patient. Instead, patients are informed of the known, minor risks associated with the COVID-19 vaccine through informed consent.

17. Vaccine administration has its own family of Current Procedural Terminology ("CPT") codes, which I and other infectious disease physicians use to bill for our professional services. The recent ACIP recommendation, adopted by the CDC, which shifts the recommendation for COVID-19 vaccines to SCDM has caused me to spend more time during patient visits discussing the COVID-19 vaccine. There is no billable code that I can use to

compensate me for the additional time now spent counseling patients who are resistant to vaccination due to the CDC's and the Secretary's spread of misinformation.

18. Unlike other vaccines subject to SCDM, the CDC's change to SCDM for the COVID-19 vaccine was issued without publication of supporting data in the CDC's Morbidity and Mortality Weekly Report ("MMWR"). Normally, the MMWR provides clinicians with an evidence-based to guide patient counseling and serves as the trigger for payer coverage. No such data or guidance accompanied the SCDM COVID-19 recommendation, leaving me and my colleagues without a clear basis to counsel patients.

19. Patients are seeking clarity regarding why the SCDM change for the COVID-19 vaccination is necessary and what additional risks have been identified necessitating the change. However, there are no studies or data indicating that this change was necessary. As a result, the change in the COVID-19 vaccine recommendation from "routine" to "SCDM" has created a sense of chaos and instilled a lack of confidence among patients regarding a vaccine that is proven to be safe and effective at preventing the spread of COVID-19. This also contributes to the increased amount of time spent on unbillable counseling time regarding the COVID-19 vaccine.

20. As an expert with more than 20 years in the field of infectious disease, I can assert confidently and without qualification that, based on my professional experience, more patients of all ages will contract COVID-19 and experience severe COVID-19 symptoms, including dying of COVID-19, if there are barriers to COVID-19 vaccination.

21. I make this declaration in my personal capacity and in my capacity as a member of IDSA.

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

Executed on: 11/30/2025

Dr. Regina LaRocque

Regina LaRocque, MD, MPH, FIDSA

EXHIBIT 26

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 RAVI JHAVERI, M.D.

I, Ravi Jhaveri, M.D., 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 and not under any disability. All of the facts set forth in this declaration are based on my personal knowledge. I submit this declaration in support of Plaintiffs' Third Amended Complaint in the above-captioned action.

2. I am a physician, presently practicing in Chicago, Illinois, and am Board Certified in Pediatrics and Infectious Diseases. I am a member and elected fellow of both the Pediatric Infectious Disease Society (PIDS) and the Infectious Disease Society of America (IDSA). I make this declaration based on my personal knowledge and experience, in my personal capacity, and as a member of PIDS and IDSA. This declaration is further informed and supported by my over-20-year career as an infectious disease expert and my training and education, which includes a Doctor of Medicine degree from Mt. Sinai School of Medicine in 1996, residency in Internal Medicine at the University of Chicago Hospitals in 1999, and a fellowship in infectious diseases at the University of California – Los Angeles Medical Center in 2003.

3. The actions of the Department of Health and Human Services that include (i) the Directive issued by Secretary of Health and Human Services Robert F. Kennedy, Jr. (the "Secretary") on May 27, 2025 designating the Covid-19 vaccine for children as Shared Clinical Decision Making ("SCDM") and removing the recommendation for the Covid-19 for pregnant individuals, and (ii) the Advisory Committee on Immunization Practices ("ACIP") new recommendation in September of this year to change the Covid-19 vaccine recommendation for adults from routine to SCDM, which the Centers for Disease Control and Prevention ("CDC") later improperly inflated with informed consent, has injected chaos, confusion, and disruption into my practice and care that I am delivering to my patients.

4. I currently practice medicine as an infectious disease specialist in Chicago, Illinois. In that capacity, I serve as a consulting physician for pediatric patients on an inpatient basis.

5. I have personally treated children who contracted Covid-19 which led them to contract other superimposed infectious, like complicated bacterial pneumonia and orbital cellulitis, that required invasive medical treatments, surgery, and extended inpatient and intensive care stays.

6. I also presently treat pediatric patients in our outpatient clinic which includes treating post-Covid patients. The patients I treat in my clinic are children ages 3 – 17 years old who suffer prolonged symptoms of Covid-19, such as chronic fatigue and persistent fevers. Many of the patients I currently treat in my clinic have such severe lingering Covid-19 symptoms or damage resulting from their initial or subsequent Covid-19 infection that they are unable to fully return to their pre-Covid activities. For instance, I have had numerous patients whose Post-Covid symptoms prevented them from consistently attending school and/or participating in the extracurricular activity (*e.g.*, sports or dance) that they loved. Part of the work I do in my clinic is

to help these patients' families to develop plans to help the affected children reintegrate into the activities they miss out on due to their Post-Covid symptoms.

7. In my professional experience, children ages 6 months to 17 years are less likely to receive vaccines that are not affirmatively recommended as routine vaccinations for that age group by the Centers for Disease Control and Prevention (the "CDC"). Like many of my colleagues, I depend on ACIP and the CDC to conduct deep, time-intensive review of scientific evidence regarding vaccines, including the Covid-19 vaccine, and to make informed, evidence-backed recommendations in light of that intensive review. Throughout my entire practice of medicine, I have relied on ACIP recommendations, which I previously knew were supported by a team of experts at the CDC, whose job is to spend most of their time reviewing the literature, analyzing clinical trial data, evaluating safety and effectiveness, and then issuing well-reasoned recommendations based on the highest quality clinical evidence.

8. I understand that at the September 2025 ACIP meeting, the new ACIP (appointed by the Secretary) changed the Covid-19 vaccine recommendation for essentially all adults under age 65 to shared clinical decision-making instead of the prior straightforward routine recommendation. I further understand that the CDC adopted this changed recommendation.

9. Based on my training and experience, when the CDC classifies a vaccine as routine, that means that the patient should get the vaccine. A routine recommendation means that the vaccine has proven over the years to be highly effective at preventing disease and saving lives with minimal risk to the patient and, therefore should be administered as a standard part of medical care for the patient. A routine recommendation indicates that unless there is a specific contraindication to administering that vaccine, the patient should receive the vaccine. I consider the CDC immunization schedule change for adults for the 2025-2026 Covid-19 vaccines from "routine" to

"SCDM" to be a downgrading of the CDC's recommendation and sending a message to patients discouraging this vaccine

10. In my clinical judgment, this downgrading to SCDM is without justification and is causing confusion and vaccine hesitancy and is undermining public health as well as the public trust in vaccines and the physicians who recommend them. It is additionally causing confusion and strain within the health care field as I see more and more of my colleagues uncertain of how to navigate these changes, practice medicine, and properly engage with patients.

11. The confusion and problems caused by downgrading to SCDM are further compounded by the fact that there is no shared or common understanding of what constitutes "SCDM." Based on my training and experience, I am not aware of any universally agreed upon or accepted definition for or guidance on the term "SCDM." To the contrary, it is my belief and understanding that "SCDM" can mean different things to different individual physicians and that individual professional organizations are left to their own devices to determine what "SCDM" means, how to engage in it, or if they want to develop or adopt a common understanding within their specialty field of medicine or organization. For example, I am unaware of any guidance or authoritative literature from the AAP defining "SCDM" for all its members, much less for the specific topic of the Covid-19 vaccine.

12. Because there is no common or universal definition for "SCDM," each physician must develop their own sense of what that term means and how to engage in it. Drawing from my training and experience, I understand "SCDM" to mean the process of discussing with a patient or their parent[s]/legal guardian their concerns about receiving the Covid-19 vaccine, no matter how factually unsupported those concerns might be, but that view might not be shared by other

physicians. As a result, patients are seeing inconsistent care delivery, furthering fragmentation and a lack of uniform standards in the practice of medicine.

13. I have been personally affected by the downgrading of the Covid vaccine to SCDM. Since that action, I have spent considerable time counseling colleagues across the Chicago metro area on how they should engage in and document their Covid-related SCDM process. Before the new ACIP recommendation was issued, when the Covid-19 vaccine was a routine recommendation for adults under 65, I spent very little time counseling on the Covid-19 vaccine because there was very little to debate about the safety and effectiveness of the Covid-19 vaccine. However, the new ACIP recommendation and CDC adoption has contributed significantly to the confusion and distrust about the Covid-19 vaccine and has increased the frequency for which I must counsel on this topic to correct the misinformation the Secretary has spread about the Covid-19 vaccine.

14. Based on my interactions with colleagues across the Chicago metro area who turn to me for guidance and advice on how to engage in SCDM discussions, it is my understanding that SCDM conversations typically can last 10 minutes or longer. Unfortunately, there is no dedicated time for these conversations, which means they are folded into the existing wellness visit for the patient. This means the physician must dedicate valuable time during that wellness visit to counsel on and address questions relating to the Covid-19 vaccine, including explaining the disconnect and fragmentation within the public health world, such as why the Covid vaccine is no longer routinely recommended or why the state might have different standards and recommendations from the federal government. This eats up time that should be spent on the primary purpose of the wellness visit, such as depression screenings, completing the necessary examination for school physicals, chronic disease management, or other treatment to address the needs of patients, especially those who present with complex conditions. As a result, the quality and quantity of the time spent on

issues at the core of the wellness visit suffer because of the downgrading of the Covid-19 vaccine from routinely recommended to SCDM.

15. The time spent engaging in SCDM is not separately billable or reimbursable as there is no dedicated CPT code for that work. This means physicians are being forced to engage in work that is not compensated. While these SCDM discussions might seem like a minor inconvenience on an individual basis, the cumulative effect of engaging in SCDM with multiple patients every day results in more time spent engaging in work that is not compensable and that detracts from other more pressing work. This places further strain the physician's time and schedule as there is more to do and cover in the wellness visit. As a result, an SCDM discussion that takes 10 or even 20 minutes is 10 or 20 minutes of time that is not reimbursed and that accumulates into hours of additional work over the course of seeing and treating multiple patients. Unlike other vaccines subject to SCDM, the ACIP's and CDC's change to SCDM for the Covid-19 vaccine for adults under the age of 65 was issued without publication of supporting data in the CDC's Morbidity and Mortality Weekly Report ("MMWR"). Normally, the MMWR provides clinicians with the evidence base to guide patient counseling and serves as the trigger for payer coverage. No such data or guidance accompanied this change, leaving me and my colleagues without a clear basis to counsel patients, which also contributes to the increased amount of time spent on unbillable counseling time on the Covid-19 vaccine.

16. I am also concerned about the CDC equating "informed consent" with SCDM. In my view, informed consent refers to participation in research or other novel and untested treatments involving experimental interventions that require thorough discussion and disclosure of the risks involved, which may be unknown. Using that term makes it sound as if Covid-19 vaccines are experimental, thus causing vaccine hesitancy and distrust. Shared clinical decision-making, on

the other hand, refers to discussing the uses and application of known and approved agents that are routine and not experimental. Conflating the two concepts adds confusion for both physicians and patients.

17. Since the ACIP's and CDC's change to SCDM for Covid-19 vaccines for adults under the age of 65, I have spent additional and unreimbursed time counseling physicians and patients, interpreting ACIP's recommendation myself, and addressing increased confusion. These harms are related directly to ACIP's September 2025 recommendation for Covid-19 vaccines, which was adopted by the CDC. If the decision were vacated or corrected, these harms would be reduced or eliminated.

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

Executed on November 30, 2025 in Chicago, Illinois.

/s/ Ravi Jhaveri

Dr. Ravi Jhaveri

EXHIBIT 27

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 DAVID WHEELER, M.D.

I, David Wheeler, M.D., 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 and not under any disability. All of the facts set forth in this declaration are based on my personal knowledge. I submit this declaration in support of Plaintiffs' Third Amended Complaint in the above-captioned action.

2. The actions of the Department of Health and Human Services that include (i) the Directive issued by Secretary of Health and Human Services Robert F. Kennedy, Jr. (the "Secretary") on May 27, 2025 designating the Covid-19 vaccine for children as Shared Clinical Decision Making ("SCDM") and removing the recommendation for the Covid-19 for pregnant women, and (ii) the Advisory Committee on Immunization Practices ("ACIP") new recommendation in September of this year to change the Covid-19 vaccine recommendation for adults from routine to SCDM, which the Centers for Disease Control and Prevention ("CDC") later improperly conflate with informed consent, has injected chaos, confusion, and disruption into my practice and care that I am delivering to my patients.

3. I am board certified in Infectious Diseases.

4. I completed medical school at the University of Virginia and I completed my residency in internal medicine at University of Colorado. I completed a fellowship in infectious diseases fellowship at the University of Maryland.

5. I am a fellow of Infectious Diseases Society of America ("IDSA") and fellow of the American College of Physicians ("ACP").

6. I have over 30 years of clinical experience in treating patients with infectious diseases. I have also served as the managing partner for a private clinical practice that serves patients throughout Northern Virginia. My practice is focused on the care of adults with serious and complex infections, both hospitalized and in the outpatient setting. I routinely counsel patients under the age of 65 on prevention of infectious diseases, including the role of vaccination.

7. I, along with my fellow infectious disease physicians, depend heavily on ACIP and the CDC to conduct the deep, time-intensive review of scientific evidence regarding vaccines, including the Covid-19 vaccine. As a practicing clinician, I spend the vast majority of my time caring for sick patients. I simply do not have the bandwidth to independently and comprehensively review every study relevant to each vaccine or vaccine policy change. Throughout my entire practice of medicine, I have relied on ACIP recommendations, which I previously knew were supported by a team of experts at the CDC, whose job is to spend most of their time reviewing the literature, analyzing clinical trial data, evaluating safety and effectiveness, and then issuing well-reasoned recommendations based on the highest quality clinical evidence.

8. During my more than three decades of taking care of patients suffering with infectious diseases, I have paid close attention to several government resources, including (i) the CDC's immunization schedule, (ii) the process that is followed by the Food and Drug

Administration ("FDA") to authorize a vaccine for use in the United States, and (iii) the process that ACIP and the CDC follow to arrive at recommendations as to how vaccines should be used by different population groups in the United States. In my experience, ACIP, supported by CDC staff—function as the brain of the system. I have relied on their synthesis of the evidence for vaccine recommendations in a transparent, organized, and methodologically sound way. Community infectious disease physicians like me serve as the arms and fingers of that system. Our role as physicians is to take those carefully developed, evidence-based recommendations from ACIP and the CDC and implement them in the real world by counseling patients and advising primary care physicians who turn to us for guidance. Over many years, there has been a harmonious relationship between ACIP and community physicians like me.

9. I understand that at the September 2025 ACIP meeting, the new ACIP (appointed by the Secretary) changed the Covid-19 vaccine recommendation for essentially all adults under age 65 to shared clinical decision-making instead of the prior straightforward routine recommendation. CDC adopted this change. I am also aware that this change by the ACIP and the CDC was made without the usual transparent presentation of GRADE tables or EtR framework for evaluating the quality of evidence, or a clear, contemporaneous explanation in the MMWR. In my practice and in conversations with colleagues, this change to the CDC immunization schedule for Covid-19 vaccines for adults has not functioned as a neutral or minor adjustment to how we talk with patients. Instead, it has significantly disrupted the prior harmonious system and created multiple layers of confusion and harm to me and my practice.

10. When the CDC classifies a vaccine as routine, that means that the patient should be offered the vaccine. A routine recommendation means that the vaccine has proven over the years to be highly effective at preventing disease and saving lives with minimal risk to the patient. A

routine recommendation also indicates that unless there is a specific contraindication to administering that vaccine, the patient should receive it. I consider the CDC immunization schedule change for adults for the 2025-2026 Covid-19 vaccines from "routine" to "SCDM" to be a downgrading of the CDC's recommendation and sending a message to patients discouraging this vaccine.

11. The effect of downgrading the recommendation of the Covid-19 vaccine for adults under age 65 to SCDM requires me and my colleagues to spend more time counseling patients about the safety and effectiveness of the Covid-19 vaccine. Counseling is part of my job as an infectious disease physician, but I am usually paid for it. Before the new ACIP recommendation was issued, when the Covid-19 vaccine was a routine recommendation for adults under 65, I spent very little time counseling my patients on the Covid-19 vaccine because there was very little to debate about the safety and effectiveness of the Covid-19 vaccine. However, the new ACIP recommendation and CDC adoption has contributed significantly to the confusion and distrust about the Covid-19 vaccine. This confusion and distrust requires me to spend more time building trust with my patients and telling them the truth about the Covid-19 vaccine to correct the misinformation the Secretary has spread about the Covid-19 vaccine.

12. As an infectious disease physician, I bill for my professional services that I provide to my patients by using Current Procedural Terminology ("CPT") codes. Each code is tied to a patient care service and is used to document and receive reimbursement for medical encounters.

13. Vaccine administration has its own family of CPT codes, with the codes tying compensation of doctors to actual administration of the vaccine during a patient visit. The recent ACIP recommendation, adopted by the CDC, which shifts the recommendation for Covid-19 vaccines to SCDM for adults under the age of 65 has caused me to spend more time during patient

visits discussing the Covid-19 vaccine. There is no billable code that I can use to compensate me for the additional time now spent counseling patients who are resistant to vaccination. Due to this new uncertainty or confusion, on average, I spend about five minutes counseling each patient who is reluctant to receive a vaccine and I may see up to four such patients in a day, so this adds up to 20 minutes per day spent on non-reimbursable vaccine counseling. This is a significant opportunity cost because I could use this time to see an additional patient and get reimbursed for that time.

14. Unlike other vaccines subject to SCDM, the ACIP's and CDC's change to SCDM for the Covid-19 vaccine for adults under the age of 65 was issued without publication of supporting data in the CDC's Morbidity and Mortality Weekly Report ("MMWR"). Normally, the MMWR provides clinicians with the evidence base to guide patient counseling and serves as the trigger for payer coverage. No such data or guidance accompanied this change, leaving me and my colleagues without a clear basis to counsel patients, which also contributes to the increased amount of time spent on unbillable counseling time on the Covid-19 vaccine.

15. One recent example illustrates the problem clearly. A patient under the age of 65 wanted to get a Covid-19 vaccine at a pharmacy. The patient's insurance company indicated it would not cover the vaccine unless there was a written prescription. The patient's primary care physician was unsure whether to write such a prescription because ACIP had moved the Covid-19 recommendation to shared clinical decision-making. Unsure how to proceed, the primary care physician contacted me. In order to answer these questions, I had to spend non-trivial time explaining the rationale for the Covid-19 vaccination. This interaction was not part of a scheduled clinic visit and was not billed as a separate service. In effect, I was doing ACIP's work for them: interpreting a vague recommendation and translating it into a concrete decision without compensation. Since the SCDM change, I have had multiple conversations with patients and

primary care physicians about Covid-19 vaccines. These unscheduled interactions represent a diversion of time and resources and an uncompensated burden that directly results from ACIP's changed recommendation for Covid-19 vaccines to SCDM.

16. The lack of evidence to support ACIP's recommendation for Covid-19 vaccines to be downgraded to SCDM (and CDC's adoption of this recommendation) has also caused a shift of the burden to physicians to research and interpret data that was previously synthesized and communicated by ACIP. In other words, I rely on the ACIP to do the work to synthesize, analyze, and interpret the data to arrive at sound recommendations with regard to vaccines. Before the current ACIP, I trusted the recommendations that came out of the ACIP. Now, the current ACIP did not do the work to analyze and interpret the data to support the change to SCDM for Covid-19 vaccines for adults under the age of 65 and the current ACIP did not provide me with the guidance I need to understand the change and apply it. This has further complicated my counseling process with patients and other providers who ask me for guidance on the Covid-19 vaccine in my community.

17. I am also concerned about the CDC equating "informed consent" with SCDM. Informed consent refers to participation in research involving experimental interventions; using that term makes it sound as if Covid-19 vaccines are experimental. Shared clinical decision-making refers to discussing the risks and benefits of an accepted, standard intervention. Conflating the two concepts adds confusion for both physicians and patients.

18. Since the ACIP's and CDC's change to SCDM for Covid-19 vaccines for adults under the age of 65, I have spent, and continue to spend, additional and unreimbursed time counseling physicians and patients, interpreting ACIP's recommendation myself, and addressing increased confusion. These harms are related directly to ACIP's September 2025 recommendation

for Covid-19 vaccines, which was adopted by the CDC. If the decision were vacated or corrected, these harms would be reduced or eliminated.

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

Executed on November 17, 2025 in Annandale, Virginia.

/s/ David Wheeler, MD
Dr. David Wheeler

EXHIBIT 28

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 WILBUR CHEN, M.D.

I, Wilbur Chen, M.D., 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 and not under any disability. All of the facts set forth in this declaration are based on my personal knowledge. I submit this declaration in support of Plaintiffs' Third Amended Complaint in the above-captioned action.

2. The actions of the Department of Health and Human Services that include (i) the Directive issued by Secretary of Health and Human Services Robert F. Kennedy, Jr. (the "Secretary") on May 27, 2025 designating the Covid-19 vaccine for children as Shared Clinical Decision Making ("SCDM") and removing the recommendation for the Covid-19 for pregnant women, and (ii) the Advisory Committee on Immunization Practices ("ACIP") new recommendation in September of this year to change the Covid-19 vaccine recommendation for adults from routine to SCDM, which the Centers for Disease Control and Prevention ("CDC") later improperly conflate with informed consent, has injected chaos, confusion, and disruption into my practice, the care that I am delivering to my patients, and to the general community.

3. I am board certified in Infectious Diseases.

4. I completed medical school at the Howard University College of Medicine and I completed my residency in internal medicine at Johns Hopkins University. I completed a fellowship in infectious diseases at the University of Maryland.

5. I am a fellow of Infectious Diseases Society of America ("IDSA").

6. I have over 20 years of clinical experience in treating patients with infectious diseases. My former practice was focused on the care of adults with serious and complex infections, both hospitalized and in the outpatient setting. I currently direct a travel medicine practice in which I routinely counsel patients under the age of 65 on prevention of infectious diseases, including the role of vaccination.

7. I formerly served as a voting member of ACIP from December 2020 through June 2024. My appointment to ACIP was formally approved by the CDC Director and the Secretary of the U.S. Department of Health and Human Services ("HHS"). During my tenure, I served under both the Trump and Biden Administrations.

8. As an ACIP member, I participated in multiple vaccine workgroups, collaborated directly with CDC scientists, reviewed epidemiologic and clinical evidence, and contributed to national vaccine policy recommendations. Throughout my time as an ACIP member, ACIP strictly adhered to its long-standing scientific and procedural standards.

9. ACIP operates pursuant to written Standard Operating Procedures ("SOPs") that establish the required structure, conflict-of-interest controls, evidence review process, and methodology for all ACIP recommendations. These SOPs serve as a binding internal framework, similar to a codebook, and govern everything from membership vetting to scientific evaluation. Historically, CDC has treated these SOPs as essential to ensuring transparency, rigor, and public

trust. In recent meetings under Secretary Robert F. Kennedy Jr.'s administration, these SOPs have been disregarded.

10. Each ACIP vaccine area (such as Covid-19) has an associated workgroup led by CDC scientists and is chaired by an assigned ACIP member. These workgroups also include invited subject matter experts, such as epidemiologists, statisticians, health economists, infectious disease specialists, and subspecialists such as OBGYNs and pediatricians. Workgroup deliberations historically involve confidential, rigorous, systematic review of all available evidence. Workgroups vote internally on whether to support a recommendation before the issue is brought to the full ACIP. These internal deliberations ensure that the full ACIP committee reviews vetted, methodologically grounded evidence. In my tenure, workgroup deliberation and internal votes were the backbone of ACIP's recommendations.

11. Under Secretary RFK Jr.'s leadership, this structure collapsed. At recent ACIP meetings, including the September 2025 meeting that resulted in the Covid-19 vaccination changed recommendation to shared clinical decision-making, non-CDC individuals with unclear expertise presented material, while many long-serving CDC scientists and other subject matter experts were absent.

12. Historically, ACIP members submit conflict-of-interest disclosures at minimum annually to the CDC Ethics Office via a secure internal server. These forms are reviewed by dedicated ethics personnel who issue written assessments. ACIP members, working group members, and external consultants must also disclose new conflicts immediately. This system no longer appears to be functioning. Under Secretary RFK Jr.'s leadership, the ethics infrastructure has been bypassed or abandoned. The ethics infrastructure is critical to the recommendations

coming out of ACIP to ensure the recommendations are unbiased, and can be trusted by the public and practicing physicians.

13. ACIP's scientific evaluation has relied on two formal, transparent methodologies: (i) GRADE (Grading of Recommendations, Assessment, Development and Evaluation): a systematic assessment of quality and biases across all available studies and (ii) Evidence-to-Recommendations (EtR) Framework: a structured, public matrix assessing benefits, harms, feasibility, acceptability, and implementation considerations. These frameworks ensure that any member of the public can trace policy back to data. It is transparent and reproducible, so the public, including practicing physicians, can trust and apply the vaccine recommendations. At the September 2025 ACIP meeting, which resulted in the downgrade of Covid-19 vaccination for adults under 65 to shared clinical decision-making ("SCDM"), no GRADE tables were presented, no EtR framework was used, and no systematic evidence review was shown. Instead, the committee received slide decks containing unsourced, ungraded assertions.

14. I, along with my fellow infectious disease physicians, depend heavily on ACIP and the CDC to conduct the deep, time-intensive review of scientific evidence regarding vaccines, including the Covid-19 vaccine. Throughout my entire practice of medicine, I have relied on ACIP recommendations, which I previously knew were supported by a team of experts at the CDC. My role as a physician is to take the carefully developed, evidence-based recommendations from ACIP and the CDC and implement them in the real world by counseling patients and advising primary care physicians who turn to me for guidance. Over many years, there has been a harmonious relationship between ACIP and infectious disease physicians like me.

15. I understand that at the September 2025 ACIP meeting, the new ACIP (appointed by the Secretary) changed the Covid-19 vaccine recommendation for essentially all adults under

age 65 to shared clinical decision-making instead of the prior straightforward routine recommendation. CDC adopted this change. I am also aware that this change by the ACIP and the CDC was made without the usual transparent presentation of GRADE tables or EtR framework for evaluating the quality of evidence, or a clear, contemporaneous explanation in the MMWR.

16. When ACIP adopts SCDM for any vaccine recommendation, CDC normally publishes explanatory guidance in the Morbidity and Mortality Weekly Report (MMWR) to assist clinicians in interpreting the change. No such guidance was published for Covid-19 vaccination after the September 2025 vote. This absence of guidance is unprecedented and has direct, widespread consequences for physician practice. In my practice, this change to the CDC immunization schedule for Covid-19 vaccines for adults to SCDM has significantly disrupted the prior harmonious system and created multiple layers of confusion and harm to me and my practice.

17. When the CDC classifies a vaccine as routine, that means that the patient should be offered the vaccine. A routine recommendation means that the vaccine has proven over the years to be highly effective at preventing disease and saving lives with minimal risk to the patient. A routine recommendation also indicates that unless there is a specific contraindication to administering that vaccine, the patient should receive it. I consider the CDC immunization schedule change for adults for the Covid-19 vaccines from "routine" to "SCDM" to be a downgrading of the CDC's recommendation and sending a message to patients discouraging this vaccine.

18. Changing a vaccine recommendation from "routine" to "SCDM" causes significant confusion for providers, patients, and the public. From a behavioral standpoint, SCDM signals that CDC is no longer strongly recommending vaccination. Physicians become hesitant to raise the subject and patients enter the conversation with distrust.

19. SCDM is like adding a ten-page consent form to a ferris wheel ride that has always been safe, creating doubt and uncertainty where none previously existed, which adds time to the physician-patient counseling discussions to overcome the new mistrust. Before the new ACIP recommendation was issued, when the Covid-19 vaccine was a routine recommendation for adults under 65, I spent very little time counseling my patients on the Covid-19 vaccine because there was very little to debate about the safety and effectiveness of the Covid-19 vaccine. However, the new ACIP recommendation and CDC adoption has contributed significantly to the confusion and distrust about the Covid-19 vaccine. This confusion and distrust requires me to spend more time building trust with my patients and telling them the truth about the safety and effectiveness of the Covid-19 vaccine.

20. Unlike other vaccines subject to SCDM, the ACIP's and CDC's change to SCDM for the Covid-19 vaccine for adults under the age of 65 was issued without publication of supporting data in the CDC's MMWR. Normally, the MMWR provides clinicians with the evidence base to guide patient counseling and serves as the trigger for payer coverage. No such data or guidance accompanied this change, leaving me without a clear basis to counsel patients, which also contributes to the increased amount of time spent on unbillable counseling time on the Covid-19 vaccine.

21. The resulting downgrade to SCDM for Covid-19 vaccination has left me and my fellow infectious disease physicians having to use our own time and resources to navigate the gap created by the absence of the MMWR guidance, abandonment of the GRADE and EtR methodology, and unscientific nature of the September 2025 ACIP vote on Covid-19 vaccines. The current ACIP did not do the work to analyze and interpret the data to support the change to SCDM for Covid-19 vaccines for adults under the age of 65 and the current ACIP did not provide

me with the guidance I need to understand the change and apply it. This has further complicated my counseling process with patients and other providers who ask me for guidance on the Covid-19 vaccine in my community.

22. Since the ACIP's and CDC's change to SCDM for Covid-19 vaccines for adults under the age of 65, I have spent, and continue to spend, additional and unreimbursed time counseling physicians and patients, addressing increased confusion, and interpreting ACIP's recommendation myself. These harms are related directly to ACIP's September 2025 recommendation for Covid-19 vaccines, which was adopted by the CDC. If the decision were vacated or corrected, these harms would be reduced or eliminated.

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

Executed on November 25, 2025 in Baltimore, Maryland.

/s/ Wilbur Chen, MD, MS

Dr. Wilbur Chen

EXHIBIT 29

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 VANDANA MADHAVAN, MD, MPH

I, Vandana Madhavan, MD, MPH, 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. I submit this declaration in support of Plaintiffs' Third Amended Complaint filed in the above-captioned action.

2. I am a pediatric infectious disease specialist and primary care physician at large hospital in Boston, Massachusetts. I serve as clinical director for the division of pediatric infectious disease. I am board-certified in both pediatrics and pediatric infectious diseases.

3. I received my medical degree from the University of Virginia in 2002. I completed my residency in pediatrics at Massachusetts General Hospital in 2005. I completed a fellowship in Pediatric Infectious Diseases from Boston Children's Hospital in 2009, concurrently completing the Harvard Pediatric Health Services Research Fellowship

4. I earned my Masters in Public Health in Clinical Effectiveness from the Harvard School of Public Health in 2009 where my research was focused on vaccine uptake rates in diverse populations.

5. I am a member of the Infectious Disease Society of America and the American Academy of Pediatrics (including the Section on Infectious Diseases).

6. I serve on the Massachusetts Vaccine Purchasing Advisory Council ("MVPAC"). Since I work in both inpatient and outpatient settings, I understand how recommendations function in real practice, and I know how delays and unclear language can affect both patient care and public trust. This is the perspective I bring to MVPAC.

7. The MVPAC advises the state on vaccine orders and reviews recommendations from the Advisory Committee on Immunization Practices ("ACIP"). In most cases the MVPAC agrees with ACIP guidance, but we sometimes discuss implementation issues in order to help simplify options specifically for Massachusetts providers, especially for smaller practices that may struggle with inventory and storage constraints. The Massachusetts Department of Public Heath ("DPH") Commissioner leads the MVPAC.

8. I am aware of the May 27, 2025 announcement on the X social media platform by Secretary of Health and Human Services Robert F. Kennedy, Jr. that he was rescinding prior ACIP recommendations that pregnant women and healthy children ages six months to 17 years old be routinely immunized against COVID-19 (the "Directive"). Following the Directive, the CDC Immunization Schedule was updated to show that the COVID-19 vaccine was no longer recommended for pregnant people and that it was recommended on the basis of shared clinical decision making ("SCDM") for children.

9. I am aware that on June 9, 2025, Secretary Kennedy terminated the appointments of all voting ACIP members. I am also aware that on June 11, 2025, Secretary Kennedy appointed eight new voting members to the ACIP, most of whom are not experts in immunizations.

10. These unusual changes were discussed during the MVPAC meeting which occurred on June 12, 2025.

11. I am aware that this new ACIP met on June 25-26, 2025 during which the COVID-19 vaccine was discussed but no recommendations were voted on. ACIP did not discuss several of the vaccines that were initially published in the Federal Register notice for the June ACIP meeting.

12. In August 2025, the FDA limited the indication for the 2025-2026 strain of the COVID-19 vaccine to individuals aged 65 and older and those under 65 with underlying health conditions. At the same time, Secretary Kennedy withdrew all Emergency Use Authorizations for COVID-19 vaccines. This, coupled with the Directive, created widespread uncertainty in Massachusetts about where people of different ages could get vaccinated against COVID-19. Families were especially confused about whether pharmacists could still vaccinate children 5 and older.

13. I am aware that the new ACIP met again on September 18-19, 2025, during which they voted to recommend the COVID-19 for all individuals using SCDM. I believe that this was wholly inappropriate from a clinical and public health point of view.

14. The concept of SCDM is not new in clinical practice, but should be reserved for situations where there are multiple reasonable options and the best choice depends on individual medical and social factors. For example, when treating cancer, SCDM can be used to determine

whether the patient should undergo surgery or try one more treatment with chemotherapy. In the case of vaccination, SCDM may be appropriate for travel-related vaccines for which an individual's risk factors need to be considered or in the setting of a patient requiring multiple catch-up vaccines and a prioritized schedule. SCDM is not the proper framework for routine vaccinations for which the safety and effectiveness data have already been established, and for which alternate options do not exist such as the COVID vaccine.

15. By issuing a "blanket" SCDM recommendation for the COVID-19 vaccine, ACIP has created unnecessary confusion among families. The ACIP has created a perception among the parents of my patients that the vaccine is now "optional" or that something has changed with the vaccine itself requiring additional conversation and education

16. In addition to the unsupported COVID-19 vaccine recommendation, this new reconstituted ACIP has used its platform to give voice to other claims about vaccine safety that are not evidence-based. As a direct result, parents now raise more questions about vaccines than ever. The amount of time required to answer these additional questions has increased, yet the current reimbursement structure for pediatric care rarely allows us to bill for this additional counseling during a well visit. Additionally, clinicians often choose not to bill based on extra time even when they technically can because families may object to unexpected charges. As a result, this time is absorbed as unpaid work.

17. Non-billable time spent correcting the misinformation proliferated directly by ACIP and Secretary Kennedy has grown to the point that it affects clinics' ability to carry out community health work that should be proactive rather than reactive. The cumulative effect is a steady loss of time and energy across the workforce.

18. Health care workers have been under significant strain since the pandemic. This is particularly true for pediatric infectious disease specialists where compensation is lower than most other specialties. Staffing shortages have worsened as a large portion of the health care workforce has left the field. Providers are routinely told to "do more with less." Burnout is real, and many of us are already struggling to meet the needs of our patients even under ordinary circumstances. When ACIP and Secretary Kennedy introduce uncertainty about vaccines that have decades of clear evidence behind them, such as the hepatitis B vaccine, it adds more and wholly unnecessary pressure to the practice of medicine. Families rely on their pediatricians for steady guidance, and when ACIP and HHS seem to question settled science, we spend even more unpaid time addressing confusion and rebuilding trust. Each of these tasks may seem small on its own, but in the aggregate, they place a real and growing burden on patient care and on the clinicians trying to provide it. This can be described as "death by a thousand cuts."

19. As ACIP chooses to revisit and potentially overturn long-standing vaccine recommendations that already rest on decades of solid evidence, such as those for MMR and varicella, and as they plan to do for hepatitis B and other routine childhood vaccines, they are failing to review and update recommendations for newer vaccines. As a direct result of ACIP's failure, MVPAC must act independently to evaluate the data for these newer products on our own. As a result, we have spent additional time analyzing the evidence and developing recommendations that can be put into practice in Massachusetts so that providers and families are not left waiting for clear direction. For example, when we met on October 9, 2025, the DPH Commissioner charged MVPAC with conducting a cost analysis of meningococcal vaccines as ACIP has disbanded the ACIP meningococcal work group and has not provided any guidance on the topic.

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

Executed on November 26, 2025 in Boston, Massachusetts.

/s/ Vandana Madhavan MD

Vandana Madhavan, MD, MPH

EXHIBIT 30

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

SUPPLEMENTAL DECLARATION OF BRENDA ANDERS PRING, MD

I, Brenda Anders Pring, MD, 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 supplemental declaration are based on my personal knowledge. I submit this supplemental declaration in support of Plaintiffs' Third Amended Complaint filed in the above-captioned action.

2. I am the President of the Massachusetts Chapter of the American Academy of Pediatrics ("MCAAP"). I have served in that role since July 1, 2024. I make this statement based on personal knowledge and if called as a witness could and would testify competently thereto.

3. I graduated from Harvard Medical School in 2010 and I completed my residency in pediatrics at the University of Colorado.

4. I am board-certified in pediatrics.

5. The MCAAP is a member organization of 1,600 Massachusetts-based primary care and specialty pediatricians across the Commonwealth. The MCAAP is committed to the attainment of

optimal physical, mental, and social health for all infants, children, adolescents, and their families, and to supporting the medical professionals who care for them.

6. MCAAP supports pediatric health professionals in the Commonwealth in maintaining high childhood immunization rates by providing state-specific logistical guidance and evidence-based educational resources, previously based on strong FDA and CDC vaccine review processes.

7. Due to the steadfast work of dedicated pediatricians, public health teams, and engaged parents, Massachusetts consistently leads the nation in routine childhood immunization. According to the 2024 National Immunization Survey, Massachusetts ranked first nationally in vaccination rates for children aged 19 to 35 months receiving the full series of seven recommended vaccines. Massachusetts parents and pediatricians have reached these historically high immunization rates relying on high quality guidance from the American Academy of Pediatrics as well as the previously standardized, science-based vaccine recommendations from the CDC. Vaccine confidence among Massachusetts parents and pediatricians is strengthened by knowing that members of the Advisory Committee on Immunization Practices ("ACIP") are thoroughly vetted and serve staggered terms, ensuring both expertise and continuity in the committee's work.

8. In Massachusetts, the Department of Public Health ("DPH") has offered educational and implementation support for evidence-based immunization practices for child health, including our Vaccines for Children and Universal Vaccine Purchase programs.

9. The Massachusetts Universal Purchase Program is a statewide initiative designed to ensure equitable access to all routinely recommended childhood vaccines, regardless of a child's insurance status or ability to pay. Administered through the Massachusetts Department of Public Health, the program uses state funds to purchase vaccines in bulk and distribute them to providers at no cost. As a result, healthcare providers throughout the Commonwealth, whether they serve patients in

private practice, public clinics, or community health centers—can offer all recommended immunizations without financial barriers.

10. Notwithstanding these initiatives, Massachusetts' childhood vaccination rates have begun to decline, in line with national trends, despite the vast majority of Massachusetts parents choosing to fully vaccinate their children as recommended by their pediatricians and the current CDC immunization schedule.

11. The May 27, 2025, video on X, posted by Secretary Kennedy featuring Robert F. Kennedy Jr., FDA Commissioner Dr. Marty Makary, and NIH Director Dr. Jay Bhattacharya, and the subsequent directive and change in the CDC schedule, are a troubling departure from the federal government's established approach to vaccine policy. This decision to curtail COVID vaccine access for children and pregnant persons ignores expert advisory committee recommendations, and even more concerning, ignores the historically standardized vaccine review and recommendation process. These decisions have profoundly endangered the health and safety of Massachusetts children while also acutely increasing emotional and professional burdens on Massachusetts pediatricians.

12. The Secretary's directive has sown confusion and created an environment of uncertainty for Massachusetts families and the pediatricians who care for them. Even for families that want to vaccinate their children, there is a lot of fear about which vaccines may be available to them now, or in the future.

13. I am aware that on June 9, 2025, all of the sitting ACIP members' appointments were terminated and replaced slowly with non-experts who did not meet the criteria for membership. I am aware that this newly constituted ACIP met on June 25-26, 2025 and included COVID-19 vaccination in their discussions. Although the ACIP did not vote on a new COVID-19 vaccine

recommendation, after this meeting, I became concerned that they would remove the recommendation entirely for some, if not all populations, in the near future. This is a concern that my patients also share. Some of them have expressed to me that they think ACIP is going to "take all the shots away."

14. In August 2025, the FDA limited the indication for the 2025-2026 strain of the COVID-19 vaccine to individuals aged 65 and older and those under 65 with underlying health conditions. At the same time, Secretary Kennedy withdrew all Emergency Use Authorizations for COVID-19 vaccines. This, coupled with the Directive, created widespread uncertainty in Massachusetts about where people of different ages could get vaccinated against COVID-19. Families were especially confused about whether pharmacists could still vaccinate children 5 and older.

15. To reduce scope of practice problems these actions created, the DPH revised its vaccine administration rules so the DPH Commissioner could decide which vaccines pharmacists were allowed to provide. The DPH Commissioner then issued a standing order to keep COVID-19 vaccines available at pharmacies. This resolved access issues for patients 5 and older with private insurance. Children under 5, who rely on pediatricians for routine shots, still faced obstacles.

16. . In my role as President of MCAAP, I had several meetings to discuss the consequences of leaving Massachusetts vaccination policies unchanged. I reached out to the DPH Commissioner with our concerns. I had to take substantial time out of my workday to arrange and attend these meetings which would not have been necessary if the Directive had not been issued.

17. Children covered by the Vaccines for Children ("VFC") program experienced a significant delay because vaccines administered as part of the VFC program rely on ACIP guidance for shipping. ACIP did not issue a recommendation for the 2025-2026 COVID-19 vaccine in during its June 2025 meeting, which meant that in August 2025 when the 2025-2026

COVID-19 vaccine was approved, Massachusetts providers could not purchase doses through the universal purchase program. As a result, children between 6 months and 5 years old were left without access at both pediatric offices and pharmacies. Some providers, including Minute Clinics that rely on nurse practitioners, were also unsure how to handle the situation, and though they stocked the vaccine, they refused to give it to some children.

18. I am aware that this newly reconstituted ACIP met from September 18 and 19 and that at this meeting the Committee discussed recommending the COVID-19 vaccine through Shared Clinical Decision Making ("SCDM") for essentially all patients. This approach was not supported by solid data or evidence. ACIP has also provided no guidance on how SCDM is supposed to work in a pediatric practice. Many pediatricians, including me, do not agree with this recommendation.

19. The direct result of the SCDM recommendation is that vaccine counseling has become more awkward and time consuming for me and for many other pediatricians. It has also created confusion for families, who often assume that an SCDM approach means the vaccine is "not important." I am seeing more patients who do not want to talk about the COVID-19 vaccine at all, and if I raise this issue, some will even forgo receiving other vaccines like influenza. Because of this, some pediatricians have stopped having these discussions altogether. On the other hand, some patients worry that the vaccine access they have now could disappear overnight, and they want to talk about getting vaccinated earlier than the guidelines allow. I understand why they feel this way, especially after the Directive abruptly took away vaccine access for pregnant women without a sound scientific basis or meaningful consideration of the consequences.

20. Even families who were comfortable getting the COVID-19 vaccine last year are now hesitant. The vaccine itself has not changed; the only thing that has changed is the rhetoric and recommendation from ACIP.

21. ACIP has not provided any supporting materials for its SCDM recommendation for the COVID-19 vaccine, and it has offered neither guidelines published in the CDC's Morbidity and Mortality Weekly Report ("MMWR") nor any guidance describing a standard SCDM process for COVID-19 vaccination. Without these, pediatricians must look to other sources to assist with the SCDM conversation.

22. The AAP has issued recommendations that differ slightly from those of the Massachusetts DPH, and both differ substantially from ACIP's SCDM approach. The AAP guidance works well for children under 2, but because I also care for older patients, I rely on the Massachusetts recommendations that advise vaccination for everyone over 6 months of age. Until June 2025, ACIP's recommendations were the standard language I used when counseling families, and they provided a consistent baseline for other clinicians as well. Since ACIP issued its baseless SCDM recommendation for COVID-19 vaccination without any additional supporting guidance, I no longer feel comfortable using their recommendation in practice and have instead chosen to follow the Massachusetts DPH guidance. Other pediatricians I have spoken with are now forced to choose which framework to adopt. This has led to noticeable differences in how providers across the state counsel their patients.

23. As a chapter, MCAAP has had to expend substantial resources to update its website to reflect the AAP guidelines, and we are considering additional materials and possible webinars to support physicians who administer the COVID-19 vaccine. In order to do so, MCAAP will have to divert resources away from other activities that are part of our mission.

24. As president of MCAAP, I also serve as the main contact for media inquiries and appearances, such as speaking publicly on TV or on the radio. The confusion created by the SCDM recommendation has led to a sharp increase in these inquiries. Because inaccurate information about vaccines can cause real harm, I feel obligated to respond quickly to every request in order to counter misinformation and support both pediatricians and families.

25. Due to the lack of supporting materials from ACIP, several MCAAP members feel uncomfortable stocking and administering COVID-19 vaccines because some pediatrician office policies require pediatricians to give out a Vaccine Information Sheet, published by CDC, with each vaccination. I am aware that the reconstituted ACIP voted to have the CDC consider publishing a new COVID-19 Vaccine Information Sheet that includes misleading claims about the vaccine, which would cause further disruption and frustrate the ability of MCAAP members to provide care to their patients.

26. In his October 6 endorsement of ACIP's SCDM recommendation, the Deputy Secretary of Health and Human Services, who is also the acting director of the CDC, said that "Informed consent is back." I disagree with this statement and do not think that he understood the implications of that statement. It suggested that pediatricians had not been obtaining informed consent, which is simply not true and is contrary to well-accepted medical practice. It also implied that SCDM and informed consent are the same, when they are completely different processes. Pediatricians have always obtained informed consent for every medical intervention, including vaccines. In contrast, we do not use SCDM for most pediatric vaccinations. Unlike informed consent, SCDM is a more drawn-out conversation that requires explaining why a vaccine might be recommended for one child but not for all children, the way routine vaccines are. Only people

who work closely in this area understand the distinction between an SCDM recommendation and a routine recommendation.

27. Taken together, the events since May 2025 have contributed to an unstable vaccine regulatory environment that harms Massachusetts pediatricians, their patients, and their families. With the erosion of these formerly rigorous processes, Massachusetts pediatricians are spending much more time in and out of the exam room in discussions with parents on what the Covid and other vaccine risks and benefits are and why the federal recommendations have changed so suddenly, with no supporting data.

28. As a result, Massachusetts pediatricians bear both fiscal and moral loads from the additional work brought on by changes in federal health recommendations that are no longer supported by either evidence or rigorous process. They are less able to focus on routine care, urgent visits, behavioral health needs, or chronic disease management across the pediatric population.

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

Executed on November 24, 2025 in Newton, Massachusetts.

/s/ Brenda Anders Pring

Brenda Anders Pring, MD

EXHIBIT 31

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

SUPPLEMENTAL DECLARATION OF DR. AARON BORNSTEIN

I, Dr. Aaron Bornstein, declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I am over 18 years old. All the facts set forth in this declaration are based on my personal knowledge and are true and correct. I submit this supplemental declaration in further support of Plaintiffs' Third Amended Complaint in the above-captioned action.

2. I reside in Massachusetts.

3. I completed medical school at the University of Pittsburgh School of Medicine in 1999 and I completed my residency at Children's Memorial Hospital in 2002.

4. I am a member of the American Academy of Pediatrics ("AAP"). I am also a member of the Massachusetts Chapter of the American Academy of Pediatrics ("MCAAP").

5. I am a board-certified pediatrician currently practicing at Middleboro Pediatrics, a private pediatric medical practice located in Lakeville, Massachusetts. We serve about 4,800 patients and their families. My practice cares for many families over multiple generations. I provide

preventive care, diagnose and treat acute and chronic illnesses, and counsel my patients and families about vaccines, including the Covid-19 vaccine.

6. Our practice serves the greater Middleboro region of Massachusetts and consists of four pediatricians and three nurse practitioners. Middleboro Pediatrics participates in the Vaccines for Children ("VFC") program and is subject to the Massachusetts Universal Purchasing Program.

7. We are one of few pediatric practices that has chosen not to dismiss patients solely for being unvaccinated. That said, we require families who choose not to vaccinate their children to sign an acknowledgment form documenting that we reviewed the risks and benefits and that they declined against medical advice. This is both to protect the child's continuity of care and to protect our practice from legal liability.

8. Our practice provides and administers childhood vaccinations to our patients, including the Covid-19 vaccine.

9. The actions of the Department of Health and Human Services that include (i) the Directive issued by Secretary of Health and Human Services Robert F. Kennedy, Jr. (the "Secretary") on May 27, 2025 designating the Covid-19 vaccine for children as Shared Clinical Decision Making ("SCDM") and removing the recommendation for the Covid-19 for pregnant individuals, and (ii) the Advisory Committee on Immunization Practices ("ACIP") new recommendation in September of this year to change the Covid-19 vaccine recommendation for individuals under age 65 from routine to SCDM, which the Centers for Disease Control and Prevention ("CDC") later improperly conflated with informed consent, has injected confusion and disruption into my practice and care that I am delivering to my patients and their families. These actions have materially increased the time I must spend counseling families about the Covid-19 vaccine (which I am not

reimbursed for); undermined parents' trust in me as their pediatrician; and impaired my ability to provide efficient, evidence-based care to my patients.

10. Throughout my career, I have relied on the CDC immunization schedule and ACIP recommendations as the backbone of evidence-based pediatric vaccination practice. As a practicing pediatrician, I do not have the capacity to independently review every study on every vaccine. Instead, I have relied on ACIP and the CDC to review the scientific evidence in a methodologically sound, transparent way and to translate that evidence into clear, stable recommendations that I can interpret and apply in my practice for my pediatric patients and their families. Prior to the Secretary's Directive and the recent ACIP recommendations on Covid-19 vaccines, my experience with ACIP recommendations and changes to the CDC immunization schedule was that they were supported by transparent presentations of the evidence, including GRADE tables and Evidence-to-Recommendation ("EtR") frameworks to evaluate the quality of the evidence, and accompanied by contemporaneous Morbidity and Mortality Weekly Report ("MMWR") publications to provide guidance. I understood ACIP to be, in essence, the general of the national immunization system, with community pediatricians like me serving as the foot soldiers that implement ACIP's evidence-based recommendations in real-world clinical practice.

11. Before the Directive and the new ACIP recommendation for Covid-19 vaccines, I could confidently tell families that Covid-19 vaccination for children was a routine recommendation endorsed by national experts after careful review of the evidence. Although I routinely discussed vaccines with parents, there was a clear baseline: a routine recommendation on the CDC immunization schedule meant that vaccination was standard of care, and that I was not acting alone when I recommended it.

12. The Secretary's Directive in May 2025 and ACIP's September 2025 recommendation, which CDC adopted in October, downgraded the Covid-19 vaccine for children from a straightforward routine recommendation to SCDM. In my experience, and in the experience of my colleagues, this has not functioned as a neutral or minor change in wording. Instead, it has signaled to many families in my practice that the Covid-19 vaccine is no longer truly recommended for children, and has fueled uncertainty and mistrust in me, which directly impacts my physician-patient relationship and results in extended and uncompensated discussions with my patients and their parents around the conflicting Covid-19 vaccine recommendations.

13. As a result of the Directive and the ACIP recommendation to change Covid-19 vaccination to SCDM for children, my conversations about Covid-19 vaccines with families have become significantly longer and more contentious. A question about Covid-19 vaccines that might once have taken a few minutes now routinely expands into a 10-minute discussion dominated by the conflict that now exists between my recommendation for Covid-19 vaccination and the Directive and ACIP recommendation to downgrade Covid-19 vaccines to SCDM. These extended counseling sessions are not compensated when my practice seeks reimbursement for my services. In our pediatric office, well-child visits are typically scheduled for about 20 minutes of physician time. When a Covid-19 vaccine SCDM discussion consumes 10 minutes, it displaces other important topics that I should cover during the visit and reduces the number of children I can see. Over time, this represents a substantial opportunity cost and a concrete burden on my practice.

14. For example, in July 2025, a parent brought in two adolescent children for a routine well visit. I recommended that both children receive the COVID-19 vaccine. The parent responded by saying that the CDC no longer recommends it, referencing recent changes to the official guidance. I explained that our practice is not following the updated CDC recommendation, as it did not

go through the usual thorough evaluation process involving the ACIP. This created more confusion for the parent, and I spent a significant portion of the visit explaining the difference between standard recommendation procedures and what occurred in this case. The conversation took about 20 minutes of a 30-minute visit. The parent ultimately agreed to have both children vaccinated. However, the extended discussion put me 20 minutes behind schedule, which delayed other patients and disrupted the normal flow of care for the rest of the day.

15. I have also witnessed the level of vaccine hesitancy among parents increase not only in relation to the Covid vaccine, but also increasingly toward other routine immunizations as well. I and my partners are spending significantly more time during wellness visits discussing vaccinations with families who are reluctant to vaccinate their children with one or more of the vaccines that we recommend. For example, I have spent at least an hour on two separate occasions with different sets of parents in counseling on vaccines. I do not recall ever before having to spend that much time counseling on vaccines. In one of these hour-long counseling sessions, parents refused to sign a standard AAP vaccine refusal form, which is our office policy for families who decline immunization. In that case, I informed the parents that refusal to sign the form would result in discharge from our practice due to failure to comply with office policy and related liability concerns. They eventually complied. The second hour-long visit involved a parent who, following media reports of outbreaks, wanted to discuss measles vaccination despite previous hesitancy. I billed insurance for that visit, which the family's commercial insurance reimbursed.

16. This level of counseling is not financially sustainable at scale. While we might be reimbursed for such visits occasionally, we cannot afford to allocate an hour for every hesitant family. Our practice serves nearly 4,800 patients, and extended counseling adds significant strain to our already full schedules. In some cases, particularly for patients on MassHealth, the combined

Medicaid and the Children's Health Insurance Program, who account for approximately 40% of our patient population, providers receive no reimbursement for the additional time spent and the provider absorbs the cost of that time entirely.

17. Since the Directive, my practice has also absorbed a disproportionate share of vaccine-hesitant families dismissed from other practices for refusing vaccinations, which has required substantial unbillable time in meet-and-greet visits occurring after regular clinic hours. Because these are meet-and-greet visits for patients who are not yet members of the practice, we cannot bill for them. We can bill for established patients, but we cannot bill for a patient who is not yet an established member of our practice. Even when we do bill for an established patient, it is a question of whether or not we will be reimbursed, and for MassHealth patients we will not be reimbursed. Since the Directive, our practice conducts approximately 10–15 meet-and-greet visits per month, amounting to 10–15 hours of uncompensated time.

18. Growing public skepticism and confusion caused by mixed messages coming from the current Secretary of Health and Human Services have contributed to a significant increase in the counseling burden at my practice and has increased uncertainty as to both insurance coverage and potential legal liability to my practice. This burden is not just clinical but also financial and operational.

19. I have cared for newborns who were hospitalized with Covid, and in at least one case, the mother had contracted Covid during labor and delivery. These situations are stressful, often result in separation of mother and infant, which disrupts bonding and poses added risks to newborns, who are especially vulnerable. Limiting maternal access to the Covid vaccine through policy changes that disincentivize or restrict coverage has had a deleterious effect on pediatric

care, particularly in the first six months of life when infants depend on maternal antibodies for protection.

20. I reviewed digested summaries of the September 2025 ACIP meeting and its SCDM recommendation for Covid-19 vaccines for essentially all individuals under age 65. I was struck by the absence of a transparent, detailed presentation of the underlying evidence. There were no GRADE tables, EtR framework, or contemporaneous publication in the MMWR that thoroughly explained or justified the change for children. As a result, I am left without the kind of clear, data-driven rationale that I have historically relied on from ACIP and the CDC to implement a vaccination recommendation in my practice.

21. Parents now ask me very specific questions about why ACIP and CDC made this change, whether new data emerged, and whether the change means that the Covid-19 vaccine is no longer necessary or beneficial for children. I cannot answer these questions with the level of certainty and transparency I previously could, because ACIP has not provided the evidence summary and published guidance for physicians on how to apply the SCDM recommendation in the MMWR. This forces me to guess based on instinct and scattered individual studies, rather than to rely on a coherent, expert-reviewed synthesis for Covid-19 vaccines for my population of patients. In effect, I am being compelled to do, in my limited personal time, the work that ACIP and CDC used to do for the entire pediatric community. This is not feasible and significantly complicates my counseling and increases the time I must spend on each encounter, which I am not reimbursed for.

22. Just last week, I treated a healthy teenage patient whose parent is currently undergoing active chemotherapy. Before the CDC change to SCDM for Covid-19 vaccination, I relied heavily on ACIP's clear, evidence-based recommendation and corresponding MMWR guidance

to support my conversations with my patients and provide my patients with straightforward, trusted public-health direction on Covid-19 vaccination. Now, because ACIP has not followed the EtR framework and the CDC has not issued any rationale or updated MMWR guidance on the SCDM recommendation for Covid-19 vaccination, I was forced to navigate the conversation without evidence-based materials from ACIP and the CDC. I went back and forth with the teenager for an extended period of time (at least an additional 10 minutes) on why I strongly recommend Covid-19 vaccination in his specific circumstances, and how vaccination is a critical layer of protection for vulnerable family members like his immunocompromised parent because I had no authoritative federal guidance to anchor the discussion or to reassure him that vaccination remains recommended in cases like his. I am not reimbursed or paid for the extended time I spent with the teenage patient engaging in this discussion on Covid-19 vaccination. This confusion, hesitancy, and the uncompensated prolonged visit are direct harms resulting from the Directive and ACIP recommendation (adopted by the CDC) changing the Covid-19 vaccination recommendation for children to SCDM and failing to provide clear guidelines on how to implement SCDM. Encounters like this are now routine in my practice, and they impair my ability to deliver efficient, evidence-grounded pediatric care.

23. Since the Directive and ACIP's change to SCDM for Covid-19 vaccines for my patients, and in light of the Secretary's public statements on Covid-19 vaccines, I have experienced a dramatic increase in mistrust from families. Parents who have known me and my practice for years (some over two generations) now question whether they can trust me when I recommend the Covid-19 vaccine. They ask why they should believe me instead of what they hear online from the Secretary and the CDC's new recommendations. Trust is the foundation of pediatric care and my physician-patient relationship. The erosion of trust caused by the SCDM downgrade and the

Secretary's public statements on Covid-19 vaccines is a real, ongoing injury to both my practice and to the health of my patients.

24. As a pediatrician, I receive only a small administration fee to provide vaccines. I do not receive any payments from vaccine manufacturers and I am not reimbursed for extended counseling on Covid-19 vaccinations. Yet I must now spend precious time rebutting the Secretary's public statement that physicians are paid agents of pharmaceutical companies and that further defending my recommendations for Covid-19 vaccination (that is supported by my professional guidelines) that now conflicts with the Secretary's Directive and ACIP recommendation for SCDM for Covid-19 vaccinations. This is time I previously used to discuss my patients' health, not to defend my integrity and explain a conflict that the Secretary and ACIP has not even explained to me and my fellow pediatricians in the field.

25. As a direct result of the Secretary's Directive and ACIP's and CDC's decision to change the Covid-19 vaccine recommendation from routine to SCDM for children I spend significantly more time in each visit addressing misinformation, and confusion about Covid-19 vaccines for children, none of which is compensated. In addition, I must devote additional time to compensating for the Secretary's and ACIP's failure to provide transparent, data-driven guidance for the pediatric SCDM change for Covid-19 vaccination. Overall, the efficiency and capacity of my practice have been reduced to the detriment of my patients and the broader community. These harms are specific, ongoing, and directly traceable to the Secretary's Directive and ACIP's and CDC's subsequent SCDM recommendation for Covid-19 vaccines for children. If those actions were vacated, the confusion and mistrust would be reduced, my uncompensated counseling burden would ease, and the harms to my practice and my patients would be diminished.

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

Executed on November 20, 2025 in Lakeville, Massachusetts.

/s/ Aaron Bornstein MD

Dr. Aaron Bornstein

EXHIBIT 32

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, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *Defendants.*	Case No. 1:25-cv-11916

SUPPLEMENTAL DECLARATION OF CARLENE PAVLOS

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

1. I am the Executive Director of the Massachusetts Public Health Association d/b/a Massachusetts Public Health Alliance ("MPHA"), a nonprofit organization incorporated in the Commonwealth of Massachusetts in 1879. MPHA exists to promote and improve the health of all residents of the Commonwealth, which obligates us to foster conditions for people to achieve their full health potential. MPHA carries out this mission through public education, advocacy, and coalition-building to strengthen our state's public health.

2. I have served as the Executive Director of MPHA since 2018. As the Executive Director of MPHA, I lead and manage MPHA's priorities, positions, and engagement with our allies and members. I submit this declaration in support of MPHA's participation as a plaintiff in

this matter. I am over the age of 18 years old and I make this declaration based on my personal knowledge and in my official capacity as Executive Director.

3. MPHA is headquartered in Massachusetts and is a statewide advocacy organization which includes both individual and organizational members who share a commitment to achieving our mission to promote and improve public health in Massachusetts. Our membership includes physicians, nurses, and other healthcare workers, academic public health professionals, public health advocates, the leadership of local boards and health departments, and community health centers.

4. MPHA's main purpose is to protect and strengthen the public health in Massachusetts and support the population of Massachusetts by assuring access to public health services and advancing racial, geographic, and economic health equity in Massachusetts. MPHA's mission also includes educating Massachusetts residents on public health and promoting public health policies that protect the health and wellbeing of residents.

5. Vaccines are a significant health and health equity issue, and vaccine policy has therefore been a priority issue for MPHA and our members for years. The Centers for Disease Control and Prevention ("CDC") immunization framework is incorporated into public health systems at every level, and national consistency is essential in immunization practice. Preventing vaccine-preventable diseases requires population-level coordination. Because viruses and other infectious diseases spread across state borders, a uniform national benchmark is crucial for ensuring that individuals receive vaccinations at evidence-based ages and intervals regardless of where they live. This consistency is critical for protecting Massachusetts residents from preventable outbreaks and is engrained in the policies for which MPHA advocates and the public health services our members provide to their communities.

6. Maintaining nationally consistent vaccination benchmarks is also essential for protecting vulnerable populations. Infants, immunocompromised individuals, older adults, and those who cannot be vaccinated rely on broad community immunity. The CDC immunization schedules ensure that providers across the country—including MPHA members—administer vaccines in a manner that achieves predictable and optimal protection levels, thereby reducing the risk of outbreaks.

7. With respect to COVID-19 vaccines, MPHA has invested time and resources to keep the population of Massachusetts and our members informed on these issues since the COVID-19 vaccines were first developed. Our members, especially those working in local health departments and community health centers, are on the front lines of Massachusetts's public health infrastructure. For decades they have relied on clear, trustworthy, science-based guidance from federal public health authorities, including the CDC immunization schedules and recommendations, to inform their work.

8. I am aware of the May 27, 2025 announcement by Secretary of Health and Human Services Robert F. Kennedy, Jr. (the "Secretary") that he was rescinding the prior recommendations of the Advisory Committee on Immunization Practices ("ACIP") that pregnant women and healthy children ages six months to 17 years old be routinely immunized against COVID-19 (the "Directive"). Following the Directive, the CDC Immunization Schedule was updated to show that the COVID-19 vaccine was no longer recommended for pregnant people and that it was recommended on the basis of shared clinical decision making ("SCDM") for children.

9. I am aware that on June 9, 2025, the Secretary terminated the appointments of all voting ACIP members. I am also aware that on June 11, 2025, the Secretary appointed eight new voting members to the ACIP, most of whom are not experts in infectious disease or immunizations.

10. I am aware that this new ACIP met on June 25–26, 2025 during which the COVID-19 vaccine was discussed but no recommendations were voted on. ACIP did not discuss several of the vaccines that were initially published in the Federal Register notice for the June ACIP meeting.

11. I am aware that in August 2025, the FDA limited the indication for the 2025–2026 strain of the COVID-19 vaccine to individuals aged 65 and older and those under 65 with underlying health conditions. At the same time, the Secretary withdrew all Emergency Use Authorizations for COVID-19 vaccines. This, coupled with the Directive, created widespread uncertainty in Massachusetts about who could administer COVID-19 vaccines and where people of different ages could get vaccinated against COVID-19. Families were especially confused about whether pharmacists could still vaccinate children 5 and older.

12. I am aware that the new ACIP met again on September 18–19, 2025, during which they voted to recommend the COVID-19 for all individuals using SCDM. I am also aware that the CDC subsequently adopted this recommendation, which changed the COVID-19 vaccine recommendation for all individuals under the age of 65 from routine to SCDM.

13. MPHA believes that the Directive and the CDC's change in the COVID-19 vaccine recommendation from "routine" to "SCDM" are life-threatening recommendations that are immediately exposing all individuals to an increased risk of severe illness and death, undermining the public's trust in vaccines, and irreparably harming the public health in Massachusetts that MPHA and our members work so hard to protect and improve.

14. MPHA has members across the Commonwealth of Massachusetts, including individual members and organizational members whose work directly involves the health of children and adults, including pregnant individuals; vaccination delivery; and pandemic response.

Our members have been irreparably injured, and will continue to be harmed, by the effects of the change of the COVID-19 vaccine recommendation from "routine" to "SCDM" and the CDC's and the Secretary's associated messaging.

15. The reliability, transparency, and scientific rigor of the ACIP process are essential to the integrity of the entire federal immunization framework. Healthcare providers and public health practitioners depend on the ACIP to apply consistent, evidence-based methodologies when issuing national recommendations. However, the ACIP's recent COVID-19 SCDM recommendation represents a substantial departure from the scientific rigor that providers historically expect. The COVID-19 SCDM recommendation was issued without a coherent scientific basis and did not reflect a meaningful or well-established scientific consensus, and it reflects a troubling decline in the quality and transparency of the ACIP's decision-making. The CDC's SCDM recommendation for the COVID-19 vaccine therefore sows distrust, making it substantially harder for MPHA and our members to promote not only COVID-19 vaccination but also other critical immunization and health programs. This immediate erosion of trust threatens to undermine overall public health efforts and cannot be easily or quickly repaired.

16. There was no reliable scientific justification for changing the COVID-19 vaccination designation to SCDM. The change of the COVID-19 vaccine recommendation for all individuals from "routine" to "SCDM" was made without the usual transparent presentation of GRADE tables or Evidence to Recommendation (EtR) framework for evaluating the quality of evidence, nor was this change accompanied by a clear, contemporaneous explanation in the CDC's Morbidity and Mortality Weekly Report ("MMWR"). As an organization based in Massachusetts—a state with a historic leadership role in advancing public health and a deeply committed public health workforce—we are particularly concerned that the new SCDM

recommendation diminishes the influence of evidence-based medicine and risks further eroding public trust. Accurate, trustworthy information is at the heart of public health, which depends upon the public's confidence in science and in our recommendations in order to change behaviors. The SCDM recommendation for the COVID-19 vaccine is not based in science and, by suggesting that there are equally valid competing views on the value of vaccination (which is demonstrably false), it threatens to reverse years of public health progress in Massachusetts on vaccine safety and equity that MPHA and its members are working every day to protect.

17. MPHA advances the public health in Massachusetts by actively promoting science-based policies and practices that foster confidence in the safety and efficacy of vaccines and assure vaccine accessibility for those who need them. Public health is rooted in science, and the science is clear: COVID-19 vaccines are safe and effective in preventing severe illness and death, including among children and pregnant women. The CDC immunization schedule change for the COVID-19 vaccine from "routine" to "SCDM" is a downgrading of the CDC's recommendation and sends a message to patients discouraging COVID-19 vaccine, without any explanation or scientific reasoning to support this messaging. MPHA has thus had to divert staff time and organizational resources away from other strategic priorities in order to respond to the confusion and misinformation created by change in the COVID-19 vaccine recommendations and the CDC's and the Secretary's associated messaging. MPHA has issued public statements, letters to the editor, and informational materials in an effort to restore public confidence in the COVID-19 vaccine and prevent further erosion of trust in public health institutions.

18. By issuing a recommendation untethered from robust scientific evidence, the ACIP and the CDC have placed MPHA and its members in an untenable position. The CDC has effectively instructed public health practitioners to implement guidance that lacks analytical

integrity and does not meet the evidentiary standards that normally govern national immunization recommendations. This has forced providers to choose between following a federal recommendation they believed was scientifically unsound or deviating from it and risking accusations of failing to follow the standard of care.

19. The CDC's COVID-19 SCDM recommendation has also created confusion in the public's understanding of vaccine safety and effectiveness. The change to a SCDM recommendation for the COVID-19 vaccine and the associated messaging from the CDC and the Secretary has led to community members across the state to doubt the safety and efficacy of all vaccinations in general. At the same time, the absence of meaningful scientific data supporting the COVID-19 SCDM recommendation has also left providers without any coherent way to explain to patients why this change was made. The ACIP offered no clear evidentiary basis, clinical rationale, or population-level justification for shifting COVID-19 vaccination into an SCDM framework. As a result, clinicians have been forced to counsel patients on a recommendation that cannot be meaningfully explained because no underlying data have been provided to support it. This has undermined patient trust, weakened the therapeutic relationship, and placed providers in a position where they cannot deliver informed, evidence-based counseling consistent with the expectations of the national standard of care.

20. No mechanism exists for MPHA and its members to recover the substantial financial costs and expenses they are incurring right now as result of the change in the COVID-19 vaccine recommendation from "routine" to "SCDM."

21. The downgrading of the CDC immunization schedule for COVID-19 vaccines from "routine" to "SCDM" is forcing the MPHA to spend funds, time, and resources to rebuild trust in

science and public health and combat the spread of misinformation about the safety and effectiveness of COVID-19 vaccinations.

22. MPHA estimates that it spends at least 3 hours each week responding to inquiries from or developing fact-based information for its members and allies regarding the change in the COVID-19 vaccination recommendation to SCDM, where vaccines are available, or whether local health departments will be able to offer COVID vaccination clinics this year. For example, before the issuance of the Directive and the change in the COVID-19 vaccination recommendation to SCDM, my day-to-day job rarely involved discussions regarding the safety and effectiveness of vaccines. Now, my day-to-day work and interactions with members frequently concerns the SCDM COVID-19 recommendation and/or combatting the distrust, confusion, and misinformation circulating as a result of the CDC's and the Secretary's actions and messaging.

23. MPHA has also had to divert at least 10 hours of its time each week to communicating with state and local health officials regarding concerns about insurance coverage for the COVID-19 vaccine as well as the ability for pharmacists to deliver COVID-19 vaccinations, and the impact of the opaque and non-evidence-based federal policy on COVID-19 vaccines and preparing and giving presentations regarding these topics to students or members of the public. As a result, MPHA has been forced to sideline its other initiatives in order to focus its time, money, and resources to helping its members and allies understand and navigate the changes to the CDC's SCDM recommendation for the COVID-19 vaccine. For example, MPHA has had to focus portions of its conferences and presentations—that would otherwise be dedicated to other public health initiatives—to combat misinformation about the safety and effectiveness of the COVID-19 vaccine.

24. For all these reasons, I ask the Court to prevent the serious, irreparable harm the CDC's SCDM recommendation for the COVID-19 vaccine is immediately and presently inflicting on MPHA, its members, and to the health of Massachusetts residents.

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

Executed on 12/1/2025.

Carlene Pavlos

Carlene Pavlos, Executive Director
Massachusetts Public Health Alliance

EXHIBIT 33

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 JENIFER LEAF JAEGER, MD, MPH, FAAP

I, Jenifer Leaf Jaeger, MD, MPH, FAAP, declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I submit this declaration in support of Plaintiffs' Third Amended Complaint because the May 19, 2025 Directive issued by the U.S. Department of Health and Human Services ("HHS") under Secretary Robert F. Kennedy Jr., designating the Covid-19 vaccine for children as Shared Clinical Decision Making ("SCDM") and recent unexplained changes by the Advisory Committee on Immunization Practices ("ACIP") (in September 2025) and Centers for Disease Control and Prevention ("CDC") (in October 2025) for Covid-19 vaccinations, will harm my patients and is interfering with my ability to practice pediatric medicine in accordance with the accepted standard of care.

2. I am a graduate of the Washington University School of Medicine. I completed a residency at Tufts University and a fellowship in pediatric infectious diseases at Brown University.

I served as an Epidemic Intelligence Service Officer for Centers for Disease Control and Prevention ("CDC") and received a Master of Public Health Degree from the Harvard T. H. Chan School of Public Health. I am board-certified in pediatrics.

3. I am currently the pediatric medical director of the New Bedford Community Health Center in New Bedford, Massachusetts ("NBCHC"), which is a Federally Qualified Health Center. I will formally resign my position at NBCHC on December 16, 2025 to join Partner's in Health, a social justice organization providing high-quality health care globally to those who need it most. Prior to joining NBCHC, I was a physician with Doctors Without Borders in Bangladesh. I have practiced pediatrics for over 30 years. I care for children from birth through 21 years of age.

4. I am a member of the Massachusetts Public Health Alliance ("MPHA"). MPHA is a statewide advocacy organization that includes both individual and organizational members who are dedicated to promoting and improving public health in Massachusetts. MPHA's membership includes physicians, nurses, and other healthcare workers, academic public health professionals, public health advocates, the leadership of local boards and health departments, and community health centers.

5. MPHA's main purpose is to protect and strengthen the public health in Massachusetts and support the population of Massachusetts with increasing access to health care and advancing racial, geographic, and economic health equity in Massachusetts. MPHA's mission also includes educating Massachusetts residents on public health and promoting public health policies that protect the health and wellbeing of residents.

6. The HHS Secretary issued the "Secretarial Directive on Pediatric COVID-19 Vaccines for Children Less than 18 years of Age and Pregnant Women" (the "May 19 Secretarial Directive"). The Secretary stated, "I have determined that the known risks associated with the use

of COVID-19 vaccines in healthy U.S. children ages six months to 17 years do not outweigh the purported benefits of the vaccine." The May 19 Directive directed the CDC to "remove COVID-19 vaccines from the recommended Child and Adolescent Immunization Schedule by Age and recommended vaccines during pregnancy." Recent actions taken by CDC, following the Directive, removing the "routine" recommendation for Covid-19 vaccination for children is contrary to evidence-based, accepted pediatrics standards of care for vaccinations supported by rigorous, evidence-based research and clinical follow-up. I am forced to either violate my oath to "do no harm" to my patients or risk professional consequences, including medical malpractice liability and potential disciplinary action by the state medical board. Not recommending the Covid-19 vaccine to my patients is bad patient care and places not only the patient but their family, household contacts, and the community at large at risk of severe morbidity and mortality.

7. The May 19 Directive, and HHS's subsequent guidance requiring SCDM for pediatric Covid-19 vaccination, has introduced confusion, fear, and hesitation among health center patients' families. It has cast unwarranted doubt on a vaccine that is proven safe and effective, and is essential for protecting our most vulnerable patients, specifically infants and children with underlying health conditions. Pediatricians are the primary trusted source for health information for families. The spurious and abrupt change in Covid-19 vaccination recommendations undermines the patient-provider relationship.

8. As a result of the downgrade to SCDM, I am required to spend additional time counseling patients and their parents as they weigh the risks and benefits of vaccination against COVID-19. By changing the CDC immunization schedule recommendation from "routine" to SCDM the Secretary, ACIP, and CDC has shifted responsibility onto parents for understanding the relative risks and benefits of the COVID vaccine vis-a-vis the potential vulnerabilities of their

child, and placed families in an impossible position of making the best medical decision, particularly those with lower health literacy or fewer educational resources. Most parents do not have the medical background or foundational understanding of vaccines (their purpose, development, risks, and benefits) to independently weigh complex scientific information, recognize inaccurate information presented in the media, and make a truly informed decision. These inequities mean that the level of understanding required for an informed decision varies dramatically across my patient population. Further, the time necessary to adequately prepare a parent to make a medically sound decision far exceeds what is feasible in a typical 20-minute well-child visit. As a result, I am forced to spend significantly more unreimbursed time counseling parents, correcting misconceptions, and attempting to bridge health literacy gaps—all of which materially detract from my ability to provide comprehensive pediatric care and directly harm my clinical practice. Despite specific and extensive counseling regarding the Covid-19 vaccine, patients and their parents have expressed less trust in the COVID-19 vaccine as a result of the SCDM designation, which is often mistaken to signal that the vaccine is no longer important.

9. The additional time spent counseling patients, as a result of the shift to SCDM, has created a substantial burden on my practice. While various billing codes for vaccine counseling exist for COVID-19, it is unclear whether these codes can be used in all settings, for all insurances, and in all states. But the core problem for me is not billing, it is time. A typical pediatric well visit in the United States is allotted 15–20 minutes (15–30 minutes in Massachusetts, with 20 minutes most common), during which providers must complete a full review of systems, perform a physical exam, provide anticipatory guidance, vaccines, and—at federally qualified health centers like mine—review multiple required screenings (SBIRT, PISQ, PHQ-2/9, GAD-7, SDOH, and others). This already allows for little room for comprehensive counseling. The SCDM requirement now

demands lengthy, individualized discussions to help parents evaluate complex clinical and epidemiological Covid-19 vaccine data that most are not equipped to interpret on their own. Adding this counseling to an already overloaded visit is nearly impossible and forces me to choose between cutting essential components of care or extending visits far beyond what is feasible. This increased time burden directly harms my ability to provide complete, evidence-based pediatric care.

10. The patient population at NBCHC includes a large number of individuals with limited English proficiency (~80% do not speak English) and health literacy. The majority are uninsured or underinsured.

11. Following the May 19 Secretarial Directive, I have seen a decline in my patients' willingness to be vaccinated or even to seek care. For example, NBCHC administered 104 doses of COVID-19 vaccines between April 1, 2024 and August 1, 2024 for all age groups between 6 months and 18 years; by comparison, fewer than 50 doses were administered between May 1, 2025 and July 1, 2025. Parents are now questioning whether they should vaccinate their children against COVID-19. With limited health literacy regarding the processes for vaccine development and production, as well as a near complete lack of knowledge regarding the difference in mode of transmission and prognosis for the various respiratory illnesses, families are also declining other respiratory virus vaccines (e.g., influenza) which will likely result in increased hospitalizations and ICU admissions, increasing medical costs and placing an increased burden on limited healthcare resources.

12. The downgrade to shared clinical decision-making for pediatric Covid-19 vaccination also has broader implications and compounding harms beyond the clinical visit. When children become ill, parents must remain home to care for them, leading to lost wages and reduced

productivity that disproportionately affect families with fewer resources. Unvaccinated children can also transmit infection to their parents, who may themselves become ill and miss additional work. As seen early in the pandemic, rising infection rates among families strain the workforce (including first responders and essential personnel) placing entire communities at heightened risk. Increased infections in the community burden EMS, emergency departments and ICUs, limiting capacity, staff, and resources required to manage other critical needs such as heart attacks and trauma care.

13. I am especially concerned about infants under 6 months old for whom the vaccine is not available. During pregnancy, the immune system is suppressed to protect the developing fetus. This places pregnant women at higher risk for severe Covid-19 infection. As infants under 6 months of age cannot receive the Covid-19 vaccine, their only protection resides in the presence of maternal antibodies. The absence of these antibodies places the infant not only at increased risk of acquiring Covid-19 infection, but of developing severe or fatal infection. Further, an unimmunized mother is more likely to experience premature birth. Being premature (depending upon how premature) is associated with increased risk of long-term complications and possibly death. In addition, premature infants who become infected are more likely to experience complications or death from Covid-19. Deterring patients from accessing the Covid-19 vaccine in this population is medically dangerous and ethically indefensible. This is exactly why the May 19 Directive and recent actions by ACIP, and the CDC, unnecessarily increase risk of infection among child who are then able to spread infection through the schools (to other students and teachers) and communities, thereby placing all vulnerable persons, not only children, at potential risk for severe infection including chronic disability from complication of long-Covid.

14. The Directive and recent actions by the ACIP and CDC are interfering with my ability to provide the standard of care I have learned from my professional training and from national professional organizations that have published practice guidelines based on experience and peer-reviewed research. These guidelines include practice guidelines from the American Academy of Pediatrics, the Pediatric Infectious Disease Society, the Infectious Disease Society of America, the Advisory Committee on Immunization Practices prior to June 2025, and UpToDate, which is an online database that is a compendium of clinical decision support tools, published clinical trial data, and detailed information on drugs that is widely used by practicing physicians. These resources all recommend the Covid-19 vaccine to all pediatric patients, including the primary series for infants. Nevertheless, by following these professional guidelines I know that I am now potentially placing myself at odds with the federal directive. I am exposing myself to malpractice liability, jeopardizing my medical license, and facing disciplinary action from the Board of Registration in Medicine, which includes having to bear the cost of defending my professional reputation—all for recommending and administering a vaccine that is FDA-approved and fully supported by pediatric standards of care. My medical judgment is now being overridden by a HHS directive that is not based in science or evidence, and the result is measurable harm: my patients delaying or foregoing Covid-19 vaccination, confusion and fear of unknown costs among my patients' parents, operational strain in my practice, and a growing sense of mistrust in the Covid-19 vaccine that is deeply damaging to the physician-patient relationship.

15. Because of vaccine hesitancy and loss of trust caused by the Directive, physicians such as myself are required to spend more time correcting misinformation with individuals and families regarding the effectiveness of the Covid-19 vaccines, which diverts time and resources away from other important health care or public health duties. If there is another severe Covid-19

outbreak, unvaccinated individuals create a risk to themselves as well as the rest of the community because they can spread infection and thereby consume limited resources; all of which is preventable. Covid-19 is still a public health threat in our communities, especially because a new variant of the virus known as NB.1.8.1 or "Nimbus" is now becoming prevalent in the United States, so being up to date on one's vaccination status is still a sound public health recommendation.

16. In short, the Secretary's May 19, 2025 Directive and recent actions by ACIP and the CDC downgrading the recommendation for Covid-19 vaccination to SCDM completely contradict the evidence of the safety and effectiveness of the Covid-19 vaccines and will result in preventable illness, hospitalizations, and death.

17. I took an oath as a physician to do no harm. Today, because of the May 19 Secretarial Directive and recent actions by ACIP and the CDC, I am being placed in an impossible situation that may result in actions that conflict with my best medical judgment and against the science that I know saves lives. The Directive puts an unfounded personal agenda of the HHS Secretary over patients.

18. For all these reasons, I ask the Court to prevent the harm that I believe the HHS's May 19 Directive and recent actions by ACIP and the CDC downgrading the recommendation for Covid-19 vaccinations will inflict on me as a physician and the patients who I presently treat.

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

Executed on December 1, 2025 in Massachusetts.

Dr. Jenifer Jaeger

Jenifer Leaf Jaeger, M.D., M.P.H., FAAP

EXHIBIT 34

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

SUPPLEMENTAL DECLARATION OF SINDHU K. SRINIVAS, MD, MSCE
(As President of the Society for Maternal Fetal Medicine)

I, Sindhu K. Srinivas, MD, MSCE, hereby declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge:

1. I am the President of the Society for Maternal-Fetal Medicine ("SMFM") and am board certified in Obstetrics and Gynecology and Maternal Fetal Medicine. In this role, I lead SMFM's relationships with its more than 7,000 physician members and oversee the publication of standards that SMFM's members consult to provide the highest level of care to their patients. As such, I have in-depth knowledge of the operations of SMFM, its members, the standard of care SMFM's physician members follow, and the facts and circumstances set forth herein.

2. All of the facts set forth in this declaration are based on my personal knowledge. If called upon to testify as to the facts stated herein as a witness, I could and would competently testify under oath. I submit this supplemental declaration in support of SMFM's participation as a plaintiff in this matter and in support of Plaintiffs' Third Amended Complaint. I am over the age

of 18 and make this declaration based on my personal knowledge and in my official capacity as President of SMFM.

3. I received my Doctor of Medicine degree from the University of Medicine and Dentistry of New Jersey, and completed a residency and fellowship at the Hospital of the University of Pennsylvania. I am currently a professor of obstetrics and gynecology and treat high-risk pregnant patients at a hospital in Pennsylvania.

4. SMFM is a professional organization dedicated to advancing the practice of maternal-fetal medicine, which involves the care of people with high-risk pregnancies. The organization focuses on education, research, and advocacy to improve outcomes for both the pregnant person and the fetus. SMFM exists to ensure that high-risk pregnant patients receive consistent, evidence-based care across the United States and provide physicians the resources to deliver this care to their patients.

5. SMFM's membership includes over 7,000 physicians nationwide who specialize in maternal-fetal medicine and provide direct care to high-risk pregnant patients in both hospital and outpatient settings across the United States. Our mission is to advance evidence-based care provide and ensure high-risk pregnant patients receive accurate, scientifically grounded medical care and guidance.

6. SMFM is dedicated to advancing optimal and equitable perinatal outcomes for all people who desire or experience pregnancy and leads the evidence-based practice of high-risk pregnancy care by providing education, promoting research, and engaging in advocacy. To accomplish these goals, SMFM offers a range of educational resources for clinicians specializing in high-risk pregnancies, including the provision of accredited medical education and clinical guidelines. SMFM also supports numerous research initiatives aimed at improving outcomes for

high-risk pregnancies and has an official society journal, PREGNANCY, which is an open-access journal that publishes innovative research, ensuring that the latest scientific advancements are freely available to the global maternal-fetal medicine community.

7. SMFM members provide direct patient care in every state across the United States, including in large health systems, rural hospitals, community practices, and academic centers. Because maternal-fetal medicine involves management of complex and high-risk pregnancies, SMFM members rely on CDC and ACIP recommendations and the CDC immunization schedule to guide patient counseling and clinical decision-making on vaccination.

8. Before the Secretary's Directive and ACIP's September 2025 vote, SMFM members uniformly relied on the CDC's "routine" recommendation for Covid-19 vaccination in pregnancy. The CDC immunization schedule recommendations were not advisory background noise; they were central tools SMFM physician members used in the exam room to ensure patient safety and meet the standard of care. Maternal-fetal medicine depends on clear, evidence-based standards, including those issued by the ACIP and CDC on vaccinations, because high-risk pregnancies require tightly calibrated risk-benefit assessments grounded in authoritative guidance.

9. SMFM has physician members throughout the United States who have been (and continue to be) directly and immediately harmed by the May 27, 2025 Directive (the "Directive") issued by United States Secretary of Health and Human Services Robert F. Kennedy Jr. (the "Secretary") rescinding "the CDC recommendation that pregnant women receive the COVID-19 vaccine" and ordering the CDC to remove Covid-19 immunizations from the CDC's recommended vaccines during pregnancy. SMFM physician members have also been directly and immediately harmed by the reconstituted Advisory Committee on Immunization Practices ("ACIP") and their September 2025 shift of Covid-19 vaccination recommendation for adults under the age of 65 to

shared clinical decision-making ("SCDM"), which the CDC subsequently mischaracterized as "informed consent."

10. These actions by the Secretary, ACIP, and the CDC have overturned the reliance framework for vaccinations under which maternal-fetal medicine specialists practice. They eliminated the uniform baseline that clinicians had used to counsel patients (i.e. the CDC immunization schedule) and have thrust our physician members into an unprecedented conflict between medical evidence and federal directives. These actions by the Secretary, ACIP, and the CDC have further caused disruption to SMFM as we have had to use SMFM resources to address the mass confusion caused by these actions.

11. SMFM's members and the patients they care for have been impacted and will continue to be impacted at the hands of the Secretary's, ACIP's, and CDC's recent changes to the CDC immunization schedule recommendation for Covid-19 vaccination for pregnant women. Members of SMFM have reported that the Secretary's Directive and recent actions by ACIP and the CDC have frustrated their ability to effectively counsel patients regarding the effectiveness of the Covid-19 vaccine at preventing illness and that the Directive and recent ACIP recommendation is compromising the standard of care by inciting patient delays or refusals to receive the Covid-19 vaccination.

12. The Directive has directly impacted SMFM physician members' ability to provide the optimal standard of care that they have been following since the Covid-19 vaccines were approved and has placed SMFM's members in a difficult situation. SMFM members have reported that their clinical judgment, which is rooted in years of medical training, board certification in maternal-fetal medicine, and reliance on data from peer-reviewed literature and prior CDC/ACIP recommendations, is now being overridden by the Directive. In addition, the recent ACIP

recommendation to change Covid-19 vaccination to SCDM for essentially all adults is essentially no recommendation at all for pregnant women and it did not address the conflict with the Directive, did not follow the transparent presentation of GRADE systematic review tables or EtR (evidence to recommendation framework for evaluating the quality of evidence, and did not have a contemporaneous explanation in the CDC's Morbidity and Mortality Weekly Report ("MMWR"). As a result, SMFM Members are being forced to justify scientifically sound recommendations for the Covid-19 vaccination during pregnancy against a federal Directive and ACIP recommendation that has no evidentiary basis in obstetrics or infectious disease. Peer-reviewed studies have demonstrated that administration of the Covid-19 vaccine during any trimester of pregnancy lowers hospitalization rates, serious illness, and adverse outcomes in pregnant people and infants. With the efforts and advocacy of SMFM, peer-reviewed studies investigating and analyzing the safety and effectiveness of administration of the Covid-19 vaccine during pregnancy have been conducted. These studies show no signal of harm to the pregnant patient, the pregnancy, or the newborn resulting from the administration of the Covid-19 vaccine during pregnancy.

13. Based on a recent survey conducted among a subset of the SMFM membership, SMFM members report that counseling patients about Covid-19 vaccination now requires an additional 10-20 minutes per patient, because patients arrive with confusion created by the Directive and ACIP's recent change to the CDC immunization schedule for Covid-19 vaccines to SCDM. The lack of clarity by the ACIP and CDC on what SCDM means for Covid-19 vaccines for pregnant women and the conflict with the Directive has increased consultation time and many SMFM members report not being able to be reimbursed for this increased consultation time, resulting in direct financial losses to SMFM members and their practices. These are quantifiable harms that did not exist prior to the Secretary's Directive, the recommendations approved by the

reconstituted ACIP, and the CDC's recent changes to the CDC immunization schedule for Covid-19 vaccination for pregnant women.

14. Further, SMFM members are reporting a rapid erosion of trust and vaccine confidence among their pregnant patients as a result of the Directive and recent action by ACIP changing the recommendation for Covid-19 vaccination for essentially all adults to SCDM. SMFM members have also reported that the Secretary's sudden and unilateral Directive removing the Covid-19 vaccine from the routine vaccination recommendations for pregnant people has undermined some patients' faith and trust in all recommended vaccinations during pregnancy, causing them to refuse other routine vaccinations and creating even more risk of serious illness and hospitalization.

15. In maternal-fetal medicine, the CDC immunization schedule has been an authoritative, central tool physicians used in exam rooms to consult with patients on vaccinations, ensure patient safety, and meet the standard of care. The Secretary, ACIP, and CDC unexplained changes to the CDC immunization schedule for Covid-19 vaccination for pregnant individual (that essentially is no recommendation for Covid-19 vaccination) has shifted the burden entirely to individual physicians to defend their medical advice on vaccination without the authoritative evidentiary framework that accompanies a change to the CDC immunization schedule that physicians and patients have long relied upon. The deterioration of trust that SMFM physician members are experiencing right now in their exam rooms with their patients is a direct result of these recent actions by the Secretary, ACIP and CDC.

16. Preserving trust is essential in high-risk pregnancy care where delayed decisions can be life threating. In the wake of the issuance of the Directive, SMFM members' patients are questioning not only the Covid-19 vaccine but also the safety and necessity of longstanding

vaccinations, such as the influenza and Tdap vaccines, during pregnancy. Some SMFM physician members are now fielding questions like "Why should I trust any of these vaccines if the government suddenly pulled the Covid vaccine for pregnancy?"—questions that were not previously part of the physician-patient dialogue. SMFM physician members report spending time and resources on counseling patients about the safety and effectiveness of the Covid-19 vaccine to rebut the mistrust and confusion that has resulted from the Directive and recent ACIP recommendation to change Covid-19 vaccination to SCDM. This growing mistrust is undermining SMFM members' physician-patient relationship and jeopardizing maternal and neonatal health.

17. Since the issuance of the Directive and these recent actions by the ACIP and CDC, SMFM has been forced to divert time, personnel, and resources away from its regular educational and policy initiatives in order to respond to the confusion caused by the policy shift. These efforts have included developing public communications, answering questions from members, correcting misinformation, and coordinating with other national medical associations to reaffirm the evidence-based guidance on Covid-19 vaccination during pregnancy. These efforts are essential to mitigate ongoing harm, and they represent a significant and unplanned burden for SMFM.

18. The Directive and the ACIP and CDC's recent change to the CDC immunization schedule for Covid-19 vaccination to SCDM have forced SMFM to divert additional time, personnel, and resources away from its regular educational and initiatives in order to address the confusion caused by the conflicting recommendations for Covid-19 vaccines for pregnant women. These efforts have included SMFM staff shifting their time away from other SMFM priorities to draft emergency statements to members,[1] respond to member emails seeking clarification, and

[1] For example, as a result of the Directive, SMFM had to spend time, resources, and money to immediately issue a statement to SMFM members addressing the Directive and reaffirming Covid-19 vaccination recommendations during pregnancy.

coordinating with other professional associations on how to interpret these actions by the Secretary, ACIP, and CDC. This time would otherwise have been spent on SMFM's core mission: guideline development, research support, and education for the evidence-based practice of high-risk pregnancy care.

19. The recent shift by the Secretary, ACIP, and CDC from the CDC immunization schedule routine recommendation for Covid-19 vaccination for pregnant women to essentially no recommendation for pregnant women has real world implications for SMFM physician members and directly burdened SMFM members' medical practices. For example, since the Directive and these recent actions by ACIP and CDC, SMFM members have reported: (i) escalating vaccine hesitancy among pregnant patients who had accepted vaccination before the Directive; (ii) longer, more complex counseling sessions devoted to addressing confusion created by the government's abrupt change to the CDC immunization schedule for pregnant women; and, (iii) legal and professional risk, as the shifts to essentially no recommendation for Covid-19 vaccination for pregnant women conflicts with the medical standard of care for high-risk pregnant patients who face severe adverse health outcomes from Covid-19 infection. These are not policy disagreements; they are real-world, predictable consequences of the Secretary, ACIP, and CDC actions that have changed the rules under which SMFM physician members are practicing right now.

20. Since the Directive and these recent actions by ACIP and the CDC changing the CDC immunization schedule recommendation for Covid-19 vaccination for pregnant women, multiple SMFM members have also been forced to contact insurers to determine coverage and coding for counseling or vaccine administration; redirect staff time to address the confusion on Covid-19 vaccination for pregnant patients caused by these conflicting actions taken by the

Secretary, reconstituted ACIP, and the CDC; and, increase documentation for Covid-19 vaccination consultation and decision-making due to the liability risk created by these actions.

21. SMFM member physicians are not passive observers of federal vaccine policy. Their clinical obligations, malpractice exposure, reimbursement, and daily operations are directly impacted by these changes to the CDC immunization schedule by the Secretary, ACIP, and CDC. Many SMFM members also report experiencing increased liability risk because removing the "routine" recommendation for Covid-19 vaccination deviates from the standard of care they are expected to provide. This forces SMFM physician members into an untenable conflict: follow the new federal directives on Covid-19 vaccination for pregnant women and risk patient harm or malpractice claims should a patient or child contract Covid-19; or follow the medical evidence and recommend Covid-19 vaccination, which risks accusations of deviating from CDC standards and insurer confusions.

22. SMFM members have informed SMFM staff that Secretary, ACIP, and CDC changes to the CDC immunization schedule recommendation for Covid-19 vaccination for pregnant women from "routine" to essentially no recommendation has forced SMFM physician members to spend significantly more unreimbursed time counseling patients on Covid-19 vaccination, correcting misconceptions, and attempting to bridge health literacy gaps, all of which materially detract from their ability to provide comprehensive care to their patients. We have received questions from our members regarding the Secretary, ACIP, and CDC's changes to the CDC immunization schedule for Covid-19 vaccination for pregnant individuals, including how to understand and apply ACIP and the CDC's recent recommendation for Covid-19 vaccination for pregnant individuals that did not follow the EtR framework and has no guidance published in the MMWR. We expect to continue to have to divert SMFM resources and staff member time to

answer SMFM questions related to the Secretary, ACIP, and CDC changes to Covid-19 vaccination for pregnant individuals. Without these additional obligations, SMFM staff would be devoting their time and resources to supporting members' efforts to advance the care provided to their patients.

23. The Secretary, ACIP, and the CDC changes to the CDC immunization schedule for Covid-19 vaccination for pregnant women imposes a significant burden and expense on SMFM members who provide direct care to high-risk pregnant women, which includes care related to Covid-19 vaccination. I am aware of SMFM members who provide care to high-risk pregnant patients, which includes Covid-19 vaccination. SMFM physician members have informed me that they are concerned about the immediate harms caused by the actions of the Secretary, ACIP, and CDC, including the cost to their medical practices, conflict with the standard of care, documentation, and liability. Both before and after the actions by the Secretary, ACIP, and the CDC, SMFM staff members have spent considerable time addressing member concerns specifically related to the changes to the CDC immunization schedule for Covid-19 vaccination for pregnant women, instead of discussing other member business or initiatives, particularly important during the respiratory virus season.

24. In sum, without prompt and immediate intervention, the Directive and the ACIP and CDC's recent changes to the CDC immunization schedule for Covid-19 vaccination for pregnant women will continue to interfere directly with the SMFM physician's medical practices, undermine the physician-patient relationship, and cause needless negative maternal and neonatal health outcomes. The harms to SMFM and SMFM members set forth above are ongoing and will continue unless the Directive and the ACIP and CDC's recent changes to the CDC immunization schedule for Covid-19 vaccination for pregnant women are vacated and the ACIP and CDC return

the evidence-based, transparent process for making vaccine recommendations for pregnant individuals.

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

Executed this 1st day of December 2025 in Philadelphia, Pennsylvania.

Dr. Sindhu Srinivas

Sindhu K. Srinivas, MD, MSCE
On behalf of the Society for Maternal-Fetal Medicine

EXHIBIT 35

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. _____

DECLARATION OF DR. CAROLINE E. ROUSE, M.D.

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

1. I submit this declaration in support of plaintiffs' motion for preliminary injunction because the health and lives of my patients are in jeopardy. I currently practice as a board-certified maternal-fetal specialist in Indianapolis, Indiana. In my practice, I treat high-risk pregnant patients. HHS's May 19, 2025 directive will cause immediate and irreparable harm caused as it halts access for pregnant women, including my patients, to receive critical, evidence-based COVID-19 vaccines.

2. The May 19 HHS directive issued is already having harmful effects on the care I provide. It has disrupted critical vaccination schedules for my patients and caused dangerous confusion in clinical practice. As a result, I am placed in an untenable position: either follow the directive or uphold the established standard of care, which includes recommending COVID-19 vaccination for pregnant patients, a practice supported by years of scientific evidence. My

patients, many of whom are immunocompromised by the veryin nature of being pregnant or face systemic barriers to care are now afraid, misinformed, and at increased risk of preventable illness and death as a result of HHS's May 19 COVID-19 directive. This directive is actively endangering the health and lives of my patients, contributing to suffering that could have been avoided.

3. I am over the age of 18 years old and I make this declaration based on my personal knowledge and experience, and if called to testify, I could and would do so truthfully. I am a physician board certified in obstetrics and gynecology and maternal-fetal medicine. I am presently practicing at a large university and medical center located in Indiana and the medical director for our outpatient clinic and maternity hospital. In 2010, I received my Doctor of Medicine degree from Indiana University School of Medicine. I then completed a residency in obstetrics and gynecology at University of Washington School of Medicine and my fellowship in maternal and fetal medicine at Brigham and Women's Hospital.

4. I am a member of the Society for Maternal-Fetal Medicine (SMFM), a professional organization committed to advancing evidence-based public health and medical care.

5. For 15 years I have cared for pregnant patients as part of my obstetric practice and regularly advise them on vaccinations recommended during pregnancy. These include the COVID-19 vaccine, influenza vaccine, Tdap (which protects against tetanus, diphtheria, and pertussis), and more recently, the RSV vaccine.

6. Since its introduction in 2021, the COVID-19 vaccine has been recognized as the standard of care for pregnant patients, based on clinical guidance from the SMFM. Following these guidelines, I have consistently recommended the COVID-19 vaccination to my pregnant patients. This is especially important because pregnancy is a well-established risk factor for increased illness, morbidity, and complications from respiratory infections such as COVID-19 and influenza.

7. The HHS Secretary issued the "Secretarial Directive on Pediatric COVID-19 Vaccines for Children Less than 18 years of Age and Pregnant Women" (the "May 19 Secretarial Directive"). The Secretary stated, "I have determined that the known risks associated with the use of COVID-19 vaccines in healthy U.S. children ages six months to 17 years do not outweigh the purported benefits of the vaccine." *See* Exhibit A. The May 19 Secretarial Directive directed the CDC to "remove COVID-19 vaccines from the recommended Child and Adolescent Immunization Schedule by Age and recommended vaccines during pregnancy."

8. The May 19 Secretarial Directive's recent decision to withdraw the universal recommendation for COVID-19 vaccination during pregnancy directly contradicts the standard of care and clinical guidance that I and other SMFM members rely on to deliver safe and effective care to our high-risk pregnant patients. This change is currently undermining the patient-provider relationship, puts my decision-making as a physician at risk, and sows confusion among my patients about whether COVID-19 vaccination is necessary or advisable.

9. The May 19 Secretarial Directive also immediately imposes barriers to access COVID-19 vaccines for pregnant women. For example, a large percentage of my patients have Medicaid insurance or are uninsured. Many of them have limited social and financial resources. If funding for vaccinations is compromised, only those patients with the financial resources necessary will be able to obtain them, worsening existing health disparities. Furthermore, hearing misinformation about vaccinations makes people's ability to make decisions about health care during pregnancy even more difficult. The impact of these immediate burdens is especially severe for my pregnant patients with underlying conditions like diabetes, hypertension, and asthma, who face a higher risk of serious complications from COVID-19. These are precisely the individuals who stand to benefit most from the protection the COVID-19 vaccine offers.

10. I practice in a region with historically low vaccine uptake, which makes clear and consistent public health messaging especially critical. I am deeply concerned that the May 19 Secretarial Directive, which withdraws the recommendation for COVID-19 vaccination during pregnancy, directly undermines both the credibility of my medical guidance and the trust I work hard to build with my patients. I routinely counsel pregnant patients on the safety and effectiveness of the COVID-19 vaccine, which I regard as the appropriate and evidence-based standard of care. The Directive now places my clinical judgment in direct conflict with federal guidance, forcing me into an untenable position: either follow what I know to be best for my patients, or align with a policy that contradicts established medical consensus. This erosion of trust is not just theoretical as it is already interfering with my ability to protect high-risk patients from a preventable and potentially deadly illness since I am unsure if they will be able to obtain a COVID-19 vaccine. If I recommend a COVID-19 vaccine to them, I do so on the belief that they will be able to obtain one. If I know that they will not be able to obtain the COVID-19 vaccine, I may advise my patients with additional information to protect themselves, in light of being unvaccinated for COVID-19.

12. During the early stages of the COVID-19 pandemic, I cared for several pregnant patients hospitalized with severe COVID-19 respiratory illness before vaccines were available. I was the medical director of the maternity hospital during this time. I specifically recall the experiences of multiple patients hospitalized for a prolonged period of time due to complications of COVID-19, prolonged ICU admissions, even mortality. Some of these situations occurred even after the vaccine was available, and the patients had declined the vaccine because they had heard misinformation about it. These experiences deeply inform my commitment to COVID-19 vaccination as a critical tool to protect my patients and their babies health.

13. Following the rollout of the COVID-19 vaccine in my community, I saw a clear reduction in severe COVID-19 cases among my pregnant patients. Those who were vaccinated and later contracted the virus generally experienced only mild, cold-like symptoms and did not need hospitalization. These observations are consistent with findings in the peer-reviewed scientific literature and reinforce the medical consensus that ongoing COVID-19 vaccination during pregnancy remains a critical component of standard care.

14. I am deeply concerned about the broader consequences of the May 19 Secretarial Directive withdrawing the COVID-19 vaccine recommendation for pregnant patients. One serious implication is that unvaccinated pregnant women cannot pass protective antibodies to their fetuses, leaving newborns and infants under six months particularly vulnerable to COVID-19 infection. In addition, several of my patients have now begun to question other standard pregnancy vaccinations—such as Tdap and influenza—as a result of HHS's recent misinformation surrounding vaccine ingredients and recommendations for pregnant women. The result of HHS's directives removing vaccine recommendations for pregnant women is an erosion of my patients trust in vaccination recommendations across the board, not just for COVID-19. This puts both pregnant patients and their newborns at risk and threatens public health efforts long championed by SMFM.

17. I understand that SMFM is a party to the litigation challenging HHS's directive withdrawing recommendation for COVID-19 vaccination for pregnant women, and I submit this declaration in support of their complaint and motion for preliminary injunction. These organizations represent clinicians like me who are being forced to choose between following well-supported professional guidelines or inconsistent and harmful federal directives. This harms my

professional autonomy, burdens my clinical judgment, and undermines my ability to protect the health of my patients.

19. For all these reasons, I ask the Court to prevent the serious, irreparable harm that HHS's directive withdrawing the recommendation for COVID-19 vaccination for my pregnant patients is immediately and presently inflicting on me as a physician and the patients that I presently treat.

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

Executed this 4th day of July 2025, in Indianapolis, Indiana.

Dr. Caroline Rouse, M.D.

EXHIBIT A

SECRETARIAL DIRECTIVE ON PEDIATRIC COVID-19 VACCINES FOR CHILDREN LESS THAN 18 YEARS OF AGE AND PREGNANT WOMEN

May 19, 2025

The Department of Health and Human Services (HHS) continually considers and evaluates available science and evidence related to the safety and effectiveness of all currently available Food and Drug Administration (FDA) approved or authorized vaccines, and any risks of severe disease, hospitalization, and death to certain populations.

By Secretarial Directive on June 18, 2022, HHS ratified the Centers of Disease Control and Prevention (CDC) recommendations concerning use of Pfizer- BioNTech and the Moderna COVID-19 vaccines in the U.S. population for children ages six months through five years, consistent with the parameters of the Emergency Use Authorizations (EUAs) issued by FDA, for the Pfizer- BioNTech and the Moderna COVID-19 vaccines.[1]

By Secretarial Directive on June 24, 2022, HHS ratified the Centers of Disease Control and Prevention (CDC) recommendations concerning use of COVID-19 vaccines in the U.S. population for children ages six through 17 years, consistent with the parameters of EUAs issued by FDA.

The CDC also currently recommends the COVID-19 vaccine during pregnancy.[2]

Based on a review of the recommendation of the FDA and National Institutes of Health (NIH), I have determined that the known risks associated with use of COVID-19 vaccines in healthy U.S. children ages six months to 17 years do not outweigh the purported benefits of the vaccine. Accordingly, the HHS Secretarial Directives ratifying CDC recommendations for use of COVID-19 vaccines for children ages six months to 17 years and are rescinded.

Based on a review of the recommendation of the FDA, I have similarly determined that the lack of high-quality data demonstrating safety of the mRNA vaccines during pregnancy combined with the uncertainty of the benefits of vaccination pose potential risks to the mother and developing baby. Therefore, the CDC recommendation that pregnant women receive the COVID-19 vaccine is rescinded.

Accordingly, the CDC is directed to remove COVID-19 vaccines from the recommended Child and Adolescent Immunization Schedule by Age and recommended vaccines during pregnancy, as noted above.

Robert F. Kennedy, Jr.
Secretary

[1] The Pfizer and Moderna vaccines are currently approved by the FDA for children 12 years of age and older.
[2] https://www.cdc.gov/vaccines-pregnancy/recommended-vaccines/index.html.

EXHIBIT 36

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 DR. PATRICK S. RAMSEY, M.D., MSPH

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

1. I submit this declaration in support of Plaintiffs' requests for relief in this litigation because my patients' lives are at stake. As a practicing board-certified physician in the field of obstetrics, gynecology, and maternal-fetal medicine, I treat high-risk pregnant patients every day and am greatly concerned about the immediate and irreparable harm caused by the actions of the U.S. Department of Health and Human Services, Secretary Kennedy, the Centers for Disease Control ("CDC"), and other branches of the federal government's public health apparatus.

2. I am aboard-certified in obstetrics and gynecology and maternal-fetal medicine. I received my Doctor of Medicine degree from the University of Wisconsin in 1994, I completed a residency in obstetrics and gynecology at the Mayo Graduate School of Medicine in 1998, and completed a fellowship in maternal and fetal medicine at the University of Alabama – Birmingham in 2001. I also received a Master of Science in Public Health from the University of Alabama –

Birmingham in 2003. I am over the age of 18 years old, and I make this declaration based on my own personal knowledge and experience, and if called to testify, I could and would do so truthfully.

3. I have extensive experience and expertise in the management of infectious diseases affecting women and fetuses during pregnancy. In addition to my clinical and academic work, I have held multiple leadership roles focused on advancing the prevention of infectious diseases in women, contributing to national and regional efforts aimed at improving maternal and fetal health outcomes through policy, education, and collaborative initiatives.

4. I am a member of the Society for Maternal-Fetal Medicine ("SMFM"), which is a professional organization committed to advancing evidence-based public health and medical fare.

5. I have been providing obstetric care for over 24 years and routinely counsel pregnant patients on immunizations recommended during pregnancy, including the Covid-19 vaccine, influenza vaccine, Tdap (tetanus, diphtheria, and whooping cough) vaccine, and more recently, the RSV (respiratory syncytial virus) vaccine.

6. Since it became available in 2001, the Covid-19 vaccine has been the standard of care in my field, as set forth in clinical guidelines issued by SMFM and other professional organizations, to recommend Covid-19 vaccination to all pregnant patients. I have followed those clinical guidelines consistently and have recommended Covid-19 vaccination to my patients in all trimesters of pregnancy, particularly because pregnancy itself is a known well-established risk factor for increased morbidity and adverse outcomes from respiratory infectious like Covid-19 and influenza.

7. I am familiar with the recent ACIP recommendation that the Covid-19 vaccine be downgraded from routinely administered to one obtained through shared clinical decision making ("SCDM") for individuals under 65 years old and pregnant persons. This approach directly

contradicts the standard of care and clinical guidance that I and other SMFM members rely on to deliver safe and effective care to our high-risk pregnant patients. This change undermines the patient-provider relationship, just as prior actions by the Secretary did in the Spring of 2025. This change also exposes me and other obstetric clinicians to unnecessary health and legal risks given the sound scientific evidence regarding Covid-19 vaccination and safety during pregnancy.

8. Based on my training and experience, there is no universal definition or common understanding for what constitutes "SCDM." Instead, "SCDM" can mean something different to different physicians based on their own understanding of the term. I similarly am not aware of any definitive guidance on or authoritative definition of SCDM issued by any of the organizations of which I am a member.

9. For my personal practice, I approach SCDM encounters first by raising the topic of vaccination with my patients. Once doing so, I then listen to my patient's concerns and do my best to respond to each concern individually and with the relevant and appropriate evidence-backed answers and reasoning necessary. I do my best to address misconceptions about the Covid vaccine to help patients make a decision based on evidence-backed science and medicine.

10. SCDM discussions are not separately scheduled and must instead be incorporated into an existing patient session or exam. On average, these conversations last about 10 minutes of an appointment that usually lasts 30 minutes. This means the SCDM portion of a patient encounter takes up roughly one-third of the time I spend with a patient. Prior to the adoption of the SCDM framework, that time would have been dedicated to other important and critical issues of maternal-fetal health, such as general advice for pregnancy or care coordination. This time spent on SCDM also leaves less time for me to properly document or complete patient files. As a result, I now spend more time after hours updating patient files and catching up on work that I was not able to

complete during the workday because of increasing episodes of lengthy SCDM discussions. All of this has resulted from the CDC's adoption of ACIP's SCDM recommendation for the Covid vaccine.

11. These SCDM sessions are becoming more frequent due to the level of misinformation and the belief that the change in recommendation status is a false reflection of the Covid vaccine not being safe or effective. Conversations with patients have become increasingly difficult to navigate, and patients are refusing vaccination at higher levels since the SCDM framework was instituted. On any given day, I receive at least 15–16 patient inquiries about the Covid vaccine. This adds up over the course of a day, a week, and a month.

12. These SCDM discussions are not separately billable and thus are not eligible for reimbursement from a payer if a patient declines vaccination. As a result, the time I reference above—time spent conducting SCDM to combat misinformation and disinformation, and time spent catching up on displaced work after hours—is all uncompensated. This results in deprived earnings and more and more uncompensated work.

13. In addition to patient inquiries, I have also received several questions from providers in the community who are seeking guidance on the current SCDM framework. Members of our practice have expressed confusion and uncertainty, causing us to develop our own practice-level recommendations and to seek the backing and support of our hospital and university.

14. Since the CDC's adoption of the SCDM framework, I have also noticed that patients are experiencing difficulties in accessing or finding the Covid vaccine. Because of the CDC's decision, our practice no longer carries the vaccine because it is no longer routinely recommended. This means my colleagues and I must now write prescriptions or issue recommendations to local pharmacies so that our patients can be vaccinated.

15. Despite the prevalence of misinformation and disinformation, I know that Covid still poses a threat to individuals who do not get vaccinated, and I know that these unvaccinated individuals run the serious risk of suffering severe adverse outcomes. I also know that there is strong evidence that vaccines mitigate the risk of complications during pregnancy, including the Covid vaccine. Nevertheless, patients are declining to be vaccinated at higher levels than ever before. I fear that these increasing numbers of unvaccinated patients will cause complications in their pregnancies and that patients will seek to hold me responsible for not more strenuously or forcefully recommending the Covid vaccine, thus exposing me to legal and professional liability.

16. Despite efforts to conflate the two, "SCDM" and "informed consent" are two distinct concepts. In my view, SCDM is a dialogue between patient and physician, whereas informed consent is a physician-led discussion where the physician tells the patient all of the information they might need to know to make an informed and competent decision as to risky medical interventions or surgery. The Covid vaccine, in my view, is not the kind of medical intervention that warrants or requires detailed informed consent since it is not a high-risk medical intervention.

17. The change to SCDM has resulted in the outcomes described above and is already causing more patients to contract Covid-19. This is even causing members of our practice to get sick, which results in them being pulled form duty and unable to work. This in turn puts greater strain on me and my colleagues who now must do more work to account for the reduced workforce. Based on my observations and experiences, I believe restoring the status quo before the SCDM framework would address and undo the negative outcomes I have described above.

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

Executed on November 30, 2025 in San Antonio, Texas.

/s/ Dr. Patrick S. Ramsey

Dr. Patrick S. Ramsey, M.D., MSPH

EXHIBIT 37

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.

DECLARATION OF ASON 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. Based on my over 25-year career as a primary care physician and internal medicine specialist, the Secretary of Health and Human Services Robert F. Kennedy, Jr. **r dd** unscientific actions concerning vaccines are causing preventable suffering and death to Americans.

2. 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 Fellow of the American College of Physicians.

3. 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.

4. I am the current President of the American College of Physicians (ACP), representing internal medicine physicians, related subspecialists, and medical students.

5. I previously r d through 2020. I r D , and I currently serve r Immunization Committee, as well as server as the President of ACP.

6. 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.

7. 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 approximately 161,000 members across the country, 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.

8. r fostering excellence and professionalism in the practice of medicine. ACP embraces health equity and is committed to stopping and preventing the spread of medical misinformation and disinformation.

9. ACP has adopted clinical practice guidelines that are considered the standard of care for our physician members and are in place to optimize and protect the care provided to our r d d ew of peer-reviewed research and evidence, the professional judgment of our members, and an assessment of the benefits and harms of alternative care options. Clinical practice guidelines follow a sound,

transparent methodology to translate best evidence into clinical practice for improved patient outcomes. They are a key component of patient-centered care.

10. Specific to COVID-19, ACP has recommended the COVID-19 vaccine for pregnant women and children consistently since the initial distribution of the vaccines in late 2020. This was also consistent with ACIP guidelines which were approved by the Center for Disease Control . ACP's Immunization Committee has consistently voted to support ACIP recommendations related to COVID-19 administration. In addition, ACP has published numerous policy statements supporting COVID-19 vaccination.

11. Physician members of my association have been recommending the COVID-19 to pregnant patients and administering the COVID-19 vaccine to pregnant women since the vaccines were approved for this population consistent with the CDC recommendations for the COVID-19 vaccine. This level of treatment has become the standard of care for our physician members and has been adopted by our association as guidelines on COVID-19 vaccines for pregnant women.

12. In fact, I am actively involved with the CDC r to ACIP, and I served on several vaccine work groups including the Pneumococcal Vaccines Work Group and the COVID-19 Vaccines Work Group.

13. In mid-2020, after there was an announcement that a COVID-19 vaccine was being developed, ACIP convened the COVID-19 Vaccines Work Group. I joined this Work Group as a liaison for ACP.

14. I eagerly accepted the role as ACPr liaison to the ACIP COVID-19 Vaccines Work Group to use my expertise to help stop the spread of the COVID-19 pandemic in the United States and beyond, as I believe vaccines are the best defense we have to prevent some respiratory diseases like COVID-19.

15. The COVID-19 Vaccines Work Group previously consisted of five ACIP voting members and various experts in the field, including, but not limited to, medical doctors, epidemiologists, a professor of microbiology and immunology, a medical officer for a state Department of Public Health, vaccine researchers, leaders of vaccine trials, and an infectious disease researcher. *See* Ex. A, *ACIP CO ID-1 accines Work Group*, CDC ACIP Meeting, at 11 (April 15, 2025) https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/01-Schechter-COVID-508.pdf (presented by Robert Schechter, MD, MSc). At inception, we met weekly while the COVID-19 vaccines were developed.

16. The COVID-19 Vaccines Work Group would have weekly, robust discussions regarding detailed scientific data about the developing COVID-19 vaccines. These discussions included the creation of the vaccines, how the vaccines were manufactured, and how clinical trials were conducted. We also discussed the triage plan, the distribution plan, and how this critical resource should be allocated. The COVID-19 Vaccines Work Group thoroughly reviewed published works from all over the world, including independent research from various institutions and data from other countries.

17. Each week, the COVID-19 Vaccines Work Group would have an agenda. We would build upon and adapt our discussions as more data were gathered. As it got closer to each ACIP meeting, each work group, including the COVID-19 Work Group, would use the Evidence-to-Recommendation (EtR) framework to craft our recommendations to the ACIP. The EtR looks at benefits and harms, feasibility, acceptability, health equity, and other similar domains. Each expert in the work group would be polled on each of the domains to reach a recommendation.

18. Once the COVID-19 Vaccines Work Group came to a consensus on a proposed recommendation to the ACIP, we would put together a presentation that detailed the benefits and

harms, feasibility, acceptability, comparators, and other domains to analyze each anticipated question from ACIP.

19. Next, the COVID-19 Vaccines Work Group would come up with a specific set of recommendation language to present to the ACIP committee. This proposed recommendation, along with our analyses from the evidence gathered, would be presented to the full ACIP committee summarizing this discussion and data.

20. In recent years, the COVID-19 Vaccines Work Group meetings adjusted to bi-weekly meetings, but we still met regularly to review the data and draft our presentation for the ACIP meetings, including the COVID-19 vaccine data presented at the April 15-16, 2025 ACIP meeting.

21. At the April 15-16, 2025 ACIP meeting, which I attended in my capacity as a Liaison for ACP, the COVID-19 Vaccines Work Group members presented five different presentations regarding the COVID-19 vaccines and ended with the dr considerations for use of the 2025-2026 COVID-19 vaccines. *See* Ex. A; Ex. B, *Use of 0 - 0 CO ID-1 accines: Work Group Considerations*, CDC ACIP Meeting (April 15, 2025) https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/05-Panagiotakopoulos-COVID-508.pdf (presented by Lakshmi Panagiotakopoulos, MD, MPH).

22. At the April 15-16, 2025 ACIP meeting, the COVID-19 Vaccines Work Group presented policy options for 2025-2026 COVID-19 vaccines based on the evidence gathered from our meetings concerning a multi-dose initial series for people ages 6 months to 4 years and those who are immunocompromised. *See* Ex. B at 8. The COVID-19 Vaccines Work Group also presented policy options regarding annual COVID-19 vaccine doses and semi-annual COVID-19 vaccine doses. *Id*. at 9-10. These policy options were a precursor to an anticipated vote at the

June 2025 ACIP meeting, where the COVID-19 Vaccines Work Group would present more data and analyses before an anticipated vote on the 2025-2026 COVID-19 vaccines.

23. No data presented by the COVID-19 Vaccines Work Group at the April 15-16, 2025 ACIP suggested that COVID-19 vaccines should not be recommended for pregnant persons or children. In fact, it was discussed that pregnancy and recent pregnancy were risk factors for severe illness of COVID-19.

24. There was no vote scheduled at the April 15-16, 2025 ACIP meeting regarding COVID-19 vaccine recommendations, meaning that ACIP committee members did not vote on changing the COVID-19 vaccine schedule for pregnant persons or children at that meeting. Indeed, the vote on the 2025-2026 COVID-19 vaccine recommendations was slated for the June 25-26, 2025 ACIP meeting. *See* Ex. C, CDC ACIP Meeting Agenda, April 15-16, 2025; Ex. B at 3.

25. On May 19, 2025, the Secretary of Health and Human Services, Robert F. Kennedy, issued a **M** -19 Vaccines for Children **D** **M** -19 vaccines in healthy U.S. children ages six months to 17 years do not outweigh the purported *See* Ex. D. The May 19 Secretarial COVID-19 vaccines from the recommended Child and Adolescent Immunization Schedule by Age **d** *Id.*

26. I found out about the directive via a YouTube video that was posted on the X social media website featuring the Secretary on May 27, 2025. In this video, the Secretary says,

As of today, the COVID[-19] vaccine for healthy children and healthy pregnant women has

been removed from the CDC recommended immunization schedule Ex. E, Robert F. Kennedy (@SecKennedy), X (May 27, 2025, 10:16 AM), https://x.com/SecKennedy/status/1927368440811008138.

27. The May 19 Secretarial Directive was issued in contravention to the robust data compiled and presented by the COVID-19 Vaccines Work Group for years regarding the effectiveness of the COVID-19 vaccines, particularly for pregnant persons and children.

28. Since the May 19 Secretarial Directive, ACP physician members have informed me that they are faced with an untenable conflict between counseling patients on what the CDC recommends and the optimal standard of care that physician members have been following since the COVID-19 vaccines were developed, particularly in regard to pregnant patients. Indeed, physician members are either being forced to provide an inferior standard of care to patients that increases the risk of hospitalization and death, or risk litigation that may impact their medical license and ability to practice medicine.

29. Physician members have also informed me that since the May 19 Secretarial Directive, when a pregnant patient has presented and requested a COVID-19 vaccine, the physician has had to turn the patient away because administering the COVID-19 vaccine is contrary to the May 19 Secretarial Directive and Adult Immunization Schedule by Medical Condition and Other Indication, which could lead to licensure issues to the physician. This could also lead to financial burdens for both the physician and patient because the physician may no longer be reimbursed by insurers for administration of the COVID-19 vaccine, in which case the patient will have to be financially responsible.. This is completely at odds with the standard of care that our physician members need to provide to pregnant patients to protect them from a harmful or deadly disease.

This risk is compounded by the increased risk of infection that is correlated with a lower vaccination rate in the general population.

30. When vaccinated patients get COVID-19, it is less severe. Consequently, if patients are not getting vaccinated and then get COVID-19, they will have much more severe illness which requires more r to treat an otherwise preventable illness.

31. Physician members have also told me that May 19 Secretarial Directive rescinding COVID-19 recommendation for pregnant women has completely frustrated their ability to consult with pregnant women and parents, which is destroying the trust that is the cornerstone of the physician-patient relationship.

32. Physician members have also told me that as a result of May 19 Secretarial Directive rescinding COVID-19 vaccine, it is becoming impossible for pregnant women to even get the COVID-19 vaccine. If the patient is unable to get the COVID-19 vaccine during this incredible time-sensitive part of pregnancy, the patient is no longer protected from COVID-19 and the risk of hospitalization and death increases dramatically. The net impact of the May 19 Secretarial Directive is a reduction in access to necessary care, a disruption in insurance coverage, and reduced vaccination rates.

33. Moreover, the p r d effectiveness of the COVID-19 vaccine at preventing serious illness and death has been completely frustrated by the May 19 Secretarial Directive. It is already compromising the standard of care by encouraging delays or refusals of vaccination.

34. r D d evidence of the effectiveness of the COVID-19 vaccines that I helped establish as a COVID-19

Vaccines Work Group member and has caused and will continue to cause needless negative health outcomes and death for **d r d** .

35. On June 9, 2025, the Secretary terminated all 17 voting members of ACIP. Because each work group must include at least two voting members of ACIP, all work groups were automatically terminated as a result.

36. The Secretary appointed new ACIP members ahead of the June 25-26, 2025 ACIP meeting, but the COVID-19 Vaccines Work Group has not met **r** of the ACIP members on June 9, 2025.

37. Typically, for prior ACIP meetings that I attended as a Work Group Liaison for ACP, I would receive an invitation to participate at the meeting along with documents and presentations that would be discussed at the ACIP meeting. This usual format was not followed prior to the June 25-26, 2025 ACIP meeting.

38. After attempting to reach out to CDC administrators regarding my ability to participate at the June 25-26, 2025 ACIP meeting, I received an invitation the night of June 24, 2025, but the time on the invitation was incorrect based on the ACIP agenda.

39. On the morning on June 25, 2025, I joined at the oom link provided by CDC, but I was not able to access my video and microphone functions. As a result, I was unable to participate in the usual rollcall of liaison members that takes place at the beginning of each ACIP meeting.

d d

40. It took several hours for the technical difficulties to be resolved, so liaisons were unable to participate for most of the ACIP meeting on June 25, 2025. Generally, liaison members are able to speak at any point during an ACIP meeting.

41. On June 26, 2025, the I was able to access the audio function, but I only participated when called on by the Chair of the ACIP.

42. On June 26, 2025, there was a presentation at the ACIP meeting regarding thimerosal-containing influenza vaccines followed by three votes on the subject, which was a complete deviation from the normal practice that I have observed and participated in as an ACIP Liaison member.

43. Whenever there is a change in recommendation for a vaccine, it goes through a certain process that is set out in the EtR framework that is published in the Mortality and Morbidity Weekly Report published by the Centers for Disease Control and Prevention. None of these processes were followed for the decision to remove thimerosal from seasonal influenza vaccines. Indeed, a layperson presented a non-peer-reviewed presentation with questionable assertions of data that contradicted standard practice. ACIP proceeded without robust peer-reviewed evidence, and without a work group-created EtR framework used unreliable and unsubstantiated junk data regarding thimerosal-containing vaccines that has been thoroughly studied and debunked. *See* Ex. F, *Thimerosal as a accine Preservative*, CDC ACIP Meeting (June 25, 2025) https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/05-influenza-redwood-508.pdf (presented by Lyn Redwood RN, MSN, FP (Retired)).

44. Following this presentation, there was a discussion during which Dr. Meissner and several liaison members, including myself, raised valid concerns about the presentation. Several public commenters also raised concerns about the presentation and the upcoming vote. However, the ACIP voting members then rushed into a series of votes, and voted yes on removing thimerosal-containing influenza vaccines for children, pregnant women, and all adults, which was not supported by the evidence.

45. Without injunctive relief, the r arbitrary decisions that are not supported D r d r dd -containing influenza vaccines is already causing and will continue to cause needless suffering and death for mine and d r r d

46. I am over the age of 18 years old. All of the facts set forth in this declaration are d dd r D Preliminary Injunction.

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

Executed on July 3, 2025, in Coral Springs, Florida

Jason M. Goldman, MD, MACP
President, American College of Physicians

EXHIBIT A

Docusign Envelope ID: F7A6B9F6-BB4E-40F0-B6A7-A2A7FA52C77B

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

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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

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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)

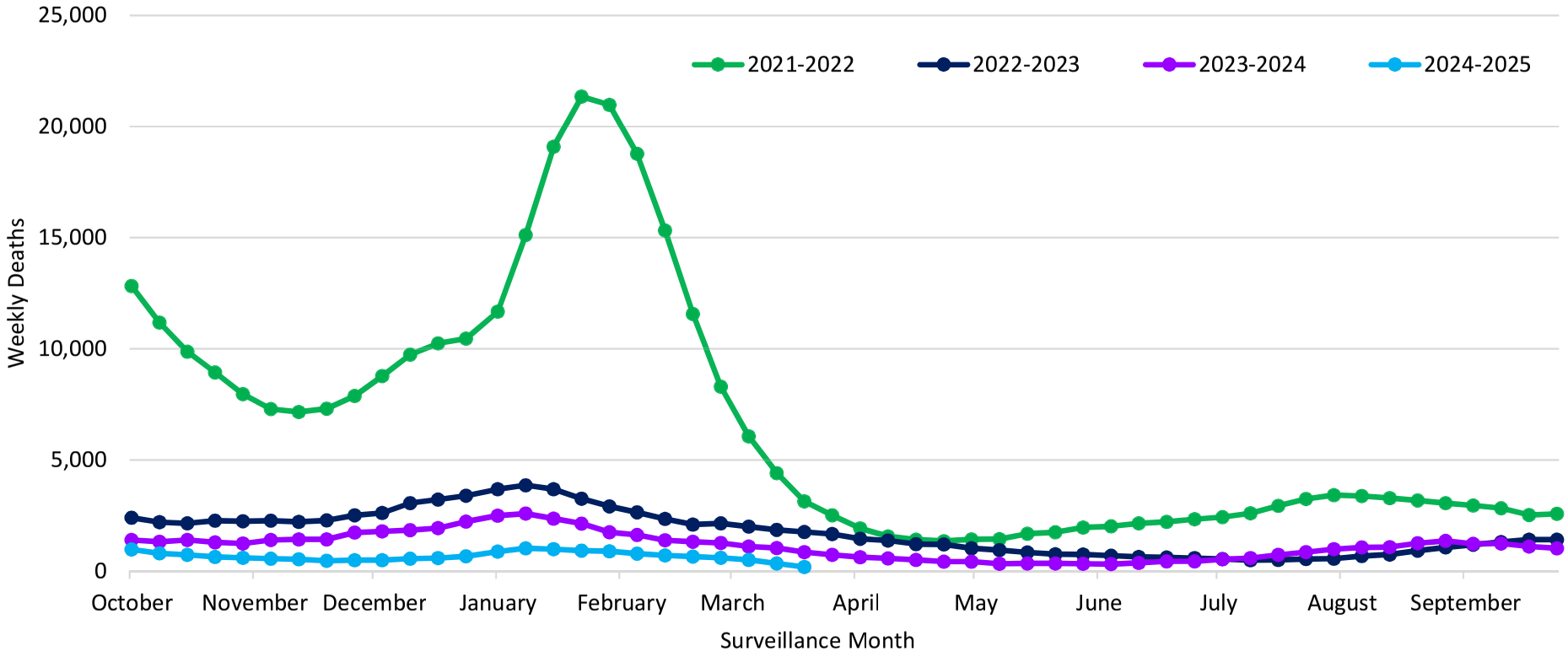
  People with moderate or severe immunocompromise may receive additional doses of 2024–2025 COVID-19 vaccines under shared clinical decision-making (minimum interval of 2 months)

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.

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

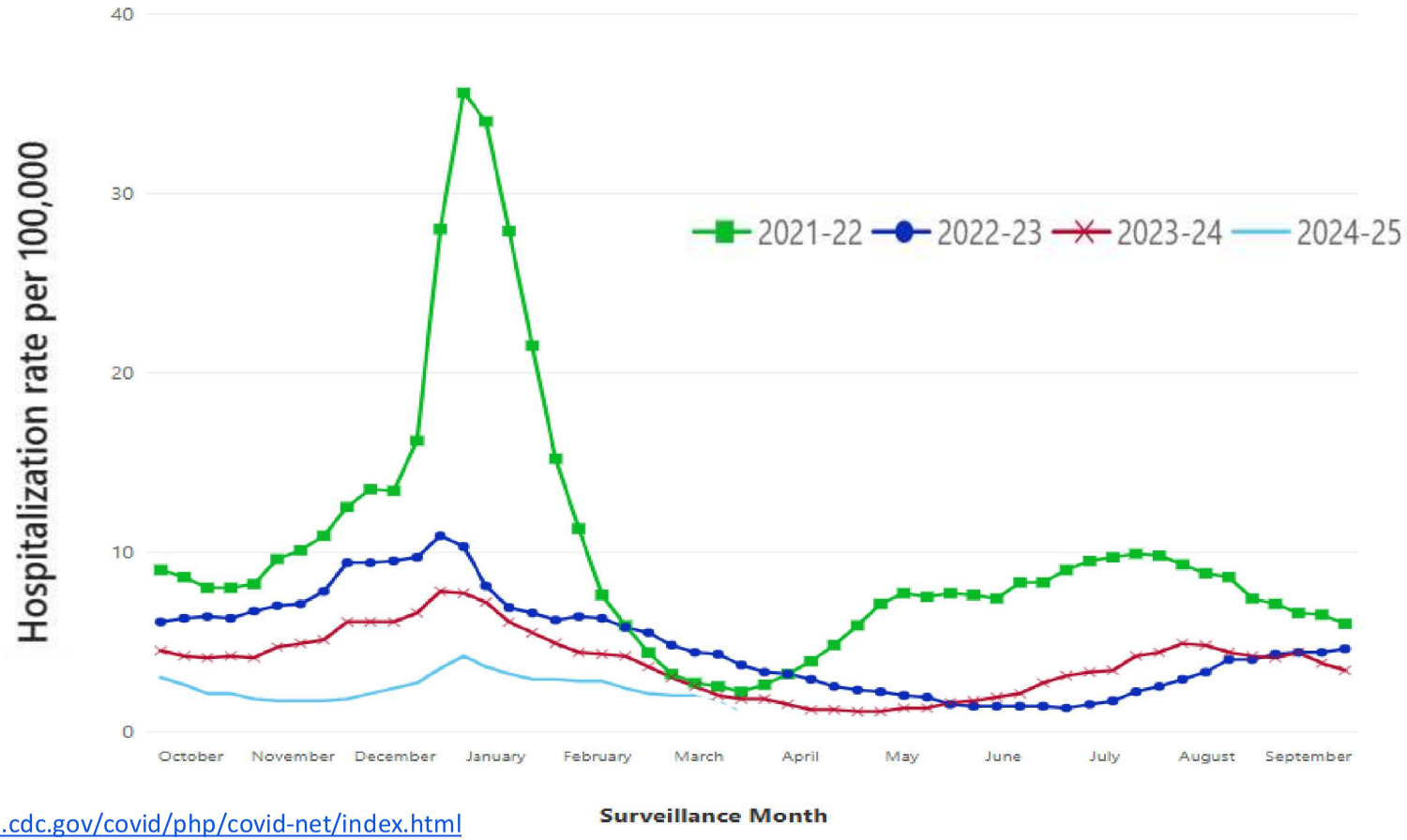


https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00
Accessed April 4, 2025

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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

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

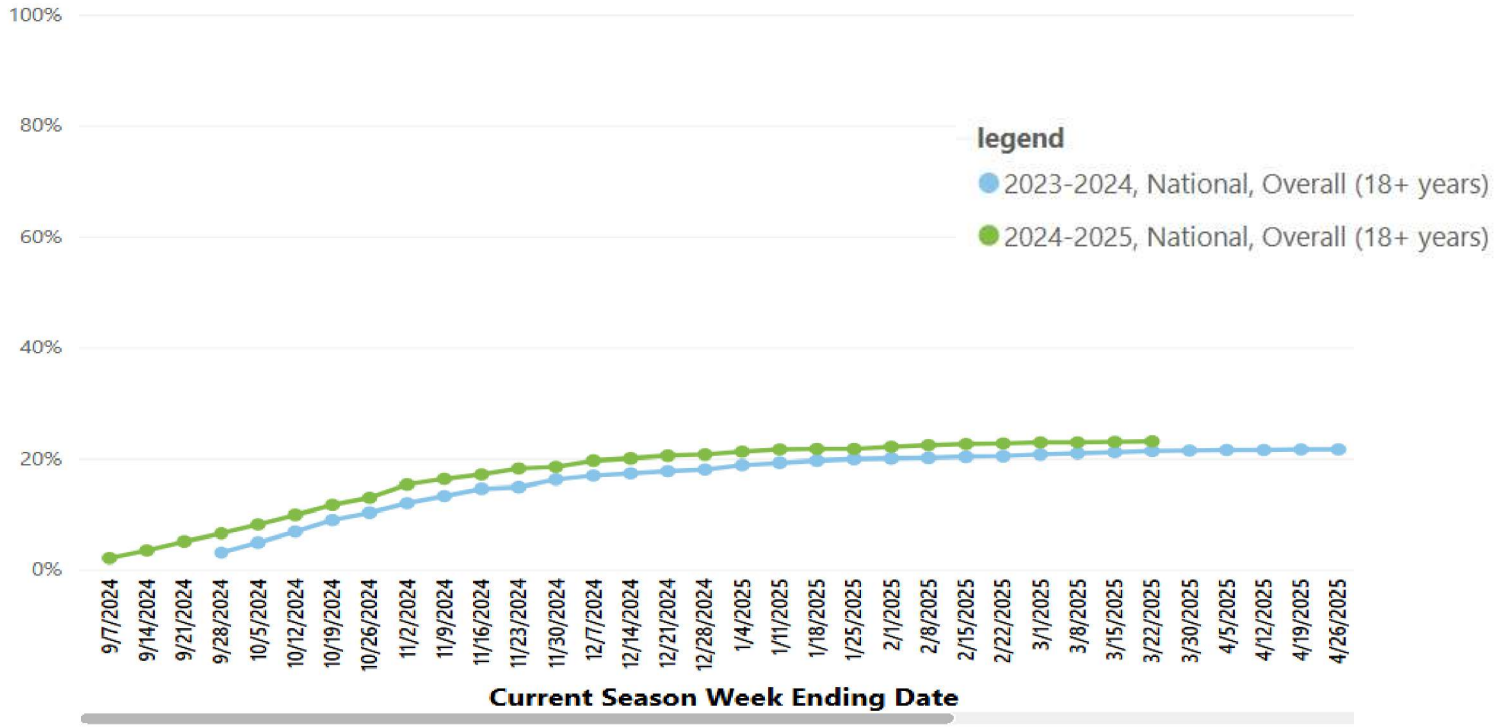
Disease	Illnesses	Outpatient Visits	Hospitalizations	Deaths
COVID-19[1]	7.7 – 13.5 Million	1.9 – 3.2 Million	220,000 – 370,000	26,000 – 43,000
Influenza[2]	44 – 76 Million	20 – 34 Million	580,000 – 1.2 Million	25,000 – 120,000

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

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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

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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

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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**

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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

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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

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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

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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.

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EXHIBIT B

Docusign Envelope ID: F7A6B9F6-BB4E-40F0-B6A7-A2A7FA52C77B

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

Lakshmi Panagiotakopoulos, MD, MPH

Advisory Committee on Immunization Practices

April 15, 2025

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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

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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)**

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Review of 2024–2025 COVID-19 vaccine policy

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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

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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

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

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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

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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.

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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

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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?

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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

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

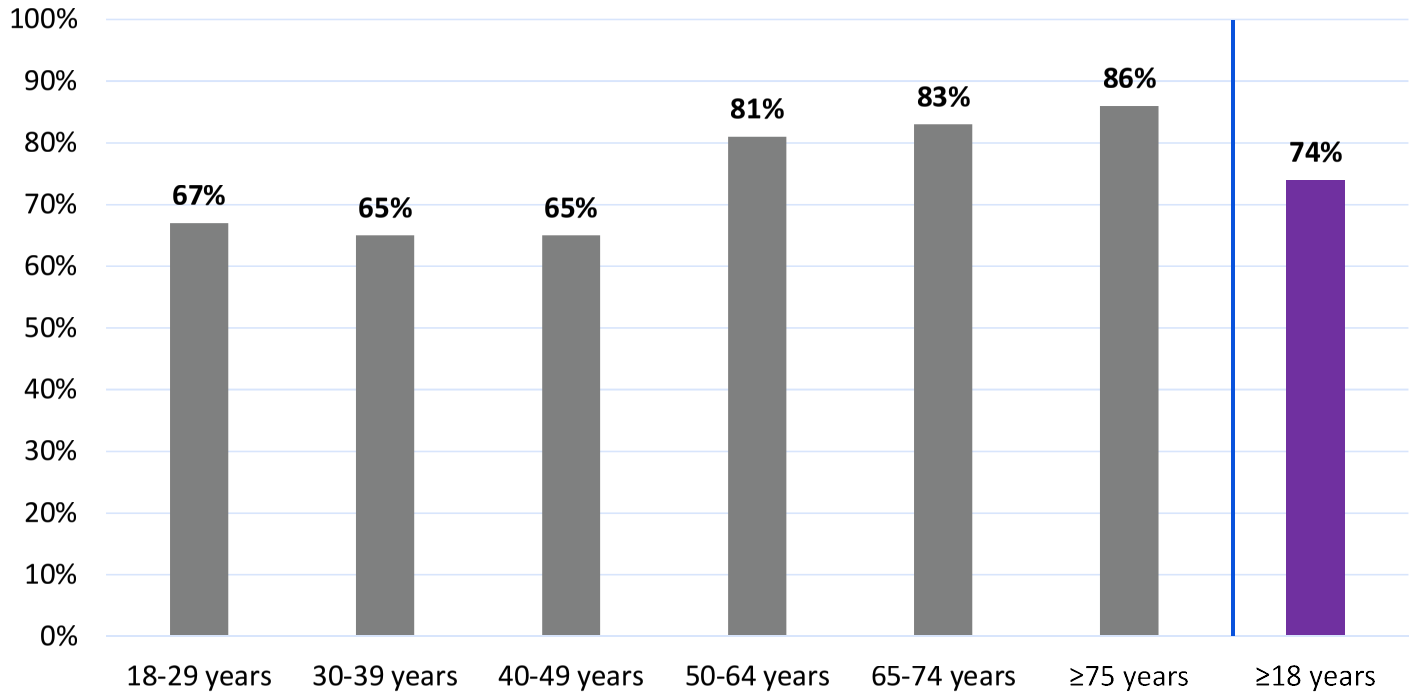
- **Asthma**
- **Cancer**
  - Hematologic Malignancies
- **Cerebrovascular disease**
- **Chronic kidney disease***
  - People receiving dialysis^
- **Chronic lung diseases** limited to:
  - Bronchiectasis
  - COPD (Chronic obstructive pulmonary disease)
  - Interstitial lung disease
  - Pulmonary embolism
  - 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

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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

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Docusign Envelope ID: F7A6B9F6-BB4E-40F0-B6A7-A2A7FA52C77B

Summary of supporting evidence

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Docusign Envelope ID: F7A6B9F6-BB4E-40F0-B6A7-A2A7FA52C77B

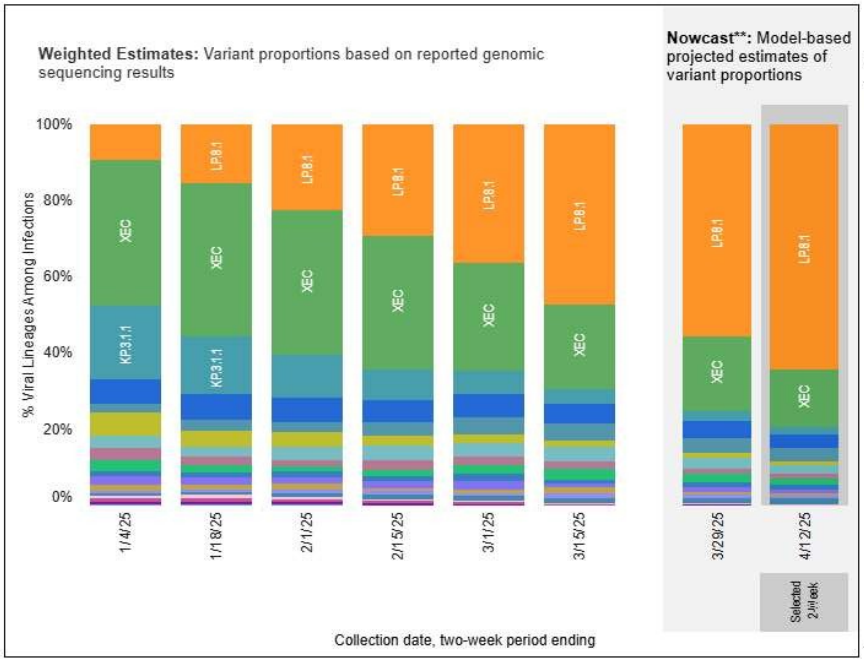
COVID-19 Epidemiology

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Docusign Envelope ID: F7A6B9F6-BB4E-40F0-B6A7-A2A7FA52C77B

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.

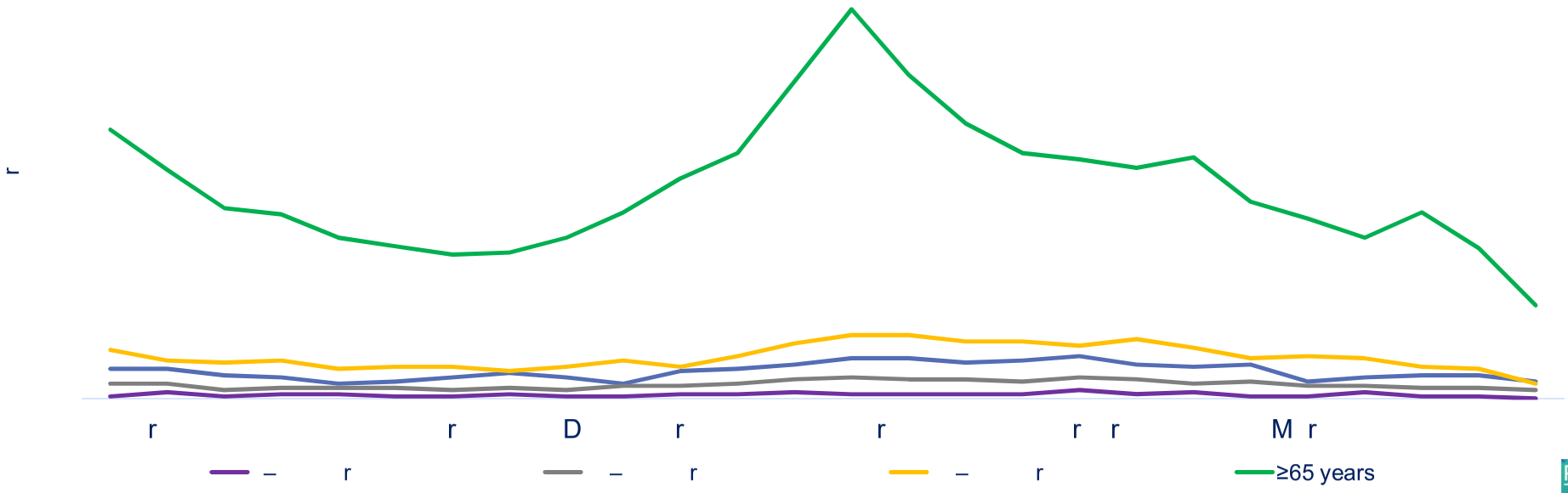
These data include Nowcast estimates, which are modeled predictions that may differ from weighted estimates generated at later dates
https://covid.cdc.gov/covid-data-tracker/#variant-proportions Accessed April 14, 2025

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Docusign Envelope ID: F7A6B9F6-BB4E-40F0-B6A7-A2A7FA52C77B

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

Crude Weekly Rates of COVID-19–Associated Hospitalizations, by Age Group — COVID-NET, 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.

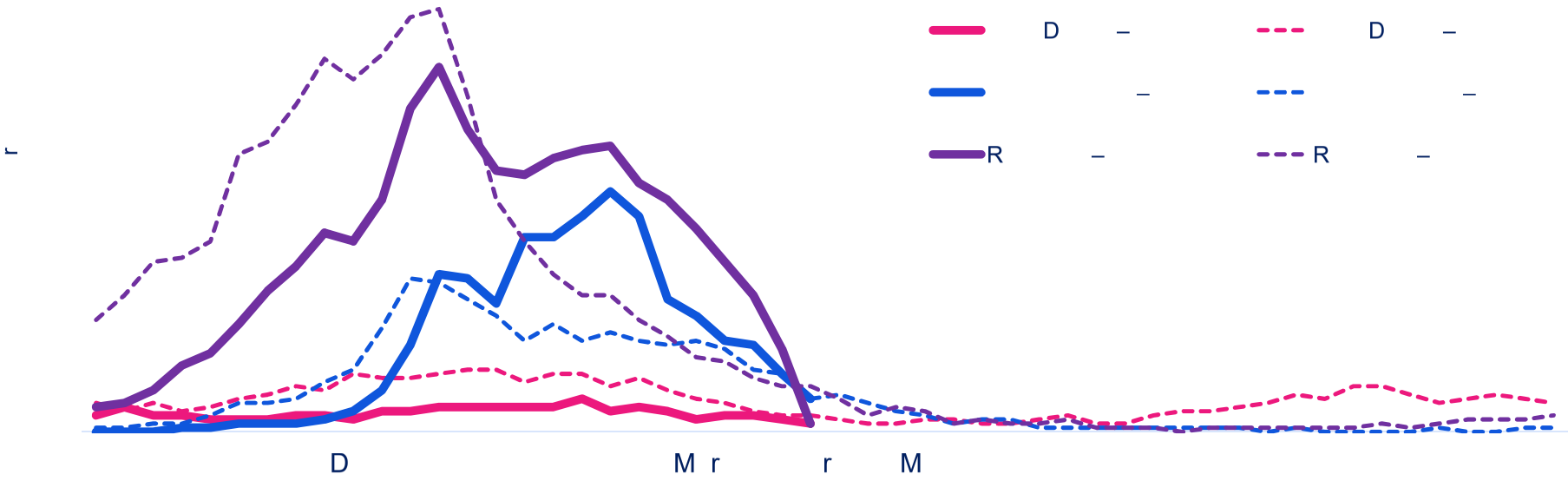
Data source: https://www.cdc.gov/resp-net/dashboard/ Accessed April 7, 2025

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Docusign Envelope ID: F7A6B9F6-BB4E-40F0-B6A7-A2A7FA52C77B

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

Crude Weekly Rates of COVID-19–, Influenza, and RSV-Associated Hospitalizations, by Surveillance Season* — RESP-NET, October 2023–March 2025



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

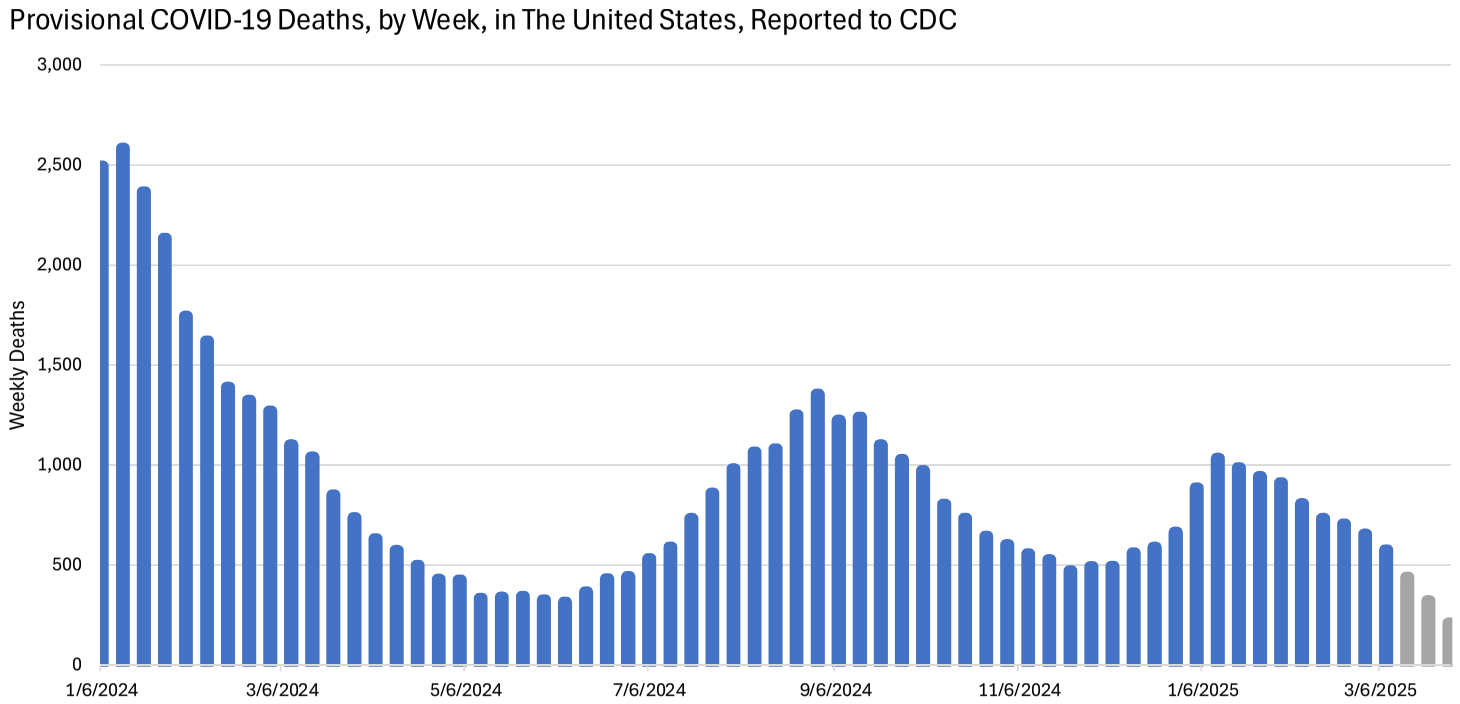
Note that rates are not adjusted for testing or limited to admissions where the respiratory infection is the likely primary reason for admission.

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

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Docusign Envelope ID: F7A6B9F6-BB4E-40F0-B6A7-A2A7FA52C77B

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

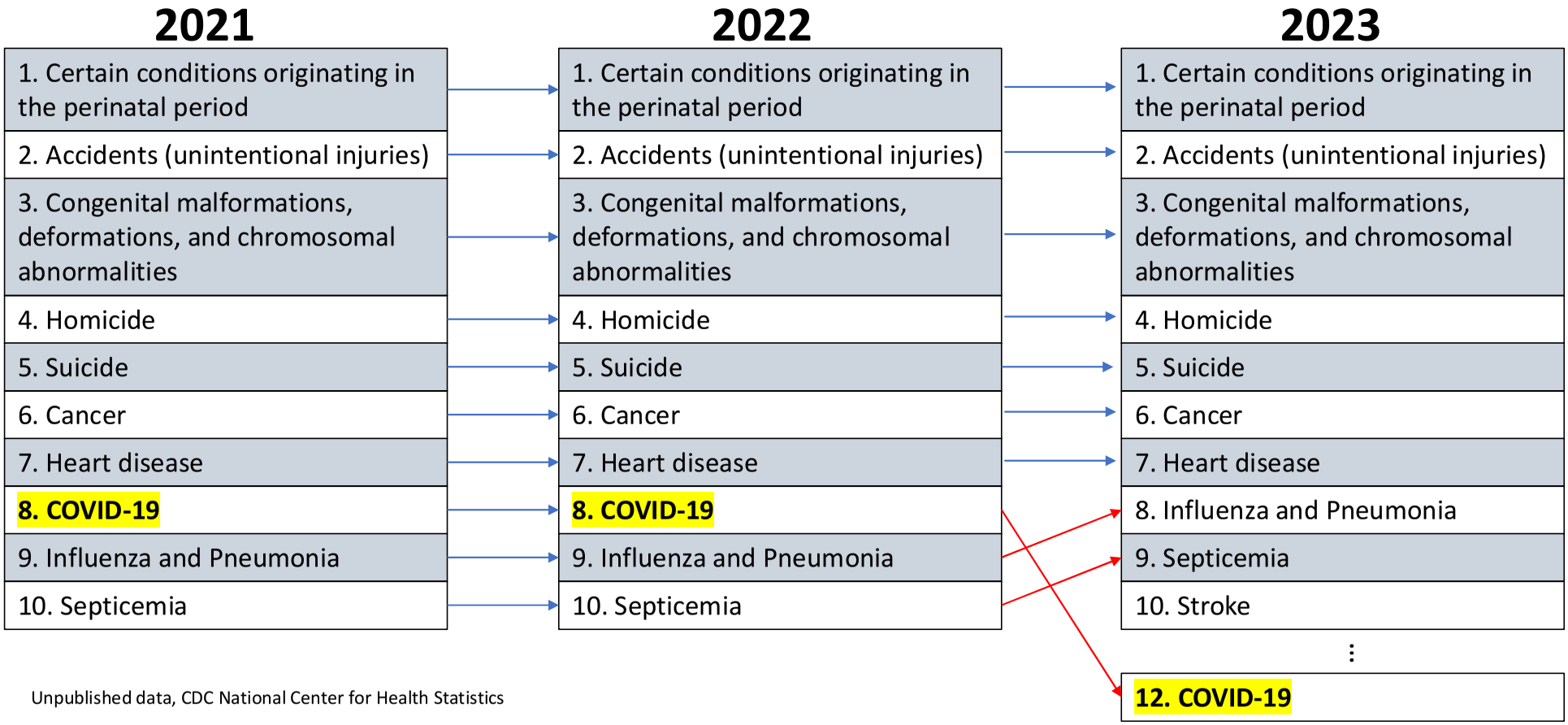


The most recent 3 weeks of mortality counts are shaded grey because NVSS reporting is <95% during this period.
Provisional data are non-final counts of deaths based on reported mortality data in NVSS. Deaths include those with COVID-19, coded as ICD–10 code U07.1, on the death certificate. Death data 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

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Docusign Envelope ID: F7A6B9F6-BB4E-40F0-B6A7-A2A7FA52C77B

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

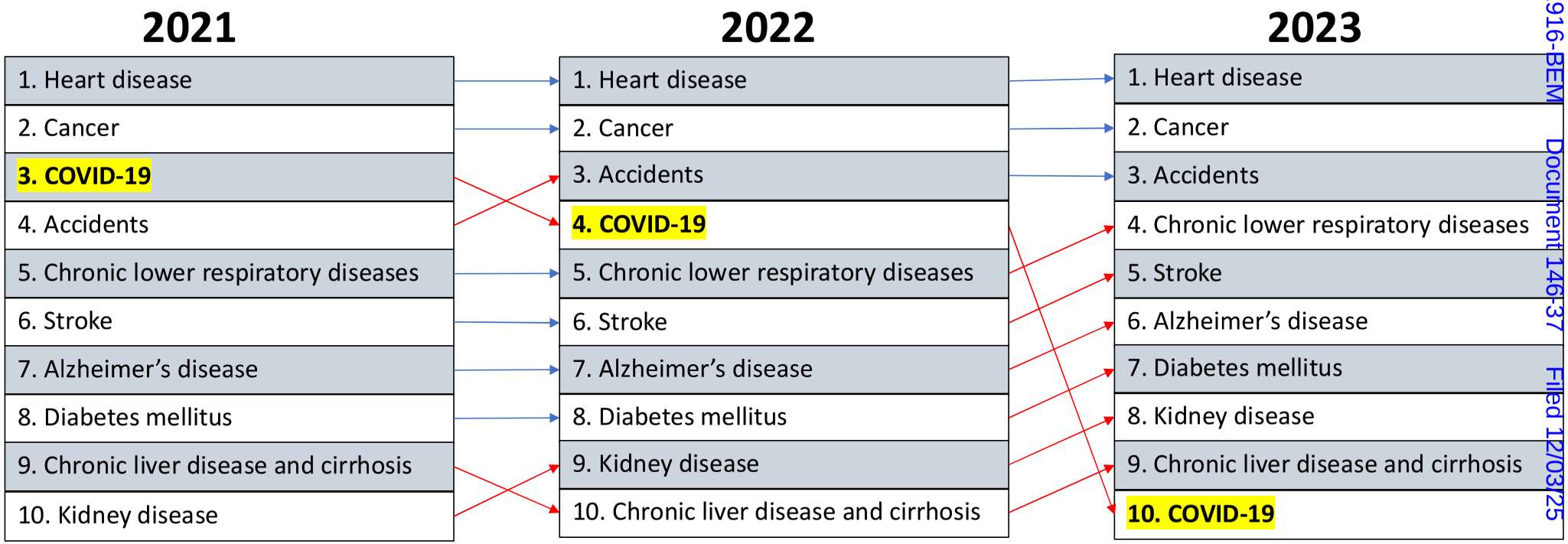


Unpublished data, CDC National Center for Health Statistics

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Docusign Envelope ID: F7A6B9F6-BB4E-40F0-B6A7-A2A7FA52C77B

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

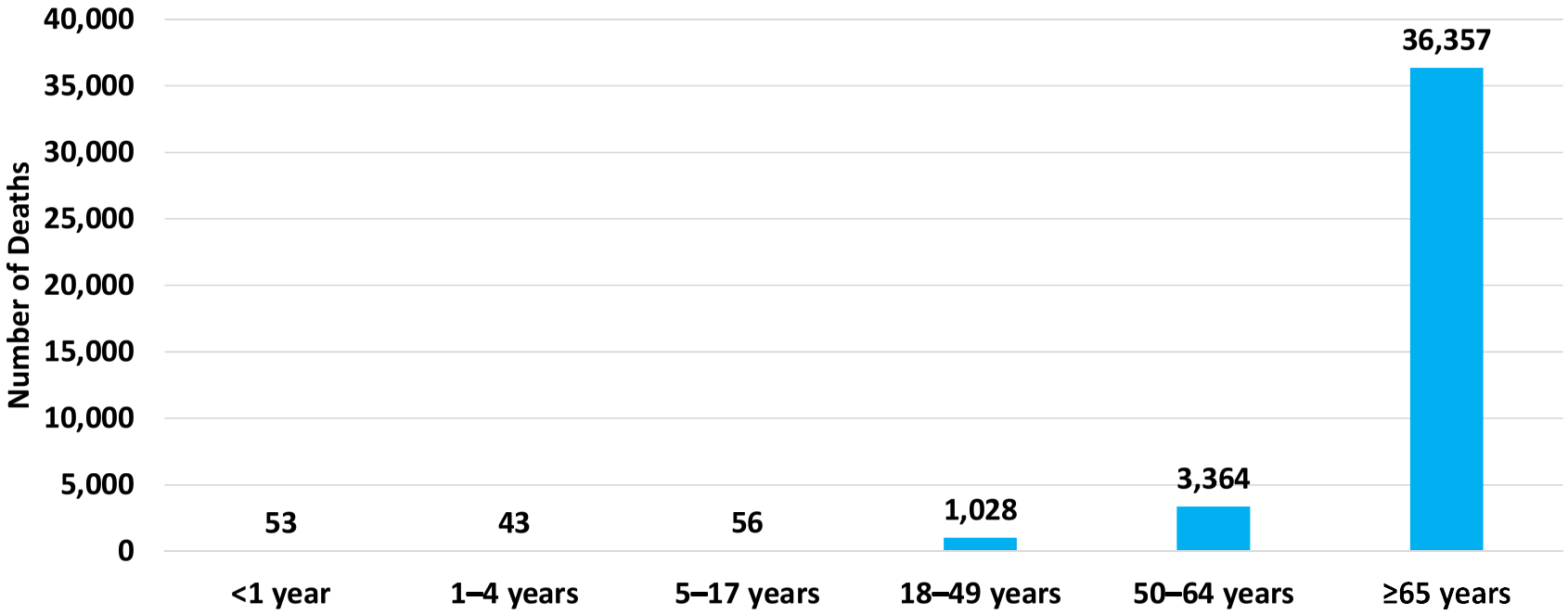


Influenza and pneumonia was ranked 9th pre-pandemic in 2019; ranked 13th in 2023
Unpublished data, CDC National Center for Health Statistics

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Docusign Envelope ID: F7A6B9F6-BB4E-40F0-B6A7-A2A7FA52C77B

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

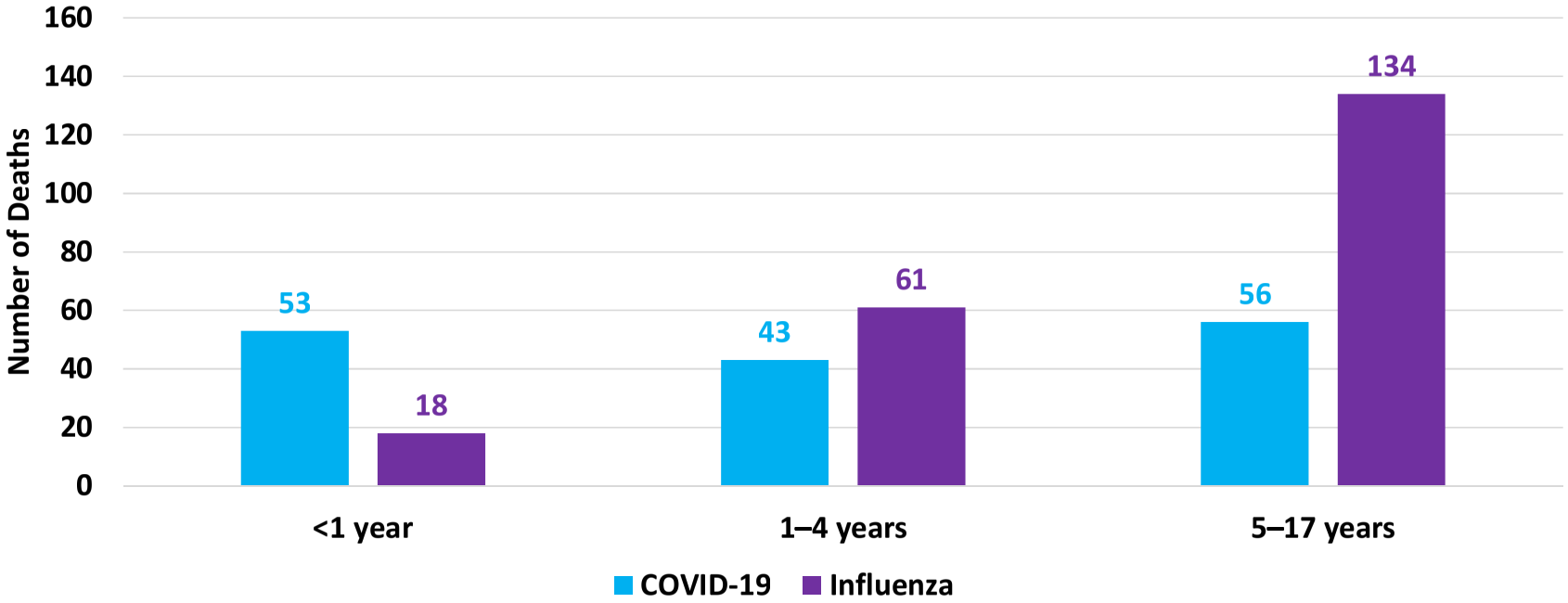


1. Provisional data
2. Underlying cause of death Source: Centers for Disease Control and Prevention, National Center for Health Statistics. National Vital Statistics System, Provisional Mortality on CDC WONDER Online Database. Data are from the final Underlying Cause of Death Files, 2018-2023, and from 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

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Docusign Envelope ID: F7A6B9F6-BB4E-40F0-B6A7-A2A7FA52C77B

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.

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Docusign Envelope ID: F7A6B9F6-BB4E-40F0-B6A7-A2A7FA52C77B

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

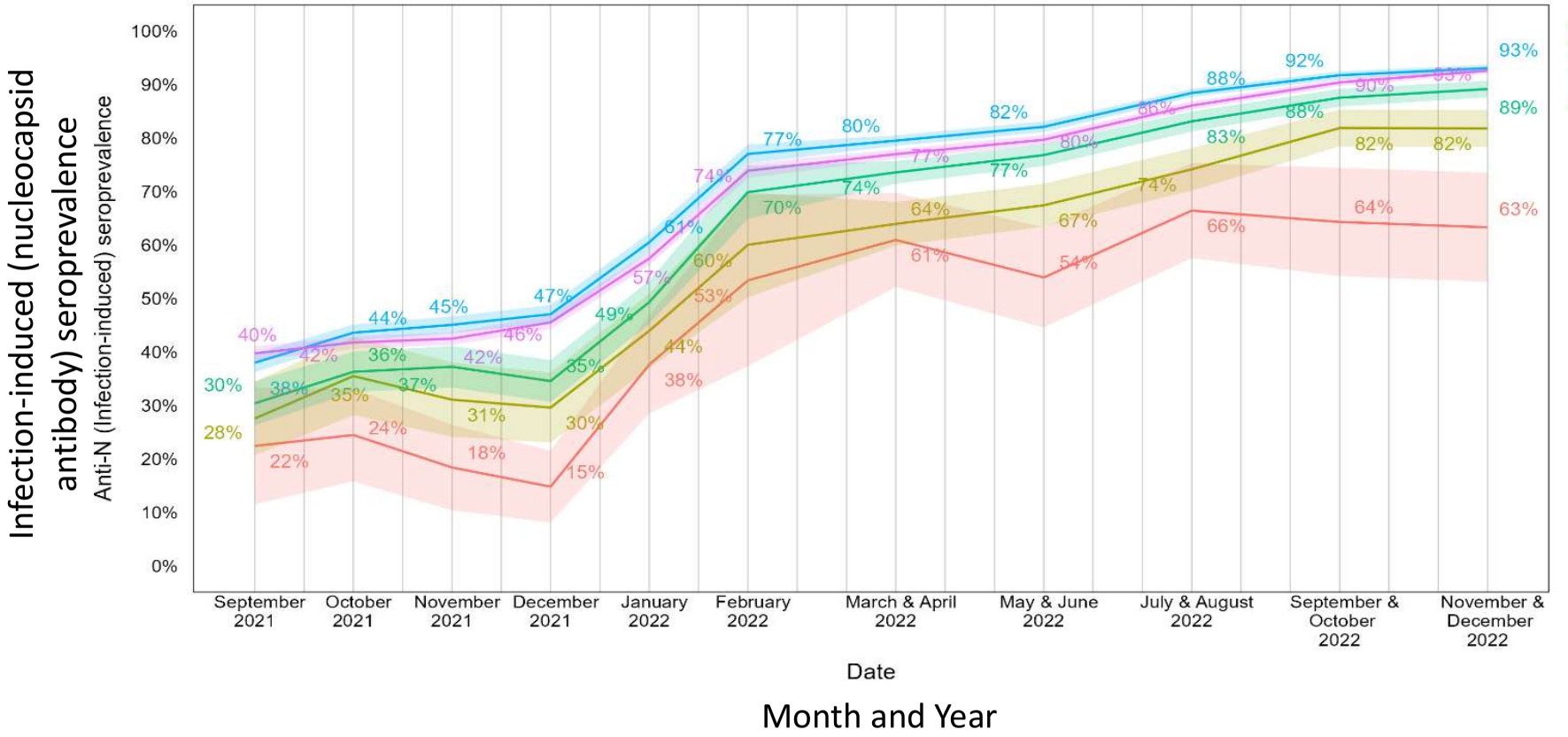
	2023–2024	2024–2025	Difference
Routine vaccine recommendation	6 months and older 65 and older: 2 doses	6 months and older 65 and older: 2 doses	No change
Vaccine coverage <18 years[1]	13.8% (13.4–14.3) (3/23/2024)	12.8% (12.2–13.4) (3/22/2025)	Similar
Vaccine coverage ≥18 years[2]	21.3% (21.0–21.5) (3/23/2024)	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

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Docusign Envelope ID: F7A6B9F6-BB4E-40F0-B6A7-A2A7FA52C77B

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

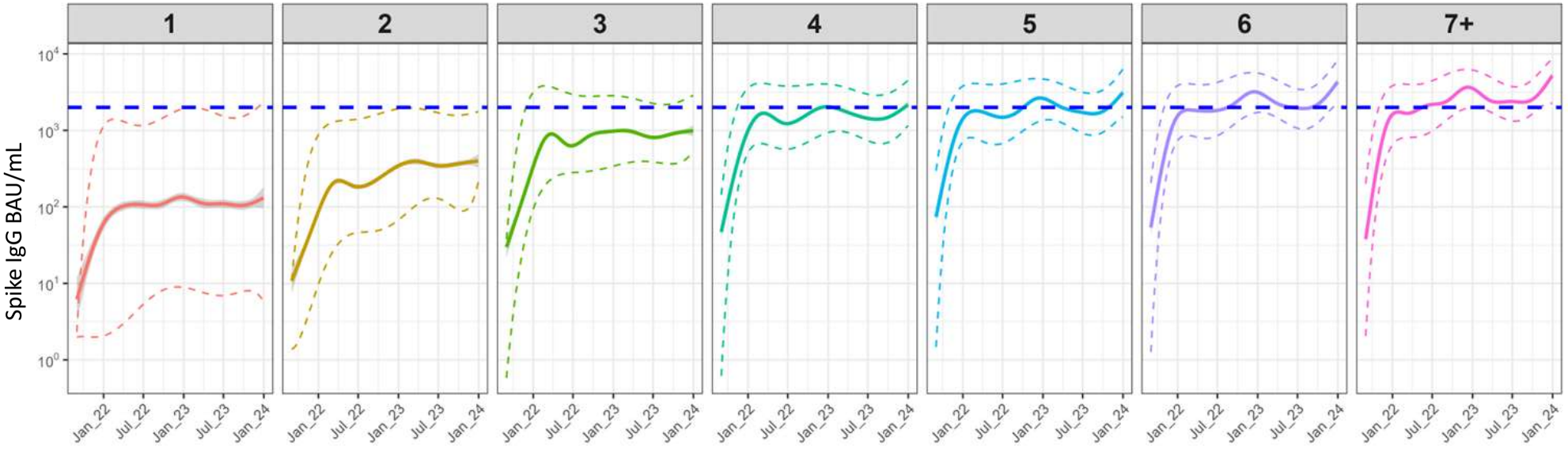


Shaded ranges depict 95% confidence intervals for the estimated seroprevalence shown by the dark line in the corresponding color.
Source: https://covid.cdc.gov/covid-data-tracker/#pediatric-seroprevalence
Accessed: March 20, 2025

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Docusign Envelope ID: F7A6B9F6-BB4E-40F0-B6A7-A2A7FA52C77B

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

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Docusign Envelope ID: F7A6B9F6-BB4E-40F0-B6A7-A2A7FA52C77B

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.

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Docusign Envelope ID: F7A6B9F6-BB4E-40F0-B6A7-A2A7FA52C77B

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

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Docusign Envelope ID: F7A6B9F6-BB4E-40F0-B6A7-A2A7FA52C77B

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

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Docusign Envelope ID: F7A6B9F6-BB4E-40F0-B6A7-A2A7FA52C77B

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

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COVID-19 Vaccine and Myocarditis

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Docusign Envelope ID: F7A6B9F6-BB4E-40F0-B6A7-A2A7FA52C77B

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.

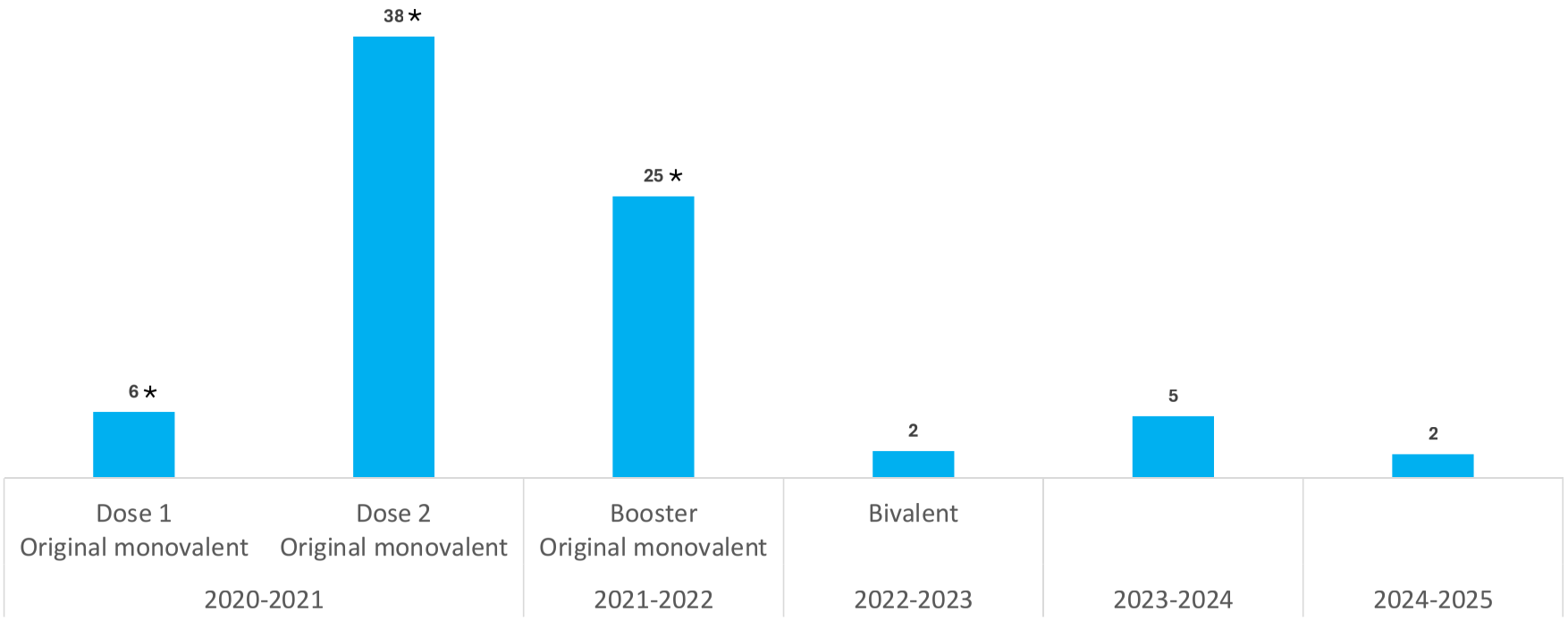
https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines-2024-2025

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Docusign Envelope ID: F7A6B9F6-BB4E-40F0-B6A7-A2A7FA52C77B

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

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Docusign Envelope ID: F7A6B9F6-BB4E-40F0-B6A7-A2A7FA52C77B

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

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Docusign Envelope ID: F7A6B9F6-BB4E-40F0-B6A7-A2A7FA52C77B

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

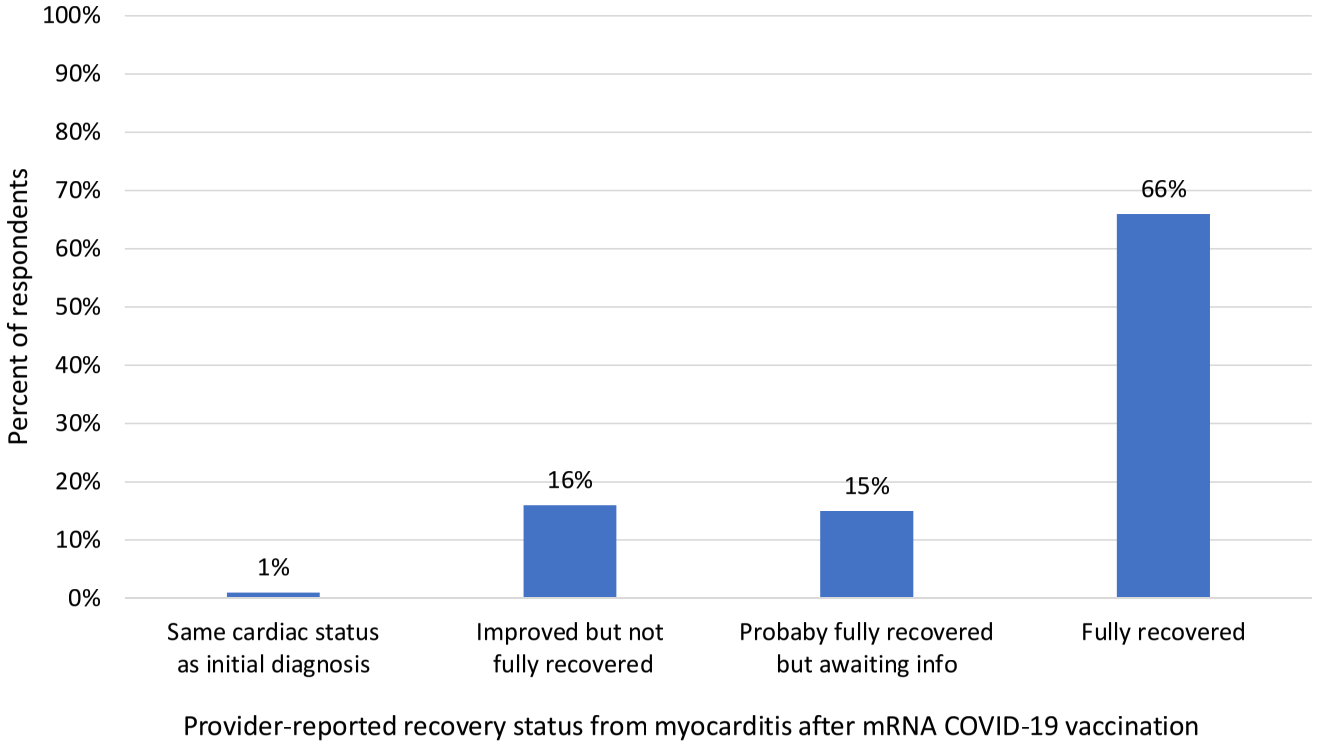
- **The reporting rates are similar to the expected background rates of <2 cases per million doses**

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

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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

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Docusign Envelope ID: F7A6B9F6-BB4E-40F0-B6A7-A2A7FA52C77B

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.

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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

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Docusign Envelope ID: F7A6B9F6-BB4E-40F0-B6A7-A2A7FA52C77B

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

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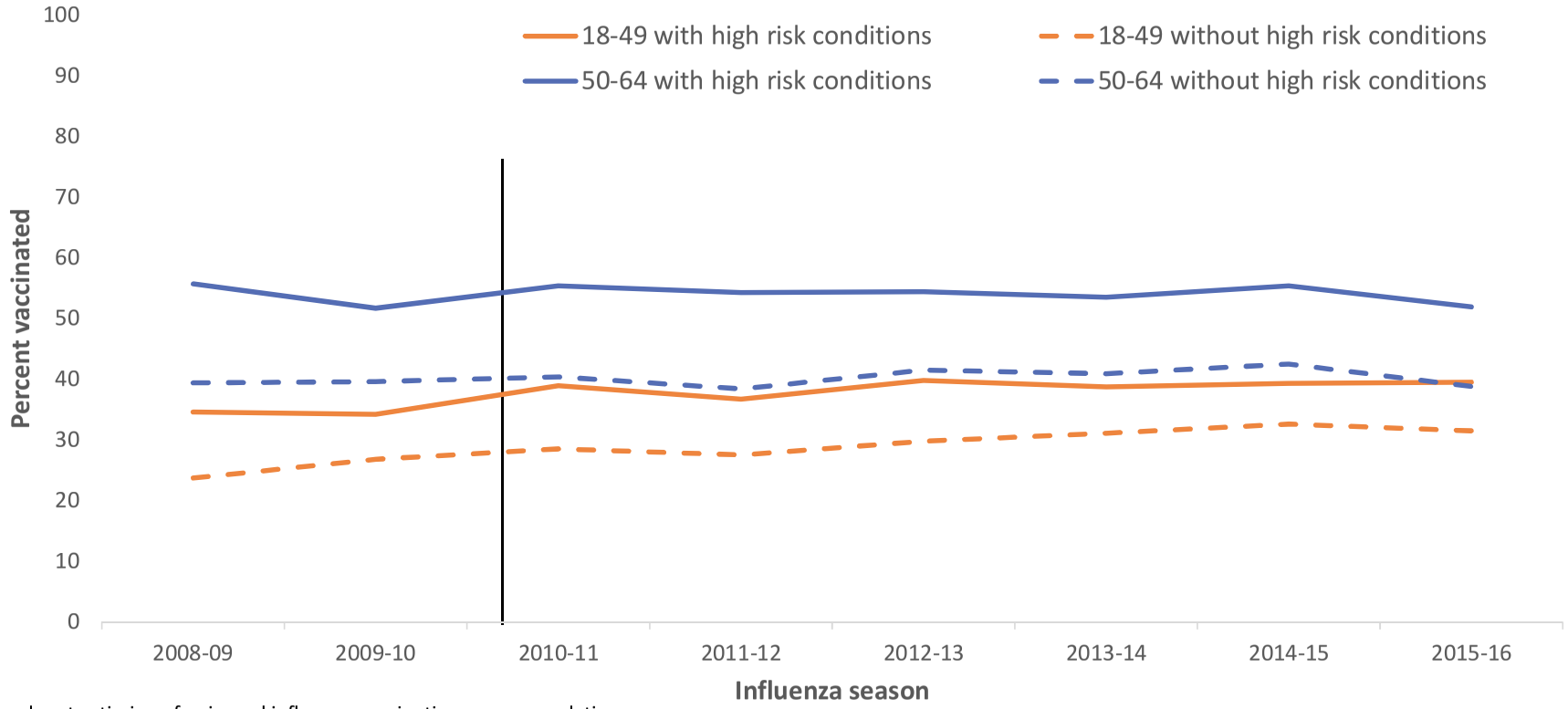
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Risk-based v. universal vaccine recommendations and vaccine coverage

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Docusign Envelope ID: F7A6B9F6-BB4E-40F0-B6A7-A2A7FA52C77B

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

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Docusign Envelope ID: F7A6B9F6-BB4E-40F0-B6A7-A2A7FA52C77B

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

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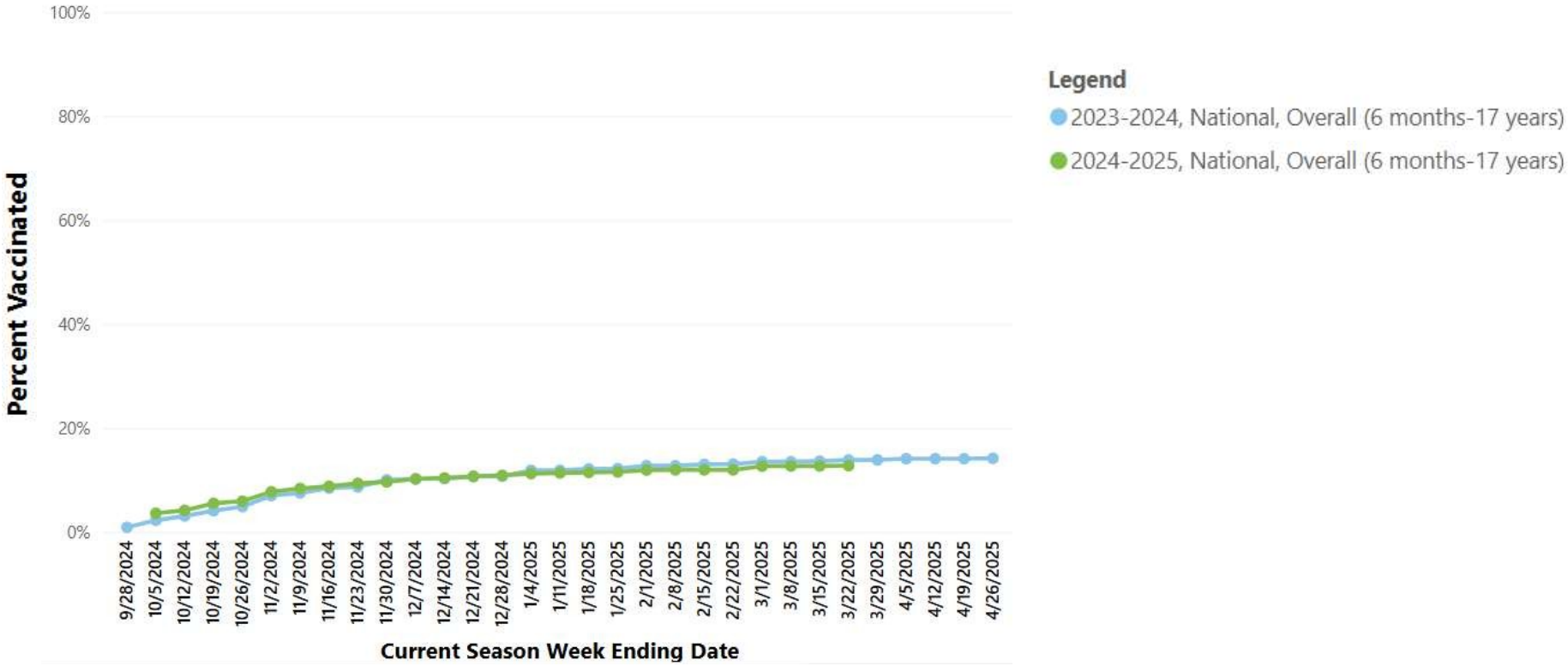
Parental vaccine confidence

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Docusign Envelope ID: F7A6B9F6-BB4E-40F0-B6A7-A2A7FA52C77B

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

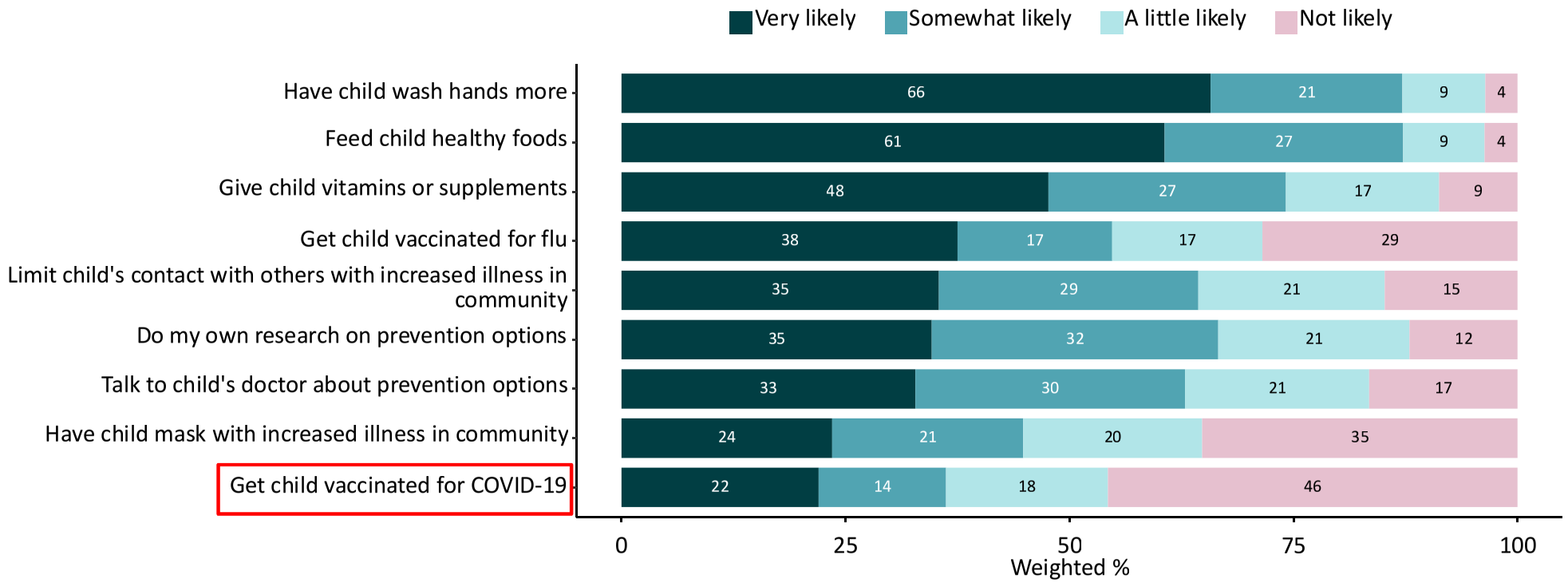
Data source: National immunization survey – Flu https://www.cdc.gov/covidvaxview/weekly-dashboard/child-coverage-vaccination.html

Accessed April 7, 2025

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Docusign Envelope ID: F7A6B9F6-BB4E-40F0-B6A7-A2A7FA52C77B

"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)

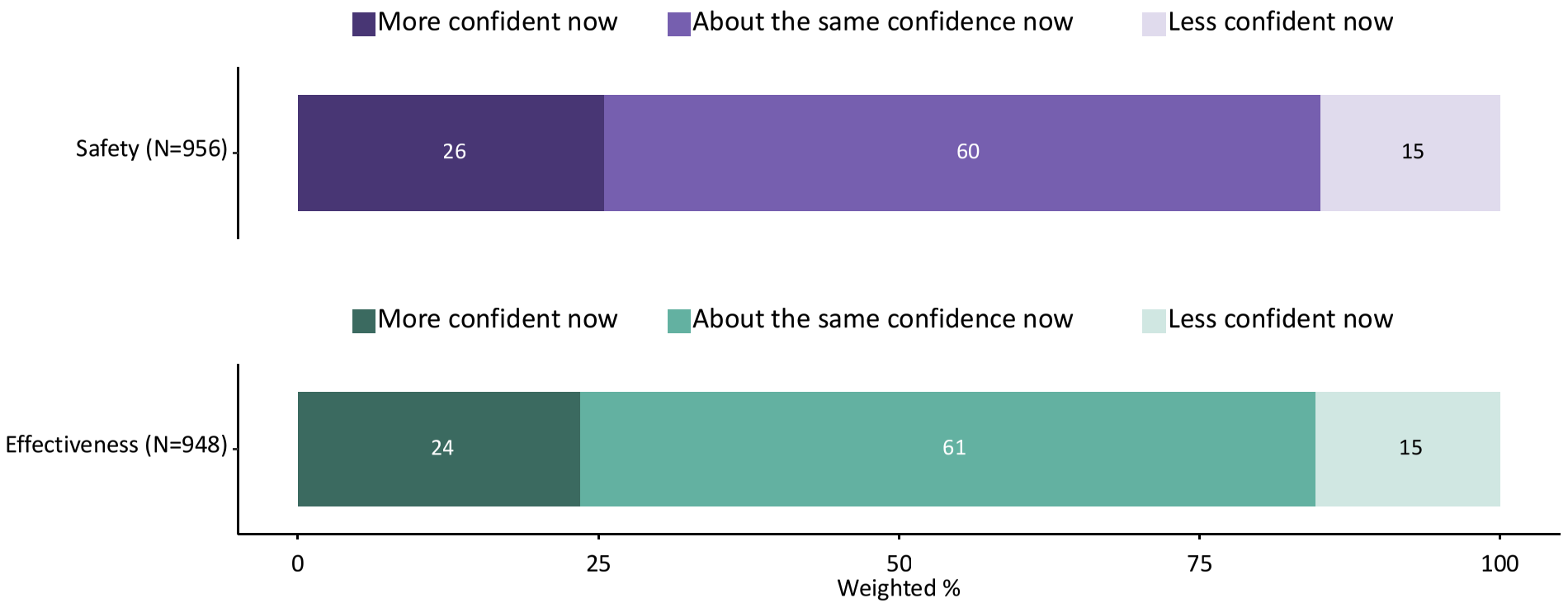


Omnibus Surveys: Data for this analysis were collected through the Ipsos KnowledgePanel and NORC AmeriSpeak Omnibus Surveys, which use probability-based panels to survey a nationally representative sample of U.S. adults ages 18 years and older. CDC fields questions about vaccination status, intent, knowledge, 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.

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Docusign Envelope ID: F7A6B9F6-BB4E-40F0-B6A7-A2A7FA52C77B

"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

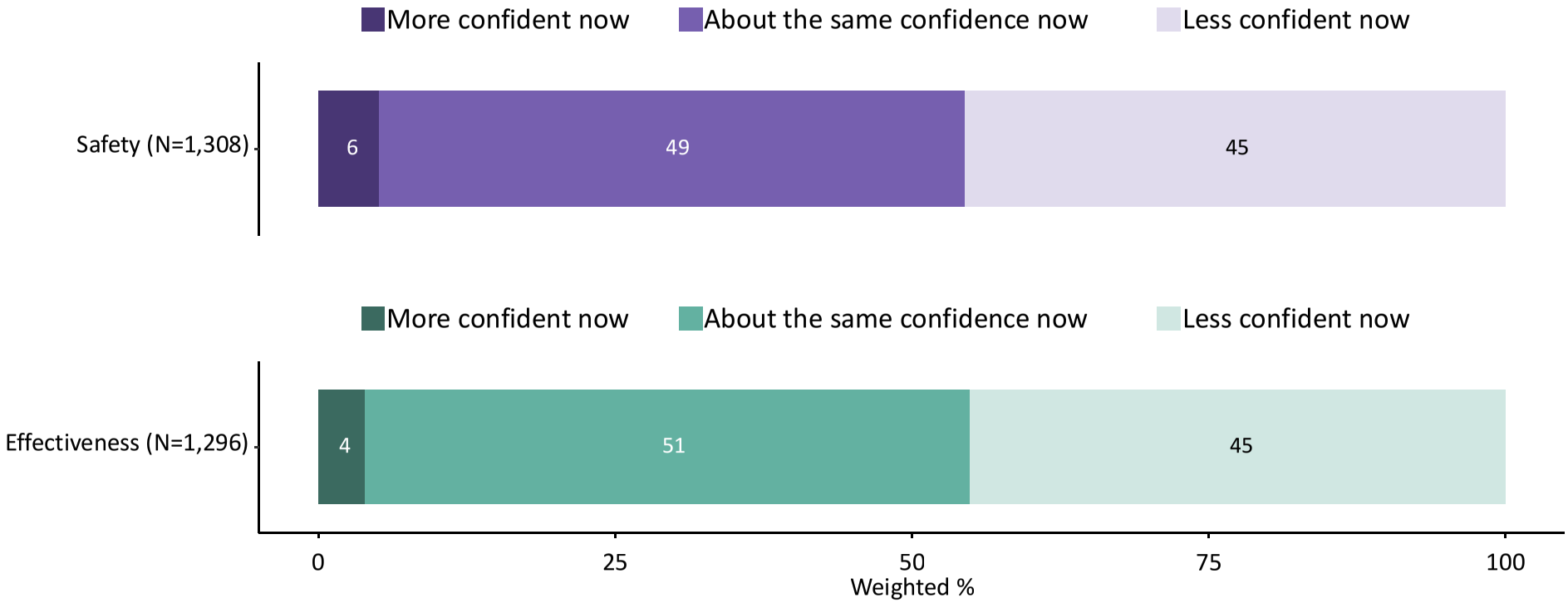


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Docusign Envelope ID: F7A6B9F6-BB4E-40F0-B6A7-A2A7FA52C77B

"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

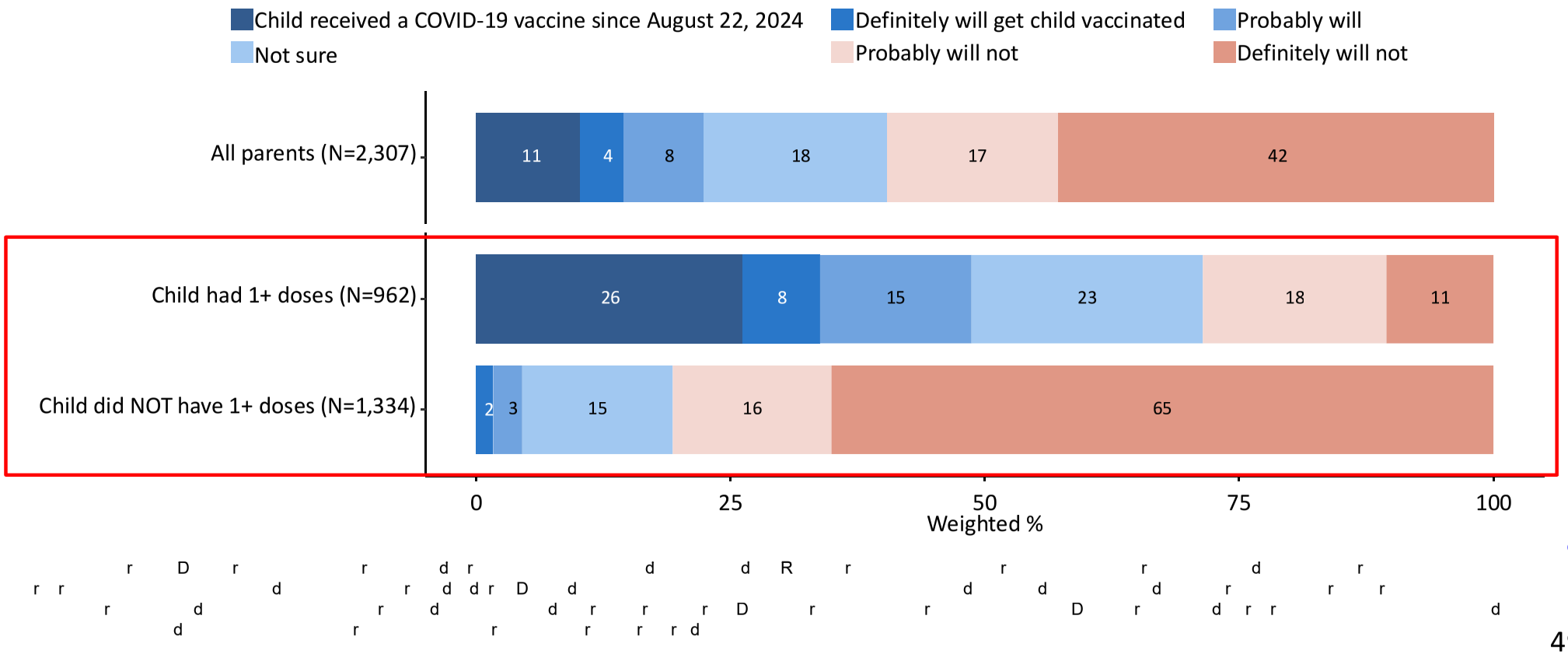


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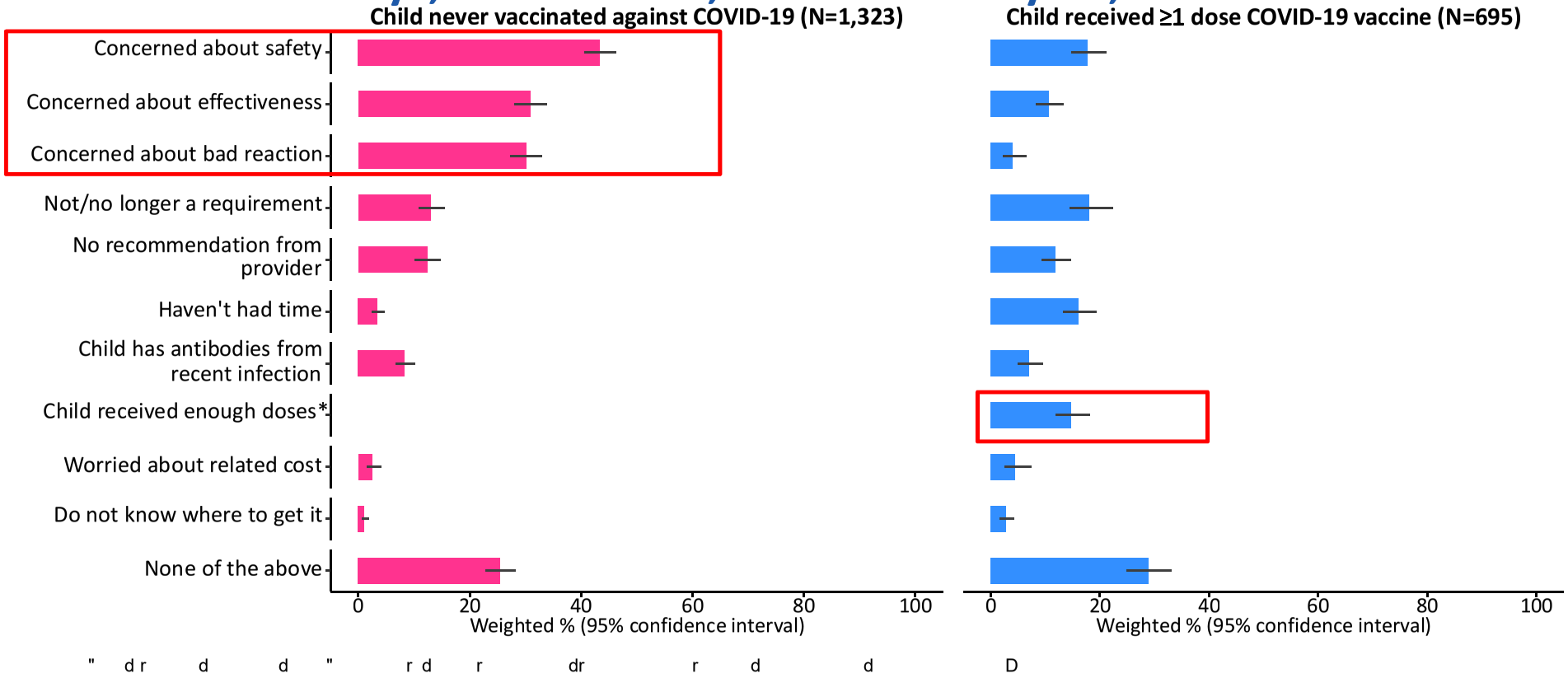
Child's 2024-2025 COVID-19 Vaccination Status And Parental Intent to Get Their Child Vaccinated, Results Among Parents of Children Ages 0–17 Years, by Receipt of Prior COVID-19 Vaccine(s), Omnibus Surveys, December 5, 2024–January 27, 2025 (N=2,312)



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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



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Recommendations in other countries

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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
Adults (routine)	Not recommended	*May receive every 12 months*	*May receive every 12 months*	Not routinely recommended **Pregnant adults and adolescents:** dose in each pregnancy***	12 months
High-risk adults**	12 months	12 months	*May receive every 12 months*	12 months	12 months
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1 https://assets.publishing.service.gov.uk/media/66e7fbf624c4f1826d81bb32/Greenbook-chapter-14a-20240916.pdf 2 https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/national-advisory-committee-immunization-summary-guidance-covid-19-vaccines-2025-summer-2026.html 3 https://www.health.gov.au/our-work/covid-19-vaccines/getting-your-vaccination/booster-doses

* 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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1 https://assets.publishing.service.gov.uk/media/66e7fbf624c4f1826d81bb32/Greenbook-chapter-14a-20240916.pdf 2 https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/national-advisory-committee-immunization-summary-guidance-covid-19-vaccines-2025-summer-2026.html 3 https://www.health.gov.au/our-work/covid-19-vaccines/getting-your-vaccination/booster-doses

* Booster refers to people who have already completed an initial series. For people who are unvaccinated, more doses may be needed than are shown on 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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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
Adults (routine)	Not recommended	*May receive every 12 months*	*May receive every 12 months*	Not routinely recommended **Pregnant adults and adolescents:** dose in each pregnancy***	12 months
High-risk adults**	12 months	12 months	*May receive every 12 months*	12 months	12 months
Immunocompromised adults	6 months	6 months	12 months, *may receive every 6 months*	6-12 months	6 months, *plus may receive additional doses at 2-month intervals*
Children (routine)	Not recommended	*May receive every 12 months*	Not recommended	Not routinely recommended	12 months
High-risk children**	12 months	12 months	Not recommended	Not routinely recommended	12 months
Immunocompromised children	6 months	6 months	**Under 5 years:** not recommended ***5-17 years:*** *May receive every 12 months*	6-12 months	6 months, *plus may receive additional doses at 2-month intervals*

1 https://assets.publishing.service.gov.uk/media/66e7fbf624c4f1826d81bb32/Greenbook-chapter-14a-20240916.pdf 2 https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/national-advisory-committee-immunization-summary-guidance-covid-19-vaccines-2025-summer-2026.html 3 https://www.health.gov.au/our-work/covid-19-vaccines/getting-your-vaccination/booster-doses

* Booster refers to people who have already completed an initial series. For people who are unvaccinated, more doses may be needed than are shown on this table

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Children (routine)	Not recommended	*May receive every 12 months*	Not recommended	Not routinely recommended	12 months
High-risk children**	12 months	12 months	Not recommended	Not routinely recommended	12 months
Immunocompromised children	6 months	6 months	**Under 5 years:** not recommended ***5-17 years:*** *May receive every 12 months*	6-12 months	6 months, *plus may receive additional doses at 2-month intervals*

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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 on this table

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Work Group Interpretations

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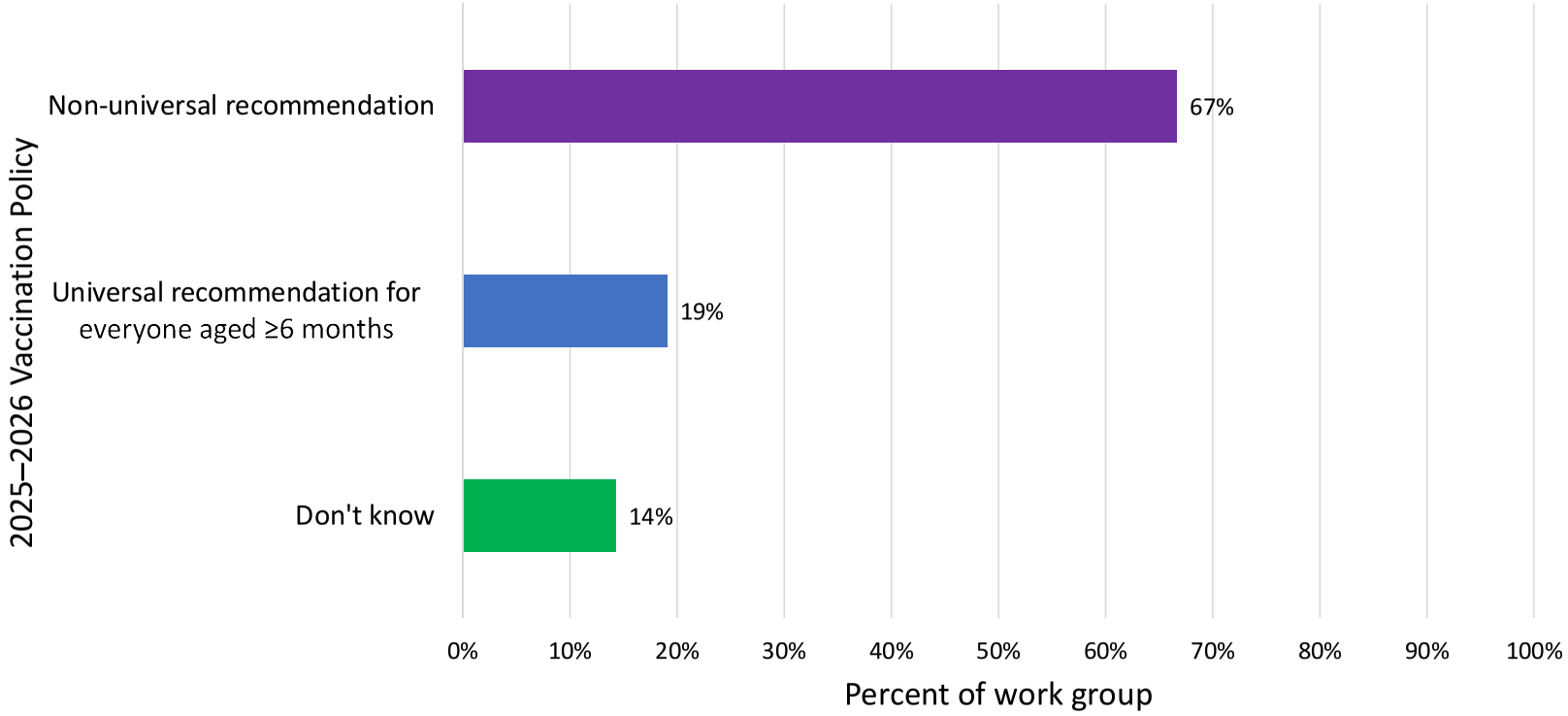
Initial Work Group interpretations

- 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.

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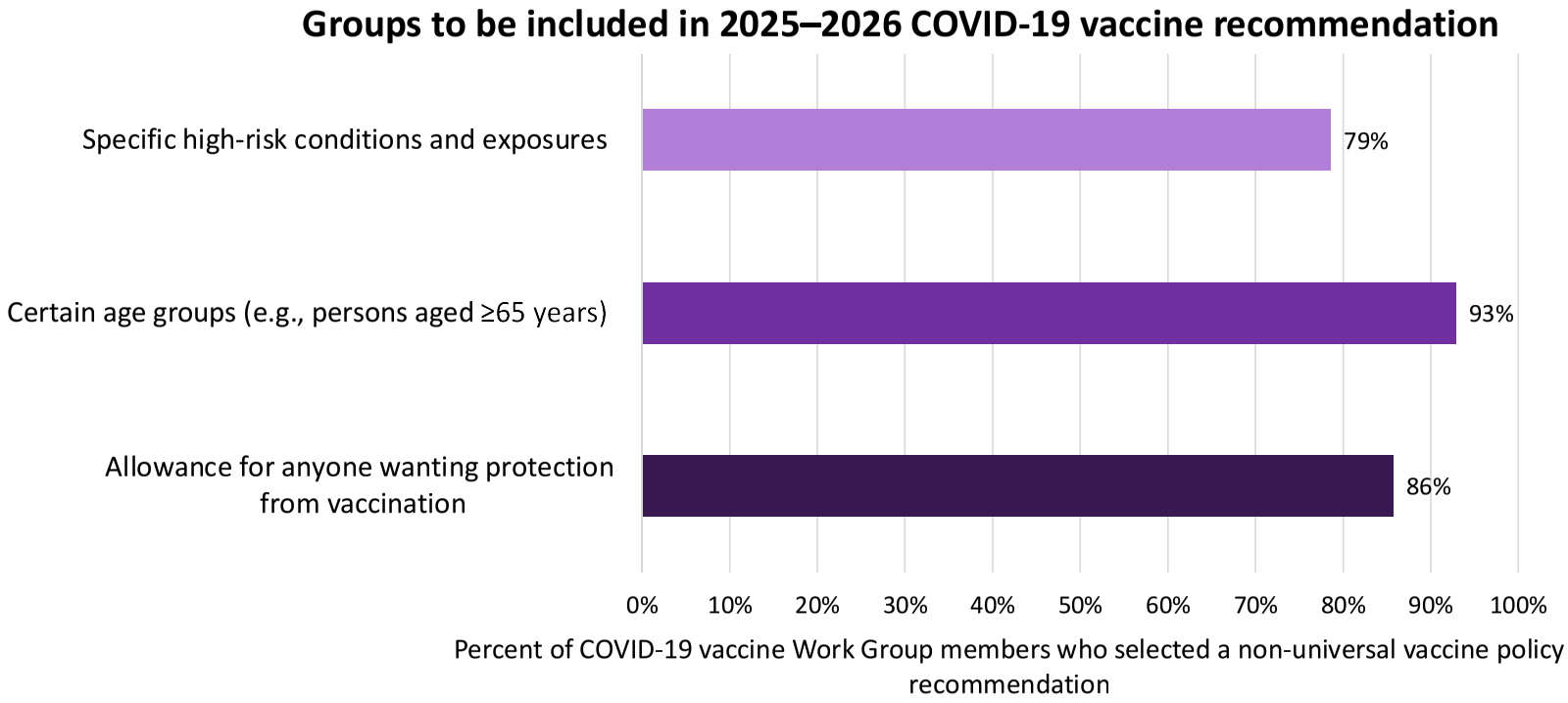
When polled on February 13, 2025, the majority of the work group supported a non-universal (risk-based) recommendation for 2025–2026 COVID-19 vaccination



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



* More than one response option could be selected.

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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)

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

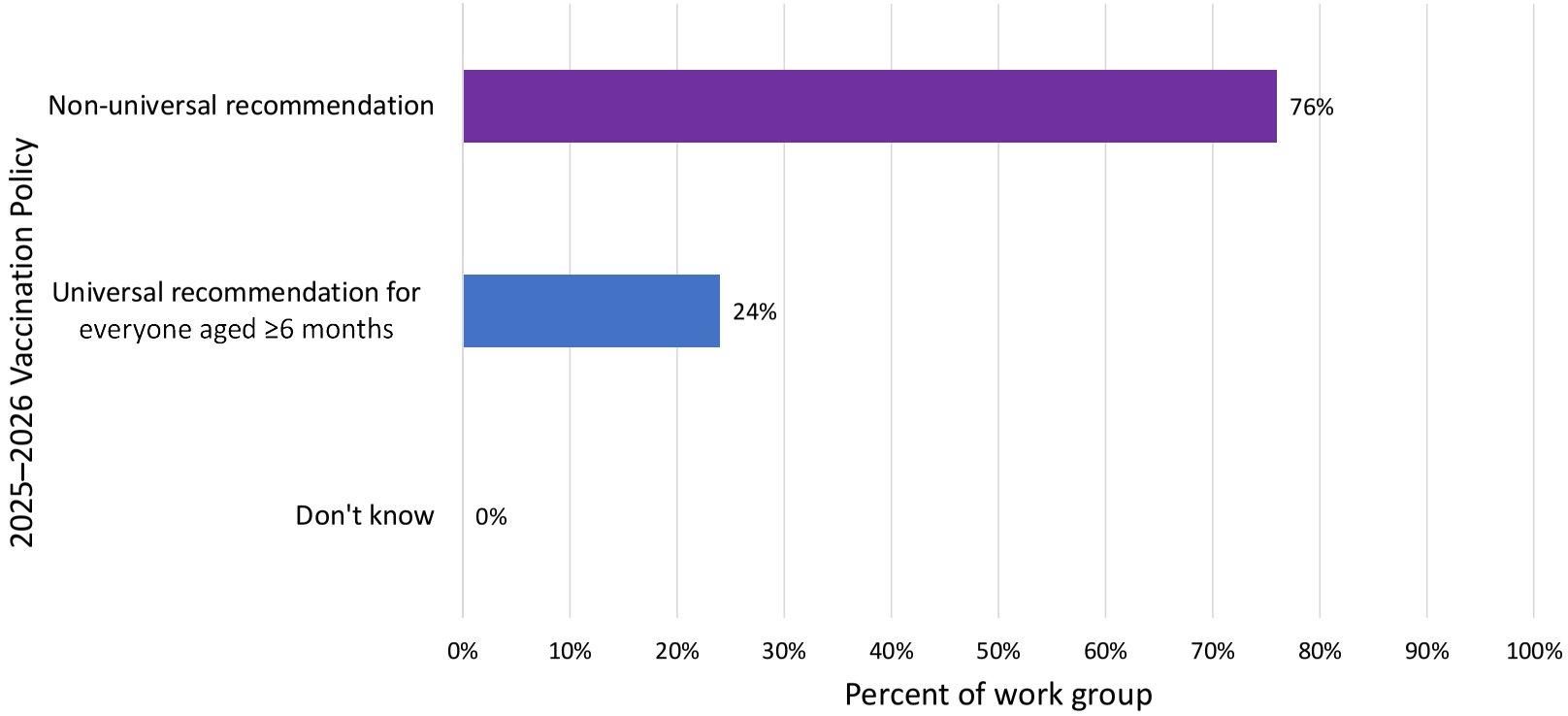
- American Academy of Family Physicians (AAFP)
- American Academy of Pediatrics (AAP)
- Association of Immunization Managers (AIM)
- American College of Physicians (ACP)
- American Pharmacists Association (APhA)
- American College of Obstetricians and Gynecologists (ACOG)

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

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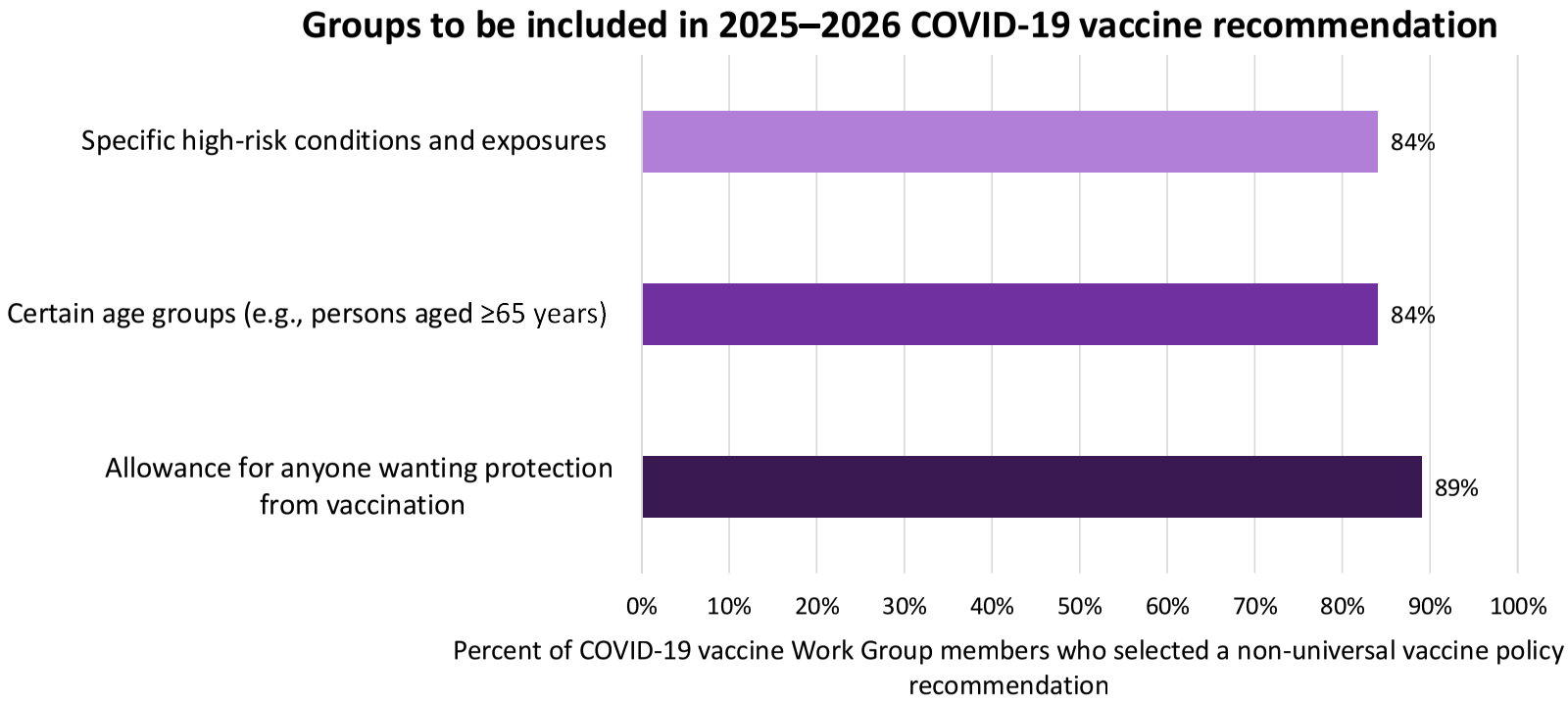
When polled on April 3, 2025, the majority of the work group continued to support a non-universal (risk-based) recommendation for 2025–2026 COVID-19 vaccination



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When polled on April 3, 2025, the Work Group continued to support all non-universal policy options*

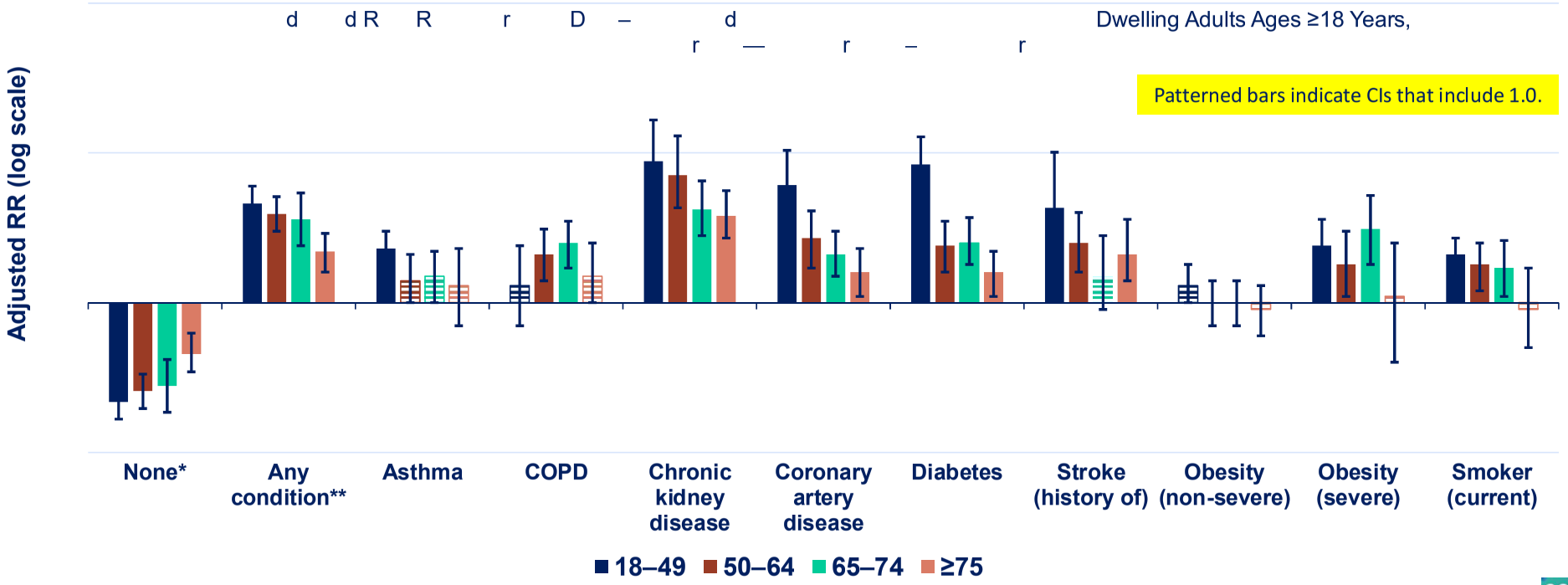


* More than one response option could be selected.

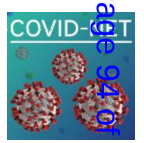
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Risk for COVID-19–associated hospitalization is increased among community-dwelling adults ages ≥18 years with underlying medical conditions.



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.



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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?

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Acknowledgements

- Lauren Roper
- Farida Ahmad
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- 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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EXHIBIT C

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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**	

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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**	

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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

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EXHIBIT D

SECRETARIAL DIRECTIVE ON PEDIATRIC COVID-19 VACCINES FOR CHILDREN LESS THAN 18 YEARS OF AGE AND PREGNANT WOMEN

May 19, 2025

The Department of Health and Human Services (HHS) continually considers and evaluates available science and evidence related to the safety and effectiveness of all currently available Food and Drug Administration (FDA) approved or authorized vaccines, and any risks of severe disease, hospitalization, and death to certain populations.

By Secretarial Directive on June 18, 2022, HHS ratified the Centers of Disease Control and Prevention (CDC) recommendations concerning use of Pfizer- BioNTech and the Moderna COVID-19 vaccines in the U.S. population for children ages six months through five years, consistent with the parameters of the Emergency Use Authorizations (EUAs) issued by FDA, for the Pfizer- BioNTech and the Moderna COVID-19 vaccines.[1]

By Secretarial Directive on June 24, 2022, HHS ratified the Centers of Disease Control and Prevention (CDC) recommendations concerning use of COVID-19 vaccines in the U.S. population for children ages six through 17 years, consistent with the parameters of EUAs issued by FDA.

The CDC also currently recommends the COVID-19 vaccine during pregnancy.[2]

Based on a review of the recommendation of the FDA and National Institutes of Health (NIH), I have determined that the known risks associated with use of COVID-19 vaccines in healthy U.S. children ages six months to 17 years do not outweigh the purported benefits of the vaccine. Accordingly, the HHS Secretarial Directives ratifying CDC recommendations for use of COVID-19 vaccines for children ages six months to 17 years and are rescinded.

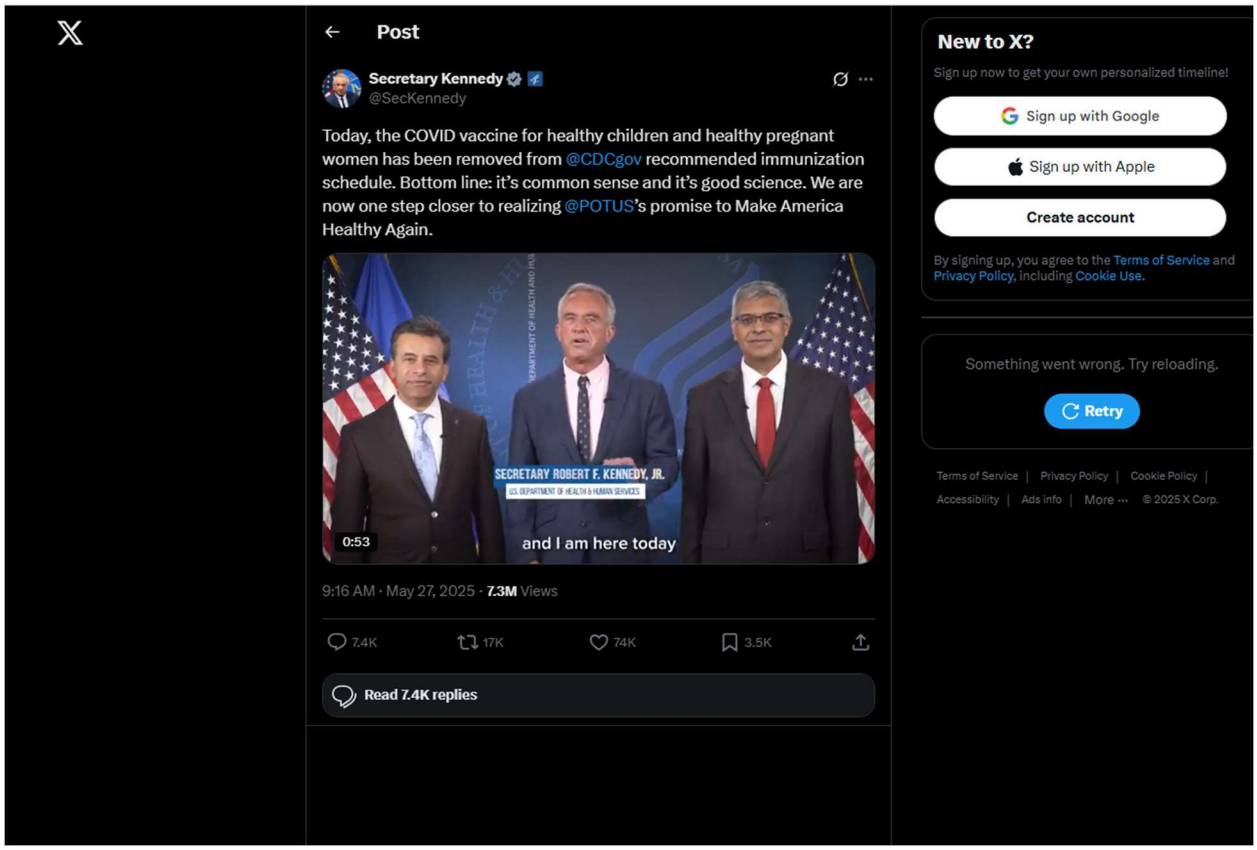
Based on a review of the recommendation of the FDA, I have similarly determined that the lack of high-quality data demonstrating safety of the mRNA vaccines during pregnancy combined with the uncertainty of the benefits of vaccination pose potential risks to the mother and developing baby. Therefore, the CDC recommendation that pregnant women receive the COVID-19 vaccine is rescinded.

Accordingly, the CDC is directed to remove COVID-19 vaccines from the recommended Child and Adolescent Immunization Schedule by Age and recommended vaccines during pregnancy, as noted above.

Robert F. Kennedy, Jr.
Secretary

[1] The Pfizer and Moderna vaccines are currently approved by the FDA for children 12 years of age and older.
[2] https://www.cdc.gov/vaccines-pregnancy/recommended-vaccines/index.html.

EXHIBIT E


Post
Secretary Kennedy
@SecKennedy
Today, the COVID vaccine for healthy children and healthy pregnant women has been removed from @CDCgov recommended immunization schedule. Bottom line: it's common sense and it's good science. We are now one step closer to realizing @POTUS's promise to Make America Healthy Again.
SECRETARY ROBERT F. KENNEDY, JR.
0:53
and I am here today
9:16 AM · May 27, 2025 · 7.3M Views
7.4K
17K
74K
3.5K
Read 7.4K replies
New to X?
Sign up now to get your own personalized timeline!
Sign up with Google
Sign up with Apple
Create account
By signing up, you agree to the Terms of Service and Privacy Policy, including Cookie Use.
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EXHIBIT F

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ACIP 2025

Thimerosal as a Vaccine Preservative

Prepared for the Advisory Committee for Immunization Practices

Lyn Redwood RN, MSN, FP (Retired)

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The Food and Drug Administration Modernization Act of 1997

- Compiled list of drugs and foods that contained intentionally introduced mercury compounds
- Provided quantitative and qualitative analysis of mercury compounds
- Report included 219 products which included 11 biologics and immunoglobulin therapies

Ref: U.S. Congress. (1997, November 21). Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296.

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1999 Joint Statement by US Public Health Service (PHS) and American Academy of Pediatrics (AAP)

- On July 9th, 1999, a joint statement issued by PHS and AAP called for the immediate reduction and elimination of the mercury based preservative thimerosal from infant vaccines based on the findings that infants and children who received vaccines preserved with thimerosal **could be exposed to mercury in excess of federal safety guidelines.**

- "because any potential risk is of concern, the Public Health Service (PHS), the American Academy of Pediatrics (AAP), and vaccine manufacturers agree that thimerosal-containing vaccines should be removed as soon as possible."

Thimerosal in Vaccines: A Joint Statement of the American Academy of Pediatrics and the Public Health Service. MMWR Weekly. July 09, 1999 / 48(26);563-565.

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Institute of Medicine
Immunization Safety Review of Thimerosal Containing Vaccines and Neurodevelopmental Disorders (October 2001)

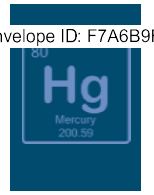
- The committee "supported prior decisions made by the ACIP and AAP to call for the removal of thimerosal from vaccines that are part of the recommended childhood immunization schedule." But they noted that "vaccines that are not part of the recommended childhood immunization schedule still contain thimerosal as a preservative and may be given to some children" and a lingering concern that there remains "on the shelf" an unknown quantity of thimerosal-containing Hib, hepatitis B, and DTaP vaccines.

- Recommended: "the use of thimerosal free DTaP, HiB and Hepatitis B vaccines despite the fact that there might be remaining supplies available" and "full consideration be given by appropriate professional societies and government agencies to removing thimerosal from vaccines administered to infants, children or pregnant women in the united States."

Institute of Medicine (US) Immunization Safety Review Committee; Stratton K, Gable A, McCormick MC, editors. Immunization Safety Review: Thimerosal-Containing Vaccines and Neurodevelopmental Disorders. Washington (DC): National Academies Press (US); 2001. Immunization Safety Review, Thimerosal-Containing Vaccines and Neurodevelopmental Disorders. Available from: https://www.ncbi.nlm.nih.gov/books/NBK223724/

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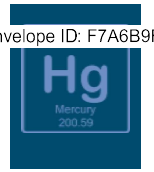
Safety Studies
Prior to Marketing Thimerosal as Vaccine Preservative

- In 1997, FDA Modernization Act prompted assessment of thimerosal use in vaccines.
- FDA was unable to find any clinical studies formally evaluating the use of thimerosal before its initial marketing in 1930's. (1)
- Single study published in 1931 where thimerosal administered to individuals suffering from meningitis. (2)
  - Not designed to specifically examine toxicity and no clinical assessments or laboratory studies reported.
- FDA grandfathered in the use of thimerosal and did not require the typical animal safety data for finished biological products, including active and inactive ingredients. (3)

(1) Ball LK, Ball R, Pratt RD. An assessment of thimerosal use in childhood vaccines Pediatrics. 2001;(107)5:1147-1153.
(2) Powell HM, Jamieson WA. Merthiolate as a germicide. Am J. Hyg. 1931;(13):296-310.
(3) Department of Health and Human Services. 21 Code of Federal Regulations: 601.25. 1985

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Thimerosal use in vaccines

- Thimerosal was first introduced as a preservative in vaccines in the 1930's after being developed and patented in 1927 and subsequently marketed by Eli Lilly under the trade name "Merthiolate" in 1928.

- After a deadly incident of bacterial contamination of vaccines in Australia where 12 children died from staphylococcal-contaminated diphtheria vaccine, the FDA began enforcing safety standards which led to regulations requiring that all multidose vaccines contain a preservative to prevent contamination.

- Thimerosal was used during the manufacturing process and in multi-dose vials to prevent bacterial and fungal contamination. By the 1930's thimerosal became widely used as a preservative in vaccines and other medical products.

Ref: 1. Ball LK, Ball R, Pratt RD. An assessment of thimerosal use in childhood vaccines Pediatrics. 2001;(107)5:1147-1153.
2. Powell HM, Jamieson WA. Merthiolate as a germicide. Am J. Hyg. 1931;(13):296-310.
3. Department of Health and Human Services. 21 Code of Federal Regulations: 601.25. 1985

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Thimerosal Not Generally Recognized as Safe and Effective (GRASE) in OTC Drugs

- In 1975, FDA convened panel of experts to evaluate the use of mercury-containing over-the-counter (OTC). The panel found evidence that thimerosal was "35.3 times more toxic for embryonic chick heart tissue than for Staphylococcus aureus" and "was no better than water in protecting mice from potential fatal streptococcal infections."

- The FDA issued a report of the panel's findings in the Federal Register in 1982 which concluded that "thimerosal was not safe for OTC topical use because of its potential for cell damage if applied to broken skin and its allergy potential, not effective "because bacteriostatic action could be reversed."

- In response to the expert panels report, the FDA published final rules in the Federal Register in 1998 that concluded **the use of thimerosal in over-the-counter products is not "generally recognized as safe or effective." (GRASE)**

Ref: Federal Register, Department of Health and Human Services, Food and Drug Administration. *Mercury-Containing Drug Products for Topical Antimicrobial Over-the-Counter Human Use; Establishment of a Monograph.* (January 5, 1982);47(2):436-442. 47 FR 436 [Docket No. 75N-0183(1) Federal Register, Department of Health and Human Services, Food and Drug Administration. Status of Certain Additional Over-the-Counter Drug Category II and III Active Ingredients. (April 22, 1998);63(77):19799-19802. 21 CFR Part 310 [Docket No. 75N-183F, 75N-183D, and 80N-0280.

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Evidence of Thimerosal Ineffectiveness as a Preservative

- In 1982, clusters of disease from Group A streptococcus infections were traced back to multi-dose vials of diphtheria toxoid, pertussis, and tetanus toxoid (DPT) vaccine which were contaminated after being opened. Thimerosal was present in acceptable limits in unopen vials of vaccine from the same lot. The authors concluded that **"Preservatives in multidose vials do not prevent short term bacterial contamination**" and the **"only feasible and cost-effective preventative measure now available is careful attention to sterile technique when administering vaccines from multidose vials."**

- In 2004, a Chiron plant that manufactured Fluvirin vaccine preserved with thimerosal was forced to close because its vaccine was contaminated with Serratia marcescens. The closure created shortages in the vaccine supply and caused concern among providers and patients. In this case and others, thimerosal failed to prevent bacterial growth.

Stetler HC, Garbe PL, Dwyer DM, Facklam RR, Orenstein WA, West GR, Dudley KJ, Bloch AB. Outbreaks of group A streptococcal abscesses following diphtheria, tetanus toxoid-pertussis vaccination. Pediatrics. 1985 Feb;75(2):299-303. PMID: 3881728.
Smith S. Safety fears cut vaccine for flu. Priority urged for the aged, frail. *Boston Globe*. (October 6, 2004).
http://www.boston.com/news/globe/health_science/articles/2004/10/06/safety_fears_cut_vaccine_for_flu?mode=PF

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Current Research
Thimerosal safety and effectiveness

- A more current in vitro investigation into the cytotoxic effects and antimicrobial activity of thimerosal was published in 2023. The authors reported that thimerosal **should be present in culture media at 100 µg/ml** concentration to achieve effective antimicrobial activity. **But all tested cell lines lost viability completely at 4.6 µg/mL.**

- "Overall, our study revealed **Thimerosal was 333-fold more cytotoxic to human and animal cells as compared to bacterial and fungal cells**. Our results promote more study on Thimerosal toxicity and its antimicrobial effectiveness to obtain more safe concentrations in biopharmaceuticals."

Rahimian A, Lakzaei M, Askari H, Dostdari S, Khafri A, Aminian M. In vitro assessment of Thimerosal cytotoxicity and antimicrobial activity. J Trace Elem Med Biol. 2023 May;77:127129. doi: 10.1016/j.jtemb.2023.127129. Epub 2023 Jan 4. PMID: 36630761.

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Evidence of Thimerosal
Developmental Neurotoxicity

- In 1987 the Commission of the European Communities initiated a research project on 10 known or suspected spindle poisons. Thimerosal was found to cause significant interference with microtubule polymerization destabilizing the spindle machinery that ensures accurate chromosome separation during cell division.
- This mechanistic disruption suggests direct mutagenic potential via structural chromosomal abnormalities, which is a known pathway to carcinogenesis or congenital defects.
- By affecting fundamental cellular structures at the molecular level, thimerosal revealed **“strong mechanistic evidence for mutagenicity and developmental toxicity”.**

Wallin, M. (1993). Effects of potential aneuploidy-inducing agents on microtubule assembly in vitro.
Mutation Research. Fundamental and Molecular Mechanisms of Mutagenesis, 287(1), 17–22. https://doi.org/10.1016/0027-5107(93)90141-2

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CALIFORNIA EPA Proposition - 65

- California's Proposition 65, requires identification of chemicals known to cause cancer, birth defects or other reproductive harm, and to ensure public warnings when people might be exposed to them. Thimerosal has been on the Prop-65 list since 1990.

- In 2003 a petition was filed on behalf of the Bayer Corporation "for reconsideration of the determination that mercury and mercury compounds (thimerosal) as reproductive toxicants."

- The CA EPA responded that **"**The scientific evidence that thimerosal cause reproductive toxicity is clear and voluminous. Thimerosal dissociates in the body to ethyl mercury. **The evidence for its reproductive toxicity includes severe mental retardation or malformations in human offspring who were poisoned when their mothers were exposed to ethyl mercury or thimerosal while pregnant,** studies in animals demonstrating developmental toxicity after exposure to either ethyl mercury or thimerosal, and data showing interconversion to other forms of mercury that also clearly cause reproductive toxicity."

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Evidence From Human Research (1)

- A study published in Pediatrics in 2000 measured blood mercury levels in preterm and term infants after administration of the Hepatitis B vaccine containing 12.5 µg ethyl mercury.
- The investigation documented elevated post-immunization concentrations relative to pre-immunization levels in all neonates studied. Levels of blood mercury after exposure in low-birth-weight infants were 7.36 (± 4.99) µg/L.
- One infant was found to have developed a mercury level of 23.6 µg/L, thus meeting the CDC criteria as a case of chemical poisoning from mercury 10µg /L. The study subjects had measurable blood Hg concentrations prior to immunization, indicating that risk assessment must include background mercury levels from other sources.

Stajich GV, Lopez GP, Harry SW, Sexson WR. Iatrogenic exposure to mercury after Hepatitis B vaccination in preterm infants. J.Pediatrics. 2000;136 (5):679-81.
Centers for Disease Control and Prevention. (2005, January 14). Case Definitions for Chemical Poisoning. MMWR Recommendations and Reports, 54(RR-1), 1–24. Retrieved from https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5401a1.htm

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Evidence From Human Research (2)

- Experts contend that there are “windows of vulnerability” which occur during neurological development and that specific types of developmental outcomes may have separate windows of vulnerability. These critical periods of development have not been established and may be relatively short in duration.

- The fact that thimerosal from vaccines has been documented to raise blood mercury levels over known thresholds where developmental effects have been documented to occur during the first few months of life, means that particular "windows of vulnerability" may have been breached. Even minor neurological impairment can have profound societal effects when amortized across the entire population and life span.

Rice D, Barone S Jr. Critical periods of vulnerability for the developing nervous system: evidence from humans and animal models. Environ Health Perspect. 2000;108 Suppl 3:511-33.

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Exposure To Vaccine Level Thimerosal

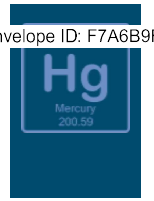
Crosses the Blood Brain Barrier and Results in Significant Deposition of Mercury in the Brain

- A 2005 study funded by NIH compared brain mercury levels in infant *Macaca fascicularis* primates exposed to: 1) injected ethyl mercury (thimerosal) and 2) equal amounts of ingested methylmercury.
- Ethyl mercury more rapidly converted to inorganic mercury in the brains of the primates which resulted in increasing levels of inorganic mercury.
- Primates exposed to ethyl mercury retained much higher levels of inorganic mercury in their brains, up to 71% vs. 10% compared to primates exposed to methyl mercury.
- Once organic mercury compounds reach the brain tissue and dealkylate, Hg2+ (toxic inorganic mercury) the mercury cannot cross the blood brain barrier and becomes trapped, resulting in neuroinflammation.

Burbacher TM, Shen DD, Liberato N, Grant KS, Cernichiari E, and Clarkson T. Comparison of blood and brain mercury levels I infant monkeys exposed to methylmercury or vaccines containing thimerosal. Environmental Health Perspectives. 2005;113(8):1015-1021.

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Inorganic Mercury and the Developing Brain

- A recent review outlined evidence from human and animal studies which estimated the inorganic mercury half-life in human brains of at least five to 27 years. (1)

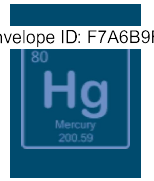
- The impact of mercury exposure to the developing brain interferes with neuronal proliferation, migration, differentiation, synaptogenesis, tightly regulated apoptosis, and other processes vital to the formation and functioning of the nervous system which can result in lifelong neurodevelopmental impacts.

- Exposure during the first trimester of pregnancy may result in deficits or defects very different from those developed by someone who is exposed during the third trimester of pregnancy. **"There may never be a safe level of mercury exposure, especially for an unborn child." (2)**

1.Rooney JP. The retention time of inorganic mercury in the brain--a systematic review of the evidence. Toxicol Appl Pharmacol. 2014 Feb 1;274(3):425-35.
2. Pletz J, Sánchez-Bayo F, Tennekes HA. Dose-response analysis indicating time-dependent neurotoxicity caused by organic and inorganic mercury-Implications for toxic effects in the developing brain. Toxicology. 2016 Mar 10;347-349:1-5. doi: 10.1016/j.tox.2016.02.006. Epub 2016 Mar 2. PMID: 26945727.

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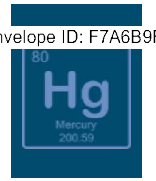


Mercury Content In Thimerosal-containing Flu Vaccines

- Thimerosal is ~49.6% mercury by weight with a concentration of 0.01% thimerosal in vaccines. This equates to 100 µg/mL of thimerosal and 50 µg/mL of ethyl mercury per ml.
- The EPA's Toxicity Characteristic Leaching Procedure (TCLP) determines whether a substance is considered hazardous waste based on its potential to leach toxic chemicals into groundwater.
- According to EPA TCLP Mercury Threshold (40 CFR § 261.24) the regulatory threshold for mercury (D009) under TCLP is: 0.2 mg/L (200 parts per billion, or 200 µg/L).
- Flu vaccine mercury concentration (~50,000 µg/L) is 250 times greater than the TCLP limit. **Therefore, thimerosal-containing vaccines exceed the TCLP threshold by orders of magnitude and are classified as D009 Hazardous Waste**

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Vaccine Mercury: Disposal Guidelines

PHARMECOLOGY® WM

PharmEcology® Provides Disposal Guidelines for the 2024-2025 Flu Season

PharmEcology Services, a division of WM Sustainability Services, is pleased to publish a summary of the proper flu vaccine disposal guidelines for the 2024-2025 flu season as a public service to the healthcare community. Please also see additional information regarding this year's vaccines following the table below.

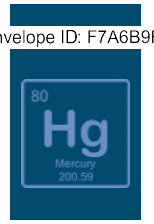
Flu vaccine summary table:

The table below summarizes the waste categorizations of the specific products available this season. Applying EPA's federal regulations to the flu vaccines, the vaccines meet the toxicity characteristic when the concentration of mercury is equal to or greater than 0.2mg/liter as a result of performing a test known as the toxicity characteristic leaching procedure (TCLP).

While we do not have results for such tests for vaccines, a calculation of the concentration of mercury in vaccines in which thimerosal is present as a preservative would cause the waste vaccine to fail the TCLP. Unless a manufacturer provides actual TCLP data indicating the mercury level to be below 0.2mg/liter or a healthcare facility has the test performed and the waste does not fail the TCLP, any vaccine waste containing thimerosal as a preservative should be managed as a toxic hazardous waste. As a result, all full or partially used multi-dose vials of the seasonal flu vaccine should be disposed of as federally hazardous waste, waste code D009 for mercury.

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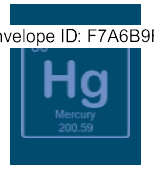


Susceptible Populations

Population	Susceptibility Factors
Fetus / Developing Infant	Rapid neurodevelopment, immature blood-brain barrier, low glutathione, high brain accumulation
Pregnant Women	Placental transfer, fetal susceptibility, breast milk transfer
Young Children	Higher exposure per kg, immature detoxification systems
Older Adults	Reduced renal clearance, pre-existing neurodegenerative conditions
Genetically Susceptible	Impaired detox (e.g., GST, MTHFR, APOE4), mitochondrial dysfunction
High Fish Consumers	Bioaccumulation through predatory fish, dietary exposure
Occupationally Exposed Workers	Inhalation exposure, chronic accumulation (e.g., dentists, miners)

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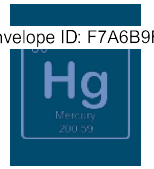


Summary (1)

- Mercury is the third most toxic element on earth, behind polonium and plutonium, and has no physiological role in the human body.
- Thimerosal was grandfathered for use without adequate safety testing by the FDA.
- Thimerosal is not “generally recognized as safe or effective” (GRASE) by the FDA OTC Division since 1998.
- There is evidence that thimerosal is not an effective preservative at vaccine levels.
- Thimerosal can cross the placenta and blood brain barriers and converts to inorganic mercury in the brain at higher levels that methyl mercury.
- Studies have identified infants with blood levels after exposure to thimerosal that breach CDC guidelines for a case of mercury chemical poisoning.

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Summary (2)

- Thimerosal is recognized as a developmental and reproductive toxicant and is listed as a chemical on the California Proposition 65 list since 1990.
- Unused doses of thimerosal preserved flu shots must be disposed of as hazardous waste.
- Tremendous progress has been made in removing thimerosal, but more than 60,000 pregnant mothers receiving Medicaid in the 2019-2020 flu season received TCVs.
- We currently have enough thimerosal free flu vaccines to recommend that all pregnant women, infants and children receive only thimerosal free vaccines.
- After a critical appraisal of this issue almost 25 years ago, the prestigious Institute of Medicine made this same recommendation.
- Removing a known neurotoxin from being injected into our most vulnerable populations is a good place to start with Making America Healthy Again.

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EXHIBIT 38

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, e*t 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-WGY District Judge: Hon. William G. Young Magistrate Judge: Hon. M. Page Kelley

DECLARATION OF DR. MOLLY O'SHEA, MD

I, Dr. Molly O'Shea, M.D., (aka Mary Doherty-O'Shea Gallucci) declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I am a graduate of the University of Michigan Medical School and completed residency at Children's Hospital of Michigan. I am a board-certified pediatrician and the owner of two pediatric practices in Michigan with locations in Bloomfield Hills (Oakland County) and Washington Township (Macomb County). I have practiced pediatrics for over 30 years. I care for children from birth through adolescence, including newborns.

2. I am a member of the American Academy of Pediatrics (AAP).

3. I saw the video that the Secretary posted on his official X account on May 27, 2025 that ordered the CDC to remove the recommendation that all children between the ages of 6 months and 17 years routinely get the Covid-19 vaccine. When I saw that video, I expected that the CDC would change its immunization schedule consistent with the Secretary's stated intent and consistent with a document titled the "Secretarial Directive On Pediatric Covid-19 Vaccines For

Children Less Than 18 Years of Age and Pregnant Women" dated May 19, 2025 (the "Directive"), and completely remove the recommendation that children get the Covid-19 vaccine from the CDC schedule.

4. However, on or about May 30, 2025, the CDC changed its immunization guidance with regard to children and the Covid-19 vaccine from routine vaccination for all children to "Shared Clinical Decision Making" ("SCDM") without explanation. When the CDC categorizes a vaccine on its immunization schedule as "routine," not only does it mean that the group of people in the category *should* get the vaccine, but in any health care setting the default decision is to vaccinate. In the past, when the Advisory Committee on Immunization Practices has recommended and the CDC has adopted SCDM for a vaccine, it has provided an explanation and published guidance on how to engage in SCDM with patients. For example, after the ACIP recommended SCDM for the Meningococcal B vaccine, the CDC published the guidance attached hereto as Exhibit A on how providers could engage in SCDM with patients. No explanation was given, however, for why the CDC listed the Covid-19 vaccine for children as SCDM, and the CDC published no guidance for providers on how to engage in SCDM with parents about the Covid-19 vaccine.

5. I and other providers at my practices were confused not only by the Directive itself, which came out of the blue and was supported with no evidence, but also by the CDC's subsequent decision to list the Covid-19 vaccine for children as SCDM without explanation or guidance. My colleagues and I took the Directive and subsequent listing of the Covid-19 vaccine for children as SCDM to be an effort by the Secretary to discourage parents and caregivers from giving their children the Covid-19 vaccine. As a board-certified pediatrician who has been practicing for more than 30 years, I wholeheartedly and vehemently disagree with the Directive and his other actions

to discourage vaccines. I am appalled that he has taken this action especially after he testified before Congress earlier this year that "I don't think people should be taking medical advice from me." Covid illness is currently on the rise. Yet, his Directive, which is de facto medical advice, will, unfortunately and very likely, lead to more illness and death.

6. The AAP released on August 19, 2025, its own immunization schedule that differs from the immunization schedules that are posted on the Centers for Disease Control and Prevention ("CDC") website. One difference between the AAP's schedule and the Secretary's schedule is that the AAP recommends the Covid-19 vaccine for children 18 years or younger without qualification. See Exhibit B, attached hereto. In addition, the AAP strongly recommends children 6 months to 2 years receive the Covid vaccine in the hope that they will develop immunity from vaccine rather than from natural illness. Data show that this age group is at high risk for complications from infection including hospitalization and death. In addition, data show that receiving vaccine before natural illness decreases the risk of other Covid complications including long Covid. AAP publishes its own immunization schedule annually before the Fall respiratory virus season, and the AAP's schedule has traditionally aligned with the CDC's immunization schedule. However, this year, the release of AAP's immunization schedule differed significantly from the CDC's schedule, including with respect to the Covid-19 vaccine.

7. The release of AAP's immunization schedule on August 19, 2025 apparently caught the attention of the Secretary, who posted that same day on his official X account the post attached hereto as Exhibit C. When I read this post, I became particularly concerned about what the Secretary said in the last paragraph: "AAP should also be candid with doctors and hospitals that recommendations that diverge from the CDC's official list are not shielded from liability under the 1986 Vaccine Injury Act." I took the Secretary's statement as a threat to me, to the doctor-

members of the AAP, and to any other providers that if they make vaccine recommendations that are inconsistent with the CDC's "official list," the Secretary would cause legal or disciplinary action to be taken against those providers. I have heard that the Secretary has a team of lawyers around the country who file or participate in litigation to pursue their anti-vaccine agenda.

8. The Secretary's threat was unsettling to me and my colleagues, so much so that I contacted my practices' insurance agent about my practices' coverage under our malpractice insurance policy. My insurance agent told me that my practices are not able to give the Covid vaccine or a prescription for the Covid vaccine to any healthy children because, if we do, we are likely not to be covered under our policy, and the carrier would likely not pay for defense counsel to defend us, in the event of a lawsuit over our decision to give the Covid vaccine to a child. The Secretary's Directive is thus exposing me to liability, as confirmed by my insurance agent, for doing my job consistent with the standard of care and consistent with my conscience.

9. I have seen the government's argument that there can be no harm to me when it is my job to counsel patients on the Covid-19 vaccine. That argument is bewildering and galling in the face of the Secretary's threat that he or his allies will go after doctors who advise their patients divergently from the CDC's "official list." I wonder how the Secretary or his allies would take it if they were exposed to legal or professional liability for following their conscience and doing the right thing. Being in this position is emotionally distressing to me.

10. My outside advisors have also counseled me that families who get the Covid vaccine for their "healthy" children may not be reimbursed by insurance and will have to pay out of pocket for the Covid vaccine. The cost to purchase the vaccine for my two practices will be about $113 - $120 per dose before excise taxes, shipping, and other costs, which I will have to charge to my patients, if they can afford it. For those who cannot afford the vaccine but really want

it, I may have to eat the cost. Right now, I am unable to purchase any doses of the Covid vaccine. I have heard that the CDC will not release any supply of the 2025-2026 Covid vaccine until after the next ACIP meeting, which is scheduled for September 18 and 19. Unlike years past, I will not be purchasing Covid vaccine to vaccinate any patient at my practices who wants it. We will be purchasing Covid vaccine for our children who meet FDA and CDC criteria. This feels morally wrong and compromises my duty as a pediatrician. I am stuck though. Should my colleagues or I, even through shared decision making, give Covid vaccine to a healthy child and that child experiences an adverse event, our potential liability will be too large to bear. Further, I am at a materially higher risk of liability for providing the vaccine to a healthy child, which is considered to be administering the vaccine "off label," because the Secretary has warned that diverging from the CDC's official list does not shield me from liability under the 1986 Vaccine Injury Act. The idea that pediatricians can employ SCDM and give the Covid-19 vaccine to anyone who wants it is misleading and a fallacy.

11. Even if I were able to purchase the 2025-2026 Covid vaccine, for healthy children I am likely to lose money because the Directive, which forces me and my colleagues to engage in SCDM, has resulted and will result in fewer parents vaccinating their children, much more time spent obtaining informed consent, and leftover vaccine which is often difficult to return. I have already seen the impact of the downgrade of the recommendation for the Covid-19 vaccine for children from routine to SCDM. Since the Directive, fewer parents are getting their children vaccinated for anything, including Covid-19, than was the case before the Directive. The vaccine conversations are much longer and more difficult. The change in vaccine uptake and more time with each family is already resulting in financial harm to my practice that can be directly tied to the Directive because I typically am not able to bill for and therefore am not paid for the extra

counseling time that the Directive has forced me to engage in. The Directive is making make me provide extra counseling on the Covid-19 vaccine for free.

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

Dated: September 19, 2025

Molly O'Shea, MD, FAAP

Dr. Molly O'Shea, MD

EXHIBIT A

Docusign Envelope ID: 775C74D9-14B9-4662-9E98-B160E5C2E595

Shared Clinical Decision-Making

Meningococcal B Vaccination

All adolescents and young adults who are at increased risk for serogroup B meningococcal disease should receive Meningococcal B (MenB) vaccine. This includes patients with anatomic or functional asplenia (including sickle cell disease), persistent complement component deficiency, or complement inhibitor use.

Shared clinical decision-making (SCDM) is recommended regarding MenB vaccination for healthy people 16–23 years of age. SCDM recommendations are meant to be flexible and informed by the characteristics, values, and preferences of the individual patient and the clinical discretion of the health care provider.

When you decide to discuss MenB vaccination with people 16–23 years of age:

Remember:



- MenB vaccine is not routinely recommended for all people in this age group.
- The vaccine series provides short-term protection against most strains of serogroup B meningococcal bacteria circulating in the United States.

Consider:



- Serogroup B meningococcal disease is an uncommon but deadly disease. In recent years, between 20 and 50 cases occurred each year in 16- through 23-year-old people in the United States.
- A low risk of exposure or infection does not mean a person cannot get a MenB vaccine. It is just one potentially important consideration in SCDM.
- Serogroup B meningococcal disease cases most commonly affect young adults who attend a four-year university, are freshmen, live in on-campus housing, or participate in sororities or fraternities.
- MenB vaccines are safe and effective, but they only offer short-term protection (1 to 2 years) to those who get vaccinated.

How to vaccinate:



- If you and your patient decide MenB vaccination is appropriate, administer a 2-dose series of a MenB vaccine, one each at month 0 (the first vaccine appointment) and 6 months later.
  - To optimize rapid protection (e.g., for students starting college in less than 6 months), a 3-dose series (0, 1–2, 6 months) may be administered.
- MenB-4C and MenB-FHbp are not interchangeable.
- MenB vaccines should not be administered to a person who has had a severe allergic reaction (e.g., anaphylaxis) to a:
  - Previous dose of MenB vaccine
  - Component of the vaccine
- In pregnant women, delay vaccination until after pregnancy unless the patient is at increased risk and the benefits of vaccination outweigh the potential risks.

Additional information:

CDC Child and Adolescent Immunization Schedule by Age:
www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html

CDC Adult Immunization Schedule by Age:
www.cdc.gov/vaccines/hcp/imz-schedules/adult-age.html

CDC Meningococcal Vaccine Recommendations:
www.cdc.gov/meningococcal/hcp/vaccine-recommendations/index.html

EXHIBIT B

Docusign Envelope ID: 775C74D9-14B9-4662-9E98-B160F5C2E595

Red Book® Online

AAP Immunization Schedule

September 9, 2025

The American Academy of Pediatrics' Recommended Child and Adolescent Immunization Schedule can be found here.

Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger

United States 2025

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

Vaccines and Other Immunizing Agents in the Child and Adolescent Immunization Schedule*

Monoclonal antibody	Abbreviation(s)	Trade name(s)
Respiratory syncytial virus monoclonal antibody	RSV-mAb	Beyfortus Enflonsia
Vaccine	**Abbreviation(s)**	**Trade name(s)**
COVID-19 vaccine	1vCOV-mRNA	Comirnaty mNEXSPIKE Spikevax
	1vCOV-aPS	Nuvaxovid
Dengue vaccine	DEN4CYD	Dengvaxia
Diphtheria, tetanus, and acellular pertussis vaccine	DTaP	Daptacel Infanrix
Haemophilus influenzae type b vaccine	Hib (PRP-T)	ActHIB Hiberix
	Hib (PRP-OMP)	PedvaxHIB
Hepatitis A vaccine	HepA	Havrix Vaqta
Hepatitis B vaccine	HepB	Engerix-B Recombivax HB
Human papillomavirus vaccine	HPV	Cardasil 9
Influenza vaccine (inactivated; egg-based)	IIV3	Multiple
Influenza vaccine (inactivated; cell-culture)	ccIIV3	Flucelvax
Influenza vaccine (recombinant)	RIV3	Flublok
Influenza vaccine (live, attenuated)	LAIV3	FluMist
Measles, mumps, and rubella vaccine	MMR	M-M-R II Priorix
Meningococcal serogroups A, C, W, Y vaccine	MenACWY-CRM	Menveo
	MenACWY-TT	MenQuadfi
Meningococcal serogroup B vaccine	MenB-4C	Bexsero
	MenB-FHbp	Trumenba
Meningococcal serogroup A, B, C, W, Y vaccine	MenACWY-TT/MenB-FHbp	Penbraya
	MenACWY-CRM/MenB-4C	Penmenvy
Mpox vaccine	Mpox	JYNNEOS
Pneumococcal conjugate vaccine	PCV15	Vaxneuvance
	PCV20	Prevnar 20
Pneumococcal polysaccharide vaccine	PPSV23	Pneumovax 23
Poliovirus vaccine (inactivated)	IPV	Ipol
Respiratory syncytial virus vaccine	RSV	Abrysvo
Rotavirus vaccine	RV1	Rotarix
	RV5	RotaTeq
Tetanus, diphtheria, and acellular pertussis vaccine	Tdap	Adacel Boostrix
Tetanus and diphtheria vaccine	Td	Tenivac Tdvax
Varicella vaccine	VAR	Varivax
Combination vaccines (use combination vaccines instead of separate injections when appropriate)		
DTaP, hepatitis B, and inactivated poliovirus vaccine	DTaP-HepB-IPV	Pediarix
DTaP, inactivated poliovirus, and *Haemophilus influenzae* type b vaccine	DTaP-IPV/Hib	Pentacel
DTaP and inactivated poliovirus vaccine	DTaP-IPV	Kinrix Quadracel
DTaP, inactivated poliovirus, *Haemophilus influenzae* type b, and hepatitis B vaccine	DTaP-IPV-Hib-HepB	Vaxelis
Measles, mumps, rubella, and varicella vaccine	MMRV	ProQuad

*Administer recommended vaccines if immunization history is incomplete or unknown. Do not restart or add doses to vaccine series for extended intervals between doses. When a vaccine is not administered at the recommended age, administer at a subsequent visit when indicated. The use of trade names is for identification purposes only and does not imply endorsement by the AAP.

Updated September 9, 2025

How to use the child and adolescent immunization schedule

1. Determine recommended vaccine by age (Table 1)
2. Determine recommended interval for catch-up vaccination (Table 2)
3. Assess need for additional recommended vaccines by medical condition or other indication (Table 3)
4. Review vaccine types, frequencies, intervals, and considerations for special situations (Notes)
5. Review contraindications and precautions for vaccine types (Appendix)
6. Review new or updated American Academy of Pediatrics (AAP) guidance (Addendum)

Report

- Suspected cases of reportable vaccine-preventable diseases or outbreaks to your state or local health department
- Clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov (Accessed August 11, 2025) or 800-822-7967
- For RSV-mAb products, clinically significant adverse events to MedWatch Adverse Event Report Program at www.accessdata.fda.gov/scripts/medwatch/index.cfm (Accessed August 11, 2025). If co-administered with other products, then report to VAERS.

Questions or comments

Submit a question or comment to www.aap.org/en/forms/immunization-schedule-questions.

Helpful information

- **Best practices for immunization (including contraindications and precautions):** www.aap.org/immunization and www.immunize.org
- ***Red Book: 2024–2027 Report of the Committee on Infectious Diseases* (33rd Edition):** www.aapRedBook.org
- **Vaccine information statements:** www.immunize.org/vaccines/vis/about-vis

View online at AAP.org/ImmunizationSchedule

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Article type: Resources
Topics: Vaccine/Immunization

The Child and Adolescent Immunization Schedule, published by the CDC, which is not currently endorsed by the AAP, can be found at https://www.cdc.gov/vaccines/hcp/imz-schedules/downloads/child/0-18yrs-child-combined-schedule.pdf.

EXHIBIT C

← Post

Secretary Kennedy ✓ ⚡
@SecKennedy

This is a screenshot from American Academy of Pediatrics' webpage, thanking the organization's top corporate donors. These four companies make virtually every vaccine on the CDC recommended childhood vaccine schedule. AAP is angry that CDC has eliminated corporate influence in decisions over vaccine recommendations and returned CDC to gold-standard science and evidence-based medicine laser-focused on children's health.

AAP today released its own list of corporate-friendly vaccine recommendations. The Trump Administration believes in free speech and AAP has a right to make its case to the American people. But AAP should follow the lead of HHS and disclose conflicts of interest, including its corporate entanglements and those of its journal—Pediatrics—so that Americans may ask whether the AAP's recommendations reflect public health interest, or are, perhaps, just a pay-to-play scheme to promote commercial ambitions of AAP's Big Pharma benefactors.

AAP should also be candid with doctors and hospitals that recommendations that diverge from the CDC's official list are not shielded from liability under the 1986 Vaccine Injury Act.



4:17 PM · Aug 19, 2025 · **1.1M** Views

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EXHIBIT 39

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 DR. PATRICK S. RAMSEY, MD, MSPH

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

1. I submit this declaration in support of plaintiffs' motion for preliminary injunction because my patients' lives are at stake. As a practicing double board-certified obstetrics & gynecologist and maternal-fetal medicine specialist in Texas, I treat high-risk pregnant patients every day and I am gravely concerned about the immediate and irreparable harm caused by HHS's May 19, 2025 directive to halt access for pregnant women to receive critical, evidence-based COVID-19 vaccines.

2. The May 19 HHS directive is already undermining patient trust, disrupting essential immunization schedules for my patients, creating dangerous confusion in the clinical setting, and forcing me to choose between following HHS's recommendations or expose myself to professional liability by following the standard of care that requires the recommendation of COVID-19 vaccines for pregnant women, which has been supported by scientific studies for years. My patients—many

of whom are medically vulnerable, immunocompromised, or face systemic barriers to care—are now afraid, misinformed, and at increased risk of preventable illness and death as a result of HHS's May 19 COVID-19 directive. The May 19 HHS COVID-19 directive is currently threatening the health and safety of the patients I serve, resulting in preventable suffering and loss of life.

3. I am a physician board certified in obstetrics and gynecology and maternal-fetal medicine. I received my Doctor of Medicine degree from the University of Wisconsin in 1994, I completed a residency in obstetrics and gynecology at the Mayo Graduate School of Medicine in 1998, and completed a fellowship in maternal and fetal medicine at the University of Alabama – Birmingham in 2001. I also received a Master of Science in Public Health from the University of Alabama – Birmingham in 2003. I am over the age of 18 years old and I make this declaration based on my personal knowledge and experience, and if called to testify, I could and would do so truthfully.

4. I have extensive experience and expertise in the management of infectious diseases affecting women and fetuses during pregnancy. In addition to my clinical and academic work, I have held multiple leadership roles focused on advancing the prevention of infectious diseases in women, contributing to national and regional efforts aimed at improving maternal and fetal health outcomes through policy, education, and collaborative initiatives.

5. I am a member of the Society for Maternal-Fetal Medicine (SMFM), which is a professional organization committed to advancing evidence-based public health and medical care.

6. I have been providing obstetric care for over 24 years and routinely counsel pregnant patients on immunizations recommended during pregnancy, including the COVID-19 vaccine, influenza vaccine, Tdap (tetanus, diphtheria, and whooping cough) vaccine, and more recently, the RSV (respiratory syncytial virus) vaccine.

7. Since the COVID-19 vaccine became available in 2021, it has been the standard of care in my field, as set forth in clinical guidelines issued by SMFM and other professional organizations, to recommend COVID-19 vaccination to all pregnant patients. I have followed those clinical guidelines consistently and recommended COVID-19 vaccination to my patients in all trimesters of pregnancy, particularly because pregnancy itself is a known risk factor for increased morbidity and adverse outcomes from respiratory infections like COVID-19 and influenza.

8. The HHS Secretary issued the "Secretarial Directive on Pediatric COVID-19 Vaccines for Children Less than 18 years of Age and Pregnant Women" (the "May 19 Secretarial Directive"). [1] The Secretary stated, "I have determined that the known risks associated with the use of COVID-19 vaccines in healthy U.S. children ages six months to 17 years do not outweigh the purported benefits of the vaccine." *See* Exhibit A. The May 19 Secretarial Directive directed the CDC to "remove COVID-19 vaccines from the recommended Child and Adolescent Immunization Schedule by Age and recommended vaccines during pregnancy."

9. Immediately following the issuance of the Directive, SMFM members requested clarification regarding the appropriate standard of care to follow and affirmation that SMFM still recommended administration of the COVID-19 vaccine during pregnancy. In response, SMFM issued the following statement the day after the Directive was publicized:

> As the experts in high-risk pregnancy, the Society for Maternal-Fetal Medicine (SMFM) strongly reaffirms its recommendation that pregnant patients receive the COVID-19 vaccine. Pregnancy increases the risk of developing severe illness compared with nonpregnant patients. Maternal immunization remains the best way to reduce maternal, fetal, and infant complications from COVID-19

[1] A true and correct copy of the directive issued by United States Secretary of Health and Human Services Robert F. Kennedy Jr., dated May 19, 2025, is attached to this declaration as **Exhibit A**.

> infection, and is safe to be given at any point during pregnancy. Maternal immunization is also associated with improved infant outcomes and decreased complications, including maternal and infant hospitalizations.
>
> SMFM recommends that all people who are considering pregnancy, pregnant, recently pregnant, or breastfeeding receive vaccination against COVID-19. Surveillance data collected since the beginning of the COVID-19 pandemic, which started in 2020, clearly demonstrates the safety and efficacy of mRNA vaccines in pregnancy.
>
> All physicians and other health care partners, along with health insurers, should continue recommending COVID-19 vaccination to pregnant patients. Maternal immunization is proven to protect patients and their infants against severe illness and death from infectious diseases.[2]

10. The Secretarial Directive directly contradicts the standard of care and clinical guidance that I and other SMFM members rely on to deliver safe and effective care to our high-risk pregnant patients. This change is currently undermining the patient-provider relationship. Additionally, this change exposes me and other obstetric clinicians to unnecessary legal risk given the sound scientific evidence regarding COVID-19 vaccination safety during pregnancy.

11. Peer-reviewed studies have repeatedly and consistently shown that administration of the COVID-19 vaccine during any trimester of pregnancy lowers hospitalization rates, serious illness, and adverse outcomes due to COVID-19 infections in pregnant people and infants.[3] A

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[2] News Release, *SMFM Reaffirms COVID-19 Vaccination Recommendations During Pregnancy*, Soc'y for Maternal-Fetal Medicine (May 28, 2025), attached hereto as **Exhibit B**.

[3] *See, e.g.*, Dingning Zhang, et al., *Systematic review and meta-analysis of neonatal outcomes of COVID-19 vaccination in pregnancy*, 94 Pediatric Research 34–42 (2023) ("COVID-19 vaccination in pregnant women does not raise significant adverse effects on neonatal outcomes and is related to a protective effect on some neonatal outcomes."), attached as **Exhibit C**; Agustín Ciapponi, et al., *Safety of COVID-19 vaccines during pregnancy: A systematic review and meta-analysis*, 41 Vaccine 25 (June 2023) (conducting a systematic review and *meta*-analysis of, among other things, clinical literature and COVID-19 vaccine studies involving 309,164 pregnant persons, mostly exposed to mRNA vaccines, to evaluate the safety of administering COVID-19 vaccines during pregnancy and finding that these studies "showed no association with adverse

recently published meta-analysis includes 67 studies with over 1.8 million women evaluated and noted no effect of COVID-19 vaccination on miscarriage or preterm birth prior to 37 weeks.[4] Additionally, vaccinated pregnant women and their infants had reduced odds of COVID-19 related hospital admission.

12. The Department of Health and Human Services ("HHS") has studied, analyzed, and published recommendations regarding the safety and efficacy of the administration of the COVID-19 vaccine during pregnancy since as early as December 2020.[5] Since then, pregnant people have consistently been included in broader COVID-19 vaccination recommendations.

13. Similar evidence-based, peer-reviewed, scientific research has consistently shown that the COVID-19 vaccine is a safe and effective way to prevent pregnant people, who have a higher risk of severe illness from COVID-19, from contracting the disease.[6] In fact, at the June 25, 2025 ACIP meeting, CDC staff closely monitoring studies regarding potential adverse effects of

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outcomes, regardless of the vaccine or the trimester of vaccination"), attached as **Exhibit D**; Torri D. Metz, et al., *Disease Severity and Perinatal Outcomes of Pregnant Patients With Coronavirus Disease 2019 (COVID-19)*, 137 OBSTETRICS & GYNECOLOGY 571 (April 2021), attached as **Exhibit E**.

[4] *See, e.g.*, Silvia Fernández-García, et al., *Effectiveness and safety of COVID-19 vaccines on maternal and perinatal outcomes: a systematic review and meta-analysis*, BMJ Global Health 1,6 (2024), attached as **Exhibit F**.

[5] The MMWR published in December 2020 referred providers consulting with pregnant patients regarding the COVID-19 vaccination to materials stating, "[i]f pregnant people are part of a group that is recommended to receive a COVID-19 vaccine (e.g., healthcare personnel), they may choose to be vaccinated." *See* CDC, *Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States* (December 30, 2020), attached as **Exhibit G**; *see also* Sara E. Oliver et al., *The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine—United States, December 2020*, 69 *Morbidity & Mortality Weekly Rep.* 1922, 1923 (Dec. 18, 2020), attached hereto as **Exhibit H**.

[6] *See, e.g.*, Lakshmi Panagiotakopoulos, *Use of 2025–2026 COVID-19 Vaccines: Work Group Considerations*, CDC ACIP Meeting, at p. 11, 53 (April 15, 2025), attached as **Exhibit I**.

administering the COVID-19 vaccine during pregnancy reported that "[a]cross CDC studies, evidence shows NO increased risk of "serious adverse maternal, pregnancy, or infant outcomes resulting from the administration of the COVID-19 vaccine during pregnancy".[7]

14. Prior to the Secretarial Directive, it was standard clinical practice for maternal-fetal medicine specialists to recommend and administer the COVID-19 vaccine to pregnant individuals. That standard was based on FDA approval of the COVID-19 vaccines for pregnant people, CDC guidance, clinical trial data, and real-world effectiveness. I have therefore consistently recommended administration of the COVID-19 vaccine to my patients. Now, I am placed in an ethical and legal dilemma: Do I continue to follow best medical practices and risk being out of alignment with the Directive, or do I follow the Directive and knowingly deny patients recommended care?

15. The May 19 Secretarial Directive to withdrawing the universal recommendation for COVID-19 vaccination during pregnancy directly contradicts the standard of care and clinical guidance that I and other SMFM members rely on to deliver safe and effective care to our high-risk pregnant patients. This change is currently undermining the patient-provider relationship, puts my decision-making as a physician at risk, and sows confusion among my patients about whether COVID-19 vaccination is necessary or advisable.

16. I am particularly concerned that the May 19 Secretarial Directive withdrawing COVID-19 vaccine recommendation for pregnant women undermines the credibility of my

[7] Sarah Meyer, *Update on CDC's COVID-19 Vaccine Safety Monitoring*, CDC ACIP Meeting, at p. 29 (June 25, 2025) (emphasis in original), attached hereto as **Exhibit J**; *see also* Ex. C ("Maternal vaccination has been shown to protect infants <6 months of age from severe outcomes of COVID-19."); Adam MacNeil, *Current Epidemiology of COVID-19*, CDC ACIP Meeting, at p. 18 (June 25, 2025), attached hereto as **Exhibit K** ("Infants <6 months experience high rates of severe COVID19 disease.").

medical advice and the trust that is critical in my conversations with patients. I regularly counsel patients on the safety and efficacy of the COVID-19 vaccine, which I consider the proper standard of care, which is advice that is now at odds with the May 19 Secretarial Directive on the COVID-19 vaccine. I am put in an impossible position to choose between what I believe to be the standard of care is for me as a physician and what HHS believes is the standard of care for my high-risk pregnant patients. This decreases patient trust in the COVID-19 vaccine and other vaccines, and is undermining the trust my patients have in my recommendations that are in their best interest to save their lives from COVID-19.

17. As a direct result of the May 19 Secretarial Directive, I have already encountered patients expressing concern and confusion now with COVID-19 vaccines. Moreover, I have observed that among my patients there has been a rise in vaccine skepticism generally. In addition, my patients have expressed a concern that they would not be able to obtain a COVID-19 booster or do not have the resources to absorb the out-of-pocket costs if their health insurance plans no longer cover the COVID-19 vaccine. These concerns did not arise before HHS withdrew its COVID-19 recommendation for pregnant women.

18. These immediate burdens fall disproportionately on my pregnant patients with comorbidities such as diabetes, hypertension, and asthma, who are at elevated risk of complications from COVID-19. These are the same patients most in need of the COVID-19 vaccine protection.

19. During the COVID-19 pandemic, I cared for many pregnant patients hospitalized with severe COVID-19 respiratory illness before vaccines were available and even after the vaccine was available. These experiences deeply inform my commitment to COVID-19 vaccination as a critical tool to protect my patients and their babies' health.

20. After the introduction of the COVID-19 vaccine in our community, I observed a noticeable decline in severe illness among my pregnant patients with COVID-19. Most of my patients who received the COVID-19 vaccine and tested positive for the virus experienced only mild cold-like symptoms and did not require hospitalization. This aligns with the broader peer-reviewed scientific literature and strongly supports the standard of care that requires continued COVID-19 vaccination during pregnancy.

21. I am also concerned about the broader ripple effects of the May 19 Secretarial Directive withdrawing the recommendation for COVID-19 vaccination for my pregnant patients. If pregnant women forego the COVID-19 vaccine, or do not have access, they will not be able to transfer antibodies to their fetuses, leaving newborns and infants under six months of age at an increased risk for contracting COVID-19. In addition, several of my patients have now begun to question other standard pregnancy vaccinations—such as Tdap and influenza—as a result of HHS's recent misinformation surrounding vaccine ingredients and recommendations for pregnant women. In addition, if vaccination rates fall, the chances that COVID viruses will mutate increases; for example, this is what we observed when the Delta variant of COVID emerged in 2021. The result of HHS's directives removing vaccine recommendations for pregnant women is an erosion of my patients' trust in vaccination recommendations across the board, not just for COVID-19. This puts both pregnant patients and their newborns at risk and threatens public health efforts long championed by SMFM.

22. I understand that SMFM is a party to litigation challenging HHS's directive withdrawing recommendation for COVID-19 vaccination for pregnant women, and I submit this declaration in support of their complaint and motion for preliminary injunction. These organizations represent clinicians like me who are being forced to choose between following well-

supported professional guidelines or inconsistent and harmful federal directives. This harms my professional autonomy, burdens my clinical judgment, and undermines my ability to protect the health of my patients.

23. For all these reasons, I ask the Court to prevent the serious, irreparable harm that HHS's directive withdrawing the recommendation for COVID-19 vaccination for my pregnant patients is immediately and presently inflicting on me as a physician and the patients that I presently treat.

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

Executed on this 29th day of July, 2025.

Dr. Patrick S. Ramsey, MD, MSPH

Docusign Envelope ID: 5B19DDD4-BEBF-468F-90EE-EDA8E40D12EC

EXHIBIT A

Docusign Envelope ID: 5B19DDD4-BEBE-460E-90EE-EDA8E40D12EC

SECRETARIAL DIRECTIVE ON PEDIATRIC COVID-19 VACCINES FOR CHILDREN LESS THAN 18 YEARS OF AGE AND PREGNANT WOMEN

May 19, 2025

The Department of Health and Human Services (HHS) continually considers and evaluates available science and evidence related to the safety and effectiveness of all currently available Food and Drug Administration (FDA) approved or authorized vaccines, and any risks of severe disease, hospitalization, and death to certain populations.

By Secretarial Directive on June 18, 2022, HHS ratified the Centers of Disease Control and Prevention (CDC) recommendations concerning use of Pfizer- BioNTech and the Moderna COVID-19 vaccines in the U.S. population for children ages six months through five years, consistent with the parameters of the Emergency Use Authorizations (EUAs) issued by FDA, for the Pfizer- BioNTech and the Moderna COVID-19 vaccines.[1]

By Secretarial Directive on June 24, 2022, HHS ratified the Centers of Disease Control and Prevention (CDC) recommendations concerning use of COVID-19 vaccines in the U.S. population for children ages six through 17 years, consistent with the parameters of EUAs issued by FDA.

The CDC also currently recommends the COVID-19 vaccine during pregnancy.[2]

Based on a review of the recommendation of the FDA and National Institutes of Health (NIH), I have determined that the known risks associated with use of COVID-19 vaccines in healthy U.S. children ages six months to 17 years do not outweigh the purported benefits of the vaccine. Accordingly, the HHS Secretarial Directives ratifying CDC recommendations for use of COVID-19 vaccines for children ages six months to 17 years and are rescinded.

Based on a review of the recommendation of the FDA, I have similarly determined that the lack of high-quality data demonstrating safety of the mRNA vaccines during pregnancy combined with the uncertainty of the benefits of vaccination pose potential risks to the mother and developing baby. Therefore, the CDC recommendation that pregnant women receive the COVID-19 vaccine is rescinded.

Accordingly, the CDC is directed to remove COVID-19 vaccines from the recommended Child and Adolescent Immunization Schedule by Age and recommended vaccines during pregnancy, as noted above.

Robert F. Kennedy, Jr.
Secretary

[1] The Pfizer and Moderna vaccines are currently approved by the FDA for children 12 years of age and older.
[2] https://www.cdc.gov/vaccines-pregnancy/recommended-vaccines/index.html.

EXHIBIT B

Society for Maternal-Fetal Medicine

(/)

SMFM Reaffirms COVID-19 Vaccination Recommendations During Pregnancy

May 28, 2025

News (/news/press)

As the experts in high-risk pregnancy, the Society for Maternal-Fetal Medicine (SMFM) strongly reaffirms its recommendation that pregnant patients receive the COVID-19 vaccine. Pregnancy increases the risk of developing severe illness compared with nonpregnant patients. Maternal immunization remains the best way to reduce maternal, fetal, and infant complications from COVID-19 infection, and is safe to be given at any point during pregnancy. Maternal immunization is also associated with improved infant outcomes and decreased complications, including maternal and infant hospitalizations.

SMFM recommends that all people who are considering pregnancy, pregnant, recently pregnant, or breastfeeding receive vaccination against COVID-19. Surveillance data collected since the beginning of the COVID-19 pandemic, which started in 2020, clearly demonstrates the safety and efficacy of mRNA vaccines in pregnancy.

All physicians and other health care partners, along with health insurers, should continue recommending COVID-19 vaccination to pregnant patients. Maternal immunization is proven to protect patients and their infants against severe illness and death from infectious diseases.

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About SMFM

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EXHIBIT C

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SYSTEMATIC REVIEW OPEN

Systematic review and meta-analysis of neonatal outcomes of COVID-19 vaccination in pregnancy

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BACKGROUND: The safety of coronavirus disease 2019 (COVID-19) vaccines during pregnancy is a particular concern. Here, we addressed the neonatal outcomes after maternal vaccination of COVID-19 during pregnancy.
METHODS: We systematically searched PubMed, EMBASE, and the WHO COVID-19 Database for studies on neonatal outcomes after maternal COVID-19 vaccination from inception to 3 July 2022. Main neonatal outcomes were related to preterm, small for gestation (SGA), NICU admission, low Apgar score at 5 min (<7), and additional neonatal outcomes such as gestation <34 weeks, low birth weight and some neonatal morbidity were all also analyzed.
RESULTS: A total of 15 studies were included. We found that maternal vaccination during pregnancy was related to the reduction rates of Preterm, SGA, Low Apgar score at 5 min (<7). In addition, there was no evidence of a higher risk of adverse neonatal outcomes after maternal vaccination of COVID-19 during pregnancy, including NICU admission, preterm birth with gestation <34 weeks, low birth weight, very low birth weight, congenital anomalies, and so on.
CONCLUSIONS: COVID-19 vaccination in pregnant women does not raise significant adverse effects on neonatal outcomes and is related to a protective effect on some neonatal outcomes.

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IMPACT:

- Present study has addressed the neonatal outcomes after maternal vaccination of COVID-19 during pregnancy.
- COVID-19 vaccination in pregnant women does not raise significant adverse effects on neonatal outcomes and is related to a protective effect on some neonatal outcomes.
- The present study could encourage pregnant women to be vaccinated against COVID-19.

INTRODUCTION

Coronavirus disease 2019 (COVID-19) is currently the most concerning health problem worldwide. Since 4 July 2022, there have been 545 million confirmed cases and 6.3 million deaths worldwide, which are reported by the WHO.[1] COVID-19 during pregnancy has already been reported to be associated with COVID-19-related morbidity and mortality.[2–5] In addition, including maternal health problems, neonates are also at increased risk of adverse outcomes.[6,7] Since the first COVID-19 vaccination was initiated by the end of 2020, the effectiveness of vaccination against COVID-19 and prevention of many complications of COVID-19 have been reported by many studies in the general population.[8–11] Although pregnant women were excluded from the initial COVID-19 vaccination trials due to safety concerns, an increasing number of following data have shown that the COVID-19 vaccination could effectively prevent severe COVID-19 in pregnant women.[12–15] Regarding the adverse events of COVID-19 during pregnancy as well as the efficacy and safety of COVID-19 vaccination during pregnancy, the WHO recommends the use of several COVID-19 vaccines in pregnant women.[16] However, COVID-19 vaccination strategies for pregnant women vary from country to country. For example, China does not recommend vaccination against COVID-19, while Israel and Europe encourage pregnant women to be vaccinated.[17–19] In addition, support from randomized controlled trials (RCTs) on the safety and effectiveness of COVID-19 vaccines as well as the optimal dosing schedule and the timing of vaccination for pregnant women are scarce due to ethical concerns. Thus, vaccination of COVID-19 during pregnancy still needs to be fully understood and explored. In terms of neonates, studies have already proven that antibodies can be transferred across the placenta, while little attention has been given paid to neonatal outcomes.[20,21] Nevertheless, several individual observational studies exploring the effects of COVID-19 vaccines on pregnancy and perinatal outcomes have included preterm birth, small for gestation (SGA), NICU admission and so on for neonatal outcomes.[22–36] Due to the importance of neonatal outcomes after

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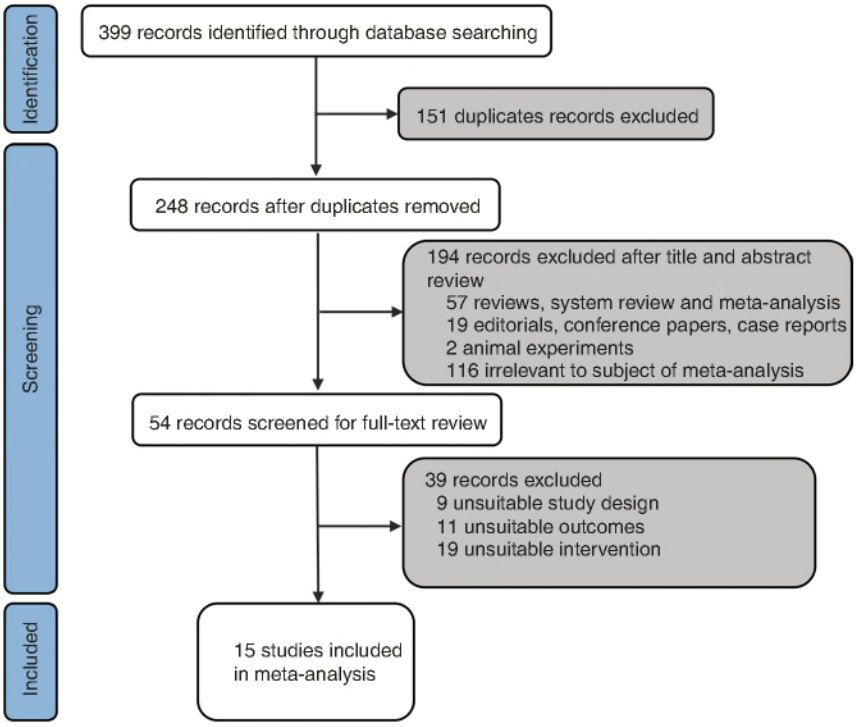


Fig. 1 Flow chart of study identification and inclusion.

maternal pregnancy, there is an immediate need for a systematic review and meta-analysis of published data to clarify differences in neonatal outcomes between COVID-19 vaccination during pregnancy and unvaccination during pregnancy.

METHODS

This systematic review and meta-analysis of neonatal outcomes of COVID-19 vaccination in pregnancy was registered with PROSPERO CRD42022343713. This study was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Supplemental table 1). Ethical approval and informed consent were not applicable for this work as it was based on previously published data.

Search strategy

We electronically searched three electronic data sources without language restrictions: PubMed, EMBASE, and the WHO COVID-19 Database, from the inception of the database to 3 July 2022. Various combinations of Medical Subject Headings and free-text aliases were searched by using the following terms: "pregnancy," "Infant, Newborn," "COVID-19," "Vaccines," and "COVID-19 Vaccines" were searched (details of the search strategy can be found in the Supplementary Methods).

Study selection

We included studies that reported the neonatal outcomes of COVID-19 vaccination during pregnancy. Studies were screened by learning the title, abstract, or full text. The main outcomes are: preterm, SGA, NICU admission, low Apgar score at 5 min (<7). The following studies were excluded: (1) irrelevant to the subject of the meta-analysis; (2) results reported in studies that did not include any main outcomes; (3) reviews, editorials, conference papers, case reports or animal experiments; and (4) studies that did not include the control group, namely, the unvaccinated pregnant group. Studies were independently screened by two reviewers following the above criteria, and discrepancies were resolved by consensus or with a third reviewer.

Data extraction

To examine the differences in neonatal outcomes between COVID-19 vaccination and unvaccination during pregnancy. The following data were extracted: country, study design, type of vaccination studied, number of pregnant women vaccinated for COVID-19, number of pregnant women unvaccinated for COVID-19, type of vaccine, number of doses received, timing of administration (trimester), vaccinated and unvaccinated pregnant women with COVID-19 infection, and single birth or not. In addition, the main neonatal outcomes: preterm, SGA, NICU admission, low Apgar score at 5 min (<7); and additional neonatal outcomes: preterm birth with gestation <34 weeks, low birth weight, very low birth weight, congenital anomalies, jaundice, low Apgar score at 1 min (<7), meconium aspiration syndrome, mechanical ventilation, seizures, hypoglycemia, sepsis, encephalopathy, intracranial hemorrhage, transient tachypnea of the newborn, respiratory distress syndrome, umbilical cord blood pH <7.1; were also extracted from studies.

Data extraction was also conducted by two reviewers independently following the context above, and discrepancies were resolved by consensus or with a third reviewer.

Quality assessment

Each study was scored according to ROBINS-I (observational)[37] independently by two reviewers, and disagreements were resolved by consensus or with a third reviewer (Supplemental Table 2).

Statistical analysis

We performed a meta-analysis to pool data from studies. All outcomes were dichotomous outcomes, and we calculated summary odds ratios and mean differences with 95% confidence intervals. Random-effects or fixed-effect models were used to pool the rates and adjusted estimates across studies separately based on the heterogeneity between estimates (I^2). Fixed-effect models were used if $I^2 \leq 50\%$, which represents low-to-moderate heterogeneity, and random-effects models were used if $I^2 \geq 50\%$, representing substantial heterogeneity. An I^2 value of 0–25%

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Table 1. Characteristics of the included studies.

Author, year, reference number	Country	Study design	Vaccinated	Unvaccinated	Data collection period	Type of vaccine	Number of doses received	Timing of administration (trimester)	Pregnancy date	Included multiple birth
Beharier et al., 2021[22]	Israel	Case control	92	140	April 2020 to March 2021	BNT162b2	≥1 doses	Second or third trimester	NA	NA
Blakeway et al., 2022[23]	UK	Cohort study	140	1188	March 1, 2020 to July 4, 2021	BNT162b2: 77.8% mRNA-1273: 12.9% Oxford-AstraZeneca: 9.3%	≥1 doses	Second trimester: 14.3% third trimester: 85.7%	Ultrasound and assisted reproductive technology	NA
Citu et al., 2022[24]	Romania	Cohort study	173	529	1 May 2021 to 1 August 2021	BNT162b2:66.4% Ad26.COV2.S:33.6%	BNT16b2:2 doses Ad26.COV2.S:1 dose	Third trimester	NA	NA
Dick (booster dose) et al.[a], 2022[25]	Israel	Cohort study	3139	3368	July to October 2021	BNT162b2 or mRNA-1273	2 doses: 90.6%; 3 doses: 9.4%	During pregnancy	Ultrasound	No
Dick et al., 2022[26]	Israel	Cohort study	2305	3313	December 2020 to July 2021	BNT162b2	≥1 doses	First trimester: 0.5% second trimester: 41.8% third trimester: 57.7%	Menstrual period or ultrasound	No
Fell et al., 2022[27]	Canada	Cohort study	22660	74,930	December 14, 2020, to September 30, 2021	BNT162b2: 79.9% mRNA-1273: 19.9% Other:1%	1 dose: 51.7%; 2 doses: 48.3%	First trimester: 0.9% second trimester: 35.5% third trimester: 63.6%	Menstrual period	Yes
Goldshtein et al., 2021[28]	Israel	Cohort study	1387	1427	December 19, 2020, to February 28, 2021	BNT162b2	≥1 doses	During pregnancy	Menstrual period	NA
Goldshtein et al., 2022[29]	Israel	Cohort study	16738	7452	March 1, 2021, to September 31, 2021	BNT162b2	≥1 doses	First trimester: 11.1% second trimester: 53.7% third trimester: 35.2%	NA	No
Halasa et al., 2022[30]	US	Case control	234	815	July 1, 2021, to March 8, 2022	BNT162b2 or mRNA-1273	Two doses	NA	NA	NA
Lipkind et al., 2022[31]	US	Cohort study	10064	36,015	December 15, 2020 to July 22, 2021	BNT162b2: 54.4% mRNA-1273: 41.4% Ad26.COV2.S: 4.2%	mRNA: 1 dose: 51.7%; 2 doses: 48.3%	First trimester: 1.7%, second trimester: 36.4% third trimester: 61.8%	Menstrual period	No
Magnus et al., 2022[32]	Sweden Norway	Cohort study	28506	129,015	January 1 2021 to January 12 2022 (Sweden), or January 15, 2022 (Norway)	BNT162b2: 71.7% mRNA-1273:26.7% AZD1222:1.7%	1 dose: 24%; 2 doses: 76%	First trimester: 3.9% second trimester: 46.1% third trimester: 50.5%	Menstrual period or ultrasound	No
Peretz-machluf et al., 2022[33]	Israel	Cohort study	3240	460	March to July 2021	BNT162b2	≥1 doses	During pregnancy	NA	No
Rottenstreich et al., 2022[34]	Israel	Cohort study	712	1063	January to April 2021	BNT162b2	2 doses	Third trimester	NA	Yes
Theiler et al., 2021[35]	US	Cohort study	140	1862	December 10 2020 to April 19, 2021	BNT162b2: 90.7% mRNA-1273: 8.6% Ad26.COV2.S: 0.7%	≥1 doses	During pregnancy	NA	NA
Wainstock et al., 2021[36]	Israel	Cohort study	913	3486	January to June 2021	BNT162b2	≥1 doses	Second or third trimester	NA	No

NA not applicable.
[a]Because refs. [25] and [26] have the same first author and published year, we have make a distinction by adding "booster dose" based on the characteristic of these studies.

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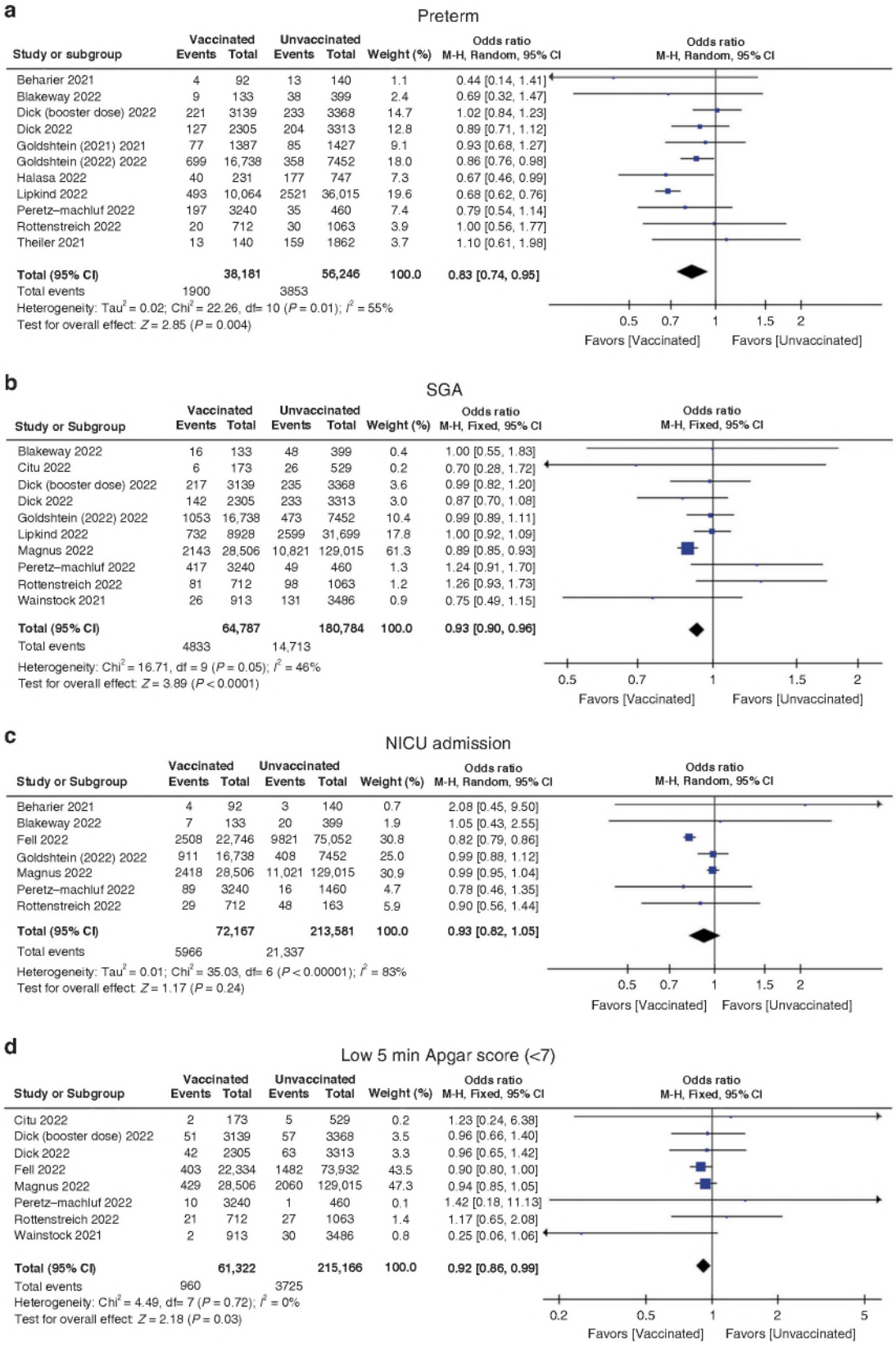


Fig. 2 Odds ratio of main neonatal outcomes when comparing maternal COVID-19 vaccination versus unvaccination during pregnancy. Forest plots showing odds ratio of **a** preterm, **b** small for gestation (SGA), **c** NICU admission, and **d** low Apgar score at 5 min (<7). Vertical ticks within the blue boxes and horizontal lines show the mean effect and 95% confidence intervals for each study. Black diamond at the bottom shows the cumulative effect with 95% confidence intervals.

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represents insignificant heterogeneity, 26–50% low heterogeneity, 51–75% moderate heterogeneity, and >75% high heterogeneity. Statistical analysis was performed by using the Cochrane Collaboration review management software (RevMan 5.4).

RESULTS

Search results and basic characteristics

Based on the search strategy, 146 studies were retrieved from PubMed, 114 studies from Embase, and 139 studies from the WHO COVID-19 Database; a total of 399 studies were identified. A total of 151 duplicates were excluded. According to the titles and abstracts, 194 studies were excluded. After selection criteria were performed based on a full-text review, 39 studies were excluded. Finally, 15 studies were included in this meta-analysis (Fig. 1).[22–36] Of the 15 studies, 2 case–control studies and 13 cohort studies reported on 90443 vaccinated pregnant women and 265063 unvaccinated pregnant women. The included studies reported data from six countries: Israel, UK, Romania, Canada, US, Sweden, and Norway (Table 1). Most of the pregnant women included in these 15 studies were vaccinated with mRNA vaccines (BNT162b2, mRNA-1273), and a very small portion of the pregnant women were vaccinated with viral vector vaccines and other vaccines (Table 1). Seven of the 15 studies reported details about the number of doses, and 8 of the 15 studies reported details about the trimester at vaccination (Table 1). However, most of these studies did not report neonatal outcomes based on the number of doses and trimester at vaccination. Nine of the 15 studies reported singleton birth, while 7 of these 9 studies excluded multiple births (Table 1). The basic characteristics of the included studies are shown in Table 1.

Meta-analysis of main neonatal outcomes

Of the 15 studies, 11 studies reported COVID-19 vaccination during pregnancy on preterm as a neonatal outcome, involving 38,181 vaccinated pregnant women and 56,246 unvaccinated pregnant women.[22,23,25,26,28–31,33–35] The pooled OR (95% CI) was 0.83 (0.74, 0.95), with an overall effect $P = 0.004$. $I^2 = 55\%$ (Fig. 2a and Table 2), which showed that the vaccine was beneficial by decreasing the rate of preterm birth. For SGA, 10 studies included this neonatal outcome.[23–26,29,31–34,36] A 7% decrease in the odds of SGA was associated with COVID-19 vaccination when compared with unvaccination during pregnancy (pooled OR 0.93; 95% CI 0.90, 0.96, 64,787 vaccinated vs. 180,784 unvaccinated, $P < 0.0001$, $I^2 = 46\%$) (Fig. 2b and Table 2). The results also suggested that there is a protective effect of COVID-19 vaccination during pregnancy. Regarding NICU admission, a total of 7 studies involving 76,127 vaccinated pregnant women and 213,581 unvaccinated pregnant women were assessed, with pooled OR 0.93, 95% CI, 0.82, 1.05, $P = 0.24$, $I^2 = 83\%$ (Fig. 2c and Table 2).[22,23,27,29,32–34] There was no significant impact of COVID-19 vaccination during pregnancy on the odds of NICU admission. For the low 5 min Apgar score (<7), an 8% decrease in the odds of SGA was associated with COVID-19 vaccination when compared with unvaccination during pregnancy (8 studies pooled OR 0.92; 95% CI 0.86, 0.99, 61,322 vaccinated vs. 215,166 unvaccinated, $P = 0.03$, $I^2 = 0\%$) (Fig. 2d and Table 2).[24–27,32–34,36] This result also indicated that COVID-19 vaccination could benefit by decreasing the odds of low Apgar score at 5 min.

Meta-analysis of additional neonatal outcomes

To deeply examine the effect of COVID-19 vaccination in neonates, we also extracted other neonatal outcomes from all 15 studies, such as preterm birth with gestation <34 weeks, jaundice, meconium aspiration syndrome, hypoglycemia, sepsis, and transient tachypnea of the newborn. As shown in Table 3, these additional neonatal outcomes were assessed with pooled meta-analysis. In general, few reported data about these additional neonatal outcomes were provided from original studies. There were 2 additional neonatal outcomes, preterm birth with gestation <34 weeks and meconium aspiration syndrome, pooled analysis from 3 studies involving 4085, 4125 vaccinated pregnant women and 1922, 2052 unvaccinated pregnant women (OR = 0.59, 95% CI, 0.33–1.05 and OR = 0.73, 95% CI, 0.34–1.56), respectively (Fig. 3 and Table 3).[23,24,33,34] In addition, other neonatal outcomes were pooled and analyzed from 2 studies, and all of the results are summarized in Table 3. The risks of encephalopathy, intracranial hemorrhage and respiratory distress syndrome were not assessable due to the low number of studies and insufficient data. According to the results from the pooled meta-analysis, there were no significant

Table 2. Meta-analysis of main neonatal outcomes in studies comparing COVID-19 vaccinated and unvaccinated pregnancies.

Neonatal outcomes	Number of studies	Vaccinated	Unvaccinated	Effect estimate	*P* value	I^2%
Preterm birth	11	38,181	56,246	0.83 (0.74, 0.95)	0.004	55
SGA	10	64,787	180,784	0.93 (0.90, 0.96)	<0.0001	46
NICU admission	7	72,167	213,581	0.93 (0.82, 1.05)	0.24	83
Low 5 min Apgar score (<7)	8	61,322	215,166	0.92 (0.86, 0.99)	0.03	0

Table 3. Meta-analysis of additional neonatal outcomes in studies comparing COVID-19 vaccinated and unvaccinated pregnancies.

Neonatal outcomes	Number of studies	Vaccinated	Unvaccinated	Effect estimate	*P* value	I^2%
Preterm birth <34 weeks	3	4085	1922	0.59 [0.33, 1.05]	0.07	10
Low birth weight <2500 g	2	16,878	9314	0.90 [0.79, 1.02]	0.10	0
Very low birth weight <1500 g	2	16,878	9314	0.79 [0.18, 3.54]	0.76	82
Congenital anomalies	2	2165	3969	0.71 [0.47, 1.06]	0.09	0
Jaundice	2	17,450	8515	0.84 [0.36, 1.95]	0.68	86
Meconium aspiration syndrome	3	4125	2052	0.73 [0.34, 1.56]	0.40	0
Mechanical ventilation	2	3952	1523	0.51 [0.26, 1.00]	0.05	0
Hypoglycemia	2	3952	1523	0.84 [0.58, 1.20]	0.33	0
Transient tachypnea of the newborn	2	3952	1523	0.66 [0.34, 1.27]	0.21	0
Fever	2	1086	4015	1.04 [0.34, 3.20]	0.94	0

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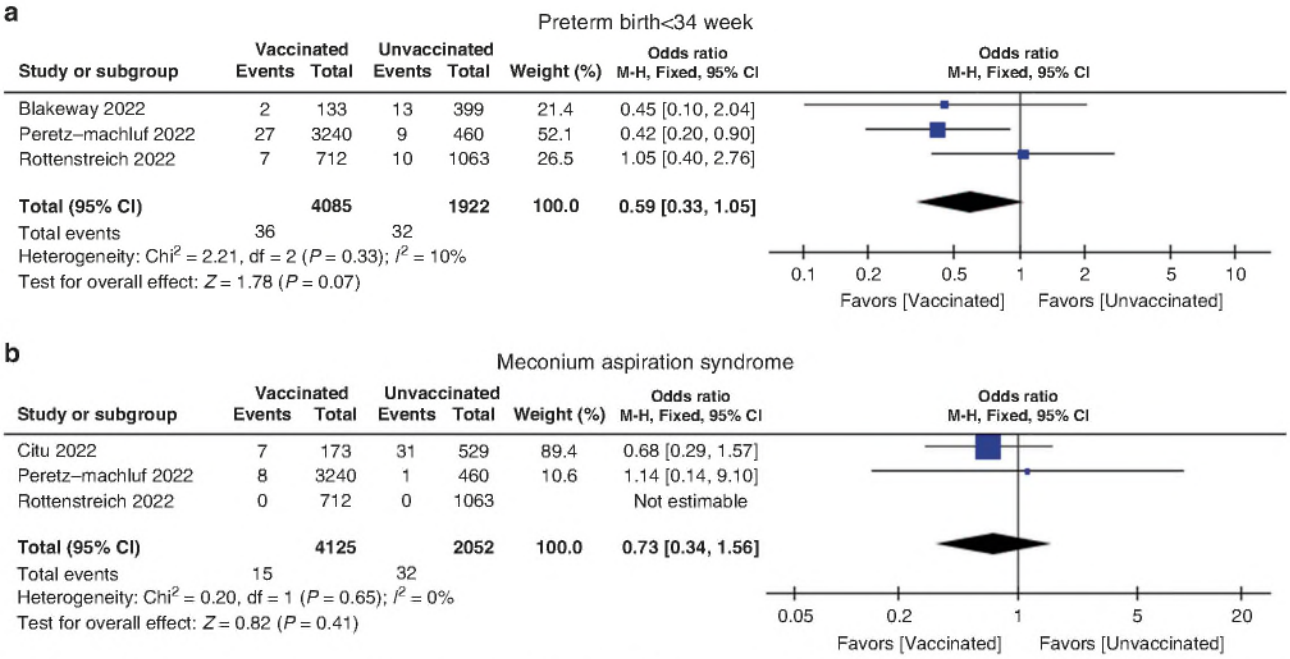


Fig. 3 Odds ratio of additional neonatal outcomes when comparing maternal COVID-19 vaccination versus unvaccination during pregnancy. Forest plots showing odds ratio of **a** preterm birth with gestation <34 weeks and **b** meconium aspiration syndrome. Vertical ticks within the blue boxes and horizontal lines show the mean effect and 95% confidence intervals for each study. Black diamond at the bottom shows the cumulative effect with 95% confidence intervals.

differences between COVID-19 vaccinated and unvaccinated pregnant women in any of the additional neonatal outcomes, which suggested that COVID-19 vaccination did not increase any adverse risk for these additional outcomes.

Heterogeneity

As shown in Table 2, preterm and NICU admission had moderate and high heterogeneity, with $I^2 = 55$ and 83%, respectively. For Preterm, statistical heterogeneity was observed, which was attributable to Lipkind et al. study.[31] After excluding data from this study, the pooled meta-analysis result showed that $I^2 = 0\%$ (pooled OR 0.89; 95% CI 0.81, 0.96, 28,117 vaccinated vs. 20,231 unvaccinated, $P = 0.005$) (Supplemental Fig. 1). However, the overall effect did not change with $P < 0.05$, which still suggested that COVID-19 vaccination during pregnancy could decrease the odds of preterm birth. For NICU admission, statistical heterogeneity was observed, which was attributable to the Fell et al. study.[27] After excluding data from this study, the pooled meta-analysis result showed that $I^2 = 0\%$ (pooled OR 0.99; 95% CI 0.95, 1.03, 49,421 vaccinated vs. 138,529 unvaccinated, $P = 0.68$) (Supplemental Fig. 1). However, the overall effect did not change, with $P = 0.68$.

Subgroup analysis

We conducted a subgroup analysis of the main neonatal outcomes based on the timing of vaccination. In all of these included studies, few COVID-19 vaccinations occurred in the first trimester. Most vaccinations occurred in the second and third trimesters. We have subgrouped these data as a percentage of vaccination in the third trimester over 80% or not. As shown in Fig. 4a, vaccination in trimesters >80% had no effect on preterm infants (pooled OR 0.87; 95% CI 0.55, 1.37, $P = 0.55$, $I^2 = 0\%$), while vaccination in trimesters <80% had a protective effect on preterm infants (pooled OR 0.80; 95% CI 0.66, 0.96, $P = 0.01$, $I^2 = 80\%$). Additionally, vaccination in trimesters >80% had no effect on the low 5 min Apgar score (pooled OR 1.17; 95% CI 0.68, 2.02, $P = 0.57$, $I^2 = 0\%$), while vaccination in trimesters <80% had a protective effect on the Low 5 min Apgar score (pooled OR 0.92; 95% CI 0.86, 0.99, $P = 0.03$, $I^2 = 0\%$) (Fig. 4b).

DISCUSSION

This systematic review and meta-analysis summarized current data on neonatal outcomes after maternal COVID-19 vaccination based on observational studies. This meta-analysis consisted of 15 studies. We found that newborns would benefit from maternal vaccination of COVID-19 with a lower incidence of preterm, SGA, and low 5 min Apgar score (<7). In addition, there was no increased risk of NICU admission or other additional neonatal outcomes, such as low birth weight, meconium aspiration syndrome, mechanical ventilation, hypoglycemia, and so on. Importantly, limited data seem to identify that vaccination with COVID-19 before the third trimester may have a protective effect on preterm as well as low 5 min Apgar score.

Due to concerns about the adverse maternal and neonatal outcomes, there is still a high rate of hesitancy among pregnant women to accept COVID-19 vaccination.[38,39] Initially, there were few clinical data about the safety and effectiveness of COVID-19 vaccination during pregnancy. Then, as time passes, due to high COVID-19-related morbidity and mortality among pregnant women as well as their neonates, several countries have recommended COVID-19 vaccination during pregnancy.[16–18] Although there are few RCT clinical studies, real-world studies about the safety and effectiveness of COVID-19 vaccines for pregnant women have already suggested that vaccination has protective effects on the prevention of COVID-19 infection without increasing the risk of adverse perinatal outcomes.[12–15] Among these data, most studies focused on maternal outcomes, while neonatal outcomes were reported in a small portion. Recently, several studies about neonatal and early infant outcomes after maternal COVID-19 vaccination have already received increasing attention.[12–15,22–36] However, a comprehensive meta-analysis of neonatal outcomes after maternal COVID-19 vaccination is still lacking.

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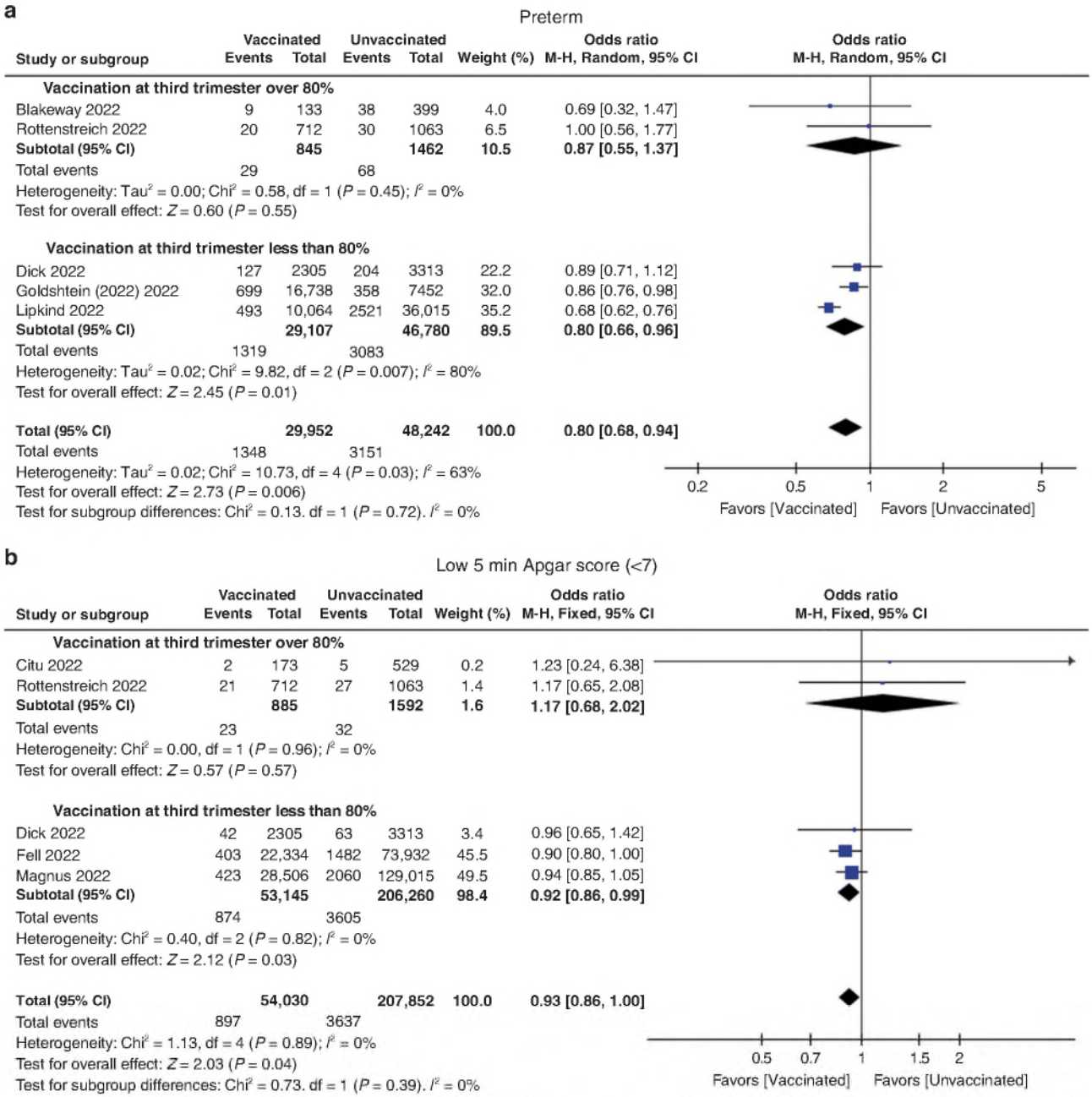


Fig. 4 Subgroup analysis in term of percentage of vaccination during pregnancy at third trimester over 80% or not. Forest plots showing odds ratio of **a** preterm and **b** low Apgar score at 5 min (<7). Vertical ticks within the blue boxes and horizontal lines show the mean effect and 95% confidence intervals for each study. Black diamond at the bottom shows the cumulative effect with 95% confidence intervals.

Thus, we conducted a systematic review and meta-analysis of published data mainly concerning neonatal outcomes after maternal COVID-19 vaccination. In the present study, the main neonatal outcomes are preterm, SGA, NICU admission, and low 5 min Apgar score (<7). In population-based larger cohorts published from Israel, Canada, Sweden, and Norway, and the US, except for data from Canada, all three other studies reported that COVID-19 vaccination during pregnancy was not significantly associated with an increased risk for adverse neonatal outcomes.[27,29,31,32] After pooling all of these data, our results showed not only no increased risk from maternal vaccination but also lower rates of adverse neonatal outcomes among those born to individuals vaccinated during pregnancy. As shown in Fig. 2 and Table 2, 17%, 7%, and 8% decreases in the odds of preterm, SGA, and low 5 min Apgar score (<7) were associated with COVID-19 vaccination when compared with unvaccination during pregnancy, respectively. These results may gain confidence to improve the acceptance of vaccines among pregnant women.

However, except for the main neonatal outcomes, more detailed additional neonatal outcomes could only be extracted from 4 studies.[23,24,33,34] Although limited data were acquired from these studies, most of these variables presented lower heterogeneity after pooling together. As shown in Table 3, there was no increased risk from maternal vaccination in any of these neonatal outcomes.

In all of 15 included studies, there are two COVID-19 vaccine platforms, the mRNA vaccine and the viral vector vaccine involved in included studies. Most of individuals were vaccinated with

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mRNA COVID-19 in included studies, though mRNA COVID-19 vaccine have already been proven to have high efficacy and to protect against different variants or strains, the major concern still persists about the uncertainty of long term adverse effect due to these are the first approved mRNA vaccines to date. As for viral vector vaccines, they have high gene transduction efficiency and high specificity of genes delivered to target cells while the current data showed the low efficacy against COVID-19.[40]

In most of the included studies, pregnant women received COVID-19 vaccination in the second and third trimesters, and few data were acquired from neonates' vaccination exposure in the first trimester. Due to antibody and cellular immune responses occurring at the early stages after vaccination, there is a question about whether vaccination at early stages of pregnancy could increase the risk of miscarriage, fetal anomalies or adverse neonatal outcomes. In previous population-based studies, no increased miscarriage risk was found after COVID-19 vaccination during early pregnancy.[41,42] However, very few studies reported neonatal outcomes according to trimester at vaccination. Thus, in the present study, based on the timing of exposure vaccination, we have subgroup studies as the vast majority of exposure vaccinations in the third trimester and the remaining part. The subgroup meta-analysis showed that vaccination before the third trimester could benefit neonates with lower rates of preterm birth, while there was neither an adverse effect nor a beneficial effect on preterm infants in the group that were primarily vaccinated in the third trimester. In fact, pregnancy received at the third trimester means that this cohort of pregnant women had already been at a late stage of pregnancy and had already excluded some preterm births in this cohort. Thus, there may be a risk of bias in this cohort. We still need future clinical studies to examine neonatal outcomes of COVID-19 vaccination based on each stage of pregnancy.

The present study has several limitations. First, due to limited data, the absence of randomized controlled trials was the biggest limitation of our meta-analysis. Second, neonatal outcomes based on different doses of vaccine, different types of vaccine and detailed trimesters at vaccination could not be deeply examined. Third, the additional neonatal outcomes were challenged by low numbers of studies. Fourth, all studies included data from developed countries, and most vaccines were mRNA vaccines, but data were not acquired from developing countries and other types of vaccines, which does not represent the true condition worldwide. Fifth, different strains could have different effect on neonatal outcomes,[43,44] due to limited information from primary data, we could not identify if there are different neonatal outcomes after maternal vaccination of COVID-19 during different strains pandemic. Even so, these limitations could encourage researchers to examine the effect of COVID-19 vaccination on neonatal outcomes according to these aspects.

The present data not only showed that COVID-19 vaccination in pregnant women does not raise significant adverse effects on neonatal outcomes but also confirmed the benefits of vaccination during pregnancy on neonatal outcomes. These neonatal outcomes including in present study focus on the adverse side. Actually, trans-placental transfer of maternal neutralizing antibodies to newborn and existence antibodies in breast milk have already been reported by several studies.[13,20] These data suggest that vaccination of COVID-19 in pregnant would not only make immunity to the pregnant individual but may also indicated a potential protective effect on the infection and vaccination of newborn.

Infection of COVID-19 has been proven to produce several adverse outcomes on pregnant women. Vaccination of COVID-19 in pregnant women is still effective method for prevention infection. However, how to relieve pregnant women's concerns on vaccination is one of important problem during vaccination. Though pregnant women were excluded from participation in initial COVID-19 vaccine trials, the persisted pandemic of COVID-19 and COVID-19 related morbidity and mortality during this population contribute to vaccination of COVID-19 in some pregnant individuals.[29] And also some national or regional policy or strategies recommends pregnant receive a COVID- 19 vaccine.[28,29] More and more data have showed benefits of COVID-19 vaccination outweigh the risks during pregnancy.[22–36] In return, professional recommendation based on these data could contribute to relieve pregnant women's concerns on vaccination. By now, the American College of Obstetricians and Gynecologists, European Board and College of Obstetrics and Gynecology, Israel Ministry of Health and so on have already recommended pregnant receive a COVID-19 vaccine.[5,17,18] In present study, we have included 15 studies. As results, the present data not only showed that COVID-19 vaccination in pregnant women does not raise significant adverse effects on neonatal outcomes but also confirmed the benefits of vaccination during pregnancy on neonatal outcomes. Our studies could provide additional data to support and improve these strategies and improve the acceptance of vaccines among pregnant women.

DATA AVAILABILITY

The data described in this manuscript are contained in published articles or available from the corresponding author upon reasonable request.

REFERENCES

1. World Health Organization. WHO coronavirus (COVID-19) dashboard. https://covid19.who.int/table (2020).
2. Jamieson, D. J. & Rasmussen, S. A. An update on COVID-19 and pregnancy. *Am. J. Obstet. Gynecol.* **226**, 177–186 (2022).
3. Mattar, C. N. et al. Pregnancy outcomes in COVID-19: a prospective cohort study in Singapore. *Ann. Acad. Med. Singap.* **49**, 857–869 (2020).
4. Male, V. SARS-CoV-2 infection and COVID-19 vaccination in pregnancy. *Nat. Rev. Immunol.* **22**, 277–282 (2022).
5. Centers for Disease Control and Prevention. Data on COVID-19 during pregnancy: severity of maternal illness. https://covid.cdc.gov/covid-data-tracker/#pregnant-population (2022).
6. Allotey, J. et al. Clinical manifestations, risk factors, and maternal and perinatal outcomes of coronavirus disease 2019 in pregnancy: living systematic review and meta-analysis. *BMJ* **370**, m3320 (2020).
7. Villar, J. et al. Maternal and neonatal morbidity and mortality among pregnant women with and without COVID-19 infection: the INTERCOVID Multinational Cohort Study. *JAMA Pediatr.* **175**, 817–826 (2021).
8. Polack, F. P. et al. Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine. *N. Engl. J. Med.* **383**, 2603–2615 (2020).
9. Voysey, M. et al. Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK. *Lancet* **397**, 99–111 (2021).
10. Heath, P. T. et al. Safety and efficacy of NVX-CoV2373 Covid-19 vaccine. *N. Engl. J. Med.* **385**, 1172–1183 (2021).
11. Sadoff, J. et al. Safety and efficacy of single-dose Ad26.COV2.S vaccine against Covid-19. *N. Engl. J. Med.* **384**, 2187–2201 (2021).
12. Luxi, N. et al. COVID-19 vaccination in pregnancy, paediatrics, immunocompromised patients, and persons with history of allergy or prior SARS-CoV-2 infection: overview of current recommendations and pre- and post-marketing evidence for vaccine efficacy and safety. *Drug Saf.* **44**, 1247–1269 (2021).
13. Garg, I., Shekhar, R., Sheikh, A. B. & Pal, S. COVID-19 vaccine in pregnant and lactating women: a review of existing evidence and practice guidelines. *Infect. Dis. Rep.* **13**, 685–699 (2021).
14. Prasad, S. et al. Systematic review and meta-analysis of the effectiveness and perinatal outcomes of COVID-19 vaccination in pregnancy. *Nat. Commun.* **13**, 2414 (2022).
15. Carbone, L. et al. COVID-19 vaccine and pregnancy outcomes: a systematic review and meta-analysis. *Int. J. Gynaecol. Obstet.* **159**, 651–661 (2022).
16. World Health Organization. WHO COVID-19 vaccines. https://www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines (2022).
17. European Centre for Disease Prevention and Control. ECDPC COVID-19 vaccination. https://www.ecdc.europa.eu/en/covid-19/prevention-and-control/vaccines (2022).

Docusign Envelope ID: 5B19DDD4-BFBF-460E-90EE-5DA8E40D12EC Case 1:25-cv-11916-BEM Document 175-39 Filed 12/23/25 Page 25 of 250

18. Israel Ministry of Health. Recommendation for pregnant women who are highly exposed to the public or with background diseases to get vaccinated. https://www.gov.il/he/departments/news/19012021-05 (2022).
19. National Health Commission of the People's Republic of China. Technical guidelines for vaccination of COVID-19 (version 1). *Chin. J. Clin. Infect. Dis.* **14**, 89–90 (2021).
20. Shen, C. J. et al. Evaluation of transplacental antibody transfer in SARS-CoV-2-immunized pregnant women. *Vaccines* **10**, 101 (2022).
21. Prahl, M. et al. Evaluation of transplacental transfer of mRNA vaccine products and functional antibodies during pregnancy and infancy. *Nat. Commun.* **13**, 4422 (2022).
22. Beharier, O. et al. Efficient maternal to neonatal transfer of antibodies against SARS-CoV-2 and BNT162b2 mRNA COVID-19 vaccine. *J. Clin. Investig.* **131**, e150319 (2021).
23. Blakeway, H. et al. COVID-19 vaccination during pregnancy: coverage and safety. *Am. J. Obstet. Gynecol.* **226**, 236.e1–236.e14 (2022).
24. Citu, I. M. et al. Immunogenicity following administration of BNT162b2 and Ad26.COV2.S COVID-19 vaccines in the pregnant population during the third trimester. *Viruses* **14**, 307 (2022).
25. Dick, A. et al. Safety of third SARS-CoV-2 vaccine (booster dose) during pregnancy. *Am. J. Obstet. Gynecol. MFM* **4**, 100637 (2022).
26. Dick, A. et al. Safety of SARS-CoV-2 vaccination during pregnancy- obstetric outcomes from a large cohort study. *BMC Pregnancy Childbirth* **22**, 166 (2022).
27. Fell, D. B. et al. Association of COVID-19 vaccination in pregnancy with adverse peripartum outcomes. *JAMA* **327**, 1478–1487 (2022).
28. Goldshtein, I. et al. Association between BNT162b2 vaccination and incidence of SARS-CoV-2 infection in pregnant women. *JAMA* **326**, 728–735 (2021).
29. Goldshtein, I. et al. Association of BNT162b2 COVID-19 vaccination during pregnancy with neonatal and early infant outcomes. *JAMA Pediatr.* **176**, 470–477 (2022).
30. Halasa, N. B. et al. Maternal vaccination and risk of hospitalization for Covid-19 among infants. *N. Engl. J. Med.* **387**, 109–119 (2022).
31. Lipkind, H. S. et al. Receipt of COVID-19 vaccine during pregnancy and preterm or small-for-gestational-age at birth - Eight Integrated Health Care Organizations, United States, December 15, 2020-July 22, 2021. *MMWR Morb. Mortal. Wkly. Rep.* **71**, 26–30 (2022).
32. Magnus, M. C. et al. Association of SARS-CoV-2 vaccination during pregnancy with pregnancy outcomes. *JAMA* **327**, 1469–1477 (2022).
33. Peretz-machluf, R. et al. Obstetric and neonatal outcomes following COVID-19 vaccination in pregnancy. *J. Clin. Med.* **11**, 2540 (2022).
34. Rottenstreich, M. et al. Covid-19 vaccination during the third trimester of pregnancy: rate of vaccination and maternal and neonatal outcomes, a multicentre retrospective cohort study. *BJOG* **129**, 248–255 (2022).
35. Theiler, R. N. et al. Pregnancy and birth outcomes after SARS-CoV-2 vaccination in pregnancy. *Am. J. Obstet. Gynecol. MFM* **3**, 100467 (2021).
36. Wainstock, T., Yoles, I., Sergienko, R. & Sheiner, E. Prenatal maternal COVID-19 vaccination and pregnancy outcomes. *Vaccine* **39**, 6037–6040 (2021).
37. Sterne, J. A. et al. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. *BMJ* **355**, i4919 (2016).
38. Du, M., Tao, L. & Liu, J. The association between risk perception and COVID-19 vaccine hesitancy for children among reproductive women in China: an online survey. *Front. Med.* **8**, 741298 (2021).
39. Goncu Ayhan, S. et al. COVID-19 vaccine acceptance in pregnant women. *Int. J. Gynaecol. Obstet.* **154**, 291–296 (2021).
40. Al-Jighefee, H. T. et al. COVID-19 vaccine platforms: challenges and safety contemplations. *Vaccines* **9**, 1196 (2021).
41. Kharbanda, E. O. et al. Spontaneous abortion following COVID-19 vaccination during pregnancy. *JAMA* **326**, 1629–1631 (2021).
42. Citu, I. M. et al. The risk of spontaneous abortion does not increase following first trimester mRNA COVID-19 vaccination. *J. Clin. Med.* **11**, 1698 (2022).
43. Adhikari, E. H. et al. COVID-19 cases and disease severity in pregnancy and neonatal positivity associated with Delta (B.1.617.2) and Omicron (B.1.1.529) variant predominance. *JAMA* **327**, 1500–1502 (2022).
44. Adhikari, E. H., SoRelle, J. A., McIntire, D. D. & Spong, C. Y. Increasing severity of COVID-19 in pregnancy with Delta (B.1.617.2) variant surge. *Am. J. Obstet. Gynecol.* **226**, 149–151 (2022).

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AUTHOR CONTRIBUTIONS

Study concept and design: F.D. and J.Z.; extraction, analysis and interpretation of data: D.Z., Z.C., L.Z., and T.H.; drafting of the manuscript: F.D.; critical revision of the manuscript: F.D., Q.G., and G.L.; statistical analysis: F.D., D.Z., and H.T.

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COMPETING INTERESTS

The authors declare no competing interests.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

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EXHIBIT D

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Review

Safety of COVID-19 vaccines during pregnancy: A systematic review and meta-analysis

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ABSTRACT

Background: Assessment of COVID-19 vaccines safety during pregnancy is urgently needed.
Methods: We conducted a systematic review and *meta*-analysis to evaluate the safety of COVID-19 vaccines, including their components and technological platforms used in other vaccines during pregnancy and animal studies to complement direct evidence. We searched literature databases from its inception to September 2021 without language restriction, COVID-19 vaccine websites, and reference lists of other systematic reviews and the included studies. Pairs of reviewers independently selected, data extracted, and assessed the risk of bias of the studies. Discrepancies were resolved by consensus. (PROSPERO CRD42021234185).
Results: We retrieved 8,837 records from the literature search; 71 studies were included, involving 17,719,495 pregnant persons and 389 pregnant animals. Most studies (94%) were conducted in high-income countries, were cohort studies (51%), and 15% were classified as high risk of bias. We identified nine COVID-19 vaccine studies, seven involving 309,164 pregnant persons, mostly exposed to mRNA vaccines. Among non-COVID-19 vaccines, the most frequent exposures were AS03 and aluminum-based adjuvants.

A *meta*-analysis of studies that adjusted for potential confounders showed no association with adverse outcomes, regardless of the vaccine or the trimester of vaccination.

Neither the reported rates of adverse pregnancy outcomes nor reactogenicity exceeded expected background rates, which was the case for ASO3- or aluminum-adjuvanted non-COVID-19 vaccines in the proportion *meta*-analyses of uncontrolled studies/arms. The only exception was postpartum hemorrhage after COVID-19 vaccination (10.40%; 95% CI: 6.49–15.10%), reported by two studies; however, the comparison with non-exposed pregnant persons, available for one study, found non-statistically significant differences (adjusted OR 1.09; 95% CI 0.56–2.12). Animal studies showed consistent results with studies in pregnant persons.
Conclusion: We found no safety concerns for currently administered COVID-19 vaccines during pregnancy. Additional experimental and real-world evidence could enhance vaccination coverage. Robust safety data for non-mRNA-based COVID-19 vaccines are still needed.

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1. Background

The unique physiological changes that occur in the immune and cardiopulmonary systems during pregnancy place pregnant persons at a higher risk of severe outcomes if infected with viral respiratory pathogens.[1-5] Reviews addressing pregnancy and COVID-19 report that intensive care unit (ICU) admission rates and requirements for invasive ventilation in this population are higher than in nonpregnant persons.[1] Pregnant persons with pre-existing comorbidities, obesity, or advanced maternal age are at an even higher risk of severe COVID-19.[6,7] Although initial phase 1–3 studies of COVID-19 vaccines excluded pregnant persons, more recently, efficacy trials of COVID-19 vaccines considered including pregnant persons[8], and only limited human data on COVID-19 vaccine safety when used during pregnancy were available for individual products at the time of emergency use authorization.[6] A survey conducted in 16 countries[9] reported that one of the top three reasons for pregnant persons declining COVID-19 vaccination, even if the vaccine was safe and freely available, was that they did not want to expose their developing baby to any possible harmful side effects.

As of the start of 2023, 10 vaccines have received an Emergency Use Listing from the WHO. Despite limited available safety data, many countries recommend COVID-19 vaccination in pregnant persons [10-12] on the basis that the benefits of vaccination are likely to outweigh the theoretical risks. Consequently, it is imperative to identify and evaluate safety signals for COVID-19 vaccines as early as possible. Given the urgency of the issue for current public health practice globally, we performed a rapid review and interim analysis of the components and platforms of selected vaccines for the COVID-19 Vaccines Global Access-Maternal Immunization Working Group (COVAX-MIWG) up to August 2020 and found no safety concerns (albeit predominantly based on indirect evidence from COVID-19 components and platforms used in other vaccines).[13] Some studies reported that low income and low education are associated with vaccine hesitancy during pregnancy.[14] More high-quality safety and surveillance studies plus clear communication to pregnant persons and health providers are needed and the results of this systematic review can support informed communication.To assist pregnant persons and their health care providers in making informed decisions, we now report a systematic review and *meta*-analysis of adverse events and pregnancy outcomes associated with COVID-19 vaccination in pregnancy. Our primary objective considered authorized COVID-19 vaccines in pregnant persons. As a secondary objective, we considered COVID-19 vaccine components and platforms used in other maternal vaccines, including animal studies, in order to address direct evidence gaps. A living systematic review and *meta*-analysis of Covid-19 vaccines for pregnant persons, by our author group, can be found in its Internet link (https://safeinpregnancy.org/lsr/).

1.1. Objectives

To study the association of COVID-19 vaccines, or their components/platforms used in other vaccines, with vaccine-related adverse events, including reactogenicity, and adverse obstetric and neonatal outcomes.

2. Methods

For this systematic review and *meta*-analysis, we followed the Cochrane methods[15,16] and the 2020 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement [17] for reporting results (see **Appendix A, Supplementary 1** PRISMA checklist). This review was registered in PROSPERO (CRD42021234185).

2.1. Inclusion criteria

We included comparative and non-comparative study designs in pregnant persons. Case-series were only included if they reported>50 exposed pregnant persons. We also included experimental studies of any sample size with exposed pregnant animals. We excluded systematic reviews (SRs) and narrative reviews but

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explored their reference lists as an additional primary study source. Passive surveillance studies with no clear denominator and articles with unavailable full text were also excluded from the review. No language or geographic restrictions were applied.

The primary exposures or interventions of interest were vaccination with a COVID-19 vaccine authorized by the World Health Organization (WHO) and/or authorized or approved by any national regulatory authority up to December 2021. As a secondary objective, we considered exposure to other vaccines used during pregnancy that use the platforms (protein/subunit, vectored, nucleic acid/mRNA-LNP) or components (antigen, vehicle, construct, adjuvants, lipid nanoparticles, etc.) used by COVID-19 vaccines in use or late-stage development, including AS03 (used in the CoV2 preS dTM-AS03 vaccine [Sanofi Pasteur]), aluminum (used in multiple vaccines including CoronaVac [Sinovac] and Covaxin [Bharat Biotech]), CpG 1018 and Matrix-M (see **Appendix A, Supplementary** Table 2 for full details).[18] These components can be found in influenza vaccines (including Arepanrix, Pandemrix, FLUAD), Tdap, and hepatitis A and B vaccines (Havrix, Engerix-B, Twinrix, Recombivax, etc.). The study was included if at least one of these exposures was explicitly described in the report. This approach, illustrated in Fig. 1 of the **Appendix A, Supplementary 1**, is aimed to provide the most complete direct and indirect evidence to assist health decision-making.

Primary studies using experimental and observational epidemiological study designs were deemed eligible for inclusion if adverse obstetric or neonatal outcomes (e.g., miscarriage, stillbirth, preterm birth, low birth weight, neonatal death, birth defects, congenital infections) were assessed in pregnant persons exposed to any of the defined exposures during pregnancy and compared to pregnant persons with no such exposure. Perinatal outcomes were based on 25 standardized case definitions developed by the Global Alignment of Immunization Safety Assessment in Pregnancy (GAIA) of prioritized obstetric and neonatal outcomes.[19] We considered outcomes concerning exposure to the vaccines based on the reported gestational age at vaccination (based on validated methods including ultrasound or last menstrual period [LMP] for human studies).

Other vaccine-related adverse events (AEs) and serious adverse events unrelated to pregnancy were also assessed. An AE was defined as any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product regardless of its causal relationship to the study treatment[20]. Injection site reactions, systemic reactions, medically attended adverse events (MAEs), adverse events of special interest (AESIs), anaphylaxis, and other post-vaccination medical events were also assessed. The operative definition of each specific AE has been reported elsewhere (PROSPERO- CRD42021234185).

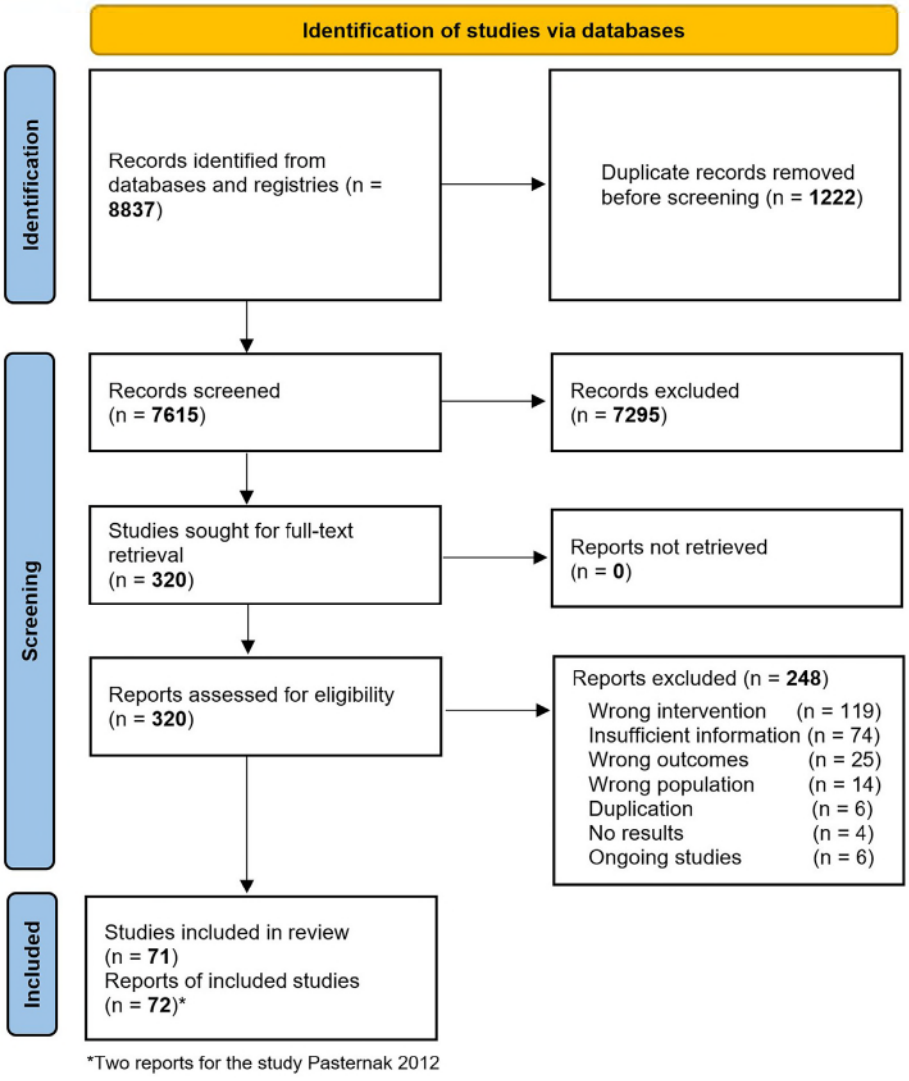


Fig. 1. Study flow diagram.

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2.2. Search strategy

We searched published and unpublished studies, without restrictions on language or publication status, from inception date to September 15, 2021 (see **Appendix A, Supplementary Methods** for search terms) in the Cochrane Library databases (from 1996), MEDLINE (from 1946), EMBASE (from 1974), Latin American and Caribbean Health Sciences Literature (LILACS; (from 1982), Science Citation Index Expanded (SCI-EXPANDED; from 19964), Global Health (from 1910), China Network Knowledge Information (CNKI; from 2015), WHO Database of publications on SARS CoV2 (from 2020), TOXLine (from 1972), preprint servers (ArXiv, biorXiv, medRxiv, search.bioPreprint), and COVID-19 research websites (PregCOV-19LSR, Maternal and Child Health, Nutrition: John Hopkins Centre for Humanitarian health, the LOVE database). The reference lists of relevant primary studies in systematic reviews retrieved by the search strategy and active COVID-19 pregnancy registries with data on vaccination during pregnancy were assessed to capture reported adverse events/safety data. The US FDA, the European Medicines Agency (EMA), and clinical trials websites were also searched. Additionally, we contacted authors and experts in the field to obtain extra information, as necessary.

3. Selection of studies, data extraction, and assessment of the risk of bias

Pairs of authors independently screened each identified record by title and abstract and retrieved full texts of the potentially eligible studies. Pairs of review authors independently examined the full-text articles for compliance with the inclusion criteria. We resolved any disagreements by discussion. The selection process was conducted through COVIDENCE[21], a software for systematic reviews.[17] If studies had multiple publications, we collated the various reports of the same study under a single study ID with multiple references.

Pairs of review authors independently extracted data from eligible studies using a data extraction form designed and pilot-tested by the authors. Any disagreements were resolved by discussion. Extracted data included study methods, population, exposures, comparisons and outcome data. We also extracted the risk of bias items for each study type described in the **Appendix A, Supplementary Methods**. We independently assessed the risk of bias of the included clinical trials using the Cochrane risk of bias assessment tool for Randomized Controlled Trials (RCT).[22] We used the Cochrane EPOC group tools[23] to assess controlled before-after studies (CBAs), nationwide uncontrolled before-after studies (UBAs), interrupted time series (ITSs), and controlled-ITSs (CITSs). We rated the risk of bias in each domain as "low", "high", or "unclear". For observational cohort, case-control, cross-sectional, and case-series studies we used the NIH Quality Assessment Tool.[24] After answering the different signaling questions "Yes", "No", "Cannot determine", "Not applicable", or "Not reported", the raters classified the study quality as "good", "fair", or "poor". For consistency with the other designs, we use the classifications "low", "unclear" or "high" risk of bias, respectively. Full assessment criteria for each study type are provided in the **Appendix A, Supplementary Methods**.

3.1. Data synthesis

Data were collected from RCTs, observational, comparative, and non-comparative studies, including registries. We conducted a paired *meta*-analysis for outcomes for which studies were deemed comparable. Given the potentially different effects on pregnancy outcomes, we conducted a subgroup analyses by the trimester of exposure and by adjuvant/component (for non-COVID-19 maternal vaccines). For maternal vaccines containing AS03 or aluminum, we *meta*-analyzed outcomes compared with no-exposure or exposure to other vaccines without these adjuvants. Sensitivity analyses were conducted, excluding studies with high risk of bias.

We described the effect estimates as reported by the authors of the included studies. For dichotomous data, we used the numbers of events in the control and intervention groups of each study to calculate risk ratios (RRs), hazard ratios (HRs), or Mantel-Haenszel odds ratios (ORs). We applied the generic inverse variance method in RevMan 5.4 and DerSimonian-Laird weights in random effects models.[25,26] For each study included in the *meta*-analyses, we opted to use adjusted effect measures (e.g. by age, smoking status, parity, body mass index, etc.) over unadjusted estimates where possible. We summarized the GRADE certainty of evidence from comparative studies in Summary of findings' tables [15,27] – estimates were downgraded for serious and very serious imprecision if 95% confidence intervals (CIs) crossed the null effect and the limits were < 0.95 and/or > 1.05, and < 0.5 and/or > 1.50, respectively; and for serious and very serious inconsistency if I^2 values were > 60% and > 75%, respectively.

To estimate the prevalence of the adverse events and pregnancy-related outcomes across the included studies, we conducted a proportional *meta*-analysis using the StatsDirect statistical software that applies an arcsine transformation to stabilize variance in proportions[28]. These data were analyzed in the context of background rates for neonatal and obstetric outcomes.

3.2. Results

We retrieved 8,837 records, of which 320 were eligible for full-text review. A total of 248 studies were excluded, mainly because they did not meet the inclusion criteria of exposure or intervention (119) or insufficient information (74). We included 71 clinical and preclinical studies (72 reports), 61 involving pregnant persons (N = 17,719,495)[29-90], and 10 involving pregnant animals (N = 389)[91-100] (The framework for evidence presentation is illustrated in **Appendix A, Supplementary** Fig. 1). The list of excluded studies and the reasons for exclusion are presented in **Appendix A, Supplementary** Table 3.

4. Description of studies

The characteristics of included studies are described in Table 1 (for COVID-19 vaccines) and **Appendix A,** Supplementary Table 4 (for non-COVID-19 vaccines). The most frequent study design was cohort studies (n = 37), followed by RCTs (n = 13), surveillance studies (n = 12), registry analyses (n = 7), cross-sectional study (n = 1), and non-RCT (n = 1). All studies reported a follow-up until delivery, but eight reported a mean follow-up of two months beyond delivery. Twenty-one (30%) of the included studies reported a relative measure effect comparing vaccinated and unvaccinated pregnant persons.[32,33,38,39,45,46,48,50,52-54,60,61,66,67,76,79-83] Ten out of the 71 studies (14%) were abstracts[41,47,51,55,56,58,73,79,80,82], and ten were conducted on animals (14%).[91-100] Only six out of 71 studies (8%) involved low- and middle-income countries (LMICs).

We identified nine COVID-19 vaccine studies, of which seven were conducted in pregnant persons and two were conducted in pregnant animals, with total population sizes of 309,164 and 133, respectively (Table 1). The seven studies in pregnant persons were conducted in the USA (n = 4), Israel (n = 2), and the UK (n = 1), and reported on exposures concerning any of the three trimesters of pregnancy (n = 4) or the first and second trimester (n = 3). Five studies reported exclusively on exposure to mRNA-containing lipid

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Table 1
Characteristic of included studies for COVID-19 vaccines.

ID	Country	Year	Type of surveillance	Trimester	Vaccine	Population	N (Ex/No Ex)	Study design	Effect measures	Outcomes	Safety concerns
Pregnant persons											
Bookstein 2021 [31]	Israel	2021	Active	1 + 2 + 3	BNT162b2	Pregnant p	390	Surveillance	IR	Mat, Neo, AEFI	No
Zauche 2021[85]	USA	2020–21	Active	1 + 2	BNT162b2, mRNA-1273	Pregnant p	2,456	Registry	IR	Mat.	No
Goldshtein 2021 [40]	Israel	2020–21	Active	1 + 2 + 3	BNT162b2	Pregnant p	15,060 (7,530/7,530)	Cohort study	IR	Mat, Neo	No
Gray 2021[41]	USA	2021	Active	1 + 2 + 3	BNT162b2, mRNA-1273	Pregnant p	84	Cohort study	IR	Mat, Neo, AEFI	No
Kharbanda 2021 [49]	USA	2020	Active	1 + 2	BNT162b2, mRNA-1273, Ad26.COV2.S	Pregnant p	271,083 (20,139/ 250,944)	Surveillance	IR, aOR	Mat.	No
Shimabukuro 2021[82]	USA	2020–21	Passive	1 + 2 + 3	BNT162b2, mRNA-1273	Pregnant p	19,252 (16,522/ 2,730)	Registry	IR	Mat, Neo, AEFI	No
Blakeway 2021 [87]	UK	2021	Active	1 + 2	BNT162b2, mRNA-1273, ChAdOx1	Pregnant p	532 (133/399)	Cohort study	IR, aOR	Mat, Neo	No
Pregnant animals											
Stebbings 2021 [94]	UK	2020	NA	NA	ChAdOx1	Animals	50 (25/25)	Non-RCT	IR	Mat, Neo.	No
Bowman 2021[89]	USA	2019-	NA	NA	BNT162b2	Animals	88 (44/44)	RCT	IR	Neo.	No

NA: Not available; **Pregnant p**: Pregnant person; **IR**: Incidence rate; **aOR**: adjusted Odds Ratio; **Mat**: Maternal; **Neo**: Neonatal; **AEFI**: Adverse Event Following Immunization.

nanoparticle (LNP) vaccines (BNT162b2 and mRNA-1273); [34,43,44,85,88] and two reported on multiple platforms (mRNA-LNP vaccines alongside the vectored vaccines Ad26.COV2-S and ChAdOx1 nCoV-19).[52,90] However, Kharbanda et al. excluded Ad26.COV2-S given that it was received only by 308 (0.2%) of pregnant persons in the study population.[52] Only 13 pregnant persons were exposed to ChAdOx1 nCoV-19), and we did not find evidence for other COVID-19 vaccines authorized by WHO or individual countries (e.g., Novavax, Sinopharm, Ad5-nCOV, or Sputnik).

A summary of the 62 studies reporting on COVID-19 vaccine components used in other vaccines is provided in **Appendix A,** Supplementary Table 4. The most frequent exposures were to the AS03 adjuvant (23 studies involving 13,846,993 pregnant persons) and aluminum-based adjuvants (31 clinical and involving 3,499,809 pregnant persons and five preclinical studies involving 214 pregnant animals).

4.1. Risk of bias in included studies

The risk of bias for the included clinical studies of COVID-19 vaccines in pregnant persons by study design is presented in **Appendix A,** Supplementary Table 5.1. After considering the responses to the 14 signaling questions, of the seven observational studies, four were rated as being of "good' overall quality, while three were rated as "fair". The risk of bias for the included studies of non-COVID-19 vaccines in pregnant persons is presented in **Appendix A,** Supplementary Table 6.1 (for observational studies) and **6.2** (for clinical trials). Out of the 57 non-COVID-19 vaccine observational studies, 19 were rated as being of "good' overall quality, 31 as "fair" and seven as "poor" quality.

4.2. Controlled studies of COVID-19 vaccines in pregnant persons

Two out of seven studies compared exposure to COVID-19 vaccines with no exposure in pregnant persons and attempted to control for potential confounders.[43,90] Blakeway et al. compared mostly mRNA-LNP vaccines (120/133; 90%) during the second and third trimester and used propensity scores calculated from the index of multiple deprivation quintile, self-reported ethnicity, antenatal medication, pregestational diabetes mellitus, maternal age, and antihypertensive medication.[90] This study reported aORs for congenital malformations (0.89; 95% CI 0.24–3.31), small for gestational age (1.00; 95% CI 0.55–1.82), and postpartum hemorrhage (PPH; 1.09; 95% CI 0.56–2.12) in exposed versus unexposed pregnant persons. The second study conducted by Goldshtein et al. compared pregnant persons receiving BNT162b2 with a matched population by age, gestational age, residential area, population subgroup, number of prior children, and having seasonal influenza vaccine.[43] The ORs were calculated for five pregnancy outcomes: spontaneous or induced abortion (1.09; 95% CI 0.84–1.40), stillbirth (0.50; 95% CI 0.05–5.51), preterm birth (0.90; 95% CI 0.66–1.23), fetal growth restriction (0.95; 95% CI 0.60–1.50), and pre-eclampsia (0.95; 95% CI 0.52–1.76). None of the estimates reported by either study (see Table 2 and Fig. 2) showed statistically nor clinically significant association with adverse outcomes, but the certainty of evidence, according to the GRADE approach, was classified as "very low".

Kharbanda et al. reported raw data on spontaneous abortions between vaccinated pregnant persons with BNT162b2 (1,128 / 20,139: 8.6%) and non-vaccinated ones (13,160 / 250,944: 8.0%).[52] Bookstein et al.[34] and Gray et al.[44] compared pregnant with nonpregnant persons. Bookstein et al.[34] found similar or lower rates of rash, fever, severe fatigue, myalgia, arthralgia, headache, local pain, swelling, and axillary lymphadenopathy following vaccination in pregnant persons than nonpregnant persons. After the second dose, paresthesia was significantly more common among pregnant persons than the nonpregnant population. There were no important differences in the rates of side effects regardless of the trimester of pregnancy, except for uterine contractions, which were significantly more common after the second dose when administered during the third trimester than during the other trimesters. No differences were noted in reactogenicity across pregnant, lactating, and nonpregnant groups by Gray et al. [44].

4.3. Uncontrolled studies of COVID-19 vaccines in pregnant persons

In Table 3**,** we present a proportional *meta*-analysis from uncontrolled studies or from the active arms of RCTs regarding pregnancy and safety outcomes for COVID-19 vaccines, alongside

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Table 2
Meta-analysis and certainty of evidence for controlled studies involving COVID-19 vaccines in pregnant persons.

Outcome	Trimester Ex.	aOR (95% CI)	# Studies (Ex vs. no-Ex)	I^2	GRADE
Abortion, spontaneous or induced[mOR][40]	All	1.09 (0.84, 1.40)	1 (7530 vs 7530)	NA	Very low[1]
Stillbirth[mOR][40]	All	0.50 (0.05, 5.51)	1 (7530 vs 7530)	NA	Very low[1]
Congenital malformations[87]	2nd/3rd	0.89 (0.24 to 3.31)	1 (133 vs 399)	NA	Very low[1]
Preterm birth[mOR][40]	All	0.90 (0.66, 1.23)	1 (7530 vs 7530)	NA	Very low[1]
Small for gestational age[87]	2nd/3rd	1.00 (0.55 to 1.82)	1 (133 vs 399)	NA	Very low[1]
Fetal growth restriction[mOR][40]	All	0.95 (0.60, 1.50)	1 (7530 vs 7530)	NA	Very low[1]
Pre-eclampsia[mOR][40]	All	0.95 (0.52, 1.76)	1 (7530 vs 7530)	NA	Very low[1]
Postpartum hemorrhage[87]	2nd/3rd	1.09 (0.56 to 2.12)	1 (133 vs 399)	NA	Very low[1]

aOR: adjusted Odds Ratio; **mOR**: OR calculated from the matched study population by age, gestational age, residential area, population subgroup, number of prior children, and having a seasonal influenza vaccine (Goldshtein 2021).
in the last year; **CI**: Confidence interval; **NA**; Not applicable; **Ex**: Exposure; **1st**: first; **2nd**: second; **3rd**: third.

1. **GRADE** certainty of evidence: started "Low" due to the observational designs, and was downgraded two levels due to very serious imprecision (crossing the null effect, and 95%CI < 0.5 and/or > 1.50.

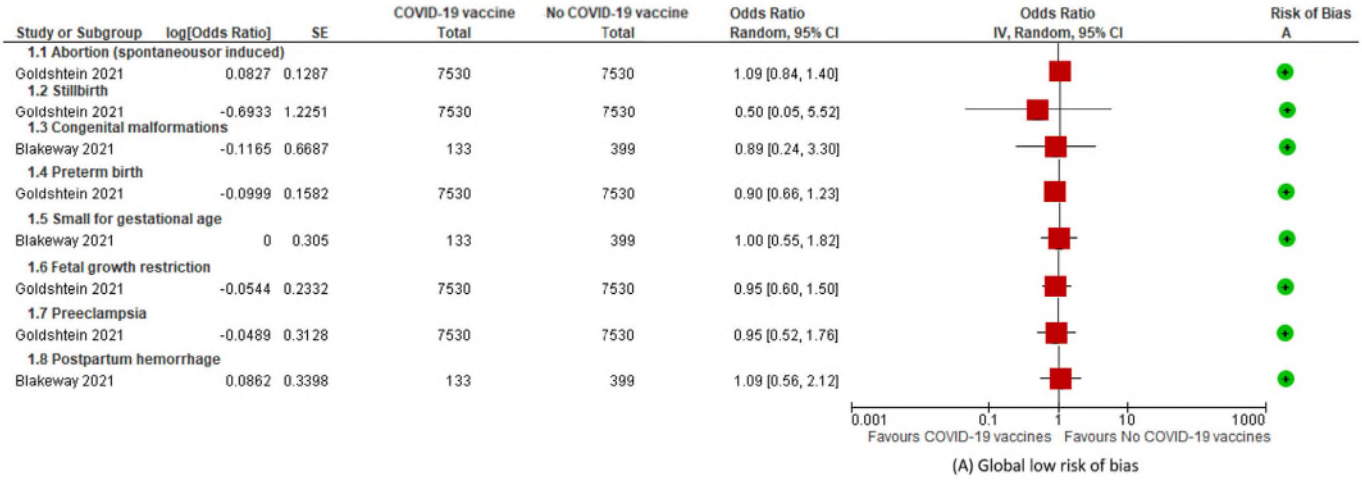


Fig. 2. Forest plots of pregnancy outcomes comparing exposure with no exposure to COVID-19 vaccines.

background rates (global and from the same countries where the studies were conducted). The estimated prevalence was 4.97% (95% CI 2.40–8.39, 5 studies) for spontaneous abortion/miscarriage (background rate [BR] 10%)[101]; 0.05 (0.00–0.20, 3 studies) for stillbirth (BR 2.9–9.6%)[102,103]; 0.49 (0.34–0.66, 2 studies) for fetal growth retardation (BR 23.8% newborns per year[104]); 7.74% (2.31–15.97, 2 studies) for gestational diabetes mellitus (BR 6–7%)[105]; 2.37% (0.15–7.17, 2 studies) for hypertensive disorders in pregnancy ranged from (BR 4–10%)[106]; 12.30% (7.31–18.4, 1 study) for small for gestational age (BR 1.2–41.5%)[107]; 5.61% (2.58–9.72, 4 studies) for preterm birth (BR 2.58–9.72) [108]; 0% (1 study) for maternal death (BR 2/100,000 livebirths) [109]; 0.43% (0.40–3.76, 1 study) for neonatal death (BR 1.4–6%) [110]; 2.32% (1.42–3.44, 2 studies) for any congenital malformation from (BR 2–4%)[111]; 0.19% (0.17–1.63, 1 study) for suspected chorioamnionitis (BR 1–4%)[112]; 0.37% (0.01–1.22, 1 study) for antenatal bleeding (BR 6%)[113]; 3.24% (2.08–4.65, 1 study) for neonatal infections (BR not available); and 1.82% (1.72–15.31, 1 study) for respiratory distress newborn (BR: 1.2–10%)[114,115].

We found a high incidence of PPH (10.40% [6.49–15.10]; 2 studies) in women who received COVID-19 vaccines during pregnancy, in comparison with the published referenced evidence (2–5%). [116] Bookstein et al.[34] included only 57 pregnant persons (of which 10.5% experienced PPH) who received two doses of the BNT162b2 vaccine and delivered during the study period. Blakeway et al. reported that 13 out of the 133 (9.8%) pregnant persons who received mRNA/viral vectored vaccines presented with PPH. [90] No maternal death rate was associated with mRNA vaccines in one study[43]. The estimated 95% CI by the random effect *meta*-analysis could range from 3.1 to 29.1 per 100,000 – very similar in absolute number to the background rate.[109].

The three most frequent non-serious adverse events with mRNA COVID-19 vaccines exposure were fatigue (50.03%), chills (36.66%), and myalgia (33.08%). Data are presently lacking on fetal death, low birth weight, neonatal encephalopathy, failure to thrive, microcephaly, systemic reactions systemic reactions, anaphylaxis, MAEs, SAEs.

We present the related forest plots, the contributing studies, and numerical outputs in **Appendix B. Forest-plots of *meta*-analysis of pregnancy outcomes**.

4.4. Controlled studies of COVID-19 vaccines in pregnant animals

Two preclinical comparative studies were conducted on pregnant animals. Following vaccination of rats with the mRNA-LNP vaccine BNT162b2, Bowman et al. documented no detrimental effects on fertility, embryo-fetal or postnatal survival, growth, physical development, or neurofunctional development in the offspring through the end of lactation.[92] Following vaccination of mice with the vectored vaccine ChAdOx1 nCoV-19, Stebbings et al. found no detrimental effects on female reproduction, fetal or pup survival, fetal external, visceral, or skeletal findings, pup

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Table 3
Proportional *meta*-analysis for uncontrolled studies involving COVID-19 vaccines in pregnant persons.

Outcomes		Rate associated with mRNA COVID-19[#] vaccines % (95 CI)	N Studies	Historical rates
Spontaneous abortion/miscarriage		4.97 (2.40–8.39)	5	10% (in clinically recognized pregnancies)[98]
Stillbirth		0.05 (0.00–0.20)	3	Finland 2010: 2.9%[110] Belgium 2010: 3.1%[99] UK 2017: 4.2%[100] Argentina, USA 2019: 3.0%[99] Australia 2010: 2.9%[99] Vietnam 2010: 9.6%[99] New Zealand 2010: 3.3%[99]
Fetal growth retardation		0.49 (0.34–0.66)	2	23.8% newborns per year[101]
Gestational diabetes		7.74 (2.31–15.97)	2	6–7%[102]
Hypertensive disorders		2.37 (0.15–7.17)	2	Hypertensive disorders: 10% Preeclampsia: 4–5%[103]
Small for gestational age		12.3 (7.31–18.4)	1	Asia: 5.3 to 41.5% Africa: 1.2 to 3.0% livebirths[104]
Preterm birth		5.61 (2.58–9.72)	4	10%[105]
Maternal death		0 (0.00–0.03)*	1	Israel: 2/100,000 livebirths[106]
Any congenital malformation		2.32 (1.42–3.44)	2	2–4%[108]
Neonatal death		0.43 (0.40–3.76)	1	Estimations for 2019[107] Argentina: 6% USA: 3.6% Australia: 2.3% UK: 2.7% Finland: 1.4% New Zealand: 2.6% Israel: 1.9%
Postpartum hemorrhage		10.40 (6.49–15.10)	2	2–5%[109]
Suspected Chorioamnionitis		0.19 (0.17–1.63)	1	USA: 1–4%[111]
Antenatal bleeding		0.37 (0.01–1.22)	1	6%[112]
Neonatal infections		3.24 (2.08–4.65)	1	NA
Respiratory distress newborn		1.82 (1.72–15.31)	1	LMICs: 1.2% to 7.2%[113] USA: 10%[114]
Injection site reactions	LMICs	58.86 (30.08–84.66)	4	–
	HICs			–
Fever		19.28 (0.78–53.55)	3	–
Headache		25.31 (1.95–62.75)	4	–
Gastrointestinal		9.47 (3.33–18.29)	1	–
Myalgia		33.08 (3.51–74.13)	3	–
Fatigue		50.03 (17.52–82.53)	3	–
Vomiting		4.55 (4.19–4.93)	1	–
Nausea		26.61 (25.83–27.39)	1	–
Chills		36.66 (35.81–37.51)	2	–
Joint pain		25.57 (24.80–26.35)	1	–

MAEs: Medically attended adverse events; **SAEs**: Serious adverse events; **NA**: Not available; **HICs**: High Income Countries; **LMICs**: Low-to-Middle-Income Countries; **#**Pfizer/BioNTech and Moderna/NIH (only 0.5% of pregnant persons were exposed to Janssen and Oxford/AstraZeneca vaccines vectored).; *None maternal death the estimated 95% CI is 3.1 to 29.1 / 100,000.

physical development, and no abnormal gross pathology findings in pups or dams.[97].

4.5. Controlled studies of non-COVID-19 vaccines in pregnant persons

A paired *meta*-analysis for the pregnancy outcomes was carried out with data from studies that adjusted for potential confounders. Results are presented by type of exposure (AS03 or aluminum adjuvants) and trimester of exposure in **Appendix A,** Supplementary Table 7 and **Appendix B**. **Forest-plots of *meta*-analysis of pregnancy outcomes**). None of the exposures showed statistically significant associations with adverse outcomes, regardless of the trimester of vaccination. However, exposure to vaccines containing AS03 (mainly influenza H1N1, Tdap, and Hepatitis A/B) was associated with a statistically significant protective effect for four outcomes: stillbirth (aHR 0.67; 95% CI 0.47–0.96) for the second trimester; fetal death (aRR 0.66; 95% CI 0.47–0.93) for the full pregnancy; low birth weight (aOR 0.88; 95% CI 0.81–0.96) for the full pregnancy; cesarean section (aOR 0.93; 95% CI 0.87–0.99) for the second/third trimester. Aluminum was associated with a statistically significant reduction in preterm birth (aHR 0.88; 95% CI 0.80–0.97) for the third trimester. The full pregnancy exposure (any trimester) to aluminum only showed a trend of a small and non-statistically significant unfavorable effect for small for gestational age outcome (aOR 1.18; 95% CI 1.00–1.39) but not in the first trimester (aOR 1.03; 95% CI 0.96–1.11) with a moderate subgroup difference by trimester of exposure (test for subgroup differences I^2 = 55%). Across maternal and fetal outcomes, the certainty of evidence, according to the GRADE approach, was classified as "low" to "very low", mainly due to imprecision or inconsistency (**Appendix A,** Supplementary Table 6).

The sensitivity analysis for AS03 exposure, restricted to studies with a low risk of bias, did not allow us to evaluate stillbirth, preeclampsia, and gestational diabetes, which were assessed via aOR by single studies of moderate or high risk of bias. The sensitivity analysis did not change the effect of full pregnancy exposure to AS03 on congenital malformations (the eliminated study[50] only represented 6.4% of the weight of the *meta*-analysis) nor preterm birth or low birth weight. After excluding Ray 2014[79], the vaccine containing AS03 showed a protective effect over the full pregnancy on very preterm birth (aOR 0.73; 95% CI 0.58–0.92) and did not change the effect on cesarean section (measured by aOR).

4.6. Uncontrolled studies of non-COVID-19 vaccines in pregnant persons

In **Appendix A,** Supplementary Table 8**,** we present the proportional *meta*-analysis from uncontrolled studies or from the active

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arms of RCTs regarding pregnancy and safety outcomes for AS03 and aluminum adjuvants in pregnant persosn. As observed for COVID-19 vaccines, the estimated rates of maternal and fetal outcomes were generally consistent with global or population-specific background rates. We present the related forest plots, the contributing studies, and numerical outputs in **Appendix B. Forest-plots of *meta*-analysis of pregnancy outcomes**.

Data on medically attended adverse events (MAEs) and serious adverse events (SAEs) were only available for aluminum exposure (proportion pooled estimates of 33.90% [11.79–99.95; 2 studies] and 12.31% [1.27–32.34; 6 studies], respectively). For exposure to AS03, the estimated prevalence of systemic reactions was 41.22% [39.48–42.97; 1 study], 25.82% [17.38–35.29; 1 study] for non-minor systemic reactions, and 0.023% [0.001–0.003; 1 study] for anaphylaxis. The three most frequent non-serious adverse events with aluminum exposure were gastrointestinal issues (17.51% [13.75–21.61]; 2 studies), fatigue (15.32% [4.57–30.84]; 6 studies), and headache (14.32% [2.37–33.92]; 9 studies); and with AS03 exposure these were headache (2.20% [0.19–0.25]; 1 study), fever (0.23% [0.20–0.27]; 1 study), and joint pain (0.05% [0.04–0.07]; 1 study).

4.7. Uncontrolled studies of non-COVID-19 vaccines in pregnant animals

Animal studies showed a smaller proportion of abortion with the ChAdOx1 vectored vaccine[97] (3.69%) than with aluminum-adjuvanted vaccines (11.81%) and the same finding was reported for any congenital malformations (0.73 and 5.22%, respectively) [92]. A novel inactivated equine influenza vaccine containing a second-generation ISCOM-Matrix as an adjuvant appear to be safe in pregnant mares.[94]. (See **Appendix B. Proportion *meta*-analysis forest plots**).

4.8. Ongoing studies in pregnant persons

As of December 2021, we identified five ongoing clinical trials recruiting pregnant persons in the COVID-19 vaccine tracker developed by the Vaccine Centre at the London School of Hygiene and Tropical Medicine databases.[117] These studies may contribute to future *meta*-analyses on this topic and include a phase 2 trial assessing the Ad26.COV2.S vaccine in the USA, Brazil, and South Africa (recruiting) [118]; a phase 2/3 trial assessing the BNT162b2 in the USA, Brazil, South Africa, Spain, and the UK (active, not recruiting) [119]; a phase 2 trial evaluating BNT162b2, mRNA-1273, ChAdOx1-S, and NVX-CoV2373 in the UK (recruiting) [120]; and two ongoing or complete phase 4 open-label trials being conducted in Belgium (evaluating BNT162 and mRNA-1273) and the Netherlands (evaluating BNT162b2, mRNA-1273, and ChAdOx1-S).[121,122] We also identified a phase 3 open-label RCT evaluating a vaccine regimen of the Ebola vaccine Ad26.ZEBOV in Rwanda (active, not recruiting).[123].

5. Discussion

This systematic review and *meta*-analysis evaluated the effects of COVID-19 vaccines administered during pregnancy, or their components/platforms used in other maternal vaccines on adverse pregnancy and non-pregnancy outcomes. Among 71 studies included in the review, there were seven studies of COVID-19 vaccine in humans. Regarding the list of authorized or approved COVID-19 vaccines up to December 2021 that guided our study, in January 2023 Shifa Pharmed - Barkat Covlran® vaccine (Inactivated, produced in Vero cell) from Iran, Nuvaxovid (recombinant nanoparticle prefusion spike protein formulated with Matrix-M™ adjuvant) and GBP510 MFDS (recombinant protein subunit) from RoKorea, and Corbevax (RBD antigen of SARS CoV-2) from India were the only vaccines with dossier accepted for review added to the list.[124] These candidate vaccines should be considered for future systematic reviews. The vast majority of pregnant persons included (>99%) were exposed to mRNA vaccines and were recruited from high-income countries. Only two comparative studies comparing exposure with non-exposure to COVID-19 vaccines were identified, covering seven perinatal outcomes (spontaneous abortion, congenital malformation, preterm birth, small for gestational age, fetal growth restriction, preeclampsia, and postpartum hemorrhage). None of the adjusted relative effects were significantly associated with adverse outcomes between exposed and unexposed pregnant persons, either clinically or statistically.

This review also presents indirect evidence regarding COVID vaccine components used in other vaccines (platform, components, or adjuvants) in pregnant humans and animals. We mostly found exposures to AS03 or aluminum-based adjuvants in maternal vaccines, and none were statistically significantly associated with adverse pregnancy outcomes. For some outcomes (stillbirth, fetal death, 5-minute Apgar score < 7, low birth weight, cesarean section, and preterm birth), these vaccines even showed protective effects associated with specific exposure times. These findings were supported by the sensitivity analysis, restricted to studies with a low risk of bias, that showed minimal to no important differences and a slightly more protective effect than in the primary analysis. These effects cannot be separated from the vaccines themselves, e.g., the influenza vaccine resulting in reductions in adverse pregnancy outcomes, or from its adjuvants. However, this apparent protective effect might be because the likelihood of being vaccinated increases with the length of gestation.[125].

We also performed proportional *meta*-analyses of safety and reactogenicity. The proportions of adverse maternal and neonatal outcomes were similar to background rates published before the pandemic.[101-111,113-116,126-131] The only outcome that exceeded the expected background rates of 2.0 to 5%[116] was PPH with a pooled proportion of 10.40% (data from Bookstein et al.[34] and Blakeway et al.[90]). However, Blakeway et al. also compared exposed with non-exposed pregnant persons, with similar rates in these two groups (9.8% vs. 9.0%, respectively; aOR after adjusting for propensity score of 1.09 [95% CI 0.56–2.12]). The width of this confidence interval, related to the small sample size, suggests a cautious interpretation but deserves further research. Reactogenicity was similar following exposure to COVID-19 vaccines, AS03, and aluminum except for fatigue, chills, and myalgia, which were more frequently reported after mRNA vaccines than other adjuvanted maternal vaccines.[85].

Our study shows no safety concerns with mRNA vaccines in pregnant persons in high-income countries. Most available studies are limited by small sample size or the lack of an unvaccinated comparison group. We found scarce data on the safety of adenoviral and protein subunit-adjuvant vaccines in pregnancy. However, after closing our literature search, a few studies provide some insight into these vaccines. A cross-sectional study using data from the Brazilian surveillance information system estimated an incidence of adverse events of 309.37/100,000 doses (95% CI 297.23–321.51), with a lower incidence associated with the Sinovac/Butantan inactivated vaccine (74.08/100,000 doses; 95% CI 63.47–84.69) than the other administered mRNA vaccines and vectored vaccines (Pfizer/BioNTech, AstraZeneca, and Janssen).[132] Since the start of a COVID-19 vaccine program in Scotland, fewer pregnant persons required hospitalization and critical care admission within 28 days of COVID-19 vaccination than within 28 days of SARS-CoV-2 infection. However, the vaccine uptake rate in pregnant persons was lower than in all women.[133] A case-control study with data from Norwegian registries on first-trimester pregnancies found that

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among persons with miscarriages, the adjusted odds ratios for Covid-19 vaccination were 0.81 (95% CI 0.69–0.95) for vaccination in the previous five weeks, consistent with a protective effect of vaccination. The results were similar across vaccine types (Pfizer/BioNTech, Moderna, AstraZeneca) and the number of doses received (one or two).[134] A retrospective cohort study including all persons who delivered between January and June 2021 at the largest birth center in Israel and applying multivariable analyses found no differences between vaccinated (second or third trimesters) and unvaccinated persons for delivery and newborn complications, the incidence of small for gestational age, and newborn respiratory complications.[135] Two recent observational studies in Israel, reported that maternal outcomes were comparable among vaccinated and non-vaccinated pregnant persons and that uptake of the mRNA COVID-19 vaccines was not associated with worse maternal outcomes.[136,137] A large, multisite, retrospective cohort study in the USA found that receipt of mRNA COVID-19 vaccine during pregnancy was not associated with increased risk for preterm birth or small for gestational age at birth. In that study, only 4.2% of pregnant persons received a vectored vaccine.[138] In a birth cohort from the Mayo Clinic Health System in the USA, COVID-19 vaccination during pregnancy was not associated with increased pregnancy or delivery complications.[139].

Concerning data from LMICs, there are some safety data regarding pregnant persons receiving Ad26-based Ebola vaccines and the vesicular stomatitis virus-vectored vaccines[140] (using components/platforms also used by COVID-19 vaccines), but no data on the safety of COVID-19 vaccination. Considerable evidence supports the safety of non-COVID-19 vaccines that use similar adjuvants (AS03 and aluminum) during pregnancy like influenza, hepatitis A and B, and Tdap. An overview of systematic reviews on adverse events and maternal immunization did not identify any risks for any vaccine and perinatal outcome.[141] Ten systematic reviews supported the safety of influenza vaccines during pregnancy.[142-151] One systematic review evaluated the safety of the hepatitis B vaccine, the pneumococcal polysaccharide vaccine, and the meningococcal polysaccharide vaccine during pregnancy and found no clear association with teratogenic effects, preterm labor, or spontaneous abortion.[152] Another systematic found moderate- to high-certainty evidence supporting the safety of vaccines frequently given to travelers, such as yellow fever, MMR (measles, mumps and rubella), influenza, Tdap, meningococcus, or hepatitis A and B in the context of pregnancy. [153]A recent rapid review published by our group showed that no safety concerns were associated with exposure to maternal vaccines with adjuvants used in COVID-19 vaccines.[154] Our findings in this full systematic review reinforce these initial preliminary conclusions.

We also found that the local and systemic reactogenicity observed with COVID-19 vaccines (mostly mRNA) are more prevalent than other adjuvanted maternal vaccines analyzed in this study including influenza, Tdap, and hepatitis A and B vaccines, in outcomes such as fatigue, chills, joint pain, and myalgia. However, the overall reactogenicity profile of mRNA vaccines seems similar between pregnant and nonpregnant populations in the literature.[85].

This systematic review has several strengths. First, we included studies from humans and animals to provide a complete and timely response to an important topic, regardless of time, language, or publication type, and spanning a wide range of maternal and neonatal outcomes. Second, we adhered to strict recommended quality standards for conducting systematic reviews, including independent data extraction and risk of bias assessment, and a comprehensive search strategy. Third, considering the still relatively scarce direct evidence of the safety of COVID-19 for pregnant persons, we categorized exposure to its vaccine components and platforms used in non-COVID-19 vaccines. Additionally, to avoid immortal time bias, a common problem in observational studies involving exposure in late pregnancy,[155] we only *meta*-analyzed comparative studies that adjusted for potential confounders. Since not all the studies adjusted for the time of exposure, we presented *meta*-analyses by trimester of exposure, and we did not find evidence of important differences between subgroups. We also provided estimations and historical rates for each region or country to to compare the safety outcomes. In summary, we synthesized, all currently available data, and critically appraised a substantial body of evidence to assess the COVID-19 vaccines in pregnant human and in animal and also other maternal non-COVID-19 vaccines.

Our study is not exempt from limitations. The majority of included studies are observational study designs, and only 30% allowed for comparisons between vaccinated and unvaccinated pregnant persons. Nevertheless, regardless of the study design and publication type, the consistent absence of safety concerns suggests that findings are robust to this limitation. Only seven studies (9.8%) reported safety information regarding COVID-19 vaccines in pregnant persons, almost exclusively exposed to mRNA-LNP vaccines, and only two studies allowed comparison of perinatal outcomes.[43,90] The paucity of direct safety data on non-mRNA vaccines is an important issue for pregnant persons and policymakers, especially in settings without access to BNT162b2 and mRNA-1273. Remarkably, only 9% of the total body of evidence comes from LMICs, limiting the generalizability to these settings, and more data from LMICs are urgently required.

Maternal immunization policies relating to COVID-19 have varied across different countries, ranging from restrictive policies that do not allow the vaccination of pregnant persons to inclusive policies that recommend or encourage maternal vaccination. From the information gathered via the COVID-19 Maternal Immunization Tracker,[12] as of July 12, 2022 COVID-19 immunization for some or all pregnant persons is recommended by 50% (n = 56) high-income countries, 30% (n = 33) upper-middle-income countries, 18% (n = 20) lower-middle-income countries, and only 5% (n = 5) low-income countries. Additionally, access, acceptance, and availability of vaccines remain very uneven worldwide.[12].

In summary, based on the available data, there is no evidence of obvious safety risks associated with the use of COVID-19 vaccines. Therefore, it is reasonable to recommend mRNA COVID-19 vaccines for pregnant persons as they are at higher risk for adverse outcomes. Data for non-mRNA vaccines are sparse, and further studies are urgently needed, especially in LMICs. Until new evidence is available, all local contextual factors should be considered for decision-making. Confidence in vaccine safety and effectiveness are known to be key predictors for vaccine acceptance,[14] and the ongoing studies will contribute additional data on vaccine safety and efficacy in both mothers and infants.

Considering the growing body of evidence on this topic, we are conducting a living systematic review to evaluate the safety, immunogenicity, and efficacy/effectiveness of COVID-19 vaccines for pregnant persons.[156] The results are being presented in a web-based, highly parameterizable interface is provided that yields available estimates and live *meta*-analyses of the above outcomes of interest by relevant subgroups.[157] We included 134 studies (87% RNA vaccines) published until December 31, 2022. We found>20 new studies that our present review evaluating the safety of COVID-19 vaccines during pregnancy [88,158-177]. Most of studies were conducted in Europe[159,160,162,169-171,177], North America[88,163,168,172,173,175] and Asia [158,161,164,167,174,176].

Only one study, conducted in the UK, Brazil, and South Africa, reported data on women who had participated in COVID-19 vaccine trials and had unintentionally become pregnant[165]. Almost all studies assessed the safety of mRNA COVID-19 vaccines,

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although there is some information on recombinant vaccine safety (ChAdOx1 nCoV-19)[8]. All except one study[161] reported no concerning trends of AEFIs or maternal-neonatal complications. In contrast with the rest of the evidence, Dick et al.[161] reported that there might be an increase in the rate of preterm birth in pregnant persons who received the vaccine during their second trimester, but there was no direct association between vaccination and adverse pregnancy and infant outcomes.

In conclusion, we found no evidence of safety concerns for currently used COVID-19 vaccines during pregnancy. The evidence provided should assist pregnant persons, healthcare providers, and policymakers in supporting COVID-19 vaccination for this group.

Data availability

Data will be made available on request.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: [Pierre M. Buekens reports financial support was provided by Bill & Melinda Gates Foundation].

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Author contributions

All authors contributed to the conception and design of this study, and AC, FA, AB, MB, SZ, BK, EPKP, FRC, AM, and PB prepared the first manuscript draft. All authors interpreted the data, revised the first draft critically, and signed off on the final version.

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Appendix. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.vaccine.2023.03.038.

References

[1] Allotey J, Stallings E, Bonet M, Yap M, Chatterjee S, Kew T, et al. Clinical manifestations, risk factors, and maternal and perinatal outcomes of coronavirus disease 2019 in pregnancy: living systematic review and meta-analysis. BMJ 2020;370:m3320.
[2] Figueiro-Filho EA, Yudin M, Farine D. COVID-19 during pregnancy: an overview of maternal characteristics, clinical symptoms, maternal and neonatal outcomes of 10,996 cases described in 15 countries. J Perinat Med 2020;48:900–11.
[3] Vergara-Merino L, Meza N, Couve-Perez C, Carrasco C, Ortiz-Munoz L, Madrid E, et al. Maternal and perinatal outcomes related to COVID-19 and pregnancy: An overview of systematic reviews. Acta Obstet Gynecol Scand 2021;100:1200–18.
[4] Zambrano LD, Ellington S, Strid P, Galang RR, Oduyebo T, Tong VT, et al. Update: Characteristics of Symptomatic Women of Reproductive Age with Laboratory-Confirmed SARS-CoV-2 Infection by Pregnancy Status - United States, January 22-October 3, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1641–7.
[5] Ciapponi A, Bardach A, Comandé D, Berrueta M, Argento FJ, Rodriguez Cairoli F, et al. COVID-19 and pregnancy: An umbrella review of clinical presentation, vertical transmission, and maternal and perinatal outcomes. PLoS One 2021;16:e0253974.
[6] Gray KJ, Bordt EA, Atyeo C, Deriso E, Akinwunmi B, Young N, et al. COVID-19 vaccine response in pregnant and lactating women: a cohort study. medRxiv : the preprint server for health sciences, 2021.
[7] WHO. WHO SAGE Roadmap for prioritizing uses of COVID-19 vaccines. 2022.
[8] To Evaluate the Safety, Tolerability, and Immunogenicity of BNT162b2 Against COVID-19 in Healthy Pregnant Women 18 Years of Age and Older. https://ClinicalTrials.gov/show/NCT04754594.
[9] Skjefte M, Ngirbabul M, Akeju O, Escudero D, Hernandez-Diaz S, Wyszynski DF, et al. COVID-19 vaccine acceptance among pregnant women and mothers of young children: results of a survey in 16 countries. Eur J Epidemiol 2021;36:197–211.
[10] Nhs. Pregnancy, breastfeeding, fertility and coronavirus (COVID-19) vaccination. National Health Service 2021.
[11] Cdc. COVID-19 vaccines while pregnant or breastfeeding. Ctr Dis Control Prev 2021.
[12] Covid-19 Maternal Immunization Tracker (COMIT) Berman Institute of Bioethics & Center for Immunization Research, Johns Hopkins University.
[13] Ciapponi A, Bardach A, Mazzoni A, Alconada T, Anderson SA, Argento FJ, et al. Safety of components and platforms of COVID-19 vaccines considered for use in pregnancy: A rapid review. Vaccine 2021;39:5891–908.
[14] Skirrow H, Barnett S, Bell S, Riaposova L, Mounier-Jack S, Kampmann B, et al. Women's views on accepting COVID-19 vaccination during and after pregnancy, and for their babies: a multi-methods study in the UK. BMC Pregnancy Childbirth 2022;22:33.
[15] Higgins J, Thomas J, Chandler J, MS. C, Li T, Page M, et al. Cochrane Handbook for Systematic Reviews of Interventions version 6.0 (updated August 2019). Cochrane, 2019. In: Cochrane, editor.2019.
[16] Garritty C, Gartlehner G, Nussbaumer-Streit B, King VJ, Hamel C, Kamel C, et al. Cochrane Rapid Reviews Methods Group offers evidence-informed guidance to conduct rapid reviews. J Clin Epidemiol 2021;130:13–22.
[17] Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: An updated guideline for reporting systematic reviews. PLoS Med 2021;18:e1003583.
[18] WHO. Status of COVID-19 Vaccines within WHO EUL/PQ evaluation process. 2021.
[19] Kohl KS, Bonhoeffer J, Chen R, Duclos P, Heijbel H, Heininger U, et al. The Brighton Collaboration: enhancing comparability of vaccine safety data. Pharmacoepidemiol Drug Saf 2003;12:335–40.
[20] CBER-FDA. Guidance for Industry -Toxicity Grading Scale or Healthy Adult and Adolescent-Volunteers Enrolled in Preventive Vaccine Clinical Trials. In: Services USDoHaH, Administration F-FaD, Research C-CfBEa, editors.2007.
[21] Covidence systematic review software. Melbourne, Australia: Veritas Health Innovation.
[22] Higgins J, Green S, (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. In: Cochrane, editor.2011.
[23] EPOC EPOoCCG. What study designs should be included in an EPOC review? EPOC Resources for review authors, 2017.
[24] NIH. Study Quality Assessment Tools In: NIH National Heart L, and Blood Institute (NHLBI), editor.2020.
[25] Review Manager (RevMan). [Computer program] Version 54 Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration; 2020.
[26] DerSimonian R, Laird N. Meta-analysis in clinical trials. Control Clin Trials 1986;7:177–88.
[27] Jan Brozek AO, Holger Schünemann. The GRADE Working Group GRADEpro. 3.2.2 for Windows. Updated March 2009. 2009.
[28] StatsDirect Ltd. StatsDirect Ltd. . In: 2013. SL, editor. England2017.
[29] Angelo M-G, David M-P, Zima J, Baril L, Dubin G, Arellano F, et al. Pooled analysis of large and long-term safety data from the human papillomavirus-16/18-AS04-adjuvanted vaccine clinical trial programme. Pharmacoepidemiol Drug Saf 2014;23:466–79.
[30] Angelo M-G, Zima J, Tavares Da Silva F, Baril L, Arellano F. Post-licensure safety surveillance for human papillomavirus-16/18-AS04-adjuvanted vaccine: more than 4 years of experience. Pharmacoepidemiol Drug Saf 2014;23:456–65.
[31] Baril L, Rosillon D, Willame C, Angelo MG, Zima J, van den Bosch JH, et al. Risk of spontaneous abortion and other pregnancy outcomes in 15–25 year old women exposed to human papillomavirus-16/18 AS04-adjuvanted vaccine in the United Kingdom. Vaccine 2015;33:6884–91.
[32] Baum U, Leino T, Gissler M, Kilpi T, Jokinen J. Perinatal survival and health after maternal influenza A(H1N1)pdm09 vaccination: A cohort study of pregnancies stratified by trimester of vaccination. Vaccine 2015;33:4850–7.
[33] Berenson AB, Hirth JM, Rahman M, Laz TH, Rupp RE, Sarpong KO. Maternal and infant outcomes among women vaccinated against pertussis during pregnancy. Hum Vaccin Immunother 2016;12:1965–71.
[34] Bookstein Peretz S, Regev N, Novick L, Nachshol M, Goffer E, Ben-David A, et al. Short-term outcome of pregnant women vaccinated with BNT162b2 mRNA COVID-19 vaccine. Ultrasound in obstetrics & gynecology : the official journal of the International Society of Ultrasound in Obstetrics and Gynecology 2021;58:450–6.

Docusign Envelope ID: 5B19DDD4-BFB5-460E-90E5-5DA8E40D12EC Case 1:25-cv-11916-WGY Document 175-39 Filed 12/23/25 Page 37 of 250

[35] Celzo F, Buyse H, Welby S, Ibrahimi A. Safety evaluation of adverse events following vaccination with Havrix. Engerix-B or Twinrix during pregnancy Vaccine 2020;38:6215–23.

[36] Chavant F, Ingrand I, Jonville-Bera AP, Plazanet C, Gras-Champel V, Lagarce L, et al. The PREGVAXGRIP study: a cohort study to assess foetal and neonatal consequences of in utero exposure to vaccination against A(H1N1)v2009 influenza. Drug Saf 2013;36:455–65.

[37] Dana A, Buchanan KM, Goss MA, Seminack MM, Shields KE, Korn S, et al. Pregnancy outcomes from the pregnancy registry of a human papillomavirus type6/11/16/18 vaccine. Obstet Gynecol 2009;114:1170–8.

[38] Donegan K, King B, Bryan P. Safety of pertussis vaccination in pregnant women in UK: observational study. BMJ 2014;349:g4219-g..

[39] Fell DB, Sprague AE, Liu N, Yasseen 3rd AS, Wen S-W, Smith G, et al. H1N1 influenza vaccination during pregnancy and fetal and neonatal outcomes. Am J Public Health 2012;102:e33–40.

[40] Folkenberg M, Callreus T, Svanstrom H, Valentiner-Branth P, Hviid A. Spontaneous reporting of adverse events following immunisation against pandemic influenza in Denmark November 2009-March 2010. Vaccine 2011;29:1180–4.

[41] Fortner KB, Edwards KM, Broder KR, Jimenez N, Zhu Y, Walter EB, et al. 343: Reactogenicity of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine (Tdap) in pregnant women. American Journal of Obstetrics and Gynecology. 2016;214:S193-S4.

[42] Galindo Santana BM, Pelaez Sanchez OR, Galindo Sardina MA, Leon Villafuerte M, Concepcion Diaz D, Estruch Rancano L, et al. Active surveillance of adverse effects of Pandemrix vaccine to prevent influenza A(H1N1) in Cuba Vigilancia activa de eventos adversos a la vacuna Pandemrixpara prevenir la influenza AH1N1 en Cuba 2011;63:231–8.

[43] Goldshtein I, Nevo D, Steinberg DM, Rotem RS, Gorfine M, Chodick G, et al. Association Between BNT162b2 Vaccination and Incidence of SARS-CoV-2 Infection in Pregnant Women. JAMA 2021;326:728–35.

[44] Gray KJ, Bordt EA, Atyeo C, Deriso E, Akinwunmi B, Young N, et al. Coronavirus disease 2019 vaccine response in pregnant and lactating women: a cohort study. Am J Obstet Gynecol 2021;225(303):e1–e17.

[45] Groom HC, Irving SA, Koppolu P, Smith N, Vazquez-Benitez G, Kharbanda EO, et al. Uptake and safety of Hepatitis B vaccination during pregnancy: a Vaccine Safety Datalink study. Vaccine 2018;36:6111–6.

[46] Groom HC, Smith N, Irving SA, Koppolu P, Vazquez-Benitez G, Kharbanda EO, et al. Uptake and safety of hepatitis A vaccination during pregnancy: A Vaccine Safety Datalink study. Vaccine 2019;37:6648–55.

[47] Guo Y, Allen V, Bujold E, Coleman B, Drews S, Gouin K, et al. Efficacy and safety of pandemic influenza vaccine in pregnancy. Can J Infect Dis Med Microbiol 2010;21:209.

[48] Haberg SE, Trogstad L, Gunnes N, Wilcox AJ, Gjessing HK, Samuelsen SO, et al. Risk of fetal death after pandemic influenza virus infection or vaccination. N Engl J Med 2013;368:333–40.

[49] Hoang HTT, Leuridan E, Maertens K, Nguyen TD, Hens N, Vu NH, et al. Pertussis vaccination during pregnancy in Vietnam: Results of a randomized controlled trial Pertussis vaccination during pregnancy. Vaccine 2016;34:151–9.

[50] Källén B, Olausson PO. Vaccination against H1N1 influenza with Pandemrix® during pregnancy and delivery outcome: A Swedish register study. BJOG 2012;119:1583–90.

[51] Katz N, Neyro S, Carrega MEP, Del Valle JM, Rancaño C, Pasinovich M, et al. Maternal immunization in argentina: The importance of a safety profile analysis. Open Forum. Infect Dis 2016;:3.

[52] Kharbanda EO, Haapala J, DeSilva M, Vazquez-Benitez G, Vesco KK, Naleway AL, et al. Spontaneous Abortion Following COVID-19 Vaccination During Pregnancy. JAMA 2021;326:1629–31.

[53] Kharbanda EO, Vazquez-Benitez G, Lipkind HS, Klein NP, Cheetham TC, Naleway A, et al. Evaluation of the Association of Maternal Pertussis Vaccination With Obstetric Events and Birth Outcomes. JAMA 2014;312:1897.

[54] Kharbanda EO, Vazquez-Benitez G, Lipkind HS, Klein NP, Cheetham TC, Naleway AL, et al. Maternal Tdap vaccination: Coverage and acute safety outcomes in the vaccine safety datalink, 2007–2013. Vaccine 2016;34:968–73.

[55] Kushner T, Youhanna J, Walker R, Erby K, Janssen RS. Safety and immunogenicity of Heplisav-B in pregnancy. Hepatology 2020;72:469A–A470.

[56] Lacroix I, Damase-Michel C, Kreft-Jais C, Castot AC, Montastruc JL. H1N1 influenza vaccine in pregnant women: French pharmacovigilance survey. Drug Saf 2010;33:908–9.

[57] Läkemedelsverket. Läkemedelsverket. Final summary of adverse drug reaction reports in Sweden with Pandemrix through October 2009-mid April 2010. June 2, 2010. Accessed 23 May 2011 from www.lakemedelsverket.se. 2010.

[58] Layton D, Dryburgh M, MacDonald TM, Shakir SA, MacKenzie IS. Pilot swine flu vaccination active surveillance study: Final results. Drug Saf 2011;34:889–90.

[59] Levi M. Vaccination against influenza A(H1N1) virus is also safe during pregnancy. Ned Tijdschr Geneeskd 2012;156.

[60] Ludvigsson JF, Strom P, Lundholm C, Cnattingius S, Ekbom A, Ortqvist A, et al. Maternal vaccination against H1N1 influenza and offspring mortality: Population based cohort study and sibling design. BMJ 2015;351:h5585.

[61] Ludvigsson JF, Strom P, Lundholm C, Cnattingius S, Ekbom A, Ortqvist A, et al. Risk for congenital malformation with H1N1 influenza vaccine: a cohort study with sibling analysis. Ann Intern Med 2016;165:848–55.

[62] Ludvigsson JF, Zugna D, Cnattingius S, Richiardi L, Ekbom A, Ortqvist A, et al. Influenza H1N1 vaccination and adverse pregnancy outcome. Eur J Epidemiol 2013;28:579–88.

[63] Mackenzie IS, MacDonald TM, Shakir S, Dryburgh M, Mantay BJ, McDonnell P, et al. Influenza H1N1 (swine flu) vaccination: a safety surveillance feasibility study using self-reporting of serious adverse events and pregnancy outcomes. Br J Clin Pharmacol 2012;73:801–11.

[64] Madhi SA, Polack FP, Piedra PA, Munoz FM, Trenholme AA, Simoes EA, et al. Vaccination of pregnant women with respiratory syncytial virus vaccine and protection of their infants. N Engl J Med 2020;383:426–39.

[65] Maertens K, Cabore RN, Huygen K, Hens N, Van Damme P, Leuridan E. Pertussis vaccination during pregnancy in Belgium: results of a prospective controlled cohort study. Vaccine 2016;34:142–50.

[66] McHugh L, Marshall HS, Perrett KP, Nolan T, Wood N, Lambert SB, et al. The safety of influenza and pertussis vaccination in pregnancy in a cohort of Australian mother-infant pairs, 2012–2015: the FluMum study. Clin Infect Dis 2019;68:402–8.

[67] Mohammed H, Roberts CT, Grzeskowiak LE, Giles LC, Verburg PE, Dekker G, et al. Safety of maternal pertussis vaccination on pregnancy and birth outcomes: A prospective cohort study. Vaccine 2021;39:324–31.

[68] Morgan JL, Baggari SR, McIntire DD, Sheffield JS. Pregnancy Outcomes After Antepartum Tetanus, Diphtheria, and Acellular Pertussis Vaccination. Obstet Gynecol 2015;125:1433–8.

[69] Moro PL, Museru OI, Niu M, Lewis P, Broder K. Reports to the vaccine adverse event reporting system after hepatitis a and hepatitis AB vaccines in pregnant women. Am J Obstet Gynecol 2014;210.

[70] Moro PL, Zheteyeva Y, Barash F, Lewis P, Cano M. Assessing the safety of hepatitis B vaccination during pregnancy in the Vaccine Adverse Event Reporting System (VAERS), 1990–2016. Vaccine 2018;36:50–4.

[71] Munoz FM, Bond NH, Maccato M, Pinell P, Hammill HA, Swamy GK, et al. Safety and Immunogenicity of Tetanus Diphtheria and Acellular Pertussis (Tdap) Immunization During Pregnancy in Mothers and Infants. JAMA 2014;311:1760.

[72] Munoz FM, Swamy GK, Hickman SP, Agrawal S, Piedra PA, Glenn GM, et al. Safety and Immunogenicity of a Respiratory Syncytial Virus Fusion (F) Protein Nanoparticle Vaccine in Healthy Third-Trimester Pregnant Women and Their Infants. J Infect Dis 2019;220:1802–15.

[73] Núñez Rojas Y, Orive Rodríguez N, Varona De La Peña F, Bermúdez Velásquez Y, Raad López AF, Muñoz Martínez Y, et al. Vaccination against influenza a H1N1 and the risk of birth defects. VacciMonitor 2010;19:209.

[74] Oppermann M, Fritzsche J, Weber-Schoendorfer C, Keller-Stanislawski B, Allignol A, Meister R, et al. A(H1N1)v2009: a controlled observational prospective cohort study on vaccine safety in pregnancy. Vaccine 2012;30:4445–52.

[75] Pasternak B, Svanstrom H, Molgaard-Nielsen D, Krause TG, Emborg HD, Melbye M, et al. influenza in pregnancy and risk of fetal death: cohort study in Denmark. BMJ 2009;2012:344.

[76] Pasternak B, Svanstrom H, Molgaard-Nielsen D, Krause TG, Emborg HD, Melbye M, et al. Risk of adverse fetal outcomes following administration of a pandemic influenza A(H1N1) vaccine during pregnancy. JAMA, Journal of the American Medical Association 2012;308:165–74.

[77] Perrett KP, Halperin SA, Nolan T, Martínez Pancorbo C, Tapiero B, Martinón-Torres F, et al. Immunogenicity, transplacental transfer of pertussis antibodies and safety following pertussis immunization during pregnancy: evidence from a randomized, placebo-controlled trial. Vaccine 2020;38:2095–104.

[78] Petousis-Harris H, Walls T, Watson D, Paynter J, Graham P, Turner N. Safety of Tdap vaccine in pregnant women: an observational study. BMJ Open 2016;6:e010911.

[79] Ray JG, McGeer AJ, Blake JM, Lebovic G, Smith GN, Yudin MH. Peripartum outcomes: non-adjuvanted v. adjuvanted H1N1 vaccination. CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne 2014;186:137.

[80] Rega A, Moore H, De Klerk N, Effler P. Maternal vaccinations in Australia-uptake, safety and impact. Aust N Z J Obstet Gynaecol 2016;56:13–4.

[81] Regan AK, Tracey LE, Blyth CC, Richmond PC, Effler PV. A prospective cohort study assessing the reactogenicity of pertussis and influenza vaccines administered during pregnancy. Vaccine 2016;34:2299–304.

[82] Sammon CJ, McGrogan A, Snowball J, De Vries CS. Swine flu vaccination in pregnancy and associated miscarriage risk. Pharmacoepidemiol Drug Saf 2011;20:S58–9.

[83] Sammon CJ, Snowball J, McGrogan A, de Vries CS. Evaluating the Hazard of Foetal Death following H1N1 Influenza Vaccination; A Population Based Cohort Study in the UK GPRD. PLoS One 2012;7.

[84] Shakib JH, Korgenski K, Sheng X, Varner MW, Pavia AT, Byington CL. Tetanus, Diphtheria, Acellular Pertussis Vaccine during Pregnancy: Pregnancy and Infant Health Outcomes. J Pediatr 2013;163.

[85] Shimabukuro TT, Kim SY, Myers TR, Moro PL, Oduyebo T, Panagiotakopoulos L, et al. Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons. N Engl J Med 2021;384:2273–82.

[86] Swamy GK, Metz TD, Edwards KM, Soper DE, Beigi RH, Campbell JD, et al. Safety and immunogenicity of an investigational maternal trivalent group B

Docusign Envelope ID: 5B19DDD4-BFB5-460E-90EE-5DA8E40D12EC Case 1:25-cv-11916-WGY Document 175-39 Filed 12/23/25 Page 38 of 250

streptococcus vaccine in pregnant women and their infants: results from a randomized placebo-controlled phase II trial. Vaccine 2020;38:6930–40.
[87] Tavares F, Nazareth I, Monegal JS, Kolte I, Verstraeten T, Bauchau V. Pregnancy and safety outcomes in women vaccinated with an AS03-adjuvanted split virion H1N1 (2009) pandemic influenza vaccine during pregnancy: a prospective cohort study. Vaccine 2011;29:6358–65.
[88] Zauche LH, Wallace B, Smoots AN, Olson CK, Oduyebo T, Kim SY, et al. Receipt of mRNA Covid-19 Vaccines and Risk of Spontaneous Abortion. N Engl J Med 2021;385:1533–5.
[89] Zheteyeva YA, Moro PL, Tepper NK, Rasmussen SA, Barash FE, Revzina NV, et al. Adverse event reports after tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccines in pregnant women. Am J Obstet Gynecol 2012;207(59):e1–7.
[90] Blakeway H, Prasad S, Kalafat E, Heath PT, Ladhani SN, Le Doare K, et al. COVID-19 vaccination during pregnancy: coverage and safety. Am J Obstet Gynecol 2021.
[91] Bielefeldt-Ohmann H, Prow NA, Wang W, Tan CSE, Coyle M, Douma A, et al. Safety and immunogenicity of a delta inulin-adjuvanted inactivated Japanese encephalitis virus vaccine in pregnant mares and foals. Vet Res 2014;45:130.
[92] Bowman CJ, Bouressam M, Campion SN, Cappon GD, Catlin NR, Cutler MW, et al. Lack of effects on female fertility and prenatal and postnatal offspring development in rats with BNT162b2, a mRNA-based COVID-19 vaccine. Reprod Toxicol 2021;103:28–35.
[93] Glenn GM, Fries LF, Smith G, Kpamegan E, Lu H, Guebre-Xabier M, et al. Modeling maternal fetal RSV F vaccine induced antibody transfer in guinea pigs. Special Issue: Advancing maternal immunization programs through research in low and medium income countries 2015;33:6488–92.
[94] Heldens JGM, Pouwels HGW, Derks CGG, Van de Zande SMA, Hoeijmakers MJH. The first safe inactivated equine influenza vaccine formulation adjuvanted with ISCOM-Matrix that closes the immunity gap. Vaccine 2009;27:5530–7.
[95] Segal L, Wilby OK, Willoughby CR, Veenstra S, Deschamps M. Evaluation of the intramuscular administration of Cervarix TM vaccine on fertility, pre- and post-natal development in rats. Reproductive toxicology (Elmsford, NY) 2011;31:111–20.
[96] Shan C, Xie X, Luo H, Muruato AE, Liu Y, Wakamiya M, et al. Maternal vaccination and protective immunity against Zika virus vertical transmission. Nature. Communications 2019:10.
[97] Stebbings R, Maguire S, Armour G, Jones C, Goodman J, Maguire AK, et al. Developmental and reproductive safety of AZD1222 (ChAdOx1 nCoV-19) in mice. Reproductive toxicology (Elmsford, NY) 2021;104:134–42.
[98] Stedman A, Wright D, Schreur PJW, Clark MHA, Hill AVS, Gilbert SC, et al. Safety and efficacy of ChAdOx1 RVF vaccine against Rift Valley fever in pregnant sheep and goats. npj Vaccines 2019:4.
[99] Warda FF, Ahmed HES, Shafik NG, Mikhael CA, Abd-ElAziz HMG, Mohammed WA, et al. Application of equine herpesvirus-1 vaccine inactivated by both formaldehyde and binary ethylenimine in equine. Veterinary world 2021;14:1815–21.
[100] Wise LD, Wolf JJ, Kaplanski CV, Pauley CJ, Ledwith BJ. Lack of effects on fertility and developmental toxicity of a quadrivalent HPV vaccine in Sprague-Dawley rats. Birth Defects Res B 2008;83:561–72.
[101] Magnus MC, Wilcox AJ, Morken N-H, Weinberg CR, Håberg SE. Role of maternal age and pregnancy history in risk of miscarriage: prospective register based study. BMJ (Clinical research ed). 2019;364:l869-l.
[102] Hug L, You D, Blencowe H, Mishra A, Wang Z, Fix MJ, et al. Global, regional, and national estimates and trends in stillbirths from 2000 to 2019: a systematic assessment. Lancet 2021;398:772–85.
[103] Kingdon C, Roberts D, Turner MA, Storey C, Crossland N, Finlayson KW, et al. Inequalities and stillbirth in the UK: a meta-narrative review. BMJ Open. 2019;9:e029672-e.
[104] de Onis M, Blossner M, Villar J. Levels and patterns of intrauterine growth retardation in developing countries. Eur J Clin Nutr 1998;52(Suppl 1):S5–S.
[105] ACOG Practice Bulletin No. 190: Gestational Diabetes Mellitus. Obstetrics and gynecology. 2018;131:e49-e64.
[106] Kuklina EV, Ayala C, Callaghan WM. Hypertensive disorders and severe obstetric morbidity in the United States. Obstet Gynecol 2009;113:1299–306.
[107] Lee ACC, Katz J, Blencowe H, Cousens S, Kozuki N, Vogel JP, et al. National and regional estimates of term and preterm babies born small for gestational age in 138 low-income and middle-income countries in 2010. Lancet Glob Health 2013;1:e26–36.
[108] Chawanpaiboon S, Vogel JP, Moller AB, Lumbiganon P, Petzold M, Hogan D, et al. Global, regional, and national estimates of levels of preterm birth in 2014: a systematic review and modelling analysis. Lancet Glob Health 2019;7:e37–46.
[109] Trends in maternal mortality. to 2017: estimates. Geneva: World Health Organization; 2000. p. 2019.
[110] UNICEF. Neonatal mortality. The neonatal period is the most vulnerable time for a child. 2020.
[111] Mai CT, Isenburg JL, Canfield MA, Meyer RE, Correa A, Alverson CJ, et al. National population-based estimates for major birth defects, 2010–2014. Birth Defects Res 2019;111:1420–35.
[112] Tita AT, Andrews WW. Diagnosis and management of clinical chorioamnionitis. Clin Perinatol 2010;37:339–54.
[113] Prabhu M, Eckert LO, Belfort M, Babarinsa I, Ananth CV, Silver RM, et al. Antenatal bleeding: Case definition and guidelines for data collection, analysis, and presentation of immunization safety data. Vaccine 2017;35:6529–37.
[114] Sivanandan S, Agarwal R. Sethi AJSif, medicine n. Respiratory distress in term neonates in low-resource settings 2017;22(4):260–6.
[115] Sweet LR, Keech C, Klein NP, Marshall HS, Tagbo BN, Quine D, et al. Respiratory distress in the neonate: Case definition & guidelines for data collection, analysis, and presentation of maternal immunization safety data. Vaccine 2017;35:6506–17.
[116] Vogel JP, Oladapo OT, Dowswell T, Gülmezoglu AM. Updated WHO recommendation on intravenous tranexamic acid for the treatment of post-partum haemorrhage. Lancet Glob Health 2018;6:e18–9.
[117] Shrotri M, Swinnen T, Kampmann B, Parker EPK. An interactive website tracking COVID-19 vaccine development. Lancet Glob Health 2021;9:e590–2.
[118] A Study of Ad26.COV2.S in Healthy Pregnant Participants (COVID-19). https://ClinicalTrials.gov/show/NCT04765384; 2021.
[119] Study to Evaluate the Safety, Tolerability, and Immunogenicity of SARS CoV-2 RNA Vaccine Candidate (BNT162b2) Against COVID-19 in Healthy Pregnant Women 18 Years of Age and Older. https://ClinicalTrials.gov/show/NCT04754594; 2021.
[120] Galiza E, Paul Heath P. COVID-19 vaccines in pregnancy (ISRCTN15279830).
[121] COVID-19: study to detect transfer of SARS-Cov-2 antibodies in breastmilk. https://www.clinicaltrialsregister.eu/ctr-search/trial/2021-000893-27/BE; 2021.
[122] PREGCOVAC-19: the follow up of pregnant women who received COVID-19 vaccination in the Dutch national vaccination program. https://www.clinicaltrialsregister.eu/ctr-search/trial/2021-002327-38/NL; 2021.
[123] Vaccines J, B.V. P, Research CfFH, Innovations CfEP, University E. A Study of a 2-dose Ebola Vaccine Regimen of Ad26.ZEBOV Followed by MVA-BN-Filo in Healthy Pregnant Women. https://ClinicalTrials.gov/show/NCT04556526; 2020.
[124] WHO. Status of COVID-19 Vaccines within WHO EUL/PQ evaluation process. 2023.
[125] Fell DB, Dimitris MC, Hutcheon JA, Ortiz JR, Platt RW, Regan AK, et al. Guidance for design and analysis of observational studies of fetal and newborn outcomes following COVID-19 vaccination during pregnancy. Vaccine 2021;39:1882–6.
[126] Zeitlin J, Mortensen L, Prunet C, Macfarlane A, Hindori-Mohangoo AD, Gissler M, et al. Socioeconomic inequalities in stillbirth rates in Europe: measuring the gap using routine data from the Euro-Peristat Project. BMC Pregnancy Childbirth 2016;16:15.
[127] Ross E, Munoz FM, Edem B, Nan C, Jehan F, Quinn J, et al. Failure to thrive: Case definition & guidelines for data collection, analysis, and presentation of maternal immunisation safety data. Vaccine 2017;35:6483–91.
[128] Morris JK, Rankin J, Garne E, Loane M, Greenlees R, Addor M-C, et al. Prevalence of microcephaly in Europe: population based study. BMJ 2016;354:i4721.
[129] Graham EM, Ruis KA, Hartman AL, Northington FJ, Fox HE. A systematic review of the role of intrapartum hypoxia-ischemia in the causation of neonatal encephalopathy. Am J Obstet Gynecol 2008;199:587–95.
[130] Cragan JD, Isenburg JL, Parker SE, Alverson CJ, Meyer RE, Stallings EB, et al. Population-based microcephaly surveillance in the United States, 2009 to 2013: An analysis of potential sources of variation. Birth Defects Res A 2016;106:972–82.
[131] Blencowe H, Krasevec J, de Onis M, Black RE, An X, Stevens GA, et al. National, regional, and worldwide estimates of low birthweight in 2015, with trends from 2000: a systematic analysis. Lancet Glob Health 2019;7:e849–60.
[132] Qiao Y, Lopes de Abreu AdJ, Dias CZ, Meng X, Ferreira RV, Gonçalves Pereira R, et al. Safety profile of COVID-19 vaccines in pregnant and postpartum women in brazil. medRxiv. 2021:2021.12.14.21267777.
[133] Stock SJ, Carruthers J, Calvert C, Denny C, Donaghy J, Goulding A, et al. SARS-CoV-2 infection and COVID-19 vaccination rates in pregnant women in Scotland. Nat Med 2022.
[134] Magnus MC, Gjessing HK, Eide HN, Wilcox AJ, Fell DB, Haberg SE. Covid-19 Vaccination during Pregnancy and First-Trimester Miscarriage. N Engl J Med 2021;385:2008–10.
[135] Wainstock T, Yoles I, Sergienko R, Sheiner E. Prenatal maternal COVID-19 vaccination and pregnancy outcomes. Vaccine 2021;39:6037–40.
[136] Bleicher I, Kadour-Peero E, Sagi-Dain L, Sagi S. Early exploration of COVID-19 vaccination safety and effectiveness during pregnancy: interim descriptive data from a prospective observational study. Vaccine 2021;39:6535–8.
[137] Burd I, Kino T, Segars J. The Israeli study of Pfizer BNT162b2 vaccine in pregnancy: considering maternal and neonatal benefits. J Clin Invest 2021;131.
[138] Lipkind H, Vazquez-Benitez G, DeSilva M, al. e. Receipt of COVID-19 Vaccine During Pregnancy and Preterm or Small-for-Gestational-Age at Birth — Eight Integrated Health Care Organizations, United States, December 15, 2020–July 22, 2021. MMWR Morb Mortal Wkly Rep ePub: 4 January 2022. 2022;71.
[139] Theiler RN, Wick M, Mehta R, Weaver AL, Virk A, Swift M. Pregnancy and birth outcomes after SARS-CoV-2 vaccination in pregnancy. Am J Obstet Gynecol MFM 2021;3:100467.
[140] Schwartz DA. Being Pregnant during the Kivu Ebola Virus Outbreak in DR Congo: The rVSV-ZEBOV Vaccine and Its Accessibility by Mothers and Infants during Humanitarian Crises and in Conflict Areas. Vaccines (Basel) 2020;8.
[141] Macias Saint-Gerons D, Sola Arnau I, De Mucio B, Arevalo-Rodriguez I, Aleman A, Castro JL, et al. Adverse events associated with the use of recommended vaccines during pregnancy: An overview of systematic reviews. Vaccine 2021;39(Suppl 2):B12–26.

Docusign Envelope ID: 5B19DDD4-BFB5-460E-90EE-5DA8E40D12EC Case 1:25-cv-11916-BEM Document 175-39 Filed 12/23/25 Page 39 of 250

[142] Bratton KN, Wardle MT, Orenstein WA, Omer SB. Maternal influenza immunization and birth outcomes of stillbirth and spontaneous abortion: a systematic review and meta-analysis. Clin Infect Dis 2015;60:e11–9.
[143] Demicheli V, Jefferson T, Ferroni E, Rivetti A, Di Pietrantonj C. Vaccines for preventing influenza in healthy adults. Cochrane Database Syst Rev. 2018;2: CD001269.
[144] Fell DB, Platt RW, Lanes A, Wilson K, Kaufman JS, Basso O, et al. Fetal death and preterm birth associated with maternal influenza vaccination: systematic review. BJOG 2015;122:17–26.
[145] Giles ML, Krishnaswamy S, Macartney K, Cheng A. The safety of inactivated influenza vaccines in pregnancy for birth outcomes: a systematic review. Hum Vaccin Immunother 2019;15:687–99.
[146] Jeong S, Jang EJ, Jo J, Jang S. Effects of maternal influenza vaccination on adverse birth outcomes: A systematic review and Bayesian meta-analysis. PLoS One 2019;14:e0220910.
[147] Michiels B, Govaerts F, Remmen R, Vermeire E, Coenen S. A systematic review of the evidence on the effectiveness and risks of inactivated influenza vaccines in different target groups. Vaccine 2011;29:9159–70.
[148] Nunes MC, Aqil AR, Omer SB, Madhi SA. The Effects of Influenza Vaccination during Pregnancy on Birth Outcomes: A Systematic Review and Meta-Analysis. Am J Perinatol 2016;33:1104–14.
[149] Polyzos KA, Konstantelias AA, Pitsa CE, Falagas ME. Maternal Influenza Vaccination and Risk for Congenital Malformations: A Systematic Review and Meta-analysis. Obstet Gynecol 2015;126:1075–84.
[150] Zhang C, Wang X, Liu D, Zhang L, Sun X. A systematic review and meta-analysis of fetal outcomes following the administration of influenza A/H1N1 vaccination during pregnancy. Int J Gynaecol Obstet 2018;141:141–50.
[151] De Rose DU, Salvatori G, Dotta A, Auriti C. SARS-CoV-2 Vaccines during Pregnancy and Breastfeeding: A Systematic Review of Maternal and Neonatal Outcomes. Viruses 2022:14.
[152] Makris MC, Polyzos KA, Mavros MN, Athanasiou S, Rafailidis PI, Falagas ME. Safety of hepatitis B, pneumococcal polysaccharide and meningococcal polysaccharide vaccines in pregnancy: a systematic review. Drug Saf 2012;35:1–14.
[153] Nasser R, Rakedzon S, Dickstein Y, Mousa A, Solt I, Peterisel N, et al. Are all vaccines safe for the pregnant traveller? A systematic review and meta-analysis. J Travel Med 2020;27.
[154] Ciapponi A, Bardach A, Mazzoni A, Alconada T, Anderson SA, Argento FJ, et al. Safety of components and platforms of COVID-19 vaccines considered for use in pregnancy: A rapid review. Vaccine 2021.
[155] Corrao G, Rea F, Franchi M, Beccalli B, Locatelli A, Cantarutti A. Warning of Immortal Time Bias When Studying Drug Safety in Pregnancy: Application to Late Use of Antibiotics and Preterm Delivery. Int J Environ Res Public Health 2020:17.
[156] Ciapponi A, Berrueta M, Ballivian J, Bardach A, Mazzoni A, Anderson S, et al. Safety, immunogenicity, and effectiveness of COVID-19 vaccines for pregnant persons: A protocol for systematic review and meta analysis. Medicine (Baltimore) 2023;102:e32954.
[157] . Living systematic review 2023.
[158] Arulappen AL, Danial M, Shanmugam G, Cheng JT, Dulasi M, Chow TS. A Multicenter Cohort Study on the Adverse Effects Evaluation After Messenger RNA COVID-19 Vaccination Among Pregnant Healthcare Employees in Penang General Hospitals. Front Public Health 2022;10:876966.
[159] Blakeway H, Prasad S, Kalafat E, Heath PT, Ladhani SN, Le Doare K, et al. COVID-19 Vaccination During Pregnancy: Coverage and Safety. Obstet Anesth Dig 2022;42:195–6.
[160] Citu IM, Citu C, Gorun F, Sas I, Bratosin F, Motoc A, et al. The Risk of Spontaneous Abortion Does Not Increase Following First Trimester mRNA COVID-19 Vaccination. J Clin Med Res 2022:11.
[161] Dick A, Rosenbloom JI, Gutman-Ido E, Lessans N, Cahen-Peretz A, Chill HH. Safety of SARS-CoV-2 vaccination during pregnancy- obstetric outcomes from a large cohort study. BMC Pregnancy Childbirth 2022;22:166.
[162] Favre G, Maisonneuve E, Pomar L, Winterfeld U, Daire C, Martinez de Tejada B, et al. COVID-19 mRNA vaccine in pregnancy: Results of the Swiss COVI-PREG registry, an observational prospective cohort study. Lancet Reg Health Eur 2022;18:100410.
[163] Fell DB, Dhinsa T, Alton GD, Török E, Dimanlig-Cruz S, Regan AK, et al. Association of COVID-19 Vaccination in Pregnancy With Adverse Peripartum Outcomes. JAMA 2022;327:1478–87.
[164] Goldshtein I, Steinberg DM, Kuint J, Chodick G, Segal Y, Shapiro Ben David S, et al. Association of BNT162b2 COVID-19 Vaccination During Pregnancy With Neonatal and Early Infant Outcomes. JAMA Pediatr 2022;176:470–7.
[165] Hillson K, Clemens SC, Madhi SA, Voysey M, Pollard AJ, Minassian AM, et al. Fertility rates and birth outcomes after ChAdOx1 nCoV-19 (AZD1222) vaccination. Lancet 2021;398:1683–4.
[166] Kadali RAK, Janagama R, Peruru SR, Racherla S, Tirumala R, Madathala RR, et al. Adverse effects of COVID-19 messenger RNA vaccines among pregnant women: a cross-sectional study on healthcare workers with detailed self-reported symptoms. Am J Obstet Gynecol 2021;225:458–60.
[167] Komine-Aizawa S, Haruyama Y, Deguchi M, Hayakawa S, Kawana K, Kobashi G, et al. The vaccination status and adverse effects of COVID-19 vaccine among pregnant women in Japan in 2021. J Obstet Gynaecol Res 2022;48:1561–9.
[168] Lipkind HS, Vazquez-Benitez G, DeSilva M, Vesco KK, Ackerman-Banks C, Zhu J, et al. Receipt of COVID-19 Vaccine During Pregnancy and Preterm or Small-for-Gestational-Age at Birth — Eight Integrated Health Care Organizations, United States, December 15, 2020–July 22, 2021. MMWR Morb Mortal Wkly Rep 2022;71:26–30.
[169] Magnus MC, Gjessing HK, Eide HN, Wilcox AJ, Fell DB, Håberg SE. Covid-19 Vaccination during Pregnancy and First-Trimester Miscarriage. N Engl J Med 2021;385:2008–10.
[170] Magnus MC, Örtqvist AK, Dahlqwist E, Ljung R, Skår F, Oakley L, et al. Association of SARS-CoV-2 Vaccination During Pregnancy With Pregnancy Outcomes. JAMA 2022;327:1469–77.
[171] Montalti M, Guaraldi F, Di Valerio Z, Ragghianti B, Tedesco D, Mannucci E, et al. Adherence to and early adverse events of COVID-19 vaccine in a cohort of 600 Italian breastfeeding and pregnant physicians. Hum Vaccin Immunother 2022:18.
[172] Moro PL, Olson CK, Clark E, Marquez P, Strid P, Ellington S, et al. Post-authorization surveillance of adverse events following COVID-19 vaccines in pregnant persons in the vaccine adverse event reporting system (VAERS), December 2020 – October 2021. Vaccine 2022;40:3389–94.
[173] Nakahara A, Biggio JR, Elmayan A, Williams FB. Safety-Related Outcomes of Novel mRNA COVID-19 Vaccines in Pregnancy. Am J Perinatol 2022;39:1484–8.
[174] Peretz-Machluf R, Hirsh-Yechezkel G, Zaslavsky-Paltiel I, Farhi A, Avisar N, Lerner-Geva L, et al. Obstetric and Neonatal Outcomes following COVID-19 Vaccination in Pregnancy. J Clin Med Res 2022;11:2540.
[175] Trostle ME, Limaye MA, Avtushka V, Lighter JL, Penfield CA, Roman AS. COVID-19 vaccination in pregnancy: early experience from a single institution. Am J Obstet Gynecol MFM 2021;3:100464.
[176] Wainstock T, Yoles I, Sergienko R, Sheiner E. Prenatal maternal COVID-19 vaccination and pregnancy outcomes. Vaccine 2021;39.
[177] Zdanowski W, Markiewicz A, Zdanowska N, Lipińska J, Waśniewski T. Tolerability of the BNT162b2 COVID-19 Vaccine during Pregnancy among Polish Healthcare Professionals. Vaccines (Basel) 2022:10.

Docusign Envelope ID: 5B19DDD4-BEBE-468F-90EE-EDA8E40D12EC

EXHIBIT E

Docusign Envelope ID: 5B19DDD4-BEBE-469E-89EE-EDA8E40D12EC Case 1:25-cv-11916-BEM Document 175-39 Filed 12/23/25 Page 41 of 250

Original Research

Disease Severity and Perinatal Outcomes of Pregnant Patients With Coronavirus Disease 2019 (COVID-19)

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OBJECTIVE: To describe coronavirus disease 2019 (COVID-19) severity in pregnant patients and evaluate the association between disease severity and perinatal outcomes.

METHODS: We conducted an observational cohort study of all pregnant patients with a singleton gestation and a positive test result for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) who delivered at 1 of 33 U.S. hospitals in 14 states from March 1 to July 31, 2020. Disease severity was classified by National Institutes of Health criteria. Maternal, fetal, and neonatal outcomes were abstracted by centrally trained and certified perinatal research staff. We evaluated trends in maternal characteristics and outcomes across COVID-19 severity classes and associations between severity and outcomes by multivariable modeling.

RESULTS: A total of 1,219 patients were included: 47% asymptomatic, 27% mild, 14% moderate, 8% severe, 4% critical. Overall, 53% were Hispanic; there was no trend in race–ethnicity distribution by disease severity. Those with more severe illness had older mean age, higher median body mass index, and pre-existing medical comorbidities. Four maternal deaths (0.3%) were attributed to COVID-19. Frequency of perinatal death or a positive

**A list of other members of the NICHD MFMU Network is available in the Appendix 1 online at http://links.lww.com/AOG/C219.*

From the Departments of Obstetrics and Gynecology, University of Utah Health Sciences Center, Salt Lake City, Utah, University of Texas Medical Branch at Galveston, Galveston, Texas, Northwestern University, Chicago, Illinois, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, Columbia University, New York, New York, University of Texas Health Science Center at Houston, Children's Memorial Hermann Hospital, Houston, Texas, University of Pennsylvania, Philadelphia, Pennsylvania, Brown University, Providence, Rhode Island, University of Alabama at Birmingham, Birmingham, Alabama, MetroHealth Medical Center, Case Western Reserve University, Cleveland, Ohio, The Ohio State University, Columbus, Ohio, University of Pittsburgh, Pittsburgh, Pennsylvania, and University of Texas at Austin, Austin, Texas; the George Washington University Biostatistics Center, Washington, DC; and the Eunice Kennedy Shriver *National Institute of Child Health and Human Development, Bethesda, Maryland.*

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neonatal SARS-CoV-2 test result did not differ by severity. Adverse perinatal outcomes were more frequent among patients with more severe illness, including 6% (95% CI 2–11%) incidence of venous thromboembolism among those with severe–critical illness compared with 0.2% in mild–moderate and 0% in asymptomatic ($P<.001$ for trend across severity). In adjusted analyses, severe–critical COVID-19 was associated with increased risk of cesarean birth (59.6% vs 34.0%, adjusted relative risk [aRR] 1.57, 95% CI 1.30–1.90), hypertensive disorders of pregnancy (40.4% vs 18.8%, aRR 1.61, 95% CI 1.18–2.20), and preterm birth (41.8% vs 11.9%, aRR 3.53, 95% CI 2.42–5.14) compared with asymptomatic patients. Mild–moderate COVID-19 was not associated with adverse perinatal outcomes compared with asymptomatic patients.

CONCLUSION: Compared with pregnant patients with SARS-CoV-2 infection without symptoms, those with severe–critical COVID-19, but not those with mild–moderate COVID-19, were at increased risk of perinatal complications.

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Existing reports of coronavirus disease 2019 (COVD-19) in pregnant patients are largely limited to single centers or geographic areas, registries requiring self-referral or health care practitioner referral, and meta-analyses of case series in the inpatient setting.[1–4] A systematic review and meta-analysis of cohort studies with pregnant patients found an association between COVID-19 and both preterm birth and neonatal intensive care unit (NICU) admission.[5] However, available data did not permit examination of other important perinatal outcomes, and the meta-analysis includes some studies in which COVID-19 was diagnosed based on clinical suspicion without testing. In addition, data from the United States are largely derived from those contained in the *Morbidity and Mortality Weekly Report*,[6] which are administrative data provided by public health departments without details regarding clinical disease course.

Recently Adhikari et al[7] performed a retrospective cohort study of pregnant patients delivering at a single academic center and found no association between COVID-19 and a composite adverse perinatal outcome of preterm birth, preeclampsia with severe features, or cesarean birth. However, 95% of the cohort had asymptomatic or mild disease, and it remains unknown whether perinatal outcomes differ by COVID-19 severity. The relationship between COVID-19 and perinatal outcomes among pregnant patients in the United States remains largely unknown.

The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) Maternal-Fetal Medicine Units (MFMU) Network consists of 12 centers with more than 30 separate academic and community hospitals. Together these sites represent the demographic, racial-ethnic and socioeconomic diversity present in the United States. At each site, trained research staff have the capacity to identify all pregnant patients with a positive test result for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) delivering there and to perform detailed medical record abstraction using a standardized protocol. Therefore, we aimed to describe COVID-19 disease severity in a large, diverse cohort of pregnant patients. In addition, we aimed to compare perinatal outcomes among patients based on disease severity. We hypothesized that patients with more severe COVID-19 would have worse perinatal outcomes.

METHODS

This study was an observational cohort of all pregnant patients with a positive SARS-CoV-2 molecular or antigen test result who delivered at 1 of 33 NICHD MFMU sites (six community and 27 academic) in 14 states between March 1, 2020, and July 31, 2020. Patients were included if they had a positive test result at any point during pregnancy (inpatient or outpatient), and a singleton gestation. Both symptomatic patients and asymptomatic patients were included. During the study time period, some of the sites performed SARS-CoV-2 testing for all patients admitted for delivery regardless of symptoms or known exposures. Patients with positive antibody testing alone were not included. Owing to public health concern and potential selection bias, data were collected under a waiver of informed consent with institutional review board approval at each of the participating institutions. Data were analyzed by an independent data coordinating center.

Gestational age at the time of the positive SARS-CoV-2 test result was calculated based on best obstetric estimated date of delivery and the date of the first positive SARS-CoV-2 test result. Detailed electronic medical record abstraction was performed by local perinatal research teams at each MFMU site after centralized training and certification by the data coordinating center. Data quality checks were performed on an ongoing basis to ensure high-quality data across all participating sites.

Descriptive data regarding maternal COVID-19 disease severity were abstracted from the electronic medical record, including symptoms, vital signs,

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imaging results, laboratory values, treatments, complications, and high-intensity interventions including intubation, dialysis, and extracorporeal membrane oxygenation. Hospitalizations and intensive care unit (ICU) admissions during pregnancy through 42 days postpartum also were enumerated. Self-reported symptoms were recorded based on record review from the patient encounter at the time of a SARS-CoV-2 test that included a duration of onset on or 14 days before the test or diagnosis date.

Patients were classified as having asymptomatic, mild, moderate, severe, or critical illness based on National Institutes of Health guidelines for severity of clinical presentation (see Appendix 2, available online at http://links.lww.com/AOG/C219).[8] Classification was based on self-reported symptoms as described above or the patient's worst clinical status from their presentation for SARS-CoV-2 testing through delivery discharge.

Maternal outcomes included death, ICU admission, venous thromboembolism, postpartum hemorrhage, hypertensive disorders of pregnancy, and cesarean birth. Venous thromboembolism was defined as cerebral venous sinus thrombosis, arterial thrombosis cerebrovascular accident, pulmonary embolism, or deep venous thrombosis. Postpartum hemorrhage was defined as estimated blood loss greater than 1,000 mL.[9] Hypertensive disorders of pregnancy were defined according to American College of Obstetricians and Gynecologists criteria for hemolysis, elevated liver enzymes, and low platelet count (HELLP) syndrome; eclampsia; preeclampsia with or without severe features; gestational hypertension; and chronic hypertension with superimposed preeclampsia.[10] Medical records were reviewed for outpatient visits and re-admissions through 42 days postpartum for maternal outcomes.

Neonatal outcomes included perinatal death, positive molecular or antigen SARS-CoV-2 test result during birth admission, and preterm birth before 37 weeks of gestation. Among live births, additional outcomes included neonatal intermediate care unit or NICU admission, birth weight, 5-minute Apgar score 3 or less as a marker of adverse neonatal outcomes,[11] and small-for-gestational-age birth weight less than the 10th percentile based on the Duryea et al[12] nomogram. Neonates were followed only through the delivery hospitalization.

Summary statistics were calculated for baseline characteristics. Race and ethnicity data were abstracted from the medical record and were based on patient self-report at the time of clinical care. All patients identified as Hispanic ethnicity, regardless of race, were categorized as Hispanic. The "other race" category includes non-Hispanic Asian, Native Hawaiian or Pacific Islander, American Indian/Alaskan Native, unknown or more than one race. These categories were collapsed to make comparisons between groups with low frequency of patients in the other race categories. In addition, those with severe and critical illness were grouped together for statistical comparisons, as were those with mild and moderate illness. The Cochran-Armitage trend test for binary variables, score test from multinomial logistic regression for multinomial variables, or Jonckheere-Terpstra trend test for continuous variables were used to assess trends in baseline characteristics and perinatal outcomes across the severe–critical, mild–moderate, and asymptomatic categories.

Severe–critical COVID-19 and mild–moderate COVID-19 were each compared with asymptomatic patients using multivariable modeling. Multivariable modeling was not performed for outcomes with low frequencies including maternal death, stillbirth or neonatal death, maternal venous thromboembolism, or positive SARS-CoV-2 test results for the neonate. Covariates for modeling were selected based on clinical relevance and included maternal age, body mass index (BMI, calculated as weight in kilograms divided by height in meters squared) at first prenatal visit or (if that was not available) preconceptionally, and major medical comorbidity (any of the following: asthma of any severity or chronic obstructive pulmonary disease, chronic hypertension, or pregestational diabetes).

Models for hypertensive disorders of pregnancy and preterm birth also included a covariate for obstetric history (categorized as no prior pregnancy 20 weeks of gestation or longer, history of preterm birth or hypertensive disorder of pregnancy, or prior pregnancy without preterm birth or hypertensive disorder of pregnancy). The model for cesarean birth included history of cesarean birth (categorized as no prior pregnancy 20 weeks of gestation or longer, history of only vaginal births, or any prior cesarean birth) in addition to the baseline demographic variables above. For continuous outcomes, generalized linear models were used to estimate the difference of means and 95% CIs. For categorical outcomes, modified Poisson regression models were used to estimate relative risks and 95% CIs.

A sensitivity analysis was performed in which missing BMI values were imputed based on a generalized linear model and adjusted models were re-run. The imputation modeled the natural-log scale BMI with linear, quadratic, and cubic natural-log scale

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BMI at delivery calculated from the most recent pregnancy weight before delivery. For patients with BMI at delivery and without prenatal (or preconceptional) BMI, imputed BMI values were the back-transformed predicted values based on the model.

Analyses were performed with SAS 9.4. Adjustments were not made for multiple comparisons.

RESULTS

Of 1,291 pregnant patients with a positive SARS-CoV-2 test result over the study time period, 1,219 (94%) had a singleton gestation and tested positive during pregnancy, and were included in the analysis (Fig. 1). Of these, 579 (47%) were asymptomatic, 326 (27%) had mild illness, 173 (14%) had moderate illness, 98 (8%) had severe illness, and 43 (4%) had critical illness (Fig. 1). Among the patients with severe–critical illness, 11% were transported from another health care facility.

The median (interquartile range) gestational age at the time of first positive SARS-CoV-2 test result was 37.7 weeks of gestation (33.7–39.1). The majority of SARS-CoV-2 tests were performed in the inpatient setting (67%). The number of days from the first positive SARS-CoV-2 test result to delivery varied by disease severity, with a median of 4 days (1–28) among those with severe–critical illness, 18 days (1–47) among those with mild–moderate illness, and 1 day (0–2) for asymptomatic individuals. Of those who were asymptomatic with a positive SARS-CoV-2 test result, 97% were tested in the context of universal screening at the time of delivery admission.

The majority of critically ill patients were classified as such owing to respiratory failure (Table 1). Overall, the most common patient-reported symptoms were cough (34%), dyspnea (19%), and myalgias (19%). Those classified as severe most frequently had tachypnea or hypoxia. Although the majority of patients with severe and critical illness had abnormal results on chest radiologic imaging (chest X-ray or computed tomography scan), only a small proportion had more than 50% lung involvement (1% and 5%, respectively).

Tests of trend were significant for differences in age, median BMI, and insurance status across disease severity (Table 2). The majority (53%) of enrolled patients were of Hispanic ethnicity; however, there was no trend in race–ethnicity distribution by severity. Tests of trend were significant for differences in frequency of medical comorbidities including asthma or chronic obstructive pulmonary disease, chronic hypertension, prepregnancy diabetes, chronic liver

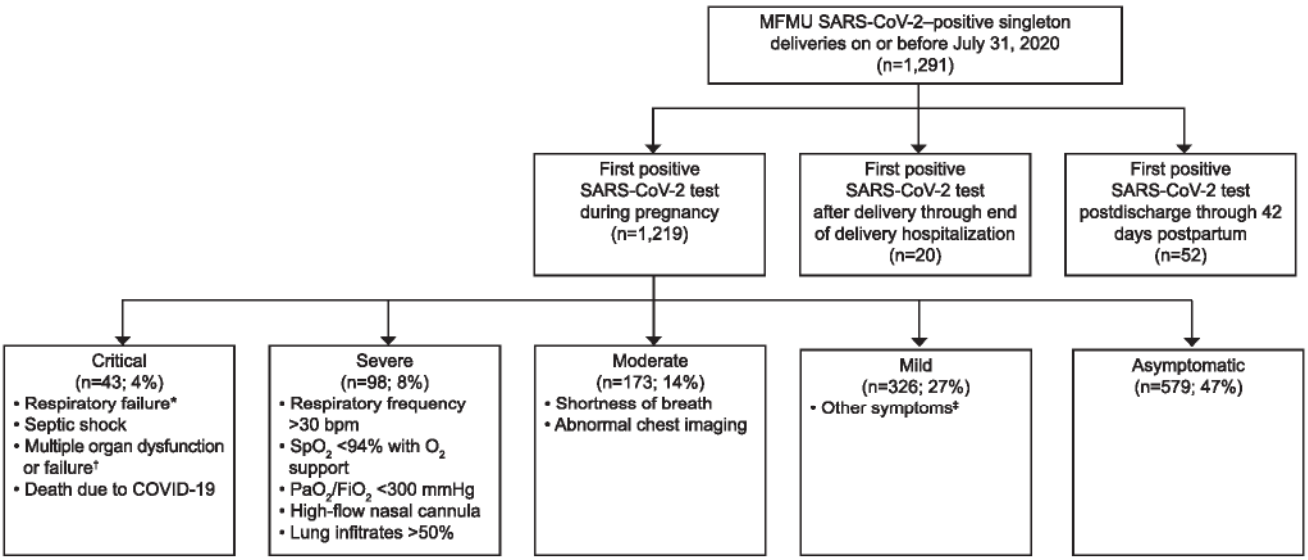


Fig. 1. Study cohort. First positive test result (molecular or antigen) for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2); coronavirus disease 2019 (COVID-19) classification based on data through delivery hospitalization. *Respiratory failure is use of any of the following: extracorporeal membrane oxygenation, continuous positive airway pressure, bi-level positive airway pressure, ventilation. †Multiple organ dysfunction or failure is two or more of the following: cardiac arrest, impaired liver function, renal insufficiency (serum creatinine greater than 1.10 mg/dL), renal failure requiring dialysis, encephalopathy, any need for pressor support, thrombocytopenia (platelets less than 100,000). ‡Other symptoms include fever, cough, sore throat, fatigue, muscle pain, chills, back pain, nausea, vomiting, joint pain, nasal stuffiness, conjunctivitis, confusion, loss of smell or taste, diarrhea, or other. MFMU, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development Maternal-Fetal Medicine Units.

Metz. COVID-19 Severity and Perinatal Outcomes. Obstet Gynecol 2021.

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Table 1. Coronavirus Disease 2019 (COVID-19) Disease Severity Classification for Study Cohort*

Data Through Delivery Hospitalization	Critical (n=43)	Severe (n=98)	Moderate (n=173)	Mild (n=326)	Asymptomatic (n=579)
Respiratory failure†	29 (67)				
Septic shock	8 (19)				
Multiple organ dysfunction or failure‡	26 (61)				
Death due to COVID-19	4 (9)				
Respiratory frequency greater than 30 breaths/min	29 (67)	70 (71)			
SpO_2 less than 94% with O_2 support	27 (63)	59 (60)			
PaO_2 or FiO_2 less than 300 mm Hg	18 (42)	4 (4)			
High-flow nasal cannula	1 (2)	6 (6)			
Lung infiltrates greater than 50% on CT or chest X-ray	2 (5)	1 (1)			
Abnormal chest imaging results (lung infiltrates less than or equal to 50%)	31 (72)	51 (52)	47 (27.2)		
Documentation of self-reported dyspnea	24 (56)	55 (56)	151 (87.3)		
Any other self-reported symptoms (excluding dyspnea)	35 (81)	84 (86)	171 (98.8)	326 (100)	
Cough	28 (65)	63 (64)	131 (75.7)	192 (58.9)	
Myalgia or body aches	15 (35)	40 (41)	76 (43.9)	101 (31.0)	
Fever	18 (42)	41 (42)	63 (36.4)	92 (28.2)	
Nasal stuffiness or rhinorrhea	3 (7)	24 (25)	65 (37.6)	111 (34.0)	
Headache	9 (21)	21 (21)	62 (35.8)	96 (29.4)	
Other symptoms	18 (42)	30 (31)	67 (38.7)	61 (18.7)	
Chills (shaking)	16 (37)	38 (39)	49 (28.3)	54 (16.6)	
Anosmia or loss of smell	8 (19)	12 (12)	43 (24.9)	78 (23.9)	
Fatigue	13 (30)	25 (26)	49 (28.3)	46 (14.1)	
Sore throat	9 (21)	20 (20)	39 (22.5)	63 (19.3)	
Nausea or vomiting	8 (19)	28 (29)	46 (26.6)	47 (14.4)	
Ageusia or loss of taste	6 (14)	12 (12)	42 (24.3)	67 (20.6)	
Back or joint pain	7 (16)	18 (18)	20 (11.6)	20 (6.1)	
Diarrhea	5 (12)	11 (11)	21 (12.1)	26 (8.0)	
Confusion	3 (7)	0	0	2 (0.6)	
Conjunctivitis	0	2 (2)	2 (1.2)	0	
No symptoms					579 (100)

COVID-19, coronavirus disease 2019; CT, computed tomography.
Data are n (%).
Many patients met multiple criteria for disease severity category.
* First positive SARS-CoV-2 test result (nucleic acid or antigen) during pregnancy; COVID-19 classification based on available data through delivery hospitalization.
† Respiratory failure is use of any of the following: extracorporeal membrane oxygenation, continuous positive airway pressure, bi-level positive airway pressure, ventilation.
‡ Multiple organ dysfunction or failure is two or more of the following: cardiac arrest, impaired liver function, renal insufficiency (serum creatinine greater than 1.10 mg/dL), renal failure requiring dialysis, encephalopathy, any need for pressor support, thrombocytopenia (platelets less than 100,000).

disease, and seizure disorder across disease severity. Illness severity was not related to ABO blood type or presence of Rhesus factor (Table 2).

Vital sign and laboratory findings by COVID-19 severity are described in Appendix 3, available online at http://links.lww.com/AOG/C219. Maternal and perinatal deaths are presented in Table 3. Four maternal deaths (0.3%) were thought to be due to COVID-19; autopsies were not performed in all cases. Two other maternal deaths occurred during the study time period and were not related to infection; both had severe COVID-19 before dying of other causes. The frequency of neonatal or fetal death by disease severity is described in Table 3.

A thromboembolic event occurred in eight patients (6%, 95% CI 2–11%) in the severe–critical group; all of these events were deep venous thromboses or pulmonary emboli. In comparison, there was one (0.2%) thromboembolism in the mild–moderate group and none (0%) in the asymptomatic group ($P<.001$ for trend across severity) (Table 3). Of those with a venous thromboembolism, five received prophylactic anticoagulation before the event, all in the severe–critical group.

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Table 2. Baseline Demographic and Clinical Characteristics

Characteristic	Disease Severity			*P* for Trend*
	Critical–Severe (n=141)	Moderate–Mild (n=499)	Asymptomatic (n=579)	
Age (y)	30±6.2	29±6.3	28±6.3	.006
BMI (kg/m²)	32.3 (27.1–37.5)	29.0 (25.2–34.3)	28.3 (24.6–33.0)	<.001
30 or higher	66 (58.4)	202 (44.7)	198 (40.0)	<.001
40 or higher	20 (17.7)	40 (8.9)	35 (7.1)	.002
Race–ethnicity†				.77
Non-Hispanic Black	30 (21.3)	122 (24.4)	123 (21.2)	
Non-Hispanic White	13 (9.2)	88 (17.6)	80 (13.8)	
Hispanic	81 (57.4)	246 (49.3)	324 (56.0)	
Other, unknown, or more than 1 race	17 (12.1)	43 (8.6)	52 (9.0)	
No prior pregnancy 20 wk or longer	48 (34.0)	153 (30.7)	187 (32.3)	.98
Previous preterm birth (20 to less than 37 wk)	13 (9.2)	49 (9.8)	61 (10.6)	.59
Previous cesarean birth	33 (23.4)	112 (22.4)	122 (21.1)	.49
Previous hypertensive disorder of pregnancy	16 (11.3)	69 (13.8)	45 (7.8)	.02
Employed	61 (61.6)	219 (55.7)	194 (50.3)	.03
Private insurance	46 (33.6)	160 (32.3)	124 (21.9)	<.001
Smoked during this pregnancy	5 (3.5)	18 (3.6)	27 (4.7)	.39
Any substance use during this pregnancy	6 (4.3)	32 (6.4)	21 (3.6)	.22
Blood type				.16
A	45 (31.9)	161 (32.3)	154 (26.6)	
B	17 (12.1)	67 (13.5)	64 (11.1)	
AB	3 (2.1)	19 (3.8)	20 (3.5)	
O	76 (53.9)	251 (50.4)	340 (58.8)	
Rh-positive	133 (94.3)	466 (93.6)	541 (93.6)	.81
Immunocompromising condition	3 (2.1)	11 (2.2)	4 (0.7)	.06
Asthma or chronic obstructive pulmonary disease	29 (20.6)	85 (17.0)	51 (8.8)	<.001
Pregestational diabetes	14 (9.9)	18 (3.6)	17 (2.9)	.002
Thrombophilia	0	4 (0.8)	3 (0.5)	.79
Chronic hypertension	16 (11.3)	35 (7.0)	29 (5.0)	.007
Chronic cardiovascular disease	2 (1.4)	9 (1.8)	3 (0.5)	.11
Chronic renal disease	1 (0.7)	2 (0.4)	0	.08
Chronic liver disease	3 (2.1)	2 (0.4)	1 (0.2)	.01
Thyroid disease	10 (7.1)	22 (4.4)	22 (3.8)	.13
Neurocognitive disorder	2 (1.4)	23 (4.6)	10 (1.7)	.25
Neuromuscular disorder	2 (1.4)	1 (0.2)	1 (0.2)	.07
Seizure disorder	5 (3.5)	5 (1.0)	4 (0.7)	.02
Inflammatory bowel disease	1 (0.7)	2 (0.4)	0	.08

BMI, body mass index.
Data are mean±SD, median (interquartile range), or n (%) unless otherwise specified.
Number of missing values: BMI (n=159), previous pregnancy (n=1), employment status (n=341), insurance status (n=20), blood type (n=2), Rh factor (n=2).
* *P*-value based on Cochran-Armitage trend test for binary variables, score test from multinomial logistic regression for multinomial variables, or Jonckheere-Terpstra trend test for continuous variables.
† All patients identified as Hispanic ethnicity, regardless of race, were categorized as Hispanic. Other race includes non-Hispanic Asian, Native Hawaiian/Pacific Islander, American Indian/Alaskan Native, unknown, and more than one race.

Overall, 6% of the cohort had an antepartum admission for treatment of COVID-19 separate from the delivery hospitalization. Fifty-nine (5%) were admitted to the ICU either during the pregnancy or within 42 days postpartum (Table 3). The majority of the ICU admissions (45/59, 76%) were for an indication of COVID-19. Among the patients initially classified as asymptomatic during the delivery hospitalization, one had a hospital readmission with ICU care for COVID-19 after delivery discharge but before 42 days postpartum. Other ICU admissions in asymptomatic patients were for indications unrelated to COVID-19.

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Table 3. Perinatal Outcomes by Coronavirus Disease 2019 (COVID-19) Severity

Outcome	Critical–Severe (n=141)	RR (95% CI)	aRR* (95% CI)	Moderate–Mild (n=499)	RR (95% CI)	aRR* (95% CI)	Asymptomatic (ref) (n=579)	*P* for Trend†
Maternal death	6 (4.3)			0			0	<.001
Venous thromboembolism‡	8 (5.7)			1 (0.2)			0	<.001
Maternal ICU admission	50 (35.5)	68.4 (21.7–216)	57.5 (17.8–186.3)	6 (1.2)	2.32 (0.58–9.23)	2.07 (0.51–8.34)	3 (0.5)	<.001
Cesarean birth	84 (59.6)	1.75 (1.47–2.09)	1.57 (1.30–1.90)	169 (33.9)	1.00 (0.84–1.18)	0.94 (0.81–1.09)	197 (34.0)	<.001
Postpartum hemorrhage§	21 (14.9)	2.05 (1.26–3.35)	2.02 (1.18–3.45)	45 (9.0)	1.24 (0.83–1.86)	1.21 (0.78–1.87)	42 (7.3)	.008
Hypertensive disorders of pregnancy‖	57 (40.4)	2.15 (1.65–2.79)	1.61 (1.18–2.20)	119 (23.8)	1.27 (1.01–1.60)	1.24 (0.98–1.58)	109 (18.8)	<.001
Fetal or neonatal death	6 (4.3)			11 (2.2)			11 (1.9)	.15
Fetal loss at less than 20 wk	3			6			4	
Fetal loss at 20 wk or later	1			4			5	
Neonatal death	2			1			2	
Preterm birth (less than 37 wk)	59 (41.8)	3.51 (2.61–4.72)	3.53 (2.42–5.14)	76 (15.2)	1.28 (0.94–1.73)	1.36 (0.97–1.91)	69 (11.9)	<.001
Spontaneous	10 (16.9)			30 (39.5)			35 (50.7)	
Indicated	49 (83.1)			46 (60.5)			34 (49.3)	
Live birth	137			489			570	
SGA (less than the 10th percentile)	11 (8.0)	0.81 (0.44–1.51)	1.22 (0.63–2.37)	59 (12.2)	1.23 (0.87–1.74)	1.48 (1.02–2.16)	56 (9.9)	.93
Birth weight (g)	2,841±726.1	−364 (−479 to −249)¶	−385 (−510 to −261)¶	3,174±600.1	−32 (−106 to 43)¶	−61 (−138 to 15)¶	3,205±603.9	<.001
NICU admission#	69 (50.4)	3.15 (2.45–4.06)	3.12 (2.32–4.20)	94 (19.2)	1.20 (0.93–1.56)	1.24 (0.93–1.66)	91 (16.0)	<.001

ref, referent; RR, relative risk; aRR, adjusted relative risk; ICU, intensive care unit; SGA, small for gestational age; NICU, neonatal intensive care unit.

Data are n (%) or mean±SD unless otherwise specified.

Number of missing values: size for gestational age (n=6).

* All models adjusted for maternal age, body mass index, and major medical comorbidity; hypertensive disorders of pregnancy and preterm birth also adjusted for obstetric history of preterm birth or hypertensive disorder of pregnancy; cesarean birth also adjusted for history of cesarean birth.

† Cochran-Armitage trend test for binary variables or Jonckheere-Terpstra trend test for continuous variables.

‡ Venous thromboembolism defined as cerebral venous sinus thrombosis, arterial thrombosis cerebrovascular accident, pulmonary embolism, deep venous thrombosis.

§ Postpartum hemorrhage defined as estimated blood loss greater than 1,000 mL.

‖ Hypertensive disorders of pregnancy defined as hemolysis, elevated liver enzymes, and low platelet count (HELLP) syndrome; eclampsia; preeclampsia with or without severe features; gestational hypertension; and chronic hypertension with superimposed preeclampsia according to American College of Obstetricians and Gynecologists definitions.

¶ Difference in means.

Neonatal intermediate or intensive care unit.

Rates for cesarean birth, postpartum hemorrhage, hypertensive disorders of pregnancy and preterm birth were 36.9%, 8.9%, 23.4% and 16.7%, respectively. Adverse maternal and neonatal outcomes were more frequent in patients with severe COVID-19 illness (Table 3). In adjusted analyses, severe–critical COVID-19 was associated with a higher risk of cesarean birth (adjusted relative risk [aRR] 1.57, 95% CI 1.30–1.90), postpartum hemorrhage (aRR 2.02, 95% CI 1.18–3.45), hypertensive disorders of pregnancy (aRR 1.61, 95% CI 1.18–2.20), and preterm birth (aRR 3.53, 95% CI 2.42–5.14) compared with asymptomatic patients. In a sensitivity analysis in which BMI was imputed for those with missing values (n=159, 13%), the adjusted association between severe–critical and postpartum hemorrhage was no longer significant (aRR 1.68, 95% CI 1.00–2.84).

Preterm births among patients with severe–critical illness were indicated (rather than spontaneous) in 83% of cases compared with 61% in patients with mild–moderate illness and 49% in patients who were symptomatic (*P*<.001 for trend across severity

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for indicated delivery among preterm births). Of those induced preterm (n=67), COVID-19 was the primary indication for induction of labor in 3%. The most common indications for induction among the preterm births were hypertensive disorders of pregnancy (33%), stillbirth (16%), and preterm prelabor rupture of membranes (13%). Of those who underwent preterm cesarean birth (n=106), COVID-19 was the primary indication for cesarean in 22%. The other common indications for cesarean among those with preterm births were nonreassuring fetal status (29%), hypertensive disorders of pregnancy (15%), and abnormal presentation (11%).

Severe–critical maternal illness was associated with NICU admission and lower birth weight. Mild–moderate maternal illness was marginally associated with small-for-gestational-age birth weight, although this association was no longer significant when BMI was imputed for those with missing values. Among patients who were induced or had cesarean birth, COVID-19 was the indication for induction or cesarean in 32 of 112 (29%) of the patients with severe–critical illness, 12 of 330 (4%) with mild–moderate illness, and 16 of 352 (5%) who were asymptomatic.

In total, 1.0% (95% CI 0.5–1.8%) of neonates tested positive for SARS-CoV-2 before discharge. The rate of positive neonatal SARS-CoV-2 test results among live births was 1.5% in the severe–critical group, 0.6% in the mild–moderate group, and 1.2% in the asymptomatic group. The percentage of neonates with a 5-minute Apgar score of 3 or less was 2.9% in the severe–critical, 0.2% in the mild–moderate, and 0.7% in the asymptomatic group. The majority (900/1,190 with available data, 76%) of neonates in the cohort were breastfed or breast and bottle fed. Among patients in whom an offer of maternal–neonatal separation owing to SARS-CoV-2 infection was documented (n=448, 37%), 312 were actually separated (26% of total population): 59 of 64 (92%) with severe–critical illness, 77 of 126 (61%) with mild–moderate illness, and 176 of 258 (68%) who were in the asymptomatic group.

DISCUSSION

We found that 12% of pregnant patients with COVID-19 had severe or critical illness. Patients with severe or critical COVID-19 are at risk for a number of perinatal complications including cesarean birth, hypertensive disorders of pregnancy, and preterm birth. Those with severe or critical illness also had increased frequency of venous thromboembolism compared with those with less severe illness. In addition, severe or critical maternal illness was associated with higher risk of NICU admission and lower birth weight compared with neonates of asymptomatic patients.

Our findings regarding preterm birth and NICU admission are consistent with a previous report.[5] However, in our cohort, the increased risk of preterm birth was driven by indicated, rather than spontaneous, preterm birth. Our work also expands what is known about perinatal outcomes in patients with COVID-19 by demonstrating that severe or critical illness is associated with a number of other adverse perinatal outcomes for both the patient and the neonate.

We observed a 6% VTE rate in the severe–critical group. National Institutes of Health treatment guidelines recommend prophylactic anticoagulation in pregnant hospitalized patients with COVID-19.[8] Nonetheless, our data are consistent with those in nonpregnant patients in that critically ill patients with COVID-19 have a high rate of VTE even when receiving prophylactic anticoagulation.[13] Ongoing randomized controlled trials are evaluating whether therapeutic anticoagulation reduces risk of VTE when compared with prophylactic anticoagulation. Further study is also needed to determine the need for anticoagulation in the setting of less severe COVID-19 illness during pregnancy as there was an isolated venous thromboembolic event in the mild–moderate group (1 in 499).

The rate of a positive neonatal SARS-CoV-2 test result was approximately 1% across sites. The majority of these neonates were breastfed or breast and bottle fed. We were limited in our capacity to evaluate for vertical transmission because only clinical testing was available, and, in many cases, this does not include serial testing of the neonate and evaluation of the placenta as required to confirm vertical transmission rather than horizontal transmission after birth.[14] Nonetheless, despite a majority of neonates receiving at least some breastfeeding, positive viral testing in the neonates was infrequent.

Initial *Morbidity and Mortality Weekly Report* data demonstrated an increased risk for hospitalization among pregnant patients compared with females of reproductive age who were not pregnant; however, it was not possible to delineate whether the patient was simply admitted for delivery (rather than COVID-19 complications).[15] Our data indicate that, overall, 6% of pregnant patients who tested positive for SARS-CoV-2 had a hospital admission for COVID-19 separate from their delivery hospitalization. Although this is similar to the 5.8% hospitalization rate published by the Centers for Disease Control

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and Prevention for nonpregnant reproductive-age females, direct comparisons cannot be made given differences in sampling strategy. In addition, patients with critical illness may have required delivery to improve maternal status during what was initially a COVID-19 hospitalization.

Centers for Disease Control and Prevention data[6] demonstrate an increased risk of death from COVID-19 and ICU admission among pregnant patients compared with nonpregnant patients. Recent hospital-level administrative data[16] also demonstrate increased risks of both of these outcomes among patients with COVID-19 compared with those without COVID-19. Our maternal death rate was 0.3% (3/1,000 patients with COVID-19), and the ICU admission rate was 4.8% (48/1,000). Both of these rates are higher than those previously published. A small proportion of the increase may reflect transports requiring critical care from other facilities to MFMU tertiary care centers. However, transports only comprised 11% of the severe–critical study population. Therefore, the higher rates may also reflect increased ascertainment of these outcomes through manual medical record abstraction rather than relying on administrative data.

Consistent with prior studies,[5] risk factors for severe or critical COVID-19 included older age, increased BMI, and underlying medical comorbidities such as asthma, chronic hypertension, and pregestational diabetes. The majority of pregnant patients with COVID-19 in our cohort were of Hispanic ethnicity (53%); however, there was no trend in COVID-19 severity based on race–ethnicity. We found a higher frequency of current employment and private insurance among those with higher disease severity, which may in part reflect transport of patients with higher illness severity to tertiary care centers included in the MFMU.

Limitations of this analysis include the fact that not all sites were performing universal screening for SARS-CoV-2 infection during the entire study period. Overall, the mean gestational age at infection was late in the third trimester, which was at least partially attributable to the inclusion criterion for this analysis being delivery by July 31, 2020; COVID-19 was not widely prevalent in the United States until March 2020. Therefore, the association between COVID-19 and early pregnancy complications such as miscarriage or congenital anomalies could not be evaluated. Many of the NICHD MFMU sites are in urban locations which may limit generalizability to more rural settings; however, both academic and community-based hospitals were included. Results regarding hypertensive disorders of pregnancy must be interpreted in the context of overlapping signs (eg hypertension and lab abnormalities) and symptoms (eg headache) between preeclampsia with severe features and severe or critical COVID-19; however, standard American College of Obstetricians and Gynecologists' diagnostic criteria were used for this endpoint to minimize subjectivity. In addition, owing to the clinical importance and descriptive nature of the data, analyses were not adjusted for multiple comparisons; therefore, some findings could be attributed to chance. Finally, treatment for COVID-19 was rapidly evolving during the study period, and the effect of current treatments on outcomes could not be evaluated.

Strengths of this study include the standardized collection methods of detailed medical record abstraction by trained and certified perinatal research staff. The study included 33 demographically and socioeconomically diverse sites, which makes these data more generalizable than single-center data. In addition, the size of the study population afforded by multiple sites allowed for a larger sample to evaluate differences in outcomes by disease severity. We included patients with positive test results in both the inpatient and outpatient setting, which expands knowledge related to COVID-19 in pregnancy, as the results are not biased by only including inpatients.

These results suggest that pregnant patients with higher levels of COVID-19 severity are at higher risk of perinatal complications. Clinicians should be aware of these risks and consider strategies to mitigate complications when possible.

REFERENCES

1. Khoury R, Bernstein PS, Debolt C, Stone J, Sutton DM, Simpson LL, et al. Characteristics and outcomes of 241 births to women with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection at five New York City medical centers. Obstet Gynecol 2020;136:273–82. doi: 10.1097/AOG.0000000000004025
2. Griffin I, Benarba F, Peters C, Oyelese Y, Murphy T, Contreras D, et al. The impact of COVID-19 infection on labor and delivery, newborn nursery, and neonatal intensive care unit: prospective observational data from a single hospital system. Am J Perinatol 2020;37:1022–30. doi: 10.1055/s-0040-1713416
3. Afshar Y, Gaw SL, Flaherman VJ, Chambers BD, Krakow D, Berghella V, et al. Clinical presentation of coronavirus disease-2019 (COVID-19) in pregnant and recently pregnant people. Obstet Gynecol 2020;136:1117–25. doi: 10.1097/AOG.0000000000004178
4. Prabhu M, Cagino K, Matthews KC, Friedlander RL, Glynn SM, Kubiak JM, et al. Pregnancy and postpartum outcomes in a universally tested population for SARS-CoV-2 in New York City: a prospective cohort study. BJOG 2020;127:1548–56. doi: 10.1111/1471-0528.16403
5. Allotey J, Stallings E, Bonet M, Yap M, Chatterjee S, Kew T, et al. Clinical manifestations, risk factors and maternal and peri-

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natal outcomes of coronavirus disease 2019 in pregnancy: living systematic review and meta-analysis. BMJ 2020;370:m3320. doi: 10.1136/bmj.m3320

6. Zambrano LD, Ellington S, Strid P, Galang RR, Oduyebo T, Tong VT, et al. Characteristics of symptomatic women of reproductive age with laboratory-confirmed SARS-CoV-2 infection by pregnancy status–United States, January 22–October 3, 2020. Accessed January 12, 2020. https://www.cdc.gov/mmwr/volumes/69/wr/mm6944e3.htm
7. Adhikari EH, Moreno W, Zofkie AC, MacDonald L, McIntire DD, Collins RRJ, et al. Pregnancy outcomes among women with and without severe acute respiratory syndrome coronavirus 2 infection. JAMA Netw Open 2020;3:e2029256. doi: 10.1001/jamanetworkopen.2020.29256
8. National Institutes of Health. Coronavirus disease 2019 (COVID-19) treatment guidelines. Accessed January 27, 2021. https://www.covid19treatmentguidelines.nih.gov
9. Postpartum hemorrhage. Practice Bulletin No. 183. American College of Obstetricians and Gynecologists. Obstet Gynecol 2017;130:e168–86. doi: 10.1097/AOG.0000000000002351
10. Gestational hypertension and preeclampsia. ACOG Practice Bulletin No. 222. American College of Obstetricians and Gynecologists. Obstet Gynecol 2020;135:e237–260. doi: 10.1097/AOG.0000000000003891
11. Cnattingius S, Johansson S, Razaz N. Apgar score and risk of neonatal death among preterm infants. N Engl J Med 2020;383:49–57. doi: 10.1056/NEJMoa1915075
12. Duryea EL, Hawkins JS, McIntire DD, Casey BM, Leveno KJ. A revised birth weight reference for the United States. Obstet Gynecol 2014;124:16–22. doi: 10.1097/AOG.0000000000000345
13. Spyropoulos AC, Levy JH, Ageno W, Connors JM, Hunt BJ, Iba T, et a. Scientific and Standardization Committee communication: clinical guidance on the diagnosis, prevention, and treatment of venous thromboembolism in hospitalized patients with COVID-19. J Thromb Haemost 2020;18:1859–65. doi: 10.1111/jth.14929
14. Blumberg DA, Underwood MA, Hedriana HL, Lakshminrusimha S. Vertical transmission of SARS-CoV-2: what is the optimal definition? Am J Perinatol 2020;37:769–72. doi: 10.1055/s-0040-1712457
15. Ellington S, Strid P, Tong VT, Woodworth K, Galang RR, Zambrano LD, et al. Characteristics of women of reproductive age with laboratory-confirmed SARS-CoV-2 infection by pregnancy status-United States, January 22 to June 7, 2020. MMWR Morb Mortal Wkly Rep 2020;69:769–75. doi: 10.15585/mmwr.mm6925a1
16. Jering KS, Claggett BL, Cunningham JW, Rosenthal N, Vardeny O, Greene MF, et al. Clinical characteristics and outcomes of hospitalized women giving birth with and without COVID-19. JAMA Int Med;2021 Jan 15 [Epub ahead of print]. doi: 10.1001/jamainternmed.2020.9241

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EXHIBIT F

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BMJ Global Health

Effectiveness and safety of COVID-19 vaccines on maternal and perinatal outcomes: a systematic review and meta-analysis

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ABSTRACT

Objective To assess the effects of COVID-19 vaccines in women before or during pregnancy on SARS-CoV-2 infection-related, pregnancy, offspring and reactogenicity outcomes.

Design Systematic review and meta-analysis.

Data sources Major databases between December 2019 and January 2023.

Study selection Nine pairs of reviewers contributed to study selection. We included test-negative designs, comparative cohorts and randomised trials on effects of COVID-19 vaccines on infection-related and pregnancy outcomes. Non-comparative cohort studies reporting reactogenicity outcomes were also included.

Quality assessment, data extraction and analysis Two reviewers independently assessed study quality and extracted data. We undertook random-effects meta-analysis and reported findings as HRs, risk ratios (RRs), ORs or rates with 95% CIs.

Results Sixty-seven studies (1 813 947 women) were included. Overall, in test-negative design studies, pregnant women fully vaccinated with any COVID-19 vaccine had 61% reduced odds of SARS-CoV-2 infection during pregnancy (OR 0.39, 95% CI 0.21 to 0.75; 4 studies, 23 927 women; I^2=87.2%) and 94% reduced odds of hospital admission (OR 0.06, 95% CI 0.01 to 0.71; 2 studies, 868 women; I^2=92%). In adjusted cohort studies, the risk of hypertensive disorders in pregnancy was reduced by 12% (RR 0.88, 95% CI 0.82 to 0.92; 2 studies; 115 085 women), while caesarean section was reduced by 9% (OR 0.91, 95% CI 0.85 to 0.98; 6 studies; 30 192 women). We observed an 8% reduction in the risk of neonatal intensive care unit admission (RR 0.92, 95% CI 0.87 to 0.97; 2 studies; 54 569 women) in babies born to vaccinated versus not vaccinated women. In general, vaccination during pregnancy was not associated with increased risk of adverse pregnancy or perinatal outcomes. Pain at the injection site was the most common side effect reported (77%, 95% CI 52% to 94%; 11 studies; 27 195 women).

Conclusion COVID-19 vaccines are effective in preventing SARS-CoV-2 infection and related complications in pregnant women.

PROSPERO registration number CRD42020178076.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Pregnant women with COVID-19 are at high risk of severe disease and death.
⇒ Pregnant women were not included in vaccine trials, resulting in a lack of data on efficacy and safety leading to vaccine hesitancy.
⇒ Existing reviews of observational studies do not account for confounding effects when combining studies, resulting in biased estimates and decreased confidence in findings.

INTRODUCTION

Pregnant and recently pregnant women with SARS-CoV-2 infection are more likely to have severe COVID-19 disease and related mortality

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WHAT THIS STUDY ADDS

⇒ Analysis of adjusted data by confounding variables implies the control of sources of bias, such as the differences in healthcare-seeking behaviour.

⇒ Fully vaccinated pregnant women are at reduced risk of having SARS-CoV-2 infection and being admitted to the hospital compared with unvaccinated pregnant women.

⇒ Unvaccinated pregnant women are more likely to experience hypertensive disorders and caesarean sections, and their neonates are more likely to be admitted to a neonatal unit.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Pregnant women should be counselled and reassured about the safety and benefits of COVID-19 vaccination during pregnancy, both for their own health and that of their babies.

⇒ As the pace of the pandemic continues to evolve, the effectiveness of COVID-19 vaccines against new variants and the duration of protection they provide should be monitored.

and morbidity than non-pregnant women of reproductive age.[1] Globally, vaccination has been the most important intervention in preventing COVID-19-related mortality and morbidity in the general population.[2] However, most phase III trials of COVID-19 vaccines excluded pregnant women, resulting in a lack of trial data on the safety and efficacy of these vaccines during pregnancy.[3] Additionally, concerns about maternal and offspring outcomes have contributed to pregnant women's reluctance to receive COVID-19 vaccination, despite current recommendations that pregnant women should receive the vaccine.[4 5]

Early observational studies on vaccine effectiveness focused on reporting the effects of any COVID-19 vaccine in pregnancy on maternal SARS-CoV-2 infection.[6–8] Subsequent reviews reporting pregnancy outcomes varied in their inclusion of studies, overlapped their search periods by only a few months and were rapidly outdated, limiting their relevance.[9–12] Some reviews only included studies from specific regions or countries and did not provide a global outlook.[13] Existing reviews on the effects of vaccines on pregnant women only included aggregate data and did not adjust for confounding variables, which implied they were not controlled for some sources of bias such as the differences in healthcare-seeking behaviour.[9 13]

We undertook a systematic review to comprehensively assess the effects of any COVID-19 vaccines administered to pregnant women before or during pregnancy on infection-related, pregnancy-related maternal and offspring and reactogenicity outcomes.

METHODS

Our prospectively registered protocol (PROSPERO CRD42020178076) on effects of SARS-CoV-2 in pregnancy was extended to evaluate the effects of COVID-19 vaccines on infection-related and pregnancy-related maternal and offspring outcomes.[14] We report our review using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidance (see online supplemental appendix 1).

Literature search

We searched major databases, preprint servers and websites that serve as repositories for COVID-19 studies, including Medline, Embase, Cochrane database, WHO COVID-19 database, Living Overview of the Evidence platform, China National Knowledge Infrastructure and Wanfang databases for relevant studies on COVID-19 in pregnant women (1 December 2019 to 30 January 2023). We coordinated our search efforts with the WHO Library, and the Cochrane Gynaecology and Fertility group. We contacted established groups coordinating or conducting surveillance and studies in pregnant women receiving COVID-19 vaccination, such as the US Centers for Disease Control and Prevention and the European Centre for Disease Prevention and Control, for information on published and upcoming data. Additional searches of preprint servers, blogs, websites that serve as repositories, social media, guidelines and reference lists of included studies were conducted.[15] No language restrictions were applied. Online supplemental appendix 2 provides details of the search strategies and databases.

Study selection

Nine pairs of independent reviewers selected studies using a two-stage process. The reviewers first screened the titles and abstracts of studies and then assessed the full text of the selected studies in detail for eligibility. Disagreements between reviewers were resolved through discussion with a third reviewer (ST, JA or SF-G). We included test-negative design studies, and comparative cohorts reporting adjusted and unadjusted effects of any COVID-19 vaccine received by women before or during pregnancy on infection-related, pregnancy-related maternal and offspring outcomes, and the rates of reactogenicity outcomes. In test-negative design studies, the source population was pregnant women with COVID-19-like illness, and outcomes of interest were maternal SARS-CoV-2 infection, severe disease and maternal hospital admission outcomes. In neonates with COVID-19-like illness, our outcome was neonatal SARS-CoV-2 infection. SARS-CoV-2 infection was diagnosed by laboratory testing. Those who tested positive were considered as cases, and those who tested negative were controls, and their vaccination status assessed. For infection-related outcomes, we only included studies where women received a complete schedule of the COVID-19 vaccine during pregnancy; for pregnancy-related maternal and offspring outcomes, women were included if they received at least one dose during pregnancy, except for miscarriage outcome where women vaccinated before pregnancy were included. We additionally included non-comparative cohort and case-control studies with a minimum of 10 participants if they reported on reactogenicity outcomes of COVID-19

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vaccines in women vaccinated during pregnancy. We excluded case reports and case series, and studies where women were vaccinated after pregnancy.

Study quality assessment and data extraction

Two independent reviewers (SF-G, LdC-A) assessed the quality of the comparative cohort studies and test-negative design case-control studies in our primary analysis using the 'Risk of Bias in Non-Randomised Studies of Interventions' (ROBINS-I) tool.[16] We used a prepiloted form to extract information on study design, recruitment period, predominant circulating SARS-CoV-2 variant at the time of study, setting (hospital, country), World Bank region, details of key adjustment variables (age, body mass index (BMI), gestational age, education, diabetes, chronic hypertension), the vaccine platform and vaccine product administered, the number of doses and time of vaccination (before or during pregnancy and trimester). The number of doses was assumed to be 'at least one dose' when the number received was unclear or when women included had received different doses. We considered the group to be 'partially vaccinated' when women received only one dose of two-dose vaccines and 'fully vaccinated' when they received one dose of single-dose vaccines or two doses of vaccines requiring two doses for immunogenicity. When women received three doses, we considered the group as 'booster dose'.

We extracted data on the adjusted estimate of the effect of COVID-19 vaccines, the number of vaccinated and non-vaccinated pregnant women and the number of events for infection-related maternal outcomes such as diagnosis of maternal SARS-CoV-2 infection before delivery, maternal hospital admission, maternal death and maternal severe COVID-19 disease defined as admission to the intensive care unit (ICU), hospitalisation due to severe disease or as defined by study authors; infection-related offspring outcomes like offspring SARS-CoV-2 infection up to 6 months after delivery; pregnancy-related maternal outcomes included miscarriage, preterm birth <37 weeks, caesarean section, postpartum haemorrhage, gestational diabetes and hypertensive disorders and offspring outcomes included stillbirth, neonatal death, neonatal intensive care unit (NICU) admission, low 5 min Apgar score (<7) and small-for-gestational-age baby. We extracted data on the number of vaccinated pregnant women who reported reactogenicity outcomes such as headache, fever, myalgia, fatigue and pain at injection site from comparative and non-comparative cohorts and case-control studies. We did not consider the booster doses for reactogenicity outcomes.

Statistical analysis

Our primary analysis was based on test-negative design and comparative cohort studies with adjusted analyses reporting the effects of COVID-19 vaccines on infection-related, and pregnancy-related maternal and offspring outcomes. We pooled the adjusted estimates using random effects meta-analysis and summarised the findings as HRs, risk ratios (RRs) or ORs with 95% CIs.

For the secondary analysis, we pooled data from all included comparative cohort studies with unadjusted estimates and summarised the findings of infection-related and pregnancy-related maternal and offspring outcomes as ORs with 95% CIs. We calculated the rates of reactogenicity outcomes from non-comparative studies as proportions with 95% CIs using DerSimonian and Laird random-effects meta-analysis, after transforming data using Freeman-Tukey double-arcsine transformation. Heterogeneity was reported using I^2. All statistical analyses were performed using Stata (V.18).

Patient and public involvement

This study is supported by Katie's team, a dedicated patient and public involvement group in women's health. The team was involved in the interpretation and reporting of this systematic review through participation in virtual meetings. Findings will be made available on our website in a format more suitable for patients and members of the public (www.birmingham.ac.uk/research/who-collaborating-centre/pregcov/index.aspx).

RESULTS

We included 67 studies (1 813 947 women) from 1 326 315 identified articles (figure 1). Twenty-four were included in the primary analysis, with eight performing adjusted analysis (185 955 women) for SARS-CoV-2 infection-related outcomes.[6–8 17–21] Six of them reported maternal SARS-CoV-2 infection, three reported maternal hospital admission and two reported severe COVID-19 disease and neonatal SARS-CoV-2 infection. Sixteen performed adjusted analysis for pregnancy-related maternal and offspring outcomes (544 314 women).[22–37] We included 16 studies (425 867 women) reporting SARS-CoV-2 infection-related outcomes[6 7 17 19 21 31 33 36 38–45] and 35 (1 362 172 women) reporting pregnancy-related maternal and offspring outcomes in the secondary analysis.[17 18 21–24 29–34 36 38 39 41–60] Twenty-three studies reported reactogenicity outcomes (94 206 women) following vaccination.[38 39 46 61–80]

Characteristics of the included studies

A third of the included studies were from the Middle East and North Africa (22/67; 193 889 women), followed by North America (28%, 19/67; 397 756 women), Europe and Central Asia (22.5%, 15/67; 1 150 470 women), East Asia and Pacific (10.5%, 7/67; 42 204 women) and Latin America and Caribbean (3%, 2/67; 22 122 women), South Asia (1.5%, 1/67; 247 women) and one was a multicountry study (1.5%, 1/67; 4618 women). Fifty-nine studies were from high-income countries (59/67; 1 782 548 women), six from upper-middle-income countries (6/67; 26 534 women), one from lower-middle-income countries (1/67; 247 women) and one from a mix of high-income, upper-middle-income and lower-middle-income countries (1/67; 4618). Overall, 45 studies

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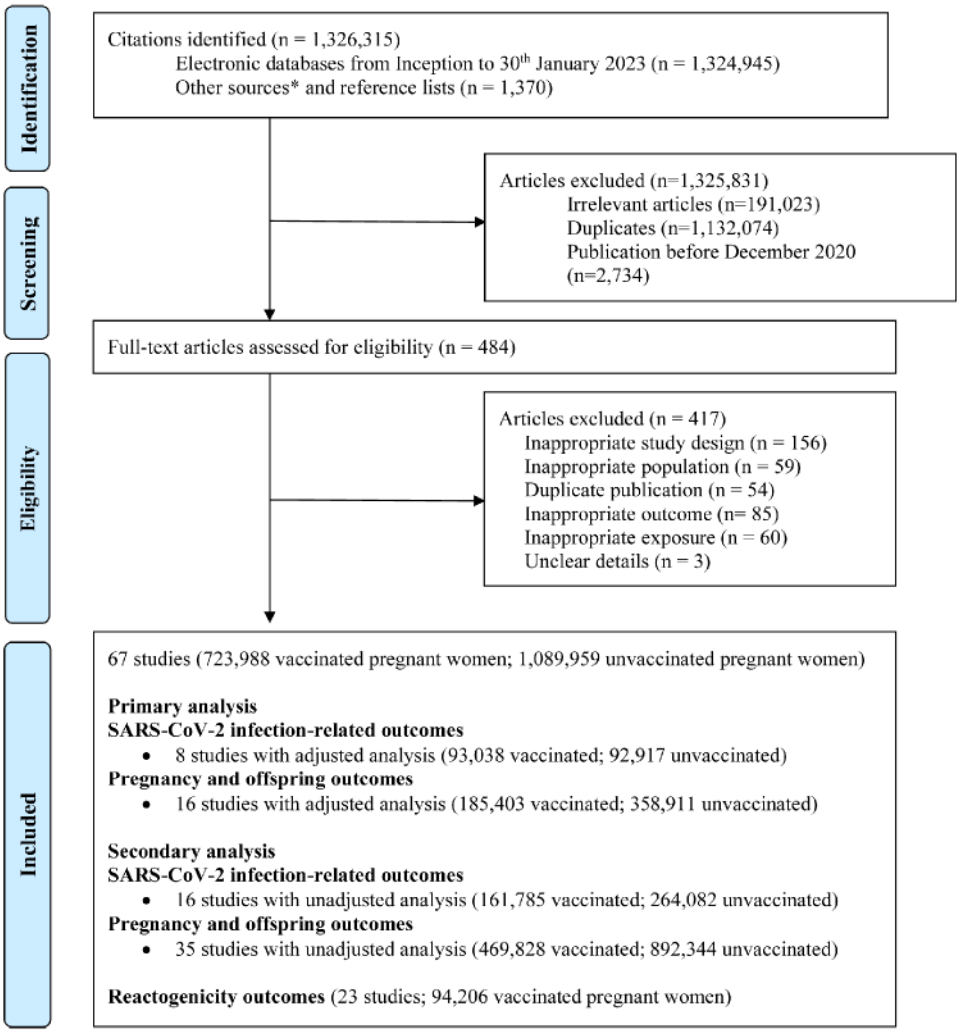


Figure 1 Study selection process in the systematic review. Created and owned by the authors. *Twitter, national reports, blog Thornton J, ObG Project, COVID-19 and Pregnancy Cases (https://www.obgproject.com/2020/04/07/covid-19-research-watch-with-dr-jim-thornton/); EPPI-Centre, COVID-19: a living systematic map of evidence (http://eppi.ioe.ac.uk/cms/Projects/DepartmentofHealthandSocialCare/Publishedreviews/COVID19Livingsystematicmapoftheevidence/tabid/3765/Default.aspx); Norwegian Institute of Public Health (NIPH), NIPH systematic and living map on COVID-19 evidence (https://www.nornesk.no/forskningskart/NIPH_mainMap.html); John Hopkins University Center for Humanitarian Health; COVID-19, Maternal and Child Health, Nutrition (http://hopkinshumanitarianhealth.org/empower/advocacy/covid-19/covid-19-children-and-nutrition/); ResearchGate, COVID-19 research community (https://www.researchgate.net/community/COVID-19); Living Overview of the Evidence, COVID-19 (https://app.iloveevidence.com/loves/5e6fdb9669c00e4ac072701d?population=5d062d5fc80dd41e58ba8459).

included women vaccinated with mRNA vaccine only (281 030 women), four studies included inactivated virus (3088 women), one study viral vector vaccine (247 women), 14 studies mRNA and/or viral vector vaccines (436 453 women), one mRNA, viral vector and inactivated virus vaccines (2886 women) and two did not report the type of vaccine (284 women). Most of the studies included in the primary analysis were adjusted by maternal age (88%, 21/24), followed by diabetes (42%, 10/24), hypertension (33%, 8/24), BMI (33%, 8/24), gestational age (17%, 4/24) and education (4%, 1/24). Three of the eight studies performing adjusted analysis for SARS-CoV-2 infection-related outcomes were from the Delta and Omicron periods (134 779 women), one study was from the Delta period (464 women), one from the Omicron period (4618 women), one from the Alpha and Beta periods (4534 women), one from the Alpha period and other variants (21 722 women) and one from the Delta period and other variants (19 838 women). Online supplemental appendix 3 describes the characteristics of all included studies.

Quality of studies included in primary analysis

Figure 2 provides the risk of bias for the included test-negative design and adjusted cohort studies included in the main analysis. For the maternal SARS-CoV-2 infection outcome, 17% of studies (1/6) were considered to be low risk, 66% (4/6) moderate risk and 17% (1/6) as serious risk. Of the two studies reporting severe COVID-19 disease, one was considered to be moderate risk and the

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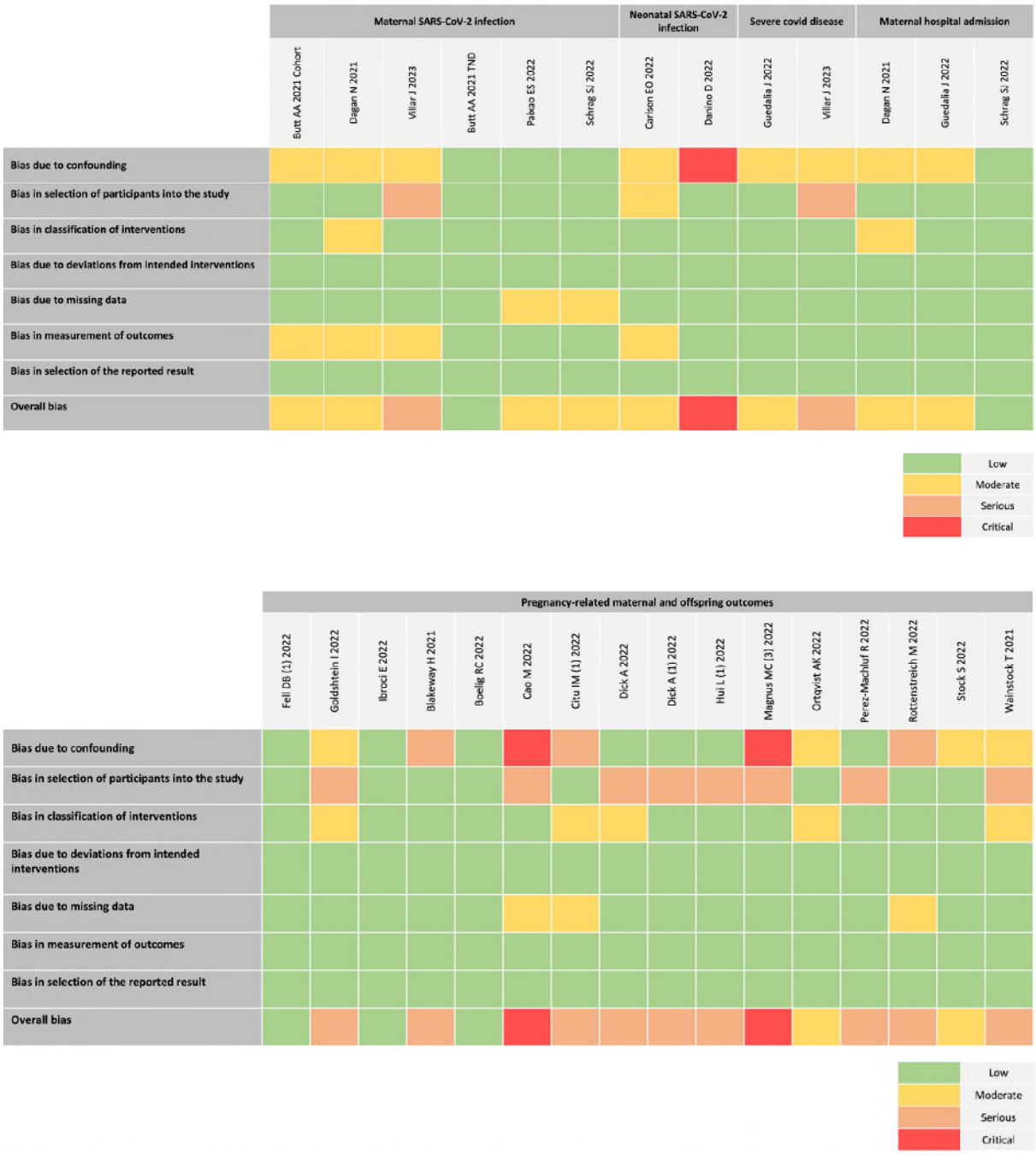


Figure 2 Quality assessment for risk of bias in studies of primary analysis using Risk of Bias in Non-Randomised Studies of Interventions tool. Created and owned by the authors.

other serious. For maternal hospital admission outcome, two studies were classified as having moderate risk and one as low risk. Of the two studies reporting neonatal SARS-CoV-2 infection, one study was considered to have critical risk of bias rating, as prematurity, a postintervention variable was used as an adjustment factor.[18] More than half of the studies reporting pregnancy-related maternal and offspring outcomes were considered to be serious risk (9/16), 19% (3/16) low risk and 12% (2/16) as moderate or critical risk. Online supplemental appendix 4 describes the consensus judgements used to assign the risk of bias in each domain.

Effects of COVID-19 vaccines on SARS-CoV-2 infection-related outcomes

In our primary analysis of test-negative design studies, women who were fully vaccinated had a 61% reduction in the odds of SARS-CoV-2 infection during pregnancy (OR 0.39, 95% CI 0.21 to 0.75; 4 studies, 23 927 women; I^2=87.2%) and a 94% reduction in the odds of hospital admission (OR 0.06, 95% CI 0.01 to 0.71; 2 studies, 868 women; I^2=92%) (figure 3). The effect of the vaccines on infection-related outcomes of the adjusted comparative cohort studies is imprecise and heterogeneous. Although it consistently shows a reduction in the hazard of

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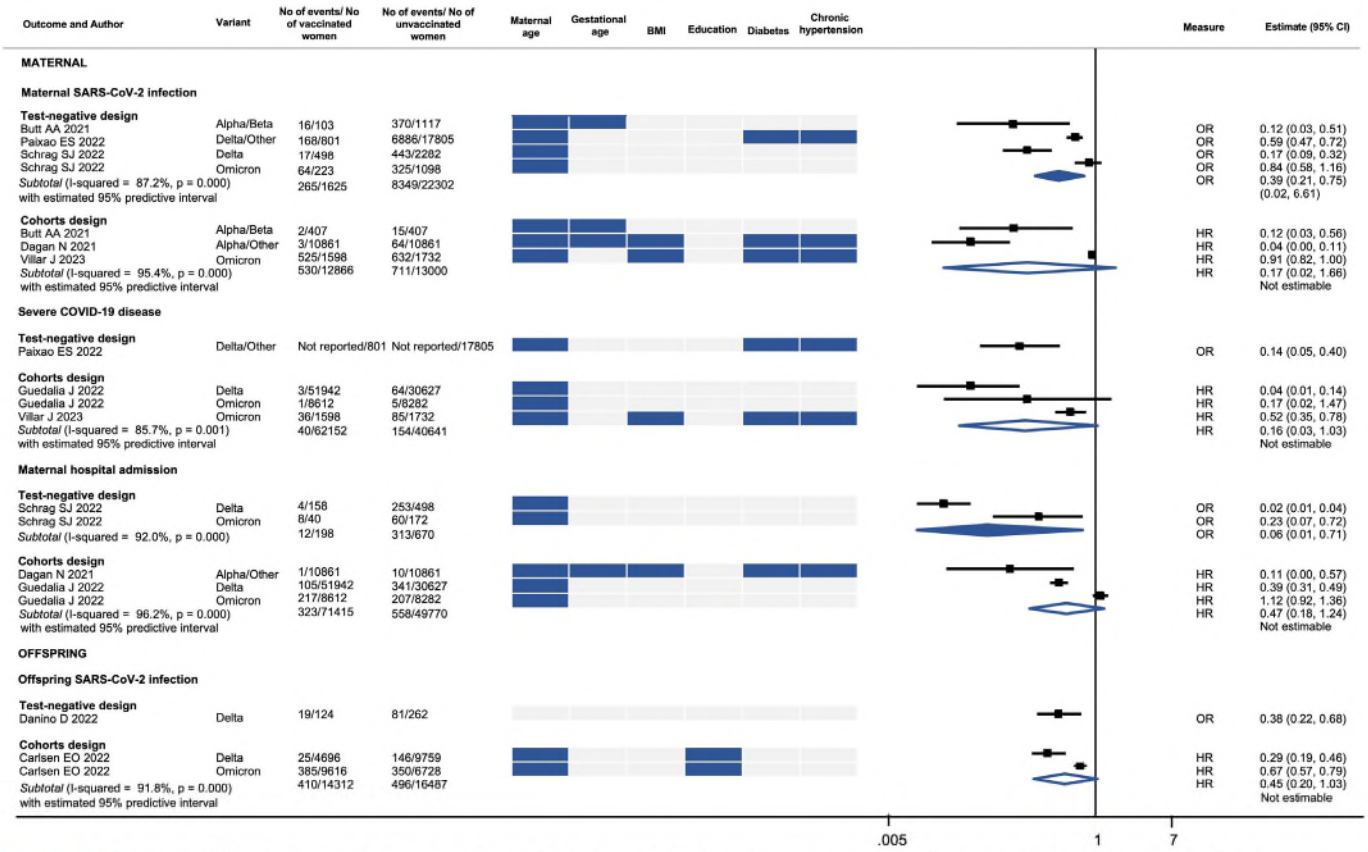


Figure 3 Vaccine effectiveness for SARS-CoV-2 infection-related outcomes. BMI, body mass index. Created and owned by the authors.

infection-related outcomes, this reduction does not reach statistical significance (figure 3). We did not find any test-negative design study or adjusted comparative cohort study reporting on maternal death. Table 1 provides the summary estimates of the effects of COVID-19 vaccines reported in test-negative design studies (adjusted), comparative cohort (adjusted) and unadjusted cohort studies. Online supplemental appendix 5 provides details of individual unadjusted cohort studies.

Effects of COVID-19 vaccines on pregnancy-related maternal and offspring outcomes

Meta-analysis of adjusted comparative cohort studies showed a 12% reduction in the risk of hypertensive disorders in pregnancy (RR 0.88, 95% CI 0.82 to 0.92; 2 studies; 115 085 women) in women vaccinated versus not vaccinated in pregnancy. The odds of caesarean section (OR 0.91, 95% CI 0.85 to 0.98; 6 studies; 30 192 women) was reduced in the pooled analysis of adjusted comparative cohorts. We did not find any association between COVID-19 vaccination and other maternal outcomes, except for gestational diabetes (table 1). We observed an 8% reduction in the risk of newborn's admission to the NICU (RR 0.92, 95% CI 0.87 to 0.97; 2 studies; 54 569 women) in babies born to vaccinated versus not vaccinated women. There were no significant differences observed in other offspring outcomes (table 1). The summary findings of data from adjusted and unadjusted cohort studies for pregnancy-related maternal and offspring outcomes are provided in online supplemental appendices 6 and 7. The summary findings from the adjusted individual studies are provided in online supplemental appendices 8 and 9.

Vaccination in pregnancy and reactogenicity outcomes

The most common side effects reported by pregnant women vaccinated with any number of doses of COVID-19 vaccine were mild pain at the injection site (77%, 95% CI 52% to 94%; 11 studies; 27 195 women), followed by fatigue (29%, 95% CI 15% to 46%; 14 studies; 72 671 women) (table 2). Other side effects, such as headache and myalgia, were reported by 12% of vaccinated pregnant women each, while fever was reported by 5% (95% CI 2% to 8%; 19 studies; 82 972 women) of vaccinated pregnant women (table 2).

DISCUSSION

COVID-19 vaccination in pregnant women reduces the risks of maternal SARS-CoV-2 infection and admission to the hospital during pregnancy. Vaccination in pregnancy appears to reduce risks of maternal hypertensive disorders during pregnancy, caesarean section and neonatal admission to ICU. Pain at injection site was the most common side effect of COVID-19 vaccination.

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Table 1 Summary estimates reported in test-negative design (adjusted), comparative cohort (adjusted) and comparative cohort (unadjusted) studies

	Test-negative design (adjusted)			Comparative cohort (adjusted)			Comparative cohort (unadjusted)		
Outcome	No. of studies (women)	HR (95% CI)	I^2 (%)	No. of studies (women)	Estimate (95% CI)	I^2 (%)	No. of studies (women)	OR (95% CI)	I^2 (%)
SARS-CoV-2 infection-related outcomes									
Maternal SARS-CoV-2 infection	4 (23 927)	0.39 (0.21 to 0.75)	87.2	3 (25 866)	OR 0.17 (0.02 to 1.66)	95.4	11 (397 679)	0.63 (0.47 to 0.85)	98.5
Severe COVID-19 disease	1 (18 606)	0.14 (0.05 to 0.40)		3 (102 793)	OR 0.16 (0.03 to 1.03)	85.7	11 (132 759)	0.47 (0.22 to 0.97)	80.9
Maternal hospital admission	2 (868)	0.06 (0.01 to 0.71)	92	3 (121 185)	OR 0.47 (0.18 to 1.24)	96.2	2 (36 782)	0.41 (0.13 to 1.28)	92
Offspring SARS-CoV-2 infection	1 (386)	0.38 (0.22 to 0.68)		2 (30 799)	OR 0.45 (0.20 to 1.03)	91.8	3 (31 848)	0.52 (0.33 to 0.82)	87.6
Maternal death							9 (148 297)	0.53 (0.12 to 2.47)	64.4
Pregnancy-related maternal outcomes									
Miscarriage				4 (43 465)	OR 0.96 (0.90 to 1.04)	0	3 (1113)	1.60 (0.70 to 1.91)	0
Preterm birth <37 weeks				5 (25 516)	OR 0.79 (0.59 to 1.06)	68.3	21 (1 104 043)	0.90 (0.83 to 0.97)	75
				1 (24 190)	RR 0.95 (0.83 to 1.10)				
Caesarean section				6 (30 192)	OR 0.91 (0.85 to 0.98)	0	15 (188 144)	1.11 (1.03 to 1.20)	48.6
				2 (54 569)	RR 0.94 (0.81 to 1.08)	34.9			
Postpartum haemorrhage				5 (30 192)	OR 1.49 (0.91 to 2.44)	86.7	6 (104 693)	0.82 (0.68 to 1.00)	0
				1 (52 775)	RR: 0.90 (0.81 to 1.00)				
Gestational diabetes				1 (5618)	OR 1.10 (0.90 to 1.30)		11 (263 319)	1.04 (0.89 to 1.21)	94.2
				2 (115 085)	RR 1.17 (1.14 to 1.20)	0			
Hypertensive disorders				5 (15 739)	OR 1.11 (0.87 to 1.43)	0	10 (217 486)	1.13 (1.02 to 1.25)	49
				2 (115 085)	RR 0.88 (0.85 to 0.92)	0			
Pregnancy-related offspring outcomes									
Stillbirth				2 (17 907)	OR 0.38 (0.09 to 1.59)	89.4	11 (1 024 952)	0.78 (0.65 to 0.92)	36.5
Admission to neonatal intensive care unit				4 (173 978)	OR 0.88 (0.71 to 1.08)	37.9	9 (108 534)	0.82 (0.79 to 0.86)	0
				2 (54 569)	RR 0.92 (0.87 to 0.97)	0			
Low 5 min Apgar score <7				4 (179 034)	OR 0.89 (0.73 to 1.08)	29.3	9 (113 540)	0.89 (0.81 to 0.99)	0
				1 (51 922)	RR 0.88 (0.77 to 1.01)				
Small for gestational age				6 (172 483)	OR 0.96 (0.90 to 1.02)	0	8 (153 813)	0.99 (0.95 to 1.03)	0
				1 (24 190)	RR 0.97 (0.87 to 1.08)				
Neonatal death				1 (24 190)	RR 0.84 (0.43 to 1.72)				

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*As reported in the individual studies, adjusted cohort results for pregnancy-related maternal and offspring outcomes are shown as OR or RR.
RR, risk ratio.

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Table 2 Reactogenicity outcomes in pregnant women vaccinated for COVID-19

Side effects	Partially vaccinated				Fully vaccinated				Any number of doses			
	No. of studies	No. of events	Proportion (95% CI)	I^2 (%)	No. of studies	No. of events	Proportion (95% CI)	I^2 (%)	No. of studies	No. of events	Proportion (95% CI)	I^2 (%)
Fever	13	1683/36 439	0.06 (0.03 to 0.10)	99.2	14	8158/28 139	0.16 (0.07 to 0.26)	99.7	19	1766/82 972	0.05 (0.02 to 0.08)	99.5
Headache	10	3987/28 491	0.10 (0.05 to 0.17)	99.4	13	9207/21 999	0.20 (0.09 to 0.34)	99.7	17	4885/40 751	0.12 (0.06 to 0.18)	99.7
Myalgia	8	2208/23 392	0.09 (0.04 to 0.15)	98.8	11	7376/17 345	0.28 (0.12 to 0.47)	99.7	13	2789/27 920	0.12 (0.08 to 0.17)	98.6
Fatigue	8	6727/22 827	0.26 (0.23 to 0.29)	86.9	10	12 751/18 746	0.52 (0.45 to 0.60)	98.1	14	8042/72 671	0.29 (0.15 to 0.46)	99.9
Pain at injection site	7	20540/22 922	0.85 (0.76 to 0.93)	99.3	8	16 896/18 608	0.80 (0.73 to 0.85)	98.1	11	21 623/27 195	0.77 (0.52 to 0.94)	99.9

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Our comprehensive review on the effects of COVID-19 vaccination in pregnant women provides robust data by focusing on test-negative design studies, which are a rigorous method to reduce the bias, and adjusted comparative cohorts in our main analysis. We used ROBINS-I tool that provides a comprehensive assessment of the risk of bias. We undertook an extensive deduplication process and minimised the risk of including duplicate data. By focusing on both SARS-CoV-2 infection-related and pregnancy-related maternal and offspring outcomes, we addressed questions that are important to women in making decisions regarding vaccination. The large sample size in our review allowed us to assess the magnitude of benefit and risk of harm with high precision, including for less common but important outcomes such as neonatal admission to ICU. We included studies from different regions and income levels, with no language restrictions.

Our review has some limitations. The trimester of exposure to vaccines was poorly reported in primary studies, which did not allow us to see the effect of the timing of vaccination on infection-related, pregnancy-related maternal and offspring or reactogenicity outcomes. We did not find any test-negative design or adjusted comparative cohort study reporting on maternal death. Some of the studies included women vaccinated before or during pregnancy and we were unable to separately give estimates for women vaccinated during pregnancy. We did not evaluate long-term effects of the vaccines and were unable to analyse data on adverse effects such as thrombocytopenia, embolic reactions or myocarditis due to the lack of enough studies reporting these outcomes. Similarly, the sample sizes and event numbers were small for outcomes such as miscarriage and maternal death requiring cautious interpretation. We found an association between vaccination and an increased risk of gestational diabetes, but this is based on two different populations from the same adjusted comparative cohort study.[35] Further data are needed to confirm this. We were unable to assess the effects of vaccines on the different variants due to the few published papers reporting separately for periods of variants of concern. Despite our comprehensive search, most of the studies that met our inclusion criteria are from high-income countries and external validity of our findings may not be accurate for middle-income and low-income settings.

In pregnant women from test-negative design studies, we found a reduction in the odds of SARS-CoV-2 infection and hospital admission after complete vaccination. The findings are similar to those observed in clinical trials and real-world data showing COVID-19 vaccines to be effective in preventing SARS-CoV-2 infections, severe COVID-19 disease and deaths, in the general adult population.[81 82] In general population, the effectiveness of COVID-19 vaccines varied depending on the type of vaccine, the population being vaccinated, the number of doses, the variant and the immunity of individuals.[82] However, we refrained from performing this analysis as

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data were only limited to non-adjusted cohort studies, with high degree of bias. Previous reviews on COVID-19 vaccines in pregnancy often limited their reporting to a few specific regions or countries, or only on SARS-CoV-2 infection.[9 13] In addition, most of these reviews did not include test-negative design studies or did not use data from adjusted comparative cohort studies analysis. Our findings, based on these study designs, are inherently controlled for some sources of bias, such as differences in healthcare-seeking behaviour and access by vaccination status and are less affected by confounding factors.[83]

COVID-19 vaccines are recommended for use in pregnancy by WHO, policymakers and professional bodies globally.[5 84–87] The exclusion of pregnant women from the initial clinical trials limited the acquisition of safety data and the ability to make evidence-based recommendations at the early stages of vaccine implementation. Our study demonstrated that reactogenicity-related side effects of COVID-19 vaccine in pregnant women were generally mild, similar to those reported in the general population. Rare adverse events such as vaccine-associated thrombotic thrombocytopenia (incidence 0.73 cases per 100 000 vaccinated persons receiving adenovirus-based vaccines), myocarditis (12.6 cases per million doses messenger RNA (mRNA) vaccine) and Guillain-Barré syndrome (7.8 cases per million doses adenovirus vaccine) may not be captured, and a very large sample size would be needed to evaluate such rare events during pregnancy.[88]

Pregnant women should be counselled and reassured about the safety and benefits of COVID-19 vaccination during pregnancy, both for their own health and that of their babies. Our findings demonstrate the effectiveness and safety of different COVID-19 vaccines. Although most available data are for the mRNA vaccines Pfizer-BioNTech BNT162b2 and Moderna mRNA-1273, our review also includes data on Sinovac-CoronaVac, Sinopharm BIBP, Janssen Ad26.COV2.S, AZD ChAdOx1-S, Cansino Ad5-nCoV-S and Bharat BBV152 Covaxin. More data on these non-mRNA vaccines would strengthen existing findings. Women should discuss their individual risks and concerns with their healthcare provider, who can help reassure and support them in making the best decision about vaccination.

The response was too slow during the pandemic, and equitable and timely distribution of COVID-19 vaccines to all communities, particularly vulnerable populations, could have saved more lives at the height of the pandemic. Barriers to vaccine access, including transportation, language and technology barriers, should be addressed and ensure that vaccine distribution sites are located in areas that are easily accessible to underserved communities.[89] An investment in providing vaccine education and outreach campaigns to promote acceptance and address hesitancy is critical. Close collaboration is needed between professional colleges and community organisations to provide accurate and appropriate information about vaccine safety and efficacy and continuous monitoring to provide updates to help build trust and confidence.

The virus has shown its ability to mutate, leading to the emergence of new variants. The effectiveness of existing vaccines against these variants is continuously monitored by vaccine manufacturers and health authorities. This has led to the recommendation of supplementary doses to enhance immunity or a single dose in each pregnancy, regardless of previous vaccination status.[90] It is important to continue research on the effectiveness of COVID-19 vaccines against different variants of the virus, the duration of protection they provide and further safety data from non-mRNA vaccines. The Human Reproduction Programme (the United Nations Development Programme/United Nations Population Fund/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction) initiatives can be adapted and generalised to prepare for quicker response in future epidemics.[91] The development of research infrastructure, which includes strengthening laboratories, research facilities and data management systems can be repurposed for epidemic outbreaks. In addition, collaboration with various stakeholders such as governments, non-governmental organisations and research institutions can facilitate faster response times and resource mobilisation. Research should also focus on identifying reasons for vaccine hesitancy, particularly among pregnant women.[92] Effective communication strategies need to be developed to address these concerns.

CONCLUSION

COVID-19 vaccination in pregnant women is highly effective in reducing the odds of maternal SARS-CoV-2 infection, and hospital admission, and improves pregnancy outcomes, with no serious safety concerns. The interpretation of our findings may be impacted by changes in vaccine recommendations and the changing landscape of SARS-CoV-2 variants.

Dissemination to participants and related patient and public communities

The PregCOV-19 Living Systematic Review Group will disseminate the findings through a dedicated website (www.birmingham.ac.uk/research/who-collaborating-centre/pregcov/index.aspx) and social media.

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Contributors ST, MB and JA conceptualised the study. DS, JS, KL, NO-L, AR, HN, NS, PSu, SMe, PSe, SA, SMa, MM, ZM, HL, MY and TK selected the studies. SF-G, DS, KL, NO-L, AP, CK, ES, JC, SR and WC extracted the data. SF-G, LdC-A and JZ conducted the analyses. All coauthors contributed to the writing of the manuscript and approved the final version. ST, JA and JZ are the guarantors. All members of the PregCOV-19 Living Systematic Review Consortium contributed to study selection and data extraction. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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REFERENCES

1 Allotey J, Stallings E, Bonet M, *et al*. Clinical manifestations, risk factors, and maternal and perinatal outcomes of Coronavirus disease 2019 in pregnancy: living systematic review and meta-analysis. *BMJ* 2020;370:m3320.
2 Watson OJ, Barnsley G, Toor J, *et al*. Global impact of the first year of COVID-19 vaccination: a mathematical modelling study. *Lancet Infect Dis* 2022;22:1293–302.
3 World Health Organization. COVID-19 vaccines technical documents. n.d. Available: https://www.who.int/groups/strategic-advisory-group-of-experts-on-immunization/covid-19-materials
4 Bhattacharya O, Siddiquea BN, Shetty A, *et al*. COVID-19 vaccine hesitancy among pregnant women: a systematic review and meta-analysis. *BMJ Open* 2022;12:e061477.
5 World Health Organization. SAGE updates COVID-19 vaccination guidance. 2023. Available: https://www.who.int/news/item/28-03-2023-sage-updates-covid-19-vaccination-guidance
6 Butt AA, Chemaitelly H, Al Khal A, *et al*. SARS-CoV-2 vaccine effectiveness in preventing confirmed infection in pregnant women. *J Clin Invest* 2021;131:e153662.
7 Dagan N, Barda N, Biron-Shental T, *et al*. Effectiveness of the BNT162b2 mRNA COVID-19 vaccine in pregnancy. *Nat Med* 2021;27:1693–5.
8 Paixao ES, Wong KLM, Alves FJO, *et al*. Coronavac vaccine is effective in preventing symptomatic and severe COVID-19 in pregnant women in Brazil: a test-negative case-control study. *BMC Med* 2022;20:146.
9 Ma Y, Deng J, Liu Q, *et al*. Effectiveness and safety of COVID-19 vaccine among pregnant women in real-world studies: a systematic review and meta-analysis. *Vaccines (Basel)* 2022;10:246.
10 Shafiee A, Kohandel Gargari O, Teymouri Athar MM, *et al*. COVID-19 vaccination during pregnancy: a systematic review and meta-analysis. *BMC Pregnancy Childbirth* 2023;23:45.
11 Rimmer MP, Teh JJ, Mackenzie SC, *et al*. The risk of miscarriage following COVID-19 vaccination: a systematic review and meta-analysis. *Hum Reprod* 2023;38:840–52.
12 Prasad S, Kalafat E, Blakeway H, *et al*. Systematic review and meta-analysis of the effectiveness and perinatal outcomes of COVID-19 vaccination in pregnancy. *Nat Commun* 2022;13:2414.
13 Pratama NR, Wafa IA, Budi DS, *et al*. mRNA COVID-19 vaccines in pregnancy: a systematic review. *PLoS One* 2022;17:e0261350.
14 Yap M, Debenham L, Kew T, *et al*. Clinical manifestations, prevalence, risk factors, outcomes, transmission, diagnosis and treatment of COVID-19 in pregnancy and postpartum: a living systematic review protocol. *BMJ Open* 2020;10:e041868.
15 Tulane University, Institute for Clinical Effectiveness and Health Policy, London School of Hygiene and Tropical Medicine. COVID-19 vaccines for pregnant persons: a living systematic review and meta-analysis. n.d. Available: safeinpregnancy.org/lsr/
16 Sterne JA, Hernán MA, Reeves BC, *et al*. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. *BMJ* 2016;355:i4919.
17 Carlsen EØ, Magnus MC, Oakley L, *et al*. Association of COVID-19 vaccination during pregnancy with incidence of SARS-CoV-2 infection in infants. *JAMA Intern Med* 2022;182:825–31.
18 Danino D, Ashkenazi-Hoffnung L, Diaz A, *et al*. Effectiveness of BNT162b2 vaccination during pregnancy in preventing hospitalization for severe acute respiratory syndrome coronavirus 2 in infants. *J Pediatr* 2023;254:48–53.
19 Guedalia J, Lipschuetz M, Calderon-Margalit R, *et al*. Effectiveness of a third BNT162b2 mRNA COVID-19 vaccination during

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pregnancy: a national observational study in Israel. *Nat Commun* 2022;13:6961.
20 Schrag SJ, Verani JR, Dixon BE, *et al*. Estimation of COVID-19 mRNA vaccine effectiveness against medically attended COVID-19 in pregnancy during periods of Delta and Omicron variant predominance in the United States. *JAMA Netw Open* 2022;5:e2233273.
21 Villar J, Soto Conti CP, Gunier RB, *et al*. Pregnancy outcomes and vaccine effectiveness during the period of Omicron as the variant of concern, INTERCOVID-2022: a multinational, observational study. *The Lancet* 2023;401:447–57.
22 Fell DB, Dhinsa T, Alton GD, *et al*. Association of COVID-19 vaccination in pregnancy with adverse peripartum outcomes. *JAMA* 2022;327:1478–87.
23 Goldshtein I, Steinberg DM, Kuint J, *et al*. Association of BNT162b2 COVID-19 vaccination during pregnancy with neonatal and early infant outcomes. *JAMA Pediatr* 2022;176:470–7.
24 Ibroci E, Liu X, Lieb W, *et al*. Impact of prenatal COVID-19 vaccination on delivery and neonatal outcomes: results from a New York City cohort. *Vaccine* 2023;41:649–56.
25 Boelig RC, Aghai ZH, Chaudhury S, *et al*. Impact of COVID-19 disease and COVID-19 vaccination on maternal or fetal inflammatory response, placental pathology, and perinatal outcomes. *Am J Obstet Gynecol* 2022;227:652–6.
26 Cao M, Wu Y, Lin Y, *et al*. Inactivated COVID-19 vaccine did not undermine live birth and neonatal outcomes of women with frozen-thawed embryo transfer. *Hum Reprod* 2022;37:2942–51.
27 Citu IM, Citu C, Gorun F, *et al*. The risk of spontaneous abortion does not increase following first trimester mRNA COVID-19 vaccination. *J Clin Med* 2022;11:1698.
28 Dick A, Rosenbloom JI, Gutman-Ido E, *et al*. Safety of SARS-CoV-2 vaccination during pregnancy- obstetric outcomes from a large cohort study. *BMC Pregnancy Childbirth* 2022;22.
29 Dick A, Rosenbloom JI, Karavani G, *et al*. Safety of third SARS-CoV-2 vaccine (booster dose) during pregnancy. *Am J Obstet Gynecol MFM* 2022;4:100637.
30 Hui L, Marzan MB, Rolnik DL, *et al*. Reductions in stillbirths and preterm birth in COVID-19–vaccinated women: a multicenter cohort study of vaccination uptake and perinatal outcomes. *Am J Obstet Gynecol* 2023;228:585.
31 Magnus MC, Örtqvist AK, Dahlqwist E, *et al*. Association of SARS-CoV-2 vaccination during pregnancy with pregnancy outcomes. *JAMA* 2022;327:1469–77.
32 Peretz-Machluf R, Hirsh-Yechezkel G, Zaslavsky-Paltiel I, *et al*. Obstetric and neonatal outcomes following COVID-19 vaccination in pregnancy. *JCM* 2022;11:2540.
33 Rottenstreich M, Sela H, Rotem R, *et al*. Uptake and outcomes of COVID-19 vaccination during the third trimester of pregnancy: a multicenter study. *AJOG* 2022;226:S401–2.
34 Wainstock T, Yoles I, Sergienko R, *et al*. Prenatal maternal COVID-19 vaccination and pregnancy outcomes. *Vaccine* 2021;39:6037–40.
35 Örtqvist AK, Dahlqwist E, Magnus MC, *et al*. COVID-19 vaccination in pregnant women in Sweden and Norway. *Vaccine* 2022;40:4686–92.
36 Blakeway H, Prasad S, Kalafat E, *et al*. COVID-19 vaccination during pregnancy: coverage and safety. *Am J Obstet Gynecol* 2022;226:236.
37 Stock* S, Calvert C, Carruthers J, *et al*. Early pregnancy outcomes following COVID-19 vaccination and SARS-coV-2 infection: a national population-based matched cohort study. *In Review* [Preprint].
38 Bleicher I, Kadour-Peero E, Sagi-Dain L, *et al*. Early exploration of COVID-19 vaccination safety and effectiveness during pregnancy: interim descriptive data from a prospective observational study. *Vaccine* 2021;39:6535–8.
39 Goldshtein I, Nevo D, Steinberg DM, *et al*. Association between BNT162b2 vaccination and incidence of SARS-Cov-2 infection in pregnant women. *JAMA* 2021;326:728–35.
40 de Freitas Paganoti C, Alkmin da Costa R, Papageorghiou AT, *et al*. COVID-19 vaccines confer protection in hospitalized pregnant and postpartum women with severe COVID-19: a retrospective cohort study. *Vaccines (Basel)* 2022;10:749.
41 Theiler RN, Wick M, Mehta R, *et al*. Pregnancy and birth outcomes after SARS-CoV-2 vaccination in pregnancy. *Am J Obstet Gynecol MFM* 2021;3:100467.
42 Piekos SN, Hwang YM, Roper RT, *et al*. Effect of COVID-19 vaccination and booster on maternal–fetal outcomes: a retrospective cohort study. *Lancet Digit Health* 2023;5:e594–606.
43 Kim H, Kim H-S, Kim HM, *et al*. Impact of vaccination and the Omicron variant on COVID-19 severity in pregnant women. *Am J Infect Control* 2023;51:351–3.
44 Halasa NB, Olson SM, Staat MA, *et al*. Maternal vaccination and risk of hospitalization for COVID-19 among infants. *N Engl J Med* 2022;387:109–19.
45 Sekkarie A, Woodruff R, Whitaker M, *et al*. Characteristics and treatment of hospitalized pregnant women with COVID-19. *Am J Obstet Gynecol MFM* 2022;4:100715.
46 Citu IM, Citu C, Gorun F, *et al*. Immunogenicity following administration of BNT162b2 and Ad26.Cov2.S COVID-19 vaccines in the pregnant population during the third trimester. *Viruses* 2022;14:307.
47 Lipkind HS, Vazquez-Benitez G, DeSilva M, *et al*. Receipt of COVID-19 vaccine during pregnancy and Preterm or small-for-gestational-age at birth — eight integrated health care organizations, United States. *MMWR Morb Mortal Wkly Rep* 2020;71:26–30.
48 Juttukonda LJ, Wachman EM, Boateng J, *et al*. The impact of maternal SARS-Cov-2 vaccination and first trimester infection on Feto-Maternal immune responses. *Am J Reprod Immunol* 2022;88:e13625.
49 Kashani-Ligumsky L, Lopian M, Cohen R, *et al*. Titers of SARS CoV-2 antibodies in cord blood of neonates whose mothers contracted SARS CoV-2 (COVID-19) during pregnancy and in those whose mothers were vaccinated with mRNA to SARS CoV-2 during pregnancy. *J Perinatol* 2021;41:2621–4.
50 Kugelman N, Riskin A, Kedar R, *et al*. Safety of COVID-19 vaccination in pregnant women: a study of the adverse perinatal outcomes. *Int J Gynaecol Obstet* 2023;161:298–302.
51 Li M, Hao J, Jiang T, *et al*. Maternal and neonatal safety of COVID-19 vaccination during the peri-pregnancy period: a prospective study. *J Med Virol* 2023;95:e28378.
52 Lis-Kuberka J, Berghausen-Mazur M, Orczyk-Pawiłowicz M. Attitude and level of COVID-19 vaccination among women in reproductive age during the fourth pandemic wave: a cross-sectional study in Poland. *Int J Environ Res Public Health* 2022;19:6872.
53 Smithgall MC, Murphy EA, Schatz-Siemers N, *et al*. Placental pathology in women vaccinated and unvaccinated against SARS-CoV-2. *Am J Obstet Gynecol* 2022;227:782–4.
54 Shanes ED, Otero S, Mithal LB, *et al*. Severe acute respiratory syndrome Coronavirus 2 (SARS-Cov-2) vaccination in pregnancy. *Obstetrics & Gynecology* 2021;138:281–3.
55 Rottenstreich M, Rotem R, Wiener-Well Y, *et al*. Covid-19 third vaccination during pregnancy: maternal and neonatal outcomes—a retrospective study. *Arch Gynecol Obstet* 2023;308:1197–205.
56 Wang Y, Ren X, Wang Z, *et al*. Receipt of Inactivated COVID-19 vaccine had no adverse influence on embryo implantation, clinical pregnancy and Miscarriage in early pregnancy. *Sci China Life Sci* 2022;65:2332–4.
57 Beharier O, Plitman Mayo R, Raz T, *et al*. Efficient maternal to neonatal transfer of antibodies against SARS-CoV-2 and BNT162b2 mRNA COVID-19 vaccine. *J Clin Invest* 2021;131:e150319.
58 Fell DB, Dimanlig-Cruz S, Regan AK, *et al*. Risk of Preterm birth, small for gestational age at birth, and Stillbirth after COVID-19 vaccination during pregnancy: population based retrospective cohort study. *BMJ* 2022;378:e071416.
59 Mayo RP, Raz T, Ben DB, *et al*. Waning of the humoral response to SARS-Cov-2 in pregnancy is variant-dependent. *medRxiv* 2021.
60 UK Health Security Agency. COVID-19 vaccine surveillance report; 2022.
61 Gray KJ, Bordt EA, Atyeo C, *et al*. Coronavirus disease 2019 vaccine response in pregnant and lactating women: a cohort study. *Am J Obstet Gynecol* 2021;225:303.
62 Kachikis A, Englund JA, Singleton M, *et al*. Short-term reactions among pregnant and lactating individuals in the first wave of the COVID-19 vaccine rollout. *JAMA Netw Open* 2021;4:e2121310.
63 Kadali RAK, Janagama R, Peruru SR, *et al*. Adverse effects of COVID-19 messenger RNA vaccines among pregnant women: a cross-sectional study on healthcare workers with detailed self-reported symptoms. *Am J Obstet Gynecol* 2021;225:458–60.
64 Komine-Aizawa S, Haruyama Y, Deguchi M, *et al*. The vaccination status and adverse effects of COVID -19 vaccine among pregnant women in Japan in 2021. *J Obstet Gynaecol Res* 2022;48:1561–9.
65 Mascolo A, di Mauro G, Fraenza F, *et al*. Maternal, fetal and neonatal outcomes among pregnant women receiving COVID-19 vaccination: the Preg-Co-VAX study. *Front Immunol* 2022;13:965171.
66 Montalti M, Guaraldi F, Di Valerio Z, *et al*. Adherence to and early adverse events of COVID-19 vaccine in a cohort of 600 Italian breastfeeding and pregnant physicians. *Hum Vaccin Immunother* 2022;18:2106747.
67 Sadarangani M, Soe P, Shulha HP, *et al*. Safety of COVID-19 vaccines in pregnancy: a Canadian national vaccine safety (CANVAS) network cohort study. *Lancet Infect Dis* 2022;22:1553–64.

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68 Shimabukuro TT, Kim SY, Myers TR, *et al*. Preliminary findings of mRNA Covid-19 vaccine safety in pregnant persons. *N Engl J Med* 2021;384:2273–82.
69 Toussia-Cohen S, Yinon Y, Peretz-Machluf R, *et al*. Early adverse events and immune response following second and third COVID-19 vaccination in pregnancy. *J Clin Med* 2022;11:4720.
70 Voiniušytė A, Černiauskaitė M, Paliulytė V, *et al*. Vaccination against COVID-19 disease during pregnancy. *Acta Med Litu* 2022;29:51–7.
71 Zdanowski W, Markiewicz A, Zdanowska N, *et al*. Tolerability of the BNT162b2 COVID-19 vaccine during pregnancy among Polish Healthcare professionals. *Vaccines (Basel)* 2022;10:200.
72 Sourouni M, Braun J, Oelmeier K, *et al*. Assessment of neonatal cord blood SARS-CoV-2 antibodies after COVID-19 vaccination in pregnancy: a prospective cohort study. *Geburtshilfe Frauenheilkd* 2022;82:510–6.
73 Arulappen AL, Danial M, Shanmugam G, *et al*. A multicenter cohort study on the adverse effects evaluation after messenger RNA COVID-19 vaccination among pregnant healthcare employees in Penang general hospitals. *Front Public Health* 2022;10:876966.
74 Ben-Mayor Bashi T, Amikam U, Ashwal E, *et al*. The association of maternal SARS-CoV-2 vaccination-to-delivery interval and the levels of maternal and cord blood antibodies. *Intl J Gynecology & Obste* 2022;156:436–43.
75 Blakeway H, Amin-Chowdhury Z, Prasad S, *et al*. Evaluation of immunogenicity and reactogenicity of COVID -19 vaccines in pregnant women. *Ultrasound Obstet Gynecol* 2022;60:673–80.
76 Bookstein Peretz S, Regev N, Novick L, *et al*. Short-Term outcome of pregnant women vaccinated with BNT162b2 mRNA COVID -19 vaccine. *Ultrasound Obstet Gynecol* 2021;58:450–6.
77 Collier A-RY, McMahan K, Yu J, *et al*. Immunogenicity of COVID-19 mRNA vaccines in pregnant and lactating women. *JAMA* 2021;325:2370–80.
78 DeSilva M, Haapala J, Vazquez-Benitez G, *et al*. Evaluation of acute adverse events after COVID-19 vaccination during pregnancy. *N Engl J Med* 2022;387:187–9.
79 Favre G, Maisonneuve E, Pomar L, *et al*. COVID-19 mRNA vaccine in pregnancy: results of the Swiss COVI-PREG registry, an observational prospective cohort study. *Lancet Reg Health Eur* 2022;18:100410.
80 Gandhi AP, Thakur JS, Gupta M, *et al*. COVID-19 vaccination uptake and adverse events following COVID-19 immunization in pregnant women in northern India: a prospective, comparative, cohort study. *J Rural Med* 2022;17:228–35.
81 Rahman MdM, Masum MdHU, Wajed S, *et al*. A comprehensive review on COVID-19 vaccines: development, effectiveness, adverse effects, distribution and challenges. *VirusDis* 2022;33:1–22.
82 Zheng C, Shao W, Chen X, *et al*. Real-world effectiveness of COVID-19 vaccines: a literature review and meta-analysis. *Int J Infect Dis* 2022;114:252–60.
83 Dean NE, Hogan JW, Schnitzer ME. Covid-19 vaccine effectiveness and the test-negative design. *N Engl J Med* 2021;385:1431–3.
84 European Centre for Disease Prevention and Control. Overview of the implementation of COVID-19 vaccination strategies and deployment plans in the EU/EEA; 2022.
85 UK Health Security Agency. COVID-19 vaccination: a guide on pregnancy and breastfeeding. 2020. Available: https://www.gov.uk/government/publications/covid-19-vaccination-women-of-childbearing-age-currently-pregnant-planning-a-pregnancy-or-breastfeeding/covid-19-vaccination-a-guide-on-pregnancy-and-breastfeeding
86 American College of Obstetricians and Gynecologists. COVID-19 vaccination considerations for obstetric–gynecologic care. 2020. Available: https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/covid-19-vaccination-considerations-for-obstetric-gynecologic-care?report=reader
87 World Health Organization. WHO SAGE roadmap on uses of COVID-19 vaccines in the context of OMICRON and substantial population immunity. 2023. Available: https://www.who.int/publications/i/item/WHO-2019-nCoV-Vaccines-SAGE-Roadmap
88 Fragkou PC, Dimopoulou D. Serious complications of COVID-19 vaccines: a mini-review. *Metabol Open* 2021;12:100145.
89 World Health Organization. Global COVID-19 vaccination strategy in a changing world. 2022. Available: https://www.who.int/publications/m/item/global-covid-19-vaccination-strategy-in-a-changing-world--july-2022-update
90 World Health Organization. WHO SAGE roadmap for prioritizing uses of COVID-19 vaccines. 2023. Available: https://www.who.int/publications/i/item/WHO-2019-nCoV-Vaccines-SAGE-Prioritization-2023.1
91 World Health Organization. HRP annual report 2022. Geneva World Health Organization; 2023.
92 Murewanhema G. Vaccination hesitancy among women of reproductive age in resource-challenged settings: a cause for public health concern. *Pan Afr Med J* 2021;38:336.

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EXHIBIT G

Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

Centers for Disease Control and Prevention

Vaccines & Immunizations

Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States

Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites

Summary of recent changes (last updated December 30, 2020):

- Additional information on antibody therapies and COVID-19 vaccination
- Information on COVID-19 vaccination and outbreak management
- Additional information on vaccination of immunocompromised persons
- Updates to contraindications and precautions to vaccination
- Information on COVID-19 vaccination and tuberculin skin testing

Background

The Advisory Committee on Immunization Practices (ACIP) has issued interim recommendations for the use of Pfizer-BioNTech and Moderna COVID-19 vaccines for the prevention of coronavirus disease 2019 (COVID-19) in the United States. Both vaccines are lipid nanoparticle-formulated, nucleoside-modified mRNA vaccines encoding the prefusion spike glycoprotein of SARS-CoV-2, the virus that causes COVID-19.

These interim CDC clinical considerations are informed by data submitted to the Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) of the vaccines, other data sources, general best practice guidelines for immunization, and expert opinion. These considerations for mRNA vaccines only apply to the currently authorized vaccine products in the United States (i.e., Pfizer-BioNTech and Moderna COVID-19 vaccines). Considerations will be updated as additional information becomes available or if additional vaccine products are authorized.

In addition to the following considerations, the EUA conditions of use and storage, handling, and administration procedures described in the prescribing information should be referenced when using the Pfizer-BioNTech and Moderna COVID-19 vaccines.

Authorized age groups

Under the EUAs, the following age groups are authorized to receive vaccination:

- Pfizer-BioNTech: ages ≥16 years
- Moderna: ages ≥18 years

Children and adolescents outside of these authorized age groups should not receive COVID-19 vaccination at this time.

Administration

The mRNA COVID-19 vaccine series consist of two doses administered intramuscularly:

- Pfizer-BioNTech (30 µg, 0.3 ml each): three weeks (21 days) apart
- Moderna (100 µg, 0.5 ml): one month (28 days) apart

Second doses administered within a grace period of ≤4 days from the recommended date for the second dose are considered valid; however, doses administered earlier do not need to be repeated. The second dose should be administered as close to the recommended interval as possible. However, there is no maximum interval between the first and second dose for either vaccine.

Interchangeability with other COVID-19 vaccine products

Either of the currently authorized mRNA COVID-19 vaccines can be used when indicated; ACIP does not state a product preference. However, these mRNA COVID-19 vaccines are **not** interchangeable with each other or with other COVID-19 vaccine products. The safety and efficacy of a mixed-product series have not been evaluated. Both doses of the series should be completed with the same product. However, if two doses of different mRNA COVID-19 vaccine products are inadvertently administered, no additional doses of either product are recommended at this time. Recommendations may be updated as further information becomes available or other vaccine types (e.g., viral vector, protein subunit vaccines) are authorized.

Coadministration with other vaccines

Given the lack of data on the safety and efficacy of mRNA COVID-19 vaccines administered simultaneously with other vaccines, the vaccine series should be administered alone, with a minimum interval of 14 days before or after administration with any other vaccine. If mRNA COVID-19 vaccines are inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine.

Booster doses

The need for and timing of booster doses for mRNA COVID-19 vaccines has not been established. No additional doses beyond the two-dose primary series are recommended at this time.

Vaccination of persons with a SARS-CoV-2 infection or exposure

Persons with a current or prior history of SARS-CoV-2 infection

Data from clinical trials indicate that mRNA COVID-19 vaccines are safe in persons with evidence of a prior SARS-CoV-2 infection. Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection. Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection solely for the purposes of vaccine decision-making is not recommended.

Vaccination of persons with known current SARS-CoV-2 infection should be deferred until the person has recovered from the acute illness (if the person had symptoms) and criteria have been met for them to discontinue isolation. This recommendation applies to persons who develop SARS-CoV-2 infection before receiving any vaccine doses as well as those who develop SARS-CoV-2 infection after the first dose but before receipt of the second dose. While there is otherwise no recommended minimum interval between infection and vaccination, current evidence suggests that reinfection is uncommon in the 90 days after initial infection. Thus, persons with documented acute SARS-CoV-2 infection in the preceding 90 days may delay vaccination until near the end of this period, if desired.

For vaccinated persons who subsequently develop COVID-19, prior receipt of an mRNA COVID-19 vaccine should not affect treatment decisions (including use of monoclonal antibodies, convalescent plasma, antiviral treatment, or corticosteroid administration) or timing of such treatments.

Persons who previously received passive antibody therapy

Currently, there are no data on the safety and efficacy of mRNA COVID-19 vaccines in persons who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment. Based on the estimated half-life of such therapies as well as evidence suggesting that reinfection is uncommon in the 90 days after initial infection, vaccination should be deferred for at least 90 days, as a precautionary measure until additional information becomes available, to avoid interference of the antibody treatment with vaccine-induced immune responses.

For persons receiving antibody therapies not specific to COVID-19 treatment (e.g., intravenous immunoglobulin, RhoGAM), administration of mRNA COVID-19 vaccines either simultaneously with or at any interval before or after receipt of an antibody-containing product is unlikely to substantially impair development of a protective antibody response. Thus, there is no recommended minimum interval between other antibody therapies (i.e., those that are not specific to COVID-19 treatment) and mRNA COVID-19 vaccination.

Vaccinating persons with a known SARS-CoV-2 exposure or during COVID-19 outbreaks

mRNA vaccines are not currently recommended for outbreak management or for post-exposure prophylaxis, which is vaccination to prevent the development of SARS-CoV-2 infection in a person with a specific known exposure. Because the median incubation period of SARS-CoV-2 is 4 to 5 days, it is unlikely that the first dose of COVID-19 vaccine would provide an adequate immune response within the incubation period for effective post-exposure prophylaxis. Thus, vaccination is unlikely to be effective in preventing disease following an exposure.

Persons in the community or outpatient setting who have had a known COVID-19 exposure should not seek vaccination until their quarantine period has ended to avoid potentially exposing healthcare personnel and other persons to SARS-CoV-2 during the vaccination visit.

Residents with a known COVID-19 exposure living in congregate healthcare settings (e.g., long-term care facilities), where exposure and transmission of SARS-CoV-2 can occur repeatedly for long periods of time, may be vaccinated. In these settings, healthcare personnel are already in close contact with residents (e.g., entering patient rooms for evaluation and treatment). Vaccinators should employ appropriate infection prevention and control procedures.

Residents of other congregate settings (e.g., correctional and detention facilities, homeless shelters) with a known COVID-19 exposure may also be vaccinated, in order to avoid delays and missed opportunities for vaccination given the increased risk for outbreaks in these settings. However, where feasible, precautions should be taken to limit mixing exposed individuals with other residents or staff (except those essential for the provision of vaccination services, who should employ appropriate infection and control procedures).

Persons residing in congregate settings (healthcare and non-healthcare) who have had an exposure and are awaiting results of SARS-CoV-2 testing may be vaccinated if the person does not have symptoms consistent with COVID-19.

In situations where facility-wide testing is being conducted to identify SARS-CoV-2 infections, facilities should attempt to complete facility-wide testing within a period that allows for test results to be received prior to vaccination in order to isolate those patients with SARS-CoV-2 infection. However, it is not necessary to wait for test results if this would create delays in vaccination. In such situations, persons without symptoms consistent with COVID-19 may be vaccinated. Although not contraindicated, vaccination may be deferred pending outcome of testing in persons with symptoms consistent with COVID-19. Viral testing for acute SARS-CoV-2 infection solely for the purposes of vaccine decision-making is not recommended.

Vaccination of persons with underlying medical conditions

mRNA COVID-19 vaccines may be administered to persons with underlying medical conditions who have no contraindications to vaccination (see 'contraindications' section below). Clinical trials demonstrated similar safety and efficacy profiles in persons with some underlying medical conditions, including those that place them at increased risk for severe COVID-19, compared to persons without comorbidities. Information on groups with specific underlying medical conditions is included below.

Immunocompromised persons

Persons with HIV infection or other immunocompromising conditions, or who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19. Data are not currently available to establish vaccine safety and efficacy in these groups. Persons with stable HIV infection were included in mRNA COVID-19 vaccine clinical trials, though data

remain limited. Immunocompromised individuals may receive COVID-19 vaccination if they have no contraindications to vaccination. However, they should be counseled about the unknown vaccine safety profile and effectiveness in immunocompromised populations, as well as the potential for reduced immune responses and the need to continue to follow all current guidance to protect themselves against COVID-19 (see below). Antibody testing is not recommended to assess for immunity to COVID-19 following mRNA COVID-19 vaccination.

At this time, re-vaccination is not recommended after immune competence is regained in persons who received mRNA COVID-19 vaccines during chemotherapy or treatment with other immunosuppressive drugs. Recommendations on re-vaccination or additional doses of mRNA COVID-19 vaccines may be updated as additional information is available.

Persons with autoimmune conditions

No data are currently available on the safety and efficacy of mRNA COVID-19 vaccines in persons with autoimmune conditions, though these persons were eligible for enrollment in clinical trials. No imbalances were observed in the occurrence of symptoms consistent with autoimmune conditions or inflammatory disorders in clinical trial participants who received an mRNA COVID-19 vaccine compared to placebo. Persons with autoimmune conditions who have no contraindications to vaccination may receive an mRNA COVID-19 vaccine.

Persons with a history of Guillain-Barré syndrome

To date, no cases of Guillain-Barré syndrome (GBS) have been reported following vaccination among participants in the Pfizer-BioNTech or Moderna COVID-19 vaccines clinical trials. With few exceptions, ACIP's general best practice guidelines for immunization does not include history of GBS as a contraindication or precaution to vaccination. Persons with a history of GBS may receive an mRNA COVID-19 vaccine unless they have a contraindication to vaccination. Any occurrence of GBS following mRNA COVID-19 vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS).

Persons with a history of Bell's palsy

Cases of Bell's palsy were reported following vaccination in participants in both the Pfizer-BioNTech and Moderna COVID-19 vaccines clinical trials. However, the FDA does not consider these to be above the frequency expected in the general population and has not concluded that these cases were causally related to vaccination. Post-authorization safety surveillance will be important to further assess any possible causal association. In the absence of such evidence, persons with a history of Bell's palsy may receive an mRNA COVID-19 vaccine unless they have a contraindication to vaccination. Any occurrence of Bell's palsy following mRNA COVID-19 vaccination should be reported to VAERS.

Vaccination of pregnant or lactating people

Pregnant people

Observational data demonstrate that while the absolute risk is low, pregnant people with COVID-19 have an increased risk of severe illness, including illness resulting in intensive care admission, mechanical ventilation, or death. Additionally, they might be at an increased risk of adverse pregnancy outcomes, such as preterm birth.

There are currently few data on the safety of COVID-19 vaccines, including mRNA vaccines, in pregnant people. Limited data are currently available from animal developmental and reproductive toxicity studies. No safety concerns were demonstrated in rats that received Moderna COVID-19 vaccine prior to or during gestation in terms of female reproduction, fetal/embryonal development, or postnatal development. Studies in pregnant people are planned and the vaccine manufacturers are following outcomes in people in the clinical trials who became pregnant. Based on current knowledge, experts believe that mRNA vaccines are unlikely to pose a risk to the pregnant person or the fetus because mRNA vaccines are not live vaccines. The mRNA in the vaccine is degraded quickly by normal cellular processes and does not enter the nucleus of the cell. However, the potential risks of mRNA vaccines to the pregnant person and the fetus are unknown because these vaccines have not been studied in pregnant people.

If pregnant people are part of a group that is recommended to receive a COVID-19 vaccine (e.g., healthcare personnel), they may choose to be vaccinated. A conversation between the patient and their clinical team may assist with decisions regarding the use of a mRNA COVID-19 vaccine, though a conversation with a healthcare provider is not required prior to vaccination.

When making a decision, pregnant people and their healthcare providers should consider the level of COVID-19 community transmission, the patient's personal risk of contracting COVID-19, the risks of COVID-19 to the patient and potential risks to the fetus, the efficacy of the vaccine, the side effects of the vaccine, and the lack of data about the vaccine during pregnancy.

Side effects can occur with COVID-19 vaccine use in pregnant people, similar to those expected among non-pregnant people. Pregnant people who experience fever following vaccination may be counseled to take acetaminophen as fever has been associated with adverse pregnancy outcomes. Acetaminophen may be offered as an option for pregnant people experiencing other post-vaccination symptoms as well.

There is no recommendation for routine pregnancy testing before receipt of a COVID-19 vaccine. Those who are trying to become pregnant do not need to avoid pregnancy after mRNA COVID-19 vaccination.

Lactating people

There are no data on the safety of COVID-19 vaccines in lactating people or the effects of mRNA COVID-19 vaccines on the breastfed infant or milk production/excretion. mRNA vaccines are not thought to be a risk to the breastfeeding infant. A lactating person who is part of a group recommended to receive a COVID-19 vaccine (e.g., healthcare personnel) may choose to be vaccinated.

Vaccination of children and adolescents

Adolescents aged 16–17 years are included among persons eligible to receive the Pfizer-BioNTech COVID-19 vaccine under the EUA. While vaccine safety and efficacy data in this age group are limited, there are no biologically plausible reasons for safety and efficacy profiles to be different than those observed in persons 18 years of age and older. Adolescents aged 16–17 years who are part of a group recommended to receive a COVID-19 vaccine may be vaccinated with the Pfizer-BioNTech COVID-19 vaccine with appropriate assent. Children and adolescents younger than 16 years of age are not authorized to receive the Pfizer-BioNTech COVID-19 vaccine at this time.

Children and adolescents younger than 18 years of age are not authorized to receive the Moderna COVID-19 vaccine at this time.

Patient counseling

Vaccine efficacy

Preliminary data suggest high vaccine efficacy in preventing COVID-19 following receipt of two doses of mRNA COVID-19 vaccine (Pfizer-BioNTech: 95.0% [95% CI: 90.3%, 97.6%]; Moderna: 94.1% [95% CI: 89.3%, 96.8%]). Limited data are currently available regarding the efficacy of a single dose. Patients should be counseled on the importance of completing the two-dose series (of the same vaccine product) to optimize protection.

Reactogenicity

Before vaccination, providers should counsel mRNA COVID-19 vaccine recipients about expected local (e.g., pain, swelling, erythema at the injection site, localized axillary lymphadenopathy on the same side as the vaccinated arm) and systemic (e.g., fever, fatigue, headache, chills, myalgia, arthralgia) post-vaccination symptoms. Depending on vaccine product (Pfizer vs. Moderna), age group, and vaccine dose, approximately 80–89% of vaccinated persons develop at least one local symptom and 55–83% develop at least one systemic symptom following vaccination.

Most systemic post-vaccination symptoms are mild to moderate in severity, occur within the first three days of vaccination, and resolve within 1–3 days of onset. These symptoms are more frequent and severe following the second dose and among younger persons compared to older persons (i.e., >55 or ≥65 years [for Pfizer-BioNTech or Moderna vaccines, respectively]). Unless persons develop a contraindication to vaccination (see below), they should be encouraged to complete the series even if they develop local or systemic symptoms following the first dose to optimize protection against COVID-19.

In clinical trials, hypersensitivity-related adverse events were observed in 0.63% of participants who received the Pfizer-BioNTech COVID-19 vaccine and 1.5% of participants who received the Moderna COVID-19 vaccine, compared to 0.51% and 1.1%, respectively, in the placebo groups. Anaphylaxis following vaccination was not observed in the Pfizer-BioNTech or

Moderna COVID-19 vaccines clinical trials. However, anaphylactic reactions have been reported following receipt of mRNA vaccines outside of clinical trials.

Antipyretic or analgesic medications (e.g., acetaminophen, non-steroidal anti-inflammatory drugs) may be taken for the treatment of post-vaccination local or systemic symptoms, if medically appropriate. However, routine prophylactic administration of these medications for the purpose of preventing post-vaccination symptoms is not currently recommended, as information on the impact of such use on mRNA COVID-19 vaccine-induced antibody responses is not available at this time.

Infection prevention and control considerations are available for healthcare personnel and long-term care facility residents (e.g., populations included in phase 1a of vaccine allocation) with systemic signs and symptoms following COVID-19 vaccination. Considerations may be updated as additional information becomes available or additional groups are prioritized for vaccine allocation.

Public health recommendations for vaccinated persons

Given the currently limited information on how much the mRNA COVID-19 vaccines may reduce transmission in the general population and how long protection lasts, vaccinated persons should continue to follow **all current guidance** to protect themselves and others. This includes wearing a mask, staying at least 6 feet away from others, avoiding crowds, washing hands often, following CDC travel guidance, following quarantine guidance after an exposure to someone with COVID-19, and following any applicable workplace or school guidance, including guidance related to personal protective equipment use or SARS-CoV-2 testing.

Contraindications and precautions

While rare, anaphylactic reactions have been reported following vaccination with mRNA COVID-19 vaccines. Although investigations are ongoing, persons with a history of an immediate allergic reaction (of any severity) to an mRNA COVID-19 vaccine or any of its components might be at greater risk for anaphylaxis upon re-exposure to either of the currently authorized mRNA COVID-19 vaccines. For the purposes of this guidance, an immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

Recommendations for contraindications and precautions are described below and summarized in Appendix A. The following recommendations may change as further information becomes available.

Contraindications

CDC considers a history of the following to be a contraindication to vaccination with both the Pfizer-BioNTech and Moderna COVID-19 vaccines:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components
- Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG])*
- Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)*

* These persons should not receive mRNA COVID-19 vaccination at this time unless they have been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available). See Appendix B for more information on ingredients included in mRNA COVID-19 vaccines.

Persons with an immediate allergic reaction to the first dose of an mRNA COVID-19 vaccine should not receive additional doses of either of the mRNA COVID-19 vaccines. Providers should attempt to determine whether reactions reported following vaccination are consistent with immediate allergic reactions versus other types of reactions commonly observed following vaccination, such as a vasovagal reaction or post-vaccination side effects (which are not contraindications to receiving the second vaccine dose) (Appendix C).

Healthcare personnel or health departments in the United States can request a consultation from the Clinical Immunization Safety Assessment COVIDvax project for a complex COVID-19 vaccine safety question about an individual patient residing in the United States not readily addressed by CDC guidance.

Precautions

CDC considers a history of any immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of mRNA COVID-19 vaccines or polysorbate) as a precaution but not a contraindication to vaccination for both the Pfizer-BioNTech and Moderna COVID-19 vaccines. These persons should be counseled about the unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination. Deferral of vaccination and/or consultation with an allergist-immunologist may be considered until further information on the risk of anaphylaxis is available. The following considerations can be used to help the provider conduct a risk assessment for mRNA COVID-19 vaccination in these individuals:

- Risk of exposure to SARS-CoV-2 (e.g., because of residence in a congregate setting such as a long-term care facility, occupation)
- Risk of severe disease or death due to COVID-19 (e.g., because of age, underlying medical conditions)
- Whether the patient has previously been infected with SARS-CoV-2 and, if so, how long ago
  - Note: Vaccination is recommended for persons with a history of COVID-19; however, because reinfection is uncommon in the 90 days following infection, persons with a precaution to vaccination and recent COVID-19 may choose to defer vaccination until further information is known about the risk of anaphylaxis following vaccination.
- The unknown risk of anaphylaxis (including fatal anaphylaxis) following mRNA COVID-19 vaccination in a person with a history of an immediate allergic reaction to other vaccines or injectable therapies
- Ability of the patient to be vaccinated in a setting where appropriate medical care is immediately available for anaphylaxis

Neither contraindications nor precautions to vaccination

Allergic reactions (including severe allergic reactions) not related to vaccines, injectable therapies, components of mRNA COVID-19 vaccines (including PEG), or polysorbates, such as food, pet, venom, or environmental allergies, or allergies to oral medications (including the oral equivalents of injectable medications) are **not** a contraindication or precaution to vaccination with either mRNA COVID-19 vaccine. The vial stoppers of these mRNA vaccines are not made with natural rubber latex, and there is no contraindication or precaution to vaccination for persons with a latex allergy. In addition, as the mRNA COVID-19 vaccines do not contain eggs or gelatin, persons with allergies to these substances do not have a contraindication or precaution to vaccination.

Observation periods following vaccination (for persons without contraindications to mRNA COVID-19 vaccines)

CDC recommends an observation period following vaccination with mRNA COVID-19 vaccines. Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause should be observed for 30 minutes. All other persons should be observed for 15 minutes.

Reporting of vaccine adverse events

Adverse events that occur in a recipient following mRNA COVID-19 vaccination should be reported to VAERS. Vaccination providers are required by the Food and Drug Administration to report the following that occur after mRNA COVID-19 vaccination under Emergency Use Authorization:

- Vaccine administration errors
- Serious adverse events
- Cases of Multisystem Inflammatory Syndrome
- Cases of COVID-19 that result in hospitalization or death

Reporting is encouraged for any other clinically significant adverse event even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by calling 1-800-822-7967.

In addition, CDC has developed a new, voluntary smartphone-based tool, v-safe. This tool uses text messaging and web surveys to provide near real-time health check-ins after patients receive COVID-19 vaccination. Reports to v-safe indicating a medically significant health impact, including pregnancy, are followed up by the CDC/v-safe call center to collect additional information to complete a VAERS report, if appropriate.

Laboratory testing

Interpretation of SARS-CoV-2 test results in vaccinated persons

Prior receipt of an mRNA COVID-19 vaccine will not affect the results of SARS-CoV-2 viral tests (nucleic acid amplification or antigen tests). Currently available antibody tests for SARS-CoV-2 assess IgM and/or IgG to one of two viral proteins: spike or nucleocapsid. Because both the Pfizer-BioNTech and Moderna COVID-19 vaccines contain mRNA that encodes the spike protein, a positive test for spike protein IgM/IgG could indicate either prior infection or vaccination. To evaluate for evidence of prior infection in an individual with a history of mRNA COVID-19 vaccination, a test specifically evaluating IgM/IgG to the nucleocapsid protein should be used. Antibody testing is not currently recommended to assess for immunity to COVID-19 following mRNA COVID-19 vaccination or to assess the need for vaccination in an unvaccinated person.

Interpretation of tuberculosis test results in vaccinated persons

Inactive vaccines do not interfere with tuberculosis (TB) test results. There is no immunologic reason to believe either a Tuberculin Skin Test (TST) (administered by intradermal placement of 0.1 cc of purified protein derivative) or blood draw for interferon gamma release assay (IGRA) would affect the safety or effectiveness of mRNA COVID-19 vaccines. We have no data to inform the impact of the COVID-19 mRNA vaccines on either TB test for infection (i.e., TST or IGRA).

For healthcare personnel or patients who require baseline TB testing (at onboarding or entry into facilities) at the same time they are to receive an mRNA COVID-19 vaccine:

- Perform TB symptom screening on all healthcare personnel or patients.
- If utilizing the IGRA, draw blood for interferon gamma release assay prior to COVID-19 vaccination.
- If utilizing the TST, place prior to COVID-19 vaccination.
- If vaccination has been given and testing needs to be performed, defer TST or IGRA until 4 weeks after COVID-19 vaccine 2-dose completion.
    - All potential recipients of COVID-19 vaccination should weigh the risks and benefits of delaying TST/IGRA with their providers.

For healthcare personnel who require testing for other reasons:

- Perform TB symptom screening on all healthcare personnel
- Test for infection should be done before or at the same time as the administration of COVID-19 vaccination. If this is not possible, prioritization of test for TB infection needs to be weighed with the importance of receiving COVID-19 vaccination based on potential COVID-19 exposures and TB risk factors.
    - Healthcare personnel with high-risk conditions for TB progression should be fully evaluated as soon as possible.
    - Healthcare personnel without high-risk conditions for TB progression should proceed with contact tracing (i.e., symptom screening, chest radiograph or other imaging, specimen for microbiologic evaluation) but delay test for TB infection (TST or IGRA) if prioritized for receiving COVID-19 vaccination.
    - All potential recipients of COVID-19 vaccination should weigh the risks and benefits of delaying TST/IGRA with their providers.

Appendix A: Triage of persons presenting for mRNA COVID-19 vaccination

MAY PROCEED WITH VACCINATION	PRECAUTION TO VACCINATION	CONTRAINDICATION TO VACCINATION

	MAY PROCEED WITH VACCINATION	PRECAUTION TO VACCINATION	CONTRAINDICATION TO VACCINATION
CONDITIONS	**CONDITIONS** • Immunocompromising conditions • Pregnancy • Lactation **ACTIONS** • Additional information provided* • 15 minute observation period	**CONDITIONS** • Moderate/severe acute illness **ACTIONS** • Risk assessment • Potential deferral of vaccination • 15-minute observation period if vaccinated	**CONDITIONS** • None **ACTIONS** • N/A
ALLERGIES	**ALLERGIES** History of allergies that are unrelated to components of an mRNA COVID-19 vaccine†, other vaccines, injectable therapies, or polysorbate, such as: • Allergy to oral medications (including the oral equivalent of an injectable medication) • History of food, pet, insect, venom, environmental, latex, etc., allergies • Family history of allergies **ACTIONS** • 30-minute observation period: Persons with a history of anaphylaxis (due to any cause) • 15-minute observation period: All other persons	**ALLERGIES** • History of any immediate allergic reaction‡ to vaccines or injectable therapies (except those related to component of mRNA COVID-19 vaccines† or polysorbate, as these are contraindicated) **ACTIONS:** • Risk assessment • Consider deferral of vaccination and/or referral to allergist-immunologist • 30-minute observation period if vaccinated	**ALLERGIES** History of the following are contraindications to receiving either of the mRNA COVID-19 vaccines†: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components • Immediate allergic reaction‡ of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components^ (including polyethylene glycol)# • Immediate allergic reaction of any severity to polysorbate^# **ACTIONS** • Do not vaccinate# • Consider referral to allergist-immunologist

* See Special Populations section for information on patient counseling in these groups

† Refers only to mRNA COVID-19 vaccines currently authorized in the United States (i.e., Pfizer-BioNTech, Moderna COVID-19 vaccines)

‡ Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

^ See Appendix B for a list of ingredients. Note: Polyethylene glycol (PEG), an ingredient in both mRNA COVID-19 vaccines, is structurally related to polysorbate and cross-reactive hypersensitivity between these compounds may occur. Information on ingredients of a vaccine or medication (including PEG, a PEG derivative, or polysorbates) can be found in the package insert.

These persons should not receive mRNA COVID-19 vaccination at this time unless they have been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available)

Appendix B: Ingredients included in Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines

An immediate allergic reaction to any component or previous dose of an mRNA COVID-19 vaccine is a contraindication to vaccination with both the Pfizer-BioNTech and Moderna vaccines. The following is a list of ingredients for the Pfizer-BioNTech and Moderna COVID-19 vaccines, as reported in the prescribing information for each vaccine.

Description	Pfizer-BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine
mRNA	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2
Lipids	2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide	PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine
	Cholesterol	Cholesterol
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102: heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate
Salts, sugars, buffers	Potassium chloride	Tromethamine
	Monobasic potassium phosphate	Tromethamine hydrochloride
	Sodium chloride	Acetic acid
	Dibasic sodium phosphate dihydrate	Sodium acetate
	Sucrose	Sucrose

* Neither vaccine contain eggs, gelatin, latex, or preservatives

Note: Both the Pfizer-BioNTech and Moderna COVID-19 vaccines contain polyethylene glycol (PEG). PEG is a primary ingredient in osmotic laxatives and oral bowel preparations for colonoscopy procedures, an inactive ingredient or excipient in many medications, and is used in a process called pegylation to improve the therapeutic activity of some medications (including certain chemotherapeutics). Additionally, cross-reactive hypersensitivity between PEG and polysorbates (included as an excipient in some vaccines and other therapeutic agents) can occur.

Information on whether a medication contains PEG, a PEG derivative, or polysorbates as either active or inactive ingredients can be found in the package insert. The National Institutes of Health DailyMed database may also be used as a resource. Medications that contain PEG and/or polysorbate are also described in the supplementary materials of Stone CA, et al. "Immediate hypersensitivity to polyethylene glycols and polysorbates: more common than we have recognized." *The Journal of Allergy and Clinical Immunology: In Practice* 7.5 (2019): 1533-1540.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6706272/pdf/nihms-1019221.pdf

Appendix C: Potential characteristics of allergic reactions, vasovagal reactions, and vaccine side effects following mRNA COVID-19 vaccination

In patients who develop post-vaccination symptoms, determining the etiology (including allergic reaction, vasovagal reaction, or vaccine side effects) is important to determine whether a person can receive additional doses of mRNA COVID-19 vaccines. The following table of signs and symptoms is meant to serve as a resource but may not be exhaustive, and patients may not have all signs or symptoms. Providers should use their clinical judgement when assessing patients to determine the diagnosis and management.

Characteristic	Immediate allergic reactions (including anaphylaxis)	Vasovagal reaction	Vaccine side effects (local and systemic)

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Characteristic	Immediate allergic reactions (including anaphylaxis)	Vasovagal reaction	Vaccine side effects (local and systemic)
Timing after vaccination	Most occur within 15-30 minutes of vaccination	Most occur within 15 minutes	Median of 1 to 3 days after vaccination (with most occurring day after vaccination)
Signs and symptoms			
Constitutional	Feeling of impending doom	Feeling warm or cold	Fever, chills, fatigue
Cutaneous	Skin symptoms present in ~90% of people with anaphylaxis, including pruritus, urticaria, flushing, angioedema	Pallor, diaphoresis, clammy skin, sensation of facial warmth	Pain, erythema or swelling at injection site; lymphadenopathy in same arm as vaccination
Neurologic	Confusion, disorientation, dizziness, lightheadedness, weakness, loss of consciousness	Dizziness, lightheadedness, syncope (often after prodromal symptoms for a few seconds or minutes), weakness, changes in vision (such as spots of flickering lights, tunnel vision), changes in hearing	Headache
Respiratory	Shortness of breath, wheezing, bronchospasm, stridor, hypoxia	Variable; if accompanied by anxiety, may have an elevated respiratory rate	N/A
Cardiovascular	Hypotension, tachycardia	Variable; may have hypotension or bradycardia during syncopal event	N/A
Gastrointestinal	Nausea, vomiting, abdominal cramps, diarrhea	Nausea, vomiting	Vomiting or diarrhea may occur
Musculoskeletal	N/A	N/A	Myalgia, arthralgia
Vaccine recommendations			
Recommended to receive 2nd dose of mRNA COVID-19 vaccine?	No	Yes	Yes

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EXHIBIT H

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The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine — United States, December 2020

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On December 13, 2020, this report was posted as an MMWR *Early Release on the* MMWR *website (https://www.cdc.gov/mmwr).*

On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 (BNT162b2) vaccine (Pfizer, Inc; Philadelphia, Pennsylvania), a lipid nanoparticle-formulated, nucleoside-modified mRNA vaccine encoding the prefusion spike glycoprotein of SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19) (*1*). Vaccination with the Pfizer-BioNTech COVID-19 vaccine consists of 2 doses (30 μg, 0.3 mL each) administered intramuscularly, 3 weeks apart. On December 12, 2020, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation* for use of the Pfizer-BioNTech COVID-19 vaccine in persons aged ≥16 years for the prevention of COVID-19. To guide its deliberations regarding the vaccine, ACIP employed the Evidence to Recommendation (EtR) Framework,† using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach.§ The recommendation for the Pfizer-BioNTech COVID-19 vaccine should be implemented in conjunction with ACIP's interim recommendation for allocating initial supplies of COVID-19 vaccines (*2*). The ACIP recommendation for the use of the Pfizer-BioNTech COVID-19 vaccine under EUA is interim and will be updated as additional information becomes available.

Since June 2020, ACIP has convened nine public meetings to review data on the epidemiology of COVID-19 and the potential use of COVID-19 vaccines, including the Pfizer-BioNTech COVID-19 vaccine (*3*). Within the EtR Framework, ACIP considered the importance of the public health problem of COVID-19, as well as issues of resource use, benefits and harms, patients' values and preferences, acceptability, feasibility, and equity for the Pfizer-BioNTech COVID-19 vaccine. To inform the EtR Framework, the COVID-19 Vaccines Work Group, comprising experts in infectious disease, vaccinology, vaccine safety, public health, and ethics, held 27 meetings to review COVID-19 surveillance data, evidence for vaccine efficacy and safety, and implementation considerations for COVID-19 vaccines, including the Pfizer-BioNTech COVID-19 vaccine. After a systematic review of the literature, the Work Group used the GRADE approach to assess the certainty of evidence for outcomes related to the vaccine, rated on a scale of 1 (high certainty) to 4 (very low certainty) (*4*). Work Group conclusions regarding the evidence for the Pfizer-BioNTech COVID-19 vaccine were presented to ACIP at public meetings.

The body of evidence for the Pfizer-BioNTech COVID-19 vaccine was primarily informed by one large, randomized, double-blind, placebo-controlled Phase II/III clinical trial that enrolled >43,000 participants (median age = 52 years, range = 16–91 years) (*5,6*). Interim findings from this clinical trial, using data from participants with a median of 2 months of follow-up, indicate that the Pfizer-BioNTech COVID-19 vaccine was 95.0% effective (95% confidence interval = 90.3%–97.6%) in preventing symptomatic laboratory-confirmed COVID-19 in persons without evidence of previous SARS-CoV-2 infection. Consistent high efficacy (≥92%) was observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions as well as among participants with evidence of previous SARS-CoV-2 infection. Although numbers of observed hospitalizations and deaths were low, the available data were consistent with reduced risk for these severe outcomes among vaccinated persons compared with that among placebo recipients. Among vaccine recipients, reactogenicity symptoms, defined as solicited local injection site or systemic reactions during the 7 days after vaccination, were frequent and mostly mild to moderate. Systemic adverse reactions were more commonly reported after the second dose than after the first dose and were generally more frequent and severe in persons aged 18–55 years than in those aged >55 years. Systemic adverse reactions had a median onset of 1–2 days after vaccine receipt and resolved in a median of 1 day. Severe local and systemic adverse reactions (grade ≥3, defined as interfering with daily activity) occurred more commonly in vaccine recipients than in placebo recipients. Among vaccine recipients, 8.8% reported any grade ≥3 reaction; the most common symptoms were fatigue (4.2%), headache (2.4%), muscle pain (1.8%), chills (1.7%), and injection site pain

* On December 12, 2020, ACIP voted 11–0 (three recusals) in favor of the interim recommendation for use of Pfizer-BioNTech COVID-19 vaccine. Three ACIP members recused themselves because of participation in clinical trials and/or other studies involving companies producing COVID-19 vaccines.

† https://www.cdc.gov/vaccines/acip/recs/grade/downloads/ACIP-evidence-rec-frame-508.pdf.

§ https://www.cdc.gov/vaccines/acip/recs/grade/about-grade.html.

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(1.4%). Generally, grade ≥3 reactions were more commonly reported after the second dose than after the first dose and were less prevalent in older than in younger participants. Serious adverse events[¶] were observed in a similar proportion of vaccine (0.6%) and placebo (0.5%) recipients and encompassed medical events occurring at a frequency similar to that within the general population (*6*). No specific safety concerns were identified in subgroup analyses by age, race, ethnicity, underlying medical conditions, or previous SARS-CoV-2 infection. A detailed summary of safety data, including information on reactogenicity, is available at https://www.cdc.gov/vaccines/covid-19/info-by-manufacturer/pfizer/reactogenicity.html.

From the GRADE evidence assessment, the level of certainty for the benefits of the Pfizer-BioNTech COVID-19 vaccine was type 1 (high certainty) for the prevention of symptomatic COVID-19. Evidence was type 3 (low certainty) for the estimate of prevention of COVID-19–associated hospitalization and type 4 (very low certainty) for the estimate of prevention of death. Data on hospitalizations and deaths are limited at this time, but a vaccine that effectively prevents symptomatic infection is expected to also prevent hospitalizations and deaths. Regarding potential harms after vaccination, evidence was type 2 (moderate certainty) for serious adverse events and type 1 (high certainty) for reactogenicity. No data were available to assess the efficacy for prevention of asymptomatic SARS-CoV-2 infection. Data reviewed within the EtR Framework supported the use of the Pfizer-BioNTech COVID-19 vaccine. ACIP determined that COVID-19 is a major public health problem and that use of the Pfizer-BioNTech COVID-19 vaccine is a reasonable and efficient allocation of resources. Whereas there might be uncertainty in how all populations value the vaccine, it was determined that for most populations, the desirable effects outweigh the undesirable effects. The vaccine is probably acceptable to implementation stakeholders and feasible to implement in spite of difficult ultracold-chain storage and requirements for handling and administration. These requirements could limit the availability of the Pfizer-BioNTech COVID-19 vaccine to some populations thereby negatively impacting health equity. Therefore, efforts should be made to overcome these challenges and advance health equity. The GRADE evidence profile and EtR supporting evidence are available at https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-pfizer-biontech-vaccine.html and https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-pfizer-biontech-etr.html.

[¶] Serious adverse events are defined as any untoward medical occurrence that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, or results in persistent disability/incapacity.

Before vaccination, the EUA Fact Sheet should be provided to recipients and caregivers. Providers should counsel Pfizer-BioNTech COVID-19 vaccine recipients about expected systemic and local reactogenicity. Additional clinical considerations, including details of administration and use in special populations (e.g., persons who are pregnant or immunocompromised or who have severe allergies) are available at https://www.cdc.gov/vaccines/covid-19/info-by-manufacturer/pfizer/clinical-considerations.html. Additional studies of safety and effectiveness are planned after authorization and will be important to inform future ACIP recommendations as well as increase public confidence in the COVID-19 vaccination program. The interim recommendation and clinical considerations are based on use of the Pfizer-BioNTech COVID-19 vaccine under an EUA and might change as more evidence becomes available. ACIP will continue to review additional data as they become available; updates to recommendations or clinical considerations will be posted on the ACIP website (https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html).

Reporting of Vaccine Adverse Events

Adverse events that occur in a recipient after receipt of COVID-19 vaccine should be reported to the Vaccine Adverse Events Reporting System (VAERS). FDA requires that vaccination providers report vaccination administration errors, serious adverse events, cases of multisystem inflammatory syndrome, and cases of COVID-19 that result in hospitalization or death after administration of COVID-19 vaccine under EUA. Reporting is encouraged for any clinically significant adverse event, whether or not it is clear that a vaccine caused the adverse event. Information on how to submit a report to VAERS is available at https://vaers.hhs.gov/index.html or 1-800-822-7967. In addition, CDC has developed a new, voluntary smartphone-based tool, v-safe, that uses text messaging and web surveys to provide near real-time health check-ins after patients receive COVID-19 vaccination. The CDC/v-safe call center follows up on reports to v-safe that indicate a medically significant health impact to collect additional information for completion of a VAERS report. Information on v-safe is available at https://www.cdc.gov/vsafe.

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Voting members of the Advisory Committee on Immunization Practices: Robert L. Atmar, Baylor College of Medicine; Kevin A. Ault, University of Kansas Medical Center; Lynn Bahta, Minnesota Department of Health; Henry Bernstein, Zucker School of Medicine at Hofstra/Northwell Cohen Children's Medical Center; Sharon E. Frey, Saint Louis University Medical School; Paul Hunter, City of Milwaukee Health Department; Veronica V. McNally, Franny Strong Foundation; Katherine A. Poehling, Wake Forest School of Medicine;

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Pablo J. Sánchez, The Research Institute at Nationwide Children's Hospital; Peter Szilagyi, University of California, Los Angeles. Members of the Advisory Committee on Immunization Practices COVID-19 Vaccines Work Group: Edward Belongia, Center for Clinical Epidemiology & Population Health, Marshfield Clinic Research Institute; Dayna Bowen Matthew, George Washington University Law School; Oliver Brooks, National Medical Association; Matthew Daley, Institute for Health Research, Kaiser Permanente Colorado; Jillian Doss-Walker, Indian Health Service; Marci Drees, Society for Healthcare Epidemiology of America; Jeffrey Duchin, Infectious Diseases Society of America; Kathy Kinlaw, Center for Ethics, Emory University; Doran Fink, Food and Drug Administration; Sandra Fryhofer, American Medical Association; Jason M. Goldman, American College of Physicians; Michael Hogue, American Pharmacists Association; Denise Jamieson, American College of Obstetricians and Gynecologists; Jeffery Kelman, Centers for Medicare & Medicaid; David Kim, U.S. Department of Health and Human Services; Susan Lett, Council of State and Territorial Epidemiologists; Kendra McMillan, American Nurses Association; Kathleen Neuzil, Center for Vaccine Development and Global Health, University of Maryland School of Medicine; Sean O'Leary, American Academy of Pediatrics; Christine Oshansky, Biomedical Advanced Research and Development Authority; Stanley Perlman, Department of Microbiology and Immunology, University of Iowa; Marcus Plescia, Association of State and Territorial Health Officials; Chris Roberts, National Institutes of Health; William Schaffner, National Foundation for Infectious Diseases; Kenneth Schmader, American Geriatrics Society; Bryan Schumacher, Department of Defense; Rob Shechter, Association of Immunization Managers; Jonathan Temte, American Academy of Family Physicians; Matthew Tunis, National Advisory Committee on Immunization Secretariat, Public Health Agency of Canada; Thomas Weiser, Indian Health Service; Matt Zahn, National Association of County and City Health Officials; Rachel Zhang, Food and Drug Administration.

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All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. No potential conflicts of interest were disclosed.

Summary

What is already known about this topic?

On December 11, 2020, the Food and Drug Administration issued an Emergency Use Authorization for the Pfizer-BioNTech COVID-19 vaccine.

What is added by this report?

On December 12, 2020, after an explicit, evidence-based review of all available data, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation for use of the Pfizer-BioNTech COVID-19 vaccine in persons aged ≥16 years for the prevention of COVID-19.

What are the implications for public health practice?

The recommendation for the Pfizer-BioNTech COVID-19 vaccine should be implemented in conjunction with ACIP's interim recommendation for allocating initial supplies of COVID-19 vaccines.

References

1. Food and Drug Administration. Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization. Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2020. https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine
2. Dooling K, McClung N, Chamberland M, et al. The Advisory Committee on Immunization Practices' interim recommendation for allocating initial supplies of COVID-19 vaccine—United States, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1857–9. PMID:33301429 https://doi.org/10.15585/mmwr.mm6949e1
3. Advisory Committee on Immunization Practices. ACIP meeting information. Atlanta, GA: US Department of Health and Human Services, CDC; 2020. https://www.cdc.gov/vaccines/acip/meetings/index.html
4. Advisory Committee on Immunization Practices. Advisory Committee on Immunization Practices (ACIP): GRADE (grading of recommendations, assessment, development and evaluation). Atlanta, GA: US Department of Health and Human Services, CDC; 2020. https://www.cdc.gov/vaccines/acip/recs/grade
5. Vaccines and Related Biological Products Advisory Committee. Vaccines and Related Biological Products Advisory Committee December 10, 2020, meeting: sponsor briefing document. Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2020. https://www.fda.gov/media/144246/download
6. Vaccines and Related Biological Products Advisory Committee. Vaccines and Related Biological Products Advisory Committee December 10, 2020, meeting: FDA briefing document. Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2020. https://www.fda.gov/media/144245/download

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EXHIBIT I

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

Lakshmi Panagiotakopoulos, MD, MPH

Advisory Committee on Immunization Practices

April 15, 2025

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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

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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)**

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Review of 2024–2025 COVID-19 vaccine policy

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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

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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

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

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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

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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.

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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

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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?

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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

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

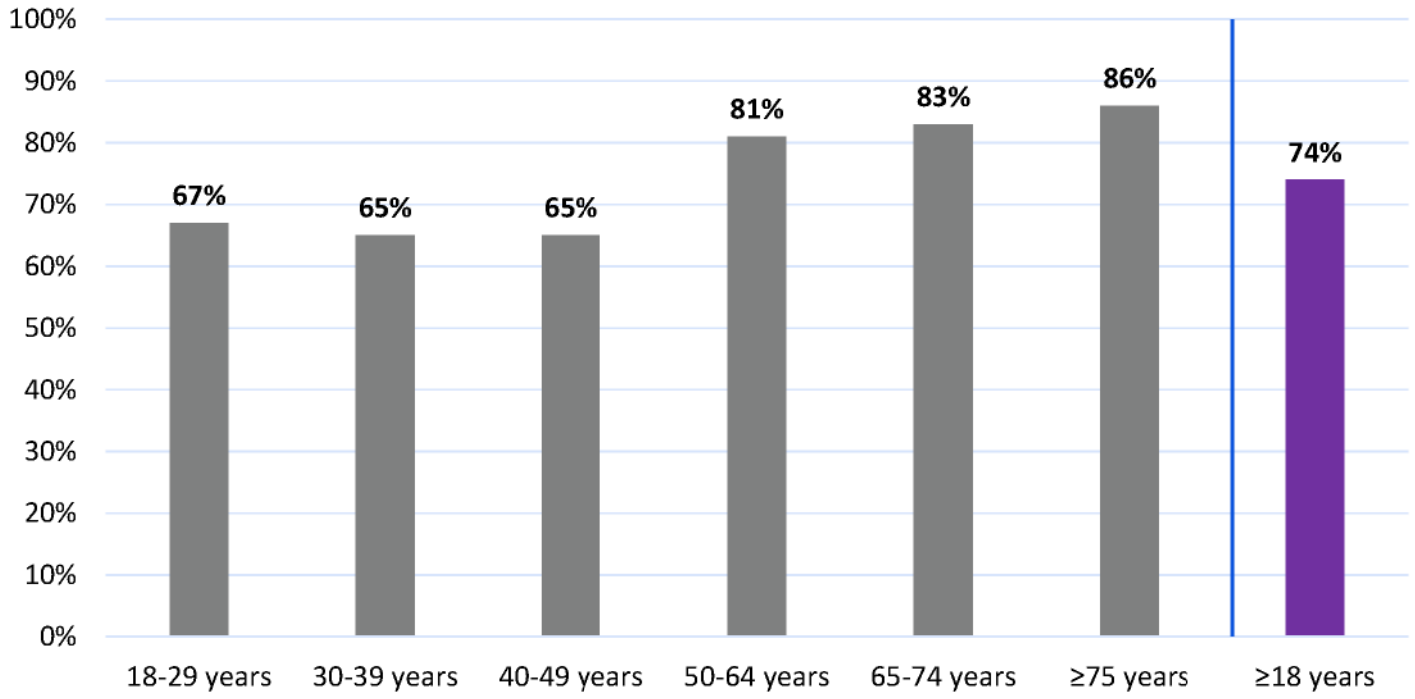
- **Asthma**
- **Cancer**
  - Hematologic Malignancies
- **Cerebrovascular disease**
- **Chronic kidney disease***
  - People receiving dialysis^
- **Chronic lung diseases** limited to:
  - Bronchiectasis
  - COPD (Chronic obstructive pulmonary disease)
  - Interstitial lung disease
  - Pulmonary embolism
  - 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

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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

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Summary of supporting evidence

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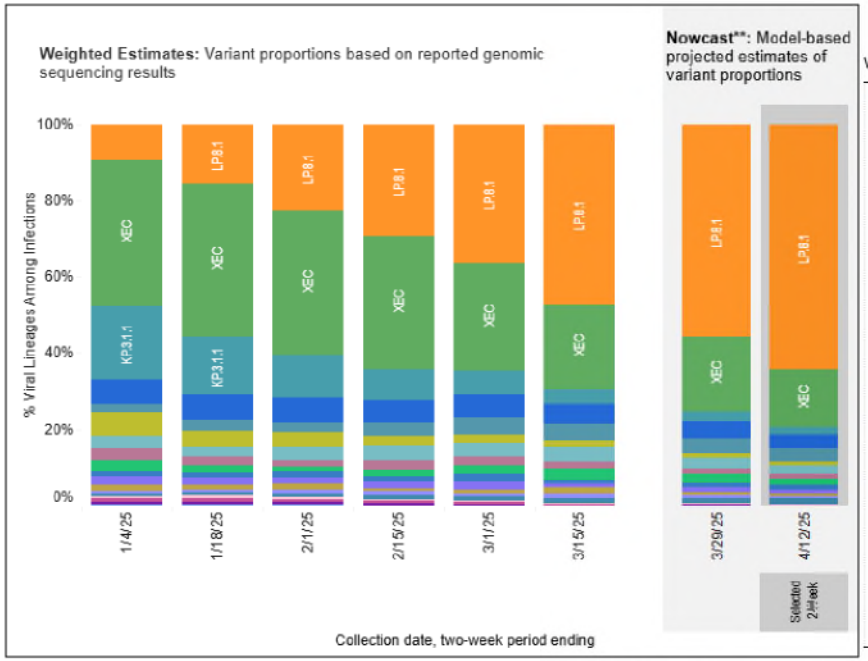
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COVID-19 Epidemiology

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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

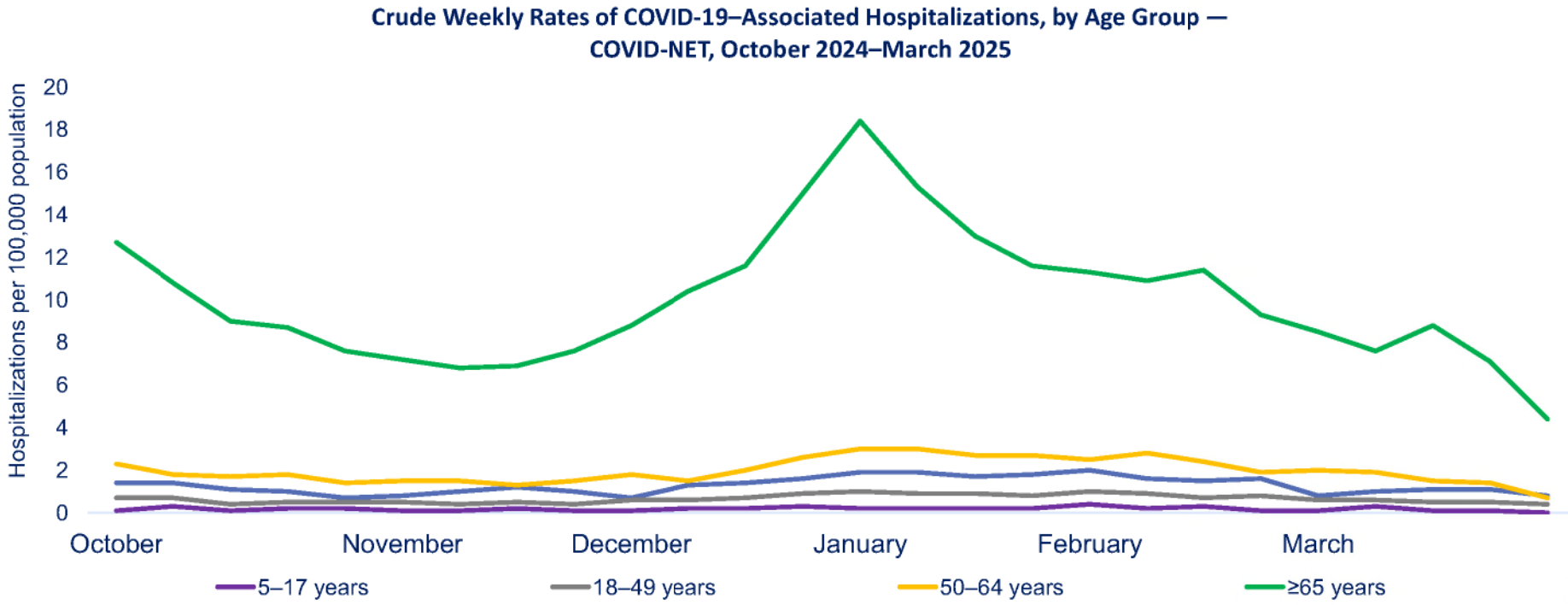
** These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates
# Enumerated lineages are US VOC and lineages circulating above 1% nationally in at least one 2-week period. "Other" represents the aggregation of lineages which are 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

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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

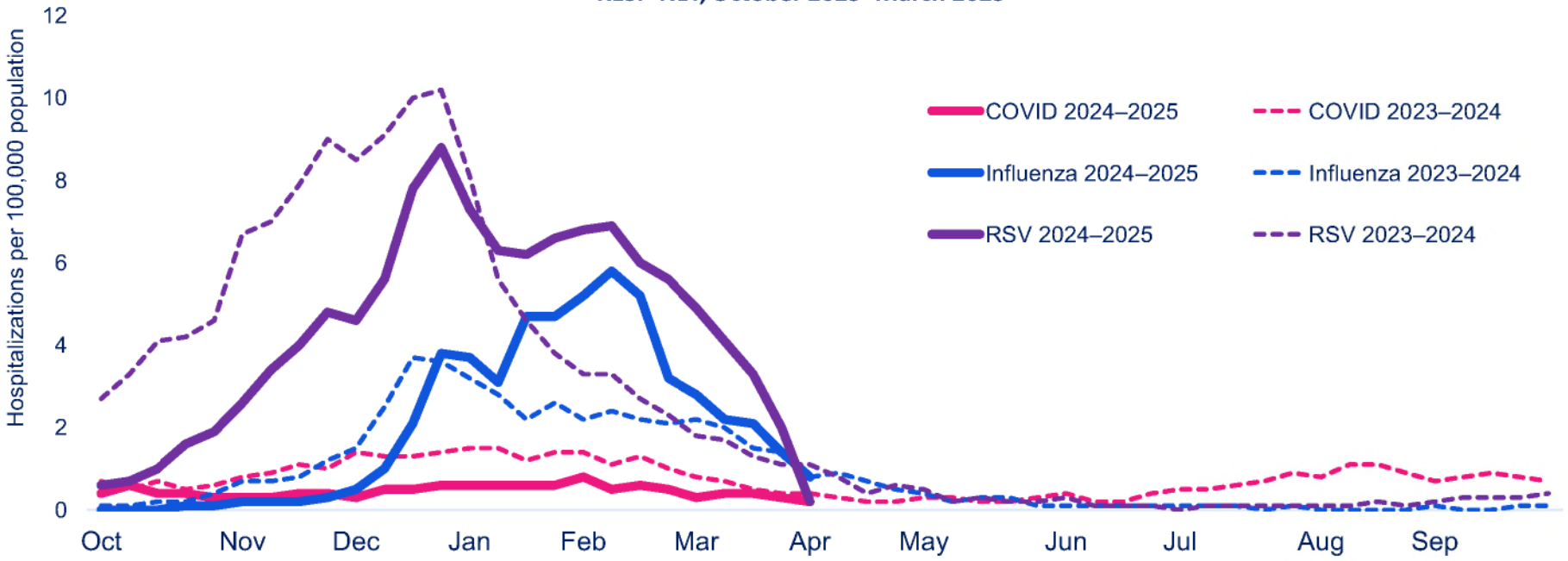
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Weekly rates of respiratory virus-associated hospitalizations in the United States among children ages 0–17 years, 2023–2025

Crude Weekly Rates of COVID-19–, Influenza, and RSV-Associated Hospitalizations, by Surveillance Season* — RESP-NET, October 2023–March 2025



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

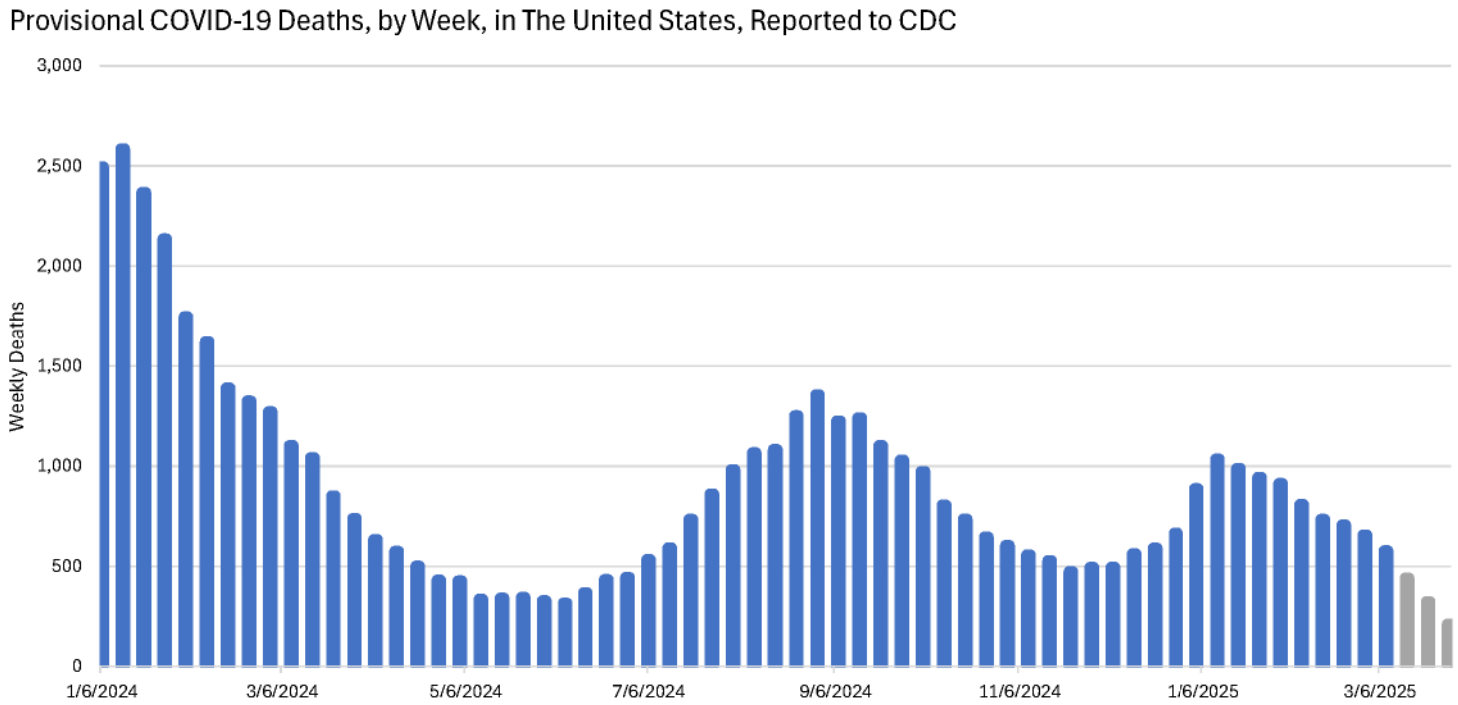
Note that rates are not adjusted for testing or limited to admissions where the respiratory infection is the likely primary reason for admission.

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

Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

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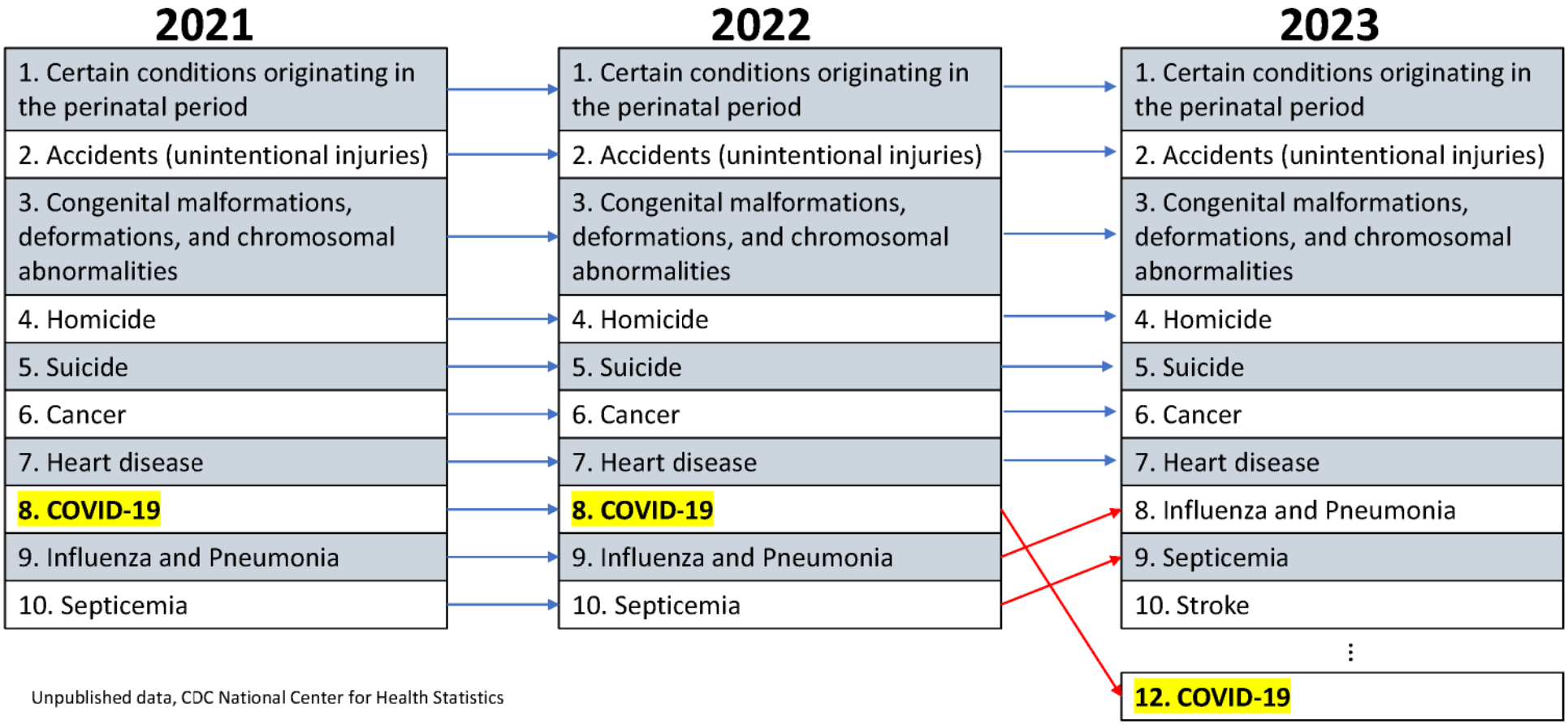
Weekly number of COVID-19 deaths reported to CDC, United States, January 1, 2024 – March 29, 2025



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

Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

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

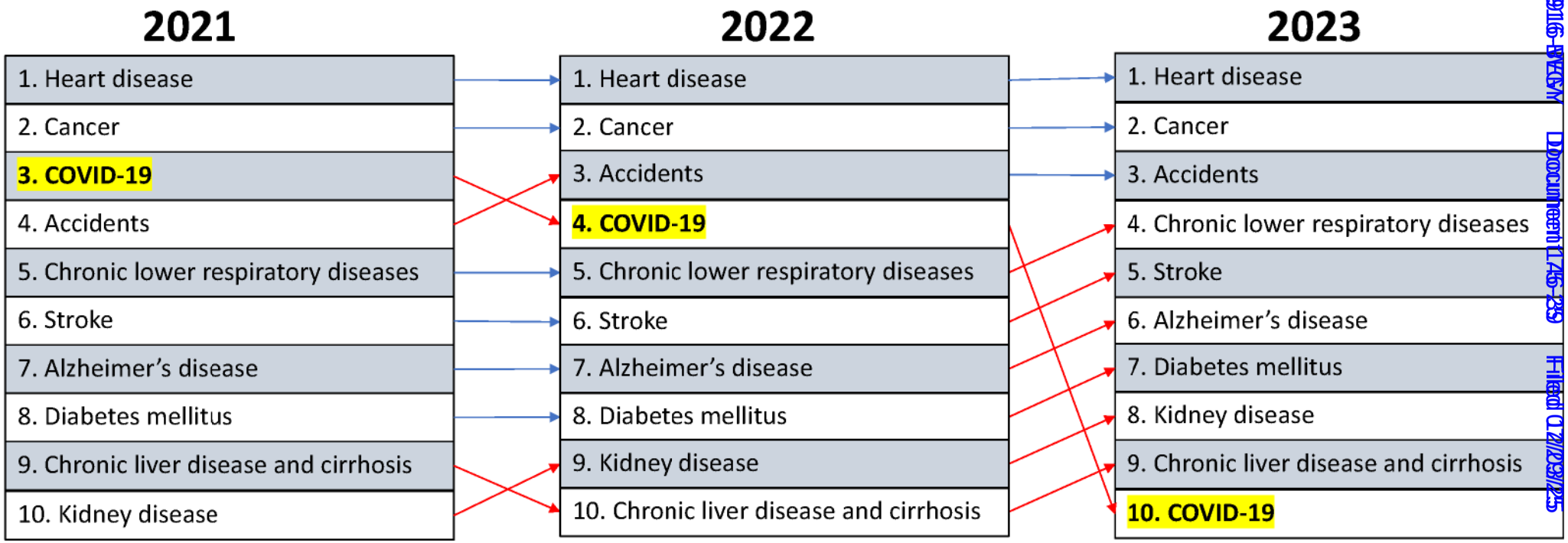


Unpublished data, CDC National Center for Health Statistics

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

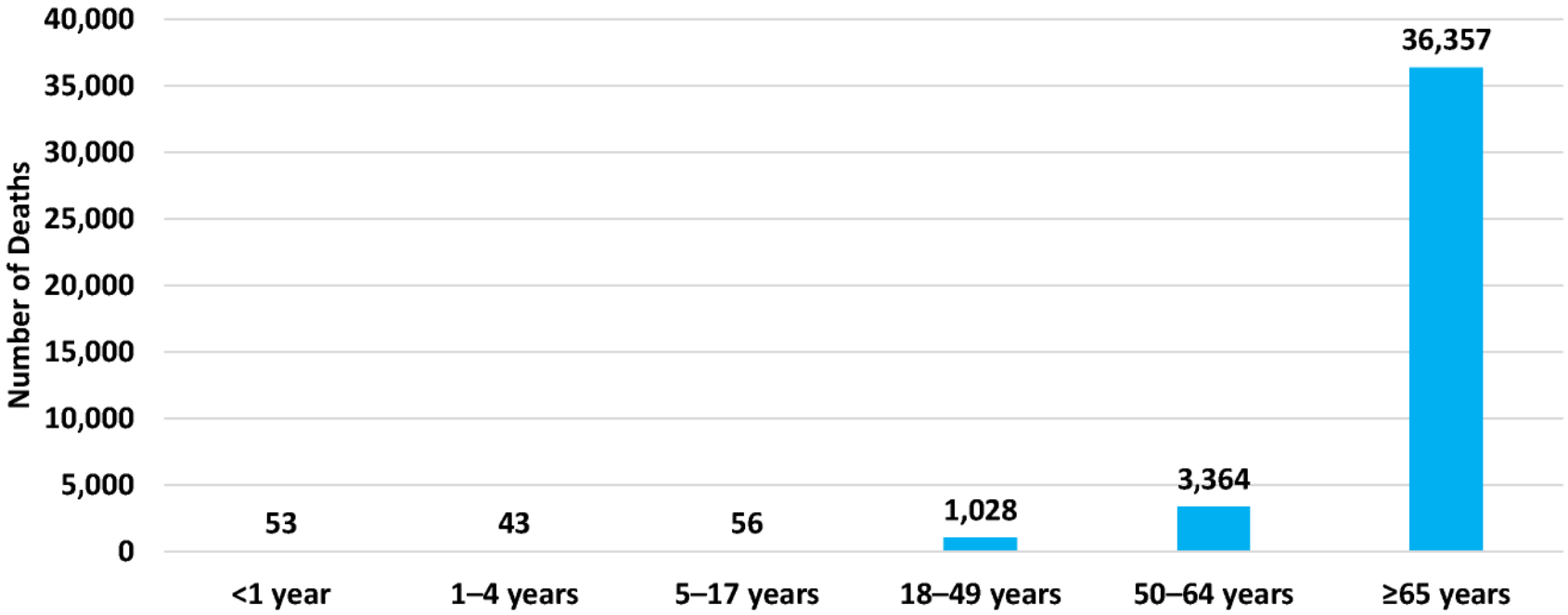


Influenza and pneumonia was ranked 9th pre-pandemic in 2019; ranked 13th in 2023
Unpublished data, CDC National Center for Health Statistics

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

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

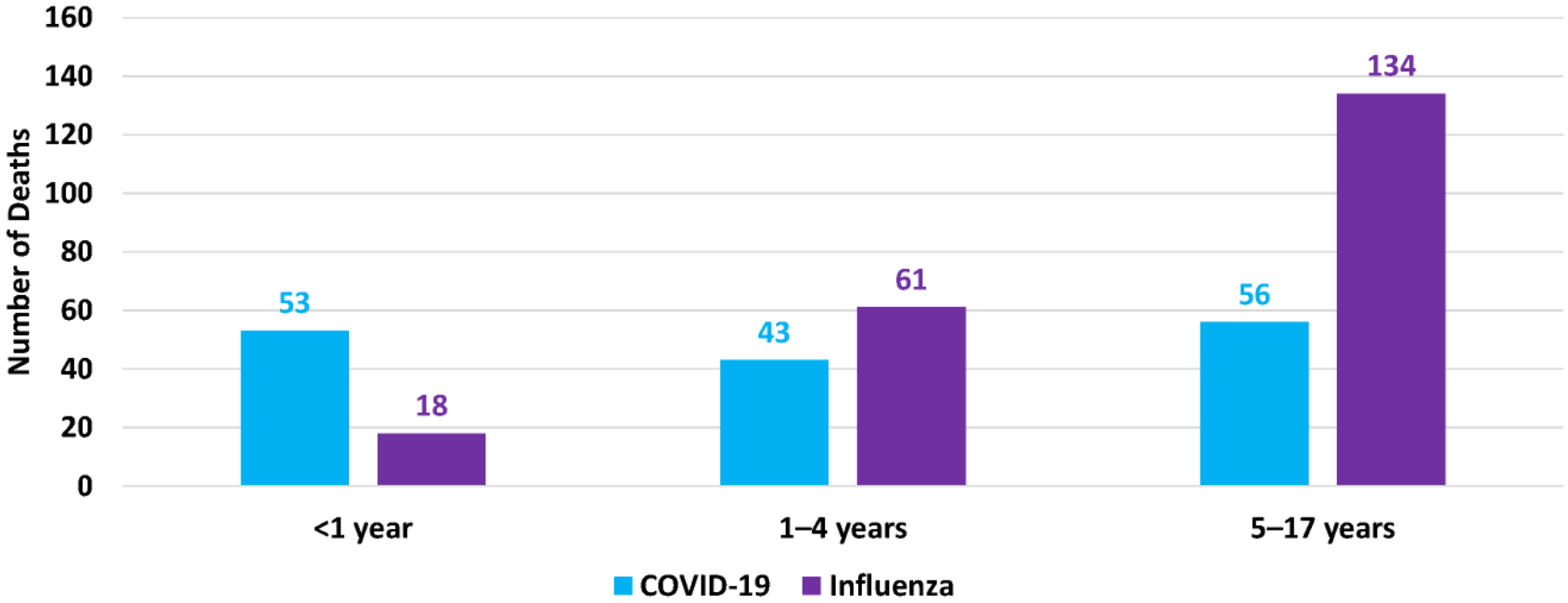


1. Provisional data
2. Underlying cause of death Source: Centers for Disease Control and Prevention, National Center for Health Statistics. National Vital Statistics System, Provisional Mortality on CDC WONDER Online Database. Data are from the final Underlying Cause of Death Files, 2018-2023, and from 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

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

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.

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

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

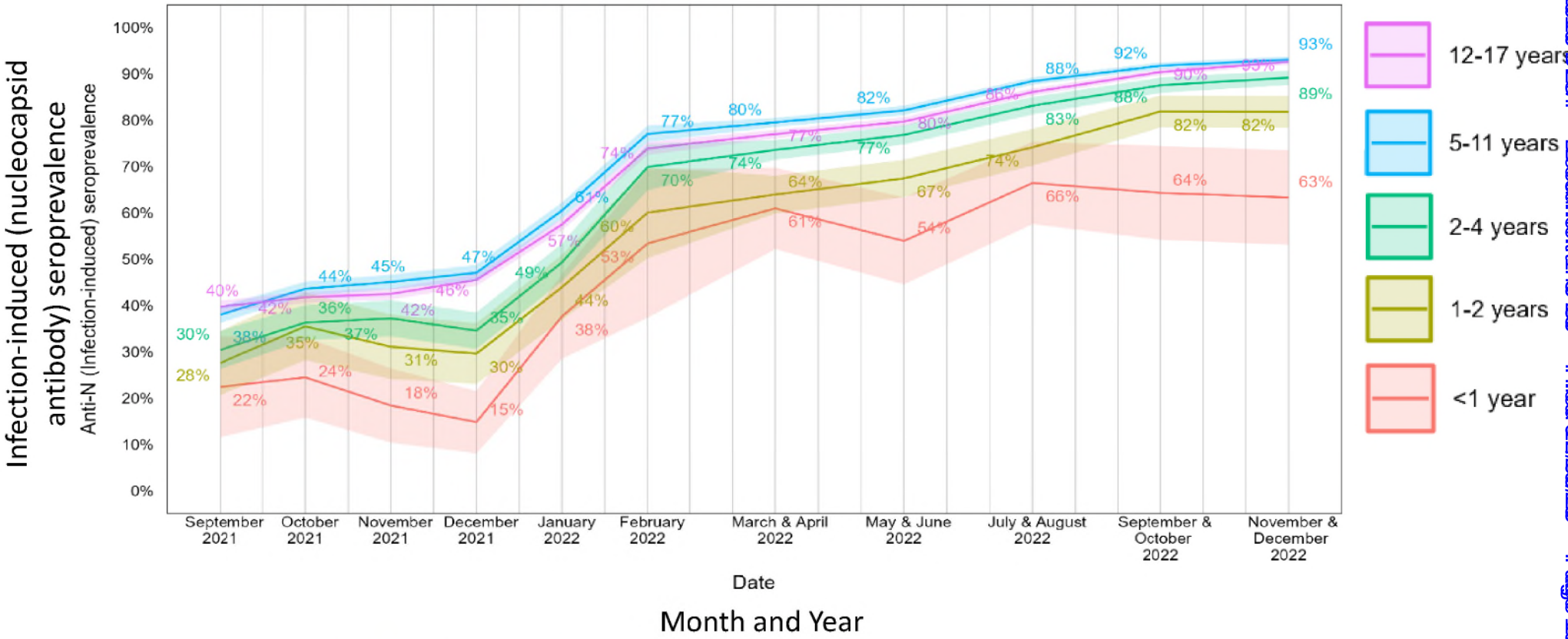
	2023–2024	2024–2025	Difference
Routine vaccine recommendation	6 months and older 65 and older: 2 doses	6 months and older 65 and older: 2 doses	No change
Vaccine coverage <18 years[1]	13.8% (13.4–14.3) (3/23/2024)	12.8% (12.2–13.4) (3/22/2025)	Similar
Vaccine coverage ≥18 years[2]	21.3% (21.0–21.5) (3/23/2024)	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

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

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

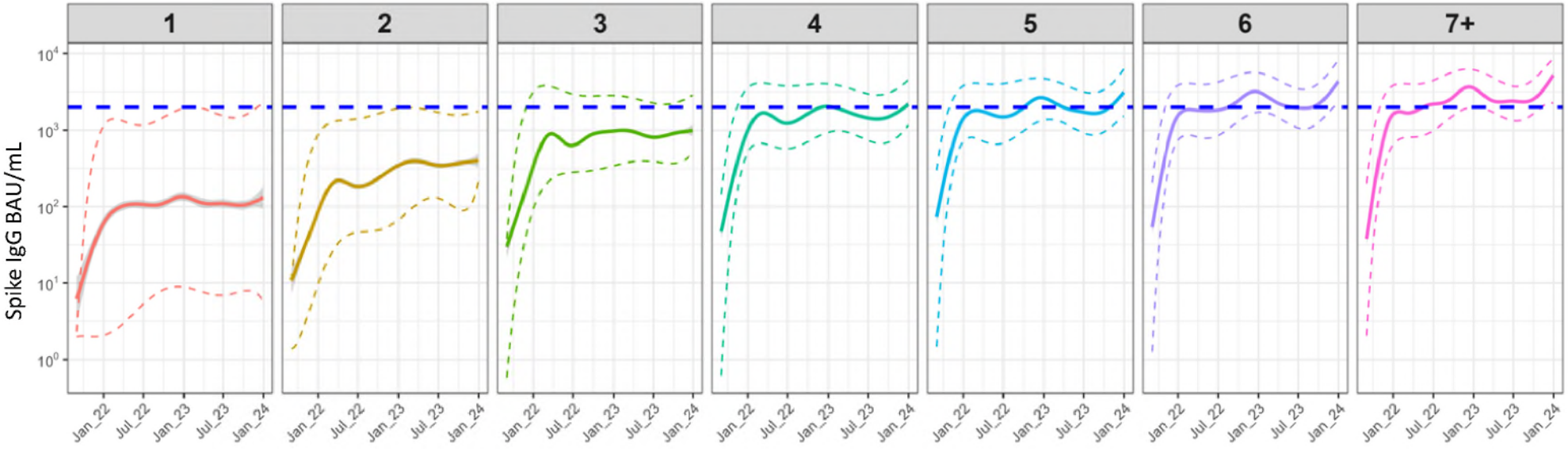


Shaded ranges depict 95% confidence intervals for the estimated seroprevalence shown by the dark line in the corresponding color.
Source: https://covid.cdc.gov/covid-data-tracker/#pediatric-seroprevalence
Accessed: March 20, 2025

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

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

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

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.

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

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

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

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

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

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

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COVID-19 Vaccine and Myocarditis

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

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.

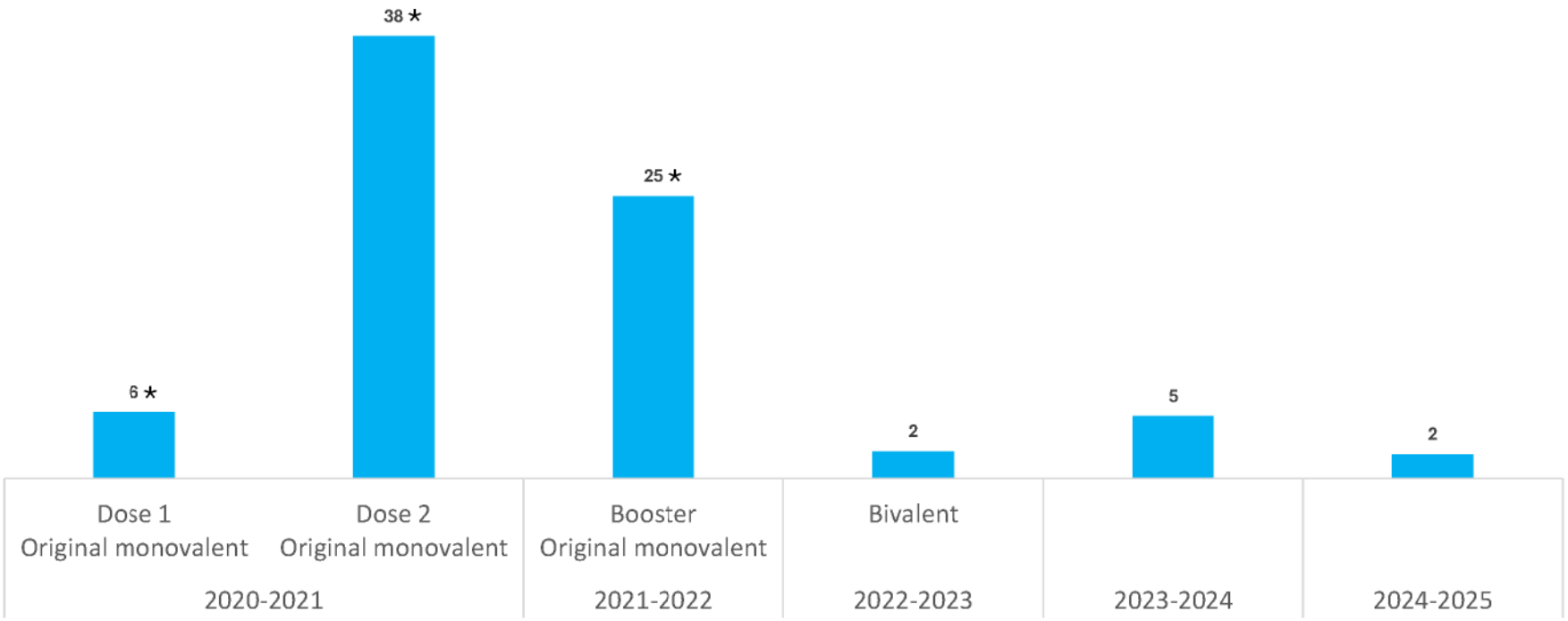
https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines-2024-2025

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

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

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

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

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

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

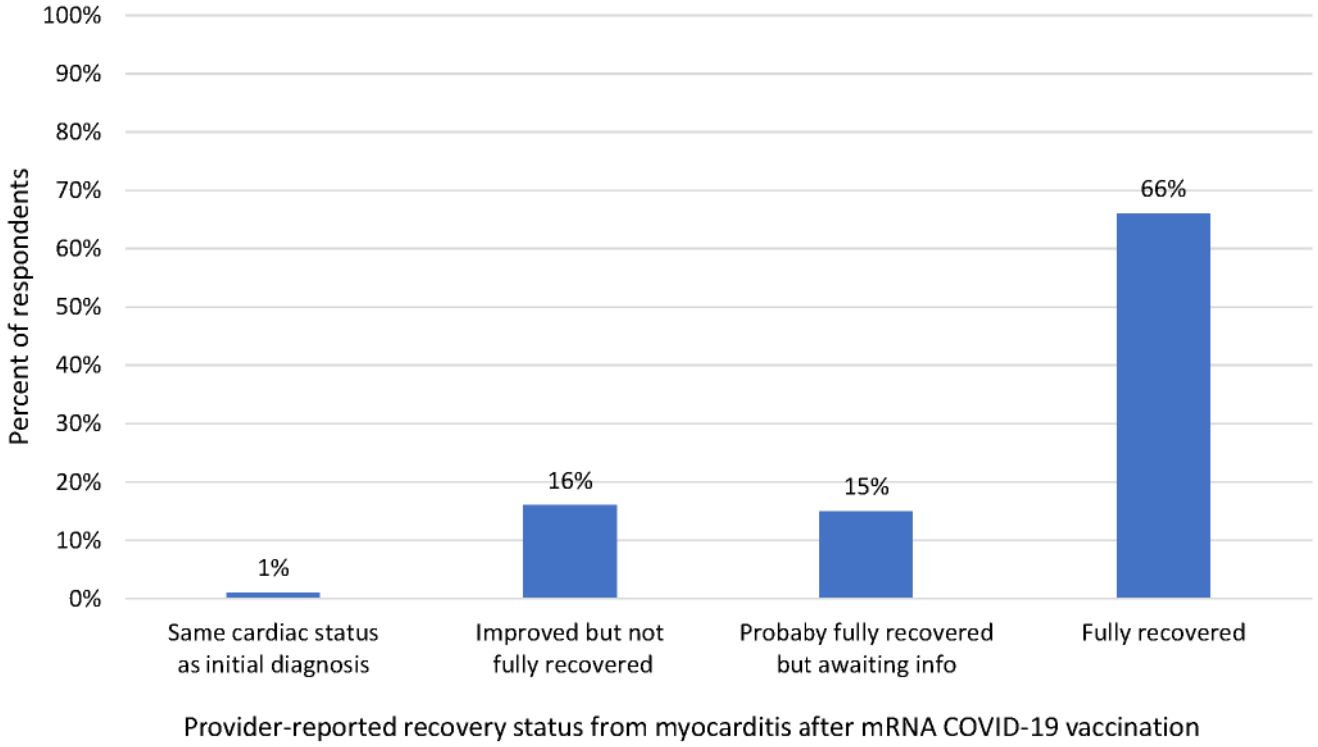
- **The reporting rates are similar to the expected background rates of <2 cases per million doses**

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

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

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



Provider-reported recovery status from myocarditis after mRNA COVID-19 vaccination

- **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

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

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.

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

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

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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

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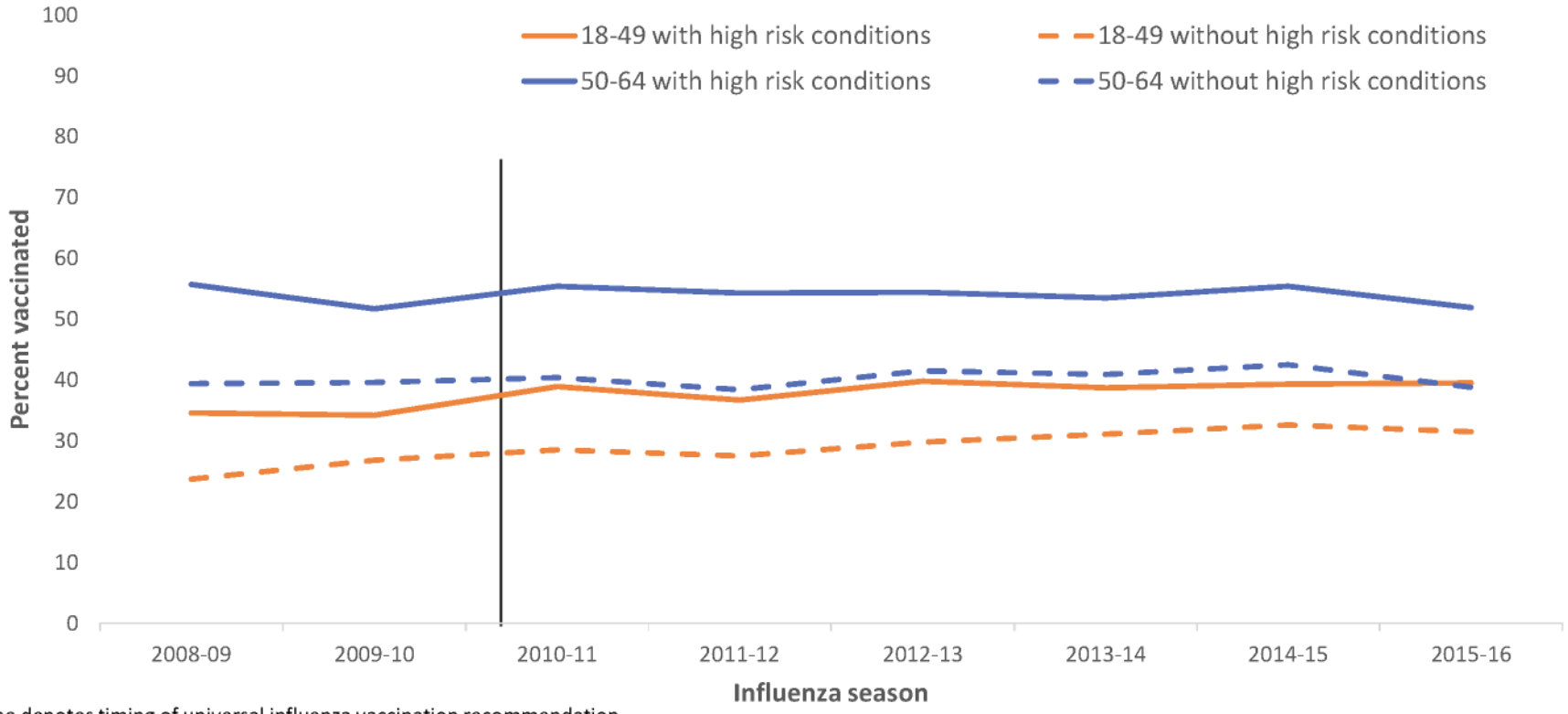
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Risk-based v. universal vaccine recommendations and vaccine coverage

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

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

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

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

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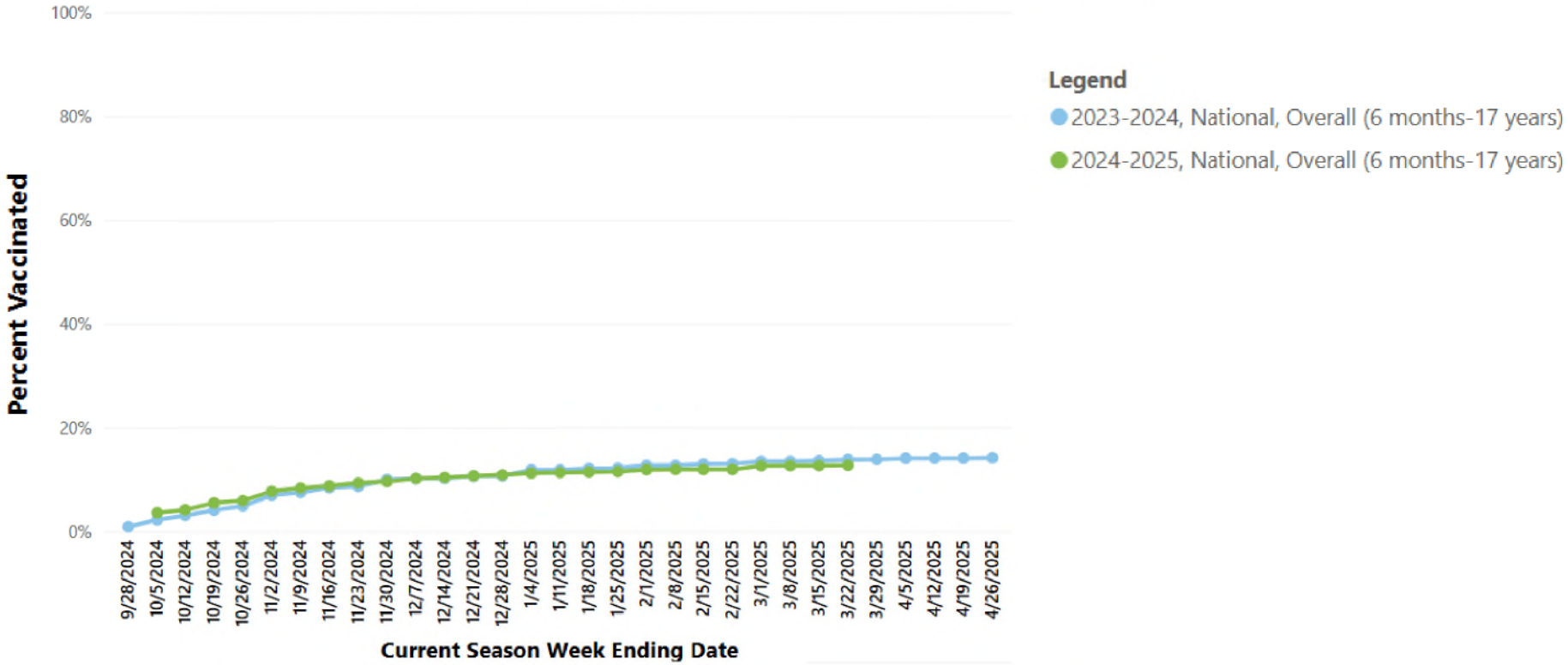
Parental vaccine confidence

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

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

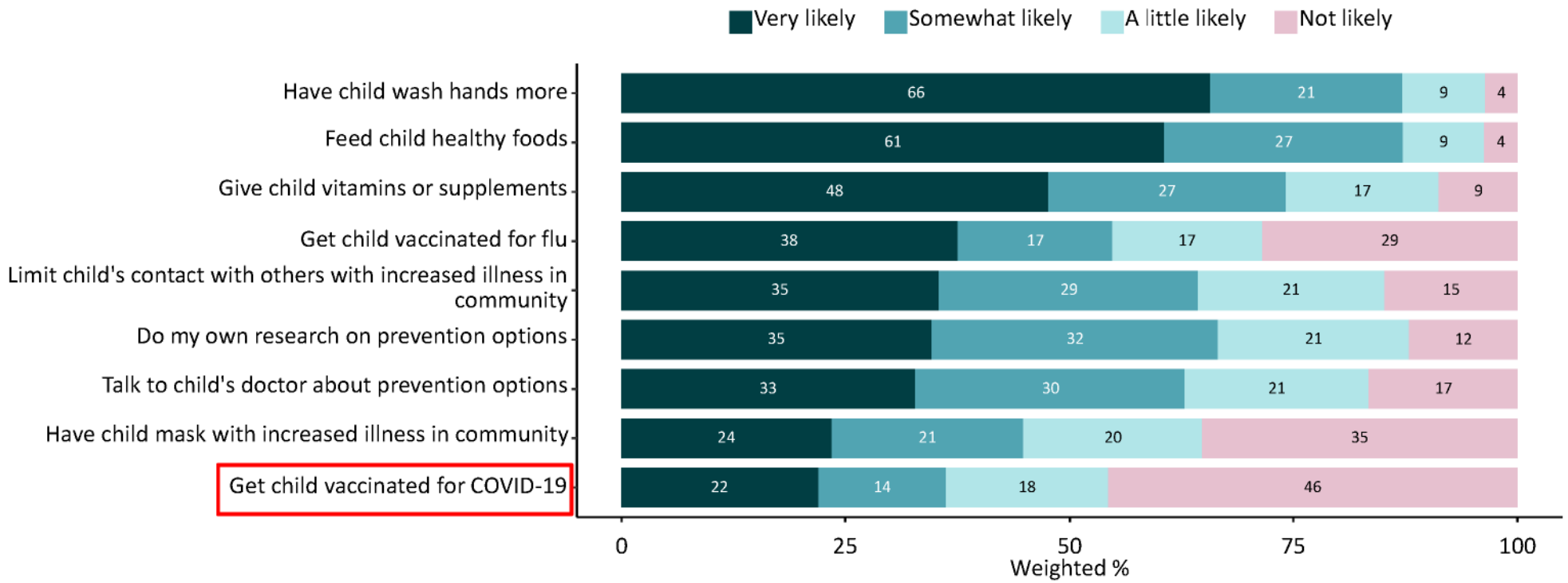
Data source: National immunization survey – Flu https://www.cdc.gov/covidvaxview/weekly-dashboard/child-coverage-vaccination.html

Accessed April 7, 2025

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"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)



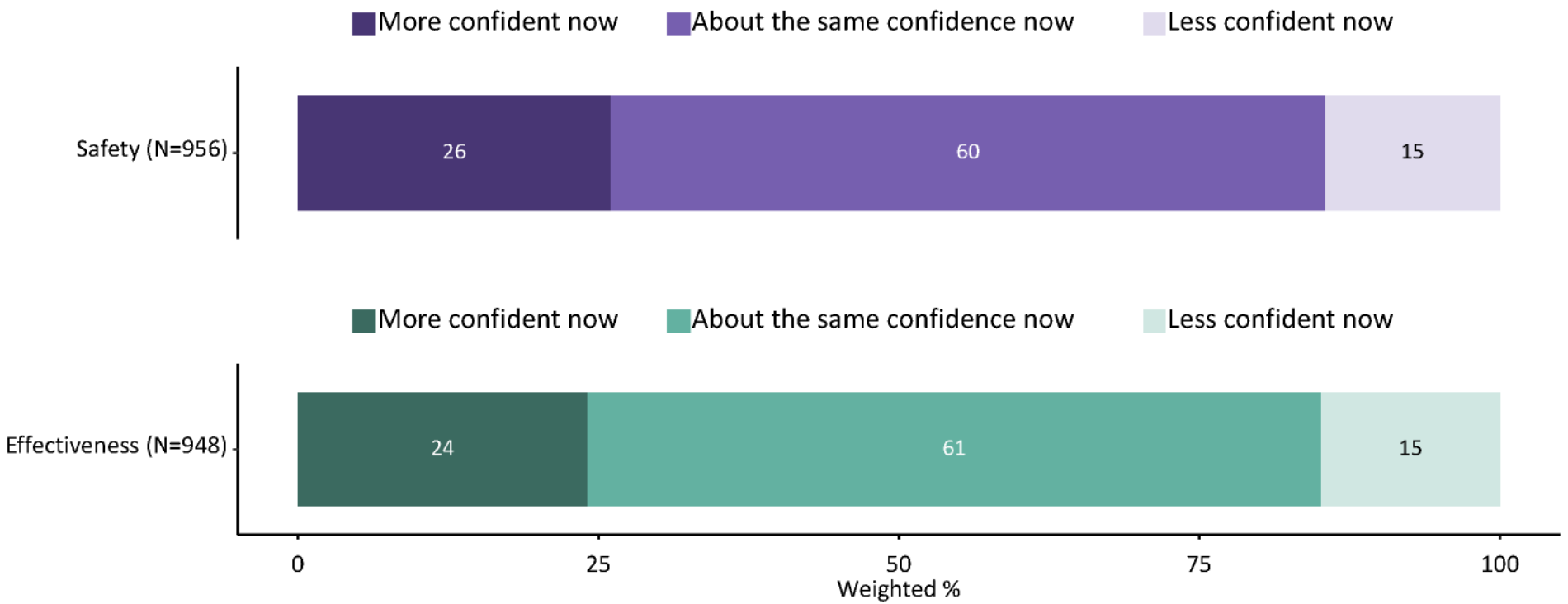
Omnibus Surveys: Data for this analysis were collected through the Ipsos KnowledgePanel and NORC AmeriSpeak Omnibus Surveys, which use probability-based panels to survey a nationally representative sample of U.S. adults ages 18 years and older. CDC fields questions about vaccination status, intent, knowledge, 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.

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

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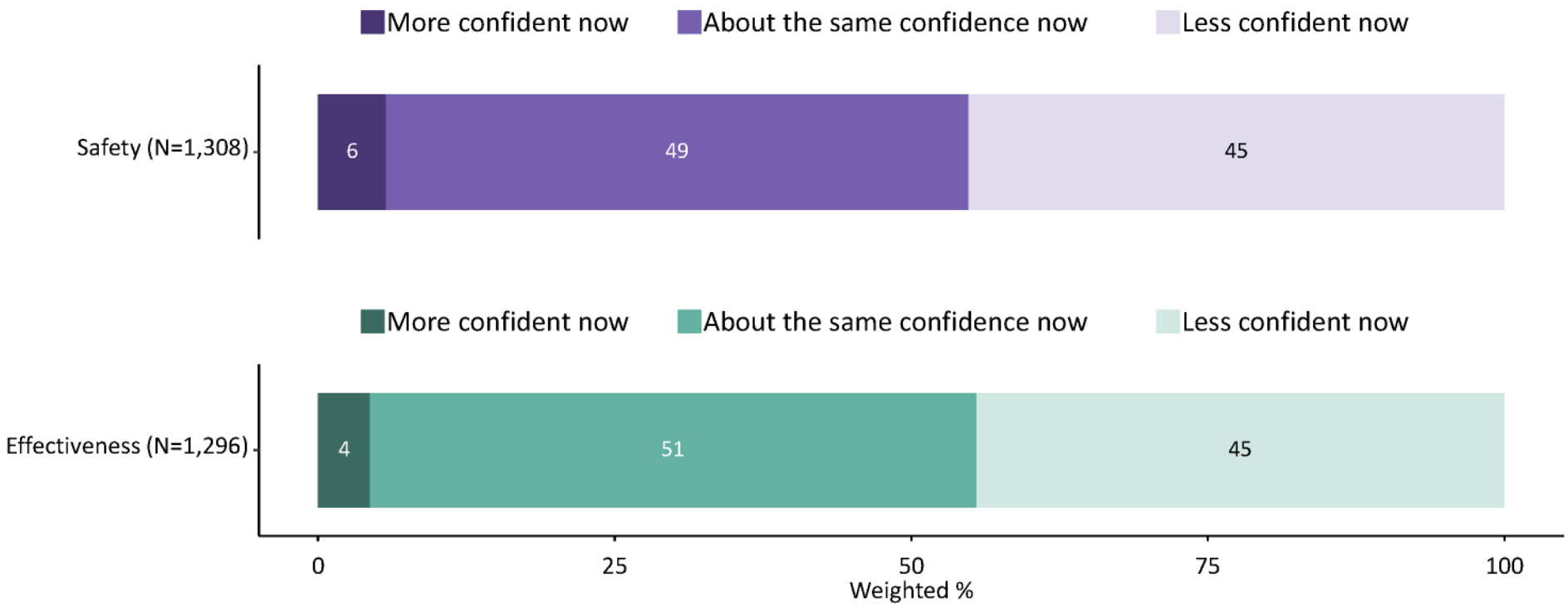
"Are you more or less confident in the safety/effectiveness of COVID-19 vaccines for children *now* compared to when they first came out?" Results Among Parents of Child Ages 0–17 Years Who Received at Least 1 Dose of a COVID-19 Vaccine, Omnibus Surveys, December 5, 2024–January 27, 2025



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 December 2024 & January 2025 (N=8,536). Data were weighted to represent the non-institutionalized U.S. population and mitigate possible non-response bias. All responses are self-reported.

Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

"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

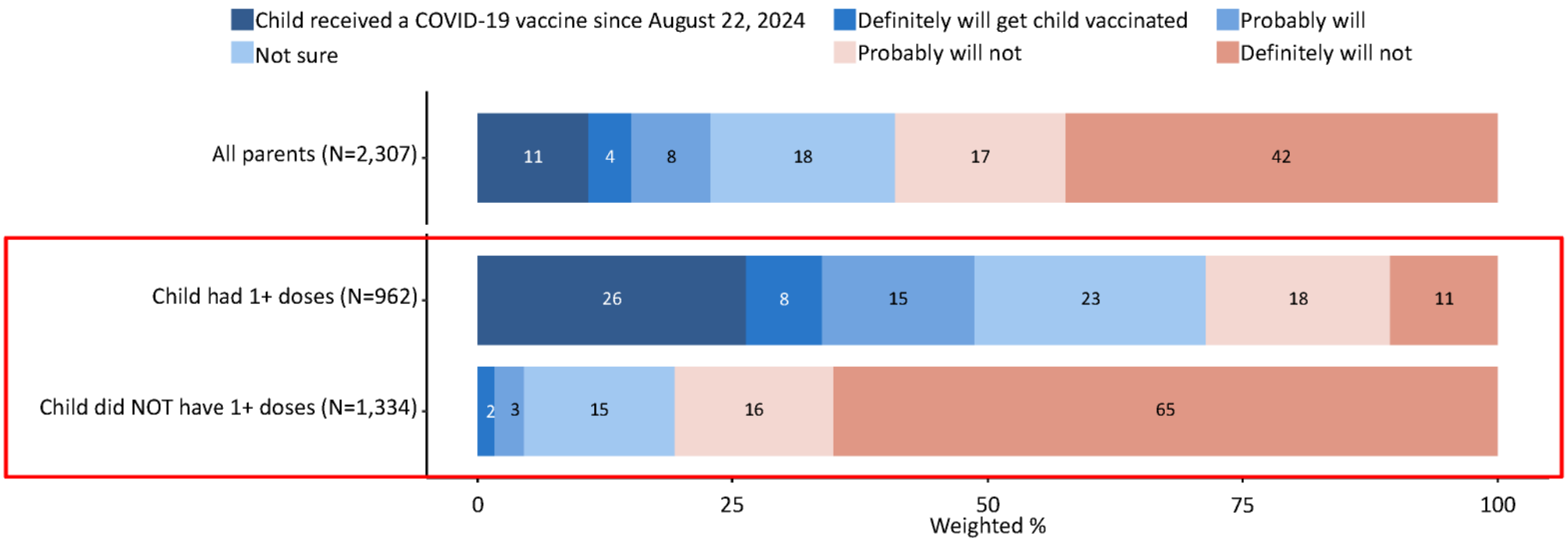


Omnibus Surveys: Data for this analysis were collected through the Ipsos KnowledgePanel and NORC AmeriSpeak Omnibus Surveys, which use probability-based panels to survey a nationally representative sample of U.S. adults ages 18 years and older. CDC fields questions about vaccination status, intent, knowledge, 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 December 2024 & January 2025 (N=8,536). Data were weighted to represent the non-institutionalized U.S. population and mitigate possible non-response bias. All responses are self-reported.

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

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)

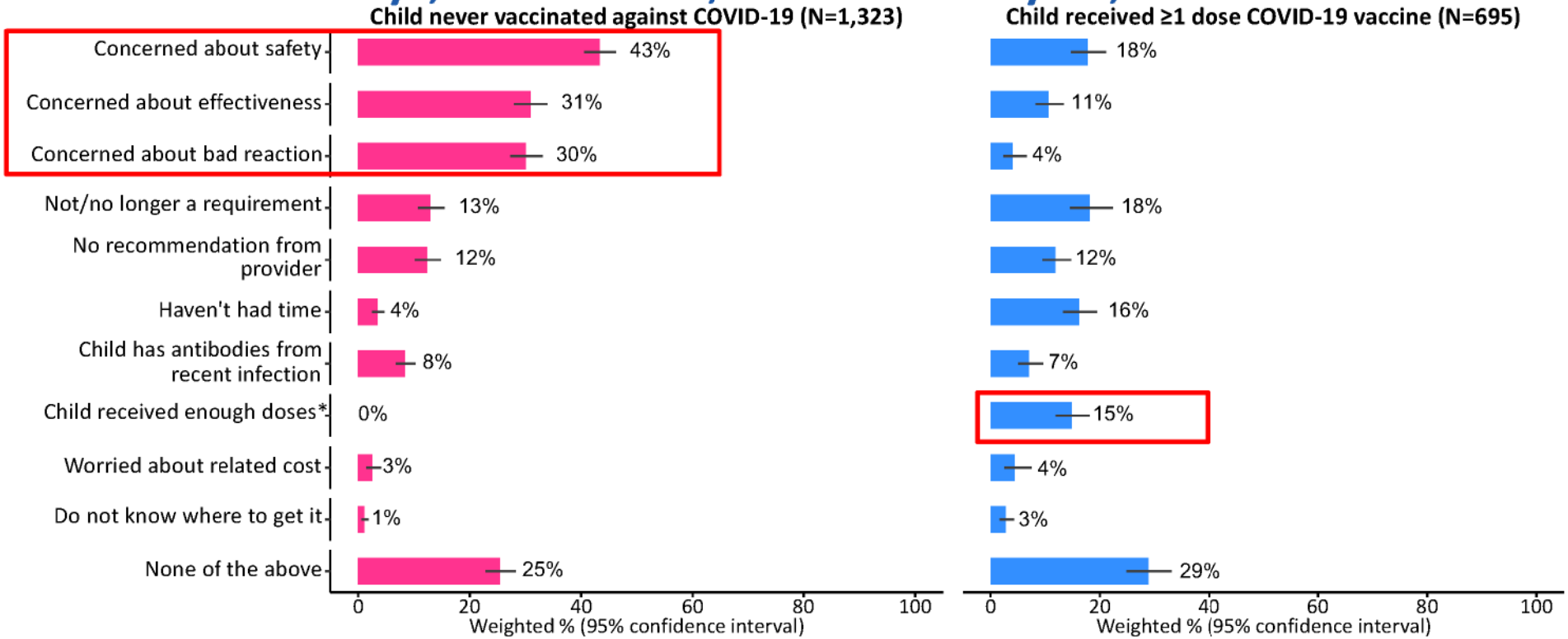


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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

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.

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 December 2024 & January 2025 (N=8,536). Data were weighted to represent the non-institutionalized U.S. population and mitigate possible non-response bias. All responses are self-reported.

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

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Recommendations in other countries

Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

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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Immunocompromised adults	6 months	6 months	12 months, *may receive every 6 months*	6-12 months	6 months, *plus may receive additional doses at 2-month intervals*
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Immunocompromised children	6 months	6 months	**Under 5 years:** not recommended ***5-17 years:*** *May receive every 12 months*	6-12 months	6 months, *plus may receive additional doses at 2-month intervals*

1 https://assets.publishing.service.gov.uk/media/66e7fbf624c4f1826d81bb32/Greenbook-chapter-14a-20240916.pdf 2 https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/national-advisory-committee-immunization-summary-guidance-covid-19-vaccines-2025-summer-2026.html 3 https://www.health.gov.au/our-work/covid-19-vaccines/getting-your-vaccination/booster-doses

* 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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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

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Work Group Interpretations

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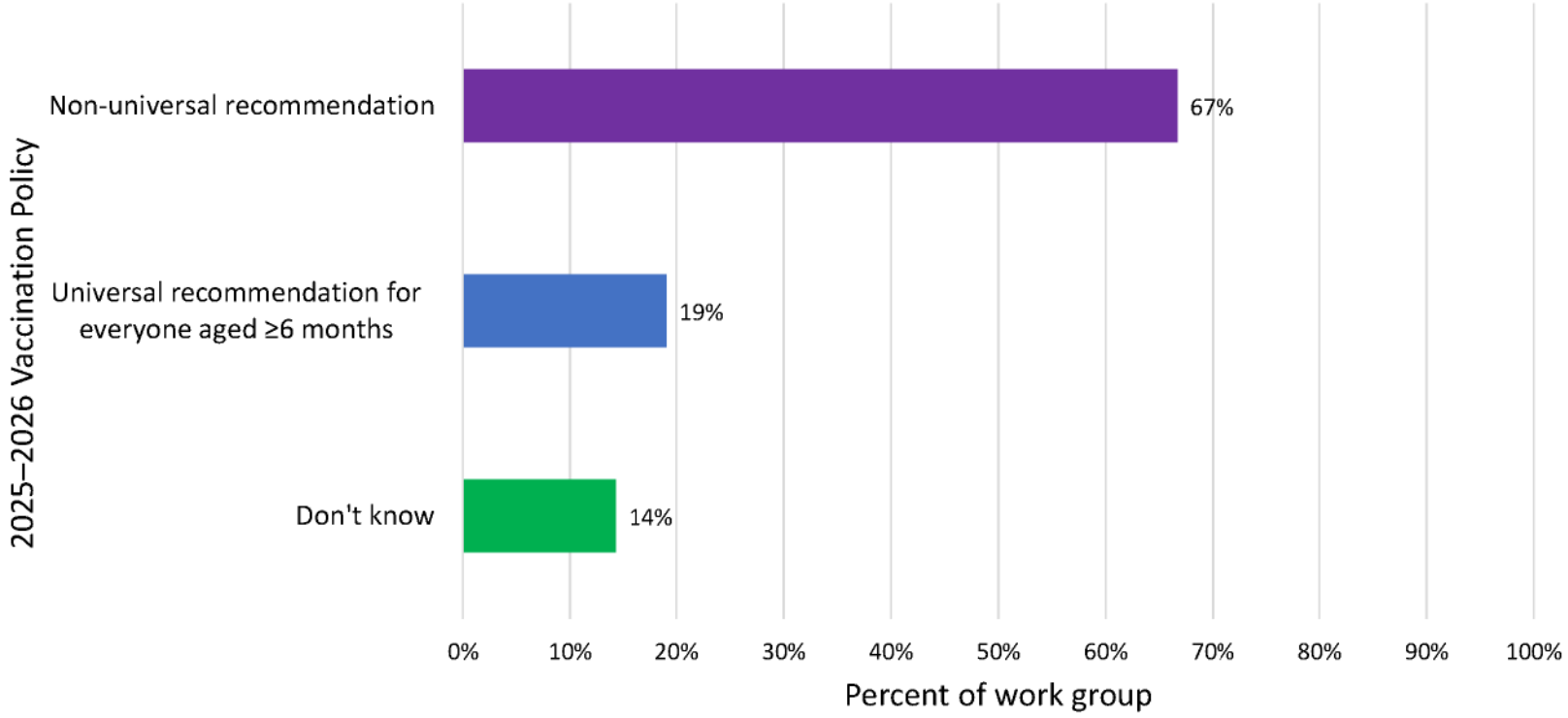
Initial Work Group interpretations

- 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.

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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

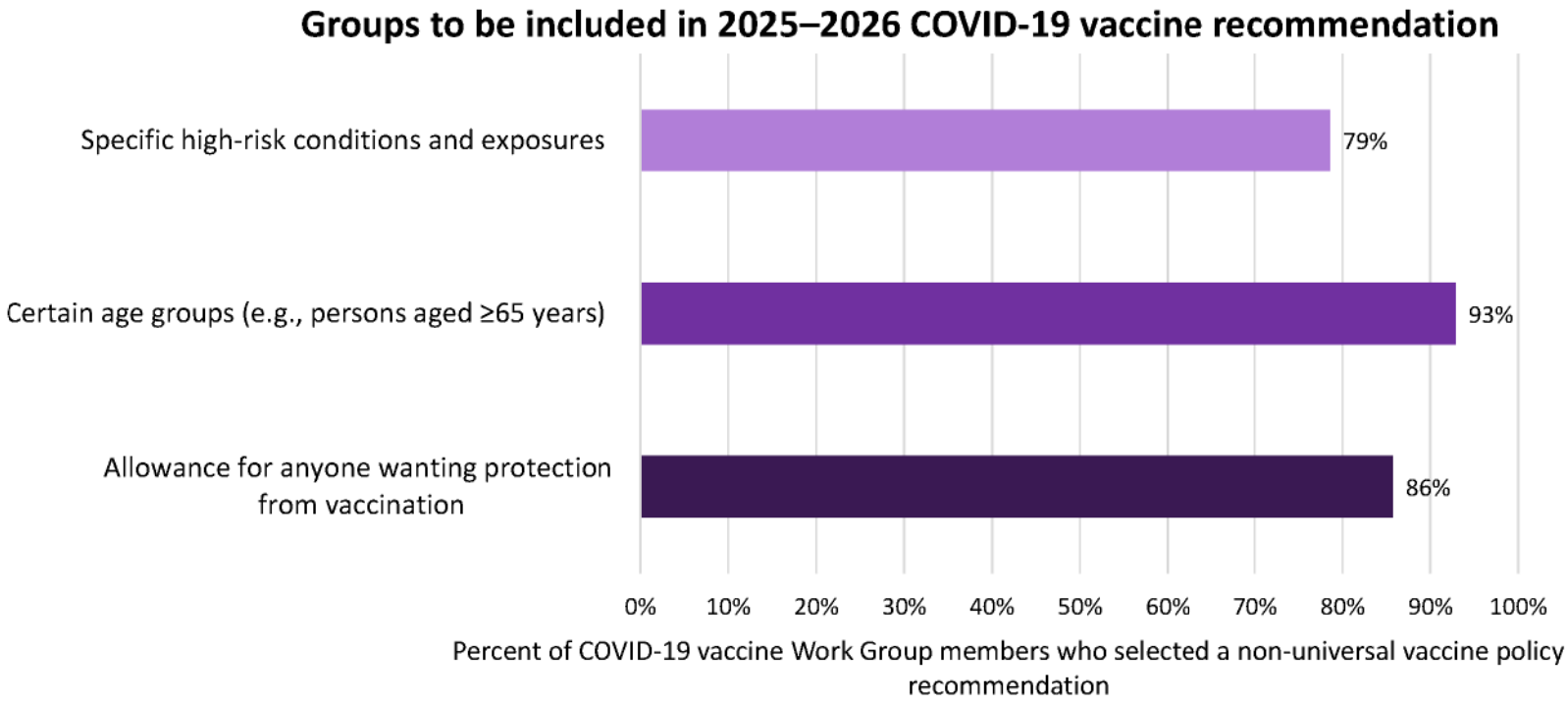


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When polled on February 13, 2025, the Work Group supported all non-universal policy options*



* More than one response option could be selected.

Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

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)

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

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

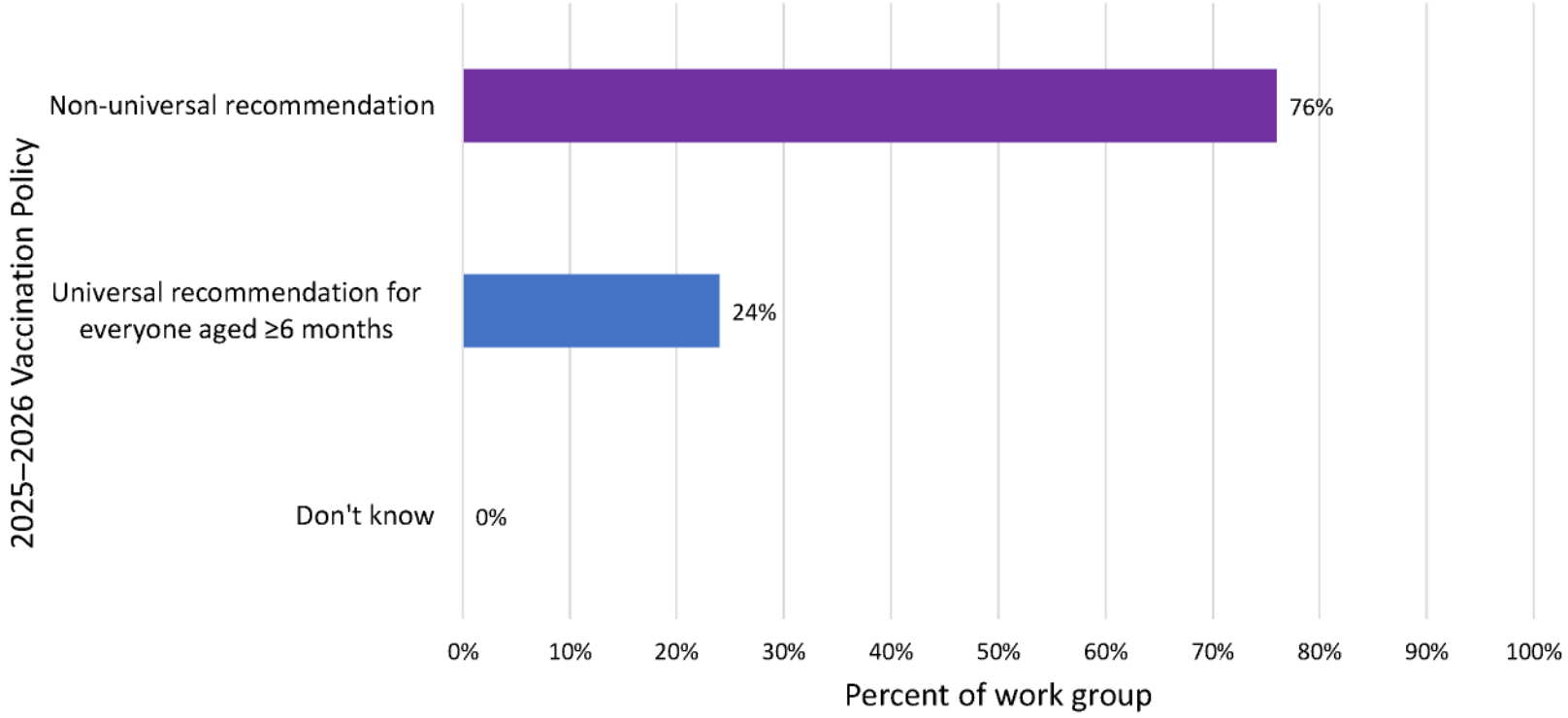
- American Academy of Family Physicians (AAFP)
- American Academy of Pediatrics (AAP)
- Association of Immunization Managers (AIM)
- American College of Physicians (ACP)
- American Pharmacists Association (APhA)
- American College of Obstetricians and Gynecologists (ACOG)

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

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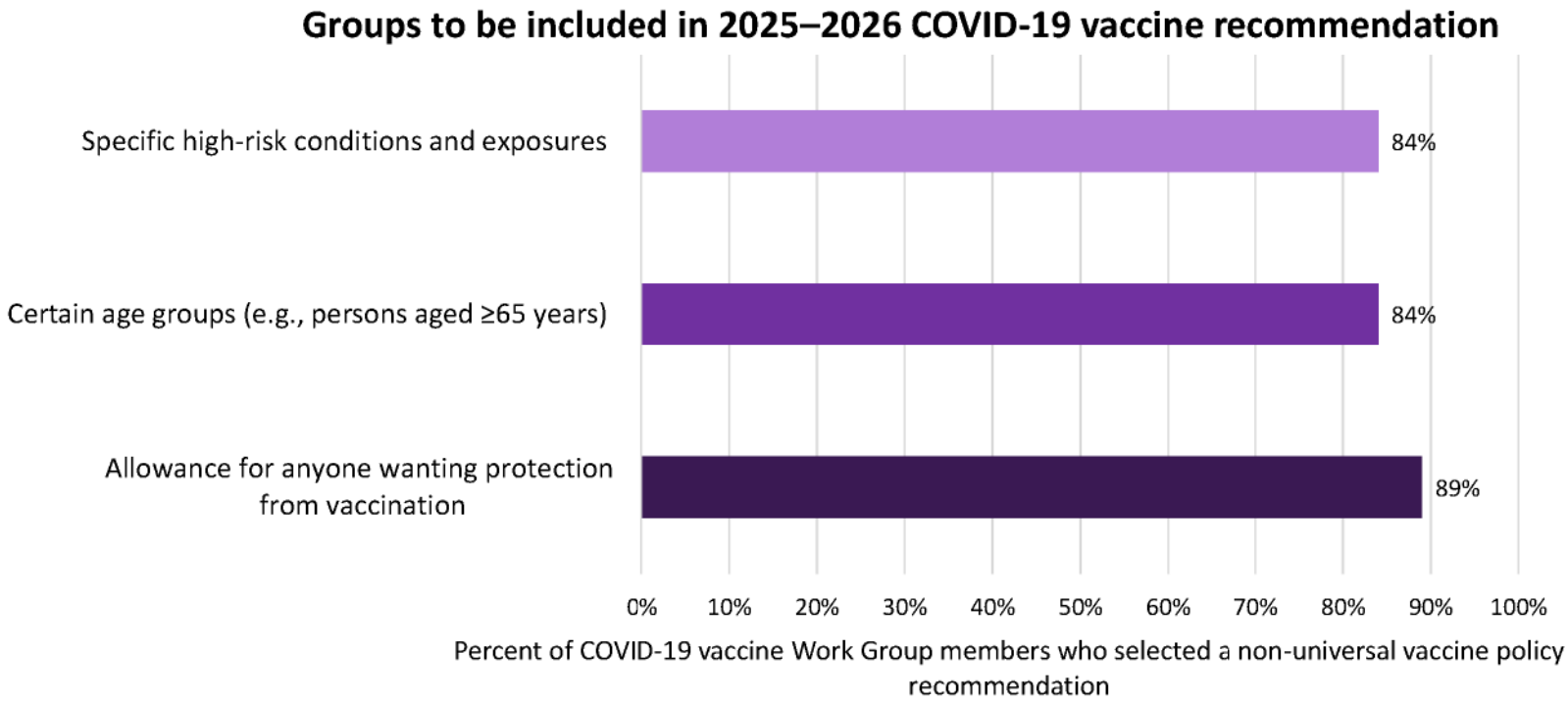
When polled on April 3, 2025, the majority of the work group continued to support a non-universal (risk-based) recommendation for 2025–2026 COVID-19 vaccination



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When polled on April 3, 2025, the Work Group continued to support all non-universal policy options*

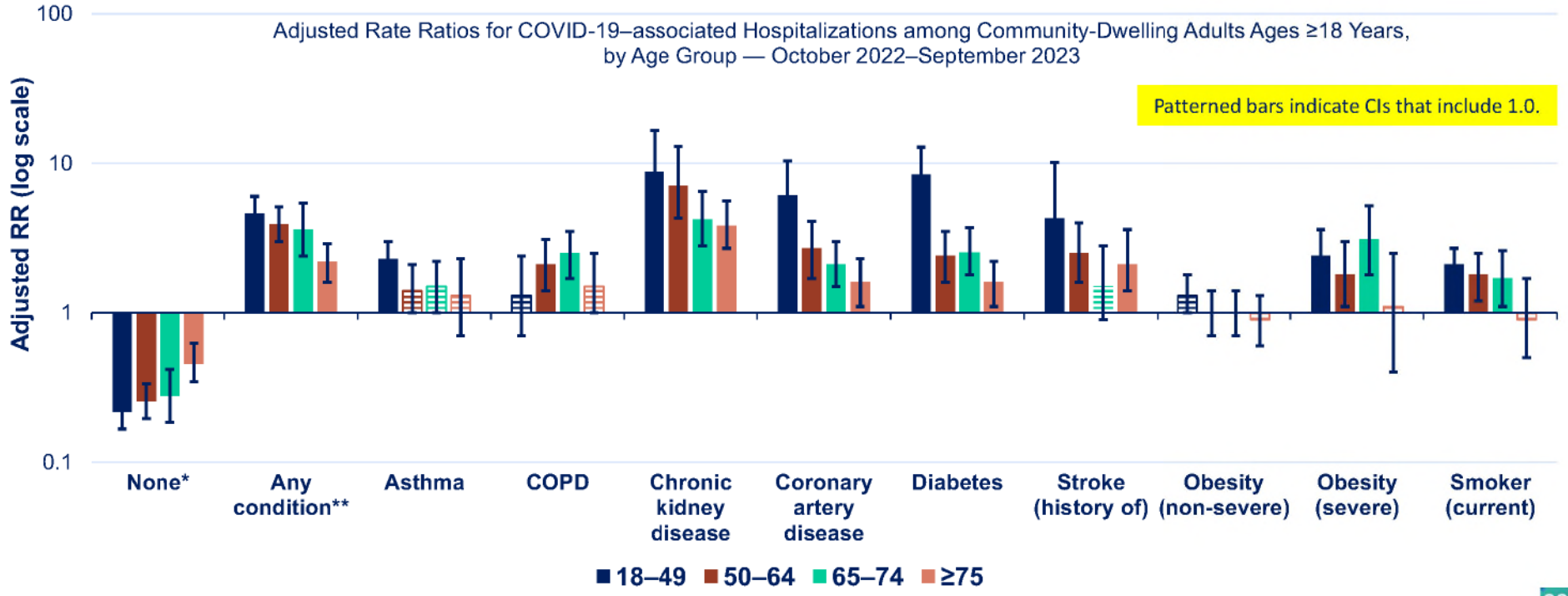


* More than one response option could be selected.

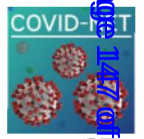
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Risk for COVID-19–associated hospitalization is increased among community-dwelling adults ages ≥18 years with underlying medical conditions.



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.



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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?

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Acknowledgements

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- Anna Yousef
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- COVID-NET Team
- Immunization Safety Office
- Immunization Services Division
- National Center for Immunization and Respiratory Diseases

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EXHIBIT J

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Update on CDC's COVID-19 Vaccine Safety Monitoring

Sarah Meyer, MD MPH

Director, CDC's Immunization Safety Office

June 25, 2025

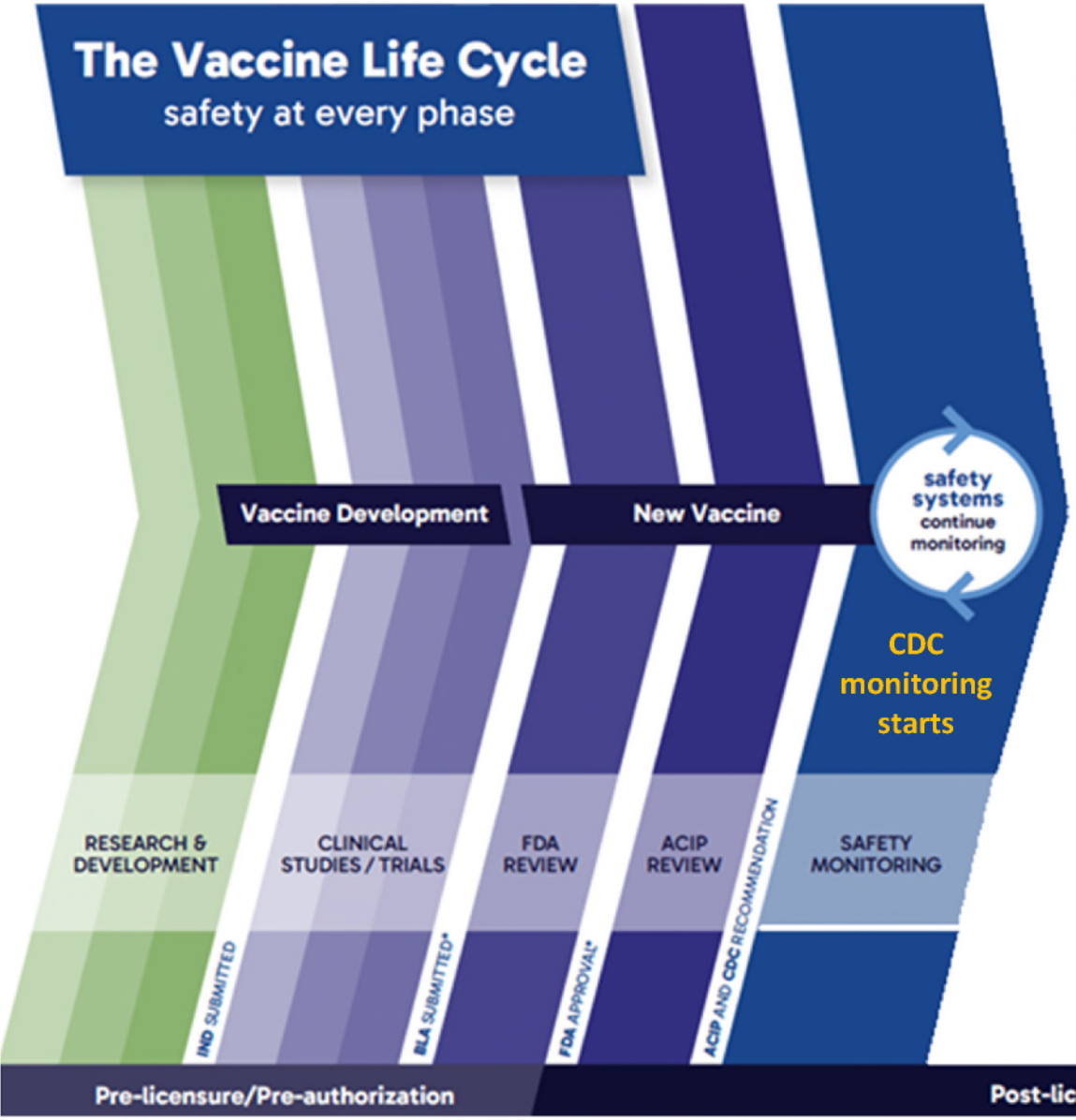
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Key Points

- CDC and interagency partners launched an extensive vaccine safety monitoring program for COVID-19 vaccines
- Many potential safety outcomes were rigorously assessed through complementary passive and active systems
- Myocarditis is causally associated with mRNA COVID-19 vaccines
  - Adverse events common to all vaccines were also observed (e.g., local and systemic reactions, allergic reactions)
- CDC continues to monitor the safety of COVID-19 vaccines

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Interagency collaboration to monitor post-licensure safety

CDC

FDA

INDIAN HEALTH SERVICE · PHS · 1955 ·

DEPARTMENT OF DEFENSE · UNITED STATES OF AMERICA

DEPARTMENT OF VETERANS AFFAIRS · UNITED STATES OF AMERICA

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CDC's Immunization Safety Office Monitors Vaccine Safety Through Strong, Complementary Systems

VAERS	VSD	CISA Project	V-safe
			
1990	*1990*	*2001*	*2020*

Systems work together to rapidly detect and assess potential safety concerns to help inform public health actions

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Vaccine Adverse Event Reporting System (VAERS)

The Nation's Early Warning System for Vaccine Safety

VAERS



- Co-managed by CDC and FDA
- Nationwide spontaneous reporting system that can rapidly detect safety signals, including rare events
- Mandated reporting by healthcare providers and manufacturers, and encouraged from anyone (e.g., patients)
- A report to VAERS does not mean that a vaccine caused an adverse event
- Used for signal detection and hypothesis generation, not typically for assessing causality

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Vaccine Safety Datalink (VSD)

Collaborative Model for High-Quality Vaccine Safety Data

VSD



- 13 integrated healthcare organizations, covering >15.5 million people per year
- Active monitoring using electronic medical records (EMR) and chart reviews
- Rapid monitoring for pre-specified events as well as monitoring for unexpected events
- Can detect and assess safety signals
- Develops innovative methods for monitoring safety

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Clinical Immunization Safety Assessment (CISA) Project

Network to Guide Vaccine Safety from the Individual to Population Level

CISA Project



- 8 medical research centers with vaccine safety experts
- Provides expert clinical consultation on complex immunization issues
- Conducts clinical research on vaccine safety
- Helps to inform CDC public health guidance on clinical immunization safety issues

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V-safe: After-Vaccination Health Checker

CDC's Tool for Direct-to-Consumer Vaccine Safety Monitoring

V-safe



- Web-based, self-reported active monitoring system established during COVID-19 pandemic
- Can serve as earliest source of information for new vaccines and in populations excluded from clinical trials
  - Used to recruit women for COVID-19 Vaccine Pregnancy Registry
- Important tool for emergency preparedness and response
- Integrated with VAERS to help streamline reporting of serious adverse events

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CDC's Comprehensive Approach to Studying COVID-19 Vaccine Safety



Surveillance
Analyze spontaneously reported events



Epidemiologic studies
Assess specific safety questions



Clinical Research
Safety studies to guide clinical practice



Pregnancy Registry
Longitudinal assessment of maternal and infant outcomes



Rapid cycle analyses
Quickly detect potential concerns for investigation



Data mining
Assess >60,000 outcomes for unexpected events

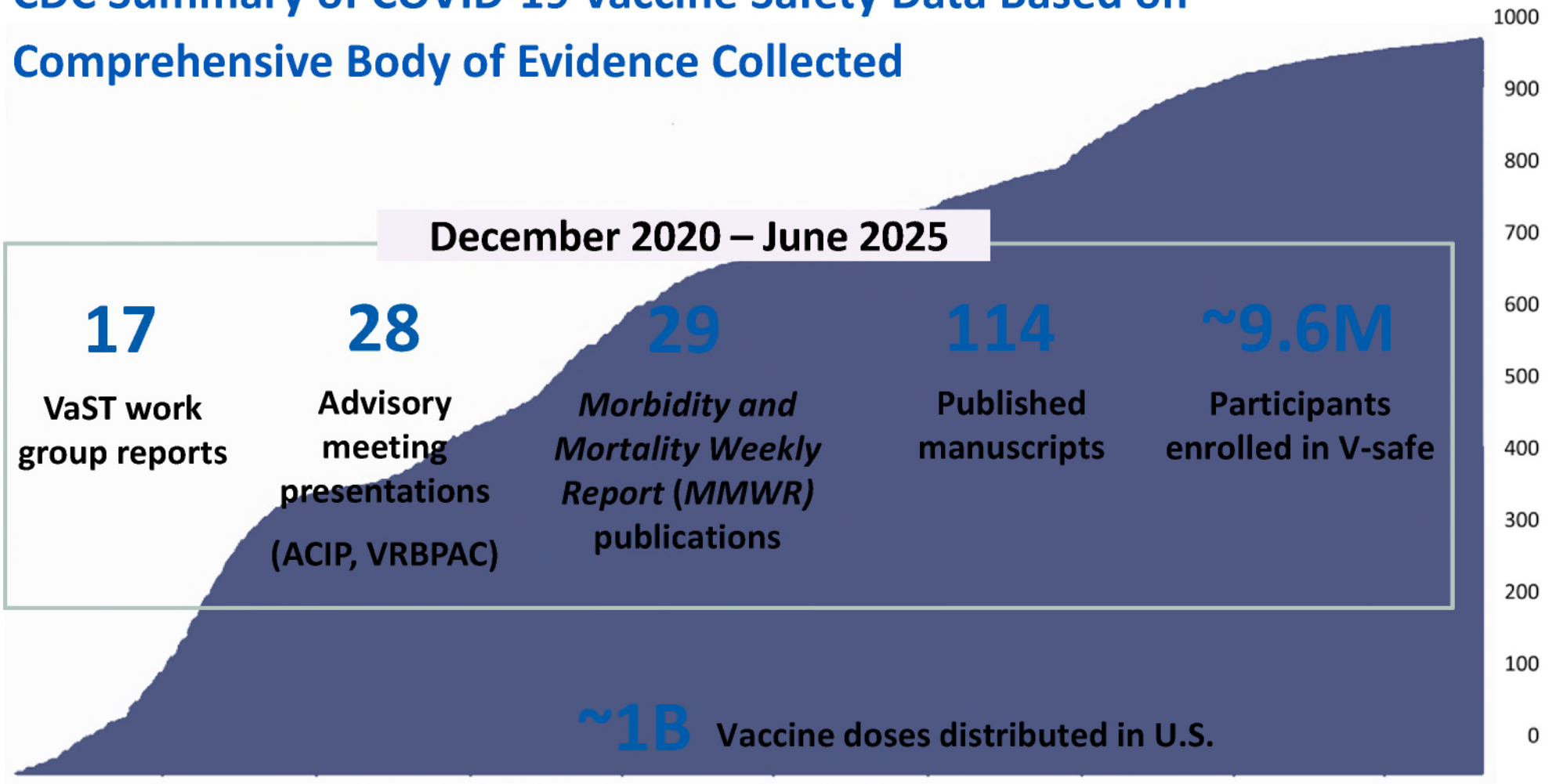


Patient surveys
Assess symptoms and health impacts

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CDC Summary of COVID-19 Vaccine Safety Data Based on Comprehensive Body of Evidence Collected



December 2020 – June 2025

17
VaST work group reports

28
Advisory meeting presentations (ACIP, VRBPAC)

29
Morbidity and Mortality Weekly Report (*MMWR*) publications

114
Published manuscripts

~9.6M
Participants enrolled in V-safe

~1B Vaccine doses distributed in U.S.

ACIP: Advisory Committee on Immunization Practices; VRBPAC: Vaccines and Related Biological Products Advisory Committee; VaST: Vaccine Safety Technical Work Group

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Three Types of COVID-19 Vaccine Received FDA Authorization or Approval in the United States

mRNA



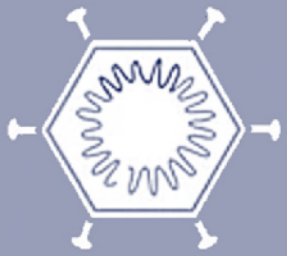
Pfizer-BioNTech
Moderna

Protein-based



Novavax

Viral Vector



Janssen

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Janssen Use Limited After Detection of Safety Concerns in April 2021, and No Longer Authorized in U.S. as of June 2023

mRNA

Pfizer-BioNTech
Moderna

Protein-based

Novavax

Viral Vector



Janssen

- By April 2021, VAERS detects 6 reports of thrombosis w/ thrombocytopenia syndrome (TTS); FDA and CDC issue a 10-day pause in use before resuming
- In December 2021, ACIP issues preferential recommendation for mRNA vaccines
- In June 2023, FDA revokes EUA

EUA: Emergency Use Authorization

Oliver S, et al. Development of COVID-19 vaccine policy — United States, 2020–2023 - ScienceDirect

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

Janssen Use Limited After Detection of Safety Concerns in April 2021, and No Longer Authorized in U.S. as of June 2023

mRNA

Pfizer-BioNTech
Moderna

Protein-based

Novavax

Viral Vector



Janssen

Highlights an example of federal safety systems working to rapidly identify and mitigate a vaccine safety issue

EUA: Emergency Use Authorization

Oliver S, et al. Development of COVID-19 vaccine policy — United States, 2020–2023 - ScienceDirect

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Limited Post-Authorization Safety Data Available for Novavax

mRNA

Pfizer-BioNTech
Moderna

Protein-based



Novavax

Limited post-authorization safety data available:

- Authorized later than other products (July 2022)
- Limited uptake in the U.S.

Viral Vector



Janssen

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Focus on mRNA COVID-19 Vaccines For This Presentation

mRNA



Pfizer-BioNTech
Moderna

Protein-based

Novavax

Viral Vector



Janssen

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Monitoring Safety of COVID-19 Vaccines

What we have learned

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CDC Has Evaluated At Least 65 Specific Outcomes to Assess COVID-19 Vaccine Safety Using a Variety of Systems and Epidemiologic Methods

Acute myocardial infarction • ICU admission • Acute disseminated encephalomyelitis • Thrombotic thrombocytopenic Purpura • Encephalopathy • Gestational diabetes • Trigeminal neuralgia and related disorders • Meningitis • Deep vein thrombosis • Anaphylaxis • Thrombocytopenia • Postmenopausal bleeding • Myocarditis • Cataplexy • Myelitis • Chronic inflammatory demyelinating polyneuropathy • Non-COVID mortality • Pulmonary embolism • Stillbirth • Major birth defects • Encephalitis • Local reactions • Vaccine-Associated Enhanced Disease after COVID-19 Vaccines • Hemorrhagic stroke • Administration errors • Acute respiratory distress syndrome • Narcolepsy • Perinatal death • Bell's Palsy • Thrombosis with thrombocytopenia syndrome • Multiple sclerosis • Systemic reactions • Spontaneous abortion • Ataxia • Hospitalization • Acute disseminated encephalomyelitis • Menstrual irregularities • Immune thrombocytopenic purpura • All-cause mortality • Pericarditis • Early childhood infections in infants of vaccinated mothers • Ischemic stroke • Shoulder injuries • Multisystem Inflammatory Syndrome in Children • Multisystem Inflammatory Syndrome in Adults • Tinnitus • Disseminated intravascular coagulation • Acute respiratory distress syndrome • Venous thromboembolism • Arthritis • Seizure • Kawasaki Disease • Arthralgia • Menstrual irregularities • NICU admission • Chronic inflammatory demyelinating polyneuropathy • Small-for-gestational age • Post-COVID conditions • Trigeminal neuralgia and related disorders

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Weekly, Sequential Monitoring of Pre-Specified Outcomes in the VSD

- Rapid cycle analyses (RCAs) conducted weekly since December 2020 of up to 23 pre-specified outcomes among over 12 million people
  - Outcomes selected based on clinical trial data, known safety findings with other vaccines, or biological plausibility

- Sequential statistical testing using automated ICD-10-CM codes
  - Compare incidence in vaccinated people during post-vaccination risk interval vs. vaccinated people in a comparison window

- If potential "statistical signal" detected, additional analyses and/or chart reviews conducted
  - System designed to be sensitive; not all detected signals represent a true safety concern



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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

Evaluation of Statistical Signals Detected for mRNA COVID-19 Vaccines through VSD's Rapid Cycle Analyses – 2020-2025

8 statistical signals detected



Acute myocardial infarction
Age 18+ years



Immune Thrombocytopenic Purpura
Age 65+ years



Seizure
18-64 years



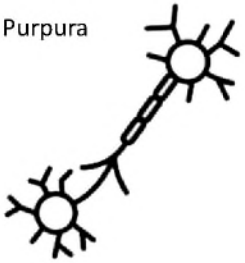
Bell's Palsy
Age 12+ years



Venous thromboembolism
Age 12+ years



Ischemic stroke
Age 50+ years



Guillain-Barré syndrome
Age 65+ years



Myocarditis
Age 12+ years

COVID-19 Vaccine Safety Technical (VaST) Work Group: Enhancing vaccine safety monitoring during the pandemic – ScienceDirect and CDC unpublished data

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Evaluation of Statistical Signals Detected for mRNA COVID-19 Vaccines through VSD's Rapid Cycle Analyses – 2020-2025

8 statistical signals detected

Acute myocardial infarction
Age 65+ years

Immune Thrombocytopenic Purpura
Age 65+ years

Seizure
18-64 years



Bell's Palsy
Age 12+ years

Venous thromboembolism
Age 12+ years

Ischemic stroke
Age 50+ years

Guillain-Barré syndrome
Age 65+ years



Myocarditis
Age 12+ years

Further investigations



Chart reviews



Trend analysis



Additional studies
(e.g., self-controlled
case series)

FDA
VA
VAERS

Query other
systems

[COVID-19 Vaccine Safety Technical (VaST) Work Group: Enhancing vaccine safety monitoring during the pandemic – ScienceDirect](#) and CDC unpublished data

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Evaluation of Statistical Signals Detected for mRNA COVID-19 Vaccines through VSD's Rapid Cycle Analyses – 2020-2025

8 statistical signals detected

Acute myocardial infarction
Age 65+ years

Immune Thrombocytopenic Purpura
Age 65+ years

Seizure
18-64 years

Bell's Palsy
Age 12+ years

Venous thromboembolism
Age 12+ years

Ischemic stroke
Age 50+ years

Guillain-Barré syndrome
Age 65+ years

Myocarditis
Age 12+ years

Further investigations

Chart reviews



Trend analysis

Additional studies
(e.g., self-controlled
case series)

FDA
VA
VAERS

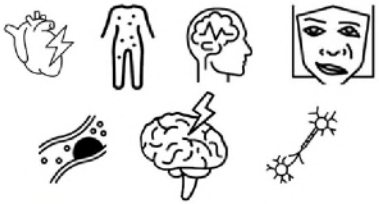
Query other
system

Safety assessment

Increased risk for myocarditis following mRNA COVID-19 vaccines



No clear or consistent evidence of a safety concern for the others

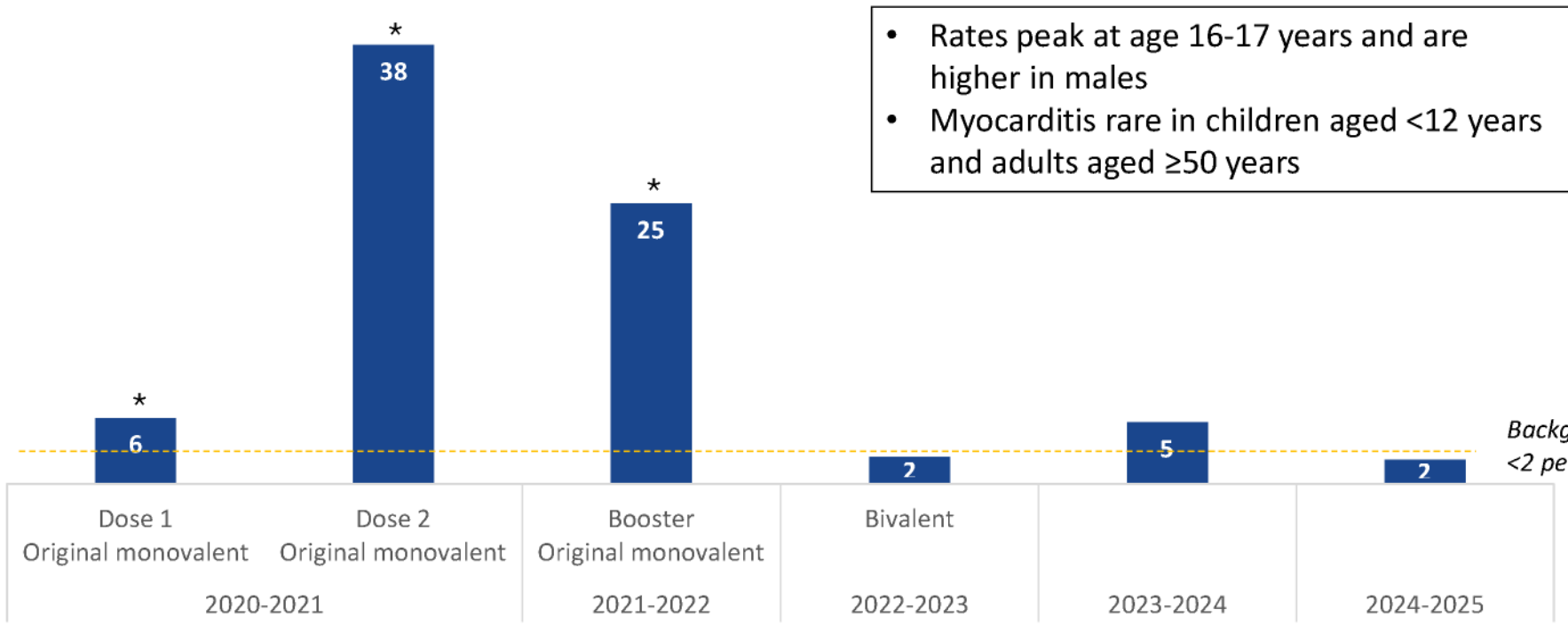


[COVID-19 Vaccine Safety Technical (VaST) Work Group: Enhancing vaccine safety monitoring during the pandemic – ScienceDirect](#) and CDC unpublished data

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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

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Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination in FDA's Biologics Effectiveness and Safety System (BEST), 2023—2024 Season

Incidence (cases per million doses) during days 1—7 following vaccine administration

Population	No. Doses	No. Cases	Rate Per Million Vaccine Doses (95% CI)
All persons 6 months–64 years of age	3,574,262	30	8.4 (5.7, 12.0)
Males 12–24 years of age	185,969	5	26.9 (8.7- 62.7)

FDA issued Safety Labeling Change (SLC) notification letters to the manufacturers on April 17, 2025, and initiated the SLC process to include new safety information on myocarditis and pericarditis for Comirnaty and Spikevax. Under the labeling negotiations, FDA has notified sponsors of the above data

2025 Safety and Availability Communications | FDA; Information courtesy of FDA

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Follow-up CDC Studies Demonstrate Most Adolescents and Young Adults Have Recovered From Myocarditis

- Surveys of individuals aged 12-29 years with myocarditis after mRNA COVID-19 vaccine, and their healthcare providers, for whom a VAERS report was filed during January 12-November 5, 2021
- Based on cardiologist or other healthcare provider assessment:

83%

Fully or probably fully recovered by at least 90 days after myocarditis onset

→

>90%

Overall, fully or probably fully recovered by at least a 1 year after myocarditis onset

- Among patients with abnormal cardiac MRI at 1-year evaluation, most common abnormality was late gadolinium enhancement
  - clinical significance unclear; majority considered recovered and cleared for all physical activity
- No known deaths or cardiac transplants

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 - The Lancet Child & Adolescent Health; Outcomes at ≥1 year based on unpublished data

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COVID-19 Vaccine Safety in Children Ages 6 Months to 11 Years

- Risk of myocarditis following COVID-19 vaccines in children aged <12 years is low, particularly for those aged 6 months to 5 years
  - Active, sequential analyses in the Vaccine Safety Datalink have demonstrated no statistical signals for myocarditis in children
  - No confirmed myocarditis cases in children aged <5 years in VAERS or VSD
- Rapid cycle analyses in the VSD demonstrate no increased risks for 22 other pre-specified outcomes following COVID-19 vaccination
- Evaluations to assess multisystem inflammatory syndrome in children (MIS-C) following COVID-19 vaccination demonstrated that most patients had evidence of preceding SARS-CoV-2 infection

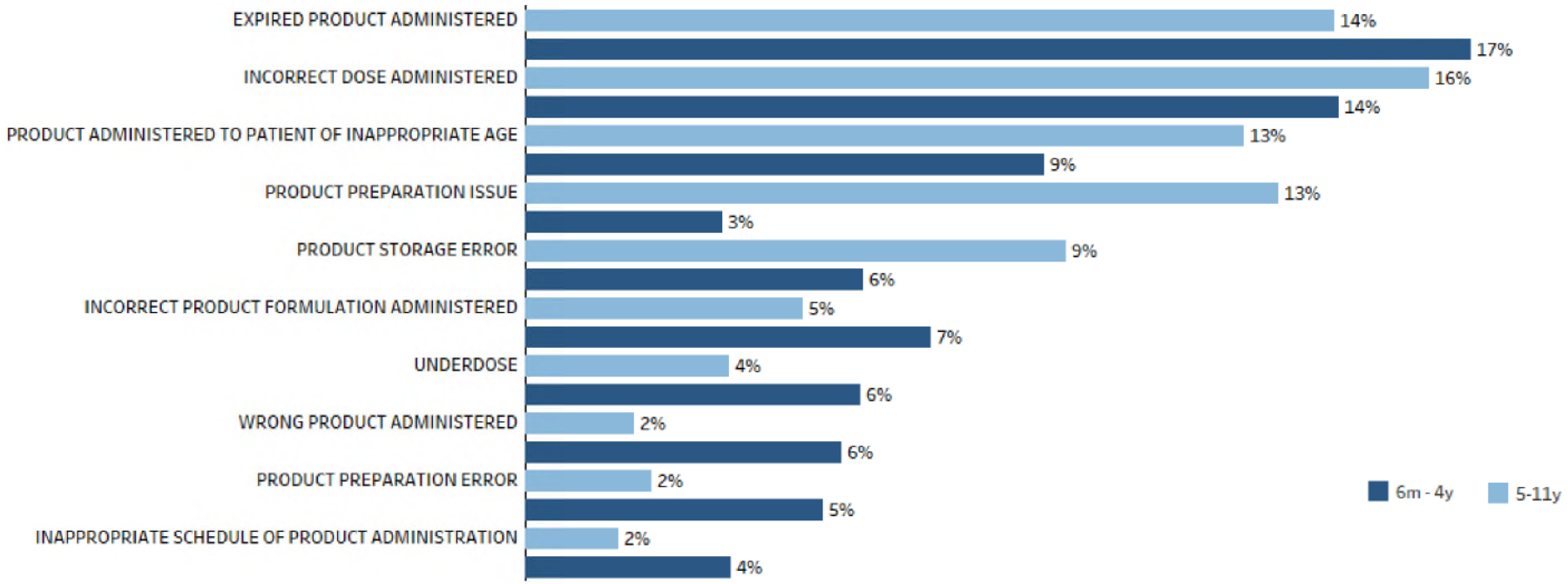
Safety of COVID-19 Vaccination in United States Children Ages 5 to 11 Years | Pediatrics | American Academy of Pediatrics; Safety Monitoring of mRNA COVID-19 Vaccine Third Doses Among Children Aged 6 Months–5 Years — United States, June 17, 2022–May 7, 2023 | MMWR; COVID-19 Vaccine Safety First Year Findings in Adolescents | Pediatrics | American Academy of Pediatrics; Safety Monitoring of Bivalent COVID-19 mRNA Vaccine Booster Doses Among Children Aged 5–11 Years — United States, October 12–January 1, 2023 | MMWR; COVID-19 mRNA Vaccine Safety Among Children Aged 6 Months–5 Years — United States, June 18, 2022–August 21, 2022 | MMWR; Safety of COVID-19 mRNA Vaccination Among Young Children in the Vaccine Safety Datalink | Pediatrics | American Academy of Pediatrics; Surveillance for Multisystem Inflammatory Syndrome in US Children Aged 5-11 Years Who Received Pfizer-BioNTech COVID-19 Vaccine, November 2021 through March 2022 – PubMed; Reported cases of multisystem inflammatory syndrome in children aged 12–20 years in the USA who received a COVID-19 vaccine, December, 2020, through August, 2021: a surveillance investigation - The Lancet Child & Adolescent Health

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Majority of COVID-19 Vaccine Reports to VAERS in Children Aged <12 Years Include at Least One Vaccine Administration Error

Approximately 77% of reports in children aged 6 months-4 years and 70% of reports in children aged 5-11 years related to administration errors between October 21, 2021 – April 30, 2025



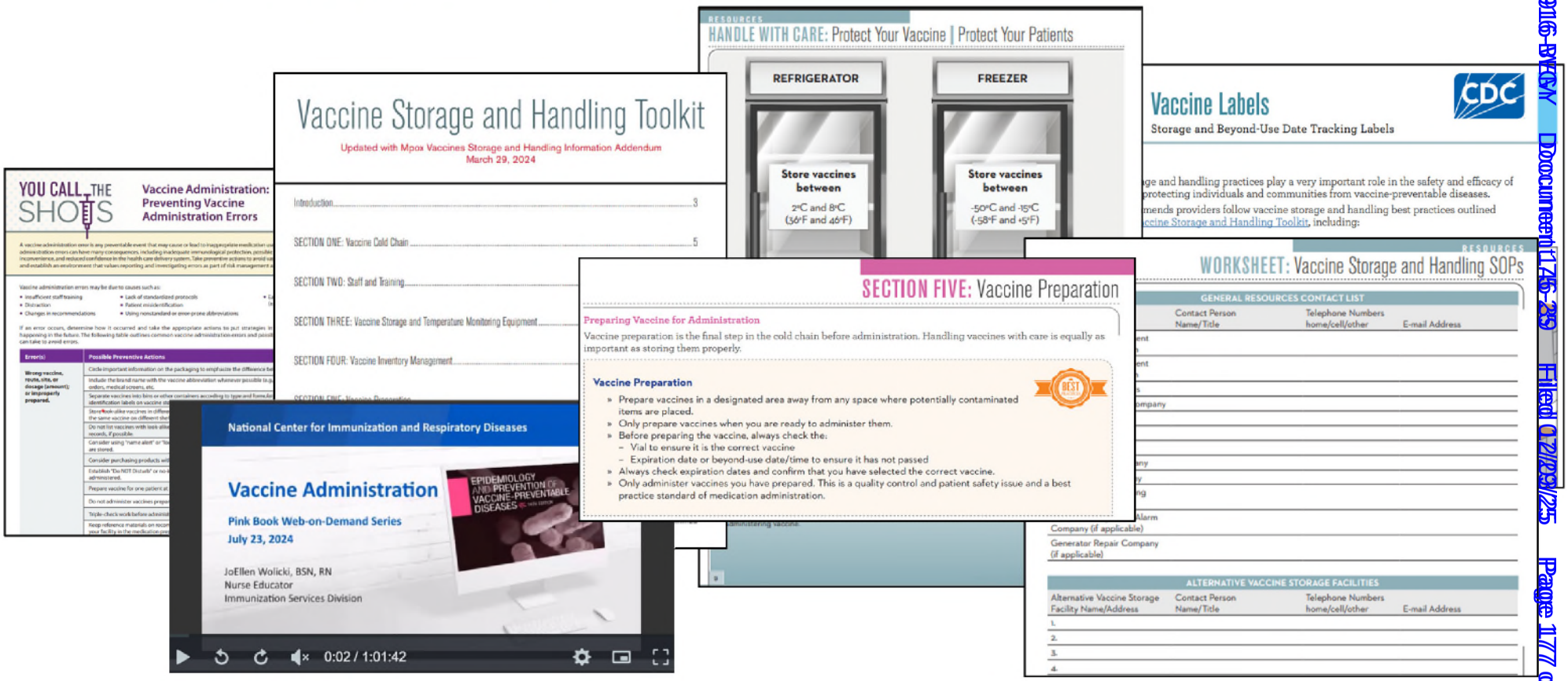
Data source: https://wonder.cdc.gov

VAERS reports may include more than one administration error type

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CDC Is Expanding Its Work to Prevent Vaccine Administration Errors

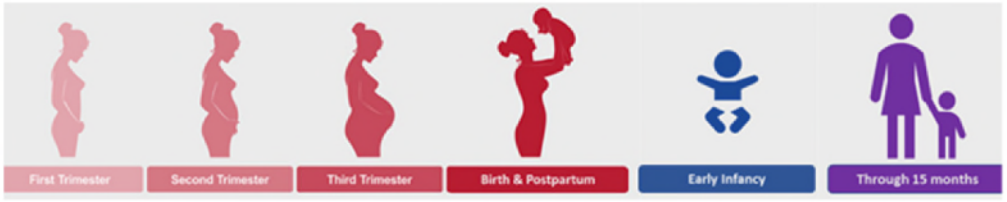


Vaccine Administration Protocols | CDC

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Evaluating Safety of COVID-19 Vaccines in Pregnant Women

CDC COVID-19 Vaccine Pregnancy Registry



- >23,000 pregnant women
- 7 analyses
- Observational studies based on survey and medical record information

Vaccine Safety Datalink



- >45,000 pregnant women
- 11 analyses to date
- Cohort, case-control, and surveillance evaluations

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COVID-19 Vaccine Safety During Pregnancy

Across CDC studies, evidence shows NO increased risk of:

Maternal outcomes

- 25 medically-attended adverse events
- Serious adverse events
- Pregnancy-related conditions
- Maternal ICU admission

Pregnancy outcomes

- Miscarriage
- Stillbirth
- Preterm birth
- Small-for-gestational age

Infant outcomes

- Major birth defects
- Neonatal ICU admission
- Infant death

Evaluation of Acute Adverse Events after Covid-19 Vaccination during Pregnancy | New England Journal of Medicine; Receipt of COVID-19 Vaccine During Pregnancy and Preterm or Small-for-Gestational-Age at Birth — Eight Integrated Health Care Organizations, United States, December 15, 2020–July 22, 2021 | MMWR; Receipt of mRNA Covid-19 Vaccines and Risk of Spontaneous Abortion | New England Journal of Medicine; Spontaneous Abortion Following COVID-19 Vaccination During Pregnancy | Public Health | JAMA | JAMA Network; COVID-19 Booster Vaccination in Early Pregnancy and Surveillance for Spontaneous Abortion; Coronavirus Disease 2019 (COVID-19) Vaccination and Stillbirth in the Vaccine Safety Datalink; Medically Attended Acute Adverse Events in Pregnant Women ; Obstetric Complications and Birth Outcomes After Antenatal Coronavirus Disease 2019 (COVID-19) Vaccination; COVID-19 Vaccination in the First Trimester and Major Structural Birth Defects Among Live Births ; Accumulating Robust Evidence for Reducing Vaccine Hesitancy in Early Pregnancy—Reply

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Examples of CDC Studies to Address Vaccine Safety Concerns from the Public

Abnormal uterine bleeding

- Conducted studies in VAERS, VSD, and v-safe for abnormal uterine bleeding
- VSD studies demonstrated:
  - Availability of COVID-19 vaccines was not associated with a change in incidence of medically-attended abnormal uterine or post-menopausal bleeding
  - Receipt of COVID-19 vaccine not associated with greater bleeding severity

Tinnitus

- Conducted data mining to assess tinnitus:
  - VAERS empirical Bayesian data mining did not find disproportionate reporting of tinnitus
  - VSD tree-based data mining found no signals for tinnitus
- Taken together, findings do not support an increased risk of tinnitus after COVID-19 vaccine

Abnormal uterine bleeding diagnoses and care following COVID-19 vaccination – ScienceDirect
Postmenopausal bleeding after COVID-19 vaccination – PubMed
Postmenopausal Bleeding After Coronavirus Disease 2019 (COVID-19) Vaccination: Vaccine Adverse Event Reporting System – PubMed
Menstrual irregularities and vaginal bleeding after COVID-19 vaccination reported to v-safe active surveillance, USA in December, 2020-January, 2022: an observational cohort study – PubMed
Tinnitus after COVID-19 vaccination: Findings from the vaccine adverse event reporting system and the vaccine safety datalink - ScienceDirect

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

Safety Monitoring of Death Reports Following mRNA COVID-19 Vaccination in VAERS

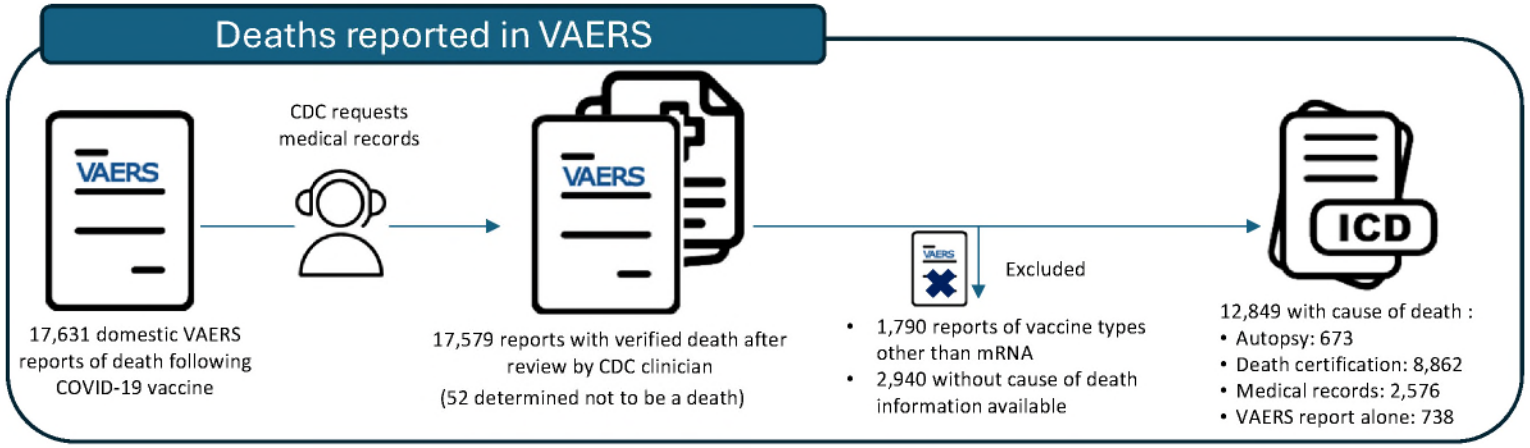
- As of May 30, 2025, there have been 19,417 domestic deaths reported to VAERS after COVID-19 vaccination
- Important considerations related to evaluation of death reports in VAERS
  - FDA Emergency Use Authorizations and CDC COVID-19 Vaccination Provider Enrollment Agreements required healthcare provider to report **all deaths** following COVID-19 vaccination to VAERS, regardless of cause or circumstances surrounding death (requirement does not apply to other vaccines)
  - VAERS generally cannot assess causality of adverse reports, including deaths
- We conducted an evaluation of deaths following mRNA COVID-19 vaccination in VAERS through January 31, 2023

Vaccine Adverse Event Reporting System. VAERS Reporting Information for COVID-19 Vaccines. https://vaers.hhs.gov/reportevent.html

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

Safety Monitoring of Death Reports Following mRNA* COVID-19 Vaccination in VAERS – December 22, 2020 – January 31, 2023

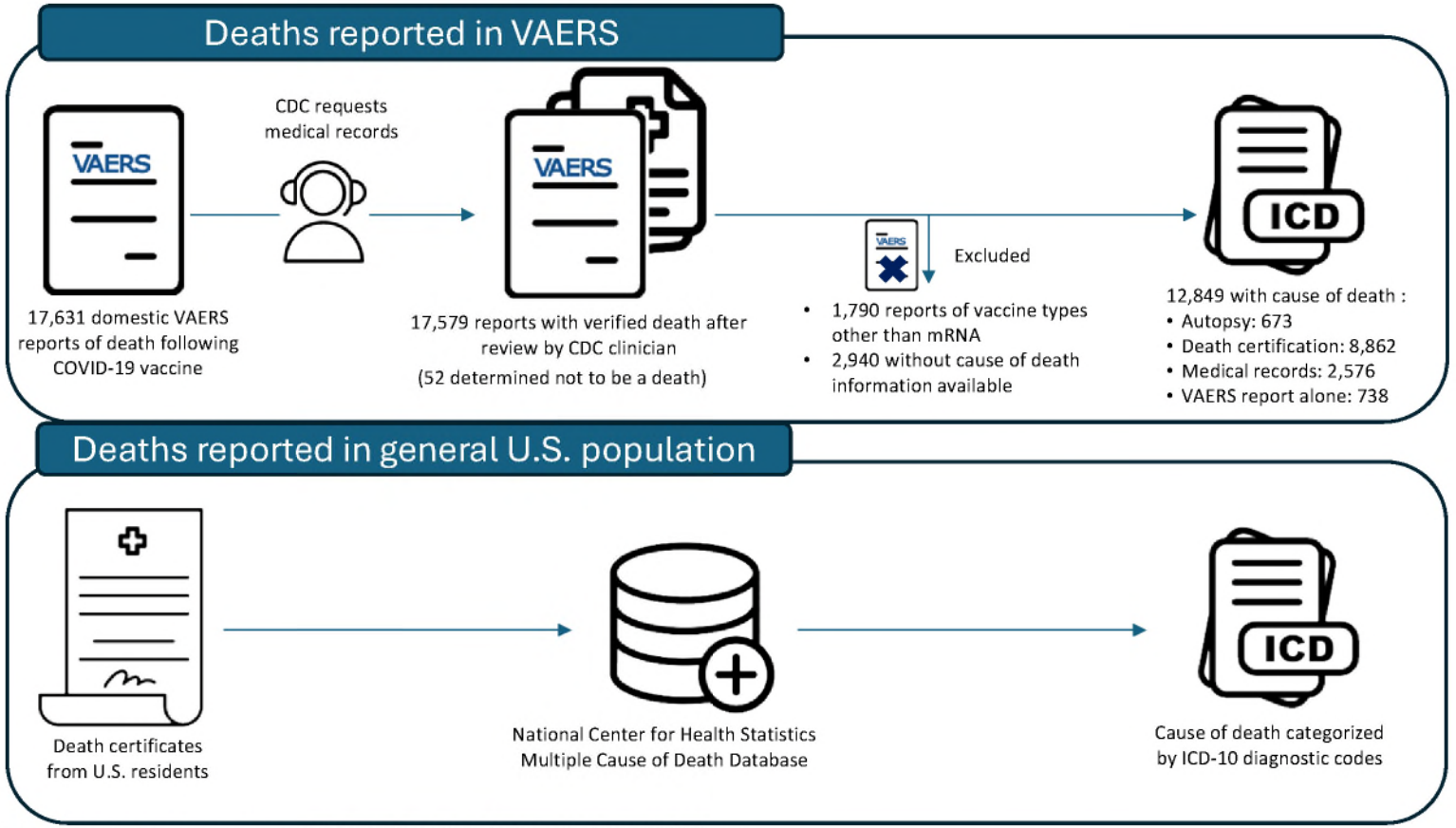


* Includes reports with missing vaccine type, but excludes reports known to be after Janssen or Novavax COVID-19 vaccine
Reports to the Vaccine Adverse Event Reporting System (VAERS) reviewed and processed during December 22, 2020 — January 31, 2023; reported date of vaccination during December 22, 2020 — January 31, 2023 or missing

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

Safety Monitoring of Death Reports Following mRNA* COVID-19 Vaccination in VAERS – December 22, 2020 – January 31, 2023



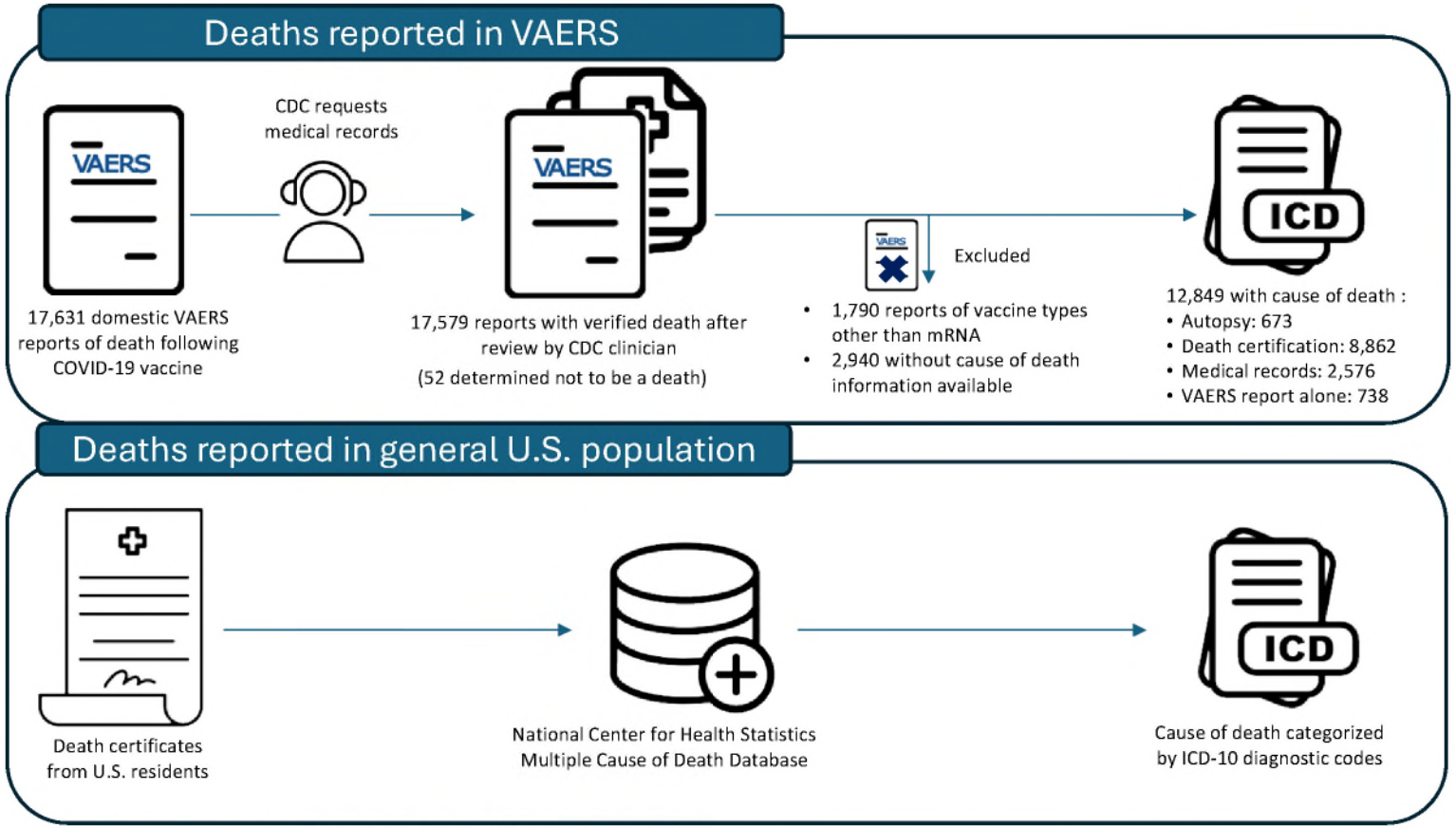
* Includes reports with missing vaccine type, but excludes reports known to be after Janssen or Novavax COVID-19 vaccine

Reports to the Vaccine Adverse Event Reporting System (VAERS) reviewed and processed during December 22, 2020 — January 31, 2023; reported date of vaccination during December 22, 2020 — January 31, 2023 or missing

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Safety Monitoring of Death Reports Following mRNA* COVID-19 Vaccination in VAERS – December 22, 2020 – January 31, 2023



Observed Rate

Number of deaths (cause-specific)
100,000 persons vaccinated

Within 42 days of vaccination

Expected Rate

Number of deaths (cause-specific)
100,000 persons in U.S. population

Within 42 days of vaccination

* Includes reports with missing vaccine type, but excludes reports known to be after Janssen or Novavax COVID-19 vaccine
Reports to the Vaccine Adverse Event Reporting System (VAERS) reviewed and processed during December 22, 2020 — January 31, 2023; reported date of vaccination during December 22, 2020 — January 31, 2023 or missing
Abara WE, et al. Expected Rates of Select Adverse Events After Immunization for Coronavirus Disease 2019 Vaccine Safety Monitoring | The Journal of Infectious Diseases; Mahaux O, et al. Pharmacoepidemiological considerations in observed-to-expected analyses for vaccines

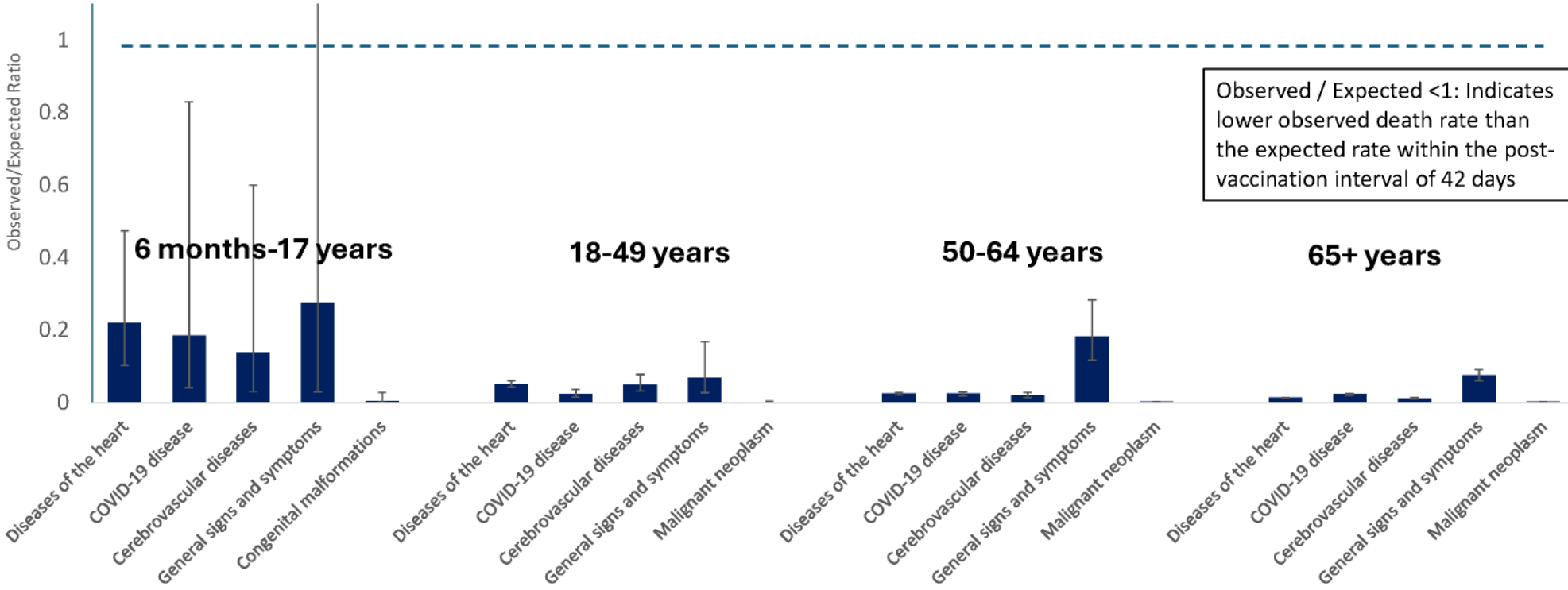
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Reporting Rates of Death After mRNA* COVID-19 Vaccination Were Below Background Rates of Death in the General U.S. Population

The most common causes of death reported to VAERS are consistent with the leading causes of death in the U.S. population



* Includes reports with missing vaccine type, but excludes reports known to be after Janssen or Novavax COVID-19 vaccine

Reports to the Vaccine Adverse Event Reporting System (VAERS) reviewed and processed during December 22, 2020 — January 31, 2023; reported date of vaccination during December 22, 2020 — January 31, 2023 or missing

Hoyert DL, Xu J. Deaths: preliminary data for 2011. Natl Vital Stat Rep. 2012; 61:1–51 ; U.S. Centers for Disease Control and Prevention. CDC WONDER. Available at https://wonder.cdc.gov/controller/datarequest/D157 Accessed March 20, 2025

Abara WE, et al. Expected Rates of Select Adverse Events After Immunization for Coronavirus Disease 2019 Vaccine Safety Monitoring | The Journal of Infectious Diseases; Mahaux O, et al. Pharmacoepidemiological considerations in observed-to-expected analyses for vaccines

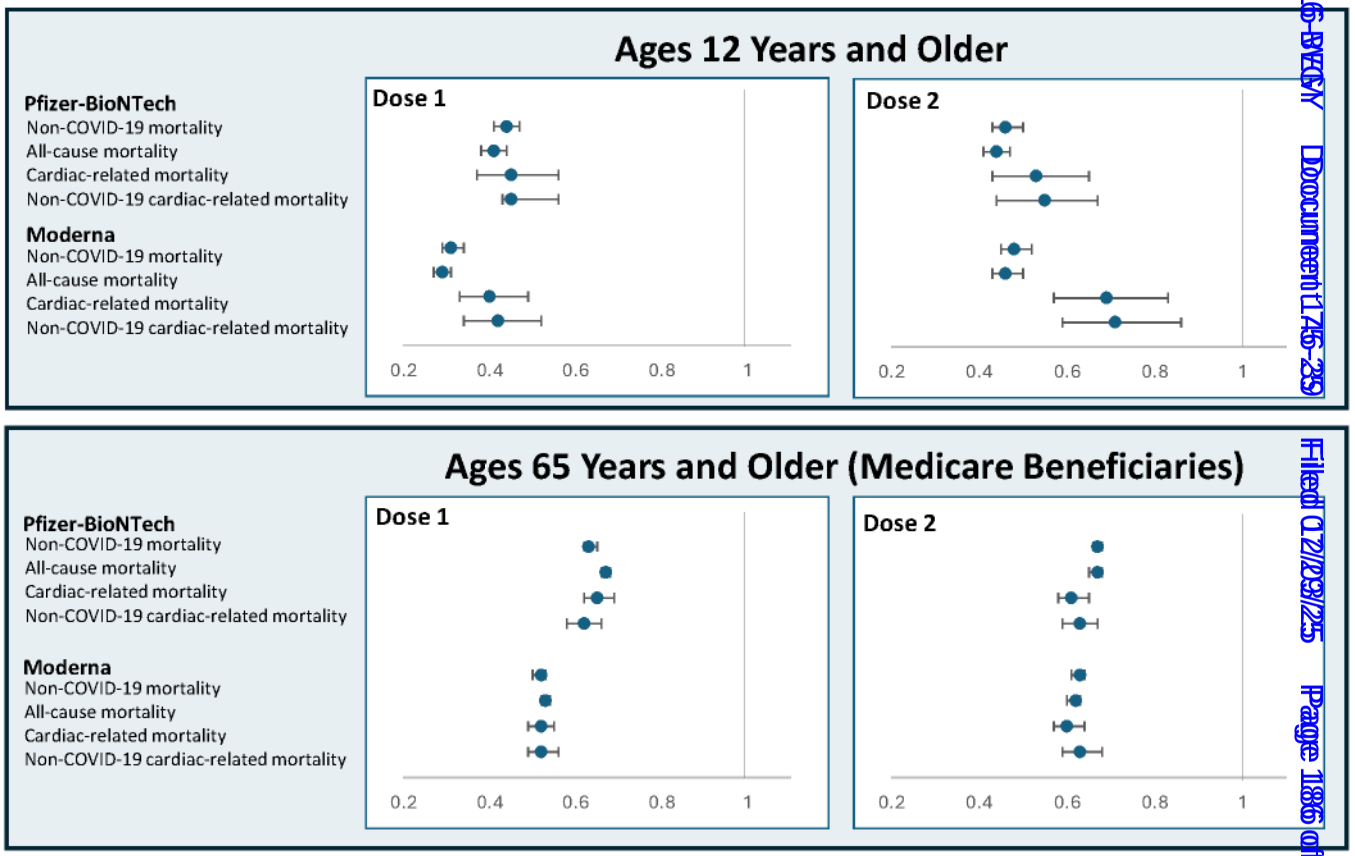
National Center for Health Statistics, National Vital Statistics System. Deaths: Leading Causes of Death for 2021. 73:4. Published April 8, 2024. https://www.cdc.gov/nchs/data/nvsr/nvsr73/nvsr73-04.pdf National Center for Health Statistics, National Vital Statistics System. Deaths: Leading Causes of Death for 2020. 72:13. Published December 5, 2023. https://www.cdc.gov/nchs/data/databriefs/db492-tables.pdf#4

Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

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Data From CDC's Vaccine Safety Datalink Shows No Increased Risk of Death Following mRNA COVID-19 Vaccines

- 2 self-controlled case series evaluations
- No increased risk in the 28 days after vaccination of:
  - Non-COVID mortality
  - All-cause mortality
  - Cardiac-related mortality
  - Non-COVID cardiac-related mortality
- Similar findings in VSD cohort study of people ages 12+ years



X axis: Relative Incidence and 95% Confidence Intervals

Mortality risk after COVID-19 vaccination: A self-controlled case series study
https://pubmed.ncbi.nlm.nih.gov/38388239/
A Modified Self-Controlled Case Series on Mortality Risk following Primary Series Doses of COVID-19 Vaccines in U.S. Medicare Beneficiaries Aged 65 Years and Older - Acumen and Vaccine Safety Datalink, unpublished pending review at journal
A safety study evaluating non-COVID-19 mortality risk following COVID-19 vaccination - PubMed
Data from December 14, 2020 through August 11, 2021

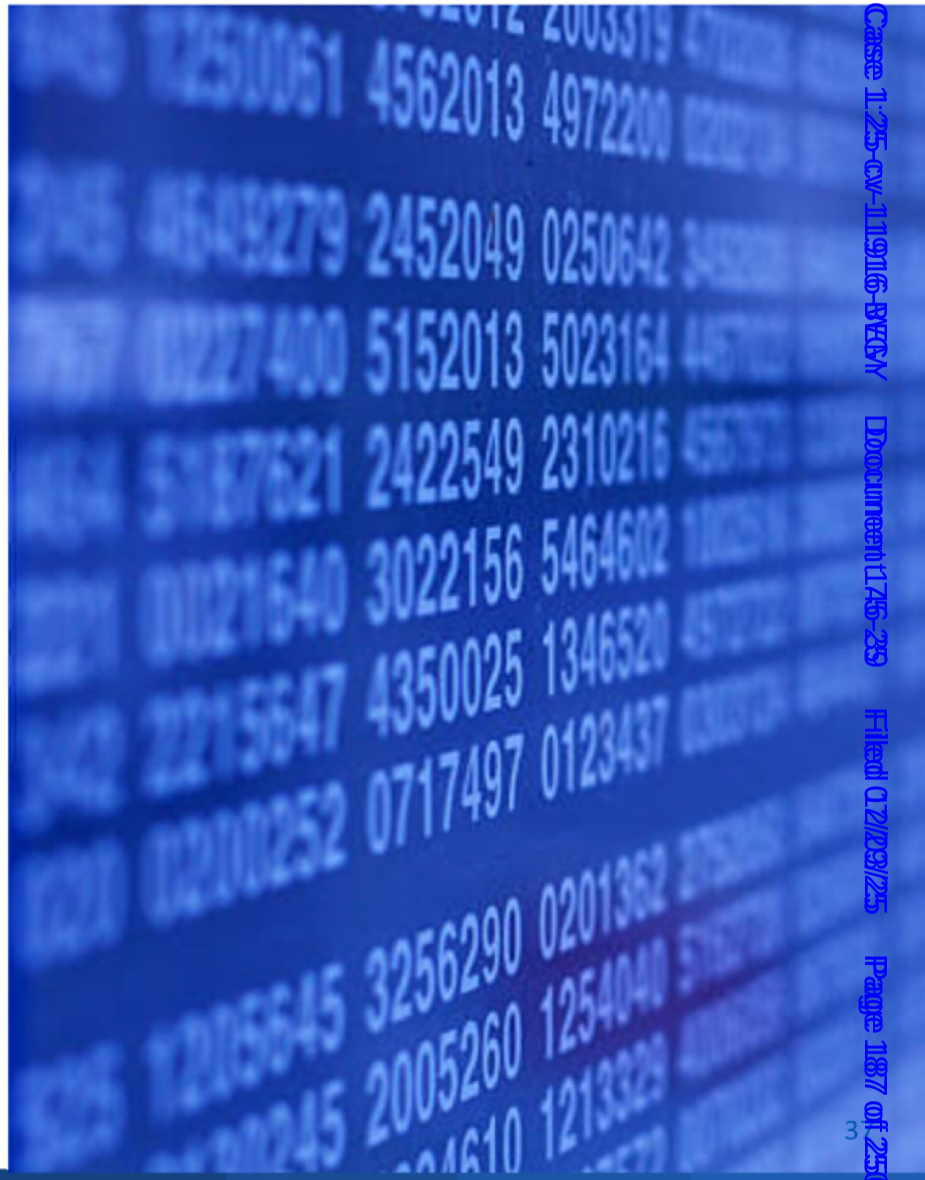
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Using Data Mining to Assess for Unexpected Events After COVID-19 Vaccination

- >60,000 possible adverse events assessed in the 70 days after vaccination using tree-based data mining of ICD-10 codes in the VSD for:
  - Primary series
  - Initial booster
  - Bivalent booster

- No new safety concerns identified outside of known events
  - E.g., myocarditis/pericarditis, allergic reactions, common local and systemic reactions



A broad assessment of covid-19 vaccine safety using tree-based data-mining in the vaccine safety datalink - PubMed
Tree-based data mining for safety assessment of first COVID-19 booster doses in the Vaccine Safety Datalink – PubMed
Safety signal identification for COVID-19 bivalent booster vaccination using tree-based scan statistics in the Vaccine Safety Datalink - PubMed

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Summary

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CDC Summary: Adverse Events Associated with mRNA COVID-19 Vaccines

Occur with any vaccines:

- Local reactions
- Systemic reactions
- Acute allergic reactions (e.g., anaphylaxis)
- Syncope (fainting)
- Shoulder injuries

Occur with COVID-19 vaccines:

- Myocarditis and pericarditis

CDC evaluated at least 65 specific safety outcomes, conducted data mining of >60,000 potential outcomes for unexpected concerns, investigated numerous signals, and conducted many epidemiologic studies

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NASEM Consensus Report on Adverse Effects of COVID-19 Vaccines – 2024

- Commissioned by Health Resources and Services Administration (HRSA)
- Reviewed nearly 600 studies on safety of COVID-19 vaccines
- Concluded evidence supported causal association between mRNA COVID-19 vaccines and myocarditis
  - Evidence favors rejection of causal relationship between vaccination and 6 additional outcomes



Front Matter | Evidence Review of the Adverse Effects of COVID-19 Vaccination and Intramuscular Vaccine Administration | The National Academies Press

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COVID-19 Vaccines Have Been Evaluated Under the Most Extensive Safety Monitoring Program in U.S. History

- Safety surveillance identified and characterized the risk of myocarditis after mRNA COVID-19 vaccination
- No other risks confirmed in the current U.S.-licensed vaccines except those seen with other vaccines (e.g., local and systemic reactions, allergic reactions)
- CDC continues to prioritize the monitoring of COVID-19 vaccine safety, with at least 30 ongoing studies or activities
- CDC continues to monitor the safety of COVID-19 vaccines

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EXHIBIT K

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Current Epidemiology of COVID-19

Coronavirus and Other Respiratory Viruses Division

Advisory Committee on Immunization Practices (ACIP)

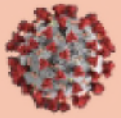
June 25, 2025

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COVID-19 continues to impact Americans' health.

Preliminary 2024-2025 U.S. COVID-19 Burden Estimates

CDC estimates* that, from October 1, 2024 through June 7, 2025, there have been:

9.8 million–16.1 million	2.4 million–3.8 million	270,000–440,000	32,000–51,000
			
COVID-19 Illnesses	COVID-19 Outpatient Visits	COVID-19 Hospitalizations	COVID-19 Deaths

* Based on data from September 29, 2024 through June 7, 2025.

Source: https://www.cdc.gov/covid/php/surveillance/burden-estimates.html

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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 reported activity limitations[1]

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

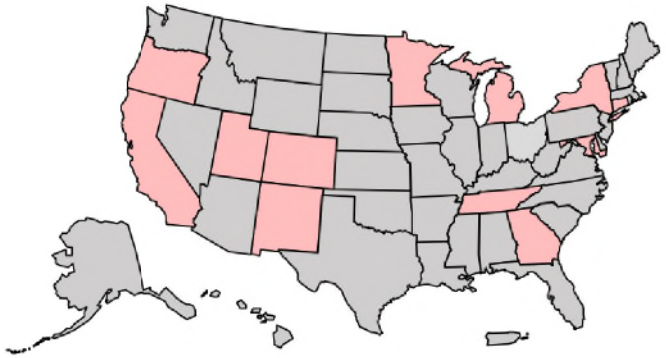
1. Vahratian, et al. Prevalence of Post–COVID-19 Condition and Activity-Limiting Post–COVID-19 Condition Among Adults. doi:10.1001/jamanetworkopen.2024.51151
2. Ford, et al. Long COVID Prevalence and Associated Activity Limitation in US Children. doi:10.1001/jamapediatrics.2024.6206

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



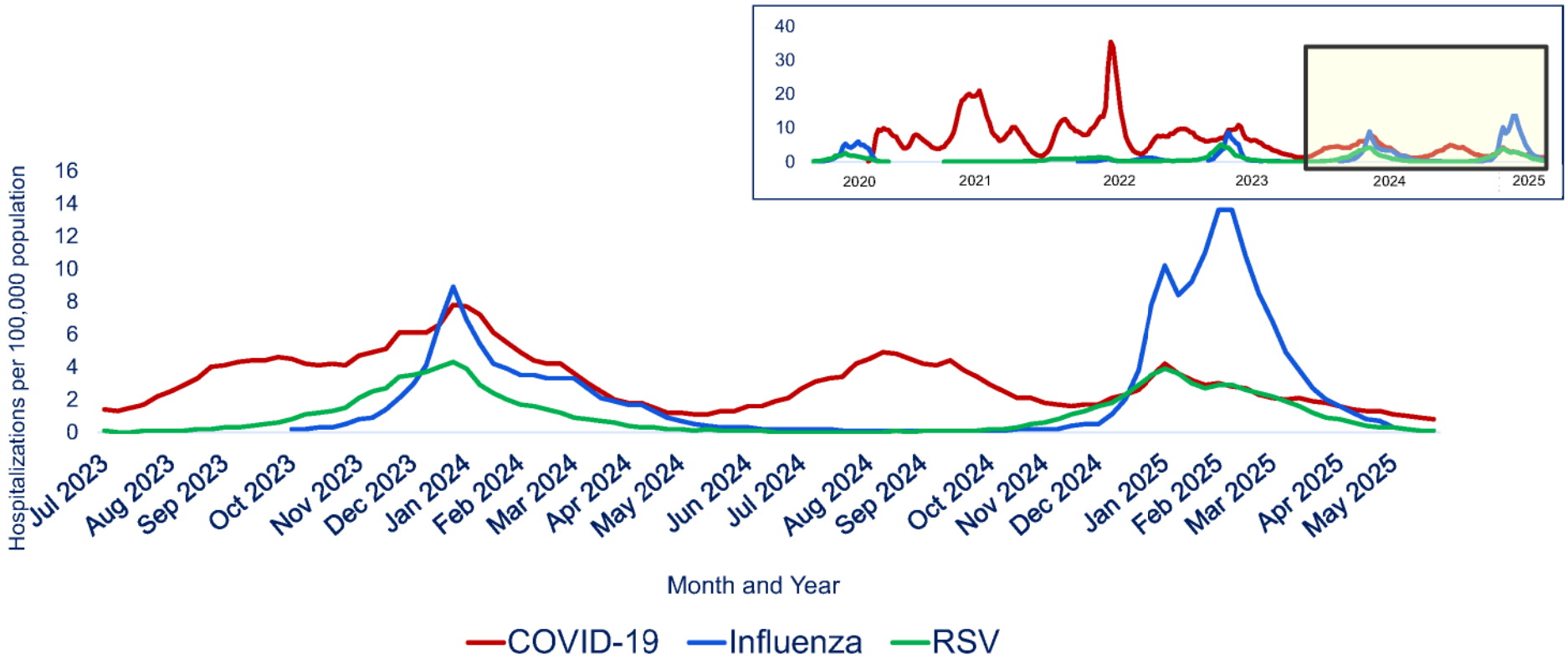
- RESP-NET includes COVID-NET, RSV-NET, FluSurv-NET
- >300 acute-care hospitals
- 185 counties in 13 states (population-based rates)
- ~10% of the U.S. population
- Positive SARS-CoV-2 test ≤14 days before admission or during hospitalization
- Screening or clinician-driven testing
- Clinical data: age- and site-stratified random sample of hospitalized patients
- Seasons defined in this presentation as July–June for rates.
  - Most recent 12 months of sampled data



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.

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Weekly COVID-19-associated hospitalization rates have peaked in both winter and summer.



Figures displays weekly Rates of COVID-19–, Influenza-, and RSV-Associated Hospitalizations — RESP-NET, July 2023–May 2025.

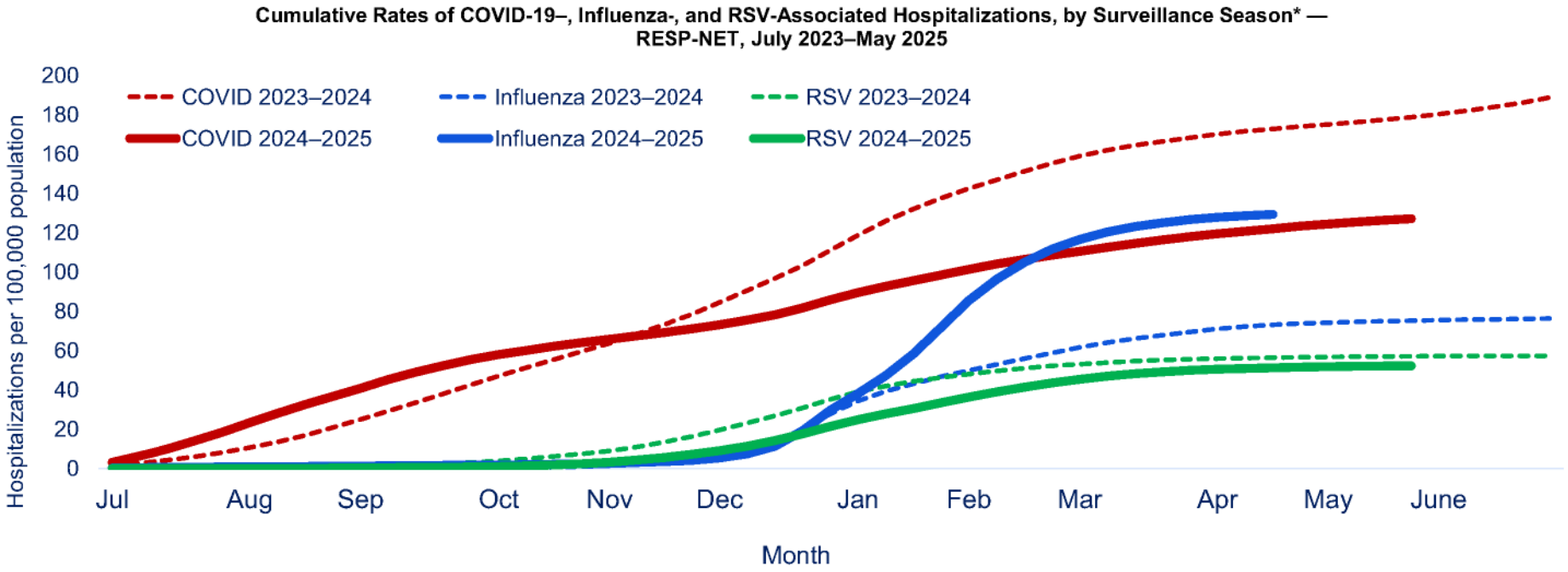
Rates for all three pathogens (COVID-19, influenza, and respiratory syncytial virus [RSV]) are laboratory-confirmed. Data source: https://www.cdc.gov/resp-net/dashboard/

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

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Cumulative COVID-19–associated hospitalization rates for the July 2024–May 2025 period were higher during summer and fall 2024 and lower during the winter months compared to July 2023–June 2024.

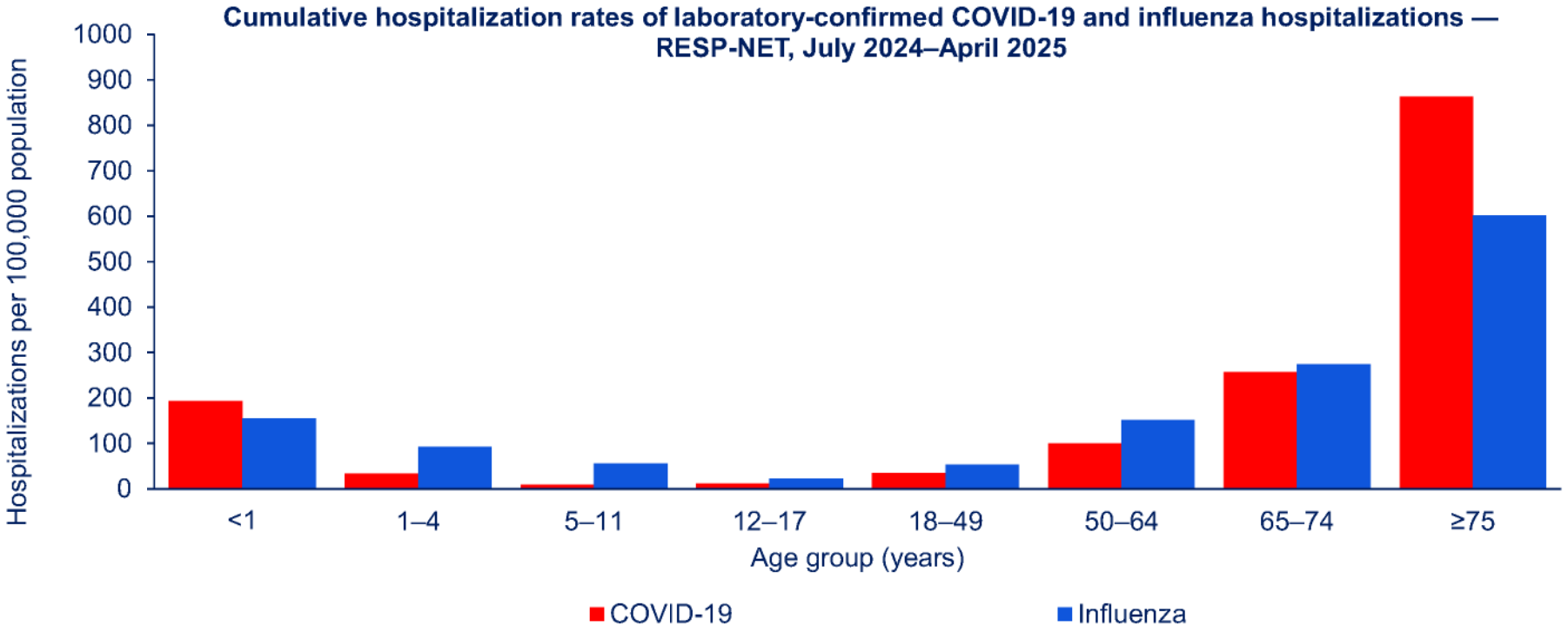


* Seasons are defined as July through June. The 2024–2025 season shows data from July 2024–May 2025 and is ongoing. Influenza surveillance is conducted October – April.
Rates for all three pathogens (SARS-CoV-2, influenza, and respiratory syncytial virus [RSV]) are laboratory-confirmed. Data source: https://www.cdc.gov/resp-net/dashboard/
Note that rates are not adjusted for testing. Rates are not limited to admissions where the respiratory infection is the likely primary reason for admission.

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From July 2024 – April 2025, a period that included a high severity influenza season[1], more infants <1 and adults ≥75 had hospitalizations associated with COVID-19 than influenza.

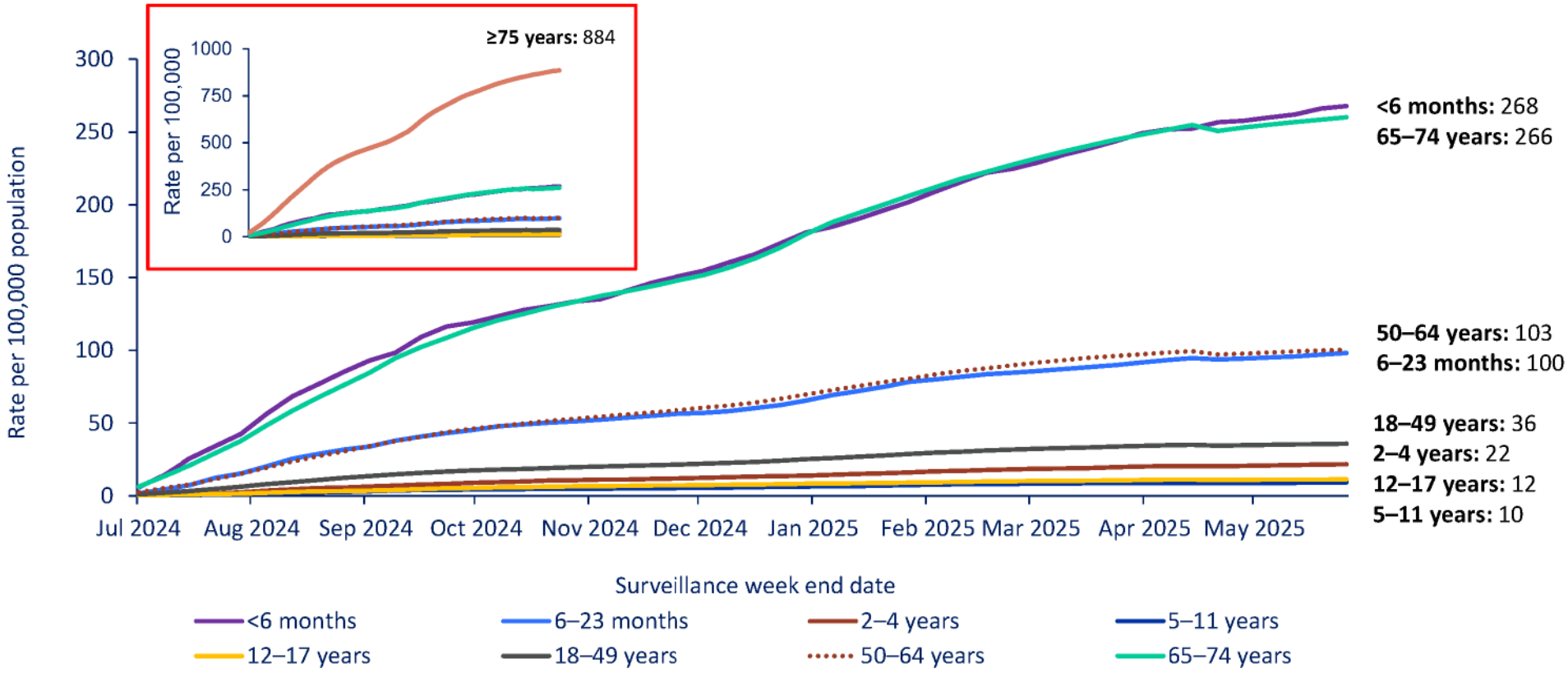


Cumulative hospitalization rates with laboratory-confirmed SARS-CoV-2 and influenza hospitalizations — RESP-NET, July 2024–April 2025. Note that influenza surveillance is conducted from October–April annually. Data source: https://www.cdc.gov/resp-net/dashboard/. Note that rates are not adjusted for testing nor limited to admissions where the respiratory infection is the likely primary reason for admission. [1]https://www.cdc.gov/flu/php/surveillance/in-season-severity.html

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Cumulative COVID-19-associated hospitalization rates are highest among adults aged ≥75 years, followed by adults aged 65–74 years and infants aged <6 months.



Weekly rates of COVID-19–associated hospitalizations per 100,000 population by age group—COVID-NET, July 2024–May 2025

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

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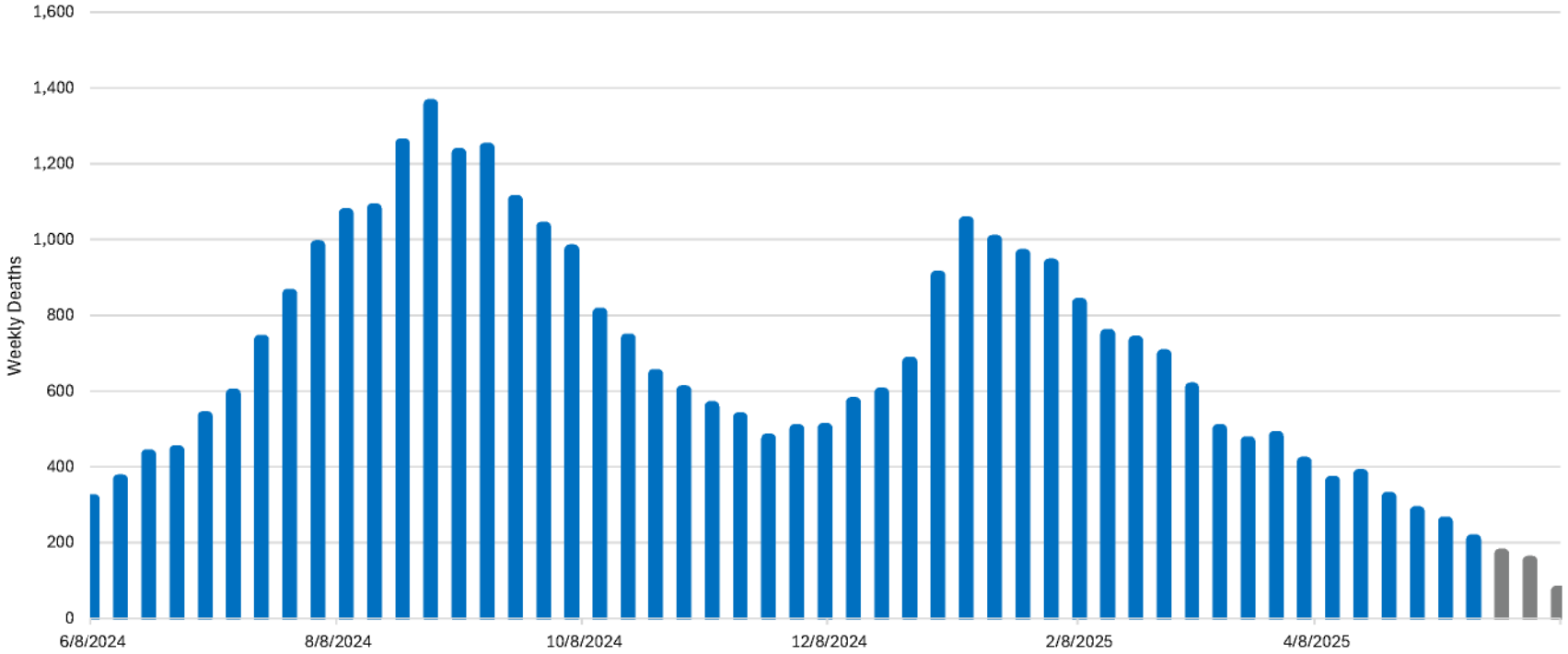
COVID-19 Mortality

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Weekly number of COVID-19-associated deaths reported to CDC, United States, June 8, 2024 – June 7, 2025

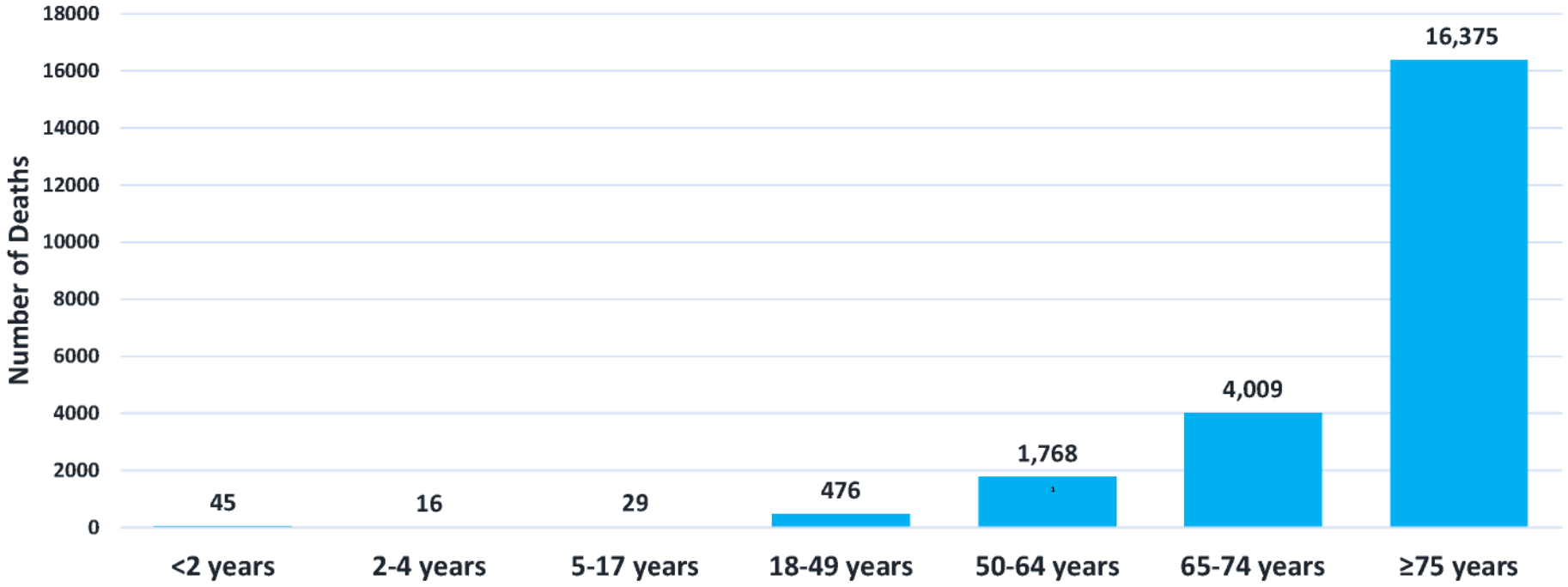


The most recent 3 weeks of mortality counts are shaded grey because NVSS reporting is <95% during this period.
Provisional data are non-final counts of deaths based on reported mortality data in NVSS. Deaths include those with COVID-19, coded as ICD–10 code U07.1, on the death certificate. Death data 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 June 18, 2025

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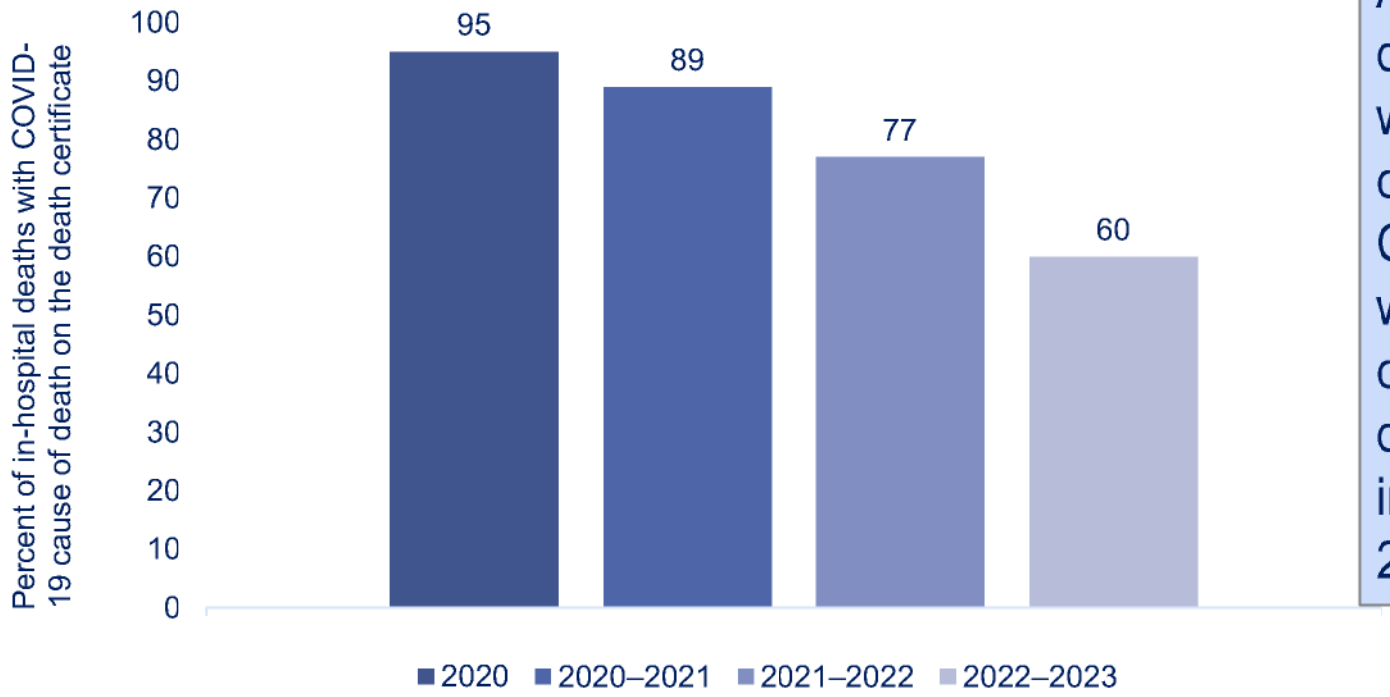
Total number of deaths with COVID-19 listed as the underlying cause[1,2] in July 2024–June 2025, by age group, United States



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, provisional data for 2024 and provisional and partial data from 2025, 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 June 20, 2025

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Death certificate data likely underestimate COVID-19-associated deaths.



Among in-hospital deaths in patients with laboratory-confirmed SARS-CoV-2, the proportion with a COVID-19 cause of death listed decreased from **95%** in 2020 to **60%** in 2022–2023.

Figure displays the weighted percentage of COVID-19-associated hospitalizations with COVID-19 listed as an underlying or contributing cause of death,* by surveillance period** — COVID-NET, March 2020–September 2023

* COVID-19 as a cause of death was defined as the inclusion of International Classification of Diseases, Tenth Edition (ICD-10) code U07.1 on the death certificate as an underlying or contributing cause of death.

**Surveillance periods are defined as October–September, except for 2020, which was defined as March 2020–September 2020.

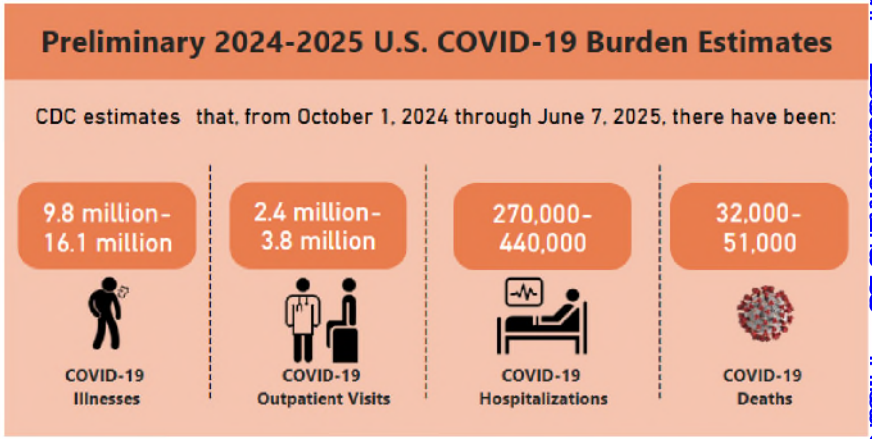
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COVID-19 continues to contribute to a large number of deaths in the United States.

Data source	Estimated COVID-19 deaths since October 2024
Death certificate data*	20,800
Modeled estimates based on multiple data sources†	32,000–51,000



* COVID-19 as a cause of death was defined as the inclusion of International Classification of Diseases, Tenth Edition (ICD-10) code U07.1 on the death certificate (October 2024-May 2025) as underlying or contributing cause of death. Provisional death certificate data from the National Center for Health statistics

† Based on data from September 29, 2024 through June 7, 2025. Source: https://www.cdc.gov/covid/php/surveillance/burden-estimates.html. Accessed June 20, 2025

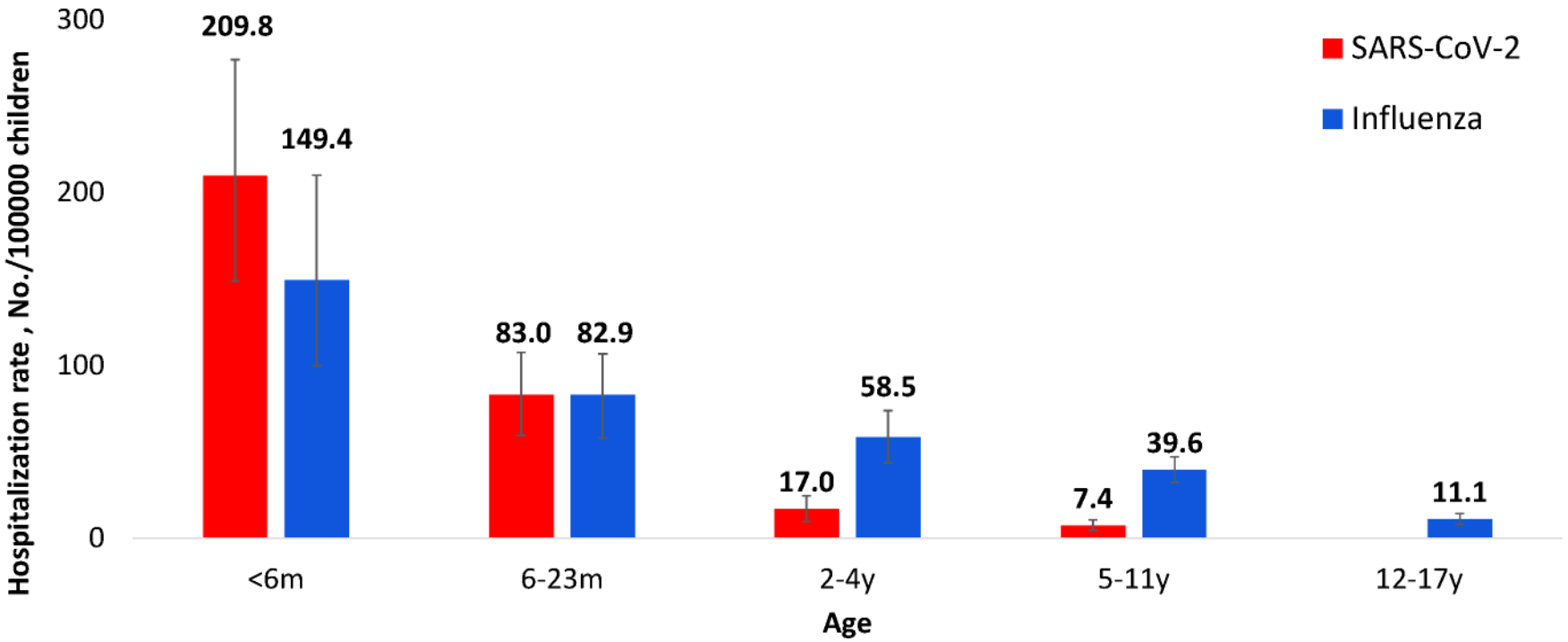
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Pediatric COVID-19–Associated Hospitalizations

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The highest rates for COVID-19 in the New Vaccine Surveillance Network were observed in infants <6 months of age.



Pediatric COVID-19 and influenza hospitalization rates among children <18 years, New Vaccine Surveillance Network (NVSN), July 2024- March 2025. Rate estimates with standard error >30 due to few detections are not presented. Annual rates presented July – June of each season, with exception of 2024-2025, which represents July 2024 – March 2025.
NVSN, unpublished data

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More than half of pediatric COVID-19-associated hospitalizations occur in children aged <2 years.

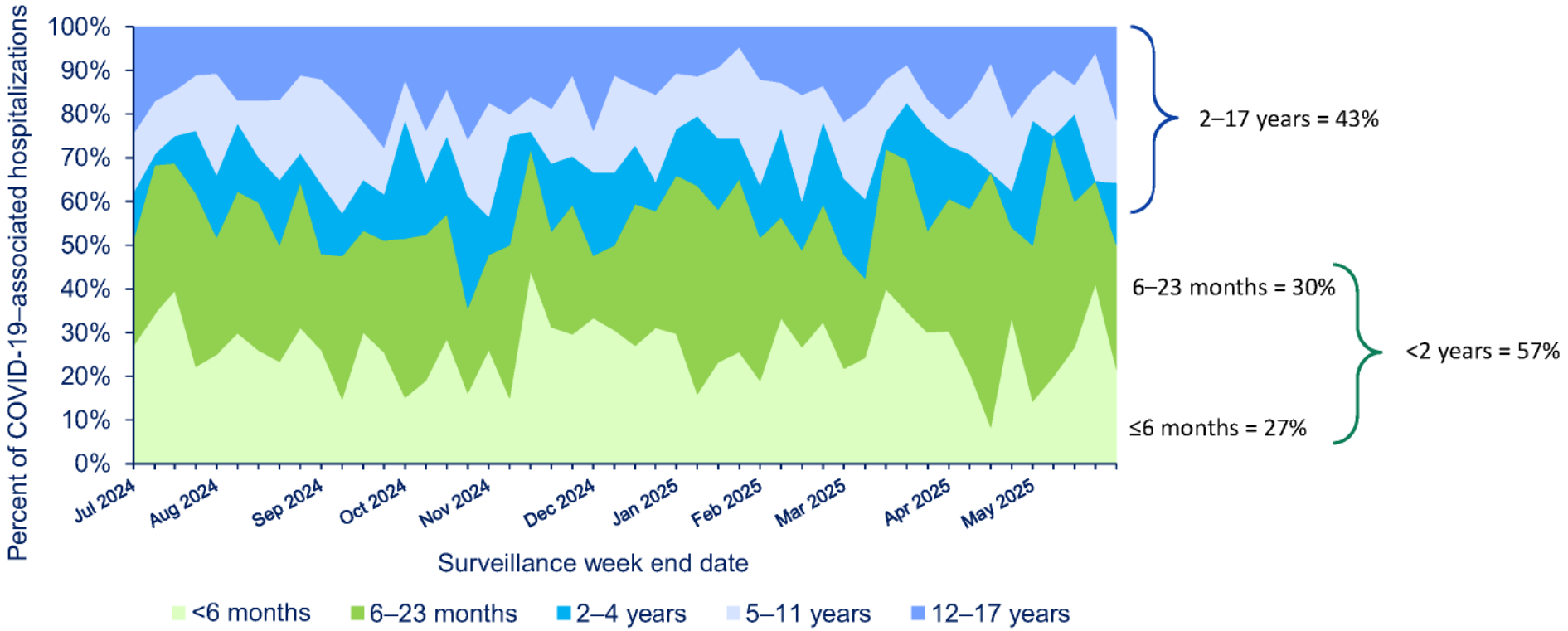


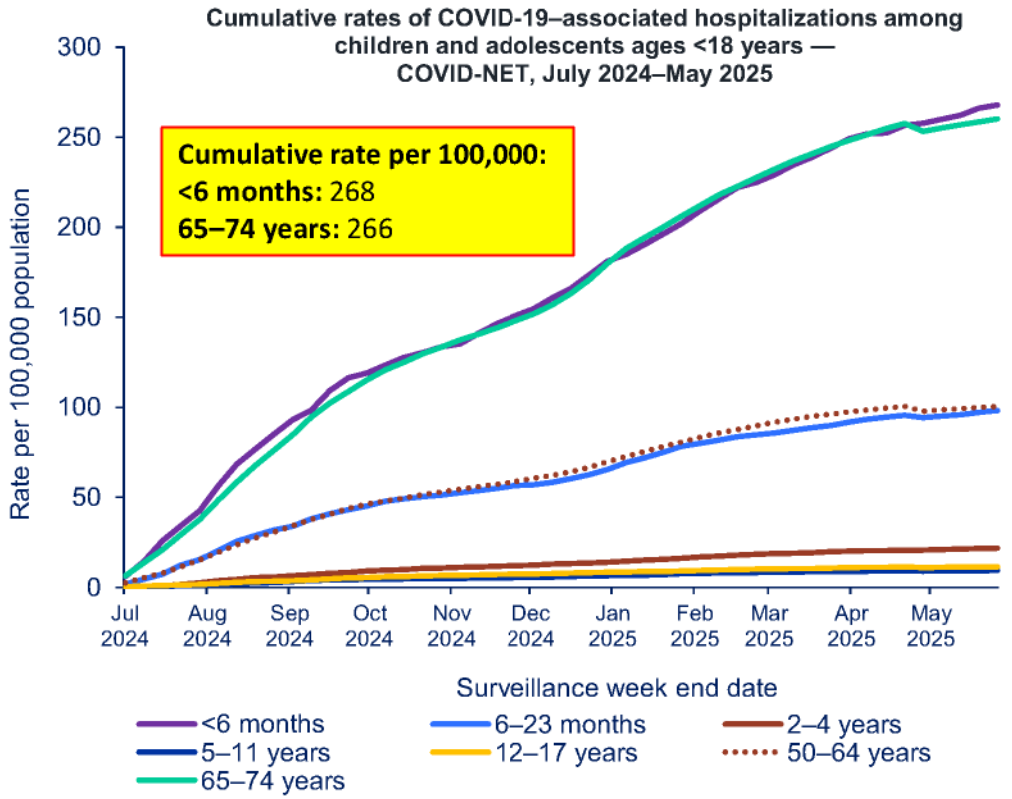
Figure displays percent of weekly COVID-19–associated hospitalizations among children and adolescents, by age group — COVID-NET, July 2024–May 2025.

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COVID-19 causes severe disease in infants ages <6 months.

- **Highest rate of COVID-19-associated hospitalization among all pediatric age groups**
  - Rates comparable to adults ages 65–74 years



Data reported from July 2024–May 2025. Excludes newborns who were admitted during the same hospitalizations as their birth. Note that rates are not adjusted for testing. Rates are not limited to admissions where the respiratory infection is the likely primary reason for admission.

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Infants <6 months experience high rates of severe COVID-19 disease.

- **Among infants <6 months hospitalized recently for COVID-19:**
  - 22% were admitted to the ICU
  - 71% had no underlying medical conditions
  - 3.5% had any record of maternal COVID-19 vaccination during pregnancy

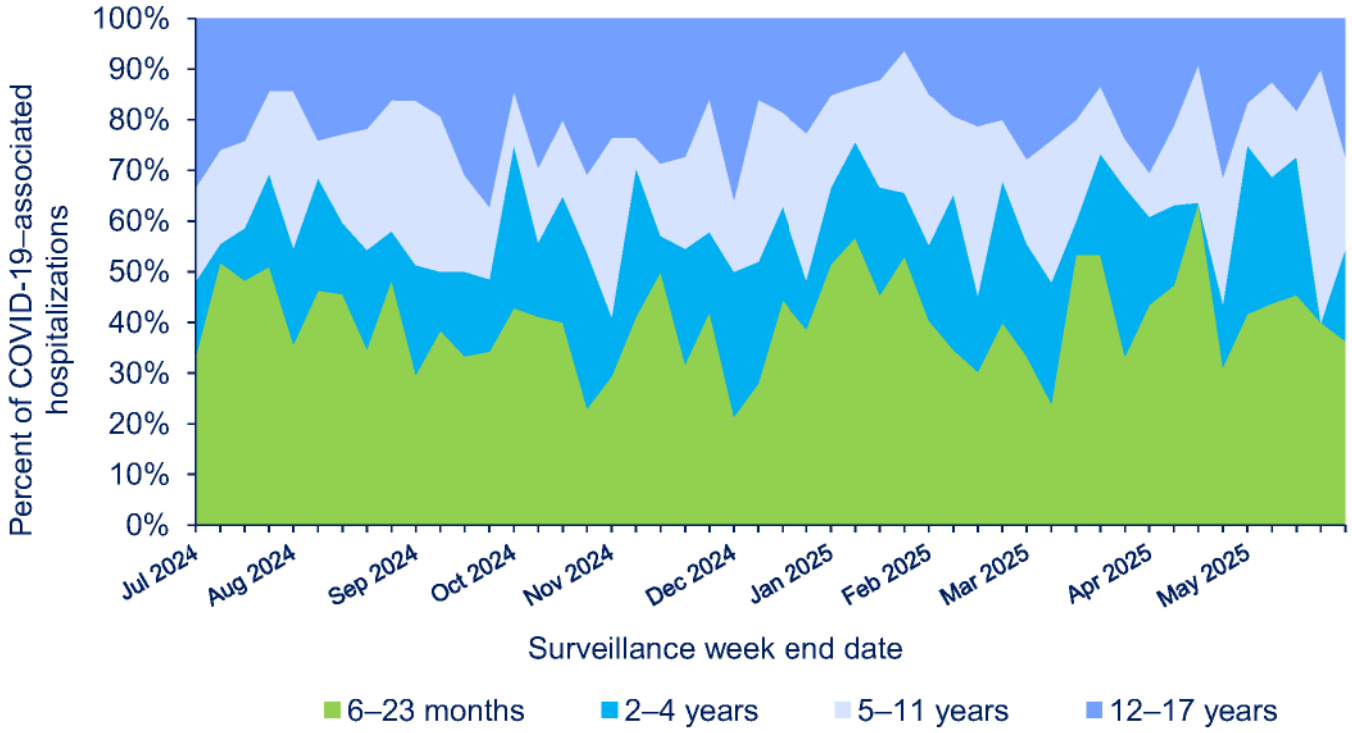
- **No COVID-19 vaccine products are approved for infants ages <6 months.**
- **Any protection must come from transfer of maternal antibodies, either from vaccination during pregnancy or prior infection**

Data reported from April 2024–March 2025. Hospitalizations are limited to those with COVID-19 as the likely reason for admission. Excludes newborns who were admitted during the same hospitalizations as their birth.

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Among vaccine-eligible children and adolescents ages 6 months–17 years, 41% of COVID-19-associated hospitalizations occurred among children ages 6–23 months.



During July 2024–May 2025:

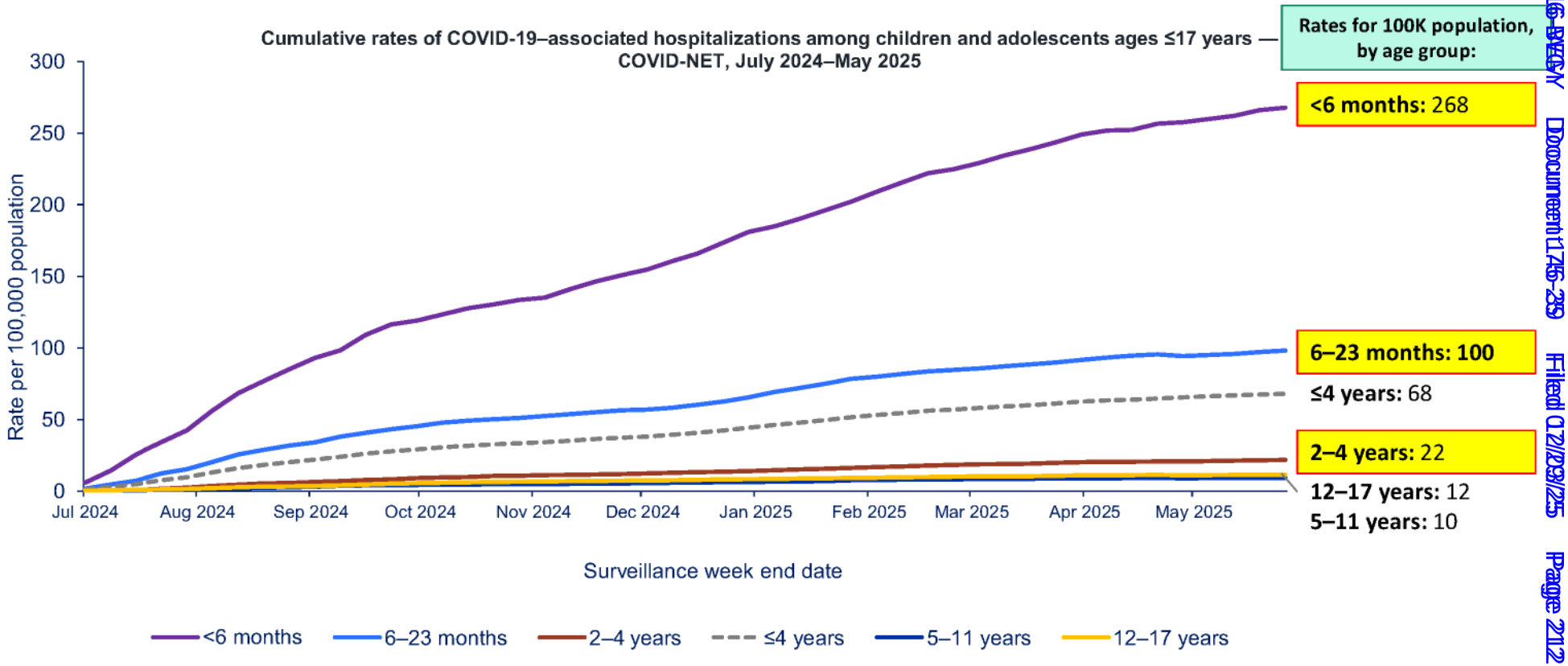
- 6–23 months = 41%
- 2–4 years = 18%
- 5–11 years = 20%
- 12–17 years = 21%

Figure displays the percent of weekly COVID-19–associated hospitalizations among children and adolescents, by age group — COVID-NET, October 2024–May 2025.

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COVID-19-associated cumulative hospitalization rates are highest among the youngest age groups.

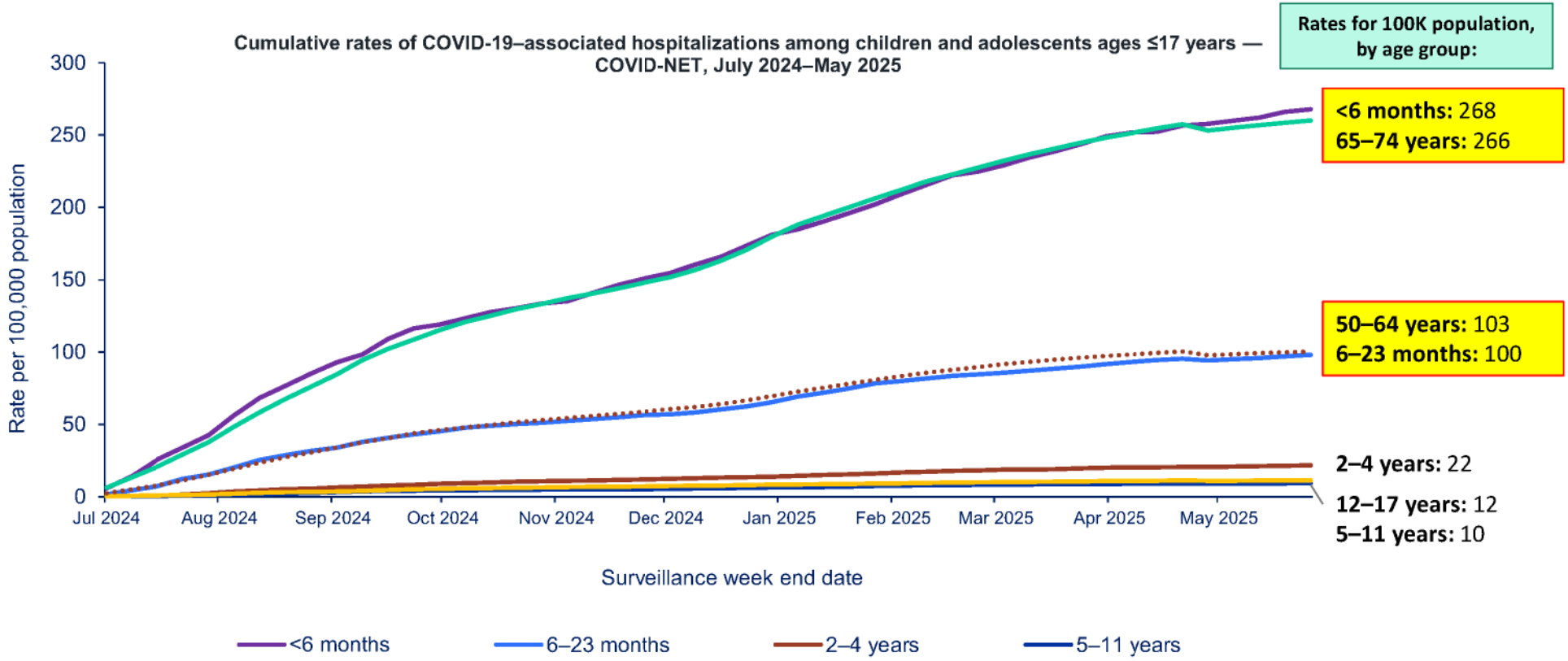


Note that rates are not adjusted for testing. Rates are not limited to admissions where the respiratory infection is the likely primary reason for admission.

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

The youngest age groups have comparable rates of cumulative COVID-19-associated hospitalization to some adult age groups, but direct comparisons are challenging.

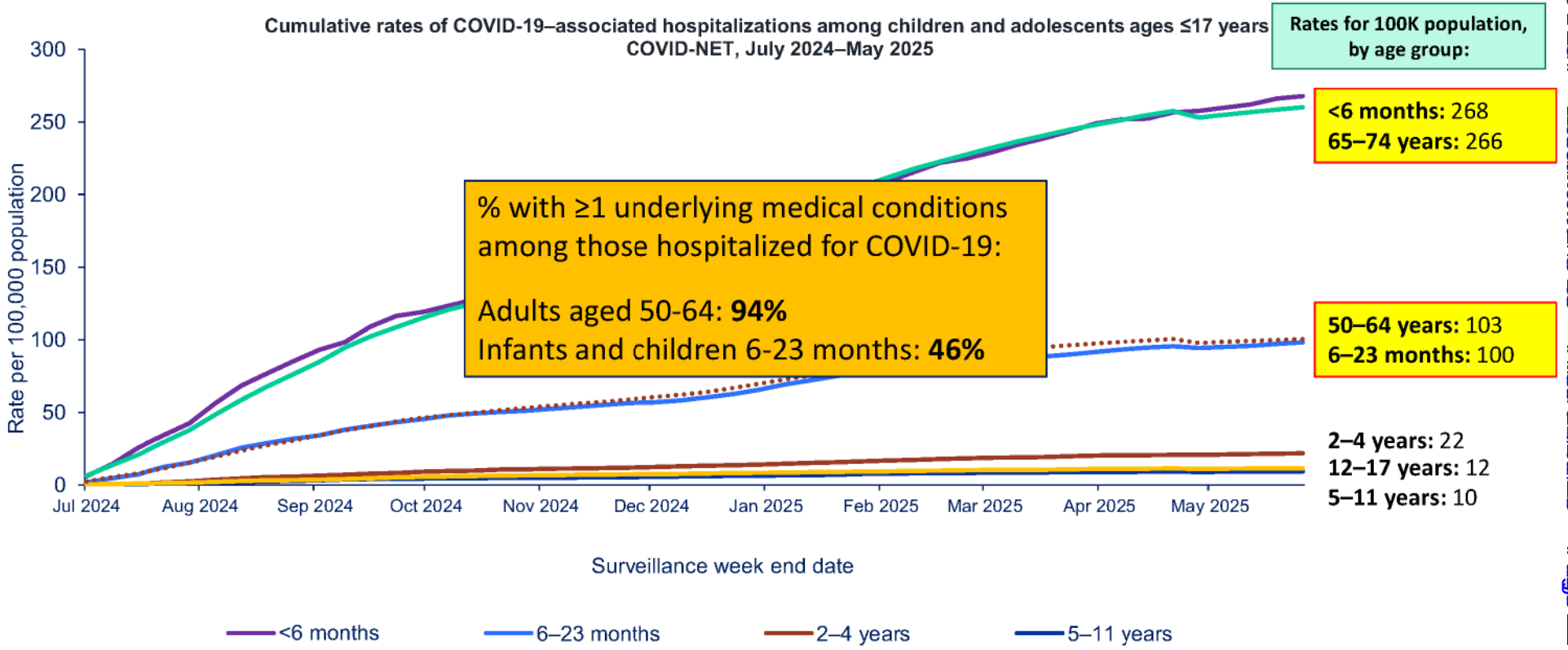


Note that rates are not adjusted for testing. Rates are not limited to admissions where the respiratory infection is the likely primary reason for admission.

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

The youngest age groups have comparable rates of cumulative COVID-19-associated hospitalization to some adult age groups, but direct comparisons are challenging.

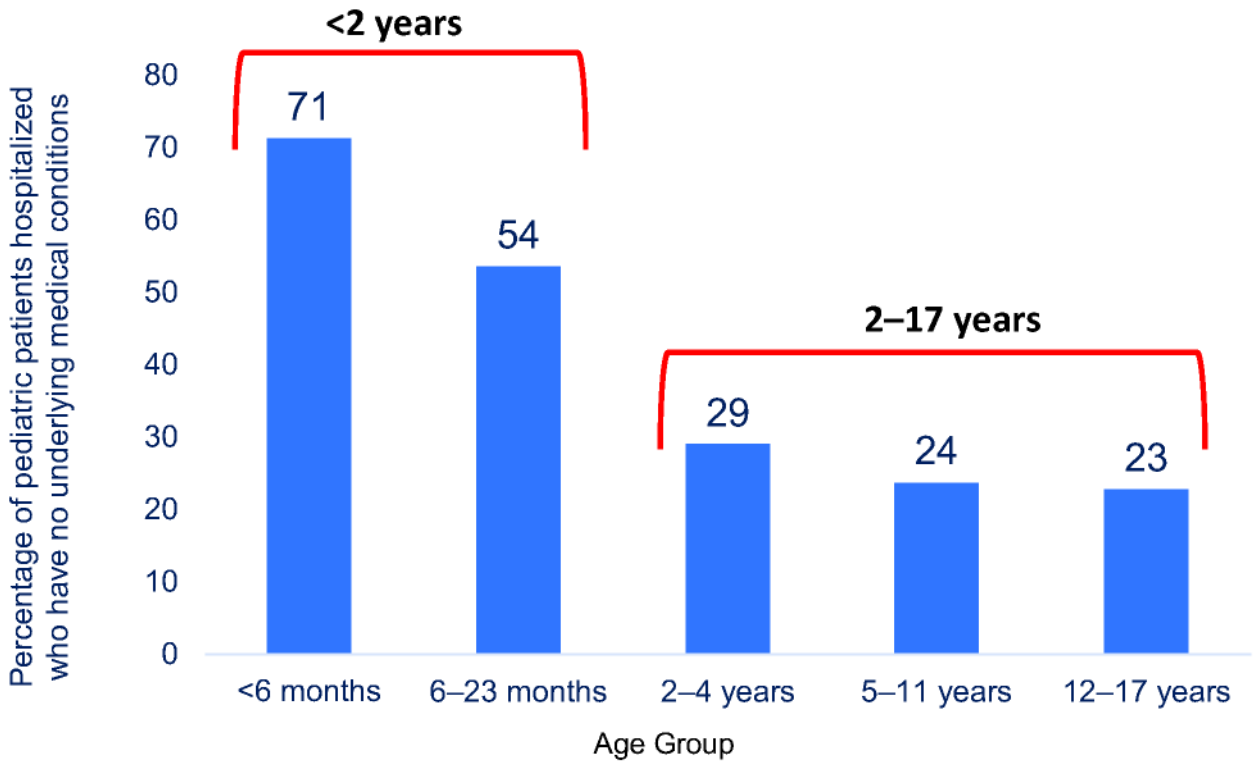


Note that rates are not adjusted for testing. Rates are not limited to admissions where the respiratory infection is the likely primary reason for admission.

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

Proportion of children hospitalized for COVID-19 who had no underlying medical conditions



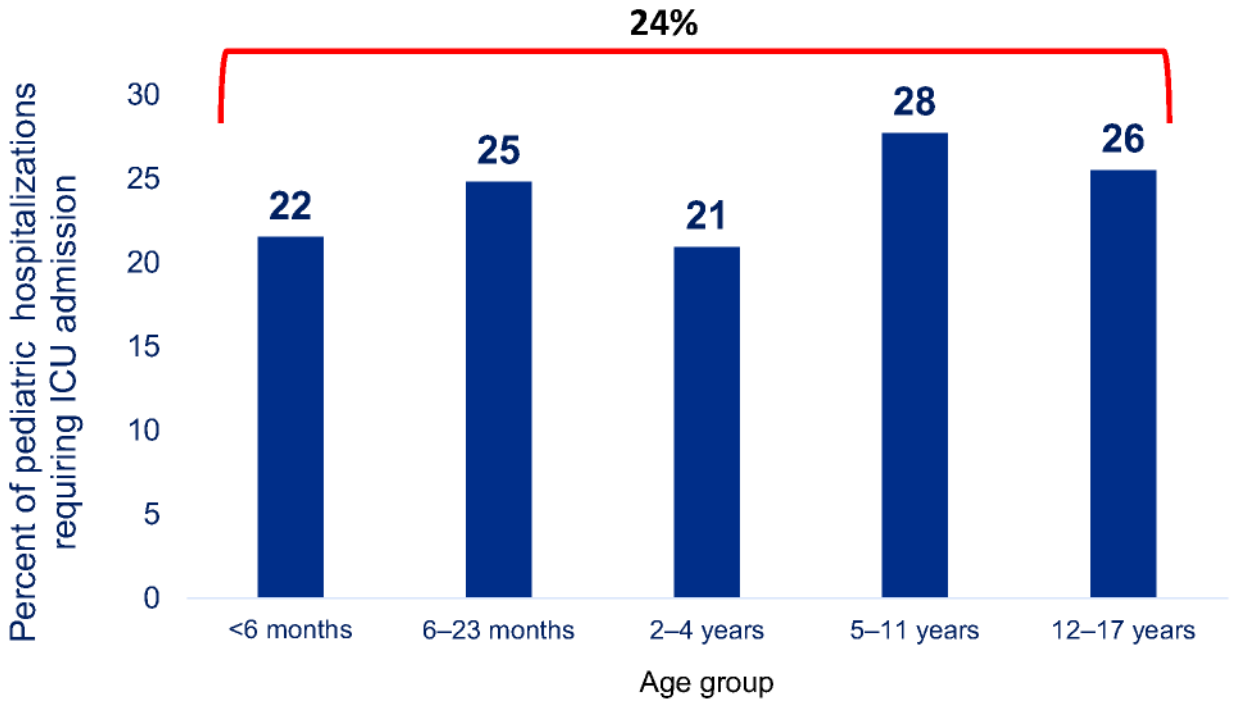
Most hospitalized children ages <2 years did not have any underlying medical condition.

Figure displays the weighted percent of children and adolescents hospitalized for COVID-19 with no underlying medical conditions, by age group — COVID-NET, April 2024–March 2025. Hospitalizations are limited to those with COVID-19 as the presenting complaint upon admission. Pregnant adolescents ages 15–17 years are excluded from proportions presented.

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

~1 in 4 children ages <18 years in all age groups hospitalized for COVID-19 required ICU admission.



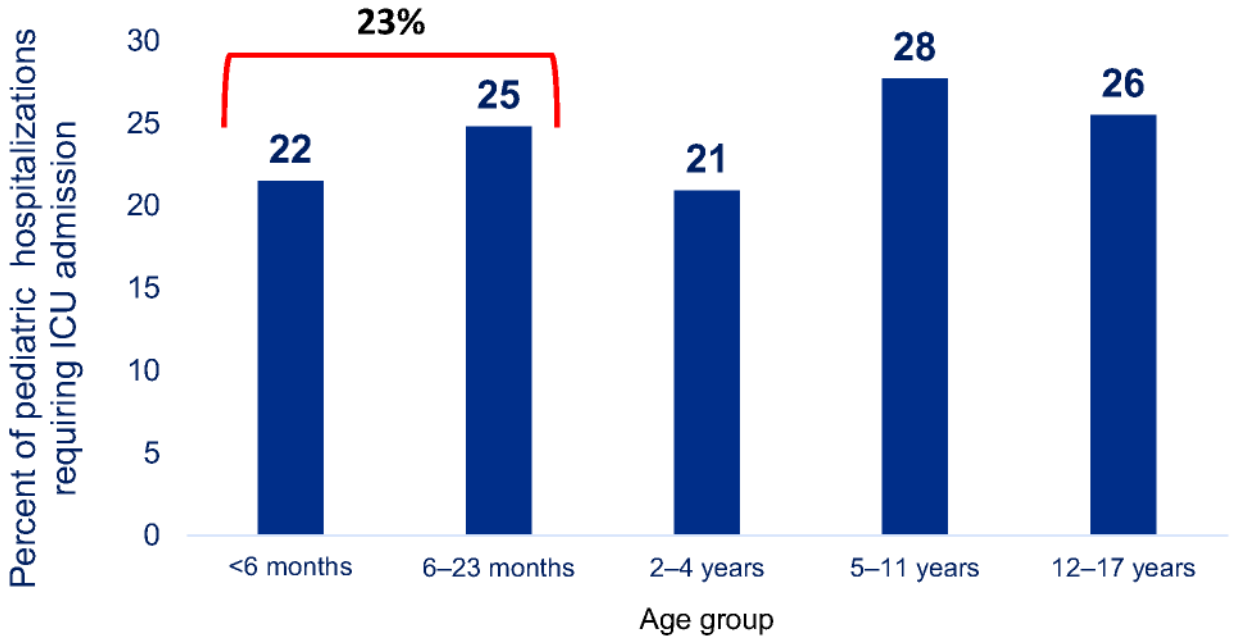
Percent of children and adolescents for COVID-19 who were admitted to the ICU, by age group — COVID-NET, April 2024–March 2025

Hospitalizations are limited to those with COVID-19 as the likely reason for admission. Pregnant adolescents ages 15–17 years are excluded from proportions presented.

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~1 in 4 children ages <18 years in all age groups hospitalized for COVID-19 required ICU admission.



Among children <2 years admitted to ICU, most (53%) did not have underlying medical conditions.

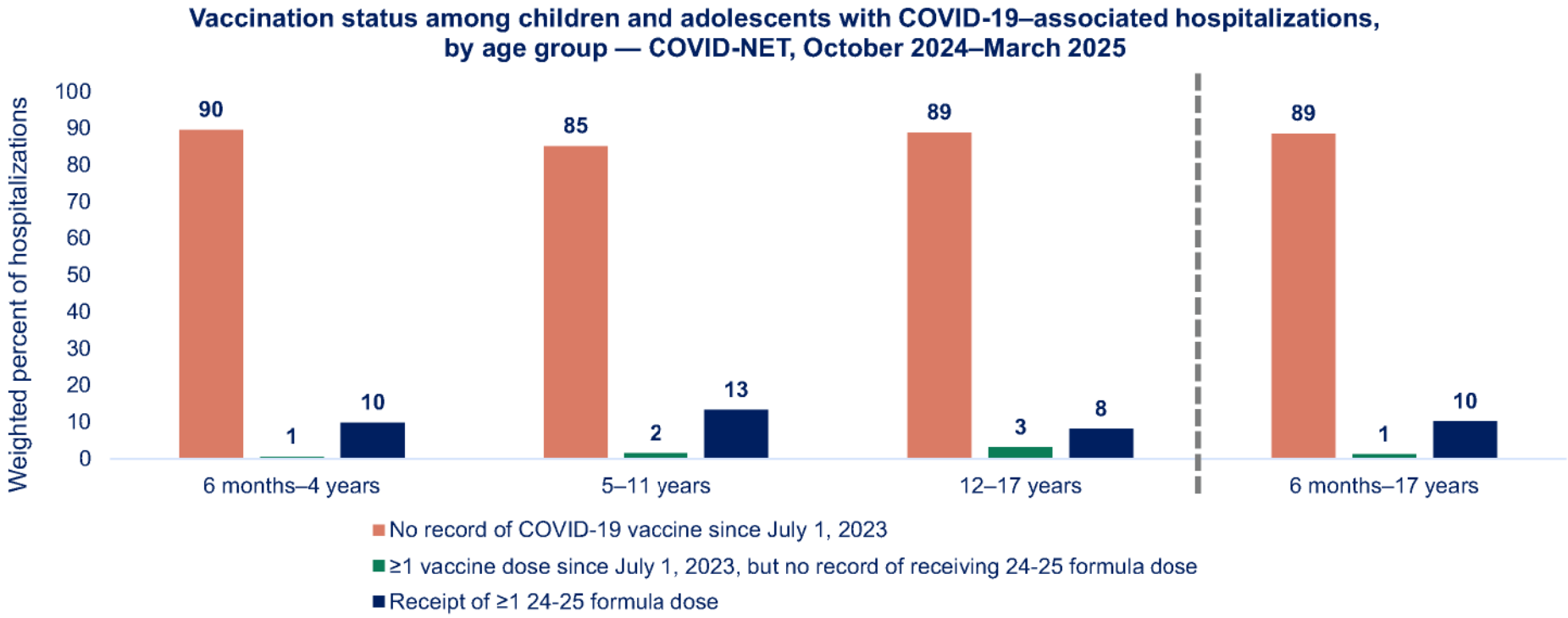
Percent of children and adolescents for COVID-19 who were admitted to the ICU, by age group — COVID-NET, April 2024–March 2025

Hospitalizations are limited to those with COVID-19 as the likely reason for admission. Pregnant adolescents ages 15–17 years are excluded from proportions presented.

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89% of COVID-19 vaccine-eligible children and adolescents who were hospitalized with COVID-19 had no record of receiving the most recently recommended COVID-19 vaccines.



No record of COVID-19 vaccine since July 1, 2023*: No recorded doses of any COVID-19 vaccine dose since July 1, 2023.* ***≥1 vaccine dose since July 1, 2023, but no 2024–2025 dose:*** *Received at least one COVID-19 vaccination since July 1, 2023, but no record of receiving 2024-2025 vaccine dose.* ***Receipt of ≥1 24-25 formula dose:*** *Received at least 1 dose of the 2024-2025 vaccine dose. Persons with unknown vaccination status (6.4%) are excluded. Hospitalizations are limited to those with COVID-19 as the presenting complaint upon admission.*

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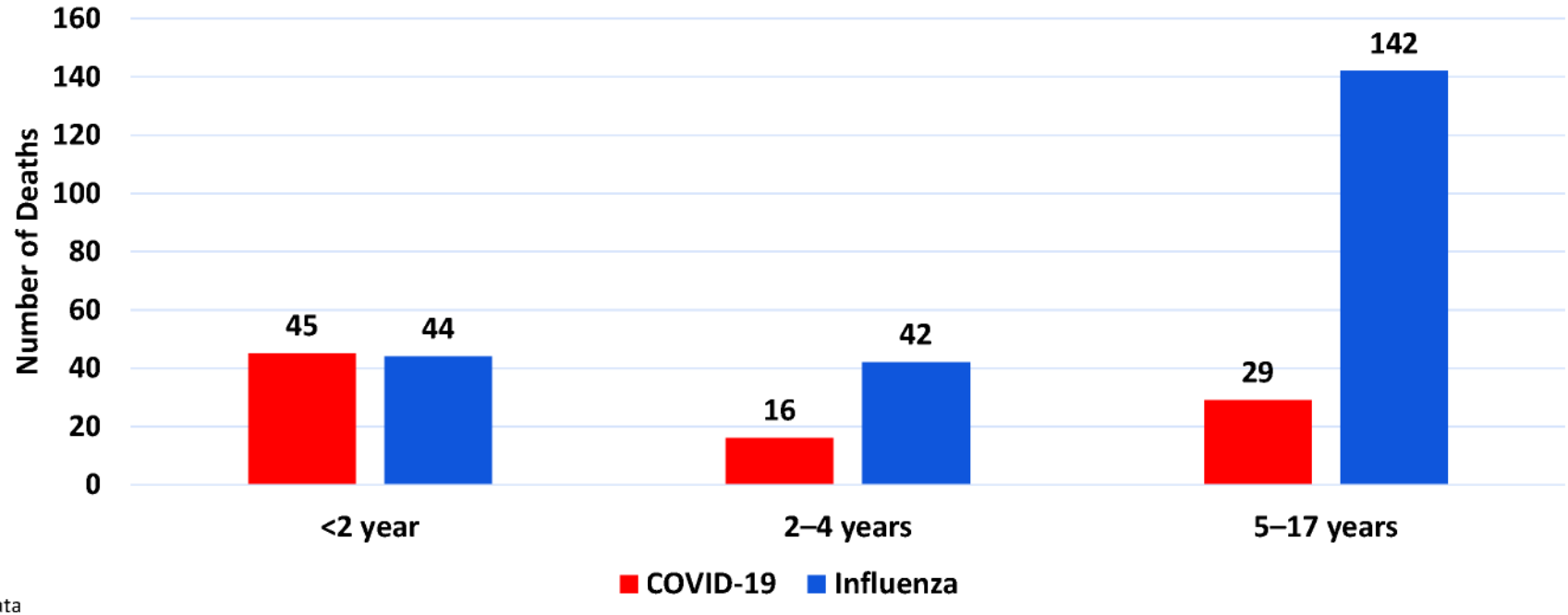
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Pediatric COVID-19 mortality

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Total number of COVID-19- and Influenza-associated deaths[1,2], among ages 0–17 years in July 2024–June 2025, 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, provisional data for 2024 and provisional and partial data from 2025, 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 June 20, 2025

Note: Estimates of pediatric influenza deaths reported to CDC can be found here: https://www.cdc.gov/fluview/surveillance/2025-week-15.html. Estimates will vary due to differences in reporting methods and timeframes used.

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Deaths among children with COVID-19-associated hospitalizations within COVID-NET catchment area

	Since March 2020	July 2022–June 2023	July 2023–March 2025
In-hospital and out-of-hospital deaths	128	32	25 (including 10* since April 2024)

COVID-NET represents 10% of the U.S. population

- **Among 25 pediatric deaths since July 2023:**
  - 13 (52%) were aged <2 years: 9 aged <6 months; 4 aged 6–23 months
  - 18 (72%) had ≥1 underlying medical condition
  - Of the 16 who were age-eligible for COVID-19 vaccination, 14 had no record of COVID-19 vaccination and none were up to date.
- **Death certificate data alone may underestimate COVID-19-associated pediatric deaths**
  - Among the 25 deaths** for whom we have death certificate data with ICD-10 codes, 7 (28%) had COVID-19 listed as a cause of death (COD)
  - Additional 9 (36%) had CODs related to other respiratory or circulatory causes

* In-hospital deaths only; complete death certificate data not yet available.

** Deaths occurred during July 2022 and August 2023.

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Summary

COVID-19 Epidemiology in Infants, Children, and Adolescents

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Summary of COVID-19 Epidemiology for Infants, Children, and Adolescents

- Most (57%) pediatric hospitalizations occur in children **ages <2 years**.
  - Most hospitalized children in these age groups **have no underlying medical conditions**, including 71% of infants ages <6 months and 54% of children ages 6–23 months.
- Rates of COVID-19–associated hospitalizations are **highest among infants ages <6 months,** followed by those ages 6–23 months.
  - Rates of COVID-19-associated hospitalizations among infants ages <6 months are comparable to rates among adults ages 65–74 years
  - No COVID-19 vaccine products are approved for infants ages <6 months. Any protection must come from transfer of maternal antibodies, either through vaccination during pregnancy or prior infection
- Outcomes among hospitalized children can be severe, with **1 in 4 admitted to ICU**.
  - Deaths from COVID-19 continue to occur among infants and children; death certificate data might undercount these.
- The majority (89%) of COVID-19 vaccine-eligible children and adolescents who were hospitalized with COVID-19 had no record of receiving the most recently recommended COVID-19 vaccine.

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

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

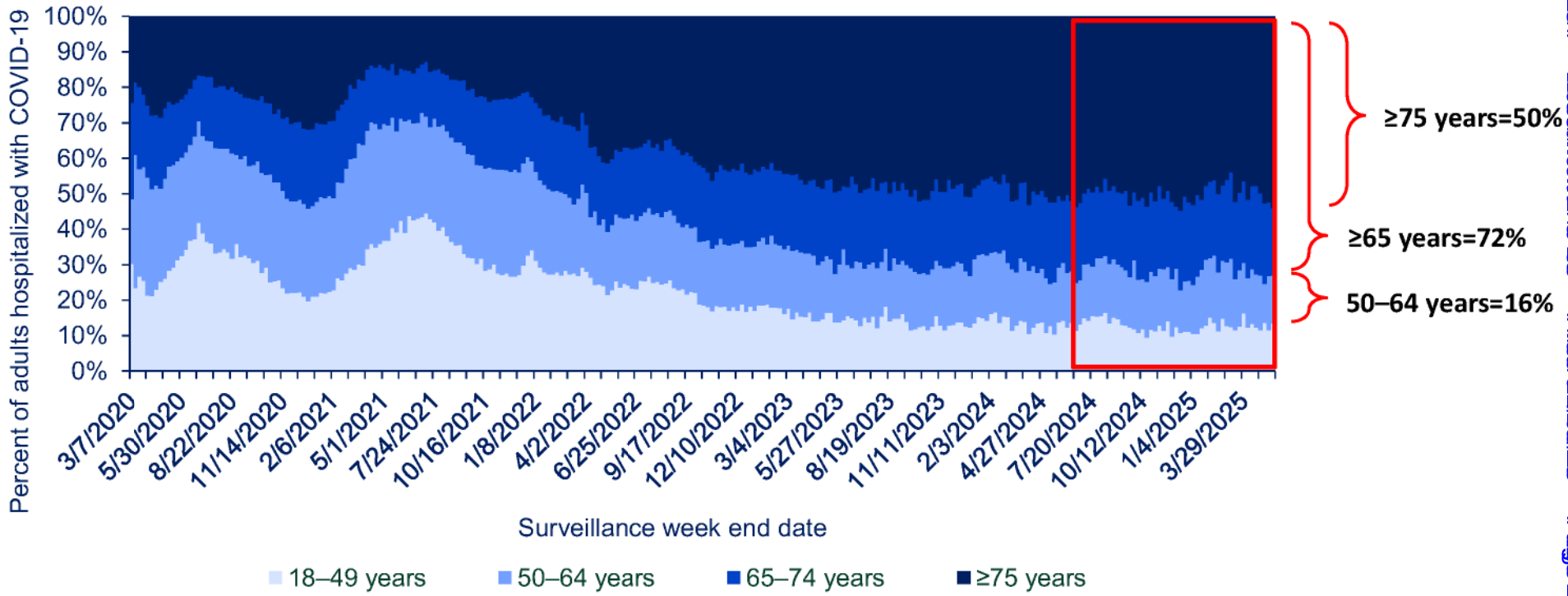
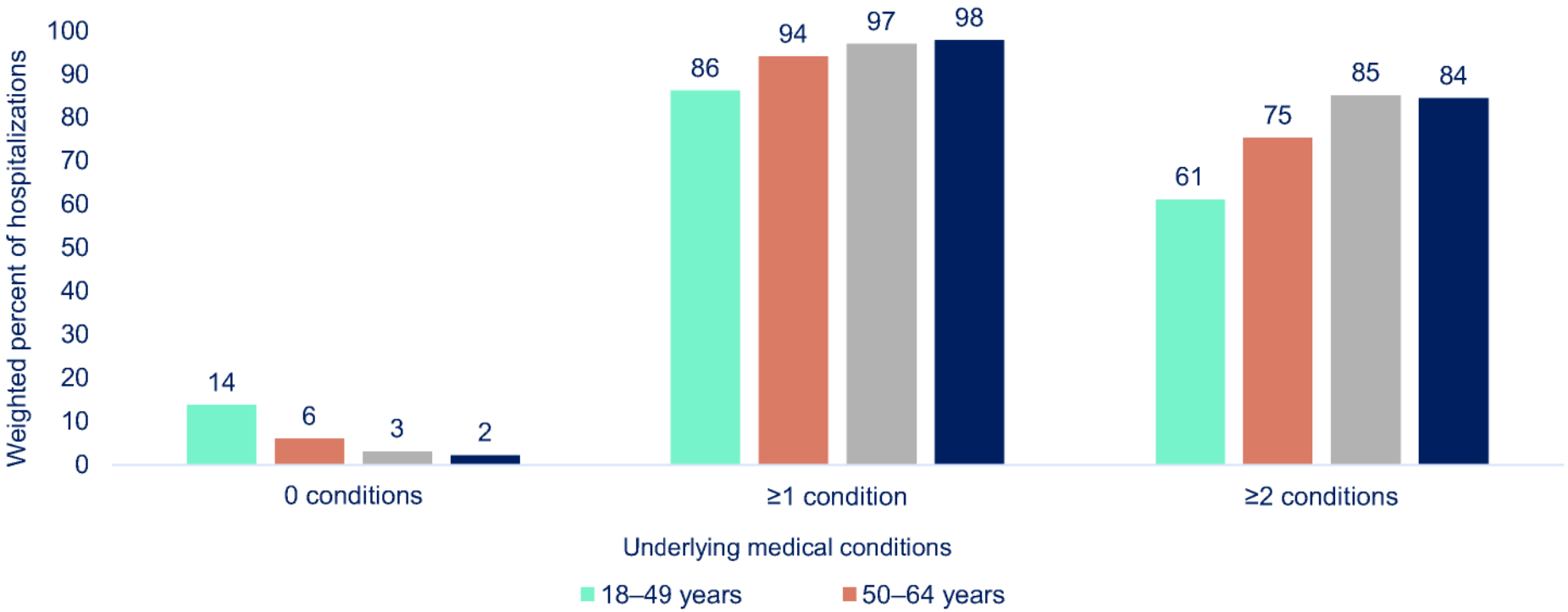


Figure displays the percent of weekly COVID-19–associated hospitalizations among adults ages ≥18 years, by age group — COVID-NET, March 2020–May 2025.
During this same period of January 2024 through March 2025, children and adolescents ages 17 years and younger comprised 4.1% of all COVID-19-associated hospitalizations.

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Most adults hospitalized for COVID-19 have ≥1 underlying medical condition; a majority have ≥2.



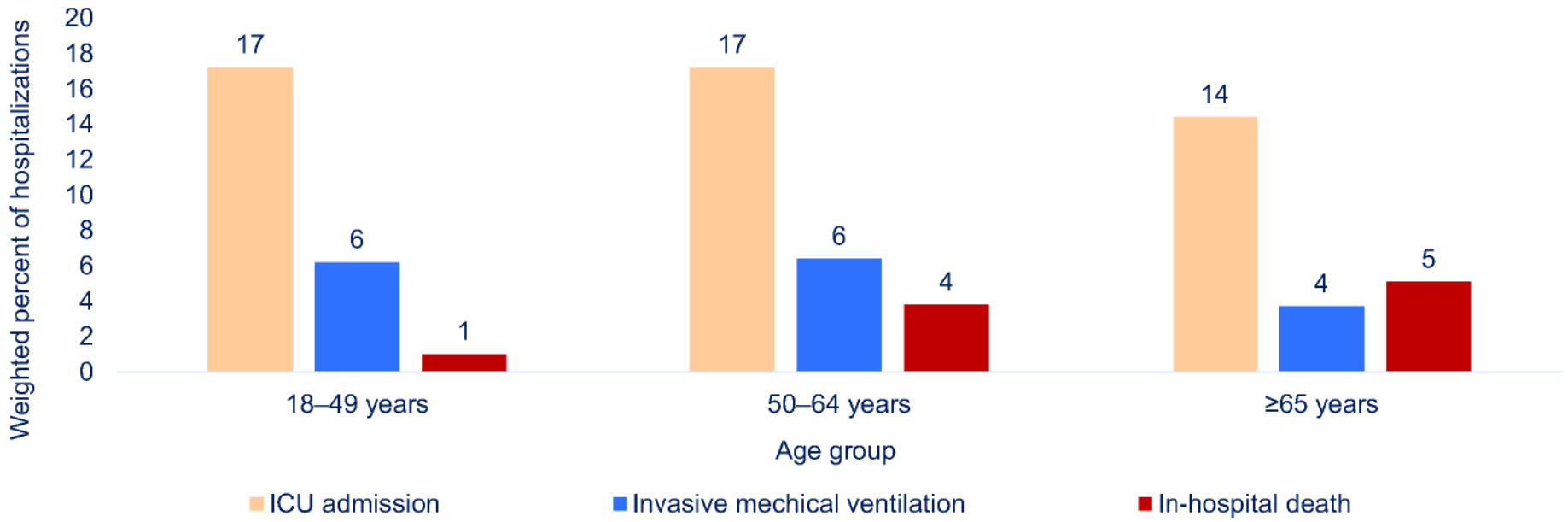
Prevalence of underlying medical conditions among adults ages ≥18 years, by age group — COVID-NET, April 2024–March 2025.

Pregnant women ages 18–49 years are excluded from proportions presented. Data are limited to hospitalizations with COVID-19 as the likely reason for admission.

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Among adults hospitalized for COVID-19, 15% were admitted to the intensive care unit (ICU).



During this period, 85% of all adults hospitalized with COVID-19 who died in-hospital were ages ≥65 years.

The figure displays the proportion of adults hospitalized for COVID-19 with interventions and outcomes, by age group — COVID-NET, April 2024–March 2025.

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 deaths that occur soon after hospital discharge that could be attributable to COVID-19-related illness. Pregnant women ages 18–49 years are excluded from proportions presented.

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

Most adults hospitalized for COVID-19 had received no COVID-19 vaccine since July 2023.

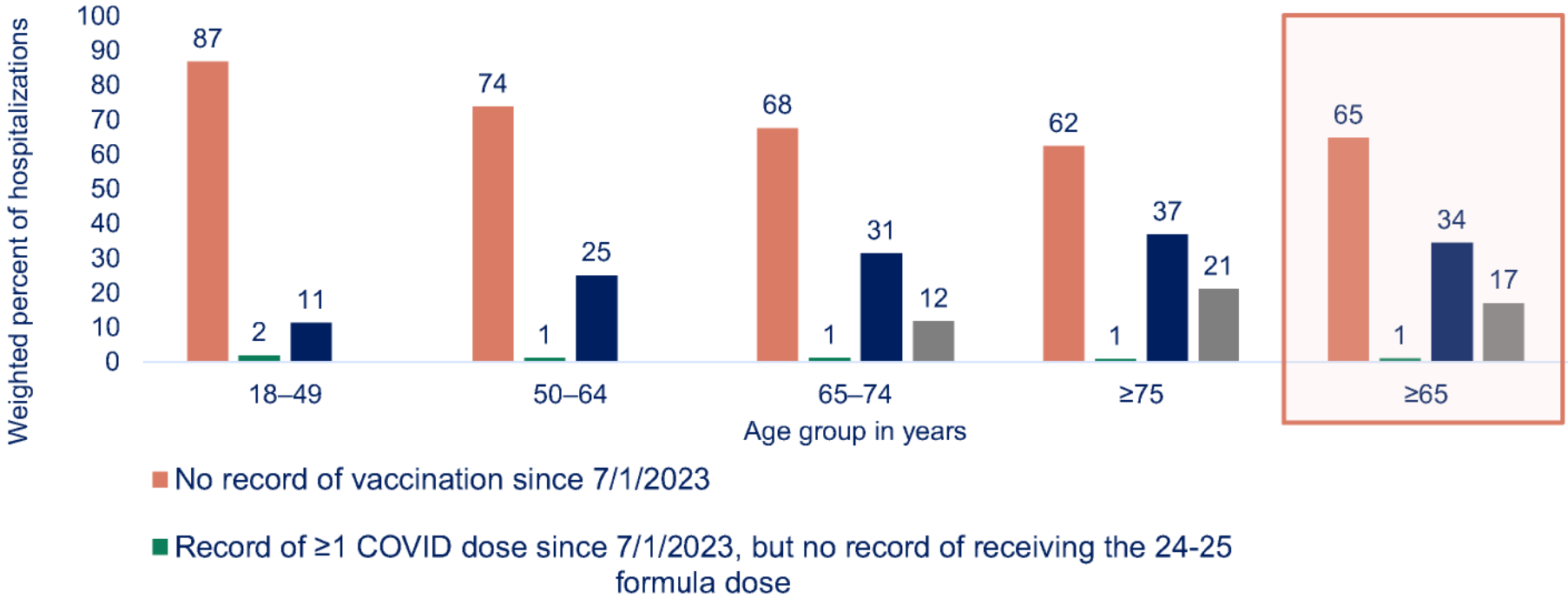


Figure displays the COVID-19 vaccination status among adults hospitalized for COVID-19, by age group — COVID-NET, October 2024–March 2025.
Data are limited to hospitalizations where COVID-19 is a likely primary reason for admission.

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COVID-19-Associated Hospitalizations among Pregnant Women

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

Pregnant women with COVID-19–associated hospitalizations, April 2024–March 2025

- Pregnancy status collected from hospitalized women ages 15–49 years
- 28.5% of women ages 15–49 years hospitalized with laboratory-confirmed SARS-CoV-2 infection were pregnant
  - 50% of those had COVID-19-related signs or symptoms



Source: COVID-NET, unpublished data.

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Pregnant women with COVID-19–associated hospitalization, April 2024–March 2025

Among 131 hospitalized pregnant women with a laboratory-confirmed SARS-CoV-2-positive test result and COVID-19-related signs or symptoms:

- 50% had no underlying conditions
- 68% were no longer pregnant at discharge, among whom:
  - 83% had a healthy newborn, 11% had a pre-term infant, 1% had an ill infant, and 5% had pregnancy loss*
- 92% have no record of vaccination since July 1, 2023
  - 5.8% received recommended 2024-25 COVID-19 vaccine dose**

* Includes spontaneous miscarriage and abortion.

** Vaccination might have occurred before the pregnancy period and is not necessarily indicative of maternal vaccination status.

Source: COVID-NET, unpublished data.

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Summary

Adults

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Summary of COVID-19 Epidemiology for Adults

- Rates of COVID-19–associated hospitalization are highest among oldest adult age groups
  - Adults aged ≥65 years comprise 72% of adult COVID-19–associated hospitalizations
  - Ages ≥75 years: 50% of adult hospitalizations
- COVID-19-associated hospitalization rates have decreased over time, but cumulative rates among adults aged ≥75 years remain high
- Risk of hospitalization with COVID-19 continues year-round, peaking in the winter and summer.
- 65% of adults ages ≥65 years hospitalized with COVID-19 had no record of receiving ≥1 dose of the recommended 2024-25 COVID-19 vaccine prior to hospitalization.
- Most adults with COVID-19-associated hospitalization have ≥1 underlying condition.
- Among SARS-CoV-2-positive pregnant women admitted during April 2024–March 2025 with COVID-19-related symptoms on admission, half had no underlying conditions and most (92%) have no record of COVID-19 vaccination since July 1, 2023

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Genomics

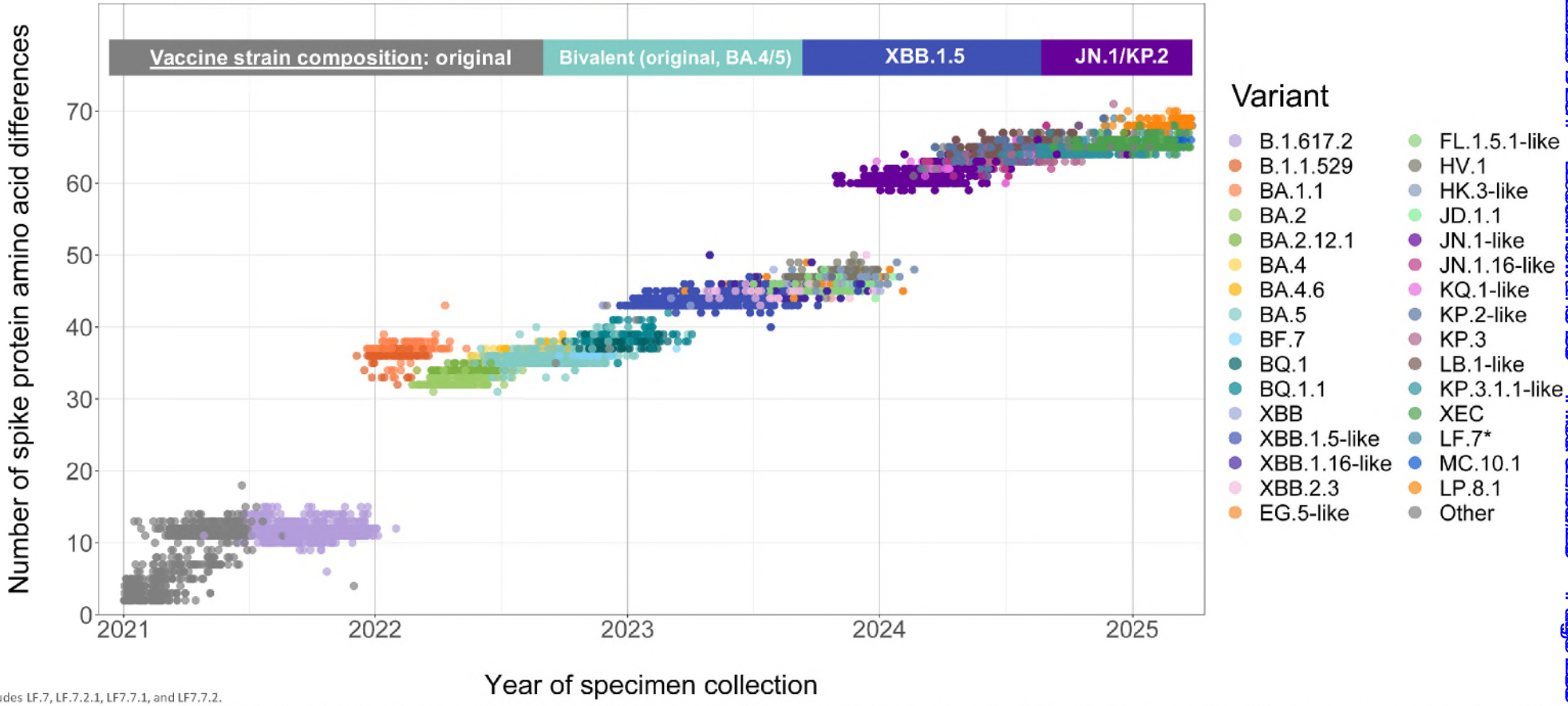
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Subsampled SARS-CoV-2 sequences by lineage group, date of specimen collection, and number of spike protein amino acid differences relative to Wuhan-Hu-1 reference

United States, January 1, 2021–March 29, 2025

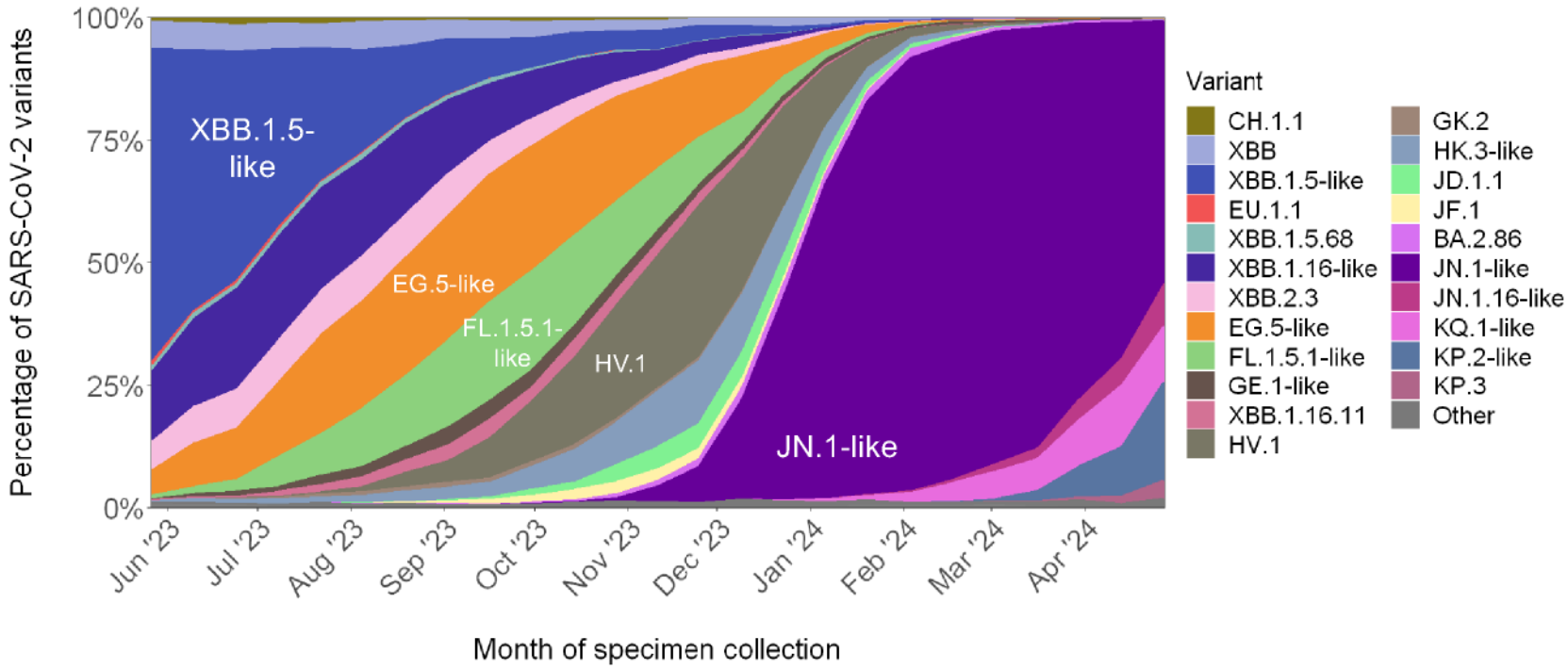


* LF.7 includes LF.7, LF.7.2.1, LF7.7.1, and LF7.7.2.

Sequences were subsampled (100 per month) for analysis from an initial dataset of >1 million sequences spanning January 1, 2021–March 29, 2025. **Only lineages circulating at >5% prevalence nationally during at least one 2-week period are displayed.** Sequences are reported to CDC through the National SARS-CoV-2 Strain Surveillance program, contract laboratories, public health laboratories, and other U.S. institutions. Lineages were ordered by date of first appearance on CDC's COVID data tracker (https://covid.cdc.gov/covid-data-tracker/#variant-proportions). Lineages with identical spike receptor binding domain amino acid sequences (residues 332 to 527) were grouped with a representative lineage and denoted as "representative lineage-like." Vaccine availability for a given composition was defined by the estimated date of earliest possible administration.

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In winter 2023-2024, we observed a strain replacement of XBB.1.5-like viruses to JN.1-like viruses.



[Genomic Surveillance for SARS-CoV-2 Variants: Circulation of Omicron XBB and JN.1 Lineages — United States, May 2023–September 2024 | MMWR]

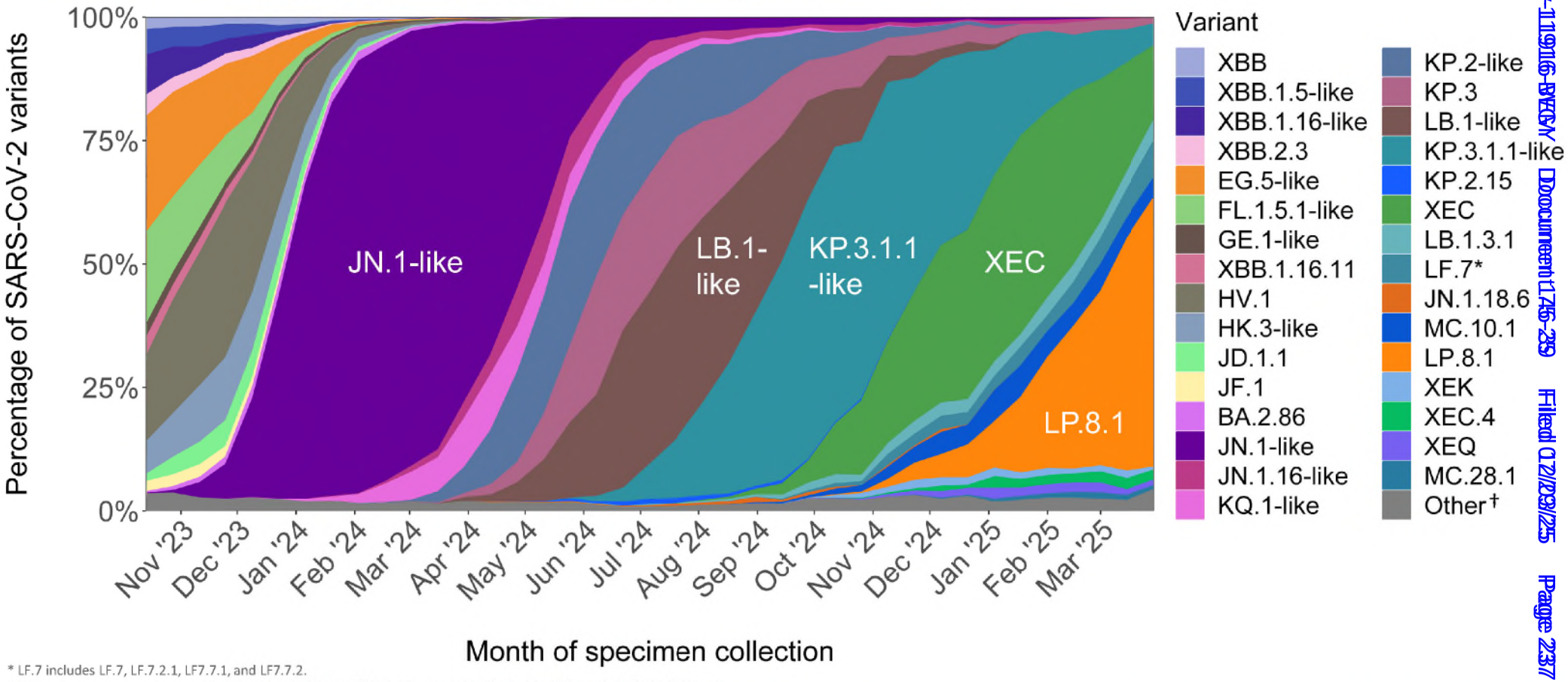
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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

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Weighted SARS-CoV-2 Variant Proportion Estimates: XBB and JN.1 Lineages

United States, October 1, 2023–March 29, 2025



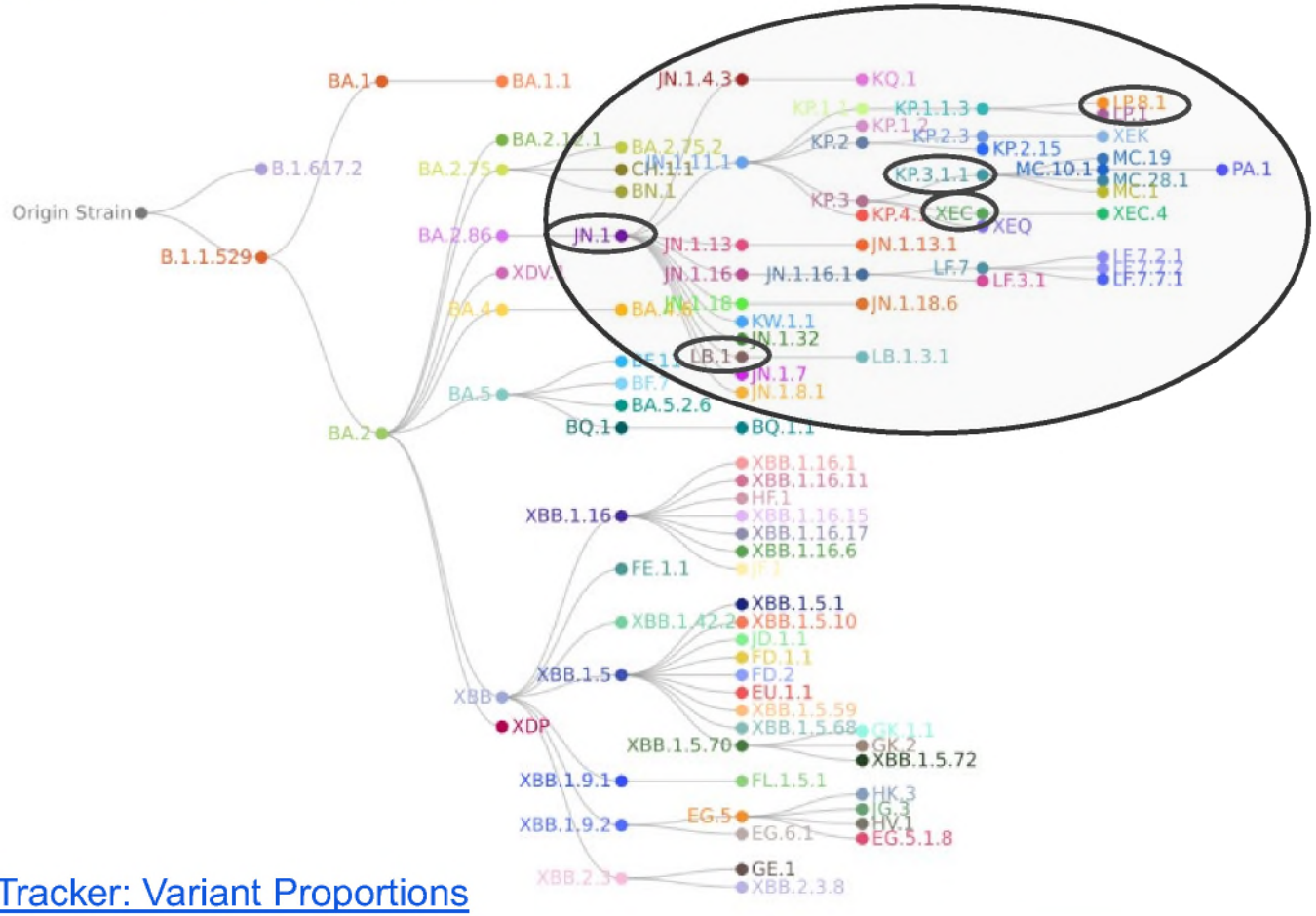
* LF.7 includes LF.7, LF.7.2.1, LF7.7.1, and LF7.7.2.

† "Other" represents aggregated lineages circulating at <1% prevalence nationally during all 2-week periods displayed.

Lineages were ordered by date of first appearance on CDC's COVID data tracker (https://covid.cdc.gov/covid-data-tracker/#variant-proportions). Lineages with identical spike receptor binding domain amino acid sequences (residues 332 to 527) were grouped with a representative lineage and denoted as "representative lineage-like."

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Viruses that have predominated since January 2025 are all JN.1 descendants.



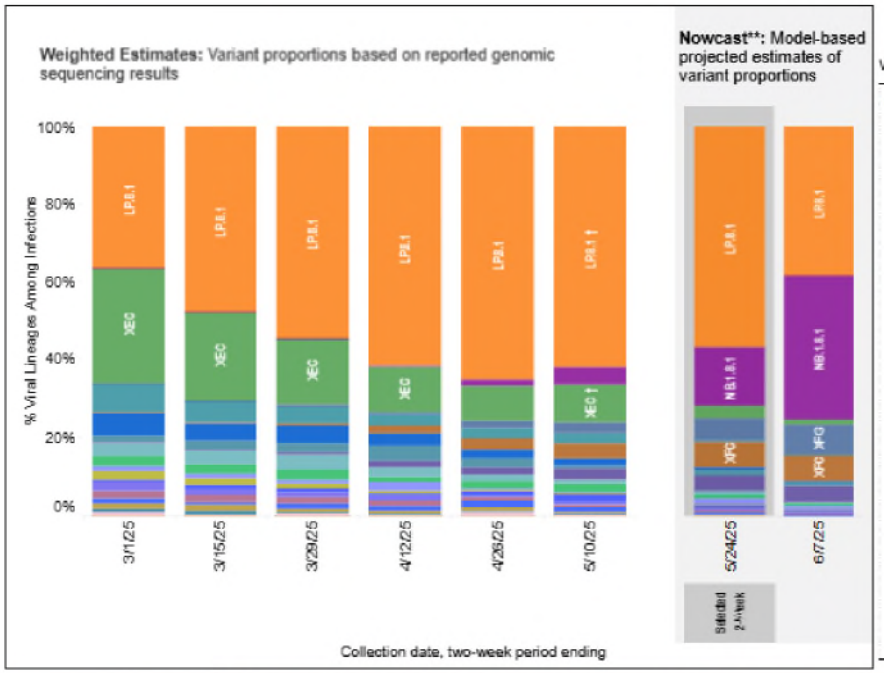
[CDC COVID Data Tracker: Variant Proportions]

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

Weighted and Nowcast Estimates in the United States for 2-week Periods, 2/16/2025 – 6/7/2025

Due to low numbers of sequences being reported to CDC, precision for the most recent reporting periods is low



USA

WHO label	Lineage #	%Total	95%PI
Omicron	LP.8.1	57%	49–64%
	NB.1.8.1	15%	7–28%
	XFC	6%	3–12%
	XFG	6%	2–13%
	LF.7.9	4%	2–6%
	XEC	3%	2–4%
	LF.7	2%	1–3%
	LF.7.7.2	1%	0–4%
	LB.1.3.1	1%	1–2%
	PA.1	1%	1–2%
	XEC.4	1%	1–2%
	LF.7.7.1	1%	0–2%
	MC.10.1	1%	0–1%
	KP.3.1.1	0%	0–1%
	KP.3	0%	0–1%
	XEQ	0%	0–1%
	XEK	0%	NA
	MC.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

[CDC COVID Data Tracker: Variant Proportions](#)
As of June 15, 2025

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Convergent Evolution of Different Omicron JN.1 Lineages

Key changes in the spike receptor binding domain (RBD)* detected relative to KP.2

Lineage	*N-terminal domain*									*Receptor binding domain*									*S2*					
	22	31	59	146	182	183	184	186	190	346	435	444	445	456	478	493	572	679	748	929	1086	1104	1235
KP.2 Reference †	T	S	F	H	K	Q	G	F	R	T	A	K	H	L	T	Q	T	K	E	S	K	L	C
KP.3										R						E							
KP.3.1.1		Δ								R						E							
KP.3.3										R						E							
KP.2.3		Δ		Q																I			
JN.1										R				F								V	
JN.1.16				Q						R												V	
JN.1.18.6	N		S																				
KP.2.15		Δ																					
LB.1		Δ				H																V	
LF.7	N	P			R				S			R					I					V	
LP.8.1		Δ						L	S				R			E					R		
MC.10.1		Δ								R	S					E							
MC.28.1		Δ									S					E							F
XEC	N		S							R						E							
XEC.4	N		S							R						E	I						
XEK	N		S							R						E			Q				
XFC	N	P			R				S				R			E		R			R		
NB.1.8.1	N		S				G				S		H		I	E							

* Lineages or lineage groups with ≥1% prevalence in at least one 2-week period and substitutions present in ≥50% of sequences belonging to a lineage were included.

† The KP.2 spike protein sequence was used as a reference because of its inclusion in updated mRNA-based 2024–2025 COVID-19 vaccines. Substitutions compared to Wuhan-Hu-1 are underlined.

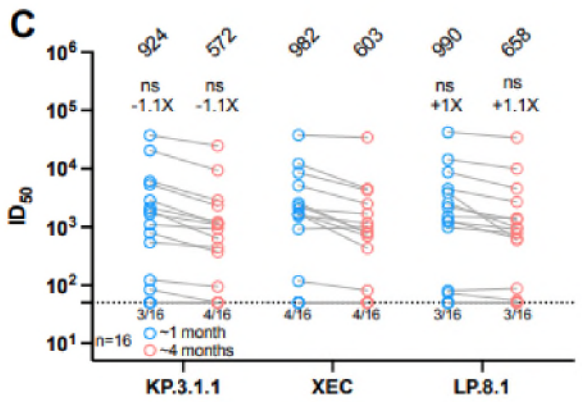
§ Indicates sites of independent substitution or deletion in at least two different evolutionary lineages.

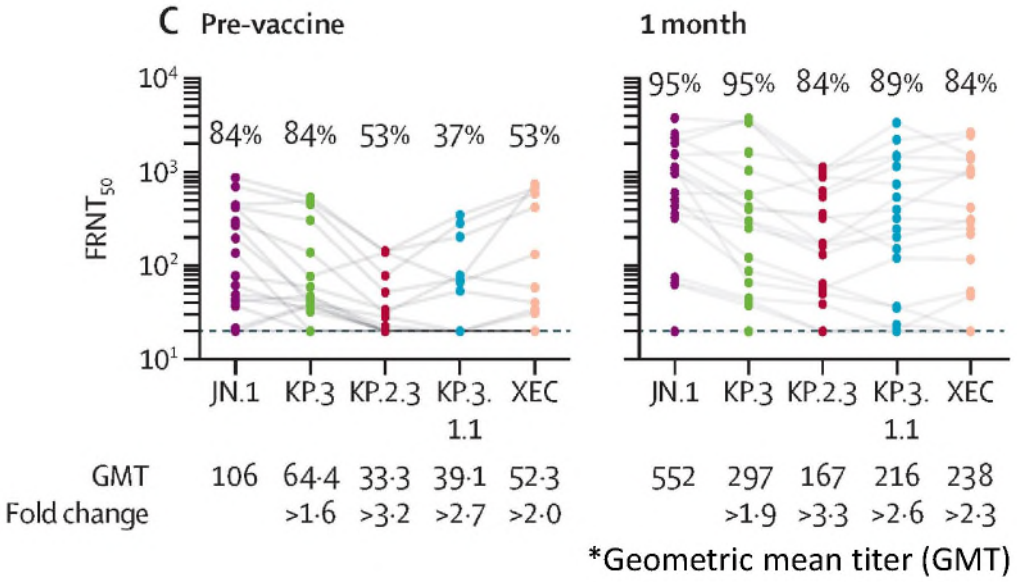
Bolded sub-lineages are expanding in the United States as of June 7, 2025.

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

Human sera collected after 2024-2025 COVID-19 vaccination neutralizes LP.8.1 pseudoviruses and XEC virus.





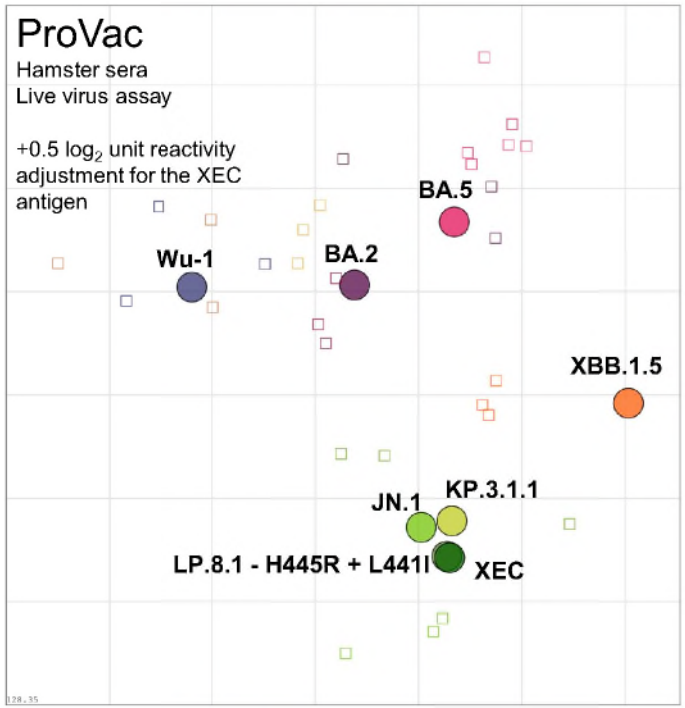
[Mellis et al. bioRxiv: Do Existing COVID-19 Vaccines Need to Be Updated in 2025?]

[Suthar et al. The Lancet Infectious Diseases: The KP.2-adapted COVID-19 vaccine improves neutralising activity against the XEC variant - ScienceDirect]

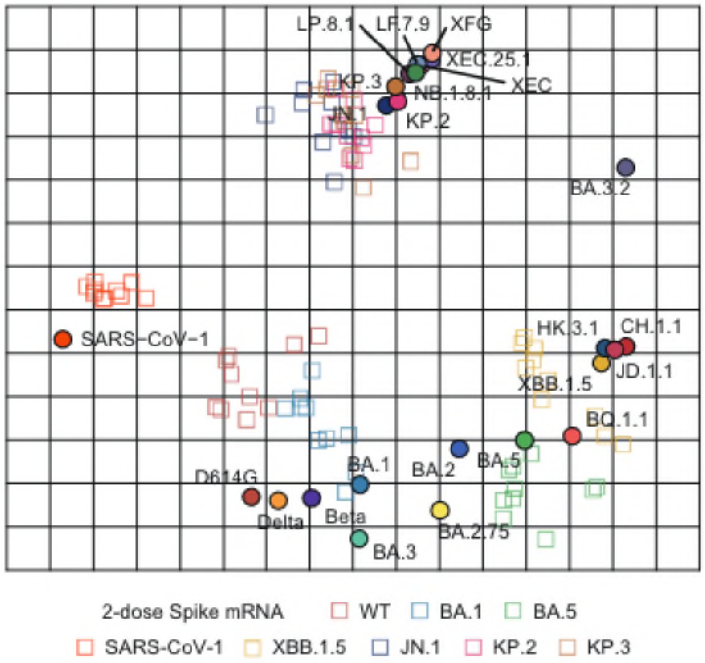
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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

Antigenic cartography with hamster and human sera indicate that JN.1 lineage viruses group together.



Francis Crick Institute
MRC University of Glasgow Centre for Virus Research
Center for Pathogen Evolution, University of Cambridge



Antigenic and Virological Characteristics of SARS-CoV-2 Variant BA.3.2, XFG, and NB.1.8.1

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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

Summary of COVID-19 Genomics

- Current viruses are JN.1 descendants with 2-3 substitutions in the spike receptor binding domain in comparison to KP.2 spike
- Current viruses are neutralized with sera from participants who received the 2024-2025 COVID-19 vaccine
- Antigenic cartography indicates JN.1 viruses are antigenically similar

- FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) reviewed genomic and phenotypic data in May and voted unanimously to recommend a monovalent JN.1-lineage vaccine composition.
  - FDA has advised manufacturers to use JN.1-lineage based COVID-19 vaccines, preferentially using the LP.8.1 strain, for the 2025-2026 COVID-19 vaccines

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Back-up

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Among all age groups, weekly rates of COVID-19–associated hospitalizations are highest among adults ages ≥75 years.

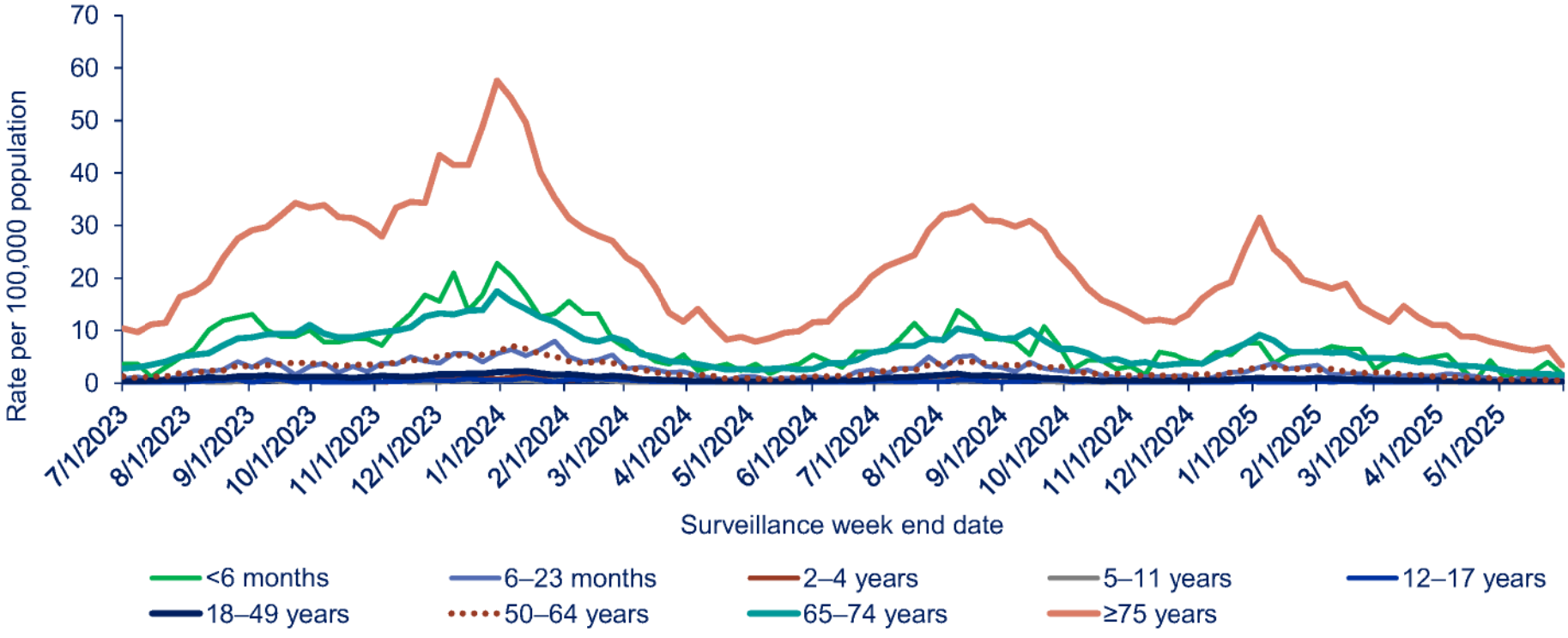


Figure displays the weekly rates of COVID-19–associated hospitalizations — COVID-NET, March 2020–May 2025.

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

Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

Among all children and adolescents, rates of COVID-19-associated hospitalizations are highest among infants and children ages <2 years.

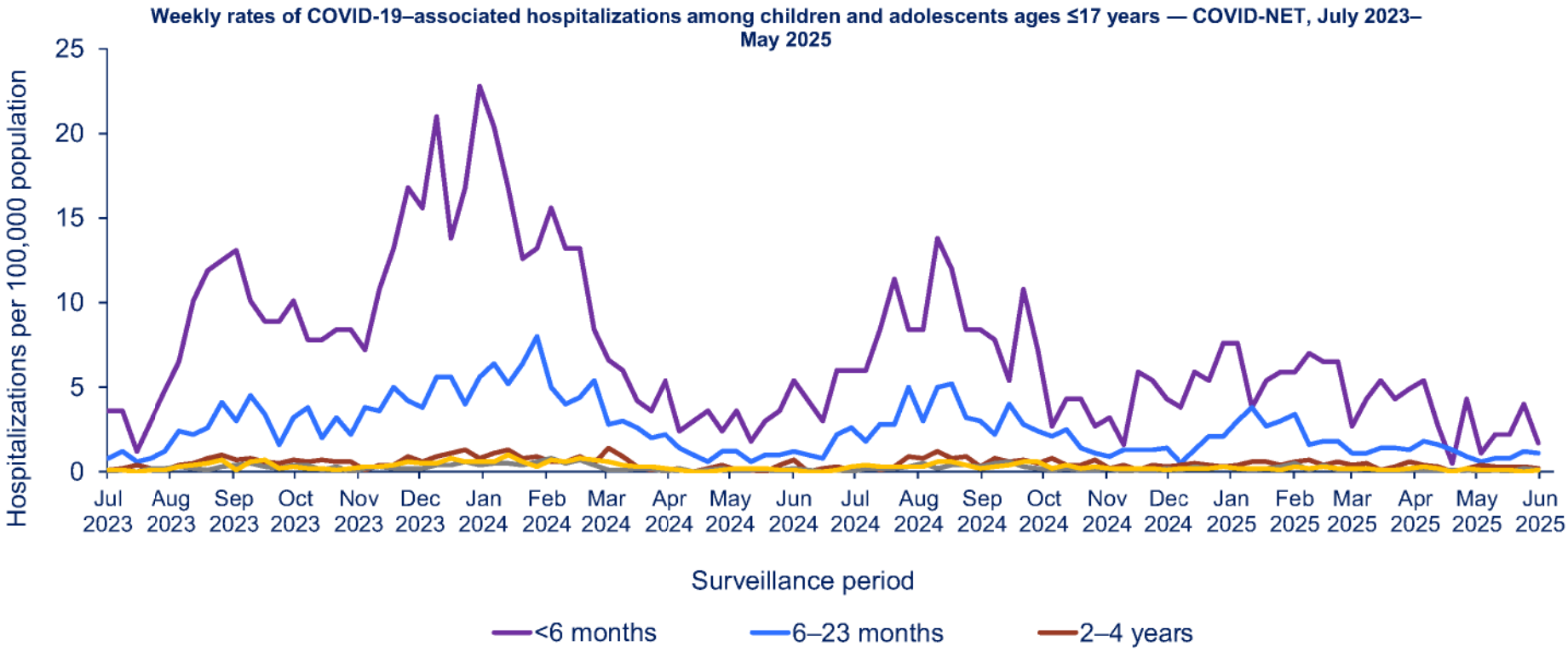
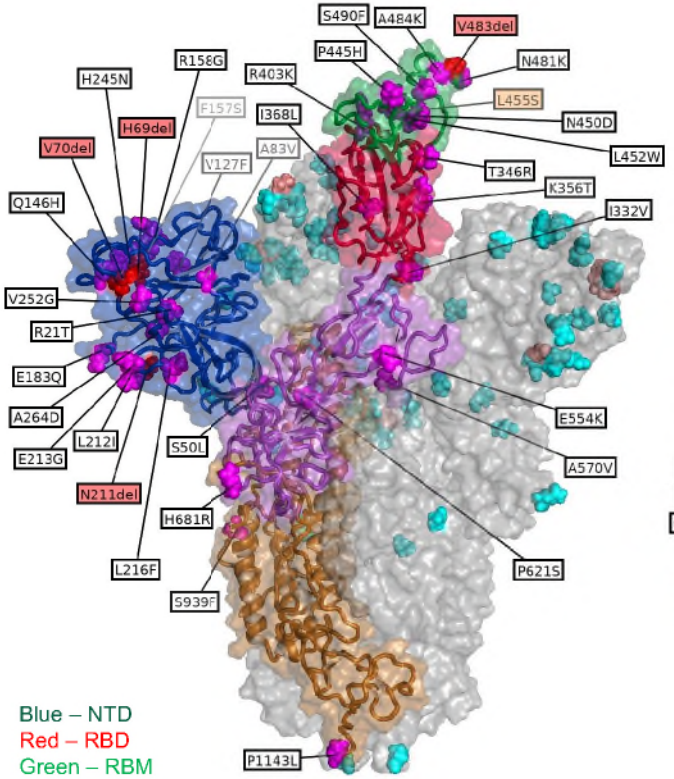


Figure displays weekly rates of COVID-19–associated hospitalizations among children and adolescents ages ≤17 years — COVID-NET, July 2023–May 2025.
Note that rates are not adjusted for testing. Rates are not limited to admissions where the respiratory infection is the likely primary reason for admission.

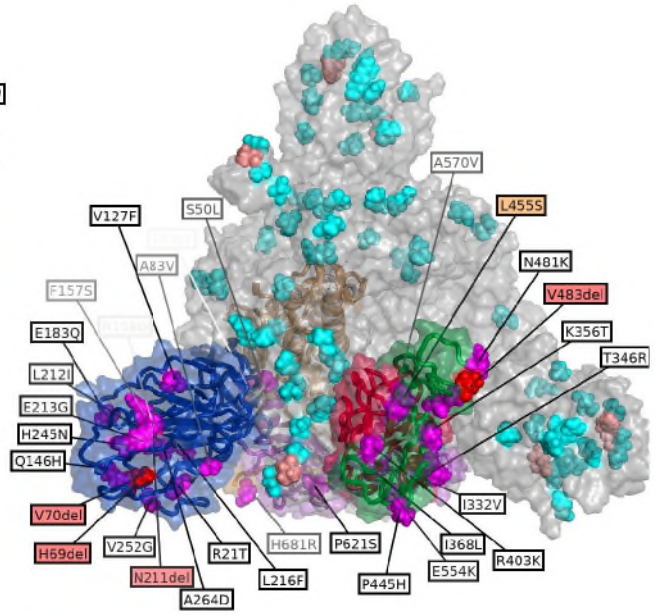
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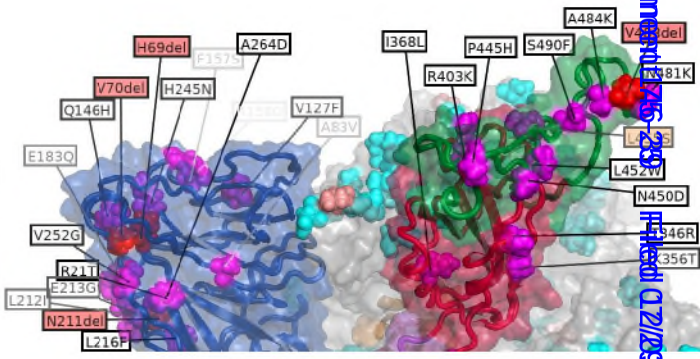
Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

Structure of XBB.1.5 vs. JN.1 spike



Blue – NTD
Red – RBD
Green – RBM
Purple – S1
Gold – FCS
Brown – S2





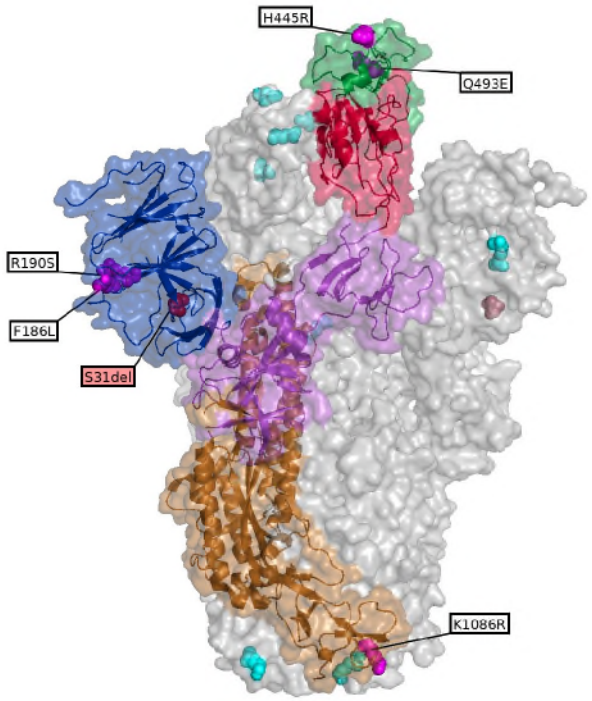
Red sphere – deletions in one chain (labeled)
Magenta sphere – substitutions in one chain (labeled)
Raspberry sphere – deletions in rest 2 chains
Cyan sphere – substitutions in rest 2 chains

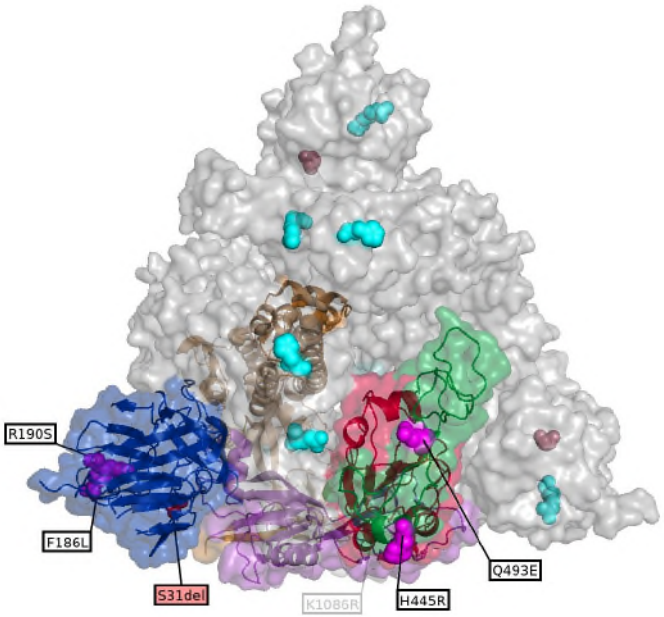
Schrodinger homology model of JN.1, starting with 7YR2 (BA.2.75)
Prepared by CDC: Megha Aggarwal, PhD

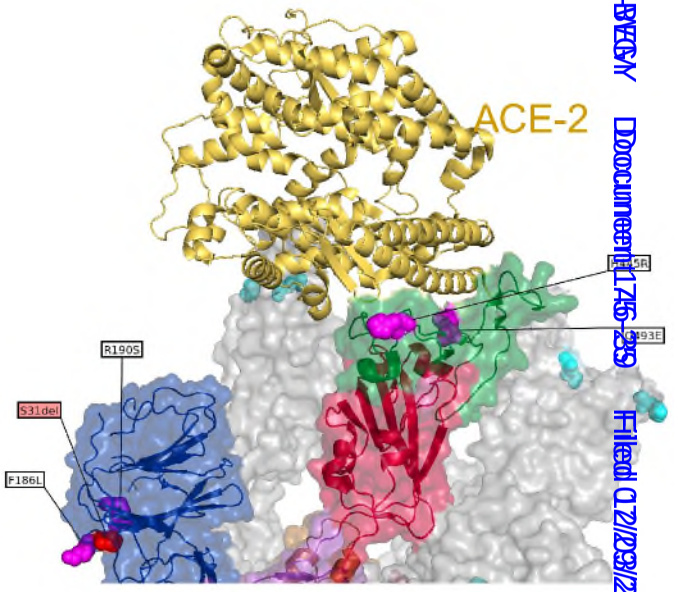
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Docusign Envelope ID: 5B19DDD4-BFBF-460F-90EE-EDA8E40D12EC

LP.8.1, the lineage that predominated this spring, has limited spike substitutions in comparison to KP.2







Blue – NTD
Red – RBD
Green – RBM
Purple – S1
Gold – FCS
Brown – S2

Red sphere – deletions in one chain (labeled)
Magenta sphere – substitutions in one chain (labeled)
Raspberry sphere – deletions in rest 2 chains
Cyan sphere – substitutions in rest 2 chains

Structure of JN.1 (PDB ID: 8Y5J)

Structure of JN.1 in complex with ACE-2 (PDB ID: 8YZE)

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COVID-NET Summary

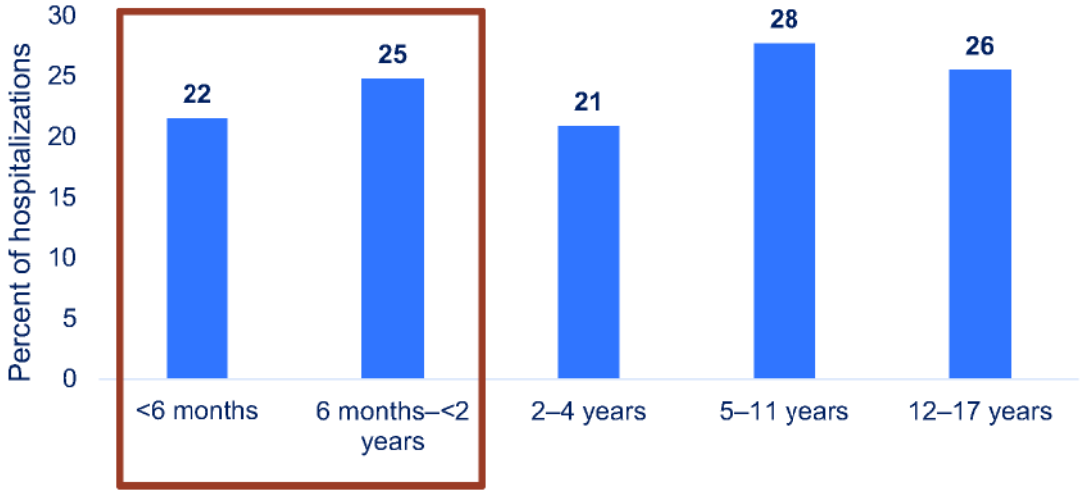
- **COVID-19 is estimated to have resulted in more than 250,000 hospitalizations since October 2024.**
- **Among children, rates of COVID-19–associated hospitalizations are highest among children ages <2 years.**
  - 89% of children ages 6 months–17 years admitted for COVID-19 had no record of recent COVID-19 vaccination
  - 1 in 5 children aged <2 years admitted for COVID-19 are admitted to the ICU
    - Of those ages <2 years admitted to the ICU, 53% had no underlying medical conditions
- **Among adults, rates of COVID-19–associated hospitalizations are highest among adults ages ≥75 years.**
- **65% of adults ages ≥65 years hospitalized with COVID-19 had no record of receiving ≥1 dose of the recommended 2024-25 COVID-19 vaccine prior to hospitalization.**
- **Most adults ages ≥18 years hospitalized for COVID-19 have ≥1 underlying medical condition.**
- **Among SARS-CoV-2-positive pregnant women admitted during April 2024–March 2025 with COVID-19-related symptoms on admission**
  - 50% had no underlying medical condition
  - 92% have no record of COVID-19 vaccination since July 1, 2023

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~1 in 4 children and adolescents hospitalized for COVID-19 are admitted to the intensive care unit (ICU)

Percent of children and adolescents with COVID-19–associated hospitalizations admitted to the ICU, by age group — COVID-NET, April 2024–March 2025



Age category	Among those admitted to ICU, % with no underlying conditions
<6 months	62%
6–23 months	48%
2–4 years	23%
5–11 years	19%
12–17 years	16%

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

Among children <2 years admitted to ICU, most did not have underlying medical conditions

Hospitalizations are limited to those with COVID-19 as the presenting complaint upon admission. Pregnant adolescents ages 15–17 years are excluded from proportions presented.

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