Immunization Update and ACIP Highlights - June 2025

July 2, 2025

The Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control (CDC) met on **June 25-26, 2025 ,** for its regular triennial vaccine meeting. For archives of minutes and slides, go to the ACIP meeting website. See page 4 for "No Votes: Evaluations & Discussions" and page 6 for "ACIP Committee Restructure."

Votes to Recommend or Approve

- **Influenza Vaccines:** ACIP approved the 2025–2026 influenza vaccine recommendation statement, which includes the trivalent vaccine composition for the upcoming season, an expanded age indication for Flublok from 18 years and older to 9 years and older, and FluMist for self- or caregiver-administration.
- **Thimerosal in Multi-Dose Influenza Vaccines:** ACIP voted to remove recommendations for multi-dose influenza vaccines containing thimerosal for administration to children, pregnant women, and adults.
- **Respiratory Syncytial Virus (RSV) Vaccine —**Maternal/Pediatric: Clesrovimab RSV monoclonal antibody was added as a recommended option for RSV prevention to be administered to infants younger than age 8 months born during or entering their first RSV season, one dose preferably in the first week of life. Clesrovimab was approved for use in the federal Vaccines for Children (VFC) program.

Questions about immunization?
Please contact Tamara Sheffield, MD, MPA, MPH, Medical Director, Immunization Programs, Intermountain Healthcare, at **801-442-3946**.

Details Supporting Votes: June 2025 Meeting

Influenza Vaccines

The 2024–2025 influenza season was classified as a high severity in all age groups and was the first high-severity season since the 2017–2018 season with an estimated 56 million illnesses and 770,000 hospitalizations. Rate of hospitalization was the highest since the 2010–2011 season. So far, there have been 246 pediatric influenza–associated deaths in the 2024–2025 season. Of those who died and were vaccine eligible, 89% were not fully vaccinated.

The estimated morbidity averted by influenza vaccination this season is 12 million illnesses and 240,000 hospitalizations, with the greatest level of disease averted in those ages 65 and older.

Flublok (recombinant influenza vaccine, trivalent; RIV3).

Presentation by Sanofi Pasteur. This presentation reported on an immunogenicity-bridging trial comparing a cohort ages 9 to 17 years to persons ages 18 to 49 years. Immune response geometric mean titer (GMT) ratios and seroconversion rates of those 9 to 17 years were non-inferior to those ages 18 to 49 years with no substantial difference in the safety profile of the two age groups. In March 2025, the U.S. Food and Drug Administration (FDA) approved Flublok for use in children and adolescents ages 9 to 17 years.

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Details Supporting Votes, Continued

The 2025–2026 season influenza vaccine recommendations are the same as the recommendations from the 2024–2025 season with three updates:

1. Influenza vaccine composition for the 2025–2026 season;
2. Inclusion of FluMist (live attenuated influenza vaccine, trivalent; LAIV3) for self- or caregiver-administration; and
3. Change in age indication for Flublok (recombinant influenza vaccine, trivalent; RIV3) from 18 years and older to 9 years and older.

ACIP voted to reaffirm the annual influenza vaccine recommendation for the 2025–2026 influenza season: 6 votes yes and 1 abstention.

Thimerosal

Thimerosal is a mercury-based preservative used in multi-dose vaccines that prevents microbial growth. The use of thimerosal as a preservative in vaccines has markedly declined due to reformulation and development of vaccines supplied in single-use presentations.[1]

Presentation by Lyn Redwood, RN. Lyn Redwood is the former president of Children's Health Defense, which is an organization founded by Secretary Kennedy and considered to be vaccine skeptical. She made an unprecedented presentation "as a private citizen" concerning thimerosal in vaccines, which was not reviewed by CDC staff prior to the meeting for inaccuracies or bias. In prior ACIP meetings, presentations not prepared and presented by CDC staff have previously been vetted by CDC staff. Ms. Redwood proposed that thimerosal is:

- An ineffective preservative at vaccine concentration levels
- Converted to inorganic mercury in the brain at higher levels than methyl mercury
- Neurotoxic
- A developmental and reproductive toxicant

Her conclusion stated, "Removing a known neurotoxin from being injected into our most vulnerable populations is a good place to start with Making America Healthy Again."

The FDA ex-officio member commented after the presentation that multi-dose influenza vaccine is the only vaccine approved for use in children and pregnant women that would potentially contain thimerosal. All other vaccines, including all vaccines on the child immunization schedule do not contain thimerosal.

Some committee members expressed concern about cumulative exposure to mercury. Dr. Kulldorff stated that due to the amount of single-dose influenza vaccine available on the market, it is feasible not to use thimerosal-containing influenza vaccines.

Liaison organization representatives expressed concern that the topic of thimerosal in vaccines had already been evaluated and decided over 20 years ago with decades of research showing no evidence of harm with use of thimerosal. They felt bringing it up again as a topic was a distraction that would increase mistrust in vaccines. **American College of Physicians** president, Dr. Jason Goldman, expressed serious concern over the presentation process and the proposed votes on thimerosal. He said many of Ms. Redwood's and committee members' statements were opinion and made without scientific evidence. Dr. Goldman asked if a CDC presentation containing peer-reviewed research would be offered or would the only presentation on the topic be "made by a lay person." **The American Pharmacy Association** liaison also asked if the CDC would provide a formal Evidence to Recommendation (EtR) presentation prior to a vote. None was provided.

The ACIP chair stated that future ACIP meetings will have comments by "a variety of people." He stated it was inappropriate to dismiss a presentation just because that presenter does not have an MD or a PhD, that the

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Details Supporting Votes, Continued

committee wants to hear from a variety of viewpoints, and it will continue to do so in future meetings.

Three votes on thimerosal were proposed and read to the committee by the committee chair. Those recommendations were not presented to the committee by the Influenza Work Group, and it did not appear that they were proposed by CDC staff.

Intermountain Health uses only single-dose vial vaccine preparations; thus, these recommendations will NOT modify current practice.

All three statements were approved with 5 votes yes, 1 vote no, and 1 abstention. They read:

1. ACIP recommends children receive influenza vaccine only in single-dose preparations that do not contain thimerosal as a preservative.
2. ACIP recommends pregnant women receive influenza vaccine only in single-dose preparations that do not contain thimerosal as a preservative.
3. ACIP recommends all adults receive influenza vaccine only in single-dose preparations that do not contain thimerosal as a preservative.

RSV Vaccines and Immunizations Maternal/Pediatric

The ACIP voted to recommend clesrovimab, a second, long-acting monoclonal antibody to protect infants against RSV. Approved by the FDA in June, this can be administered to infants younger than age 8 months born during or entering their first RSV season. Votes were 5 to 2 in favor of recommending clesrovimab. Dosage is 105mg/0.7mL, intramuscular single injection with no difference in dose by infant weight.

Other recommended options (only one can be used) for first-season infant protection are:

- **Nirsevimab:** A long-acting monoclonal antibody for infants younger than 8 months as well as for use in the second RSV season for high-risk infants ages 8 through 19 months.
- **RSV vaccine ABRYSO:** Approved for pregnant mothers during weeks 32–36 gestation; only a single pregnancy is approved.

An advantage to having clesrovimab as a second monoclonal antibody on the market is that viral resistance in one can be offset by continued effectiveness of another option since nirsevimab and clesrovimab target different binding sites.

Effectiveness: In the 2024–2025 season, maternal immunization and infant monoclonal antibody protected 57% of infants. **For nirsevimab:**

- Product effectiveness in the VISION and NSVN study sites was 79–82% against hospitalization.
- Two population-based surveillance networks showed a 31–38% reduction in RSV-associated hospitalization rates in infants ages 0–7 months during the season. Reduction of hospitalization was greatest among infants ages 0–2 months at 46–47%.

Safety: ABRYSVO is not associated with acute safety outcomes, preterm birth, small for gestational age at birth, or stillbirth. Maternal vaccine ABRYSVO is associated with a small but statistically increased risk for hypertensive disorders of pregnancy (HDP). Some Work Group members were concerned about the increased risk for HDP, but other Work Group members and ACOG were unconcerned because the effect size was small and the HDP severity was similar between vaccinated and unvaccinated women based on rates of C-section, hospital admission after birth, and length of stay.

Safety for nirsevimab is reassuring with no serious adverse outcomes noted. Among 74,000 doses administered, there have been no cases of anaphylaxis and only a small number of cases of allergic urticaria.

For infants born October through March, long-acting monoclonal antibodies should be administered in the first week of life, ideally during the birth hospitalization. Increased birthing hospital enrollment in the VFC program and improved early supply of monoclonal antibody should provide greater protection from RSV in the upcoming season.

No Vote : Evaluations & Discussions

COVID-19 Vaccines

COVID-19 continues to cause extensive morbidity and mortality in the U.S. CDC estimates 270,000–440,000 hospitalizations and 32,000–51,000 deaths from COVID-19 during October 1, 2024–June 7, 2025. Peak infections have occurred in both the winter and summer.

In May 2025, per the U.S. Department of Health and Human Services (USHHS) directive, the CDC updated COVID-19 vaccine recommendations to shared clinical decision-making for healthy children ages 6 months through 17 years and "no guidance/not applicable" for pregnant women.

The current Chief Medical and Scientific Officer of the FDA, Vinay Prasad, MD, MPH, and FDA Commissioner Martin Makary, MD, MPH co-authored a paper in the *New England Journal of Medicine* on May 20, 2025, proposing a risk-based approach to COVID-19 vaccines for persons ages 6 months through 64 years and recommending that all adults ages 65 and older be vaccinated.[2] To define those at risk, they used the CDC's 2025 list of underlying medical conditions that increase a person's risk for severe COVID. The list is quite broad and includes pregnant persons and recently pregnant persons.

During the June 2025 ACIP meeting, CDC reported that infants less than age 6 months have the same rate of hospitalization due to COVID-19 as persons ages 65–74 years, and for infants ages less than 6 months who were recently hospitalized, 22% were admitted to the ICU and 71% had no underlying medical conditions, and only 3.5% had any record of maternal vaccination during pregnancy. Because vaccine is not approved for these infants, their only protection comes from maternal antibodies passed in utero, emphasizing the need for maternal vaccination. CDC presented epidemiology supporting maternal COVID-19 vaccination to protect both the mother and infant, and 2024–2025 vaccine effectiveness against hospitalization was greater than 50% in pregnant women.

In a presentation of vaccine effectiveness (VE) for the 2024–2025 formula from the VISION and IVY networks, VE was:

- 28–36% for adults in preventing ED/urgent care visits
- 32–53% against hospitalizations for adults
- 43–70% for critical illness

The vaccine was also effective for immunocompromised adults. These relative VE results show added protection due to a dose of the most recent formula vaccine compared to a real-world control population of persons who already have immunity due to previous vaccines or infections but were not vaccinated with the most recent formula.

In May, the FDA approved Novavax's NUVAXOID (2024–2025 Formula) and Moderna's MNEXSPIKE (2024–2025 Formula, lower dose 10mcg/0.2mL) for persons ages 12 through 64 years at high risk for severe COVID-19 and all adults ages 65 years and older. Due to post-marketing safety data, FDA has added risk of myocarditis and pericarditis, particularly in males ages 12 through 24 years, as a precaution to its label for COVID-19 mRNA vaccines.

Current circulating viruses are JN.1 descendants and are antigenically similar to each other. The FDA's Vaccines and Related Biological Products Advisory Committee met to discuss strain selection for the 2025–2026 COVID-19 vaccines, and the FDA then advised manufacturers that 2025–2026 Formula COVID-19 vaccines should be monovalent JN.1-lineage-based, preferentially using the LP.8.1 strain.

The COVID-19 Work Group presented a risked-based recommendation option for COVID vaccine in the April 2025 ACIP meeting that included full recommendation for ages 6 through 23 months, high-risk recommendation for those with underlying medical conditions including pregnancy for those ages 2 through 64 years, and a 2-dose recommendation for those ages 65 and older and immunocompromised. Due to the removal of the prior ACIP committee members, the Work Group was unable to meet to create a final recommendation to bring to ACIP for vote in the June meeting. No future COVID-19 vaccine vote was

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No Vote: Evaluations & Discussions, Continued

mentioned, but there is a proposed September/October ACIP meeting on the ACIP website that could be used for a COVID vaccine vote. Implications are unknown if an ACIP vote does not occur in connection with the new 2025–2026 formulation, given the May 2025 HHS directive for changing the vaccine schedule without an ACIP vote.

CDC clinical considerations and recommended doses presented at the June ACIP meeting have essentially not changed for the 2024–2025 COVID-19 vaccine except for shared clinical decision-making to occur for persons ages 6 months through 17 years.

ACIP committee members were critical of the case-control, test-negative study design that is standardly used by the CDC for determining real-world vaccine effectiveness and advocated for greater placebo-control post-marketing studies.

Chikungunya Vaccines

Chikungunya vaccines are recommended for use in travelers and laboratory workers. Evidence to recommend for use in U.S. territories and states at risk of the virus-like particle and live, attenuated chikungunya vaccines will be presented at a future meeting. In the meantime, there is a safety pause issued by the CDC and FDA against use of live-attenuated vaccine for those ages 60+ while awaiting FDA investigation of serious adverse events.

Anthrax Vaccine Work Group

A workgroup is being formed to evaluate the use of licensed anthrax vaccine adsorbed, adjuvanted (AVA,A: Cyfendus) for domestic post exposure prophylaxis (PEP).

Measles Mumps Rubella (MMR) and Varicella Combination (MMRV) Vaccine and Febrile Seizures

In 2009, the CDC recommended administration of separate MMR and varicella vaccines as preferred to the MMRV combination vaccine (PROQUAD) for ages 12 to 47 months for the first dose, but either separate vaccines or the combination vaccine may be administered. There is an excess incidence of fevers and febrile seizures in the 7 to 10 days post-vaccination with MMRV vaccine in infants ages 12 to 23 months.

The ACIP committee chair, Dr. Martin Kulldorff, presented this topic and proposed that since there exists a safe, equally effective alternative of using separate MMR and varicella vaccines, that the ACIP should recommend that MMRV vaccine not be administered to children under age 47 months. The committee plans to discuss this at a future meeting.

Meningococcal ACWY Vaccine

Pentavalent Meningococcal ACWY + Meningococcal B vaccine (Men ABCWY:Penmenvy®) was licensed in February 2025, and its use was recommended by the ACIP in their April 2025 meeting. In the absence of a CDC director, that recommendation has not been ratified by the USHHS secretary.

Meningococcal vaccines were not discussed in the June 2025 ACIP meeting.

Respiratory Syncytial Virus (RSV) Vaccines – Adults

The FDA has expanded the approved age indication for mResvia® RSV vaccine to include at-risk persons ages 18–59 years. There was no discussion of adult RSV vaccines in the June 2025 ACIP meeting.

In its April 2025 ACIP meeting, the committee voted to approve the use of one lifetime dose of Abrysvo® and Arexvy® RSV vaccines in persons at risk for lower respiratory disease caused by RSV ages 50 through 59 years. In the absence of a CDC director, that recommendation has not yet been ratified by the USHHS secretary.

Anticipated Vaccine Topics – Deferred

Votes had been anticipated for HPV vaccine recommendation changes, pneumococcal vaccine recommendation clarifications, and outbreak recommendations for adolescents for Mpox vaccine. Those topics were not addressed in the June 2025 ACIP meeting.

U.S. Measles Update

No update was provided.

ACIP Committee Restructure

On **June 9, 2025**, USHHS secretary, Robert Kennedy Jr. announced that he had removed all 17 current voting members of the ACIP. The ACIP Executive Secretary, who is the federal officer for the ACIP, was also replaced.

Secretary Kennedy appointed eight new committee members of the ACIP. Prior member selections included a nomination process with extensive vetting by the CDC and ratification by the CDC director. One of the new committee members resigned prior to the June 2025 meeting, leaving seven voting members. Those new members include:

- **Martin Kulldorff, PhD, Chair** — Biostatistician and epidemiologist, focus is vaccine safety, worked with Vaccine Safety Datalink, co-author of Great Barrington Declaration concerning COVID restrictions
- **Joseph Hibbeln, MD** — Psychiatrist, former Chief of Section on Nutritional Neuroscience at NIH
- **Retsef Levi, PhD** — Operations management at MIT, risk management, decision support for vaccine safety
- **Cody Meissner, MD** — Pediatric professor at Dartmouth, peds ID epidemiology, former ACIP member and VRPAC member
- **Robert W. Malone, MD** — Vaccine development: cell-based influenza vaccines, mRNA delivery
- **Vicky Pebsworth, PhD, RN** — Director of research National Vaccine Information Center – vaccine safety
- **James Pagano, MD** — Retired ER physician

The 11 current Work Groups will continue their work. Work Groups are not allowed to meet without an ACIP member present; therefore, the COVID vaccine work group was unable to meet to formulate a recommendation for vote in the June 2025 meeting. New chairs are being appointed to Work Groups.

The new ACIP chair is proposing two new work groups:

1. The first Work Group is to study the cumulative effects of the child and adolescent vaccine schedules, examining coadministration, number of vaccines, timing of doses.
2. The second Work Group is to review vaccine recommendations, which have not been reviewed in the past seven years, such as newborn Hepatitis B vaccine and 12– to 15-month MMR vaccine.

The American Academy of Pediatrics (AAP) has publicly expressed concern over the potential negative impact of ACIP changing pediatric vaccine schedules as well as MMR and Hep B recommendations.

References:

1. U.S. Food & Drug Administration. *Thimerosal and Vaccines*. FDA Website. Updated January 15, 2025. **https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/thimerosal-and-vaccines#:~:text=Thimerosal%20is%20a%20mercury%2Dcontaining,into%20the%20vaccine%20during%20use**. Accessed June 26, 2025.
2. Prasad V, Makary MA., An evidence-based approach to Covid-19 vaccination. *NEJM*. 2025;392:2484-2486. Available at: **https://www.nejm.org/doi/full/10.1056/NEJMsb2506929**. Accessed June 26, 2025.

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