Immunization Update and ACIP Highlights - September 2025

October 7, 2025

The Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control (CDC) met on **September 18–19, 2025,** for its regular triennial vaccine meeting. For archives of minutes and slides, go to the ACIP meeting website and click on "Meeting Materials." Below are the key highlights including an overview of ongoing ACIP committee restructuring on **Page 7**.

Key Meeting Highlights

Votes to Recommend or Approve

- **Measles, Mumps, Rubella, and Varicella (MMRV) Vaccine**

  ACIP recommends not administering the combination MMRV vaccine in children ages 12 through 47 months and instead to administer separate MMR and varicella vaccines due to concerns about an increased risk of febrile seizures with MMRV. Previously, separate vaccines for that age group were recommended.

- **Vaccines for Children (VFC Resolution) – MMRV Vaccine**

  Based on alignment with ACIP recommendations, VFC will not cover MMRV vaccine for children ages 12 through 47 months. The resolution to change VFC program coverage to match the new ACIP recommendation was initially voted down, which would have resulted in allowing VFC coverage for children under age 4 years. The resolution was reconsidered the next day and was approved.

- **Hepatitis B Vaccine**

  The committee voted that pregnant women should be tested for hepatitis B infection. A second proposed vote was presented to not recommend a birth dose of hepatitis B vaccine to an infant whose mother tests negative for hepatitis B surface Antigen. That proposed vote was tabled due to the committee's desire to further discuss the evidence.

- **COVID-19 Vaccines**

  ACIP voted to recommend FDA-approved COVID-19 vaccines to persons ages 6 months and older based on individual-based decision making/shared clinical decision making and emphasized that the benefit for those ages 6 months through 64 years is greatest in those who are at high risk of severe COVID disease as outlined on the CDC's list of risk factors.[1]

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

Meeting Details

MMR and Varicella Combination (MMRV) Vaccine (PROQUAD®)

ACIP voted to not recommend combination MMRV for children ages 12 months through 47 months. The current committee elevated the prior recommended preference for separate vaccines to a full recommendation based on reinterpretation of available data; no additional safety or effectiveness data informed the changes.

Liaison members objected that there was no formal Evidence to Recommend (EtR) presentation to provide the public with potential benefits and harms of the revision as well as no analysis of implementation feasibility, acceptability by stakeholders, and considerations of equity.

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Meeting Details, Continued

The vote to not recommend MMRV shifts away from parent/provider choice and potentially reduces access. Commercial insurance will not be required to cover MMRV vaccine for ages 12 months through 47 months due to lack of ACIP recommendation, but payers can choose whether to cover the vaccine. MMRV continues to be preferred for ages 4 years and older according to prior ACIP recommendation.

Prior to vaccine development, measles, mumps, rubella, and varicella caused significant disease burden in the U.S. Vaccine introduction against these viruses has resulted in:

- Elimination of endemic measles in 2000
- Elimination of endemic rubella in 2004
- A 99% decline in mumps cases by early 2000
- A 97% decline in varicella incidence by 2019

In 2005, the Federal Drug Administration (FDA) approved the MMRV combination vaccine (PROQUAD). It is considered to have equal protection against measles, mumps, rubella, and varicella, although it contains more varicella antigen than varicella vaccine (VARIVAX®) to achieve equal immunogenicity.

Febrile seizures occur in approximately 1 per 3,000–4,000 MMR doses administered to children ages 7 years and younger. Due to evidence of double the incidence of febrile seizures in the 7 to 10 days post-vaccination with MMRV vaccine in infants ages 12 to 23 months, the ACIP recommended in 2009 a preference for administering separate MMR and varicella vaccines rather than the MMRV combination vaccine (PROQUAD) for the first dose in ages 12 to 47 months. The CDC guidance stated that unless the parent or guardian expresses a preference for MMRV vaccine, providers should administer separate MMR and varicella vaccines.

Currently, prior to this recommendation, MMRV accounts for 15% of first dose measles, mumps, rubella and varicella vaccination in children ages 19–35 months, and 75% of second dose administration at ages 4–6 years.

With a potential of up to seven doses of vaccines recommended at the 12-month well child visit, some parents opt for the combination vaccine to decrease the number of injections given. The updated recommendation removes that option.

VFC Resolution for MMRV Vaccine Voted Against

The Vaccines for Children (VFC) program is a federally funded program that provides free vaccines to children who are covered by Medicaid, are uninsured, or are American Indian/Alaska Natives (AI/AN) as well as to some underinsured who receive care at a Federally Qualified Health Center (FQHC).

VFC vaccines must be recommended by ACIP to be covered by the program. When ACIP makes a vaccine recommendation, VFC program presents a resolution to the ACIP to align the program qualifications with the ACIP recommendation. For the first time (by a vote of 8 “No,” 1 “Yes,” and 3 “Abstain”), the ACIP committee initially voted against the VFC resolution to align with their newly revised MMRV recommendation. This would have resulted in:

- The prior MMRV VFC resolution standing
- The MMRV vaccine being covered by the VFC program for children ages 12 months through 12 years.

Committee members expressed confusion about the initial proposed vote. Because of their lack of experience with ACIP, some members did not understand the VFC resolution process and voted against the resolution. Others who voted against the resolution may have been trying to maintain VFC coverage even though they had voted against recommending the vaccine for those under age 4 years.

ACIP unanimously overturned the initial vote the next day of the meeting and approved the VFC resolution to cover MMRV vaccine only for children 4 years through 12 years.

Centers for Medicare & Medicaid Services (CMS) coverage is dictated by ACIP recommendation. Therefore, coverage criteria by the CHIP program, and by individual and small group market plans would have differed from VFC coverage if the VFC resolution had not been approved.

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Meeting Details, Continued

Hepatitis B Virus (HBV) Vaccine

Two votes were proposed regarding birth dose hepatitis B vaccine; that:

1. "All pregnant women should be tested for hepatitis B infection." The committee voted to recommend.
2. "The pediatric vaccine schedule should be updated to reflect the following change:

   If a mother tests HBsAG-negative:

   — The first dose of hepatitis B vaccine is not given until the child is at least one month old.

   — Infants may receive a dose of hepatitis B vaccine before one month according to individual-based decision-making.*

   *Also referenced as shared clinical decision making."

   After much debate, the second vote was tabled due to the committee's desire to further discuss the evidence.

Debate revolved around two questions:

1. **What had stimulated the desire to change this recommendation at this time; had a safety signal stimulated this analysis?** — There was no safety signal. The chair stated that he proposed the question together with the CDC. Committee member Robert Malone explained that the signal stimulating this analysis is, "...not one of safety – it is one of trust." The committee believed that:

   — Not enough informed consent occurs with birth-dose hepatitis B vaccine

   — The benefit and risk in infants born to hepatitis B-negative mothers should be reevaluated since fears about giving a newborn a vaccine had been expressed by some of the population,

   Several liaisons objected, saying that evidence, not fear, should be driving the work of the committee.

2. **Why was one month chosen as the time to vaccinate infants with their first dose?** — Shifting first vaccination timing to age one month was selected because that is the current recommendation for the next recommended dose at 1–2 months. Stratified data does not exist that would indicate any gradient of adverse risk events at one month or two months or beyond.

   Committee members brought forward the argument that many other countries do not start hepatitis B vaccination until later, but most of those countries have universal health coverage with higher rates of maternal hepatitis B testing and follow-up preventive care. In the U.S., 15% of mothers do not have prenatal hepatitis B screening.

CDC-PRESENTED EVIDENCE AGAINST RESCINDING HEPATITIS B BIRTH DOSES

The CDC presented the potential risks of rescinding universal hepatitis B birth-dose recommendations:

- Increased cases of perinatal HBV transmission
- Increased administrative complexity and failure points for providers and health systems
- Lack of safety net given gaps in access to perinatal care, HBV screening and hepatitis B immune globulin (HBIG) access
- Disproportionate harm to uninsured patients or those with low healthcare engagement
- Lower rates of hepatitis B childhood vaccine series completion
- Higher lifetime healthcare costs from missed opportunities to prevent and eliminate hepatitis B

The single benefit to rescinding the recommendations was a potential reduction in the rare cases of hepatitis B vaccine adverse events. CDC presented that anaphylaxis occurs in 1.1 cases per 1,000,000 doses. While there are few local or systemic reactions seen post vaccination in newborns, some members were concerned about fevers, irritability, crying, and poor feeding.

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Meeting Details, Continued

HEPATITIS B PREVALENCE DATA AND POSITIVE OUTCOMES OF BIRTH DOSES

Up to 2.4 million people are infected with hepatitis B virus in the U.S., and 50% are unaware that they are infected. Persons born outside the U.S. account for 70% of those infected.

Hepatitis B is highly infectious. When children are born to hepatitis B virus-infected mothers:

- 85% will become infected without intervention (vaccination and HBIG administration).
- 90% of infants perinatally infected will develop chronic hepatitis B.
- 25% of children infected with hepatitis B virus will die prematurely due to cirrhosis or liver cancer.

Hepatitis B virus can remain infectious for 7 days on a surface at room temperature, and infants can be infected by household or community contacts, not just perinatally. Prior to hepatitis B birth-dose vaccine, 7–11% of infants born to immigrant mothers without hepatitis B infection became infected.

Since ACIP recommended hepatitis B universal birth dose in 1991, cases have dropped by 88% as compared to 2023, the last year of data collection.

COVID-19 Vaccines

ACIP voted to recommend FDA-approved COVID-19 vaccines to all persons ages six months and older based on individual-based decision making/shared clinical decision making, They emphasized that the benefit for those ages 6 months through 64 years is greatest in those who are at high-risk of severe COVID disease as outlined in the ***CDC's Underlying Conditions and the Higher Risk for Severe COVID-19***, including pregnancy and recent pregnancy.

Three other statements proposed and voted on were:

1. A recommendation for CDC to expand risk information in its communications, including in the Vaccine Information Statement (VIS) form. The statement reads, "It is the sense of the committee that the CDC engages in an effort to promote more consistent and comprehensive informed consent processes, and as part of that considers adding language accessible to patients and providers to describe at least the six risks and uncertainties included in the work group chair presentation." That vote passed.

   These risks and uncertainties presented reflect the opinions of the work group chair and are not necessarily factual or evidence-based, particularly those statements that appear in bold type below:

   - Current assessments regarding the protection provided by COVID-19 vaccines and especially seasonal COVID-19 boosters against severe outcomes (e.g., death, hospitalization and long COVID) are of **low quality**. At best, the additional protection provided by a seasonal booster is moderate and of short duration.
   - There is evidence that repeated seasonal mRNA boosters cause acquired changes in the immune system and **may be associated with increased vulnerability to future infections**, including SARS-CoV-2 and other respiratory viruses. These risks, as well as potential risks of **autoimmunity, chronic inflammation, immune tolerance, and impaired immune surveillance** including immune fatigue or suppression, are currently not well understood.
   - There are documented deaths from symptomatic and subclinical myocarditis, pericarditis, and potentially

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New COVID-19 Work Group Members:

- Retsef Levi PhD has been appointed as Chair of the COVID-19 vaccine work groups.
- Robert Malone MD and James Pagano MD are new members.

Meeting Details, Continued

other cardiovascular conditions post COVID-19 vaccination, **including of healthy children, with probable causal relationship to the mRNA vaccines**. This risk is likely relatively small but currently not well understood.

- Clinical reports demonstrate that in some cases COVID-19 vaccines can cause prolonged and debilitating **post vaccine syndrome** (PVS). The injuries associated with PVS involve diverse symptoms and conditions, many overlapping with long COVID injuries. Some of the observed symptoms and conditions may include insomnia, chronic pain and fatigue, dysautonomia (e.g., POTS), immune dysregulation and deficiency, autoimmune disorders, severe neuropathy and other neurodegenerative conditions, cardiovascular and neurovascular injuries, and severe clotting. The frequency of PVS and related risk factors are currently not well understood.
- There is evidence that in some individuals vaccinated with mRNA COVID-19 vaccines, **the resulting spike protein, the mRNA and the nano-lipids formulation components persist in different body organs, including lymph nodes and the heart, for a prolonged period of months and possibly years in some patients.** Prolonged and persistent exposure to spike, mRNA, and nano-lipids particles is associated with PVS injuries as well as potentially other side effects that are currently only partially understood.
- The safety and the efficacy of COVID-19 vaccination during pregnancy have never been tested in appropriately powered randomized clinical trials. In one randomized trial there was observed numerical imbalance of higher number of babies with congenital malformation among those born to vaccinated women.

Some discussion attempted to clarify or refute these statements, but there was not much time between their presentation by Dr. Levi and the vote, not allowing them to be properly vetted.

2. A proposed aspirational statement outlining what should be included in informed consent also passed. It reads:

   "It is the sense of the committee that in conversations with patients before COVID-19 vaccination, authorized healthcare providers discuss the risks and benefits of the vaccination for the individual patient. The discussion should consider known risk factors for severe outcomes from COVID-19, such as age, prior infections, immunosuppression, and certain comorbidities identified by the CDC, and include a discussion of the potential benefits and risks of vaccination and related uncertainties, especially those outlined in the vaccine information statement, as part of informed consent."

3. A recommendation that state and local jurisdictions require a prescription for administration of COVID-19 vaccine did not pass. The vote was 6 "Yes" and 6 "No," but the tie was broken by the Dr. Kulldorff, the ACIP chair, rejecting the recommendation.

CDC COVID-19 EPIDEMIOLOGICAL PRESENTATION

This research presented by CDC staff focused on vaccine coverage, location of administration, and vaccine effectiveness (VE).

Vaccine coverage in the past year was highest in those ages 65 and older at 44.1%. Approximately 13% of children between 6 months and 17 years of age were up to date with COVID vaccination at the end of April 2025. Approximately 40% of health care workers received the vaccine, and approximately 50% of physicians were vaccinated with the 2024–2025 COVID-19 vaccine.

The National Immunization Survey reported that 67.3% of adults surveyed who received a COVID vaccine in the last year, reported receiving it at a pharmacy.. The American Pharmacists Association conducted billing code analysis and found that 90% of COVID-19 vaccines were administered at a pharmacy.

Vaccine Effectiveness (VE) for preventing infant hospitalization due to COVID-19 ages 0 to 2 months via maternal vaccination prior to birth was 54% during

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Meeting Details, Continued

March 2022 through May 2023. A VE of 54% means in a vaccinated population, 54% fewer people will have the outcome of interest when they are exposed to the virus compared to an unvaccinated population.

Dr. Levi objected to test negative case control methodology for determining VE.

After epidemiologic presentation by CDC staff, some committee members were concerned that current epidemiologic surveillance overestimates the number of hospitalizations, severe outcomes, and death attributable or "due" to COVID-19 rather than "with" a COVID-19 infection. CDC explained the algorithm they use to identify attributable outcomes. Of hospitalizations among SARS-CoV-2-positive patients in the past year, 87% were due to COVID-19 based on reason for admission.

New members of the COVID-19 Work Group were invited by the work group to present. Wafik El-Deiry, MD, PhD, FACP from Legoretta Cancer Center at Brown University and Charlotte Kuperwasser, PhD from Tufts University School of Medicine discussed uncertainties around mRNA vaccines including:

- Immune changes after vaccination leading to persistent cytokine changes and risk of persistent or recurring infections
- Biodistribution of vaccine components
- Genetic frameshifting
- Impurity identification in vaccine lots with temporal association with cancers

These uncertainties were proposed to need more study, but funding for mRNA research has been pulled. For example, Bruce Carlton from University of British Columbia was studying genetic markers that might be related to the risk of myocarditis development, but his study funding was cancelled this spring.

DATA ON COVID-19 VACCINE COST EFFECTIVENESS

As the incidence of COVID infections has decreased, the number needed to vaccinate (NNV) to avert disease has increased and COVID vaccination has become less cost-effective. The NNV is low and consistent among age and risk groups at 12–16 doses needed to avert a case of COVID-19 infection. But the NNV to avert hospitalizations and death differs widely by age and risk. For persons ages 65 and older who are high-risk, the NNV to prevent a hospitalization is 296 doses at a cost of $21,344. NNV increases to 778 at a cost of $102,729 when those 65 and older are not high-risk The NNV high-risk persons 65 and older to avert a single death is 5,642 and costs $400,000, while the NNV to avert a death in a non-high-risk adult ages 18–49 years is 1.1 million doses at a cost of $195 million.

The Incremental Cost-Effectiveness Ratio in dollars per quality adjusted life year (QALY) saved has doubled from estimates presented last year and ranges from $43,537/QALY for high-risk ages 65 and older, to $498,000 for non-high-risk ages 18–49.

Ongoing ACIP Committee Restructure

Committee Membership

U.S. Department of Health and Human Services (HHS) Secretary Kennedy appointed these five additional committee members to the ACIP:

- **Hilary Blackburn, PharmD, MBA** – First pharmacist to serve on the ACIP; works at AscensionRx and hosts a podcast, Talk to Your Pharmacist
- **Evelyn Griffin, MD** – Obstetrics/gynecology, lifestyle medicine, and functional medicine practitioner
- **Kirk Milhoan, MD, PhD** – Pediatric cardiologist with focus on myocardial inflammation, who is an affiliate of the Independent Medical Alliance
- **Raymond Pollak, MD, FACS, FRCS** – Transplant surgeon and transplant immunobiologist
- **Catherine Stein, PhD** – Epidemiology professor at Case Western University who has written that the risks of COVID-19 have been overstated

In the committee chair's opening statement, Dr. Martin Kulldorff reported that you should trust scientists who will debate the issues. He reported that it was regrettable that the American Academy of Pediatrics was unwilling to attend the meeting and invited them to debate him. He commented on the statement by nine former CDC directors published by the New York Times on **September 1, 2025**, which said that the new ACIP committee members were, "...unqualified individuals who share [Secretary Kennedy's] dangerous and unscientific views." Dr. Kulldorff invited those former CDC directors to debate him.

Procedural Concerns

Throughout the meeting, liaison members and agencies presenting during public comment continued to advocate fora systematic evidence-based process using Evidence to Recommend (EtR) and GRADE methodologies for synthesizing vaccine recommendations, for presentations to the publicand forgaining confidence of the medical community. They pressed the chair to tell them what process would be used to formulate recommendations, but Dr. Kulldorff did not provide a framework or process that would be followed.

Work Groups

Liaison members of the ACIP committee have been removed from the 11 current committee work groups. When that occurred in August, the reason given was to eliminate bias. When asked during the meeting about reasons for liaison members removal, Dr. Kulldorff referenced the Federal Advisory Committee Act (FACA) as the policy dictating liaison members removal because they represent their agencies, not themselves. He said that ACIP was previously not in compliance with FACA, and liaisons were removed to comply.

The chair announced two new work groups to:

1. Review vaccines in pregnancy
2. Study the cumulative effects of the whole child and adolescent vaccine schedule, examining coadministration, number of vaccines, and dose timing.

REFERENCE:

1. Centers for Disease Control and Prevention (CDC). *Underlying Conditions and the Higher Risk for Severe COVID*. CDC.gov. February 6, 2025. https://www.cdc.gov/covid/hcp/clinical-care/underlying-conditions.html. Accessed October 7, 2025.

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