Immunization Update and ACIP Highlights - December 2025

January 7, 2026

The Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control (CDC) met on **December 4–5, 2025,** to discuss hepatitis B vaccine birth dose, and other potential issues impacting the Child/Adolescent Vaccine Schedule. For archives of minutes and slides, go to the **ACIP meeting website**.

Past Meeting Highlights:

- September 2025
- June 2025
- April 2025

Key Meeting Highlights

Votes to Recommend or Approve

- **Hepatitis B Vaccine.** ACIP voted to recommend:
  - Changing the hepatitis B (Hep B) vaccine birth dose from routine to individual-based decision making for infants born to mothers known to be hepatitis B surface antigen (HBsAg) negative
  - Not administering the first dose of the series prior to age 2 months for those infants.
  - There was no change in recommendations for infants born to HBsAg positive mothers or where mother's HBsAg is unknown. The acting CDC director ratified this recommendation.
- **Hepatitis B Antibody Test.** ACIP voted to suggest that parents consult with their provider about drawing blood from their infant to test for hepatitis B antibody levels prior to administering subsequent doses of the 3-dose series. The CDC has not yet accepted this testing recommendation, which remains under review.
- **Hepatitis B Vaccine VFC Resolution.** ACIP voted to support a revised Vaccines for Children (VFC) Resolution to align the wording with the hepatitis B vaccine birth-dose recommendation. VFC coverage of the hepatitis B vaccine will not change due to these votes.

At this time, there are no changes recommended to vaccine protocols at Intermountain Health. Intermountain Health facilities will continue to offer hepatitis B vaccine to all newborns, regardless of maternal antibody status.

Parent/guardians should be informed that, if they request antibody testing between doses of the primary 3-dose series, those tests may not be covered by insurance.

The information provided concerning the ACIP recommended changes to the vaccine schedule is for informational purposes only.

Details Informing Votes: December 2025 Meeting

The child/adolescent vaccine schedule work group evaluated the hepatitis B vaccine schedule for this meeting and proposed the voting language. The newly restructured work group consisted of:

- Four ACIP members
- Two consultants (a U.S. general pediatrician and global health physician from Denmark)
- The ex officio representative from FDA who spent time practicing in Denmark and made a presentation on the Danish vaccine schedule.

The standardized Grading of Recommendations, Assessment, Development and Evaluation (GRADE) process and Evidence to Recommendations (EtR) decision-making framework previously used by the ACIP

Continued on page 2...

Select Health

Details Informing Votes, Continued

were not used. No framework for the presentation of evidence was established or used.

After revamping three initial votes on hepatitis B vaccine for children proposed on the first day of the meeting, on the second day of the meeting, two votes and a preamble were proposed and accepted regarding birth-dose hepatitis B vaccine and serologic testing during the primary 3-dose series:

> **Preamble** "There will be no change to the vaccination recommendation for infants born to women who test HBsAg-positive or have an unknown HBsAg status – existing recommendation remains the same.
>
> **"VOTE 1** For infants born to HBsAg-negative women: ACIP recommends individual-based decision making, in consultation with a health care provider, for parents deciding when or if to give the HBV vaccine, including the birth dose. Parents and health care providers should consider vaccine benefits, vaccine risks, and infection risks. For those not receiving the HBV birth dose, it is suggested that the initial dose is administered no earlier than 2 months of age.
>
> (1) Parents and health care providers should also consider whether there are risks, for example, such as a household member is HBsAg-positive or when there is frequent contact with persons who have emigrated from areas where Hepatitis B is common."
>
> **"VOTE 2** When evaluating the need for a subsequent HBV vaccine dose in children, parents should consult with health care providers to determine if a post-vaccination anti-HBs serology testing should be offered. Serology results should determine whether the established protective anti- HBs titer threshold of ≥10 mIU/mL has been achieved. The cost of this testing should be covered by insurance."

On **December 16, 2025**, the acting CDC director ratified the recommendation to change the hepatitis B birth dose to an individual-based decision-making recommendation for infants of HBsAg negative mothers. The second recommendation to offer serology testing between doses is still under consideration by the CDC.

In the **September 2025** ACIP meeting, the proposed hepatitis B vaccine recommendation vote was tabled to consider questions by committee members including:

- What had stimulated the desire to change the recommendation at this time?
- Was a safety signal initiating a change?
- Why, if the birth dose was not given, should the initial dose be given at age 2 months?

Evidence to answer those questions was not provided at the December meeting.

Concerning Vote 1, the beliefs of the work group that proposed the revised Hepatitis B birth-dose recommendations include:

- CDC predictive models are overestimating the prevalence of Hepatitis B, and the risk of horizontal transmission to young children is overstated.
- The U.S. universal birth-dose recommendation is an outlier from other low-prevalence countries. U.S. prevalence is 0.5% (the CDC expert counterpoint is many countries without universal birth dose are moving toward that recommendation).
- Parents should be able to decline vaccination and are not given the opportunity or information to make an informed decision (the counterpoint is current recommendations already allow parents to decline).
- While the CDC hepatitis B vaccine experts declare there are no known risks associated with the vaccine, the possibility of unknowns should be considered.
- Although CDC experts report that a targeted approach was not sufficient to protect all infants in part due to system failures, the work group feels that a targeted approach is sufficient and system failures should be fixed.

Continued on page 3...

Details Informing Votes, Continued

- Parsimony (providing the lowest number of doses and antigens) and the desire to focus on the individual and their risk or benefit should take precedence over desire for virus elimination or consideration of the collective risks and benefits to the population. The work group does not believe that universal vaccination will eliminate the virus.

No evidence was presented to support why two months should be the recommended age of first-dose administration to infants of HepBsAg-negative mothers rather than younger as the current schedule recommends and the FDA label approves.

Concerning Vote 2, less time was available to discuss this recommendation to advise parents of the option to draw the infant's blood to test for seropositivity after the first or second dose of the three-dose series.

A serum hepatitis B surface antibody level (anti-HBs) of 10 mIU/mL is considered an indicator of long-term immune protection against Hepatitis B virus after a completed hepatitis B vaccine series. Studies of long-term protection have been conducted in those who received a 3-dose series. **No data was presented by the work group on persistence of protection** if persons have only received one or two doses of the initial three-dose series, even if anti-HBS levels of ≥10 mIU/mL were achieved after a dose.

Among healthy infants, 25% achieve anti-HBs levels ≥10 mIU/mL following the first dose and 63% achieve anti-HBs levels ≥10 mIU/mL after the second dose. The 3-dose HepB vaccine series produces a protective antibody response (anti-HBs ≥10 mIU/mL) in approximately 95% of healthy infants overall (the response is lower for infants with lower birth weights).

ACIP members in favor of the recommendation to test between doses indicated that testing could also be used after a three-dose series to see if the infant would be one of the 5% not achieving a seroprotection level after administration of an initial series.

ACIP committee members opposed to the recommendation to offer serologic testing objected that no evidence was presented to support the recommendation, declared the recommendation had no merit, was "made up," and called it a "never-never land" proposal.

ACIP voted to align the Vaccines for Children (VFC) resolution to match the new recommendations; the alignment does not change access to HepB vaccine for eligible infants and children.

It is likely that parents could be responsible for the serology testing cost. Federal law only requires insurance to cover vaccinations recommended by ACIP. Although ACIP voted to recommend that insurance cover infant serology testing for HBs antibodies, public and private insurance has no requirement to follow that recommendation.

CMS INFORMATION PRESENTED ON PUBLIC AND PRIVATE INSURANCE COVERAGE FOR VACCINES

Coverage of vaccines is anchored to ACIP recommendations, and the adult and pediatric vaccine schedules based on those recommendations. Both state Medicaid programs and the Children's Health Insurance Program (CHIP) are required to cover all vaccines recommended by CDC/ACIP included on the immunization schedules without cost sharing for most beneficiaries. Recommendations included on the immunization schedules that refer to shared clinical decision making (also known as individual-based decision making) are mandatorily covered in both Medicaid and CHIP.

The Vaccines for Children program provides federally purchased vaccines to children through age 18 who are either enrolled in Medicaid, are uninsured, underinsured, or American Indian/Alaska Native. Each state runs a VFC program according to CDC guidelines, typically through the state health department, and makes state coverage decisions. Coverage under the VFC program is based on the information included in the VFC resolution approved by ACIP. If language about shared clinical decision-making is included in the VFC program, then shared clinical decision-making is covered by the VFC program.

Continued on page 4...

Details Informing Votes, Continued

Vaccine coverage flexibility for public and private insurance includes:

- **Public Programs:** States have flexibility to determine Medicaid/CHIP coverage beyond mandatory coverage anchored to the ACIP/CDC recommendation that is not on the pediatric vaccine schedule. Any recommendation that narrows the criteria will lead to variable coverage across state Medicaid and CHIP programs. If states opt to provide expanded coverage, they will receive federal match for the full scope of coverage. States may not need approval from CMS to provide coverage beyond the ACIP recommendation.
- **Private Programs:** Non-grandfathered, employer-sponsored plans and non-grandfathered group and individual health insurance coverage are required to cover all ACIP-recommended vaccines for routine use without cost-sharing including recommended vaccines on the pediatric vaccine schedule.

With respect to employer-sponsored and individual health insurance coverage (as opposed to self-insured employer-sponsored plans governed by ERISA), states may impose benefit mandates, including vaccination mandates, that are more expansive than Federal requirements.

Plans and issuers are required to continue to cover the vaccine in a manner consistent with the current recommendation for the duration of a plan or policy year before the applicable plan or policy year of the new recommendation, unless doing so would pose a significant safety concern.

Although serology testing has been recommended by ACIP, public and private insurance is not required to cover that testing.

ADDITIONAL TOPICS

Additional presentations included a review of the evolution of the child/adolescent vaccine schedule by Andrew Siri, a lawyer specializing in vaccine injury lawsuits, a presentation on Denmark's vaccine schedule that recommends fewer vaccines than the U.S., and an overview of adjuvants.

ACIP Committee Restructure

Dr. Martin Kulldorff, the chair for the June and September meetings, has been appointed as the chief science officer with the U.S. Department of Health and Human Services, and has stepped down as chair, leaving 11 members.

Kirk Milhoan, MD, PhD, a pediatric cardiologist with focus on myocardial inflammation, who is an affiliate of the Independent Medical Alliance has been appointed as the Chair of the ACIP. He was traveling during the meeting and intermittently attended. Robert Malone, Vice Chair of the ACIP, acted as chair during this meeting.

Tracy Beth Hoeg, MD, PhD, FDA ex officio representative to ACIP and newly appointed acting director of FDA's Center for Drug Evaluation and Research was added to the Child/Adolescent Vaccine Schedule Work Group. She presented and was frequently asked to comment during the meeting.

RESOURCES:

1. Mast E, Margolis H, Fiore A, et al. A comprehensive immunization strategy to eliminate transmission of Hepatitis B virus infection in the United States—Part 1: Immunization of infants, children, and adolescents. *MMWR*. 2005;54(RR-16):1-23.
2. Schillie S, Vellozzi C, Reingold A, et al. Prevention of Hepatitis B virus infection in the United States: Recommendations of the Advisory Committee on Immunization Practices. *MMWR Recomm Rep*. 2018;67(No. RR-1):1–31.
3. Immunization Action Coalition. *IZ Express #1848*. **Immunize.org** website. Dec 10, 2025. https://www.immunize.org/news/iz-express/issue/1848/. Accessed January 15, 2026.

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

Select Health