Summary of Information

Childhood/Adolescent Schedule Workgroup
Hepatitis B Virus Vaccine Birth Dose
December 4, 2025

Overview

- Childhood/Adolescent Schedule Workgroup
- Workgroup Process
- Workgroup Findings
- Proposed Voting Language

Workgroup Members

ACIP members

Kirk Milhoan, MD, PhD
Martin Kulldorff, PhD
Evelyn Griffin, MD
Vicky Pebsworth, PhD, RN

Outside Experts

Brian Morse, MD, PhD,
Christine Stabell Benn, MD

Ex-officio

Tracy Beth Hoeg, MD, PhD

Policy Request

Assess the use of a universal birth dose of Hepatitis B vaccine in children whose mothers are HBsAg-negative.

(Which necessarily involves more than the birth dose.)

Terms of Reference Document

“Review the efficacy and safety of the immunization schedule for children and adolescents, identify efficacy and safety problems, and address stakeholder concerns.”

Motivation and Public Health Importance

- Feedback from stakeholders
- Misalignment with existing recommendations in most developed countries
- Prolonged time since last comprehensive review as per ACIP's charter

Workgroup Process

- September 18-19, 2025, ACIP Meeting

- Request to CDC for Additional Information to Address ACIP Questions
  16 questions: descriptive safety and data

- Workgroup Meetings
  Between 10/17/25 and 11/24/25, the workgroup met 7 times

- Workgroup Process - Presentations, Discussions, and Straw Polls
  12 presentations by CDC staff, workgroup members, and invited ad hoc experts that covered clinical ethics, non-specific vaccination effects, aluminum adjuvant exposures, clinical practice challenges and solutions, and the Alaska Hepatitis B vaccine trials.

Workgroup Findings: Areas of Full/Nearly Full Agreement (1)

- Hepatitis B virus can be transmitted **vertically and horizontally** to infants, is a serious disease, and can be **prevented by vaccination with the HBV vaccine**
- There is **uncertainty** about true rates of incidence, prevalence and horizontal **transmission rates**
- There is **uncertainty** about whether all **three recommended doses** are needed to acquire protection
- There are gaps in evidence and limitations related to **evidence of safety (per GRADE quality of safety evidence is poor)**

Workgroup Findings: Areas of Full/Nearly Full Agreement (2)

- Infants born to mothers who test **positive for HBsAg** should continue to be vaccinated with HBV vaccine and receive hepatitis B immunoglobulin soon after birth

- Any **gaps in screening** pregnant women for HBsAg should be eliminated so that all infants receive appropriate care

- **Re-screening** of pregnant mothers upon admission for delivery should be considered so that there are **no mothers whose HBsAg is "unknown"** which should be regarded as a serious quality of care problem, if not a medical error, and a "never event"

- Infants born to mothers who test **negative for HBsAg** have extremely low risk of horizontal infection during childhood and particularly in first months of life and therefore, do not need to be routinely vaccinated with the HBV vaccine at birth

Workgroup Findings: Central Themes Related to Hepatitis B Preventive Care

Improving Quality and Appropriateness of Hepatitis B Preventive Care

- screen all pregnant mothers (no unknowns), appropriately treat all newborns

Minimizing AEFI in Vulnerable Newborns

- avoid unnecessary early life exposures

Fostering Individual-based Decision-making and Respect for Parental Autonomy

- permit clinical flexibility and individual risk assessments

Improving Safety Monitoring and Research

- close evidence gaps

Modifying US Policy, Consider other Countries

- return to a targeted and successful strategy more in line with other developed countries with low endemicity

Evaluation of Voting Language Categories

- Universal Vaccination Option
- No Recommendation Option
- **Individual-based Decision-making Option**
  (preferred first choice for Workgroup members.)

Rationale for Preferring an Individual-based Decision-making Option (1)

- The overwhelming majority of infants born to mothers who test negative for hepatitis B surface antigen are not at high risk of being infected with the hepatitis B virus, especially in the first few months of life.

- The 1991 recommendation was made in error.

- Vaccine safety risks are not well understood and were never assessed appropriately.

- An individualized, risk-based approach is needed, with recommendations tailored to risk/benefit profiles and preferences and involve informed consent.

Rationale for Preferring an Individual-based Decision-making Option (2)

- It has the potential to allow the parent to choose a point in time closer to the onset of risky behaviors sometimes encountered in adolescence, and, for those who prefer to wait, the “catch-up” schedule could be used by those who delay until age 11.

- It also provides options for avoiding vaccinating in early infancy and adolescence when there are biological windows of vulnerability.

- Creates an opportunity to use serology testing to determine whether additional doses of vaccine are needed for protection.

- Could end disputes between parents of newborns, hospital staff and others who do not agree about administration of a birth dose, consent, and cease to be the “gateway to vaccine hesitancy.”

Rationale for Preferring an Individual-based Decision-making Option (3)

- Provides for a return of decision-making to parents in collaboration with the health care provider who wants to be able to recommend a flexible schedule and the ability to tailor care to individual needs, risks and preferences.

- Benefits of using two months for starting HBV vaccine series
    - the additional two months of maturation, as it relates to the blood-brain barrier, liver, and kidney function, is desirable.
    - is in line with the policy of other comparable countries
    - would permit the use of combination vaccines and limit the number of injections, as well as access to lower-aluminum-containing products.

Rationale for NOT Preferring an Individual-based Decision-making Option

- Concerns about rare exposures to the hepatitis B virus that could cause an infection and a chronic infection
- Concerns about acceptability to the medical and public health communities and others, media backlash, unfair treatment by medical boards
- The system that's in place that will be difficult to change
- It will take too much time to counsel patients about risks and benefits, and access to educational materials isn't obvious
- Concerns about liability, payments, additional paperwork
- The safety concern may be more theoretical than real

Implementation Considerations

- PEP in births to HBsAg+ mothers:
  - Strengthen maternal screening programs
  - Immigrant medical examination screening

- Delaying the timing of the first dose will allow choice of using different vaccines, monovalent and polyvalent

	Birth dose	2/4/6 month	4 years	8 years	12 years
Target groups	HBsAg+ only	All or high risk HHs	All	All	All
Vaccine type	Monovalent/poly valent mix	Polyvalent	Monovalent series	Monovalent	Monovalent

Implementation Considerations

- Even under the existing universal dose policy not all babies are vaccinated at birth with no detectable increase in incidence of HBV infections

- Data from the 2016-2021 Centers for Medicare & Medicaid Services (CMS) Transformed Medicaid Statistical Information System (T-MSIS)[1]

  Comments:
  - T-MSIS Analytic Files are research-optimized collection data submitted as part of state-level Medicaid submission.
  - Includes enrollment data, demographics, and service utilization.[2]
  - Hepatitis B antigen tests identified using Current Procedural Terminology [CPT] codes

[1] https://www.medicaid.gov/medicaid/data-systems/macbis/transformed-medicaid-statistical-information-system-t-msis/index.html

[2]https://www.medicaid.gov/medicaid/data-systems/macbis/transformed-medicaid-statistical-information-system-t-msis/t-msis-analytic-files

CMS Medicaid

- Pregnancies:
  - At least one ICD-10 diagnosis code ('O80', 'O81', 'O82', 'O83', 'O84', 'Z370', 'Z372', 'Z375') in inpatient or other service files

- Live Born Pregnancies:
  - At least one ICD-10 Diagnosis code ('O80', 'O81', 'O82', 'O83', 'O84', 'Z370', 'Z372', 'Z375')
  - Death not recorded during first hospitalization

Table 1: Receipt of HBV Vaccine Among Infants CMS Medicaid Births, 2016-2020

	Total Birth	% Total Births
Total Births	7,284,953	100%
Infants Receiving First HBV Dose by 2 yrs (0-730 days)	6,573,976	90%
Infants Receiving HBV Birth Dose (0-30 days)	5,076,855	70%

Age of First HBV Vaccination within first 730 Days

Age of First HBV Vaccination	Total Vaccinated	Total Vaccinated %
Birth Dose Received During Birth Hospitalization	4,966,112	76%
1 - 30 days	110,743	2%
31 - 180 days	1,289,749	20%
181 - 365 days	145,947	2%
365 - 730 days	61,425	1%
Infants Receiving First Dose by 2 yrs (0-730 days)	6,573,976	100%

Public Health and Vaccination Ethics

- **Markman, Putting Public Health Ethics Into Practice**
  - Expected health benefits for the target population
  - Potential harms and burdens for all stakeholders
  - Impact on autonomy
  - Impact on equity
  - Expected efficiency

- **Ethics of Vaccination**
  - Preserve Health
  - Means-end Proportionality
  - Discretion
  - Parsimony

- Marckmann G, Schmidt H, Sofaer N, Strech D. Putting public health ethics into practice: a systematic framework. Front Public Health. 2015 Feb 6;3:23. doi: 10.3389/fpubh.2015.00023. PMID: 25705615; PMCID: PMC4319377.

ACIP Childhood/Adolescent Immunization Schedule Workgroup

Vote Language, 12/3/25

VOTE 1

- ACIP recommends a birth dose of Hepatitis B virus (HBV) vaccine and Hepatitis B Immunoglobulin for infants born to women who test HBsAg-positive. ACIP recommends individual-based decision-making, in consultation with a health care provider, for parents deciding whether to give the HBV vaccine birth dose to infants born to women who are HBsAg-negative or whose HBsAg status is unknown. Parents should consult with health care providers and decide when or if their child will begin the HBV vaccine series.[1] 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. Y/N

VOTE 2

- When evaluating the need for 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 prior to subsequent HBV vaccine dose administration. 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. Y/N

[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.