Hepatitis B Virus Vaccine Birth Dose

Vicky Pebsworth, PhD, RN

Advisory Committee on Immunization Practice

Childhood/Adolescent Schedule Workgroup

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Presentation Overview

- Introduction and Policy Context
- Burden of Disease
- Efficacy
- Safety
- Conclusions

Introduction to Policy Context

Policy Request

- Assess the current recommended schedule, including the use of a universal birth dose of Hepatitis B Virus (HBV) vaccine in children whose mothers test negative for HBsAg at delivery

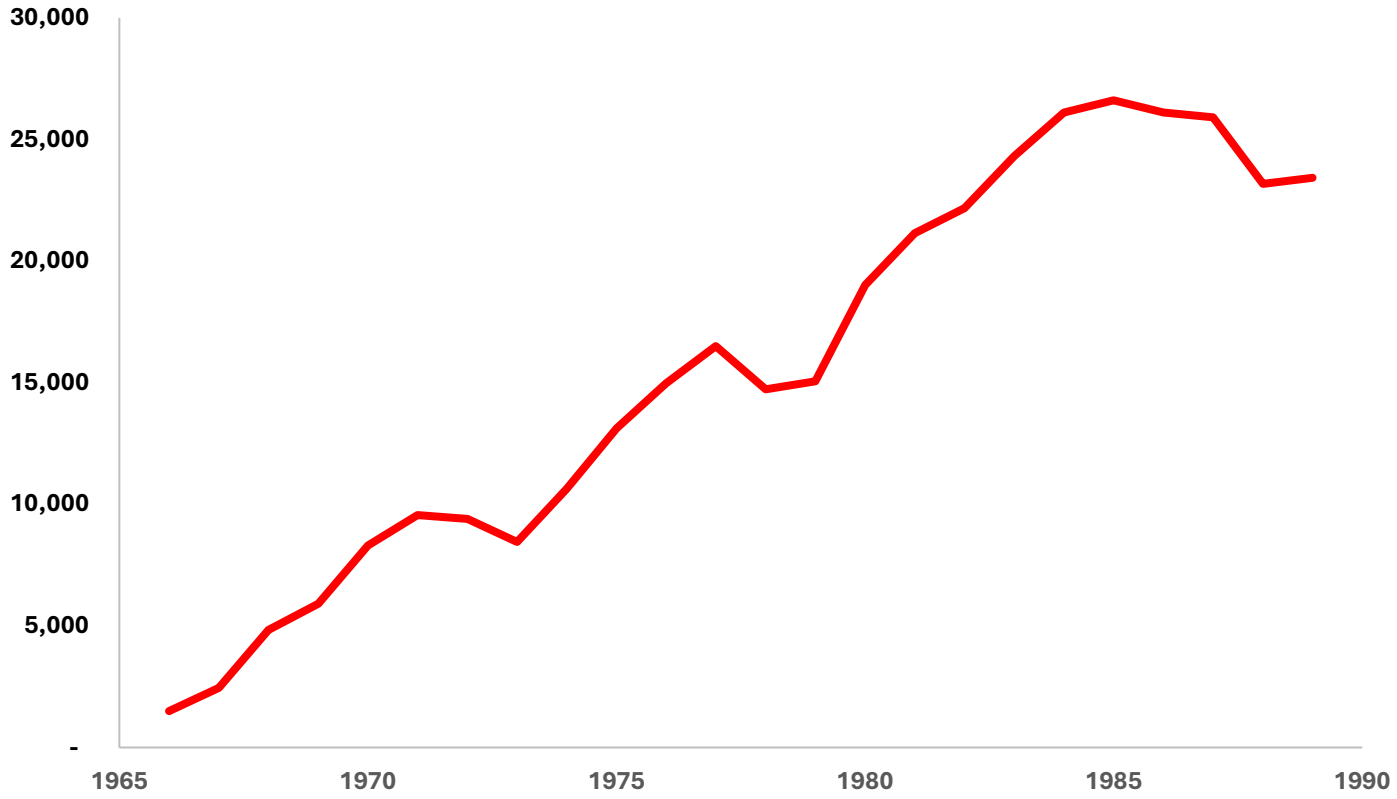
- **Why Are We Here Today?**

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

How Did We Get to Where We Are Now?

- Rising transmission of acute hepatitis from 1960s to the mid-1980s due to blood-borne exposures in high-risk groups
- Introduction of plasma-based vaccine in 1981, high-risk groups targeted
- Concerns over vaccine safety, technology changes, reduced liability
- Evolution of ACIP birth recommendations during the 1980s
- Dissatisfaction with targeting strategy, ambitious new strategy proposed
- Leap to universal birth dose made in 1991

Rapid Rise of Reported Acute U.S. Cases of Hepatitis B



Source: CDC National Center for HIV, Viral Hepatitis, STD, and Tuberculosis Prevention, Viral Hepatitis Division, Epidemiology and Surveillance Branch

Factors That Affected Policy Shifts

- New Vaccine Licensed in 1981
- Safety Concerns Related to Donor Source Material in Plasma-Derived Vaccine
- Availability of New Recombinant Technology Platform and Hepatitis B Antigen-based Product Manufactured in Yeast
- Approval of the National Childhood Vaccine Injury Act in 1986
- Policymaker Support

Worldwide Elimination of Hepatitis B Transmissions: We Have the Way, We Need the Will

JAMA, April 28, 1989—Vol 261, No. 16

Taken together, the accumulating data indicate that hepatitis B immunization efforts could eliminate the transmission of HBV infection worldwide. Hepatitis B immunization is unique because it prevents both acute illness as well as chronic diseases such as cirrhosis and primary hepatocellular carcinoma. If vaccinations were given universally at birth to infants in populations that have a high rate of perinatal HBV transmission, and with childhood immunizations to infants in other parts of the world, a worldwide cohort of persons protected from this long-term infection would be established.

In areas of the world where the rate of infection is high, it has been recommended strongly that hepatitis B immunization be integrated into existing childhood immunization programs.[1] In the United States, selective immunization of groups at risk of infection has not been effective in lowering the overall incidence of disease,[2] and immunization strategies targeted at both infants and adolescents also should be considered if we are to control this disease. The elimination of HBV transmission is a sizable undertaking that requires a substantial commitment of effort and resources. The cost of hepatitis B vaccine has been declining rapidly on the world market, making the resources required much less than previously estimated. The savings in terms of human suffering and medical expenditures are considerable and provide a convincing argument for the adoption of this disease prevention strategy. So why not do it?

Donald P. Francis, MD, DSc
Centers for Disease Control
Atlanta, Ga
California Department of Health Services
Berkeley
Harold S. Margolis, MD
Centers for Disease Control
Atlanta, Ga

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Evolution of ACIP Recommendations: Infant Target Groups, Treatments/Vaccines

ACIP meeting	Target group	Infant treatment	Vaccine type	Recommendation change logic
6/25/1982	Infants born to HBsAg+ mothers	First infant PEP • HBIG at birth • Vaccine at 3 months	Heptavax licensed 11/16/81 Recommended for high-risk groups	New vaccine licensed. Numerous risk groups targeted Infant treatment timing unclear
6/1/1984	Infants born to HBsAg+ mothers	Refined infant PEP • HBIG within 12 hours of birth • Vaccine with 7 days	Heptavax	1983 Lancet study tested 3 different dosing schedules w/HBIG & vaccine. Schedule B was the rec'n
6/7/1985	Infants born to HBsAg+ mothers	Concurrent PEP dosing • HBIG and vaccine <12 hours	Heptavax	1984 Lancet study finds no interference with HBIG and vaccine. 1985 JAMA study doses concurrently
6/19/1987	Infants born to HBsAg+ mothers	Concurrent PEP dosing • HBIG and vaccine <12 hours	Recombivax-HB licensed and recommended Heptavax	New vaccine licensed Concerns over plasma vaccine cited Concurrent dosing schedule kept
11/22/1991	Universal infant vaccination	Vaccination before hospital discharge, no later than 2 months, added to childhood schedule	Recombivax-HB Engerix-B	Concerns w/failure of targeted policy Safety in infant/child trials cited
12/23/2005	Universal infant vaccination	Vaccination within 12-24 hrs of birth	Recombivax-HB Engerix-B	Provide a "safety net" for medical errors Eliminate "flexible"/"inconsistent" practices

Motivations to Ask The Question? What Are We Trying to Accomplish Today?

- Address Stakeholder/Parent Dissatisfaction
- Report on the required periodic review conducted by the Workgroup
- Consider policies that:
  - are better aligned with other countries similar to ours
  - Are based on evidence and target the needs of high-risk persons and populations
  - Explicitly consider the principles of public health and vaccination ethics

The Importance of Stakeholders

- **Terms of Reference – IOM Stakeholder Concerns**

  2002 - *Multiple Immunizations and Immune Dysfunction*

  2013 - *The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies*

- **Stakeholder Surveys**

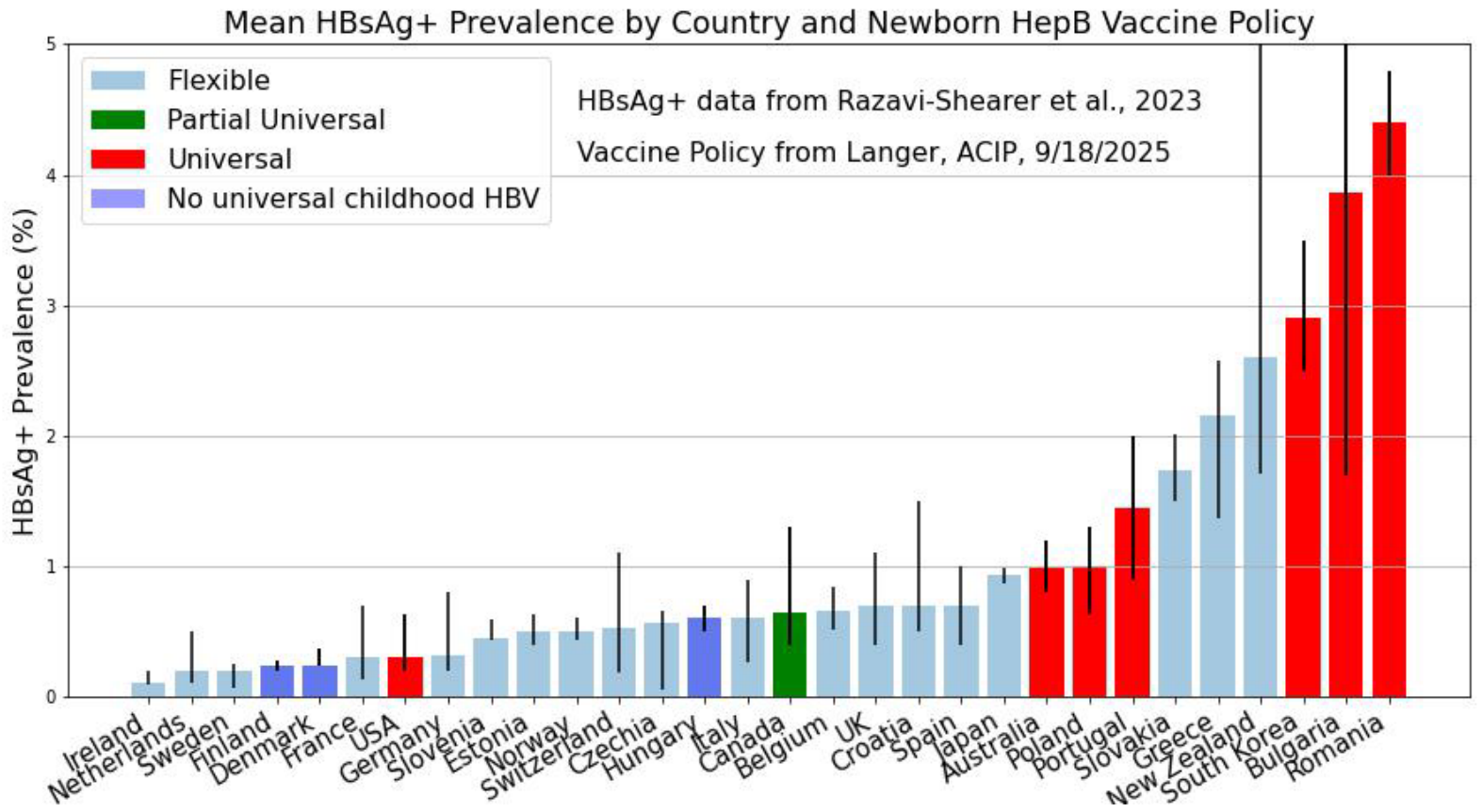
  Oregon Survey of Hepatitis B Vaccine Refusal in Newborns, 2014

  KFF/Washington Post Survey of Parents, 2025

Stakeholder Feedback

Oregon Survey 2014	KFF/Washington Post Survey 2025
• 5% Refused HBV birth dose • 8% wanted to wait • 6% were undecided. **Why?** • 78.1% baby was too young • 70.4 % vaccine safety concerns • 43.8% baby was at low risk of infection	• 13% skipped/delayed HBV • 16% skipped/delayed vaccines ---67% side effects concerns ---53% vaccine safety doubts ---51% vaccines not necessary ---42% not wanting multiple shots ---35% safety testing lacking ---26% CDC recommends too many vaccines ---41% want to space out shots ---58% little/no confidence in federal agencies

U.S. Birth Dose Policy is an Outlier Among Low-prevalence Nations



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.

Policy Context Summary (1)

- Causes of hepatitis B increases in 1970s-80s diminished with targeted measures
- Universal birth dose set out to eliminate worldwide transmission
- Other countries with similar incidence and prevalence of Hepatitis B use a selective vaccination practice, and not a universal birth dose
- Some parent stakeholder groups would like greater flexibility and the ability to decide what is best for their child.

Policy Context Summary (2)

- Stakeholder dissatisfaction has been documented for 25 years, is of societal significance, and creates challenges for immunization policymaking.
- The belief that universal vaccination can eradicate Hepatitis B was endorsed by leaders and shaped public policy.
- In response, between 1983 and 1991, ACIP recommendations shifted from an approach that only targeted high-risk infants to one that targets all infants.
- The context included the emergence of advanced vaccine technologies and fewer liability concerns.