ACIP Meeting Materials for Public Posting: Hepatitis B Birth Dose Briefing Document

Contents

1. Background

Introduction

Hepatitis B virus (HBV) infection can be transmitted from mother-to-child during pregnancy and delivery. Without any interventions, up to 85% of infants born to women with HBV infection acquire HBV infection. Perinatally acquired HBV infection has severe health and economic consequences: about 90% of infants perinatally infected with HBV will develop chronic hepatitis B, and 25% of people infected with HBV during childhood will die prematurely due to HBV-related complications including liver cirrhosis and liver cancer. (1, 2)

Up to 2.4 million people in the United States are estimated to have hepatitis B; about half of people with hepatitis B in the U.S. are unaware of their infection. About 75% of people with chronic hepatitis B in the United States were born in counties with intermediate and high prevalence of hepatitis B and predominantly were infected at birth or during early childhood. In the United States, decades of evolving hepatitis B vaccination recommendations among infants and children have shifted the epidemiology of acute hepatitis B cases from children to unvaccinated adults. In 2023, 14,400 acute hepatitis B cases were estimated to occur in the U.S., with the highest rates among adults aged 40-59 years; among reported cases of acute hepatitis B, only 26% reported an associated risk behavior, with 28% reporting no risk, and 46% missing data on risk factors. Unlike children, adults who acquire new HBV infection have higher viral clearance rates and lower risk for developing chronic infection. (3-9)

Hepatitis B vaccination is the cornerstone of hepatitis B prevention and control. The hepatitis B vaccine is the first anti-cancer vaccine and has been available in the United States for more than 40 years. Two types of products are available for prophylaxis against perinatal HBV infection: hepatitis B vaccine, which provides long-term protection against HBV infection and is recommended for both preexposure and postexposure prophylaxis; and hepatitis B immune globulin (HBIG), which provides temporary protection and is indicated only in certain postexposure settings. Two single-antigen hepatitis B recombinant vaccines are FDA-approved for the vaccination of persons starting at birth in the U.S.: Recombivax HB, approved in 1986 and Engerix-B, approved in 1989. Hepatitis B vaccination is a multidose series, typically consisting of 3 doses, with increasing seroprotection after each dose. Three doses of hepatitis B are needed to ensure full protection where 95% of healthy infants develop a protective antibody response

(anti-HBs ≥ 10 mIU/mL). When administered shortly after birth to infants born to HBsAg-positive women, hepatitis B vaccination and HBIG reduce mother-to-child transmission by 94%. (1, 10-13)

Prevention of perinatal or early life HBV infection underpins the recommendation for hepatitis B vaccination starting at birth. Since 1988, universal hepatitis B screening (with HBsAg) has been recommended for all pregnant women in the first trimester of pregnancy, as has testing later in pregnancy for women with risk behaviors and testing at delivery for women whose hepatitis B status is unknown. Hepatitis B vaccination has been recommended at birth for all infants born to women known to have HBV infection since 1984 (specified to within 12 hours of birth in 1988), and among all infants born to women with unknown hepatitis B status since 1991. Hepatitis B immune globulin has been recommended to be administered within 12 hours of birth for all infants born to women known to have HBV infection since 1984, and among infants born to women with unknown hepatitis B status since 2018. In 1991, the US adopted a strategy for universal hepatitis B vaccination of all infants. Beginning in 2005, the first dose of hepatitis B vaccine among infants born to HBsAg-negative women was recommended to be administered at the birth hospital; this was updated in 2018 to specify within 24 hours of birth. (1, 14-20)

In the context of these evolving hepatitis B vaccination recommendations among newborns and children, the number of reported US cases of acute hepatitis B has dropped 88% from 1991 (18,003 cases) to 2023 (2,214 cases). The United States' comprehensive strategy to prevent hepatitis B is based on: 1) routine testing of all pregnant women for HBsAg; 2) postexposure prophylaxis within 12 hours of birth with hepatitis B vaccine and HBIG of all infants born to women who are HBsAg-positive or HBsAg-status unknown; 3) universal vaccination of all infants beginning at birth; 4) routine vaccination of previously unvaccinated children, adolescents, and adults aged 19-59 years; and 5) vaccination of all adults at risk for HBV infection or who request vaccination. (1, 9, 20, 21)

Transmission, Natural History of Disease, and Associated Healthcare Costs

HBV transmission occurs through percutaneous or mucosal exposure to infectious blood or body fluids. The virus can remain viable for over 7 days on environmental surfaces at room temperature. The two primary sources of HBV infection among children are perinatal transmission from mothers with hepatitis B and horizontal transmission from infected household contacts. Prior to the widespread availability of postexposure prophylaxis (i.e., vaccine and HBIG within 12 hours of birth), the proportion of infants born to HBsAg-positive women who acquired HBV infection was as high as 85%. Children living with a person with chronic HBV infection in a household or community setting are also at risk and transmission rates have ranged to up to 11% in US settings. (1, 22-24)

Young children with acute hepatitis B rarely have symptoms, but 90% of infants who are infected with HBV become chronically infected. In contrast, among persons 5 years of age and older, fewer than 5% develop chronic infection. Since the risk of chronic infection increases with decreasing age, people who are infected in early childhood experience a disproportionately higher burden of disease attributable to chronic HBV infection. About 25% of individuals chronically infected during childhood will develop end

stage liver disease or liver cancer and die prematurely. Fulminant hepatitis occurs in ≤1% of acute infections, but the incidence of fulminant hepatitis B is higher in infancy than in other pediatric age groups. (1, 8, 21, 25-28)

Chronic HBV infection can progress to cirrhosis, hepatocellular carcinoma (HCC), liver transplant, and death. Based on US cancer data from the Surveillance, Epidemiology and End Results (SEER) Program, over 38,000 HCC cases were forecasted for 2020 and over 56,000 HCC cases were forecasted for 2030. HBV is an important cause of HCC, with 10% to 15% of patients with HCC attributed to HBV infection. The burden of US hepatitis B related hospitalizations is significant; each year, more than $1 billion is spent on hepatitis B-related hospitalizations, not including indirect costs such as poor quality of life, reduced economic productivity, long-term disability, and premature death. The estimated annual costs of treating one patient with hepatitis B in the United States, adjusted for inflation are up to $93,935 for those with less severe disease and up to $324,849 for those requiring liver transplant. (2, 29-33)

Hepatitis B is Vaccine Preventable with Robust Seroprotection

Hepatitis B vaccination is the most effective measure to prevent HBV infection and its consequences. The plasma-derived hepatitis B vaccine was licensed in 1981; recombinant hepatitis B vaccines replaced the plasma-derived vaccines in the U.S. by the late 1980's. Hepatitis B recombinant vaccines are available as a single-antigen formulation and in combination with other vaccines. Two single-antigen vaccines recommended for use in the United States, Engerix-B and Recombivax HB, are used for the vaccination of persons starting at birth. An extensive body of literature resulting from over more than 40 years of use in the United States and other countries demonstrates that the hepatitis B vaccines are safe and effective in protecting infants from hepatitis B. (1)

The efficacy of the hepatitis B vaccine alone in preventing perinatal transmission is ~75%. Hepatitis B immunoglobulin provides passively acquired anti-HBs and temporary protection (i.e., 3–6 months) and is generally used as an adjunct to hepatitis B vaccine in infants born to HBsAg-positive mothers and in certain other postexposure prophylaxis situations. The efficacy of HBIG alone is around 71%. When combined with the hepatitis B vaccine, the efficacy of HBIG and hepatitis B birth dose (HepB-BD) vaccine is 94%. The sooner the HepB-BD vaccine is provided after birth, the greater its effectiveness in preventing perinatal transmission. The optimal recommended timing is to provide the vaccine within 24 hours of birth, accelerated to within 12 hours if the maternal HBsAg status is positive or unknown. Unvaccinated infants remain at risk of non-perinatal HBV acquisition through exposure to a person with HBV infection in a household or community setting. HepB-BD provides protection for infants at risk from household exposure after the perinatal period. (1, 23, 24, 34, 35)

Among healthy infants, 25% and 63% achieve protective hepatitis B surface antibody levels after the first and second dose, respectively, however full protection is only achieved with the complete vaccine series. The 3-dose hepatitis B vaccine series produces a protective antibody response in 98% of healthy term infants, and 95% of healthy infants overall. Seroprotection from vaccination lasts for decades. In one

Alaska-based study, over 90% of primary responders were estimated to have protective immunity for more than 30 years after vaccination. (1, 11, 13, 28, 36-40)

Hepatitis B Birth Dose Provides a Critical Safety Net in the Prevention of Perinatal and Early Childhood Transmission

Universal HepB-BD provides a critical safety net for infants who may have unrecognized exposure(s) to HBV infection during pregnancy or early childhood due to a multitude of reasons resulting in gaps in protection against perinatal infection. Reasons for missed opportunities to prevent perinatal transmission include lack of prenatal care, where overall 15% of pregnancies receive inadequate or no prenatal care (where inadequate care is defined as care after the 4th month of pregnancy and includes less than 50% of visits). Additionally, missed opportunities arise from gaps in maternal screening implementation, incorrect screening tests performed, errors in interpreting the screening test or the transcription of the screening test, lapses in providing standard of care postexposure prophylaxis, and acute/window period infection. Gaps in perinatal HBV testing during pregnancy indicate 12-16% of pregnant women in the United States had no record of being tested for HBsAg, with lower testing rates among Medicaid-enrolled women. Further, despite a robust national perinatal hepatitis B prevention program, the program identifies less than one-half of infants estimated to be born to HBsAg-positive women each year, highlighting a critical gap in identifying perinatally exposed infants. Case reports of the medical outcomes for perinatally exposed infants demonstrate the catastrophic impact when universal HepB-BD is not fully implemented. (41-47)

Infants who receive HepB-BD are more likely to complete their vaccination series and had a positive impact on rates of being up to date for other age-appropriate vaccines. Additionally, there is a risk for horizontal transmission in the household from persons who are not aware of their infection status; 50% of people in the US are unaware of their infection. Universal HepB-BD is of critical importance and provides a safety net for infants who may have unrecognized exposure(s) to HBV infection during pregnancy or early childhood. (1, 3, 19, 25, 48, 49)

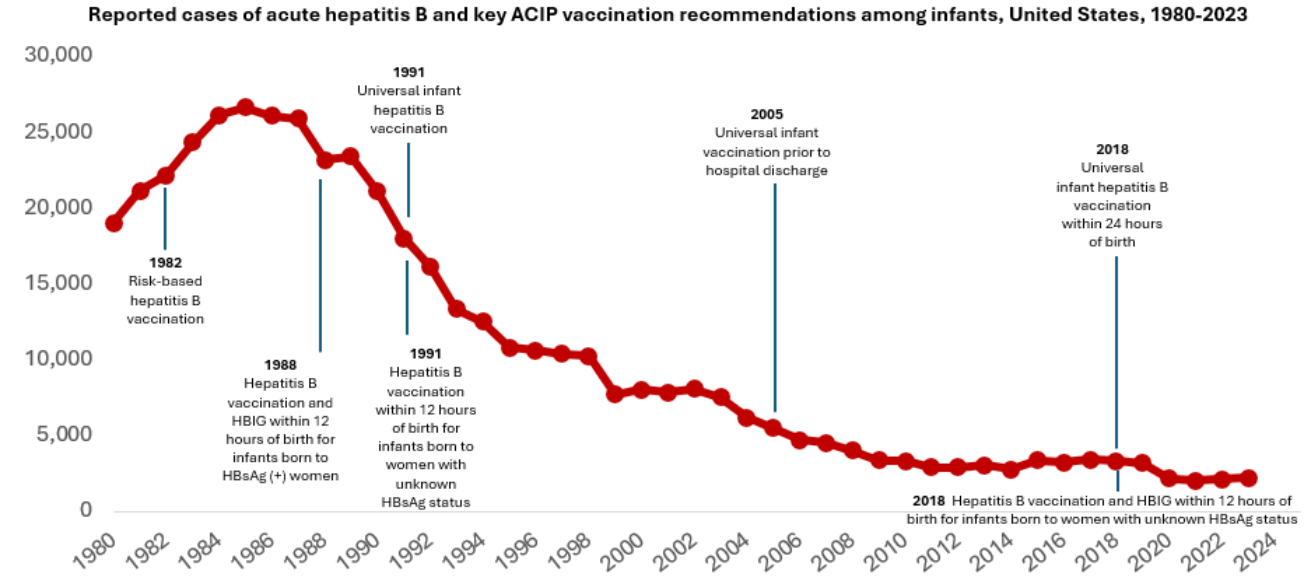
2. Epidemiology

Shifting Epidemiology of Acute Hepatitis B in the U.S. Reflects Success of Hepatitis B Vaccination among Newborns and Infants

Three decades of evolving hepatitis B vaccination recommendations among newborns and infants have paralleled marked reductions in acute hepatitis B cases in the United States. Following the introduction of recommendations for all infants born to HBsAg+ women to receive hepatitis B vaccination and HBIG within 12 hours of birth, the reported number of acute hepatitis B cases in the U.S. fell by 22% from 23,177 in 1988 to 18,003 in 1991. Following the 1991 recommendations which included providing hepatitis B vaccination within 12 hours of birth for infants born to women with unknown HBsAg status as well as introducing universal hepatitis B vaccination for all infants, reported number of acute hepatitis B cases dropped another 69% from 1991 to 2005 (5,494). Finally, following the 2005 recommendation specifying that the first dose of infant hepatitis B vaccination occur prior to hospital discharge and the

further specification that the dose occur within the first 24 hours of life, the reported number of acute hepatitis B cases fell an additional 60% from 2005 to 2023 (2,214).

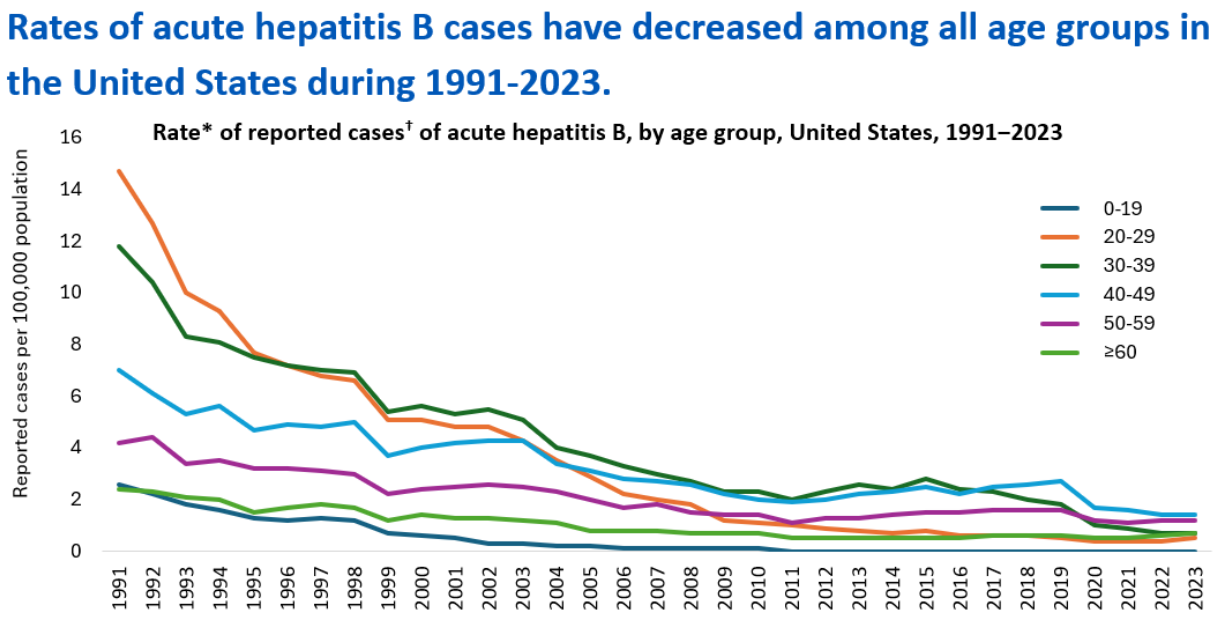
Figure 1



HBIG = Hepatitis B immune globulin; CDC NNDSS Viral Hepatitis Surveillance (https://www.cdc.gov/hepatitis/php/statistics-surveillance/index.html)

From 1991 through 2023, rates of reported cases of acute hepatitis B have decreased among all age groups, with the lowest rates among persons <19 years of age and those aged 20-29 years, indicating a generational impact of more than 3 decades of evolving hepatitis B vaccination recommendations among newborns and infants. (9, 17, 19, 21, 25, 50)

Figure 2 Viral Hepatitis Surveillance Reports | Viral Hepatitis | CDC



References: CDC NNDSS Viral Hepatitis Surveillance: (https://www.cdc.gov/hepatitis/php/statistics-surveillance/index.html); (4, 9, 21)

3. Updated Rapid Systematic Review for studies on hepatitis B birth dose vaccine within 24 hours of birth

In response to the request from the ACIP Chair to provide "*results from randomized trials concerning the administration of the HepB vaccine within 24 hours of birth, with all results stratified by the HepB infection status of the mother. Include both efficacy data and adverse events, including all-cause morbidity and mortality. For children whose mothers are HepB negative, present results for all children combined as well as stratified by pre-mature birth and birth weight. If randomized data is lacking for any of the requested populations, please mention that*", an updated rapid systematic review (URSR) for studies on hepatitis B birth dose (HepB-BD) vaccination within 24 hours of birth was conducted spanning 12/17/2011 – 8/14/2025, building on an existing systematic review (ESR) (28) spanning 1/1/1987 – 12/16/2011.

The inclusion criteria for the review included studies for newborn infants receiving a monovalent hepatitis B vaccine within 24 hours of birth for a list of outcomes (seroprotection, efficacy, safety, morbidity and mortality). The definitions and timepoints for seroprotection, efficacy, and safety outcomes are as follows: seroprotection is defined as anti-HBs ≥10 mIU/mL mL at least 1-2 months after the final dose in the vaccine series or between 9-12 months of age and is the first time point reported immediately following the last dose in a vaccine series; efficacy is defined as HBsAg and/or HBV DNA positivity at the latest available timepoint; safety is reported by local and systemic adverse events and is reported at birth or the closest time point immediately after the birth dose. Morbidity is defined as severe illness or hospitalization and mortality is defined as death.

The ESR search (n=833) and the URSR (n=1380) were further assessed using the inclusion criteria focused on the ACIP request. Seventeen studies met the inclusion criteria (7 from the ESR and 10 from the URSR). The 17 studies were grouped by efficacy trials, timing of the vaccination, product or formulation differences, dose and schedule, and HBIG co-intervention for the specified outcomes of interest (seroprotection, efficacy and safety outcomes). The two HBIG co-intervention trials were reviewed but not included in the briefing document since these studies did not address the question. Other intervention characteristics included the vaccine type administered (Engerix, Recombivax or other hep B vaccines), dose and schedule.

Across intervention study types (timing of vaccination (birth vs 18 months); efficacy trials; product and formulation; dose of vaccine and schedule) meeting the rapid systematic review inclusion criteria can be summarized as:

- Hepatitis B vaccine series first administered at birth achieved high levels of seroprotection in infants born to HBsAg-positive women and HBsAg-negative women;
- Among infants born to HBsAg-positive mothers, hepatitis B birth dose vaccination demonstrated efficacy in the prevention of perinatal transmission;
- Hepatitis B birth dose vaccine is safe and resulted in few local and systemic adverse effects, including infants born to HBsAg-negative mothers; and
- Head-to-head comparisons of various hepatitis B recombinant vaccine products, doses, and schedule showed no meaningful differences in reported outcomes.

The URSR did not identify placebo-controlled trials assessing efficacy; given that the efficacy of the HepB vaccine was established in the 1980s and 1990s, this is unsurprising as it is unethical to withhold a proven, safe and effective intervention simply to include a placebo group. There were also limited reporting outcomes for preterm, low birth weight and extremely low birthweight infants, as well as for morbidity and mortality. Bias was assessed using the Cochrane Risk of Bias, version 2 (RoB 2) (51). This tool assesses risk of bias in RCTs related to the following domains: randomization process, deviation from intended intervention, missing outcome data, measurement of outcome and selection of reported results. Of note, many of the studies were done before the wide application of the CONSORT statement (52), which seeks to improve reporting of randomized controlled trials (RCTs) Most of the RCTs (59%) assessed had a high risk of overall bias primarily due to the domains of randomization and measurement of outcomes. In summary, the body of evidence from the ESR and the URSR support the findings that:

- Hepatitis B birth dose induces high seroprotection and efficacy;
- Hepatitis B birth dose vaccine is safe; and
- Head-to-head comparisons of various hepatitis B recombinant vaccine products, doses, and schedule show no meaningful differences in reported outcomes in efficacy and safety.

Appendix 1

Hepatitis B screening recommendations for pregnant women and ACIP hepatitis B vaccination recommendations for infants, United States, 1984-2022.

Recommendation	Current?	Date of Initial Recommendation	Date Recommendation Superseded or Modified
Perinatal strategies			
Screening and testing for pregnant women			
Universal HBsAg screening in first trimester	Yes	1988[1]	
Test for HBsAg later in pregnancy for risk behaviors or acute hepatitis	Yes	1988[1]	
Test for HBsAg at delivery if status is unknown	Yes	1988[1]	
Post-exposure prophylaxis for infants born to HBsAg (+) pregnant women			
Administer HBIG within 12 hours of birth and HepB vaccine simultaneously or within 7 days of birth	No	1984[2]	1987[3]
Administer HBIG and HepB vaccine at birth*	No	1987[3]	1988[1]
Administer HBIG and HepB vaccine within 12 hours of birth*	Yes	1988[1]	
Infants born to HBsAg status unknown pregnant women			
In populations where screening is not feasible, administer HepB vaccine within 12 hours of birth*	No	1991[4]	2018[5]
Administer HepB vaccine and HBIG within 12 hours of birth*	Yes	2018[5]	
Infant vaccination strategies			
Universal HepB vaccine before leaving the birth hospital* or within 2 months of age	No	1991[4]	2005[6]
Universal HepB vaccine at the birth hospital*	No	2005[6]	2018[5]
Universal HepB vaccine within 24 hours of birth*	Yes	2018[5]	

Modified from Bixler PHR 2023, Suppl Table 2.

ACIP = Advisory Committee on Immunization Practices; HBIG = hepatitis B immune globulin; HepB, hepatitis B vaccine.

*Only single-antigen HepB vaccine should be used for the birth dose.

Note: All hepatitis B birth dose vaccinations are considered to be the first dose of the infant series except among pre-term infants weighing <2,000 grams who are born to mothers who are HBsAg positive.

1. CDC. MMWR Morb Mortal Wkly Rep 37, 341-346, 351 (1988).
2. CDC. MMWR Morb Mortal Wkly Rep 33, 285-290 (1984).
3. CDC. Update on hepatitis B prevention. MMWR Morb Mortal Wkly Rep 36, 353-360, 366 (1987).
4. CDC. Recommendations of the Immunization Practices Advisory Committee (ACIP). MMWR Recomm Rep 40, 1-25 (1991).
5. Schillie, S. et al. MMWR Recomm Rep 67, 1-31 (2018).
6. Mast, E. E. et al. MMWR Recomm Rep 54, 1-31 (2005).
7. Bixler D et al. Public Health Rep. 2023 Jun 9

Appendix 2

Global hepatitis B vaccination policies and prevalence in pregnant women

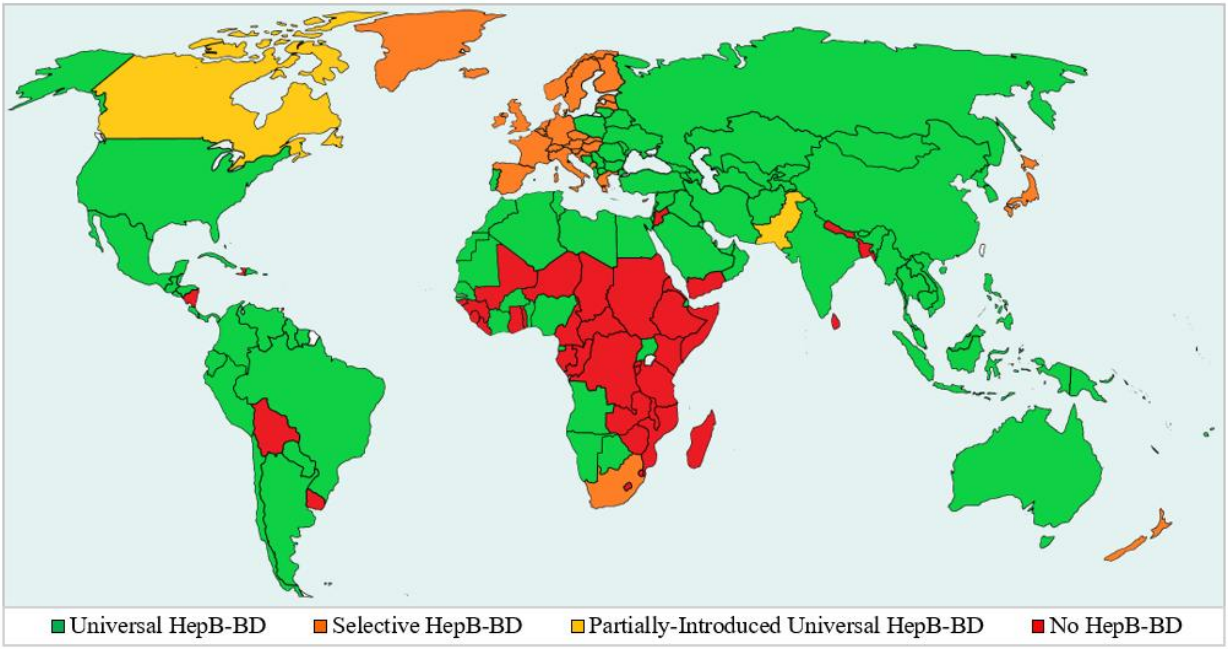
Global Hepatitis B Birth Dose Vaccination Policies

In 1987, the WHO Hepatitis and Immunization Technical Advisory groups emphasized the importance of hepatitis B vaccination to control infections globally and recommended hepatitis B vaccination in infancy focusing on countries where HBsAg prevalence was higher than 2%. In 2004, the WHO recommended hepatitis B birth dose vaccination as soon as possible after birth (within 24 hours) focusing on countries with intermediate and high endemicity (HBsAg prevalence >2%) while also recommending hepatitis B vaccination in low endemicity settings especially to infants born to HBsAg positive mothers. In 2009 and then in 2017, the WHO Strategic Advisory Group of Experts reevaluated the data and based on evidence to recommendations analysis, recommended universal hepatitis B birth dose vaccination as soon as possible after birth, preferably within 24 hours of birth, followed by completion of 3 or 4 dose hepatitis B vaccination series among all infants in all countries irrespective of HBsAg prevalence. Those vaccination recommendations have evolved based on global goals which focused in the 1990s and early 2000s on controlling hepatitis B through scale up of childhood immunization and then progressed in 2015 to focus on eliminating viral hepatitis as a public health threat by 2030 through the scale up of prevention, screening and treatment. The United States has endorsed the global goals of elimination of viral hepatitis by 2030 and developed national strategies to achieve the targets.

Globally, of the 194 WHO member states, 116 countries recommend universal hepatitis B birth dose vaccination to all newborns, in alignment with global recommendations. Relatively few countries (33) provide selective hepatitis B birth dose to infants born to mothers who are either HBsAg-positive or of HBsAg-unknown status. Two countries have partially introduced universal HepB-BD. In Canada, New Brunswick, the Northwest territories and Nunavut provide universal HepB-BD while other provinces provide selective HepB-BD. Pakistan introduced universal HepB-BD in two of its most populated provinces (Punjab and Sindh).

The 43 countries that have not introduced HepB-BD are mostly countries in Sub-Saharan Africa, but this is changing and in 2024, many countries have either initiated introduction this year or expressed interest in introducing HepB-BD in their immunization schedule in the next 3-5 years.

Map: **Hepatitis B vaccine birth dose vaccination policy by county, 2025**



Sources: Provincial and territorial routine and catch-up vaccination schedule for infants and children in Canada - Canada.ca ; Hepatitis B vaccine – NHS; Vaccine Scheduler | ECDC; 9. Hepatitis B – Health New Zealand | Te Whatu Ora; Introduction of Hepatitis B vaccine; Hepatitis B | The Australian Immunisation Handbook; 20240220_Immunization_Schedule_english.pdf; National Immunization Program for children | Policy&Services : KDCA; Hepatitis B

Universal HepB-BD: Hepatitis B birth dose vaccine provided to all newborns.

Selective HepB-BD: Hepatitis B birth dose vaccine provided only to infants born to women who test positive for HBsAg.

Partially introduced universal HepB-BD: Hepatitis B vaccine strategy among infants varies by geographic location within the country.

Based on the request from the ACIP chair, we analyzed hepatitis B vaccination policies and schedule in 37 countries which include, Canada, countries in the European Union (EU) (n=27) and European Economic Area (EEA) (Iceland, Liechtenstein, and Norway), the United Kingdom (UK), Switzerland, Australia, New Zealand, South Korea and Japan and compared them to the United States.

Among infants born to women with known HBV infection (HBsAg positive women), the U.S. is aligned with Canada, all EU/EEA countries, the United Kingdom (UK), Switzerland, Australia, New Zealand, South Korea and Japan which all recommend the hepatitis B birth dose to be given at birth simultaneously with HBIG, either before discharge from the hospital or within 24 hours of birth.

For infants born to HBsAg-negative women, countries with a universal hepatitis B birth dose vaccination policy give all children the first dose following the same schedule as children born to HBsAg positive mothers.

Among the 37 countries assessed, 26 implement selective HepB-BD for infants born to HBsAg-positive women and the universal infant vaccination with three doses of hepatitis B vaccine to all infants irrespective of mothers' HBsAg status. Children born to HBsAg-negative mothers receive the first dose of hepatitis B vaccine by 3 months of age in 24 of the 26 countries (18 countries at 2 months of age and 6 countries at 3 months of age).

Table: age at receipt of first dose of hepatitis B vaccine in selected countries *

Age at first dose	**Number of countries**
At what age is the first dose recommended for children born to HBsAg (+) women? (N=38)	
Before discharge from the hospital, or within 24 hours of birth	36
Ideally within 24 hours of birth but no later than 7 days after birth	1 (Ireland)
Within 48 hours of birth (majority of newborns are vaccinated within 24 hours)	1 (Denmark)
At what age is the first dose recommended for children born to HBsAg (-) women?	
Countries that provide a universal HepB-BD (N=8)	
Same schedule as children born to HBsAg (+) women	7
Within 24 hours but no later than 7 days after birth	1 (Australia)
Countries that provide selective HepB-BD and universal infant hepatitis B vaccination policy (N=26)	
At the age of 2 months	18
At the age of 3 months	6
At the age of 12-13 years	1 (Hungary)
Varies by province (2 months; 11 or 12 years)	1 (Canada)

*United States, Canada, all EU/EEA countries, UK, Norway, Switzerland, Iceland, Australia, New Zealand, South Korea and Japan.

Sources: Provincial and territorial routine and catch-up vaccination schedule for infants and children in Canada - Canada.ca ; Hepatitis B vaccine – NHS; Vaccine Scheduler | ECDC; 9. Hepatitis B – Health New Zealand | Te Whatu Ora; The Australian Immunisation Handbook; 20240220_Immunization_Schedule_english.pdf; National Immunization Program for children | Policy&Services : KDCA; Hepatitis B

High-income countries base their decisions on vaccination schedule using cost-benefit and cost-effectiveness assessments, especially countries that provide free universal health care, along with epidemiological profile and high levels of maternal hepatitis B screening in the population. For example, in 2016-2017, Japan and the United Kingdom switched from selective infant hepatitis B vaccination to universal infant vaccination after reviewing country-specific epidemiological and cost-effectiveness data. In 2020, Slovenia switched from providing the first dose of hepatitis B at school entry to providing universal hepatitis B infant vaccination starting at 3 months of age. To date, no country in the world has reverted from universal to selective hepatitis B vaccination schedules.

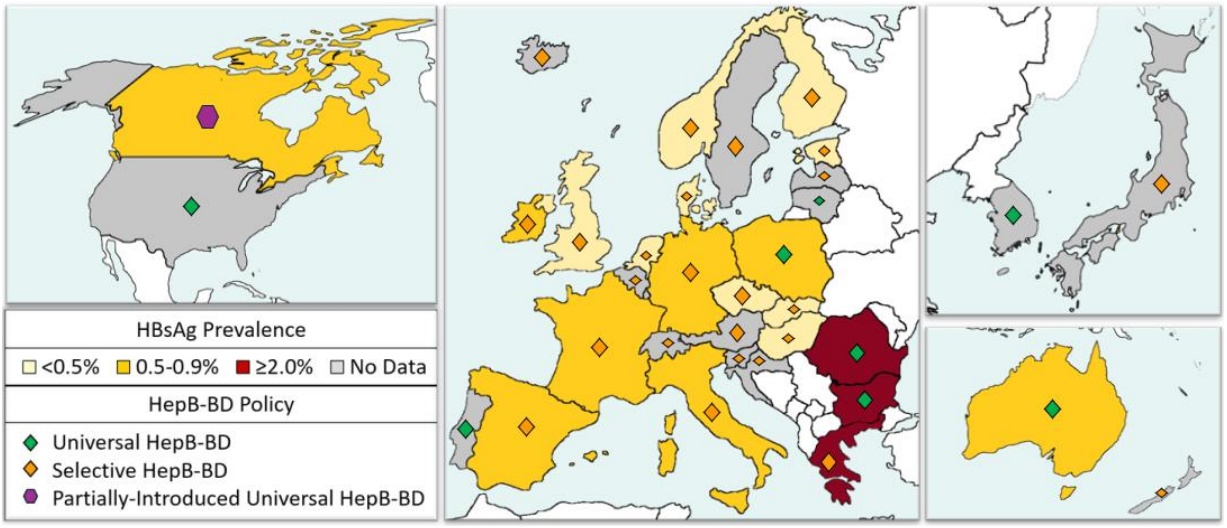
Hepatitis B prevalence and screening in pregnant women

Based on the request from the ACIP chair, we analyzed hepatitis B prevalence and screening among pregnant women in 37 countries which include: Canada, countries in the European Union (EU) (n=27) and European Economic Area (EEA) (Iceland, Liechtenstein, and Norway), the United Kingdom (UK), Switzerland, Australia, New Zealand, South Korea and Japan and compared them to the United States.

Prevalence estimates of hepatitis B among pregnant women were available in 20 of the 37 assessed countries. Overall, 9 countries had less than 0.5% prevalence of hepatitis B surface antigen among pregnant women while 8 countries reported a prevalence ranging from 0.5 to 0.9% and 3 countries reported a prevalence greater than 2% in pregnant women. There are no data on the prevalence of hepatitis B in pregnant women in the United States in the last 10 years.

Only 6 of the 37 selected countries have national registries that can track hepatitis B screening among pregnant women and estimate prevalence on an annual basis. The other 31 countries and the United States do not track hepatitis B screening during pregnancy. In those countries, hepatitis B prevalence estimates when available are based on surveys or special studies completed in previous years.

Figure: Prevalence of hepatitis B surface antigen among pregnant women in selected countries*



* United States, Canada, all EU/EEA countries, UK, Norway, Switzerland, Iceland, Australia, New Zealand, South Korea and Japan.

Sources: Hepatitis B in England 2024 - GOV.UK; Hepatitis B and C in Pregnancy and Children: A Canadian Perspective – PMC; Evidence brief - prevention of hepatitis B and C in Europe and the UK; Uptake of perinatal immunoprophylaxis for infants born to women with a record of hepatitis B in Victoria (2009–2017) – ScienceDirect; Updated-National Hepatitis Elimination Profile- Switerland-July2023_0.pdf; Gaps in Prenatal Hepatitis B Screening and Management of HBsAg Positive Pregnant Persons in the U.S., 2015–2020 - PMC

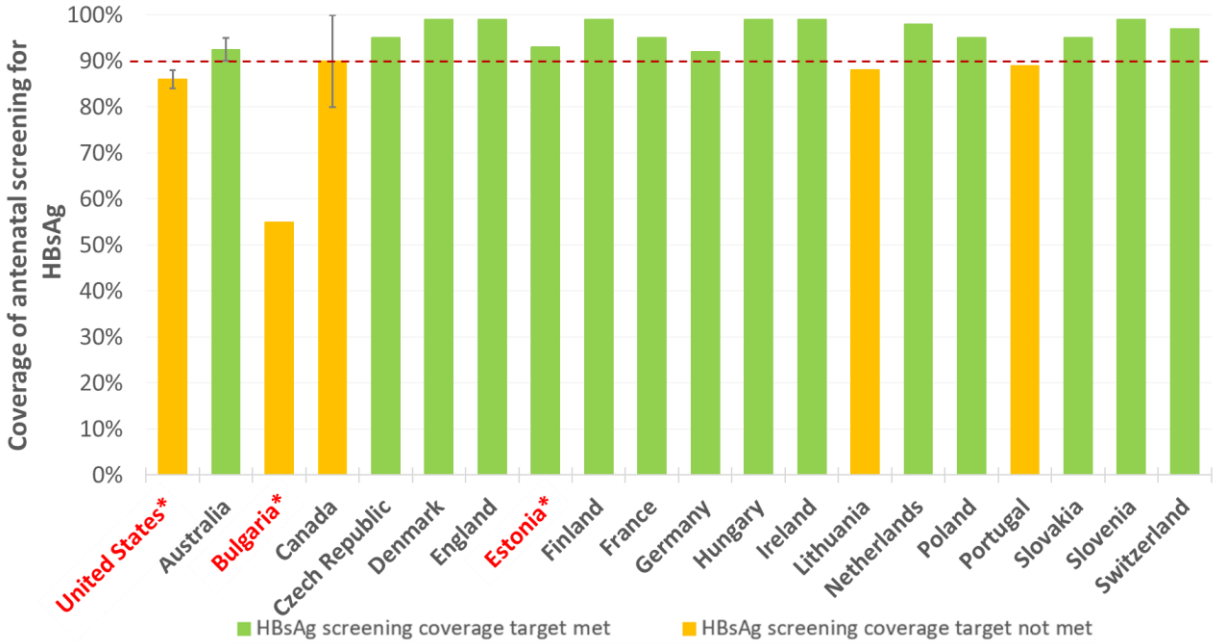
All of the 37 selected countries, except two, provide universal health care access to all citizens (including residents and migrants).

Of the 29 countries that provide selective HepB-BD, five countries have national registries that can track the percentage of pregnant women screened for hepatitis B and subsequent care cascade of mother and infant. The remaining countries either have systems similar to the perinatal hepatitis B prevention program in the U.S. or report positive hepatitis B test results to a national notifiable disease surveillance system. Unlike countries that provide selective HepB-BD, the United States does not have universal healthcare coverage with free access to antenatal care and vaccinations to the population. This is a critical difference between the United States and the countries that provide selective HepB-BD.

As a result of lack of adequate systems to track screening in pregnant women and subsequent post-exposure prophylaxis in exposed infants, most of the countries with selective HepB-BD policies cannot track whether they are succeeding in preventing perinatal transmission of hepatitis B on a regular basis (outside of special studies). However, they provide universal healthcare to all the population with access to free antenatal care and vaccination services.

To highlight the limited data availability in the 37 assessed countries, we compiled publicly available data on the percentage of pregnant women who are screened for hepatitis B surface antigen during pregnancy in each of those countries. Of the 37 countries selected to compare to the United States, only 19 had publicly available data on percentage of pregnant women screened for hepatitis B. Overall, 15 countries reported that more than 90% of pregnant women are screened for hepatitis B, which is the 2030 global indicator for validation of elimination. The United States is one of five countries not meeting the 2030 global screening target. All countries that provide selective hepatitis B birth dose vaccination that have available antenatal screening data have achieved the 90% global antenatal screening coverage target for hepatitis B.

Figure: Coverage of antenatal screening for hepatitis B in selected countries



*No universal healthcare coverage

2023 data except for the following countries: Lithuania, 2021; United States, 2015-2019; France, Germany, and Poland, data >5 but <10 years old.

No data is publicly available for Austria, Belgium, Croatia, Cyprus, Greece, Iceland, Italy, Japan, Latvia, Lichtenstein, Luxembourg, Malta, New Zealand, Norway, Romania, South Korea, Spain, or Sweden.

Sources: Hepatitis B in England 2024 - GOV.UK; Hepatitis B and C in Pregnancy and Children: A Canadian Perspective – PMC; Evidence brief - prevention of hepatitis B and C in Europe and the UK; Uptake of perinatal immunoprophylaxis for infants born to women with a record of hepatitis B in Victoria (2009–2017) – ScienceDirect; Updated-National Hepatitis Elimination Profile- Switerland-July2023_0.pdf; Gaps in Prenatal Hepatitis B Screening and Management of HBsAg Positive Pregnant Persons in the U.S., 2015–2020 - PMC

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