



Viral Hepatitis Prevention Board

To: Chairman Kulldorff and Members of the Advisory Committee on Immunization Practices (ACIP)

From: Viral Hepatitis Prevention Board (VHPB)

Re: Importance of Timely Universal Hepatitis B Vaccination of Newborns

Date: 12th November 2025

The Viral Hepatitis Prevention Board (VHPB) is writing to express its strong support for the continued recommendation by the Advisory Committee on Immunization Practices (ACIP) for **universal hepatitis B vaccination of all newborns within 24 hours of birth**, followed by completion of the three dose vaccine series. This policy is essential to sustain the progress made towards eliminating hepatitis B virus (HBV) infection and its devastating health consequences (1).

For more than three decades, the VHPB has promoted evidence-based policies and strategies for hepatitis B prevention and control across Europe with global outreach. Since its establishment in 1992, the Board has collaborated with national immunization programs, health authorities, and international partners to strengthen hepatitis B vaccination policies and improve coverage, particularly for newborns and infants, who are the persons at the highest risk of developing chronic HBV infection and a one-in-four risk of premature mortality from HBV-related liver disease and liver cancer in later life (2 - 6, 8, 12).

The scientific and public health evidence supporting universal hepatitis B birth dose vaccination is unequivocal (7, 8). Infants born to hepatitis B positive mothers have a **25-90% risk of acquiring the infection at birth, depending on the maternal HBV DNA level** (8-11). Of newborns infected with HBV, 80%-90% become chronically infected with the virus. Universal newborn vaccination prevents HBV infection along with HBV-related morbidity and mortality (8). Hepatitis B vaccine is the world's first vaccine to prevent cancer. Globally, primary liver cancer, which is often caused by chronic HBV infection, is the third leading cause of cancer-related deaths.

Timely administration of the hepatitis B birth dose within 24 hours for exposed newborns is key to prevention. As the child has already become exposed to the virus, the vaccine must be immediately delivered to the newborn to rapidly develop antibodies to prevent HBV infection. A delay in the hepatitis B birth dose by a day or more weakens protection needlessly increasing the risk of HBV infection, chronic incurable disease and premature mortality for exposed newborns (13).

Experience from the United States, Europe and around the world demonstrates that **selective vaccination strategies alone, such as screening all pregnant women and vaccinating (at birth) only newborns of hepatitis B-positive mothers, are insufficient** to prevent perinatal and early childhood HBV infection (14 - 19). While antenatal HBV screening can help identify pregnant women living with HBV and guide newborn vaccination, it is not consistently implemented, and test results are not always available at the time of delivery (18, 20, 21). In addition, there are access issues to such screening programs (including health literacy, health insurance coverage, and financial barriers, among others) (22, 23).



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In the European Union/European Economic Area (EU/EEA), all countries report implementation of universal antenatal HBV screening. However, only 12 of 30 currently meet the WHO 2025 interim target of 90% coverage of antenatal screening or have data on it (24).

Both the EU and the United States have a higher burden of hepatitis B among at-risk populations where routine HBV screening for pregnant women is not always accessible (25, 26). These system gaps that threaten access to prenatal care highlight the importance of maintaining a universal birth dose of hepatitis B vaccine as the safety net that protects every child, regardless of maternal screening status or healthcare setting. For these reasons, countries like Australia and Canada have provided the evidence supporting the move from selective to universal hepatitis B birth dose implementation (27 - 28).

The safety and effectiveness of the hepatitis B vaccine offered at birth have been confirmed through decades of research, continuous pharmacovigilance, and billions of doses administered globally. The vaccine has an excellent safety profile, with rare adverse reactions and overwhelming evidence of benefit in preventing infection, cirrhosis, and liver cancer (8, 29 - 33). Besides its proven effectiveness, there is important evidence from modelling that birth dose and infant HBV vaccination can be not only cost-effective but even cost-saving, providing value for money (28). For decades the ACIP's transparent, evidence-based decision-making process has contributed to the remarkable success of hepatitis B prevention in the United States. Revising or weakening the universal newborn vaccination policy could risk reversing decades of progress and expose new generations to preventable infection and disease including cancer.

In summary, the Viral Hepatitis Prevention Board urges ACIP to **maintain its current recommendation for universal hepatitis B birth dose vaccination of newborns** as a cornerstone of hepatitis B elimination. Sustaining this recommendation ensures that the United States continues to lead by example in protecting the health of children and preventing hepatitis B-related disease and death.



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