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Clinical Considerations for Hepatitis B Vaccines and Vaccination in Newborns in New Jersey

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The New Jersey Department of Health has reviewed the relevant scientific literature and medical professional guidance related to the hepatitis B vaccine among newborns.

The New Jersey Department of Health continues to recommend that all newborns receive a hepatitis B vaccine birth dose within 24 hours of delivery. Newborns born to birth parents who test positive for hepatitis B infection or have an unknown status should be vaccinated within 12 hours of birth. Additionally, all children should complete the full vaccination series within 18 months. These recommendations align with the American Academy of Pediatrics' Recommended Child and Adolescent Immunization Schedule.ⁱ

This document reinforces key information about the importance of hepatitis B vaccination in infants.

Hepatitis B Infection:

- Hepatitis B is a viral infection that attacks the liver and can cause both acute and chronic disease, including cirrhosis, liver failure, liver cancer, and death.ⁱⁱ
- Perinatal transmission of hepatitis B can occur if the birthing person is infected. Hepatitis B screening during pregnancy to identify those with the disease before delivery is recommended by the American College of Obstetricians and Gynecologists and the United States Preventative Services Task Force.^{iii,iv} However, challenges and errors still occur:^v
 - In some cases, birthing parents who have hepatitis B may be unaware of their status, resulting in information not being reported or being inaccurately reported to the delivery facility.
 - Hepatitis B laboratory reports may be misinterpreted. Negative antibody tests can be mistaken for negative antigen results, leading to inaccurate documentation.
 - Birthing parents without known risk factors who test negative during screening early in pregnancy may acquire hepatitis B between testing and delivery or may have a false-negative initial test if the infection is new.
- Infants can also contract hepatitis B from caregivers, household contacts, and others with known or unknown hepatitis B infection, or from surfaces and objects contaminated with blood containing hepatitis B virus.
 - Up to 2.4 million people are estimated to have hepatitis B infection in the United States, among whom an estimated 50% are unaware of their infection.^{vi,vii}
 - Hepatitis B is a resilient virus and can live on surfaces such as toothbrushes,

- washcloths, and nail clippers for up to 7 days.ⁱⁱ
 - Prior to hepatitis B birth dose, some U.S. born children born to immigrant mothers without hepatitis B infection had hepatitis B prevalences of 7-11% attributable to community or household exposures.
- Hepatitis B infection is particularly devastating to infants.^{viii}
 - Of infants infected with the virus in the first year of life, 90% develop chronic hepatitis B.^{viii}
 - One in four people infected with hepatitis B virus during childhood die from liver cirrhosis or liver cancer in later life.^{ix}

Hepatitis B Vaccination:

- The birth dose and completion of the vaccine series within the first 18 months of life, regardless of the hepatitis B infection status of the birth parent, is essential to reduce the risk of chronic hepatitis B and related sequelae.
- Risk-based vaccination strategies (e.g., vaccinating only babies born to parents known to have hepatitis B) have historically been insufficient to prevent perinatal and early childhood transmission.^x A 2023 study estimated that 12 –16% of pregnant people do not receive the recommended hepatitis B screening, illustrating the potential gaps in a risk-based approach.^{xi}
- Since 1991, the year the Centers for Disease Control and Prevention and the American Academy of Pediatrics recommended universal hepatitis B vaccination for newborns, hepatitis B infections in children and teens have decreased by 99%.^{xii}
- Safety and efficacy of the vaccine have been well-established. The hepatitis B vaccine is 80% to 100% effective in preventing infection or clinical hepatitis in those who receive the complete vaccine series.^{xiii} Hepatitis B vaccine has a strong safety profile, with adverse effects that are typically mild and transient. According to post-licensure surveillance, the most frequently reported reactions include localized pain, erythema, or swelling at the injection site, as well as low-grade fever and fatigue, all of which generally resolve within 24–48 hours. **Large meta-analyses and systematic reviews that include millions of children have consistently found no link between vaccines and autism.**^{xiv,xv} Severe adverse reactions are estimated to occur at a rate of 1.1 per million doses, consistent with the overall rate of anaphylaxis to vaccines.^{xiii}

Hepatitis B in New Jersey:

- New Jersey has been participating in the Perinatal Hepatitis B Prevention Program (PHBPP) since 1993. The PHBPP has emphasized the benefits of the birth dose of hepatitis for all eligible babies and appropriate post-exposure prophylaxis for babies born to hepatitis B positive persons and persons with unknown status.
- Using these evidence-based strategies, no confirmed cases of perinatal hepatitis B have been reported in NJ since 2013. Since 2003, the NJ PHBPP has followed over 5,500 children born to HBV positive mothers
- Additional information is available at https://www.nj.gov/health/cd/topics/hepatitisb_perinatal.shtml

The hepatitis B vaccine birth dose and completion of the hepatitis B vaccine series in the first 18 months of life protects infants and children during a vulnerable time of their lives. Delaying vaccination misses a crucial period of potential exposure, putting infants at risk. Clinicians should continue to administer hepatitis B vaccine to all newborns

at birth and administer the full vaccination series in accordance with the American Academy of Pediatrics' recommendations.

ⁱ American Academy of Pediatrics. Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States 2025. September 17, 2025 <https://downloads.aap.org/AAP/PDF/AAP-Immunization-Schedule.pdf>

ⁱⁱ Offit P. Hepatitis B Vaccine. Chop.edu. Published 2020. <https://www.chop.edu/vaccine-education-center/vaccine-details/hepatitis-b-vaccine>

ⁱⁱⁱ American College of Obstetricians and Gynecologists. Viral Hepatitis in Pregnancy. Clinical Practice Guideline 6, September, 2023. <https://www.acog.org/clinical/clinical-guidance/clinical-practice-guideline/articles/2023/09/viral-hepatitis-in-pregnancy>

^{iv} US Preventative Services Task Force. Hepatitis B Virus Infection in Pregnant Women: Screening, Final Recommendations Statement. July 23, 2019 <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/hepatitis-b-virus-infection-in-pregnant-women-screening>

^v Hepatitis B virus: a comprehensive strategy for eliminating transmission in the United States through universal childhood vaccination. Recommendations of the Immunization Practices Advisory Committee (ACIP). *MMWR Recomm Rep*. 1991;40(RR-13):1-25. <https://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm>

^{vi} Wong RJ, Brosgart CL, Welch S, et al. An Updated Assessment of Chronic Hepatitis B Prevalence Among Foreign-Born Persons Living in the United States. *Hepatology*. 2021;74(2):607-626. doi:10.1002/hep.31782

^{vii} Bixler D, Barker L, Lewis K, Peretz L, Teshale E. Prevalence and awareness of Hepatitis B virus infection in the United States: January 2017 - March 2020. *Hepatol Commun*. 2023;7(4):e0118. Published 2023 Mar 30. doi:10.1097/HC9.0000000000000118

^{viii} Kimberlin D, Banarjee R, Barnett E, Lynfield R, Sawyer M,. Hepatitis B. In: Kimberlin D, Banarjee R, Barnett E, Sawyer M, Lynfield R, eds. *Red Book: 2024–2027 Report of the Committee on Infectious Diseases (33rd Edition)*. American Academy of Pediatrics; 2024:437-457.

^{ix} 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. DOI: <http://dx.doi.org/10.15585/mmwr.rr6701a1>

^x Hepatitis B virus: a comprehensive strategy for eliminating transmission in the United States through universal childhood vaccination, 1991

^{xi} Pham TTH, Maria N, Cheng V, et al. Gaps in Prenatal Hepatitis B Screening and Management of HBsAg Positive Pregnant Persons in the U.S., 2015-2020. *Am J Prev Med*. 2023;65(1):52-59. doi:10.1016/j.amepre.2023.01.041

^{xii} Why Hepatitis B Vaccination Begins at Birth | Johns Hopkins Bloomberg School of Public Health. Johns Hopkins Bloomberg School of Public Health. Published September 24, 2025. <https://publichealth.jhu.edu/2025/why-hepatitis-b-vaccination-begins-at-birth>

^{xiii} Centers for Disease Control and Prevention. *The Epidemiology and Prevention of Vaccine-Preventable Diseases (The Pink Book)*. 14th ed. 2021. <https://www.cdc.gov/pinkbook/hcp/table-of-contents/index.html>

^{xiv} Dudley MZ, Halsey NA, Omer SB, et al. The state of vaccine safety science: systematic reviews of the evidence. *Lancet Infect Dis*. 2020;20(5):e80-e89. doi:10.1016/S1473-3099(20)30130-4

^{xv} Taylor LE, Swerdfeger AL, Eslick GD. Vaccines are not associated with autism: an evidence-based meta-analysis of case-control and cohort studies. *Vaccine*. 2014 Jun 17;32(29):3623-9. doi: 10.1016/j.vaccine.2014.04.085.