

Perinatal Hepatitis B Prevention Protocol



Disease Summary

Perinatally acquired hepatitis B is a serious public health concern. Infants born to mothers who are infectious with the hepatitis B virus (HBV) are at significant risk of acquiring the disease, which can cause lifelong chronic HBV infection. Transmission most commonly occurs during the birthing process, although intrauterine transmission is possible. Approximately 90% of infants who acquire the disease at birth will develop chronic HBV infection, and one-fourth of the affected individuals will die prematurely from cirrhosis or liver cancer. Infants infected with HBV are typically asymptomatic.

The Centers for Disease Control and Prevention (CDC) estimate only half of all pregnant women infected with HBV in the United States are identified, which increases the risk of infections caused by perinatal transmission. This is of special significance to West Virginia (WV), as WV has experienced the highest rate of acute HBV in the United States since 2007. In 2016, the average rate of acute HBV in the United States was 1.0 per 100,000 persons. In comparison, WV's rate of HBV was 14.6 per 100,000 persons, more than 14 times the national average. Identification of HBV-positive pregnant women so that immunoprophylaxis can be administered to their newborns after birth is the key to perinatal HBV prevention. Hepatitis B immune globulin (HBIG) and hepatitis B vaccine given within 12 hours of birth followed by timely completion of the hepatitis B vaccine series is up to 95% effective in preventing chronic HBV infection in infants.

National Guidelines for Preventing Perinatal Transmission of HBV

Preventing perinatal transmission of HBV is part of the national strategy to eliminate hepatitis B in the United States. According to the CDC, national guidelines include:

1. Universal screening of pregnant women for hepatitis B surface antigen (HBsAg) during each pregnancy.
2. Screening all HBsAg-positive pregnant women for HBV DNA to guide the use of maternal antiviral therapy during pregnancy. The American Association for the Study of Liver Diseases (AASLD) suggests maternal antiviral therapy when HBV DNA is > 200,000 IU/mL.
3. Case management of HBsAg-positive mothers and their infants.
4. Provision of immunoprophylaxis for infants born to infected mothers, including hepatitis B vaccine and hepatitis B immune globulin (HBIG) within 12 hours of birth.
5. Routine vaccination of all infants with the hepatitis B vaccine series, with the first dose administered within 24 hours of birth.

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Perinatal Hepatitis B Prevention Program

The Perinatal Hepatitis B Prevention Program (PHBPP) is a case management and surveillance program created by the CDC in 1990, when Congress recognized the importance of preventing perinatal transmission of HBV in the United States (US). It is part of the national strategy to eliminate hepatitis B in the US and is included in the National Viral Hepatitis Action Plan. The mission of the program is to prevent transmission of HBV from infected mothers to their infants through identification and case management. Goals of the PHBPP include:

- Identification of HBsAg pregnant women before delivery
- Administration of hepatitis B immune globulin (HBIG) and hepatitis B vaccine administered to at-risk newborns within 12 hours of birth
- Timely completion of the hepatitis B vaccine series as recommended by the Advisory Committee on Immunization Practices (ACIP)
- Completion of post-vaccination serological testing (PVST) when the infant is 9-12 months of age

Pregnant women who are positive for HBV are enrolled in the PHBPP for case management when they are reported to the local health department (LHD).

Prenatal Care Provider Responsibilities

1. All pregnant women should have a hepatitis B surface antigen (HBsAg) laboratory test with each pregnancy, even if vaccinated or tested previously. The test should be done at an early prenatal visit. If the mother is HBV-positive, she should be referred to a medical specialist for evaluation.
2. If the HBsAg is negative, but the woman is at high risk for HBV infection, the HBsAg test should be repeated closer to delivery. High risk behaviors include injection drug use, multiple sex partners, and having other sexually transmitted infections. If the woman is HBsAg negative and hepatitis B surface antibody (Anti-HBs) negative, she may need to be evaluated for hepatitis B vaccination during pregnancy, depending on her risk for infection. If hepatitis B vaccine is given during pregnancy, HBsAg testing should be avoided until 1-2 months after the vaccine was administered to avoid transient HBsAg positivity.
3. If the HBsAg is positive, additional testing is recommended, including HBV DNA. HBV DNA > 200,000 IU/mL in a pregnant woman can increase the risk of perinatal HBV transmission. Pregnant women with HBV DNA > 200,000 IU/mL should be evaluated by a specialist for consideration of antiviral therapy to help prevent mother-to-child transmission of HBV, according to the AASLD.

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4. Healthcare providers are to report cases of HBV infection to the LHD serving the patient's county of residence within 24 hours of diagnosis, per the WV Reportable Disease Rule (64 CSR-7). This includes positive serologies for HBsAg, HBV DNA or HBV e antigen (HBeAg). **Please include pregnancy status with positive HBV laboratory results.**
5. Patient education should include:
 - a) Transmission and prevention of HBV infection
 - b) The importance of hepatitis B immune globulin (HBIG) and hepatitis B vaccine being administered within 12 hours of birth
 - c) That all household, sexual, and needle-sharing contacts should be tested for HBV infection and vaccinated if susceptible
 - d) The importance of attending prenatal and other medical appointments
 - e) The LHD will follow up with her, as HBV infection is a reportable condition
6. Anticipate the need to work with LHDs to:
 - a. Supply appropriate clinical information
 - b. Supply additional demographic information and next of kin
 - c. Supply additional laboratory results
7. CDC guidelines to prevent perinatal HBV transmission for prenatal care providers can be found here:
<https://www.cdc.gov/hepatitis/hbv/pdfs/PrenatalCareProviderPoliciesAndProcedures.pdf>

Guidance for Delivery Facilities

The CDC recommends every pregnant woman have a HBsAg laboratory test with each pregnancy, even if vaccinated or tested previously. The results should be available to the delivery facility and made a part of the mother's medical record before delivery. In July 2018, The Joint Commission added the requirement that maternal HBV status be documented in a pregnant woman's medical record upon admission to labor and delivery as a provision of care.

Even though HBsAg testing is recommended for every woman with each pregnancy, not all pregnant women receive adequate prenatal care. Some women have had no medical care for their pregnancy until they arrive at the hospital ready to deliver, or they may arrive with the newborn infant in arms. There is a higher prevalence of HBsAg positivity in pregnant women who do not seek medical care. Because women who have not had prenatal care are at higher risk of being infected with HBV, it is necessary for all delivery facilities to have policies and procedures in place to ensure HBsAg status is always known and documented. When the mother is HBsAg positive, HBIG and hepatitis B vaccine should be administered to the newborn

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within 12 hours of birth per the ACIP recommendations. The sooner HBIG is administered the better, but it can be given up to seven days after delivery and still be effective. Maternal HBsAg status should be documented in the infant's medical record. Please refer to **Table 1** (page 15) for complete recommendations from the ACIP for appropriate administration of HBIG and hepatitis vaccine after birth.

Information on developing policies and protocols for the prevention of perinatally acquired HBV can be found at:

www.immunize.org/catg.d/p2130.pdf

For all medically stable infants weighing >2,000 grams at birth and born to HBsAg-negative mothers, the CDC and the ACIP recommend the first dose of hepatitis B vaccine to be administered within 24 hours of birth. Information on the universal birth dose and how to be included on the Hepatitis B Honor Roll, recognizes birthing facilities that have attained high coverage rates for administering hepatitis B vaccine at birth can be found at:

www.immunize.org/protect-newborns/

Healthcare facilities are to report cases of HBV infection to the LHD serving the patient's county of residence within 24 hours of diagnosis, per the WV Reportable Disease Rule (64 CSR-7). Please notify the WV PHBPP when an infant has been born to a HBsAg positive mother by submitting a completed **Perinatal Hepatitis B Prevention Birth Report** form by fax to (304) 558-6335 or by calling (304) 558-5358 ext.1.

Pediatric Care Provider Responsibilities

1. All infants born to HBV-positive mothers should follow the ACIP recommended immunization schedule as shown in **Table 1** (page 15).
2. Post-vaccination serological testing (PVST) is to be done for infants born to HBsAg-positive mothers, as well as infants born to mothers whose status remains unknown. PVST is to be done when the infant is 9 -12 months of age or 1-2 months after the last dose if the series is delayed. PVST includes:
 - a. **Hepatitis B Surface Antigen (HBsAg)** to check for HBV infection and
 - b. **Hepatitis B Surface Antibody (Anti-HBs)** to check for immunity to the HBV

Results are reported to the LHD and/or the WV PHBPP Coordinator and can be sent to the PHBPP fax (304) 558-6335. HBsAg-negative infants with anti-HBs >10mIU/mL are protected and need no further medical management. HBsAg-negative infants with anti-HBs < 10mIU/mL will

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need additional hepatitis B vaccination and subsequent PVST. HBsAg-positive infants should be referred to a medical specialist for appropriate follow-up.

Laboratory Responsibilities

Laboratories are in an important position to prevent mother-to-child HBV transmission by improving the identification of HBV-infected pregnant women. The CDC estimates less than half of HBsAg-positive pregnant women are identified by health departments, which increases the risk of exposed infants not receiving timely post-exposure prophylaxis through vaccination. Underidentification of HBsAg-positive pregnant women can be minimized if laboratory reporting indicates that a woman is pregnant at the time of testing for HBsAg. Laboratories are responsible for:

1. Reporting per WV Reportable Disease Rule (64 CSR-7):
 - For paper copies of positive HBV laboratory results (HBsAg, anti-HBc IgM, HBeAg, HBV DNA), forward a copy to the LHD of the county of the patient's residence within 24 hours of report.
 - For electronic lab reporting (ELR) facilities, positive HBV laboratory results (HBsAg, anti-HBc IgM, HBeAg, HBV DNA) must be reported to the WV Electronic Disease Surveillance System (WVEDSS) within 24 hours of report.
2. **Clearly indicate pregnancy status** when available on all HBsAg-positive test results reported to health departments and ordering clinicians. These test results include, but are not limited to:
 - Orders originating as obstetric ("OB") panels or prenatal screening panels that include HBsAg testing as a component
 - Individual HBsAg test orders originating from an OB or prenatal panel performed elsewhere (HBsAg outsourced to a reference lab)
 - Orders originating as an original prenatal HBsAg test
 - Orders for a standalone HBsAg test that is not part of an OB or prenatal panel but where pregnancy status is indicated elsewhere on the order (e.g. as a pregnancy-related ICD-9/10 diagnosis code)

RECOMMENDED METHOD OF IDENTIFICATION: Insert the word "PRENATAL" into reported test results, either next to test name of results sent by paper/fax or in the OBR-13 field of results sent by ELR.

3. Please also include:
 - a. Patient's full name, date of birth, address and phone number
 - b. Patient's demographic information including age, sex, race, and ethnicity
 - c. Full name, address, and phone number of ordering physician

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- d. Additional laboratory results, normal values, and interpretation including:
- 1) Hepatitis B surface antigen (HBsAg)
 - 2) Hepatitis B DNA (HBV DNA)
 - 3) Hepatitis B e antigen (HBeAg)
 - 4) Hepatitis B surface antibody (anti-HBs)
 - 5) IgM antibody to Hepatitis B core antigen (IgM anti-HBc)
 - 6) Hepatitis B core total antibody (total anti-HBc)
 - 7) Hepatitis B Genotype

Additional information on laboratory reporting of pregnancy status for hepatitis B-positive women can be found at:

www.cdc.gov/hepatitis/hbv/pregstatuslabreporting.htm

Local Health Responsibilities

HBsAg laboratory results that are positive are reportable to the LHD within 24 hours. The LHD should determine pregnancy status for *all* women who have had a positive HBsAg result reported and document in the WVEDSS. The following should be completed when a woman is found to be pregnant.

Prenatal

1. Notify the PHBP Coordinator by email or phone call at (304) 558-5358 ext. 1.
2. Contact the ordering provider to determine if the patient has been notified of the positive HBV results and educated about the need for postexposure immunoprophylaxis for her newborn. Remind the provider that HBV DNA testing is now recommended in HBsAg positive pregnant women. If the mother's HBV DNA is greater than 200,000 IU/ml, the risk of mother to child transmission is increased. Request the estimated date of delivery (EDD) and anticipated delivery hospital. Inform the provider that the pregnant woman will be contacted by the LHD to provide information about perinatal hepatitis B prevention and will be enrolled in the PHBPP for case management.
3. Contact the mother to let her know she and her infant have been enrolled in the PHBPP. The PHBPP will help to ensure the delivery hospital is prepared to administer HBIG and hepatitis B vaccine within 12 hours of birth. The program will also follow her infant through completion of the vaccine series and post vaccination serological testing (PVST) at 9 -12 months of age. PVST is very important to ensure that the vaccinations were effective (there is adequate protection against HBV) and to check for infection.
 - a. Educate her about the significance of HBV infection as well as the importance of her receiving care and keeping medical appointments.

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- b. Educate her on the prevention of transmission of hepatitis B to her baby and others:
 - 1) The disease can be transmitted to others through blood or body fluid exposure (see Mode of Transmission, page 11)
 - 2) Infants of positive mothers are exposed during childbirth
 - a. HBIG and hepatitis B vaccine should be administered to the infant within 12 hours after birth and is up to 95% effective in preventing transmission
 - b. The infant will need to complete the hepatitis B vaccine series (usually 3-4 vaccinations before 8 months of age) on time to prevent infection and to ensure immunity
 - c. The infant will need to have serological testing done between 9 – 12 months of age to check for infection and to ensure the vaccinations were effective in providing protection from HBV
 - 3) It is safe to breastfeed as long as the baby has received appropriate administration of HBIG and hepatitis B vaccine after birth
 - 4) Handouts on Perinatal Protection When Pregnant can be found at:
www.cdc.gov/hepatitis/hbv/pdfs/HepBPerinatal-ProtectWhenPregnant.pdf
www.cdc.gov/hepatitis/hbv/pdfs/HepBPerinatal-ProtectHepBYourBaby.pdf
- c. Request the mother's household and sexual contacts for HBV testing and vaccination.
- d. Verify her EDD and where she plans to deliver.
- e. Request her country of birth and type of insurance.
4. Please complete the **Intake Form** and send along with a copy of the laboratory results to the PHBP Coordinator by email or fax number (304) 558-6335.
5. Contact the facility where the mother plans to deliver at the time of notification as well as 30 days prior to mother's estimated date of delivery (EDD). Ensure they are prepared to administer HBIG and hepatitis B vaccine to the newborn within 12 hours after delivery and send them a copy of the **Perinatal Hepatitis B Prevention Birth Report**. The form is to be completed at delivery and sent back to local health or to the PHBP Coordinator at the fax number on the form.
6. Stay in touch with the mother as needed during pregnancy and keep up to date contact information for her. If she relocates to another county or state, please notify the PHBP Coordinator so the appropriate transfer can be made.

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Postnatal

1. Notify the PHBP Coordinator of the birth by submitting the completed delivery form within 2 days of birth to ensure the administration of HBIG within 7 days of delivery. The form may be sent by fax to (304) 558-6335.
2. Contact the infant's pediatrician named on the delivery form:
 - a) Confirm the infant has a follow up appointment scheduled within 1-2 months of birth with plans for the next dose of hepatitis B vaccine to be administered
 - b) Ensure the pediatrician is aware that the infant is at high risk for HBV infection and will need to complete the hepatitis B vaccine series on time per ACIP recommendations as shown in **Table 1** (page 15)
 - c) Provide information about the need for post vaccination serological testing to be done at 9-12 months of age
3. Continue case management efforts throughout completion of PVST

Lost to Follow Up

1. Each LHD should maintain a policy on how to manage patients who are lost to follow up (LTFU).
2. A patient may be considered LTFU if the patient is unable to be located within 15 days at any time during case management and after the LHD has attempted at least three good faith attempts to contact the patient which includes but is not limited to:
 - a) Three phone call attempts on separate days
 - b) Two letters sent (preferably one certified)
3. If the LHD determines that the patient is LTFU, please notify the PHBPP Coordinator who will request assistance from the WV Department of Health and Human Resources (DHHR) Disease Information Specialist (DIS).
4. Cases for infants enrolled in the PHBPP will not be closed as LTFU at the state office until the infant is at least two years of age.

State Health Responsibilities

1. Oversee the case management of HBsAg-positive pregnant women and their infants until PVST has been completed or until the infant reaches two years (24 months) of age.
2. Provide support as needed to LHDs in all case management activities.
3. Provide support to LHDs in locating a mother and/or infant who have been LTFU, which may include assistance from DHHR's Disease Intervention Specialists.

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4. Provide up to date information on policies, procedures, and laws to prevent perinatal HBV infection for prenatal care providers, delivery hospitals, pediatric care providers and LHDs.
5. Completion of an annual report to be submitted to the CDC summarizing perinatal hepatitis B prevention case management in WV.
6. Prompt and complete reporting of perinatally acquired hepatitis B cases to the CDC through the WVEDSS.

Disease Prevention and Control Objectives

The goal of perinatal hepatitis B prevention is to stop the transmission of the disease from HBV positive mothers to their infants by:

1. Identification of HBV-positive pregnant women which includes:
 - a. Testing every pregnant woman for HBsAg with each pregnancy
 - b. HBsAg testing of mothers who present for delivery when their HBV status is unknown or not documented
 - c. Reporting all HBV positive results to the state or LHD.
 - d. Including pregnancy status when reporting positive HBsAg results
2. Appropriate administration of HBIG and Hepatitis B vaccine to all newborns per ACIP recommendations as shown in **Table 1** (page 15).
3. Timely completion of the hepatitis B series for all infants.
4. PVST for infants born to mothers who are HBV-positive and for infants whose mother's hepatitis B status is unknown.

The CDC and the ACIP recommend universal administration of the hepatitis B birth dose for medically stable newborns weighing > 2000 grams within 24 hours of birth. Only single-antigen Hepatitis B vaccine should be used for the birth dose. The universal birth dose of hepatitis B vaccine is a national standard of care and helps to prevent:

- a) Mother-to-infant transmission of HBV
- b) Household transmission of HBV from infected family members or other caregivers
- c) HBV transmission due to medical errors

Disease Surveillance Objectives

1. Determine the rate of perinatal hepatitis B infection in WV.
2. Identify pregnant women who have a positive HBsAg in WV.
3. Identify infants who are exposed to HBV at birth in WV.

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4. Evaluate the administration of HBIG and hepatitis B vaccine given to infants exposed to HBV at birth within 12 hours in WV.
5. Evaluate completion rates, including timeliness, of the hepatitis B vaccination series for infants exposed to hepatitis B at birth in WV.
6. Evaluate completion of post vaccination serological testing for infants exposed to hepatitis B at birth in WV.

Public Health Significance

Perinatal transmission of HBV is very efficient and is the most common form of transmission leading to chronic infection. Worldwide, most people living with chronic HBV acquired it perinatally or at a very young age. There are more than 240 million people living with the disease throughout the world, and over 600,000 people will die annually due to chronic HBV infection. It is in the top 20 causes of mortality among humans.

In the United States (US), the rate of new HBV infections declined from 1990-2014, mostly due to routine vaccination of children recommended since 1991. However, there has been an increase in new HBV infections in the US since 2014, most likely due to the increase in injection drug use. In 2016, the CDC estimated there were 20,900 acute HBV cases in the US. WV began to see increases in HBV infections starting in 2012, by 2016, the rate of acute hepatitis B infections in WV was more than 14 times the national average.

Perinatal transmission of HBV infection is significant because the younger the individual is when the disease is acquired, the higher their risk is of becoming chronically infected. Age at the time of infection is the primary determinant of risk of progressing to chronic infection. Approximately 90% of infants perinatally infected will develop chronic HBV infection. Twenty-five to fifty percent of children age 1-5 years are at risk of remaining chronically infected as compared with 5% of adults (95% of adults recover completely and do not progress to chronic HBV infection). Twenty-five percent of infants and children who acquire chronic HBV infection will die prematurely of from HBV-related hepatocellular carcinoma or cirrhosis.

Clinical Description

Perinatally acquired HBV infection is usually asymptomatic, although it is possible for symptoms to range from mildly symptomatic to fulminant hepatitis. Infants are least likely to be symptomatic, as the likelihood of developing symptoms is age dependent.

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Etiologic Agent

HBV is a small DNA virus belonging to the family *Hepadnaviridae*. Important components of the particle include the HBsAg contained on the outer protein coat, the partially double-stranded DNA in the center, and inside the virus, the HBeAg which is an index of viral replication and infectivity.

Reservoir

Humans are the only known host. It is common for those who are infectious to be asymptomatic, therefore, testing for all pregnant women with each pregnancy is recommended, even if they have been vaccinated or tested previously.

Mode of Transmission

HBV is easily transmitted through direct percutaneous (an opening in the skin) or mucosal exposure to infectious blood and body fluids. Perinatal HBV infection occurs through vertical (mother-to-child) transmission when the infant is exposed to HBV in utero, during childbirth or after birth.

- 1) Intrauterine exposure – accounts for < 10% of perinatal hepatitis B infections and is most likely to occur when the mother has HBV DNA > 200,000 IU/mL *and* a positive hepatitis B e antigen
- 2) Exposure during childbirth – this has the most impact due to the significant exposure of the infant to blood and body fluids during delivery
- 3) Exposure after delivery – when coming into contact with mother's blood and body fluids

People who are infected with HBV and are asymptomatic are often referred to as carriers of the virus. Asymptomatic carriers are still infectious and capable of transmitting the virus to others.

Incubation Period

The incubation period for acute HBV infection is 45-160 days, with an average of 90 days.

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Period of Communicability

All persons who are HBsAg positive are potentially infectious, even if they are asymptomatic.

Case Definition

In the event that a child less than 24 months of age has had positive HBV serology including a hepatitis B surface antigen (HBsAg), hepatitis B e antigen (HBeAg) or hepatitis B DNA (HBV DNA), please notify DIDE within 24 hours, enter the information into WVEDSS, and ensure the child has been linked to care. Please refer to the Council of State and Territorial Epidemiologists (CSTE) case definition for case classification. The current case definition for perinatally acquired hepatitis B virus infection can be found here:

wwwn.cdc.gov/nndss/conditions/hepatitis-b-perinatal-virus-infection/

The CSTE case definition is provided below:

Hepatitis B, Perinatal Infection 2017 Case Definition CSTE Position Statement(s)

Background

Great progress has been made in identifying hepatitis B surface antigen (HBsAg)-positive pregnant women and immunizing their infants with hepatitis B (hepB) vaccine and hepatitis B immune globulin (HBIG) to prevent vertical infection, but there are still infants who acquire hepatitis B virus (HBV) infection. This is because either their mothers are not recognized as infected and the infant does not receive HBIG and the full hepB vaccine series or the intervention does not prevent infection. Without post-exposure prophylaxis with HBIG and hepB vaccine, approximately 45% of infants born to HBV-infected mothers will become infected and up to 90% of those infected will develop chronic, life-long infection. Among infants who do develop infection, 25% will die prematurely of liver cirrhosis or cancer. It is estimated that 1,000 newborns are infected annually.¹ Although, treatment of HBV infection is now possible and can attenuate the impact of infection, Hepatitis B cannot yet be cured.²

It is important to assure adequate immunity in infants of HBV-infected mothers and to determine if infection of the infant occurred with or without post-exposure prophylaxis. The Centers for Disease Control and Prevention (CDC) and the Advisory Committee on

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Immunization Practices (ACIP) recommend universal testing of pregnant women for HBsAg, post-exposure prophylaxis within 12 hours of birth with HBIG and the first dose of hepB vaccine for infants born to HBV-infected mothers, universal birth dose administration to all infants regardless of the mother's HBsAg status, completion of a valid three dose vaccine series in all infants, and post-vaccination serologic testing (PVST) for HBsAg and anti-HBs at 9-12 months for infants born to HBV-infected mothers or infants born in regions of high and intermediate HBV endemicity. The CDC Perinatal Hepatitis B Prevention Program helps promote these recommendations and provides case management of HBV-infected mothers and their infants. Evaluation of the program depends on the follow-up of exposed infants.

Clinical Criteria

Perinatal HBV infection in a child ≤ 24 months of age may range from asymptomatic to fulminant hepatitis.

Laboratory Criteria for Diagnosis

Laboratory evidence of HBV infection in an infant consists of one or more of the following:

- Positive hepatitis B surface antigen (HBsAg) test (only if at least 4 weeks after last dose of hep B vaccine)
- positive hepatitis B e antigen (HBeAg) test
- detectable HBV DNA

Epidemiologic Linkage

Born to a HBV-infected mother.

Case Classification

Probable

Child born in the US and positive for HBsAg at ≥ 1 month of age and ≤ 24 months of age **OR** positive for HBeAg or HBV DNA ≥ 9 months of age and ≤ 24 months of age, but whose mother's hepatitis B status is unknown (i.e. epidemiologic linkage not present).

Confirmed

Child born in the US to a HBV-infected mother and positive for HBsAg at ≥ 1 month of age and ≤ 24 months of age **OR** positive for HBeAg or HBV DNA ≥ 9 months of age and ≤ 24 months of age.

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Comments

Infants born to HBV-infected mothers should receive HBIG and the first dose of hepB vaccine within 12 hours of birth, followed by the second and third doses of hepB vaccine at 1 and 6 months of age, respectively. PVST for HBsAg and anti-HBsAg is recommended 1 to 2 months following completion of the vaccine series, but not earlier than 9 months of age.

If the mother is known to not be infected with HBV, refer to the case definition for acute hepatitis B.

Preventive Interventions

Prevention of perinatally acquired HBV infection includes the appropriate administration of HBIG and hepatitis B vaccine to newborns (see **Table 1**, page 15) when the mother is HBsAg positive during pregnancy. This will ensure protection from exposure to the virus at and after delivery. In addition, evaluating pregnant mothers for antiviral therapy when HBV DNA is >200,000 IU/mL is recommended to decrease the risk of mother to child transmission. Universal hepatitis B vaccination to all infants within 24 hours of birth prevents transmission from possible household contacts, caregivers and in the community. It also serves as a safeguard to prevent perinatal transmission among infants born to HBsAg-positive mothers who were not identified.

Surveillance Indicators

1. The proportion of cases that received the first hepatitis B vaccine dose < 12 hours after birth.
2. The proportion of cases that received HBIG < 12 hours after birth.
3. The proportion of cases that received the third hepatitis B vaccine dose < 8 months after birth.
4. The proportion of cases that received greater than or equal to three hepatitis B vaccine doses.
5. The proportion of cases that complete PVST before the infant is 18 months of age.

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TABLE 1. From MMWR 2018; 67 (RR 1); 33-34
Hepatitis B vaccine schedules for infants, by infant birthweight and maternal HBsAg status

Birthweight	Maternal HBsAg status	Single-antigen vaccine		Single-antigen + combination vaccine		
		Dose	Age	Dose	Age	
≥2,000 g	Positive	1	Birth (≤12 hrs)	1	Birth (≤12 hrs)	
			HBIG [§]	Birth (≤12 hrs)	HBIG	Birth (≤12 hrs)
		2	1–2 mos	2	2 mos	
		3	6 mos [¶]	3	4 mos	
				4	6 mos [¶]	
	Unknown*	1	Birth (≤12 hrs)	1	Birth (≤12 hrs)	
		2	1–2 mos	2	2 mos	
		3	6 mos [¶]	3	4 mos	
				4	6 mos [¶]	
Negative	1	Birth (≤24 hrs)	1	Birth (≤24 hrs)		
	2	1–2 mos	2	2 mos		
	3	6–18 mos [¶]	3	4 mos		
			4	6 mos [¶]		
<2,000 g	Positive	1	Birth (≤12 hrs)	1	Birth (≤12 hrs)	
			HBIG	Birth (≤12 hrs)	HBIG	Birth (≤12 hrs)
		2	1 mos	2	2 mos	
		3	2–3 mos	3	4 mos	
		4	6 mos [¶]	4	6 mos [¶]	
	Unknown	1	Birth (≤12 hrs)	1	Birth (≤12 hrs)	
			HBIG	Birth (≤12 hrs)	HBIG	Birth (≤12 hrs)
		2	1 mos	2	2 mos	
		3	2–3 mos	3	4 mos	
		4	6 mos [¶]	4	6 mos [¶]	
	Negative	1	Hospital discharge or age 1 mo	1	Hospital discharge or age 1 mo	
		2	2 mos	2	2 mos	
		3	6–18 mos [¶]	3	4 mos	
				4	6 mos [¶]	

Abbreviations: HBIG = hepatitis B immune globulin; HBsAg = hepatitis B surface antigen.

* Mothers should have blood drawn and tested for HBsAg as soon as possible after admission for delivery; if the mother is found to be HBsAg positive, the infant should receive HBIG as soon as possible but no later than age 7 days.

† Pediarix should not be administered before age 6 weeks.

§ HBIG should be administered at a separate anatomical site from vaccine.

¶ The final dose in the vaccine series should not be administered before age 24 weeks (164 days).

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Perinatal Hepatitis B Prevention Protocol



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