WISCONSIN PERINATAL HEPATITIS B PREVENTION PROGRAM MANUAL



Immunization Program
Bureau of Communicable Diseases
Division of Public Health
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Glossary of Terms and Abbreviations

AAP American Academy of Pediatrics

AAFP American Academy of Family Physicians

ACIP Advisory Committee on Immunization Practices
ACOG American College of Obstetricians and Gynecologists

ALT alanine aminotransferase AST aspartate aminotransferase

Anti-HBc antibody to hepatitis B core antigen
Anti-HBe antibody to hepatitis B e antigen
Anti-HBs antibody to hepatitis B surface antigen
BCD Bureau of Communicable Diseases
DHS Department of Health Services
DPH Division of Public Health
EDC expected date of confinement

HBeAg hepatitis B e antigen

HBIG hepatitis B immunoglobulin HBsAg hepatitis B surface antigen

HBV hepatitis B virus
IP infection preventionist
IDU injecting drug use
L&D labor and delivery
LHD local health department
NICU neonatal intensive care unit

PHN public health nurse

PVST postvaccination serologic testing

STAT medical abbreviation for Latin 'statim' meaning immediately

VFC Vaccines for Children VPD vaccine preventable disease

WEDSS Wisconsin Electronic Disease Surveillance System

WIR Wisconsin Immunization Registry
WSLH Wisconsin State Laboratory of Hygiene

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Introduction

Hepatitis B is caused by infection with Hepatitis B virus (HBV). The range in incubation period from the time of exposure to onset of symptoms is 45-180 days (average 60-90 days). Clinical signs and symptoms occur more often in adults than in infants or children, who usually have asymptomatic acute courses. However, approximately 50% of adults who have acute infections are asymptomatic. Among those with clinical illness, the onset is usually insidious, with anorexia, vague abdominal discomfort, nausea and vomiting, sometimes with arthralgia and rash. Clinically apparent illness often progresses to jaundice. Most acute infections among adults result in complete recovery; however, approximately 5% of all acute HBV infections progress to chronic infection. Each year 200 to 300 Americans die as a result of fulminant disease (case fatality rate, 63% to 93%). CDC estimates that 800,000 to 1,400,000 persons in the U.S. are infected with HBV; approximately 38,000 new infections occur annually (1).

Persons with chronic HBV infection are often asymptomatic and may not be aware that they are infected. The risk of chronic infection is inversely related to age at infection. As many as 90% of infants infected at birth and 30% to 50% of children who are infected with HBV when they were aged 1 to 5 years become chronically infected, compared with 2% to 6% of persons infected with HBV when they were adults. Persons with chronic HBV infection have a higher risk of developing cirrhosis and hepatocellular carcinoma (2).

HBV transmission results from percutaneous and mucosal exposure to infective body fluids. Major modes of HBV transmission include sexual or close household contact with an infected person, perinatal parent-to-infant transmission, injecting drug use, and nosocomial exposure. Persons with either acute or chronic HBV infection should be considered infectious whenever HBsAg is present in the blood.

The CDC Division of Viral Hepatitis has described the elimination of perinatal hepatitis B as one of the priority goals in the national strategy for elimination of HBV infection. This strategy is focused on reducing the number of HBV infections each year to make progress toward elimination of chronic HBV infection and liver cancer in the U.S. To accomplish these goals, it is imperative for both public and private health care providers in Wisconsin to implement and support practices and policies designed to prevent perinatal transmission of HBV.

The CDC's strategy to eliminate transmission of HBV infection includes:

- Universal screening of pregnant persons for HBsAg during each pregnancy.
- Provision of immunoprophylaxis to infants born to HBsAg-positive persons, including hepatitis B vaccine and HBIG within 12 hours of birth.
- Routine hepatitis B vaccination within 24 hours of birth for all medically stable infants weighing ≥2,000 grams.
- Vaccination of previously unvaccinated children and adolescents through age 18 years.
- Vaccination of previously unvaccinated adults aged 19–59 years and adults aged ≥60 years with risk factors for HBV infection or without identified risk factors but seeking protection.

Refer to the Glossary of Terms and Abbreviations to clarify abbreviations used throughout the manual.

Case Definitions and Classifications

Perinatal Hepatitis B Case Definition and Case Classification

Clinical Case Definition: Perinatal hepatitis B in the newborn may range from asymptomatic to fulminant hepatitis.

Case Classification, confirmed:

- Child born in the US to a HBV-infected parent and positive for HBsAg at ≥ 1 month of age and ≤ 24 months of age or
- Positive for HBeAg or HBV DNA \geq 9 months of age and \leq 24 months of age.

Laboratory criteria for diagnosis: HBsAg positive

Perinatal Transmission of Hepatitis B Virus

Approximately 24,000 persons with chronic HBV infection (identified through prenatal HBsAg laboratory testing) give birth in the U.S. each year (3). Of perinatal HBV infections, 90% can be prevented by administration of postexposure prophylaxis with hepatitis B vaccine and HBIG to each infant born to an HBsAg-positive person. Routine vaccination with the hepatitis B vaccine series is recommended to ensure each infant is protected against HBV infection from an early age.

The following scenarios describe settings and circumstances for acquisition of many of the perinatal HBV infections and should be considered when developing and implementing local protocols and services to prevent HBV infection among infants:

- A pregnant person is tested for HBsAg early in pregnancy and is found to be negative. They develop HBV infection later in pregnancy, but it is not detected despite the CDC recommendation that pregnant persons at high risk for acquiring HBV in pregnancy be tested again later in the pregnancy. The infection is not clinically detected by their medical care providers, so their infant does not receive hepatitis B vaccine and HBIG at birth.
- A pregnant person with chronic HBV infection is tested using the wrong laboratory test. The negative test result leads the clinician to believe that the person is not at risk for transmitting HBV to their infant. The infant does not receive hepatitis B vaccine and HBIG at birth.
- A pregnant person is not tested during the current pregnancy. Their prenatal care provider believes they are not at risk for acquiring HBV infection and reports a negative test result for HBsAg screening from a previous pregnancy (in fact, they acquired HBV infection since their previous pregnancy). Their infant does not receive hepatitis B vaccine and HBIG at birth.
- Prenatal HBsAg screening test results are not reported to the birthing hospital; the pregnant person presenting at the birthing hospital for delivery is not tested for HBsAg upon admission to L&D. Their infant does not receive hepatitis B vaccine and HBIG at birth.
- A parent is vaccine hesitant and does not think their infant is at risk for HBV infection. They refuse the hepatitis B birth dose prior to hospital discharge and delay hepatitis B vaccination until the child is ready for entrance into kindergarten. Their young child is infected with HBV by an unidentified household or community source.

An additional important scenario that involves infants and young children is when a parent is HBsAgnegative, but an infant or young child is infected with HBV by another family member or caregiver. This accounts for the majority of cases of childhood transmissions of HBV to young children.

Preventing Perinatal Transmission of Hepatitis B Virus

Based on these recommendations, previous ACIP recommendations, and CDC priority strategies for the elimination of HBV infection in the U.S., the Wisconsin Perinatal Hepatitis B Prevention Program has identified several gaps that must be closed if we are to meet this goal, including:

- Identify each pregnant person at risk of transmitting HBV.
- Decrease the number of infants born to HBsAg-positive persons who are lost to follow-up.
- Test each pregnant person for HBsAg during an early prenatal visit in each pregnancy.
- Conduct timely follow-up of each report received on an HBsAg-positive person of childbearing age (12-55 years old) to determine if they are pregnant.
- Decrease the number of pregnant persons who are admitted to birthing hospitals for delivery without a history of prenatal care (approximately 3-5% annually and increasing in some subpopulations).
- Increase provider reporting of HBsAg-positive pregnant persons to the local health department.
- Increase birthing hospital support for and implementation of a universal hepatitis B vaccine birth dose policy.
- Appropriately manage persons identified as contacts of an HBsAg-positive pregnant person and infant(s) born to them (i.e., test and vaccinate).
- Educate providers regarding the racial and ethnic disparities associated with perinatal transmission of HBV and the misperception that the birthing person and their newborn infant are not at risk of perinatal transmission of HBV (e.g., because they tested HBsAg-negative during a previous pregnancy).

ROLE OF LOCAL HEALTH DEPARTMENTS

Case Management

The purpose of perinatal hepatitis B case management is to ensure that steps have been taken to prevent transmission of HBV from HBsAg-positive birthing persons to their infant during and immediately following birth. In addition, case investigation assures that appropriate steps have been taken by the LHD to prevent further HBV transmission in the household setting.

For each reported HBsAg-positive pregnant person, the LHD should:

- Create a new disease incident in WEDSS or attach the laboratory result to their existing WEDSS incident.
- Verify the test results with the ordering physician or laboratory.
- Conduct hepatitis B case management to ensure that all household and sexual contacts of the pregnant person are tested for HBV infection.
- Investigate any additional acute or chronic cases identified as being associated with the index case.
- Ensure vaccination of all susceptible perinatal and sexual contacts with the hepatitis B vaccine series followed by postvaccination serologic testing.
- Ensure that the birthing hospital, identified as the location for delivery, is notified of the HBsAgpositive status of the pregnant person.
- Ensure that the birthing hospital is aware of the recommendations to provide hepatitis B vaccine and HBIG to the infant born to a HBsAg-positive person within 12 hours of birth.
- Provide education and consultation to the pregnant person and their health care provider(s) to prevent additional transmission of HBV.
- Work with caregivers of the infant to assure that the infant completes the hepatitis B vaccine series on schedule, followed by postvaccination serologic testing (at age 9-12 months) to verify immunity.
- Serve as a resource for local prenatal health care providers regarding perinatal hepatitis B prevention.

Protocol for Managing Contacts of HBV-Infected Pregnant Persons

The LHD case manager is responsible for working in partnership with local health care providers to ensure that all household and sexual contacts of a HBsAg-positive pregnant person are identified and tested for HBV infection, susceptible contacts are vaccinated, each infant born to a HBsAg-positive parent receives immunoprophylaxis within 12 hours of birth and completes the hepatitis B vaccine series (Table), and postvaccination serologic testing is conducted to verify HBV immunity.

The LHD case manager will also educate the person about their infection, the implications for their infant, and the importance of following recommended prophylaxis guidelines to prevent HBV transmission. The case manager will also ensure that the parent understands the importance of routine pediatric care for their baby and how to minimize the risk of HBV exposure in the household and community settings. The <u>Vaccines for Children Program</u> may be a helpful resource for the family. Case managers should also monitor and report completion of the hepatitis B vaccine series and

postvaccination serologic testing for infants born to HBsAg-positive person in WEDSS within the infant's contact investigation. Cases are generally open for 9-18 months following birth.

Following is the step-by-step protocol:

1. Upon receipt of a HBsAg-positive laboratory test result in the pregnant person,

- Note that if you receive a positive HBsAg, HBeAg or HBV DNA test result in a person of childbearing age (aged 12 to 55 years), pregnancy status should be assessed.
- Create a new disease incident in WEDSS Case Reporter after verifying that they were not previously reported.
- Contact the prenatal care provider to confirm the positive HBsAg test result(s) and pregnancy status; if positive, determine if the patient has been notified.
- If the person was previously reported in Wisconsin, use the existing WEDSS incident to document case follow up.
- Initiate contact with the case to provide education on how to avoid transmission to contacts and identify household and/or sexual contacts.
- Ensure that the delivery hospital is notified of the HBsAg status of the person and verify that hepatitis B vaccine and HBIG will be available for immunoprophylaxis of the infant within 12 hours of birth.

2. Contact Investigation

- Assess immunization and immune status of all household or sexual contacts of the HBsAgpositive person and offer testing and vaccination, where appropriate.
- For contacts without a documented history of receiving the hepatitis B vaccine series, collect blood for laboratory testing for HBsAg, anti-HBs, and anti-HBc (triple panel screen) and administer the first dose of hepatitis B vaccine.

If all three tests are negative,

- Administer the second dose of hepatitis B vaccine at least one month after the first dose.
- If using a vaccine product that requires three doses for immunity, administer the third dose of hepatitis B vaccine at least six months after the first dose.

Repeat laboratory tests for HBsAg, anti-HBs, and anti-HBc 1-2 months after completing the hepatitis B vaccine series to determine if immune.

Contacts who do not respond to the first series of hepatitis B vaccine should complete a second three-dose vaccine series.

If positive for HBsAg, the contact is infected, refer for medical follow-up and evaluation.

If positive for anti-HBs and negative for anti-HBc and HBsAg, the contact is immune as a result of hepatitis B vaccination and does not need additional doses of vaccine.

If positive for anti-HBs and anti-HBc and negative for HBsAg, the contact is immune as a result of natural infection and does not need additional doses of vaccine.

If positive for anti-HBc and negative for anti-HBs and HBsAg, interpretation is unclear; four possibilities include:

• Resolved infection (most common)

- False-positive anti-HBc, thus susceptible
- "Low level" chronic infection
- Resolving acute infection

Refer to the interpretation of hepatitis B serologic test results chart.

For further information, refer to the MMWR

3. Upon the birth of an infant born to a HBsAg positive person

- Enter the infant into WEDSS and create a contact investigation through the parent's disease incident in WEDSS.
- Initiate perinatal case management of the infant as soon as possible after discharge from the birthing hospital.
- Provide information on the parent's HBsAg status to the physician who will provide primary pediatric care for the infant and ensure that an appointment has been made for 1-2 months following birth for the infant to receive the second dose of hepatitis B vaccine.
- Determine if there are any new or unvaccinated contacts in the infant's household who may be at risk of transmitting HBV to the infant; use contact investigation protocol above.

4. Documentation in the WIR and WEDSS

- Record all dates of Hepatitis B vaccine and HBIG administration in the WIR if it was not autopopulated from vital records.
- Report the dates of administration of hepatitis B vaccine and HBIG, and the date of postvaccination serologic testing and results in the infant's contact investigation in WEDSS.
- Complete the "Perinatal Hepatitis B follow-upV01" section found at the bottom of the Investigation tab in WEDSS.
- Report families lost to follow-up in WEDSS.
- Report to the Perinatal Hepatitis B Prevention Program transfers to another jurisdiction, diagnosis of HBV infection in an infant, and death of infant with HBV infection.

5. Lost to follow-up

- At least three valid contact attempts should be made by telephone. Valid contact attempts include leaving a voicemail message (when the answering service indicates that the phone number is correct) or speaking to a person answering the telephone who acknowledges that the HBsAg-positive parent and infant live at that address.
- If unable to reach the HBsAg-positive parent by telephone, a letter should be sent recommending that the parent or guardian reach out to the local health department and include educational materials. Document all contact attempts in WEDSS and upload a copy of letters sent to the WEDSS file cabinet.
- The infant's physician should be contacted to determine whether postvaccination serologic testing was completed. If done, request the test results from the physician, and document the results in WEDSS.
- If all contact attempts are unsuccessful, the physician does not have additional information, and 12 months have passed since the infant's last hepatitis B vaccine dose (if date is known), the parent and infant should be classified as "lost to follow-up."

Pediatric Hepatitis B Vaccination for Infants Born to HBsAg-Positive Persons

There are three hepatitis B-containing vaccines that are used during infancy. The vaccine schedules are as follows:

Pediatric Hepatitis B Vaccine Schedules

Dose	Single Antigen Vaccine	Combination Vaccine	Combination Vaccine
	Engerix B or Recombivax HB	DTaP-HepB-IPV	DTaP-IPV-Hib-HepB
		Pediarix	Vaxelis
Dose 1	Within 12 hours of birth	Use only single antigen vaccine	Use only single antigen vaccine
		for birth dose	for birth dose
Dose 2	1-2 months	2 months	2 months
Dose 3	6 months	4 months	4 months
Dose 4	NA	6 months	6 months

Single antigen hepatitis B vaccine:

- Administer 0.5 mL of single antigen hepatitis B vaccine IM within 12 hours of birth: For each infant born to a HBsAg-positive person, administer HBIG, 0.5 mL IM at birth at a different anatomic site from where the vaccine is given (e.g., other thigh).
- Complete the hepatitis B vaccine series with two additional doses of single antigen vaccine administered at 2 and 6 months of age.
- A total of three valid doses of single antigen vaccine are needed to complete the series.

Combination hepatitis B vaccines:

Do not administer combination hepatitis B vaccines at birth; use a dose of single antigen hepatitis B vaccine for the first dose in all infants born to HBsAg-positive person.

- Pediarix is licensed for use as a three-dose series at 2, 4, and 6 months of age when none of the components are contraindicated. Pediarix may be used to complete the hepatitis B vaccine primary series.
- Vaxelis is licensed for use as a three-dose series at 2, 4, and 6 months of age when none of the components are contraindicated. Vaxelis may be used to complete the hepatitis B vaccine primary series.

For pre-term infants who weigh <2,000 grams at birth and who are born to HBsAg-positive persons or persons with unknown HBsAg status, administer hepatitis B vaccine and HBIG within 12 hours of birth. The initial dose should not be counted as part of the three-dose hepatitis B vaccine series because pre-term infants with low birth weight have a decreased response to hepatitis B vaccine administered before 1 month of age. Three additional doses of hepatitis B vaccine are needed to complete the vaccine series.

ROLE OF THE PRIVATE PROVIDER

To eliminate perinatal hepatitis B, public and private health care providers must work together to implement and support practices and policies designed to prevent perinatal transmission of HBV.

Role of the Prenatal Care Provider

- Routinely test each pregnant person in Wisconsin for HBsAg during an early prenatal visit in each pregnancy.
 - o Offer triple panel (HBsAg, anti-HBs, and anti-HBc) screening to all pregnant persons aged ≥18 years who have not previously been screened with a triple panel.
 - Pregnant persons with a history of previous triple panel screening without subsequent risk for exposure to HBV (i.e., no new HBV exposures since triple panel screening) only need HBsAg screening during subsequent pregnancies.
- Send a copy of the original HBsAg test result for the current pregnancy with prenatal records to the delivery hospital.
- Inform the HBsAg-positive person of their status and stress the importance of their infant receiving immunoprophylaxis with hepatitis B vaccine and HBIG.
- Retest pregnant persons with risk factors for acquiring HBV infection later in the pregnancy. This includes HBsAg-negative pregnant persons who have:
 - o An HBsAg-positive partner.
 - O Had more than one sex partner in the last six months.
 - o A history of injecting drug use (non-prescription).
 - o Been treated for a sexually transmitted infection.
- Report each HBsAg-positive pregnant person to the patient's local public health department of jurisdiction within 72 hours of discovery or diagnosis. The report should be made to the local health department of residence. Please refer to the <u>Wisconsin local public health department and tribal agency listing</u>.
- Refer the HBsAg-positive pregnant person for appropriate medical management if needed (e.g., a hepatologist, a gastroenterologist, infectious disease specialist, or primary care physician with expertise in managing patients with HBV infection).
- All HBsAg-positive pregnant persons should be tested for HBV DNA to guide the use of antiviral therapy during pregnancy for the prevention of perinatal HBV transmission. The American Association for the Study of Liver Disease suggests antiviral therapy when the birth person's HBV DNA is >200,000 IU/mL.
- On admission to Labor and Delivery (L&D) for delivery, verify each patient's HBsAg status for the current pregnancy.
 - Order "STAT" HBsAg testing for any pregnant person with unknown HBsAg status on admission to L&D. Repeat HBsAg testing if parent reports new risk behaviors during pregnancy.
- A copy of the original laboratory report indicating the pregnant person's HBsAg-positive status should be provided to the hospital or birthing facility where the delivery is planned and to the HCP who will care for the newborn infant.

Role of Birthing Hospitals

The following are recommended for all birthing hospitals:

- Universal standing orders for admission to L&D requiring documentation of HBsAg status for the current pregnancy. The universal standing orders should also include an order for HBsAg (STAT) testing, upon admission, for all pregnant persons admitted for delivery who have no record of HBsAg prenatal testing for the current pregnancy.
- Documentation of prenatal HBsAg test results in the patient medical record (by the time of admission to L&D) for each pregnant person for the current pregnancy.
- Universal standing orders (for L&D units) for the administration of hepatitis B immunoprophylaxis with a dose of single antigen hepatitis B vaccine and HBIG to each infant born to an HBsAgpositive parent within 12 hours of birth. Documentation must include the date and time of administration of hepatitis B vaccine and HBIG.
- Universal standing orders (for L&D units) for the administration of a dose of single antigen hepatitis B vaccine within 12 hours of birth to each infant born to a person with unknown HBsAg status at the time of delivery. If the parent's HBsAg status remains unknown or is unavailable, HBIG must be administered within seven days of birth.
- Documentation of the birth parent's HBsAg status in the infant's medical record.
- If it is not possible to determine the parent's HBsAg status (e.g., when a parent or person with lawful custody safely surrenders an infant confidentially shortly after birth), the vaccine series should be completed according to a recommended schedule for infants born to HBsAg-positive parents. These infants should receive postvaccination serologic testing at age 9-12 months, and revaccination if necessary.
- Universal standing orders (for L&D units) for the administration of a dose of single antigen hepatitis B vaccine to each infant within 24 hours of birth.
 - o For infants weighing <2000 grams, born to parents with unknown HBsAg status, give a dose of single antigen hepatitis B vaccine. If the parent's HBsAg status cannot be determined within 12 hours of birth, HBIG should be given as well. These infants will need three additional doses of hepatitis B vaccine to complete the hepatitis B series because of their low birth weight.
 - o For infants weighing <2000 grams born to HBsAg-negative parents, either administer the first dose of hepatitis B vaccine before hospital discharge or delay the first dose of hepatitis B vaccine until 1 month of age. Specific recommendations for infants weighing <2000 grams, titled "Hepatitis B Immunization Management of Preterm Infants Weighing <2000g, by Maternal Hepatitis B Surface Antigen (HBsAg) Status" is available at: http://www.cdc.gov/hepatitis/hbv/pdfs/correctedtable4.pdf.

Care of Birthing Persons and Infants in Labor and Delivery (L&D) Units

Upon admission to the birthing hospital L&D unit:

- Review the HBsAg prenatal test result for the current pregnancy and place a copy in the infant medical record after delivery.
 - o If the parent is HBsAg-positive, notify the nursery that the infant will need postexposure immunoprophylaxis with hepatitis B vaccine and HBIG within 12 hours of birth.
 - o If the parent has risk factors for acquiring HBV infection during pregnancy, repeat HBsAg testing on admission; notify the laboratory to call immediately with results and document them in the birth person and infant medical records.

- For pregnant persons without laboratory documentation of HBsAg testing for the current pregnancy
 - o Perform HBsAg (STAT) testing; notify the laboratory to call immediately with results and document them in the birth person and infant medical records.
 - o If the parent is HBsAg-positive, notify the nursery that the infant will need postexposure immunoprophylaxis with hepatitis B vaccine and HBIG within 12 hours of birth.
 - o If the parent is HBsAg-negative, order administration of a dose of single antigen hepatitis B vaccine for the infant within 24 hours of birth.
 - o If HBsAg laboratory results are not available during delivery, and the baby weighs <2000 grams, administer a dose of single antigen hepatitis B vaccine and a dose of HBIG within 12 hours of birth.
 - o If HBsAg laboratory results are not available during delivery, and the baby weighs ≥2000 grams, administer a dose of single antigen hepatitis B vaccine within 12 hours of birth and allow the laboratory results to guide administration of HBIG (HBIG must be administered within 7 days of birth).

Role of the Pediatric Care Provider

If the parent is HBsAg-negative:

- Ensure that the birth person HBsAg status is recorded in the infant medical record.
- Ensure that each infant receives a dose of single antigen hepatitis B vaccine within 24 hours of birth and educate all parents on the importance of on-schedule immunization.
- Ensure that each infant completes the hepatitis B vaccination series.

If the parent is HBsAg-positive or HBsAg status is unknown:

- Ensure that each infant born to an HBsAg-positive parent or parent with unknown HBsAg status receives appropriate immunoprophylaxis and has postvaccination serologic testing (PVST) at age 9-12 months, or 1-2 months after completion of at least three doses of the hepatitis B vaccine series. If a combination vaccine product (i.e., Pediarix) was used, the infant will have received more than three doses of hepatitis B-containing vaccine.
- Support birthing hospitals in their development and implementation of standing orders for administration of HBIG and hepatitis B vaccine to infants born to HBsAg-positive parents within 12 hours of birth.
- Complete postvaccination serologic testing, including HBsAg and anti-HBs 1-2 months after completion of the hepatitis B vaccine series (no earlier than age 9 months), generally at age 9-12 months.
 - o If negative for both tests, the child is susceptible. The child can either be revaccinated with a second complete Hep B vaccine series followed by PVST 1-2 months after the final dose, or revaccinated with a single dose of hepatitis B vaccine and then complete PVST. Infants with anti-HBs <10 mIU/mL following single dose revaccination should receive two additional doses of hepatitis B vaccine to complete the second series, followed by PVST 1-2 months after the final dose. Persons who fail to respond to two appropriately administered series and who are HBsAg-negative should be considered susceptible to HBV infection.
 - o If positive for anti-HBs and negative for HBsAg, the child is immune and does not need additional doses of vaccine.
 - o If positive for HBsAg, the child is infected and should be referred for medical evaluation.

- Enter all vaccine administration dates into the WIR and forward results of postvaccination serologic testing to the LHD.
- Ensure that children aged 0-18 years who were not vaccinated at birth and who are from a country with a high rate of HBV infection are tested and vaccinated as needed.

The following resources are available from the Wisconsin DHS to assist providers who administer vaccines:

• Vaccines for Children Program (VFC)

The Wisconsin Immunization Program participates in the federally funded VFC Program that supplies free childhood vaccines to physicians, clinics and hospitals serving eligible children 0-18 years of age. All childhood vaccines are available through VFC. To enroll in VFC, or for more information on this program, call 608-266-2346.

• Wisconsin Immunization Registry (WIR)

The WIR is a computerized, web-based application developed and maintained by DHS. It is used to record, store, and monitor vaccination records for Wisconsin residents. All LHDs and many private providers use the WIR to record vaccines administered and to access historical records. Vaccine inventory and report functions are also available to the enrolled provider. Training, technical assistance and help desk services are also offered to WIR users. To enroll as a WIR user, or for more information, call the WIR help desk at 608-266-9691.

Frequently Asked Questions

1. Where can I obtain a copy of the current recommendations of the ACIP for the prevention of perinatal transmission of HBV infection?

On the Centers for Disease Control and Prevention website at https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.PDF

2. What blood test should be used to screen a pregnant person for HBV infection?

- Test each pregnant person using a triple panel screen (HBsAg, anti-HBs, and anti-HBc) if not previously screened with a triple panel and generally for **HBsAg** early during each subsequent pregnancy.
- Pregnant persons who are found to be HBsAg positive should be reported to the LHD for enrollment in case management services and should be referred for medical evaluation. (Wisconsin Communicable Disease Law, Wis. Stat. ch. 252 and Wis. Admin. Code ch. DHS 145 requires reporting of HBsAg-positive pregnant persons to the local health department.)
- HBsAg positive persons should be tested for HBV DNA (viral load) during pregnancy.
- Pregnant persons, without documentation of HBsAg status for the current pregnancy, who are admitted for delivery, should be tested for HBsAg (STAT) upon admission to L&D.

3. Do persons who have been previously vaccinated against HBV infection still need to be screened during pregnancy?

Yes. Persons who have received hepatitis B vaccine should be screened using a triple panel screen (HBsAg, anti-HBs, and anti-HBc) if not previously screened with a triple panel and generally for HBsAg early during each subsequent pregnancy.

4. Is it safe to give hepatitis B vaccine to a pregnant person?

Yes. Limited data indicate that there is no apparent risk for adverse events in developing fetuses following administration of hepatitis B vaccine to a pregnant person. Current vaccines contain noninfectious HBsAg and should pose no risk to the fetus. If the parent is at risk for HBV infection (e.g., a person with a sexually transmitted infection, an injecting drug user, has multiple sex partners, is the sex partner of a known HBsAg-positive person), vaccination with hepatitis B vaccine should be initiated as soon as their risk factor is identified. Acquiring HBV infection during pregnancy could result in severe disease for the parent or infant.

5. To whom should the HBsAg-positive pregnant person be referred?

Refer each pregnant HBsAg-positive person to the LHD of jurisdiction for their residence. A list of Wisconsin local public health departments can be found at: https://www.dhs.wisconsin.gov/lh-depts/counties.htm

Each HBsAg-positive pregnant person reported to the LHD will be contacted and enrolled in perinatal hepatitis B case management services.

6. What is perinatal hepatitis B case management, and why is it important to refer HBsAgpositive pregnant persons to public health?

Perinatal transmission of HBV from an infected parent to their infant can be very efficient and has lifelong consequences. Perinatal hepatitis B case management is a prevention strategy involving

individual case investigation, testing and immunization, health education, and surveillance to prevent transmission of HBV to infants born to HBsAg-positive persons.

7. Is it safe for an HBsAg-positive person to breastfeed their infant?

Yes. Any HBsAg-positive parent who wishes to breastfeed their infant should be encouraged to do so, including immediately following delivery. However, the infant should receive HBIG and a dose of single antigen hepatitis B vaccine within 12 hours of birth. Although HBsAg can be found in breast milk, studies conducted before hepatitis B vaccine was available showed that breastfed infants born to HBsAg-positive parents did not demonstrate an increased risk for perinatal or early childhood HBV infection. More recent studies have shown that among infants who have received postexposure prophylaxis to prevent perinatal HBV infection, there was no increased risk of infection attributed to breastfeeding.

8. Are there additional steps that can be taken to prevent perinatal transmission of HBV? Support universal standing orders at each Wisconsin birthing hospital to ensure that:

- Prenatal triple panel or HBsAg testing is done for each pregnant person during each pregnancy and is repeated for those at risk.
- There are L&D admission orders for HBsAg (STAT) testing for each pregnant person admitted for delivery without documented HBsAg testing during the current pregnancy.
- Immunoprophylaxis (including HBIG and hepatitis B vaccine) is ordered for and administered to each infant born to an HBsAg-positive person within 12 hours of birth.
- Hepatitis B vaccine is offered to all infants within 24 hours of birth.

9. What is HBeAg and why is it important?

HBeAg is a useful marker associated strongly with the number of infective HBV particles in the serum and a higher risk of infectivity. HBeAg is a marker used to guide treatment for HBV infection.

10. What is the risk to a newborn for acquiring hepatitis B infection during the birth process?

Perinatal transmission of HBV is very efficient and usually occurs from blood exposure during labor and delivery. Studies indicate that *in utero* transmission is rare and accounts for <2% of perinatal infections. Infants born to HBsAg and HBeAg-positive parents have a 70%-90% chance of becoming infected in the absence of immunoprophylaxis (with hepatitis B vaccine and HBIG). The risk of perinatal transmission is about 10% if the parent is positive only for HBsAg.

11. What are the recommendations for infants weighing <2000 grams at birth?

<u>Hepatitis B Immunization Management of Preterm Infants Weighing <2000 g</u>, by Maternal Hepatitis B Surface Antigen (HBsAg) Status http://www.cdc.gov/HEPATITIS/HBV/PDFs/CorrectedTable4.pdf

12. What is the hepatitis B vaccine recommendation for infants born to HBsAg-negative parents? Each medically stable infant weighing ≥2,000 grams should receive a dose of single antigen

hepatitis B vaccine within 24 hours of birth.

13. What prophylaxis should be administered to infants born to persons for whom HBsAg testing results during pregnancy are not available but other evidence suggestive of birth person HBV infection exists (e.g., presence of HBV DNA, HBeAg-positive, or parent known to be chronically infected with HBV)?

These infants should be managed as if born to an HBsAg-positive parent.

14. Why is it necessary to vaccinate infants without known risk for perinatal HBV transmission within 24 hours of birth?

Administration of a dose of single antigen hepatitis B vaccine to all infants within 24 hours of birth is very important in preventing perinatal HBV infection. Although infants who require immunoprophylaxis should be identified through birth person prenatal screening, administration of the birth dose to all infants within 24 hours of birth serves as a safety net to prevent perinatal infection of infants born to persons who were misclassified as HBsAg-negative because of errors in birth person prenatal testing or who were born to persons with unknown HBsAg status. CDC estimates that as many as 15% to 20% of perinatal hepatitis B exposures occur in infants born to HBsAg-negative persons or to persons who did not have prenatal hepatitis B screening.

15. How do health care providers ensure that infants transferred to a different facility after birth (e.g., hospital with higher level of neonatal care) receive timely prophylaxis?

Staff at the transferring and receiving facilities should communicate regarding the infant's hepatitis B vaccination and HBIG receipt.

16. How stable is HBV in the environment?

HBV is quite stable in the environment and remains viable for up to seven days on environmental surfaces at room temperature. All blood spills, including those that have already dried, should be cleaned and disinfected with a mixture of bleach and water (one part household bleach to 10 parts water). Gloves should always be used when cleaning up blood spills.

17. What types of equipment cleaners are virucidal against HBV?

Any disinfectant with specific label claims for HBV.

18. What are the recommendations for hepatitis B vaccine for health care personnel?

The Occupational Safety and Health Administration (OSHA) requires that hepatitis B vaccine be offered to health care personnel likely to be exposed to blood while at work. Complete recommendations for vaccination of adults for hepatitis B can be found at: http://www.cdc.gov/mmwr/PDF/rr/rr5516.pdf

19. What can birthing hospitals do to ensure that infants receive the birth dose?

Birthing hospitals can develop and implement written policies and procedures for giving a dose of single antigen hepatitis B vaccine to each infant within 24 hours of birth.

20. How does a hospital report an identified case of hepatitis B?

A report may be entered directly into the Wisconsin Electronic Disease Surveillance System (WEDSS) or by mail or fax using an Acute and Communicable Disease Case Report found at: http://www.dhs.wisconsin.gov/forms/F4/F44151.pdf

A Wisconsin local public health department and tribal agency listing can be found at: https://www.dhs.wisconsin.gov/lh-depts/counties.htm

A report should be submitted within 72 hours upon recognition of a case or suspected case.

22. Where can I obtain a copy of the most current infant and child immunization schedules? The current immunization schedules for persons 0-18 years of age are available at: http://www.cdc.gov/vaccines/schedules/index.html

23. Are there any special procedures to follow when admitting an infant to the newborn nursery or NICU who was born to an HBsAg-positive person?

Upon admission to a newborn care unit:

- Ensure that the birthing person's HBsAg status is recorded in the infant's medical record.
- Ensure that the pediatric care provider responsible for the care of the infant is aware of the HBsAg status of the birthing person.
- Ensure that hepatitis B immunoprophylaxis with HBIG and a dose of single antigen hepatitis B vaccine have been ordered and administered within 12 hours of delivery.
- Ensure that doses of HBIG and hepatitis B vaccine administered to the infant are accurately documented in the medical record, including date and time of administration.

References

- 1. U.S. Department of Health and Human Services. Combating the Silent Epidemic of Viral Hepatitis: Action Plan for the Prevention, Care and Treatment of Viral Hepatitis. Accessed November 27, 2019. Available from: https://www.hhs.gov/sites/default/files/action-plan-viral-hepatitis-2011.pdf
- 2. Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Hamborsky J, Wolfe S, Kroger A, eds. 13 ed. Washington DC: Public Health Foundation, 2015.
- 3. Centers for Disease Control and Prevention. Assessing Completeness of Perinatal Hepatitis B Virus Infection Reporting Through Comparison of Immunization Program and Surveillance Data United States. MMWR 2011;60:410-413.
- 4. Centers for Disease Control and Prevention. A Comprehensive Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States. MMWR 2005;54:1-23.
- 5. Centers for Disease Control and Prevention. Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices. MMWR 2018;67:1-31.
- 6. American Academy of Pediatrics. Hepatitis B. In: Kimberlin DW, Barnett ED, Lynfield R, Sawyer MH, eds. *Red Book*: 2021-2024 Report of the Committee on Infectious Diseases. 32nd ed. Itasca, IL. American Academy of Pediatrics; 2021: 401-428
- 7. Weng MK, Doshani M, Khan MA, et al. Universal Hepatitis B Vaccination in Adults Aged 19–59 Years: Updated Recommendations of the Advisory Committee on Immunization Practices United States, 2022. MMWR Morb Mortal Wkly Rep 2022;71:477–483.
- 8. Conners EE, Panagiotakopoulos L, Hofmeister MG, et al. Screening and Testing for Hepatitis B Virus Infection: CDC Recommendations United States, 2023. MMWR Recomm Rep 2023;72(No. RR-1):1–25.

Resources for Health Professionals

Immunization Schedules

- Child and Adolescent Immunization Schedules https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf
- Adult Immunization Schedule https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf

Journal Articles

- Shortened Interval for Postvaccination Serologic Testing of Infants Born to Hepatitis B-Infected Mothers: https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6439a6.htm
- A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States: http://www.cdc.gov/mmwr/PDF/rr/rr5416.pdf
- Recommendations for Identification and Public Health Management of Persons with Chronic Hepatitis B Virus Infection: http://www.cdc.gov/mmwr/PDF/rr/rr5708.pdf
- General Recommendations on Immunization http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm?s cid=rr6002a1
- HIPAA Privacy Rule and Public Health http://www.cdc.gov/mmwr/pdf/other/m2e411.pdf
- Gaps in Hospital Policies and Practices to Prevent Perinatal Transmission of Hepatitis B Virus, *Pediatrics* April 2010: http://pediatrics.aappublications.org/content/125/4/704.full
- A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States, Recommendations of the Advisory Committee on Immunization Practices (ACIP), Part II: Immunization of Adults: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5516a1.htm

Books

CDC Pink Book. Epidemiology and Prevention of Vaccine Preventable Diseases, Hepatitis B: http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/hepb.pdf

Websites

- CDC sources for IG and HBIG http://www.cdc.gov/hepatitis/IG-HBIG_Sources.htm
- Hepatitis B Information for Health Professionals: http://www.cdc.gov/hepatitis/HBV/PerinatalXmtn.htm
- Prenatal Care Provider Policies and Procedures to Prevent Perinatal Hepatitis B Virus Transmission
 - http://www.cdc.gov/hepatitis/HBV/PDFs/PrenatalCareProviderPoliciesAndProcedures.pdf
- Delivery Hospital Policies and Procedures to Prevent Perinatal Hepatitis B Virus Transmission: http://www.cdc.gov/hepatitis/HBV/PDFs/DeliveryHospitalPreventPerinatalHBVTransmission.pdf
- Admission orders for Labor and Delivery and Newborn Units to Prevent Hepatitis B Virus (HBV) Transmission http://www.immunize.org/catg.d/p2130.pdf
- Interpretation of Hepatitis B Serologic Test Results http://www.cdc.gov/hepatitis/HBV/PDFs/SerologicChartv8.pdf

- Wisconsin Communicable Disease Reporting http://legis.wisconsin.gov/statutes/stat0252.pdf
- Wisconsin Local Public Health Department and Tribal Agency Listing https://www.dhs.wisconsin.gov/lh-depts/counties.htm
- Disease fact sheet: Hepatitis B http://www.dhs.wisconsin.gov/immunization/hepb.htm
- Vaccine Information Statements (VIS): http://www.cdc.gov/vaccines/hcp/vis/index.html
- Give the birth dose...Hepatitis B vaccine at birth saves lives! http://www.immunize.org/catg.d/p2125.pdf
- CDC Perinatal Hepatitis B Information for Health Professionals, Viral Hepatitis Home Page http://www.cdc.gov/hepatitis/HBV/index.htm
- Hepatitis B Information for Health Professionals http://www.cdc.gov/hepatitis/HBV/VaccChildren.htm
- American Academy of Family Practice: Hepatitis B https://www.aafp.org/afp/2019/0301/p314.html
- Immunization Action Coalition: Hepatitis B http://www.immunize.org/hepatitis-b/
- Wisconsin State Health Plan: Healthiest Wisconsin 2020 http://www.dhs.wisconsin.gov/hw2020
- Sample Text for Admission Orders for Hepatitis B Vaccine Birth Dose in Newborn Nursery: http://www.immunize.org/catg.d/p2131.pdf
- Healthcare Personnel Vaccination Recommendations http://www.immunize.org/catg.d/p2017.pdf
- HBV Postexposure Prophylaxis, http://www.cdc.gov/hepatitis/HBV/PEP.htm
- Decision to Not Vaccinate My Child form, http://www.immunize.org/catg.d/p4059.pdf
- Testing and Public Health Management of Persons with Chronic Hepatitis B Virus Infection http://www.cdc.gov/hepatitis/hbv/testingchronic.htm

Resources for Patients and Parents

Websites

- Hepatitis B General Information: Who is at risk?
 http://www.cdc.gov/hepatitis/HBV/PDFs/HepBGeneralFactSheet.pdf
- Hepatitis B: Questions and Answers, Information About the Disease and Vaccines http://www.immunize.org/catg.d/p4205.pdf
- Hepatitis B, Are you at risk? http://www.cdc.gov/hepatitis/HBV/PDFs/HepBAtRisk.pdf
- Questions Frequently Asked About Hepatitis B http://www.immunize.org/catg.d/p4090.pdf
- Vaccine Information Statements (VIS)—Hepatitis B http://www.cdc.gov/vaccines/hcp/vis/visstatements/hep-b.html
- Vaccines and Immunizations, Parents, What you Need to Know http://www.cdc.gov/vaccines/parents/index.html
- National Immunization Action Coalition, Hepatitis B: www.immunize.org/hepb
- All Kids Need Hepatitis B Shots: http://www.immunize.org/catg.d/p4055.pdf
- Personal belief exemptions for vaccination put people at risk. Examine the evidence for yourself. http://www.immunize.org/catg.d/p2069.pdf

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