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This manual is available online at www.doh.wa.gov/phbguidelines.

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email civil.rights@doh.wa.gov.

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Chapter Overview

The *Perinatal Hepatitis B Prevention Program Guidelines* contains four chapters intended for different audiences involved with perinatal hepatitis B prevention. Many of the chapters have similar information. You may want to save or print out the chapters that apply to your work.

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Perinatal Hepatitis B Prevention Program Guidelines

Chapter 1: What Local Health Jurisdictions Need to Know

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Perinatal Hepatitis B Prevention Program: Goal and Objectives

Federal recommendations

The Washington State Department of Health (DOH) Office of Immunization and Child Profile (OICP) follows federal recommendations for hepatitis B immunization. These recommendations, made by the Advisory Committee on Immunization Practices (ACIP), include control of perinatal hepatitis B virus infection (HBV). The latest updated ACIP recommendations target delivery hospital policies, procedures, and case management programs.

To provide appropriate clinical care to a newborn, you must put the mother’s data in the infant’s medical record, as recommended by ACIP. This does NOT violate the Health Insurance Portability and Accountability Act (HIPAA). The HIPAA Privacy Rule allows the use of some health information:

“...A covered entity is permitted, but not required, to use and disclose protected health information, without an individual’s authorization, for the following purposes or situations: (1) To the Individual; (2) Treatment, Payment, and Health Care Operations...”

Find a summary document of the HIPAA Privacy Rule here.

Goal

Washington State’s Perinatal Hepatitis B Prevention Program (PHBPP) has an overall goal to work with partners to assure coordination of activities to prevent perinatal hepatitis B transmission to newborns. The program has several key elements.

- It is both a surveillance and case management program to help manage perinatal hepatitis B cases.
- It promotes universal birth dose.
- It relies on multiple reporting mechanisms.
- It works with partners to assure coordination of activities.

Local health jurisdictions in our state are key in completing these tasks, including supporting effective delivery hospital policies specifying birth dose vaccinations, standing orders, and case management to:
• Identify HBsAg-positive pregnant women.
• Ensure HBV DNA testing is done for all HBsAg-positive pregnant women to guide the use of maternal antiviral therapy during pregnancy for the prevention of perinatal HBV transmission.
• Make sure their babies get proper post-exposure prevention. Correct post-exposure prevention for babies includes hepatitis B immune globulin (HBIG) and hepatitis B vaccine within 12 hours of birth, followed by two more doses of vaccine (at 1-2 months and 6 months of age).
• Make sure post-vaccine testing is completed.
• Report all data on administration of follow-up doses of vaccine and post-testing of the infant to DOH.

Objectives

1. 100% of all pregnant women get screened for HBsAg prenatally or at delivery.
2. 100% of delivery hospitals adopt policies, procedures, & standing orders for HBsAg verification & for testing mothers at delivery.
3. At least 90% of expected births to HBsAg-positive mothers are identified.
4. At least 95% of babies born to HBsAg-positive mothers get HBIG and 1 dose of hepB vaccine within 12 hours of birth and 3 vaccine doses by 6 months.
5. At least 90% of these babies get a blood test (HBsAg and anti-HBs) 1-2 months after the last dose of hepB vaccine or by 9-12 months.
6. 100% of all HBsAg-positive babies get reported to DOH and CDC through the National Notifiable Disease Surveillance System.
Hepatitis B Facts

Acute (short-term) and chronic (long-lasting) effects of hepatitis B virus (HBV) infection are a major health problem.

About 79,000 infections occur in the U.S. each year; 21,000 of those cases are acute (short-term) and symptomatic (showing symptoms) (Centers for Disease Control and Prevention).

As many as 1.6 million people in the U.S. have chronic HBV and can potentially spread the disease to others.

Hepatitis B is a leading cause of liver cancer in the U.S. HBV can be passed from mom to baby during birth (perinatal infection). About 25,000 HBV-infected moms give birth each year in the U.S. Infants infected at birth may later experience potentially deadly complications, like chronic liver disease and liver cancer. Each year, about 4,000 to 5,000 people die from chronic liver disease.

Hepatitis B infection in the Asian-Pacific Islander population is 10%. That’s 60 times higher than the infection rate of the general population.

The number of foreign-born residents living with chronic hepatitis B will continue to increase with ongoing immigration from countries where hepatitis B is common.

Unless they get proper post-exposure prevention, up to 90% of babies born to mothers with hepatitis B get infected, and 85% to 95% of those will be chronically infected. Up to one in four chronically infected babies will die from primary hepatocellular carcinoma or cirrhosis of the liver later in life.

While screening rates are high, reporting rates of HBsAg-positive pregnant women remain a problem. Nationally, about 95% of pregnant women receive prenatal HBsAg serologic testing, yet only 47% of expected births to HBsAg-positive pregnant women are identified and reported to perinatal hepatitis B programs (CDC Peritable Outcomes, 2014)

Getting immunized with hepatitis B vaccine is the most effective way to prevent HBV infection. Pregnant women who are infected with HBV can prevent giving HBV to their babies at birth if the baby gets:
- Hepatitis B immune globulin (HBIG) and hepatitis B vaccine within 12 hours of birth.
- Additional doses of vaccine at 1-2 months and 6 months of age.

CDC recommends testing all pregnant women for HBV early in each pregnancy even if they already had the vaccine or test. Women who test HBsAg-negative early in pregnancy but are in a high-risk category for HBV should be retested at the delivery hospital.

Pregnant women who test HBsAg positive should be referred to the local health jurisdiction’s PHBPP and receive counseling, medical management, and information about HBV. Emerging evidence suggests HBV treatment during the third trimester is safe and reduces rates of transmission.
Local Health Jurisdiction Tasks Overview

Local health jurisdictions (LHJs) receive funds from the state Department of Health for perinatal hepatitis B prevention. Each LHJ must:

1. Identify and report HBsAg-positive mothers and their babies.
2. Manage and track infant cases to make sure they get the correct doses at the correct ages and proper testing as follows:
   a. The first dose of HBIG and hepatitis B vaccine within 12 hours of birth.
   b. The second dose at 1-2 months of age.
   c. The third dose at 6 months of age.
   d. Post-vaccination testing at 9–12 months of age, or 1-2 months after the final dose of vaccine.

Under this program:
- LHJs should manage cases and complete reports electronically in the Perinatal Hepatitis B Module at [https://fortress.wa.gov/doh/cpir/webhepatitis B/welcome.jsp](https://fortress.wa.gov/doh/cpir/webhepatitis B/welcome.jsp).
- State-supplied hepatitis B vaccine is available for all babies born to HBsAg-positive women and for household contacts and sexual partners who are younger than 20 years old.
- LHJs can get help from DOH to develop, build, and carry out the program. Take advantage of site visits by DOH staff, as well as informational and educational materials for health care providers and HBsAg-positive pregnant women.
Case Management Snapshot

Managing a perinatal hepatitis B case always starts with the pregnant woman and involves pre-screening, opening a confidential case report in the module, tracking the woman’s baby, following up with phone calls and mail, and closing a case when follow-up is finished. Cases may be open for as long as two years. Find a visual snapshot of this process below.

START: Health care provider pre-screens pregnant woman in first trimester of pregnancy.

HBsAg test is NEGATIVE.

No hepatitis B case.

HBsAg test is POSITIVE.

Health care provider or hospital reports HBsAg-positive woman to LHJ Hepatitis B Coordinator.

To guide the use of antiviral therapy during pregnancy for prevention of perinatal HBV transmission, an HBV DNA test should be done for all HBsAg-positive pregnant women.

Hep B Coordinator opens a confidential case on the HBsAg-positive woman using “New Case” in the Perinatal Hepatitis B Module.

BABY is BORN!
Hospital gives HBIG and birth dose of hepatitis B vaccine.

Hep B Coordinator calls hospital for infant’s information and dates of HBIG and hepB vaccine.

Hep B Coordinator enters infant information into the mother’s open case in the Perinatal Hepatitis B Module.

When all follow-ups with mother and baby have been documented for pre-screenings, HBIG, vaccination series and post-testing, Hep B Coordinator “closes” the open case in the Perinatal Hepatitis B Module.

Hep B Coordinator works with mother & pediatrician to make sure baby gets full vaccination series and post-testing.

Also, cases get closed for other reasons.

Based on pre-screening, Hep B Coordinator either:
- Refers contacts and partners to a specialist, or
- Makes sure contacts and partners get vaccinated and..

Hep B Coordinator closes a case for other reasons, such as if mother refuses follow-up, can’t be located, or if the pregnancy ends.

Also, cases get closed for other reasons.
Perinatal Hepatitis B Module: Overview

Local health jurisdictions (LHJs) should manage and complete reports of HBsAg-positive pregnant women and their babies in the online Perinatal Hepatitis B Module. The Module can be found here.

You must have a username and password to access the Module. Ask the administrator in your program for help.

The Module electronically captures all the information needed to manage, report, and close hepatitis B cases. It is efficient and user-friendly. You can:

- Add records (mother, infant, household contact, sexual partner)
- Search and view records
- Edit records
- Run reports

**User Guide**

- See the User Guide for detailed instructions.

**Technical support**

- If you can’t access the Module, please contact 360-236-3595 and ask to talk with the database specialist for access to the module, or email phbpp@doh.wa.gov.
- For Public Health Seattle-King County, call 206-296-4447 or visit their PHBPP website.

Managing Cases

To manage your cases and complete reports, use the online Perinatal Hepatitis B Module. The User Guide can help answer questions.

Identification of HBsAg-positive pregnant women

- Maintain a list of prenatal care providers serving the highest number of HBsAg-positive pregnant women and a list of birthing facilities.
- Send information on PHBPP and program requirements.
- Remind providers about the need to notify Perinatal Hepatitis B Coordinators of all HBsAg-positive women.
- Deliver feedback regarding cases not reported to PHBPP.
Protocol for Perinatal Hepatitis B Infection

Follow this protocol to manage cases of hepatitis B infected pregnant women and their babies. Most tasks involve recall and reminders to hospitals, health care providers, and those infected. We encourage you to focus on relationship-building, strong communication skills, and organizing an efficient tracking system for follow-up calls and mailings.

If you don’t get information on the pregnant woman until after delivery, skip to number 4 (Reminder).

1) RECALL: One week after getting information on a pregnant woman

1. Call the prenatal care provider, clinic nurse, or clinic manager to get this information:
   a. The pregnant woman’s knowledge of her HBsAg status (yes or no)
   b. The woman’s preferred or primary language
   c. The woman’s address and telephone number
   d. The woman’s due date
   e. The delivery hospital
   f. The date of positive HBsAg test result
   g. The woman’s insurance status

2. Tell the provider you will contact the woman to provide information about perinatal hepatitis B prevention, including case management and follow-up for her infant and household/sexual contacts.

3. Ask the provider to mail or fax a copy of the original HBsAg-positive lab results to their local health jurisdiction.

4. Educate the provider about the need to identify household contacts and sexual partners. Discuss what actions they will take to screen and immunize them.

5. Enter the mother/infant case contact report into the Perinatal Hepatitis B Module.

2) RECALL: Two weeks after provider confirms that the pregnant woman knows her status

1. Follow up with a phone call to the infected pregnant woman. If you cannot reach her by phone, send her a letter asking her to call you.

2. Counsel her regarding:
   - How hepatitis B spreads and how to prevent spreading it.
   - The need to screen household contacts and sexual partners for hepatitis B.
   - The need for a 3-dose series of hepatitis B vaccine for at-risk household contacts and sexual partners.
   - The need for her sexual partners to get HBIG if she has an acute (short-term) infection.
   - The need for her infant to get HBIG and the first dose of hepatitis B vaccine within 12 hours of birth, and doses 2 and 3 of hepatitis B vaccine on time.
   - The need to test her infant between 9 and 12 months of age (1-2 months after vaccine dose 3) to make sure the baby is protected and has no infection.
   - The need to get medical follow-up for herself and family members who may be HBV carriers.
3. Confirm which hospital she plans to use for delivery. Let her know you will contact the hospital to make sure that her baby gets HBIG and the first dose of hepatitis B vaccine within 12 hours of birth.

4. Tell her you will follow up with her until her infant gets all three doses of vaccine and has had post-vaccination testing.

5. Get the name and contact information of the pediatric care provider. Encourage the woman to choose a provider before delivery.

6. Record the woman’s race, ethnicity, and insurance status/information.

7. Record the names, birth dates, race, ethnicity, healthcare providers, and screening and immunization status (or the plan for screening and immunization) of the woman’s household contacts and sexual partners.

8. Follow-up is suggested with these at-risk contacts and partners. Work with the pregnant woman, contacts, partners, and healthcare providers to make sure they get screened and immunized.

9. Send a letter to the woman explaining the Perinatal Hepatitis B Prevention Program and provide written educational materials.

3) REMINDER: Four weeks prior to the woman’s estimated due date (EDC) and if the pregnant woman has tested HBsAg-positive

1. Send a letter to the obstetrical (OB) nurse manager, infection control nurse, or designated staff at the hospital with DOH Guidelines for Hospitals (Chapter 3 of this Guidebook) and a packet of written educational materials.

2. Ask the OB nurse manager, infection control nurse, or designated staff to report when the baby is born, with the following information:
   - Date and time of birth
   - Gestational age
   - Birth weight
   - Name
   - Sex
   - Healthcare provider information
   - Time and date both HBIG and hepatitis B vaccine dose 1 were given
   - Insurance or source of payment

3. Contact the pediatric care provider to confirm they know of the pregnant woman’s HBsAg status, the infant’s need for vaccine, the importance of the correct vaccine dosage and schedule, and to confirm screening and immunization status of other children in the house.

4) REMINDER: Two weeks after birth

1. If you have not received notification of the infant’s birth within two weeks after EDC, contact the hospital nursery or medical records unit to get the status of the infant.

2. If the child has been born, find out from the delivery hospital if the baby had HBIG and the first dose of hepatitis B vaccine. Get the necessary information about the infant (see the checklist in #2 above) and enter the mother/infant case contact report into the Perinatal Hepatitis B Module.
a. *When reporting past cases:* If the mother was known to be HBsAg-positive at time of delivery, enter into the Perinatal Hepatitis B Module. If the mother’s HBsAg status was unknown at the time of delivery, enter her as a household contact into the Household Contact case report in the module.

3. Send a reminder card to the mother when her baby should get vaccine dose 2.
4. Send a reminder card to the pediatric care provider about the baby’s need for a second dose of hepatitis B vaccine.
5. Contact the pediatric care provider or clinic nurse to find out when they have scheduled the baby to get the second dose of hepatitis B vaccine.

5) **RECALL:** One week after appointment for second dose

1. Contact pediatric care provider to find out if the baby came in for his or her appointment. If yes, record date of vaccination, vaccine brand, and payment source.
2. Enter the dose information into the Infant report of the module.
3. Determine the date the baby should get vaccine dose 3. Send a reminder card to the provider about the importance of the baby getting the third dose of vaccine on time.

6) **REMEMBER:** Two weeks before the third dose is due

1. Send a reminder card to the mother for her baby’s third dose of hepatitis B vaccine.
2. Send a reminder card to the pediatrician that the baby needs the third dose.

7) **RECALL:** One week after appointment for third dose

1. Contact the pediatric care provider to find out if the baby came to his or her appointment. If yes, record date of vaccination, vaccine brand, and payment source.
2. Enter the dose information into the Mother/Infant screen of the module.
3. Send a reminder card to the pediatric care provider that the baby should be screened for HBsAg and anti-HBs between 9 and 12 months of age.
4. Determine the date the baby should get post-vaccination testing.
5. Call the mother about her baby’s need to get a post-vaccination test between 9 and 12 months of age.

8) **REMINDER:** Two weeks before the post-vaccination test is due

1. Send a reminder card to the mother about her baby’s post-vaccination test.
2. Send a reminder card to the pediatric care provider about the baby’s post-vaccination test.

9) **RECALL:** A week after post-vaccination test appointment

1. Contact the pediatric care provider to find out if the appointment was kept. If yes, record the date of the screening, screening results, and payment source in the Mother/Infant case report of the Perinatal Hepatitis B Module.
2. If a post-vaccination test was not given, follow up with the provider and document the reasons why it was not given.
3. If testing was not done, make three attempts to contact the mother and fax a reminder to the pediatrician.
4. If vaccinations and testing are incomplete or completed too early, recall infant and fax a reminder to the pediatrician
5. Inquire whether mother was evaluated for hepatitis B during pregnancy. Obtain contact information for liver specialist.

Reporting HBsAg-Positive Babies

The local health jurisdiction’s hepatitis B coordinator must follow up with HBsAg-positive babies to track their progress.

1. First, check the success of hepatitis B vaccination by making sure these babies get a blood test after their vaccination series is complete. Complete the testing at 9–12 months of age, generally at the infant’s next routine well-child visit.
2. Second, report all HBsAg-positive babies as acute hepatitis B cases, even if they have no symptoms. (This is different from acute hepatitis B reporting for older children or adults.) See the CDC case definition here.

Remember: When you prevent the spread of perinatal hepatitis B, you prevent a possibly fatal chronic infection.

Correct reporting means you must:

1. Report the outcome of the pregnancy to the Department of Health Perinatal Hepatitis B Prevention Program by phone or fax.
2. Relay information about HBsAg-positive babies to the LHJ communicable disease surveillance team. The surveillance team, in turn, reports it to DOH’s immunization office (360-236-3595) and Communicable Disease Epidemiology Program (206-418-5500).

Make sure you do proper follow-up and reporting, because:

- Not all babies become fully immune after vaccination. About 5% of vaccinated babies will not develop full immunity after three doses of hepatitis B vaccine (CDC). These babies need either re-vaccination or medical management of their infection.
- Vaccinated babies may still get infected. Up to 6% of babies born to HBsAg-positive women may still get infected even after getting proper post-exposure prevention. These babies need either re-vaccination or medical management of their infection.
- State health departments report perinatal HBV infection weekly to the Centers for Disease Control and Prevention (CDC) as a nationally notifiable condition.
## Closing Cases

To close your open hepatitis B cases and complete reports, use the [Perinatal Hepatitis B Module](#). A [User Guide](#) is also available.

If you can’t access the module, contact the program administrator to gain access to the module so that you can enter the case.

### Protocol for Closing a Case

Follow this protocol when you have completed your tasks or when a situation makes further communication impossible or not applicable.

<table>
<thead>
<tr>
<th>Mothers</th>
<th>Babies</th>
</tr>
</thead>
<tbody>
<tr>
<td>• The mother has moved:</td>
<td>• The baby has moved:</td>
</tr>
<tr>
<td>o Be sure to notify DOH staff of any county, state, or country move by the mother.</td>
<td>o Be sure to notify DOH staff of any county, state, or country move by the contact or partner.</td>
</tr>
<tr>
<td>o If she has moved to another county within Washington, contact DOH staff about the move and make a note in the Perinatal Hepatitis B Module of her new address so she can get follow up from the new local health jurisdiction. Use the Notes section to record that you made a referral to the agency.</td>
<td>o If baby has moved to another county within Washington, contact DOH staff about the move and make a note in the Perinatal Hepatitis B Module of the new address so the baby can get follow-up from the new local health jurisdiction. Use the Notes section to record that you made a referral to the agency.</td>
</tr>
<tr>
<td>o If the mother has moved to another state or country, contact DOH staff about the move so they can notify her new state or country of residence. Document the move in the Notes section of the Module or the case report form.</td>
<td>o If the baby has moved to another state or country, contact DOH staff about the move so they can notify the baby’s new state or country of residence. Document the move on the Notes section of the Module or the case report form.</td>
</tr>
<tr>
<td>• The mother has a false positive HBsAg result.</td>
<td>• The baby can’t be located.</td>
</tr>
<tr>
<td>• The mother can’t be located.</td>
<td>• The baby’s information was never on file.</td>
</tr>
<tr>
<td>• The pregnancy ended.</td>
<td>• The mother refuses follow-up for the baby.</td>
</tr>
<tr>
<td>• The mother refuses follow-up.</td>
<td>• The baby completed proper prevention (got three doses of hepatitis B vaccine and post-vaccination screening and results sent by pediatric care provider).</td>
</tr>
<tr>
<td>• The baby was adopted or referred to Child Protective Services (CPS).</td>
<td>• The baby died.</td>
</tr>
<tr>
<td>• The baby died.</td>
<td>• The baby died.</td>
</tr>
</tbody>
</table>
**Finding a Client**

Finding the client is vital due to the infectious nature of hepatitis B. Before closing an infant case, check with other communicable disease investigators and case managers. Case managers and staff may have additional methods or contacts that can assist in locating clients. All attempts to locate clients should be documented in the module. After all attempts to locate the client are exhausted, close the case. Based on local health’s capacity, a policy addressing minimum criteria for investigation before closing a case as lost to follow-up is suggested.

**Client locating checklist**

<table>
<thead>
<tr>
<th>Tried?</th>
<th>Resource</th>
<th>Remarks/Comments/Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>Contact last Health Care Provider (secure phone number or ask for emergency contact number)</td>
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<tr>
<td>☐</td>
<td>Search Washington State Immunization Information System for contact information</td>
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<tr>
<td>☐</td>
<td>Search PHB module for subsequent pregnancies</td>
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<tr>
<td>☐</td>
<td>Contact TB/STD/CD programs</td>
<td></td>
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<tr>
<td>☐</td>
<td>Contact Provider One and WIC programs</td>
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<tr>
<td>☐</td>
<td>Phone book/directory (People search, reverse phone/address search)</td>
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<tr>
<td>☐</td>
<td>Hospitals</td>
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<td>☐</td>
<td>Prenatal clinic</td>
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<td>☐</td>
<td>Family planning clinic</td>
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<tr>
<td>☐</td>
<td>School nurse</td>
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<tr>
<td>☐</td>
<td>Voter registration or Google voter lookup</td>
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<td>☐</td>
<td>Department of Motor Vehicles</td>
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<td>☐</td>
<td>US Post Office information request</td>
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<td>☐</td>
<td>Utility company (electric, water, gas, etc.)</td>
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<td>☐</td>
<td>PUBLICDATA.COM</td>
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<tr>
<td>☐</td>
<td>Internet search engine (Include person, phone number or address. Try spousal search.)</td>
<td></td>
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<tr>
<td>☐</td>
<td>Property tax information</td>
<td></td>
</tr>
</tbody>
</table>

*Adapted from Texas Perinatal Hepatitis B program and Public Health Seattle & King County*
## Transfers

<table>
<thead>
<tr>
<th>In State</th>
<th>Out of State</th>
<th>Out of Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>When clients move from one reporting jurisdiction to another, the coordinator should obtain locating information, communicate with the new jurisdiction, and place transfer information in the module.</td>
<td>When clients move from one state to another, the state PHBPP coordinator will notify and forward the case information to the appropriate jurisdiction when the transfer process is complete.</td>
<td>When client moves out of the country, contact the state PHBPP coordinator for follow up.</td>
</tr>
</tbody>
</table>
Required Notification

Washington state follows three levels of required notification for certain medical conditions to prevent and control communicable and noninfectious diseases. Different agencies take care of these different notification levels.

1. Notification to local health jurisdictions (LHJ): by every prenatal health care provider or hospital.
3. Notification to the Centers for Disease Control and Prevention (CDC): by DOH.

Washington considers EACH pregnancy in any HBsAg-positive woman a notifiable condition. This can increase the chance that babies born to HBsAg-positive mothers will get proper post-exposure prevention. Because of this, the notifications must happen correctly as explained and shown in the picture below.

1. Healthcare providers notify the LHJ Perinatal Hepatitis B Coordinator of the pregnant woman’s status.
2. The Hepatitis B Coordinator then enrolls the woman in the Perinatal Hepatitis B Prevention Program, manages her case (including her baby, household contacts, and sexual partners), and notifies the correct agency programs.
3. DOH notifies CDC weekly about all hepatitis B-infected infants.

Notification Process

**Hepatitis B Coordinator**
- Contacts HBsAg-positive woman to enroll her in Perinatal Hepatitis B Program.
- Notifies DOH of pregnancy and outcomes at:
  - Communicable Disease Epidemiology at 206-418-5500 or in PHIMS
  - DOH Office of Immunization and Child Profile-360-236-3595

**DOH staff** notify CDC of each positive hepatitis B case.

**Pregnant woman tests HBsAg-positive at her prenatal care provider, healthcare provider, or the hospital.**

**Provider or hospital** notifies local health jurisdiction’s Hepatitis B Coordinator.
Required Reportable Conditions

Hepatitis B Surface Antigen (HBsAg) Positivity During Pregnancy

Since December 2000, HBsAg-positive status during pregnancy has been a required reportable condition per Washington state law (Washington Administrative Code [WAC] 246-101-101 and WAC 246-101-301). Healthcare providers and health care facilities, such as hospitals, must report this status to local health jurisdictions within three working days.

Why Report?

Identifying and reporting HBsAg-positive pregnant women during each pregnancy helps prevent the spread of hepatitis B virus to their babies. These babies have a very high risk of getting the infection and developing serious long-term medical conditions unless they get proper post-exposure prevention.

Local public health jurisdiction staff work with health care providers to make sure that:

- Mothers get counseled about preventing the spread of HBV to their babies and their household contacts.
- Mothers get screened and, if appropriate, referred to a specialist during pregnancy (see page 2 of this infographic).
- Mother’s sexual partner(s) get referred to a specialist for follow-up.
- Babies get hepatitis B immune globulin (HBIG) and 3 doses of hepatitis B vaccine (birth, 1-2 months, 6 months).
- Babies get post-vaccination testing (HBsAg and anti-HBs) between 9 and 12 months of age (at least 1 to 2 months after the third dose of hepatitis B vaccine) to check for infection and immune status.

When to Report

A report should be made at any time during each pregnancy in which the pregnant woman tests HBsAg positive. It is the prenatal care provider’s responsibility to make sure the delivery hospital knows of an HBsAg-positive mother prior to the birth so the baby gets proper treatment.

Reporting Requirements

Per WAC 246-101-101 and WAC 246-101-301, healthcare providers and health care facilities who request the HBsAg test during prenatal care or at time of delivery must report all HBsAg-positive pregnant women to the provider’s LHJ within three working days.

Reporting Resources from DOH

- How to report notifiable conditions
- Reporting posters
- Hepatitis B as a notifiable condition
- If you have other questions, contact the Department of Health at 360-236-3595.
Vaccine Specifics: Administering Hepatitis B Vaccine

**Route and Site**

Give hepatitis B vaccine intramuscularly into the deltoid muscle of adults and children and into the anterolateral thigh muscle of newborns and babies. **Do not** give hepatitis B vaccine intradermally or into the buttock.

You can give hepatitis B vaccine at the same time as other vaccines, but use separate injection sites.

**Dose and Schedule**

Babies born to HBsAg-positive mothers should get the following. You can use different brands of the single-antigen vaccine for the vaccine doses.

**Vaccination of Premature Babies**

- Premature babies born to HBsAg-positive mothers or mothers with unknown status must get HBIG AND hepatitis B vaccine less than 12 hours after birth. If these babies weigh less than 2,000 grams at birth, do not count the first dose of hepatitis B vaccine as one of the doses in the series. The baby should get three additional doses of hepatitis B vaccine, starting when medically stable and at least 1 month of age. *MMWR, 2018*. This will be a total of 4 doses.

- Premature babies born to HBsAg-negative mothers, regardless of birth weight, should get vaccinated at the same chronological age and with the same schedule and precautions as full-term babies. Use the full recommended dose of each vaccine, because divided or reduced doses cannot count as valid. Studies demonstrate that decreased seroconversion rates might occur among certain premature babies with low birth weight (less than 2,000 grams) after getting hepatitis B vaccine at birth. However, by chronological age 1 month, all premature babies regardless of initial birth weight or gestational age *can respond as adequately as older and larger babies*. 
Vaccine Specifics: Recommended Doses of Currently Licensed Monovalent Hepatitis B Vaccines

Recombivax and Engerix-B vaccines both have three doses in their series. Engerix-B also is licensed for a four-dose series given at 0, 1-2, and 6 months. Dialysis patients should get Engerix-B at 0, 1, 2, and 6 months.

<table>
<thead>
<tr>
<th>Group</th>
<th>Merck Recombivax HB Dosage</th>
<th>GSK Engerix-B Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Babies,¹ children &amp; adolescents (0–19 years of age)</td>
<td>5 mcg (0.5 mL)² Pediatric/adolescent formulation. YELLOW cap and stripe on vial and cartons and orange banner on the vial labels and cartons stating “preservative free”</td>
<td>10 mcg (0.5 mL)³ Pediatric formulation BLUE-top vial Single-dose vials and prefilled disposable TIP-LOK syringe</td>
</tr>
<tr>
<td>Adolescent (11–15 years of age) Merck (11–19 years of age) GSK</td>
<td>10 mcg (1.0 mL) Adult formulation GREEN cap and stripe vial and orange banner on vial label</td>
<td>10 mcg (0.5 mL) OLIVE GREEN top vial</td>
</tr>
<tr>
<td>A two-dose series for adolescents (11-15) is also acceptable</td>
<td>10 mcg (1.0 mL) Adult Formulation GREEN-top vial</td>
<td>20 mcg (1.0 mL) Adult Formulation ORANGE-top vial</td>
</tr>
<tr>
<td>Adults (20 years &amp; older)</td>
<td>10 mcg (1.0 mL) Adult Formulation GREEN-top vial</td>
<td>40 mcg (2.0 mL) (Two 20 mcg doses) Adult Formulation ORANGE-top vial</td>
</tr>
<tr>
<td>Predialysis and dialysis patients</td>
<td>40 mcg (1.0 mL) Dialysis formulation BLUE cap and stripe vial with orange banner</td>
<td>40 mcg (1.0 mL) Adult Formulation ORANGE-top vial</td>
</tr>
</tbody>
</table>

**Key:**

- HBsAg = Hepatitis B surface antigen
- mcg = microgram
- mL = milliliter
- GSK = GlaxoSmithKline

**Sources:**

- [MMWR, Centers for Disease Control, January 12th, 2018](https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6701a2.htm)

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¹ Infants born to HBsAg-positive mothers should also receive hepatitis B immune globulin (HBIG) 0.5 mL intramuscularly at a site different from that used for the hepatitis B vaccine.

² Change in dose, licensed in 1998. Infants born to HBsAg-negative mothers now receive the same dose as infants born to HBsAg-positive mothers. “If the suggested formulation is not available, the appropriate dosage can be achieved from another formulation provided that the total volume of vaccine administered does not exceed 1 mL.”

³ Change in adolescent dose, licensed in 1995.
Vaccine Specifics: Administering HBIG

**Route and Site**
For newborns and babies: Give HBIG intramuscularly into the anterolateral thigh muscle.

**Dose and Schedule**
Newborns and babies should get 0.5 ml of HBIG within 12 hours of birth. They should also get dose 1 of hepatitis B vaccine at the same time at a separate injection site.

For other exposed persons, the dose of HBIG is 0.06 mL per kilogram of body weight. To calculate the dose:
- Convert body weight to kilograms (kg)
- Multiply the number of kilograms by 0.06 mL

For example, if the person weighs 110 pounds, the number of kilograms = 110 lbs ÷ 2.2 (number of pounds per kilogram) = 50.0 kg. The correct dose of HBIG then would be 50.0 kg x 0.06 (the amount per kg), giving a dose of 3.0 mL.

**HBIG Dosage at a Glance**
Use the following table to identify dosage based on weight.

<table>
<thead>
<tr>
<th>Body weight in pounds (lbs)</th>
<th>Body Weight in kilograms (kg)</th>
<th>Dose in milliliters (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>45.5</td>
<td>2.7</td>
</tr>
<tr>
<td>110</td>
<td>50.0</td>
<td>3.0</td>
</tr>
<tr>
<td>120</td>
<td>54.5</td>
<td>3.3</td>
</tr>
<tr>
<td>130</td>
<td>59.1</td>
<td>3.5</td>
</tr>
<tr>
<td>140</td>
<td>63.6</td>
<td>3.8</td>
</tr>
<tr>
<td>150</td>
<td>68.2</td>
<td>4.1</td>
</tr>
<tr>
<td>160</td>
<td>72.7</td>
<td>4.4</td>
</tr>
<tr>
<td>170</td>
<td>77.3</td>
<td>4.6</td>
</tr>
<tr>
<td>180</td>
<td>81.8</td>
<td>4.9</td>
</tr>
<tr>
<td>190</td>
<td>86.4</td>
<td>5.2</td>
</tr>
<tr>
<td>200</td>
<td>90.9</td>
<td>5.5</td>
</tr>
<tr>
<td>210</td>
<td>95.5</td>
<td>5.7</td>
</tr>
<tr>
<td>220</td>
<td>100.0</td>
<td>6.0</td>
</tr>
<tr>
<td>230</td>
<td>104.5</td>
<td>6.3</td>
</tr>
<tr>
<td>240</td>
<td>109.1</td>
<td>6.5</td>
</tr>
<tr>
<td>250</td>
<td>113.6</td>
<td>6.8</td>
</tr>
</tbody>
</table>

*Dose = 0.06 mL per kg of body weight; 1 kg = 2.2 lbs*
Vaccine Specifics: Storing and Handling Hepatitis B Vaccine and HBIG

**Always read the package insert.** Read the table below for storage and handling supplemental information, but this does not take the place of the package insert.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Shipping Requirements:</strong></td>
<td>Use insulated container. Must ship with refrigerant.</td>
</tr>
<tr>
<td><strong>Condition on Arrival:</strong></td>
<td>Should not have been frozen. Refrigerate on arrival.</td>
</tr>
<tr>
<td><strong>Storage Requirements:</strong></td>
<td>Refrigerate immediately upon arrival. Store at 2°-8°C (35°-46°F). <strong>Do not freeze.</strong></td>
</tr>
<tr>
<td><strong>Shelf Life/Expiration:</strong></td>
<td>Hepatitis B vaccine - up to 3 years. Check date on container or vial.</td>
</tr>
<tr>
<td></td>
<td>HBIG - up to 12 months. Check date on container or vial.</td>
</tr>
<tr>
<td><strong>Instructions for Reconstitution or Use:</strong></td>
<td>Inspect visually for particulate matter or discoloration.</td>
</tr>
<tr>
<td></td>
<td>Shake vial or fill syringe well before use.</td>
</tr>
<tr>
<td><strong>Shelf Life after Reconstituting or Opening:</strong></td>
<td>Check expiration date on vial, or manufacturer-filled syringe. Give the vaccine shortly after withdrawal. If pre-filled syringe, administer after the needle is attached to the syringe.</td>
</tr>
<tr>
<td><strong>Special Instructions:</strong></td>
<td>Rotate stock so that you use the material with the earliest expiration date first.</td>
</tr>
</tbody>
</table>

**Best Practices for Storing and Handling All Vaccines**

- Have policies and procedures in place to rotate stock and check expiration date of vaccine weekly. Use vaccine with earliest expiration date so none become outdated.
- Do not use outdated vaccine.
- Never store vaccine in refrigerator door.
- When transporting vaccine, always use an insulated container with ice packs.
- [Vaccine storage and handling information from the Department of Health](#)
- [Vaccine storage and handling recommendations and guidelines from the CDC](#)
Vaccine Specifics: Ages and Intervals

The table below shows hepatitis B (hepB) vaccine doses, with recommended ages, intervals, and minimum ages for getting the vaccines.

### Recommended and Minimum Ages and Intervals between Doses*

<table>
<thead>
<tr>
<th>Vaccine and dose number</th>
<th>Recommended age for this dose</th>
<th>Minimum age for this dose</th>
<th>Recommended interval to next dose</th>
<th>Minimum interval to next dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>HepB-dose 1**</td>
<td>Birth</td>
<td>Birth</td>
<td>1-4 months</td>
<td>4 weeks</td>
</tr>
<tr>
<td>HepB-dose 2</td>
<td>1-2 months</td>
<td>4 weeks</td>
<td>2-17 months</td>
<td>8 weeks</td>
</tr>
<tr>
<td>HepB-dose 3***</td>
<td>6- months</td>
<td>24 weeks</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Source: Epidemiology and Prevention of Vaccine-Preventable Diseases, CDC

** Combination vaccines with a hepatitis B component are available (Comvax, Pediarix, and Twinrix). These vaccines should not be administered to infants younger than 6 weeks because other components in the vaccines are not suitable for this age group (i.e., Hib, DTaP, HepA, and IPV).

*** Hepatitis B-dose 3 should be administered at least 8 weeks after dose 2 and at least 16 weeks after dose 1.

Laboratory Reporting

According to WAC 246-101-201, labs are required to report acute hepatitis B infection within 24 hours to the LHJ, and HBsAg, HBeAg, and HBV DNA positive results monthly. Pregnancy status is NOT currently a required field in these reports. However, to improve identification of HBsAg-positive women, 4 major commercial labs indicate pregnancy status of HBsAg-positive women on lab reports sent to LHJs. As more labs work to improve this identification, it is expected that the proportion of hepatitis B labs with pregnancy status will increase.

Lab indicators for probable pregnancy include:
- HBsAg test ordered as part of prenatal panel
- Individual prenatal HBsAg test
- Pregnancy-related diagnostic code (ICD-9/ICD-10) or pregnancy status indicated on requisition form
- “Pregnant” or “prenatal” is included in an HL7 messaging segment (for transferring data from one electronic system to another)

Laboratory Screening: Guidelines

This section identifies which screening test(s) to order for pregnant women and babies.

HBsAg: Pregnant Women

A positive HBsAg screening test identifies HBV-infected pregnant women. HBV DNA testing should be done for all HBsAg-positive pregnant women to guide the use of maternal
antiviral therapy during pregnancy for the prevention of perinatal HBV transmission. Babies born to HBsAg-positive mothers are at high risk of infection unless they receive the proper post-exposure prevention. The American Association for the Study of Liver Diseases (AASLD) suggests antiviral therapy to reduce the risk of perinatal transmission of hepatitis B in HBsAg positive pregnant individuals with an HBV DNA greater than 200,000 IU/mL.

Women whose HBsAg lab results during pregnancy are not available but other evidence is suggestive of maternal HBV infection (e.g., presence of HBV DNA, HBeAg-positive, or mother known to be chronically infected with HBV) should have the infant managed as if born to an HBsAg-positive mother. In certain cases, HBsAg tests may be reported inconclusively as “indeterminate,” “borderline,” or “weakly positive.” Check with the lab to make sure a repeat HBsAg confirmatory assay was done. If the repeat HBsAg assay is still not conclusive, repeat the HBsAg test in the last trimester of pregnancy. If the mother’s HBsAg status is still unknown at the time of delivery, assume she is HBsAg-positive and treat her infant accordingly.

If it is not possible to determine the mother’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 the recommended schedule for infants born to HBsAg-positive mothers.

**HBsAg and Anti-HBs: Babies 9-12 months old, or 1-2 months after the final dose**

For babies born to HBsAg-positive/unknown mothers, blood (or serologic) testing after proper post-exposure prevention shows whether the baby is infected with or fully protected against HBV. If the baby is on schedule with hepatitis B vaccine, testing should happen at 9-12 months of age or 1-2 months after the final vaccine dose. Testing should not be performed before age 9 months to avoid detection of anti-HBS from HBIG administered during infancy and to maximize the likelihood of detecting late HBV infection (MMWR, 2018). Testing for HBsAg identifies infected babies who need medical follow-up. Testing for anti-HBs identifies HBsAg-negative babies who still need to repeat the series of hepatitis B vaccine for full protection.

**Interpret results this way:**

1. HBsAg (-) and anti-HBs (+) = infant is immune or fully protected against HBV.
2. HBsAg (+) and anti-HBs (-) = infant is infected and needs medical follow-up.
3. HBsAg (-) and anti-HBs (-) = infant is still **susceptible** and needs three additional doses of hepatitis B vaccine followed by re-testing.

**HBsAg and Anti-HBs OR Anti-HBc only: Household Contacts and Sexual Partners**

Household contacts and sexual partners of HBsAg-positive pregnant women are at high risk of becoming infected. Both should get pre-vaccination testing if possible and those who are susceptible should be immunized. **Sexual contacts of HBsAg-positive women should also get post-vaccination testing.** Health care providers make the decision about which test(s) to order. The following information may help in the decision-making process.
1. Testing for HBsAg identifies acute and chronic (carrier) HBV infections.
2. Testing for anti-HBs, a marker of immunity, identifies antibody to HBsAg. Its presence indicates protective antibody from HBIG or hepatitis B vaccine.
3. Testing for anti-HBc identifies current and previous HBV infections but does not distinguish between the two.
4. A positive test for HBsAg or anti-HBs indicates the individual does not need vaccine.
5. A positive anti-HBc alone indicates the individual should be referred to his or her health care provider for further evaluation.

Sources:
- MMWR, Centers for Disease Control, January 12, 2018.
## Laboratory Screening: Serologic Markers

Use the table below* to find explanations of hepatitis B markers (antibodies) in blood serum.

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Name</th>
<th>Definition/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBsAg</td>
<td>Hepatitis B surface antigen</td>
<td>Detection of a large quantity of surface antigen(s) of HBV in serum indicates infection.</td>
</tr>
<tr>
<td>Anti-HBs</td>
<td>Antibody to Hepatitis B surface antigen</td>
<td>Detection of antibodies to HBsAg. Indicates past infection with immunity to HBV, passive antibody from HBIG, or immune response from hepatitis B vaccine.</td>
</tr>
<tr>
<td>HBcAg</td>
<td>Hepatitis B core antigen</td>
<td>A marker of current or past hepatitis B infection.</td>
</tr>
<tr>
<td>Anti-HBc</td>
<td>Antibody to Hepatitis B core antigen</td>
<td>Detection of antibodies to HBc indicates prior or recent infection with HBV.</td>
</tr>
<tr>
<td>IgM anti-HBc</td>
<td>IgM class antibody</td>
<td>Detection of IgM class antibodies indicates recent infection with HBV. IgM is detectable for 4 to 6 months after infection.</td>
</tr>
<tr>
<td>HBeAg</td>
<td>Hepatitis B e antigen</td>
<td>Detection of HBeAg correlates with higher levels of HBV in serum and increased infectivity.</td>
</tr>
<tr>
<td>Anti-HBe</td>
<td>Antibody to Hepatitis B e antigen</td>
<td>Presence of Anti-HBe in the serum of HBsAg carrier indicates lower titer of HBV.</td>
</tr>
</tbody>
</table>

* Source: [Immunization Action Coalition](https://www.immunize.org/)

---

Perinatal Hepatitis B Prevention Program Guidelines, Ch 1: What LHJs Need to Know
### Laboratory Screening: Interpreting Test Results

Use this table* for help interpreting hepatitis B test results, also called the hepatitis B panel:

<table>
<thead>
<tr>
<th>Tests</th>
<th>Results</th>
<th>Interpretation</th>
<th>Vaccinate?</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBsAg anti-HBc anti-HBs</td>
<td>negative negative negative</td>
<td>Susceptible</td>
<td>Vaccinate if indicated</td>
</tr>
<tr>
<td>HBsAg anti-HBc anti-HBs</td>
<td>negative negative positive with &gt;10mIU/mL**</td>
<td>Immune due to vaccination</td>
<td>No vaccination necessary</td>
</tr>
<tr>
<td>HBsAg anti-HBc anti-HBs</td>
<td>negative positive positive</td>
<td>Immune due to natural infection</td>
<td>No vaccination necessary</td>
</tr>
<tr>
<td>HBsAg anti-HBc IgM anti-HBc anti-HBs</td>
<td>positive positive positive</td>
<td>Acutely infected</td>
<td>No vaccination necessary</td>
</tr>
<tr>
<td>HBsAg anti-HBc IgM anti-HBc anti-HBs</td>
<td>positive positive negative</td>
<td>Chronically infected</td>
<td>No vaccination necessary (may need treatment)</td>
</tr>
</tbody>
</table>
| HBsAg anti-HBc anti-HBs | negative positive negative                   | Four interpretations possible:  
  1. May be recovering from acute HBV infection.  
  2. May be distantly immune, but the test may not be sensitive enough to detect a very low level of anti-HBs in serum.  
  3. May be susceptible with a false positive anti-HBc.  
  4. May be chronically infected and have an undetectable level of HBsAg present in the serum. | Use clinical judgment |

* Source: [Immunization Action Coalition](https://www.immunize.org)

** Post-vaccination testing, when recommended, should be done 1-2 months after the last dose of vaccine. Infants born to HBsAg-positive mothers should be tested for HBsAg and anti-HBs after they've had at least three doses of a licensed hepatitis B vaccination series. This means at 9-12 months, typically at the next well-child visit.
References and Resources

This section contains references and helpful resources for local health jurisdiction staff.

References

- CDC Perinatal Hepatitis B Prevention Program [Case Transfer Form]
- CDC Hepatitis B Vaccine: What You Need to Know – [Vaccine Information Sheet (VIS)]
- Immunization Action Coalition [Hepatitis B Facts: Testing and Vaccination]
- MMWR (Morbidity and Mortality Weekly Report) Recommendations and Reports – [Recommendations for Identification and Public Health Management of Persons with Chronic Hepatitis B Virus Infection], 9/19/08
- WAC 246-101-101 [Notifiable Conditions and the Health Care Provider]
- WAC 246-101-201 [Notifiable Conditions and Labs]
- WAC 246-101-301 [Notifiable Conditions and Health Care Facilities]
- List of [Washington state local health jurisdiction perinatal hepatitis B coordinators]

LHJ Resources

- Sample letters from DOH:
  - Before Baby is Born
  - After Baby is Born
  - Completion of Serology (Blood) Testing
- Local Health Jurisdiction [Perinatal Hepatitis B Coordinators List]
- Stickers for medical charts. *Print these stickers on Avery mailing labels 5163 to flag hospital medical charts of babies born to HBsAg-positive mothers. Print in color.*
  - Prenatal stickers: [Reporting HBsAg-positive Mothers Required]
  - Hospital Sticker: ALERT: Give HBIG and Hepatitis B Vaccine: [available upon request].
  - Pediatric Sticker: Baby requires hepatitis B immunization.
- Order [hepatitis B materials from DOH]
- WAC 246-101-101, Notifiable Conditions and the Health Care Provider
- Testing during pregnancy for prenatal care providers (PDF, CDC)
- Guidebook: [What Hospitals Need to Do to Protect Newborns] (Immunization Action Coalition)
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Perinatal Hepatitis B Prevention Program: Goal and Objectives

Federal recommendations

The Washington State Department of Health (DOH) Office of Immunization and Child Profile (OICP) follows federal recommendations for hepatitis B immunization. These recommendations, made by the Advisory Committee on Immunization Practices (ACIP), include control of perinatal hepatitis B virus infection (HBV). The latest updated ACIP recommendations target delivery hospital policies, procedures, and case management programs.

To provide appropriate clinical care to a newborn, you must put the mother’s data in the infant’s medical record, as recommended by ACIP. This does NOT violate the Health Insurance Portability and Accountability Act (HIPAA). The HIPAA Privacy Rule allows the use of some health information:

"A covered entity is permitted, but not required, to use and disclose protected health information, without an individual's authorization, for the following purposes or situations: (1) To the Individual; (2) Treatment, Payment, and Health Care Operations..."

Find a summary document of the HIPAA Privacy Rule here.

Goal

Washington State’s Perinatal Hepatitis B Prevention Program (PHBPP) has an overall goal to work with partners to assure coordination of activities to prevent perinatal hepatitis B transmission to newborns. The program has several key elements.

- It is both a surveillance and case management program to help manage perinatal hepatitis B cases.
- It promotes universal birth dose.
- It relies on multiple reporting mechanisms.
- It works with partners to assure coordination of activities.

Local health jurisdictions in our state are key in completing these tasks, including supporting effective delivery hospital policies specifying birth dose vaccinations, standing orders, and case management to:

- Identify HBsAg-positive pregnant women.
• Ensure HBV DNA testing is done for all HBsAg-positive pregnant women to guide the use of maternal antiviral therapy during pregnancy for the prevention of perinatal HBV transmission.
• Make sure their babies get proper post-exposure prevention. Correct post-exposure prevention for babies includes hepatitis B immune globulin (HBIG) and hepatitis B vaccine within 12 hours of birth, followed by two more doses of vaccine (at 1-2 months and 6 months of age).
• Make sure post-vaccine testing is completed.
• Report all data on administration of follow-up doses of vaccine and post-testing of the infant to DOH.

Objectives

1. 100% of all pregnant women get screened for HBsAg prenatally or at delivery.
2. 100% of delivery hospitals adopt policies, procedures, & standing orders for HBsAg verification & for testing mothers at delivery.
3. At least 90% of expected births to HBsAg-positive mothers are identified.
4. At least 95% of babies born to HBsAg-positive mothers get HBIG and 1 dose of hepB vaccine within 12 hours of birth and 3 vaccine doses by 6 months.
5. At least 90% of these babies get a blood test (HBsAg and anti-HBs) 1-2 months after the last dose of hepB vaccine or by 9-12 months.
6. 100% of all HBsAg-positive babies get reported to DOH and CDC through the National Notifiable Disease Surveillance System.
Hepatitis B Facts

Acute (short-term) and chronic (long-lasting) effects of hepatitis B virus (HBV) infection are a major health problem.

About 79,000 infections occur in the U.S. each year; 21,000 of those cases are acute (short-term) and symptomatic (showing symptoms) (Centers for Disease Control and Prevention).

As many as 1.6 million people in the U.S. have chronic HBV and can potentially spread the disease to others.

Hepatitis B is a leading cause of liver cancer in the U.S. HBV can be passed from mom to baby during birth (perinatal infection). About 25,000 HBV-infected moms give birth each year in the U.S. Infants infected at birth may later experience potentially deadly complications, like chronic liver disease and liver cancer. Each year, about 4,000 to 5,000 people die from chronic liver disease.

Hepatitis B infection in the Asian-Pacific Islander population is 10%. That’s 60 times higher than the infection rate of the general population.

The number of foreign-born residents living with chronic hepatitis B will continue to increase with ongoing immigration from countries where hepatitis B is common.

Unless they get proper post-exposure prevention, up to 90% of babies born to mothers with hepatitis B get infected, and 85% to 95% of those will be chronically infected. Up to one in four chronically infected babies will die from primary hepatocellular carcinoma or cirrhosis of the liver later in life.

While screening rates are high, reporting rates of HBsAg-positive pregnant women remain a problem. Nationally, about 95% of pregnant women receive prenatal HBsAg serologic testing, yet only 47% of expected births to HBsAg-positive pregnant women are identified and reported to perinatal hepatitis B programs (CDC Peritable Outcomes, 2014)

Getting immunized with hepatitis B vaccine is the most effective way to prevent HBV infection. Pregnant women who are infected with HBV can prevent giving HBV to their babies at birth if the baby gets:

- Hepatitis B immune globulin (HBIG) and hepatitis B vaccine within 12 hours of birth
- Additional doses of vaccine at 1-2 months and 6 months of age.

CDC recommends testing all pregnant women for HBV early in each pregnancy even if they already had the vaccine or test. Women who test HBsAg-negative early in pregnancy but are in a high-risk category for HBV should be retested at the delivery hospital.

Pregnant women who test HBsAg positive should be referred to the local health jurisdiction’s PHBPP and receive counseling, medical management, and information about HBV. Emerging evidence suggests HBV treatment during the third trimester is safe and reduces rates of transmission.
Prenatal Care Providers Tasks Overview

The following seven strategies can help guide you, as a prenatal care provider, to prevent perinatal hepatitis B transmission.

1. Develop and follow a written policy to screen **every** pregnant woman for HBsAg **early** in each pregnancy. Both the Centers for Disease Control and Prevention and the American College of Obstetricians and Gynecologists recommend this policy. **If the woman tests HBsAg negative but remains or becomes high-risk for hepatitis B infection, do the HBsAg testing again late in her pregnancy.** High-risk behaviors or markers include injection drug use, multiple sexual partners, and having other sexually transmitted infections. If it is not possible to determine the mother’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 the recommended schedule for infants born to HBsAg-positive mothers.

2. Screen all pregnant women. HBV DNA testing should be done for all HBsAg-positive pregnant women to guide the use of maternal antiviral therapy during pregnancy for the prevention of perinatal HBV transmission.

3. Offer hepatitis B vaccine at any time during the pregnancy to HBsAg-negative and anti-HBs-negative pregnant women who are at high risk of infection. Women can get vaccinated during pregnancy (no contraindication exists). However, consult with the patient’s provider before giving any vaccine to a pregnant woman. If you give hepatitis B vaccine during pregnancy, do HBsAg serologic testing 1-2 months later to avoid transient HBsAg positivity.

4. Report **every** HBsAg-positive pregnant woman to your local health jurisdiction (LHJ) within three working days. **State law requires that you report every case of perinatal hepatitis B** (see WAC 246-101-101). Your LHJ provides case management and follow-up services for infants, household contacts, and sexual partners. Use DOH’s perinatal hepatitis B program coordinators list.

5. Tell each HBsAg-positive pregnant woman about:
   - How hepatitis B spreads.
   - How to prevent hepatitis B.
   - The need for her to get medical follow-up with a liver specialist.
   - Her infant’s need to get protection. The baby needs HBIG and hepatitis B vaccine within 12 hours of birth; two additional doses of hepatitis B vaccine at 1-2 and 6 months of age; and post-vaccine screening at 9-12 months of age.
   - The need for her household contacts and sexual partners to get pre-vaccination screening. If the household contacts and sexual partners are HBsAg-negative and anti-HBs negative, they need to get three doses of hepatitis B vaccine at intervals of 0, 1-2, and 4-6 months.
   - How her LHJ will contact her to follow up with necessary services for her family.
   - Referrals for infected household contacts and sexual partners.

6. Send all HBsAg-positive lab results to the hospital before the pregnant women gets admitted for delivery to make sure her baby gets proper post-exposure prevention.

7. Provide educational materials about hepatitis B.
Case Management Snapshot

Managing a perinatal hepatitis B case always starts with the pregnant woman and involves pre-screening, opening a confidential case report in the module, tracking the woman’s baby, following up with phone calls and mail, and closing a case when follow-up is finished. Cases may be open for as long as two years. Find a visual snapshot of this process below.

START: Health care provider pre-screens pregnant woman in first trimester of pregnancy.

HBsAg test is NEGATIVE.

No hepatitis B case.

HBsAg test is POSITIVE.

Health care provider or hospital reports HBsAg-positive woman to LHJ Hepatitis B Coordinator.

Hep B Coordinator opens a confidential case on the HBsAg-positive woman using “New Case” in the Perinatal Hepatitis B Module.

BABY is BORN!
Hospital gives HBIG and birth dose of hepatitis B vaccine.

Hep B Coordinator calls hospital for infant’s information and dates of HBIG and hepB vaccine. Hep B Coordinator enters infant information into the mother’s open case in the Perinatal Hepatitis B Module.

Hep B Coordinator works with mother & pediatrician to make sure baby gets full vaccination series and post-testing.

Based on pre-screening, Hep B Coordinator either:
- Refers contacts and partners to a specialist or
- Makes sure contacts and partners get vaccinated and post-tested.

When all follow-ups with mother and baby have been documented for pre-screenings, HBIG, vaccination series and post-testing, Hep B Coordinator “closes” the open case in the Perinatal Hepatitis B Module.

Also, cases get closed for other reasons

Also, cases get closed for other reasons
Required Notification

Washington State follows three levels of required notification for certain medical conditions to prevent and control communicable and noninfectious diseases. Different agencies take care of these different notification levels.

4. Notification to local health jurisdictions (LHJ): by every prenatal health care provider or hospital.
5. Notification to the Washington State Department of Health: by every local health jurisdiction.

Washington considers EACH pregnancy in any HBsAg-positive woman a notifiable condition. This can increase the chance that babies born to HBsAg-positive mothers will get proper post-exposure prevention. Because of this, the notifications must happen correctly as explained and shown in the picture below.

4. Healthcare providers notify the LHJ Perinatal Hepatitis B Coordinator of the pregnant woman’s status.
5. The Hepatitis B Coordinator then enrolls the woman in the Perinatal Hepatitis B Prevention Program, manages her case (including her baby, household contacts, and sexual partners), and notifies the correct agency programs.
6. DOH notifies CDC weekly about all hepatitis B-infected infants.

Notification Process

Pregnant woman tests HBsAg-positive at her prenatal care provider, healthcare provider, or the hospital.

Provider or hospital notifies local health jurisdiction’s Hepatitis B Coordinator.

Hepatitis B Coordinator
• Contacts HBsAg-positive woman to enroll her in Perinatal Hepatitis B Program.
• Notifies DOH of pregnancy and outcomes at:
  • Communicable Disease Epidemiology at 206-418-5500 or in PHIMS
  • DOH Office of Immunization and Child Profile-360-236-3595

DOH staff notify CDC of each positive hepatitis B case.
Required Reportable Conditions

**Hepatitis B Surface Antigen (HBsAg) Positivity During Pregnancy**

Since December 2000 in Washington State, HBsAg-positive status during pregnancy has been a required reportable condition per state law (Washington Administrative Code [WAC 246-101-101](https://app.leg.wa.gov/codewa/Laws?ch=246-101-101) and [WAC 246-101-301](https://app.leg.wa.gov/codewa/Laws?ch=246-101-301)). Healthcare providers and health care facilities, such as hospitals, must report this status to local health jurisdictions within three working days.

**Why Report?**

Identifying and reporting HBsAg-positive pregnant women during each pregnancy helps prevent the spread of hepatitis B virus to their babies. These babies have a very high risk of getting the infection and developing serious long-term medical conditions unless they get proper post-exposure prevention.

Local public health jurisdiction staff work with health care providers to make sure that:

- Mothers get counseled about preventing the spread of hepatitis B virus to their babies and their household contacts.
- Mothers get screened and, if appropriate, referred to a specialist during pregnancy (see page 2 of this infographic).
- Mother’s sexual partner(s) get referred to a specialist for follow-up.
- Babies get hepatitis B immune globulin (HBIG) and 3 doses of hepatitis B vaccine (birth, 1-2 months, 6 months).
- Babies get post-vaccination testing (HBsAg and anti-HBs) between 9 and 12 months of age (at least 1 to 2 months after the third dose of hepatitis B vaccine) to check for infection and immune status.

**When to Report**

A report should be made at any time during each pregnancy in which the pregnant woman tests HBsAg positive. It is the prenatal care provider’s responsibility to make sure the delivery hospital knows of an HBsAg-positive mother prior to the birth so the baby gets proper treatment.

**Reporting Requirements**

Per [WAC 246-101-101](https://app.leg.wa.gov/codewa/Laws?ch=246-101-101) and [WAC 246-101-301](https://app.leg.wa.gov/codewa/Laws?ch=246-101-301), healthcare providers and health care facilities who request the HBsAg test during prenatal care or at time of delivery must report all HBsAg-positive pregnant women to the provider’s LHJ within three working days.

**Reporting Resources from DOH**

- [How to report notifiable conditions](https://www.doh.wa.gov/Health/NotifiableDiseases/ListingOfNotifiableDisease.htm)
- [Reporting posters](https://www.doh.wa.gov/PHI/Infographics/Pages/ReportingPoster.aspx)
- [Hepatitis B as a notifiable condition](https://www.doh.wa.gov/Health/NotifiableDiseases/ListingOfNotifiableDisease.htm)
- If you have other questions, contact the Department of Health at 360-236-3595.
Vaccine Specifics: Administering Hepatitis B Vaccine

**Route and Site**

Give hepatitis B vaccine intramuscularly into the deltoid muscle of adults and children and into the anterolateral thigh muscle of newborns and babies. **Do not** give hepatitis B vaccine intradermally or into the buttock.

You can give hepatitis B vaccine at the same time as other vaccines, but use separate injection sites.

**Dose and Schedule**

Babies born to HBsAg-positive mothers should get the following. You can use different brands of the single-antigen vaccine for the vaccine doses.

<table>
<thead>
<tr>
<th>Vaccine Administration</th>
<th>Vaccine Details</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Within 12 hours of birth</strong></td>
<td>0.5 ml of hepatitis B immune globulin (HBIG)</td>
<td>These can be given at the same time but at different injection sites.</td>
</tr>
<tr>
<td></td>
<td>Hepatitis B vaccine dose 1 (Engerix-B 10mcg/0.5ml or Recombivax 5mcg/0.5ml)</td>
<td></td>
</tr>
<tr>
<td><strong>1-2 months old</strong></td>
<td>Hepatitis B vaccine dose 2 (Engerix-B 10mcg/0.5ml or Recombivax 5mcg/0.5ml)</td>
<td></td>
</tr>
<tr>
<td><strong>6 months old</strong></td>
<td>Hepatitis B vaccine dose 3* (Engerix-B 10mcg/0.5ml or Recombivax 5mcg/0.5ml)</td>
<td></td>
</tr>
</tbody>
</table>

**Vaccination of Premature Babies**

- Premature babies born to HBsAg-positive mothers or mothers with unknown status must get HBIG AND hepatitis B vaccine less than 12 hours after birth. If these babies weigh less than 2,000 grams at birth, do not count the first dose of hepatitis B vaccine as one of the doses in the series. The baby should get three additional doses of hepatitis B vaccine, starting when medically stable and at least 1 month of age. **MMWR, 2018**. This will be a total of 4 doses.

- Premature babies born to HBsAg-negative mothers, regardless of birth weight, should get vaccinated at the same chronological age and with the same schedule and precautions as full-term babies. Use the full recommended dose of each vaccine, because divided or reduced doses cannot count as valid. Studies demonstrate that decreased seroconversion rates might occur among certain premature babies with low birth weight (less than 2,000 grams) after getting hepatitis B vaccine at birth. However, by chronological age 1 month, all premature babies regardless of initial birth weight or gestational age can respond as adequately as older and larger babies.
Vaccine Specifics: Recommended Doses of Currently Licensed Monovalent Hepatitis B Vaccines

Recombivax and Engerix-B vaccines both have three doses in their series. Engerix-B also is licensed for a four-dose series given at 0, 1-2, and 6 months. Dialysis patients should get Engerix-B at 0, 1, 2, and 6 months.

<table>
<thead>
<tr>
<th>Group</th>
<th>Merck Recombivax HB Dosage</th>
<th>GSK Engerix-B Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Babies, children &amp; adolescents (0–19 years of age)</td>
<td>5 mcg (0.5 mL)&lt;sup&gt;5&lt;/sup&gt; Pediatric/adolescent formulation. YELLOW cap and stripe on vial and cartons and orange banner on the vial labels and cartons stating “preservative free”</td>
<td>10 mcg (0.5 mL)&lt;sup&gt;6&lt;/sup&gt; Pediatric formulation BLUE-top vial Single-dose vials and prefilled disposable TIP-LOK syringe</td>
</tr>
<tr>
<td>Adolescent (11–15 years of age) Merck (11–19 years of age) GSK</td>
<td>10mcg (1.0 mL) Adult formulation GREEN cap and stripe vial and orange banner on vial label</td>
<td>10mcg (0.5 mL) OLIVE GREEN top vial</td>
</tr>
<tr>
<td>A two-dose series for adolescents (11-15) is also acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adults (20 years &amp; older)</td>
<td>10 mcg (1.0 mL) Adult Formulation GREEN-top vial</td>
<td>20 mcg (1.0 mL) adult formulation ORANGE-top vial</td>
</tr>
<tr>
<td>Predialysis and dialysis patients</td>
<td>40 mcg (1.0 mL) Dialysis formulation BLUE cap and stripe vial with orange banner</td>
<td>40 mcg (2.0 mL) (Two 20 mcg doses) Adult formulation ORANGE-top vial</td>
</tr>
</tbody>
</table>

Sources:
- MMWR, Centers for Disease Control, January 12, 2018
- Recombivax HB package insert, March 2014
- Engerix B package insert, December 2015

Key:
- HBsAg = Hepatitis B surface antigen
- mcg = microgram
- mL = milliliter
- GSK = GlaxoSmithKline

Infants born to HBsAg-positive mothers should also receive hepatitis B immune globulin (HBIG) 0.5 mL intramuscularly at a site different from that used for the hepatitis B vaccine.

Change in dose, licensed in 1995. Infants born to HBsAg-negative mothers now receive the same dose as infants born to HBsAg-positive mothers. “If the suggested formulation is not available, the appropriate dosage can be achieved from another formulation provided that the total volume of vaccine administered does not exceed 1 mL.”

Change in adolescent dose, licensed in 1995.
Vaccine Specifics: Administering HBIG

**Route and Site**
For newborns and babies: Give HBIG intramuscularly into the anterolateral thigh muscle.

**Dose and Schedule**
Newborns and babies should get 0.5 ml of HBIG within 12 hours of birth. They should also get dose 1 of hepatitis B vaccine at the same time at a separate injection site.

For other exposed persons, the dose of HBIG is 0.06 mL per kilogram of body weight. To calculate the dose:
- Convert body weight to kilograms (kg)
- Multiply the number of kilograms by 0.06 mL

For example, if the person weighs 110 pounds, the number of kilograms = \( \frac{110 \text{ lbs}}{2.2 \text{ lbs/kg}} \) = 50.0 kg. The correct dose of HBIG then would be 50.0 kg x 0.06 (the amount per kg), giving a dose of 3.0 mL.

**HBIG Dosage at a Glance**
Use the following table to identify dosage based on weight.

<table>
<thead>
<tr>
<th>Body weight in pounds (lbs)</th>
<th>Body Weight in kilograms (kg)</th>
<th>Dose in milliliters (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>45.5</td>
<td>2.7</td>
</tr>
<tr>
<td>110</td>
<td>50.0</td>
<td>3.0</td>
</tr>
<tr>
<td>120</td>
<td>54.5</td>
<td>3.3</td>
</tr>
<tr>
<td>130</td>
<td>59.1</td>
<td>3.5</td>
</tr>
<tr>
<td>140</td>
<td>63.6</td>
<td>3.8</td>
</tr>
<tr>
<td>150</td>
<td>68.2</td>
<td>4.1</td>
</tr>
<tr>
<td>160</td>
<td>72.7</td>
<td>4.4</td>
</tr>
<tr>
<td>170</td>
<td>77.3</td>
<td>4.6</td>
</tr>
<tr>
<td>180</td>
<td>81.8</td>
<td>4.9</td>
</tr>
<tr>
<td>190</td>
<td>86.4</td>
<td>5.2</td>
</tr>
<tr>
<td>200</td>
<td>90.9</td>
<td>5.5</td>
</tr>
<tr>
<td>210</td>
<td>95.5</td>
<td>5.7</td>
</tr>
<tr>
<td>220</td>
<td>100.0</td>
<td>6.0</td>
</tr>
<tr>
<td>230</td>
<td>104.5</td>
<td>6.3</td>
</tr>
<tr>
<td>240</td>
<td>109.1</td>
<td>6.5</td>
</tr>
<tr>
<td>250</td>
<td>113.6</td>
<td>6.8</td>
</tr>
</tbody>
</table>

\( \text{Dose} = 0.06 \text{ mL per kg of body weight; 1 kg = 2.2 lbs} \)
Vaccine Specifics: Storing and Handling Hepatitis B Vaccine and HBIG

Always read the package insert. Read the table below for storage and handling supplemental information, but this does not take the place of the package insert.

<table>
<thead>
<tr>
<th>Shipping Requirements:</th>
<th>Use insulated container. Must ship with refrigerant.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Condition on Arrival:</td>
<td>Should not have been frozen. Refrigerate on arrival.</td>
</tr>
<tr>
<td>Storage Requirements:</td>
<td>Refrigerate immediately upon arrival. Store at 2°-8°C (35°-46°F). Do not freeze.</td>
</tr>
<tr>
<td>Shelf Life/Expiration:</td>
<td>Hepatitis B Vaccine - up to 3 years. Check date on container or vial. HBIG - up to 12 months. Check date on container or vial.</td>
</tr>
<tr>
<td>Instructions for Reconstitution or Use:</td>
<td>Inspect visually for particulate matter or discoloration. Shake vial or fill syringe well before use.</td>
</tr>
<tr>
<td>Shelf Life after Reconstituting or Opening:</td>
<td>Check expiration date on vial, or manufacturer-filled syringe. Give the vaccine shortly after withdrawal. If pre-filled syringe, administer after the needle is attached to the syringe.</td>
</tr>
<tr>
<td>Special Instructions:</td>
<td>Rotate stock so that you use the material with the earliest expiration date first.</td>
</tr>
</tbody>
</table>

Best Practices for Storing and Handling All Vaccines

- Have policies and procedures in place to rotate stock and check expiration date of vaccine weekly. Use vaccine with earliest expiration date so none become outdated.
- Do not use outdated vaccine.
- Never store vaccine in refrigerator door.
- When transporting vaccine, always use an insulated container with ice packs.
- Vaccine storage and handling information from the Department of Health
- Vaccine storage and handling recommendations and guidelines from the CDC
Vaccine Specifics: Ages and Intervals

The table below shows hepatitis B vaccine (hepB) doses, with recommended ages, intervals, and minimum ages for getting the vaccines.

### Recommended and Minimum Ages and Intervals between Doses*

<table>
<thead>
<tr>
<th>Vaccine and dose number</th>
<th>Recommended age for this dose</th>
<th>Minimum age for this dose</th>
<th>Recommended interval to next dose</th>
<th>Minimum interval to next dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>HepB-dose 1**</td>
<td>Birth</td>
<td>Birth</td>
<td>1-4 months</td>
<td>4 weeks</td>
</tr>
<tr>
<td>HepB-dose 2</td>
<td>1-2 months</td>
<td>4 weeks</td>
<td>2-17 months</td>
<td>8 weeks</td>
</tr>
<tr>
<td>HepB-dose 3***</td>
<td>6- months</td>
<td>24 weeks</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Source: Epidemiology and Prevention of Vaccine-Preventable Diseases, CDC

** Combination vaccines with a hepatitis B component are available (Comvax, Pediarix, and Twinrix). These vaccines should not be administered to infants younger than 6 weeks because other components in the vaccines are not suitable for this age group (i.e., Hib, DTaP, HepA, and IPV).

*** Hepatitis B-dose 3 should be administered at least 8 weeks after dose 2 and at least 16 weeks after dose 1.

### Laboratory Reporting

According to WAC 246-101-201, labs are required to report acute hepatitis B infection within 24 hours to the LHJ, and HBsAg, HBeAg, and HBV DNA positive results monthly. Pregnancy status is NOT currently a required field in these reports. However, to improve identification of HBsAg-positive women, 4 major commercial labs indicate pregnancy status of HBsAg-positive women on lab reports sent to LHJs. As more labs work to improve this identification, it is expected that the proportion of hepatitis B labs with pregnancy status will increase.

Lab indicators for probable pregnancy include:
- HBsAg test ordered as part of prenatal panel
- Individual prenatal HBsAg test
- Pregnancy-related diagnostic code (ICD-9/ICD-10) or pregnancy status indicated on requisition form
- “Pregnant” or “prenatal” is included in an HL7 messaging segment (for transferring data from one electronic system to another)

### Laboratory Screening: Guidelines

This section identifies which screening test(s) to order for pregnant women and babies.

#### HBsAg: Pregnant Women

A positive HBsAg screening test identifies HBV-infected pregnant women. HBV DNA testing should be done for all HBsAg-positive pregnant women to guide the use of maternal antiviral
therapy during pregnancy for the prevention of perinatal HBV transmission. Babies born to HBsAg-positive mothers are at high risk of infection unless they receive the proper post-exposure prevention. Published evidence indicates that maternal antiviral therapy during pregnancy further reduces perinatal HBV transmission; hence, AASLD suggests antiviral therapy when maternal HBV DNA is >200,000 IU/mL.

Women whose HBsAg lab results during pregnancy are not available but other evidence is suggestive of maternal HBV infection (e.g., presence of HBV DNA, HBeAg-positive, or mother known to be chronically infected with HBV) should have the infant managed as if born to an HBsAg-positive mother. In certain cases, HBsAg tests may be reported inconclusively as “indeterminate,” “borderline,” or “weakly positive.” Check with the lab to make sure a repeat HBsAg confirmatory assay was done. If the repeat HBsAg assay is still not conclusive, repeat the HBsAg test in the last trimester of pregnancy. If the mother’s HBsAg status is still unknown at the time of delivery, assume she is HBsAg-positive and treat her infant accordingly.

If it is not possible to determine the mother’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 the recommended schedule for infants born to HBsAg-positive mothers.

---

**HBsAg and Anti-HBs: Babies 9-12 months, or 1-2 months after the final dose**

For babies born to HBsAg-positive mothers, blood (or serologic) testing after proper post-exposure prevention shows whether the baby is infected with or fully protected against HBV. If the baby is on schedule with hepatitis B vaccine, testing should happen at 9-12 months of age or 1-2 months after the final. Testing should not be performed before age 9 months to avoid detection of anti-HBS from HBIG administered during infancy and to maximize the likelihood of detecting late HBV infection (MMWR, 2005). Testing for HBsAg identifies infected babies who need medical follow-up. Testing for anti-HBs identifies HBsAg-negative babies who still need to repeat the vaccine series for full protection.

**Interpret results this way:**

4. HBsAg (-) and anti-HBs (+) = infant is immune or fully protected against HBV.
5. HBsAg (+) and anti-HBs (-) = infant is infected and needs medical follow-up.
6. HBsAg (-) and anti-HBs (-) = infant is still susceptible and needs three additional doses of hepatitis B vaccine followed by re-testing.

---

**HBsAg and Anti-HBs OR Anti-HBc only: Household Contacts and Sexual Partners**

Household contacts and sexual partners of HBsAg-positive pregnant women are at high risk of becoming infected. Both should get pre-vaccination testing if possible and those who are susceptible should be immunized. **Sexual contacts of HBsAg-positive women should also get post-vaccination testing.** Health care providers make the decision about which test(s) to order. The following information may help in the decision-making process.
6. Testing for HBsAg identifies acute and chronic (carrier) HBV infections.
7. Testing for anti-HBs, a marker of immunity, identifies antibody to Hepatitis B Surface Antigen. Its presence indicates protective antibody from HBIG or hepatitis B vaccine.
8. Testing for anti-HBc identifies current and previous HBV infections but does not distinguish between the two.
9. A positive test for HBsAg or anti-HBs indicates the individual does not need vaccine.
10. A positive anti-HBc alone indicates the individual should be referred to his or her health care provider for further evaluation.

Sources:
- MMWR, Centers for Disease Control, January 12, 2018.
Laboratory Screening: Serologic Markers

Use the table below* to find explanations of hepatitis B markers (antibodies) in blood serum.

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Name</th>
<th>Definition/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBsAg</td>
<td>Hepatitis B surface antigen</td>
<td>Detection of a large quantity of surface antigen(s) of HBV in serum indicates infection.</td>
</tr>
<tr>
<td>Anti-HBs</td>
<td>Antibody to Hepatitis B surface antigen</td>
<td>Detection of antibodies to HBsAg. Indicates past infection with immunity to HBV, passive antibody from HBIG, or immune response from hepatitis B vaccine.</td>
</tr>
<tr>
<td>HBcAg</td>
<td>Hepatitis B core antigen</td>
<td>A marker of current or past hepatitis B infection.</td>
</tr>
<tr>
<td>Anti-HBc</td>
<td>Antibody to Hepatitis B core antigen</td>
<td>Detection of antibodies to HBc indicates prior or recent infection with HBV.</td>
</tr>
<tr>
<td>IgM anti-HBc</td>
<td>IgM class antibody</td>
<td>Detection of IgM class antibodies indicates recent infection with HBV. IgM is detectable for 4 to 6 months after infection.</td>
</tr>
<tr>
<td>HBeAg</td>
<td>Hepatitis B e antigen</td>
<td>Detection of HBeAg correlates with higher levels of HBV in serum and increased infectivity.</td>
</tr>
<tr>
<td>Anti-HBe</td>
<td>Antibody to Hepatitis B e antigen</td>
<td>Presence of Anti-HBe in the serum of HBsAg carrier indicates lower titer of HBV.</td>
</tr>
</tbody>
</table>

* Source: Immunization Action Coalition
**Laboratory Screening: Interpreting Test Results**

Use this table* for help interpreting hepatitis B test results, also called the hepatitis B panel:

<table>
<thead>
<tr>
<th>Tests</th>
<th>Results</th>
<th>Interpretation</th>
<th>Vaccinate?</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBsAg, anti-HBc, anti-HBs</td>
<td>negative negative negative</td>
<td>Susceptible</td>
<td>Vaccinate if indicated</td>
</tr>
<tr>
<td>HBsAg, anti-HBc, anti-HBs</td>
<td>negative negative positive with &gt;10mIU/mL**</td>
<td>Immune due to vaccination</td>
<td>No vaccination necessary</td>
</tr>
<tr>
<td>HBsAg, anti-HBc, anti-HBs</td>
<td>negative positive positive</td>
<td>Immune due to natural infection</td>
<td>No vaccination necessary</td>
</tr>
<tr>
<td>HBsAg, anti-HBc, IgM anti-HBc, anti-HBs</td>
<td>positive positive negative</td>
<td>Acutely infected</td>
<td>No vaccination necessary</td>
</tr>
<tr>
<td>HBsAg, anti-HBc, IgM anti-HBc, anti-HBs</td>
<td>positive positive negative negative</td>
<td>Chronically infected</td>
<td>No vaccination necessary (may need treatment)</td>
</tr>
<tr>
<td>HBsAg, anti-HBc, anti-HBs</td>
<td>negative positive negative</td>
<td>Four interpretations possible:</td>
<td>Use clinical judgment</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5. May be recovering from acute HBV infection.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>6. May be distantly immune, but the test may not be sensitive enough to detect a very low level of anti-HBs in serum.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>7. May be susceptible with a false positive anti-HBc.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>8. May be chronically infected and have an undetectable level of HBsAg present in the serum.</td>
<td></td>
</tr>
</tbody>
</table>

* Source: Immunization Action Coalition

** Post-vaccination testing, when recommended, should be done 1-2 months after the last dose of vaccine. Infants born to HBsAg-positive mothers should be tested for HBsAg and anti-HBs after they’ve had at least three doses of a licensed hepatitis B vaccination series. This means at 9-12 months, typically at the next well-child visit.
References and Prenatal Resources

This section contains references and helpful resources for prenatal care providers.

References

- CDC Perinatal Hepatitis B Prevention Program [Case Transfer Form]
- CDC Hepatitis B Vaccine: What You Need to Know – [Vaccine Information Sheet (VIS)]
- Hepatitis B Facts: Testing and Vaccination
- WAC 246-101-101 [Notifiable Conditions and the Health Care Provider]
- List of [Washington state local health jurisdiction perinatal hepatitis B coordinators]

Prenatal Resources

- Stickers for medical charts. *Print these stickers on Avery mailing labels 5163 to flag hospital medical charts of babies born to HBsAg-positive mothers. Print in color.*
  - Prenatal stickers: [Reporting HBsAg-Positive Mothers Required]
  - Hospital Sticker: ALERT: Give HBIG and Hepatitis B Vaccine: [available upon request]
  - Pediatric Sticker: baby requires hepatitis B immunization: [available upon request]
- Order [hepatitis B materials from DOH]
- [WAC 246-101-101], Notifiable Conditions and the Health Care Provider:
- [Pregnancy and Hepatitis B] (Hepatitis B Foundation)
Chapter 3: What Hospitals Need to Know

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   i. WAC: Notifiable Conditions and the Health Care Provider
Perinatal Hepatitis B Prevention Program: Goal and Objectives

Federal recommendations

The Washington State Department of Health (DOH) Office of Immunization and Child Profile (OICP) follows federal recommendations for hepatitis B immunization. These recommendations, made by the Advisory Committee on Immunization Practices (ACIP), include control of perinatal hepatitis B virus infection (HBV). The latest updated ACIP recommendations target delivery hospital policies, procedures, and case management programs.

To provide appropriate clinical care to a newborn, you must put the mother’s data in the infant’s medical record, as recommended by ACIP. This does NOT violate the Health Insurance Portability and Accountability Act (HIPAA). The HIPAA Privacy Rule allows the use of some health information:

“A covered entity is permitted, but not required, to use and disclose protected health information, without an individual's authorization, for the following purposes or situations: (1) To the Individual; (2) Treatment, Payment, and Health Care Operations...”

Find a summary document of the HIPAA Privacy Rule here.

Goal

Washington State’s Perinatal Hepatitis B Prevention Program (PHBPP) has an overall goal to work with partners to assure coordination of activities to prevent perinatal hepatitis B transmission to newborns. The program has several key elements.

- It is both a surveillance and case management program to help manage perinatal hepatitis B cases.
- It promotes universal birth dose.
- It relies on multiple reporting mechanisms.
- It works with partners to assure coordination of activities.

Local health jurisdictions in our state are key in completing these tasks, including supporting effective delivery hospital policies specifying birth dose vaccinations, standing orders, and case management to:
• Identify HBsAg-positive pregnant women.
• Ensure HBV DNA testing is done for all HBsAg-positive pregnant women to guide the use of maternal antiviral therapy during pregnancy for the prevention of perinatal HBV transmission.
• Make sure their babies get proper post-exposure prevention. Correct post-exposure prevention for babies includes hepatitis B immune globulin (HBIG) and hepatitis B vaccine within 12 hours of birth, followed by two more doses of vaccine (at 1-2 months and 6 months of age).
• Make sure post-vaccine testing is completed.
• Report all data on administration of follow-up doses of vaccine and post-testing of the infant to DOH.

Objectives

1. 100% of all pregnant women get screened for HBsAg prenatally or at delivery.
2. 100% of delivery hospitals adopt policies, procedures, & standing orders for HBsAg verification & for testing mothers at delivery.
3. At least 90% of expected births to HBsAg-positive mothers are identified.
4. At least 95% of babies born to HBsAg-positive mothers get HBIG and 1 dose of hepB vaccine within 12 hours of birth and 3 vaccine doses by 6 months.
5. At least 90% of these babies get a blood test (HBsAg and anti-HBs) 1-2 months after the last dose of hepB vaccine or by 9-12 months.
6. 100% of all HBsAg-positive babies get reported to DOH and CDC through the National Notifiable Disease Surveillance System.
Hepatitis B Facts

Acute (short-term) and chronic (long-lasting) effects of hepatitis B virus (HBV) infection are a major health problem.

About 79,000 infections occur in the U.S. each year; 21,000 of those cases are acute (short-term) and symptomatic (showing symptoms) (Centers for Disease Control and Prevention).

As many as 1.6 million people in the U.S. have chronic HBV and can potentially spread the disease to others.

Hepatitis B is a leading cause of liver cancer in the U.S. HBV can be passed from mom to baby during birth (perinatal infection). About 25,000 HBV-infected moms give birth each year in the U.S. Infants infected at birth may later experience potentially deadly complications, like chronic liver disease and liver cancer. Each year, about 4,000 to 5,000 people die from chronic liver disease.

Hepatitis B infection in the Asian-Pacific Islander population is 10%. That's 60 times higher than the infection rate of the general population.

The number of foreign-born residents living with chronic hepatitis B will continue to increase with ongoing immigration from countries where hepatitis B is common.

Unless they get proper post-exposure prevention, up to 90% of babies born to mothers with hepatitis B get infected, and 85% to 95% of those will be chronically infected. Up to one in four chronically infected babies will die from primary hepatocellular carcinoma or cirrhosis of the liver later in life.

While screening rates are high, reporting rates of HBsAg-positive pregnant women remain a problem. Nationally, about 95% of pregnant women receive prenatal HBsAg serologic testing, yet only 47% of expected births to HBsAg-positive pregnant women are identified and reported to perinatal hepatitis B programs (CDC Peritable Outcomes, 2014).

Getting immunized with hepatitis B vaccine is the most effective way to prevent HBV infection. Pregnant women who are infected with HBV can prevent giving HBV to their babies at birth if the baby gets:

- Hepatitis B immune globulin (HBIG) and hepatitis B vaccine within 12 hours of birth
- Additional doses of vaccine at 1-2 months and 6 months of age.

CDC recommends testing all pregnant women for HBV early in each pregnancy even if they already had the vaccine or test. Women who test HBsAg-negative early in pregnancy but are in a high-risk category for HBV should be retested at the delivery hospital.

Pregnant women who test HBsAg positive should be referred to the local health jurisdiction’s PHBPP and receive counseling, medical management, and information about HBV. Emerging evidence suggests HBV treatment during the third trimester is safe and reduces rates of transmission.
Hospital Tasks Overview

The following four strategies guide hospitals to prevent perinatal hepatitis B transmission. Also see the Immunization Action Coalition’s hepatitis B hospital guide.

1) Screening procedures

Develop and follow a written policy and procedure to screen every pregnant woman admitted for delivery for HBsAg who has an unknown hepatitis B status and is at risk for HBV infection during pregnancy. Women with unknown status include those with no prenatal care or who have not already been tested. Risk behaviors for HBV include:

- More than one sexual partner in the previous 6 months.
- Evaluation or treatment for sexually transmitted disease.
- Recent or current injection drug use.
- HBsAg-positive sexual partner(s).
- Clinical hepatitis since previous testing.

Include in your written policy the following procedures for each stage of the hospital stay for women delivering babies (admission, after delivery, standing orders, infant discharge).

Admission for Delivery:

- Review hepatitis B surface antigen (HBsAg) status of all pregnant women.
- Review HBV DNA testing for all pregnant women that are HBsAg-positive.
- Record maternal HBsAg & HBV DNA test results on both the labor delivery record and on the infant’s delivery summary sheet.
- Do HBsAg testing as soon as possible on women who do not have an HBsAg test result, who have risk for HBV infection during pregnancy, and who had clinical hepatitis since previous testing.

After Delivery:

- Identify and manage all infants born to HBsAg-positive mothers, and infants born to mothers with unknown HBsAg status.
- Give HBig and hepatitis B vaccine dose 1 to infants of all HBsAg-positive pregnant women, within 12 hours of birth.
- If the mother’s HBsAg test results are unavailable but evidence suggests of maternal HBV infection, the infant should be managed as if born to an HBsAg-positive mother.
- Document the mother’s HBsAg-positive status and the infant’s HBig and hepatitis B vaccine doses at the hospital; give this information to the pediatric care provider.
**Standing Orders:**

- Review HBsAg and HBV DNA test results for every pregnant woman admitted for delivery. Make sure all mothers have been tested for HBsAg prenatally or at time of admission. Document the test results.
- For women with no HBsAg test results, test them as soon as possible after admission for delivery.
- Premature babies born to HBsAg-positive mothers or mothers with unknown status must get HBIG AND hepatitis B vaccine within 12 hours after birth. If these babies weigh less than 2,000 grams at birth, do not count the first dose of hepatitis B vaccine as one of the doses in the series. The baby should get 3 additional doses of hepatitis B vaccine, starting when medically stable and at least 1 month of age (MMWR, 2018). This will be a total of 4 doses.
- For all infants, add the mother’s HBsAg test results to the infant’s medical record, and the date and time the infant got HBIG and hepatitis B vaccine.

**Time of Infant Discharge:**

Give the infant’s immunization record to the mother and remind her to take it to the baby’s first pediatrician visit.

**2) VFC (Vaccines for Children Program)**

For all delivery hospitals: Enroll in the federal VFC program to get free birth-dose hepatitis B vaccine for eligible newborns. Eligible newborns include Medicaid eligible, American Indian or Alaska Native, underinsured, or uninsured babies.

**3) Notification**

Notify your local health jurisdiction (LHJ) of the birth of an infant to an HBsAg-positive mother so follow-up can begin for the infant and for the mother’s household contacts and sexual partners. State law requires you to report every HBsAg-positive pregnant woman. Your LHJ provides case management and follow-up services for these infants and contacts.

**4) Information for the patient**

Counsel and provide information on these subjects to every HBsAg-positive woman who is pregnant or has just delivered:

- How hepatitis B spreads.
- How to prevent hepatitis B.
- The need for her to get medical follow-up with a liver specialist.
- Her infant’s need to get protection. The baby needs HBIG and hepatitis B vaccine within 12 hours of birth, two additional doses of hepatitis B vaccine at 1-2 and 6 months of age, and post-vaccine screening at 9-12 months of age.
- The need for her household contacts and sexual partners to get pre-vaccination screening. If any of these people prove at risk, they need to get three doses of hepatitis B vaccination at intervals of 0, 1-2, and 4-6 months.
- How her LHJ will contact her to follow-up with necessary services for her family.
Case Management Snapshot

Managing a perinatal hepatitis B case always starts with the pregnant woman and involves pre-screening, opening a confidential case report in the module, tracking the woman’s baby, following up with phone calls and mail, and closing a case when follow-up is finished. Cases may be open for as long as two years. Find a visual snapshot of this process below.

START: Health care provider pre-screens pregnant woman in first trimester of pregnancy.

HBsAg test is NEGATIVE.

No hepatitis B case.

Hep B Coordinator closes a case for other reasons, such as if mother refuses follow-up, can’t be located, or if the pregnancy ends.

Also, cases get closed for other reasons

HBsAg test is POSITIVE.

To guide the use of antiviral therapy during pregnancy for prevention of perinatal HBV transmission a HBV DNA test should be done for all HBsAg-positive pregnant women.

Based on pre-screening, Hep B Coordinator either:
• Refers contacts and partners to a specialist or
• Makes sure contacts and partners get vaccinated and post-tested.

Health care provider or hospital reports HBsAg-positive woman to LHJ Hepatitis B Coordinator.

Hep B Coordinator opens a confidential case on the HBsAg-positive woman using “New Case” in the Perinatal Hepatitis B Module.

BABY is BORN!
Hospital gives HBIG and birth dose of hepatitis B vaccine.

Hep B Coordinator calls hospital for infant’s information and dates of HBIG and hepB vaccine. Hep B Coordinator enters infant information into the mother’s open case in the Perinatal Hepatitis B Module.

Hep B Coordinator works with mother & pediatrician to make sure baby gets full vaccination series and post-testing.

When all follow-ups with mother and baby have been documented for prescreenings, HBIG, vaccination series and post-testing, Hep B Coordinator “closes” the open case in the Perinatal Hepatitis B Module.

To guide the use of antiviral therapy during pregnancy for prevention of perinatal HBV transmission a HBV DNA test should be done for all HBsAg-positive pregnant women.
Required Notification

Washington state follows three levels of required notification for certain medical conditions to prevent and control communicable and noninfectious diseases. Different agencies take care of these different notification levels.

7. Notification to local health jurisdictions (LHJ): by **every prenatal health care provider or hospital**.

8. Notification to the Washington State Department of Health: by **every local health jurisdiction**.


Washington considers **EACH** pregnancy in any HBsAg-positive woman a notifiable condition. This can increase the chance that babies born to HBsAg-positive mothers will get proper post-exposure prevention. Because of this, the notifications must happen correctly as explained and shown in the picture below.

7. Healthcare providers notify the LHJ Perinatal Hepatitis B Coordinator of the pregnant woman’s status.

8. The Hepatitis B Coordinator then enrolls the woman in the Perinatal Hepatitis B Prevention Program, manages her case (including her baby, household contacts, and sexual partners), and notifies the correct agency programs.

9. DOH notifies CDC weekly about all hepatitis B-infected infants.

In WA: Did you know?

EVERY pregnancy in a HBsAg-positive woman is a notifiable condition.
Required Reportable Conditions

Hepatitis B Surface Antigen (HBsAg) Positivity During Pregnancy

Since December 2000 in Washington State, HBsAg-positive status during pregnancy has been a required reportable condition per state law (Washington Administrative Code [WAC 246-101-101 and WAC 246-101-301]). Healthcare providers and health care facilities, such as hospitals, must report this status to local health jurisdictions within three working days.

Why Report?

Identifying and reporting HBsAg-positive pregnant women during each pregnancy helps prevent the spread of hepatitis B virus to their babies. These babies have a very high risk of getting the infection and developing serious long-term medical conditions unless they get proper post-exposure prevention.

Local public health jurisdiction staff work with health care providers to make sure that:

- Mothers get counseled about preventing the spread of HBV to their babies and their household contacts.
- Mothers get screened and, if appropriate, referred to a specialist during pregnancy (see page 2 of this infographic).
- Mother’s sexual partner(s) get referred to a specialist for follow-up.
- Babies get hepatitis B immune globulin (HBIG) and 3 doses of hepatitis B vaccine (birth, 1-2 months, 6 months).
- Babies get post-vaccination testing (HBsAg and anti-HBs) between 9 and 12 months of age (at least 1 to 2 months after the third dose of hepatitis B vaccine) to check for infection and immune status.

When to Report

A report should be made at any time during each pregnancy in which the pregnant woman tests HBsAg positive. It is the prenatal care provider’s responsibility to make sure the delivery hospital knows of an HBsAg-positive mother prior to the birth so the baby gets proper treatment.

Reporting Requirements

Per WAC 246-101-101 and WAC 246-101-301, healthcare providers and health care facilities who request the HBsAg test during prenatal care or at time of delivery must report all HBsAg-positive pregnant women to the provider’s LHJ within three working days.

Reporting Resources from DOH

- How to report notifiable conditions
- Reporting posters
- Hepatitis B as a notifiable condition
- If you have other questions, contact the Department of Health at 360-236-3595.
Vaccine Specifics: Administering Hepatitis B Vaccine

**Route and Site**
Give hepatitis B vaccine intramuscularly into the deltoid muscle of adults and children and into the anterolateral thigh muscle of newborns and babies. **Do not** give hepatitis B vaccine intradermally or into the buttock.

You can give hepatitis B vaccine at the same time as other vaccines, but use separate injection sites.

**Dose and Schedule**
Babies born to HBsAg-positive mothers should get the following. You can use different brands of the single-antigen vaccine for the vaccine doses.

### Vaccination of Premature Babies
- Premature babies born to HBsAg-positive mothers or mothers with unknown status must get HBIG AND hepatitis B vaccine less than 12 hours after birth. If these babies weigh less than 2,000 grams at birth, do not count the first dose of hepatitis B vaccine as one of the doses in the series. The baby should get three additional doses of hepatitis B vaccine, starting when medically stable and at least 1 month of age. **MMWR, 2018**. This will be a total of 4 doses.

- Premature babies born to HBsAg-negative mothers, regardless of birth weight, should get vaccinated at the same chronological age and with the same schedule and precautions as full-term babies. Use the full recommended dose of each vaccine, because divided or reduced doses cannot count as valid. Studies demonstrate that decreased seroconversion rates might occur among certain premature babies with low birth weight (less than 2,000 grams) after getting hepatitis B vaccine at birth. However, by chronological age 1 month, all premature babies regardless of initial birth weight or gestational age can respond as adequately as older and larger babies.
# Vaccine Specifics: Recommended Doses of Currently Licensed Monovalent Hepatitis B Vaccines

Recombivax and Engerix-B vaccines both have three doses in their series. Engerix-B also is licensed for a four-dose series given at 0, 1-2, and 6 months. Dialysis patients should get Engerix-B at 0, 1, 2, and 6 months.

<table>
<thead>
<tr>
<th>Group</th>
<th>Merck Recombivax HB Dosage</th>
<th>GSK Engerix-B Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Babies, infants (0-19 years of age)</td>
<td>5 mcg (0.5 mL)&lt;sup&gt;8&lt;/sup&gt; Pediatric/adolescent formulation. YELLOW cap and stripe on vial and cartons and orange banner on the vial labels and cartons stating &quot;preservative free&quot;</td>
<td>10 mcg (0.5 mL)&lt;sup&gt;9&lt;/sup&gt; Pediatric formulation BLUE-top vial Single-dose vials and prefilled disposable TIP-LOK syringe</td>
</tr>
<tr>
<td>Adolescent (11-15 years of age) Merck</td>
<td>10mcg (1.0 mL) Adult formulation GREEN cap and stripe vial and orange banner on vial label</td>
<td>10mcg (0.5 mL) OLIVE GREEN top vial</td>
</tr>
<tr>
<td>A two-dose series for adolescents (11-15) is also acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adults (20 years &amp; older)</td>
<td>10 mcg (1.0 mL) Adult Formulation GREEN-top vial</td>
<td>20 mcg (1.0 mL) Adult Formulation ORANGE-top vial</td>
</tr>
<tr>
<td>Predialysis and dialysis patients</td>
<td>40 mcg (1.0 mL) Dialysis formulation BLUE cap and stripe vial with orange banner</td>
<td>40 mcg (2.0 mL) (Two 20 mcg doses) Adult formulation ORANGE-top vial</td>
</tr>
</tbody>
</table>

### Sources:
- [MMWR, Centers for Disease Control, January 12, 2018](https://www.cdc.gov/mmwr)  
- [Recombivax HB package insert](https://www.merckgroupcitizenship.com), March 2014  
- [Engerix B package insert](https://www.gsk.com), December 2015

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<sup>7</sup> Infants born to HBsAg-positive mothers should also receive hepatitis B immune globulin (HBIG) 0.5 mL intramuscularly at a site different from that used for the hepatitis B vaccine.

<sup>8</sup> Change in dose, licensed in 1998. Infants born to HBsAg-negative mothers now receive the same dose as infants born to HBsAg-positive mothers. “If the suggested formulation is not available, the appropriate dosage can be achieved from another formulation provided that the total volume of vaccine administered does not exceed 1 mL.”

<sup>9</sup> Change in adolescent dose, licensed in 1995.
**Vaccine Specifics: Administering HBIG**

**Route and Site**
For newborns and babies: Give HBIG intramuscularly into the anterolateral thigh muscle.

**Dose and Schedule**
Newborns and babies should get 0.5 ml of HBIG within 12 hours of birth. They should also get dose 1 of hepatitis B vaccine at the same time at a separate injection site.

For other exposed persons, the dose of HBIG is 0.06 mL per kilogram of body weight. To calculate the dose:
- Convert body weight to kilograms (kg)
- Multiply the number of kilograms by 0.06 mL

For example, if the person weighs 110 pounds, the number of kilograms = 110 lbs ÷ 2.2 (number of pounds per kilogram) = 50.0 kg. The correct dose of HBIG then would be 50.0 kg x 0.06 (the amount per kg), giving a dose of 3.0 mL.

**HBIG Dosage at a Glance**
Use the following table to identify dosage based on weight.

<table>
<thead>
<tr>
<th>Body weight in pounds (lbs)</th>
<th>Body Weight in kilograms (kg)</th>
<th>Dose in milliliters (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>45.5</td>
<td>2.7</td>
</tr>
<tr>
<td>110</td>
<td>50.0</td>
<td>3.0</td>
</tr>
<tr>
<td>120</td>
<td>54.5</td>
<td>3.3</td>
</tr>
<tr>
<td>130</td>
<td>59.1</td>
<td>3.5</td>
</tr>
<tr>
<td>140</td>
<td>63.6</td>
<td>3.8</td>
</tr>
<tr>
<td>150</td>
<td>68.2</td>
<td>4.1</td>
</tr>
<tr>
<td>160</td>
<td>72.7</td>
<td>4.4</td>
</tr>
<tr>
<td>170</td>
<td>77.3</td>
<td>4.6</td>
</tr>
<tr>
<td>180</td>
<td>81.8</td>
<td>4.9</td>
</tr>
<tr>
<td>190</td>
<td>86.4</td>
<td>5.2</td>
</tr>
<tr>
<td>200</td>
<td>90.9</td>
<td>5.5</td>
</tr>
<tr>
<td>210</td>
<td>95.5</td>
<td>5.7</td>
</tr>
<tr>
<td>220</td>
<td>100.0</td>
<td>6.0</td>
</tr>
<tr>
<td>230</td>
<td>104.5</td>
<td>6.3</td>
</tr>
<tr>
<td>240</td>
<td>109.1</td>
<td>6.5</td>
</tr>
<tr>
<td>250</td>
<td>113.6</td>
<td>6.8</td>
</tr>
</tbody>
</table>

*Dose = 0.06 mL per kg of body weight; 1 kg = 2.2 lbs*
Vaccine Specifics: Storing and Handling Hepatitis B Vaccine and HBIG

**Always read the package insert.** Read the table below for storage and handling supplemental information, but this does not take the place of the package insert.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Shipping Requirements:</td>
<td>Use insulated container. Must ship with refrigerant.</td>
</tr>
<tr>
<td>Condition on Arrival:</td>
<td>Should not have been frozen. Refrigerate on arrival.</td>
</tr>
<tr>
<td>Storage Requirements:</td>
<td>Refrigerate immediately upon arrival. Store at 2°-8°C (35°-46°F). <strong>Do not freeze.</strong></td>
</tr>
<tr>
<td>Shelf Life/Expiration:</td>
<td>Hepatitis B Vaccine - up to 3 years. Check date on container or vial. HBIG - up to 12 months. Check date on container or vial.</td>
</tr>
<tr>
<td>Instructions for Reconstitution or Use:</td>
<td>Inspect visually for particulate matter or discoloration. Shake vial or fill syringe well before use.</td>
</tr>
<tr>
<td>Shelf Life after Reconstituting or Opening:</td>
<td>Check expiration date on vial, or manufacturer-filled syringe. Give the vaccine shortly after withdrawal. If pre-filled syringe, administer after the needle is attached to the syringe.</td>
</tr>
<tr>
<td>Special Instructions:</td>
<td>Rotate stock so that you use the material with the earliest expiration date first.</td>
</tr>
</tbody>
</table>

**Best Practices for Storing and Handling All Vaccines**

- Have policies and procedures in place to rotate stock and check expiration date of vaccine weekly. Use vaccine with earliest expiration date so none become outdated.
- Do not use outdated vaccine.
- Never store vaccine in refrigerator door.
- When transporting vaccine, always use an insulated container with ice packs.
- [Vaccine storage and handling information from the Department of Health](http://www.health.state.ny.us/)
- [Vaccine storage and handling recommendations and guidelines from the CDC](http://www.cdc.gov/)
Vaccine Specifics: Ages and Intervals

The table below shows hepatitis B vaccine (hepB) doses, with recommended ages, intervals, and minimum ages for getting the vaccines.

**Recommended and Minimum Ages and Intervals between Doses**

<table>
<thead>
<tr>
<th>Vaccine and dose number</th>
<th>Recommended age for this dose</th>
<th>Minimum age for this dose</th>
<th>Recommended interval to next dose</th>
<th>Minimum interval to next dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>HepB-dose 1**</td>
<td>Birth</td>
<td>Birth</td>
<td>1-4 months</td>
<td>4 weeks</td>
</tr>
<tr>
<td>HepB-dose 2</td>
<td>1-2 months</td>
<td>4 weeks</td>
<td>2-17 months</td>
<td>8 weeks</td>
</tr>
<tr>
<td>HepB-dose 3***</td>
<td>6- months</td>
<td>24 weeks</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Source: Epidemiology and Prevention of Vaccine-Preventable Diseases, CDC

** Combination vaccines with a hepatitis B component are available (Comvax, Pediarix, and Twinrix). These vaccines should not be administered to infants younger than 6 weeks because other components in the vaccines are not suitable for this age group (i.e., Hib, DTaP, HepA, and IPV).

*** Hepatitis B-dose 3 should be administered at least 8 weeks after dose 2 and at least 16 weeks after dose 1.

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In WA: Did you know?

In WA State, about 70% of birthing hospitals list correct doses of HBIG; about 84% list correct hepB vaccine doses.
References and Hospital Resources

This section contains references and helpful resources for hospitals

Manual References

- CDC Perinatal Hepatitis B Prevention Program Case Transfer Form
- CDC Hepatitis B Vaccine: What You Need to Know – Vaccine Information Sheet (VIS)
- Hepatitis B Facts: Testing and Vaccination
- WAC 246-101-101 Notifiable Conditions and the Health Care Provider
- List of Washington state local health jurisdiction perinatal hepatitis B coordinators

Hospital Resources

- IAC Guidebook: What Hospitals Need to Do to Protect Newborns: a complete resource to help birthing institutions establish, implement, and optimize their birth dose policies. (Immunization Action Coalition)
- Give the Birth Dose (PDF, IAC)
- Medical Errors (PDF, IAC)
- Admission Orders for Labor & Delivery and Newborn Units to Prevent Hepatitis B Virus Transmission (PDF, IAC)
- Sample Text for Admission Orders for Hepatitis B Vaccine Birth Dose in Newborn Nursery (PDF, IAC)
- Stickers for medical charts. Print these stickers on Avery mailing labels 5163 to flag hospital medical charts of babies born to HBsAg-positive mothers. Print in color.
  - Prenatal stickers: Reporting HBsAg-positive Mothers Required
  - Hospital Sticker: ALERT: Give HBIG and hepatitis B Vaccine: available upon request.
  - Pediatric Sticker: baby requires hepatitis B immunization: available upon request.
- Order hepatitis B materials from DOH
- WAC 246-101-101, Notifiable Conditions and the Health Care Provider:
- Pregnancy and Hepatitis B (Hepatitis B Foundation)
# Chapter 4: What Pediatric Care Providers Need to Know

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    m. PKIDS
Perinatal Hepatitis B Prevention Program: Goal and Objectives

Federal recommendations

The Washington State Department of Health (DOH) Office of Immunization and Child Profile (OICP) follows federal recommendations for hepatitis B immunization. These recommendations, made by the Advisory Committee on Immunization Practices (ACIP), include control of perinatal hepatitis B virus infection (HBV). The latest updated ACIP recommendations target delivery hospital policies, procedures, and case management programs.

To provide appropriate clinical care to a newborn, you must put the mother’s data in the infant’s medical record, as recommended by ACIP. This does NOT violate the Health Insurance Portability and Accountability Act (HIPAA). The HIPAA Privacy Rule allows the use of some health information:

“A covered entity is permitted, but not required, to use and disclose protected health information, without an individual’s authorization, for the following purposes or situations: (1) To the Individual; (2) Treatment, Payment, and Health Care Operations...”

Find a summary document of the HIPAA Privacy Rule here.

Goal

Washington State’s Perinatal Hepatitis B Prevention Program (PHBPP) has an overall goal to work with partners to assure coordination of activities to prevent perinatal hepatitis B transmission to newborns. The program has several key elements.

- It is both a surveillance and case management program to help manage perinatal hepatitis B cases.
- It promotes universal birth dose.
- It relies on multiple reporting mechanisms.
- It works with partners to assure coordination of activities.
Local health jurisdictions in our state are key in completing these tasks, including supporting effective delivery hospital policies specifying birth dose vaccinations, standing orders, and case management to:

- Identify HBsAg-positive pregnant women.
- Make sure their babies get proper post-exposure prevention. Correct post-exposure prevention for babies includes hepatitis B immune globulin (HBIG) and hepatitis B vaccine within 12 hours of birth, followed by two more doses of vaccine (at 1-2 months and 6 months of age).
- Make sure post-vaccine testing is completed.
- Report all data on administration of follow-up doses of vaccine and post-testing of the infant to DOH).

### Objectives

1. 100% of all pregnant women get screened for HBsAg prenatally or at delivery.
2. 100% of delivery hospitals adopt policies, procedures, & standing orders for HBsAg verification & for testing mothers at delivery.
3. At least 90% of expected births to HBsAg-positive mothers are identified.
4. At least 95% of babies born to HBsAg-positive mothers get HBIG and 1 dose of hepB vaccine within 12 hours of birth and 3 vaccine doses by 6 months.
5. At least 90% of these babies get a blood test (HBsAg and anti-HBs) 1-2 months after the last dose of hepB vaccine or by 9-12 months.
6. 100% of all HBsAg-positive babies get reported to DOH and CDC through the National Notifiable Disease Surveillance System.
Hepatitis B Facts

Acute (short-term) and chronic (long-lasting) effects of hepatitis B virus (HBV) infection are a major health problem.

About 79,000 infections occur in the U.S. each year; 21,000 of those cases are acute (short-term) and symptomatic (showing symptoms) (Centers for Disease Control and Prevention).

As many as 1.6 million people in the U.S. have chronic HBV and can potentially spread the disease to others.

Hepatitis B is a leading cause of liver cancer in the U.S. HBV can be passed from mom to baby during birth (perinatal infection). About 25,000 HBV-infected moms give birth each year in the U.S. Infants infected at birth may later experience potentially deadly complications, like chronic liver disease and liver cancer. Each year, about 4,000 to 5,000 people die from chronic liver disease.

Hepatitis B infection in the Asian-Pacific Islander population is 10%. That's 60 times higher than the infection rate of the general population.

The number of foreign-born residents living with chronic hepatitis B will continue to increase with ongoing immigration from countries where hepatitis B is common.

Unless they get proper post-exposure prevention, up to 90% of babies born to mothers with hepatitis B get infected, and 85% to 95% of those will be chronically infected. Up to one in four chronically infected babies will die from primary hepatocellular carcinoma or cirrhosis of the liver later in life.

While screening rates are high, reporting rates of HBsAg-positive pregnant women remain a problem. Nationally, about 95% of pregnant women receive prenatal HBsAg serologic testing, yet only 47% of expected births to HBsAg-positive pregnant women are identified and reported to perinatal hepatitis B programs (CDC Peritable Outcomes, 2014)

Getting immunized with hepatitis B vaccine is the most effective way to prevent HBV infection. Pregnant women who are infected with HBV can prevent giving HBV to their babies at birth if the baby gets:

- Hepatitis B immune globulin (HBIG) and hepatitis B vaccine within 12 hours of birth
- Additional doses of vaccine at 1-2 months and 6 months of age.

CDC recommends testing all pregnant women for HBV early in each pregnancy even if they already had the vaccine or test. Women who test HBsAg-negative early in pregnancy but are in a high-risk category for HBV should be retested at the delivery hospital.

Pregnant women who test HBsAg positive should be referred to the local health jurisdiction’s PHBPP and receive counseling, medical management, and information about HBV. Emerging evidence suggests HBV treatment during the third trimester is safe and reduces rates of transmission.
Pediatric Care Providers Tasks Overview

The following five tasks help guide pediatric care providers to prevent perinatal hepatitis B transmission. Babies born to HBsAg-positive mothers are at high risk of getting hepatitis B virus (HBV) infection themselves, becoming lifelong (chronic) carriers, and developing serious conditions later in life unless they get proper prevention.

1) Follow Recommendations

Follow the national Advisory Committee on Immunization Practices (ACIP) recommendations for infants born to HBsAg-positive mothers. Use the Provider Checklist to record all vaccination and testing dates and results. Give your infant patients:

- HBIG and hepatitis B vaccine within 12 hours of birth.
- Hepatitis B vaccine dose 2 at 1-2 months of age.
- Hepatitis B vaccine dose 3 at 6 months of age.
- Post-vaccine screening including both HBsAg and anti-HBs at 9 to 12 months of age.

2) Manage Cases

Work with your local health jurisdiction (LHJ) Hepatitis B Coordinator to manage all infant and child hepatitis B cases. Your LHJ likely is already involved in the case of an HBsAg-positive mother so expect contact from them to follow up with her baby’s hepatitis B vaccination and testing. LHJ staff also will follow up with the mother’s household contacts and sexual partners to get proper prevention. If you aren’t contacted by your LHJ, contact them to make sure the baby’s family gets follow-up. Share the information on your Provider Checklist with your LHJ.

3) Third Dose

Be sure all infants born to HBsAg-positive mothers get dose 3 of hepatitis B vaccine at 6 months of age. This is a stringent schedule to prevent infection. Use the Provider Checklist to record all vaccine and testing dates and results. Notify your LHJ of the date baby got dose 3.

4) Post-Vaccination Screening

Complete post-vaccination screening for all infants born to HBsAg-positive mothers at 9 to 12 months of age. Educate the baby’s parents about the importance of this screening and be sure to tell them the test will show if the infant has developed antibodies to, or has become infected with, HBV. To reduce the stress related with this blood draw, write an order for the test and send the infant to a phlebotomist with experience in pediatric blood draws. Use the Provider Checklist to record all vaccination and testing dates and results. Send the date and laboratory results of the baby’s post-vaccination screening to your LHJ’s Hepatitis B Coordinator.

5) Repeat Series

Repeat the hepatitis B vaccine series at intervals of 0, 1-2, and 6 months for all infants who test HBsAg-negative and antibody-negative at the post-vaccination screening. Order a second post-vaccination test 1-2 months after the series is completed. Use the Provider Checklist to record all vaccination and testing dates and results. Notify your LHJ about the dates of re-vaccination and results of tests.
Case Management Snapshot

Managing a perinatal hepatitis B case always starts with the pregnant woman and involves pre-screening, opening a confidential case report in the module, tracking the woman’s baby, following up with phone calls and mail, and closing a case when follow-up is finished. Cases may be open for as long as two years. Find a visual snapshot of this process below.

START: Health care provider pre-screens pregnant woman in first trimester of pregnancy.

HBsAg test is NEGATIVE.

No hepatitis B case.

HBsAg test is POSITIVE.

Health care provider or hospital reports HBsAg-positive woman to LHJ Hepatitis B Coordinator.

Hep B Coordinator opens a confidential case on the HBsAg-positive woman using "New Case" in the Perinatal Hepatitis B Module.

To guide the use of antiviral therapy during pregnancy for prevention of perinatal HBV transmission a HBV DNA test should be done for all HBsAg-positive pregnant women.

Based on pre-screening, Hep B Coordinator either:
- Refers contacts and partners to a specialist or
- Makes sure contacts and partners get vaccinated and post-tested.

BABY is BORN!
Hospital gives HBIG and birth dose of hepatitis B vaccine.

Hep B Coordinator enters infant information into the mother’s open case in the Perinatal Hepatitis B Module.

Hep B Coordinator calls hospital for infant’s information and dates of HBIG and hepB vaccine. Hep B Coordinator works with mother & pediatrician to make sure baby gets full vaccination series and post-testing.

Hep B Coordinator closes a case for other reasons, such as if mother refuses follow-up, can’t be located, or if the pregnancy ends.

Also, cases get closed for other reasons.

When all follow-ups with mother and baby have been documented for pre-screenings, HBIG, vaccination series and post-testing, Hep B Coordinator “closes” the open case in the Perinatal Hepatitis B Module.
## Laboratory Screening: Serologic Markers

Use the table below* to find explanations of hepatitis B markers (antibodies) in blood serum.

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Name</th>
<th>Definition/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBsAg</td>
<td>Hepatitis B surface antigen</td>
<td>Detection of a large quantity of surface antigen(s) of HBV in serum indicates infection.</td>
</tr>
<tr>
<td>Anti-HBs</td>
<td>Antibody to Hepatitis B surface antigen</td>
<td>Detection of antibodies to HBsAg. Indicates past infection with immunity to HBV, passive antibody from HBIG, or immune response from hepatitis B vaccine.</td>
</tr>
<tr>
<td>HBcAg</td>
<td>Hepatitis B core antigen</td>
<td>A marker of current or past hepatitis B infection.</td>
</tr>
<tr>
<td>Anti-HBe</td>
<td>Antibody to Hepatitis B e antigen</td>
<td>Detection of HBeAg correlates with higher levels of HBV in serum and increased infectivity.</td>
</tr>
<tr>
<td>IgM anti-HBc</td>
<td>IgM class antibody</td>
<td>Detection of IgM class antibodies indicates recent infection with HBV. IgM is detectable for 4 to 6 months after infection.</td>
</tr>
</tbody>
</table>

* Source: Immunization Action Coalition
Laboratory Screening: Interpreting Test Results

Use this table* for help interpreting hepatitis B test results, also called the hepatitis B panel:

<table>
<thead>
<tr>
<th>Tests</th>
<th>Results</th>
<th>Interpretation</th>
<th>Vaccinate?</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBsAg anti-HBc anti-HBs</td>
<td>negative negative negative</td>
<td>Susceptible</td>
<td>Vaccinate if indicated</td>
</tr>
<tr>
<td>HBsAg anti-HBc anti-HBs</td>
<td>negative positive with &gt;10mIU/mL**</td>
<td>Immune due to vaccination</td>
<td>No vaccination necessary</td>
</tr>
<tr>
<td>HBsAg anti-HBc anti-HBs</td>
<td>positive positive</td>
<td>Immune due to natural infection</td>
<td>No vaccination necessary</td>
</tr>
<tr>
<td>HBsAg anti-HBc IgM anti-HBc anti-HBs</td>
<td>positive positive negative</td>
<td>Acutely infected</td>
<td>No vaccination necessary</td>
</tr>
<tr>
<td>HBsAg anti-HBc IgM anti-HBc anti-HBs</td>
<td>positive negative negative</td>
<td>Chronically infected</td>
<td>No vaccination necessary (may need treatment)</td>
</tr>
<tr>
<td>HBsAg anti-HBc anti-HBs</td>
<td>negative positive negative</td>
<td>Four interpretations possible:</td>
<td>Use clinical judgment</td>
</tr>
<tr>
<td><strong>Post-vaccination testing, when recommended, should be done 1-2 months after the last dose of vaccine.</strong> Infants born to HBsAg-positive mothers should be tested for HBsAg and anti-HBs after they’ve had at least three doses of a licensed hepatitis B vaccination series. This means at 9-12 months, typically at the next well-child visit.**</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Source: Immunization Action Coalition

**
Required Notification

Washington State follows three levels of required notification for certain medical conditions to prevent and control communicable and noninfectious diseases. Different agencies take care of these different notification levels.

10. Notification to local health jurisdictions (LHJ): by every prenatal health care provider or hospital.

Washington considers EACH pregnancy in any HBsAg-positive woman a notifiable condition. This can increase the chance that babies born to HBsAg-positive mothers will get proper post-exposure prevention. Because of this, the notifications must happen correctly as explained and shown in the picture below.

10. Healthcare providers notify the LHJ Perinatal Hepatitis B Coordinator of the pregnant woman’s status.
11. The Hepatitis B Coordinator then enrolls the woman in the Perinatal Hepatitis B Prevention Program, manages her case (including her baby, household contacts, and sexual partners), and notifies the correct agency programs.
12. DOH notifies CDC weekly about all hepatitis B-infected infants.
Required Reportable Conditions

Hepatitis B Surface Antigen (HBsAg) Positivity During Pregnancy

Since December 2000 in Washington State, HBsAg-positive status during pregnancy has been a required reportable condition per state law (Washington Administrative Code [WAC] 246-101-101 and WAC 246-101-301). Healthcare providers and health care facilities, such as hospitals, must report this status to local health jurisdictions within three working days.

Why Report?

Identifying and reporting HBsAg-positive pregnant women during each pregnancy helps prevent the spread of hepatitis B virus to their babies. These babies have a very high risk of getting the infection and developing serious long-term medical conditions unless they get proper post-exposure prevention.

Local public health jurisdiction staff work with health care providers to make sure that:

- Mothers get counseled about preventing the spread of hepatitis B virus to their babies and their household contacts.
- Mothers get screened and, if appropriate, referred to a specialist during pregnancy (see page 2 of this infographic).
- Mother’s sexual partner(s) get referred to a specialist for follow-up.
- Babies get hepatitis B immune globulin (HBIG) and 3 doses of hepatitis B vaccine (birth, 1-2 months, 6 months).
- Babies get post-vaccination testing (HBsAg and anti-HBs) between 9 and 12 months of age (at least 1 to 2 months after the third dose of hepatitis B vaccine) to check for infection and immune status.

When to Report

A report should be made at any time during each pregnancy in which the pregnant woman tests HBsAg positive. It is the prenatal care provider’s responsibility to make sure the delivery hospital knows of an HBsAg-positive mother prior to the birth so the baby gets proper treatment.

Reporting Requirements

Per WAC 246-101-101 and WAC 246-101-301, healthcare providers and health care facilities who request the HBsAg test during prenatal care or at time of delivery must report all HBsAg-positive pregnant women to the provider’s LHJ within three working days.

Reporting Resources from DOH

- How to report notifiable conditions
- Reporting posters
- Hepatitis B as a notifiable condition
- If you have other questions, contact the Department of Health at 360-236-3595.
Vaccine Specifics: Administering Hepatitis B Vaccine

Route and Site
Give hepatitis B vaccine intramuscularly into the deltoid muscle of adults and children and into the anterolateral thigh muscle of newborns and babies. Do not give hepatitis B vaccine intradermally or into the buttock.

You can give hepatitis B vaccine at the same time as other vaccines, but use separate injection sites.

Dose and Schedule
Babies born to HBsAg-positive mothers should get the following. You can use different brands of the single-antigen vaccine for the vaccine doses.

Vaccination of Premature Babies
- Premature babies born to HBsAg-positive mothers or mothers with unknown status must get HBIG AND hepatitis B vaccine less than 12 hours after birth. If these babies weigh less than 2,000 grams at birth, do not count the first dose of hepatitis B vaccine as one of the doses in the series. The baby should get three additional doses of hepatitis B vaccine, starting when medically stable and at least 1 month of age. (MMWR, 2018). This will be a total of 4 doses.

- Premature babies born to HBsAg-negative mothers, regardless of birth weight, should get vaccinated at the same chronological age and with the same schedule and precautions as full-term babies. Use the full recommended dose of each vaccine, because divided or reduced doses cannot count as valid. Studies demonstrate that decreased seroconversion rates might occur among certain premature babies with low birth weight (less than 2,000 grams) after getting hepatitis B vaccine at birth. However, by chronological age 1 month, all premature babies regardless of initial birth weight or gestational age can respond as adequately as older and larger babies.
Vaccine Specifics: Recommended Doses of Currently Licensed Monovalent Hepatitis B Vaccines

Recombivax and Engerix-B vaccines both have three doses in their series. Engerix-B also is licensed for a four-dose series given at 0, 1-2, and 6 months. Dialysis patients should get Engerix-B at 0, 1, 2, and 6 months.

<table>
<thead>
<tr>
<th>Group</th>
<th>Merck Recombivax HB Dosage</th>
<th>GSK Engerix-B Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Babies, 1 children &amp; adolescents (0–19 years of age)</td>
<td>5 mcg (0.5 mL)² Pediatric/adolescent formulation. YELLOW cap and stripe on vial and cartons and orange banner on the vial labels and cartons stating “preservative free”</td>
<td>10 mcg (0.5 mL)³ Pediatric formulation BLUE-top vial Single-dose vials and prefilled disposable TIP-LOK syringe</td>
</tr>
<tr>
<td>Adolescent (11–15 years of age) Merck (11–19 years of age) GSK</td>
<td>10mcg (1.0 mL) Adult formulation GREEN cap and stripe vial and orange banner on vial label</td>
<td>10mcg (0.5 mL) OLIVE GREEN top vial</td>
</tr>
<tr>
<td>A two-dose series for adolescents (11-15) is also acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adults (20 years &amp; older)</td>
<td>10 mcg (1.0 mL) Adult Formulation GREEN-top vial</td>
<td>20 mcg (1.0 mL) Adult Formulation ORANGE-top vial</td>
</tr>
<tr>
<td>Predialysis and dialysis patients</td>
<td>40 mcg (1.0 mL) Dialysis formulation BLUE cap and stripe vial with orange banner</td>
<td>40 mcg (2.0 mL) (Two 20 mcg doses) Adult formulation ORANGE-top vial</td>
</tr>
</tbody>
</table>

Sources:
- MMWR, Centers for Disease Control, January 12, 2018
- Recombivax HB package insert, March 2014
- Engerix B package insert, December 2015

¹ Infants born to HBsAg-positive mothers should also receive hepatitis B immune globulin (HBIG) 0.5 mL intramuscularly at a site different from that used for the hepatitis B vaccine.

² Change in dose, licensed in 1998. Infants born to HBsAg-negative mothers now receive the same dose as infants born to HBsAg-positive mothers. “If the suggested formulation is not available, the appropriate dosage can be achieved from another formulation provided that the total volume of vaccine administered does not exceed 1 mL.”

³ Change in adolescent dose, licensed in 1995.
Vaccine Specifics: Storing and Handling Hepatitis B Vaccine and HBIG

**Always read the package insert.** Read the table below for storage and handling supplemental information, but this does not take the place of the package insert.

<table>
<thead>
<tr>
<th>Shipping Requirements:</th>
<th>Use insulated container. Must ship with refrigerant.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Condition on Arrival:</td>
<td>Should not have been frozen. Refrigerate on arrival.</td>
</tr>
<tr>
<td>Storage Requirements:</td>
<td>Refrigerate immediately upon arrival. Store at 2°-8°C (35°-46°F). <strong>Do not freeze.</strong></td>
</tr>
</tbody>
</table>
| Shelf Life/Expiration:                      | Hepatitis B Vaccine - up to 3 years. Check date on container or vial.  
                                            HBig - up to 12 months. Check date on container or vial. |
| Instructions for Reconstitution or Use:     | Inspect visually for particulate matter or discoloration.  
                                            Shake vial or fill syringe well before use. |
| Shelf Life after Reconstituting or Opening: | Check expiration date on vial, or manufacturer-filled syringe. Give the vaccine shortly after withdrawal. If pre-filled syringe, administer after the needle is attached to the syringe. |
| Special Instructions:                       | Rotate stock so that you use the material with the earliest expiration date first. |

**Best Practices for Storing and Handling All Vaccines**

- Have policies and procedures in place to rotate stock and check expiration date of vaccine weekly. Use vaccine with earliest expiration date so none become outdated.
- Do not use outdated vaccine.
- Never store vaccine in refrigerator door.
- When transporting vaccine, always use an insulated container with ice packs.
- **Vaccine storage and handling information from the Department of Health**
- **Vaccine storage and handling recommendations and guidelines from the CDC**
Vaccine Specifics: Ages and Intervals

The table below shows hepatitis B vaccine (hepB) doses, with recommended ages, intervals, and minimum ages for getting the vaccines.

<table>
<thead>
<tr>
<th>Vaccine and dose number</th>
<th>Recommended age for this dose</th>
<th>Minimum age for this dose</th>
<th>Recommended interval to next dose</th>
<th>Minimum interval to next dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>HepB-dose 1**</td>
<td>Birth</td>
<td>Birth</td>
<td>1-4 months</td>
<td>4 weeks</td>
</tr>
<tr>
<td>HepB-dose 2</td>
<td>1-2 months</td>
<td>4 weeks</td>
<td>2-17 months</td>
<td>8 weeks</td>
</tr>
<tr>
<td>HepB-dose 3***</td>
<td>6- months</td>
<td>24 weeks</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Source: Epidemiology and Prevention of Vaccine-Preventable Diseases, CDC

** Combination vaccines with a hepatitis B component are available (Comvax, Pediarix, and Twinrix). These vaccines should not be administered to infants younger than 6 weeks because other components in the vaccines are not suitable for this age group (i.e., Hib, DTaP, HepA, and IPV).

*** Hepatitis B-dose 3 should be administered at least 8 weeks after dose 2 and at least 16 weeks after dose 1.

In WA: Did you know?

In WA State, about 70% of birthing hospitals list correct doses of HBIG; about 84% list correct hepB vaccine doses.
References and Pediatric Resources

This section contains references and helpful resources for pediatric care providers.

References

- CDC Perinatal Hepatitis B Prevention Program [Case Transfer Form]
- CDC Hepatitis B Vaccine: What You Need to Know – [Vaccine Information Sheet (VIS)]
- [Hepatitis B Facts: Testing and Vaccination]
- WAC 246-101-101 [Notifiable Conditions and the Health Care Provider]
- List of [Washington state local health jurisdiction perinatal hepatitis B coordinators]

Pediatric Care Resources

- [Pediatric Care Provider Checklist (PDF, DOH)]
- [What the Physician Can Do for the Child with Chronic Hepatitis B Virus Infection (PDF, Immunization Action Coalition)]
- [Hepatitis B information for Health Care Professionals, Parents, and More (Hepatitis B Foundation)]
- [Pediatric Recommendations (American Academy of Pediatrics)]
- Vaccination of premature infants: [Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices] Centers for Disease Control and Prevention, MMWR, 2018
- [Hepatitis B Facts: Testing and Vaccination (PDF, IAC)]
- [Medical Errors (PDF, IAC)]
- Pediatric stickers for medical charts, “Baby requires hepatitis B immunization”; available upon request.
- Order [hepatitis B materials from DOH]
- [WAC 246-101-101, Notifiable Conditions and the Health Care Provider]
- [Pregnancy and Hepatitis B (Hepatitis B Foundation)]
- [PKIDS (Parents of Kids with Infectious Diseases)]