

Perinatal Hepatitis B Prevention Program Guidelines

Chapter 1: What Local Health Jurisdictions Need to Know

Table of Contents

Pages 4-34

1. **Perinatal Program: Goal and Objectives**
2. **Hepatitis B Facts**
3. **LHJ Tasks Overview**
4. **Case Management Snapshot**
5. **Prevention Procedures Detail**
6. **Perinatal Hepatitis B Module Overview**
7. **Managing Cases**
8. **Reporting HBsAg-positive Babies**
9. **Closing Cases**
10. **Required Notification**
11. **Required Reportable Conditions**
 - 1) Reporting Matrix
 - 2) Reporting LHJ Contact List
 - 3) Notifiable Conditions
12. **Vaccine Specifics**
 - 1) Administering Vaccine
 - 2) Recommended Doses
 - 3) Administering HBIG
 - 4) Storage and Handling
 - 5) Ages and Intervals
13. **Laboratory Screening**
 - 1) Guidelines
 - 2) Free Blood Testing
 - 3) Submitting Blood Samples
 - 4) Serologic Markers
 - 5) Interpreting Test Results
14. **References and LHJ Resources**
 - 1) Manual References
 - 2) Sample Letters (Before Baby is Born, After Baby is Born, Blood Testing)
 - 3) Local Health Jurisdiction Perinatal Hepatitis B Coordinators List
 - 4) Stickers for Medical Charts (Mothers, Newborns, Babies)
 - 5) Order Hepatitis B Materials
 - 6) WAC: Notifiable Conditions and the Health Care Provider



Perinatal Program: Goal and Objectives

Federal recommendations

The Washington State Department of Health (DOH) Immunization Program CHILD Profile (IPCP) 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 and procedures and case management programs.

To provide appropriate clinical care to a newborn, you must document the mother's data in the infant's medical record. ACIP recommends putting maternal data in the baby's medical record and it 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....."

Clearly, for treatment and health care relevant to the newborn, we must gather and use maternal health information. Find a summary document of the HIPAA Privacy Rule at <http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary>.

Goal

Washington State's Perinatal B Prevention Program has an overall goal ***to reduce the incidence of B virus (HBV) in babies born to hepatitis B surface antigen (HBsAg)-positive mothers***. Local health jurisdictions in our state must complete the tasks to reach this goal, including setting up effective delivery hospital policies and case management to:

- Identify HBsAg-positive pregnant women, their household contacts, sexual partners, and babies.
- Make sure their at-risk contacts get a three-dose series of hepatitis B vaccine.
- 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 additional doses of vaccine (at 1-2 months and 6 months of age).

Objectives

Objectives to reach this goal include helping to ensure:

- 100 percent of all pregnant women get screened for HBsAg prenatally or at delivery.
- 100 percent of delivery hospitals adopt written policies, procedures, and written standing orders for HBsAg verification and for testing pregnant mothers when they come to the hospital for delivery.
- Identifying at least 90 percent of expected births to HBsAg-positive mothers.
- At least 95 percent of babies born to HBsAg-positive mothers get hepatitis B immune globulin (HBIG) and Dose #1 of hepatitis B vaccine within 12 hours of birth and complete the 3-dose hepatitis B vaccine series by 6 months of age.
- At least 90 percent of babies born to HBsAg-positive women get a blood test (to check for HBV antibodies) 1-2 months after their last dose of hepatitis B vaccine or by 9-18 months of age.
- At least 90 percent of at-risk sexual partners and household contacts of HBsAg-positive pregnant women complete the three-dose hepatitis B vaccine series.
- 100 percent of all HBsAg-positive babies get reported to the Centers for Disease Control and Prevention (CDC) through the National Notifiable Disease Surveillance System (NNDSS).

Hepatitis B Facts

- Acute (short-term) and chronic (long-lasting) effects of hepatitis B virus (HBV) infection are a major health problem.
- The Centers for Disease Control and Prevention (CDC) estimates that 79,000 infections occur in the United States (U.S.) each year with 21,000 of those acute (short-term) and symptomatic (showing symptoms).
- About 1.25 million people in the U.S. have chronic HBV and can potentially spread the disease to others.
- Many people with chronic HBV infection are at risk of getting long-term conditions such as chronic liver disease and liver cancer. Each year, about 4,000-5,000 of these people die from chronic liver disease.
- Hepatitis B infection in the Asian Pacific Islander population is 10 percent or 60 times greater than that of the general population.
- Hepatitis B infection can spread from mother to child during labor. About 19,000 babies born in the U.S. each year have an HBV-infected mother, which means they are exposed to the virus. Unless they get proper post-exposure prevention, up to 90 percent of these babies get infected. Of those infected, 90 percent will become chronically infected. Up to 25 percent of the babies who become chronically infected will die from primary hepatocellular carcinoma or cirrhosis of the liver, usually as adults.
- Getting immunized with hepatitis B vaccine is the most effective way to prevent HBV infection. Pregnant women who are chronically infected with HBV – called hepatitis B surface antigen-positive or HBsAg-positive – can prevent giving HBV to their babies during birth. These women must be identified and their babies must get prevention after birth, which means:
 - Hepatitis B immune globulin (HBIG) *and* hepatitis B vaccine within 12 hours of birth, and
 - 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 have had the vaccine or test previously. Women who test HBsAg-negative early in pregnancy but are in a high-risk category for getting HBV should be retested when they get to the delivery hospital.

Local Health Jurisdiction Tasks Overview

Local health jurisdictions (LHJs) get funds (through the consolidated contract) for Perinatal Hepatitis B Prevention program tasks. Each LHJ must:

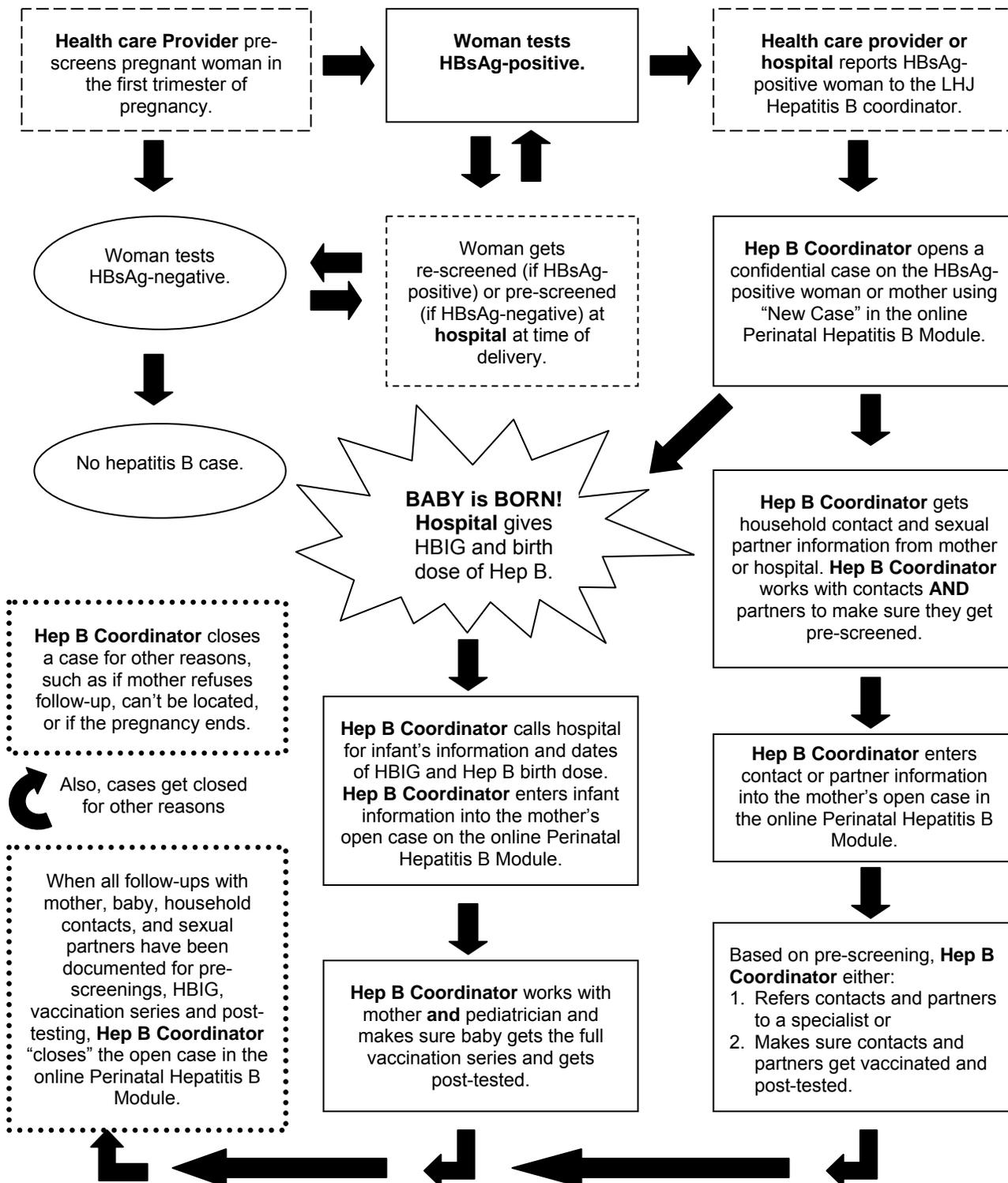
1. Identify and report HBsAg-positive mothers and their babies.
2. Manage and track infant cases to make sure they get the correct doses at the correct ages and proper testing as follows:
 - The first dose of HBIG and hepatitis B vaccine within 12 hours of birth.
 - The second dose at 1-2 months of age.
 - The third dose at 6 months of age.
 - Post-vaccination testing at 9–18 months of age.
3. Identify and track at risk-household contacts and sexual partners of HBsAg-positive pregnant women to make sure they get pre-vaccination testing, HBIG and/or hepatitis B vaccine, and post-vaccination testing if appropriate.

Under this program:

- LHJs should manage cases and complete reports electronically in the Perinatal Hepatitis B Module at the Department of Health Immunization Program CHILD Profile Web site at www.doh.wa.gov/cfh/immunize/diseases/hepatitis_b/hep-b-module.htm or directly here:
 - Perinatal Hepatitis B Module:
<https://fortress.wa.gov/doh/cpir/webhepb/welcome.jsp>
 - User Guide:
www.doh.wa.gov/cfh/immunize/documents/hepbmoduserguide.pdf
- 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 may get free laboratory screening for hepatitis B **if** the blood gets drawn by the LHJ **and** sent to Public Health – Seattle & King County Laboratory and must get tested for:
 - Pregnant women **if** they do not have Medicaid or another third party payment source that will cover testing;
 - Household contacts and sexual partners of HBsAg-positive pregnant women **if** the contacts/partners do not have Medicaid or another third party payment source that will cover *pre- and post-vaccination testing*; or
 - Babies born to HBsAg-positive mothers **if** the babies do not have Medicaid or another third party payment source that will cover *post-vaccination testing*.
- LHJs can get help from the Department of Health Immunization Program CHILD Profile (IPCP) to develop, build, and carry out the program. Take advantage of site visits by IPCP 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, finding household contacts and sexual partners, tracking the woman's baby, following-up with phone calls and mail as necessary with contacts, partners, and babies, 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 system below. See next page for another snapshot of the procedure.



To get the most updated versions of Prevention Procedures Detail, please print it from the Internet: www.doh.wa.gov/cfh/immunize/documents/hepbprevproc.pdf

Perinatal Hepatitis B Module: Overview

Local health jurisdictions (LHJs) should manage and complete reports of HBsAg-positive pregnant women, their household contacts, sexual partners, and babies in the online Perinatal Hepatitis B Module. The Module can be found on the Department of Health Immunization Program CHILD Profile's Web site at www.doh.wa.gov/cfh/Immunize/diseases/hepatitis_b/hep-b-module.htm or directly here:

- Perinatal Hepatitis B Module:
<https://fortress.wa.gov/doh/cpir/webhepb/welcome.jsp>.

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

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

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

See the User Guide for detailed instructions at this website www.doh.wa.gov/cfh/Immunize/diseases/hepatitis_b/hep-b-module.htm or directly here:

- User Guide: www.doh.wa.gov/cfh/Immunize/documents/hepbmoduserguide.pdf

For technical support, contact:

- Chrystal Averette at 360-236-3565 or chrystal.averette@doh.wa.gov or
- Belinda Baker at 360-236-3587 or belinda.baker@doh.wa.gov

Managing Cases

To manage your cases and complete reports, use the online Perinatal Hepatitis B Module. The User Guide can help answer questions. You can access the Module and the User Guide from the Department of Health Immunization Program CHILDP Profile's Web site at www.doh.wa.gov/cfh/immunize/diseases/hepatitis_b/hep-b-module.htm or directly here:

- Perinatal Hepatitis B Module: <https://fortress.wa.gov/doh/cpir/webhepb/welcome.jsp>.
- User Guide: www.doh.wa.gov/cfh/immunize/documents/hepbmoduserguide.pdf

If you can't access the Module, download copies of the forms, fill them out by hand, and fax them to the Immunization Program CHILDP Profile (IPCP) at 360-236-3670. Download from www.doh.wa.gov/cfh/immunize/diseases/hepatitis_b/hep-b-peri-pubs.htm or directly here:

- Household Contact: www.doh.wa.gov/cfh/immunize/documents/348-035.pdf
- Mother/Infant: www.doh.wa.gov/cfh/immunize/documents/348-030.pdf

Protocol for Perinatal Hepatitis B Infection

Follow this protocol to manage cases of hepatitis B infected pregnant women and their babies, household contacts, and sexual partners. Most tasks deal with recalls 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, please skip to number 4.**

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

- a. Call the prenatal care provider, clinic nurse, or clinic manager to get the following information:
 - i. The pregnant woman's knowledge of her HBsAg status (yes or no)
 - ii. The primary language of the case
 - iii. The pregnant woman's address and telephone number
 - iv. The pregnant woman's due date
 - v. The delivery hospital
 - vi. The date of positive HBsAg test result
 - vii. The pregnant woman's payment source
- b. Tell the prenatal care provider that you will contact the pregnant woman to provide information about perinatal hepatitis B prevention, including case management and follow-up for her infant and household/sexual contacts.
- c. Ask the prenatal care provider to mail or fax a copy of the original HBsAg-positive lab results his or her local health jurisdiction.

- d. Educate the prenatal care provider about the need to identify household contacts and sexual partners. Discuss what actions they will take to screen and immunize them.
- e. Enter the Mother/Infant case contact report into the Perinatal Hepatitis B Module.

2. RECALL: Two weeks after getting confirmation from a provider that the pregnant woman knows her status.

- a. Follow up with a telephone call to the pregnant woman. If you cannot reach her by telephone, send her a letter asking her to call you.
- b. Counsel the infected pregnant woman regarding:
 - i. How hepatitis B spreads and how to prevent spreading it.
 - ii. The need to screen household contacts and sexual partners for hepatitis B infection.
 - iii. The need for a 3-dose series of hepatitis B vaccine for at-risk household contacts and sexual partners.
 - iv. The need for sexual partners to get HBIG if the pregnant woman has an acute (short-term) infection.
 - v. The need for her infant to get HBIG and the first dose of hepatitis B vaccine within 12 hours of birth and two additional doses of hepatitis B vaccine at 1-2 months of age, and 6 months of age.
 - vi. The need to test her infant at 9-18 months of age to make sure the baby has protection and no infection.
 - vii. The need to get medical follow-ups for the pregnant woman and family members who may be HBV carriers.
- c. Confirm which hospital the pregnant woman 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.
- d. Tell the pregnant woman that you will follow-up with her until her infant gets all three doses of vaccine and has had post-vaccination testing.
- e. Find the name, address, and telephone number of the pediatric care provider. Encourage the pregnant woman to choose a provider before she delivers her baby.
- f. Record the pregnant woman's race, ethnicity, and insurance.
- g. Record the names, birth dates, race, health care providers, screening and immunization status, or the plan for screening and immunization, of the pregnant woman's household contacts and sexual partners.
- h. Follow-up with the pregnant woman's at-risk household contacts and sexual partners. Work with the pregnant woman, contacts, partners, and health care providers to make sure they get screened and immunized.
- i. Send a letter to the pregnant woman explaining the Perinatal Hepatitis B Prevention Program to introduce yourself and include written educational materials.
- j. Enter a Household Contact case report into the Perinatal Hepatitis B Module (see module section for details).

3. REMINDER: Four weeks prior to the woman's estimated due date (also known as EDC) and if the pregnant woman tested HBsAg-positive before delivery.

- a. Send a letter to the obstetrical (OB) nurse manager, infection control nurse, or designated staff at the hospital with DOH Guidelines for Hospitals and a packet of written educational materials.
- b. Ask the OB nurse manager, infection control nurse, or designated staff to report when the baby is born, with the following information:
 - i. Date of birth
 - ii. Name
 - iii. Gender
 - iv. Health care provider information
 - v. HBIG and date hepatitis vaccine dose #1 given
 - vi. Pregnant woman's insurance or source of payment
- c. Contact the pediatric care provider (when you have this information) to confirm that he or she knows of the pregnant woman's HBsAg status, the infant's need for hepatitis B 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

- a. If you have not received notification of the infant's birth within two weeks after delivery, contact the hospital nursery or medical records unit to get the status of the infant.
- b. 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 list in 3b above) and enter the Mother/Infant case contact report into the Perinatal Hepatitis B Module.
 - i. When reporting past cases: If the mother's HBsAg status was known to be positive at the time of delivery, enter into the Perinatal Hepatitis B Module. If the mother's HBsAg status was unknown at the time of delivery, enter the "case" as a household contact into the Household Contact case report in the Perinatal Hepatitis B Module.
- c. Send a reminder card or letter to the mother when her baby should get Dose #2 of hepatitis B vaccine.
- d. Send a reminder card or letter to the pediatric care provider about the baby's need for a second dose of hepatitis B vaccine.
- e. 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

- a. Contact pediatric care provider to find out if the baby came in for his or her appointment. If yes, record the date of vaccination, vaccine brand, and payment source.
- b. Enter second hepatitis B dose information into the Infant report of the Perinatal Hepatitis B Module.

- c. Determine the date the baby should get the third dose of vaccine. Send a reminder card or letter to the provider about the importance of the baby getting the third dose of hepatitis B vaccine at six months of age.

6. REMINDER: Two weeks before the third dose is due

- a. Send a reminder card or letter to the mother for her baby's third dose of hepatitis B vaccine.
- b. Send a reminder card or letter to the pediatric care provider about the baby's need for the third dose of hepatitis B vaccine.

7. RECALL: One week after appointment for third dose

- a. Contact the pediatric care provider to find out if the baby came to his or her appointment. If yes, record the date of vaccination, vaccine brand, and payment source
- b. Enter third dose information into the Mother/Infant screen of the Perinatal Hepatitis B Module.
- c. Send a reminder card or letter to the pediatric care provider about the recommendation that the baby be screened for HBsAg and anti-HBs at 9-18 months of age.
- d. Determine the date the baby should get post-vaccination tested.
- e. Call the mother about her baby's need to get a post-vaccination test at 9-18 months of age.

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

- a. Send a reminder card or letter to the mother about her baby's post-vaccination test.
- b. Send a reminder card or letter to the pediatric care provider about the baby's post-vaccination test.

9. RECALL: A week after post-vaccination test appointment

- a. 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.
- b. Enter screening information into the Mother/Infant case report of the Perinatal Hepatitis B Module.
- c. If a post-vaccination test was not given, follow-up with the provider and document the reasons why it was not given.

Reporting HBsAg-Positive Babies

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

First, you must check the success of hepatitis B vaccination by making sure these babies get a blood test after their vaccination. Complete the testing at 9–18 months of age, generally at the next routinely scheduled well-child visit for the high- risk infant.

Second, you must report all HBsAg-positive children as acute hepatitis B cases. Unlike acute hepatitis B reporting for older children or adults, you must report perinatal hepatitis B cases even if the baby has no symptoms (see the CDC case definition at www.cdc.gov/ncphi/diss/nndss/casedef/hepatitisb2000.htm). **Remember:** when we prevent the spread of perinatal hepatitis B, we 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.
2. Relay information about HBSAg-positive babies to the communicable disease surveillance team of his or her local health jurisdiction. The surveillance team, in turn, reports it to the agency's Immunization Program CHILD Profile (360-236-3698) and Communicable Disease Epidemiology Program (1-877-539-4344 or 206-418-5500).

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

- Not all babies become fully immune after vaccination. The Centers for Disease Control and Prevention (CDC) estimates about five percent of vaccinated babies will not develop full immunity after getting three doses of hepatitis B vaccine. These babies need more follow up, either re-vaccination or medical management of their infection.
- Vaccinated babies may still get infected. Up to 6 percent of babies born to HBsAg-positive women may still become infected even after getting proper post-exposure prevention. These babies need more follow up, either re-vaccination or medical management of their infection.
- State health departments report perinatal HBV infection weekly to CDC as one of more than 50 nationally notifiable conditions.

Closing Cases

To close your open hepatitis B cases and complete reports, use the online Perinatal Hepatitis B Module. The User Guide can help answer questions. Access the Module and the User Guide from the Department of Health Immunization Program CHILD Profile website at www.doh.wa.gov/cfh/immunize/diseases/hepatitis_b/hep-b-module.htm or directly here:

- Perinatal Hepatitis B Module: <https://fortress.wa.gov/doh/cpir/webhepb/welcome.jsp>.
- User Guide: www.doh.wa.gov/cfh/immunize/documents/hepbmoduserguide.pdf

If you can't access the Module, download copies of the forms, fill them out by hand, and fax them to the Immunization Program CHILD Profile (IPCP) at 360-236-3590. Download from www.doh.wa.gov/cfh/immunize/diseases/hepatitis_b/hep-b-peri-pubs.htm or directly here:

- Household Contact: www.doh.wa.gov/cfh/immunize/documents/348-035.pdf
- Mother/Infant: www.doh.wa.gov/cfh/immunize/documents/348-030.pdf

Protocol for Perinatal Hepatitis B Infection

Follow this protocol to close or “complete” your hepatitis B infection cases when you have completed your tasks or when a situation makes further communication impossible or not applicable. Below are examples for closing or “completing” mother, household contacts, sexual partners, and baby cases in the Perinatal Hepatitis B Module.

For mothers, close or complete the case if you find that:

1. Mother has moved.
 - a. Be sure to notify Department of Health Immunization Program CHILD Profile (IPCP) staff of any county, state, or country move by the mother.
 - i. If mother has moved to another county within Washington State, contact IPCP staff about the move and make a note in the Perinatal Hepatitis B Module of mother's 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.
 - ii. If mother has moved to another state or country, contact IPCP staff about the move so IPCP can notify the mother's new state or country of residence. Document the mother's move on the Notes section of the Module or the case report form.
2. Mother has a false positive HBsAg result.
3. Mother can't be located.
4. Mother's pregnancy ended.
5. Mother refuses follow-up.
6. Mother delivered her baby and the baby was adopted or referred to Child Protective Services (CPS).
7. Mother's baby died.

For household contacts or sexual partners, close or complete the case if you find that:

1. Contact or partner has moved:
 - a. Be sure to notify Department of Health Immunization Program CHILD Profile (IPCP) staff of any county, state, or country move by the contact or partner.
 - i. If contact or partner has moved to another county within Washington State, contact IPCP staff about the move and make a note in the Perinatal Hepatitis B Module of contact's or partner's 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.
 - ii. If contact or partner has moved to another state or country, contact IPCP staff about the move so IPCP can notify the contact's or partner's new state or country of residence. Document the contact's or partner's move on the Notes section of the Module or the case report form.
2. Contact or partner can't be located.
3. Contact or partner refuses follow-up.
4. Contact or partner was screened and immunized properly.
5. Contact or partner died.

For babies, close or complete the case if you find that:

1. Baby has moved:
 - a. Be sure to notify Department of Health Immunization Program CHILD Profile (IPCP) staff of any county, state, or country move by the contact or partner.
 - i. If baby has moved to another county within Washington State, contact IPCP staff about the move and make a note in the Perinatal Hepatitis B Module of baby's new address so he or 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.
 - ii. If baby has moved to another state or country, contact IPCP staff about the move so IPCP can notify the baby's new state or country of residence. Document the baby's move on the Notes section of the Module or the case report form.
2. Baby can't be located.
3. Baby's information was never on file.
4. Baby's mother refuses follow-up for baby.
5. Baby completed proper prevention (got three doses of hepatitis B vaccine and post-vaccination screening and results sent by pediatric care provider).
6. Baby died.

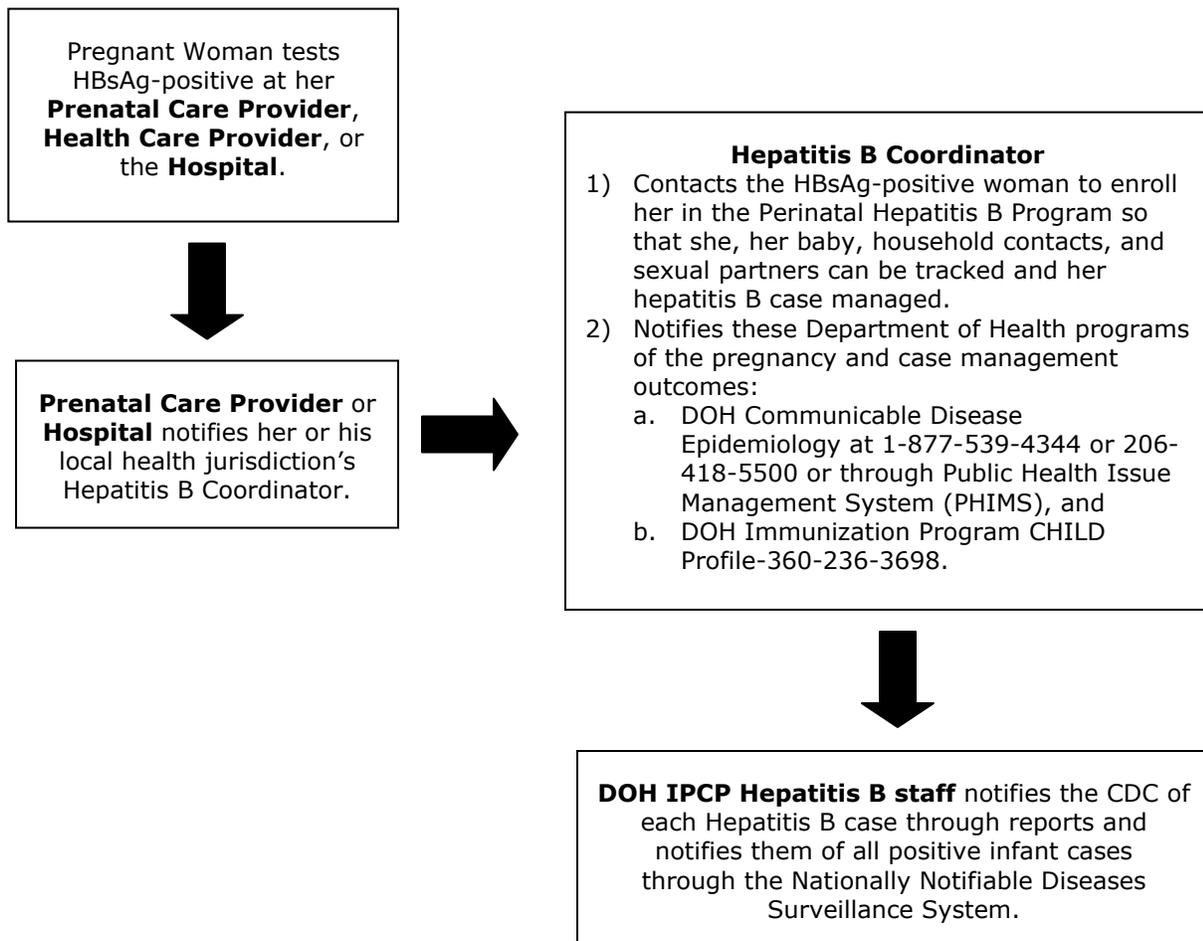
Required Notification

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.**
2. Notification to the Washington State Department of Health: **by every local health jurisdiction.**
3. Notification to the Centers for Disease Control and Prevention (CDC): **by the Washington State Department of Health, Immunization Program CHILD Profile (ICP).**

We consider **EACH** pregnancy in any HBsAg positive woman a notifiable condition in Washington State. 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. Health care providers notify the Hepatitis B Coordinator at his or her local health jurisdiction of the 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. As a nationally notifiable condition, ICPP notifies the CDC weekly about all perinatal Hepatitis B cases.



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. Health care providers must report this status to local health jurisdictions within three working days, according to state law (see Washington Administrative Code (WAC) 246-101-101).

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;
 - Mother's sexual partner(s) get referred to a specialist for follow-up;
 - Babies get hepatitis B immune globulin (HBIG) and hepatitis B vaccine Dose #1 at birth, Dose #2 at 1-2 months of age, and Dose #3 at 6 months of age;
 - Babies get post-vaccination testing (HBsAg and anti-HBs) at 9-18 months of age (1-2 months after the third dose of hepatitis B vaccine) to check for infection and immune status; and,
 - Household contacts and sexual partners get pre-vaccination testing and immunization with hepatitis B vaccine, if at risk.

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 her baby's birth so that the baby gets proper treatment.

Reporting Requirements?

Health care providers who request the HBsAg test during prenatal care or at the time of delivery must report all HBsAg-positive pregnant women to the provider's local health jurisdiction.

More Information

These resources may be helpful for you when reporting:

- **Reporting Matrix**
English only www.doh.wa.gov/cfh/Hepatitis/docs/rptmatrix.pdf
- **Reporting LHJ Contact List**
English only www.doh.wa.gov/notify/other/lhjcontacts.pdf
- **Notifiable Conditions**
English only www.doh.wa.gov/notify/other/providerposter.pdf

If you have other questions, please contact your local health jurisdiction or the Washington State Department of Health Immunization Program CHILD Profile at 360-236-3698.

Vaccine Specifics:

Administering Vaccine for Preventing Hepatitis B

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 sites.

Dose and Schedule

You can use different brands of vaccine for the three hepatitis B doses.

- Babies born to HBsAg-positive mothers should get 0.5 ml of Hepatitis B Immune Globulin (HBIG) **within 12 hours of birth** and hepatitis B vaccine Dose #1 (Engerix-B 10mcg/0.5ml or Recombivax 5mcg/0.5ml) at the same time but at a different site.
- Give Dose #2 (Engerix-B 10mcg/0.5ml or Recombivax 5mcg/0.5ml) at 1-2 months of age.
- Give Dose #3 (Engerix-B 10mcg/0.5ml or Recombivax 5mcg/0.5ml) at 6 months of age.

Vaccination of Premature Babies

- A premature infant born to **HBsAg-positive mothers** and mothers with unknown status must get HBIG AND hepatitis B vaccine less than 12 hours after birth. If these babies weigh <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. (Redbook, 2009 Report of the Committee on Infectious Diseases, 2009; and MMWR, 2005)
- Premature babies born to **HBsAg-negative mothers**, regardless of birth weight, should get vaccinated at the same chronological age and according to 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 (<2,000 grams) after getting hepatitis B vaccine at birth. However, we know that 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. (General Immunization Recommendations, update 2006)

Vaccine Specifics:

Recommended Doses of Currently Licensed Monovalent Hepatitis B Vaccines

Recombivax and Engerix-B vaccines have three doses in their series. Engerix-B also has a licensed for a four-dose series given at 0, 1, 2, and 12 months. Dialysis patients should get Engerix-B at 0, 1, 2, and 6 months.

Key:

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

Group	Merck Recombivax HB Dosage	GSK Engerix-B Dosage
Babies, ¹ children & adolescents (0–19 years of age)	5 mcg (0.5 mL)² Pediatric/Adolescent Formulation YELLOW Top Vial	10 mcg (0.5 mL)³ Pediatric Formulation OLIVE GREEN Top Vial
Adolescent (11–15 years of age) Merck (11–19 years of age) GSK A two dose series for adolescents (11-15) is also acceptable	10mcg (1.0) Adult Formulation GREEN Top Vial	10mcg (0.5 mL) OLIVE GREEN Top Vial
Adults (20 years of age & older)	10 mcg (1.0 mL) Adult Formulation GREEN Top Vial	20 mcg (1.0 mL) Adult Formulation ORANGE Top Vial
Predialysis and Dialysis patients	40 mcg (1.0 mL) Dialysis Formulation BLUE Top Vial	40 mcg (2.0 mL) (Two 20 mcg doses) Adult Formulation ORANGE Top Vial

Sources:

- MMWR, Centers for Disease Control, December 23, 2005/Vol. 54/No. RR-16: www.cdc.gov/mmwr/PDF/rr/rr5416.pdf
- Recombivax HB package insert, December 2010.
- Engerix B package insert, December 2010.

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

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 site.

For other exposed persons, the dose of HBIG is 0.06 ml/kg of body weight. To calculate the dose:

- Convert body weight to kilograms (kg)
- Multiply the number of kilograms by 0.06 ml/kg

For example, if the person weighs 110 lbs, the number of kilograms = $110 \text{ lbs} \div 2.2$ (number of pounds per kilogram) = 50.0 kg. The correct dose of HBIG is $50.0 \text{ kg} \times 0.06 \text{ ml/kg}$ or 3.0 ml.

HBIG Dosage at a Glance

Use the following table to identify dosage based on weight.

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

Dose = 0.06 ml x 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.

Shipping Requirements:	Use insulated container. Must ship with refrigerant.
Condition on Arrival:	Should not have been frozen. Refrigerate on arrival.
Storage Requirements:	Refrigerate immediately upon arrival. Store at 2°-8°C (35°-46°F). Do not freeze.
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 Reconstitution 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

1. 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.
2. Do not use outdated vaccine.
3. Never store vaccine in refrigerator door.
4. When transporting vaccine, always use an insulated container with ice packs.

Vaccine Specifics: Ages and Intervals⁴

The table below shows the vaccine dose of particular vaccines, with recommended ages, intervals, and minimum ages for getting the vaccines.

Vaccine & dose number	Recommended age for this dose	Minimum age for this dose	Recommended interval to next dose	Minimum interval to next dose
Hepatitis B1 ⁵	Birth—2 months	Birth	1—4 months	4 weeks
Hepatitis B2	1—4 months	4 weeks	2—17 months	8 weeks
Hepatitis B3 ⁶	6—18 months	6 months ⁷	--	--

Source:

- MMWR, Centers for Disease Control, December 23, 2005/Vol. 54/No. RR-16: www.cdc.gov/mmwr/PDF/rr/rr5416.pdf

⁴ Combination vaccines are available. Using licensed combination vaccines is preferred over separate injections of their equivalent component vaccines. (Source: CDC Combination vaccines for childhood immunization; recommendations of the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP). MMWR 1999;48 [No. RR-5:5]. When administering combination vaccines, the minimum age for administration is the oldest age for any of the individual components; the minimum interval between doses is equal to the greatest interval of any of the individual antigens.

⁵ A combination hepatitis B-Hib vaccine is available (Comvax®, manufactured by Merck Vaccine Division). This vaccine should not be administered to infants aged <6 weeks because the Hib component.

⁶ Hepatitis B3 should be administered ≥8 weeks after Hepatitis B2 and 16 weeks after Hepatitis B1, and it should not be administered before age 24 weeks (164 days). This applies to all infants, regardless of mothers HBsAg status.

⁷ Calendar months.

Laboratory Screening: Guidelines

The following information identifies which screening test(s) should be ordered for pregnant women and babies.

HBsAg: Pregnant Women

A positive HBsAg screening test identifies HBV-infected pregnant women. Babies born to HBsAg-positive pregnant women are at high risk of infection unless they receive the proper post-exposure prevention. To prevent perinatal spread of hepatitis B, you do not need to know if the woman has acute or chronic HBV infection. However, HBsAg-positive women identified during screening may have HBV-related liver disease and should be evaluated for this chronic condition.

In certain cases, HBsAg tests may be reported inconclusively as “indeterminate,” “borderline,” or “weakly positive.” Check with the lab to make sure that 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.

HBsAg and Anti-HBs: Babies (3-9 months after Dose #3)

For babies born to HBsAg-positive mothers, blood (or serologic) testing after proper post-exposure prevention shows if the baby is infected with or fully protected against HBV. If the baby is on schedule with hepatitis B doses, testing should happen 3-9 months after Dose #3. 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 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 identifies antibody to Hepatitis B Surface Antigen, which is a marker of immunity. 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 that the individual does not need vaccine.
- 5) A positive anti-HBc alone indicates that the individual should be referred to his or her health care provider for further evaluation.

Sources:

- MMWR, Centers for Disease Control, December 23, 2005/Vol. 54/No. RR-16, page 4: www.cdc.gov/mmwr/PDF/rr/rr5416.pdf
- Department of Health and Human Services, Centers for Disease Control, May 2009 11th Edition, Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book), pages 101-103.

Laboratory Screening:

Free Blood Testing at Public Health-Seattle & King County Laboratory

Local health jurisdictions (LHJs) can get free laboratory testing for the prevention of perinatal hepatitis B **if** the blood is drawn by the LHJ **and** sent to Public Health – Seattle & King County Laboratory. The Immunization Program CHILD Profile (IPCP) will pay the costs of lab testing for the following groups:

1. Pregnant women **if** they do not have Medicaid or insurance that will cover the cost of testing.
2. Babies born to HBsAg-positive mothers **if** the babies do not have Medicaid or insurance that will cover the cost of *post-vaccination testing*.
3. Household contacts and sexual partners of HBsAg-positive pregnant women **if** the contacts/partners do not have Medicaid or insurance that will cover the cost of *pre-vaccination testing*.
4. Sexual partners of HBsAg-positive pregnant women **if** the partners do not have Medicaid or insurance that will cover the cost of *post-vaccination testing*.

Laboratory Screening:

Submitting Blood Samples to Public Health-Seattle & King County Laboratory

For people whose hepatitis B testing will be paid by the Immunization Program CHILD Profile (IPCP), follow this procedure when submitting their blood samples. See “Free Blood Testing” for information on which individuals can use this free testing.

1. Ship one **red-top tube or 2-3 ml of serum** in a standard leak-proof, screw cap tube or vial.
 - a. Place the vial in a primary container with sufficient absorbent material surrounding the vial to prevent the contents from escaping should leakage occur during shipment.
 - b. Place the primary container in a leak-proof plastic bag and insert it into the outer shipping package.
 - c. Include a Public Health – Seattle & King County Laboratory form. This form **must** be sent with each blood sample. Find at www.kingcounty.gov/healthservices/health/communicable/lab.aspx
 - d. Mark the outer shipping package, “Clinical Specimen.”
2. When filling out a Public Health – Seattle & King County Laboratory form, remember:
 - a. The appropriate box under **Perinatal Hepatitis B section** of the form must be marked to ensure payment for the testing by the IPCP
 - b. Mark the correct tests for the blood sample. See “Laboratory Screening Guidelines” for information on which test(s) to order.
3. Send blood samples directly to:
Public Health – Seattle & King County Laboratory
325 - 9th Avenue, Room BWC03
Box 359973
Seattle, WA 98104-2499
4. Order lab forms and mailing containers from Public Health-Seattle & King County Laboratory by calling **206-744-8950** or going to www.kingcounty.gov/healthservices/health/communicable/lab.aspx

Laboratory Screening: Serologic Markers

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

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

Source:

- Immunization Action Coalition, www.immunize.org/askexperts/experts_hepb.asp

Laboratory Screening: Interpreting Test Results

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

Tests	Results	Interpretation	Vaccinate?
HBsAg anti-HBc anti-HBs	negative negative negative	Susceptible	Vaccinate if indicated
HBsAg anti-HBc anti-HBs	negative negative positive with $\geq 10\text{mIU/mL}$ ⁸	Immune due to vaccination	No vaccination necessary
HBsAg anti-HBc anti-HBs	negative positive positive	Immune due to natural infection	No vaccination necessary
HBsAg anti-HBc IgM anti-HBc anti-HBs	positive positive positive negative	Acutely infected	No vaccination necessary
HBsAg anti-HBc IgM anti-HBc anti-HBs	positive positive negative negative	Chronically infected	No vaccination necessary (may need treatment)
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, www.immunize.org/askexperts/experts_hepb.asp

⁸ 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 9-18 months – typically at the next well-child visit.

References and Resources

References for this Hepatitis B Prevention Program Guidelines Manual and Helpful Resources for Local Health Jurisdiction Staff

Manual References

- CDC Perinatal Hepatitis B Prevention Program Case Transfer Form
www.cdc.gov/hepatitis/Partners/Perinatal/docs/CDC_Case_Transfer_Form.doc
- CDC Hepatitis B Vaccine: What You Need to Know – Vaccine Information Sheet (VIS) www.cdc.gov/vaccines/pubs/vis/downloads/vis-hep-b.pdf
- Hepatitis B Facts: Testing and Vaccination www.immunize.org/catg.d/p2110.pdf
- MMWR (Morbidity and Mortality Weekly Report) Recommendations and Reports – *A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP) Dec. 23, 2005*
www.cdc.gov/mmwr/PDF/rr/rr5416.pdf
- MMWR (Morbidity and Mortality Weekly Report) Recommendations and Reports – *Recommendations for Identification and Public Health Management of Persons with Chronic Hepatitis B Virus Infection* www.cdc.gov/mmWR/PDF/rr/rr5708.pdf
Sept. 19, 2008
- WAC 246-101-101 Notifiable Conditions and the Health Care Provider:
<http://apps.leg.wa.gov/WAC/default.aspx?cite=246-101-101>

LHJ Resources

- Sample Letters www.doh.wa.gov/cfh/immunize/forms#hepb-sample-letters
 - Before Baby is Born
 - After Baby is Born
 - Completion of Serology (Blood) Testing
- Local Health Jurisdiction Perinatal Hepatitis B Coordinators List:
www.doh.wa.gov/cfh/Immunize/document/perihepbcoord.pdf
- Stickers for medical charts:
 - Prenatal stickers: Reporting HBsAg-positive Mothers Required (www.doh.wa.gov/cfh/Immunize/documents/reportingmother.doc)
Print stickers on Avery mailing labels 5163 to flag prenatal medical charts of HBsAg-positive pregnant women. Print in color.
 - Hospital Sticker: ALERT: Give HBIG and Hep B Vaccine (www.doh.wa.gov/cfh/Immunize/documents/hepbalertbaby.doc)
Print stickers on Avery mailing labels 5163 to flag hospital medical charts of babies born to HBsAg-positive mothers. Print in color.
 - Pediatric Sticker: This baby requires hepatitis B immunization (www.doh.wa.gov/cfh/Immunize/documents/hepbthisbaby.doc)

Print stickers on Avery mailing labels 5163 to flag pediatric medical charts of babies born to HBsAg-positive mothers. Print in color.

- Order Hepatitis B Materials: www.doh.wa.gov/cfh/immunize/forms/default.htm
- WAC 246-101-101 Notifiable Conditions and the Health Care Provider: <http://apps.leg.wa.gov/WAC/default.aspx?cite=246-101-101>

If you have a disability and need this document in another format, please call 1-800-525-0127 (TDD/TTY 1-800-833-6388).