

Chapter 4: What Pediatric Care Providers Need to Know

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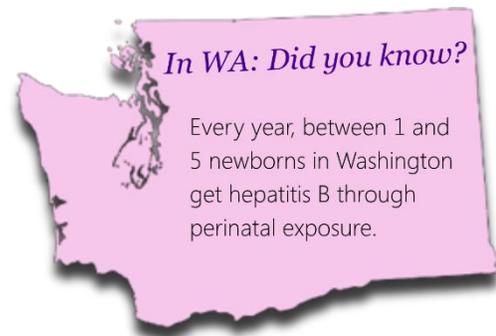
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Perinatal Hepatitis B Prevention Program: Goal and Objectives

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

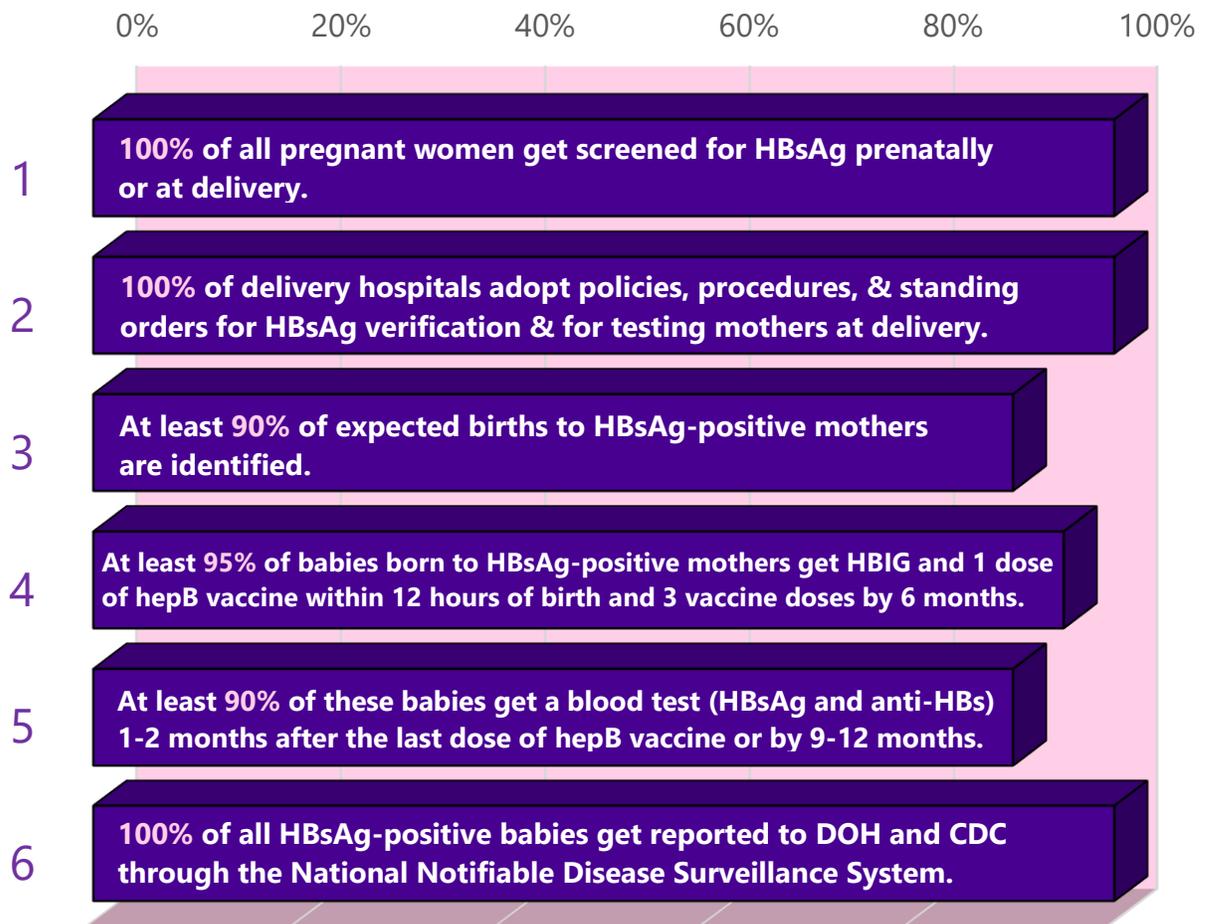
Washington State's Perinatal Hepatitis B Prevention Program (PHBPP) has an overall goal **to work with partners to assure coordination of activities to prevent perinatal hepatitis B transmission to newborns**. The program has several key elements.

- 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.
- 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



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

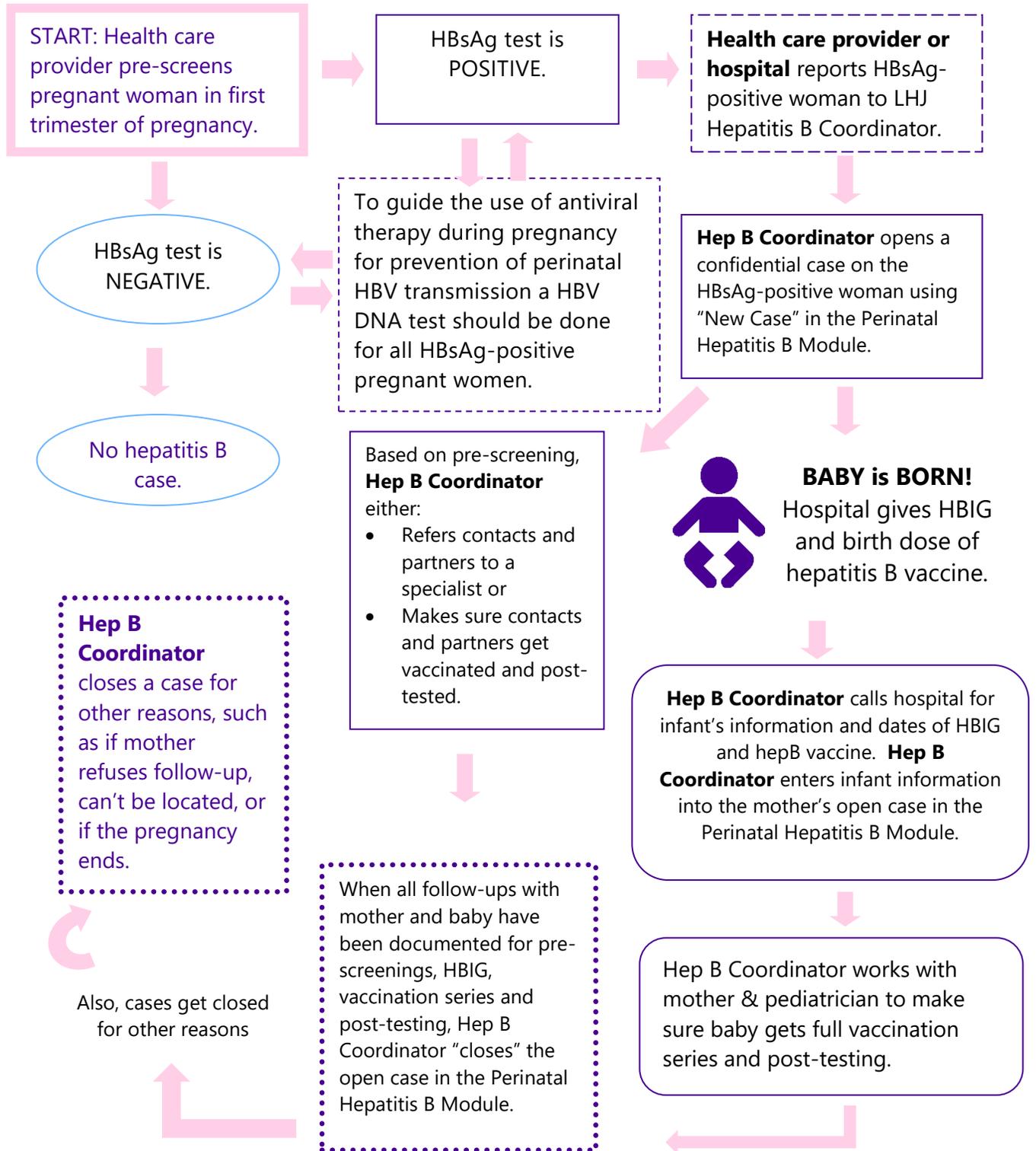
Complete post-vaccination screening for all infants born to HBsAg-positive mothers at 9 to 12 months of age. Educate the baby's parents about the importance of this screening and be sure to tell them the test will show if the infant has developed antibodies to, or has become infected with, HBV. To reduce 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.



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 hepatitis B 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](#)

Laboratory Screening: Interpreting Test Results

Use this table* 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 $\geq 10\text{mIU/mL}^{**}$	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

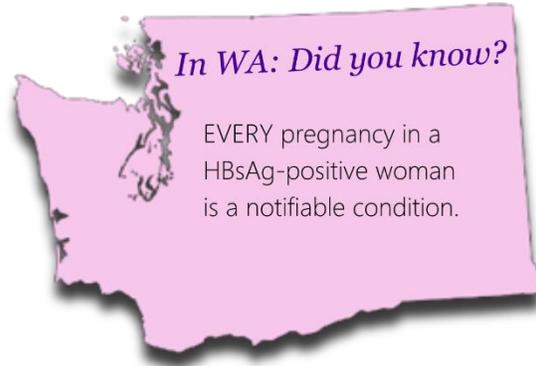
* Source: [Immunization Action Coalition](#)

** 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.

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.

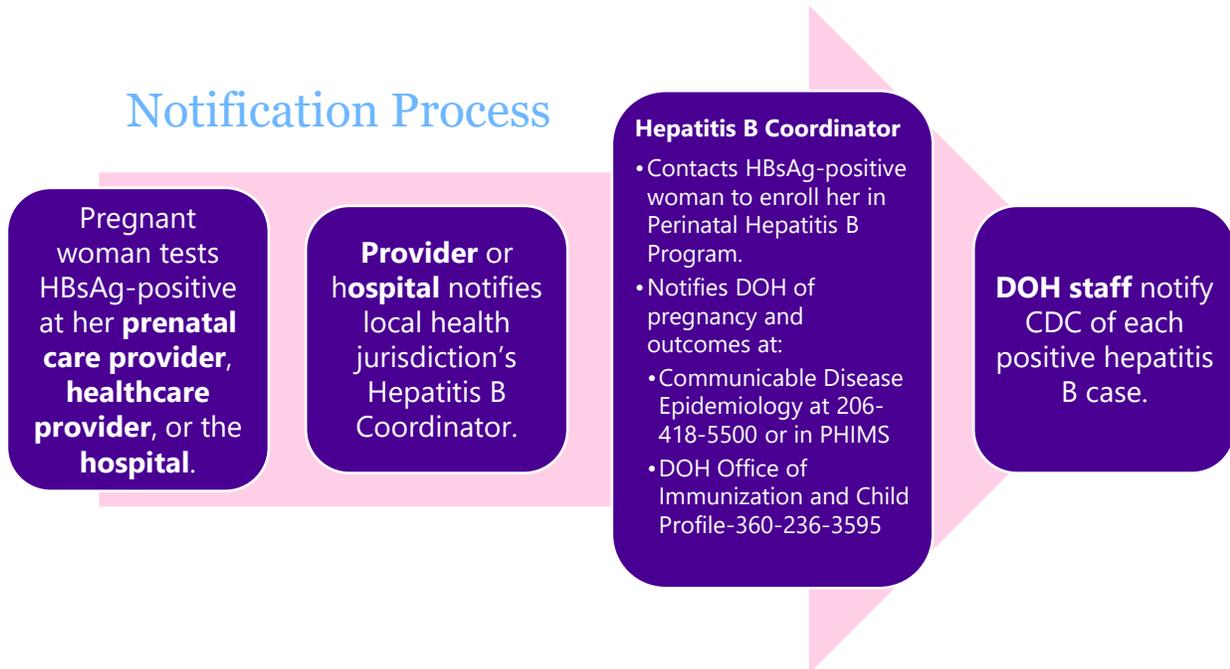
- 10. Notification to local health jurisdictions (LHJ): by **every prenatal health care provider or hospital**.
- 11. Notification to the Washington State Department of Health: by **every local health jurisdiction**.
- 12. Notification to the Centers for Disease Control and Prevention (CDC): by the Washington State Department of Health.



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.

Notification Process



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

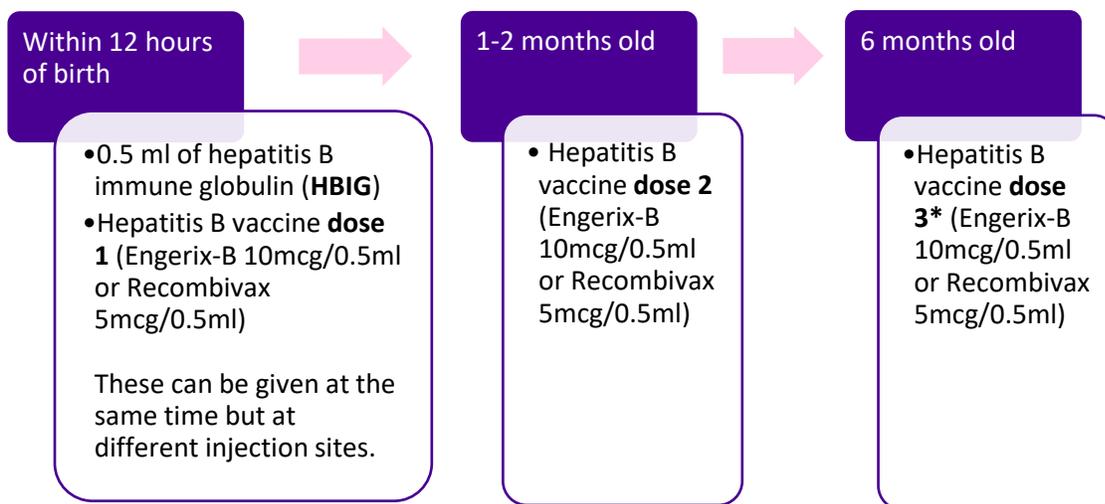
Route and Site

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.

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 cap and stripe on vial and cartons and orange banner on the vial labels and cartons stating “preservative free”	10 mcg (0.5 mL) ³ Pediatric formulation BLUE-top vial Single-dose vials and prefilled disposable TIP-LOK syringe
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 mL) Adult formulation GREEN cap and stripe vial and orange banner on vial label	10mcg (0.5 mL) OLIVE GREEN top vial
Adults (20 years & 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 cap and stripe vial with orange banner	40 mcg (2.0 mL) (Two 20 mcg doses) Adult formulation ORANGE-top vial

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.

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 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.

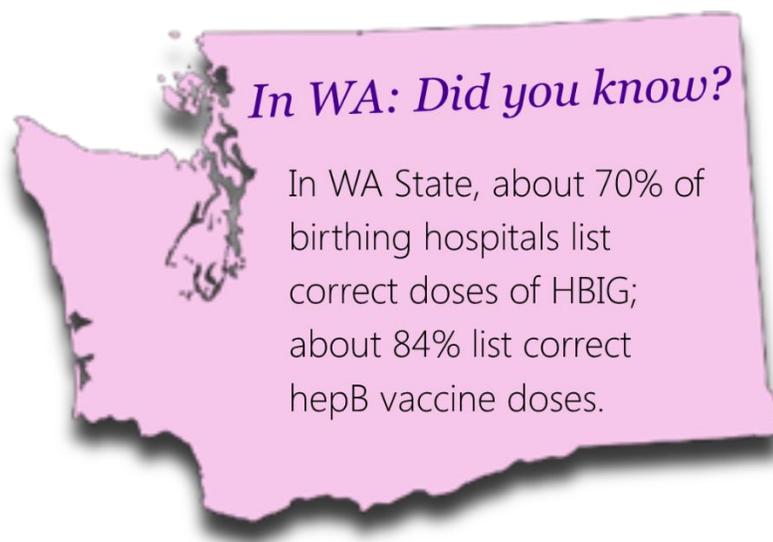
*Recommended and Minimum Ages and Intervals between Doses**

Vaccine and dose number	Recommended age for this dose	Minimum age for this dose	Recommended interval to next dose	Minimum interval to next dose
HepB-dose 1**	Birth	Birth	1-4 months	4 weeks
HepB-dose 2	1-2 months	4 weeks	2-17 months	8 weeks
HepB-dose 3***	6- months	24 weeks	—	—

* 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.



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](#)
- MMWR (Morbidity and Mortality Weekly Report) Recommendations and Reports – [Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices](#)
- MMWR (Morbidity and Mortality Weekly Report) Recommendations and Reports – [Recommendations for Identification and Public Health Management of Persons with Chronic Hepatitis B Virus Infection](#)
- 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)