

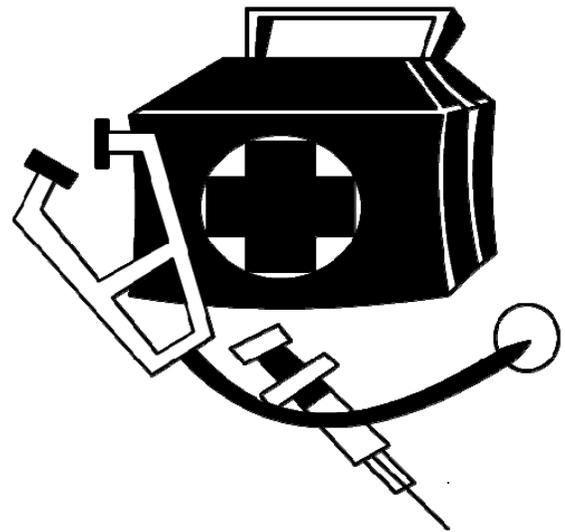
Perinatal Hepatitis B Prevention Program Guidelines

Chapter 3: What Hospitals Need to Know

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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 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 carriers of HBV (or chemically 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.

Hospital Tasks Overview

The following four strategies help guide hospitals to maximize their perinatal hepatitis B prevention work.

1. Develop and follow a written policy and procedure to screen **every** pregnant woman for HBsAg who has an unknown hepatitis B status and all who have risk for HBV infection during pregnancy. Women with unknown status include those with no prenatal care or who did not get tested by their health care provider. 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.

The written policy should include the following procedures for each stage of the hospital stay for women delivering babies. We list these stages as:

- Admission for Delivery
- After Delivery
- Standing Orders
- Infant Discharge

Admission for Delivery:

- Review hepatitis B surface antigen (HBsAg) status of all pregnant women.
- Record maternal HBsAg 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:

- Give HBIG and Dose #1 of hepatitis B vaccine to infants of all HBsAg-positive pregnant women, **within 12 hours of birth**.
- If the mom's HBsAg test result has not returned at the time of delivery, give Dose #1 of hepatitis B vaccine within 12 hours following birth. If the test result comes back later but before she leaves the hospital (gets discharged) and is positive, give HBIG to the infant as soon as possible.
- If the result comes back after she has left the hospital (after discharge) and is positive, notify the pediatric health care provider that the infant needs to get HBIG within three days of birth and that the mother and her household and sexual contacts need medical follow-up.
- Document the mother's HBsAg-positive status and immunization of the infant with HBIG and Dose #1 of hepatitis B vaccine at the hospital and **give this information to the pediatric care provider**.

Standing Orders:

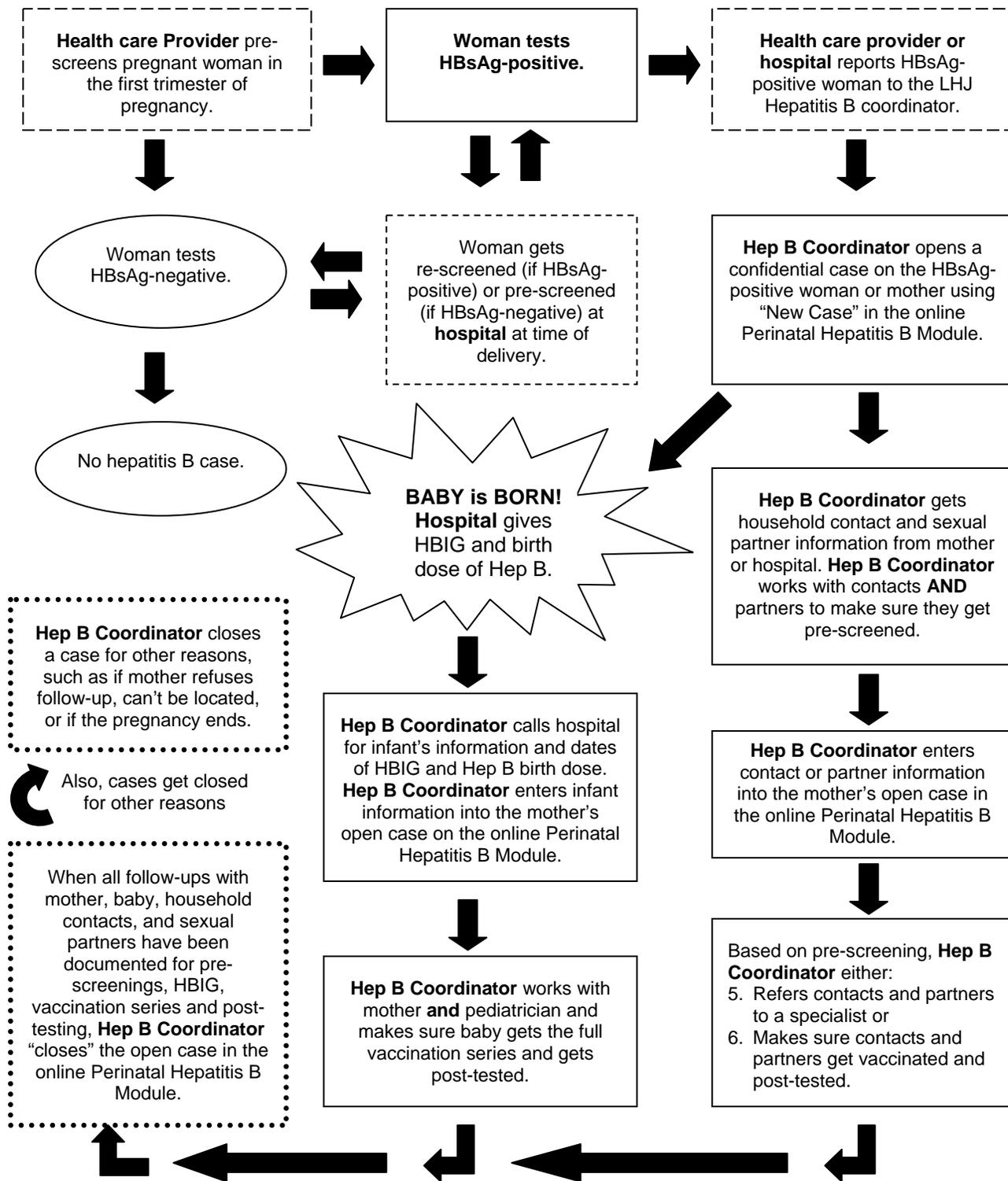
- For all pregnant women, review HBsAg test results when admitted for delivery. Make sure all mothers have been tested for HBsAg prenatally or at the time of admission for delivery. Document the test results if they are not already recorded.
- For women who do not have an HBsAg test result, do HBsAg testing as soon as possible after admission for delivery.
- Premature infants weighing <2000 grams need a single dose of hepatitis B vaccine. This dose should not be counted as part of the vaccine series. Three more doses should be given starting when the infant reaches age one month.
- Identify and manage all infants born to HBsAg-positive mothers.
- Identify and manage all infants born to mothers with unknown HBsAg status.
- 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.

At 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. For all delivery hospitals: Enroll in the federally funded Vaccines for Children Program (VFC) 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. **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 the mother's household contacts and sexual partners. **Remember that 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.
 4. Counsel and provide information to **every** HBsAg-positive pregnant woman or who has just delivered 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 9-18 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, 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

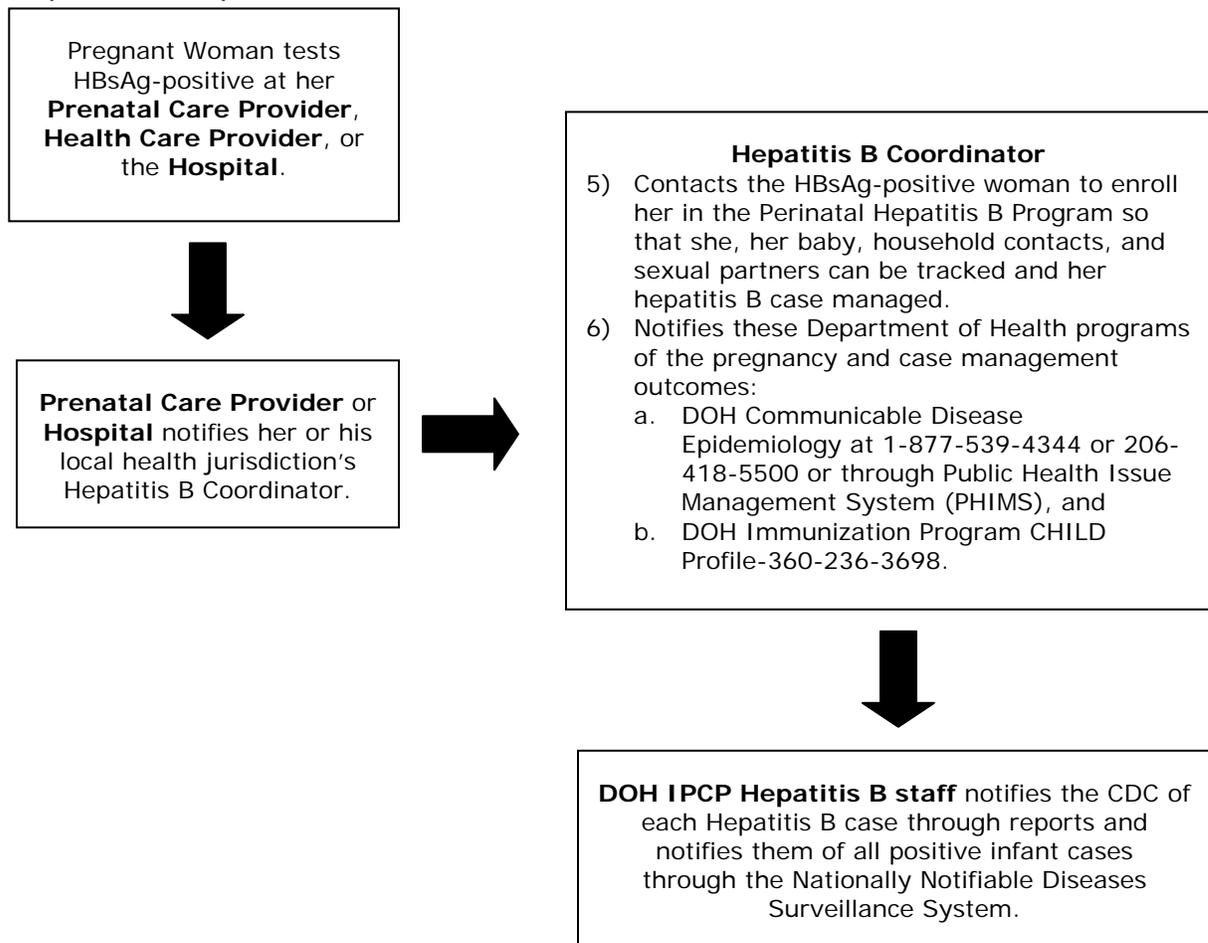
Required Notification

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 (IPCP).**

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 DOH programs.
3. As a nationally notifiable condition, IPCP 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.
 - 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 his or her 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 2005)

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, ¹⁶ children & adolescents (0–19 years of age)	5 mcg (0.5 mL)¹⁷ Pediatric/Adolescent Formulation YELLOW Top Vial	10 mcg (0.5 mL)¹⁸ 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.

¹⁶ 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.

¹⁷ 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."

¹⁸ 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 that 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 Intervals¹⁹

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 ²⁰	Birth—2 months	Birth	1—4 months	4 weeks
Hepatitis B2	1—4 months	4 weeks	2—17 months	8 weeks
Hepatitis B3 ²¹	6—18 months	6 months ²²	--	--

Source:

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

¹⁹ 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.

²⁰ 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.

²¹ 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.

²² Calendar months.

References and Hospital Resources

References for this Hepatitis B Prevention Program Guidelines Manual and Helpful Resources for Hospitals

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), 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, 2008*
www.cdc.gov/mmWR/PDF/rr/rr5708.pdf
- WAC 246-101-101 Notifiable Conditions and the Health Care Provider:
<http://apps.leg.wa.gov/WAC/default.aspx?cite=246-101-101>

Hospital Resources

- Give the Birth Dose www.immunize.org/catg.d/p2125.pdf
- Medical Errors www.immunize.org/catg.d/p2128.pdf
- Admission Orders for Labor & Delivery and Newborn Units to Prevent Hepatitis B Virus Transmission www.immunize.org/catg.d/p2130.pdf
- Sample Text for Admission Orders for Hepatitis B Vaccine Birth Dose in Newborn Nursery www.immunize.org/catg.d/p2131.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

- Pregnancy and Chronic Hepatitis B
www.hepb.org/learnguide/print/print.html#a21

- WAC 246-101-101 Notifiable Conditions and the Health Care Provider:
<http://apps.leg.wa.gov/WAC/default.aspx?cite=246-101-101>