PERINATAL HEPATITIS B PREVENTION PROGRAM GUIDELINES

January 2015

Table of Contents

Addendums

UTAH DEPARTMENT OF HEALTH
PERINATAL HEPATITIS B PREVENTION PROGRAM

INTRODUCTION

In 2009,* about 24,000 infants were born to hepatitis B infected mothers across the United States, yet less than half of these infants were identified and treated. Without immunoprophylaxis (vaccine and hepatitis B immuno globulin [HBIG]), approximately 9,000 infants would become chronically infected, and approximately 2,300 would die from chronic liver disease. Thanks to the dedicated efforts of public health professionals in Utah, immunoprophylaxis has increased. In 2009,* approximately 94% of infants born to mothers known to be infected with hepatitis B received hepatitis B vaccine and HBIG within 12 hours of birth. Between 101 and 147 births to hepatitis B surface antigen (HBsAg) positive women in Utah were expected in 2009,* and 105 were identified and case managed. Currently, the majority of perinatal case mothers identified in Utah were born in endemic regions outside the U.S., or are among Asian and Pacific Island populations inside the U.S.

*The most current perinatal hepatitis B data and recommendations are from 2009.

MISSION & PURPOSE

The mission of the Perinatal Hepatitis B Prevention Program is to increase identification and case management of HBsAg positive women, their infants, and sexual and household contacts.

The purpose of Perinatal Hepatitis B Prevention Program is to prevent transmission of the hepatitis B virus (HBV) from infected mothers to their infants.

PERINATAL HEPATITS B PROGRAM GOALS

Ensure the following:

- All pregnant women are screened for HBsAg status during an early prenatal visit in each pregnancy.
- Infants born to HBsAg positive women receive the first dose of hepatitis B vaccine and HBIG within 12 hours of birth.
- Infants born to HBsAg positive mothers receive the remaining 2 doses of hepatitis B vaccine by 6-8 months of age.
- Infants born to HBsAg positive mothers receive post vaccination serological testing (HBsAg and hepatitis B surface antibody [HBsAb] status), with tests done 1- 2 months after 3rd dose of hepatitis B vaccine, at 9 months of age (minimum) or older.
- Identification, testing, and vaccination of household contacts.
- Timely reporting of cases by local health department case managers.
- Awareness of Perinatal Hepatitis B Prevention Program increased among both public and private providers.

CLINICAL FEATURES AND EPIDEMIOLOGY OF HEPATITIS B

Signs and Symptoms

Clinical signs and symptoms occur more often in adults than in infants or children, who usually have an asymptomatic acute course. However, approximately 50% of adults who have acute infections are asymptomatic. When symptoms occur in acute hepatitis B virus infection, they may occur in the following patterns.

- The *preicteric* or *prodromal phase* from initial symptoms to onset of jaundice usually lasts from 3 to 10 days. It is characterized by insidious onset of malaise, anorexia, nausea, vomiting, right upper quadrant abdominal pain fever, headache, myalgias, skin rashes, arthralgia and arthritis, and dark urine, beginning 1 to 2 days before the onset of jaundice.
- The *icteric phase* is variable, but usually lasts from 1 to 3 weeks, and is characterized by jaundice, light or gray stools, hepatic tenderness and hepatomegaly. Splenomegaly is less common.
- During c*onvalescence*, malaise and fatigue may persist for weeks or months, while jaundice, anorexia, and other symptoms disappear.

Modes of Transmission

Hepatitis B virus is found in blood and blood products, semen, vaginal secretions, and saliva. The virus is transmitted through one or more of the following modes.

- *Percutaneous Transmission* – Inoculation of infected blood or blood products, such as needle-stick injury, shared IV/IM needle use, ear or body piercing, tattooing, inadequate sterilization of medical equipment (contaminated needles and other sharps, such as broken glass contaminated with blood) and splashes to eyes, nose, or mouth.
- *Sexual Transmission* – Absorption of HBV into mucosal surfaces (sexual activity).
- *Perinatal Transmission* – Acquiring HBV from mother to infant.
- *Horizontal Transmission* – Occurs in such situations and settings as shared toothbrushes, razors and combs or passed child-to-child by biting

Incubation Period

Six weeks to six months, with an average of 120 days.

Period of Communicability

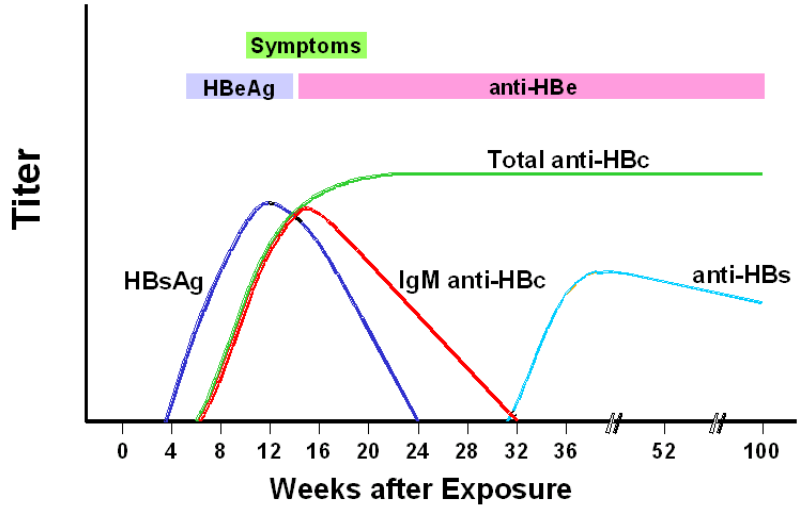
All persons who are HBsAg positive are considered to be infectious. The HBsAg may be present several weeks before the onset on illness and last for several weeks or years. If the chronic carrier state develops, patients will most likely remain HBsAg positive for their lifetime.

CHARACTERISTIC PATTERN OF SPECIFIC ANTIGEN AND ANTIBODIES

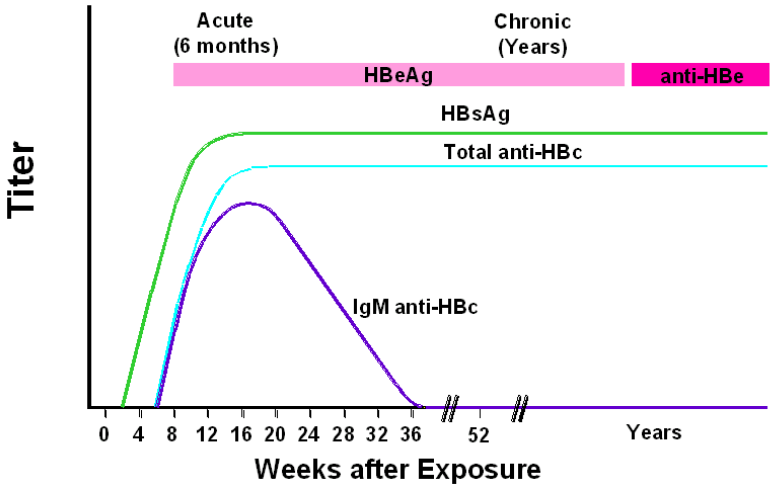
First the HBsAg and HBeAg become positive, about one to three weeks after exposure and four to five weeks before jaundice appears. The ALT levels increase about one to two weeks before jaundice. These elevations persist for one to three months and decrease as clinical improvement progresses. The appearance of anti-HBc and anti-HBe is a favorable prognostic sign. HbcAg, although present, is not detectable by any currently available practical test. However, anti-HBc is detectable at onset of jaundice, initially as IgM, indicating acute or early convalescent hepatitis B infection. Both anti-HBs and anti-HBc persist for many years. With chronic infection, HBsAg persists for many years and possibly a lifetime. HbeAg may persist as well; more likely if the infection was symptomatic. Chronic infection is more likely in cases symptoms were mild or absent than in cases with significant clinical disease.

TIME SEQUENCE OF SEROLOGIC MARKERS

Acute Hepatitis B Virus Infection with Recovery
Typical Serologic Course



Progression to Chronic Hepatitis B Virus Infection
Typical Serologic Course



LABORATORY TESTS FOR HEPATITIS B

Interpretation of Hepatitis B Serologic Test Results		
Tests	**Results**	**Interpretation**
HBsAg anti-HBc anti-HBs	negative negative negative	Susceptible
HBsAg anti-HBc anti-HBs	negative positive positive	Immune due to natural infection
HBsAg anti-HBc anti-HBs	negative negative positive	Immune due to Hepatitis B vaccination
HBsAg anti-HBc IgM anti-HBc anti-HBs	positive positive positive negative	Acutely infected
HBsAg anti-HBc IgM anti-HBc anti-HBs	positive positive negative negative	Chronically infected
HBsAg anti-HBc anti-HBs	negative positive negative	Interpretation unclear; four possibilities: 1. Resolved infection (most common) 2. False-positive anti-HBc, thus susceptible 3. "Low level" chronic infection 4. 4. Resolving acute infection
Hepatitis B surface antigen (HBsAg): A protein on the surface of HBV; it can be detected in high levels in serum during acute or chronic HBV infection. The presence of HBsAg indicates that the person is infectious. The body normally produces antibodies to HBsAg as part of the normal immune response to infection. HBsAg is the antigen used to make Hepatitis B vaccine. **Hepatitis B surface antibody (anti-HBs):** The presence of anti-HBs is generally interpreted as indicating recovery and immunity from HBV infection. Anti-HBs also develops in a person who has been successfully vaccinated against Hepatitis B. **Total Hepatitis B core antibody (anti-HBc):** Appears at the onset of symptoms in acute Hepatitis B and persists for life. The presence of anti-HBc indicates previous or ongoing infection with HBV in an undefined time frame. **IgM antibody to Hepatitis B core antigen (IgM anti-HBc):** Positivity indicates recent infection with HBV (≤6 months). Its presence indicates acute infection.		

HBsAg – most commonly used test for detecting carriers or diagnosing hepatitis B virus infections. HBsAg can be detected as early as one or two weeks.

Anti-HBc (Total) – includes both IgG and IgM, which indicates either current or past HBV infection at some undetermined time.

IgM anti-HBc – indicates recent infection with HBV; circulates for four or six months after infection. A negative test or IgM anti-HBc, together with a positive test for HBsAg in a single blood sample, identifies a probable chronic HBV infection.

HBeAg – useful marker for contagiousness. The presence of HbeAg correlates strongly with the number of infective HBV particles in the serum and is associated with a high risk of infectivity.

HBsAb (Anti-HBs) – associated with long-term immunity. Using radioimmunoassay (RIA), a minimum of 10 sample ratio units should be used to designate immunity. Using enzyme immunoassay (ELISA), the manufacturer's recommended positive should be considered as appropriate measure of immunity. The level on anti-HBs may also be expressed in milli-International Units/ml (mIU/ml). Ten mIU/ml is considered to indicate a protective level of immunity. The presence of anti-HBs indicates recovery and immunity from reinfection. Anti-HBs can be acquired as an immune response to hepatitis B vaccine or passively transferred by the administration of HBIG.

FOLLOW-UP LABORATORY WORK

Repeat HBsAg testing six months after initial testing to determine confirmed carrier status, then annually for two years thereafter if they remain infected and when necessary to determine appropriate control measures for persons exposed.

CHRONIC AND ACUTE HEPATITIS B CASES

For acute infection, no medication is available; treatment is supportive.

For chronic infection, several antiviral drugs (adefovir dipivoxil, interferon alfa-2b, pegylated interferon alfa-2a, lamivudine, entecavir, and telbivudine) are available. Chronically infected persons need medical evaluation every 6–12 months to assess the status of their liver health and their need for antiviral therapy, as well as to screen for liver cancer. A patient who is chronically infected with HBV should consult a specialist knowledgeable in the treatment of liver disease so care is optimized.

The risk for chronic infection varies according to the age at infection and is greatest among young children. Approximately 90% of infants and 25%–50% of children aged 1–5 years will remain chronically infected with HBV. By contrast, approximately 95% of adults recover completely from HBV infection and do not become chronically infected.

People with HBV infection should be educated about their disease and how to protect others. Household members and sex partners should be tested for HBV infection (HBsAg and antiHBs) and vaccinated if found to be susceptible. Chronic and acute hepatitis B cases should be reported to the state or local health department with 24 hours of a positive lab result (Communicable Disease Rule (R386-702).

PERINATAL HEPATITIS B CASE DEFINITION

PERINATAL HEPATITIS B CASE: An HBsAg-positive female who is pregnant or post-partum (within two years post-delivery). A perinatal hepatitis B case should be case managed as a *Hepatitis B Pregnancy Event* in UT-NEDSS.

SUSPECT PERINATAL HEPATITIS B CASE: A pregnant or post-partum female (within two years post-delivery) with undetermined HBsAg status who is suspected to be hepatitis B positive should be worked first as suspect hepatitis B infection (chronic or acute). When HBsAg-positive status is determined the case meets the perinatal hepatitis B case definition and perinatal hepatitis B case management should be initiated.

Prevention of perinatal hepatitis B transmission requires the coordinated transfer of information between laboratories, prenatal care providers, hospital staff, and the local/state health departments.

RESPONSIBILITIES OF STATE HEALTH DEPARTMENT PERINATAL COORDINATOR

The state perinatal hepatitis B coordinator ensures that:

- State perinatal hepatitis B case management guidance and responsibilities are clearly defined for laboratories, prenatal care providers, hospitals/delivery facilities, and LHD case managers/workers;
- Laboratory reported HBsAg-positive pregnancies or suspect perinatal cases are forwarded on to local health department (LHD) case managers/workers for follow-up;
- UT-NEDSS perinatal hepatitis B related data guidelines are clearly defined and case data entry is complete and timely;
- Coordination is maintained between the perinatal hepatitis B case management and hepatitis B chronic and acute case management;
- Perinatal cases that move to another state are transferred;
- Annual reports to the Centers for Disease Control and Prevention on required perinatal activities are completed.

RESPONSIBILITIES OF LABORATORIES

Laboratory-based reporting is the route by which hepatitis B surface antigen-positive (HBsAg-positive) cases are identified. The goal of the Perinatal Hepatitis B Prevention Program (PHBPP) is to ensure that all HBsAg-positive pregnant women are identified and their lab results are reported in a timely manner. To assist in achieving this goal:

1. Report all HBsAg-positive test results **(including repeat testing, even if the results have been previously reported)** within 24 hours

to the state health department (Communicable Disease Rule R386-702-4).

2. Report all HBsAg test results to the ordering physician's office.

All laboratories that provide HBsAg testing of pregnant women should use an FDA-licensed or approved HBsAg test and should perform testing according to the manufacturer's labeling, including testing of initially reactive specimens with a licensed neutralizing confirmatory test (MMWR 12/23/05, 54 (RR16); 1-23).

RESPONSIBILITIES OF PRENATAL CARE PROVIDERS

Prenatal care providers are required to:

- Test every pregnant woman during every pregnancy for HBsAg (even if they have been previously vaccinated or tested, including women previously identified as chronically infected)
- Inform pregnant women of HBsAg status
- Forward prenatal HBsAg test results, for this pregnancy to delivery hospital

If the patient is HBsAg-positive:

- Report every positive result to the local health department within 24 hours (including women who have been previously reported due to chronic infection)
- Counsel and provide or refer for medical evaluation and case management

If the patient is HBsAg-negative:

- Assess risk for HBV infection
- Counsel and provide transmission and prevention education
- Vaccinate if high risk
- Retest during last trimester if high risk

RESPONSIBILITIES OF HOSPITALS/DELIVERY FACILITIES

All hospitals should implement policies and procedures which include standing orders to ensure that all:

Pregnant women:

- Have HBsAg laboratory results for the **current pregnancy** in their medical record ***(Do not rely on a handwritten or transcribed HBsAg test result)***
- Without HBsAg laboratory results for the current pregnancy are tested STAT
- Who have a HBsAg-negative test result, but who are at risk for hepatitis B virus (HBV) infection are tested again at the time of hospital admission
- Who have a HBsAg-positive test result are reported within 24 hours, after discovery or diagnosis, to the local health department
- Who have a HBsAg-positive test result are reported to the Perinatal Hepatitis B Prevention Program at the local or state health department

Infants:

- Have maternal HBsAg laboratory results for the current pregnancy in their medical record (Do not rely on a handwritten or transcribed HBsAg test result)

- **Born to HBsAg-positive women:**
  - Receive and have documented administration of the hepatitis B (hepB) vaccine and hepatitis B immune globulin (HBIG) within 12 hours of birth in their medical record
  - Report administration status of the hepatitis B (hepB) vaccine and hepatitis B immune globulin (HBIG) to the Perinatal Hepatitis B Prevention Program at the local or state health department within 24 hours of infant's birth.
- **Born to women with unknown HBsAg status:**
  - Receive hepB vaccine within 12 hours of birth and HBIG if their mother is found to be HBsAg-positive
  - Report administration status of the hepatitis B (hepB) vaccine and hepatitis B immune globulin (HBIG) to the Perinatal Hepatitis B Prevention Program at the local or state health department within 24 hours of infant's birth.
- **Born to HBsAg-negative women:**
  - Receive hepB vaccine prior to hospital discharge

Recommendations for HBIG administration and 1st dose hepatitis B vaccination vary depending on mother's HBsAg status:

Infants > 2000 grams born to ***HBsAg-positive Women***

Biologic	Dose	Age of Infant
HBIG [1]	0.5 mL	Within 12 hours of birth
Hepatitis B Vaccine - birth dose [1]	0.5 mL	Within 12 hours of birth

Preterm Infants <2000 grams born to ***HBsAg-positive Women****

Biologic	Dose	Age of Infant
HBIG [1]	0.5 mL	Within 12 hours of birth
Hepatitis B Vaccine - birth dose [1]	0.5 mL (dose is not counted in the series)	Within 12 hours of birth
Hepatitis B Vaccine - dose 1	0.5 mL	1 month [2]

*For **preterm infants** weighing <2,000 grams, the initial vaccine dose (birth dose) should **not** be counted as part of the vaccine series because of the potentially reduced immunogenicity of hepatitis B vaccine in these infants; an additional dose of vaccine should be administered beginning when the infant reaches the chronological age of 1 month.

Infants > 2000 grams born to ***HBsAg negative Women***

Biologic	Dose	Age of Infant
Hepatitis B Vaccine - birth dose	0.5 mL	Before hospital discharge

Preterm Infants <2000 grams born to ***HBsAg negative Women***

Biologic	Dose	Age of Infant
Hepatitis B Vaccine - birth dose	0.5 mL	Delay until 1 month after birth or hospital discharge

[1] The birth dose of the Hepatitis B vaccine should be given IM at the same time as HBIG but in different injection sites. The preferred sites are anterolateral thighs. If necessary, HBIG can be administered up to seven days post-partum.

Discrepant HBsAg Results

Discrepant results occur when the mother's HBsAg test during the current pregnancy event yields conflicting results such as:

- HBsAg-positive prenatally and HBsAg-negative at delivery.
- HBsAg-negative prenatally and HBsAg-positive at delivery.
- HBsAg-positive at delivery and HBsAg-negative 6 months after delivery.

It is the role of the delivery hospital to administer HBIG and the hepatitis B vaccine-birth dose within 12 hours of birth to infants born to mothers with known discrepant HBsAg results and report results to the local health department.

Discrepant Mother's HBsAg Test Results			
HBsAg Test Results	**Prenatally**	**At Delivery**	**Hospitals**
	+	**-**	➢ Administer HBIG and hepatitis B vaccine-birth dose within 12 hours of birth ➢ Report case to district perinatal manager or state perinatal coordinator
	-	**+**	

Every delivery hospital should have a written policy requiring that women admitted for delivery whose HBsAg status is unknown have blood drawn for STAT testing. Infants born to women with an unknown HBsAg status should be vaccinated according to the following schedule:

Infants > 2000 grams born to ***women whose HBsAg Status is Unknown***

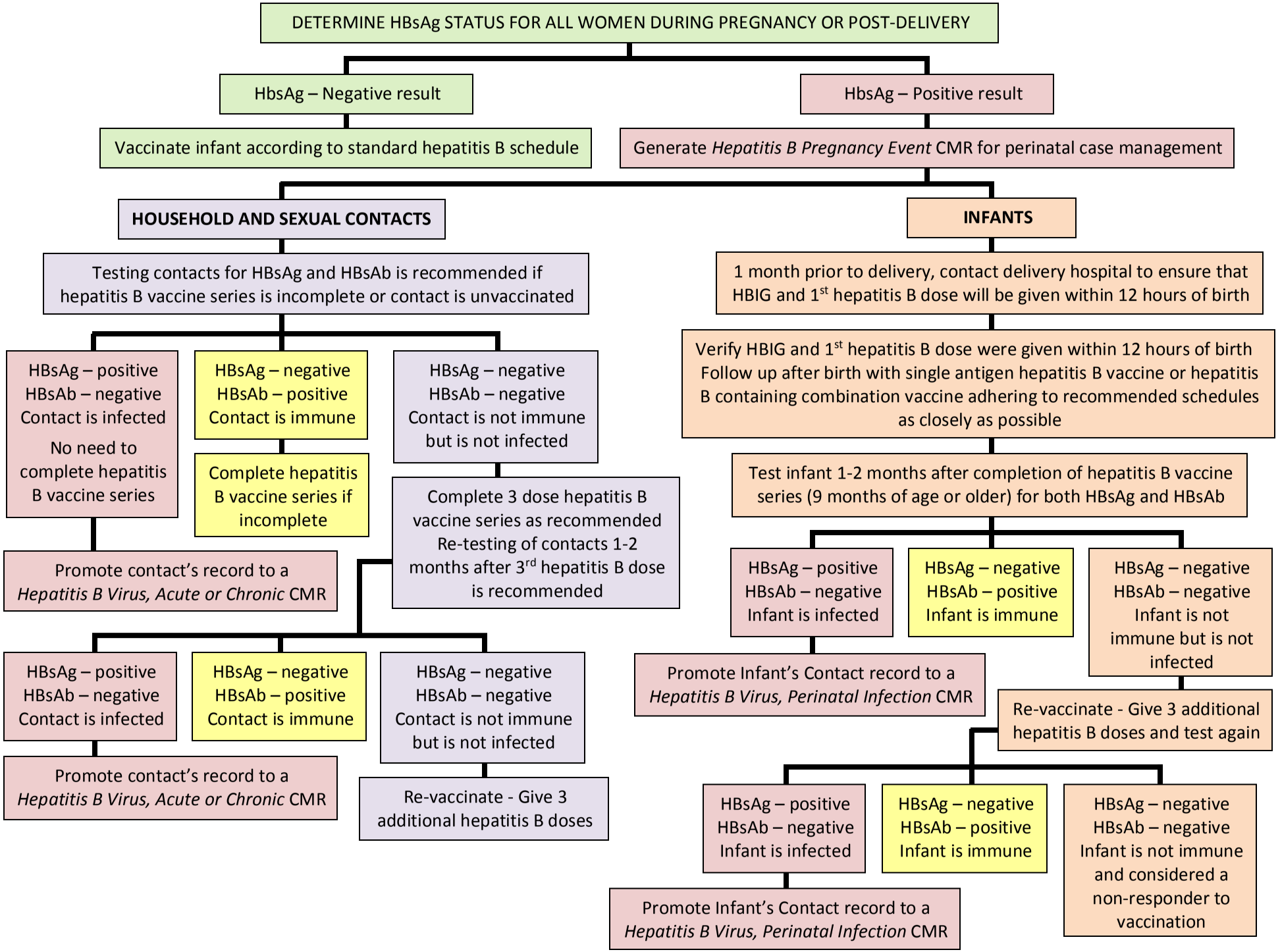
Biologic	**Dose**	**Age of Infant**
HBIG [1]	0.5 mL	If mother is postnatally found to be HBsAg-positive, administer HBIG to infant as soon as possible, but **no later than 7 days after birth**
Hepatitis B Vaccine dose 1 (birth dose) [1]	0.5 mL	Within 12 hours of birth

Preterm Infants <2000 grams born to ***women whose HBsAg Status is Unknown****

Biologic	**Dose**	**Age of Infant**
HBIG [1]	0.5 mL	Within 12 hours of birth
Hepatitis B Vaccine - birth dose [1]	0.5 mL (dose is not counted in the series)	Within 12 hours of birth
Hepatitis B Vaccine - dose 1	0.5 mL	1 month [2]

*****Women admitted for delivery without documentation of HBsAg test results should have blood drawn and tested as soon as possible after admission. While test results are pending, all full-term infants born to women without documentation of HBsAg test results should receive the birth dose of single-antigen hepatitis B vaccine (without HBIG) within 12 hours of birth. Alert infant's pediatric health-care provider if an infant is discharged before the mothers HBsAg is available.

FLOWCHART FOR PERINATAL HEPATITIS B CASE MANAGEMENT



RESPONSIBILITIES OF LOCAL HEALTH DEPARTMENT CASE MANAGERS

Perinatal hepatitis B case managers will be identified within each local health district. Each local health department will forward their perinatal hepatitis B case manager contact information to the state Perinatal Heptatitis B Coordinator annually or when a change occurs. Case managers/workers are responsible for:

- Identifying, educating, and tracking reported HBsAg-positive pregnant women and their infants;
- Ensuring vaccination and post vaccination serological testing of infants born to HBsAg-positive pregnant women;
- Reporting cases within 2 weeks and documenting case information in UT-NEDSS on a timely basis;
- Case managers/workers are also responsible for educating, testing, and immunizing susceptible household and sexual contacts.

The average time required to complete a perinatal hepatitis B case is 18-24 months, but cases should be actively worked up to 3 years post-delivery until complete. This length of time presents unique challenges. The local health department perinatal hepatitis B case manager will have long periods of time between contacts with the patient. To manage this lengthy and complicated case management, it is important to establish a tracking system which will enable you to develop a schedule for subsequent telephone or letter contacts to remind the mother to have her infant vaccinated or to remind the healthcare provider that the infant needs vaccination or testing.

Case managers are expected to document each perinatal hepatitis B case in UT-NEDSS ***within 2 weeks*** of identifying a case.

1. Initial perinatal hepatitis B case notification to state occurs when a new *Hepatitis B Pregnancy Event* CMR is entered into UT-NEDSS and the *Expected delivery date and/*or *Expected delivery facility* field is completed and saved (in order to allow adequate time for delivery of HBIG, documentation of *Expected delivery facility* should be done no later than 2 months before the mother is due, unless notification of pregnancy occurs 2 months or less from the expected delivery date).
2. The state perinatal coordinator should be notified directly by phone in the following circumstances:
    a. A case is initiated less than two months before the expected delivery date (it is necessary in order to expedite the delivery of HBIG to the hospital).
    b. A delivery date is not obtained, or is changed, with less than two months remaining before delivery.
    c. A case is found post-delivery (consequently no notification goes directly to the state because neither *Expected delivery date* nor *Expected delivery facility* will be entered).
    d. A case mother or infant moves out of state or out of the country (all case information must be transferred as soon as possible to the state to which the mother and/or infant moves, by the state perinatal coordinator).

Every effort should be made to collect all required *Index Case CMR Info* initially and information should be documented in UT-NEDSS. On the following table, required fields in regular type should be entered initially, required fields in italics should be added as available (please refer to the Perinatal Hepatitis B SOP for detailed data entry procedures):

Index Case CMR Info	'Infant' Contact Info	Other Contacts' Info
First and Last Name	'Unknown, Baby' (name placeholder before birth)	*First and Last Name*
Address and Phone	Disposition 'Active follow-up'	*Date of Birth*
Date of Birth	Disposition date	*Disposition*
Race and Ethnicity	Contact type as 'Infant'	*Disposition date*
HBsAg Test Date	*First and Last Name (once known)*	*Contact type (other than Infant)*
Expected Delivery Date	*Gender*	*Screening date and results*
Expected Delivery Hospital	*Date of birth*	*Hepatitis B vaccination dates*
Delivery Outcome	*HBIG and hepatitis B vaccination dates*	*Post-vaccination test date & results*
Actual Delivery Date	*Post-vaccination test date & results*	
Actual Delivery Facility		
Insurance Status at Delivery		
Insurance Status of Infant at Birth		

Review all cases and document case updates in UT-NEDSS by the ***30th of each month***. Timely case management updates are needed for reports required by the CDC.

1) IDENTIFICATION, EDUCATION AND TRACKING OF HBsAg POSITIVE PREGNANT WOMEN

A. TESTING

Since 1988, the American College of Obstetricians and Gynecologists (ACOG), the American Academy of Pediatrics (AAP), and the Advisory Committee on Immunization Practices (ACIP) have recommended that all pregnant women be serologically screened for HBV infection. All case managers should work with state perinatal coordinator and hospitals in their area to promote birth dose hepatitis B vaccine, encourage hospitals to have written policies for testing, report deliveries of HBsAg positive women, document hepatitis B vaccine and HBIG received by infants born to HBsAg positive women, and verify receipt of hepatitis B vaccination and HBIG administration.

1. ***All*** pregnant women should be routinely tested for HBsAg at the same time that other routine prenatal screening tests are ordered. This should be done in ***each*** pregnancy.
2. In special situations (e.g., when acute hepatitis is suspected, when a history of exposure to hepatitis has been reported, or when the mother has high-risk behaviors, such as injectable drug use or sexually transmitted disease), an additional HBsAg test should be ordered before delivery.

3. Hepatitis HBsAg status should be confirmed or determined post-delivery before leaving the hospital.
4. If the HBV status was unknown prior to delivery, and the first documented HBsAg-positive result was identified at delivery then testing for HBsAg, anti-HBs, and anti-HBc (total) should be drawn six months after the first positive HBsAg result to determine the new mother's status (acute or chronic). The mother should be referred for appropriate medical follow-up with a health care professional when post-partum serology testing indicates that she is a chronic carrier.
5. Hepatitis B status should also be determined or confirmed for every mother whose infant's birth certificate cites hepatitis B as a risk factor, or whose infant received HBIG within 7 days after birth.

B. REPORTING & DOCUMENTING

Communicable Disease Rule (R386-702) requires that cases of viral hepatitis be reported to the local health department or Utah Department of Health, Office of Epidemiology (801-538-6191 or 1-888-EPI-UTAH). Reporting is required for both acute and chronic cases. Reports may come from a variety of sources including: labs, provider offices, and hospitals.

1. Local health departments are required to identify and report chronic or acute hepatitis B cases to the Office of Epidemiology through the UT-NEDSS reporting system.
2. Upon identification of a positive HBsAg in a pregnant woman, the local health department perinatal case manager is required to submit a Hepatitis B Pregnancy Event Confidential Morbidity Report in UT-NEDSS (the *Perinatal Hepatitis B SOP* procedures should be followed for case reporting in UT-NEDSS).
3. Information that a pregnant woman is HBsAg positive must be transferred among all providers (e.g. lab, prenatal provider, delivery hospital, pediatric provider). When these linkages are weak or nonexistent, information can be lost or misinterpreted and high-risk infants left untreated.
4. Required perinatal case information should be documented in UT-NEDSS initially, and thereafter as information is available. Case updates should be made no less frequently than on a monthly basis when new information is acquired or received.
5. Instances when a hospital/delivery facility fails to comply with the Communicable Disease Rule or fails to follow recommended perinatal guidelines for mothers with HBsAg-positive or HBsAg-unknown test results and their infants, should be reported to the state perinatal coordinator.

C. EDUCATION

Educational materials are available from the Utah Department of Health Immunization Program for patients, providers and hospitals. Mothers should be contacted and provided with both verbal instruction and written materials.

1. Contact client to obtain pertinent medical history and personal information. (*Establishing contact with the HBsAg-positive pregnant woman is critical and is the first step in the case management process. The client should be*

contacted as soon as possible following identification, preferably, by phone. In the event the client is reluctant to provide information, ask if her physician can be contacted to provide the needed information. Remember, client consent is not required to obtain laboratory confirmed HBsAg test results from the provider. During the telephone conversation, services that will be provided by the local health department should be explained to the client, and a face-to-face visit should be arranged, if needed. If the client is unable to travel to a local health department, the case managers/workers should consider conducting home visits to provide services. If the client cannot be contacted by phone (e.g., phone is disconnected, no answer after 5 attempts at different times and days of the week, etc.), a letter should be sent to the home address that includes contact information. HBsAg status should not be disclosed in the letter due to possible breach in confidentiality. The letter should be sent with "Forwarding Address Requested" stamped on the front of the envelope. If incorrect or outdated demographic information was supplied by the reporting source, contact the prenatal physician again for current contact information.)

2. Explain what it means to be HBsAg-positive. *(Ensure that educational materials are provided in a culturally sensitive manner. Utilize translation language services when appropriate. A family member that is 18 years or older can provide translation.)*
3. Explain the importance of ongoing medical follow-up for her chronic hepatitis B virus infection.
4. Explain the communicability of the HBV virus and the importance of protecting against HBV transmission.
5. Explain the importance of having her infant receive HBIG at birth and complete the hepatitis B vaccination schedule on time.
6. Explain the importance of post-vaccination testing for the infant to assure immunity.
7. Explain the importance of testing household/sexual contacts for hepatitis B and vaccinating as necessary.
   (Brochures with pertinent patient information for pregnant HBsAg positive women are available free of charge from the Utah Immunization Program in a variety of languages. Call (801) 538-9450 to order.)

2) MANAGEMENT OF INFANTS BORN TO HBsAg POSITIVE WOMEN

A. TREATMENT

The Utah Department of Health Immunization Program, Perinatal Hepatitis B Prevention Program will provide HBIG for infants born to HBsAg positive women free of charge.

1. Approximately 1 month prior to the mother's due date, the perinatal case manager should contact the Perinatal Hepatitis B Prevention Program to assure that HBIG is available at the delivery facility.
2. Case managers should notify the delivery facility in advance of the infant's due date to ensure prompt administration of hepatitis B vaccine and HBIG.
3. Case managers should obtain verification that infant received HBIG and the 1st dose hepatitis vaccination from delivery facility.

4. Case managers should inform mothers who are HBsAg positive that they may breast-feed their infants.
5. Case managers should ensure timely administration of the second and third doses of hepatitis B vaccine to infants through reminders to parents and/or medical provider.
6. If the mother's HBsAg status is positive or positive pending confirmation, their infants should be immunized using the following schedules according to the infant's birth weight:

Infants > 2000 grams born to *HBsAg-positive Women*

Biologic	Dose	Age of Infant
HBIG [1]	0.5 mL	Within 12 hours of birth
Hepatitis B Vaccine - birth dose [1]	0.5 mL	Within 12 hours of birth
Hepatitis B Vaccine - dose 2	0.5 mL	1 to 2 months [2]
Hepatitis B Vaccine - dose 3	0.5 mL	6 - 15 months [2, 3]

Preterm* Infants <2000 grams born to *HBsAg-positive Women

For **preterm infants** weighing <2,000 grams, the initial vaccine dose (birth dose) should **not** be counted as part of the vaccine series because of the potentially reduced immunogenicity of hepatitis B vaccine in these infants; 3 additional doses of vaccine (for a total of 4 doses) should be administered beginning when the infant reaches the chronological age of 1 month.

Biologic	Dose	Age of Infant
HBIG [1]	0.5 mL	Within 12 hours of birth
Hepatitis B Vaccine - birth dose [1]	0.5 mL (dose is not counted in the series)	Within 12 hours of birth
Hepatitis B Vaccine - dose 1	0.5 mL	1 month [2]
Hepatitis B Vaccine - dose 2	0.5 mL	2 months [2]
Hepatitis B Vaccine - dose 3	0.5 mL	6 - 15 months [2, 3]

[1] The birth dose of the Hepatitis B vaccine should be given IM at the same time as HBIG but in different injection sites. The preferred sites are anterolateral thighs. If necessary, HBIG can be administered up to seven days post-partum.

[2] CDC indicates recommended intervals for vaccination in months, however, minimum intervals are indicated in weeks. Minimum hepatitis B vaccination intervals are as follows: hepatitis B vaccine dose 3 should be administered at least 8 weeks after hepatitis B vaccine dose 2 and at least 16 weeks after hepatitis B vaccine dose 1, and should not be administered before age 24 weeks of age.

[3] Final dose of single antigen Hep B or Pediarix for infants is recommended at 6 months. Final dose of Comvax is recommended at 12-15 months.

VACCINES

Two single-antigen vaccines and three combination vaccines are currently licensed in the United States.

Single-antigen Hepatitis B vaccines

- ENGERIX-B®
- RECOMBIVAX HB®

Combination vaccines

- COMVAX®: Combined Hepatitis B-Haemophilus influenzae type b (Hib) conjugate vaccine. Cannot be administered before age 6 weeks or after age 71 months.
- PEDIARIX®: Combined Hepatitis B, diphtheria, tetanus, acellular pertussis (DTaP), and inactivated poliovirus (IPV) vaccine. Cannot be administered before age 6 weeks or after age 7 years.
- TWINRIX®: Combined Hepatitis A and Hepatitis B vaccine. Recommended for persons aged ≥18 years who are at increased risk for both Hepatitis A virus and HBV infections.

Recommended doses of currently licensed formulations of Hepatitis B vaccine, by age group and vaccine type

Age Group		Single-antigen vaccine				Combination vaccine					
		Recombivax HB		Engerix-B		Comvax*		Pediarix†		Twinrix§	
		Dose (µg)¶	Vol(mL)	Dose (µg)¶	Vol(mL)	Dose (µg)¶	Vol (mL)	Dose (µg)¶	Vol (mL)	Dose (µg)¶	Vol (mL)
Infants (<1 yr)		5	0.5	10	0.5	5	0.5	10	0.5	NA**	NA
Children (1–10 yrs)		5	0.5	10	0.5	5*	0.5	10†	0.5	NA	NA
Adolescents	11–15 yrs	10††	1.0	NA	NA	NA	NA	NA	NA	NA	NA
	11–19 yrs	5	0.5	10	0.5	NA	NA	NA	NA	NA	NA
Adults (≥20 yrs)		10	1.0	20	1.0	NA	NA	NA	NA	20§	1.0
Hemodialysis patients and other immuno-compromised persons	<20 yrs§§	5	0.5	10	0.5	NA	NA	NA	NA	NA	NA
	≥20 yrs	40¶¶	1.0	40***	2.0	NA	NA	NA	NA	NA	NA

* Combined Hepatitis B–*Haemophilus influenzae* type b conjugate vaccine. This vaccine cannot be administered at birth, before age 6 weeks, or after age 71 months.
† Combined Hepatitis B, diphtheria, tetanus, acellular pertussis adsorbed, inactivated poliovirus vaccine. This vaccine cannot be administered at birth, before age 6 weeks, or at age >7 years.
§ Combined Hepatitis A and Hepatitis B vaccine. This vaccine is recommended for persons aged ≥18 years who are at increased risk for both Hepatitis B virus and Hepatitis A virus infections.
¶ Recombinant Hepatitis B surface antigen protein dose.
** Not applicable.
†† Adult formulation administered on a 2-dose schedule.
§§ Higher doses might be more immunogenic, but no specific recommendations have been made.
¶¶ Dialysis formulation administered on a 3-dose schedule at 0, 1, and 6 months.
*** Two 1.0-mL doses administered at one site, on a 4-dose schedule at 0, 1, 2, and 6 months.

B. POST VACCINATION SEROLOGY

1. Infants should receive post-vaccination serological testing 1- 2 months after their first series of hepatitis B vaccine is complete, (ideally 9-18 months of age), but never before 9 months of age. This testing should include both HBsAg and HBsAb (also called anti-HBs).

2. Serological test results:
    a. **Immune:** Infants HBsAg-negative and HBsAb-positive (anti-HBs of >10mIU/ml) are protected. This is the most common result and up to 95% of infants acquire immunity following proper immunizations alone.
    b. **Susceptible:** Infants are considered to be susceptible if both HBsAg-negative and HBsAb-negative (anti-HBs <10 mIU/ml). If this is the case after the first hepatitis B vaccine series, three additional doses of hepatitis B vaccine must be administered and post vaccination testing repeated 1-2 months after the 2nd 3 dose series has been completed. If child has not developed immunity after the second vaccine series and remains negative for both HBsAg and HBsAb, the child is a non-responder.
    c. **Infected:** If the post vaccination serology shows that the infant is HBsAg-positive and HBsAb-negative, this indicates the infant is infected with hepatitis B and has a 90% change of becoming a chronic carrier. This occurs in about 1-3% of cases. These infants should be referred to a medical provider, preferable a pediatric gastroenterologist or pediatric hepatologist for follow-up.
3. The Utah Department of Health Immunization Program, Perinatal Hepatitis B Prevention Program will provide testing for uninsured infants free of charge if testing is done at the State Lab (state approval for testing at any other lab must be obtained in advance).

C. DOCUMENTATION
1. Required Infant contact information should be documented in UT-NEDSS initially, and thereafter as information is available. Case updates should be made no less frequently than on a monthly basis when new information is acquired or received.
2. HBIG, vaccinations and post-vaccination serology test results are not valid without a date.

3) MANAGEMENT OF HOUSEHOLD AND SEXUAL CONTACTS

A. TESTING AND TREATMENT

Case managers work in conjunction with healthcare providers to identify and vaccinate the household and/or sexual contacts of the identified woman that are in his or her care.

1. Verify all household/sexual contact names, dates of birth, dates of hepatitis B vaccinations, and dates and results of any hepatitis B blood tests.
2. Educate contacts about HBV, communicability of the virus, the importance of protecting against HBV transmission if infected, and importance of vaccination if susceptible.
3. Assess for immunity, susceptibility, or carrier status of hepatitis B virus and vaccinate as necessary.
4. Ensure that educational materials are provided in a culturally sensitive manner. Utilize translation language services when appropriate. A family member that is 18 years or older can provide translation.

Interpretation of the Hepatitis B Blood Test Results

Tests	Results	Interpretation
HBsAg HBsAb (anti-HBs)	Negative Negative	Susceptible – Give hepatitis B series
HBsAg HBsAb (anti-HBs)	Negative Positive	Immune – No vaccination necessary
HBsAg HBsAb (anti-HBs)	Positive Negative	Infected – No vaccination necessary

5. Post-vaccination testing (HBsAg and HBsAb) is necessary for household/sexual contacts to confirm adequate response to vaccination. This should be done 1-2 months after the third dose of vaccine. Contacts are considered to be susceptible if the HBsAg and HBsAb are both negative. If this is the case, three additional doses of hepatitis B vaccine must be administered and post vaccination serological testing repeated 1-2 months after the 2nd 3 dose series has been completed.
6. The Utah Department of Health Immunization Program, Perinatal Hepatitis B Prevention Program will provide vaccination and testing for uninsured household/sexual contacts free of charge if testing is done at the State Lab.

C. DOCUMENTATION

1. Household/sexual contact information should be documented in UT-NEDSS as information is available. Case updates should be made no less frequently than on a monthly basis when new information is acquired or received.
2. Vaccinations and serology test results are not valid without a date.

4) COMPLETION OF PERINATAL HEPATITIS B CASES

Every attempt must be made to identify and follow-up on all infant contacts. A case should not be closed until all means of finding the mother and infant and/or verifying case information is exhausted. This should include letters, phone calls, home visits, calls to providers, etc. If the family has moved, find out their new location and inform the state perinatal hepatitis B coordinator so case records can be transferred and appropriate follow-up can continue. When initiated, household/sexual contacts should be followed, completed, and closed at the time the *Hepatitis B Pregnancy Event* CMR is closed. Non-cooperative and non-compliant mothers or contacts should remain open no longer than 3 years.

A. MOTHERS: The following information in the mother's Pregnancy Event CMR should be complete in UT-NEDSS before closing an investigation:

Mother's Information needed before closing case in UT-NEDSS
First and Last Name
Address and Phone
Date of Birth
Race and Ethnicity
HBsAg Test Date(s)
Expected Delivery Date
Expected Delivery Hospital
Delivery Outcome
Actual Delivery Date
Actual Delivery Facility
Insurance Status at Delivery
Insurance Status of Infant at Birth

Delivery Outcome, Actual delivery date, Actual delivery facility, Mother's insurance status and Infant's insurance status at birth fields should be completed in UT-NEDSS as soon as possible in the case management process, but must be complete when the case is closed.

Case information on Administrative tab
If the case is closed due to a move out of state, the state to which the mother or infant is moving should be documented on the Administrative tab of the mother's CMR. When closing the case, include the *LHD case status,* the *LHD investigation started* and *LHD closed* dates (these may differ from the date the case is closed), and the *Investigation Outcome*.

B. INFANTS: The following information in the Infant contact records should be complete in UT-NEDSS before closing an investigation:

'Infant' Contact Information needed before closing case in UT-NEDSS
First and Last Name, or 'Unknown, Baby' *(if closed before birth)*
Disposition 'Closed: *(with appropriate reason)*'
Disposition date
Contact type as 'Infant'
Gender *(if available)*
Date of Birth (if available)
HBIG and hepatitis B vaccination dates *(if available)*
Post-vaccination test date(s) & results *(if available)*

INFANTS are closed with the designation of one the following dispositions:

- **Closed: Completed** *(Infant is complete only when one or two series of hepatitis B vaccine & dates are documented and post- vaccination HBsAg & HBsAb test dates are documented in UT-NEDSS)*
- **Closed: Unable to locate** *(must make multiple attempts to contact)*
- **Closed: False positive mother**
- **Closed: Refusal to participate**

- **Closed: Non-compliance**
- **Closed: Transferred to another state** *(state moved to should be documented & address should be documented if possible)*
- **Closed: Left state (unable to transfer)**
- **Closed: Moved out of country** *(country moved to should be documented)*
- **Closed: Infant adopted**
- **Closed: Infant died**
- **Closed: Miscarriage/terminated**
- **Closed: Other** *(explain in notes)*

If the case is closed before delivery information is available, all contact records should be closed with the applicable disposition and an explanation for closure should be documented on the Notes tab of the mother's CMR and the Administrative tab under *Investigation Outcome*.

C. HOUSEHOLD/SEXUAL CONTACTS: The following information in the Household/sexual contact records should be complete in UT-NEDSS before closing an investigation:

Contacts' Information needed before closing case in UT-NEDSS
First and Last Name
Date of Birth
Disposition
Disposition date
Contact type *(other than 'Infant')*
Screening test date *(if available)*
Hepatitis B vaccination dates *(if available)*
Post-vaccination test date(s) & results *(if available)*

HOUSEHOLD/SEXUAL CONTACTS are closed with the designation of one the following dispositions:

- **Closed: Completed** *(Contact is complete only if test dates for HBsAg & HBsAb before vaccination and one or two series of hepatitis B vaccine with dates are documented in UT-NEDSS)*
- **Closed: Unable to locate** *(must make multiple attempts to contact)*
- **Closed: False positive mother**
- **Closed: Refusal to participate**
- **Closed: Non-compliance**
- **Closed: Transferred to another state**
- **Closed: Left state (unable to transfer)**
- **Closed: Moved out of country**
- **Closed: Other** *(explain in notes)*

All contacts listed on the mother's CMR should have a Contact Type designated, a 'Closed' *Disposition* status and a *Disposition date*, before the investigation and necessary documentation are complete.

5) INCENTIVE FUNDS

The Utah Department of Health, Immunization Program provides each local health district with funds that are to be used specifically for perinatal hepatitis B prevention activities. Such activities may include but are not limited to:

- Training (including conferences) for hepatitis B case managers
- Incentive awards for clients
- Incentive awards for staff
- Payment for blood draws
- Development of educational materials
- Hiring specific personnel for case management

UTAH DEPARTMENT OF HEALTH

PERINATAL HEPATITIS B PREVENTION: INDEX CASE INFORMATION

HBsAg - POSITIVE MOTHER

Name		Date of Birth / /
Address	City	Zip Code
Telephone #	Telephone # 2	

Race ❒ Asian/PI ❒ Black ❒ White ❒ American Indian ❒ Alaska Native ❒ Other _____ ❒ Unknown

Ethnicity ❒ Hispanic ❒ Non-Hispanic ❒ Unknown	Country of Birth
If yes, What Language?	Interpreter Needed? ❒ Y ❒ N
Mother's Insurance Status at Time of Birth ❒ Private ❒ Medicaid ❒ Uninsured	UT-NEDSS Record #

TEST DATE and RESULTS (+P=Positive/Reactive -N=Negative/Non-Reactive U=Unknown)

HBsAg	/ /	❒ +P ❒ -N ❒ U	Repeat HBsAg	/ /	❒ +P ❒ -N ❒ U

DELIVERY DATE & DELIVERY HOSPITAL

EXPECTED Delivery Date	/ /	Expected Delivery Hospital		
ACTUAL Delivery Date	/ /	Actual Delivery Hospital		
Multiple Births? ❒ Y ❒ N	Number of Infants	Pregnancy Number	Hospital Contact #	

PROVIDER

Provider Name	Phone

Notes:

INFANT (Infant born to HBsAg+ Mother)

Name	DOB / /	Sex ❒ Male ❒ Female
Birth Weight if Under 2,000g / 4.4 lbs.	UT-NEDSS Contact Record #	

Infant's Insurance at Time of Birth ❒ Private ❒ Medicaid ❒ Uninsured

INFANT VACCINATIONS & LAB RESULTS (+P =Positive/Reactive -N =Negative/Non-Reactive)

1st Hep B Series	Date Given	2nd Hep B Series	Date Given	Post-Vaccination Serology Results	Test Date
HBIG	/ /	Hep B #1	/ /	HBsAg ❒ (+P) ❒ (-N)	/ /
Hep B #1	/ /	Hep B #2	/ /	HBsAb (Anti-HBs) ❒ (+P) ❒ (-N)	/ /
Hep B #2	/ /	Hep B #3	/ /	HBsAg ❒ (+P) ❒ (-N)	/ /
Hep B #3	/ /			HBsAb (Anti-HBs) ❒ (+P) ❒ (-N)	/ /
Hep B #4	/ /				
Hep B #5	/ /				

INFANT FOLLOW-UP CARE PROVIDER

Provider's Name	Phone

Notes:

UTAH DEPARTMENT OF
HEALTH

HOUSEHOLD/SEXUAL CONTACT #________		
Name	DOB / /	Sex ❐ Male ❐ Female
Contact's Insurance Status ❐ Private ❐ Medicaid ❐ Uninsured	UT-NEDSS Contact Record #	
Relationship to Infant	Phone	

CONTACT LAB RESULTS & VACCINATIONS **(+P =Positive/Reactive -N =Negative/Non-Reactive)**

Susceptibility Screening Results	**Test Date**	**Vaccinations**			
HBsAg ❐ (+P) ❐ (-N)	/ /	**1st Hep B Series**	**Date Given**	**2nd Hep B Series**	**Date Given**
HBsAb (Anti-HBs) ❐ (+P) ❐ (-N)	/ /	Hep B #1	/ /	Hep B #1	/ /
Post Vaccination Serology	**Test Date**	Hep B #2	/ /	Hep B #2	/ /
HBsAg ❐ (+P) ❐ (-N)	/ /	Hep B #3	/ /	Hep B #3	/ /
HBsAb (Anti-HBs) ❐ (+P) ❐ (-N)	/ /	Hep B #4	/ /		

HOUSEHOLD/SEXUAL CONTACT #________		
Name	DOB / /	Sex ❐ Male ❐ Female
Contact's Insurance Status ❐ Private ❐ Medicaid ❐ Uninsured	UT-NEDSS Contact Record #	
Relationship to Infant	Phone	

CONTACT LAB RESULTS & VACCINATIONS **(+P =Positive/Reactive -N =Negative/Non-Reactive)**

Susceptibility Screening Results	**Test Date**	**Vaccinations**			
HBsAg ❐ (+P) ❐ (-N)	/ /	**1st Hep B Series**	**Date Given**	**2nd Hep B Series**	**Date Given**
HBsAb (Anti-HBs) ❐ (+P) ❐ (-N)	/ /	Hep B #1	/ /	Hep B #1	/ /
Post Vaccination Serology	**Test Date**	Hep B #2	/ /	Hep B #2	/ /
HBsAg ❐ (+P) ❐ (-N)	/ /	Hep B #3	/ /	Hep B #3	/ /
HBsAb (Anti-HBs) ❐ (+P) ❐ (-N)	/ /	Hep B #4	/ /		

HOUSEHOLD/SEXUAL CONTACT #________		
Name	DOB / /	Sex ❐ Male ❐ Female
Contact's Insurance Status ❐ Private ❐ Medicaid ❐ Uninsured	UT-NEDSS Contact Record #	
Relationship to Infant	Phone	

CONTACT LAB RESULTS & VACCINATIONS **(+P =Positive/Reactive -N =Negative/Non-Reactive)**

Susceptibility Screening Results	**Test Date**	**Vaccinations**			
HBsAg ❐ (+P) ❐ (-N)	/ /	**1st Hep B Series**	**Date Given**	**2nd Hep B Series**	**Date Given**
HBsAb (Anti-HBs) ❐ (+P) ❐ (-N)	/ /	Hep B #1	/ /	Hep B #1	/ /
Post Vaccination Serology	**Test Date**	Hep B #2	/ /	Hep B #2	/ /
HBsAg ❐ (+P) ❐ (-N)	/ /	Hep B #3	/ /	Hep B #3	/ /
HBsAb (Anti-HBs) ❐ (+P) ❐ (-N)	/ /	Hep B #4	/ /		

UTAH DEPARTMENT OF HEALTH

HEPATITIS B PERINATAL PREVENTION PROGRAM:
HBIG & Birth Dose Hepatitis B Vaccination Reporting Form

For Infants born to mothers who are HBsAg-positive or whose HBsAg status is unknown

DELIVERY FACILITY					
Hospital or Delivery Facility Name					
Name of Person Completing This Form			Telephone #		
HBsAg - POSITIVE MOTHER					
Mom's Name		Telephone #		Date of Birth / /	
Mom's Insurance ❒ Insured ❒ Medicaid ❒ Uninsured					
FOLLOW-UP CARE PROVIDER for MOTHER					
Facility's Name			Provider's Name		
Telephone #			County		
MOTHER'S TEST DATE and RESULTS (P=Positive/Reactive N=Negative/Non-Reactive U=Unknown)					
HBsAg	/ /	❒ P ❒ N ❒ U	Repeat HBsAg	/ /	❒ P ❒ N ❒ U
INFANT					
Name			DOB / /		Sex ❒ Male ❒ Female
Was birth weight less than 2,000 g (4.4 lbs)? ❒ Yes ❒ No			Infant's Insurance ❒ Insured ❒ Medicaid ❒ Uninsured		

INFANT HEPATITIS B IMMUNE GLOBULIN (HBIG) & HEPATITIS B VACCINATION STATUS		
Administered	**Vaccine**	**Date Given**
❒ Yes ❒ No	HBIG	/ /
❒ Yes ❒ No	Hep B Birth Dose	/ /
❒ Yes ❒ No	Hep B #1 (Additional dose at one month or at discharge for infants with birth weight < 2,000 g / 4.4 lbs)	/ /

FOLLOW-UP CARE PROVIDER for INFANT	
Facility's Name	Provider's Name
Telephone #	County

Submit information within 24 hours of delivery to your local health department or the Utah Department of Health, Immunization Program.

Local Health Department
FAX: ( ) -
PHONE: ( ) -

Utah Department of Health
Immunization Program
FAX: (801) 538-9440
PHONE: (801) 538-9450

Tri-Part Perinatal Hepatitis B Lab Form

UTAH DEPARTMENT OF HEALTH
IMMUNIZATION PROGRAM
PERINATAL HEPATITIS B PREVENTION PROJECT
LABORATORY TESTING FORM

Collection Date_____ Form Number_____
mm/dd/yy

Testing will not be performed unless form is completely filled out. Blood specimen accompanying this form must be labeled with the patient's name and form number.

PATIENT INFORMATION

Type of Patient & Serological Test ☐ Pregnant HBsAg ☐ Contact HBsAg & Anti-HBs ☐ Newborn Follow-up. 9-12 months, HBsAg & Anti-HBs

Patient Name _____ DOB ____/____/____ Sex_____
Street Address _____ Home Phone _____
City, State, Zip _____ Work Phone _____

ETHNICITY:
☐ American Indian ☐ Alaskan Native ☐ Asian ☐ Black
☐ Hispanic ☐ Pacific Islander ☐ White ☐ Other
☐ Unknown

If pregnant, Estimated Date of Delivery _____/_____/_____
If contact or newborn, Name of HBsAg + mother_____

INSURANCE STATUS: ☐ Uninsured ☐ Medicare/Medicaid ☐ Insurance

PROVIDER INFORMATION

Provider Code ☐☐☐☐ (If known) Route

Facility or location where specimen was drawn:
Facility Name _____
Street Address _____
City, State, Zip _____
Phone _____

Person submitting testing form:
Name _____
Title _____
Facility _____
Phone _____
Date Submitted _____/_____/_____

COMMENTS, SPECIAL INSTRUCTIONS, OR CLARIFICATION

(Results will be sent to the person submitting the testing form and to the Immunization Program unless specified below.)

_____
_____
_____

Send **WHITE** copy with the blood specimen to Unified State Laboratories, 4431 South 2700 West, Taylorsville, Utah 84119. Phone 801-965-2400.
Send **CANARY** copy to the Utah Department of Health, Immunization Program, PO Box 142001, SLC, UT 84114-2001. Phone 801-538-9450.
Place **PINK** copy in the patient chart.

(These forms may be ordered online at www.immunize-utah.org, or through the Utah Immunization Program at 801-538-9450.) 10/12/11

SAMPLE

Date

Dear Labor and Delivery Unit Nurse Manager,

The Utah Department of Health, Hepatitis B Prevention Program has identified the following patient as a hepatitis B surface antigen positive pregnant woman who is expected to deliver at your hospital.

Patient's Name _____

Patient's Provider _____

Patient's DOB _____

Patient's EDC _____

In order to prevent transmission of hepatitis B from this mother to her infant, it is vitally important that her infant receive 0.5 ml of hepatitis B immune globulin (HBIG) *and* hepatitis B vaccine within 12 hours of birth. HBIG is provided free of charge for all patients enrolled in the Hepatitis B Prevention Program. HBIG will be delivered to the hospital pharmacy approximately one month before the patient's estimated due date.

Please feel free to me at (___) ___-____ if you have any questions. Thank you for your cooperation.

We ask that you complete and Fax the enclosed notification to us within 24 hours of this patient's delivery:

_____Health Department

(_____) _____-_____

Sincerely,

06/14 – Hospital

SAMPLE

Date

Dear Dr.

The Utah Department of Health, Hepatitis B Prevention Program has identified the following patient as an infant who was born to a hepatitis B surface antigen positive mother. Our records indicate the following treatments were received by this patient in the hospital or birthing center.

Infant Patient's Name _____

Infant Patient's DOB _____/_____/_____

Mother's Name _____

Delivery Facility _____

Infant was pre-term <2,000 g (4.4 lbs) at birth Yes No

If yes, pre-term birth dose of hepatitis B vaccine given _____/_____/_____

HBIG given Yes No

If yes, HBIG was given _____/_____/_____

1ST dose of hepatitis B vaccine given Yes No

If yes, 1ST dose was given _____/_____/_____

It is imperative that this infant receives subsequent doses of hepatitis B vaccine at one month and six months of age. This child will also need to have post vaccination serologic testing 1-2 months after the final dose of hepatitis B vaccine (9-18 months of age). This testing should include both HBsAg and anti-HBs.

Next dose of hepatitis B vaccine DUE _____/_____/_____

Please feel free to me at (____) ____-_____ if you have any questions. Thank you for your cooperation.

Sincerely,

06/14 – Doctor

SAMPLE

Date

Dear

We have been informed that a recent blood test shows that you are infected with the hepatitis B virus. The virus can be passed to your baby at birth. The Utah Department of Health, Hepatitis B Prevention Program would like to help you protect your baby from getting hepatitis B infection. Your baby will need two shots within 12 hours of birth, hepatitis B vaccine and hepatitis B immune globulin (HBIG). Your baby will also need to have hepatitis B vaccine at one month and six months of age.

I will work with you and your baby's healthcare provider to make sure that your baby gets all doses of vaccine needed to prevent infection and that your baby's blood gets tested after the shots to make sure your baby is protected.

We can also help protect your household members against hepatitis B virus. We can test them and immunize them, if necessary. This service is provided free of charge to you.

Please feel free to call me at (___) ___-____ if you have any questions.

Sincerely,

06/14 – Mother

Frequently Asked Questions

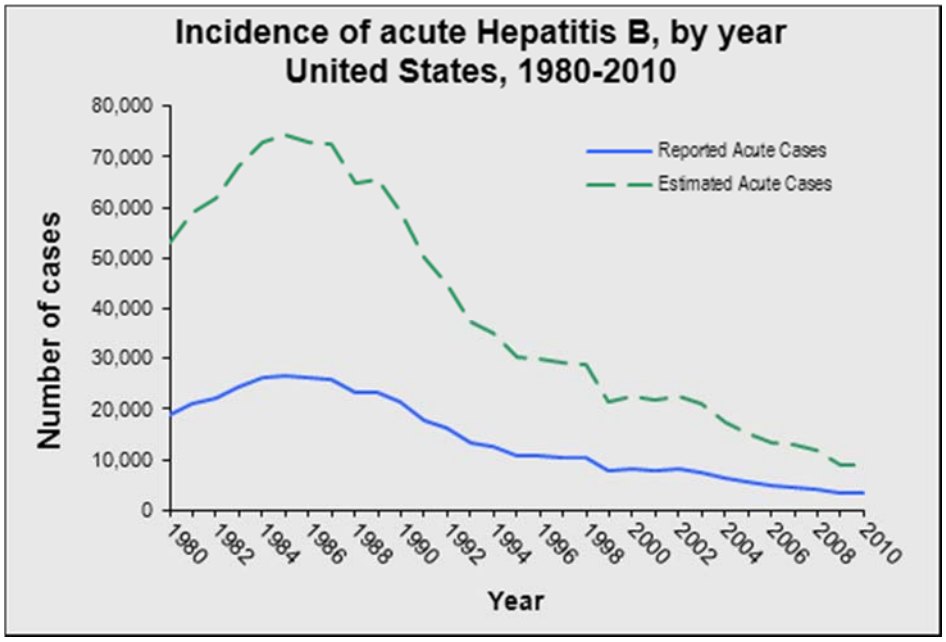
Overview and Statistics

What is hepatitis B infection?

In 2009, 3,374 cases of acute Hepatitis B in the United States were reported to CDC; the overall incidence of reported acute Hepatitis B was 1.5 per 100,000 population, the lowest ever recorded. However, because many HBV infections are either asymptomatic or never reported, the actual number of new infections is estimated to be approximately tenfold higher. In 2009, an estimated 38,000 persons in the United States were newly infected with HBV. Rates are highest among adults, particularly males aged 25–44 years. An estimated 800,000–1.4 million persons in the United States have chronic HBV infection. Hepatitis B is a highly infectious virus that attacks the liver and can lead to severe illness, liver damage, and in some cases, death. The best way to be protected from hepatitis B infection is to be vaccinated with hepatitis B vaccine, a vaccine used in the U.S. for more than three decades and proven safe and effective.

Has the rate of new HBV infections in the United States declined?

The rate of new HBV infections has declined by approximately 82% since 1991, when a national strategy to eliminate HBV infection was implemented in the United States. The decline has been greatest among children born since 1991, when routine vaccination of children was first recommended.



How common is chronic HBV infection in the United States?

An estimated 800,000–1.4 million persons in the United States have chronic HBV infection. Chronic infection is an even greater problem globally, affecting approximately 240 million persons. An estimated 786,000 persons worldwide die from HBV-related liver disease each year.

Where can I find more information about viral hepatitis incidence and prevalence in the United States?
Viral hepatitis surveillance reports and guidelines are available at http://www.cdc.gov/hepatitis/statistics.htm.

Transmission, Symptoms, and Treatment

How is HBV transmitted?
HBV is transmitted through activities that involve percutaneous (i.e., puncture through the skin) or mucosal contact with infectious blood or body fluids (e.g., semen, saliva), including

- Sex with an infected partner
- Injection drug use that involves sharing needles, syringes, or drug-preparation equipment
- Birth to an infected mother
- Contact with blood or open sores of an infected person
- Needle sticks or sharp instrument exposures
- Sharing items such as razors or toothbrushes with an infected person

HBV is not spread through food or water, sharing eating utensils, breastfeeding, hugging, kissing, hand holding, coughing, or sneezing.

How long does HBV survive outside the body?
HBV can survive outside the body at least 7 days and still be capable of causing infection.

What should be used to remove HBV from environmental surfaces?
Any blood spills — including dried blood, which can still be infectious — should be cleaned using 1:10 dilution of one part household bleach to 10 parts of water for disinfecting the area. Gloves should be used when cleaning up any blood spills.

Who is at risk for HBV infection?
The following populations are at increased risk of becoming infected with HBV:

- Infants born to infected mothers
- Sex partners of infected persons
- Sexually active persons who are not in a long-term, mutually monogamous relationship (e.g., >1 sex partner during the previous 6 months)
- Men who have sex with men
- Injection drug users
- Household contacts of persons with chronic HBV infection
- Health care and public safety workers at risk for occupational exposure to blood or blood-contaminated body fluids
- Hemodialysis patients
- Residents and staff of facilities for developmentally disabled persons
- Travelers to countries with intermediate or high prevalence of HBV infection

Are international travelers at risk for HBV infection?
The risk for HBV infection in international travelers is generally low, except for certain travelers to regions where the prevalence of chronic HBV infection is high or intermediate (i.e., Hepatitis B surface antigen prevalence of ≥2%). Hepatitis B vaccination should be administered to unvaccinated persons traveling to those countries.

More information about Hepatitis B and travel is available from CDC's Travelers' Health site.

What are the signs and symptoms of HBV infection?
The presence of signs and symptoms varies by age. Most children under age 5 years and newly infected immunosuppressed adults are asymptomatic, whereas 30%–50% of persons aged ≥5 years have initial signs and symptoms. When present, signs and symptoms can include

- Fever
- Fatigue
- Loss of appetite
- Nausea
- Vomiting
- Abdominal pain
- Dark urine
- Clay-colored bowel movements
- Joint pain
- Jaundice

Persons with chronic HBV infection might be asymptomatic, have no evidence of liver disease, or have a spectrum of disease ranging from chronic hepatitis to cirrhosis or hepatocellular carcinoma (a type of liver cancer).

What is the incubation period for Hepatitis B?
Symptoms begin an average of 90 days (range: 60–150 days) after exposure to HBV.

When symptoms of acute Hepatitis B occur, how long do they usually last?
Symptoms typically last for several weeks but can persist for up to 6 months.

How serious is acute HBV infection?
Acute infection ranges from asymptomatic or mild disease to — rarely — fulminant hepatitis. Disease is more severe among adults aged >60 years. The fatality rate among acute cases reported to CDC is 0.5%–1%.

How serious is chronic HBV infection?
Approximately 25% of those who become chronically infected during childhood and 15% of those who become chronically infected after childhood die prematurely from cirrhosis or liver cancer, and the majority remain asymptomatic until onset of cirrhosis or

end-stage liver disease. In the United States, chronic HBV infection results in an estimated 2,000–4,000 deaths per year.

How likely is HBV infection to become chronic?

The risk for chronic infection varies according to the age at infection and is greatest among young children. Approximately 90% of infants and 25%–50% of children aged 1–5 years will remain chronically infected with HBV. By contrast, approximately 95% of adults recover completely from HBV infection and do not become chronically infected.

How is HBV infection treated?

For acute infection, no medication is available; treatment is supportive.

For chronic infection, several antiviral drugs (adefovir dipivoxil, interferon alfa-2b, pegylated interferon alfa-2a, lamivudine, entecavir, and telbivudine) are available. Persons with chronic HBV infection require medical evaluation and regular monitoring to determine whether disease is progressing and to identify liver damage or hepatocellular carcinoma.

Hepatitis B Serology

How long does it take for blood to test HBsAg-positive after exposure to HBV?

HBsAg will be detected in an infected person's blood an average of 4 weeks (range: 1–9 weeks) after exposure to the virus. About 1 of 2 patients will no longer be infectious by 7 weeks after onset of symptoms, and all patients who do not remain chronically infected will be HBsAg-negative by 15 weeks after onset of symptoms.

What do the different Hepatitis B serologic markers mean?

***Hepatitis B surface antigen (HBsAg*)**: A protein on the surface of HBV; it can be detected in high levels in serum during acute or chronic HBV infection. The presence of HBsAg indicates that the person is infectious. The body normally produces antibodies to HBsAg as part of the normal immune response to infection. HBsAg is the antigen used to make Hepatitis B vaccine.

***Hepatitis B surface antibody (anti-HBs*)**: The presence of anti-HBs is generally interpreted as indicating recovery and immunity from HBV infection. Anti-HBs also develops in a person who has been successfully vaccinated against Hepatitis B.

Total Hepatitis B core antibody (anti-HBc): Appears at the onset of symptoms in acute Hepatitis B and persists for life. The presence of anti-HBc indicates previous or ongoing infection with HBV in an undefined time frame.

IgM antibody to Hepatitis B core antigen (IgM anti-HBc): Positivity indicates recent infection with HBV (≤6 months). Its presence indicates acute infection.

Hepatitis B e antigen (HBeAg): A secreted product of the nucleocapsid gene of HBV that is found in serum during acute and chronic Hepatitis B. Its presence indicates that the virus is replicating and the infected person has high levels of HBV.

Hepatitis B e antibody (HBeAb or anti-HBe): Produced by the immune system temporarily during acute HBV infection or consistently during or after a burst in viral replication. Spontaneous conversion from e antigen to e antibody (a change known as seroconversion) is a predictor of long-term clearance of HBV in patients undergoing antiviral therapy and indicates lower levels of HBV.

How do I interpret Hepatitis B serologic test results?

Interpretation of Hepatitis B Serologic Test Results		
Tests	**Results**	**Interpretation**
HBsAg anti-HBc anti-HBs	negative negative negative	Susceptible
HBsAg anti-HBc anti-HBs	negative positive positive	Immune due to natural infection
HBsAg anti-HBc anti-HBs	negative negative positive	Immune due to Hepatitis B vaccination
HBsAg anti-HBc IgM anti-HBc anti-HBs	positive positive positive negative	Acutely infected
HBsAg anti-HBc IgM anti-HBc anti-HBs	positive positive negative negative	Chronically infected
HBsAg anti-HBc anti-HBs	negative positive negative	Interpretation unclear; four possibilities: 1. Resolved infection (most common) 2. False-positive anti-HBc, thus susceptible 3. "Low level" chronic infection 4. 4. Resolving acute infection
Hepatitis B surface antigen (HBsAg): A protein on the surface of HBV; it can be detected in high levels in serum during acute or chronic HBV infection. The presence of HBsAg indicates that the person is infectious. The body normally produces antibodies to HBsAg as part of the normal immune response to infection. HBsAg is the antigen used to make Hepatitis B vaccine. **Hepatitis B surface antibody (anti-HBs):** The presence of anti-HBs is generally interpreted as indicating recovery and immunity from HBV infection. Anti-HBs also develops in a person who has been successfully vaccinated against Hepatitis B. **Total Hepatitis B core antibody (anti-HBc):** Appears at the onset of symptoms in acute Hepatitis B and persists for life. The presence of anti-HBc indicates previous or ongoing infection with HBV in an undefined time frame. **IgM antibody to Hepatitis B core antigen (IgM anti-HBc):** Positivity indicates recent infection with HBV (≤6 months). Its presence indicates acute infection. **Adapted from:** A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices. Part I: Immunization of Infants, Children, and Adolescents. MMWR 2005;54(No. RR-16).		

Where can I learn more about viral hepatitis serology?

CDC offers an online training that covers the serology of Hepatitis B and other types of viral hepatitis, available at http://www.cdc.gov/hepatitis/ResourceCntr/Professionals/Training/SerologyStart.htm.

Hepatitis B Vaccination

Who should be vaccinated against Hepatitis B?

The Advisory Committee on Immunization Practices recommends that the following persons be vaccinated against Hepatitis B:

- All infants, beginning at birth
- All children aged <19 years who have not been vaccinated previously
- Susceptible sex partners of Hepatitis B surface antigen (HBsAg)-positive persons
- Sexually active persons who are not in a long-term, mutually monogamous relationship (e.g., >1 sex partner during the previous 6 months)
- Persons seeking evaluation or treatment for a sexually transmitted disease
- Men who have sex with men
- Injection drug users
- Susceptible household contacts of HBsAg-positive persons
- Health care and public safety workers at risk for exposure to blood or blood-contaminated body fluids
- Persons with end-stage renal disease, including predialysis, hemodialysis, peritoneal dialysis, and home dialysis patients
- Residents and staff of facilities for developmentally disabled persons
- Travelers to regions with intermediate or high rates of endemic HBV infection
- Persons with chronic liver disease
- Persons with HIV infection
- Unvaccinated adults with diabetes mellitus who are aged 19 through 59 years (discretion of clinicians for unvaccinated adults with diabetes mellitus who are aged ≥60 years)
- All other persons seeking protection from HBV infection — acknowledgment of a specific risk factor is not a requirement for vaccination

Is Hepatitis B vaccination recommended in certain settings?

Yes. In certain health care, evaluation, or treatment settings, a high proportion of clients have known risk factors for HBV infection. The Advisory Committee on Immunization Practices recommends universal vaccination of adults who receive care in those settings, including

- Sexually transmitted disease treatment facilities
- HIV testing and treatment facilities
- Facilities providing drug-abuse treatment and prevention services
- Health care settings targeting services to injection drug users
- Correctional facilities
- Health care settings targeting services to men who have sex with men
- Chronic hemodialysis facilities and end-stage renal disease programs
- Institutions and nonresidential day care facilities for developmentally disabled persons

What are the Hepatitis B vaccines licensed for use in the United States?

Two single-antigen vaccines and three combination vaccines are currently licensed in the United States.

Single-antigen Hepatitis B vaccines

- ENGERIX-B®
- RECOMBIVAX HB®

Combination vaccines

- COMVAX®: Combined Hepatitis B-Haemophilus influenzae type b (Hib) conjugate vaccine. Cannot be administered before age 6 weeks or after age 71 months.
- PEDIARIX®: Combined Hepatitis B, diphtheria, tetanus, acellular pertussis (DTaP), and inactivated poliovirus (IPV) vaccine. Cannot be administered before age 6 weeks or after age 7 years.
- TWINRIX®: Combined Hepatitis A and Hepatitis B vaccine. Recommended for persons aged ≥18 years who are at increased risk for both Hepatitis A virus and HBV infections.

What are the recommended doses of Hepatitis B vaccines?

Recommended doses of currently licensed formulations of Hepatitis B vaccine, by age group and vaccine type

Age Group		Single-antigen vaccine				Combination vaccine					
		Recombivax HB		Engerix-B		Comvax*		Pediarix†		Twinrix§	
		Dose (µg)¶	Vol(mL)	Dose (µg)¶	Vol(mL)	Dose (µg)¶	Vol (mL)	Dose (µg)¶	Vol (mL)	Dose (µg)¶	Vol (mL)
Infants (<1 yr)		5	0.5	10	0.5	5	0.5	10	0.5	NA**	NA
Children (1–10 yrs)		5	0.5	10	0.5	5*	0.5	10†	0.5	NA	NA
Adolescents	11–15 yrs	10††	1.0	NA	NA	NA	NA	NA	NA	NA	NA
	11–19 yrs	5	0.5	10	0.5	NA	NA	NA	NA	NA	NA
Adults (≥20 yrs)		10	1.0	20	1.0	NA	NA	NA	NA	20§	1.0
Hemodialysis patients and other immuno-compromised persons	<20 yrs§§	5	0.5	10	0.5	NA	NA	NA	NA	NA	NA
	≥20 yrs	40¶¶	1.0	40***	2.0	NA	NA	NA	NA	NA	NA

* Combined Hepatitis B–*Haemophilus influenzae* type b conjugate vaccine. This vaccine cannot be administered at birth, before age 6 weeks, or after age 71 months.
† Combined Hepatitis B, diphtheria, tetanus, acellular pertussis adsorbed, inactivated poliovirus vaccine. This vaccine cannot be administered at birth, before age 6 weeks, or at age >7 years.
§ Combined Hepatitis A and Hepatitis B vaccine. This vaccine is recommended for persons aged ≥18 years who are at increased risk for both Hepatitis B virus and Hepatitis A virus infections.
¶ Recombinant Hepatitis B surface antigen protein dose.
** Not applicable.
†† Adult formulation administered on a 2-dose schedule.
§§ Higher doses might be more immunogenic, but no specific recommendations have been made.
¶¶ Dialysis formulation administered on a 3-dose schedule at 0, 1, and 6 months.
*** Two 1.0-mL doses administered at one site, on a 4-dose schedule at 0, 1, 2, and 6 months.

What are the recommended schedules for Hepatitis B vaccination?
The vaccination schedule most often used for children and adults is 3 intramuscular injections, the second and third doses administered 1 and 6 months, respectively, after the first dose. Alternate schedules have been approved for certain vaccines and/or populations. CDC vaccination schedules for children and adults are available at: http://www.cdc.gov/vaccines/schedules/index.html.

Who should not receive Hepatitis B vaccine?
Anyone who has had a serious allergic reaction to a prior dose of Hepatitis B vaccine, a component of the Hepatitis B vaccine, or yeast should not receive Hepatitis B vaccine.

Can a patient receive the first dose of Hepatitis B vaccine from one manufacturer and subsequent doses from another manufacturer?
Yes. No differences in immune response are observed when vaccines from different manufacturers are used to complete the vaccine series.

If there is an interruption between doses of Hepatitis B vaccine, does the vaccine series need to be restarted?
No, the series does not need to be restarted.

- If the vaccine series was interrupted after the first dose, the second dose should be administered as soon as possible.
- The second and third doses should be separated by an interval of at least 8 weeks.
- If only the third dose is delayed, it should be administered as soon as possible.

Is it harmful to administer an extra dose(s) of Hepatitis A or Hepatitis B vaccine or to repeat the entire vaccine series if documentation of vaccination history is unavailable?
No. If necessary, administering extra doses of Hepatitis A or Hepatitis B vaccine is not harmful.

Can Hepatitis B vaccine be administered concurrently with other vaccines?
Yes. When Hepatitis B vaccine has been administered at the same time as other vaccines, no interference with the antibody response of the other vaccines has been demonstrated. Separate body sites and syringes should be used for simultaneous administration of injectable vaccines.

How long does protection from Hepatitis B vaccine last?
Studies indicate that immunologic memory remains intact for at least 20 years among healthy vaccinated individuals who initiated Hepatitis B vaccination >6 months of age. The vaccine confers long-term protection against clinical illness and chronic Hepatitis B virus infection. Cellular immunity appears to persist even though antibody levels might become low or decline below detectable levels.

Among vaccinated cohorts who initiated Hepatitis B vaccination at birth, long-term follow-up studies are ongoing to determine the duration of vaccine-induced immunity.

Why should an infant receive Hepatitis B vaccine at birth before hospital discharge, even if the mother is negative for Hepatitis B surface antigen (HBsAg)?

Infants born to HBV-infected mothers require Hepatitis B vaccine and Hepatitis B immune globulin (HBIG) within 12 hours of birth to protect them from infection. However, because errors or delays in documenting, testing, and reporting maternal HBsAg status can and do occur, administering the first dose of Hepatitis B vaccine soon after birth to all infants acts as a safety net, reducing the risk for perinatal infection when maternal HBsAg status is either unknown or incorrectly documented at delivery. Also, initiating the Hepatitis B vaccine series at birth has been shown to increase a child's likelihood of completing the vaccine series on schedule.

Can Hepatitis B vaccine be given during pregnancy or lactation?

Yes. Hepatitis B vaccine contains no live virus, so neither pregnancy nor lactation should be considered a contraindication to vaccination of women. On the basis of limited experience, there is no apparent risk of adverse effects to developing fetuses when Hepatitis B vaccine is administered to pregnant women. Meanwhile, new HBV infection in a pregnant woman might result in severe disease for the mother and chronic infection for the newborn.

Can Hepatitis B vaccine be given to immunocompromised persons, such as persons on hemodialysis or persons with HIV infection?

Yes, although a larger vaccine dose is required to induce protective antibody in hemodialysis patients. Larger doses or additional doses might also be necessary for other immunocompromised persons. Serologic testing of hemodialysis patients and other immunocompromised persons is recommended 1–2 months after administration of the final dose of the primary vaccine series to determine the need for revaccination. Detailed guidance on vaccination of hemodialysis patients and other immunocompromised persons is available from the Advisory Committee on Immunization Practices recommendations on adult Hepatitis B vaccination (available at http://www.cdc.gov/mmwr/PDF/rr/rr5516.pdf).

Can Hepatitis B vaccine be given after exposure to HBV?

Yes. After a person has been exposed to HBV, appropriate prophylaxis, given as soon as possible but preferably within 24 hours, can effectively prevent infection. The mainstay of postexposure immunoprophylaxis is Hepatitis B vaccine, but in certain circumstances the addition of HBIG will provide increased protection.

Is there any benefit or risk in vaccinating a person who has been infected with HBV?

Persons who have already been infected with HBV will receive no benefit from vaccination. However, there is no risk to a previously infected person who receives vaccination.

Should persons be tested for immunity to Hepatitis B before being vaccinated?

Historically, routine prevaccination testing has not been recommended because it has not generally been found to be cost-effective with regard to vaccination. However, with the availability of antiviral agents to treat chronic HBV infection, new recommendations

for identifying persons with chronic HBV infection are being developed. CDC currently recommends that certain populations undergo testing for HBV infection, including

- Hemodialysis patients
- Pregnant women
- Persons with known or suspected exposure to HBV including:
  - infants born to HBV-infected mothers
  - household contacts of HBV-infected persons
  - persons with known occupational or other exposures to infectious blood or body fluids
- Foreign-born persons from countries of high HBV endemicity
- HIV-positive persons

For these populations, serologic assays for HBsAg and anti-HBs should be used to determine infection or immunity prior to vaccination.

Who should receive postvaccination testing?

Testing for immunity is advised only for persons whose subsequent clinical management depends on knowledge of their immune status, including

- Infants born to HBsAg-positive mothers
- Health care workers and public safety workers at high risk for continued percutaneous or mucosal exposure to blood or body fluids
- Chronic hemodialysis patients, HIV-infected persons, and other immunocompromised persons (e.g., hematopoietic stem-cell transplant recipients or persons receiving chemotherapy)
- Sex partners of persons with chronic HBV infection

When should postvaccination testing be done?

When necessary, postvaccination testing for antibody to Hepatitis B surface antigen (anti-HBs) should generally be performed 1–2 months after completion of the vaccine series.

For infants born to HBsAg-positive mothers, postvaccination testing should be performed 1–2 months after completion of ≥3 doses of a licensed Hepatitis B vaccine series (i.e., at age 9–18 months, generally at the next well-child visit). To avoid detection of anti-HBs from Hepatitis B immune globulin administered during infancy and to maximize detection of late HBV infection, testing should not be performed before age 9 months nor within 4 weeks of the most recent vaccine dose.

Are booster doses of Hepatitis B vaccine recommended?

Booster doses of Hepatitis B vaccine are recommended only in certain circumstances:

- For **hemodialysis patients**, the need for booster doses should be assessed by annual testing for antibody to Hepatitis B surface antigen (anti-HBs). A booster dose should be administered when anti-HBs levels decline to <10 mIU/mL.
- For **other immunocompromised persons** (e.g., HIV-infected persons, hematopoietic stem-cell transplant recipients, and persons receiving

chemotherapy), the need for booster doses has not been determined. When anti-HBs levels decline to <10 mIU/mL, annual anti-HBs testing and booster doses should be considered for those with an ongoing risk for exposure.

For persons with normal immune status who have been vaccinated, booster doses are not recommended.

Communicable Disease Rule: R386-702-9

Special Measures to Prevent Perinatal and Person-to-Person Transmission of Hepatitis B Infection

(1) A licensed healthcare provider who provides prenatal care shall routinely test each pregnant woman for hepatitis B surface antigen (HBsAg) at an early prenatal care visit. The provisions of this section do not apply if the pregnant woman, after being informed of the possible consequences, objects to the test on the basis of religious or personal beliefs.

(2) The licensed healthcare provider who provides prenatal care should repeat the HBsAg test during late pregnancy for those women who tested negative for HBsAg during early pregnancy, but who are at high risk based on:

(a) evidence of clinical hepatitis during pregnancy;

(b) injection drug use;

(c) occurrence during pregnancy or a history of a sexually transmitted disease;

(d) occurrence of hepatitis B in a household or close family contact; or

(e) the judgement of the healthcare provider.

(3) In addition to other reporting required by this rule, each positive HBsAg result detected in a pregnant woman shall be reported to the local health department or the Utah Department of Health, as specified in Section 26-6-6. That report shall indicate that the woman was pregnant at time of testing if that information is available to the reporting entity.

(4) A licensed healthcare provider who provides prenatal care shall document a woman's HBsAg test results, or the basis of the objection to the test, in the medical record for that patient.

(5) Every hospital and birthing facility shall develop a policy to assure that:

(a) when a pregnant woman is admitted for delivery, or for monitoring of pregnancy status, the result from a test for HBsAg performed on that woman during that pregnancy is available for review and documented in the hospital record ;

(b) when a pregnant woman is admitted for delivery if the woman's test result is not available to the hospital or birthing facility, the mother is tested for HBsAg as soon as possible, but before discharge from the hospital or birthing facility;

(c) if a pregnant woman who has not had prenatal care during that pregnancy is admitted for monitoring of pregnancy status only, if the woman's test result is not available to the hospital or birthing facility, the mother is tested for HBsAg status before discharge from the hospital or birthing facility;

(d) positive HBsAg results identified by testing performed or documented during the hospital stay are reported as specified in this rule;

(e) infants born to HBsAg positive mothers receive hepatitis B immune globulin (HBIG) and hepatitis B vaccine, administered at separate injection sites, within 12 hours of birth;

(f) infants born to mothers whose HBsAg status is unknown receive hepatitis B vaccine within 12 hours of birth, and if the infant is born preterm with birth weight less than 2,000 grams, that infant also receives HBIG within 12 hours; and

(g) if at the time of birth the mother's HbsAg status is unknown and the HBsAg test result is later determined to be positive, that infant receives HBIG as soon as possible but within 7 days of birth.

(6) Local health departments shall perform the following activities or assure that they are performed:

(a) Infants born to HBsAg positive mothers complete the hepatitis B vaccine series as specified in Table 3.18, page 328 and Table 3.21, page 333 of the reference listed in subsection (9).

(b) Children born to HBsAg positive mothers are tested for HBsAg and antibody against hepatitis B surface antigen (anti-HBs) at 9 to 15 months of age (3-9 months after the third dose of hepatitis B vaccine) to monitor the success of therapy and identify cases of perinatal hepatitis B infection.

(i) Children who test negative for HBsAg and do not demonstrate serological evidence of immunity against hepatitis B when tested as described in (b) receive additional vaccine doses and are retested as specified on page 332 of the reference listed in subsection (9).

(c) HBsAg positive mothers are advised regarding how to reduce their risk of transmitting hepatitis B to others.

(d) Household members and sex partners of HBsAg positive mothers are evaluated to determine susceptibility to hepatitis B infection and if determined to be susceptible, are offered or advised to obtain vaccination against hepatitis B.

(7) The provisions of subsections (5) and (6) do not apply if the pregnant woman or the child's guardian, after being informed of the possible consequences, objects to any of the required procedures on the basis of religious or moral beliefs. The hospital or birthing facility shall document the basis of the objection.

(8) Prevention of transmission by individuals with chronic hepatitis B infection.

(a) An individual with chronic hepatitis B infection is defined as an individual who is:

(i) HBsAg positive, and total antibody against hepatitis B core antigen (anti-HBc) positive (if done) and IgM anti-HBc negative; or

(ii) HBsAg positive on two tests performed on serum samples obtained at least 6 months apart.

(b) An individual with chronic hepatitis B infection should be advised regarding how to reduce the risk that the individual will transmit hepatitis B to others.

(c) Household members and sex partners of individuals with chronic hepatitis B infection should be evaluated to determine susceptibility to hepatitis B infection and if determined to be susceptible, should be offered or advised to obtain vaccination against Hepatitis B.

(9) The Red Book Plus: 2009 Report of the Committee on Infectious Diseases, as referenced in R386- 702-12(4) is the reference source for details regarding implementation of the requirements of this section.

Perinatal Hepatitis B Prevention Pocket Guide

Perinatal Hepatitis B Prevention Pocket Guide

Management of Pregnant Women

Prenatal HBsAg Testing

- Test ALL pregnant women within first trimester of EACH pregnancy, even if tested before or had hepatitis B vaccines.
- Send copy of lab report with the HBsAg-positive results to the hospital of delivery and the infant's healthcare provider.
- Report to local/state health dept. all HBsAg-positive women within one working day of knowledge of the pregnancy.
- Refer for or provide HBsAg-positive women counseling and medical management. Give the following information:
  - ✓ Modes of hepatitis transmission.
  - ✓ Perinatal concerns (i.e. HBsAg-positive mothers may breastfeed, treatment of newborns for exposure to hepatitis B).
  - ✓ Prevention of HBV to contacts, include vaccine prophylaxis for infant(s) and testing and/or hepatitis B vaccination for household, sexual, and needle-sharing contacts.
  - ✓ Substance abuse treatment and/or mental healthcare if appropriate.
  - ✓ Medical evaluation and possible treatment of chronic hepatitis B.

Management of Delivery and Infant

At admission for delivery:

- Review HBsAg status of all pregnant women. Perform HBsAg testing as soon as possible on women who:
  - ✓ do not have a documented HBsAg test result,
  - ✓ were at risk for HBV infection during pregnancy, or
  - ✓ had clinical hepatitis since previous testing.
- Retest HBsAg-negative women (at time of hospital delivery) with high-risk behaviors for infection:
  - ✓ Injection-drug use,
  - ✓ More than one sex partner in 6 months,
  - ✓ HBsAg-positive sexual partner,
  - ✓ Evaluation or treatment for sexually transmitted disease (STD),
  - ✓ Exhibits clinical hepatitis symptoms.
- Place copy of maternal HBsAg results on labor/delivery record, infant's delivery summary, and nursery medical record.

After delivery:

ALL infants should receive:	If mother's HBsAg status is:	Also give infant:
Hep B vaccine within 12 hours of birth	Positive	HBIG within 12 hours of birth
	Negative	No HBIG needed
	Unknown (at discharge)	Give HBIG if test positive Must be given within 7 days of birth

Adapted from Minnesota Immunization Program

- Preterm infants weighing less than 2,000g:
  - ✓ Born to HBsAg-positive mothers: give hep B vaccine and HBIG within 12 hours of birth.
  - ✓ Born to HBsAg-negative mothers: give first dose of hep B vaccine at one month of age.
  - ✓ Born to mothers whose HBsAg status is unknown: give hep B vaccine and HBIG within 12 hours of birth.
- For HBsAg-positive mothers and mothers whose HBsAg status is unknown at time of discharge
  - ✓ Fax "Hospital Report Form" to health department within 1 working day of infant's birth.
  - ✓ Alert infant's pediatric provider.
- Record date and time vaccines and HBIG were given on infant's record.

Case Management of Infants Born to HBsAg-positive Mothers

- Completion of hep B vaccine series at 1-2 months and 6 months of age (using monovalent vaccine).
- If using a combination hep B vaccine (e.g. Hib-hep B or DTaP-IPV-hep B), final dose should NOT be administered before age 24 weeks (164 days).
- Administration of 4 doses of hep B vaccine is permissible when giving combination vaccines after the birth dose.
- Report all vaccine dates to local and/or state health departments.
- Perform post-vaccination serology at 12 months of age. (No earlier than 9 months of age.)
- Test for both HBsAg and anti-HBs.
- Report test results to local and/or state health department.

Interpretation of Serology Results	
Result	Follow-up needed
Anti-HBs positive HBsAg-negative	None. Infant is protected.
Anti-HBs negative HBsAg-negative	No response. Infant is susceptible to infection. Repeat 3 doses of hep B vaccine series as soon as possible. Schedule of 0,1,4 months. Recheck serology 4-6 weeks after last dose. Monovalent hepatitis B vaccine must be used for second series.
Anti-HBs negative HBsAg-positive	Infant infected with hepatitis B. Needs regular check-ups and liver function tests.
Remember to report HBsAg-positive test results to local and/or state health department.	

UTAH DEPARTMENT OF HEALTH
Immunization Program
Utah Immunization Program
P.O. Box 142001
Salt Lake City, UT, 84114-2001
801-538-9450
www.immunize-utah.org

11/13

'Hepatitis B & Moms-to-Be' Brochure

Moms with HBV You're important too!

Remember to get screened for liver disease

You probably have no symptoms and feel healthy, but are still at increased risk for liver damage or liver cancer. However, regular screening and appropriate treatment can reduce this risk and help you lead a normal, healthy life. Ask your doctor for the following tests:

Every	Test	Screens for
6 months	ALT blood test	liver damage
	AFP blood test	liver cancer
1 year	ultrasound	liver cancer

Don't rush into treatment

Not every person with chronic HBV infection needs treatment. But if your ALT level is elevated, treatment with antiviral medication may be appropriate.

Be sure to review all medications with your doctor. Even some over-the-counter or herbal medications can injure your liver.

Get the hepatitis A vaccine

Avoid drinking alcohol

Protect your loved ones

Make sure your family and partner are tested for HBV, and vaccinated if they are not already protected. Your local health department may contact you to ensure your baby is fully protected against HBV.

Unite against HBV.

The **Jade Ribbon** is folded like the Chinese character for people "人" to symbolize the united voices of those fighting hepatitis B and liver cancer worldwide.

Asian Liver Center at Stanford University
490 S. California Ave, Suite 300
Palo Alto, CA 94306
Tel: 1-888-311-3331
Fax: (650) 566-8863

liver.stanford.edu
HepBMoms.org

Hepatitis B & Moms-to-Be

Available in:
English
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Lao
Tagalog
Spanish

HBV and Moms-to-Be

- Hepatitis B (HBV) is the most common serious viral infection of the liver, and can lead to premature death from liver cancer or liver failure.
- In the U.S., approximately 10-15 people die every day as a result of HBV infection.
- Hepatitis B can be transmitted from an infected mother to her child during the birthing process.
- Newborns who become infected with HBV have a 90% chance of developing chronic (lifelong) infection.

Fortunately, HBV can be prevented with a very safe and effective vaccine.

Ask your doctor for the results of your HBV test

Most people with chronic HBV infection have no symptoms. As an expecting mother, you should have already been tested for HBV with the following blood test:

- **Hepatitis B surface antigen (HBsAg):** Tells if you have chronic hepatitis B (also known as being a hepatitis B carrier).

Protect yourself and your baby with the first "anti-cancer vaccine"

If you have not been infected, get vaccinated

Hepatitis B can still be transmitted through unprotected sex and contaminated blood (sharing toothbrushes, razors, or needles for tattoos/piercings).

The 3 shots given over 6 months are safe, even during pregnancy. The hepatitis B vaccine is so effective in preventing HBV and liver cancer that it is known as the first "anti-cancer vaccine."

Make sure your baby is vaccinated at birth

Since 1991, U.S. national guidelines have recommended that all newborns be vaccinated against HBV. The 3 shots can protect your baby for life against hepatitis B, reducing the risk of liver cancer and liver damage in the future.

Time	Infant should receive
At birth	birth dose of hepatitis B vaccine
1-2 months	2nd dose of hepatitis B vaccine
6 months	3rd dose of hepatitis B vaccine

The vaccine is safe, even for premature babies.

Take extra precautions if you are a mom with HBV

During pregnancy:

Protect yourself. Ask your doctor to monitor your liver blood test for liver damage and refer you to a liver specialist for further evaluation. If you are already on hepatitis B antiviral treatment before becoming pregnant, discuss with your doctor.

Cesarean sections (C-sections) have not been found to prevent HBV transmission from mother to child. Hepatitis B vaccination along with the HBIG shot is the best way to protect your newborn against HBV infection.

After your baby is born:

In addition to the first shot of the hepatitis B vaccine, make sure your newborn receives the hepatitis B immunoglobulin (HBIG) shot.

Time	Infant born to mother with HBV should receive
At birth	birth dose of hepatitis B vaccine **and hepatitis B immunoglobulin (HBIG)**
1-2 months	2nd dose of hepatitis B vaccine
6 months	3rd dose of hepatitis B vaccine
9-18 months	**HBsAg and anti-HBs* tests to confirm that your child is protected**

* The hepatitis B surface antibody (anti-HBs) blood test checks for protection against HBV.

In the first 6 months:

It is critical for your child to complete the hepatitis B vaccine series on time. This will be more than 95% effective in protecting your newborn against HBV infection.

Breastfeeding is safe if your baby received the hepatitis B vaccine and HBIG at birth. HBV is not transmitted through breast milk.

UTAH DEPARTMENT OF HEALTH
Immunization Program

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Summary of Infant Schedules for Hepatitis B Vaccine
(Note: 2,000 grams = 4.4lbs)

Infants > 2000 grams born to *HBsAg-positive Women*

Biologic	Dose	Age of Infant
HBIG [1]	0.5 mL	Within 12 hours of birth
Hepatitis B Vaccine – dose 1 (birth dose) [1]	0.5 mL	Within 12 hours of birth
Hepatitis B Vaccine - dose 2	0.5 mL	1 to 2 months [2]
Hepatitis B Vaccine - dose 3	0.5 mL	6 - 15 months [2, 3]

Preterm Infants <2000 grams born to *HBsAg-positive Women**

Biologic	Dose	Age of Infant
HBIG [1]	0.5 mL	Within 12 hours of birth
Hepatitis B Vaccine - birth dose [1]	0.5 mL (dose is not counted in the series)	Within 12 hours of birth
Hepatitis B Vaccine - dose 1	0.5 mL	1 month [2]
Hepatitis B Vaccine - dose 2	0.5 mL	2 months [2]
Hepatitis B Vaccine - dose 3	0.5 mL	6 - 15 months [2, 3]

*For **preterm infants** weighing <2,000 grams, the initial vaccine dose (birth dose) should **not** be counted as part of the vaccine series because of the potentially reduced immunogenicity of hepatitis B vaccine in these infants; 3 additional doses of vaccine (for a total of 4 doses) should be administered beginning when the infant reaches the chronological age of 1 month.

Infants > 2000 grams born to *women whose HBsAg Status is Unknown*

Biologic	Dose	Age of Infant
HBIG [1]	0.5 mL	If mother is postnatally found to be HBsAg-positive, administer HBIG to infant as soon as possible, but **no later than 7 days after birth**
Hepatitis B Vaccine dose 1 (birth dose) [1]	0.5 mL	Within 12 hours of birth
Hepatitis B Vaccine - dose 2	0.5 mL	1 to 2 months [2]
Hepatitis B Vaccine - dose 3	0.5 mL	6 - 15 months [2, 3]

Preterm Infants <2000 grams born to *women whose HBsAg Status is Unknown***

Biologic	Dose	Age of Infant
HBIG [1]	0.5 mL	Within 12 hours of birth
Hepatitis B Vaccine - birth dose [1]	0.5 mL (dose is not counted in the series)	Within 12 hours of birth
Hepatitis B Vaccine - dose 1	0.5 mL	1 month [2]
Hepatitis B Vaccine - dose 2	0.5 mL	2 months [2]
Hepatitis B Vaccine - dose 3	0.5 mL	6 - 15 months [2, 3]

****Women admitted for delivery without documentation of HBsAg test results should have blood drawn and tested as soon as possible after admission. While test results are pending, all full-term infants born to women without documentation of HBsAg test results should receive the birth dose of single-antigen hepatitis B vaccine (without HBIG) within 12 hours of birth. Alert infant's pediatric health-care provider if an infant is discharged before the mothers HBsAg is available.

UTAH DEPARTMENT OF HEALTH
Immunization Program

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Summary of Infant Schedules for Hepatitis B Vaccine
(Note: 2,000 grams = 4.4lbs)

Infants > 2000 grams born to *HBsAg negative Women*

Biologic	Dose	Age of Infant
Hepatitis B Vaccine – dose 1 (birth dose)	0.5 mL	Before hospital discharge
Hepatitis B Vaccine - dose 2	0.5 mL	1 to 2 months [2]
Hepatitis B Vaccine - dose 3	0.5 mL	6 - 15 months [2, 3]

Preterm Infants <2000 grams born to *HBsAg negative Women*

Biologic	Dose	Age of Infant
Hepatitis B Vaccine – dose 1 (birth dose)	0.5 mL	Delay until 1 month after birth or hospital discharge
Hepatitis B Vaccine - dose 2	0.5 mL	1 to 2 months [2]
Hepatitis B Vaccine - dose 3	0.5 mL	6 - 15 months [2, 3]

[1] The birth dose of the Hepatitis B vaccine should be given IM at the same time as HBIG but in different injection sites. The preferred sites are anterolateral thighs. If necessary, HBIG can be administered up to seven days post-partum.

[2] CDC indicates recommended intervals for vaccination in months, however, minimum intervals are indicated in weeks. Minimum hepatitis B vaccination intervals are as follows: hepatitis B vaccine dose 3 should be administered at least 8 weeks after hepatitis B vaccine dose 2 and at least 16 weeks after hepatitis B vaccine dose 1, and should not be administered before age 24 weeks of age.

[3] Final dose of single antigen Hep B or Pediarix for infants is recommended at 6 months. Final dose of Comvax is recommended at 12-15 months.

Post Serology Testing

Perform post-vaccination testing for ***anti-HBs (titer) Quantitative and HBsAg** 1-2 months after completion of the vaccine series at 9 through 18 months of age (never earlier than 9 months of age).

- HBsAg-negative infants with anti-HBs of >10mIU/ml are protected.
- HBsAg-negative infants with anti-HBs <10 mIU/ml, revaccinate with a second 3 dose series of single-antigen hepatitis B vaccine and re-test after last dose.
- Infants HBsAg-positive must be reported to Department of Health.

- Tricore - HBSABT
- SED - HBsAB Quantitation (7717)
- Quest - HBsAB Quantitation (8475)