

Hepatitis B



Section 1:

ABOUT THE DISEASE

A. Etiologic Agent

The hepatitis B virus (HBV) is a DNA hepadnavirus. Important components of the viral particle include hepatitis B surface antigen (HBsAg), hepatitis B core antigen (HBcAg), and hepatitis B e antigen (HBeAg).

B. Clinical Description

Infection with HBV may result in acute or chronic disease, both of which can be asymptomatic. If symptoms are present, onset of acute disease is usually insidious, with loss of appetite, vague abdominal discomfort, nausea, vomiting, and sometimes arthralgias and rash, often progressing to jaundice. Fever may be absent or low-grade. Liver enzyme levels are markedly elevated. Severity of the disease ranges from unapparent cases (detectable only by liver function tests) to fulminant, fatal disease. The case-fatality rate in hospitalized patients is about 1%. Disease tends to be worse and mortality higher in those over 40 years old. Asymptomatic infections are common in children <10 years of age. Approximately 30–50% of older children, adolescents, and adults have asymptomatic infections.

The risk of chronic infection decreases with age at infection. More than 90% of infants infected at birth (perinatally) will develop chronic HBV infection, compared to between 25–50% of children infected between 1–5 years of age and 6–10% of those acquiring infection as older children or adults. Chronically infected persons are at increased risk for developing chronic liver disease (e.g., cirrhosis or chronic hepatitis) or liver cancer (primary hepatocellular carcinoma) later in life. Up to 25% of those infected during early childhood will ultimately die at an early age from the complications of cirrhosis and liver cancer. Patients who develop acute HBV infection while immunosuppressed and patients with an underlying chronic illness have an increased risk of developing chronic infection.

Resolved hepatitis B is defined as the clearance of HBsAg and normalization of serum transaminase concentrations; development of antibody to HBsAg (anti-HBs), which provides protection from HBV infection, may also be noted. Chronically infected adults clear HBsAg and develop anti-HBs at the rate of 1–2% annually; during childhood, the annual clearance rate is <1%. Reactivation of inactive chronic infection is possible with immunosuppression.

C. Vectors and Reservoirs

Humans are the only natural host for HBV.

D. Modes of Transmission

HBV is transmitted through blood or body fluids, including wound exudates, semen, vaginal secretions, and saliva. Blood and serum contain the highest concentrations of the virus; saliva contains the lowest. Common modes of transmission include percutaneous and permucosal exposure to infectious body fluids, sharing or using non-sterilized needles or syringes, sexual contact with an infected person, and perinatal exposure from an infected mother.

Some examples of parenteral exposures are: needle sticks, sharing or reusing non-sterile needles or syringes, transfusion of blood and blood products (rare in the U.S. due to current blood donor screening and testing protocols), hemodialysis, and tattooing. The most common permucosal exposures are through perinatal

transmission from an infected mother to her infant at birth (vertical transmission) and sexual (heterosexual and homosexual) activity (horizontal transmission). Per mucosal exposures have occurred in laboratories and health care settings, contributing to horizontal transmission in facilities and communities. However, with universal immunization of health care workers who are at risk, this has become rare in the U.S.

Person-to-person spread of HBV can occur in settings involving interpersonal contact over extended periods, such as when a chronically infected person resides in a household. In household settings, nonsexual transmission occurs primarily from child to child, and young children are at highest risk for infection. The precise mechanisms of transmission from child to child are unknown; however, frequent interpersonal contact of non-intact skin or mucous membranes with blood-containing secretions or saliva are the most likely means of transmission. Sharing of personal items such as washcloths, towels, razors, or toothbrushes, are behaviors that could facilitate transmission. Fecal-oral transmission does not appear to occur. Approximately one-third of infected persons do not have a readily identifiable risk factor.

E. Incubation Period

The incubation period of HBV infection averages 60–90 days, with a range of 45–160 days. HBV can remain infectious at ambient temperatures in the environment for one week or longer.

F. Period of Communicability or Infectious Period

A person is considered infectious as long as HBsAg is detectable in the blood. Persons who have chronic HBV (known as carriers) remain infectious indefinitely. Persons with acute and chronic HBV with circulating HBeAg are more infectious than those who are HBeAg negative. Measurable levels of HBeAg are associated with higher levels of HBV replication.

G. Epidemiology

Worldwide, HBV is a major cause of chronic liver disease and liver cancer. The frequency of HBV infection and patterns of transmission vary greatly throughout the world. In most areas of the U.S., Canada, Western Europe, Australia, and southern South America, the infection rate is low, and infection occurs primarily in adolescents and adults; 5–8% of the total population is infected, and 0.2–0.9% has a chronic infection. In contrast, HBV infection is highly endemic in China, Southeast Asia, the Pacific Islands, Eastern Europe, the Central Asian republics, and in most of the Middle East, Africa, and the Amazon Basin. In these areas, most infections occur in infants or children under the age of five years; 70–90% of the adult population has been infected, and 8–15% have a chronic infection. In the rest of the world, HBV infection is of intermediate endemicity and occurs in all age groups, with chronic HBV carriage occurring in 2–7% of the population.

In the U.S., sexual contact is the most common risk factor for HBV infection, and injection drug use and household contact with a chronic carrier are the second and third most common risk factors.

Within the U.S., there are pockets of high endemicity, including first-generation immigrants from areas where HBV is endemic, Alaskan Natives, and some inner city populations. The highest risk of early childhood infection is among children born to mothers from HBV endemic countries. Other young children at risk of infection include: a) household contacts of people with chronic HBV infection; b) residents of institutions for the developmentally disabled; c) patients undergoing hemodialysis; and d) patients with clotting disorders and others repeatedly receiving blood products.

Although fewer than 10% of new HBV infections occur in children, approximately one third of the estimated 1.25 million Americans with chronic HBV acquired the infection as infants or young children.

Acute HBV infection occurs most commonly among adolescents and adults. Groups at highest risk include users of injection drugs, people with multiple heterosexual partners, and young men who have sex with men. Others at increased risk include staff of institutions and non-residential childcare programs for the developmentally disabled, patients undergoing hemodialysis, and sexual or household contacts of people with an acute or chronic infection. The prevalence of infection among adolescents and adults is 3–4 times greater for blacks than for whites. HBV infection in adolescents and adults is associated with other sexually transmitted diseases, including syphilis and human immunodeficiency virus (HIV).

H. Bioterrorist Potential

This pathogen is not considered to be of risk for use in bioterrorism.



Section 2:

REPORTING CRITERIA AND LABORATORY TESTING

A. What to Report to the Massachusetts Department of Public Health (MDPH)

Report any of the following:

- ◆ Hepatitis B surface antigen (HBsAg) positive;
- ◆ Immunoglobulin M (IgM) antibody to hepatitis B core antigen (anti-HBc) positive;
- ◆ Hepatitis B e antigen (HBeAg) positive;
- ◆ Hepatitis B e antibody (anti-HBe) positive; or
- ◆ Hepatitis B DNA (HBV DNA or PCR) positive.

The following table contains selected hepatitis B serologic markers (what is looked for in blood samples) and their definitions.

Hepatitis B Serologic Markers*

Marker	Abbreviation	Definition/Significance
Hepatitis B surface antigen	HBsAg	Indicates infectivity. Present in acutely and chronically infected persons. Persists indefinitely in chronic carriers. Antigen used in hepatitis B vaccine.
Antibody to hepatitis B surface antigen (HBsAg)	anti-HBs	Indicates immunity, either from past infection or vaccination.
Total antibody or IgG antibody to hepatitis B core antigen (HBcAg)	anti-HBc	Indicates prior infection at some unknown time. Immunization does not produce anti-HBc.
IgM antibody to hepatitis B core antigen (HBcAg)	IgM anti-HBc	Indicates infection within the past six months (including in HBsAg-negative persons during the “window” phase of infection). This is the best test to diagnose acute hepatitis B.

Marker	Abbreviation	Definition/Significance
Hepatitis B e antigen	HBeAg	Identification of infected persons at increased risk for transmitting HBV. Seen transiently in most infections, and persists indefinitely in some carriers.
Antibody to hepatitis B e antigen (HBeAg)	Anti-HBe	Identification of infected persons with lower risk for transmitting HBV.
Hepatitis B DNA	HBV DNA or HBV PCR	Indicates infectivity. Detects or measures circulating viral DNA. ** Amount of DNA does not indicate prognosis.

Table adapted from: American Academy of Pediatrics. *2003 Red Book, Report of the Committee on Infectious Diseases, 26th Edition*. Illinois, American Academy of Pediatrics; 2003: 322.

* Patients usually have several hepatitis B serological tests done in order to establish a diagnosis. Please see *Attachment A: Interpretation of Select Hepatitis B Serologic Tests* (located at the end of this chapter) for a chart of hepatitis B test results and their interpretations.

** Because the viral DNA encodes hepatitis B surface antigen, the presence of hepatitis B DNA indicates the presence of hepatitis B surface antigen. The presence of either indicates infectivity. The hepatitis B DNA marker can therefore be used as a proxy for the hepatitis B surface antigen marker.

Please feel free to consult with the epidemiologist on-call at the MDPH Division of Epidemiology and Immunization at (617) 983-6800 or (888) 658-2850 for assistance in the interpretation of laboratory results or if you have any other questions regarding a case of HBV infection (acute and/or chronic). Refer to Section 3C of this chapter for information on how to report a case.

B. Laboratory Testing Services Available

The MDPH State Laboratory Institute (SLI) does not perform routine laboratory testing for HBV. Testing is generally conducted through private, commercial laboratories.



Section 3:

REPORTING RESPONSIBILITIES AND CASE INVESTIGATION

A. Purpose of Surveillance and Reporting

- ◆ To identify sources/sites of transmission, and to prevent spread from such sources.
- ◆ To ensure identification of infected pregnant women, and to prevent perinatal transmission to their babies.

B. Laboratory and Health Care Provider Reporting

Hepatitis B infection is reportable to the local board of health (LBOH). The MDPH requests that health care providers immediately report to the LBOH in the community where the case is diagnosed, all confirmed or suspect cases of hepatitis B infection, as defined by the reporting criteria in Section 2A.

Health care providers (public, private, and hospital-based) must report all cases of HBsAg-positive pregnant women to the LBOH within 1–2 business days.

Laboratories testing any specimens taken from Massachusetts residents that yield evidence of hepatitis B infection shall report such evidence of infection directly to the MDPH within 24 hours.

Laboratories (public, private, commercial, and hospital) must report HBsAg+, IgM anti-HBc+, HBeAg+, anti-HBe+, and HBV DNA+ results to the MDPH within 24 hours.

C. Local Board of Health (LBOH) Reporting and Follow-Up Responsibilities

Reporting Requirements

MDPH regulations (*105 CMR 300.000*) stipulate that hepatitis B infection is reportable to the LBOH and that each LBOH must report any case of hepatitis B infection or suspect case of hepatitis B infection, as defined by the reporting criteria in Section 2A. Cases should be reported to the MDPH Bureau of Communicable Disease Control, Office of Integrated Surveillance and Informatics Services (ISIS) using an official MDPH *Hepatitis B Case Report Form* and the appropriate supplement (located at the end of this chapter). Refer to the *Local Board of Health Timeline* at the end of this manual's *Introduction* section for information on prioritization and timeliness requirements of reporting and case investigation.

Because the process of obtaining information for a case report form can take time, the LBOH should initially send or fax the laboratory report to ISIS within 24 hours, with a notation that a case report form will follow (see Section 2E for fax and address). *This is especially important if the case is a pregnant woman.* If you received the laboratory report from ISIS or from the SLI, there is no need to do this. The LBOH should then follow-up with an official MDPH *Hepatitis B Case Report Form* as soon as all needed information is collected.

Case Investigation

1. Complete a MDPH *Hepatitis B Case Report Form* (located at the end of this chapter) by interviewing the case and others who may be able to provide the pertinent information. Most of the information required on the form can be obtained from the health care provider or from the medical record. Keep the following points in mind when completing the case report form:
 - a. If the case is a woman of reproductive age (14–44 years of age), it is important to document her pregnancy status. If the case is pregnant, complete a MDPH *Hepatitis B Case Report Form, Supplement A*. This information will facilitate follow-up by the MDPH Immunization Program.
 - b. If the case is a child <5 years of age, complete a MDPH *Hepatitis B Case Report Form, Supplement B*.
 - c. If the case is suspected for or confirmed with acute hepatitis B, complete a MDPH *Hepatitis B Case Report Form, Supplement C*. Be sure to record the date and the time of the onset of illness and symptoms accurately. Using the incubation period for hepatitis B (six weeks to six months), pay special attention to the section on the MDPH *Hepatitis B Case Report Form* that pertains to the “Case Risk History.” Some of these questions are sensitive in nature. Reassure the patient that all information is kept strictly confidential and is only obtained to determine their likely source of exposure and to protect others who might be at risk.

2. In order to prevent perinatal transmission of hepatitis B, the MDPH Immunization Program coordinates follow-up and case management for pregnant hepatitis B carriers and their infants and household contacts, with assistance from the LBOH and other programs. Case management ensures that the mother, obstetrician, delivery hospital, and pediatrician are aware of the need for vaccination of the infant, with reminders sent for each dose of vaccine as well as post-vaccination screening. Follow-up is also done for screening, and if necessary, vaccination of household contacts.

To ensure that all cases are promptly referred to case management, please notify the MDPH Immunization Program Perinatal Hepatitis B Nurse at (617) 983-6800 or (888) 658-2850 as soon as you identify a pregnant HBsAg-positive woman or an HBsAg-positive woman who has recently given birth.

3. Household and sexual contacts should be assessed and immunized, if necessary, according to the recommendations listed in Section 4 of this chapter. Contacts requiring prophylaxis should be listed on the MDPH *Hepatitis B Case Report Form, Supplement A*, with dates of any HBIG and/or vaccine that have been administered. Refer to *Attachment B: Case Finding and Management of Hepatitis B Surface Antigen (HBsAg)-Positive Persons During Delivery of Vaccination Services* (located at the end of this chapter) for specific guidance that will help complete investigation and follow-up with contacts of a HBsAg-positive case.
4. If you have made several attempts to obtain case information but have been unsuccessful (e.g., the case or health care provider does not return your calls or respond to a letter, or the case refuses to divulge information or is too ill to be interviewed), fill out the case report form with as much information as you have gathered. Please note on the form the reason(s) why it could not be filled out completely.
5. After completing the case report form and appropriate supplements, attach laboratory report(s) and fax or mail (in an envelope marked "Confidential") to ISIS. The confidential fax number is (617) 983-6813. Call ISIS at (617) 983-6801 to confirm receipt of your fax. The mailing address is:

**MDPH, Office of Integrated Surveillance and Informatics Services (ISIS)
305 South Street, 5th Floor
Jamaica Plain, MA 02130
Fax: (617) 983-6813**

6. Institution of disease control measures is an integral part of case investigation. It is the responsibility of the LBOH to understand, and if necessary, institute the control guidelines listed in Section 4.



Section 4: **CONTROLLING FURTHER SPREAD**

A. Isolation and Quarantine Requirements (*105 CMR 300.200*)

Minimum Period of Isolation of Patient

No restrictions, except for exclusion from organ and blood donation. Case shall receive counseling to modify activities in order to prevent transmission.

Minimum Period of Quarantine of Contacts

Personal surveillance for high-risk contacts who should receive hepatitis B immune globulin (HBIG) and vaccine. Infants born to infected women should also receive HBIG and vaccine. Otherwise, no restrictions.

B. Protection of Contacts of a Case

Immunization of contacts: Products necessary for postexposure prophylaxis are hepatitis B immune globulin (HBIG) and hepatitis B vaccine.

Infants Born to HBsAg-Positive Mothers

Newborns who weigh ≥ 2000 g and are born to HBsAg-positive mothers should be treated as follows:

- ◆ Give HBIG (0.5 mL IM) and hepatitis B vaccine IM according to the following table:

Immunoprophylaxis of Infants Born to HBsAg-Positive Mothers

Vaccine/HBIG Dose	Age
First hepatitis B vaccine	Birth (within 12 hours)
HBIG ¹	Birth (within 12 hours)
Second hepatitis B vaccine	1–2 months (4–8 weeks)
Third hepatitis B vaccine	6 months (24 weeks)

¹ Give HBIG (0.5mL IM) simultaneously with, but at a different site from, the first dose of hepatitis B vaccine.

- ◆ Screen the infant for HBsAg and anti-HBs after completion of the immunization series at 9–15 months of age, to monitor the success or failure of the immunization. Testing should not be performed before nine months of age to avoid detection of anti-HBs from HBIG administered during infancy and to maximize the likelihood of detecting HBV infections. If HBsAg is not present and anti-HBs antibody is ≥ 10 mIU/mL, children can be considered protected.
- ◆ Infants with anti-HBs concentrations of < 10 mIU/mL and who are HBsAg-negative should receive three additional doses of vaccine in a zero, one, and six-month schedule, followed by testing for anti-HBs 1–2 months after the third dose. This approach is usually more practical than serologic testing after one or more doses. No data suggest that children who have no detectable antibody after six doses of vaccine would benefit from any additional doses.

- ◆ Infants who become HBsAg-positive despite immunization (because of intrauterine infection or vaccine failure) should be referred to a pediatric hepatologist for follow-up, and the parents should be counseled. Since perinatal HBV infection is a reportable disease, the HBsAg-positive infant should be reported to the MDPH and the MDPH Immunization Program Perinatal Hepatitis B Nurse, as described in Section 3C.

Infants Born to Mothers Whose HBsAg Status is Unknown

Newborns who weigh ≥ 2000 g and are born to mothers whose HBsAg status is not known should be given hepatitis B vaccine within twelve hours of birth while awaiting HBsAg test results on the mother. If the mother is determined to be positive, the infant should receive HBIG as soon as possible, within seven days of birth. This child should then complete the three-dose hepatitis B vaccination series according to the table above. The child should then be screened for HBsAg and anti-HBs at 9–18 months of age, as described in Section 4B.

If the mother is determined to be HBsAg-negative, the infant should complete the three-dose hepatitis B vaccine series according to the the schedule for infants born to HBsAg-negative mothers (0, 1–2, 6–18 months).

If the mother's HBsAg status remains unknown, the infant should complete the vaccine series according to the recommended schedule for infants born to HBsAg-positive mothers (0, 1–2, 6 months). Administration of HBIG is not necessary.

Infants Born to HBsAg-Negative Mothers

Please refer to Section 4D. For guidance on policies and procedures for delivery to hospitals, refer to *Attachment C: Delivery Hospital Policies and Procedures to Prevent Perinatal HBV Transmission*.

Preterm and Low Birth Weight Infants

Newborns who weigh < 2000 g and who are born to HBsAg-positive mothers or mothers of unknown HBsAg status should be treated according to the table in *Attachment D: Hepatitis B Immunoprophylaxis Scheme for Infants* (located at the end of this chapter). Please note, these infants require four doses of hepatitis B vaccine.

Infants Exposed After Birth

Infants (i.e., younger than twelve months of age) who have close contact with primary caregivers with acute infection require immunoprophylaxis. If at the time of exposure, the infant has been fully immunized or has received at least two doses of vaccine, the infant should be presumed protected, and HBIG is not required. If only one dose of vaccine has been administered, the second dose should be administered if the interval is appropriate, or HBIG should be administered if immunization is not due. If immunization has not been initiated, the infant should receive HBIG (0.5 mL) and should initiate and complete the three-dose hepatitis B vaccine series according to the table in Section 4D as soon as possible.

Sexual Exposure to Acute HBV Infection

Sexual contacts of a person with acute HBV, if susceptible, should receive a single dose of HBIG (0.06 mL/kg) and should begin the hepatitis B vaccine series according to the table in Section 4D (on page 368). The period after sexual exposure during which HBIG is effective is unknown, but is unlikely to exceed 14 days.

Sexual Exposure to Chronic HBV Infection

Sexual contacts of persons with chronic HBV, if susceptible, should initiate and complete the three-dose series of hepatitis B vaccine according to the table in Section 4D.

Household/Close Contact Exposure to Acute HBV Infection

Susceptible nonsexual household contacts of a person with acute HBV who have had a blood exposure to a case (such as sharing toothbrushes or razors) should receive a single dose of HBIG (0.06 mL/kg) and should initiate and complete the three-dose series of hepatitis B vaccine according to the table in Section 4D. The three-dose hepatitis B vaccination series should also be considered for contacts who do not have a blood exposure, particularly children and adolescents, who should be vaccinated according to the table in Section 4D.

Household/Close Contact Exposure to Chronic HBV Infection

All susceptible household contacts, including infants, of persons with chronic hepatitis B should initiate and complete the three-dose series of hepatitis B vaccine according to the tables in Section 4D as soon as possible.

Percutaneous and Mucosal Exposure to Acute or Chronic HBV Infection

Appropriate post-exposure management depends on the HBsAg status of the source of the exposure and the hepatitis B vaccination status of the individual exposed.

HBsAg-Positive Source

- ◆ Unvaccinated persons or persons known not to have responded to a complete hepatitis B vaccine series should receive both hepatitis B immune globulin (HBIG) and hepatitis B vaccine as soon as possible after exposure (preferably ≤ 24 hours). For sexual exposures, HBIG should not be administered more than 14 days after exposure. Hepatitis B vaccine may be administered simultaneously with HBIG in a separate injection site. The hepatitis B vaccine series should be completed using the age-appropriate vaccine dose and schedule.
- ◆ Persons who are in the process of being vaccinated but who have not completed the vaccine series should receive the appropriate dose of HBIG and should complete the vaccine series.
- ◆ Children and adolescents who have written documentation of a complete hepatitis B vaccine series and who did not receive post-vaccination testing should receive a single vaccine booster dose.

Source with Unknown HBsAg Status

- ◆ Unvaccinated persons should receive the hepatitis B vaccine series with the first dose initiated as soon as possible after exposure, preferably ≤ 24 hours. The vaccine series should be completed using the age-appropriate dose and schedule.
- ◆ Persons who are not fully vaccinated should complete the vaccine series.
- ◆ Children and adolescents with written documentation of a complete hepatitis B vaccine series require no further treatment.

The recommendations for post-exposure prophylaxis of susceptible persons with percutaneous or mucosal exposure to an acute or chronic case of hepatitis B are summarized in the table on the next page.

Recommended Postexposure Prophylaxis for Percutaneous or Permucosal Exposure to Hepatitis B Virus

Vaccination status of exposed person		Treatment when source is found to be:		
		HBsAg-positive	HBsAg-negative	Unknown or not tested
Unimmunized		Administer 1 dose of HBIG ¹ and initiate hepatitis B vaccine series ²	Initiate hepatitis B vaccine series ²	Initiate hepatitis B vaccine series ²
Previously Immunized	Known responder	No treatment	No treatment	No treatment
	Known non-responder	1 dose of HBIG <u>and</u> initiate revaccination ³ , or 2 doses of HBIG ^{1,2}	No treatment	If known high-risk source, treat as if source were HBsAg-positive ²
	Response unknown	Test exposed person for anti-HBs ⁴ <ul style="list-style-type: none"> • If adequate, no treatment • If inadequate, 1 dose of HBIG¹ and a vaccine booster dose⁵ 	No treatment	Test exposed person for anti-HBs ⁴ <ul style="list-style-type: none"> • If adequate, no treatment • If inadequate, vaccine booster dose⁵

HBsAg indicates hepatitis B surface antigen; HBIG, hepatitis B immune globulin; anti-HBs, antibody to HBsAg.

1 Dose of HBIG, 0.06 mL/kg, intramuscularly.

2 Immunoprophylaxis should be administered as soon as possible, preferably ≤ 24 hours. Studies are limited on the maximum interval after exposure during which post-exposure prophylaxis is effective, but the interval is unlikely to exceed 7 days for percutaneous exposures and 14 days for sexual exposures. The hepatitis B vaccine series should also be completed.

3 The option of giving one dose of HBIG (0.06 mL/kg) and reinitiating the vaccine series is preferable for non-responders who have not completed a second three-dose vaccine series. For people who previously completed a second vaccine series but failed to respond, two doses of HBIG (0.06 mL/kg) are preferable, one dose as soon as possible after exposure and the second one month later.

3 Adequate anti-HBs is ≥ 10 mIU/mL.

4 The person should be evaluated for antibody response after the vaccine booster dose. For persons who received HBIG, anti-HBs testing should be done when passively acquired antibody from HBIG is no longer detectable (e.g., 4–6 months); if they did not receive HBIG, anti-HBs testing should be done 1–2 months after the vaccine booster dose. If anti-HBs is found to be inadequate (< 10 mIU/mL) after the vaccine booster dose, two additional doses should be administered to complete a three-dose revaccination series.

Sources:

American Academy of Pediatrics. *2003 Red Book. Report of the Committee on Infectious Diseases, 26th Edition*. Illinois: American Academy of Pediatrics, 2003: 335.

CDC. A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP); Part 1: Immunization of Infants, Children, and Adolescents. *MMWR*. 2005; 54(RR-16): 31.

C. Managing Special Situations

School and Daycare

The risk of transmission of HBV in the school and childcare setting has always been low. It is now negligible as a result of universal childhood and adolescent vaccination and immunization requirements for entry into childcare, kindergarten, 7th grade, and college. If hepatitis B were to spread in a school or childcare setting, it would most likely occur through direct blood contact, such as a bite that breaks the skin and allows the virus to enter the bloodstream of a non-immune person.

To prevent the transmission of HBV and other bloodborne infections in these settings, the following guidelines should be followed:

1. Ensure compliance with all hepatitis B immunization requirements for school and childcare entry. Vaccination is also recommended for unvaccinated classmates and staff in contact with HBV carriers who behave aggressively (e.g., biting, frequent scratching) or who have medical conditions, such as open skin lesions (e.g., generalized dermatitis or bleeding problems), that increase the risk of exposing others to infectious blood or serous secretions.
2. Hepatitis B vaccination is recommended for staff whose responsibilities include first aid. Federal Occupational Safety and Health Administration (OSHA) regulations require employers to offer hepatitis B vaccine to childcare staff whose responsibilities include first aid (*29 CFR 1910.1030*). Serologic proof of immunity or a health care provider's written documentation of past disease may be substituted for immunization.
3. Persons exposed to potentially infectious blood or other body fluids should be treated according to the guidelines in the table, "Recommendations for Hepatitis B Prophylaxis After Percutaneous Exposure to Blood That Contains or Might Contain Hepatitis B Virus" (see page 364).
4. Children who bite pose a concern. Existing data in humans suggest a small risk of HBV transmission from the bite of a child with chronic HBV infection. For susceptible victims of bites by children with chronic HBV infection, prophylaxis with HBIG and hepatitis B immunization is recommended. The risk of HBV acquisition when a susceptible child bites someone who has chronic HBV infection is unknown. A theoretical risk exists if HBsAg-positive blood enters the oral cavity of the biter, but transmission by this route has not been reported. Most experts would initiate the hepatitis B vaccine series but would not give HBIG to a susceptible biting child who does not have oral mucosal disease if the amount of blood transferred was small. In the common circumstance in which the HBsAg status of both the biting child and the victim is unknown, the risk of HBV transmission is extremely low because of the expected low seroprevalence of HBsAg in most groups of preschool-aged children, the low efficiency of disease transmission from bites, and routine hepatitis B immunization of preschool children. Serologic testing generally is not warranted for the biting child or the recipient of the bite, but each situation should be evaluated individually.
5. Ensure school and childcare staff receive regular training on the prevention of bloodborne infections.
6. Use Standard Precautions for all contact with blood; all body fluids, secretions, and excretions; nonintact skin; and mucous membranes. These precautions must be used at all times regardless of a person's infection status or diagnosis.
7. Do not permit sharing of personal items that may become contaminated with blood or body fluids, (e.g., toothbrushes, eating utensils, water bottles).
8. Cover open skin lesions.
9. Store contaminated clothing or washable items separately in sealed plastic bags, and send them home with the owner for laundering with detergent and hot water.
10. Supervise children and students closely to discourage and prevent aggressive behavior.
11. Provide age-appropriate education to adolescents and young adults about prevention of sexually transmitted diseases, including HBV.

Students and staff infected with HBV do not need to be identified to school personnel or parents of other children attending school/childcare. Because HBV-infected children and adolescents will not be identified, policies and procedures to manage potential exposures to blood or blood-containing materials should be established and implemented. Parents and students should be educated about the types of exposure that present a risk for school contacts. Although a student's right to privacy should be maintained, decisions about activities at school should be made by parents or guardians, together with a physician, on a case-by-case basis and while keeping the health needs of the infected student and the student's classmates in mind.

Exclusions:

- ◆ Staff and students ill with acute HBV should stay home until they feel well and until fever and jaundice are gone.
- ◆ Students who are chronically infected with HBV and who have no behavioral or medical risk factors, such as unusually aggressive behavior (e.g., biting), generalized dermatitis, or a bleeding problem, should be admitted to school and childcare without restrictions.

Reported Incidence Is Higher Than Usual/Outbreak Suspected

If the number of reported cases in your city/town is higher than usual or if you suspect an outbreak, investigate clustered cases in an area or institution to determine the source of infection. If evidence indicates a common source, applicable preventive or control measures should be instituted. Consult with the epidemiologist on-call at the MDPH Division of Epidemiology and Immunization at (617) 983-6800 or (888) 658-2850 for assistance in investigation and the implementation of control measures.

D. Preventive Measures

General control and prevention measures include implementing all hepatitis B immunization requirements and recommendations, as described below.

Maternal Screening

The Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC), in consultation with the American College of Obstetrics and Gynecology, and the American Academy of Pediatrics (AAP), recommend that all pregnant women should be routinely tested for HBsAg during an early prenatal visit in each pregnancy. If a woman has not been screened prenatally or if the results are unavailable at the time of delivery, HBsAg testing should be done upon admission for delivery. This identifies infants born to HBsAg-positive mothers for prompt prophylaxis at birth, as well as at 1–2 and 6 month follow-up. Also, household members and sexual partners of HBV carriers should be evaluated for the need for hepatitis B vaccine.

Pre-exposure Prophylaxis

1. All infants, weighing ≥ 2000 g, who are born to HBsAg-negative mothers should initiate and complete the three-dose hepatitis B vaccine series, according to the following table. For infants weighing < 2000 g, see *Attachment D: Hepatitis B Immunoprophylaxis Scheme for Infants*.

Routine Schedule for Infants Born to HBsAg-Negative Mothers

Dose	Recommended Age	Accelerated Schedule
1	Birth	1 st visit
2	1–2 months	At least 1 month after the 1 st dose
3	6–18 months	At least 2 months after 2 nd dose, at least 4 months after 1 st dose, and no earlier than 24 weeks of age

Note: Alternate dosing schedules are approved for use in the older age groups only. There are no maximum intervals.

Universal Vaccination of Infants

Standing order and policies

All hospitals should have policies and standing orders ensuring:

- ◆ Identification of all infants born to HBsAg-positive and HBsAg-unknown mothers; and
- ◆ Proper hepatitis B vaccination of all infants (see *Attachment C: Hepatitis B Immunoprophylaxis Scheme for Infants*).

Documentation

The date and time of administration of hepatitis B vaccine and HBIG (if appropriate) should be recorded in the infant's medical record.

Deviation from the recommended schedule

The birth dose for infants weighing $\geq 2,000$ g born to HBsAg-negative mothers may be delayed only in rare circumstances and only if the following conditions are well documented in the infant's medical record:

- ◆ A copy of the mother's actual HBsAg-negative laboratory result (notations on prenatal screening checklists are not acceptable); and
- ◆ A physician's order to withhold the birth dose.

For these infants, the first dose of hepatitis B vaccine should be given no later than two months of age.

DTaP-HepB-IPV and Hepatitis B Vaccine:

- ◆ Birth dose of hepatitis B vaccine: The ACIP, the AAP, the American Academy of Family Physicians (AAFP), and the MDPH recommend that all infants should continue to receive the first dose of hepatitis B vaccine at birth. This is an extremely important public health measure and must continue, even when an infant might receive the combination DTaP-HepB-IPV vaccine for all three doses of the primary series of those antigens. Although this will result in a fourth dose of hepatitis B vaccine, data show this to be safe, and therefore, it is considered acceptable by the ACIP, AAP, AAFP, and the MDPH.
 - ◆ Use of DTaP-HepB-IPV in infants born to HBsAg-positive women: The ACIP states that DTaP-HepB-IPV vaccine may be used in infants born to HBsAg-positive women (or in infants whose mother's HBsAg status is unknown). These infants must receive the first dose of hepatitis B vaccine at birth, which can then be followed by DTaP-HepB-IPV at two, four, and six months of age. The first dose of DTaP-HepB-IPV may be used beginning at 6–8 weeks of age. The third dose of DTaP-HepB-IPV should be administered ≥ 16 weeks after the first dose and ≥ 8 weeks after the 2nd dose, but not before 24 weeks of age.
2. All unvaccinated children and adolescents through 18 years of age should initiate and complete the 3-dose hepatitis B vaccine series according to the following tables:

Routine Schedule for Children (<11 years of age) and Adolescents (11–19 years of age)

Dose	Schedule ¹	Accelerated Schedule
1	1 st visit	1 st visit
2	1–2 months after 1 st dose	At least 1 month after 1 st dose
3	4–6 months after 1 st dose	At least 2 months after 2 nd dose, at least 4 months after 1 st dose

¹ For older children and adolescents, doses may be given in a schedule of 0, 1, and 6 months or of 0, 1–2, and 4–6 months. For adolescents, spacing at 0, 12, and 24 months results in equivalent immunogenicity.

**Optional Two-dose Hepatitis B Vaccine Schedule Using Recombivax HB®
for Adolescents (11–15 years of age)^{1,2}**

Dose	Schedule ¹	Accelerated Schedule
1	1 st visit	1 st visit
2	1–2 months after 1 st dose	At least 1 month after 1 st dose

¹ Adolescents (11–15 years of age only) may also use a two-dose scheduling option. This can be accomplished by administering, per dose, either:

- 1.0 ml of Merck’s Recombivax HB® Adult Formulation (1 X 10 mcg/1.0 mL); or
- 1.0 ml of Merck’s Recombivax HB® Pediatric Formulation (2 X 5.0 mcg/0.5 mL).

Administer the first dose at month 0, and the second dose 4–6 months later (minimum interval between doses is four months). Both doses must be administered while the adolescent is 11–15 years of age, with the 2nd dose given by the 16th birthday.

² GlaxoSmithKline’s hepatitis B formulation (Energix-B®) is not currently licensed for the two-dose schedule.

3. Massachusetts public employees who are at risk of occupational exposure to blood and body fluids should initiate and complete the three-dose series of hepatitis B vaccine according to the following table.

Routine Schedule for Adults

Dose	Schedule	Accelerated Schedule
1	1 st visit	1 st visit
2	1–2 months after 1 st dose	At least 1 month after 1 st dose
3	4–6 months after 1 st dose	At least 2 months after 2 nd dose, at least 4 months after 1 st dose

4. Adults at high risk should initiate and complete the three-dose hepatitis B vaccine series according to the table above. These include:
 - ◆ All full-time and part-time college health science students and all full-time undergraduate and graduate students.
 - ◆ Household contacts and sexual partners of persons with chronic HBV infection.
 - ◆ Users of intravenous drugs.
 - ◆ Sexually active heterosexual persons with more than one sexual partner in the last six months, or who have a sexually transmitted disease.
 - ◆ Sexually active men who have sex with men.
 - ◆ Health care personnel and others at occupational risk of exposure to blood or blood-contaminated body fluids.
 - ◆ Residents and staff of institutions for developmentally disabled persons.
 - ◆ Staff of nonresidential childcare and school programs for developmentally disabled persons, if the program is attended by a known HBsAg-positive person.

- ◆ Patients undergoing hemodialysis.
- ◆ Patients with bleeding disorders who receive clotting factor concentrates.
- ◆ Household contacts of HBsAg-positive persons.
- ◆ Long-term (>6 months) international travelers to areas in which HBV infection is of high or intermediate endemicity.
- ◆ Inmates of juvenile detention and other correctional facilities.
- ◆ Persons with chronic liver disease (e.g., hepatitis C infection).
- ◆ Persons with HIV infection.
- ◆ Commercial sex workers.

For the most current information about the availability of state-supplied hepatitis B vaccine, contact the MDPH Immunization Program at (617) 983-6800 or (888) 658-2850.

Pre-Vaccination Serologic Testing

Pre-vaccination serologic testing is not indicated before routine vaccination of children or adolescents. It may be considered when vaccinating adolescents and adults in groups with high rates of HBV infection (i.e., HBV markers seroprevalence of >20%), as long as testing does not delay or impede immunization efforts. These groups include:

- ◆ Alaskan Natives,
- ◆ Pacific Islanders,
- ◆ Children of immigrants from endemic countries, and
- ◆ Unvaccinated household, sexual, and needle-sharing contacts of HBV carriers.

Anti-HBc is the test of choice for prevaccination testing. Persons tested for anti-HBc and found to be anti-HBc negative are susceptible and should complete the vaccine series. Persons found to be anti-HBc positive should be tested for HBsAg. HBsAg testing may be performed on the same specimen collected for anti-HBc testing. If the HBsAg test result is positive, the person should receive appropriate management. In most situations, the first vaccine dose should be administered immediately after collection of the blood sample for serologic testing.

Post-Vaccination Serologic Testing

For more information on post-vaccination testing of infants born to HBsAg-positive mothers, refer to Section 4B. Post-vaccination serologic testing is not routinely recommended for most infants, children, adolescents, and adults. It should, however, be considered for persons whose subsequent management depends on knowing their immune status, including:

- ◆ Infants born to HBsAg-positive women (test for HBsAg and anti-HBs at 9–18 months of age).
- ◆ Dialysis patients (test annually and administer a booster dose of the appropriate formulation if anti-HBs levels are <10 mIU/mL).
- ◆ Immunodeficient persons.

- ◆ Health care workers who have significant exposure to HBV (a catch-up program of serologic testing for previously vaccinated health care providers is not recommended; these individuals should be tested as necessary if they have significant exposure to HBV).
- ◆ Sex partners of HBsAg-positive persons.

It is difficult to interpret the meaning of a negative anti-HBs serology in a person who received the hepatitis B vaccination series in the past and was not tested in the post vaccination period. Without post-vaccination testing, it is not possible to determine if persons testing negative years after vaccination represent true vaccination failure (i.e., no initial response), or have anti-HBs antibody levels that decreased to below detectable by the test. The latter is the most likely explanation because up to 60% of vaccinated people lose detectable antibody (but not protection) 9–15 years after vaccination. However, studies show that nearly all vaccinated, immunocompetent individuals are still protected against HBV infection.

Management of Non-Response to Hepatitis B Vaccine

When indicated, post-vaccination testing should be performed 1–2 months after completion of the vaccine series. If anti-HBs levels are <10 mIU/mL:

- ◆ Complete a second series of three doses of hepatitis B vaccine;
- ◆ Administer using an appropriate schedule: the usual schedule (0, 1, 6 months) or the accelerated schedule (0, 1, 4 months); and
- ◆ Retest 1–2 months after completing the second series.

This approach is usually more practical than serologic testing after one or more doses.

A second, probably less expensive, option is to administer a single dose of hepatitis B vaccine, and to test for anti-HBs in 4–6 weeks. If the person is anti-HBs positive, this most likely indicates a booster response in a previous responder, and no further vaccination (or serologic testing) is needed. If the person is anti-HBs negative after this “booster” dose, then a second series should be completed (i.e., two more doses).

Fewer than 5% of vaccinees do not develop anti-HBs antibody after 6 valid doses of hepatitis B vaccine. These vaccinees may be non-responders or “hypo-responders.”

Persons who do not respond to revaccination should be tested for HBsAg.

- ◆ If the HBsAg test result is positive, the person should receive appropriate management and any household, sexual, or needle-sharing contacts should be identified and vaccinated (see *Attachment B: Case Finding and Management of Hepatitis B Surface Antigen (HBsAg)-Positive Persons During Delivery of Vaccination Services*).
- ◆ Persons who test negative for HBsAg should be considered susceptible to HBV infection and should be counseled about precautions to prevent HBV infection and the need to obtain HBIG post-exposure prophylaxis for any known or likely parenteral exposure to HBsAg-positive blood.

Booster Doses

Booster doses are not recommended for persons with a normal immune status who were vaccinated as infants, children, or adolescents. Serologic testing is not recommended to assess antibody levels in any age group, except in specific circumstances, as outlined below:

- ◆ For hemodialysis patients, the need for booster doses should be assessed by annual antibody to hepatitis B surface antigen (anti-HBs) testing. 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. Annual anti-HBs testing and booster doses when anti-HBs levels decline to <10 mIU/mL should be considered in persons with an ongoing high risk for exposure.

Minimum Dosing Intervals, Management of Persons Who Were Incorrectly Vaccinated or Who Had an Interrupted Schedule

Minimum Intervals

- ◆ The 3rd dose of vaccine must be administered at least 8 weeks after the 2nd dose and should follow the 1st dose by at least 16 weeks; the minimum interval between the 1st and 2nd doses is 4 weeks. In infants, administration of the final dose is not recommended before age 24 weeks (164 days). For calculating minimum intervals: 1 month = 4 weeks = 28 days.
- ◆ Decreasing the recommended age or interval between doses may interfere with antibody protection. Inadequate doses of hepatitis B vaccine or doses received before the recommended age or after a shorter-than-recommended dosing interval **should** be readministered.

Interruption in Schedule

- ◆ There are **no** maximum intervals and it is **not** necessary to restart the series of any vaccine due to extended intervals between doses.

State Immunization Requirements

Hepatitis B vaccine is required for all children who are enrolled in preschool, childcare, or kindergarten through 12th grade, all full-time and part-time college health sciences students, and all full-time undergraduate and graduate students.

Please refer to the MDPH's *Childhood Immunization Guidelines* for the most current information about immunization requirements and the grades to which they apply. You can obtain this document by calling the MDPH Division of Epidemiology and Immunization at (617) 983-6800 or (888) 658-2850.

Hepatitis B Vaccine, Health Care Workers, and Others with Potential Occupational Exposure to Hepatitis B Virus

OSHA has issued regulations requiring employers to offer hepatitis B immunization to their employees at the employer's expense, if there is a risk that the employee may be expected to come into contact with blood or other potentially infectious material in the course of their job duties (Bloodborne Pathogen Standard, 29 *CFR* 1910.1030). In Massachusetts, the OSHA Bloodborne Standard does not apply to public employees. However, recent legislation affecting Medicare requires that an equivalent standard apply at public hospitals.

Hepatitis B vaccination is recommended for staff whose responsibilities include first aid, and OSHA regulations also require employers to offer hepatitis B vaccine to staff with responsibility for first aid and to have an exposure plan in place.

Serologic Testing: In 1997, the ACIP and the Hospital Infection Control Practices Advisory Committee (HICPAC) recommended that health care workers who have contact with patients or blood and are at ongoing risk for injuries with sharp instruments or needlesticks, should routinely be tested 1–2 months after completion of the three-dose vaccination series for anti-HBs. However, a catch-up program of serologic testing for health care providers vaccinated prior to December 1997 was not recommended. These individuals should be tested as necessary, if they have a significant exposure to HBV.

Education

Please refer to the *References* section, the most current versions of the MDPH's *Immunization Guidelines*, the MDPH's model standing orders for hepatitis B vaccine, and the *Massachusetts Immunization Program-State Supplied Vaccines and Patient Eligibility Criteria* for recommended schedules, groups recommended, and groups eligible to receive state-supplied vaccine. These, as well as other relevant resources, are available through the MDPH Division of Epidemiology and Immunization at (617) 983-6800 or (888) 658-2850, and on the MDPH website at www.mass.gov/dph/cdc/epii/imm/imm.htm#mso.

Discuss sexual transmission of HBV with patients. Indicate that HBV may be transmitted during sex. All contact with blood during sex should be avoided. Emphasize latex barrier protection as a way to prevent the spread of HBV, as well as to prevent exposure to and transmission of other pathogens.



ADDITIONAL INFORMATION

The following is the formal CDC surveillance case definition for acute hepatitis B. It is provided for your information only and should not affect the investigation or reporting of a case that fulfills the criteria in Section 2A of this chapter. (The CDC and the MDPH use the CDC case definitions to maintain uniform standards for national reporting.) For reporting a case to the MDPH, always use the criteria outlined in Section 2A.

Note: The most up-to-date CDC case definitions are available on the CDC website at www.cdc.gov/epo/dphsi/casedef/case_definitions.htm.

Acute Hepatitis B

Clinical Case Definition

An acute illness with: a) discrete onset of symptoms; and b) jaundice or elevated serum aminotransferase.

Laboratory Criteria for Diagnosis

- ◆ IgM antibody to hepatitis B core antigen (anti-HBc) positive (if done); or
- ◆ Hepatitis B surface antigen (HBsAg) positive and IgM antibody to hepatitis A virus (anti-HAV) negative (if done).

*Case Classification***Confirmed**

A case that meets the clinical case definition and is laboratory-confirmed (see criteria above).

Acute Perinatal HBV Infection Acquired in the U.S. or U.S. Territories*Clinical Case Definition*

Perinatal hepatitis B in the newborn may range from asymptomatic to fulminant hepatitis.

Laboratory Criteria for Diagnosis

Hepatitis B surface antigen (HBsAg) positive.

*Case Classification***Confirmed**

HBsAg positivity in any infant aged >1–24 months who was born in the U.S. or in U.S. territories to an HBsAg-positive mother.

**REFERENCES**

- American Academy of Pediatrics. [Hepatitis B.] In: Pickering L.K., ed. *Red Book 2003: Report of the Committee on Infectious Diseases, 26th Edition*. Elk Grove, IL, American Academy of Pediatrics; 2003: 318–336.
- American College of Obstetricians and Gynecologists (ACOG). Immunization During Pregnancy. ACOG Committee Opinion No. 282, January 2003.
- Centers for Disease Control and Prevention (CDC). Case Definitions for Infectious Conditions Under Public Health Surveillance. *MMWR*. 1997; 46(RR-10).
- CDC. A Comprehensive Strategy for Eliminating Transmission of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP); Part 1: Immunization of Infants, Children, and Adolescents. *MMWR*. 2005; 54(RR-16): 1–32.
- CDC. Immunization of Health-Care Workers: Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC). *MMWR*. 1997; 46(RR-18).
- CDC. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. *MMWR*. 2001; 50(RR-11).

Heymann, D.L. ed. *Control of Communicable Diseases Manual, 18th Edition*. Washington, DC, American Public Health Association, 2004.

MDPH. *Regulation 105 CMR 300.000: Reportable Diseases, Surveillance, and Isolation and Quarantine Requirements*. MDPH, Promulgated November 4, 2005.

Sarri, T.N., and the Committee on Infectious Diseases. Immunization of Preterm and Low Birth Weight Infants. *Pediatrics*. 2003; 112: 193–198.

ATTACHMENTS

Attachment A: Interpretation of Select Hepatitis B Serologic Tests

Attachment B: Case Finding and Management of Hepatitis B Surface Antigen (HBsAg)-Positive Persons During Delivery of Vaccination Services

Attachment C: Delivery Hospital Policies and Procedures to Prevent Perinatal HBV Transmission

Attachment D: Hepatitis B Immunoprophylaxis Scheme for Infants

Attachment A

Interpretation of Select Hepatitis B Serologic Tests

HBsAg	anti-HBs	anti-HBc IgM	anti-HBc IgG	Interpretations	Comments
+	-	-	-	Early acute infection	Patient is infectious; consider vaccination of susceptible household and sexual contacts.
+	-	+	+	Acute infection	Patient is infectious; consider vaccination of susceptible household and sexual contacts.
+	-	-	+	Chronic infection	Patient is infectious and should be evaluated for chronic liver disease; vaccinate susceptible household and sexual contacts.
-	+	+/-	+	Resolved infection	Patient is immune.
-	-	+	-	“Window period” following acute infection	Patient is not infectious.
-	-	-	+	<ol style="list-style-type: none"> 1. Recovering from acute infection 2. Remote infection with loss of detectable anti-HBs 3. Remote infection with undetectable level of HBsAg 4. False positive test. <i>Note: Vaccination does not produce anti-HBc</i>	Patient is non-infectious in most settings (household, sexual, needlestick).
-	+	-	-	<ol style="list-style-type: none"> 1. Immune following vaccination 2. Resolved infection with loss of detectable anti-HBc 	Patient is immune.
-	-	-	-	Not infected Vaccinated with loss of anti-HBs	Patient is susceptible to HBV infection and should be vaccinated, if not already vaccinated.

Adapted from: Centers for Disease Control and Prevention. *Manual for the Surveillance of Vaccine-Preventable Diseases*. Centers for Disease Control and Prevention. Atlanta, GA, 2002.

Attachment B

Case Finding and Management of Hepatitis B Surface Antigen (HBsAg)-Positive Persons During Delivery of Vaccination Services

Chronically infected persons are at high risk for chronic liver disease and are a major reservoir of hepatitis B virus (HBV) infection. Foreign-born persons, especially persons from Africa, Asia, and the Pacific Islands, have high* rates of chronic HBV infection. During delivery of recommended hepatitis B vaccination services (e.g., HBsAg screening of pregnant women and serologic testing to assess susceptibility), vaccination providers will identify persons who are HBsAg-positive. These persons require counseling and medical management for chronic HBV infection to reduce their risk for chronic liver disease. Their susceptible household, sexual, and needle-sharing contacts also need to be vaccinated against hepatitis B. Few programs have been implemented to identify HBsAg-positive persons, to provide or to refer these persons to appropriate medical management, and to provide vaccination to their contacts.¹ Extending these services to persons identified as HBsAg-positive will help prevent serious sequelae in chronically infected persons and will enhance vaccination strategies for elimination of HBV transmission. This Attachment addresses case finding and management of persons with chronic HBV infection in the context of vaccine delivery. The recommendations are not intended to represent a comprehensive prevention program for chronically infected persons.

Case Finding in the Context of Vaccination Service Delivery

- ◆ All foreign-born persons (including immigrants, refugees, asylum seekers, and internationally-adopted children) born in Asia, the Pacific Islands, Africa, and other regions with high endemicity of HBV infection (see box below) should be tested for HBsAg, regardless of vaccination status.
 - For all persons born in high-endemic countries who are applying for permanent U.S. residence, HBsAg screening and appropriate follow-up on the basis of HBsAg test results should be included as part of the required overseas pre-migration and domestic adjustment-of-visa status medical examination process.² HBsAg-positive persons should be considered eligible for migration and adjustment-of-visa status, and they should be counseled and recommended for follow-up medical evaluation and management in U.S. resettlement communities.
 - Providers should identify children born in high endemic countries and should provide HBsAg testing and follow-up in all settings that provide health care. Retesting of persons who were tested for HBsAg in other countries should be considered.

Geographic Areas with High* Hepatitis B Virus Endemicity

Africa: All countries except Algeria, Egypt, Lybia, and Tunisia.

South Asia: All countries except Afghanistan, Bangladesh, Bhutan, India, Malaysia, Maldives, Nepal, Pakistan, and Sri Lanka.

Western Pacific: All countries except Australia, Guam, Japan, and New Zealand.

Middle East: Jordan and Saudi Arabia.

Eastern Europe and Newly Independent States of the former Soviet Union: Albania, Armenia, Azerbaijan, Bulgaria, Croatia, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Turkmenistan, and Uzbekistan.

Western Europe: Malta

North America: Alaska Natives and indigenous populations in Northern Canada and Greenland.

South America: Amazonian areas of Bolivia, Brazil, Columbia, Peru, and Venezuela.

* Hepatitis B surface antigen (HBsAg) prevalence of >8%.

- ◆ Other persons who should be tested for HBsAg as part of vaccination services include:
 - All pregnant women;
 - Persons who receive prevaccination testing for susceptibility and who test positive for anti-HBc;
 - Hemodialysis patients; and
 - Nonresponders to vaccination.

Management of Persons Identified as HBsAg-Positive

- ◆ All persons with HBsAg-positive laboratory results should be reported to the state or local health department.
- ◆ To verify the presence of chronic HBV infection, HbsAg-positive persons should be retested. The absence of immunoglobulin M (IgM) antibody to HBcAg or the persistence of HBsAg for six months indicates chronic HBV infection.
- ◆ Persons with chronic HBV infection should be referred to evaluation by a physician experienced in the management of chronic liver disease.³ Certain patients with chronic hepatitis B will benefit from early intervention with antiviral treatment or screening to detect hepatocellular carcinoma at an early stage.
- ◆ Household, sexual, and needle-sharing contacts of chronically infected persons should be identified. Unvaccinated sex partners and household and needle-sharing contacts should be tested for susceptibility to HBV infection and should receive the first dose of hepatitis B vaccine immediately after collection of the blood sample for serologic testing. Susceptible persons should complete the vaccine series using an age-appropriate vaccine dose and schedule. Persons who are not fully vaccinated should also complete the vaccine series.
- ◆ Sex partners of HBsAg-positive persons should be counseled to use methods (e.g., condoms) to protect themselves from sexual exposure to infectious body fluids (e.g., semen or vaginal secretions) unless they have been demonstrated to be immune after vaccination (i.e., anti-HBs ≥ 10 mIU/mL) or previously infected (anti-HBc positive).
- ◆ To prevent or reduce the risk for transmission to others, HBsAg-positive persons should be advised concerning the risks for:
 - Perinatal transmission to infants born to HBsAg-positive women and the need for such infants to receive hepatitis B vaccine beginning at birth; and
 - Transmission to household, sexual, and needle-sharing contacts and the need for such contacts to receive hepatitis B vaccine.
- ◆ HBsAg-positive persons should also be advised to:
 - Use methods (e.g., condoms) to protect non-immune sex partners from acquiring HBV infection from sexual activity until the sex partners can be vaccinated and immunity can be documented;
 - Cover cuts and skin lesions to prevent the spread of infectious secretions or blood;
 - Refrain from donating blood, plasma, tissue, or semen (organs may be donated to HBV-immune or chronically infected persons needing a transplant); and
 - Refrain from sharing household articles (e.g., toothbrushes, razors, or personal injection equipment) that could become contaminated with blood.
- ◆ To protect the liver from further harm, HBsAg-positive persons should be advised to:
 - Avoid or limit alcohol consumption because of the effects of alcohol on the liver;
 - Refrain from beginning to take any new medicines, including over-the-counter and herbal medicines, without consulting their health care provider; and
 - Obtain vaccination against hepatitis A if chronic liver disease is found to be present.
- ◆ When seeking medical or dental care, HBsAg-positive persons should be advised to inform those responsible for their care of their HBsAg status so they can be evaluated and their care can be managed appropriately.

◆ Other counseling messages:

- HBV is not spread by breastfeeding, kissing, hugging, coughing, ingesting food or water, sharing eating utensils or drinking glasses, or casual contact.
- Persons should not be excluded from school, play, childcare, work, or other settings on the basis of their HBsAg status, unless they are prone to biting.⁴
- Health care workers who are infected with HBV should keep in mind that their body fluids may be harmful to patients. However, no modification of patient care responsibilities is necessary. Affected individuals should follow all recommended infection control practices, including standard precautions and appropriate use of hand washing, protective barriers, and care in the use and disposal of needles and other sharp instruments.⁵
- Involvement with a support group might help patients cope with chronic HBV infection.

References

Weinberg, M.S., Gunn, R.A., Mast, E.E., Gresham, L., Ginsberg, M. Preventing Transmission of Hepatitis B Virus from People with Chronic Infection. *Am J Prev Med.* 2001; 20: 272–6.

CDC. Medical Examinations. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2005.
<www.cdc.gov/ncidod/dq/health.htm>.

Lok, A.S., McMahon, B.J. Chronic Hepatitis B. *Hepatology.* 2001; 34: 1225–41.

Shapiro, C.N., McCaig, L.F., Gensheimer, K.F. et al. Hepatitis B Virus Transmission between Children in Day Care. *Pediatr Infect Dis J.* 1989; 8: 870–5.

CDC. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. *MMWR.* 2001; 50(RR-11).

Attachment C

Delivery Hospital Policies and Procedures to Prevent Perinatal HBV Transmission

At Time of Admission for Delivery

- ◆ Review hepatitis B surface antigen (HBsAg) status of all pregnant women.
- ◆ Record maternal HBsAg test results on both labor and delivery record and on infant's delivery summary sheet.
- ◆ 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 (e.g., more than one sex partner in the previous six months, evaluation or treatment for a sexually transmitted disease, recent or current injection-drug use, or HBsAg-positive sex partner); or
 - Had clinical hepatitis since previous testing.

After Delivery

HBsAg-positive Mothers and Their Infants

- ◆ Administer single-antigen hepatitis B vaccine and hepatitis B immune globulin (HBIG) to all infants born to HBsAg-positive mothers ≤ 12 hours after birth, and record date and time of administration of HBIG and hepatitis B vaccine in infant's medical record.
- ◆ Provide information regarding hepatitis B to HBsAg-positive mothers, including:
 - Advice that they may breastfeed their infants upon delivery;
 - Modes of HBV transmission;
 - Need for vaccination of their susceptible household, sexual, and needle-sharing contacts;
 - Need for substance abuse treatment, if appropriate; and
 - Need for medical management and possible treatment for chronic hepatitis B.

Mothers with Unknown HBsAg Status and Their Infants

- ◆ Administer single-antigen hepatitis B vaccine (without HBIG) to all infants born to mothers with unknown HBsAg status ≤ 12 hours after birth and record date and time of administration of hepatitis B vaccine on infant's medical record.
- ◆ Alert infant's pediatric health-care provider if an infant is discharged before the mother's HBsAg test result is available; if the mother is determined to be HBsAg positive, HBIG should be administered to the infant as soon as possible, but no later than age seven days.

All Mothers and Their Infants

- ◆ Administer a dose of single-antigen hepatitis B vaccine to all infants weighing $\geq 2,000$ g.
- ◆ Ensure that all mothers have been tested for HBsAg prenatally or at the time of admission for delivery, and document test results.

At Time Infant is Discharged

- ◆ Provide infant's immunization record to mother, and remind her to take it to the infant's first visit to pediatric health-care provider.

Source: CDC. A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP); Part 1: Immunization of Infants, Children and Adolescents. *MMWR*. 2005; 54(RR-16): 15.

Attachment D

Massachusetts Department of Public Health (MDPH) Immunization Program

Hepatitis B Immunoprophylaxis Scheme for Infants¹

Maternal Status	Infant $\geq 2000\text{g}$	Infant $< 2000\text{g}$
HBsAg Positive	Hepatitis B vaccine + HBIG (within 12 hours of birth).	Hepatitis B vaccine + HBIG (within 12 hours of birth).
	Immunize with 3 doses of hepatitis B vaccine at 0, 1–2, and 6 months of chronologic age; ² or Complete the series with a hepatitis B containing combination vaccination after birth dose.	Immunize with 4 doses of hepatitis B vaccine at 0, 1–2, 2–3, and 6–7 months of chronologic age ³ ; or Complete the series with a hepatitis B containing combination vaccination after birth dose.
	Check anti-HBs and HBsAg at 9–18 months of age.	Check anti-HBs and HBsAg at 9–18 months of age.
	If infant is HBsAg and anti-HBs negative, re-immunize with 3 doses at 2-month intervals (9–15, 11–17, and 13–19 months of chronologic age), and retest for HBsAg and anti-HBs.	If infant is HBsAg and anti-HBs negative, re-immunize with 3 doses at 2-month intervals (9–15, 11–17, and 13–19 months of chronologic age), and retest for HBsAg and anti-HBs.
HBsAg Status Unknown	Hepatitis B vaccine within 12 hours of birth. Test mother for HBsAg immediately.	Hepatitis B vaccine within 12 hours of birth. Test mother for HBsAg immediately. If results are unavailable, administer HBIG by 12 hours.
	If mother tests HBsAg-positive, administer HBIG (within 7 days). Follow HBsAg-positive schedule for infants $\geq 2000\text{g}$.	If mother tests HBsAg-positive, make sure HBIG was administered, and follow HBsAg-positive schedule for infants $< 2000\text{g}$.
	Check anti-HBs and HBsAg at 9–18 months of age.	Check anti-HBs and HBsAg at 9–18 months of age.
	If mother tests negative, complete HBsAg negative schedule for infants $\geq 2000\text{g}$.	If mother tests negative, complete HBsAg negative schedule for infants $< 2000\text{g}$.
HBsAg Negative	Hepatitis B vaccine at birth preferred. ⁴	Hepatitis B vaccine dose 1 at age 1 month, or at hospital discharge.
	Immunize with 3 doses of hepatitis B vaccine at 0, 1–2, and 6–18 months of chronologic age. ²	Immunize with 3 doses of hepatitis B vaccine at 1–2, 2–4, and 6–18 months of chronologic age. ²
	May give hepatitis B containing combination vaccine beginning at 6–8 weeks of chronologic age.	May give hepatitis B containing combination vaccine beginning at 6–8 weeks of chronologic age.
	Follow-up anti-HBs and HBsAg testing not needed.	Follow-up anti-HBs and HBsAg testing not needed.

HBsAg indicates hepatitis B surface antigen; HBIG = hepatitis B Immune Globulin; anti-HBs = antibody to hepatitis B surface antigen.

¹ Extremes of gestational age and birth weight are no longer a consideration for timing of hepatitis B doses.

² Do not administer dose 3 before 24 weeks of age.

³ Do not administer dose 4 before 24 weeks of age.

⁴ The birth dose may be delayed only in rare circumstances if the mother's HBsAg-negative laboratory result and physician's order to withhold birth dose are included in the infant's medical record.

Sources:

American Academy of Pediatrics. [Hepatitis B.] In: Pickering L.K., ed. *Red Book: 2003 Report of the Committee on Infectious Diseases, 26th Edition*. Elk Grove Village, IL, American Academy of Pediatrics; 2003: 328.

CDC. A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP); Part 1: Immunization of Infants, Children and Adolescents. *MMWR*. 2005; 54(RR-16): 9.

CDC. FDA Licensure of Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, hepatitis B (Recombinant), and Poliovirus Vaccine Combinations, (PEDIARIX TM) for Use in Infants. *MMWR*. 2003; 52: 203–4.

CDC. Recommended Childhood and Adolescent Immunization Schedule—United States, January–June 2004. *MMWR*. 2004; 53Q1–4.

Sarri TN, and the Committee on Infectious Diseases. Immunization of Preterm and Low Birth Weight Infants. *Pediatrics*. 2003; 112: 193–8.



FORMS & WORKSHEETS

Hepatitis B

Hepatitis B



LBOH Action Steps

This form does not need to be submitted to the MDPH with the case report form. It is for LBOH use and is meant as a quick-reference guide to hepatitis B case investigation activities.

LBOH staff should follow these steps when hepatitis B is suspected or confirmed in the community. For more detailed information, including disease epidemiology, reporting, case investigation, and follow-up, please refer to the preceding chapter.

- Obtain a copy of all hepatitis B serologic test results for a suspect or confirmed case of hepatitis B infection. Hepatitis B serologic test results that should be reported are:
 - Hepatitis B surface antigen (HBsAg) positive;
 - Immunoglobulin M (IgM) antibody to hepatitis B core antigen (anti-HBc) positive;
 - Hepatitis B e antigen (HBeAg) positive;
 - Hepatitis B e antibody (anti-HBe) positive; or
 - Hepatitis B DNA (HBV DNA or PCR) positive.
- Because the process of obtaining information for a MDPH *Hepatitis B Case Report Form* can take time, mail or fax the laboratory report(s) to the MDPH Bureau of Communicable Disease Control, Office of Integrated Surveillance and Informatics Services (ISIS) within 24 hours, with a notation that a case report form will follow.
- Complete a MDPH *Hepatitis B Case Report Form*.
- Determine if the case is pregnant, and if so, complete a MDPH *Hepatitis B Case Report Form, Supplement A*. Include demographic and hepatitis B vaccination information about sexual and household contacts.
- If the case is pregnant or has recently given birth, notify the MDPH Immunization Program Perinatal Hepatitis B Nurse at (617) 983-6800 or (888) 658-2850 **as soon as possible**.
- Determine if the case is a child <5 years of age, and if so, complete a MDPH *Hepatitis B Case Report Form, Supplement B*.
- If the case is suspect or confirmed with *acute* hepatitis B, complete a MDPH *Hepatitis B Case Report Form, Supplement C*.
- Identify other potentially exposed persons, including household and sexual contacts, and recommend immunoprophylaxis when appropriate.
- Send the completed MDPH *Hepatitis B Case Report Form*, with laboratory reports attached and appropriate supplements, to ISIS.
 - Confidential fax: (617) 983-6813.
 - Mailing address:
MDPH, Office of Integrated Surveillance and Informatics Services (ISIS)
305 South Street, 5th Floor
Jamaica Plain, MA 02130