

HEPATITIS B SURVEILLANCE PROTOCOL

Public Health Action

1. Educate providers about appropriate use of the hepatitis B vaccine, especially in newborns and adolescents.
2. Educate the general public about hepatitis B risk factors, hepatitis B vaccine, and prevention of hepatitis B transmission.
3. Educate health care providers and laboratories to report hepatitis B surface antigen (HBsAg) positive or hepatitis B core IgM (HBc IgM) positive patients to the HIV/AIDS/STD Program at the West Virginia Bureau for Public Health (WVBPH) within 24 hours.
4. Within 24 hours of receiving a report of an HBsAg or HBcAb IgM positive patient, the HIV/AIDS/STD Program will assign the newly reported case to the appropriate Disease Investigation Specialist (DIS). Women of childbearing age who have previously been reported as HBsAg positive will be referred to the West Virginia Immunization Program to determine if they are pregnant. Within 24 hours of assignment, the DIS and the local health department should negotiate shared responsibilities to accomplish the following:
 - a. Contact the physician to determine if the patient meets the case definition for acute hepatitis B.
 - b. Ask if the patient is pregnant. If yes, notify the Perinatal Hepatitis B Coordinator at the Immunization Program immediately (1-800-642-3634).
 - c. If the patient meets the case definition for **acute hepatitis B infection**, complete a reportable disease case report card and the CDC hepatitis form, attach laboratory studies (including hepatitis A virus immunoglobulin M (HAV IgM), alanine transferase (ALT), HBsAg, HBcAb IgM, and hepatitis C testing results, if available), and send all documents to the HIV/AIDS/STD Program.
5. Investigate *forward* (to prevent disease in contacts):
 - a. Identify all **sexual contacts** and determine the date of last contact with the source patient. If the last contact with the patient is within 14 days, and the vaccine or immune status is not known:
 - i. Submit a blood sample from the contact(s) to the West Virginia Office of Laboratory Services (OLS) for a hepatitis B screen.
 - ii. Administer hepatitis B immunoglobulin (HBIG) and the first dose of hepatitis B vaccine to the contact(s).
 - iii. If hepatitis serologies are positive, stop the vaccination series and refer the patient for medical care. If serologies are negative, complete the full immunization series.
 - iv. Complete the tracking form and submit it to the HIV/AIDS/STD Program.
 - b. Identify all **needle sharing contacts** and determine the last contact with the source patient. If the date of the last needle sharing event with the source patient is within seven days, and vaccine and immune status are not known:
 - i. Submit a blood sample from the contact(s) to the OLS for a hepatitis B screen.

- ii. Administer HBIG as well as the first dose of hepatitis B vaccine to the contact(s).
 - iii. If hepatitis serologies are positive, stop the vaccination series and refer the patient for medical care. If serologies are negative, complete the full immunization series.
 - iv. Complete the tracking form and submit it to the HIV/AIDS/STD Program.
 - v. HBIG must be administered within a week after the last needle sharing event with the source patient.
- c. Identify all **household contacts** and determine if they have had any blood exposure to the source patient (e.g. shared razor, etc.). If a blood exposure is identified within 14 days:
- i. Draw a blood sample from the contact(s) and send it to the OLS for a hepatitis B screen.
 - ii. Administer HBIG and the first dose of hepatitis B vaccine to the contact(s).
 - iii. If hepatitis serologies are positive, stop the vaccination series and refer the patient for medical care. If serologies are negative, complete the full immunization series.
 - iv. Complete the tracking form and submit it to the HIV/AIDS/STD Program.
 - v. If the household contact is an infant and the mother or primary care giver has acute hepatitis B infection, administer HBIG and hepatitis B vaccine to the infant immediately. Complete the series for the infant. For partially or fully immunized infants, contact IDEP for an individualized recommendation.
 - vi. If the source patient is or becomes a hepatitis B carrier, all household contacts should receive the hepatitis B vaccine series.
- d. If the index patient is **pregnant**, the local health department should negotiate with the physicians and the West Virginia Immunization Program Hepatitis B Perinatal Coordinator to assure that all of the following occur:
- i. **Before birth:**
 - (1) The mother should be educated about hepatitis B.
 - (2) HBIG and a dose of hepatitis B vaccine should be shipped to the birthing facility in advance of the due date.
 - (3) Physician's orders should be written to assure that HBIG and the first dose of hepatitis B vaccine will be administered within 12 hours of birth of the infant.
 - (4) A pediatric immunization provider should be identified.
 - (5) The local health department and the Immunization Program should be notified when the child is delivered.
 - ii. **At birth:**
 - (1) Assure that HBIG and the first dose of hepatitis B vaccine are given and the immunization record is reported to the West Virginia Statewide Immunization Information System (WVSIIS).
 - (2) **Premature infants** born to HBsAg-positive mothers should receive hepatitis B vaccine and HBIG beginning at or shortly after birth.
 - (3) Again, assure that the child will be followed up by an immunization provider.
 - iii. **After birth:**
 - (1) Assure that the infant receives doses number two and three on schedule and that the immunization record is reported to the WVSIIS.
 - (2) Assure that HBsAg and HBsAb (check both "perinatal" and "postvaccination" on the form for OLS) are drawn three to nine

months after the third dose of hepatitis B vaccine (i.e. at nine to 15 months of age) and results are reported to the Immunization Program. If HBsAg is not present and anti-HBs antibody is present, children can be considered to be protected.

- (3) If HBsAb and HBsAg are negative, assure repetition of the series.
- (4) If HBsAg is positive, refer the infant for medical care.

6. For cases with **acute hepatitis B**, investigate *backward*, as follows:
 - a. Using a calendar, determine the incubation period for the case. The incubation period is six weeks to six months prior to the date of onset.
 - b. Collect information on all possible risk factors during the incubation period, and record it on the reportable disease case report card and the CDC hepatitis form. Discuss any unusual risk factors or clustering of risk factors with the West Virginia Infectious Disease Epidemiology Program (IDEP). Risk factors and possible risk factors include:
 - i. Contact with a person with suspected or confirmed HBV infection;
 - ii. Employment involving contact with human blood;
 - iii. Receipt of blood transfusion or blood products;
 - iv. Dialysis or kidney transplant patient;
 - v. Injecting drug use;
 - vi. Number of different male sexual partners;
 - vii. Number of different female sexual partners;
 - viii. Hospitalization and/or surgery;
 - ix. Intravenous infusions or injections received in outpatient settings;
 - x. Residence in a long term care facility (e.g. nursing home);
 - xi. Dental work/oral surgery;
 - xii. Accupuncture/tattooing/body piercing; and
 - xiii. Puncture with a needle or other object contaminated with blood.
 - c. Investigate vaccination history and record as part of the investigation, including:
 - i. Number of vaccine doses, dates(s) of vaccination, and post-vaccination test results, if available, and
 - ii. Missed opportunities for hepatitis B vaccination, including:
 - (1) Household or sex contact with an HBV-infected person;
 - (2) Ever in a correctional facility;
 - (3) Ever treated for a sexually transmitted disease; or
 - (4) Ever in treatment for injecting drug use.
7. For patients with chronic hepatitis B, record all action taken on the reportable disease case report card and submit it with copies of all lab tests to the HIV/AIDS/STD Program.
8. For patients with acute hepatitis B, record all action taken on the reportable disease case report card, and submit it with copies of all lab tests and the completed CDC supplemental form to the HIV/AIDS/STD Program.

Disease Prevention Objectives

1. Reduce the incidence of hepatitis B by:
 - a. Assuring full hepatitis B immunization of all infants.

- b. Assuring “catch-up” hepatitis B immunization of all adolescents at the adolescent visit.
 - c. Assuring full hepatitis B immunization of high-risk individuals to include:
 - i. Sexually active adolescents and adults (including adolescents in STD clinics);
 - ii. Household contacts and sexual partners of HBV carriers;
 - iii. Health care personnel and those who have occupational exposure to blood;
 - iv. Residents and staff of institutions for the developmentally disabled;
 - v. Hemodialysis patients;
 - vi. Recipients of certain blood products;
 - vii. International travelers;
 - viii. Injection drug users; and
 - ix. Inmates in long term correctional facilities.
2. Reduce the incidence of hepatitis B through community education and programs to prevent drug use and sharing of needles.
 3. Prevent nosocomial transmission of hepatitis B through effective infection control measures.
 4. Prevent transmission of hepatitis B through screening of blood and organ donors.

Disease Control Objectives

1. Identify and investigate community-based and nosocomial outbreaks of hepatitis B in a timely fashion so that appropriate control measures can be applied.
2. Reduce transmission from persons with hepatitis B infection including:
 - a. Perinatal transmission; and
 - b. Transmission to household, sexual, and drug-using partners.

Surveillance Objectives

1. Determine the incidence of acute hepatitis B in West Virginia.
2. Determine the risk factors associated with acute and chronic hepatitis B in West Virginia.
3. Determine the demographic characteristics of persons with acute and chronic hepatitis B.
4. Distinguish between failure to immunize (preventable cases) versus failure of vaccine (non-preventable cases) among the reason(s) for continued occurrence of hepatitis B.
5. Detect outbreaks, clusters, or unusual patterns of transmission of hepatitis B.
6. Estimate the annual number of newly diagnosed chronic cases of hepatitis B.

Public Health Significance

Hepatitis B is a vaccine preventable disease. When the vaccine was first introduced in 1982, it was recommended for high-risk groups (e.g. men who have sex with men, persons with multiple sexual partners or a history of a sexually transmitted disease, injection drug users, health care workers or persons with occupational exposure to blood, etc.). However, the number of cases of hepatitis B continued to increase after the vaccine was introduced. In 1991, universal infant immunization was instituted, followed by a recommendation for catch-up vaccination of adolescents in 1996. At this time, the incidence of hepatitis B is declining.

Chronic hepatitis B virus infection is associated with the development of hepatocellular carcinoma. In Southeast Asia, HBV infection is endemic and hepatocellular carcinoma is a common cause of cancer death. After launching a nationwide vaccination program in Taiwan to control hepatitis B, the HBsAg carrier rate in children declined from about 10% to 1% within 10 years of implementation. Concurrently, the average annual incidence of hepatocellular carcinoma per 100,000 children six to 14 years of age declined from 0.70 between 1981 and 1986; to 0.57 between 1986 and 1990; and to 0.36 between 1990 and 1994. The incidence of hepatocellular carcinoma in children six to nine years of age declined from 0.52 per 100,000 for those born between 1974 and 1984 to 0.13 per 100,000 for those born between 1984 and 1986. This was the first demonstration that mass vaccination could reduce the incidence of a specific cancer in humans.

According to the CDC, one of 20 persons in the U.S. has been infected with hepatitis B virus during their lifetime (about 12.5 million); one of 200 persons has chronic (lifelong) infection with hepatitis B virus (about 1.25 million); and 4,000 to 5,000 persons die each year from hepatitis B-related chronic liver disease (cirrhosis, liver cancer).

In the United States, children become infected with HBV through a variety of means. The risk of perinatal HBV infection among infants born to HBV-infected mothers ranges from 10% to 85% depending on each mother's hepatitis B e antigen (HBeAg) status. Infants who become infected by perinatal transmission have a 90% risk of chronic infection, and up to 25% will die of chronic liver disease as adults. Even when not infected during the perinatal period, children of HBV-infected mothers remain at high risk of acquiring chronic HBV infection by person-to-person horizontal transmission during the first five years of life. More than 90% of these infections can be prevented if HBsAg positive mothers are identified so that their infants can receive hepatitis B vaccine and hepatitis B immune globulin (HBIG) soon after birth.

Clinical Description

Signs and Symptoms of Acute Disease

Typical symptoms include tiredness, headache, loss of appetite, nausea, vomiting, fever, and chills with onset three to 10 days prior to jaundice. Right upper quadrant pain is common. Urine may become dark, and stools may become clay-colored. The hallmark of the disease is jaundice (yellow color of the skin and sclera). Infants and children are usually asymptomatic, and an estimated 50% of adults with acute HBV are asymptomatic.

Fulminant hepatitis occurs in very few patients and is usually fatal. Duration of illness is usually several weeks, with symptoms occasionally persisting beyond three to four months.

Signs and Symptoms of Chronic Infection

Ninety to ninety-four percent of adults with acute HBV will develop protective antibodies within six months of the infection. A small proportion (6-10%) of adult patients with acute HBV will develop chronic infection. Most persons with chronic infection will not have symptoms but will continue to be infectious. Complications of chronic hepatitis B infection may include cirrhosis and hepatocellular carcinoma.

Etiologic Agent

HBV is a small double-stranded DNA virus. The outer protein coat contains the hepatitis B surface antigen.

Reservoir

This virus is found only in humans. Chimpanzees are susceptible, but an animal reservoir in nature has not been identified.

Mode of Transmission

In the United States, the most common risk factor for transmission of HBV is sexual contact with an infected person; however, the greatest risk for development of chronic infection is through perinatal transmission. The hepatitis B virus is also transmitted by parenteral or mucosal exposure to body fluids containing the virus. Breaks in the skin, such as scratches, abrasions, and burns, may serve as routes for the virus to enter the body.

The virus can be found in blood, body fluids (e.g. wound exudates), semen, cervical fluid, and saliva of persons who are HBsAg positive. Blood and serous fluids have the highest concentration of virus, and saliva the lowest.

Person-to-person transmission may occur in household settings. In these settings, non-sexual transmission occurs predominantly from child to child, and young children are at highest risk. The precise mechanism for child to child transmission is not known; however, frequent personal contact between non-intact skin or mucous membranes with blood containing secretions or, perhaps, saliva, are possible mechanisms. Transmission from sharing inanimate objects may also occur because HBV can survive at ambient temperature for one week or longer.

Incubation Period

The incubation period is usually 45 to 180 days, with an average of 60 to 90 days. Time to detection of HBsAg can be as short as two weeks or as long as six to nine months, depending on inoculum, host factors, and other variables.

Infectious Period

All persons who are HBsAg positive are potentially infectious. The presence of HBeAg is associated with a very high level of infectivity.

Case Definition for Acute Hepatitis B

Clinical Description

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

Laboratory Criteria for Diagnosis

- IgM antibody to hepatitis B core antigen (anti-HBc) positive or hepatitis B surface antigen (HbsAg) positive.
- IgM anti-HAV negative (if done).

Case Classification

Confirmed: a case that meets the clinical case definition and is laboratory confirmed.

Comments

Persons who have chronic hepatitis or persons identified as HBsAg positive should not be reported as having acute viral hepatitis unless they have evidence of an acute illness compatible with viral hepatitis (with the exception of perinatal hepatitis B infection).

Delta hepatitis is not a nationally notifiable disease.

Case Definition for Perinatal HBV Infection

Clinical Description

Perinatal HBV infection in a newborn can range from asymptomatic to fulminant hepatitis.

Laboratory Criterion for Diagnosis

Hepatitis B surface antigen (HBsAg) positive.

Case Classification

Confirmed: HBsAg positivity in any infant >1 month old to 24 months old who was born in the United States or in U.S. territories to an HBsAg-positive mother.

Laboratory Testing

The table below is adapted from Mandell (Principles and Practice of Infectious Diseases, Fifth Edition). It is a quick guide to interpretation of hepatitis B serologies. It is important to

recognize that unusual or inconsistent serologies are frequently reported. If in doubt about the patient diagnosis based on the laboratory results, it is often useful to repeat the testing.

Stage of Infection	HBsAg	Anti-HBsAg	IgG Anti-HBc	IgM Anti-HBc	HBeAg	Anti-HBeAg
Late incubation period of hepatitis B (person is infectious but symptoms have not yet developed)	+	-	-	-	+/-	-
Acute hepatitis B	+	-	+	+	+	-
Chronic HBV (sometimes called a healthy carrier since virus is not replicating at a rapid rate)	+	-	+	+/-	-	+
Chronic HBV (positive HBeAg indicates higher degree of infectivity)	+	-	+	+/-	+	-
Recent HBV infection	-	+	+	+/-	-	+
Remote HBV infection	-	+/-	+/-	-	-	-
Recent HBV vaccination	-	+	-	-	-	-

To send specimens to the OLS, collect the blood in a red top tube or a red and gray striped tube. Complete the hepatitis form and enclose it with the specimen. OLS offers three choices for testing:

- “Perinatal” will give HBsAg results.
- “Screen” will give HBsAg, HBc Ab total. Other tests will be run if either or both of the screen markers are positive. Other markers possible are: IgM to HBc, antiHBsAg, confirmation of HBsAg.
- “Postvaccine” will give anti-HBsAg or antibody to HBsAg.

To get HBsAg and anti-HBsAg, check “perinatal” and “postvaccination.”

Preventive Interventions

Hepatitis B vaccine is a very safe and effective vaccine for prevention of hepatitis B, and it is recommended for all babies, for adolescents who have not already had the vaccine, and for people who are at risk for hepatitis B:

- Babies who are born to a mother who is HBsAg positive;
- People who have a job that involves contact with blood and blood products;
- Injection drug users;
- Sexually active persons who have had more than one partner in the last six months or who have a sexually transmitted disease;
- Sexually active men who have sex with men;

- Household contacts and sexual partners of persons who are chronically HBsAg-positive;
- Residents and staff of institutions for developmentally disabled persons;
- Staff of nonresidential child care 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;
- Members of households with adoptees who are HBsAg-positive;
- International travelers to areas in which HBV infection is of high or intermediate endemicity;
- Inmates of juvenile detention and other correctional facilities.

Treatment

Patients should check with their doctor about treatment for chronic hepatitis B. No specific therapy for acute HBV infection is available. In chronically infected adults, interferon alpha has been demonstrated to induce a long-term remission in 25% to 40% of treated patients. The drug has been less effective for chronic infections acquired during early childhood. Lamivudine is also licensed for treatment of chronic HBV infection in adults, but no data are available for use in children.

Surveillance Indicators

- The proportion of acute cases with complete risk factor information.
- The proportion of acute cases with complete demographic data.
- The proportion of pregnant mothers for whom hepatitis B surface antigen status is known.
- The proportion of infants born to hepatitis B surface antigen positive mothers who receive at least three doses of hepatitis B vaccine before seven months of age.
- The proportion of infants born to HBsAg positive mothers who have blood drawn for anti-HBsAg and HBsAg.
- The number of household, sexual contact, and needle sharing contacts identified per case.
- The proportion of contacts of acute and previously unreported chronic cases that have complete information on the hepatitis B immunization status or missed opportunities.