

# Hepatitis B

(Acute, Chronic, Perinatal)

## **DISEASE REPORTABLE WITHIN 24 HOURS OF DIAGNOSIS**

Per N.J.A.C. 8:57, healthcare providers and administrators shall report by mail or by electronic reporting within 24 hours of diagnosis, confirmed cases of all acute and chronic infections, including positive hepatitis B tests in pregnant women, to the health officer of the jurisdiction where the ill or infected person lives, or if unknown, wherein the diagnosis is made. A directory of local health departments in New Jersey is available at <http://www.state.nj.us/health/lh/community/>

If the health officer is unavailable, the healthcare provider or administrator shall make the report to the Department by telephone to 609-826-5964, between 8:00 A.M. and 5:00 P.M. on non-holiday weekdays or to 609-392-2020 during all other days and hours.



## Hepatitis B

# 1 THE DISEASE AND ITS EPIDEMIOLOGY

### A. Etiologic Agent

The hepatitis B virus (HBV) is a DNA virus in the family *Hepadnaviridae*. HBV contains numerous antigenic components, including hepatitis B surface antigen (HBsAg), hepatitis B core antigen (HBcAg), and hepatitis B e antigen (HBeAg).

### B. Clinical Description and Laboratory Diagnosis

The clinical course of acute HBV infection is indistinguishable from that of other types of acute viral hepatitis. The incubation period ranges from 45 to 160 days (average of 120 days). Clinical signs and symptoms occur more often in adults than in infants or children, who usually have an asymptomatic acute course. However, approximately 50% of adults who have acute infections are asymptomatic. The pre-icteric, or prodromal phase from initial symptoms to onset of jaundice usually lasts from 3 to 10 days. It is nonspecific and is characterized by insidious onset of malaise, anorexia, nausea, vomiting, right upper quadrant abdominal pain, fever, headache, myalgia, skin rashes, arthralgia and arthritis, and dark urine, beginning 1 to 2 days before the onset of jaundice. The icteric phase is variable but usually lasts from 1 to 3 weeks and is characterized by jaundice, light or gray stools, hepatic tenderness and hepatomegaly (splenomegaly is less common). During convalescence, malaise and fatigue may persist for weeks or months, while jaundice, anorexia, and other symptoms disappear. Most acute HBV infections in adults result in complete recovery with elimination of HBsAg from the blood and the production of anti-HBs, creating immunity to future infection.

Approximately 1% to 2% of acutely infected persons develop fulminant hepatitis with a case-fatality rate of 63% to 93% (about 200 to 300 Americans each year).

The risk of chronic infection decreases with age at infection. As many as 90% of infants infected at birth (perinatal infection) develop chronic HBV infection, compared with 30% to 50% of children infected between one and five years of age and average of 5% 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 liver cancer (primary hepatocellular carcinoma) later in life. Approximately 25% of those infected during early childhood will ultimately die at an early age from the complications of cirrhosis and liver cancer.

Serologic markers of HBV infection vary depending on whether the infection is acute or chronic. Please see Table 1. for assistance with interpretation of HBV laboratory results. In addition, detection of HBV DNA within the blood can assist with diagnosis.

### C. Reservoirs

Humans are the only natural hosts.

## D. Modes of Transmission

HBV is transmitted by parenteral or mucosal exposure to HBsAg-positive body fluids from persons who have acute or chronic HBV infection. The highest concentrations of virus are in blood and serous fluids; lower titers are found in other fluids, such as saliva, tears, urine, and semen. Semen is a vehicle for sexual transmission other types of exposure, e.g., to saliva through kissing, are unlikely modes of transmission. There have been reports of transmission of HBV with human bites, likely to be from blood contamination rather than saliva itself. Transmission of HBV via tears, sweat, urine, stool, or droplet nuclei has not been clearly documented.

In the United States, the most important routes of transmission are perinatal and sexual contact, either heterosexual or homosexual, with an infected person. Fecal-oral transmission does not appear to occur. However, transmission occurs among men who have sex with men, possibly via contamination from asymptomatic rectal mucosal lesions. In the past two decades, outbreaks of hepatitis B have occurred in long-term care facilities (e.g., assisted living facilities and nursing homes) as the result of lack of infection control practices related to blood glucose monitoring.

Hepatitis B virus remains infectious for at least 7 days on environmental surfaces and is transmissible in the absence of visible blood. Direct percutaneous inoculation of HBV by needles during injection-drug use is an important mode of transmission. Breaks in the skin without overt needle puncture, such as fresh cutaneous scratches, abrasions, burns, or other lesions, may also serve as routes for entry. Nosocomial exposures such as transfusion of blood or blood products, hemodialysis, use of meters and lancets for glucose monitoring, insulin pens, and needle-stick or other “sharps” injuries sustained by hospital personnel have all resulted in HBV transmission. Rare transmission to patients from HBsAg-positive healthcare personnel has been documented. Outbreaks have been reported among patients in dialysis centers in many countries through failure to adhere to recommended infection control practices against transmission of HBV and other blood-borne pathogens in these settings. Immune globulin preparations, heat-treated plasma protein fraction and albumin are considered safe. In the past, outbreaks have been traced to tattoo parlors, acupuncturists, and barbers.

Contamination of mucosal surfaces with infective serum or plasma may occur during mouth pipetting, eye splashes, or other direct contact with mucous membranes of the eyes or mouth, such as hand-to-mouth or hand-to-eye contact when hands are contaminated with infective blood or serum. Transfer of infective material to skin lesions or mucous membranes via inanimate environmental surfaces may occur by touching surfaces of various types of hospital equipment. Contamination of mucosal surfaces with infective secretions other than serum or plasma could occur with contact involving semen.

Perinatal transmission from mother to infant at birth is very efficient. In the absence of postexposure prophylaxis, if the mother is positive for both HBsAg and HBeAg, approximately 85% of infants will become infected; if the mother is only HBsAg positive the rate of transmission is about 30%. With postexposure prophylaxis, comprised of HepB vaccine and HBIG at birth, followed by completion of the HepB vaccine series, 0.7%–1.1% of infants develop infection. As many as 90% of infant HBV infections will progress to chronic infection.

### **E. Incubation Period**

The incubation period of HBV infection is an average of 90 days, with a range of 45 to 160 days.

### **F. Period of Communicability or Infectious Period**

A person is considered infectious as long as HBsAg is detectable in the blood. Most people are infectious from one to two months before to one to two months after the onset of symptoms. Persons who have chronic HBV infection (known as carriers) remain infectious indefinitely. Persons with acute and chronic HBV infection with circulating HBeAg are more infectious than are those that are HBeAg-negative. Measurable serologic levels of HBeAg are associated with higher levels of HBV replication.

### **G. Epidemiology**

The frequency of infection and patterns of transmission vary in different parts of the world. Approximately 45% of the global population live in areas with a high prevalence of chronic HBV infection (8% or more of the population is HBsAg positive), 43% in areas with a moderate prevalence (2% to 7% of the population is HBsAg positive), and 12% in areas with a low prevalence (less than 2% of the population is HBsAg positive).

In China, Southeast Asia, most of Africa, most Pacific Islands, parts of the Middle East, and the Amazon Basin, 8% to 15% of the population carry the virus. The lifetime risk of HBV infection is greater than 60%, and most infections are acquired at birth or during early childhood, when the risk of developing chronic infections is greatest. In these areas, because most infections are asymptomatic, very little acute disease related to HBV occurs, but rates of chronic liver disease and liver cancer among adults are very high. In the United States, Western Europe, and Australia, HBV infection is a disease of low endemicity. Infection occurs primarily during adulthood, and only 0.1% to 0.5% of the population are chronic carriers. Lifetime risk of HBV infection is less than 20% in low prevalence areas.

## **2 REPORTING CRITERIA AND LABORATORY TESTING SERVICES**

### **A. What to report to the New Jersey Department of Health**

Report any of the following labs:

- 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 DNA (HBV DNA or PCR positive)

## B. New Jersey Department of Health Case Definitions

Hepatitis B cases are reported by states to Centers for Disease Control and Prevention (CDC) through the National Notifiable Diseases Surveillance System (NNDSS). The New Jersey Department of Health (NJDOH) Vaccine Preventable Disease Program follows the most current case definition as published on the CDC NNDSS website. For the most recent case definitions please visit:

<https://wwwn.cdc.gov/nndss/conditions/search/hepatitis+B/>

### 1. Acute HBV Infection

An acute illness with

- A discrete onset of any sign or symptom\* consistent with acute viral hepatitis (e.g., fever, headache, malaise, anorexia, nausea, vomiting, diarrhea, and abdominal pain), AND either
  - Jaundice OR
  - Elevated serum alanine aminotransferase levels (ALT) > 100 IU/L

\*A documented negative hepatitis B surface antigen (HBsAg) laboratory result within 6 months prior to a positive test (either HBsAg, hepatitis B “e” antigen (HBeAg), or hepatitis B virus nucleic acid testing (HBV NAT) including genotype) result does not require an acute clinical presentation to meet the surveillance case definition.

### Laboratory Criteria for Diagnosis

- Hepatitis B surface antigen (HBsAg) positive

**AND**

- Immunoglobulin M (IgM) antibody to hepatitis B core antigen (IgM anti-HBc) positive (if done)

### Case Classification

#### **CONFIRMED**

A case that meets the clinical case definition, is laboratory confirmed, and is not known to have chronic HBV infection.

#### **PROBABLE**

Not used

#### **POSSIBLE**

Not used

## 2. Chronic HBV Infection

### Clinical Description

No symptoms are required. Persons with chronic hepatitis B virus (HBV) infection may have no evidence of liver disease or may have a spectrum of disease ranging from chronic hepatitis to cirrhosis or liver cancer.

### Laboratory Criteria for Diagnosis

- IgM antibodies to hepatitis B core antigen (HBcAb-IgM) negative

### AND

- a positive result on one of the following tests:
  1. Hepatitis B surface antigen (HBsAg)
  2. Hepatitis B e antigen (HBeAg)
  3. Hepatitis B virus (HBV) DNA (including qualitative, quantitative and genotype testing)

### OR

- HBsAg positive or HBV DNA-positive (including qualitative, quantitative and genotype testing) or HBeAg positive two times at least 6 months apart (Any combination of these tests performed six months apart is acceptable.)

### Case Classification

#### CONFIRMED

A person that meets either of the above laboratory criteria for diagnosis.

#### PROBABLE

A person with a single HBsAg positive or HBV DNA positive (including qualitative, quantitative and genotype testing) or HBeAg positive lab result and does not meet the case definition for acute hepatitis B.

#### POSSIBLE

Not used

#### COMMENT

Multiple laboratory tests indicative of chronic HBV infection may be performed simultaneously on the same patient specimen as part of a "hepatitis panel." Testing performed in this manner may lead to seemingly discordant results, e.g., HBsAg-negative **AND** HBV

DNA-positive. For the purposes of this case definition, any positive result among the three laboratory tests mentioned above is acceptable, regardless of other testing results. Negative HBeAg results and HBV DNA levels below positive cutoff level do not confirm the absence of HBV infection.

### **Negative Lab tests**

Negative labs that are part of the case definition can be entered in the laboratory section of Communicable Disease Surveillance and Reporting System (CDRSS). If the lab test is not available in CDRSS enter that result as a comment in the Laboratory and Diagnostic Test Information section in CDRSS.

Liver enzymes or liver bilirubin levels results should also be entered in CDRSS.

## **3. Perinatal HBV Infection**

### **Clinical Case Definition**

Perinatal HBV infection in a child  $\leq 24$  months of age may range from asymptomatic to fulminant hepatitis.

### **Laboratory Criteria for Diagnosis**

Laboratory evidence of HBV infection in an infant consists of one or more of the following:

- positive hepatitis B surface antigen (HBsAg) test (only if at least 4 weeks after last dose of Hep B vaccine)
- positive hepatitis B e antigen (HBeAg) test
- detectable HBV DNA

### **Case Classification**

#### **CONFIRMED**

Child born in the US to a HBV-infected mother and positive for HBsAg at  $\geq 1$  month of age and  $\leq 24$  months of age

#### **OR**

positive for HBeAg or HBV DNA  $\geq 9$  months of age and  $\leq 24$  months of age

#### **PROBABLE**

Child born in the US whose mother's hepatitis B status is unknown (i.e. epidemiologic linkage not present) and positive for HBsAg at  $\geq 1$  month of age and  $\leq 24$  months of age

#### **OR**

positive for HBeAg or HBV DNA  $\geq 9$  months of age and  $\leq 24$  months of age

#### **POSSIBLE**

Not used

**COMMENT**

Infants born to HBV-infected mothers should receive HBIG and the first dose of HepB vaccine within 12 hours of birth, followed by the second and third doses of HepB vaccine at 1 and 6 months of age, respectively. Postvaccination serologic testing (PVST) for HBsAg and anti-HBs is recommended 1 to 2 months following completion of the vaccine series, not earlier than 9 months of age and before or at 12 months of age.

If the mother is known to not be infected with HBV, refer to the case definition for acute Hepatitis B.

**C. Laboratory Testing Services Available**

The New Jersey Department of Health (NJDOH) Public Health Environmental Laboratories (PHEL) does not perform routine laboratory testing for HBV for the general public. Testing is usually conducted through hospital and/or private commercial laboratories.



# 3 DISEASE REPORTING AND CASE INVESTIGATION

## A. Purpose of Surveillance and Reporting

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

## B. Laboratory and Healthcare Provider Reporting Requirements

The New Jersey Administrative Code (N.J.A.C. 8:57) stipulates that laboratories report (by telephone, confidential fax, over the Internet using the CDRSS, or in writing) all cases of HBV infection (acute, chronic, and HBsAg-positive pregnant woman) to the local health officer having jurisdiction over the locality in which the patient lives or, if unknown, to the health officer in whose jurisdiction the healthcare provider requesting the laboratory examination is located. The healthcare providers must report all above cases to the local health officer having jurisdiction over the locality in which the patient lives.

## C. Local Health Department Reporting and Follow-Up Responsibilities

### 1. Reporting Requirements

N.J.A.C. 8:57 stipulates that each local health officer must report the occurrence of acute and chronic HBV infection.

### 2. Case Investigation

- a. The health officer (or his/her designee) is responsible for investigating HBV cases. If a laboratory report is received by NJDOH, the report will be sent to the local health department (LHD) for data entry in CDRSS and case investigation is the responsibility of the LHD. If the patient address is not listed on the lab report, contact the lab or healthcare provider for a complete patient address. The primary objective is to determine if the patient has acute or chronic disease; as well as establishing current pregnancy status for all women of childbearing age (15-55 years old).
- b. Local health agencies must recognize and investigate cases of acute HBV, newly diagnosed chronic HBV and perinatal HBV infection to identify clusters or outbreaks, provide counseling and ensure appropriate prophylaxis of contacts including neonates. In order to better focus efforts, individuals with isolated HBcAb-Total, HBeAb or Anti-HBs do not need to be entered into CDRSS and do not require investigation. **Individuals with HBsAg, HBeAg, HBcAb-IgM and all HBV DNA** testing results including genotyping must be entered into CDRSS and must be investigated.
- c. Correct interpretation of HBV serology will guide the public health investigation.

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- d. For interpretation of HBV serology, refer to Table 1. In addition, the investigator may need to contact the physician to obtain clinical information to determine if the case is a newly diagnosed acute or a previous or newly diagnosed chronic HBV infection. **The pregnancy status for HBV positive women aged 15 to 55 must also be investigated and documented in the case for each new positive laboratory result (including HBsAg, HBV DNA, HBeAg and HBcAb-IgM) entered into CDRSS.** Pregnancy findings are entered in CDRSS and this includes NO, not pregnant.
- e. When case findings indicate the patient is pregnant, indicate YES in the pregnancy status section; also provide estimated date of delivery (EDD) and hospital delivery site in the section where indicated. This information is required for perinatal case management.
- f. A case report form (CDS-37) is available at <http://web.doh.state.nj.us/apps2/forms> and can be used as needed by the LHD to assist in obtaining specific case information.
- g. Use the following guidelines in completing a case report: If possible, accurately record the date and time of the onset of illness and symptoms to establish the incubation period for acute HBV infection (six weeks to six months and determine sexual and household contacts). Do not enter arbitrary dates of onset, if unknown leave blank. Some patient information is sensitive in nature. When contacting the patient, reassure them that all information is kept strictly confidential and is obtained only to determine his/her likely source of exposure and to protect others who might be at risk of infection. Persons with acute infection are considered to be infectious for up to 2 months before and 2 at least months after diagnosis (if individual becomes a chronic carrier, infectiousness may be indefinite). Transmission is through blood or body fluids. If a case is determined to be an acute infection, the following questions should be asked regarding a time period of six weeks to six months prior to illness onset. Note that the questions are associated with risk factors for HBV transmission. If a risk factor is determined, indicate so in CDRSS.
- h. Institution of disease control measures is an integral part of case investigation. It is the local health officer's responsibility to understand and, if necessary, institute the control guidelines listed below in section 4, Controlling Further Spread.
- i. Investigation of infants (aged 1 to 24 months) with HBV serology indicating infection, and not immunity from HBV vaccination, should be promptly investigated to
  - 1) determine HBsAg status of the birth mother,
  - 2) verify the infant's and the mother's country of birth,
  - 3) verify HBV postexposure prophylaxis consisting of HBIG and HBV vaccination within 12 hours of birth, and
  - 4) Verify the dose dates for administration of the second and third HBV vaccination (in some cases a fourth vaccination will be necessary dependent upon the type of vaccine used). Document case findings for vaccination in CDRSS.
  - 5) Obtain from the provider who administered the vaccine to the child, the vaccine lot numbers of each HBV vaccine dose. Enter this information in CDRSS.

- j. Sexual, household or other at-risk contacts of acutely infected persons should be referred to their medical provider for HBV serology and/or HBV vaccination.
- k. In cases of persons with an acute infection that may be associated with a healthcare procedure or healthcare institution immediately notify your health officer, your regional epidemiologist and the state health department. This approach will ensure coordination of investigation.
- l. All information should be recorded appropriately into CDRSS in the specific sections for that information. When a specific section does not exist information should be entered as a comment.

#### D. Other Reporting/Investigation Issues

1. Laboratory-confirmed or healthcare-provider-reported cases of chronic HBV infection **previously reported** in CDRSS and classified as “CONFIRMED” should be managed in CDRSS as follows:
  - a. Verify that the case meets the case definition for confirmed and has been previously investigated and closed. If the case does meet CDC case definition for chronic and is not a female of reproductive age (15 to 55 years) then the new lab does not have to be entered in CDRSS. Duplicative positive HBV serology data that does not change the case definition does not need to be entered in CDRSS. The patient may be under medical care and have frequent HBV serology completed; this does not change the CDC case definition. The case is not required to be investigated, however if the LHD chooses to contact the patient, they may do so.
  - b. Request to reopen CDRSS cases of females of reproductive age (15 to 55 years) when a new HBsAg-positive serology/lab is received. **The LHD is required to investigate the case to determine pregnancy status.** Indicate the pregnancy status as “YES” or “NO” in the CDRSS case. CDRSS will open automatically reopen cases for labs of females between the ages of 15 - 55 years (or persons with unknown gender) so pregnancy status can be indicated.
2. Laboratory profiles suggestive of past infection (positive HBc-IgG and negative HBsAg) or immunity (positive Anti-HBs, negative HBsAg) do not need to be entered in CDRSS, if they have been entered, no investigation is required. Classify the case as “NOT A CASE” in CDRSS. Please note that individuals with these lab profiles do not need to be entered into CDRSS.
3. Out-of-state cases should be classified as “Out of State, Not a New Jersey resident. NJDOH will complete an interstate notification.
4. Once LHD completes its investigation and assigns a report status of “LHD CLOSED,” NJDOH will review the case. NJDOH will approve the case by changing the report status to “DHSS APPROVED.” At this time, the case will be submitted to the CDC and the case will be locked for editing. If additional information is received after a case has been placed in “DHSS APPROVED,” you will need to contact NJDOH CDRSS help desk to reopen the case. This should be done only if the additional information changes the case status of the report.

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5. Every effort should be made to complete an HBV investigation. Contact the physician who ordered the lab test to determine the diagnosis or to obtain additional information. Contact the patient after contacting the physician to ensure the patient has been informed by the healthcare provider of the diagnosis. If, upon completion of the investigation, it is determined that the case meets the case definition for an acute, chronic, or perinatal infection, assign the appropriate case status. You do not need to send paperwork to NJDOH.
6. If, upon completion of the investigation, it is determined that the case does not meet case definition, the case status should be changed to "NOT A CASE." You do not need to send paperwork to NJDOH.
7. If a case has been found to be entered in CDRSS in duplicate merge the cases.

## E. Case Management

### 1. Pregnant Women

The NJDOH Perinatal Hepatitis B Prevention Project is responsible for coordinating activities related to the prevention of perinatal transmission of HBV. LHDs assume the lead role in their jurisdiction for case management and timely and appropriate follow-up of the child of the HBsAg-positive mother to ensure completion of postexposure prophylaxis at the hospital, the HBV vaccine doses and postvaccination serologic testing. LHD should also complete case investigation to identify and refer the sexual partner and other identified susceptible household contacts for HBV testing and/or HBV vaccination. Perinatal HBV case management is comprehensive and it also includes counseling the pregnant woman.

All pregnant women should be tested by the prenatal provider for HBsAg at the earliest prenatal visit. Women who are identified as HBsAg positive must be entered in CDRSS for case management. These women should also be tested for HBV DNA to guide the use of maternal antiviral therapy during pregnancy. HBsAg positive women should consult with their physicians to facilitate this testing and/or treatment. Later when the child is born, the newborn should be entered in CDRSS as a perinatal case. The newborn should be linked to the mother's case as a contact in CDRSS.

For infants born to an HBsAg positive mother who are subsequently placed in a foster home, notify the NJDOH Perinatal Hepatitis B Prevention Program staff for assistance.

When the newborn's case is created in CDRSS document the administration dates for HBIG and the birth dose of HBV vaccine, the newborn's birth weight and insurance type (public (Medicaid), private, uninsured or unknown). The case should remain open until completion of case management. Perinatal cases can stay open in CDRSS as a possible/LHD open for 24 months after case's date of birth. Perinatal case management includes documentation in of the subsequent HBV vaccine series doses (depending on vaccine type) and postvaccination serology that is completed 1-2 months after the last HBV dose, no earlier than 9 months of age and recommended to be completed by 12 months of age. Postvaccination serologic testing includes quantitative hepatitis B surface antibody (anti-HBs) and qualitative hepatitis B surface antigen (HBsAg) tests. The lab results for postvaccination serologic testing must be entered in CDRSS. Infants who successfully complete the HBV

vaccine series and develop antibodies, are anti-HBs positive ( $\geq 10$  mIU/mL) and HBsAg negative, can have their cases closed and classified as “NOT A CASE”, antibodies detected.

Infants who have infection will have serology that is HBsAg positive and anti-HBs negative ( $< 10$  mIU/mL). These labs are entered in the case and the case is confirmed as a perinatal infection; close case as a “CONFIRMED.”

For non-responders to HBV vaccine see section 4 B.

For questions or additional information about perinatal case management contact the Program at 609-826-5964.

# 4 CONTROLLING FURTHER SPREAD

## A. Isolation and Quarantine Requirements (N.J.A.C. 8:57)

The current recommendations of the CDC and NJDOH are as follows:

### Minimum Period of Isolation of Patient

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

### Minimum Period of Quarantine of Contacts

High-risk contacts should receive HBIG and the HBV vaccine series. Infants born to HBV infected women should also receive HBIG and the HBV vaccine series.

## B. Post-exposure Prophylaxis

Products available for postexposure prophylaxis include HBIG and HBV vaccine series.

### 1. Infants Born to HBsAg-positive mothers

- a. Give HBIG (0.5 mL IM) and HBV vaccine (0.5 mL IM) at separate injection sites within 12 hours of birth .
- b. Screen the infant for HBsAg and anti-HBs 1-2 months after receiving final dose of HBV vaccine, no earlier than 9 months of age and before or at 12 months of age. If HBsAg is negative and anti-HBs concentration is 10 mIU/mL or greater, the infant is considered to have protective antibodies and is considered immune to HBV.
- c. HBsAg-negative infants with anti-HBs <10 mIU/mL should be revaccinated with a single dose of HepB vaccine and receive postvaccination serologic testing 1–2 months later. Infants whose anti-HBs remains <10 mIU/mL following single dose revaccination should receive two additional doses of HepB vaccine to complete the second series, followed by postvaccination serologic testing 1–2 months after the final dose. Based on clinical circumstances or family preference, HBsAg-negative infants with anti-HBs <10 mIU/mL may instead be revaccinated with a second, complete 3-dose series, followed by postvaccination serologic testing performed 1–2 months after the final dose of vaccine. Available data do not suggest a benefit from administering additional HepB vaccine doses to infants who have not attained anti-HBs ≥10 mIU/mL following receipt of two complete HepB vaccine series.
- d. Infants who become HBsAg positive should be referred for comprehensive medical management. Ensure the laboratory data (positive HBsAg and negative anti-HBs (<10mIU/mL)) is entered in the CDRSS and case is confirmed as a perinatal infection.
- e. Infants born to mothers with unknown HBsAg status should be given HBV vaccine within 12 hours of birth while awaiting the mother's HBsAg status. If the mother is HBsAg positive, the infant should receive HBIG as soon as possible and no later than 7 days after birth. This child should then complete the HBV vaccine series per ACIP recommendations. Upon completion of the vaccine series, the infant should be complete lab testing for HBsAg and anti-HBs as defined

above. If the mother is determined to be HBsAg negative, the infant should complete the HBV vaccine series per ACIP recommendations.

- f. Because of potentially decreased immunogenicity of vaccine in infants with birth weight less than 2,000 grams whose mother's HBsAg status is unknown should receive hepatitis B vaccine within 12 hours of birth. If the maternal HBsAg status cannot be determined within 12 hours of birth, HBIG should also be administered. The vaccine dose administered at birth should not be counted as part of the series, and the infant should receive three additional doses beginning at age 1 month (total number of doses should be at least 4). The vaccine series should be completed by 6 months of age.

## 2. Other Contacts

### a. *Infants exposed to primary caretakers with acute HBV infection*

Unvaccinated infants exposed to a primary caretaker with acute HBV infection should receive a single dose of HBIG and the first dose of the HBV vaccine series as soon as possible. The infant should complete the HBV vaccine series per ACIP recommendations.

### b. *Post-exposure management of healthcare personnel after occupational percutaneous or mucosal exposure to blood or body fluids*

Healthcare personnel with occupational exposure or mucosal exposure to blood and body fluids should be evaluated for post-exposure prophylaxis. Prophylaxis is dependent on the HBV vaccination and immune status of the exposed individual and the HBV status of the source, if known. See Table 3 for further details.

### c. *Post-exposure management after distinct non-occupational percutaneous or mucosal exposure to blood or body fluids*

Persons with distinct non-occupational percutaneous or mucosal exposure to blood or body fluids should be evaluated for post-exposure prophylaxis. Prophylaxis is dependent on the HBV vaccination status of the exposed individual and the HBV status of the source, if known. See Table 4 for further details.

## C. Pre-exposure Prophylaxis

Individuals should be immunized in accordance with Advisory Committee on Immunization Practices (ACIP) recommendations for HBV vaccine. The ACIP guidelines can be accessed at <http://www.cdc.gov/vaccines/hcp/acip-recs/index.html>

## D. Managing Special Situations

### 1. School and Child Care

The risk of HBV transmission in school and child care settings has always been very low. This risk is now even lower because the proportion of susceptible children is decreasing. The Advisory Committee on Immunization Practices recommends that all children initiate the HBV vaccine series within 24 hours after birth. In addition, in accordance with N.J.A.C. 8:57 – 4, children must complete the HBV vaccine series prior to school entry in Kindergarten through Grade 12. To prevent the transmission of HBV and other bloodborne diseases in these settings, however, the following guidelines should be followed.

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**Primary prevention:** Encourage parents and guardians to have children vaccinated in accordance with ACIP recommendations. Ensure compliance with all HBV vaccination requirements for schools. Ensuring that all children are fully vaccinated will provide protection in situation where they might be exposed to the virus through contact with chronically infected individuals. Vaccination is particularly important in setting where individuals may 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.

**Secondary prevention:** Persons exposed to potentially infectious blood or other body fluids should be offered post-exposure prophylaxis as outlined in Table 4. However, in the case of a bite by a person whose HBV status is unknown, it is unlikely that it will result in transmission, and blood testing is not recommended for either the biter or victim. The risk of HBV acquisition when a susceptible child bites an HBV carrier is not known. However, most experts would not give HBIG to the susceptible biting child who does not have oral mucosal disease when the amount of blood transferred is small.

**Notification:** Parents may wish to inform the school nurse or child care program director about a child who is a known HBV carrier (HBsAg positive) to allow for proper precautions and assessment of behavior issues that could facilitate transmission. However, this is not a requirement since the school policies and procedures to manage exposure to blood or blood-containing materials should already be established and implemented. Parents of other children attending the school/child care do NOT need to be informed.

**Exclusions:** Adults and children ill with acute HBV infection should stay home until they feel well and fever and jaundice are gone. There is no reason to exclude a person with HBV infection from employment or attendance once he/she has recovered from the acute illness.

**Admission of a known HBV carrier (HBsAg positive)** with specific risk factors, such as biting, open rashes or sores that cannot be covered, or bleeding problems, should be assessed on an individual basis by the child's doctor, school/child care, and responsible public health authorities. Because these children might pose a risk to others in child care, consideration may be given to exclusion from child care until the aggressive behavior ceases or until all contacts have been vaccinated. However, over the next few years, the proportion of children who are vaccinated will increase. Concern about bites and HBV transmission should also decrease over this time period.

**Prevention Guidelines:** School staff must receive training regarding the school's Exposure Control Plan for the prevention of bloodborne pathogens as defined by the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standard and other pertinent policies regarding infection prevention. Students should be provided age-appropriate instruction regarding hand washing, personal hygiene and the modes of transmission of bloodborne pathogens including HBV.

- Ensure the availability of appropriate personal protective equipment including gloves for staff at risk for contact with blood or body fluids.
- Ensure the availability of hand-washing supplies and procedures.
- Always treat all blood and body fluids as potentially infectious and ensure that school staff practices appropriate standard precautions.
- Do not permit sharing of personal items that may become contaminated with blood or body fluids, such as toothbrushes or razors.



- Cover open skin lesions.
- Dispose of items contaminated with blood or body fluids appropriately
- Ensure appropriate decontamination of environmental surfaces.
- Ensure policies and appropriate supplies are in place for handling spills of blood and body fluids.

## **2. Reported Incidence is Higher than Usual/Outbreak Suspected**

If the number of reported acute HBV cases in your city/town is higher than usual, or if you suspect a cluster or an outbreak, investigate thoroughly to determine the source or risk factor associated with the acute infections. If evidence indicates a common source, applicable preventive or control measures should be instituted. Notify your health officer and contact the regional epidemiologist and the state health department at 609-826-5964.

## **3. Healthcare-Associated Cases**

In cases of persons with an acute infection that may be associated with a healthcare procedure or healthcare institution, including dialysis facilities, immediately notify your health officer, your regional epidemiologist and the state health department. This approach will ensure coordination of investigation. Dialysis facilities caring for chronically infected patients who are HBsAg positive should follow guidance available through the CDC website at:

<https://www.cdc.gov/dialysis/guidelines/index.html>

## **4. Unusual Serology**

At times, healthcare providers might encounter unusual HBV serology results (e.g., HBsAg negative but high HBV DNA). Please contact the state health department for assistance with interpretation of unusual serology and to assist with specialized testing.

## Additional Information

The NJDOH Vaccine Preventable Disease Program (VPDP) can be reached at 609-826-4861

The NJDOH website for hepatitis B is: <http://www.nj.gov/health/cd/topics/hepatitisb.shtml>

CDC's Viral Hepatitis Program Web site: <http://www.cdc.gov/ncidod/diseases/hepatitis> Hepatitis B

Foundation Web site: <http://www.hepb.org>

Immunization Action Coalition Web site: <http://immunize.org>

Hepatitis B Reporting Letter, CDS-37: <http://web.doh.state.nj.us/apps2/forms/>

## References

American Academy of Pediatrics. Copyright. In: Kimberlin DW, Brady MT, Jackson MA, Long SS, eds. *Red Book: 2018 Report of the Committee on Infectious Diseases*. American Academy of Pediatrics; 2018.

Centers for Disease Control and Prevention. Case definitions for infectious conditions under public health surveillance. *MMWR Morb Mortal Wkly Rep*. 1997;46:RR-10.

Centers for Disease Control and Prevention. Hepatitis B virus: a comprehensive strategy for eliminating transmission in the United States through universal childhood immunization. Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Morb Mortal Wkly Rep*. 1991;40:RR-13.

Centers for Disease Control and Prevention. Immunization of health-care workers: Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC). *MMWR Morb Mortal Wkly Rep*. 1997;46:RR-18.

Centers for Disease Control and Prevention. Update: Shortened Interval for Postvaccination Serologic Testing of Infants Born to Hepatitis B-Infected Mothers *MMWR Morb Mortal Wkly Rep*. 2015;64(39):1118-20.

Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C. Public Health Foundation, 2015.

Schillie S, Vellozzi C, Reingold A, et al. Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices. *MMWR Recomm Rep* 2018;67(No. RR-1):1–31. DOI: <http://dx.doi.org/10.15585/mmwr.rr6701a1>.

## TABLES

**Table 1. How do I interpret some of the common hepatitis B panel results?**

HBsAg	Total anti-HBc	IgM anti-HBc	Anti-HBs	HBV DNA	Interpretation
-	-	-	-	-	Never infected
+	-	-	-	+ or -	Early acute infection; transient (up to 18 days) after vaccination
+	+	+	-	+	Acute infection
-	+	+	+ or -	+ or -	Acute resolving infection
-	+	-	+	-	Recovered from past infection and immune
+	+	-	-	+	Chronic infection
-	+	-	-	+ or -	False-positive (i.e., susceptible); past infection; "low-level" chronic infection; or passive transfer of anti-HBc to infant born to HBsAg-positive mother
-	-	-	+	-	Immune if anti-HBs concentration is $\geq 10$ mIU/mL after vaccine series completion; passive transfer after hepatitis B immune globulin administration

**Abbreviations:** - = negative; + = positive; anti-HBc = antibody to hepatitis B core antigen; anti-HBs = antibody to hepatitis B surface antigen; HBsAg = hepatitis B surface antigen; HBV DNA = hepatitis B virus deoxyribonucleic acid; IgM = immunoglobulin class M.

Source: <https://www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm>

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**Table 2. The Immunoprophylaxis of Infants at birth**

**TABLE 3. Hepatitis B vaccine schedules for infants, by infant birthweight and maternal HBsAg status**

Birthweight	Maternal HBsAg status	Single-antigen vaccine		Single-antigen + combination vaccine	
		Dose	Age	Dose	Age
≥2,000 g	Positive	1	Birth (≤12 hrs)	1	Birth (≤12 hrs)
		HBIG <sup>§</sup>	Birth (≤12 hrs)	HBIG	Birth (≤12 hrs)
		2	1–2 mos	2	2 mos
		3	6 mos <sup>¶</sup>	3	4 mos
	Unknown*	1	Birth (≤12 hrs)	1	Birth (≤12 hrs)
		2	1–2 mos	2	2 mos
		3	6 mos <sup>¶</sup>	3	4 mos
		4	6 mos <sup>¶</sup>	4	6 mos <sup>¶</sup>
	Negative	1	Birth (≤24 hrs)	1	Birth (≤24 hrs)
		2	1–2 mos	2	2 mos
		3	6–18 mos <sup>¶</sup>	3	4 mos
		4	6 mos <sup>¶</sup>	4	6 mos <sup>¶</sup>
<2,000 g	Positive	1	Birth (≤12 hrs)	1	Birth (≤12 hrs)
		HBIG	Birth (≤12 hrs)	HBIG	Birth (≤12 hrs)
		2	1 mos	2	2 mos
		3	2–3 mos	3	4 mos
	Unknown	4	6 mos <sup>¶</sup>	4	6 mos <sup>¶</sup>
		1	Birth (≤12 hrs)	1	Birth (≤12 hrs)
		HBIG	Birth (≤12 hrs)	HBIG	Birth (≤12 hrs)
		2	1 mos	2	2 mos
	Negative	3	2–3 mos	3	4 mos
		4	6 mos <sup>¶</sup>	4	6 mos <sup>¶</sup>
		1	Hospital discharge or age 1 mo	1	Hospital discharge or age 1 mo
		2	2 mos	2	2 mos
		3	6–18 mos <sup>¶</sup>	3	4 mos
		4	6 mos <sup>¶</sup>	4	6 mos <sup>¶</sup>

Abbreviations: HBIG = hepatitis B immune globulin; HBsAg = hepatitis B surface antigen.

\* Mothers should have blood drawn and tested for HBsAg as soon as possible after admission for delivery; if the mother is found to be HBsAg positive, the infant should receive HBIG as soon as possible but no later than age 7 days.

† Pediarix should not be administered before age 6 weeks.

§ HBIG should be administered at a separate anatomical site from vaccine.

¶ The final dose in the vaccine series should not be administered before age 24 weeks (164 days).

Source: <https://www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm>

**Table 3. Postexposure management of healthcare personnel after occupational percutaneous or mucosal exposure to blood or body fluids, by healthcare personnel HepB vaccination and response status**

HCP status	Postexposure testing		Postexposure prophylaxis		Postvaccination serologic testing
	Source patient (HBsAg)	HCP testing (anti-HBs)	HBIG	Vaccination	
Documented responder after complete series	No action needed				
Documented nonresponder after two complete series	Positive/unknown	-*	HBIG x2 separated by 1 month	-	N/A
	Negative	No action needed			
Response unknown after complete series	Positive/unknown	<10 mIU/mL	HBIG x1	Initiate revaccination	Yes
	Negative	<10 mIU/mL	None		
	Any result	<10 mIU/mL		Initiate revaccination	Yes
	No action needed				
Unvaccinated/incompletely vaccinated or vaccine refusers	Positive/unknown	-	HBIG x1	Complete vaccination	Yes
	Negative	-	None	Complete vaccination	Yes

**Abbreviations:** anti HBs = antibody to hepatitis B surface antigen; HBIG = hepatitis B immune globulin; HBsAg = hepatitis B surface antigen; HCP = health care personnel; N/A = not applicable.

\* Not indicated.

Source: <https://www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm>

**Table 4. Postexposure management after distinct nonoccupational percutaneous or mucosal exposure to blood or body fluids**

Exposure*	Management	
	Unvaccinated person	Previously vaccinated person
HBsAg-positive source	HepB vaccine series and HBIG	HepB vaccine dose
HBsAg status unknown for source	Hep B vaccine series	No management

Abbreviations: HepB = hepatitis B; HBsAg = hepatitis B surface antigen; HBIG = hepatitis B immune globulin.

\* Exposures include percutaneous (e.g., bite or needlestick) or mucosal exposure to blood or body fluids, sex or needle-sharing contact, or victim of sexual assault/abuse.

### Persons recommended to receive serologic testing prior to vaccination\*

- Household, sexual, or needle contacts of hepatitis B surface antigen (HBsAg)-positive persons†
- HIV-positive persons†
- Persons with elevated alanine aminotransferase/aspartate aminotransferase of unknown etiology†
- Hemodialysis patients†
- Men who have sex with men†
- Past or current persons who inject drugs†
- Persons born in countries of high and intermediate hepatitis B virus (HBV) endemicity (HBsAg prevalence ≥2%)
- U.S.-born persons not vaccinated as infants whose parents were born in countries with high HBV endemicity (≥8%)
- Persons needing immunosuppressive therapy, including chemotherapy, immunosuppression related to organ transplantation, and immunosuppression for rheumatologic or gastroenterologic disorders
- Donors of blood, plasma, organs, tissues, or semen

\* Serologic testing comprises testing for hepatitis B surface antigen (HBsAg), antibody to HBsAg, and antibody to hepatitis B core antigen.

† Denotes persons also recommended for hepatitis B vaccination. Serologic testing should occur prior to vaccination. Serologic testing should not be a barrier to vaccination of susceptible persons. The first dose of vaccine should typically be administered immediately after collection of the blood for serologic testing.

### Persons recommended to receive postvaccination serologic testing\* following a complete series of HepB vaccination

- Infants born to hepatitis B surface antigen (HBsAg)-positive mothers or mothers whose HBsAg status remains unknown (e.g., when a parent or person with lawful custody safely surrenders an infant confidentially shortly after birth infants safely surrendered at or shortly after birth)†
- Health care personnel and public safety workers
- Hemodialysis patients and others who might require outpatient hemodialysis (e.g., predialysis, peritoneal dialysis, and home dialysis)
- HIV-infected persons
- Other immunocompromised persons (e.g., hematopoietic stem-cell transplant recipients or persons receiving chemotherapy)
- Sex partners of HBsAg-positive persons

\* Postvaccination serologic testing for persons other than infants born to HBsAg-positive (or HBsAg-unknown) mothers consists of anti-HBs.

† Postvaccination serologic testing for infants born to HBsAg-positive (or HBsAg-unknown) mothers consists of anti-HBs and HBsAg. Persons with anti-HBs < 10 mIU/mL after the primary vaccine series should be revaccinated. Infants born to HBsAg-positive mothers or mothers with an unknown HBsAg status should be revaccinated with a single dose of HepB vaccine and receive postvaccination serologic testing 1–2 months later. Infants whose anti-HBs remains < 10 mIU/mL following single dose revaccination should receive two additional doses of HepB vaccine, followed by postvaccination serologic testing 1–2 months after the final dose. Based on clinical circumstances or family preference, HBsAg-negative infants with anti-HBs < 10 mIU/mL may instead be revaccinated with a second, complete 3-dose series, followed by postvaccination serologic testing performed 1–2 months after the final dose of vaccine. For others with anti-HBs < 10 mIU/mL after the primary series, administration of 3 additional HepB vaccine doses on an appropriate schedule, followed by anti-HBs testing 1–2 months after the final dose, is usually more practical than serologic testing after ≥1 dose of vaccine.

Source: <https://www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm>