Hepatitis B

(Acute, Chronic, Perinatal)

**DISEASE REPORTABLE WITHIN 24 HOURS OF DIAGNOSIS**

Per NJAC 8:57, health care 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 HBsAg 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/directory/lhdselectcounty.shtml](http://www.state.nj.us/health/lh/directory/lhdselectcounty.shtml).

If the health officer is unavailable, the health care 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.

June 2011
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 60 to 180 days (average of 90 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 preicteric or prodromal phase, from initial symptoms to onset of jaundice, usually lasts from three to ten days. It is nonspecific and is characterized by fever, loss of appetite, vague abdominal discomfort, nausea, vomiting, and sometimes arthralgias and rash, beginning one to two days before the onset of jaundice. The icteric phase is variable but usually lasts from one to three weeks and is characterized by jaundice, light or gray stools, hepatic tenderness, and hepatomegaly. 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 antibody to HBsAg (HBsAb), 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 an average of 30% of children infected between one and five years of age and 2% to 6% 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. 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 through infected blood or body fluids via a parenteral or permucosal (mucous membrane) exposure. The highest concentrations of the virus are in blood and serous fluids; lower titers are found in semen and even lower titers are found in saliva.

Some examples of parenteral exposures are needle sticks, sharing or reusing nonsterile needles or syringes, transfusion of blood and blood products (rare in the United States due to routine blood donor screening), hemodialysis, acupuncture, body piercing, and body tattooing. The most common permucosal exposure is through perinatal transmission from an infected mother to her infant at birth (vertical transmission) and sexual (heterosexual and homosexual) activity (horizontal transmission). Permucosal exposures also occur in laboratories and healthcare settings, contributing to horizontal transmission in facilities and communities. However, with universal HBV immunization of health care and other 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 nonintact skin or mucous membranes with blood-containing secretions or perhaps saliva are the most likely means of transmission. Transmission from sharing personal objects, such as washcloths, towels, razors, or toothbrushes, also can occur because HBV can survive at ambient temperatures in the environment for one week or longer. 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 is an average of 60 to 90 days, with a range of 45 to 180 days, and can occasionally be as long as six to nine months.

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

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 United States, Canada, Western Europe, Australia, and South America, the infection rate is low and occurs primarily in adolescents and adults; 5% to 8% of the total population has been infected, and 0.2% to 0.9% has a chronic infection.

Within the United States there are pockets of high endemicity, including first-generation immigrants from areas where HBV is endemic, among Alaskan Natives, and among low socioeconomic inner-city groups. The highest risk of early childhood infection is in children born to mothers who are from HBV-endemic countries and are carriers of HBV. The majority of early childhood infections, however, occur in African American and white children. Before routine childhood HBV immunization in the United States, an estimated 33,000 children born to HBsAg-negative mothers were infected each year during their early childhood. In developed countries, populations at high risk for HBV exposure include injecting drug users, heterosexuals with multiple partners, homosexual men, residents and staff of institutions for the developmentally disabled, employees in hemodialysis centers, and people in certain healthcare and public safety occupations.

In contrast, in China, Southeast Asia, the Pacific Islands, Eastern Europe, the Central Asian republics, most of the Middle East, Africa, the Amazon Basin, and some Caribbean islands, HBV infection is highly endemic, with a lifetime risk of HBV infection greater than 60%. In these areas, most infections occur in infants or children under the age of five years; 70% to 90% of the adult population has been infected; and 8% to 15% have a chronic infection. In the rest of the world, HBV infection is of intermediate endemicity with chronic HBV carriage occurring in 2% to 7% of the population.

2 REPORTING CRITERIA AND LABORATORY TESTING SERVICES

A. What to report to the New Jersey Department of Health and Senior Services

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 and Senior Services Case Definitions

1. Acute HBV Infection

2011 Clinical Case Definition

An acute illness with

- discrete onset of symptoms AND
- jaundice or serum aminotransferase levels (ALT) > 200 IU/L

Laboratory Criteria for Diagnosis

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

OR

- Hepatitis B surface antigen (HBsAg) positive
  AND

- IgM antibody to hepatitis A virus (IgM anti-HAV) negative (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

COMMENT
None.

2. Chronic HBV Infection

Clinical Description

No symptoms are required. Persons with chronic 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.
Communicable Disease Service Manual

Laboratory Criteria for Diagnosis

- IgM antibodies to hepatitis B core antigen (HBcAb-IgM) negative
  **AND**
- a positive result on one of the following tests:

  
  
  
  Hepatitis B surface antigen (HBsAg),
  
  
  
  Hepatitis B e antigen (HBeAg) or
  
  
  
  Hepatitis B virus (HBV) DNA
  
  
  
  **OR**

  
  
  
  HBsAg positive or HBV DNA-positive 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 case that meets either of the above laboratory criteria for diagnosis.

PROBABLE
A person with a single HBsAg positive or HBV DNA positive or HBeAg positive lab result and does not meet the criteria for acute HBV infection.

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, such as 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 such as a negative hepatitis A IGM can be entered in the laboratory section of Communicable Disease Surveillance and Reporting System (CDRSS). Select from laboratory drop down box, select and enter.
Liver enzymes or liver bilirubin levels results should also be entered in the laboratory section of CDRSS. Select from laboratory drop down box and type liver enzymes level in CDRSS.

3. **Perinatal HBV Infection**

**Clinical Case Definition**

Perinatal HBV in the newborn may range from asymptomatic to fulminate hepatitis.

**Laboratory Criteria for Diagnosis**

- **HBsAg-positive**

**Case Classification**

**CONFIRMED**

HBsAg-positive serology in any infant aged 1 to 24 months who was born in the United States or in U.S. territories to an HBsAg-positive mother

**PROBABLE**

Not used

**POSSIBLE**

Not used

**COMMENT**

Infants born to HBsAg-positive mothers should receive hepatitis B immune globulin (HBIG) and the first dose of HBV vaccine within 12 hours of birth, followed by the second and third doses of vaccine at one and six months of age, respectively or other accepted FDA-approved, ACIP-recommended HBV vaccine series. These infants should be tested for HBsAg and HBsAb at least 1-2 months following completion of the HBV vaccine series; testing should not be performed before age 9 months to avoid detection of HBsAb from HBIG administered during infancy. HBcAb testing of infants is not recommended because passively acquired maternal HBcAb might be detected in infants born to HBV-infected mothers to age 24 months.

**C. Laboratory Testing Services Available**

The New Jersey Department of Health and Senior Services (NJDHSS) Public Health Environmental Laboratories (PHEL) does not perform routine laboratory testing for HBV for the general public. Testing is usually conducted through 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 (NJAC 8:57-1.8) stipulates that laboratories report (by telephone, confidential fax, over the Internet using the CDRSS, or in writing) all cases of HBV infection (acute, chronic, andHBsAg-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. Please refer to the lists of reportable diseases at http://nj.gov/health/cd/documents/reportable_diseases.pdf for information.

C. Local Health Department Reporting and Follow-Up Responsibilities

1. Reporting Requirements

NJAC 8:57-1.8 stipulates that each local health officer must report the occurrence of acute and chronic HBV infection, as defined by the reporting criteria in section 2A above. Refer to the Health Officers Reporting Timeline (http://nj.gov/health/cd/documents/reportable_diseases.pdf) for information on prioritization and timeliness requirements of reporting and case investigation.

2. Case Investigation

1. The health officer (or his/her designee) is responsible for investigating HBV cases. If a laboratory report is received by NJDHSS, 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.

2. 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 HBsAb 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.

3. Correct interpretation of HBV serology will guide the public health investigation.

4. 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 HBsAg positive women aged 15 to 45 must also be investigated. And documented in the case. Pregnancy findings are entered in CDRSS and this includes NO, not pregnant. The information for pregnancy status is placed in the pregnancy tab found in the clinical status module of CDRSS.

5. When case findings indicate the patient is pregnant, select YES in the pregnancy status tab; additional pop boxes/fields will appear requesting the estimated date of delivery (EDD) and hospital delivery site. This information is required for perinatal case management.

6. A form letter for healthcare providers (CDS-L2) 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 from the physician.

7. 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). 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 months after diagnosis. 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, go to CDRSS risk factor tab and select the risk factor.

- Intravenous recreational drug use?
- Unprotected sexual activity?
- Commercial sex worker?
- Multiple sexual partners?
- Man who has sex with men?
- Acupuncture, tattooing or body piercing?
- Household or sexual or other contact with a person who was diagnosed with suspect or confirmed HBV infection?
- Accidental puncture with a needle or other object contaminated with blood?
• Health care worker or employment in a medical, dental, or other field that involves contact with human blood?
• Dialysis or kidney transplant patient?
• If a dialysis patient did they recently receive the HBV vaccine (within 30 days of positive HBV blood test)?
• Hospitalized and/or surgery including outpatient invasive medical procedures?
• In patient status or residence in a Long Term Care Facility?
• Known bleeding disorder and receiving blood clotting factor concentrates?
• Receipt of blood transfusion prior to 1992?
• Outpatient intramuscular injections or intravenous infusions?
• Dental work and/or dental surgery?
• Is the patient a diabetic?; if yes,
  (1) Did the patient have multiple finger-stick blood sampling in a healthcare setting?
  (2) Did the patient use a shared blood glucose-monitoring device at home or while in the healthcare setting?

8. 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.

9. 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. Document case findings for vaccination in the immunization tab found in the clinical module of 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.

10. Sexual and household or other at risk contacts of acutely infected persons should be referred to their medical provider for HBV serology and/or HBV vaccination.

11. Persons with an acute infection that may be associated with a health care procedure or health care institution immediately notify your health officer, your regional epidemiologist and the state health department. This approach will ensure coordination of investigation.
CDRSS Entry
The following table can be used as a quick reference guide to using CDRSS to report a case of HBV infection accurately and thoroughly. Add a new case after performing person search using the case management button.

<table>
<thead>
<tr>
<th>CDRSS Screen</th>
<th>Required Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient Info</strong></td>
<td>Select disease name (Hepatitis B) and enter patient demographics. Select subgroup of acute or chronic, if known, or mark as “PENDING” if investigation is incomplete.</td>
</tr>
<tr>
<td><strong>Addresses</strong></td>
<td>Enter any alternate address. Entering an alternate address will allow other disease investigators to access the case if it pertains to their jurisdiction.</td>
</tr>
<tr>
<td><strong>Clinical Status</strong></td>
<td>Enter physician and, if applicable, hospitalization information including the name of the hospital. Document pregnancy status. If patient is pregnant, indicate estimated date of delivery, the anticipated delivery hospital, and investigation start date. Disease onset date, if not known, can be left blank.</td>
</tr>
<tr>
<td><strong>Signs/Symptoms</strong></td>
<td>Check appropriate boxes for signs and symptoms, and indicate onset date. Please note if physician did not provide this information. The information is critical to determine if the case is acute or chronic. Individuals with chronic infection “HBV carriers” usually do not have symptoms; indicate asymptomatic infection as appropriate.</td>
</tr>
<tr>
<td><strong>Risk Factors</strong></td>
<td>Enter complete information about risk factors, if known. Items 2 to 7 may not be known until investigation has been completed.</td>
</tr>
<tr>
<td><strong>Laboratory Eval</strong></td>
<td>Enter appropriate lab tests and results. For acute case investigation, liver enzymes and total bilirubin lab results are entered in the lab section. Select from the lab test drop down box.</td>
</tr>
<tr>
<td>CDRSS Screen</td>
<td>Required Information</td>
</tr>
<tr>
<td>------------------------------</td>
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</tr>
<tr>
<td>Contact Tracing</td>
<td>Use this screen to enter information about contacts, if known. For perinatal cases, enter the mother of the newborn as a case contact. Search for the mother in CDRSS using the mother’s CDRSS case identification number. HBsAg-positive mothers should already be in CDRSS; if not then enter the mother in CDRSS first then link to child/case. For other contacts, please enter information about HBV vaccine or HBIG administration in the CLINICAL STATUS/IMMUNIZATION MODULE. Any case contact with serologic evidence of HBV infection that meets case definition must be entered in CDRSS. Case can then be linked as a contact using the cases CDRSS ID number.</td>
</tr>
<tr>
<td>Case Comments</td>
<td>Enter only summary case comments that are pertinent to the case. Information entered into the comments box is NOT available to be run in a report. <strong>NOTE:</strong> All other screens in CDRSS also have a “COMMENTS” box.</td>
</tr>
<tr>
<td>Epidemiology (optional screen)</td>
<td>Route of transmission may be determined through investigation of risk factors. Document method of case detection (e.g., by receipt of a lab report, through contact investigation, or unknown).</td>
</tr>
<tr>
<td>Case Classification</td>
<td>Case status options are “REPORT UNDER INVESTIGATION (RUI),” “POSSIBLE,” “PROBABLE,” “CONFIRMED,” and “NOT A CASE.”</td>
</tr>
</tbody>
</table>
| Report Status                | • All cases entered by laboratories should be assigned a case status of “REPORT UNDER INVESTIGATION (RUI).” • Cases still under investigation by the LHD should be assigned a case status of “REPORT UNDER INVESTIGATION (RUI).” • All perinatal cases should be assigned a case status of “POSSIBLE” until post-vaccination serologic testing is completed (12 – 15 mos. of age). • Upon completion of the investigation, the LHD should assign a case status on the basis of the case definition. “CONFIRMED,” “PROBABLE,” and “NOT A CASE” are the only appropriate options for classifying a case of HBV infection (see section 2A). • Perinatal cases are managed through CDRSS as possible/LHD open until completion of post vaccine serology. Report status options are “PENDING,” “LHD OPEN,” “LHD REVIEW,” “LHD CLOSED,” “DELETE,” “REOPENED,” “DHSS
CDRSS Screen | Required Information
---|---
OPEN,” “DHSS REVIEW,” and “DHSS APPROVED.”
- Cases reported by laboratories should be assigned a report status of “PENDING.”
- Once the LHD begins investigating a case, the report status should be changed to “LHD OPEN.”
- The “LHD REVIEW” option can be used if the LHD has a person who reviews the case before it is closed (e.g., health officer or director of nursing).
- Once the LHD investigation is complete and all the data are entered into CDRSS, the LHD should change the report status to “LHD CLOSED.”
- “LHD CLOSED” cases will be reviewed by DHSS and be assigned one of the DHSS-specific report status categories. If additional information is needed on a particular case, the report status will be changed to “REOPENED” and the LHD will be notified by e-mail. Cases that are “DHSS APPROVED” cannot be edited by LHD staff.
If a case is inappropriately entered (e.g., a case of hepatitis C was erroneously entered as a case of HBV) the case should be assigned a report status of “Delete.” A report status of “Delete” should NOT be used if a reported case of HBV simply does not meet CDC case definition. Rather, it should be assigned “Not a case” as described above.

D. Other Reporting/Investigation Issues

1. Laboratory-confirmed or healthcare-provider-reported cases of chronic HBV infection diagnosed prior to the current reporting year, and not reported previously in CDRSS, should be managed as follows in CDRSS:
   a. Enter the patient’s illness onset date as reported by provider. If the exact illness date is unknown, enter January 1 if the month and day are not known, followed by the year that the HBV chronic infection diagnosis was made.
   b. Select the “CONFIRMED” option under “Case Status.”
   c. Select “CASE DIAGNOSED IN A PREVIOUS YEAR” from the “Reason for Update” drop-down menu that appears next to the “Case Status” box.

2. 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:
Communicable Disease Service Manual

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 (15-45) 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 investigate, however if the LHD chooses to contact patient they may do so.

b. Request to reopen CDRSS cases of females of reproductive age (15 to 45 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 clinical status pregnancy tab. CDRSS will open automatically reopen cases for labs of females between the ages of 15 -45 years (or persons with unknown gender) so pregnancy status can be indicated.

3. Laboratory profiles suggestive of past infection (positive HBc-IgG and negative HBsAg) or immunity (positive HBsAb, 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.

4. Out-of-state cases should be classified as “Out of State, Not a New Jersey resident. DHSS will complete an interstate notification.

5. Once LHD completes its investigation and assigns a report status of “LHD CLOSED,” NJDHSS will review the case. NJDHSS will approve the case by changing the report status to “DHSS APPROVED.” At this time, the case will be submitted to the Centers for Disease Control and Prevention (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 NJDHSS CDRSS help desk to reopen the case. This should be done only if the additional information changes the case status of the report.

6. 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 NJDHSS.

7. 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 NJDHSS.

8. If a case has been found to be entered in CDRSS in duplicate merge the cases or notify DHSS so cases can be merged.
E. Case Management

1. Pregnant Women

The NJDHSS 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 the HBV vaccine doses and post vaccine serology 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. Later when the child is born, enter the newborn in CDRSS as a perinatal/possible case. The newborn will be linked to the mother’s case; link the cases by searching for the mother in the case contact tab using her CDRSS case ID.

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

Note: Adding the mother through use of the CDRSS case ID will automatically link the mother and the child.

When the newborns case is created in CDRSS document the administration dates for HBIG and the birth dose of HBV vaccine and the subsequent HBV doses in the immunization tab found in the clinical module. The case can stay open as a Possible until completion of case management. Perinatal cases can stay open in CDRSS as a possible/LHD open for 24 months. Perinatal case management includes documentation in the immunization tab of the three or four HBV vaccine doses (depending on vaccine type) and post-vaccination serology that is completed 2-3 months after the last HBV dose. The lab results for post vaccine serology testing must be entered in the lab module of CDRSS. Infants who successfully complete the HBV vaccine series and develop antibodies, are HBsAb positive and HBsAg negative. This case can be closed and classified as “NOT A CASE”, antibodies detected. Infants who have infection will have serology that is HBsAg positive and HBsAb negative. These labs are entered in case and case is confirmed as a perinatal infection; close case as a “CONFIRMED CASE.” For non-responders to HBV vaccine see section 4 B.

For questions or additional information about perinatal case management contact the Program at 609-826-4860.
4 CONTROLLING FURTHER SPREAD

A. Isolation and Quarantine Requirements (NJAC 8:57-1.12)

The current recommendations of the CDC and NJDHSS 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 for infants born to HBsAg positive mothers

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 according to Table 2.
   b. Screen the infant for HBsAg and HBsAb at 12 – 15 months of age or two to three months after the last vaccine dose. If HBsAg is not present and HBsAb concentration is 10 mIU/mL or greater, the infant is considered to have protective antibodies.
   c. Infants who do not respond to the initial vaccine series (HBsAb concentration is less than 10 mIU/mL and HBsAg-negative) should be given a second three-dose series of HBV vaccine (same schedule as initial series). The physician should retest the infant for adequate antibody response two to three months after the last vaccine dose.
   d. Infants who become HBsAg positive should be referred for comprehensive medical management. Ensure the laboratory data (positive HBsAg and negative HBsAb) 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 days of birth. This child should then complete the HBV vaccine series. Upon completion of the vaccine series, the infant should be complete lab testing for HBsAg and HBsAb as defined above. If the mother is determined to be HBsAg negative, the infant should complete the three-dose HBV vaccine series.
2. Other Contacts

a. 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.

b. Household and sexual contacts of a person with acute or chronic HBV infection or an individual who sustains a percutaneous or mucosal exposure to a potentially HBsAg positive source should receive HBIG and the HBV vaccine series.

C. Pre-exposure Prophylaxis

Individuals should be immunized in accordance with ACIP guidelines for HBV vaccine. The ACIP guidelines can be accessed at [http://www.cdc.gov/vaccines/pubs/ACIP-list.htm](http://www.cdc.gov/vaccines/pubs/ACIP-list.htm).

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 since children need to 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.

Primary prevention: Ensure compliance with all HBV vaccination requirements for schools. Vaccination is also recommended for unvaccinated classmates of 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.

Secondary prevention: Persons exposed to potentially infectious blood or other body fluids should be offered postexposure 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 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 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. 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.

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 609-826-4860.

Additional Information

The NJDHSS Vaccine preventable disease program (VPDP) can be reached at 609-826-4860. The Perinatal Hepatitis B Coordinator and staff of the VPDP are responsible for all HBV case investigations and management.

A Hepatitis B Fact Sheet can be obtained at the NJDHSS Web site at http://www.state.nj.us/health/. Click on the “Health Topics A-Z” link and scroll down to “Hepatitis B.”.


References


TABLES

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

<table>
<thead>
<tr>
<th>Tests</th>
<th>Results</th>
<th>Interpretation</th>
<th>Vaccinate?</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBsAg</td>
<td>negative</td>
<td>susceptible</td>
<td>vaccinate if indicated</td>
</tr>
<tr>
<td>HBcAb</td>
<td>negative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HBsAb</td>
<td>negative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HBsAg</td>
<td>negative positive with ≥10mIU/mL*</td>
<td>immune due to vaccination</td>
<td>no vaccination necessary</td>
</tr>
<tr>
<td>HBcAb</td>
<td>positive</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HBsAb</td>
<td>positive</td>
<td>immune due to natural infection</td>
<td>no vaccination necessary</td>
</tr>
<tr>
<td>HBsAg</td>
<td>positive</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HBcAb</td>
<td>positive</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HBsAb</td>
<td>positive</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Communicable Disease Service Manual**

<table>
<thead>
<tr>
<th>HBsAg</th>
<th>HBeAg</th>
<th>HBeAb</th>
<th>HBV DNA</th>
</tr>
</thead>
<tbody>
<tr>
<td>positive</td>
<td>Positive</td>
<td>Positive</td>
<td>Positive</td>
</tr>
<tr>
<td>negative</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Interpretations

**HBsAg positive, HBcAb positive, HBsAb negative**
- **Acutely infected**: No vaccination necessary.
- **Chronically infected**: No vaccination necessary (may need treatment).

<table>
<thead>
<tr>
<th>HBsAg</th>
<th>HBeAg</th>
<th>HBeAb</th>
<th>HBV DNA</th>
</tr>
</thead>
<tbody>
<tr>
<td>negative</td>
<td>Positive</td>
<td>Positive</td>
<td>Positive</td>
</tr>
<tr>
<td>positive</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Four Interpretations Possible†
1. May be recovering from acute HBV infection
2. May be distantly immune, but the test may not be sensitive enough to detect a very low level of HBsAb in serum
3. May be susceptible with a false positive HBcAb
4. May be chronically infected and have an undetectable level of HBsAg present in the serum

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* Post-vaccination testing, when it is recommended, should be performed 1-2 months after the last dose of vaccine. Infants born to HBsAg-positive mothers who received HBIG and HBV vaccine should be tested for HBsAg and HBsAb at least 1 – 2 months after completion of a licensed HBV vaccination series; testing should not be performed before age 9 months to avoid detection of HBsAb from HBIG administered during infancy. HBeAb testing of infants is not recommended because passively acquired maternal HBeAb might be detected in infants born to HBV-infected mothers to age 24 months.

† 1. May be recovering from acute HBV infection
   2. May be distantly immune, but the test may not be sensitive enough to detect a very low level of HBsAb in serum
   3. May be susceptible with a false positive HBcAb
   4. May be chronically infected and have an undetectable level of HBsAg present in the serum

Source: Immunization Action Coalition: Ask the Experts
### Table 2. The Immunoprophylaxis of Infants Born to HBsAg-positive Mothers

<table>
<thead>
<tr>
<th>Dose</th>
<th>Age</th>
<th>Single-antigen vaccine*</th>
<th>Dose</th>
<th>Age</th>
<th>Single-antigen* + combination vaccine†</th>
</tr>
</thead>
<tbody>
<tr>
<td>1‡</td>
<td>Birth (within 12 hours)</td>
<td></td>
<td>1†‡</td>
<td>Birth (within 12 hours)</td>
<td></td>
</tr>
<tr>
<td>HBIG§</td>
<td>Birth (within 12 hours)</td>
<td></td>
<td>HBIG§</td>
<td>Birth (within 12 hours)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>1-2 months</td>
<td>2</td>
<td></td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>6 months§</td>
<td>3</td>
<td></td>
<td></td>
<td>3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Pediatric formulation of either RECOMBIVAX HB or ENGERIX-B.
†COMVAX (combined hepatitis B-Hib conjugate vaccine) and PEDIARIX (combined hepatitis B-DTaP-IPV vaccine) cannot be administered at birth or before 6 weeks of age.
‡Pediatric formulation of either RECOMBIVAX HB or ENGERIX-B can be used beginning at birth.
§Hepatitis B immunoglobulin (0.5mL) given intramuscularly in a separate site from vaccine.
¶PEDIARIX administered at 2, 4, and 6 months of age to complete immunization against HBV and primary immunization against diphtheria, tetanus, pertussis, and polio. COMVAX administered at 2, 4, and 12 to 15 months of age to complete immunization against both HBV and *Haemophilus influenzae* type b.
¶The last dose in the vaccine series should not be administered before age 24 weeks (164 days).
Table 3. Immunoprophylaxis of Infants Born to HBsAg-negative Mothers

<table>
<thead>
<tr>
<th>Single-antigen vaccine*</th>
<th>Birth-dose† + combination‡</th>
<th>Combination† without birth dose‡</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dose</strong></td>
<td><strong>Age</strong></td>
<td><strong>Dose</strong></td>
</tr>
<tr>
<td>1†</td>
<td>Birth (before discharge)§</td>
<td>1†</td>
</tr>
<tr>
<td>2</td>
<td>1-4 months</td>
<td>2†</td>
</tr>
<tr>
<td>3‖</td>
<td>6-18 months</td>
<td>3†</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4†‖</td>
</tr>
</tbody>
</table>

*Pediatric formulation of either RECOMBIVAX HB or ENGERIX-B.

†COMVAX (combined hepatitis B-Hib conjugate vaccine) and PEDIARIX (combined HBV-DTaP-IPV vaccine) cannot be administered at birth or before 6 weeks of age.

‡Pediatric formulation of either RECOMBIVAX HB or ENGERIX-B can be used beginning at birth.

§The first dose can be delayed until after hospital discharge only if there is a physician’s order to defer the vaccine at birth based on specific documentation of a negative HBsAg test during this pregnancy. If the first dose is not administered before hospital discharge, it should be administered by age 2 months.

‖The last dose should not be administered before age 24 weeks (164 days).
### Table 4. Recommendations for Postexposure Prophylaxis after Percutaneous or Permucosal Exposure to HBV

<table>
<thead>
<tr>
<th>Vaccination and antibody status of exposed person</th>
<th>Source HBsAg-positive</th>
<th>Source HBsAg-negative</th>
<th>Source unknown or not tested</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>High Risk</td>
<td>Low Risk</td>
<td></td>
</tr>
<tr>
<td><strong>Unvaccinated</strong></td>
<td>HBIG† (1 dose) and begin HBV vaccine series</td>
<td>Begin HBV vaccine series</td>
<td>Begin HBV vaccine series</td>
</tr>
<tr>
<td><strong>Previously vaccinated</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Known responder‡</td>
<td>No treatment</td>
<td>No treatment</td>
<td>No treatment</td>
</tr>
<tr>
<td>Nonresponder‡</td>
<td>HBIG (1dose) and begin a revaccination series</td>
<td>No treatment; begin a revaccination series</td>
<td>HBIG (1 dose) and begin a revaccination series</td>
</tr>
<tr>
<td>Not revaccinated§</td>
<td>HBIG (2 doses)‖</td>
<td>No treatment</td>
<td>HBIG (2 doses)‖</td>
</tr>
<tr>
<td>After revaccination§</td>
<td>Test for HBsAb</td>
<td>No treatment</td>
<td>No treatment</td>
</tr>
<tr>
<td>Antibody response unknown</td>
<td>If adequate,‡ no treatment</td>
<td>No treatment</td>
<td>If adequate,‡ no treatment</td>
</tr>
<tr>
<td></td>
<td>If inadequate, HBIG × 1 and vaccine booster</td>
<td>No treatment</td>
<td>If inadequate, give vaccine booster and check anti-HBs in 1 to 2 months</td>
</tr>
</tbody>
</table>

*Persons known to have been infected with HBV are immune and require no treatment.
†Hepatitis B immunoglobulin (0.6 mL/kg) administered intramuscularly.
‡Adequate response to HBsAb $\geq$10mIU/mL after vaccination.
§Revaccination = additional series of HBV vaccine administered after the primary series.
‖First dose as soon as possible after exposure and the second dose 1 month after the first dose.