Hepatitis B Virus
(Acute, Chronic and Perinatal)
Investigation Guideline

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  • Fact Sheet (vs. 12/2014)
### Revision History:

<table>
<thead>
<tr>
<th>Date</th>
<th>Replaced</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/2015</td>
<td>05/2012</td>
<td>Updated “Pregnancy and Delivery” section of Managing Special Situations with updated contact information for Perinatal Coordinator and testing recommendations for infants. Updated Notification, Investigator Responsibilities, and Data Management sections with disease surveillance indicator targets.</td>
</tr>
<tr>
<td>10/2014</td>
<td>05/2012</td>
<td>Details added to Investigators Responsibilities and Data Management. Reformatted Standard Case Investigation section to assist with EpiTrax system data entry. Updated references and web links. Edits to needle exposure section.</td>
</tr>
<tr>
<td>05/2012</td>
<td>04/2009</td>
<td>Updated to CDC 2012 Case Definition. Added Notification Section. Edited Laboratory Analysis Section. Data Management (Closing of Chronic Cases). Removed reference to KS-EDSS. Edited Data Management Section.</td>
</tr>
</tbody>
</table>
Hepatitis B Virus
Disease Management and Investigative Guidelines

CASE DEFINITION – Acute (CDC, 2012)

Clinical Description for Public Health Surveillance (Acute):
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 a) jaundice, or b) elevated serum alanine aminotransferase (ALT) levels >100 IU/L.

*A documented negative hepatitis B surface antigen (HBsAg) laboratory test 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 Case Classification (Acute):
- HBsAg positive, AND
- Immunoglobulin M (IgM) antibody to hepatitis B core antigen (IgM anti-HBc) positive (if done).

Case Classification (Acute):
- **Confirmed**: A case that meets the clinical case definition is laboratory confirmed, and is not known to have chronic hepatitis B.
- **Probable**: Laboratory result with positive IgM antibody to hepatitis B core antigen case and missing or incomplete clinical information. *(KDHE definition for data management; requires further investigation by LHD.)*

CASE DEFINITION – Chronic (CDC, 2012)

Clinical Description for Public Health Surveillance (Chronic):
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.

Laboratory Criteria for Case Classification (Chronic):
- Immunoglobulin M (IgM) antibodies to hepatitis B core antigen (IgM anti-HBc) negative AND a positive result on one of the following tests: hepatitis B surface antigen (HBsAg), hepatitis B e antigen (HBeAg), or nucleic acid test for hepatitis B virus DNA (including qualitative, quantitative and genotype testing), OR HBsAg positive or nucleic acid test for 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 6 months apart is acceptable)

Case Classification (Chronic):
- **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 case definition for acute hepatitis B.

**Note**: 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.
CASE DEFINITION – Perinatal (CDC, 1995)

Clinical Description for Public Health Surveillance (Perinatal):
Perinatal Hepatitis B in the newborn may range from asymptomatic to fulminant hepatitis.

Laboratory Criteria for Case Classification (Perinatal):
- Hepatitis B surface antigen (HBsAg) positive).

Case Classification (Perinatal):
- **Confirmed**: HBsAg positivity in any infant aged >1 to 24 months who was born in the United States or in U.S. territories to HBsAg-positive mother.

LABORATORY ANALYSIS

- The Kansas Health and Environmental Laboratories (KHEL) is equipped to test for HBV on a limited basis for diagnosis of acute and chronic disease among clients of local health departments and some state-operated facilities. Emphasis is on testing perinatal patients and household and sexual contacts of HBsAg positive clients.

- For additional information and/or questions concerning specimen submission, collection/transport and laboratory kits call (785) 296-1620 or refer to online guidance at [www.kdheks.gov/labs/lab_ref_guide.htm](http://www.kdheks.gov/labs/lab_ref_guide.htm)

- Description of Hepatitis B Laboratory Tests:

<table>
<thead>
<tr>
<th>Tests</th>
<th>Marker Of</th>
<th>Indicates</th>
<th>Detection</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBsAg</td>
<td>Hepatitis B surface antigen</td>
<td>infectivity</td>
<td>acute or chronic natural infection</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1 or 2 weeks to 11 or 12 weeks after exposure</td>
</tr>
<tr>
<td>Anti-HBs or HBsAB</td>
<td>Antibody to Hepatitis B surface antigen</td>
<td>immunity</td>
<td>natural infection or vaccination or passively acquired antibody</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>during recovery (after HBsAg is no longer detected); lasts for life</td>
</tr>
<tr>
<td>Anti-HBc (total) or HBcAb</td>
<td>Antibody to Hepatitis B core antigen</td>
<td>nonspecific</td>
<td>natural infection that could be acute, chronic or resolved [Need to determine why testing was done to ensure case is not acute or chronic.]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Time of illness onset (after HBsAg is detectable); lasts for life</td>
</tr>
<tr>
<td>IgM anti-HBc</td>
<td>IgM antibody subclass of anti-HBc</td>
<td>recent infection within the past 6 months</td>
<td>acute natural infection</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Time of illness onset (after HBsAg is detectable) until 4-6 weeks after exposure</td>
</tr>
<tr>
<td>HBeAg</td>
<td>Hepatitis B “e” antigen</td>
<td>high degree of infectivity</td>
<td>high level of HBV replication (used for clinical management of chronic infection)</td>
</tr>
<tr>
<td>Anti-HBe</td>
<td>Antibody to Hepatitis B “e” antigen</td>
<td>nonspecific (infected or immune person)</td>
<td>in chronic HBV infection, its presence suggests a low viral titer and a low degree of infectivity</td>
</tr>
<tr>
<td>HBV-DNA</td>
<td>HBV Deoxyribonucleic acid</td>
<td>viral replication</td>
<td>Correlates well with infectivity (used to monitor treatment of chronic HBV patient)</td>
</tr>
</tbody>
</table>
Interpretation of laboratory tests for HBV:

<table>
<thead>
<tr>
<th>HBsAg</th>
<th>anti-HBc</th>
<th>IgM anti-HBc</th>
<th>anti-HBs</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Susceptible</td>
</tr>
<tr>
<td>-</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>Immune due to natural infection</td>
</tr>
<tr>
<td>-</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>Immune due to Hepatitis B vaccination</td>
</tr>
<tr>
<td>-</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>Interpretation unclear; four possibilities*</td>
</tr>
<tr>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>Acutely infected</td>
</tr>
<tr>
<td>+</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>Chronically infected</td>
</tr>
</tbody>
</table>

1) Resolved infection (most common)  2) False-positive anti-HBc, thus susceptible
3) “Low level” chronic infection  4) Resolving acute infection

Acute Hepatitis B Virus Infection with Recovery

Window Period: Time during which HBsAg or HBV DNA is undetectable and before anti-HBs is detectable.

Additional training for HBV serology:
www.cdc.gov/hepatitis/Resources/Professionals/Training/Serology/training.htm

EPIDEMIOLOGY

Hepatitis B virus (HBV) is a major cause of chronic liver disease and cancer worldwide. In developed countries, the infection rate is low. In the United States, the rate of new HBV infections has declined by approximately 82% since 1991, when a national strategy to eliminate HBV infection was implemented and routine vaccination was recommended. In 2009, the overall incidence of reported acute Hepatitis B was 1.5 per 100,000 persons, the lowest ever recorded. However, because many HBV infections are either asymptomatic or never reported, the actual number of new infections is estimated to be approximately tenfold higher. Rates are highest among adults; particularly males aged 25-44 years.

An estimated 800,000-1.4 million persons in the United States have chronic HBV infection. Globally, chronic HBV affects approximately 350 million persons. An estimated 620,000 persons worldwide die from HBV-related liver disease each year.
Persons at increased risk for Hepatitis B include:
- Infants born to infected mothers
- Sex partners of infected persons
- Sexually active persons who are not in a long-term, mutually monogamous relationship (e.g., >1 sex partner during the previous 6 months)
- Men who have sex with men
- Injection drug users
- Household contacts of persons with chronic HBV infection
- Health care and public safety workers at risk for occupational exposure to blood or blood-contaminated body fluids
- Hemodialysis patients
- Residents and staff of facilities for developmentally disabled persons
- Travelers to countries with intermediate or high prevalence of HBV infection

DISEASE OVERVIEW

A. Agent:
   The Hepatitis B virus is a DNA hepadnavirus.

B. Clinical Description:
   HBV infection may be acute or chronic, both of which may be asymptomatic. If symptoms are present, onset is usually subtle with loss of appetite, vague abdominal discomfort, nausea, vomiting and sometimes arthralgia and rash often progressing to jaundice. Fever may be absent or low-grade. Liver enzyme levels are markedly elevated. Severity ranges from inapparent to fatal cases. Disease tends to be worse and mortality higher in those >60 years old. Asymptomatic infections are common in children <5 years of age. The risk of chronic infection decreases with age. Chronic infection increases the risk of chronic liver disease or liver cancer later in life.

C. Reservoirs: Humans

D. Mode(s) of Transmission:
   HBV is transmitted through blood or body fluids. The highest concentrations of the virus are in blood; lower titers are in semen and even lower titers in saliva.

E. Incubation Period: Range from 45-160 days; average 60-90 days.

F. Period of Communicability:
   A person is considered infectious as long as Hepatitis B surface antigen (HBsAg) is detectable. Most people are infectious from 1-2 months before to 1-2 months after the onset of symptoms. Persons who have chronic Hepatitis B (i.e., carriers) remain infectious indefinitely. Persons with circulating Hepatitis B e antigen (HBeAg) are more infectious than those that are HBeAg negative.

G. Susceptibility and Resistance:
   Protective immunity follows infection if antibody to HBsAg (anti-HBs) develops and HBsAg is negative. After three intramuscular doses of Hepatitis B vaccine, more than 90% of healthy adults and more than 95% of infants, children, and adolescents develop adequate antibody responses. However, there is an age-specific decline in immunogenicity.

H. Treatment
   Supportive only during the acute phase. Persons who have chronic HBV infection require medical evaluation and regular monitoring.
NOTIFICATION TO PUBLIC HEALTH AUTHORITIES

Hepatitis B (acute, perinatal, and chronic) disease shall be designated as infectious or contagious in their nature, and cases or suspect cases shall be reported within seven days:

1. Health care providers and hospitals: report to the local public health jurisdiction.
2. Local public health jurisdiction: report to KDHE-BEPHI (see below).
3. Laboratories: report to KDHE-BEPHI (see below.)

Kansas Department of Health and Environment (KDHE)
Bureau of Epidemiology and Public Health Informatics (BEPHI)
Phone: 1-877-427-7317 Fax: 1-877-427-7318

(Local public health can report cases with New CMR creation in EpiTrax.)

Further responsibilities of state and local health departments to the CDC:
As a nationally notifiable condition, Hepatitis B (acute, chronic, and perinatal) cases require a STANDARD report to the Center of Disease Control and Prevention (CDC).

1. STANDARD reporting requires KDHE-BEPHI to file an electronic report for within the next reporting cycle. (KDHE will file electronic reports weekly with CDC.)
2. Local public health jurisdiction will report information requested in the Kansas electronic surveillance system, as soon as possible. For an acute case investigation the electronic form should be completed within 5 days or receiving a notification of an acute hepatitis case.

INVESTIGATOR RESPONSIBILITIES

1) Report all cases to the KDHE-BEPHI.
2) Investigate all cases to determine if testing was for acute disease.
   • Start the investigation within 3 days of notification for acute disease.
3) Contact medical provider to collect additional information and confirm diagnosis using current case definition.
   • Collect all information requested in Step 1) of case investigation.
   • For females, ages 12-55 years, determine if the case is pregnant.
     – The Hepatitis B (Pregnancy) Investigation Guideline should be used to manage the pregnancy; this will require the creation of a Hepatitis B Pregnancy, Event in EpiTrax.
   • Ensure that case is aware of his/her diagnosis.
4) Conduct a case investigation to identify potential source of acute infection.
   • Acute infection – collect data requested on the Hepatitis B Acute Form within 5 days of receiving a notification of a case.
   • Chronic infection that has never been investigated – complete an interview to collect data requested on the Hepatitis B, Chronic Form.
5) Conduct contact investigation to identify additional cases, as needed.
6) Identify whether the source of infection is major public health concern.
7) Initiate any needed control and prevention measures.
8) Record data, collected during the investigation, in the KS EpiTrax system under the data’s associated [tab] in the case morbidity report (CMR).
9) As appropriate, use the disease fact sheet to notify individuals or groups.
STANDARD CASE INVESTIGATION

**Case Investigation**

1) Contact the medical provider who ordered testing of the case and obtain the following information. (This includes medical records for hospitalized patients.)
   - Obtain clinical information on:
     - Reason for testing.  
     - Acute case only: record earliest symptom onset and diagnosis date on the [Clinical] tab.
     - Chronic case: record diagnosis year on [Investigation-Exposure] tab.
     - Acute Symptoms: jaundice, dark urine, diarrhea, anorexia, abdominal pain, clay stools, fatigue, or other symptoms. [Investigation-Symptoms]
     - Jaundice noted: record date of jaundice onset. [Investigation-Symptoms]
     - Liver enzymes levels at diagnosis (ALT and AST with reference values of upper limit of normal and date of result.) [Investigation-Symptoms]
   - Examine laboratory testing.  [Laboratory]
     - For a probable chronic HBV with only a single HBsAg test available, determine if previous testing occurred > 6 months prior to the laboratory report. (i.e. HBsAG, HBV DNA positive or HBeAg)
     - If there is a possibility of acute infection, encourage or coordinate testing for IgM to anti-HBc on the original specimen or testing for HBsAg >6 months after the original testing.
     - If needed, obtain copies of reports required for case confirmation that have not been reported. Scan and attach the copies to the CMR [Notes]
   - Request Hepatitis B immunization history, post-vaccine antibody titers, or information why the case, if less than 18 years of age, is not immunized or fully immunized. [Investigation-Vaccination History]
     - If not available from the medical records, attempt to collect the information from another credible source.
   - Collect patient’s demographics (address, birth date, gender, race/ethnicity, primary language, and phone number(s)). [Demographic]
   - Record hospitalizations: location, duration of stay, and reason.  [Clinical]
     - After saving the record, indicate whether the reason for hospitalization was for Hepatitis. This question will only appear after the CMR is saved.
   - Record outcomes: survived or death (with cause and date of death) [Clinical]
     - After saving the record, indicate whether the reason for death was for Hepatitis. This question will only appear after the CMR is saved.
   - Record pregnancy status for women ages 12-55 years. [Clinical]
   - Report whether case was imported. [Epidemiological]

2) Interview the patient to perform a risk assessment:
   - Collect epidemiological information for:
     - Patient’s occupation: medical/dental field, public safety officer, correctional facility association, group living arrangements and specifically list the occupation. [Epidemiological]
     - Examining occupation, record patient’s potential contact with human blood, including frequency of direct contact. [Epidemiological]
     - Record any Place Exposure(s) (where illness could have been acquired). [Epidemiological]
As you prepare to interview the patient, consider:

- **Acute HBV exposure occurs within 6 weeks – 6 months prior to onset.**
- **Chronic HBV patients are evaluated every 6 to 12 months; all laboratory results are reported but may not require follow-up if there are no changes in patient status, especially a new pregnancy. Evaluate for pregnancy.**
- **Individuals belonging to groups in which most chronic HBV infections are attributable to perinatal or early childhood infection with HBV (e.g. emigrants from HBV endemic countries) do not require collection of risk factor information. [Note] association to endemic country and mark “Out of Country” on Import Status. [Epidemiological]**

<table>
<thead>
<tr>
<th>Acute cases: inquire on activities within 6 weeks – 6 months prior to onset.</th>
<th>Chronic cases: inquire on activities that were “ever” experienced (not limited to a time period, unless specifically noted).</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Note patient’s activities related to the following: [Investigation-Exposure]</td>
<td></td>
</tr>
<tr>
<td>- Contact with a HBV case.</td>
<td></td>
</tr>
<tr>
<td>o Note the name and address of suspect case and his or her relationship to patient (sexual, household or other).</td>
<td></td>
</tr>
<tr>
<td>o Investigate any epi-linkage (refer to step 3).</td>
<td></td>
</tr>
<tr>
<td>- Number of male and female sex partners.</td>
<td></td>
</tr>
<tr>
<td>- Use any type of substances illegally.</td>
<td></td>
</tr>
<tr>
<td>→ If yes, were any injected.</td>
<td></td>
</tr>
<tr>
<td>→ If yes, were any needles or equipment shared.</td>
<td></td>
</tr>
<tr>
<td>→ The last time substances were injected. (&lt; or &gt; 6 months)</td>
<td></td>
</tr>
<tr>
<td>- Receipt of tattoo(s) or body piercing</td>
<td></td>
</tr>
<tr>
<td>→ If yes, what type of provider (commercial, private, correctional)</td>
<td></td>
</tr>
<tr>
<td>→ Was the procedure done in the last 6 months?</td>
<td></td>
</tr>
<tr>
<td>→ If yes, specify facility name and city.</td>
<td></td>
</tr>
<tr>
<td>- Receipt of acupuncture or long-term hemodialysis.</td>
<td></td>
</tr>
<tr>
<td>→ Was the procedure done in the last 6 months?</td>
<td></td>
</tr>
<tr>
<td>→ If yes, specify facility name and city.</td>
<td></td>
</tr>
<tr>
<td>- Ever received an organ transplant.</td>
<td></td>
</tr>
<tr>
<td>→ If yes: year, organ, and facility, provider, and city where received.</td>
<td></td>
</tr>
<tr>
<td>- Before 1992, received a blood transfusion.</td>
<td></td>
</tr>
<tr>
<td>- Before 1987, received clotting factor concentrates.</td>
<td></td>
</tr>
<tr>
<td>- Currently, use of blood monitoring equipment by finger-stick or lancet.</td>
<td></td>
</tr>
<tr>
<td>→ If yes, was any testing equipment shared.</td>
<td></td>
</tr>
<tr>
<td>- In the past 6 months: any dental work or oral surgery, other surgery, receipt of blood or blood products, or receipt of IV infusions or injections; specify facility name, provider name, city and procedure type.</td>
<td></td>
</tr>
<tr>
<td>• Inquire on patient’s last donation of blood products (if the case was identified by a recent donation, ask about the donation prior to the most recent.) [Investigation-Exposure]</td>
<td></td>
</tr>
<tr>
<td>- For any recent blood or plasma to that may not been identified by routine screening processes. Refer to Managing Special Situations.</td>
<td></td>
</tr>
<tr>
<td>• Collect information on potential contacts that may require testing.</td>
<td></td>
</tr>
<tr>
<td>• Hepatitis B status of mother if patient is less than ≤ 5 year of age, note location of birth.</td>
<td></td>
</tr>
</tbody>
</table>
3) Collect information needed for the Contact Investigation or Management.
4) Investigate epi-links among cases (clusters, household, co-workers, etc).
   - Inquire about others in the household with similar symptoms.
   - For suspected outbreaks to Managing Special Situations Section.

**Contact Investigation**

1) Review the patient’s occupation and activities that were collected during the case investigation and recorded on the [Epidemiological] and [Investigation-Exposure] tab, especially during the period 2 months prior to illness onset for acute cases and for the last 6 months for chronic cases.

2) Consider the following types of contacts during the contact investigation:
   - Household members of HBsAg positive individuals.
   - Infants born to HBsAg positive mothers (only if positive at time of birth).
   - Infants < 12 months of age with household exposure to a primary caregiver with acute Hepatitis B.
   - Individuals with mucosal or percutaneous exposure to infectious body fluid of an infections person.
   - Sexual partners of HBsAg positive individuals.

3) Obtain the following information from the patient:
   - Names of household members.
   - Names of sexual contacts.
   - With history of drug use, potential contacts involved in the activity.

4) After identifying potential contacts, evaluate whether a risk of transmission exits. ONLY if a risk of transmission exists, create a line listing of contacts at-risk of developing disease. [Contact]

5) Contact notification will be required for at-risk contacts in a manner that respects the privacy of the case and contacts. (See note below.)

6) Follow-up with at-risk contacts as instructed in Contact Management.

*Note:* Contact notification is well-established in the Kansas STD program; the program’s specialists have expertise in reaching the types of contacts identified with HBsAg-positive patients and might be able to provide guidance on procedures and best practices. For further assistance, contact the Director or Assistant Director of the Kansas STD Program at (785) 296-5596.

**Isolation, Work and Daycare Restrictions**

Persons should not be excluded from work, school, play, child care, or other settings on the basis of their HBV infection status. There is no evidence of HBV transmission from food handlers, teachers, or other service providers in the absence of blood-to-blood contact.

To prevent exposure to blood and body fluids, universal precautions should be followed. Safe-sex practices reduce risk of sexual transmission.

There are no current recommendations to restrict professional activities of healthcare workers with HBV infection. As recommended for all health-care workers, those who are HBV-positive should follow strict aseptic technique and standard precautions, including appropriate use of hand washing, protective barriers, and care in the use and disposal of needles and other sharp instruments.
Refer to further guidance in CDC’ MMWRs:

- Updated CDC Recommendations for the Management of Hepatitis B Virus–Infected Health-Care Providers and Students: MMWR 2012;61(RR-12);1-12
- CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management MMWR 2013;62(rr10);1-19

**Case Management**

1) **Educate** those with acute illness on measures to avoid disease transmission.
2) For acute cases, repeat testing for HBsAg after 6 months to determine the clearance or continued presence of HBsAg.
   - Those still HBsAg positive are considered confirmed chronic carriers and should be reported in the state electronic surveillance system.
3) **Council** chronic carriers on measures to avoid disease transmission, including risks to newborns, and measures to take to protect the liver.

**Contact Management**

1) If a contact listing was created because of the high possibility of disease transmission, follow-up with the listed contacts. [Contact]
2) Evaluate each contact’s susceptibility and initiate PEP for susceptible contacts as soon as possible (preferably within 24 hours).
3) Consider these contacts as susceptible:
   - Have not completed or initiated their hepatitis B series, and
   - Are without documentation of a prior HBV infection or of a response to a completed hepatitis B series; documentation is indicated by:
     (a) HBsAg positive laboratory reports (for chronic carriers), or
     (b) Positive report of a protective level of anti-HBs (≥10 mIU/mL).
4) Unvaccinated past or present sex, household, and needle-sharing contacts should be tested for HBsAg and anti-HBs, and at the time of testing:
   - Receive an initial hepatitis B vaccine with or without immune globulin, as recommended in Table 1.
5) Contacts determined to be HBsAg-positive are:
   - Do not require additional PEP or post vaccination serological testing.
   - Reported and managed as hepatitis B cases and referred for medical care.
     (On the [Contact] Tab of the CMR, click ‘Show’ beside the contact on the listing. When View Contact Event opens in show mode, select ‘Promote to CMR.’)
   - For suspected outbreaks refer to Managing Special Situations section
6) Contacts testing positive with a protective level of anti-HBs do not require additional PEP or post vaccination serological testing.
7) Contacts determined to be HBsAg-negative and without a protective level of anti-HBs are provided additional PEP as recommended in Table 1.
8) After completion of the immunization series, susceptible contacts should be tested for anti-HBs and HBsAg 1-2 months following completion of the series.
   - If both labs are negative, repeat 3 doses of hepatitis B vaccine and testing 1-2 months following completion.
9) Provide education on avoiding further exposures and to ensure proper medical care is obtained and precautions taken if symptoms develop.
10) Report the final disposition of each contact investigated. [Contact]

11) Report any adverse event that occurs after the administration of a vaccine to Vaccine Adverse Events Reporting System at http://vaers.hhs.gov/index.

Table 1. Recommended PEP for Uninfected (HBsAg Negative) Contacts Based on Receipt of Hepatitis B Vaccine and Documented Immune Response

<table>
<thead>
<tr>
<th>Status of Hepatitis B Series and Immune Response</th>
<th>Household Exposure</th>
<th>Initial sexual exposure &lt;14 days prior or initial percutaneous exposure &lt;7 days prior</th>
<th>Initial sexual exposure &gt;14 days prior or initial percutaneous exposure &gt;7 days prior</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unvaccinated (anti-HBs negative)</td>
<td>Administer Hepatitis B vaccine series.</td>
<td>Administer HBIG and * Hepatitis B vaccination series.</td>
<td>Administer Hepatitis B vaccine series.</td>
</tr>
<tr>
<td>Incomplete series (anti-HBs negative)</td>
<td>Administer remaining doses of Hepatitis B series.</td>
<td>Administer HBIG and * remaining doses of Hepatitis B vaccination.</td>
<td>Administer remaining doses of Hepatitis B series.</td>
</tr>
<tr>
<td>Completed series but without documented anti-HBs &lt;10 miU/mL</td>
<td>No booster dose needed.</td>
<td>Administer a booster dose of Hepatitis B vaccine.</td>
<td>Administer a booster dose of Hepatitis B vaccine.</td>
</tr>
<tr>
<td>Completed series with a documented anti-HBs ≥10 miU/mL</td>
<td>No booster dose needed.</td>
<td>No booster dose needed.</td>
<td>No booster dose needed.</td>
</tr>
</tbody>
</table>

* If appropriate, administer HBIG simultaneously with vaccine in a separate injection site.

* For more information, refer to “A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States”.

Environment

None, unless a health care or long-term care facility or a facility that provides tattoo, body piercing or cosmetic procedures is implicated in transmission. In which case, an inspection of the facility should be coordinated through the proper regulatory agency.

Education

1) Advise persons with acute HBV infection:
   - That their blood and other secretions are infectious to others until the HBsAg has cleared, typically within 2-3 months and
   - Postpone non-emergency dental care and surgery until viremia cleared.

2) Advise all persons who are HBsAg-positive and/or with acute HBV infection:
   - How the virus is transmitted.
   - How to prevent the transmission of the virus to others.
   - How contacts (future and present) can be protected by Hepatitis B prophylaxis including vaccination.
   - Detailed instructions should include:
     o The importance of notifying household, sex, and needle-sharing contacts (future and present) to allow testing for markers of HBV infection, vaccination against hepatitis B, and, if susceptible,
completion of the vaccine series.

- How to prevent the transmission of the virus through sexual contact by the practice abstinence, use of condoms, or other practices until the sex partners are vaccinated with immunity documented
- Not to donate blood, plasma, tissue, or semen. (Organs may be donated to HBV-immune or chronically infected persons needing a transplant.);
- To cover cuts or skin lesions to lessen chances of others having contact with secretions or blood.
- Not to share household articles (e.g., toothbrushes, razors, or personal injection equipment) that could be contaminated with blood.
- To clean and properly disinfect surfaces contaminated with saliva and blood, and objects potentially contaminated with blood (e.g., razors, toothbrushes) should not be shared with other people.
- Not to share needles with other people.
- When seeking medical or dental care, HBsAg-positive persons should be advised to inform those responsible for their care of their HBsAg status so they can be evaluated and their care managed appropriately.

3) Pregnant women and chronic female cases should be told about the risk of hepatitis B infection to newborns and of the importance of prophylaxis for such newborns.

4) Parents/guardians of HBsAg-positive persons with functional disabilities should be alerted to the risk of HBV infection associated with excessive drooling or aggressive behavior, such as biting and scratching.

5) Advise chronic cases:
   - To prevent future liver damage by avoiding or limiting alcohol consumption; refraining from beginning to take any new medicines, including over-the-counter and herbal medicines, without consulting their health-care provider; and to obtain vaccination against Hepatitis A.
   - To always consider the recommendations listed above, to prevent transmission of the virus.

MANAGING SPECIAL SITUATIONS

A. Outbreak Investigation:
   There are no formal outbreak definitions; however, the investigator may consider the possibility of an outbreak when ≥ 2 cases are clustered in time and/or space or when the epidemic threshold is exceeded for the community.
   - Notify KDHE immediately, 1-877-427-7317.
   - Active case finding will be an important part of any investigation.

   Further guidance on outbreaks related to healthcare delivery can be found at: www.cdc.gov/hepatitis/Outbreaks/index.htm.

B. Recent Blood Donor or Recipient:
   - Notify the KDHE-BEPHI at 1-877-427-7317, for the following:
     - Case has donated blood or plasma ≤ 8 weeks prior to symptoms onset.
     - Transfused blood or blood products are suspected as a possible source.
• Further investigation will determine what notifications should occur.
• Testing for HBsAg or anti-HBc may be required of the blood that is still available or of the donors themselves.

C. Pregnancy or Recent Delivery:
Preventing perinatal transmission is perhaps the most important part of case follow-up. For this reason, the State of Kansas has a Perinatal Hepatitis B Prevention Program (785-296-5588). Case management activities include:
• Within 12 hours of birth, both full term and premature infants of HBsAg-positive mothers should receive HBIG (0.5 ml) and the first dose in the hepatitis B vaccination series. Premature infants should NOT be given divided or reduced doses.
• If a mother’s HBsAg status is unknown, the infant should receive hepatitis B vaccine within 12 hours of birth and a STAT HBsAg test should be performed on the mother; administer HBIG to the infant if the mother is HBsAg positive.
• At 9 months of age or older, perinatally-exposed infants should be tested for both anti-HBs and HBsAg. This should occur 1-2 months following the last hepatitis B vaccine dose.
  – The presence of anti-HBs at less than 9 months of age, following receipt of HBIG at birth, may be the result of transient HBIG antibodies and is not indicative of active immunity to hepatitis B.
  – The presence of anti-HBs at 9 months of age or older following immunization indicates active immunity to hepatitis B.
  – Hepatitis B-immunized children who are not anti-HBs positive should repeat the 3-dose series; 15-25% will have an antibody response after the fourth dose and 30-50% will respond after the sixth dose. Children who do not respond to 6 doses of vaccine will most likely never respond.
• Coordinate with the birthing facility to ensure HBIG and vaccine are available (and given) and with the infant’s pediatrician to ensure that subsequent vaccine doses are given.

D. Needle-stick and Similar Exposures:
• For occupational exposures, refer to Kansas Regulation 28-1-23 Management of Occupational Exposures and follow the facility’s “Bloodborne Pathogen Exposure Protocol.
• For other situations, further guidance is available in Appendix B of “A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States”
• Persons who suffer such injuries or exposures should have a baseline blood sample collected followed by testing again at 6 months.

E. Correctional Facilities:
• Coordinate with proper administrative authorities.
• Refer to “Prevention and Control of Infections with Hepatitis Viruses in Correctional Settings”
DATA MANAGEMENT AND REPORTING TO THE KDHE

A. Accept the case assigned to the LHD and record the date the LHD investigation and control measures were initiated was started on the [Administrative] tab.

B. Organize and collect data, using appropriate questionnaires, case listings (spreadsheets), and investigation forms, including:
   - Acute HBV: Hepatitis B Acute Form
   - Chronic HBV, follow-up needed: Hepatitis B, Chronic Form—especially:
     - Symptoms Section: include data that indicates it is not an acute infection; as needed provide additional [Notes].
     - Pregnancy information is important for all female cases. [Clinical]
   - Chronic HBV, previously reported female of childbearing age (12-55 yrs): Collect information on pregnancy status [Clinical]
   - Chronic HBV, previously reported: female >55 years or a male:
     - A case in which the name and birth date match a case in EpiTrax is considered previously reported; a new laboratory report is not entered.
     - If there is a discrepancy, with the spelling of the name or the DOB, the local investigator will need to investigate to identify if the case is a previously reported case or is actually a new case.
   - Pregnant HBV case identified:
     - Report all pregnant cases to the KS Perinatal Hepatitis B Prevention Program as a Hepatitis B, Pregnancy Event
     - Specific guidance on creating a Hepatitis B, Pregnancy event is found in the Hepatitis B, Pregnancy Event DIG Data Management section.
     - Complete Hepatitis B Pregnancy Event Contact Form
     - For pregnant, HBsAg positive females, the infant will be treated as a contact of the pregnant mother.
   - Perinatal HBV cases (those diagnosed with acute HBV at >1 year to 24 months of age who were born in the United States or U.S. territories):
     - Complete Hepatitis B Pregnancy Event Form (Contact Section)
   - Investigators can collect and enter all required information directly into EpiTrax [Investigation], [Clinical], [Demographics], [Contact], and [Epidemiological] tabs without using the paper forms.
   - During outbreak investigations, refer to guidance from a KDHE epidemiologist for appropriate collection tools.

C. Report data collected during the course of the investigation via EpiTrax.
   - Verify that all data requested on the applicable forms has been recorded on an appropriate EpiTrax [tab], or that actions are completed for a case lost to follow-up as outlined below.
   - Some data that cannot be reported on an EpiTrax [tab] may need to be recorded in [Notes] or scanned and attached to the record.
   - Paper report forms do not need to be sent to KDHE after the information is recorded in EpiTrax. The forms should be handled as directed by local administrative practices.
D. If a case is lost to follow-up, after the appropriate attempts to contact the case have been made:
   • Indicate ‘lost to follow-up’ on the [Investigation] tab with the number of attempts to contact the case recorded.
   • Record at least the information that was collected from the medical records.
     – Cases identified as a result of blood or plasma donation: mark reason for testing as “Blood/organ donor screening” and symptomatic as “No”
   • Record a reason for ‘lost to follow-up’ in [Notes].

E. After the requirements listed under Case Investigation have been completed, record the “Date LHD investigation completed” field located on the bottom of the [Administrative] tab.
   • Record the date even if the local investigator’s Contact Management (i.e. testing 1 months after vaccination) for the contact is not “Complete”.

F. Once the investigation included contact management is completed, the LHD investigator will click the “Complete” button. This will trigger an alert to the LHD Administrator so they can review the case before sending to the state.
   • The LHD Administrator will then “Approve” or “Reject” the CMR.
   • Once a case is “Approved” by the LHD Administrator, BEPHI staff will review the case to ensure completion before closing the case.

G. Review the EpiTrax User Guide, Case Routing for further guidance

Note:
1) HBsAg positive laboratory reports (with no information on anti-HBc or other testing) are initially reported as “Hepatitis B, chronic”. Information from the local investigation may result in a case being changed to “Hepatitis B, acute.”
2) For cases reported as acute and >6 months later be determined to have converted to chronic,
   • The initial “Hepatitis B, Acute” event will remain and
   • A second event “Hepatitis B, Chronic” will be created (deep copy). The record number for the first event will be noted under the new event.
3) The date of diagnosis on the [Clinical] tab is used by KDHE when a “Probable, Chronic Hepatitis B” case that was reported in a previous year is confirmed.
   • The date the most recent (confirmatory) lab was collected is recorded as the diagnosis date on the [Clinical] tab.
   • The Year of Diagnosis on the [Investigation-Exposure] tab can remain as the earliest year diagnosed.
ADDITIONAL INFORMATION / REFERENCES


C. Case Definitions: www.cdc.gov/nndss/

D. Kansas Regulations/Statutes Related to Infectious Disease: www.kdheks.gov/epi/regulations.htm

E. Pink Book: Epidemiology and Prevention of Vaccine-Preventable Diseases. www.cdc.gov/vaccines/pubs/pinkbook/index.html


G. CDC Hepatitis MMWR Resource Center: www.cdc.gov/hepatitis/Resources/Professionals/MMWRs.htm

H. CDC Hepatitis page: www.cdc.gov/hepatitis/

ATTACHMENTS

To view attachments in the electronic version:
1. Go to <View>;<Navigation Pane>;<Attachments> – OR – Click on the “Paper Clip” icon at the left.
2. Double click on the document to open.