

Hepatitis B

Surveillance and Investigation Protocol



Disease Summary

Hepatitis B is a serious liver infection caused by the hepatitis B virus (HBV) and is spread through exposure to infected blood or body fluids. In the United States, the two most common methods of transmission are intravenous drug use and sexual intercourse. An acute infection can range in severity from a mild illness with few or no symptoms to a serious condition requiring hospitalization. Most people with HBV infections are asymptomatic; less than 10% of children and 30-50% of adults with acute hepatitis B develop symptoms 30 to 180 days after infection. Symptoms are non-specific and can include the rapid onset of nausea, vomiting, jaundice (yellow skin and/or eyes), fatigue, dark urine, or abdominal pain. Often, the body can fight off the infection and develop immunity to the virus. Those who do not recover from the infection develop what is known as chronic hepatitis B. Chronic hepatitis B is a lifelong infection that can progress to serious conditions such as hardening of the liver, scarring, and liver cancer.

Public Health Significance

The number of new cases of hepatitis B infections declined by 85% since 1980, but progress stalled in recent years due to the opioid epidemic. West Virginia is among the states hit hardest by the opioid epidemic and leads the nation in new cases of HBV infection.

According to the National Viral Hepatitis Action Plan 2017-2020, it is estimated that only 33% of people living with hepatitis B are aware of their infection status. This is a major public health concern as hepatitis B, if undiagnosed and untreated, can lead to the development of liver disease and liver cancer, which has the fastest growing death rate of any type of cancer in the United States.

In addition to the lack of infection status awareness, there are many challenges that must be addressed to improve hepatitis B prevention. One barrier to prevention is the limited awareness of viral hepatitis among healthcare providers. Adequate healthcare provider training is required to ensure there are fewer missed opportunities for vaccination, screening, and linkage to care. Other challenges to advancing the goals of the action plan include limited data, low public awareness and perceived risk, limited public health and health system response, and the high cost of treatment.

There have been major advances in the effort to eliminate hepatitis B including the development of a safe and effective hepatitis B vaccine program, multiple treatment options for those living with chronic hepatitis B, the availability of an affordable insurance option through the Affordable Care Act (ACA), and the implementation of harm reduction/syringe exchange services. It is imperative to continue to address identified gaps in order to make

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progress in the prevention of new cases of hepatitis B infection and identification and treatment of chronic infections.

Healthcare Provider Responsibilities

1. Report cases of acute, chronic, or perinatal hepatitis B to the local health department serving the patient's county of residence within 24 hours of diagnosis by telephone and follow up with a written report.
2. Evaluate and test patients who present with signs and symptoms of acute hepatitis B.
3. Conduct appropriate screening of pregnant women.
4. Consider screening patients who are asymptomatic but who have risk factors for viral hepatitis infection.

Laboratory Responsibilities

1. Report all lab results for hepatitis B to the local health department serving the patient's county of residence by telephone within 24 hours of report followed by a written copy (if the report has not already been reported by electronic laboratory reporting (ELR)) and include the following patient information:
 - a. Patient's full name, date of birth, address and phone number
 - b. Patient's demographic information including age, sex, race, and ethnicity
 - c. Full name, address, and phone number of ordering physician
 - d. Laboratory results, normal values, and interpretation including:
 - i. IgM antibody to HAV (IgM anti-HAV)
 - ii. Hepatitis B surface antigen (HBsAg)
 - iii. IgM antibody to hepatitis B core antigen (IgM anti-HBc)
 - iv. Hepatitis B DNA
 - v. Hepatitis B Genotype
 - vi. Antibody to HCV (anti-HCV)
 - vii. HCV RNA
 - viii. Bilirubin levels
 - ix. Transaminase levels

Local Health Department Responsibilities

1. Education and Outreach

- a. Educate providers about the importance and the appropriate use of hepatitis B vaccine, especially in newborns, adolescents, and those with reported risk factors.
- b. Educate providers about the importance of screening and identifying pregnant women who are HBV positive, and the importance of notifying local health departments.

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- c. Educate the general public about hepatitis B risk factors, hepatitis B vaccine, and prevention of hepatitis B transmission.
- d. Per the Reportable Disease Rule (WV Code 16-3-1; 64CSR7), local health departments will:
 - i. Educate healthcare providers about the requirement to report hepatitis B, acute, chronic or perinatal, to the local health department within 24 hours of diagnosis.
 - ii. Educate laboratories about the requirement to report hepatitis B surface antigen (HBsAg) positive, IgM antibody to hepatitis B core antigen (HBcAb-IgM), hepatitis B “e” antigen (HBeAg), and hepatitis B DNA (hepatitis B DNA) laboratory serology to the local health department within 24 hours of positive results.

2. Investigations

- a. Within 24 hours of receiving a report of HBsAg, HBeAg or hepatitis B DNA, the local health department shall:
 - i. Report all hepatitis B lab results to West Virginia Electronic Disease Surveillance System (WVEDSS) by:
 - 1. Searching WVEDSS for previous investigations.
 - 2. Reviewing local health department case records of previously reported cases.
 - 3. Contacting the DHHR’s Division of Infectious Disease Epidemiology (DIDE) to search database records and determining if the patient was reported outside of the local health department’s jurisdiction.
- b. Contact the healthcare provider to gather additional information (if not yet available) including:
 - i. Demographic information.
 - ii. Clinical information.
 - iii. Patient’s pregnancy status (if patient is pregnant, please notify the Perinatal Hepatitis B Prevention Coordinator with DIDE).
 - iv. Other related laboratory results (hepatitis A, hepatitis C, or liver enzymes).
 - v. Social risk factor information such as substance use, etc.
 - vi. Hepatitis B vaccination history.
 - vii. Determine if the patient is aware of their hepatitis B positive diagnosis.
 - viii. Inform the provider that you will be contacting the patient to complete the public health investigation.
- c. Interview the patient to collect information not already obtained from previous sources, such as:

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- i. Demographic or clinical information.
- ii. Exposure and risk factor information.
- iii. Healthcare-associated infection (HAI) potential exposures including:
 - 1. No risk factor identified other than a healthcare procedure that occurred within 180 days of the date of onset of symptoms.
 - 2. If the patient has had an invasive medical procedure within 180 days prior to the date of symptom onset and reports no other risk factors for hepatitis B infection, the local health department should report the case to the DIDE at (304) 558-5358, extension 1, immediately.
 - 3. A suspect case of healthcare-associated hepatitis B infection warrants an investigation. Steps for investigation a single case of hepatitis B infection suspected of being related to healthcare delivery can be found at:
<http://www.cdc.gov/hepatitis/outbreaks/pdfs/healthcareinvestigationguide.pdf>.
- d. Obtain hepatitis B vaccination records on patient.
- e. Obtain information about disease contacts including:
 - i. Name of contact and date of birth.
 - ii. Type of contact (sexual, drug, or household).
 - iii. Contact's address and phone number.

3. Public Health Action for Local Health Departments

- a. Educate patient and contacts about hepatitis B prevention and transmission.
- b. Refer the patient to a physician for further testing and disease management if needed.
- c. Investigate and notify potential contacts of the index case (see page 4, section 4).
 - i. Provide disease education, offer testing and vaccination (if necessary), and post exposure prophylaxis (PEP) (See Table 1).
- d. Document public health actions taken and date of action in WVEDSS.
- e. Submit the case investigation to the Regional Epidemiologist with your local health department for review.

4. Managing Contacts of Acute and Chronic Cases

- a. Provide partner notification to:
 - i. Sexual partners.
 - ii. Household contacts.
 - iii. Needle/drug-use equipmentsharing contacts.
- b. Complete the contact tracing section in the WVEDSS investigation prior to submitting case to the regional epidemiologist.

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- c. Testing contacts (see Appendix A for guidance):
 - i. Submit a blood sample from the contact(s) to the West Virginia Office of Laboratory Services for a hepatitis B screen and enter the results into WVEDSS. Note: on the West Virginia Office of Laboratory Services lab specimen submission form, patient type is “investigation” for contacts identified during a hepatitis B case investigation.
- d. Vaccinating contacts:
 - i. Administer hepatitis B immunoglobulin (HBIG) when appropriate (see Table 1), and the first dose of hepatitis B vaccine to the contact(s) prior to testing for hepatitis B if patient is not known to have had the disease or received the vaccine previously.
 - ii. If the hepatitis serology results are positive, stop the vaccination series and refer the patient for medical care. If serology results are negative, complete the full immunization series.
 - iii. If a patient receives HBIG and/or hepatitis B vaccine, the local health department should document vaccines administered into the WVEDSS investigation and into the West Virginia Statewide Immunization Information System (WVSIS).
 - iv. If the source patient has chronic hepatitis B or develops a chronic infection, all household contacts should receive the hepatitis B vaccine series, unless there is proof of vaccination or immunity to hepatitis B.
- e. Provide education to contacts about hepatitis B prevention and transmission.
- f. Document public health actions and date taken in the WVEDSS investigation.

5. Linkage to Care

- a. Linkage to care (LTC) refers to the initiation of care for those who are infected with hepatitis B and/or C. All persons who are chronically infected with hepatitis B and/or C should be linked to outpatient care for disease staging, treatment initiation, treatment completion, and testing for sustained virologic response (SVR).
 - i. For the purposes of case management, the LHD should:
 - 1. Document LTC information in the case report form in WVEDSS
 - ii. If possible, the LHD may also:
 - 1. Assist the case patient in making an appointment to see a provider in the respective area/region.
 - 2. Share the contact information of any providers in the area/region able to provide care for hepatitis B and/or C with the case patient.

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6. Lost to Follow Up/Disease Intervention Specialists

- a. Each local health department should maintain a policy on how to manage patients who are lost to follow up.
- b. A patient may be considered lost to follow up if the patient cannot be located within two weeks after initial assignment, and after the local health department has documented three good faith attempts in the WVEDSS to contact the patient which includes, but is not limited to:
 - i. Three phone call attempts on separate days.
 - ii. Two letters (preferably one certified).
- c. If the local health department determines that the patient is lost to follow up, the case investigation may be submitted to the DIDE's Hepatitis B Epidemiologist as lost to follow up (LTFU).
- d. The Viral Hepatitis Disease Intervention Specialist will perform the following duties:
 - i. If the patient is located, interview using the hepatitis B case investigation report form.
 - ii. Interview the patient for all contacts including sexual, household, and needle/drug-use equipment sharing contacts.
 - iii. Provide patient contacts with disease notification services if contact information is provided by the patient.
 - iv. Refer the patient back to the local health department for follow up.
 - v. Update the WVEDSS with any additional information obtained through interview.
 - vi. Complete and submit a field record to the Disease Intervention Specialist supervisor.
- e. The Viral Hepatitis Disease Intervention Specialist will attempt to locate the patient for up to four weeks after receiving the lost to follow up case. If the patient is unable to be located within four weeks, it will be closed as lost to follow up.

State Health Responsibilities

Viral Hepatitis Surveillance Staff

1. Timely and complete reporting of hepatitis B cases to the Centers for Disease Control and Prevention (CDC) through the WVEDSS.
 2. Provide technical guidance and consultation on surveillance, investigation, control measures and the prevention of hepatitis B.
 3. Notify the CDC of suspected outbreaks identified in West Virginia.
 4. Assist local health jurisdictions in investigating hepatitis B outbreaks.
 5. Annually summarize surveillance data and disseminate information to partners.
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6. Provide hepatitis B immune globulin for contacts of cases to local health department when hepatitis B immune globulin is recommended.
7. Offer laboratory testing for hepatitis B through the West Virginia Office of Laboratory Services at no cost for the contacts of acute and chronic hepatitis B cases.
8. Assist with difficult investigations including:
 - a. Interface with providers on behalf of the local health department as necessary.
 - i. Provide assistance via DIDE Viral Hepatitis Disease Intervention Specialist to the local health department for investigating cases that are lost to follow up.
 - ii. Investigation of possible exposures in unusual settings
 - 1) Investigation of outbreaks of hepatitis B.
 - 2) Investigation of healthcare-associated HBV infections.

Viral Hepatitis Disease Intervention Specialist

1. Receive cases identified by the State Hepatitis B Epidemiologist as lost to follow up from Disease Intervention Specialist supervisor.
2. Attempt to locate patient within four weeks of case assignment.
3. If the patient is located:
 - a. Interview the patient using the hepatitis B case report form.
 - b. Interview the patient for all contacts including sexual, household, and needle/drug-use equipment sharing contacts and provide partner notification services if applicable.
4. Refer the patient to their respective local health department for follow up if they are not already seeing a physician for hepatitis disease management.
5. Update the WVEDSS to reflect any new case information obtained through the interview.
6. Submit a field record to the Disease Intervention Specialist Supervisor.
7. If the patient is unable to be located within four weeks, the case will be closed as lost to follow up.

Viral Hepatitis Prevention Coordinator

1. Collaborate with stakeholders to enhance existing hepatitis prevention programs.
2. Work to develop new initiatives aimed at improving hepatitis prevention, increased screening, and LTC for patients with hepatitis B.
3. Plan and manage internal and external stakeholder prevention group meetings.
4. Provide educational opportunities for partners, stakeholders, and the public focusing on relevant policies, reporting requirements, insurance reimbursements for recommended testing and treatment of hepatitis B.

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5. Work closely with the viral hepatitis surveillance staff and other partners to monitor and evaluate policies and strategies that impact testing, care and treatment of those who have hepatitis B.
6. Participate in activities for the federal cooperative agreement including program evaluation, progress reporting, and renewal applications.

Occupational Health

Hepatitis B has long been recognized as an occupational risk for healthcare workers and those who work in close contact with blood. The highly infectious virus can be transmitted in the absence of observable blood and can continue to be infectious on environmental surfaces for at least 7 days. All healthcare workers should be advised to immediately report blood or body fluid exposures to occupational health for evaluation of the appropriate measures to prevent transmission of bloodborne pathogens such as hepatitis B, hepatitis C or HIV.

For guidance on evaluating and ensuring protection against HBV for healthcare workers, as well as post-exposure prophylaxis recommendations for those without adequate vaccine protection, please see Appendix B or the CDC's "Guidance for Evaluating Healthcare Personnel for Hepatitis B Protection and for Administering Post-exposure Management"; available online at <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6210a1.htm>.

Needlestick Reporting

West Virginia Legislative Rule 64CSR82 and West Virginia Code §16-36 established specific standards and procedures concerning needlestick injury prevention in the following facilities:

- All hospitals licensed under the provisions of §16-5B-1
- All long-term care facilities licensed under the provisions of §16-5C-1
- Every local health department
- Every home health agency certified by DHHR's Office of Health Facility Licensure and Certification
- All hospitals and nursing homes operated by the State or any agency of the State
- All hospitals, nursing homes, local health departments, and home health agencies which are staffed in whole or in part by public employees

To report a needlestick incident, please contact The West Virginia Needlestick Injury Prevention Program at (800) 642-8244. For more information on needlesticks and state reporting requirements, please visit <https://dhhr.wv.gov/oeps/prevention/Pages/ReportingForms.aspx>.

Disease Control and Prevention Objectives

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The National Viral Hepatitis Action Plan 2017-2020, developed by federal public health partners and community stakeholders, outlines four major goals to guide the nation's response to viral hepatitis including:

1. Prevent new viral hepatitis infections.
2. Reduce deaths and improve the health of people living with viral hepatitis.
3. Reduce viral hepatitis health disparities.
4. Coordinate, monitor, and report on implementation of viral hepatitis activities.
5. Facilitate LTC for newly reported cases of hepatitis B.

Disease Surveillance Objectives

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

Clinical Description

Signs and Symptoms of Acute Infection

Persons with acute hepatitis B may be asymptomatic or symptomatic; infants and children are usually asymptomatic whereas an estimated 50% of adults experience symptoms. Symptoms can include tiredness, headache, loss of appetite, nausea, vomiting, fever, and chills with onset three to 10 days prior to jaundice. Right upper quadrant pain is common. Urine may become dark, and stools may become clay-colored. The hallmark of the hepatitis B is jaundice (yellow color of the skin and sclera). Fulminant hepatitis occurs in very few patients and is usually fatal. Duration of illness is usually several weeks, with symptoms occasionally persisting beyond three to four months.

Signs and Symptoms of Chronic Infection

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

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Etiologic Agent

Hepatitis B is a small, double-stranded DNA virus and a member of the *Hepadnaviridae* family of viruses. The outer protein coat contains the hepatitis B surface antigen.

Reservoir

Humans are the only known reservoir.

Mode of Transmission

HBV is transmitted by parenteral or mucosal exposure to HBV-infected body fluids. The virus can be found in blood, body fluids (e.g. wound exudates), semen, cervical fluid, and saliva of infected persons. Blood and serous fluids have the highest concentration of virus, and saliva the lowest. There is no evidence to support transmission of hepatitis B via tears, sweat, urine, stool, or droplet nuclei.

In the US, the most commonly reported risk factors for the transmission of hepatitis B are injection drug use and multiple sex partners; however, the greatest risk for development of chronic infection is through perinatal transmission. Perinatal transmission from mother to infant at birth is very efficient. Transmission of perinatal hepatitis B infection can be prevented in approximately 95% of infants born to infected mothers when immunization and hepatitis B immune globulin is administered to the infant within 12 hours of birth.

Person-to-person transmission of hepatitis B can occur in settings involving interpersonal contact over extended periods of time, such as in a household with a person with chronic hepatitis B infection. Transmission from sharing inanimate objects may also occur because the hepatitis B virus can survive for up to seven days at room temperature. The virus is inactivated by commonly used disinfectants, such as a 1:10 bleach solution. Hepatitis B is not transmitted by the fecal oral route.

Risk Factors for HBV Infection:

1. Babies who are born to a mother who is HBsAg positive
2. Those who have a job that involves contact with blood and blood products
3. Injection drug users
4. Sexually active persons who have had more than one partner in the last six months or who have a sexually transmitted disease previously
5. Sexually active men who have sex with men
6. Household contacts and sexual partners of persons who are chronically infected and HBsAg-positive

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7. Residents and staff of institutions for developmentally disabled persons
8. Staff of nonresidential childcare and school programs for developmentally disabled persons if the program is attended by a known HBsAg-positive person
9. Patients undergoing hemodialysis
10. Patients with bleeding disorders who receive clotting factor concentrates
11. Members of households with adoptees who are HBsAg-positive
12. International travelers to areas in which hepatitis B infection is of high or intermediate endemicity
13. Inmates of juvenile detention centers and other correctional facilities

Incubation Period

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

Period of Communicability

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

Outbreak Recognition

An outbreak of hepatitis B may be considered when:

1. There is an increase in the number of acute cases of hepatitis B above the expected number of cases
2. Two or more cases of hepatitis B that are determined to be epidemiologically linked
3. Cases of hepatitis B that are identified as healthcare-associated infections

If an outbreak of hepatitis B unrelated to a healthcare-associated outbreak is suspected, a thorough investigation should be undertaken to determine the source of the outbreak and the necessary control and prevention measures needed to eliminate further spread of disease.

Healthcare-Associated Infections

Healthcare exposures should be considered when investigating a case of acute hepatitis B infection in a patient who has no other risk factors than a healthcare procedure that occurred within 180 days prior to the date of onset of symptoms. Any single case of suspected healthcare associated hepatitis B infection warrants an investigation. Investigation of these suspected cases is a vital public health response, as it can result in the identification of an outbreak and/or unsafe clinical practices that can place additional patients at risk. Steps for investigating a single

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case of hepatitis B infection suspected of being related to healthcare delivery can be found at:
<http://www.cdc.gov/hepatitis/outbreaks/pdfs/healthcareinvestigationguide.pdf>.

Outbreak-associated hepatitis B infections are defined as those with epidemiologic evidence supporting healthcare-related transmission and include patients/residents identified with acute infection or previously undiagnosed chronic infections with epidemiologic evidence indicating they were likely outbreak-related incident cases that progressed from acute to chronic. Patients/residents identified as likely (previously infected) sources for transmission are not included. In the outbreak investigation setting, case definitions are based on laboratory profile and clinical evidence rather than CDC surveillance case definitions which may omit asymptomatic cases.

Case Definitions

The most current CDC case definition should be used for case classification and may not be reflected in this protocol. This information is available from
<https://wwwn.cdc.gov/nndss/conditions/>.

Hepatitis B, Acute (2012 Case Definition)

Clinical Description

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 (hepatitis B NAT) including genotype) result does not require an acute clinical presentation to meet the surveillance case definition.

Laboratory Criteria for Diagnosis

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 hepatitis B.

Not a case – Any case that does not meet ALL the requirements listed above for a confirmed case.

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Hepatitis B, Chronic (2012 Case Definition)

Clinical Description

No symptoms are required. Persons with chronic hepatitis B virus 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

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 hepatitis B 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

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

Confirmed - A person who meets either of the above laboratory criteria for diagnosis.

Comments:

Multiple laboratory tests indicative of chronic hepatitis B 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 hepatitis B 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 hepatitis B DNA levels below positive cutoff level do not confirm the absence of hepatitis B infection.

Vaccine Recommendations

For current hepatitis B vaccine recommendations, please see Appendix C or visit:

<https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hepb.html>. For more information on the two-dose hepatitis B vaccine, Heplisav B, visit <https://www.cdc.gov/vaccines/schedules/vacc-updates/heplisav-b.html>.

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Treatment

Patients should check with their physician about treatment options for hepatitis B. Guidelines for treatment from the American Association for the Study of Liver Disease (AASLD) are available at <https://www.aasld.org/publications/practice-guidelines-0>.

Surveillance Indicators

1. Proportion of cases with complete demographic information.
2. Proportion of cases with complete clinical information.
3. Proportion of cases with complete risk factor/exposure information.
4. Proportion of cases with complete vaccination history.
5. Proportion of cases that have received education and been linked to care.
6. Proportion of cases reported to public health within the required timeframe.

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Appendix A

Guidance on testing contacts

Table 1. Testing, Immunization and Postexposure Prophylaxis Recommendations for Contacts of Patients with Open Acute or Chronic Hepatitis B Investigations in WVEDSS

	Testing Recommended	Immunization Recommended	HBIG Recommended
Contacts – Hepatitis B Acute Case			
Sexual contact within last 14 days	Yes	Yes	Yes
Household contact with NO known blood/body fluid exposure	Yes	Yes	No
Household contact with known exposure within last 14 days (e.g. shared toothbrush, razor, blood contact)	Yes	Yes	Yes
Needle sharing contact within last 7 days	Yes	Yes	Yes
Contacts – Hepatitis B Chronic Case			
Sexual contact NOT within last 14 days	Yes	Yes	No
Sexual contact within last 14 days	Yes	Yes	Yes
Household contact with NO known blood/body fluid exposure within last 14 days	Yes	Yes	No
Household contact with known blood/body fluid exposure within last 14 days (e.g. shared toothbrush, razor, blood contact)	Yes	Yes	Yes
Needle sharing contact NOT within last 7 days	Yes	Yes	No
Needle sharing contact within last 7 days	Yes	Yes	Yes

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Appendix B

Guidance on evaluating and ensuring protection against HBV for health-care workers

Education and Infrastructure

The CDC recommends the evaluation of healthcare workers for pre-exposure assessment of current or past anti-HBs (Hepatitis B surface antibody) results upon at entry or hire dependent upon the level of occupational risk. At the time of hire, healthcare providers and healthcare institutions should provide training to improve recognition and encourage timely reporting of blood and body fluid exposures. Institutions should ensure that healthcare personnel have rapid access to post-exposure testing and prophylaxis, including hepatitis B immune globulin and the hepatitis B vaccine.

Vaccination

The CDC recommends that all healthcare workers whose work, training, and volunteer activities involve anticipated exposure to blood or body fluids should be vaccinated with a complete hepatitis B vaccine series. The Occupational Safety and Health Administration mandates that vaccination be available for employees with occupational risk to bloodborne pathogens such as hepatitis B within 10 days of initial work assignment. Healthcare personnel should complete the hepatitis B vaccine series before the possibility of exposure to blood or body fluids.

Post Vaccine Serological Testing

In 1991, the ACIP recommended post vaccine serological testing (PVST) for anti-HBs for healthcare workers at risk for needlestick exposure. In 1997, the ACIP recommended PVST 1-2 months after completion of the hepatitis B vaccine series to ensure immunity. Many healthcare workers received the hepatitis B vaccine series in infancy or as an adolescent with no post vaccine serologic testing. Without post vaccination testing 1 to 2 months after completion of the series it is difficult to distinguish between:

- True vaccine failure (i.e., no initial response or non-responders)
- Anti-HBs that have waned to below a level detectable by the test

60% of those vaccinated lose detectable antibodies (but not protection) 9 to 15 years after vaccination.

The Challenge Dose and Detecting Anti-HBs

Previously vaccinated healthcare personnel for whom pre-exposure evaluation fails to detect protective anti-HBs should receive a “challenge dose” of hepatitis B vaccine to assess

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protection, which will cause a rise in anti-HBs, or “memory” response to the vaccine. Those who respond to the challenge dose do not require additional management, even if exposed. Healthcare workers who do not respond to the challenge dose should complete the hepatitis B vaccine series. They should then be tested for anti-HBs 1 to 2 months after completion of the vaccine series. Those who respond to the first series do not require additional management, even if exposed. Persons who do not respond to the first series of hepatitis B vaccine should complete a second hepatitis B vaccine series on schedule according to the manufacturer’s directions. Healthcare workers and others for whom PVST is recommended should be retested 1 to 2 months after completion of the second vaccine series. Those who respond to PVST after the second series do not require additional management, even if exposed. Persons who fail to develop detectable anti-HBs (<10 mIU/mL) after two complete vaccine series are non-responders or may already be infected with the hepatitis B virus.

Non-responders

Persons who fail to develop detectable anti-HBs (<10 mIU/mL) after two separate vaccine series should be tested for the HBsAg. Those who are found to be HBsAg positive should be counseled accordingly. Persons who fail to respond to two appropriately administered vaccine series, and who are HBsAg negative should be documented as a non-responder. These persons should be considered susceptible to hepatitis B infection and should be counseled regarding precautions to prevent hepatitis B infection and the need to obtain post exposure prophylaxis for any known or probable exposure to HBsAg-positive blood.

Factors associated with vaccine nonresponse include older age, male gender, obesity, smoking and chronic illness. Fewer than 5% of persons receiving two series of hepatitis B vaccine fail to develop detectable anti-HBs.

Managing Vaccinated Healthcare Workers

For vaccinated healthcare workers (who have written documentation of a complete, hepatitis B vaccine series) with documented anti-HBs ≥ 10 mIU/mL, testing the source patient for HBsAg is unnecessary. No post-exposure management for hepatitis B is necessary, regardless of the source patient’s HBsAg status.

Managing Healthcare Workers Who Lack Documentation of Vaccination, are Unvaccinated or are Incompletely Vaccinated

For unvaccinated or incompletely vaccinated healthcare workers (including those who refused vaccination), the source patient should be tested for HBsAg as soon as possible after the exposure. Testing unvaccinated or incompletely vaccinated healthcare workers for anti-HBs is not necessary and can be misleading, because anti-HBs ≥ 10 mIU/mL as a correlate of vaccine

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induced protection has only been determined for persons who have completed an approved vaccination series.

Appendix C

Vaccine Recommendations

As of February 2018, the Advisory Committee on Immunization Practices (ACIP) recommends a new, two-dose vaccine for hepatitis B called Heplisav-B (HepB-CpG) for adults, 18 years of age and older. HepB-CpG is available in single dose 0.5mL vials, and is administered in two doses, one month apart. It is important to remember the 2-dose hepatitis B vaccine only applies when both doses in the series consist of HepB-CpG.

No clinical studies regarding the safety of HepB-CpG have been conducted in pregnant women, and until safety data are available, the APIC recommends providers continue to vaccinate pregnant women with vaccine from a different manufacturer. Additional information is available online: <https://www.cdc.gov/mmwr/volumes/67/wr/mm6715a5.htm>

TABLE 3. Recommended doses of hepatitis B vaccine, by group and vaccine type

Age group (yrs)	Single-antigen vaccine				Combination vaccine			
	Recombivax		Engerix		Pediarix*		Twinrix†	
	Dose (μ g)	Vol (mL)	Dose (μ g)	Vol (mL)	Dose (μ g)	Vol (mL)	Dose (μ g)	Vol (mL)
Birth–10	5	0.5	10	0.5	10*	0.5	N/A	N/A
11–15	10 [§]	1	N/A	N/A	N/A	N/A	N/A	N/A
11–19	5	0.5	10	0.5	N/A	N/A	N/A	N/A
≥20	10	1	20	1	N/A	N/A	20 [†]	1
Hemodialysis patients and other immune-compromised persons								
<20	5	0.5	10	0.5	N/A	N/A	N/A	N/A
≥20	40	1	40	2	N/A	N/A	N/A	N/A

Abbreviation: N/A = not applicable.

* Pediarix is approved for use in persons aged 6 weeks through 6 years (prior to the 7th birthday).

† Twinrix is approved for use in persons aged ≥18 years.

§ Adult formulation administered on a 2-dose schedule.

¶ Higher dosages might be more immunogenic, but no specific recommendations have been made.

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** Dialysis formulation administered on a 3-dose schedule at 0, 1, and 6 months.

†† Two 1 mL doses administered at one site on a 4-dose schedule at 0, 1, 2, and 6 months.

Table Source: https://www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm#T3_down

TABLE 4. Hepatitis B 3-dose vaccine schedules for children, adolescents, and adults	
Age group	Schedule (interval represents time in months from first dose)
Children (1–10 yrs)*	0, 1, and 6 mos
	0, 1, 2, and 12 mos
Adolescents (11–19 yrs)	0, 1, and 6 mos
	0, 12, and 24 mos
	0 and 4–6 mos [†]
	0, 1, 2, and 12 mos 0, 7 days, 21–30 days, 12 mos [§]
Adults (≥20 yrs)	0, 1, and 6 mos
	0, 1, 2, and 12 mos
	0, 1, 2, and 6 mos ^{††}
	0, 7 days, 21–30 days, 12 mos [§]

*The ACIP recommends all medically stable infants, weighing 2000 grams at birth, born to HBsAg negative mothers receive the first dose of the single-antigen vaccine within the first 24 hours after birth.

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

Table 5. Hepatitis B 2-Dose Vaccine Schedules for children, adolescents, and adults	
Age Group	Schedule (interval represents time in months from first dose)
Children (1-10 yrs)	N/A
Adolescents (11-17 yrs)	N/A
Adults (≥ 18 yrs)	0, 1 mos

Table source: <https://www.cdc.gov/vaccines/hcp/clinical-resources/downloads/2018-Pediatric-Hepatitis-B-Vaccine-Supply-Update-and-Guidance-Table.pdf>

The 2-dose HepB vaccine series only applies when both doses in the series consist of HepB-CpG. Series consisting of a combination of 1 dose of HepB-CpG and a vaccine from a different manufacturer should consist of 3 total vaccine doses and should adhere to the 3-dose schedule minimum intervals of 4 weeks between dose 1 and 2, 8 weeks between dose 2 and 3, and 16

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weeks between dose 1 and 3. Doses administered at less than the minimum interval should be repeated. However, a series containing 2 doses of HepB-CpG administered at least 4 weeks apart is valid, even if the patient received a single earlier dose from another manufacturer. Additional information regarding pediatric hepatitis B vaccine guidance can be found at <https://www.cdc.gov/vaccines/hcp/clinical-resources/downloads/2018-Pediatric-Hepatitis-B-Vaccine-Supply-Update-and-Guidance-Table.pdf>