Utah Department of Health & Human Services

Hepatitis B (chronic, acute, and perinatal) and hepatitis D

Disease plan

Quick links

Last updated: October 18, 2022, by Ethan Farnsworth
CSTE case definition updated January 2024

Questions about this disease plan?

Contact the Utah Department of Health and Human Services Office of Communicable Diseases: 801-538-6191.

Hepatitis B critical clinical information

Clinical evidence

Signs/symptoms

There are generally 3 phases of hepatitis B symptoms:

1. Pre-icteric or prodromal phase:
    - Nonspecific and usually presents with malaise, anorexia, nausea, vomiting, right upper quadrant abdominal pain, fever, headache, myalgia, skin rashes, arthralgia and arthritis, and dark urine; generally lasts for 3–10 days.
2. Icteric phase:
    - Occurs at the onset of jaundice, and is usually accompanied by light or gray stools, hepatic tenderness and liver enlargement. This phase can last from 1–3 weeks.
3. Convalescent phase:
    - Can last for weeks to months, and is characterized by malaise and fatigue.

Period of communicability

- As long as HBsAg is detectable in the blood, a person is considered infectious.
- An infected person can spread the virus to others starting a few weeks before symptoms appear and as long as they are infected.
- Chronically infected people remain infectious for the rest of their lives.
- The period of time just prior to onset of acute illness is likely the most infectious period.

Incubation period

- Range of 45–160 days, with an average of 90 days after exposure.

Mode of transmission

- Blood or body fluids (semen, vaginal secretions, and saliva) via sexual contact, contact with contaminated blood, or perinatally.

Laboratory testing

Type of lab test	Also known as	Type of specimens	Collection timing
Hepatitis B surface antigen	HBsAg	Blood/serum, recalcified plasma, plasma	≥2 weeks after suspected exposure
Hepatitis B e antigen	HBeAg	Blood/serum, recalcified plasma, plasma	≥2 weeks after suspected exposure
Nucleic acid test for hepatitis B DNA, including qualitative, quantitative, and genotype testing	HBV-DNA	Blood/serum, recalcified plasma, plasma	≥2 weeks after suspected exposure
Hepatitis B core antigen IgM	Anti-HBc	Blood/serum, recalcified plasma, plasma	≥2 weeks after suspected exposure
Hepatitis B core Ab	Anti-HBcAb	Blood/serum, recalcified plasma, plasma	≥2 weeks after suspected exposure

Hepatitis B surface antibody	HBsAb	Blood/serum, recalcified plasma, plasma	≥2 weeks after suspected exposure

Treatment recommendations

Type of treatment

- For acute infection, no medication is available; treatment is supportive.
- There are several antiviral medications for people who have chronic infection. People with chronic HBV infection require linkage to care with regular monitoring to prevent liver damage and/or hepatocellular carcinoma.

Time period to treat

- As soon after exposure as possible

Prophylaxis

- Hepatitis B immune globulin (HBIG)
- Hepatitis B vaccine for those at risk of additional exposure
- For infants born to an infected gestational parent, the combination of HBIG and vaccine is effective at preventing infection.

Contact management

- Unvaccinated household members, syringe sharing partners, and sexual partners should start and complete post-exposure prophylaxis, which may include HBIG and/or hepatitis B vaccine according to age specifications. See additional post-exposure prophylaxis guidelines.
- Infants born to HBsAg-positive gestational parents should receive HBIG (0.5mL IM) and the first dose of hepatitis B vaccine within 12 hours of birth.
    - Infants should be screened for HBsAg and anti-HBs after their immunization series is completed at 9–12 months of age.
    - If HBsAg is not present and anti-HBs antibody is ≥10 mIU/mL, children can be considered protected.
    - Infants with anti-HBs concentrations of <10 mIU/mL and who are HBsAg-negative should receive 3 additional doses of vaccine in a 0, 1, and 6-month schedule, followed by testing for anti-HBs 1–2 months after the third dose.
    - Infants who become HBsAg-positive despite immunization should be referred to a pediatric hepatologist for follow-up.
- Infants born to gestational parents whose HBsAg status is unknown should be given hepatitis B vaccine within 12 hours of birth while awaiting HBsAg test results on the gestational parent. If the infant weighs less than 2000g, HBIG should be administered as well.
    - If the gestational parent is determined to be positive, the infant should receive HBIG as soon as possible, within 7 days of birth. The infant should then complete the 3-dose hepatitis B vaccination series. The child should then be screened for HBsAg and anti-HBs at 9–12 months of age.
    - If the gestational parent is determined to be HBsAg-negative, the infant should complete the 3-dose hepatitis B vaccine series according to the schedule for infants born to HBsAg-negative gestational parents (0, 1–2, 6–18 months).

    - If the gestational parent's HBsAg status remains unknown, the infant should complete the vaccine series according to the recommended schedule for infants born to HBsAg-positive gestational parents (0, 1–2, 6 months).
- Infants who are <12 months of age and exposed after birth by primary caregivers with acute infection should receive HBIG (0.5mL IM) unless the infant is fully immunized or has received at least 2 doses of vaccine.

Isolation of case

- Those who are ill with acute HBV should stay home until fever and jaundice has resolved.

Hospital

N/A

Quarantine

N/A

Infection control procedures

- Vaccination
- Universal precautions
- Any blood spills, including dried blood which can still be infectious, should be cleaned using 1:10 dilution of 1 part household bleach to 10 parts of water for disinfecting the area. Gloves should be used when cleaning up any blood spills.

Why are hepatitis B and hepatitis D important to public health?

Hepatitis B is a liver infection caused by the hepatitis B virus (HBV). HBV is transmitted when blood, semen, or another body fluid from a person infected with HBV enters the body of someone who is not infected. This can happen through sexual contact or sharing needles, syringes, or other drug-injection equipment. In addition, infected gestational parents can transmit the infection to their infants at birth. For some people, HBV infection is an acute, or short-term illness, but for others it can become a long-term, chronic infection. Risk for chronic infection is related to age: approximately 90% of infected infants become chronically infected compared with 2–6% of adults. Ongoing surveillance for acute HBV is needed to monitor and evaluate the effectiveness of current strategies for the control of disease and to identify people who are exposed who will benefit from post-exposure prophylaxis.

An estimated 850,000 people are living with HBV infection in the U.S. People who have chronic HBV infection are a major reservoir for transmission of HBV infections. With widespread screening for HBV infection and the advent of laboratory reporting, an increasing number of people who test positive for hepatitis B surface antigen (HBsAg) are identified by state health departments. Chronic HBV carriers are at risk for infection with hepatitis D virus (HDV). HDV is an incomplete virus that requires the helper function of HBV to replicate. HDV infection of chronically infected HBV-carriers may lead to fulminant acute hepatitis or severe chronic active hepatitis, which often progresses to cirrhosis. Surveillance data is needed to monitor the disease burden of chronic infection and to develop prevention programs.

Disease and epidemiology

Clinical description

Acute infection

Once a person is infected with HBV, they will develop an acute infection. Symptoms may appear at this stage which can last for months. People with acute infection can either make a complete recovery (which includes immunity to subsequent infection) or become chronic carriers. Most acute HBV infections in adults result in complete recovery with elimination of HBsAg from the blood and the production of anti-hepatitis B surface antibody (anti-HBs), creating immunity to future infection. There are generally 3 phases of HBV symptoms.

- **Pre-icteric or prodromal phase**
  The pre-icteric or prodromal phase is nonspecific and usually presents with malaise,

anorexia, nausea, vomiting, right upper quadrant abdominal pain, fever, headache, myalgia, skin rashes, arthralgia and arthritis, and dark urine. It generally lasts for 3–10 days.

- **Icteric phase**
  The icteric phase occurs at the onset of jaundice, and is usually accompanied by light or gray stools, hepatic tenderness and hepatomegaly. This phase can last from 1–3 weeks.
- **Convalescent phase**
  The convalescent phase can last for weeks to months, and is characterized by malaise and fatigue.

Severity of the disease ranges from unapparent cases (detectable only by liver function tests) to fulminant, fatal disease. Asymptomatic infections are common in children <5 years and among immunocompromised adults, but can occur at any age. Among people ≥5 years, 30–50% will develop signs and symptoms.

Chronic infection

Overall, approximately 5% of all acute HBV infections progress to chronic infection. The risk for chronic HBV infection decreases with age. As many as 90% of infants who acquire HBV infection from their gestational parent at birth become chronically infected. Of children who become infected with HBV between 1 year and 5 years of age, 30–50% become chronically infected. By adulthood, the risk of acquiring chronic HBV infection is approximately 2–6%. People with chronic infection are often asymptomatic and may not be aware they are infected; however, they are capable of infecting others and are termed “carriers.”

Most people acutely infected completely recover from the disease with no complications. However, 1–2% may develop fulminant hepatitis. The majority of complications occur with chronic infection. Chronic infection may result in chronic hepatitis, cirrhosis, liver failure, and hepatocellular carcinoma. Approximately 25% of people with chronic HBV infection die prematurely from cirrhosis or liver cancer. Chronic active hepatitis develops in more than 25% of carriers and often results in cirrhosis.

Perinatal infection

Perinatal transmission from gestational parent to infant at birth is very efficient. If the gestational parent is positive for both HBsAg and hepatitis e-antigen (HBeAg), 70%–90% of infants will become infected in the absence of post-exposure prophylaxis. The risk of perinatal transmission is about 10% if the gestational parent is positive only for HBsAg. Infants infected with HBV have a 90% chance of becoming chronic carriers.

Hepatitis D coinfection

An HDV coinfection occurs when a patient infected with HBV is infected with HDV. The onset of acute coinfection is typically abrupt and resembles the signs and symptoms of acute HBV infection, including anorexia, abdominal pain, nausea, vomiting, and jaundice. Although coinfection usually results in self-limited disease, the likelihood of fulminant hepatitis is higher with coinfection and can be as high as 5%. Like HBV infections, HDV infections can also be acute or chronic. Progression to cirrhosis is believed to be more common with HBV-HDV chronic infections.

Causative agent

HBV infection is caused by the hepatitis B virus, a double-stranded DNA virus in the family Hepadnaviridae. Important components of the viral particle include hepatitis B surface antigen (HBsAg), hepatitis B core antigen (HBcAg), and hepatitis B e antigen (HBeAg).

HDV is a single-stranded RNA virus that contains hepatitis B surface antigen (HBsAg) within its coat. HDV requires the HBV as a “helper” virus, and it cannot produce infection in the absence of HBV infection. It is in the same viral family as HBV.

Differential diagnosis

Hepatitis has a variety of causes including, but not limited to: viral hepatitides (A, B, C, D, E, X), Epstein-Barr virus, cytomegalovirus, drug-induced hepatitis, toxin-induced hepatitis, auto-immune hepatitis, and alcohol liver disease.

Laboratory identification

Hepatitis B

HBV infection cannot be definitively diagnosed without a blood test that measures various serologic markers for hepatitis B virus.

Serology panels

Infection with HBV is associated with characteristic changes in the serum levels of HBV antigens and antibodies. These markers are used to define different clinical states.

Hepatitis B surface antigen and antibody

Hepatitis B surface antigen (HBsAg) is the serologic hallmark of HBV infection. It can be detected by radioimmunoassays (RIA) or enzyme immunoassays (EIA).

HBsAg appears in serum 1 to 10 weeks after an acute exposure to HBV, prior to the onset of hepatitic symptoms or elevation of serum alanine aminotransferase (ALT) (Figure 1). In patients who subsequently recover, HBsAg usually becomes undetectable after 4 to 6 months. Persistence of HBsAg for more than 6 months implies chronic infection. It is estimated that fewer than 1% of immunocompetent adult patients with genuine acute HBV infection progress to chronic infection. Among patients with chronic HBV infection, the rate of clearance of HBsAg is approximately 0.5% per year.

The disappearance of HBsAg is followed by the appearance of hepatitis B surface antibodies (anti-HBs). In most patients, anti-HBs last for life, which results in long-term immunity. In some patients, however, anti-HBs may not be detectable until after a window period of several weeks to months, during which neither HBsAg nor anti-HBs can be detected. At this time, the serologic diagnosis may be made by the detection of IgM antibodies against hepatitis B core antigen (IgM anti-HBc).

HBV can be classified into at least 8 genotypes and 4 major serotypes. All HBV serotypes share 1 common antigenic determinant: "a." The “a” determinant of HBV is the most important target for diagnosis and immunoprophylaxis. Antibodies to the "a" determinant result in protection to all HBV serotypes.

Paradoxical coexistence of HBsAg and anti-HBs has been reported in approximately 24% of HBsAg positive individuals. In most instances, the antibodies are unable to neutralize the circulating virions. These individuals should therefore be regarded as carriers of HBV.

Hepatitis B core antigen and antibody

Hepatitis B core antigen (HBcAg) is an intracellular antigen that is expressed in infected hepatocytes. It is not detectable in serum. Anti-HBc can be detected throughout the course of HBV infection (Figure 1).

During acute infection, anti-HBc is predominantly of IgM class. IgM anti-HBc is the sole marker of HBV infection during the window period between the disappearance of HBsAg and the appearance of anti-HBs. The detection of IgM anti-HBc is usually regarded as an indication of acute HBV infection.

However, IgM anti-HBc may remain detectable up to 2 years after the acute infection. Furthermore, the titer of IgM anti-HBc may increase to detectable levels during flare ups of chronic

HBV infection. This can present a diagnostic problem, incorrectly suggesting acute HBV infection, particularly in endemic areas in which many HBsAg-positive patients who present with acute hepatitis actually have flare ups of chronic HBV infection. Other common causes of acute flare ups of chronic HBV infection are superinfected with HDV or hepatitis C virus (HCV).

Anti-HBc continues along with anti-HBs in patients who recover from acute HBV infection. It also continues in association with HBsAg in those who progress to chronic HBV infection.

Isolated anti-HBc

The isolated presence of anti-HBc in the absence of HBsAg and anti-HBs has been reported in 0.4–1.7% of blood donors in low prevalence areas and in 10–20% of the population in endemic countries. Isolated detection of anti-HBc can occur in 3 settings: during the window period of acute HBV infection when the anti-HBc is predominantly IgM class; many years after recovery from acute HBV infection when anti-HBs has fallen to undetectable levels; and after many years of chronic HBV infection when the HBsAg titer has decreased below the cutoff level for detection. As noted above, loss of detectable HBsAg occurs in approximately 0.5% of patients with chronic HBV per year.

The clinical significance of isolated anti-HBc is unclear. Although HBV-DNA has been detected in the serum of individuals with isolated anti-HBc when tested by PCR assays, the frequency of detection varies from 0–20%. HBV-DNA can be detected in the liver of most (more than 70%) people with isolated anti-HBc. Transmission of HBV infection has been reported from blood and organ donors with isolated anti-HBc, but the incidence ranged widely from 0.4–78 %. The risk is highest when livers from anti-HBc positive donors are transplanted.

Studies in the late 1980s suggest (based upon the development of a primary anti-HBs response to HBV vaccination of asymptomatic individuals with isolated anti-HBc) as many as 50-80% of people with isolated anti-HBc have false positive test results. Nonspecific results appear to be more common with anti-HBc enzyme immunoassays than with radioimmunoassays. However, improvement of enzyme immunoassays in the past decade has decreased the rate of false positive results.

The evaluation of individuals with isolated anti-HBc should include repeat testing for anti-HBc, HBsAg, anti-HBe, and anti-HBs. In addition:

- Among patients who remain positive for isolated anti-HBc IgG, those with evidence of a recent HBV exposure, symptoms of acute hepatitis, and/or markedly elevated ALT levels should be tested for the presence of anti-HBc IgM to rule out recent HBV infection.
- Individuals with evidence of chronic liver disease should be tested for HBV-DNA to exclude low level chronic HBV infection.

Hepatitis B e antigen and antibody

Hepatitis B e antigen (HBeAg) is a secretory protein processed from the pre-core protein. It is generally considered to be a marker of HBV replication and infectivity. The presence of HBeAg is usually associated with high levels of HBV DNA in serum and higher rates of transmission of HBV infection from carrier gestational parents to their babies and from patients to healthcare workers.

HBeAg to anti-HBe seroconversion occurs early in patients with acute infection, prior to HBsAg to anti-HBs seroconversion (Figure 1). However, HBeAg seroconversion may be delayed for years to decades in patients with chronic HBV infection. In such patients, the presence of HBeAg is usually associated with the detection of high levels of HBV DNA in serum and active liver disease. However, HBeAg-positive patients with perinatally acquired HBV infection may have normal serum ALT concentrations and minimal inflammation in the liver.

Seroconversion from HBeAg to anti-HBe is usually associated with a decrease in serum HBV DNA and remission of liver disease. However, some patients continue to have active liver disease after HBeAg seroconversion. Such individuals may have low levels of wild type HBV or HBV variants with a stop codon in the pre-core or dual nucleotide substitutions in the core promoter region that prevent or decrease the production of HBeAg.

Serum HBV-DNA assays

Qualitative and quantitative tests for HBV-DNA in serum have been developed to assess HBV replication. The sensitivity limit of these assays depends on which techniques are used.

Recovery from acute HBV infection is usually accompanied by the disappearance of HBV-DNA in serum as determined by hybridization or bDNA assays. However, HBV-DNA may remain detectable in serum for many years if tested by PCR assays. This observation suggests the virus persists after recovery, but is controlled by the immune system.

HBV-DNA levels are also detectable in patients with HBeAg negative chronic hepatitis, although levels are generally lower than in patients with HBeAg positive chronic hepatitis.

Several serologic tests are needed to determine the status of the patient's immunity and/or infection. The 3 most commonly ordered tests that make up the basic HBV testing panel are HBsAg, anti-HBc, and anti-HBs. The following table displays serologic test interpretations.

Table 1 below outlines the available serologic tests for hepatitis b and what the results usually mean.

Table 1. Antibody and antigen biomarkers for hepatitis B infection

Clinical state	HBsAG	Total anti-HBs	Total anti-HBc	Action
Chronic infection	Positive	Negative	Positive (negative IgM)	Link to hepatitis B-directed care
Acute	Positive	Negative	Positive (positive IgM)	Link to hepatitis B-directed care
Resolved infection	Negative	Positive	Positive	Counseling, reassurance
Immune (immunization)	Negative	Positive	Negative	Reassurance
Susceptible (never infected and no evidence of immunization)	Negative	Negative	Negative	Vaccinate
*Isolated core antibody	Negative	Negative	Positive	Depends on situation

Notes:

*can be a result of:

[1]False positive: Repeat testing required

[2]Past infection: No action needed

[3]Occult HBV infection: Needs to be known if patient ever becomes immunosuppressed or given chemotherapy or treated with antiviral therapy for hepatitis C virus infection. Consider monitoring HBV-DNA.

[4]Passive transfer to infant born to HBsAg-positive gestational parent: No specific action needed.

Figure 1. Acute hepatitis B virus infection with recovery

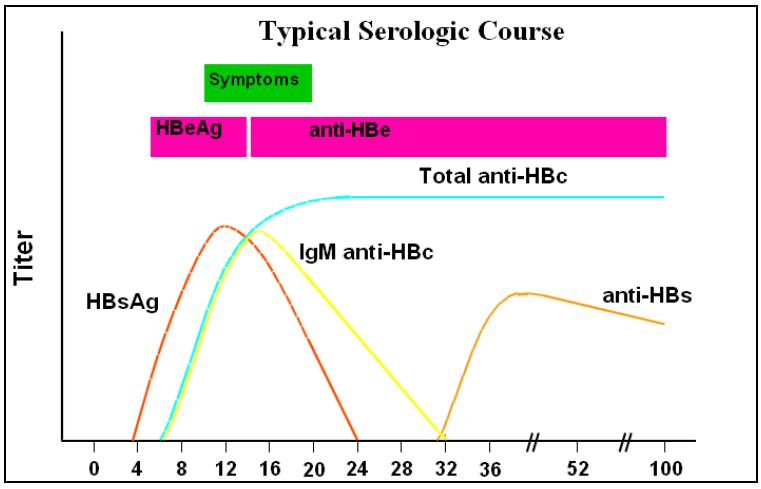


Image: Courtesy CDC

Figure 2. Progression to chronic hepatitis B virus infection

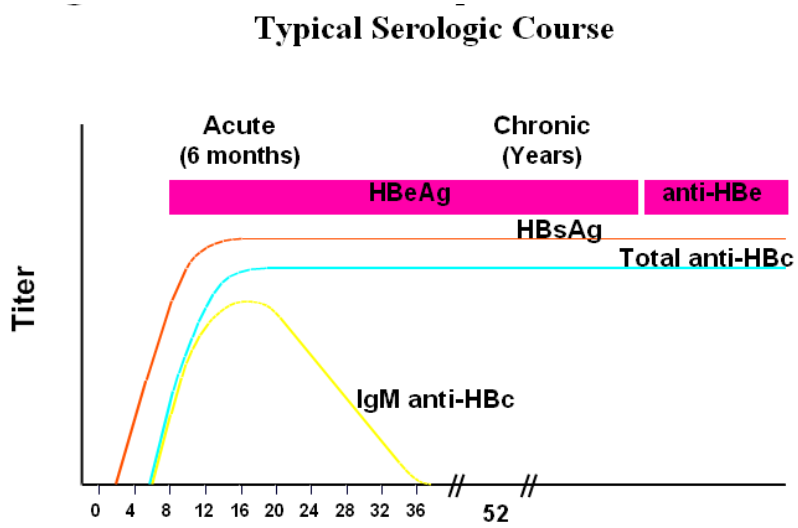


Image: Courtesy CDC

Hepatitis D

Hepatitis D is a liver disease caused by the hepatitis D virus (HDV). It can only infect people who are also infected by HBV. HDV exists with HBV as either a coinfection or a superinfection. A coinfection is when a person is simultaneously infected with HBV and HDV while a superinfection is when HDV is acquired after the person was infected with HBV. Laboratory tests for HDV include IgM anti-HDV, IgG anti-HDV, HDAg, and HDAb (anti-HDV). A person infected with HDV will always be IgM anti-HDV positive. However, for a co-infection, they will also be IgM anti-HBV positive, whereas, for a superinfection, they will be IgM anti-HBV negative.

In about 15% of patients the only evidence of HDV infection may be the detection of either IgM anti-HDV alone during the early acute period of illness or IgG anti-HDV alone during convalescence. Anti-HDV generally declines to sub-detectable levels after the infection resolves, and there is no serologic marker that persists to indicate the patient was ever infected with HDV. HDAg can be detected in serum in only about 25% of patients with HBV-HDV coinfection. When HDAg is detectable, it generally disappears as HBsAg disappears, and most patients do not develop chronic infection. Tests for IgG anti-HDV are commercially available in the U.S.

Figure 3. HBV-HDV co-infection

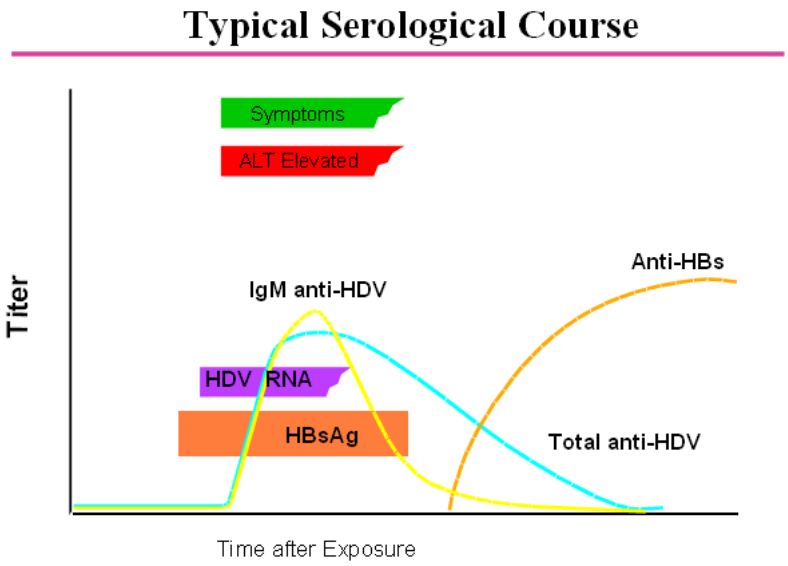


Image: Courtesy CDC

In patients with chronic HBV infection who are superinfected with HDV, several characteristic serologic features generally occur, including: 1) the titer of HBsAg declines at the time HDAg appears in the serum, 2) HDAg and HDV RNA remain detectable in the serum because chronic HDV infection generally occurs in most patients with HDV superinfection, unlike the case with co-infection, 3) high titers of both IgM and IgG anti-HDV are detectable, which persist indefinitely.

Figure 4. HBV-HDV superinfection

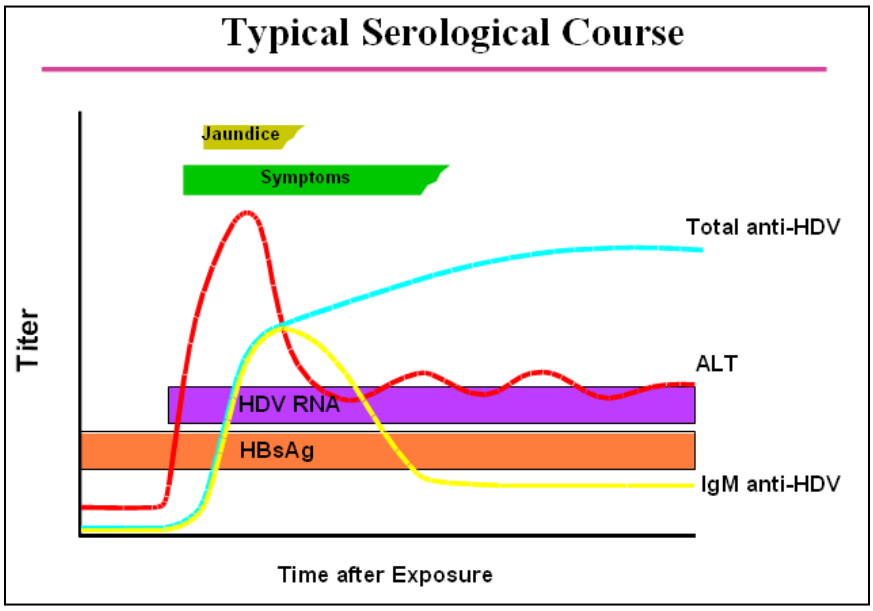


Image: Courtesy CDC

Chemistry panels

Liver function tests, such as ALT and AST (aminotransferases), are sensitive for liver damage, but are not specific for HBV. In patients without jaundice, elevated serum aminotransferase levels are required to meet the clinical case definition. The normal value for ALT and AST is up to 50 mIU/mL, but reference ranges can be laboratory specific, so, it is appropriate to ask the laboratory performing this test to provide its reference range.

Utah Public Health Laboratory (UPHL)

The UPHL performs HBsAg (including confirmatory testing), and anti-HBs testing. Testing is performed twice a week, once on every Monday and Thursday.

Treatment

Treatment for acute HBV and HDV is mainly supportive. In recent years, there have been an increasing number of antiviral treatment options for chronic HBV and HDV.

- **Tenofovir:** Tenofovir is used as first-line therapy for treatment-naïve patients and for most patients with drug-resistant virus. Resistance to tenofovir is unlikely to develop, even among patients who have been treated for up to 8 years. Tenofovir is effective in suppressing wild-type as well as lamivudine, telbivudine, or entecavir-resistant HBV. It is also effective in suppressing adefovir-resistant HBV, although the efficacy is lower in patients with double mutations.
    - Dosing recommendations:
        - Tenofovir is given at a dose of 300 mg daily; the dose needs to be adjusted in renal impairment.

- **Interferon:** The advantages of interferon compared with the other options are its finite duration of treatment, the absence of selection of resistant mutants, and a more durable response. On the other hand, side effects from interferon cause problems for many patients, and (in some less common cases) can be severe. Furthermore, interferon cannot be used in patients who have decompensated disease. The main role of interferon is primarily treatment of young patients who have well compensated liver disease who do not wish to be on long-term treatment or are planning to be pregnant within the next 2 to 3 years. Interferon is also an attractive option for patients with HBV genotype A infection. Interferon is the most effective treatment for chronic HBV and HDV carriers and is successful in 25–50% of cases.
    - Dosing recommendations:
        - For adults: 5 MU daily or 10 MU 3 times per week.
        - For children: 6 MU/M(2) 3 times weekly with a maximum of 10 MU.

        - Treatment duration for HBeAg positive chronic hepatitis is 16 to 32 weeks.
        - Treatment duration for HBeAg negative hepatitis is 12 to 24 months.

- **Lamivudine:** The main advantages of lamivudine are its lower cost compared to the other oral agents and the many years of experience confirming its safety, including its use during pregnancy. Compared to adefovir, lamivudine has more rapid and more potent virus suppression, but entecavir, telbivudine, and tenofovir are superior to lamivudine in suppressing viral replication. The main disadvantage of lamivudine is the high rate of drug resistance. The role of lamivudine in the care of HBV is diminishing with the availability of new therapies which are associated with lower rates of drug resistance. Lamivudine may still have a role in patients who are co-infected with HIV (in whom lamivudine may be part of the antiretroviral regimen which contains a second drug with anti-HBV activity such as tenofovir).
    - Dosing recommendations:
        - The recommended dose for adults with normal renal function without concomitant HIV infection is 100 mg daily. Dose adjustment is required in those with decreased renal function.
        - The recommended dose for children is 3 mg/kg per day with a maximum of 100 mg/day.
        - The recommended dose for those who are co-infected with HIV is 150 mg twice daily (along with other antiretroviral drugs).

- **Adefovir:** The main advantage of adefovir is its activity against lamivudine-resistant HBV and a lower rate of drug resistance compared to lamivudine. However, virus suppression is slow at the approved dose and as many as 25% of patients experience minimal or no viral suppression. Adefovir at high doses has been associated with nephrotoxicity. At the approved dose of 10 mg daily, reversible increase in serum creatinine has been reported in 39% of patients after 4 to 5 years of treatment. Adefovir resistance was not detected after 1 year of treatment but the rate of drug resistance has been reported to be as high as 29% after 5 years of treatment. The most important role of adefovir is in the treatment of patients with lamivudine-resistant HBV, preferably in combination. With the approval of tenofovir, which is more potent, the role of adefovir is rapidly diminishing.
    - Dosing recommendations:
        - Adefovir is administered orally. The dose is 10 mg daily. The dosing interval should be adjusted for patients who have impaired renal function.

- **Entecavir:** The main advantages of entecavir are its potent antiviral activity and a low rate of drug resistance. Entecavir has a more important role in primary treatment of HBV than in patients with lamivudine-resistant HBV. Entecavir may also have an important role in patients with decompensated cirrhosis because of its potent antiviral activity and low rate of drug resistance.

    - Dosing recommendations:
        - Entecavir is administered orally. The recommended dose is 0.5 mg once daily for nucleoside-naïve adults and adolescents older than 16 years of age. The dose for those who have lamivudine resistance and those with decompensated liver disease is 1 mg daily. The dose should be adjusted in patients with a creatinine clearance of <50 mL/min.

- **Telbivudine:** Telbivudine appears to have slightly more potent antiviral effects compared with lamivudine and adefovir, but it selects for the same resistant mutants as lamivudine and is more expensive. Thus, its role as primary therapy is limited. Furthermore, there have been rare cases of myopathy and peripheral neuropathy.
    - Dosing recommendations:
        - Telbivudine is administered orally. The recommended dose is 600 mg once daily.

The rationale for treatment in patients with chronic HBV is to reduce the risk of progressive chronic liver disease, transmission to others, and other long-term complications from chronic HBV such as cirrhosis and hepatocellular carcinoma. The optimal treatment of HDV is uncertain. Thus, patients should ideally be treated as part of a clinical trial. The only treatment approved for chronic HDV is interferon. The aim of treatment for HDV is to eradicate or achieve long-term suppression of both HDV and HBV.

Case fatality

The World Health Organization (WHO) estimates more than 2 billion people have been infected with HBV globally (including 240 million chronically infected). An estimated 5% of the 240 million people infected with HBV globally have serologic evidence of exposure to HDV. Each year approximately 600,000 people die as a result of HBV infection. The case-fatality rate in hospitalized patients is about 1%. Disease tends to be worse and mortality higher in those who are older than age 40.

Reservoir

Humans are the only natural host for HBV and HDV. Chimpanzees are susceptible, but an animal reservoir in nature has not been recognized. Closely related hepadnaviruses are found in woodchucks, squirrels, and other animals, such as snow leopards and German herons; none cause disease in humans.

Transmission

Hepatitis B

HBV is transmitted through blood or body fluids, including wound exudates, semen, vaginal secretions, and saliva. Blood and serum contain the highest concentrations of the virus; saliva contains the lowest. Common modes of transmission include sexual contact, contact with contaminated blood, or perinatally—from a gestational parent to child at birth. Contact with contaminated blood can occur through needle sticks, sharing or reusing non-sterile needles or syringes, transfusion of blood and blood products (rare in the U.S. due to current blood donor screening and testing protocols), hemodialysis, and tattooing.

Person-to-person spread of HBV can occur in settings involving interpersonal contact over extended periods, such as when a chronically infected person lives 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 non-intact skin or mucous membranes with blood-containing secretions or saliva are the most likely means of transmission. HBV can survive outside the body for at least 7 days. During this time, the virus can still cause infection if it enters the body of a person who is not protected by the vaccine. Sharing personal items, such as washcloths, towels, razors, or toothbrushes, are behaviors that can make transmission easy. Fecal-oral transmission does not appear to occur. Approximately one-third of infected people do not have a readily identifiable risk factor.

Hepatitis D

HDV can be transmitted through blood or blood products, injection drug use, or sexual contact, as long as HBV is also present in the patient.

Susceptibility

Once infected with HBV, a person cannot get the disease again. However, HBV infection does not protect against other types of hepatitis. HDV can be transmitted only if HBV is also present in the patient.

Incubation period

Hepatitis B

Symptoms of HBV develop slowly and on average appear 90 days after exposure, with a range of 45–160 days. The likelihood of developing symptoms of acute hepatitis is age dependent: fewer

than 1% of infants younger than 1 year, 5–15% of children 1 through 5 years of age, and 30–50% for people older than 5 years of age are symptomatic, although few data are available for adults older than age 30.

Hepatitis D

The incubation period for HDV superinfection is about 2–8 weeks. With acute co-infection of HBV and HDV, the incubation period is similar to that of HBV (45–160 days; average, 90 days).

Period of communicability

A person with HBV infection is considered infectious as long as HBsAg is detectable in the blood. An infected person can spread the virus to others starting a few weeks before symptoms appear and as long as they are infected. People who are chronically infected remain infectious for the rest of their lives. HDV is likely transmissible during all phases of infection. The period of time just prior to the onset of acute illness is likely the most infectious period.

Epidemiology

Hepatitis B

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. Approximately 45% of people worldwide live in regions of high HBV endemicity, where the prevalence of chronic HBV infection is 8% or greater. Historically in these regions, most new infections occurred as a result of perinatal or early childhood infections.

Figure 5. Worldwide prevalence of hepatitis B

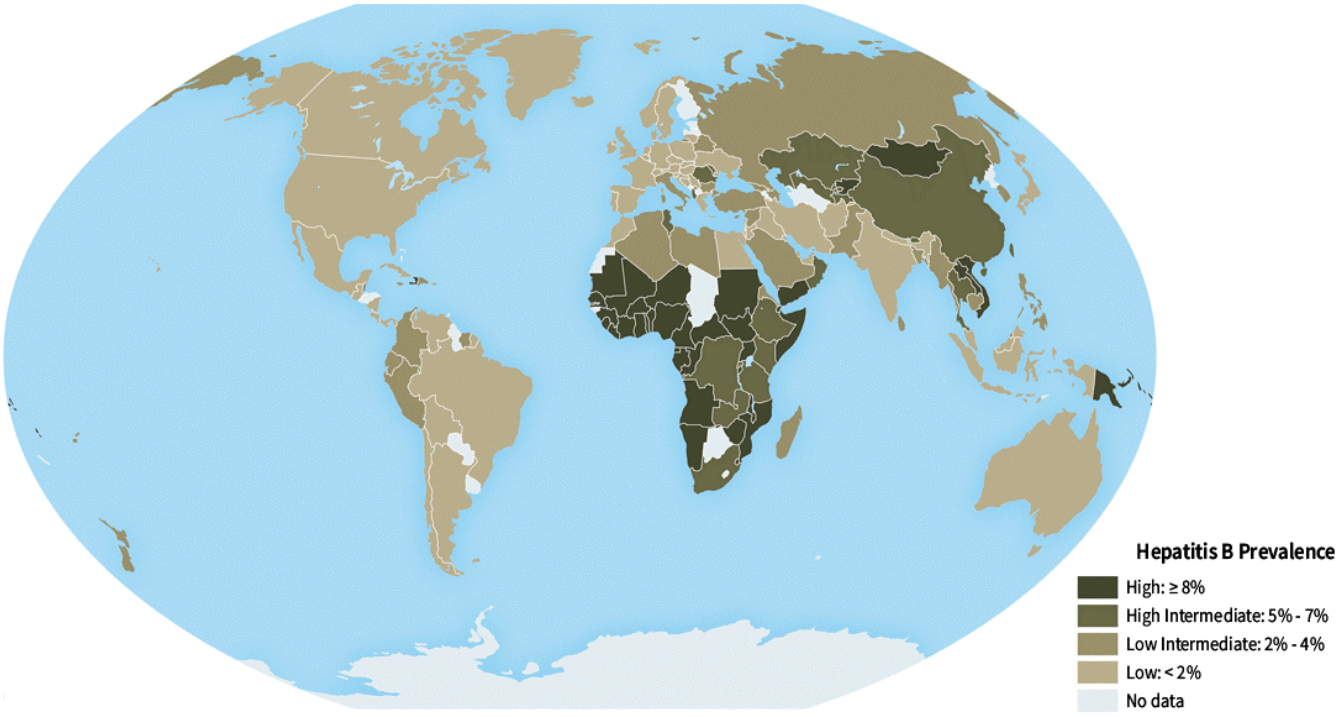


Image: Courtesy CDC (2020)

Acute HBV infection is reported most commonly among adults age 30 through 49 in the U.S. Since 1990, the incidence of acute HBV infection has declined in all age categories. Perinatal transmission in the U.S. is low because of high coverage with the HBV vaccine and immunoglobulin of infants born to chronically infected gestational parents at birth. In addition, since 1982 when the HBV vaccine first became available, the Advisory Committee on Immunization Practices (ACIP) has gradually evolved recommendations toward universal vaccination of infants as part of a comprehensive strategy to eliminate HBV transmission.

There are pockets of high endemicity within the U.S. including first-generation immigrants from areas where HBV is endemic, Alaska Native people, and some inner city populations. The highest risk for early childhood infection is among children born to gestational parents from HBV endemic countries.

Other people at risk of infection include:

- Household contacts of people with chronic HBV infection
- Residents of institutions for the developmentally disabled
- Patients undergoing hemodialysis
- Patients with clotting disorders and others repeatedly receiving blood products.

In the U.S., the most common risk factors for HBV infection are injection drug use, people who have multiple heterosexual partners, and men who have sex with men. Acute HBV infection occurs most commonly among adolescents and adults.

Groups at highest risk include:

- Men who have sex with other men
- Heterosexuals who have multiple sex partners
- People diagnosed with a recently acquired sexually transmitted disease
- Sex workers
- People who inject drugs and share needles
- Inmates of long-term correctional facilities
- People undergoing hemodialysis
- Healthcare workers exposed to blood or blood products without appropriate protective equipment.

Hepatitis D

An estimated 18 million people worldwide are co-infected with HDV and HBV. In the U.S., the incidence of HDV cannot be directly calculated from national surveillance data because HDV is not currently nationally reportable. However, in prevalence studies among patients with acute HBV infection, 1.5–7.2% had serologic evidence of HBV-HDV coinfection.

In general, the global pattern of HDV infection corresponds with the prevalence of chronic HBV infection; however, several distinct features about the distribution of HDV infection have been identified. In countries with a low prevalence of chronic HBV infection, HDV prevalence is generally low among both asymptomatic HBV carriers (<10%) and among patients with chronic HBV-related liver disease (<25%). HDV infection in these countries occurs most commonly among people who inject drugs and people with hemophilia. In countries with moderate and high levels of chronic HBV prevalence, the prevalence of HDV infection is highly variable. In southern Italy and in parts of Russia and Romania, the prevalence of HDV infection is very high among both asymptomatic HBV carriers (>20%) and among patients with HBV-related chronic liver disease HBV (>60%). Other countries, including northern Italy, Spain, Turkey, and Egypt, have a moderate prevalence of HDV infection among asymptomatic HBV carriers (10%–19%) and among patients with chronic HBV-related liver disease (30%–50%). However, in most of southeast Asia and China, where the prevalence of chronic HBV infection is very high, HDV infection is uncommon. In some South American countries in the Amazon River Basin, periodic epidemics of HDV infection have occurred among chronic HBV carriers in relatively isolated regions. Disease related to HDV infection in these outbreaks has been very severe, with rapid progression to fulminant hepatitis and case-fatality rates of 10%–20%. The cause of the atypical course of HDV infection in these populations is unknown.

Public health control measures

Public health responsibility

- Investigate suspect cases of disease for the following groups and enter data into UT-NEDSS:
    - Pregnant people (12–50 years of age)
    - Coinfected individuals (with hepatitis C, D, or HIV/AIDS)
    - Suspected acute cases
- Provide education to the general public and clinicians regarding disease transmission and prevention.
- Identify clusters or outbreaks of this disease.
- Identify sources of exposure to stop further transmission.
- Ensure identification of infected pregnant people, and prevent perinatal transmission to their babies.
- Collect surveillance data in order to assess groups and areas where public health intervention may be needed.

Prevention

People with acute or chronic HBV and/or HDV infections should prevent their blood and other potentially infectious body fluids from contact with other people. They should not donate blood or share toothbrushes or razors with household members. Testing all pregnant people for HBsAg is recommended because measures can be implemented to prevent spread from infected gestational parents to their infants. Donated blood should be tested for HBsAg and rejected if positive. Syringes, acupuncture, and tattooing needles should never be reused. Household contacts of infected people should be vaccinated. Vaccination is highly effective in preventing HBV infection. Since HDV cannot be transmitted in the absence of HBV infection, the prevention of HBV infection through immunization is the best way to prevent HDV infection. However, no products exist to prevent HDV superinfection of people with chronic HBV infection. Thus, prevention of HDV superinfection depends primarily on education to reduce risk behaviors.

*Any blood spills, including dried blood, which can still be infectious, should be cleaned using 1:10 dilution of 1 part household bleach to 10 parts of water to disinfect the area. Gloves should be used when cleaning blood spills.

Post-exposure prophylaxis

When indicated, hepatitis B immune globulin (HBIG) should be given as soon after exposure as possible. HBV vaccine is also recommended for people at high risk for additional exposure. Depending on the exposure circumstance, the HBV vaccine series may be started at the same time as treatment with HBIG. For infants born to infected gestational parents, the combination of HBIG and vaccine is effective at preventing infection. HBV vaccination and 1 dose of HBIG administered within 24 hours after birth are 85–95% effective in preventing both acute HBV infection and chronic infection in the infant. Vaccination against HBV will prevent HDV co-infection.

Vaccine

Three single-antigen (e.g., monovalent) recombinant HBV vaccines are available for use in the U.S.: Engerix-B, Recombivax HB, and Heplisav-B. These vaccines are supplied in different concentrations and have different doses. They can be used interchangeably, except only Recombivax HB can be used for the 2-dose series in adolescents aged 11–15 years and Heplisav-B is only approved for adults ≥ 18 years. Additionally there is 1 three-antigen hepatitis B vaccine approved in 2021 in the US: PreHevbrio. This vaccine is approved for adults ≥ 18.

In addition, recombinant hepatitis B vaccine is a component in 3 combination vaccines, which can be used if the person receiving vaccine is due for the other vaccine components:

- Pediarix—Diphtheria and tetanus toxoids and acellular pertussis (DTaP), hepatitis B (Engerix-B 10 mcg/mL), and inactivated poliovirus vaccine (IPV), are typically administered at 2, 4, and 6 months of age; the DTaP-HepB-IPV combination vaccine should not be administered before 6 weeks or after age 7.
- Twinrix—Hepatitis A and hepatitis B (Engerix-B 20 mcg); this vaccine is approved for individuals ≥18 years of age.
- Vaxelis—DTaP, IPV, Haemophilus influenza type b, and hepatitis B approved for infants and children age 1-4 years.

See Vaccine Administration and SIRVA infographic for more information about proper IM vaccine administration.

Hepatitis B vaccines are administered intramuscularly (IM). HBV vaccines administered by any route other than IM should not be counted as valid and should be repeated. Hepatitis B vaccines should be refrigerated at a temperature between 36°F and 46°F (2°C and 8°C). Dosing requirements are shown in the table below:

Table 2. Recommended doses of currently licensed formulations of hepatitis B vaccine, by age group and vaccine type.

Hepatitis B Vaccine, Age Group (yrs)*	*Dose (µg)*	*Vol (mL)*	*Schedule*
Recombivax HB			
Infants (<1 yr)	5	0.5	3-doses at age 0, 1–2, 6–18 mos
Children (1–10 yrs)	5	0.5	3 doses at 0, 1–2, 6 mos
Adolescents (11–19 yrs)†	5	0.5	3 doses at 0, 1, 6 mos†
Adults (≥20 yrs)	10	1	
Patients on hemodialysis and other immune-compromised persons, <20 yrs§	5	0.5	
Patients on hemodialysis and other immune-compromised persons, ≥20 yrs	40	1	
Engerix-B			
Infants (<1 yr)	10	0.5	3-doses at age 0, 1–2, 6–18 mos
Children (1–10 yrs)	10	0.5	3 doses at 0, 1–2, 6 mos
Adolescents (11–19yrs)	10	0.5	3 doses at 0, 1, 6 mos
Adults (≥20 yrs)	20	1	
Patients on hemodialysis and other immune-compromised persons, <20 yrs§	10	0.5	
Patients on hemodialysis and other immune-compromised persons, ≥20 yrs	40	2	4 doses at 0, 1, 2, 6 mos ¶
Heplisav-B			
Adults (≥18 yrs**)	20	0.5	2 doses at 0 and 1 mos
PreHevbrio (FDA-approved in 2021)			
Adults (≥18 yrs**)	10	1	3 doses at 0, 1, 6 mos
Pediarix (combination hepatitis B, diphtheria, tetanus, acellular pertussis, and inactivated poliovirus)			
Infants (<1 yr)	10	0.5	3-doses at age 0, 1–2, 6–18 mos
Children (1–6 yrs)††	10	0.5	3 doses at 0, 1–2, 6 mos
Vaxelis (combination diphtheria, tetanus, acellular pertussis, inactivated poliovirus, *Haemophilus influenzae* type b, and hepatitis B)			
Infants (<1 yr)	10	0.5	3 doses at age 0, 1–2, 6–18 mos
Children (1–4 yrs)§§	10	0.5	3 doses at 0, 1–2, 6 mos
Twinrix (combination hepatitis A-hepatitis B)¶¶			
Adults (≥18 yrs)	20	1	3 doses at 0, 1, 6 mos (standard) or 4 doses at 0, 7d, 21–30 d, 12 mos (accelerated)

* Refer to package inserts for further information. For all ages, when the hepatitis B vaccine schedule is interrupted, the vaccine series does not need to be restarted. If a 3-dose series is interrupted after the first dose, the second dose should be administered as soon as possible, and the second and third doses should be separated by an interval of at least 8 weeks. If only the third dose has been delayed, it should be administered as soon as possible. The final dose of a 3-dose series vaccine must be administered at least 8 weeks after the second dose and should follow the first dose by at least 16 weeks; the minimum interval between the first and second doses is 4 weeks. Inadequate doses of hepatitis B vaccine or doses received after a shorter-than-recommended dosing interval should be readministered, using the correct dosage or schedule. Vaccine doses administered ≤4 days before the minimum interval or age are considered valid. Because of the unique accelerated schedule for Twinrix, the 4-day guideline does not apply to the first three doses of this vaccine when administered on a 0-day, 7-day, 21–30-day, and 12-month schedule. PreHevbrio is a three-antigen HepB vaccine that was FDA approved in 2021.

† A 2-dose schedule of Recombivax HB adult formulation (10 µg) is licensed for adolescents age 11 through 15 years. When scheduled to receive the second dose, adolescents age 16 years or older should be switched to a 3-dose series, with doses 2 and 3 consisting of the pediatric formulation administered on an appropriate schedule.

§ Higher doses might be more immunogenic, but no specific recommendations have been made.

¶ Engerix-B for adults on hemodialysis: Administer series of 4 doses (2 mL each) as a single 2-mL dose or as two 1-mL doses on a 0-, 1-, 2-, 6-month schedule. Recombivax HB for adults on hemodialysis is a 3-dose series.

** Data on Heplisav-B and PreHevbrio are currently insufficient to inform vaccine-associated risks in pregnancy. Thus, providers should vaccinate pregnant people who need HepB vaccination with Engerix-B, Recombivax HB, or Twinrix.

†† Pediarix cannot be administered at birth, before age 6 weeks, or at age ≥7 years.

§§ Vaxelis is approved for use as a 3-dose series in children age 6 weeks through 4 years.

¶¶Twinrix is recommended for people age ≥18 years who are at increased risk for both HAV and HBV infections.

The HBV vaccine is both safe and effective. After 3 intramuscular doses of HBV vaccine, more than 90% of healthy adults and more than 95% of infants, children, and adolescents (from birth to 19 years of age) develop adequate antibody responses. The vaccine is 80–100% effective in preventing infection or clinical hepatitis in those who receive the complete course of vaccine. Immune memory remains intact for more than 15 years following immunization, and both adults and children with declining antibody levels are still protected against significant HBV infection. Chronic HBV infection has only rarely been documented in those who respond to vaccine.

HDV is prevented by routine HBV vaccination. Apart from the morbidity and mortality associated with HBV infection, these individuals are at risk for HDV infection. Thus, every effort should be made to reduce the risk of HDV transmission to HBV carriers.

Who should be vaccinated against hepatitis B?

- All infants
- Unvaccinated children age <19 years
- Adults age 19 through 59 years
- Adults age 60 years and older with risk factors for hepatitis B

The following groups may receive hepatitis B vaccination:

- Adults age 60 years and older without known risk factors for hepatitis B

Risk factors for hepatitis B

- People at risk for infection by sexual exposure
    - Sex partners of people who test positive for hepatitis B surface antigen (HBsAg)
    - Sexually active people who are not in a long-term, mutually monogamous relationship (e.g., people with more than 1 sex partner during the previous 6 months)
    - People seeking evaluation or treatment for a sexually transmitted infection

    - Men who have sex with men
- People at risk for infection by percutaneous or mucosal exposure to blood
    - People with current or recent injection use
    - Household contacts of people who test positive for HBsAg
    - Residents and staff of facilities for people with developmental disabilities
    - Healthcare and public safety personnel with reasonably anticipated risk for exposure to blood or blood-contaminated body fluids
    - People on maintenance dialysis, including in-center or home hemodialysis and peritoneal dialysis, and people who are predialysis
    - People with diabetes at the discretion of the treating clinician
- Others
    - International travelers to countries with high or intermediate levels of endemic hepatitis B virus (HBV) infection (HBsAg prevalence of ≥2%)
    - People with hepatitis C virus infection
    - People with chronic liver disease (including, but not limited to, people with cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, and an alanine aminotransferase [ALT] or aspartate aminotransferase [AST] level greater than twice the upper limit of normal)
    - People with HIV infection
    - People who are incarcerated

HBV vaccination is also recommended in certain settings where there is a high proportion of individuals with known risk factors for HBV infection. Settings include:

- sexually transmitted disease treatment facilities,
- HIV testing and treatment facilities,
- facilities who provide drug-abuse treatment and prevention services,
- healthcare settings targeting services to people who inject drugs,
- correctional facilities,
- healthcare settings targeting services to men who have sex with men,
- chronic hemodialysis facilities and end-stage renal disease programs, and
- institutions and nonresidential day care facilities for people with developmental disabilities.

Pre-vaccination serologic testing

Pre-vaccination serologic testing is not indicated before routine vaccination of children or adolescents. Pre-vaccination testing is recommended for:

- Foreign-born people from endemic countries
- Children of immigrants from endemic countries
- Unvaccinated household, sexual, and needle-sharing contacts of HBV carriers

- People with HIV infection

Pre-vaccination testing should be considered for:

- Men who have sex with men
- People who use injection-drugs
- People who are incarcerated

Post-vaccination serologic testing

Post-vaccination serologic testing is not routinely recommended for most infants, children, adolescents, and adults. It should, however, be considered for people whose subsequent management depends on knowing their immune status, including:

- Infants born to HBsAg-positive women
- Chronic hemodialysis patients
- Immunocompromised people
- People with HIV infection
- Healthcare workers who have significant exposure to HBV
- Sex partners of HBsAg-positive people

Post-vaccination testing should be performed 1–2 months after completion of the vaccine series. Children born to HBsAg-positive women should be tested at 9–18 months. Healthcare workers who have contact with patients or blood and are at ongoing risk for injuries with sharp instruments or needle sticks should be routinely tested for antibodies after vaccination.

Management of non-response to hepatitis B vaccine

The current recommendation for all healthy individuals who do not develop an adequate anti-HBs response to the primary vaccine series is to administer 1 or more additional doses. An adequate antibody response is seen in 15–25% after 1 additional dose and in 50% after 3 additional doses. As a result, it may be reasonable to repeat a 3-dose schedule, retesting 2 to 3 months after the third dose. Individuals who fail to respond after 3 additional doses of appropriately administered vaccine are unlikely to benefit from further vaccination. However, these individuals may still mount an adequate immune response and recover from HBV infection.

Individuals who fail to respond after 2 courses of HBV vaccine should be tested for HBsAg, particularly in countries where pre-vaccination testing is not performed or is performed using anti-HBs test only. Non-responders who test negative for HBsAg should be educated on how to prevent HBV infection, including the need for hepatitis B immune globulin (HBIG) if they have an exposure to blood or other body fluids of a person who is HBsAg-positive.

Booster doses

Booster doses are not recommended for people with a normal immune status who were vaccinated as infants, children, or adolescents. However, booster doses are recommended for hemodialysis patients, if annual testing of anti-HBs levels decline to <10 mIU/mL.

For other immunocompromised people (e.g., HIV-infected people, hematopoietic stem cell transplant recipients, and people receiving chemotherapy), the need for booster doses has not been determined. Annual anti-HBs testing and booster doses when anti-HBs levels decline to <10 mIU/mL should be considered in people who have an ongoing high risk for exposure.

Interruption in schedule

There are no maximum intervals, and it is not necessary to restart the series of any vaccine due to extended intervals between doses.

***Sound-alike/look-alike issues**

- Engerix-B adult may be confused with Engerix-B pediatric/adolescent.
- Recombivax HB may be confused with Comvax.
- Recombivax HB may be confused with Recombivax HB Dialysis Formulation.

Isolation and quarantine requirements

Isolation: Standard precautions.

Hospital: NA

Quarantine: NA

Case investigation

Reporting

All forms of HBV infection should be reported to the Utah Department of Health and Human Services (DHHS). Report any illness to DHHS that meets any of the following criteria:

Acute hepatitis B infections (CSTE position statement, 2024)

Clinical criteria

N/A

Laboratory criteria

- IgM antibody to hepatitis B core antigen (IgM anti0HBc) is reactive, **OR**
- Hepatitis B surface antigen (HBsAg)* is reactive, **OR**
- Hepatitis B e antigen (HBeAg) is reactive, **OR**
- Detection of HBV DNA by nucleic acid test, including qualitative, quantitative, or genotype testing.

**If HBsAg confirmatory neutralization was performed as recommended, HBsAg positive by confirmatory neutralization*

Vital records criteria

- A person whose death certificate lists HBV infection as an underlying cause of death or a significant condition contributing to death, OR
- A gestational parent listed as having HBV infection on an infant's birth certificate.

Healthcare record criteria

- A person whose healthcare record contains a diagnosis of HBV infection.

Other recommended reporting procedures

- All cases of acute HBV infection should be reported.
- Reporting should be ongoing and routine.
- Frequency of reporting should follow the routine schedule of DHHS.

Table 3. Criteria for reporting hepatitis B (CTSE 2024)

Criterion	Reporting
Laboratory criteria for reporting	
IgM antibody to hepatitis B core antigen (IgM anti-HBc) is reactive	S
Hepatitis B surface antigen (HBsAg)† is reactive	S
Hepatitis B e antigen (HBeAg) is reactive	
Detection of HBV DNA by nucleic acid test, including qualitative, quantitative, or genotype testing	
Vital record criteria for reporting	
A person whose death certificate lists HBV infection as an underlying cause of death or a significant condition contributing to death	S
A birthing parent listed as having HBV infection on an infant's birth certificate	S
Healthcare record criteria for reporting	
A person whose healthcare record contains a diagnosis of HBV infection	S

Notes:

S = This criterion alone is sufficient to report a case

† *If HBsAg confirmatory neutralization was performed as recommended, HBsAg positive by confirmatory neutralization*

Table 4. Criteria for reporting perinatal hepatitis B (CSTE 2016)

Criterion	Gestational parent	Gestational parent	Infant/ child	Infant/ child	Infant
Clinical evidence					
Diagnosis of hepatitis B infection		N		O	
Pregnant	N	N			
Born to a gestational parent with evidence of hepatitis B infection (HBsAg, HBeAg, or HBV-DNA positive) or diagnosis of hepatitis B infection					O
HBsAg status of gestational parent unknown at time of hospital discharge					O
Laboratory evidence					
HBsAg positive	O		O		

HBeAg positive	O		O		
HBV-DNA positive	O		O		
Demographic					
24 months of age or younger			N	N	
Newborn					N

Notes:
S = This criterion alone is sufficient to report a case.
N = All N criteria in the same column are necessary to report a case.
O = At least 1 of these O (one or more) criteria in each category (e.g., clinical evidence and laboratory evidence) in the same column—in conjunction with all N criteria in the same column—is required to report a case.
*A requisition or order for any of the S laboratory tests is sufficient to meet the reporting criteria.
For purposes of perinatal HBV surveillance, gestational parent and infant status should be ascertained.

Pregnant people

All pregnant people should be tested for HBsAg during each pregnancy as part of routine prenatal care. All HBV-infected women must be reported to the state or local public health authority as mandated by law or regulation.

Report pregnancy status along with test results for pregnant people to public health authorities who meet any of the following criteria:

Positive result for any 1 of the following 3 laboratory tests:

- hepatitis B surface antigen (HBsAg)
- hepatitis B e antigen (HBeAg)
- nucleic acid test for HBV-DNA (including qualitative, quantitative and genotype testing)

Immediately determine HBsAg status on all pregnant people who present for labor and delivery without documentation of HBsAg test results for current pregnancy and those with risk factors regardless of previous HBsAg test results.

Other recommended reporting procedures:

- All cases of chronic HBV should be reported.
- All cases of HBV should be reported with sex and age accurately documented and should include pregnancy status, if known.
- Reporting should be ongoing and routine.

Infants

Report all infants who are delivered to gestational parents who are HBsAg positive or HBsAg status unknown to the health authority.

Report all infants with evidence of HBV infection as evidenced by the following laboratory tests: HBsAg, hepatitis B nucleic acid (HBV DNA), or hepatitis B e antigen (HBeAg).

Disease-specific data elements

Gestational parent

- Country of birth
- Race
- Ethnicity
- Date of birth
- HBsAg—result, date
- HBeAg—result, date
- HBV DNA (or genotype)—result, date
- Alanine aminotransferase (ALT)
- Gestational parent antiviral therapy, if any (yes/no/unknown)
- Coinfection with human immunodeficiency virus or HCV
- State/territory of residence at time of infant's diagnosis

Infant

- HBsAg, HBeAg and HBV DNA test results and date of test performance
- Anti-HBs test results and date of test performance
- HBIG administration—time and date
- HBV vaccine birth dose time and date, dates of other valid HBV vaccine doses
- Birthweight
- Date of birth
- Time of birth (military time)
- State/territory of birth
- State/territory of residence at time of diagnosis

Case definition

Hepatitis B, acute (CSTE position statement, 2024)

Clinical criteria

In the absence of a more likely, alternative diagnosis*, acute onset or new detection of at least one of the following:

- Jaundice,
- Total bilirubin ≥ 3.0 mg/dL, or
- Elevated serum alanine aminotransferase (ALT) > 200 IU/L

**Alternative diagnoses may include evidence of acute liver disease due to other causes or advanced liver disease due to hepatitis B reactivation, pre-existing chronic HBV infection, other causes including alcohol exposure, other viral hepatitis, hemochromatosis, or conditions known to produce false positives of hepatitis B surface antigen, etc.*

Confirmatory laboratory evidence (acute HBV)

Tier 1

- Detection of HBsAg **AND** detection of IgM anti-HBc, **OR**
- Detection of HBeAg **AND** detection of IgM anti-HBc, **OR**
- Detection of HBV DNA **AND** detection of IgM anti-HBc, **OR**
- Detection of HBsAg, HBeAg, or HBV DNA within 12 months of a negative HBsAg test result (seroconversion)

Tier 2

- Detection of HBV surface antigen (HBsAg) **AND** IgM antibody to HBV core antigen (IgM anti-HBc) not done or not available, **OR**
- Detection of HBV DNA **AND** IgM anti-HBc test not done or not available

Presumptive laboratory evidence:

- Detection of IgM anti-HBc, **AND**
- Negative or not done for HBsAg, HBV DNA, or HBeAg

Case classification

Confirmed acute

- Meets Tier 1 confirmatory laboratory evidence of acute HBV, **OR**
- Meets clinical criteria AND Tier 2 confirmatory laboratory evidence

Probable acute

- Meets clinical criteria **AND** presumptive laboratory evidence

Table 5. Criteria for classification of acute hepatitis B (CSTE 2024)

Case definition				
Criterion	**Confirmed**			**Probable**
Clinical evidence				
Jaundice			O	O
Total bilirubin ≥ 3.0 mg/dL			O	O
Elevated ALT > 200 IU/L			O	O
Absence of more likely, alternative diagnosis			N	N
Acute onset or new detection			N	N
Laboratory evidence				
Detection of HBV surface antigen (HBsAg)		O	O	
Detection of HBV e antigen (HBeAg)		O		
Detection of HBV DNA by nucleic acid test, including qualitative, quantitative, or genotype testing		O	O	
IgM antibody to core HBV core antigen (IgM anti-HBc) test not done or result not available			N	
IgM anti-HBc test negative or not done				
Detection of IgM anti-HBc		N		N
Negative or not done for HBsAg, HBV DNA, or HBeAg				N
HBsAg seroconversion by detection of HBsAg, HBeAg, or HBV DNA within 12 months (365 days) of a negative HBsAg test result	S			

Notes:
N = This criterion in conjunction with all other N and any O criteria in the same column is required to classify a case.
O = At least one of these O criteria in each category in the same column (e.g., clinical presentation and laboratory findings)—in conjunction with all other N criteria in the same column—is required to classify a case.
S = This criterion alone is sufficient to report a case.

Hepatitis B, chronic (2024)

Clinical criteria

No clinical criteria is required.

Confirmatory laboratory evidence

- Detection of HBsAg in two clinical specimens ≥ 6 months apart, **OR**
- Detection of HBeAg in two clinical specimens ≥ 6 months apart, **OR**
- Detection of [HBsAg **OR** HBeAg] **AND** total anti-HBc, **OR**
- Detection of HBsAg AND HBeAg, **OR**

- Detection of HBV DNA

Presumptive laboratory evidence:

- Detection of [HBsAg OR HBeAg] AND IgM anti-HBc test negative, not done, or result not available

Case classification (chronic)

Confirmed

- Meets either of the above confirmatory laboratory criteria for diagnosis.

Probable

- Meets presumptive laboratory evidence.

Table 6. Criteria for classification of chronic hepatitis B (CSTE 2024)

	Case definition				
Criterion	Confirmed				Probable
Laboratory evidence					
Detection of HBsAg		O	N		O
Detection of HBeAg		O	N		O
Detection of HBV DNA					
IgM anti-HBc test not done or result not available					N
Igm anti-HBc test negative or not done					N
Detection of HBsAg in two clinical specimens taken ≥ 6 months apart	S				
Detection of HBeAg in two clinical specimens taken ≥ 6 months apart	S				
Positive total anti-HBc		N			

Notes:

N = This criterion in conjunction with all other N and any O criteria in the same column is required to classify a case.

O = At least 1 of these O criteria in each category in the same column—in conjunction with all other N criteria in the same column—is required to classify a case.

S = This criterion alone is sufficient to report a case.

Hepatitis B, perinatal (CSTE position statement, 2016)

Clinical description

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

Laboratory criteria

Laboratory evidence of HBV infection in a child consists of 1 or more of the following:

- positive HBsAg test (only if at least 4 weeks after last dose of HBV vaccine)
- positive HBeAg test, or
- detectable HBV DNA.

Epidemiologic linkage

Born to a HBV-infected gestational parent.

Case classification

Confirmed

A child born in the U.S. to a HBV-infected gestational parent and positive for HBsAg at ≥1 month of age and ≤24 months of age **or** positive for HBeAg or HBV DNA ≥9 months of age and ≤24 months of age.

Probable

A child born in the U.S. and positive for HBsAg at ≥1 month of age and ≤24 months of age **or** positive for HBeAg or HBV DNA ≥9 months of age and ≤24 months of age, but whose gestational parent's HBV status is unknown (e.g., epidemiologic linkage not present).

Comment

Infants born to HBV-infected gestational parents should receive HBIG and the first dose of HBV vaccine within 12 hours of birth, followed by the second and third doses of HBV vaccine at 1 and 6 months of age, respectively. PVST for HBsAg and anti-HBsAg is recommended 1 to 2 months following completion of the vaccine series, but not earlier than 9 months of age.

If the gestational parent is known not to be infected with HBV, refer to the case definition for acute HBV.

Table 7. Criteria for classification of perinatal hepatitis B (CSTE 2016)

Criterion	Probable			Confirmed		
Demographic						
Age ≥1 and < 9 months	O			O		
Age ≥ 9 and ≤ 24 months	O	N	N	O	N	N
Born in the U.S.	N	N	N	N	N	N
Laboratory evidence						
HBsAg positive	N			N		
HBeAg positive		N			N	
Detectable HBV-DNA			N			N
≥4 weeks since last dose of HBV vaccine	N			N		
Epidemiological evidence						
Gestational parent HBV infection				N	N	N
HVB status of mother unknown	N	N	N			

Notes:
N = All N criteria in the same column are necessary to classify a case. A number following an N indicates this criterion is only required for a specific subtype (see below). If the absence of a criterion (e.g., criterion **not** present) is required for the case to meet the classification criteria, list the absence of criterion as a necessary component.
O = At least 1 of these O (1 or more) criteria in each category (e.g., clinical evidence and laboratory evidence) in the same column—in conjunction with all N criteria in the same column—is required to classify a case. (These O criteria are alternatives, which means that a single column will have either no O criteria or multiple O criteria; no column should have only one O.) A number following an O indicates this criterion is only required for a specific disease/condition subtype.

Hepatitis D, co-infection

Clinical case definition

No clinical case definition is available.

Laboratory criteria

- IgM antibody to hepatitis D (anti-HDV) positive **and**
- IgM antibody to hepatitis B core antigen (anti-HBc) positive.

Case classification

Confirmed

A confirmed case meets the clinical case definition and is laboratory confirmed.

Hepatitis D, superinfection

Clinical case definition

No clinical case definition is available.

Laboratory criteria

- IgM antibody to hepatitis D (anti-HDV) positive **and**
- IgM antibody to hepatitis B core antigen (anti-HBc) negative.

Case classification

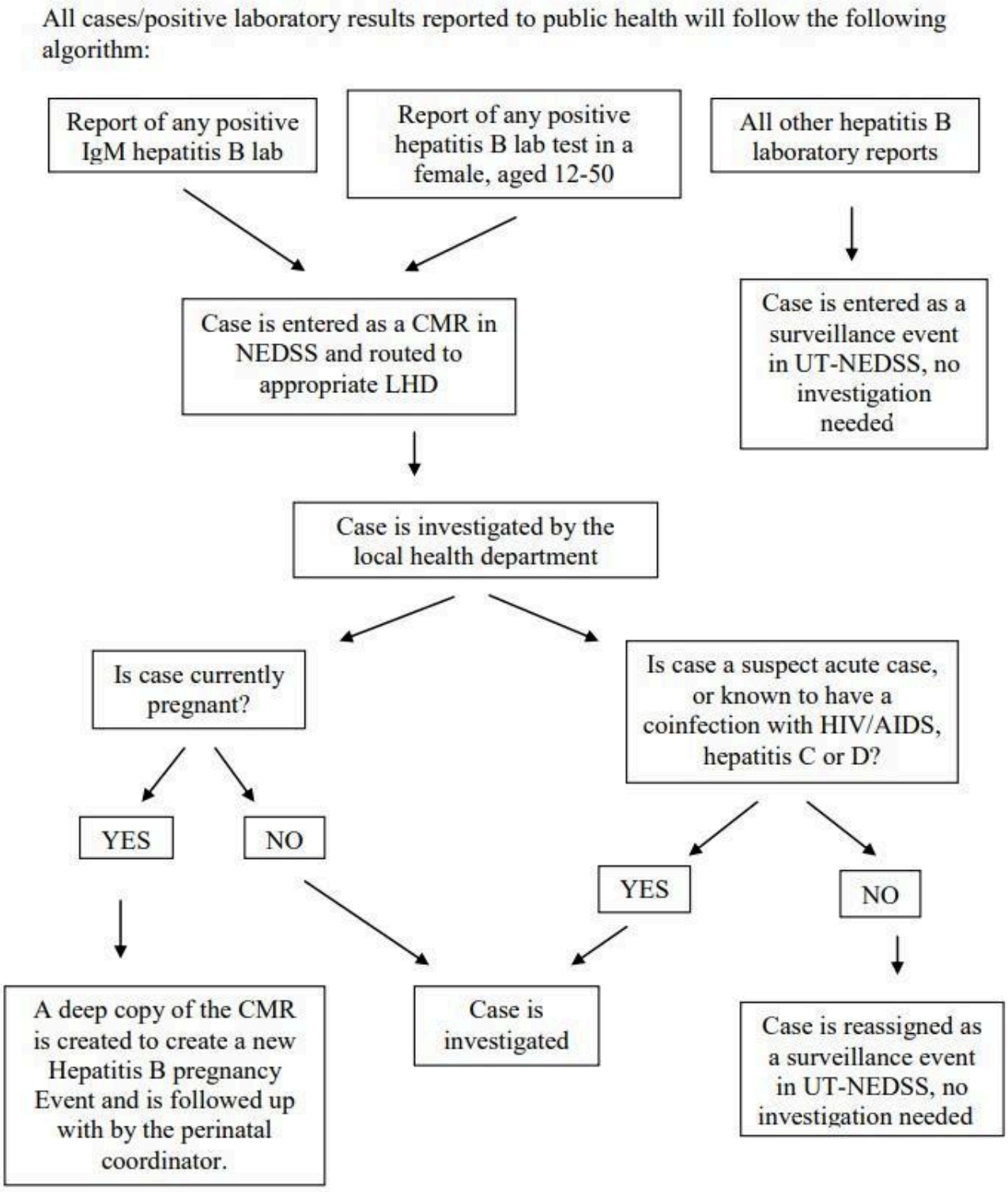
Confirmed

A confirmed case meets the clinical case definition and is laboratory confirmed.

Case investigation process

- Enter a confidential morbidity report (CMR) into UT-NEDSS as a Hepatitis B, chronic (investigation will determine if this needs to be changed later to an acute case classification).
- The following groups are to be investigated when a positive HBV lab report or report of disease is given to public health:
    - Suspect acute cases
    - Individuals who are co-infected with one of the following: hepatitis C, hepatitis D, HIV or AIDS
    - Women of child bearing age (12–50 years of age)
        - People who are found to be pregnant should have a new CMR created in UT-NEDSS through a deep copy of the existing record and classified as a Hepatitis B pregnancy event for perinatal case management and follow-up
- Although rare, the following should also be investigated:
    - Infants born to HBsAg positive gestational parents who were not given prenatal care and/or no vaccine was administered to the infant
    - Gestational parents with unknown HBsAg status, whose infant has been reported as receiving HBIG within 7 days of birth
        - Gestational parent would be investigated as a pregnancy event
- Ensure all case contacts of the above investigated groups are identified and appropriately managed.

Hepatitis B case investigation process for local health jurisdictions



Outbreaks

HBV and HDV do not typically cause outbreaks. When 2 or more cases occur in association with some common exposure, search for additional cases. Consider vaccination of susceptible people who are at risk for exposure.

Identifying case contacts

Close contacts of people diagnosed with HBV and/or HDV are household members and sex partners. Transmission of HBV in schools and childcare settings is most likely to occur through direct exposure to blood after an injury or from bites or scratches that break the skin and introduce blood or body secretions from an HBV carrier into another person. The risk of transmission of HBV and/or HDV in the school and childcare setting has always been low, and with universal vaccination, exposure in the school setting does not require contact notification. Currently there are no recommendations by CDC or the Committee on Infectious Diseases (authors of the Red Book) to implement contact investigations in school or child care settings. Universal precautions should be followed by staff.

Case contact management

Infants born to HBsAg-positive gestational parents

- Newborns born to HBsAg-positive gestational parents should receive HBIG (0.5 mL IM) and the first dose of HBV vaccine within 12 hours of birth. The vaccination schedule is dependent on weight at birth.
    - Infants born who weigh ≥2000 grams should receive a 3-dose vaccination series with doses administered at 0, 1–2, and 6 months of age.
    - Infants born who weigh <2000 grams should receive a 4-dose vaccination series with doses administered at 0, 1–2, 2–3, and 6–7 months of age.
    - Hepatitis B-containing combination vaccines may be used for perinatal children, but not as a birth dose. Perinatal children who receive combination vaccines should have a HBV birth dose, then transition to the combination vaccine.
- The infant should be screened for HBsAg and anti-HBs after completion of the immunization series at 9–12 months of age, to monitor the success or failure of the immunization. Testing should not be performed before 9 months of age to avoid detection of anti-HBs from HBIG administered during infancy and to maximize the likelihood of detecting HBV infections. If HBsAg is not present and anti-HBs antibody is ≥10 mIU/mL, children can be considered protected.
- Infants with anti-HBs concentrations of <10 mIU/mL and who are HBsAg-negative should receive 3 additional doses of vaccine in a 0, 1, and 6-month schedule, followed by testing

for anti-HBs 1–2 months after the sixth dose. No data suggest that children who have no detectable antibody after 6 doses of vaccine would benefit from any additional doses.
- Infants who become HBsAg-positive despite immunization (because of intrauterine infection or vaccine failure) should be referred to a pediatric hepatologist for follow-up, and the parents should be counseled.

Infants born to gestational parents whose HBsAg status is unknown

- Newborns born to gestational parents whose HBsAg status is not known should be given HBV vaccine within 12 hours of birth while awaiting HBsAg test results on the gestational parent.
- If the gestational parent is determined to be positive, the infant should receive HBIG as soon as possible, within 7 days of birth. The child should then complete the 3-dose HBV vaccination series according to birth weight and be screened for HBsAg and anti-HBs at 9–12 months of age.
- If the gestational parent is determined to be HBsAg-negative, the infant should complete the 3-dose HBV vaccine series according to the schedule for infants born to HBsAg-negative gestational parents (0, 1–2, 6–18 months).
- If the gestational parent's HBsAg status remains unknown, the infant should complete the vaccine series according to the recommended schedule for infants born to HBsAg-positive gestational parents (0, 1–2, 6 months). Administration of HBIG is not necessary.

Infants exposed after birth

- Children younger than 12 months of age who have close contact with primary caregivers with acute infection require immunoprophylaxis.
- If at the time of exposure, the infant has been fully immunized or has received at least 2 doses of vaccine, the infant should be presumed protected, and HBIG is not required.
- If only 1 dose of vaccine has been administered, the second dose should be administered if the interval is appropriate, or HBIG should be administered if immunization is not due.
- If immunization has not been initiated, the infant should receive HBIG (0.5 mL) and should initiate and complete the 3-dose HBV vaccine series.

Sexual exposure to HBV infection

- Sexual contacts of a person with HBV who is under investigation (women of childbearing age, suspect acute cases, and co-infected individuals) if susceptible, should begin the hepatitis B vaccine series.
    - Contacts who are insured by a health insurance plan should use that for vaccine coverage.

    - For uninsured adult contacts, LHDs or private providers can offer vaccine purchased privately or publicly (as available) and bill according to established billing policies.
    - For children contacts <18 years of age, vaccine is available through the Vaccines for Children (VFC) Program for children who are eligible for that program. In certain situations, parents may have to pay an administrative fee out-of-pocket.
- Pre-vaccination serologic testing can determine if the sexual contact is susceptible to HBV.
- If the sexual exposure is to a person with acute HBV infection, then the contact should receive a single dose of HBIG (0.06 mL/kg) with the first vaccine dose.
- HBIG administration is unlikely to be beneficial if given more than 14 days after exposure.

Household/close contact exposure to HBV infection

- All susceptible household contacts, including infants of people who are under investigation (women of childbearing age, suspect acute cases, and co-infected individuals) with HBV should initiate and complete the 3-dose series of HBV vaccine according to age specifications.
    - Contacts who are insured by a health insurance plan should use that for vaccine coverage.
    - For uninsured adult contacts, LHDs or private providers can offer vaccine purchased privately or publicly (as available) and bill according to established billing policies.
    - For contacts <18 years of age, vaccine is available through the Vaccines for Children (VFC) Program for children who are eligible. In certain situations, parents may have to pay an administrative fee out-of-pocket.
- Susceptible nonsexual household contacts of a person with acute HBV who have had a blood exposure to a case (such as sharing toothbrushes or razors) should receive a single dose of HBIG (0.06 mL/kg) with the first vaccine dose.

Percutaneous and mucosal exposure to HBV infection

Appropriate post-exposure management depends on the HBsAg status of the source of the exposure and the hepatitis B vaccination status of the individual exposed.

HBsAg-positive source

- Unvaccinated people or people known not to have responded to a complete hepatitis B vaccine series should receive both HBIG and hepatitis B vaccine as soon as possible after exposure (preferably within 24 hours). The hepatitis B vaccine series should be completed using the age-appropriate vaccine dose and schedule.
- People who are in the process of being vaccinated but who have not completed the vaccine series should receive the appropriate dose of HBIG and should complete the vaccine series.

- Children and adolescents who have written documentation of a complete HBV vaccine series and who did not receive post-vaccination testing should receive a single vaccine booster dose.

Source with unknown HBsAg status

- Unvaccinated people should begin the HBV vaccine series within 24 hours after exposure. The vaccine series should be completed using the age-appropriate dose and schedule.
- People who are not fully vaccinated should complete the vaccine series.
- Children and adolescents with written documentation of a complete HBV vaccine series require no further treatment.
- Fully vaccinated adults with a positive response to a complete HBV vaccine series (HBsAb titer ≥ 10 mIU/mL) need no additional hepatitis B testing or post-exposure treatment.

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Version control

Updated April 2016: General update to formatting, added the importance to public health section, added reporting narrative and swimlanes, and added case classification swimlanes and updated to current CTSE guidelines. Added UT-NEDSS Minimum/Required fields, reviewed and updated case fatality, reservoir, susceptibility, period of communicability, transmission, epidemiology, and incubation period, added treatment information, updated immunizations (*Comvax discontinued in 2014). Updated serologic testing, updated references.

Updated December 20, 2016: Added Perinatal HBV case classification and reporting swimlanes based on updated CSTE guidelines.

Updated May 1, 2018: Reviewed and verified disease updates.

Updated August 9, 2018: Added Critical Clinician Information.

Updated September 27, 2018: Reviewed and updated Minimum Data Set Requirements based on current case investigation form and message mapping guides, added Hepatitis B Rules for Entering Laboratory Test Results section.

Updated April 2019: Updated Critical Clinician Information, Laboratory Identification, Vaccine Information and Case Investigation Process.

Updated January 2022: Updated perinatal swimlane to match CSTE.

Updated September 2022: Updated vaccine and epidemiology information. Changed each instance of “mother” to “gestational parent.”

Updated December 2023: Updated reporting criteria and case classification to reflect the updated 2024 CSTE position statement.

UT-NEDSS/EpiTrax minimum/required fields by tab

Demographic

- First name
- Last name
- Birth sex
- County
- Date of birth
- Country of birth
- Ethnicity
- Race
- State
- City
- Area code
- ZIP code
- Street number
- Phone number

Clinical

- Date diagnosed
- Date of death
- Died
- Disease
- Onset date
- Reason for testing
- Aware of hepatitis prior to lab testing?
- Pregnant; due date
- Jaundiced?
- Symptoms
- Does the patient also have hepatitis D?
- Does the patient have diabetes?
- Diagnosis date
- Acute onset
- History of vaccination for HBV?
- If vaccinated, now many doses has the patient received?
- Provider of care for hepatitis?
- Clinician first name
- Clinician last name
- Diagnostic facility (DF)
- DF city
- DF county
- DF state

Laboratory

- ALT >100 IU/L
- Bilirubin >3.0 mg/dl
- Collection date
- Lab
- Organism
- Result value
- Test type
- Test result
- Negative HBV test in last 12 months?
- Test date
- Negative HBV test in last 6 months?
- Test date

Investigation

- Prior to onset of symptoms or seroconversion, was patient hospitalized?
- Prior to onset of symptoms or seroconversion, was patient a resident of a LTCF?
- Ever inject drugs?
- Ever used street drugs, but not inject?
- Did the patient undergo hemodialysis?
- Did patient ever receive blood or blood products?
- Had a history of accidental stick or puncture with a contaminated sharps?
- Did patient receive blood or blood products?

- Did the patient receive any IV infusions and/or injections in an outpatient setting?
- Did the patient have other exposure to another person's blood?
- Was the patient employed in the medical or dental field having direct contact with blood?
- Was the patient employed as a public safety worker having contact with blood?
- Has patient ever had a tattoo?
- Has patient ever had a body piercing (other than ear)?
- Did the patient have dental work or oral surgery?
- History of surgery, other than oral
- Incarcerated longer than 24 hours?
- Type of facility
- Ever incarcerated longer than 6 months? Number of months and year of most recent incarceration
- Was patient ever treated for an STD? If yes, most recent year of treatment
- Contact of a confirmed or suspect case. If yes, type of contact (sexual, household (non-sexual), other)
- Number of female sex partners?
- Number of male sex partner?

Reporting

- Date first reported to public health

Administrative

- Outbreak name
- State case status
- Outbreak associated
- Infection resolved?
- Resolved date

Hepatitis B rules for entering laboratory test results

The following rules describe how laboratory results reported to public health should be added to new or existing events in UT-NEDSS. These rules have been developed for the automated processing of electronic laboratory reports, although they also apply to manual data entry.

Test-specific rules

Test specific rules describe what test type and test result combinations are allowed to create new morbidity events in UT-NEDSS, and what test type and test result combinations are allowed to update existing events (morbidity or contact) in UT-NEDSS.

Test type	Test result	Create a new event	Update an existing event
Antigen by EIA/ELISA	Positive	Yes	Yes
	Negative	No	Yes
	Equivocal	No	Yes
Core antibody (HBcAb)	Positive	No	Yes
	Negative	No	Yes
	Equivocal	No	Yes
	Other	No	Yes
E antigen (HBeAg)	Positive	Yes	Yes
	Negative	No	Yes
	Equivocal	No	Yes
E antibody (HBeAb)	Positive	No	Yes
	Negative	No	Yes
	Equivocal	No	Yes
Liver function tests (ALT, AST, bilirubin)	All	No	Yes
Genotype by PCR	Positive	Yes	Yes
	Negative	No	Yes
	Equivocal	No	Yes
PCR/amplification	Positive	Yes	Yes
	Negative	No	Yes
	Equivocal	No	Yes
Surface antibody (HBsAb)	Positive	No	Yes
	Negative	No	Yes
	Equivocal	No	Yes
	Other	No	Yes

Surface antigen (HBsAg)	Positive	Yes	Yes
	Negative	No	Yes
	Equivocal	No	Yes
Surface antigen (HBSAg) confirmation	Positive	Yes	Yes
	Negative	No	Yes
	Equivocal	No	Yes
Total antibody	Positive	No	Yes
	Negative	No	Yes
	Equivocal	No	Yes
Viral load -- quantitative	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
Viral load -- qualitative	Positive	Yes	Yes
	Negative	No	Yes
	Equivocal	No	Yes
Genotype by sequencing	Positive	Yes	Yes
	Negative	No	Yes
Pregnancy	Positive	No	Yes
	Negative	No	Yes
Core IgM antibody*	Positive	Yes	Yes
	Negative	No	Yes
	Equivocal	No	Yes

*A positive result for this test would create a hepatitis B, acute case.

Whitelist rules

Whitelist rules describe how long an existing event can have new laboratory data appended to it. If a laboratory result falls outside the whitelist rules for an existing event, it should not be added to that event, and should be evaluated to determine if a new event (CMR) should be created.

Hepatitis B morbidity whitelist rule: Never a new case.

Hepatitis B contact whitelist rule: If the specimen collection date of the laboratory result is 6 months or less after the event date of the contact event, the laboratory result should be added to the contact event.

Liver function test morbidity whitelist rule: Never a new case.

Liver function test whitelist rule: Always added to contact.

Graylist rules

We often receive laboratory results through ELR that cannot create cases, but can be useful if a case is created in the future. These laboratory results go to the graylist. The graylist rule describes how long an existing event can have an old laboratory result appended to it.

Hepatitis B graylist rule: If the specimen collection date of the laboratory result is 18 months before to 7 days after the event date of the morbidity event, the laboratory result should be added to the morbidity event.

Liver function test graylist rule: If the specimen collection date of the laboratory result is 30 days before to 7 days after the event date of the morbidity event, the laboratory result should be added to the morbidity event.

Other electronic laboratory processing rules

- If an existing event has a state case status of “not a case,” ELR will never add additional test results to that case. New labs will be evaluated to determine if a new CMR should be created.