Acute Hepatitis B

Signs and symptoms	Often asymptomatic. About 20–30% of newly infected persons have symptoms including fatigue, abdominal pain, poor appetite, and/or jaundice.
Incubation	Typically 60-90 days, range 45-180 days.
Case classification	**Confirmed:** Meets Tier 1 confirmatory laboratory evidence **OR** meets clinical criteria **and** Tier 2 laboratory evidence of acute HBV infection. **Probable:** Meets clinical criteria AND presumptive laboratory evidence of acute HBV infection. **Laboratory criteria for acute HBV infection:** Tier 1: detection of IgM anti-HBc **AND** at least one of the following: HBsAg, HBeAg, or HBV DNA; **OR** detection of HBsAg, HBeAg, or HBV DNA within 12 months of a negative HBsAg result (i.e., HBsAg seroconversion). Tier 2: detection of HBsAg without an IgM anti-HBc result (test not done or results not available) **OR** detection of HBV DNA without an IgM anti-HBc result. Presumptive: detection of IgM anti-HBc **AND** negative or not done for [HBsAg, HBV DNA, or HBeAg] **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) levels > 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 (see section VIB), 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.*
Differential diagnosis	Hepatitis A or C, chemical hepatitis (e.g., alcoholism, medications, natural remedy), autoimmune hepatitis, biliary disease, malignancy, metabolic disease (e.g., Wilson's)
Treatment	Supportive
Duration	Acute illness asymptomatic or lasting several weeks
Exposure	Blood (shared drug paraphernalia, rarely medical device or procedure), sexual fluids, birth. Acute case is communicable before symptom onset until resolved.
Laboratory testing	Local Health Jurisdiction (LHJ) and Communicable Disease Epidemiology (CDE) arrange testing if part of a suspected cluster. • Washington State Public Health Laboratories (PHL) will hold specimen or forward to CDC. • **Best specimen**: Acute serum, spun down, separated, and frozen immediately. See: https://centersfordiseasecontrol.sharefile.com/share/view/sed42e98472b646ad87bf7f30a1df5085 *Specimen shipping (Section 4):* • Hospital must keep all specimens **frozen, ship with dry ice** and use the WA PHL Serology form. https://www.doh.wa.gov/Portals/1/Documents/5230/302-017-SerVirHIV.pdf
Public health actions	• Interview case for exposures including potential bloodborne and health care exposures. • If suspected healthcare-associated case **report to CDE at 206-418-5500 or 877-539-4344**. • *Infection control*: Use standard precautions in health care settings. • Facilitate collection and freezing of serum if source of illness is possible healthcare exposure; conduct sequencing if part of a suspected cluster. • Identify susceptible contacts and recommend HBIG/vaccine as appropriate. • Educate acute case to avoid alcohol; obtain hepatitis A vaccine if needed; get evaluated for hepatitis C if needed; and avoid transmission to others. Prevention measures include the use of barrier methods during sex; not sharing drug paraphernalia, blood testing equipment, razors, toothbrushes, or nail clippers. Household and sexual contacts should be vaccinated. • Retest adults in 6+ months to establish if infection has cleared. • May need to recommend special precautions to health care providers with acute infection. • Enter case into Washington Disease Reporting System (WDRS).

Signs and symptoms	**Chronic HBV**: typically asymptomatic, often diagnosed due to screening or liver damage. **Perinatal HBV**: typically (but not always) asymptomatic.
Case classification	**Chronic HBV, Confirmed:** Meets any of the confirmatory laboratory criteria below. **Chronic HBV, Probable:** Meets the presumptive laboratory criteria below. **Laboratory criteria for chronic HBV infection:** <u>Confirmatory</u>: • Detection of HBsAg in two clinical specimens taken ≥ 6 months apart, OR • Detection of HBeAg in two clinical specimens taken ≥ 6 months apart, OR • Detection of [HBsAg OR HBeAg] AND total anti-HBc, OR • Detection of HBsAg AND HBeAg, OR • Detection of HBV DNA (qualitative, quantitative, or genotype) <u>Presumptive</u>: • Detection of [HBsAg OR HBeAg] AND IgM anti-HBc test negative, not done, or result not available
	HBV detection in pregnancy: positive HBsAg test in a pregnant person (required for confirmed perinatal HBV case definition).
	Perinatal HBV, Confirmed: child born in the US to an HBV-infected mother/birthing person 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. **Perinatal HBV, Probable:** child born in the US 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 mother's/birthing person's hepatitis B status is unknown.
Differential diagnosis	Hepatitis A or C, chemical hepatitis (e.g., alcoholism, medications, natural remedy), autoimmune hepatitis, biliary disease, malignancy, metabolic disease (e.g., Wilson's).
Treatment	Consult GI specialist for antiviral protocols.
Duration	Chronic infection is lifelong.
Exposure	Blood (shared drug paraphernalia, rarely medical device or procedure), sexual fluids, birth. A chronic case is communicable lifelong.
Laboratory testing	Local Health Jurisdiction (LHJ) and Communicable Disease Epidemiology (CDE) arrange testing if case is part of a suspected cluster. • Washington State Public Health Laboratories (PHL) will hold specimen or forward to CDC. • **Best specimen**: Acute serum, spun down, separated, and frozen immediately. See: https://centersfordiseasecontrol.sharefile.com/share/view/sed42e98472b646ad87bf7f30a1df5085 *Specimen shipping (Section 4):* • Hospitals must keep all specimens **frozen, ship with dry ice** and the WA PHL Serology form. https://www.doh.wa.gov/Portals/1/Documents/5230/302-017-SerVirHIV.pdf
Public health actions	• Interview case for exposures including potential bloodborne and health care exposures. • If suspected health care-associated case, **report to CDE at 206-418-5500 or 877-539-4344**. • *Infection control*: Use standard precautions in health care settings. • Facilitate collection and freezing of serum if source of illness is a possible healthcare exposure, conduct sequencing if case is determined to be part of a suspected cluster. • Identify susceptible contacts and recommend HBIG/vaccine as appropriate. • Educate case to avoid alcohol; obtain hepatitis A vaccine if needed; get evaluated for hepatitis C if needed; and avoid transmission to others. Transmission prevention measures include the use of barrier methods during sex and not sharing drug paraphernalia, blood testing equipment, razors, toothbrushes, or nail clippers. Household and sexual contacts should be vaccinated.

	• Infants born to HBV-infected mothers/birthing persons should receive HBIG and the first dose of Hep B vaccine within 12 hours of birth, followed by the second and third doses of Hep B vaccine at 1-2 and 6 months of age, respectively. Post-vaccination serologic testing 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. • Enter case into Washington Disease Reporting System (WDRS).

Hepatitis B

1. DISEASE REPORTING

A. Purpose of Reporting and Surveillance

1. To identify sources of infection and prevent further transmission from such sources.
2. To identify new groups at risk and reduce further cases.
3. To inform cases about treatment options.
4. To educate cases about hepatitis B and how to reduce the risk of transmission.
5. To identify contacts and recommend appropriate preventive measures.
6. To better understand the epidemiology of hepatitis B virus infection and the burden of morbidity from chronic infection.

B. Legal Reporting Requirements (See Appendix A)

1. Acute Hepatitis B

a. Health care providers: notifiable to local health jurisdiction within 24 hours.
   i. Providers must also report pregnancy status for patients 12-50 years of age.

b. Health care facilities: notifiable to local health jurisdiction within 24 hours.
   i. Facilities must also report pregnancy status for patients 12-50 years of age.

c. Laboratories: hepatitis B virus (acute) by IgM positivity notifiable within 24 hours. Specimen submission is on request only in outbreak settings.
   i. When available and associated with a positive result indicated above, laboratories must also report pregnancy status and hepatocellular enzyme levels.

d. Local health jurisdictions: notifiable to Washington State Department of Health (DOH) Communicable Disease Epidemiology (CDE) (206-418-5500) within 7 days of case investigation completion or summary information required within 21 days, via WDRS.

2. Chronic Hepatitis B (initial diagnosis and previously unreported prevalent cases)

a. Health care providers: notifiable to local health jurisdiction within three business days.
   i. Providers must also report pregnancy status for patients 12-50 years of age.

b. Health care facilities: notifiable to local health jurisdiction within three business days.
   i. Facilities must also report pregnancy status for patients 12-50 years of age.

c. Laboratories: all hepatitis B virus by HBsAg (surface antigen), HBeAg (little “e” antigen), or HBV DNA notifiable to local health jurisdiction of patient residence (or ordering health care provider, if patient residence is unknown) within 24 hours.

i. When available and associated with a positive result indicated above, laboratories must also report pregnancy status, hepatocellular enzyme levels, and negative IgM anti-HBc results.

d. Local health jurisdictions: notifiable to DOH CDE within 7 days of case investigation completion, or summary information required within 21 days of initial notification to local health authorities, via WDRS.

3. Hepatitis B Surface Antigen Positive (HBsAg+) Pregnant Persons (each pregnancy)

a. Health care providers: notifiable to local health jurisdiction within 3 business days.

b. Health care facilities: notifiable to local health jurisdiction within 3 business days.

c. Laboratories: all hepatitis B virus by HBsAg (surface antigen), HBeAg (e antigen), or HBV DNA notifiable within 24 hours..

d. Local health jurisdictions: notifiable to DOH CDE Perinatal Hepatitis B Prevention Program (PHBPP) via WDRS within 7 days of case investigation completion, or summary information required within 21 days of initial notification to local health authorities.

4. Perinatal Hepatitis B

a. Health care providers: notifiable (as acute hepatitis B) to local health jurisdiction within 3 business days of receiving confirming test result.

b. Health care facilities: notifiable (as acute hepatitis B) to local health jurisdiction within 3 business days of receiving confirming test result.

c. Laboratories: all hepatitis B virus by HBsAg (surface antigen), HBeAg (e antigen), or HBV DNA notifiable within 24 hours.

i. When available and associated with a positive result indicated above, laboratories must also report pregnancy status, hepatocellular enzyme levels, and negative IgM anti-HBc results.

d. Local health jurisdictions: notifiable to CDE (206-418-5500) within 7 days of case investigation completion, or summary information required within 21 days of initial notification to local health authorities, via WDRS.

C. Local Health Jurisdiction Investigation Responsibilities

Determine if the person was previously reported as an acute or chronic hepatitis B case.

1. Acute Hepatitis B

a. Begin follow-up investigation within one working day.

b. Recommend hepatitis B immune globulin (HBIG) and/or vaccine as indicated for susceptible contacts.

c. Attempt to determine the source of infection, particularly medical or dental exposures including diabetes blood testing in residential facilities.

d. Educate the case about hepatitis B and how to reduce the risk of transmission.

e. Educate the case about minimizing disease progression and emphasize the importance of vaccination for hepatitis A. If applicable, recommend measures such as not sharing injection drug equipment to prevent possible future infection with bloodborne agents.

f. Report all confirmed and probable acute hepatitis B cases to CDE. Complete the case report form (https://www.doh.wa.gov/Portals/1/Documents/5100/210-031-ReportForm-HepB-Acute.pdf) and enter into (WDRS) as an acute hepatitis B case.

2. Chronic Hepatitis B

   Local health jurisdiction investigation responsibilities relate to all confirmed and probable cases of chronic hepatitis B. Check WDRS to determine if case is newly reported or previously reported.

   For previously reported cases, if case is already confirmed, no further action is required. If the case classification was previously probable, enter laboratory results into WDRS and ensure case classification updates to confirmed.

   For newly reported cases, collect basic case reporting information including laboratory test results, demographics, and risk factor information. Within 7 days of completing an investigation, enter data into WDRS. The surveillance data collection form is available at: (https://www.doh.wa.gov/Portals/1/Documents/5100/420-225-ReportForm-HepB-ChronicSurveillance.pdf). The patient interview form is available at: (https://www.doh.wa.gov/Portals/1/Documents/5100/210-078-ReportForm-HepB-ChronicInterview.pdf).

3. Ensure each pregnancy in an HBsAg positive person is reported to the local Perinatal Hepatitis B Coordinator who will enroll the pregnant person in the Perinatal Hepatitis B Prevention Program (PHBPP) and enter the case information into WDRS. Investigate if the report is an initial diagnosis of chronic (or less likely acute) infection (see above). The local Perinatal Hepatitis B Prevention Coordinator will track the pregnancy, ensure the infant is appropriately treated starting at birth, and recommend testing for the infant at the appropriate time.

4. Report all infants who meet the case definition for perinatal hepatitis B virus infection to CDE. Enter the report in WDRS as a new case of perinatal hepatitis B. Note that discrete onset of symptoms is **not** required for perinatal hepatitis B cases.

5. Local health jurisdiction priorities in conducting chronic hepatitis B case investigations should include follow-up of cases among individuals who could become pregnant (i.e., sex at birth = female and age 12-50 years), as well as cases for whom age or other risk factors suggest new transmission (see Section 5 for more guidance). Whenever possible, these cases, and all other persons with chronic hepatitis B, should receive messaging regarding ways to protect and promote liver health and to prevent transmission to others. Key messages include avoiding liver toxins (particularly alcohol), the importance of both hepatitis-related and routine primary care, as well as recommendation for hepatitis C and HIV screening as necessary, along with hepatitis A vaccination as indicated. All persons should be provided or otherwise directed to resources promoting patient education, access to care and self-management. Sources include the Hepatitis Education Project (http://hepeducation.org/) and CDC (CDC DVH - Hepatitis B - Patient Education Resources). See Section 6 below for further messaging details.

2. THE DISEASE AND ITS EPIDEMIOLOGY

A. Etiologic Agent

Hepatitis B virus (HBV) is a DNA virus in the Hepadnavididae family. It is one of several viruses known to cause hepatitis in humans. Hepatitis B virus is completely unrelated to the viruses that cause hepatitis A, hepatitis C, hepatitis D, and hepatitis E.

B. Clinical Manifestations

Hepatitis B virus infection may be transient or chronic, and either may be asymptomatic. If acute symptoms occur, onset is usually insidious with loss of appetite, right upper quadrant abdominal discomfort, nausea and vomiting, fatigue, and sometimes arthralgia or rash, with illness often progressing to jaundice. Liver enzyme levels may be markedly elevated. Fever may be absent or mild. Rarely, acute infections result in fulminant liver necrosis and death. Hepatitis B cannot be reliably distinguished clinically from hepatitis A, hepatitis C, or other viral hepatitides. Asymptomatic infections are the rule in infants or young children, and are not uncommon even among adults. For this reason many people have serologic evidence of previous infection but do not recall a consistent illness.

Chronic hepatitis B infection carries a risk of severe sequelae (e.g.,, chronic active hepatitis, cirrhosis, or hepatic cancer) decades later. The likelihood of chronic infection occurring is highest for younger ages. Around 5-10% of acute infections in adults become chronic, compared with as many as 90% of perinatal infections. As a result, perinatal hepatitis B has a high health burden globally, particularly in areas with high prevalence.

C. Hepatitis B in Washington

In recent years, the Department of Health has received an average of 39 reports of acute hepatitis B per year and approximately 1700 cases per year of chronic hepatitis B. The Office of Communicable Disease Epidemiology's Perinatal Hepatitis B Prevention Program follows about 200-330 reported hepatitis B surface antigen-positive pregnant persons per year with reports of 0-3 cases of perinatal hepatitis B virus infections per year.

D. Reservoir

Infected humans are the reservoir for hepatitis B. Chronic cases are probably the most important sources of hepatitis B virus transmission because they are infectious for many years, compared to the few weeks that resolved acute hepatitis B are infectious. Efforts to identify persons with chronic infections and to offer prophylaxis to their contacts are thus at least as important as follow-up directed towards acute cases. Infected pregnant persons particularly need follow-up so post-exposure prophylaxis can be given to prevent hepatitis B in the newborn, which would carry a high risk of developing chronic infection. About 10% of perinatal hepatitis B infection will eventually result in cirrhosis or liver cancer.

E. Modes of Transmission

Hepatitis B virus is usually transmitted by contact with the blood, semen or vaginal secretions of an infected (HBV DNA-positive or HBsAg-positive) person. The virus is introduced through mucous membranes or broken skin. HBV may also be found at low levels in saliva and other body fluids. However, breastfeeding is *not* a significant route of

transmission. Infection can occur with minor blood contact, such as within a household, and often a specific exposure event cannot be determined.

Known hepatitis B transmission modes include:

- Sharing blood-contaminated object (e.g., drug paraphernalia, razors) and sexual contact.
- In utero transmission is rare, but perinatal transmission occurs in about a third of deliveries to infected mothers/birthing persons unless the infant receives prompt post-exposure prophylaxis with hepatitis B immune globulin (HBIG) and hepatitis B vaccine series initiation.
- Less common modes include:
    - Blood or sexual fluid into mucosa or broken skin (e.g., blood splash in an eye),
    - Receipt of blood product or organ, or exposure to blood-contaminated medical equipment (e.g., endoscope, shared diabetes testing device, drug vial).
    - Nosocomial transmission was significant in the past but outbreaks still occur.

Under some conditions, hepatitis B virus remains viable on environmental surfaces for over a week (e.g., dried blood) but the contribution to transmission is unknown.

While the US has a low prevalence of hepatitis B virus infection (<2%), there is a higher prevalence in many areas of the world. Estimations of worldwide prevalence of chronic hepatitis B infection are available: Hepatitis B - Chapter 4 - 2020 Yellow Book | Travelers' Health | CDC.

F. Incubation Period

The incubation period for hepatitis B varies from 45 to 180 days and is usually between 60 and 90 days.

G. Period of Communicability

A person is communicable while HBsAg and/or HBV DNA are present in the blood, regardless of symptoms. If symptoms occur, viremia begins several weeks before onset and lasts several months if the infection resolves, or indefinitely in chronic infections.

H. Treatment

Antiviral drugs are available for the treatment of chronic hepatitis B based on appropriate medical evaluation by a specialist. See: https://www.aasld.org/practice-guidelines/chronic-hepatitis-b

3. CASE DEFINITIONS

A. Acute Hepatitis B (2024)

1. **Clinical criteria:** In the absence of a more likely, alternative diagnosis*, acute onset or new detection of at least one of the following: a) jaundice, b) total bilirubin ≥ 3.0 mg/dL, or c) elevated serum alanine aminotransferase (ALT) levels > 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 (see section VIB), 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.

2. **Laboratory criteria:**

Confirmatory Laboratory Evidence for Acute HBV Infection:
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 (qualitative, quantitative, or genotype) **AND** detection of IgM anti-HBc, **OR**
- Detection of HBsAg, HBeAg, or HBV DNA within 12 months (365 days) of a negative HBsAg test result. (i.e., HBsAg seroconversion)

Tier 2

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

Presumptive Laboratory Evidence for Acute HBV Infection:

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

3. Case classification

Confirmed: A case that meets Tier 1 confirmatory laboratory evidence of acute HBV infection, **OR** meets clinical criteria AND Tier 2 laboratory evidence.

Probable: Meets clinical criteria **AND** presumptive laboratory evidence of acute HBV infection.

B. Chronic Hepatitis B (2024)

1. **Clinical criteria**: No symptoms are required. Persons with chronic HBV infection may have no evidence of liver disease or may have a spectrum of disease ranging from chronic hepatitis to cirrhosis or liver cancer.

2. **Laboratory criteria:**

Confirmatory Laboratory Evidence for Chronic HBV Infection:

- Detection of HBsAg in two clinical specimens taken ≥ 6 months apart, **OR**
- Detection of HBeAg in two clinical specimens taken ≥ 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 for Chronic HBV Infection:

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

3. Case classification

   Confirmed: A case that meets confirmatory laboratory evidence for chronic HBV infection.

   Probable: A case that meets presumptive laboratory evidence for chronic HBV infection.

C. Hepatitis B Surface Antigen Positive Pregnant Persons

1. Case classification

   Confirmed: Any pregnant person who tests positive for hepatitis B surface antigen.

   Comment: Infants born to HBV-infected mothers/birthing persons should receive HBIG and the first dose of Hep B vaccine within 12 hours of birth, followed by the second and third doses of Hep B vaccine at 1 and 6 months of age, respectively. Post-vaccination serologic testing 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.

D. Perinatal Hepatitis B (2017)

1. Clinical case definition: Perinatal hepatitis B in the newborn may range from asymptomatic to fulminant hepatitis.
2. Laboratory criteria for diagnosis:

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

3. Epidemiologic linkage: Born to an HBV-infected mother/birthing person.
4. Case classification
   Probable: Child born in the US 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 mother's/birthing person's hepatitis B status is unknown (i.e. epidemiologic linkage not present).

   Confirmed: Child born in the US to an HBV-infected mother/birthing person 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.

   Comment: Perinatal hepatitis B cases are reported to CDC by the infant's year of diagnosis.

4. DIAGNOSIS AND LABORATORY SERVICES

A. Laboratory Diagnosis

Acute and chronic hepatitis B infections are most commonly diagnosed by identifying specific antigens or antibodies in the blood. The most common serologic markers and the

interpretations are shown in Table 1. An explanation of the antigens/antibodies tested can be found in Appendix B. Recently, newer molecular tests have been developed to detect HBV DNA in serum. These tests are primarily used for patients with chronic hepatitis B to determine candidacy for and response to antiviral therapies.

Table 1. Typical interpretation of hepatitis B lab results

HBsAg	Total anti-HBc	Anti-HBc IgM	Anti-HBs	HBV DNA	Possible Interpretation*
–	–	–	–	–	Never infected; susceptible if never vaccinated or vaccine failure
+	–	–	–	+ or –	Early acute infection (if HBV DNA is positive); transiently positive for HBsAg after vaccination (if HBV DNA is negative)†
+	+	+	–	+	Acute infection
–	+	+	+ or –	+ or –	Acute resolving infection; "window period" if anti-HBs is negative
–	+	–	+	–	Recovered from past infection and immune
+	+	–	–	+	Chronic HBV infection
–	–	–	+	–	Immune from vaccination; passive anti-HBs transfer after hepatitis B immune globulin administration
–	+	–	–	+ or –	Isolated total anti-HBc positive‡
–	+ or –	–	+ or –	+	Occult HBV infection§
+ or – §	+	+ or –	+ or –	+	Possible HBsAg mutant infection

Table modified from https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.PDF.

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

*Ingestion of high levels of biotin can significantly interfere with certain commonly used biotinylated immunoassays and cause false-positive or false-negative laboratory test results. The US Food and Drug Administration (FDA) is investigating thresholds associated with false-positive and false-negative tests. This section will be updated as more information becomes available.
Reference: https://www.fda.gov/medical-devices/safety-communications/update-fda-warns-biotin-may-interfere-lab-tests-fda-safety-communication.

†People who receive hepatitis B vaccine might be transiently positive for HBsAg, with reports of transient positivity 18 days post-vaccination (56). Retesting of patients who are positive for HBsAg shortly after hepatitis B vaccination at a later time is needed to determine the true HBV infection status.

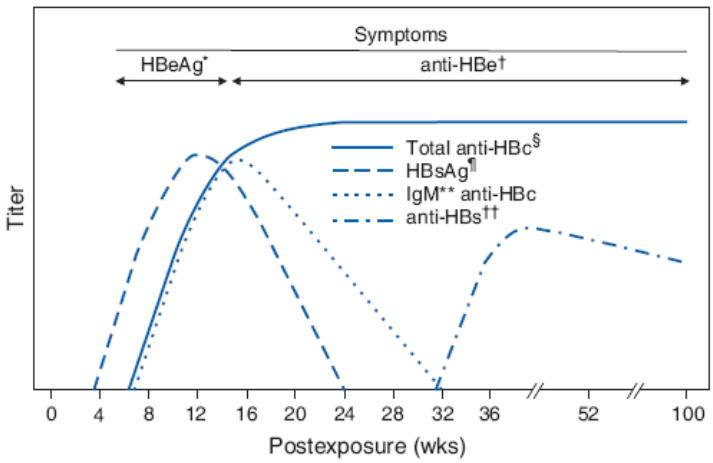
‡Could result from:

- Loss of anti-HBs after past resolved infection. HBV DNA is negative.
- False-positive total anti-HBc, i.e., susceptible. HBV DNA is negative. To resolve the ambiguity of a false-positive total anti-HBc result, test a follow-up sample 4–8 weeks later. If found positive, interpret as a resolved infection. If negative, interpret as false-positive.
- Passive transfer of total anti-HBc to infant born to an HBsAg-positive mother/birthing person for up to 24 months. HBV DNA is negative.
- Occult HBV infection. HBV DNA is positive, typically at low levels. Anti-HBs might or might not be positive.
- HBsAg mutant infection. HBV DNA is positive, typically at high levels. Anti-HBs might or might not be positive.

§HBsAg mutants will not be detectable if testing was performed using an older assay that cannot detect HBsAg mutants. HBsAg mutant strains can be detected by some HBsAg assays that first became available in the United States in 2015, including Abbot ARCHITECT instrument, ETI-MAK-2 PLUS, and Siemens Advia Centaur XP or XPT instrument. Though specimens should be tested using an assay that can detect HBsAg mutants, older HBsAg assays that cannot detect HBsAg mutants remain available. Reference: Apata I W, Nguyen D B, Khudyakov Y, et al. Hepatitis B virus mutant infections in hemodialysis patients: A case series. *Kidney Medicine* 2019; 1(6): 347-353. DOI: https://doi.org/10.1016/j.xkme.2019.07.011.
Downloads of this figure: PDF | PPT

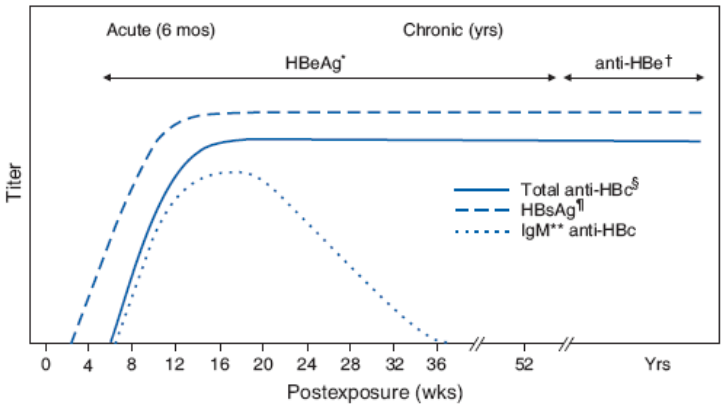
A typical serologic course of acute hepatitis B with recovery or with progression to chronic infection is shown in Figures 1 and 2. Occasionally, a person will have neither HBsAg nor anti-HBs detectable during late acute illness but may still be infectious for 1–2 weeks. During this "window phase," the only positive serological test may be core antibodies (anti-HBc).

FIGURE 1. Typical serologic course of acute hepatitis B virus infection with recovery



* Hepatitis B e antigen.
† Antibody to HBeAg.
§ Antibody to hepatitis B core antigen
¶ Hepatitis B surface antigen.
** Immunoglobulin M.

FIGURE 2. Typical serologic course of acute hepatitis B virus (HBV) infection with progression to chronic HBV infection



* Hepatitis B e antigen.
† Antibody to HBeAg.
§ Antibody to hepatitis B core antigen
¶ Hepatitis B surface antigen.
** Immunoglobulin M.

Source: Centers for Disease Control and Prevention. Recommendations for Identification and Public Health Management of Persons with Chronic Hepatitis B Virus Infection. MMWR 2008;57(No. RR-8):1–20.

In occult HBV infection HBV DNA is detected but not HBsAg. An occult HBV infection may reactivate if the person develops immunosuppression due to disease or therapeutics such as during treatment for malignancy.

Rare hepatitis B virus "escape mutants" with altered HBsAg have been reported. Serology of an infected person shows HBeAg and anti-HBs, and there will also be detectable HBV DNA. Vaccine and HBIG are not effective against escape mutant viruses, which can be responsible for vaccine failures. Other mutant forms of hepatitis B viruses have been found after liver transplant.

B. Tests Available at the Washington State Public Health Laboratories (PHL)

Tests for hepatitis B are widely available at commercial laboratories. In certain cluster investigations, Communicable Disease Epidemiology (CDE) may request a specimen from a case for molecular sequencing at the Centers for Disease Control and Prevention. See: https://centersfordiseasecontrol.sharefile.com/share/view/sed42e98472b646ad87bf7f30a1df5085. CDE will complete the special CDC hepatitis submission form (HRL manifest).

Note that PHL requires that all clinical specimens have two patient identifiers, a name **and** a second identifier (e.g., date of birth) both on the specimen label and on the submission form. Due to laboratory accreditation standards, specimens will be rejected for testing if not properly identified. Also include specimen source and collection date.

C. Specimen Collection

Anti-HBV serology can be done from onset of symptoms to 4–6 months after onset. Virus is detectable lifelong in chronic cases. Obtain a serum or EDTA tube, spin promptly, separate the serum into a shipping tube, and promptly ship cold with PHL Virology form: https://www.doh.wa.gov/Portals/1/Documents/5230/302-017-SerVirHIV.pdf

5. ROUTINE CASE INVESTIGATION

A. Evaluate the Diagnosis

Review laboratory tests to distinguish between acute and chronic cases of hepatitis B virus infections. Check WDRS and follow up a newly diagnosed acute or chronic case.

1. Health Care Provider or Health Care Facility Report of Acute Case or Laboratory Evidence of Acute Infection (e.g., IgM anti-HBc positive):

   - Obtain information from the health care provider, hospital infection control staff, or patient to determine if the patient meets the acute hepatitis B case definition.
   - If the patient meets the acute hepatitis B case definition, proceed to Section 5B.
   - Local health jurisdictions are encouraged to provide education (see Section 6) to patients who meet the chronic hepatitis B case definition, focusing efforts on those likely to have a new diagnosis or potential nosocomial exposure.

2. Laboratory Reports Only (including reports from hospital laboratories):

   - Determine if the patient has been previously reported as a case.
   - If hepatitis B infection has not been previously reported for this patient, proceed with case investigation activities as described above in Local Health Jurisdiction Investigation Responsibilities (Section 1C). Priority in investigations should also be given to any case likely to be associated with a health care facility or medical device (e.g., dialysis).
   - Persons who meet the acute hepatitis B case definition should be investigated as described in Section 5B. An acute hepatitis B event should be created for the person in WDRS.
   - If the patient was previously reported as an acute hepatitis B case, and new laboratory evidence indicates chronic infection (e.g., new labs such as HBsAg or HBV DNA collected at least six months after the original labs associated with the acute event), report a new chronic hepatitis B event for this person including the case classification (probable or confirmed) indicated by the newly reported laboratory data. In WDRS, this person will have both acute and chronic sub-types selected within the same hepatitis B event; see Washington Disease Reporting System (WDRS) | Washington State Department of Health for more information.
   - If the patient was previously reported as a confirmed chronic case, no further active investigation is needed. Update the existing case report as necessary with any descriptive (e.g., demographic) data newly reported in the current lab report.
   - If the patient was previously reported as a probable chronic case, and the new laboratory evidence suggests confirmed infection (see confirmed case definition in Section 3B), update the case classification to confirmed, enter any new laboratory test result data, and update the case record with any newly reported information.
   - Local health jurisdiction priorities in conducting chronic hepatitis B case investigation should include at a minimum determining if the report involves a

pregnant person and identifying reports suggesting a new transmission (such as in persons using injection drugs or persons under the age of 40); see section 5E. .

- If the report involves a pregnant person see Section 7E and 7F. At every opportunity, local health jurisdictions are encouraged to provide patient education messaging, materials, and resources. See Section 1C and Section 6 for details.

B. Identify the Source of Infection

For acute infections and those suspected to have been infected through medical, dental or commercial procedures, collect information about possible exposures, including high risk behaviors, during the period 45–180 days before the onset of illness. Emphasis should be placed on the 60–90 days before onset. However, detailed investigation of earlier exposures may be appropriate for a person with documented negative hepatitis status prior to a specific event such as a medical procedure with subsequent positive test.

Exposure and risk behavior information should include:

- Parenteral drug use as well as use of drugs not prescribed by a provider but the route of administration is unknown.
- Close contact with any household member, sexual partner or acquaintance with recent hepatitis or known chronic infection (obtain names, phone numbers, and addresses).
- Occupational or other needlestick injuries.
- Receipt of blood transfusion, other blood products, tissues, or organs.
- Potential medical or dental exposures within the 6 months prior to onset of current illness, including organ or tissue transplant, dialysis, dental or surgical care, diabetes blood testing in a long term residential facility, and IV or injection in an outpatient setting. See: https://www.cdc.gov/hepatitis/outbreaks/healthcareinvestigationguide.htm

  1. List date of all healthcare encounters during the likely exposure period.
  2. Determine the types of procedures and surgeries performed during each healthcare encounter, especially those involving percutaneous exposures (e.g., injections, infusions, skin puncture with a needle/lancet).
  3. Review regulatory/medical board reports/complaints to determine if the health care facility and/or providers have been under investigation.
  4. Contact the health care facility to tell them of the investigation and determine if they were aware of the current case(s) under investigation or any additional infections.
  5. For additional support or guidance, contact HAIEpiOutbreakTeam@doh.wa.gov.

- Other parenteral exposures within the 6 months prior to onset of current illness, including tattooing, piercing, or acupuncture.
- Accidental exposure of skin, eyes, mucous membranes, or a wound to blood of another person.
- Work in occupational settings with elevated risk of exposure (e.g., medical, dental, or clinical laboratory setting, or facilities for mentally disabled persons).

- Sexual contact (homosexual or heterosexual) with multiple sex partners or a sex partner with a risk for hepatitis B virus infection.
- Sharing of razors, toothbrushes, or nail care items.
- Birth outside of the United States, and/or if the mother/birthing person has a history of hepatitis B infection.

Identifying a specific source of infection for recently identified chronically infected persons may be difficult. Possible sources should be pursued if there is a good chance of identifying additional chronic hepatitis B infections or a preventable source. For example, if the newly diagnosed case is a child, it would be reasonable to screen parents and other household members for evidence of infection. Likely health or dental care associated exposures should also be investigated.

People with inactive chronic hepatitis B or resolved hepatitis B can experience hepatitis B reactivation, characterized by ALT elevation with or without symptoms. In some cases, anti-HBc IgM may be present. People at greatest risk of hepatitis B reactivation include those:

- Undergoing cancer chemotherapy,
- Receiving immunosuppressive therapy (particularly anti-B cell therapy),
- With HIV infection who have discontinued antiretroviral drugs with activity against HBV (e.g., tenofovir),
- Undergoing solid organ or bone marrow transplantation, and
- Co-infected with hepatitis C virus who are undergoing treatment with direct-acting antivirals (DAAs).

A suspected hepatitis B reactivation case may meet either the acute or chronic case classification criteria, depending on laboratory results and symptoms. It's important to obtain a clinical history from the patient's provider including exploration of factors listed above, as a history of acute or chronic hepatitis B can help distinguish between a hepatitis B reactivation case or a newly diagnosed acute or chronic hepatitis B case. Cases previously reported in Washington (e.g., the person has an acute or chronic hepatitis B event in WDRS) should not be reported as a newly diagnosed acute case, even if the person meets the acute case definition by presence of symptoms and appropriate supporting laboratory evidence.

C. Identify Potentially Exposed Persons

1. Identify persons potentially exposed to the case during the communicable period. These include household members, sexual contacts, drug paraphernalia sharing contacts, and others potentially exposed to blood or sexual fluids. See Section 6 below for additional information regarding contact management.
2. If the case is a dentist, surgeon, or other health care worker, evaluate the potential for exposing patients (see Section 7A).
3. Determine if case has donated blood or plasma in the 6 months prior to onset or any time thereafter. If so, notify the blood bank or plasma center with particulars (date, etc.)
4. If the patient is pregnant, see Section 7E.

E. Environmental Evaluation

Usually none, unless exposure and/or transmission may have occurred in a childcare center, dialysis center, or health care facility by means of environmental surfaces or inanimate objects.

F. Prioritizing Chronic Case Investigations

Local health jurisdictions should review and analyze hepatitis B case reports regularly to identify cases and clusters of hepatitis B that merit further investigation. When resources are limited, these categories should be prioritized for investigation based on the degree of public health importance:

- People of childbearing age who are or have the potential to become pregnant, indicating the potential for perinatal transmission,
- Children ≤ 24 months of age to detect perinatal transmission,
- People in age and demographic groups for whom infection may be acute due to recent transmission, including those ≥ 70 years of age (indicating possible healthcare-associated transmission),
- People who were previously vaccinated to characterize possible vaccine failures,
- People born after 1990 to distinguish between failure of vaccine and failure to vaccinate, or to identify those whose infections may have been acquired recently,
- People receiving hemodialysis with evidence of acute hepatitis B (including those with test conversions),
- People lacking typical behavioral risk behaviors or exposures for hepatitis B (e.g., people who use injection drugs) who have evidence of acute infection to identify other potential causes of HBV transmission,
- People with other indicator(s) of possible acute or recent infection, including those:
    - With elevated ALT or jaundice,
    - With positive anti-HBc IgM,
    - With recent or current injection drug use history,
    - Who were tested at locations frequented by people at high-risk for acute infection (e.g., STI/HIV clinics, syringe service programs, correctional facilities, emergency departments, and medication-assisted treatment for opioid use disorder centers), or
    - Who were in a residential facility or custodial care, including long-term care or correctional facilities, for ≥ 6 months prior to the onset of symptoms.

6. CONTROLLING FURTHER SPREAD

A. Infection Control Recommendations/Case Management

1. Hospitalized patients should be cared for using standard precautions. All health care providers with risk for blood exposure should complete the hepatitis B vaccine series.
2. Residential or childcare restrictions: The risk of transmission of hepatitis B virus in the residential or childcare setting is usually low and can be reduced through sound infection control procedures and environmental cleanliness. Personal items that could be

contaminated with blood or saliva should not be shared. Contaminated objects or surfaces should be cleaned and disinfected as soon as possible. The risk is greatest for an individual with HBeAg-positive chronic infection, open skin lesions, demonstrated aggressive scratching or biting behavior, a bleeding disorder, or manifesting frank breaches of personal hygiene. Immunization is recommended for staff and patients in residential care settings with developmentally disabled patients. The health jurisdiction should carefully evaluate situations involving a childcare facility to determine whether exclusion of the child from child care or vaccination of classroom contacts is indicated.

3. Health care worker restrictions: If the case is a health care worker with potential for exposing patients, see Section 7A.
4. Persons who are HBV DNA-positive or HBsAg-positive should be instructed that their blood and other body fluids (particularly semen or vaginal secretions) are infectious to others and should be educated about ways to reduce the spread of infection.
    - Susceptible household and sexual contacts should be advised to obtain a full hepatitis B vaccination series.
    - Surfaces contaminated with saliva and blood should be cleaned and properly disinfected.
    - Cuts and skin lesions should be kept covered.
    - Infected persons should not share items potentially contaminated with blood with other people (e.g., needles, syringes, drug works, blood glucose testing equipment, razors, toothbrushes). Disposable needles should be used only once. As a last resort, undiluted household bleach can be used to clean syringes and needles. Direct active injection drug users to needle exchange programs and drug rehabilitation services.
    - Infected persons should be educated to practice abstinence, use barrier methods, or otherwise practice "safer" sex with potentially susceptible partners. Susceptible partners should be vaccinated against hepatitis B.
    - Infected persons should not donate blood, plasma, tissue, organs, or semen.
    - Infected pregnant persons and their health care providers should ensure prompt preventive treatment is given to the newborn.
    - HBsAg-positive persons who seek medical or dental care should notify involved personnel of their hepatitis B status.
5. Persons with acute hepatitis B should have a repeat test for HBV DNA or HBsAg six months after the first test to determine the clearance or continued presence of viremia. Those who continue to be HBV DNA-positive or HBsAg-positive are considered confirmed chronic infections and should be counseled accordingly.
6. Persons with chronic hepatitis B or hepatitis D virus infection should be educated to avoid further harm to the liver. Recommendations should include:
    - See a provider with experience managing chronic hepatitis B infections and treatment.

- Ask their provider about use of over-the-counter drugs (e.g., acetaminophen) that can damage the liver.
- Stop behaviors that could result in transmission of hepatitis B or hepatitis D virus.
- Avoid drinking alcohol.
- Get vaccinated against hepatitis A if susceptible.
- Get tested for hepatitis C infection.

7. Pregnant or sexually active women or other persons who could become pregnant should be told about the risk of hepatitis B infection for newborns of infected mothers, and of the importance of prophylaxis for such newborns. If the person is pregnant, see Section 7E.

B. Contact Management

1. Postexposure Prophylaxis

Passive immunization with HBIG and active vaccination with hepatitis B vaccine together can prevent infection in contacts of an acute case or in those newly exposed to a chronic hepatitis case (e.g., needle stick injury in a health care provider or new sexual partner). For greatest effectiveness, give prophylaxis as soon as possible after exposure. Consider the exposed person's prior history of hepatitis B infection, vaccination, and vaccine response status (if known), but treatment should not be unduly delayed while awaiting test results.

Postexposure prophylaxis is appropriate in the following situations:

- Perinatal exposure to HBV DNA-positive or HBsAg-positive mother/birthing person (see Section 7F).
- Non-occupational exposure to an HBV DNA-positive or HBsAg-positive individual through sexual contact or percutaneous/permucosal exposure to blood. For greatest effectiveness, prophylaxis should be given as soon as possible after exposure (preferably within 24 hours). There are no data to indicate that HBIG is of any value more than 7 days after a percutaneous exposure or 14 days after a sexual exposure. See Table 2.
- Occupational exposure to an HBV DNA-positive or HBsAg-positive or potentially infected individual. For greatest effectiveness, prophylaxis should be given as soon as possible after exposure. There are no data to indicate that HBIG is of any value more than 7 days after a percutaneous exposure. See Table 3.
- Household exposure of an infant < 12 months old to a primary care giver with acute hepatitis B.

Table 2: Guidelines for postexposure prophylaxis* of persons with non-occupational exposure to blood or infected body fluids of an HBV DNA or HBsAg-positive individual

Vaccination status of exposed person	Treatment
Unvaccinated	HBIG§ x 1 and initiate HB vaccine

Incomplete vaccine series	HBIG§ x 1 and complete vaccine series
Written documentation of a completed series but antibody response unknown	Single vaccine booster dose

* When indicated, immunoprophylaxis should be initiated as soon as possible, preferably within 24 hours. Studies are limited on the maximum interval after exposure during which postexposure prophylaxis is effective, but the interval is unlikely to exceed 7 days for percutaneous exposures or 14 days for sexual exposures. The hepatitis B vaccine series should be completed once initiated.
§ Hepatitis B immunoglobulin; dose is 0.06 ml/kg administered IM
Adapted from: MMWR 2018;67(No. RR-1):1-31
https://www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm

Table 3: Recommended postexposure prophylaxis for occupational exposure to HBV

Health care personnel status*		**Intervention**	
		Source HBsAg Positive or Unknown	*Source HBsAg Negative*
Unvaccinated or incompletely vaccinated		Conduct baseline HBsAg and anti-HBc testing immediately after exposure and 6 months later. HBIG§ x 1 and initiate or complete HBV vaccine series. Test anti-HBs at 1-2 months after series completion to document vaccine response for future exposures.	Initiate or complete HBV vaccine series Test anti-HBs 1-2 months after series completion to document vaccine response for future exposures.
Vaccinated	Documented non-responder after 6 doses††	HBIG§ x 2 separated by 1 month.	No action needed.
	Antibody response unknown after 3 doses	Test anti-HBs and HBsAg. If anti-HBs ≥ 10mIU/mL no action needed. If < 10mIU/mL HBIG§ x 1 and initiate revaccination. Retest HBsAg and total anti-HBs at 6 months.	Test anti-HBs. If anti-HBs ≥ 10mIU/mL no action needed. If < 10mIU/mL initiate revaccination. Retest anti-HBs 1-2 months after vaccination completed and if still < 10 mIU/mL, HCP should receive two additional doses of HBV vaccine to complete the series. Test for anti-HBs 1-2 months after final dose to document vaccine response for future exposures.
	Documented responder after ≥3 doses**	No action needed.	No action needed.

*Persons documented as previously infected with HBV do not require postexposure prophylaxis.

§ Hepatitis B immunoglobulin; dose is 0.06 ml/kg administered IM.

**Responder: person with adequate levels of antibody to HBsAg (anti-HBs ≥ 10mIU/mL after ≥3 doses).

††Non-responder: person with inadequate response to vaccination (anti-HBs < 10mIU/mL).

§§ The option of giving one doses of HBIG and reinitiating the vaccine series is preferred for non-responders who have not completed a second 3-dose vaccine series. For persons who previously completed a second series but failed to respond, two doses of HBIG are preferred.

Adapted from: MMWR 2018;67 (RR-1):1-31 https://www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm

2. Contacts of Persons with Chronic Hepatitis B

Long-term sexual contacts and persons who have had direct (percutaneous or mucosal) exposure to blood (e.g., needle-sharing partners) should be educated about transmission of hepatitis and tested for HBsAg and HBsAb if they are not known to be immune or infected. Vaccination can be started when testing is initiated if the contact is unlikely to return for results. If susceptible, the contact should complete the hepatitis B vaccine series and if susceptible the hepatitis A vaccine series. Contacts found to be HBsAg-positive should be evaluated as cases.

Active injection drug users should be directed to needle exchange programs and drug rehabilitation services.

C. Environmental Measures

Ensure that surfaces and objects contaminated with blood are properly disinfected using gloves and appropriate disinfectant solutions.

7. MANAGING SPECIAL SITUATIONS

A. Needle sticks and Similar Exposures

The risk of hepatitis B virus (HBV) transmission following unintentional parenteral exposure is 6-20%. See Section 6B for post-exposure prophylaxis. For occupational exposures to HIV, viral hepatitis, and other bloodborne pathogens, the National Clinicians Post-Exposure Prophylaxis Hotline (PEPline) operated by the University of California, San Francisco is available for consultation seven days a week: https://nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis/.

Centers for Disease Control and Prevention maintains resources for post-exposure prophylaxis: https://www.cdc.gov/nora/councils/hcsa/stopsticks/whattodo.html

B. Case is a Health Care Worker

Chronic HBV infection itself should not preclude the practice or study of medicine, surgery, dentistry, or allied health professions. If the case is a dentist, physician, nurse, or other health care worker with potential for exposing patients by blood or other body fluids:

1. If the person has acute illness, the person should be discouraged from working until the acute clinical illness has resolved.
2. Standard precautions and fundamental infection-control principles should be adhered to rigorously in all health care settings for the protection of both patient and provider, regardless of HBV status, including safe injection practices and appropriate aseptic techniques.

3. Employees should receive annual education on standard precautions to include hand hygiene, glove use, sharp safety and injection safety.
4. Chronically infected health care workers, particularly those who are HBeAg-positive or who have HBV levels 1,000 IU/mL or higher, should be encouraged to voluntarily seek confidential counseling from employee health services/occupational health regarding risk reduction strategies if they perform exposure-prone procedures (e.g., gynecologic, cardiothoracic surgery).
5. Hospitals, medical and dental schools, and other institutions should have written policies and procedures for the identification and management of HBV-infected health care providers, students and school applicants. These policies should include relevant guidelines and recommendations before considering the management of HBV-infected providers performing exposure-prone procedures. See: https://www.cdc.gov/hepatitis/populations/healthcaresettings.htm and https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6103a1.htm

C. Case is a Suspected Iatrogenic or Healthcare-Associated Infection

If a possible iatrogenic case occur in a patient, and the case has no other identified plausible source of infection, or other circumstances suggesting the possibility of iatrogenic infection, notify Communicable Disease Epidemiology at 206-418-5500. If available, hold frozen serum or EDTA tube (at -70º C) on the cases for potential future laboratory work. Centers for Disease Control and Prevention (CDC) have a patient notification toolkit: https://www.cdc.gov/healthcare-associated-infections/hcp/patient-notification-toolkit/?CDC_AAref_Val=https://www.cdc.gov/injectionsafety/pntoolkit/index.html. If one case underwent a medical or dental procedure and has no other identified plausible source of infection, contact the dental or health care provider and review infection control procedures. Consider storing serum or EDTA tube (if available) at -70º C for genotyping in the event an additional case is identified with a potential shared exposure. Contact the WA DOH viral hepatitis team for instructions at hepatitis@doh.wa.gov. There are CDC resources available to investigate a single case of suspected iatrogenic infection:

- http://www.cdc.gov/hepatitis/Outbreaks/HealthcareInvestigationGuide.htm
- http://www.cdc.gov/hepatitis/Outbreaks/HealthcareInvestigationCheckList.htm
- http://www.cdc.gov/hepatitis/Outbreaks/index.htm (main page)

G. Case Is a Recent Blood Donor or Recipient

The blood bank should be notified so that any unused product can be recalled and other persons be tested as appropriate (e.g., other recipient or donor for case).

H. Testing Pregnant Persons for Hepatitis B

All pregnant persons should be tested during each pregnancy for HBsAg. It is particularly important to screen pregnant persons born in high prevalence regions and those who were birthed by persons born in such regions (e.g., Africa, Southeast Asia including China, most of the Middle East, South and Western Pacific islands, the interior Amazon River basin, and certain parts of the Caribbean). High-risk persons who are HBsAg negative early in pregnancy should be retested late in pregnancy so that results are available at the

time of delivery. Those who test positive for HBsAg should have a complete hepatitis panel, receive education about hepatitis B, and be enrolled in the Perinatal Hepatitis B Prevention Program.

I. Perinatal Hepatitis B Prevention Program (PHBPP)

Health care providers are required to report each pregnancy in a person with hepatitis B to her local health jurisdiction (LHJ) of residence. Every LHJ in Washington should have a Perinatal Hepatitis B Prevention Program (PHBPP) coordinator or have identified a designee to follow up on such reports to assure that the person is enrolled in the PHBPP which is focused on preventing the spread of hepatitis B virus from infected mothers/birthing persons to newborns.

The goal of a PHBPP is to reduce the incidence of hepatitis B in infants by establishing an effective follow-up system to assure that each infant born to a person infected with hepatitis B receives appropriate post-exposure prophylaxis. Information about this program can be found at https://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/PublicHealthSystemResourcesandServices/Immunization/PerinatalHepatitisBPreventionProgram.

Women or other pregnant persons that have tested positive for HBV DNA or HBsAg should be enrolled in the program during each pregnancy. The LHJ PHBPP Coordinator should follow up to assure that hepatitis B immunoglobulin (HBIG) and vaccine doses have been given to an infant on a timely basis, that the remaining recommended doses are received and that post-testing for the infant is done. PHBPP guidance for local coordinators (including information on the management of premature infants) is available in the DOH PHBPP Program Manual which can be found at: Perinatal Hepatitis B Prevention Program Guidelines. It can also be obtained by contacting the DOH Office of Communicable Disease Epidemiology at 206-418-5500.

The key steps of the program are briefly summarized below:

1. Maternal hepatitis B surface antigen testing recommendations:

   All pregnant persons should be tested for HBsAg once during each pregnancy and upon admittance for delivery.

2. Report and track HBsAg-positive pregnant persons:

   All pregnant persons that are infected with hepatitis B must be reported to the local perinatal hepatitis B prevention program.

3. **Treat Infants at Birth with HBIG and Hepatitis B Vaccine**

   As soon as possible, but always within 12 hours of birth, infants born to mothers/birthing persons infected with hepatitis B (including preterm and low birth weight infants) should be given hepatitis B immune globulin (HBIG) (0.5 ml IM) and, like all other newborns, the first dose of hepatitis B vaccine (0.5 ml IM). HBIG and vaccine can be given simultaneously, but should be given at different body sites.

4. Complete Hepatitis B Vaccine Series

Full-term infants should receive the second and third vaccine doses at ages one to two months and six months. The local health jurisdiction should encourage providers to adhere to this schedule to the extent possible. In addition to receiving the vaccine dose they received at birth, infants with a birth weight <2 kg should receive a full three-dose hepatitis B vaccination series initiated at age one month (i.e. they should receive a total of four vaccine doses).

5. Test Infants

Perinatally-exposed infants should be tested for both anti-HBs and HBsAg 1-2 months following the final dose of vaccine in the series (usually at ~9-12 months of age).

- The local PHBPP coordinator should also notify the DOH PHBPP coordinator of all PHBPP post-immunization serologic test results through WDRS.
- The presence of anti-HBs indicates immunity to hepatitis B.
- Hepatitis B-immunized children who do not show serologic evidence of immunity after the initial series should repeat the three-dose series.
- Children who fail to respond to the receipt of six doses of vaccine and test positive for HBsAg should be reported to DOH Communicable Disease Epidemiology as perinatal hepatitis B cases.
- An HBsAg+ test result obtained on any child under age 2 years whose mother/birthing person was not enrolled in the PHBPP should be reported to the DOH Communicable Disease Epidemiology as a suspected case of perinatal hepatitis B.
- Perinatal hepatitis B is a nationally notifiable condition and will be reported to CDC.

A DOH PHBPP Coordinator is available to work with LHJ PHBPP Coordinators to support patient education and the use WDRS for case enrollment and management. The DOH PHBPP Coordinator can be reached by email at phbpp@doh.wa.gov or phone at the DOH CDE main phone number (206-418-5500).

8. ROUTINE PREVENTION

A. Immunization Recommendations

Hepatitis B vaccination is recommended for all infants and children ages 0–18 years old not previously vaccinated or infected. For infants the usual vaccine schedule includes a series of three vaccine doses administered at birth, 1–2 months, and 6–18 months.

The Advisory Committee on Immunization Practices (ACIP) also recommends that all adults aged 19-59 years and adults aged 60 years and older with risk factors for hepatitis B should receive hepatitis B vaccine. Adults aged 60 years and older without known risk factors for hepatitis B may receive hepatitis B vaccine. Risk factors for hepatitis B include:

- Persons at risk for infection by sexual exposure:

  - Sex partners of persons who test positive for hepatitis B surface antigen (HBsAg)
  - Sexually active persons who are not in a long-term, mutually monogamous relationship (e.g., persons with more than one sex partner during the previous 6 months)
  - Persons seeking evaluation or treatment for a sexually transmitted infection
  - Men who have sex with men.
- Persons at risk for infection by percutaneous or mucosal exposure to blood:
  - Persons with current or recent injection use
  - Household contacts of persons who test positive for HBsAg
  - Residents and staff of facilities for persons with developmental disabilities
  - Health care and public safety personnel with reasonable anticipated risk for exposure to blood or blood-contaminated body fluids
  - Persons on maintenance dialysis, including in-center or home hemodialysis and peritoneal dialysis, and persons who are predialysis
  - Persons 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%)
  - Persons with hepatitis C infection
  - Persons with chronic liver disease (including, but not limited to, persons with cirrhosis, fatty liver disease, autoimmune hepatitis, or an alanine aminotransferase [ALT] or aspartate aminotransferase [AST] level greater than twice the upper limit of normal)
  - Persons with HIV infection
  - Incarcerated persons

Some of these groups should also receive hepatitis A vaccine routinely. For additional information regarding vaccine scheduling, dosing, contraindications, and testing for seroconversion, please see:

Centers for Disease Control and Prevention. Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices. MMWR 2022; 71(13):477-483. Available at: https://www.cdc.gov/mmwr/volumes/71/wr/mm7113a1.htm

Centers for Disease Control and Prevention. Recommendations of the Advisory Committee on Immunization Practices for Use of a Hepatitis B Vaccine with a Novel Adjuvant. MMWR 2018; 67(15):455–458. Available at https://www.cdc.gov/mmwr/volumes/67/wr/mm6715a5.htm

B. Routine Prevention (https://www.cdc.gov/hepatitis-b/hcp/vaccine-administration/index.html#:~:text=The%20Advisory%20Committee%20on%20Immunization,identified%20risk%20factors%20but%20seeking)

Provide the following information to persons at risk of infection:

- Hepatitis B vaccine is the best protection.
- If you are having sex, but not with one steady partner, use barrier methods correctly and every time you have sex. The efficacy of barrier methods in preventing infection with hepatitis B virus is unknown, but their proper use might reduce transmission.
- If you are pregnant, you should get a blood test for hepatitis B infection. Infants born to hepatitis B-infected mothers/birthing persons should be given HBIG (hepatitis B immune globulin) and vaccine within 12 hours after birth.
- People who inject drugs should be directed to syringe service programs and offered referrals to substance use treatment programs. Washington State Department of Health provides a list of sites offering harm reduction services in Washington State (https://doh.wa.gov/you-and-your-family/drug-user-health/syringe-service-programs/syringe-service-program-directory). Information for sites providing substance use treatment can be found here (https://www.warecoveryhelpline.org/). People living with HBV should not share needles, syringes, or other injection-related equipment with other people. Information for persons who inject drugs (PWID) without access to sterile needles and syringes may be found at the following link: https://www.cdc.gov/hiv/pdf/risk/cdc-hiv-injection-drug-use.pdf. Do not share personal care items that might have blood on them (e.g., razors, toothbrushes, home medical devices such as blood sugar testing devices).
- Consider the risks if you are thinking about getting a tattoo or body piercing. You might get infected if the tools have someone else's blood on them or if the artist or piercer does not follow good infection control practices.
- If you have or had hepatitis B, do not donate blood, organs, or tissue.
- If you are a health care or public safety worker, get vaccinated against hepatitis B, and always follow routine barrier precautions and safely handle needles and other sharps.

C. Persons Recommended to Receive Serologic Testing for Hepatitis B

Many persons with chronic HBV infection are unaware of their infection and therefore will not receive education for routine prevention. HBV testing should be offered to:

- Pregnant persons.
- Infants born to HBsAg-positive mothers/birthing persons.
- Household, sexual, or need contacts of hepatitis B surface antigen positive persons.
- Persons who are the source of blood or body fluid exposures that might warrant postexposure prophylaxis (e.g., needlestick injury to a health care worker).
- HIV-positive persons.
- Persons with elevated ALT/AST of unknown etiology.
- Hemodialysis patients.
- Men who have sex with men.
- Past or current persons who inject drugs.

- Persons born in countries of high and intermediate HBV endemicity (HBsAg prevalence of ≥2%).
- US-born persons not vaccinated as infants whose parents were born in countries with high HBV endemicity (≥8%).
- Persons needing immunosuppressive therapy, including chemotherapy, immunosuppression related to organ transplantation, and immunosuppression for rheumatologic or gastroenterologic disorders.
- Donors of blood, plasma, organs, tissues, or semen.

For specifics see: https://www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm

ACKNOWLEDGEMENTS

This document is a revision of the Washington State Guidelines for Notifiable Condition Reporting and Surveillance published in 2002 which were originally based on the Control of Communicable Diseases Manual (CCDM), 17th Edition; James Chin, Ed. APHA 2000. We would like to acknowledge the Oregon Department of Human Services for developing the format and select content of this document.

UPDATES

January 2011:
The Legal Reporting Requirements section has been revised to reflect the 2011 Notifiable Conditions Rule revision. Criteria were specified for prioritizing investigations of cases likely to be new diagnoses (Section 5).

February 2012:
In Section 3 case definition updated with the required aminotransferase level going from 200 to 100 IU/L. Laboratory criteria include any hepatitis B virus nucleic acid testing including genotype. Documented asymptomatic seroconversion is a confirmed case.
In Section 8, routine vaccination is now recommended for adults with diabetes under 60 years of age.

May 2014: Chronic hepatitis investigations transitioned to sampling framework for enhanced surveillance.

August 2016: Front page added, minor wording changes.

February 2017: Perinatal hepatitis B case definition updated.

April 2018: Perinatal hepatitis B case definition updated. WDRS language updated. References to enhanced surveillance follow-up framework removed.

December 2022:

- Added clarifying language throughout. For Perinatal Hepatitis B Prevention Program activities, changed responsible office within WADOH to OCDE from Office of Immunization. Where indicated, updated surveillance data to reflect recent reporting from the last decade. Reference links were updated and are all now current.
- Updated Section 1B with new reporting requirements per changes to WAC 246-101 effective January 1, 2023. Specifically, health care providers, laboratories, and health care facilities must report pregnancy status for patients 12-50 years of age with acute and chronic hepatitis B reports. Additionally, when available and when associated with a positive HBsAg, HBeAg, and/or HBV DNA, laboratories must report hepatocelluclar enzyme levels, pregnancy status, and negative IgM anti-HBc results. Reporting timelines also changed: chronic hepatitis B changed from notifiable by health care providers and facilities to public health within three days (previously one month) and by laboratories to public health to within 24 hours (previously monthly), including reports in pregnancy. Clarified local health jurisdiction reporting requirements are to occur via WDRS or the Perinatal Hepatitis B Prevention Program module (for case management activities in pregnant chronic carriers).
- Updated Section 4A with new hepatitis B test result interpretation table to include additional scenarios.

- Updated Section 5A with clarification of the use of WDRS for ongoing reports of hepatitis B-positive labs in a person previously reported as a chronic infection, and the use of multiple sub-types of hepatitis B (i.e., a person can have an acute infection and a chronic infection reported within the same event). Added detail in Section 5B for specific investigation guidance related to suspected healthcare-acquired infections as well as additional risk factors to explore with a case (sharing of personal care items and birth outside of the United States, or birth to a mother with a history of hepatitis B). Added detail on hepatitis B reactivation, including who is most at risk and clarified surveillance activities related to the reporting of reactivation cases. Section 5E, Prioritizing Chronic Case Investigations, is new and intended to help local health jurisdictions with limited resources prioritize chronic hepatitis B case investigations.
- Table 3 within Section 6B was updated to include clarification for testing and prophylaxis requirements within different scenarios.
- Contact information for the National Clinicians Post-Exposure Prophylaxis Hotline was added to Section 7A. Section 7B was re-written to reflect the most recent CDC guidance related to health care workers living with hepatitis B infection. Guidance for suspected health care exposure was changed in Section 7C to recommend initiation of investigation at one suspected case (instead of two or more), and new resources were added.
- Immunization recommendations in Section 8A were updated to reflect recent universal vaccine recommendations put forth by the American Committee on Immunization Practices (ACIP). Language in Section 8B was revised to encourage access to syringe service programs and substance abuse disorder treatment for persons who inject drugs.

May 2024:

- Updated case classification criteria for acute and chronic hepatitis B cases to align with CDC's 2024 case definitions.
- Updated language throughout to clarify that perinatal hepatitis B refers to the transmission of hepatitis B virus from a birthing person to an infant regardless of that person's gender or their status as a parent (e.g., changed "pregnant women" to "pregnant persons" and "mothers" to "mothers/birthing persons.")
- Updated references to the Perinatal Hepatitis B Prevention Program (PHBPP) module to indicate that these data are now housed within the Washington Disease Reporting System (WDRS).
- Updated data in section 2C: "Hepatitis B in Washington."
- Updated links to CDC webpages that have new addresses

Contact: Hepatitis B Surveillance Program, Office of Communicable Disease Epidemiology, Washington State Department of Health (DOH), 206-418-5500 | Hepatitis@doh.wa.gov

Note: The DOH Hepatitis B team acknowledges that there is language in this document that is gendered (e.g., "maternal antibodies") for the purposes of clinical accuracy. Whenever possible, we use gender neutral language to affirm the fact people of all genders have the capacity for pregnancy and birth.

Appendix A: Hepatitis B Reporting Requirements

HEPATITIS B
REPORTING REQUIREMENTS
Washington State

	Health Care Providers	Health Care Facilities	Laboratories
	Report to Local Health Jurisdiction	**Report to Local Health Jurisdiction**	**Report to Local Health Jurisdiction**
Acute	Within 24 hours	Within 24 hours	Within 24 hours
Pregnancy in HBV surface antigen + persons, ***each*** pregnancy	Within 3 working days	Within 3 working days	Within 24 hours
Perinatal Hepatitis B *	Within 3 working days	Within 3 working days	Within 24 hours
Chronic	Within 3 working days	Within 3 working days	Within 24 hours

* Perinatal Hepatitis B is defined as a child:
1) ≤ 24 months of age
2) born to a hepatitis B surface antigen positive (HBsAg+) or HBV DNA positive mother/birthing person
3) testing positive for HBsAg
Most perinatal cases have no symptoms.

Appendix B: Glossary of Terms

ALT: Alanine aminotransferase (usually abbreviated as ALT or SGOT) is a liver enzyme and is particularly sensitive for assessing liver damage secondary to HCV. The acute hepatitis A, B, and C case definitions require an elevation in ALT to over 200 IU/L.

AST: Aspartate aminotransferase (usually abbreviated as AST or SGPT). Another liver enzyme useful for evaluating liver damage.

Hepatitis A Testing

IgM anti-HAV: IgM antibody to HAV. Indicates acute infection with HAV.

Anti-HAV total: combined antibody to HAV including IgM with acute infection and IgG with long term protection.

Hepatitis B Testing

HBsAg: hepatitis B surface antigen, a marker of replicating virus. It occurs as part of acute infection and persists in chronic infection. Its presence indicates that the patient is considered to be infectious.

Anti-HBs: hepatitis B surface antibody. It demonstrates immunity through infection or vaccination.

IgM Anti-HBc: IgM antibody to hepatitis B core antigen, indicative of recent infection with hepatitis B virus. Antibody to core antigen only occurs following infection, not immunization.

Anti-HBc: total antibody to hepatitis B core antigen. This marker becomes positive at the onset of symptoms in acute hepatitis B then persists for life. Therefore, it does not distinguish between recent, past, or chronic infection.

HBeAg: hepatitis B e antigen, a core protein exported from infected liver cells and a marker of high levels of infectivity. Similar to HBsAg, it occurs (albeit transiently) as part of acute infection and may persist in chronic infections.

HBeAb: hepatitis B e antibody is produced by the immune system temporarily during acute HBV infection and may persist in chronic infections. Spontaneous conversion from e antigen to e antibody is a predictor of long-term clearance of HBV in patients undergoing antiviral therapy and indicates lower levels of HBV. Chronic hepatitis B surface antigen carriers can be positive for either HBeAg or anti-HBe, but are less infectious when anti-HBe is present.

Hepatitis B virus DNA: signifies active replication of the virus and indicates that the patient is infectious. It is usually measured to test for chronic infection, and the viral load may be used to decide whether treatment is warranted.

Hepatitis C

Anti-HCV EIA: enzyme immunoassay to measure hepatitis C virus (HCV) antibody. Indicates presence of antibody only and cannot be used to distinguish between recent and past infection. Additional testing is required to determine if the individual is chronically infected.

Signal-cutoff ratio: can be used to help determine the likelihood that a positive anti-HCV EIA represents a true positive. Each assay has a cut-off value that is considered a “positive” result; the signal-cutoff ratio can be calculated by dividing the optical density (OD) value of the sample being tested (e.g., the client’s test result) by that particular assay’s cut-off value. Each test kit or

assay has a signal-cutoff ratio above which the client has a 95% probability of being HCV-positive and should be reported as a case.

PCR: polymerase chain reaction, used to measure HCV RNA and indicates active replication of the virus (e.g., the chronic infection state). The qualitative PCR is more sensitive than the quantitative assay and is preferred for the initial test. The quantitative PCR is often used to guide initial treatment decisions and to follow the progress of individuals undergoing treatment.

HCV genotype: HCV can be divided into at least 6 different genotypes. Genotype 1 is the most common in the United States, accounting for 70–75% of infections. A positive genotype indicates the presence of HCV RNA.