

# **Chronic Hepatitis B**

# Investigative Guidelines August 2024

**REPORT WITHIN 1 WORKING DAY** 

#### 1. DISEASE REPORTING

#### 1.1 Purpose of Reporting and Surveillance

- 1. To assess the risk of transmission of infection to additional persons, and to prevent such transmission
- 2. To educate people about how to reduce their risk of infection
- 3. To identify additional cases
- 4. To characterize the epidemiology of this infection including social, environmental, and behavioral contexts for transmission
- 5. To identify communities and populations at elevated risk for disease or severe illness and inform equity-centered outreach, in support of OHA's strategic goal of eliminating health inequities in Oregon by 2030

### 1.2 Laboratory and Clinician Reporting Requirements

Laboratories, physicians, and other persons providing health care are required to report cases to the Local Health Department (LHD) within one working day following identification or diagnosis. All positive tests indicative of and specific for chronic hepatitis B must be reported by licensed laboratories within one working day.

#### 1.3 Local Health Department Reporting and Follow-Up Responsibilities

- 1. Report all confirmed and presumptive cases (see definitions below) to the Oregon Public Health Division (PHD) Acute and Communicable Disease Prevention (ACDP) Section as soon as possible, but no later than the end of the working day following the initial physician/lab report. All persons testing positive for hepatitis B must be reported and investigated; see §4.4 if case has been previously reported. ACDP staff can search for reports back through 1988. See §3 for case definitions.
- 2. Begin follow-up investigation within one working day. Submit all case data electronically within fourteen days of initial report.
- 3. Recommend prophylaxis if indicated (e.g., hepatitis B immune globulin [HBIG] or vaccine) to contacts of confirmed and presumptive cases.

- 4. At time of initial report, and **upon receipt of new lab results for previously investigated cases**, verify the pregnancy status of confirmed and presumptive cases who are between the ages of 15 44 and have the potential for pregnancy (e.g., have a uterus, have not experienced menopause).
- 5. Confirmed and presumptive cases who are pregnant must be enrolled with each pregnancy into the Oregon Perinatal Hepatitis B Prevention Program (PHBPP). The case should be enrolled in the PHBPP within one calendar week of receiving the laboratory report. This includes creating a record of the pregnancy in the electronic communicable disease database (i.e., Orpheus).

#### 2. THE DISEASE AND ITS EPIDEMIOLOGY

#### 2.1 Etiologic Agent

Hepatitis B virus (HBV) is a hepadnavirus that is one of several viruses known to cause hepatitis (liver inflammation) in humans. Until the 1970s, laboratory tests were not available to distinguish among these clinically similar infections, but HBV is now known to be completely unrelated to other viruses that cause hepatitis (HAV, HCV, HEV).

#### 2.2 Description of Illness

Exposure to HBV may result in transient or chronic infections, either of which can be asymptomatic. Onset is usually insidious (comes on slowly) with loss of appetite, vague abdominal discomfort, nausea, vomiting, and sometimes arthralgia (joint pain) and skin rash, often progressing to jaundice. Liver enzyme levels are markedly elevated. Fever may be absent or mild. Although often more severe, hepatitis B cannot be reliably distinguished clinically from other viral hepatitis. Asymptomatic infections are common among children and adults; less than 10% of children and 30-50% of adults show symptoms.

Chronic carriers are at greatly increased risk of developing life-threatening sequelae (e.g., chronic active hepatitis, cirrhosis, or hepatic cancer) decades later. Fewer than 5% of acutely infected adults in the US become chronic carriers, compared with one third of children who are infected before age 6.(1) Among chronic carriers, 25% develop liver cancer.(2)

People with HBV are also vulnerable to the "satellite infection" hepatitis D (HDV), or delta hepatitis, which can present in either acute or chronic manifestation. Superinfection, where a person who already has HBV contracts HDV is even more dangerous than coinfection (becoming infected with HBV and HDV simultaneously). More information about HDV is available from the CDC: https://www.cdc.gov/hepatitis/hdv/index.htm

#### 2.3 Reservoirs

Infected humans are the reservoir for HBV. While relatively few infected persons become chronic carriers, they are probably the most important sources of HBV transmission, because they are infectious indefinitely rather than a few weeks. Efforts to identify chronic carriers and to offer prophylaxis to their contacts, therefore, is at least as important as follow-up directed towards acute cases.

# 2.4 Serologic Markers

Serologic markers of HBV infection are identified by antigen and antibody assays and by nucleic acid amplification test (NAAT) for HBV DNA (i.e., PCR testing). The markers most tested for are shown in Table 1.

**Table 1.** Serological Markers of Hepatitis B

Marker	Abbreviations	Significance/interpretation
Surface antigen	HBsAg	Marker of infectivity. Persists indefinitely in chronic carriers.
Surface antibody	anti-HBs	Usually indicates the development of immunity, either from past infection or immunization. Most carriers never develop anti-HBs (but if they do, they remain HBsAg positive as well). Anti-HBs levels may decline to undetectable levels over time (years), especially if their presence is the result of from immunization and not infection.
Viral DNA	HBV DNA/ HBV NAAT	Marker of infectivity. Rises to high concentrations during incubation and falls with the onset of hepatic disease in transient infection. Detectable in about 50% of chronic carriers, can be present when HBsAg is undetectable.
Core antibody (total)	anti-HBc total anti-HBc core anti-HBc	Marker of past infection. Generally, remains elevated for at least two years after transient infection and may remain elevated for life. Vaccination does not produce anti-HBc.
Core antibody (IgM)	lgM anti-HBc	Marker of infection in the recent past (usually <6 months).
e antigen	HBeAg	Marker of enhanced infectivity. Seen transiently in most infections and persists in some carriers indefinitely. Needlestick exposure data suggest that HBeAg-positive individuals are 3-5 times more infectious than HBeAg-negative counterparts.(3)
e antibody	HBeAb	Antibody to HBeAg

The appearance of these markers relative to exposure and subsequent illness in typical infections is illustrated in Figure 1. Occasionally, in the later stages of clinical illness, a person will have neither HBsAg nor anti-HBs detectable in the blood. They

may still be infectious, however, for 1-2 weeks. During this so-called "window phase," the only positive serological test may be for core antibodies (total anti-HBc and IgM anti-HBc).

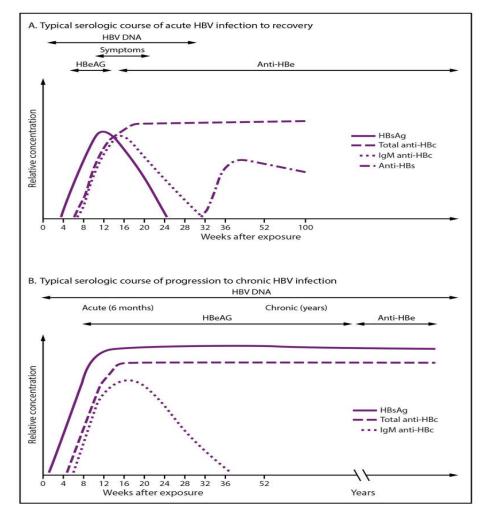


Figure 1. Appearance of Serologic Markers in HBV Cases (Acute and Chronic)

*Note*. Figure reproduced from Conners EE, Panagiotakopoulos L, Hofmeister MG, et al. Screening and testing for hepatitis B virus infection: CDC Recommendations - United States, 2023. *MMWR Recomm Rep.* 2023;72(1):1-25.

People are most commonly identified as chronic HBV carriers based on their HBsAg or HBV DNA test results. Many infections are asymptomatic, including the great majority of persons infected at an early age. A surprisingly high proportion of people have been exposed to hepatitis B, many of them without ever being sick or diagnosed, much less reported.

#### 2.5 Sources and Routes of Transmission

HBV is usually transmitted by contact with the blood, semen, or vaginal secretions of an infected person. Because of the high concentration of virus in blood, an extremely small inoculum is sufficient to transmit infection. The virus must be introduced through broken skin or come into contact with mucous membranes for infection to occur. While HBV may also be found in saliva and other body fluids, HBV is <u>not</u> transmitted via saliva. Breastfeeding is also not a significant route of transmission. HBV can remain viable on environmental surfaces for up to a week (e.g., in dried blood).

The most common modes of transmission include:

- 1. Anal, vaginal, or oral sexual contact among people of any genders, particularly without the use of barrier methods.(4)
- 2. Sharing of contaminated objects or using contaminated equipment that may penetrate the skin. This could include hypodermic needles and other injection paraphernalia, razor blades, renal dialysis equipment, blood glucose monitoring equipment, and multiuse medication vials.
- 3. Perinatal transmission from an infected person to their child during pregnancy or childbirth—see OHA Investigative Guidelines for perinatal transmission at <a href="https://www.oregon.gov/oha/PH/DISEASESCONDITIONS/COMMUNICABLEDISEASE/REPORTINGCOMMUNICABLEDISEASE/REPORTINGGUIDELINES/Documents/hepbperi.pdf">https://www.oregon.gov/oha/PH/DISEASESCONDITIONS/COMMUNICABLEDISEASE/REPORTINGGUIDELINES/Documents/hepbperi.pdf</a>
- 4. Needlestick or similar accidental injury.

The following routes of transmission are less common, but have been documented in the literature:

- Transfusion, infusion or inoculation of blood or blood products from an infected person or plasma pool (in the US, however, all blood is routinely screened for HBV markers [HBsAg, HBV DNA and anti-HBc] before use, so this risk is now extremely low).
- 2. Contact of infective fluid with a mucosal surface (e.g., a splash of blood to the mouth or eye).
- 3. Contact of lacerated, scratched, or otherwise broken skin with blood or contaminated environmental surfaces (e.g., countertops, blood-smear slides or specimen tubes in laboratories).
- 4. Biting by an infected person or scratching with saliva-contaminated nails leading to percutaneous introduction of virus to another person.

### 2.6 Risk Dynamics

Any person can be infected with hepatitis B. However, people at certain life stages, with certain pre-existing conditions or who engage in certain behaviors may be at greater risk of infection, severe disease or prolonged status as a carrier of HBV. This includes living and working conditions that put people at risk of being exposed to bodily fluids. People's living and working conditions are often associated with their socioeconomic status, race, gender, sexuality and disability.

Groups of people who are especially vulnerable to HBV - either infection or more severe disease post-infection - include:

- People with a history of sexually transmitted infections or multiple sex partners
- People with hepatitis C infection or a history of hepatitis C virus infection
- People incarcerated or formerly incarcerated in a jail, prison, or other detention setting
- Correctional workers
- Infants birthed by HBsAg-positive people
- People born in regions with HBV infection prevalence of ≥2%
- US-born people not vaccinated as infants whose parents were born in geographic regions with HBsAg prevalence of >8%
- People who have ever injected drugs
- People with HIV infection
- Men who have ever had sex with men because of elevated HIV and hepatitis C prevalence in this group, they are considered vulnerable to HBV infection despite little evidence of elevated HBV prevalence (5)
- Household contact or former household contacts of people with known HBV infection
- Needle-sharing or sexual contacts of people with known HBV infection
- People on maintenance dialysis, including in-center or home hemodialysis and peritoneal dialysis
- People with elevated liver enzymes
- Refugees, asylum-seekers and internally displaced people (6) who have lived in in low- and middle-income countries

HBV transmission patterns and the prevalence of chronic HBV infection vary worldwide. In 2020, approximately 45% of the world's population lived in regions of high HBV endemicity (i.e., where prevalence of chronic HBV infection is >8%), and 43% lived in areas of intermediate endemicity (where prevalence of chronic HBV infection is 2%-8%).(7) Regions of high or intermediate prevalence include much of Eastern Europe, Asia, Africa, the Middle East, and the Pacific Islands (see Figure 2).

Within and across national borders, Indigenous peoples have historically had elevated rates of HBV.(8,9) There are political and economic causes for these differences, and some communities - such as Inuit and Alaska Native villages - have seen decreases after vaccination and other prevention programs. Similarly, minoritized people are disproportionately affected, such as ethnic minorities in China.(10)

It is difficult to find recent, high-quality estimates of HBV prevalence for Indigenous, Pacific Islander and Alaska Native people. A study conducted with people who received care through the Veterans Administration system in 2002 – 2003 found much higher prevalence in these groups than in the general veteran population, which was estimated to have 13.6% prevalence - an elevated prevalence compared to the US

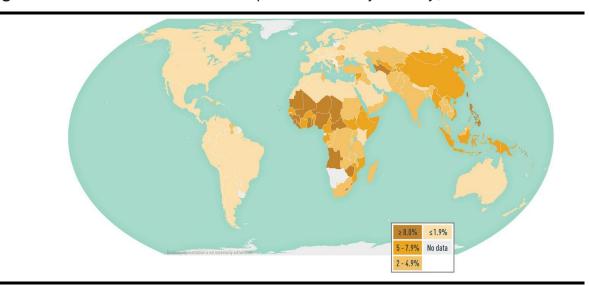


Figure 2. Estimated Prevalence of Hepatitis B Virus by Country, 2021

Note. Map reproduced from Harris, Aaron M. Hepatitis B. In: CDC Yellow Book 2024. Oxford University Press; 2023. Accessed September 19, 2023.

https://wwwnc.cdc.gov/travel/yellowbook/2024/infections-diseases/hepatitis-b

overall. All of the estimates had a large confidence interval (a measure similar to margin of error), so the following estimates should be interpreted with caution: 24.2% among Asian/Pacific Islander people and 46.8% for American Indian and Alaska Native people.(11) The state of Hawaii, which has high proportions of residents from kānaka maoli (Native Hawaiian) and Asian and Pacific Islander backgrounds - both US-born and immigrant - experiences a very high burden of hepatitis B and related mortality.(12)

In Oregon, the risks of household, perinatal, and sexual transmission may be elevated among people who have immigrated from, travel to or have social connections with people from areas of higher prevalence. People who have lived or spent time in low-resource environments of high endemicity may encounter another layer of elevated risk, due to potential exposures such as re-use of medical equipment or lack of adequate sanitization equipment in low-resource communities.

In endemic areas, transmission usually occurs during infancy, often leading to chronic infection. A meta-analysis of childhood HBV prevalence in West Africa, a high-endemicity region, showed that prevalence was related to HIV prevalence as well as the gestational parent's HBV status.(13) By contrast, new acute HBV cases in the US are generally among adults and resolve before turning into chronic disease. Another demographic trend is rising anti-HBc prevalence in 60–69-year-olds, presumably linked to transmission during the 1960s–1980s when HBV vaccines were not available and universal precautions had not yet been employed in the blood banking system.(14) Much of these data on US prevalence come from the NHANES study, which must be interpreted with caution. NHANES excludes persons experiencing homeless, incarcerated, hospitalized, nursing home residents, active-duty military and Native Americans living on reservations; furthermore, large proportions of participants

declined to answer questions about behaviors associated with HBV risk.(14) There are many ways to quantify the impact of HBV on communities, and Table 2 presents a variety of measures for understanding differences among populations.

Table 2. Hepatitis B surface antigen (HBsAg) prevalence among different populations

	HBsAg (active, infectious HBV)
Living conditions	•
Incarcerated persons(15)	0.9–11.4
People experiencing homelessness(16)	0.4–1.2
Health status	
People living with HIV(17)	2
Occupation	
Healthcare professionals(16)	0.1–8.1
Veterans(16)	0.3–0.8
Place of birth	
US-born(18)	0.1
Non-US born(18)	1.2
Behavior	
Ever an illicit drug user(18)	0.4
Men who have sex with men(19)	1–3
People who inject drugs (N. America)(20)	4.5
Race/ethnicity	
Asian non-Hispanic(18)	2.6
Black/African American non-Hispanic(18)	0.5
Indigenous populations of the circumpolar Arctic prior to vaccine introduction (includes non-US areas)(8)	2

#### 2.7 Incubation Period

The incubation period varies from 45 to 180 days, but is usually between 60–90 days.

#### 2.8 Period of Communicability

A person is infectious if HBsAg, HBeAg, or HBV DNA is detectable in the blood. Viremia begins several weeks before the onset of symptoms and persists for several months (in most instances) or, for those who become chronic carriers, indefinitely. A similar period of viremia occurs among asymptomatically infected individuals.

#### 2.9 Treatment

Supportive only during the acute phase. Persons who progress to chronic HBV infection need medical management to monitor the onset and progression of liver disease, assess need for treatment and screen for liver cancer.

#### 3. CASE DEFINITIONS, DIAGNOSIS, AND LABORATORY SERVICES

#### 3.1 Confirmed Case Definition

An individual with **at least one** of the following test result options:

- Detection of HBsAg<sup>†</sup> in two clinical specimens taken ≥ 6 months apart
- Detection of HBeAg in two clinical specimens taken ≥ 6 months apart
- Detection of HBsAg<sup>†</sup> OR HBeAg AND total anti-HBc
- Detection of HBsAg<sup>†</sup> AND HBeAg, OR
- Detection of HBV DNA<sup>††</sup>.

### 3.2 Presumptive Case Definition

A presumptive case must meet **both** of the following conditions:

1. Detection of HBsAg<sup>†</sup> or HBeAg

#### AND

2. IgM anti-HBc test negative, not done, or result not available

# 3.3 Suspect Case (not to be used)

These have been defined out of existence; suspect should not be used as a case classification.

# 3.4 Criteria to Distinguish a New Case of Acute or Chronic Hepatitis B from Reports or Notifications which Should Not be Enumerated as a New Case for Surveillance

A case of HBV infection classified as Perinatal HBV can be additionally enumerated as a case of chronic HBV infection if a positive HBV viral detection test (HBsAg, HBeAg, or HBV DNA) is obtained after the case is greater than 24 months of age.

An acute case of HBV infection may be additionally enumerated as a new chronic case of HBV infection if a positive HBV viral detection test is reported 6 months or longer after acute case onset or, if asymptomatic, after the initial positive test result. In

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<sup>&</sup>lt;sup>†</sup> If information on HBsAg test method is available and HBsAg confirmatory neutralization was performed as recommended, HBsAg positive by confirmatory neutralization. A positive qualitative HBsAg result with a negative HBsAg confirmatory neutralization result is not considered a detection of HBsAg.

<sup>&</sup>lt;sup>††</sup> DNA detection by nucleic acid test, including qualitative, quantitative, or genotype testing.

this situation, a new chronic HBV case shall be created in Orpheus; the acute HBV case's status and classification shall not be changed.

A chronic case of HBV infection shall not be previously enumerated as a case of chronic HBV infection (i.e., avoid duplicate case creation).

#### 3.5 Services Available at the Oregon State Public Health Laboratories

The OSPHL offers serologic testing for HBsAg (without confirmatory neutralization testing on positive HBsAg samples), anti-HBs, anti-HBs, anti-HBs IgM, and anti-HBs Total (IgG and IgM). For complete information about specimen collection, handling, and transport, refer to the OSPHL Test Menu at <a href="https://www.healthoregon.org/labtests">www.healthoregon.org/labtests</a>.

#### 4. ROUTINE CASE INVESTIGATION

# 4.1 Confirming the Diagnosis

It is important to distinguish between acute cases of hepatitis B and newly identified chronic carriers. If only a single positive result (HBsAg, HBeAg or HBV DNA) is available, try to get information from the ordering provider about presence/absence of symptoms, prior history, other hepatitis B panel results (such as IgM anti-HBc and total anti-HBc) and any other information that may help to establish a diagnosis. If the laboratory report notes that confirmatory testing has been ordered or is pending, try to obtain the confirmatory test results as negative results may not get reported automatically. A positive qualitative HBsAg result with a negative HBsAg confirmatory neutralization result is not considered a detection of HBsAg. It may also be helpful to check whether the person was recently vaccinated as people who receive hepatitis B vaccine might be transiently positive for HBsAg for up to 18 days post-vaccination.(21)

# 4.2 Investigation of Newly Reported Cases (not previously reported in Oregon)

Routine case investigation should include the documentation of case demographic, laboratory, risk factor and clinical data. Personal information should be collected based on people's self-reported identities and should include "REAL-D" and "SOGI" information.

#### 4.2.1 Identify the Source of Infection

Identifying a specific source of infection for recently identified carriers may be difficult, if not impossible. The risk questions for chronic hepatitis B (see Orpheus or archival versions at

https://www.oregon.gov/oha/PH/DiseasesConditions/CommunicableDisease/ReportingCommunicableDisease/ReportingForms/Pages/index.aspx) focus on selected lifetime risk factors, and these data will be used mainly to help inform programmatic efforts towards disease control. Try to identify a case's country of birth, as high rates of chronic hepatitis B have been observed in people born in certain countries.

#### 4.2.2 Identify Potentially Exposed Persons

The purpose of the disease investigation is to identify persons who: 1) may be candidates for prophylaxis or 2) are at risk for being chronic carriers themselves such as long-term sexual partners, household contacts (with elevated risk for immigrants from endemic countries), and offspring of the infected person.

Immunization is recommended for susceptible individuals who anticipate continued sexual contact with an infected person or with multiple partners, and use of barrier methods (condom, dental dam) can be recommended until the series is completed. The first dose of hepatitis B vaccine should be administered during the same visit with serologic testing. However, HBsAg testing is not a requirement for vaccination, and in settings where testing is not feasible, vaccination of recommended populations should continue.

If the case has had sexual contact with a new partner in the past two weeks, hepatitis B immune globulin (HBIG) is recommended for the partner. Partners whose sexual history with the case goes back more than two weeks are unlikely to benefit from prophylaxis, but they should be informed of their exposure and tested by LHD staff or encouraged to seek testing elsewhere.

For anyone who has had permucosal or percutaneous contact with the case's body fluids (e.g., by needle sharing, blood splashes) within the last 7 days, HBIG is recommended (see §5.3). Those exposed >7 days ago should be advised of their exposure.

If the case is a dentist, surgeon, or other health care worker, evaluate the potential for exposing patients (see §6.1).

If the case has donated blood or plasma in the 8 weeks before onset, see §6.3.

If the patient is pregnant, see *§6.4* and the Perinatal Hepatitis B Investigative Guidelines

(https://www.oregon.gov/oha/PH/DISEASESCONDITIONS/COMMUNICABLEDISEAS E/REPORTINGCOMMUNICABLEDISEASE/REPORTINGGUIDELINES/Documents/hepbperi.pdf).

#### 4.3 Cases Previously Reported as Acute Hepatitis B

Persons who have been reported in the past as acute HBV cases and contacted for case investigation should be re-interviewed as a new chronic HBV case. Cases should be contacted to ensure that they have been notified of their chronic status and likely lifetime infectivity. HBsAg testing (and, if appropriate, immunization) should be offered to any new household or sexual contacts. Case education should reinforce bloodborne pathogen precautions (see  $\S 5.1$ ). People aged 15–44 who have the potential for pregnancy (have a uterus, have not experienced menopause) should be checked for pregnancy status, either via contacting the provider or the case. Cases who are pregnant should be enrolled in the Perinatal Hepatitis B Prevention Program (see  $\S 6.4$ ). If the case cannot be reached directly, a letter should be sent reviewing basic information about HBV transmission and offering contact screening at LHD.

#### 4.4 Cases Previously Reported as Chronic Hepatitis B

Persons who have been reported in the past as chronic HBV cases and contacted for case investigation need not be re-interviewed for risk factor information. However, they should be contacted to identify any new sexual or household contacts. Updated lab results and demographic/contact information should be entered. HBsAg testing (and, if appropriate, immunization) should be offered to any new household or sexual contacts. Case education should reinforce bloodborne pathogen precautions (see §5.1). People aged 15–44 who have the potential for pregnancy (have a uterus, have

not experienced menopause) should be checked for pregnancy status, either via contacting the provider or the case. Cases who are pregnant should be enrolled in the Perinatal Hepatitis B Prevention Program (see §6.4). If diagnosis status has changed from Presumptive to Confirmed, this should be updated in Orpheus.

#### 4.5 Cases Who are Institutionalized or Incarcerated

If the case cannot be interviewed because the person is incarcerated in a jail/prison or is residing in treatment facility (mental health, substance use disorder etc.), case investigation can be completed by facility staff using the case report form. Completed forms should be forwarded to the local health department. If the case is in a state institution, OHA should be notified for follow-up.

#### 5. CONTROLLING FURTHER SPREAD

#### 5.1. Education

Cases (persons who are HBV DNA, HBsAg or HBeAg-positive) should be instructed that their blood and other secretions are infectious to others; chronic carriers usually are infectious for life. (A few do lose measurable HBsAg over time.)

Scrupulous attention to standard precautions is important while the case is positive. Surfaces contaminated with saliva and blood should be cleaned and properly disinfected. Objects potentially contaminated with blood (e.g., drug paraphernalia, razors, sex toys, toothbrushes) should not be shared with other people. Contaminated sharps should be discarded in an approved sharps container.

It is especially risky for infected persons to share hypodermic needles with other people. Disposable needles should never be used more than once. Both syringe and needle must be discarded once they have been used.

Cases should be advised that the virus may be transmitted through sexual contact. Patients should be counseled about abstinence, barrier methods and other strategies for "safer" sex. Sexual partners who are anti-HBc positive (from previous infection) are not at risk; vaccination has an estimated 95% efficacy and should be recommended to sexual partners of cases.

People who could potentially get pregnant should be counseled about the risk of hepatitis B infection to infants who are birthed by people who are infected, and of the importance of prophylaxis for these newborns. If the case is pregnant, see §6.4.

Caregivers of chronic HBV cases with functional disabilities should be alerted to the risk of HBV infection associated with excessive drooling and behaviors such as biting and scratching.

To protect the liver from further harm, cases should be advised to:

- Seek health-care services from a provider experienced in the management of hepatitis B
- Avoid or limit alcohol consumption because of the effect of alcohol on the liver (investigator should provide referral to care for persons needing evaluation or treatment for alcohol abuse)
- 3. Obtain vaccination against hepatitis A (2 doses, 6-18 months apart) if chronic liver disease is present

4. Notify personnel of their hepatitis B status when seeking medical or dental care

Other counseling messages including the following:

- 1. HBV is not spread by breastfeeding, kissing, hugging, coughing, ingesting food or water, sharing eating utensils or drinking glasses or casual touching.
- 2. Persons should not be excluded from school, play, childcare, work or other settings on the basis of their HBV status, unless they are prone to biting.
- 3. HBV-infected health-care workers should follow published guidelines and applicable state laws and regulations regarding recommended practices to reduce the risk of HBV transmission in the workplace. See §6.1.

#### 5.2 Isolation and Work or Day Care Restrictions

Standard precautions (hand washing) are adequate to minimize the risk of further transmission.

Hospitalized patients with acute or chronic HBV infections pose a minimal risk to staff or other patients given the implementation of standard precautions and the appropriate pre-exposure use of hepatitis B vaccine.

If the case is a health care worker with potential for exposing patients, see §6.1.

The risk of transmission of HBV in the school or day care setting is usually low and can be reduced through sound infection control procedures and environmental cleanliness. Toiletry items that could be contaminated with blood or saliva should not be shared. Toys and other contaminated objects should be cleaned and disinfected as soon as possible to prevent transmission. Children in the communicable stages of hepatitis B infection may be excluded from attending school or childcare if, in the opinion of the local health officer, the child poses an unusually high risk to other children (e.g., exhibits uncontrollable biting or spitting). See Oregon Administrative Rule 333-019-0010:

http://public.health.oregon.gov/DiseasesConditions/CommunicableDisease/Reporting CommunicableDisease/Pages/rules.aspx.

# 5.3 Prophylaxis

1. Vaccination

Refer to the Oregon Health Authority Immunization Protocols (formerly Immunization Standing Orders) for the recommended hepatitis B vaccine doses and schedules (Document location:

https://www.oregon.gov/oha/ph/preventionwellness/vaccinesimmunization/immunizationproviderresources/pages/stdgordr.aspx)

2. Post-Exposure Prophylaxis (PEP)

HBIG is rarely indicated for contacts of chronic carriers due to the difficulty of determining onset date (see §4.2). See Tables 3 and 4 for more details about post-exposure prophylaxis.

3. Pre-Exposure Prophylaxis (PrEP)

Universal infant immunization has been recommended since early 1992. Hepatitis B vaccination is also recommended for individuals aged <59 years and those 60 or older with increased risk of infection because of medical history, living or working conditions, high-risk behaviors, or ongoing intimate contact with an HBV carrier. Additionally, adults aged 60 or older without known risk factors may receive vaccination. Vaccination should be recommended to persons who are identified as being at risk in the course of routine public contacts, in addition to those identified in the course of an HBV case investigation. Vaccination is also recommended for nonsexual household contacts of acute HBV cases, especially children and adolescents. Questions about vaccine availability should be directed to the Immunization Program (1-800-980-9431).

Pre-exposure prophylaxis is recommended for the following types of people (22):

- All infants
- Persons aged <19 years</li>
- Adults aged 19 59 years
- Adults aged ≥ 60 years with risk factors for hepatitis B:
  - Persons at risk for infection by sexual exposure:
    - Sex partners of persons testing positive for 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:

- People with current or recent injection drug use
- Household contacts of persons testing positive for HBsAg
- Residents and staff members of facilities for persons with developmental disabilities
- Health care and public safety personnel with reasonably 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 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, alcoholic liver disease, autoimmune hepatitis, and an alanine aminotransferase (ALT) or aspartate aminotransferase (AST) level greater than twice the upper limit of normal)

- Persons with HIV infection
- Persons who are incarcerated
- Adults aged ≥60 years without known risk factors for hepatitis B may receive hepatitis B vaccines
- 4. Alternative schedules For a variety of reasons, some individuals cannot be immunized on the recommended 0, 1 and 6-month schedule. In fact, many alternatives work almost as well (and some conceivably better). An interrupted vaccination schedule can be resumed at any time without modifying the number or timing of subsequent doses. In other words, there is no problem (other than delayed benefit) with giving the second "one-month" dose at two months (or later) or the third "six-month" dose at eight months (or eight years). If an accelerated schedule is considered, the third dose should not be given <2 months after the second, unless a fourth dose is scheduled >4 months after the third dose.
- Occupational risks Persons with jobs that put them at risk for occupational exposures may be eligible for vaccination at their employer's expense. For more information, contact OR-OSHA (contact information for office locations). See Table 3 for post-exposure prophylaxis recommendations.
- 6. Post-vaccination serologic testing following a complete series of Hepatitis B vaccination is recommended for specific populations, including:
  - Infants delivered by a parent who was HBsAg-positive or whose HBsAg status remains unknown
  - Healthcare personnel and public safety workers at risk for blood or body fluid exposure
  - People who currently or in the future might require hemodialysis
  - People living with HIV
  - Immunocompromised persons
  - Sex partners of HBsAg-positive persons
- 7. Seroconversion response Vaccinees with a defined, ongoing risk should be tested for seroconversion 16 months after completion of the original 3-dose schedule. For perinatal exposures, see §6.4. A minority of persons do not seroconvert after immunization, and they continue to be at risk for infection. Among persons vaccinated 5.9 17.5 years ago at age <1 year who have anti-HBs levels <10 mIU/mL, approximately 60.0%–97.4% showed a response to a single challenge dose of HBV vaccine demonstrating protective levels of anti-HBs ≥10 mIU/mL. Among persons vaccinated 9-22 years ago at age ≥1 year who have anti-HBs levels <10 mIU/mL, 69.2%-96.4% showed a response to a single challenge dose of HBV vaccine demonstrating protective levels of anti-HBs ≥10 mIU/mL.(23)

Smoking, higher BMI and greater age may be associated with decreased response to hepatitis B immunization. Although > 90% of adults <40 years of age develop immunity, only 75% of adults who receive vaccine over the age of 60 years achieve protective antibody titers. A study demonstrated protective anti-HBs levels in previous non-responders after receiving a double dose of Twinrix™ at 0,1 and 6 months. Among non-responders, 95% had protective anti-HBs levels after the third dose.(24)

#### **CHRONIC HEPATITIS B**

**Table 3.** Recommended Post-exposure Prophylaxis for Occupational Exposure to Hepatitis B Virus(22)

Vaccination and	Treatment		
antibody response status of exposed worker*	Source HBsAg positive or unknown/not available for testing	Source HBsAg negative	
Unvaccinated	Hepatitis B immune globulin (HBIG) <sup>†</sup> x 1 and initiate HB vaccine series	Initiate HB vaccine series	
Previously Vaccinated	,	,	
Known responder§	No treatment	No treatment	
Known non- responder**	HBIG x 1 and initiate revaccination or HBIG x 2 one month apart¶	No treatment	
Response unknown	Test exposed person for anti-HBs  1. If adequate, no treatment is necessary.  2. If inadequate, administer HBIG x 1 and initiate revaccination.	Test exposed person for anti-HBs  1. If adequate, no treatment is necessary.  2. If inadequate, initiate revaccination.	

<sup>\*</sup> Persons who have previously been infected with HBV are immune to reinfection and do not require post-exposure prophylaxis.

Table 4. Recommended Post-exposure Prophylaxis\* for Non-occupational Exposure\*\* to Hepatitis B Virus(22)

Exposure**	Treatment		
	Unvaccinated person <sup>†</sup>	Previously vaccinated person§	
HBsAg-positive source	Administer hepatitis B vaccine series and hepatitis B immune globulin (HBIG). HBIG dose is 0.06 mL/kg intramuscularly	Administer hepatitis B vaccine booster dose	
Perinatal exposure to HBsAg-positive pregnant people or in infants weighing less than 2,000 grams to pregnant people with unknown HBsAg status	Initiate hepatitis B vaccine series and hepatitis B immune globulin (HBIG) within 12 hours of birth	Not applicable	

<sup>†</sup> Dose is 0.06 mL/kg intramuscularly

<sup>§</sup> A responder is a person with adequate levels of serum antibody to HBsAg (i.e., anti-HBs ≥10 mIU/mL).

<sup>\*\*</sup> A non-responder is a person with inadequate levels of serum antibody to HBsAg (i.e., anti-HBs <10 mIU/mL).

<sup>¶</sup> The option of giving one dose of HBIG and reinitiating the vaccine series is preferred for non-responders who have not completed a second 3-dose vaccine. For those who have not responded after completing two complete vaccine series, do not give additional doses of vaccine.

HBsAg status unknown Administer hepatitis B vaccine No treatment series

#### 6. MANAGING SPECIAL SITUATIONS

#### 6.1 Case is a Health Care Worker

HBV-infected health care providers (HCPs) should not be prohibited from participating in patient-care activities solely on the basis of their HBV infection; standard precautions should be adhered to rigorously in all healthcare settings for the protection of both patient and provider. The 1000 IU threshold is equivalent to  $\sim$ 5 ×  $10^3$  GE/mL (genome equivalents per milliliter mL of blood), and is a revised threshold disseminated by SHEA in 2022.(25)

Additionally, HCPs who, despite appropriate treatment, have titers of HBV DNA greater or equal to ≥ 1000 IUs should not perform Category III/exposure-prone procedures (see <u>SHEA guidelines</u>), such as open resuscitation efforts.

Current SHEA guidelines (25) suggest that HCPs living with HBV whose circulating viral loads can be consistently suppressed to <1000 IUs can perform category III/exposure-prone procedures, as long as the person:

- 1. Has not been previously identified as having transmitted infection to patients while on appropriate suppressive therapy;
- 2. Obtains advice from an oversight panel about recommended practices to minimize risk of exposure events;
- Is followed by a personal physician who has expertise in the management of HBV infection and who is allowed by the HCP to participate in or communicate with the oversight panel about the individual's clinical status;
- 4. Is monitored on a periodic basis (e.g., every 6 months) to assure that the viral load remains <1000 IUs and
- 5. Signs a written agreement to follow the recommendations of the oversight panel.

## 6.2 Case is a Suspected latrogenic Infection

If two or more iatrogenic (healthcare-associated) cases occur in patients of the same dental or health care provider, residential care facility, or non-hospital health care facility (i.e., dialysis center) and the cases have no other identified plausible source of infection—or if other circumstances suggest the possibility of iatrogenic infection—refer to the <a href="Hepatitis B">Hepatitis B</a> and C Outbreaks in Healthcare Settings guidance. For assistance, consult with the ACDP on-call epidemiologist at 971-673-1111.

<sup>\*</sup>When indicated, immunoprophylaxis should be initiated as soon as possible, preferable 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.

<sup>\*\*</sup>Examples of such exposures include bites or needlesticks, mucosal exposures to HBsAg-positive blood or body fluids; sex or needle-sharing contact; or the victim of sexual assault/abuse.

<sup>†</sup> A person who is in the process of being vaccinated but who has not completed the vaccine series should complete the series and receive treatment as indicated.

<sup>§</sup> A person who has written documentation of a complete hepatitis B vaccine series and who did not receive post-vaccination testing.

#### 6.3 Case is a Recent Blood Donor

If the case has donated blood or plasma within the eight weeks prior to onset of symptoms, the agency that received the blood or plasma should be notified (as well as ACDP) so that any unused product can be recalled.

#### 6.4 Case is Pregnant or Has Just Delivered a Child

Pregnant people who are HBsAg-positive should be tested for HBV DNA. Antiviral therapy to reduce perinatal transmission may be indicated when the HBV DNA level is >200,000 IU/mL.(22)

Preventing perinatal transmission is perhaps the most important part of case follow-up, and for this reason the Oregon Immunization Program has an official Perinatal Hepatitis B Prevention Program. Participation in this program is mandatory for local health departments. Case management activities and requirements for reporting these activities are described in detail in the Oregon Perinatal Hepatitis B Prevention Program Investigative Guidelines

(https://www.oregon.gov/oha/PH/DISEASESCONDITIONS/COMMUNICABLEDISEAS E/REPORTINGCOMMUNICABLEDISEASE/REPORTINGGUIDELINES/Documents/hepbperi.pdf).

## 6.5 Case is IgM anti-HBc Positive, without Documented HBsAg

The physician ordering the test should be contacted about additional tests performed. It is important to rule out HBsAg antigenemia. Persons who are in fact HBsAgnegative may be in the window phase (see Figure 1). Otherwise, they most likely have acute infection (with or without symptoms). Refer to the Acute HBV Investigative Guidelines

(https://www.oregon.gov/oha/PH/DISEASESCONDITIONS/COMMUNICABLEDISEAS E/REPORTINGCOMMUNICABLEDISEASE/REPORTINGGUIDELINES/Documents/hepb-acute.pdf)

#### 6.6 Case is Co-infected or Superinfected with Hepatitis D

If the patient's serology results include antibody to hepatitis D virus (HDV) or another marker of HDV infection, create a separate case report for this disease. If the person has a positive HDV RNA by nucleic acid test (qualitative, quantitative, or genotype testing) create a confirmed Hepatitis D case and if the person has a positive total antibody to hepatitis D virus (total anti-HDV) create a presumptive Hepatitis D case. Hepatitis D is an unrelated virus whose modes of transmission are similar to HBV but is a "defective" virus that can only infect persons with HBV. Approximately 15 million persons worldwide are infected with HDV,(26) but it is not routinely screened for in the United States. No additional investigative measures are called for, assuming that the patient has been investigated according to the HBV guidelines.

#### 6.7 Possible Common-source Outbreak

Contact communicable disease epidemiologists at ACDP immediately at 971-673-1111.

#### GLOSSARY OF TERMS FOR ALL HEPATITIDES

**ALT/AST:** These are both liver enzymes classified as serum aminotransferases or transaminases and are useful indicators of liver damage. Alanine aminotransferase is usually abbreviated as ALT (or SGOT) and is particularly sensitive for assessing liver damage secondary to hepatitis C (HCV) infection. Aspartate aminotransferase is referred to as AST (or SGPT).

**Anti-HCV EIA:** Enzyme immunoassay to measure 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.

**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.

**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 the chronic carrier state.

**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 (a change known as seroconversion) 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.

**HBV 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 war- ranted.

**HCV genotype:** HCV can be divided into at least 6 different genotypes. Genotype 1 is the most common in the US, accounting for 70%-75% of infections.

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

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

**PCR:** Polymerase chain reaction, used to measure HCV RNA and indicates active replication of the virus (e.g., the chronic carrier 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.

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#### **UPDATE LOG**

August 2024 – Updated case definitions to match CSTE position statement updates; expanded prevalence table, description of illness; revised for equity language, including adding "Risk Dynamics" section, revising "Purpose and of Reporting and Surveillance" goals, and reducing gendered and potentially stigmatizing language; updated viral load threshold for SHEA guidelines; vaccination schedule, including adding newly approved PreHevbrio; edits to prevalence estimates for subpopulations AUGUST 2024 PAGE 21 OF 24

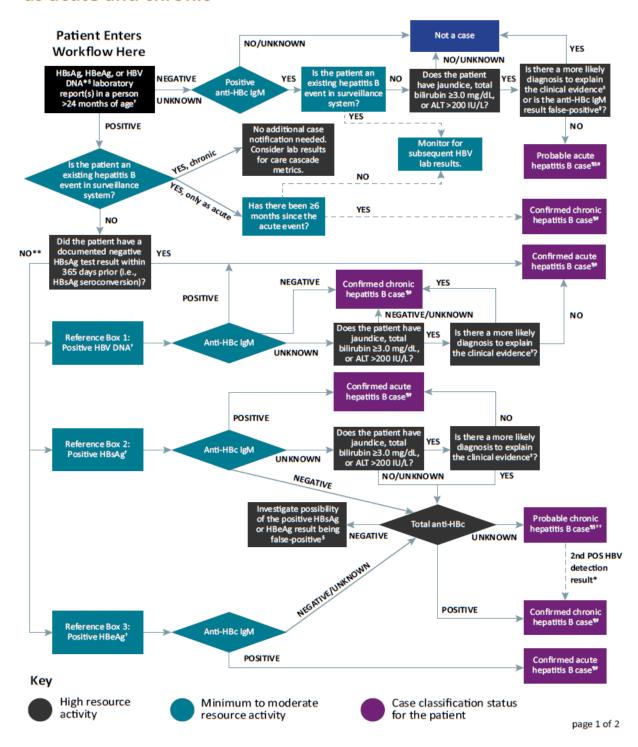
#### **CHRONIC HEPATITIS B**

- based on the most recent literature; edited for formatting and visual and written clarity, AMA style, parallel language to other IGs. (Lisa Iguchi, Shannon Obrien, Tasha Martin, Gabriela Escutia, Moriah McSharry McGrath/Nicole Iroz-Elardo)
- July 2018: Updates for alignment with the new ACIP recommendations and the acute and perinatal hep B guidelines; added figure 2 (world map), updated table 2, added tables 3 and 4 for post-exposure prophylaxis guidance, referenced standing orders for vaccine recommendations; removed summary of perinatal hepatitis B investigation in section 6.4; edits for clarity and consistency between all hep B guidelines. (Takeuchi)
- April 2011: Updated guidelines for cases who are institutionalized or incarcerated. (Grace Van Ness and Margaret Cunningham)
- April 2009: New chronic-HBV-specific document adapted from previous hepatitis B (acute and chronic) guidelines. Expanded (4.A-E) contact investigation and (5.E) case education sections; (4.B-D) added specific procedures for investigation of previously reported cases; updated (2.E) population prevalence table and (5.D) pre-exposure prophylaxis guidelines to reflect CDC recommendations issued
- September 2008. March 2008: IC.4 LHDs encouraged to verify pregnancy status on women of childbearing age (15–44 years).
- May 2007: D2. Pre-exposure vaccination recommendations expanded to include nonsexual household contacts of acute HBV cases, especially children and adolescents, and household and sexual contacts of all HBsAg+ persons. Eliminated "indeterminate" case definition. Expanded the acute case definition to include +HBsAg results

Appendix 1. Process for classifying cases of hepatitis B as acute and chronic Algorithm available online here:

https://www.cdc.gov/hepatitis/statistics/surveillanceguidance/HepatitisB.htm#figure3-3

Figure 3-3. Process for classifying cases of hepatitis B as acute and chronic



# Figure 3-3. Process for classifying cases of hepatitis B as acute and chronic

#### **Footnotes**

\*For surveillance case classification, HBsAg, HBeAg, and HBV DNA results are considered HBV detection results. If HBsAg confirmatory neutralization results were received, HBsAg was positive by confirmatory neutralization. Nucleic acid testing for HBV DNA, including qualitative, quantitative, and genotype testing. An isolated positive hepatitis B 'e' antigen (HBeAg) test result should prompt further investigation into the hepatitis B surface antigen (HBsAg) and/or HBV DNA results. Negative HBeAg results and HBV DNA levels below the positive cutoff level do not confirm the absence of HBV infection.

\*Children ≤24 months of age and born in the United States to a gestational parent with documented evidence of HBV infection should be classified and reported using the 2017 perinatal hepatitis B case definition unless there is evidence that exposure occurred via a non-perinatal mechanism (e.g., health care-acquired). Children ≤24 months of age whose mode of exposure is not perinatal should be classified under the 2024 acute or chronic hepatitis B case definitions. Surveillance programs should provide prevention programs with information on individuals who have positive test outcomes for post-test counseling and referral to treatment and care, as appropriate.

<sup>†</sup>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 hepatitis B, other causes including alcohol exposure, other viral hepatitis, hemochromatosis, etc. If there is documentation from the patient's health care provider explaining that the clinical evidence is due to another reason other than acute hepatitis B, the patient should not be evaluated under the acute hepatitis B case definition.

<sup>§</sup>If a false-positive result is suspected, jurisdictions should consider other available test results, such as the total anti-HBc result, to aid with interpretation. If results are determined to be false-positive, they should not be used to classify cases as confirmed or probable.

<sup>¶</sup>A new acute hepatitis B case is an incident case that has not been previously notified as an acute or chronic hepatitis B case. A new chronic hepatitis B case is an incident case that has not been previously notified as a chronic hepatitis B case.

<sup>5</sup>A probable acute hepatitis B case that is confirmed within the same reporting year (before the NNDSS close-out date) can be transmitted as an update to the same case, but if the case is confirmed following the initial reporting year, it should not be transmitted to NNDSS again. A probable chronic hepatitis B case that is confirmed within the same reporting year (before the NNDSS close-out date) can be transmitted as an update to the same case, but if the case is confirmed following the initial reporting year, it should not be transmitted to NNDSS again.

"A confirmed or probable acute hepatitis B case may be additionally enumerated as a new confirmed chronic hepatitis B case if a positive HBV viral detection test is reported ≥6 months after acute case onset, or if asymptomatic, after the initial positive test result (e.g., consider reactivation).

\*\*Refer to the appropriate reference box based on the positive HBV detection test(s) received.

<sup>††</sup>Classify as confirmed chronic hepatitis B if ≥2 HBV detection results are positive (e.g., positive for both HBsAg and HBeAg, positive for HBsAg in two clinical specimens taken ≥6 months apart, or positive for HBeAg in two clinical specimens taken ≥6 months apart).



Figure~3.3~graphic~rendered~from:~https://www.cdc.gov/hepatitis/statistics/surveillanceguidance/index.htm (2024~update~in~press).