1. Case Definition

1.1 Confirmed Case of Acute Infection
Laboratory confirmation of infection as demonstrated by:
- hepatitis B surface antigen (HBsAg) positive PLUS immunoglobulin M antibody to hepatitis B core antigen (anti-HBc IgM) positive in the context of a compatible clinical history or probable exposure
  OR
- loss of HBsAg within a six month period after testing HBsAg positive in the context of a compatible clinical history or probable exposure (1).

1.2 Confirmed Case of Chronic Infection
Laboratory confirmation of infection as demonstrated by:
- HBsAg positive for longer than six months with or without symptoms
  OR
- HBsAg positive, anti-HBc IgM negative and anti-HBc total positive
  OR
- detection of hepatitis B virus (HBV) DNA over a period greater than six months by a validated nucleic acid amplification test (1, 2).

1.3 Confirmed Unspecified Case
- HBsAg positive
  OR
- detection of HBV DNA by a validated nucleic acid amplification test
  AND
- does not fit the criteria for either acute or chronic case definitions above (1).

2. Reporting Requirements

2.1 Reporting to Manitoba Health and Other Requirements
- All positive laboratory results noted in the case definition are reportable to the Public Health Surveillance Unit (204-948-3044 secure fax).
- Positive test results are referred to the health jurisdiction (i.e., Regional Health Authority [RHA], First Nations Inuit Health Branch [FNIB]) of residence for follow-up.
- The Investigation Form for Hepatitis B and C Positive Cases should be completed by Public Health for all clients testing positive (this applies to all cases new to Manitoba) with assistance from the ordering practitioner, and forwarded to the Public Health Surveillance Unit (204-948-3044).
- Operators of Manitoba clinical laboratories are required to submit the residual serum or plasma specimens from individuals who tested positive for hepatitis B virus to Cadham Provincial Laboratory within seven days of report for surveillance purposes.
- Positive test results identified through the local Canadian Blood Services are reportable to the Public Health Surveillance Unit (204-948-3044 secure fax).

2.2 Reporting to Canadian Blood Services
- If there is reasonable possibility that the source of infection in a client testing positive for hepatitis B is the receipt of blood or blood products, or there is a history of blood donation, Manitoba Health will inform Canadian Blood Services.
3. Clinical Presentation/Natural History

3.1 Acute Infection

Initial infection with hepatitis B virus (HBV) may be asymptomatic in up to 50 per cent of adults and 90 per cent of children (3, 4). When symptoms occur, they may include anorexia, vague abdominal pain, nausea, vomiting and jaundice (3, 4). Fever may be absent or mild (4). Extrahepatic manifestations such as arthralgias, arthritis, macular rashes, thrombocytopenia or papular acrodermatitis (Gianotti-Crosti syndrome) can occur early in the course of the illness and may precede jaundice (5). Acute illness may last up to three months and has a case fatality rate of one to two per cent, which increases with age (3). Acute HBV infection cannot be distinguished from other forms of acute viral hepatitis on the basis of clinical signs and symptoms or nonspecific laboratory findings (5).

3.2 Chronic Infection

While the majority of individuals infected with HBV are able to clear the virus, some individuals fail to mount an adequate immune response, leading to chronic infection (6). The exact mechanisms by which chronic liver injury occurs in HBV infection are not known (7). Hepatitis B virus infection becomes chronic in approximately 90 per cent of infants infected at birth (5), 20 to 50 per cent of children infected from one to five years (5) and one to 10 per cent of individuals infected as older children and adults (3-5). Individuals with chronic infection may present in one of four phases of infection: 1) immune tolerant, 2) immune clearance (hepatitis B early antigen [HBeAg] positive chronic HBV), 3) the inactive carrier state or 4) reactivation (HBeAg negative chronic HBV) (6, 8-10). Not all patients go through every phase (9). If chronic infection is established, the spectrum of illness ranges from the healthy carrier state to all of the sequelae of chronic hepatitis, including mild to moderate fibrosis, compensated cirrhosis, hepatic decompensation and hepatocellular carcinoma (HCC) (3, 8). The single most important risk factor for HCC is cirrhosis (8). Individuals who are immunosuppressed or have an underlying chronic illness are at increased risk of developing chronic infection (4, 5). Factors that may influence the natural history of chronic infection include gender, race, alcohol use, and co-infection with hepatitis A, hepatitis C or hepatitis D viruses or human immunodeficiency virus (HIV) (5). Reactivation of resolved chronic infection is possible with immunosuppression (5). Although HCC is more common in the fifth decade of life, HCC occasionally occurs in children who become infected perinatally or in early childhood (5). It is estimated that 15 to 25 per cent of individuals with chronic HBV infection will die prematurely of either cirrhosis or HCC (4, 5). Antiviral therapy can modify the natural history of chronic HBV infection (9).

Superinfection or co-infection is not uncommon in patients with chronic HBV infection. Acute hepatitis delta virus (HDV) may be acquired as a co-infection simultaneously with HBV or as a superinfection in a patient who is already a carrier of HBV (10). Infection with HDV in HBV infected individuals is associated with more severe and/or progressive liver disease than is HBV monoinfection (10).

The natural course following acute hepatitis C virus (HCV) superinfection has not been well studied. The long-term prognosis following acute HCV superinfection is worse than that following HDV superinfection (11).

HIV co-infection tends to accelerate the natural history of HBV (10). Individuals co-infected with the parasite Schistosoma (Schistosomiasis) are more likely to have more severe hepatitis B manifestations and become chronic carriers of HBV (12).

4. Etiology

Hepatitis B virus, belonging to the Hepadnaviridae family, is a small enveloped DNA virus whose partially double-stranded DNA genome is maintained in a circular conformation (4, 6, 7, 13, 14). The nucleocapsid core antigen (HBCAg) is surrounded by an outer lipoprotein coat containing the surface antigen (HBsAg) (5). On the basis of the antibody response to HBsAg, four major
subtypes of HBsAg have been recognized and designated adw, ayw, adr and ayr (4). The distribution of the four subtypes varies geographically; however, because of the common “a” antigen, protection against one subtype appears to confer protection against the other subtypes (4). No differences in clinical features have been related to subtype (4).

Eight HBV genotypes (A-H) have been described (4, 6), with genotype A being the most common in northern Europe and North America (6). Recent data suggest that HBV genotype may play a role in the progression from acute to chronic HBV infection (6, 15-17).

Hepatitis B virus primarily infects hepatocytes (7). The existence of asymptomatic hepatitis B carriers with normal liver histology and function suggests that the virus is not directly cytopathic (7). Protection from HBV infection is conferred by antibody to HBsAg (18).

5. Epidemiology

5.1 Reservoir and Source
Humans are the only known reservoir, although chimpanzees are susceptible to human strains (4). Individuals with chronic HBV infection are the main reservoir for infection (5). Other primates such as gibbons, orangutans, African green monkeys and squirrel monkeys have been found positive for HBsAg (7).

5.2 Transmission
The virus may be transmitted from individuals having acute or chronic infection (18). Hepatitis B virus is found mainly in the blood, vaginal secretions, semen and serous fluids of an infected individual (3, 4, 18). There appears to be no transmission of HBV through tears, sweat, urine, stool or droplet nuclei (18).

Transmission occurs by percutaneous (IV, IM, SC or intradermal) and permucosal exposure to infective body fluids (4). The most common transmission route reported in Manitoba is sexual contact. Risk factors associated with sexual transmission among heterosexuals include having unprotected sexual contact with an infected partner, having unprotected sexual contact with multiple partners, and history of another sexually transmitted infection (STI) (14, 19, 20). Risk factors associated with sexual transmission among men who have sex with men (MSM) include having multiple sex partners, history of another STI and anal intercourse (19).

Percutaneous exposures that could result in HBV transmission include: transfusion of blood or blood products, human bites, sharing needles during injection drug use, hemodialysis, acupuncture, tattooing, body piercing and needlesticks or other injuries from sharp instruments sustained by health care personnel (3, 4, 18). The risk of transfusion-related hepatitis B is extremely low in Canada because all blood and blood products are tested (3). The precise role of saliva in the transmission of HBV is not clearly known; however, saliva is considered potentially infectious in bite wounds with broken skin involving the percutaneous inoculation of saliva, or when it is visibly tainted with blood (3). Other types of exposure to saliva such as kissing are unlikely modes of transmission (18).

Perinatal transmission of HBV is highly efficient and usually occurs from blood exposures during labour and delivery (5). In utero transmission of HBV is rare (5).

Household and community transmission may occur through sharing inanimate objects such as washcloths, towels, razors or toothbrushes (4, 5). Hepatitis B virus can survive for long periods on environmental surfaces (at least seven days) (5, 7, 18). As such, exposure to even minute amounts of blood or contaminated secretions may transmit the virus (7). Infection can occur in settings of prolonged personal contact, such as that which occurs between children or among residents of institutions for the developmentally disabled (7). Fecal-oral or vectorborne transmission has not been demonstrated (4, 5). Approximately one-third of infections identified in Canada are acquired with no apparent risk factors (3).

Perinatal transmission is the major mode of transmission in high-prevalence areas, whereas
horizontal transmission accounts for most cases of chronic HBV infection in intermediate-prevalence areas (7). Unprotected sexual intercourse and intravenous drug use in adults are the primary routes of spread in low-prevalence areas (7).

5.3 Occurrence

5.31 General

Hepatitis B virus is endemic worldwide with little seasonal variation (4). It is estimated that HBV infection affects approximately two billion persons worldwide (8). Approximately 350 million of these individuals have chronic infection (4). Hepatitis B remains highly or moderately endemic in the Far East, the Middle East, Africa, South America, Eastern Europe and Central Asia, with carrier rates of 2% to 20% in the general population (3). In the United States, Western Europe, and Australia, HBV infection is a disease of low endemicity (18). In Western countries, the disease is acquired primarily in adulthood, whereas in Asia and most of Africa, chronic HBV infection is common and usually acquired perinatally or in childhood (21).

5.32 Canada

The incidence of hepatitis B has decreased in all age groups in recent years, coinciding with the increasing use of vaccine (3, 10); however, immigration continues to introduce additional HBV-infected individuals to Canada (10). In general, Canada is considered an area of low endemicity (3); however, prevalence varies in different subgroups as identified in the “Host Susceptibility and Resistance” and “Transmission” sections of the protocol. In 2008, the overall reported rate of acute hepatitis B infection in Canada was 0.74 individuals infected per 100,000 people living in Canada (22). It is estimated that less than five per cent of Canadian residents have markers of past infection and less than one per cent are HBsAg carriers (3). Immigrants constitute the largest group of HBV carriers, particularly those from geographical regions with high endemic rates of HBV, such as Asia (10). As immigrants have a tendency to favour urban areas in Canada, hepatitis B is not evenly distributed across the country (10).

5.33 Manitoba

In 2011, 245 hepatitis B cases were reported as new to the Public Health Surveillance System at Manitoba Health; of these, six were identified as acute cases, while the remainder were categorized as either chronic or unspecified type of infection. The surveillance system captures cases with positive test result for the hepatitis B surface antigen (HBsAg), and in the majority of cases is unable to distinguish chronic and unspecified cases. Acute cases can be distinguished by detection of immunoglobulin M core antibody (anti-HBc IgM) and these numbers are reported annually to the national notifiable disease surveillance system, Public Health Agency of Canada (PHAC). In 2011, as in other years, the majority of hepatitis B cases reported residence in the Winnipeg Health Region (83%). Nearly one third of newly reported cases were 30-39 years of age at time of test (approximately 31%) followed by 40-49 years of age (21%). Of the 245 newly reported cases in 2011, approximately half (n=153 cases) reported their birthplace as a country outside of Canada.

Over the past 10 years, the crude rate of reported HBV cases increased between 2002 and 2011; however, it is important to note that the number of reported acute cases of hepatitis B has varied between two and twelve cases per year. Males historically have had higher crude rates of reported infection compared to females; however, rates in both sexes appear to have slowly and steadily increased over this period in Manitoba.

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a HBsAg prevalence is 8% or higher (4, 7).
b HBsAg prevalence is from 2% to 7% (4, 7).
c HBsAg prevalence is under 2% (4, 7).
d It should be noted that 83 cases did not have a completed investigation form.
e This number includes all positive reports of hepatitis B surface antigen (HBsAg) and includes those with acute, chronic, and undetermined infection status as reported to Manitoba Health via case report forms.
5.4 Incubation
The incubation period for HBV ranges from 45 to 180 days with an average of 60 to 90 days (4). Hepatitis B surface antigen (HBsAg) may be detected as early as two weeks post-infection. Incubation is dependent upon inoculum size, mode of transmission and host factors (4).

5.5 Host Susceptibility and Resistance
Susceptibility in humans is general. Disease is often milder in children and is usually asymptomatic in infants (4). Individuals with Down’s syndrome, lymphoproliferative disease, human immunodeficiency virus (HIV) infection and those on hemodialysis appear more likely to develop chronic infection (4). Protective immunity follows infection if antibodies to HBsAg (anti-HBs) develop and the individual becomes HBsAg negative (4). In most individuals who recover from acute HBV infection, anti-HBs persists for life, conferring long-term immunity (7). Immunity against HBV is believed to persist for at least 15 years after successful immunization (3). However, antibody response rate is lower in immunocompromised individuals such as those with diabetes mellitus and individuals infected with HIV (20). Groups at higher risk of acquiring HBV infection due to behavioural factors are described in the “Transmission” section.

5.6 Period of Communicability
All chronic cases should be considered infectious (3, 15). When symptoms are present in individuals with acute HBV infection, HBsAg can be found in blood and body fluids for one to two months before and after the onset of symptoms (18). The presence of HBsAg, HBeAg and/or high levels of HBV DNA in individuals are indicators of communicability.

6. Diagnosis

NOTE: Where the testing for HBV is being done pursuant to an order issued under The Testing of Bodily Fluids and Disclosure Act, refer to the Integrated Post-Exposure Protocol for HIV, HBV and HCV: Guidelines for Managing Exposures to Blood and Body Fluids available at:

Diagnosis of acute or chronic hepatitis B virus infection may sometimes be very difficult. Often one needs a clear history, physical and serological tests to try to determine this. See “Case Definition” section. Patient history is also important to assist the laboratory in determining testing needs.

6.1 Acute Cases
Diagnosis of acute HBV infection is typically based upon the detection of both HBsAg and anti-HBc IgM. HBsAg can be detected in serum from several weeks before onset of symptoms to days, weeks or months after in acute cases. HBsAg declines, disappears and is followed by the appearance of anti-HBs in acute cases which resolve. Anti-HBc IgM is present in high titer in acute cases and usually disappears within six months. See Table 1 for interpretation of serologic test results.

6.2 Chronic Cases
The diagnosis of chronic HBV infection is based upon the persistence of HBsAg for more than six months. The presence of HBsAg and anti-HBc total antibody, in the absence of anti-HBc IgM is also diagnostic of chronic infection. Other markers that may be tested for include HBeAg and anti-HBe. See Table 1 for interpretation of serologic test results.

6.3 Unspecified Cases
Cases that are HBsAg positive or in which HBV DNA has been detected by a validated nucleic acid amplification test, but which do not fit the acute or chronic case definition, are termed “unspecified.” It is recommended that repeat testing (HBsAg) be performed six months after initial testing to determine if chronicity has developed.

Testing for hepatitis B DNA is not routinely performed except by reference laboratories. Testing for HBV DNA may be used to improve the diagnosis, to determine candidacy for treatment or to monitor the effectiveness of therapy.
7. Key Investigations

- Determination of risk factors for acquisition of hepatitis B.
- Contact identification to determine source and extent of transmission of infection and to prevent further spread by immunization.
- Immunization history.

8. Control

For the purposes of this protocol, “Public Health” refers to provincial regional public health authorities as well as First Nations Inuit Health.

<table>
<thead>
<tr>
<th>Test</th>
<th>Acute Through Infection</th>
<th>Immunity Through Vaccination</th>
<th>Chronic Hepatitis B</th>
<th>“Inactive” Carrier</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBsAg*</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Anti-HBs</td>
<td>-</td>
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<tr>
<td>HBeAg*</td>
<td>+/-</td>
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<td>Anti-HBe</td>
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<td>Anti-HBc</td>
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<tr>
<td>Anti-HBc IgM</td>
<td>+</td>
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<td>HBV DNA*</td>
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NOTE: While occult HBV infections are believed to occur, they are still under investigation.

* Patients having positive tests for one or more of these markers are considered to be infectious (3, 5).

Abbreviation       Marker
HBsAg              hepatitis B surface antigen
Anti-HBs           antibody to hepatitis B surface antigen
HBeAg              hepatitis B early antigen
Anti-HBe           antibody to hepatitis B early antigen
Anti-HBc           antibody to hepatitis B core antigen
Anti-HBc IgM       IgM antibody to hepatitis B core antigen
HBV DNA            hepatitis B virus nucleic acid

8.1 Management of Cases

For the purposes of case and contact management, unspecified cases should be managed as acute cases unless and until further testing indicates that they fit the case definition for chronic infection.

- Any patient with hepatitis B infection believed to have been acquired sexually should be considered at high risk for other STIs, including HIV, and should be offered testing for gonorrhea, chlamydia, syphilis and HIV (14). Human papillomavirus (HPV) vaccine should be discussed with women as per the recommendations outlined in the Canada Communicable Disease Report, Volume 33 ACS-2 (2007) National Advisory Committee on Immunization (NACI) statement on Human papillomavirus vaccine (14).
• Any patient with hepatitis B infection believed to have been acquired parenterally should be considered to be at risk for HIV and HCV, and should be offered testing for both (14).

8.11 Management of Acute Cases
• There is no specific therapy for acute HBV infection. Treatment is supportive (18). Acute HBV infection usually does not warrant referral to a hepatitis specialist (5).
• Medication lists should be reviewed and patients should be reminded to avoid medications metabolized by the liver (e.g., acetaminophen) if possible, or limit the doses (7).
• Public Health will contact cases to advise on follow-up testing and for contact identification and follow-up.
• Acute cases should be tested for both HBsAg and anti-HBs six months after initial detection of HBsAg, to assess whether chronicity has developed and to determine the need for ongoing precautions. See “Education of Acute and Chronic Cases” below.

8.12 Management of Chronic Cases
• The objective of treatment in chronic hepatitis B is to prevent the development of cirrhosis and its consequences, liver failure and hepatocellular carcinoma (HCC) (10).
• All patients diagnosed with chronic hepatitis B should be referred to an expert in the field or the Viral Hepatitis Investigative Unit (204-787-3630) for evaluation, treatment if indicated and for advice on over-the-counter medications.
• Treatment may be indicated for individuals presenting with HBeAg positive or HBeAg negative chronic hepatitis B.
• Public Health will contact cases to identify and arrange for follow-up of contacts.
• All patients with chronic HBV infection who have chronic liver disease and who are not immune to hepatitis A should receive hepatitis A vaccine (3, 5, 15, 23).
• See “Education of Acute and Chronic Cases” below.
• All current sexual, needle/razor/toothbrush sharing and/or household contacts as well as those contacts within the previous six months should be identified (3, 19). This timeframe should be extended further back if contact was frequent and after infection developed (when this can be estimated). See “Management of Contacts” below.

8.13 Special Considerations for Management of Pregnant Women
• Consultation with an expert in the field or the Viral Hepatitis Investigative Unit (204-787-3630) is recommended.
• Pregnant women or women who wish to become pregnant and who have hepatitis B infection should be counselled on the risk of transmission to the newborn and the method of preventing such transmission (e.g., hepatitis B immune globulin and HBV vaccine for the infant)(7).
• Pregnant women with acute HBV infection should be retested one month prior to expected date of delivery to determine HBV status. If the pregnant woman is still positive, follow immunization procedures detailed under “Neonatal Contacts” below at time of delivery.
• The same procedures detailed under “Neonatal Contacts” should be followed for infants born to women with chronic HBV infection.
8.14 Education of Acute and Chronic Cases

Cases should be educated about how hepatitis B virus is spread and counselled on how to limit/prevent transmission to others (e.g., immunization of household, sexual, needle, razor or toothbrush-sharing contacts, barrier methods for sexual partners) (7, 15).

- Cases should be instructed not to share toothbrushes, razors or injection drug use equipment (e.g., needles), or donate blood or organs (18, 19).
- Individuals with HBV infection should be instructed to prevent their blood (e.g., cover open wounds) and other potentially infective body fluids (e.g., saliva) from contacting other individuals (7, 18).
- Patients should be educated on how to properly clean up blood spills (15).
- Patients should be advised on the need to inform individuals providing health care or other personal services to them that they have been infected with HBV (23).
- Cases who are medical or dental personnel should be advised not to perform exposure-prone procedures unless they have sought counsel from an expert review panel and have been advised under what circumstances, if any, they may continue to perform these procedures (4, 24, 25).
- Cases should be advised to limit or avoid alcohol consumption as alcohol consumption is a risk factor for more rapid progression to cirrhosis (7, 23).

8.2 Management of Contacts

For management of neonatal contacts see “Neonatal Contacts” below.

Contacts of cases are: all sexual, household as well as needle, razor or toothbrush-sharing contacts within the six months prior to the symptom onset date of the case (3, 19).

Refer to the Integrated Post-Exposure Protocol for HIV, HBV and HCV: Guidelines for Managing Exposures to Blood and Body Fluids available at: http://www.gov.mb.ca/health/publichealth/cdc/protocol/hiv_postexp.pdf for complicated exposure to blood and body fluids situations that are not covered in this protocol (e.g., motor vehicle accidents, occupational needlestick injuries).

Consult a physician specializing in infectious diseases for the post-exposure management of immunocompromised contacts.

Public Health will attempt to locate contacts of cases and inform them of the potential risk of acquiring infection and the need for immunization, unless screening indicates immunity. For sexual partners, barrier methods should be used until immunizations have been administered and adequate anti-HBs demonstrated (19).

- Contacts should be identified and interviewed as soon as possible to initiate and maximize efficacy of immunoprophylaxis. If the case is asymptomatic, the date of onset is the date testing was done. These contacts should be tested for hepatitis B infection (HBsAg) and susceptibility or immunity (anti-HBs). Contacts should be offered the first dose of hepatitis B vaccine after blood has been drawn for testing. See “Acquisition and Administration of HBV Vaccine and HBIG.” If indicated (i.e., HBsAg negative and anti-HBs negative), second and third doses of vaccine should be given one and six months after the first dose to complete the immunization series (3).

- For contacts of acute hepatitis B cases: The following groups should be offered hepatitis B immune globulin (HBIG) in addition to hepatitis B vaccine (3, 19). See section “Acquisition and Administration of HBV Vaccine and HBIG” for indications and clinical use information:
  - all sexual contacts within the last 14 days
  - all needle/toothbrush/razor-sharing contacts within the last seven days
  - all sexual and needle/toothbrush/ razor-sharing contacts, regardless of the interval since last exposure, if there is any chance of future, similar exposures to the case.
• HBlg is not routinely indicated for household contacts of an acute HBV case with the exception of newborns when the mother is acutely or chronically infected (3).

• HBlg may be considered for children younger than 12 months of age who have close contact with a primary caregiver with acute or chronic HBV if the child has received less than two doses of HBV vaccine (5).

• For contacts of chronic hepatitis B cases: HBlg should be considered if sexual or needle/razor/toothbrush sharing contact occurred for the first time in the previous 14 days (3). See section below “Acquisition and Administration of HBV Vaccine and HBlg” for indications and clinical use information.

• Pre-immunization screening of all contacts for markers of infection may be performed at the same time as the first dose of vaccine or vaccine plus HBlg are given (3). In these situations, the blood for pre-immunization screening should be drawn before the administration of hepatitis B vaccine and HBlg to prevent the immunization(s) from interfering with testing results. When requesting screening tests, please indicate “High Risk Pre-Immunization Hep B Screening.” Cadham Provincial Laboratory (CPL) will then automatically screen for HBsAg and anti-HBs. See Table 2 below for follow-up.

**NOTE:** Vaccine and HBlg may be given at the same time but at different injection sites using separate needles and syringes (3).

• Post-immunization testing for anti-HBs should be undertaken in contacts one to six months after completion of the vaccine series (3). If the individual tests anti-HBs negative, administration of additional doses of hepatitis B vaccine (up to three doses) will produce an antibody response in 50% to 70% of healthy adults and children who fail to respond after the first series of vaccine (3). Post-immunization testing is recommended one month after each additional dose. Individuals who fail to respond to three additional doses of vaccine are unlikely to benefit from further immunization (3).

### 8.21 Neonatal Contacts

**Infants Born to HBsAg-Positive Mothers:**

Infants born to HBsAg-positive mothers should receive HBlg (0.5mL) and 0.5 mL HBV pediatric vaccine within 12 hours of birth (refer to product monographs for more information) (3). Vaccine and HBlg may be given at the same time but at different injection sites, using separate needles and syringes (3). The efficacy of HBlg decreases significantly after 48 hours, but may be given up to seven days after exposure (3).

• The second and third dose of the vaccine series should be given one and six months after the first dose (3). The sixth month dose can be given as DTaP-HB-IPV-Hib vaccine (3) subject to availability and current provincial eligibility criteria. See “Acquisition and Administration of HBV Vaccine and HBlg” below for indications and clinical use information.

| Table 2: Recommended Follow-up of Contacts Based on Pre-immunization Serological Test Results |
|---------------------------------|---------------------------------|---------------------------------|
| **HBsAg Positive** | **HBsAg Negative** |
| Anti-HBs Positive | Rare inconsistent finding: Call CPL for clarification and possible repeat testing. | Individual is immune. No further HBV immunization is required. |
| Anti-HBs Negative | Individual is infected. See “Case Management.” Discontinue immunization if already started. | Individual is susceptible. Complete HBV immunization series. Administer HBlg in the indicated groups detailed above. |
• Health care providers are asked to complete the *Hepatitis B-Propylaxis-Record Sheet for Infants* as well as the *Manitoba Immunization Monitoring System (MIMS)* Immunization Monitoring Form for Hospitals and Clinics at the time of prophylaxis. These forms are provided with each vial of HBIG and hepatitis B pediatric vaccine and should be returned along with the infant’s post-partum referral to the regional public health office of the parent/guardian’s region of residence for appropriate public health follow-up including:

  - generating follow-up form letters (to be signed by Regional Medical Officer of Health or designate or First Nations Inuit Health) to the infant’s physician/practitioner and parent/guardian. The follow-up letters will advise that two additional doses of HBV vaccine should be given at one and six months following the first dose.

  - ensuring that there is a plan in place for completion of the HBV vaccine immunization series and post-immunization testing (i.e., notifying the patient/guardian and the infant’s physician/practitioner by letter of what needs to be done). Immunizations (including HBIG) should be entered into MIMS (by either infant’s physician/practitioner or Public Health), once the infant’s Personal Health Information Number (PHIN) is assigned.

• Post-immunization testing of infants for HBsAg and anti-HBs is recommended one month after completion of the HBV vaccine series to determine if protective antibody levels have been achieved in infants born to HBsAg positive mothers (3). If the infant is negative for both HBsAg and anti-HBs (i.e., a vaccine non-responder), additional doses of vaccine (up to a second full course) should be given, followed by repeated serologic testing for antibody response (3) after each dose. If HBsAg is found, the child is likely to become a chronic carrier (see “Management of Chronic Cases”).

**Pre-term Infants Born to HBsAg-Positive Mothers:**

• Pre-term infants (less than 37 weeks gestation) weighing 2,000 grams or more at birth require three doses of hepatitis B pediatric vaccine as described above under *Infants Born to HBsAg Positive Mothers*.

• The response to hepatitis B vaccine may be diminished in pre-term infants weighing less than 2,000 grams at birth (3). Therefore, these infants require four doses of hepatitis B pediatric vaccine, given at birth, and at one, two and six months of age (3, 5). DTaP-HB-IPV-Hib vaccine can be used for the two month and six month doses (3), subject to availability and current provincial eligibility criteria.

• Post-immunization testing should be done one month after the fourth vaccine dose.

**Unscreened Mother About to Deliver:**

• Pregnant women whose hepatitis B status is unknown at delivery should undergo blood (HBsAg) testing as soon as possible to determine their infection status (call Cadham Provincial Laboratory at 204-945-6123 to arrange).

• While awaiting test results, the infant should receive HBIG and the first dose of hepatitis B pediatric vaccine (0.5 mL) within 12 hours of birth (as described above under *Infants Born to HBsAg-Positive Mothers*).

• If the mother is found to have hepatitis B infection (i.e., HBsAg-positive), the hepatitis B pediatric vaccine series should be completed in the infant and post-immunization testing performed as described above under *Infants Born to HBsAg-Positive Mothers*. If the mother tests HBsAg negative subsequent to initiation of immunoprophylaxis, completion of the hepatitis B vaccination series in the infant is still recommended; however, post-immunization testing of the infant is not necessary.

**Other HBsAg-Positive Household Members:**

• If a household member of the infant’s family other than the mother is HBsAg-positive, hepatitis B pediatric vaccine (0.5 mL) should be administered to the infant as described above
under *Infants Born to HBsAg-Positive Mothers.* HBIG is not indicated. See section below “Acquisition and Administration of HBV Vaccine and HBIG.”

**Mother’s Infection Recognized During the First Year of the Infant’s Life:**

- The infant’s HBV status should be assessed urgently and the infant started immediately on the full immunoprophylaxis with hepatitis B vaccine and HBIG as described above under *Infants Born to HBsAg-Positive Mothers.* Immunoprophylaxis should be completed if the infant is found not to be already infected or immune (3).

### 8.3 Acquisition and Administration of HBV Vaccine and HBIG

Sites authorized to stock adult and pediatric formulations of HBIG and hepatitis B vaccines are listed below; specific formulations may or may not be stocked at these sites. To obtain HBIG and HBV vaccine from sites other than those listed below, contact the Provincial Vaccine Warehouse at 204-948-1333 or 1-855-683-3306. After regular office hours the on-call warehouse staff may be contacted at 204-805-4096. A current Biologics/Vaccine Order Form is available by calling the warehouse.

Assistance in determining the need for HBIG and HBV vaccine can be obtained from the local Medical Officer of Health (MOH). Contact information is available at: [http://www.gov.mb.ca/health/publichealth/contactlist.html](http://www.gov.mb.ca/health/publichealth/contactlist.html). After regular office hours, the MOH on-call may be contacted at (204) 788-8666. HBIG and HBV vaccine can be released to a hospital, Public Health Unit or physician.

**Hospitals in Winnipeg:**
- Concordia Hospital
- Grace Hospital
- Health Sciences Centre (Children’s and Adult Emergency)
- Misericordia Urgent Care
- Seven Oaks General Hospital
- St. Boniface General Hospital
- Victoria General Hospital

**Hospitals and Health Centres Outside Winnipeg:**
- Brandon Regional Health Centre
- Boundary Trails Health Centre
- Churchill Health Centre Pharmacy
- Dauphin Regional Health Centre
- Flin Flon General Hospital
- Portage District General Hospital
- Swan River Health Centre
- Thompson General Hospital

Immunization providers should consult the respective product monograph prior to administering HBIG and HBV vaccine for information such as storage and handling requirements, administration schedule, injection site, dose specific to age and weight (for HBIG) etc.

**Note:** Vaccine and HBIG may be given at the same time but at different injection sites using separate needles and syringes (3).

- **HBIG:**
  - Administration is intramuscular (anterolateral thigh muscle of infants; deltoid muscle of children and adults) (3).
  - The standard HBIG dose for newborns and children up to 8.3 kg is 0.5 mL; the dose for children over 8.3 kg and adults is 0.06 mL/kg.

- **HBV Vaccine:**
  - Administration is intramuscular (anterolateral thigh muscle of infants; deltoid muscle of children and adults) (3).
  - There are various HBV vaccine schedules, formats, strengths.
  - Infants born to HBV-positive (or suspected to be positive) mothers should receive 0.5 mL (5 µg) of the pediatric formulation for each dose.
  - Preferred schedule: second and third doses of HBV vaccine should be administered one and six months after the start of the immunization series unless otherwise indicated (e.g., serologic testing demonstrates HBsAg positivity).
8.4 Management of Outbreaks

- A thorough investigation should be undertaken to determine source and institute preventive measures if possible.
- See Manitoba Provincial Outbreak Response Plan (ORP).
- Consider mass immunization in situations where control of transmission is likely to be difficult (e.g., correctional facilities).

8.5 Preventive Measures

8.51 Screening

- Prenatal screening is strongly recommended for all women for each pregnancy, even if they were HBsAg positive in the past, so that newborns can receive prophylaxis if necessary (3, 5). Practitioners are requested to tick-off the “prenatal” box on the Cadham Provincial Laboratory (CPL) requisition.
- Screening of blood donors and individuals at high risk of infection, including individuals entering a health care profession, persons or adopted children from countries or family situations in which there is a high prevalence of infection, men who have sex with men, bisexual males and heterosexual males or females with multiple sexual partners or with a recent history of sexually transmitted infection, injection drug users and those with a hepatitis B carrier in the household (3, 5, 14).

8.52 Immunization

- Universal pre-exposure immunization programs as well as ongoing immunization of populations at increased risk. Please see the eligibility criteria for provision of publicly funded vaccine on the Communicable Disease Control Branch web site at: www.gov.mb.ca/health/publichealth/cdc/vaccineligibility.html.
- Please refer to the most recent edition of the Canadian Immunization Guide for indications and clinical use information.

8.53 Contact Investigation and Follow-up

- Appropriate identification and follow-up of:
  - Contacts of acute and chronic cases
  - Perinatal contacts
  - Individuals who have sustained an exposure to blood and body fluids (e.g., needlestick injury in a health care worker) and are deemed at risk of acquiring infection. Refer to the Integrated Post-Exposure Protocol for HIV, HBV and HCV: Guidelines for Managing Exposures to Blood and Body Fluids available at: http://www.gov.mb.ca/health/publichealth/cdc/protocol/hiv_postexp.pdf

8.54 Post-immunization Testing

- For individuals who may respond sub-optimally to hepatitis B vaccine (e.g., immunocompromised);
- For high risk pregnant women who are immunized before or during pregnancy;
- For individuals at high risk of exposure or re-exposure to HBV-infected individuals which may include the following:
  - infants born to HBV-infected mothers;
  - sexual partners and household contacts of acute cases and chronic carriers of hepatitis; and
  - those who have been immunized because of risk of occupational exposure or percutaneous or mucosal exposure to hepatitis B (3, 5).

8.55 Health Care Precautions

- Routine Practices including safe disposal of sharps.
- Adequate sterilization of instruments used in invasive procedures, including personal care services (e.g., piercing, tattooing).
- Avoidance of personal care services (e.g., piercing, tattooing).
- Appropriate disinfection measures following body fluid spills.
- Restricting the performing of exposure-prone procedures for medical and dental personnel who are infected with HBV, unless they have sought counsel from an expert review panel and have been advised under what circumstances, if any, they may continue to perform these procedures (4, 24, 25).
8.56 Harm Reduction Activities

- The risk of HBV transmission through injection drug use (IDU) can be significantly reduced by use of a new needle, syringe, and all other IDU equipment (e.g., filters, water, spoon) for each injection.
- Harm reduction activities such as safe injection practices may help to reduce HBV transmission within injection drug using populations.

9. Additional Resources

9.1 Canadian Liver Foundation
9.2 Canadian Association for the Study of the Liver
9.3 Cadham Provincial Laboratory Guide to Services

References


