## Communicable Disease Management Protocol

## Hepatitis B Newborn Prophylaxis



Public Health Branch

The following hepatitis B newborn prophylaxis protocol applies to:

- A. Infants Born to Hepatitis B Surface Antigen (HBsAg)-positive Mothers
- B. Infants Born to Unscreened Mothers
- C. Infants Born to Families with a Household Member Known to be HBsAg-positive

Immunization providers should consult the respective product monograph prior to administering hepatitis B immune globulin (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. to ensure appropriate use.

NOTE: As the follow-up of the newborn is determined by the parent/guardian's area of residence, which may be in a First Nations Inuit Health jurisdiction, references to Public Health or instructions for Regional Public Health include First Nations Inuit Health Branch.

At the time of prophylaxis, health care providers should: (1) complete the *Hepatitis B – Prophylaxis Record Sheet for Infants* <a href="http://www.gov.mb.ca/health/publichealth/cdc/protocol/hepb\_infantrecord.pdf">http://www.gov.mb.ca/health/publichealth/cdc/protocol/hepb\_infantrecord.pdf</a> and (2) enter the immunization data (HBIG and HBV vaccine) directly into the Public Health Information Management System (PHIMS), the Manitoba immunization registry. Where direct data entry or submission of the tariff code(s) through claims is not possible, immunization providers are to complete the *Immunization Inputting Form for Health Care Providers* <a href="http://www.gov.mb.ca/health/publichealth/cdc/div/docs/iifhcp.pdf">http://www.gov.mb.ca/health/publichealth/cdc/div/docs/iifhcp.pdf</a>. These forms 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 followup letters will advise that two additional doses of hepatitis B pediatric 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 hepatitis B pediatric 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 should be entered into PHIMS (by either direct entry or through submission of claims by the infant's physician/practitioner), once the infant's Personal Health Information Number (PHIN) is assigned. If a provider does not have direct access to the immunization registry or claims, complete and submit to the local public health office as soon as possible the *Immunization Inputting Form for Health Care Providers* <a href="http://www.gov.mb.ca/health/publichealth/cdc/div/docs/iifhcp.pdf">http://www.gov.mb.ca/health/publichealth/cdc/div/docs/iifhcp.pdf</a>.

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### A. Infants Born to Hepatitis B Surface Antigen (HBsAg)-positive Mothers

When a pregnant woman is identified as being HBsAg-positive from prenatal serology, Cadham Provincial Laboratory (CPL) will notify Manitoba Health, Seniors and Long-Term Care (MHSLTC) who will forward the information to Regional Public Health. Regional Public Health will generate a follow-up form letter (to be signed by the Regional Medical Officer of Health or designate) to the mother's prenatal care physician/practitioner. The follow-up letter will advise that hepatitis B pediatric vaccine and HBIG should be given at birth as described below.

For the prevention of perinatal transmission of hepatitis B virus (HBV) in infants born to HBsAgpositive mothers, monovalent hepatitis B pediatric vaccine and HBIG may be given at the same time but at different injection sites, using separate needles and syringes. Passive antibody from HBIG does not interfere with an active response to hepatitis B pediatric vaccine.

- 1) Give HBIG (0.5 mL IM) in the anterolateral thigh immediately after birth (within 12 hours) (refer to product monograph).
- 2) Give 0.5 mL monovalent hepatitis B pediatric vaccine IM (refer to product monograph).
- 3) The infant will require two additional doses of vaccine at **one** and at **six** months of age. Other hepatitis B virus containing vaccines (instead of the monovalent vaccine) can be used for the sixmonth vaccine dose. The regional health authority of residence of the infant's parent/guardian will send a letter to the parent/guardian as well as to the infant's physician/practitioner indicating that two more doses of vaccine are required, along with ordering instructions and a reminder that immunizations should be entered into the Manitoba immunization registry.

  NOTE: The response to hepatitis B pediatric vaccine may be diminished in pre-term infants (<37 weeks gestation) weighing less than 2,000 grams at birth. Therefore, these infants require a total of four doses of hepatitis B vaccine, given at **birth**, and at **one**, **two** and **six** months of age. Other HBV containing vaccines (instead of the monovalent vaccine) can be used for the two-month and six-month vaccine doses.
- 4) **Post-immunization testing:** In order to avoid detection of passive anti-HBs (antibody to hepatitis B surface antigen) from HBIG administered at birth, and to maximize the likelihood of detecting late HBV infection, infants born to HBV-infected mothers should not be tested for HBsAg (to see if the infant is infected) and anti-HBs (to see if the infant is protected), prior to nine months of age. Testing should be conducted at least one month and no more than four months after the last dose of vaccine is administered. The post-immunization testing recommendation is included in the letter to the infant's parent/guardian as well as in the letter to the infant's regular physician/practitioner.

#### **B. Infants Born to Unscreened Mothers**

• 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).

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- If maternal hepatitis B status is not available within 12 hours of delivery, administer monovalent hepatitis B pediatric vaccine. In addition, consider administering HBIG while the mother's results are pending if there is any suspicion that the mother could be infected (i.e., consider the mother's risk factors).
- HBIG effectiveness following exposure decreases over time, with a significant decrease reported after 48 hours of delivery. HBIG may be provided up to seven days after delivery, but optimally within 12 to 48 hours after delivery.
- Hepatitis B vaccine effectiveness may be decreased in newborns with low birthweight (<2000g). Therefore, early administration (within 12 hours of delivery) of HBIG together with monovalent hepatitis B pediatric vaccine is recommended for newborns with low birthweight (<2000g) if there is uncertainty regarding the mother's risk of infection.
- 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 in steps 3 and 4 in Section A. 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.

# C. Infants Born to Families with a Household Member known to be HBsAgpositive

• 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 in steps 2 to 4 in Section A. HBIG is not indicated.