# Maternity: Neonatal Hepatitis B Prevention and Vaccination

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**Version History V1**
Maternity: Neonatal Hepatitis B Prevention and Vaccination

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Maternity: Neonatal Hepatitis B Prevention and Vaccination

1. Introduction
Hepatitis B is a DNA virus that is transmitted by exposure to infected body fluids through sexual contact, sharing contaminated equipment or from mother to child during pregnancy or birth. Infection causes significant morbidity and mortality, and remains an important public health problem globally. Prevalence is increasing in Australia. Vaccination is highly effective in prevention of transmission of perinatally acquired hepatitis B. This policy aims to implement the NSW Neonatal Hepatitis B Prevention and Vaccination Policy for SLHD Women and Babies. A secondary aim to provide a brief educational overview of hepatitis B for staff in newborn care settings.

2. The Aims / Expected Outcome of this Policy Compliance Procedure
- All women will be screened for hepatitis B during pregnancy
- All HBsAg positive women will be tested for viral load and liver function
- All infants born to HBsAg positive women will be administered HBIG within 12 hours of birth
- All infants born to HBsAg positive women will be administered hepatitis B vaccine within 7 days of birth
- All infants born to HBsAg positive women will have a letter sent to the their GP confirming immunoprophylaxis
- All infants born to HBsAg positive women will have serology assessed 3 months after completion of primary hepatitis B vaccination course

3. Risk Statement
SLHD Enterprise Risk Management System (ERMS) Risk # 1 - Unwarranted deviation from standards of clinical care

4. Scope
- RPAH Women and Babies and Canterbury Maternity and Neonatal Units

5. Resources
Australian Society for Infectious Diseases: Management of Perinatal Infections
Royal Australia and New Zealand College of Obstetricians and Gynaecologists: Management of Hepatitis B in Pregnancy
Hepatitis B vaccination information brochure for parents
Pregnancy vaccination information brochure for parents
Both the above brochures are available in 23 languages at the NSW health immunisation website.
Australian Immunisation Handbook
http://www.hepbhelp.org.au/
6. **Implementation**

- Key performance indicators as detailed below to be reported annually by SLHD Immunisation Coordinator to Health Protection NSW
- Incident Information Management System (IIMS) reporting as detailed

7. **Key Performance Indicators and Service Measures**

- All women will be screened for hepatitis B during pregnancy or up to 2 hours following delivery
- All HBsAg positive women will be tested for viral load and liver function
- All infants born to HBsAg positive women will be administered HBIG within 12 hours of birth
- All infants born to HBsAg positive women will be administered hepatitis B vaccine within 7 days of birth
- All women with a high viral load (>200,000IU/ml or liver function test ALT >40IU/L) will be referred to a liver clinic/specialist hepatologist for an appointment prior to 32 weeks
- All infants born to HBsAg positive women will have serology assessed 3 months after completion of primary hepatitis B vaccination course
- All incidents where the above measures were missed will be reported via IIMS

8. **Guidelines**

8.1 **Summary**

Hepatitis B is a DNA virus. Infection causes significant morbidity and mortality, and remains an important public health problem globally. It is transmitted through contact with the blood or bodily fluids of an infectious person. Hepatitis B is commonly acquired either perinatally, by sexual contact, by sharing injecting equipment or by exposure to infectious fluids. Vaccination is the most effective way of preventing Hepatitis B. Vertical transmission of hepatitis B from a carrier mother to baby can be prevented in >90% by administration of hepatitis B vaccine and immunoglobulin to the baby within 72 hours of birth.

**Key points:**

- All neonates should be offered hepatitis B vaccination at birth, or within 7 days of birth
- Infants born to HBsAg positive mothers should receive HBIG within 12 hours of birth plus hepatitis B vaccination
- Infants of HBsAg positive mothers require follow up serology 3-12 months after their primary hepatitis B vaccination course (not before 9 months of age), to be organised by their GP
- Before discharge from the postnatal ward, there must be a letter to the GP regarding follow up serology, with a copy for and explained to the mother. A sticker should be placed on the ‘immunisation’ page of the blue book as a reminder.
8.2 Incidence

Prevalence of hepatitis B varies widely around the world, and may be more than 10% in some countries in Sub-Saharan Africa and South East Asia. In Australia, prevalence is estimated at approximately 1% of the population, with 0.7 new cases per year per 100,000.1 Although incidence has declined by 50% over the past 10 years, prevalence has increased primarily due to the increase in migrants from countries where hepatitis B is endemic.

8.3 Aetiology and Risk Factors

- There are 4 major routes of transmission of hepatitis B virus:
  - Vertical transmission from mother to child during pregnancy or delivery
  - Exposure to infected body fluids, eg sharing injecting equipment
  - Sexual contact
  - Horizontal transmission, eg exposure through household contacts or open wounds

The majority of cases of vertical transmission usually occur around the time of delivery, via exposure to infected blood and cervical secretions. Transplacental transmission is responsible for the remainder of vertical infection.

8.3.1 Risk factors for transmission

- **Maternal hepatitis B e antigen (HBeAg) status.** Mothers who are HBeAg positive have a 70-90% chance of transmission of hepatitis B to their infant in the absence of post-exposure immunoprophylaxis. Neonatal active and passive immunisation reduces the transmission rate to 1-10%. HBeAg negative mothers in contrast, have a 10-40% rate of transmission.2
- **High maternal viral load** is related to the risk of transmission, and may contribute to the failure of immunisation to prevent hepatitis B.3
- **Active and passive neonatal immunisation** reduces the transmission rate to around 1-10%.4-6
- **Obstetric procedures** such as amniocentesis or fetal scalp electrodes may increase risk of transmission, but is rare. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists recommend careful antenatal counselling of mothers, avoidance if possible and consideration of alternative options, eg non-invasive prenatal tests.7

There is no evidence at present that the following alter the transmission of hepatitis B:

- **Mode of delivery.** Elective Caesarean section has not been shown to reduce hepatitis B transmission.8
- **Breastfeeding.** Hepatitis B DNA and HBsAg may be detected in breast milk. However, meta-analysis shows no difference in transmission rates in breastfeeding infants compared to formula feeding infants provided the infant has received hepatitis B vaccination and immunoglobulin.9
- **Preterm premature rupture of membranes**3
8.4 Diagnosis

Diagnosis is made on serological testing. For a simple summary of hepatitis B serology, see Table 1.

<table>
<thead>
<tr>
<th>Serological marker (abbreviation)</th>
<th>Description</th>
<th>Indications of a positive test</th>
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<tr>
<td>Hepatitis B Surface Antigen (HBsAg)</td>
<td>Protein on the surface of hepatitis B virus, appears 1-10 weeks after exposure to the virus</td>
<td>Active infection (acute or chronic)</td>
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<tr>
<td>Hepatitis B Early Antigen (HBeAg)</td>
<td>Protein secreted by infected cells.</td>
<td>Usually indicates active viral replication and high infectivity</td>
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<tr>
<td>Hepatitis B Core Antigen (HBcAg)</td>
<td>Intracellular antigen found in infected hepatocytes</td>
<td>Not detectable within serum – antibody response is looked for instead</td>
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<tr>
<td>Antibody to HBsAg (Anti-HBs)</td>
<td>Appears during recovery from acute infection</td>
<td>Immunity from successful vaccination or previous infection</td>
</tr>
<tr>
<td>Antibody to HBcAg (Anti-HBc)</td>
<td>Appears at the onset of infection and persists for life.</td>
<td>Infection - current or previous IgM anti-HBc = acute or recent (&lt;6 months) infection</td>
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<tr>
<td>Antibody to HBeAg (Anti-HBe)</td>
<td>Appears with recovery from acute infection</td>
<td>Usually indicates inactivity of virus and low infectivity</td>
</tr>
<tr>
<td>Hepatitis B DNA (HBV DNA)</td>
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<td>Quantification of viral load</td>
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Table 1. Summary of hepatitis B serology

All pregnant women must be offered screening for hepatitis B surface antigen (HBsAg). HBsAg positive women must be offered further testing to determine staging of disease and risk of infectivity, including viral load and history of prior maternal infant transmission. Please see Interventions and Appendix 1 for a flow chart of Referral and Management of HBsAg positive Women and Infants.

Maternal results are entered into Cerner Maternity, and should also be documented on the maternal antenatal card.

HBsAg positive pregnant women with a high viral load (>200,000IU/ml) or liver function test ALT result 40IU/L or higher should be under the care of a liver specialist.
8.5 Consequences

As discussed above, even with vaccination 1-10% of infants of mothers with hepatitis B will become infected.4-6 Infants infected at birth are almost always asymptomatic. Of those infants infected with hepatitis B, up to 90% will become chronic carriers, with approximately 25% of those with chronic infection dying prematurely of cirrhosis or hepatocellular carcinoma.7

8.6 Interventions

8.6.1 All neonates:

Parents of all infants born at SLHD should be offered the Hepatitis B Vaccination for your Newborn Baby brochure to ensure informed decision making when consenting to the Hepatitis B vaccination programme.

All neonates (regardless of maternal HBsAg status) should be offered the Hepatitis B vaccination preferably within 24 hours of birth and before 7 days of age. Administration of the vaccine is entered into Cerner Maternity and the neonate’s Personal Health Record.

The birth dose of Hepatitis B vaccine must not be given any later than 7 days of age, based on the expected period that the vaccine may be effective as prophylaxis, should an unexpected exposure have occurred at birth and to prevent interference with the next dose due at 6 weeks of age. A catch dose of Hepatitis B vaccine is not recommended if the birth dose has not been administered.

All neonates require a three dose course of hepatitis B-containing combination vaccine at 6 weeks, 4 and 6 months.

Low birth weight and preterm infants do not respond as well to Hepatitis B vaccines as term infants. For low birth weight infants (<2kg) and/or those born before 32 weeks gestation (regardless of weight), it is recommended that the vaccine is administered at birth, 6 weeks, 4 months and 6 months of age, followed by either:

- Measuring the anti-HBs antibody level of 7months of age. If the antibody titre level is <10mlU/ml, giving a booster at 12 months of age or
- Giving a boosters of hepatitis B vaccine at 12months of age (without measuring the antibody titre)

The infant’s Personal Health Record must be updated with every encounter to ensure completeness of information.

8.6.2 Neonates born to HBsAG positive mothers:

These neonates must be offered hepatitis B immunoglobulin (HBIG) within 12 hours of birth and a total of 4 doses of hepatitis B vaccine at birth, 6 weeks, 4 and 6 months of age. HBIG and hepatitis B vaccine can be given concurrently using a different thigh.

If HBsAg positive mothers refuse administration of the vaccine and HBIG, counselling should be provided regarding the risks of contracting hepatitis B disease and its consequences. A report should be forwarded to the child protection services at Family and Community...
Services regarding HBsAg positive women who refuse HBIG and the birth dose of hepatitis B vaccine for their infant. An incident information management system report (IIMS) must also be submitted.

8.6.3 **Further testing and follow up of infants born to HBsAg positive mothers**

All infants born to HBsAg positive mothers are to be monitored for completion of their primary hepatitis B vaccination course.

All infants born to HBsAg positive mothers require follow up serology 3-12 months after completion of their primary hepatitis B vaccination course (and not before 9 months of age) to check if they are protected.

A neonatal hepatitis B follow up letter must be completed and forwarded to the mother’s doctor upon discharge from the hospital. A copy of this letter should be given to the mother upon discharge with a full explanation of the infant’s follow up requirements. A sticker (kept in NICU) should be placed on the immunisation page of the Blue Book as a reminder.

Infants with an anti-HBs level of <10IU/ml of who are HBsAg positive must be referred to the Paediatric Viral Hepatitis Network (at The Children’s Hospital, Westmead) or a local specialist service (e.g. Infectious Diseases Clinic at Sydney Children’s Hospital, Randwick) for ongoing management.

**Contact details:**
- CHW Gastroenterology: 02 9845 3999
- SCH Infectious diseases: 02 9382 3418
- CHW Infectious diseases: 02 9382 1508

**8.7 Reporting requirements**

- An IIMS report must be submitted by the person that identifies an incident when:
  - A pregnant women has not been screened for hepatitis B during pregnancy or up to 2 hours after delivery;
  - A neonate born to a HBsAg positive mother has not received hepatitis B immunoglobulin within 12 hours of birth;
  - A neonate born to an HBsAg positive mother has not received hepatitis B vaccine within 7 days of birth;
  - A HBsAg positive mother is not provided with a copy of the infant’s follow-up letter to the GP;
  - An infant born to an HBsAg positive mother has not been followed-up to ensure completion of the hepatitis B vaccination course and follow-up serology recommended (does not include ‘lost to follow-up’ infants).

**9. Consultation**

RPAH Newborn Care Guidelines Committee
Clinical Midwifery Consultant, Canterbury Hospital
Neonatology, Canterbury Hospital
Paediatrics, Canterbury Hospital
10. References


10.1 National Safety and Quality Health Service (NSQHS) Standards, 2nd Ed.

- Standard 1: Clinical Governance
- Standard 2: Partnering with Consumers
- Standard 3: Preventing and Controlling Healthcare-Associated Infection
- Standard 8: Recognising and Responding to Acute Deterioration