Neonatal Hepatitis B Prevention and Vaccination Program

Summary  This policy directive specifies the requirements for neonatal hepatitis B prevention and vaccination which includes screening of pregnant women for hepatitis B surface antigen, referral of HBsAg positive women to a hepatologist specialist service, treatment and follow-up of infants born to HBsAg positive women, vaccination of all infants against hepatitis B and reporting of neonatal hepatitis B vaccination program data.

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Distributed to  Divisions of General Practice, Government Medical Officers, Ministry of Health, NSW Ambulance Service, Private Hospitals and Day Procedure Centres, Public Health System, Tertiary Education Institutes
Audience  All clinical staff, nursing, administration staff

Secretary, NSW Health
This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is mandatory for NSW Health and is a condition of subsidy for public health organisations.
NEONATAL HEPATITIS B PREVENTION AND VACCINATION PROGRAM

PURPOSE
This policy aims to ensure consistent implementation of the NSW Neonatal Hepatitis B Prevention and Vaccination Program in all Local Health Districts (LHDs). The policy focuses on screening of all pregnant women for hepatitis B disease and their referral to a specialist hepatology service and the follow-up and management of all infants born to hepatitis B surface antigen (HBsAg) positive women.

MANDATORY REQUIREMENTS
All pregnant women must be offered HBsAg screening and provided with verbal and written communication about hepatitis B disease and the neonatal hepatitis B vaccination program. All infants must be offered hepatitis B vaccine at birth (within 7 days) and all infants born to HBsAg positive women must also be offered hepatitis B immunoglobulin (HBIG) within 12 hours of birth. All infants born to HBsAg positive women must also be followed-up to ensure completion of their primary hepatitis B vaccination course and subsequent serology.

IMPLEMENTATION
Local Health Districts will:
- Establish definitive governance pathways to ensure that all implementation responsibilities (Sections 2, 3, 4 and 5) are assigned to the relevant staff to meet the requirements of this policy directive. This will require extensive consultation, collaboration and agreement within each LHD.
- Report to Health Protection NSW as specified in Section 6.
- Report to Health Protection NSW on the program’s Key Performance Indicators (Section 7).
- Manage Incident Information Management System reporting as detailed in Section 8.

Health Protection NSW will:
- Collate LHD quarterly and KPI reports and report on program performance to the Deputy Secretary Population and Public Health and Chief Health Officer.
- Provide support to LHDs regarding program implementation as required.
REVISION HISTORY

<table>
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<th>Version</th>
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<th>Amendment notes</th>
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<td>October 2017</td>
<td>Deputy Secretary, Population and Public Health and Chief Health Officer</td>
<td>The previous PD2005_222 Hepatitis B Vaccination Policy provided direction on vaccination of at-risk groups and was last reviewed in 2005. The revised policy focuses on the referral and management of HBsAg positive women and their infants.</td>
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1 BACKGROUND

1.1 About this policy
This policy specifies the requirements for neonatal hepatitis B vaccination and reporting with regard to:

- Screening of pregnant women for hepatitis B surface antigen (HBsAg);
- Referral of HBsAg positive women to specialist services;
- Treatment of neonates born to HBsAg positive mothers;
- Follow-up of infants born to HBsAg positive mothers;
- Vaccination of all infants;
- Neonatal hepatitis B vaccination program data.

This policy relates only to neonatal hepatitis B vaccination recommendations and should be read in conjunction with the current edition of *The Australian Immunisation Handbook*. The National Health and Medical Research Council’s hepatitis B vaccination recommendations for additional groups of people (i.e. Aboriginal people, health care workers and child care workers) should be followed as specified in the current edition of *The Australian Immunisation Handbook*.

Each Local Health District must have definitive governance pathways established to ensure that responsibilities are assigned to the relevant staff to meet the requirements of this policy directive.

1.2 Prevalence, Risk and Prevention
Hepatitis B virus is transmitted through contact with blood or body fluid of an infectious person, and is commonly acquired either perinatally, by sexual contact, by sharing injecting equipment or by exposure to infectious fluids. In NSW in excess of 2,000 new hepatitis B diagnoses are made each year and newly acquired cases of hepatitis B virus (HBV) mostly occur in young adults\(^1\). Vaccination is the best way to prevent hepatitis B. A strategy for the prevention of hepatitis B through immunisation commenced in Australia in the early 1980’s and a universal infant hepatitis B program commenced nationally in 2000\(^2\). In NSW an adolescent hepatitis B vaccination program commenced in 2004 and continued until 2013, when all infants vaccinated in the universal program reached adolescence. Currently all infants in NSW are offered four doses of hepatitis B vaccine, at birth, 6 weeks, 4 and 6 months of age. The rationale for recommending the birth dose for all newborn infants is not only to prevent vertical transmission from a mother with chronic hepatitis B infection (there may be incomplete or delayed maternal testing, reporting, communication or appropriate response), but also to prevent horizontal transmission to the infant in the first months of life from persons with chronic hepatitis B infection who are household or other close contacts. NSW Health has released its inaugural *NSW Hepatitis B Strategy 2014-2020* which details the priorities to reduce the transmission of hepatitis B in NSW\(^3\).
1.3 Key definitions

**Australian Immunisation Register (AIR)** – a system that records the information about vaccinations given to all persons in Australia. The AIR was previously known as the Australian Childhood Immunisation Register (ACIR) which was established in 1996 and held the information about vaccinations given to children from birth up to seven years of age. The ACIR transitioned to the AIR in September 2016 and records information about vaccinations given at any age.

**Follow-up** – involves reasonable attempts (up to six attempts are considered reasonable) to contact a hepatitis B positive mother and provide advice on the importance of completing her infant’s primary hepatitis B vaccinations (if they are overdue) and serological testing requirements following completion of the primary hepatitis B vaccinations.

**Hepatitis B surface antigen** (HBsAg) – a protein on the surface of the hepatitis B virus. It can be detected in high levels in serum during acute or chronic hepatitis B virus infection.

**HBsAg positive serology result** – the presence of HBsAg indicates active hepatitis B infection which can be spread to others.

**Hepatitis B Immunoglobulin** – a protein extract from blood that provides temporary immunity to hepatitis B disease.

**Hepatitis B vaccination schedule** – the National Health and Medical Research Council (NH&MRC) recommends a birth dose of hepatitis B vaccine (administered within 7 days of birth) followed by three further doses at 6 weeks, 4 and 6 months of age.

**Incident Information Management System (IIMS)** – a state-wide system that records all healthcare incidents for follow-up by the relevant manager to minimise the clinical risks in health services through the management of health care incidents as they occur.

**Incidents** – refers to instances where the requirements of this policy have not been met and as specified in Section 8 Incident Information Management System.

**Hospital Neonatal Hepatitis B Coordinator** – a person who has been nominated by the hospital as an appropriate staff member with the knowledge and skills to coordinate the neonatal hepatitis B vaccination program and report to the local Public Health Unit (PHU) Immunisation Coordinator monthly and as specified in Section 6.

**LHD Immunisation Coordinator** – a senior public health unit officer responsible for liaising with the private and public hospitals in their local health district regarding implementation of the neonatal hepatitis B vaccination program and reporting to Health Protection NSW as specified in Attachment 4.

**Lost to follow-up** – an infant is considered ‘lost to follow up’ when they are overdue one month after their scheduled due date of their fourth dose of hepatitis B vaccine (includes birth dose) and their mother is not contactable by the Local Health District (LHD) Coordinator. This includes children who were born in Australia but have moved overseas. Children should only be classified as lost to follow-up when all reasonable attempts have been undertaken to contact the mother or their primary health care provider. A child who is lost to follow-up must not be counted in the ‘overdue for completion of hepatitis B’ reporting. Should an Aboriginal child be at risk of being lost to follow up, a referral should be made to the Aboriginal Immunisation Health Worker at the PHU to facilitate further follow up.
Neonatal Hepatitis B Prevention and Vaccination Program

PROCEDURES

Neonate – a live newborn infant from birth to 28 days old.

Overdue for completion of hepatitis B vaccination course – an infant is considered overdue for completion of their hepatitis B vaccination course one month after the scheduled due date of the fourth dose (includes birth dose) of vaccine, however for reporting purposes, only infants who are three months overdue are counted in the ‘overdue for completion of hepatitis B course’ report and not counted in the lost to follow-up data.

1.4 Legal and legislative framework

Under the NSW Public Health Act 2010, hepatitis B disease is a Schedule 1 Category 3 notifiable medical condition, for example, laboratories are required to notify detection of viral antigen or of HBV deoxyribonucleic acid (DNA).

2 SCREENING AND REFERRAL

All pregnant women

• All pregnant women must be offered screening for hepatitis B surface antigen (HBsAg) and provided with verbal and written information about hepatitis B disease and the neonatal hepatitis B vaccination program (refer to the NSW Health Hepatitis B Vaccination for your Newborn Baby brochure). 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.

• The screening results must be entered into the eMaternity or Cerner Maternity databases according to whichever system is used in the LHD. The results should also be recorded on the NSW Health Antenatal Card in case the woman delivers outside the LHD.

• Women who do not have a known HBsAg status at the time of admission to hospital or labour ward should have urgent HBsAg testing to determine their hepatitis B status as soon as possible.

• HBsAg positive pregnant women with a high viral load$^4 (>200,000IU/ml) or liver function test ALT result 40IU/L or higher must be referred to a liver clinic/specialist hepatologist (unless they are already under the care of a specialist) for an appointment to enable sufficient time for assessment and commencement of antiviral therapy according to local and/or international guidelines$^5 as anti-viral medication administered in the third trimester may further reduce the risk of transmission of hepatitis B to the neonate. Commencement of treatment will be at the discretion of the treating specialist.

• Management of all other HBsAg positive women (with a viral load $\leq$200,000IU/ml or liver function test ALT less than 40IU/L) must include monitoring of their hepatitis B disease and their infant’s screening and vaccination by either their GP or specialist liver service.

• An interpreter service must be used where there is any doubt about the woman’s English comprehension.

• An incident information management system (IIMS) report must be submitted according to the circumstances specified in section 8.
3 VACCINATION

All neonates

- Parents of all neonates should be given the *Hepatitis B Vaccination for your Newborn Baby* brochure to ensure informed decision making when consenting to the neonatal hepatitis B vaccination program.

- All neonates (regardless of the HBsAg status of the mother), must be offered hepatitis B vaccine preferably within 24 hours and definitely within 7 days of birth, and recorded in the eMaternity or Cerner Maternity database and the neonate's Personal Health Record.

- The birth dose of hepatitis B vaccine must be given no later than 7 days of age, based on the expected period that the vaccine may be effective as prophylaxis, should an undetected exposure have occurred at birth, and to prevent interference with the next dose due at 6 weeks of age. Therefore, catch-up of the birth dose is not recommended if it has not been administered within 7 days of birth.

- Following the birth dose of hepatitis B vaccine, all infants require a three-dose course of hepatitis B-containing combination vaccine at 6 weeks, 4 and 6 months of age.

- Low birth weight and preterm newborn neonates do not respond as well to hepatitis B-containing vaccines as full-term infants. Thus, for low birth weight neonates (<2000g) and/or those born at <32 weeks gestation (irrespective of weight), it is recommended that the vaccine is given in a 4-dose schedule at 0 (birth), 2 (can be given as early as 6 weeks of age if infant’s weight is ≥1.5kg, seek specialist advice as necessary), 4 and 6 months of age, followed by either:
  - measuring the anti-HBs antibody level at 7 months of age, and if the antibody titre is <10 mIU/mL, giving a booster at 12 months of age (due to a better immunogenic response at this age compared with a younger age); or
  - giving a booster of a hepatitis B vaccine at 12 months of age (without measuring the antibody titre).

- The infant’s Personal Health Record must be updated at each encounter to ensure completeness of information to inform all clinicians involved in their care.

Neonates born to HBsAg positive mothers

Refer Section 5 for detailed information on screening and vaccination.

- Neonates born to HBsAg positive mothers must be offered hepatitis B immunoglobulin (HBIG) within 12 hours of birth and a total of four doses of hepatitis B vaccine at birth, 6 weeks, 4 and 6 months of age. The birth dose of hepatitis B vaccine can be given concurrently with HBIG using a different thigh.

- Counselling regarding the risks of contracting hepatitis B disease and its consequences should be provided by staff (with expertise in hepatitis B disease) to HBsAg positive mothers who refuse HBIG and/or hepatitis B vaccination for their infant. 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 (IIMS) report must be submitted according to the circumstances specified in section 8. All incidents must be discussed with the Nursing Unit Manager/Midwifery Unit Manager of the ward prior to maternal discharge.

4 IMPLEMENTATION RESPONSIBILITIES

• Each hospital maternity unit must designate one person as the Hospital Neonatal Hepatitis B Coordinator (‘Hospital Coordinator’) and forward their contact details to their LHD Immunisation Coordinator at the local PHU.

• Each LHD must designate one person as the neonatal hepatitis B vaccination program LHD Immunisation Coordinator.

• Within each LHD, collaboration between all relevant staff must occur to ensure that responsibilities are appropriately designated to ensure that:
  − pregnant women with a high viral load are referred to a liver specialist;
  − infants born to HBsAg positive women are followed up to check for timely completion of their primary hepatitis B vaccination course and subsequent serology, and;
  − infants with an anti-HBs level <10IU/mL or who are HBsAg positive are 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 (see Section 11 ‘Resources’ for more information).

• Refer to Attachments 2-4 for reporting requirements and documentation.

5 FURTHER TESTING AND FOLLOW-UP OF INFANTS BORN TO HBsAg POSITIVE MOTHERS

• Attachment 5 provides a clinical pathway for the management of an HBsAg positive woman and her infant. The pathway may be adapted according to the model of care in each LHD, for example, in some LHDs all HBsAg positive women are referred to the liver clinic/specialist for assessment, treatment and management.

• All women with a high viral load must be referred (according to LHD policy) to a liver clinic/specialist for ongoing management. Her infant’s vaccination record must be checked to ensure timely completion of the primary hepatitis B vaccination schedule. Where a child is found to be late with their scheduled vaccinations, the woman should be prompted to make arrangements to have her child vaccinated.

• All infants born to a HBsAg positive woman are to be monitored for completion of their primary hepatitis B vaccination course (refer to the flowchart in Attachment 5).

• 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 nine months of age) to check if they are protected. Mothers of infants born to HBsAg positive mothers must be educated prior to discharge about their infant’s requirement for follow-up serology as even optimal preventive measures fail in some cases.
Each maternity unit must complete a neonatal hepatitis B follow-up letter (refer to the template in Attachment 1) for neonates born to HBsAg positive mothers and forward this letter to the mother's doctor upon discharge from hospital (this could be the mother’s doctor or in their absence, it could be the mother’s obstetrician). The letter should be generated from the template in eMaternity or Cerner Maternity and amended as appropriate.

A copy of the neonatal hepatitis B follow-up letter must be given to the mother upon discharge from hospital along with a full explanation regarding the infant’s follow-up requirements and documented in the infant’s Personal Health Record. Translation services should be used as required.

5.1 Infants born to HBsAg positive women with a high viral load

- Women with a high viral load >200,000IU/ml or liver function test ALT greater than 40IU/L, must be referred to a liver clinic/specialist for an appointment to enable sufficient time for assessment and commencement of antiviral therapy according to local and/or international guidelines.
- A mechanism must be in place within each LHD to check that referred women have been booked in and attended the liver clinic for assessment.
- The liver clinic/specialist will decide on each woman’s requirement for treatment and management, including anti-viral treatment to prevent perinatal transmission, and according to current evidence and best practice guidelines.
- Each infant’s hepatitis B vaccination record must be checked for completion of the primary course and where a child has been identified as being not up to date, the mother must be prompted to make arrangements to have her child vaccinated.
- The mother’s GP must be provided with a letter recommending an infant serology test three months following completion of the infant’s primary hepatitis B vaccination course (not before nine months of age). Refer to Section 6 Reporting Requirements.
- Infants with an anti-HBs level <10IU/mL or 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 (see Section 11 ‘Resources’ for more information). The referral details must be documented in the records section of the infant’s Personal Health Record.

5.2 Infants born to HBsAg positive women with a low viral load

- Women with a viral load ≤200,000IU/ml and liver function test ALT less than 40IU/L, may be managed under the care of their GP or specialist liver clinic, according to LHD policy.
- Infants must be followed up to ensure timely completion of their hepatitis B vaccination course. The AIR overdue reports and/or hospital records and GP records may be used for this purpose. If a mother is unable to be contacted her infant should be considered as ‘lost to follow up’.
PROCEDURES

• Infants with an anti-HBs level <10IU/mL or 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 (see section 11 ‘Resources’ for more information).

• All attempts to contact the mother (and outcomes) must be documented and retained as specified in the State Records Authority of New South Wales (2004) General Retention and Disposal Authority Public Health Services: Patient/Client Records. Refer to Section 6 Reporting Requirements.

6 REPORTING REQUIREMENTS

• The Hospital Coordinator must:
  o Collate the Maternity Unit Record Form (Attachment 2) for every infant born to a HBsAg positive mother, provide a copy to the LHD Coordinator monthly and store the original report in the infant’s medical record. Ensure that the mother’s doctor details are complete;
  o Complete the Hospital Coordinator Monthly Report Form (Attachment 3), and;
  o Forward Attachments 2 and 3 to the LHD Immunisation Coordinator monthly.

• Should a neonate who is born to an HBsAg positive mother be transferred to another hospital, local processes must be determined to ensure they are included in the delivery unit’s monthly report to the LHD Immunisation Coordinator as appropriate.

• A neonatal hepatitis B follow-up letter (refer to the template in Attachment 1) must be forwarded to the mother’s doctor which includes a full explanation of the infant’s follow-up requirements.

• The LHD Immunisation Coordinator is responsible for collating the neonatal hepatitis B vaccination program data from their maternity units and must report quarterly to the Manager of the NSW Health Immunisation Unit (Attachment 4) by the specified reporting timeframes as follows:

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<th>Birth Cohort</th>
<th>Report Form Due</th>
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<tr>
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<td>the following 31 December</td>
</tr>
<tr>
<td>Births April, May, June</td>
<td>the following 31 March</td>
</tr>
<tr>
<td>Births July, Aug, Sept</td>
<td>the following 30 June</td>
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<td>Births Oct, Nov, Dec</td>
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• While the LHD Immunisation Coordinator reporting schedule incorporates timeframes to allow follow up of infants at 9 months of age, the Hospital Coordinator reporting to the LHD Immunisation Coordinator should be monthly, due the 8th working day of the
• The LHD Immunisation Coordinator must report to the AIR (via secure email) on children identified as having moved overseas.

7 KEY PERFORMANCE INDICATORS

The LHD Immunisation Coordinator must also report annually on hospital performance against the following indicators:

• 100% of women screened for hepatitis B during pregnancy or up to 2 hours following delivery (if no antenatal care was received);
• 100% of HBsAg positive women tested for viral load and liver function
• 100% of infants born to HBsAg+ women administered HBIG within 12 hours of birth;
• 100% of infants born to HBsAg+ women administered hepatitis B vaccine within 7 days of birth;
• 100% of women with a high viral load >200,000IU/ml or liver function test ALT 40IU/L or higher referred to a liver clinic/specialist hepatologist for an appointment prior to 32 weeks gestation;
• 100% of infants born to HBsAg positive women recommended for completion of serology three months after primary hepatitis B vaccination course, and;
• 100% of incidents (as specified in Section 8) are entered onto the Incident Information Management System.

8 INCIDENT INFORMATION MANAGEMENT SYSTEM (IIMS)

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 (refer to “follow-up” in section 1.3 Key Definitions) to ensure completion of the hepatitis B vaccination course and follow-up serology recommended (does not include ‘lost to follow-up’ infants).
9 LIST OF ATTACHMENTS

1. Neonatal Hepatitis B Follow up Template Letter to GPs
2. Maternity Unit Record Form
3. Hospital Coordinator Monthly Report Form
4. LHD Immunisation Coordinator Quarterly Report Form
5. Flowchart Referral and Management of HBsAg+ women and infants in NSW

10 REFERENCES


11 RESOURCES

Hepatitis B Vaccination for your Newborn Baby Brochure

Pregnancy – Protection & Vaccination from Preconception to Birth

Both brochures are available in 23 community languages on the NSW Health website at www.health.nsw.gov.au/immunisation


Infectious Diseases and Microbiology at Sydney Children’s Hospital, Randwick: https://www.schn.health.nsw.gov.au/parents-and-carers/our-services/infectious-diseases/sch
Attachment 1

NEONATAL HEPATITIS B FOLLOW UP LETTER TEMPLATE TO GPs

Follow up of babies born to hepatitis B surface antigen positive (HBsAg) mothers

Baby of [Insert First name] [Insert Last name]

DOB: [Insert date of birth] Time of birth: [Insert time] MRN: [Insert MRN] Gender: [Insert sex]

This baby’s mother was HBsAg positive, accordingly the baby was given…..

- Hepatitis B immunoglobulin (HBIG) within 12 hrs of birth [insert date/time]:
- Hepatitis B vaccine within 7 days of birth [insert date/time]:

What to do next.

1. Vaccinate the infant on time with Infanrix-hexa® at 2 months (can be given as early as 6 weeks), 4 and 6 months of age.
2. Serologically test the infant for confirmation of immunity 3 to 12 months after completing the vaccination course (and not before 9 months of age). Anti-HBs and HBsAg should be measured.

It is estimated that up to 90% of infants infected with hepatitis B virus (HBV) as neonates become chronic HBV carriers. Therefore, preventing neonates becoming HBV carriers can avoid the serious complications associated with hepatitis B infections.

For neonates born to HBsAg positive mothers, the NH&MRC recommends that following the birth dose of hepatitis B vaccine and HBIG, three subsequent doses of Infanrix-hexa® vaccine should be administered at 6 – 8 weeks, 4 and 6 months of age. There is no need to catch-up the birth dose of hepatitis B vaccine if it is not administered within the first 7 days of life.

Serologic confirmation of post-vaccination immunity of all infants born to HBsAg positive mothers is required 3 to 12 months after completion of the primary vaccination course (and not before 9 months of age). Hepatitis B surface antigen antibody (Anti-HBs) and HBsAg levels should be measured. Children who have Anti-HBs antibody levels ≥ 10 m IU / mL and are HBsAg negative are considered to be protected.

If the Anti-HBs antibody level is < 10mIU/mL, the possibility of hepatitis B infection should be investigated and expert advice sought regarding revaccination and/or further testing. Children who test HBsAg positive should be referred to a paediatrician experienced in viral hepatitis.

Additional important considerations include:

- Specialist assessment of HBsAg positive mothers.
- Hepatitis B vaccination is recommended for any susceptible household contacts.

Please do not hesitate to contact the immunisation team at your local Public Health Unit on 1300 066 055 if you require any additional advice regarding the management of this infant.

[insert name] Hospital
[insert date] printed
Order this form via the Stream Direct Catalogue as a POD item number NH700268
HOSPITAL COORDINATOR MONTHLY REPORT FORM

NAME OF HOSPITAL: _______________________________________

REPORT FOR MONTH: ____________________YEAR: ____________

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<tr>
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<tr>
<td>3. Number of women who birthed and tested HBsAg positive</td>
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<tr>
<td>4. Number of HBsAg+ Indigenous women</td>
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<tr>
<td>5. Number of women with viral load &gt;200,000IU/mL or liver function test ALT 40IU/L or higher</td>
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<tr>
<td>6. Number of all live neonates</td>
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<tr>
<td>7. Number of neonates born to HBsAg positive mothers</td>
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<tr>
<td>8. Number of neonates born to HBsAg positive mothers who received HBIG</td>
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<tr>
<td>9. Number of neonates born to HBsAg positive mothers who received HBIG within 12 hours of birth</td>
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<tr>
<td>10. Number of neonates born to HBsAg positive mothers who received hepatitis B vaccine within 7 days of birth</td>
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<tr>
<td>11. Number of all neonates who received hepatitis B vaccine within seven days of birth</td>
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<tr>
<td>12. Number of incidents identified (refer to section 8 IIMS)</td>
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<td>13. Number of incidents reported in IIMS</td>
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Completed by (print name): ____________________________________________

Contact phone number: (   ) ____________________________________________

Forward this form monthly to the Neonatal Hepatitis B Vaccination Program LHD Immunisation Coordinator
**LHD QUARTERLY REPORT FORM**

**LOCAL HEALTH DISTRICT:** ___________________________________________________

**SUBMITTED BY** (please print name): ___________________________________________

<table>
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<tr>
<td>Births July, Aug, Sept</td>
<td>the following 30 June</td>
<td></td>
</tr>
<tr>
<td>Births Oct, Nov, Dec</td>
<td>the following 30 Sept</td>
<td></td>
</tr>
</tbody>
</table>

**PERFORMANCE INDICATOR**

<table>
<thead>
<tr>
<th><strong>TOTAL</strong></th>
<th><strong>1. Number of women who birthed</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>2. Number of women who birthed and had been screened for HBsAg</strong></td>
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<tr>
<td></td>
<td><strong>3. Number of women who birthed and tested HBsAg positive</strong></td>
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<tr>
<td></td>
<td><strong>4. Number of HBsAg+ Indigenous women</strong></td>
</tr>
<tr>
<td></td>
<td><strong>5. Number of women with viral load &gt;200,000IU/ml or liver function test ALT 40IU/L or higher</strong></td>
</tr>
<tr>
<td></td>
<td><strong>6. Number of all live neonates</strong></td>
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<tr>
<td></td>
<td><strong>7. Number of neonates born to HBsAg positive mothers</strong></td>
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<tr>
<td></td>
<td><strong>8. Number of neonates born to HBsAg positive mothers who received HBIG</strong></td>
</tr>
<tr>
<td></td>
<td><strong>9. Number of neonates born to HBsAg positive mothers who received HBIG within 12 hours of birth</strong></td>
</tr>
<tr>
<td></td>
<td><strong>10. Number of neonates born to HBsAg positive mothers who received hepatitis B vaccine within 7 days of birth</strong></td>
</tr>
<tr>
<td></td>
<td><strong>11. Number of all neonates who received birth dose hepatitis B vaccine within 7 days of birth</strong></td>
</tr>
<tr>
<td></td>
<td><strong>12. Number of neonates born to HBsAg positive mothers who are more than 3 months overdue for their six month [i.e. 4th dose] hepatitis B vaccination</strong></td>
</tr>
<tr>
<td></td>
<td><strong>13. Number of infants born to HBsAg positive mothers who are lost to follow-up</strong></td>
</tr>
<tr>
<td></td>
<td><strong>14. Number of incidents identified (refer to section 8 IIMS)</strong></td>
</tr>
<tr>
<td></td>
<td><strong>15. Number of incidents reported in IIMS</strong></td>
</tr>
</tbody>
</table>

Forward this form **quarterly** to the Manager Immunisation Unit, Health Protection NSW at: vaccreports@doh.health.nsw.gov.au

* Infants are overdue one month after the scheduled date of their 4th dose of hepatitis B however for reporting purposes, only infants who are three months overdue are counted in the ‘overdue for completion of hepatitis B course’ report and not counted in the lost to follow-up data. Attempts to contact with the mother must be ongoing.

** Infants are ‘lost to follow-up’ when all reasonable attempts to contact the mother are exhausted – these infants are not counted in the overdue report.
ATTACHMENT 5

REFERRAL & MANAGEMENT OF HBsAg+ WOMEN & INFANTS

1. Pregnant woman screened for HBsAg

2. Liver clinic/specialist assumes clinical management including anti-viral treatment (AVT) to prevent perinatal transmission if appropriate

3. Woman referred to liver clinic/specialist for appointment to enable sufficient time for assessment and commencement of antiviral therapy according to local or international guidelines

4. Infant's record of vaccination monitored for completion of primary hepatitis B vaccination at 6 weeks, 4 and 6 months

5. Advise woman on timing of ceasing AVT

6. Continue with routine antenatal care

7. At birth, infant offered birth dose hepatitis B vaccine followed by primary vaccination schedule at 6 weeks, 4 and 6 months

8. Letter to GP recommending infant serology 3 months following completion of primary course (and not before 9 months of age)

9. Continue with routine antenatal care, refer to GP or hepatologist for care of chronic hepatitis B

10. At birth, infant offered Hepatitis B Immunoglobulin (HBIG) within 12 hours and hepatitis B vaccine within 7 days of birth

11. Mother and infant discharged from hospital with advice regarding importance of completion of primary hepatitis B vaccination course and serology 3 months following completion of primary course (and not before 9 months of age)

12. Infant’s record of vaccination monitored for completion of primary hepatitis B vaccination at 6 weeks, 4 and 6 months

13. Advise woman on timing of ceasing AVT

14. Infant referred to specialist paediatric service for ongoing management

References:
1. Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) Management of Hepatitis B in pregnancy (July 2016)

*This clinical pathway may be adapted according to the model of care within each LHD (i.e. where all HBsAg+ women are referred to the liver clinic/specialist for assessment)

NOTE: Women who do not have a known HBsAg status at the time of admission to hospital or labour ward should have urgent HBsAg testing to determine their hepatitis B status and infants born to HBsAg+ women must be managed as specified in this policy. The infant’s Personal Health Record must be updated at each encounter.