# Neonatal and Infant Hepatitis B Prevention and Vaccination Program Policy Directive

**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 specialist services, 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.

**Document type** Policy Directive

**Document number** PD2023_032

**Publication date** 13 October 2023

**Author branch** Communicable Diseases

**Branch contact** (02) 9391 9195

**Replaces** PD2017_036

**Review date** 13 October 2028

**Policy manual** Not applicable

**File number** 17/2438

**Status** Active

**Functional group** Clinical/Patient Services - Infectious Diseases, Maternity
Population Health - Communicable Diseases, Infection Control

**Applies to** Ministry of Health, Public Health Units, Local Health Districts, Board Governed Statutory Health Corporations, Chief Executive Governed Statutory Health Corporations, Specialty Network Governed Statutory Health Corporations, Affiliated Health Organisations, NSW Health Pathology, Public Health System Support Division, Cancer Institute, Government Medical Officers, Community Health Centres, NSW Ambulance Service, Public Hospitals, Private Hospitals and day Procedure Centres

**Distributed to** Ministry of Health, Public Health System, Divisions of General Practice, Government Medical Officers, NSW Ambulance Service, Private Hospitals and Day Procedure Centres, Tertiary Education Institutes

**Audience** All Clinical Staff, Nursing, Administration Staff;Maternity Units;General Practitioners (GPs)

Secretary, NSW Health

NSW Health

POLICY DIRECTIVE

# Neonatal and Infant Hepatitis B Prevention and Vaccination Program

## POLICY STATEMENT

NSW Health is committed to reducing the risk of hepatitis B transmission to neonates born in NSW. This Policy Directive focuses on the screening of all pregnant women for hepatitis B disease, appropriate referral to a specialist hepatology service/ specialist hepatologist as required, and the follow-up and management of all infants born to hepatitis B surface antigen (HBsAg) positive women.

## SUMMARY OF POLICY REQUIREMENTS

This Policy Directive must be read in conjunction with the current edition of *The Australian Immunisation Handbook*.

The Policy Directive aims to ensure consistent implementation of the NSW Neonatal and Infant Hepatitis B Prevention and Vaccination Program in all local health districts; and applies to NSW ante- and post-natal services, maternity hospitals, and public health units within the local health district.

All maternity facilities must offer hepatitis B surface antigen (HBsAg) screening and referral where appropriate to all pregnant women. HBsAg positive pregnant women with a high viral load (>200,000 or 5.3 $\log_{10}$ IU/mL) are recommended to be referred to a hepatology service/ specialist hepatologist.for management and follow up. HBsAg positive pregnant women with a low viral load (≤200,000 or 5.3 $\log_{10}$ IU/mL) can be managed by either their general practitioner or hepatology service.

All maternity facilities are required to offer Hepatitis B immunoglobulin (HBIG) to all neonates born to HBsAg positive mothers within 12-hours of birth. In addition, all neonates regardless of mothers HBsAg status must be offered the hepatitis B vaccine within 7-days of birth.

For reporting requirements, all maternity facilities are required to enter hepatitis B data onto eMaternity or Cerner as appropriate and report regularly to their Local Health District

The Neonatal Hepatitis B Hospital Coordinator must forward a copy of the Neonatal and Infant Hepatitis B Follow Up Letter to the LHD Neonatal and Infant Hepatitis B Lead and the mother's nominated doctor, if known to assist with following up babies born to a HBsAg positive mother.

In addition, the Neonatal Hepatitis B Hospital Coordinator must complete the Maternity Unit Record Form for every infant born to a HBsAg positive mother. The completed form must be sent to the LHD Neonatal and Infant Hepatitis B Lead to ensure all reporting and monitoring responsibilities are met.

The LHD Neonatal and Infant Hepatitis B Lead is required to send a copy of the *Neonatal and Infant Hepatitis B Follow Up Letter to General Practitioners* and the *Maternity Unit*

*Record Form* to the local PHU Immunisation Coordinator for monitoring and follow up of vaccination course completion.

All neonates born to HBsAg positive mothers outside of NSW Health facilities should be notified to the local public health unit to assist with monitoring the completion of their primary hepatitis B vaccination course.

Following collection of the data, the local health district is responsible for reporting program performance and follow-up all neonates born to HBsAg positive mothers who are overdue for vaccination.

## REVISION HISTORY

| Version | Approved By | Amendment Notes |
|---|---|---|
| October 2023 (PD2023_032) | Deputy Secretary, Population and Public Health and Chief Health Officer | Clarification on the timeframe requirement for HBsAg testing and referral process for HBsAg positive women. Refined follow up serology and vaccination recommendations which focus on neonates born to HBsAg positive women with a high viral load >200,000 or 5.3 $\log_{10}$ IU/mL.<br>Updated responsibilities of Chief Executives to ensure the monitoring and reporting requirements of the program in their facilities and LHD are met.<br>Inclusion of a new Local Health District Action Template to support and facilitate Local Health District agreement on the responsibilities for each action in the Policy Directive. |
| October 2017 (PD2017_036) | Deputy Secretary, Population and Public Health and Chief Health Officer | 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. |
| January 2005 (PD2005_222) | Deputy Secretary, Population and Public Health and Chief Health Officer | Initial version. |

# CONTENTS

# 1. BACKGROUND

The 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. Over 2,000 new diagnoses of hepatitis B are made in NSW each year, mainly of longstanding infection amongst people born in high burden countries[1].

Newly acquired hepatitis B is rarely reported in NSW. 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[Error! Reference source not found.]. In NSW an adolescent hepatitis B vaccination program commenced in 2004 and continued until 2013, when adolescents would have been eligible for the universal infant program.

Currently all infants in NSW are offered a four-dose schedule of hepatitis B vaccine at birth, 6-weeks, 4- and 6-months of age. The rationale for recommending the birth dose for all neonates 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 people with chronic hepatitis B infection who are household or other close contacts.

NSW Health has released the *NSW Hepatitis B Strategy 2023-2026* which details the priorities to reduce hepatitis B transmission in NSW[3].

## 1.1. About this document

This Policy Directive specifies the requirements for reducing the risk of hepatitis B transmission to neonates and infants through:

- screening of pregnant women for hepatitis B surface antigen (HBsAg)
- referral of HBsAg positive women with a viral load >200,000 or 5.3 $\log_{10}$ IU/mL to a hepatology service/ specialist hepatologist
- management of HBsAg positive women with a viral load ≤200,000 or 5.3 $\log_{10}$ IU/mL by either their GP or a hepatology service
- preventative measures and treatment of neonates born to HBsAg positive mothers
- follow-up of infants born to HBsAg positive mothers
- vaccination of all infants
- neonatal and infant hepatitis B vaccination program data.

This Policy Directive relates only to neonatal and infant hepatitis B vaccination recommendations and should be read in conjunction with The Australian Immunisation Handbook and the *NSW Hepatitis B Strategy 2023-2026*.

Recommendations for additional groups of people (such as Aboriginal people, health care workers and childcare workers) should be followed as specified in the online 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. Key definitions

| | |
|---|---|
| **Australian Immunisation Register (AIR)** | A system that records the information about vaccinations given to all persons of all ages in Australia.<br>The AIR was previously known as the Australian Childhood Immunisation Register (ACIR) and was established in 1996. It held information about vaccinations given to children from birth up to 7-years of age. The ACIR transitioned to the AIR in September 2016 and records information about vaccinations given at any age. |
| **Follow-up** | Reasonable attempts (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 for infants born to HBsAg positive mothers with a high viral load (>200,000 or 5.3 $\log_{10}$ IU/mL). |
| **HBsAg positive serology result** | The presence of HBsAg indicates active hepatitis B infection which can be spread to others.<br>The terms HBsAg positive and HBsAg+ are used interchangeably in this Policy Directive. |
| **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. |
| **Hepatitis B immunoglobulin (HBIG)** | A protein extract from blood that provides temporary immunity to hepatitis B disease. |
| **Hepatitis B vaccination schedule** | The National Immunisation Program (NIP) recommends hepatitis B in a four- dose schedule, administered at or within 7-days of birth, followed by a dose administered at 6-weeks, 4 and 6-months of age. |
| **High viral load** | Viral load >200,000 or 5.3 $\log_{10}$ IU/mL. |

| | |
|---|---|
| **Highest viral load** | The highest recorded viral load in the current pregnancy. |
| **Hospital Neonatal Hepatitis B Coordinator (Hospital 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. |
| **Local Health District Neonatal and Infant Hepatitis B Lead** | A person who is responsible for the Local Health District reporting and monitoring of Neonatal and Infant Hepatitis B Vaccination Program data. |
| **Low viral load** | Viral load ≤ 200,000 or 5.3 $\log_{10}$ IU/mL. |
| **Incident Management System (ims+)** | A NSW Health 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** | Instances where the requirements of this Policy Directive have not been met. |
| **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. |
| **Public Health Unit (PHU) Immunisation Coordinator** | A senior PHU officer who is responsible for monitoring and reporting on hepatitis B vaccination course completion in all infants born to HBsAg positive women. |
| **Specialist hepatologist** | A specialist medical doctor trained in the diagnosis and treatment of liver diseases. |

# 2. SCREENING AND REFERRAL

## 2.1. All pregnant women

All pregnant women must be offered screening for the hepatitis B surface antigen (HBsAg) and provided with verbal and written information about hepatitis B disease and the Neonatal and Infant Hepatitis B Vaccination Program (refer to the NSW Health *Hepatitis B vaccination for your Newborn Baby* brochure). The screening results must be entered into the relevant local health district maternity database. The results must also be recorded on the NSW Health Antenatal Card in case the woman births outside the local health district.

If the woman has been screened outside the facility, such as by a general practitioner (GP) as part of her pre-natal care, hepatitis B screening results are to be requested and entered into the relevant local health district maternity database. This may require contacting the woman's GP, obstetrician, or other healthcare provider.

If results are not available re-screening must occur. Refer to the *Local Health District Action Template* (see Appendix 6) to support agreement on responsibility and referral to specialist care.

## 2.2. Women with unknown HBsAg status

Women with an unknown HBsAg status at the time of admission to hospital or birthing environment, require urgent blood serum to be collected within 2-hours of admission to determine their hepatitis B status. NSW Health laboratories may take up to 14 hours from the neonate's birth to provide a result.

In the event that HBsAg results are not available within 12-hours of birth, Hepatitis B Immunoglobulin (HBIG) administration should be considered with parental consent for the neonate. Where deemed appropriate and based on consultation with a clinician, HBIG should be administered. An ims+ report will be required to be submitted (see Section 8).

## 2.3. Women who are HBsAg positive

HBsAg positive women must be further assessed including review of any previous births for evidence of maternal-infant transmission, stage of disease, and viral load.

### 2.3.1. HBsAg positive women with high viral load

HBsAg positive pregnant women with a high viral load[4] (>200,000 or 5.3 $\log_{10}$ IU/mL) must be referred to a hepatology service/ specialist hepatologist prior to 32-weeks' gestation for an appointment (unless they are already under the care of a specialist). This is 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 reduce the risk of transmission of hepatitis B to the neonate.

Commencement of treatment will be at the discretion of the pregnant woman and the treating specialist.

### 2.3.2. HBsAg positive women with low viral load

Management of all other HBsAg positive women (with a viral load ≤200,000 or 5.3 $\log_{10}$ IU/mL) must include monitoring of their hepatitis B disease and their infant's vaccination schedule by either their GP or hepatology service.

## 2.4. Aboriginal women

Refer to the Aboriginal Health Worker/ Practitioner nominated for all follow up of Aboriginal women. If an Aboriginal Health Worker/ Practitioner has not been nominated by the woman, offer referral to Aboriginal Maternal Infant Health Services (AMIHS).

# 3. VACCINATION AND IMMUNOGLOBULIN

## 3.1. All neonates and infants

Parents of all neonates should be given the NSW Health *Hepatitis B Vaccination for your Newborn Baby* brochure to support informed decision making when consenting to the Neonatal and Infant Hepatitis B Vaccination Program.

All neonates must be offered the hepatitis B vaccine which must be administered within 7-days of birth (preferably before discharge from the birthing environment). The birth dose provides the best protection for all neonates, including those who may have contracted the virus from the mother during birth. The birth dose also helps protect neonates from hepatitis B virus until they are old enough to receive the hepatitis B-containing vaccine with their routine childhood immunisations from 6-weeks of age.

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

All immunisations must be reported to the Australian Immunisation Register. The infant's Blue Book record (My Personal Health Record) may also be updated at each encounter to support completeness of information and to inform all clinicians involved in their care.

## 3.2. Low birth weight and preterm neonates

Low birth weight and preterm neonates do not respond as well to hepatitis B-containing vaccines as full-term neonates. 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 four-dose schedule at 0 (birth), 6-weeks 4- and 6-months of age followed by either:

- giving a booster of a hepatitis B vaccine at 12-months of age (further antibody testing is not required), or
- measuring the hepatitis B surface antibody (anti-HBs) level at 7-months of age, and at least 1-month after the 6-month dose. If the antibody titre is <10 mIU/mL, give a booster at 12-months of age (due to a better immunogenic response at this age when compared with a younger age).

## 3.3. Neonates born to HBsAg positive mothers

All neonates born to HBsAg positive mothers (regardless of viral load) must be offered hepatitis B immunoglobulin (HBIG) shortly after birth and within 12-hours of birth, followed by a four-dose schedule 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 alternate thighs. If not given concurrently, the HBIG should be given as soon as possible.

In the event that a neonate is unwell at birth and requires transfer to a neonatal unit or another facility, administration of HBIG, will be at the discretion of the treating specialist. In this situation, it must be administered with parental consent, and within 12-hours.

Counselling regarding the risks of contracting hepatitis B disease and its consequences must be provided by staff (with expertise in hepatitis B disease) to HBsAg positive mothers who refuse HBIG and/or hepatitis B vaccination for their neonate.

Where a HBsAg positive mother or the co-parent, refuses HBIG and the birth dose of hepatitis B vaccine for their newborn infant despite being clearly informed of the risks, clinicians should apply the NSW Child Protection Mandatory Reporter Guide (MRG) using the decision tree 'Neglect – Medical Care'. The treating clinician is required to report the incident to the NSW Child Protection Helpline.

An incident management system (ims+ or equivalent system in private hospitals) report must be submitted according to the circumstances specified in Section 8. All incidents must be documented and discussed with the Nursing Unit Manager/ Midwifery Unit Manager of the ward prior to maternal discharge.

All neonates born to HBsAg positive mothers outside of NSW Health facilities should be notified to the local public health unit to assist with monitoring the completion of their primary hepatitis B vaccination course and serology as required.

# 4. FURTHER TESTING AND FOLLOW-UP

## 4.1. All neonates born to HBsAg positive mothers

Each maternity unit must complete the *Neonatal and Infant Hepatitis B Follow Up Letter to General Practitioners* (see Appendix 1) for neonates born to hepatitis B surface antigen (HBsAg) positive mothers and forward this letter to the mother's nominated doctor upon discharge from hospital. This could be the mother's GP or in their absence, it could be the mother's obstetrician. The letter should be generated from the template in the relevant local health district maternity database and drafted as appropriate.

A copy of the letter must be forwarded to the Local Health District Neonatal and Infant Hepatitis B Lead who is required to send a copy to the local PHU Immunisation Coordinator to assist with monitoring the completion of their primary hepatitis B vaccination course (refer to the flowchart in Appendix 5). Where an infant has been identified as being not up to date, the mother must be prompted by the PHU Immunisation Coordinator (or delegate) to make arrangements to have her infant vaccinated. PHU Immunisation Coordinators (or delegate) are recommended to seek further advice from their PHU Directors where concerns have been identified with infants not completing hepatitis B vaccination and serology.

All infants who do not complete a full hepatitis B vaccination course are recommended to have serology to screen for HBsAg. Refer to the *Local Health District Action Template* (Appendix 6) to support agreement on responsibility and referral.

The letter and any associated correspondence regarding each woman must be managed in accordance with the NSW State Records *General Retention and Disposal Authority Public health services: patient/client records* (GDA-17)[6].

A copy of the *Neonatal and Infant Hepatitis B Follow Up Letter to General Practitioners* must be given to the mother upon discharge from hospital, along with a full explanation regarding the infant's follow-up requirements. Interpreter services should be used as required.

## 4.2. Infants born to HBsAg positive women with a high viral load

All infants born to HBsAg positive mothers with a high viral load (>200,000 or 5.3 $\log_{10}$ IU/mL) require follow-up serology 3-12 months after completion of their primary hepatitis B

vaccination course (minimum of 3-months following final hepatitis B vaccine and 9-months after administration of hepatitis B immunoglobulin (HBIG) to check if they are protected.

Mothers of infants born to HBsAg positive mothers with a high viral load must be educated prior to discharge regarding their infant's requirement for follow-up serology.

The mother's nominated GP (or treating clinician in the absence of the GP) must be provided with a letter recommending an infant serology test 3-months following completion of the infant's primary hepatitis B vaccination course (see Section 6 Reporting Requirements).

### 4.3. Infants who are HBsAg positive or anti-HBs negative

Paediatric specialist advice regarding revaccination or further testing is recommended for infants with anti-HBs antibody level <10 mIU/mL. Infants who are HBsAg positive are to be referred to the Gastroenterology and Hepatology service at The Children's Hospital, Westmead or a paediatric specialist service such as the Department of Infectious Diseases and Microbiology at Sydney Children's Hospital, Randwick, Gastroenterology and Hepatology at John Hunter Children's Hospital, Newcastle or other local paediatric infectious diseases services for ongoing management (see Section 10 'Resources' for more information).

The referral details may be documented in the records section of the infant's Blue Book.

### 4.4. 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 PHU Immunisation Coordinator. This includes children who were born in Australia but have moved overseas. The AIR should be notified where a return to mail has been confirmed.

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 considered to 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.

## 5. IMPLEMENTATION RESPONSIBILITIES

Chief executives are responsible for ensuring that each hospital maternity unit has a designated hospital neonatal hepatitis B coordinator ('hospital coordinator') who is responsible for the reporting and monitoring the Neonatal and Infant Hepatitis B Vaccination Program data. The hospital coordinator must forward the contact details for all neonates born to hepatitis B surface antigen (HBsAg) positive women to the LHD Neonatal and Infant Hepatitis B Lead following discharge. The LHD Neonatal and Infant Hepatitis B Lead is required to send a copy of the *Neonatal and Infant Hepatitis B Follow Up Letter to General Practitioners* (Appendix 1) and the *Maternity Unit Record Form* (Appendix 2) to the local PHU Immunisation Coordinator.

The PHU Immunisation Coordinator is responsible for monitoring and reporting vaccination course completion on all infants born to HBsAg positive mothers.

Within each local health district, collaboration between all relevant staff (including staff in private maternity hospitals) must occur to ensure that responsibilities are appropriately designated to ensure that:

- pregnant women with a high viral load are referred to a hepatology service/ specialist hepatologist.
- all infants born to hepatitis B surface antigen (HBsAg) positive women are followed up to check for timely completion of their primary hepatitis B vaccination course. Infants born to a HBsAg positive mother with a viral load >200,000 or 5.3 $\log_{10}$ IU/mL must also have HBsAg serology.
- paediatric specialist advice regarding re-vaccination or further testing is recommended for all infants with an anti-HBs antibody level <10 mIU/mL.
- all infants who are HBsAg positive are to be referred to the Gastroenterology and Hepatology service at The Children's Hospital, Westmead or a paediatric specialist service such as the Department of Infectious Diseases and Microbiology at Sydney Children's Hospital, Randwick, Gastroenterology and Hepatology at John Hunter Children's Hospital, Newcastle or other local paediatric infectious diseases services for ongoing management (see Section 10).

## 6. REPORTING REQUIREMENTS

Within each local health district, chief executives are responsible for ensuring all reporting and monitoring responsibilities are met and escalated as appropriate. Hospital neonatal hepatitis B coordinators are required to complete the following reports for each neonate born to a hepatitis B surface antigen (HBsAg) positive mother:

- The *Neonatal and Infant Hepatitis B Follow Up Letter Template to General Practitioners* (see Appendix 1)
- The *Maternity Unit Record Form* (see Appendix 2). Store the original report in the neonate's medical record. Ensure that the mother's doctor's details are complete,
- The *Hospital Neonatal Hepatitis B Coordinator Report Form* (see Appendix 3),

A copy of the completed Appendix 1 and Appendix 2 forms relating to each neonate born to a HBsAg positive mother must be forwarded to the LHD Neonatal and Infant Hepatitis B lead.

The LHD Neonatal and Infant Hepatitis B Lead is responsible for forwarding Appendix 1 and Appendix 2 to the PHU Immunisation Coordinator.

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 maternity unit's report to the local PHU Immunisation Coordinator.

The *Neonatal and Infant Hepatitis B Follow Up Letter Template to General Practitioners* (see Appendix 1) must be forwarded, upon discharge to the mother's nominated doctor which includes a full explanation of the infant's follow-up requirements.

The following table provides a guide on the suggested reporting timeframes within each LHD:

***Table 1. Neonatal and Infant Hepatitis B Reporting Schedule***

| Birth Cohort | Report Form Due |
|---|---|
| Births Jan, Feb, March | the following 31 December |
| Births April, May, June | the following 31 March |
| Births July, Aug, Sept | the following 30 June |
| Births Oct, Nov, Dec | the following 30 Sept |

The hospital neonatal hepatitis B coordinator is responsible for collating and reporting the Neonatal and Infant Hepatitis B Vaccination Program data from their maternity units to the LHD Neonatal and Infant Hepatitis B Lead.

For reporting purposes, only infants who are not counted in the lost to follow-up data and are 3-months overdue are counted in the 'overdue for completion of hepatitis B course' report.

The PHU Immunisation Coordinator must report to the Australian Immunisation Register (AIR) [via secure email] on children identified and confirmed as having moved overseas.

## 7. KEY PERFORMANCE INDICATORS

Chief executives must monitor their local health district's performance against the following indicators:

- 100% of women screened for hepatitis B during pregnancy or had serum bloods collected within 2-hours of admission to hospital or birthing environment (if the woman's HBsAg status is not known)
- 100% of hepatitis B surface antigen positive women tested for viral load
- 100% of neonates born to HBsAg positive women administered hepatitis B immunoglobulin (HBIG) shortly after birth (within 12-hours of birth)
- 100% of neonates born to HBsAg positive women administered hepatitis B vaccine within 7-days of birth
- 100% of women with a high viral load >200,000 or 5.3 $\log_{10}$ IU/mL referred to a hepatology service/ specialist hepatologist for an appointment prior to 32-weeks' gestation
- 100% of infants born to HBsAg positive women with a high viral load >200,000 or 5.3 $\log_{10}$ IU/mL recommended for completion of serology three months after primary hepatitis B vaccination course
- 100% of incidents (as specified in Section 8) are entered into the Incident Management System ims+.

## 8. GOVERNANCE AND MONITORING

Preventing and Controlling Infections Standard, Action 3.05 Surveillance of the National Safety and Quality Health Service (NSQHS), requires all NSW Health agencies to monitor, assess and use surveillance strategies to reduce the risks associated with infections.

In addition, chief executives are responsible for ensuring:

- Neonatal and Infant Hepatitis B Vaccination Program data results are discussed and tabled as a standing agenda item on locally agreed infection prevention and control and, maternal and neonatal health committees where applicable, to ensure compliance issues are addressed, and action is taken to improve compliance.
- a process is established to regularly assess compliance with this NSW Health Policy requirements and ensure that program data results are retained and readily available to the NSW Health agency chief executive/ executive team as required.

## 9. INCIDENT MANAGEMENT SYSTEM (IMS+)

An ims+ report must be submitted by the person who identifies an incident when:

- a pregnant woman has not been screened for hepatitis B during pregnancy or not had serum bloods collected within 2-hours from the time of admission to hospital or birthing environment (if no antenatal care was received)
- a serum HBsAg result has not been received within 14-hours after the birth of the neonate
- a neonate whose mother's hepatitis B status remains unknown 12- or more hours after birth and who has not been assessed for hepatitis B immunoglobulin (HBIG) administration
- a neonate born to a HBsAg positive mother has not received HBIG 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 *Neonatal and Infant Hepatitis B Follow Up Letter Template to General Practitioners*
- an infant born to an HBsAg positive mother has not been followed-up (refer to Section 4) to ensure completion of the hepatitis B vaccination course and follow-up serology recommendations (does not include 'lost to follow-up' infants).

Refer to the *Local Health District Action Template* (see Appendix 6) to support agreement on responsibility and referral for ims+.

## 10. REFERENCES

1. Australian Department of Health and Aged Care. Australian Immunisation Handbook. 2023

   Available from: https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/hepatitis-b

2. National Centre for Immunisation Research & Surveillance Hepatitis B Fact Sheet September 2019

   Available from:https://www.ncirs.org.au/new-resource-hepatitis-b-vaccines-australians-fact-sheet

3. *NSW Hepatitis B Strategy 2023-2026*.

   Available from:

   https://www.health.nsw.gov.au/hepatitis/Publications/hepatitisbstrategy.pdf

4. Lubel, JS, Strasser, SI, Thompson, AJ, Cowie, BC, MacLachlan, J, Allard, NL, Holmes, J, Kemp, WW, Majumdar, A, Iser, D, Howell, J & Matthews, GV 2022, 'Australian consensus recommendations for the management of hepatitis B', Medical journal of Australia, vol. 216, no. 9, pp. 478–486.

5. European Association for the Study of the Liver. Clinical Practice Guidelines on the management of hepatitis B virus infection. Journal of Hepatology 2017; 67:370-398.

6. NSW State Records *General Retention and Disposal Authority Public health services: patient/client records* (GDA-17). Available from:

   https://arp.nsw.gov.au/gda-17-general-retention-and-disposal-authority-public-health-services-patientclient-records/

## 11. RESOURCES

1. *Hepatitis B Vaccination for your Newborn Baby*
2. *Pregnancy – Protection & Vaccination from Preconception to Birth*
3. *NSW Immunisation Resource Order Form*
4. *Children's Guardian Act 2019, NSW*
5. NSW Government Communities and Justice: The Mandatory Reporter Guide (MRG)
6. Gastroenterology and Hepatology, The Children's Hospital at Westmead
7. Gastroenterology & Hepatology, John Hunter Children's Hospital
8. Infectious Diseases and Microbiology at Sydney Children's Hospital, Randwick
9. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists Management of Hepatitis B in Pregnancy (July 2019)

## 12. APPENDICES

1. Neonatal and Infant Hepatitis B Follow Up Letter Template to General Practitioners
2. Maternity Unit Record Form
3. Hospital Neonatal Hepatitis B Coordinator Report Form
4. Local Health District Quarterly Report Form
5. Flowchart: Referral and Management of HBsAg Positive Women, Neonates, and Infants
6. Local Health District Action Template

## 12.1. Appendix 1: Neonatal and Infant Hepatitis B Follow Up Letter Template to General Practitioners

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

**Dear Doctor [insert name]** **Medical Centre Address [insert name]**

**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 infant's mother was HBsAg positive [Insert mother's HBsAg viral if known], accordingly the infant was given:**

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

This infant is now under your care. What to do next:

1. Vaccinate the infant on time with a hepatitis B-containing vaccine at 2-months (can be given as early as 6-weeks), 4- and 6-months of age.
2. Infants born to HBsAg positive mothers **with a high viral load (>200,000 or 5.3 $\log_{10}$ IU/mL)** require measurement levels of hepatitis B surface antigen (HBsAg) and anti-HBs (antibody to HBsAg) 3-12 months after completing the infant vaccine course, such as 9-12 months of age (not before 9-months of age).
3. If anti-HBs antibody level is adequate (≥10 mIU/mL) and, HBsAg is negative – infant is protected, and no further action is required.
4. If the Anti-HBs antibody level is <10 mIU/mL, the possibility of hepatitis B infection should be investigated, and expert advice (referral to paediatrician) sought regarding revaccination and/or further testing.
5. If HBsAg is positive, the infant is considered to be infected with hepatitis B. Appropriate referral to a paediatrician or treating specialist is required.

**Educational notes:**

- It is estimated that up to 90% of neonates infected with hepatitis B virus (HBV) become chronic HBV carriers.
- For neonates born to HBsAg positive mothers, the National Health, and Medical Research Council (NHMRC) recommends that following the birth dose of hepatitis B vaccine and Hepatitis B immunoglobulin (HBIG), three subsequent doses of a hepatitis B-containing vaccine should be administered at 2-months (can be given as early as 6 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.

Additional important considerations include:

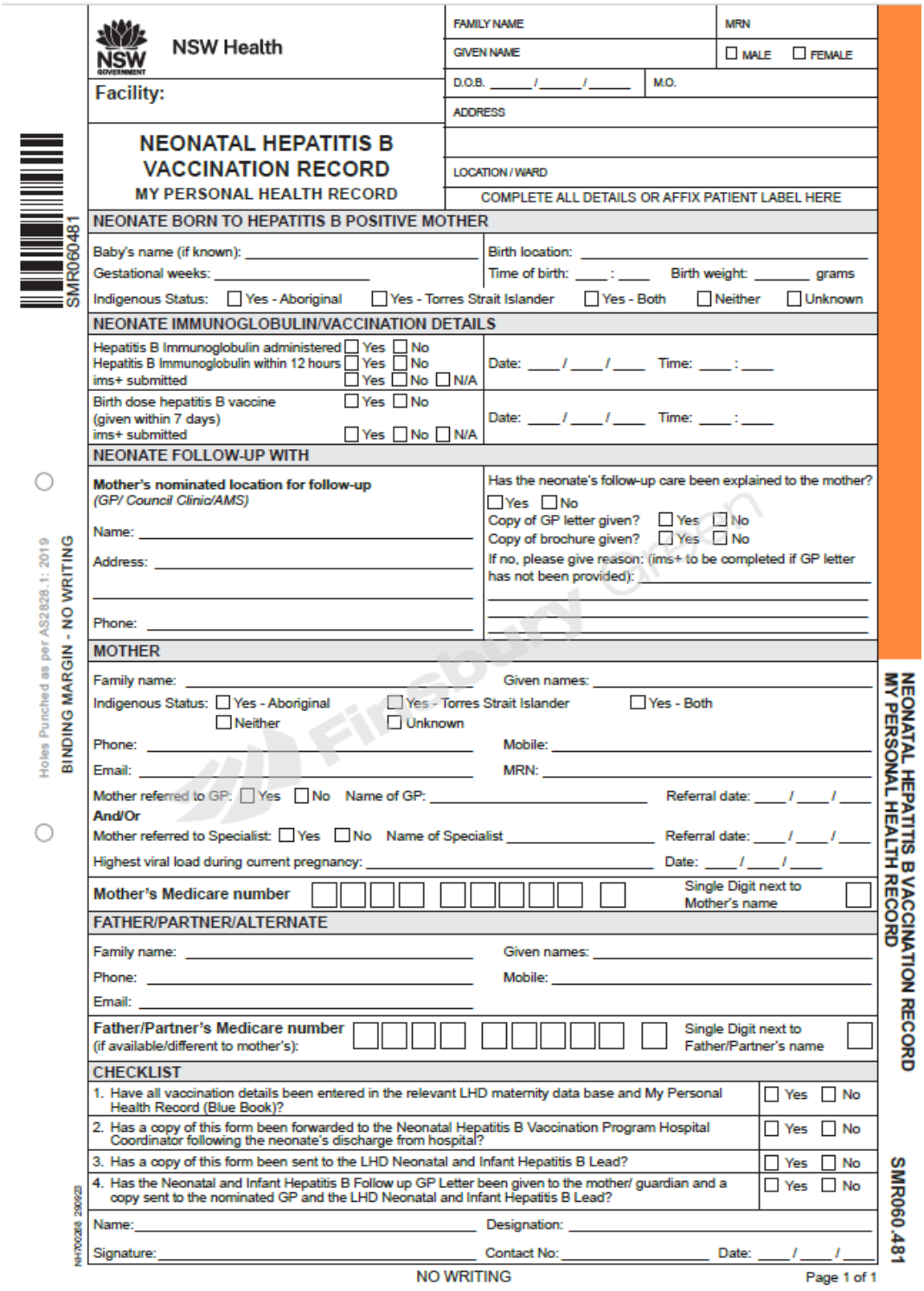
- **Hepatology service/ specialist hepatologist assessment of HBsAg positive mothers.**
- **Hepatitis B vaccination is recommended for any susceptible household contacts.**

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

## 12.2. Appendix 2: Maternity Unit Record Form



NSW Health

Facility:

FAMILY NAME | MRN

GIVEN NAME | ☐ MALE ☐ FEMALE

D.O.B. ____/____/____ | M.O.

ADDRESS

LOCATION / WARD

COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE

**NEONATAL HEPATITIS B VACCINATION RECORD**

**MY PERSONAL HEALTH RECORD**

SMR060481

**NEONATE BORN TO HEPATITIS B POSITIVE MOTHER**

Baby's name (if known): _____ Birth location: _____

Gestational weeks: _____ Time of birth: ____:____ Birth weight: _____ grams

Indigenous Status: ☐ Yes - Aboriginal ☐ Yes - Torres Strait Islander ☐ Yes - Both ☐ Neither ☐ Unknown

**NEONATE IMMUNOGLOBULIN/VACCINATION DETAILS**

Hepatitis B Immunoglobulin administered ☐ Yes ☐ No
Hepatitis B Immunoglobulin within 12 hours ☐ Yes ☐ No
ims+ submitted ☐ Yes ☐ No ☐ N/A
Date: ____/____/____ Time: ____:____

Birth dose hepatitis B vaccine ☐ Yes ☐ No
(given within 7 days)
ims+ submitted ☐ Yes ☐ No ☐ N/A
Date: ____/____/____ Time: ____:____

**NEONATE FOLLOW-UP WITH**

**Mother's nominated location for follow-up**
*(GP/ Council Clinic/AMS)*

Name: _____

Address: _____

Phone: _____

Has the neonate's follow-up care been explained to the mother?
☐ Yes ☐ No
Copy of GP letter given? ☐ Yes ☐ No
Copy of brochure given? ☐ Yes ☐ No
If no, please give reason: (ims+ to be completed if GP letter has not been provided): _____

**MOTHER**

Family name: _____ Given names: _____

Indigenous Status: ☐ Yes - Aboriginal ☐ Yes - Torres Strait Islander ☐ Yes - Both ☐ Neither ☐ Unknown

Phone: _____ Mobile: _____

Email: _____ MRN: _____

Mother referred to GP: ☐ Yes ☐ No Name of GP: _____ Referral date: ____/____/____

**And/Or**

Mother referred to Specialist: ☐ Yes ☐ No Name of Specialist _____ Referral date: ____/____/____

Highest viral load during current pregnancy: _____ Date: ____/____/____

**Mother's Medicare number** ☐☐☐☐ ☐☐☐☐☐ ☐ Single Digit next to Mother's name ☐

**FATHER/PARTNER/ALTERNATE**

Family name: _____ Given names: _____

Phone: _____ Mobile: _____

Email: _____

**Father/Partner's Medicare number** (if available/different to mother's): ☐☐☐☐ ☐☐☐☐☐ ☐ Single Digit next to Father/Partner's name ☐

**CHECKLIST**

| | |
|---|---|
| 1. Have all vaccination details been entered in the relevant LHD maternity data base and My Personal Health Record (Blue Book)? | ☐ Yes ☐ No |
| 2. Has a copy of this form been forwarded to the Neonatal Hepatitis B Vaccination Program Hospital Coordinator following the neonate's discharge from hospital? | ☐ Yes ☐ No |
| 3. Has a copy of this form been sent to the LHD Neonatal and Infant Hepatitis B Lead? | ☐ Yes ☐ No |
| 4. Has the Neonatal and Infant Hepatitis B Follow up GP Letter been given to the mother/ guardian and a copy sent to the nominated GP and the LHD Neonatal and Infant Hepatitis B Lead? | ☐ Yes ☐ No |

Name: _____ Designation: _____

Signature: _____ Contact No: _____ Date: ____/____/____

NO WRITING

Page 1 of 1

Holes Punched as per AS2828.1: 2019 BINDING MARGIN - NO WRITING

NEONATAL HEPATITIS B VACCINATION RECORD MY PERSONAL HEALTH RECORD

SMR060.481

NH700268 290923

**Order this form via the Stream Direct Catalogue as a POD item number NH700268.**

## 12.3. Appendix 3: Hospital Neonatal Coordinator Report Form

**Forward this form to the designated Local Health District Lead who is responsible for reporting and monitoring the neonatal and infant hepatitis B program data.**

Name of Hospital:

| Report for month: | Year: | |
|---|---|---|

| Indicators | Monthly Total |
|---|---|
| 1. Number of women who birthed (live births) | |
| 2. Number of women who birthed and had been screened for HBsAg (live births) | |
| 3. Number of women who birthed and tested HBsAg positive (live births) | |
| 4. Number of HBsAg+ Indigenous women (live births) | |
| 5. Number of women with viral load >200,000 or 5.3 $\log_{10}$ IU/mL | |
| 6. Number of all live neonates | |
| 7. Number of neonates born to HBsAg positive mothers | |
| 8. Number of neonates born to HBsAg positive mothers who received HBIG | |
| 9. Number of neonates born to HBsAg positive mothers who received HBIG within 12 hours of birth (lives births) | |
| 10. Number of neonates born to HBsAg positive mothers who received hepatitis B vaccine within 7 days of birth | |
| 11. Number of all neonates who received hepatitis B vaccine within seven days of birth | |
| 12. Number of incidents identified (refer to section 8 IMS+) | |
| 13. Number of incidents reported in IMS+ (or equivalent system for private hospitals) | |

**Completed by (print name):**

**Contact Phone Number:**

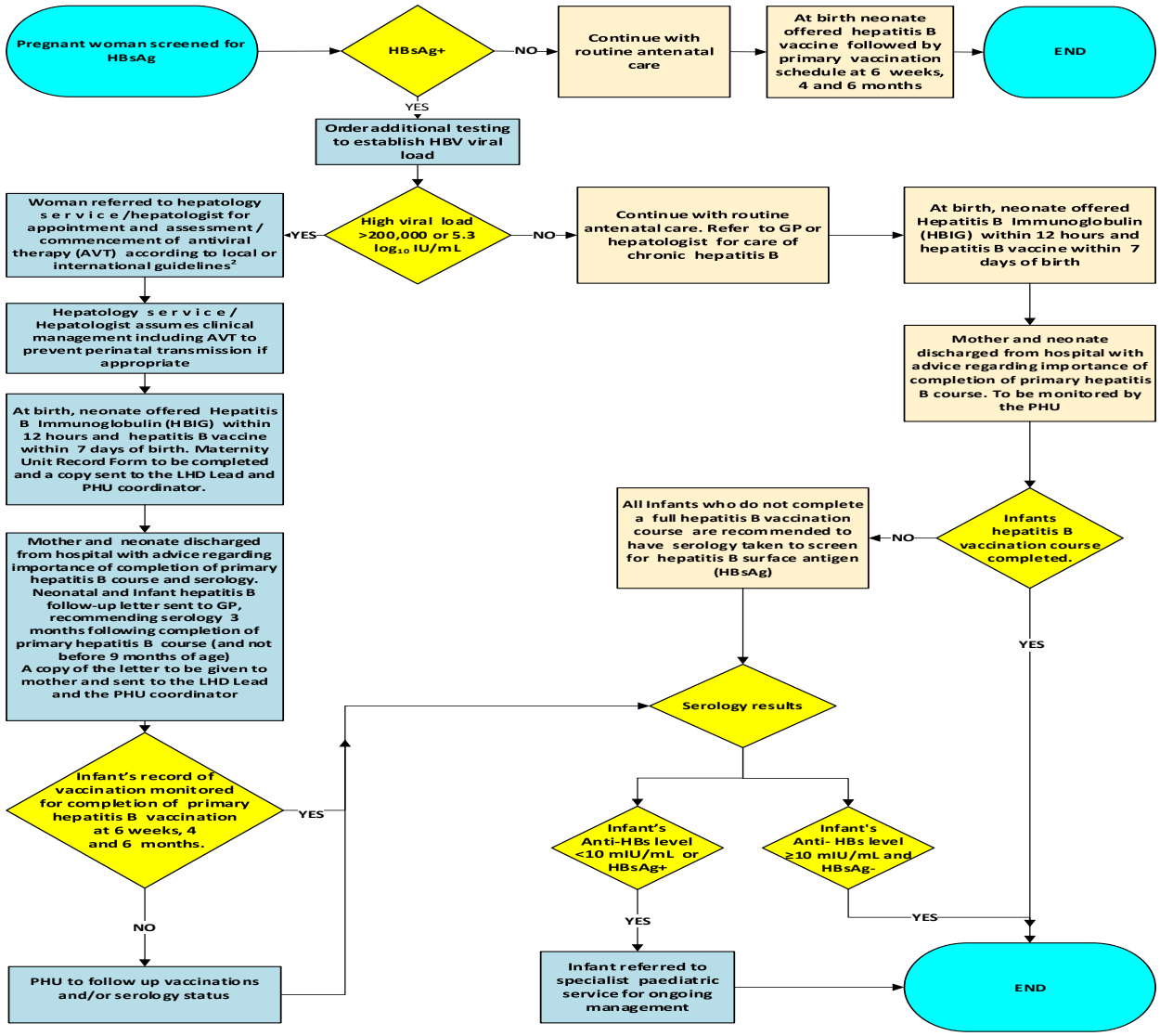
## 12.4. Appendix 4: Template example: Local Health District Quarterly Report

| Birth Cohort | Report Form Due | Date Report Submitted |
|---|---|---|
| Births Jan, Feb, March | the following 31 December | |
| Births April, May, June | the following 31 March | |
| Births July, Aug, Sept | the following 30 June | |
| Births Oct, Nov, Dec | the following 30 Sept | |

| Performance Indicator | Total |
|---|---|
| 1. Number of women who birthed (live births) | |
| 2. Number of women who birthed and had been screened for HBsAg (live births) | |
| 3. Number of women who birthed and tested HBsAg positive (live births) | |
| 4. Number of HBsAg positive Indigenous women (live births) | |
| 5. Number of women with viral load >200,000 or 5.3 $\log_{10}$ IU/mL | |
| 6. Number of all live neonates | |
| 7. Number of neonates born to HBsAg positive mothers | |
| 8. Number of neonates born to HBsAg positive mothers who received HBIG | |
| 9. Number of neonates born to HBsAg positive mothers who received HBIG within 12 hours of birth (live births) | |
| 10. Number of neonates born to HBsAg positive mothers who received hepatitis B vaccine within 7- days of birth | |
| 11. Number of all neonates who received birth dose hepatitis B vaccine within 7-days of birth | |
| 12. Number of infants born to HBsAg positive mothers who are more than 3 months overdue for their six month [i.e., 4th dose] hepatitis B vaccination* | |
| 13. Number of infants born to HBsAg positive mothers who are lost to follow-up** (liaise with local PHU) | |
| 14. Number of incidents identified (refer to Section 8 ims+) | |
| 15. Number of incidents reported in ims+ (or equivalent system for private hospitals) | |

* 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 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.

## 12.5. Appendix 5: Flowchart Referral and Management of HBsAg positive Women, Neonates, and Infants




References

1. European Association for the Study of the Liver. EASL 2017 Clinical Practice Guidelines for the management of hepatitis B virus infection. Journal of Hepatology (2017).

2. Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) Management of Hepatitis B in pregnancy (July 2019). This clinical pathway may be adapted according to the model of care with each Local Health District i.e., where depending on viral load count all HBsAg+ women are referred to the liver clinic/ specialist/GP for assessment.

Note: Women who do not have a known HBsAg status at the time of admission to hospital or birthing environment 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 Blue Book record must be updated at each encounter.

## 12.6. Appendix 6: Local Health District Action Template

This appendix supports and facilitates local health district (LHD) agreement on the responsibilities for each action in the Policy Directive. The template should be used to assist LHDs to assign appropriately designated and relevant staff and teams within each LHD.

### 12.6.1. Stage: Screening and referral

| Groups | Actions | Responsible Team/ Person |
|---|---|---|
| All pregnant women | Perform screening for hepatitis B surface antigen (HBsAg) and provide women with verbal and written information regarding hepatitis B disease and the Neonatal and Infant hepatitis B Vaccination Program (refer to the NSW Health *Hepatitis B Vaccination for your Newborn Baby* brochure). | *e.g., Antenatal Clinic, General Practitioner or Obstetrician* |
| | Enter the screening results into the relevant LHD maternity database and record the results on the NSW Health Antenatal Card in case the woman births outside of the LHD. | |
| | Follow the clinical pathway in Appendix 5. | |
| | Develop a mechanism within each LHD to check that the referred women have been booked in and/or have attended a hepatology service/ specialist hepatologist. | |
| | Refer to the Aboriginal Health Professional nominated for all follow up of Aboriginal women. If an Aboriginal Health Professional has not been nominated by the woman, offer referral to Aboriginal Maternal Infant Health Services (AMIHS). | |

| | | |
|---|---|---|
| Women with an unknown HBsAg status | Women who have unknown HBsAg status at the time of admission to hospital or birthing environment should have urgent HBsAg testing collected within 2-hours to determine their hepatitis B status.<br>In the event that HBsAg results are not available within 12-hours of birth, hepatitis B immunoglobulin (HBIG) administration should be considered with parental consent for the neonate. Where deemed appropriate and based on consultation with a clinician HBIG should be administered. | |
| | Completion of an ims+ report for women who at the time of admission to hospital or birthing environment have an unknown HBsAg status (see Section 8). | |
| Women who are HBsAg positive | Request further testing to determine staging of disease and risk of infectivity, including viral load and history of prior maternal infant transmission. Commencement of treatment will be at the discretion of the pregnant woman and treating specialist. | |
| | For HBsAg+ women with a high viral load (>200,000 or 5.3 $\log_{10}$ IU/mL), refer to a hepatology service/specialist hepatologist for assessment, treatment, and management prior to 32 weeks gestation. This is to allow sufficient time for assessment and commencement of antiviral therapy. | |
| | For HBsAg+ women with a low viral load (≤200,000 or 5.3 $\log_{10}$ IU/mL), continue with routine antenatal care and refer to mother's treating clinician/GP or hepatology service for care of chronic hepatitis B. | |

### 12.6.2. Stage: Vaccination and Immunoglobulin

| Groups | Actions | Responsible Team/ Person |
|---|---|---|
| All neonates and infants | Provide the parents of all neonates with the *Hepatitis B Vaccination for your Newborn Baby* brochure when consenting to the Neonatal and Infant hepatitis B Vaccination Program. | |
| | Offer a hepatitis B vaccine preferably within 24-hours and within 7-days of birth, followed by a hepatitis B-containing combination vaccine at 6-weeks, 4- and 6-months of age.<br>Record each vaccination encounter in the relevant LHD maternity database as well as the infants Blue Book record. | |
| Low birth weight and preterm neonates, <2000g and/or infants born at <32 weeks gestation (irrespective of weight) | Administer the vaccine in a four-dose schedule at 0 (birth), 6-weeks, 4- and 6-months of age followed by either:<br>• Administration of a booster at 12-months of age without measuring the antibody titre.<br>OR<br>• Measuring the anti-HBs antibody level at 7-months of age, and at least 1-month after the 6-month dose. If the antibody titre is <10 mIU/mL, give a booster at 12-months of age. | |
| All neonates born to HBsAg positive mothers | Administer hepatitis B immunoglobulin (HBIG) shortly after birth and within 12-hours of birth, followed by a four-dose schedule 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 alternate thighs. If not given concurrently, give as soon as possible. | |
| | Counselling regarding the risks of contracting hepatitis B disease and its consequences should be provided to the mother or the co-parent who refuse HBIG and/or hepatitis B vaccination for their neonates. | |

| | | |
|---|---|---|
| | Discuss all incidents with the Nursing Unit Manager/ Midwifery Unit Manager of the ward prior to maternal discharge and submit an Incident Management System+ (ims+) report for the circumstances specified in Section 8. | |
| | Where a HBsAg+ mother or the co-parent, refuses HBIG and the birth dose of hepatitis B vaccine for their neonate, despite being clearly informed of the risks, clinicians should apply the NSW Child Protection Mandatory Reporter Guide (MRG) using the decision tree 'Neglect – Medical Care'. The treating clinician is required to report the incident to the NSW Child Protection Helpline. | |
| | Each maternity unit must complete the *Neonatal and Infant Hepatitis B Follow Up Letter to General Practitioners* (see Appendix 1). The template can be generated from the relevant LHD maternity database. | |
| | Provide the mother with a copy of the *Neonatal and Infant Hepatitis B Follow Up Letter to General Practitioners* upon discharge from the hospital and give advice on the infant's follow-up requirements. Document the encounter in the infant's Blue Book record. | |
| | Forward the *Neonatal and Infant Hepatitis B Follow Up Letter to General Practitioners* to the mother's nominated GP (or treating clinician in the absence of the GP) upon discharge from the hospital. | |
| | Forward a copy of the *Neonatal and Infant Hepatitis B Follow Up Letter to General Practitioners* (see Appendix 1) and the Maternity Unit Record Form (see Appendix 2) to the LHD Neonatal and Infant Hepatitis B Lead.<br>Store the original copy in the neonate's medical record. | |
| | Forward a copy of the *Neonatal and Infant Hepatitis B Follow Up Letter to General Practitioners* (see Appendix 1) and the Maternity Unit Record Form (see Appendix 2) to the local PHU Immunisation Coordinator. | |

| | | |
|---|---|---|
| | All neonates born to HBsAg positive mothers outside of NSW Health facilities should be notified to the local public health unit to assist with monitoring the completion of their primary hepatitis B vaccination course and serology as required. | |
| Infants born to HBsAg positive women with a low viral load ≤200,000 or 5.3 $log_{10}$ IU/mL | Monitor the completion of the infant's primary hepatitis B vaccination course (refer to the flowchart in Appendix 5). | *PHU Immunisation Coordinator* |
| | Continue to follow up with the mother if an infant is identified as being not up to date with vaccinations. All Infants who do not complete a full hepatitis B vaccination course are recommended to have serology taken to screen for hepatitis B surface antigen (HBsAg) [see section 4]. | *PHU Immunisation Coordinator* |
| | Document all attempts to contact the parents of the infant as well as outcomes and retain the records. | *PHU Immunisation Coordinator* |
| Infants born to HBsAg positive women with a high viral load >200,000 or 5.3 $log_{10}$ IU/mL | Monitor the completion of the infant's primary hepatitis B vaccination course. | *PHU Immunisation Coordinator* |
| | Ensure serology has been collected from the infant 3 to 12-months after completion of their primary hepatitis B vaccination course (and not before nine months of age) to check if they are protected (refer to the flowchart in Appendix 5). | *PHU Immunisation Coordinator* |
| Infants who are HBsAg positive or anti-HBs negative | Refer the infant for paediatric specialist advice regarding revaccination or further testing.<br>Infants who are HBsAg+ are to be referred to the Gastroenterology and Hepatology service at The Children's Hospital, Westmead or a paediatric specialist service such as the Department of Infectious Diseases and Microbiology at Sydney Children's Hospital, Randwick, or other local paediatric infectious diseases services for ongoing management. | |

## Stage: Further Reporting Requirements

| Groups | Actions | Responsible Team/ Person |
|---|---|---|
| Data collection and reporting | Complete the *Hospital Neonatal Coordinator Report Form* (see Appendix 3) and report to the Local Health District *Neonatal Hepatitis B Lead.* | *e.g., Hospital Coordinator* |
| | Monitor, collate and report hepatitis B vaccination program performance data from hospital maternity units in the local health district. | *Local Health District Neonatal Hepatitis B Lead* |