

**Royal Hospital for Women (RHW)**  
**NEONATAL BUSINESS RULE**  
**COVER SHEET**



**Health**  
South Eastern Sydney  
Local Health District

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<b>SUMMARY</b>	To guide clinicians in the management of neonates born to Hepatitis B Positive Mothers
<b>Key Words</b>	Hepatitis B, Hepatitis B immunoglobulin, hepatitis B vaccine, neonate

## Hepatitis B Positive Mother – Neonatal management

RHW CLIN133

### Contents

1	BACKGROUND .....	3
2	RESPONSIBILITIES .....	3
2.1	Staff (medical, midwifery, Nursing, Allied health) .....	3
3	PROCEDURE .....	3
3.1	Equipment .....	3
3.2	Clinical Practice (Appendix 1) .....	3
3.3	Documentation .....	5
3.4	Education Notes .....	5
3.5	Abbreviations .....	6
3.6	Related Policies/procedures .....	6
3.7	References .....	6
4	ABORIGINAL HEALTH IMPACT STATEMENT DOCUMENTATION .....	7
5	CULTURAL SUPPORT .....	7
6	NATIONAL STANDARDS .....	7
7	REVISION AND APPROVAL HISTORY .....	8
	Appendix 1. Neonatal management – Algorithm .....	9
	Appendix 2 Blood & Blood Products Administration .....	10
	Appendix 3 Authority to Issue Blood Products.....	11
	Appendix 4 Neonatal Hepatitis B Vaccination Record .....	12
	Appendix 5 Letter to General practitioner/paediatrician .....	13
	Appendix 1 Neonatal hepatitis B vaccination record.....	23
	Appendix 2 Letter to GPs .....	24

## Hepatitis B Positive Mother – Neonatal management

RHW CLIN133

*This Clinical Business Rule (CBR) is developed to guide safe clinical practice at the Royal Hospital for Women (RHW). Individual patient circumstances may mean that practice diverges from this Clinical Business Rule. Using this document outside RHW or its reproduction in whole or part, is subject to acknowledgement that it is the property of RHW and is valid and applicable for use at the time of publication. RHW is not responsible for consequences that may develop from the use of this document outside RHW.*

*Within this document we will use the term woman, this is not to exclude those who give birth and do not identify as female. It is crucial to use the preferred language and terminology as described and guided by each individual person when providing care.*

## 1 BACKGROUND

The aims are (1) reduction in mother to neonate transmission of Hepatitis B virus (HBV), and (2) arrange postnatal follow up of neonates. This CBR is developed in line with the current New South Wales Policy Directive.<sup>1</sup>

## 2 RESPONSIBILITIES

### 2.1 Staff (medical, midwifery, Nursing, Allied health)

- 2.1.1 Midwifery/nursing – Reduce the risk of HBV transmission from mother to neonate by appropriate maternal screening, administer Hepatitis B vaccination (Hep B vaccine) for all newborns, and the use of prophylactic Hepatitis B Immunoglobulin (HBIG) for neonates of HBsAg-positive mothers.
- 2.2.2 Medical – Prescription of Hep B vaccine and HBIG for neonates in Newborn Care Centre. Signing of standing orders within 24 hours of administration by a midwife. Arrangement for follow up.

## 3 PROCEDURE

### 3.1 Equipment

- Hep B Vaccine
- Intramuscular injection needle 23g or 25g 16mm length
- HBIG 100 International units

### 3.2 Clinical Practice (Appendix 1)

- Routine antenatal screening of pregnant women for HBsAg enables appropriate management to prevent newborn neonates developing hepatitis B. For maternal management information, including maternal serology, refer to the RHW CBR

## Hepatitis B Positive Mother – Neonatal management

RHW CLIN133

Hepatitis B: Universal Screening in Pregnancy and the Management of a Positive Woman.

- Intramuscular Hep B Vaccine (0.5mL) and HBIG (100 International units) can be administered by a standing order in birth unit. Ensure medical officer signs the order within 24 hours of administration.
- For neonates in NCC; medical officer to prescribe Intramuscular Hep B vaccine (0.5 mL) and HBIG (100 International units) on the neonatal medication chart on day of birth.
- Clean the neonate's eyes and non-intact skin with water as soon as possible after the birth.
- Obtain verbal consent from the woman for her neonate to receive Hepatitis B vaccine and written consent for the immunoglobulin using Blood and Blood products Administration form (SEI130.060) [Appendix 2].
- Request immunoglobulin from blood bank on Authority to Issue Blood Products form (S1289) [Appendix 3].
- Administer vaccine and immunoglobulin at birth. Both must be given within 12 hours of birth, preferably before leaving birth unit. Ensure this is double checked with a second midwife/RN.
- Clean the injection sites with alcohol swab before administering injections, allow skin to dry before administering injections.
- Administer intramuscular HBIG and Hep B vaccine on separate thighs. The anterolateral aspect of the thigh is recommended. The gluteal area should not be used in a neonate.
- Record administration of the vaccine (including batch number and expiry date) in:
  - K2 Guardian
  - eMR medication chart
  - eRIC medication chart (if baby is transferred or admitted to the Newborn Care Centre)
  - Newborn Care Centre (NCC) admission sheet (if baby is transferred or admitted to the Newborn Care Centre)
  - Neonatal Vaccination Record (orange form)
  - Newborn Personal Health Record (blue book)

### NOTE:

Missed doses of Hep B vaccine or HBIG significantly increases the risk of neonatal infection. If a dose is missed, this requires an incident management system (IMS+) notification to be made.

- Complete the Neonatal Vaccination Record (Appendix 4) form COMPLETELY and file in maternal/neonatal notes. Provide a copy for the woman.
- Inform the Infection Prevention and Control (IPC) Clinical Midwifery Consultant (CMC) of the maternal and neonatal details. The IPC CMC will inform New South Wales Public Health Unit.
- Remind parents before discharge of the importance of the neonate receiving second, third and fourth vaccinations at six weeks, four months and six months. For newborns admitted to NCC, schedule a task in eRIC to prompt a reminder for the 6-week vaccinations.

## Hepatitis B Positive Mother – Neonatal management

RHW CLIN133

- Ensure women has been given parent information leaflets ([Hepatitis B vaccination, For your newborn baby](#) and [Hepatitis B Mothers and Babies | Hepatitis NSW](#)).
- Give woman discharge summary and Hepatitis B letter (generated from eMaternity - see Appendix 5) to take to GP for follow up testing of baby (HBS Ag and Anti-HBs) at 9-12 months of age.
- The neonate is considered protected against hepatitis B if:
  - anti-HBs (antibody to HBS AG) levels are adequate ( $\geq 10$  mIU/mL) and
  - HBsAg is negative.

### NOTE:

Do not test the infant before 9 months of age, to avoid detecting anti-HBs from the HBIG given at birth.<sup>6</sup>

If any follow-up tests return positive, further follow-up by a paediatrician is necessary

### 3.3 Documentation

- eRIC
- NCC admission sheet
- Neonatal Care plan
- eMEDS
- Guardian K2
- Personal Health Record (Baby's blue book)
- Blood and Blood Products Administration (SEI130060)
- Authority to Issue Blood Products (S1289)
- Neonatal Hepatitis B Vaccination Record (SMR060481)

### 3.4 Education Notes

- After acute hepatitis B infection, up to 12% of affected adults and up to 90% of infected neonates may become chronically infected carriers. The virus is spread via blood and body fluids and can potentially be transmitted from mother to baby in-utero (4%)<sup>2</sup>, at birth (most often) or after birth.
- For a neonate born to a mother with HBV infection, the risk of mother-to-child transmission of HBV can be as high as 90% without the use of active and passive immunization.<sup>3</sup> Hepatitis B vaccination reduces the risk of infection by 70%; the addition of HBIG at birth augments this risk reduction to over 90%.<sup>4</sup>
- HBsAg positive women can breastfeed their babies providing the baby is immunized.
- Children diagnosed with chronic Hepatitis B should be referred to a paediatric service with expertise in viral hepatitis. Although most will have minimal liver disease early in life, this is not true for all children with chronic infection. A recent study reported that referral of these children for assessment is rarely occurring in Australia.<sup>5,6</sup>
- Caesarean section is known to lower the risk of perinatal transmission in chronically infected HBeAg positive mothers with high viral loads, however, the benefit of caesarean section is only marginal and caesarean section may not be protective without active/passive immunisation of the baby. Therefore, Hepatitis B infection should not alter

## Hepatitis B Positive Mother – Neonatal management

RHW CLIN133

the mode of delivery with caesarean section being reserved for the usual obstetric indications.<sup>6</sup>

- It is vital to ensure neonates born to HBsAg and HBeAg positive mothers receive HB vaccine plus HB immunoglobulin at birth. The Hepatitis B vaccine course must be completed with doses at 6 weeks, 2 months and 6 months of age.<sup>5,6,7,8</sup>
- Birth doses of HB vaccines are monovalent vaccines. There are 2 paediatric monovalent vaccines are available:
  - Engerix-B: Each 0.5 mL contains 10 µg HBsAg protein, adsorbed onto 0.25 mg aluminium as aluminium hydroxide hydrate.
  - H-B-Vax II: Each 0.5 mL contains 5 µg recombinant HBsAg protein, adsorbed onto 0.25 mg amorphous aluminium hydroxyphosphate sulfate.

### 3.5 Abbreviations

HBV	Hepatitis B Virus	Hep B vaccine	Hepatitis B vaccine
HBIG	Hepatitis B immunoglobulin	HBsAg	Hepatitis B surface Antigen
IPC	Infection Prevention and Control	CMC	Clinical Midwifery Consultant
Anti-HBs	Hepatitis B surface antibody	HBeAg	Hepatitis B e antigen

### 3.6 Related Policies/procedures

- ANMF Hepatitis B vaccine
- ANMF Hepatitis B Immunoglobulin
- RHW CBR Hepatitis B: Universal Screening in Pregnancy and the Management of a Positive Woman
- RHW CBR Hepatitis B vaccine administration for the neonate
- NSW Health Neonatal and Infant Hepatitis B Prevention and Vaccination Program Policy Directive PD2023\_032
- SESLHD Standing Order Hepatitis B vaccine and Hepatitis B Immunoglobulin-Administration in Maternity Services.

### 3.7 References

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3. Stevens CE, Beasley RP, Tsui J, Lee WC. Vertical transmission of hepatitis B antigen in Taiwan. N Engl J Med 1975; 292:771.



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## Hepatitis B Positive Mother – Neonatal management

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RHW CLIN133

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6. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists. Hepatitis B. RANZCOG College Statement C-Gen 3. 2019.
7. Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook, Australian Government Department of Health, Canberra, [www.immunisationhandbook.health.gov.au](http://www.immunisationhandbook.health.gov.au). Accessed on 23 July 2024.
8. Australasian Society for Infectious Diseases (ASID). Management of Perinatal Infections, Third edition 2022, edited by P Palasanthiran, M Starr, C Jones, M Giles.

## 4 ABORIGINAL HEALTH IMPACT STATEMENT DOCUMENTATION

- Considerations for culturally safe and appropriate care provision have been made in the development of this Business Rule and will be accounted for in its implementation.
- When clinical risks are identified for an Aboriginal and/or Torres Strait Islander woman or family, they may require additional supports. This may include Aboriginal health professionals such as Aboriginal liaison officers, health workers or other culturally specific services

## 5 CULTURAL SUPPORT

- For a Culturally and Linguistically Diverse CALD woman, notify the nominated cross-cultural health worker during Monday to Friday business hours
- If the woman is from a non-English speaking background, call the interpreter service: NSW Ministry of Health Policy Directive PD2017 044-Interpreters Standard Procedures for Working with Health Care Interpreters.

## 6 NATIONAL STANDARDS

- Standard 1 Clinical Governance
- Standard 2 Partnering with Consumers
- Standard 3 Infection Prevention and Control
- Standard 4 Medication Safety
- Standard 5 Comprehensive Care
- Standard 6 Communicating for Safety
- Standard 7 Blood Management

**Hepatitis B Positive Mother – Neonatal  
management**

**RHW CLIN133**

## 7 REVISION AND APPROVAL HISTORY

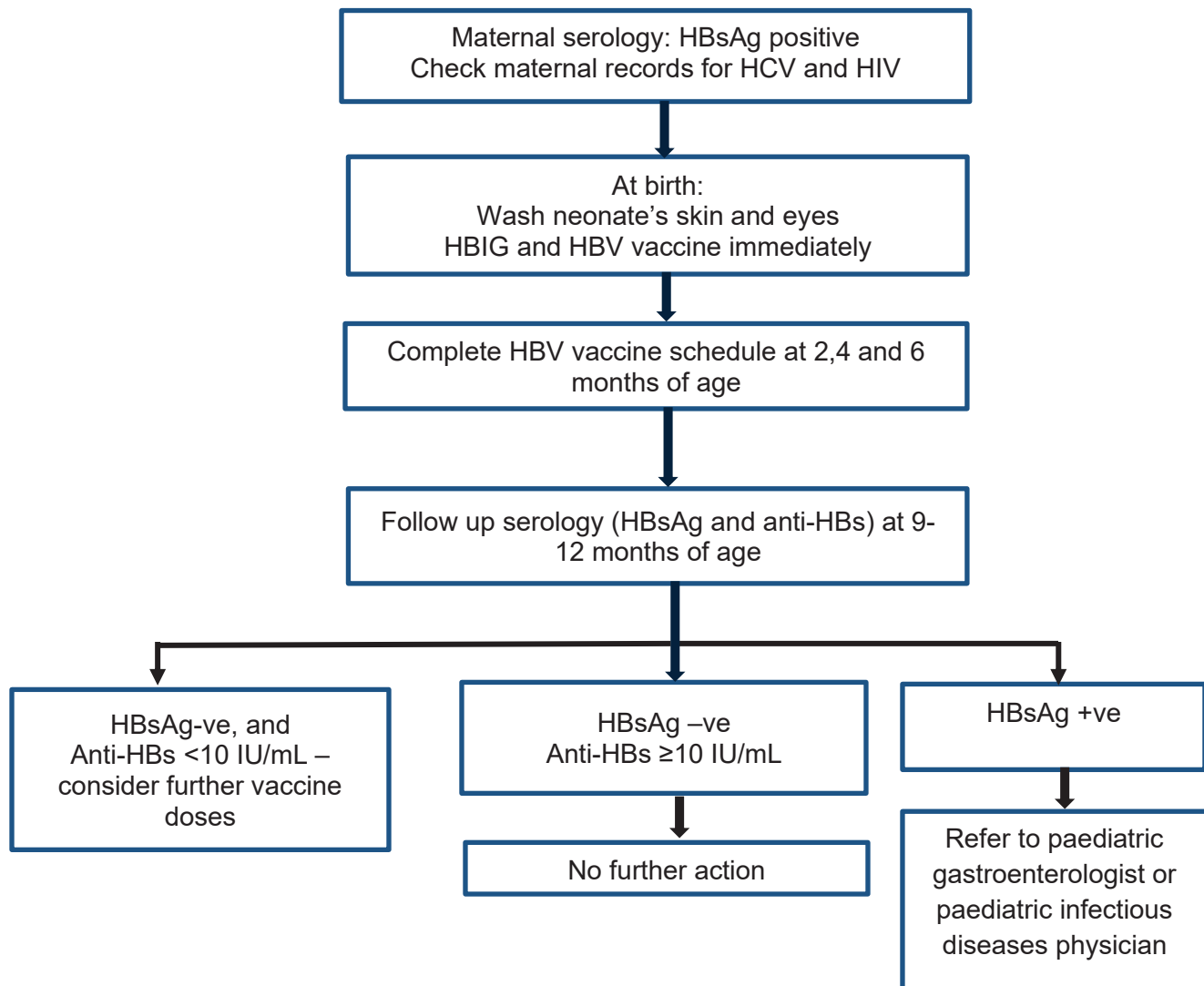
Date	Revision No.	Author and Approval
14/9/04	1	Endorsed Neonatal Clinical Committee 8/7/03 & Maternit Services Clinical Committee 14/9/04 Approved Quality Council 20/9/04
	2	Previously titled Hepatitis B Program Procedure for Babies of Hepatitis B Positive Mothers
October 2012	3	Reviewed and endorsed Maternit Services Division LOPs group October 2012 Approved Quality & Patient Safety Committee December 2012
9/2/21	4	Reviewed and endorsed Maternity Services LOPs group 9/2/21
6.2.2025	5	Srinivas Bolisetty (Neonatologist), Phoebe Williams (Paediatric Infectious Diseases Physician) Endorsed by NCC CBR Committee
14.4.25	5	RHW BRGC



**Hepatitis B Positive Mother – Neonatal  
management**

**RHW CLIN133**



**Appendix 1. Neonatal management – Algorithm**



**Hepatitis B Positive Mother – Neonatal  
management**

RHW CLIN133

**Appendix 2 Blood & Blood Products Administration**

 SEI130060	 <b>Health</b> South Eastern Sydney Local Health District Illawarra Shoalhaven Local Health District Sydney Children's Hospital Randwick	FAMILY NAME _____ MRN _____ GIVEN NAME _____ <input type="checkbox"/> MALE <input type="checkbox"/> FEMALE D.O.B. ____/____/____ M.O. _____ ADDRESS _____ LOCATION / WARD _____ COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE
	<b>Facility:</b> _____	BLOOD & BLOOD PRODUCTS ADMINISTRATION
	<b>MEDICAL OFFICER TO COMPLETE PRIOR TO ADMINISTRATION</b>	
	Indication for blood/blood products _____ _____ _____	Previous adverse reaction to blood products? <input type="checkbox"/> Yes <input type="checkbox"/> No (if yes, give details): _____ _____ _____
	<b>CONSENT FOR BLOOD/BLOOD PRODUCTS (to be signed by Patient/Parent/Guardian)</b> Interpreter present? <input type="checkbox"/> Yes <input type="checkbox"/> No Dr _____ has discussed my present condition and as part of the management has recommended the administration of blood products for myself / my child / person under guardianship. <input type="checkbox"/> I have received information about the risks, benefits and alternatives to treatment with blood / blood products. <input type="checkbox"/> I have read and understand the written information. <input type="checkbox"/> I have had the opportunity to ask questions and am satisfied with the explanations and answers to my questions. <input type="checkbox"/> I understand the nature of the treatment and that undergoing the treatment carries risks. <input type="checkbox"/> I understand that I may withdraw this consent at any time prior to, or during the treatment. <input type="checkbox"/> I understand that this consent will be reviewed if my condition or circumstances change. <input type="checkbox"/> I hereby consent to the treatment described above for myself / my child / person under guardianship.	
<b>Consenting Medical Officer:</b> Print Medical Officer's Name _____ Medical Officer's Signature _____ Pager No. _____ Date _____ If a valid consent has been sighted the patient DOES NOT need to sign again. Please write date of original consent here _____ and sign below. Print Medical Officer's Name _____ Medical Officer's Signature _____ Pager No. _____ Date _____		
<b>A) Sign here for one admission episode (refer to policy):</b> Name of Parent/Carer/Guardian _____ Signature _____ Date _____		
<b>B) Sign here for multiple episodes over 12 months:</b> I am / my child is receiving blood / blood products on a regular basis and would like to consent for multiple episodes for the next 12 months. Name of Parent/Carer/Guardian _____ Signature _____ Date _____		
<b>Interpreter</b> Print Name Of Interpreter _____ Interpreter's Signature _____ Date _____		

NO WRITING

Page 1 of 2

## Hepatitis B Positive Mother – Neonatal management

RHW CLIN133

### Appendix 3 Authority to Issue Blood Products

**AUTHORITY TO ISSUE BLOOD PRODUCTS**

Please check on Patient Product Inquiry to ensure the blood product is ready for collection prior to requesting the product from Blood Bank.

Unless you have a designated satellite blood fridge please do not request blood products until patient and staff are adequately prepared.

Ward \_\_\_\_\_

Theatre \_\_\_\_\_

Please deliver to the messenger:

\_\_\_\_\_ units Packed Red Cells

\_\_\_\_\_ units Platelets

\_\_\_\_\_ units Extended Life Plasma (adult size)

\_\_\_\_\_ units Fresh Frozen Plasma (adult size)

\_\_\_\_\_ units Fresh Frozen Plasma (paediatric size)

\_\_\_\_\_ units Cryoprecipitate

\_\_\_\_\_ 5% Normal Serum Albumin 500mL

\_\_\_\_\_ 5% Normal Serum Albumin 250mL

\_\_\_\_\_ 20% Normal Serum Albumin 100mL

\_\_\_\_\_ 20% Normal Serum Albumin 50mL

\_\_\_\_\_ grams Intravenous Immunoglobulin (specify) \_\_\_\_\_

\_\_\_\_\_ grams Subcutaneous Immunoglobulin (specify) \_\_\_\_\_

\_\_\_\_\_ Anti-D 250IU

\_\_\_\_\_ Anti-D 625IU

\_\_\_\_\_ Prothrombinex-VF®

\_\_\_\_\_ Tetanus Immunoglobulin-VF (250 IU)

\_\_\_\_\_ (other, please specify)

Surname: \_\_\_\_\_

First Name: \_\_\_\_\_

MRN: \_\_\_\_\_ D.O.B.: \_\_\_\_\_

**Special Requirements**

☐ Irradiated

☐ CMV negative

☐ Other: \_\_\_\_\_

**Critical Bleeding Protocol**

☐ **NON ROTEM**

☐ Pack 1

☐ Pack 2

☐ **ROTEM**

Authorised by: \_\_\_\_\_ (print)

Signature \_\_\_\_\_

Date: \_\_\_\_\_ Time: \_\_\_\_\_

**Note:**


1. The messenger must deliver the blood product to the ward/theatre immediately after collection
2. The blood product must not be stored in a ward or domestic fridge
3. If there is a delay in administering a blood product or it is no longer required it MUST be stored in a satellite blood fridge (red cells only) or returned to Blood Bank within 30 minutes of the product being dispensed
4. Single use dispensing applies unless critical bleeding protocol has been activated, apheresis procedure or satellite blood fridge is available to store red cells.

NHSIS1289 040324 See Over

## Hepatitis B Positive Mother – Neonatal management

RHW CLIN133

### Appendix 4 Neonatal Hepatitis B Vaccination Record

 <b>NSW Health</b> Facility: _____	FAMILY NAME _____ MRN _____ GIVEN NAME _____ <input type="checkbox"/> MALE <input type="checkbox"/> FEMALE D.O.B. ____/____/____ M.O. _____ ADDRESS _____ LOCATION / WARD _____ COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE	
	<b>NEONATAL HEPATITIS B VACCINATION RECORD</b> <b>MY PERSONAL HEALTH RECORD</b>	
<b>NEONATE BORN TO HEPATITIS B POSITIVE MOTHER</b> Baby's name (if known): _____ Birth location: _____ Gestational weeks: _____ Time of birth: ____:____ Birth weight: _____ grams Indigenous Status: <input type="checkbox"/> Yes - Aboriginal <input type="checkbox"/> Yes - Torres Strait Islander <input type="checkbox"/> Yes - Both <input type="checkbox"/> Neither <input type="checkbox"/> Unknown		
<b>NEONATE IMMUNOGLOBULIN/VACCINATION DETAILS</b> Hepatitis B Immunoglobulin administered <input type="checkbox"/> Yes <input type="checkbox"/> No Hepatitis B Immunoglobulin within 12 hours <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Date: ____/____/____ Time: ____:____ Birth dose hepatitis B vaccine (given within 7 days) <input type="checkbox"/> Yes <input type="checkbox"/> No Date: ____/____/____ Time: ____:____ im+ submitted <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A		
<b>NEONATE FOLLOW-UP WITH</b> 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? <input type="checkbox"/> Yes <input type="checkbox"/> No Copy of GP letter given? <input type="checkbox"/> Yes <input type="checkbox"/> No Copy of brochure given? <input type="checkbox"/> Yes <input type="checkbox"/> No If no, please give reason: (ims+ to be completed if GP letter has not been provided): _____		
<b>MOTHER</b> Family name: _____ Given names: _____ Indigenous Status: <input type="checkbox"/> Yes - Aboriginal <input type="checkbox"/> Yes - Torres Strait Islander <input type="checkbox"/> Yes - Both <input type="checkbox"/> Neither <input type="checkbox"/> Unknown Phone: _____ Mobile: _____ Email: _____ MRN: _____ Mother referred to GP: <input type="checkbox"/> Yes <input type="checkbox"/> No Name of GP: _____ Referral date: ____/____/____ And/Or Mother referred to Specialist: <input type="checkbox"/> Yes <input type="checkbox"/> No Name of Specialist: _____ Referral date: ____/____/____ Highest viral load during current pregnancy: _____ Date: ____/____/____		
Mother's Medicare number <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Single Digit next to Mother's name <input type="text"/>		
<b>FATHER/PARTNER/ALTERNATE</b> Family name: _____ Given names: _____ Phone: _____ Mobile: _____ Email: _____ Father/Partner's Medicare number (if available/different to mother's): <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Single Digit next to Father/Partner's name <input type="text"/>		
<b>CHECKLIST</b> 1. Have all vaccination details been entered in the relevant LHD maternity data base and My Personal Health Record (Blue Book)? <input type="checkbox"/> Yes <input type="checkbox"/> 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? <input type="checkbox"/> Yes <input type="checkbox"/> No 3. Has a copy of this form been sent to the LHD Neonatal and Infant Hepatitis B Lead? <input type="checkbox"/> Yes <input type="checkbox"/> 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? <input type="checkbox"/> Yes <input type="checkbox"/> No		
Name: _____ Designation: _____ Signature: _____ Contact No: _____ Date: ____/____/____		



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**Hepatitis B Positive Mother – Neonatal  
management**

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**RHW CLIN133**

## **Appendix 5 Letter to General practitioner/paediatrician**

Date: xx/xx/xxxx

Address

Dear Dr

RE: Baby of XX DOB: xx/xx/xxxx MRN: XXXXXXXXXX. Gender: Birthweight:

- \* Hepatitis B vaccine: Given on xx/xx/xxxx
- \* Hepatitis B immunoglobulin (HBIG): Given on xx/xx/xxxx xx:00 hrs
- \* Peak maternal viral load xxx /mL (dated xx/xx/xxxx) and peak maternal ALT xxx (dated (xx/xx/xxxx))

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.

We recommend the following:

1. Complete 3 subsequent doses of hepatitis B containing vaccine as per routine vaccine schedule at 2, 4 and 6 months of age. 2-month dose can be at 6 weeks 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.
2. Perform Hepatitis B surface antigen antibody (Anti-HBs) and HBsAg levels at 9-12 months of age (not before 9 months of age). This is to confirm the immunity for the infant. Children who have Anti-HBs levels  $\geq 10$  m IU / mL and are HBsAg negative are considered to be protected.
3. If the Anti-HBs level is  $< 10$  mIU/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 or paediatric infectious diseases specialist clinic at Sydney Children's Hospital, Randwick.

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.