HEPATITIS B POSITIVE WOMAN AND HER NEONATE(S)

This LOP is developed to guide clinical practice at the Royal Hospital for Women. Individual patient circumstances may mean that practice diverges from this LOP.

1. AIM

- Appropriate identification and management of woman with Hepatitis B infection
- Reduce mother to child infection of Hepatitis B
- Arrange postnatal follow-up optimising maternal and neonatal treatment

2. PATIENT

- Pregnant woman with chronic or acute Hepatitis B in pregnancy

3. STAFF

- Medical, midwifery, and nursing staff
- Student midwives

4. EQUIPMENT

- Personal protective equipment (PPE)

5. CLINICAL PRACTICE

ANTENATAL

- Counsel and screen pregnant woman for Hepatitis B at booking with Hepatitis B surface antigen (HBsAg) and document results on antenatal card and in medical record
- Inform woman if she is HBsAg positive using clear language e.g. “You have Hepatitis B infection”
- Arrange an appointment for the woman who is HBsAg positive in maternity outpatients antenatal clinic for ‘Infection in Pregnancy’. Place checklist in woman’s notes (see appendix 1)
- Give woman the information sheet “Hepatitis B in pregnancy” (Appendix 2)
- Recommend further serology testing by South Eastern Sydney Laboratory Services (SEALS) if HBsAg positive:-
    - Anti-HBe (anti-HBe or HBeAb positive status indicates the woman is at lower risk of spreading HBV infection than HBeAg positive women)
    - HBV viral load (HBV DNA) provides an accurate reflection of infectivity (high risk carriers have high viral loads)
    - Liver function test (repeat at 26-28 weeks)
    - Full Blood Count (FBC)
    - International Normalised Ratio (INR)
    - Consider HBV DNA polymerase chain reaction (PCR) to detect pre-core mutants
- If HBsAg positive, SEALS automatically test, HBcAb, HBeAg, HBeAb, HBsAb, HBeAg (the e antigen identifies a high infective status)

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- See table below for interpretation of results:

INTERPRETATION OF SCREEN POSITIVE RESULTS

Hepatitis B surface antigen	HBsAg	Indicates current infection
Hepatitis B e-antigen	HbeAg	Indicates the presence of the virus that can be passed to others. Not all strains of hepatitis B produce e-antigen.
Hepatitis B surface antibody	HbsAn or Anti-HBs	Indicates immunity either through natural clearance or through vaccination.
Hepatitis Be antibody	HbeAb or Anti-Hbe	Shows the virus is not actively replicating.
Anti-hepatitis B core antigen	Anti-HBc	An antibody to the hepatitis B core antigen. The core antigen disappears early in the course of the infection. Anti-HBc may indicate acute, chronic, or past infection
Hepatitis B virus DNA	HBV DNA	Measures the amount of virus in the bloodstream and is an indicator of how actively the virus is replicating

- Ensure woman has been tested for Hepatitis C and Human Immuno-Deficiency Virus (HIV) in current pregnancy
- Refer Hepatitis B positive woman:
  - to Prince of Wales (POW) Liver Clinic at 20 weeks gestation, with full medical officer details provided (e.g. provider number and contact details). Fax 02 9650 4898 or telephone 02 9382 3100
  - who requires interpreter services to Infectious Diseases clinic at POW (instead of Liver clinic), with full medical officer details provided (e.g. provider number and contact details). Fax 93823403 or telephone 93823405
- Inform the woman that Hepatitis B is a notifiable disease
- Notify the Public Health Unit (PHU) of a new diagnosis via telephone 93828333 and fax 93828314 during normal business hours or On-Call PHU nurse after hours through POW Switch 93822222
- Inform the Hepatitis B positive woman that all her household contacts should be referred to their GP for screening and vaccination, if they have not previously been vaccinated. HBV vaccine is free for high risk individuals
- Inform woman of recommendation for neonatal vaccination, and administration of Hepatitis B immunoglobulin to the neonate within four hours after birth (preferably prior to leaving Delivery Suite)

INTRAPARTUM

- Take HbsAg (and full antenatal bloods) on admission for woman who has had not been screened or who has had no antenatal care. The HbsAg and HIV should be marked as urgent. The results are required within 12 hours of birth, so neonate can be vaccinated
- Contact the laboratory by telephone between 0800-1700 hours on ext. 29152. After Hours telephone central reception desk ext. 29601
- Avoid fetal blood sampling and the use of fetal scalp electrodes for fetal monitoring, particularly if HbeAg positive
- Use standard PPE
- Recommend health care workers who are non responders to Hepatitis B vaccine to avoid attendance at the birth of a woman with a high viral load (e.g. HbeAg) due to the amount of blood at a birth

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HEPATITIS B POSITIVE WOMAN AND HER NEONATE(S) cont'd

POSTNATAL/NEONATAL

- Prescribe Hepatitis B vaccine and immunoglobulin on the neonatal medication chart by the medical officer in Delivery Suite 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). Request immunoglobulin from blood bank on *Authority to Issue Blood Products* form (S1289)
- Administer vaccine and immunoglobulin as soon as possible after birth i.e. < four hours postpartum and prior to leaving delivery suite
- Clean the injection sites with alcohol swab before administering injections
- Administer intramuscular immunoglobulin and vaccine in different sites. The anterolateral aspect of the thigh is preferred. The gluteal area should not be used in a neonate
- Record administration of the immunoglobulin and vaccine:
  - on medication chart with batch number and
  - in Personal Health Record plus Immunisation Record page for vaccine and immunoglobulin
  - Complete Neonatal Hepatitis B Vaccination Record (Appendix 2)
- Remind parents before discharge of the importance of the neonate receiving second, third and fourth vaccinations at two months (can be given as early as six weeks), four months and six months
- Give woman discharge summary and Hepatitis B letter (generated from eMaternity - see Appendix 3) to take to GP for follow up testing of baby (HBS Ag and Anti-HBs) at 9-12 months of age. If any follow-up tests return positive, further follow-up by a paediatrician is necessary
- Notify the Hepatitis B coordinator by placing the neonatal Hepatitis B vaccination record in the identified Hepatitis B folder on delivery suite or postnatal ward, at time of discharge. The coordinator will inform New South Wales PHU.

6. DOCUMENTATION

- Medical Record
- Antenatal Card
- 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)

7. EDUCATIONAL NOTES

- Hepatitis B is a viral infection that can cause both acute and chronic liver infection and damage [1,3]
- After acute 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 at or around the time of childbirth. Carriers may be asymptomatic[3]
- Hepatitis B is a vaccine-preventable disease, and four doses of Hepatitis B vaccine in the first year of life to be given at birth, 2 months, 4 months, and 6 months are recommended in the current Australian National Immunisation Program Schedule[2,6]
- For a neonate born to a mother with HBV infection, Hepatitis B vaccination reduces the risk of infection by 70%; the addition of HBIG at birth augments this risk reduction to over 90%
- HBsAg positive women can breastfeed their babies providing the baby is immunized

HEPATITIS B POSITIVE WOMAN AND HER NEONATE(S) cont'd

- Acute Hepatitis B is rare in Australia. Most Hepatitis B infections are acquired prenatally and most of these infections can be prevented by appropriate prophylaxis given at the time of birth. Women with acute hepatitis caused by Hepatitis B virus (HBV) and those with chronic Hepatitis B viral infection (HBsAg positive) may transmit HBV to their infants. Acute Hepatitis B diagnosed in the first or second trimester carries a perinatal transmission risk of approximately 10%. Acute Hepatitis B diagnosed in the third trimester carries a perinatal transmission risk of approximately 75%. There are no data to justify a recommendation on the mode of birth in acute hepatitis [1,6]
- 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 [5,6]
- For a **woman who has very high viral load** (>200,000 IU/ml), active/passive immunisation (vaccine/HBIG) of babies at birth is effective in preventing transmission of Hepatitis B in more than 95 % of babies. The 5% of babies who fail to be protected by this regimen and develop Hepatitis B are usually those who do not receive the full regimen of vaccination, those who fail to develop antibodies (anti-HBs), or who are born to mothers with very high levels of HBV DNA [4,5,6]
- There is agreement that the risk of immunoprophylaxis failure is extremely rare when HBV DNA is <5.3 $\log_{10}$ IU/ml (<200,000 IU/ml) and clinically significant when HBV DNA is >7.0 $\log_{10}$ IU/ml. Controversy remains when maternal HBV DNA levels are within the 'grey zone' (between 5.3 and 7.0 $\log_{10}$ IU/ml). Societal guidelines suggest that antiviral prophylaxis should be administered if the maternal HBV DNA is >200,000 IU/ml, acknowledging that this cut-off is a conservative choice to minimize any risk of MTCT[12]
- Oral antiviral agents given from 30 weeks gestation have been shown to reduce the viral load and reduce risk of mother-to-child transmission at delivery, however, are not available on authority prescription [4,6]
- Consider treatment with oral tenofovir or telbivudine from 28-30 weeks of gestation until delivery, or earlier if amniocentesis or invasive procedure is required or preterm birth is likely. It may be continued for a month after delivery. Rebound rise in HBV viral load and or ALT may occur. Informed consent should be obtained [4,9]
- 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 the mode of delivery with caesarean section being reserved for the usual obstetric indications[6]
- It is vital to ensure babies 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 2, 4 and 6 months of age [5,6,8]

8. RELATED POLICIES / PROCEDURES / CLINICAL PRACTICE LOP

- Hepatitis B vaccine for newborn infants
- Sexual transmitted infections (STI) / blood born viruses (BBV) Antenatal screening and treatment
- Infection Prevention and Control Policy PD2017_013
- Table of Infectious Diseases, Modes Transmission and Recommended Precautions (POWH)

9. RISK RATING

- Medium

10. NATIONAL STANDARD

- Comprehensive Care – Standard 5

HEPATITIS B POSITIVE WOMAN AND HER NEONATE(S) cont'd

11. REFERENCES

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10 Australian Government, Dept of Health and Ageing 2020: National Health (Immunisation Program - Designated Vaccines) Determination 2014 (No. 1) F2020C00014

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REVISION & APPROVAL HISTORY

Reviewed and endorsed Maternity Services LOPs group 9/2/21
Approved Quality & Patient Safety Committee December 2012
Reviewed and endorsed Maternit Services Division LOPs group October 2012
Previously titled *Hepatitis B Program Procedure for Babies of Hepatitis B Positive Mothers*
Endorsed Neonatal Clinical Committee 8/7/03 & Maternit Services Clinical Committee 14/9/04
Approved Quality Council 20/9/04

FOR REVIEW : FEBRUARY 2024

…./Appendices

Appendix 1

CHECKLIST

ACTION	DATE	SIGNED
Arrange further serology/bloods (including viral load (HBV) and record in electronic medical record)		
Patient information leaflet given re vaccination and immunoglobulin to baby		
Household contacts screened and vaccinated	Names	
Liver clinic or infectious disease clinic referral		
Date seen in liver or infectious disease clinic		
Postnatal follow-up with liver or infectious disease clinic arranged		
Hepatitis B Coordinator notified (postnatally via folder)		
GP letter and discharge summary for baby follow up		

Appendix 2

Hepatitis B Information for Women

Blood tests have shown that you have tested positive to a virus called Hepatitis B. This virus can cause jaundice or infection in the liver.

Many women have the virus in their blood for a long time without knowing that they have been infected. The virus may remain in their blood for many years without even causing illness. This is very common in certain parts of the world including the Mediterranean, Asia, Aboriginal communities, and the Pacific islands. These affected people are often called carriers.

When Hepatitis B is present in the body, the virus can be found in the person's blood and body secretions such as saliva, semen, vaginal fluid, breast milk, urine, and tears. Until the virus has completely gone from your system, it is possible to infect others who may contract Hepatitis B as well. For others to become infected, they need to have contact with your blood or body secretions.

All members of your household are advised to be vaccinated against Hepatitis B if they have not already done so. This can be done with their GP. Until a vaccination course is complete, it is important to avoid sharing any sharp instruments such as razors, toothbrushes, or earrings, etc. since small amounts of blood can be exchanged through these items. Also, infected individuals should be careful to keep all cuts properly covered.

Blood spills should be cleaned with gloves and a 10% bleach/water solution. Hepatitis B is not transmitted casually, and it cannot be spread through sneezing, coughing, hugging, or eating food prepared by someone who is infected with Hepatitis B.

If you are Hepatitis B Surface Antigen (HBsAg) positive, you require further blood tests to assess your liver function and check your viral load.

This virus may also be passed from mother to baby at birth and soon after. Babies who develop the infection, are much more likely to carry the infection for their whole life. To prevent this occurring, we recommend that all babies of women who are Hepatitis B positive have injections to immunise and protect their baby.

The immunisation consists of 2 injections immediately after birth. One injection contains antibodies that protect the baby from the virus for several weeks (immunoglobulin). The second injection (Hepatitis B vaccine) stimulates the baby to produce its own antibodies to protect him/herself. This vaccine is repeated for your baby at 2 (can be given from 6 weeks), 4 and 6 months of age as per the immunisation schedule. This then assists in protecting the baby for life against Hepatitis B. These vaccines are supplied by the NSW Department of Health free of charge. After the 2 immediate injections the baby can breastfeed.

During your pregnancy you will see an obstetrician, a midwife, and be referred to the Prince of Wales Liver or Infectious Disease clinic. At the Liver or Infectious Disease clinic you will be monitored for changes in your health, related to the Hepatitis B. You will also be seen at the Liver or Infectious Disease clinic after the baby is born to see if you should have any treatment to clear the infection. Your baby will need to be seen by your GP (family doctor) at 9 months of age for follow up Hepatitis tests.

If you have any further questions, contact your Midwife or Doctor.

Appendix 3

NSW GOVERNMENT Health

Facility:

NEONATAL HEPATITIS B VACCINATION RECORD

FAMILY NAME | MRN

GIVEN NAME | ☐ MALE ☐ FEMALE

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

ADDRESS

LOCATION / WARD

COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE

SMR060481

Holes Punched as per AS2828.1: 2012

BINDING MARGIN - NO WRITING

NEONATE BORN TO HEPATITIS B POSITIVE MOTHER

Time of birth: ____ : ____ Birth Weight: _____ grams | Birth location: _____

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

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 Mother referred to Specialist ☐ Yes ☐ No

Peak viral load: _____ Date: ____/____/____ Peak LFT (ALT): _____ Date: ____/____/____

Mother's Medicare number ☐☐☐☐ ☐☐☐☐☐ ☐

FATHER/PARTNER

Family name: _____ Given names: _____

Phone: _____ Mobile: _____

Email: _____

INFANT VACCINATION DETAILS

Hepatitis B Immunoglobulin (*within 12 hrs of birth*)	Date: ____/____/____ Time: ____ : ____
1st dose Hepatitis B vaccine (*within 7 days of birth*)	Date: ____/____/____ Time: ____ : ____

INFANT FOLLOW-UP

Mother's nominated location for follow-up
(*Hospital/Local Doctor/Council/ Early Childhood Centre*)

Name: _____

Address: _____

_____

Phone: _____

Has the infant'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:

CHECKLIST

1. Have all vaccination details been entered in eMaternity/Cerner Maternity and Personal Health Record?	☐ Yes ☐ No
2. Has a copy of this form been forwarded to the Neonatal Hepatitis B Vaccination Program Hospital Coordinator following the infant's discharge from hospital?	☐ Yes ☐ No

Name: _____ Designation: _____

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

NHT00268 110917

NO WRITING

NEONATAL HEPATITIS B VACCINATION RECORD SMR060481

Appendix 4

Royal Hospital for Women

15/06/2020
Royal Sanity
85 Smith Street
Randwick 2031 NSW

Dear Royal

RE: Baby of Sanity MRN: 11138004 Royal Hospital for Women
Baby # 1 DoB: 03/06/2020 12:00 MRN: 11138007 Sex: F Born: Royal Hospital for Women

* Hepatitis B vaccine within 7 days of birth: Given on 03/06/2020
* Hepatitis B immunoglobulin (HBIG) within 12 hrs of birth: Given on 03/06/2020 14:00

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.