Approved by Quality & Patient Safety Committee
December 2012

HEPATITIS B POSITIVE MOTHERS AND THEIR BABIES

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.

- **AIM**
  - Appropriate identification and management of women with Hepatitis B infection
  - Reduce mother to child infection of Hepatitis B
  - Arrange appropriate postnatal follow-up to optimize maternal and neonatal treatment

- **PATIENT**
  - Pregnant woman with chronic or acute Hepatitis B in pregnancy

- **STAFF**
  - Registered Midwives
  - Medical Staff
  - Student Midwives
  - Registered Nurses

- **EQUIPMENT**
  - Hepatitis B vaccine
  - Hepatitis B immunoglobulin

- **CLINICAL PRACTICE**

  ANTENATAL
  - Screen all pregnant women for Hepatitis B at booking with Hepatitis B Surface Antigen (HBsAg) and document results on Yellow Card and in ObstetriX
  - Inform the woman if she is HBsAg positive. The medical officer / midwife should use clear language (e.g. “You have Hepatitis B”)
  - Arrange referral for woman who is HBsAg positive to see an obstetrician
  - Give woman the information sheet “Hepatitis B in pregnancy”
  - Recommend neonatal vaccination and Hepatitis B immunoglobulin for the baby within 12 hours after birth (preferably prior to leaving Delivery Suite)
  - Arrange for serology testing by SEALS if HBsAg positive: (see table below for interpretation of results). If HBsAg positive, SEALS automatically go on to test, HBcAb, HBeAg, HBeAb, HBsAb

    HBeAg (the e antigen identifies a high infective status)
    - 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 28 weeks)
  - Consider HBV DNA polymerase chain reaction (PCR) to detect pre-core mutants
  - Perform tests for Full Blood Count (FBC) and International Normalised Ratio (INR)
  - Ensure patient has been tested for Hepatitis C and Human Immuno-Deficiency Virus (HIV) in this pregnancy

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HEPATITIS B POSITIVE MOTHERS AND THEIR BABIES cont'd

- Refer Hepatitis B positive woman to be seen at the Prince of Wales (POW) Liver Clinic at around 20 weeks gestation, with a medical referral with the name and provider number of the medical officer,
  Fax 02 9650 4898 Phone 02 9382 3101
- Inform the woman that it is a notifiable disease and notify the Public Health Unit if it is a new diagnosis
- Inform the woman that all household contacts of women with Hepatitis B should be referred to their GP for screening and vaccination, if they have not previously been vaccinated. (HBV vaccine is free from GPs for high risk groups)

INTRAPARTUM

- Take HBsAg (and antenatal bloods) on admission for woman who has had not been screened or who has had no antenatal care. The HBsAg should be marked as urgent, as results are required within 12 hours of birth, so vaccine can be administered within 12 hours. The laboratory must be phoned: between 8am-5pm Ext. 29152. After Hours phone central reception desk Ext. 29601
- Avoid the use of fetal scalp electrodes during fetal monitoring, particularly if HBeAg positive.
- Avoid fetal blood sampling, particularly if HBeAg positive
- Implement standard precautions for care of all women
- Health care workers who are non responders to Hepatitis B vaccine should not be present at the birth of a women with a high viral load e.g. HBeAg (due to the amount of blood)

NEONATAL

- Clean the neonate's eyes and non-intact skin with water as soon as possible after the birth
- Obtain written consent from the mother for the baby to receive the immunoglobulin using the Blood Products Transfusion form
- Obtain verbal consent from the mother for the baby to receive Hepatitis B vaccine
- Prescribe Hepatitis B vaccine and immunoglobulin on the baby's medication chart by the medical officer in Delivery Suite on day of birth.
- Administer vaccine and immunoglobulin as soon as possible after birth and within 12 hours
- Clean the injection sites well before administering injections
- Administer the immunoglobulin and vaccine by intramuscular injection in different sites. The anterolateral aspect of the thigh is the preferred site. The gluteal area should not be used in infants.
- Record administration of the immunoglobulin and vaccine to the baby:
  - On medication chart with batch number
  - In Personal Health Record (Page 6.5), Immunisation Record (Page 16.2) for vaccine
  - Personal Health Record, Immunisation Record (Page 16.2) for immunoglobulin
- Remind parents before discharge of the importance of the baby receiving second, third and fourth vaccinations at 2 months, 4 months and 6 months
- Refer baby to a GP for follow up testing (HBS Ag and Anti-HBs) at 9-12 month of age (by Paediatric Resident Medical Officer (RMO) prior to discharge). (Good place to record this advice would be on the immunisation record (P16.2) in personal health record)
- Advise (by Paediatric RMO) parents of the importance of follow-up at 9-12 months and possible further follow-up by a paediatrician if any of the follow-up tests return positive. Notify the Infection Control CNC Ext. 26339 (by the midwife who has administered vaccination and immunoglobulin to the baby). Infection Control CNC will contact the New South Wales Public Health Unit

HEPATITIS B POSITIVE MOTHERS AND THEIR BABIES cont'd

- **DOCUMENTATION**
  - Integrated clinical notes
  - ObstetriX
  - Yellow card
  - Medication chart
  - Personal Health Record
  - Immunization Record
  - Blood Product Consent Form

- **EDUCATIONAL NOTES**
  - Hepatitis B is a viral infection that can cause both acute and chronic liver infection and damage
  - 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.
  - Hepatitis B is a vaccine-preventable disease, and 4 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
  - 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 immunised
  - Acute Hepatitis B (HB) 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
  - 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.

Women who have very high viral loads (≥ 107 HBV DNA copies / 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
  - Oral antiviral agents given from 32 weeks gestation have been shown to reduce the viral load and reduce risk of mother-to-child transmission at delivery, however there are not available on Authority prescription
  - Consider treatment with oral Telbivudine 600 mg daily from 32 weeks of gestation until delivery. 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
  - Caesarean section is known to lower the risk of perinatal transmission in chronically infected HBeAg positive mothers, however, the benefit of caesarean section is only marginal and caesarean section may not be protective without active / passive immunisation of the baby. It is therefore 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

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ROYAL HOSPITAL FOR WOMEN

LOCAL OPERATING PROCEDURE

CLINICAL POLICIES, PROCEDURES & GUIDELINES

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HEPATITIS B POSITIVE MOTHERS AND THEIR BABIES cont'd

- **RELATED POLICIES / PROCEDURES / CLINICAL PRACTICE LOP**
  - Hepatitis B vaccine for newborn infants
  - Antenatal screening and treatment Sexual transmitted infections (sti) / blood born viruses (bbv)

- **REFERENCES**

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2 Australian Government, Department of Health and Aging 2007 National Immunisation Program. http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/E875BA5436C6DF9BCA2575BD001C80BF/$File/nip-schedule-card-july07.pdf

3 National Hepatitis B Strategy 2010–2013. Australian Government. Department of Health and Aging 2010. http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-national-strategies-2010-hepb/$File/hepb.pdf

4 Peters MG. Special Populations with Hepatitis B Virus Infection. Hepatology 2009;49:S146-S155

5 Lee C, Gong Y, Brok J, et al. Effect of hepatitis B immunisation in newborn infants of mothers positive for hepatitis B surface antigen: systematic review and meta-analysis. **BMJ**. 2006;332(3737):328-36.

6 The Royal Australian and New Zealand College of Obstetricians and Gynaecologists. Hepatitis B. RANZCOG College Statement C-Gen 3. 2009.

7 NSW Ministry of Health '*Screening for Sexually Transmissible Diseases (STDs) and Blood Borne Viruses (BBVs) in Pregnancy'* Doc No GL2005_024 http://www.health.nsw.gov.au/policies/GL/2005/pdf/GL2005_024.pdf

8 Australian Immunisation Handbook 9th ed 2008. Australian Government Department of Health and Aging. http://www.immunise.health.gov.au/

9 Management of Perinatal Infections, 1st ed 2006. Edited by Dr Pamela Palasanthiran, Dr Mike Starr, and Dr Cheryl Jones. AUSTRALASIAN SOCIETY FOR INFECTIOUS DISEASES 2002

10 Australian Government , Dept of Health and Ageing 2011 : National Health (Immunisation Program - Designated Vaccines) Determination 2011 (No. 2) F2011L01616

REVISION & APPROVAL HISTORY

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

HEPATITIS B POSITIVE MOTHERS AND THEIR BABIES cont'd

CHECKLIST

ACTION	DATE	SIGNED
Arrange further serology/bloods		
Patient information leaflet given re vaccination and immunoglobulin to baby		
Household contacts screened and vaccinated	Names	
Liver clinic referral		
Date seen in liver clinic		
Postnatal follow-up with liver clinic arranged		
Infection Control CNC notified		
GP Referral for baby follow up		

INTERPRETATION OF SCREENING RESULTS

Hepatitis B surface antigen	HBsAg	A positive results 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

HEPATITIS B POSITIVE MOTHERS AND THEIR BABIES cont'd

APPENDIX A

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 been. For this they should see your GP. Until your vaccine series 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 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 again at 2, 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 Clinic. At the Liver Clinic you will be monitored for changes in your health, related to the Hepatitis B. You will also be seen at the Liver 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.