Policy

Clinical Guideline

Hepatitis B in Pregnancy

Policy developed by: SA Maternal & Neonatal Community of Practice
Approved SA Health Safety & Quality Strategic Governance Committee on: 19 April 2016
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Summary	Clinical practice guideline on hepatitis B in pregnancy
Keywords	hepatitis b in pregnancy, hepatitis b virus, hbv, hepatitis b e antigen, hbeag, hepatitis b surface antigen, hbsag, anti-hbe, antibody to hepatitis b 'e' antigen, polymerase chain reaction, pcr, clinical guideline
Policy history	Is this a new policy? **N** Does this policy amend or update an existing policy? **Y 4.0** Does this policy replace an existing policy? **N** If so, which policies?
Applies to	All SA Health Portfolio
Staff impact	All Staff, Management, Admin, Students, Volunteers All Clinical, Medical, Nursing, Allied Health, Emergency, Dental, Mental Health, Pathology
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Note

This guideline provides advice of a general nature. This statewide guideline has been prepared to promote and facilitate standardisation and consistency of practice, using a multidisciplinary approach. The guideline is based on a review of published evidence and expert opinion.

Information in this statewide guideline is current at the time of publication.

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Health practitioners in the South Australian public health sector are expected to review specific details of each patient and professionally assess the applicability of the relevant guideline to that clinical situation.

If for good clinical reasons, a decision is made to depart from the guideline, the responsible clinician must document in the patient's medical record, the decision made, by whom, and detailed reasons for the departure from the guideline.

This statewide guideline does not address all the elements of clinical practice and assumes that the individual clinicians are responsible for discussing care with consumers in an environment that is culturally appropriate and which enables respectful confidential discussion. This includes:

- The use of interpreter services where necessary,
- Advising consumers of their choice and ensuring informed consent is obtained,
- Providing care within scope of practice, meeting all legislative requirements and maintaining standards of professional conduct, and
- Documenting all care in accordance with mandatory and local requirements

Explanation of the aboriginal artwork:
The aboriginal artwork used symbolises the connection to country and the circle shape shows the strong relationships amongst families and the aboriginal culture. The horse shoe shape design shown in front of the generic statement symbolises a woman and those enclosing a smaller horse shoe shape depicts a pregnant women. The smaller horse shoe shape in this instance represents the unborn child. The artwork shown before the specific statements within the document symbolises a footprint and demonstrates the need to move forward together in unison.

Australian Aboriginal Culture is the oldest living culture in the world yet Aboriginal people continue to experience the poorest health outcomes when compared to non-Aboriginal Australians. In South Australia, Aboriginal women are 2-5 times more likely to die in childbirth and their babies are 2-3 times more likely to be of low birth weight. The accumulative effects of stress, low socio economic status, exposure to violence, historical trauma, culturally unsafe and discriminatory health services and health systems are all major contributors to the disparities in Aboriginal maternal and birthing outcomes. Despite these unacceptable statistics the birth of an Aboriginal baby is a celebration of life and an important cultural event bringing family together in celebration, obligation and responsibility. The diversity between Aboriginal cultures, language and practices differ greatly and so it is imperative that Perinatal services prepare to respectively manage Aboriginal protocol and provide a culturally positive health care experience for Aboriginal people to ensure the best maternal, neonatal and child health outcomes.

Hepatitis B virus (HBV)

- HBV is excreted in body fluids and infects the liver[1]
- Many carriers of HBV are asymptomatic[2]
    - Asymptomatic persons with HBV were once thought to be 'healthy carriers'. However, all people with chronic hepatitis B should receive regular, lifelong monitoring of disease progression by a general practitioner (GP), infectious diseases or liver specialist. Routine monitoring (biannually) even when there are no symptoms, can prevent severe liver disease including liver cancer[3]
- If a mother is hepatitis B e antigen (HBeAg) positive the risk of transmission to the neonate without postpartum vaccination and immunoprophylaxis can be as high as 70-90% at 6 months of age, with up to 90% of these infants developing chronic HBV infection. However, by administering hepatitis B immunoglobulin (HBIG) and the hepatitis B vaccine soon after birth, it can decrease vertical transmission to 5-10%. The other important predictor of perinatal transmission is maternal hepatitis B viral load [4]
- There is sufficient evidence to suggest that using monotherapy anti hep B viral medication (lamivudine, telbivudine or tenofovir) in high risk women during pregnancy could add to the effectiveness of both hepatitis B immunoglobulin and vaccination by suppressing maternal viral load before delivery[5]
- There are no data to justify a recommendation on the mode of birth in acute hepa

- There is insufficient evidence that offering caesarean section provides additional protection against perinatal hepatitis B transmission over the recommended neonatal regimen of hepatitis B immunoglobulin and vaccination[6]. It is therefore vital to ensure babies born to HBsAg positive mothers receive HB vaccine plus HB immunoglobulin at birth. The HB vaccine course must be completed with doses at 6-8 weeks, 4 and 6 months of age [2,6]

Transmission of HBV

- Transmission of HBV may result from inoculation through broken or penetrated skin, or by mucosal contact with blood or other body fluids (mainly vaginal fluids and semen) from an infectious person
- Women with acute hepatitis caused by HBV and those with chronic hepatitis B viral infection (HBsAg positive) may transmit HBV to their infants [2]
    - Acute hepatitis B diagnosed in the first or second trimester carries a perinatal transmission risk of about 10%, increasing to about 75% in the third trimester. Although not routinely recommended, maternal vaccination has been shown to be safe and effective in pregnancy [2,6]
- The risk of spread is increased when there are higher levels of virus in the blood. The level of virus varies considerably between people infected with hepatitis B
- Acute hepatitis B (HBV) is rare in Australia. Most hepatitis B infections are acquired perinatally and most of these infections can be prevented by appropriate prophylaxis given at the time of birth
- In Australia the most likely ways children will have become infected are:
    - Mother-to-baby transmission at or around the time of birth, particularly for people born outside Australia in countries where hepatitis B is common, and in remote Aboriginal and Torres Strait Island communities
    - Child-to-child contact usually through contact between open sores or wounds, particularly for people born outside Australia in countries where hepatitis B is common, and in remote Aboriginal and Torres Strait Island communities
- Other ways of contracting hepatitis B include:
    - sharing equipment used for injecting drugs
    - unprotected sex (anal and vaginal)
    - tattooing and body piercing with unsterilized equipment
    - household contact including sharing razors, hair clippers and toothbrushes
    - accidental needle stick or blood splash to broken skin or mucous membrane

Antenatal screening

- In South Australia, routine antenatal screening for hepatitis B surface antigen (HBsAg) is offered to ALL pregnant women at their first antenatal appointment
    - Hepatitis B surface antigen (HBsAg) positivity implies infection with hepatitis B
    - If HBsAg is negative, and HBsAb is positive, the patient is considered not infected
- Viral mutations in the HBsAg can result in a false negative test (detectable hepatitis B DNA with negative HBsAg) for the detection of hepatitis B infection when requesting only HBsAg and HBsAb on routine antenatal screening. In women from at risk groups (see below) the initial screening should include HBsAg, HBsAb and HbcAb. This is recommended to help identify those at risk of hepatitis B occult infection
- If HbcAb is positive then Hepatitis B viral load and additional testing should be requested. If all three tests are negative the woman does not have hepatitis B infection and she should be vaccinated post-delivery, unless a significant exposure to hepatitis B occurs during pregnancy

Screening tests[6]

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- Serology for HBsAg, HBsAb are recommended for all women
- **Women from at risk groups (see below) should have serology for HBsAg, HBsAb AND HBcAb**
- If HBsAg, HBcAb and HBsAb are all negative, this indicates that the woman is not infected and non-immune to hepatitis B infection. For further information on exposure in pregnancy to hepatitis B see section on 'Exposure to HBV in pregnancy' below
- Ensure household contacts have been screened (by their general practitioner) for hepatitis B and vaccinated if non-immune

At risk groups[2,7]

Women from areas of high prevalence (more than 2 %)[7]

Women from at risk groups should have serology for HBsAg, HBsAb AND HBcAb

- ***Australian Aboriginal and Torres Strait Islanders***
- New Zealand Maoris
- Pacific Islands: Melanesia, Micronesia, Polynesia
- South Asia: India, Bangladesh, Pakistan, Sri Lanka
- South East Asia: Cambodia, Indonesia, Laos, Malaysia, Philippines, Singapore, Thailand, Vietnam
- East Asia: China, Hong Kong, Korea, Taiwan
- Africa (except white South African)
- South America: Chile
- Mediterranean – Crete, Cyprus, Greece, Italy, Malta
- Middle East: Egypt, Iran, Jordan, Lebanon, Turkey
- Central Europe: Romania, Yugoslavia

Non-immune women with a history of:

- Household / intimate contact with a known hepatitis B carrier
- Multiple sexual partners
- Intravenous drug use
- Tattoos / body piercing
- Jaundice or other clinical or biochemical features of acute hepatitis

Notification and counselling of women who are HBsAg positive

- The attending medical officer should inform the woman of her chronic hepatitis B infection, explaining the associated risk to baby and caregivers
- Provide the woman with information about:
    - Transmission risk including subsequent pregnancies AND
    - Lifelong monitoring of liver health
- **Hepatitis B is a notifiable condition[9]**
- The 'Report of notifiable condition or related death' form is not used for hepatitis B
- The forms for notification of hepatitis B are not yet available online (in process and will be available at the end of 2016)
    - Once available online, use the following link: http//www.sahealth.sa.gov.au/NotifiableDiseaseReporting

Currently, the medical officer should either

- Telephone CDCB on 1300 232 272, Monday to Friday (8.30 am to 5.00 pm) with patient details including risk factor information

Or

- The medical officer completes the medical notification form sent out to the medic upon receipt of a positive laboratory result. Fax form to the Communicable Dise

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Control Branch (CDCB) on (08) 8226 7187

- **This form is NOT to be sent by email for reasons of confidentiality**

Aboriginal women should be referred to their nominated aboriginal health professional

Appropriate medical counselling should include:

- Use of interpreter service as required
- Inform the woman early in the consultation of her HBsAg result
- The medical officer should use clear language (e.g. “You have hepatitis B”)
- Explain that hepatitis B is a notifiable disease
- A positive diagnosis is often a shock. Aim to minimise the psychological impact at this time. Reassure the woman about confidentiality and offer information about available sources of support
- It is important to assess how much information the woman can process. There may be a need to arrange a number of consultations to discuss implications for the woman and her unborn baby.
- It is important for the woman to understand her condition so that she can make informed decisions about:
    - Her baby’s care during the perinatal period
    - Care in any subsequent pregnancies
    - Her own health by embarking on a program of lifelong monitoring of liver health including screening for the need for possible treatment and / or hepatocellular carcinoma
- Verbal and written information should be given about:
    - Course of the illness
    - Preventing transmission
    - Need for further serology and monitoring throughout pregnancy and beyond
    - Issues around disclosure and stigmatisation
- The woman’s General Practitioner should be informed to facilitate ongoing care (e.g. contact tracing other family members, vaccinating household contacts if still susceptible)

Available support services

Viral hepatitis nurses:

- Provide advice to GPs on the management of patients with viral hepatitis, including assistance with referral to specialists. Patients may also speak to the nurses directly
- Support is also available for people in country areas
- For contact details, link to http://www.sahealth.sa.gov.au/hepatitisnurse

PEACE Multicultural Services at Relationships Australia

- This service employs workers with a long experience of working with those with chronic hepatitis B who are from a country other than Australia. They have a well-developed understanding of cultural issues and can be contacted to:
    - Provide the woman with further information and support to deal with c

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- Guide and refer to services that will help meet her needs
- Accompany the woman to medical appointments or other relevant services
- For further resources follow link to 'Chronic Hepatitis B the four stages'. http://www.youtube.com/watch?v=ZhL92VZtMHw

- Telephone contact: (08)82458100

Aboriginal Maternal Infant Care (AMIC) workers

- ***Health care workers can contact the AMIC worker or aboriginal health professional (e.g. Aboriginal Liaison officer) in their local area to provide support for Aboriginal and Torres Strait Islander women***

Investigations for women who are HBsAg positive OR HBcAb positive

Obtain further blood for[6]:

- HBeAg (the e antigen identifies a high infective status)
- HBeAb positive status indicates the woman is at lower risk of spreading HBV infection than HBeAg positive women)
- HBcAb if from at risk group (as above) and not done already
- Liver function test (repeat at 28 weeks)
- Complete blood picture
- HBV viral load (HBV DNA) provides an accurate reflection of infectivity (high risk carriers have high viral loads). This should be done before 32 weeks of gestation
- **NOTE:** Once blood results are available refer to Infectious Diseases or Hepatologist

Women with very high antenatal viral loads (≥ 10^7 [greater than or equal to 10 million] HBV DNA 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, who fail to develop antibodies (anti-HBs), or who are born to mothers with very high levels of HBV DNA
- In consultation with the woman, the Infectious Diseases specialist or Hepatologist will consider treatment with either one of the following agents: telbivudine (600 mg daily), oral lamivudine (100 mg daily), OR tenofovir (300 mg daily) from approximately 28 to 32 weeks
- Oral antiviral agents given from 32 weeks gestation have been shown to reduce the viral load and reduce the risk of mother-to-child transmission at delivery.[10]
- If treatment is solely for prevention of perinatal transmission then antiviral therapy is often stopped between 4 and 12 weeks post-partum. However, rebound rise in HBV viral load and / or ALT may occur[1,19,20]
- Give HBIG and HBV to the baby at birth

Women with antenatal viral loads (< 10^7 [less than 10 million] HBV DNA IU / mL)

- At present there is no evidence for routine initiation of antiviral therapy to prevent vertical transmission to the baby
- Antiviral therapy may be considered in cases of hepatitis B transmission to baby previous pregnancy

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- Give HBIG and HBV to the baby at birth

Exposure to HBV during pregnancy[6]

- For patient information regarding Hepatitis B exposure – post exposure prophylaxis (PEP), follow link to www.sahealth.sa.gov.au/hepatitisbPEP
- If previously known to be hepatitis B immune (previously documented anti HBs titre ≥ 10 IU / mL) no intervention is required
- In the absence of previously documented anti HBs titre ≥ 10 IU / mL, antibody levels should be determined as quickly as possible. If maternal anti HBs titre < 10 IU / mL with significant exposure, and there is no evidence of hepatitis B infection (HBsAg negative) give mother:
    - **Hepatitis B immunoglobulin (HBIG) (400 IU, IM) as soon as possible but within 72 hours of exposure AND
    - HB vaccine as soon as possible but within 7 days (percutaneous, ocular or mucous membrane exposures) or 14 days (sexual exposures) of exposure, and repeat at 1 and 6 months post initial dose
- Repeat testing of mother for HBsAG at 1 month and 3 months
- **Obtain HBIG from the Hospital Transfusion service (Request with a Transfusion Request Form). If there is no 24 hour Transfusion service, contact the Australian Red Cross Service Inventory and Distribution Department at (08) 83593164 and fax a Transfusion request form for HBIG 100 units to fax (08) 83325741

Infection control measures

- Standard precautions with blood and body secretions when giving injections, taking blood or performing vaginal examinations
- Women identified antenatally as HBsAg positive should receive counselling from a clinician with expertise in infectious diseases to provide information and advice
- Arrange single room with own toilet facilities for women following birth (risk of blood cross contamination) Arrange single room with own toilet facilities for women following birth (risk of blood cross contamination)
- There is no evidence to suggest that amniocentesis or chorionic villus sampling increases the risk of vertical transmission. However, in the presence of high level viraemia (e.g. during a primary infection) the risk may be higher

Intrapartum management

Caesarean section for prevention of HBV transmission

- With regard to mother-to-infant transmission of HBV during birth, disagreements still exist on the issue of whether a different mode of birth (mainly caesarean section versus vaginal birth) will affect the risk of mother-to-infant HBV transmission
- Routine caesarean section is not recommended

- Of the cases of mothers to infant transmission of HBV, a large proportion occurs during the intrapartum period. Underlying mechanisms may include:
    - The level of viraemia in the pregnant mother[13]

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- Transfusion of the mother's blood to the fetus during labour contractions
- Infection after the rupture of membranes
- Direct contact of the fetus presumably through breaches to natural barriers with infected secretions or blood from the maternal genital tract

- Common sense measures should be taken to avoid procedures that may inoculate the baby, for example:
  - Fetal scalp electrodes
  - Fetal scalp blood sampling
  - Vigorous aspiration or oral suctioning of the baby
- If there is an obstetric indication to expedite delivery in second stage, an instrumental delivery may be the safest mode; however, there is a small risk of traumatising the fetal skin and inoculating the baby

At birth

- Standard precautions - protective eyewear, gown / apron and gloves should be worn by the attending clinicians

Care of the newborn baby

- Standard precautions should be utilised when handling the baby
- The skin at the injection site should be cleaned with soap and water (if visible blood) OR with an alcohol swab before administering hepatitis B vaccine, immunoglobulin and Konakion® (vitamin K)
- The baby should remain in the birthing room until transfer to the ward unless transfer to the nursery is indicated
- Babies direct rooming in with their mother may be cared for in the ward nursery as required
- Consider washing (with soap and water) any visible blood and body fluids from hair or skin before contact with extended family
- HBV DNA and HBsAg have been detected in breast milk[6]
- Breastfeeding does not appear to increase the risk of HBV transmission to the infant
- Breastfeeding is encouraged
- Women receiving antiviral therapy (lamivudine, telbivudine or tenofovir) may breastfeed but should seek specific advice from an Infectious Diseases specialist and the Obstetric and Paediatric Medicines Information Service at the Women's and Children's Hospital (08 8161 7222) as the drugs are excreted in breast milk[21]

Aboriginal woman should be consulted on the care of the newborn baby in the first instance. Consult with the preferred aboriginal health professional if requested

Newborn Immunoglobulin and vaccination

Maternal HBsAg positive

- The hepatitis B immunoglobulin (HBIG) AND hepatitis B vaccine (HB vaccine) should preferably be given to the baby within 12 hours after birth
- Ensure details of the immunoglobulin / vaccine are entered in the 'Birth details' page 5 and 'Immunisation record' page 14 sections of the Government of South Australia "My health record"

HBIG

- Obtain HBIG from the Hospital Transfusion service (Request with a Transfusion Request Form). If there is no 24 hour Transfusion service, contact the Australian Red Cross Service Inventory and Distribution Department at (08) 83593164 and fax a Trans request form for HBIG 100 units to fax (08) 83325741

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- Give HBIG 100 units in an intramuscular injection (thigh) within 12 hours of birth (must be within 48 hours as efficacy decreases markedly if delayed beyond this time)[6]

Hepatitis B vaccine

- Give thiomersal-free monovalent HB vaccine (0.5 mL) 5 micrograms HB-Vax-II OR 10 micrograms Engerix-B paediatric – in an intramuscular injection (opposite thigh)
- If concurrent administration with HBIG is not possible, vaccine should not be delayed beyond 7 days of birth
- Early administration of HB vaccine (within 12 hours) results in seroconversion rates of more than 90 % in neonates, despite concurrent administration of HBIG[6]
- *Refer to hospital standard for administration guidelines
- Three subsequent doses of hepatitis B containing vaccine should be given at 6-8 weeks, 4 months and 6 months so that the infant receives a total of 4 doses of hepatitis B containing vaccines

Low birth weight (LBW) preterm newborn[2,6]

- The 4 dose schedule at 0 (birth), 6-8 weeks, 4,and 6 months of age is recommended as LBW preterm newborn infants (< 2,000g and / or preterm < 32 weeks gestation) do not respond as well to hepatitis B containing vaccines as full-term infants, followed by either:
    - Measuring anti-HBc, anti-HBs level at 7 months of age, and if the antibody titre is < 10 IU/mL giving a booster at 12 months of age (due to a better immunogenic response at this age compared with a younger age); OR
    - Giving a booster of a hepatitis B containing vaccine at 12 months of age (without measuring antibody titre)

Universal recommendation for vaccination

- The National Health and Medical Research Council[2] recommends that all children should be offered a four dose course of Hepatitis B vaccine, beginning with the first dose a short time after birth (preferably within 48 hours but always within 7 days), then combination vaccines at 2, 4 and 6 or 12 months (timing dependent on combination vaccine used)
- Details of the vaccine should be entered in the 'Immunisation record' section (page 16) of the Government of South Australia "My Health and Development Record"

Follow up

- All babies born to HBsAg positive women should be followed up with medical review approximately 2 months after completion of the primary immunisation course (8-12 months)
- The baby's blood should be tested for HBsAg and HBsAb
- If HBsAg is positive, referral to paediatric gastroenterologist or infectious diseases paediatrician is recommended
- In cases where HBV is diagnosed during pregnancy, inform the woman's General Practitioner (GP). Provide copies of any relevant blood tests and advise the GP if the woman has been referred to a hepatology clinic
    - Blood for Hepatitis B status should be taken from the woman's partner and any other household contacts and vaccination offered if the partner is non-immune
- HBsAg positive women should be followed up by their General Practitioner and/or infectious diseases or hepatologist every 12 months to assess their liver function, viral markers, etc

- ***All follow up of Aboriginal women should be referred to the nominated Aboriginal Health Professional***
- Follow up the status of known hepatitis B carriers in subsequent pregnancies

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Useful web sites

RANZCOG "Management of hepatitis B in pregnancy", under "Infections in pregnancy" at URL: http://www.ranzcog.edu.au/college-statements-guidelines.html

SA Department of Health: You've got what – hepatitis B
http://www.sahealth.sa.gov.au/wps/wcm/connect/Public+Content/SA+Health+Internet/Healthy+living/Protecting+your+health/Youve+got+what/Youve+got+what
Centers for Disease Control and Prevention: Frequently asked questions
http://www.cdc.gov/hepatitis/B/bFAQ.htm

Abbreviations

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CDCB	Communicable Disease Control Branch
DNA	Deoxyribonucleic acid
e.g.	For example
GP	General practitioner
HB	Hepatitis B
HBcAb	Hepatitis B core antibody
HBeAg	Hepatitis B e antigen
HBIG	Hepatitis B immune globulin
HBsAb	Hepatitis B surface antibody
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B virus
HBV DNA	Hepatitis B virus Deoxyribonucleic acid
IU	International units
IM	Intramuscular
LBW	Low birth weight
mL	Millilitre/s
NHMRC	National Health and Medical Research Council
PCR	Polymerase chain reaction
%	Percent
RCOG	Royal College of Obstetricians and Gynaecologists
URL	Uniform Resource Locator

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