Hepatitis B Screening and Multidisciplinary care of pregnant women known to be Hepatitis B Positive

This guidance does not override the individual responsibility of health professionals to make appropriate decision according to the circumstances of the individual patient in consultation with the patient and /or carer. Health care professionals must be prepared to justify any deviation from this guidance.

Introduction

Guidance on the screening and management of hepatitis B in pregnancy.

This guideline is for use by the following staff groups:

All Midwives and obstetric doctors who participate in the management of hepatitis B in pregnancy.

Lead Clinician(s)

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Approved by Maternity Governance Meeting on:	21st April 2023
Review Date: This is the most current document and should be used until a revised version is in place	21st April 2026

Key amendments to this guideline

Date	Amendment	Approved by:
April 2023	Full Guideline Review	Maternity Governance Meeting

Introduction

- This pathway has been reviewed in line with NHS IDPS programme PHE, National Institute for Health and Care Excellence (NICE) hepatitis B (chronic): diagnosis and management: clinical guideline 165
- British Association for the Study of the Liver (BASL), British Viral Hepatitis Group (BVHG) Consensus Statement – UK guidelines for the management of babies born to women who are HBsAg positive
- Immunisation against Infectious Disease: Green Book, chapter 18

Hepatitis B is an infectious disease caused by the Hepatitis B virus (HBV) that effects the liver. The virus causes both acute and chronic infections. Hepatitis B is more infectious than other blood borne viruses like hepatitis C and HIV.

Hepatitis B virus can be passed from person to person through unprotected sexual intercourse, direct contact with the blood of an infected person, including with the household (horizontal transmission), sharing contaminated needles and through perinatal transmission. Globally, perinatal transmission vertically (from mother to baby) is the most common route of HBV acquisition. The transmission rate, in the absence of immunisation of the newborn at birth, can be as high as 90% from higher infectivity mothers and approximately 10-40% from lower infectivity mothers.

The aim of the Public Health England (PHE) selective hepatitis B immunisation programme is to prevent babies acquiring HBV following exposure to their mothers' blood and body fluids especially around the time of birth. As this is a post-exposure vaccination programme, timely administration of all doses of vaccine (±HBIG at birth) is vital in preventing the baby becoming persistently infected with hepatitis B virus.is to prevent babies acquiring HBV around the time of birth.

Health professionals should be aware of the importance of ensuring that babies born to women with hepatitis B require an accelerated course of hepatitis B immunisation starting at birth. This vaccine course is **urgent targeted treatment** for babies that have been significantly exposed to HBV around the time of birth.

Post exposure vaccination is critical targeted treatment for babies that have been significantly exposed to HBV around the time of birth

All pregnant women should be offered screening for Hepatitis B, via antenatal serology booking bloods, irrespective of their previous results and care. At the point of offer, all women should be signposted to and given access to the NSC leaflet 'Screening Tests for you and Your Baby' either electronically via Badgernet or in leaflet form. Copies in other languages can be downloaded or printed form the GOV.UK website. This offer and acceptance/decline of testing must be entered into Badgernet by the professional offering the test.

Women who decline:

Community midwives must also inform the Antenatal Screening team of any patient that declines infectious disease screening. The team will follow up with a formal re offer of testing by 20 weeks gestation or within 2 weeks if already ≥20 weeks.

Unbooked women

Any pregnant woman who attends maternity services, at any gestation, unbooked MUST have booking bloods taken as a priority. If delivery is imminent these should be done urgently and discussed directly with the on call microbiology team. The antenatal screening team must be informed or any positive results.

Notification of HBV positive results and role of the Screening Team

- All HBV positive results should be conveyed to the Antenatal Screening team, by the oncall laboratory microbiologist via the generic E-mail account.
- The Screening Midwife will contact the women directly offering a face to face consultation (within 10 working days) to discuss results and obtain blood samples for further investigations on behalf of the specialist team and the national neonatal Hep B surveillance programme via Colindale. Who will then review results at outpatient appointment.
- A booking appointment will be made for consultant ANC with the Maternal Medicine Consultant to plan the ongoing pregnancy.
- Upon receipt of a positive result the screening team will refer directly to the Infectious Diseases and Maternal Medicine teams via e-mail. An appointment will be arranged directly by the team. If high infectivity, or a new diagnosis this appointment should be within 6 weeks from the date of confirmation. Women booking later than 24 weeks pregnant should be referred immediately for clinical evaluation.
- The women will be made aware that an appointment with the Infectious Diseases and Maternal Medicine teams will be sent via post and added to Badger. She should also be given the leaflet 'Hepatitis B how to protect your baby'. This will be given either by the screening or specialist teams.
- The screening team will notify Child Health, local vaccination team, West Midlands screening and immunisation team, CMW and G.P using designated form via e-mail.

Role of Infectious Diseases Team (IDT)

- A full assessment of the patient's Hepatitis B status will be undertaken with complete serology, HBV DNA levels and liver function tests and U&Es along with the stage of any underlying liver disease. Monitoring of these results will determine if maternal oral antiviral therapy is required. This decision will be made by the ICT.
- LFT'S will be monitored in each Trimester
- The ICT will liaise with the Maternal medicine team as to whether the baby will require just Hep B vaccinations or Vaccination plus HBIG. (See attachments within pathway).

- Assessment for relevant contact tracing will take place.
- Offer tenofovir disoproxil to women with HBV DNA greater than 10^7 IU/ml in the third trimester to reduce the risk of transmission of HBV to the baby.

Role of Obstetrician

- To inform the women of the implications of the positive result and discuss the risk of mother to child transmission.
- To make a plan of care for the pregnancy
- Complete an Antenatal Paediatric referral

Antenatal care

Fetal Anomaly screening

- There has been no association between HBV and fetal anomalies. No additional surveillance should be offered unless indicated at a later date.

Prenatal diagnosis by chorionic villus sampling or amniocentesis

- There is no data regarding procedures such as amniocentesis or CVS and the risk of vertical transmission. The indication and risk of abnormality must be balanced against the potential increase in transmission risk and woman should be appropriately counselled.

Frequency of antenatal checks

- These should be dictated by the women's needs and the clinical picture according to medical and obstetric condition of the patient.

Monitoring the pregnancy

- LFTs should be measured in each trimester. Baseline values will be useful to distinguish between HBV-related liver dysfunction and that from pregnancy induced complications such as gestational hypertension/HELLP syndrome or cholestasis of pregnancy. These are routinely monitored by IDT.
- There is no report of an increase incidence of preterm labour, SGA or fetal distress in the pregnancies of women with HBV.
- In the absence of other contributory factors, no specific recommendations can be made for fetal assessment during pregnancy.

Preterm rupture of membranes

- Prolonged rupture of membranes should be avoided.
- If there is premature rupture of membranes an assessment should be made of the risk of premature delivery against the risk of transmission of HBV. This discussion should take place between physician, obstetrician, paediatrician and the parents.

Induction of Labour

- HBV infection is not an indication for induction of Labour
- IOL should be for obstetric indications.
- Women with spontaneous ruptured membranes ≥36+6 should be offered immediate augmentation

Discussion regarding mode of delivery

- Hep B positive diagnosis is not an indication delivery by caesarean section. Vaginal delivery is recommended unless other obstetric complications dictate.

Delivery suite and postnatal management of women with lower infectivity

- There should be agreed protocols in place to ensure an MDT approach to caring for women with HBV when they present in labour. These should include:
    - informing the screening team of the woman's admission
    - Arranging administration of monovalent hepatitis B vaccine within 24 hours of the baby's birth
    - Completion of the PHCR red book hepatitis vaccination page
    - Notify screening team of birth and returning notes and checklist to the team

Delivery suite and postnatal management of women with higher infectivity

- On admission to delivery suite:
    - inform screening team of admission
    - ensure the PHE 'hepatitis B delivery suite box' containing HBIG is transferred to delivery suite and stored appropriately according to the Medicines Act in a locked fridge. This will be found, stored in the locked fridge in NICU.

After delivery, following the 'PHE hepatitis B delivery suite box' instructions:

- take maternal serology sample
- take neonatal HBV DBS prior to vaccination- the paed will do this at the same time of giving the Hep B vaccine and HBIG to baby.
- administer HBIG plus monovalent hep B vaccine (from local stock found in NICU fridge)
- complete all paperwork and store with samples in the box
- notify screening team of birth and return notes, box and checklist to the team as soon as possible
- if weekend or bank holiday – store in fridge at 2°C to 8°C and ensure it is delivered to screening team next day
- complete PHCR red book hepatitis vaccination page

Screening team responsibilities following delivery:

- Check maternal blood and newborn DBS samples have been taken
- Check laboratory request forms for maternal blood and newborn DBS samples & PHE notification form is fully completed
- Dispatch maternal samples and DBS to PHE BBVU in Virus Reference department, Colindale using prepaid supplied envelope7
- Ensure the CHIS, local vaccination team and GP are notified of:
    - vaccine administration at birth
    - The requirement for the second vaccine at 4 weeks and completion of selective immunisation schedule. The second vaccine will be administered by local vaccination team NOT the GP.
- Complete:
    - PHE hepatitis B in pregnancy maternal and paediatric checklist
    - PHE IDPS Integrated screening outcomes surveillance service (ISOSS) hepatitis B database

Intrapartum management

- There is some evidence of transmission of infection with the procedures that promote mixing of fetal and maternal blood, such as the use of scalp electrodes and fetal blood sampling. These procedures should be avoided.
- External cardiotocography should be used where continuous fetal monitoring is clinically indicated, fetal scalp electrodes should not be used
- Although there is no data regarding the duration of membrane rupture and vertical transmission rates, it would seem sensible to maintain membrane integrity as long as possible to avoid fetal exposure to potentially infected cervical-vaginal secretions. Similarly, episiotomy should require careful consideration
- A previous delivery of a child infected perinatal with HBV does not increase the risk of transmission in subsequent pregnancies.
- As in all Labours universal precautions should be observed. <u>There is no need to isolate either mother or infant</u>

Breastfeeding:

- Advise women that there is no risk of transmitting HBV to their babies through breastfeeding if guidance on hepatitis B immunisation has been followed, and that they may continue antiviral treatment while they are breastfeeding.

Infant immunisation:

- If the woman is deemed to be higher infectivity, then HBIG should be requested from PHE Colindale's Hepatitis B Infant Coordinator using the current HBIG request form. Indications for HBIG in addition to hep B vaccine are detailed in the Green Book and summarised below. The HBIG is requested by the antenatal screening co-ordinator which is then released to the hospital approx. 6 weeks prior to the EDD. The is then kept in the fridge on NICU until required following delivery.

- Please see the neonatal Network Guideline for information how to order emergency dose of HBIG if not ordered.

Babies are considered 'high risk' of vertical transmission and should receive HBIG as well as vaccine if:

- mother is HBsAg positive and HBeAg positive
- mother is HBsAg positive and anti-HBe negative
- mother is HBsAg positive and e markers are not available
- mother has acute hepatitis B in pregnancy
- mother is HBsAg positive and infant is born weighing 1,500g or less
- mother is HBsAg positive and known to have an HBV DNA level equal to or above 1 x 10^6 iu/ml in any antenatal sample in this pregnancy

Babies receive hepatitis B vaccine but do not receive HBIG if:

- mother is anti-HBe positive and HBeAg negative (and no other indication listed above)
- Newly diagnosed women should follow the higher or lower infectivity pathway according to their infectivity status.

Higher Infectivity Pathway

All pregnant women offered and recommended screening for hepatitis B in every pregnancy regardless of previous results (Ref 1)

Pregnant woman with a positive screening result or known positive hepatitis B status

Screening team contacts woman and offers face-to-face appointment to discuss result ≤ 10 days of result/notification (Ref 1/2/3)

Screening team consultation appointment (≤ 10 days of result/notification [Ref 1/2/3/5/8])

Infomation

use PHE 'hepatitis B. A guide to your care' leaflet to explain main points to the woman, including:

- aetiology of hepatitis B and MDT care in pregnancy and beyond
- importance of completing neonatal vaccination schedule
- PHE hepatitis B surveillance processes
- the requirement to inform all health professionals of her plan of care and to notify their positive status to GP / CHIS / Health Visitor / Health Protection Teams

Actions

- take additional serology tests as per local clinical protocols- viral loads, LFTs etc. and send to laboratory
- take PHE maternal venous sample and send to PHE Virus Reference Department, Colindale in pre-paid packaging (result will be sent back to you to report to specialist team)
- check and record all other antenatal results
- commence PHE Hepatitis B in Pregnancy Checklist

Infectivity status established

Higher infectivity pregnancy

Lower infectivity pregnancy

See lower infectivity pathway

Screening teams action

Arrange appointment with specialist team within 6 weeks of result or by 24 weeks gestation to plan care as per national guidelines (Ref 2/8/9)

- create neonatal alert for postnatal neonatal vaccination +/- HBIG as required (Ref 8)
- request HBIG from PHE Colindale for women with higher infectivity. This will prompt delivery of Hep B Delivery Suite box to the screening team
- notify HPT team, GP, Health Visitor and CHIS of antenatal positive status and plans for care (Ref 4)

Specialist service

Women seen in specialist service within 6 weeks of result or by 24 weeks gestation to plan care as per national guidelines (Ref 2/8/9)

- higher infectivity: 3rd trimester review and antiviral therapy if required
- newly diagnosed/ lower infectivity- go to lower infectivity pathway

3rd trimester review with screening team to prepare for birth (Ref 8). Match HBIG with Delivery Suite Box and record location in notes. Using PHE Protecting your baby against hepatitis B leaflet discuss:

- importance of prompt registration with a GP and prompt registration of the baby's birth
- importance of completing vaccination schedule
- PHE hepatitis B surveillance processes post-delivery

Delivery suite/Postnatal

Delivery suite team

- **inform screening team of admission**
- **locate hep B box and follow instructions:**
  - take maternal serology sample after delivery
  - take baby's 'hep B dried bloodspot' sample PRIOR to HBIG/hep B vaccination
  - administration of HBIG + vaccine ≤ 24 hrs of birth
  - completion of hep B page in Red Book and PHE paperwork
  - notify birth and return notes, checklist and hep B box with paperwork and samples to screening team

Babies with a birthweight of 1500g or less need HBIG plus vaccine regardless of the maternal infectivity status (Ref 7).

Screening team ensure GP, CHIS and Health Visitor informed of:

- vaccine administration at birth
- need for 2nd vaccine at 4 weeks and completion of selective at risk neonatal immunisation schedule (Ref 1/4/7/8)

Screening Team return paperwork & samples in hep B box to PHE Virus Reference Department, Colindale in pre-paid packaging and acknowledge receipt by email

Screening team complete PHE hepatitis B in Pregnancy Checklist and PHE IDPS Integrated screening outcomes surveillance service (ISOSS) hepatitis B database

Lower Infectivity Pathway

All pregnant women offered and recommended screening for hepatitis B in every pregnancy regardless of previous results (Ref 1)

Pregnant woman with a positive screening result or known positive hepatitis B status

Screening team contacts woman and offers face-to-face appointment to discuss result ≤ 10 days of result/notification (Ref 1/2/3)

Screening team assessment appointment (≤ 10 days of result/notification [Ref 1/2/3/5/8])

Infomation

Use PHE 'hepatitis B. A guide to your care' leaflet to explain main points to the woman, including:

- aetiology of hepatitis B and multidisciplinary team care in pregnancy and beyond
- importance of completing neonatal vaccination schedule
- PHE hepatitis B surveillance processes the requirement to inform all health professionals of her plan of care and to notify their positive status to GP/ CHIS/Health Visitor/Health Protection Team

Actions

- take additional serology tests as per local clinical protocols- viral loads, LFTs etc. and send to laboratory
- take PHE maternal venous sample and send to PHE Virus Reference Department, Colindale in pre-paid packaging (result will be sent back to you to report to specialist team) Check and record all other antenatal results
- commence PHE Hepatitis B in Pregnancy Checklist

Infectivity status established

Lower infectivity pregnancy

Higher infectivity pregnancy

See higher infectivity pathway

Screening teams action

Arrange appointment with specialist team to plan care as per national guidelines (Ref 8/9)

- < 24 weeks gestation, within 18 weeks of receipt of referral
- ≥ 24 weeks gestation, within 6 weeks of receipt of referral

- create neonatal alert for delivery suite neonatal vaccination (Ref 7,8)
- notify Health Protection Team, GP, Health Visitor and CHIS of antenatal positive status and plans for care (Ref4)

Specialist service

3rd trimester review with screening team to prepare for birth (Ref 8)

Using PHE 'Protecting your baby against hepatitis B' leaflet discuss:

- importance of prompt registration with a GP and prompt registration of the baby's birth
- importance of completing vaccination schedule

Lower infectivity pregnancy

Woman seen in specialist service to plan care as per national clinical guidelines (Ref 8/9)

Delivery suite/Postnatal

Babies with a birthweight of 1500g or less need HBIG plus vaccine regardless of the maternal infectivity status (Ref 7)

Delivery suite team

- inform screening team of admission
- administration of hep B vaccine ≤ 24 hrs of birth
- completion of hep B page in Red Book
- notify birth, return notes and checklist to screening team

Screening team ensure GP, CHIS and Health Visitor informed of:

- vaccine administration at birth
- need for 2nd vaccine at 4 weeks and completion of selective at risk neonatal immunisation schedule (Ref 1/4/7/8)

Selective at risk neonatal immunisation schedule (Ref 1/7)

Screening team complete PHE Hepatitis B in Pregnancy Checklist and PHE IDPS Integrated screening outcomes surveillance service (ISOSS) hepatitis B database

APPENDIX Pathway for care of women admitted to Delivery suite

known to be Hepatitis B positive

- Notify on-call obstetrician and Paediatrician of admission in Labour
- Universal precautions
- Delay A.R.M as long as possible
- Avoid FSE/FBS
- External cardiotocography should be used where continuous fetal monitoring is clinically indicated.
- For all needlestick injuries-contact the microbiologist on call. (Immunoglobulin will then be issued. The decision regarding giving the second dose will depend on the “e” antigen status of the source blood).
- Inform the antenatal screening team of admission (as a failsafe to ensure that they are aware of patient)
- Follow care pathway for either lower infectivity or higher infectivity women (as attached above)

Breastfeeding

- Breastfeeding is not contra-indicated.

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Infant immunisation

- Hep B vaccination is recommended for babies born to Hepatitis B positive mothers
- Stock of Hep B vaccinations stored in NICU fridge
- HbIg to be ordered by Screening Coordinator. In an emergency please refer to embedded Neonatal HbIg request form

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Infant testing

- Do not do cord bloods or bloods for hepatitis screening in the neonatal period (high false positive rate).

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Monitoring

Page/ Section of Key Document	Key control:	Checks to be carried out to confirm compliance with the Policy:	How often the check will be carried out:	Responsible for carrying out the check:	Results of check reported to: *(Responsible for also ensuring actions are developed to address any areas of non-compliance)*	Frequency of reporting:
	WHAT?	**HOW?**	**WHEN?**	**WHO?**	**WHERE?**	**WHEN?**
	Data Feeding into national audit	Audit collection Data	Continuously	Antenatal Screening Team	National Audit	Quarterly & Yearly

Contribution List

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This key document has been circulated to the following individuals for consultation;

Designation
All Maternity Staff – Via Guidelines Newsletter

This key document has been circulated to the chair(s) of the following committee's / groups for comments;

Committee
Maternity Governance Meeting