

Management of Hepatitis B in Pregnancy

A Clinical Guideline recommended

For use in:	Maternity Services
By:	Midwives/Obstetricians/Hepatologists/Virologists/ Neonatologists
For:	Women who are hepatitis B positive
Division responsible for document:	Women and Children
Key words:	Hepatitis B, Hepatitis C, vaccination, HBIG
Name of document author:	Jon Lartey and Alison Evans
Job title of document author:	Consultant Obstetrician, Subspecialist in Maternal Medicine / Antenatal and Newborn Screening Coordinator
Name of document author's Line Manager:	Anna Haestier
Job title of author's Line Manager:	Chief of Service
Assessed and approved by the:	The Maternity Guideline Committee If approved by committee or Governance Lead Chair's Action; tick here
Date of approval:	09/08/2021
Ratified by or reported as approved to (if applicable):	Clinical Safety and Effectiveness Sub-Board
To be reviewed before:	09/08/2024
To be reviewed by:	Alison Evans
Reference and / or Trust Docs ID No:	847
Version No:	7
Compliance links: (is there any NICE related to guidance)	No
If Yes - does the strategy/policy deviate from the recommendations of NICE? If so why?	N/A

Management of Hepatitis B in Pregnancy

Version and Document Control:

Version Number	Date of Update	Change Description	Author
5	28/10/2020	Amendment to immunisation guideline, with a flowchart to highlight roles and responsibilities.	Jon Lartey and Alison Evans
6	28/05/2021	National changes to process including increased surveillance testing and requirements for HBIG	Alison Evans
7	09/08/2021	Diagnosis wording amended	Alison Evans

This is a Controlled Document

Printed copies of this document may not be up to date. Please check the hospital intranet for the latest version and destroy all previous versions.

Quick reference

This guideline is to be used in conjunction with the Trust Guideline for Immunisation for Infants at Risk of Hepatitis B Infection (CA2017 V3) [Id No: 1183](#).

- All pregnant women to be offered screening for hepatitis B.
- Women found to be hepatitis B positive should be screened for hepatitis C and HIV and syphilis.
- Women found to be positive referred to appropriate specialists – Consultant Obstetrician specializing in blood borne viruses and a Consultant Hepatologist.
- Hepatitis B positive women with a high viral load should be offered antiviral therapy (lamivudine or tenofovir) by the Consultant Hepatologist.
- NICU alert system to identify babies in need of vaccination schedule.
- Virologist to advise re need of HBIG and vaccine or vaccine only.

Management

- All pregnant women should be counselled and offered screening for hepatitis B along with HIV and syphilis in line with PHE recommendations. Acceptance or decline of the test should be documented in the maternity hand held notes and on the antenatal blood form. All women should be signposted to the national screening digital information “Screening tests for you and your baby” or given a paper copy prior to this appointment, to enable informed consent.
- If a patient declines screening, they should be offered discussion with the Antenatal and Newborn Screening (ANS) Midwives by 20 weeks gestation to ensure informed consent and re-offered testing. Where this has not been possible a re-offer of testing should be made again at 28 weeks gestation. A woman who declines should be advised they can change their mind if they wish for testing at any point in the pregnancy.

Management of Hepatitis B in Pregnancy

- If a patient books after 24 weeks gestation or presents in labour, infectious disease screening should be given priority and treated as urgent. It is imperative that the on call virologist is informed of the need for urgent testing otherwise there will be delay ([Trustdocs ID: 16848](#)). The ANS Midwives will be informed via Datix submission of any woman presenting in labour to ensure follow up of results and referral to Specialist if necessary.
- If a patient is known to be hepatitis B positive it is still advised for her to be screened for full hepatitis and HIV virology screen to obtain up to date information.
- Any positive results will be communicated by the laboratory to the ANS Midwives via their generic screening NHS.net email plus by phone.
- If a woman is found to be hepatitis B positive on the initial screen the following markers are automatically tested as per Virology protocol on the initial sample
 - AntiHBc (total)
 - AntiHBc IgM
 - HBeAg
 - AntiHBe

Antenatal roles and responsibilities – see IDS pathway, hepatitis B positive result (Appendix 1)

Consultant Virologist

- Produce a vaccination communication proforma (Appendix 2) indicating whether HBIG is required in addition to vaccine and upload in the ANS shared Infectious diseases checklist.
- Order HBIG using PHE request form available via link (<https://www.gov.uk/government/publications/hepatitis-b-requesting-issue-of-immunoglobulin-for-infants>).

ANS midwives

- Make an appointment for the woman with the Lead Obstetric Consultant for blood borne viruses within 10 working days of the result being issued, regardless of whether known diagnosis or not, in line with national standards. This appointment is to ensure the correct pathway is in place and that the woman is aware of her care plan.
 - Either the ANS Midwives or Antenatal Clinic receptionist will contact the woman by phone with the appointment. If unable to contact, a letter will be sent with appointment details. If the woman does not attend the appointment, the community midwife will be informed to contact her to arrange appointment or identify if moved etc.
- Refer the patient to the Consultant Hepatologist and, if newly diagnosed or of high infectivity, the specialist will see the woman within 6 weeks of result being issued. If the woman is already known to the Hepatology team and is

Management of Hepatitis B in Pregnancy

low infectivity, referral should be made so the Hepatologist can plan appropriate care plan.

- Document result and alerts on E3.
- Complete the “Hepatitis B screening and immunisation maternal and paediatric checklist” and attach a copy to E3 record, updating where required, paper copy in buff folder. Available via link:
<https://www.gov.uk/government/publications/hepatitis-b-maternal-and-neonatal-checklist>.
- Complete and send NICU alert directly to Consultant Neonatologist Lead for blood borne viruses.
- Email vaccination proforma to all members of MDT as per IDS pathway, hepatitis B positive result (appendix 1) and attach to E3 record.
- Prepare and print out blood request forms for ANC appointment plus Colindale surveillance sample
- Attach a copy of the newborn immunization flowchart to E3 record ([Trustdocs ID: 1183](#)).
- Notify Child Health Information Service (CHIS), Health Visitor and GP of pregnancy by completing appropriate form and sending by email as per flow chart (Appendix 3), by post to GP.
- Where HBIG required – the national team at Colindale will send the patient specific delivery box 7 weeks prior to EDD to the ANS midwives, this must be matched up with HBIG from pharmacy and be stored in Delivery Suite’s blood fridge, so available at any time for birth.
- Complete Integrated screening outcomes surveillance service (ISOSS) notification and reporting
- Inform all MDT and national team at Colindale if fetal loss at any stage or woman moves away.

Obstetrician

- When the woman attends the Obstetric appointment, testing should be done for the following markers:
 - Measurement of (HBV) viral load. HBV DNA viral load testing should be undertaken preferably twice at least three months apart with one test at 28 to 32 weeks.
 - Test for other blood borne viral infections: HIV antibody, syphilis, hepatitis C (HCV) antibody, if not already tested.
 - Assess chronic disease status (full blood count, liver function test including ALT, albumin, renal function tests electrolytes, prothrombin time and APTT).
 - PHE surveillance blood test – specific bottles/boxes kept and to be sent by ANS Midwives.

Management of Hepatitis B in Pregnancy

This will enable appropriate triage of all newly positive and known positive women. This will also inform/confirm the ordering and coordination of the infant HBIG. These results will be available when the Consultant Hepatologist reviews the woman.

- At the first ANC appointment the woman should be given the PHE leaflet “Hepatitis B: A guide to your care in pregnancy and after your baby is born” which is available in a number of languages. The ANS Midwives will print this to be available for the appointment or available via link:

<https://www.gov.uk/government/publications/protecting-your-baby-against-hepatitis-b-leaflet>

- At the 3rd trimester appointment the woman will be given the PHE leaflet “Protecting your baby against hepatitis B” which is available in a number of languages. The ANS Midwives will print this to be available for the appointment or it is available via the above link.
- Although interventions in labour should be avoided where possible e.g., use of fetal scalp electrode, to reduce risk of transmission of infection to baby, they are not absolutely contraindicated and so can be considered following discussion with the Consultant. Hepatitis B infection in the mother is NOT an indication, on its own, for LSCS.
- Breast feeding is not contra-indicated.

After delivery – roles and responsibilities

Delivery Suite Midwife

- Inform Neonatal team of birth and need for vaccine +/- HBIG within 24hrs as per Trust Guideline for Immunisation for Infants at Risk of Hepatitis B Infection (CA2017 V3) [Id No: 1183](#).

If HBIG required

- Follow instructions in the patient specific delivery box:
 - Take surveillance sample from the woman in the bottle provided, complete and store in box.
 - Take bloodspot sample from the baby on the card provided before vaccine/HBIG administered. Complete and store in box.
- Inform ANS midwives of delivery and samples – to be stored in blood fridge at weekends/bank holidays for collection by ANS midwives next working day.

Neonates

- Prescribe and administer vaccine +/- HBIG within 24hrs of birth as per Guideline.
- Email a copy of the completed infant vaccination schedule ([Trustdocs ID: 13631](#)) to the ANS Midwives via their generic NHS.net email.
- Inform ANS midwives if parents decline vaccine +/- HBIG.

ANS Midwives

Management of Hepatitis B in Pregnancy

- Collect delivery box with completed samples and send to national team at Colindale.
- Notify Child Health Information Service (CHIS), Health Visitor and GP of birth by completing appropriate form and sending by email as per flow chart (Appendix 4), post to GP.
- Complete ISOSS reporting.

Discharging midwife

- Ensure documentation of both the mother's hepatitis B infection and the offer/acceptance/decline of the baby's vaccination on the discharge paperwork.

Failsafe

All screen positive results are documented in a shared spreadsheet by the ANS midwives kept on the "S" drive, accessible by the Lead Obstetric Consultant for blood borne infectious diseases, Consultant Neonatologist with special interest in blood borne viruses, Consultant Virologists and the Chief Biomedical Scientist (BMS) for Microbiologist leading antenatal screening. On receipt of a positive result the ANS Midwives populate the spreadsheet with the required information. The Neonatologist checks that a NICU alert has been received and that a plan is in place for delivery and neonatal management. The Chief BMS cross checks the spreadsheet monthly to ensure all screen positive results recorded and actioned.

Screening safety incidents

Due to the nature and characteristics of screening tests, safety incidents within screening programmes require special attention and management. Where an incident occurs along any of the antenatal and newborn screening pathways the ANSC should be informed and the PHE document "Managing Safety Incidents in NHS Screening Programmes: updated Jan 2018" referred to.

Objective

The objective of the guideline is for women who are hepatitis B positive to be offered appropriate specialist care to benefit their own health. The aim of the screening, management and vaccination pathway is to prevent perinatal hepatitis B infection.

Rationale

Hepatitis B is an infectious disease caused by the hepatitis B virus (HBV). It is transmitted through infected blood and other body fluids. Transmission can occur through sexual contact or perinatal transmission from mother to baby. The risk of perinatal transmission is dependent on the status of the maternal infection. Approximately 70 - 90% of mothers who are HBV e-antigen (HBeAg) positive will transmit the infection to the baby. The rate of transmission is approximately 10%-40% in women with antibody to e antigen (AntiHBe).

Management of Hepatitis B in Pregnancy

Infection can result in an acute or chronic infection. A chronic infection with HBV may result in cirrhosis of the liver and liver cancer. The earlier in life the infection occurs, the greater the risk that it will lead to chronic infection, liver disease and early death. Vaccination of the baby should be within 24 hours of delivery, at 4 weeks then 8, 12 and 16 weeks with routine immunisations and at 12 months to be effective in preventing transmission of infection from mother to baby. In babies born to women with a higher risk of transmission, the addition of Hepatitis B Specific Immune Globulin (HBIG) can reduce the risk further. With this strategy, transmission can be prevented to under 5%.

Guidelines have been produced in the UK and Europe concerning the assessment, management and treatment of pregnant women with hepatitis B infection. Department of Health recommendations are that HBV DNA viral load testing undertaken by clinicians to inform the management of pregnant women, should be included as a factor determining whether HBIG is required

The guideline has been updated in line with the PHE “Guidance on the hepatitis B antenatal screening and selective neonatal immunisation pathway” January 2021.

Broad Recommendations

- To identify all hepatitis B positive women.
- For all hepatitis B positive women to be referred for assessment and management by an appropriate specialist (e.g. a Hepatologist / Gastroenterologist / Infectious diseases specialist) and be seen by the Lead Consultant Obstetrician within 10 working days to be informed of their care plan.
- Newly diagnosed women and those with high infectivity must be seen by the Hepatologist within 6 weeks of the screening test result being received by maternity services. For the infant vaccination schedule to be offered for their babies and that the first dose is administered by the neonatal team within 24 hours of delivery and arrangements for completion of the schedule are initiated. See Trust Guideline for the Immunisation of Infants at Risk of Hepatitis B Infection ([Trustdocs ID: 1183](#)).

Clinical Audit Standards

Quarterly KPI data of hepatitis B positive women being seen by specialist (Hepatologist) within 6 weeks.

Summary of development and consultation process undertaken before registration and dissemination

During the development of this guideline advice has been sought from Maternal Medicine Obstetricians, Neonatology Consultant, Consultant Virologist and Consultant Hepatologist. The Clinical Guidelines Assessment Panel has endorsed this current version.

Distribution list / dissemination method

Mr Jon Lartey, Consultant Obstetrician, Maternal Medicine Subspecialist

Management of Hepatitis B in Pregnancy

Dr Samir Dervisevic, Consultant Virologist

Dr Claire Williams, Consultant Virologist

Dr Syed Alam, Consultant Hepatologist

Chris McDonnell, Senior Biomedical Scientist, Microbiology

Evidence review and evaluation

This guideline is based on the 2015 BASHH 2015 guideline for the management of viral hepatitis, which is accredited by NICE.

References

- PHE Guidance on the hepatitis B antenatal screening and selective neonatal immunisation pathway January 2021
- NHS Infectious Diseases in Pregnancy Screening Programme Handbook 2016 to 2017 Public Health England
- NHS Infectious Diseases in Pregnancy Screening Programme – Laboratory Handbook 2016 to 2017 Public Health England
- Hepatitis B: The Green Book, Chapter 18, November 2019 (Department of Health)
- NICE guideline – CG 62 Antenatal Care 2008 –updated Jan 2017(section 1.8.5)
- PHE Managing Safety Incidents in NHS Screening Programmes: August 2017 (updated Jan 2018)

Management of Hepatitis B in Pregnancy

Appendix 1

Antenatal Infectious Disease Screening Pathway Hepatitis B positive result

1. NNUH Hepatitis B Communication Proforma (updated)

Clinical Guideline for: Management of Hepatitis B in Pregnancy

Author/s: J Larty and A Evans

Approved by: MGC

Available via Trust Docs

Version: 7

Author/s title: Consultant Obstetrician and Antenatal and Newborn Screening Coordinator

Date approved: 09/08/2021

Trust Docs ID: 847

Review date: 09/08/2024

Page 9 of 17

Screening for Hepatitis B Virus Infection in NNUH Antenatal Women

NNUH Hepatitis B Communication Proforma

All antenatal women attending for booking at the NNUH Antenatal Clinic are offered screening for HBV infection and will have their blood tested for HBsAg unless they specifically decline the testing.

If an antenatal woman declines the testing for HBV infection the booking Virology request form should contain an annotation to this effect.

Screening for HBV infection should be reoffered to all women who declined the initial offer, ideally, by 20 weeks gestation.

Patient Name:

Patient Date of birth:

Patient hospital number:

EDD:

Results of hepatitis B screen

HBsAg:

Further screen results if HBsAg detected:

Date	Sample number	HBsAg	anti-HBc	Anti-HBc IgM	HBeAg	Anti-HBe	HBV DNA

Serological profile consistent with:

High risk/urgent referral (acute HBV, HBeAg with high virus load, new diagnosis to the Trust): YES or NO

If HBsAg is detected, duty Virologist will inform the HPU in Thetford about the hepatitis B profile.

Management of Hepatitis B in Pregnancy

ACTIONS TO BE TAKEN

Neonate requires HBIG (hepatitis B immunoglobulin):

Neonate requires hepatitis B vaccine:

If HBIG required has this been ordered from PHE:

Duty Virologist to place a link to the completed proforma in the IDS checklist -
S:\Division 3 - Women, Children & Sexual Health\Ante-natal Screening\Infectious
Disease Screening\IDS checklists

The Antenatal and newborn Screening Midwives will email a copy to the following
members of a multidisciplinary team:

Obstetrician: Mr Jon Lartey

Midwife: Ms Alison Evans

Neonatologist: Dr Florence Walston

Pharmacist: Sarah Wright

Arrangements should be made for an appointment with a hepatologist
within 6 weeks of the screening test result being issued to maternity services.

Hepatologist: Dr S Alam

This proforma was completed by:

Dr Samir Dervisevic (Consultant Virologist)

Dr Claire Williams (Consultant Virologist)

Management of Hepatitis B in Pregnancy

Appendix 3

Notification letter – antenatal

[Add GP address and date of letter]

Date

Dear Dr [*insert name*]

Notification of maternal positive hepatitis B antenatal result form

- **Child Health Information System (CHIS): see section A**
- **Actions for primary care: see section B**

Maternal demographics and pregnancy details		
Name of pregnant woman	Date of birth	NHS number
Address		
Estimated due date	Additional information	

Section A: action for CHIS

This woman is hepatitis B positive so can you please create a record for her?

Section B: actions for primary care

The baby will need **6 vaccinations** to protect him or her from acquiring chronic hepatitis B virus (HBV) in line with the Public Health England (PHE) Green Book. The first vaccination

Management of Hepatitis B in Pregnancy

+/- human immunoglobulin (HBIG) will be given within 24 hours of birth. Please ensure you schedule appointments for:

- 2 extra hepatitis B vaccinations – at **4 weeks** and **12 months**
- routine childhood immunisation schedule (containing the hexavalent vaccine) at **8, 12** and **16 weeks**
- a blood test to check infectivity status at **12 months** (ideally using the dried blood spot card available at www.gov.uk/guidance/hepatitis-b-dried-blood-spot-dbs-testing-for-infants)

Additional information on management of mother and baby

We have referred the woman to hepatology/gastroenterology for specialist management and multidisciplinary care. The sexual and household contacts of an adult with HBV will benefit from hepatitis B testing and vaccination in primary care. We will notify your practice again when the baby has been born to support prompt registration of the baby with your practice and timely scheduling of extra appointments.

Timeliness of vaccinations is important to prevent viral transmission.

Yours sincerely

Antenatal & Newborn Screening Midwives

01603 286802

nnu-tr.ANS@nhs.net

Management of Hepatitis B in Pregnancy

Appendix 4

Notification letter – newborn

[Insert GP address]

[Insert date of letter]

Dear Dr [insert name]

Notification of birth: baby of mother with hepatitis B form

Maternal details			
Name	Date of birth	NHS number	Address

Neonatal details			
Name	Date of birth	NHS number	Address (if different)

Hepatitis B vaccination/HBIG details			
Date/time vaccine administered		Vaccine batch number	
Date/time immunoglobulin given if required		Human immunoglobulin (HBIG) batch number	
Vaccinator name (print and sign)			

Management of Hepatitis B in Pregnancy

Section A: actions for CHIS

You must:

- mark this woman as hepatitis B positive on the system
- mark this baby as an infant of a woman who is hepatitis B positive on the system (as a failsafe to ensure follow up of the baby's vaccinations)

Section B: actions for primary care

The baby will need **6 vaccinations** to protect him/her from acquiring chronic hepatitis B virus (HBV) in line with the Public Health England (PHE) Green Book www.gov.uk/government/publications/hepatitis-b-the-green-book-chapter-18. The first vaccination +/- Human Immunoglobulin (HBIG) has been administered within the first 24 hours after the birth (see above).

The baby will now need **5 more vaccinations**. Please ensure you schedule appointments for:

- 2 extra hepatitis B vaccinations at **4 weeks** and **12 months**
- routine childhood immunisation schedule (containing the hexavalent vaccine) at **8, 12** and **16 weeks**
- a blood test to check infectivity status at **12 months** (ideally using the PHE dried bloodspot available at www.gov.uk/guidance/hepatitis-b-dried-blood-spot-dbs-testing-for-infants)

Additional information on management of the mother and her baby

Please support prompt registration of the baby with your practice and timely scheduling of the extra appointments.

Timeliness of vaccinations is important to prevent viral transmission.

The sexual and household contacts of an adult with HBV will benefit from hepatitis B testing and vaccination in primary care.

Yours sincerely

Antenatal & Newborn Screening Midwives

01603 286802

nnu-tr.ANS@nhs.net

Clinical Guideline for: Management of Hepatitis B in Pregnancy

Author/s: J Larty and A Evans

Approved by: MGC

Available via Trust Docs

Version: 7

Author/s title: Consultant Obstetrician and Antenatal and Newborn Screening Coordinator

Date approved: 09/08/2021

Trust Docs ID: 847

Review date: 09/08/2024

Page 15 of 17

Management of Hepatitis B in Pregnancy

Clinical Guideline for: Management of Hepatitis B in Pregnancy

Author/s: J Larty and A Evans

Approved by: MGC

Available via Trust Docs

Version: 7

Author/s title: Consultant Obstetrician and Antenatal and Newborn Screening Coordinator

Date approved: 09/08/2021

Trust Docs ID: 847

Review date: 09/08/2024

Page 16 of 17

Management of Hepatitis B in Pregnancy

Appendix 5

Neonatal vaccination schedule [Trustdocs ID: 13631](#)