Hepatitis B infection in pregnancy: Screening & management

Classification:	Guideline
Authors Name:	Anita Males, Miss F Nizami
Authors Job Title:	Antenatal & Newborn Screening Co-ordinator, Consultant Obstetrician & Gynecologist
Authors Division:	Women's and Children's Health
Departments/Group this Document applies to:	Maternity and Paediatrics

Approval Group: Women's Health Guideline Review Group 31/07/2019 Women's Health CIG 04/09/2019 Paediatric Improvement Group 05/08/2019 Trust Documentation Committee 25/09/2019	**Date of Approval:**	07/10/2020
	Last Review:	June 2020
	Review Date:	01/10/2023

Unique Identifier: MIDW/GL/57	**Status: Approved**	**Version No:** 6.1

Guideline to be followed by (target staff):
Midwifery, Laboratory, Infectious Diseases Specialist, Gastroenterology, Paediatrics, Child Health & Primary Care.

CQC Fundamental standards:
Regulation 9 – person centred care
Regulation 10 – dignity and respect
Regulation 11 – Need for consent
Regulation 12 – Safe care and treatment
Regulation 13 – Safeguarding service users from abuse and improper treatment
Regulation 16 – Receiving and acting on complaints
Regulation 17 – Good governance
Regulation 19 – Fit and proper

Disclaimer

Since every patient's history is different, and even the most exhaustive sources of information cannot cover every possible eventuality, you should be aware that all information is provided in this document on the basis that the healthcare professionals responsible for patient care will retain full and sole responsibility for decisions relating to patient care; the document is intended to supplement, not substitute for, the expertise and judgment of physicians, pharmacists or other healthcare professionals and should not be taken as an indication of suitability of a particular treatment for a particular individual.
The ultimate responsibility for the use of the guideline, dosage of drugs and correct following of instructions as well as the interpretation of the published material **lies solely with you** as the medical practitioner.

Index

Guideline Statement

The aim of this guideline is to enable staff in the provision of a screening and immunisation service for Hepatitis B.

Executive Summary

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, for example, through sexual contact or vertical 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 HBeAg positive will transmit the infection to the baby. The rate is approximately 10% in women where there is maternal antibody to e-antigen (PHE, 2014).

Above 90% of infants born to infectious (HBeAg +ve) mothers will become chronic carriers unless immunised immediately at birth (Brook et al, (2015)).Babies born to these mothers should therefore be offered Hepatitis B specific Immunoglobulin (HBIG) as well as Hepatitis B vaccine.

Women with antibody to Hepatitis B e-antigen (HBsAg + ve, anti HBeAg + ve) are generally considered low infectivity and babies born to these mothers should be offered Hepatitis B vaccine only.

Management of the infant should be based on the results of e-markers and hepatitis B viral load testing of the mother. HBIG should ideally be ordered well in advance of the birth and given simultaneously with vaccine but at a different site. If this is not possible, HBIG should be ordered to be given within 24 hours of the first dose of vaccine.

Table: Vaccination of babies according to the hepatitis B status of the mother (PHE, 2017)

Hepatitis B status of mother	**Baby should receive Hepatitis B vaccine**	**Baby should receive HBIG**
Mother is HBsAg positive and HBeAg positive	Yes	Yes
Mother is HBsAg positive, HBeAg negative and anti-HBe negative	Yes	Yes
Mother had acute hepatitis B during pregnancy	Yes	Yes
Mother is HBsAg positive and anti-HBe positive	Yes	No
Mother is HBsAg positive and known to have an HBV DNA level equal or above $1x10^6$IUs/ml in any antenatal sample during this pregnancy (regardless of HBeAg and anti-HBe status)	Yes	Yes
Mother is HBsAg positive and baby weighs 1500g or less	Yes	Yes

Babies born to mothers infected with hepatitis B and identified as requiring vaccination should be vaccinated using the accelerated immunisation schedule, where a dose of hepatitis B containing vaccine is administered at birth, 4 weeks and 8 weeks. Monovalent hepatitis B vaccine should be administered at birth and 4 weeks. As hepatitis B is now part of the routine childhood immunisation, these babies will then receive hexavalent hepatitis B containing vaccines at 8 weeks

The care of women who test positive in pregnancy and the subsequent immunisation of their babies and household contacts will involve partnership working with health care practitioners crossing several organisational boundaries. This guideline is intended to clarify respective roles in the interests of the individuals affected

Abbreviations:

ANSC: Antenatal and Newborn Screening Co-Ordinator
AntiHBc: Hepatitis B core antibody
AntiHBe: Hepatitis Be Antibody
AntiHBs: Hepatitis B surface antibody
HBeAg: Hepatitis B e antigen
HBsAg: Hepatitis B surface antigen
HBV: Hepatitis B Virus
HCV: Hepatitis C
IDPS: Infectious Diseases in Pregnancy Screening Programme
MDT: Multi-disciplinary team
NSC: National Screening Committee
PHE: Public Health England
DBS: Dried Blood Spot

1.0 Roles and Responsibilities:

Please refer to section 3.0.

2.0 Implementation and dissemination of document

This guideline will be available on the Trust intranet through team meetings and newsletters .

3.0 Processes and procedures

For guidance on giving screening information, obtaining blood sample and handling of results please refer to Screening in Pregnancy guideline.

3.1 Antenatal Testing:

3.1.1 Role of Community Midwives

- Screening for Hepatitis B virus surface antigen (HBsAg) is offered & recommended to all antenatal women at booking (PHE, 2016, PHE, 2017). This blood test is taken as part of the routine antenatal booking blood tests.

- Women will be given information regarding this screening test at the booking interview in the form of *'Screening tests for You and Your Baby'* leaflet (PHE, 2017), available online in several languages.

- Interpreters must be arranged if any language barriers are identified.

- If a woman declines the test for whatever reason, the midwife must explain to the woman about the risks of declining tests, the benefits of early treatment & vaccination of the baby and document this on e-care. The ANSC should be informed by emailing at mkg-tr.mkscreeningmidwives@nhs.net. The benefits of the blood tests should be re-iterated and re-offered by 20 weeks gestation at the latest by the ANCS or their Deputy. If the woman still declines this should be clearly documented on e-care.

- An urgent obstetric consultant appointment should be made, and a baby alert should be completed. The woman should be provided with the contact details of the Midwifery Screening Team / Community Midwife in case she changes her mind so a blood test can be arranged.

- A woman known to be Hep B positive will be offered and recommended screening in every pregnancy, irrespective of the results in any previous pregnancy. This ensures there is a current result in the laboratory and maternity IT systems and reduces the risk of missed entry into the care pathway.

- For all known hepatitis B positive women, the community midwives should fast track referrals to ANSC at mkg-tr.mkscreeningmidwives@nhs.net .

- Women who are known positive with HIGH viral load should be seen **within 10 working days** by the ANNB screening team and within 6 weeks by Hepatology. This is also for women with known infection and LOW viral load who never had care in UK.

- Women who are known positive with LOW viral load should be seen by ANNB screening team within 10 working days and referred to Hepatology.

- If a woman informs the community midwife that her partner or husband is Hepatitis B positive , the ANSC should be informed by email to ensure all relevant blood tests are requested and a baby alert is completed as the baby will need to be vaccinated.

- Women are advised about the availability of sexual health testing at any stage of pregnancy and to report any symptoms of genitourinary infection as soon as possible. Repeat tests will be offered and recommended if a woman changes her sexual partner, injects recreational drugs, is a sex worker, has a partner who is known to be bisexual, has a partner who is known to have HIV or hepatitis, or if either partner is diagnosed with a sexually transmitted infection (STI) or requests a test.

3.2 Managing Screen Positive Results:

3.2.1 Role of Microbiology Laboratory

The laboratory will follow their Standard Operating Procedure: M1/102 'Antenatal Screening; Requesting and Monitoring of Repeat Samples'

- The results of the confirmatory test will be sent directly to the ANSC and deputy at mkg-tr.mkscreeningmidwives@nhs.net .
- Notify ANSC or deputy if second (confirmatory) samples are not received within 10 days of request at mkg-tr.mkscreeningmidwives@nhs.net .
- Ensure that samples labelled **"Urgent"** are processed within 24 hours. **NB:** The laboratory must be notified by telephone of all **URGENT** samples. The laboratory must be notified if the sample is taken close to delivery for urgent communication of interim positive results.

- Inform requester within 24 hours if sample is rejected/not tested and inform ANSC team.
- Maintain a sample list of "screen positive" "rejected" and "not tested" for audit purposes. A **weekly summary** should, be emailed to the ANSC on mkg-tr.mkscreeningmidwives@nhs.net and this list should also be held in the Microbiology Department.
- Inform PHE for acute hepatitis B cases as per PHE notification guidance.
- This is done via PHE SGSS (Second Generation Surveillance System) electronically. Acute Hepatitis B would also be telephoned to CCDC.
- The CCDC is South Midlands and Hertfordshire Public Health Centre

  Address: PHE East of England, 2nd Floor, Goodman House, Station Approach, Harlow, Essex. CM20 2ET

  Phone: 0300 303 8537 (Office Hours, Monday – Friday, 9am – 5pm)
  Medicom: 01603 481221 (Outside of office hours) Ask for Public Health 1st on-call
  Fax: 0300 303 8541
  Primary Email: smh@phe.gov.uk
  NHS Email: phe.smh@nhs.net

3.2.2 Role of Antenatal & Newborn Screening Co-ordinator (ANSC)

- To ensure that all antenatal hepatitis screening results are chased, positive results are acted on within agreed timeframes, rejected samples are actioned and repeat samples are received by the laboratory where requested. The ANSC is supported in her role by the deputy ANSC and failsafe officer.

- Confirmed positive screening tests must be reported directly to the IDPS MDT within 8 days of receipt of sample in the screening laboratory (standard 4). This is to enable recall of the woman within 10 working days of the positive result or known status being reported to maternity services (standard 5) (PHE, July 2019)
- **NB:** If a woman with a screen positive result has miscarried or had a termination, she should still be notified of results and referral made as appropriate. If a sample is rejected and requires repeating, the woman should be offered the chance to complete screening even if she were screen negative.
- If the woman was found to be screen positive, the ANSC or deputy will telephone the woman directly for a face-to-face appointment or send notification to the community midwife with an appointment letter to be hand delivered to her. This appointment should be as close as possible to contact with the community midwife in order to minimise anxiety.
- At the appointment, the ANSC or deputy will:
  - Inform woman of the positive results.
  - Establish if previous known Hepatitis B positive
  - Obtain blood sample for testing of hepatitis C serology, hepatitis D antibody, hepatitis B viral load, hepatitis B e antigen, IgM antibody for hep B core antigen, HIV antibody, hepatitis A antibody, FBC, liver function tests, urea and electrolytes/INR and AFP.
  - The 'Danger of Infection' stickers are labelled on the blood specimen bag.

  - ***Antenatal maternal surveillance sample:***

    The first maternal surveillance venous sample should be taken at the screening assessment appointment with the antenatal and newborn screening team to discuss the woman's positive HBV result:

- this sample will be requested from all HBV screen positive mothers (higher and lower infectivity risk)
- the sample should be collected in provided purple (EDTA) blood tubes and sent to the PHE laboratory in Colindale with a completed request form in pre-paid return packaging.
- This surveillance blood sample should not interfere with the collection of samples for HBV viral load and marker testing as per local practice as agreed with the virology laboratory and hepatology clinical team. The packs and request forms are in the ANNB screening cupboard in the quiet room in ANC.
- The ANNB screening midwives to email phe.hepatitisbbabies@nhs.net to notify sample has been sent.
- The maternal blood test results will be sent back to the ANSC/screening team to report to the specialist team responsible for the woman's postnatal hepatology care.

- Discuss what Hepatitis B means in terms of her pregnancy, her health and her baby's health and provide *'Hepatitis B: a guide to your care in pregnancy and after your baby is born'* (2020) leaflet, available online in several languages, at: https://www.gov.uk/government/publications/protecting-your-baby-against-hepatitis-b-leaflet
- If English is not the first language, appropriate language specific leaflets should, be provided to the woman. Considerations should be made around arrangements with translation services for these appointments.
- Discuss the referral arrangements to a specialist and the benefit of attending all these appointments.
- As part of the failsafe process, ANSC will refer to the IDPS spreadsheet thrice a week to confirm that all screen positive women have consultant appointments booked and attended.
- Advise on the importance of completing the baby's vaccination schedule (and HBIG if required) and give a copy of the leaflet *'Protecting your baby against Hepatitis B with the Hepatitis B vaccine'.*

- For all women who decline IDPS screening in pregnancy, arrange a joint appointment with the Consultant Obstetrician and ANSC or deputy to discuss and formally re-offer screening by 20 weeks gestation.

- A 'baby alert' is completed for all women who decline maternal antenatal booking bloods
  - If the parent(s) ***decline*** vaccination of the infant (see Appendix 6)

- Complete Hepatitis B Positive Record sheet and enter details onto the Hepatitis B screening spreadsheet as well as entering information onto e-care

- Using the standard letter and email inform:
  - Community Midwife (letter)
  - General Practitioner, Practice Nurse and Health Visitor (letter)
  - Consultant Obstetrician (email)
  - Child Health Department (email: cms.chis@nhs.net)
  - East of England, Public Health England (email: phe.eoehpt@nhs.net)
- Complete Referral to Consultant Gastroenterology/Infectious Diseases: All newly diagnosed hepatitis B positive women or women already known to be hepatitis B positive with high infectivity markers detected in the current pregnancy are to be seen by the appropriate specialist within 6 weeks of result being made available to ANSC (standard 6). Referral is

made via secure email to the specialist and clarification sought by the ANSC or deputy the appointment has been booked.

- Complete Hepatitis B Baby Alert – Risk of Infectivity form for Neonatal Consultant team

- Request for HBIG following appropriate PHE guidance (see Appendix 7)

- HBIG will be delivered directly to MKUH pharmacy department from PHE. The ANSC will be informed by pharmacy via telephone when it is received. The ANSC will then collect the HBIG and take to NNU, along with the named baby box with all the paperwork. The HBIG and named baby box will then be stored together in the NNU fridge (please see SOP – HBIG: Hepatitis B Immunoglobulin pathway).

- When the infant receives the first vaccine, a letter notification is sent by Neonatal Unit staff to ANSC via internal post.

- ANSC /deputy will refer to IDPS spreadsheet each working day to check that all eligible babies have received vaccination.

- The ANSC or deputy will inform Child Health that baby has delivered, and first vaccination has been given via secure email of the infant's date of birth and date and time of first vaccination: Child Health email: cms.chis@nhs.net.

- Integrated Screening Outcomes Surveillance Service (ISOSS) data is submitted via https://www.isoss-online.org/

3.2.3 Role of Consultant in Gastroenterology/Consultant in Infectious Diseases

- All pregnant women diagnosed on antenatal screening as having hepatitis B should have further evaluation of their hepatitis B infection in the Gastroenterology or Infectious Diseases clinic.

  Testing will be done for the following markers:
  - AntiHBc (total)
  - AntiHBc IgM
  - HBeAg
  - AntiHBe
  - Measurement of (HBV) viral load.
  - HBV DNA viral load testing should be undertaken preferably twice at least three months apart with one test during third trimester.
  - Test for other blood borne viral infections: HIV antibody, hepatitis C (HCV)
  - antibody, and hepatitis D (HDV) antibody o
  - Assess chronic disease status (full blood count, liver function test including
  - ALT, albumin, renal function tests electrolytes, prothrombin time and APTT.

- The suggestion to whether to administer only vaccination or vaccination + HBIG to baby should be clearly documented on e-Care by the gastroenterology consultant.
- The Consultant will discuss with the woman the benefits and risks of antiviral treatment for them and their baby.
- Tenofovir disoproxil 245mg OD should be offered to women with HBV DNA greater than 10^7IU/ml in the third trimester to reduce the risk of transmission of HBV to the baby.

- Quantitative HBV DNA should be monitored 2 months after starting Tenofovir disoproxil and ALT monthly after the birth to detect postnatal HBV flares in the woman.
- Tenofovir disoproxil should be stopped 4 to 12 weeks after the birth unless the mother meets the criteria for long-term treatment.
- A management plan for the woman as well as for the baby is then communicated by the gastroenterology consultant to the Consultant Obstetrician, Neonatologist, ANSC, and the GP. The letter will be available to review on EDM.
- Women who ***do not*** attend their appointment should be discussed within a multidisciplinary framework involving the Gastroenterology/Infectious Diseases specialist, the obstetrician, the neonatologist and ANSC.(Gastroenterology department should inform ANSC of non-attendance) and an action plan should then be formulated.

3.2.4 Role of Lead Consultant Obstetrician

- An appointment with the Lead Obstetric Consultant for blood borne infectious diseases should be made within 10 working days regardless of whether known diagnosis or not, in line with UKNSC standards. This appointment is to ensure the correct pathway is in place and that the woman is aware of her care plan

  The obstetrician should review the recommendations and the management plan made by the gastroenterology consultant.

  A birth plan should be discussed at the antenatal appointment. The woman should be informed that although interventions in labour should be avoided where possible e.g., use of fetal scalp electrode & fetal blood sampling to reduce risk of transmission of infection to baby, they are not absolutely contraindicated and so can be considered if clinically indicated. Hepatitis B infection in the mother is NOT an indication, on its own, for LSCS.

  For women requesting a home birth, there should be an individualised care plan for the baby to receive the first Hepatitis B vaccine. This should be agreed following consultation with the Lead Obstetric Consultant for blood borne infections, Consultant Paediatrician and the homebirth team midwives.

  Women should be advised 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.

3.2.5 Role of Lead Clinician in Neonates

- To review the specified Hepatitis B Baby Alert response form and provide additional action point(s) if required.
- ***Put a plan in place for those babies whose mothers decline to have them vaccinated/receive HBIG (see Appendix 6)***
- After having signed the specified Hepatitis B Baby Alert response form. Copies are placed in Baby Alert folders on NNU and Labour Ward.
- Postnatally, neonatal medical team prescribes the vaccinations and immunoglobulin.

3.2.6 Care Of Women On Labour Ward Who Have Not Accessed Antenatal Care

All women attending Labour Ward that have not accessed antenatal care will be offered & recommended screening on admission. Where this is not possible, screening will be offered and recommended prior to discharge from maternity services.

- These specimens will be sent to Clinical Microbiology for testing marked **URGENT** and the clinical microbiology team will be informed over telephone for urgent processing of the samples on extension 85782. (Out of hours, please call On-call microbiologist via switchboard).

- If a woman books late and/or a Hepatitis test result is not available, Hepatitis B vaccine is given to the infant unless a result will be available within 24 hours of delivery or before discharge (whichever is the sooner). All results should be followed up before discharge.

- If the vaccination is declined refer to Appendix 6

3.2.7 Role of Midwifery Staff – Labour /Postnatal Ward/ on call obstetric team

- On presentation to the Labour ward check "Baby Alert" folder. If baby is identified to be at risk of vertical transmission of Hepatitis B, then contact duty Paediatric SHO or ANNP to prescribe and administer Hepatitis B vaccine +/- HBIG. This must take place within 24 hours of birth (standard 7).

- Labour ward should also notify ANSC of admission so that ANSC/deputy can follow up that baby has received vaccine/immunoglobulin. Out of hours this is via generic email: mkg-tr.mkscreeningmidwives@nhs.net.

  Contact the Consultant Neonatologist immediately if the parents decline the vaccine (see Appendix 6)

  NB: The monovalent vaccine is stored in the fridge on the NNU.

- ***Postnatal maternal surveillance sample:***

  The second maternal venous surveillance sample should be taken on delivery suite from those women classified as being of **higher infectivity** after the woman has delivered her baby. EDTA blood tubes, request forms and pre-paid return envelopes will be available in the 'hep B delivery suite box' which, along with the HBIG, will be sent to maternity units approximately 7 weeks prior to the estimated delivery date.

  Note: the named baby boxes are stored in the fridge on NNU

  Newborn DBS sample:

  A DBS test should be taken on delivery suite from babies born to mothers classified as being at higher infectivity ***before administration of the vaccine and HBIG.***

  The DBS cards, instructions on collection and pre-paid return envelopes will be provided in the 'hep B delivery suite box', which along with the HBIG, will be delivered to maternity units approximately 7 weeks prior to the estimated delivery date.

  Note: The named baby box is stored in the fridge on NNU.

This surveillance blood sample is different to the newborn blood spot screening sample taken on day 5 after the baby's birth. The mother should be informed that the baby will still need to have the newborn blood spot screen sample on day 5. This DBS is not subject to the standards or requirements of the newborn blood spot screening programme.

The baby's birth DBS result will not be reported at the time of testing as it will not influence the immediate management of the baby.

If the woman declines to have maternal serology and or neonatal DBS taken it should be recorded in her notes and on the completed request forms and returned to PHE Colindale.

- Ensure that immunisation has been administered within 24 hours and top page of "Hepatitis B Infant Immunisation Programme" form has been completed and sent to Antenatal & Newborn Screening Department within a day of giving vaccine.

- Insert remaining sheets of the "Hep B Infant Vaccination Programme" form into the PCHR (red book)

- Before discharge, give the parents a copy of the *'Hepatitis B: a guide to your care in pregnancy and after your baby is born'* (2020) leaflet, available in several languages online at: https://www.gov.uk/government/publications/protecting-your-baby-against-hepatitis-b-leaflet, that includes information on completing the full course & schedule of vaccines (monovalent vaccine administered at birth and 4 weeks and thereafter hepatitis b vaccinations are included in the childhood immunisation schedule at 8 weeks, 12 weeks, 16 weeks and 12 months, with a blood test following 12-month vaccine (this is arranged by the GP).

- Record the woman's hepatitis B status and the baby's vaccination schedule on the postnatal discharge letter as well as the Personal Child Health Record. Ensure discharge and contact details are correct.

- Hepatitis B positive women in premature labour who are transferred to another unit for delivery must be accompanied by the relevant paperwork and the HBIG where required.

- On call obstetric team will ensure that women with hepatitis B who have not seen an appropriate specialist (Gastroenterologist or infectious diseases specialist) *during pregnancy* are referred postnatally to see the specialist team. This can be done by a direct referral to the gastroenterology team.

3.2.8 Role of Paediatric SHO/ANNP

- See Appendix 8.

- Once notified that a Hepatitis B positive mother has been admitted to Labour ward - ensure availability of Hepatitis B vaccine for children and adolescents in NNU fridge +/- HBIG in Blood Transfusion

- Once notified of the birth of the infant, obtain verbal consent from the parent(s) and document consent on e-care.

If the parent(s) decline Hepatitis B vaccination or HBIG for the infant (see Appendix 6)

Note: Paediatrician to ensure a DBS test has been taken on delivery suite from babies born to mothers classified as being at higher infectivity before administration of the vaccine and HBIG.

- Prescribe and administer Hepatitis B vaccine, intramuscularly on the anterolateral surface of the thigh(s) not the buttock. HBIG can be given in the upper outer quadrant of the buttock or anterolateral thigh, but at a different site to the vaccine. If more than 3ml HBIG is to be given, it must be given in divided doses at different sites. Both vaccine and HBIG (if required) ***must be administered as soon as possible after birth and no later than 24 hours.***
- If birth weight of infant is 1500 grams or less, give both HBIG and vaccine regardless of maternal Hepatitis e-antigen status.
- HBIG dose is 200 iu to be given IM
- For urgent supply contact Public Health England, Colindale 0208 327 7471

NB. Always check available vaccine and doses in the current paediatric BNF and the "Green Book. "Enter record of immunisation into the "Hep B Infant Vaccination Programme" form.

- Ensure that the top copy of the "Hep B Infant Vaccination Programme" form is handed to the ward clerk/midwife to be sent to Antenatal & Newborn Screening Department as a matter of priority.
- Inform parents of the need and benefits to complete the Immunisation Programme.
- Ensure effective hand-over of the case where applicable.
- As a safety net, review "e-care" at the time of neonatal examination for risk factors including Hepatitis B. Ensure appropriate action has taken place.

Notes on HBIG immunisation: If immunoglobulin has been administered first, then an interval of 3 months should be observed before administering a live viral vaccine.

3.2.9 Role of Neonatal unit

- For babies admitted to NNU, ensure adherence to Hepatitis B vaccination and immunisation schedule for baby's duration of stay. Escalate to the Consultant Neonatologist if this is not being adhered to.
- If birth weight of infant is 1500 grams or less, give both HBIG and vaccine regardless of maternal Hepatitis e-antigen status.
- If no results are available for maternal screening (the mother's status is unknown); a late booker or declined booking bloods. The infant will require the Hepatitis B vaccine following a discussion with the parents by the Consultant Neonatologist.

4.0 Role of General Practitioner

- Ensure the following groups receive counselling, relevant testing and immunisation as required:
  - Other family members and children
  - Any recent sexual contacts
  - People who may have shared the same needles (in case of drug users)
- Ensure follow up vaccines for babies at risk at 1, 2 and 12 months and blood testing following 12-month vaccine.

- Initiate follow-up for infected infants.

5.0 If parent(s) decline the infant to receive the Hepatitis B vaccine and/or HBIG

(see Appendix 6)

Escalate to the Consultant Neonatologist, Consultant Obstetrician and ANSC as soon as identified. 'Baby alert' to be completed and sent to the Neonatal Consultants indicating maternal refusal to vaccinate baby, ***even if a previous alert has already been sent.***

5.1 During the pregnancy

- Refer to ANSC and/or deputy
- ANSC or deputy to arrange joint face-to-face appointment with Consultant Obstetrician and Consultant Neonatologist

5.2 Postnatal:

- Immediately contact the on-call Consultant Neonatologist to attend and discuss the risks of not consenting to the vaccine with the parents.

6.0 References:

BNF for Children (2019) [Online]. Available from: https://bnfc.nice.org.uk/ [Accessed 8 March 2019]

Brook, G. et al., Clinical Effectiveness Group British Association for Sexual Health and HIV (2015) *United Kingdom national guideline on the management of the viral hepatitides A, B and C 2015.* International Journal of STD & AIDS 0(0) 1–25 https://www.bashhguidelines.org/media/1066/uk-bashh-hepatitis-guidelines-2015.pdf
2017 interim update https://www.bashhguidelines.org/media/1161/viral-hepatitides-2017-update-18-12-17.pdf

Department of Health [2011] *Hepatitis B: pathway stages to protection: actions, roles, responsibilities and standards.* [Online]. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/215621/dh_126201.pdf [Accessed 13 March 2019]

National Clinical Guideline Centre (2013; last updated Oct 2017) *Hepatitis B (chronic) Diagnosis and management of chronic hepatitis B in children, young people and adults. Clinical guideline. Methods, evidence and recommendations / commissioned by the National Institute for Health and Care Excellence.* [Online]. Available from: https://www.nice.org.uk/guidance/cg165/evidence/full-guideline-pdf-190175005 [Accessed 13 March 2019]

National Institute for Health and Care Excellence (2014) *Hepatitis B*. [QS65]. [Online]. Available from: https://www.nice.org.uk/guidance/qs65 [Accessed 13 March 2019]

Public Health England (2008) *Infants born to hepatitis B-infected mothers: immunoglobulin policy.* [Online]. Available from: https://www.gov.uk/government/publications/infants-born-to-hepatitis-b-infected-mothers-immunisation-policy [Accessed 13 March 2019]

Public Health England (2016) *NHS Infectious Diseases in Pregnancy Screening Programme standards 2016 to 2017.* [Online]. London: PHE. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/733044/IDPS_Programme_Standards_2016_to_2017.pdf [Accessed 8 March 2019]

Public Health England (2017a) *Hepatitis B: requesting issue of immunoglobulin for infants. Form.* [Online]. Available from: https://www.gov.uk/government/publications/hepatitis-b-requesting-issue-of-immunoglobulin-for-infants [Accessed 13 March 2019]

Public Health England (2017b) *Hepatitis B: the green book, chapter 18.* [Online]. June 2017. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/628602/Greenbook_chapter__18.pdf [Accessed 8 March 2019]

Public Health England (2017c) *The hexavalent DTaP/IPV/Hib/HepB combination vaccine: information for healthcare practitioners about the neonatal selective immunisation programme for babies at risk of hepatitis B.* [Online]. London: PHE. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/740421/Hexavalent_combination_vaccine_guidance_selective.pdf [Accessed 13 March 2019]

Public Health England (2018a) *Infectious diseases in pregnancy screening standards valid for data collected from 1 April 2018.* [Online]. Available from: https://www.gov.uk/government/publications/infectious-diseases-in-pregnancy-screening-programme-standards/infectious-diseases-in-pregnancy-screening-standards-valid-for-data-collected-from-1-april-2018 [Accessed 8 March 2019]

Public Health England (2018b) *Our approach to infectious diseases in pregnancy screening standards.* [Online]. Available from: https://www.gov.uk/government/publications/infectious-diseases-in-pregnancy-screening-programme-standards/our-approach-to-infectious-diseases-in-pregnancy-screening-standards [Accessed 8 March 2019]

Public Health England (2018c) *Protecting your baby against hepatitis B with the hepatitis B vaccine.* [Online]. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/736029/Protecting_your_baby_against_hepatitis_B_leaflet.pdf [Accessed 8 March 2019]
Translated versions also available for download at:
https://www.gov.uk/government/publications/protecting-your-baby-against-hepatitis-b-leaflet

Public Health England (2021) Guidance: guidance on the hepatitis B antenatal screening and selective neonatal immunisaiton pathway. [Online]. Available from: https://www.gov.uk/government/publications/protecting-your-baby-against-hepatitis-b-leaflet [Accessed 14 April 2021]

External weblinks: Please note that although Milton Keynes University Hospital NHS Foundation Trust may include links to external websites, the Trust is not responsible for the accuracy or content therein.

7.0 Governance

7.1 Record of changes to document

Version number: 6		**Date:** June 2020		
Section Number	**Amendment**	**Deletion**	**Addition**	**Reason**
	Comprehensive guideline review and update			Update
	Updated – 14.04.2021			
6.1	updated		3.2.2, 3.2.7	Changes to maternal surveillance sample

7.2 Consultation History

Stakeholders Name/Board	**Area of Expertise**	**Date Sent**	**Date Received**	**Comments**	**Endorsed Yes/No**
Prakash Gupta	Consultant Gastroenterologist			Acknowledged and included	Yes
Mansoor Raza	Consultant in Infectious Diseases and Microbiology			Acknowledged and included	Yes
Prithwiraj Chakrabarti	Consultant Microbiologist for Serology			Comments acknowledged and included	
Staff working in Women's and Children's health				Comments acknowledged	
Julie Cooper	Head of Midwifery		23.06.20	Comments received and included	
James Bursell	Consultant Paediatrician				
Dr R Shetty	Consultant Paediatrician				
Zuzanna Gawlowski	Consultant Paediatrician				
Marian Forster	Neonatal Practice Educator				
Irene Miotto	Senior Quality Assurance Advisor, Midlands & East PHE Screening				
Carol Jones	Chief Biomedical Scientist Microbiology	15/07/19	06/08/19	Comments received and included	

Suraiya Chandratillake	Principal Pharmacist, Antimicrobials	24/06/20	24/06/20	Comments received and included	
Maternity guideline review group	CSU	28/04/21			

7.3 Audit and monitoring

Audit/Monitoring Criteria	Tool	Audit Lead	Frequency of Audit	Responsible Committee/Board
Time to intervention: timely assessment for screen positive and known positive women (Standard 5)	NHS Infectious Diseases in Pregnancy Screening Programme Annual Data Collection	Antenatal & Newborn Screening Co-ordinator	Yearly	ANNB Programme Management Board
Timely assessment of women with hepatitis B by a specialist (Hepatologist/Gastroenterologist) within 6 weeks of identifying in the current pregnancy	NHS Screening Programmes Key Performance Indicators (KPIs)	Antenatal & Newborn Screening Co-ordinator	Quarterly	ANNB Programme Management Board
Intervention and treatment: Hepatitis B – timely neonatal vaccine and immunoglobulin ≤ 24 hours (Standard 7)	NHS Infectious Diseases in Pregnancy Screening Programme Annual Data Collection	Antenatal & Newborn Screening Co-ordinator	Yearly	ANNB Programme Management Board

7.4 Equality Impact Assessment

As part of its development, this Guideline and its impact on equality, has been reviewed. The purpose of the assessment is to minimise and if possible remove any disproportionate impact on thegrounds of race, gender, disability, age, sexual orientation, religion or belief, pregnancy and maternity, gender reassignment or marriage and civil partnership. No detriment was identified. Equality Impact assessments will show any future actions required to overcome any identified barriers or discriminatory practice.

Equality Impact Assessment			
Division	Women and Children's Health	Department	Maternity
Person completing the EqIA	Anita Males	Contact No.	85236
Others involved:		Date of assessment:	31/07/2019
Existing policy/service	Yes	New policy/service	No

Will patients, carers, the public or staff be affected by the policy/service?	Yes
If staff, how many/which groups will be affected?	*All staff*

Protected characteristic	Any impact?	Comments
Age	NO	Positive impact as the policy aims to recognise diversity, promote inclusion and fair treatment for patients and staff
Disability	NO	
Gender reassignment	NO	
Marriage and civil partnership	NO	
Pregnancy and maternity	NO	
Race	NO	
Religion or belief	NO	
Sex	NO	
Sexual orientation	NO	

What consultation method(s) have you carried out?
Via email, face to face meetings, WH Guideline review group
How are the changes/amendments to the policies/services communicated?
intranet post
What future actions need to be taken to overcome any barriers or discrimination?

What?	Who will lead this?	Date of completion	Resources needed
Review date of EqIA	10/2023		

Appendix 1: Hepatitis B Care Pathway

Antenatal Screening and Immunisation of Neonates

Hepatitis B screening discussed and offered at booking interview by Community Midwife/Midwife

HBsAg Negative No further action

HBsAg positive: Laboratory to inform IDPS MDT within 8 days of receipt of sample in the screening laboratory. To enable recall of the woman within 10 working days of the positive result or known status being reported to maternity services.

HBeAg negative and AntiHBe positive

Neonatal prophylaxis with Hepatits B vaccination (vaccine available on NNU)
1st dose within 24 hours of birth then at 1, 2 and 12 months of age If birth weight is 1500g or less, give both HBIG and vaccine regardless of maternal hepatitis e-antigen status

Test (the infant) for Anti HBs 2 months after last dose of vaccine

If Anti HBs level is <10 IU/ml the lab will automatically test for HBsAg

HBeAg positive OR HBeAg negative and Anti-HBe negative or
*HBV DNA (viral load) more than 1 x 106 IU/ml (i.e. acute Hepatitis B infection)

Neonatal Prophylaxis with Hepatitis B vaccination 1st dose within 24 hours of birth, then at 1, 2 and 12 months of age (vaccine available on NNU)
AND
Hepatitis B immunoglobulin as soon as possible after birthand no later than 24 hours

Test (the infant) for Anti HBs 2 months after last dose of vaccine

* HBV DNA viral load is provided in patient known to have acute hepatitis B infection. HBV DNA viral load cannot be performed on the screening serum sample as this test requies and additional EDTA sample.

All Positive Women:

- Appointment for Consultant Antenatal Clinic for first available
- Arrange for Liver Function Tests and HBV DNA (VIRAL LOAD), antenatal surveillance sample
- Referred to and seen by Hepatologist within 6 weeks of receiving the screening test result and seek advice on the management of the patient including interpretation of HBV DNA result and requirement for antivirals
- Baby Alert completed as soon as positive result received
- Inform Community Midwife, GP, Practice Nurse, Health Visitor and Hearing Screeners
- Inform Colindale (020 8327 6439 or out of hours 0208 200 4400) of an Acute Hepatitis B patient for issue of Hepatitis B Immunoglobulin for the neonate

If parent(s) *decline* Hepatitis B vaccine and/or HBIG: refer to ANSC, Consultant Obstetrician and Consultant Neonatologist (see Appendix 6)

Appendix 2: Hepatitis B Positive Screening Checklist

HEPATITIS B POSITIVE SCREENING CHECKLIST

Year

Month

Patient Details: **New diagnosis** ☐

Previously Known ☐

EDD by USS_____

GP Surgery:_____

ANTE NATAL SPECIMEN - LABORATORY RESULTS

Date of specimen: _____

Date results reported:_____

Date of confirmatory sample if new diagnosis:_____

	Positive	Negative
HbsAG	☐	☐
HBeAG	☐	☐
Anti-HBe	☐	☐
Anti-HBc IgM	☐	☐
Anti-HBc	☐	☐

High Infectivity: (Baby to receive course of Hepatitis B Vaccine AND HBIG single dose) ☐

Low Infectivity: (Baby to receive course of Hepatitis B Vaccine only) ☐

Vaccine Received within 24hrs of Birth ☐

Referral to Gastroenterology Date:_____ ☐

Appointment date in Gastroenterology within 6 wks ☐ Attended Yes / No

Consultant Obstetrician ANC appointment made ☐

Inform **Date**_____

Community Midwife,
GP, Health Visitor & Practice Nurse,
Consultant Obstetrician,
Lead Paediatrician –
Child Health,
Newborn Hearing Screening Coordinator,
Public Health England

Baby Alert ☐

Appendix 3: Hepatitis B Gastroenterology Referral

Milton Keynes University Hospital NHS
NHS Foundation Trust

Antenatal and Newborn Screening
Tel: 01908 995236 or
07790 935490

Email: mkg-tr.mkscreeningmidwives@nhs.net

Standing Way
Eaglestone
Milton Keynes
MK6 5LD
01908 660033
www.mkhospital.nhs.uk

For people who have hearing loss
Minicom 01908 243924

Private and Confidential

DATE

Dear Dr

RE:

EDD by USS

At routine Antenatal screening this patient was found to be Hepatitis B Positive with the following results confirmed from the reference laboratory.

ANTE NATAL SPECIMEN - LABORATORY RESULTS
Date of specimen: _____
Date results reported: _____
Date of confirmatory sample if New diagnosis:_____
Previously Known ☐

	Positive	Negative
HbsAG	☐	☐
HBeAG	☐	☐
Anti-HBe	☐	☐
Anti-HBc IgM	☐	☐
Anti-HBc	☐	☐

We would be grateful for your expertise and input in the management of their Hepatitis.B. Please can you arrange for this lady to be seen in one of your clinics within six weeks of the date of this letter and inform us of the date. In order for us to comply with National Screening Committee Standards.

Yours sincerely

Antenatal and Newborn Screening Team

Appendix 4: Hepatitis B Notification Letter

Milton Keynes University Hospital NHS
NHS Foundation Trust

Antenatal and Newborn Screening
Tel: 01908 995236 or
07790 935490

Email: mkg-tr.mkscreeningmidwives@nhs.net

Standing Way
Eaglestone
Milton Keynes
MK6 5LD
01908 660033
www.mkhospital.nhs.uk

For people who have hearing loss
Minicom 01908 243924

Private and Confidential

DATE

Dear

Ref Patient

EDD by USS

At routine Antenatal screening this patient was found to be Hepatitis B Positive with the following results confirmed from the reference laboratory

Date of specimen: _____
Date results reported:_____
Date of confirmatory sample if New diagnosis:_____
Previously Known ☐

	Positive	Negative
HbsAG	☐	☐
HBeAG	☐	☐
Anti-HBe	☐	☐
Anti-HBc IgM	☐	☐
Anti-HBc	☐	☐

Following birth her baby will require Hepatitis B vaccination at birth, one, two and twelve months followed by a blood test to check for HBs AG.

A referral has been made to the Gastroenterology department for assessment and management. Please can you arrange for other family members or sexual partners to be screened for Hepatitis B.

Yours sincerely

Antenatal and Newborn Screening Team.

Appendix 5: Hepatitis B Baby Alert – Risk of Infectivity

	BABY ALERT	

Contact Tel.:…… Due Date:……

Risk Identified:

Baby low risk of vertical transmission - **baby requires Hepatitis B vaccine only within 24 hours of birth**. ☐

Baby at high risk of vertical transmission – **baby requires HBIG and Hepatitis B Vaccine within 24 hours of birth** ☐

N.B. If the infant's birth weight is 1500 grams or less, **both HBIG and vaccine** should be given regardless of maternal infectivity status within the first 24 hrs of birth

Paediatric Decisions: Consultant Name……....Date……

Consultant Signature……

Midwife to:

- Remind parents of need to give baby Hep. B vaccine and HBIG, as required within 24 hours of birth, and that verbal consent will be sought prior to immunisation.
- Emphasise importance of completion of full 4 dose course (at birth, 1 month, 2 months and 12months) and give copy of 'Hepatitis B - How to protect your baby' leaflet in the appropriate language.
- Send completed top copy of "Hep B Infant Vaccination Programme" form, to ANSC and file the remainder in the Personalised Child Health Record (PCHR).

Paediatric SHO to:

- Check availability of Hep B vaccine for children and adolescents (NNU fridge) and HBIG (Blood Transfusion for both high risk and low birth weight babies), as required.
- Seek verbal consent, prior to vaccination **and tick box below**.
- Give Hep B vaccine and HBIG, if required – dosage and administration according to the "Green Book" (Immunisations against Infectious Disease)/Paediatric BNF
- Complete "Hep B Infant Vaccination Programme" form and give to Midwife/Ward Clerk

Parents aware of need for, and agree to, immunisation…☐…… **(tick box)**

Inform the Paediatricians

When? On admission to Labour ward **and** shortly after birth

Who? SHO or ANNP for Labour ward between 9am – 5pm

Duty SHO or ANNP after 5pm and on weekends or holidays

Baby been seen by Paediatric team following delivery and all appropriate actions taken?
YES / NO

Please file with maternity notes (e-care and EDM)

Appendix 6: Flow Chart for Parents who Decline Hepatitis B Vaccine and/or Immunoglobulin for the Newborn

ANSC and/or deputy to discuss at the first face-to-face appointment the Hepatitis B vaccination schedule for the infant. Verbal and written information is provided to the parents to make an informed decision. An interpreter will be requested if required.

If parents decline the Hep B vaccine and/or immunoglobulin the ANSC or deputy will escalate to the Consultant Obstetrician and Consultant Neonatologist – face-to-face consultations will be arranged with the parents to discuss the risks of not consenting to treatment.

A 'Baby Alert' to be completed highlighting ***declined vaccine and/or immunoglobulin*** – even if an alert has already been completed.

On admission to Labour Ward: midwife to discuss Hepatitis B vaccine/Immunoglobulin for the infant with the parents prior to delivery. If the parents decline then the midwife must escalate to the on-call Consultant Neonatologist to discuss the risks of not consenting to treatment.

Postnatal: Hepatitis B vaccine and/or immunoglobulin to be offered as soon as possible following the birth and before 24 hours. If parents decline the infant to be vaccinated, then immediately escalate to the on-call Consultant Neonatologist to discuss the risks of not consenting to treatment.

If parents continue to decline the infant to be vaccinated following discussion with the Consultant Neonatologist; immediately escalate to the Safeguarding and Legal Teams including GP & health visitor.

Appendix 7: Issue of Hepatitis B Immunoglobulin for Infants at Risk of Hepatitis B Infection

Hepatitis B: requesting issue of immunoglobulin for infants - GOV.UK (www.gov.uk)

Appendix 8: PHE Changes to Hepatitis B HBIG Dosage and Delivery Methods

Public Health England

Protecting and improving the nation's health

PHE Immunisation, Hepatitis and Blood Safety Department
61 Colindale Avenue
London NW9 5EQ

T +44 (0)20 8327 6439
F +44 (0)20 8327 7404

www.gov.uk/phe

Screening Coordinator/team

Monday, 10 May 2021

NOTIFICATION OF IMMINENT CHANGES TO THE HEPATITIS B HBIG DOSAGE AND DELIVERY METHODS

Dear Colleagues,

As you are aware, the screening and immunisation teams at PHE have been conducting a review of the pathways for women with hepatitis B and their babies, aiming for an enhanced pathway launch in 2020. We are finalising guidelines and resources to support your local quality improvement review.

In the meantime, two changes are being introduced around supply and delivery of Hepatitis B Human Immunoglobulin (HBIG). Currently HBIG is issued, upon receipt of a named request for babies born to higher infectivity risk mothers, in a box with the relevant paperwork.

The two imminent changes are:

1. **HBIG vial size/dose:**

The current vial size/dose of HBIG is 200IU (infant dose) which should be administered along with the hepatitis B vaccine immediately after birth (within 24hrs) to women with higher infectivity. The manufacturer, Bio Products Laboratory (BPL), has withdrawn this size/dose vial and will now only issue in 500IU dose vials (which are conventionally an adult dose). The dose recommendations have been amended as follows:

- as the JCVI recommended dose for neonates is 200IU, PHE recommends that **half of the 500IU vial (approximately 250IU / 1.75 mls) is given**.
- low birth weight babies (≤1500g) can be given the injection in divided doses, within 7 days of birth, but should still receive a full 250IU.

2. **Method of delivery:**

We currently issue "named baby" HBIG 7weeks prior to EDD. This may be sent to a variety of departments in trusts e.g. virology, pharmacy, maternity unit.

PHE has a contract with a logistics and distribution company to send providers PHE vaccines for the national immunisation programmes. This is to reduce delivery errors; ensure cold chain is maintained in transit and track dispatch and delivery. As such the following changes to HBIG issue are being made:

- all future vials of "**named baby" HBIG** that are issued will be delivered by the logistics company to your **hospital pharmacy department**.
- the delivery will consist of the HBIG vial, a delivery note which quotes "PHE Ref No:XXXX_" along with an information leaflet for pharmacy which states the HBIG has been issued for a "named baby" (leaflet appended)
- the **named baby HepB delivery suite box** containing the birth notification paperwork will be issued to the **default address** for your hospital currently on our system **for the attention of theAntenatal Screening Coordinator/team.**
- the screening coordinator is responsible for "**matching up"** the named baby HBIG vial from pharmacy with the named baby HepB delivery suite box and ensure these are stored securely according to local arrangements so that they are available 24/7 to the delivery team for that named baby.

You will notice revised wording reflecting these changes to HBIG in the Green Book (https://www.gov.uk/government/publications/hepatitis-b-the-green-book-chapter-18) and Immunoglobulin-when to use guidance (https://www.gov.uk/government/publications/immunoglobulin-when-to-use).

Actions for you:
Please email updated contact details for your screening team as we will now use these for delivery of the HepB delivery suite box:

- lead antenatal screening co-ordinator name and email
- screening team phone number
- generic team nhs.net email address

Email the correct information to hepatitisbbabies@phe.gov.uk or call the hep B babies coordinator on +44 (0)20 8327 6439. Do not hesitate to contact us if you have any queries.

Yours sincerely

Dr Sema Mandal
Consultant Epidemiologist
Immunisation and Countermeasures Division
National Infection Service, PHE
Sema.mandal@phe.gov.uk

Appendix 9: Hepatitis B Vaccine/Immunoglobulin Notification Slip

HEPATITIS B VACCINE / IMMUNOGLOBULIN NOTIFICATION SLIP

Baby Sticker	Mother Sticker

Date of Birth _____ Date of Vaccination _____

Time of Birth _____ Time of Vaccination _____

Gestation _____

Birth Weight _____

Please complete and return to Antenatal and Newborn Screening Office

HEPATITIS B VACCINE / IMMUNOGLOBULIN NOTIFICATION SLIP

Baby Sticker	Mother Sticker

Date of Birth _____ Date of Vaccination _____

Time of Birth _____ Time of Vaccination _____

Gestation _____

Birth Weight _____

Please complete and return to Antenatal and Newborn Screening Office