Babies at High Risk of Hepatitis B - Full Clinical Neonatal Guideline Derby & Burton

Reference no.: NIC IN 15

1. Introduction

Hepatitis B is an infection of the liver caused by the hepatitis B virus (HBV). The World Health Organisation (WHO) estimates >390 million people worldwide are chronically infected. The overall prevalence of HBV antenatal women in the UK is around 0.14%, although there are regional variations with some inner cities rising to 1% (DH 2006).

Transmission – the virus is transmitted by parental exposure to infected blood or body fluids. Vertical transmission (mother to child) is an effective mode of transmitting HBV infection and can happen any time during pregnancy or at delivery. Babies who are infected during pregnancy and at birth are at high risk of being chronic carriers (DH 2000). Hepatitis B prophylaxis (via an accelerated four dose immunisation programme) is given to babies born to infected mothers can be 90-95% effective in preventing the development of chronic Hepatitis B infection (HPA 2005).

The Hepatitis B programme was highlighted to NICE because some babies born to infected mothers are not receiving the complete course of vaccines at the right time (NICE 2009).

Since 2017 Hepatitis B vaccination has been part of the routine childhood immunisation schedule. This guideline covers babies who are at high risk of early viral transmission and therefore require an accelerated schedule.

2. Aim and Purpose

For Health care professionals to correctly identify all babies born to Hepatitis B or high risk families and ensure that they follow and complete the immunisation programme as directed by the NICE guidelines (2009).

3. Definitions, Keywords

See appendix 1 for important definitions

Hepatitis B, Hep B, IVDU, Immunoglobulin, Vaccination, Unbooked Mothers

4. Identifying Risk

High Risk Babies include:

- All babies born to mothers who are known to be hepatitis B positive
- Babies born to mothers who are Hepatitis B negative but are returning to a household where a person is known to be Hepatitis B positive.

Babies Born to hepatitis B infected mothers

Hepatitis status of the mother **(see appendix for definitions)**	**Baby should receive Hepatitis B vaccine**	**Hepatitis B Immunoglobulin**
HBsAg positive & HBeAg positive	Yes	Yes
HBsAg positive, HBeAg negative & anti-HBe negative	Yes	Yes
HBsAg positive where e-markers have not been determined	Yes	Yes
Mother had acute Hepatitis B during pregnancy	Yes	Yes
Mother is HBsAg seropositive & infant is born weighing 1500g or less	Yes	Yes
HBsAg positive and known to have any HBV DNA level equal or above $1x10^6$ IUs/ml in any antenatal sample during pregnancy	Yes	Yes
HBsAg positive & anti-HBe positive (unless < 1500g)	Yes	No

Babies born to Hepatitis B negative mothers with household Hepatitis B infection

- Single dose of monovalent hepatitis B vaccine before discharge and then go onto the normal schedule. No further follow-up is required. GP should be notified.

Babies born to mothers inject drugs or with Hepatitis C Infection

- Routine vaccination schedule.

5. Pathways of Care

Maternal screening - Positive Hepatitis B serology

When a positive hepatitis serology is identified the Antenatal Screening Coordinator (ANSC) or Consultant Obstetrician will issue a letter documenting details of:

- Maternal Hep B e antigen and antibody status (as below)
- Recommended vaccination course for baby.
- Request for Hepatitis B immunoglobulin to be administered if required.

This information can be found in maternal obstetric notes, documented in baby notes and a copy of the maternal Hepatology referral letter is sent to the Consultant Paediatrician by email outlining the maternal serology:

- Hepatitis B surface antigen **positive**
- Hepatitis B e antigen **Detected / NOT detected** delete as appropriate
- Hepatitis B e antibody **Detected / NOT detected** delete as appropriate
- Hepatitis B DNA Quantification: **Detected / NOT detected** delete as appropriate

These letters are kept in the NICU Hepatitis B expected babies file

It is the responsibility the neonatal doctor completing the alert form to ensure that immunoglobulin is ordered (see section 6).

Unbooked mothers presenting in labour

Should have a rapid HBsAg test and vaccination given as appropriate to infant. Discuss high risk or low birth weight babies with ANSC or on-call consultant Microbiologist.

Mother declined screening

Consider screening bloods in baby after birth and if high risk repeat at 3 months of age.

6. Actions after Birth

Babies identified as high risk (section 4) should receive their first dose of vaccination as soon as possible after birth (and always within 24 hours). If Immunoglobulin is required this should be given at the same time ***intramuscularly*** in the contralateral thigh.

Prior to vaccination informed consent should be sought from parents and the appropriate page of the red book signed.

Hepatitis B Vaccination

Monovalent Hepatitis B Vaccination should be given intramuscularly into the thigh by the neonatal team. It is available from Pharmacy at both sites.

Hepatitis B Immunoglobulin

250 international units should be given into the contralateral thigh by the neonatal team. It should be ordered in advance and available from pharmacy at both sites.

If no immunoglobulin is available it can be sourced in the following manner:

- During office hours: call 0330 1281020 option 2 and email request to: phe.hepatitisbbabies@nhs.net Out of hours: call 020 8327 7471 and speak to the duty doctor
- If administration of HBIG is delayed for more than 48 hours, Consultant Microbiologist and/or Consultant in Communicable disease should be consulted.

Cautions:

- If HBIG has been administered then an interval of 3 months should be observed before administering a live virus vaccine
- If HBIG has been given within 3 weeks of administering a live vaccine, then the vaccine should be repeated 3 months later (except in yellow fever vaccine)

Breast Feeding

Breast feeding should be encouraged and supported. There is no contra-indication to breast feeding when a baby is born to a Hep B positive mother and begins the Hep B immunisation programme within 24 hours of birth.

Documentation

- After indicating there are risk factors for Hepatitis B during the NIPE examination a letter will be generated by NIPE Smart. This must be printed off and sent to the appropriate parties as listed (See appendix)
- In Derby this includes (Total 4)
    - 1 copy to **Health Visitor** (**FILE** in babies' PCHR 'red book' in an envelope FAO Health Visitor) or email to Health Visitor team generic email address.
    - 1 copy to **GP**, send by post or electronically attached to PN discharge - address FAO Practice Nurse (Please **DO NOT** give to mums).
    - 1 copy to **Antenatal Screening Specialist Team**, email to dhft.antenatalandnewbornscreeningRDH@nhs.net
    - 1 copy to **CHIS**, Team Manager **Child Health** email to scwcsu.derbyshire.chis@nhs.net

- In Burton this includes (Total 5)
    - 1 copy to Health Visitor (**FILE** in babies' PCHR 'red book' in an envelope FAO Health Visitor).
    - 1 copy to **GP**, send by post or electronically attached to PN discharge - address FAO Practice Nurse (Please **DO NOT** give to mums).
    - 1 copy to **Antenatal Screening Specialist Midwife**, Antenatal Clinic or email bhft.antenatalscreening@nhs.net
    - 1 copy to **West Midlands Health Protection Team**, Stonefield House, Corporation Street, Stafford, ST16 3SR or phe.wmnoids@nhs.net
    - 1 copy to CHIS, Team Manager **Child Health**, Mellor House, Corporation Street, Stafford, ST16 3SR or email childhealth@sshis.nhs.uk
    - copy to **NHS England** Screening & Immunisation Team via email england.hbat@nhs.net

- Also complete and Insert 'Hepatitis B infant immunisation programme' (Appendix 2) in Personal Child Health Record (Red book).

7. Follow-up

Babies covered by the above guideline will require Hepatitis serology (anti-HBs) at 15-16 months. This should be initiated by the GP.

Immunisation Schedule

Age	Routine Childhood Programme	Babies born to hepatitis B infected mothers	Responsible Clinician
Birth	X	Monovalent Hep B +/- HBIG	Neonatal Staff
4 weeks	X	Monovalent Hep B	GP
8 weeks	DTaP/IPV/Hib/HepB	DTaP/IPV/Hib/HepB	GP
12 weeks	DTaP/IPV/Hib/HepB	DTaP/IPV/Hib/HepB	GP
16 weeks	DTaP/IPV/Hib/HepB	DTaP/IPV/Hib/HepB	GP
1 year	Non-hep B Vaccinations	Monovalent Hep B Test for HBsAG	GP

Changes Log (Version 4)

Changed dose of HBIB immunoglobulin from 200 IU to 250 IU (As per green book)

HBsAg positive and known to have any HBV DNA level equal or above 1x106 IUs/ml in any antenatal sample during pregnancy included in table

Change in contact details for OOH Immunoglobulin

- Update of contacts to Send
- New HB1 Forms

8. References (including any links to NICE Guidance etc.)

1 Green Book Chapter 18, Hepatitis B (babies born after July 2017) https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/628602/Greenbook_chapter_18.pdf

2 Hepatitis B antenatal screening and newborn immunisation programme, Best Practice Guideline (department of health 2011) https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/215622/dh_132637.pdf

3 Immunisation of Neonates at high risk of hepatitis B in England and Wales: National Surveillance. BMJ 1988, 297:249-253.

4 Department of Health Document (28.1.02) "Consultation on Guidance on Children in Need and Blood-borne viruses" - HIV & Hepatitis

9. Documentation Controls

Reference Number NIC IN 15	**Version** V004		**Status** Final	
Version / Amendment History	Version	Date	Author	Reason
	V003	Nov 2020	Dr Jonathan Riley	Review and Update
	V004	Dec 2023	Dr Jonathan Riley	Review and Update
Intended Recipients: All Paediatric Medical Staff All Paediatric Nursing Staff Emergency Department Staff				
Training and Dissemination: Cascade the information via BU newsletter and address training				
Development of Guideline: Dr Bala Subramaniam Consultant Paediatrician at Derby Dr Dominic Muogbo Consultant Paediatrician at Burton Dr Jonathan Riley Paediatric Registrar				
In Consultation with: Paediatric Team Derby and Burton Public Health England				
Linked Documents: (Nice guidance/Current national guidelines)				
Keywords: (Search term for KOHA) Hepatitis B, Hep B, IVDU, Immunoglobulin, Vaccination, Unbooked Mothers				
Business Unit Sign Off			**Group:** Paediatric Guidelines Group **Date: 20th December 2023**	
Divisional Sign Off			**Group:** Women's and Children's Clinical Governance Group **Date: 21st December 2026**	
Date of Upload			28/12/2023	
Review Date			December 2026	
Contact for Review			Dr Bala Subramaniam	

10. Appendices

Appendix 1 – Definitions

HBsAg is Hepatitis B surface antigen, historically and familiarly known as Australia antigen. This marker is found in both acute and carrier states. In most cases HBsAg disappears about 3 months after the onset.

Anti-HBs is the antibody to the above. When a case of Hepatitis B seroconverts, anti-HBs can be detected and the patient is no longer infectious. Anti-HBs is also detectable after successful vaccination or treatment with HBIG (Hepatitis B Immunoglobulin).

HBcAG Hepatitis B core antigen is the infectious DNA core of the virus particle. It is produced only in the liver and does not circulate in the blood. It is not, therefore, ordinarily detectable nor is it tested for (but see 'e' markers, below).

Anti-HBc is the immune response to core antigen. It is found in acute, convalescent and carrier states. It does NOT confer immunity and is not found in the vaccine response. In the absence of HBsAg, the test for core antibody is used to detect past experience of the virus in selected cases, e.g. organ donors, drug abusers with a history of hepatitis, chronic hepatitis and so on.

HBeAg Hepatitis Be antigen. This antigen is produced in the liver as an essential part of the process of core antigen production. It follows that the presence of 'e' antigen in the blood indicates that complete virus is being produced and that the patient is infectious. It is not necessary to test for it in acute cases since it will always be present. An HBsAg carrier who also has HB'e'Ag is considered to be able to infect contacts far more easily than a carrier of HBsAg only. HBsAg carriers will be tested for 'e' markers.

Anti-HBe This marker, the antibody to 'e' antigen, indicates that a patient producing little or no complete virus particles and is NOT a dangerous carrier.

HB1 form

University Hospitals of Derby and Burton NHS Foundation Trust

Child at risk of Hepatitis B infection from birth at Royal Derby Hospital – first vaccination given. Notification to healthcare professional to deliver subsequent vaccine doses

Dear Doctor,

We would like to inform you of an infant who is at risk of Hepatitis B infection and requires a full course of Hepatitis B Vaccine. The first dose has been given (see details below). This infant is at risk of Hepatitis B infection for the following reason (*please tick)*:

1. Mother has Hepatitis B infection ☐
2. Father or close household contact has Hepatitis B ☐

1st DOSE MUST BE GIVEN **WITHIN 24 HOURS OF BIRTH.**

Refer to GP to complete full course of Hepatitis B vaccine. Schedule as below:

It is of vital importance for full protection to be achieved that the second dose is given exactly at 4 weeks after the first dose was given & at 12 months (this is in addition to the routine Hexavalent (Hep B vaccinations given to all babies at 8, 12 & 16 weeks).

Baby antigen & antibody levels should be checked 1-4 months following completion of the immunisation schedule as per Colindale Reference Laboratory. Serum samples can be taken in local surgeries or via the Phlebotomy Service available at Derby Children's Hospital.

Maternal Details (affix label):

Surname:……First name:…….
DOB:……. NHS Number:…….....
Hospital Number:……

Maternal Hepatitis Status Antenatally:

	Positive	Negative	Unkown
HBsAntigen	☐	☐	☐
HBeAntigen	☐	☐	☐
Anti-HBe	☐	☐	☐

Viral Load:……iu/ml Date:…….

Acute Hepatitis in Pregnancy: Yes / No

Infant Details (affix label where available):
Surname:…….....First name:…….
DOB:……...NHS Number:…….....
Hospital Number:……

Hep B vaccine given to baby: Yes / No
Date:……Time:……
Baby's **Time of Birth:**……
If **not** given <24 hours of age document & datix.
Batch Number:……..Thigh: Left / Right
Administered by (Print & Sign):……

Hep B Immunoglobulin given to baby: Yes / No
Date:…….. Time:……
Baby's **Time of Birth:**……
If **not** given <24 hours of age document & datix.
Batch Number:……Thigh: Left / Right
Administered by (Print & Sign):……

Yours faithfully,

The Antenatal & Newborn Screening Team,
Royal Derby Hospital,
Any queries please contact 01332 785435 or 01332 789924

Paediatrician or ANNP giving vaccine or HBIG completes this HB1 form:

1 copy in baby notes (original filed after copying).
3 photocopies minimum required
(prior to discharge by the discharging Midwife):

- 1 copy to **Health Visitor** (**FILE** in babies' PCHR 'red book' in an envelope FAO Health Visitor) or email to Health Visitor team generic email address.
- 1 copy to **GP**, send by post or electronically attached to PN discharge - address FAO Practice Nurse (Please **DO NOT** give to mums).

Thank you for your cooperation

- 1 copy to **Antenatal Screening Specialist Team**, email to dhft.antenatalandnewbornscreeningRDH@nhs.net
- 1 copy to **CHIS**, Team Manager **Child Health** email to scwcsu.derbyshire.chis@nhs.net

Any forms sent by email request confirmation of receipt please

Thank you for your cooperation

HB1 form

University Hospitals of Derby and Burton NHS Foundation Trust

Child at risk of Hepatitis B infection from birth at Queen's Hospital Burton – first vaccination given. Notification to healthcare professional to deliver subsequent vaccine doses

Dear Doctor,

We would like to inform you of an infant who is at risk of Hepatitis B infection and requires a full course of Hepatitis B Vaccine. The first dose has been given (see details below). This infant is at risk of Hepatitis B infection for the following reason (*please tick)*:

1. Mother has Hepatitis B infection ☐
2. Father or close household contact has Hepatitis B ☐

1st DOSE MUST BE GIVEN **WITHIN 24 HOURS OF BIRTH.**

Refer to GP to complete full course of Hepatitis B vaccine. Schedule as below:

It is of vital importance for full protection to be achieved that the second dose is given exactly at 4 weeks after the first dose was given & at 12 months (this is in addition to the routine Hexavalent (Hep B vaccinations given to all babies at 8, 12 & 16 weeks).

Baby antigen & antibody levels should be checked 1-4 months following completion of the immunisation schedule as per Colindale Reference Laboratory. Serum samples can be taken in local surgeries or via the Phlebotomy Service available at Derby Children's Hospital.

Maternal Details (affix label):

Surname:……First name:…….
DOB:……. NHS Number:…….....
Hospital Number:……

Maternal Hepatitis Status Antenatally:

	Positive	Negative	Unkown
HBsAntigen	☐	☐	☐
HBeAntigen	☐	☐	☐
Anti-HBe	☐	☐	☐

Viral Load:……iu/ml Date:…….

Acute Hepatitis in Pregnancy: Yes / No

Infant Details (affix label where available):

Surname:…….....First name:…….
DOB:……...NHS Number:…….....
Hospital Number:……

Hep B vaccine given to baby: Yes / No

Date:……Time:……

Baby's **Time of Birth:……**

If **not** given <24 hours of age document & datix.

Batch Number:……..Thigh: Left / Right

Administered by (Print & Sign):……

Hep B Immunoglobulin given to baby: Yes / No

Date:…….. Time:……

Baby's **Time of Birth:……**

If **not** given <24 hours of age document & datix.

Batch Number:……Thigh: Left / Right

Administered by (Print & Sign):……

Yours faithfully,

The Antenatal & Newborn Screening Team,
Queen's Hospital Burton,
Any queries please contact;
01283511511 ext 4339/4297

Paediatrician or ANNP giving vaccine or HBIG completes this HB1 form:

1 copy in baby notes (original filed after copying).

4 photocopies minimum required (prior to discharge by the discharging Midwife):

- 1 copy to Health Visitor (**FILE** in babies' PCHR 'red book' in an envelope FAO Health Visitor).
- 1 copy to **GP**, send by post or electronically attached to PN discharge - address FAO Practice Nurse (Please **DO NOT** give to mums).

Thank you for your cooperation

- 1 copy to **Antenatal Screening Specialist Midwife**, Antenatal Clinic or email bhft.antenatalscreening@nhs.net
- 1 copy to **West Midlands Health Protection Team**, Stonefield House, Corporation Street, Stafford, ST16 3SR or phe.wmnoids@nhs.net
- 1 copy to CHIS, Team Manager **Child Health**, Mellor House, Corporation Street, Stafford, ST16 3SR or email childhealth@sshis.nhs.uk
- copy to **NHS England** Screening & Immunisation Team via email england.hbat@nhs.net

Any forms sent by email request confirmation of receipt please

Thank you for your cooperation