Frimley Health
NHS Foundation Trust

Antenatal & Newborn Screening: Neonatal Hepatitis B vaccination

Key Points

- Hepatitis B vaccine
- Hepatitis B immunoglobulin
- Immunisation schedule

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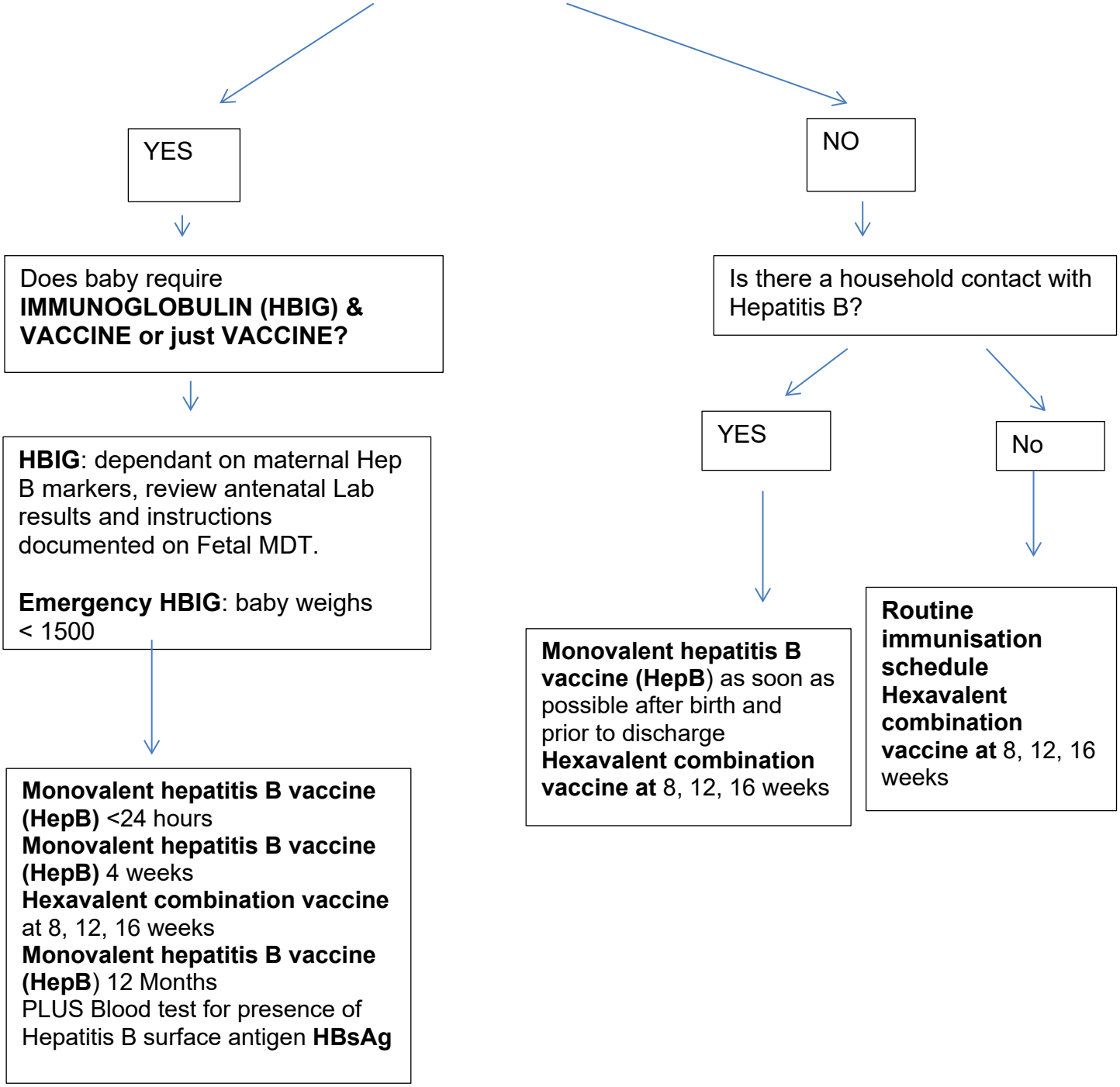
Abbreviations

CHIS	Child Health Information system
DBS	Dried blood spot test
EDD	Estimated date of delivery
HBIG	Hepatitis B immunoglobulin
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B Virus
LW	Labour Ward
PHE	Public Health England

Quick reference guide

Hepatitis B Vaccination schedule within 24 hours of birth

Baby born to Hepatitis B positive Mother (antenatal screening)



Contents

1. BACKGROUND

If a pregnant woman has chronic Hepatitis B infection, then there is

- 70-90% likelihood that hepatitis B infection will be transferred to the baby from women with high infectivity.
- 90% of babies infected at the time of birth will develop persistent Hepatitis B infection and be at risk of premature death, cirrhosis, or hepatocellular carcinoma.
- Timely immunisation can prevent the development of persistent Hepatitis B infection in over 90% of these cases.

2. ANTENATAL PROCESS

All women booked to give birth at Wexham Park or Frimley Park Hospital will be strongly advised to complete antenatal screening for Hepatitis B. It is the responsibility of the midwife booking the women to explain the importance of Hepatitis B testing, obtain verbal consent and ensure the test is completed and the result reviewed and actioned appropriately.
The Screening team will coordinate the multidisciplinary care of women who screen positive.

Further information is available in the Infectious Disease Screening in Pregnancy guideline.

3. AIM OF THIS GUIDELINE

- Ensure all babies born to Hepatitis B positive women are immunised and protected against Hepatitis B Virus (HBV) promptly according to the recommended schedule, and have testing at 12 months of age, preferably with a dried blood spot test (DBS).

- Ensure infants who require Hepatitis B immunoglobulin (HBIG) receive this along with their first Hepatitis B vaccination.

4. HEPATITIS B VACCINE IMMUNISATION SCHEDULE

4.1 Post exposure immunisation schedule: infants born to HBV positive mothers.

In addition to the vaccines given in the national routine immunisation programme at 8, 12 and 16 weeks of age, the post-exposure vaccination schedule includes:

- A critical early monovalent hepatitis B vaccine within the first 24h of life. Can be considered up to a week after exposure.
- Repeat monovalent HBV vaccine at 4 weeks of age.
- Booster monovalent HBV vaccine at 12 months of age along with a blood test for hepatitis B surface antigen (HBsAg) to check for infection.
- A subgroup of this population will require hepatitis B IVIG with the first vaccination (see below).
- Total = 6 doses of HBV containing vaccine.

4.2 Infants born to HBV negative mothers but who are going home to a household contact with HBV infection -> Pre-exposure neonatal HBV immunisation programme.

- Infants born to a HBV negative mother but who disclose that they are going home to a household contact with HBV infection, need to follow the pre-exposure hepatitis B vaccination programme.

- In addition to the vaccines given in the national routine immunisation programme at 8, 12 and 16 weeks of age, this pre-exposure vaccination schedule includes:
- Monovalent dose of hepatitis B offered as soon as possible after birth and prior to discharge.
- Total = 4 doses of a hepatitis B containing vaccine.

- They do not require a dose at 4 weeks of age or a booster at 12 months of age.

- If the infant is being discharged to a home without a contact with HBV **and** the mother is HBV negative, the infant can be vaccinated routinely at 8, 12 and 16 weeks of age.

N.B. Post discharge: if it becomes apparent that baby is living with a household member, positive for HBV and not previously disclosed so not vaccinated after birth, please refer to GP to discuss with paediatrics.

4.3 Table 1: Hepatitis B Immunisation Schedule

AGE	**Routine Childhood immunisation schedule (Mother HBV –ve AND no household contact with HBV)**	**Post exposure hepatitis B vaccination schedule (Mother HBV positive)**	***Pre exposure hepatitis B vaccination schedule (Mother HBV –ve AND baby going home to HBV infected household contact)**
BIRTH <24 HOURS *(AS SOON AS POSSIBLE AFTER BIRTH AND BEFORE DISCHARGE)	X	Monovalent HepB (Engerix B or HBvaxPRO Paediatric) (with HBIG if indicated)	*Monovalent HepB (Engerix B or HBvaxPRO Paediatric)
4 WEEKS	X	Monovalent HepB (Engerix B or HBvaxPRO Paediatric)	X
8 WEEKS	DTaP/IPV/Hib/HepB (Infanrix hexa)	DTaP/IPV/Hib/HepB (Infanrix hexa)	DTaP/IPV/Hib/HepB (Infanrix hexa)
12 WEEKS	DTaP/IPV/Hib/HepB (Infanrix hexa)	DTaP/IPV/Hib/HepB (Infanrix hexa)	DTaP/IPV/Hib/HepB (Infanrix hexa)
16 WEEKS	DTaP/IPV/Hib/HepB (Infanrix hexa)	DTaP/IPV/Hib/HepB (Infanrix hexa)	DTaP/IPV/Hib/HepB (Infanrix hexa)
1 YEAR	X	Monovalent HepB (Engerix B or HBvaxPRO Paediatric) Test for HBsAg	X

5. VACCINES AVAILABLE

Available as a single or combined product (see table 1 for correct choice of vaccine):

Monovalent hepatitis B vaccine (HepB)
Hexavalent combination vaccine: diphtheria/tetanus/acellular pertussis/inactivated polio vaccine/Haemophilus influenza type B/hepatitis B (DTaP/IPV/Hib/HepB).

Hepatitis B vaccine (monovalent) is effective at preventing infection if given shortly after exposure, ideally within 24 hours, but can be considered up to a week after exposure.

A complete vaccination course is required for full protection.

Adverse reactions:
Monovalent Hepatitis B vaccine: generally, well tolerated. Most common adverse reaction is redness and swelling at the injection side.
Hexavalent DTaP/IPV/Hib/HepB vaccine: fever, pain, swelling or redness at the injection side. Small painless nodule may form at the injection site, usually spontaneously resolves, and is of no consequence.

6. HEPATITIS B IMMUNOGLOBULIN (HBIG)

Immunoglobulin (HBIG) is used in a subgroup of high-risk infants after exposure to give rapid protection until the active immunity triggered by hepatitis B vaccination becomes effective. If hepatitis B infection has already occurred at the time of immunisation, virus multiplication may not be inhibited completely with the use of HBIG, but severe illness and the development of the carrier state may be prevented.

Hepatitis B status of mother	Baby should receive	
	Hepatitis B vaccine	HBIG
HBsAg positive and HBeAg positive	yes	yes
HBsAg positive and HBeAg negative/anti-HBeAb negative	yes	yes
HBsAg positive, e markers undetermined	yes	yes
Acute Hepatitis B during pregnancy	yes	yes
HbsAg positive, anti-HbeAb positive	yes	No
HbsAg positive and known HBV DNA level equal to or above 1x106 IUs/ml in an antenatal sample (even if anti-HBe positive) * * where viral load testing has been performed to inform the management of the mother.	yes	yes
HBsAg positive and infant born ≤ 1500g, regardless of e antigen status	yes	yes

ALL ANTENATAL DOCUMENTATION MUST BE REVIEWED TO ESTABLISH IF BABY REQUIRES HBIG

Decision for HBIG is made following review of maternal blood markers and maternal viral load.

6.1 Planned HBIG

1. It is the responsibility of the multidisciplinary team which includes the virology consultant and hepatology/infectious diseases consultant to establish if baby requires HBIG.
2. If the initial antenatal screening blood suggests HBIG is needed, then it will be stated in the comments on the mothers antenatal screening infectious diseases report.
3. The need for HBIG may change following a review of the maternal viral load. A later decision that HBIG is required will be made by the multidisciplinary team including hepatology and virology.
4. It is the responsibility of the antenatal screening team to order the HBIG from Centre for infectious diseases ,Colindale https://www.gov.uk/government/publications/hepatitis-b-requesting-issue-of-immunoglobulin-for-infants and email completed form to hepatitisBBabies@nhs.net
5. The screening team will receive an **individual patient named box** from Colindale to inform them that the HBIG has arrived in pharmacy. The box will contain clear management instructions that must be followed by the professional administering.
6. The screening team are responsible for liaising with pharmacy and bringing together the named box and HBIG and placing it in the Labour Ward fridge.

Where both vaccine and HBIG are recommended, the two injections should be given in different sites.

6.2 Emergency HBIG

1. Baby weighing <1500 g where maternal markers would not normally indicate need.
2. High infectivity mother presenting unbooked with our service.

Emergency stock

- Contact PHE Colindale directly:
  Out of hours service: Mon-Fri 17:00-09:00 & all weekend (Fri 17:00-Mon 09:00)
  Tel: 0208 200 4400 or 0330 128 1020 and ask for the duty doctor service.
  Out of hours Immunoglobulin can be delivered via Movianto by courier.

6.3 HBIG dose

The HBIG dose in a newborn is 250 IU.
HBIG is only available in 500 IU vials, so half the vial is given.
If appropriate, premature, and small infants can be given the injection in divided doses but should still receive a full 250 IU.

NB: Screening team track all Hepatitis B positive mothers and ensure vaccine and immunoglobulin has been administered appropriately. In the case of a mother booking at Frimley Health but delivery taking place elsewhere the screening team will ensure the immunoglobulin, if ordered, is disposed of around the mothers estimated due date or if informed that baby has delivered.

7. ADMINISTRATION OF THE VACCINE

- **The vaccine/HBIG can be administered by a midwife, nurse or paediatrician.**
- **Administration site:** intramuscularly in the upper arm or anterolateral thigh. The buttock must not be used because vaccine efficacy of neonatal Hepatitis B vaccination may be reduced.
- Hepatitis B vaccines can be given at the same time as other vaccines but should be given at a separate site.
- **Dose:** The vaccine must be prescribed by a paediatrician (all prescribers and administers are responsible for checking the correct dose in the green book)
  Engerix B: 0-15 years, 10 micrograms (0.5ml).
  HBvaxPRO Paediatric: 0-15 years, 5 micrograms (0.5ml).
  This is given as soon as possible and certainly within 24 hours.
- Midwives or nurses administering any vaccine should complete the appropriate level of training and annually update their knowledge. This is currently supported by completing the immunisation chapter on eLearning for Health.
- There is no contra-indication to breast-feeding when a baby born to a carrier mother begins immunisation at birth and proceeds with a complete course of immunisation.
- Premature babies should follow this schedule regardless of gestational age or birth weight. If the volume of HBIG is large relative to the baby's muscle bulk, it may be given in divided doses, i.e. at several sites simultaneously.
- Babies who weigh less than 1500g should receive immunoglobulin if they are born to hepatitis B positive mothers, regardless of risk.
- Women who arrive unbooked or with their hepatitis status unknown should have blood taken and sent for testing as a matter of urgency. If the results of e-markers cannot be obtained within 24 hours of delivery, then the baby should be assumed to be at high risk and should be given HBIG and hepatitis vaccine**.**
  See Emergency HBIG section 6.2

8. ADMINISTRATION PROCESS

Paediatrician/Midwife

1. Screening team will create a Fetal problem banner which will be present on the EPIC story board to alert staff to review maternal problem list. (WPH site use a Hepatitis B alert proforma and place in the labour ward Hepatitis B folder**. Blank proforma available from the WPH screening team)**
2. Paediatric /Midwifery staff to chart review all maternal antenatal multidisciplinary team documentation.
3. Paediatric /Midwifery staff chart review Fetal MDT documentation, during antenatal period this can be found within the pending baby record but following delivery fetal MDT plan can be viewed within the baby's chart review notes.
4. Provide written or verbal information to parents. Leaflets are available in many different languages but always consider use of trust interpreting services.

   https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/736029/Protecting_your_baby_against_hepatitis_B_leaflet.pdf

5. Paediatrician to prescribe Hepatitis B vaccine +/- immunoglobulin on neonatal MAR

6. Obtain consent following discussion with mother especially the importance of completing the immunisation schedule. The efficacy of the vaccine will be reduced if doses are late or missed.

7. Record site at which vaccine was given, batch number, expiry date on the MAR and the handheld personal child health record ('red book').

8. Email or EPIC message the screening team to inform them of delivery.

9. If HBIG required, this will have been ordered for the 'named patient' and stored in the labour ward fridge.

10. If HBIG required, follow all the instructions in the HBIG box. A postnatal maternal venous sample and baby single dried blood spot is required and needs to be sent back to PHE Colindale. All details and the blood spot card will be in the HBIG box.

NOTE: ALL Babies born < 1500 grams will require HBIG and vaccine regardless of maternal hepatitis B markers

Antenatal screening failsafe:

- Note EDD in the screening spreadsheet and review documentation after delivery.
- Complete the immunisation notification form and email the correct child health information service (CHIS) for the area the family are resident.
- Complete EPIC SMART Text letter **GP Notification of neonatal Hepatitis B vaccination from maternity services** (see Appendix 1).
- Epic failsafe report for screening teams to review babies born to Hepatitis B positive women to ensure appropriate vaccination has been completed.

REFERENCES

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FULL VERSION CONTROL RECORD

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Version Control Sheet

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1.0	March 2021	K Franks	Final	
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2.0	May 2024	K Franks	Final	Approved at Cross site Obstetrics Clinical Governance Meeting 21/5/24

Related Documents

Document Type	Document Name
Guideline	Infectious diseases screening in pregnancy