East of England Neonatal ODN
(Hosted by Cambridge University Hospitals)

Clinical Guideline: Management of babies born to mothers who are Hepatitis B positive

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For use in: EoE Neonatal Units
Guidance specific to the care of neonatal patients.

Used by: All neonatal/paediatric medical & nursing staff

Key Words: Hepatitis B, vaccination, immunoglobulin, intravenous drug abuse

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Approved by:

Neonatal Clinical Oversight Group	
Clinical Lead Mark Dyke	

Ratified by ODN Board:

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Audit Standards:

Audit points

1. **All infants born to mothers with Hepatitis B infection should have a postnatal plan made antenatally**
2. **All those considered high risk should receive Hepatitis B Immunoglobulin as well as vaccination at birth**
3. **Those at high risk where a family member (not mother) is HepatitisB positive or infants of intravenous drug users should receive a monovalent dose of Hepatitis B vaccine prior to discharge from hospital**

Introduction

Infants born to Hepatitis B virus (HBV) infected mothers are at high risk of acquiring HBV infection themselves at or around the time of birth (perinatal transmission), particularly if the mother has a high level of HBV DNA and hepatitis B e antigen (HBeAg) in her plasma. Without intervention the risk of transmission from an HBeAg seropositive mother is 70-90% compared with the risk of about 10% from an HBeAg negative mother. Infants who acquire infection perinatally have a high risk of becoming chronically infected with the virus. The development of chronic infection after perinatal transmission can be prevented in over 90% of cases by appropriate vaccination starting at birth of all infants born to infected mothers.
UK guidelines recommend that all pregnant women should be offered screening for Hepatitis B infection during each pregnancy. Where an un-booked mother presents in labour, an urgent Hepatitis B surface antigen (HBsAg) test should be performed to ensure that vaccine can be given to babies born to positive mothers within 24 hours of birth.

Antenatal Management

Refer to obstetric guideline.

Post Exposure Prophylaxis

There has been a universal Hepatitis B vaccination program in the UK since late 2017.
However, all infants born to HBsAg seropositive mothers should receive vaccination with the monovalent Hepatitis B vaccine at birth and 4 weeks. . The routine vaccination schedule then ensures they get given further doses of Hepatits B (hexavalent) at 8, 12 and 16 weeks. They then need a further Hepatitis B vaccination (monovalent) at 12 months. In total they will receive 6 doses of Hepatitis B vaccine. This aims to ensure immunity and prevent mother to child transmission.
For those infants who are at high risk (see below), they should receive Hepatitis B Immunoglobulin (HBIG) in addition to vaccination as soon as possible after birth and ideally within 24 hours of birth. If an infant is later identified as having missed HBIG at birth despite being eligible, HBIG can be given up to 7 days after birth.

Close Family Contacts of an individual with chronic Hepatitis B infection

Newborn infants born to a hepatitis B negative woman but known to be going home to a household with another hepatitis B infected person may be at immediate risk of hepatitis B infection. In these situations, a monovalent dose of hepatitis B vaccine should be offered before discharge from hospital. They should then continue on the routine childhood schedule commencing at 8 weeks.

Infants born to Intravenous Drug users

A monovalent dose of Hepatitis B vaccine should be offered before discharge from hospital. They should then continue on the routine childhood schedule commencing at 8 weeks.

Premature and low birth weight infants (less than 1500 grams)

The early response to hepatitis B vaccination is known to be lower in pre-term and low birth weight infants than in term, appropriately grown infants, although the final response rates are comparable. Therefore, as a precautionary measure, Hepatitis B Immunoglobulin (HBIG) is recommended in addition to vaccination in this group. They should be prescribed 250 units (1.75ml) but may receive it in divided doses within the first 7 days of life.

High Risk Infants

Infants are considered high risk if maternal antenatal serology indicates:

- HBsAg positive and HBeAg positive
- HBsAg positive, HBeAg negative and anti-HBe negative
- Mother had acute hepatitis B during pregnancy
- 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)
- Mother is HBsAg positive and baby weighs 1500g or less

All of the above infants should receive HBIG and hepatitis B vaccination.
See appendix 1

Low Risk Infants

Infants are considered low risk if maternal antenatal serology indicates:

- HBsAg positive and anti-HBe positive

These infants should receive hepatitis B vaccination

Vaccination Dosage and Schedule

Engerix B® (monovalent) 10 micrograms (0.5ml) by intramuscular injection in anterolateral thigh, given at birth and 12 months of age.
Give low birth weight and preterm babies the full neonatal dose.
Infanrix hexa® (hexavalent) 0.5ml by intramuscular injection in anterolateral thigh given at 8, 12 and 16 weeks.
See appendix 2.

Hepatitis B Immunoglobulin Dosage

250 units (1.75ml) by intramuscular injection in anterolateral thigh (in contralateral thigh to Hepatitis B vaccine injection site). The maximum intramuscular volume that should be administered to a newborn is 1ml so this must be given in 2 doses.
Vials of “named baby” HBIG that are issued will be delivered to the hospital pharmacy department 7 weesk before the estimated date of delivery. The named baby HepB delivery suite box containing the birth

notification paperwork will be issued to the hospital for the attention of the Antenatal 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 ensuring that these are stored securely according to local arrangements so that they are available 24/7 to the delivery team for that named baby.

If an emergency supply is required, this is also stocked in the emergency drug fridge. The indication must be confirmed with the microbiologist in emergency cases. Fill in the form enclosed with the vial obtained from pharmacy and return the form to microbiology.
The form that accompanies the vial should be completed by the administering doctor and forwarded to Public Health England (PHE).

Give low birth weight and preterm babies the full neonatal dose of 250 units which they may receive in divided doses within the first 7 days of life.

Breastfeeding

Breast feeding should be encouraged and supported. There is no contraindication to breastfeeding when a baby born to a mother who is Hepatitis B positive begins immunisation. Mothers, however, should not donate their milk.

Subsequent Management

All infants receiving Hepatitis B vaccination and HBIG (if indicated) should have the Hepatitis B vaccination documented in the appropriate place according to local practice.
A letter should also be sent to the GP or Child Health Department informing them of the increased risk of vertical transmission of Hepatitis B. The GP or Child Health Department should also arrange further appointments to complete the vaccination course and organise for a dried blood spot (DBS) sample to be done at the same time as the fourth dose is given to check if transmission has occurred. This process is offered and monitored by PHE.
For those infants where prophylaxis has not been successful and who have become chronically infected, they should be referred for assessment and further management to a paediatrician with a special interest in paediatric infectious diseases who should arrange on-going follow up in outpatient clinic, as well as referral to a tertiary paediatric hepatology team.

References

Hepatitis B Guidance gov.uk website https://www.gov.uk/government/collections/hepatitis-b-guidance-data-and-analysis#infants-born-to-hepatitis-b-infected-mothers

Immunisation policy
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/324083/Immunisation_Policy_HBIG23.pdf

Green Book chapter 18 "Immunisation against Infectious disease: the Green Book"
https://www.gov.uk/government/publications/hepatitis-b-the-green-book-chapter-18

The national dried blood spot (DBS) testing service for infants born to hepatitis B infected mothers (2017) **https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/779444/PHE_national_dried_blood_spot_testing_for_babies_born_to_hepatitisb_infected_mothers.pdf**

Appendix 1 Summary of Immediate Postnatal Treatment of Infants born to Hepatitis B positive Mothers

Maternal Status	Vaccine required Engerix B® 10 micrograms i.m.	HBIG required 250 units i.m.
HBsAg positive and HBeAg positive	Yes	Yes
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

Appendix 2 Hepatitis B immunisation schedule for routine childhood and selective neonatal immunisation programmes following the introduction of hexavalent hepatitis B-containing vaccine

Age	**Routine Childhood Programme**	**Babies born to hepatitis B infected mothers**	**Babies born into household with close family contact of Hepatitis B infection or intravenous drug user**
Birth	**x**	Monovalent HepB	Monovalent HepB
4 weeks	**x**	Monovalent HepB	-
8 weeks	√	DTaP/IPV/Hib/HepB	DTaP/IPV/Hib/HepB
12 weeks	√	DTaP/IPV/Hib/HepB	DTaP/IPV/Hib/HepB
16 weeks	√	DTaP/IPV/Hib/HepB	DTaP/IPV/Hib/HepB
1 year	**x**	Monovalent HepB	-

Appendix 3 Suggested Neonatal Care Pathway for adaptation at local hospital

1. Neonatal plan made at fetal medicine meeting and inserted into mother's hospital notes.
2. When infant is born neonatal team alerted – results of mothers' serology and neonatal plan reviewed.
3. Administration of Hepatitis B vaccine and HBIG if indicated.
4. Hepatitis B vaccination flimsy filled in (for red book) or documented in appropriate place and accompanying paperwork if HBIG given.
5. Letter to GP/ Child health generated.
6. GP/ Child health to organise subsequent vaccinations and testing with 4th dose (dried blood spot sent to Public Health England laboratory).
7. GP to refer infants with chronic carrier status for assessment and further management.

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Exceptional Circumstances Form

Form to be completed in the **exceptional** circumstances that the Trust is not able to follow ODN approved guidelines.

Details of person completing the form:	
Title:	Organisation:
First name:	Email contact address:
Surname:	Telephone contact number:
Title of document to be excepted from:	
Rationale why Trust is unable to adhere to the document:	
Signature of speciality Clinical Lead: Date:	Signature of Trust Nursing / Medical Director: Date:
Hard Copy Received by ODN (date and sign):	Date acknowledgement receipt sent out:

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