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

Authors: Dr Sakina Ali
Consultant Neonatologist, Luton and Dunstable University Hospital

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

Used by: All neonatal/paediatric medical & nursing staff

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Approved by:

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<tr>
<th>Neonatal Clinical Oversight Group</th>
<th>Clinical Lead Mark Dyke</th>
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Ratified by ODN Board:

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<tr>
<th>Date of meeting</th>
<th>26th March 2019</th>
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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 Hepatitis B 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 Hepatitis 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.

Babies born to mothers who are HIV positive or Hepatitis C positive

All babies born to mothers who are HIV positive or Hepatitis C positive follow the universal Hepatitis B vaccination program and do not need additional vaccine doses.

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.

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 all babies who have a birth weight less than 1500 grams

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 $1 \times 10^{6}$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, 4 weeks and 12 months of age. Different brands are interchangeable in case of shortage. HbVaxPRO 5 micrograms (0.5ml) can be given as an alternative.

Give low birth weight and preterm babies (weighing less than 1500 grams) 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

200 units (2ml) by intramuscular injection in anterolateral thigh (in contralateral thigh to Hepatitis B vaccine injection site). Give those with a birth weight of less than 1500 grams the full neonatal dose.
The vial should be signed for by the antenatal clinic midwife and then stored in the delivery suite fridge until delivery of the infant. This is also stocked in the emergency drug fridge if emergency supply is required. 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).

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 (see appendix 4). 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 sixth (final) 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


Immunisation policy

Green Book chapter 18 “Immunisation against Infectious disease: the Green Book”

The national dried blood spot (DBS) testing service for infants born to hepatitis B infected mothers (2017)
Appendix 1 Summary of Immediate Postnatal Treatment of Infants born to Hepatitis B positive Mothers

<table>
<thead>
<tr>
<th>Maternal Status</th>
<th>Vaccine required (Engerix B®)</th>
<th>HBIG required</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBsAg positive and HBeAg positive</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>HBsAg positive, HBeAg negative and anti-HBe negative</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Mother had acute hepatitis B during pregnancy</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Mother is HBsAg positive and anti-HBe positive</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Mother is HBsAg positive and known to have an HBV DNA level equal or above 1x10⁶ IUs/ml in any antenatal sample during this pregnancy (regardless of HBeAg and anti-HBe status)</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Mother is HBsAg positive and baby weighs 1500g or less</td>
<td>Yes</td>
<td>Yes</td>
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Appendix 2 Hepatitis B immunisation schedule for routine childhood and selective neonatal immunisation programmes following the introduction of hexavalent hepatitis B-containing vaccine

<table>
<thead>
<tr>
<th>Age</th>
<th>Routine Childhood Programme</th>
<th>Babies born to hepatitis B infected mothers</th>
<th>Babies born into household with close family contact of Hepatitis B infection or intravenous drug user</th>
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</thead>
<tbody>
<tr>
<td>Birth</td>
<td>x</td>
<td>Monovalent HepB</td>
<td>Monovalent HepB</td>
</tr>
<tr>
<td>4 weeks</td>
<td>x</td>
<td>Monovalent HepB</td>
<td>-</td>
</tr>
<tr>
<td>8 weeks</td>
<td>√</td>
<td>DTaP/IPV/Hib/HepB</td>
<td>DTaP/IPV/Hib/HepB</td>
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<tr>
<td>12 weeks</td>
<td>√</td>
<td>DTaP/IPV/Hib/HepB</td>
<td>DTaP/IPV/Hib/HepB</td>
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<tr>
<td>16 weeks</td>
<td>√</td>
<td>DTaP/IPV/Hib/HepB</td>
<td>DTaP/IPV/Hib/HepB</td>
</tr>
<tr>
<td>1 year</td>
<td>x</td>
<td>Monovalent HepB</td>
<td>-</td>
</tr>
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Appendix 3 Suggested Neonatal Care Pathway for adaptation at local hospital

1. Neonatal plan made at fetal medicine meeting after reviewing maternal serology and inserted into mother’s hospital notes.
2. When infant is born neonatal team alerted and neonatal plan reviewed.
3. Administration of Hepatitis B vaccine and HBIG if indicated.
4. Hepatitis B vaccination documented and accompanying paperwork completed if HBIG given.
5. Letter to GP generated from NIPE.
6. GP to organise subsequent vaccinations and serology testing with 6th dose (dried blood spot sent to Public Health England laboratory).
7. GP to refer infants with chronic carrier status for assessment and further management.
Appendix 4 Suggested GP letter template for NIPE

Neonatal Hepatitis B Vaccination – Notification to GP Letter

Date: ………………………

Dear Dr

Re:

Problem: Infant born to Hepatitis B infected mother

This baby is at increased risk of Hepatitis B infection. The parents have consented for him / her to have post exposure prophylaxis (selective neonatal immunisation schedule).

He / She had the first dose of Hepatitis B vaccine on ………………………
Prophylactic Hepatitis B immunoglobulin was / was not given.

We would be grateful if you could ensure the completion of the immunisation course with the monovalent Hepatitis B vaccine at 4 weeks.

The routine vaccination schedule will ensure they get given further doses of Hepatitis 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.

Please organise serology (dried blood spot) once the course has been completed as per Public Health England guidance.

Yours sincerely,

(Sign)…………………………………
(Print name) Dr ……………………………
(Grade)…………………………………

Neonatal Consultant: Dr ……………………………..
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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.

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<th>Signature of Trust Nursing / Medical Director:</th>
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<th>Date acknowledgement receipt sent out:</th>
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EOE ODN Executive Administrator
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Cambridge University Hospital
Hills Road
Cambridge CB2 0QQ