Hepatitis B in Pregnancy

Guideline No: 54  Hepatitis B — management in pregnancy

<table>
<thead>
<tr>
<th>VERSION</th>
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Hepatitis B in Pregnancy: Management — clinical guideline, v1
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Approved by Medicines Clinical Guidance Subcommittee: February 2013
### MONITORING COMPLIANCE WITH THE GUIDELINE

<table>
<thead>
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<th>Minimum requirement to be monitored</th>
<th>Auditable Standards – See below</th>
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<td>Process for monitoring</td>
<td>Audit of Guideline</td>
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<tr>
<td>Responsible individual/group/committee</td>
<td>Risk Management Department</td>
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<tr>
<td>Responsible individual/group/committee for review of results</td>
<td>Obstetric &amp; Gynaecology Audit Meeting</td>
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<td>Responsible individual/group/committee for development of action plan</td>
<td>Audit Lead</td>
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<tr>
<td>Responsible individual/group/committee for monitoring of action plan</td>
<td>Clinical Governance Steering Group</td>
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### COMPLIANT WITH:

1. UK National Screening committee: antenatal and newborn screening program
2. NICE GUIDELINES 2008: Antenatal care: routine care for the healthy pregnant woman
3. NHSL STANDARDS 2012

### AUDITABLE STANDARDS

1. All pregnant women with hepatitis B infection are referred for a comprehensive assessment by a specialist with expertise in the management of hepatitis B
2. A specialist assessment is undertaken within 6 weeks of the screening test result being reported to maternity services
3. Where indicated hepatitis B immunoglobulin (HBIG) is administered with the first hepatitis B vaccine within 24 hours of birth
4. Vaccine +/- HBIG available from 28 weeks gestation and stored in delivery suite fridge
5. Women who have high viral loads (i.e. HBV DNA > 10^7 IU/ml) are considered for therapy with a potent antiviral agent from the 32^nd week of pregnancy
6. First dose of vaccination (+/- HBIG) to be documented within 24 hours of birth.
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1.0 INTRODUCTION
Hepatitis B is an infectious disease caused by the Hepatitis B virus (HBV). The risk of perinatal transmission depends on the status of the maternal infection. Approximately 70-90% of mothers who are HBV e-antigen (HBeAg) positive will transmit infection to the baby. The rate of transmission is approximately 10% in women with antibody to e antigen (antiHBe).

Infection can result in an acute or chronic infection. A chronic infection with HBV may result in cirrhosis of the liver and liver cancer. The earlier in life the infection occurs the greater the risk that it will lead to chronic infection, liver disease and early death. Vaccination of the baby within 24 hours of delivery, and at 1, 2 and 12 months is effective in preventing transmission of infection from mother to baby. In babies born to women with a higher risk of transmission, the addition of Hepatitis B Specific Immune Globulin (HBIG) can reduce the risk further. With this strategy, transmission can be prevented in over 90% of infants exposed to maternal infection.

2.0 GUIDELINE REGIME

2.1 Assessment and Testing of the Pregnant Woman
All pregnant women with hepatitis B infection should be referred for a comprehensive assessment by a specialist with expertise in the management of hepatitis B (e.g. hepatology, gastroenterology, infectious diseases). A specialist assessment should be undertaken within 6 weeks of the screening test result being reported to maternity services. Women booking late (> or = 24 weeks) should be referred immediately to gastroenterology for evaluation. This is to ensure that:

- Further tests are undertaken
- The woman’s identity is confirmed
- Advice on the infection is offered
- Treatment options are considered

It is also an opportunity for clinicians to notify the Health Protection Agency and to discuss the need for management of contacts. All women referred to an appropriate specialist should undergo testing as outlined in the BVHG guidelines for initial testing and referral of individuals who are HBsAg positive, these are:

- HBV serology – including HBsAg positive
- HBV DNA level
- Delta virus testing
- HCV testing
- Liver function tests, including tests of synthetic function (INR)
- Liver ultrasound
Results from these tests should be fed back to maternity services. HIV results should be made available to the clinician by maternity services. HIV testing should be re-offered if this was declined during the initial screening encounter.

All Hepatitis B positive women to be managed in MDT setting, non attendance at a specialist appointment to be reviewed by MDT and an action plan developed.

2.2 Issues relating to the Postnatal Vaccination
- Discuss with women the benefits of vaccination.
- Seek and document maternal consent with neonatal vaccination.
- Prescribe, order and give vaccination (+/- HBIG as required) in advance of estimated delivery date.
- Communicate the confirmed results to specialists involved in women’s care: Health care professional responsible, GP, health visitor, HPU, PCT immunisation lead.

2.3 Indications for HBIG
Where indicated hepatitis B immunoglobulin (HBIG) should be administered with the first hepatitis B vaccine within 24 hours of birth. The requirement for HBIG is assessed during pregnancy. It should be administered if the mother is:
- HBsAG and HBeAg positive
- HBsAg positive HBeAg/anti-HBe negative
- HBsAg positive and e markers not available
- HBsAg positive and infant birth weight ≤ 1500g
- HBsAg positive and HBV DNA level ≥ 1x10^6 IU/ml*
- Or has acute hepatitis B during pregnancy

2.4 Information about risk reduction
The woman should be reassured that:
- Hepatitis B is usually acquired around the time of birth and intrauterine infection is rare.
- The full infant vaccination schedule is usually effective in preventing transmission to the newborn.
- Breastfeeding is not contraindicated.
- Hepatitis B cannot be spread casually.

Information should also be offered on:
- The modes of hepatitis B transmission and means of preventing it e.g. avoidance of sharing objects which may transmit infected blood such as razors, earrings and toothbrushes.
- The way which the results of the tests may affect the pregnancy plan e.g. place of birth, treatment in late pregnancy and may alter the indication for administration of postnatal HBIG.
The woman should be informed that the information relating to hepatitis B will be shared with maternity services and primary care to facilitate her care and the vaccination of the baby.

Contact Management:
Discussion on the benefits of tracing, testing and managing household and/or sexual contacts should be initiated within a specialist environment where hepatitis B infection is being comprehensively addressed. This should be handled sensitively with regard for the woman’s individual circumstances and the likely impact on the pregnancy.

2.5 Preparations for First Vaccination
- Decision regarding need for HBIG made by consultant microbiologist.
- Vaccine +/- HBIG available from 28 weeks gestation and stored in delivery suite fridge. HBIG ordered from Health Protection Agency via microbiologist. Vaccine available from pharmacy.

2.6 Treatment
References BVHG, EASL, BASHH, RCOG, DH Green Book, HPA.

Women who have high viral loads (i.e. HBV DNA > 10^7 IU/ml) should be considered for therapy with a potent antiviral agent from the 32nd week of pregnancy. The risks and benefits and the limited evidence for this approach should be discussed with the patient. (BVHG)

Some chronically infected women who are HBeAg negative may have high HBV DNA levels, and may be more likely to transmit the infection to their baby. Where HBV DNA testing has been performed to inform the management of the mother, a viral load > 10^6 UL/ml is an indication for neonatal HBIG in addition to vaccination. (Green Book)

It is important that the result of HBV DNA viral load testing is reported to maternity services as this may affect the requirement for HBIG. Maternity services should also be informed of plans to treat in late pregnancy.

2.7 Management of Pregnancy and Delivery
2.7.1 Care during pregnancy:
- Ensure MDT care – maternity services, gastroenterology and infectious diseases.
- Maternity services should ensure that the woman has attended the specialist appointment and that information relevant to the place of delivery and infant vaccination, such as test results is appropriately recorded.
- Reassess management plan at every attended appointment.
- Non attendance at appointments should be reviewed within a multidisciplinary framework and a management/action plan developed.
- Systems, protocols and pathways should be in place to support this.
2.7.2 **Intrapartum Care:**
- Ensure information is available to delivery team, this is to include: maternal disease status, neonatal vaccination requirements, avoidance of invasive neonatal tests, inform neonatal team responsible for neonatal vaccination that the woman is in labour.

2.7.3 **Postpartum Period:**
- Vaccination schedule as per DH Green Book documented.
- First dose of vaccination (+/- HBIG) to be documented within 24 hours of birth.
- Responsibility for notifying relevant professionals and ensuring completion of vaccination schedule will be specialist midwife for infectious diseases in pregnancy.

2.8 **Un-booked women**
Tests for hepatitis B, HIV, syphilis and rubella are recommended for women arriving in labour who are not already booked for antenatal care. Priority should be given to hepatitis B, HIV and syphilis. The approach to offering the tests should be based on a case by case assessment. Considerations should include the stage of labour and risk factors specific to these infectious diseases.

2.9 **Low Birth Weight Considerations**
For low birth weight babies born to hepatitis B positive women, HBIG should be ordered as a matter of urgency.

3.0 **REFERENCES**
1. Infectious diseases in pregnancy screening program standards; UK national screening committee 2010.
2. The Green Book 2009
3. The NICE Intrapartum care Guidelines
4. British Viral Hepatitis Group (BVHG) consensus statement on the management of hepatitis B positive women 2008

4.0 **RELATED DOCUMENTS**
Guideline No. 73 Infectious Diseases in Pregnancy Screening
Guideline No. 66 Maternal antenatal screening tests

5.0 **APPENDICES**
Management of Women with Hepatitis B in Pregnancy

Management of Hepatitis B in pregnancy and birth

Assessment and testing of the pregnant woman

Information about risk reduction

Treatment

Management of pregnancy and delivery

Unbooked women

Low Birth Weight considerations

Live Birth

Stillbirth

Issues relating to the postnatal vaccination

Indication for HBIG

Preparations for first vaccination

Go to HBV Immunisation (pathway in development)

See Section 2.1

See Section 2.4

See Section 2.6

See Section 2.7

See Section 2.8

See Section 2.9
HEPATITIS B POSITIVE CARE PATHWAY

Patient Details:  
Consultant Obstetrician:  
Midwife:  
Consultant Microbiologist  
Contact Phone Number:  
EDD:  

Date of first test: / /  
Date of second test: / /  

Hepatitis B Surface Antigen:  
POSITIVE/NEGATIVE  
POSITIVE/NEGATIVE  

Hepatitis B e Antigen:  
POSITIVE/NEGATIVE  
POSITIVE/NEGATIVE  

Hepatitis B e Antibody:  
POSITIVE/NEGATIVE  
POSITIVE/NEGATIVE  

*PLEASE SEE OVERLEAF FOR NEONATAL TREATMENT PLAN

Interpreter:  
Required/Not Required  
Name:  
Contact Phone Number:  

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<th>Signature</th>
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Patient informed of result  
Written and verbal information re Hepatitis B given to patient  
Partner advised re Hepatitis B screening  

Confirmatory Hepatitis B screen obtained if new diagnosis and Hepatitis C screen offered:  
Declined/Accepted  

Public Health Contact Tracing Form completed  
GP informed  
Consultant Obstetrician informed  
Paediatric Team informed; Neonatal Alert Form completed  
Referral to Gastroenterologist made  

Support visits if required:  
1)  
2)  
3)  

Hepatitis B vaccine/immunoglobulin available from Pharmacy / HPA at 28 weeks gestation  
(Via Microbiology)  

Baby requires HEPATITIS B VACCINE/ IMMUNOGLOBULIN at birth to be administered by Paediatric SHO at any viable gestation  

Paediatric discharge letter to GP requesting they complete Hepatitis B vaccine regime  

VACCINE TO BE GIVEN AT:  
1 month (2nd dose)  
2 months (3rd dose)  
1 year (final dose)  

Baby Public Health Forms to be completed by Infectious Disease Co-ordinator Midwife  

Photocopy completed form and copy to be filed in mum and neonatal notes  


Appendix 2
HEPATITIS B POSITIVE CARE PATHWAY - CONTINUED

Hepatitis B vaccine (Engerix B) 10 micrograms ( = 0.5mL) intramuscularly into thigh
Hepatitis B immunoglobulin 200 Units given intramuscularly into thigh (at a different site to the vaccine)

<table>
<thead>
<tr>
<th>Maternal Antigen Status</th>
<th>BABY SHOULD RECEIVE</th>
<th>HBIG Single Dose</th>
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<tbody>
<tr>
<td>Mother is surface antigen (HbsAg) positive and 'e' antigen (HbeAg) positive/ 'e' antibody negative</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Mother is surface antigen (HbeAg) negative</td>
<td>×</td>
<td>×</td>
</tr>
<tr>
<td>Mother had acute Hepatitis B during pregnancy and/or markers not available (i.e., concern that mother may be both surface antigen and 'e' antigen positive)</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Mother is surface antigen (HbsAg) positive and 'e' antigen (HbeAg) negative/ 'e' antibody positive</td>
<td>✓</td>
<td>×</td>
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**Note**
- Babies with a birthweight of 1500gms or less, born to mothers infected with Hepatitis B should receive HBIG in addition to vaccine, regardless of the e-antigen status of the mother.
- In an emergency Hepatitis B immunoglobulin can be obtained via the Consultant Microbiologist On-Call from Aintree
- Engerix B is the vaccine of choice. If HBvaxPRO is used, the dose is 5 micrograms

**Reference**
Immunisation Against Infectious Disease. Department of Health (www.dh.gov.uk/greenbook)

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Dr J Cuninffe: Consultant Microbiologist