

## Trust Guideline for the Immunisation of Infants at Risk of Hepatitis B Infection

### A Clinical Guideline

<b>For use in:</b>	Delivery Suite, Blakeney Ward, NICU, Cley Ward
<b>By:</b>	Paediatric medical and nursing staff and midwifery staff
<b>For:</b>	For Infants at risk of Hepatitis B infection
<b>Division responsible for document:</b>	Women / Children
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<b>Assessed and approved by the:</b>	Clinical Guidelines and Assessment Panel (CGAP) chair  If approved by committee or Governance Lead Chair's Action; tick here <input checked="" type="checkbox"/>
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<b>To be reviewed before:</b> This document remains current after this date but will be under review	23 October 2023
<b>To be reviewed by:</b>	Dr Florence Walston, Consultant Neonatologist
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<b>Compliance links: (is there any NICE related to guidance)</b>	None
<b>If Yes - does the strategy/policy deviate from the recommendations of NICE? If so why?</b>	No

This guideline has been approved by the Trust's Clinical Guidelines Assessment Panel as an aid to the diagnosis and management of relevant patients and clinical circumstances. Not every patient or situation fits neatly into a standard guideline scenario and the guideline must be interpreted and applied in practice in the light of prevailing clinical circumstances, the diagnostic and treatment options available and the professional judgement, knowledge and expertise of relevant clinicians. It is advised that the rationale for any departure from relevant guidance should be documented in the patient's case notes.

The Trust's guidelines are made publicly available as part of the collective endeavour to continuously improve the quality of healthcare through sharing medical experience and knowledge. The Trust accepts no responsibility for any misunderstanding or misapplication of this document.

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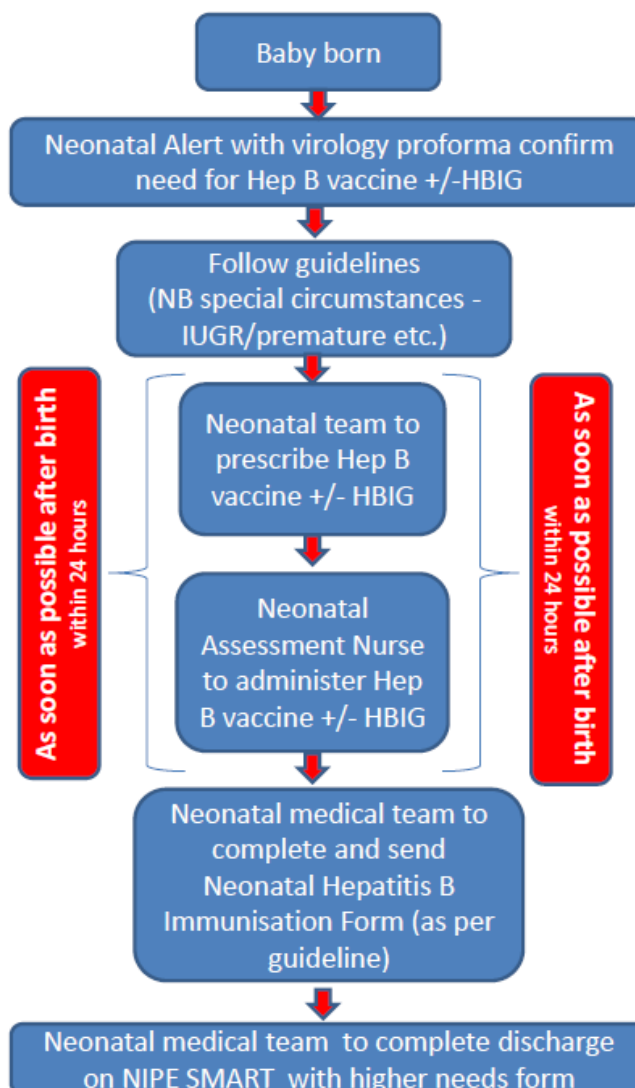
## Version and Document Control:

Version Number	Date of Update	Change Description	Author
8	14/05/2020	Removal of Appendix 1. Addition of hyperlink to ID No: 13631	Florence Walston
9	30/09/2020	Text re-arranged and addition of a flow chart.	Florence Walston
10	22/10/2020	Change to dose of HBIG from 200iu to 250iu as per Public Health England's advice.	Florence Walston

## This is a Controlled Document

Printed copies of this document may not be up to date. Please check the hospital intranet for the latest version and destroy all previous versions.

## Quick reference guideline



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## Abbreviations:

HBV and Hep B:	Hepatitis B virus
HBIG:	Hepatitis B immunoglobulin
HBsAg:	Hepatitis B virus surface antigen
HBeAg:	Hepatitis B virus e-antigen
anti-HBe:	antibodies against Hepatitis B e-antigen
IM	intramuscular

## Objective of guideline

To immunise those infants at risk of infection with Hepatitis B virus

## Rationale for the recommendations

Perinatal transmission of maternal HBV infection accounts for up to 50% of cases of chronic hepatitis B carriage.

- Since April 2000, screening for HBV has been routinely offered to all women in early pregnancy. This aims to identify infants at risk of Hepatitis B infection.
- Risk of vertical transmission of the virus is associated with the e-antigen status of the mother.
- Perinatal transmission of HBV can be reduced by immunisation of the infant - a Cochrane Review concludes that 'vaccine, Hepatitis B immunoglobulin (HBIG), and vaccine plus Hepatitis B immunoglobulin prevent Hepatitis B occurrence in newborn infants of Hepatitis B surface antigen (HBsAg) positive mothers.<sup>1</sup>
- Low birth weight infants weighing <1500g born to mothers who are Hepatitis B positive should receive both Hepatitis B vaccine and Hepatitis B immunoglobulin regardless of the e-antigen status.<sup>2, 3</sup>
- Eligible preterm infants should receive the full paediatric dose of Hepatitis B vaccine<sup>4</sup>

## Broad recommendations

To identify infants at risk of HBV infection and offer immunisation in the form of:

- Active immunisation (vaccine) alone or
- Active plus additional passive immunisation with Hepatitis B immunoglobulin (HBIG) depending on the *risk category* (see below)

## Antenatal Management

- The neonatal unit should be notified via the Neonatal Alert system when antenatal screening serology has identified a woman infected with Hepatitis B virus.
- Hepatitis B Proforma is issued by the Virologists giving details of the hepatitis B serological profile and outlining the management of the neonate born to a

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mother infected with hepatitis B virus. This Proforma should be included with the maternal and neonatal medical records and attached to the Neonatal Alert.

- There is a separate Trust guideline 'Hepatitis screening in pregnancy and neonatal vaccination' which outlines antenatal management in detail. See [Trustdocs ID: 1183](#)

### Post natal management

#### a) Parent Information Leaflet

Please give all eligible parents NHS Information Leaflet (S:\Division 3 - Women, Children & Sexual Health\NICU\Parent Information)

#### b) Immunisation of infants

The following protocol describes the immunisation strategy for infants of mothers infected with Hepatitis B. The virology proforma (attached to the Neonatal Alert) will inform team of the necessary management of the baby. Immunisation should occur **as soon as possible** (within 24 hours of delivery).

##### i) Term infants

Hepatitis B status of mother	Baby should receive	
	Hepatitis B vaccine	HBIG single dose
HBsAg positive and HBeAg positive	Yes	Yes
HBsAg positive, HBeAg negative and anti-HBe negative	Yes	Yes
HBsAg positive where e-markers not determined	Yes	Yes
Acute hepatitis B during pregnancy	Yes	Yes
HBsAg positive, anti-HBe positive	Yes	No
HBsAg positive and known to have HBV DNA level $\geq 1 \times 10^6$ IU/ml in an antenatal sample	Yes	Yes

##### ii) Very low birth weight infants 1500g or less

Both vaccine and HBIG should be given to infants of Hepatitis B-infected mothers regardless of the e antigen status of the mother.

##### iii) Preterm infants

Preterm infants of Hepatitis B-infected mothers should receive full paediatric dose of Hepatitis B vaccine, according to above.

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### c) Hepatitis B Immunoglobulin (HBIG)

HBIG is available via the Department of Microbiology, on a named patient basis only.

It is also available in an emergency from Pharmacy, but only if authorised by the Duty Virologist (ext: 4531) or, if out of hours, by the Consultant Virologist on call (via NNUH switchboard).

### d) At Risk Babies

Other babies born at risk will be offered Hepatitis B immunisation – these should include babies born to:

1. Primary caregiver(s) with a history of current or previous substance abuse e.g. heroin, crack cocaine
2. Primary caregiver(s) on Methadone Programme
3. Human immunodeficiency virus (HIV) positive mothers
4. Hepatitis C Virus (HCV) positive mothers
5. Mothers from high HBV prevalence area with unknown HBV status (a country has 'high prevalence' if the chronic infection rate is >8%. <http://www.medic8.com/travel/viral-hepatitis-b.htm>)
6. Father known hepatitis B carrier.

### e) Schedule

Infants at risk of infection should receive Hepatitis B vaccine (and HBIG if required) **as soon as possible (within 24 hours) after birth.**

Further doses are then to be administered at 1 month, 2 months and at 12 months of age. There is no need to adhere to one brand of Hepatitis B vaccine for the whole vaccination schedule.

<b>At birth</b>	Hepatitis B vaccine
	<b>HBIG IF REQUIRED</b>
<b>1 month</b>	Hepatitis B vaccine
<b>2 months</b>	Hepatitis B vaccine can be at the same time as the first routine immunisation.
<b>12 months</b>	Hepatitis B vaccine

### f) Dosage

To be given ***as soon as possible*** (within 24 hours) after birth

Hepatitis B vaccine 0.5mL IM anterolateral aspect of thigh  
HBIG 250 iu IM anterolateral aspect of thigh  
(contralateral thigh to vaccine)

- The dose of vaccine administered varies with brand, but the ***volume administered is 0.5mL***, regardless of brand (please confirm in BNF).

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- Public Health England recommends a dose of **HBIG 250iu as of 9.2020**.

### g) Documentation

Neonatal Hepatitis B Immunisation Form **MUST** be completed for each immunisation ([Trustdocs ID No: 13631](#)) by the neonatal medical team:

- Original to be filed in infant's medical case notes
- 1 copy emailed to Copy emailed to Screening Midwives: [Antenatal.NewbornScreening@nnuh.nhs.uk](mailto:Antenatal.NewbornScreening@nnuh.nhs.uk)
- Copy emailed to CHIS (Child Health Information Service): [provide.chiseastanglia@nhs.net](mailto:provide.chiseastanglia@nhs.net)
- 1 copy to GP at time of discharge
- 1 copy for parents, to keep in the 'Red Book' at time of discharge

### h) Follow up

- Following receipt via email of the Neonatal Hepatitis B Immunisation Form, CHIS (Child Health Information Service) will ensure that the correct reminders are sent out for immunisations and that Hep B testing kits are sent to either the GP or Specialist Health Visitor as a baby reaches their first birthday.
- A discharge summary should be completed (using NIPE SMART - as with all Higher Needs infants), stating that the immunisation was given and that the emails were sent as above

## Special Circumstances

### i) Non-consent to HBIG and vaccination

Due to the significant health risk posed by transmission of Hepatitis B to an infant, it is imperative to ensure that every effort is made to counsel the parents both antenatally and postnatally about the importance of their infant receiving a full-course of Hepatitis B vaccination. It is necessary to ensure that communication to the parent is in an appropriate format (i.e. access to translation services is available if necessary).

If despite best efforts it is not possible to gain consent to vaccinate the child, please discuss with the NICU consultant and Virology consultant on-call. It will be necessary to agree a continued care plan for the mother and child. This may include referral to specialist services for further discussion or referral via 'safeguarding' protocols to child social services, if the child is deemed at significant risk.

### j) No booking bloods available

If a woman presents in labour with no booking bloods available, the appropriate screening tests will be sent urgently by the midwifery team. The midwifery team must contact the on call virologist to ensure the samples are processed urgently. The results will be available within 24 hours to allow for timely administration of vaccine.

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### k) Home birth

All women who are Hepatitis B positive will be offered a hospital birth to ensure the vaccination could be given in the appropriate timeframe. If the baby delivered at home unexpectedly, the NICU alert sticker will flag the issue to the community midwife who should contact the NICU registrar to arrange appropriate treatment. If there are any concerns these should be discussed with the NICU consultant on-call and the Virologist on-call.

### Clinical audit standards derived from guideline

- All infants at risk of HBV identified
- All at risk infants offered immunisation
- Immunisation within the recommended time frame
- Correct documentation and timely communication of immunisation status

### Summary of development and consultation process undertaken before registration and dissemination

The authors listed above drafted the guideline. During its development it was reviewed at the neonatal unit guideline development meeting and amended based on recommendations arising from that forum.

This version is endorsed by the virologists (Department of Microbiology) at NNUH and Clinical Guidelines Assessment Panel.

### Distribution list / dissemination method

NICU  
Delivery Suite  
Blakeney Ward  
Cley Ward  
Trust Intranet

### References / source documents

1. Lee et al The Cochrane Database of Systematic Reviews 2006 Issue 2
2. Losonsky et al *Pediatrics* 1999; 103 (2): E14
3. Immunisation against infectious disease: Dept of Health 2006 – “The Green Book”  
[http://www.dh.gov.uk/en/Policyandguidance/Healthandsocialcaretopics/Greenbook/DH\\_4097254](http://www.dh.gov.uk/en/Policyandguidance/Healthandsocialcaretopics/Greenbook/DH_4097254)
4. Saari et al *Pediatrics* 2003; 112; 193-198

**Hyperlink to - Neonatal Hepatitis B Immunisation Form**  
[Trustdocs ID No: 13631](#)