Selective Neonatal and Infant Hepatitis B pathway

Approved by: Antenatal Forum

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Contents

1. Purpose of guidance

The following guidance is designed to ensure that all babies born at risk of hepatitis B infection are immunised promptly according to the recommended accelerated immunisation schedule. In addition to vaccination, it is equally important infants attend for their appropriate serology test at 15 months of age.

This guidance aims to ensure that:

- All babies at risk are identified, mothers are encouraged to consent to the immunisation schedule and the first vaccine (and HBIG where appropriate) is administered within 24 hours of birth.
- There is effective handover from maternity services to the team completing the immunisation schedule, with effective communication between all professionals until the care pathway is complete.
- 15 month serology testing is undertaken to identify where immunisation has been unsuccessful at preventing transmission.
- The Health Board's Strategic Immunisation Group is assured that all processes have been followed, with the expectation health professionals will undertake appropriate action in the event a child has missed an immunisation and / or serology testing.

2. Background

Please also refer to the Hepatitis B (chapter 18) of 'The Green book'.
Hepatitis B is an infectious disease caused by the Hepatitis B Virus (HBV). It is transmitted through blood and other body fluids and can result in an acute or chronic infection of the liver which can cause serious illness and premature death. The hepatitis B neonatal and infant vaccine forms part of the national immunisation programme and is delivered alongside the hepatitis B antenatal screening programme.

Infants who are infected during pregnancy and birth are at high risk (90%) of becoming chronic carriers. A timely and complete immunisation course for the baby prevent development of persistent HBV infection in over 90% of cases. (DH 2013). This relies on consistent clear practice and record keeping as well as effective communication between partner agencies involved.

The hepatitis B surface antigen (HBsAg) is used to screen for the presence of this infection. It is the first detectable viral antigen to appear during infection. Shortly after the appearance of the HBsAg, another antigen - hepatitis B e antigen (HBeAg) will appear. Traditionally, the presence of HBeAg in a host's serum is usually associated with much higher rates of viral replication and enhanced infectivity. During the natural course of an infection, the HBeAg may be cleared, and antibodies to the 'e' antigen (anti-HBe) will arise immediately afterwards. This conversion is usually associated with a dramatic decline in viral replication.

Individuals who remain HBsAg positive for at least six months are considered to be hepatitis B chronic carriers. PCR tests detect and measure the amount of HBV DNA - viral load, to assess a person's infection status and to monitor treatment.

3. Screening Pregnant Women

Screening for infectious diseases is an integral aspect of antenatal care. Occasionally, women are not screened due to non- attendance at antenatal clinic or refusal to allow blood tests. In women who refuse, please ask the obstetric or midwifery staff to send blood from the woman urgently and ring virology to request fast tracking and let the maternity services team know the results urgently.

4. Babies born to Hepatitis B positive women

Post-exposure immunisation is provided to infants born to mothers with hepatitis B infection, identified through antenatal screening, to prevent mother to child transmission at or around the time of birth. After obtaining parental consent, immunisation of babies of mothers with hepatitis B should be commenced as soon as possible after birth.

5. The Hepatitis B vaccination

There are two classes of products available for immunisation against hepatitis B: a vaccine that confers active immunity and a specific immunoglobulin that provides passive and temporary immunity while awaiting response to vaccine.

- The selective neonatal immunisation programme consists of 6 doses of vaccine given intra-muscularly.
- Hepatitis B immunoglobulin, if required (see table 1 in the care pathway below), is given in a dose of 200 IU to the newborn at the time of the first vaccination. It should be given at a different site from the hepatitis B vaccination.

6. Hepatitis B immunisation schedule for selective neonatal programme for infants born on or after 1 August 2017

From Autumn 2017, all babies born on or after 1st August were eligible for a hexavalent vaccine that includes Hepatitis B for their primary immunisations. Whilst this should benefit infants at increased risk of hepatitis B as they are more likely to complete the full course of hepatitis B, these babies still require the critical early doses at birth and one month of age.

These high risk infants should receive the post exposure hepatitis B vaccination schedule that includes the monovalent hepatitis B vaccine at birth and 4 weeks of age, and then three doses of infanrix hexa at 8, 12 and 16 weeks of age. They should then receive a booster dose of the monovalent hepatitis B vaccine at 12 months of age, after which time they should also have a blood test for hepatitis B surface antigen (HBsAg) to check for infection (15 months old). Where there is a delay in the second (4 week) monovalent vaccination, specific guidance on timing of subsequent doses is given in the national guidance document

7. Hepatitis B schedule for selective neonatal Hepatitis B programme

Age	Babies born to hepatitis B infected mothers
Birth	✓ Monovalent HepB (+/- Hepatitis B immunoglobulin as per pathway) in hospital within 24 hours
4 weeks	✓ Monovalent HepB in Neonatal outpatient clinic
8 weeks	✓ DTaP/IPV/HIB/HepB at GP surgery alongside other with routine immunisations
12 weeks	✓ DTaP/IPV/HIB/HepB at GP surgery alongside other routine immunisations
16 weeks	✓ DTaP/IPV/HIB/HepB at GP surgery alongside other routine immunisations
1 year of age	✓ Monovalent HepB at Neonatal outpatient clinic ✓
15 months of age	✓ Test for HBsAg

If mothers who are hepatitis B positive refuse the vaccination of their infants, then this becomes an <u>immediate</u> child protection issue.

We also strongly advise the immunisation of babies born to **hepatitis B negative** women in the following **high-risk groups**, but this cannot be enforced against maternal wishes:

- IV drug abusers
- Current or past history of drug misuse.
- Those with HIV or Hepatitis C
- Women whose partners are known to be Hep B, Hep C or HIV positive
- Women from high and intermediate prevalence countries (see green book for further details)

8. Care Pathway of pregnant woman who is Hepatitis B +ve

a. Ante-natally

1.Midwife to provide the woman with an information sheet "Information for pregnant women who are hepatitis B positive" – available from Antenatal Screening Wales website: http://www.antenatalscreening.wales.nhs.uk/sitesplus/documents/968/Information%20for%20women%20who%20are%20Hepatits%20B%20Positive%20English%20April%202020.pdf
2. Confirmatory sample and viral load sample to be taken at the time of giving results.

3. Antenatal Screening Midwife to notify the Health Protection Nurse - Health protection team at Public Health Wales (0300 00 300 32), Public Health Wales, Matrix House, Northern Boulevard, Swansea Enterprise Park, Swansea. SA6 8DP of names and dates of births of other children and father of baby. They will notify the GP (and copy the named Health Visitor) and undertake contact tracing if necessary. It is the GP's responsibility to ensure vaccination of these individuals and any other household contacts. Swansea Bay UHB Immunisation co-ordinator to be copied in any email for information.
4. If other children are in care, the midwife should notify the Consultant Community Child Health giving names and dates of births of the children and placement if known.
5. If mother is Hepatitis B positive and HBe Ag positive or no HBe markers or HBe Ab negative, viral load will be measured by the virology lab. If there is acute hepatitis B during pregnancy, viral load is to be measured.
6. Consultant Microbiologist/Virologist will write to the Consultant in the Neonatal Unit, Antenatal Screening Midwife and Consultant Obstetrician with advice.
7. With consent, the woman should be referred to the gastroenterologist. Please state EDD and results of all tests (including viral load). *If high viral load mother will be treated with Lamivudine in last trimester.*
8. If HBIG is indicated, an order form is to be completed by screening midwife and sent to Pharmacy so that the gamma globulin is available in Labour Ward fridge prior to delivery of baby. Further supplies Pharmacy.
9. Midwife to ensure gamma globulin (HBIG) is ordered and in Labour ward fridge. One spare dose of gamma globulin to be kept in Labour ward fridge in case of emergency. (There is also 1 spare vial in Pharmacy emergency cupboard)
10. Information must be given to the mother by her midwife in advance in case she delivers elsewhere.
11. If a woman presents in labour (or late in pregnancy) and has not been screened for hepatitis B, HIV or syphilis, please gain consent and take samples ASAP. These need to be sent urgently to the lab and the lab must be informed to perform rapid testing.

Note: individual email addresses may change and should be checked

b. At delivery

1. Paediatric doctor to give mother Information sheet, if not already given. Link: http://www.antenatalscreening.wales.nhs.uk/sitesplus/documents/968/Information%20for%20women%20who%20are%20Hepatits%20B%20Positive%20English%20April%202020.pdf and copy to be put in baby's red book. Mother to sign vaccination consent for HBIG (if indicated) and first vaccination

2.Hepatitis B gamma globulin (HBIG), if indicated, needs to be given as soon as possible after birth by the paediatric doctor. Aim to give 100% within a few hours of birth. Need written consent from parent. Record batch no. in notes. The dose is 200 IU given intramuscularly. Note if using an adult vial of 500 units, you will need to draw up 1/2 of the volume of the vial. The volume is variable, but is stated on the vial. Complete form accompanying the HBIG and return to Pharmacy .

Indications for Hepatitis B Immunoglobulin

All babies with any of the following:

a) Mothers with high viral load (>1x 106 IU/mL) even if treated with Lamivudine.

b) Low birth weight < 1.5 kg (irrespective of HBe Ag status)

c) Mothers with acute hepatitis B during pregnancy.

Maternal status				
HBsAg	**HBeAg**	**HBeAb**	Anti-HBV Immunoglobulin 200 IU within 12hrs	HBV Vaccine
+	+	-	Yes	Yes
+	-	+	No	Yes
+	-	-	Yes	Yes
+	Not available	Not available	Yes	Yes

3.Baby given 1st hepatitis B vaccination (Hep B Vaxpro) as soon as possible after birth by paediatric doctor, (aim to give 100% within a few hours of birth). This includes pre-term infants. Need written consent from parent. Dose is 0.5 ml (5 mcg if HBVax pro and 10 mcg if Engerix B) given IM. (Also kept in Labour Ward fridge).

4. Vaccination (+/- HBIG)to be recorded in:

- Child's 'Red book'
- Hospital notes.
- Neonatal clinic referral letter for follow-up (see below) with copies sent as below (including to the Child Health Department in order for the vaccination history to be recorded on the child health computer (CYPRiS).

5. Paediatrician to explain to mother the need to complete all the vaccinations and for testing to be undertaken at 15 months of age. Conversation is to be recorded in notes and mother's queries answered.

6. *Important* Paediatrician to please complete referral form see template below – appendix 1) stating indication for hepatitis B accelerated immunisation programme,

mother's serology results, and requesting follow-up appointment in hepatitis B clinic in 4 weeks for 2nd immunisation.

Copies of letter to be sent to:

1. **Consultant in Neonatal Unit,**
2. **GP**
3. **Central Child Health Clinic**
4. **Antenatal and Newborn Screening Midwife**

7. To ensure adequate immunity Hepatitis B vaccinations are required at birth, 1 month, 2 months and 1 year (*kindly refer to changes from August 2017).
Appointments for further doses will be organised by the Consultant in the Neonatal Unit

Baby needs blood test at 15 months to confirm immunity and lack of infection.
Poor responders should receive a booster dose and non-responders should receive a repeat course of vaccination.
Failure to attend subsequent appointments or comply with vaccination policy then the consultant in charge is required to:

- Notify health visitor, GP and practice nurse immediately
- Notify Health protection team, who will inform Immunisation coordinator
- Notify Child Protection coordinator immediately.
- Notify Social Services.

c. Post-natally

1. Ante-natal screening midwife to inform Health protection team and Immunisation coordinator via e mail names of any infants that have received Hep B IG and first monovalent Hep B vaccine.
2. Immunisation coordinator to contact named HV or if within a Flying Start area, to contact the Operational Team Leader to advise of vaccine given with advice to HV to confirm infant has an appointment for 2nd monovalent vaccine within a month of receiving the first dose. Immunisation coordinator to liaise with Child Health Department with information to ensure accurate data entry onto CYPRiS
3.Health protection team to write to infant's GP and Health Visitor informing them of the infant's details and vaccination doses received in hospital.
3. Health visitor and GP to ensure child is brought to GP clinic for subsequent hexavalent doses at 2, 3 and 4 months. HV to ensure appointments are received for 12 month dose and bloods at 15 months at Singleton Hospital.
4. Health protection team to inform GP and Health Visitor of any delayed or missed doses in the vaccination schedule within 1 week. Immunisation co-ordinator to be copied in for information.
5. Health Visitor to inform HPT if child on caseload, who is currently on the selective Hepatitis B schedule moves out of area.

6. Health visitor to inform HPT if a child who is on the selective Hepatitis B schedule has moved into the area. Health visitor to advise the HPT of any Hepatitis B vaccines and on the advice of the HPT to ensure any missed vaccines are followed up.
7. All Hepatitis B vaccines to be recorded on CYPRiS (child health dept) and TARIAN (HPT)
8. Any delays in the child receiving any Hepatitis B vaccine as per schedule (either at SGH or at the child's GP) to be highlighted at the Strategic Immunisation Group who will review current guidance and practice.

Antenatal Screening Wales: Information for women leaflet

Available at: http://www.antenatalscreening.wales.nhs.uk/public/hepatitis-b

Appendix 1: Checklist for the management of Hepatitis B Positive results in pregnancy

ADDRESSOGRAPH

Community Midwife_____

Obstetrician_____

E.D.D_____

Date of 1st hepatitis screen_____

Date of positive result_____

Initial viral load taken_____

28/40 viral load

Antenatal – at the time of identification of women who are hepatitis B positive

ACTION	PERSON RESPONSIBLE	COMMENTS	DATE & SIGNATURE
Lower infectivity result ☐ Higher infectivity result ☐	Obstetric Team		
Date woman notified _____ *Suitable arrangements should be made for women to return to antenatal clinic for their results – within 1 week*	Antenatal Clinic Midwife		
Confirmatory screen and viral load bloods taken at the time of recall for results *Please state 'antenatal confirmatory tests and HBV Viral Load' on form*	Antenatal Clinic Midwife		
Antenatal Screening Wales (ASW) leaflet given – Information for Women who are Hepatitis B Positive	Antenatal Clinic Midwife		
Refer to consultant led care – next available appointment	Antenatal Clinic Midwife		
Date and sign All-Wales Maternity Record and include plan of care and actions taken to date – with consent	Antenatal Clinic Midwife		
Inform obstetrician, antenatal screening coordinator, GP and community midwife with consent. *If the GP is not requesting the test then consent to inform needs to be sought from the woman.* *Screening midwife:* SBU.AntenatalScreeningMidwife@wales.nhs.uk *HEALTH PROTECTION TEAM SHOULD BE AUTOMATICALLY INFORMED BY THE LAB – THIS WILL BE CONFIRMED BY THE SCREENING MIDWIFE*	Antenatal Clinic Midwife		
Referral to gastroenterologist/hepatologist once confirmatory screen completed and eAg/eAb status is known (Referral form attached) Email: SBU_HepatologyBBVService@wales.nhs.uk	Obstetric team/Screening Midwife		

Antenatal – at the time of 1st obstetric appointment

ACTION	PERSON RESPONSIBLE	COMMENTS	DATE & SIGNATURE
Referral to consultant paediatrician Dr. Sree Nittur. *Paediatric referral should be made within 10 working days of the woman receiving the result. Arrangements to be made for neonatal plan of care for infants born to women who are Hepatitis B positive to ensure rapid treatment post-birth*	Obstetric team		
Further discussion with the woman regarding household transmission, treatment plan and vaccinations for baby along with any other information guided by the obstetrician	Obstetric team		
Future appointments arranged including repeat viral load screen at 28/40	Obstetric team		

Antenatal – **lower infectivity result**

ACTION	PERSON RESPONSIBLE	COMMENTS	DATE & SIGNATURE
Ensure prescription available for Hepatitis B vaccine for infant *To be administered within 24 hours of birth by paediatrician*	Paediatric team		
28/40 bloods arranged for viral load *If high viral load – move on to higher infectivity plan and inform screening midwife*	Obstetric team		

Antenatal – **higher infectivity result**

ACTION	PERSON RESPONSIBLE	COMMENTS	DATE & SIGNATURE
Ensure HBIG ordered via Public Health England *Inform screening midwife and she will do this – this is only required if indicated by the lab/gastro team*	Antenatal screening coordinator		
Ensure 28/40 bloods for viral load are taken	Obstetric team		
Ensure HBIG available on LW fridge approx. 6 weeks prior to EDD	Antenatal screening coordinator		

Delivery Suite – Lower infectivity result. Please note: Babies born weighing less than 1500g will need HBIG and should be managed as per higher infectivity result post-birth.

ACTION	PERSON RESPONSIBLE	COMMENTS	DATE & SIGNATURE
On admission to delivery suite ensure vaccination is available	Delivery suite midwife		
Alert paediatric team of admission	Delivery Suite midwife		
Ensure vaccination administered within 24 hours of birth	Paediatric team		
Ensure documentation completed and returned	Paediatric team		
Comprehensive handover to postnatal staff	Delivery suite midwife		

Delivery Suite – higher infectivity result. Please note: Babies born weighing less than 1500g will also require HBIG even if lower infectivity result antenatally.

ACTION	PERSON RESPONSIBLE	COMMENTS	DATE & SIGNATURE
On admission to delivery suite ensure vaccination and HBIG available *HBIG should be stored in LW fridge 6 weeks prior to EDD. Contact pharmacy if this is not available, emergency dose stored there.*	Delivery suite midwife		
Alert paediatric team of admission	Delivery suite midwife		
Following birth - administer HBIG and vaccination separately – see pathway	Paediatric team		
Comprehensive handover to postnatal staff	Delivery suite midwife		
Ensure HBIG/vaccination status recorded on documentation sent to Child Health	Delivery suite midwife		

Postnatal

ACTION	PERSON RESPONSIBLE	COMMENTS	DATE & SIGNATURE
Importance of completing vaccination schedule discussed with woman and documented	Paediatric team/Postnatal ward midwife		
Referral to Dr. Sree Nittur completed for 2nd vaccination (Referral form attached)	Paediatric team		
Information letter discussed with woman and put into red book to aid communication with health visitor	Postnatal ward midwife/Paediatric team		
Clearly document that 1st vaccination (and HBIG if relevant) has been given in postnatal process and red book.	Postnatal ward midwife		
Ensure hepatitis B information is clearly documented on the discharge notification and state that baby is on accelerated hep B programme (This will need to be added as a note in the discharge details)	Postnatal ward midwife		
Discharge notification to be sent to Health Protection Team & Immunisation Team	Screening midwife		

Date: ……/……/……..

Dear, Dr. Ch'ng,

Please accept this referral for: _____.

Hospital number: _____

Date of birth: _____

She is _____ weeks pregnant and has tested positive for hepatitis B during her antenatal screening. She has been referred to an obstetric consultant and her appointment is arranged for _____

A confirmatory blood sample has been sent and a viral load requested.

I have been informed by the virology lab that her baby will/will not require immunisation with HBIG immunoglobulin at birth and this has been ordered (if applicable); baby will also need hepatitis B vaccination at birth.

Please review at your earliest convenience,

Many thanks.

Katie Donovan
Antenatal and Newborn Screening Co-ordinator,
Swansea Bay Health Board
Katie.donovan@wales.nhs.uk
07773535141

Date:……/……/……..

Dear Dr Nittur,

I would be grateful if you could review this infant in your clinic in 4 weeks who requires an accelerated hepatitis B immunisation course.

This infant was born to a mother with: hepatitis B / hepatitis C infection / at risk of hepatitis B **(please delete as appropriate)** due to

……

Gestation: Mode of delivery: Birth weight:

Mother's ethnicity: Father's ethnicity:

Maternal serology: (please complete all details)

HEP B

Hb S Antigen: ☐ +ve ☐ -ve Anti HBS Ag: ☐ +ve ☐ -ve

Hb 'e' antigen: ☐ +ve ☐ -ve Anti Hbe antigen: ☐ +ve ☐ -ve

Hep B core IgG: ☐ +ve ☐ -ve Hep B core IgM: ☐ +ve ☐ -ve

HEP C

Anti HCV antibody: ☐ +ve ☐ -ve ☐ +ve ☐ -ve

HCV PCR: ☐ +ve ☐ -ve ☐ Unknown

HIV

HIV serology: ☐

Immunisation / immunoglobulin:

1st Hep B immunisation given after delivery: ☐ Given ☐ Not given

Date given: Batch number:

Immunoglobulin: ☐ Given ☐ Not given

Date given: Batch number:

Please ensure the referral form is fully completed. I would be grateful if you would see this infant in your hepatitis B clinic in 4 weeks and make arrangements for the subsequent immunisations.

Many Thanks,

Name ……. Designation: ……

Cc: GP
Central Child Health Clinic (SBU.CommunitychildhealthSwanseaNPT@wales.nhs.uk)
Antenatal and Newborn Screening Midwife (SBU.AntenatalScreeningMidwife@wales.nhs.uk)

Appendix 2: Hep C Referral Form

Hep C Referral Form

Please email completed form to: SBU.BBV@wales.nhs.uk

Patient Name			
Date of Birth			
Hospital Number			
NHS Number			
Est Date of Delivery			
Address			
Patient Contact Telephone Number			
Hep C Anti-Body	Yes / No		Date
Genotype			Date
HCV PCR			Date
Referred by		Contact Number	Date

Maternity Services

Checklist for Clinical Guidelines being Submitted for Approval

Title of Guideline:	Selective Neonatal and Infant Hepatitis B pathway
Name(s) of Author:	Katie Donovan
Chair of Group or Committee approving submission:	Antenatal Forum
Brief outline giving reasons for document being submitted for ratification	
Details of persons included in consultation process:	Antenatal forum members
Name of Pharmacist (mandatory if drugs involved):	
Issue / Version No:	1
Please list any policies/guidelines this document will supercede:	
Date approved by Group:	January 2021
Next Review / Guideline Expiry:	January 2024
Please indicate key words you wish to be linked to document	Hepatitis, Hepatitis B, Hep B,
File Name: Used to locate where file is stores on hard drive	