NHS England

Public Health England

PHE Screening and Immunisation Team
Good Practice Guidance for the management of the NHS Hepatitis B Neonatal and Infant Immunisation Programme in NHS England South (South West) area.

Document title:

Neonatal and Infant Hepatitis B immunisation Protocol

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2.0	Nov 2016	Draft completed
2.1	Nov 2016	Added Dried Blood spot guidance

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Introduction

The following guidance is designed to ensure that all babies born to women identified as Hepatitis B positive are immunised promptly according to the recommended schedule and have their appropriate serology test at 12 months. The document clarifies the respective roles and responsibilities of the agencies involved in the Hepatitis B screening and immunisation pathway from the mother's Hepatitis B screening in pregnancy through to the vaccination and subsequent testing of infants. All provider Trusts and other local stakeholders involved should have written protocols and pathways that reflect this guidance and the standards specific to Hepatitis B in the NHS Infectious Diseases in Pregnancy screening programme.

All staff involved should be mindful of the following key documents:
1. The Green Book: https://www.gov.uk/government/publications/hepatitis-b-the-green-book-chapter-18

2. Hepatitis B antenatal screening and Newborn immunisation programme: Best practice guidance: www.gov.uk/government/publications/hepatitis-b-antenatal-screening-and-newborn-immunisation-programme-best-practice-guidance

3. NHS Employer/BMA Vaccination and Immunisation Programmes 2016/17
http://www.nhsemployers.org/your-workforce/primary-care-contacts/general-medical-services/vaccination-and-immunisation/2016-17-vaccination-and-immunisation

4. NHS Infectious Diseases in Pregnancy Screening Programme standards:
https://www.gov.uk/government/publications/infectious-diseases-in-pregnancy-screening-programme-standards

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.

If a pregnant woman has chronic HBV infection, then a timely and complete course of vaccination for her baby can prevent development of persistent HBV infection in

over 90% of these cases. This relies on consistent clear practice and record keeping as well as effective communication between partner agencies involved.

This guidance focuses on the management of the NHS Hepatitis B neonatal and infant vaccination programme but starts from the identification of a Hepatitis B infected (HBsAg positive) antenatal patient. Clinical management of the mother's Hepatitis B status will be addressed by prompt referral for assessment by an appropriate specialist.

The 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 services completing the immunisation schedule.
- call/recall systems are in place to enable timely uptake of the full immunisation schedule (according to the green book)
- systems are in place to support data reporting at appropriate points
- 12 month serology testing is undertaken to identify where immunisation has been unsuccessful at preventing transmission
- a failsafe audit of all eligible babies with incomplete or delayed immunisation is administered to ensure full completion of immunisation schedule

Hepatitis B neonatal/infant immunisation schedule (babies born to Hepatitis B positive mothers)*	
Scheduled age	**Target standard**
Dose 1	Birth (within 24 hours of birth) **With HBIG where indicated
Dose 2	1 month (at least one month after dose 1)
Dose 3	2 months (at least one month after dose 2)
Dose 4	12 months (at least six months from dose 3)
Blood test (HBsAg surface antigen) via Dried Blood Spot kit	12 months to check child's infection status (or as soon as possible after 12 months)
Dose 5	With pre-school booster at 3yrs 4mths.

*If mother is not infected with Hepatitis B but child is identified as 'at risk Hepatitis B lifestyle', the pre-exposure schedule as described in the Green Book should be followed

**For babies born to women of high infectivity (as defined in the Green Book a dose of hepatitis B specific immunoglobulin – HBIG - should be given with the first dose of vaccine).

Overview of key responsibilities for the Hepatitis B neonatal and infant vaccination pathway

Antenatal

HBsAg positive pregnant woman identified

Bloods taken ideally during 1st trimester but can be anytime during pregnancy. Women who present later in pregnancy should be screened ASAP (even at delivery)

Maternity will:

- Take confirmatory specimen
- Send blood to PHE Laboratory - ensuring that any required vaccine or immunoglobulin is issued for the baby at the optimum time and place
- Inform patient of positive result offering discussion and written information
- Document results within ten working days
- Refer all newly diagnosed Hepatitis B positive women and women already known to be Hepatitis B positive with high infectivity markers detected in current pregnancy for assessment and management by appropriate specialist (to be assessed within six weeks of screening result)
- Inform GP and Child Health Information Service (CHIS) of positive result

Child Health Information Service (CHIS) will: (see CHIS Hepatitis B Operational Pathway - Appendix Two)

Post-natal

Following birth of baby to HBsAg positive mother

Maternity will:

- Explain implications and obtain parental consent for baby's immunisation
- Administer 1st Hep B vaccine and, if appropriate, HBIG within 24 hrs of birth
- Ensure the parent(s) understand the baby's immunisation schedule and importance of completion
- Record 1st vaccination in maternity notes, and notify CHIS and GP (letter from neonatologist)
- If baby is born outside maternity unit, arrange for immediate immunisation via GP or hospital with HBIG if appropriate

CHIS will: (see CHIS Hepatitis B Operational Pathway - Appendix Two)

General Practice will: (as per NHS Employers – Vaccinations and Immunisations Programmes 2016-17)

http://www.nhsemployers.org/your-workforce/primary-care-contacts/general-medical-services/vaccination-and-immunisation/2016-17-vaccination-and-immunisation

- Reinforce with parent(s) the importance of completing immunisation schedule (including the continuity of care if child is moving out of the area)
- Administer 1st vaccination (where not administered in hospital), 2nd and 3rd primary vaccinations and 4th and 5th booster – as indicated in above schedule. (Where the primary schedule is delayed or disrupted, scheduling for the 5th booster may be a prompt to review outstanding vaccinations/serology)
- Carry out serology for HBsAg surface antigen (**see Appendix One)** at the point of administering the 4th vaccination at 12 months (or if vaccinations are delayed, at or as soon as possible after 12 months which may not correspond to an appointment scheduled for vaccination).
- Communicate result of test to parent
- Refer baby for paediatric assessment and management if test is positive

Health Visitors will:

- Ensure the infant is registered with general practice and, where infant has not received first vaccination at delivery, arrange for immediate completion in general practice or hospital
- Ensure parents understand the infant's immunisation schedule and the importance of completion

Screening and Immunisation Team (PHE) will:

- Receive monthly audit reports of infants up to age 2 years with delayed/ incomplete Hepatitis B immunisations from CHIS
- Contact the relevant Practice regarding any infants with delayed/incomplete immunisation schedule. Follow up with letter asking the Practice to make every effort to ensure the infant is vaccinated.
- Inform CHIS if any babies are found to have moved out of the area or moved to another practice in the area
- Feedback any updated results to CHIS so their records can be updated

Appendix One:

Infant Hepatitis B testing for HBsAG suface antigen.

Dried Blood Spot (DBS) testing

Infants with Hepatitis B infection are usually asymptomatic and do not display signs of infection at the time of testing. Testing infants born to Hepatitis B positive mothers at 12 months of age (at the same time as the 4th vaccination at 12 months or, if vaccinations are delayed, at, or as soon as possible after 12 months which may not correspond to an appointment scheduled for a vaccination) is importance to enable a timely assessment and refer for paediatric assessment and management where appropriate, reducing the risk of long term complications and disease in later life.

To improve ease and uptake of testing Public Health England (PHE) has developed a free dried blood spot (DBS) test that has been validated for detecting hepatitis B surface antigen. The test uses a single-use safety lancet to prick the heel of the infant allowing health care professionals to obtain blood which is applied to a filter paper and posted to the laboratory at PHE – Colindale.

Offering the dried blood spot test in primary care will:

- remove the need for patients to travel long distances to specialist clinics and help prevent dropout rates which increase with the number of visits required
- reduce risk of non-attendance at hospital appointment and subsequent potential clinical risk re. long term complications and disease in later life
- remove the need for practices to check that the patient has attended hospital serology appointment and chase further appointments where necessary

Local arrangements:

The following local arrangements are informed by national guidance as described in the link below (**the link includes clear guidance on how to undertake a DBS**).
https://www.gov.uk/guidance/hepatitis-b-dried-blood-spot-dbs-testing-for-infants

- PHE Screening and Immunisation Team oversee the DBS scheme locally acting as the hub for kits which are then distributed to local CHIS teams.
- CHIS administer the DBS kits and will send out a kit at the same time as scheduling the infant for the 4th vaccination at 12 months.
- Kit instructions and paperwork are followed and the DBS sample is returned to the PHE lab at Colindale.
- PHE lab will send the infant's GP a laboratory report outlining the diagnosis and any further public health actions. An electronic copy of the report will also be made available to the PHE Screening and Immunisation Coordinator who is responsible for overseeing the DBS scheme locally.
- GPs will inform parents and CHIS of the DBS test result and record appropriately.
- In the event of a positive test for Hepatitis B, the GP will refer baby for paediatric assessment and management.

Appendix Two:
Child Health Managers Communities of Practice Group
CHIS Hep B Operational Pathway
(SOP0001)

Timetable - To be completed when Hep B positive notification received
The SOP links to South west PHE Screening and Immunisation Team Good Practice Guidance for the Management of the NHS Hep B Neonatal and Infant Immunisation Programme

Local variation to the process can be found in Table 1

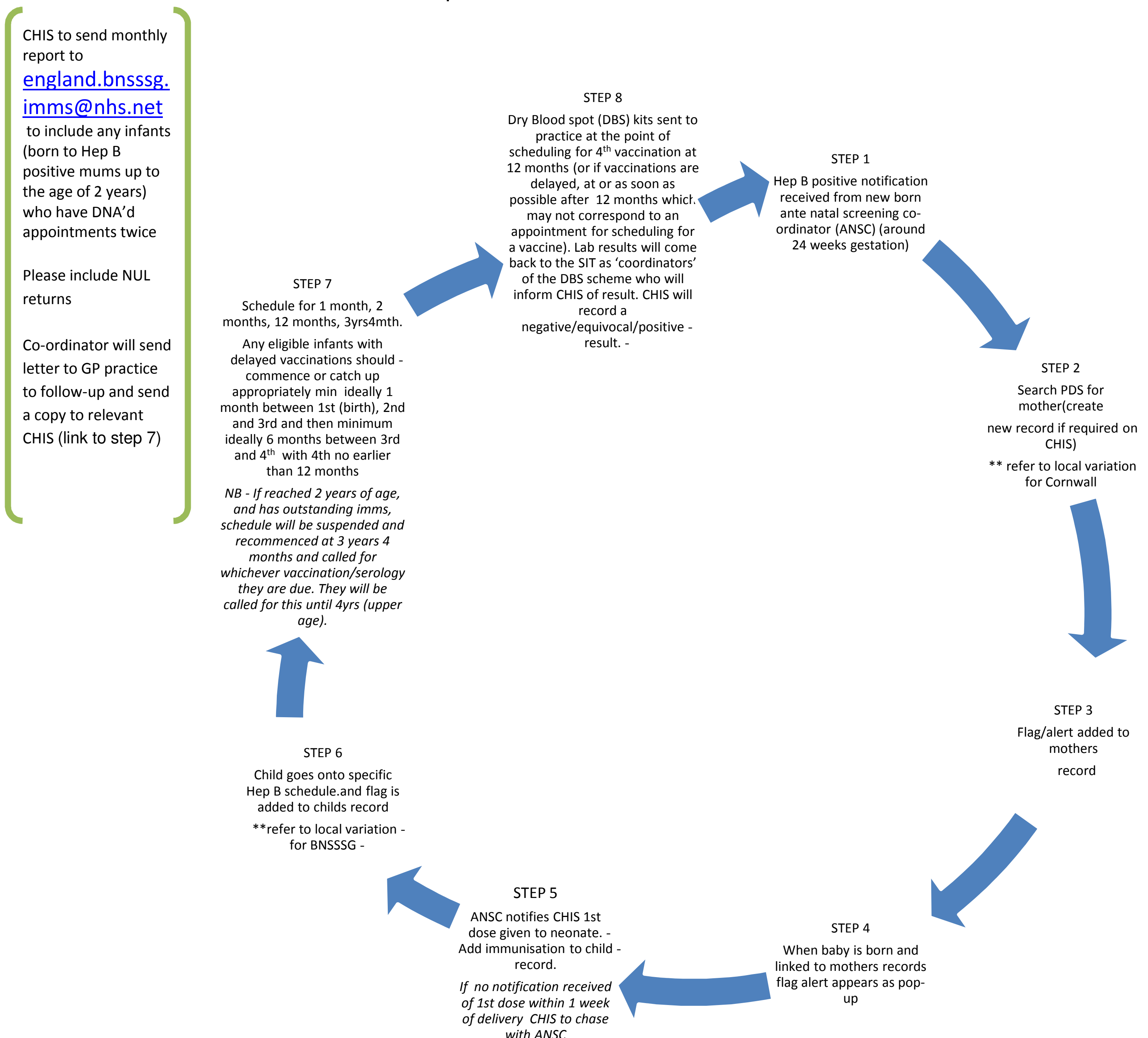

**Table 1 - Local Variations -

BNSSSG	Step 6 – Child is added to routine immunisation schedule (annotated for HepB as required)
Cornwall	Step 3 – Record the Hep B status on the mother's record, but it is not a pop up alert. Step 4 – When baby is born, the mother can be linked and the Hep B status viewed *(no automatic pop up alert/flag)* Steps 5,6,7 – Not currently scheduling for Hep B (ante-natal new-born co-ordinators proforma used to notify GP Hep B positive)

Version Control	
Author/s	CHIS Managers COP Group
Date agreed	
Version/s **(should follow standard format for version control e.g. *draft V00.01 Final V01.00*)**	• V00.01 – draft for discussion • V00.02 – revised draft (18/05/2016) • V00.03 – revised (26/05/2016) • V01.00 – sent for final agreement (01/06/2016) • V02.00 – amendments from SIC (09/06/2016). Include Null returns (19/08/2016) • V003.00 – Cornwall local variation added (22/09/2016) • V004.00 – Following HepB incident meeting • V005.00 – Following amendments from SIC (04/11/2016) • V006.00 – Following teleconference to discuss kits and schedules 23/11/2016
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