Public Health England

PHE South West
Screening and Immunisation Team

Good Practice Guidance for the management of the NHS Hepatitis B Neonatal and Infant Immunisation Programme in NHS England South West

This guidance covers: Devon, Cornwall, Isles of Scilly, Bristol, North Somerset, Somerset, South Gloucestershire and Dorset.

About Public Health England

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Public Health England
133-155 Waterloo Road
Wellington House
London SE1 8UG
Tel: 020 7654 8000
http://www.gov.uk/phe
Twitter: @PHE_uk

Prepared by: Sara Dove, Screening and Immunisation Coordinator
For queries relating to this document, please contact:
england.swscreeningandimms@nhs.net

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Document information	
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Lead author	Sara Dove, Screening and Immunisation Co-ordinator, Public Health England/NHS England South West
Owner	Comments may be sent to Sara Dove: england.swscreeningandimms@nhs.net in readiness for review
Document objective	To provide guidance on local management of high risk infants born to hepatitis B positive mothers
Target audience	Health Professionals working on this pathway including Maternity, Child Health Information Service, General Practice, Health Protection Teams, Screening and Immunisation Teams, and Health Visiting Service.

Background

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 local guidance has been updated to include the introduction of the hexavalent vaccine which includes hepatitis B for primary routine immunisations of all infants born on or after 1 August 2017. This vaccine, called Infanrix hexa will replace the pentavalent infant vaccines Infanrix – IPV+Hib and Pediacel. Whilst this should benefit infants born to an infected mother, these infants still require a targeted approach as described in this guidance.

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

3. The hexavalent DTaP/IPV/Hib/HepB combination vaccine -
Information for healthcare practitioners about the neonatal selective immunisation programme for babies at risk of hepatitis B
https://www.gov.uk/government/publications/hexavalent-combination-vaccine-programme-guidance

Purpose of guidance

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 of age. 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.

The 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 (via dried blood spot 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 schedule for infants born on or after 1 August 2017

From Autumn 2017, all babies born on or after 1st August 2017 are eligible for a hexavalent vaccine that includes hepatitis B (Hep B) for their primary immunisations. This vaccine, called Infanrix hexa, will replace the pentavalent infant vaccines Infanrix-IPV+Hib and Pediacel. Whilst this should benefit infants at increased risk of hepatitis B (e.g. those born to an infected mother) 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 vaccine at 8, 12 and 16 weeks of age. They should then receive a booster dose of monovalent hepatitis B vaccine at 12 months of age, at which time they should also have a blood test for hepatitis B surface antigen (HBsAg) to check for infection. Where there is a delay of the second (4 week) monovalent vaccination, specific guidance on timing of subsequent doses is given in the national guidance document - please see page 8 of https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/623745/Hexavalent_combination_vaccine_guidance_selective.pdf

Table one: Hepatitis B doses in the immunisation schedule for routine childhood and selective neonatal hepatitis B programmes

Age	Routine childhood		Babies born to hepatitis B infected mothers	
Birth	✗		✓	Monovalent HepB (Engerix B or HBvaxPRO Paediatric) (with HBIG if indicated)
4 weeks	✗		✓	Monovalent HepB (Engerix B or HBvaxPRO Paediatric)
8 weeks	✓	DTaP/IPV/Hib/HepB (Infanrix hexa)	✓	DTaP/IPV/Hib/HepB (Infanrix hexa)
12 weeks	✓	DTaP/IPV/Hib/HepB (Infanrix hexa)	✓	DTaP/IPV/Hib/HepB (Infanrix hexa)
16 weeks	✓	DTaP/IPV/Hib/HepB (Infanrix hexa)	✓	DTaP/IPV/Hib/HepB (Infanrix hexa)
1 year	✗		✓	Monovalent HepB (Engerix B or HBvaxPRO Paediatric) Test for HBsAg

Hepatitis B vaccine boosters for infants born on or after 1 August 2017

After the 12 month monovalent booster, a further dose of hepatitis B vaccine at 3 yrs and 4 months will no longer be recommended for high risk infants who have completed their routine primary immunisations with the hexavalent hepatitis B containing vaccine.

Hepatitis B schedule for infants born before 1st August 2017

High risk infants born to hepatitis B positive mothers before 1st August 2017 should continue to receive the monovalent hepatitis B vaccine as per the previous schedule at 0, 1, 2, 12 months of age, with the serology blood test also at 12 months of age to check whether they have acquired infection.

Hepatitis B schedule for infants at risk of exposure to hepatitis B from household contact

Infants born to a hepatitis B negative mother but known to be going home to a household with another hepatitis B infected person should receive the pre-exposure immunisation schedule. Where there is an immediate risk of exposure, a monovalent dose of hepatitis B should be offered as soon as possible after birth. These infants will then receive the routine doses of hexavalent vaccine at 8, 12 and 16 weeks of age so that they receive a total of four doses of a hepatitis B containing vaccine. They do not require a dose at 4 weeks of age or a booster at 12 months of age. Other infants, who are not at immediate risk, can be vaccinated routinely at 8, 12 and 16 weeks of age.

Key agency 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 taken anytime during pregnancy. Women who present later in pregnancy should be screened immediately, 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 pathway - Appendix Two.

PHE Health Protection Team on receipt of positive hepatitis B notification of pregnant woman from the laboratory will:

- Inform relevant acute Trust Antenatal Screening Coordinator (in the event that the case was not identified via antenatal screening)
- Write to the GP with advice regarding:
    - referring the patient to hepatology
    - infection control
    - managing contacts
    - immunising and testing the infant.

Post-natal

Following birth of baby to HBsAg positive mother

Maternity will:

- Explain implications and obtain parental consent for baby's immunisation
- Administer 1st hepatitis B vaccination and, if appropriate, HBIG within 24 hours 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 the maternity unit, arrange for immediate immunisation via GP or hospital with HBIG, if appropriate.

CHIS will: See CHIS hepatitis B pathway - Appendix Two, Three and Four.

General Practice will:

- Reinforce with parent(s) the importance of completing immunisation schedule (including continuity of care if infant is moving out of the area)
- Administer 1st monovalent hepatitis B vaccination as soon as possible after birth (where not administered in hospital), 2nd monovalent hepatitis B vaccine at 4 weeks of age, the 3 primary Hexavalent vaccinations at 8, 12, and 16 weeks of age, and the 12 month booster as indicated in above schedule
- Carry out serology for HBsAg surface antigen using the dried blood spot testing kit (see Appendix One**)** at the point of administering the 6th vaccination at 12 months of age, If the vaccinations are delayed, the serology test should be as soon as possible after 12 months of age. Note: this may not correspond to an appointment scheduled for vaccination
- Communicate result of serology test to parent (s)
- Refer infant 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.

PHE Screening and Immunisation Team will:

- Receive monthly failsafe audit reports of infants up to age 2 years with delayed/ incomplete Hepatitis B immunisations and/or serology from CHIS
- Contact the relevant General Practice regarding any infants with delayed/incomplete immunisations and/or serology. Follow up with letter asking the Practice to make every effort to ensure the infant is vaccinated and tested for HBsAg.
- 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 HBsAg Dried Blood Spot (DBS) testing

Infants with hepatitis B infection are usually asymptomatic at the time of serology testing at 12 months. Testing infants born to hepatitis B positive mothers at the same time as the booster vaccination at 12 months is critical to enable a timely assessment of whether the infant has become infected with hepatitis B, and to ensure an immediate referral to a paediatric team where appropriate, to reduce the risk of long term complications and disease in later life. Serology testing for HBsAg at 12 months (or as soon as possible thereafter) is still necessary even if some vaccinations have been delayed.

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 that is then 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, thus lowering dropout rates that tend to increase where additional visits are required
- Reduce the risk of non-attendance at hospital appointment and subsequent potential clinical risk of 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

- The PHE Screening and Immunisation Team oversee the SW DBS scheme acting as the local hub for kits that are then distributed to local CHIS teams
- CHIS Teams administer the DBS kits and will send out a kit at the same time as scheduling the infant for the booster vaccination at 12 months
- The GP practice will take the DBS sample (kit instructions and paperwork included) and return the DBS sample to the PHE lab at Colindale
- The PHE lab will send a laboratory report to the infant's GP outlining the diagnosis and any further public health actions required. 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
- The PHE Screening and Immunisation Coordinator will inform CHIS of the DBS result
- The GP will inform the parent(s) 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.

The expectation is that GP Practices will use the dried blood spot testing kit for the purpose of the Hep B infant serology test. However, if a GP Practice does refer an infant to an acute Trust for serology instead of using the dried blood spot kit, the Practice is required to inform CHIS of the serology result so that the child's CHIS record can be updated and for failsafe purposes. The serology result options are:

- HBsAg negative
- HBsAg positive.

National arrangements

Practice need to be aware that the National DBS Service are running their own process of checking that infants born to mothers with high infectivity have had serology testing at 12 months. The Screening and Immunisation Team is working with the National DBS Service to try to avoid practices receiving a second letter and kit, however on occasions this may be unavoidable. Please be reminded that the infant only needs to have one serology test. If the infant has already had serology testing, the second kit can be discarded. If practices have any queries, please contact the Screening and Immunisation Team on: england.swscreeningandimms@nhs.net

Appendix Two
Child Health Information Service (CHIS) high risk infant post-exposure Hep B vaccination pathway

Hep B positive notification received from Antenatal and Newborn Screening Co-ordinator (ANSC) around 24 weeks gestation

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Search PDS for mother (create new record if required)

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Flag/alert added to mother's record

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Baby born and record linked to mother's record, hepatitis B flag/alert appears as pop up

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ANSC notifies CHIS that 1st dose hepatitis B vaccination (and HBIG if appropriate) given to neonate at birth. CHIS add immunisation to child record. *If no notification received of 1st dose within 1 week of delivery, CHIS to chase with ANSC*

↓

Child entered on high-risk post exposure hepatitis B schedule, flag added to child record

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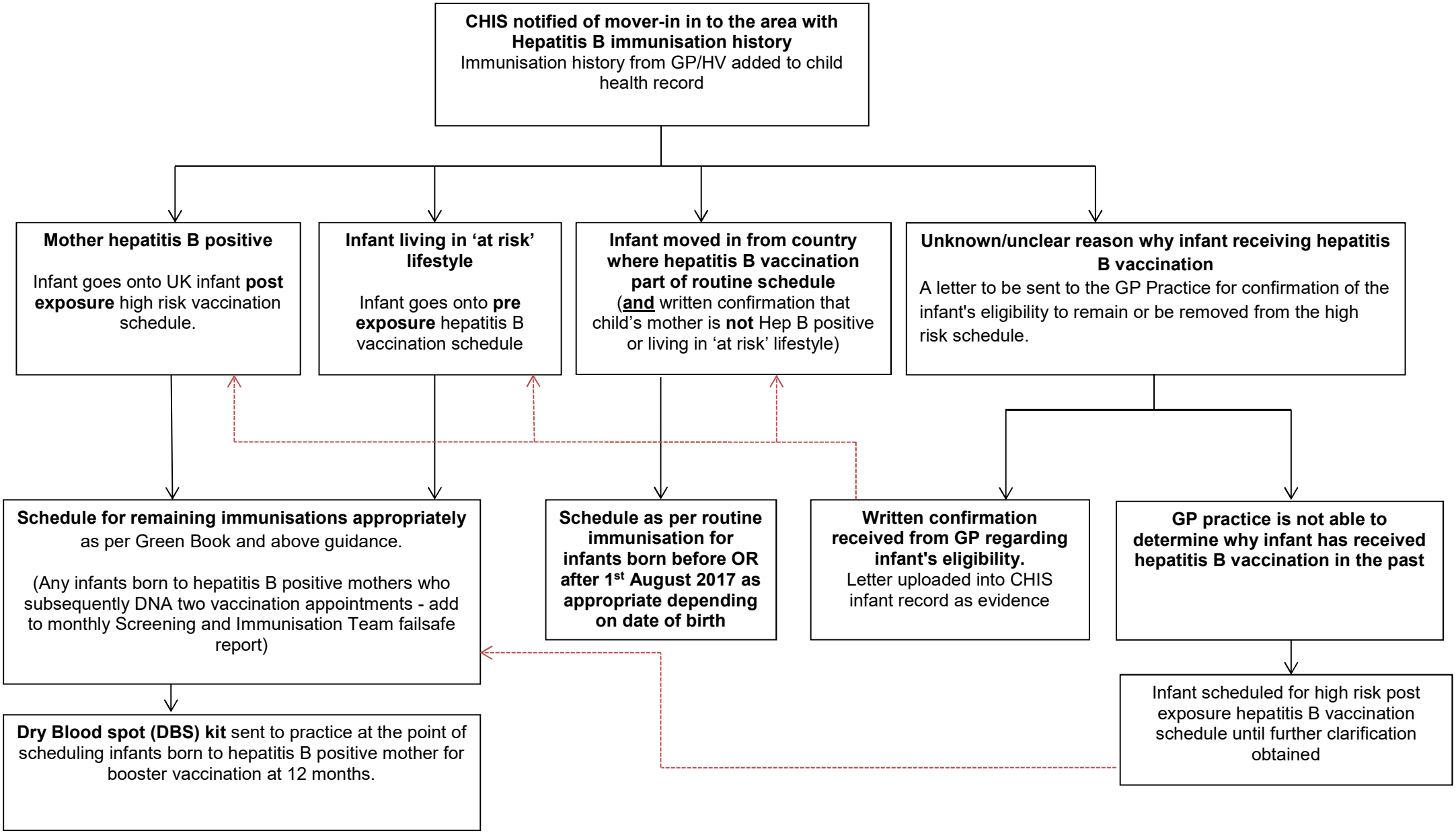
When infant reaches 2 weeks of age, CHIS contact the practice to ensure the infant is registered with them, the 4 week appointment has/will be made, vaccine in stock/on order and GP is aware to inform CHIS of DNA. Contact GP surgery when baby is 4 weeks 2 days to confirm 2nd dose given. If not, check again at 5 weeks. If more than 2 weeks late, modify schedule for 6/10/12 weeks.
Where the practice or CHIS has any queries/concerns they should contact england.swscreeningandimms@nhs.net

↓

Dry blood spot (DBS) kits sent to practice at the point of scheduling for 6th vaccination at 12 months of age (or if vaccinations are delayed, as soon as possible after 12 months, which may not correspond to an appointment scheduled for a vaccination). Serology results will be sent to the Screening and Immunisation Team (SIT) as the Co-ordinator of the SW DBS scheme, who will inform CHIS of result. CHIS will record a negative/ equivocal/ positive result.

Hep B infant vaccination reporting: See Appendix Four	Monthly failsafe reports sent to: england.swscreeningandimms@nhs.net Will include any infants up to age 2 years born to hepatitis B positive mothers, who have DNA'd vaccination or dried blood spot serology appointments twice. Reports to include NIL returns. SCRIMMS Co-ordinator to follow up with GP practice.

Appendix Three
Child Health Information Service (CHIS) Hepatitis B infant movers in pathway



Appendix Four: CHIS infant Hepatitis B vaccination reporting

Note: This is separate to the monthly failsafe report.

1. CHIS to complete quarterly COVER report:
   - completed Hep B vaccinations at 12 months
   - completed Hep B vaccinations at 24 months

2. CHIS to submit additional quarterly reporting using table below to: england.swscreeningandimms@nhs.net

CHIS Quarterly Infant Hepatitis B Vaccination Reporting (in addition to COVER report)							
	Total number of infants in the cohort, as defined by COVER parameters	**Number of infants who have received the full number of primary doses: Born before 01/08/17: 4 doses Born after 01/08/17: 6 doses**	**Number of infants with NO serology results recorded**	**Number of infants with NEGATIVE serology results recorded**	**Number of infants with POSITIVE serology results recorded**	**Number of infants with EQUIVOCAL serology results recorded**	**Exemption report with commentary (to include the number of vaccinations given) for each infant with incomplete/delayed vaccinations and no serology result**
Infants at 12 months	*Same denominator as for COVER report*						
Infants at 24 months	*Same denominator as for COVER report*						