

NHSEI Southwest

Screening and Immunisation Team

Management of the NHS Hepatitis B Neonatal and Infant Immunisation Programme

Good Practice Guidance

This guidance covers the Southwest of England

Version 7, 1 February 2022

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Document information	
Title	Good Practice guidance for the management of neonatal and infant hepatitis B vaccination programme NHS England South West
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Lead author	Sara Dove, Screening and Immunisation Co-ordinator, NHSEI
Owner	Comments may be sent to Gemma Piron: 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 person 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. Further updates to this guidance have been added to address the enhanced pathway which was introduced in April 2021.

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>

4. PHE Guidance for Hep B Screening Pathway

[Guidance on the hepatitis B antenatal screening and selective immunisation pathway:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/967528/PHE_11596_Hep_B_guidance.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/967528/PHE_11596_Hep_B_guidance.pdf)

Purpose of guidance

The following guidance is designed to ensure that all babies born to individuals identified as hepatitis B positive are immunised promptly according to the recommended schedule, and have their appropriate serology test at 12 months of age. It also aims to highlight the additional steps introduced to the pathway in April 2021 for pregnant people with high levels of hepatitis B virus. The document clarifies the respective roles and responsibilities of the agencies involved in the hepatitis B screening and immunisation pathway, from the from 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 pregnant individual'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.
- The parent(s) are encouraged to consent to the immunisation schedule and that 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 individual) 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 years 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 individuals 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 individual 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.

Enhanced Pathway for infants born to individuals who have higher levels of the virus

Up to now it has not been possible to know if babies with hepatitis B were exposed before they were born, during delivery, or whether the vaccine was not effective (vaccine failure). From 1 April 2021 the pathway requests blood samples from all pregnant people who screen positive for hepatitis B using surveillance kits sent to all trusts from UKHSA Colindale. UKHSA Colindale will request further samples from individuals who have higher levels of the virus at the time of delivery. Babies of individuals with higher levels of the virus will also have a blood spot taken at delivery prior to the vaccine and immunoglobulin.

Together with the baby's final blood test at 12 to 13 months, the results from these samples will:

- give scientists a much clearer picture of how the virus behaves
- help us evaluate the impact of the immunisation programme on numbers of babies getting hepatitis B

Combining this with more effective monitoring of care in pregnancy will mean that lessons can be learnt to inform the treatment and management of hepatitis B in pregnancy in the future and reduce the possibility of transmission of the virus from mother to baby

Key agency responsibilities for the hepatitis B neonatal and infant vaccination pathway

Antenatal

HBsAg positive pregnant person identified

Bloods taken ideally during 1st trimester but can be taken anytime during pregnancy. Those who present later in pregnancy should be screened immediately, even at delivery.

Maternity will:

- Arrange assessment appointment within 10 days of positive result and take additional bloods using surveillance kits sent by UKHSA Colindale
- Send blood to UKHSA Colindale and ensure that any required vaccine, immunoglobulin, or hep B delivery suite box 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 individuals and those 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

Hep B delivery Suite Box – for those who have higher levels of the virus

The hep B delivery suite box will contain EDTA blood tubes, request forms, DBS cards with instructions, prepaid envelopes, and HBIG, and will be sent to maternity units approximately 7 weeks before the expected due date. Delivery of the box is arranged by Colindale where necessary after receipt of prenatal surveillance blood samples. The maternity unit should determine a system for tracking and storage of this box. At the third trimester screening review the HBIG should be matched with delivery suite box, and the location recorded in the individual's notes.

Child Health Information Service (CHIS) will: See CHIS hepatitis B pathway in Appendix Two.

UKHSA Health Protection Team on receipt of positive hepatitis B notification of pregnant individual 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 individual

Maternity will:

- Explain implications and obtain parental consent for baby's immunisation
- Administer 1st hepatitis B vaccination 24 hours of birth
- Explain the details of the baby's immunisation schedule and highlight the importance of completion to the parent(s)
- 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.

For those with high levels of the virus:

- Explain implications and obtain consent for maternal surveillance sample and baby's DBS if appropriate
- Take maternal enhanced surveillance blood sample and send to Colindale
- Take newborn dried blood spot sample before administering vaccine and HBIG, and send to the laboratory using the pre-paid envelope
- Everything needed for the enhanced pathway will be in a box which is delivered to the maternity unit approximately 7 weeks before estimated delivery date

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:

- Check 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
- Explain the details of the infant's immunisation schedule and the importance of completion to the parent(s)

NHSEI 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 individuals 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, UKHSA 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 UKHSA, 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 local CHIS teams act as the local hub for DBS testing kits and will send out a kit to the practice 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 UKHSA lab at Colindale
- The UKHSA 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 CHIS who will record it in the child's record.

- 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.

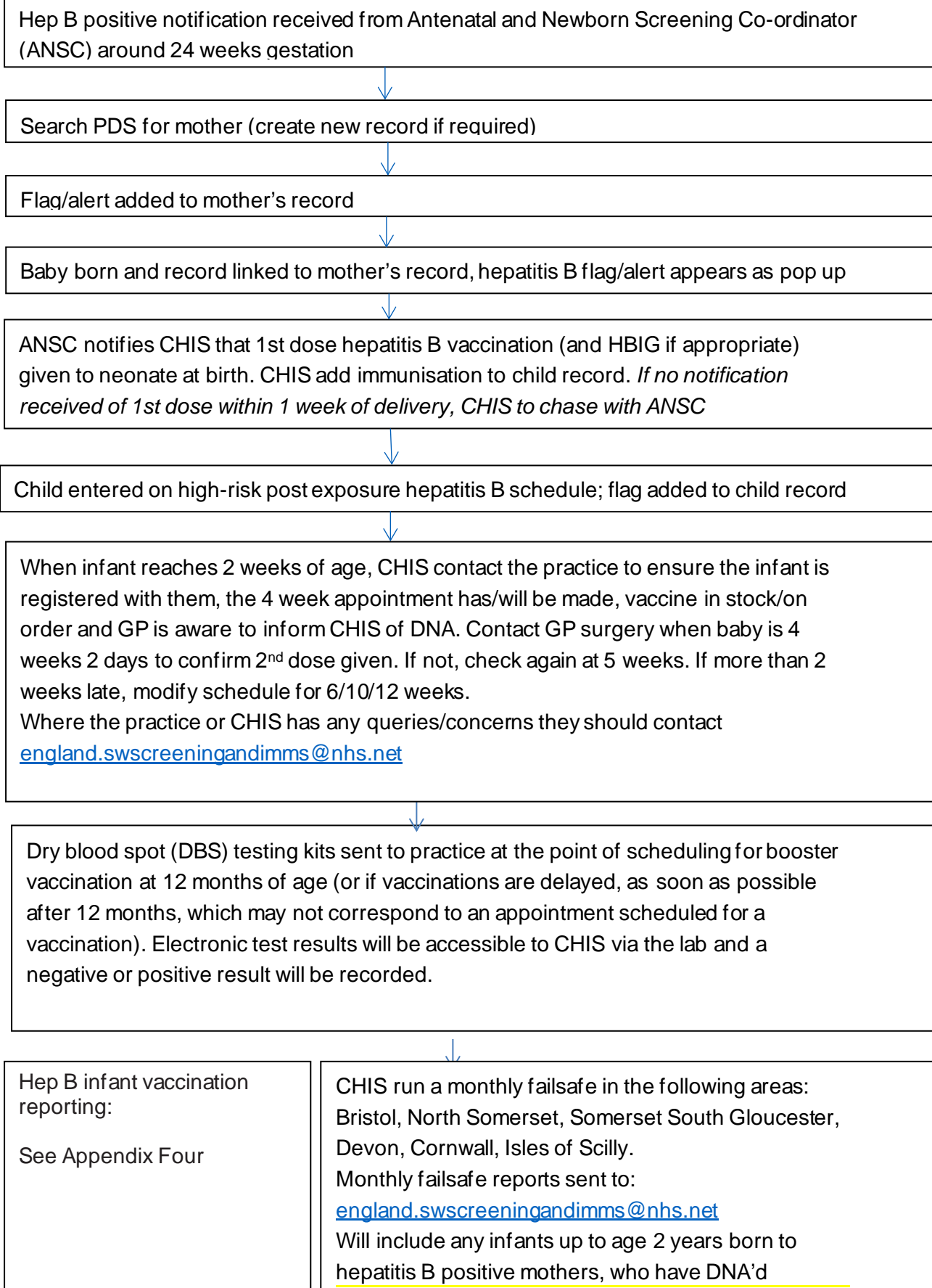
National arrangements

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:

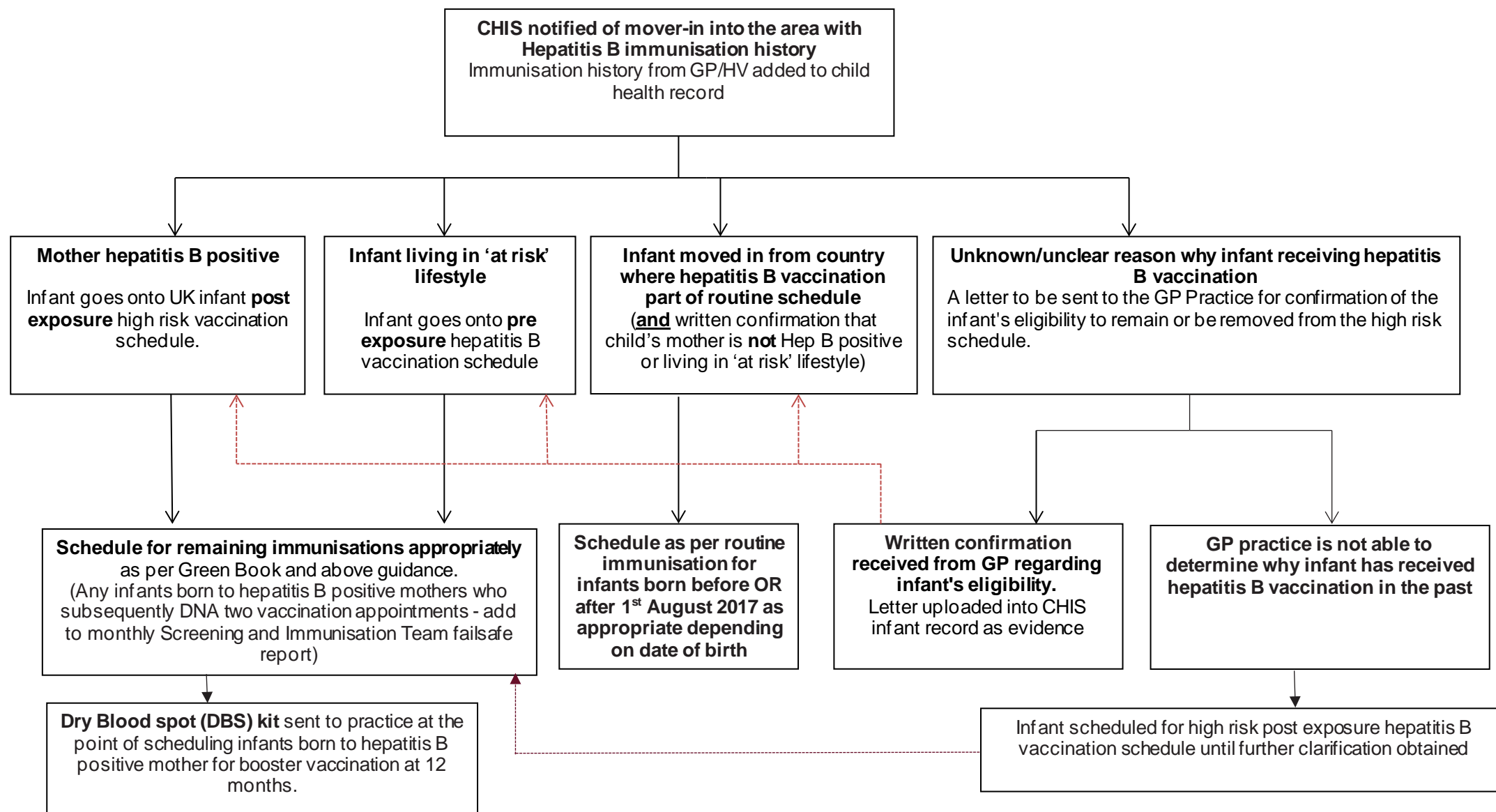
england.swscreeningandimms@nhs.net

Appendix Two

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



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



Appendix Four

CHIS infant Hepatitis B vaccination reporting

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

	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	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					