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NHS public health functions agreement 2019-20

**Service specification No.1
Neonatal hepatitis B immunisation programme**

NHS England and NHS Improvement



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Service specification No.01 Neonatal hepatitis B immunisation programme

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- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic and those who do not share it (as required under the Equality Act 2010); and
- Given due regard to the need to reduce inequalities between patients in access to, and outcomes from, healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities (in accordance with the duties under sections 13G and 13N of the NHS Act 2006, as amended).

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Service specification No.1

This is a service specification to accompany the 'NHS public health functions agreement 2019-20 (the '2019-20 agreement').

This service specification is to be applied by NHS England and NHS Improvement in accordance with the 2019-20 agreement. Where a specification refers to any other published document or standard, it refers to the document or standard as it existed at the date when the 2019-20 agreement was made between the Secretary of State and NHS England and NHS Improvement Board, unless otherwise specified. Any changes in other published documents or standards may have effect for the purposes of the 2019-20 agreement in accordance with the procedures described in Chapter 3 of the 2019-20 agreement

Service specifications should be downloaded in order to ensure that commissioners and providers refer to the latest document that is in effect.

The 2019-20 agreement is available at www.gov.uk (search for 'commissioning public health').

All current service specifications are available at www.england.nhs.uk (search for 'commissioning public health').

This service specification is not intended to replicate, duplicate or supersede any other legislative provisions that may apply. It must always be read in conjunction with the [core service specification](#) and the online version of the [Green Book](#).

1 Purpose of the neonatal hepatitis B immunisation programme

- 1.1 This document relates to the newborn hepatitis B vaccine, which protects newborn babies who are at risk of hepatitis B infection from their infected mothers. Hepatitis B is a chronic infection of the liver which can cause serious illness and premature death. This vaccine forms part of the national immunisation programme and is delivered alongside the hepatitis B antenatal screening programme. The purpose of the service specification is to enable NHS England and NHS Improvement to commission the newborn hepatitis B vaccine immunisation services of sufficient quantity and quality. This means achieving timely vaccination with high coverage rates in this group in appropriate settings across England. This programme requires evaluation and monitoring within the context of populations with protected characteristics as defined by the Equality Act 2010.
- 1.2 This specification provides a brief overview of the vaccines including the diseases they protect against, the context, evidence base, and wider health outcomes and should be read alongside the core immunisation service specification which underpins national and local commissioning practices and service delivery.
- 1.3 The existing programme provides a platform on which local services can develop and innovate to better meet the needs of their local population and work towards improving outcomes. This specification will also promote a consistent and equitable approach to the provision of the commissioning and delivery of the newborn hepatitis B vaccine across England. It is important to note that this programme can change and evolve in the light of emerging best practice, scientific evidence and changing vaccine formulation. NHS England and NHS Improvement and providers will be required to reflect these changes accordingly in a timely way as directed by the National schedule.
- 1.4 Immunisation against infectious disease (known as the [Green Book](#)), issued by Public Health England (PHE) provides guidance and has the latest information on vaccines and vaccination procedures for all the vaccine preventable infectious diseases that may occur in the UK. This service specification must be read in conjunction with the core immunisation service specification, the online version of the Green Book and all relevant official public health letters, and with additional evidence, advice and recommendations issued by the JCVI ([Joint Committee on Vaccination and Immunisation](#)). [Best practice guidance](#) was also issued by Department of Health (DH) in 2012 and is an important reference tool to support the delivery of high quality and robust hepatitis B antenatal screening and vaccination services.
- 1.5 This service specification is not designed to replicate, duplicate or supersede any relevant legislative provisions that may apply, e.g. the Health and Social Care Act 2012. The specification will be reviewed annually and amended in line with any new recommendations or guidance, and in line with reviews of the Section 7A agreement.

2 Population needs

Background

- 2.1 The neonatal hepatitis B vaccine is routinely used to protect newborns that have been exposed to hepatitis B infection from their mother at the time of birth. These babies are at extremely high risk of developing chronic hepatitis B infection and therefore going on to develop liver disease and liver cancer.

Hepatitis

- 2.2 Hepatitis B infection is a risk to public health. Mortality rates from liver disease are rising in the UK. Whilst there are multiple causes of progressive chronic liver disease, around 25% of all liver disease cases in the UK are due to hepatitis infections. A major cause of liver disease is infection with hepatitis B virus (HBV). When not treated, persistent HBV infection leads to premature death due to either cirrhosis or hepatocellular carcinoma in a large proportion of infected individuals.
- 2.3 If a pregnant woman has a chronic HBV infection, then:
- there is a 70–90% likelihood that hepatitis B infection will be transferred to the baby for the 10–15% of infected women who are of high infectivity.
 - there is a 10% likelihood that that hepatitis B infection will be transferred to the baby for the 90% of infected women who are of lower infectivity.
 - around 90% of babies infected at the time of birth will develop persistent HBV infection and be at risk of serious liver disease in later life.
 - timely immunisation can prevent the development of persistent HBV infection in over 90% of these cases.
- 2.4 Chronic HBV infection is unevenly distributed throughout the UK with some areas of the country having a higher prevalence of infection than other areas. The prevalence is generally highest in populations who have migrated from endemic countries (including most of Africa, Asia and parts of Eastern Europe). Hepatitis B service delivery models therefore need to be flexible and responsive according to local need. Department of Health policy has supported the provision of universal screening of pregnant women for hepatitis B and immunisation of babies at risk since 2000. The aim of the antenatal screening and infant immunisation pathway is to prevent perinatal hepatitis B infection. The hepatitis B antenatal screening and newborn immunisation programme best practice guidance is available here: <https://www.gov.uk/government/publications/hepatitis-b-antenatal-screening-and-newborn-immunisation-programme-best-practice-guidance>

Neonatal hepatitis B – key details

- 2.5 The key details are that:
- around 25% of all chronic liver disease in the UK is due to viral hepatitis infections.

- pregnant women are offered screening for hepatitis B; The UK National Screening Committee has issued [guidance](#) to support the commissioning and delivery of an effective screening programme.
- where pregnant women are identified through the screening process as being chronically infected with hepatitis B (i.e. hepatitis B surface antigen positive), or if the mother has acute hepatitis B in pregnancy, it is recommended that the baby is vaccinated from birth. Babies born to women of high infectivity, for example are also hepatitis B “e” antigen positive or have a high viral load, should also receive a single dose of hepatitis B specific immunoglobulin. See the [Green Book chapter 18](#) for more information.
- Since the introduction of universal infant hepatitis B immunisation into the routine childhood schedule for babies born on after 1 August 2017, babies born to hepatitis B infected mothers are vaccinated using a schedule of five doses of hepatitis B containing vaccine followed by a reinforcing dose at 12 months of age. These babies will have doses of monovalent hepatitis B vaccine at birth and 4 weeks of age. The third, fourth and fifth doses of hepatitis B containing vaccine are given as DTaP/IPV/Hib/HepB, which is now given to all babies at 8, 12 and 16 weeks of age. See the schedule at 4.5 below. At 12 months of age the baby also has a final dose of monovalent hepatitis B vaccine and a blood test (hepatitis B surface antigen) to check whether or not chronic infection has been prevented.
- timely immunisation is vitally important for these babies and can prevent persistent hepatitis B infection in around 90% of individuals who would have otherwise developed the infection.
- the blood test at 12 months old (preferably by dried blood spot testing to improve uptake) is a critical to identify persistent hepatitis B infection which is predominantly asymptomatic in this age group.

3 Scope

Aims

- 3.1 The aim of the neonatal hepatitis B vaccine programme is to protect those infants, identified to be at risk through antenatal screening of their mothers, from becoming persistently infected with hepatitis B.

Objectives

- 3.2 The aim will be achieved by delivering a targeted evidence-based immunisation programme that:
- identifies the eligible population and ensures effective and timely delivery with optimal coverage based on the target population set out in the Green Book.
 - is safe, effective, of a high quality and is independently monitored.
 - is delivered and supported by suitably trained, competent health-care professionals who participate in recognised ongoing training and development in line with national standards.
 - delivers, manages and stores vaccine in accordance with national guidance.
 - is supported by regular and accurate data collection using the appropriate returns.
 - ensures the appropriate handover of mother and baby from maternity services to those services completing the immunisation schedule in a timely manner.
 - achieves timely vaccination and 100% coverage for all babies born to hepatitis B infected mothers.
 - builds in robust arrangements for completion of the immunisation schedule and a 12-month blood test (i.e. dried blood spot or venous sample) to identify where immunisation has been unsuccessful at preventing transmission.
 - ensures referral of those infants who become persistently infected with hepatitis B despite vaccination to specialist care.

Direct health outcomes

- 3.3 In the context of health outcomes, the neonatal hepatitis B vaccine programme aims to:
- reduce the number of at risk newborn babies developing persistent hepatitis B infection.
 - reduce the number of preventable hepatitis B infections, sequelae/complications and their onward transmission.
 - minimise adverse physical/psychological/clinical aspects of immunisation (e.g. anxiety, adverse reactions).

Baseline vaccine coverage

- 3.4 Local services must ensure they maintain and improve current immunisation coverage with the aim of 100% of at risk newborn babies being immunised on time

in concordance with the [Green Book](#), and the Hepatitis B antenatal screening and newborn immunisation programme [Standards](#) and [Handbook](#), [Best practice guidance](#) and other official DH/PHE guidance including standards, performance indicators and key deliverables that are set out in Annex B of the NHS Public Health Functions Agreement (Section 7A) for 2019-20.

4 Service description / care pathway

Local service delivery

- 4.1 The delivery of immunisation services at the local level is based on evolving best practice. This section of the document specifies the high-level operational elements of the newborn hepatitis B vaccine programme, which can be delivered in a variety of health care settings, based on that best practice that NHS England and NHS Improvement must use to inform local commissioning, contracts and service delivery. There is also scope to enable NHS England and NHS Improvement and providers to enhance and build on specifications to incorporate national or local service aspirations that may include increasing local innovation in service delivery. It is essential, in order to promote a nationally aligned, high-quality programme focusing on improved outcomes, increasing coverage and local take-up that all the following core elements are included in contracts and specifications.

Target population

- 4.2 The neonatal hepatitis B vaccination must be made available to all newborn babies identified through the hepatitis B antenatal screening programme.
- 4.3 This includes babies born to mothers found to be hepatitis B surface antigen (HBsAg) positive through the antenatal screening programme and babies born to women who deliver without being screened but are known to be hepatitis B surface antigen positive.
- 4.4 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.

Vaccine schedule

- 4.5 The schedule¹ for all newborn babies identified as being at risk is as follows:

¹ This schedule may change with the advent of changed vaccine formulations.

Scheduled age	Immunisation given and follow up	Target standard
Birth	Monovalent HepB	Within 24 hours of birth. With HBIG, where indicated
4 weeks	Monovalent HepB	
8 weeks	Hexavalent DTaP/ IPV/HiB/HepB	
12 weeks	Hexavalent DTaP/ IPV/HiB/HepB	
16 weeks	Hexavalent DTaP/ IPV/HiB/HepB	
12 months	Monovalent HepB	
12 months	Blood test	To check the child's infection status (test for HBsAg). Referral to specialist if positive.
With pre-school booster at 3 years and 4 months		Check that at-risk infants born before introduction of hexavalent vaccine are up-to-date and have completed a primary hepatitis B course and have had a blood test performed at 12 months of age; if not, they should be done at this visit.

- As the newborn baby has already been exposed to infection (at the time of birth), to ensure adequate protection, providers should aim to give the first dose of vaccine (with hepatitis B immunoglobulin if indicated) within 24 hours of birth.
- Timeliness of the 4 week dose is also critical; vaccination should not be delayed because a birth certificate has not yet been issued. There is no regulatory requirement to prove identity, address, immigration status or an NHS number in order to register as a patient and no contractual requirement for GPs to request this.
- Services should also aim to complete the schedule as near as possible to the recommended ages. Sufficient immunisation appointments must be available so that individuals can receive vaccinations on time.
- Children found to be positive for hepatitis B surface antigen at 12 months of age must be referred for specialist assessment.
- Public Health England (Colindale) offers a free dried blood spot testing service for infants born to hepatitis B infected mothers. For further information on the DBS testing service for at risk infants: <https://www.gov.uk/guidance/hepatitis-b-dried-blood-spot-dbs-testing-for-infants>
- Further information on scheduling is available in the relevant chapters of the Green Book: <https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>

- For further information on best practice guidance: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126195

Vaccine ordering

- 4.6 NHS hospital based service providers can obtain monovalent hepatitis B vaccine through NHS framework agreements. In other settings monovalent hepatitis B vaccine may be obtained from nationally approved pharmaceutical wholesalers who will have local arrangements for the delivery of these vaccines or direct from the manufacturers. All centrally procured vaccines (e.g. DTaP/IPV/Hib/HepB), are to be used only for the delivery of the programme to the target groups detailed above, must be ordered via the ImmForm online ordering system, details of which are given in the core immunisation specification.
- 4.7 Hepatitis B specific immunoglobulin (HBIG) for babies born to mothers of high infectivity is supplied free of charge from Public Health England. Supply should be ordered early in the antenatal period using the form on the [website](#). Where an unbooked mother presents in labour, an urgent maternal HBsAg test and e-markers and/or viral load should be undertaken rapidly to advise on whether vaccine and HBIG are required for the baby. If HBIG is required urgently, stock can be accessed through the Public Health England 24-hour on-call service (0208 200 6868).