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Service specification No.1

Neonatal hepatitis B immunisation programme

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Neonatal hepatitis B immunisation programme

Prepared by Public Health England

Contents

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This is a service specification within Annex C of the ‘NHS public health functions agreement 2015-16 (the ‘2015-16 agreement’) published in December 2014.

This service specification is to be applied by NHS England in accordance with the 2015-16 agreement. This service specification is not intended to replicate, duplicate or supersede any other legislative provisions that may apply.

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 2015-16 agreement was made between the Secretary of State and NHS England Board. Any changes in other published documents or standards may have effect for the purposes of the 2015-16 agreement in accordance with the procedures described in Chapter 3 of the 2015-16 agreement

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

The 2015-16 agreement including all service specifications within Annex C is available at www.gov.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 https://www.gov.uk/government/publications/public-health-commissioning-in-the-nhs-2015-to-2016 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 from 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 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 and scientific evidence. NHS England 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 Hep 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 Hep B vaccine is routinely used to protect newborns who have been exposed to hepatitis B infection from their mother at the time of birth. These babies are at extremely high risk from 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. Childhood infection accounts for an estimated 21% of all new persistent infections acquired in the UK.

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. Hepatitis B Antenatal Screening and Newborn Immunisation Vaccine Programme. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126195

Neonatal Hep 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.
- hepatitis B infection transmitted from mother to child accounts for 21% of newly acquired hepatitis B infections in the UK
- 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 (Hepatitis B surface antigen positive) it is recommended that the baby is vaccinated. Babies born to women of high infectivity should also receive a single dose of hepatitis B specific immunoglobulin.
- the baby is vaccinated using an accelerated schedule comprising of three vaccines followed by a booster dose at 12 months of age. The baby is also given a blood test at 12 months to check whether or not infection has been prevented.
- timely immunisation can prevent persistent hepatitis B infection in around 90% of individuals who would have otherwise developed the infection.

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 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 on going 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
- achieve timely vaccination and high coverage across all groups identified
- that builds in robust arrangements for completion of the immunisation schedule and a 12-month blood test to identify where immunisation has been unsuccessful at preventing transmission.
- ensures referral of those infants who become persistently infected with hepatitis 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 newborns at risk from developing persistent hepatitis B infection
- reduce the number of preventable hepatitis B infections 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 offered immunisation in concordance with the Green Book, and the *Hepatitis B antenatal screening and newborn immunisation programme*, *Best practice guidance* and other official DH/PHE guidance including performance indicators and key deliverables that are set out in Annex B of the NHS Public Health Functions Agreement (Section 7A) for 2015-16

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 must use to inform local commissioning, contracts and service delivery. There is also scope to enable NHS England 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 newborn hep B vaccines should be made available to:

- all newborns identified through the hepatitis B antenatal screening programme to be at high risk of hepatitis B infection as set out in the Green Book.

4.3. This includes babies born to mothers found to be hepatitis B surface antigen 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 *Immunisation against infectious disease* 2006 (a dose of hepatitis B specific immunoglobulin (HBIG) should be given with the first dose of vaccine.

Vaccine schedule

4.5. The schedule for all newborn babies identified as “at risk” is.

	Scheduled age	Target standard
Dose 1	Birth	Within 24 hours of birth With HBIG where indicated
Dose 2	1 month	
Dose 3	2 months	
Dose 4	12 months	At least one month from dose 3
Blood test	12 months	To check the child’s infection status (test for HBsAg)

Dose 5	With pre-school booster	To be given to those at continued risk from Hep B

- As the child has already been exposed to infection (at the time of birth), to ensure adequate protection, providers should aim to give the first dose Within 24 hours of birth
- Children found to be positive for hepatitis B surface antigen at 12 months of age must be referred for specialist assessment.
- Providers 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.
- Further information on scheduling is available in the relevant chapters or *Immunisation against infectious disease* 2006
- For further information follow http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126195

Vaccine ordering

4.6. Hospital providers can obtain vaccine through NHS framework agreements. In other settings supplies may be obtained from nationally approved pharmaceutical wholesalers who will have local arrangements for the delivery of these vaccines or direct from the manufacturers.

Hepatitis B specific immunoglobulin for babies born to mothers of high infectivity is supplied free of charge from Public Health England. Supply should be ordered in the antenatal period using the form on the website. For unbooked deliveries, stock can be accessed through the 24-hour on-call service (0208 200 6868).