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of Health



NHS public health functions agreement 2015-16

Service specification No.2

Neonatal BCG immunisation programme

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Neonatal BCG immunisation programme

Prepared by Public Health England

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Service specification No.2

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: <https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>

1. Purpose of neonatal BCG immunisation programme

- 1.1. This document relates to the neonatal BCG immunisation programme, which aims to protect newborn babies who are at an increased risk from exposure to, or developing human tuberculosis (TB) which may result in serious illness and premature death.
- 1.2. The purpose of the service specification is to enable NHS England to commission neonatal BCG vaccine immunisation services that are of sufficient quantity and quality to achieve high coverage rates in the identified at risk population and which are delivered in appropriate settings across England. Services must be equitable and within the context of populations with protected characteristics as defined by the Equality Act 2010.
- 1.3. This specification provides a brief overview of the vaccine(s) and the disease against which protection is conferred the context, evidence base, and wider health outcomes, and should be read alongside the core service specification which underpins national and local commissioning practices and service delivery.
- 1.4. The existing, highly successful programme provides a firm platform on which local services can develop and innovate to better meet the needs of their local population and work towards improving uptake and outcomes. This specification will also promote a consistent and equitable approach to the commissioning, provision and delivery of the neonatal BCG vaccine across England. It is important to note that this programme may be subject to change in response to epidemiological changes, 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.
- 1.5. *Immunisation against infectious disease* (known as 'The Green Book'), issued by Public Health England provides guidance and is the main evidence base for all immunisation programmes. This service specification must be read in conjunction with the core immunisation service specification, the online version of the Green Book, other official Public Health letters and guidance/recommendations issued by the Joint Committee on Vaccination and Immunisation (JCVI), and must be reflected in the commissioning of this immunisation programme. This specification must also be read in conjunction with additional evidence, guidance and literature issued by the Joint Committee on Vaccination and Immunisation (JCVI).

Link to Green Book:

<https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book>

Link to JCVI web pages:

- 1.6. <https://www.gov.uk/government/policy-advisory-groups/joint-committee-on-vaccination-and-immunisation>

- 1.7. 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 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 BCG vaccine is routinely used to protect newborn babies who are at an increased risk of or exposure to TB infection,
- 2.2. Human tuberculosis (TB) is caused by infection with bacteria of the *Mycobacterium tuberculosis* complex (*M. tuberculosis*, *M. bovis* or *M. africanum*) and may affect almost any part of the body. The most common form is pulmonary TB, which accounts for almost 60% of all cases in the UK. Non-respiratory forms of TB are more common in young children in communities with connections to areas of the world with high prevalence, and in those with impaired immunity.
- 2.3. Almost all cases of TB in the UK are acquired through the respiratory route, by breathing in infected respiratory droplets from a person with infectious respiratory TB. The risk of transmission is increased when the index case is smear positive and where there is prolonged close contact e.g. living in the same household.
- 2.4. As Latent TB infection may reactivate in later life, particularly if an individual's immune system has become weakened, for example by disease (e.g. HIV), certain medical treatments (e.g. cancer chemotherapy, corticosteroids) or in old age newborn babies may be unknowingly exposed to the infection.

BCG immunisation programme

- 2.5. The BCG immunisation programme was introduced in the UK in 1953. However in response to changing trends in the epidemiology of TB the programme, which was initially targeted at children of school-leaving age
- 2.6. is now delivered as a risk-based programme. A key part of this risk based approach is the selective neonatal programme targeted at those infants most at risk of exposure to TB.
- 2.7. This service specification relates only to the selective neonatal immunisation programme.

Neonatal BCG – key details

- 2.8. The key details are that:
 - following a continued decline in TB rates in the indigenous population the schools based BCG programme was stopped in 2005
 - it has been replaced with a risk-based programme, the key part being the neonatal programme which targets those infants most at risk from or exposure to TB
 - it is offered to all infants (0–12 months) living in areas of the UK where annual incidence of TB is 40/100,000 or greater

- it is offered to all infants (0–12 months) where one or more parent or grandparent was born in a country where the annual incidence of TB is 40/100,000 or greater¹
- the BCG (Bacillus Calmette-Gurein) vaccine contains a live attenuated strain of mycobacterium. A single dose is required for infants under 12 months in line with national recommendations.
- It is important that the guidance on neonatal BCG immunisation in the Green Book is followed at all times: <https://www.gov.uk/government/publications/tuberculosis-the-green-book-chapter-32>
- analysis shows the vaccine to be 70 to 80% effective against the most severe forms of the disease that includes TB meningitis in children.

Universal vaccination may operate in areas of the country where TB incidence is 40/100,000 or greater. This is applied for operational reasons since these geographical areas generally have a high concentration of families who come from regions of the world where the TB incidence is 40/100,000 or greater. The decision to offer universal BCG immunisation is likely to be made in consultation with local consultants in health protection, public health, epidemiologists and TB/respiratory consultants. They may choose to offer it for example to the whole of a local authority area or selected districts.

¹ For country information on prevalence see: www.who.int/tb/country/data/profiles/en/index.html

3. Scope

Aims

- 3.1. The aim of the selective neonatal BCG immunisation programme is to protect those infants (0-12 months of age), identified in 'at risk' groups as being at an increased risk from or exposure to TB infection.

Objectives

- 3.2. The aim will be achieved by delivering an evidence-based, population-wide immunisation programme that:
- identifies the eligible population and ensures effective timely delivery with optimal coverage based on the target population set out in paragraph 4.4
 - is safe, effective, equitable and of a high quality and is independently monitored via the Area Team
 - is delivered and supported by appropriately trained, competent healthcare professionals who participate in 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 as required nationally and/or locally.

Direct health outcomes

- 3.3. In the context of health outcomes the selective neonatal BCG vaccine programme aims to:
- reduce the number of new-borns at risk from or exposure to TB infection
 - reduce the number of preventable infections and their onward transmission
 - achieve high coverage across the groups identified
 - 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 accordance with the Green Book. As uptake has been shown to be higher if immunisation is given in the postnatal ward setting compared to community setting, providers should aim to vaccinate eligible newborn babies prior to discharge.

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 selective neonatal BCG vaccine programme, which may be delivered in a variety of health care settings, and which NHS England must use to inform local commissioning, contracts, service delivery and performance. Whilst there is scope to enable NHS England and providers to enhance and build on specifications to incorporate national or local service aspirations and local innovations in service delivery, it is essential, in order to promote a nationally aligned, high-quality, equitable programme which focuses on improved outcomes, increased coverage and local take-up that all of the core elements which are set out in the core specification are included in contracts..
- 4.2. More detailed information on at risk groups is available in chapter 32 of the Green Book <https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book>

Target population

- 4.3. Providers will be required to make the neonatal BCG vaccine available to:
 - all infants (aged 0–12 months) living in areas of the UK where annual incidence of TB is 40/100,000 or greater
 - all infants (aged 0–12 months) with one or more parent or grandparent who was born in a country where the annual incidence of TB is 40/100,000 or greater.

Vaccine schedule

- 4.4. A locally commissioned service should immunise those new-borns identified as at risk with a single dose of vaccine in accordance with the national recommendations. Contraindications as outlined in the Green Book must be observed.
 - For further information follow <https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book>

Vaccine ordering

- 4.5. All centrally procured vaccines must be ordered via the ImmForm online ordering system, details of which are given in the core immunisation specification.

