



Public Health  
England



# NHS public health functions agreement 2019-20

Service specification No.2  
Neonatal BCG immunisation programme

NHS England and NHS Improvement



# **NHS public health functions agreement 2019-20**

## **Service specification No.2**

### **Pertussis pregnant women immunisation programme**

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Promoting equality and addressing health inequalities are at the heart of NHS England and NHS Improvement values. Throughout the development of the policies and processes cited in this document, we have:

- 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).

# Contents

Service specification No.2 .....	5
1 Purpose of neonatal BCG immunisation programme .....	6
2 Population needs .....	7
Background.....	7
BCG immunisation programme .....	7
Neonatal BCG – key details.....	7
3 Scope.....	9
Aims.....	9
Objectives .....	9
Direct health outcomes .....	9
Baseline vaccine coverage .....	9
4 Service description/care pathway .....	10
Local service delivery .....	10
Target population .....	10
Vaccine schedule.....	10
Vaccine ordering .....	10

## Service specification No.2

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](http://www.gov.uk) (search for 'commissioning public health').

All current service specifications are available at [www.england.nhs.uk](http://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 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 and NHS Improvement 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 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 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 NHS Improvement 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 England 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.
- 1.6 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 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*, *M. africanum* or *M. microti*) and may affect almost any part of the body. Pulmonary TB accounts for just over 50% 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/open 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 is 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.
- 2.6 This service specification relates only to the selective neonatal immunisation programme.

### Neonatal BCG – key details

- 2.7 The key details are that:
  - the risk-based programme targets those infants most at risk from exposure to TB infection;
  - 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 greater<sup>1</sup>;
  - antenatal risk assessment to accurately identify these babies is a cornerstone of this programme;
  - the BCG (Bacillus Calmette-Guérin) vaccine contains a live attenuated strain of mycobacterium. A single dose is required for infants under 12 months in line with national recommendations;

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<sup>1</sup> For country information on prevalence see: [www.who.int/tb/country/data/profiles/en/index.html](http://www.who.int/tb/country/data/profiles/en/index.html)

- 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 - 80% effective against the most severe forms of the disease that includes TB meningitis in children.

2.8 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.



## 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 4.3;
  - is safe, effective, equitable and of a high quality and is independently monitored via the Screening and Immunisation Teams based within NHS England and NHS Improvement;
  - 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; and
  - is supported by systematic 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; and
  - 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 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 selective neonatal BCG vaccine programme, based on the best practice that NHS England and NHS Improvement must use to inform local commissioning, contracts and service delivery.
- 4.2 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 core elements that are set out in the core specification are included in contracts and specifications.

### 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-born babies 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 visit <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.