University Hospitals Sussex
NHS Foundation Trust

Neonatal BCG Immunisation Programme

Maternity Protocol: MP065

Date agreed: January 2022

Guideline Reviewer:	Bettina Reulecke & Marie Hornsby
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Contents

Key Principles:

A protocol is a set of measurable, objective standards to determine a course of action. Professional judgement may be used in the application of a protocol.

Scope:

This protocol applies to all women; those booking at any stage of pregnancy, women who deliver and those who receive postnatal care.

Neonatal BCG vaccine is offered to

- All infants (0-12 months) living in areas of the UK where annual incidence of TB is 40/10,000 or greater.
- 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.

University Hospital Trust is responsible for antenatal identification of babies who meet the criteria for neonatal BCG and for referring these babies at birth

University Hospital Trust is financially responsible under national Maternity Pathway Payment rules for all babies born at Brighton & Sussex University Hospitals who receive a neonatal BCG vaccination

Responsibilities:

Midwives & Obstetricians

- To access, read, understand and follow this guidance

Paediatricians & Neonatologists

- To access, read, understand and follow this guidance

Management Team

- To ensure the protocol is reviewed as required in line with Trust and national recommendations
- To ensure the protocol is accessible to all relevant staff
- To ensure the protocol is aligned with the external neonatal BCG service commissioned
- To ensure the protocol and procedures are compliant with Caldicott guidance and information sharing governance

1 Neonatal BCG Immunisation Programme

1.1 The aim of the neonatal BCG immunisation programme is 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 neonatal BCG vaccine is routinely used to protect newborn babies who are at increased risk of exposure to TB infection.

1.3 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

1.4 The key details of neonatal BCG are

- It is 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 40/10,000 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**
- 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
- It is important 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

1.5 The referral form (Appendix A) identifies the countries with a high risk of TB (120). This form is reviewed annually and countries amended according to WHO list of countries with prevalence > 40 per 100,000.

2 BCG Vaccination Pathway

2.1 Antenatal Pathway

2.1.1 All women/ people have a booking appointment with a midwife. At booking the midwife will identify all babies who require a BCG. The midwife will-

- Record in maternity notes (handheld notes) that the baby will require a BCG
- Record on the Booking Form that the baby will require a BCG using the field provided
- Ensure that all eligible women are given a BCG vaccination information leaflet
- Signpost women to website if there is no leaflet available

2.2 Booking forms are sent to the maternity administration office where information is taken from the form and put onto the maternity IT database (Maternity Smart).

2.3 The identification of babies requiring BCG vaccine will not be recorded on Maternity Smart at this time. These women and babies will be recorded on the BCG database specifically established for this purpose.

2.4 The following information must be entered onto the BCG database for all babies identified at risk

- NHS number of woman
- Estimate Date of Delivery (EDD)
- Address
- Date of booking appointment
- Date baby inputted onto the BCG database

2.5 Postnatal Pathway

2.5.1 Following the delivery of baby, the clinician undertaking the Newborn Infant Physical Examination (NIPE) must;

- Check whether the baby was identified antenatally as requiring BCG vaccine using handheld notes
- Identify whether the baby meet the neonatal BCG vaccination criteria.
- Explain the implications of TB and the protection offered by the BCG to the parents and provide a BCG vaccination information leaflet
- Gain consent to refer and refer the baby to the local, external BCG immunisation service

2.6 Referral to BCG vaccination service

2.6.1 The clinician making the referral must

- Ensure the electronic referral form is completed in full (incomplete forms will be returned by the service provider)
- Midwives email the referral directly to the administrators. Doctors/ANNP'S will save the referral in the Team Drive folder (Team Drive -> TMBUSHO -> NIPE REFERRAL LETTERS -> BCG REFERRALS) from which it will be picked up by the administrator

2.6.2 The administrator must

2.6.2.1 Email any referrals to the service provider as requested by clinicians

2.6.2.2 Save a copy of completed referral form in the Team Drive folder called BCG referrals

2.6.2.3 Update the BCG database with

- DOB of the baby
- Baby's initials
- The date the referral was made (Baby identified at birth and date electronic referral made)
- Acknowledgement of the referral is received from the external immunisation service (Receipt of referral acknowledged by SCT)

2.7 Referral Protocol

2.7.1 The following must be adhered to for all referrals

- Referrals must be made electronically on the agreed referral form (Appendix A) within 72 hours to the Sussex Community Trust.
- Referrals must be complete or they will be returned by the service provider
- Only one referral can be sent in an email
- The initials for the baby and DOB must be in the email Subject box
- Record on the database that receipt of referral has been acknowledged

2.7.2 Babies who are referred for BCG and whose mother is HIV positive will also require a letter from the nominated neonatal lead (Dr Bomont) to be sent to the neonatal BCG vaccination service. It is the responsibility of the clinician making the referral to include the HIV status of the mother on the referral form and to notify the neonatal lead of the referral.

3 Neonatal BCG Vaccination Service

3.1 The BCG vaccination service is delivered by Sussex Community Trust (SCT) under an SLA arrangement.

3.2 The service commissioned is expected to meet the NHSE national specification (updated local specification awaited) and meets the Surrey & Sussex BCG Pathway (Appendix B) as defined below;

- 3rd Party provider to acknowledge referral
- Record, send appointment & document consent for BCG immunisation with parent and send information leaflet
- Following immunisation - record immunisation including batch number and date given in Red Book, health records and/or Community Information System (CIS)
- Notify CHRD that BCG has been given, who will notify GP (SCT will notify GP direct)
- If baby does not attend (DNA) for immunisation after two invitations, letter to be sent to GP and copy to Health Visitor Team and CCHIB

3.3 The following arrangements have been reached with SCT

- Return of incomplete or ineligible forms to the BSUH administrator
- Acknowledgment of receipt of all referrals
- Escalation of babies that are referred by clinicians NOT in BSUH midwifery or neonatology/paediatric services e.g. health visitors or GPs. This will be done be done by email by SCT to nominated BSUH representatives
- Input of date of BCG into the shared database by SCT for all babies born at BSUH
- Information requirements as per identified reporting requirements in next section

3.4 SCT will support national and local reporting with the provision of timely and accurate data in line with the national reporting requirements (Section 5).

4 Failsafe Procedures

4.1 BCG vaccination database to be checked by administrator monthly to ensure all babies with expected EDD have been born and referred for a BCG. Investigation of those that have not been referred but for which there is no known reason, e.g. they have not yet delivered, moved away or still birth, will be by a Lead midwife for BCG.

4.2 Acknowledgement from provider on the receipt of every referral and recorded on database

4.3 Investigation by the Lead midwife for BCG of all babies that have been escalated by Sussex Community Trust who were born at Royal Sussex County Hospital, Princess Royal or at home who were NOT identified and referred by maternity services or paediatricians/neonatologists but referred instead by health visitors or GPs (as examples).

5 Reporting Requirements

5.1 The following are the local reporting requirements in place:

- SCT will provide a monthly activity report detailing all the babies that have received a BCG vaccination that month
- SCT will provide a monthly invoice

5.2 National reporting requirements are defined in the NHS England, 2016/17 NHS Standard Contract Particulars for NHS Neonatal BCG Immunisation Programme: Schedule 6 – Contract Management, reporting and information requirements; B. Reporting Requirements document (Table 1 below). It is BSUH's responsibility to report on this service however SCT will support BSUH reporting by:

- Providing routine data to NHS England, Public Health England, and the Health and Social Care Information Centre, in a timely manner.
- Contribute to national data collection exercises where required
- Provide annual data measuring performance against both standards and the Key Performance Indicators.

5.3 Table 1: Reporting Requirements

Local Requirements & Reported Locally	Reporting Period	Format of Report	Timing and Method for delivery of Report	BSUH/SCT Application
A robust tracking and failsafe system is in place and is monitored appropriately	May 2016	Ratified SOP	To be submitted to commissioner by end May 2016	To be in place by June 2016
Number of babies identified at birth as eligible for neonatal BCG vaccination	Monthly, 5th of the month	Number per month – denominator (eligible cohort)	Submitted a full calendar month after birth, so all babies born in April will be reported after the end of May	Start June 2016 (report after end of Aug)
Of those the number who were identified antenatally	Monthly, 5th of the month	Number per month -	Submitted a full calendar month after birth, so all babies born in April will be reported after the end of May	Link to antenatal identification will be in place from Dec 2016 (report after end of Jan 2017)
All babies in the eligible cohort who were offered BCG vaccination prior to discharge or referred to a third party provider (as identified in SOP)	Monthly, 5th of the month	Number per month -	Submitted a full calendar month after birth, so all babies born in April will be reported after the end of May. This allows direct comparison of like for like cohort	June 2016 (report after end of Aug)
All babies in the eligible cohort who were given BCG vaccination within 30 days of birth	Monthly, 5th of the month	Number per month -	Submitted a full calendar month after birth, so all babies born in April will be reported after the end of May. This allows direct comparison of like for like cohort	June 2016 (report after end of Aug)
Service User Experience	Annual	Written report	Annual Report	Annual - Feedback opportunities and Friends & Family used in the whole service
Improving Service Users & Carers Experience	Annual	Written report	Annual report	Annual - Feedback opportunities and Friends & Family used in the whole service
Reducing Inequalities and Barriers		If 100% offer and uptake not achieved, audit and analysis	Annual Immunisation Health Equality Action Plan	Review in a year once robust governance and processes in place
Improving Productivity and reducing vaccine waste	Biannual	Written report	Performance dashboards reviewed quarterly	To be provided by SCT
Storage - Compliance with cold chain according to PHE national guidance		Quarterly exception reports to SIT Evaluation shared quarterly	Weekly cold chain audit undertaken by provider. Evaluation shared quarterly	SCT compliant and to provide next evaluation and any exception reports.
Documentation	Annually	Written report	Share evidence of audits undertaken with NHSE and SIT	Annual - SCT to share with BSUH.
Vaccine related incidents Report any vaccine significant events and serious incidents to SIT	By exception	SI/SE form	Completed Vaccine Incident Report Form sent to SIT	SCT to notify SIT as per current process. BSUH to be notified of any incidents.

Appendix A: BCG vaccine referral form

PLEASE COMPLETE ONE FORM PER CHILD

ALL FIELDS UNLESS STATED ARE MANDATORY – INCOMPLETE REFERRALS WILL BE RETURNED

Please return each completed form by email to: SC-TR.imms-team@nhs.net

CHILDS DETAILS					
Child's Forename: *(please print)*		**Child's Surname:** *(please print)*			
Address:		**Date of Birth:**		**Age:**	
		NHS Number:		**Sex:**	**F** ☐ **M** ☐
Postcode:		**School:** *(if applicable)*			
Contact Number of Person with Parental Responsibility: *(to opt out of text reminders tick here)* ☐		Is an interpreter required for the BCG appointment? **Yes** ☐ **No** ☐ **If answered yes,** *please specify the language:*			
GP Name:		**Hospital of Birth:**			
GP Practice Address:		**CPP** ☐ **LAC** ☐ Please tick if applicable	Please ensure person with parental responsibility is available for consent.		

Please answer all of the following questions.	**YES**	**NO**
Was the child born in one of the TB high risk countries overleaf? **If answered yes,** *please specify the country:*		
Does the child have a parent or grandparent who was born in one of the TB high risk countries overleaf? **If answered yes,** *please specify the country:*		
Has the child lived in a TB high risk country for longer than 3 consecutive months? **If answered yes,** *please specify the country:*		
Are there any clinically relevant medical conditions? (e.g. prematurity, maternal HIV etc) **If answered yes,** *please state the clinically relevant medical conditions below*: (e.g. prematurity, maternal HIV etc		
Has the **mother** received TNFa antagonists or other biological immunosuppressive treatment either in pregnancy or whilst breast feeding? **If answered yes,** *the immunisation will be postponed and the Immunisation Team will contact mother to discuss.*		
For maternal HIV only, *please tick box to state risk of transmission **OR** please provide most recent maternal HIV viral load before baby was born in the box provided below*		
High risk ☐	Low risk ☐	Very low risk ☐	Viral load result:
Any other relevant information? (e.g. SCBU, plans to travel)		

REFERRERS DETAILS			
Name: *(please print)*		**Job Title:**	
Contact Number:		**Address/Base:**	
Date:		**Signature:**	

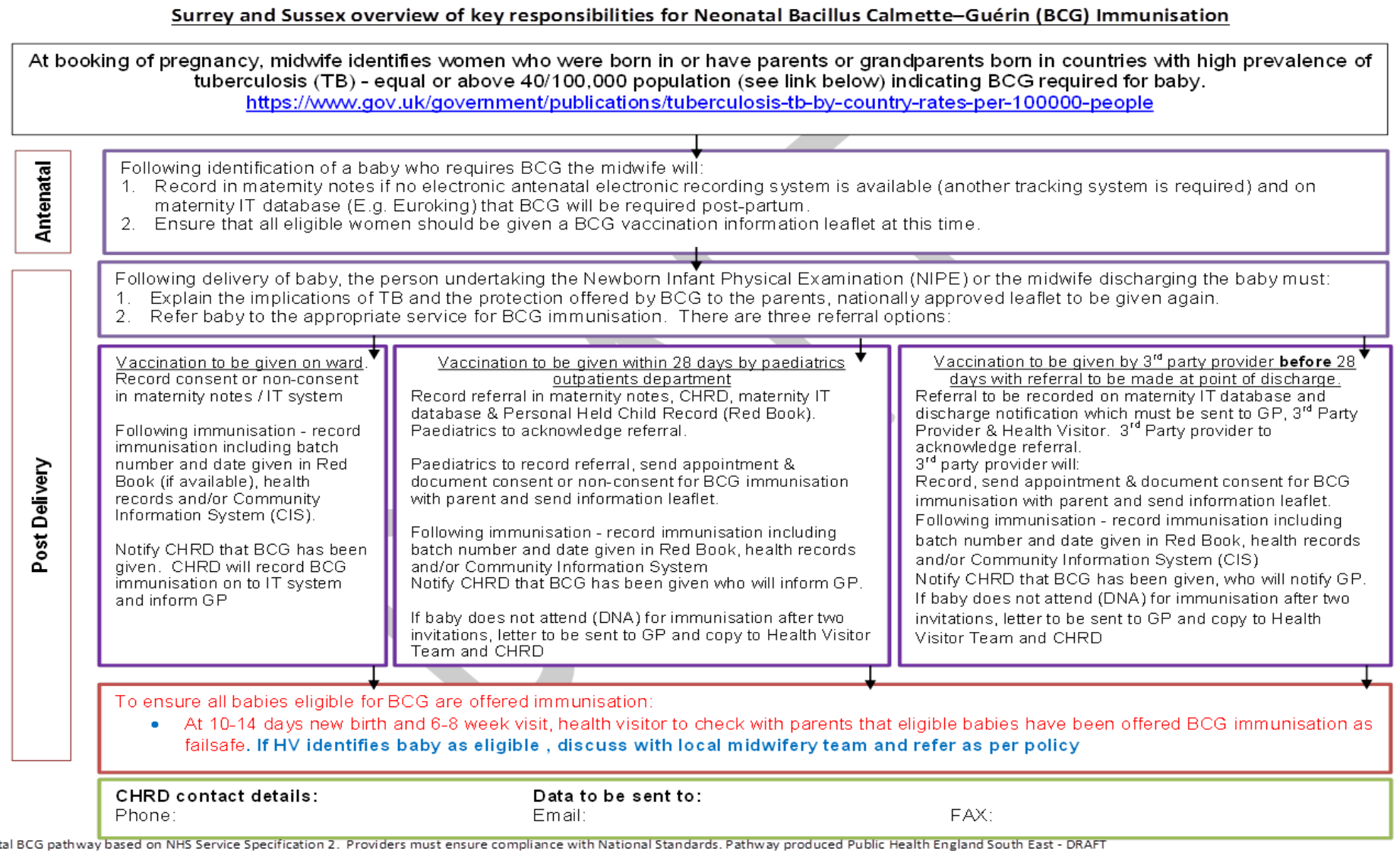
COUNTRIES WITH A HIGH RISK OF TB				
Afghanistan	DPR Korea	Iraq	Nepal	Somalia
Algeria	DR Congo	Kazakhstan	Nicaragua	South Africa
Angola	Djibouti	Kenya	Niger	South Sudan
Azerbaijan	Dominican Republic	Kiribati	Nigeria	Sri Lanka
Bangladesh	Ecuador	Kyrgyzstan	Niue	Sudan
Benin	El Salvador	Lao PDR	Northern Mariana Islands	Tajikistan
Bhutan	Equatorial Guinea	Lesotho	Pakistan	Thailand
Bolivia (Plurinational State of)	Eritrea	Liberia	Palau	Timor-Leste
Botswana	Eswatini	Libya	Panama	Togo
Brazil	Ethiopia	Lithuania	Papua New Guinea	Turkmenistan
Brunei Darussalam	Fiji	Madagascar	Paraguay	Tuvalu
Burkina Faso	Gabon	Malawi	Peru	Uganda
Burundi	Gambia	Malaysia	Philippines	Ukraine
Cabo Verde	Georgia	Mali	Rep. Korea	UR Tanzania
Cambodia	Ghana	Marshall Islands	Republic of Moldova	Uzbekistan
Cameroon	Greenland	Mauritania	Romania	Vanuatu
Central African Republic	Guam	Micronesia (FSO)	Russian Federation	Venezuela (Bolivarian Republic of)
Chad	Guinea	Mongolia	Rwanda	Viet Nam
China	Guinea-Bissau	Morocco	Sao Tome & Principe	Yemen
China, Hong Kong	Guyana	Mozambique	Senegal	Zambia
China, Macao SAR	Haiti	Myanmar	Sierra Leone	Zimbabwe
Congo	India	Namibia	Singapore	
Côte d'Ivoire	Indonesia	Nauru	Solomon Islands	

Source

https://www.gov.uk/government/publications/tuberculosis-tb-by-country-rates-per-100000-people

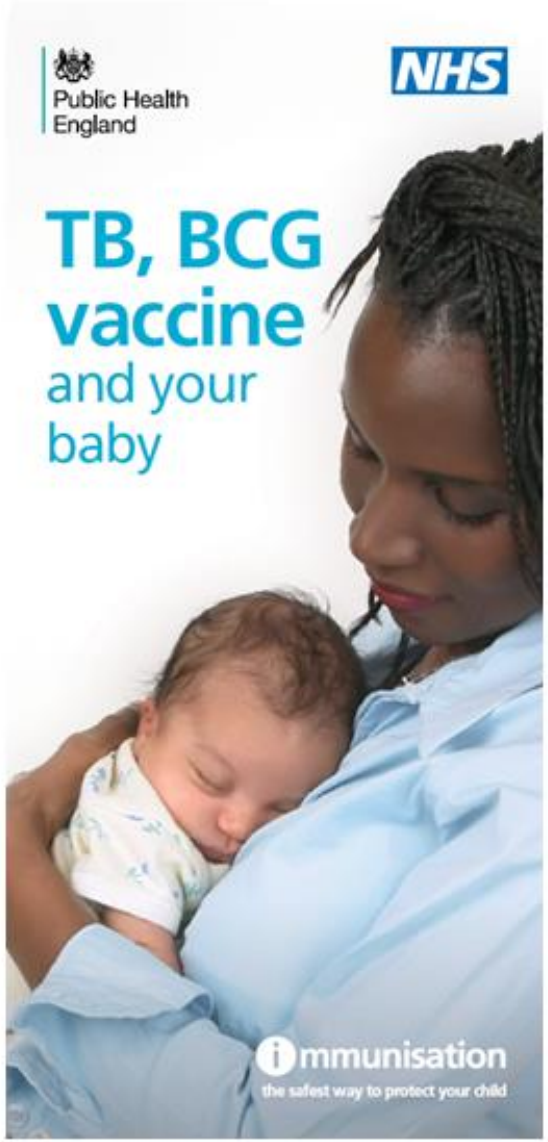
IMMUNISATION TEAM DETAILS *If submitting the referral by post, please send to relevant address below*	
South Referrals 01273 696011 ext. 8100	Immunisation Team, Westhampnett Centre, 28 – 29 Westhampnett Road, Chichester PO19 7HH
North Referrals 01293 227792	Immunisation Team, Crawley Hospital, 4th Floor, West Green Drive, Crawley RH11 7DH
Brighton and Hove Referrals 01273 696011 ext. 3789	Immunisation Team, Children and Families Clinic, D Block, Brighton General Hospital, Elm Grove, Brighton BN2 3EW

Appendix B: Surrey & Sussex Overview



Neonatal BCG pathway based on NHS Service Specification 2. Providers must ensure compliance with National Standards. Pathway produced Public Health England South East - DRAFT
Unless a baby has moved out of the area, the maternity unit remains responsible for funding the neonatal BCG if it is given at any time in the first year of life as a part of the MPP.

Appendix C: Public Health England Patient leaflet (https://www.gov.uk/government/publications/tb-bcg-and-your-baby-leaflet)



This leaflet is about the BCG (Bacillus Calmette-Guérin) vaccination that is being offered to protect your baby against tuberculosis (TB).

What is BCG vaccine?

BCG vaccine contains a weakened form of the bacteria (germ) that causes TB. Because it is weakened it doesn't actually cause TB, but it helps your baby develop protection (immunity) against TB in case he or she ever comes into contact with it. The BCG vaccination is particularly effective in protecting babies and young children against the more rare severe forms of TB such as TB meningitis (swelling of the lining of the brain).

What is TB?

TB is a bacterial infection, it usually affects the lungs but can also affect any part of the body. Infection with the TB germ may not develop into TB disease. TB disease develops slowly in the body, and it takes several months for symptoms to appear. Most people who have TB infection will never develop TB disease. In these people, the TB bacteria remain inactive for a lifetime. In other people (for example, those who have weak immune systems), the bacteria may become active and cause TB disease. Most people in this country recover fully after treatment, but this takes several months.

2

What are the symptoms of TB?

TB can affect any part of the body. The symptoms will vary and the signs of disease in a baby may be different from those of an adult. As TB is infectious, it is important that you can recognise the disease in someone else.

You should contact a doctor if you, your baby, or any other member of your family, or a friend has any of the following:

- Persistent cough that lasts for more than three weeks
- Fever
- Sweating, especially at night
- Unexplained weight loss
- A general and unusual sense of tiredness and being unwell
- Coughing up blood

How is TB caught?

You can only catch TB from someone whose lungs or throat are already infected and who is coughing. When they cough, a spray of tiny droplets is produced that contain the bacteria. If you breathe in the droplets you too can catch the infection. It takes close and prolonged contact with an infected person, for example living in the same house, to be at risk of being infected.

3

How common is TB?

In the UK in the 1950s, there were over 50,000 new cases of TB every year. Today, this number has dropped to just over 6,000 new cases a year. So, while it is unlikely that you will get infected, everybody should be aware of the symptoms of TB.

This is especially important because TB is a widespread disease worldwide.

The risk of disease is higher in people who have lived or worked in countries with high rates of TB. Children from these families are also more likely to have close contact with infected members of their community, either in the UK or in their country of origin.

Why is my baby being offered BCG?

In the UK, like many other countries, BCG is offered to babies who are likely to come into contact with someone with TB. This includes babies who live in an area with high rates of TB or babies with parents or grandparents from a country with high rates of TB (see page 7 for more information).

How is my baby immunised?

Your baby will be given the BCG vaccination in the upper part of the left arm.

The vaccination is usually offered after birth while your baby is still in hospital, but it can be given at any time up to five years.

Are there any side effects?

Immediately after the injection, a raised blister will appear. This shows that the injection has been given properly.

Within two to six weeks of the injection a small spot will appear. This may be quite sore for a few days, but it should gradually heal if you don't cover it. It may leave a small scar.

Occasionally, your baby may develop a shallow sore where they had the injection. If this is oozing fluid and needs to be covered, use a dry dressing – never a plaster – until a scab forms. This sore may take as long as several months to heal.

If you are worried or you think the sore has become infected, see your doctor.

Are there any reasons why my baby shouldn't have the BCG vaccination?

As with most other immunisations, the injection may not be given or should be delayed if:

- your baby has a high fever.
- your baby is suffering from a generalised infected skin condition. (If eczema is present, an injection site will be chosen that is free from skin lesions).

Rarely, in children who have weakened immune systems, the bacteria in the vaccine can cause serious infection.

It is very important that you tell the nurse or doctor if your child has, or is suspected of having, a weakened immune system. For example:

- the child is on treatment for cancer or other serious conditions.
- the child's mother had immunosuppressive biological therapy in pregnancy.
- there is a family history of problems with immune system (including HIV).

Which babies need to have BCG

Even if you don't live in area where all babies are offered BCG your baby may still need the vaccine.

If you answer '**Yes**' to any of the following questions you should ask your doctor or nurse about BCG for your baby.

- Does your baby, the baby's mother, father or grandparents, or anyone who lives with you, come from a country with a high rate of TB?
- Will you and your baby be going to live or to stay with friends and family in one of these countries?
- Does anyone who lives with you, or who spends a lot of time with your baby, have TB now or had TB in the past?

Countries with high rates of TB are taken from World Health Organization (WHO) figures at:

www.gov.uk/government/publications/tuberculosis-tb-by-country-rates-per-100000-people

Do I need to know anything else?

Your baby can start their routine immunisations at eight weeks of age regardless of when they have their BCG. You should make sure that your baby is not given another injection in the same arm as the BCG for at least three months afterwards; otherwise the glands in that area may swell.

Make sure that there is a record of the BCG vaccination in your child's Personal Child Health Record (Red book) for future reference.

More information

If you want more information on TB, or the BCG vaccine or any other immunisations, speak to your doctor, health visitor, midwife or nurse; or visit our website at **www.nhs.uk/vaccinations**.

Remember, treating TB takes a long time, preventing it is much easier.

NHS

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To order more copies of this booklet, visit: **www.orderline.dh.gov.uk** or phone: 0300 123 1002, Minicom: 0300 123 1003 (8am to 6pm, Monday to Friday).

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www.nhs.uk/vaccinations