

BCG Vaccination (TB) in the Newborn - Paediatric Full Clinical Guideline - UHDB

Reference no.: NIC IN14 NICU

1.0 Background

Human Tuberculosis (TB) is caused by infection with bacteria of Mycobacterium Tuberculosis Complex and may affect any part of the body. The most common form is pulmonary TB which accounts for almost 55% of all cases in the UK. The risk of disease is higher in people who have lived or worked in countries with high rates of TB or those with social risk factors. 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. The BCG vaccination is shown to be 70% - 80% effective in protecting babies and young children against the rarer severe forms of the disease such as TB meningitis and disseminated TB.

2.0 Who needs vaccination?

In 2005 the department of health announced changes in the national BCG vaccination policy, the adolescent programme was stopped due to declining numbers of TB. The BCG immunisation programme is now a risk-based neonatal programme targeted at those most at risk of exposure to TB.

The BCG vaccine should be offered to:

- All infants (age 0 -12 months) born in an area with an annual notification rate >40/100 000.
- All infants (age 0 - 12 months) with a parent or grandparent born in a high incidence country (annual rate >40/100000) [Tuberculosis by country: rates per 100,000 people - GOV.UK \(www.gov.uk\)](http://www.gov.uk)
- Previously unvaccinated children aged one to five years with a parent or grandparent born in a high incidence country (annual rate >40/100000).
- Previously unvaccinated tuberculin negative children aged six to 16 years with a parent or grandparent born in a high incidence country (annual rate >40/100000).
- Previously unvaccinated tuberculin negative individuals under 16 years of age who are household or close contacts of cases of smear positive pulmonary or laryngeal TB.
- Previously unvaccinated tuberculin negative individuals under 16 years of age who were born in or lived in (for 3 months or more) a country where annual rates of TB are >40/100000.
- Individuals under the age of 16 who are travelling for more than 3 months to a country where annual rates of TB are >40/100000 and who will stay with family/friends or local

people.

The need for the BCG vaccination should be identified where possible antenatally or postnatally by the midwife caring for the mother and an appropriate information leaflet provided - see [TB, BCG vaccine and your baby \(publishing.service.gov.uk\)](https://www.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/614219/tb_bcg_vaccine_and_your_baby.pdf)

3.0 When is it contraindicated?

The TB vaccine is Bacillus Calmette-Guerin a live attenuated strain of Mycobacterium Bovis. As it is a live vaccine it is contraindicated in the following situations:

The vaccine should not be given to:

- a) those who have already had a BCG vaccination
- b) those with a past history of TB
- c) those with an induration of 5mm or more following Mantoux tuberculin skin testing
- d) those who have had a confirmed anaphylactic reaction to a component of the vaccine
- e) children less than two years of age in a household where an active TB case is suspected or confirmed
- f) Immunisation with live vaccines, including BCG, should be delayed for 6 months in children born of mothers who were on immunosuppressive biological therapy during pregnancy or during breastfeeding.
- g) Those who are receiving, or have received in the past 6 months,
 - immunosuppressive chemotherapy or radiotherapy for malignant disease or non-malignant disorders
 - immunosuppressive therapy for a solid organ transplant (with exceptions, depending upon the type of transplant and the immune status of the patient)
- h) Those who are receiving or have received in the past 12 months
 - immunosuppressive biological therapy (e.g., anti-TNF therapy such as alemtuzumab, ofatumumab and rituximab) unless otherwise directed by a specialist.
- i) Those who are receiving or have received in the past 3 months immunosuppressive therapy including:
 - Adults and children on high-dose corticosteroids (>40mg prednisolone per day or >2mg/kg/day in children under 20kg) for more than 1 week
 - Adults and children on lower dose corticosteroids (>20mg prednisolone per day or >1mg/kg/day in children under 20kg) for more than 14 days
 - non-biological oral immune modulating drugs e.g., methotrexate >25mg per week, azathioprine >3.0mg/kg/day or 6-mercaptopurine >1.5mg/kg/day
 - for children on non-biological oral immune modulating drugs, specialist advice should be sought prior to vaccination.
- j) BCG vaccine is absolutely contraindicated in all HIV positive persons regardless of CD4 count and viral load. Infants born to HIV positive mothers should only be given BCG vaccination when the exclusively formula fed infant is confirmed HIV uninfected at 12-14 weeks, however, infants considered at low risk of HIV transmission (maternal VL <50 HIV RNA copies/ml at or after 36 weeks gestation) but with a risk of TB exposure may be given BCG at birth (British HIV Association, 2014).

For babies born to mothers who are 'low risk' or 'very low risk' where BCG is indicated it can be given as routine after birth. For mothers who are high risk the BCG should be arranged once the baby has had three negative HIV RNA results (see guidelines: Management of Babies born to HIV Positive Mothers - Full

Paediatric Clinical Guideline – Joint Derby and Burton on the intranet).

- k) Those suspected or confirmed to have SCID.

4.0 What are the complications?

The vaccine is administered via the intradermal route. Almost all babies will develop an induration at the injection site followed by a papule which may ulcerate then subside over weeks to months to form a small flat scar. Regional lymph nodes may enlarge up to 1cm. More severe local reactions, abscess formation and keloid scar formation may occur if injection technique is faulty.

Rarely fever and enlargement of regional lymph nodes and abscess formation may occur even with correct injection technique. Disseminated BCG infection is rare. Allergic reactions are rare.

5.0 Should consent be obtained?

Informed Consent must be obtained and appropriately documented (forms/hospital notes). If Consent is refused this must be clearly documented in Red Book and Medical Notes. Child Health and the child's GP should be notified.

6.0 What is the pathway for referral for vaccination?

In September 2021 the SCID (Severe Combined Immune Deficiency) screening programme was introduced for neonates. This requires the BCG vaccination to be delayed until a negative SCID screen is obtained. Referrals to the TB service are mostly received from Maternity services. Please see the referral pathway in Appendix 1 for both Royal Derby Hospital and Queens Hospital Burton.

See Appendix 2 for the BCG vaccination referral form to the Derby TB Service and Appendix 3 for the referral form to Burton TB services. Referrals are received via email or telephone:

Derby TB Service email: dhft.tb@nhs.net or 01332 787826 or Extension 87826

Burton TB Service email: uhdb.tb@nhs.net or Tel: 01283 593306 or Extension 5050

Should a BCG referral be missed at birth referrals are also accepted from other practitioners looking after the infant, e.g., GPs, practice nurses, health visitors or self-referrals from parents; the referral is managed according to the pathway.

7.0 References

British Association for Paediatric Tuberculosis (2023) **Clinical Guidance**
Care of children and young people exposed to or infected with tuberculosis

NICE Guideline NG33 BCG Vaccine [BCG vaccination | Information for the public | Tuberculosis | Guidance | NICE](#)

Tuberculosis the Green Book Chapter 32 [Tuberculosis: the green book, chapter 32 - GOV.UK \(www.gov.uk\)](#)

UKSHA Guidance TB, BCG vaccine and your baby [TB, BCG vaccine and your baby - GOV.UK \(www.gov.uk\)](#)

UKHSA Immunisation against infectious disease
www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book

Salisbury D, Begg N (Ed). Immunisation against Infective Diseases, 1996, HMSO (and draft updates on NHS website)

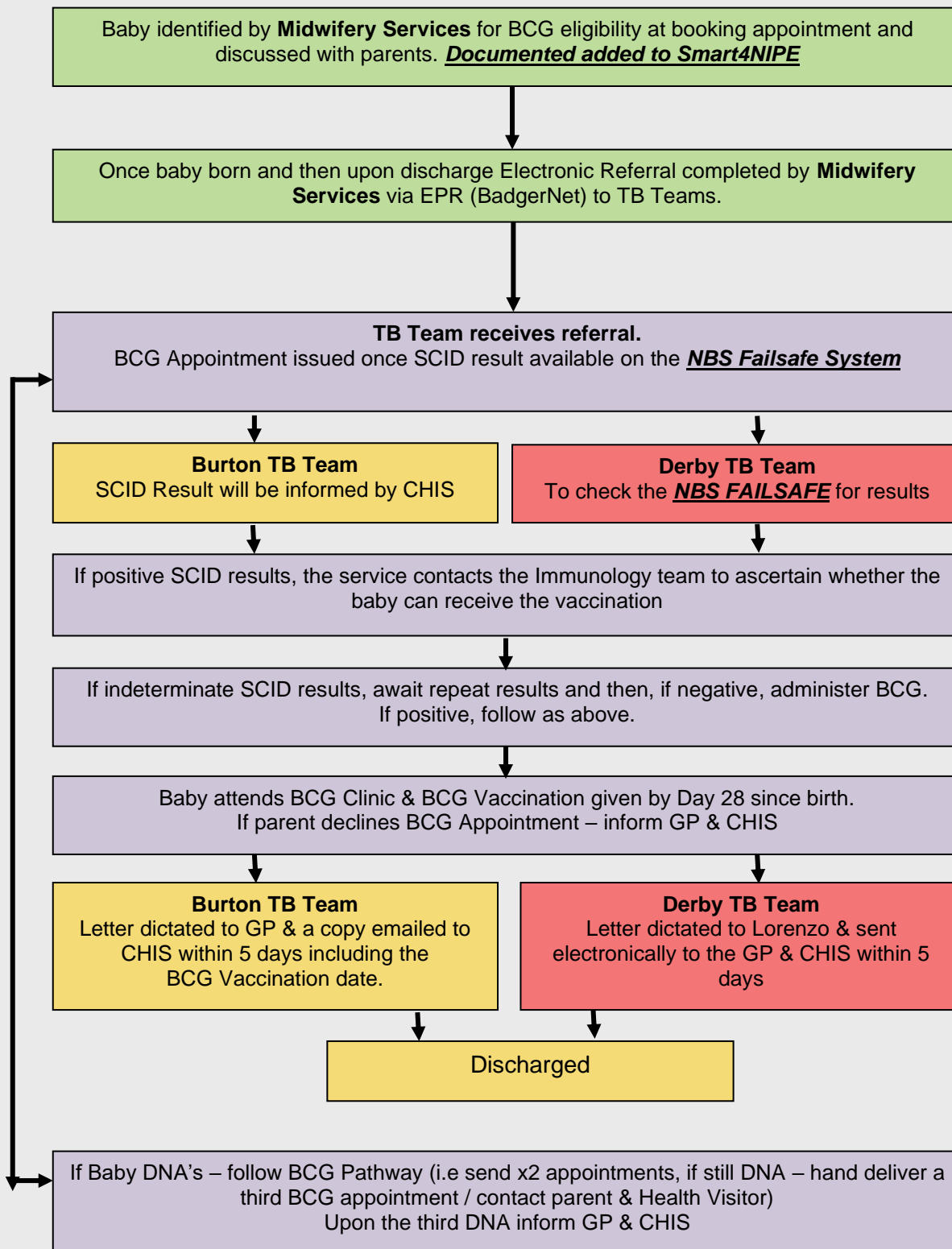
DOH Aug 05 – Operational note to profession *Changes in BCG Vaccination Programme in England*

8.0 Documentation Controls

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Version / Amendment History	Version	Date	Author	Reason
	006	18/10/2023	Dr Bala & Dr Ahmed	Review & Update
	6.1	June 2024	Lauren Wilkinson - Risk Support Midwife on behalf of Dr Bala Subramaniam	Flowchart updated - references removed to Lorenzo/Meditech V6 due to implementation of BadgerNet in maternity
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Appendix 1

DERBY & BURTON SCID / BCG SERVICE REFERRAL PATHWAY



Appendix 2

Royal Derby Hospital Baby / Child BCG Vaccine

Surname		First name	
DOB		Baby's NHS Number	
Address		Baby's H/N	
		Parent / Carer Phone number:	
GP Details		Male/Female	
Is Mum Retroviral Disease positive or immunosuppressed? Details: Has Mum taken any immunosuppressive therapy during pregnancy? Details:			
Family's Country of origin / Nationality of Parents/Grandparents: *Please see WHO TB incidence by country Country Details:			
Referrer's Name			
Referrer's Job Title			
Referrer's Contact	Email	Telephone	

Referral**Neonatal BCG Vaccination Referral Criteria**

- All infants born in an area with a notification rate of >40 per 100,000 [Tuberculosis by country: rates per 100,000 people - GOV.UK \(www.gov.uk\)](#)
- All infants with a parent or grandparent who was born in a country where the annual incidence of TB is 40/100,000 or greater*
- Previously unvaccinated children aged one to five years with a parent or grandparent born in a high incidence country (annual rate >40/100000).
- Previously unvaccinated tuberculin negative children aged six to 16 years with a parent or grandparent born in a high incidence country (annual rate >40/100000).
- Previously unvaccinated tuberculin negative individuals under 16 years of age who are household or close contacts of cases of smear positive pulmonary or laryngeal TB.
- Previously unvaccinated tuberculin negative individuals under 16 years of age who were born in or lived in (for 3 months or more) a country where annual rates of TB are >40/100000.
- Individuals under the age of 16 who are travelling for more than 3 months to a country where annual rates of TB are >40/100000 and who will stay with family/friends or local people.

Please complete in full & email completed form to the
Derby TB Services on: dhft.tbservice@nhs

Appendix 3

Queens Hospital Burton Neonatal BCG Vaccine Referral

Surname		First name	
DOB		Unit No	
Address		Mothers name	
Phone number		Baby's NHS Number	
Is Mum Retroviral disease positive or immunosuppressed Details:			
Referrer		Reason for BCG Referral	
*Please see WHO TB incidence by country		Nationality of parents/grandparents	

Criteria for infants requiring the BCG vaccine:

- All infants born in an area with a notification rate of >40 per 100,000 [Tuberculosis by country: rates per 100,000 people - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/statistics/tuberculosis-by-country-rates-per-100000-people)
- All infants with a parent or grandparent who was born in a country where the annual incidence of TB is 40/100,000 or greater*
- Previously unvaccinated children aged one to five years with a parent or grandparent born in a high incidence country (annual rate >40/100000).
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- Individuals under the age of 16 who are travelling for more than 3 months to a country where annual rates of TB are >40/100000 and who will stay with family/friends or local people.

BCG to be given at 28 days of age or at an earlier opportunity providing a SCID screening result is available.

*For country information on prevalence see:

[Tuberculosis by country: rates per 100,000 people - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/statistics/tuberculosis-by-country-rates-per-100000-people)

Please email completed form to the TB Services on: uhdb.tbserviceburton@nhs.net

