Royal Cornwall Hospitals
NHS Trust

Neonatal BCG Vaccination Clinical Guideline

V5.0

October 2025

Summary

Booking Midwife:

Identifies and documents any indications for BCG (Bacillus Calmette- Guerin) vaccination (see below).

- Have a parent or grandparent born in a country where the incidence of TB is over 40/100,000 population.
- Have a family history of TB (tuberculosis) in the past 5 years.
- Are under 12 months of age born or living in an area with a high number of cases (more than 40 cases of TB a year in every 100,000 population).

Midwife or Doctor performing Newborn and Infant Physical Examination (NIPE):

- Indication for BCG referral confirmed with parents.
- Incidence of TB checked against UK government database.
- Contraindications excluded.
- Referral form (appendix 3) **fully** completed and sent.
- If performed within RCHT parents advised to book into BCG clinic at maternity reception and next available appointment booked.

Child Health BCG Doctor:

- Referral form reviewed.
- Indication confirmed (Incidence of TB checked against UK government database).
- Maxims letter generated if BCG indicated and sent to BCG clinic.
- Patient added to pending list and booked to next available appointment by booking team.

Midwife running BCG clinic on receipt of Maxims letter:

- Checks Newborn Screening Database for Severe Combined Immunodeficiency (SCID) status on newborn blood spot (NBBS) (see section 2.5).
- If positive screen informs Neonatal Service Consultant- cancels BCG appointment or has patient removed from pending list.
- If negative screen (or not eligible for SCID screening) then continues with BCG clinic.

On day of clinic:

- Confirms and documents patient details, indication and lack of contraindications with family.
- Gains informed consent.
- Administers BCG vaccine as per protocol.
- Provides written information to family as per UK gov information leaflet (translations available) https://www.gov.uk/government/publications/tb-bcg-and-your-baby-leaflet.
- Documents vaccination and submits forms as per section 2.7.

1. Aim/ Purpose of this Guideline

1.1. Tuberculosis (TB) is a notifiable disease in the UK. NICE Guidance (2016) now recommends 'at risk' group vaccination only. This guideline aims to outline procedures to be followed across the Peninsula for at risk babies to be identified and referred for bacilli Calmette- Guerin (BCG) vaccination.

1.2. This guideline applies to Midwives, Health Visitors, Medical and Nursing staff performing neonatal examinations where infants may be identified as meeting criteria for BCG vaccination. The guidance aims to standardise the process for appropriate referral to the BCG clinic in the first year of life.

1.3. This version supersedes any previous versions of this document.

Data Protection Act 2018 (UK General Data Protection Regulation – GDPR) Legislation.

The Trust has a duty under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team.

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2. The Guidance

2.1. For babies born in low-risk countries BCG vaccination is only recommended for infants within at-risk groups as defined by Department of Health and Social Care (DoH).

2.2. To identify TB rates by country the World Health Organisation provide an updated record at TB profile.

2.3. **Indications for BCG Vaccine:**

Current Department of Health recommendations are to offer vaccination to infants who:

- Have a parent or grandparent born in a country where the incidence of TB is over 40/100,000 population.
- Have a family history of TB in the past 5 years.
- are under 12 months of age born or living in an area with a high number of cases (more than 40 cases of TB a year in every 100,000 population).
- The vaccine is not necessary for short (less than 4 weeks) travel to countries with high incidence.

2.4. **Contraindications:**

- BHIVA (British HIV (Human Immunodeficiency Virus) Association) guideline 2025 on the management of HIV in pregnancy and the postpartum period 2025) recommends that infants at high risk of HIV transmission, BCG should be deferred until PCR testing is completed at 12 weeks of age, or 1 month after cessation of breastfeeding if deemed high- risk, and they are known to be negative.

- BHIVA guideline 2025 recommends that infants at low risk of HIV transmission should receive BCG at the same time and for the same indication as for infants unexposed to HIV (including those who are breast /chest fed).

- All VL measurements for the mother/birthing parent < 50 HIV RNA (Ribonucleic Acid) copies/ml in 10 weeks preceding delivery and delivery day VL for the mother/birthing parent< 50 HIV RNA copies/ml = low risk.

- Household with active TB case suspected or confirmed.

- Immunodeficiency such as Severe Combined Immunodeficiency (or family history of) or DiGeorge Syndrome.

- Mother receiving immunosuppressive drugs.

- Infected skin lesions.

2.5. **Care Pathway or Best Practice Points:**

2.5.1. When the pregnancy is booked screening data identifies ethnicity of parents and health details of tuberculosis within the family. This should be documented in the maternal notes for notification of babies requiring vaccination after birth.

2.5.2. At the initial neonatal health check babies who meet current indications for vaccination should be referred by the person performing the neonatal check using BCG Referral form (section 7) or notify the GP of need to refer and record/ copy referral notification in medical notes.

Prior to signing the referral form contraindications listed must be checked for and any translation needs required for the clinic must be notified.

Clinic is held on the Gwithian Paediatric Outpatient.

2.5.3. Babies should be seen when aged at least 4 weeks to allow for the result of the SCID (Severe Combined immunodeficiency) screening on NBBS (if undertaken) result to be available. Prior to vaccination the SCID status for all patients should be checked on the newborn screening database.

- A positive SCID screen is a contraindication to BCG vaccination and no vaccination should be offered.

- A negative SCID screen, with no other contraindications, should allow vaccination to proceed.

- At present (2022) there is no routine SCID screening in the Southwest. If testing has not been undertaken, and there are no other contraindications, vaccination can proceed with consent.

2.5.4. Prior to vaccination any contraindications should be checked for and verbal consent from the parent/guardian should be gained and documented in the medical notes.

2.5.5. **Vaccination details**[4] BCG vaccine contains a live attenuated strain derived from M. bovis. Vaccine is sourced and supplied by hospital pharmacy and is approved for administration in this clinic.

2.5.6. The vaccine and the diluent are supplied in two separate boxes in very similar packaging. Prior to the clinic it is important to confirm that both the diluent and vaccine are in date and that there are supplies of both components.

2.5.7. Reconstitution must occur with the diluent supplied. After reconstitution the vaccine can be used for 4 hours. The vial contains 20 infant doses of 0.05ml.

2.5.8. BCG vaccination should only be given by staff trained and competent to perform the injection as the commonest problems occur with inappropriately deep (subcutaneous) delivery rather than intradermal route.

2.5.9. Preferred site is upper arm at the insertion of the deltoid muscle, just above the middle of the left upper arm- the left arm is recommended by WHO. Higher site has greater association with keloid scarring.

2.5.10. The needle (26g) should be inserted intradermally with the bevel uppermost. Skin resistance should be felt as the vaccine is injected. The vaccine should result in a visible ‘bleb’ under the skin. The expected reaction to successful BCG vaccination, seen in 90 to 95% of recipients, is induration at the injection site followed by a local lesion which starts as a papule two or more weeks after vaccination. It may ulcerate and then slowly subside over several weeks or months to heal, leaving a small, flat scar. It may also include enlargement of a regional lymph node to less than 1cm[4].

2.5.11. **No further immunisation should be given in the arm used for BCG immunisation for at least three months because of the risk of regional lymphadenitis.**

2.6. **Parent Information.**

Parents should be given written information and informed not to cover the site, to bathe baby as normal and to contact GP if any sign of abscess occur (rare complication) Routine first vaccinations do not need to be delayed but live vaccines should be given either at the same time or after a 4 week interval.

Leaflets are available for parents indicating indications for BCG vaccination, side effects, contraindications (updated 2010).

Department of Health information leaflets are available to download in many languages from: TB, BCG and your baby - GOV.UK (www.gov.uk) https://www.gov.uk/government/publications/tb-bcg-and-your-baby-leaflet.

2.7. **Documentation.**

Following vaccination, details should be recorded in the medical notes (including vaccine batch and expiry date). Physical copies of red book sheets are no longer sent to CHIS or GP but a computer form (accessed here S:\TR11\Neonatal\Immunisation Form\Notification Of Immunisation.docx) from CHIS is completed and sent to them within 48hrs of vaccination (usually sent at the end of the clinic). The MAXIMS clinic outcomes are also completed at this time. The ward clerk then completes the PAS clinic outcomes and generates letters to parents/GP and notes.

3. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Number of babies referred for BCG vaccination to BCG.
Lead	Christopher Bell; Neonatal Consultant.
Tool	BCG clinic attender records.
Frequency	Yearly audit and report.
Reporting arrangements	TB Advisory Group.
Acting on recommendations and Lead(s)	TB Advisory Group Lead Alison Blake and annual return of data to Public Health. Audit of activity for infant BCG referrals and vaccines will be minuted and recommendations made via advisory group.
Change in practice and lessons to be shared	Required changes to practice will be identified and actioned within 3 months, immediately if required. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant staff/ stakeholders.

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the Equality Diversity And Inclusion Policy or the Equality and Diversity website.

4.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Neonatal BCG Vaccination Clinical Guideline V5.0
This document replaces (exact title of previous version):	Neonatal BCG Vaccination Clinical Guideline V4.1
Date Issued/Approved:	October 2025
Date Valid From:	October 2025
Date Valid To:	October 2028
Directorate/Department responsible (author/owner):	Dr. Christopher Bell; Neonatal Consultant
Contact details:	01872 252667
Brief summary of contents:	Indication and referral process for BCG vaccination in the newborn.
Suggested Keywords:	BCG, neonatal, immunisation, vaccination, TB, maternity.
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Neonatal Audit and Guidelines Group
Manager confirming approval processes:	Caroline Chappell
Name of Governance Lead confirming consultation and ratification:	Michael Cross
Links to key external standards:	None required
Related Documents:	Department of Health publications and statistics Statistics at DHSC - Department of Health and Social Care - GOV.UK. National Institute for Clinical Excellence (NICE) Tuberculosis NG33 Overview | Tuberculosis | Guidance | NICE.

Information Category	Detailed Information
	Health Protection Agency (2018) TB incidence database Health Protection Agency - GOV.UK accessed 5.2.2018. Green Book (2013) Chapter 32 BCG Vaccination Department of Health.
Training Need Identified?	No
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical/ Newborn Care

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
August 2005	V1.0	Initial Issue.	Judith Clegg, ANNP Dr Kumar, Dr Munyard-Consultants.
November 2012	V2.0	Addition of BCG referral form and updated referral clinic.	Judith Clegg, ANNP.
March 2018	V3.0	2.1 Current incidence, London incidence. 2.5 Care pathway or best practice points: Clinic is held on the Postnatal Ward, Vaccine is soured [..] in this clinic, vaccine can be used for 6 hours. Appendix 1: suggested keywords, inclusion of TB and maternity. Related documents: new versions of documents 2, 3 and 4.	Karen Needham, Deputy Postnatal Ward Manager.
March 2022	V4.0	Reviewed and updated: Contact information. Flow chart to clarify process. SCID screening and action plan.	Chris Bell; Neonatal Consultant.
August 2023	V4.1	Updated to new Trust format. Appendix 3 updated. Full definitions of acronyms provided.	Charlotte Lea, Neonatal Guidelines Lead.

Date	Version Number	Summary of Changes	Changes Made by
October 2025	V5.0	Full review. Flowchart updated to indicate to book patients into BCG clinic, add patient to pending list and remove from patient pending list if screen positive. TB profile link added at section 2.2. Section 2.4 contraindications updated. Section 2.5.3 updated. Section 2.5.6 added to guidance.	Charlotte Lea, Neonatal Guidelines Lead.

All or part of this document can be released under the Freedom of Information Act 2000.

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust The Policy on Policies (Development and Management of Knowledge Procedural and Web Documents Policy). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity, and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy/policy/proposal/service function to be assessed:	Neonatal BCG Vaccination Clinical Guideline V5.0
Directorate and service area:	Newborn Care
Is this a new or existing Policy?	Existing
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Neonatal Audit and Guidelines Group
Contact details:	01872 252667

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	To provide clear pathway for BCG Vaccinations for babies at risk of TB infection.
2. Policy Objectives	To provide clear referral process.
3. Policy Intended Outcomes	Maintain guidance for any referrer to BCG service for newborns.
4. How will you measure each outcome?	Number of BCG referrals.
5. Who is intended to benefit from the policy?	All infants at risk of TB infection.

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/visitors: No • Local groups/system partners: No • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/groups:** Neonatal Audit and Guidelines Group.
6c. What was the outcome of the consultation?	Approved.
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff, or patient surveys:** No.

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	Any information provided should be in an accessible format for the parent/ carer/ patient's needs- i.e., available in different languages if required/access to an interpreter if required.

Protected Characteristic	(Yes or No)	Rationale
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	Those parent/ carer/ patients with any identified additional needs will be referred for additional support as appropriate- i.e., to the Liaison Team or for specialised equipment. Written information will be provided in a format to meet the family's needs e.g., easy read, audio etc.
Religion or belief	No	All staff should be aware of any beliefs that may impact on the decision to treat and should respond accordingly.
Marriage and civil partnership	No	All staff should be aware of any marital arrangements that may have an impact on care (for example: separated parents, domestic abuse).
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Neonatal Audit and Guidelines Group.

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis.

Appendix 3. Maxims Internal Referral Service Request Form

Maxims Internal Referral Service Request form	
All sections below must be completed	
Service Owner: Name and Designation **Contact Details**	
Second Service Owner: Name and Designation **Contact Details**	
Is this a NEW Service or review of an existing Service	New service
Service Name? (Service name must end with a Service Description as below) example "Dermatology add to WL"	BCG Vaccination Clinic – referral pathway for neonates identified at risk of contracting tuberculosis (TB)
Service Description	Outpatient Service: BCG Vaccination
What Speciality does the service come under and Care Group	Speciality: Paediatrics Care Group: Women, Childrens and HIV
For a new Service/Tooltip Rationale for service? Who sends requests? Who receives them?	Referrals currently made by the Neonatal Unit, midwives in the hospital or midwives in the community setting. Currently completed on a paper form and posted to Dr K Kyaw, BCG Clinic Referral, Child. Health, Gwithian Unit, Level 4, Tower Block.
Which Trust does the Service come under?	RCHT.
Any questions requiring to be answered by the referrer? (please specify questions in template below)	Yes.
Date Service to be made active?	ASAP

Maxims Internal Referrals – Service Specific Questions

Service Name (Please state Specialty and then select if Inpatient/Outpatient/Add to Waiting List/Request)

Number	Question	Mandatory	Answer Type *	Answer Content
1	Is the mother HIV positive with the infant identified at high risk (Neonatal BCG Vaccination Clinical Guideline – section 2.4)	Y	Y/N	
2	Does the infant live in a household with active TB case suspected or confirmed	Y	Y/N	
3	Does the infant have immunodeficiency such as Severe Combined Immunodeficiency (or family history of) or DiGeorge Syndrome	Y	Y/N	
4	Is the mother receiving immunosuppressive drugs	Y	Y/N	
5	Does the infant have infected skin lesions	Y	Y/N	
6	Indication/ Country of origin	Y	Free Text	
7	Will a translator be required for the appointment	Y	Y/N	
8		Y/N		
9		Y/N		
10		Y/N		

* Answer Type: Free Text

Single Select
Multi Select
Yes/No
Number

Once you have completed this form please return it electronically to maximsteam@nhs.net