A Clinical Guideline for Referral of Neonates Identified at Risk of Exposure to Tuberculosis.

Document Control: Obstetrics and Gynaecology/ Neonatal

For Use In:	Norfolk and Norwich Hospital Obstetrics and Gynaecology/ Neonatal		
Search Keywords	Neonate, BCG, vaccination		
Document Author:	Alison Evans, Antenatal and Newborn Screening Midwife		
Document Owner:	Women and Children's – the Antenatal and Newborn Screening Team		
Approved By:	Maternity Guidelines Committee		
Ratified By:	Clinical Standards Group and Clinical Safety and Effectiveness Sub-Board		
Approval Date:	NMCP Board – 12th October 2023	**Date to be reviewed by:** This document remains current after this date but will be under review	12/10/2026
Implementation Date:	As above		
Reference Number:	13593		

Version History:

Version	Date	Author	Reason/Change
V1.0	05/01/2017	Sharon Stone	BCG referral Process
V2.0	22/11/2019	Alison Evans	BCG referral process
V3.0	20/04/2023	Charlotte Aldous	BCG referral process, Antenatal Screening Team failsafe process

Distribution Control

Printed copies of this document should be considered out of date. The most up to date version is available from the Trust Intranet.

Consultation

The following were consulted during the development of this document:
Neonatal Consultants, BCG Nurses, Child Health Information Services and Antenatal and Newborn Screening Team. The guideline was drafted by the authors and initially distributed for comments to medical, nursing and midwifery colleagues in Women

and Childrens, Division 3. Following amendments, the guideline was re-drafted and presented at a guideline meeting for the department

Monitoring and Review of Procedural Document

The document owner is responsible for monitoring and reviewing the effectiveness of this Procedural Document. This review is continuous however as a minimum will be achieved at the point this procedural document requires a review e.g. changes in legislation, findings from incidents or document expiry.

Relationship of this document to other procedural documents

This document is a clinical guideline applicable the Norfolk and Norwich University Foundation Trust; please refer to local Trust's procedural documents for further guidance, as noted in Section 5.

A Clinical Guideline for Referral of Neonates Identified at Risk of Exposure to Tuberculosis

Contents Page

A Clinical Guideline for Referral of Neonates Identified at Risk of Exposure to Tuberculosis

1. Introduction

1.1. Rationale

To develop the knowledge base of healthcare practitioners regarding the Neonatal Bacille Calmette-Guerin (BCG) vaccination programme and referral pathway.

To support healthcare practitioners involved in discussing BCG vaccination with those eligible by providing evidence-based information.

To promote high uptake of BCG vaccination in those eligible by increasing the knowledge of those involved in delivering the vaccination programme.

Provide information on the administration of BCG vaccines.

1.2. Objective

Neonatal BCG vaccination should be given to eligible high-risk infants soon after birth. The BCG vaccination should be administered strictly by the intradermal route. It is essential that all health professionals involved in the administration of BCG vaccines are properly trained in all aspects of the process involved in BCG vaccination.

1.3. Overview

Almost all cases of Tuberculosis in the UK are acquired through respiratory route, by breathing in infected respiratory droplets from a person with infectious respiratory TB Incidence of TB in UK [2013] 12.3/100,000.

This guideline aims to ensure early identification of the neonate that requires BCG vaccination at birth and to facilitate appropriate and timely administration.

1.4. Scope

This document covers the identification of those who require BCG vaccination postnatally subsequent referral to the Child Health Services (CHIS) to initiate this vaccination.

1.5. Glossary

The following terms and abbreviations have been used within this document:

Term	Definition
ANS	Antenatal Screening Team
BCG	Bacille Calmette-Guerin
CHIS	Child Health Information Services
E3	Euroking
NEMS	National Events Management service
NIPE	Newborn Infant Physical Examination
S4N	Smart 4 NIPE
TB	Tuberculosis
WHO	World Health Organisation

2. Responsibilities

All health care professionals to fully comply with this guideline to ensure timely review and management of results.

3. Policy Principles

3.1. Criteria for Inclusion

BCG vaccination should be discussed with the parents or legal guardian for any newborn baby at increased risk of tuberculosis.

Neonates at increased risk include:

- Those born in a local authority with a notification rate greater or equal than 40 per 100,000 (See section 3.4 WHO Estimates)
- With one or more parents or grandparents born in a high incidence country as defined by NICE. The current countries (updated 13/06/2022) can be found at:

  https://www.gov.uk/government/publications/tuberculosis-tb-by-country-rates-per-100000-people
- With a family history of tuberculosis within the last five years.

3.1.1. Criteria for Exclusion

Below details exclusions for babies entering the BCG vaccination programme.

- BCG should **not** be given to babies who are likely to be HIV positive. For infants born to HIV-positive mothers plans will be devised antenatally to ensure BCG vaccine is administered timely. However, if there is very low or low risk of HIV transmission and BCG at birth is indicated this should not be delayed
- Babies living in a household where an active TB case is suspected or confirmed
- Babies who are immunocompromised by virtue of disease or treatment e.g. any baby receiving corticosteroid or immunosuppressive treatment (inhaled steroids are not a contraindication).
- Any baby suffering from a malignant condition (e.g. leukaemia)
- Current viral infections

3.2. Processes to be followed

Below specifies the responsibility of practitioners by profession to complete the BCG referral process.

3.2.1. Newborn Examiners

The primary mechanism for notifying the Child Health Information Services (CHIS) of any baby who requires BCG vaccination is via the Smart4NIPE (S4N) and National Events Management service (NEMS) systems (See Appendix 1 for BCG Referral Quick Reference Guide).

Upon completion of the Neonatal Infant Physical Examination (NIPE), the neonatal examiner must document the outcome of this examination on the S4N system. When inputting the outcome of the NIPE into S4N, one of the mandatory fields is to specify if the baby is eligible for BCG vaccination. Selection of eligibility for BCG on the S4N system is the method of distinguishing which babies born at the NNUH require BCG for the CHIS. Neonatal examiners must ensure this is correctly entered to ensure all babies eligible are flagged to the CHIS team.

The action of inputting the eligibility for BCG on the S4N system allows CHIS to retrieve this data via NEMS daily. Subsequent to its retrieval, CHIS provide this information to The Immunisations Team. The Immunisations Team invite all babies eligible for BCG vaccination into their clinic to perform this vaccination. CHIS will contact the ANS if eligibility on S4N requires amending to reflect true eligibility.

3.2.2. Antenatal Screening Team

To mitigate the risk that a neonatal examiner has not specified an eligible baby on the S4N system, the ANS team will perform a failsafe check on a weekly basis. This failsafe check involves checking E3 records from booking, delivery and discharge to ascertain if the babies born within the selected time frame are featured on both E3 and S4N records as requiring BCG vaccination. Any baby who is identified on E3 as requiring BCG vaccination records but not on S4N will have their eligibility verified and S4N updated to reflect the true risk. It is therefore imperative that the midwife conducting the antenatal, delivery and discharge reviews correctly documents the need of BCG vaccination. CHIS will receive this updated notification the following day via NEMS allowing referral to The Immunisations Team.

To allow the above checks to be performed, midwives must correctly identify babies at risk of tuberculosis on E3 at the following check points:

At booking

- Current Pregnancy- Topics Discussed. Any woman whose baby will require BCG vaccination at birth. A comment should be included to specify the reason BCG is required.

At delivery

- A BCG requirement prompt will appear on E3
- Highlight in postnatal and neonatal notes “BCG required”. A comment should be included to specify the reason BCG is required.

Discharging home from hospital

- Complete ‘Transfer to the Community’ section in Neonatal Record and on E3
- Electronic referral will be sent automatically
- Ensure patient has been given national patient BCG information leaflet (TB, BCG and your baby - GOV.UK (www.gov.uk)

Discharge from midwifery care

Community Midwife to:

- Complete Transfer of Care page to inform the Health Visitor
- Secure transfer page summary into red book
- Discuss at joint monthly HV/CMW meetings

3.3. Out of area babies

When performing the S4N and E3 record failsafing, if any baby is noted to have delivered at the NNUH but home address resides outside the East of England (Norfolk, Suffolk, Cambridge, Peterborough, Herts, Beds, Luton, Milton Keynes and Essex) the ANS team will email hct.hepbbcgnorfolk@nhs.net to notify that the baby requires BCG vaccination in their locality.

3.4. WHO Estimates

To ensure all staff have the correct 'Tuberculosis rates per country' document the ANS team will review the WHO Estimates of TB Incidence by Country and Territory Spreadsheet (*https://www.gov.uk/government/publications/tuberculosis-tb-by-country-rates-per-100000-people*) every 6 months to ensure an updated list is circulated to all areas of community, MLBU, Blakeney, Delivery Suite and NICU. To ensure this is actioned an automatic alert is set to the ANS Team shared calendar on a six-monthly basis.

3.4.1. Administration of BCG vaccination

Specialist qualifications, training, experience and competence required in the clinical context of the BCG administration, for this reason NNUHT refer neonates eligible for vaccination specialist services coordinated by CHIS. The legal status of the medicines is prescription only medicine (POM).

3.4.2. Information regarding follow-up management

BCG vaccine is given into the lateral aspect of the left upper arm at the level of the insertion of the deltoid muscle (just above the middle of the left upper arm).

The expected reaction to successful BCG vaccine 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 is not necessary to protect the site from becoming wet during washing. The ulcer should be encouraged to dry. Should any oozing occur, a temporary dry dressing may be used until a scab forms. Following BCG vaccination, the baby should not receive any vaccinations in the same limb used for the vaccination for three months.

4. Training & Competencies

BCG vaccines are not administered at NNUH and are performed by the Schools Immunisations Team who are responsible for their own training and competency audit.

5. Related Documents

Tuberculosis by country rates per 100,000

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

6. References

DoH leaflet "TB, BCG vaccine and your baby"
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/469555/PHE_8584_TB_BCG_8_page_DL_leaflet_2015_09_web.pdf

Green Book TB chapter. Available at:
https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book

7. Monitoring Compliance

Compliance with the process will be monitored through the following:

Key elements	Process for Monitoring	By Whom (Individual / group /committee)	Responsible Governance Committee /dept	Frequency of monitoring
Audit for eligible population and referrals	Audit via Euroking	Maternity/Neonatal Teams	Clinical Governance	Annually
Documentation completed on transfer Health visitor informed	Audit via Euroking	Practice Development Midwives	Clinical Governance	Annually

The audit results are to be discussed at relevant governance meeting such as Clinical Governance, the Antenatal and Newborn Steering Group Meeting and externally at the NHSE Antenatal and Newborn Screening Board Meetings. These groups will review the results and recommendations for further action. Then sent to the relevant committee or Sub-Board who will ensure that the actions and recommendations are suitable and sufficient.

8. Appendices

Appendix 1- BCG Referral Quick Reference Guide

Appendix 1- BCG Referral Quick Reference Guide

9. Equality Impact Assessment (EIA)

Type of function or policy	Existing

Division	Women and Children's	**Department**	Maternity and Gynaecology
Name of person completing form	Charlotte Aldous	**Date**	19/4/2023

Equality Area	Potential Negative Impact	Impact Positive Impact	Which groups are affected	Full Impact Assessment Required YES/NO
Race	None	Yes	N/A	No
Pregnancy & Maternity	None	Yes	N/A	No
Disability	None	Yes	N/A	No
Religion and beliefs	None	Yes	N/A	No
Sex	None	Yes	N/A	No
Gender reassignment	None	Yes	N/A	No
Sexual Orientation	None	Yes	N/A	No
Age	None	Yes	N/A	No
Marriage & Civil Partnership	None	Yes	N/A	No
EDS2 – How does this change impact the Equality and Diversity Strategic plan (contact HR or see EDS2 plan)?		N/A		

- **A full assessment will only be required if: The impact is potentially discriminatory under the general equality duty**
- **Any groups of patients/staff/visitors or communities could be potentially disadvantaged by the policy or function/service**
- **The policy or function/service is assessed to be of high significance**

IF IN DOUBT A FULL IMPACT ASSESSMENT FORM IS REQUIRED

The review of the existing policy re-affirms the rights of all groups and clarifies the individual, managerial and organisational responsibilities in line with statutory and best practice guidance.