CLINICAL GUIDELINE FOR NEONATAL BCG VACCINATION V3.0
1. **Aim/Purpose of this Guideline**

1.1. Tuberculosis is a notifiable disease in the UK and although incidence is low it remains a Public Health concern as cases have increased in recent years. Due to low incidence of tuberculosis in most areas of the UK, changes to Department of Health (DoH) policy in 2005 resulted in the abolishment of mass Bacillus Calmette-Guérin (BCG) vaccination across UK schools. 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 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.

2. **The Guidance**

2.1. Tuberculosis is endemic in about one third of the world’s population, around 2 billion people, although many do not develop the disease due to latent forms. It causes 2 million deaths worldwide each year. All countries in the African Region, Eastern Europe/Mediterranean, Southeast Asia and Russia have high incidence (over 40 per 100,000 Population). Current incidence (2018) in the UK is 10/100,000 (New 2018) although heavily populated cities have higher numbers; London incidence 25/100,000 (2018) (New 2018). For babies born in low risk countries BCG vaccination is only recommended for infants within at risk groups as defined by DoH.


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)

2.4 **Contraindications:**

- HIV positive mother or infant
- Household with active TB case suspected or confirmed
- Immunodeficiency such as Severe Combined Immunodeficiency (or family history of) or Di George Syndrome
- Mother receiving immunosuppressive drugs
• Infected skin lesions

The vaccine is not necessary for short (less than 4 weeks) travel to countries with high incidence

2.5 Care Pathway or Best Practice Points:

• 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.

• 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. Referral forms should be sent to Dr A Prendiville, Consultant Paediatrician, Child Health, Tower Block, Royal Cornwall Hospital TR1 3LJ for an appointment in the BCG Clinic. Clinic is held on the Postnatal Ward (New 2018).

• Prior to vaccination any contraindications should be checked for and written consent (RCH Immunisation Consent form) from the parent/guardian should be gained and documented in the medical notes.

• Vaccination details. 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 (New 2018).

After reconstitution the vaccine can be used for 6 hours (New 2018). The vial contains 20 infant doses of 0.05ml

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.

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.

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.

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 the 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:

2.7 Documentation

Following vaccination, details should be recorded in the medical notes (including vaccine batch and expiry date) Parent Held Child Health Record (PHCR Red Book) notification (imunisation consent form) completed and sent for the NHS Child Health Computer records (via Pendragon House, RCH) and copy to inform GP

References

1. Department of Health publications and statistics
2. National Institute for Clinical Excellence (NICE) Tuberculosis NG33
http://guidance.nice.org.uk/NG33 accessed 5.3.2018
3. Monitoring compliance and effectiveness

<table>
<thead>
<tr>
<th>Element to be monitored</th>
<th>Number of babies referred for BCG vaccination to BCG clinic</th>
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<tbody>
<tr>
<td>Lead</td>
<td>Dr Prendiville/Dr Kyaw (Paediatricians)</td>
</tr>
<tr>
<td>Tool</td>
<td>BCG clinic attenders records</td>
</tr>
<tr>
<td>Frequency</td>
<td>Yearly audit and report</td>
</tr>
<tr>
<td>Reporting arrangements</td>
<td>TB Advisory Group</td>
</tr>
<tr>
<td>Acting on recommendations and Lead(s)</td>
<td>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.</td>
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| Change in practice and lessons to be shared | Annual report and minutes of TB advisory group Dr Prendiville lead |

4. Equality and Diversity

4.1 This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement.

4.2 Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.
## Appendix 1. Governance Information

<table>
<thead>
<tr>
<th>Document Title</th>
<th>CLINICAL GUIDELINE FOR NEONATAL BCG VACCINATION V3.0</th>
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<tr>
<td>Date Issued/Approved:</td>
<td>14th February 2018</td>
</tr>
<tr>
<td>Date Valid From:</td>
<td>14th February 2018</td>
</tr>
<tr>
<td>Date Valid To:</td>
<td>14th February 2021</td>
</tr>
<tr>
<td>Directorate / Department responsible (author/owner):</td>
<td>Judith Clegg, Advanced Neonatal Nurse Practitioner, NNU, RCH</td>
</tr>
<tr>
<td>Contact details:</td>
<td>01872 252667</td>
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<tr>
<td>Brief summary of contents</td>
<td>Indications and referral process for BCG Vaccination in the newborn</td>
</tr>
<tr>
<td>Suggested Keywords:</td>
<td>BCG. Neonatal. Immunisation. Vaccination. TB. Maternity</td>
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<td>Target Audience</td>
<td>RCHT    CPFT   KCCG</td>
</tr>
<tr>
<td>Executives Director responsible for Policy</td>
<td>Medical Director</td>
</tr>
<tr>
<td>Date revised:</td>
<td>1st March 2018</td>
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<tr>
<td>This document replaces (exact title of previous version):</td>
<td>CLINICAL GUIDELINE FOR NEONATAL BCG VACCINATION V2.0</td>
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<tr>
<td>Approval route (names of committees)/consultation:</td>
<td>Obstetric Guidelines Group RCH&lt;br&gt;Neonatal Guidelines Group RCH&lt;br&gt;Peninsula Neonatal Network Guidelines Group</td>
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<tr>
<td>Divisional Manager confirming approval processes</td>
<td>David Smith</td>
</tr>
<tr>
<td>Name and Post Title of additional signatories</td>
<td>Not Required</td>
</tr>
<tr>
<td>Name and Signature of Divisional/Directorate Governance Lead confirming approval by specialty and divisional management meetings</td>
<td>Name: Caroline Amukusana</td>
</tr>
<tr>
<td>Signature of Executive Director giving approval</td>
<td>Original Copy Signed</td>
</tr>
<tr>
<td>Publication Location (refer to Policy on Policies – Approvals and Ratification):</td>
<td>Internet &amp; Intranet&lt;br&gt;✓ Intranet Only</td>
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### Related Documents:

1. Department of Health publications and statistics  

2. National Institute for Clinical Excellence (NICE) Tuberculosis NG33  
   [https://www.nice.org.uk/guidance/NG33](https://www.nice.org.uk/guidance/NG33)  
   Accessed 5.3.2018

   [www.hpa.org.uk](http://www.hpa.org.uk)  
   accessed 5.2.2018


### Version Control Table

<table>
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<tr>
<th>Date</th>
<th>Version No</th>
<th>Summary of Changes</th>
<th>Changes Made by (Name and Job Title)</th>
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<td>August 2005</td>
<td>V1.0</td>
<td>Initial Issue</td>
<td>Judith Clegg, ANNP</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Dr Kumar, Dr Munyard Consultants</td>
</tr>
<tr>
<td>2 Nov 2012</td>
<td>V2.0</td>
<td>Addition of BCG referral form and updated referral clinic</td>
<td>Judith Clegg, ANNP</td>
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<td>14 Mar 2018</td>
<td>V3.0</td>
<td>2.1 Current incidence, London incidence</td>
<td>Karen Needham, Deputy post-natal ward manager</td>
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<td>2.5 Care pathway or best practice points:</td>
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<td>Clinic is held on the Postnatal Ward, Vaccine is soured [...] in this clinic, vaccine can be used for 6 hours</td>
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<td>Related documents: new versions of documents 2, 3 and 4</td>
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**All or part of this document can be released under the Freedom of Information Act 2000**

**This document is to be retained for 10 years from the date of expiry.**

**This document is only valid on the day of printing**

**Controlled Document**

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Appendix 2. Initial Equality Impact Assessment Form

This assessment will need to be completed in stages to allow for adequate consultation with the relevant groups.

<table>
<thead>
<tr>
<th>Name of the strategy / policy / proposal / service function to be assessed</th>
<th>CLINICAL GUIDELINE FOR NEONATAL BCG VACCINATION V3.0</th>
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<tbody>
<tr>
<td>Name of individual completing assessment:</td>
<td>Karen Needham</td>
</tr>
<tr>
<td>Telephone:</td>
<td>01872 252159</td>
</tr>
</tbody>
</table>

1. **Policy Aim***
   - Who is the strategy / policy / proposal / service function aimed at?
   - 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 the outcome?**
   - Number of BCG referrals

5. **Who is intended to benefit from the policy?**
   - All infants at risk of TB infection

6a Who did you consult with
   - Workforce | Patients | Local groups | External organisations | Other
   - X | X |

   b). Please identify the groups who have been consulted about this procedure.
   - Clinical Guideline Group
   - Obstetrics and Gynaecology Directorate
   - Local practitioners TB Advisory Group

What was the outcome of the consultation?
   - Guideline approved
7. The Impact
Please complete the following table. If you are unsure/don’t know if there is a negative impact you need to repeat the consultation step.

Are there concerns that the policy could have differential impact on:

<table>
<thead>
<tr>
<th>Equality Strands:</th>
<th>Yes</th>
<th>No</th>
<th>Unsure</th>
<th>Rationale for Assessment / Existing Evidence</th>
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<tr>
<td>Age</td>
<td>x</td>
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<td></td>
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<tr>
<td>Sex (male, female, trans-gender / gender reassignment)</td>
<td></td>
<td>x</td>
<td></td>
<td></td>
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<tr>
<td>Race / Ethnic communities /groups</td>
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<td></td>
<td>Beneficial to babies from higher risk countries</td>
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<td>Disability - Learning disability, physical impairment, sensory impairment, mental health conditions and some long term health conditions.</td>
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<td>x</td>
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<td>Religion / other beliefs</td>
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<td></td>
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<td>Marriage and Civil partnership</td>
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<tr>
<td>Pregnancy and maternity</td>
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<td>Beneficial to maternity patients</td>
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<td>Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian</td>
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</table>

You will need to continue to a full Equality Impact Assessment if the following have been highlighted:
- You have ticked “Yes” in any column above and
- No consultation or evidence of there being consultation- this excludes any policies which have been identified as not requiring consultation. or
- Major this relates to service redesign or development

8. Please indicate if a full equality analysis is recommended. Yes | No x

9. If you are not recommending a Full Impact assessment please explain why.
This guideline has a beneficial equality impact
Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead
c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Knowledge Spa,
Truro, Cornwall, TR1 3HD

This EIA will not be uploaded to the Trust website without the signature of the
Human Rights, Equality & Inclusion Lead.

A summary of the results will be published on the Trust’s web site.

Signed Sarah-Jane Pedler

Date 14th March 2018
Appendix 3

BCG Referral Form

BCG Vaccination referral for infants at risk of tuberculosis (TB) infection

**Indications:**
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)


**Contraindications:**
- HIV positive mother or infant
- Household with active TB case suspected or confirmed
- Immunodeficiency such as Severe Combined Immunodeficiency (or family history of) or Di George Syndrome
- Mother receiving immunosuppressive drugs
- Infected skin lesions
  - The vaccine is not necessary for short (less than 4 weeks ) travel to countries with high incidence

Please accept referral of NAME:
Date of Birth:
NHS / CR number:

Mother’s name and NHS Number:
Address and contact telephone number:

**Indication/ Country of origin:**
Please note if any translator required for appointment:
I confirm that to my knowledge there are no contraindications (eg. Maternal HIV status at booking) as listed above to baby receiving this vaccine

Signed: Print Practice area: Date:

Please send completed form to: Dr.A Prendiville, Consultant Paediatrician, BCG clinic referral, Child Health, Royal Cornwall Hospital, TR1 3LJ. Parents will receive the next available appointment