BCG Vaccination protocol for newborn infants (CG584)

TO BE READ IN CONJUNCTION WITH ROYAL BERKSHIRE HOSPITAL PATIENT GROUP DIRECTION PGD023/089 REF: ADMINISTRATION OF INTRADERMAL BCG VACCINE FOR NEONATES

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<tr>
<th>Approval Group</th>
<th>Job Title, Chair of Committee</th>
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<tr>
<td>Paediatric Clinical Governance</td>
<td>Chair, Paediatric Clinical Governance Committee</td>
<td>16th September 2016</td>
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<td>Maternity Clinical Governance</td>
<td>Chair, Maternity Clinical Governance Committee</td>
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Change History

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Author, job title</th>
<th>Reason</th>
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<tr>
<td>1</td>
<td>30th July 2012</td>
<td>Dr Nicola Pritchard Samantha Fleming Tracey Langham</td>
<td>Additional information to compliment PGD to cover vaccination of at risk postcodes, infants on antibiotics and preterm infants</td>
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<td>1.1</td>
<td>13th November 2012</td>
<td>Dr Nicola Pritchard</td>
<td>Changes following Paediatric P&amp;P meeting</td>
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<td>24th October 2013</td>
<td>Dr Nicola Pritchard Samantha Fleming Tracey Langham</td>
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<td>2.0</td>
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<td>Samantha Fleming (Practice Educator) Dr Yaliwal (Paediatric Consultant)</td>
<td>Complete overhaul of existing guidance</td>
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</table>

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Date: September 2016
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**Purpose**  
To give guidance in immunising and administering intradermal BCG to newborns against Tuberculosis as part of the DOH national immunisation programme.

**The Function of the policy:**  
To identify high risk new-borns for Tuberculosis, contraindications, precautions, recommendations for premature infants and alternative provisions for vaccination if not done as an in-patient. It also includes administering and monitoring instructions.

**1.0 Introduction**  
Human tuberculosis is caused by infection with *Mycobacterium tuberculosis* complex and may affect almost any part of the body. In the UK, about 60% of all cases involve the respiratory system; non-respiratory forms are more common in young children in communities with connections to areas of the world with high prevalence, and in those with impaired immunity. Tuberculosis is most frequently acquired by aerosolised droplet spread; such transmission is only likely when the index case is sputum smear-positive for the bacillus, and after prolonged close contact.  
The BCG immunisation programme is a risk based programme, the key part being a neonatal programme targeted at protecting those children most at risk of exposure to Tuberculosis, particularly from the more serious childhood forms of disease (70-80% effective).

Bacillus Calmette-Guérin (BCG) is the only licensed vaccine against tuberculosis currently available for humans in the UK. It is a live attenuated strain derived from *Mycobacterium bovis*, which stimulates the development of antibodies to *Mycobacterium tuberculosis* (and other Mycobacteria).

**2.0 Indications**  
- All neonates’ ≥ 34 weeks or preterm infants’ ≥ 34 weeks corrected gestational age identified as at a higher risk of developing tuberculosis according to DOH and NICE guidance.
- Neonates living in areas of the UK where the annual incidence rate of TB is 40/100,000 or greater.
- Neonates with a parent or grandparent who was born in a country where the annual incidence of TB is 40/100,000 or greater (latest rates available from www.hpa.org.uk - WHO Estimates of TB by country)
- There is a family history of TB in the last five years.
- If the baby is likely to travel to a high incidence country, for more than 3 months in the next five years. (Latest rates available from www.hpa.org.uk - WHO Estimates of TB by country; TB Specialist Nurses to forward updated list annually.)
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**Babies on observations** can have the vaccination as long as they do not have a temperature and are not acutely unwell if not vaccinated arrangements should be made for vaccination when well

**Babies on intravenous, oral or topical antibiotics** can be vaccinated provided they are not acutely unwell and do not have a temperature, if not vaccinated arrangements should be made for vaccination when well

**Babies requiring vaccination discharged from Buscot** to post natal wards should be identified as fit for vaccination and receive the vaccine on postnatal ward if the BCG was not given on Buscot Ward.

Parents seeking vaccination for their babies should be assessed for specific risk factors for TB. Those without risk factors should not be offered BCG vaccination but should be advised of the current policy and given written information. Further information is available at [www.immunisation.nhs.uk](http://www.immunisation.nhs.uk).

### 3.0 Contraindications

The vaccine must **not** be given to:

- Those who have already had a BCG vaccination
- Those who have had a confirmed anaphylactic reaction to a component of the vaccine
- Neonates in a household where an active TB case is suspected or confirmed. **Refer to the TB nurse urgently for contact tracing and vaccination as required.**
- Neonates who are immuno-compromised by virtue of disease, treatment or in-utero exposure: See Appendix 2
  - Those receiving corticosteroid or other immunosuppressive treatment Inhaled steroids are not a contraindication.
  - If there has been in-utero exposure to TNFalpha antagonist and other biological medicines vaccination should be delayed until at least 6 months of age. See Appendix 2 Those suffering from neonatal malignancy.
  - Neonates born to HIV-positive mothers. However, BCG can be administered after three appropriately timed (Birth, 6 weeks & 3 months) negative postnatal PCR tests for HIV infection. These babies should be referred to the Department of Respiratory Medicine once 3 negative postnatal PCR tests for HIV have been performed.

### 3.1 Precautions

- Minor illnesses without fever or systemic upset are not a valid reason to postpone immunization
- If baby is acutely unwell, immunisation should be postponed until they have fully recovered. This is to avoid confusing the differential diagnosis of
any acute illness by wrongly attributing any signs or symptoms to the adverse effects of the vaccine. Babies on antibiotics can be vaccinated if they are systemically well.

- Babies with generalised septic skin conditions should not be vaccinated. If eczema exists, an appropriate (preferably the other arm) immunisation site should be chosen that is free from skin lesions.
- BCG should not be carried out within four weeks of receiving any other live vaccine. It can be given on the same day as another live vaccine but not in the same arm as the BCG.
- BCG should not be given if a baby has been given immunoglobulins as this may interfere with the immune response to BCG vaccination. BCG vaccination can be given after 3 months.
- No further vaccines should be given in the arm used for BCG for at least three months because of the risk of lymphadenitis.

4.0 Premature Infants:
- As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed.
- It is important that premature babies have their immunisations at the appropriate chronological age and not corrected gestational age as per the DofH vaccination schedule.
- The occurrence of apnoea following vaccination is especially increased in infants who were born very prematurely. If the baby has previously had apnoea, bradycardia, or desaturation after other immunisations the BCG immunisation should be given in hospital, with respiratory monitoring for 48-72 hours and the case discussed with the paediatric team.
- Very premature infants born (born ≤ 28 weeks gestation) who are in hospital should have respiratory monitoring for 48-72 hrs when given their first immunisation, particularly those with a previous history of respiratory immaturity.
- If the baby is an appropriate gestational age but ≤ 1.8 Kg please seek advice from a paediatrician as there is less safety information available below this weight and risk will have to be assessed individually

If unsure of BCG vaccination safety for any baby or baby please seek advice from a paediatrician.
5.0 Action for excluded babies

- Neonates that require the BCG vaccination but are not vaccinated in the hospital but meeting the criteria for BCG vaccination should be referred to the chest clinic in the Department of Respiratory Medicine as soon as possible for later vaccination.

- Those babies with short term ill health or other short term medications/treatment, which may affect BCG response or with adverse skin conditions, should have further arrangements to ensure the infant is vaccinated as soon as possible when well, individual plans for vaccination should be made based on the reason for exclusion from BCG vaccination at this point. (NB see information for infants on intravenous antibiotics)

- For babies who meet the exclusion criteria for other reasons, BCG vaccination should not be given, parents will be advised of the potential risk of TB and if available a multi-lingual information sheet given (supplied by DOH publication translations) [www.immunisation.nhs.uk](http://www.immunisation.nhs.uk)

6.0 Action if parents decline vaccination

Those that do not wish to receive the BCG must have their reasons clearly documented within their screening health record along with a signature and the GP informed. Parents will be advised of the potential risk of TB and if available and a DOH information sheet given. (Supplied by DOH publication translations) [www.immunisation.nhs.uk](http://www.immunisation.nhs.uk)

7.0 Method of Administration

Please refer to Trust PGD Information

**Staff criteria: Professional qualifications required**: Registered Nurse and/or Registered Midwife

The practitioner administrating the medicines described within the following Group Directions must be a registered nurse or registered midwife (current registration with the NMC). The professional responsibility and consequent accountability of individual practitioners the NMC has clarified principles for practice in The Code (2015). Competence in all aspects of immunisations, including the contraindication to specific vaccines, based on the current Green Book (Immunisation against infectious disease 2006) need to be considered in line with this documentation and linked to individual knowledge.

Nurses and midwives providing immunisations are expected to be familiar with the current Green Book (Immunisation against infectious disease). The up-to-date chapter for Tuberculosis is on the DOH website.

**Specialist/additional qualifications, experience or training required:**

Nurses and midwives or medical staff delivering the BCG vaccination must undergo training with either the specialist TB nurse or a midwife that has been identified and assessed as competent to train. The staff member will require certification to show that they are...
competent in the administration of the BCG vaccination to neonates. Training and competency should include all aspects of immunisations, including the contraindication to specific vaccines

**Requirements for continuing training and education:**
Each individual is responsible for maintaining their own level of competency and ensuring any relevant professional development necessary to maintain this level of competency is undertaken.

Reviews should be carried out or interim reviews may be required if changes in practice occur. The following should be discussed:
- The need for training should be assessed.
- Issues should be brought to review that have arisen as part of continuing professional development.
- If there has been a break of more than 6 months in performing this procedure, retraining will need to be taken and it is the individuals own responsibility to maintain this competency **Annual training in the recognition of anaphylaxis and basic life support is recommended, as per Trust guidelines**

**Method of administration:**

**Name:** Intradermal BCG (Bacillus Calmette-Guerin) Vaccine SSI

**Form & Strength:** BCG Vaccine SSI is supplied in a glass vial containing the equivalent of 10 adult or 20 infant doses, it is fitted with a bromobutyl rubber stopper that does not contain latex. BCG Vaccine SSI is a freeze-dried, white crystalline powder containing the bacteria Mycobacterium bovis (Bacillus Calmette –Guérin), Danish strain 1331, live attenuated as the active substance. The vaccine powder must only be mixed with the solvent, Diluted Sauton SSI, before use. 1ml of the ready to use vaccine contains between 2 and 8 million live units of *Mycobacterium bovis* BCG.

**Dose for infants under 12 months of age:** 0.05ml of the reconstituted vaccine

**Route:** Intradermal Injection

The vial of vaccine powder should be diluted using aseptic precautions, a sterile tuberculin syringe, and suitable large sterile needle, with 1ml of solvent, diluted Sauton SSI (Do not use any other diluents). The vial, rubber stopper and in particular the vaccine, must not be contaminated with any antiseptic or detergent. Invert the vial of reconstituted vaccine a few times to re-suspend the lyophilized BCG completely. **DO NOT SHAKE.** Gently swirl the vial of re-suspended vaccine before drawing up each subsequent dose. Jet injectors and multiple puncture devices should **NOT** be used.

The BCG vaccine must be stored in the original packing in a refrigerator at 2°C - 8°C, protected from light, and must not be frozen.
Once reconstituted, the vaccine should appear a homogenous, slightly opaque and colourless suspension. It should be reconstituted with the diluents supplied by the manufacturer and used immediately. Any reconstituted vaccine should be discarded after four hours. Any unused reconstituted vaccine together with any equipment used for vaccination should be safely discarded into a sharps bin for incineration. The BCG vaccine must be given strictly intradermally with a fresh needle and syringe for each patient.

A minimum of 0.05ml (under 12 months of age should be drawn into a fine 1ml tuberculin syringe from the vial of made up vaccine. A short bevel 25 or 26 gauge needle is then attached to the syringe and excess air and vaccine expelled to leave the correct dose of 0.05ml. The needle hub must be attached firmly.

**Vaccination site:**

The recommended site for the BCG vaccination is 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 left arm is recommended by WHO).

The upper arm must be adequately exposed and held at approximately 45° to the body or in neonates the arm is held firmly in an extended position.

If the skin is visibly dirty it should be washed with soap and water. The operator stretches the skin between the thumb and forefinger of one hand and with the other slowly inserts the needle with the bevel upwards for about 3mm into the superficial layers of the dermis almost parallel with the surface. The bevel of the needle can usually be seen through the epidermis. Considerable resistance is felt when the fluid is being injected. A correctly given intradermal injection results in a tense blanched raised bleb, usually with a peau d’orange appearance. A bleb is typically of 3mm diameter following a 0.05ml intradermal injection. If little resistance is felt when injecting and a diffuse swelling occurs, the needle is too deep. The needle should be withdrawn and reinserted intradermally.

*If there is vaccine leakage do not give more vaccine, instead document in the notes and advise the parents to contact the Department of Respiratory Medicine if no reaction appears after 8 weeks.*

The infant should remain in the clinical area for 20 mins after vaccination and before leaving, the parents should be advised how to care for the vaccination site and to report any adverse effects.

**Disposal:**

Equipment used for vaccination, including used vials or ampoules should be disposed of at the end of a session by sealing in a proper puncture resistant sharp box.

**Frequency of administration:**

Minimum and maximum total doses: Once only

Follow up actions required: None
Legal status of medicine: Prescription only Licensed

8.0 Written and verbal advice given to parents
Pre or post treatment:
The parents/guardians are counselled about the BCG vaccination and consent obtained prior to the administration of the BCG. Record of vaccination is recorded in the babies ‘red book’, medical records and a leaflet is provided on care of the site (See Appendix 1). The parents of infants requiring vaccination after discharge should be referred by a health care professional in the community (MW, HV or GP).

8.1 Parental Advice re: Adverse Reactions
Relevant warnings, including potential adverse reactions/contraindications and identification and management of adverse reactions:
Severe injection site reactions, large, local discharging ulcers, abscesses and keloid scarring are most commonly caused by faulty injection technique, choosing sites higher on the arm or shoulder, excessive dose or vaccinating individuals who are tuberculin positive. It is essential that all health professionals are properly trained in all aspects of the process involved in BCG vaccination.

Adverse reactions to the vaccine include fever, and enlargement of a regional lymph node to greater than 1cm which may ulcerate.

Allergic reactions (including anaphylactic reactions - contact doctor urgently), more severe local reactions such as abscess formation and disseminated BCG complications (such as osteitis and osteomyelitis) are rare.

Circumstances in which further advice should be sought from a Doctor:
In the event of severe local reactions or disseminated BCG infection advice should be sought from a paediatrician or chest physician for further investigation and management.

Record of supply/administration and details to be kept for audit:
Patient notes
Personal Child Health Book ‘The Red book’
CMIS

9.0 Reporting procedure of adverse reactions
All serious or unusual adverse reactions possibly associated with BCG vaccination should be reported to the Commission on Human Medicines through the Yellow Card system, and vaccination protocols and techniques should be reviewed. Every effort should be made to recover and identify the causative organism from any lesion constituting a serious complication. In addition a copy of the adverse reaction report to be sent to the TB nurse.
• Record adverse reactions in patient’s notes.
• Any drug errors, i.e. overdose of vaccine should be reported as an incident in accordance to Trust procedure and doctor informed

10.0 Supporting Documentation and References
This document must be read in conjunction with
• Royal Berkshire Hospital Patient Group Direction PGD023 Ref: Administration of Intradermal BCG vaccine for neonates
• HPA guidance on countries/areas at high risk of TB

Other supporting documents
• World Health Organization (WHO) estimates of tuberculosis incidence by country, 2010
• Changes to the BCG vaccination Programme PL CNO (2005)3 DOH 2005
• TB, BCG vaccine and your baby DOH 2008
• Royal Berkshire Hospital Patient Group Direction PGD Ref: Administration of Intradermal BCG vaccine for neonates July 2011
• Green Book Immunisation against Infectious Diseases Chapter 32 Tuberculosis Sept 2013
• cBNF

11.0 Training
Training required to fulfil this policy will be as laid out in Trust PGD for BCG administration. Retraining will be required if there is a gap of more than 6 months in performing BCG administration.

12.0 Monitoring of Compliance

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<th>Aspect of compliance or effectiveness being monitored</th>
<th>Monitoring method</th>
<th>Individual or dept. responsible for the monitoring</th>
<th>Frequency of the monitoring activity</th>
<th>Group/committee which will receive the findings/monitoring report</th>
<th>Committee/individual responsible for ensuring that the actions are completed</th>
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<td>BCG administration for eligible infants</td>
<td>Audit</td>
<td>Midwifery team</td>
<td>Monthly</td>
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The Trust reserves the right to amend its monitoring requirements in order to meet the changing needs of the organisation.
Appendix 1 – BCG Care of site leaflet for parents

Possible side effects:
Severe allergic reactions (redness/swelling of the face, neck or throat; skin rash; breathing difficulties) may occur in rare cases. Contact the midwife immediately if your baby develops any of these shortly after the vaccine has been given.

Uncommon side effects; (may be less than 1 in 100 cases)
Fever; swelling of lymph nodes in the armpit larger than 1cm across; an oozing ulcer at the injection site larger than 1cm across.

Rare side effects; (may occur in less than 1 in 1,000 cases)
Inflammation of lymph nodes, sometimes with oozing ulcers, possibly abscess; infection with the vaccine bacteria which can spread throughout the body.
Some side effects will require treatment.

Further advice:
Your baby can start their routine immunisations regardless of whether they have had the BCG, but you must make sure that no other injections are given in the left arm for at least 3 months.
Please make sure the vaccine is documented in your baby’s red Personal Child Health Record.
If you are experiencing problems with the BCG vaccine site, or are concerned, please ring: Tracey Langham, Anita Cleary or Kay Perry; TB Nurses on: 0118 322 5260 or 0118 322 6892.

Royal Berkshire NHS Foundation Trust
London Road, Reading RG1 5AN
Telephone 0118 322 5111 www.royalberkshire.nhs.uk

This leaflet is for the parents and carers of newborn babies who will be offered the BCG vaccination at, or soon after, birth. Bacille Calmette-Guérin (BCG) was developed by Calmette and Guérin at the Pasteur Institute (Lille), and contains a weakened form of the bacteria (germs) that cause tuberculosis (TB). It does not cause TB, but helps your baby develop protection (immunity) against the disease should he/she ever come into contact with it.

What is TB and how is it caught?
TB is a serious infectious disease that can lead to TB meningitis (swelling of the lining of the brain) in babies and young children. In young people and adults, TB commonly affects the lungs but can occur in almost any part of the body. Only TB of the lungs or throat can be passed on to others and it usually takes close, lengthy contact with someone who is coughing the germs for the disease to spread. TB is curable with a course of special antibiotics.

Are there reasons he/she should not have the BCG?
The vaccine should not be given (or should be delayed) if your baby has a high fever (temperature); is having treatment/has a condition that weakens the immune system; there is a history of parenteral HIV infection; has a skin condition on the left upper arm (site where BCG is given).
The vaccine should be delayed until the infant is 6 months old if the baby’s mother was taking biological medicines (TNF antagonists) during pregnancy, as this can cause the baby to suffer from a BCG infection.

Why is my baby being offered the BCG?
In the UK, the BCG is offered to babies who are more likely than the general population to come into close contact with someone who has TB. That is babies whose parents or grandparents come from a country with high rates of TB.

Care of the BCG vaccination site
- The vaccine injected into the outer skin layer makes a tiny white ‘blebb’, which must be left alone. This will disappear within about half an hour. In most cases, although not all, the BCG causes a reaction at the injection site, usually between 2-8 weeks following the vaccination.
- A small red lump, often containing pus, with scaling and blistering of the site, occurs frequently. It is quite normal for the area to weep a little. This will crust over after some time and a scab will then form.
- Do not pick, knock, scratch or wash the site or scab. It will make it sore and it will take much longer to heal and could get infected and cause a worse scar.
- It is important to keep the BCG vaccination site dry and let the air get to it as much as possible. Do not cover it, wear light clothing if needed, but avoid tight and itchy clothes such as woolen jumpers.
- Do not keep getting the area wet and certainly not scoopy. If you take baby swimming, cover the site with a waterproof plaster, take the plaster off as soon as possible, pat the skin dry and let the air get at it again. For a bath or shower, do not cover the area but be careful not to rub it at all. Again, pat it dry afterwards and let the air get to it.
- With care, the BCG vaccination site should not cause any problems. After about 6-8 weeks, sometimes longer, the scab should come off on its own and leave a small red mark which will fade slowly over time and eventually leave a small scar.
Appendix 2 – Immunosuppression
The following lists are not exhaustive; the specialist treating the mother’s disease would have made a decision if and when to stop treatment during pregnancy. The stage at which treatment was stopped during pregnancy will influence the immune status of the neonate. Communication with the prescribing physician is vital.

- Adalimumab
- Certolizumab Pegol
- Etanercept
- Golimumab
- Infliximab
- Rituximab
- Abatacept
- Belimumab
- Secukinumab
- Tocilizumab
- Ustekinumab
- Methotrexate

Example of some primary and acquired immunodeficiency causing conditions:

- Acute and chronic leukaemias
- Lymphoma
- Hodgkin’s Disease
- Current or previous treatment of malignant disease
- Immunosuppression due to HIV/AIDS
- Cellular Immune Deficiencies
- Crohns Disease