

# STANDARD OPERATING PROCEDURE

## BCG Vaccinations for Neonates

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<b>RATIFIED BY :</b>  Perinatal Governance Group	<b>DATE:</b>  August 2021
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<b>PURPOSE</b>
This SOP outlines the identification process of those babies that should receive a BCG Vaccination and the process of administration and documentation that should be followed, updated to allow for the changes due to the SCID (Severe Combined Immunodeficiency) evaluation. This evaluation involves screening for SCID as part of the routine Newborn Bloodspot Screening (NBBS) and the BCG vaccine should not be given until the SCID screening outcome is known.
<b>OBJECTIVE</b>
To be able to follow the correct process for administration of BCG vaccination to neonates.
<b>SCOPE</b>
This guidance is relevant to the following staff groups: <ul style="list-style-type: none"> <li>• All midwifery and maternity staff who work within maternity</li> <li>• Midwives/ANNP/Doctors who have completed the necessary competencies in order to administer BCG vaccinations</li> </ul>
<b>COMPETENCIES</b>
Staff who administer BCG Vaccinations to neonates must be compliant and have completed the necessary competencies in order to administrate the vaccine correctly
<b>INDICATIONS</b>
Identification of those infants who require a BCG should occur at the time of their NIPE (Newborn and Infant Physical Examination) by asking parents screening questions to identify if the baby meets the criteria for BCG Vaccine as defined by Public Health England.

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In accordance with Public Health England the following infants should be offered a BCG Vaccine:

- All infants (aged 0-12 months) with a parent or grandparent who was born in a country where the annual incidence of TB is 40/100,000 or greater - <https://www.gov.uk/government/publications/tuberculosis-tb-by-country-rates-per-100000-people>

**Confirm with parent country of birth for both parents and all grandparents.**

- All infants (aged 0-12 months) living in areas of the UK where the annual incidence of TB is 40/100,000 or greater - <https://www.gov.uk/government/publications/tuberculosis-tb-in-england-surveillance-data>
- All infants (aged 0-12 months) who are going to live with local people for more than 3 months in an area with high rates of TB or where the risk of multi-drug-resistant TB is high - [https://www.nhs.uk/?\\_sm\\_au=iVVb5ss1Wb3W1swsHM3GvK06QHpkJ](https://www.nhs.uk/?_sm_au=iVVb5ss1Wb3W1swsHM3GvK06QHpkJ)
- Once a baby has been identified as being appropriate to receive the BCG vaccine the records on both BadgerNet and Smart for NIPE (S4N) must be updated accordingly.

**BCG vaccine and prematurity**

Prematurity is not a contraindication to receiving the BCG vaccine. However the vaccine should be withheld until an infant is preparing for discharge. Administration of the vaccine should not be delayed until the day of discharge, instead it should be given 2-3 days before discharge if the baby is deemed to be well. The SCID result should also be reviewed prior to giving the BCG vaccine. If the baby is being discharged before the SCID result is received then an appointment will need to be made for the baby to come back approximately two weeks after the NBBS sample has been sent.

**BCG vaccine and maternal HIV**

Infants considered at very low or low risk of HIV transmission (i.e maternal VL <50 HIV RNA/mL at or after 36 weeks gestation) but with a high risk of TB exposure may be given BCG at birth if indicated. Infants at higher risk of HIV transmission must have BCG vaccine deferred until they are confirmed HIV negative, usually at 12-14 weeks. The SCID result should also be reviewed prior to giving the BCG vaccine.

**Contraindications**

The BCG vaccine is contraindicated in the following cases:

- All infants who have already received a BCG vaccine
- All infants who come from a household where an active TB case is suspected or confirmed

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- All infants born to a mother who has received immunosuppressive biological therapy during pregnancy (See Green Book for further information).
- All infants who have not had a SCID screening outcome of either 'not screened', 'declined', or 'not suspected' recorded.

If an infant is being treated with antibiotics the BCG vaccine should be withheld until the course of antibiotics is complete. However antibiotics are not a contraindication in themselves. There may be instances where it is appropriate for an infant on antibiotics to receive the vaccine. This should be assessed on an individual basis, according to the infant's clinical condition in conjunction with the Neonatal Team.

## PROCESS

### Identification

Eligible babies will initially be identified through the TB Risk assessment form on Badgernet by the booking midwife. The screening questions will then be asked again at the time of the NIPE examination and eligibility for BCG will be documented on S4N (and updated on Badgernet if previously incorrectly recorded). Practitioners should be aware that if 'No to all risk factors' is selected this will also default to BCG not required and this will need to be changed if needed.

The NIPE practitioner will inform the parents of the baby's eligibility for BCG vaccination and provide the following information leaflet:

- Public Health England – TB, BCG vaccine and your baby  
[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/782109/TB\\_BCG\\_baby\\_leaflet.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/782109/TB_BCG_baby_leaflet.pdf)

If the parents wish their baby to have the vaccination, parents should be informed that they will be given an appointment for when their baby is approximately 21 days old, to allow for the SCID screening outcome to have been received. If possible this appointment should be made, and an appointment letter given to the parents, prior to discharge. If the parents decline the vaccine then this should be recorded on both Badgernet and S4N. At the end of each shift, the NIPE practitioner should send an email to [asp-tr.nipefailsafeteam@nhs.net](mailto:asp-tr.nipefailsafeteam@nhs.net) with a list of all babies identified as eligible for BCG vaccination and whether an appointment has been made or vaccination declined.

### SCID screening outcomes

The failsafe officer will be responsible for tracking the babies identified as eligible for BCG and ensuring that the SCID screening outcome is available prior to the BCG appointment. The emailed list from the NIPE practitioner will be checked against the S4N and Badgernet records to ensure no babies are missed, and additional appointments will be made as needed.

SCID screening outcomes will be provided 3 times per week by Child Health (CHIS) and added to the tracking spreadsheet by the failsafe officer. At least two days prior to each clinic the failsafe officer will ensure that all babies for that clinic have a SCID screening outcome

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recorded. If no SCID screening outcome has been recorded, the parents will be contacted and given a new appointment.

### **Consent**

Prior to administering the BCG vaccine parental consent should be obtained. Pre-printed BCG Consent forms are available for this. The vaccine can be given under a Patient Group Directive however if a baby has been identified as SCID suspected but subsequently confirmed as negative, then the vaccine will need to be given under a Patient Specific Directive.

### **Administration**

The correct administration procedure for giving a BCG vaccine is described in **Appendix 1**.

BCG vaccines should only be given by those individuals trained and deemed competent to administer intradermal (ID) injections. The competency document for administration of BCG Vaccines can be found in **Appendix 2**.

- Dose for infants <12 months of age – 0.05ml via ID injection, using a 26G needle.
- The vaccine stopper must not be wiped with any antiseptic or detergent. If an alcohol swab is used to clean the rubber stopper of the vial it must be allowed to evaporate before the stopper is penetrated with a needle.
- Ensure the vaccine is reconstituted with the correct diluent – From 2016-2018 interruptions to licenced BCG Vaccine (AJV) manufacturing meant that an unlicensed version of the BCG Vaccine (InterVax) had to be used. The licensed BCG Vaccine (AJV) is now available, meaning both AJV and InterVax BCG Vaccines are in circulation. Take care to ensure that the vaccine you use is reconstituted with its corresponding diluent.
- Reconstituted vaccine may be used for up to four hours at room temperature, after which time any unused reconstituted vaccine should be discarded.
- Ensure that there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination.
- BCG vaccines should be administered into the lateral aspect of the left upper arm at the level of the deltoid muscle via intradermal (ID) injection. Correct technique will produce a 'bleb' under the surface of the skin.
- Dispose of waste into 'purple lidded' sharps bin for waste that is potentially cytotoxic/cytostatic.
- Provide parents/carers with 'BCG Vaccine – Aftercare Guidance' Leaflet

### **Documentation**

The following documentation should be completed for all BCG vaccines given:

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- Parental Consent Form
- Drug Chart
- Personal Child Health Record 'Red Book' – BCG Vaccination. The third page (yellow) should be given to the ward clerks and sent to Child Health.
- NIPE system - BCG administration
- Maternity BadgerNet – Immunisation form
- Neonatal BadgerNet – Immunisations form (If under Neonatal care)
- SCID pathway tracking spreadsheet, to include batch numbers for vaccine and diluent
- Notification to GP via BadgerNet (confirm and send BCG report)
- Monthly report to be sent to NHS England by failsafe officer

### **DNA (Did Not Attend) process**

Any DNAs will be recorded on the tracking spreadsheet by the vaccinator. The failsafe officer will follow up all DNAs and offer a second appointment. Ideally contact will be by telephone but if parents cannot be contacted by telephone then an attempt will be made at face to face contact and an appointment will be sent by post. The aim should be for this second appointment to be before the baby is 28 days old.

If the baby is not brought for the second appointment then baby will be discharged from this service and the GP will be notified accordingly.

### **RESPONSIBILITIES**

All clinical staff are responsible for complying with this Standard Operating Procedure.

### **REFERENCES**

National Institute for Health and Care Excellence (2016) *Tuberculosis*. Available at: <https://www.nice.org.uk/guidance/ng33/chapter/recommendations#bcg-vaccination> (Accessed 16 June 2019)

Public Health England (2013) *Tuberculosis: the green book, chapter 3*. Available at: [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/731848/Greenbook\\_chapter\\_32\\_Tuberculosis\\_.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/731848/Greenbook_chapter_32_Tuberculosis_.pdf) (Accessed 16 June 2019)

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[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/726380/BCG\\_transition\\_to\\_licensed\\_vaccine\\_.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/726380/BCG_transition_to_licensed_vaccine_.pdf) (Accessed 16 June 2019)

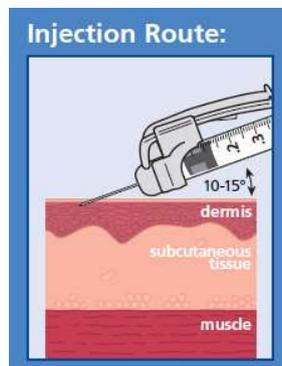
## AUDIT

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## Appendix1

### BCG Vaccine Administration Procedure

1. Identify infant eligibility for BCG Vaccine and update TB risk assessment on BadgerNet
2. Give information leaflet. Obtain written consent from parent using BCG Consent Form.
3. Ensure BCG Vaccine is prescribed correctly as per Neonatal Formulary – 0.05ml via Intradermal (ID) Injection
4. Collect BCG Vaccine and corresponding diluent from fridge, check expiry dates.
5. Gather correct equipment:
  - Blue Tray
  - 2.5ml Syringe
  - Red Filter Needle
  - 1ml Syringe
  - 26G Needle
  - Gauze
  - Purple Lidded Sharps Bin
6. Wash and dry hands as per infection control protocol, and **apply gloves and apron.**
7. Reconstitute BCG Vaccine powder as per manufacturers guidelines, and draw up 0.05ml dose using 1ml syringe and 26G Needle.
8. Position baby onto their right side, ensuring that the left arm is exposed. Spread the skin over the lateral aspect of the upper left arm taut. Insert the needle tip at a 10-15° just under the skin surface. Inject slowly. Look for bleb under skin surface.



9. Dispose of Needle, Syringe and Reconstituted Vaccine into Purple lidded Sharps Bin. Remove gloves and apron and wash hands.
10. Give aftercare leaflet
11. Document BCG Vaccination on Drug Chart, Red Book, Badger, NIPE System and Vaccine Folder.

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## Appendix 2

### BCG Vaccine Administration Competency Document

This competency document should be completed by ANNPs (Advanced Neonatal Nurse Practitioners), Doctors and midwives authorised to administer BCG Vaccines to infants <12 months of age.

Assessment of Competency should only be undertaken by a registered healthcare professional who is already deemed competent (having completed this document or similar) to administer BCG Vaccines, and has experience of doing so.

<b>Name:</b>	
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BCG Vaccine Administration		Summative Assessment		
Competency Statement		ANNP/Doctor (Self Assessment)	Assessor	Date
1	Can provide evidence of previous Immunisation Training – e-learning/face to face.			
2	Able to access relevant online publications for BCG Vaccination – Green Book, Public Health England, NICE Guidance.			
3	Discuss trust policy and procedure in relation to BCG Vaccine.			
4	Demonstrates an understanding of vaccines and how they are effective – live/inactivated and routes of administration.			
5	Can explain incident response and reporting process in case of procedural error or needle stick injury as per local protocol.			
6	Identify and discuss rationale for BCG Vaccine.			
7	Correctly identify infants who are at risk of TB and should therefore receive the BCG Vaccine.			
8	Demonstrates knowledge and understanding of the contraindications to BCG vaccine administration.			
9	Able to discuss with parents/legal guardian the rationale behind BCG vaccination and the associated risks.			
10	Demonstrates the ability to take fully informed consent from parent/legal guardian, and appropriately completes BCG consent form.			
11	Checks that the vaccine has been appropriately prescribed.			
12	Checks the presentation of vaccine products, expiry date, and how they have been stored prior to administration.			
13	Demonstrates awareness of need to ensure the correct vaccine is reconstituted with the correct diluent.			

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14	Accurately prepares BCG vaccination as per manufacturers guidelines.			
15	Demonstrates correct Intradermal (ID) injection technique, using correct size needle at the correct site, achieving the required bleb.			
16	Disposes of sharps, vaccine vials and vaccine equipment safely in line with local guidelines.			
17	Demonstrates ability to appropriately discuss aftercare with parents/legal guardian following administration.			
18	Correctly completes associated paperwork – including Drug Chart, NIPE system, Badger, Vaccine Folder and Red Book.			

Evidence of Practice								
<b>To be signed off as competent the ANNP/Doctor/Midwife must be overseen performing three BCG Vaccine Administrations, achieving the required bleb.</b>								
	1	2	3	4	5	6	7	8
<b>Date:</b>								
<b>Bleb Achieved:</b>								
<b>Signature of Assessor:</b>								

BCG Administration Competency Sign Off Statement	
<p><b>Competent:</b> YES / NO</p> <p><i>(Delete as appropriate)</i></p>	<p><i>I the undersigned assessor have assessed the registered ANNP/Doctor/Midwife in practice and deem him/her to be competent to the level laid out in this competency document. Where he/she is not competent or requires further training I have agreed an action plan and set a time frame for completion.</i></p>
<b>Signature of Assessor:</b>	
<b>Date:</b>	