

Standard Operating Procedure (SOP)

Title	Neonatal BCG Vaccination		
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Care Group	Women and Children's		
Version Number	5		
Effective Date	11 th October 2024	Review Date	October 2027
Author	Dr S Ray, Consultant Neonatologist Consultation: Jan Baker (Antenatal Screening Midwife), Julie Tromans (Paediatric Nurse)		
Approved by	Neonatal Governance		
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Document Control				
Version	Date	Author	Status	Comments
	March 2007	Dr SA Deshpande		
1	March 2015	Dr S Ray		Full review For next review in March 2019
2	January 2018	Dr S Ray		Amendment in view of changed referral administrative process
3	February 2019	Dr S Ray		Full review Changes to the list of high-risk countries, and updated information from DoH 'Green Book 2018' regarding infants born to HIV mothers
3.1	April 2019	Dr S Ray		Change to criteria for administration of live vaccines (as per 'Green Book')
3.2	May 2020	Dr S Ray		Change to contraindications in view of new guidance on risk stratification of HIV exposed babies and incorporates WMNODN network guidance 2019-2021

4	January 2022	Dr S Ray	Ratified	Input from Jan Baker (Lead Midwife for Antenatal Screening) and BCG Clinic Nurses Changed format of BCG referral form Incorporation of revised BCG vaccination programme pathway, based on introduction of screening for SCID
4.1	July 2022	Dr S Ray	Ratified	Inclusion of comments from NHSEI – as per National Service Specification 2 for Neonatal BCG Immunisation Programme (1 April 2022 – 31 March 2023) and local BCG vaccination failsafe process. Consultation with Jan Baker (Screening Midwife) and Julie Tromans (BCG Clinic Paediatric Nurse)
4.2	April 2023	Dr S Ray	Ratified	Inclusion of electronic referral pathway for Neonatal BCG vaccine via the BadgerNet system
5	11 th October 2024	Dr S Ray	Live	Pathway reviewed with updated source of eligibility list and inclusion of the local quality requirements of NHS England as auditable standards.
SOP Objectives		To provide guidance on the pathways for administration of the BCG vaccine to at risk infant groups		
Scope		Neonatal and Maternity Services SaTH		

Compliance with this guideline/SOP will be audited as part of the Shrewsbury and Telford Hospital NHS Trust's five-year rolling programme of NICE and local guideline audits, unless circumstances require an earlier or more frequent audit. The audit will be carried out using the auditable standards and the results will be reported and acted on in accordance with the Trust Clinical Audit Policy (CG25).

The local quality requirements as per NHS England schedule can be used as auditable standards and will be monitored by the antenatal screening programme midwife and Paediatric BCG clinic nurse at SaTH.

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	Task	Actioned by
1	BCG eligibility (Appendix 1) identified at booking appointment and recorded in maternal notes.	Midwives discuss neonatal BCG and provide patient information leaflet
2	Following birth and NIPE (newborn and infant physical examination) assessment, BCG eligibility to be entered on NIPE S4N (which communicates to CHIS), local maternity IT system and discharge summary to GP/HV. See Appendix 3 for Local BCG Vaccination Failsafe Process	Midwife or Tier 1/Tier 2 neonatal team (if required to undertake the NIPE)
3	A referral for neonatal BCG vaccination should be completed for all eligible babies. This is to be undertaken electronically on BadgerNet (see Appendix 4) so that it can be automatically sent through to Bookings Office. Ensure family has had information leaflet in required language.	Midwife or Tier 1/Tier 2 neonatal team (if required to undertake the NIPE)
4	If the electronic form cannot be used, the completed paper referral form (see page 10) should be sent to Women and Children's Bookings Office, Treatment Centre, Royal Shrewsbury Hospital ext 1044. This should be the exception (as electronic referrals preferred) and should be sent at the time of completion, else there may be a delay in offering immunisation to these 'at risk' babies.	Midwife Ward Clerk Postnatal Ward
5	Data transferred about baby's SCID (Severe Combined Immunodeficiency Syndrome) screening results and BCG eligibility to CHIS (Child Health Information System)	via NEMS (National Events Messaging System)
6	Appointment sent out to baby's parents to attend for BCG vaccination.	BCG Clinic Nurse Bookings Office OPD administrative support
7	Eligibility (Appendix 1) and contraindications (Appendix 2) to be checked, with informed consent to be obtained and recorded at the time of vaccination. BCG providers are to check CHIS to access the SCID results. If SCID screening has been declined by parents/guardians, ensure that they are aware of the implications of baby having SCID and giving live vaccines and document this discussion.	BCG Clinic Nurse
8	Recorded on Personal Child Health Record (PCHR) whether BCG given, not given or declined.	BCG Clinic Nurse
9	CHIS notified about information on vaccines administered, offered, declined and non-attendances within 5 working days.	BCG Clinic Nurse
10	Non-attendees are re-appointed x1. There should be at least two attempts to contact the parent/guardian if they have not specifically declined the vaccination. CHIS informed. If they do not attend the second appointment that is offered to family, letter sent to parents about their non-attendance and to be copied to the GP and HV.	One of the attempts to contact parents/guardian must be by the BCG Clinic Nurse. OPD administrative support
11	The service should be reviewed on a regular basis to ensure that eligible babies are being identified, offered the vaccine and receiving it in the recommended timeframe. Monitoring of attendance rates and non-attendances is recommended.	BCG Clinic Nurse CHIS, PHE, NHSE informatics
12	All eligible infants who are 'missed' should be offered the BCG vaccine by 1 year of age	Health Visitor/GP/Practice Nurse to refer child to Women and Children's Bookings Office, SaTH

APPENDIX 1

IDENTIFYING ‘AT RISK’ NEONATES WHO ARE ELIGIBLE FOR THE BCG VACCINE

The following babies should be offered the BCG vaccine:

- All infants (aged 0 to 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
- All infants (aged 0 to 12 months) living in areas of the UK where the annual incidence of TB is 40/100,000 or greater
- Mother with TB treatment completed in pregnancy or past history of TB
- Infants who are contacts of a TB case who is not smear positive
- If travelling for more than 3 months to a country where the annual incidence of TB is 40/100,000 or greater or risk of multi-drug resistant TB is high

Identify ‘at risk’ infants by referring to the most up-to-date list of countries with an annual incidence of TB of 40/100,000 or greater. This is no longer available on the gov.uk website since 13 June 2024 and can be found on the WHO website (link below).

https://worldhealthorg.shinyapps.io/tb_profiles/?_inputs_&lan=%22EN%22

Other considerations:

- Even if only one parent comes from a high-risk country, baby should be offered the BCG vaccine.
- Even if the parents of the baby were born in this country or do not visit the country of origin, baby should still be offered the BCG vaccine if their grandparents were born in a high-risk country and may have relatives visiting from that country.

Most ‘at risk’ babies will be referred by the midwives. However, any ‘missed’ babies should be referred to the Women and Children’s Bookings Office, Treatment Centre, Royal Shrewsbury Hospital, Tel: 01743 261000 ext 1044

Babies eligible for the BCG will only be given the vaccine:

- prior to or at 28 days old and on receipt of a SCID screen result of ‘SCID not suspected’, or ‘SCID not offered’ result if not within an area involved in the evaluation, or ‘SCID screen declined’ provided the parents are aware of the implications of baby having SCID and live vaccine and this is documented.

If a baby with ‘SCID suspected’ outcome is inadvertently given the BCG vaccine, their management should be discussed with the local specialist immunology team to whom they are referred as they may develop serious complications, which could be fatal. The Yellow

Card scheme should be completed and this event regarded and managed as a serious untoward incident (SUI).

APPENDIX 2

CONTRAINDICATIONS AND PRECAUTIONS

Contraindications to neonatal BCG vaccination:

- Temperature >38°C or acutely unwell
- Severe eczema (give at suitable lesion-free site)
- Baby in household where an active TB case suspected or confirmed, see **Tuberculosis (investigation and management following exposure in pregnancy)** network guideline
- Immunodeficient or on high-dose corticosteroids
 - defer BCG until 3 months after stopping corticosteroids if given prednisolone 1 mg/kg/day for > 2 weeks, 2 mg/kg/day for > 1 week, (or equivalent doses of another corticosteroid, e.g., dexamethasone 150 micrograms = prednisolone 1 mg)
- Maternal immunosuppressive biological treatment during pregnancy or breastfeeding – postpone BCG which should be delayed for 6 months and until as long as postnatal influence on the immune state of the infant remains possible
 - e.g. anti-TNF therapy (adalimumab, infliximab)
 - treatment for Covid-19 virus with medications, such as tocilizumab or sarilumab
- HIV positive
- HIV positive mother (see local guideline on '**Infants of HIV positive mothers: management**')
 - if baby has high risk of HIV transmission and exclusively formula feeding, give vaccine only after baby is confirmed HIV uninfected at aged 12–14 weeks
 - if baby has very low risk or low risk of HIV transmission and exclusively formula feeding, BCG can be given to baby and do not delay
 - if high risk of TB exposure and maternal HIV viral load <50 copies/mL after 36 weeks' gestation, BCG can be given
 - encourage maternal HIV testing but do not withhold BCG if mother declines testing unless mother from sub-Saharan Africa, in which case refer to HIV team for counselling about testing

Special cases:

- No need to delay routine vaccinations
 - BCG vaccine can be given simultaneously with other vaccines [including rotavirus vaccine oral or palivizumab (Synagis®) IM but not in same arm]
 - no further vaccination should be given in arm used for BCG vaccination for at least 3 months due to risk of regional lymphadenitis
 - if not given at the same time, other live vaccines can be given any time before or after each other
 - BCG vaccine can be given without deferral if infant has received immunoglobulin therapy in the neonatal period

APPENDIX 3

LOCAL BCG VACCINATION FAILSAFE PROCESS

	Task	Actioned by
1	CHIS has access to NIPE S4N, which will be updated with baby's eligibility for BCG vaccine once this is entered after the NIPE. CHIS to send daily email to Screening Midwives with list of eligible babies identified from NIPE S4N.	CHIS
2	List of babies eligible for BCG vaccine to be entered in to local BCG vaccine spreadsheet, which is accessible to Screening Midwives and BCG Clinic Nurses.	Screening Midwife
3	CHIS to email a daily list of SCID screening results of all babies eligible for BCG vaccine to Screening Midwife.	CHIS
4	List of SCID screening results of all babies eligible for BCG vaccine to be entered in to local BCG vaccine spreadsheet. This will enable the SCID results to be known prior to the baby attending for their BCG vaccine.	Screening Midwife
5	Weekly report to be run from NIPE S4N to ensure that all babies eligible for BCG vaccine have had a BCG vaccine referral sent and an appointment generated. Any babies who do not have a BCG vaccine appointment are re-referred.	Screening Midwife
6	Date of eligible baby's BCG vaccine appointment to be entered on to the local BCG database.	Screening Midwife
7	Screening Midwives and BCG Clinic Nurses to be emailed if there are any eligible babies who have not had their BCG vaccine recorded and require follow up.	CHIS
8	To investigate any 'missed cases', to subsequently offer the BCG vaccine, and to update CHIS.	Screening Midwife BCG Clinic Nurse
9	CHIS notified about information on vaccines administered, offered, declined and non-attendances within 5 working days.	BCG Clinic Nurse
10	Baby's records updated on the CHIS system.	CHIS

REFERENCES

Data from Public Health England, World Health Organisation and www.gov.uk

- The Green Book: Tuberculosis, Chapter 32, August 2017
- The Green Book: The UK Immunisation schedule, Chapter 11, March 2022
- The Green Book: Contraindications and special considerations, Chapter 6, August 2017
- PHE Vaccine update, issue 283, August 2018
- BCG Patient Pathway Flowchart, updated 9 December 2021
- Changing the timing of the neonatal BCG immunisation programme to a 28 day immunisation programme: effective from 1 September 2021
- National service specification 2: Neonatal BCG Immunisation Programme 2022/2023 (NHSEI)
- Schedule 4: Quality Requirements 2023-24 (NHSEI)
- Evaluation of NHS newborn screening for SCID extended to March 2024
- UKPA BCG Vaccine AJV Patient Group Direction (PGD) 31 August 2023

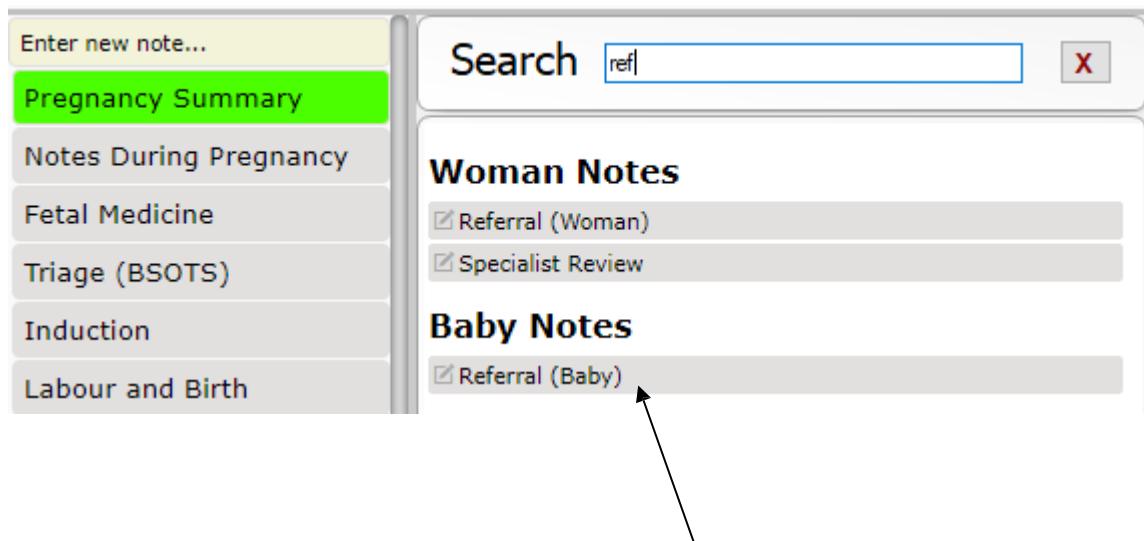
APPENDIX 4

ELECTRONIC NEONATAL BCG REFERRALS ON BADGERNET

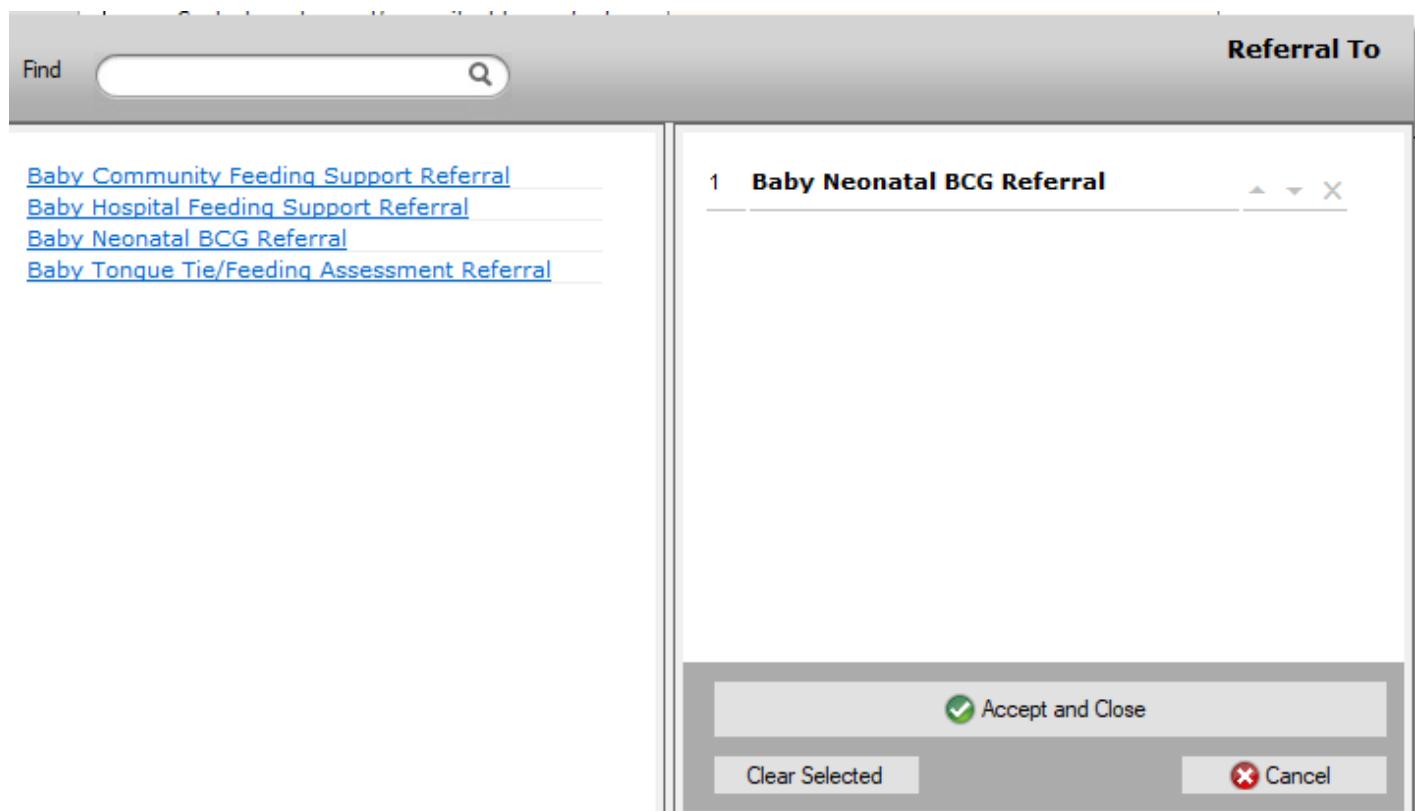
BCG Referrals can be sent through BadgerNet by following the steps below.

→ Open the woman's record

→ Search using enter new note for referral (baby)



→ Select Baby Neonatal BCG Referral (You can just search for BCG)



→ Complete all fields and then Select Neonatal BCG tab and add ethnicity of baby into additional notes.

Referral Details

Neonatal BCG

Neonatal BCG

Role of Referrer

Contact number and/or email address of referrer

Referral Accepted by Mother/Guardian Yes No

Additional Notes

Referral Sent Yes No

→ Click Save and Close. The PDF will be displayed. Click confirm and save

Displaying Baby Neonatal BCG Referral Report

Princess Royal Maternity Telford
maternity
Apley Castle, Grainger Dr, Telford, Shropshire, TF1 6TF.

Baby Neonatal BCG Referral - 18 Nov 22 at 09:55

Editestpatient, Baby (NHS: NOT RECORDED | Hospital Number: 999201T)
DOB: 21 Jul 22 at 13:58 | F | Baby 1 of 1 | 1 GUILD OF MONKS COTTAGES, SUTTON, NEWPORT, SHROPSHIRE, TF10 9DE | TEL?
Type of Birth: Spontaneous Cephalic | Gestation at Birth: 40+0 | Birthweight: 3500 | Apgar: 1min: 8 5mins: 10

Baby Neonatal BCG 1

Date	18 Nov 22 at 09:55	Age at Referral	Postnatal 17 weeks, 1 day
Referred by	Lisa Yeaman	Role of Referrer	Midwife
Referral Accepted by Mother/Guardian	Yes		

Patient: Baby Editestpatient. Hospital Number: 999201T Requested by Yeaman, Lisa at 18/11/22 09:58
NHS Confidential: Personal Data about a patient



→ Click authorise and complete the login section

Saving patient report

Time of confirmation 18 Nov 22 at 09:58

Report Baby Neonatal BCG Referral - 18 Nov 22 at 09:55

Recipients TEST

Additional Recipients

Additional Documents

Comments

Confirmed by Authorise

Report Data Quality
No outstanding items

Save & Close Cancel

→ Click save and close

The referral is now sent.

Once the referral is sent, it will appear in the 'Referral (Baby)' tab under 'Full Notes' for Baby.

The Bookings Office gets this electronic referral automatically and books baby into a BCG clinic.

THE SHREWSBURY AND TELFORD HOSPITAL NHS TRUST
REFERRAL FOR NEONATAL BCG VACCINATION
TO BE COMPLETED FOR ALL ELIGIBLE BABIES FOLLOWING THE NIPE

Please refer to the current WHO list of countries with high incidence of TB and only refer if parents and/or grandparents are from a high-risk country that is on the list.

Please identify which high risk country the parents/grandparents are from:

Place of birth. PRH, Telford Home

Other Hospital

NHS Number

Childs Name

Home Address

Postcode

Sex Male Female

Date of birth

Please return the completed form to Women and Children's Booking Office, Treatment Centre, Royal Shrewsbury Hospital Tel: 01743 26100 x 10

