Neonatal BCG Vaccination

This is the most current document and should be used until a revised version is in place

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Key Amendments

Date	Amendment	Approved by

INTRODUCTION

A third of the World's population is infected with Tubercle Bacillus. It causes approximately 2 million deaths per year (more than Aids and Malaria combined) and there are 7000 new cases diagnosed in the UK each year. Worcestershire is an area where there is low incidence but funding has been provided to inoculate neonates at risk.

This document outlines the BCG Policy for neonates born at the Alexandra Hospital, Redditch and the Worcestershire Royal Hospital.

THIS GUIDELINE IS FOR USE BY THE FOLLOWING STAFF GROUPS:

Named Neonatal Nurses /Paediatric Nurses and/or Midwives who have undertaken a period of training and accreditation. This training must consist of 5 observed administrations overseen by Consultant or Registrar Paediatricians or Zoe Ashenford, BCG link midwife. Attendance at a 1 hour workshop is also required, led by Zoe Ashenford, BCG Link Midwife. The practitioner should also be signed up to the Trust PGD DA/NU/06 allowing them to administer BCG to neonates.

Zoe Ashenford contact details : Transitional Care Unit, WRH via 01905 763333 or int. ext.30120

INTRODUCTION

In keeping with the Department of Health Guidelines on BCG Vaccination the policy is to offer BCG vaccination to:

- All neonates living in the areas of the UK where the annual incidence of TB is 40 per 100,000 or greater – currently no areas in the W Midlands offer universal neonatal BCG vaccination

- All neonates with a parent or grandparent who was born in a country where the annual incidence of TB is 40 per 100,000 or greater.

- Neonates where there is a family history of TB within the last 5 years (NIHCE TB Guideline recommendation)

- Neonates planning to visit a high risk country and live amongst local people for longer than one month (NIHCE TB Guideline)

SEE APPENDIX 4 FOR A LIST OF RELEVANT COUNTRIES

NB. Please be aware that Poland NO longer qualifies as the prevalence is now below 40 per 100,000.

Countries with lower than 40 cases per 100,000 per population – at present – are North America, parts of Europe, Australia and New Zealand. For up to date list refer to: http://www.hpa.org.uk/web/HPAweb&HPAwebStandard/HPAweb_C/1195733758290

If a parent requests vaccination for reasons other than those outlined, then they should see their G.P as the Trust will not offer vaccination to babies outside of those considered to be at risk.

Contra-indications

(a) Impaired Immunity due to immunodeficiency disorder in the baby or a sibling – discuss with Paediatricians.

(b) Where mother is known to be HIV positive, vaccination should be deferred until the child's HIV status is known.

(c) Acute febrile illness – defer until recovered.

(d) Severe generalised septic skin conditions – defer until recovered.

(e) Neonates in a household where an active TB case is suspected or confirmed.

Methods Used

The preliminary tuberculin test Mantoux is not necessary for neonates.

BCG – the vaccine should be given by the intra-dermal method, and should be given at the insertion of the deltoid muscle near the middle of the left upper arm.

The procedure for the administration and documentation of Neonatal BCG vaccination should be followed as this guideline.

The person administering the vaccine will be responsible for ensuring they are familiar with the method/technique used to administer intradermal vaccine.

Midwives and Neonatal Nurses are to undertake this skill 'for the needs of the service' and not at the detriment of their nursing or midwifery duties.

Procedure For Neonatal BCG Vaccination

1. Consent for Vaccination

Identification of neonates, who require BCG vaccination, should be confirmed by a Neonatal Nurse or Midwife trained in BCG inoculation or a Paediatrician. Explanation and the patient information leaflet (Appendix 1) should be given to the mother or person with parental

responsibility. Written consent is **NOT** necessary if a parent is present for the vaccination. If parent cannot be present written consent can be recorded on a standard trust consent form – specific consent forms for vaccination are **NOT** required. If used the consent form should be filed in the baby notes.

2. Timing of Vaccination

Ideally the vaccine should be given before the neonate leaves hospital. The precise timing however is not important but the baby should remain in the hospital for at least 20 minutes following vaccination.

There is a Nurse Led vaccination clinic in children's outpatients every Tuesday. Babies can be brought back to this clinic in the first few months of life to have their BCG vaccination – this facility should only be used if discharge is being greatly delayed by lack of staff to administer vaccine whist baby is in hospital. The Post Natal Ward Clerks can book children into this clinic by going to W Nurse Children's Clinic in OASIS and clicking on micro session and selecting Nurse Led Immunisation Clinic. Parents need to **bring Red Book**. BCG will be prescribed by children's clinic staff.

3. Dosage and Administration for Intra-dermal Technique

It is recommended that BCG vaccine be administered intra-dermally using a tuberculin syringe and brown needle Size 26⅜G.

The freeze-dried vaccine should be protected from light, stored between 2º and 8ºC and never frozen. It should not be used after its expiry date. The multi dose vial should be diluted with the SSI diluent as instructed on the package insert using aseptic precautions (use a 2ml syringe and a green needle). The vaccine may be **swirled** around to aid dilution but never shaken. Once reconstituted the vaccine must be used within two hours. The vaccine suspension should appear homogeneous, slightly opaque and colourless; any unused reconstituted vaccine should be discarded.

i. Freeze dried BCG SSI should be diluted with 1ml of Solvent (Diluted Sauton SSI) and reconstituted before administration.

ii. Using a 1ml graduated syringe & blue 23g/orange 25g needle draw up slightly more than 0.05ml. Change the needle to a brown needle 26⅜G, turn the needle so that the bevel is inline with the markings on the syringe and firmly fix needle to the syringe. Prime the needle of syringe to 0.05ml. Taking care not to spray contents of syringe.

The vaccine should be given at the insertion of the deltoid muscle near the middle of the upper **left arm**. (The left arm is used internationally and the scar aids innoculation identification if there is a language problem) If the skin requires cleansing, the area should be lightly prepared with alcohol and must be allowed to dry completely by evaporation before vaccinating.

The vaccine must be given **strictly intra-dermally**. The dose is 0.05ml for infants under 12 months of age.

iii. Stretch the skin between the thumb and forefinger of one hand and with the other hand slowly insert the needle, with the bevel uppermost, for approximately 2mm into the superficial layers of the dermis almost parallel with the surface. The needle can usually be seen through the epidermis. Great care must be taken not to insert the needle subcutaneous or intramuscularly. The needle should be withdrawn and reinserted if this occurs before the vaccine is deployed. A correctly given intra-dermal injection results in a tense blanched raised bleb (peau d'orange) and resistance can be felt when the vaccine is being injected.

iv. Excess fluid should be wiped away. No dressing is required. The parents must always be advised of the normal reaction to the injection and necessary aftercare as explained in information leaflet. (Appendix 1)

4. Records and Documentation

If BCG Vaccination is given:

(i) It **MUST BE PRESCRIBED** on a prescription chart; BCG cannot be given unless prescribed.

(ii) Record in the **Red Book** on

a. Pg.5 "Baby discharge summary by midwife" – the top, 2nd and 4th copies are left in the Red Book, the third copy (pink) should be removed and stuck into the Purple Postnatal notes for baby – page 19. [applies to inpatients only]

b. Pg.33 "BCG Vaccination" – the top copy is left in the red book; the 2nd copy (yellow) should be removed and sent to Child Health Admin Team*. The 3rd copy (green) should be sent to GP.

(iii) The discharging midwife should record BCG on **Bluespier** Computer System – this letter goes to GP and Community Midwife.

(iv) If baby is in-patient on TCU or NICU or receiving iv antibiotics on Postnatal Ward (ie has a Badgernet record) then BCG vaccination should be recorded on the **Badgernet** Computer System.

NOTE : Use of a checklist (Appendix 2a and 2b) is **optional** – use it if you find it helps, then file in patient's notes.

Written consent is **not** required if parent present for vaccination.

"Notification to child health system of vaccination – unscheduled attendance" form is only required if **no Red book** available. The duplicate of Page 33 sent to Child Health replaces this form

*Child Health System Admin. Team,
Kidderminster Health centre,
Bromsgrove Street,
Kidderminster,
DY10 1PG

5. If BCG is Contra-indicated, Declined or Missed :

If a neonate does not receive BCG in the hospital or parents decline vaccination please inform the TB specialist nurses telephone 01905 681831 or mobile 07949572244. Please be aware that TB specialist nurses will not be responsible for administering BCG in the community. Document the fact that baby has missed BCG in medical notes and, if possible red book. Document the telephone call to TB specialist nurses in medical notes.

6. Advice to Parents

General advice on the care of the vaccination site is contained in the leaflet "TB, BCG vaccine and your baby" (Appendix 1) which should be given to the parents. It can be downloaded from the Department of Health website in several languages.

REFERENCES

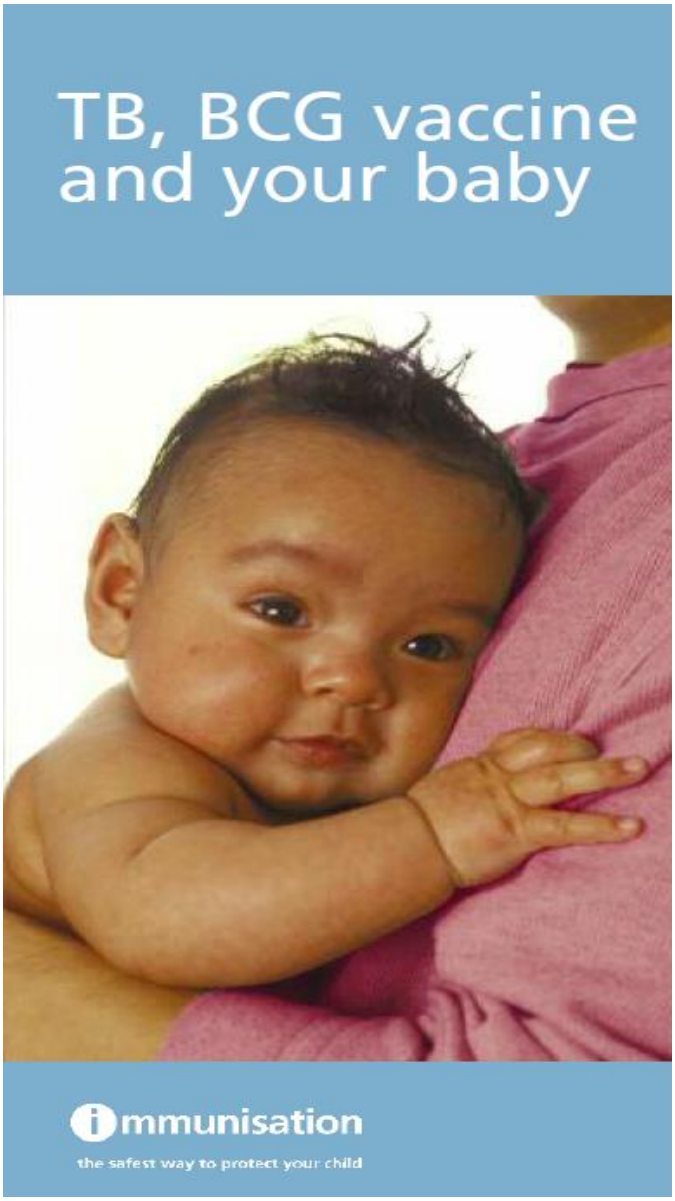
1. *Immunisation against Infectious Disease.* Department of Health 'The Green Book' Chapter 32 Updated July 2001 accessed via www.dh.gov.uk

2. WHO Global Tuberculosis Control - - Surveillance, Planning, Financing http://www.who.int/tb/publications/global_report/en/index.html

3. Health Protection Agency http://www.hpa.org.uk

4. NICE Guidance CG117, Issued March 2011 via www.nice.org.uk

APPENDIX 1: Patient Information Leaflet from the Department of Health



This leaflet can be also downloaded in other languages from the Department of Health website.

POSTNATAL WARD/TRANSITIONAL CARE UNIT - BCG CHECK LIST
Appendix 2a

DATE ……..

Affix Patient label here

REASON FOR BCG VACCINE	TICK	COMMENTS
Parent/grandparent born in high risk country		
Living with a family member who's had TB in last 5yrs		
Going to live with local people, in high risk country for longer than 1 month		

PRE VACCINATION	YES	NO	COMMENTS
Is anyone in the family being treated for TB			If yes DO NOT give vaccine
Is the Mother's HIV screen result positive?			If yes DO NOT give vaccine
Have any live vaccines been given in last 4 weeks			If yes DO NOT give vaccine
Does the child have any known allergies?			
Is the child on any medication?			
Is the child well at present?			
Does the child need medical review?			
Are parent/s aware of any possible side effects?			
Have they received written information?			
Has vaccine been prescribed?			

REMEMBER DOSE IS 0.05ML OF BCG VACCINE BY INTRADERMAL INJECTION

POST VACCINE	YES	NO	COMMENTS
Has the child's red book (p5 &33) been completed and page 33 copy sent to child health and GP? Page 5 copy stuck in purple notes ?			
Has vaccine administration been signed for on prescription chart?			
Has Badger system been completed for TCU babies & PNW babies who have received IV antibiotics?			
Is midwife aware vaccine has been given & aware to complete postnatal notes & bluespier system?			

Signed ……..... Designation ……..

CHILDREN'S CLINIC –NEONATAL BCG CHECK LIST APPENDIX 2b

DATE ……..

Affix Patient Label Here

CONSULTANT …….....

REASON FOR BCG VACCINE	TICK	COMMENTS
Parent/grandparent born in high risk country		
Living with a family member who's had TB in last 5yrs		
Going to live in high risk country, with local people, for longer than 1 month		

PRE VACCINATION	YES	NO	COMMENTS
Has the child ever had this vaccine before?			If yes DO NOT repeat vaccine
Is anyone in the family being treated for TB			If yes DO NOT give vaccine
Is the Mother's HIV screen result positive?			If yes DO NOT give vaccine
Have any live vaccines* been given in last 4 weeks			If yes DO NOT give vaccine
Does the child have any allergies?			
Is the child on any medication?			
Is the child well at present?			
Does the child need medical review?			
Are parent/s aware of any possible side effects?			
Have they received written information?			
Is the child due any other routine vaccines?			If so, no vaccines in same arm for 3 months and no live vaccine for 1 month*.

REMEMBER DOSE IS 0.05 ML OF BCG VACCINE BY INTRADERMAL INJECTION FOR ALL INFANTS

*does not include live oral rotavirus vaccine which does not affect response to BCG

POST VACCINE	YES	NO	COMMENTS
Has vaccine administration been signed for on prescription chart?			
Has the child's red book been completed?			
Has a copy of BCG p33 of red book been sent to Child Health?			
Has a copy of BCG p33 of red book been sent to the GP?			
Have the parents got contact numbers?			

Signed ……..... Designation …….....

Appendix 3

COUNTRIES CONSIDERED HIGH PREVALENCE FOR TUBERCULOSIS FOR THE PURPOSE OF NEONATAL BCG VACCINATION

This list has been prepared from 2010 data supplied by WHO updated with current information from Website (23.07.12)

AFRICA (INCLUDING NORTH):

- Algeria
- Angola
- Benin
- Botswana
- Burundi
- Burkina Faso
- Cape Verde
- Cameroon
- Chad
- Central African Republic
- Congo
- Cote d'Ivore
- Democratic Republic of Congo
- Dijibouti
- Equatorial Guinea
- Eritrea
- Ethiopia
- Gabon
- Guinea
- Guinea Bissau
- Gambia
- Ghana
- Kenya
- Lesotho
- Liberia
- Madagascar
- Mali
- Malawi
- Mauritania
- Morocco
- Mozambique
- Namibia
- Nigeria
- Niger
- Rwanda
- Sao Tome & Principe
- Sudan
- Senegal
- Sierra Leone
- Somalia

APPENDIX 3 CONTINUED…LIST OF RELEVANT COUNTRIES

- South Africa
- Swaziland
- Togo
- Tanzania
- Uganda
- Zimbabwe
- Zambia

SOUTH AND CENTRAL AMERICA:

- Belize
- Bolivia
- Brazil
- Dominican Republic
- Ecuador
- Guyana
- Guatemala
- Haiti
- Honduras
- Nicaragua
- Peru
- Panama
- Paraguay
- Suriname

CENTRAL AND SOUTH ASIA:

- Afghanistan
- Bangladesh
- Bhutan
- Brunei Darussalam
- Cambodia
- China
- China, Macao SAR
- Hong Kong
- India
- Indonesia
- Kazakhstan
- Korea
- Lao Peoples Democratic Republic
- Laos
- Malaysia
- Mongolia
- Myanmar (Burma)
- Nepal
- Pakistan
- Phillipines
- Sri Lanka
- Taiwan

APPENDIX 3 CONTINUED…LIST OF RELEVANT COUNTRIES

- Thailand
- Tajikistan
- Turkmenistan

- Uzbekistan
- Timor-Leste
- Vietnam
- Wallis & Futuna Islands

MIDDLE EAST:

- Bahrain
- Iraq
- Yemen

EUROPE:

- Armenia
- Azerbaijan
- Belarus
- Bosnia & Herzegovina
- Bulgaria
- Croatia
- Georgia
- Krgyzstan
- Lithuania
- Romania
- Republic of Moldova
- Russian Federation
- Ukraine
- Turkey

PACIFIC:

- Papua New Guinea
- Tuvalu
- Kiribati
- Marshall Islands
- Nauru
- Tokelau
- Micronesia
- Northern Mariana Islands
- Niue
- Vanuatu
- Solomon Islands
- Palau
- Guam

EASTERN MED:

- Libyan Aran Jamahiriya

MONITORING TOOL

How will monitoring be carried out? Audit

Who will monitor compliance with the guideline? Obstetric Governance Committee

STANDARDS	%	CLINICAL EXCEPTIONS
BCG vaccine should be offered to all babies identified as being at risk as highlighted in the introduction	100	Those babies with contraindication, or when parents refuse to give consent.

CONTRIBUTION LIST

Key individuals involved in developing the document

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