Bwrdd Iechyd Prifysgol
Abertawe Bro Morgannwg
University Health Board

Women and Child Health Directorate

Maternity Department

Neonatal BCG vaccination for at risk infants

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1.0 Purpose

The purpose of this policy is to provide guidance for midwives, obstetricians, paediatric nurses and neonatologists on the offer and administration of neonatal BCG vaccination for at risk infants.

2.0 Background

The aim of the UK BCG immunisation programme is to immunise those at increased risk of developing severe disease and/or of exposure to tuberculosis (TB) infection. Evidence from clinical trials show BCG vaccine is most effective in protecting infants and children who might come into contact with infectious tuberculosis against the more serious forms of the disease (National Public Health Service for Wales (NPHS 2007).

Human TB is caused by infection with bacteria of the *Myobacterium tuberculosis complex* and may affect almost any part of the body (Green Book, TB chapter 2010). The most common form is pulmonary TB which accounts for 60% of cases in the UK. Non – respiratory forms of TB are more common in young children in communities with connections to areas of the world with high prevalence, and in those with impaired immunity (Green Book, TB chapter 2010).

UK TB – Provisional surveillance data 2009

In 2009 in the UK, 9,153 TB cases were provisionally reported to enhanced national surveillance, a rate of 14.9 per 100,000 population (Health Protection Agency (HPA) 2009). This represents a 5.5% increase compared with the number of cases reported in 2008. The majority of reports were from England (92%). Wales accounted for 2.4% of cases with a larger proportional increase (HPA 2009). Table 1 (page 3) shows the three year average TB case reports and rates by Local Board in Wales 2001 – 2009 (Health Protection Agency 2010).

Table 1. Three year average TB case reports and rates by Local Board in Wales 2001 – 2009 (Health Protection Agency 2010).

Local Health Board	Year range					
	2001 – 2003		2004 - 2006		2007 - 2009	
	Average number of cases	Rate per 100,000	Average number of cases	Rate per 100,000	Average number of cases	Rate per 100,000
ABM University	28	6	32	7	36	7
Aneurin Bevan	32	6	28	5	31	5
Betsi Cadwaladr University	23	3	38	6	31	5
Cardiff and Vale University	45	10	47	11	63	14
Cwm Taf	22	8	13	4	19	7
Hywel Dda	15	4	20	5	9	2
Powys	3	2	5	4	5	4

3.0 Antenatal screening to identify at risk babies

Pregnant women whose babies, when born, who are eligible for BCG immunisation will be identified at the antenatal booking visit. The midwife will identify these babies using the list of countries where the annual incidence of TB is 40/100,000 or greater (appendix 1). This checklist is available in a laminated format for each community midwife for easy reference.

Guidance set out in the Green Book 2006 (updated TB chapter 2010) recommends that BCG immunisation should be offered to:

- 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 (see checklist on page 5)
- 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.

> **Green Book 2006**
> *BCG immunisation is recommended for infants and children in some other circumstances, for example, those in families going to live or work with local people for more than three months in a country where the annual incidence of TB is 40 / 100,000 or greater, or those who were contacts of tuberculosis. Arrangements for immunisation in these circumstances should be made through existing arrangements, for example, either in local BCG clinics for children, or via the contact tracing services, as appropriate.*

Community midwives must record:

- The discussion and offer of neonatal BCG vaccination In the All Wales Held Maternity Hand Record
- As a "paediatric alert" on the Myrddin Maternity Information System *

Written information for parents

The Department of Health have produced an information leaflet "TB, BCG vaccine and your baby" for parents. These are available in 24 different languages. Community midwives should provide this leaflet to women during the antenatal period and record this in the All Wales hand held maternity record and the antenatal leaflet section in the Myrddin Maternity Information System*. A supply can be downloaded from:

http://wales.gov.uk/topics/health/protection/immunisation/leaflets/bcg-babies

- *The Myrddin Maternity Information System has "gone live" in the West Division March 2011, followed by the East Division later in 2011.*

4.0 Postnatal period

Midwives providing postnatal care in the hospital and community setting will identify babies at risk of developing TB infection. For babies who are in – patients in the Neonatal Intensive Care in Singleton Hospital and Special Care Baby Unit in Princess of Wales Hospital, this responsibility lies with the neonatal nurses or paediatricians. The Health Board wide *Flowchart for the offer and administration of Neonatal BCG vaccination* is detailed on page 8.

4.1 Preterm infants *(Green Book Tuberculosis Chapter June 2010)*

It is important that preterm infants have their immunisations at the appropriate chronological age, according to the schedule. The occurrence of apnoea following vaccination is especially increased in infants who are born preterm. Preterm infants born at 28 weeks gestation or less who are in hospital should have respiratory monitoring for 48 – 72 hours when given their first immunisation, particularly those with a previous history of respiratory immaturity. If the infant suffers apnoea, bradycardia or desaturations after the first immunisation, the second immunisation should also be given in hospital, with respiratory monitoring for 48 – 72 hours

Within the Health Board BCG vaccination is offered at around 35 weeks onwards. BCG vaccine is not offered to a very preterm infant as there is the risk of impaired tcell immunity associated with prematurity which may cause a disseminated reaction. These infants who are in hospital until this time are unlikely to be in contact with TB.

4.2 Contraindications (*Green Book Tuberculosis Chapter June 2010)*

The vaccine should not be given to:

- **Neonates in a household where an active TB case is suspected or confirmed**
- Those who have already had a BCG vaccination
- Those with a history of TB
- Those with an induration of 6mm or more following Mantoux (SSI) tuberculin testing
- Those who have had a confirmed anaphylactic reaction to a component of the vaccine
- Those who are immunocompromised by virtue of disease or treatment e.g. patients receiving corticosteroid or other immunosuppressive treatment, including general radiation
- Those suffering from a malignant condition such as lymphoma, leukaemia, Hodgkin's disease or other tumour of the reticuloendothelial system.

HIV positive status of mother (*Green Book Tuberculosis Chapter June 2010)*

Where vaccination is indicated for babies born to HIV positive mothers, this can be administered after two appropriately timed negative PCR tests for HIV infection.

4.3 Precautions (*(Green Book Tuberculosis Chapter June 2010)*
Minor illnesses without fever or systemic illness are not valid reasons to postpone immunisation.

If an individual 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.

Individuals with generalised septic skin conditions should not be vaccinated. If eczema exists, an immunisation site should be chosen that is free from skin lesions.

Women and Child Health Directorate

Flowchart for the offer and administration of Neonatal BCG vaccination

Antenatal Booking Visit

- Midwife uses checklist of countries where TB incidence is 40 /100,000 or greater to identify "at risk" babies
- Midwife to record offer and discussion of BCG immunisation in All Wales hand held maternity record
- Midwife completes "Paediatric Alert" on Myrddin Maternity Information System (following "go live")*
- "TB, BCG vaccine and your baby" Information leaflet given to woman in appropriate language and recorded in All Wales hand held maternity record and Myrddin Maternity Information System*.

Postnatal

Midwife providing postnatal care / nurse or paediatrician providing neonatal care identifies at risk baby who requires BCG vaccination.

Information leaflet provided in appropriate language (if mother does not have this from the antenatal period)

Midwife / nurse / paediatrician records whether the mother accepts or declines the offer of TB vaccination in postnatal record / neonatal record, Child Health Record (the red book). Midwife to record in Myrddin Maternity Information System. *

If midwife / nurse uncertain re contraindications refer to paediatrician prior to discharge. If baby born at home telephone paediatrician for advice.

Where mother accepts BCG vaccination for baby, baby's addressograph to be inserted into BCG vaccination register (loose leaf folder –appendix 2) kept in each clinical area.

Midwife / paediatrician performing first neonatal examination will confirm that the offer and arranging BCG vaccination has taken place.

**The Myrddin Maternity Information System has "gone live" in the West Division in March 2011, followed by the East Division later in 2011.*

Singleton
Ward 18, Midwife led Unit and Neonatal Intensive Care Unit

Pages from BCG vaccination register taken by clerical staff to Paediatric outpatient staff on a weekly basis (appendix 2).

Paediatric OPD clerical staff posts next available appointment to baby's mother - baby to attend paediatric outpatient appointment in Singleton.

Princess of Wales
Ward 12 and Special Care Baby Unit

Pages from BCG vaccination register taken by clerical staff to Amanda Slade (Paediatric Respiratory Nurse) in POW Paediatric outpatient department (appendix 2).

Amanda Slade arranges appointment and posts to mother.

Neath Port Talbot
Birth Centre

Midwife completes BCG vaccination referral form and sends to Amanda Slade in Princess Of Wales (see appendix 3).

Amanda Slade arranges appointment and posts to mother.

Home Birth

Swansea	Bridgend / Neath Port Talbot
Community midwife will telephone Ward 18 and ask ward staff to record baby's details in BCG vaccination register: Singleton Ward 18: 01792 285046	Community midwife completes BCG vaccination referral form and sends to Amanda Slade in Princess Of Wales (appendix 3). Princess of Wales: 01656 752309

Babies transferred out of NICU /SCBU

Neonatal staff to record in discharge summary if baby requires BCG vaccination.

BCG unscheduled vaccination forms

Following administration of BCG vaccination, unscheduled vaccinations forms completed and sent to appropriate Child Health Record Department.

Non – attendance for BCG vaccination

If baby does not attend outpatient appointment for BCG vaccination, outpatient clinic staff will search appropriate Patient Administration system to ensure suitability to send repeat appointment (IPM, PIMS, Myrddin*).

If baby does not attend second appointment, GP informed by letter. Action to be recorded in infant medical records.

5.0 Administration of BCG vaccination

The BCG vaccine must be administered intradermally, normally into the lateral aspect of the left upper arm (Green Book TB Chapter 2010).

Dosage: For infants under 12 months 0.05ml.

5.1 Storage

The unconstituted vaccine and its diluent should be stored in the original packaging at +2 degrees Celsius to +8degrees Celsius and protected from light. All vaccines are sensitive to some extent to heat and light. Effectiveness of vaccines cannot be guaranteed unless they have been stored at the correct temperature. Heat speed up the decline in potency of most of most vaccines, thus reducing shelf life. Freezing may cause increased reactogenicity and loss of potency in some vaccines. It can also cause hairline cracks in the container, leading to contamination of the contents. If the vaccine and /or diluent has been frozen, it must not be used.

5.2 Presentation

The vaccine is a freeze dried powder for suspension for injection. BCG vaccine SSI is supplied in a glass vial containing the equivalent of 10 adult or 20 infant doses, fitted with a bromobutyl rubber stopper which does not contain latex. The powder must be reconstituted with 1ml of the diluted Sauton SSI diluent which is supplied separately.

5.3 Adverse reactions

Faulty injection technique can result in injection site reactions. These include large, local discharging ulcers, abcesses and keloid scarring. These can also be caused by excessive dosage or vaccinating individuals who are tuberculin positive. It is essential that health professionals are properly trained in all aspects of the process involved in tuberculin skin tests and BCG vaccination. Training material for health professionals are available from the Department of Health Publications (e-mail: dh@prolog.uk.com). Further details can be accessed from www.immunistaion.nhs.uk

Adverse reactions to the vaccine include headache, fever and enlargement of a regional lymph node to greater than 1cm and may ulcerate. Allergic reactions such as abcess formation and disseminated BCG complications such as osteitis or osteomyleitis are rare.

References

Green Book Updated (2010) *Tuberculosis.* June, Chapter 32, pp. 391 - 409 Department of Health. http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_116577.pdf (Accessed: 16th December 2010).

Health Protection Agency, (2009) *Tuberculosis Update.* http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1267551047404

Health Protection Agency, (2010) *Tuberculosis Update. Report on the tuberculosis surveillance in the UK 2010.* London: Health Protection Agency Centre for Infections. *http://www.hpa.org.uk/Publications/InfectiousDiseases/Tuberculosis/1011TuberculosisintheUK/* (Accessed: 23rd December 2010).

Appendix 1 *(updated: July 2013)*

World Health Organization (WHO) estimates of tuberculosis incidence by country, 2011 (sorted by country)

Definition of high incidence

With reference to the National Institute for Health and Clinical Excellence (NICE) recommendations for BCG vaccination and screening in England and Wales, countries/territories with an estimated incidence rate of 40 per 100,000 or greater are considered to have a high incidence of tuberculosis

Country/Territory	Estimated rate per 100,000 population
Afghanistan	189
Albania	13
Algeria	90
American Samoa	7.8
Andorra	5.9
Angola	310
Anguilla	21
Antigua and Barbuda	6.9
Argentina	26
Armenia	55
Aruba	6.4
Australia	6
Austria	3.7
Azerbaijan	113
Bahamas	13
Bahrain	18
Bangladesh	225
Barbados	1.7
Belarus	70
Belgium	8.1
Belize	40
Benin	70
Bermuda	0.26
Bhutan	192
Bolivia (Plurinational State of)	131
Bonaire, Saint Eustatius and Saba	<1
Bosnia and Herzegovina	49
Botswana	455
Brazil	42
British Virgin Islands	2.2
Brunei Darussalam	70
Bulgaria	35
Burkina Faso	57
Burundi	139
Cambodia	424
Cameroon	243
Canada	4.5
Cape Verde	145
Cayman Islands	7.5
Central African Republic	400
Chad	151
Chile	18

Country/Territory	Estimated rate per 100,000 population
China	75
China, Hong Kong SAR	78
China, Macao SAR	73
Colombia	34
Comoros	34
Congo	387
Cook Islands	6
Costa Rica	12
Côte d'Ivoire	191
Croatia	17
Cuba	9.3
Curaçao	<1
Cyprus	4
Czech Republic	6
Democratic People's Republic of Korea	345
Democratic Republic of the Congo	327
Denmark	6.5
Djibouti	620
Dominica	13
Dominican Republic	65
Ecuador	62
Egypt	17
El Salvador	27
Equatorial Guinea	202
Eritrea	97
Estonia	25
Ethiopia	258
Fiji	26
Finland	7.5
France	4.3
French Polynesia	23
Gabon	450
Gambia	279
Georgia	125
Germany	4.5
Ghana	79
Greece	3.8
Greenland	178
Grenada	4.1
Guam	65
Guatemala	61
Guinea	183
Guinea-Bissau	238
Guyana	110
Haiti	220
Honduras	43
Hungary18	18
Iceland	4.8
India	181
Indonesia	187
Iran (Islamic Republic of)	21
Iraq	45

Country/Territory	Estimated rate per 100,000 population
Ireland	7.5
Israel	5.8
Italy	2.8
Jamaica	6.6
Japan	20
Jordan	6
Kazakhstan	129
Kenya	288
Kiribati	356
Kuwait	36
Kyrgyzstan	128
Lao People's Democratic Republic	213
Latvia	42
Lebanon	15
Lesotho	632
Liberia	299
Libyan	40
Lithuania	59
Luxembourg	<1
Madagascar	238
Malawi	191
Malaysia	81
Maldives	34
Mali	62
Malta	9.1
Marshall Islands	536
Mauritania	334
Mauritius	21
Mexico	23
Micronesia (Federated States of)	200
Monaco	3.2
Mongolia	223
Montenegro	17
Montserrat	3.5
Morocco	103
Mozambique	548
Myanmar	381
Namibia	723
Nauru	33
Nepal	163
Netherlands	6.8
Netherlands Antilles	4.9
New Caledonia	25
New Zealand	7.6
Nicaragua	40
Niger	108
Nigeria	118
Niue	40
Northern Mariana Islands	60
Norway	6.1
Oman14	14

Country/Territory	Estimated rate per 100,000 population
Pakistan	231
Palau	153
Panama	48
Papua New Guinea	346
Paraguay	45
Peru	101
Philippines	270
Poland	23
Portugal	24
Puerto Rico	1.8
Qatar	37
Republic of Korea	100
Republic of Moldova	161
Romania	101
Russian Federation	97
Rwanda	94
Saint Kitts and Nevis5.5	5.5
Saint Lucia	5.1
Saint Vincent and the Grenadines	24
Samoa	9.6
San Marino	1.4
Sao Tome and Principe	94
Saudi Arabia	17
Senegal	136
Serbia	16
Seychelles	30
Sierra Leone	723
Singapore	37
Sint Maarten (Dutch part)	6
Slovakia	7.2
Slovenia	9.3
Solomon Islands	103
Somalia	286
South Africa	993
South Sudan	146
Spain	15
Sri Lanka	66
Sudan	117
Suriname	44
Swaziland	1317
Sweden	6.8
Switzerland	4.8
Syrian Arab Republic	19
Tajikistan	193
Thailand	124
The Former Yugoslav Republic of Macedonia	20
Timor-Leste	498
Togo	73
Tokelau	N/A
Tonga	16
Trinidad and Tobago	21
Tunisia	30
Turkey	24
Turkmenistan	74

Country/Territory	Estimated rate per 100,000 population
Turks and Caicos Islands	24
Tuvalu	228
Uganda	193
Ukraine	89
United Arab Emirates	3.7
United Kingdom of Great Britain and Northern Ireland	14
United Republic of Tanzania	169
United States of America	3.9
Uruguay	21
US Virgin Islands	7.7
Uzbekistan	101
Vanuatu	67
Venezuela (Bolivarian Republic of)	33
Viet Nam	199
Wallis and Futuna Islands	21
West Bank and Gaza Strip	3
Yemen	44
Zambia	444
Zimbabwe	603

Notes: Data presented here are an extract of data available for download from the WHO website. Only 'best estimate' figures of incidence are included here. Uncertainty bounds for these estimates are included in data downloadable from the WHO website and should be referred to if further interpretation of the figures is required. Full details of the methods used for the estimation of incidence can be found in the WHO Global tuberculosis report 2012 [external link].

Source: WHO TB burden estimates [external link], and Global tuberculosis report 2012 [external link]. Accessed 29/11/2011.

Prepared by: TB Section, Health Protection Services - Colindale

Appendix 2

Bwrdd Iechyd Prifysgol
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Women and Child Health Directorate

Babies who require neonatal BCG vaccination

Please take this list of babies details on a weekly basis:

- **Singleton appointments**: To clerk in Paediatric Outpatient Department
- **Princess of Wales appointments:** To Amanda Slade Paediatric Respiratory Nurse in Paediatric Outpatient Department

Baby's addressograph	Requesting ward	Date of referral	OPD staff – Record appointment date

Appendix 3

GIG CYMRU NHS WALES | Bwrdd Iechyd Prifysgol Abertawe Bro Morgannwg University Health Board

Neonatal BCG Referral Form (Princess of Wales Hospital)

Please complete and return to:

Amanda Slade
Paediatric Respiratory Nurse Specialist
Children's Clinic, Princess of Wales Hospital, Coity Road
Bridgend, CF31 1RQ

Date of referral----------

Infant's name …… DOB……..

Home address…….

Postcode……..

Telephone number……..

GP……..

To be completed by midwife

Reason for referral ……..

Has the infant had any viral illness recently? **YES/NO**

Is the infant receiving treatment that lowers his/her resistance to disease e.g. steroids, radiotherapy, drugs used for treating cancer? **YES / NO**

Does the infant have a medical condition that affects his/her resistance to disease e.g. cancer, leukaemia / HIV? YES /NO (Important to be aware of HIV status of mother)? **YES / NO**

HIV positive status of mother
Where vaccination is indicated for babies born to HIV positive mothers, this can be administered after two appropriately timed negative PCR tests for HIV infection (Green Book TB Chapter 2010).

Has the infant received ultra-violet light treatment recently? YES/NO

If yes please specify……..

Midwife's signature ---------- **Date**----------