Chapter 2

Tuberculin Skin Tests

A tuberculin skin test must be carried out before BCG immunisation. The only exception to this rule is infants up to three months of age, who may be immunised without a prior test, provided they have no known recent contact with T.B. The tuberculin test assesses an individual’s sensitivity to tuberculin protein.

Previous practice has been to vaccinate children up to one year without a prior tuberculin skin test. However, recent publications (Immunisation against Infectious Diseases (1996) H.M.S.O. & Immunisation Guidelines for Ireland, 2002 Edition) recommend that children over three months should have a tuberculin skin test prior to vaccination.

Over the years, two techniques have been recommended for the tuberculin skin test - the Mantoux test and the Heaf test. Both tests use Purified Protein Derivative (PPD). Several strengths of PPD are available and it is important that the correct solution is used. The World Health Organisation has stated that the Mantoux test is the preferred test and this has been endorsed by the Report of the Working Party on Tuberculosis (Department of Health 1996).

2.1 STORAGE, STOCK CONTROL, DISTRIBUTION AND DISPOSAL OF TUBERCULIN

Requirements for above are similar to those outlined in Chapter 1 for BCG Vaccine. It is important to note that all tuberculin (PPD) must be stored between +2°C and +8°C (never frozen) and protected from light. Once an ampoule is opened its contents should be used within four hours and not retained beyond that time. PPD tends to absorb onto syringe surfaces and should, therefore, be used within thirty minutes of filling the syringe. Note that PPD may persist on the surface of any non-disposable syringe, which needs careful cleaning after use.

2.2 THE MANTOUX TEST

2.2.1 Dosage

The PPD preparation for routine use in the Mantoux Test is supplied in 1.5ml ampoules. The following strengths are available: 1, 2, 5 and 10 tuberculin units (T.U.) per 0.1ml. 5 T.U. is no longer recommended. 1 T.U. is not readily available.

It is recommended that 2T.U./0.1ml be used for tuberculin tests in connection with BCG vaccination. Children who may have been exposed to tuberculosis must be tuberculin tested using 2T.U./0.1ml before any BCG vaccination.

2.2.2 Technique

The Mantoux test is performed using a 1ml syringe and a short bevel (brown) 26 gauge needle. To prevent cross infection, a separate syringe and needle must be used for each subject.
The test is normally performed on the flexor surface of the middle third of the left forearm. If visibly dirty the site is cleaned with spirit and allowed to dry. Then 0.1ml of the appropriate PPD strength is injected intradermally so that a bleb (peau d'orange) of 8-10mm diameter is produced.

2.2.3 Reading

- The results of the Mantoux test must be read 48 to 72 hours later.
- The tranverse diameter of the induration should be measured using a standard transparent 15cms (6 inch) ruler.
- The area of flare (erythema) is irrelevant in the measurement: only induration or thickening of the skin is recorded.
- A positive reaction consists of induration with a transverse diameter of 5mm or greater.
- A false negative reaction may occur after certain viral infections (e.g. measles and glandular fever), tumour diseases or sarcoidosis (Section 2.3). A false negative reaction may also be seen for a period after vaccination with live viruses.

2.2.4 Interpretation

A Mantoux response of less than 5mm induration is regarded as negative, 5mm or greater is regarded as positive. However, this approach may need to be modified in certain specific clinical situations, see Section 2.3.

2.2.5 Side Effects

Extremely tuberculin-sensitive individuals may develop blisters and surface skin necrosis in the centre of the tuberculin reaction. The necrosis will gradually resolve.

2.3 FACTORS AFFECTING THE TUBERCULIN TEST

The reaction to the tuberculin protein may be suppressed by the following:

- Infectious mononucleosis.
- Viral infections in general, including those of the upper respiratory tract.
- Severe bacterial, fungal or viral illness (e.g. measles or chickenpox). An interval of 4 to 6 weeks should be left before a tuberculin test is carried out.
- Live viral vaccines (i.e. MMR, oral Polio and Yellow Fever). As suppression does not appear within the first 48 hours, it is recommended that tuberculin tests should be done either on the same day as vaccination with a live vaccine, or an interval of four to six weeks should be left between receiving the live vaccine and undertaking a tuberculin test.
- Hodgkin’s Disease
- Sarcoidosis
- Corticosteroid therapy
- Immunosuppressant treatment or diseases, including HIV and malignancies.
2.4 THE BOOSTER PHENOMENON

This term is used to describe increased tuberculin skin reactions with re-testing in the absence of new infection. The prevalence of the boosting phenomenon is correlated with the prevalence of initial tuberculin reactions. Thus it is more common in individuals who have had BCG vaccination, the elderly (previous exposure) and in individuals from endemically high incidence countries (exposure).

Boosting is greatest if the interval between the first and second tuberculin test is between 1 and 5 weeks. It is less frequent if the interval is greater than 8 weeks.
3.1 BCG VACCINATION

The Bacillus Calmette-Guerin (BCG) vaccine contains a live attenuated strain derived from Mycobacterium Bovis.

3.1.1 Dosage

NOTE: Vaccine data sheets should always be read prior to vaccination as dosage for infants may vary according to manufacture:

Currently, the manufacturer (Statens Serum Institute) of the vaccine used in Ireland recommends a dose of 0.05ml for infants under 1 year. For children over 1 year and adults the recommended dose is 0.1ml. This should be drawn into a tuberculin syringe and a 3/8” 25g (0.5 x 10mm) or 26g (0.45 x 10mm) short bevelled needle attached to give the injection. The needle must be attached firmly with the bevel uppermost.

The recommended dosage for the Statens Serum Institute BCG vaccine is:

- Infants under 1 year of age: 0.05ml in two divided doses in adjacent sites.
- Adults and children over 1 year of age: 0.1ml in two or three divided doses in adjacent sites.

3.1.2 Technique

BCG vaccine should be given by intradermal injection into the left arm, over the insertion of the deltoid muscle, with a fresh needle and syringe for each subject. Sites higher on the arm are more likely to lead to keloid formation, the tip of the shoulder particularly.

For older children and adults the upper arm should be approximately 45° to the body. This can be achieved if the hand is placed on the hip with the arm abducted from the body.

If the skin is visibly dirty it should be swabbed with spirit and allowed to dry.

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 2mm into the superficial layers of the dermis, almost parallel to the surface.
The needle can usually be seen through the epidermis. A correctly given intradermal injection results in a tense blanched raised bleb (peau d’orange) and considerable resistance is felt when the fluid is being injected. A bleb of approximately 3-4mm diameter follows a 0.05ml injection. In infants where the dose is halved the blebs will be correspondingly smaller. If little resistance is felt when injecting and a diffuse swelling occurs, as opposed to a tense blanched bleb, the needle is too deep. The needle should be withdrawn and reinserted intradermally before more vaccine is given.

For re-vaccination the right arm should be used.

3.1.3 Initial local reaction at immunisation site and care of the immunisation site

Following intradermal administration of BCG, a local reaction normally develops at the immunisation site within two to six weeks, beginning as small papules which increase in size for a few weeks widening into a circular area up to 7mm in diameter with scaling, crusting and occasional bruising. Occasionally, a shallow ulcer up to 10mm in diameter develops. It is not necessary to protect the site from becoming wet during washing and bathing. However, should any oozing occur, a temporary dry dressing may be used until a scab forms. It is essential that air is not excluded. If absolutely essential (for example, to permit swimming), an impervious dressing may be applied for a short period only as it may delay healing and cause a larger scar. The lesions slowly subside over several months and eventually heal leaving only small flat scars.
BCG vaccination simulates a primary infection and comprises regional lymph node involvement as well as a local reaction. A minor degree of adenitis may occur in the weeks following immunisation and should not be regarded as a complication. Occasionally the lymph node process becomes suppurative, followed by adhesion to the skin and fistula formation, usually three to six months after vaccination. This process is benign and heals spontaneously.

### 3.1.4 Adverse Events Following BCG Vaccination

- Vertigo and dizziness have occasionally been reported. Rarely, immediate allergic type or anaphylactic reactions have been reported. (See Section 5.2)
- Severe injection site reactions, large ulcers and abscesses are most commonly caused where some or all of the dose is administered too deeply (subcutaneously instead of intradermally). The immunisation of individuals who are tuberculin positive may also give rise to such reactions. The reactions may initially be treated by application of a dry dressing. People with severe reactions should be referred to a physician familiar with the treatment of such complications.
- Keloid formation at the injection site is an uncommon and largely avoidable complication of BCG immunisation. Some sites are more prone to keloid formation than others and those immunising should adhere to the site as recommended in Section 3.1.2.
- Apart from these injection site reactions, other complications following BCG immunisation are rare. Very rarely a lupoid type of local lesion has been reported. A few cases of dissemination of the infected organisms have been reported.

Please record and report any reaction to the Irish Medicines Board. The SAMO should also be informed.

### 3.2 CONTRAINDICATIONS TO BCG VACCINATION

- Corticotrophins or systemic corticosteroid therapy (other than as replacement), or other immunosuppressive treatment including radiotherapy.
  - **Children:** Prednisolone 2mg/kg daily for more than two weeks, or 1mg/kg daily for more than one month. Children on lower daily doses of systemic corticosteroids for less than two weeks, and those on alternate day regimens for longer periods, may be given BCG vaccine.
  - **Adults:** 40mg or more daily of prednisolone, or the equivalent dose of another steroid for more than 1 week.

Inhaled steroids are not a contraindication.

- Blood dyscrasias, lymphoma or malignant neoplasms involving bone marrow or the lymphoreticular system, or gammaglobulin deficiency or abnormality.
- Pyrexia >38°C.
- Generalised eczema: BCG should only be given if a suitable eczema free site is available.
- Generalised septic skin conditions e.g. infected dermatitis. The effect of BCG vaccine may be exaggerated in these patients and a more generalised reaction is possible.
- Pregnancy.
- Positive tuberculin test
- HIV positivity. Infants born to women known to be HIV positive should have BCG deferred until 2 HIV PCR tests, the second of which is at or after six weeks of age, are negative.
- Within 3 months of blood or plasma transfusion.
3.3 GENERAL ADVICE

- BCG vaccine may be given simultaneously, at a separate site, with all other vaccines and immunoglobulins. If they are not given at the same time, an interval of at least four weeks is normally recommended between two live vaccines (Immunisation Guidelines for Ireland, 2002 Edition). Live oral polio vaccine generates immunity in the gastro-intestinal tract and this need not delay BCG vaccination.
- BCG need not delay primary childhood immunisations, i.e. DTaP/IPV/Hib (5-in-1), and meningococcal C.
- Because of the risk of regional lymphadenitis no further immunisation should be given for at least three months in the arm used for BCG immunisation.
- Parents should be advised of the necessity to inform the vaccinating doctor if they have reason to believe that the child’s mother may be HIV positive.

3.4 ISSUES RELATING TO NEONATAL BCG

- BCG vaccination is contraindicated within 3 months of a blood or plasma transfusion.
- Interaction between BCG vaccination and hepatitis B immunoglobulin
  - Infants who have received hepatitis B vaccination or immunoglobulin on the first day of life can still be given BCG at the normal time. (Immunisation Guidelines for Ireland, 2002 Edition).
  - If immunoglobulin is given after day one, either give BCG simultaneously with immunoglobulin at separate sites, or, for the present, withhold BCG for three months (clarification is awaited from the National Immunisation Advisory Committee).
  - If immunoglobulin has not been given pending serology results, proceed with BCG vaccination as, if required, immunoglobulin may be given later.
- If a mother is known to be HIV positive, BCG vaccination of the baby should be postponed pending clarification of the baby's status. Lack of information on HIV status of mother is not a contraindication for BCG vaccination.
- For infants born to immigrants, the following guidelines apply:
  - Infants born in Ireland to immigrants from high incidence countries where the mother has received all ante-natal care in Ireland and where maternal HIV status is either negative or unavailable, should receive neonatal BCG in the maternity hospital. It is not necessary to check the HIV status of the infant in this situation (see Immunisation Guidelines for Ireland, 2002 Edition).
  - Infants born to women known to be HIV positive should have BCG deferred until two HIV PCR tests, the second of which is at or after six weeks of age, are negative.
  - For infants of very late bookers (newly arrived immigrants who have been unable to avail, or have not availed of antenatal screening), maternal HIV testing is desirable prior to administering BCG to the infant.
- Newborn babies who are contacts of a sputum positive TB case should not be given BCG vaccination. They should be referred to the appropriate paediatric/TB contact tracing service for prophylactic isoniazid and the tuberculin test performed after six months. If this tuberculin test is negative, give BCG. If it is positive, refer back to paediatric / TB contact tracing service for reassessment.
Chapter 4

Guidelines for Administration of the Tuberculin Skin Test and BCG Vaccination

4.1 INTRODUCTION

It is the policy in the Eastern Region (Dublin, Kildare and Wicklow) to provide neonatal BCG vaccination. The programme is delivered mainly in the maternity hospitals as it makes the BCG service more accessible and friendly for new mothers. All Community Care Areas run BCG clinics as a back-up service for babies who did not receive BCG in the maternity hospital. These guidelines therefore apply mainly to BCG and Mantoux Test for neonates and children.

4.2 BCG VACCINATION IN MATERNITY HOSPITALS

- In the absence of contraindications neonates weighing 2.5kg or more on the day of vaccination may be vaccinated.
- Any baby born before midnight who is stable and has tolerated one feed may be vaccinated the following morning.
- Jaundice is not a contraindication to vaccination provided the baby is feeding well and in a post-natal ward.
- Babies receiving phototherapy should not be vaccinated.

4.3 COMMUNITY BASED BCG CLINICS

As recommended in the National Guidelines, clinics are held in Community Care Health Centres to provide a BCG service for:

- Babies not vaccinated in maternity hospitals
- Babies/children from other countries and areas of Ireland where neonatal BCG is not offered.

Formerly, adults attended for one of the following reasons:

- Travel to countries where tuberculin status is a requirement for entry.
- Travel to countries where the risk of infection with TB is high.
- For occupational health reasons.

With the increasing development of both occupational health and travel health services, it is more appropriate that adults attend a service relevant to their particular needs.

4.4 GUIDELINES FOR MANTOUX TESTING AND BCG VACCINATION

These guidelines apply to healthy people attending the clinic from countries with low incidence of TB and no contraindication to BCG vaccination.

In those with a BCG scar tuberculin testing is not necessary because, irrespective of the result, they will not be given a further BCG vaccination.

In those with no BCG scar tuberculin testing is recommended. Unless a Mantoux test has been performed within the previous four weeks, 2 TU Mantoux should be carried out.

The following is the recommended approach:

- If under 3 months of age and no contact with TB, give BCG without Mantoux testing. See Section 3.4
- Children from 3 months of age up their 15th birthday presenting for BCG for the first time (no known previous history of BCG vaccination and no contact with TB) carry out Mantoux testing prior to vaccination. See Fig. 1, Page 19
- Children from 3 months of age up to their 15th birthday with history of previous vaccination and no scar. See Fig. 2, Page 20
- Children from 3 months of age, up to their 15th birthday referred from a TB contact tracing clinic for BCG. If 2TU Mantoux Test was carried out during the previous 4 weeks and was less than 5mm give BCG vaccination. If the 2TU Mantoux Test was carried out more than 4 weeks previously, repeat 2 TU Mantoux Test and continue as in Fig. 2, Page 20.
- People after their 15th birthday with no scar and no previous BCG or unable to recall if BCG given. See Fig. 3, Page 21
  (Appendix E shows screening questionnaire which may be used prior to possible Mantoux testing).
Children from 3 months of age up their 15th birthday presenting for BCG for the first time (i.e. no known previous history of BCG vaccination and no contact with TB).
Children from 3 months of age up to their 15th birthday presenting with no BCG scar following previous vaccination.

Fig. 2

- **2 TU Mantoux Test**
  - **0 - <5 mm**
    - Give BCG
  - **5 - >10 mm**
    - No history of TB contact in previous 2 years
      - Discharge with advice re TB symptoms
    - History of TB contact in previous 2 years
      - Refer to TB contact tracing clinic
  - **> 10 mm**
    - Refer to TB contact tracing clinic
People after their 15th birthday with no scar and no previous BCG or unable to recall if BCG given.

Fig. 3

- **2 TU Mantoux Test**
  - **0 - <5 mm**
    - Give BCG
    - Discharge with advice re TB symptoms
  - **5 - >15 mm**
    - No history of TB contact in 2 years
    - Refer to TB contact tracing clinic
  - **> 15 mm**
    - History of TB contact in 2 years
    - Refer to TB contact tracing clinic

(Health Care Staff - see separate guidelines)
4.5 SCAR INSPECTION

4.5.1 Babies Vaccinated with BCG

There is a high conversion rate following BCG vaccination. Any child seen by the Public Health Nurse (PHN) at the routine three-month check who has no BCG scar should be referred to the local BCG clinic. Similarly, any child attending for a nine-month AMO development check who has no BCG scar should be referred to the BCG clinic.

4.5.2 Audit

A child who has no visible scar should be notified to the area SAMO using the standard form (See Appendix D1 & D2). This is for audit purposes.

4.5.3 Procedure at BCG Clinic for those infants with NO scar.

Mantoux should be carried out with 2 TU. If this is negative, give a second BCG vaccination. This re-vaccination is given in the RIGHT arm. It is not necessary to inspect this scar. Advise not to have any vaccination in the right arm for three months after BCG.

4.6 SCREENING OF CONTACTS

TB contacts should not be investigated at BCG Clinics. They should be referred to the appropriate contact tracing service.

4.7 SCREENING OF PEOPLE FROM COUNTRIES WITH A HIGH INCIDENCE OF TB

These guidelines are dealt with in a separate document.
5.1 GUIDELINES FOR MEDICAL STAFF IMMUNISING CHILDREN

Doctors and nurses involved in tuberculin skin testing and administration of BCG vaccine should be given instructions in the interpretation of tuberculin skin tests and training in the giving of intradermal injections. Regular instruction in Cardio Pulmonary Resuscitation techniques should be given to all members of the immunisation team.

- Information about BCG vaccination and its sequelae should be given to parents / guardians prior to consenting to vaccination.
- An informed written consent for immunisation (and Mantoux testing) should be obtained, or a mark witnessed where necessary. Parents / guardians should be offered the opportunity to discuss BCG vaccination with the doctor.
- The team of AMO and PHN should record the temperature of the cool box at the beginning and end of each immunisation session. They should also together identify the product (ensuring that it is either BCG or tuberculin), its manufacturer, expiry date and batch number, and record this information on the clinic Summary Sheet (Appendix: B & C). The number of BCG vaccinations and Mantoux tests undertaken in the clinic should be recorded on the summary sheet.
- Vaccine should not be used after the expiry date on the label.
- The AMO should ensure that appropriate equipment and drugs for treatment of anaphylaxis are immediately accessible, and that these drugs and equipment are not out of date (See Section 5.2).
- The AMO should ensure that reconstituted vaccine is used within the recommended period, according to the manufacturer’s instructions. Once opened, multi-dose vials of vaccine should not be kept after the end of a session and any unused vaccine should be discarded in the appropriate sharp bin.
- At the end of the vaccination session, unopened vaccine should be marked R (return) and the number of vials of vaccine and water remaining should be written on the box prior to returning to the stock fridge. This vaccine should be used for the next vaccination session.
- The name of the vaccine, manufacturer, batch number, expiry date, date of immunisation, vaccine site and signature of the immunising doctor should be recorded on the consent form immediately after each child is immunised, and not at the end of the session.
5.1 Continued

- The AMO should use suitable containers for sharps disposal, and ensure that all needles and unused opened vaccine vials are disposed of safely.
- Adverse reactions are rare, but if they occur they should be reported via the yellow card system to the Irish Medicines Board, Block A, Earlsfort Terrace, Dublin 2. Reports should include the batch number of the vaccine. A copy of this should be given to the SAMO in the area.

5.2 RESUSCITATION

Refer to the Immunisation Guidelines for Ireland, 2002 Edition. Resuscitation equipment and drugs should be checked regularly before clinics and drugs with imminent expiry dates should be flagged.

5.3 TRAINING

Because of the expertise needed to properly administer BCG, a core team of trained AMOs, PHN's and Clerical / Administrative Staff should be appointed in each Community Care Area. This should ensure availability of trained staff during leave, etc and maintain consistency in vaccine administration.

5.4 AUDIT

Audit of the BCG immunisation service should be undertaken at regular intervals.
Appendix A

STOCK CHECK FORM AT ISSUE / RETURN OF VACCINE FROM HEALTH BOARD AREA STORAGE

Maternity Hospital / Clinic ________________________________

Date of Issue _____ / _____ / ____  Date of Return _____ / _____ / ____

<table>
<thead>
<tr>
<th>Product</th>
<th>Manufacturer</th>
<th>Batch Number</th>
<th>Expiry Date</th>
<th>No. of Vials Issued</th>
<th>Temp. on Issue</th>
<th>No. of Vials Returned</th>
<th>Temp. on Return</th>
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</thead>
<tbody>
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<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>2 TU</td>
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<tr>
<td>10 TU</td>
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Signatures of Health Board Personnel at Issue:

Area Medical Officer ________________________________

Clerical Officer ________________________________

Signatures of Health Board Personnel on Return:

Area Medical Officer ________________________________

Clerical Officer ________________________________
**BCG RETURN FORM: MATERNITY HOSPITAL**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Batch Number</th>
<th>Expiry Date</th>
<th>Temp. of cool box at start of clinic</th>
<th>Temp. of cool box at end of clinic</th>
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<tbody>
<tr>
<td>BCG</td>
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</tbody>
</table>

**Signature of Area Medical Officer** __________________________________________

**Signature of Public Health Nurse:** _________________________________________
BCG RETURN FORM: CLINIC

Clinic:

Date: ____ / ____ / ____

<table>
<thead>
<tr>
<th>Birth up to 3 months of age</th>
<th>3 months to 14 years (15th birthday)</th>
<th>15 years and over</th>
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<tbody>
<tr>
<td>BCG Vaccination</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mantoux 2 TU</td>
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<tr>
<td>Mantoux 10 TU</td>
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CHILDREN WHO HAVE HAD BCG AND ARE SCAR NEGATIVE

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<tbody>
<tr>
<td>Number Mantoux Tested</td>
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<tr>
<td>Number who Received Repeat BCG</td>
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Number attending with adverse reactions to BCG / Mantoux test _______________________

PRODUCT DETAILS

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<th>Vaccine</th>
<th>Manufacturer</th>
<th>Batch No.</th>
<th>Expiry Date</th>
<th>Temp. of cool box at start of clinic</th>
<th>Temp. of cool box at end of clinic</th>
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<tbody>
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<td>BCG</td>
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</tr>
<tr>
<td>2 TU</td>
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<td>10 TU</td>
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Signature of Area Medical Officer: ________________________________

Signature of Public Health Nurse: ________________________________
Appendix D (1)

Record of babies who received BCG with no scar formation found at 3 months PHN surveillance visit.

<table>
<thead>
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<table>
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<tbody>
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<table>
<thead>
<tr>
<th>Place of Immunisation:</th>
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<tbody>
<tr>
<td>Coombe Women’s Hospital</td>
</tr>
<tr>
<td>National Maternity Hospital, Holles Street</td>
</tr>
<tr>
<td>Rotunda Hospital</td>
</tr>
<tr>
<td>Mount Carmel Hospital</td>
</tr>
<tr>
<td>Other (state where)</td>
</tr>
</tbody>
</table>

Child referred to BCG Clinic at: ________________________________

Signed: ________________________________

Date: ___ / ___ / ___

Completed form to be returned to Senior Area Medical Officer

For Senior Area Medical Officer Use Only

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<thead>
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<th>Vaccination carried out by:</th>
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<table>
<thead>
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<th>Initial Vaccine Manufacturer:</th>
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<table>
<thead>
<tr>
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</table>

<table>
<thead>
<tr>
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<tbody>
<tr>
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<table>
<thead>
<tr>
<th>Result of 2 TU Mantoux:</th>
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<table>
<thead>
<tr>
<th>Second BCG vaccination given:</th>
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<tbody>
<tr>
<td>Yes ___ No ___</td>
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Appendix D (2)

Record of babies who received BCG with no scar formation found at 9 month developmental examination by AMO

Surname: ________________________________  First Name: ________________________________
Address: ____________________________________________________________

Telephone Number: ______________________________

Male / Female: ____________________ Date of Birth: _____ / _____ / _____

Date of BCG Immunisation: _____ / _____ / _____

Place of Immunisation: Coombe Women’s Hospital ______
(Tick as appropriate) National Maternity Hospital, Holles Street ______
Rotunda Hospital ______
Mount Carmel Hospital ______
Other (state where) __________________________________________

Child referred to BCG Clinic at: ______________________________

Signed: ___________________________________________

Date: _____ / _____ / _____

Completed form to be returned to Senior Area Medical Officer

For Senior Area Medical Officer Use Only

Vaccination carried out by: ________________________________________________

Initial Vaccine Manufacturer: ______________________________________________

Batch No: ______________________

Expiry Date: _____ / _____ / _____

Result of 2 TU Mantoux: ________________________________________________

Second BCG vaccination given: Yes ______  No ______
Appendix E

Health Questionnaire

Surname: ________________________________ First Name: ________________________________

Address: __________________________________________________________________________
________________________________________________________________________________
________________________________________________________________________________

Telephone Number: ______________________ Occupation: ________________________________

Male / Female: __________________________ Date of Birth: _____ / _____ / ______

Family Doctor: __________________________

Name of Clinic Attended: __________________ Date of Attendance: _____ / _____ / ______

Do you have any of the following:

Cough Yes ☐ No ☐
Sputum / Spit Yes ☐ No ☐
Shortness of Breath Yes ☐ No ☐
Weight Loss Yes ☐ No ☐
Unusual Tiredness Yes ☐ No ☐
Night Sweats Yes ☐ No ☐
Any serious illness Yes ☐ No ☐
(If Yes, please specify) ___________________________

Are you taking any drugs or medication Yes ☐ No ☐
(If Yes, please specify) ___________________________

Have you had a previous BCG vaccination Yes ☐ No ☐
(If Yes, give approximate date of same) ______________

Have you had TB in the past Yes ☐ No ☐
(If Yes, give approximate date) ______________

How long was treatment taken ______________

Type of treatment ______________

Name of doctor attended ______________

Have you had a tuberculin skin test Yes ☐ No ☐
(If Yes, give approximate date) ______________

Have any of your family or friends had TB in the past two years Yes ☐ No ☐

FOR DOCTOR’S USE

BCG Scar Yes ☐ No ☐

If no scar:

Mantoux: 2 TU Result _____ Signed _____________ 10 TU Result _____ Signed _____________

CXR: Date _______ Result _____________ Signed _____________

BCG Given: Yes ☐ No ☐ Date _______ Signed _____________

Scar Inspection: Present _____ Not Present _____ Signed _____________ Date _____________
BCG Information Leaflet / Card

BCG protects against tuberculosis (TB), a serious infectious disease, which can affect any part of the body, most commonly the lungs (chest).

It is vital that you discuss with the vaccinating doctor, prior to vaccination, if the person receiving the vaccination:

- Has a condition which lowers the body’s immune system, including HIV / AIDS, cancer, leukaemia
- Is receiving steroid medication or immunosuppressive treatment including radiotherapy
- Has a temperature or infection
- Is pregnant
- Has a generalised septic skin infection such as infected dermatitis
- Has had a serious infectious illness, e.g. measles or chickenpox, in the last three weeks
- Has been vaccinated with live vaccine, e.g. MMR, in the last three weeks
- Has received blood or any blood product in the last three months
- Has been in contact with anyone who has had infectious TB in the last two years

If any of the above apply, it may be necessary to postpone BCG vaccination.

AFTER BCG VACCINATION

In most cases small red pimples or sores will appear after some weeks at the site of the BCG vaccination. They will remain for some weeks and may discharge slightly. The sores will heal eventually, leaving small scars on the arm. It is not necessary to protect the site during washing or bathing. No treatment should be applied to the sores even though they resemble small boils.

If necessary, where there is a discharge, a dry dressing may be applied, which should be changed daily. It is essential that air is not excluded. No other vaccinations should be given in the left arm for three months following BCG vaccination.

You may notice swollen glands in the armpit. This is a normal reaction to the vaccine.

If you have any concerns following BCG, you may contact an AMO at the telephone number on this leaflet.
Information Leaflet

Tuberculin Skin Test (Mantoux Test)

A tuberculin skin test is carried out before immunisation, except in infants less than three months of age. It assesses the individual’s need for BCG immunisation.

It is normally carried out on the flexor (front) surface of the middle third of the left forearm. The injection will result in the immediate formation of a wheal or papule of 8-10mm in diameter, which will remain visible for about 10 minutes. Approximately 48 - 72 hours later an area of redness and / or swelling will develop at the site of the injection in positive reactors. You should return to the clinic 48 - 72 hours after the test is performed to have the results read.

Side effects:
Immediately after the injection, pain, irritation or discomfort may, in rare cases, develop at the test site, subsiding after a short period of time. Occasionally, mild fever or swelling of glands has been noted. In individuals who are extremely sensitive to tuberculin, a more severe reaction may occur at the injection site. This will gradually disappear.

Please discuss with the immunising doctor if your child

- Has been vaccinated with live vaccines, e.g. MMR in the previous 4 to 6 weeks
- Has had a viral infection, such as measles, chickenpox or infectious mononucleosis (glandular fever) in the previous 4 to 6 weeks
- Has had Sarcoidosis
- Is receiving a medication or immunosuppressive treatment including radiotherapy
- Has a condition which lowers the body’s immune system, including HIV / AIDS, cancer, leukaemia
- Had a previous severe reaction to a tuberculin product

If you have any concerns following this skin test, please contact an AMO at the telephone number on this leaflet.
CONSENT FORM

NEONATAL BCG VACCINATION SERVICE (Hospital)

PLEASE SIGN THE CONSENT FORM BELOW

I HAVE READ THE INFORMATION ON THE REVERSE SIDE AND THE INFORMATION LEAFLET GIVEN WITH THIS FORM.

I CONSENT TO HAVE MY CHILD VACCINATED AGAINST TUBERCULOSIS WITH BCG VACCINE.

Child’s Surname Forename Date of Birth

Address Sex Birth Weight

Tel. No. Maternity Hospital

Signature Date

Parent / Guardian

BCG Manufacturer BATCH NO. Expiry Date Date Given

Route / Site

Doctor’s Signature

For Office Use

Appendix H

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BCG protects against tuberculosis (TB), a serious infectious disease, which can affect any part of the body, most commonly the lungs.

If you have any queries please contact the area health board's number shown.

You may notice some minor skin reactions following BCG vaccination. This is a normal reaction to the vaccine.

No other vaccinations should be given in the arm for three months following BCG vaccination.

Where there is a discharge, dry dressing may be applied and this should be changed daily. It is essential that air is not excluded. Where there is no discharge, no treatment should be applied, as the sores will heal very slowly. These small sores on the arm are not necessary to protect the site and may disappear slowly. The area will feel slightly sore, leaving small scars on the arm. It is not necessary to protect the site in almost all cases. Small red pimples or sores will appear at the site of the BCG vaccination. They will remain for some weeks.

**AFTER BCG VACCINATION**

If any of the above apply to you or your child, it may be necessary to postpone BCG vaccination.

- You have been in contact with anyone who has infectious TB in the last two years.
- Your child has received immunoglobulin, blood or any other blood product since birth.
- Your child is receiving steroid medication.
- Your child is receiving intravenous sodium bicarbonate.
- Your child is receiving intravenous antibiotics.
- Your child has a cancerous tumour.
- You or your child has a condition which lowers the body's immune system, including HIV / AIDS, cancer, leukaemia.

If it is vital that you discuss this with the vaccinating doctor, please ask the doctor prior to vaccination.

If you have any queries please contact the vaccine programme coordinator at the telephone number shown.

The Area Health Board wishes to inform you that some of the information collected in connection with this programme may be used on a database to assist the board to provide a better service.

Appendix H continued
CONSENT FORM

BCG VACCINATION SERVICE (Clinic)

Child’s Surname __________________________ Forename __________________________ Date of Birth ______________

Address __________________________________________ Sex __________ Birth Weight __________

______________________________________________ Tel. No. __________ Clinic ______________________

PLEASE SIGN THE CONSENT FORM BELOW

I HAVE READ THE INFORMATION ON THE REVERSE SIDE AND THE INFORMATION LEAFLET GIVEN WITH THIS FORM.
I CONSENT TO HAVE MY CHILD TUBERCULIN TESTED

Signature __________________________ Date _______________

Parent / Guardian

I CONSENT TO HAVE MY CHILD VACCINATED AGAINST TUBERCULOSIS WITH BCG VACCINE.

Signature __________________________ Date _______________

Parent / Guardian

For Office Use

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<th>BATCH NO.</th>
<th>Expiry Date</th>
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<th>Date Read</th>
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<th>Expiry Date</th>
<th>Date Given</th>
<th>Dose</th>
<th>Route / Site</th>
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A BCG skin test is carried out before BCG immunisation, except in infants less than three months of age. It assesses the individual’s need for BCG immunisation. An area of redness may develop 48 - 72 hours after the test.

BCG vaccination protects against tuberculosis (TB), a serious infectious disease which may affect any part of the body. In adults, 90% of individuals need BCG immunisation. An area of redness may develop 48 - 72 hours after the test.

If any of the above apply to your child it may be necessary to postpone BCG vaccination.

If you have any queries please ask the doctor prior to vaccination.

Appendix I continued