DEPARTMENT OF HEALTH

INFORMATION FOR HEALTH WORKERS ABOUT

*i*ntradermal BCG *I*mmunisation

EXPANDED PROGRAMME ON IMMUNISATION

PART 1: INTRODUCTION

Since 1960 BCG *(Bacille Calmette-Guérin,* vaccine against Tuberculosis) has been given routinely to infants at birth or their first contact with the health care services. As from April 2000, the route for administration of BCG vaccine will change from percutaneous to intradermal. Children *under one year of age* who did not receive BCG earlier will be given one dose (0.05ml) of BCG vaccine with a syringe and needle, as an intradermal injection.

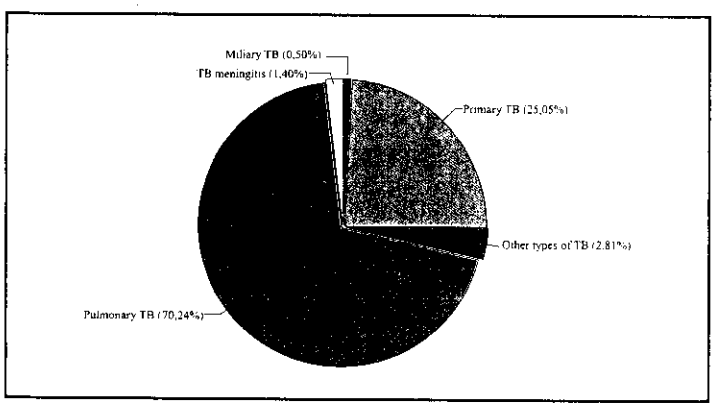
The intradermal route for administering BCG is used world wide (except Japan) and is advocated by the World Health Organisation (WHO). The technique allows for more accurate measuring and administration of the dose. The change from percutaneous to intradermal BCG immunisation in South Africa has been piloted successfully in Mpumalanga and in Durban.

PART 2: DISEASE BURDEN

WHO recommends BCG immunisation to all infants in countries with a high incidence of Tuberculosis (TB). TB incidence is still extremely high in South Africa, which implies a high risk of exposure of infants to the infecting organism *Mycobacterium tuberculosis*.

More than a 100 000 new Tuberculosis cases occur annually in South Africa. Of that, 20% of cases occur in the under 5 population. Based on the efficacy rates of the intradermal BCG vaccine, 41% of the TB case load in children under 5 years of age are preventable. This represents the disease burden due to notified cases of TB meningitis, miliary TB and primary TB. In the last 5 years, more than 600 cases and 80 deaths due to TB meningitis were notified in the under 5 population (1994-1998).

Figure 1: Distribution of TB types in the under 5 population, South Africa, 1980-1989.



Source: Official Notifications as received by the Dept. of Health, Pretoria.

PART 3: USE OF INTRADERMAL BCG VACCINE IN THE EPI PROGRAMME IN SOUTH AFRICA

Intradermal BCG vaccine contains a live attenuated strain of bacterium derived from *Mycobacterium bovis*. There are two brands of intradermal BCG vaccines registered in South Africa. Both are approved for use in infants.

Protection. Intradermal BCG vaccine protects against invasive TB infections. Protective efficacy rates quoted are 52% for TB meningitis; 80% for Miliary TB and 32% for Primary TB. The vaccine also provides between 60 to 80% protection against disseminated forms of TB in infants.

Description and Presentation. BCG is freeze dried as a white powder and the liquid diluent is specifically for reconstitution of intradermal BCG vaccine. The presentation of the vaccine is 20 infant doses per vial, packed 10 per box.

Storage. In provincial stores, the intradermal BCG vaccine may be kept in the freezer, while the diluent may remain outside the cold chain. At district and health facility level, *both* the intradermal BCG vaccine component and the diluent should be stored in the top third of the vaccine fridge, between *0-8°C*. The vaccine and diluent should be transported in a cold box with ice packs and a thermometer. Do not store the diluent directly on ice or ice packs.

Wastage. A multidose vial of vaccine should be opened even if only one child is to be vaccinated and the rest of the vaccine goes to waste. This wastage is termed "unavoidable" wastage, and it is preferential to not having vaccinated the child. The wastage that is "avoidable" may be due to opening too many multidose vials in a busy immunisation session, or due to improper management of the cold chain.

Target group and schedule . All infants should receive intradermal BCG vaccine *at birth*, or at the *first contact* with the health care services, together with the first dose of oral polio vaccine (OPV). Children older than one (1) year of age need not receive the vaccine, even if they have not been immunised with BCG previously. BCG offers less protection in older children and tend to cause more side effects.

Dose, route and site . The recommended dose is *0.05ml (one infant dose)* of the reconstituted

intradermal BCG vaccine, administered as an intradermal injection. The recommended site for BCG is the Right arm, at the *insertion* of the deltoid muscle. The site is not as high on the right upper arm as with percutaneous BCG vaccine.

EPI(SA) OPEN VIAL POLICY

1. Reconstituted vials of intradermal BCG vaccine may NOT be used in subsequent immunisation sessions and may be kept for a **maximum of 6 HOURS, provided** that EACH of the following conditions have been met -

- the expiry date has not passed; **and**
- the vaccines are stored under appropriate cold chain conditions (0-8°C);
- all reconstituted multi-dose vials of intradermal BCG vaccines which have been taken **out** of the health centre for immunisation activities e.g. outreach, **must be discarded after 6 hours or at the end of the session, whichever comes first.** These vials **may not be used** in subsequent immunisation sessions;

2. A reconstituted vial of Intradermal BCG vaccine **must be discarded immediately** if any of the following conditions applies:

- 6 hours have elapsed since the time of reconstitution written on the vial, **or**
- the time of reconstitution is **not written** on a reconstituted vial and/or the time written on the vial is **not clearly visible, or**
- aseptic procedures have **not** been fully observed; **or**
- there is even a suspicion that the reconstituted vial has been **contaminated, or**
- there is visible **evidence** of contamination, eg. a change in the normal appearance of the liquid or floating particles in the vial.

Intradermal BCG vaccine must always be *injected intradermally* and not intramuscularly.
Care should be taken to ensure that *percutaneous* BCG vaccine is *not injected.*

PART 4: MANAGEMENT OF SIDE EFFECTS

During the change to intradermal BCG, it is important that the development of a papule ("pimple" in parent/care giver pamphlet) and the formation of the subsequent scar is not regarded as an "error" or an "adverse reaction" to BCG, but a normal process. Therefore health workers and the public alike should be shown a normal intradermal BCG papule. In addition, it should be emphasized that no antiseptic should be used on the papule.

Parents and Care givers will have to be warned about the nature of the papule and the scar and the following should be emphasized:

- Not to excise or apply any antiseptics or dressings to the papule.
- It is not necessary to protect the injection site from water but should any oozing occur, a temporary *dry* dressing may be used until a scab forms.
- *Waterproof* dressings should be avoided as these may delay healing and cause a larger scar.
- Care-givers who are concerned with the papule should be encouraged to return the child to the clinic for an examination of the injection site.

Side effects after intradermal BCG vaccine may be described and categorized as Mild, Early and Severe. These side effects are due to a combination of variations in individual response and the injection technique. Mild side effects do not need intervention and should not be regarded as Adverse Events Following Immunisation (AEFIs). However, concerned health workers should be encouraged to consult a Paediatrician familiar with national guidelines for this purpose.

A. Normal BCG papule and scar

Following intradermal injection of live BCG vaccine -

- a small papule with induration appears within approximately 2-3 weeks.;
- the papule increases in size for a few weeks after immunisation widening into a circular area up to 7mm in diameter with scaling and crusting (occasional bruising or a shallow ulcer up to 10mm in diameter may develop);
- a minor degree of regional lymph node enlargement, usually in the axilla, is regarded as normal in the weeks following intradermal BCG immunisation.;
- the scar slowly subsides, usually over 3 months (occasionally up to 6 months).

Factors that may influence the size and shape of the papule and the scar:

- Giving the vaccine too deep or too superficially or injecting the wrong dose.
- Characteristics of the recipient eg. scar size may vary with age and exposure to TB infection.

Routine observation of the BCG papule and scar:

Development of a normal scar should be routinely observed and evaluated during the six week visit, and at each subsequent immunisation visit, up to the age of 14 weeks, to keep track of any vaccine complications encountered.

Recommended criteria for observation of the scar:

- visible or palpable scar;
- brief oozing at the injection site;
- small abscess at the injection site (may range between 7-10 mm in size (but not more than 10mm in size);
- axillary lymphadenopathy (more than 1.5 cm);
- suppurative axillary lymphadenopathy.

Evaluation. During observation, certain side effects may require treatment and therefore the injection site should be checked for the following:

- Lymph nodes in the axilla and supraclavicular fossa.
  ☞ *Lymph node swelling of up to 1.5cm diameter* should be regarded as a *normal response* to intradermal BCG vaccine.
- An abscess at the injection site (more than 10mm in size).
- Axillary lymphadenopathy (more than 1.5 cm).
- Suppurative axillary lymphadenophathy.
  ☞ *Axillary lymphadenopathy of more than 1.5 cm and suppurative axillary lymphadenophathy should be referred* to a specialist/clinician for further investigation and possible treatment.

B. Early side effects

The red swelling may be more severe and may appear earlier than 2 weeks after the injection if a child already has some immunity to tuberculosis. This may mean that the child has already had BCG, or that the child has had a tuberculosis infection.

What to do:

- Do not be concerned if the child had BCG vaccine previously and it was not recorded on the RTHC.
- On suspicion that the child might have TB, consult a senior health worker immediately.

C. Severe side effects

In rare instances, there may be a more severe local inflammation or a deeper abscess. The lymphatic glands near the elbow or in the axilla may sometimes swell. This may be because -

- the vaccine was injected too deeply under the skin;
- the vaccine was injected too high on the right upper arm, instead of at the *insertion of the deltoid* (injecting on the deltoid can result in enlarged clavicular glands);
- a larger dose of vaccine was given than recommended;
- the needle used was not sterile.

What to do:

- If the reaction remains local, no treatment is needed, except perhaps a dry dressing.
- If a very large lesion forms, or if the lymphatic glands swell, refer the child to a senior health worker for advice, as some of these children do need treatment.

REMEMBER:

- The BCG papule heals by itself. If it bursts or does not resolve, it should be reported.
- Normally, intradermal BCG immunisation leaves a small scar, about 5 mm across.
- No repeat BCG immunisation should be given at 6 weeks or any other age, if no scar is visible.
- The Road-to-Health Card should be the *only* criterion used to check if intradermal BCG was given.

PART 5: CONTRAINDICATIONS AND ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI)

Contraindications. The current EPI(SA) contra-indication for BCG applies:

- Do *not* give BCG vaccine to a child with *symptomatic AIDS*.
- In general, do not immunise a very sick child when hospitalisation is required or if the mother seriously objects, but encourage the parent/care giver to bring the child for immunisation on recovery.

Adverse Events Following Immunisation (AEFIs). When a suspected AEFI is detected, the procedure for AEFI surveillance should be followed (refer to the EPI Disease Surveillance Field Guide, October 1998). In such an event, the EPI(SA) AEFI reporting and case investigation form should be used to report and investigate a suspected AEFI. For further investigation, it will be useful to record the *batch/lot number of the vaccine* on the RTHC.

Local reactions. A local abscess has been found to occur in some South African children immunised with intradermal BCG as was seen in Mpumalanga during the first year after the change to intradermal BCG vaccine. This is still relatively rare with a good prognosis, although it is better to refer suspected cases for expert medical opinion. Two forms of local abscess may occur:

- Early abscess, not to be confused with the non-purulent papule that is a normal reaction. This usually occurs within the first two months following immunisation and often is the result of incorrect injection technique.
- Late abscess, occurs most commonly in excess of two months after immunisation and healing of the primary papule with a scar.

Regional lymphadenopathy may occur but is unusual if the *correct dose and injection site* are used. It may present with or without suppuration or discharge. If suppuration occurs it should be reported as a suspected AEFI and should be referred for treatment to a clinician, preferably a surgeon, for aspiration

Suggested treatment of regional lymphadenopathy with suppuration, by a clinician:

- Aspiration of the node, by introducing a needle subcutaneously 2-3cm from the node (to avoid iatrogenic sinus formation).
- Mild compression of the node while aspirating the pus.
- INH for 1-2 months (rarely necessary).

Systemic reactions. BCG osteitis and disseminated BCG infection are very rare complications which should be reported as suspected AEFIs and should be referred for treatment to a clinician.

The injection technique and suspected AEFIs:

After the change to intradermal BCG, health workers will develop and improve their skills in administering intradermal BCG vaccine with time. It should be noted that certain conditions may occur more frequently during this period and are most commonly caused by faulty injection technique:

- Where part or all of the dose is administered too deeply, which may result in possible severe injection site reactions, large ulcers and abscesses might appear.
- When the injection is administered too high, near the shoulder (instead of the site at the insertion of the deltoid muscle), keloid scar formation at the injection site may occur more frequently.

PART 6: CORRECT AND SAFE ADMINISTRATION OF INTRADERMAL BCG VACCINE

Training of health workers. Correct administration of intradermal BCG vaccine to infants is an *acquired skill.* The correct technique should be *demonstrated* to vaccinators. Vaccinators without previous experience in administering intradermal BCG vaccine, should be given the opportunity to practice the skill with supportive supervision.

Skills training of health workers should include at least:

- A practical demonstration of intradermal BCG injection technique observed by the health worker.
- Four intradermal BCG injections, administered to infants during supportive supervision of a previously trained health worker.
- Individual health workers should be given the option to request additional sessions if there is a need for them.

Important points about the administration of intradermal BCG vaccine

- Always use a *BCG syringe* to measure the correct dose of *0.05ml* accurately - do *not* use any other type of syringe eg. tuberculin or insulin syringes.
- Always reconstitute with diluent from the same manufacturer, never use diluent from another manufacturer of the same type of vaccine or any other type of vaccine, for reconstitution.
- Always check the label of the vial before administering ANY vaccine for *"intradermal* BCG vaccine" - it is not sufficient to only check for "BCG vaccine".

PART 7: SURVEILLANCE AFTER THE CHANGE TO INTRADERMAL BCG IMMUNISATION

The Change to intradermal BCG vaccine should be carefully documented. Issues that need to be addressed include:

- Surveillance to monitor the frequency of certain reactions after immunisation with a different kind of vaccine strain.
  - Special caution is required when a particular vaccine is replaced with another.
  - Suppurative axillary lymphadenitis varies with the kind of vaccine strain used (i.e. reports from EPI programmes in other countries about "outbreaks" of suppurative lymphadenitis in the last twenty years were connected with a change of vaccine).
- Tertiary and Academic hospitals will be requested to introduce sentinel surveillance systems to monitor miliary and disseminated TB, and TB meningitis in children after introduction of intradermal BCG vaccine.

Immunisation Coverage. Routine immunisation coverage will continue to be monitored. The current forms include the following:

- Road-to-Health Card.
- Immunisation Tally Sheet (GW 8/124).
- Monthly Immunisation Statistics form (GW 20/8).

☞ For more information about the intradermal BCG injection technique, the normal scar and information for parents/care givers contact the provincial EPI Coordinator.

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