

Bacille Calmette Guerin Vaccination

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Functional Sub group Clinical/ Patient Services - Infectious diseases
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Summary Specifies when BCG is recommended for TB.

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Applies to Area Health Services/Chief Executive Governed Statutory Health Corporation, Board Governed Statutory Health Corporations, Affiliated Health Organisations, Community Health Centres, Dental Schools and Clinics, Divisions of General Practice, Government Medical Officers, NSW Ambulance Service, NSW Dept of Health, Private Hospitals and Day Procedure Centres, Private Nursing Homes, Public Health Units, Public Hospitals

Distributed to Public Health System, Community Health Centres, Dental Schools and Clinics, Divisions of General Practice, Government Medical Officers, NSW Ambulance Service, NSW Department of Health, Public Health Units, Public Hospitals, Private Hospitals and Day Procedure Centres, Private Nursing Homes

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CIRCULAR

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This Circular supersedes Circular 94/91 BCG Vaccination

Bacille Calmette Guerin Vaccination

Introduction

Bacille-Calmette-Guerin (BCG) vaccine contains a live attenuated strain of *Mycobacterium bovis* - that is, the *Mycobacterium* has lost much of its virulence but retains many of its antigenic properties. BCG vaccination does not always prevent tuberculosis disease. A wide variation in protective efficacy in adults, demonstrated in clinical trials (ranging from 0-80%) has been attributed to differences in vaccine stains, prevalence of (protective) local environmental mycobacteria and host factors such as age at vaccination and nutritional status.

BCG is more effective in children, providing 50 to 80% protection against meningeal and military TB.¹

Definition

BCG is provided as a freeze-dried powder. The diluent comes in a separate vial containing 1.5 ml buffered saline all of which is used to reconstitute the vaccine. The reconstituted vaccine provides 10 adult or 20 infant doses of the vaccine. BCG vaccine is for intradermal use only.

BCG vaccine is a Schedule 4 drug.

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Indications

Given the low incidence of TB in Australia and the variable efficacy in adults, BCG is not recommended for use in the general population.

BCG is recommended for the following:

- Aboriginal and Torres Strait Islander neonates living in regions of high incidence. In Australia, high incidence areas for TB are the Northern Territory, northern South Australia or far North Queensland where rates of disease are 10-15 times greater than the Australian born non indigenous population. BCG vaccination is not currently recommended for Aboriginal and Torres Strait Islander neonates born or living in NSW.
- Neonates born to patients with leprosy.
- Children under the age of 5 years who will be travelling to live in countries of high TB prevalence for longer than 3 months (the World Health Organisation defines 'high risk' countries as those with an annual incidence of TB in excess of 100 cases per 100,000 population).
- Children and adolescents aged less than 16 years who continue to be exposed to an individual with active TB; and where the child or adolescent cannot be placed on isoniazid therapy and/or the source case has multi drug resistant TB.

In addition to the above categories, there are other groups of individuals who are at increased risk of TB, but for whom the value of BCG vaccine is less certain:

- In low TB incidence countries such as Australia, health care workers (HCWs) at risk of infection should be monitored for evidence of infection with periodic Tuberculin Skin Tests (TSTs), see Circular 94/95. HCWs who decline to be monitored by TSTs should be offered BCG vaccination together with written information about the vaccine's efficacy, advantages and disadvantages.
- Travellers 5 years of age and over who will spend 3 months or more in high TB prevalence areas may be offered BCG or alternatively TST evaluation prior to and following travel.

Contraindications

The use of BCG vaccine is contraindicated for the following:

- People who have previously had TB,
- People with HIV infection and those who are immune suppressed due to corticosteroids, immune-suppressive drugs, radiation therapy, or malignancies involving bone marrow or lymphoid systems (because of the risk of disseminated BCG infection in these individuals), and
- People with a high risk of HIV infection.

The use of BCG is not recommended for the following

- People with TST reactions greater than or equal to 5mm,

- People with generalised skin diseases such as eczema, furunculosis, atopic dermatitis, or other exudative inflammatory dermatological conditions sufficiently severe to obscure any reasonable injection site,
- Pregnant women - BCG has never been shown to cause foetal damage, however, the use of live vaccines in pregnancy is not recommended, and
- BCG should not be administered simultaneously with isoniazid preventive therapy, as isoniazid will inactivate BCG.

The administration of BCG should be delayed in

- People with a significant fever.

Dosage and Administration

1. BCG vaccine must be ordered through chest clinics in NSW. BCG vaccine should only be administered by a Registered Nurse who has successfully completed the NSW Health Department Immunisation Program for Registered Nurses, and has been accredited by the NSW State TB Coordinator, or a nominated delegate, to perform BCG vaccinations.
2. A TST should be routinely performed prior to BCG vaccination in all individuals except infants under 6 months of age. Infants under 6 months should be assessed for the risk of TB infection and if there is any risk for TB infection then TST should be performed prior to vaccination. Refer to Circular 94/90, Mantoux Test.
3. BCG should only be administered to persons who have a TST less than 5 mm of induration.
4. The dose of BCG is 0.1 mL for children and adults; 0.05 ml for infants under 12 months of age.
5. A short (10 mm) 26-27 gauge needle with a short bevel should be used. The risk of spillage can be minimised by using an insulin syringe to which the needle is already attached. Note: care should be taken when recapping the needle following the drawing up of the vaccine see Circular No. 99/87 Infection Control Policy section 7.7: Re-sheathing needles.
6. The BCG recipient should be instructed to look away from the injection site during the administration of the vaccine and protective eyewear should be worn by the administering nurse to protect against the risk of eye splash from the intradermal injection. If an eye splash occurs, the eye should be washed with saline or water immediately.
7. The site of injection is very important if the risk of keloid formation is to be minimised. The skin over the region of the insertion of the deltoid muscle into the humerus is recommended. This is just above the mid-point of the arm.
8. For consistency and to assist those who may subsequently want to find evidence of prior BCG vaccination, it is recommended that the internationally agreed convention of using the left upper arm for BCG vaccination be adopted wherever possible.
9. The skin should be swabbed with alcohol and allowed to dry. Stretch the skin between a

finger and thumb and insert the bevel into the dermis, bevel uppermost, for a distance of about 2 mm. The bevel should be visible through the transparent epidermis.

10. The BCG injection should raise a blanched bleb of about 7 mm in diameter with the features of peau d'orange. This indicates that the injection was truly intradermal. Considerable resistance will be felt as the injection is given. If this resistance is not felt, the needle may be in the subcutaneous tissues. If that is the case, withdraw the needle and re-insert at a nearby site intradermally.

The person should be advised of the expected response, and possible adverse events following the injection (see below).

LOCAL RESPONSE TO BCG VACCINATION

A small red papule forms and eventually ulcerates, usually within 2-3 weeks of vaccination. The ulcer heals over several weeks with minimal scarring. There may be swelling and tenderness in local lymph nodes. Subjects who are given BCG despite previous tuberculous infection will experience an accelerated response characterised by induration within 24-48 hours, pustule formation in 5-7 days and healing within 10-15 days.

ADVERSE EVENTS AND PRECAUTION

Abscesses, lymphadenopathy, gross local reaction and disseminated infections occur rarely. Anaphylactoid reactions have also been reported. Gross local or generalised infection can be treated with anti tuberculous drugs. Keloid formation can occur, but the risk is minimised if the injection is not given higher than the level of the insertion of the deltoid muscle into the humerus.

BCG can cause disseminated infection in immunocompromised individuals, and is therefore contraindicated in this group.

Care of the vaccination site

- The site should ideally be kept open - ie. no dressings or topical treatments,
- Sterile gauze may be applied loosely, if strictly necessary for cosmetic purposes. Do not apply strapping near the ulcer,
- Bumps and scratches should be avoided,
- The person may continue normal activities - eg swimming, sports.

Assessing Response

The size of the tuberculin reaction induced by BCG ranges from 0-15 mm, but it should be noted that clinical trials have not shown a consistent relationship between the size of tuberculin reactions and the protection provided by the vaccines. For this reason, TST of BCG vaccinees to test for a response is not routinely recommended. Because of waning hypersensitivity, most adults who were vaccinated with BCG in early childhood will have a negative TST result.

The administration of more than one BCG vaccination to an individual is not recommended.

Transport, storage and handling of BCG vaccine

Unconstituted (freeze-dried or lyophilised) BCG vaccine: if transporting under normal (non-frozen) conditions, transport in an insulated container with approved freeze monitor, and time-temperature monitor.

BCG can be stored in a refrigerator at 2°C to 8°C. Diluent should be stored at 2°C to 8°C and not frozen. Check expiry date on vial or container before storage. Rotate stock so that shortest date vaccines are used first. Protect from light (sunlight or fluorescent).

BCG vaccine must be reconstituted using the diluent supplied. Reconstituted BCG vaccine is very unstable and should be used during 1 working session of 5 to 6 hours. Reconstituted BCG vaccine must not be frozen and any unused vaccine discarded at the end of one 5 to 6 hour session regardless of how many doses remain in the vial or ampoule. This precaution is taken to reduce the risk of contamination as BCG does not contain bacteriostatic agents. In addition, the reconstituted vaccine loses potency. (See also Appendix 1 - Transport and Storage of Vaccines in The Australian Immunisation Handbook 7th Edition).

Special considerations

All intending BCG recipients should be aware that it may take up to 3 months before the BCG vaccination achieves maximum protection. Therefore, BCG vaccination should be given at least 3 months prior to potential exposure.

Vaccination with BCG produces varying immunity. The protection of BCG wanes after 5 - 10 years in some individuals.

Other live vaccines can be administered on the same day as BCG, however, with the exception of oral polio vaccine, other live vaccines should not be administered within one month pre or post BCG vaccination. This avoids possible interference with the immune responses to the vaccines.

Indications for BCG vaccination for overseas travellers are as follows:

The value of BCG vaccination for persons older than 5 years of age is unclear.

In recommending the use of BCG for persons who travel overseas for a prolonged period or frequently factors such as the likelihood of contact with infectious persons and the level of multi drug resistant TB needs to be evaluated by a practitioner with experience in TB management.

Travellers over the age of 5 years who will spend 3 months or more in high TB prevalence areas may be offered BCG or alternatively TST evaluation prior to and following travel.

Differences in the recommendations for use of BCG Vaccine

Of note is the difference in recommendations for BCG vaccination between this policy and the Australian Immunisation Handbook, 7th Edition 2000, National Health and Medical Research Council. It is NSW Health Department policy that BCG is not routinely recommended for use in:

- Neonates born to patients with TB as it is preferable to provide these contacts with screening, preventive therapy and to treat the infectious person so the neonate is no longer at risk, or

- Neonates or children who live in households with migrants or visitors from countries of high TB incidence as available data in NSW does not demonstrate a high risk of TB in this group.

1. The Australian Immunisation Handbook 7th Edition, NHMRC

Michael Reid
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