



VACCINE: TUBERCULOSIS



1. Vaccine indication

Tuberculosis vaccine (Bacille Calmette-Guérin) is indicated for the active primary prevention of tuberculosis in persons not previously infected with *Mycobacterium tuberculosis*.

2. Rationale for vaccination

The primary objective of BCG vaccination is the prevention of infection with *M. tuberculosis*, thereby preventing

- Pulmonary tuberculosis
- Disseminated tuberculosis
- TB meningitis

3. Type of vaccine

Live-attenuated bacterial vaccine.

4. Composition of the vaccine

BCG vaccine is a live bacterial vaccine prepared from attenuated strains of *M. bovis*. The vaccine is available as a freeze-dried product and is reconstituted before administration using diluent provided by the manufacturer.

5. Immunogenicity and efficacy of the vaccine

BCG has been shown not to confer primary prevention of infection with *M. tuberculosis*. What it does is to retard growth of organisms at site of primary infection, thereby protecting against the most serious forms of tuberculosis, meningitis and disseminated disease, particularly in young children. BCG also protects against leprosy.

Studies have shown the efficacy of BCG to range from 0% to 80%. The reasons for such variations are unclear as immune response to tuberculosis and BCG is not well understood.

6. Candidates for vaccination

In South Africa, BCG vaccine is given to all newborn babies at birth as part of the EPI-SA schedule.

In addition, the following persons are at risk of *M. tuberculosis* infection and should be vaccinated:

- Persons repeatedly exposed to untreated or inadequately treated TB
- Babies born to infectious mothers, who after three months of isoniazid treatment are tuberculin negative
- Health care workers in constant contact with TB patients
- Laboratory workers who handle tubercle bacilli cultures
- Miners
- Military personnel
- Travellers to TB endemic countries.

7. Vaccination regimen and route of administration

BCG vaccine is given intradermally to the upper left arm or shoulder for both infants and older children/adults. For infants the vaccine is administered at birth, and for other groups when the need for vaccination arises.

8. Side effects and special precautions

BCG is a safe vaccine that is well tolerated. Local reactions following vaccination are common but long term complications are rare. Local reactions include swelling or abscesses at the site of injection.

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