BCG Vaccination

The live attenuated strain of *Mycobacterium bovis* known as bacillus Calmette-Guérin (BCG) uses shared antigens to stimulate the development of cross-immunity to *Mycobacterium tuberculosis* and *Mycobacterium leprae*.

BCG vaccine is also used as an intravesicular immunomodulator in the management of bladder cancer (see the separate article on Bladder Cancer).

The BCG immunisation programme was introduced in the UK in 1953. The programme was initially targeted at children of school-leaving age (then 14 years), as the peak incidence of tuberculosis (TB) was in young, working-age adults.

In 2005, following a continued decline in TB rates in the indigenous UK population, the schools programme was stopped. The BCG immunisation programme is now a risk-based programme, the key part being a neonatal programme targeted at protecting those children most at risk of exposure to TB, particularly from the more serious childhood forms of the disease.

BCG vaccine contains a live attenuated strain derived from *M. bovis*. Studies of the effectiveness of BCG vaccine range from no protection to 70-80% protection. However, the vaccine is 70-80% effective against the most severe forms of the disease, such as TB meningitis in children. It is less effective in preventing respiratory disease, which is the more common form in adults.[1]

Protection has been shown to last for 10 to 15 years. Data on duration of protection after this time are limited, but protection may wane with time. Although the protection afforded by BCG vaccine may lessen with time, there is no evidence that repeat vaccination offers significant additional protection and repeat BCG vaccination is not recommended.[1]

There are few data on the protection provided by BCG vaccine when it is given to adults (aged 16 years or over), and no data for persons aged 35 years or over. BCG is not usually recommended for people aged over 16 years, unless the risk of exposure is great (eg, healthcare or laboratory workers at occupational risk).[1]

Administration[1]

BCG vaccine must be administered intradermally, normally into the lateral aspect of the left upper arm at the level of the insertion of the deltoid muscle. The left arm is recommended by the World Health Organization (WHO).

No further immunisation should be given in the arm used for BCG immunisation for at least three months because of the risk of regional lymphadenitis. BCG should ideally be given at the same time as other live vaccines such as measles, mumps and rubella (MMR). If live vaccines cannot be administered simultaneously, a four-week interval is recommended.

A single dose should be given of:

- 0.05 ml for infants under 12 months.
- 0.1 ml for children aged 12 months or older and adults.

Indications[1]

BCG immunisation should be offered to:

- 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.
- 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.
- Previously unvaccinated children aged 1 to 5 years with a parent or grandparent who was born in a country where the annual incidence of TB is 40/100,000 or greater.
- Previously unvaccinated, tuberculin-negative children aged from 6 to under 16 years with a parent or grandparent who was born in a country where the annual incidence of TB is 40/100,000 or greater.
- Previously unvaccinated, tuberculin-negative individuals aged under 16 years who are contacts of cases of respiratory TB.
- Previously unvaccinated, tuberculin-negative individuals under 16 years of age who were born in or who have lived for a prolonged period (at least three months) in a country with an annual TB incidence of 40/100,000 or greater.

Mantoux testing should not be done routinely before BCG vaccination in children younger than 6 years unless they have a history of residence or prolonged stay (more than one month) in a country with a high incidence of TB.[2]

Individuals at occupational risk

People in the following occupational groups are more likely than the general population to come into contact with someone with TB:

- Healthcare workers who will have contact with patients or clinical materials.
Laboratory staff who will have contact with patients, clinical materials or derived isolates.
Veterinary and staff such as abattoir workers who handle animal species known to be susceptible to TB.
Prison staff working directly with prisoners.
Staff of care homes for the elderly.
Staff of hostels for homeless people and facilities accommodating refugees and asylum seekers.

Unvaccinated, tuberculin-negative individuals aged under 35 years in these occupations are recommended to receive BCG. There are no data on the protection afforded by BCG vaccine when it is given to adults aged 35 years or over.

Not all healthcare workers are at an equal risk of TB. There are likely to be categories of healthcare workers who are at particular risk of TB, and should be part of the clinical risk assessment when the use of BCG is being considered for a healthcare worker over 35 years of age.

**Travellers and those going to reside abroad**

BCG may be required for previously unvaccinated, tuberculin-negative individuals according to the destination and the nature of travel. The vaccine is recommended for those under 16 years who are 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.

**Contra-indications**

The vaccine should not be given to:

- Those who have already had a BCG vaccination.
- Those with a past history of TB.
- Those with an induration of 6 mm or more following Mantoux tuberculin skin testing.
- Those who have had a confirmed anaphylactic reaction to a component of the vaccine.
- Neonates in a household where an active TB case is suspected or confirmed.
- People who are immunocompromised by virtue of disease or treatment - eg:
  - Patients receiving corticosteroid or other immunosuppressive treatment, including general radiation. Inhaled steroids are not a contra-indication
  - Those suffering from a malignant condition such as lymphoma, leukaemia, Hodgkin's disease or other tumour of the reticulo-endothelial system.

BCG is contra-indicated in symptomatic HIV-positive individuals. In countries such as the UK where the risk of TB is low, it is recommended that BCG is also withheld from all those known to be or suspected to be HIV-positive, regardless of clinical status.

**Precautions**

- Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation.
- If a person 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 sign 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.

No harmful effects on the fetus have been shown from BCG during pregnancy; however, it is wise to avoid vaccination, especially in the first trimester, and wherever possible to delay until after delivery. Breast-feeding is not a contra-indication to BCG.

**Immunisation reaction and care of the immunisation site**

The usual reaction to successful BCG vaccination is induration at the injection site, followed by a local lesion which starts as a papule two or more weeks after vaccination. It may ulcerate and then slowly subside over several weeks or months to heal, leaving a small, flat scar. It may also include enlargement of a regional lymph node to less than 1 cm.

It is not necessary to protect the site from becoming wet during washing and bathing. A temporary dry dressing may be used until a scab forms if any oozing occurs.

Severe injection site reactions, large, local discharging ulcers, abscesses and keloid scarring are most often caused by faulty injection technique, excessive dosage or vaccinating individuals who are tuberculin-positive.

Other adverse reactions to the vaccine include headache, fever and enlargement of a regional lymph node to greater than 1 cm and which may ulcerate. Allergic reactions (including anaphylactic reactions), more severe local reactions such as abscess formation, and disseminated BCG complications (such as osteitis or osteomyelitis) are rare.

All serious or unusual adverse reactions possibly associated with BCG vaccination (including abscess and keloid scarring) should be recorded and reported to the Commission on Human Medicines through the Yellow Card System, and vaccination protocols and techniques should be reviewed. Every effort should be made to recover and identify the causative organism from any lesion constituting a serious complication.
Management of adverse reactions

Individuals with severe local reactions (ulceration greater than 1 cm, caseous lesions, abscesses or drainage at the injection site) or with regional suppurative lymphadenitis with draining sinuses following BCG vaccination should be referred to a chest physician or paediatrician for investigation and management.

An adherent, suppurating or fistulated lymph node may require incision and drainage.

Disseminated BCG infection should be referred to a chest physician or paediatrician for specialist advice and will normally require systemic anti-TB treatment following current guidance for managing M. bovis infection. In vitro testing has shown that both isoniazid and rifampicin are effective. However, it is unclear if oral antibiotics (isoniazid, erythromycin, or a combination of isoniazid plus rifampicin) are effective for the resolution of BCG-induced disease.

Future developments

BCG is ineffective at protecting against adult pulmonary tuberculosis in the parts of the world where a good vaccine is most needed. Many new vaccines are in development. The new candidates include live attenuated M. tuberculosis, recombinant BCG, DNA vaccines and fusion proteins with novel adjuvants, and all aim to provide a stronger and longer-lasting immune response in heterogeneous populations.

Further reading & references

- Tuberculosis; NICE Guideline (January 2016)
- Tuberculosis; NICE CKS, January 2009
- Immunisation against infectious disease - the Green Book (latest edition); Public Health England
- Tuberculosis; NICE Clinical Guideline (March 2011)

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