

Tuberculosis Vaccine (BCG)

Bacille Calmette-Guérin (BCG) for the prevention of tuberculosis in children

Prevention

While new vaccines are in development, BCG vaccine is currently the only approved and available vaccination against tuberculosis (TB) to date and represents an important prevention tool for use in controlling the spread of TB. Immunization of infants with BCG lowers the risk of TB infection, including the most severe forms of the disease, TB meningitis and miliary TB. World Health Organization (WHO)-initiated vaccination programs in high burden areas (>20/100,000) have made an impact in slowing the development and spread of TB. Of note, BCG vaccination does not prevent against adult pulmonary TB. Along with BCG vaccine, early diagnosis, closely observed treatment, and public health and infection control measures are necessary to effectively manage the spread of the disease.

Mechanism of Action

BCG vaccine is prepared from a live culture of the BCG bovine strain, *Mycobacterium bovis*, and is suitable as a live attenuated vaccine. The vaccine is safe and does not interfere with the efficacy of other vaccines. Multiple studies have shown widely varying results regarding the efficacy of BCG vaccine in pulmonary tuberculosis. The average protective effect of BCG vaccine against TB has been determined to be approximately 50%. Those who have received BCG may have a positive TB skin test result, which makes determining latent TB difficult. Infants and children diagnosed with HIV infection or other immunodeficiency should not be vaccinated with BCG vaccine.

Current Use in Low TB Burden Settings

In settings with a low incidence of TB (<20/100,000), widespread vaccination is not necessary, and children can instead be monitored with strengthened case detection and early treatment methodologies. Therefore, BCG vaccination tends to be rare in low burden settings and administered only in instances where a child will be continually exposed to the disease and cannot be separated from adults who have the disease.

Application in High TB Burden Settings

BCG is currently one of the most widely used vaccines in countries with a high burden of communicable diseases, reaching more than 80% of infants in TB endemic regions. In these contexts, BCG vaccination is usually a part of standardized pediatric immunization programs. For those who live in high burden areas or where BCG is a standard vaccine, WHO recommends a single dose delivered to all infants as soon as possible after birth.

PREVENTION/TREATMENT



PREVENTION



DIAGNOSTIC



TREATMENT



GLOBAL ANNUAL DEATHS ASSOCIATED WITH PEDIATRIC TB:

| | NUMBER |
|-------------------------|--------------------|
| Children who acquire TB | at least 1,000,000 |
| Children who die of TB | 210,000 |

REPRESENTATIVE PRODUCTS

WHO Prequalified BCG Manufacturers

| MAKE | MODEL | PROCUREMENT PRICE | TECH | STATUS | NOTES |
|--|------------------------------|-------------------|---------|----------|------------------------------|
| Intervax Ltd (Canada) | Lyophilised; 20 dose ampoule | \$0.0748 | Vaccine | Marketed | UNICEF referenced price 2015 |
| Japan BCG Laboratory | Lyophilised | \$0.1370 | Vaccine | Marketed | UNICEF referenced price 2015 |
| Serum Institute of India Ltd | Lyophilised | \$0.0680 | Vaccine | Marketed | UNICEF referenced price 2015 |
| Statens Serum Institute (Denmark) | Lyophilised | \$0.1570 | Vaccine | Marketed | UNICEF referenced price 2015 |

CHARACTERISTICS OF REPRESENTATIVE PRODUCT

| | TECHNOLOGY CHARACTERISTICS | OPERATIONAL PARAMETERS | POTENTIAL OPPORTUNITIES FOR IMPROVEMENT |
|------------------------------------|-------------------------------------|--|--|
| SKILLS REQUIRED | Intended end user | Pediatric clinician, child | |
| | Training required | Hours | |
| | Time required per use | Minutes | |
| ENVIRONMENT/ INFRASTRUCTURE | Power required | None | |
| | Waste collection | Sharps | |
| | Complementary technologies required | None | |
| | Temperature and storage | Store at 2°C-8°C; Protect from direct sunlight | |
| | Maintenance | None | |
| COST | Device cost (approximate) | N/A | |
| | Cost/course (approximate) | \$0.06-\$0.15 | |
| OTHER | Portability | <10g | |
| | Regulatory | Widely approved | |
| | Efficacy | Controversial | Vaccine efficacy trials have shown variable protective benefit with the use of BCG ranging from 0-80% but overall protective effect can be considered 50%. |

Sources:

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