

TB Elimination

BCG Vaccine

Introduction

BCG, or bacille Calmette-Guérin, is a vaccine for tuberculosis (TB) disease. Many foreign-born persons have been BCG-vaccinated. BCG is used in many countries with a high prevalence of TB to prevent childhood tuberculous meningitis and miliary disease. However, BCG is not generally recommended for use in the United States because of the low risk of infection with *Mycobacterium tuberculosis* (*M. tuberculosis*), the variable effectiveness of the vaccine against adult pulmonary TB, and the vaccine's potential interference with tuberculin skin test reactivity. The BCG vaccine should be considered only for very select persons who meet specific criteria and in consultation with a TB expert.

Recommendations

Children. BCG vaccination should only be considered for children who have a negative tuberculin skin test (TST) and who are continually exposed, and cannot be separated from, adults who

- Are untreated or ineffectively treated for TB disease (if the child cannot be given long-term treatment for infection); or
- Have TB caused by strains resistant to isoniazid and rifampin.

Health Care Workers. BCG vaccination of health care workers should be considered on an individual basis in settings in which

A high percentage of TB patients are infected with *M. tuberculosis* strains resistant to both isoniazid and rifampin;

- There is ongoing transmission of such drug-resistant *M. tuberculosis* strains to health care workers and subsequent infection is likely; or
- Comprehensive TB infection-control precautions have been implemented, but have not been successful.

Health care workers considered for BCG vaccination should be counseled regarding the risks and benefits associated with both BCG vaccination and treatment of latent TB infection (LTBI).

Contraindications

Immunosuppression. BCG vaccination should not be given to persons who are immunosuppressed (e.g., persons who are HIV infected) or who are likely to become immunocompromised (e.g., persons who are candidates for organ transplant).

Pregnancy. BCG vaccination should not be given during pregnancy. Even though no harmful effects of BCG vaccination on the fetus have been observed, further studies are needed to prove its safety.

Testing for TB in BCG-Vaccinated Persons

The TST and TB blood tests to detect TB infection are not contraindicated for persons who have been vaccinated with BCG.

TST. BCG vaccination may cause a false-positive reaction to the TST, which may complicate decisions about prescribing treatment. The presence or size of a TST reaction in persons who have been vaccinated with BCG does not predict whether BCG will provide any protection against TB disease. Furthermore, the size of a TST reaction in a BCG-vaccinated person is not a factor in determining whether the reaction is caused by LTBI or the prior BCG vaccination. (*See below for specific guidance on skin test results.*)

TB Blood Tests. Blood tests to detect TB infection, unlike the TST, are not affected by prior BCG vaccination and are less likely to give a false-positive result.

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Treatment for LTBI in BCG-Vaccinated Persons

Treatment of LTBI substantially reduces the risk that TB infection will progress to disease. Careful assessment to rule out the possibility of TB disease is necessary before treatment for LTBI is started. Evaluation of TST reactions in persons vaccinated with BCG should be interpreted using the same criteria for those not BCG-vaccinated. Persons in the following high-risk groups should be given treatment for LTBI if their reaction to the TST is at least 5 mm of induration or they have a positive result using a TB blood test:

- HIV-infected persons
- Recent contacts to a TB case
- Persons with fibrotic changes on chest radiograph consistent with old TB
- Patients with organ transplants
- Persons who are immunosuppressed for other reasons (e.g., taking the equivalent of >15 mg/day of prednisone for 1 month or longer, taking TNF- α antagonists)

In addition, persons in the following high-risk groups should be considered for treatment of LTBI if their reaction to the TST is at least 10 mm of induration or they have a positive result using a TB blood test:

- Recent arrivals (less than 5 years) from high-prevalence countries
- Injection drug users
- Residents and employees of high-risk congregate settings (e.g., correctional facilities, nursing homes, homeless shelters, hospitals, and other health care facilities)
- Mycobacteriology laboratory personnel
- Persons with clinical conditions that place them at high-risk for developing TB disease (e.g., diabetes)
- Children less than 4 years of age, or children and adolescents exposed to adults in high-risk categories

Persons with no known risk factors for TB may be considered for treatment of LTBI if their reaction to the tuberculin test is at least 15 mm of induration or they have a positive result using a TB blood test. Targeted skin testing programs should only be conducted among high-risk groups. All testing activities should be accompanied by a plan for follow-up care for persons with TB infection or disease.

Additional Information

1. CDC. Development of new vaccines for tuberculosis: recommendations of the Advisory Council for the Elimination of Tuberculosis (ACET). *MMWR* 1998; 47 (No. RR-13). <http://www.cdc.gov/mmwr/preview/mmwrhtml/00054407.htm>
2. CDC. The role of BCG vaccine in the prevention and control of tuberculosis in the United States: a joint statement by ACET and the Advisory Committee on Immunization Practices. *MMWR* 1996; 45 (No. RR-4). <http://www.cdc.gov/mmwr/preview/mmwrhtml/00041047.htm>
3. World Health Organization. Issues Relating to the Use of BCG in Immunization Programmes-A Discussion Document (1999). <http://www.who.int/vaccines-documents/DocsPDF99/www9943.pdf>
4. CDC. Interferon-Gamma Release Assays (IGRAs) - Blood Tests for TB Infection. *MMWR* 2010; 59 (No. RR-5). <http://www.cdc.gov/tb/publications/factsheets/testing/IGRA.htm>

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