

## Bacille Calmette-Guerin (BCG) Revaccination: Is it Beneficial for Tuberculosis Control?

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### Abstract

**Background:** The duration of the protective efficacy of BCG vaccine plays an important role in the establishment of vaccination policies particularly for tuberculosis endemic countries. The effectiveness of revaccination with two or more doses is still a controversial issue. In this systematic review, we qualitatively appraised available epidemiological evidence.

**Method:** A search strategy using both PubMed and Embase databases and manual search was done up to January 2013. The main search terms used include BCG, revaccination, tuberculosis, mortality and adverse reaction. The studies were grouped by designs; randomized-control trials, cohort and case-control studies. Outcomes were categorized into primary outcomes (tuberculosis and mortality from tuberculosis) and secondary outcomes (vaccine efficacy, immunity and adverse reaction from BCG revaccination).

**Results:** Nine articles were selected and data on the primary and secondary outcomes were extracted. The review noted no significant difference in the incidence rate ratio (range 0.57-1.74), relative risk [0.39 (0.31-0.49)] and hazard ratio [1.20 (0.77-1.89)] from tuberculosis in the BCG revaccinated group compared to BCG non-revaccinated group. Comparison between the two groups also noted no significant difference in the relative risk of adverse reaction [2.3 (0.67-7.80)] and vaccine efficacy [8 (-77-52)], but a significant increase in immune response in revaccinated group.

**Conclusion:** In summary, our review demonstrated the available evidences do not support BCG revaccination as a strategy to reduce tuberculosis.

### Keywords:

### Background

Tuberculosis (Tb) is a leading cause of death and disability worldwide. The World Health Organization (WHO) estimates that approximately 1 billion people are infected with *Mycobacterium tuberculosis* complex, the causative agent of Tb. In Malaysia, Tb remains a significant public health problem, with an estimated 1.2 million people infected. The Bacille Calmette-Guerin (BCG) vaccine is the only available vaccine against Tb. BCG is a live attenuated strain of *Mycobacterium bovis* and is widely used in many countries, including Malaysia. BCG is known to provide protection against Tb, but the duration of its protective efficacy is still a matter of debate. Some studies suggest that BCG provides long-term protection, while others suggest that its protective effect is short-lived. This systematic review aims to evaluate the effectiveness of BCG revaccination in reducing the incidence of Tb and its complications. The review included studies published up to January 2013. The main search terms used were BCG, revaccination, tuberculosis, mortality, and adverse reaction. The studies were grouped by design: randomized-controlled trials, cohort studies, and case-control studies. The primary outcomes were tuberculosis incidence and mortality, and the secondary outcomes were vaccine efficacy, immunity, and adverse reactions. The results showed that there was no significant difference in the incidence rate ratio, relative risk, or hazard ratio for tuberculosis between the BCG revaccinated and non-revaccinated groups. However, there was a significant increase in immune response in the revaccinated group. The review also noted no significant difference in the relative risk of adverse reactions and vaccine efficacy between the two groups. In conclusion, the available evidence does not support BCG revaccination as a strategy to reduce tuberculosis.

### Methods

#### Study selection

The search strategy was designed to identify relevant studies on BCG revaccination for tuberculosis control. The search was conducted in PubMed and Embase databases. The search terms used were BCG, revaccination, tuberculosis, mortality, and adverse reaction. The search was limited to English language and human studies. The search was conducted up to January 2013. The search results were screened based on the following criteria: (1) study design: randomized-controlled trials, cohort studies, and case-control studies; (2) population: individuals aged 18 years and above; (3) intervention: BCG revaccination; (4) outcomes: tuberculosis incidence and mortality, vaccine efficacy, immunity, and adverse reactions. The search results were screened based on the following criteria: (1) study design: randomized-controlled trials, cohort studies, and case-control studies; (2) population: individuals aged 18 years and above; (3) intervention: BCG revaccination; (4) outcomes: tuberculosis incidence and mortality, vaccine efficacy, immunity, and adverse reactions. The search results were screened based on the following criteria: (1) study design: randomized-controlled trials, cohort studies, and case-control studies; (2) population: individuals aged 18 years and above; (3) intervention: BCG revaccination; (4) outcomes: tuberculosis incidence and mortality, vaccine efficacy, immunity, and adverse reactions.

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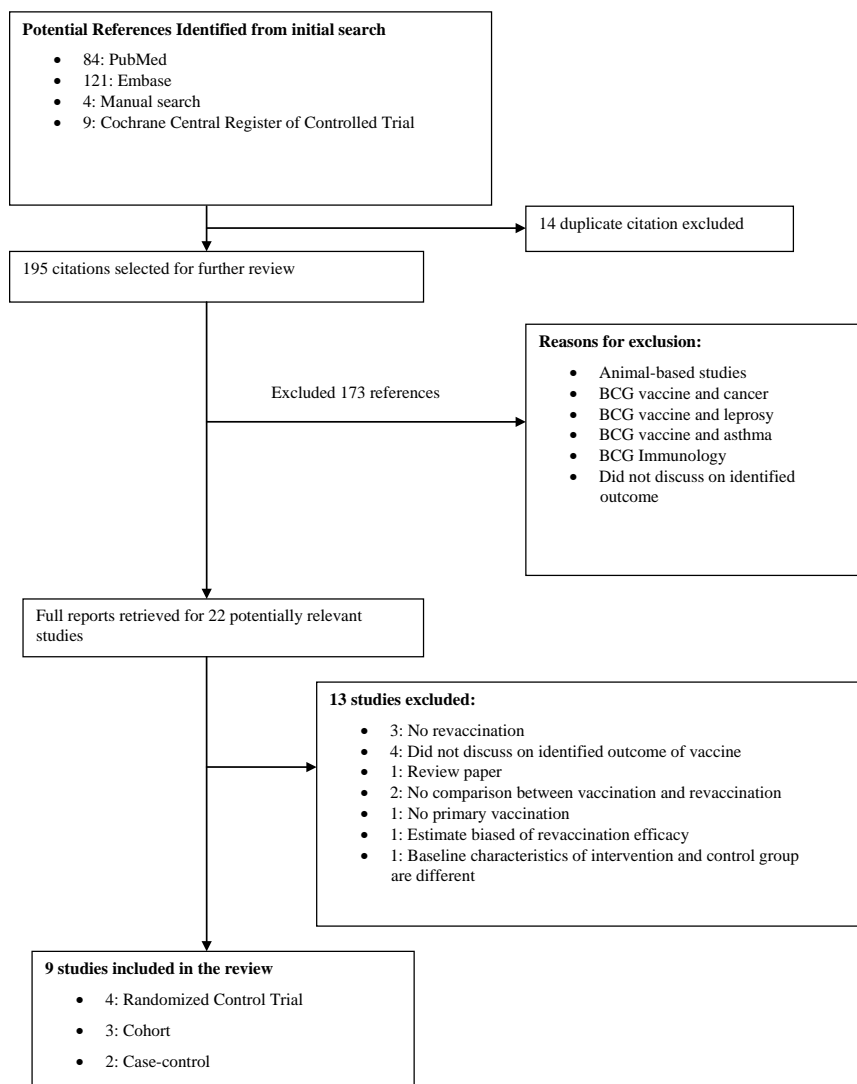
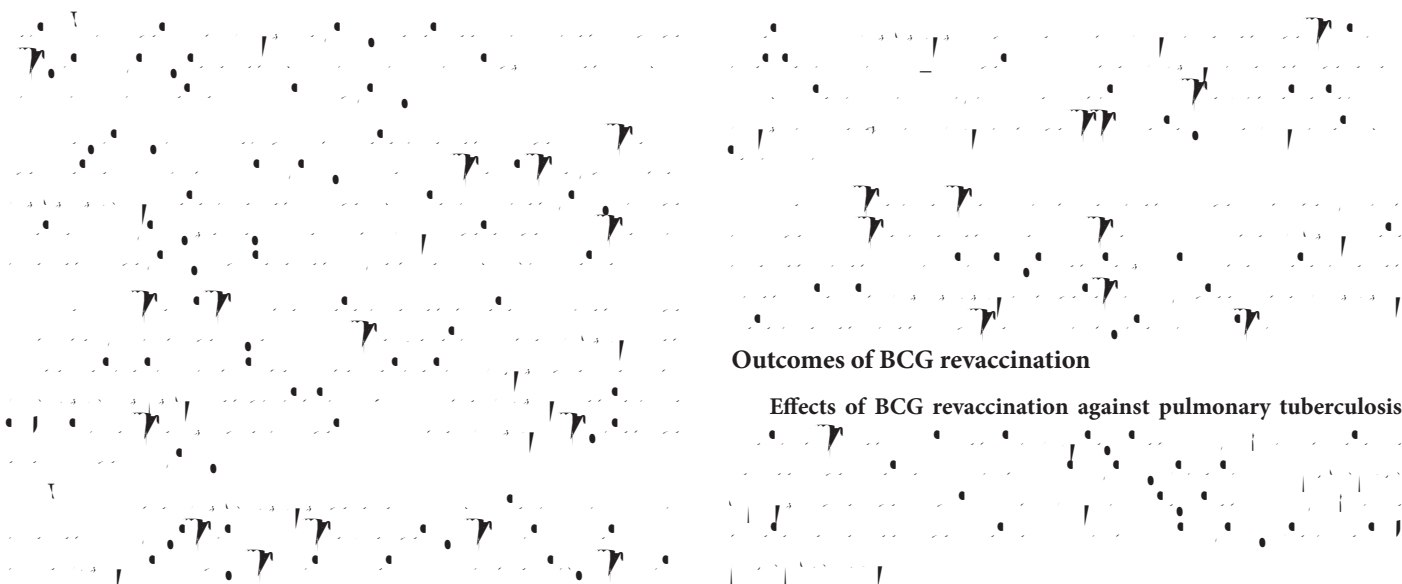
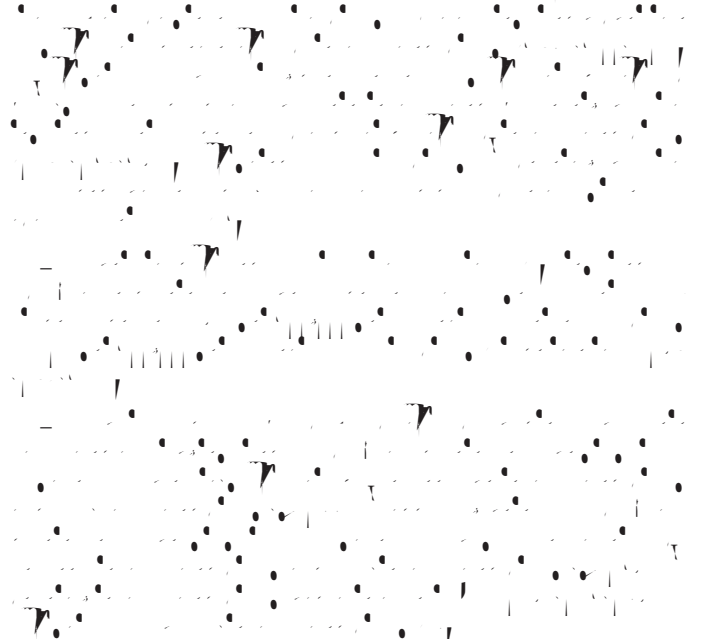


Figure 1:





**Effects of BCG revaccination against both pulmonary tuberculosis and extrapulmonary tuberculosis:**



**Effect of BCG revaccination against mortality:**



**Effect of BCG revaccination against secondary outcomes:**



