

# PREVENT TB Study



Tuberculosis (TB) is one of the world's leading infectious killers, and has not yet been eliminated in the U.S. Despite the significant burden of the disease, major medical advances in preventing, diagnosing, and treating TB have been rare. The current standard treatment for latent TB infection is effective when completed, but it is decades-old, lengthy, and complicated — which contributes to poor adherence.

The Centers for Disease Control and Prevention has been at the forefront of research into new, simpler ways to treat latent TB infection in order to prevent the spread of TB disease. The recently completed PREVENT TB study, sponsored by CDC, was one of the largest U.S. government clinical trials conducted to date on latent TB treatment. The results, described below, represent one of the most significant advances in TB research in decades.

## Study Overview

### Background

- ▶ The PREVENT TB trial tested the effectiveness of a new preventive TB treatment regimen among individuals with latent TB infection who are at high risk of progressing to TB disease (see box, this page).

### Methodology

- ▶ Study enrolled more than 8,000 participants (n=8,053). Most were in the U.S. and Canada, though some lived in Brazil and Spain.
- ▶ Participants were randomly assigned to receive one of two regimens:
  - *Current standard treatment regimen*: A self-administered daily dose of isoniazid taken for 9 months
  - *Study treatment regimen*: A once-weekly dose of rifapentine and isoniazid taken for 3 months, and given with supervision (called directly observed therapy)
- ▶ Trial lasted approximately 10 years.

### Key Findings

- ▶ The new regimen is safe and as effective in preventing new cases of TB disease as the current standard regimen. There were very few cases of TB disease in either arm: 7 cases among those taking the study regimen and 15 cases among those taking the current standard regimen.
- ▶ In addition, there was higher adherence to the new regimen, with 82 percent of participants completing the 3-month course of medication, compared to 69 percent who completed the 9-month course.

### Latent TB Infection vs. TB Disease

Individuals with latent TB infection have TB bacteria in their bodies, but do not feel sick, do not have any symptoms, and cannot spread TB to others. The only sign of latent TB infection is a positive reaction to a special skin test or TB blood tests. More than 11 million people in the U.S. have latent TB (about 4 percent of the total population).

While not everyone with latent TB infection will develop TB disease, about 5 to 10 percent of infected persons will if not treated. Some of those people will develop TB disease soon after infection (within the first two years), while others will develop TB disease later — particularly if their immune systems become weak, such as those who are also infected with HIV. Persons with TB disease may spread TB bacteria to others, although this typically requires prolonged exposure. In 2010, there were more than 11,000 reported cases of TB disease in the U.S.

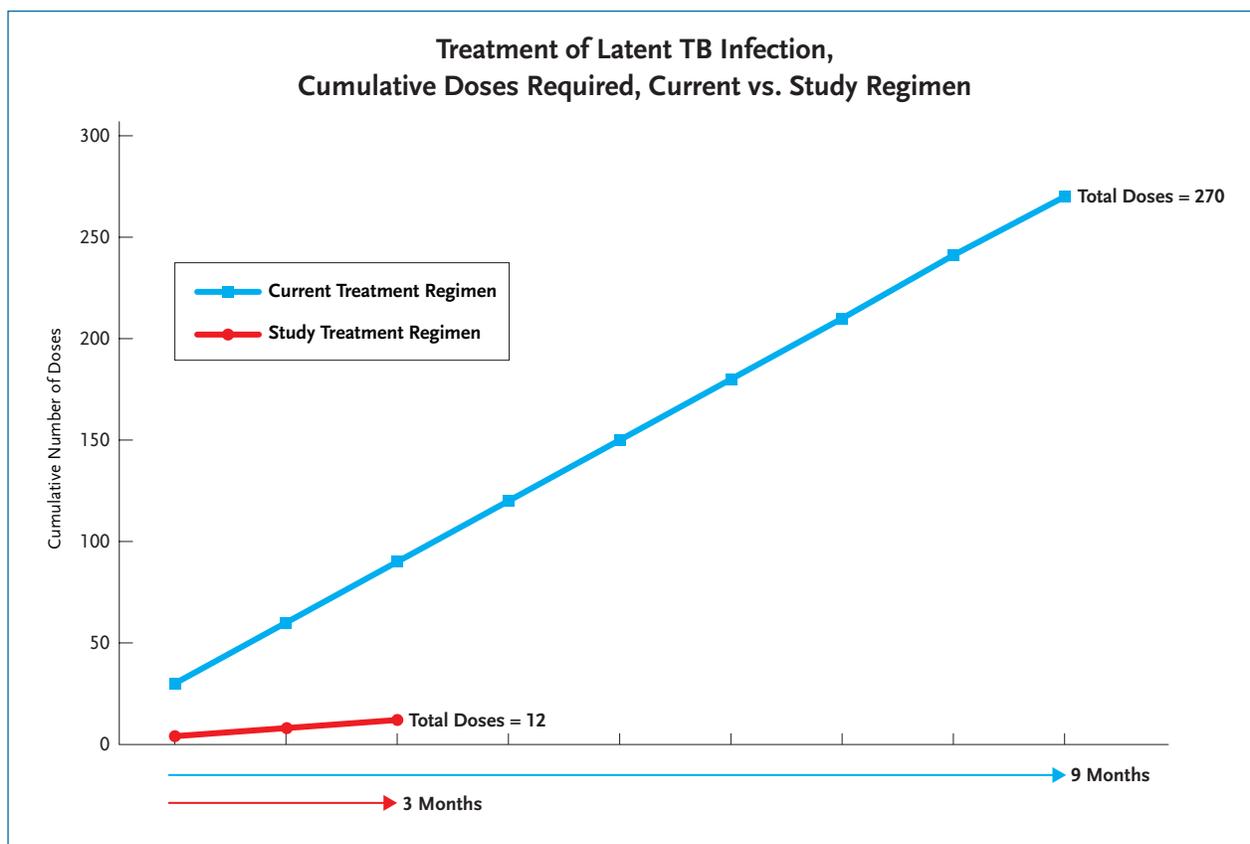


## Study Implications

The outcome of the PREVENT TB trial represents a major advance in TB treatment:

- ▶ The new regimen is simpler — reducing the required treatment from 270 daily doses over 9 months to 12 once-weekly doses over 3 months.
- ▶ The study results suggest that we may soon be able to treat latent TB infection more easily, which would prevent more cases and slow the spread of TB disease.
- ▶ The trial results are applicable only to countries with low-to-medium TB incidence. Additional research will likely be needed before the new regimen can be recommended in countries with a high incidence of TB.

CDC recently convened an expert consultation to review the data and begin working on new treatment guidelines for the use of the new regimen in the U.S. These guidelines are expected later this year.



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