

Addendum to *Latent Tuberculosis Infection: A Guide for Primary Health Care Providers and the Core Curriculum on Tuberculosis: What the Clinician Should Know*

December 9, 2011

CDC has issued recommendations on the use of a new treatment regimen for latent tuberculosis infection (LTBI).¹ This new regimen, referred to as the 12-dose regimen, is a combination regimen of isoniazid (INH) and rifapentine (RPT) given in 12 once-weekly doses under directly observed therapy (DOT). DOT is recommended for this regimen; missed doses, altered dosing intervals or amounts, or incomplete treatment could jeopardize the 12-dose regimen efficacy or safety.

The 12-dose regimen adds to other current LTBI guidelines and does not replace those guidelines (see Table 1 for LTBI treatment options).² The 12-dose once-weekly regimen is recommended as an option equal to the standard INH 9-month daily regimen for treating LTBI in otherwise healthy people, 12 years of age and older, who were recently in contact with infectious TB, or who had tuberculin skin test conversions or positive blood test for TB infection. The 12-dose regimen can be considered for other groups when it offers practical advantages, such as completion within a limited timeframe.

The 12-dose regimen is NOT recommended for

- Children younger than 2 years old,
- People with HIV/AIDS who are taking antiretroviral treatment,
- People who are presumed to have been infected with INH or rifampin (RIF)-resistant *M. tuberculosis*,
- Pregnant women, or women expecting to be pregnant within the 12-week regimen.

The choice between the 12-dose once-weekly regimen and other approved LTBI treatment regimens depends on several factors, including:

- Feasibility of DOT,
- Resources for drug procurement,
- Program operations including patient monitoring,
- Expectance of treatment completion considering medical and social circumstances of the patient, and
- Preferences of the patient and the prescribing physician.

The preferred regimen for children aged 2 to 11 years is 9 months of daily INH.

Table 1: Regimen Options for the Treatment of Latent TB Infection

Drug(s)*	Duration	Interval	Minimum Doses
Isoniazid (INH)	9 months	Daily	270
		Twice weekly†	76
	6 months	Daily	180
		Twice weekly†	52
Isoniazid (INH)and Rifapentine (RPT)	3 months	Once weekly†	12
Rifampin (RIF)	4 months	Daily	120

*See guidelines^{1,2} for dosing guidance; †Use Directly Observed Therapy (DOT)

Patients using the 12-dose regimen should undergo monthly clinical monitoring, including inquiries about side effects and a physical assessment for signs of adverse effects.

While the 12-dose regimen was well tolerated in the three reported treatment trials, severe adverse effects (defined as effects requiring hospital admission or fatalities) should be reported to FDA MedWatch and local and state health departments immediately for inclusion in CDC’s LTBI treatment adverse effects surveillance system.

The American Thoracic Society, the Infectious Diseases Society of America, and CDC are revising their joint guidelines for finding and treating LTBI. Those guidelines are expected to augment the new recommendations.

References

1. Recommendations for Use of an Isoniazid–Rifapentine Regimen with Direct Observation to Treat Latent *Mycobacterium tuberculosis* Infection. *MMWR* 2011
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6048a3.htm?s_cid=mm6048a3_w
2. ATS/CDC. Targeted tuberculin testing and treatment of latent TB infection. *MMWR* 2000;49(No. RR- 6). <http://www.cdc.gov/MMWR/PDF/rr/rr4906.pdf>

Additional Resources

- CDC TB Website: <http://www.cdc.gov/tb>

