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THE 12-DOSE REGIMEN

- One of the Biggest Breakthroughs in Treatment for Latent TB Infection

Treatment for latent tuberculosis infection (LTBI) is easier than ever before following the Centers for Disease Control and Prevention's (CDC) release of guidelines for the use of a shorter regimen with fewer doses. The recommendations were published on December 9, 2011 in CDC's *Morbidity and Mortality Weekly Report* (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6048a3.htm?s_cid=mm6048a3_w)

This new regimen for the treatment of latent TB infection, called the 12-dose regimen, reduces treatment from 270 daily doses over 9 months to 12 once-weekly doses given over 3 months. This is considered one of the biggest breakthroughs in treatment for latent TB infection since the 1960s.

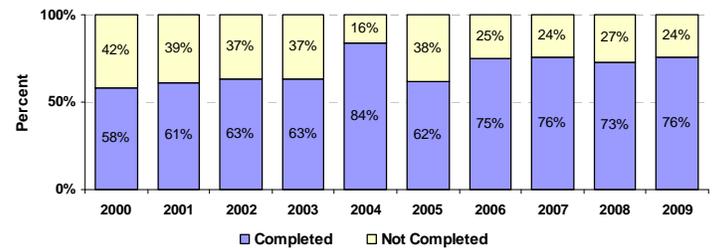
LTBI in the Nation and Washoe County

CDC estimates more than 11 million people living in the United States have LTBI. People with latent TB infection have TB bacteria in their body but do not feel sick, do not have symptoms, and cannot spread TB bacteria to others. However, about 5 to 10 percent (550,000 to 1.1 million) of those infected with TB in the United States will develop TB disease if not treated. Of those with LTBI, an estimated 300,000 to 400,000 people begin preventive treatment each year in the United States. Among those who begin treatment, 60 percent or less never completes the current treatment regimen, i.e., 270-dose isoniazid (INH) regimen, which is usually self-administered by patients daily over nine months. The Healthy People 2010 national health objective for completing treatment of LTBI is 85% of all persons who start a course of treatment. The 2015 National TB Program Objectives for completing treatment of LTBI is 79% of all contacts who start a course of treatment.

In 2010, Washoe County Health District (WCHD) estimated there were approximately 12,000 – 20,000 persons living with LTBI in Washoe County based on population and the average number of active TB cases over the past five years. The overall completion rate for treatment of LTBI among all persons who started treatment in 2009 was 76% (68/89). The completion rate for the period 2000-2009 can be seen

in Figure 1. Health District clients' completion rate is well above the national figure.

Figure 1. Completion Rate for Treatment of LTBI, TBPCP*, 2000-2009



(* TB Prevention and Control Program)

What is the New 12-Dose Regimen?

- ◆ It is a combination regimen of isoniazid (INH) and rifapentine (RPT) given in 12 once-weekly doses under directly observed therapy (DOT).
- ◆ It reduces the required treatment for LTBI from 270 daily doses by self-administration over 9 months to 12 once-weekly doses given over 3 months under DOT.
- ◆ It does not replace other recommended LTBI treatment regimens; the 12-dose regimen is another effective regimen.
- ◆ The 12-dose treatment guideline does not replace the current LTBI guidelines (<http://www.dcd.gov/MMWR/PDF/rr/rr4906.pdf>); it is a supplemental guideline.

CDC's recommendations are a result of a recent large randomized control trial which found the 12-dose regimen to be as effective for preventing TB as other regimens. The new regimen is also more likely to be completed than the current U.S. standard regimen of 9 months of daily isoniazid given without directly observed therapy.

Two additional studies also found the 12-dose regimen to be as effective as other regimens in preventing new cases of TB disease.

CDC recommendations for the 12-dose treatment regimen

The 12-dose regimen is an equivalent treatment option to previous recommended regimens for treating LTBI and maybe used for:

- ◆ Otherwise healthy people
- ◆ Persons 12 years of age and older
- ◆ Recent Tuberculin Skin Test (TST) conversions among contacts to infectious TB
- ◆ TST conversions or positive blood test for TB infection
- ◆ HIV-infected people who are otherwise healthy and not taking anti-retroviral medicines
- ◆ Other groups when it offers practical advantages, such as completion within a limited timeframe.
- ◆ The preferred regimen for children aged 2 to 11 years old is 9 months of daily isoniazid. However the 12-dose regimen may be considered for this age group when there is risk for non completion with the standard 9 month regimen.
- ◆ DOT is strongly recommended for the 12-dose regimen. (see below)

The 12-dose regimen is NOT recommended for:

- ◆ Children younger than 2 years of age,
- ◆ People with HIV/AIDS who are taking anti-retroviral therapy,
- ◆ Pregnant women or women who expect to become pregnant during treatment, and
- ◆ People who are presumed to have been infected with isoniazid-resistant or rifampin-resistant *M. tuberculosis*.

Evidence for broader usage of the 12-dose regimen is currently being gathered; the Health District will be participating with the CDC in a multi-site assessment. Additional studies on self-administration of the 12-dose regimen are also underway.

Directly Observed Therapy (DOT) in the 12-Dose Regimen

DOT is a key component of this new 12-dose regimen. DOT is a treatment method in which a healthcare worker observes each dose of TB medication taken by the patient. This method is designed to reduce the risk of drug resistance, provide early identification of adverse effects and to ensure patient adherence to the regimen.

Washoe County TB Public Health Nurses are skilled at assessing patient responses to therapy and providing education about adverse effects

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 latent TB infection treatment adverse effects surveillance system.

“The 12-dose regimen provides a simpler way to treat latent TB infection, allowing more people to successfully complete their treatment while also preventing the development of TB disease”

– Dr. Kevin Fenton, Director of the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, CDC

“Achieving CDC’s goal of TB elimination in the United States means not only treating people who already have TB disease, but also successfully treating people with latent TB infection who are at high risk for developing TB disease and potentially transmitting it to others”

– Dr. Kenneth Castro
Director of the Division of Tuberculosis Elimination
CDC

“Patients are more likely to complete a once-weekly, shorter duration regimen; and, clinicians may also be more likely to prescribe a shorter regimen. This is truly a welcome breakthrough in TB treatment.”

– Dr. Joseph Iser
Washoe County District Health Officer

Please contact TBPCP Coordinator Diane Freedman at 775-785-4787 should you have additional questions regarding the 12-dose regimen and other TB related questions.

Please share this document with all physicians & staff in your facility/office.