

Appendix C

National Surveillance for Severe Adverse Events Associated with Treatment for Latent Tuberculosis Infection — Reporting Information

This information is included to alert our public health partners to the importance of reporting severe (i.e., hospitalization or death) adverse events associated with treatment for latent TB infection (LTBI). Data regarding severe adverse events (SAEs) among persons receiving treatment for LTBI are needed to serve as a basis for periodic evaluation of LTBI treatment guidelines.

In April 2000, after the publication of updated *Guidelines for Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection*,¹ CDC's Division of Tuberculosis Elimination (DTBE) began receiving reports of SAEs related to use of a 2-month course of rifampin and pyrazinamide for LTBI treatment. In response, DTBE requested and received reports and conducted on-site investigations of liver injury among persons on LTBI treatment, and treatment guidelines were revised to recommend against the general use of rifampin and pyrazinamide for treating LTBI.^{2,3} In January 2004, DTBE implemented the National Surveillance System for Severe Adverse Events Associated with Treatment for LTBI, which collects reports about SAEs associated with any LTBI treatment regimen, to quantify the frequency of SAEs and to characterize the clinical features of affected patients.⁴

Local medical providers should report possible LTBI treatment-associated SAEs to their respective local or state health departments. State health departments should report SAEs that occurred on or after January 1, 2004, to DTBE (e-mail: LTBIdrugevents@cdc.gov). Any SAEs should also be reported to the U.S. Food and Drug Administration's MedWatch program, using the Online Voluntary Reporting Form available at: <https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>.

References

1. American Thoracic Society/CDC. Targeted tuberculin testing and treatment of latent tuberculosis infection. *Am J Respir Crit Care Med* 2000;161:S221–47. Available at: http://www.atsjournals.org/doi/abs/10.1164/ajrccm.161.supplement_3.ats600#.V9wOcWrylPY.
2. American Thoracic Society/CDC. Update: Adverse event data and revised American Thoracic Society/CDC recommendations against the use of rifampin and pyrazinamide for treatment of latent tuberculosis infection—United States, 2003. *MMWR* 2003;52:735–9. Available at: <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5231a4.htm>.
3. American Thoracic Society. An official ATS statement: hepatotoxicity of antituberculosis therapy. *Am J Respir Crit Care Med* 2006;174:935–52. Available at: <https://www.thoracic.org/statements/resources/mtpi/hepatotoxicity-of-antituberculosis-therapy.pdf>.
4. CDC. Severe isoniazid-associated liver injuries among persons being treated for latent tuberculosis infection—United States, 2004–2008. *MMWR Morb Mortal Wkly Rep* 2010;59:224–9. Available at: <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5908a3.htm>.