

Peer Review and Public Comment Plan for “Update on Recommendations for Use of Once-weekly Isoniazid-Rifapentine Regimen to Treat Latent *Mycobacterium tuberculosis* Infection”

Title: Update on Recommendations for Use of Once-weekly Isoniazid-Rifapentine Regimen to Treat Latent *Mycobacterium tuberculosis* Infection

Subject of Planned Report: This document summarizes the evidence informing clinical practices for using the 3-month once-weekly isoniazid-rifapentine regimen for treatment of persons who have latent *Mycobacterium tuberculosis* Infection (LTBI) and are at risk for developing tuberculosis disease, and provides guidance for optimal clinical and public health management.

Purpose of Planned Report: This document updates and replaces the 2011 recommendations “Centers for Disease Control and Prevention (CDC). Recommendations for use of an isoniazid-rifapentine regimen with direct observation to treat latent *Mycobacterium tuberculosis* infection. *MMWR* 2011; 60(48):1650.”

Type of Dissemination: Influential Scientific Information (ISI)

Timing of Review (including deferrals): In person meeting of subject matter experts (SME) July 20, 2017

Type of Peer Review (panel, individual or alternative procedure): Individual

Opportunities for the Public to Comment (how and when): In addition to the peer review by individual SMEs, the updated recommendations were presented and discussed during the scheduled public access meeting of the DHHS Secretary’s Advisory Council for the Elimination of Tuberculosis on December 11-12, 2017, to allow for public comment. The meeting was recorded to provide a complete and accurate record.

Peer Reviewers Provided with Public comments before the Review: No

Anticipated Number of Reviewers: 9

Primary Disciplines or Expertise: Diagnosis, treatment, prevention, surveillance, and epidemiology of LTBI and TB, clinical research, pulmonology, infectious diseases, pediatrics, HIV/AIDS diagnosis and treatment, public health programs, and patient advocacy in the United States

Reviewers Selected by (agency or designated outside organization): CDC

Public Nominations Requested for Reviewers: No

Charge to Peer Reviewers: CDC solicited individual SME’s perspectives of a systematic review of the 3HP regimen, current implementation of the 3HP regimen in various programmatic settings and populations, and proposed updates to the previous 2011 CDC recommendations. The individual SME were instructed to disclose competing interests and were notified that they would be disqualified from participating in the review if: 1) the documents to be reviewed are a critical review and evaluation of work outside the meeting or that of employer, 2) SME’s professional obligation requires to publicly defend or defeat an established position on an issue relevant to the functions to be performed in this activity, 3) SME’s participation will enable to obtain access to a competitor’s or potential competitor’s confidential proprietary information, 4) as a current or former U.S. government employee (civilian or military), there are federal competing interest restrictions that may apply in connection with this activity, 5) SME is interested in seeking an award under the program for which the group is developing the request for proposals, work statement, or specifications, and employed in some capacity by, or have a financial interest in or other economic relationship with, any person or organization that is interested in seeking an award under this program, 5) SME or a member of immediate family hold a financial, equity, or proprietary interest in, or receive research support from, an organization whose product or product concept is involved in the deliberations at this meeting, 6) SME or a member of immediate family hold financial, equity, or proprietary interest in, or receive research support from, an organization whose product or product concept is

competing with a product or product concept being discussed at the meeting, 7) SME or a member of immediate family is seeking employment in an organization or serve as an officer, director, trustee, partner, or employee of an organization whose product or product concept competes with, is involved in the deliberations of, or would benefit from research in an area that is on this meeting's agenda, 8) SME or a member of immediate family hold financial, equity, or proprietary interest in, or receive research support from, an organization whose product or product concept is being discussed or would substantially benefit from research emphasis in a defined area. No competing interests were identified.

Peer Reviewers:

Neil Schluger, M.D.

Chief, Division of Pulmonary, Allergy and Critical Care Medicine, Columbia University

Expertise: diagnosis, treatment, prevention and epidemiology of LTBI and TB, clinical research, pulmonology, infectious diseases

Robert Belknap, M.D.

Director, TB Clinic, Denver Health

Expertise: diagnosis, treatment, prevention, surveillance, and epidemiology of LTBI and TB, clinical research, public health programs

Andrea Cruz, M.D.

Pediatrician, Pediatric Infectious Diseases, Texas Children's Hospital

Expertise: diagnosis, treatment, prevention, and epidemiology of pediatric LTBI and TB, pediatrics, infectious diseases

Jenny M. Flood M.D., M.P.H.

Chief, TB Control Program, California Department of Public Health

Expertise: diagnosis, treatment, prevention, surveillance, and epidemiology of LTBI and TB, HIV/AIDS diagnosis and treatment, public health

James (Mike) Holcombe, MPPA

TB Control Program Manager, Office of TB and Refugee Health, Mississippi State Department of Health

Expertise: diagnosis, treatment, prevention, surveillance, and epidemiology of LTBI and TB, public health

David Ashkin, M.D.

TB Program Officer, TB Program, Florida Department of Public Health;

Assistant Professor, Division of Infectious Diseases and Global Medicine, University of Florida

Expertise: Diagnosis, treatment, prevention, surveillance, and epidemiology of LTBI and TB, clinical research, infectious diseases, HIV/AIDS diagnosis and treatment, public health

Masa Narita, M.D.

Director, TB Control Program, Seattle and King County Public Health Department

Expertise: diagnosis, treatment, prevention, surveillance, and epidemiology of LTBI and TB, clinical research, public health

John Bernardo, M.D.

Tuberculosis Control Officer, TB Control Program, Massachusetts Department of Public Health;

Professor of Medicine, Boston University

Expertise: Diagnosis, treatment, prevention, surveillance, and epidemiology of LTBI and TB, clinical research, public health

Mike Frick, M.P.H.

TB/HIV Project Director, Treatment Action Group

Expertise: prevention and epidemiology of LTBI, TB, HIV/AIDS, and patient advocacy in the United States