Summary of the Federal TB Task Force Conference Call
July 22, 2013

The Federal TB Task Force (FTTF) conference call was held on Monday, July 22, 2013 at 2:30 p.m. Eastern Standard Time hosted by the Division of Tuberculosis Elimination (DTBE).

Updates from three tracks (Diagnostics, Drug Shortages, and Science) of the last FTTF face-to-face meeting that was held on April 8, 2013 in Bethesda, Maryland are included.

Working Group Updates:

Diagnostics

- Peter Kim, NIAID, reported that the future priorities of the Diagnostics Working Group were identified at the last FTTF meeting. The future priorities are as follows:
    - Diagnosis of resistance for important drugs besides PZA (e.g., fluoroquinolones, aminoglycoside, and new drugs)
    - Use of molecular detection of drug resistance for drug surveillance
    - Diagnosis of TB in the Pediatric Population

To address these issues NIAID and CDC are planning three scientific workshops in the coming year.

1. TB Diagnostics Research Forum meeting will be held September 30 – October 1, 2013
    a. The Forum, which is an outgrowth of the 2011 workshop, is now a part of the CPTR (Critical Path to TB Drug Regimens)
    b. Primary focus of the forum is to advance research and development in the field of Diagnostics for TB Drug Resistance
    c. Four working groups of the forum are: Enabling Science, Surveillance, Assay Development, and Economic Assessment/Impact Modeling
    d. Annual meeting of the TB Diagnostics Forum (which is now a part of the CPTR)

- Bonnie Plikaytis, CDC, reported on the Standardization of Reporting TB Molecular Diagnostic Results consultation that will be held October 1-2, 2013 at the Roybal Campus in Atlanta, Georgia. Purpose is to standardize the reporting language for molecular diagnostic results to diagnose TB and also to detect drug resistance for TB. The audience consists of clinicians, laboratorians, and surveillance and informatics subject matter experts**.**

  Three major points to address during consultation are as follows:

  1. Establish standardized laboratory reporting language associated with available molecular assays for the testing of mycobacterium TB and mutations associated with drug resistance.
  2. Determine the essential components of the comprehensive laboratory report to clinician and public health programs.

3. Determine which components of the molecular detection of drug resistant results are appropriate for reporting to state and national surveillance systems and what format is needed.

- Patrick Jean-Philippe, NIAID/HJF, gave an update on the validation of the consensus case definitions of Pediatric TB issued from the 2011 workshop and published last year (2012). Validation data from retrospective application of these definitions to a randomized trial following prospectively > 1300 HIV-infected and uninfected infants were being finalized for abstract submission as a late-breaker at the Union Paris meeting in October 2013. He also briefly discussed early plans for a TB diagnostic biomarker workshop to be organized by NIAID with support from NICHD and planned for late spring 2014

- Kenneth Castro, CDC, reported that FDA reposted reclassification of new TB diagnostic in the Federal Register on July 19, 2013 for a 90 day period. FTTF members are welcome to provide comments during the 90 day public comment period.

  Dr. Castro also reported that CDC has been collaborating with Janssen Therapeutics with regard regards to how the government can facilitate access to the reference labs within the U.S. for conducting bedaquline drug susceptibility testing.

Science

- Christine Sizemore, NIAID, reported once the NIH internal TB working group is reinstituted, a new-team member will join in mid-August and revise the group to include discussions about scientific aspects that the NIH and other federal agencies can undertake. Non NIH participants are welcome to participate on the science track. Please send your name to Dr. Sizemore (CSizemore@niaid.nih.gov) if interested.

Drug and Biologic Shortages

- Terence Chorba, DTBE/CRB, reported that the Drugs and Biologic Shortages Working Group was proposed at the last FTTF face-to-face meeting. CDC proposed to take leader on this working group. The summary of TB Drug Shortages working group will be sent to FTTF members shortly after this telephone conference. Please refer to p.5 of the summary and confirm the names listed.

  Dr. Chorba mentioned that he is awaiting the proceedings of the conversation about drug shortages that Drs. Frieden and Hamburg will be having on July 29, 2013. The outcome will be shared with members of the Drugs and Biologic Shortages Working Group.

Round Robin Table Discussion:

- Charlotte Colvin, USAID, reported that William Wells has joined the Research Team as the Research Innovation Officer.
- Rupali Doshi, HRSA, asked for questions in reference to HRSA's presentation on TB and the homeless population that was given during ACET meeting in June 2013.
- Hannah Peavy, NHLBI, reported that NHLBI's TB Systems Biology group is planning a steering committee meeting in September 2013.
- Kenneth Castro, CDC, will begin a detail on August 19, 2013 to serve as Acting Director of the Division of HIV/AIDS Prevention (DHAP) until a permanent Director of DHAP is selected. Dr. Philip LoBue will serve as Acting Director, DTBE, until a permanent Director is selected.

Participants:
Kenneth Castro, CDC
Christine Sizemore, NIAID
Philip LoBue, CDC
Terence Chorba, CDC
Susan Maloney, CDC
Drew Posey, CDC
Diana Elson, ICE
Carol Worrell, NICHD
Marc Leffer, FOH
Charlotte Colvin, USAID
Janet Phillips, USAID
Mary Sanitato, USAID
Alan Ou, NIH/NIAID
Virginia Lipke, CDC
Sally Hojvat, FDA
Janice Washington, FDA
Steve Gitterman, FDA
Ribhi Shawar, FDA
Rupali Doshi, HRSA
Dan Johnson, NIAID
Michele Pearson, CDC
Bonnie Plikaytis, CDC
Wanda Walton, CDC
Patrick Jean-Philippe, NIAID
Peter Kim, NIAID
Mary Betsy Smith, NIAID
Sharon Williams, NIAID
Naomi Aronson, DOD
Candrea Cherry, USMS

Stephen Martin, CDC
John Ridderhof, CDC
Eugene McCray, CDC
Eileen Navarro, FDA
Joe Toerner, FDA
Hannah Peavy, NHLBI
Yvonne Shea, FDA
Barbara Sina, FIC
Jeanne McDermott, FIC