U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Division of Tuberculosis Elimination

Virtual Meeting of the
Advisory Council for the Elimination of Tuberculosis
April 17, 2018

Record of the Proceedings

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ADVISORY COUNCIL FOR THE ELIMINATION OF TUBERCULOSIS
April 17, 2018

Minutes of the Virtual Meeting

The U.S. Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC), National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP), Division of Tuberculosis Elimination (DTBE) convened a virtual meeting of the Advisory Council for the Elimination of Tuberculosis (ACET). The proceedings were held on April 17, 2018 beginning at 10:00 a.m. EST.

ACET is formally chartered under the Federal Advisory Committee Act (FACA) to provide advice and recommendations to the HHS Secretary, HHS Assistant Secretary for Health, and CDC Director regarding the elimination of tuberculosis (TB). The charter authorizes ACET to make recommendations regarding policies, strategies, objectives, and priorities; address the development and application of new technologies; provide guidance and review on CDC's TB Prevention Research portfolio and program priorities; and review the extent to which progress has been made toward TB elimination.

Information for the public to attend the virtual ACET meeting via webinar or teleconference was published in the *Federal Register* in accordance with FACA regulations and rules. All sessions of the meeting were open to the public (*Attachment 1: Participants' Directory*).

Opening Session

Hazel Dean, ScD, DrPH (Hon), MPH, FACE
Deputy Director, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
ACET Designated Federal Officer (DFO)

Dr. Dean conducted a roll call to confirm the attendance of the ACET voting members, *ex-officio* members, and liaison representatives. She announced that ACET meetings are open to the public and all comments made during the proceedings are a matter of public record. She informed the ACET voting members of their responsibility to disclose any potential individual

and/or institutional conflicts of interest for the public record and recuse themselves from voting or participating in these matters.

ACET Voting Member (Institution/Organization)	Potential Conflict of Interest
Ana Alvarez, MD, FAAP (University of Florida, College of Medicine)	No conflicts disclosed
Lisa Armitige, MD, PhD (Heartland National Tuberculosis Center)	No conflicts disclosed
Barbara Cole, RN, MSN, PHN (Riverside County Department of Public Health)	No conflicts disclosed
Jennifer Flood, MD, MPH (California Department of Public Health)	No conflicts disclosed
Robert Horsburgh, Jr., MD, MUS (Boston University School of Public Health)	No conflicts disclosed
Eric Houpt, MD (University of Virginia)	No conflicts disclosed
Jeffrey Starke, MD (Baylor College of Medicine)	Member of the Otsuka Pharmaceutical Company Data Safety Monitoring Board for pediatric clinical trials of Delamanid, an anti-TB drug, to treat multidrug-resistant TB (MDR-TB)
James Sunstrum, MD (Wayne County, Michigan TB Clinic)	No conflicts disclosed
David Warshauer PhD, (ABMM) (Wisconsin State Laboratory of Hygiene)	Recipient of federal funding from the CDC TB Cooperative Agreement (CoAg)

Dr. Dean confirmed that the 20 voting members and *ex-officio* members in attendance (or their alternates) constituted a quorum for ACET to conduct its business on April 17, 2018. She called the proceedings to order at 10:00 a.m. EST and welcomed the participants to the virtual ACET meeting.

Dr. Dean made several announcements regarding the changes that have occurred in ACET's membership since the previous meeting.

- The terms of four ACET members will expire on June 30, 2018: Drs. Eric Houpt, Michael Lauzardo, James Sunstrum, and David Warshauer. Certificates of appreciation will be mailed to the four outgoing members in recognition of their service to ACET, CDC, and HHS.
- Dr. Matthew Lin, the HHS Deputy Assistant Secretary for Minority Health and Director of the HHS Office of Minority Health (OMH) is now serving as the *ex-officio* member for HHS/ OMH.
- CDC sent a letter to the U.S. Department of Labor, Occupational Safety and Health Administration, on January 31, 2018, with a request to identify a new *ex-officio* member to replace Ms. Caroline Freeman.
- Dr. Bruce San Filippo (primary *ex-officio* member) and Mr. Jose Velasco (alternate *ex-officio* member) are no longer with the U.S. Section of the U.S.-Mexico Border Health Commission. CDC will send a letter to the HHS Office of Global Affairs with a request to identify a replacement for Dr. San Filippo.

- CDC sent a letter to the Association for Professionals in Infection Control and Epidemiology with a request to identify a new liaison representative to replace Mr. Eddie Hedrick.
- CDC sent a letter to the Indian Health Service, on November 1, 2017, with a request to identify a new *ex-officio* member to replace Dr. Sarah Linde.
- ACET sent an original letter in August 2017 and a follow-up letter on February 6, 2018 to the Association of State and Territorial Health Officials with a request to identify a new liaison representative to replace Dr. Jay Butler.

Barbara Cole, RN, MSN, PHN, ACET Chair
TB Controller
Riverside County (California) Department of Public Health

Ms. Cole also welcomed the participants to the virtual ACET meeting. She announced that in response to ACET's previous requests, video conferencing is available for the members to utilize over the course of the meeting. ACET requested this technology during previous meetings in an effort to more fully engage the members during webinars. She planned to solicit input from the members on the video conferencing feature during the Business Session to inform CDC's audiovisual staff of any problems that need to be resolved before the next virtual ACET meeting.

NCHHSTP Director's Report

Jonathan Mermin, MD, MPH (RADM, USPHS)
Director, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

Dr. Mermin covered several topics in the NCHHSTP Director's report to ACET. At the agency level, Dr. Robert Redfield was appointed as the new CDC Director in March 2018. Dr. Mermin highlighted the key milestones in Dr. Redfield's distinguished background and career in clinical medicine research and public health, particularly in both domestic and global HIV treatment and research. Dr. Redfield's most frequent quote to CDC staff is "never underestimate the possible."

CDC provided support to the National Governors Association to host a learning laboratory for states on March 15-16, 2018 in Louisville, Kentucky. This event was convened for high-level officials in eight states to explore approaches to decrease the transmission of infectious diseases among people who inject drugs (PWID), including opioids, develop plans, and share successful policies and practices. The eight participating states included teams from Alabama, Arkansas, Delaware, Kentucky, Michigan, Utah, Virginia, and Washington.

At the CDC center level, NCHHSTP recently announced Dr. John Ward's new position with the Task Force for Global Health after serving as the Director of the Division of Viral Hepatitis (DVH) for 13 years. He is still a CDC employee, but his new position will allow him to expand his activities with global virus hepatitis programs. Dr. Mermin asked the participants to join him in recognizing Dr. Ward for his outstanding leadership and contributions to improve domestic and international viral hepatitis efforts during his tenure as the DVH Director. Dr. Paul Weidle will serve as the Acting DVH Director until Dr. Ward's permanent replacement is appointed.

NCHHSTP also will launch recruiting efforts to fill two DVH Branch Chief positions that are open at this time.

The NCHHSTP Office of Health Equity updated the CDC Correctional Health website with several helpful resources, including recommendations and guidance, scientific reports on correctional health, and a map of state Departments of Corrections and public health departments. The updated website now serves as a "one-stop" resource for correctional staff throughout the country.

NCHHSTP released new provisional TB surveillance data and conducted several other activities in recognition of World TB Day on March 24, 2018. *TB Chronicles* were featured on the CDC.gov website to describe the history of TB and highlight the public health success that has been made over time. NCHHSTP also recognized several "TB Elimination Champions" to celebrate people and organizations in the field that are on the frontline of national TB elimination efforts.

NCHHSTP awarded approximately $3.8 million to support year 1 of a CoAg, "Accelerating the Prevention and Control of HIV, Viral Hepatitis, STDs, and TB in the U.S.-Affiliated Pacific Islands" (USAPIs). The grant recipients include American Samoa, Northern Mariana Islands, Federated States of Micronesia, Guam, Marshall Islands, and Palau.

At the division level, DVH has been providing assistance to health departments in Kentucky, Michigan, California, and Utah since March 2017 to combat the spread of hepatitis A outbreaks. Homeless people, close contacts, PWID, and people who use non-injection drugs accounted for the vast majority of the outbreaks. To date, more than 2,000 cases and 49 deaths have been reported. DVH's assistance to the health departments includes providing epidemiology and laboratory support, testing more than 1,000 specimens, and supporting vaccine policy development and supply.

DVH published the Zibbell, *et al.* study in January 2018 that reported an association between increased hepatitis C virus (HCV) infections and increased admissions for opioid injections. The study analyzed CDC's hepatitis surveillance data and data collected by the Substance Abuse and Mental Health Services Administration (SAMHSA) on admissions to substance use disorder treatment facilities. The CDC and SAMHSA data showed that during the dramatic rise of HCV and opioid injections among White Americans from 2004-2014, HCV rates increased by 300 percent and admissions to treatment facilities for opioid injections increased by 134 percent.

The Division of HIV/AIDS Prevention (DHAP) updated its "HIV Treatment as Prevention" (TasP) webpage on the CDC.gov website with the latest data on HIV transmission and a new technical fact sheet. The TasP webpage summarizes data from over 3,000 couple-years of people who are on antiretroviral therapy (ART) and have had a viral load that is undetectable or under 400 copies/mL. None of these studies documented transmission of HIV to sexual partners, including men who have sex with men and heterosexual men and women.

The TasP webpage is expected to play an important role in disseminating up-to-date information to decrease HIV-related stigma and increase awareness of the benefits of taking ART, particularly living a longer life and preventing HIV transmission. DHAP currently is testing TasP messaging among providers and people who are and are not living with HIV.

DHAP awarded $400 million in January 2018 to state, local, and territorial health departments to conduct integrated HIV surveillance and prevention activities. The five-year CoAg, "Integrated HIV Surveillance and Prevention Programs for Health Departments," is intended to promote more efficient, coordinated, and data-driven prevention efforts. The grant recipients will be expected to focus on the following priority areas of the CoAg: knowledge of HIV status, viral suppression, pre-exposure prophylaxis, community-level prevention, cluster investigations, and outbreak response.

DHAP collaborated with DVH to release a new publication in March 2018, *Managing HIV and Hepatitis C Outbreaks Among People Who Inject Drugs: A Guide for State and Local Health Departments*. The guide is intended to assist health departments in responding to HIV and/or HCV outbreaks among PWID.

The Division of STD Prevention (DSTDP) is continuing to celebrate STD Awareness Month in April to increase STD prevention, diagnoses, and linkages to treatment. The theme of the 2018 event, "Treat Me Right," focuses on strengthening the patient/provider relationship. Patients are encouraged to ask questions, present for testing, access treatment, and take control of their sexual health. Providers are encouraged to build trust with their patients, take a thorough sexual history, and reassure their patients of the confidentiality of all information that is provided. The prevention resources that DSTDP developed for STD Awareness Month are available on the STD Awareness website.

DSTDP recently released an updated version of *Syphilis: A Provider's Guide to Treatment and Prevention*. The purpose of the pocket guide is to disseminate information to physicians and other healthcare providers on the diagnosis, treatment, and prevention of syphilis. New syphilis infections in heterosexual men and women as well as new cases of congenital syphilis are increasingly being reported to CDC.

The Division of Adolescent and School Health (DASH) published an article in the January 5, 2018 edition of the *Morbidity and Mortality Weekly Report* (*MMWR*) with data from the Youth Risk Behavior Surveillance System (YRBS). The article reported that the proportion of high school students who ever had sexual intercourse significantly declined overall and also decreased among students in the ninth and tenth grades. Decreases in the initiation of sexual intercourse were highest among African American students in all grades and among Hispanic students in three grades.

DASH announced a new Notice of Funding Opportunity (NOFO), "Promoting Adolescent Health Through School-Based HIV Prevention," that will award approximately $17 million per year over the five-year project period. The funding will be targeted to education agencies at state, local, and territorial levels as well as tribal governments. The grant recipients will be expected to conduct activities in several areas to improve adolescent health: school-based surveillance, HIV and STD prevention, technical assistance, and capacity building.

ACET GUIDANCE

Several ACET members advised Dr. Mermin to consider new opportunities to incorporate TB into the activities of other NCHHSTP divisions outside of DTBE.

TB Activities in DASH

- Dr. Flood questioned whether opportunities are available to include TB prevention in the DASH NOFO that will award funding to education agencies and tribal governments to

promote adolescent health through school-based HIV prevention. She emphasized that the inclusion of TB in the NOFO will play an important role in addressing the health of students who travel outside of the United States.

- Dr. Starke announced that the Baylor College of Medicine published its recent research on educating high school students in Houston to identify TB risk factors, performing TB screening in this population, and providing interferon gamma release assay (IGRA) testing. The study was extraordinarily successful in terms of providing health education in high schools that specifically focused on TB. Most notably, the voluntary TB testing protocol resulted in a participation rate of over 80 percent, including the hard-to-reach student population of high school sophomore boys. In support of Dr. Flood's suggestion, he advised DASH to review the Baylor study to obtain experiences and lessons learned on integrating TB into adolescent health prevention activities.

TB Activities in DHAP

- Ms. Cole questioned the rationale for the successful promotion, implementation, and adoption of TasP for HIV only. She pointed out that ACET is on record regarding the critical need to focus on "TB TasP" to treat active TB cases and prevent ongoing transmission of disease. She raised the possibility of DTBE obtaining guidance from their DHAP colleagues to advance TB TasP. She also noted that much more progress will be made on TB TasP if the Affordable Care Act covered this service to eliminate barriers to treatment.
- Dr. Reves explained that TB TasP should focus on the treatment of latent TB infection (LTBI) as the best method to prevent childhood TB. This approach will help to address household transmission of active TB disease from adults and older siblings to children. For example, the Mayo Center Clinic for Tuberculosis administered a survey in collaboration with partners. Based on a survey question to providers regarding the factors that influence patients to choose TB treatment, the prevention of infection in family members was one of the most common responses. He fully supported Ms. Cole's comments regarding the need to strengthen the focus on TB TasP. However, his position was that TB TasP efforts should be targeted to LTBI treatment rather than the treatment of active TB cases.

Dr. Mermin provided a detailed response to Dr. Sunstrum's question regarding the capacity of surveillance to rapidly identify an HIV outbreak. To obtain additional information on this topic, he advised the ACET members to review the commentary that CDC recently published in the *Journal of the American Medical Association* (*JAMA*) in April 2018.

In response to Dr. Flood's comments, Dr. Mermin clarified that the YRBS dataset is broad in its scope, magnitude, and function and will serve as the foundation for all initiatives conducted under the DASH NOFO. As a result, he did not foresee any barriers to the funded education agencies considering TB risks in the context of adolescent health. He confirmed that he will follow-up with Dr. Kathleen Ethier, the DASH Director, to discuss potential opportunities for the grant recipients to also include TB in their activities.

In response to Ms. Cole's comments, Drs. Mermin and LoBue agreed that TB TasP also should be promoted and implemented for widespread adoption. They advised ACET to invite DHAP staff to a future meeting to present an overview of their efforts in promoting and implementing HIV TasP to identify successful approaches that potentially can be replicated for TB TasP.

DTBE Director's Report

Philip LoBue, MD
Director, Division of Tuberculosis Elimination
Centers for Disease Control and Prevention

Dr. LoBue covered four key areas in the DTBE Director's report to ACET: (1) CDC's FY2018 budget, (2) 2017 provisional TB surveillance data; (3) "Primary Care and Public Health: Partners in Prevention" meeting; and (4) ICD-10 Coding Workgroup.

CDC'S FY2018 BUDGET

The Omnibus bill was passed by both Houses in March 2018 and was signed by the President. The DTBE appropriation was the same as the funding levels in previous years. DTBE will operate with this budget until the end of the current fiscal year (FY) on September 30, 2018.

2017 PROVISIONAL TB SURVEILLANCE DATA

The decrease in the TB case count from 9,256 cases in 2016 to 9,093 cases in 2017 reflected a reduction of 1.8 percent. The decrease in the TB rate from 2.86/100,000 in 2016 to 2.79/100,000 in 2017 reflected a reduction of 2.5 percent. The data show that decreases in TB case rates have slowed over time. For example, the overall percent change in TB rates was a decrease of 11.4 percent in 2008 versus a decrease of 2.5 percent in 2017.

By country of origin, the percent change in TB rates among non-U.S.-born people/populations (USBPs) was a higher decrease of 6.9 percent in 2008 and a much lower decrease of 0.9 percent in 2017. The percent change in TB rates among USBPs was a higher decrease of 15 percent in 2008 and a much lower decrease of 7 percent in 2017.

By state, 18 states and the District of Columbia reported increases in TB rates that ranged from 5 percent in Minnesota to 101.9 percent in Wyoming. Decreases in TB rates reported by 32 states ranged from 0.2 percent in Virginia to 51.1 percent in Idaho. The vast majority of states reported TB case rates in 2017 that were at or below the national average of 2.8/100,000. States that reported TB case rates above the national average in 2017 (e.g., California, New York, and Texas) have large populations and the highest number of TB cases.

By race/ethnicity in USBPs, the highest to the lowest TB rates per 100,000 population in 2017 were in American Indians/Alaska Natives (AI/ANs), Native Hawaiians/Pacific Islanders (NHPIs), non-Hispanic Blacks (NHBs), Hispanics, Asians, and non-Hispanic Whites (NHWs). However, the data showed that recent progress has been made in reducing the TB disparity among U.S.-born NHBs since 2008.

By race/ethnicity in non-USBPs, the highest to the lowest TB rates per 100,000 population in 2017 were in Asians, NHBs, NHPIs, Hispanics, and NHWs. AI/ANs were not represented in this dataset due to small and unstable population denominators. By years since arrival in the United States, non-USBPs with U.S. residence of 10 years or more have steadily accounted for the highest TB case counts from 2008 (35 percent) to 2017 (45 percent). Non-USBPs with U.S. residence of less than one year also have steadily accounted for a significant proportion of TB case counts from 2008-2017. These data show that LTBI is reactivated among non-USBPs who have lived in the United States for a substantial period of time.

Compared to USBPs, non-USBPs have steadily accounted for the vast majority of MDR-TB case counts in the United States from 2007-2016. These differences primarily are due to USBPs becoming infected with drug-resistant TB strains outside of the United States. By origin of birth, the percent of MDR-TB cases in the United States among people with TB has continued to be higher in non-USBPs (1.2-1.5 percent) than in USBPs (0.2-0.4 percent) from 2007-2016.

By congregate setting, homeless populations (4.3 percent), incarcerated populations (3 percent), and long-term care facilities (LTCFs) (1.6 percent) accounted for the highest percentages of TB cases in the United States from 2008-2017. However, these data showed decreases in the percentage of TB cases among homeless and incarcerated populations since 2008. DTBE's efforts with various programs to apply genotyping data to conduct prevention activities, identify and interrupt disease transmission, and respond to outbreaks have played an important role in reducing TB cases in congregate settings.

USBPs only accounted for 30 percent of all TB cases reported in 2017, but the contribution of this population was much higher in congregate settings. Most notably, USBPs accounted for 61 percent of TB cases in homeless populations, 45 percent of TB cases in LTCFs, and 39 percent of TB cases in incarcerated populations.

"PRIMARY CARE AND PUBLIC HEALTH: PARTNERS IN PREVENTION" MEETING

NCHHSTP planned to convene the meeting on January 23-24, 2018 to explore collaborative strategies with national primary care organizations to enhance screening and referral to treatment for NCHHSTP's four diseases of interest. The meeting was postponed due to the one-day lapse in appropriations that caused a shutdown of the federal government. The meeting has been rescheduled for May 7-8, 2018. Dr. LoBue will include an overview of key outcomes from the NCHHSTP meeting that pertain to DTBE in his update to ACET during the August 2018 meeting.

ICD-10 CODING WORKGROUP

CDC and the National Tuberculosis Controllers Association (NTCA) formed a joint ICD-10 Coding Workgroup. The workgroup submitted a proposal to the CDC National Center for Health Statistics (NCHS) Classification Team in January 2018 with a set of clinical modifications to make the ICD-10 codes more useful for TB practitioners. After its review of the workgroup's proposal, NCHS concluded that the clinical modifications were not aligned with the conventional process and procedures to change ICD-10 codes.

The NCHS Classification Team found the proposed clinical modifications to have unacceptable alterations to code designations that previously were established by the World Health Organization (WHO). NCHS also noted that some parts of the proposal by the ICD-10 Coding Workgroup included concepts outside the scope of health encounter classification diagnoses. NCHS informed the workgroup that its preference is to educate providers on correctly using the existing ICD-10 codes rather than making changes to match alternative uses of the codes by providers in the field.

The NCHS Classification Team currently is providing guidance to the ICD-10 Coding Workgroup to resolve these issues and assist in the development of an acceptable proposal. The workgroup's goal is to revise and resubmit the proposal for consideration during the NCHS Coordination and Maintenance meeting in September 2018. If NCHS accepts the workgroup's revised proposal, changes to the ICD-10 codes will begin to be implemented in the United States in October 2018.

ACET DISCUSSION: DTBE DIRECTOR'S REPORT

Dr. LoBue provided additional details on the following topics in response to ACET's questions.

- DTBE's plans to include data on TB cases in the USAPIs in the final TB surveillance report that will be published in the fall of 2018.
- The approximate number of states that intend to implement LTBI reporting, specific barriers to states in achieving this goal, and DTBE's communications plan for its LTBI Concept of Operations.
- The potential impact on TB screening recommendations based on the length of residence of non-USBPs in the United States.

ACET GUIDANCE

- Dr. Flood returned to the previous comments by Dr. Reves regarding the survey that the Mayo Center Clinic for Tuberculosis and its partners administered to providers. She advised DTBE to distribute the summary results of the survey to assist states in facilitating collaborations with their providers regarding TB/LTBI treatment.
- Dr. Houpt encouraged the CDC/NTCA Workgroup to simplify and streamline the ICD-10 codes in its ongoing efforts with the NCHS Classification Team. He explained that many of the existing codes are redundant and confusing from a clinical perspective.
- The ACET members emphasized the need to improve surveillance systems and strengthen the capacity of TB programs to better validate and more precisely capture TB-related deaths. Efforts should be made in this area at this time because TB-related deaths will continue to increase as people living with TB age.
    - Dr. Houpt announced that a paper was published in *JAMA* in April 2018 on TB-related mortality in the United States. Based on modeling data, the paper estimated that 850 deaths per year are attributable to TB. The estimated TB mortality rate of approximately 10 percent is consistent with CDC's provisional surveillance data of 9,093 TB cases reported in 2017. Regardless of whether the cause of death is listed as "from" or "with" active TB, the 10 percent mortality rate is too high.
    - Dr. Flood reported that 10 percent of TB cases in California have steadily died over the past 20 years (or more than 200 deaths per year from over 2,000 cases annually). She also informed ACET that a retrospective study, "Tuberculosis Mortality in the United States: Epidemiology and Prevention Opportunities," recently was published in the *Annals of the American Thoracic Society* on February 28, 2018. The objective of the study was to identify risk factors for TB-related deaths in adults. Of 1,304 deaths in adults with TB who died before treatment completion, 942 (or 72 percent) were TB-related. Of 847 TB-related deaths with death certificates available, 378 (or 45 percent) did not list TB as a cause of death.

Overview of the 2020 Report of Verified Case of Tuberculosis

Elvin Magee, MPH, MS
Surveillance Team, Surveillance, Epidemiology, and Outbreak Investigations Branch (SEOIB)
Division of Tuberculosis Elimination
Centers for Disease Control and Prevention

Advice requested from ACET by DTBE:

1. What are ACET's general comments regarding the overall presentation and recommendations on the Report of Verified Case of Tuberculosis (RVCT) that is being revised for 2020?
2. What are ACET's comments on the identified challenges and recommendations in the 2020 RVCT?

Mr. Magee presented an overview of the role of the 2020 RVCT in CDC's new directions and priorities for national TB surveillance. CDC launched its National TB Surveillance System in 1953 with aggregate data in a paper format and made several improvements over time: electronic submission of individual TB case reports in 1985; rollout of the first electronic Survs-TB System/ TB Information Management System, including the first RVCT, in 1993; and major revisions to the RVCT in 2009. The next set of major revisions to the RVCT is projected to be released in 2020.

DTBE's ongoing efforts to revise the RVCT for 2020 are based on several key factors. First, improved surveillance on TB drug resistance is a critical need according to the *2015 National Action Plan for Combating Multidrug-Resistant Tuberculosis*. The data needs for describing TB epidemiology in the United States are continuing to evolve. Problematic data elements that need to be revised or replaced should be identified. Concerns about the burden and feasibility of existing TB data collection efforts should be addressed.

DTBE established five-year goals as surveillance priorities in the release of the 2020 RVCT: (1) revise the RVCT to better capture TB epidemiology data in the United States; (2) promote and increase innovative uses of surveillance data to better understand the evolving TB epidemiology; and (3) implement a National LTBI Surveillance System.

DTBE formed an RVCT Workgroup to oversee and implement the revision process. The major activities that the workgroup has conducted over the past two years are highlighted as follows. A comprehensive review of the current RVCT was performed in 2016, particularly to address quality assurance issues. The current RVCT includes 49 data elements that cover 300 variables and presents information in six categories: demographics, laboratory and behavioral data, living conditions, visa status, drug susceptibility test (DST) results, and case completion report data.

An in-person meeting was held in August 2016 at CDC in Atlanta for the workgroup to obtain input on the current RVCT and solicit suggestions on the major areas in the form that warrant revision. The participants included a diverse group of external TB partners from high, medium, and low TB morbidity jurisdictions. To maintain the momentum of the in-person meeting, 30 facilitated conference calls were regularly convened until September 2017. A *Message Mapping Guide* was developed in December 2017. A list of new and revised RVCT variables was finalized in March 2018.

A suggestion form was created to facilitate the submission of input on the revised RVCT. The suggestion form requested the name and a brief background of the variable; the reason for the proposed change to the variable (e.g., deletion, revision, or addition); a discussion to support the proposed change, including statistics or other data, web links, and other relevant information; and a summary or final thoughts. The suggestion form resulted in the submission of 79 formal recommendations. In addition, the workgroup received informal feedback.

DTBE asked the RVCT Workgroup to consider several important issues to complete two major tasks in its charge. First, the current RVCT will be evaluated in the context of the anticipated data collection needs when the revised form is projected to be implemented in 2020. The workgroup's considerations for this task included the addition of drug resistance treatment data in accordance with the National MDR-TB Action Plan; the addition of other data elements; and a critical review of existing data elements to revise or eliminate.

Second, strong emphasis will be placed on avoiding an increase in the data collection burden. The workgroup's considerations for this task included the relative difficulty of locating information in patient records compared to the public health usefulness of these data as well as the importance of data elements for "routine" public health surveillance versus other approaches to obtain the information.

DTBE also charged the RVCT Workgroup with producing two key deliverables. First, a list of data elements will be developed, including all variables in the current RVCT and any proposed additions. Second, an evaluation will be performed for each data element based on its strengths and weaknesses. Based on the evaluation results, recommendations will be made to DTBE in one of the following categories: add a new data element; retain the existing data element; revise the definition or instructions of an existing data element; or delete the existing data element in its entirety. The workgroup was advised to strive for consensus rather than a "majority rule" because the RVCT needs to be acceptable to all participants that use the form to report verified TB cases to CDC.

The 2020 RVCT will focus on a revision of current data elements and the addition of new variables. The major differences between the current and 2020 RVCTs are outlined below.

New Additions to the RVCT

- Census tract data
- Pregnancy status
- Country of usual residence
- Diabetes status
- Industry
- "Homeless ever" as a risk factor
- Smoking status
- Travel to certain countries
- Previous LTBI episodes
- Date of Illness
- Contact investigation status
- Epidemiological link status
- Additional drug regimen questions
- Molecular DST
- Treatment administration
- Final disease outcome

Modifications to the RVCT

- Revised language to better harmonize with CDC's generic, standardized questions for reportable diseases
- Initial reason evaluated for TB
- Occupation (based on National Institute for Occupational Safety and Health coding)

- Expanded language to improve reporting of previous TB disease
- New TB medications
- Medication administration

Deletions from the RVCT
- Date submitted
- Corrections/U.S. Immigration and Customs Enforcement status
- Immigration status
- Within-state relocation
- Type of healthcare provider

The 2020 RVCT will include nine sections. The unchanged, revised, and new variables in the sections are outlined below. (*Note:* Variables with no superscript numbers are "unchanged." Variables with a superscript [1] are "revised." Variables with a superscript [2] are "new.")

Administrative
- Date Reported
- Date Counted[1] (by *MMWR* week/year)
- State Case Number
- City/County Case Number
- Case Already Counted by Another Reporting Area[1]

Demographics and Initial Evaluation
- Reporting Address[1]
    - City, Patient Residence Within City Limits, County, Zip Code
    - Census Tract (This variable will substantially improve cluster detection and recent transmission estimates.)
- Date of Birth
- Sex at Birth[1]
    - Unknown (This variable was added for circumstances in which the reporting area is unable to determine the gender that was assigned at birth.)
    - Pregnancy Status[2]
- Ethnicity (The "Other" category was added for consistency with Census data.) [1]
- Race (The "Other" category was added for consistency with Census data.)[1]
- Nativity[1]
    - If Not Born in United States:
        - Date of U.S. arrival
        - Eligible for U.S. Citizenship (regardless of country of birth)
- United States Residency (for case counting purposes)[2]
    - Country of Usual Residence
    - If NOT U.S. reporting area, remained in the United States for ≥90 days after Report Date
- Status at TB Diagnosis[1]
- Initial Reason Evaluated for TB[1]
    - Contact Investigation
    - Screening
    - TB Symptoms
    - Other

- Unknown

Diagnostic Testing (Non-DST)

- Complete the Table (unlimited number of rows may be entered) for Tuberculosis Skin Test and All Non-DST TB Laboratory Test Results[1]
  - Test Type: Includes all results of Smear, Pathology, Cytology, NAA [Nucleic Acid Amplification], Culture, TST [Tuberculin Skin Test], QFT [QuantiFERON], T-SPOT, IGRA-Unknown, HIV CD4 Count[2], Hemoglobin A1c[2], Fasting Blood Glucose[2], Other (specify), etc.

Date Collected/ Placed	Date Reported/ Read	Specimen Source Site	Test Type	Test Result (Qualitative)	Test Result (Quantitative)	Test Result (Units of Measure)

- Complete the Table (unlimited number of rows may be entered) for Chest Radiograph or Other Chest Imaging Study Results[1]
  - Study Type: Includes Plain Radiograph, CT [Computed Tomography] Scan, MRI[2] [Magnetic Resonance Imaging], PET[2] [Positron Emission Tomography], Other[2]
    - Result Options: Not Consistent with TB, Consistent with TB, Not Done, Unknown

Date of Study	Study Type	Result	Cavity?	Miliary?

Risk Factors (includes a combination of risk behaviors, living conditions, and clinical factors at time of diagnostic evaluation)[1]

- Diabetes Status
- HIV Status
- Primary Occupation and Industry
- Resident of Correction Facility
- Resident of Long-Term Care Facility
- Smoking Status[2]
- Residence or Travel in Countries Other than the United States, Canada, Australia, New Zealand, or Countries in Northern or Western Europe for >60 consecutive days[2]
- Homeless in The Past 12 Months
- Homeless Ever[2]
- Injecting Drug Use in the Past 12 Months
- Non-Injecting Drug Use in the Past 12 Months
- Heavy Alcohol Use in the Past 12 Months
- TNF-alpha Antagonist Therapy
- Post-Organ Transplantation
- End Stage Renal Disease
- Other Immunocompromised Condition (not HIV/AIDS)
- Other (Specify)

Clinical History and Findings

- Previous TB Disease or LTBI Diagnosis (unlimited number of rows may be entered)[1]

    - Diagnosis Type: TB Disease, LTBI
    - State Case Number: NTSS [National TB Surveillance System] or TBLISS [TB Latent Infection Surveillance System] state case number of previous episode, if available
    - Completed Treatment
- Date of Illness Onset/Symptom State Date[2]
    - Site of TB Disease
        - Select all that apply

Epidemiologic Investigation

- Case Identified During the Contact Investigation Around Another Case[2]
    - If Yes, Evaluated for TB During that Contact Investigation
- Contact Investigation Conducted Around This Case[2]
- Complete Table for All Known TB and LTBI Cases Epidemiologically Linked to this Case (an unlimited number of rows may be entered)[1]
    - State Case Number
    - Type of Link: Contact, Location, Other
    - Strength of Link: Definite, Probable, Possible
    - Directionality: Source, Secondary, Undetermined

Initial Treatment Information

- Date of Therapy
- Was the patient initially treated with the recommended four-drug therapy (RIPE)? If NO, why not?[2]
    - Drug contraindication/interaction (e.g., RIF [Rifampin] in HIV+, PZA [Pyrazinamide] in pregnant women)
    - Drug susceptibility testing results already known
    - Suspected drug resistance (e.g., contact of drug-resistant TB case, history of prior TB)
    - Drug shortage
    - Other (specify)

Case Outcome

- Sputum Culture Conversion Documented
    - Document FIRST consistently negative sputum culture
        - IF NO, document reason for not documenting Sputum Culture
- Moved During Therapy[1]
- Date Therapy Stopped
- Reason Therapy Stopped or Never Started[1]
    - Added dying (treatment stopped because of imminent death, regardless of cause of death)
- Reason TB Disease Therapy Extended >12 Months, if applicable[1]
- Treatment Administration[1]
    - DOT (Directly Observed Therapy, in Person)
    - EDOT (Electronic DOT, via video call or other electronic method)[2]
    - Self-Administered
- Final TB Disease Case Outcome[2]
    - Cured
    - Treatment Completed

- Treatment Failed
- Died (Date of Death)
- Lost to Follow-up
- Not Evaluated/Unknown

Genotyping and Drug Susceptibility Testing

- Isolate Submitted for Genotyping
- Was Phenotypic/Growth-Based Drug Susceptibility Testing Done?[1]
  - If YES, Complete Table (unlimited number of rows may be entered)

Drug Name	Date Collected	Date Reported	Specimen Type	Result

- Was Genotypic/Molecular Drug Susceptibility Testing Done?[2]
  - If YES, Complete Table (unlimited number of rows may be entered)

Gene Name	Date Collected	Date Reported	Specimen Type	Results	Nucleic Acid Change	Amino Acid Change	Indel	Test Type

Lori Armstrong, PhD, RN, MS
Senior Epidemiologist, SEOIB Surveillance Team
Division of Tuberculosis Elimination
Centers for Disease Control and Prevention

Dr. Armstrong presented additional details on the new variables in the 2020 RVCT that will collect molecular DST results. Drug resistance can be diagnosed using newer and more rapid molecular methods that do not need to be cultured. TB programs are treating patients based on the results of mutations associated with drug resistance. The RVCT has collected DST results based on conventional growth-based methods since 1993, but the current form does not capture DST results based on the newer tests.

The new variables on molecular DST results in the 2020 RVCT will be aligned with the primary goal of the DTBE Surveillance Team to collect and report drug-resistant TB cases in the United States. Molecular DST data will be collected based on the following variables:

- Date specimen collected
- Source of specimen (sputum or tissue)
- Gene name
- Results (mutation or no mutation detected)
  - If mutation detected:
    - Nucleic Acid change
    - Amino Acid change
    - Insertions and deletions
- Test type (non-sequencing, sequencing, or other)

Dr. Armstrong presented a table of the genes that are associated with anti-TB drug resistance. The table reflects the drop-down menu in the 2020 RVCT that will list the names/abbreviations

of all first-line TB drugs, second-line injectable drugs, and the mutations associated with resistance to each drug. The 2020 RVCT will include three third-line drugs as well: Bedaquilin, Delamanid, and Linezolid. TB programs also will have the ability to enter the names of other drugs and the results of other genes tested that are not included in the drop-down menu.

The 2020 RVCT will include detailed instructions for TB programs to complete and submit the Molecular DST Report. Guidance will be provided on reporting the following variables: source of clinical sample or isolate, date specimen collected, and gene name and drug associated with the gene. Patient scenarios will be provided as examples to ensure that TB programs appropriately record molecular DST results in the RVCT according to the definitions of the variables/items. Laboratory reports also will be included in the 2020 RVCT as examples.

Neha Shah, MD, MPH
Field Medical Officer, California Department of Public Health
DTBE Field Services Branch
Centers for Disease Control and Prevention

Dr. Shah presented additional details on the new MDR-TB Supplemental Surveillance Form that will be included in the 2020 RVCT. The new form was developed in direct response to the *2015 National Action Plan for Combating Multidrug-Resistant Tuberculosis* that was released by the White House. The Action Plan described three major goals: (1) strengthen domestic capacity to combat MDR-TB; (2) improve international capacity and collaboration to combat MDR-TB; and (3) accelerate basic and applied research and development to combat MDR-TB. The new form primarily addresses Goal 1, Objective 1.1 of the Action Plan that calls for TB surveillance to be upgraded to ensure complete and accurate detection of drug-resistant TB.

The standardized MDR-TB surveillance form was revised to include the proposed MDR-TB variables. To ensure consistency with the RVCT format, the new form was piloted in two parts: follow-up 1 after one year of treatment and follow-up 2 at the end of MDR-TB treatment. A retrospective chart abstraction of MDR-TB patients in the United States from 2012-2016 was performed. Due to time constraints, CDC field medical officers collaborated with local TB control programs to obtain a convenience sample.

CDC's guidelines for evaluating public health surveillance systems were used to assess seven of the nine attributes in the existing MDR-TB surveillance system. CDC's field medical officers conducted a qualitative evaluation through telephone interviews and email feedback. A quantitative evaluation was performed through an electronic survey that allowed the participants to rank the attributes of the MDR-TB surveillance system from 1 (lowest) to 5 (highest). Key stakeholders also provided informal, unstructured feedback.

The following modifications were made to the existing form after the new MDR-TB Supplemental Surveillance Form was piloted and evaluated. The form was condensed to one page to collect MDR-TB results at the end of treatment only. Multiple variables were deleted, including "expert consultation" and "hospitalization." To better understand treatment groups, the "medications collected" variable was expanded from a "yes/no" question to a data element that is designed to gather results on the specific medications given to patients in six-month time intervals. The "side effects" variable was modified as well.

The new MDR-TB Supplemental Surveillance Form includes detailed instructions, definitions, and examples. TB programs will be advised to complete the form for "patients with laboratory

evidence of MDR-TB (resistance to at least Isoniazid and Rifampin) OR patients with a clinical diagnosis of TB (according to RVCT definitions) who are a known contact to an MDR-TB case." The unique identifiers for each patient will include "State Case Number," "Male/Female," and "Date of Birth." However, gender will be removed when data from the form are incorporated into the larger RVCT. The seven variables in the form are outlined below.

1. History of treatment with second-line TB drugs for the treatment of TB disease (not LTBI)
2. Date MDR-TB therapy started
3. Drugs used for MDR-TB treatment (select one option for each drug): <1 month, 1-6 months, 6-12 months, >12 months, Not taken
4. Date injectable medication was stopped
5. Was surgery performed to treat MDR-TB?
6. Did the patient experience any of the following side effects during treatment that resulted in a PERMANENT DISCONTINUATION OF MEDICATION?
7. At the END OF TREATMENT, were any of the following side effects related to MDR-TB treatment present?

The combination of the variables in the new MDR-TB Supplemental Surveillance Form and the 2020 RVCT data can provide significant insight on MDR-TB treatment in the United States. However, the RVCT Workgroup acknowledges the need to periodically reevaluate the new MDR-TB variables, particularly as new clinical trial data and medications are released in the future.

Mr. Magee concluded the overview by announcing that the RVCT Workgroup will take several actions over the next year to prepare for the implementation of the revised RVCT in January 2020.

- Initiate pilot testing in May 2018 for a period of four to six weeks
- Initiate the CDC and Office of Management and Budget (OMB) clearance process in 2018
- Develop orientation materials in the fall and summer of 2018
- Continue to develop software through 2019
- Rollout comprehensive training through webinars and other formats in 2019

Mr. Magee, Dr. Armstrong, and Dr. Shah thanked their RVCT Workgroup colleagues, state and local health department partners, and other subject-matter experts for their outstanding efforts in revising the RVCT for 2020. Mr. Magee noted that the most recent draft of the 2020 RVCT was updated on February 22, 2018. This version of the document was included in the ACET meeting packets for the members to review and provide input.

ACET GUIDANCE

- Dr. Armitige pointed out the language in the Risk Factor Section, Variable 21: "If Resident of Correctional Facility at Diagnostic Evaluation, Type of Facility." She cited CDC's recent data that demonstrated the high incidence of active TB disease in correctional facilities: 29/100,000 in jails, 25/100,000 federal prisons, and 8/100,000 in state prisons. A strong focus on collecting TB data from correctional facilities is particularly important because 39 percent of USBPs who are incarcerated will be released at some point to U.S. communities. Other recent studies also have reported incarceration as a significant driver of extensive TB transmission. She emphasized that

more in-depth variables, such as "Incarceration in the previous two years" and "Incarceration ever," will allow CDC to collect more detailed individual- and population-level data on the impact of TB transmission in correctional facilities on communities.

- Ms. Bur expressed her strong support of Dr. Armitige's comments and suggestions. She added that the rate of active TB disease in correctional facilities ranges from 2 to 7 times higher than in the general U.S. population. A published study reported the TB rates in correctional settings among USBPs in the state of Georgia in 2011: incarceration in the 12 months prior to diagnosis (16 percent); incarceration in the 24 months prior to diagnosis (23 percent); and incarceration ever prior to diagnosis (49 percent). This paper issued excellent state-based data, but more in-depth variables in the 2020 RVCT on TB as a risk factor in correctional facilities will provide a unique opportunity for CDC to build a robust national dataset on this issue for the first time. Moreover, correctional facilities serve as tremendous sites to ensure the completion of LTBI treatment.
- Dr. Warshauer pointed out the language in the Genotyping and DST Section, Variable 36: "Was Genotypic/Molecular DST Done?" He raised the possibility of revising this variable to allow laboratories to interpret gene mutations. Most notably, several mutations are not associated with TB drug resistance. Moreover, molecular DST results now serve as a basis for clinicians and TB programs to make decisions on administering TB therapy.
- Dr. Ahuja encouraged the RVCT Workgroup to perform an analysis with the existing variables to determine the rates at which TB programs have fully completed and submitted data to CDC over time. This effort might help to further streamline and improve the 2020 RVCT by deleting specific variables with high non-completion rates among TB programs. She also advised the workgroup to include a new "TB cure" variable in the 2020 RVCT. This outcome is difficult to document because TB programs are challenged by obtaining additional specimens to perform a confirmatory negative culture at the end of treatment. To support the further deletion of ineffective variables and the addition of a new "TB cure" variable, she advised the workgroup to solicit input from TB programs on the final draft of the 2020 RVCT before the national rollout in January 2020.

Overview of the 2018 Tuberculosis Technical Instructions (TIs) for Panel Physicians and Civil Surgeons

Joanna Regan, MD, MPH, FAAP
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National Center for Emerging and Zoonotic Infectious Diseases
Division of Global Migration and Quarantine, Immigrant, Refugee, and Migrant Health Branch
Centers for Disease Control and Prevention

Dr. Regan presented an overview of the 2018 TB TIs for immigrant visa and status adjustment applicants that the CDC Division of Global Migration and Quarantine (DGMQ) currently is updating with the TB TI Workgroup. However, she emphasized that the 2018 TB TIs are still in draft form and are subject to change during the final clearance process.

Several uniform definitions apply to TB and all other diseases or disorders that are covered in the TIs. "Immigrants" are people who officially applied for and obtained U.S. lawful permanent resident status (LPR) overseas. Their full examinations are performed overseas by panel physicians. Immigrants can apply to become U.S. citizens after maintaining their LPR status for

five years. "Refugees" technically are not LPRs. Unlike immigrants, refugees are under a "protected status" upon their arrival to the United States. Refugees are required to apply for an adjustment of their status at one year to become LPRs. Their examinations, including TB screening, primarily are performed overseas by panel physicians. However, refugees can opt to have the vaccination portion of their examination performed in the United States after arrival.

"Status adjusters" are people who are already in the United States on other types of terms, such as a one-year worker's visa or a student visa, and apply for LPR status (i.e., a green card). Their medical screening is performed by a civil surgeon in the United States. Status adjusters can apply to become U.S. citizens after maintaining their LPR status for five years. "Naturalization" is the process of becoming a U.S. citizen rather an adjustment of status. "Medical examinations" are not a complete medical evaluation and can only screen for conditions that are relevant to U.S. immigration law. The TIs are "requirements" for panel physicians and civil surgeons rather than "recommendations" and must be completed for the applicant to immigrate to or adjust their status in the United States.

The TIs have defined TB as a disease of public health concern for several years, but the TB TIs were last updated in 2009. The TIs clearly describe the requirements for panel physicians and civil surgeons to screen for TB. The MDR-TB outbreak in approximately 16,000 Hmong refugees who resettled from Thailand to the United States in 2005 was a major event that has guided the evolution of the TB TIs over time. The U.S. screening program, including DGMQ and panel physicians, was criticized after 37 TB cases were detected in the Hmong refugees, including four MDR-TB cases. The TB/MDR-TB cases were extremely expensive to control in the United States.

DGMQ placed strong emphasis on improving the overseas medical screening process to prevent additional importations of TB/MDR-TB cases into the United States. In the 2007 TB TIs, DGMQ applied modern diagnostics by requiring three sputum smears for acid-fast bacillus testing and three solid and liquid cultures to be performed during the TB screening process. A rigorous standard of care for treatment was established. Most notably, DOT was required for all overseas applicants who tested positive for TB prior to their U.S. arrival.

TB diagnoses increased overseas and decreased in the United States. During the implementation of the 2007 TB TIs, the number of smear-negative/culture-positive TB cases that were diagnosed overseas among U.S.-bound immigrants and refugees increased from four cases in 2007 to 629 cases in 2012. The number of reported TB cases among non-USBPs within one year after U.S. arrival decreased from 1,504 cases in 2002 to 940 cases in 2012. Many of the 940 cases in non-USBPs likely represented people who were in the United States on short-term work, tourist, or student visas. The remaining cases in 2012 were in the country on other terms and were not subject to panel physician screening that is required for official immigrants. A future expansion of screening for people who travel to the United States on temporary work or student visas might further decrease TB case counts in the country.

DGMQ acknowledged that despite these successes, the current TB TIs are still problematic in some areas. For example, the last revision of the TB TIs in 2009 reflects outdated data. The classification of overseas applicants living with HIV with negative cultures was changed via revisions to the U.S. Department of State form. The digital radiography requirement was announced via a website posting rather than included in the TB TIs. The TB indicators were changed without updating the TB TIs. The one-year waiting period after the end of treatment for people who refuse DOT was misunderstood and inconsistently applied.

DGMQ established several goals to guide the revision of the 2018 TB TIs. The requirements for the TB component of the immigrant visa and status adjustment medical examinations will be thoroughly defined. All points of confusion will be clarified. Newer technologies that are available to panel physicians and civil surgeons will be addressed. The format will be modernized to be consistent with CDC requirements, particularly the format for web content. However, the 2018 TB TIs will not serve as a clinical manual for diagnosing TB, bench standard operating procedures for performing laboratory tests, guidelines for clinical treatment, or a protocol for administering DOT.

DGMQ is leading the effort to revise the 2018 TB TIs, but extensive input is being provided by the TB TI Workgroup members who represent NTCA, ACET, Stop TB USA, and DTBE. The International Panel Physicians Association also is providing feedback. The workgroup has been drafting, revising, and reviewing the 2018 TB TIs since April 2017. After the CDC clearance process is complete, the 2018 TB TIs will be formatted for and posted on the CDC.gov website. Beginning on October 1, 2018, all overseas panel physicians and U.S. civil surgeons will screen applicants according to the 2018 TB TIs.

Dr. Regan highlighted several revisions that will be featured in the 2018 TB TIs. Overseas panel physicians currently have the option to use TST or IGRA during TB screening. For high-burden countries as defined by WHO's estimated TB rate of $\geq$20/100,000, the TB TIs require TST or IGRA testing for children 2-14 years of age. Panel physicians have the option of using either test. The current IGRA requirements for civil surgeons were updated in October 2009. To fulfill the requirement of testing for cell-mediated immunity to TB in the United States, civil surgeons are allowed to use IGRA or TST in applicants 2 years of age or older.

DGMQ recognizes that the current TB TIs do not reflect the actual use of IGRA in the field in the United States. A 2017 published guideline reported that IGRA is recommended instead of TST in patients 5 years and older who meet the following criteria: (1) patients who are likely to be infected with *M. tuberculosis* (MTB); (2) patients who have a low or intermediate risk of disease progression; (3) patients in whom LTBI testing is warranted; and (4) patients who either have a history of *Bacillus Calmette-Guérin* (BCG) vaccination or are unlikely to return to obtain a reading of their TST results.

CDC's preliminary unpublished data documented the use of and actions with TST and IGRA among health departments. The sample included 45,951 children 2-14 years of age who were diagnosed with LTBI in high-burden countries overseas. A majority of this cohort (53 percent) with Class B2 LTBI were retested after U.S. arrival. When TST results were positive overseas and IGRA was used for retesting in the United States, 69 percent of people were IGRA-negative. Health departments initiated LTBI treatment at the following percentages: (1) 63 percent of the time with a TST-positive result overseas and a TST-positive retest in the United States; (2) 76 percent of the time with a TST-positive result overseas and a repeat IGRA-positive result; and (3) 81 percent of the time with repeat TST- and IGRA-positive results. Providers confirmed that retesting will decrease with a shift to IGRA.

Based on these data and input from the TB TI Workgroup, DGMQ proposed a new IGRA requirement for panel physicians and civil surgeons. In all places in the TB TIs that previously provided an option for TST or IGRA testing, the 2018 TB TIs will require IGRA to be performed if the test is available in the country of examination. Moreover, testing will be expanded to adult populations overseas in high-burden countries. Civil surgeons already test adults for LTBI in the United States.

The allowable IGRA tests include those that are approved by the U.S. Food and Drug Administration (FDA): QIAGEN QuantiFERON® (or any FDA-approved iteration) and Oxford Immunotec TB-SPOT®.TB. For status adjusters in the United States, civil surgeons will be required to use IGRA instead of TST for all people in this population who are 5 years of age and older. The requirement to use IGRA in children 2-4 years of age is still under discussion.

The 2018 TB TIs will include the following definition for "availability in a country." If an FDA-approved IGRA is licensed for use in a country, the test will be deemed as available and must be used according to the TB TIs. Immigrants and refugees in countries with the WHO-estimated TB rate of ≥20/100,000 will receive IGRA testing overseas. The use of IGRA in children 2-4 years of age is still under discussion, but IGRA must be used instead of TST for all overseas applicants who are 5 years of age and older. In addition to the chest x-ray, IGRA testing in high-burden countries will be expanded to include adults.

The current "recommendation" for U.S. civil surgeons to report LTBI cases to health departments will be changed to a "requirement" in the 2018 TB TIs. A box will be included in Form I-693, *Report of Medical Examination and Vaccination Record*, for civil surgeons to document whether the applicant has LTBI and report the case to the health department. U.S. Citizenship and Immigration Services will initiate an inquiry if civil surgeons do not report the identified LTBI cases to health departments.

DGMQ has been providing advance notice to overseas panel physicians and U.S. civil surgeons regarding the resource implications of the 2018 TB TIs as well as financial, logistical, and implementation issues. For example, IGRA costs vary across countries, but typically are more expensive than TST costs. Applicants will be responsible for all costs associated with the overseas examination, including travel expenses to the panel site. The Consular Section of the country establishes the fee for the overseas examination. However, applicants might be able to generate cost-savings if same-day test results are available.

Status adjusters in the United States can use health insurance to cover their medical screening costs or pay out-of-pocket, but U.S. health departments should not provide IGRA testing for status adjustment purposes or bear the burden of these costs. A major goal of the IGRA testing requirement for immigrants and status adjusters in the 2018 TB TIs will be to reduce retesting and the associated costs to health departments when using TST.

The TB TI Workgroup currently is in the final stage of resolving two outstanding issues: IGRA testing in immigrant, refugee, and status adjuster children 2-4 years of age and the civil surgeon requirement to report LTBI cases to U.S. health departments. Additional areas might be revised during the final CDC clearance process.

ACET GUIDANCE

- Drs. Starke and Alvarez were in favor of including a requirement in the 2018 TB TIs for IGRA testing in immigrant, refugee, and status adjuster children 2-4 years of age. They asked DGMQ to consider ACET's support of this issue during its ongoing discussions.
- Dr. Flood commended DGMQ on its sound approach of providing advance notice to overseas panel physicians and U.S. civil surgeons regarding the resource, financial, logistical, and implementation issues associated with the 2018 TB TIs. She advised DTBE to apply the same strategy for TB control programs in the United States. For example, TB programs should be given a final draft of the 2018 TB TIs to facilitate their preparedness and readiness before the implementation date on October 1, 2018. Ms.

Cole also encouraged DTBE to provide local jurisdictions with guidance on the management and follow-up of individual LTBI cases that are reported to health departments by civil surgeons via Form I-693.

- Dr. Nilsen thanked DGMQ for its leadership in revising the 2018 TB TIs. The implementation of the updated TB TIs will play an important role in guiding evaluations by TB control programs in the United States. Dr. Flood added that the 2018 TB TIs also will help to advance national TB elimination efforts.
- Ms. Cole emphasized the need for DGMQ to disseminate clear messaging, particularly to clarify that the TB TIs are intended for overseas panel physicians and U.S. civil surgeons only. Some non-civil surgeons are concerned that all providers will be required to perform IGRA testing instead of TST.

Dr. Regan provided follow-up remarks in two areas based on ACET's suggestions and questions. First, DGMQ will issue a "Dear Colleague" letter to all TB control programs immediately after CDC clears the 2018 TB TIs for dissemination. DGMQ is making strong efforts at this time to finalize all outstanding issues, complete the clearance process, and post the 2018 TB TIs on the CDC.gov website well in advance of the implementation date on October 1, 2018.

Second, a shift to the "e-medical" platform is underway. The current paper-based process will be replaced to support the electronic transfer of overseas medical records. Moreover, CD-based x-rays from overseas will be replaced with digital x-rays.

Updated Recommendations for TB Screening and Testing of Healthcare Personnel-United States 2018

Lynn Sosa, MD
Deputy State Epidemiologist, Tuberculosis Control Program
Connecticut Department of Public Health

Advice requested from ACET by DTBE:

1. What is ACET's feedback on the draft updated recommendations for TB screening and testing of healthcare personnel (HCP), particularly in the following areas: methodology, practicality, clarity, and usefulness?

Dr. Sosa co-chairs the HCP Screening Guidelines Workgroup that NTCA established to update the recommendations for TB screening and testing of HCP in the United States. She presented an overview of the workgroup's progress since 2015 in updating the guidelines.

CDC published the *Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Healthcare Settings* in 2005. The shortage of purified protein derivative and concerns about the use of IGRA for serial testing of low-risk people raised questions about the effectiveness of serial TB testing. The National Society of TB Clinicians and the National Tuberculosis Nurses Coalition held a joint session during the 2015 NTCA conference to focus on these issues. Based on the outcomes of these discussions, a workgroup was convened in the summer of 2015. The workgroup launched its systematic review process in January 2017 to specifically focus on TB screening and testing of HCP.

The workgroup used the *Community Guide* systematic review methodology to evaluate and summarize the available evidence. For each study that was included in the systematic review, two reviewers independently screened and abstracted data. Disagreements were resolved by consensus between the two reviewers. Data were analyzed using "metafor" and "meta" packages in R.

The workgroup conducted a search to identify studies that screened and/or tested HCP for LTBI. Electronic databases also were searched, including MEDLINE, EMBASE, and Scopus. The original search was conducted from January 2006-February 2017 and the updated search was conducted from February 2017-November 2017 with the MEDLINE database only. The systematic review was limited to English-language studies only.

The workgroup established rigorous inclusion and exclusion criteria for the systematic review. The study designs included randomized controlled trials, observational studies, cross-sectional surveys, quasi-experimental studies, and other designs with concurrent comparison groups. The target population included paid or volunteer HCP. The outcomes of interest included TB prevalence, conversion, and reversion rates; TB transmission rates; and TB disease rates. The settings included high-income countries with a low incidence of TB.

The following study designs were excluded from the systematic review: case reports, descriptive articles on nosocomial outbreaks, editorials, and commentaries. Of 1,129 studies identified during the original search and 18 studies identified during the updated search, 36 studies in total were included in the systematic review for analysis.

The findings of the systematic review are summarized as follows. Of HCP in the United States at baseline, approximately 3 percent tested positive for MTB with TST; 5 percent tested positive with IGRA; and less than 1 percent converted from a negative to a positive baseline test when TST was used during serial testing. The conversion rate was 4 percent when IGRA was used for testing.

Of HCP in the United States, approximately 62 percent who tested positive at baseline reverted to a negative test when TST was used during serial testing. The reversion rate was 48 percent when IGRA was used for testing. No HCP developed active TB in any of the studies that were included in the systematic review. However, the evidence was insufficient to assess the incidence and transmission of TB disease among HCP in the United States based on occupational and non-occupational risks.

The workgroup acknowledged several limitations in the systematic review. The included studies were highly heterogeneous in terms of their populations, study designs, and types of tests used. The designs of most of the included studies were of "moderate" or "least" suitability. The designs of only seven studies were of "good" suitability. Only a few studies used T-SPOT.TB for testing. Most of the included studies focused on TST and QFT. Because only a few of the included studies reported demographic data, the extent to which the evidence was representative of the HCP population in the United States was difficult to ascertain. Most of the evidence was limited to the hospital setting. Due to these limitations, the proposed recommendations primarily are based on the workgroup's expert opinion.

The draft 2018 guidelines for TB screening and testing of HCP in the United States are highlighted as follows. The terminology of "healthcare worker" (HCW) was replaced with "healthcare personnel" to be consistent with the currently preferred language of HHS and CDC.

However, the definition of "HCW" in the 2005 guidelines was not changed. "TB screening" is defined as the broad process that includes a risk assessment, symptom evaluation, an LTBI test (either TST or IGRA), and additional work-up for TB disease as needed. "TB testing" refers to either TST or IGRA, but no preference is given to either test.

Dr. Sosa presented a table to compare the recommendations in the 2005 and 2018 guidelines for TB screening and testing of HCP in the United States.

Category	2005 Recommendation	2018 Recommendation
Baseline Screening and Testing	On-hire testing of all HCP with IGRA or TST.	On-hire testing of all HCP with IGRA or TST.[1] Include a TB risk assessment.[2]
Postexposure Screening and Testing	In HCP with a baseline negative test, IGRA or TST at the time exposure is identified and 8-10 weeks after exposure. Symptom assessment for HCP with a baseline positive test.	In HCP with a baseline negative TB test, IGRA or TST at the time exposure is identified and 8-10 weeks after exposure. Symptom assessment for HCP with a baseline positive test.[1]
Serial Screening and Testing: Occupational Risk	Based on facility risk assessment and the healthcare setting (inpatient versus outpatient).	Not recommended, but can consider for select HCP groups.[2]
Serial Screening and Testing: Non-Occupational Risk	Not addressed	Consider periodic (e.g., annual) risk assessment of all HCP.[2] Testing based on new risk identified.[2]
Follow-Up of Positive Test Results	Consider referral for LTBI treatment of HCP diagnosed with LTBI at increased risk for TB progression.	Strongly recommend treatment for all HCP diagnosed with LTBI unless contraindications exist.[2]

[1]Unchanged recommendations from the 2005 guidelines.
[2]New recommendations in the 2018 guidelines

Dr. Sosa presented additional details on the proposed recommendations in the draft 2018 guidelines for TB screening and testing of HCP in the United States. Baseline (pre-employment) testing with TST or IGRA (not both tests), a TB risk assessment for the individual HCP, and an evaluation of symptoms are recommended upon hire. "Low-risk" HCP, as defined by the individual risk assessment, who test positive should be given a second test to confirm a positive result. This recommendation is consistent with CDC's *TB Diagnostic Guidelines*.

A shift in the focus from facility-level risk to individual-level risk of HCP is recommended for serial or annual testing. Occupational and non-occupational risks, such as travel, are recommended for inclusion in the HCP risk assessment. An emphasis on the treatment of HCP with LTBI is recommended. A focus on a known exposure that occurs in the healthcare setting without adequate personal protection is recommended for post-exposure screening and testing. For HCP with no history of a positive TB test, an assessment of symptoms and a TB test are recommended at the time the exposure is identified. A follow-up test is recommended 8-10 weeks after the last exposure. For HCP with a history of a positive TB test and with or without a history of treatment, an assessment of symptoms without a TB test is recommended.

Routine testing of HCP is not recommended at any interval in the absence of a known exposure or ongoing transmission in an individual facility. Based on historical risk, healthcare facilities are welcome to conduct routine testing of specific HCP groups (e.g., pulmonologists and respiratory therapists) or staff in specific settings (e.g., emergency departments). Decisions regarding TB screening and testing based on occupational risk should be specific to the individual healthcare facilities. However, state and local health departments can be consulted to assist in the decision-making.

The importance of recognizing non-occupational TB exposures and risk factors for TB progression in HCP is emphasized. Consideration of a periodic (e.g., annual) risk assessment of HCP for non-occupational TB exposure (e.g., travel) or new risks for TB progression is recommended for healthcare facilities. The individual risk assessment is recommended as the basis for healthcare facilities to make decisions on pursuing additional testing of HCP.

For HCP with a positive TB test result, chest imaging, an assessment of symptoms, and further evaluation for TB disease (if warranted), are recommended for the follow-up of positive test results. All HCP with LTBI should be offered and encouraged to complete treatment unless a contraindication exists.

Dr. Sosa concluded her overview by informing ACET that the workgroup plans to publish the 2018 guidelines for TB screening and testing of HCP in the *MMWR* in the summer of 2018. The workgroup also is drafting a companion document to the guidelines to provide healthcare facilities with more in-depth guidance on implementing the recommendations. The workgroup expects to release the companion document shortly after the 2018 guidelines are published in the *MMWR*.

ACET GUIDANCE

- ACET commended the workgroup on producing an extraordinary set of updated guidelines for TB screening and testing of HCP.
    - Several ACET members pointed out that the recommendation to treat HCP with LTBI will generate cost-savings and play a significant role in the elimination of active TB disease and transmission in healthcare facilities.
    - Other ACET members clarified that the section on post-exposure screening and testing does not adequately address HCP who are hired years before a TB exposure, such as 10 years. The companion document should provide clarification on baseline testing and screening to focus on these types of issues in the healthcare setting.
- Dr. Elson advised the workgroup to provide clear guidance on HCP with a positive TB test result and a negative chest x-ray result as well as recommendations for or against an annual chest x-ray. She noted that this guidance could help to minimize confusion on serial chest x-rays following a positive TST result among non-TB clinicians with limited expertise in this area.
- Ms. Bur recognized that the 2018 TB screening and testing guidelines will be targeted to HCP in healthcare facilities. However, she emphasized the critical need to also include HCP in correctional settings in the dissemination efforts of the guidelines. She conveyed that the Federal Bureau of Prisons (BOP) recently performed an analysis of the annual TB results of its employees. The analysis showed a TB conversion rate of 0.2 percent.
- Ms. Cole encouraged the workgroup to include messaging in the companion document to clearly distinguish between the “individual HCP” and the “healthcare facility” risk assessment.

Ms. Suzanne Marks, of DTBE, advised the workgroup to ensure that the 2018 guidelines on TB screening and testing of HCP are consistent with the existing American Thoracic Society guidelines, particularly the recommendations on TB testing of high-risk HCP. She also encouraged the workgroup to review a recently published paper on the cost-effectiveness of using TST alone, IGRA alone, or a combination of both tests in non-USBPs. The study reported the cost-effectiveness of any testing combination that used IGRA. The paper was published in October 2017 with Abriana Tasillo as the first author.

Dr. Sosa confirmed that the workgroup will consider the extremely helpful suggestions and comments by ACET to DTBE in its ongoing efforts to further revise and finalize the 2018 guidelines. In response to Ms. Cole's suggestion, for example, she reported that a model of an individual HCP risk assessment will be included in the guidelines.

Update by the Congregate Settings Workgroup

Lisa Armitige, MD, PhD
Medical Consultant, Heartland National Tuberculosis Center
University of Texas Health Center at Tyler
ACET Member & Workgroup Chair

Dr. Armitige presented an update on the recent activities of the Congregate Settings Workgroup. During the NTCA All-Member Call on March 21, 2018, DTBE led a discussion on the "TB Funding Formula Frequently Asked Questions." DTBE reported that additional funding will be available for TB programs to address people with social risk factors, such as homelessness and substance abuse. DTBE will award these additional resources to assist TB programs in overcoming barriers to treatment adherence, follow-up, and contact investigations in these populations.

The workgroup expressed its concerns regarding the omission of correctional settings as a social risk factor in the TB funding formula for the 2020-2024 CoAg. However, the workgroup was pleased that DTBE and NTCA extensively discussed and considered this issue during the decision-making process. The workgroup reached out to the six states in the country that will be most significantly impacted due to their high incarceration rates of newly diagnosed TB cases. To date, four of the six states have contacted the workgroup to further discuss this issue.

The workgroup reviewed the recent publication on the use of three months of isoniazid/rifapentine (3HP) in BOP populations and the increase in completion rates of TB therapy with this regimen. The workgroup will closely collaborate with DTBE to widely disseminate messaging on the effectiveness of 3HP in correctional settings.

Dr. Armitige reported that during the workgroup's next teleconference, she will provide an update on the key outcomes from the April 2018 ACET meeting related to congregate settings. First, the DTBE Director presented 2017 provisional TB surveillance data that showed decreases in the percentages of reported TB cases in congregate settings from 2016-2017: from 4.9 percent to 4.3 percent in homeless populations and from approximately 4 percent to 3 percent in incarcerated populations.

Second, DTBE staff presented a comprehensive overview of its ongoing efforts to revise the RVCT. Dr. Armitige was pleased that the 2020 RVCT will be more inclusive of congregate settings to assist TB programs in improving the management of TB cases in these populations. During ACET's discussion, however, she emphasized the need for DTBE to expand the correctional facility data element in the 2020 RVCT to include more detailed variables. She planned to restate her comments as a formal motion during the Business Section and call for ACET's vote.

Update by the Essential Components Workgroup

Barbara Cole, RN, MSN, PHN, ACET Chair
TB Controller
Riverside County (California) Department of Public Health

Ms. Cole reported that the workgroup is updating references and making minor revisions in the editing process to finalize the *Essential Components of a Public Health Tuberculosis Prevention, Control, and Elimination Program: Recommendations of the Advisory Council for the Elimination of Tuberculosis (ACET) and the National Tuberculosis Controllers Association (NTCA)* document. The workgroup's next step will be to submit the document to the CDC clearance process for publication and dissemination.

Ms. Cole announced that in anticipation of the release of the *2018 American Academy of Pediatrics (AAP) Red Book®* in May 2018, the Essential Components document references the option of using IGRA in children 2 years of age and older. However, CDC's current recommendation on the use of IGRA in children 5 years of age and older is cited as well. She requested feedback from Dr. LoBue on whether these two references in the document are incongruent.

Dr. LoBue clarified that he was unable to directly respond to Ms. Cole's question without first reviewing the current language in the Essential Components document. Although CDC currently recommends the use of IGRA in children 5 years of age and older and prefers TST in children younger than 5 years of age, he explained that no language in any of CDC's guidelines prohibits the use of IGRA testing in children 2-4 years of age.

Update by the TB Drug Supply Workgroup

Barbara Cole, RN, MSN, PHN, ACET Chair
TB Controller
Riverside County (California) Department of Public Health

Advice requested from ACET by the TB Drug Supply Workgroup:
1. What are ACET's suggestions on specific topics that the workgroup should address?

Ms. Cole reported that the TB Drug Supply Workgroup reconvened on April 4, 2018. During the meeting, the members reviewed the workgroup's previous efforts (e.g., CDC's TB emergency drug stockpile), identified key gaps, and explored new areas that need to be addressed. The members discussed and agreed to recruit a pharmacist to serve as a new workgroup member.

The workgroup proposed the following language as its new charge: (1) identify strategies to ensure an uninterrupted drug supply for treating TB disease and LTBI and (2) address drug pricing manufacturing issues and distribution shortages. In response to Ms. Cole's request for feedback, the ACET members expressed their support of the workgroup's proposed charge.

The workgroup will hold its next meeting on June 5, 2018 from 4:00-5:00 p.m. EST. The Treatment Action Group will present an update on its efforts to address the cost of bedaquiline and the formulation of rifapentine. The workgroup also plans to invite a guest speaker to discuss the requirements of the 340B Drug Pricing Program.

Dr. Dean reminded the workgroup of the FACA rule that requires two voting members of the parent committee to serve on a workgroup. In response to Dr. Dean's comment, Ms. Cole facilitated a discussion to clarify the workgroup's membership. An ACET voting member needs to be identified to serve as the workgroup chair. Dr. Nilsen is the ACET liaison representative for NTCA. She offered to serve in the capacity on the workgroup. Ms. Ann Cronin, the DTBE Associate Director for Policy, will continue to serve as the workgroup's liaison to CDC to provide technical assistance.

Update by the LTBI Workgroup

Jeffrey Starke, MD
Professor of Pediatrics, Baylor College of Medicine
Texas Children's Hospital
ACET Member & Workgroup Co-Chair

Dr. Starke reported that due to emergency eye surgery, he was unable to convene the first teleconference for the workgroup to draft its formal charge and scope of work. However, he planned to consult with Dr. Flood, the workgroup co-chair, and Dr. Thomas Navin (Chief of DTBE/ SEOIB), the workgroup's liaison to CDC, to coordinate the workgroup's first teleconference over the next two weeks.

Dr. Starke announced that Ms. Donna Wegener, Executive Director of NTCA, has been assisting the workgroup co-chairs in their preliminary efforts of gathering background data, such as articles related to LTBI and existing LTBI guidelines from states. He confirmed that he and Dr. Flood will present the workgroup's first substantive update to ACET during the August 2018 meeting.

Update by the TB Funding Formula Workgroup (FFWG)

Terence Chorba, MD, MPH, DSc (Workgroup Co-Chair)
Chief, Field Services Branch
Division of Tuberculosis Elimination
Centers for Disease Control and Prevention

Dr. Chorba reported that his update would focus on FFWG's response to the advice and guidance provided by ACET during the December 2017 meeting. However, he first revisited two major areas that were covered in the December 2017 presentation and played a role in FFWG's response to ACET. First, FFWG described its diverse representation. The membership includes NTCA as CDC/DTBE as the co-chairs; the five TB Centers of Excellence

(COEs) for Training, Education, and Medical Consultation (formerly, the Regional Training and Medical Consultation Centers); and TB control programs (including those in big cities as well as in high, medium, and low incidence states). The response to ACET reflects input by the full FFWG membership.

Second, FFWG presented two tables to illustrate the differences in the data elements and weights between the FY2015 and the proposed FY2020 TB funding formulas. FFWG slightly modified some of the data elements in response to the advice and guidance ACET provided during the December 2017 meeting, but none of the weights were changed for the 2020 TB funding formula.

TB Prevention and Control Formula Element: Needs-Based Components and Weights	FY2015	FY2020
TB incident cases	24%	39%
TB in non-U.S.-born and U.S.-born minorities	24%	8%
Sputum smear-positive TB cases with respiratory and pleural site of disease	12%	12%
HIV/TB comorbidity	4%	0%
Medical factors and co-morbidities: ➢ (Diabetes, HIV, end-stage renal disease, post-organ transplant, other immunocompromised conditions, hepatitis B virus, hepatitis C virus)	0%	4%
MDR-TB	4%	5%
TB in homeless populations	4%	0%
Substance abuse	4%	0%
Social risk factors: ➢ (Homelessness, injection drug use (IDU), non-IDU, excessive alcohol use)	N/A	4%
Class B arrivals	4%	4%

TB Prevention and Control Formula Element: Performance-Based Components and Weights	FY2015 Weights (20%)	FY2020 Weights (24%)
Completion of treatment for TB cases	15%	10%
Drug susceptibility testing	5%	5%
Completion of LTBI treatment for TB contacts	N/A	5%
Completion of examination for immigrants and refugees with Class B1 status	N/A	4%

Dr. Chorba's summary of FFWG's response to the advice and guidance provided by ACET during the December 2017 meeting is set forth in the table below.

FFWG RESPONSE TO ACET GUIDANCE	
ACET Recommendation	**FFWG Response**
Describe the potential opportunities for DTBE to scale-up funding for LTBI testing and treatment.	The 2020 TB funding formula will include indicators for (1) the completion of LTBI treatment in TB contacts and (2) the completion of examination for immigrants and refugees with Class B1 status. A broader effort that is more community-focused will need to be based on available funds.
Maintain the capacity of an increasing number of TB programs in low incidence states over time in the event of level funding or budget cuts.	FFWG recommended an increase in threshold funding from $100,000 to $125,000 for the 2020 TB funding formula. In the current formula, nine programs receive threshold funding. In the 2020 formula, 13 programs will receive threshold funding.
Clarify the rationale for the reduction in the weight (from 24 percent to 8 percent) for non-U.S.-born and U.S.-born minority TB patients.	The current TB funding formula assigns weights of 24 percent for both (1) TB cases in U.S.-born and non-U.S.-born minorities and (2) TB incident cases. Because U.S.-born and non-U.S.-born minorities account for the majority of demographics of TB cases in the United States, these cases currently are being doubly funded in the current formula. On a case basis, the burden of caring for these populations does not consume twice the level of resources compared to U.S.-born non-minorities. TB controllers who serve on the FFWG have first-hand knowledge of and experience in allocating funds to care for TB cases in non-U.S.-born and U.S.-born minorities. Based on their strong recommendation, FFWG reduced the weight for these populations from 24 to 8 percent to increase the weight for TB incident cases from 24 to 39 percent.
Ensure alignment between the 2020 TB funding formula and TB incidence.	The funding distribution that is proposed for the 2020 TB funding formula was compared to a strictly incidence-based allocation. According to this analysis, the 2020 TB funding formula will (1) utilize 2 percent of the total funds that would have been awarded to 22 programs if an incidence-only funding formula was used and (2) distribute the funds among the remaining 39 programs. The decrease will range from $6,183 to $351,295, while the increase will range from $296 to $116,016. The analysis also showed that under the proposed 2020 TB funding formula, 40 programs will receive more funding and 21 programs will receive less funding. FFWG's position is that compared to incidence-only funding, formula-based funding is more equitable and favorable to most programs overall. The purpose of incorporating variables into a funding formula is to redistribute funding to address the added costs of treating certain cases.

FFWG RESPONSE TO ACET GUIDANCE	
ACET Recommendation	**FFWG Response**
Revise the 2020 TB funding formula to account for TB cases in correctional settings, particularly since contact investigations for these cases place a tremendous burden on programs.	Contact investigations in state or federal prisons typically are managed by staff in these facilities. Contact investigations in local or county jails might require more involvement by public health department staff and additional expenses. Overall, resources will not be at a level that will warrant the inclusion of TB cases in correctional settings in the 2020 TB funding formula.
Consider revising the 2020 TB funding formula to account for molecular DST results, including the proposed weight of 5 percent for DST.	The collection of expanded molecular DST variables currently is scheduled for the 2020 RVCT. After these data are gathered, molecular DST results will be considered in the TB funding formula for funding purposes along with conventional test results.
Consider including drug intolerance in the "Medical Factors" variable of the 2020 TB funding formula based on the following reasons: (1) an increased intolerance of TB drugs in the aging population and (2) similar difficulties in treating some MDR-TB cases and patients with an intolerance to TB drugs.	The subjective nature of "drug intolerance" increases the difficulty in harmonizing a standard definition and promoting uniform data collection across all TB programs. Drug intolerance often appears after a patient has been on a drug for some period of time. Due to limited capacity to support a standardized definition and consistent data collection, drug intolerance will not be included in the 2020 TB funding formula. However, the 2020 RVCT is expected to include a variable to identify and report TB patients who did not use first-line drugs. This variable will be designed to capture changes in the patient's regimen within the first two weeks of TB treatment initiation. Similar to the 2020 TB funding formula, however, the 2020 RVCT also will not include a specific variable to capture data on drug intolerance.

FFWG RESPONSE TO ACET GUIDANCE	
ACET Recommendation	**FFWG Response**
Further examine patients who transfer between jurisdictions to address the issue of split funding.	The first jurisdiction will serve as the jurisdiction of record for the purpose of allocating funding under the 2020 TB funding formula. To support this recommendation, FFWG reviewed data and considered two categories of TB patients who account for the majority of cross-jurisdictional transfers. ➢ For MDR-TB patients, a "pro-rating" funding formula based on the number of months spent in a specific jurisdiction will be complex to implement and difficult to make equitable decisions for all jurisdictions involved in the case. Moreover, data show that the majority of MDR-TB patients relocate to other countries rather than to other states in the United States. ➢ For follow-up examinations of immigrants and refugees in the United States, Electronic Disease Notification records (i.e., the TB Follow-up Worksheet) do not necessarily capture the jurisdiction that performs the TB examination. The "Date of Patient Transfer" variable is not designed to identify the specific jurisdiction that performed the TB examination. However, DTBE and DGMQ currently are collaborating to revise the TB Follow-up Worksheet to capture the specific jurisdiction that performs an examination. The revised worksheet has been submitted to OMB and is expected to be launched for TB programs to collect these data by the end of 2018.
Consider accounting for the denominator of TB cases in jurisdictions in addition to the numerator.	Dr. Shama Ahuja, the ACET liaison representative for the Council of State and Territorial Epidemiologists, was invited to propose potential strategies to FFWG to address this issue. Several key points were raised during the discussion. ➢ Multiple denominators potentially can be used, but no single denominator has been identified that will be appropriate in all analytic frameworks to reasonably reflect an increased workload per population member. ➢ Any new or alternate denominator will need to be systematically gathered over the same cohort periods to be used in the 2020 TB funding formula. ➢ A denominator variable is not being considered for inclusion in the 2020 RVCT. Moreover, a denominator variable has not been systematically gathered to date as part of the activities conducted by TB CoAg-funded jurisdictions. FFWG reached consensus on not recommending an adjustment to the 2020 TB funding formula to account for a denominator of TB cases.

Dr. Chorba concluded his update by describing FFWG's next steps. The FFWG co-chairs will complete the final editing process and present the proposed 2020 TB funding formula to Dr. LoBue in late May/early June 2018. FFWG will consider additional input provided by ACET during the April 2018 meeting. The DTBE-approved funding formula will begin to be implemented in the 2020 TB CoAg.

ACET GUIDANCE

- Dr. Ahuja noted that FFWG's response on split funding was based on the transfer of MDR-TB patients between two jurisdictions. She questioned whether FFWG considered the involvement of multiple jurisdictions in the cross-jurisdictional transfer of one TB case. Dr. Chorba clarified that FFWG did not address this issue.
- Dr. Armitige thanked FFWG for its thoughtful consideration of her previous suggestion to revise the 2020 TB funding formula to account for TB cases in correctional settings. Based on Dr. Chorba's update, however, FFWG will take no action in this regard because staff in federal/state prisons and local/county jails are responsible for the oversight and management of TB cases, contact investigations, and cross-jurisdictional transfers of their incarcerated populations. During the final editing process of the 2020 TB funding formula, she urged FFWG to be mindful of the lack of public health expertise or interest in public health impact among corrections staff. As a resource in the final decision-making process, she offered to provide the FFWG co-chairs with contact information for health departments in the six states of the country that will be most significantly impacted due to their high incarceration rates of newly diagnosed TB cases.

Preparation for the ACET Business Session

Barbara Cole, RN, MSN, PHN, ACET Chair
TB Controller
Riverside County (California) Department of Public Health

Ms. Cole reviewed the updates and overviews that were presented over the course of the ACET meeting. She noted that some of the key points ACET raised after the presentations will warrant formal action, follow-up discussions, or future agenda items.

Follow-up Discussions:

- Opportunities to include TB in the prevention and health education activities of NCHHSTP divisions other than DTBE, such as DHAP and DASH
- Increased emphasis on LTBI as the best method for TB TasP

Future Agenda Items:

- Status report on LTBI reporting, including the communications plan for DTBE's Concept of Operations
- Update by the CDC/NTCA ICD-10 Coding Workgroup
- Overview of key outcomes from NCHHSTP's rescheduled meeting, "Primary Care and Public Health: Partners in Prevention"

Formal Motion:

- Dr. Armitige's proposed language to revise the correctional facility variable in the 2020 RVCT

Ms. Cole pointed out that in addition to Dr. Armitige, other members are free to place a formal motion on the floor during the Business Session and call for ACET's vote.

ACET Business Session

Barbara Cole, RN, MSN, PHN, ACET Chair
TB Controller
Riverside County (California) Department of Public Health

Ms. Cole opened the Business Session and facilitated a review of old and current business items that warrant ACET's formal action at this time, additional discussion, or requests for future agenda items.

Business Item 1: Approval of Previous ACET Meeting Minutes

A motion was properly placed on the floor by Dr. Lisa Armitige and seconded by Dr. Jeffrey Starke for ACET to approve the previous meeting minutes.

ACET approved the Draft December 11-12, 2017 Meeting Minutes with no changes or further discussion.

Business Item 2: ACET Letter to the HHS Secretary

Ms. Cole announced that in the interest of time, she would limit ACET's review of the current version of the letter to the eight requests in the "Assistance from the HHS Secretary" section on page 4. She noted that the revised section reflects the extensive input provided by ACET during the December 2017 meeting.

None of the ACET members proposed any additional changes to the eight requests to the HHS Secretary. However, Ms. Cole noted that she will delete "and treatment" from the first request.

Dr. Dean described the next steps to send the letter to the HHS Secretary. The letter will be finalized, placed on ACET letterhead, and signed by Ms. Cole. The letter will be forwarded to all points within the CDC policy and review process for submission to the HHS Secretary.

Business Item 3: TB Medical Consultation Services

Ms. Cole returned to ACET's previous resolution that endorsed the formation of an external workgroup with representation by ACET, DTBE, NTCA, and the TB COEs to examine new and innovative modalities for the delivery of TB medical consultation services. She acknowledged that agreement was reached to table this update until DTBE announces the awards to the TB COEs under the re-competed CoAg. She planned to revisit this agenda item at the August 2018 ACET meeting.

Business Item 4: Draft Executive Order on the "Public Charge" Definition

Dr. Robert Benjamin is the ACET liaison representative for the National Association of County and City Health Officials. He informed ACET of a draft Executive Order that is circulating related to changes to the current "public charge" definition. A public charge is defined as an individual who is likely to become primarily dependent on the government for subsistence.

The Department of Homeland Security previously issued guidance on the federally funded programs that would not be included in the public charge definition: Medicaid and the Children's Health Insurance Program; the Supplemental Nutrition Assistance Program; the Women, Infants, and Children Program; and school meals, housing assistance, job training, and unemployment benefits programs. However, the draft Executive Order reverses this policy and greatly expands the types of programs and services to include in the public charge definition.

According to the draft Executive Order, immigrants who receive benefits or services under any of these federally funded programs could be denied permanent resident status and/or be at risk for deportation within their first five years of residing in the United States. Based on DTBE's 2017 provisional TB surveillance data, nearly 50 percent of TB cases in immigrants have been residing in the United States for less than five years.

Dr. Benjamin announced that several national organizations are closely monitoring potential changes in the public charge definition. If approved, the draft Executive Order will have a significant impact on, and might well deter immigrants who have symptoms that are compatible with TB, from presenting to a provider to seek diagnosis, care, and treatment. Ms. Cole asked Dr. Benjamin to continue to inform ACET of future developments related to the draft Executive Order on the public charge definition.

Business Item 5: 2020 Report of Verified Case of Tuberculosis

Dr. Armitige proposed a revision to the correctional facility variable in the 2020 RVCT to be more consistent with the language in the homeless variable.

> ACET recommends revising Variable 21 of the 2020 RVCT ("If resident of correctional facility at diagnostic evaluation, type of facility?") by adding two new data elements: "Incarcerated in the previous two years" and "Incarcerated ever."

Action	Description
Chair's call for a vote	Dr. Lisa Armitige properly placed a motion on the floor for ACET to approve the proposed revision to the 2020 RVCT. Dr. David Warshauer seconded the motion.
Outcome of the vote	**The motion was unanimously approved by 9 ACET voting members.**
Next steps	Dr. Dean will forward ACET's formal recommendation on the 2020 RVCT to DTBE staff.

Business Item 6: 2018 TB Technical Instructions

Dr. Alvarez proposed the following language for ACET's consideration: "ACET recommends including the use of IGRA in children 2-4 years of age as a requirement in the 2018 TB Technical Instructions for Panel Physicians and Civil Surgeons."

Action	Description
Chair's call for a vote	Dr. Ana Alvarez properly placed a motion on the floor for ACET to approve the proposed recommendation for the 2018 TB TIs to require the use of IGRA in children 2-4 years of age. Dr. Lisa Armitige seconded the motion.
Outcome of the vote	**The motion was approved by a majority vote of 8 ACET voting members and 1 abstention (Barbara Cole).**
Next steps	Ms. Cole will inform the DGMQ TB TI Workgroup of ACET's formal recommendation.

Business Item 7: Advice Requested from ACET

Ms. Cole presented a table with the advice that the presenters requested from ACET during the December 2017 meeting. She led ACET in a review of these topics to determine whether any further action is needed.

ADVICE REQUESTED FROM ACET	
Topic	**Action**
2020 TB Laboratory Funding Formula	Dr. LoBue confirmed that the DTBE Laboratory Branch considered and discussed ACET's comments and suggestions. **ACET agreed that no further action is needed.**
Universal Whole-Genome Sequencing (WGS) of MTB in the United States	DTBE's communications plan to provide TB programs with important clinical information related to genetic mutations based on WGS will be placed on a future ACET meeting agenda.
CDC's Updated 3HP Recommendations	Dr. LoBue confirmed that DTBE considered ACET's input. The latest draft of CDC's updated 3HP guidelines reflects ACET's suggestions related to the age restriction on the use of 3HP by self-administered therapy (SAT), monthly in-person evaluations of patients who are on 3HP-DOT and 3HP-SAT, and drug interactions. **ACET agreed that no further action is needed.**
ACET's 2018-2019 Strategic Plan	Ms. Cole will present the results of the self-assessment that ACET conducted as part of its strategic planning process during the August 2018 meeting. This update will be placed on the August 2018 ACET meeting agenda.

ADVICE REQUESTED FROM ACET	
Topic	**Action**
Distribution of the Final Essential Components document	ACET previously discussed posting the Essential Components document on various websites in addition to the *MMWR* publication. **ACET agreed that no further action is needed.**
Update by the Child and Adolescent Workgroup	During the December 2017 meeting, ACET provided extensive input in response to the workgroup's request for advice. During the April 2018 meeting, Dr. LoBue provided further clarification on the differences between the recommendations by CDC and the *AAP Red Book*® regarding the use of IGRA in children 2-4 years of age. **ACET agreed that no further action is needed.**

Business Item 8: Future Agenda Items

Ms. Cole confirmed that the Agenda Setting Workgroup will convene a teleconference to draft an agenda based on the topics ACET proposed over the course of the meeting. The draft agenda will be circulated to ACET for review in advance of the August 2018 meeting.

Presenter	Agenda Item
NCHHSTP	Follow-up discussion: Opportunities to include TB in the prevention and health education activities of NCHHSTP divisions other than DTBE, such as DHAP and DASH.
DHAP/DTBE	Follow-up discussions: ➢ Overview of efforts in promoting, implementing, and adopting HIV TasP to identify successful approaches that potentially can be replicated for TB TasP. ➢ Increased emphasis on LTBI as the best method for TB TasP.
Dr. Philip LoBue	DTBE Director's Report: ➢ Overview of key outcomes from NCHHSTP's Primary Care and Public Health: Partners in Prevention" meeting on May 7-8, 2018 that pertain to DTBE [rescheduled from the April 2018 meeting]. ➢ Status report on the revised proposal that the CDC/NTCA ICD-10 Coding Workgroup will submit to the CDC/NCHS Classification Team. ➢ Status report on LTBI reporting, including the communications plan for DTBE's Concept of Operations.
Ms. Barbara Cole	Update on the results of ACET's self-assessment as part of its strategic planning process during the December 2017 meeting.
Dr. Jeffrey Starke Dr. Jennifer Flood	First update by the co-chairs on the draft charge and scope of work for the new LTBI Workgroup.

Presenter	Agenda Item
Dr. Philip LoBue Dr. Peter Davidson	Status report on ACET's previous resolution that endorsed the formation of an external workgroup to examine new and innovative modalities for the delivery of TB medical consultation services. [Note: This update will continue to be tabled until DTBE announces the awards of the TB COEs under the re-competed TB CoAg.]
Mr. Jeff Caballero	Overview of successful TB prevention activities by the Association of Asian Pacific Community Health Organizations, particularly in the area of stigma reduction.
To Be Determined	Overview of key outcomes related to global or domestic TB from the high-level ministerial meeting that will be held at the United Nations in New York City in September 2018 [December 2018 agenda item].

Dr. Flood requested a status report on the meeting that the previous CDC Director planned to convene on TB elimination efforts. However, Dr. LoBue clarified that this item will not be included on a future ACET agenda. The meeting was targeted to high-burden states and was not intended for public discussion.

Business Item 9: Video Conferencing for ACET Webinars

Ms. Cole asked the participants to describe their experiences in using video conferencing technology during the current meeting and identify any areas that need to be improved. On the one hand, Drs. Armitige and Alvarez encountered no problems with the login process and were pleased with the ability to see their ACET colleagues and CDC staff during the meeting. On the other hand, Dr. Houpt's video conferencing connection was poor and unreliable.

The CDC audiovisual staff confirmed that the technical problems related to video conferencing will be resolved by the next ACET webinar in August 2018.

Public Comment Session

No members of the public provided comments for ACET's consideration.

Closing Session

The published agenda listed the dates of the next two ACET meetings: August 21, 2018 (webinar) and December 11-12, 2018 (in-person meeting in Atlanta). Ms. Margie Scott-Cseh, the ACET Committee Management Specialist, will poll the members via email to determine their availability and confirm the dates of the next two meetings.

With no further discussion or business brought before ACET, Ms. Cole adjourned the meeting at 3:30 p.m. EST on April 17, 2018.

CHAIR'S CERTIFICATION

I hereby certify that to the best of my knowledge, the foregoing Minutes of the proceedings are accurate and complete.

Date

Barbara Cole, RN, MSN, PHN
Chair, Advisory Council for the
Elimination of Tuberculosis

Attachment 1: Participants' Directory

ACET Members Present

Ms. Barbara Cole, Chair
Dr. Ana Alvarez
Dr. Lisa Armitige
Dr. Jennifer Flood
Dr. Robert Horsburgh, Jr.
Dr. Eric Houpt
Dr. Jeffrey Starke
Dr. James Sunstrum
Dr. David Warshauer

ACET Member Absent

Dr. Michael Lauzardo

ACET *Ex-Officio* Members Present

Dr. Naomi Aronson
U.S. Department of Defense

Dr. Amy Bloom
U.S. Agency for International Development

Dr. Ulana Bodnar
U.S. Department of Justice

Ms. Sarah Bur
Federal Bureau of Prisons

Ms. Marla Clifton
U.S. Department of Veteran Affairs
(Alternate for Dr. Gary Roselle)

Dr. Karen Elkins
U.S. Food and Drug Administration

Dr. Diana Elson
U.S. Department of Homeland Security
Immigration and Customs Enforcement

Dr. Mamodikoe Makhene
National Institute of Allergy and Infectious Diseases, National Institutes of Health

Mr. Stephen Martin
National Institute for Occupational Safety and Health

Dr. Deborah Parham Hopson
Health Resources and Services Administration

Dr. Kevin Taylor
U.S. Department of Defense
(Alternate for Dr. Naomi Aronson)

Dr. David Yost
Indian Health Service
(Alternate)

ACET *Ex-Officio* Members Absent

Dr. Anthony Campbell
Substance Abuse and Mental Health Services Administration

Ms. Kali Crosby
Agency for Healthcare Research and Quality

Dr. Matthew Lin
U.S. Department of Health and Human Services, Office of Minority Health

Dr. Gary Roselle
U.S. Department of Veteran Affairs

ACET Liaison Representatives Present

Dr. Shama Ahuja
Council of State and Territorial Epidemiologists

Dr. Robert Benjamin
National Association of County and City Health Officials

Mr. Surajkumar Madoori
Treatment Action Group

Dr. Robert Morris
National Commission on Correctional Health

Dr. Diana Nilsen
National Tuberculosis Controllers Association

Dr. Susan Ray
Infectious Disease Society of America

Dr. Randall Reves
International Union Against TB and Lung Disease

ACET Liaison Representatives Absent

Mr. David Bryden
RESULTS

Dr. Fran du Melle
American Thoracic Society

Dr. Mayleen Ekiek
Pacific Island Health Officers Association

Dr. Ilse Levin
American Medical Association

Dr. Howard Njoo
Public Health Agency of Canada

Dr. Amee Patrawalla
American College of Chest Physicians

Dr. Jennifer Rakeman
Association of Public Health Laboratories

Dr. Gudelia Rangel
Mexico Section, U.S.-Mexico Border Health Commission

Ms. Susan Rappaport
American Lung Association

Dr. Michael Tapper
Society for Healthcare Epidemiology of America

Dr. Lornel Tompkins
National Medical Association

Mr. Bobby Watts
National Health Care for the Homeless Council

ACET Designated Federal Officer

Dr. Hazel Dean
NCHHSTP Deputy Director

CDC Representatives

Dr. Lori Armstrong
Dr. Terence Chorba
Ms. Ann Cronin
Mr. Justin Davis
Mr. Bruce Everett
Dr. Neela Goswami
Ms. Carla Jeffries
Ms. Kathryn Koski
Dr. Lauren Lambert
Dr. Adam Langer
Rebecca Levine, Esq.
Dr. Philip LoBue
Mr. Elvin Magee
Ms. Suzanne Marks
Dr. Jonathan Mermin
Dr. Sapna Morris
Dr. Thomas Navin
Mr. Gibril Njie
Mr. James Nowicki
Dr. Drew Posey
Mr. Robert Pratt
Dr. Joanna Regan
CDR Melanie Ross

Ms. Margie Scott-Cseh
Dr. Neha Shah
Ms. Donnica Smalls
Ms. Clarisse Tsang
Dr. Carla Winston
Ms. Kai Young

Guest Presenters/ Members of the Public

Dr. Robert Belknap
Denver Public Health

Dr. Lynn Sosa
Connecticut Department of Public Health

Attachment 2: Glossary of Acronyms

Acronym	Definition
3HP	Three Months of Isoniazid/Rifapentine
AAP	American Academy of Pediatrics
ACET	Advisory Council for the Elimination of Tuberculosis
AI/ANs	American Indians/Alaska Natives
ART	Antiretroviral Therapy
BCG	*Bacillus Calmette-Guérin*
BOP	Federal Bureau of Prisons
CDC	Centers for Disease Control and Prevention
CoAg	Cooperative Agreement
COEs	Centers of Excellence
CT	Computed Tomography
DASH	Division of Adolescent and School Health
DFO	Designated Federal Officer
DGMQ	Division of Global Migration and Quarantine
DHAP	Division of HIV/AIDS Prevention
DOT	Directly Observed Therapy
DST	Drug Susceptibility Test
DSTDP	Division of STD Prevention
DTBE	Division of Tuberculosis Elimination
DVH	Division of Viral Hepatitis
EDOT	Electronic Directly Observed Therapy
FACA	Federal Advisory Committee Act
FDA	U.S. Food and Drug Administration
FFWG	Funding Formula Workgroup
FY	Fiscal Year
HCP	Healthcare Personnel
HCV	Hepatitis C Virus
HCW	Healthcare Worker
HHS	U.S. Department of Health and Human Services
IDU	Injection Drug Use

Acronym	Definition
IGRA	Interferon Gamma Release Assay
JAMA	*Journal of the American Medical Association*
LPR	Lawful Permanent Resident
LTBI	Latent Tuberculosis Infection
LTCFs	Long-Term Care Facilities
MDR-TB	Multidrug-Resistant Tuberculosis
MMWR	*Morbidity and Mortality Weekly Report*
MRI	Magnetic Resonance Imaging
MTB	*Mycobacterium tuberculosis*
NAA	Nucleic Acid Amplification
NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
NCHS	National Center for Health Statistics
NHBs	Non-Hispanic Blacks
NHPIs	Native Hawaiians/Pacific Islanders
NHWs	Non-Hispanic Whites
NOFO	Notice of Funding Opportunity
NTCA	National Tuberculosis Controllers Association
NTSS	National TB Surveillance System
OMB	Office of Management and Budget
OMH	Office of Minority Health
PET	Positron Emission Tomography
PWID	People Who Inject Drugs
PZA	Pyrazinamide
QFT	QuantiFERON
RIF	Rifampin
RVCT	Report of Verified Case of Tuberculosis
SAMHSA	Substance Abuse and Mental Health Services Administration
SAT	Self-Administered Therapy
SEOIB	Surveillance, Epidemiology, and Outbreak Investigations Branch
TasP	Treatment as Prevention
TB	Tuberculosis
TBLISS	TB Latent Infection Surveillance System
TIs	Technical Instructions
TST	Tuberculin Skin Test
USAPIs	U.S.-Affiliated Pacific Islands
USBPs	U.S.-Born People/Populations
WGS	Whole-Genome Sequencing
WHO	World Health Organization
YRBS	Youth Risk Behavior Surveillance System