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

Meeting of the
Advisory Council for the Elimination of Tuberculosis
December 11-12, 2017
Atlanta, Georgia

Record of the Proceedings

TABLE OF CONTENTS

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ADVISORY COUNCIL FOR THE ELIMINATION OF TUBERCULOSIS
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Minutes of the 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 meeting of the Advisory Council for the Elimination of Tuberculosis (ACET). The proceedings were held on December 11-12, 2017 at the CDC Corporate Square Campus, Conference Room 1A/B/C, in Atlanta, Georgia.

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 ACET meeting in person or participate remotely via 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: December 11, 2017

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
Michael Lauzardo, MD, MSc (University of Florida College of Medicine)	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
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 December 11, 2017. She called the proceedings to order at 10:00 a.m. 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.

- Mr. Surajkumar Madoori, U.S. and Global Health Policy Director, is the new liaison representative for the Treatment Action Group.
- Ms. Caroline Freeman has retired from the U.S. Department of Labor (DOL), Occupational Safety and Health Administration. CDC will send a letter to DOL with a request to identify a replacement for Ms. Freeman.
- Mr. Eddie Hedrick is no longer serving as the liaison representative for the Association for Professionals in Infection Control and Epidemiology (APICE). CDC sent a letter to APICE with a request to identify a replacement for Mr. Hedrick.
- Dr. Sarah Linde is no longer serving as the *ex-officio* member for the Indian Health Service (IHS). CDC sent a letter to IHS on November 1, 2017 with a request to identify a replacement for Dr. Linde.

- Dr. Nadine Gracia is no longer serving as the *ex-officio* member for the HHS Office of Minority Health (OMH). CDC sent a letter to OMH on November 27, 2017 with a request to identify a replacement for Dr. Gracia.
- Dr. Jay Butler is no longer serving as the liaison representative for the Association of State and Territorial Health Officials (ASTHO). CDC sent a letter to ASTHO in August 2017 with a request to identify a replacement for Dr. 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 ACET meeting. She announced that the meeting was called to order 1.5 hours later than the time on the published agenda due to technical difficulties. However, she confirmed that the lunch hour and scheduled breaks will be shortened to accommodate all of the scheduled agenda items.

NCHHSTP Office of the Director's (OD) Report

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 DFO

Dr. Dean covered several topics in the NCHHSTP OD report to ACET. At the agency level, Dr. Brenda Fitzgerald marked her 100-day milestone as the Director of CDC with a CDC-wide All-Hands meeting on November 17, 2017. She emphasized that the purpose of CDC is to provide the common defense of the country against health threats. She also pointed out that CDC is committed to and relies on three key pillars: science, surveillance to guide its investigations and interventions, and service to people who need its assistance domestically and globally.

Dr. Fitzgerald announced the establishment of four programmatic "Communities of Practice" to promote greater synergy across CDC programs and areas of expertise as well as to encourage more lateral interactions across centers. The proposed Communities of Practice and their leaders are listed below.

- Dr. Robin Ikeda, Deputy Director for Noninfectious Diseases
- Dr. Sonja Rasmussen, Deputy Director for Infectious Diseases
    - NCHHSTP will be housed in the Infectious Diseases Community of Practice.
- Dr. Chesley Richards, Deputy Director for Public Health Science [proposed]
- Dr. Stephen Redd, Deputy Director for Public Health Services [proposed]

CDC, the National Institute on Drug Abuse, the Substance Abuse and Mental Health Services Administration, and the Appalachian Regional Commission awarded nine CoAgs in fiscal year (FY) 2018 to support five-year demonstration projects to address the opioid crisis in rural regions of the country. The grant recipients will use their funds to develop comprehensive approaches to prevent and treat the consequences of opioid injection, including overdose, substance use disorder, HIV, hepatitis B and C virus (HBV/HCV) infections, and STDs.

At the center level, NCHHSTP recently launched the new High-Impact Prevention (HIP) website to promote one of its primary strategies for preventing HIV, STDs, viral hepatitis, and TB. In general, HIP includes the use of proven, cost-effective, and scalable interventions that are evaluated and implemented to prevent the greatest amount of disease or disparities. In particular, HIP includes four major activities: assess the efficacy and effectiveness of programs; establish the cost and cost-effectiveness per infections averted and life-years saved; develop epidemic models to project the impact of intervention combinations; and implement and evaluate programs.

The HIP website includes important information for key partners and other stakeholders, such as case studies.

NCHHSTP and the *American Journal of Public Health* are collaborating to publish a theme issue on applying methods, metrics, and indicators for measuring disparities in health outcomes and risk behaviors for the prevention and treatment of HIV, viral hepatitis, STDs, and TB in the United States and promoting adolescent and school health. The call for papers seeks original research articles, brief reports, systematic reviews, commentaries, analytic or historical essays, and public health practice reports. The deadline for submissions is January 31, 2018. Instructions for the theme issue are available on the American Journal of Public Health's website.

NCHHSTP's recent staff changes include the appointment of Ms. Debra Byrd, NCHHSTP's new Management Officer, and a vacancy by Ms. Jessica Lacy, NCHHSTP's former Associate Director for Communication Science. Ms. Rachel Powell will serve in an acting position until Ms. Lacy's permanent replacement has been appointed. Recruitment efforts are underway to fill the position of the NCHHSTP Associate Director for Health Equity. The job announcement will close on December 18, 2017.

At the division level, the Division of HIV/AIDS Prevention (DHAP) released the November/ December 2017 CDC *VitalSigns*™ report that focused on HIV testing. The report documented that nearly 40,000 people were diagnosed with HIV in the United States in 2015. Of this population, 1 in 2 people have been living with HIV for three years or more. The report also highlighted a major missed opportunity. Most notably, 7 out of 10 people at high risk who were not tested for HIV in the past year were seen by a healthcare provider at that time.

DHAP issued its 2017-2020 Strategic Plan. The updated strategic plan for HIV/AIDS prevention reflects advances in prevention science, including pre-exposure prophylaxis.

The Division of Viral Hepatitis (DVH) recently published a report, *Progress Toward Viral Hepatitis Elimination in the United States–2017*. The inaugural report highlights the progress that has been made to date in elimination efforts, particularly the use of recommended interventions and their impact on the prevention of viral hepatitis transmission, disease, and associated mortality. The report also shows that significant progress has not been made in meeting several viral hepatitis elimination goals. Most notably, the goal to "reduce the rate of HBV-related deaths" is the only current annual target that has been met or exceeded. The ongoing effects of the national opioid epidemic have led to challenges in achieving the other elimination targets for viral hepatitis.

Did not meet the current annual target, but advancing toward the target in the most recent data year

- Increase the percentage of children 19-35 months of age who receive two or more doses of hepatitis A virus (HAV) vaccine
- Reduce the rate of HCV-related deaths

No change/movement in the target

- Reduce the rate of reported HAV infections
- Increase the percentage of infants who receive HBV vaccine within three days of birth
- Reduce the rate of reported acute HBV infections among people 19 years of age and older
- Reduce the rate of reported acute HCV infections

DVH provided technical assistance (TA) in response to reports of multiple HAV outbreaks in 2017 among homeless populations and people who inject drugs. The 665 HAV cases reported by California, the 555 cases reported by Michigan, and the 87 cases reported by Utah accounted for 934 hospitalizations and 41 deaths.

The Division of STD Prevention (DSTDP) recently released the *2016 STD Surveillance Report* that showed record high numbers of STD cases reported in the United States in 2016: 1.6 million chlamydia cases, 470,000 gonorrhea cases, and 88,000 syphilis cases. The largest increases in the growing syphilis rate were among men who have sex with men (MSM) and women. Most notably, men accounted for more than 89 percent of all primary and secondary syphilis cases in 2016. The surveillance report also documented more than 600 cases of congenital syphilis and a 22 percent increase in gonorrhea among men.

DSTDP issued a new infographic that also highlighted the record high numbers of STD cases reported in the United States in 2016. States and local jurisdictions can enter their individual surveillance data into the infographic to generate a specific "State of STDs" report.

DSTDP recently awarded a total of $4 million to strengthen local capacity to address congenital syphilis and support an enhanced response in this area. Syphilis among newborns has increased from 461 cases in 2014 to 628 cases in 2016. The nine state and city health departments that were awarded funds account for 71 percent of congenital syphilis cases in the country: California, Chicago, Florida, Georgia, Los Angeles, Louisiana, Maryland, Ohio, and Texas.

The Division of Adolescent and School Health (DASH) recently published *Results from the School Health Policies and Practices Study (SHPPS)–2016* that showed progress in some areas. SHPPS is a national survey that is designed to collect data from public and private elementary, middle, and high schools to assess school health policies, practices, and activities. The 2016 SHPPS report noted improvements in policies and practices to prevent violence, bullying, and suicide. However, improvements are still needed in student health education, HIV/STD services, and substance use prevention.

DASH recently released *School Health Profiles–2016* in November 2017 that showed only a few schools teach key sexual health topics to their students. The survey is designed to analyze the components of school health policies and activities in individual jurisdictions. The key data points in the 2016 report include the median percent of middle schools teaching at least 19 sexual health topics (14 percent) and the median percent of high schools teaching all sexual health topics (38 percent).

DTBE released *Reported Tuberculosis in the United States–2016* in November 2017 that showed slow progress toward TB elimination. The surveillance report documented 9,272 TB cases in the United States in 2016. The national incidence of 2.9 TB cases per 100,000 people in 2016 reflected a small decrease of only 2.9 percent from 2015. This rate is too slow to achieve TB elimination in the current century. California, Florida, New York, and Texas accounted for the highest number of TB cases in 2016.

DTBE released two sets of TB infographics that highlight key surveillance data:

- the national TB infographic; and the
- state and local jurisdictions TB infographic can be customized for their specific needs.

DTBE Director's Report

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

Dr. LoBue covered three major areas in the DTBE Director's report to ACET: (1) CDC's FY2018 budget, (2) DTBE's key accomplishments in 2017 in five categories, and (3) DTBE's new activities in 2018.

CDC's FY2018 Budget

CDC and all other federal agencies operated under the first continuing resolution in FY2018 from October 1-December 8, 2017. The continuing resolution authorized essentially level funding and was extended until December 22, 2017.

DTBE's 2017 Programmatic Accomplishments

The 2016 TB surveillance report that was published in November 2017 showed the fewest number of cases and the lowest rate of TB since systematic data have been collected in the United States. The comprehensive report includes 67 tables of TB data, a surveillance slide set, and extensive information on genotyping and estimates of recent transmission.

The Regional Training and Medical Consultation Centers (RTMCCs) were rebranded as the "TB Centers of Excellence (COEs) for Training, Education, and Medical Consultation." DTBE completed the re-competition of this CoAg and will announce the results pending CDC's final financial negotiations.

Guidance was released, *Implementing an Electronic Directly Observed Therapy (eDOT) Program: A Toolkit for Tuberculosis Programs*, to provide TA in this area. Epi-Aids were conducted in Alaska to address TB in the homeless population and in Minnesota to address drug-resistant TB. A mini-stockpile of TB drugs is continuing to be maintained to address potential shortages. A turnover plan for expiring drugs was developed as well.

DTBE's 2017 Scientific Accomplishments

A new paper was published, *High Rate of Treatment Completion in Program Settings with 12-Dose Weekly Isoniazid and Rifapentine (3HP) for Latent Mycobacterium tuberculosis (MTB) Infection*. The paper documented that completion of 3HP by DOT in the study population was as good as or better than the results reported from clinical trials and much better than historically observed outcomes using other regimens, particularly among non-adherent populations.

The Tuberculosis Trials Consortium (TBTC) published a new paper on Study 33, *Self-Administered versus Directly Observed Once-Weekly Isoniazid and Rifapentine Treatment of Latent Tuberculosis Infection (LTBI)*. The paper demonstrated the use of self-administered 3HP as a potential alternative.

A benchmark was achieved with the enrollment of more than 1,000 participants in TBTC Study 31. The design of the clinical trial includes the evaluation of four-month TB treatments. Enrollment was initiated in New York City for the randomized trial of eDOT. The protocols were finalized for the economic evaluation of live or recorded eDOT versus in-person DOT.

DTBE'S 2017 LABORATORY ACCOMPLISHMENTS

The National Tuberculosis Molecular Surveillance Center was established at the Michigan Public Health Laboratory. Beginning in 2018, Michigan will perform whole-genome sequencing (WGS) of all isolates of MTB that are received from newly diagnosed patients. The Molecular Detection of Drug Resistance Service is continuing for health departments. In FY2017, 110 multidrug-resistant (MDR) isolates of MTB were detected or confirmed. Efforts are underway to continue to explore enhancements to improve the rapid detection of MDR-TB.

The existing partnership with the Association of Public Health Laboratories (APHL) was used to expand the number of low-volume public health laboratories that submit samples to the National Public Health Laboratory Drug Susceptibility Testing (DST) Reference Center at the California Microbial Diseases Laboratory. The APHL partnership also was used to begin coordinating TB testing for Puerto Rico with three state public health laboratories in Florida, Georgia, and Virginia in response to the aftermath of Hurricane Maria. A five-year analysis of trends in public health laboratory testing of MTB was published to describe the critical importance of public health laboratories as part of the national laboratory system.

DTBE'S 2017 COMMUNICATION AND EDUCATION ACCOMPLISHMENTS

The annual TB Program Managers Course was well attended in 2017 by state, regional, and large city TB program managers. A new awareness video, "5 Things to Know About Tuberculosis," was posted on the CDC.gov website and has received over 10,000 views to date. New content and videos were produced and will soon be posted on the CDC.gov website to highlight TB personal stories, particularly the experiences, challenges, and triumphs of four TB survivors. The personal stories have the capacity to educate diverse audiences, including patients, providers, and policymakers. Leadership was provided for World TB Day in March 2017 by conducting promotion and awareness activities and featuring success stories from 13 state and local TB elimination champions.

DTBE'S 2017 POLICY ACCOMPLISHMENTS

Official recommendations were released, *American Thoracic Society (ATS)/Infectious Diseases Society of America (IDSA)/Centers for Disease Control and Prevention Clinical Practice Guidelines: Diagnosis of Tuberculosis in Adults and Children*. A meeting was convened with external experts to develop *Updated Guidance for the Use of Isoniazid-Rifapentine Regimen to Treat Latent Mycobacterium tuberculosis*. The draft recommendations will be presented later in the meeting for ACET's review and input.

DTBE'S NEW ACTIVITIES IN 2018

DTBE medical officers and National Tuberculosis Controllers Association (NTCA) representatives jointly formed a new International Classification of Diseases (ICD)-10 Coding Workgroup to respond to ACET's previous guidance. The workgroup confirmed that the World Health Organization (WHO) adopted "LTBI" terminology in 2016 under the "carrier of infectious disease group" ICD-10 code. New LTBI terminology does not need to be proposed, but the workgroup found the current ICD-10 billing code for LTBI to be suboptimal. The North American Collaborating Center is housed in the CDC National Center for Health Statistics (NCHS) and can be used as a resource to offer clinical modifications to the current code.

The ICD-10 Coding Workgroup is drafting a set of clinical modifications to make the code more useful for U.S. practitioners. The workgroup is considering several key issues in this effort: (1) develop the proposed clinical modifications to be logical and user-friendly; (2) ensure the code is able to facilitate reimbursement; (3) ensure the code has the capacity to capture interferon gamma release assays (IGRAs) and tuberculin skin testing (TST) for the testing procedures and LTBI for the diagnosis (e.g., LTBI); and (4) ensure the code is able to facilitate surveillance of LTBI. After DTBE leadership and NTCA conduct a final review in January 2018, the draft clinical modifications will be proposed during the NCHS Coordination and Maintenance meeting in March 2018 for formal approval and adoption. The clinical modifications will become effective in October 2018.

Planning efforts to recompete the next 10-year cycle of the TBTC CoAg will be initiated in 2019 in preparation of the end of the current 10-year cycle in 2020. DTBE will convene an external peer review panel to obtain feedback on TBTC's ongoing activities, research priorities, future directions, and overall infrastructure. An update will be presented to ACET after the external peer review is held in April 2018.

NCHHSTP will convene the "Public Health and Primary Care: Partners in Prevention" meeting in January 2018. The purpose of the meeting will be to engage 10-15 leaders from national primary care organizations to exchange information on enhancing screening and referral to treatment for NCHHSTP's four diseases of interest. DTBE's role in the meeting will be to obtain external expertise in response to two key questions. First, how can primary care providers (PCPs) be engaged and encouraged to test at-risk populations for LTBI? Second, how can PCPs be encouraged to treat patients who are diagnosed with LTBI instead of referring these patients to health departments?

ACET DISCUSSION: DTBE DIRECTOR'S REPORT

ACET requested additional details on the following topics during the question/answer session with Dr. LoBue.

- The current progress on developing national measures for LTBI testing and treatment.
- CDC's representation at the "Global Ministerial Conference on Ending Tuberculosis in the Sustainable Development Era" in Moscow in November 2017 and the follow-up ministerial meeting that will be held at the United Nations in New York City in September 2018.

ACET GUIDANCE

- DTBE should ask the external peer review panel to provide input on whether pediatric TB clinical trials and studies should be prioritized in the next 10-year cycle of the TBTC CoAg.
- DTBE and state/local TB programs should take much more proactive and aggressive actions to widely publicize the 2016 U.S. Preventive Services Task Force (USPSTF) Grade B recommendation to screen adults at increased risk for LTBI. These activities should include targeted outreach, publications, and presentations to diverse groups to identify strong champions. These efforts might help to reinvigorate interest in developing national measures for LTBI testing and treatment. During NCHHSTP's Public Health/ Primary Care Partners meeting in January 2018, DTBE should obtain input from the external experts on the types of measures for LTBI testing and treatment that can be incorporated into and accepted by primary care settings.
- DTBE should invite the National Commission on Correctional Health Care (NCCHC) to attend NCHHSTP's Public Health/Primary Care Partners meeting in January 2018. People in correctional settings are a "forgotten" or "overlooked" population that has high rates of TB disease and LTBI. NCCHC is uniquely positioned to convey key primary care

recommendations from NCHHSTP's upcoming meeting to correctional settings across the country.

Update on CDC's TB Emergency Drug Stockpile

Carla Jeffries, MPH
Policy Analyst, Division of Tuberculosis Elimination
Centers for Disease Control and Prevention

Ms. Jeffries presented an update on CDC's TB emergency drug stockpile. TB drug shortages present major challenges for state and local health departments. Interruptions in the supply of drugs and biologics that are required for LTBI treatment, drug-susceptible TB disease, MDR-TB, and extensively drug-resistant TB can lead to multiple problems. These issues include increased opportunities for prolonged transmission of TB disease and substantial human resource needs at local, state, and national levels to respond to and mitigate acute and chronic shortages or stockouts.

The majority of TB control programs in the United States have experienced TB drug shortages that resulted in adverse outcomes for their individual jurisdictions and patients. Most notably, the shortage of isoniazid (INH) in 2012 required TB programs to change suppliers, provide drugs only to patients at highest risk, delay treatment of patients with LTBI, or transition to alternative LTBI treatment regimens.

In response to the INH shortage in 2012, a survey was administered to TB control programs in 2013. The survey showed that 81 percent of programs with MDR-TB cases reported second-line drug shortages and 79 percent of programs reported difficulties in obtaining INH (including 41 percent of programs with an expectation of an INH shortage within one month of the survey and 15 percent of programs with no INH at the time of the survey).

Congress appropriated $160 million for CDC's Antibiotic Resistance (AR) Solutions Initiative in FY2016. The purpose of this activity was to transform strategies for CDC and its public health partners to address and slow the growth of AR as well as to empower the U.S. response to AR. CDC allocated a portion of its appropriation to DTBE to establish the TB Emergency Drug Stockpile. These resources included AR Solutions Initiative funds of $1.9 million in FY2016 and a combination of AR Solutions Initiative/DTBE funds of approximately $2.37 million in FY2017.

Ms. Jeffries presented a flowchart of the TB Emergency Drug Stockpile to illustrate all of the steps that are involved in the activation process. The process begins when a grant recipient notifies DTBE of a drug shortage and ends when the HHS Supply Center delivers the requested drugs to the grant recipient's point of contact. DTBE uses the ATS/CDC Treatment Guidelines as a resource to prioritize patients if substantial TB drug shortages threaten a depletion of the stockpile. Priority 1 patients are those who are receiving treatment for active TB disease. Priority 2 patients are those who are receiving treatment for LTBI and are in one of the following categories: diagnosed during contact tracing of contagious TB, less than five years of age, or immunocompromised.

The TB Emergency Drug Stockpile maintains drugs in three categories. Rifampin (RIF) (40 percent of total doses) and INH (40 percent of total doses), including 300 mg and 100 mg (scored) for pediatric doses, are available as first-line drugs. Capreomycin (5 percent of total doses) and

amikacin (5 percent of total doses) are available as second-line drugs. Rifapentine (RPT) (10 percent of total doses) is available for LTBI.

DTBE's partners have various roles and functions in the TB Emergency Drug Stockpile. The U.S. Food and Drug Administration (FDA) verifies the nationwide manufacturing shortage. NTCA provides advice on the distribution, ordering, and other needs for TB drugs when a shortage is announced. The HHS Supply Service Center receives funding via an interagency agreement with CDC to purchase, store, distribute, and manage the inventory of the stockpile.

DTBE developed a plan to manage the expiration of TB drugs to ensure that the stockpile remains usable for as long as possible. An interagency agreement was established with the FDA to apply its Shelf-Life Extension Program that allows TB drugs to be stored under verifiable conditions and stamped as "usable" for a longer period of time than their original expiration dates. However, RIF is the only TB drug that is eligible for the FDA Shelf-Life Extension Program.

Grant recipients can request TB drugs through DTBE, but rigorous criteria are applied to distribute drugs that are approaching their expiration dates. First, programs must present evidence of a sufficient volume of TB patients in their jurisdictions and provide assurance that the requested drugs can be used by their expiration dates to treat these patients. Priority will be given to jurisdictions with the highest TB burden as reported to the National TB Surveillance System.

Second, the performance of programs in locating and treating patients and ensuring completion of therapy of all active TB cases in their jurisdictions must meet the National Tuberculosis Indicators Project measures. Programs with a completion of therapy rate of less than 85 percent for patients with newly diagnosed TB disease and for whom 12 months or less of treatment is indicated will not be eligible for drugs as direct assistance. Third, programs must present documentation of their capacity to secure a point of contact for the safe delivery of TB drugs.

For programs that meet these criteria, the TB consultant will apply standard operating procedures for the TB Emergency Drug Stockpile to authorize requests for drugs as direct assistance. DTBE also can transfer expiring drugs to other federal agencies and non-funded jurisdictions through the General Services Administration's Surplus Property Program.

ACET DISCUSSION: TB EMERGENCY DRUG STOCKPILE

ACET requested additional details on the following topics during the question/answer session with Ms. Jeffries and Dr. LoBue.

- The number of requests for drugs from the stockpile in FY2017.
- DTBE's plans to secure an ongoing, more stable funding stream for the stockpile in the future.
- DTBE's process to monitor a shortage of or distribution problems with TB drugs directly with the manufacturer.

Ms. Jeffries reported that steps already have been taken to address ACET's comments regarding the need for bidirectional communications between DTBE and TB programs. The current approach to manage the expiration of drugs in the TB emergency drug stockpile calls for programs to initiate the request by contacting DTBE. During the re-competition of the TB CoAg, however, DTBE will include the following new language in the Notice of Funding Opportunity (NOFO): "Direct assistance is available in the form of TB drugs."

Recommendations by the TB Funding Formula Workgroup

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

Dr. Chorba summarized the background and history of the TB Funding Formula Workgroup for Prevention and Control (P&C). The workgroup was established to improve strategies for the allocation of TB P&C funds. TB funding for human resources development is awarded based on incidence alone, while TB laboratory funding is determined through a separate formula. The TB P&C grant recipients include all 50 states, nine large cities, five territories, and three sovereign nations that were former territories.

DTBE introduced two performance-based components in FY2013 (e.g., completion of TB treatment and DST on isolates) and then took steps to accelerate 100 percent implementation of funding allocations by FY2015 based on the formula. To achieve this goal, the TB P&C Formula Workgroup was reconvened in June 2016 to improve the formula for implementation in FY2020. The workgroup established a major objective to guide its activities in 2016-2017. An updated formula would be recommended for the 2020-2024 TB P&C CoAg by assessing the impact of performance-based funding and the overall conversion on full formula-based funding.

The TB P&C Formula Workgroup's diverse membership reflects national coverage: Dr. Chorba (CDC) and Dr. Davidson (NTCA) as co-chairs; one representative from each of the TB programs in big cities as well as in high, medium, and low incidence states; one representative from NTCA and each of the five RTMCCs (now known as the TB COEs); and 10 CDC/DTBE leadership and staff.

Of the total budget of $84.5 million for the FY2015 TB CoAg, approximately $75.4 was allocated to TB P&C activities, including a set-aside of $917,242 for the Pacific Islands and $100,000 each to nine low-burden programs (or a total of $900,000). The remainder of the FY2015 TB CoAg funds was allocated to TB laboratory activities ($6.7 million) and training/education and human development (approximately $1.8 million). The breakdown of the FY2015 TB P&C funding formula is highlighted below.

Needs Component (80 percent or approximately $59 million)

- TB incidence (24 percent)
- TB in non-U.S.-born or U.S.-born minorities (24 percent)
- Smear-positive pulmonary TB (12 percent)
- MDR-TB (4 percent)
- HIV/TB comorbidity (4 percent)
- TB in homeless populations (4 percent)
- Substance abuse/TB comorbidity (4 percent)
- Follow-up of TB in immigrants and refugees (4 percent)

Performance Component (20 percent or approximately $15 million)

- Completion of TB treatment (15 percent)
- Reported DST (5 percent)

Peter Davidson, PhD (Workgroup Co-Chair)
Immediate Past President, National Tuberculosis Controllers Association
TB Program Manager, Michigan Department of Community Health

Dr. Davidson presented two tables to illustrate the differences in the components and weights between the FY2015 and the proposed FY2020 TB P&C funding formulas.

TB Prevention and Control Formula Element	FY2015 Weights (80%)	FY2020 Weights (76%)
Needs-Based Components and Weights		
TB incident cases	24%	39%
TB in non-U.S.-born and U.S.-born minorities	24%	8%
Sputum smear-positive TB cases	12%	12%
HIV/TB comorbidity	4%	0%
TB patients with medical risk factors: ➢ (Diabetes, HIV, end-stage renal disease, HCV, post-organ transplantation, other immunocompromised conditions)	0%	4%
MDR-TB	4%	5%
TB in homeless populations	4%	0%
Substance abuse/TB comorbidity	4%	0%
TB patients with social risk factors: ➢ (Homelessness, injection drug use (IDU), non-IDU, alcohol use)	N/A	4%
Class B arrivals	4%	4%

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

Dr. Davidson reviewed the TB P&C Formula Workgroup's recommendations to date that will be presented to DTBE for the 2020 TB P&C CoAg. The workgroup's consensus recommendations were designed to improve the equitability of the distribution of funds to TB programs. Most notably, the proposed changes will increase recognition of the importance of performance and emphasis on prevention; streamline and expand inclusion of medical and social factors; and ensure resources for maintaining capacity in states with low TB incidence.

The workgroup will recommend several changes from the FY2015 TB P&C funding formula, but the FY2020 formula will maintain its emphasis on performance and prevention. For example, the

12 percent weight for smear-positive pulmonary TB (i.e., the proxy for contact investigations) will not be changed. The current performance indicators will be maintained, including a proposed change in the weight for completion of TB treatment from 15 to 10 percent and no change in weight for DST of 5 percent. New prevention-focused performance indicators will be added: completion of LTBI treatment for TB contacts at a weight of 5 percent and completion of examination for Class B1 at a weight of 4 percent.

The recommended FY2020 TB P&C funding formula includes additional medical and social risk factors. HIV, at a weight of 4 percent, is the only medical risk factor in the FY2015 formula. The medical risk factor category will be maintained at a weight of 4 percent, but will be expanded to include HIV, diabetes, end-stage renal disease, post-organ transplantation, HCV, and other immunocompromised conditions. Homelessness and substance abuse, at weights of 4 percent each, are the only social risk factors in the FY2015 formula. The weight of 4 percent will be maintained in the FY2020 formula, but both social risk factors will be combined into one category and substance abuse will include IDU, non-IDU, and alcohol abuse. An analysis of current data showed that 95 percent of patients who reported homelessness also reported substance abuse.

The workgroup also will propose an increase in the funding threshold for the lowest-incidence states, from $100,000 to $125,000, to account for inflation from 2020-2024. The funding threshold will ensure that TB programs have adequate resources to maintain capacity, particularly to support one full-time nursing staff. Grant recipients will be programs for whom the formula calculation would award less than $125,000. Instead, these programs will receive the $125,000 threshold amount. In the current funding formula, seven to nine TB programs are eligible for the $100,000 funding threshold. Based on more recent modeling data, however, 13 TB programs will be eligible for the $125,000 funding threshold.

The workgroup considered other factors in its deliberations on the FY2020 TB P&C funding formula. For example, “burden” cases can significantly impact the resources of TB programs, such as the transfer of patients with MDR-TB to another jurisdiction during treatment; non-countable cases that are not considered in surveillance systems due to the lack of consistent data; and the secondary migration of immigrants and refugees.

The workgroup extensively discussed the results of TB cases and agreed not to split funding between programs. Most notably, the workgroup determined that awarding funding for MDR-TB cases based on the proportion of time patients spend in individual jurisdictions would not be a practical or equitable approach. Moreover, “secondary migration” data extracted from the CDC Electronic Disease Notification System do not correlate with the date patients move to the jurisdiction that provides services. The workgroup also acknowledged that the transfer of data on immigrants and refugees from the CDC Division of Global Migration and Quarantine (DGMQ) to DTBE is not sufficiently robust at this time to support an equitable split of funding.

The workgroup’s next steps will be to continue holding biweekly meetings through April 2018 to refine the final document and recommendations for presentation to DTBE. The workgroup will continue its efforts to determine cohort data for the new indicators, such as the medical risk factors, social risk factors, completion of LTBI treatment for TB contacts, and complete examination for Class B1. The workgroup also will assess the need to phase-in the FY2020 TB P&C funding formula to minimize disruptions to programs and develop a process if needed.

ACET DISCUSSION: TB P&C FUNDING FORMULA

ACET requested additional details on the following topics during the question/answer session with Drs. Chorba, Davidson, and LoBue.

- Potential opportunities for DTBE to scale-up funding for LTBI testing and treatment in the future.
- DTBE's ability to maintain the capacity of an increased number of TB programs in low incidence states from 2020-2024, particularly if CDC receives level funding or budget cuts during this time.
- The workgroup's rationale for the significant reduction in the weight for TB in non-U.S.-born and U.S.-born minorities: 24 percent in the FY2015 formula versus 8 percent in the proposed FY2020 formula.
- Alignment between the funding formula and the TB incidence of states.

ACET GUIDANCE

- The workgroup should make every effort to revise the funding formula to account for TB cases in correctional settings. These cases place a tremendous burden on TB programs, particularly contact investigations that are associated with individuals who are transferred to different correctional facilities with high-risk populations.
- The workgroup's recommendation to maintain the 5 percent weight for DST in the TB funding formula does not consider changes that are on the horizon. Most notably, multiple TB programs are likely to shift from the use of conventional DST to molecular testing modalities in the future. The TB funding formula should be revised to account for advancements in this area.
- The workgroup should expand the TB funding formula element of "medical risk factors" to include two additional categories: increased intolerance of TB drugs in the aging population and patients with an intolerance to TB drugs who actually are not, but are treated as MDR-TB cases.
- The workgroup's decision not to recommend splitting funds between programs in the TB funding formula is understandable. However, further deliberations are warranted by the workgroup on a scenario that frequently occurs between TB programs. For example, a TB patient will receive no treatment or services from Program 1, while Program 2 will actually provide care to the patient. Based on the proposed TB funding formula, Program 2 will receive no funds for its care of the patient and also will be unable to count the case in its TB morbidity rate. The workgroup should explore and recommend an equitable approach in the TB funding formula to account for this scenario.
- The workgroup should revise the TB funding formula to better reflect the denominator of TB cases in jurisdictions in addition to the numerator.

Dr. Davidson noted that ACET questioned whether the TB P&C Formula Workgroup addressed the performance of TB programs to routinely conduct nucleic acid amplification testing (NAAT) on sputum regardless of if the smear is positive or negative. He explained that this performance indicator is covered under the TB laboratory funding formula. He pointed out that an update on the TB funding formula for laboratory issues is scheduled on the current ACET agenda.

In response to Ms. Cole's questions regarding the workgroup's timeline, Dr. Davidson confirmed that the final draft of the recommendations on the FY2020 TB P&C funding formula will be ready to present to ACET during the April 2018 meeting. The workgroup will make additional revisions following ACET's discussion and submit the final recommendations to DTBE for approval.

Update by the TB Laboratory Funding Formula Workgroup

Angela Starks, PhD
Chief, Laboratory Branch
Division of Tuberculosis Elimination
Centers for Disease Control and Prevention

Advice requested from ACET by DTBE:

1. What are ACET's general comments in response to the overall presentation and the potential modifications to the TB laboratory funding formula?

Dr. Starks presented an update on the recent activities and progress of the TB Laboratory Funding Formula Workgroup. From 1992-2014, DTBE provided laboratory support for upgrades and enhancements to 50 states, the District of Columbia, six large cities, and Puerto Rico. The original focus of this funding was to improve laboratory performance through the use of rapid methodologies and other state-of-the-art technologies, such as liquid culture and fluorescence microscopy. However, DTBE incorporated a workload-based formula with multiple variables in FY2011 and shifted the focus of the CoAg from implementing state-of-the-art technologies to strengthening the capacity of laboratories in FY2015.

The Laboratory Formula Workgroup reviewed the existing funding formula to shift from a narrow incidence-based perspective to a full perspective of all TB activities that are conducted by laboratories. The workgroup's deliberations included the funding floor, the evolving role of public health laboratories, and declining test volumes in some jurisdictions. The workgroup's efforts were parallel to those by the TB P&C Formula Workgroup.

The membership of the Laboratory Formula Workgroup includes 10 representatives from laboratories with low, medium, and high testing volumes as well as six representatives collectively from NTCA, APHL, and the DTBE Laboratory Branch. The workgroup extensively communicated through conference calls and emails from July-November 2017 to begin fulfilling its charge. The workgroup identified several key questions to consider during its deliberations.

- Does the current formula need revision? What additional data, such as information on IGRAs, might be available for consideration as part of the formula? Should any elements of the formula be adjusted based on referrals to the National DST Reference Center?
- Should the funding floor of $35,000 be maintained? Does a more efficient, beneficial strategy exist to support lower volume laboratories?
- Does the current approach of basing the formula calculations on a three-year rolling average of data need to be reevaluated?
- Given the shrinking total budget that is spread over 58 jurisdictions, should CDC continue to fund all jurisdictions or consider other alternative service delivery approaches?

The Laboratory Formula Workgroup developed the following evaluation process: review the historical impacts of the formula, brainstorm alternative variables and approaches to the formula, assess the impact on funding amounts for different calculations (e.g., changing the weight of a specific variable), and consider the future role of public health laboratories in TB testing. The current weights of the six TB laboratory formula elements and their corresponding amounts are set forth in the table below.

TB Laboratory Formula Element	Amount	Amount Per Site
Laboratory Funding Formula: $6.7 Million		
Total number of clinical specimens (10%)	$670,000	Proportion of element
Number of individual patients for whom a clinical specimen is processed and TB culture is inoculated (15%)	$1,005,000	Proportion of element
Number of individual patients for whom a reference isolate is received to rule out or confirm identification of the MTB complex (15%)	$1,005,000	Proportion of element
Patient access to NAAT for direct detection of the MTB complex from a clinical specimen based on volume and positivity (25%)	$1,675,000	Initial amount based on volume tiers; remainder based on NAA positivity
Number of individual patients for whom drug susceptibility testing is performed for first-line drugs (25%)	$1,675,000	Proportion of element
Development of an integrated laboratory system (10%)	$670,000	3 tiers based on the number of TB cases

The Laboratory Formula Workgroup made the following recommendations in response to the key question of whether the current laboratory funding formula needs modification. The formula element weights will not change, but the calculation method for the laboratory system element will be revised. The funding calculations used for laboratories that make referrals to the National DST Reference Center will remain the same. The use of IGRAs and molecular DST were considered, but were not included in the laboratory funding formula.

The Laboratory Formula Workgroup made the following recommendations in response to other issues that were considered. The funding floor of $35,000 should be maintained. The three-year average of workload data should continue to be used for formula calculations. Minimal funding should be maintained, but core services might be reevaluated based on the volume of an individual laboratory. The workgroup acknowledged that the loss of TB laboratory capacity will be a disservice to public health in general and individual states in particular.

Overall, the intent of TB laboratory funding continues to focus on strengthening laboratory services. The current laboratory formula appears to be appropriate for the next funding cycle and needs only one minor modification (e.g., three tiers for the development of an integrated laboratory system). The funding floor of $35,000 should be maintained. Core services and data collection should be reevaluated to account for the changing landscape, such as a shift to using molecular DST. Because referrals are an essential component of the national laboratory system, strong relationships with external laboratories will continue to be critical to ensure quality testing.

ACET GUIDANCE: TB LABORATORY FUNDING FORMULA

- The workgroup should reconsider its recommendation to maintain the funding floor of $35,000. This amount is extremely low and does not cover the basic cost of maintaining a facility or laboratory staff.

- The workgroup should review the "true needs" budgets that are submitted by laboratories to CDC to determine whether any of these items could be incorporated into and supported by the TB laboratory funding formula.
- The workgroup should reconsider its recommendation not to include the use of IGRAs in the TB laboratory funding formula. TB programs are unable to make significant progress in LTBI testing because no funding is available for the cost of IGRAs. The workgroup also should assess the level of compliance with the USPSTF recommendation for private rather than public health laboratories to pay the cost of IGRAs.
- Smear-positive and culture TB results should be included in the funding formula as in-house, core components of TB laboratories. This approach will help to minimize the cost, delays, and other efforts involved with shipping specimens to other laboratories.

Dr. Starks made several comments in follow-up to ACET's questions and guidance. DTBE asks laboratories to submit a "true needs" budget to cover items that are beyond the scope of the TB laboratory CoAg funds, such as additional equipment or operating costs. However, the DTBE budget has not been adequate over the past few years to support the "true needs" of laboratories in addition to the core components of the CoAg.

Dr. Starks reported that the TB Laboratory Formula Workgroup did not propose concrete solutions or recommendations to address consolidation. The workgroup recognized that caution must be taken on this sensitive issue because low-volume public health laboratories have emphasized the critical need to maintain their core capacity in terms of providing ongoing support to staff and local TB control programs.

The workgroup also acknowledged that DTBE already is leveraging opportunities to consolidate TB laboratory services as a cost-saving measure, particularly since the number of low prevalence states and territories will continue to increase over time. Most notably, DTBE and APHL collaborated to expand the number of low-volume public health laboratories that submit samples to the National Public Health Laboratory DST Reference Center. "Low-volume" laboratories are defined as those that perform DST on fewer than 50 isolates per year. At this time, the 13 or 14 laboratories that are enrolled users of the National DST Reference Center are referring MTB isolates to obtain access to first-line DST, second-line DST, and pyrosequencing as needed.

DTBE's Whole-Genome Sequencing Data Sharing Plan

James Posey, PhD
Applied Research Team Lead
Division of Tuberculosis Elimination
Centers for Disease Control and Prevention

Advice requested from ACET by DTBE:
1. What are ACET's comments and feedback on DTBE's implementation plan for universal WGS of MTB in the United States?

Dr. Posey presented DTBE's WGS data sharing plan in response to ACET's request for this agenda item during the August 2017 meeting. DTBE will launch prospective universal WGS of all culture-confirmed TB cases in March 2018. As part of this activity, DTBE developed a plan to place WGS data in the public domain. After DTBE leadership gave its formal approval, the WGS

data sharing plan was presented to the NTCA membership in April 2017 and the NTCA Board in November 2017.

The federal government has a long history of creating policies, memoranda, and plans to place federally funded data into the public domain for use by the broader scientific community. For example, CDC issued a data policy in 2005. The White House Office of Science and Technology Policy implemented a policy in 2013 to increase access to the results of federally funded scientific research. CDC released a plan in 2015 to increase access to its funded scientific publications and digital science data. The Congressional appropriation for the 2013-2018 Advanced Molecular Detection Initiative called for CDC to place key data and findings from this activity in the public domain.

DTBE outlined three key components in the WGS data sharing plan. First, the types of WGS data that will be shared will include raw sequencing file data and limited metadata. Second, DTBE will collect WGS data for a period of 18 months and then release the data in the public domain on a quarterly basis. Third, the National Center for Biotechnology Information BioProject will serve as the public domain of the WGS data to ensure open access. However, the WGS data sharing plan will not interfere with the ability of TB programs to access their individual datasets. The DTBE Surveillance, Epidemiology, and Outbreak Investigations Branch currently is designing a platform to share the datasets with its grant recipients.

Dr. Posey reported that DTBE expects to enter 9,000 whole-genome sequences per year into the public domain. He presented a table to illustrate the required information that the research and scientific communities must provide to gain access to the WGS metadata in the public domain.

Data Field	Data Entry
Sample name	CDC0000001 ➢ The randomized number will ensure that the data are not linked to the information of a particular patient.
Organism	*Mycobacterium tuberculosis* complex
Collected by	CDC
Collection date	Year sequenced ➢ The year will be used to prevent the use of identifiable information.
Geographic location name	USA
Host	Homo sapiens
Host disease	Tuberculosis
Isolate source	Sputum or tissue with anatomic code ➢ Report of Verified Case of Tuberculosis (RVCT) data, line-items 18 and 19
Latitude/longitude	"Missing"
Strain	"Missing"
Isolate	"Missing"
Antibiogram	Initial DST result ➢ RVCT data, line-item 40
Country of birth	WHO region

ACET DISCUSSION: WGS DATA SHARING PLAN
ACET requested additional details on the following topics during the question/answer session with Dr. Posey.

- DTBE's intended use of the WGS data in the public domain (e.g., research and surveillance purposes).
- DTBE's recent meeting with scientists in England on their ongoing preparations to implement universal WGS.

Update on CDC's 3HP Guidelines

Andrey Borisov, MD, MPH
Medical Epidemiologist
Division of Tuberculosis Elimination
Centers for Disease Control and Prevention

Advice requested from ACET by DTBE:
1. What are ACET's general comments on CDC's updated 3HP recommendations?
2. What is ACET's input on the uptake and potential impact of CDC's updated 3HP recommendations?
3. Are CDC's updated 3HP recommendations aligned with the strategy of eliminating TB in the United States?

Dr. Borisov presented an update on *CDC's Recommendations for the Use of Once-Weekly Isoniazid-Rifapentine Regimen to Treat Latent Mycobacterium tuberculosis Infection*. In 2011, CDC recommended the short-course, 12-week 3HP regimen by DOT for the treatment of LTBI in the United States. The guidelines limited the use of 3HP in certain populations, such as children under 12 years of age and people living with HIV/AIDS (PLWHA). The guidelines also limited the administration of 3HP by DOT only.

In 2017, CDC convened a steering committee with DTBE leadership and staff to review and update the 2011 3HP guidelines. The steering committee identified two key areas to address in its deliberations: expanded use of 3HP in vulnerable populations and self-administration of the 3HP regimen. The steering committee's methodology included conducting a systematic review and meta-analyses using the *Guide to Community Preventive Services*. The literature search covered the publication of studies from 1995 to June 2017.

As part of the literature search, two reviewers independently screened citations and abstracted data on the characteristics of interventions, demographics, benefits, harms, considerations for implementation, and gaps in evidence. The key outcomes of interest included the prevention of TB, treatment completion, adverse events (AEs) due to 3HP, discontinuation of 3HP due to AEs, or death while on the 3HP regimen. Each study was assessed for its internal and external validity. The steering committee submitted results of the systematic review for publication in the *American Journal of Preventive Medicine*.

DTBE held an in-person consultation with eight subject-matter experts (SMEs) with backgrounds and expertise in the following disciplines: diagnosis, treatment, and prevention of TB and LTBI, epidemiology, clinical research, pediatrics, HIV/AIDS, public health programs, and patient advocacy. The major topics that were presented during the expert consultation included the

results of the steering committee's systematic review and meta-analyses, findings of large randomized controlled trials (RCTs), and the draft 3HP recommendations.

The SMEs were asked to provide their individual perspectives; describe their experiences with implementing the current 3HP regimen in various programmatic settings and populations; and offer their individual viewpoints on proposed updates to the 2011 3HP guidelines. The SMEs described the benefits of 3HP, particularly increased acceptance of the regimen and completion of treatment. However, limited uptake of the regimen was noted due to the 2011 recommendation to administer 3HP by DOT only. CDC's four updated 3HP recommendations are summarized below.

1. **CDC continues to recommend the use of 3HP for the treatment of LTBI.**
   Rationale:
   - Evidence from the systematic review and meta-analyses on the effectiveness, safety, and treatment completion rates of 3HP support the recommendation.
   - The individual viewpoints of the SMEs were thoughtfully considered.

2. **CDC recommends the use of 3HP by DOT in people 2-17 years of age.**
   Rationale:
   - A large RCT with children 2-17 years of age (with approximately 50 percent of cohort 2-11 years of age) reported two major findings. First, 3HP was as well tolerated and effective as nine months of daily isoniazid (9H) for preventing TB in children with LTBI. Second, 3HP was safe and had higher treatment completion rates than 9H.
   - Some SMEs reported that several health departments currently are using 3HP in children as young as 2 years of age and have observed high treatment completion rates.
   - Data are not available on the use of 3HP by self-administered therapy (SAT) in children or on the safety and pharmacokinetics of RPT in children younger than 2 years of age.

3. **CDC recommends the use of 3HP in PLWHA who have LTBI and are on antiretroviral therapy (ART) with acceptable drug-drug interactions with RPT.**
   Rationale:
   - CDC's systematic review and meta-analyses showed that 3HP is effective in PLWHA who are taking ART. Clinically significant drug interactions between once-weekly RPT and either efavirenz or raltegravir were not reported.
   - The *HHS Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV* are frequently updated and provide information on drug-drug interactions between anti-TB agents and antiretroviral agents.
   - The use of concomitant LTBI treatment and antiretroviral agents should be guided by clinicians who are experienced in the management of both conditions.

4. **CDC recommends the use of 3HP by DOT or SAT in people 18 years of age and older.**
   Rationale:
   - TBTC Study 33 demonstrated non-inferiority in the efficacy and safety of 3HP-SAT compared with 3HP-DOT in people over 18 years of age in the United Sates.

- Health programs may consider their programmatic operations and available resources in choosing between 3HP-DOT and 3HP-SAT for LTBI treatment.
- Healthcare providers (HCPs) should make decisions with each individual patient and consider the patient's medical history, social circumstances, and risk factors for progression to development of TB.
- No data have been reported from RCTs on the use of 3HP-SAT in people less than 18 years of age.

In addition to the four specific recommendations, CDC's updated 3HP guidelines also will include broad, overarching guidance.

3HP IMPLEMENTATION (EDUCATION, DRUG INTERACTIONS, MONITORING, AND REPORTING)
The SMEs emphasized the importance of educating HCPs and patients about 3HP. In response to this input, DTBE will revise its webpage, Latent Tuberculosis Infection: A Guide for Primary Health Care Providers, to include additional educational resources on 3HP-SAT for HCPs and patients

Data will be referenced to show that less than 3.5 percent of patients on 3HP experience systemic drug reactions (SDRs) and approximately 5 percent of patients discontinue 3HP due to AEs. Reports of hypotension and syncope have been rare (e.g., 2 cases per 1,000 population). If symptoms occur that are suggestive of an SDR, patients should stop the 3HP regimen while the cause is being determined. In most cases, however, symptoms will resolve without treatment within 24 hours.

Because RPT induces the metabolism of multiple medications, monitoring should be performed when 3HP is prescribed with affected medications, such as methadone or warfarin. Women who use any form of hormonal birth control should be advised to add or switch to a barrier method. Patients on 3HP-SAT should be encouraged to record their medication intake and report any deviations from the prescribed regimen to their HCPs. At a minimum, monthly in-person patient evaluations should be performed for people on 3HP-DOT and 3HP-SAT to assess their adherence and AEs as well as to receive pertinent educational messages from their HCPs.

Any AEs that are associated with LTBI treatment and lead to hospital admission or death should be reported to local or state health departments for inclusion in the CDC National Surveillance System for Severe Adverse Events Associated with Treatment for Latent Tuberculosis Infection. Serious drug side effects, medication errors, product use errors, product quality problems, and therapeutic failures should be reported to the FDA MedWatch Safety Information and Adverse Event Reporting Program.

3HP GUIDANCE TO HCPS (EARLY DETECTION AND MANAGEMENT OF AES)
Clinical vigilance should be applied to determine whether patients, particularly pediatric patients, are exhibiting signs and symptoms of active TB disease. Patients should be informed of possible AEs and given instructions to seek medical attention at the first appearance of these symptoms. A clinical assessment should be conducted for patients when the first sign or symptom of a possible AE occurs. Monthly interviews and physical examinations should be performed to detect treatment-associated AEs in patients who are on the 3HP regimen (e.g., SDRs, loss of appetite, vomiting, yellow eyes, tenderness of the liver, easy bruising, or rash).

Baseline hepatic chemistry blood tests (e.g., aspartate aminotransferase (AST) at a minimum) should be ordered for patients with specific conditions: HIV infection, the immediate postpartum

period (i.e., 3 months or less after delivery of the infant), liver disorders, regular alcohol usage, intravenous drug use, or uptake of medications with a known possible interaction with INH or RPT. A baseline hepatic chemistry blood test should be considered on an individual basis for older patients, particularly those who are taking medications for chronic medical conditions.

Blood tests should be conducted at subsequent clinical encounters for patients whose baseline testing is abnormal and for other patients who are at risk for liver disease. The 3HP regimen should be discontinued if a serum AST is 5 times or more the upper limit of normal or 3 times or more the upper limit of normal in the presence of symptoms. All patients should be evaluated for signs and symptoms of active TB disease before and during treatment of LTBI.

The 3HP regimen should be discontinued and supportive medical care should be provided in cases of a possible severe adverse reaction, such as hypotension that requires intravenous fluid support. For cases of mild to moderate reactions to 3HP, such as constitutional symptoms, a conservative management approach should be applied (e.g., rest and oral fluids to treat dizziness); clinical and laboratory monitoring should be performed; and the continuation of treatment should be considered under observation.

Overall, CDC's updated 3HP guidelines will continue to recommend the use of the short-course, 12-week 3HP regimen for the treatment of LTBI. The guidelines also will emphasize CDC's updated 3HP recommendations in the areas of age limits, HIV infection, and treatment administration: (1) the use of 3HP by DOT only in children 2-17 years of age; (2) the use of 3HP in PLWHA with LTBI who are taking antiretroviral medications with acceptable drug-drug interactions with RPT; and (3) the use of 3HP by DOT or SAT in people 18 years of age and older.

Dr. Jonathan Mermin, Director of NCHHSTP, joined the meeting and made several comments for ACET to consider in its discussion. He questioned the recommendation in CDC's updated guidelines that will call for HCPs to perform monthly in-person evaluations of their patients who are on 3HP-DOT and 3HP-SAT. As a more feasible approach, he raised the possibility of revising the language for HCPs to assess their patients via electronic, video, or other technology. For example, patients who are on 3HP-SAT could use their Smartphones to regularly upload and send photographs of themselves to their treating physicians. He was concerned that the recommendation for monthly in-person evaluations will be expensive, time-consuming, and severely limit broad uptake of the regimen to an estimated population of several million people in the United States.

ACET GUIDANCE: CDC'S UPDATED 3HP GUIDELINES

- DTBE should reach out to the Federal Bureau of Prisons to obtain its input, support, and formal endorsement of CDC's updated 3HP guidelines before the document is published.
- The language in Recommendation 4 should be changed as follows: "TBTC Study 33 demonstrated non-inferiority in the completion and safety of 3HP-SAT …".
- DTBE plans to take a reactive approach by responding to 3HP-related AEs that are reported to FDA MedWatch. However, DTBE should take a proactive approach by monitoring prospective cohorts that are on 3HP-SAT in multiple jurisdictions to identify and respond to the occurrence of AEs. This approach is needed because patients on SAT are not monitored as frequently and might develop serious AEs that were not detected in the past. For example, patients in the 3HP clinical trial might have been routinely monitored on a weekly basis.
- The updated CDC guidelines will recommend the use of 3HP in people 2-17 years of age by DOT only. The rationale for the age restriction is that no data have been reported from

RCTs on the use of 3HP-SAT in people less than 18 years of age. However, the exclusion of children from TBTC Study 33 was unethical and bordered on immoral. No safety issues or other fundamental reasons were reported to support the exclusion of children from the study. Children have the same rights as adults to benefit from TB care and research, but HCPs must now make clinical decisions on the use of 3HP-SAT in children without data. CDC's updated guidance on not using 3HP-SAT in children is questionable because the regimen is recommended for use in other populations that were not included in TBTC Study 33. Overall, CDC's restriction of the use of 3HP-SAT to people 18 years of age and older in its updated guidelines should be reconsidered. The unintended consequences of eliminating the ability of children to receive 3HP-SAT will cause more harm than benefit. Most notably, CDC's efforts to protect a vulnerable population are commendable, but the evidence shows that 3HP is effective in preventing TB disease in children with LTBI due to high treatment completion rates. No evidence has been reported to date to show that children do not tolerate 3HP or have a higher AE profile than adults who are on the regimen. Moreover, CDC's direct guidance to HCPs will recommend monthly in-person evaluations of patients who are on 3HP-SAT to ensure adherence to the regimen and facilitate early detection and management of AEs. California and other jurisdictions already are administering 3HP-SAT to their pediatric TB patients.

- Some ACET members considered and responded to Dr. Mermin's comments. The recommendation for HCPs to perform monthly in-person evaluations of their patients who are on 3HP-DOT and 3HP-SAT should be maintained in CDC's updated 3HP guidelines. For example, New York City has received multiple reports of pharmacists incorrectly giving TB patients RIF for their RPT prescriptions. Patients also can be easily confused by the 3HP regimen of one dose per week over a 12-week period. Tremendous education on properly taking the 3HP regimen, close monitoring, and follow-up of patients will be necessary to detect and manage AEs. Moreover, wide-scale telemedicine-based approaches will be extremely difficult to implement in a population that is estimated to include several million people.
- CDC's updated 3HP guidelines will include a link to the *HHS Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV* for clinicians to obtain information on drug-drug interactions between anti-TB agents and antiretroviral agents. The 3HP guidelines also will reference data to show that clinically significant drug interactions between once-weekly RPT and either efavirenz or raltegravir have not been reported. Instead of providing a link to the HHS guidelines, new language should be included in the 3HP guidelines on drug interactions between RPT and more commonly used antiretroviral agents. Most notably, efavirenz and raltegravir are no longer commonly used as antiretroviral medications for PLWHA.
- The target audience for messaging and communications should be clearly defined prior to the release of the recommendation on 3HP-SAT. For example, primary care and family practice physicians have no experience or knowledge in writing a prescription for "INH 900 mg + RPT 900 mg q week." SAT is a liberating approach that will make progress in the treatment of LTBI in the United States, but the prescribers likely will not be the broad group of primary care or family practice physicians. As a result, messaging and communications on prescribing 3HP-SAT should be targeted to a subset of specialty physicians.

Dr. LoBue provided several remarks in response to some of the comments and concerns that ACET raised during the discussion.

- CDC took a conservative approach in not recommending 3HP-SAT for children less than 18 years of age due to external feedback from the broader TB control community and the significant concerns that were raised regarding AEs.
- The link to the HHS guidelines will be included in the 3HP guidelines because this living document is frequently and easily updated electronically. DTBE has been unable to apply the "living document" approach to its major TB guidelines due to strong opposition by external partners that serve as coauthors, particularly ATS and IDSA. To develop future TB guidelines as living documents, DTBE would be required to dissolve its relationships with ATS/IDSA and serve as the sole author.

Dr. Mermin also responded to ACET's concerns regarding CDC's recommendation to use 3HP-SAT in people 18 years of age and older. If the language is revised to allow the use of 3HP-SAT in children, he noted that cohort evaluations could be performed to document actual treatment completion rates of the regimen in pediatric populations. The data also could play an important role in changing clinical practice.

Overview of the NCHHSTP Program and Performance Improvement Office (PPIO)

Patricia Dietz, DrPH
Associate Director, NCHHSTP Program and Performance Improvement Office
Centers for Disease Control and Prevention

Dr. Dietz presented an overview of PPIO's purpose, primary functions, and ongoing activities. The *NCHHSTP Strategic Plan Through 2020* established a vision and framework for "achieving a future free of HIV, viral hepatitis, STDs and TB." The Strategic Plan emphasizes HIP as a guiding principle and highlights six key strategies: the use of data for program improvement; scientific discovery and evaluation; increased knowledge and adoption of healthy behaviors; prevention through health care; program collaboration and service integration (PCSI); and organizational excellence.

PPIO was established to support the NCHHSTP divisions by improving their efficiency, outcomes, and impact. PPIO achieves this goal by conducting activities in four major categories.

STRENGTHEN MODELING AND DATA USE
PPIO oversees the NCHHSTP Epidemiologic and Economic Modeling Agreement (NEEMA) that CDC is funding to identify the most cost-effective approaches to reducing HIV, viral hepatitis, STDs, and TB. The purpose of NEEMA is to improve national, state, and local approaches to prevention and interventions to decrease incidence, morbidity, mortality, and health disparities. The three grant recipients (e.g., Emory, Harvard, and the University of California, San Francisco [UCSF]) partner with NCHHSTP staff from all divisions. Year 4 of the five-year NEEMA CoAg is underway. The project period will end in September 2019.

NCHHSTP increased NEEMA funding from $3.5 million in year 1 to $4.7 million in year 4. The NEEMA grant recipients have made several notable accomplishments to date, such as 22 ongoing projects, including 12 new projects in year 4 alone; 32 abstracts; 30 published, accepted, or pending manuscripts; and four tools that are completed or currently are being developed.

The NEEMA projects have influenced public health in several areas. For example, a NEEMA project determined that catch-up HAV vaccination was not cost-effective and reaffirmed the current recommendations. A NEEMA project currently is estimating the number of LTBI residents in California by state and county. This project will assist states in advocating for resources and initiating their programmatic planning efforts.

Several NEEMA projects are identifying a combination of interventions that are cost-effective and provide information to affect policy and programs. These projects are designed to estimate the costs of recruiting, testing, and treating LTBI in non-U.S.-born populations. UCSF's TB elimination model influenced the development of California's TB Elimination Plan and Medicaid policy. Most notably, RPT is now accessible in Medi-Cal managed care plan formularies. California also directed health plans in the state to ensure coverage of LTBI testing and treating in their contracts. on NEEMA are available on NEEMA's website.

PPIO uses data and indicators to monitor the performance of grant recipients of NCHHSTP divisions. These data include *Progress Toward Viral Hepatitis Elimination in the United States, 2017* (DVH); TB State Progress Reports (DTBE); and Rapid Feedback Reports (RFRs) (DHAP).

PPIO oversees NCHHSTP's data-driven reviews (DDRs) with a multidisciplinary group of staff from both the center and division levels. The DDR is an ongoing collaborative review of data that is designed to improve NCHHSTP's effectiveness in select areas by exploring three key questions: (1) What are the current trends? (2) What is driving the trends? (3) What actions can be taken to improve the trends? PPIO intends to explore these data in further detail and develop a DDR plan or guidance.

The DDRs have been useful in aligning the priorities of NCHHSTP senior management with the indications of the data; increasing NCHHSTP's focus on important issues; and identifying new strategies, initiatives, and internal guidance for NCHHSTP. Examples of topics that have been driven by DDRs at both the center and division levels are highlighted below.

- *NCHHSTP:* Well-being of individual employees and the overall workforce, human resource issues, pre-clearance guidance, and a process to resolve disagreements between authors and reviewers of pending publications.
- *DHAP:* Release of a NOFO targeting Hispanic MSM, data-to-care initiatives, health department RFRs, and community-based organization RFRs.
- *DSTDP:* Supplemental funding awards to address congenital syphilis, current trends in chlamydia, and syphilis among MSM.
- *DTBE:* Current trends in TB and upcoming state trends and performance in TB.
- *DVH:* Current trends in acute HCV and HCV-related deaths.

PPIO oversees the release of and updates to AtlasPlus. This platform is available to the public to review and download NCHHSTP's HIV, viral hepatitis, STD, and TB surveillance data. Depending on the indicator, state- and county-level data currently are available from 2000-2016. AtlasPlus stratifies data by age, race/ethnicity, gender, transmission category (for HIV), and country of origin. However, state-/county-level surveillance data and data stratifications are not available for viral hepatitis.

AtlasPlus is designed for users to create maps, charts, and tables. AtlasPlus will be expanded in February 2018 to include new social determinants of health indicators, such as poverty, education, rural/urban communities, housing vacancy, and uninsured populations.

ENHANCE PCSI

PPIO oversees the integrated U.S-Affiliated Pacific Island (USAPI) NOFO. The small, resource-limited USAPIs previously were required to submit four different applications to NCHHSTP to receive funding for their HIV, viral hepatitis, STD, and TB activities. In 2013, however, NCHHSTP streamlined the application process and reporting systems for the USAPIs. The goal of this PCSI initiative is to eliminate duplication, enhance synergies, identify areas for improvement within healthcare systems, and increase the capacity of healthcare systems to prevent, manage, and respond to HIV, viral hepatitis, STDs, and TB.

The new cycle of the USAPI NOFO will begin in January 2018 with six grant recipients: American Samoa, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Guam, Palau, and Republic of the Marshall Islands. A total of $20 million will be awarded to the USAPIs over the five-year project period. The grant recipients will use their funds to (1) improve the efficient use of resources through integrated screening and treatment of HIV, STDs, TB, and viral hepatitis among people in the USAPIs with similar risk factors; (2) reduce health disparities among USAPI residents; (3) strengthen the infrastructure and service delivery of USAPI health systems; and (4) decrease the incidence of HIV, STDs, TB, and viral hepatitis in USAPI communities.

PPIO conducts other PCSI activities across NCHHSTP. Quarterly meetings are held with NCHHSTP project officers and program consultants to provide training and share information on key topics, such as data visualization and the use of data to improve program outcomes. Site visits are coordinated to identify successes, determine major barriers, and encourage appropriate collaborative efforts across NCHHSTP. "PCSI 2.0" was launched by interviewing NCHHSTP branch chiefs on the usefulness of PCSI and developing a list of core PCSI components that will be approved by NCHHSTP division directors and promoted among grant recipients.

MAXIMIZE OPPORTUNITIES IN HEALTHCARE SYSTEMS

PPIO oversees NCHHTP's collaborative efforts with health systems. For example, NCHHSTP represents CDC on the federal HIV Health Improvement Affinity Group (HHIAG) with HHS, the Health Resources and Services Administration (HRSA), and the Centers for Medicaid & Medicare Services. The HHIAG successfully convened state public health and Medicaid/Children's Health Insurance Program (CHIP) agencies in 19 states to identify opportunities to improving sustained virologic suppression rates among Medicaid/CHIP enrollees who are living with HIV.

NCHHSTP's involvement in other multi-state learning collaboratives includes the Hepatitis C Medicaid Affinity Group, the School-Based Health Affinity Group, and the Pre-Exposure Prophylaxis Health Policy Learning Series. NCHHSTP also conducts other quality improvement activities with Medicaid.

NCHHSTP will convene the "Public Health and Primary Care: Partners in Prevention" meeting on January 23-24, 2018. The purpose of the meeting will be to engage external experts from national primary care organizations. The participants will exchange information on opportunities to enhance screening of HIV, HBV/HCV, STDs, and LTBI within primary care settings and ensure appropriate treatment for people who are infected. NCHHSTP has extended invitations to the following organizations:

- American Medical Association
- American Academy of Family Physicians
- American College of Physicians
- American Association of Nurse Practitioners

- American Academy of Pediatrics
- American Academy of Physician Assistants
- American College of Obstetricians and Gynecologists
- Society for Adolescent Health and Medicine
- National Hispanic Medical Association
- National Council of Asian & Pacific Islander Physicians
- National Association of Community Health Centers

SUPPORT HIP

PPIO oversees NCHHSTP's HIP activities. HIP is an approach to disease prevention that supports the implementation of proven, cost-effective, and scalable interventions with available resources to prevent the greatest amount of infections or reduce disparities. PPIO's role in this effort includes aligning the NOFOs of individual divisions with the NCHHSTP 2020 Strategic Plan and HIP initiatives. To achieve this goal, PPIO uses a logic model as a framework to outline detailed strategies and activities; clearly defines targets and performance measures; and includes language in NOFOs for CDC to provide RFRs to grant recipients on their program performance, including their progress toward meeting the HIP targets.

NCHHSTP launched its new High Impact Prevention (HIP) website on December 4, 2017 with three key tabs for additional information: "Questions and Answers about HIP;" "HIP Case Studies;" and "HIP Resources, Tools, and Models." Dr. Dietz concluded her overview by presenting an organizational chart of the PPIO staff.

ACET's Strategic Planning Discussion: Part 1

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

Advice requested from ACET by the Chair:
1. What additional actions are needed for ACET's current priorities?
2. What issues should be included as top priorities in ACET's 2018-2019 Strategic Plan?

Ms. Cole facilitated part 1 of ACET's strategic planning discussion. However, she first reviewed several changes that have been made over time to improve the organizational structure of ACET meetings and strengthen the overall productivity of the membership.

- An Agenda Setting Workgroup was formed that convenes teleconferences after each ACET meeting. The workgroup drafts future meeting agendas based on ACET's requests for specific presentations or updates and other topics that are relevant to TB elimination.
- A standing agenda item, "Advice Requested from ACET," is held during each meeting to ensure that ACET responds to or takes formal action on requests for its input by CDC and individual DTBE programs.
- Updates by the DTBE Director and program staff are presented during each meeting to highlight actions that were taken in direct response to ACET's formal resolutions and/or guidance. Based on ACET's recommendation, for example, DTBE and NTCA formed a new ICD-10 Coding Workgroup to modify the current billing codes to better address LTBI. Moreover, NTCA will administer a survey to the TB control programs in the United States

to support ACET's recommendation for DTBE to revise the current Aggregate Report for Tuberculosis Program Evaluation (ARPE) form.

Ms. Cole announced that part 1 of the strategic planning discussion would focus on a systematic review of ACET's current charter and a self-evaluation on the performance of the membership. To conduct the self-assessment, she pointed out that a document was created with the language from the charter and a table for the members to rank each category as "meets," "needs improvement," or "actions needed." The results of ACET's self-evaluation are outlined below.

OBJECTIVE AND SCOPE OF ACTIVITIES

1. Conduct, encourage, cooperate with, and assist other appropriate public authorities, scientific institutions, and scientist in the conduct of research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases, and other impairments.
2. Assist states and their political subdivisions in preventing and suppressing communicable diseases and other preventable conditions and in promoting health and well-being.

ACET did not rank its performance in this category. Dr. LoBue clarified that this generic language was developed by HHS and is not specific to ACET's duties. Agreement was reached to change the heading to "Objective and Scope of Activities of HHS" in the next amendment of the ACET charter.

DESCRIPTION OF DUTIES

1. Provide recommendations regarding the elimination of tuberculosis to the Secretary, HHS; the Assistant Secretary for Health, HHS; and the Director, CDC.
2. Provide recommendations regarding policies, strategies, objectives, and priorities.
3. Address the development and application of new technologies.
4. Provide guidance and review on CDC's Tuberculosis Prevention Research portfolio and program priorities.
5. Review the extent to which progress has been made toward eliminating tuberculosis.

Meets	Needs Improvement	Actions Needed
Duty 1 Provides recommendations to the HHS Secretary by submitting letters on priority issues and a comprehensive annual report of ACET's key activities over the past year.	N/A	N/A

Meets	Needs Improvement	Actions Needed
N/A	**Duty 1**	Use the ACET/NTCA *Essential Components of a Public Health Tuberculosis Prevention, Control, and Elimination Program* document as a model to develop a cohesive LTBI strategic plan (similar to the plan for the elimination of TB disease). ➢ ACET should aggressively leverage HHS's leadership role to facilitate implementation of the new LTBI strategic plan at the national level. This approach could help to normalize and massively scale-up LTBI testing and treatment in TB programs and primary care settings, particularly among non-U.S.-born populations.
N/A	**Duty 1**	Provide guidance to the HHS Secretary on the unmet goals and objectives of the TB elimination plan and recommend the major changes that are needed to achieve this goal in the United States. ➢ ACET will initiate this effort by reviewing the most recent version of the TB elimination plan for the United States.
N/A	**Duty 2**	Engage ACET members in the development of TB guidelines (similar to the roles of ATS and IDSA as coauthors). ➢ ACET does not provide formal input or recommendations on CDC's TB diagnosis and treatment guidelines.
Duty 3 Addresses the development and application of new technologies (e.g., WGS and IGRAs).	N/A	N/A
Duty 4 Provides ongoing guidance and review during each ACET meeting on CDC's presentations of its TB Prevention Research portfolio and program priorities.	N/A	N/A
N/A	**Duty 5**	Engage partners outside of DTBE to review the data, identify emerging issues, and provide an honest critique on the current state of TB elimination efforts.

Meets	Needs Improvement	Actions Needed
N/A	**Duty 5**	Expand ACET's duties to also address global TB issues. ➢ ACET's sole focus on domestic TB has served as a major barrier to progress in TB elimination. For example, 80 percent of children who develop TB disease in the United States have a connection to a non-U.S.-born TB case.
N/A	**Duty 5**	Increase ACET's focus on TB in correctional settings due to the extremely high rates of active TB disease in this population. ➢ Non-U.S.-born people who are detained by the U.S. Marshals Service and transported to other jurisdictions transmit TB disease to U.S.-born detainees in these facilities. However, federal, state, and local agencies typically take no responsibility for these TB cases due to the tremendous amount of resources involved in multi-state contact investigations.

ESTIMATED NUMBER AND FREQUENCY OF ACET MEETINGS

1. Three meetings per year
2. Effectiveness of meetings
3. Attendance at meetings

Meets	Needs Improvement	Actions Needed
Convenes three meetings per year.	N/A	N/A
Distributes the agenda and other meeting materials to the ACET membership well in advance of meetings.	N/A	N/A
Maintains a detailed record of ACET's guidance, formal recommendations, and action items in the meeting minutes.	N/A	N/A
Achieves and maintains high meeting attendance rates among the ACET voting members and *ex-officio* members.	N/A	N/A
N/A	**Meeting effectiveness**	Make video conferencing technology available at the ACET webinars to better engage the members.
N/A	**Meeting effectiveness**	Revise the format of the presentations for the speakers to highlight the "advice requested from ACET" at the beginning.

Meets	Needs Improvement	Actions Needed
N/A	**Meeting effectiveness**	Change one of the ACET webinars to an in-person meeting that potentially could be held before the annual NTCA TB Conference.
N/A	**Meeting effectiveness**	Revise the format of the webinars to be more practical and useful. ➢ The difference in ACET's productivity between the in-person meetings and webinars is significant. The webinars do not fully and meaningfully engage the ACET membership to provide concrete advice and guidance to CDC. For example, one ACET member found the webinars to be "a waste of time."
N/A	**Meeting**	Contact the liaison representatives who do not regularly attend ACET meetings to identify the reasons for their absence.

MEMBERSHIP COMPOSITION

1. Ten voting members, including a person who has had TB disease or the parent of a child who has TB disease.
2. Non-voting agency representatives.

Meets	Needs Improvement	Actions Needed
Maintains 10 ACET voting members. ➢ CDC responded to ACET's request to amend its charter. Beginning in 2019, a person who has had TB disease or the parent of a child who has TB disease will be added as a new voting member.	N/A	N/A
N/A	Liaison representatives	Consider effective approaches to increase the participation of liaison representatives at ACET meetings on an ongoing basis.

SUBCOMMITTEES

Subcommittees are composed of members and non-voting representatives of the parent committee and may be established with the approval of the HHS Secretary or designee. Subcommittees must report back to the parent committee and do not provide advice or work products directly to the agency.

Ms. Cole clarified that ACET's organizational structure does not include any subcommittees, but three workgroups are operational at this time. Unlike subcommittees, however, workgroups are charged with completing specific tasks or deliverables by a certain date. She asked the chairs to provide their perspectives on the roles of the workgroups in ACET's 2018-2019 Strategic Plan.

1. The Congregate Settings Workgroup is charged with addressing TB in corrections and homeless populations.
2. The TB Drug Supply Workgroup is charged with addressing barriers to maintaining a supply of key TB drugs.
3. The Child and Adolescent Workgroup is charged with addressing issues related to TB in children and adolescents.

ACET Workgroup	Meets	Actions Needed
Congregate Settings	Not at this time	Dr. Armitige, the Workgroup Chair, reported that the membership needs to revisit its charge to determine whether additional activities should be conducted. On the one hand, the workgroup is making progress in clearly defining and focusing on issues that are important for TB in congregate settings. On the other hand, CDC does not appear to be taking action to address the workgroup's guidance. Most notably, TB in correctional settings is not included in the FY2020 TB funding formula.
TB Drug Supply	The workgroup will convene a meeting prior to the next ACET meeting.	Ms. Cole reported that a chair needs to be identified for this workgroup. Under the former chair, the workgroup played an instrumental role in CDC's establishment of the TB emergency drug stockpile. The status and future role of the workgroup will be discussed during the Business Session on the following day.
Child and Adolescent TB	Not at this time	Dr. Starke, the Workgroup Chair, reported that the membership needs to increase its focus on LTBI to make progress on TB elimination in this population, particularly for non-U.S.-born children. For example, children who are tested overseas and have positive results, but are not treated for the TB infection can still enter the United States. LTBI will remain untreated in these children in the United States if their parents are uninsured immigrants or refugees who are not eligible for Medicaid.

Dr. Mermin made several remarks in follow-up to part 1 of ACET's strategic planning discussion. He fully supported ACET's proposal to develop a new LTBI strategic plan. He emphasized that the capacity to address LTBI currently is a major issue for the entire nation, particularly the screening of non-U.S.-born people who resettle in the United States and the screening of 6 to 13 million people who already are U.S. residents. Monumental changes will be needed to make progress in decreasing LTBI rates, such as revolutionizing TB programs, engaging entirely new components of the U.S. health care system, developing new LTBI measures and indicators, and modifying current systems to strengthen the effectiveness of LTBI surveillance.

Dr. Mermin raised the possibility of establishing a new ACET LTBI Subcommittee or increasing the duration of one of the ACET webinars to accommodate extended discussions on LTBI and systematically address this issue. He noted that DGMQ and the Division of Global HIV and TB in the CDC Center for Global Health will need to be engaged in ACET's new LTBI activities.

Dr. Dean reported that earlier in the year, CDC began contacting the organizations of liaison representatives who are not regularly attending ACET meetings. In response to ACET's request,

she agreed to present an annual "report card" of the organizations that did not attend an ACET meeting in the current year.

Ms. Cole concluded part 1 of ACET's strategic planning discussion by confirming that the self-evaluation forms will be compiled, tabulated, and distributed to the members for review.

ACET's Strategic Planning Discussion: Part 2

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

Ms. Cole facilitated part 2 of ACET's strategic planning discussion. She announced that the topics in this session would include actions taken by ACET in response to the May 2000 Institute of Medicine (IOM) report, *Ending Neglect: The Elimination of Tuberculosis in the United States*, and ACET's top priorities for 2018-2019. For the first topic, she led ACET in a review of the IOM recommendations.

Actions Taken by ACET	Actions Needed by ACET
IOM Goal 1: Maintain Control of TB	
• Proposed changes to the RVCT. • Updated the Essential Components document. • Formed the Congregate Settings, TB Drug Supply, and Child and Adolescent Workgroups. • Endorsed the concept and principle that longitudinal consultation is necessary to move forward to meet the medical consultation needs of TB programs.	No further action needed

Actions Taken by ACET	Actions Needed by ACET
IOM Goal 2: Accelerate the Decline	
• Recommended that DTBE develop a system for voluntary reporting of LTBI and provided input on the Concept of Operations for LTBI reporting. • Provided recommendations to DTBE on the communication plan for the USPSTF Grade B recommendation on targeted TB testing.	• Advise DTBE to allocate funding to health departments to support the use IGRAs and 3HP to treat LTBI in both adults and children. • Revisit ACET's previous discussions and guidance to implement LTBI reporting. ➢ Because the increased use of RPT will follow pharmaceutical prescribing patterns of the 3HP regimen, this opportunity should be used to collect data across the country to support a strong, evidence-based recommendation on LTBI reporting. • Advise DTBE to increase its focus on and collaborative efforts with primary care providers in Federally Qualified Health Centers (FQHCs). • Submit a recommendation to the HHS Secretary to facilitate CDC's efforts to obtain and centralize LTBI data from multiple sources. ➢ HRSA-funded FQHCs should provide DTBE with baseline data on LTBI testing and treatment in their facilities. ➢ HRSA-funded Ryan White clinics should regularly provide DTBE and states with their aggregate summary reports of LTBI testing and treatment. ➢ These federally-funded data sources can provide DTBE with important information on LTBI in terms of demographics, high-risk populations, and the names and locations of providers in each state who serve high-risk populations.
IOM Goal 3: Develop New Tools	
• Provided recommendations on the DTBE research plan. • Requested and received an update on CDC's transition to WGS.	• Advise DTBE to develop a model to assist people in locating services for LTBI testing and treatment. ➢ Online risk assessment tools are available for people to enter their potential risk for STDs or HCV and obtain the location of the nearest testing facility based on the zip code. A similar tool is needed for LTBI.
IOM Goal 4: Reduce the Global Burden of TB	
• Requested and received an update on CDC's global TB activities. • Raised the concern that TB was omitted from the WHO Global Priority List of Antibiotic Resistant Bacteria.	No further action needed

Actions Taken by ACET	Actions Needed by ACET
IOM Goal 5: Mobilize and Sustain Support	
• Participated on the DGMQ workgroup to update the 2009 TB technical instructions (TIs). • Voted on and formally endorsed the recommendations in the NTCA/RTMCC white paper, *New Strategies for Approaching Medical Consultation for Tuberculosis*.	No further action needed
IOM Goal 6: Track Progress	
• Requested and received updates on TB trends. • Requested and received an update on CDC's response to the IOM recommendations for TB elimination. • Update by Stop TB USA on progress on the IOM recommendations for TB elimination.	No further action needed

Randall Reves, MD
Past President, The Union-North America Region
International Union Against TB and Lung Disease (IUATLD)
Reves Consulting Services
ACET Liaison Representative

Dr. Reves presented an overview to guide ACET's discussion on its top priorities for 2018-2019. NTCA and Stop TB USA issued a joint statement in September 2017, *Tuberculosis: An Opportunity to Eliminate a Disease in the United States*. The statement raised three key points to highlight the failure of the U.S. TB elimination plan.

First, domestic and global TB elimination efforts have remained chronically underfunded over time. Second, both domestic and global approaches will be required to advance TB research and development, enhance TB diagnosis and treatment, and improve programmatic activities related to LTBI diagnosis and treatment.

Third, modeling studies show that the societal cost of not achieving the goal of TB elimination in the United States is over $400 million per year. Although TB disease is the cause of death for 500 Americans annually, a sense of urgency to address the TB elimination plan is lacking. Moreover, TB morbidity is higher than the number of deaths in the United States from other global threats, including Ebola, anthrax, malaria, or severe acute respiratory syndrome.

The NTCA/Stop TB USA statement recommended three major changes to make progress on the TB elimination plan for the United States.

- Establish a focus on domestic TB elimination within the Executive branch by forming a "Presidential TB Elimination Initiative."
- Support funding for domestic TB elimination activities of up to $195.7 million annually to address funding gaps for U.S. TB control programs due to chronic underfunding; develop

a national prevention initiative; and support increased research for new diagnostic tools, vaccines, and antibiotics.
- Increase funding to $450 million annually for global TB control and prevention programs through CDC and the U.S. Agency for International Development.

Dr. Reves reported that the Center for Strategic & International Studies (CSIS) is a non-profit policy research organization with a mission to provide strategic insights and policy solutions for domestic and global issues. CSIS recently issued a report with the following recommendations to make progress on the U.S. TB elimination plan:

- Expand screening for migrants who enter the United States
- Accelerate TB control in 10-15 countries that have the greatest impact on disease in the United States
- Stimulate increased domestic investments in middle-income countries
- Increase and support TB research and development

ACET DISCUSSION: STRATEGIC PLANNING

Ms. Cole asked ACET to consider the key points that were raised during its extensive strategic planning discussion to identify priorities or propose other topics to include in the 2018-2019 Strategic Plan. ACET's input in this area is outlined below.

Proposed Priority/Topic 1:

ACET should form a new workgroup to lead the development of a national LTBI strategic plan. The workgroup's preliminary charge should be to review the original CDC/ACET Strategic Plan for TB Elimination in 1989, the IOM report in 2000, and guidance from other sources. The review should be used to take an inventory of completed activities and document current gaps in TB elimination efforts in the United States. The new workgroup also should act on Dr. Mermin's suggestion to engage other TB expertise outside of DTBE and ACET.

Dr. Mermin advised ACET to initiate the development of a national LTBI strategic plan in a two-step process. In step 1, the scope of activities for the workgroup should be clearly defined, such as research, programmatic activities, or the development of guidelines. In step 2, the scope of activities should be used to identify the membership of the workgroup. If a decision is made to charge the workgroup with focusing on LTBI research, for example, the National Institutes of Health should be invited to serve as a member.

If ACET formally approved the establishment of a new LTBI workgroup, several members proposed an additional issue that should be addressed. The current reality and difficulties in targeting LTBI elimination goals and recommendations to undocumented people in the United States must be acknowledged. Access to care has significantly decreased among undocumented adults and children in the United States due to fears of being deported.

Proposed Priority/Topic 2:

Dr. Armitige (Congregate Settings Workgroup Chair) and Dr. Starke (Child and Adolescent Workgroup Chair) reiterated the need to continue these workgroups in ACET's 2018-2019 Strategic Plan because the respective memberships have not yet fulfilled their charges. During the 2018 ACET meetings, the chairs will continue to present updates on their progress.

ACET reached agreement on retaining the TB Drug Supply Workgroup, but several members proposed suggestions to modify its charge.

- The surge in LTBI cases will have implications for the TB drug supply. The workgroup should establish and maintain relationships with appropriate drug manufacturers to take proactive measures to meet this demand.
- The workgroup's charge should be expanded to address co-pay and payment issues that continue to be problematic for TB patients who are uninsured or covered by public or private insurance. The high cost of TB drugs is the primary reason that patients with active TB disease do not complete treatment.
- The workgroup should draft recommendations on strategies to effectively implement CDC's updated 3HP guidelines in the field.
- The workgroup should draft recommendations on pediatric dose formulations of TB drugs. The workgroup also should provide advice to ACET on submitting guidance to the FDA, through the HHS Secretary, on disbursable drugs that currently are not available in the United States.

Proposed Priority/Topic 3:
CDC should issue an age-based screening recommendation for TB that is similar to its current guidance for other diseases. For example, CDC recommends HIV testing of all people 13-64 years of age and HCV testing of all people in the 1945-1965 birth cohort (i.e., "baby boomers"). CDC's new guidance should recommend at least one TB test with an IGRA for all people 5-60 years of age. The recommendation should be prioritized in ACET's 2018-2019 Strategic Plan as a more effective strategy for TB testing.

Other ACET members agreed with the overall intent of the proposal to issue a recommendation with stronger and clearer language. However, the need to maintain the focus on TB screening in populations by risk rather than by age was emphasized. Instead of "all people 5-60 years of age," for example, at least one TB test with an IGRA should be recommended for non-U.S.-born people, homeless people, and people in correctional settings.

Proposed Priority/Topic 4:
TB in people with diabetes is an ongoing problem in the United States. However, the *American Diabetes Association's Standards of Medical Care in Diabetes-2017* do not mention the higher incidence of TB in this population or emphasize the need for TB screening of these patients.

Some ACET members raised the possibility of including diabetes biologics and other contributing factors to TB as an additional issue for the new LTBI Workgroup to address in its charge.

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 on day 1 of the ACET meeting. She noted that the discussions on the presentations resulted in ACET's overall guidance to CDC/ DTBE programs, suggestions by individual members, and/or requests for updates on future agendas. However, she pointed out that the following two topics will require ACET's formal action during the Business Session on the following day.

- ACET will take a formal vote to recommend a major change in CDC's updated 3HP guidelines. ACET will advise CDC to issue a more permissive recommendation for the use of 3HP-SAT in people less than 18 years of age.
- ACET will take a formal vote to recommend the establishment of a new LTBI Workgroup with an initial charge of proposing a scope of work for the membership

With no further discussion or business brought before ACET, Ms. Cole recessed the meeting at 4:30 p.m. on December 11, 2017.

Opening Session: December 12, 2017

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

Dr. LoBue served as the DFO on day 2 of the ACET meeting in the absence of Dr. Dean. He conducted a roll call to confirm the attendance of the ACET voting members, *ex-officio* members and liaison representatives (or their alternates). He announced that ACET meetings are open to the public and all comments made during the proceedings are a matter of public record.

Dr. LoBue reminded 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. None of the ACET voting members publicly disclosed any individual or institutional conflicts of interest for the record that were new or different than those declared on day 1 of the meeting.

Dr. LoBue 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 December 12, 2017. He reconvened the proceedings at 8:30 a.m. and welcomed the participants to day 2 of the ACET meeting.

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

Ms. Cole also welcomed the participants to day 2 of the ACET meeting. In her review of the agenda, she announced that a series of updates would be made on current workgroup activities. The remainder of the meeting would be devoted to the ACET Business Session.

Update by the Essential Components Workgroup

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

Advice requested from ACET by the Workgroup:
1. What are ACET's recommendations on the distribution of the final Essential Components document?

Ms. Cole reported that the workgroup has completed its core task of updating 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 document is undergoing the final editing process at this time and will be submitted to the *Morbidity and Mortality Weekly Reports* in January 2018 for publication.

Ms. Cole announced that the workgroup plans to convene a meeting with the National Association of County and City Health Officials and other key stakeholders to discuss and develop a dissemination plan for the Essential Components document. She thanked the workgroup members for contributing their expertise to serve as authors of the various sections. She also thanked the ACET and NTCA members for serving as expert reviewers and/or providing extremely helpful input on an ongoing basis.

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 reported that the primary focus of the Congregate Settings Workgroup over the past year has been the interagency transfer of individuals with TB who are incarcerated. Efforts are underway to develop common clinical and programmatic standards in this area between the public health and corrections communities. DTBE has provided the workgroup with extremely helpful TA and expertise on the appropriate transfer of incarcerated TB cases between responsible jurisdictions.

Dr. Armitige noted that the Congregate Settings Workgroup's next steps will be to develop a template with concrete recommendations on the interagency transfer of incarcerated individuals with TB between jurisdictions. The workgroup will formulate the guidance to ensure that the care, costs, and other responsibilities involved in transferring incarcerated people with TB are equitably shared among agencies.

Dr. Armitige confirmed that two new priorities of the Congregate Settings Workgroup in 2018 will be well aligned with the topics in DTBE's strategic planning process. First, the workgroup will engage DTBE in a thoughtful and critical discussion on the rationale for excluding TB cases in correctional settings from the 2020-2024 TB P&C funding formula. The workgroup's goal in this effort will be to ensure that incarcerated TB cases are included in the funding formula. Second, the workgroup will advise DTBE, through ACET, to obtain input, support, and formal endorsement of CDC's updated 3HP guidelines from correctional partners and organizations to ensure that the recommendations are fully implemented in these settings.

Update by the Child and Adolescent Workgroup

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

Advice requested from ACET by the Workgroup:

1. What actions can ACET take to determine whether CDC will agree to the changes in the American Academy of Pediatrics (AAP) *Red Book*®? How can these revisions be incorporated into CDC's guidance and publications?
2. How should children and adolescents be considered for CDC's guidance on the use of 3HP-SAT?
3. Based on CDC's current educational publications on TB in children and adolescents, what is CDC's role in educating pediatric providers about risk assessment, testing, and treatment of LTBI?

Dr. Starke reported that the Child and Adolescent Workgroup has been focusing on LTBI testing and treatment in children. He summarized the key findings of the literature reviews the workgroup has conducted to support this effort.

A study was conducted to determine the current knowledge and practices of pediatric infectious disease providers in terms of LTBI testing and treatment. The study found that this group of experts primarily utilize the following sources of information: AAP Red Book® and statements, CDC website, ATS/IDSA guidelines, WHO guidelines, and primary source materials (e.g., books and journals, up-to-date Internet articles, e-medicine platforms, and applications). The study emphasized the need to better understand the practices of pediatricians and family medicine physicians.

During the ACET December 2016 meeting, Dr. Christine Ho, the Tuberculosis Epidemiologic Studies Consortium (TBESC) Project Officer, presented the findings of TBESC's latest research on LTBI. In non-U.S.-born people five years of age and older, the latent class analysis (LCA) showed that the tuberculin skin test (TST) had limited capacity in predicting people with LTBI. Both the QuantiFERON (QFT) and T-SPOT blood tests had high positive predictive values (PPVs) of 97.6 and 98.6 percent, respectively.

In non-U.S.-born children less than five years of age, the LCA estimated an LTBI prevalence of 4 percent. The PPV was only 10 percent for positive TST results ≥10 mm. The LCA data supported recommendations that preferred either serial testing (TST followed by IGRAs) or the use of IGRAs as the initial screening test in non-U.S.-born children less than five years of age.

The Mandalakas and Highsmith study collected anonymous data from Oxford of approximately 44,000 T-SPOT TB results. Because epidemiologic data were not available, the sensitivity, specificity, PPV, and negative predictive value of the tests could not be validated. The study showed minimal variation in invalid test results by age. These data raise a theoretical question regarding the guidance that would be recommended if IGRAs were developed first and the use of TST was now being considered.

The 2016 Cruz, *et al.* study reported the findings of a survey that was administered to pediatric infectious disease physicians in the IDSA Emerging Infections Network. Despite the release of multiple guidance documents, the responses show broad variability and non-uniformity in the knowledge and practices of this group of experts.

- *What is the youngest age at which you routinely use IGRAs?*
  - Do not routinely use IGRAs (9 percent)
  - Routinely use IGRAs in all ages (7 percent)

- Use IGRAs at 1 year of age (6 percent); 2-3 years of age (25 percent); 4-5 years of age (24 percent); and 5 years of age and older (29 percent)

- *In an immunocompromised school-aged child who has not received the Bacillus Calmette-Guérin (BCG) vaccine, is there a TST in duration above which you would not obtain an IGRA?*
  - ≥15 mm (46 percent)
  - ≥20 mm (9 percent)
  - Other TST size, such as 10 or 25 mm (4 percent)
  - Would obtain an IGRA in all such children regardless of TST size (28 percent)
  - Do not obtain IGRAs in my practice (5 percent)
  - Unsure (8 percent)

Which test would you use to determine LTBI in the following children?

- *U.S.-born child 10 years of age with Crohn's disease who is on steroids and about to begin tumor necrosis factor-alpha (TNF-α) antagonist therapy?*
  - TST only (9 percent)
  - IGRA only (37 percent)
  - Both TST and IGRA (51 percent)
  - Tiered testing (3 percent)

- *U.S.-born child 3 years of age whose mother recently was diagnosed with pulmonary TB?*
  - TST only (61 percent)
  - IGRA only (3 percent)
  - Both TST and IGRA (28 percent)
  - Tiered testing (8 percent)

- *U.S.-born child 15 years of age whose mother recently was diagnosed with pulmonary TB?*
  - TST only (32 percent)
  - IGRA only (39 percent)
  - Both TST and IGRA (20 percent)
  - Tiered testing (9 percent)

- *BCG-vaccinated immigrant 1 year of age from India?*
  - TST only (46 percent)
  - IGRA only (15 percent)
  - Both TST and IGRA (16 percent)
  - Tiered testing (23 percent)

- *BCG-vaccinated immigrant 6 years of age from India?*
  - TST only (9 percent)
  - IGRA only (62 percent)
  - Both TST and IGRA (13 percent)
  - Tiered testing (16 percent)

- *How would you treat LTBI in a U.S.-born child 3 years of age?*
  - INH for 9 months (86 percent)
  - RIF for 4 months (0.6 percent)

- RIF for 6 months (0 percent)
- INH and RPT weekly for 12 weeks (5 percent)
- Any of the above regimens, depending on the family's choice (7 percent)
- Unsure (0.6 percent)

- *How long would you treat an adolescent with Crohn's disease and newly diagnosed LTBI with anti-TB medication prior to initiating the TNF-α antagonist?*
  - 2 weeks (10 percent)
  - 1-2 months (50 percent)
  - 4 months (2 percent)
  - 6 months or longer (5 percent)
  - Initiate at the same time (14 percent)
  - Unsure (18 percent)

- *How would you treat LTBI, presumably caused by an MDR-TB strain, in the following scenario: a high school teacher who is diagnosed with MDR-TB, resistant to INH and RIF, and susceptible to other medications, but has several students with LTBI who have no travel history and are immunocompetent?*
  - Fluoroquinolone (FQ) monotherapy, e.g., moxifloxacin or levofloxacin (13 percent)
  - Ethambutol (EMB) plus pyrazinamide (PZA) (13 percent)
  - FQ plus PZA or EMB (27 percent)
  - FQ plus high-dose INH (0 percent)
  - Other second-line drugs (0 percent)
  - Would not treat, but evaluate the children monthly (2 percent)
  - Other regimen (9 percent)
  - Unsure (36 percent)

The Child and Adolescent Workgroup reviewed the following recommendations on the use of IGRAs in children that will be included in the 2018 AAP Red Book®. IGRAs can be used in immunocompetent children two years of age and older (previously five years of age and older) in all situations when a TST would be used. Some experts will use IGRAs in immunocompetent children as young as one year of age, but caution will be emphasized for this pediatric population.

IGRAs are particularly useful or preferred for children who have received BCG vaccination. The recommendations on IGRA risk factors and frequency of testing will be the same as those for TST. Because IGRAs and TST are imperfect, the need for clinical judgment will be strongly recommended. As a companion document to the 2018 Red Book®, the committee will develop and release a separate policy statement on LTBI testing and treatment in children. The 2018 AAP Red Book® will be issued in May 2018.

The 2015 AAP Red Book® issued the following recommendations on LTBI treatment in children. The preferred regimen was 9H. The regimen of four months of RIF (4R) should be used only if the patient has INH resistance or intolerance. However, some experts will choose to treat children younger than 12 years of age with six months of RIF. The 3HP regimen should not be used routinely for children younger than 12 years of age, but can be considered when the likelihood of completing another regimen is low.

The 2015 Villarino, *et al.* study reported the findings of a pediatric sub-study from the larger 3HP RCT that included approximately 7,800 patients. The pediatric component included 905 children 2-17 years of age who were evaluated to determine the effectiveness of the 3HP regimen. The

completion rates were 88 percent in the 3HP arm and 91 percent in the 9H arm. In the 3HP arm, 0 of 471 children developed TB and 3 of 539 children experienced a Grade 3 AE. In the 9H arm, three of 434 children developed TB and 1 of 493 children experienced a Grade 3 AE. None of the children experienced hepatotoxicity or a Grade 4 AE. The pediatric sub-study concluded that 3HP was at least as effective and safe as 9H, but had a higher completion rate than 9H.

The Gaensbauer, *et al.* unpublished study reported the findings of a retrospective, non-randomized observational trial. The cohorts included 395 children in the 4R arm and 779 children in the 9H arm from the Denver Metro Tuberculosis Clinic in 2015-2016. Drug toxicity was all dermatologic: 1.5 percent in the 4R arm and 0.7 percent in the 9H arm. No known treatment failures were reported. The completion rates of 83.5 percent in the 4R arm and 68.8 percent in the 9H arm were higher when an IGRA was used and a known contact with a TB case was present.

The AAP Red Book® Committee was presented with 4R data from the Menzies study, but these unpublished and blinded data have not been approved for release at this time. However, the key finding of the study was that 4R was well tolerated and had higher completion rates than 9H in a cohort of approximately 400 children in the RCT.

The Child and Adolescent Workgroup reviewed the following recommendations on LTBI treatment in children that will be included in the 2018 AAP Red Book®. The regimens will be described in the following order: 3HP, 4R, and 9H. The only limitation will state that 3HP cannot be used in children less than two years of age due to the lack of pharmacokinetics data on RPT. A specific preference will not be definitively stated, but 3HP as the preferred regimen among some experts will be noted.

The Child and Adolescent Workgroup reviewed the current data on RIF dosing. The ability of currently recommended RIF doses to lead to low serum levels and areas under the curve has been known for quite some time. Moreover, the majority of AEs caused by RIF are not dose-dependent. For example, much larger doses of up to 2,400 mg/day in adults are generally well tolerated. As a result, multiple experts are now advocating for higher doses, particularly for meningitis and other serious illnesses. In the 2018 Red Book®, the recommended RIF dose will be increased to 15-20 mg/kg/day and the guidance will state that “at least 20 mg/kg/day should be used for life-threatening disease and for any indication in infants and toddlers.”

Overall, the comprehensive literature reviews resulted in the Child and Adolescent Workgroup identifying essential needs to make further progress on childhood TB in the United States in 2018. Effective methods should be determined to locate, assess, test, and treat at-risk children and adolescents. A decision is needed on whether CDC should recommend 3HP-DOT versus 3HP-SAT in children. Education should be strengthened for HCPs, parents, and children. Funding for TB research and development should be increased.

The submission of U.S. applications for pediatric preparations of current and new TB drugs should be increased. For example, new dispersible TB medications that were developed by the TB Alliance are being distributed globally, but specific licensing restrictions are prohibiting the availability of these drugs in the United States. However, the rationale for these barriers is unclear because the new dispersible TB medications primarily are developed in the United States and are supported by U.S. funding. Children should be placed on the agenda of the United Nations General Assembly TB Meeting that will be held in September 2018.

ACET DISCUSSION: CHILD AND ADOLESCENT WORKGROUP UPDATE

ACET requested additional details on the following topics during the question/answer session with Dr. Starke.

- Efforts to ensure alignment between the 2018 AAP Red Book® recommendations and other guidance: (1) CDC's updated 3HP guidelines on the use of 3HP-SAT in children and (2) the ATS guidelines that recommend a dual TB testing approach to maximize sensitivity of the test in immunocompromised children.
- AAP's current guidance on LTBI testing and treatment in BCG-vaccinated children less than one year of age.
- Strategies that will be implemented to widely publicize and inform the pediatric community of the new 2018 AAP Red Book® recommendations: dissemination of *What's New in the Red Book®?*; conferences and meetings to discuss changes in the guidance with the Red Book® Committee; the development and release of a separate policy statement on LTBI testing and treatment in children; and the development of educational materials for physicians and patients.

ACET GUIDANCE

- The strategies that will be implemented to publicize the 2018 AAP Red Book® appear to be effective for pediatricians, but likely will not reach the broader provider community. In the Southeast, for example, general physicians, internal medicine practitioners, family physicians, and other non-pediatricians are the primary providers for children. However, these providers typically have no knowledge of the Red Book®. As a result, CDC should announce its formal endorsement of the 2018 AAP Red Book® to ensure that the non-pediatric community is aware of the new recommendations on LTBI screening and treatment in children.
- The Red Book® should address TB screening of children in congregate settings, particularly to provide clear and specific recommendations for pediatric populations of the U.S. Immigration and Customs Enforcement (ICE). Most notably, this type of guidance would help to inform the high volume of TB screening that ICE conducts daily during the intake of BCG-vaccinated children, unaccompanied minors, and infants who are housed in its family residential centers. If this type of guidance is beyond the scope of the Red Book®, however, the Congregate Settings Workgroup should discuss the possibility of advising ACET to recommend that CDC develop and issue guidelines on TB screening of children in congregate settings.
- Dr. Flood advised the Congregate Settings Workgroup to delay taking action on this suggestion until the new TB TIs are released. The new TB TIs will instruct overseas panel physicians and U.S. civil surgeons to use IGRAs in the screening process to determine whether BCG-vaccinated children who are over two years of age truly have LTBI.

In response to some of ACET's comments, Dr. LoBue confirmed that DTBE will review and compare CDC's current and upcoming guidelines on LTBI testing and treatment with the 2018 AAP Red Book® recommendations to identify any potential opportunities for harmonization in terms of pediatric populations.

CDC Office of Infectious Diseases Board of Scientific Counselors

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

Advice requested from ACET by the Chair:
1. What actions should be taken to monitor how TB, as a priority pathogen, is addressed by WHO?

Ms. Cole presented an update in her role as the ACET liaison to the CDC Office of Infectious Diseases, Board of Scientific Counselors (BSC). The BSC convened its most recent meeting on December 6-7, 2017. Updates were presented by the National Center for Emerging and Zoonotic Infectious Diseases (Waterborne Disease Prevention Branch) and the National Center for Immunization and Respiratory Diseases. The Advisory Committee on Immunization Practices presented its new recommendations as well.

After the update by the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Ms. Cole was informed that WHO is addressing ACET's concern regarding the omission of TB from the global priority list of pathogens. The Presidential message for Antibiotic Awareness Week that was issued on November 13, 2017 was presented. NCHHSTP covered the following topics in its update to the BSC on TB-related issues.

- Slow progress toward achieving TB elimination in the United States as documented by the 2016 TB Surveillance Report.
- The availability of a new awareness video, "5 Things to Know About Tuberculosis," on the CDC.gov website.
- A call for papers by NCHHSTP and the *American Journal of Public Health* (with a deadline for submissions on January 31, 2018) on applying methods, metrics, and indicators for measuring disparities in health outcomes and risk behaviors for the prevention and treatment of HIV, viral hepatitis, STDs, and TB in the United States.

The BSC was asked to consider and provide input on effective strategies to implement routine LTBI, HIV, viral hepatitis, and STD screening in hospitals, clinics, and emergency departments.

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. James Sunstrum for ACET to approve the previous meeting minutes.

ACET approved the Draft August 22, 2017 Meeting Minutes with no changes or further discussion.

Business Item 2: ACET's 2018-2019 Strategic Plan

Ms. Cole returned to ACET's discussion on the previous day of priority topics that should be included in its 2018-2019 Strategic Plan.

Action	Description
Chair's call for a vote	Dr. Jeffrey Starke properly placed a motion on the floor for ACET to approve the establishment of a new LTBI Workgroup that initially will be charged with drafting a scope of work for the membership. Dr. Lisa Armitige seconded the motion.
Outcome of the vote	**The motion was unanimously approved by 9 ACET voting members.**
Next steps	• The composition of the new LTBI Workgroup will include Jennifer Flood and Jeffrey Starke (co-chairs) and Shama Ahuja, Lisa Armitige, Karen Elkins, Robert Horsburgh, Eric Houpt, Surajkumar Madoori, and Diana Nilsen (members). • Dr. LoBue will appoint staff to represent DTBE on the workgroup. • The workgroup will present its draft scope of work during the April 2018 meeting for ACET's review and comment.

Business Item 3: CDC's Updated 3HP Guidelines

Dr. Starke reminded ACET of the two recommendations with age restrictions that will be included in CDC's updated 3HP guidelines. Recommendation 2 addresses pediatric populations: "CDC recommends the use of 3HP by DOT in people 2-17 years of age." Recommendation 4 addresses the use of 3HP-SAT: "CDC recommends the use of 3HP by DOT or SAT in people 18 years of age and older." He proposed the following language to revise the two recommendations.

> *Preamble:* Although children and adolescents 2-17 years of age were not included in TBTC Study 33, there is no inherent reason why taking 3HP by self or parenteral administration would be unsafe or ineffective in children. Therefore, 3HP can be given to persons 2-17 years of age by directly observed therapy (DOT) or by self-administered therapy (SAT) using the same criteria as stated under the updated recommendations for SAT.
>
> *Recommendation 2:* "CDC recommends the use of 3HP in people 2-17 years of age."

Recommendation 4: "CDC recommends the use of 3HP by DOT or SAT in people 2 years of age and older."

Action	Description
Chair's call for a vote	Dr. Jeffrey Starke properly placed a motion on the floor for ACET to approve the revisions to recommendations 2 and 4, as proposed above, for inclusion in CDC's updated 3HP guidelines. Dr. Ana Alvarez seconded the motion.
Outcome of the vote	**The motion was unanimously approved by 9 ACET voting members.**
Next steps	Dr. LoBue will ensure that the language in recommendations 2 and 4 is reconciled for consistency.

Dr. Horsburgh returned to his suggestion on the previous day for DTBE to take a proactive approach in monitoring prospective cohorts that are on 3HP-SAT in multiple jurisdictions to identify and respond to the occurrence of AEs. However, Ms. Cole explained that this suggestion will need to be restated as a formal motion for DTBE to take action.

Action	Description
Chair's call for a vote	Dr. Robert Horsburgh properly placed a motion on the floor for ACET to recommend that CDC seriously consider implementing prospective cohort studies of the rollout of 3HP-SAT in the population of persons who will be on this regimen to assess their rates of completion and tolerability. Dr. Eric Houpt seconded the motion.
Outcome of the vote	**The motion was unanimously approved by 9 ACET voting members.**

ACET returned to the concerns Dr. Mermin raised on the previous day regarding the recommendations in CDC's updated 3HP guidelines that call for a "monthly in-person patient evaluation, interview, and physical examination" of patients who are on 3HP-DOT and 3HP-SAT. Several members believed the language was overly directive and should be revised to be more permissive.

As an example, Dr. Yost noted that IHS extensively uses telemedicine-based approaches because a large proportion of its patient population is required to travel hundreds of miles to present to an IHS clinic for care. As a result, the recommendation to perform monthly in-person evaluations of patients who are on 3HP-DOT and 3HP-SAT will not be feasible or practical for IHS providers in these geographic settings.

Dr. LoBue clarified that the language on "monthly in-person patient evaluations" was extracted directly from CDC's existing LTBI recommendations for inclusion in the updated 3HP guidelines. Before any revisions are made to this language, DTBE will need to consult with its partners that served as coauthors of the current, broader LTBI treatment guidelines to ensure alignment and harmonization of the recommendations. Although the guidance on "monthly patient evaluations" must remain in the updated 3HP guidelines, the specific approaches for providers to conduct the evaluation likely can be modified to be less directive.

ACET agreed that a formal motion would not be required for this topic because the deletion of "in-person" and "physical examination" from CDC's updated 3HP guidelines would fully resolve this issue. Several members noted that the recommendation for a physical examination for the early detection and management of AEs associated with LTBI treatment is not supported by findings from the 3HP RCT.

Business Item 4: Advice Requested by ACET

Ms. Cole pointed out that a table was distributed with ACET's formal motions, guidance, and action items from the August 2017 meeting. She led ACET in a review of these topics.

- ACET asked DTBE to determine whether new LTBI diagnostic codes could be included in ICD-10 codes.
- ACET formally endorsed the concept and principle that longitudinal consultation is the current reality and also is necessary to move forward to meet the medical consultation needs of TB programs.
- ACET formally endorsed the formation of an external workgroup (with representation by ACET, DTBE, NTCA, and the RTMCCs) to examine new and innovative modalities for the delivery of medical consultation services and investigate a Medicare designation for the care of TB disease. ACET made a commitment to identify a representative to serve on the new NTCA/RTMCC Workgroup.
- ACET asked DTBE to modify the ARPE and consider including the following new variables: age, medical and exposure risk factors, specific test used, prior treatment administered, treatment completion, and country of birth. In response to ACET's request, NTCA agreed to conduct a survey of TB controllers to obtain their input on the impact of proposed changes to the ARPE.

ACET agreed that no further action was needed because all of these topics were sufficiently addressed by DTBE's presentations, resolved during ACET's discussions, or requested as future agenda items for the April or August 2018 meeting.

Business Item 5: ACET Letter and Report to the HHS Secretary

Ms. Cole announced that the current drafts of ACET's letter and report to the HHS Secretary on its key activities in 2016-2017 reflect the extremely helpful input the members provided during the August 2017 meeting. She opened the floor for ACET's feedback on the revised versions of these documents.

ACET Letter to the HHS Secretary

Page 2

- Add a new statement to introduce ACET's four concerns.
    - The failure of the current TB elimination plan should be documented and the need for major changes should be emphasized to achieve this goal in the United States by the target date of 2035. However, other ACET members proposed alternate language: "The current TB elimination plan is promising, but has not met its full potential due to the lack of political will, resources, and other support." More

positive wording was suggested because the HHS Secretary likely will be reluctant to take action on a "failing" TB elimination plan.

Page 2, Concern 2

- Add "continuity of care" in the paragraph that addresses TB in congregate settings with an emphasis on corrections and homeless settings.
- Add a new, more prominent statement to emphasize the need to promote the increased use of 3HP in correctional settings.
    - To support the new statement, ACET should cite key data (e.g., a 92 percent completion rate of 3HP in Federal Bureau of Prisons populations and an 85 percent completion rate in a Santa Clara, California jail population). ACET also should reiterate that CDC adopted and took action on its previous recommendation to endorse and support the use of 3HP in correctional settings.

Page 4, Assistance from the HHS Secretary

- Change the verb tense in all of the strategies to be more action-oriented (e.g., change "providing" to "provide," "expanding" to "expand," and "developing" to "develop").
- Revise strategy 1 as follows: "Provide financial resources to ensure physicians in public/ private sectors diagnose and treat LTBI (up to 13 million Americans) and Medicare/ Medicaid cover the USPSTF recommended treatment regimens."
- Revise strategy 7 as follows: "Direct the Centers for Medicare & Medicaid Services (CMS) to establish a mandatory national coverage determination (NCD) for LTBI testing and treatment and develop a metric to evaluate performance."
- Revise the order of the strategies to improve the flow of the guidance (e.g., combine strategy 8 with strategy 1).
- Use the same recommendation from the September 2017 joint NTCA/Stop TB USA statement as a new strategy to the HHS Secretary: "Establish a focus on domestic TB elimination within the Executive branch by forming a Presidential TB Elimination Initiative."
- Add the following language as a new strategy to the HHS Secretary: "Provide assistance to public health in maintaining the continuity of Medicaid coverage to reduce threats to public health that are aggravated by the loss of or interruptions in Medicaid coverage for the treatment of LTBI in correctional settings."
    - Alternate wording proposed: "Remove barriers to the treatment of TB disease and LTBI by addressing the loss of Medicaid coverage when people become incarcerated or are released from correctional settings."
- Use the wording from the first paragraph after strategy 8 to add the following language as a new strategy to the HHS Secretary: "Strengthen HHS support for reducing TB in congregate settings and enhancing programs that facilitate binational and transnational continuity of care."
- Add the following language as a new strategy to the HHS Secretary: "Collaborate and coordinate efforts with the U.S. Mission to the United Nations to ensure extensive representation of the U.S. domestic TB program at the U.N. General Assembly TB Meeting that will be convened in New York City in September 2018."

ACET REPORT TO THE HHS SECRETARY

Page 2, Convened the following workgroups

- Add new language to describe the major deliverable of each workgroup:

- Congregate Settings Workgroup: "The outcome of this workgroup is to increase representation of congregate settings in CDC's guidance and approach to TB care in these populations."
- Child and Adolescent Workgroup: No additional language proposed.
- TB Drug Supply Workgroup: "The outcome of this workgroup is to ensure an uninterrupted supply of drugs nationwide and remove any barriers to access, including costs."

Page 2, Key recommendations provided to DTBE

- Add the following language as the new recommendation "E:" "Recommended voluntary

Dr. LoBue emphasized that several of the proposed strategies in ACET's letter to the HHS Secretary are specific and focused, such as the need for CMS to establish a mandatory NCD for LTBI testing and treatment and the need for continued Medicaid coverage when people with TB disease or LTBI are incarcerated. However, other parts of the letter are vague and likely will result in ACET receiving a generic letter of support from HHS staff. He noted that the submission of a letter with clear and concrete guidance will prompt the HHS Secretary to take more definitive actions and also will enable ACET to easily monitor the progress of its recommendations.

Ms. Cole confirmed that her next steps will be to revise the letter and report to the HHS Secretary based on ACET's specific comments and Dr. LoBue's guidance. She hoped that by the April 2018 meeting, a permanent HHS Secretary will be appointed and ACET will approve the submission of the final letter and report.

Business Item 6: DGMQ TB Technical Instructions Workgroup

Ms. Cole announced that the DGMQ-TI Workgroup has been focusing on molecular testing in terms of its indications for use and an approach to clearly explain this issue in the new TB TIs. An update by the workgroup on the proposed changes from the 2009 TB TIs was requested for the current meeting, but the draft document is still not ready to be presented for ACET's review and input. ACET agreed that the action step for this business item will be to reschedule the workgroup's update for the April 2018 meeting.

Business Item 7: 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 April 2018 meeting. Because the next meeting will be a one-day webinar, however, she clarified that some of the proposed agenda items will need to be tabled until the August or December 2018 meeting.

Presenter	Agenda Item
Dr. Philip LoBue	Update on the key findings of the external peer review panel that DTBE will convene in April 2018 to provide input on the next 10-year cycle of the TBTC CoAg. **[August 2018 agenda item]**

Presenter	Agenda Item
Dr. Terence Chorba Dr. Peter Davidson	Update on the final draft of the proposed recommendations to DTBE by the TB Funding Formula Workgroup for Prevention and Control for ACET's review and input.
Dr. James Posey	Update on DTBE's programmatic rollout of its data sharing plan for universal WGS. ➢ The update will respond to ACET's request for specific details, such as the training, software, and other resources that will be provided to TB programs to utilize, interpret, and analyze WGS data to identify TB clusters and investigate outbreaks at the local level. **[August 2018 agenda item]**
Dr. Philip LoBue Dr. Peter Davidson	Status report on ACET's previous motion to endorse the formation of an external workgroup with representation by ACET, DTBE, NTCA, and the TB COEs for Training, Education, and Medical Consultation (formerly, the RTMCCs) to examine new and innovative modalities for the delivery of TB medical consultation services. ➢ The update will be tabled until DTBE announces the COEs that are awarded funds under the re-competed CoAg.
Dr. Philip LoBue	Update on DTBE's final submission to WHO in March 2018 to determine whether new LTBI diagnostic codes can be incorporated into ICD-10 codes for reimbursement and surveillance. ➢ If DTBE does not receive a response from WHO by the April 2018 meeting, the update will be scheduled for the August 2018 meeting.
Dr. Philip LoBue Dr. Diana Nilsen	Update on the DTBE/NTCA collaboration to respond to ACET's previous guidance to revise the current ARPE form. ➢ The update will include the results of a survey that NTCA will administer to TB control programs early in 2018 to obtain their input on draft changes to the ARPE form and the potential impact of these modifications.
DGMQ-TI Workgroup	Overview on the proposed changes in the new TB TIs for ACET's review and comment. **[Priority topic; rescheduled from the December 2017 ACET meeting]**
Ms. Barbara Cole	ACET's review and facilitated discussion of the NTCA/Stop TB USA joint statement, *Tuberculosis: An Opportunity to Eliminate a Disease in the United States*, and its potential role in ACET's 2018-2019 Strategic Plan for TB Elimination.
Dr. Philip LoBue	Overview of DTBE's portion of NCHHSTP's Public Health and Primary Care: Partners in Prevention" meeting in January 2018. ➢ The update will describe (1) the potential implications of input from primary care providers on outreach to promote the USPSTF TB recommendations and (2) potential approaches for periodic monitoring and reporting of LTBI diagnosis and treatment in primary care settings and challenges in this area.
Dr. Jennifer Flood Dr. Jeffrey Starke	First update by the co-chairs of the new ACET LTBI Workgroup on the draft scope of work for the membership.
CDC Division of Global HIV and TB	Periodic updates to explore synergies between the domestic and global TB programs.
Dr. Shama Ahuja Dr. Philip LoBue	Progress report on making LTBI a nationally reportable condition.

Presenter	Agenda Item
To Be Determined	Overview of zoonotic TB. ➢ The agenda item was requested due to reports of bovine TB cases from strains in cattle or deer. IUATLD recently issued a roadmap to convene TB experts in both humans and animals. After reviewing the IUATLD roadmap, ACET should discuss its potential role in providing guidance on zoonotic TB.
DTBE	Status report on the rollout of the pilot LTBI surveillance project.
DTBE	Update on the future of the Affordable Care Act in terms of its impact on access to TB care and the U.S. TB elimination plan. **[August 2018 agenda item]**

Public Comment Session

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

Closing Session

The published agenda listed the proposed dates of the next three ACET meetings: April 10, 2018 (webinar); August 21, 2018 (webinar) and December 11-12, 2018 (in-person meeting in Atlanta). Due to other commitments by the ACET members, however, April 14, 2018 was proposed as an alternate date for the first webinar in 2018.

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 three meetings. DTBE staff also confirmed that efforts are underway to address ACET's request to make video conferencing technology available for the webinars.

With no further discussion or business brought before ACET, Ms. Cole adjourned the meeting at 11:20 a.m. on December 12, 2017.

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. Michael Lauzardo
Dr. Jeffrey Starke
Dr. James Sunstrum
Dr. David Warshauer

ACET *Ex-Officio* Members Present

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)

Ms. Kali Crosby
Agency for Healthcare Research and Quality

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

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

Dr. Deborah Parham Hopson
Health Resources and Services Administration

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

Mr. Stephen Martin
National Institute for Occupational Safety and Health

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. Naomi Aronson
U.S. Department of Defense

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

Dr. Anthony Campbell
Substance Abuse and Mental Health Services Administration

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

Dr. Bruce San Filippo
U.S. Section, U.S.-Mexico Border Health Commission

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

Ms. Nuala Moore
American Thoracic Society
(Alternate for Dr. Fran du Melle)

Dr. Robert Morris
National Commission on Correctional Health

Dr. Diana Nilsen
National Tuberculosis Controllers Association

Dr. Howard Njoo
Public Health Agency of Canada

Dr. Amee Patrawalla
American College of Chest Physicians

Ms. Susan Rappaport
American Lung Association

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. Jennifer Rakeman
Association of Public Health Laboratories

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

Dr. Susan Ray
Infectious Disease Society of America

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. Andrey Borisov
Dr. Deron Burton
Dr. Terence Chorba
Mr. Jeff Chrismon
Dr. Patricia Dietz
Mr. Vincent Fears
Dr. Neela Goswami
Ms. Carla Jeffries
Dr. Awal Khan
Rebecca Levine, Esq.
Dr. Philip LoBue
Ms. Suzanne Marks
Dr. Jonathan Mermin
Mr. Mark Miner
Dr. James Posey
Ms. Margie Scott-Cseh
Ms. Maria Fraire Sessions
Dr. Angela Starks
Dr. Andrew Vernon
Dr. Carla Winston
Ms. Sara Zeigler

Invited Guests/ Members of the Public

Dr. Peter Davidson
National Tuberculosis Controllers Association

Dr. Brent Gibson
National Commission on Correctional Health

Ms. Donna Wegener
National Tuberculosis Controllers Association

Attachment 2: Glossary of Acronyms

Acronym	Definition
3HP	Three Months of Isoniazid/Rifapentine
4R	Four Months of Rifampin
9H	Nine Months of Daily Isoniazid
AAP	American Academy of Pediatrics
ACET	Advisory Council for the Elimination of Tuberculosis
AEs	Adverse Events
APHL	Association of Public Health Laboratories
APICE	Association for Professionals in Infection Control and Epidemiology
AR	Antibiotic Resistance
ARPE	Aggregate Report for Tuberculosis Program Evaluation
ART	Antiretroviral Therapy
AST	Aspartate Aminotransferase
ASTHO	Association of State and Territorial Health Officials
ATS	American Thoracic Society
BCG	*Bacillus Calmette-Guérin*
BSC	Board of Scientific Counselors
CDC	Centers for Disease Control and Prevention
CHIP	Children's Health Insurance Program
CMS	Centers for Medicaid & Medicare Services
CoAg	Cooperative Agreement
COEs	Centers of Excellence
CSIS	Center for Strategic & International Studies
DASH	Division of Adolescent and School Health
DFO	Designated Federal Officer
DGMQ	Division of Global Migration and Quarantine
DHAP	Division of HIV/AIDS Prevention
DOL	U.S. Department of Labor
DOT	Directly Observed Therapy
DST	Drug Susceptibility Testing

Acronym	Definition
DSTDP	Division of STD Prevention
DTBE	Division of Tuberculosis Elimination
DVH	Division of Viral Hepatitis
eDOT	Electronic Directly Observed Therapy
EMB	Ethambutol
FACA	Federal Advisory Committee Act
FDA	U.S. Food and Drug Administration
FQ	Fluoroquinolone
FQHCs	Federally Qualified Health Centers
FY	Fiscal Year
HAV	Hepatitis A Virus
HBV	Hepatitis B Virus
HCPs	Healthcare Providers
HCV	Hepatitis C Virus
HHIAG	HIV Health Improvement Affinity Group
HHS	U.S. Department of Health and Human Services
HIP	High-Impact Prevention
HRSA	Health Resources and Services Administration
ICD	International Classification of Diseases
ICE	U.S. Immigration and Customs Enforcement
IDSA	Infectious Diseases Society of America
IDU	Injection Drug Use
IGRAs	Interferon Gamma Release Assays
IHS	Indian Health Service
INH	Isoniazid
IOM	Institute of Medicine
IUATLD	International Union Against TB and Lung Disease
LCA	Latent Class Analysis
LTBI	Latent Tuberculosis Infection
MDR-TB	Multidrug-Resistant Tuberculosis
MSM	Men Who Have Sex With Men
MTB	*Mycobacterium tuberculosis*
NAAT	Nucleic Acid Amplification Testing
NCCHC	National Commission on Correctional Health Care
NCD	National Coverage Determination
NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
NCHS	National Center for Health Statistics
NEEMA	NCHHSTP Epidemiologic and Economic Modeling Agreement
NOFO	Notice of Funding Opportunity
NTCA	National Tuberculosis Controllers Association

Acronym	Definition
OD	Office of the Director
OMH	Office of Minority Health
P&C	Prevention and Control
PCPs	Primary Care Providers
PCSI	Program Collaboration and Service Integration
PLWHA	People Living With HIV/AIDS
PPIO	Program and Performance Improvement Office
PPVs	Positive Predictive Values
PZA	Pyrazinamide
QFT	QuantiFERON
RCTs	Randomized Controlled Trials
RFRs	Rapid Feedback Reports
RIF	Rifampin
RPT	Rifapentine
RTMCCs	Regional Training and Medical Consultation Centers
RVCT	Report of Verified Case of Tuberculosis
SAT	Self-Administered Therapy
SDRs	Systemic Drug Reactions
SHPPS	School Health Policies and Practices Study
SMEs	Subject-Matter Experts
TA	Technical Assistance
TB	Tuberculosis
TBESC	Tuberculosis Epidemiologic Studies Consortium
TBTC	Tuberculosis Trials Consortium
TIs	Technical Instructions
TNF-α	Tumor Necrosis Factor-Alpha
TST	Tuberculin Skin Testing
UCSF	University of California, San Francisco
USAPI	U.S.-Affiliated Pacific Island
USPSTF	U.S. Preventive Services Task Force
WGS	Whole-Genome Sequencing
WHO	World Health Organization