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

Virtual Meeting of the
Advisory Council for the Elimination of Tuberculosis
August 22, 2017

Record of the Proceedings

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ADVISORY COUNCIL FOR THE ELIMINATION OF TUBERCULOSIS
August 22, 2017

Minutes of the Virtual Meeting

The U.S. Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC), National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP), Division of Tuberculosis Elimination (DTBE) convened a virtual meeting of the Advisory Council for the Elimination of Tuberculosis (ACET). The proceedings were held on August 22, 2017 from 10:00 a.m. – 3:30 p.m. EST.

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

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

Opening Session

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

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

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

CONFLICT OF INTEREST DISCLOSURES

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
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 August 22, 2017. She called the proceedings to order at 10:06 a.m. and welcomed the participants to the virtual 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 the virtual ACET meeting. She summarized the items on the published agenda, but she particularly noted two major topics. First, a significant portion of the meeting would be devoted to ACET's continued focus on issues related to latent TB infection (LTBI). Second, the most recent draft of the Essential Components document, dated August 14, 2017, would be presented for ACET's high-level review, discussion, and formal vote.

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's report to ACET. Dr. Brenda Fitzgerald was appointed as the 17th Director of CDC on July 7, 2017. The key milestones of Dr. Fitzgerald's distinguished career include her appointment as the Commissioner of the Georgia Department of Public Health (2011-2017) and her medical background as a practicing board-certified obstetrician/gynecologist.

Dr. Anne Schuchat, who served as the acting CDC Director, has returned to her position as the Principal Deputy Director. Another recent change in CDC's leadership is Dr. Rima Khabbaz's dual role as the Director of the National Center for Emerging and Zoonotic Infectious Diseases and the acting Director of the Office of Infectious Diseases.

CDC hosted the first "Georgia Day Open House" on April 21, 2017 at its headquarters, the Roybal Campus, in Atlanta. The invited guests and attendees included representatives of state universities, Georgia Congressional offices, the city of Atlanta and other local government officials, the business community, and private organizations. The featured exhibits and presentations created opportunities for dialogue between CDC and policy, business, and community leaders in Georgia. NCHHSTP highlighted its ongoing activities during this event, including AtlasPlus, advanced molecular detection, the availability of the *STD Treatment Guidelines* for mobile devices, and the response to the Indiana HIV outbreak.

The NCHHSTP divisions issued new publications, launched new social media tools, and conducted a number of other activities to make progress on their HIV, viral hepatitis, STD, and TB prevention and elimination goals. DTBE published a new paper, "Latent Tuberculosis Infection: The Final Frontier of Tuberculosis Elimination in the USA," in *The Lancet Infectious Diseases* on May 8, 2017. The article noted the level decline in TB cases and emphasized the need to better address LTBI in people at high risk of reactivated TB. DTBE also issued a "Dear Colleague" letter to summarize the article.

DTBE debuted a new YouTube video, "5 Things to Know About Tuberculosis." The video highlights the burden of TB in the United States and articulates the importance of addressing LTBI through targeted testing and treatment. The video is aimed at general audiences and can be shared via social media.

The Division of HIV/AIDS Prevention (DHAP) released its most recent HIV surveillance report, "Monitoring Selected National HIV Prevention and Care Objectives by Using HIV Surveillance Data: United States and 6 Dependent Areas, 2015," in July 2017. The report includes recent data and key indicators that showed progress in HIV prevention, care, and treatment goals in the United States.

Positive trends were reported for nine of the 16 HIV indicators that were assessed. Of 1.1 million people living with HIV (PLWH) in the United States, 85 percent are diagnosed. Of PLWH with a diagnosed infection in 2015, 62 percent had received HIV care and 49 percent were virally suppressed through treatment (compared to CDC's estimate of 28 percent in 2010). The 2015 HIV surveillance report is available on the CDC website.

The Division of Viral Hepatitis (DVH) released preliminary surveillance data that showed the number of new hepatitis C virus (HCV) infections reported to CDC nearly tripled from 850 cases in 2010 to 2,436 cases in 2015. Due to limited testing and underreporting, however, CDC estimates that 34,000 Americans actually were newly infected with HCV in 2015. The current incidence reflects the highest number of reported cases in 15 years. The increase in acute HCV

cases primarily is due to increasing injection drug use. Because HCV has few symptoms, nearly 50 percent of people living with the virus have no knowledge of their infection. As a result, the vast majority of new infections are undiagnosed.

DVH published an article in the *Morbidity and Mortality Weekly Report* (*MMWR*) on May 12, 2017 that analyzed state HCV incidence and characterized preventive services in one of five categories ranging from "least" to "most" comprehensive. Of all 50 states, 18 have the least comprehensive laws for prevention (i.e., no laws to authorize syringe exchange programs or other measures). Maine, Nevada, and Utah have the most comprehensive laws for prevention. Of all 50 states, 24 have restrictions that require patients to have a period of sobriety prior to receiving HCV treatment through Medicaid.

The Division of STD Prevention (DSTDP) released the "CDC Call to Action on Syphilis: Let's Work Together to Stem the Tide of Rising Syphilis in the United States" in April 2017. The Call to Action emphasizes the need for public/private sectors and affected communities to be engaged in efforts to reduce syphilis. The Call to Action also calls for the development of new tools to detect and treat syphilis. Most notably, no rapid test is available for syphilis at this time. Moreover, the same medications have been used to treat syphilis for the past 75 years.

The Call to Action describes CDC's four commitments: (1) develop new laboratory guidelines, (2) create a repository of specimens, (3) evaluate new technologies, and (4) develop novel diagnostic tools and improve molecular surveillance capacity.

Dr. Jonathan Mermin (NCHHSTP Director) and Dr. Gail Bolan (DSTDP Director) recently published commentary articles on Medscape to highlight the national increase in syphilis rates and describe the health issues of lesbian/gay/bisexual (LGB) students. "Health Risks Faced by Lesbian, Gay, and Bisexual Youth" was published on May 22, 2017. "The Rising Tide of Syphilis: Coming to a Patient Near You" was published on July 14, 2017.

DSTDP released a new YouTube video, "Drug-Resistant Gonorrhea: An Urgent Public Health Issue." The video aims to raise awareness of drug resistance and includes an animation that illustrates the history of gonorrhea overpowering drugs to treat this infection. The key message in the video is that more than 800,000 new infections occur each year in the United States.

The Division of Adolescent and School Health (DASH) compiled data from the Youth Risk Behavior Surveillance System to develop and release three new communication products. The two new infographics for health care providers emphasize the important role of clinicians in keeping LGB/transgender (LGBT) youth healthy and describe the health risks faced by LGBT youth, particularly higher risks for bullying, sexual violence, and suicide. The palm card for public health and education professionals highlights higher health risks faced by LGB youth. DASH's new communication products are available on the CDC website.

DTBE Director's Report

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

Dr. LoBue covered several topics in the DTBE Director's report to ACET. Fiscal year (FY) 2017 will end on September 30, 2017. The FY2017 budget reflects essentially level funding for DTBE. The final appropriation is approximately $142 million minus a 0.69 percent recission. FY2018 will begin on October 1, 2017.

The FY2018 budget has not yet been released, but the President's budget proposal calls for a 17.9 percent reduction in overall HHS funding (or approximately $15 billion). If approved, the DTBE appropriation would be $130 million (or a $12 million budget cut). The House Appropriations Committee approved level funding for DTBE at approximately $142 million, while the Senate Appropriations Committee has not yet released information on the FY2018 budget.

DTBE is evaluating both traditional and electronic forms of directly-observed therapy (DOT) for TB treatment at four clinical settings in New York City. The crossover, non-inferiority trial will randomize patients to either one of two study arms: traditional in-person DOT (ipDOT) or electronic DOT (eDOT). The primary outcome of the study will be to compare the proportion of medication doses that are directly observed by ipDOT versus eDOT at the conclusion of the eight-week crossover period. The study design also includes secondary analyses to evaluate eDOT conducted in "real time" or "live" DOT (LVDOT) with a recorded video (RVDOT). DTBE leveraged funding through the Antimicrobial Resistance Solutions Initiative to support the study and began enrolling patients in July 2017.

DTBE is performing an economic evaluation of eDOT for TB treatment to formally collect data from both patient and health department perspectives. DTBE will use these data to estimate the total costs of various DOT modalities (e.g., DOT at the TB clinic, DOT in the home, LVDOT, and RVDOT) and develop evidence-based recommendations. DTBE will retrospectively collect start-up and health department costs, but will prospectively gather patient costs from a sample of patients at each participating site.

DTBE will utilize a standardized form to collect cost data from three types of sites. Rhode Island reports less than 50 TB cases annually and will serve as the low incidence site. This cohort will include 20-25 patients. San Francisco reports 51-500 TB cases annually and will serve as the medium incidence site. This cohort will include 35-40 patients. New York City reports more than 500 TB cases annually and will serve as the high incidence site. This cohort will include 45-50 patients.

DTBE is conducting several activities in the following four categories in response to the 2016 U.S. Preventive Services Task Force (USPSTF) Grade B recommendation to screen adults at increased risk for LTBI. The first category of activities focuses on communication and education. DTBE created and posted key LTBI messages and resources on the CDC.gov website for TB programs and other groups to use as talking points to providers and communities. The messages cover multiple topics, including the risk factors for LTBI, differences between LTBI and TB disease, testing for TB infection, and LTBI treatment. References also are provided for stakeholders to obtain additional information on LTBI.

DTBE published three articles to widely disseminate messages on LTBI and make further progress on TB elimination in the United States: "The End Game: Eliminating Tuberculosis in America" (*Huffington Post*, September 2016); "Latent Tuberculosis Infection: The Final Frontier of Tuberculosis Elimination in the USA" (*The Lancet Infectious Diseases*, May 2017); and "Tuberculosis: A New Screening Recommendation and an Expanded Approach to Elimination in the United States" (*American Journal of Nursing*, July 2017).

DTBE is presenting available communication resources to stakeholders and also is providing communication assistance to TB programs in the field. For example, DTBE is collaborating with the California Department of Public Health to develop a communication strategy to ensure that its statewide TB elimination plan reaches providers and at-risk populations. DTBE is updating its online LTBI resources hub with new information, materials, and links to other sources. The hub serves as a "one-stop shop" for LTBI resources.

DTBE is collaborating with external developers of medical applications and websites, such as Medscape, Epocrates®, and UpToDate®, to ensure that clinicians are able to easily access accurate LTBI information. DTBE created a slide set on TB testing and LTBI treatment that can be downloaded and customized for outreach and education activities. The slide set can be used to present information on TB and LTBI risk factors, testing and the selection of specific tests, diagnosis and treatment regimens, and case studies.

DTBE developed sample communication templates for both general and clinical audiences. The ready-to-print articles can be used for any type of publication, including online and print media, bulletins, newsletters, and web features. TB programs, health care organizations, and other partners can customize the templates with location-specific data, contact information for local subject-matter experts (SMEs), and links to other resources.

LTBI resources for the clinical audience include "Latent Tuberculosis Infection: A Guide for Primary Health Care Providers;" the online Medscape expert commentary; a mobile application for health care providers; and infographics, graphics, and web buttons to make presentations. LTBI resources for the general audience include fact sheets and patient education materials. The Regional Training and Medical Consultation Centers (RTMCCs) also have created and posted LTBI educational products.

DTBE has increased its use of social media to "talk TB" via Twitter (@CDC_TB) and Facebook (@CDCTB). Graphics have been found to increase the reach and appeal of social media messages. The most popular messages include the following content.

- "People with LTBI do not feel sick, but might still need treatment."
- "TB disease rates are at an all-time low, but TB disease is just the tip of the iceberg."
- "Who should get tested for tuberculosis?"
- "People who have LTBI do not feel sick, do not have any symptoms, and cannot spread TB to others."
- "The treatment of LTBI reduces your risk of developing TB disease."

DTBE's next steps in its communication and education activities will be to continue to promote targeted testing and treatment of LTBI through CDC's communication channels. Resources will continue to be provided to partners and stakeholders for their use in promoting targeted testing and treatment of LTBI through their individual communication channels. Feedback will be systematically gathered from partners in the field to identify additional activities or materials that

might need to be developed to meet their individual needs. Outreach will be targeted to medical and public health professionals to continue to inform and provide education on LTBI to these audiences.

The second category of activities focuses on outreach. DTBE initiated outreach at the national level to the broader public health community, primary care professional societies, medical providers, insurers, and stakeholders to further emphasize the need for LTBI testing and treatment. NCHHSTP will convene a consultation with major primary care professional societies in the first or second quarter of FY2018 to discuss the implementation of relevant public health preventive interventions.

DTBE is targeting its outreach to the following public providers due to their important roles in LTBI testing and treatment.

- Centers for Medicare and Medicaid Services (Regulatory agency for Medicare to adopt the USPSTF recommendation)
- Health Resources and Services Administration (HRSA), Bureau of Primary Health Care (Funding agency)
- Indian Health Service and Veterans Health Administration (Primary health care provider)
- National Association of Community Health Centers (Representative body for primary care providers)

DTBE is targeting its outreach to the following professional societies because their memberships of private providers can reach diverse patient populations that likely are more at risk for LTBI. These organizations also have a tremendous influence in the medical field by publishing national recommendations, guidelines, position statements, and newsletters; advocating for the health of patients and communities; developing clinical performance measures; and providing continuing education, certification, and other resources.

- American College of Physicians
- National Council of Asian Pacific Islander Physicians
- American College of Preventive Medicine
- American Academy of Family Physicians
- Society of General Internal Medicine
- American Medical Association
- American Association of Physicians of Indian Origin
- National Hispanic Medical Association
- National Medical Association
- Hep B United

The third category of activities focuses on insurance coverage and billing. DTBE has been reviewing existing legislation to better understand the Medicare National Determination of Coverage. Most notably, Medicare and its administrative contractors establish National Coverage Determinations (NCDs) to provide coverage information and determine whether certain services offered by participating providers are reasonable and necessary. Because NCDs are mandated at the national level, all fiscal intermediaries, carriers, and Medicare administrative contractors are required to follow these guidelines. DTBE and CMS informally discussed the possible establishment of a mandatory NCD for LTBI, but the lack of progress in this area might warrant a formal request.

A DTBE workgroup is coordinating efforts with agency leadership to improve International Classification of Diseases (ICD)-10/ICD-11 codes for LTBI, explore potential revisions, and better track the level of LTBI testing and treatment. For example, ICD-10 Code R76.11, "Non-specific positive reaction to tuberculin test without active TB," is used for LTBI services. However, the code is confusing and does not mention the need to perform a blood test. DTBE's position is that the code can be revised with simpler and more understandable language, such as "Diagnosis of latent tuberculosis infection."

The fourth category of activities focuses on updated TB guidance. DTBE and the National Tuberculosis Controllers Association (NTCA) are collaborating to develop the NTCA/CDC *LTBI Treatment Guidelines*. The guidance will serve as an update to the 2000 American Thoracic Society/Infectious Diseases Society of America/CDC statement.

DTBE convened a consultation in July 2017 to obtain external expertise on updating CDC's 2011 *TB Treatment Guidelines*. The major change will be the inclusion of new data on 3HP (i.e., the three-month isoniazid (INH)/rifapentine (RPT) regimen) to reflect self-administered therapy as well as the use of 3HP in children 2-12 years of age and PLWH on antiretroviral therapy. DTBE will present a draft of the updated *TB Treatment Guidelines* to ACET for review and comment during the December 2017 meeting.

Dr. LoBue announced that Dr. Wanda Walton, former Chief of the DTBE Communications, Education and Behavioral Studies Branch, provided outstanding leadership in the development of the LTBI communication and educational products prior to her retirement in July 2017. He informed ACET that CDC's efforts to hire Dr. Walton's permanent replacement are pending due to the current federal hiring freeze.

ACET DISCUSSION: DTBE DIRECTOR'S REPORT

The ACET members commended DTBE for developing and launching a comprehensive approach to address LTBI by conducting activities in multiple categories: communication and education, outreach, insurance coverage and billing, and updated TB guidance. The ACET members made three key suggestions for DTBE to consider in refining this initiative.

- For the "outreach" category, DTBE should include health care providers in correctional settings and homeless shelters as additional sources to deliver LTBI testing and treatment services. Incidence data have consistently shown that incarcerated people in correctional settings and homeless people in shelters have a disproportionately high risk for LTBI. However, outcome data have documented relatively high TB treatment completion rates in these populations.
- For the "insurance coverage and billing" category, DTBE should review ICD-10 Code R76.12 to determine whether this language should be revised or updated. This code is embedded in electronic medical records and is used for LTBI testing with interferon gamma release assays (IGRAs).
- DTBE should consider the possibility of adding a new "evaluation" category. Although the multi-level approach is comprehensive, crosscutting indicators are still needed to measure impact and assess the effectiveness of the activities in reducing LTBI rates over time. For example, a crosscutting indicator could be the collection of pharmacy data to identify changes in INH prescriptions and determine the number of people who receive LTBI treatment over time.

In response to Ms. Cole's question regarding ACET's potential role in CMS establishing a mandatory NCD for LTBI, Dr. LoBue clarified that ACET is not chartered to provide guidance directly to CMS. However, ACET could raise this issue in a letter to the HHS Secretary.

Dr. Andrew Vernon, Chief of the DTBE Clinical Research Branch, informed ACET of several significant LTBI research activities and advancements that are underway. The results of the first formal randomized trial of four months of rifampin for LTBI treatment will be released in the fall/early winter of 2017. The results of four weeks of daily INH and RPT in PLWH in high-risk settings, particularly in sub-Saharan Africa, will be released in early 2018. A trial of six weeks of daily RPT only will be launched in early 2018. The development of a new biomarker for LTBI is ongoing to determine its ability to predict TB.

Ms. Suzanne Marks, of DTBE, announced that the University of California, San Francisco (UCSF) is one of the grant recipients of the NCHHSTP Epidemiologic and Economic Modeling Agreement. UCSF is modeling the impact of the USPSTF LTBI recommendation and expects to release preliminary data by the end of September 2017.

Update by the Council of State and Territorial Epidemiologists (CSTE)

Shama Ahuja, PhD, MPH
Director of Surveillance and Epidemiology, Bureau of Tuberculosis Control
New York City Department of Health and Mental Hygiene
ACET Liaison Representative for CSTE

Dr. Ahuja provided ACET with the background and an overview of the events that led to the presentation of an LTBI case definition during the 2017 CSTE Annual Conference on June 4-8, 2017. CSTE serves as a "professional home for applied epidemiologists." The mission of CSTE is four-fold: (1) promote effective use of epidemiologic data to guide public health practice and improve health; (2) support effective public health surveillance and epidemiologic practice through training, capacity development, and peer consultation; (3) develop standards for practice; and (4) advocate for resources and scientifically-based policy.

CSTE developed a process for position statements to represent the documentation and analysis of policy issues affecting public health and cover any issue of importance to CSTE members. Position statements can be in the form of either general policy statements or a call for placing health conditions under standardized surveillance (including establishing case definitions and placing conditions on the national notifiable diseases list). Position statements are submitted each spring for a discussion and formal vote by the CSTE membership during the Annual Conference in June. Authors of position statements must be active CSTE members, but associate members may be co-authors.

A position statement for standardized surveillance of diseases or conditions must include the following information:

- Statement of the problem
- Background and justification
- Statement of the desired action(s) to be taken
- Goals of surveillance
- Methods for surveillance

- Criteria for case identification
- Case definition for case classification
- Period of surveillance
- Data sharing/release issues and print criteria
- Revision history
- References
- Coordination
- Author Information

In terms of the CSTE approval process, all CSTE members are encouraged to attend the position statement discussions during the Annual Conference. CSTE Steering Committees organize these discussions for each position statement to be presented by the author for a discussion and formal vote. The author is required to attend the Annual Conference to present the position statement. CSTE members must meet a quorum to vote on a position statement. Position statements that are approved by the Steering Committee are submitted during the CSTE business meeting for final approval. Representatives from state and territorial health agencies vote on the position statement. Each state and territory is given one vote. All approved position statements become CSTE policy and are posted on the CSTE website.

NTCA formed an LTBI Surveillance Workgroup in 2016. Mr. Andrew Tibbs, a TB epidemiologist in Massachusetts, chairs the workgroup. Members of NTCA's subsections were asked to join the workgroup, including the Society for Epidemiology in TB Control (SETC) (NTCA's epidemiology subsection) as well as the clinician and nurse subsections. The workgroup is broadly represented by various types of jurisdictions, including 17 states, two counties, one city, and CDC.

The NTCA Board charged the workgroup with completing five major tasks: (1) review and consider key questions in the discussion of LTBI; (2) review existing programs, infrastructures, and the literature to establish a roadmap for LTBI reporting in the future; (3) define the purpose of LTBI surveillance; (4) establish a definition for an LTBI "case;" and (5) explore strategies to support programs in the implementation of LTBI surveillance. The workgroup considered and discussed the following questions to fulfill its charge.

- How should LTBI be considered in the context of declining TB cases?
- Would the same approaches work?
- What is LTBI?
- Should reporting LTBI be universal, sentinel, or modeled?
- What would the purpose be?
- What public health action or intervention would result?
- Who is already doing some surveillance for infection?
- Are all jurisdictions equally prepared, capable, and interested?
- What resources can be expected to do this work?
- Who are the patients? Where do they get tested? Where do they get treated?
- What data are required to achieve the defined objectives?

The workgroup's initial steps were to apply the CSTE process for standardized surveillance to define a case definition for surveillance rather than for clinical purposes. The workgroup held internal discussions with its members and external discussions with stakeholders in their

jurisdictions over several months. The finalized case definition was entered into the CSTE template and presented during the 2017 CSTE Annual Conference on June 4-8, 2017.

The workgroup presented the following case definitions for LTBI. "Suspected LTBI is a case that meets one or more of the laboratory criteria (+TST or IGRA) AND *M. tuberculosis* complex was not isolated from a clinical specimen, if a specimen was collected." "Confirmed LTBI is a case that meets one of the laboratory criteria for TB infection (+TST or IGRA) AND *M. tuberculosis* complex was not isolated from a clinical specimen, if a specimen was collected, AND meets the clinical criteria for TB infection (no TB symptoms or chest imaging consistent with TB)."

The standard definition of LTBI that was prepared and submitted by the NTCA/SETC LTBI Reporting Workgroup, with a focus on LTBI reporting and surveillance, was successfully and unanimously passed by the Infectious Disease Subcommittee and officially adopted by CSTE on June 8, 2017. However, CSTE has not made LTBI a nationally notifiable condition. Moreover, CSTE has no authority to mandate the reporting of a condition in any jurisdiction.

The workgroup's next steps will be to disseminate the LTBI case definition for surveillance for use by programs. The workgroup will expand its ongoing discussions to engage the CDC surveillance team. However, emphasis will be placed on the differences between reporting jurisdictions in terms of their resources, political environments, databases, staffing levels, and surveillance infrastructures. As a result, the workgroup will recommend a tiered approach to LTBI reporting and will begin identifying potential tiers in this effort.

ACET DISCUSSION: CSTE UPDATE ON LTBI REPORTING

The ACET members discussed the following topics with Drs. Ahuja and LoBue during the question/answer session.

- The level of enthusiasm for and the feasibility of jurisdictions actually adopting and implementing CSTE's LTBI case definition, particularly states that already have developed LTBI reporting systems.
- The interface between CSTE's LTBI case definition for surveillance and DTBE's proposed concept of operations for LTBI reporting.
- The need to use LTBI tests with a high level of specificity to overcome administrative issues.
- The differences between CSTE's case definition and the definition of "TB disease" in CDC's Report of Verified Case of Tuberculosis.

The question/answer session led to the ACET members providing guidance to DTBE on the following topics.

- CSTE's leadership and the NTCA workgroup's extensive efforts in establishing a standardized case definition for LTBI reporting are commendable. However, the workgroup should carefully consider important nuances of these criteria, beyond an IGRA or tuberculin skin test (TST), in its ongoing discussions. These challenges include:
    - The additional burden of locating information on whether a specimen was collected.

- The eight-week wait for a negative test result because the definition calls for not isolating the *Mycobacterium tuberculosis* (MTB) complex from a clinical specimen.
- The difficulty in collecting specimens from children.
- The additional burden of collecting LTBI data and uncertainties regarding the quality of these data.

An example of a much simpler, but cruder approach would be to count positive IGRA or TST results to obtain a broad LTBI denominator.

- The case definition should include an option that does not compel programs to report a positive LTBI test result if the result is not found to be meaningful. For example, false-positive LTBI test results have led to side effects in some people from unnecessary treatment.

- DTBE should investigate whether the stages of LTBI diagnosis, such as "prior treatment" and "treatment completed," can be included in ICD-10 codes. These types of diagnostic codes have been established for other diseases and have been extremely helpful to community providers in caring for their patients across jurisdictions.

Dr. LoBue commended CSTE and the NTCA workgroup on their diligent efforts in establishing an LTBI case definition for surveillance. He agreed with ACET's comments regarding the need to address key challenges associated with LTBI reporting. As a result, he fully supported the workgroup's plan to recommend a tiered, incremental approach over time. He also was in favor of the workgroup's suggestion for individual jurisdictions to customize their approaches to LTBI reporting based on local needs and capacity, particularly since additional resources for this effort have not been allocated at this time.

Dr. LoBue asked Dr. Flood to contact him to further discuss her suggestion for DTBE to explore whether new LTBI diagnostic codes could be included in ICD-10 codes.

Dr. Vernon advised the NTCA workgroup to revise the case definition to more easily update the language on diagnostic technologies. For example, instead of referencing specific tests, such as "…one of the laboratory criteria for TB infection (+TST or IGRA)," the language could be changed to "currently approved laboratory criteria."

Evaluating Contact Investigations Using the Aggregate Reports for Program Evaluation (ARPE)

Maureen Kolasa, MPH
Program Evaluation and Health Economics Team Leader
Data Management, Statistics, and Evaluation Branch, DTBE
Centers for Disease Control and Prevention

Ms. Kolasa presented an update on DTBE's use of the ARPE to evaluate contact investigations (CIs). The ARPE is an annual standardized report on CIs that is submitted to CDC by each of the 61 TB control jurisdictions. The ARPE summarizes the evaluation of contacts to TB cases and treatment of contacts diagnosed with LTBI by the type of TB cases investigated (i.e., sputum smear-positive, sputum smear-negative, culture-positive, or other). Examples of other

types of contact investigations include associate-contact investigations or source-case investigations performed due to a child with TB. The ARPE also identifies areas for improvement in CI methods.

ARPE data are directly entered into and are available in the National Tuberculosis Indicators Project (NTIP). NTIP is a monitoring system for tracking the progress of TB control programs toward achieving national TB program objectives. The indicators are used to measure progress for each objective. The national targets for 2020 are based on statistical models using 2000-2011 ARPE data of TB grant recipients performing at the top 10 percent of TB programs in the United States. These targets are provided as guidance to TB grant recipients as aspirational targets by the year 2020.

DTBE established the following indicators and targets for the 2020 national TB program objectives related to CIs.

Measurable Outcomes of Contact Investigation	Target
Contact Elicitation ➢ For TB patients with sputum Acid-Fast Bacillus (AFB) smear-positive results, increase the proportion with contacts elicited	100%
Examination ➢ For contacts to sputum AFB smear-positive TB cases, increase the proportion examined for infection and disease	93%
Treatment Initiation ➢ For contacts to sputum AFB smear-positive TB cases diagnosed with LTBI, increase the proportion starting treatment	91%
Treatment Completion ➢ For contacts to sputum AFB smear-positive TB cases that have started treatment for LTBI, increase the proportion that complete treatment	81%

Ms. Kolasa presented images of the *ARPE Training Manual and User's Guide* and the ARPE form that are available to TB grant recipients. She also summarized the performance of TB grant recipients based on 2010-2014 ARPE data.

- For the "contact elicitation" indicator, the percentage of sputum AFB smear-positive TB cases with contacts elicited slightly decreased from 95.4 percent in 2010 to 93.6 percent in 2014.

- For the "examination" indicator, the percentage of contacts to sputum AFB smear-positive TB cases with contacts examined slightly decreased from 82.5 percent in 2010 to 81.1 percent in 2014.

- For the "treatment initiation" indicator, the percentage of contacts to sputum AFB smear-positive TB cases who were diagnosed with LTBI and started treatment remained relatively level from 72 percent in 2010 to 71.6 percent in 2014.

- For the "treatment completion" indicator, the percentage of contacts to sputum AFB smear-positive TB cases who completed LTBI treatment increased from 67.9 percent in 2010 to 73.5 percent in 2014.

- Of 64,148 contacts to sputum AFB smear-positive TB cases in the United States in 2014, 52,029 were examined, 8,594 were diagnosed with LTBI, 6,156 initiated treatment, and 4,522 completed treatment. Although 52.6 percent of contacts who were diagnosed with LTBI in 2014 completed treatment, 28.4 percent (or 2,438 contacts) did not initiate treatment. Another 5.1 percent of contacts were lost to follow-up, had an unknown/ missing result (4.4 percent), moved (1.2 percent), or chose to stop treatment (5.9 percent).

- Other indicators that were evaluated in CIs of sputum AFB smear-positive TB cases from 2010-2014 are highlighted below:
    - The average number of contacts per case decreased from 18.7 in 2010 to 17.8 in 2014.
    - The TB disease rate slightly decreased from 0.9 percent in 2010 to 0.8 percent in 2014.
    - The LTBI rate decreased from 19.1 percent in 2010 to 16.5 percent in 2014.
    - LTBI treatment completion increased from 66.7 percent in 2010 to 73.5 percent in 2014.

TB grant recipients can access NTIP online to view and compare their individual ARPE results with the program targets, state and national averages, and national targets. However, DTBE acknowledges the limitations of ARPE data. The aggregated nature of the ARPE data reported to CDC limits epidemiologic analyses. Moreover, the types of diagnostic tests and LTBI treatment regimens are not specified. Furthermore, ARPE data that are reported to CDC by TB grant recipients have not been validated.

DTBE reached several key conclusions based on the 2014 ARPE results. Level performance was observed for most CI indicators from 2010-2014. Program evaluation is needed to identify strategies to assist the TB grant recipients in meeting the 2020 national objectives for contact elicitation, examination, treatment initiation, and treatment completion. The increase in LTBI treatment completion likely is due to short-course regimens, such as 3HP. The decrease in the percentage of contacts diagnosed with LTBI is likely due to the increased usage of IGRA, which leads to a more accurate diagnosis of people with TB infection. Because IGRA tests generate fewer false-positive results, fewer contacts are identified with LTBI.

Jurisdictions can develop program evaluation plans by using APRE results to (1) assess the effectiveness and efficiency of their current CI strategies and (2) develop, implement, and evaluate innovative strategies to help meet the 2020 national TB program objectives. These strategies could include developing new tools to promote treatment initiation and completion among contacts and improving contact tracing to reduce the number of contacts lost to follow-up.

Overall, the ARPE is DTBE's only data system that captures the productivity of CIs, trends, and results from TB grant recipients over time. Moreover, the ARPE summarizes changes due to new strategies and treatment regimens; serves as a tool to identify areas for improvement in CI processes; provides a foundation for developing program evaluation plans to assess CI strategies; and facilitates opportunities for communication within and between jurisdictions.

DTBE's next steps to evolve the ARPE will be to explore linkages with the National Tuberculosis Surveillance System (NTSS) and emerging national LTBI registry. A web-based application has

been implemented to allow TB grant recipients to interactively view ARPE data. Ms. Kolasa concluded her update with a live demonstration of the web-based application.

ACET DISCUSSION: EVALUATING CIS USING THE ARPE

Dr. Mermin raised the possibility of DTBE modifying the current ARPE form with the inclusion of two new fields: "What diagnostic test was used?" "What treatment regimen was used?" He made this suggestion because DTBE cannot use ARPE data at this time to definitively ascertain whether the increase in LTBI treatment completion is actually due to the uptake in 3HP or if the decrease in LTBI is actually due to the use of IGRAs. Moreover, no increase was reported for the treatment initiation indicator from 2010-2014.

Ms. Kolasa clarified that aggregate ARPE data reported by the TB grant recipients do not include individual-level data. If NTSS is expanded to include CI information and treatment outcomes of patients, however, DTBE could link the ARPE and NTSS datasets to collect individual-level data. In follow-up to Ms. Kolasa's comments, Dr. Mermin emphasized that health departments currently have knowledge of and the ability to report aggregate data on the type of diagnostic test and treatment regimen used.

The ACET members provided guidance on the following two topics for DTBE to consider in revising the current ARPE form.

- The ARPE should be revised to include new stratifications that will allow for more effective use of aggregate data. For example, a new field should be added to identify and better characterize risk groups of contacts, such as a foreign-born or U.S.-born contact.
- The ARPE is an excellent tool to obtain a general sense of CIs, but the addition of new data elements should be limited because the data collected and reported by TB programs greatly vary. For example, some programs gather ARPE data on the medical risks of contacts based on their specific settings, exposure risks, and nosocomial infections. Moreover, some programs will be unable to obtain and report ARPE data on the type of diagnostic test and treatment regimen used.

Dr. LoBue confirmed that DTBE could easily modify the ARPE form based on the suggestions by Dr. Mermin and ACET because aggregate data would continue to be collected. However, he explained that DTBE would need to address two key issues prior to the implementation of the revised ARPE form. First, Office of Management and Budget approval would need to be obtained before the TB grant recipients could use the revised ARPE form to report data to CDC. Second, the TB grant recipients would need to be surveyed to provide their input and perspectives on any additional burden and time to collect, aggregate, and report ARPE data on the new fields.

Dr. LoBue advised Ms. Kolasa to contact Ms. Donna Wegener, Executive Director of NTCA, to determine NTCA's interest in collaborating with DTBE on modifying the ARPE form and administering a survey to the TB grant recipients.

Dr. Diana Nilsen, President of NTCA and ACET liaison representative, fully supported the excellent suggestions by Dr. Mermin and ACET to revise the ARPE form. Most notably, new aggregate data on the type of diagnostic test and treatment regimen used as well as risk groups of contacts could help to formulate policies and facilitate decision-making.

Dr. Nilsen also agreed with Dr. LoBue's suggestion for NTCA to administer a survey before any changes are made to the current ARPE form. She expected that many of the 61 TB control jurisdictions, particularly those with no capacity to collect, aggregate, and report the new data elements, would voice strong opposition to the revised ARPE form.

Implementation of Universal Whole-Genome Sequencing (WGS) of *Mycobacterium tuberculosis* in the United States

James Posey, PhD
Applied Research Team Leader
Laboratory Branch, DTBE
Centers for Disease Control and Prevention

Dr. Posey described the implementation of universal WGS of MTB in the United States. The CDC National TB Genotyping Service was established in 2004 to genotype one isolate from each culture-confirmed TB case in the United States. The genotyping methods that CDC currently uses include spoligotyping and mycobacterial interspersed repetitive units/variable number tandem repeat (MIRU-VNTR).

These methods are targeted to regions of the genome that are known to vary across MTB strains. To date, more than 25,000 unique genotypes have been identified. A genotype cluster is formed when MTB isolates collected from at least two TB cases share the same genotype. Based on 2010-2015 data, 58 percent of all isolates in the United States are part of a genotype cluster, ranging from 2-394 isolates per cluster.

Conventional genotyping examines less than 1 percent of the pathogen's genome. The targets are stable over extended periods of time, but interpretation can be difficult when highly related strains remain circulating in the community for long periods of time. By contrast, WGS examines more than 90 percent of the pathogen's genome and provides a more accurate determination of strain relatedness. The key milestones in CDC's transition from conventional genotyping to WGS over time are highlighted below.

- Implementation of conventional genotyping (1995)
- Partnership with the Association of Public Health Laboratories (APHL) to fund five public health laboratories to perform both retrospective and prospective sequencing of approximately 200 isolates per month (2016)
- Funding of a sixth laboratory to also perform retrospective and prospective sequencing (2017)
- Release of a funding opportunity announcement (FOA) to provide universal WGS (2017)
- Implementation of universal WGS and MIRU (early 2018)
- Implementation of whole-genome multi-locus sequence typing (wgMLST) to generate TB cluster alerts (2020 or later)

The CDC Antibiotic Resistance Coordination and Strategy Unit and the Office of Advanced Molecular Detection partnered to establish the new National TB Molecular Surveillance Center. The funding mechanisms for the center include the existing Epidemiology and Laboratory Capacity and the APHL CoAgs (for equipment only). The center will function as part of the Antibiotic Resistance Laboratory Network. As the CoAg recipient, the Michigan Department of

Health and Human Services Bureau of Laboratories will genotype one isolate from each culture-confirmed TB case; perform MIRU-VNTR and WGS to collect data for three years (2018-2020); and shift to WGS only (2021).

CDC is conducting activities in the following three categories to support the transition to universal WGS. For data generation, equipment will be procured (e.g., NextSeq and robotics) in August-September 2017. CDC and the vendor will install the equipment and provide training in October-December 2017. Quality control runs will be performed in January-February 2018. Universal WGS will be initiated in March 2018.

For data analytics, data will be transferred to CDC and the wgMLST scheme will be finalized (six months). The cluster algorithm and naming scheme will be developed, tested, and validated using wgMLST data (24 months). The naming scheme will be integrated into the TB Genotyping Information Management System (TB GIMS) (one month). The whole-genome single nucleotide polymorphism (wgSNP) analysis will be tested and validated with a modified pipeline (six months).

The drug resistance pipeline will be integrated into Bionumerics (three to six months) and tested and validated (two months). Alerts will be developed and tested alerts (one month). The timeline for developing a mechanism to export the rich dataset from WGS to a drug resistance surveillance system will be determined. A data sharing plan recently was finalized and submitted to the NTCA board for review. The plan calls for CDC to share raw data and limited meta-data that will be entered into the National Center for Biotechnology Information database as part of a bioproject.

For data integration and visualization, the typing and naming schemes will be finalized to allow wgMLSType and surveillance data to be entered into TB GIMS. This approach should be fairly seamless and similar to the GENtype integration. Phylogenetic maps will be overlaid with surveillance data. However, interviews with TB programs are underway to identify their actual needs and determine the most useful format for CDC to share these data with states. The evaluation of CDC's existing platforms and methods is ongoing.

Dr. Posey presented two schematics to illustrate the WGS methods and data flow during the transitional period (2018-2020) and in the future (beginning in 2021). WGS data during the transitional period will be produced in a non-regulatory environment and used for surveillance purposes only, such as outbreak detection and drug resistance. The data cannot be used for patient management. Centralized testing will be performed by one laboratory. WGS data in the future potentially could be produced in a regulatory environment, used for clinical management (e.g., species identification and drug resistance), and surveillance (e.g., outbreak detection and drug resistance). Decentralized testing might be possible in the future as well.

Overall, the transitional period from 2018-2020 will include the integration of GENtype data into TB GIMS, cluster alerts, and retrospective sequencing of CIs as funding allows. Universal WGS will be launched in 2018 with wgMLST and wgSNP. The wgMLSType will be developed and integrated into TB GIMS. Current algorithms will be adapted for outbreak detection using wgMLSType data. Interactive phylogenetic maps will be created for end-users to easily modify.

ACET DISCUSSION: IMPLEMENTATION OF UNIVERSAL WGS

The ACET members discussed the following topics with Dr. Posey during the question/answer session.

- CDC's plans to redesign its Molecular Detection of Drug Resistance Service to complement the shift to universal WGS.
- Strategies to avoid duplicating efforts between jurisdictions that currently are using and clinically reporting WGS data and CDC's implementation of universal WGS in 2018.
- CDC's ongoing efforts to further advance the WGS field.
- CDC's plans to provide training to both laboratorians and epidemiologists.
- CDC's plans to use WGS data for other applications, such as identifying cross-laboratory contamination and initiating investigations of false-positive results.

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 Congregate Settings Workgroup is continuing to address an important issue. During the December 2016 meeting, the workgroup informed ACET that no single public health agency is responsible for coordinating CIs of congregate settings when inmates with active TB disease are transferred to different facilities in other jurisdictions. The workgroup is specifically focusing on correctional facilities because people in other types of congregate settings are relatively stable.

Because individual states are attempting to oversee cross-jurisdictional CIs, the workgroup plans to develop a guidance document. The goal of the guidance document will be to clearly define responsibilities and offer recommendations to ensure that inmates with active TB disease who cross jurisdictions are not overlooked. The workgroup expects to present the draft guidance document to ACET for review and comment during the December 2017 meeting.

Ms. Cole advised the workgroup to consult with NTCA in the development of the new guidance document. NTCA could play an instrumental role in engaging and obtaining input from other jurisdictions that are not represented on the workgroup.

Update by the TB Drug Supply Workgroup

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

Ms. Cole reported that the TB Drug Supply Workgroup is developing recommendations in the following two categories to ensure an uninterrupted supply of TB drugs: (1) supply, purchasing, and distribution and (2) pricing and access. To fulfill its charge, the workgroup invited guest speakers to make presentations on other drug supply models, such as the Federal Bureau of Prisons, the CDC Vaccines for Children Program, and the HRSA-funded AIDS Drug Assistance Program.

Ms. Cole announced that Ms. Jennifer Cochran was the past chair of the workgroup, but her term as an ACET member expired in June 2017. She asked the participants to join her in commending Ms. Cochran for her outstanding leadership of the workgroup. She confirmed that if a current ACET voting member does not volunteer to serve as the new chair by the workgroup's next meeting, she would undertake this role to maintain momentum.

Update by the Essential Components Workgroup

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

Ms. Cole presented the August 14, 2017 draft of 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)*.

Ms. Cole reported that the workgroup thoroughly reviewed and considered more than 17 pages of comments and revisions submitted for the previous drafts of the Essential Components document. As a result, ACET's discussion during the meeting should serve as a high-level review, rather than line-by-line editing, of the content in the current draft and any essential components that are missing from the document. NTCA will provide the workgroup with an editor to address any technical issues, such as verb tense and sentence structure.

In preparation of ACET's high-level review, Ms. Cole summarized the essential components of a public health TB prevention, control, and elimination program that have been revised and are highlighted in the current draft.

Essential Component	Task
Role of Health Departments	Identify the unique role and responsibilities of the public health department in TB treatment and prevention.
Overall Planning and Policy	Develop an overall TB control strategy, including written policies and procedures to provide guidance and oversight to facilities and practitioners involved in TB Control.
Surveillance and Reporting of Persons with Confirmed TB Disease	Maintain a surveillance system for timely and accurate reporting of persons with suspected or confirmed TB disease.
Data Analysis	Conduct routine data collection and analysis of trends within the jurisdictions of the program and apply the results to policy, planning, and prevention efforts.
Program Evaluation and Quality Improvement	Evaluate programs, both internally and externally, to provide guidance for improvement.
Laboratory and Other Testing	Maintain access to the most appropriate laboratory and radiology tests recommended for TB disease, drug resistance, and TB infection.

Essential Component	Task
Identification, Management and Treatment of Persons with Latent TB Infection	Identify, manage, and treat contacts and selected other persons infected with MTB.
Identification, Management and Treatment of Persons with TB Disease	Manage persons with suspected or confirmed TB disease as soon as possible, begin an appropriate treatment regimen, and provide case management throughout treatment.
Epidemiologic Investigation	Provide a thorough and timely investigation, whether a source case or contact investigation.
Training and Education	Ensure the provision of training and education to TB program staff, other health departments, clinicians, patients and families, community groups, and the general public.
Partnerships and Collaboration	Work with stakeholders and high-risk populations to maximize efforts and minimize expenses. Elimination of TB cannot be done by public health alone.
Research	Participate in local, national, and international research as program capacity allows.

The workgroup made the following revisions to the Essential Components document based on input submitted by ACET, NTCA, and SMEs in the field.

- Several content areas were reorganized for continuity of the information.
- The following sections were expanded or modified: Contact Investigation, Source Case Investigation, Pediatrics, Corrections, Laboratory, and Research.
- The document was reviewed in its entirety, with input from CDC communications staff, to address stigmatizing language.
    - "TB suspect" was changed to "person suspected of having TB."
    - "Control" is included in the list of stigmatizing TB language, but the workgroup agreed to retain "TB control" in the document. This terminology is an important public health function and a valid concept when referring to the program and disease.
- New references were added.
- All of the appendices were updated.
    - Glossary
    - Core Public Health Functions and Essential Services
    - Responsibilities of the TB Controller and the TB Program Manager
    - CDC-funded Resources

- Tests Used to Assess TB Infection and Disease, and to Monitor Treatment Progress
- LTBI Regimens and Treatment of LTBI in Special Populations
- Education and Training Resource List
- Current Research Questions

Ms. Cole 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. She was confident that the Essential Components document would greatly benefit public health programs in their TB prevention, control, and elimination efforts.

ACET DISCUSSION: ESSENTIAL COMPONENTS WORKGROUP REPORT

The ACET members applauded the workgroup on its diligent efforts to update the 1995 Essential Components document and revise multiple drafts over a long period of time. The workgroup also was commended for widely soliciting input from a diverse group of stakeholders. The ACET members found the current version to be an excellent document and proposed only two revisions for the workgroup to consider in producing the final draft.

- A clear statement should be included in the Laboratory section on the use of the GeneXpert® test to release TB patients from airborne isolation.
- The content on page 15, lines 426-428, should be changed as follows: "Effective infection control measures should be in place based on CDC, federal and state guidelines [*14*]. Comprehensive approaches include appropriate implementation of administrative controls and respiratory protection."

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 or further discussion in the future.

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. David Warshauer for ACET to approve the previous meeting minutes.

ACET approved the Draft April 11, 2017 Meeting Minutes, with no changes or further discussion, by a majority vote of 9 members in favor and 2 abstentions (Drs. Ana Alvarez and Jennifer Flood).

Business Item 2: ACET Vote on the Essential Components Document

Ms. Cole announced that the majority of NTCA members have approved the August 17, 2017 draft of the Essential Components document through an electronic voting process. She opened the floor for ACET's formal vote.

MOTION 1

Action	Description
Chair's call for a vote	Ms. Barbara Cole properly placed a motion on the floor for ACET to approve and endorse the content in the Essential Components of a Public Health Tuberculosis Prevention, Control, and Elimination Program Document Dr. Lisa Armitige seconded the motion.
Outcome of the vote	**The motion was unanimously approved by 9 ACET voting members.**
Next steps	The workgroup will follow-up with NTCA to determine the outcome of the final vote of its entire membership.

MOTION 2

Action	Description
Chair's call for a vote	Ms. Barbara Cole properly placed a motion on the floor for ACET to approve the submission of the Essential Components document to the *MMWR* Recommendations and Reports for publication. Dr. Ana Alvarez seconded the motion.
Outcome of the vote	**The motion was unanimously approved by 9 ACET voting members.**
Next steps	The workgroup will engage external expertise to complete the technical editing; reformat the Essential Components document in accordance with *MMWR* guidelines; and submit the document to the *MMWR* Recommendations and Reports for publication. Other journals will be explored if the document is not accepted by the *MMWR*. In addition to publication in a journal, an abbreviated version of the document also will be posted online to simplify and streamline future updates.

Business Item 3: ACET Report to the HHS Secretary—2017

Ms. Cole noted that the most recent draft of ACET's 2017 report to HHS Secretary Thomas Price was distributed to the members for review and comment. She pointed out that the current draft reflects input provided by the ACET members during the April 2017 meeting.

ACET DISCUSSION: 2017 REPORT TO THE HHS SECRETARY

The ACET members proposed several revisions for Ms. Cole to consider in producing the next draft of the 2017 report to the HHS Secretary.

- Section 2:
    - Change the heading to "TB in congregate settings with an emphasis on corrections and homeless settings."
    - Revise the first sentence as follows: "ACET has recommended prioritization of activities to address TB in the United States."

- Section 4:
    - Change the heading to "Strengthening the TB public health infrastructure."
    - Revise the first sentence as follows: "It is important to ensure that adequate financial resources are available to perform basic TB control functions and address the reservoir of millions of people with LTBI."
    - Delete the entire second sentence that discusses "the ability to address emerging and re-emerging infectious diseases, such as Ebola and Zika."
    - Include new language with a specific request for the HHS Secretary to focus on and endorse the concept of a National Prevention Initiative to strengthen the TB public health infrastructure.

- Summary:
    - Rename the "Summary" heading.
    - Provide more details on the two strategies that are described to eliminate TB in the United States: collaborate with the private sector and assist with global TB control efforts to protect the country from imported TB cases.

- Page 3: Include new language with a specific request for the HHS Secretary to encourage CMS to establish a mandatory NCD for LTBI testing and treatment. Based on the DTBE Director's report by Dr. LoBue, Medicare and its administrative contractors establish NCDs to provide coverage information and determine whether certain services offered by participating providers are reasonable and necessary.

- Include new language to highlight two requests to the HHS Secretary: (1) provide a more visible statement regarding "no cost-sharing for LTBI treatment" and (2) provide guidance to emphasize the importance of developing national indicators for LTBI testing and treatment (similar to indicators that have been established for other Medicaid/Medicare services).

Dr. Mermin advised Ms. Cole to review the two sentences in the Summary section to determine whether the content fully and adequately expresses ACET's perspectives on the actual needs to meet challenges for TB prevention, control, and elimination over the next decade. He noted that stronger language might be warranted in this regard.

Ms. Cole planned to revise the 2017 report to the HHS Secretary, based on the input provided by ACET and Dr. Mermin, and circulate the next draft to the members for review and comment. However, she requested clarification from Dr. Dean on the timeline of CDC's internal review process. Most notably, ACET's review of the next draft during the December 2017 meeting likely will not allow for sufficient time to finalize and submit the report to the HHS Secretary in 2017. She pointed out that ACET's draft document on its "Key Activities for 2016" also will be outdated by December 2017 and will need to be revised.

Dr. Dean explained that after ACET formally votes to approve the final draft of the report, the document will be processed through various policy channels at CDC and ultimately submitted to the Office of the HHS Secretary. Dr. Price will send a response letter to CDC that will be addressed to Ms. Cole. Dr. Dean or her staff will distribute Dr. Price's letter to the entire ACET membership for review. During the next public meeting, ACET can discuss the response letter and determine whether follow-up actions are needed.

Business Item 4: Division of Global Migration and Quarantine (DGMQ) TB Technical Instructions (TI) Workgroup

Ms. Cole represents ACET on the DGMQ-TI Workgroup that was established to update the 2009 TB TIs. She summarized the three major issues that the workgroup has been addressing during its two meetings to date.

- In countries with a TB incidence rate of 20 or more cases per 100,000 population as estimated by the World Health Organization (WHO), panels currently are required to perform LTBI testing on children 2-14 years of age with TST or IGRA. The workgroup has proposed to make a similar change in the new TIs with the following language: "In countries with a WHO-estimated TB incidence rate of 20 or more case per 100,000 population, panels are required to test for LTBI using IGRA. TST can only be used if IGRA cannot be obtained in the country where the examination is occurring. Civil surgeons will be required to use IGRA only for all applicants 2 years of age and older. TST will not be an option unless an IGRA shortage is not projected to be remedied in a defined amount of time."

- Panel physicians currently perform LTBI testing in children 2-14 years of age only in countries with an incidence rate of 20 or more cases per 100,000 population. The workgroup is interested in increasing this age range and has proposed the following language for the new TIs: "In countries with an incidence rate of 20 or more cases per 100,000 population, IGRA testing in all immigrant applicants 2 years of age and older is required." People 15 years of age and older in these countries will be required to undergo IGRA testing in addition to their usual chest X-rays. Panels can substitute TST for IGRA only if IGRA is not available in their country.

- The workgroup will discuss LTBI reporting by civil surgeons to local health departments during the next meeting.

Ms. Cole reminded the members that DGMQ is scheduled to present an overview of the 2017 TB TIs during the December 2017 ACET meeting.

Dr. Nilsen commended the DGMQ-TI Workgroup on its ongoing efforts to update the 2009 TB TIs. She emphasized that the new TIs will play a critical role in helping TB programs to better manage their patients, particularly New York City and other jurisdictions with large populations of immigrants who migrate to the United States from high incidence countries. Based on Ms. Cole's update, she noted that the workgroup plans to discuss LTBI reporting by civil surgeons to local health departments during its next meeting. However, she urged the workgroup to include

an additional requirement in the new TIs for civil surgeons to also report the use of blood-based IGRAs.

Business Item 5: Follow-up on a Previous ACET Motion

Ms. Cole reminded the members that ACET unanimously approved a motion during the April 2017 meeting to develop a position statement to express its concern regarding the omission of TB from the WHO global priority list of pathogens. During the previous meeting, the ACET members emphasized that the inclusion of TB in the list would help to guide research, discovery, and the development of new antibiotics. Because ACET has not taken any further action on drafting the position statement, Ms. Cole asked the members to propose the next steps to close-out the motion.

Dr. LoBue announced that Stop TB Partnership led a campaign for multiple organizations to sign a letter to Dr. Margaret Chan, the WHO Director-General, to address this issue. However, the letter by the organizational partners has not influenced WHO to change its position and include TB in the global priority list of pathogens.

The ACET members agreed with Ms. Cole's suggestion to take no further action on the motion. Most notably, a written statement is not needed because ACET's formal position regarding the omission of TB from the WHO global priority list of pathogens is on public record.

Business Item 6: Previous Advice Requested from ACET

Peter Davidson, PhD
Tuberculosis Control Program Manager
Michigan Department of Health and Human Services

Dr. Davidson reported that the NTCA/RTMCC Workgroup was formed to develop guidance regarding the need to support an expanded range of TB medical consultation services. The workgroup compiled its guidance to draft a white paper, *New Strategies for Approaching Medical Consultation for Tuberculosis*. Dr. Alfred Lardizabal, a workgroup member, presented the draft white paper to ACET during the December 2016 meeting.

The NTCA/RTMCC Workgroup's presentation included a request for ACET to endorse, formally approve, and submit the white paper to DTBE for action. However, ACET asked the workgroup to more clearly define its request. In response to this comment, the workgroup refined its request and is now asking ACET to focus on the following four issues that warrant action at this time.

- Support should be provided to expand TB medical consultation to meet the needs for longitudinal care. Services should be offered at three levels to meet the needs of programs and providers.

- Consultation, as needed, at the current funding level: This level of service would involve single consultation with follow-up as requested by a TB program or provider.
- Longitudinal consultation: (1) Routine, long-distance conference meetings would be held on either a biweekly or monthly basis to review ongoing complex cases and clinical needs as requested by the TB program. (2) Formal arrangements would be made to provide long-distance, comprehensive case management support and technical assistance.
- Access to specialty in-patient services for complex TB care.

- Additional resources should be identified for the RTMCCs to grow their capacity to offer expanded and longitudinal consultation.

- Current and future funding for TB programs should be preserved to maintain or build necessary TB program capacity.

- The establishment of a Medicare public health exemption should be investigated to ensure that complex TB patients, who otherwise cannot be treated in the community and require high-specialty care, can access centers of excellence, even across state lines.

Dr. Davidson noted that although the NTCA/RTMCC Workgroup addressed ACET's request for more clarification on the white paper, additional efforts are still needed before DTBE can take action on and respond to the recommendations to expand TB medical consultation. Most notably, interactions between TB programs and the RTMCCs need to be clearly defined. In the interim, he asked for ACET's endorsement and formal approval of the workgroup's recommendations on the following three topics to reflect the current funding environment and enable an investigation of innovative delivery systems.

1. ACET should endorse 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.

2. ACET should recommend that DTBE give explicit permission to the RTMCCs to redirect their current and future funding, within specified parameters, to support longitudinal medical consultation costs.

3. ACET should endorse the formation of an external workgroup to examine new and innovative modalities for the delivery of medical consultation services and investigate a Medicare designation for TB care. The new external workgroup should include diverse representation by ACET, DTBE, NTCA, and the RTMCCs.

ACET DISCUSSION: NTCA/RTMCC WHITE PAPER

The ACET members made three key suggestions for DTBE to consider while the NTCA/RTMCC Workgroup refines the white paper recommendations.

- DTBE should explore the possibility of supporting a web-based platform for all TB medical consultants to access and review X-ray reports, comments from other providers, and other important information.

- DTBE should ensure that longitudinal consultation is well coordinated between state and local health departments due to the diversity of their needs across the United States.
- Recommendation 3 should be revised with more specific language: "…a Medicare designation for the care of TB disease."

In response to ACET's questions on recommendation 2, Dr. LoBue explained that the RTMCCs have no restrictions to redirect their funds to support the cost of longitudinal medical consultation. However, additional resources will need to be allocated to the RTMCCs for training, education, and medical consultation. He noted that new language in the 2018 FOA will require the RTMCCs to consider all aspects related to longitudinal consultation.

In response to ACET's questions on recommendation 3, Ms. Cole confirmed that ACET is permitted to serve on external workgroups outside of DTBE. For example, ACET currently is represented on the DGMQ-TI Workgroup and the CDC Office of Infectious Diseases, Board of Scientific Counselors.

MOTION 1: RECOMMENDATION 1

Action	Description
Chair's call for a vote	Ms. Barbara Cole properly placed a motion on the floor for ACET to endorse 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. Dr. Robert Horsburgh seconded the motion.
Outcome of the vote	**The motion was unanimously approved by 9 ACET voting members.**

ACET agreed with Ms. Cole's suggestion to take no formal action on recommendation 2. During the discussion, Dr. LoBue confirmed that DTBE has established a process for RTMCCs to redirect their funds to provide longitudinal medical consultation services.

MOTION 2: RECOMMENDATION 3

Action	Description
Chair's call for a vote	Ms. Barbara Cole properly placed a motion on the floor for ACET to endorse 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. Dr. David Warshauer seconded the motion.
Outcome of the vote	**The motion passed by a majority vote of 8 members in favor and 1 abstention (Dr. Michael Lauzardo).**
Next steps	NTCA will initiate planning efforts to form the external workgroup, including the sponsoring organization and the chair. Dr. Davidson will ask the authors of the NTCA/RTMCC white paper to serve as workgroup members, while Ms. Cole will identify representation from ACET. An update by the external workgroup will be placed on the agenda of the December 2017 ACET meeting.

Business Item 7: Update on Stigmatizing Language

Dr. Armitige reminded the ACET members that during the April 2017 meeting, Dr. LoBue asked for examples of materials currently posted on the DTBE website with stigmatizing language. She performed a cursory search of "TB suspect" and found that this terminology was included in only a few materials. She forwarded these examples to Dr. LoBue for review.

Dr. LoBue explained that the use of "TB suspect" is limited to older documents developed by DTBE seven to 11 years ago. Older documents, including archived materials, are retained on the CDC.gov website for extended periods of time. DTBE would be unable to change these materials, particularly published papers and reports. However, DTBE will conduct an inventory of its web-based materials in the fall of 2017 to ensure that active training documents and educational resources for providers and patients do not contain stigmatizing language.

Dr. LoBue clarified that in its upcoming review and inventory, DTBE likely will be unable to identify all instances of stigmatizing language because the web-based materials total thousands of pages. As a result, he asked the ACET members to notify DTBE staff of current web-based materials that should be revised with more enabling language. For example, DTBE already has made a decision to replace "foreign-born" with "non-U.S.-born" in its documents due to the stigma associated with this terminology. This change will be reflected in the new TB Surveillance Report that DTBE will release in the fall of 2017.

Business Item 8: Future Agenda Items

Ms. Cole confirmed that the Agenda Setting Workgroup would convene a teleconference to draft an agenda based on the topics ACET proposed over the course of the meeting. The draft agenda would be circulated to ACET for review in advance of the December 2017 meeting.

Presenter	Agenda Item
Dr. Philip LoBue	DTBE Director's Report: ➢ Ongoing updates on DTBE's study and economic evaluation of electronic forms of DOT ➢ Report on whether new LTBI diagnostic codes can be included in ICD-10 codes ➢ Draft of the updated 3HP guidelines
Dr. Andrew Vernon	Overview of ongoing research on various LTBI treatment regimens [December 2018 meeting]
Ms. Suzanne Marks	Overview of UCSF's preliminary modeling data on the impact of the USPSTF LTBI recommendation
ACET Workgroup Chairs	Workgroup Reports: ➢ Congregate Settings Workgroup (Draft guidance document to assist states in conducting cross-jurisdictional CIs of inmates) ➢ TB Drug Supply Workgroup (An ACET member is needed to serve as the new chair.)

Presenter	Agenda Item
Dr. Peter Davidson	Update by the new external workgroup (with representation by ACET, DTBE, NTCA, and the RTMCCs) that will be formed to examine new and innovative modalities for the delivery of TB medical consultation services
Ms. Maureen Kolasa	Update on DTBE's new collaborative effort with NTCA to survey the TB grant recipients and revise the ARPE form
Dr. Terence Chorba Dr. Peter Davidson	Preliminary recommendations by the TB Funding Formula Workgroup to obtain initial feedback from ACET. This agenda item also should include an overview of revisions to the TB laboratory funding formula.
Dr. James Posey	ACET's input on the data sharing plan for universal WGS of MTB that DTBE submitted to NTCA for review
Ms. Barbara Cole	Closeout of two business items in 2017: ➢ Final draft of ACET's 2017 report to the HHS Secretary ➢ Updated version of ACET's "Key Activities for 2016"

Public Comment Session

Ms. Cole opened the floor for public comments; no participants responded.

In response to a question regarding ACET's amended charter, Dr. Dean announced that a TB survivor or a parent of a child with TB will be appointed to serve as a new voting member when a vacancy becomes available in 2019.

Closing Session

The next ACET meeting will be an in-person meeting that will be convened on December 11-12, 2017 in Atlanta. With no further discussion or business brought before ACET, Ms. Cole adjourned the virtual meeting at 3:20 p.m. on August 22, 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. James Sunstrum
Dr. David Warshauer

ACET Member Absent

Dr. Jeffrey Starke

ACET *Ex-Officio* Members Present

Dr. Naomi Aronson
U.S. Department of Defense

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

Dr. Ulana Bodnar
U.S. Department of Justice

Ms. Sarah Bur
Federal Bureau of Prisons

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

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. David Weissman
National Institute for Occupational Safety and Health
(Alternate for Mr. Stephen Martin)

Dr. David Yost
Indian Health Service
(Alternate for Dr. Sarah Linde)

ACET *Ex-Officio* Members Absent

Dr. Anthony Campbell
Substance Abuse and Mental Health Services Administration

Ms. Caroline Freeman
U.S. Department of Labor,
Occupational Safety and Health Administration

Dr. Sarah Linde
Indian Health Service

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

Mr. Stephen Martin
National Institute for Occupational Safety and Health

Dr. 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

Dr. Robert Morris
National Commission on Correctional Health

Dr. Diana Nilsen
National Tuberculosis Controllers Association

Dr. Jennifer Rakeman
Association of Public Health Laboratories

Dr. Randall Reves
International Union Against TB and Lung Disease

Mr. Bobby Watts
National Health Care for the Homeless Council

ACET Liaison Representatives Absent

Mr. David Bryden
RESULTS

Dr. Fran du Melle
American Thoracic Society

Dr. Mayleen Ekiek
Pacific Island Health Officers Association

Mr. Kenyon Farrow
Treatment Action Group

Mr. Eddie Hedrick
Association for Professionals in Infection Control and Epidemiology

Dr. Ilse Levin
American Medical Association

Dr. Howard Njoo
Public Health Agency of Canada

Dr. Amee Patrawalla
American College of Chest Physicians

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

Ms. Susan Rappaport
American Lung Association

Dr. Susan Ray
Infectious Disease Society of America

Dr. Michael Tapper
Society for Healthcare Epidemiology of America

Dr. Lornel Tompkins
National Medical Association

ACET Designated Federal Officer

Dr. Hazel Dean
NCHHSTP Deputy Director

CDC Representatives

Dr. Maria Aslam
Mr. Greg Bautista
Dr. Lara Bull
Ms. Ann Cronin
Dr. Patricia Dietz
Dr. Brian Edlin
Ms. Maureen Kolasa
Ms. Kathryn Koski
Rebecca Levine, Esq.
Dr. Philip LoBue
Dr. Jonathan Mermin
Dr. Thomas Navin
Dr. Kwame Owusu-Edusei, Jr.
Dr. James Posey

Ms. Margie Scott-Cseh
Ms. Maria Sessions
Dr. Benjamin Silk
Dr. Angela Starks
Ms. Clarisse Tsang
Ms. Michelle Van Handel
Dr. Thara Venkatappa
Dr. Andrew Vernon
Ms. Abigail Viall
Mr. Matthew Whipple
Ms. Rachel Wingard
Ms. Sara Zeigler

Invited Guests/ Members of the Public

Dr. Peter Davidson
National Tuberculosis Controllers Association

Ms. Donna Wegener
National Tuberculosis Controllers Association

Attachment 2: Glossary of Acronyms

Acronym	Definition
3HP	Three-Month Isoniazid/Rifapentine Regimen
ACET	Advisory Council for the Elimination of Tuberculosis
AFB	Acid-Fast Bacillus
APHL	Association of Public Health Laboratories
ARPE	Aggregate Report for Tuberculosis Program Evaluation
CDC	Centers for Disease Control and Prevention
CIs	Contact Investigations
CoAg	Cooperative Agreement
CSTE	Council of State and Territorial Epidemiologists
DASH	Division of Adolescent and School Health
DFO	Designated Federal Officer
DGMQ	Division of Global Migration and Quarantine
DHAP	Division of HIV/AIDS Prevention
DOT	Directly-Observed Therapy
DSTDP	Division of STD Prevention
DTBE	Division of Tuberculosis Elimination
DVH	Division of Viral Hepatitis
eDOT	Electronic Directly-Observed Therapy
FACA	Federal Advisory Committee Act
FOA	Funding Opportunity Announcement
FY	Fiscal Year
HCV	Hepatitis C Virus
HHS	U.S. Department of Health and Human Services
HRSA	Health Resources and Services Administration
ICD	International Classification of Diseases
IGRAs	Interferon Gamma Release Assays
INH	Isoniazid
ipDOT	In-Person Directly-Observed Therapy
LGBT	Lesbian/Gay/Bisexual/Transgender

Acronym	Definition
LTBI	Latent TB Infection
LVDOT	Live Directly-Observed Therapy
MIRU-VNTR	Mycobacterial Interspersed Repetitive Units/Variable Number Tandem Repeat
MMWR	*Morbidity and Mortality Weekly Reports*
MTB	*Mycobacterium tuberculosis*
NCDs	National Coverage Determinations
NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
NTCA	National Tuberculosis Controllers Association
NTIP	National Tuberculosis Indicators Project
NTSS	National Tuberculosis Surveillance System
OD	Office of the Director
PLWH	People Living With HIV
RPT	Rifapentine
RTMCCs	Regional Training and Medical Consultation Centers
RVDOT	Recorded Video Directly-Observed Therapy
SETC	Society for Epidemiology in TB Control
SMEs	Subject-Matter Experts
TB	Tuberculosis
TIs	Technical Instructions
TST	Tuberculin Skin Test
UCSF	University of California, San Francisco
USPSTF	U.S. Preventive Services Task Force
wgMLST	Whole-Genome Multi-Locus Sequence Typing
WGS	Whole-Genome Sequencing
wgSNP	Whole-Genome Single Nucleotide Polymorphism
WHO	World Health Organization