

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



**Virtual Meeting of the
Advisory Council for the Elimination of Tuberculosis
April 11, 2017**

Record of the Proceedings

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**ADVISORY COUNCIL FOR THE ELIMINATION OF TUBERCULOSIS
April 11, 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 April 11, 2017 from 10:00 a.m. – 3:00 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 (or their alternates). 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
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
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 (Baylor College of Medicine)	Member of a Data Safety Monitoring Board for pediatric pharmacokinetics studies 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

Dr. Dean confirmed that the 20 voting members and *ex-officio* members (or their alternates) in attendance constituted a quorum for ACET to conduct its business on April 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 changes to ACET's membership that have occurred in since the December 2016 meeting.

- The term of Jennifer Cochran, MPH will expire on June 30, 2017. Dr. Dean asked the participants to join her in acknowledging Ms. Cochran's outstanding service to ACET, CDC and the broader TB community. A letter of appreciation and a certificate of service will be mailed to Ms. Cochran.
- CAPT Ulana Bodnar, MD, FACP is the Associate Medical Director at the U.S. Department of Justice (DOJ), U.S. Marshals Service. She has replaced CDR Edward Chin as the *ex-officio* member for DOJ.
- Deborah Parham Hopson, PhD, RN is the Senior Health Advisor at the Health Resources and Services Administration (HRSA). She has replaced Dr. Rupali Doshi as the *ex-officio* member for HRSA.
- Nadine Gracia, MD, MSCE is the former Deputy Assistant Secretary for Minority Health and Director of the Office of Minority Health (OMH) at HHS. CDC sent a letter to the acting OMH Director on March 17, 2017 with a request to designate a new *ex-officio member* to replace Dr. Gracia.
- Mr. John Lozier has resigned from his position at the National Coalition for the Homeless. CDC sent a letter to this organization with a request to designate a new liaison representative to replace Mr. Lozier.

- CDC sent a letter to the Association of State and Territorial Health Officials in August 2016 with a request to designate a new liaison representative to replace Dr. Jay Butler.

Barbara Cole, RN, MSN, PHN, ACET Chair

TB Controller

Riverside County (California) Department of Public Health

Ms. Cole also welcomed the participants to the virtual ACET meeting. Although several updates and presentations would be made over the course of the meeting, she confirmed that the agenda was structured with ample time for ACET's discussions.

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 Designated Federal Officer (DFO)

Dr. Dean covered several topics in the NCHHSTP OD report to ACET. At the agency level, Dr. Thomas Frieden resigned from his appointment as the CDC Director in January 2017. Dr. Anne Schuchat began her career at CDC in 1988 and is serving as the acting Director. Dr. Patricia Simone is serving as the acting Principal Deputy Director of CDC.

The stopgap spending bill extends federal government funding through April 28, 2017. The fiscal year (FY) 2017 continuing resolution calls for an across-the-board cut of 0.69%. CDC has no knowledge at this time of any additional reductions in FY2017. The President's FY2018 budget request was released on March 16, 2017. If the request is approved, HHS's budget would be decreased by approximately \$15 billion. A more detailed budget is expected to be released in May 2017.

At the National Center level, NCHHSTP launched an updated and improved version of the Atlas. This interactive, online mapping tool allows users to search for HIV/AIDS, viral hepatitis STD and TB surveillance data. Atlas also enables users to identify areas of the United States that have the greatest disease burden and view other epidemiologic data.

The new [AtlasPlus](#) was updated with 2015 data for HIV, STDs and TB and 2014 data for viral hepatitis. Atlas Plus features a mobile-friendly design; improved visuals of CDC's most recent data by county, state or U.S. totals; a table function that is easier to use; and the capacity for users to create more maps, charts and presentation-ready slides.

At the division level, DTBE served as the lead for CDC on the 2016 publication of the American Thoracic Society/Infectious Diseases Society of America/CDC [Clinical Practice Guidelines: Diagnosis of Tuberculosis in Adults and Children](#). The guidelines provide recommendations on the diagnosis of latent TB infection (LTBI), pulmonary TB and extrapulmonary TB. The 23 evidence-based recommendations also provide guidance on newer tests for diagnosing TB disease and LTBI.

DTBE used World TB Day on March 24, 2017 as an opportunity to highlight [TB elimination champions across the country](#). The DTBE website features activities and personal stories of individuals and organizations that are working to end TB in the United States.

The Division of HIV/AIDS Prevention (DHAP) released new data that showed an 18% decline in the estimated number of annual HIV infections in the United States (or from 45,700 in 2008 to 37,600 in 2014). Marked decreases in annual HIV infections were observed in several priority populations: persons who inject drugs (56%), heterosexuals (36%), and young gay/bisexual males 13-24 years of age (18%). The data also showed that the prevention of 33,200 HIV cases from 2008-2014 resulted in an estimated cost-savings of \$14.9 billion in lifetime medical care. DHAP presented these data at the Conference on Retroviruses and Opportunistic Infections in February 2017.

DHAP's position is that the reductions in annual HIV infections reflect the success of its national HIV prevention and treatment efforts. However, approximately 1.1 million persons are still living with HIV (PLWH) in the United States. Dr. Dean presented a map to illustrate the estimated HIV prevalence among persons ≥ 13 years of age as of 2014.

The Division of Viral Hepatitis (DVH) served as the lead for CDC's co-sponsorship of the National Academies of Science, Engineering and Medicine's Phase Two Report, *A National Strategy for the Elimination of Hepatitis B and C*, that was released on March 28, 2017. The report proposes targets to eliminate hepatitis B and C viruses (HBV and HCV) in the United States as public health threats by 2030.

The report also identifies opportunities for preventing transmission and recommends actions to ensure testing, case management and linkage to care. Several of the recommendations in the report resonate with CDC's priorities for viral hepatitis prevention, such as decreasing deaths by increasing testing and treatment for persons living with HBV and HCV; reducing the spread of HBV and HCV associated with drug use and other common routes; and preventing mother-to-child transmission of HBV and HCV.

DVH analyzed HCV antibody testing among persons with commercial health insurance over the 10-year period from 2005-2014. "Baby boomers" (i.e., persons in the 1945-1965 birth cohort who account for 75% of HCV cases) had a 136% increase in HCV antibody testing, but overall testing in this population is still low. The percentage of baby boomers who were tested increased by 91% (or from 1.7% in 2011 to 3.3% in 2014). DVH noted that the increase in this population likely is due to early adoption of recommendations by CDC and the U.S. Preventive Services Task Force (USPSTF) for one-time HCV testing of baby boomers.

The Division of STD Prevention (DSTDP) currently is celebrating STD Awareness Month in April, but the activities primarily are targeted to syphilis prevention. DSTDP updated its website with the 2017 theme of the campaign, "Syphilis Strikes Back," and has disseminated multiple resources to partners, providers and the public. New visuals on DSTDP's website and social media platforms include key milestones in syphilis and public health posters since the 1940s. During this era, antibiotics were introduced and a successful effort was launched to halt the disease. DSTDP is collaborating with several partners to deliver messaging during STD Awareness Month.

DSTDP is strengthening its focus on syphilis due to increases that have been reported from 2014-2015 in all four regions of the country, in all age groups of males from 15-44 years of age,

and in nearly all racial/ethnic groups. These data serve as a reminder that syphilis can occur and tremendously impact communities at any time and at any location.

The Division of Adolescent and School Health (DASH) recently launched its newly designed website. The website features an updated Healthy Youth home page; a new webpage on [teen health services](#); and a new infobrief that advises parents to ensure that their teens have one-on-one discussions with a healthcare provider.

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. CDC currently is operating under a continuing resolution that will maintain funding at the current level, with the exception of the 0.69% rescission, through April 28, 2017. CDC anticipates that a more detailed budget will be released in May 2017, but the FY2018 administration budget proposal calls for a 17.9% reduction in overall HHS funding (or approximately \$15 billion). The President's FY2018 budget request does not include specific information on appropriations for domestic TB.

DTBE published an article in the *Morbidity and Mortality Weekly Report (MMWR)* on March 24, 2017, "Tuberculosis – United States, 2016," in recognition of World TB Day. In general, the preliminary TB surveillance data showed that the number of TB cases decreased from 26,673 in 1992 to 9,287 in 2016. In particular, DTBE used the provisional data as of February 17, 2017 to perform several analyses.

- TB morbidity has decreased in the United States from 3.4/100,000 persons in 2011 (or 10,510 cases) to 2.9/100,000 persons in 2016 (or 9,287 cases).
- The proportion of TB cases by race/ethnicity in 2016 showed persistent disparities: Asians (34%), Hispanics (28%), African Americans (21%), and Whites (13%). American Indian/ Alaska Natives, Native Hawaiian/Pacific Islanders, multi-racial persons, and persons with unknown race/ethnicity or missing data accounted for the remaining 4% of reported TB cases in 2016.
- The number of TB cases among foreign-born persons/populations (FBPs) was fairly stable at approximately 7,500 cases from 1993-2008, began to decrease in 2009, and has remained level at approximately 6,000 cases since that time. However, the percentage of total TB cases among FBPs has steadily increased from 1993-2016 and is slowing approaching 70% at this time.
- The subset of FBPs who have resided in the United States for at least 10 years accounted for 45%-50% of all TB cases in this population from 1993-2016.
- The percentage of total multidrug-resistant TB (MDR-TB) cases has been fairly stable at 1%-1.5% from 2005-2015. This analysis shows that 80-120 MDR-TB cases are reported in the United States each year.
- The extensively drug-resistant TB (XDR-TB) case count in the United States, based on the initial drug susceptibility test result, has greatly fluctuated from 1993-2015: 10 XDR-TB cases reported in 1993; 6 XDR-TB cases reported in 1994, 1999, 2002 and 2008; and 1 XDR-TB case reported in 1995, 1998, 2000, 2010 and 2015).

DTBE published an additional *MMWR* article on World TB Day, “Tuberculosis Among Foreign-Born Persons Diagnosis \geq 10 Years After Arrival in the United States – 2010-2015.” The data showed that the number and proportion of TB cases among FBPs who arrived in the United States 10 or more years before their diagnosis increased from 1,360 cases in 1993 (or 18.4%) to 2,922 in 2015 (or 46%).

Among foreign-born TB cases, the median age was 56 years and the top three countries of origin that contributed to the U.S. TB burden were Mexico (26.8%), the Philippines (14%) and Vietnam (9.5%). However, the distribution of foreign-born TB cases by the top five countries differed based on the length of residence in the United States.

- U.S. residency of less than 10 years prior to diagnosis: Mexico (14%), India (11%), the Philippines (10%), Vietnam (6%), China (6%), and other countries (53%).
- U.S. residency of 10 or more years prior to diagnosis: Mexico (27%), the Philippines (14%), Vietnam (9%), China (7%), India (6%), and other countries (37%).

DTBE adjusted its analyses to account for other factors in the multi-variable model and found that FBPs with U.S. residency of 10 or more years were more likely to be 40 years of age or older; be of Hispanic ethnicity; reside in a long-term care facility at diagnosis; report excess alcohol use; and have a history of a non-HIV-related immunocompromising condition (e.g., diabetes, end-stage renal disease, use of tumor necrosis factor-alpha antagonist therapy or organ transplantation). Overall, a strong focus must be placed on FBPs with U.S. residency of 10 or more years in TB elimination efforts.

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 problems related to multi-state TB contact investigations of incarcerated persons. The workgroup members described ongoing incidents in which three individuals with infectious TB have been incarcerated in multiple states. However, these persons are not being given adequate TB treatment and care due to the lack of coordination among states. The workgroup, including its CDC technical experts, is exploring strategies to address this issue and hopes to propose potential solutions to ACET during the next meeting.

Update by the Child and Adolescent TB Workgroup

Jeffrey Starke, MD

Professor of Pediatrics, Baylor College of Medicine
Texas Children’s Hospital
ACET Member & Workgroup Chair

Dr. Starke reported that the Child and Adolescent TB Workgroup distributed a summary of its most recent discussions to ACET for review in advance of the meeting. The summary highlights the workgroup’s focus on five key emerging TB issues in the pediatric population.

Use of Interferon Gamma Release Assays (IGRAs) in Young Children

- The American Academy of Pediatrics Committee on Infectious Diseases (i.e., the “Red Book” Committee) will hold a meeting later in April 2017 to finalize the 2018 TB chapter. However, the workgroup has identified recommendations by various groups in several areas that need to be harmonized. Dr. Christine Ho, the Tuberculosis Epidemiologic Studies Consortium (TBESC) Project Officer, presented an unpublished dataset during the December 2016 ACET meeting regarding the 10% positive predictive value (PPV) of the tuberculin skin test (TST) in children less than 5 years of age. Because most of the children in the TBESC study were foreign-born and had a history of Bacillus Calmette-Guérin (BCG) vaccination, two strategies were proposed: the use of IGRAs alone or serial testing with TST followed by IGRAs.

The other unpublished dataset is based on an anonymous database of over 44,000 T-SPOT results from 5,057 children less than 5 years of age. The dataset is not sufficient to validate the sensitivity, specificity, PPV and negative predictive value of the T-SPOT results, but the borderline and invalid results are extremely low, even among children in the youngest age groups.

Similar to the diverse perspectives of the workgroup, the use of IGRAs in children less than 5 years of age also is expected to be a topic of debate during the Red Book Committee meeting. However, a large segment of the pediatric TB community increasingly is using IGRAs in children as young as 18 months to 2 years of age. The workgroup believes that the 2018 TB chapter likely will be developed with more permissive language on the use of IGRAs in children 2-4 years of age. The workgroup plans to raise two key questions during the Red Book Committee meeting: (1) Should additional datasets be pursued through the National Tuberculosis Controllers Association (NTCA) or other sources to address the best use of IGRAs in the youngest children? (2) If so, what is the best approach in this regard? After the Red Book Committee reaches consensus on the guidance to include in the 2018 TB chapter, the workgroup plans to present any recommendations that are different from current CDC practice to ACET for review and discussion.

Treatment of TB Infection

- The 2015 edition of the Red Book recommended nine months of isoniazid (INH) as the preferred regimen for children, but this guidance will be extensively revised in the 2018 edition. The current draft recommends the three most acceptable TB regimens for children by order of preference: three months of INH/rifapentine (3HP), four months of rifampin (RIF), or nine months of INH.

MDR-TB

- CDC is leading an effort to develop new GRADE-based guidelines (i.e., Grading of Recommendations Assessment, Development and Evaluation) for the management and treatment of MDR-TB in the United States. The workgroup will draft the pediatric section with language to emphasize that an effective MDR-TB regimen for adults also would be effective for children. Instead of addressing efficacy, the pediatric section will place more emphasis on safety, tolerability and pharmacokinetic data of an MDR-TB regimen.

TB Meningitis

- The workgroup discussed an upcoming meeting that the National Institute of Allergy and Infectious Disease will convene on May 21-22, 2017. Experts from around the world will be in attendance to consider basic and clinical questions and discuss critical needs regarding TB meningitis, including diagnosis, immunotherapy and new approaches to antimicrobial therapy. The workgroup is interested in the outcomes of the meeting because TB meningitis preferentially affects children.

BCG Vaccination

- Dr. Starke was appointed as a member of the World Health Organization's (WHO) newly established BCG Strategic Advisory Group of Experts. Over the next 18 months, the workgroup will consider all aspects of BCG vaccination, including supply, cost, strain variation, age at immunization, revaccination, efficacy for TB, and effects on leprosy, non-tuberculous mycobacteria and all-cause mortality in children. Data that show a decrease in all-cause mortality with BCG vaccination will be important to consider as clinical trials are launched for new TB vaccines.

Update by the Essential Components Workgroup

Barbara Cole, RN, MSN, PHN, ACET Chair

TB Controller

Riverside County (California) Department of Public Health

Ms. Cole reported that after the December 2016 ACET meeting, the workgroup received several helpful comments to refine the joint ACET/NTCA document, *Essential Components of a Public Health Tuberculosis Prevention, Control and Elimination Program*. The workgroup is still addressing a number of key concerns that ACET and NTCA identified to revise the December 2016 draft of the document.

- Clearly distinguish between “core” components and “important” issues to address if resources allow. For example, research is important to advance toward TB elimination, but some state and local TB programs might not have sufficient resources to conduct this activity.
- Strengthen the Contact Investigation/Source Case Investigation sections with a better review of epidemiological links.
- Place more emphasis on pediatric TB.
- Add a new “Quality Improvement” section in addition to the Program Evaluation section.
- Enhance the Laboratory section.
- Include additional information on health literacy and health communication.
- Consider relocating some of the research content from the appendix to the body of the document.
- Review the entire document to ensure the use of patient-centered, non-stigmatizing language.
- Review the content on LTBI and co-morbidities to show a stronger interface between these two areas.
- Develop a separate section on TB in correctional settings.

The workgroup's next steps will be to continue revising the Essential Components document and present the final draft to ACET for review and formal approval during the August 22, 2017

webinar. The workgroup will continue to explore potential venues to publish the document. For example, an online version will allow the document to be more easily updated in a timelier manner when new data are gathered, such as the introduction of new technologies. The workgroup's suggestions of peer-reviewed journals for publication include the *American Journal of Public Health* and *Public Health Reports*. Because the Essential Components document is not based on the GRADE approach, the workgroup likely will not seek publication in the *MMWR*.

Dr. LoBue explained that the GRADE approach is a requirement for CDC guidelines, but not for all *MMWR* articles. He advised the workgroup to contact the *MMWR* editor to obtain clarification on the requirements for publication.

Update on CDC's Global TB Activities

Shannon Hader, MD, MPH

Director, Division of Global HIV & TB (DGHT)
Centers for Disease Control and Prevention

Dr. Hader presented an update on CDC's global TB activities. The strong connection between global and local efforts is well documented based on the patterns of human mobility and migration across the world. For example, airport traffic data show that individuals travel to local and global locations for long periods of time or for short-term connections with families, communities and businesses. Moreover, the Global Health Security Agenda demonstrates similar patterns of interaction and emphasizes the theme of "TB anywhere is TB everywhere." Commitments by the U.S. government to improve global health security networks abroad should be widely publicized to diverse audiences. Most notably, the domestic TB elimination goal cannot be achieved without addressing the global burden of the disease.

TB is among the greatest health threats worldwide and claims 1.8 million lives each year. Recent data show that 1 in 4 people worldwide has LTBI and nearly 10.4 million individuals become ill with the disease each year. TB transmission is person-to-person and can spread across borders. The ongoing spread of TB is driven by two major factors. First, the proportion of undetected or unreported TB cases is estimated at 40%. Second, MDR-TB is a global health crisis and is now reported by every country in the world. MDR-TB accounts for 480,000 new cases and over 200,000 deaths each year.

Missed and inappropriately treated TB cases lead to disease transmission and resistance. In 2015, no notification was provided for 41% of 10.4 million TB cases and 75% of 580,000 MDR-TB cases. These data show that only 1 in 10 MDR-TB cases is successfully diagnosed, appropriately treated and cured. A 2015 modeling study projected the MDR-TB burden by 2050 if no changes are made to the current course of action. Deaths from antimicrobial-resistant infections will outnumber every other major disease. MDR-TB will account for 75 million deaths and cost the world economy \$17 trillion. The non-healthcare losses will include lost growth and an inability for individuals to participate in their communities.

The literature includes numerous analyses, modeling studies and other data to document the cost-effectiveness of TB investments. An expert panel, including Nobel Laureates, identified 19 sustainable development goal (SDG) targets with the best returns on investment from 2016-2030. The expert panel reached three major conclusions.

- A strong focus on the SDG targets would quadruple the impact of aid budget without the need for extra spending.
- A 95% reduction in TB deaths would result in a \$43 gain in environmental, economic and social benefits per \$1 spent.
- The governments of affected countries already account for 84% of TB funding, but the \$2 billion shortfall to reach global TB targets has not been addressed to date.

Additional investments are particularly needed to increase access to high-quality TB services and develop new TB diagnostic tools, treatment and prevention techniques. Programmatic, systematic and capacity issues related to the ability to appropriately target and spend TB dollars need to be resolved as well.

Despite the current gaps, a great deal of progress and momentum has been achieved in global TB over the past two decades. From 1995-2014, 66 million TB patients were successfully treated. From 2000-2015, TB and TB/HIV treatment regimens saved 49 million lives. Since 2000, TB/HIV activities have saved 8.4 million lives. The global TB goal of a 10%-17% annual reduction in the TB incidence has not been reached, but data have shown a steady decrease of 1.5% per year.

New techniques, enhanced diagnostic tools and improved treatment regimens have been introduced to further accelerate progress in global TB. The Xpert® MTB/RIF assay is a cartridge-based nucleic acid amplification test that revolutionized TB control by contributing to the rapid diagnosis of TB disease and drug resistance. The rollout of the Xpert® assay included the delivery of over 10 million cartridges. The number of MDR-TB case notifications has doubled since 2010. The U.S. Food and Drug Administration approved the use of two new anti-TB drugs for MDR-TB. WHO endorsed a shorter MDR-TB regimen of 9-12 months. New tools were endorsed for the rapid detection of second-line drug resistance.

The current global trend of reducing the TB incidence by 1.5% per year must be accelerated to reach the target of ending TB and MDR-TB by 2035. Effective efforts should be scaled-up and investments should be targeted to promote innovation in the following areas: optimize the use of current and new TB tools emerging from the pipeline; pursue universal health coverage and social protection for TB; and introduce new TB tools (e.g., a TB vaccine, new drugs and regimens for the treatment of active TB disease and LTBI, and a point-of-care (POC) TB test).

At the agency level, CDC is aware that the major strategies to achieve TB elimination by 2050 include mitigating risk factors, preventing infections, and treating active TB disease and LTBI. To reach this goal, CDC is contributing its unique scientific, technical and operational expertise to build sustainable TB and HIV programs and public health systems at both country and global levels. CDC also is strategically using data to increase the impact, efficiency and cost-effectiveness of its current global TB activities and new innovations.

CDC's presence in over 50 countries includes 73% of staff in the field. Of the 50 countries with a CDC presence, approximately 22 have a high burden of HIV/TB co-infection and provide opportunities to leverage sustainable TB funding from the President's Emergency Plan for AIDS Relief (PEPFAR) platform. However, other countries with low HIV/TB co-infection rates and no PEPFAR support are still critically important to the United States due to shared families and communities. CDC engages a diverse group of domestic and international partners to build on and improve its existing global TB activities.

At the division level, DGHT collaborates with Ministries of Health (MOHs) and other partners to fulfill the mission of its global TB strategy to reduce TB morbidity and mortality in high-burden countries. DGHT ensures continuous quality improvement and disseminates recommendations and guidelines in three major areas. Technical support and training are provided to strengthen in-country capacity and ensure the operation of new and existing TB tools. Operational research and implementation science are conducted to build an evidence base for improved TB control and prevention strategies. Flagship or model programs are implemented to help countries to translate TB evidence into action, inform data-driven decision-making, and scale-up TB interventions.

CDC's key priorities in its global TB efforts fall under four broad categories. Examples of CDC's accomplishments in these areas are highlighted below.

Prevent TB

- Treat LTBI among high-risk populations. CDC established a 3HP panel physician site in Vietnam.
- Improve TB infection control measures to stop transmission. CDC launched TB BASICS (Building and Strengthening Infection Control Strategies) to stop transmission in healthcare settings.
- Optimize TB/HIV integration and increase treatment to all patients with TB/HIV. CDC scaled-up antiretroviral therapy (ART) and TB screening among PLWH to decrease morbidity and mortality.

Find TB Cases

- Find the missing 4 million TB cases and target screening to high-risk populations. CDC targeted TB case-finding and diagnostic tools to children.

Cure TB Disease

- Monitor new TB drugs and regimens and expand access to treatment adherence support, including innovative patient-centered, patient-empowered care models. CDC launched innovative projects to increase access to TB treatment and adherence support in mining communities.

Build TB Capacity

- Develop the TB workforce, strengthen TB laboratory capacity and improve TB surveillance systems. CDC offered training courses, improved implementation of the Xpert® assay, and administered prevalence and catastrophic cost surveys.

CDC partnered with governments and local partners to implement in-country flagship programs in India, China, Kenya and Vietnam and launch projects under the full spectrum of the “find/cure/ prevent/build” continuum. CDC mobilized project-specific support in countries with a high prevalence and incidence of TB that national governments ideally will be able to transform. For countries with a high burden of TB infection only, CDC contributes its expertise in global health security and antimicrobial resistance to leverage support, explore new innovations, and implement critical projects to achieve the goal of eliminating TB globally and domestically. Overall, CDC's periodic, ongoing commitments are designed to help governments to identify the next steps in global TB efforts for their countries.

CDC's ongoing global TB projects under the “find/cure/prevent/build” continuum are described as follows. A pilot 3HP feasibility study on LTBI testing and voluntary treatment is underway at

a panel physician site in Ho Chi Minh City, Vietnam. The major outputs of the pilot are the feasibility and acceptability of the strategy and 3HP completion rates among immigrants resettling to the United States. The results of the pilot will be used to determine whether LTBI testing and voluntary 3HP treatment should be included as part of the U.S. medical examination process for U.S.-bound immigrants. The pilot also will be used to identify key factors that should be considered for successful scale-up and implementation of this strategy. CDC is collaborating with several internal divisions, academia and international partners in this effort.

BASICS is a systematic, quality assurance and quality improvement approach to break the cycle of transmission in healthcare facilities and HIV clinics. TB BASICS focuses on four core areas to transform the safety of facilities for patients and healthcare professionals: (1) assess TB infection control in healthcare facilities; (2) design tailored intervention packages to address gaps; (3) implement ongoing monitoring, evaluation and continuous program improvement; and (4) emphasize sustainable, local capacity development. Due to the success of TB BASICS, Nigeria is scaling-up the initiative nationwide with a focus on healthcare facilities that serve PLWH.

Efforts are being targeted to finding and curing childhood TB. In Kenya, CDC is identifying the most rapid and effective approaches and assessing the most sensitive and specific combination of specimens and tests to accurately diagnose TB among children with and without HIV. In Mozambique and Uganda, CDC is implementing and evaluating approaches for household-based contact investigations to identify children at risk of TB. CDC's activities in South Africa have resulted in WHO changing its guidelines for the treatment of drug-resistant TB among children.

CDC is collaborating with the World Bank and local government partners in Eastern and Southern Africa on a \$120-million, five-year effort to increase access to TB diagnosis and appropriate treatment for miners, their families and communities. This initiative is targeted to miners due to their high risk of TB from occupational exposures and high rates of TB/HIV co-infection. Moreover, large mining sectors in several countries still institute extremely discriminatory workforce policies that permanently ban individuals with a history of TB from working in the mining sector.

The key activities to improve TB treatment and adherence support in mining communities include mapping and targeting "hot spots" within affected communities; developing new models for active TB case finding, diagnosis and treatment; scaling-up TB screening with a focus on miners and their families; and testing models for continuity of care and treatment adherence support. This initiative also will focus on silicosis as a tremendous occupational risk factor to miners.

CDC is collaborating with in-country and MOH partners to use local data to identify gaps in areas that warrant improved interventions. The *2015 WHO Global TB Report* showed substantial gaps in the provision of ART between the number of reported versus estimated HIV-positive TB patients in 19 PEPFAR countries with a high TB/HIV burden in 2014. In Nigeria, for example, 16,066 TB/ HIV cases were diagnosed and reported in 2014 (or 16% per year), but estimates projected up to 100,000 active cases.

Of the 16,000 reported TB/HIV cases, 11,997 were on ART in 2014 (or 12% per year). The coverage levels of TB/HIV diagnosis and treatment would be lower if 12% of the 100,000 estimated cases were on ART. However, CDC has limited confidence in the HIV data reported

by Nigeria. The actual number of TB/HIV cases might be lower, but gaps in the number of missed cases would still be significant.

CDC is using data to improve programmatic decision-making. The global health community has fully embraced and prioritized the rollout of the Xpert® MTB/RIF assay for rapid POC diagnostics for TB and RIF resistance. PEPFAR supported the implementation of 37% of 131 GeneXpert instruments in 126 facilities in Kenya and 84% of 110 instruments in countries with a high TB/HIV burden. Several factors were considered in the placement of GeneXpert instruments, including TB burden, prevalence of priority populations, and the availability of networks for referral and reporting of results. The placement of instruments directly impacts patient access, utilization and time to diagnosis and treatment.

CDC and its domestic and international partners will continue to play a leadership role in making investments to end global TB. Rapid and mobile POC diagnostic tools for TB are needed to quickly collect urine, blood, breath or sweat. New treatment regimens are needed, such as therapies and drugs for all forms of TB, novel treatment regimens for adults and children, and alternative treatment delivery methods to improve adherence and outcomes. An effective TB vaccine is needed as well.

Investments in the response to TB, new developments and innovations should be prioritized by all countries in light of the volume and burden of the disease globally. However, incentives should be offered to the private sector to promote innovation and re-imagine the existing public health market. An op-ed article was published in the *Washington Post* in May 2016 that highlighted disparities in new drug development. For example, nearly 836 drugs or vaccines currently are being developed for cancer, including 82 drugs for breast cancer alone. Of 37 antibiotics that are in clinical development at this time, only 13 are in Phase III trials. Of the 13 antibiotics in Phase III trials, only three target the types of bacteria that CDC considers to be an urgent public health threat.

ACET DISCUSSION: GLOBAL TB

ACET thanked DGHT for its comprehensive, informative and enlightening presentation to illustrate the significant impact of global TB on the U.S. burden of the disease. However, Dr. Reves noted that the global TB activities of CDC and its partners are not adequately communicated to policymakers and the general public. For example, extensive media coverage of the Zika and Ebola viruses educated the public on the impact of global diseases on the United States. However, the urgent need to address TB and the ongoing transmission of MDR-TB globally to achieve the TB elimination goal in the United States is not well understood.

Elimination of Stigmatizing Language in TB Communications

Lisa Armitige, MD, PhD

Medical Consultant, Heartland National Tuberculosis Center (HNTC)
University of Texas Health Center at Tyler
ACET Member

Dr. Armitige presented an overview of efforts that are underway to identify and eliminate stigmatizing language in TB communications. Based on a Google search, stigma is defined as “a mark of disgrace associated with a particular circumstance, quality or person.” Based on the

1963 Goffman study, stigma is defined as “a sign or a mark that designates the bearer as spoiled and therefore as valued less than normal people.”

Dr. Armitige explained that this item was placed on the agenda for ACET to discuss TB-related stigma from the patient perspective. Research has been conducted in several health disciplines to determine the effects of stigma on the treatment of patients. For example, the use of “crazy,” “drug addict” or other stigmatizing language was found to affect the outcomes of mental health patients. As a result, a tremendous effort was made in the field to replace stigmatizing labels with actual mental health terminology, such as “substance abuse,” “bipolar disorder” and “schizophrenia.” The HIV/AIDS field applied the experiences and lessons learned by the mental health field because these patients faced extraordinary stigma in their families, communities and workplaces in the early, pre-treatment era of the disease.

A 2013 published study reported that stigma affects health care. Most notably, stigma is linked to poor health and is associated with greater social isolation. Social isolation increases the risk for poor health outcomes. The stigma-health relationship is significantly strained after adjusting for social isolation.

A 2010 published study reported that stigma affects TB care by contributing to a delay in diagnosis. Based on the study findings, “at-risk individuals report that fear of TB stigma and the social and economic impact of stigma affects their willingness to undergo TB screening and to seek medical care after the onset of symptoms associated with TB.” The study further concluded that “individuals with TB and their healthcare providers also identify TB stigma as a cause of non-completion of treatment.”

A reference in the literature describes TB as “a social disease.” Its understanding demands that the impact of social and economic factors on the individual be considered as much as the mechanisms by which tubercle bacilli cause damage to the human body.” Another reference in the literature notes that the “fear of infection is the most common cause of TB stigma.” The use of non-stigmatizing language can serve as an initial step to begin to break down stigma associated with TB. The ability of language to be stigmatizing is reflected in the following quote: “Words are important. If you want to care for something, you call it a ‘flower.’ If you want to kill something, you call it a ‘weed.’”

CDC addressed the issue of stigmatizing language by posting a chart on its website that compares and contrasts “people-first language” versus “language to avoid.” People-first language is respectful and avoids defining people in terms of their disabilities. In most cases, the reference to a disability should be placed after the reference to a person. For example, the people-first language to use would be “a person with a disability” or “a person living with a disability.” The language to avoid would be “a disabled or handicapped person.”

Stigma research in TB patients is not as extensive or advanced as the stigma literature on mental health and HIV/AIDS patients. However, a movement was launched that called for a change in existing stigmatizing and criminalizing TB care language. Dr. Armitige presented a series of papers that provide guidance on the preferred language to use in TB care communications and publications. Most of these published papers emphasize the critical need to shift from the traditional “blame-the-patient” paradigm to the use of patient-centered terminology.

Dr. Armitige cited three examples of common TB language that stigmatizes patients. First, the TB community has a long history of labeling an individual who might have the disease as a “suspect,” but this terminology only has a negative connotation. The definition of suspect as a verb is “to believe or feel that (someone) is guilty of an illegal, dishonest or unpleasant act, without certain proof.” The definition of suspect as a noun is a “person thought to be guilty of a crime or offense.” The TB community’s rationale to transfer “suspicion” of the disease to the patient is unclear. Most notably, this terminology is not used for persons who might have other diseases, such as a “diabetes suspect,” “influenza suspect” or “cancer suspect.”

Second, the TB community has a long history of labeling an individual who interrupts treatment as a “defaulter.” Regardless of the context, however, this terminology only has a negative connotation: “a person who fails to fulfill a duty, obligation or undertaking” (definition context based on the Oxford English dictionary); “a person who fails to repay a loan” (banking context); “a person who fails to appear in court when summoned by a judge” (legal context); and “a person who fails to take part in or complete a scheduled contest” (competitive context).

The common feature in all of the “defaulter” definitions is that an individual in a decision-making position assigns blame to another individual in the community. The “blame-the-patient” approach does not consider the social determinants of health or other underlying causes for “default” in TB treatment in both domestic and global settings.

- Lack of a regular, uninterrupted supply of drugs
- The requirement for patients to pay for their drugs out-of-pocket
- Increased travel costs and time due to limited accessibility to ambulatory treatment centers in rural and urban settings
- Inconvenient clinic hours and long waiting times
- An insufficient number of health workers who are motivated and friendly
- Inappropriate patient education, particularly in languages other than English
- Minimal options for alternative forms of treatment support (e.g., community and workplace settings)
- Lack of combined HIV/TB services that are readily accessible

Third, the TB community has a long history of labeling its activities as “control,” but this terminology has a negative connotation in terms of the management and treatment of patients. The definition of control as a verb is “to limit, regulate or restrict an activity or a process” and “to maintain influence and authority over behavior.” Synonymous terms for control include “power,” “domination” and “in charge.”

Federal, state and local governments have established “TB Control Programs,” but the entity that is being controlled is unclear (e.g., control of the disease, patient or affected community). Moreover, “control” of TB might inadvertently lead to programs taking control of patients by infringing on their rights and autonomy. For example, public health authorities have prohibited TB patients from leaving their homes or boarding an airplane. Overall, control might be interpreted as “something done to” rather than “something done for” a patient.

The Global TB Community Advisory Board (CAB) posted the following notice on its website: “Civil society calls for the retirement of stigmatizing and criminalizing language from the global TB discourse.” The Global TB CAB also published an open letter in March 2015 with a request for the International Union Against TB and Lung Disease (the Union) to take steps to retire the

use of stigmatizing and criminalizing terminology from papers published in its journals and abstracts submitted to its conferences.

The Global TB CAB submitted the following statement to support its request: “Language is very powerful. It is important for all of us to change the way we speak and write about this disease. We hope that this letter and actions taken by the Union will open a dialogue between advocates, members of civil society, researchers, health professionals and academics necessary to truly eliminate stigmatizing terminology in TB.”

The Union addressed two major issues in its supportive response to the letter by the Global TB CAB. First, the Union fully acknowledged that the long-term use of some terminology to describe TB activities has stigmatized persons affected by TB. The Union recognized that the provision of effective and high-quality TB treatment and care is the ultimate responsibility of the healthcare system rather than individuals impacted by the disease.

Second, the Union confirmed its commitment to communicate in a manner that embodies respect for all persons affected by TB. The Union planned to include guidance and a link to the Stop TB Partnership *Language Guide* in its abstract submission instructions for conference participants. The Union also shared the letter by the Global TB CAB with the editors-in-chiefs of its two journals, the *International Journal of Tuberculosis and Lung Disease* and *Public Health Action*, to pursue the development of appropriate guidance on TB language.

HNTC has joined forces with the Global TB CAB, the Union and other partners in the national movement to identify and eliminate stigmatizing TB language. HNTC’s key activities in this effort are highlighted below.

- HNTC redefined its patient population and the type of assistance that is provided. For example, “defaulters” are now “TB patients who are lost to follow-up” due to hardships that were not addressed or other factors. “TB suspects” are now “persons who might have TB disease.” “TB control” activities are now “TB prevention and care” interventions. Moreover, Dr. Barbara Seaworth, Medical Director of HNTC, issued the following statement to her staff: “We all recognize the stigma our patients face. What I did not realize for too long is how I may have added to that with my words.”
- HNTC sends a letter to all speakers who are invited to present at any of its upcoming conferences, trainings and other events, including the annual conference of the National Society of Tuberculosis Clinicians (NSTC). The letter includes a request for speakers to eliminate the use of stigmatizing language in their presentations; describes examples of “hurtful” TB terminology that should be replaced; and provides a link to multiple resources in HNTC’s “Stop the Stigma” campaign.
- HNTC recruited TB patients from a local hospital in Texas to meet with staff, in both English- and Spanish-speaking sessions, and provide their personal perspectives on stigmatizing language. Videos of these sessions are available on the HNTC website.
- HNTC updated its website with a new “Eliminating Stigmatizing Language” page.
 - A patient is featured who is holding the following sign: “I am a person living with tuberculosis who needs prevention and care. I am not a TB suspect who needs TB control.”

- Links are provided for two major resources in support of HNTC's Stop the Stigma campaign: (1) *Every Word Counts: Suggested Language and Usage for Tuberculosis Communications* and (2) a chart of key terms that replaces stigmatizing TB language with "non-hurtful" language.
- HNTC is using its social media platforms for broad marketing and advertising of its activities. Most notably, a pledge to join HNTC in an effort to stop the use of stigmatizing language is posted on its Twitter and Facebook pages with the following hashtags: #StopTheStigma #TB; #SpeakFromTheHeart #TB; #Language Matters #TB; and #CommitToChange #TB.

Dr. Armitige cited a 2013 published study: "The failure to consider stigma in theoretical and statistical models not only leads to an under-appreciation of the social factors that produce poor health, but can also undermine the efficacy of public health interventions." She referenced this research because "foreigner" might serve as a new source of stigma. The definition of foreigner as a noun is "a person born in or coming from a country other than one's own." The informal definition of foreigner is "a person not belonging to a particular place or group, a stranger or an outsider." Synonymous terms for foreigner include "alien," "non-native," "stranger" and "outsider."

Dr. Armitige concluded her presentation by reminding ACET that TB providers throughout the United States and worldwide utilize and repeat the language in CDC's guidance documents. As a result, she asked ACET to consider recommending the elimination of stigmatizing language from all CDC educational materials, guidance documents, forms and publications. Resources that can be used in this effort include educational documents, products and other materials developed by the Union, NTCA, HNTC, NSTC and Treatment Action Group.

DTBE provided its perspectives for ACET to consider in its discussion. Dr. LoBue emphasized that CDC's guidance documents and educational materials are not intended to use or promote stigmatizing TB language. CDC agrees that some commonly used terms in TB, particularly "suspect," are stigmatizing and should be removed from all communications. However, the replacement of other terms is debatable. For example, most state and local health departments in the country have the word "control" in the names of their infectious/communicable disease programs, such as the "[State/City] Tuberculosis Control Program." These programs aim to "control" a disease rather than an individual. The same rationale applies to the CDC Division of Tuberculosis Elimination. DTBE has a mission to "eliminate" TB rather than people.

Dr. LoBue clarified that the word "defaulter" originated in the international community. CDC has no history of using this terminology in its TB communications. Overall, the organizations that are leading the movement to eliminate stigmatizing language must offer alternative or replacement terminology to meet the diverse needs of the TB community beyond advocacy efforts, such as scientific and epidemiologic needs. CDC is facing the same problem in its ongoing efforts to replace "foreign-born" with less stigmatizing language. From epidemiological and surveillance perspectives, however, the U.S. Census defines the foreign-born population.

Dr. Wanda Walton is Chief of the DTBE Communications, Education and Behavioral Studies Branch. She conveyed that DTBE strives to include enabling language in all of its educational materials. For example, DTBE replaced "compliance" with "adherence" several years ago. Moreover, DTBE has not used "TB suspect" in any of its patient education materials for quite some time.

Dr. Walton informed ACET that all of DTBE's educational materials must undergo CDC's rigorous clearance process prior to their release and dissemination to the public. The key components include formative research, evaluation, focus groups to test materials with the target population, multi-level reviews, and adherence to plain-language standards to ensure materials are understandable to lay audiences. Similar to the Union, HNTC and other organizations, DTBE also understands the importance of using non-stigmatizing TB language and strives to produce high-quality educational materials. Overall, DTBE's educational materials aim to empower patients to view themselves as full and equal partners with their providers in terms of ensuring appropriate diagnosis and treatment until cured.

ACET DISCUSSION: ELIMINATION OF STIGMATIZING TB LANGUAGE

- A uniform list of alternative terminology should be developed and distributed nationally to promote usage of less stigmatizing TB language. For example, "contact investigation" has an authoritative, "legal-like" connotation and should be replaced with "contact tracing" or "contact management." "Directly-observed therapy" has a punitive tone and should be replaced with "facilitated therapy" or other terminology that is more generous, enabling and helpful to TB patients.
- CDC has made tremendous progress in eliminating stigmatizing TB language from its patient education materials, but minimal efforts have been directed toward revising materials for healthcare providers. Because CDC's reporting forms still include "TB suspect," for example, providers repeat this language and cause distress to their patients. Moreover, "TB suspect" is being used for political agendas to promote conservative immigration policies rather than for public health purposes. CDC has taken a passive role in the internal and external reviews of its educational materials. CDC should leverage its leadership role, national influence and expertise to change stigmatizing TB language and improve education to both providers and patients. CDC's revised set of appropriate TB terminology should be widely publicized and marketed to health departments and providers.
- Consideration should be given to adopting the definition by the international community. "TB suspect" has been replaced with "person with presumptive TB." However, caution should be taken in this area because suspected TB is "questionable," while presumptive TB is "likely."
- The TB community should take responsibility for developing and using two sets of nomenclature in its communications with different audiences: (1) internal scientific language for providers and (2) external, non-stigmatizing and respectful language for patients, their families and communities.
- "Control" is included in the list of stigmatizing TB language, but this word should not be replaced from the perspective of public health protection. State and local TB controllers have a public health mandate to control "the disease" in their communities. In some cases, however, the movement of "the patient" must be controlled, particularly for persons with contagious/infectious TB who do not comply with home isolation requirements. TB controllers are required to exercise their authority if other options have failed, such as incentives, enablers, plain-language education, non-stigmatizing language and high-quality care.
- States and localities should follow DTBE's example by replacing the word "control" and renaming their programs as the "[State/City] Tuberculosis Elimination Program." The new name would increase opportunities to describe the national TB elimination plan.

- Similar to HNTC’s efforts, activities by the broader TB community to replace stigmatizing language with other terminology also should extensively engage TB patients and survivors at the outset.

Dr. LoBue urged the ACET members to immediately inform him of any current CDC educational document, whether to patients or providers, that includes the term “TB suspect.” Because CDC is not advocating for or intentionally using this language, any document with “TB suspect” will be revised and re-released without this term.

Ms. Cole added that the current draft of the 2017 Essential Components document includes several terms in the list of stigmatizing TB language: “TB suspect,” “contact investigation” and “source case investigation.” In its ongoing review and revision process, she confirmed that the workgroup would replace this terminology. However, consensus has not been reached on replacing “TB control” and “TB controllers” because these terms are broadly used by federal, state and local public health programs.

To assist the workgroup in its review of the 2017 Essential Components document, Dr. Armitige offered to provide Ms. Cole with HNTC’s list of stigmatizing TB language and replacement terminology. Dr. Walton noted that DTBE’s communication staff also is available to assist the workgroup in its review. She offered to review the document for potential stigmatizing language. Ms. Cole confirmed that she would send the document to Dr. Walton for her review.

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. Eric Houpt for ACET to approve the previous meeting minutes.

ACET unanimously approved the Draft December 12-13, 2016 Meeting Minutes with no changes or further discussion.

Business Item 2: ACET Report to the HHS Secretary—2017

Ms. Cole announced that the current draft of the 2017 ACET report to the HHS Secretary was distributed to the members for review and comment. She reviewed the major topics that are highlighted in the letter and report.

- Description of the legal basis for ACET
- Summary of the ACET charter

- Background information on TB: current problems and challenges; epidemiology of the disease; and a reference to the 2000 Institute of Medicine report, Ending Neglect: The Elimination of Tuberculosis in the United States
- Competing priorities
- Emerging infections at local, state, national and global levels
- Intermittent shortages of TB drugs
- TB in congregate settings with an emphasis on correctional facilities and homeless populations
- TB along the U.S.-Mexico border
- The need to strengthen the public health infrastructure
- The USPSTF Grade B recommendation for LTBI screening
- CDC's Concept of Operations for LTBI Reporting
- ACET's request to the HHS Secretary: "Provide support to ensure that strategies to identify, treat and eliminate TB are able to be implemented"
- ACET's key activities in 2016: key recommendations, workgroups, amendment of the charter, and specific guidance to DTBE

ACET DISCUSSION: 2017 REPORT TO THE HHS SECRETARY

- "Competing Priorities" section:
 - Change "current" to "recent" Ebola virus disease outbreaks
 - Add new text on the Zika virus
 - Revise the content to avoid comparing TB to other diseases
- Emphasize the need for additional funding and resources to DTBE and reference the "National Action Plan for Combating Multidrug-Resistant Tuberculosis" that includes a TB prevention initiative.
 - DTBE's level funding over time, accounting for inflation, has caused a significant deficit in its budget.
- Highlight the substantial cost of ongoing failures in TB treatment that limit progress in achieving rigorous elimination targets.
- Add a clear recommendation for the HHS Secretary to support the inclusion of MDR-TB in the broader antimicrobial resistance effort during the G20 Summit. Use Dr. Hader's slide set to highlight CDC's key global TB activities.

Ms. Cole will revise the 2017 report to the HHS Secretary based on ACET's feedback and circulate the next iteration of the draft to the members for review and comment.

Business Item 3: Amended ACET Charter

Ms. Cole announced that CDC filed ACET's amended charter on March 15, 2017. 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. The amended charter will expire on March 15, 2019 and was distributed to ACET for review.

Business Item 4: CDC Office of Infectious Diseases, Board of Scientific Counselors (BSC) Meeting

Ms. Cole reported on two major topics that were covered during the most recent BSC meeting. First, the BSC discussed efforts that were made to accomplish CDC's mission with investments from the Prevention and Public Health Fund (PPHF) from FY2010-FY2016. The discussion included a description of expenditures with discretionary funding; a review of PPHF resources that have allowed CDC to support states to strengthen their capacity to detect and respond to domestic infectious diseases and other public health threats; and a summary of funding allocations by state.

Second, the BSC discussed the enactment of the 21st Century Cures Act; its focus on information technology and electronic health records; and the potential implications of this legislation on public health.

Business Item 5: WHO Global Priority List of Antibiotic-Resistant Bacteria

Dr. Robert Benjamin is the ACET liaison representative for the National Association of County and City Health Officials. He noted that the WHO Global Priority List of Antibiotic-Resistant Bacteria was distributed to ACET in preparation for this business item. The list primarily focuses on hospital-acquired infections, but WHO is on record with its statement that TB is the leading bacterial cause of death. TB is addressed in only one sentence in the entire seven-page document: "Mycobacteria (including *Mycobacterium tuberculosis*, the cause of human tuberculosis), was not subjected to review for inclusion in this prioritization exercise as it is already a globally established priority for which innovative new treatments are urgently needed."

Dr. Benjamin announced that the Program for Monitoring Emerging Diseases (ProMED) is an online communication platform for the international infectious disease community. He provided his personal perspectives on the exclusion of TB from the WHO global priority list of pathogens, but the ProMED moderators did not post his "outspoken" views on the network. As a result, he asked Ms. Cole to include this item in the business session for ACET to consider its potential role in this regard. For example, ACET could post a formal statement on ProMED or encourage WHO to include TB in the global priority list of pathogens.

Ms. Cole pointed out that the WHO document provides a comprehensive background, including the scope of work, methodology, and criteria for the expert panel to select and prioritize the pathogens. In response to Dr. Benjamin's comments, she conveyed that ACET might not be in a position to take any actions other than raising awareness of the exclusion of TB from the global priority list of pathogens. However, she asked the ACET members to provide their input and perspectives on this issue.

ACET DISCUSSION: WHO GLOBAL PRIORITY LIST OF PATHOGENS

- NTCA has been actively collaborating with several partners to address WHO's egregious omission, serious disconnect and disappointing result. ACET should develop and submit a formal statement to WHO to express its strong support for including TB on the global priority list of pathogens.
- Dr. Margaret Chan, the WHO Director-General, recently participated in a teleconference for CDC, other federal agencies and TB advocacy organizations to voice their concerns regarding the exclusion of TB from the global priority list of pathogens. She made a commitment for WHO to consider the feedback and produce a revised list, but a number of experts believe that TB will still be omitted. The major changes likely will be a new

name for the list and a clearer, more detailed explanation of WHO’s rationale for excluding TB. ACET should submit an evidence-based statement to WHO to inform the decision-making process on the revised list.

- ACET should emphasize this issue in its 2017 report to HHS Secretary Dr. Thomas Price. The new content should emphasize the urgency of revising the WHO global priority list of pathogens, describe the benefits of this effort during G20 Summit in July 2017, and highlight CDC’s leadership role in global health. ACET also should use its liaison representatives to maintain ongoing communications on this issue with national TB organizations.
- Mr. David Bryden is the ACET liaison representative for RESULTS. He planned to ask a Congressional member to write a letter to Dr. Chan to address this issue.
- The WHO document indicates that TB “already is a globally established priority.” ACET should submit rigorous data to demonstrate that issues related to drug-resistant TB are not adequately addressed at this time.
- The WHO list of “critical,” “high” and “medium” priority pathogens for research and development of new antibiotics includes several TB drugs. For example, ACET should encourage WHO to take a pragmatic approach and include TB in its current focus on fluoroquinolone resistance to other organisms.

Dr. Susan Maloney, the CDC Global TB Coordinator, announced that DGHT recently drafted a letter to WHO under Dr. Schuchat’s signature. The letter discusses the exclusion of TB from the WHO global priority list of pathogens and the downgrade of drug-resistant gonococcus.

Dr. LoBue made several clarifying remarks in response to the discussion. The provision of ACET’s advice and recommendations is limited to the HHS Secretary and CDC Director. As a result, ACET’s support of CDC’s letter to WHO and the inclusion of new text on the WHO global priority list of pathogens in the 2017 report to the HHS Secretary are well within the scope of ACET’s charter. Direct communications with WHO are beyond ACET’s purview.

MOTION 1

Action	Description
Chair’s call for a vote	Dr. Lisa Armitige properly placed a motion on the floor for ACET to include a statement in its 2017 report to the HHS Secretary regarding the omission of TB from the WHO global priority list of pathogens. The statement will emphasize the critical need to include TB because the list prioritizes research and development of antibiotics that are important for the management of TB, such as fluoroquinolones. The statement also will express support for including this issue on the agenda of the G20 Summit in July 2017. Dr. James Sunstrum seconded the motion.
Outcome of the vote	The motion was tabled by the ACET Chair to allow the members to review the proposed language in writing prior to the vote.

MOTION 2

Action	Description
Chair's call for a vote	Dr. Robert Horsburgh properly placed a motion on the floor for ACET to support the letter by Dr. Anne Schuchat, the acting CDC Director, to WHO with a request to reconsider the exclusion of TB from the global priority list of pathogens. ACET is advising Dr. Schuchat to ensure that CDC mobilizes technical and/or analytical support to WHO to make this change.
Outcome of the vote	The motion was unanimously passed by 8 ACET voting members.

RECALL OF MOTION 1

Action	Description
Chair's call for a vote	Dr. Lisa Armitige properly placed a motion on the floor for ACET to develop a position statement to express its concern that TB was omitted from the WHO global priority list of pathogens. The statement should be included in ACET's 2017 report to the HHS Secretary and emphasize that the list should be a part of discussions during the G20 Summit to guide research, discovery and the development of new antibiotics." Dr. Robert Horsburgh seconded the motion.
Outcome of the vote	The motion was unanimously passed by 8 ACET voting members.
Next steps	Ms. Cole will include the position statement in ACET's 2017 report to the HHS Secretary and circulate the revised draft for ACET's review and comment.

Business Item 6: ACET's Responses to CDC's Previous Requests for Advice

Ms. Cole reviewed CDC's requests for advice from ACET on three topics that still need to be addressed.

CDC's Request for Advice to ACET	ACET Action
Expanded TB medical consultation services	ACET agreed to table this item until the August 22, 2017 webinar.
ACET's recommended strategies to monitor TB rates in U.S. territories	ACET noted that TB rates and cases in U.S. territories are being monitored and reported at this time. The most recent data are highlighted in the 2016 TB Annual Report. ACET marked this issue as resolved and will take no further action.

CDC's Request for Advice to ACET	ACET Action
ACET representation on the Division of Global Migration and Quarantine (DGMQ) Workgroup	<p>DGMQ formed a workgroup to update the 2009 TB technical instructions (TIs) and requested an ACET member to be engaged in this effort. Ms. Cole is representing ACET on the workgroup and attended the first organizational meeting on March 22, 2017. ACET members who are interested in proposing revisions to the TB TIs for the workgroup's consideration should email Ms. Cole. DGMQ will present the updated TB TIs to ACET for review and comment when the draft is available for circulation. The workgroup anticipates that six months will be required to complete the entire process of updating the TB TIs.</p> <p>ACET made three key suggestions for Ms. Cole to convey to the DGMQ Workgroup.</p> <ul style="list-style-type: none"> • The 2017 TB TIs should be expanded to include overseas screening of visa holders who enter and remain in the United States for six months and longer. • The 2017 TB TIs should particularly emphasize screening in countries with a TB incidence >20/100,000 as defined by WHO. • ACET should not make recommendations on overseas LTBI treatment with 3HP among immigrants who are resettling to the United States until DGHT collects and presents data from its pilot feasibility study.

Business Item 7: 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 August 2017 meeting.

Presenter	Agenda Item
ACET Membership	Discussion on whether ACET should submit a formal resolution to CDC to develop TB screening recommendations for FBPs with U.S. residency of 10 or more years.
DGHT	Update on findings from CDC's global TB pilot projects, ongoing studies and other activities.

Presenter	Agenda Item
ACET Workgroup Chairs	<p>Presentation of formal recommendations for ACET's review, discussion and vote:</p> <ul style="list-style-type: none"> • Congregate Settings Workgroup (Multi-state TB contact investigations of incarcerated persons) • Children and Adolescent TB Workgroup (Red Book Committee's recommendations on the use of IGRAs in young children) • Essential Components Workgroup (Final draft of the 2017 document)
Dr. Lisa Armitige	Update on stigmatizing TB language: Review of current CDC educational materials and recommendations on alternative language.
Dr. Peter Davidson	Update on the joint NTCA/Regional Tuberculosis Training and Medical Consultation Center white paper on expanded TB medical consultation services.
Dr. Richard Menzies (or his designee)	<p>Data from the international study on four months of RIF versus nine months of INH for LTBI.</p> <ul style="list-style-type: none"> • The presentation should include any other new research findings on LTBI treatment.
To Be Determined	<p>CDC's launch of a new initiative to publicize the results of the September 2016 USPSTF recommendation that encourages providers to test for LTBI in populations at increased risk.</p> <ul style="list-style-type: none"> • The presentation should include the impact to date of CDC's new initiative. For example, practitioners at TBESC sites who are conducting a pilot project on targeted, active TB surveillance should be surveyed to determine the reach of CDC's new initiative. Because Dr. LoBue clarified that CDC could not administer this survey, Dr. Reeves suggested an agenda item as an option. A Community Health Center in Houston is providing LTBI treatment to immigrants. Key outcomes from this project will be presented at the TBESC meeting in May 2017. • Drs. Reeves and Horsburgh will make efforts to identify a speaker for this agenda item during the May 2017 TBESC meeting. The speaker will be asked to report on the effectiveness of recommendations for increased LTBI screening in Community Health Centers or primary care settings. • The presentation should cover uptake of the USPSTF guidelines (with a particular emphasis on the complex, difficult-to-reach and large number of TB cases among persons from foreign countries who have lived in the United States for more than 10 years). • A representative from the American Diabetes Association should be invited to participate in the presentation because none of the current guidelines mention TST screening or LTBI treatment for the foreign-born diabetic population.
DGMQ	Overview of the 2017 TB TIs (December 2017 meeting).
DTBE	<p>Update on 2003-2012 Aggregate Reports for Tuberculosis Program Evaluation (ARPE) results for contact investigations that showed dismal acceptance and completion rates of treatment among infected TB contacts.</p> <ul style="list-style-type: none"> • The presentation should include more recent data after 2012 to reflect TB programs that have switched to shorter treatment regimens and IGRAs.

Presenter	Agenda Item
DTBE	Update on CDC's efforts to switch to whole-genome sequencing.
Dr. Sharma Ahuja	Update on the July 2017 meeting of the Council of State and Territorial Epidemiologists that will continue the ongoing discussion on whether a case definition for LTBI should be developed.

Public Comment Session

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

Closing Session

The next ACET meeting will be a webinar on August 22, 2017. With no further discussion or business brought before ACET, Ms. Cole adjourned the virtual meeting at 3:01 p.m. on April 11, 2017.

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. Lisa Armitige
Dr. Robert Horsburgh, Jr.
Dr. Eric Houpt
Dr. Michael Lauzardo
Dr. Jeffrey Starke
Dr. James Sunstrum
Dr. David Warshauer

ACET Members Absent

Dr. Ana Alvarez
Ms. Jennifer Cochran

ACET Ex-Officio Members Present

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

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

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

Mr. David Bryden
RESULTS

Dr. Peter Davidson
National Tuberculosis Controllers
Association

Mr. Suraj Madoori
Treatment Action Group
(Alternate for Mr. Kenyon Farrow)

Dr. Robert Morris
National Commission on Correctional
Health

Dr. Randall Reves
International Union Against TB and Lung
Disease

Dr. Lornel Tompkins
National Medical Association

ACET Liaison Representatives Absent

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. Ameer Patrawalla
American College of Chest Physicians

Dr. Jennifer Rakeman
Association of Public Health Laboratories

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

Ms. Susan Rappaport
American Lung Association

Dr. Susan Ray
Infectious Disease Society of America

Dr. Michael Tapper
Society for Healthcare Epidemiology of
America

Mr. Bobby Watts
National Health Care for the Homeless
Council

ACET Designated Federal Officer

Dr. Hazel Dean
NCHHSTP Deputy Director

CDC Representatives

Dr. Hammad Ali
Ms. Sara Bingham
Dr. Lara Bull
Dr. Deron Burton
Dr. Terence Chorba
Ms. Ann Cronin
Dr. Anand Date
Dr. Patricia Dietz
Ms. Molly Dowling
Mr. Bruce Everett

Dr. Neela Goswami
Dr. Shannon Hader
Ms. Amara Khan
Dr. Awal Khan
Ms. Kathryn Koski
Dr. Philip LoBue
Dr. Susan Maloney
Mr. Mark Miner
Ms. Brittany Moore
Dr. Thomas Navin
Dr. Joanna Regan

Ms. Margie Scott-Cseh
Ms. Sarah Segerlind
Ms. Maria Sessions
Dr. Sarita Shah
Dr. Hank Tomlinson
Ms. Michelle Van Handel
Ms. Abigail Viall
Dr. Wanda Walton
Ms. Rachel Wingard
Ms. Sara Zeigler



Attachment 2: Glossary of Acronyms

Acronym	Definition
3HP	Three-Month Isoniazid/Rifapentine Regimen
ACET	Advisory Council for the Elimination of Tuberculosis
ARPE	Aggregate Report for Tuberculosis Program Evaluation
ART	Antiretroviral Therapy
BASICS	Building and Strengthening Infection Control Strategies
BCG	Bacillus Calmette-Guérin
BSC	Board of Scientific Counselors
CAB	Community Advisory Board
CDC	Centers for Disease Control and Prevention
DASH	Division of Adolescent and School Health
DFO	Designated Federal Officer
DGHT	Division of Global HIV & TB
DGMQ	Division of Global Migration and Quarantine
DHAP	Division of HIV/AIDS Prevention
DOJ	U.S. Department of Justice
DSTD	Division of STD Prevention
DTBE	Division of Tuberculosis Elimination
DVH	Division of Viral Hepatitis
FACA	Federal Advisory Committee Act
FBPs	Foreign-Born Persons/Populations
FY	Fiscal Year
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HHS	U.S. Department of Health and Human Services
HNTC	Heartland National Tuberculosis Center
HRSA	Health Resources and Services Administration
IGRAs	Interferon Gamma Release Assays
INH	Isoniazid
LTBI	Latent TB Infection

Acronym	Definition
MDR-TB	Multidrug-Resistant TB
<i>MMWR</i>	<i>Morbidity and Mortality Weekly Reports</i>
MOHs	Ministries of Health
MTB	<i>Mycobacterium tuberculosis</i>
NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
NSTC	National Society of Tuberculosis Clinicians
NTCA	National Tuberculosis Controllers Association
OD	Office of the Director
OMH	Office of Minority Health
PEPFAR	President's Emergency Plan for AIDS Relief
PLWH	Persons Living With HIV
POC	Point-of-Care
PPHF	Prevention and Public Health Fund
PPV	Positive Predictive Value
ProMED	Program for Monitoring Emerging Diseases
RIF	Rifampin
SDG	Sustainable Development Goal
TB	Tuberculosis
TBESC	Tuberculosis Epidemiologic Studies Consortium
The Union	International Union Against TB and Lung Disease
Tis	Technical Instructions
TST	Tuberculin Skin Test
USPSTF	U.S. Preventive Services Task Force
WHO	World Health Organization
XDR-TB	Extensively Drug-Resistant TB