

**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
March 4, 2014**

Record of the Proceedings

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**ADVISORY COUNCIL FOR THE ELIMINATION OF TUBERCULOSIS
March 4, 2014**

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) on March 4, 2014.

ACET is chartered to provide advice to the Secretary of HHS and the Director of CDC regarding the elimination of tuberculosis (TB); make recommendations regarding policies, strategies, objectives and priorities; address the development and application of new technologies; provide guidance on CDC's TB Prevention Research portfolio and program priorities; and review the extent to which progress has been made toward eliminating TB.

Opening Session

Hazel Dean, ScD, MPH

Deputy Director, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
ACET Designated Federal Officer

Dr. Dean conducted a roll call to determine the ACET voting members, *ex-officio* members and liaison representatives who were attending the virtual meeting. She announced that ACET meetings are open to the public and all comments made during the proceedings are a matter of public record.

Dr. Dean informed the ACET voting members of their individual responsibility to identify potential conflicts of interest and recuse themselves from voting or participating in these matters. During the roll call, she asked the ACET voting members to publicly disclose their individual and/or institutional conflicts of interest for the record.

- Jennifer Cochran, MPH: Recipient of funding from the CDC TB Cooperative Agreement (CoAg)

Dr. Dean announced that the voting members and *ex-officio* members constituted a quorum for ACET to conduct its business on March 4, 2014 (*Attachment 1: Participants' Directory*). She called the proceedings to order at 11:01 a.m. EST and welcomed the participants to the virtual ACET meeting. She reviewed the instructions for the ACET members to be recognized by the Chair and pose questions or make comments remotely.

Dr. Dean concluded her opening remarks by describing both temporary and permanent changes to ACET's membership.

- The term of Mr. Shannon Jones, the former ACET Chair, has ended. Ms. Barbara Cole, a TB Controller at Riverside County (California) Department of Public Health, was welcomed as the new ACET Chair.
- Mr. José Velasco, Executive Director of the U.S. Section of the U.S. Mexico Border Health Commission, was named as the permanent alternate *ex-officio* member for this agency in the event of Dr. Bruce San Filippo's absence.
- Ms. Marla Clifton would serve as the *ex-officio* member for the U.S. Department of Veteran Affairs during the current meeting in the absence of Dr. Gary Roselle.
- Dr. YaDiul Mukadi would serve as the *ex-officio* member for the U.S. Agency for International Development (USAID) during the current meeting in the absence of Dr. Amy Bloom.
- Efforts are underway to replace Ms. Tiffany Moore, the former *ex-officio* member for the U.S. Marshals Service.
- The terms of four ACET members would expire in June 2014: Drs. Eric Brenner, Marcos Burgos, Jane Carter and Gail Cassell. The outgoing members were commended for their excellent service and commitment to TB elimination efforts for ACET, CDC and the nation. On January 14, 2014, DTBE submitted nomination packages to the CDC Committee Management Office to replace the four outgoing members.

Barbara Cole, RN, MSN, PHN

TB Controller

Riverside County (California) Department of Public Health

ACET Chair

Ms. Cole joined Dr. Dean in welcoming the participants to the virtual ACET meeting. She noted her privilege and honor in serving as the new ACET Chair. She concluded the opening session by reviewing the agenda items and emphasizing the importance of the members participating in all sessions of the virtual meeting to ensure that ACET maintains its quorum.

NCHHSTP Director's Report

Hazel Dean, ScD, MPH

Deputy Director, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
ACET Designated Federal Officer

Dr. Dean covered the following topics in the NCHHSTP Director's report to ACET. At the agency level, CDC's FY2014 appropriation of ~\$6.8 billion includes \$30 million for the establishment of an Advanced Detection Molecular Program. CDC will use these funds to more accurately and rapidly diagnose infectious diseases; investigate and control outbreaks, including TB outbreaks; better understand transmission patterns; determine antimicrobial resistance; and develop and target prevention measures, including vaccines.

CDC published its second *U.S. Health Disparities and Inequalities Report* in 2013 that highlighted differences in mortality and disease risks for multiple conditions related to behaviors, access to health care and social determinants of health. In addition to covering HIV infection and 18 other topics that were featured in the first report, the second report also included TB and nine other new topics. The second report noted that compared to whites, TB rates in 2010 were ~25 times higher among Asians/Pacific Islanders, ~8 times higher among African Americans, and ~7 times higher among Hispanics.

CDC published its *2013 Prevention Status Reports* that described the status of public health policies and practices in all 50 states and the District of Columbia to prevent or reduce important public health problems. The priority health topics covered in the report included excessive alcohol use, food safety, healthcare-associated infections, heart disease and stroke, HIV, motor vehicle injuries, nutrition, physical activity and obesity, prescription drug overdose, teen pregnancy and tobacco use.

CDC published its *Antibiotic Resistance Threats in the United States Report* in October 2013. The report noted that of >2 million persons who are infected with an antibiotic-resistant infection each year, 23,000 die. The report classified antibiotic-resistant threats into one of three categories: "urgent," "serious" or "concerning." Drug-resistant gonorrhea was classified as an "urgent" threat, while drug-resistant TB was classified as a "serious" threat." CDC's three 2013 reports are available for review on the CDC.gov website.

At the National Center level, NCHHSTP is responding to changes in its leadership. Dr. Kenneth Castro, Director of DTBE, is serving as the Acting Director of the Division of HIV/AIDS Prevention (DHAP) until a permanent replacement is appointed. Instead of returning to his position, however, Dr. Castro has announced his plans to retire later in 2014.

Dr. Dean asked the participants to join her in congratulating Dr. Castro on his long and distinguished public health career as an Epidemic Intelligence Officer with the CDC HIV/AIDS Program beginning in 1983, a Commissioned Corps Officer in the U.S. Public Health Service (USPHS), and the Director of DTBE for the past 20 years. The ACET members were encouraged to inform their colleagues and peers of the March 14, 2014 deadline to submit applications for the position of the DHAP Director.

Dr. Castro's upcoming retirement will create a vacancy in the position of the DTBE Director, but Dr. Philip LoBue is serving as the Acting Director until a permanent replacement is appointed. CDC broadly announced this position through multiple venues, including direct communications with its TB partners, TB and public health newsletters, the CDC.gov website and CDC's social media platforms. After the eligibility certificates of potential candidates are validated over the next few weeks, the CDC Search Committee will conduct interviews in April-May 2014.

NCHHSTP released its expanded "Atlas" with local, county-level epidemiologic data for HIV and STDs to enhance capacity to identify areas of the United States with the greatest disease burden. NCHHSTP published two supplements to *Public Health Reports*: "Applying Social Determinants of Health to Public Health Practice" and "Program Collaboration and Service Integration" (PCSI). The NCHHSTP Office of Health Equity celebrated its 10th anniversary on November 7, 2013 and featured a keynote presentation, "From Theory to Action: Applying Social Determinants of Health to Public Health Practice."

At the division level, the DTBE budget increased from the FY2013 operating level of ~\$133 million to the FY2014 Omnibus appropriation of \$135 million. DTBE issued guidance on a new anti-TB drug in 2013. Bedaquiline is the first new drug that the U.S. Food and Drug Administration (FDA) has specifically approved for TB since 1968. Bedaquiline also serves as an additional tool against multidrug-resistant TB (MDR-TB).

DTBE is leading a post-marketing surveillance study to determine whether a three-month, once-weekly isoniazid/rifapentine regimen for latent TB infection (LTBI) treatment can be successfully adopted for TB prevention. DTBE is collaborating with 22 external partners in this effort and has enrolled 1,500 patients in the study to date. DTBE recently released a mobile application for healthcare providers (HCPs), "Latent TB Infection: Guide for Diagnosis and Treatment." The application can be downloaded from the AppStore and Google Play websites.

DHAP released interim guidance on the use of pre-exposure prophylaxis (PrEP) for injection drug users based on study results that showed PrEP prevented HIV in this population. DHAP published the *2013 National HIV Prevention Progress Report* that showed 62% of targets established for national HIV prevention efforts were met or exceeded.

DHAP issued its first Rapid Feedback Report for grantees of the "Young Men Who Have Sex with Men and Transgender Persons of Color" Funding Opportunity Announcement (FOA). The report compares progress and performances across the entire FOA and provides each grantee with individual feedback. DHAP launched "Reasons/Razones" as the first national bilingual campaign to encourage HIV testing among Latino gay/bisexual men as well as the second phase of the "Let's Stop HIV Together" campaign in English and Spanish.

The Division of Adolescent and School Health (DASH) is now being led by its new Director, Dr. Stephanie Zaza, who has had a distinguished public health career at CDC since 1991. DASH awarded funds for a new five-year school health FOA, "Promoting Adolescent Health Through School-Based HIV/STD Prevention and School-Based Surveillance." The funding amounts were based on the highest HIV burden of states and the HIV/STD burden, poverty level and number of students of local school districts.

DASH released the updated "Health Education Curriculum Analysis Tool" to help school districts and schools analyze and ensure that their health education curricula follow federal guidelines. DASH released results of the "2012 School Health Policies and Practices Study." The national

study assesses school health policies and practices. The study reported a decrease in the percentage of school districts that require elementary schools to teach HIV prevention from 59% in 2000 to 40% in 2012.

The Division of Viral Hepatitis (DVH) published guidelines that recommended hepatitis C virus (HCV) testing of persons born between 1945 and 1965 due to increased risk of infection in this population. DVH published the first HCV treatment cascade in the *New England Journal of Medicine* that reported <10% of infected persons have been treated and cured. DVH led CDC's investigation that successfully identified pomegranate seeds from Turkey as the source of a multi-state outbreak of hepatitis A. DVH launched the "Know More Hepatitis B" Campaign in June 2013. The national multimedia campaign is targeted to Asians/Pacific Islanders and was released in English, Chinese, Vietnamese and Korean.

The Division of STD Prevention (DSTDP) began awarding funds in January 2014 under its new FOA, "Improving Sexually Transmitted Disease Programs Through Assessment, Assurance, Policy Development and Prevention Strategies." The new FOA will provide programs with greater flexibility to target resources to areas based on local needs.

DTSTDP completed a clinical trial that found two new antibiotic regimens successfully treated gonorrhea infections. DSTDP published a study in June 2013 that reported a 56% decrease in vaccine-type human papillomavirus (HPV) prevalence among female teens 14-19 years of age since the introduction of HPV vaccine in 2006. DSTDP and its partners released an application for the new STD Treatment Guidelines that are available to clinicians and other HCPs. The application can be downloaded from the AppStore and Google Play websites.

The NCHHSTP Director's report resulted in ACET making comments and suggestions in two areas. First, CDC should create a repository or a specific website with links to all of its mobile applications. A "one-stop" resource for these applications would be extremely helpful to state and local health departments.

Second, ACET requested more details on the criteria that CDC used to classify and define antibiotic-resistant infections as an "urgent," "serious" or "concerning" threat. Several members expressed concern that CDC's 2013 report, *Antibiotic Resistance Threats in the United States*, classified gonorrhea as an "urgent" threat and drug-resistant TB as a "serious" threat."

The ACET members noted that because drug-resistant TB is a global problem, CDC's lower classification of "serious" rather than "urgent" could have an adverse public health impact. The ACET members also pointed out although the TB case count is much lower than case counts of gonorrhea or other infectious diseases, airborne transmission of TB is a much greater threat to the public than sexual transmission of gonorrhea.

DTBE Director's Report

Philip LoBue, MD, FACP, FCCP

Acting Director, Division of Tuberculosis Elimination
Centers for Disease Control and Prevention

Dr. LoBue explained that the DTBE Director's report to ACET would focus on one specific topic. DTBE initiated a strategic alignment process of its TB priorities, activities, staffing and budget after the 2013 budget sequestration. DTBE realized that reactive across-the-board funding cuts would be unsustainable and eventually would lead to all major TB activities and programs (e.g., Regional Training and Medical Consultation Centers (RTMCCs), Tuberculosis Epidemiologic Studies Consortium, and Tuberculosis Trials Consortium) being under-funded and unable to meet goals.

DTBE agreed that the preferred approach would be to make strategic rather than across-the-board cuts to preserve higher priority activities and eliminate lower priority activities if the budget sequestration continued in the future. DTBE also recognized that growing staff costs could not be sustained over time. DTBE further agreed that its existing vision, mission, priorities, core activities and indicators were well defined and did not need to be revisited or modified.

DTBE's initial effort in its strategic alignment process was to determine the best distribution of funding based on three areas described in the 1989 plan to eliminate TB: make optimal use of existing tools, develop new tools, and translate new tools into practice. However, DTBE's review and initial discussions showed that these three activities were difficult to clearly define, make sharp distinctions and implement in the field. Most notably, the three activities overlap and have varying definitions. DTBE eventually concluded that additional emphasis and funding would be needed to support the translation of new tools into actual practice.

DTBE convened and charged a group of mid-level leaders (*i.e.*, the "Think Tank") with offering creative and concrete recommendations for cross-cutting activities to implement DTBE's mission over the next 3-5 years in the face of changes in TB epidemiology and limited resources for TB prevention and control. The Think Tank proposed nine topics to be considered for inclusion in the DTBE strategic alignment plan: funding of state and local TB programs, outbreaks and genotyping, surveillance, global TB control, research, laboratory proficiency, RTMCCs, workforce issues, and the capacity of the U.S. National TB Program to serve as a system.

DTBE formed three workgroups to focus on contingency budgets for program, research and staffing plans, the need for more translational activities, and approaches to incorporate the Think Tank's proposed concepts into the strategic alignment plan. The workgroups were asked to identify DTBE's priorities based on budget projections of \$125 million and \$100 million.

Several events have impacted the timing and direction of DTBE's strategic alignment process, including the 2014 Omnibus budget that deferred the 2013 budget sequestration; comparable DTBE funding between the FY2013 and FY2014 levels; and changes to DTBE's permanent leadership in 2014. Although the FY2014 budget is stable and will not be cut in the immediate future, DTBE will maintain momentum on its strategic planning efforts to ensure that TB priorities continue to be aligned with its vision, mission and core functions in the future. The stable FY2014 budget also will allow DTBE to consider level funding scenarios. However, the staffing plan most likely will be developed last due to its dependence on and need to be informed by the program and research plans.

These events required DTBE to revise the approach to its strategic alignment process. Activities of the program and research plans will be identified, prioritized and aligned with strategic priorities that DTBE established in the past. These activities will be developed independently of the \$125 million and \$100 million budgets that were projected for DTBE.

Staffing will be aligned with and optimized for priority activities. Multiple budget scenarios will be applied, including level funding, to the priority program and research agendas. A list of prioritized activities that cannot be funded with existing resources will be compiled and retained if additional funds become available or new, more urgent funding requests are made in the future.

DTBE identified its next steps and developed a tentative timeline to complete the strategic alignment activities in the second and third quarters of 2014: complete the program plan, research agenda and budget scenarios; initiate the internal CDC vetting process; obtain external input from ACET, other key partners and stakeholders; and finalize all of the plans.

The DTBE Director's report resulted in ACET making comments and suggestions in the following areas.

- DTBE is to be commended on its intention to obtain broad input on the strategic alignment process from ACET and other external sources. However, DTBE should extensively engage front-line TB control programs earlier in the process, particularly in the development of the program and research plans.
- DTBE will establish priorities for its strategic alignment process based on four budget scenarios: FY2014 level funding of \$135 million, a \$125 million budget, a \$100 million budget, and priority activities that cannot be supported by current funding. However, DTBE should inform its partners and key stakeholders that the \$100 million budget is considered to be the "worst-case" scenario.
- ACET should determine its specific role in helping DTBE to advance the strategic alignment process and identify priorities in the current environment of severe budget constraints. For example, ACET could submit a formal resolution to the HHS Secretary and the CDC Director to emphasize the following points.
 - "TB is an airborne infectious disease."
 - "TB is embedded in CDC's core public health function to control and prevent diseases."
 - "Because significant cuts to the TB budget have tremendously impaired state and local programs, DTBE should be held harmless from budget cuts in the future."

Update on TB-Related Affordable Care Act Issues

Ann Cronin

Associate Director for Policy and Issues Management
Division of Tuberculosis Elimination
Centers for Disease Control and Prevention

Christine Ho, MD, MPH

Medical Officer, Division of Tuberculosis Elimination
Centers for Disease Control and Prevention

Ms. Cronin and Dr. Ho presented an update on the Affordable Care Act (ACA) in the context of TB-related issues. The U.S. Preventive Services Task Force (USPSTF) is funded by the Agency for Healthcare Research and Quality (AHRQ) as an independent expert panel to grade

screening services based on the quality of treatment and the number of persons needed to treat a specific disease or condition in order to prevent a case.

USPSTF recommendations are extremely important in the current health reform environment because ACA does not require a co-pay for screening services with a USPSTF “A” or “B” grade. Instead of renewing the existing “A” grade for LTBI screening, USPSTF issued a new recommendation that deferred to CDC’s guidelines in order to avoid duplicating efforts and resources by another federal agency. Moreover, coverage of LTBI treatment under ACA is at the discretion of each individual state because the federal government has no authority to rule or regulate “health.” ACA requires all states to cover a minimum set of essential health services, but each state is allowed to select a benchmark plan of preventive, rehabilitative and other services that will be covered.

The ACA regulations and USPSTF’s decision to defer to CDC’s guidelines instead of renewing its existing grade “A” recommendation led to an unintended consequence in which TB screening would not be covered without a co-pay. To resolve this problem, CDC and AHRQ entered into an interagency agreement to jointly fund a competitive contract to support USPSTF’s updated review of LTBI screening.

As the awarded contractor, Research Triangle Institute (RTI) will propose a research strategy by the end of March 2014 for USPSTF to consider in its updated systematic review. CDC intends to circulate RTI’s proposed research strategy to its internal TB experts, ACET, the National Tuberculosis Controllers Association (NTCA) and other key stakeholders for review and comment. RTI’s revised research strategy will be published for broader input before being forwarded to the USPSTF systematic review process.

In the interim of the lengthy process for USPSTF to issue a new grade, states are allowed to add TB screening to their state Medicaid plans and TB control programs are free to consult with their local health plans to obtain coverage for LTBI treatment. To support this effort, TB control programs should inform their local health plans of the low cost of covering LTBI treatment compared to the extremely high cost of covering TB patients who are hospitalized and/or isolated.

ACET advised CDC to re-categorize “LTBI treatment” as “primary” or “secondary” prevention of active TB disease. The failure to treat LTBI allows TB cases to continue to transmit disease to others. ACET urged CDC to convey this perspective and provide supporting data to encourage USPSTF to renew the grade “A” recommendation for LTBI screening.

Update by the ACET Essential Components Workgroup

Eric Brenner, MD

Adjunct Associate Professor, Department of Epidemiology and Biostatistics
University of South Carolina
ACET Member & Essential Components Workgroup Chair

Dr. Brenner covered the following topics in his update to ACET on the workgroup’s recent activities. The workgroup is represented by ACET members, NTCA, Stop TB USA and other key stakeholder organizations. The workgroup was charged with revisiting and updating ACET’s January 1995 recommendations, “Essential Components of a Tuberculosis Prevention

and Control Program,” to reflect more recent TB data, the sharp decline in U.S. TB cases over the past 20 consecutive years, and the stronger focus on TB elimination rather than TB control and prevention.

The workgroup was unable to meet its proposed timeline of completing the draft updated Essential Components report in time for the March 2014 meeting, but the document will be presented during the June 2014 meeting for ACET’s review, discussion and input. The workgroup is focusing on the following areas to fulfill its charge.

- The workgroup is aware that NCHHSTP supports the inclusion of TB elimination efforts in its HIV/AIDS, viral hepatitis and STD prevention activities. The workgroup also recognizes that NCHHSTP has emphasized the critical need to identify potential opportunities to integrate preventive services across all of its infectious disease programs. For example, patients should be able to have their TB, HIV, STD and HCV needs met in one prevention visit on the same day.
- The workgroup reviewed existing guidelines that advised programs to plan for integrated service delivery to individual patients, increase the efficiency and effectiveness of treatment and preventive measures, aim to improve the health of each patient, and diminish the risk of disease transmission. Based on the workgroup’s literature review, ~15 sets of recommendations and reports on integrated services have been published since 1995. The workgroup will incorporate key messages from these guidelines into the updated Essential Components report.
- The workgroup’s literature review identified 129 TB-specific articles that have been published in the *Morbidity and Mortality Weekly Report (MMWR)* since 1993. The workgroup will consider key concepts from these publications to include in the updated Essential Components report.
 - A 1995 *MMWR* article emphasized the importance of using alternative approaches to TB control (e.g., the expanded use of directly-observed therapy (DOT)). Since that time, however, DOT has become the standard of care by the majority of health departments rather than an alternate form of care. Moreover, the American Thoracic Society (ATS)/CDC/Infectious Disease Society of America Treatment Guidelines noted that TB control strategies always should include an adherence plan with particular emphasis on DOT.
 - The March 31, 2006 *MMWR* article questioned the health status, treatment outcomes and public health impact of 130 patients in New Orleans who were being treated for TB during Hurricane Katrina, but were relocated to other cities and might still be infectious. The extensive and collaborative efforts of TB controllers in neighboring states led to all 130 TB patients being found to assure completion of TB treatment.
 - A 2013 *MMWR* article described the implications for public health practice to address issues related to natural disasters. The article advised TB control programs to continue to conduct systematic planning that would enable a timely response.

The workgroup’s next steps will be to thoroughly review the *MMWR* articles to identify specific wording to revise for the updated Essential Components report and decide whether the existing “Assessment, Assurance and Evaluation” model should be included as a one-page addendum. This model is conceptually powerful and widely used by public health, but does not include the essential core vocabulary that traditionally has been used to discuss TB programs.

Update by the DTBE Corrections Workgroup

Lauren Lambert, MPH

Epidemiologist, Division of Tuberculosis Elimination
Centers for Disease Control and Prevention

Advice Requested from ACET by DTBE:

- What are ACET's next steps to continue its collaboration with the DTBE Corrections Workgroup and other correctional partners (e.g., NTCA, Immigration and Customs Enforcement (ICE), and Federal Bureau of Prisons (BOP)) to create a national strategic action plan to assist in preventing and controlling TB in correctional facilities?

Ms. Lambert described the Corrections Workgroup's accomplishments to date in the first part of her update to ACET. DTBE has established strong collaborations with several internal and external partners, including various NTCA Corrections Workgroups and the NCHHSTP Corrections Coordinator, CAPT Laurie Reid. DTBE created a corrections slide set with national surveillance data that will be revised and updated every two years. The slide set is available on the CDC.gov/tb website under the "TB in Specific Populations" section.

An online correctional liaison course was created by the Heartland National TB Center with input from partners, including DTBE. Extensive interest was shown when the online course was piloted in February 2014. NTCA compiled a list identifying at least 1 correctional liaison for each state. The list is available on the NTCA website. The DTBE Molecular Epidemiology Activity staff is developing genotyping methods to identify corrections-related TB clusters.

Ms. Lambert focused the second part of her update on ACET's resolution to the Corrections Workgroup that was unanimously approved during the December 2012 meeting. The formal resolution included 20 action items that were addressed.

ACET RESOLUTION	CORRECTIONS WORKGROUP RESPONSE
Topic 1: Coordination	
Strengthen the coordination and oversight of TB prevention and control in correctional and detention facilities in partnership with state TB programs.	<u>Fully initiated</u> ; DTBE is developing a proactive plan that will include a systematic approach to address these issues. The Corrections Workgroup has been meeting on a monthly basis since January 2013.
Conduct a formal evaluation to assess the need for a full-time equivalent to coordinate corrections activities.	<u>Partially initiated</u> ; DTBE created three work groups that will focus on the strategic alignment of staffing, programs and science for all TB activities. DTBE has created 3 strategic work groups: Staffing, Programs, and Science. The Staffing and Programs work groups will be discussing this issue; however, the creation of a full-time position to specifically coordinate corrections activities will likely not be possible in the near future due to the reduction in overall staffing within the division.

ACET RESOLUTION	CORRECTIONS WORKGROUP RESPONSE
Develop ongoing collaborative partnerships with national and regional correctional organizations to advance TB education, prevention and control efforts.	<u>Partially initiated</u> ; Ms. Tara Wildes, Chief of the Jail Division in the Jacksonville (Florida) Sheriff's Office, is now serving as the ACET liaison representative for the National Commission on Correctional Health. DTBE hopes to collaborate with additional correctional liaison representatives in the future from the organizations that ACET proposed: American Correctional Association, National Institute of Corrections, American Jail Association, American Sheriff's Association, Coalition of Correctional Health Authorities, Society of Correctional Physicians, and correctional health care companies.
Topic 2: Correctional Liaison Defined in the TB CoAg	
Incorporate language into the 2015 TB CoAg for each grantee to designate a correctional liaison and include a brief summary of activities in their interim and final progress reports. Utilize the "NTCA Public Health TB Corrections Liaison Model Duty Statement" as a guide in determining local priorities for correctional liaisons in each jurisdiction.	<u>Fully initiated</u> ; DTBE has attended meetings with CDC staff that is responsible for developing and releasing CoAgS. Language similar to ACET's proposed language will be included in the 2015 TB CoAg.
Topic 3: Surveillance	
Develop a plan for using TB surveillance as a programmatic tool to identify the burden of disease and the need for interventions. Publish a brief annual summary of trends that would be widely available and promoted for use by state TB programs to guide data-driven decisions about resource allocations.	<u>Fully initiated</u> ; DTBE created a corrections slide set with national surveillance data that will be revised and updated every two years. The slide set is available on the CDC.gov/tb website under the "TB in Specific Populations" section.
Add the following question to the next update of the Report of Verified Case of Tuberculosis (RVCT): "History of incarceration in the last 1 or 2 years."	<u>Partially initiated</u> ; DTBE will submit a formal proposal to add this question when the RVCT Workgroup reconvenes in 2015. In the interim, the RVCT Quality Assurance Workgroup is revising instructions for this variable.
Topic 4: TB Case Detection	
Identify methods to improve TB screening, case detection and medical management of persons with infectious TB.	<u>Partially initiated</u> ; Most impressively with the New York City Department of Health and Mental Hygiene when the NYC jail system piloted a project in 2011 in which the tuberculin skin test (TST) was replaced with an interferon gamma release assay (IGRA) for routine LTBI screening at intake in women's jail facilities. The pilot project was expanded to include all men's jail facilities in August 2012. New York

ACET RESOLUTION	CORRECTIONS WORKGROUP RESPONSE
	City is now the largest correctional system in the United States that uses IGRA for routine LTBI screening at intake. The pilot project showed that of >57,000 men and women who were screened for LTBI with an IGRA in New York City jails, 4%-5% had positive results.
Emphasize the appropriate use of rapid testing in diagnostic evaluations of persons in the legal custody of law enforcement agencies.	<u>Fully initiated</u> ; The October 13, 2013 edition of the <i>MMWR</i> published guidelines on the use of nucleic acid amplification testing. Molecular Detection Drug Resistance and polymerase chain reaction testing were found to be easier and faster than obtaining acid-fast bacillus (AFB) smear results. DTBE hopes the guidelines will be increasingly used by correctional facilities over time.
Develop algorithms for returning inmates with suspected pulmonary TB to the general inmate population.	<u>Fully initiated</u> ; CDC and its partners have released several sets of guidelines with specific criteria and supporting data on releasing inmates with TB from airborne infection isolation: <i>Prevention and Control of Tuberculosis in Correctional and Detention Facilities; Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Healthcare Settings; and Controlling Tuberculosis in the United States</i> . The guidelines recommend that institutions collect three negative AFB smears before hospitalized TB patients are returned to a congregate setting, homeless shelter or detention facility. However, ICE is developing new algorithms that will provide more detailed and specific action steps than the criteria outlined in the current guidelines to return inmates and detainees with TB to the general population.
Topic 5: Continuity of Care	
Conduct state-specific analyses to determine the rationale for the low rate of TB treatment completion among persons incarcerated at diagnosis. Collaborate with state and local health departments to improve TB treatment completion rates.	<u>Partially initiated</u> ; DTBE agrees that these analyses are important and could play an instrumental role in compiling best practices and developing other tools based on the performance of states with high TB treatment completion rates. Several states are partnering with DTBE at this time to conduct analyses as an initial effort to improve their TB completion rates. The 2012 Mitruka study showed that incarcerated persons had a four-fold higher risk for TB, but were less likely than non-incarcerated persons to complete TB

ACET RESOLUTION	CORRECTIONS WORKGROUP RESPONSE
	treatment. The Mitruka follow-up study, "Trends and Predictors of No Treatment Completion Among Incarcerated Persons at Diagnosis (1999-2009)" is being conducted at this time.
Evaluate the effectiveness of CURE-TB and TB-NET for transnational TB referrals and explore long-term funding.	<u>Partially initiated</u> . DTBE works with these organizations and the DTBE Corrections Workgroup plans to reach out to these partners.
Explore the possibility of establishing a central system to obtain TB treatment completion data on patients who have been repatriated back to their countries of origin.	<u>Deferred</u> ; No formal or systematic notification process has been created between CDC in the United States and foreign countries. The International Research and Programs Branch of DTBE notifies the country of origin and attempts to obtain TB treatment completion data when foreign-born TB patients return to the United States. However, this action can be taken only if states are made aware of and inform DTBE of the return of foreign-born TB patients to the United States or back to their country of origin.
Identify programs that have a successful track record of improving continuity of care and increasing treatment completion rates of TB cases in correctional facilities. Disseminate information about these effective models.	<u>Partially initiated</u> ; DTBE is requesting that states will report successes to us in order to produce a best practices documents.
Topic 6: TB Education	
Instruct the RTMCCs and appropriate DTBE branches to coordinate strategies to identify and meet TB learning needs of correctional administrators, correctional HCPs and infection control personnel, law enforcement/correctional officers, and inmates. Conduct the following activities to support this effort: <ul style="list-style-type: none"> • Conduct a needs assessment. 	<u>Partially initiated</u> ; The Southeastern National TB Center conducted a needs assessment of correctional liaisons in each state and currently is analyzing the data. NTCA will produce a report of these findings.

ACET RESOLUTION	CORRECTIONS WORKGROUP RESPONSE
<ul style="list-style-type: none"> • Develop, disseminate and evaluate TB educational tools. 	<p><u>Partially initiated</u>; The Heartland National TB Center piloted an online correctional liaison course in February 2014. DTBE is pleased that two courses, “Arresting TB: Best Practices for Controlling TB in Corrections” and “Contact Investigation and Discharge Release Planning,” were extremely well received. NCHHSTP developed a new document with an overview of model integrated programs and a description of integrated health services, including TB, that potentially could be offered in prisons. The document currently is undergoing the CDC clearance process.</p>
<ul style="list-style-type: none"> • Develop TB competency assessment tools for correctional HCPs. 	<p><u>Partially initiated</u>; NTCA has created competencies for nurse consultants and TB case managers. The competencies are now available on the “Resources” section of the NTCA website, but efforts are underway to more prominently feature this tool on the NTCA home page.</p>
<ul style="list-style-type: none"> • Collaborate with correctional partners to identify methods to assure correctional HCPs and infection control staff receive TB education and strategies are available to demonstrate TB competency. 	<p><u>Fully initiated</u>; The RTMCCs have developed an on-line “Correctional Liaison Training Course.” DTBE currently is developing a slide set for non-medical correctional workers.</p>
Topic 7: Treatment of LTBI	
<p>Identify approaches to expand treatment of LTBI in correctional facilities, including expanded use of the three-month, once-weekly isoniazid/rifapentine (3HP) regimen.</p>	<p><u>Fully initiated</u>; CDC published guidelines in October 2013 on the use of the 12 dose regimen of isoniazid and rifapentine for LTBI treatment. The 3HP regimen has been piloted at the national level by BOP and at the local level by a county jail in Santa Clara, California. Both of these pilot projects currently are in the post-marketing phase. However, DTBE looks forward to receive results from other correctional settings that have implemented the 3HP regimen.</p>
Topic 8: Funding	
<p>Partner with key stakeholders to leverage existing and future resources for TB prevention and control in correctional and detention facilities (e.g., funding and resources for PCSI activities; emergency preparedness programs; HIV, viral hepatitis and diabetes-related organizations; programs that serve immigrant populations; and national correctional organizations).</p>	<p><u>Ongoing</u>; DTBE is challenged in taking action on this recommendation at this time in the current era of severe budget constraints. However, funding issues will be maintained as a critical agenda item during the monthly meetings of the Corrections Workgroup.</p>

Ms. Lambert concluded her update by describing the progress the Corrections Workgroup along with multiple partners, has made to date in accomplishing the 20 action items in ACET's resolution. She explained that two categories were added, "Deferred" and "Ongoing." Most of the steps that have been "fully" or "partially initiated" are also "Ongoing."

- The number of action items that the Corrections Workgroup has "fully initiated" increased from 1 in 2013 to 8 in 2014.
- The number of action items that the Corrections Workgroup has "partially initiated" decreased from 15 in 2013 to 10 in 2014.
- The number of action items that the Corrections Workgroup has "not initiated" decreased from 4 in 2013 to 0 in 2014.

ACET commended DTBE and its Corrections Workgroup partners on their outstanding efforts, accomplishments and rapid progress. ACET made several comments and suggestions for the workgroup to consider in its ongoing activities.

- The new TB corrections algorithms and updated TB corrections guidelines should provide instructions for facilities to coordinate efforts, clearly define their jurisdictional authority and responsibilities, and assure equitable TB care regardless of the inmate "type." Guidance on TB prevention, control and care vary among federal, state and local correctional facilities. For example, a local jail immediately would screen short-term inmates for TB at intake, but the same local jail would only hold federal detainees for pick-up with no TB screening. The new algorithms and guidelines should emphasize the importance of correctional facilities applying the same TB prevention, control and care measures regardless of whether the individual is a short-term inmate in a jail, a long-term state prisoner or a federal detainee.
- The Corrections Workgroup should explore the possibility of conducting an additional activity under the "surveillance" category. Arizona, California, Florida, Georgia and Texas account for 70% of all TB cases in U.S. correctional facilities. The workgroup should collect and thoroughly review TB surveillance data from correctional facilities in these five states to determine smear positivity rates as a proxy for diagnostic delay and treatment completion rates with cavitory X-ray as a proxy for diagnostic delay. These data analyses would be extremely helpful in characterizing the source of problems related to delays in diagnosing TB in correctional facilities.
- The Corrections Workgroup should administer a survey to determine vitamin D intake among incarcerated populations.
- The Corrections Workgroup's proposal to add a question to the next update of the RVCT should be worded as follows: "Has the patient ever been incarcerated? If yes, when was the patient's most recent incarceration?" The question should be worded in this manner because the time between TB infection and disease greatly varies. A focus on the patient's history of incarceration for the past one or two years only might overlook persons who acquired TB infection in prison.

Update on TB Drug and Biologic Shortages in the United States

Donna Wegener
Executive Director
National Tuberculosis Controllers Association

Advice Requested from ACET by NTCA:

- What guidance can ACET provide to HHS on actions that should be expedited to ensure further consequences of TB drug and biologic shortages for TB programs and patients are avoided?

Ms. Wegener described ongoing national efforts by NTCA and its partners to address TB drug/biologic shortages. The TB drug supply is vulnerable and includes numerous weaknesses: few drug options for multi-drug regimens, a limited number of manufacturers, current shortages that are continuing to worsen, increases in drug costs, and the absence of a safety net for a drug supply. Of the 4 first-line drugs (FLDs), 3 have a shortage or have experienced a large price increase. Of the 8 second-line drugs (SLDs), 5 are produced by a single manufacturer.

NTCA partnered with the Treatment Action Group (TAG) and the Program for Appropriate Technology in Health to co-host a high-level meeting on January 15, 2014. The purpose of the meeting, “Solving the Silent Crisis,” was to resolve and prevent domestic TB drug shortages and serve as a follow-up to the larger conference that TAG convened in January 2013 to address the isoniazid (INH) shortage. The 2014 meeting served as a platform for a diverse group of federal and national organizational partners to explore interagency solutions to more effectively prevent and respond to TB drug/biologic shortages.

The opening presentation described the background and need for the “Solving the Silent Crisis” meeting. Progress in TB control and elimination in the United States increasingly is threatened by problems in accessing life-saving TB drugs/diagnostics. Interruptions in the domestic TB drug supply have worsened. The fragmented nature of the domestic TB procurement system has created instability in markets and supplies. Communications and reporting systems among federal agencies and between federal agencies and state/local TB programs are inadequate. Few manufacturers for TB products exist at this time.

Other presentations focused on current TB procurement strategies available to U.S. programs, models implemented in other countries (e.g., Brazil, Canada and the United Kingdom) that potentially could be adapted in the United States, and the Global Drug Facility (GDF). The partners agreed on the merit and value of exploring GDF as a promising and economical option to address TB drug/biologic shortages in the United States.

The “Solving the Silent Crisis” meeting report recommended immediate, ongoing and future action items. For the immediate action item, a rotating inventory reserve system will be developed to address acute TB drug shortages and create a strong TB drug safety net. For the ongoing action items, emphasis will be placed on creating a centralized procurement system in the United States, expanding the pool of U.S. suppliers, increasing the number of markets to maintain existing U.S. suppliers, and improving interagency communications.

For the future action items, two key areas will be targeted to achieve the goal of obtaining a more stable and affordable TB drug supply in the United States. First, a rotating, vendor-managed inventory reserve will be created. The quantity of the current TB drug supply will be

determined. A tracking system will be developed to forecast and monitor the national supply of TB drugs/biologics. New and necessary resources will be determined.

Second, the pool of U.S. suppliers will be expanded. FDA will explore the possibility of expediting reviews of products that already have been approved under stringent regulatory authorities as well as waiving or reducing registration fees for life-saving TB drugs. GDF will help to provide incentives for manufacturers to register in the United States. NTCA will provide FDA with a list of medically necessary TB drugs. ATS will draft language to enhance FDA's capacity to collaborate with CDC and GDF to resolve TB drug shortages.

The partners have made tremendous and rapid progress in currently conducting or completing a number of the recommended action items: compiling a list of medically necessary TB drugs; investigating the possibility of developing an inventory reserve system; creating a schematic and a process to monitor risks to the TB drug supply in the United States; and including language in the reauthorization of the Comprehensive TB Elimination Action to support FDA's regulatory actions.

The next steps by the partners to develop a centralized procurement system will be to explore funding options and design a U.S. model based on the GDF model. FDA will evaluate recent TB drug shortages and breakdowns in communications to facilitate the creation of a cross-cutting system. Beginning in the spring of 2014, NTCA and TAG will jointly convene additional meetings with an expanded group of stakeholders, including industry representatives, to discuss progress from the "Solving the Silent Crisis" meeting and identify unresolved gaps.

Prior to co-hosting the "Solving the Silent Crisis" meeting in January 2014, NTCA explored the possibility of creating the first system in the United States to formally collect, maintain and report data on TB drug/biologic shortages. Multiple state and local health departments and community partners across the country reported Tubersol shortages to NTCA. NTCA also recognized that drugs are the strongest tools in the TB arsenal. Drugs that are not available or are too expensive for TB programs and patients to purchase undermine public health efforts to control, prevent and ultimately eliminate TB.

NTCA's initial effort in the development of a reporting system for TB drug/biologic shortages was to solicit input from and initiate a vetting process with multiple states, partners and TB programs in the field. NTCA used this feedback to identify the most appropriate data elements to collect and determine the most efficient format to gather information. NTCA also was aware that participation by state and local TB programs and community partners would be greater with an easy and streamlined reporting system requiring minimal time and burden.

NTCA launched its new web-based system in November 2013 to collect, maintain and report the following data elements on TB drug/biologic shortages.

- TB drug/biologic shortage data, including specific dates, manufacturers, suppliers and affected unit dosages
- Impacts of shortages or price increases on TB programs and patient care
- Price data, including dates and actual costs supported by invoices
- Organizational data, including the organization's location, type and participation in drug procurement programs

NTCA acknowledges the limitations of preliminary data on its web-based reporting system for TB drug/biologic shortages. The three-month data collection period from November 21, 2013 to March 2, 2014 was extremely short. Data were gathered after the Tubersol shortage and after production had resumed due to the resolution of manufacturing issues. State TB programs were experiencing tremendous problems in accessing TB drugs/biologics. Active follow-up and efforts to market NTCA's new web-based reporting system have been minimal to date.

Preliminary results of NTCA's new web-based reporting system are highlighted as follows. Several states and counties, Puerto Rico and the Northern Mariana Islands have submitted 62 reports to NTCA to date. County TB programs (~48%) and state TB programs (~35%) accounted for the top two organizational types that submitted reports to NTCA. Correctional facilities and regional TB programs that cover >2 counties or cities each accounted for 4.4% of reports. Hospitals, pharmacies, city TB programs and federal agencies each accounted for 2.2% of reports. A county government employee health center, a home healthcare facility and a public health laboratory accounted for the remaining three reports.

Various TB drugs/diagnostics have been reported to the NTCA system to date: Tubersol (60%), Pyrazinamide (PZA) (19%), Aplisol (9%), INH (3%), Ethambutol (EMB) (3%), Kanamycin (KAN) (2%), Cycloserine (2%), and Rifamate (2%). Manufacturers with reported TB drug/diagnostic issues were Sanofi Pasteur (~62%), VersaPharm (~18%), JHP Pharmaceuticals (~11%), Chao Center (~2%), and Sandoz (~2%). The types of issues reported included shortages (66%), price increases (23%), a combination of shortages/price increases (9%), and other issues (e.g., a recall on EMB) (2%).

TB drugs/diagnostics with reported shortages included Tubersol (76%), Aplisol (13%), INH (3%), KAN (3%), Cycloserine (3%), and EMB (2%). TB drugs/diagnostics with reported price increases included PZA (84%), INH (8%), and Rifamate (8%). Of the respondents that reported a Tubersol shortage, 78% described changes in their routine practice of testing for TB infection. The most common changes reported by respondents were prioritized TB testing to high-priority groups (83%), delayed TB testing (63%), and no testing of low-priority groups (48%).

The Tubersol shortage resulted in TB programs delaying or temporarily suspending testing to persons seeking TB screening for work or school (64% of programs), HCPs (40% of programs), substance abuse treatment center residents and outpatients (28% of programs), shelter clients (24% of programs), and TST or IGRA converters with a documented TB test in the past two years (20% of programs). Programmatic decisions to delay or temporarily suspend TB screening of some groups (e.g., emergency medical services personnel, firefighters and other first responders) due to the Tubersol shortage are of particular concern and might place the safety of some communities at risk.

The current price of PZA of \$153 for 100 tablets has doubled or tripled in Alabama, Oregon, Puerto Rico and Vermont in a one-year time period. The per-tablet cost of PZA has increased from ~\$0.70 to ~\$1.50 in some states. The price increase of PZA has required several states to purchase more expensive substitutes or switch to a sub-optimal treatment regimen. NTCA has initiated dialogue with the manufacturer of PZA to better understand the rationale for the rapid price increase. NTCA will continue to report key outcomes of these discussions to CDC and FDA.

Overall, NTCA's new web-based system will serve as an important tool for real-time data reporting. Preliminary data from the system showed that shortages in the TB drug/diagnostic

supply are continuing to interrupt and negatively impact patients and programs. Multiple states increasingly are experiencing difficulties in accessing Tubersol on an ongoing basis. Due to the significant price increase of PZA, some states have omitted this essential drug from their TB regimens.

NTCA will continue to collaborate with its partners to address risks in several areas. A single manufacturer produces a large percentage of FLDs and SLDs. Interruptions in the TB drug/diagnostic supply, cost increases and barriers to access have increased and made the procurement system more vulnerable. Both short- and long-term strategies need to be expedited.

Ann Cronin

Associate Director for Policy and Issues Management
Division of Tuberculosis Elimination
Centers for Disease Control and Prevention

Advice Requested from ACET by DTBE:

- What guidance can ACET provide to assist DTBE in developing a long-term plan for an uninterrupted supply of all TB drugs and diagnostics?

Ms. Cronin described ongoing national efforts by DTBE to address TB drug/biologic shortages. DTBE recently compiled a list of drugs/biologics that all TB and LTBI patients in the United States would need for a six-month supply. DTBE forwarded the list to the USPHS Supply Service Center, the drug distribution center for the entire U.S. government (USG), with a request to obtain the cost of purchasing all of the TB drugs/biologics at the same time through a centralized procurement system. DTBE was extremely surprised that the estimated cost of purchasing a six-month supply of drugs/biologics for all TB and LTBI patients in the United States would be \$21 million. TST and SLDs accounted for the majority of the purchase price.

DTBE has assumed for a long period of time that the importation of drugs through GDF would be virtually impossible due to FDA's inability to assure the quality of drugs entering the United States. However, DTBE consulted with GDF to review the current TB drug schedule and determine the types of approvals that are available at this time. DTBE was pleased to learn that three drugs sold through GDF are available in a U.S. FDA-approved formula: Cycloserine, KAP and Para-Aminosalicylic Acid (PAS). DTBE has informed TB programs that are unable to procure these three SLDs through regular mechanisms of their ability to purchase the drugs directly from GDF. TB programs also were directed to the GDF website to obtain forms and instructions on ordering and purchasing drugs.

DTBE also learned that some overseas drug manufacturers are U.S. subsidiaries. During a recent teleconference, FDA and USAID informed DTBE that TB programs could purchase U.S. FDA-approved subsidized drugs through GDF. DTBE will continue its dialogue with FDA and USAID to explore strategies to expand the number of FDA-approved drugs that are available through GDF and provide TB programs with a wider selection of products. Instead of taking action on the "Solving the Silent Crisis" recommendation to design a centralized procurement system in the United States based on the GDF model, U.S. TB programs might be able to directly access the GDF model.

ACET discussed the following topics during the question/answer session with Ms. Wegener and Ms. Cronin on ongoing efforts to address TB drug/biologic shortages in the United States.

- The rationale for some programs retesting TST or IGRA converters who have a documented TB test within the past two years.
- Marketing strategies to widely publicize the availability of NTCA's web-based system to increase reporting of TB drug/biologic shortages, particularly among correctional facilities.
- The need to encourage FDA to take concrete action steps (e.g. reducing fees, granting waivers or expediting the approval process) to remove regulatory barriers for companies that supply TB drugs to GDF.

ACET advised CDC to consult with two groups that currently are focusing on antimicrobial resistance: the Restricted Interagency Policy Committee on National Preparedness for Combating Antibiotic-Resistant Bacteria and the President's Council of Advisors on Science and Technology. The purpose of CDC's collaboration with these two groups would be to explore strategies to stimulate the development of anti-pyogenic drugs and secure a better TB drug market in the United States. ACET emphasized that the prices of TB drugs in the GDF stockpile will steadily rise as the number of cases continues to decline.

Update on CDC's Global TB Activities

Susan Maloney, MD, MHSc

Global TB Coordinator, Center for Global Health
Centers for Disease Control and Prevention

Advice Requested from ACET by CDC:

- What are ACET's recommendations to CDC in the following areas?
 - CDC's global TB measures and targets
 - The membership and structure of the proposed Global TB Steering Committee
 - CDC's proposed Global TB Strategic Framework and critical elements for the Global TB Strategic Plan
 - Effective approaches to expand and sustain the "TB Building and Strengthening Infection Control Strategies" (BASICS) Initiative

Dr. Maloney presented an update on CDC's global TB coordination activities. Global TB activities at CDC are conducted by three National Centers and four divisions. Despite differences in their mandates, organizational structures and funding streams, all of these entities have a long history of collaboration and coordination on global TB issues.

An expert panel conducted a peer review of CDC's global TB portfolio in November 2012 and made recommendations in two major areas. First, CDC should develop a forward-looking, agency-wide Global TB Strategy that prioritizes 2-3 focus areas: (1) application of CDC's core competencies to a wide range of TB issues (e.g., epidemiology, disease surveillance, research, laboratory training, infrastructure development, infection control, and translation of evidence-based policies into action); (2) factors driving the TB epidemic (e.g., HIV/AIDS, MDR-TB and diabetes); and (3) TB in vulnerable populations.

Second, CDC should implement a mechanism to increase internal and external coordination, communication and advocacy; build broader partnerships; and optimize utilization of its resources for a greater impact on global TB.

In response to the peer review panel's recommendation to increase internal and external coordination, CDC established a new Global TB Coordination Office (GTBCO) with several goals. Leadership and coordination will be provided for the development and implementation of CDC's unified global TB goals, strategies and programmatic priorities. Internal and external communication, coordination and collaboration will be improved through stakeholder meetings, workgroups, consultations and implementation planning. GTBCO will seek to increase programmatic synergies and as much as possible optimized utilization of resources to maximize impact.

CDC's role in implementing the USG Global TB Strategy will be strengthened. Substantial support and contributions will be targeted to achieving the 2011-2015 goals of the Global Plan to Stop TB. Strategic information will be shared more effectively with external partners to help identify adequate resources to achieve the goals. Leadership and coordination will be provided for initiatives identified by the CDC, Center for Global Health and NCHHSTP Directors.

GTBCO is conducting a number of activities to meet its global TB coordination goals. GTBCO is being established as an agency-wide focal point for CDC's global TB activities by leading internal and external data calls with key partners, responding to media and information requests, convening briefings, and hosting international visitors and Congressional delegations. GTBCO has developed solid relationships with several partner organizations to improve TB control efforts in Asia, Africa and other countries, including the World Health Organization (WHO), Stop TB Partnership, Global Fund, International Union Against TB and Lung Disease (IUATLD), and Ministries of Health (MOHs).

GTBCO and its federal partners provided technical assistance (TA), subject-matter expertise and input to the Center for Strategic International Studies (CSIS). CSIS was funded by the Gates Foundation to perform a one-year analysis of global TB activities and develop a policy paper with recommendations to the Obama Administration. A white paper from the CSIS analysis, *Tackling TB Abroad: The Answer to TB Elimination in the United States*, will be of particular interest to ACET for its focus on domestic TB. GTBCO began holding stakeholder meetings to improve coordination and communication. GTBCO's new TB BASICS Initiative led to the establishment of the new TB Infection Control Workgroup.

GTBCO serves as a co-chair on the Global TB Workgroup and helped to develop CDC's 2012-2015 Global Health Strategy to achieve the goal of a unified Global TB Strategy. The workgroup defined the global TB objective as "reducing TB morbidity and mortality" and also reviewed several existing indicators to create unified global TB measures and targets in CDC-supported countries that would be used to monitor impact in these areas over time:

- The percent of TB patients with known HIV status
- The percent of HIV/TB patients on antiretroviral therapy
- The number of countries reaching the global targets to reduce TB mortality
- The number of countries reaching the global targets to reduce TB prevalence

- The percent of MDR-TB cases detected based on WHO's estimates of the MDR-TB burden

The workgroup's recent global TB strategic planning efforts resulted in several significant outcomes, including the creation of an information packet with details on CDC's unified Global TB Strategy; publication of the *CDC Annual Global Health Report* describing accomplishments and progress toward meeting the global TB measures and targets; and agreement to establish a Global TB Steering Committee that would be more formal than the existing workgroup.

The proposed charge of the Steering Committee will be provide oversight and guidance on developing and implementing CDC's unified Global TB Strategy; increase programmatic coordination and synergies; and make recommendations on resources that will be needed to achieve CDC's global TB goals. Specific activities that have been proposed for the Steering Committee include providing feedback on the draft Global TB Strategy, offering TA to strengthen regional and local coordination and collaboration, and providing oversight of the TB BASICS Initiative. Multiple divisions and offices across CDC Headquarters and in the field have been proposed as Steering Committee members.

GTBCO, in collaboration with CDC global TB stakeholders, drafted a framework outlining the strategic approaches, priority areas and specific divisions involved in developing and implementing CDC's Global TB Strategy.

Strategic Approach	Priority Area	Responsible Divisions
Strengthen in-country capacity and provide technical support	Surveillance and impact measurement Laboratory systems	Division of Tuberculosis Elimination Division of Global HIV/AIDS
Build an evidence base for improved TB control and prevention strategies	TB/HIV Drug-resistant TB	Division of Global Health Protection
Translate research into practice to inform decision-making	TB infection control Vulnerable populations	Division of Global Migration and Quarantine (DGMQ) Division of Health Care Quality Promotion

The workgroup will update CDC's Global TB Strategy to emphasize critical elements: (1) ensure a strong programmatic and geographic focus; (2) optimize onsite TA and planning overseas with long-term TA models, one-country CDC and USG Global TB plans, and capacity building through fellowships; (3) strengthen and expand partnerships; and (4) improve metrics for monitoring and measuring impact. The revised Global TB Strategy will be shared with the new Steering Committee and external stakeholders over the next four months for review and comment. After the Global TB Strategy is finalized, an implementation plan will be developed.

In addition to its global TB strategic planning efforts, GTBCO also has been focusing on the important, but often neglected issue of TB infection control. Low- and middle-income countries account for 90% of the global TB burden due to their high rates of disease and limited resources. Because the majority of these resources are targeted to case detection and short-

course DOT, infection control strategies typically are not implemented, awareness of risks to HCPs and patients often is lacking, and HCPs frequently are assumed to be already infected.

Studies have shown that implementation of TB infection control interventions, including relatively inexpensive measures, are associated with a decline in TB outbreaks. However, evaluations to determine the impact of TB infection control are challenging due to the primary focus on process rather than impact indicators, the difficulty in demonstrating and measuring reduced transmission, and the use of TB and LTBI in HCPs as surrogates.

Data on nosocomial transmission are limited, but the 2006 Joshi, *et al.* study indicated a large burden. The study estimated ranges of LTBI and TB disease among HCPs in low- and middle-income countries: LTBI prevalence of 33%-79% with an average of 54%; annual risk of LTBI of 0.5%-14.3%; annual incidence of TB disease of 69-5,780/100,000 population; and attributable risk for TB disease of 25-5,361/100,000 population. LTBI and TB disease in these settings were found to be consistently higher than in the general population and also linked to the degree of TB exposure and the absence of TB infection control measures. Data on the implementation of TB infection control also are limited, but indicators suggest these measures are inadequate or absent in many settings.

CDC acknowledges that opportunities to improve TB infection control globally are imperative and critically important because of the dual epidemics of HIV and drug-resistant TB. Available TB infection control strategies that are relatively simple and inexpensive have been proven to decrease transmission, generate a long-term impact on the workforce and healthcare system, prevent other diseases and protect patients.

To make progress in this area, Dr. Thomas Frieden, Director of CDC, issued a directive in April 2013 for CDC programs to prioritize and accelerate efforts to strengthen TB infection control. He emphasized the need for a new initiative with an integrated response to rapidly identify and interrupt nosocomial TB transmission. The new initiative should result in the public health outcomes of a greater number of TB cases averted and more lives saved through increased TB case detection and decreased TB transmission.

Dr. Frieden also encouraged collaboration between CDC programs and external partners to maximize impact through TB infection control assessments, interventions, evaluations and scale-up of activities. In response to Dr. Frieden's directive, multiple CDC divisions jointly designed TB BASICS to assist countries with high TB, MDR-TB and/or HIV burdens in assessing and improving TB infection control in healthcare facilities.

CDC established several key objectives for TB BASICS: develop rapid and robust TB infection control assessment tools for adoption in the local context; design tailored TB infection control intervention packages to address gaps; develop effective monitoring and evaluation plans, including indicators and benchmarks; and answer key programmatic and operations research questions.

Training and capacity building in the four areas of TB BASICS (rapid assessment, intervention planning, implementation of interventions, and monitoring and evaluation) will be targeted to multiple audiences: MOH stakeholders, healthcare facility staff, implementation partners, country-based CDC/field staff, and CDC Headquarters staff.

CDC has conducted several activities and made numerous accomplishments in TB BASICS to date. The best and most promising TB infection control tools were identified, collected and compiled in an inventory. TB infection control assessment and intervention tools were adapted for inpatient and outpatient settings.

The TB BASICS Toolkit was designed with the following TB infection control resources: national, local and facility background information forms; standard operating procedures and a protocol; templates for a facility checklist, report and recommendations; an indicators dashboard and other planning and intervention tools; and slide sets, videos and other training resources. Mumbai, India was selected as the site to pilot the initial toolkit and validate the process in November 2013. The second pilot will be conducted in Zimbabwe, Africa to test the toolkit in a setting with a higher HIV burden, and the first collaborative planning visit is set for March 2014.

CDC's next steps will be to apply lessons learned and experiences from the two TB BASICS pilot sites to additional sites. Approaches will be identified for countries to take leadership of and sustain their individual TB BASICS plans over time. For example, CDC will support a TB BASICS Fellow to develop a Nigeria-specific plan to launch and implement the model from a country level. CDC, WHO, USAID and other global partners will co-sponsor a consultation in May 2014 to build consensus on the development of TB infection control indicators and monitoring and evaluation plans.

The TB BASICS Toolkit will be enhanced with additional resources, including quick-learn videos and iPad/iPhone applications. Additional resources will be identified to increase support and sustainability of TB BASICS. Collaborative efforts will be undertaken with Kenya and Mumbai to fill important gaps in global TB operational research: an evaluation of the relative impact and cost effectiveness of TB infection control interventions; HCP surveillance models; the use of molecular epidemiology to better understand the transmission dynamics of TB in healthcare facilities; and best practices for environmental assessments and interventions in resource-limited settings.

Overall, CDC plans to maximize its impact on global TB by following a roadmap with specific components: publication of the Global Health Strategy and Global TB Strategy; optimized coordination, communication and collaboration; engagement of broader partnerships; and dedicated funding to empower strategic investments based on core competencies.

ACET discussed the following topics during the question/answer session with Dr. Maloney on CDC's global TB activities.

- Opportunities for integration and coordination between the CDC and USAID global TB portfolios, such as plans by both agencies to develop models of long-term TA overseas.
- CDC's collaboration and consultation with WHO and other global partners to assure the following: (1) CDC's in-country presence is welcome, respectful, and culturally sensitive/appropriate; (2) CDC's "stronger and more sophisticated infrastructure of American power, funding and expertise" will not overpower or entirely dilute the country's ongoing global TB activities.

ACET made comments and suggestions in two areas for CDC to strengthen the role of its domestic TB portfolio in global TB activities. First, the operational research questions that CDC plans to address with Kenya and Mumbai to build global TB infection control capacity also

should be directed to U.S. TB programs. Emphasis on these same issues at national, state and local levels could play an important role in improving TB infection control in the United States. Second, CDC should increase collaborative opportunities for DGMQ and DTBE to inform the other division of their global and domestic TB control efforts on an ongoing basis. The DGMQ/DTBE collaboration particularly should focus on continuity of care, drug resistance status and treatment outcomes of foreign-born TB patients who are evaluated overseas upon their U.S. arrival and foreign-born TB patients in the United States who return to their countries of origin. ACET reiterated the need for DTBE's domestic TB control programs to play a greater role in CDC's global TB infection control and elimination efforts.

Public Comment Session

Ms. Cole opened the floor for public comments; none of the participants responded.

ACET Business Session

Ms. Cole opened the business session and called for ACET's review, discussion and/or formal action on the following topics.

Topic 1: Adoption of the Draft ACET Meeting Minutes

Ms. Cole entertained a motion for ACET to approve the previous meeting minutes. A motion was properly placed on the floor and seconded by Drs. Eric Brenner and Robert Horsburgh, respectively, for ACET to approve the previous meeting minutes.

ACET unanimously adopted the Draft December 3, 2013 Meeting Minutes with no changes or further discussion.

Topic 2: IGRA Resolution

The presentation of the IGRA resolution was **TABLED** due to the need to refine the language. Dr. Susan Dorman, an ACET member, confirmed that she would present the revised resolution during the June 2014 meeting for ACET's review, discussion and formal vote.

Topic 3: Action Items

Ms. Cole led ACET in a review of the action items and other tasks that were raised over the course of the meeting.

- CDC will provide ACET with clarification on specific criteria that were used to categorize and define “antibiotic-resistant infections.” ACET expressed concern that CDC’s 2013 report, *Antibiotic Resistance Threats in the United States*, classified gonorrhea as an “urgent” threat and MDR-TB as a “serious” threat.
- ACET will routinely revisit DTBE’s strategic priorities and proposed budget scenarios to monitor their impact on state and local TB control programs over time.
- ACET will develop formal guidance to assist CDC in its ongoing efforts to obtain a USPSTF grade for TB preventive care and Medicaid coverage of this service. Although USPSTF’s sole focus is on targeted TB screening, ACET’s position is that treatment of active TB disease and LTBI also should be included as preventive services and eligible for Medicaid coverage. To prepare for ACET’s development of a formal resolution on this issue, the members were asked to consult with and obtain input from their local and state agencies that are responsible for managing ACA plans.
- ACET will provide the Essential Components Workgroup with more specific guidance on its proposed framework. To guide this effort, the workgroup will present a draft document during the June 2014 meeting for ACET’s review, discussion and ongoing input.
- ACET will propose strategies to widely publicize that written guidelines on TB prevention and control are available for incarcerated populations.
- ACET will continue to provide CDC, NTCA and their partners with concrete advice on their ongoing efforts to address TB drug/biologic shortages in the United States. Most notably, ACET agreed to review the key issues for action outlined on the form for this agenda item to determine whether a formal resolution should be drafted for any of these issues. Ms. Wegener agreed to post a new link on the NTCA website to the GDF website to inform state, large-city and county TB programs of their ability to purchase Cycloserine, KAP and PAS directly from GDF.
- ACET will review TB BASICS in more detail to identify opportunities in which CDC could apply global experiences, lessons learned and research from this initiative at national, state and local levels in the United States.
- ACET noted that CDC has not formally responded to many of its consensus resolutions. For example, ACET has not received feedback on its recent letter to the HHS Secretary. ACET is unaware of the status of its resolution for the HHS Secretary to establish a national TB drug stockpile. Several ACET members viewed the shortage of TB drugs/biologics in the United States as a priority issue and drafted a resolution in this regard during the current meeting. However, the members were unwilling to present the resolution because CDC had not formally responded to or taken action on ACET’s previous resolution on this same topic. ACET emphasized that its efforts to provide expert guidance are pointless if CDC does not formally respond or take concrete action. To address this concern, Ms. Cole confirmed that she would work with CDC staff to determine the status of all of ACET’s outstanding resolutions. The findings would be reported to ACET during the June 2014 meeting. Several members pointed out that the update by the DTBE Corrections Workgroup during the current meeting should serve as

a model for CDC to provide a succinct, comprehensive and formal response to all of ACET's resolutions. Most notably, the workgroup described its activities and progress to date on the resolution and categorized each individual action item as "partially initiated," "fully initiated," "deferred," or "ongoing."

- ACET agreed to maintain a small standing workgroup that would work with CDC staff to plan and draft future agendas.

Topic 4: Future Agenda Items

ACET proposed several topics to include on future meeting agendas.

- Status report on ACET's outstanding resolutions
- Potential items to include in a TB research agenda
- DTBE's organizational structure and future directions under its new leadership
- In-depth discussion on a strategic plan and concrete action steps for CDC and public health departments across the country to jointly identify and treat the large group of TB infections that are at risk of progressing to disease. A status report of CDC's existing recommendations on this topic should be included in this agenda item.

Closing Session

Ms. Cole thanked the ACET members for their ongoing commitment, expertise and guidance to assist CDC in achieving its national TB elimination goal. She also thanked the CDC staff for preparing comprehensive overviews and informative updates to guide ACET's discussions. ACET commended Ms. Cole on her new role as the ACET Chair. Several members were impressed by her concise and accurate summary of key issues and action items from each presentation.

The remaining two ACET meetings in 2014 would be held on June 9-10, 2014 (an in-person meeting in Atlanta, Georgia) and on December 2, 2014 (a webinar).

With no further discussion or business brought before ACET, Ms. Cole adjourned the virtual meeting at 3:21 p.m. on March 4, 2014.

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. Eric Brenner
 Dr. Marcos Burgos
 Dr. Jane Carter

Dr. Gail Cassell
 Ms. Jennifer Cochran
 Dr. Susan Dorman
 Dr. Robert Horsburgh, Jr.

ACET *Ex-Officio* Members Present

Dr. Naomi Aronson
 Department of Defense

Dr. William Baine
 Agency for Healthcare Research and
 Quality

Ms. Sarah Bur
 Federal Bureau of Prisons

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

Dr. Diana Elson
 U.S. Immigration and Customs Enforcement

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

Dr. Nadine Gracia
 Office of Minority Health
 U.S. Department of Health and Human
 Services

Dr. Warren Hewitt
 Substance Abuse and Mental Health
 Administration

Dr. Susan Karol
 Indian Health Service

Mr. Stephen Martin
 National Institute for Occupational Safety
 and Health

Dr. YaDiul Mukadi
 (Alternate for Dr. Amy Bloom)
 U.S. Agency for International Development

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

ACET Ex-Officio Members Absent

Dr. Rupali Doshi
HIV/AIDS Bureau
Health Resources and Services
Administration

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

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

Dr. Sheldon Morris
U.S. Food and Drug Administration

ACET Liaison Representatives Present

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

Dr. Jennifer Flood
National Tuberculosis Controllers
Association

Dr. Ilse Levin
American Medical Association

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

Ms. Eileen Napolitano
Stop TB USA

Dr. Jennifer Rakeman
Association of Public Health Laboratories

Dr. Lee Reichman
American College of Chest Physicians

Dr. Lornel Tompkins
National Medical Association

Dr. David Trump
Council of State and Territorial
Epidemiologist

Ms. Tara Wildes
National Commission on Correctional
Health

ACET Liaison Representatives Absent

Mr. David Bryden
RESULTS

Ms. Colleen Daniels
Treatment Action Group

Dr. Mayleen Ekiek
Pacific Island Health Officers Association

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

Dr. Saul Levin
Association of State and Territorial
Health Officials

Dr. Susan Ray
Infectious Disease Society of America

Mr. John Lozier
National Coalition for the Homeless

Dr. Edward Nardell
International Union Against TB and Lung
Disease

Dr. Howard Njoo
Public Health Agency of Canada

Dr. Michael Tapper
Society for Healthcare Epidemiology of
America

ACET Designated Federal Officer

Dr. Hazel Dean
NCHHSTP Deputy Director

CDC Representatives

Dr. Lori Armstrong
Ms. Sara Bingham
Mr. Kevin Borden
Dr. Terence Chorba
Ms. Ann Cronin
Ms. Molly Dowling
Ms. Teresa Durden
Ms. Peri Hopkins
Dr. Amera Khan
Ms. Katrina Kosler
Ms. Lauren Lambert
Ms. Ann Lanner

Dr. Philip LoBue
Mr. Elvin Magee
Dr. Susan Maloney
Ms. Suzanne Marks
Mr. Mark Miner
Dr. Thomas Navin
Ms. Margie Scott-Cseh
Ms. Sarah Segerlind
Mr. Brian Sizemore
Mr. Phillip Talboy
Mr. Erik Williams
Dr. Wanda Walton

Members of the Public

Ms. Sue Etkind
Stop TB USA

Ms. Donna Wegener
National TB Controllers Association



Attachment 2: Glossary of Acronyms

3HP	Three-month, once-weekly Isoniazid/Rifapentine
ACA	Affordable Care Act
ACET	Advisory Council for the Elimination of Tuberculosis
AFB	Acid-Fast Bacillus
AHRQ	Agency for Healthcare Research and Quality
ATS	American Thoracic Society
CDC	Centers for Disease Control and Prevention
CoAg	Cooperative Agreement
CSIS	Center for Strategic International Studies
DASH	Division of Adolescent and School Health
DGMQ	Division of Global Migration and Quarantine
DHAP	Division of HIV/AIDS Prevention
DOT	Directly-Observed Therapy
DTBE	Division of Tuberculosis Elimination
DVH	Division of Viral Hepatitis
EMB	Ethambutol
FBP	Federal Bureau of Prisons
FDA	U.S. Food and Drug Administration
FLDs	First-Line Drugs
FOA	Funding Opportunity Announcement
GDF	Global Drug Facility
GTBCO	Global TB Coordinating Office
HCPs	Healthcare Providers
HCV	Hepatitis C Virus
HHS	U.S. Department of Health and Human Services
HPV	Human Papillomavirus
ICE	Immigration and Customs Enforcement
IGRA	Interferon Gamma Release Assay
INH	Isoniazid
IUATLD	International Union Against TB and Lung Disease
KAN	Kanamycin
LTBI	Latent TB Infection
MDR-TB	Multidrug-Resistant TB
MMWR	<i>Morbidity and Mortality Weekly Reports</i>
MOHs	Ministries of Health

NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
NTCA	National Tuberculosis Controllers Association
PAS	Para-Aminosalicylic Acid
PCSI	Program Collaboration and Service Integration
PrEP	Pre-Exposure Prophylaxis
PZA	Pyrazinamide
RTI	Research Triangle Institute
RTMCCs	Regional Training and Medical Consultation Centers
RVCT	Report of Verified Case of Tuberculosis
SLDs	Second-Line Drugs
TA	Technical Assistance
TAG	Treatment Action Group
TB	Tuberculosis
TB BASICS	TB Building and Strengthening Infection Control Strategies
TST	Tuberculin Skin Test
USAID	U.S. Agency for International Development
USG	U.S. Government
USPHS	U.S. Public Health Service
USPSTF	U.S. Preventive Services Task Force