U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL CENTER FOR HIV/AIDS, VIRAL HEPATITIS, STD AND TB PREVENTION
DIVISION OF TUBERCULOSIS ELIMINATION

Meeting of the
Advisory Council for the Elimination of Tuberculosis
June 9-10, 2014

DRAFT Record of the Proceedings

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ADVISORY COUNCIL FOR THE ELIMINATION OF TUBERCULOSIS
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DRAFT Minutes of the Meeting

The U.S. Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC), National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP), Division of Tuberculosis Elimination (DTBE) convened a meeting of the Advisory Council for the Elimination of Tuberculosis (ACET). The proceedings were held on June 9-10, 2014 in Building 8 of CDC's Corporate Square Campus, Conference Room A/B/C, in Atlanta, Georgia.

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: June 9, 2014

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 (DFO)

Dr. Dean conducted a roll call to determine the ACET voting members, *ex-officio* members and liaison representatives who were attending the meeting either in person or remotely. 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 reminded the ACET voting members of their responsibility to disclose any potential individual and/or institutional conflicts of interest for the public record and recuse themselves from voting or participating in these matters.

CONFLICT OF INTEREST DISCLOSURES

ACET Voting Member (Institution/Organization)	**Potential Conflict of Interest**
Ana Alvarez, MD, FAAP (University of Florida College of Medicine)	No conflicts disclosed
Eric Brenner, MD (Arnold School of Public Health University of South Carolina)	No conflicts disclosed
Marcos Burgos, MD (New Mexico Department of Health & University of New Mexico School of Medicine)	No conflicts disclosed
Jane Carter, MD (Alpert School of Medicine at Brown University & The Miriam Hospital)	President of the International Union Against TB and Lung Disease (IUATLD)
Gail Cassell, PhD (Harvard University Department of Global and Social Medicine)	Participant in the Eli Lilly MDR-TB Partnership that established the Lilly TB Drug Discovery Initiative; Chair of the American Society for Microbiology Biomedical Research Committee of the Public and Scientific Affairs Board
Jennifer Cochran, MPH (Massachusetts Department of Public Health)	Grantee of the CDC TB Cooperative Agreement (CoAg)
Barbara Cole, RN, MSN, PHN (Riverside County Department of Public Health)	No conflicts disclosed
Susan Dorman, MD (Johns Hopkinds University School of Medicine)	No conflicts disclosed
Robert Horsburgh, Jr., MD, MUS (Boston University School of Public Health)	No conflicts disclosed

Dr. Dean announced that the voting members and *ex-officio* members in attendance constituted a quorum for ACET to conduct its business on June 9, 2014. She called the proceedings to

order at 8:32 a.m. and welcomed the participants to day 1 of the ACET meeting. Dr. Dean noted the temporary and permanent changes to ACET's membership.

- Dr. Randall Reves has replaced Dr. Edward Nardell as the liaison representative for IUATLD. Dr. Reves is the IUATLD President-elect.
- Dr. Christopher Archibald would serve as the alternate liaison representative for the Public Health Agency of Canada in the absence of Dr. Howard Njoo.
- Dr. Michael Bartholomew would serve as the alternate *ex-officio* member for the Indian Health Service in the absence of Dr. Susan Karol.
- Dr. Susan Robilotto would serve as the alternate *ex-officio* member for the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau in the absence of Dr. Rupali Doshi.
- Ms. Sue Etkind would serve as the alternate liaison representative for Stop TB USA in the absence of Ms. Eileen Napolitano.
- The U.S. Marshals Service is still in the process of identifying an *ex-officio* member to replace Ms. Tiffany Moore.
- The terms of four ACET members would expire at the end of June 2014: Drs. Eric Brenner, Marcos Burgos, Jane Carter and Gail Cassell. However, the outgoing ACET members will serve for an additional 180 days until their replacements are formally approved. The final nomination packages for the new members were submitted to the CDC Committee Management Office on May 28, 2014.

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

Ms. Cole joined Dr. Dean in welcoming the participants to day 1 of the ACET meeting. She explained that a significant portion of the meeting would be devoted to a status report on the resolutions and recommendations ACET formally approved in 2011, 2012 and 2013. During this discussion, the ACET members would be asked to provide concrete input on strategically advancing these items to assist CDC in achieving the national goal of TB elimination.

NCHHSTP Director's Report

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

Dr. Mermin covered the following topics in his Director's report to ACET. At the agency level, sequester reductions led to the restoration of $569 million in the FY2014 CDC budget. CDC allocated $30 million of these funds to the National Center for Emerging and Zoonotic Infectious

Diseases to establish a new Advanced Molecular Detection (AMD) Program. The AMD Program will target funding and efforts to five major activities.

- Improved pathogen identification and detection
- New diagnostics
- Technical assistance (TA) to states to meet their bioinformatics and genomics needs
- Enhanced laboratory information systems
- Prediction, modeling and early recognition of infections

CDC partnered with U.S. government (USG) agencies, other nations, international groups, and public/private stakeholders to launch a "Global Health Security Agenda." The purpose of this initiative is to accelerate progress toward achieving worldwide safety and security related to infectious disease threats and also to promote global health security in three major areas.

First, the likelihood of natural, accidental or intentional outbreaks will be prevented and reduced. Second, threats will be detected early to save lives. Third, multi-sectorial coordination and communication will be deployed internationally to ensure a rapid and effective response. Due to increased concerns regarding antimicrobial resistance, CDC hopes to use the Global Health Security Agenda to allocate resources to TB.

At the National Center level, NCHHSTP received ~$25.2 million from the sequester reductions that were restored to CDC's FY2014 budget. For TB initiatives, NCHHSTP allocated ~$2.1 million primarily to restore cuts to the TB Prevention, Control and Laboratory CoAgs, Tuberculosis Epidemiologic Studies Consortium (TBESC), and Tuberculosis Trials Consortium (TBTC).

CDC's new AMD Program awarded $917,240 to NCHHSTP to conduct five new AMD projects.

1. Characterization of microbial transmission networks by combining epidemiologic and genetic data
2. Advanced molecular detection of hepatitis C virus outbreaks
3. Genomic surveillance of *Mycobacterium tuberculosis* (*M.tb*) in New York City over the 2011-2014 time period
4. Whole-genome sequencing (WGS) for national TB outbreak detection and investigations
5. Genomic sequencing of *Neisseria gonorrhoeae* to more effectively respond to the urgent threat of antimicrobial-resistant gonorrhea

NCHHSTP implemented a new strategic planning process to identify the best approaches to achieve maximum impact on reducing health disparities, disease incidence, morbidity and mortality for HIV, viral hepatitis, STDs and TB. NCHHSTP held meetings and retreats with staff at the Office of Director, division and branch levels to obtain internal input on the strategic planning process. Key informant interviews also were conducted with partners to obtain external guidance on opportunities and challenges related to HIV, viral hepatitis, STD and TB

prevention. After NCHHSTP develops the draft Strategic Plan, the document will be shared and vetted with a broader group of partners and stakeholders.

NCHHSTP launched a new "Prevention Through Health Care" website as an online resource to help leverage changes in the healthcare system at multiple levels: state, local and tribal public health agencies, community-based organizations and other partners. NCHHSTP published success stories and outcomes of demonstration projects related to its Program Collaboration and Service (PCSI) initiative. A supplement on PCSI also was published in the January/ February 2014 edition of *Public Health Reports*. NCHHSTP published the *2013 Annual Report* to highlight its center-wide activities and accomplishments. NCHHSTP updated its "Atlas" with 2012 surveillance data for STDs and TB. All of these resources and publications are available on the CDC.gov/nchhstp website.

NCHHSTP conducted a number of workforce development and capacity building activities. A new seminar series on laboratory science was offered to epidemiologists. A new scientific writing course was held for NCHHSTP scientists. The Coaching and Leadership Initiative was piloted in 2013 with 60 team leaders. NCHHSTP continued to conduct its Ambassador Program to assist new employees during their transition to the workforce.

NCHHSTP recently announced the appointment of Dr. Stephanie Zaza as the new Director of the Division of Adolescent and School Health. NCHHSTP expects to appoint permanent Directors for DTBE and the Division of HIV/AIDS Prevention over the next month.

At the division level, DTBE released several publications in observance of World TB Day. DTBE published a *Morbidity and Mortality Weekly Report* (*MMWR*) article on March 21, 2014 to report TB trends in the United States in 2013. TB cases are continuing to decline with 9,588 cases reported in 2013. Estimates indicate that U.S. TB prevention and control efforts have helped to prevent >200,000 cases since 1993. However, dramatic disparities still exist with persistently higher TB rates among racial/ethnic minority groups than whites.

DTBE published "Treatment Practices: Outcomes and Costs of Multidrug-Resistant and Extensively Drug-Resistant Tuberculosis in the United States, 2005-2007," in *Emerging Infectious Diseases* in May 2014. DTBE hosted a Public Health Grand Rounds in March 2014, "Multidrug-Resistant Tuberculosis, Tools for Tackling a New Face of an Old Foe." DTBE participated in a briefing with Congressional staffers in its ongoing efforts to increase the interest in and visibility of TB. DTBE emphasized that CDC makes a sound return on TB investments Congress allocates to CDC.

Acting DTBE Director's Report

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

Dr. LoBue covered the following topics in his Acting Director's report to ACET. Of DTBE's FY2014 budget of ~$143 million, the actual spending amount is ~$138.7 million because a portion of the funds are set aside to support general activities at both the agency and center levels. The FY2014 budget increase restored ~$2.1 million of the $7 million reduction in the FY2013 budget. The line-items in the FY2014 budget increase included restoration of ~$1.4 million to the TB Prevention, Control and Laboratory CoAgs; restoration of ~$440,000 to the TB research budget (~$250,000 to TBTC and ~$190,000 to TBESC); and a 1% cost-of-living adjustment based on a full-time equivalent (FTE) budget of $27 million (excluding contractors).

DTBE had several changes in its leadership over the past few months. Dr. Angela Starks replaced Dr. Michael Iademarco as Chief of the Laboratory Branch. Dr. Bonnie Plikaytis will be retiring from her position as Deputy Chief of the Laboratory Branch. Dr. Jose Becerra will be retiring from his position as Chief of the Data Management and Statistics Branch. Searches will be initiated in the near future to permanently fill the two leadership positions.

DTBE expects to publish the new 2015-2019 TB Prevention, Control and Laboratory Funding Opportunity Announcement (FOA) on July 1, 2014, announce the awards on December 1, 2014, and allocate funds to grantees on January 1, 2015. After the FOA is published, applicants will be given 45 days to submit their applications through the Grants.gov website. Eligibility for funding will be limited to state/local health departments that previously were TB CoAg grantees. The TB funding formula will be 100% implemented in 2015.

DTBE will not revise the Report of Verified Case of Tuberculosis (RVCT) to capture molecular drug susceptibility testing data until input is obtained from a wide range of state partners. To support the RVCT revisions, multiple systems would need to be updated because various programs utilize their individual systems to submit data to CDC's central repository. As a result, both CDC and individual TB programs would incur high costs and increased complexity. In the interim, however, DTBE is coordinating efforts with partners to improve the RVCT instructions.

DTBE received its second year of funding from the CDC Office of Antimicrobial Resistance to improve the accuracy of laboratory data reported through the RVCT. DTBE established a new "Data Re-Release Agreement" that now allows CDC to report county-level data and conduct more granular analyses. However, the rules regarding data suppression will be maintained to assure the protection and confidentiality of TB patients.

DTBE provided technical input and expertise to inform the U.S. Food and Drug Administration's (FDA) decision-making process on the reclassification of molecular TB assays. DTBE emphasized that reclassification of and special controls for molecular TB assays would lessen the burden on industry for commercialization of these devices, while mitigating their associated risks. DTBE's description of the public health benefits of these devices in diagnosing TB played a significant role in an FDA Advisory Panel unanimously voting in favor of reclassification. In May 2014, FDA downgraded nucleic acid-based *in vitro* diagnostics to detect *M.tb* from respiratory specimens from the Class III, pre-market approval category to Class II with special controls.

DTBE is extremely proud of the national leadership, accomplishments and future directions of its research consortia. For TB epidemiologic research, TBESC initially conducted studies to compare the predictive value of three latent TB infection (LTBI) tests. However, TBESC was unable to reach its sample size targets and gather statistically meaningful results due to the low rate of progression to TB disease and the minimal number of endpoints. TBESC is now shifting the focus of its epidemiologic research for TB programs and community partners to track LTBI in populations at highest risk and maximize efforts to expand LTBI testing and treatment.

For TB treatment research, TBTC has made significant contributions to the published literature. Study 26 is completed and compared a three-month, once-weekly isoniazid/rifapentine (3HP) regimen to a nine-month isoniazid (INH) regimen. Study 26 led to the development of three new papers that are in various stages of publication: submission of a pediatric sub-study manuscript, ongoing clearance of a hypersensitivity manuscript, and preparation of a draft HIV sub-study. Study 29X is completed and examined a high-dose rifapentine (RPT) regimen for treatment of TB disease in a Phase II trial. The manuscript for Study 29X is ready for publication at this time.

Study 31 is pending and will be initiated in early 2015 to examine a four-month RPT-based regimen for treatment of TB disease in a Phase III trial. DTBE and FDA will meet later in June 2014 to discuss the study protocol. Study 33 is underway and is examining self-administration of the 3HP regimen to gather more data on adherence and tolerability. The major goal of the study will be to overcome major obstacles in directly-observed therapy that hinder broad implementation of an LTBI regimen. Because the entire cohort has been fully enrolled at this time, Study 33 is expected to be concluded in August 2014.

DTBE recently released four TB Self-Study Modules on the CDC.gov/tb website in addition to the "Introduction" and "Glossary."

- Module 6: "Managing Tuberculosis Patients and Improving Adherence"
- Module 7: "Patient Rights and Confidentiality in Tuberculosis Control"
- Module 8: "Contact Investigations for Tuberculosis"
- Module 9: "Tuberculosis Outbreak Detection and Response"

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), TBTC and TBESC) 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 staff costs were growing at an unsustainable rate.

Several events have impacted the timing and direction of DTBE's strategic alignment process: the 2014 Omnibus budget that deferred the 2013 budget sequestration; restoration of a portion of funding to DTBE's FY2014 budget; and the impact on current planning efforts due to upcoming changes in DTBE's permanent leadership. The stable FY2014 budget will ease the pressure of time constraints, but DTBE will maintain momentum of its current strategic planning efforts. This process is valuable for advance planning and also will allow DTBE to consider level funding scenarios.

DTBE formed three workgroups to propose agendas, priorities and contingency budget plans in the areas of staffing, research and program. The Staffing and Research Workgroups completed and distributed their interim reports to ACET for review and comment, but the Program Workgroup currently is revising its interim report to address additional funding scenarios. Key recommendations proposed by the Staffing and Research Workgroups and DTBE's preliminary responses are set forth below.

STAFFING WORKGROUP	
Workgroup Recommendation	**DTBE Response**
Establish a three-year target for DTBE personnel spending to achieve a reduction from $27 million to $24 million.	DTBE will maintain personnel spending at $27 million at this time. Economizing measures proposed by the workgroup will be implemented when possible.
Develop a strategy and a defined process to assess new hires from a division perspective.	DTBE has implemented this process.
Consider reorganizing DTBE by regrouping division functions to increase efficiency and flexibility.	DTBE will defer its response in order for the permanent DTBE Director to weigh in and consider this suggestion.
Encourage a robust culture of mentoring and opportunities for professional development of staff.	DTBE strongly supports this suggestion, but specific and concrete input is needed from staff to make improvements in this area.

RESEARCH WORKGROUP	
Strengthen oversight of the DTBE research portfolio with an internal oversight board and external peer review process.	DTBE strongly supports this suggestion, but the final decision will be at the discretion of the permanent DTBE Director.
Develop a method and criteria to establish and evaluate DTBE's research priorities.	Response pending.
Emphasize the importance of supporting time-limited innovative research projects because all of DTBE's research funding and efforts are targeted to TBTC and TBESC at this time.	Response pending.
Advance to next steps: • Create an internal oversight board • Plan for an external peer review process • Develop and prioritize a list of current and potential research projects • Develop contingency planning to conduct TB research under various budget scenarios	Response pending.

ACET discussed the following topics with Dr. LoBue on DTBE's recent activities.

- Reasons for the delay in selecting a permanent DTBE Director.
- The potential for the FY2015 budget to restore even more funding to the $7 million reduction in the FY2013 budget.
- The anticipated timeline for DTBE to provide ACET with a list of its research priorities and division functions that will be reorganized and regrouped.
- The anticipated timeline for DTBE to begin revising the RVCT.
- The possibility of DTBE analyzing and demonstrating the increased cost per TB case due to the shift to TB elimination and the continued decline in the reported number of cases.
- Expected changes in funding levels to states due to 100% implementation of the TB funding formula in 2015.
- CDC's programs and incentives to address attrition in the aging TB workforce due to retirements in DTBE and its funded state/local health department staff.
- ACET's future role, strategies and priorities to provide DTBE with the best advice during its reorganization and transition to new leadership.

Dr. LoBue explained that most of ACET's comments could not be addressed until after the permanent DTBE Director has been appointed, the FY2015 budget has been allocated by Congress, and the 2015-2019 TB CoAg has been awarded. However, he responded to three of ACET's questions. In terms of DTBE's research priorities, the Research Workgroup currently is developing an inventory of ongoing and emerging research projects. After the list is prioritized

based on a specific set of criteria and budget scenarios, DTBE expects to convene an external peer review panel in 2015 to obtain broader input.

In terms of the reorganization of division functions, DTBE needs to further analyze workforce statistics, field staff and other data to inform its decision-making. In terms of ACET's future advisory role, DTBE would benefit from guidance and input on broader issues. For example, updates should continue to be placed on agendas, but future meetings should be structured for ACET to provide advice on a major theme or topic.

The discussion resulted in ACET advising DTBE to engage an external group of industry experts to share their experiences and lessons learned in enrolling participants in domestic and international clinical trials. ACET noted that this input would be valuable in helping the TBTC grantees to more rapidly identify and enroll the cohort for Study 31.

CDC's Strategic Approach to Reduce TB Among Foreign-Born Persons in the United States Through Global TB Activities

Eugene McCray, MD
Chief, International Research and Program Branch, DTBE
Centers for Disease Control and Prevention

Dr. McCray described CDC's strategic approach to reduce TB among foreign-born persons (FBPs) in the United States through global TB activities. CDC's investment in global TB control is needed because TB elimination in the United States cannot be achieved if the global TB burden remains high and cross-border travel continues. The percentage of TB cases among U.S.-born persons has dramatically decreased by ~63% since 2000, but has only declined by ~18% among FBPs.

The TB epidemic in the United States is highly concentrated to specific populations and geographic areas: FBPs account for 64% of all cases; four high-burden states account for 50% of all cases; six countries account for 63% of all cases among FBPs (China, India, Kenya, Mexico, Philippines and Vietnam); and FBPs account for 91% of all multidrug-resistant TB (MDR-TB) cases.

CDC's global TB control activities are based on two global initiatives. Strategy 1 is to achieve the global goals of the 2011-2015 Global Plan to Stop TB: achieve the "1990" TB prevalence and mortality by 2015, reduce TB mortality by 75% by 2015, and reduce TB incidence by 50% by 2015. The goal of TB elimination can be achieved by 2050 if the target of a 20% reduction in cases per year is met. However, the current rate of decline is 2% of cases per year in the United States, 3%-4% of cases per year in China and Cambodia, and 10% of cases per year in Western Europe post-World War II.

Strategy 2 is to achieve the global goals of the 2010-2014 Lantos-Hyde USG Tuberculosis Strategy: accelerate TB detection and treatment in 25 countries, scale-up prevention and treatment of MDR-TB, expand coverage and interventions for TB/HIV co-infection, and strengthen health systems. CDC is extensively engaged with its global partners in revising the Lantos-Hyde USG TB Strategy for 2015.

The DTBE International Research and Program Branch (IRPB) serves as the leader of CDC's global TB control efforts, but other entities also play a major role in these activities. The Division of Global Migration and Quarantine (DGMQ) is responsible for overseas screening and follow-up of immigrants and refugees prior to U.S. entry. The Global Disease Detection Branch is responsible for active case finding in hospital-based and outpatient-based settings in developing countries. The Division of Global HIV/AIDS is responsible for delivering TB/HIV and other interventions in HIV settings.

IRPB used the DTBE strategic planning process as an opportunity to identify major challenges in its leadership role for CDC's global TB control efforts. IRPB identified the first challenge as resources. IRPB operates with an overall program budget of $7 million; 24 U.S.-based staff to support 31 countries; and 5.5 staff as in-country deployments in Botswana, China, India, Kenya and Thailand.

IRPB identified the second challenge as the funding shortfall. IRPB reviewed 2012 global mortality data that showed HIV accounted for 1.6 million deaths, TB accounted for 1.3 million deaths, and malaria accounted for 660,000 deaths. However, USG and CDC resources for global TB control are not aligned with the epidemic because the least amount of funding for the three infectious diseases is allocated to TB.

IRPB identified the third challenge as its future direction. IRPB has been extremely successful in leveraging funds outside of CDC. The President's Emergency Plan for AIDS Relief, U.S. Agency for International Development (USAID) and other external sources account for ~75% of IRPB's budget, while CDC contributes ~25% of funding. Because IRPB's projects and priorities are narrowly defined with scopes of work that are specific to these external funding streams, its activities have been viewed as being disconnected from and not significantly contributing to DTBE's mission and mandate. IRPB's external funding sources also have limited its ability to coordinate and sustain efforts with internal CDC partners.

IRPB shifted its traditional approach from ad hoc funding opportunities to a more strategic approach to address these challenges. This effort includes the development of an evidence-based, comprehensive, focused and coherent plan for global TB control to improve alignment between DTBE and IRPB priorities and achieve greater and more sustainable impact over time. IRBP branded its new effort with a vision of "A World Free of TB" and a mission of collaborating with partners to prevent TB transmission and reduce TB morbidity and mortality in target countries.

IRPB will conduct a number of activities to achieve the goals of its new strategic approach. An evidence base will be built for effective TB control through basic epidemiology, clinical research and evaluation of new tools. TB prevention and control will be improved through research and evaluation that are relevant to programs. Technical support will be provided to build in-country capacity. Public health systems will be strengthened by assessing weaknesses and guiding corrective actions. Research will be translated into practice by informing and developing global TB control guidelines and policies. Internal and external partnerships will be leveraged to access expertise and support that are necessary to achieve IRPB's mission.

IRPB reviewed recent data to identify countries for implementation of its strategic approach: 22 high-burden countries that represent ~80% of global TB morbidity, 27 countries with the highest MDR-TB burden, and countries with the highest HIV burden. IRPB then ranked the countries based on their disease burdens, contributions to TB among FBPs, and overall composite scores over the past five years.

IRPB prioritized six countries for implementation of its new strategic approach after applying objective and subjective data and feasibility criteria: Haiti, India, Kenya, Philippines, South Africa and Vietnam. The six priority countries already have a USG presence and partnerships, strong political will, and significant resources from the Global Fund to Fight AIDS, Tuberculosis and Malaria. TA and support will continue to be provided in other countries with a high TB burden on a case-by-case basis, but IRPB will dedicate 80% of its funding, staff and other resources to improve global TB control efforts in the six priority countries. IRPB identified four focus areas that will be targeted to the six priority countries.

Priority Area 1

- *Goal:* Reduce TB among FBPs in the United States through research and program support in the priority countries
- *Approach:* Decrease the overall TB burden in select countries where this strategy is most appropriate (e.g., countries with many U.S.-bound immigrants who do not undergo screening and/or countries with a large number of entrants to the United States)
- *Target Countries:* Haiti, India, Philippines, Vietnam (Mexico to be added if political will and interest, a USG presence, and resources are obtained)

Priority Area 2

- *Goal:* Conduct research to decrease TB among U.S.-bound immigrants
- *Approach:* Closely collaborate with DGMQ to conduct research and modeling to achieve the following outcomes: (1) determine the best strategies to decrease TB among U.S.-bound immigrants prior to U.S. entry; (2) identify FBPs at highest risk of progressing from LTBI to TB disease based on country of origin and other factors; and (3) expand screening of active TB to long-term visitors and students from high-risk countries

Priority Area 3

- *Goal:* Guide global TB policies by providing innovative and impactful research and programmatic support
- *Approach:* Conduct research and provide support to programs to determine the best strategies to accelerate the decline of TB in the priority countries
- *Target Countries:* Haiti, India, Kenya, Philippines, South Africa, Vietnam

Priority Area 4

- *Goal:* Inform global TB control efforts by translating research into policy and practice
- *Approach:* Apply evidence-based knowledge and research to inform policy and practice in the priority countries through collaboration with the World Health Organization (WHO), IUATLD and other international partners

In addition to focusing on the four priority areas, IRPB also intends to increase its field presence in the six priority countries based on experiences and lessons learned. In 1993-2011, for example, CDC had a consistent field presence in India that included direct TA, strong guidance and comprehensive support. Data from IRPB's ecological analysis showed that compared to China and other countries without CDC's ongoing field presence, India had much more success in reducing TB incidence, influencing TB policy and directly impacting TB program activities.

Overall, IRPB's shift from an approach of missed opportunities to a comprehensive and synergistic strategy will more closely focus on global TB/HIV co-infection, MDR-TB and infection control in the six priority countries. IRPB's new strategic approach to reduce TB among FBPs in the United States also will enhance collaboration with DTBE's surveillance, laboratory and training programs to increase overall impact.

IRPB acknowledges that additional resources will be needed to successfully implement its new strategic approach: more FTEs in the six target countries; dedicated CDC funding to conduct the priority activities; stronger internal and external coordination, particularly with the CDC Global Health Security Branch to leverage resources for antimicrobial resistance and MDR-TB; and advocacy and support from external partners and stakeholders. IRPB hopes to make more rapid progress with its new strategic approach after the permanent DTBE Director is appointed.

ACET discussed the following topics with Dr. McCray on CDC's new strategic approach to reduce foreign-born TB cases in the United States.

- The rationale for excluding China from the six priority countries: (1) China is one of the major contributors to foreign-born TB cases in the United States. (2) China is a global leader in MDR-TB research, surveillance, WGS, and provision of second-line drugs (SLDs) for TB.
- Potential opportunities for CDC to take advantage of new requests for TA, programmatic research, evaluation or other aspects of the redesigned Global Fund to increase its field presence in the six priority countries.

- The possibility of CDC and WHO engaging the International Labour Organization as a new global partner due to the increased interest of this group in HIV/AIDS and other health aspects of the global workforce.
- The need to increase TB screening of foreign-born minor children prior to U.S. entry.
- CDC's use of vitamin D therapy as an intervention for TB in overseas populations.
- Barriers to USG implementation of global TB control activities in Russia.

The discussion resulted in ACET making two key suggestions for CDC to consider in refining its new strategic approach to reduce foreign-born TB cases in the United States.

- CDC is continuing to engage Ministries of Health (MOHs) in its global TB control efforts, but more emphasis should be placed on involving, educating and obtaining endorsement from Ministries of Finance that control in-country funding, program implementation and staffing.
- CDC intends to add Mexico as a priority country if political will and interest, a USG presence and resources are obtained. However, a more proactive approach should be taken because Mexico accounts for ~30% of foreign-born TB cases in the United States. ACET should devote time during a future meeting to propose effective strategies for CDC to leverage support, resources and endorsement for TB from the Mexico MOH. For example, CDC and its global partners currently are revising the Lantos-Hyde USG TB Strategy for 2015. ACET should draft language for the updated strategy to emphasize the critical need to include Mexico as a priority country for TB among FBPs in the United States. The focus on this issue should include Latin America as well.

Overview of the U.S. Preventive Services Task Force (USPSTF) Draft Research Plan

Christine Ho, MD, MPH
Medical Officer, Division of Tuberculosis Elimination
Centers for Disease Control and Prevention

Advice Requested from ACET by DTBE:
- What is ACET's input on the inclusion or exclusion of public health clinics in the USPSTF recommendations?
- What is ACET's input on specific patients who should be excluded from the USPSTF recommendations?

Dr. Ho presented an overview of the USPSTF draft research plan that will serve as the basis to assess the evidence for LTBI treatment as prevention. The Affordable Care Act (ACA) requires coverage of preventive services with a USPSTF Grade A or B recommendation without cost sharing for newly insured patients. The CDC Advisory Committee on Immunization Practices

and HRSA recommendations call for TB testing of children at high risk for TB (e.g., children with foreign-born parents or recent exposure to TB).

USPSTF gave LTBI screening of high-risk persons a Grade A recommendation in 1996, but did not renew the grade in its 2002 recommendations. Instead, USPSTF's guidance recognized the importance of targeted screening for TB and deferred to CDC's guidelines for LTBI testing. CDC and the Agency for Health Research and Quality jointly funded a review in 2013 to inform USPSTF's systematic review of the evidence for LTBI screening.

USPSTF's scope covers the provision and grading of recommendations on screening, but not treatment. USPSTF's recommendations typically are limited to asymptomatic patients in primary care settings and are based on its systematic reviews of the existing published literature rather than primary research. USPSTF's process for its systematic review of LTBI screening is outlined below.

USPSTF drafted a research plan in collaboration with researchers from the Evidence-Based Practice Center (EPC) to guide the development of the LTBI screening recommendation. The draft research plan has been posted on the USPSTF website for a 30-day public comment period and will be finalized after all of the comments have been reviewed and addressed. The EPC researchers will use the final research plan to conduct a systematic review of the published evidence and draft an evidence report. The systematic review will be based on studies published since 1996, but older data that are relevant to addressing the key questions will be considered as well.

The draft evidence report will be posted on the USPSTF website for public comment and will be finalized after all of the comments have been reviewed and addressed. USPSTF will use the final evidence report to draft the LTBI screening recommendation. The draft recommendation will be posted on the USPSTF website for public comment. All of the comments will be reviewed and addressed. The final LTBI screening recommendation will be published based on USPSTF's vote to ratify. CDC expects the entire process to be completed by the end of 2015.

USPSTF will use a series of structured key questions (KQs) to guide the systematic review of the evidence for the LTBI screening recommendation.

Benefits of screening: Does screening for the disease result in decreased incidence? Does screening result in reduced morbidity or mortality? Are screening tests accurate?

- KQ 1: What is the direct evidence that targeted screening for LTBI in asymptomatic adults at increased risk for developing active TB (such as persons in populations with a high prevalence of active TB or with documented increased risk for progression from LTBI to active TB) in primary care settings improves quality of life and reduces the incidence of active TB infection, transmission of TB and mortality?

Risks of screening: What are the harms to screening or the diagnostic work-up?

- KQ 2a: What is the accuracy and reliability of using either tuberculin skin tests (TSTs) or interferon-gamma release assays (IGRAs) for screening asymptomatic adults who are at increased risk for developing active TB?
- KQ 2b: What is the accuracy and reliability of using sequential screening (e.g., TST followed by IGRA for persons with a particular TST result) in adults who are at increased risk for developing active TB?

Benefits of treatment

- KQ 3a: For adults with LTBI, to what extent does treatment using recommended pharmacotherapy regimens improve quality of life and reduce progression to active TB, transmission of TB and mortality?

Harms of screening

- KQ 4: What harms (including false-positive results, anxiety, labeling and stigma) are associated with screening for LTBI?
- KQ 4a: How do the harms differ by screening method or screening strategy?
- KQ 4b: How do the harms differ by populations screened?

Harms of treatment

- KQ 5: What are the harms associated with treatment of LTBI using CDC-recommended pharmacotherapy regimens?

The USPSTF draft research plan includes a proposed analytic framework that will be used to apply the KQs. KQ 1 will be used to determine the impact of LTBI screening on active TB, reduction in transmission of TB, improved quality of life, and mortality among asymptomatic adults in higher risk populations. KQ 2 will be used to determine the accuracy of screening tests in diagnosing LTBI. KQ 3 will be used to determine whether treatment results in a reduction of active TB transmission, morbidity and mortality among persons with LTBI. KQs 4 and 5 will be used to determine the harms of LTBI screening and treatment.

In addition to the structured KQs, the USPSTF draft research plan also proposes five contextual questions that will be considered in the systematic review of the evidence for the LTBI screening recommendation.

1. What are the estimated U.S. adult prevalence rates of LTBI and active TB in populations at increased risk for TB receiving care in primary care settings, including limitations or uncertainties regarding these prevalence rate estimates?
2. What proportion of U.S. adults receiving care in primary care settings are members of these populations at increased risk?
3. What populations of active TB cases in U.S. adults originate in these populations at increased risk?

4. What is the evidence on the incremental net benefit of more or less frequent screening for LTBI using different screening intervals in adults at increased risk in primary care settings?
5. What is the reported frequency of LTBI screening in U.S. adults in primary care settings, both overall and for populations at increased risk?

CDC identified topics for discussion in two key areas in its review of the USPSTF draft research plan. Topic 1 is the role of public health clinics. USPSTF recommendations traditionally have been targeted to primary care providers, but public health clinics historically have served as the setting for LTBI preventive care and treatment for underserved or marginalized patients with no other access to care.

Topic 2 is a clear definition of patient populations. Patients who are tested and treated for LTBI as part of a standard disease management protocol would not be included in the USPSTF recommendation for LTBI screening. For example, HIV-infected patients or patients with rheumatoid arthritis on TNF blockers would be excluded from the systematic literature review and the USPSTF recommendations. However, some patients who are proposed to be excluded (e.g., patients with head/neck cancer) do not have well-known disease management protocols that would guarantee automatic LTBI screening by their providers.

Dr. Ho noted that the USPSTF draft research plan was distributed to ACET for review and comment. As the external advisory body for CDC's TB Prevention Research portfolio, she hoped ACET would set aside time during the meeting to draft a formal response to the plan. She pointed out that the public comment period would close on July 2, 2014.

ACET discussed the following topics with Dr. Ho on the USPSTF draft research plan.

- The inability of the systematic review to determine improved quality of life, a reduction in TB transmission, and decreased TB mortality because these endpoints are based on treatment outcomes rather than existing studies in the published literature.
- The absence of public health representation and expertise on the USPSTF to address population-based issues.

Ms. Cole confirmed that ACET would revisit the USPSTF draft research plan for LTBI screening during its upcoming discussion on DTBE's proposed research agenda. She also noted that ACET would have an opportunity during the Business Session on the following day to draft and vote on its formal response. In the interim, several ACET members suggested issues that should be addressed in its formal response.

- Clear prevention messages should be directed to both primary care and public health settings. For example, all patients on TNF blockers are not routinely screened for LTBI as part of a standard disease management protocol.

- DTBE should gather and provide USPSTF with relevant TBESC data. For example, data from Task Order 9 could be used to identify high-risk patients who were seen in primary care settings, but were not screened for LTBI. TBESC genotyping data also could be used to determine the percentage of reactivation cases.
- A distinction should not be made between primary care and public health settings due to the critical role and existing expertise of public health clinics. For example, primary care providers can evaluate patients for LTBI screening, but public health clinics also need to be extensively involved with these cases due to the nature of TB transmission.
- Data from TB contact investigations should be considered in the USPSTF systematic review.
- USPSTF should be given solid definitions and examples that make a clear distinction between persons at "increased" and "high" risk for developing active TB.

Overview of CDC's New Advanced Molecular Detection Program

Ed Ades, PhD
Associate Director for Laboratory Science
National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

Dr. Ades presented an overview of CDC's new AMD Program. CDC initiated this effort based on the results of an internal review that showed outdated technology and insufficient capacity in its AMD approaches and bioinformatics methods. CDC submitted a proposal to the President's budget with a request of $40 million to make improvements in these areas, but the actual allocation was $30 million/ year for a five year period beginning in FY2014.

CDC's release of a call for research proposals in March 2014 to its three National Centers in the Office of Infectious Disease and the Center for Global Health resulted in the submission of 72 AMD related proposals. CDC funded 23 proposals based on the outcomes of the scientific review and evaluation process. However, CDC will need to identify effective strategies to sustain the AMD Program over time, particularly since funding for years 3-5 is not guaranteed.

CDC formed a Planning Team to clearly define the goals, metrics, focus areas and cross-cutting functional categories of the AMD Program that will be reported to Congress. For example, years 1-2 funding will be used to build a strong infrastructure, enhance capacity and provide training for AMD, bioinformatics and information technology at CDC and in state public health laboratories.

The Planning Team also will develop a communications plan and a dedicated website to ensure that partners, other stakeholders and the public are regularly informed and engaged in the AMD Program. Most notably, CDC will collaborate with state partners in prioritizing state PHL

projects as part of the AMD projects. CDC established a Steering Committee to provide oversight and input on efforts by the Planning Team.

The key features of CDC's new AMD Program are highlighted as follows. CDC will use the AMD Program to link the five-year, high-level spending plan to individual goals and functional categories. CDC will use the AMD Program to enhance its microbiology and bioinformatics capabilities to detect and prevent infectious disease outbreaks by conducting five major activities.

- Improve pathogen identification and detection
- Adapt new diagnostics to meet evolving public health needs
- Assist states in meeting their future reference testing needs in a coordinated manner
- Implement enhanced, sustainable and integrated laboratory data systems
- Develop prediction, modeling and early recognition tools

CDC will use the AMD Program to combine the cutting-edge approaches of bioinformatics, traditional epidemiology and genomic sequencing. The foundation of genetic analyses, samples and sequenced generations, and epidemiology will allow CDC to more easily make an association to disease and prevalence. CDC will use the AMD Program to improve public health through new technologies. Genomic sequencing will be used to achieve earlier case recognition and reporting, more rapid and targeted outbreak responses, and the prevention of more potential cases.

CDC will use the AMD Program to enhance its focus on transmission networks. The inference of transmission networks will facilitate epidemiologic investigations to better understand the spread of infectious diseases and antimicrobial drug resistance. Epidemiologic data (e.g., age, gender, causative agent, disease, partners, number of infections, location and environmental source) traditionally have been used to determine transmission networks and characterize persons in specific genetic networks.

Sequencing technologies have replaced traditional methods by using microbial genetic data (e.g., single nucleotide polymorphism (SNP), sub-genome or WGS) to determine transmission networks. Methods that combine sequence analyses and epidemiologic data are lacking, but are needed to characterize networks and target prevention efforts.

CDC will use the AMD Program to align its existing prevention goals with new efforts to reduce transmission networks, particularly those with multiple links. This strategy can be adapted for any pathogen or emerging infection to reduce the number of new infections, decrease transmitted drug resistance, and increase awareness of infection status. The approach of targeting prevention efforts to reduce transmission networks has been applied to outbreak investigations and population-based prevention efforts.

CDC will use the AMD Program to focus on molecular epidemiology of microbes. Microbial sequences can be unique to each infected individual. Many microbes are measurably evolving pathogens that accumulate sequence diversity within hosts. Microbial sequences can be examined to gather evidence on a recent association to infer potential transmission links. Microbial sequences have been successfully used to detect transmission clusters of several infectious diseases, including HIV, TB, hepatitis C, drug-resistant gonorrhea and bacterial infections.

CDC will use the AMD Program to conduct two major bioinformatics activities: (1) develop computational methods to study the structure, function and evolution of genes, proteins and whole genomes and (2) develop methods to manage and analyze biological data arising from genomics and high-throughput biological experiments.

CDC has been challenged in leveraging bioinformatics expertise due to competition with industry and other entities. Most notably, CDC has filled only 4 of its 25-30 new bioinformatics positions and fellowships to date. CDC's projections show that at least 33% of the public health laboratory workforce will need bioinformatics skills over the next five years to remain competitive with the private sector in the areas of point-of-care, diagnostics and genomic sequencing. CDC is aware of the critical need to train current and new public health staff in bioinformatics to be competitive and maintain pace with the private sector.

CDC will use the AMD Program to develop a bioinformatics pipeline that will improve its capacity to conduct epidemiologic and laboratory investigations, perform data searches, analyze and visualize data, and report results to state and local partners. The bioinformatics pipeline will include the collection of patient data, generation of sequence data, merger of epidemiologic and laboratory data into a single database, automated searches and extractions of genotype drug-resistant cases, and a standardized template for state/local partners to report results and identify targeted interventions.

CDC will use the AMD Program to conduct molecular surveillance that will include sequences, computer modeling of bioinformatics and epidemiologic data to generate transmission links. These data can then be used for global molecular tracking.

At the division level, CDC awarded funding to DTBE to conduct two projects under the AMD Program. DTBE will weigh the advantages and disadvantages of conventional genotyping versus WGS. In terms of conventional genotyping, the CDC National TB Genotyping Service genotypes one isolate from each culture-confirmed TB case in the United States. A genotype cluster is formed when *M.tb* isolates are collected from at least two TB cases that share the same genotype.

Conventional genotyping methods have been targeted toward regions of the genome that are known to vary among *M.tb* strains. These targets are stable over long periods of time. To date, >10,000 different genotypes have been identified. However, conventional genotyping only

examines <1% of the genetic content of the complete *M.tb* genome. Moreover, conventional genotyping data are difficult to interpret when highly related strains continue to circulate in communities for long periods of time.

In terms of WGS, >90% of the genetic content of the complete *M.tb* genome can be examined. Mutations accumulate at a rate of 0.5 SNPs per year. However, DTBE will be challenged by conducting WGS on TB clinical specimens rather than isolates. Moreover, "unclean" samples in meta-genomics that will require TB and host DNA to be separated will impair DTBE's ability to conduct WGS. The goals, approaches and expected outcomes of DTBE's two AMD projects are outlined below.

DTBE AMD Project 1

- Determine whether WGS can improve the accuracy of TB outbreak detection and the effectiveness of TB outbreak investigations.
- Conduct WGS for all suspected large TB outbreaks identified through genotyping surveillance and compare these findings to epidemiologic data to determine the spread of infection and any potential linkages between cases.
- Demonstrate whether public health resources could be more efficiently targeted if WGS has the ability to improve the accuracy of TB outbreak detection.
- Demonstrate the greater impact of public health interventions if field investigations have stronger capacity to identify the spread of infection and pinpoint geographic locations that are most important to TB outbreaks.

DTBE AMD Project 2

- Review genomic *M.tb* surveillance data from the New York City 2011-2014 dataset that already has been used to discover previously undetected transmission of TB by locating cases caused by the same bacterial strain.
- Use the New York City dataset to identify flaws in the traditional approximation-based approach for genotyping (e.g., false clustering of "different" isolates that actually are the same according to the remainder of the *M.tb* genome).
- Demonstrate whether the use of WGS will result in different outcomes in the New York City dataset: examination of >90% of the *M.tb* genome; provision of more precise data to public health officials to detect and more rapidly response to TB outbreaks; and enhanced ability to more strongly focus investigations on truly clustered cases.

ACET discussed the following topics with Dr. Ades on CDC's new AMD Program.

- The ability of WGS/bioinformatics to make more rapid progress in TB control as opposed to proper and full implementation of existing tools for TB prevention and control.
- The possibility of replicating the U.K. model in the United States in which WGS is used for management of difficult TB cases.

The discussion resulted in ACET making several recommendations for CDC to consider in implementing its new AMD Program.

- CDC should consult with the Clinton Health Access Initiative because this organization plays a major role in TB bioinformatics. Ms. Colleen Daniels, liaison representative for the Treatment Action Group, will provide CDC with point-of-contact information.
- States have limited resources and capacity to analyze or take other actions with its TB molecular epidemiology, genotyping or WGS data. A portion of AMD Program funding should be set aside and directly targeted to building an infrastructure in states at the outset to assure application of these data for case management in the field.
- CDC should reconsider its focus on attempting to recruit persons with expertise in bioinformatics. These personnel might not be needed due to new analytics, algorithms and other technologies that currently are being utilized for other bacterial infections and diagnostics.

In response to one of ACET's suggestions, Dr. Ades confirmed that CDC is exploring several options to address the lack of AMD resources and capacity in states. Option 1 would be regionalization in which states would submit their samples to a centralized source in the region to conduct WGS. Option 2 would be the deployment of CDC staff to states to build capacity in conducting WGS. Option 3 would be CDC's purchase of equipment for states to conduct genotyping and WGS and submit their data to CDC for analysis. CDC would then provide each state with a report of its individual data analysis results.

ACET Discussion: Resolution/Recommendation Process

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

Ms. Cole moderated the two parts of ACET's discussion on its resolution/recommendation process. For part 1 of the discussion, DTBE prepared and distributed three spreadsheets with all of the items that were placed for formal ACET votes in 2011, 2012 and 2013. Ms. Cole asked DTBE to describe its plans to address the unresolved items. She also encouraged ACET to provide DTBE with additional guidance on "partially implemented" items and propose next steps for "fully implemented" items that warrant further action.

Item No.	Unresolved Resolution/Recommendation	Action Step
2011-1	DTBE to collect outcome data for all patients whose specimens are submitted to the	Dr. LoBue will provide ACET with a response on whether the manuscript

Item No.	Unresolved Resolution/Recommendation	Action Step
	Molecular Detection of Drug Resistance Service.	that is being prepared for this project specifically addresses the resolution.
2011-3	DTBE to update the guidelines on TB prevention and control among the homeless.	Dr. LoBue will provide ACET with a timeline on when the Homeless Workgroup expects to complete the "Best Practices" document.
2011-5b 2011-5c 2011-5d	DTBE to conduct various activities to address racial/ethnic disparities in TB: • Commission or perform studies to enable an estimation of the attributable risks of established acquired and genetic risk factors within major racial/ethnic groups (2011-5b). • Commission or perform studies to enable an estimation of the attributable risks of vitamin D deficiency within major racial/ethnic groups (2011-5c). • Institute routine surveillance of presentation with cavitary disease with major racial/ethnic groups as an indicator of presumed treatment delay (2011-5d).	ACET advised DTBE to fully implement these items by conducting rigorous epidemiologic analyses and presenting these data to ACET for review. The analyses should identify disparities in TB by geographic location, racial/ethic group (particularly among African Americans), and drug use history.
2011-6	DTBE to routinely report on the health equity implementation and evaluation plans as put forth by the NCHHSTP Office of Health Equity.	Dr. Dean will schedule an update on NCHHSTP's recent health equity activities for the next ACET meeting. The presenter will be Dr. Wayne Duffus, Associate Director for Health Equity in NCHHSTP.
2011-15	ACET to establish a new "TB Elimination Workgroup."	ACET will discuss whether the workgroup fulfilled its charge or if current members should volunteer to reestablish the workgroup.
2011-22	CDC to assess the public health benefits and cost effectiveness of NCHHSTP's activities and demonstrate how these activities support TB elimination efforts and impact TB morbidity.	ACET will discuss this item to provide DTBE with clearer guidance and propose next steps.
2013-1	DTBE to extend the timeline of the ACET National TB Program Workgroup.	ACET will discuss whether the workgroup fulfilled its charge during the six-month extension or if current members should volunteer to reestablish the workgroup.
2013-4	ACET to conduct activities to "recast core TB program components in a period of	ACET's initial document on Bacille Calmette-Guerin vaccination for TB

Item No.	Unresolved Resolution/Recommendation	Action Step
	epidemiologic, financial and healthcare system change."	was expanded to include additional infection control measures for U.S. healthcare providers and other citizens who would be working abroad. The paper has been accepted by a journal for publication. ACET will be provided with the link after the paper has been published.
2013-6	The HHS Secretary to direct FDA to facilitate the importation of WHO-qualified SLDs.	CDC initiated several activities to respond to this item. FDA eventually informed CDC that non-approved drugs manufactured overseas cannot be imported into the United States. However, ACET will discuss next steps to determine whether the HHS Secretary reviewed and responded to its letter on this important issue.
2013-7	CDC to make efforts on obtaining a USPSTF Grade A or B recommendation for LTBI treatment as prevention.	The USPSTF draft research plan for LTBI screening was distributed to ACET for review. ACET will draft and vote on its formal response to the research plan.
2013-9	The ACET Chair to submit ACET's 2011-2013 report to the HHS Secretary.	The HHS Secretary sent a letter to acknowledge that ACET's 2011-2013 report was received and reviewed. ACET will discuss next steps for the new HHS Secretary to take action on the issues outlined in the report.
2013-10	CDC to make efforts on improving TB screening of H-1B work visa applicants.	DGMQ will continue to provide regular updates to and obtain guidance from ACET on this issue. ACET will discuss a process to provide input at a higher level to the G8 and G20.
2013-16	ACET to draft a letter to the HHS Secretary and Dr. Thomas Frieden, Director of CDC, to emphasize the potential impact of funding cuts on TB programs.	Because no action was taken in this regard, ACET will determine whether the letter is still needed.

For part 2 of the discussion, Ms. Cole summarized the key components of ACET's charter, including its authority, objective and scope of activities, description of duties, and reporting authorities. She asked ACET to determine whether its current resolution/recommendation

process is the best approach to provide advice to the HHS Secretary and CDC Director on reaching the goal of TB elimination. She also asked ACET to propose options to improve its advisory role.

- DTBE was unable to implement some of ACET's formally approved items in the past (e.g., new guidelines, studies or data collection efforts) due to competing priorities, lack of staff and/or limited funding. As a result, ACET's advisory role should be more aligned with, targeted to and focused on existing activities in DTBE's portfolio for TB prevention, control and elimination. A strategic approach with input on existing and planned initiatives rather than recommendations for new efforts will enhance DTBE's ability to prioritize and conduct more of ACET's formally approved items. ACET's strategic approach to providing guidance also will be important for DTBE's transition to new leadership, shift to a healthcare reform environment, and efforts to address budget constraints.
- ACET should formulate and direct its guidance to topics that are permitted by external advisory bodies, but are prohibited by federal agencies (e.g., funding or controversial issues).
- ACET should continue to propose resolutions/recommendations for action, but with a significant reduction in the number of these items. In the past, for example, ACET formally approved items that focused on the institutions or organizations of its *ex-officio* members and liaison representatives. In the future, ACET should thoughtfully consider and limit its formally approved items to activities in DTBE's long-term strategic plan for TB and also to broad, overarching and important public health issues that the HHS Secretary should address at a higher level outside of CDC. Moreover, agendas should only include presentations that directly respond to ACET's charge to address TB elimination.
- ACET and DTBE should develop meeting agendas to resolve problems with timely and efficient follow-up and tracking of formally approved items. For example, agendas should set aside time for ACET and DTBE to fully address old business items from the previous meeting before the members propose new business items during the current meeting. ACET also should use regular status reports as an opportunity to evaluate the impact of its formally approved items on TB elimination efforts over time.
- The ACET Chair and DFO should schedule a briefing with Dr. Frieden or his designee after each in-person meeting to summarize key outcomes and elevate the importance of TB at the level of the CDC Director.
- The Research Workgroup for the DTBE strategic alignment process proposed the formation of a new external peer review panel to strengthen oversight of CDC's TB research portfolio. According to the description of duties in its charter, however, ACET is charged with providing guidance and reviewing CDC's TB Prevention Research portfolio and program priorities. A process should be established for DTBE to leverage expertise from ACET and other sources to provide a critical review and rigorous evaluation of its TB research portfolio.

- ACET's resolution/recommendation process typically has focused on small, important issues for TB prevention and control, but its guidance should be at a much higher level to address the broader scope of TB elimination.
  - The 2000 Institute of Medicine (IOM) report included several recommendations to accelerate progress toward TB elimination. The IOM report advised the HHS Secretary to routinely report on the status of implementing these recommendations, but no action has ever been taken in this regard. ACET should provide the HHS Secretary with concrete action steps to make progress on implementing the IOM recommendations for TB elimination.
  - ACET's guidance to the HHS Secretary has emphasized the importance of addressing the SLD shortage. However, ACET should provide the HHS Secretary with concrete action steps to develop an entirely new TB regimen as recommended by the Federal TB Task Force in 1992 and 2009.
- ACET should increase its prominence, visibility and recognition in the broader TB community to accelerate progress in TB elimination.
  - ACET should publish guidelines, position statements and other documents that would be independent of CDC and would not require CDC clearance and approval. ACET's paper on infection control measures for U.S. citizens working abroad that has been accepted for journal publication should serve as a model in this effort.
  - ACET should be informed of activities in the broader TB community through regular updates from its liaison representatives and *ex-officio* members (e.g., Department of Defense, Department of Veteran Affairs and FDA).
  - ACET should galvanize partners across the country to develop, obtain approval and leverage funding for a President's Strategic Plan for TB Elimination. Dr. John Ward, Director of the NCHHSTP Division of Viral Hepatitis, should be invited to a future ACET meeting to describe experiences and lessons learned in the creation of the National Viral Hepatitis Action Plan that could be applied to TB.
  - ACET should replicate the HIV model for TB in which more emphasis is placed on providing broad guidance on the social determinants of health that drive an epidemic, such as poverty, no insurance coverage and homelessness.
  - ACET should direct more efforts to educating the broader TB community by compiling, disseminating and presenting key outcomes from its meetings to stakeholder organizations.

Dr. Dean advised ACET to review experiences and lessons learned from the meeting structure and resolution process of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHAC). For example, ACET takes an opportunistic approach in formulating guidance, while CHAC develops its agendas based on a few important themes and then proposes resolutions in response to these strategic issues. Dr. Dean emphasized that a strategic rather than an opportunistic approach would improve ACET's advice to the HHS Secretary and CDC Director.

Ms. Cole noted that based on the discussion, ACET would reorganize and restructure its current resolution/recommendation process to ensure its business is conducted with a more strategic, focused and global approach. Due to the ability, expertise and passion of its membership, she was confident that ACET could advance beyond providing guidance on TB prevention and control to focus more on TB elimination.

ACET Discussion: DTBE Research Agenda

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

Ms. Cole moderated ACET's discussion on the TB research agenda that was proposed during the DTBE strategic planning process. She noted that the interim report by the DTBE Research Workgroup was distributed to guide ACET's discussion.

- Synergy, research opportunities and partnerships should be maximized with USAID and the National Institute of Allergy and Infectious Diseases. Most notably, the USAID Congressional appropriation of $120 million for product development likely will include research components.
- DTBE's high-priority research projects should include analytics and strong support to ensure implementation of these initiatives in the field.
- CDC's Small Business Innovation Research Program should be reviewed to identify opportunities for TB research grants, such as research funding for the AMD Program and TB drugs.
- DTBE maintains external advisory bodies for both TBTC and TBESC, but ACET should provide overall guidance on allocating resources, establishing priorities and identifying future directions for all of its research initiatives.
- Efforts should be made to complete previous TB research projects that were not fully analyzed, evaluated and published (e.g., a TBESC genotyping study) before DTBE initiates new research projects.
- Consideration should be given to conducting TB research in the following areas:
  - The feasibility of forming TB teams in primary care settings in order to improve TB treatment completion rates.
  - The viability of developing a TB vaccine for prevention.
  - The role of social determinants of health in targeting populations at risk for TB.
  - A meta-analysis of ongoing studies that are comparing various LTBI screening tests.
  - Host factors that drive the progression from LTBI to active TB disease.
  - Translation of TB research into meaningful TB control practice in the field (e.g., use of 3HP, gene expression and other technical advances).

- Rigorous cost-effectiveness studies and economic evaluations of TB prevention and elimination.

Ms. Cole returned the discussion to the USPSTF draft research plan for LTBI screening and entertained a motion for ACET to submit its formal response by the July 2, 2014 deadline. Based on its previous discussion, ACET's formal response would address four major gaps.

1. Patients with HIV and diabetes as well as those taking TNF blockers are excluded from LTBI screening due to the "inaccurate" assumption that LTBI screening and treatment are part of a standard disease management protocol for these patient populations in primary care settings.
2. Persons in correctional settings are excluded from LTBI screening.
3. The role of public health clinics in LTBI screening is not mentioned.
4. Data from TB contact investigations will not be considered in the USPSTF systematic review.

Chair's call for a vote	Motion properly made by Dr. Ana Alvarez for ACET to submit its formal response to the USPSTF draft research plan for LTBI screening Motion seconded by Dr. Gail Cassell
Outcome of vote	**Motion and second withdrawn**
Next steps	A small writing group will present a draft of ACET's formal response for the membership to discuss, revise and vote on during the Business Session.

Dr. Dean noted that several members expressed an interest in submitting comments on the USPSTF draft research plan outside of ACET. As a result, she clarified the difference between an "individual comment" and a "formal ACET response." Individual ACET members are free to comment on any document as private citizens or members of other institutions or organizations, but cannot submit comments on behalf of ACET. A formal ACET response to any document must be presented, discussed and voted on by the entire membership during a public in-person, webinar or teleconference meeting.

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's initial effort to address its charge was to review CDC's September 8, 1995 *MMWR* publication, *Essential Components of a Tuberculosis Prevention and Control Program*. The workgroup's review emphasized the need to update and replace CDC's 1995 document with more recent guidance on TB essential components for 2015 and in the foreseeable future.

The workgroup drafted its report, *Essential Components of a Tuberculosis Prevention and Control Program: Recommendations of the Advisory Council for the Elimination of Tuberculosis*, and planned to present the document during the current meeting. However, the revision process is still underway. Dr. Brenner announced that the workgroup's draft report would be presented during the next meeting for ACET's consideration, deliberation and formal vote. In the interim, he highlighted the key points of the draft report.

- The Summary/Introduction section describes the purpose and context of the report by providing a comprehensive background on the essential components of TB prevention and control programs.
  - The marked decline in TB rates in the United States over the past 60 years.
  - The need to continue to implement well-established strategies to make further progress on TB control in the United States.
  - The responsibility of state/local health departments in TB prevention and control.
  - Other important activities for TB control beyond the essential elements: data-driven analyses to prioritize TB control efforts; coordination of patient care and other TB control activities through collaborative networks with partners; and incorporation of the most current TB diagnosis, treatment and control strategies into routine program activities.
- Essential training and education components are recommended in various formats for TB staff at multiple levels, healthcare providers and community members.
  - A "TB Control 101" course with an orientation and training session should be targeted to all TB control staff, including newly-hired TB controllers and more experienced TB controllers who could benefit from a refresher course on the essential components.
  - A condensed technical summary should be targeted to non-TB public health staff that needs education on TB control. Bureau chiefs with responsibility for multiple disease control programs should have knowledge of basic TB control elements. Directors of other disease control programs, particularly those in low-incidence areas, should be knowledgeable in this area to effectively collaborate with TB staff in complex outbreak investigations.
  - National standards for essential components should be targeted to TB control programs. These standards would be useful for internal and external reviewers during evaluations of TB programs and also for health departments, legislators and other funding entities for advocacy efforts.

- The data sections are being reviewed to determine whether updates are needed in specific areas.
  - Case reporting, including data collection, analysis and program evaluation
  - TB registry data
  - Protection of patient confidentiality
  - Drug resistance surveillance
- Global revisions are being made to the terminology as appropriate: replace "tuberculin skin testing" with "testing for TB infection" and replace "screening" with "targeted testing."
- A new process is being recommended that will allow TB controllers to access documents related to the essential components of TB prevention and control in a more efficient and rapid manner. Instead of separately accessing each CDC statement through the CDC.gov website, for example, a succinct and up-to-date PDF file would include links and references to all documents that have been published over time.
- Additional guidance will be included based on the overview of CDC's new AMD Program that was presented during the current meeting.
  - Each TB program needs to maintain capacity for traditional laboratory methods in addition to developing skill sets related to AMD. The results of AMD methods (e.g., WGS and analyses requiring advanced bioinformatics techniques) increasingly will need to be available to all programs as more progress is made toward TB elimination the United States.
  - Depending on the burden of TB and public health laboratory capacity, jurisdictions may take different approaches to incorporating AMD capacity into their programs. These strategies include developing in-house capabilities, forming regional collaboration with neighboring states, and creating protocols for collaboration with AMD capabilities that are emerging at CDC.
- Decisions will be made on whether language in the 1995 CDC document regarding community coalitions is still needed.

Update by the ACET Corrections Workgroup

Jane Carter, MD, ACET Member
Associate Professor, Alpert School of Medicine at Brown University
The Miriam Hospital

Dr. Carter reported that the workgroup has been dormant. In 2012, ACET formally approved the workgroup's draft recommendations and DTBE took subsequent actions on many of these items. In 2013, ACET formally approved the reestablishment of the workgroup due to the need for an ongoing focus on TB in correctional settings. However, the workgroup has not conducted any activities since that time. Dr. Carter and Ms Sarah Bur, the *ex-officio* member for the Federal Bureau of Prisons, are the only two remaining members on the workgroup.

Dr. Carter proposed the reestablishment of the workgroup with volunteers from the current membership. The workgroup's initial charge would be three-fold: (1) evaluate activities DTBE has conducted to address ACET's previous recommendations on TB in correctional settings; (2) review recent publications on the dramatic contribution of correctional settings to TB cases; and (3) serve as a liaison between ACET and the DTBE Corrections Workgroup.

ACET agreed by consensus to reestablish the Corrections Workgroup with the following members.

- Dr. Jane Carter, Chair (ACET member)
- Ms. Sarah Bur (*ex-officio* member, Federal Bureau of Prisons)
- Dr. Diana Elson or Ms. Tiffany Moore (*ex-officio* member, U.S. Immigration and Customs Enforcement)
- DTBE staff (to be named) for technical support and expertise

Update by the DTBE Drug Shortages Workgroup

Ann Cronin
Associate Director for Policy and Issues Management, DTBE
Centers for Disease Control and Prevention

Ms. Cronin covered the following topics in her update to ACET on the workgroup's recent activities. Data show that problems related to SLD shortages have been ongoing for more than 10 years. Reports submitted to CDC from the field also identified shortages in two critical first-line drugs: INH and Tubersol that eventually affected the supply of Aplisol. The limited number of manufacturers also plays a significant role in TB drug shortages.

CDC released seven papers to widely publicize the TB drug shortage problem, but no long-term solutions have been proposed to date. Most notably, the federal government cannot require industry to manufacture drugs or target the distribution of drugs to at-risk populations. Private companies are free to discontinue the manufacture of any product at any time. CDC is exploring potential options to overcome barriers to the TB drug shortage problem.

- The federal government has been successful in improving communications regarding impending drug shortages and locations to access products during shortages. Drug companies, particularly those that manufacture products for communicable diseases and serious or life-threatening illnesses, are required to notify FDA of anticipated shortages or their plans to discontinue the production of drugs.
- FDA has discussed the possibility of offering incentives to U.S. manufacturers to remain in the market, granting approval to overseas companies to sell their products in the

United States through the TB Global Drug Facility (GDF), and mitigating the $500,000 application fee for FDA approval.

- An early warning system has been established in which TB controllers in the field notify CDC of drug shortages. CDC then conveys the information to FDA.
- CDC developed a system to rapidly track existing inventories of influenza vaccine and widely publicize the availability of these products. CDC is discussing the possibility of creating a similar system for TB drugs.
- CDC has engaged its partners in discussions to determine the feasibility of establishing a National TB Pharmaceutical Repository.
- The option of a "temporary buffer" is being explored in which a certain amount of drugs would be retained and circulated to TB controllers prior to their expiration date. However, CDC's assessment showed that $21 million would be needed to retain a six-month supply.
- Pooled purchasing was not found to be a viable option because the market for TB drugs would need to be expanded with more patients. Drug sharing also would not be feasible because inflexible funding streams would not allow a state health department to share its drugs with another state. However, this barrier potentially could be resolved through memoranda of understanding in which states would share resources in a public health event.
- The purchase of TB drugs through the GDF was not found to be an effective solution to address the drug shortage problem. The drugs must be purchased through the GDF stockpile, but none of these drugs are FDA approved as required. Moreover, only three SLDs are available in the GDF and must be purchased in bulk.

ACET agreed that the TB drug shortage problem should be one of the high-priority, broad themes in its new strategic process for resolutions/recommendations. Several members noted that ACET's long-term focus and ongoing persistence would be needed to make progress on this important topic. The members described a number of issues that should be considered in ACET's future guidance on TB drug shortages.

- Reframe TB drug shortages as a "public health emergency" in all future guidance.
- Provide guidance that includes clearly defined strategies to assist FDA in resolving Congressional or legislative barriers to TB drug shortages.
- Elevate the discussion on TB drug shortages to a much higher level by directing guidance to the HHS Secretary and Dr. Margaret Hamburg, Commissioner of FDA.
- Link guidance on the TB drug shortage problem to broader antimicrobial resistance efforts in the United States. Most notably, Congress has acknowledged antimicrobial resistance as a national health threat. A new high-level federal committee has been formed to address antimicrobial resistance long-term.

With no further discussion or business brought before ACET, Ms. Cole recessed the meeting at 4:46 p.m. on June 9, 2014.

Opening Session: June 10, 2014

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 meeting either in person or remotely. 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 reminded the ACET voting members of their responsibility to disclose any potential individual and/or institutional conflicts of interest for the public record and recuse themselves from voting or participating in these matters. None of the voting members publicly disclosed any individual or institutional conflicts of interest for the record that were new or different than those declared on day 1 of the meeting.

Dr. Dean announced that the voting members and *ex-officio* members in attendance constituted a quorum for ACET to conduct its business on June 10, 2014. She called the proceedings to order at 8:32 a.m. and welcomed the participants to day 2 of the ACET meeting.

Asian Health Services Perspective: Community Partners in the Management of TB

Susan Huang, MD
Chief Medical Officer
Asian Health Services

Dr. Huang described the perspective of Asian Health Services (AHS) on the role of community partners in the management of TB. She explained that the purpose of her presentation would be three-fold: (1) improve TB control and elimination among Asian American/Pacific Islanders (AAPIs); (2) better understand the role and value of Federally Qualified Health Centers (FQHCs) as community partners in this effort; and (3) inform next steps for TBESC to plan for community partnerships.

The Community Health Center (CHC) movement is based on the early principles of community-based primary care and social medicine that were initiated in the 1800s in South Africa. As a result of the War on Poverty and the Civil Rights Movement in the 1960s, these principles were introduced in the United States with a focus on epidemiology, population statistics, and

community organization and outreach. A $1.2 million grant was awarded to two physicians in 1965 to pilot two CHC sites in Boston and Mississippi.

CHCs are unique due to three major factors. First, CHCs are community-responsive and must be located in federally-designated medically underserved areas or target services to underserved populations (e.g., racial/ethnic minorities, persons with low English proficiency (LEP), persons with low incomes, under-insured and uninsured persons and homeless persons). The 1,300 CHCs cover >9,000 locations in the United States and serve >22 million patients.

Second, CHCs are heavily regulated. Legislation requires CHCs to be nonprofit organizations; adhere to the "51% rule" in which the majority of its board members must be CHC users or community consumers; and submit annual reports to HRSA on patient demographics, staffing, clinical quality and costs. Third, CHCs are patient-centered and are the only part of the American healthcare system that allows patients and the community to guide their individual primary care providers, policies and programs.

The East Bay Asians for Community Action conducted a needs assessment in the early 1970s that showed the majority of Asian residents lacked health care due to poverty and/or language barriers. These early efforts led to the establishment of AHS in Oakland, California in 1974 with a foundation based on civil rights, immigration status and community organization.

AHS is an FQHC with a mission to serve and advocate for the Asian community regarding its health rights and also to assure access to healthcare services regardless of income, insurance status, language or culture. AHS's 38 FTEs of licensed medical, dental and behavioral health professionals serve 24,000 patients with >110,000 visits annually. AHS's target populations include AAPIs and LEP groups.

In terms of demographics, 54% of AHS patients are below the Federal Poverty Level (FPL) and 43% are at 100%-200% of the FPL. Compared to the poverty level of AAPI populations in Oakland (22%), Alameda County (11%) and the total county (10%), AHS patients are poorer. ACA has been successful in reducing the uninsured status of AHS patients from 45% to 10%.

AHS patients are defined by federal guidelines as an LEP group and face linguistic isolation at a much higher rate (90%) compared to AAPI populations in Oakland (48%), Alameda County (31%) and the total county (9%). AHS provides its patients with onsite interpretation for 12 different Asian languages. Unlike other FQHCs, AHS has a much larger patient population of seniors (>20%).

The AHS infrastructure includes three primary care medical homes that provide a full spectrum of services across the life cycle, two school-based clinics, one integrated specialty mental health/primary care site, two primary oral health clinics, and a rotating school-based dental services team. Other parts of AHS's infrastructure include pediatric, teen and geriatric clinics,

acupuncture and manual medicine, group visits, specialty care, and advanced specialties in dental care. AHS recently made a full transition to electronic health records (EHRs) for both its primary care medical homes and dental services sites.

AHS offers several programs and services that are unique to its AAPI patient population. Patient and family advisory councils and community liaison units were established to engage the community in important local issues, such as voter rights, health education and advocacy efforts. A language cooperative was formed to provide oral and written translation services to patients and other community providers and also to offer certified training to interpreters. A clinical research department was developed to conduct community-based participatory research on engaging difficult-to-reach AAPI populations. A dental residency program was created.

AHS has included universal TB testing in its screening and disease management protocols for patients due to the high incidence of active TB and LTBI in AAPI populations. The EHR includes an electronic reminder for providers to perform TB screening. The status of the TB test must be documented for each patient. AHS also uses electronic practice management records to collect patient demographics data (e.g., primary language, insurance status, country of origin and immigration status). AHS's position is that more consistent and frequent use of these data over time will play an important role in mapping the epidemiology of TB cases in AAPI populations prior to U.S. entry.

AHS maintains a number of essential partnerships to conduct its activities. The Alameda County Public Health Department reports, tests and tracks active TB cases; regularly conducts grand rounds and in-services at AHS's facilities; and provides direct, point-of-care medical consultation and case management. The Community Health Center Network was formed in 1996 and includes eight CHCs that deliver services to their specific target populations in Alameda County, California: AAPIs, African Americans, Hispanics and Native Americans.

The Association of Asian Pacific Community Health Organizations (AAPCHO) was established in 1987 and now has a membership of >34 FQHCs and other community health organizations. AAPCHO is dedicated to advocacy and collaboration for the improvement of health and health access for Asian American, Native Hawaiian and Other Pacific Islanders (AA/NHOPIs) nationwide. AAPCHO members collectively serve >500,000 AAPIs across the country.

The Community Health Applied Research Network (CHARN) was established in 2010 by HRSA to build research capacity and serve as a data warehouse for safety net CHCs. CHARN includes 18 CHCs in nine states and targets research to the health and healthcare of underserved populations. The four CHARN nodes collaborate with their individual academic partners and submit data with a standardized dataset.

The AAPCHO research node includes four CHCs that primarily serve AA/NHOPIs and account for 80% of CHARN data on these populations. The four CHCs have unique cultural and linguistic expertise and effective engagement with its highly diverse target populations. To date,

2006-2012 data have been collected on >850,000 AA/NHOPI patients for the CHARN dataset: patient demographics (e.g., language and insurance status), provider encounters, diagnoses (e.g., HIV, TB, hepatitis and chronic diseases), and laboratory and medication data. The CHARN data will be essential in identifying significant health disparities in AA/NHOPI patients.

The next steps in these efforts will focus on three major activities. First, data will be refined. CHARN will integrate new data on enabling services and utilization (e.g., interpretation services, community resource linkages, eligibility processing, and utilization of emergency departments/ hospitals). AAPCHO will expand its network data with the addition of new data on enabling services and data from other CHCs that serve AA/NHOPIs. AHS will expand the use of EHR technology to focus on population-based health management, conduct panel management on a much broader level, and assure patient-level linkage to care from diagnosis to management and risk reduction of various illnesses and diseases.

Second, efforts will be targeted to identifying and leveraging long-term funding streams to ensure AHS's services to patients are sustained over time. Most notably, <1% of federal healthcare-related grant funding was targeted to CHC-type populations in 1986-2000, but AA/ NHOPIs account for >6% of the U.S. population. Third, AHS will collaborate with TBESC to strengthen relationships between FQHCs and public health and promote the translation of community-based research or data into best practices nationwide.

ACET discussed the following topics with Dr. Huang on AHS's management of TB in the AAPI community.

- The critical need to tailor the AHS model for other populations with high rates of active TB disease and LTBI to achieve the national TB elimination goal.
- The importance of replicating AHS's research component in other CHCs.
- Strategies AHS implemented to enroll and retain patients in ACA.
- The need for CHCs to improve LTBI reporting to public health departments.

ACET applauded Dr. Huang for her compelling and eloquent presentation. Several members commended AHS on its outstanding accomplishments, particularly its leadership in engaging difficult-to-reach AAPI populations in the healthcare system. ACET found AHS to be a model for other CHCs in the nation to deliver services to their target populations. The members proposed three areas that should be considered in providing guidance on the role of CHCs in TB.

- The 2005 American Thoracic Society/CDC/Infectious Diseases Society of America guidelines recommended four priority strategies for TB control in the United States. However, ACET should craft language to recommend public health/CHC collaborations as an additional priority strategy when the guidelines are updated.
- DTBE should collect and analyze TB data from CHCs, such as the number of TB patients served, prevalence of LTBI, and rates of TB treatment initiation and completion.

These data could be used to determine the impact of TB in CHC populations on broader TB control efforts in the United States. DTBE should explore whether TBESC could use CHARN as a research mechanism in this effort.

- ACET should formulate guidance to recommend making TB infection a nationally reportable disease. Surveillance data need to be presented to Congress to demonstrate that 12 million Americans currently are living with TB.

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: 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 by Dr. Jane Carter and seconded by Dr. Gail Cassell for ACET to approve the previous meeting minutes.

ACET unanimously adopted the Draft March 4, 2014 Meeting Minutes with no changes or further discussion.

Topic 2: Status Report on the March 2014 Action Items

Ms. Cole moderated ACET's discussion on the status of the action items that were raised during the March 4, 2014 meeting.

Action Item	Status
1. CDC to provide clarification on specific criteria that were used to categorize and define "antibiotic-resistant infections."	Completed; Dr. Philip LoBue circulated an e-mail message to ACET on March 5, 2014 with definitions for each type of threat and CDC's criteria to rank antibiotic-resistant infections into specific threat categories.
2. ACET to routinely revisit and monitor the impact of DTBE's strategic priorities and proposed budget scenarios.	Ongoing; ACET will develop a more effective and responsive approach to DTBE's request for guidance. For example, ACET does not

Action Item	Status
	routinely provide DTBE with direct responses to "advice requested from ACET" described on presenters' summary sheets.
3. ACET to develop formal guidance to assist CDC in obtaining a USPSTF grade for TB preventive care and Medicaid coverage of this service.	Completion pending; ACET will discuss, revise and vote on its formal response to the USPSTF draft research plan for LTBI screening during the Business Session. Ongoing; ACET will routinely revisit and monitor the status of the USPSTF systematic review process for LTBI screening in order to provide input as needed. • If LTBI screening is approved, ACET will provide guidance to assure that Medicaid coverage is a national rather than a state-specific standard. • If LTBI screening is not approved, ACET will provide guidance to the Community Preventive Services Task Force.
4. ACET to provide the Essential Components Workgroup with more specific guidance on its proposed framework.	Completion pending; ACET will discuss and propose revisions to the workgroup's draft report that will be presented for a formal vote during the next meeting.
5. ACET to propose strategies to widely publicize the availability of TB prevention and control guidelines for incarcerated populations.	Completion pending; The ACET Corrections Workgroup will present the proposed strategies for ACET's consideration and discussion during the next meeting.
6. ACET to continue to provide CDC and its partners with concrete advice to address TB drug/biologic shortages in the United States.	Ongoing; ACET will take several actions to maintain the TB drug shortage problem as a high-priority issue requiring a persistent, long-term focus. • ACET will consider the update by the DTBE Drug Shortages Workgroup on the previous day and follow-up suggestions proposed by the members in formulating future guidance. • ACET will directly request or ask Dr. Frieden to invite a high-level FDA official to attend the next in-person meeting: Dr. Margaret Hamburg (Commissioner of FDA) or Dr. Edward Cox (Director, FDA Office of Antimicrobial Products). Based on the appropriate chain of command, Dr. Gail

Action Item	Status
	Cassell (ACET member) will follow-up on ACET's request by directly communicating with Dr. Hamburg. ACET will clearly define objectives for FDA to address during the meeting, such as limitations on the importation of TB drugs/biologics into the United States from GDF and FDA's perspective on potential strategies to resolve these barriers. • ACET will communicate with Dr. Sheldon Morris, the *ex-officio* member for FDA, to determine reasons for his persistent absence from ACET meetings. ACET will emphasize the critical need for Dr. Morris to attend meetings to provide FDA's perspective on the important issue of TB drug shortages in the United States.
7. ACET to identify opportunities for CDC to apply global experiences, lessons learned and research from TB BASICS to TB control at national, state and local levels in the United States.	Ongoing; ACET will continue to address this issue. In the interim, ACET provided CDC with feedback on its new strategic approach to reduce TB among foreign-born populations in the United States through global TB activities.
8. CDC to report the status of ACET's outstanding resolutions.	Completed; DTBE prepared and distributed three spreadsheets with all of the items that were placed for a formal ACET vote in 2011, 2012 and 2013. ACET engaged in an extensive discussion on the status of these items.
9. ACET to maintain a small standing workgroup to plan and draft future agendas in collaboration with CDC staff.	Completed; ACET formed an Agenda Setting Workgroup.

Topic 3: USPSTF Draft Research Plan on LTBI Screening

Dr. Susan Dorman, an ACET member, presented a draft of ACET's formal response to the USPSTF draft research plan on LTBI screening. ACET extensively discussed and suggested several changes to the draft response, particularly in the areas of populations, settings and study designs that the USPSTF has proposed to be included or excluded from LTBI screening.

The revised response was presented for a vote based on the changes ACET proposed during the discussion.

> The Advisory Council for the Elimination of Tuberculosis (ACET) provides advice and recommendations regarding the elimination of tuberculosis (TB) to the Secretary, Department of Health and Human Services; Assistant Secretary for Health; and Director, Centers for Disease Control and Prevention (CDC). ACET affirms the importance of answering the Key Questions in a systematic review in order to inform inclusion of screening for latent tuberculosis infection (LTBI) in adults in the U.S. Preventive Service Task Force recommendations.
>
> For consideration, ACET has the following comments on the draft Research Plan:
>
> **Section II. Proposed Key Questions to be Systematically Reviewed**
> *Question 1.* Four separate outcomes are included in the draft question. ACET recommends that these outcomes be considered separately as separate questions, specifically:
>
> What is the direct evidence that targeted screening for LTBI in asymptomatic adults at increased risk for developing active TB (such as persons in populations with a high prevalence of active TB or with documented increased risk for progression from LTBI to active TB):
>
> a) Improves quality of life?
> b) Reduces progression to active TB?
> c) Reduces transmission of TB?
> d) Reduces mortality?
>
> An additional important consideration within Question 1 is whether the Question 1 target population (asymptomatic adults at high risk for developing active TB) receives care in primary care clinics. This could be addressed as a Key Question or Contextual Question.
>
> *Question 3.* Four separate outcomes are included in the draft question. ACET recommends that these outcomes be considered separately as separate questions, specifically:
>
> For adults with LTBI, to what extent does treatment using CDC-recommended pharma-cotherapy regimens:
>
> a) Improve quality of life?
> b) Reduce progression to active TB?
> c) Reduce transmission of TB?
> d) Reduce mortality?

Section IV. Proposed Research Approach

Populations: Studies of close contacts of persons with active TB provide critical information that is relevant to all populations at risk for LTBI. Those studies should not be excluded from the Evidence Report.

Settings: Correctional facilities are settings in which primary care is provided. Therefore, correctional facilities should not be excluded from the Evidence Report.

The HIV epidemic has evolved such that HIV clinics are settings in which primary care is provided. Therefore, HIV clinics should not be excluded from the Evidence Report.

Public health clinics serve as primary care settings and should be considered a potential target of this review.

Chair's call for a vote	Motion properly made by Dr. Robert Horsburgh for ACET to submit its revised formal response to the USPSTF draft research plan for LTBI screening Motion seconded by Dr. Ana Alvarez
Outcome of vote	**Motion unanimously passed by 9 ACET voting members**
Next steps	Ms. Cole will electronically submit ACET's formal response to the USPSTF draft research plan by the July 2, 2014 deadline. Ms. Cole also will e-mail the response to the entire ACET membership.

Topic 4: ACET's Advisory Role in TB Elimination

Ms. Cole moderated ACET's discussion on assessing, clarifying and improving its existing resolution/recommendation process to have a greater impact on TB elimination. As a starting point in ACET's future guidance, she reiterated the six recommendations in the 2000 IOM report to accelerate progress toward TB elimination.

1. Maintain control of TB
2. Accelerate the rate of decline of TB
3. Develop new tools to diagnose and treat TB
4. Increase involvement in global TB efforts
5. Mobilize and sustain public support for TB
6. Track progress toward TB elimination

Ms. Cole asked the members to provide feedback on a systematic process or next steps for ACET to regularly review progress toward TB elimination and provide effective guidance. For

example, ACET could structure future meetings with updates on activities that have been conducted to date to address specific IOM recommendations. ACET could use the updates as the basis to begin formulating guidance on TB elimination.

- ACET's next steps to improve its advisory role in TB elimination should be targeted to three major areas: (1) review existing data to identify gaps in implementation of the IOM recommendations; (2) propose concrete strategies to fill these gaps and accelerate progress; and (3) present the findings to the new DTBE Director to assure alignment with DTBE's strategic plan, vision and future direction for TB elimination.
- ACET's ongoing focus on the TB drug shortage problem in the United States should be linked to IOM recommendation 1 to maintain control of TB. ACET's guidance should acknowledge that the private sector will play a much larger role in the procurement and availability of drugs for TB treatment in a health reform environment through monitored or low-cost drugs.
- ACET initially should direct its guidance to IOM recommendations 2, 4 and 5 because the least amount of progress has been made in these three areas.
    - ACET's guidance on item 2 should focus on LTBI. (1) Progress on the completion of LTBI treatment should be evaluated because the decline in TB rates cannot be accelerated without a significant reduction in the incidence of LTBI. (2) The critical role of CHCs in TB elimination should be emphasized. ACET's guidance should promote Asian Health Services as a CHC model in detecting LTBI in communities and support the replication of this effort in CHCs across the country. (3) "Completion of LTBI treatment" should be included as an endpoint in ACET's recommendation to make LTBI a nationally reportable disease. The Council of State and Territorial Epidemiologists (CSTE) should be invited to a future ACET meeting to present the criteria and describe the process to add LTBI as a new nationally notifiable disease. Prior to formulating this guidance, however, ACET should review data, experiences and lessons learned from California and Massachusetts to carefully weigh the benefits and negative implications of national LTBI reporting. For example, state TB programs will have an additional reporting requirement with no new resources and LTBI patients will be pressured to undergo treatment. Representatives from state TB programs that would be responsible for national LTBI reporting should be invited to a future meeting to provide ACET with insights from the field.
    - ACET's focus on item 4 would be timely and aligned with CDC's new strategic approach to reduce TB among foreign-born populations in the United States through global TB activities.
    - ACET's expertise and extensive relationships with stakeholder organizations in the field would play an important role in item 5 to mobilize and sustain public support for TB.
- ACET should review the Stop TB USA "Call for Action on the Tuberculosis Elimination Plan for the United States." The report includes a table that illustrates whether progress was or was not made in implementing the IOM recommendations as of 2010.

- ACET should formulate guidance on the impact of the aging public health workforce in hindering TB elimination efforts. Retirements of TB physicians, nurses and other providers as well as the inability to attract new professionals are resulting in the loss of TB expertise and knowledge. ACET's guidance should emphasize that the national goal of TB elimination cannot be achieved without a trained TB workforce in the field. A TB nurse in the field should be invited to a future ACET meeting to educate the new DTBE Director on the unique role of this position in TB control compared to other parts of the public health workforce.
- ACET should initiate discussions on innovative strategies for TB elimination (e.g., regionalization, global rather than country-specific management of the TB drug supply, and application of the Occupational Safety and Health Administration rule for control of infectious diseases).
- ACET should convey its concerns to the HHS Secretary and CDC Director about the potential resurgence in TB due to persistent reductions in federal, state and local TB funding. TB elimination cannot be achieved if this effort is inadequately funded. ACET should gather and provide the HHS Secretary and CDC Director with solid data to demonstrate the actual magnitude of the TB burden in the United States. Congress might be less likely to decrease TB funding in the future based on data that show 12 million Americans are living with TB, while ~1.2 million Americans are living with HIV.

ACET's extensive discussion on strategies to improve its advisory role in TB elimination resulted in a request for a formal resolution.

Chair's call for a vote	Motion properly made by Dr. Marcos Burgos for ACET to establish a new LTBI Workgroup Motion seconded by Dr. Robert Horsburgh
Outcome of vote	**Motion unanimously passed by 9 ACET voting members**
Next steps	Dr. Horsburgh will chair the new workgroup, poll ACET by e-mail to identify additional members, and apply ACET's suggestions to craft the charge of the new workgroup. • Review existing data to weigh the advantages and disadvantages of national LTBI reporting, particularly at state and local levels. • Identify barriers to national LTBI reporting and propose strategies to overcome these challenges. • Explore approaches to redefine or reclassify "latent TB infection" as "TB infection" because persons with LTBI are not captured in surveillance systems as TB cases. • Use the findings to draft and present recommendations for ACET's consideration, deliberation and formal vote.

Topic 5: New CDC TB Nurse Consultant

Dr. Eric Brenner, an ACET member, presented the "New CDC TB Nurse Consultant" resolution for ACET's consideration and discussion.

Whereas, TB Nurse Case Management (TBNCM) is an effective intervention for use in TB control to ensure successful completion of treatment for the TB patient;

Whereas, the TB Nurse brings a special body of knowledge to case management reflected in diplomacy, scientific knowledge, clinical skills, as well as compassion for the most fragile members of society;

Whereas, nurses are the largest single segment of the public health workforce and possess core competencies to carry out assessments, policy development, and assurance of functions of public health activities;

Whereas, TBNCM is not only effective but an essential component to the vision of TB elimination;

Whereas, there is an ever increasing shortage of nurses across the country, a National TB Nurse Consultant (TBNC) leader is key to promoting, maintaining, and supporting an effective public health workforce.

BE IT RESOLVED, that ACET advises CDC to develop a position for a dedicated TBNC to provide national leadership for TB Nurses across the country:

1. The TBNC will work closely with medical and program consultants to provide comprehensive, effective consultative services for public health programs and their partners.

2. The TBNC will advance the body of scientific knowledge and to develop evidenced-based case management skills as part of the benefits of TBNCM.

3. The TBNC will collaborate with partners to develop a National TB Nurse Certification process to validate the practice of TBNCM.

4. The TBNC will help promote the national TB Nurse Network Group and be part of regular calls with RTMCC nurse consultants.

5. The TBNC will promote the value of nursing specialty care, especially for the most vulnerable populations, in order to improve the public's health.

Ms. Cole explained that only the concept of the TBNC resolution was being presented at this time. ACET would not take formal action until its resolution/recommendation process was clarified. In the interim, she asked for ACET to propose suggestions on the resolution.

- Obtain feedback from other sources to refine the resolution: insights from the new DTBE Director, expertise from deans of schools of nursing, input from public health nurses who are responsible for TB control in the field, and perspectives from the Staffing Workgroup for the DTBE strategic planning process.
- Expand the resolution as a broader TB workforce issue.
- Determine whether the resolution can be directly linked to ACET's focus on TB elimination.

Topic 6: IGRA Resolution

Ms. Cole announced that the IGRA resolution is being **TABLED** to further refine the language regarding the TB Technical Instructions. She noted that ACET also needs to clarify its new strategic approach for resolutions/recommendations before taking formal action. In response to Dr. LoBue's comment, she confirmed that DGMQ staff would be engaged in all of ACET's future communications on the IGRA resolution.

Topic 7: ACET Report to the HHS Secretary (2011-2013)

Ms. Cole announced that Mr. Shannon Jones, former Chair of ACET, submitted the report in April 2014 to inform the HHS Secretary of ACET's priority issues, key areas of focus and major recommendations in 2011-2013.

- TB drug shortages in the United States
- TB in correctional and detention facilities
- TB control and continuity of care along the U.S.-Mexico border
- CDC's collaborations with federal partners to address problems with the non-travel status of infectious TB patients who are scheduled for deportation from the United States
- TB surveillance
- Racial/ethnic disparities in TB
- Decreases in TB funding

The HHS Secretary sent a letter to CDC acknowledging receipt of the report, but Ms. Cole asked ACET to propose next steps in this regard.

- Request a meeting with Dr. Frieden, particularly to emphasize decreases in TB funding and other important issues outlined in ACET's report to the HHS Secretary.
- Thank the Office of the HHS Secretary in writing for responding to ACET's report and use the letter as an opportunity to reinforce two high-priority issues: (1) the TB drug shortage problem in the United States and (2) the need for the new HHS Secretary to contact the Mexico MOH to discuss the contribution of Mexico to TB cases in the United States.

Topic 8: ACET Meeting Formats

Ms. Cole announced that the next three ACET meetings were scheduled for December 2, 2014 (a webinar), March 3, 2015 (a webinar), and June 2-3, 2015 (an in-person meeting in Atlanta, Georgia). Due to the restoration of a portion of the TB budget, she asked DTBE to respond to ACET's request to convene two in-person meetings and one webinar per year.

Dr. Dean explained that all agencies across the government are urged to implement cost-cutting measures for their Federal Advisory Committees with less expensive platforms than in-person meetings. Due to this directive, ACET's request for two in-person meetings and one webinar per fiscal year likely will not be approved. As a result, she advised ACET to focus on improving the effectiveness of all meetings regardless of the platform. For example, DTBE significantly decreased the number of agenda items to increase the productivity of ACET webinars.

ACET made several suggestions in follow-up to Dr. Dean's remarks.

- Travel expenses for *ex-officio* members and liaison representatives are not supported by their institutions and organizations. The lack of support would limit their ability to attend two in-person meetings per year.
- Workgroups should be used to identify key strategic issues for each agenda item, particularly since Federal Advisory Committee Act rules and regulations do not apply to workgroups. Workgroups could use teleconferences, e-mail communications or other platforms to prepare a few agenda items for ACET's focused discussion and deliberation during webinars.
- CDC should explore the feasibility of requiring a quorum with voting members only. For example, CDC could convene more in-person meetings if travel support was only needed for the nine ACET voting members. The ACET *ex-officio* members and liaison representatives could remotely participate on webinars with no travel costs involved.
- ACET's in-person meeting should be the first meeting of the year and structured as a strategic working meeting that would be devoted to key agenda items, broad themes and formal resolutions.

- Efforts should be made for new members to attend their first meeting face-to-face. New members who attend their first two meetings by webinar and have never met their ACET colleagues or CDC staff typically feel disconnected and detached from the federal advisory process. CDC also should determine whether ACET's webinars could be replaced with video conferencing technology to ensure that both new and current members remain fully engaged.

Drs. Dean and LoBue responded to two suggestions ACET proposed during the discussion that would require major changes to the current meeting format. First, ACET expressed an interest in changing the one-day webinar on December 2, 2014 to a two-day in-person meeting due to the appointment of the new DTBE Director and four new ACET members.

CDC reported that this change would impact the schedule of all future meetings if ACET's request for two in-person meetings per fiscal year (October 1-September 30) is not approved and the current meeting format is maintained. For example, if ACET convenes an in-person meeting in December 2014 (*i.e.*, new fiscal year 2015), the next in-person meeting could not be held until after October 1, 2015 (*i.e.*, new fiscal year 2016).

Second, ACET raised the possibility of convening one annual meeting in the Washington, DC area to increase participation by the Office of the HHS Secretary and high-level officials in HHS agencies. ACET also emphasized that 13 of its 15 *ex-officio* members are based in the DC metropolitan area.

CDC reported that a cost analysis was performed to compare support needed for an ACET meeting held in Atlanta versus the DC metropolitan area. Even if an ACET meeting was held on the campus of an HHS agency at no cost, the cost analysis showed that a DC meeting still would be more expensive than an Atlanta meeting due to the need to support travel for multiple CDC staff.

Despite CDC's clarifying remarks and ACET's suggestions to make webinars more effective, some members were still concerned about the current meeting format. The members were in favor of formally going on record with a statement that would be conveyed to Dr. Frieden.

> ACET understands that all federal agencies are urged to implement cost-cutting measures for their Federal Advisory Committees with less expensive platforms than in-person meetings. ACET supports the use of video conferencing technology to hold two of its three annual meetings in the future. At this time, however, ACET is requesting CDC support to convene two in-person meetings per fiscal year to address important new developments and maintain momentum on critical issues.

- DTBE will have a new Director for the first time in 20 years. ACET will miss a valuable opportunity to provide guidance to new leadership at the outset while DTBE's priorities and future directions are being established. With the current

meeting format, for example, ACET will not meet the new DTBE Director for nearly one year after his/her appointment.

- TB funding is reduced or remains stable each fiscal year due to the continued decline in the number of cases in the United States. ACET's guidance at the federal level is needed to address threats to TB funding in a consistent and ongoing manner.
- DTBE continues to solicit and value ACET's advice on strategies to overcome barriers to the TB drug shortage problem in the United States.
- ACET continues to provide guidance and support to DTBE by raising awareness of risks to traditional TB control efforts in the field.

ACET's position is that one in-person meeting per year is not an effective, useful or helpful approach to provide guidance to CDC. Webinars do not allow ACET members to network, engage in important off-the-record discussions, and make significant progress in TB elimination in an ongoing manner. If CDC truly values ACET's advice on achieving the national TB elimination goal, ACET strongly recommends two in-person meetings per year to provide this guidance.

Topic 9: Outgoing ACET Members

Dr. Dean presented letters and certificates of appreciation signed by Dr. Thomas Frieden (Director of CDC) and Dr. Jonathan Mermin (Director of NCHHSTP) to four ACET members whose terms would expire at the end of June 2014: Drs. Eric Brenner, Marcos Burgos, Jane Carter, and Gail Cassell. The participants joined Dr. Dean in applauding the four outgoing members for their valuable service and outstanding contributions to CDC and their excellent advisory role as ACET members.

Topic 10: Agenda Items

Ms. Cole moderated ACET's discussion, review and summary of new agenda items that were raised over the course of the meeting.

NEW AGENDA ITEMS	
Presenter(s)	**Topic**
DTBE (Dr. Angela Starks)	1. Overview of CDC's collaborative efforts with the Critical Path to TB Drug Regimen, the Diagnostics Workgroup and other

NEW AGENDA ITEMS	
Presenter(s)	**Topic**
	partners on developing a new "Global TB Drug Resistance Database"
NCHHSTP (Dr. Wayne Duffus)	2. Update on NCHHSTP's recent health equity activities
ACET Membership	3. Ongoing business items: • ACET discussion on its advisory role in TB elimination • ACET discussion on its draft resolution for CDC to hire a new TB Nurse Consultant, including an overview by a TB nurse in the field • ACET discussion on strategies to overcome barriers to the TB drug shortage problem in the United States
ACET (Dr. Randall Reves)	4. Overview of progress made to date in implementing the IOM recommendations following the release of Stop TB USA's 2010 "Call for Action on the Tuberculosis Elimination Plan for the United States"
HRSA Bureau of Primary Health Care (Dr. Theresa Watkins-Bryant) HRSA Office of Quality and Data	5. Overview of HRSA's perspective on the ability and feasibility of expanding CHCs to focus more on TB elimination efforts Overview of efforts to include TB in HRSA's Uniform Data System
DTBE	6. Overview of the TB cascade of care that is being targeted to TBESC sites
Guest Speakers	7. National LTBI Reporting: • Overview by CSTE on the criteria and process to add LTBI as a new nationally notifiable disease • Overview by state TB programs on the potential impact of national LTBI reporting in the field

Topic 11: Action Items

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

ACTION ITEMS	
Responsibility	**Action Step**
Dr. Hazel Dean	1. Provide the ACET Agenda Setting Workgroup with the May 2014 CHAC agenda as a potential model to develop future ACET agendas
ACET (Dr. Charles Daley)	2. Provide Dr. Ho with data from the six systematic reviews that the WHO Task Force commissioned to inform the USPSTF systematic review process for LTBI screening
Dr. Philip LoBue	3. Provide ACET with an inventory of DTBE's ongoing and emerging research projects after the Research Workgroup completes this document
ACET (Ms. Colleen Daniels)	4. Provide Dr. Ades with point-of-contact information for the Clinton Health Access Initiative
ACET (Dr. Gail Cassell)	5. Provide Dr. Huang with point-of-contact information for the National Institute of Dental Research and the National Institute of Child Health and Human Development
ACET Membership	6. Follow-up with the new HHS Secretary on the ACET 2011-2013 report
ACET Chair and DFO	7. Schedule briefings with Dr. Frieden or his designee after each in-person meeting to summarize key outcomes and elevate the importance of TB at the level of the CDC Director

Public Comment Session

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

Closing Session

Ms. Cole thanked the members for providing excellent and thoughtful input over the course of the meeting to improve ACET's advisory role and also for continuing to contribute their expertise to achieve the national goal of TB elimination. Ms. Cole asked the participants to join her in applauding Dr. Dean, Dr. LoBue, Ms. Margie Scott-Cseh, the ACET Committee Management Specialist, and other CDC staff for their outstanding support of ACET meetings. The participants commended Ms. Cole for her superb leadership as the ACET Chair.

The next three ACET meetings are scheduled for December 2, 2014 (a webinar), March 3, 2015 (a webinar), and June 2-3, 2015 (an in-person meeting in Atlanta, Georgia), but these dates are not confirmed. In response to ACET's request, the Agenda Setting Workgroup and DTBE will revisit the dates and platforms of these meetings. ACET asked DTBE to change the one-day webinar on December 2, 2014 to a two-day in-person meeting due to the appointment of the new DTBE Director and four new ACET members. ACET's request for two in-person meetings per fiscal year will be conveyed to Dr. Frieden.

With no further discussion or business brought before ACET, Ms. Cole adjourned the meeting at 1:56 p.m. on June 10, 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

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

Dr. Michael Bartholomew
(Alternate for Dr. Susan Karol)
Indian Health Services

Ms. Sarah Bur
Federal Bureau of Prisons

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

Dr. James Mancuso
(Alternate for Dr. Naomi Aronson)
Department of Defense

Mr. Stephen Martin
National Institute for Occupational Safety and Health

Ms. Tiffany Moore
(Alternate for Dr. Diana Elson)
U.S. Immigration and Customs Enforcement

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

Dr. Susan Robilotto
(Alternate for Dr. Rupali Doshi)
HIV/AIDS Bureau, Health Resources and Services Administration

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

Mr. José Velasco
(Alternate for Dr. Bruce San Filippo)
U.S. Section, U.S. Mexico Border Health Commission

ACET *Ex-Officio* Members Absent

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

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

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

Dr. Susan Karol
Indian Health Service

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

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

ACET Liaison Representatives Present

Dr. Christopher Archibald
(Alternate for Dr. Howard Njoo)
Public Health Agency of Canada

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

Dr. Charles Daley
(Alternate for Dr. Fran du Melle)
American Thoracic Society

Ms. Colleen Daniels
Treatment Action Group

Ms. Sue Etkind
(Alternate for Ms. Eileen Napolitano)
Stop TB USA

Dr. Jennifer Flood
National Tuberculosis Controllers Association

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

Mr. John Lozier
National Coalition for the Homeless

Dr. Jennifer Rakeman
Association of Public Health Laboratories

Dr. Randall Reves
International Union Against TB and Lung Disease

Dr. Michael Tapper
Society for Healthcare Epidemiology of America

Dr. Lornel Tompkins
National Medical Association

Dr. David Trump
Council of State and Territorial Epidemiologist

ACET Liaison Representatives Absent

Mr. David Bryden
RESULTS

Dr. Fran du Melle
American Thoracic Society

Dr. Mayleen Ekiek
Pacific Island Health Officers Association

Dr. Ilse Levin
American Medical Association

Dr. Saul Levin
Association of State and Territorial Health Officials

Ms. Eileen Napolitano
Stop TB USA

Dr. Howard Njoo
Public Health Agency of Canada

Dr. Susan Ray
Infectious Disease Society of America

Dr. Lee Reichman
American College of Chest Physicians

Ms. Tara Wildes
National Commission on Correctional Health

ACET Designated Federal Officer

Dr. Hazel Dean
NCHHSTP Deputy Director

CDC Representatives

Dr. Eddie Ades
Dr. Stuart Berman
Dr. Terence Chorba
Ms. Ann Cronin
Mr. Justin Davis
Ms. Molly Dowling
Dr. Stefan Goldberg
Dr. Christine Ho
Dr. Amera Khan
Ms. Kathryn Koski
Ms. Ann Lanner
Dr. Philip LoBue
Ms. Allison Maiuri
Ms. Suzanne Marks
Dr. Sundari Mase
Dr. Eugene McCray
Dr. Jonathan Mermin
Dr. Patrick Moonan
Dr. Thomas Navin
Ms. Bonnie Plikaytis
Ms. Margie Scott-Cseh
Ms. Sarah Segerlind
Mr. Brian Sizemore
Dr. Angela Starke
Mr. Craig Studer
Dr. Andrew Vernon
Dr. Wanda Walton

Members of the Public

Dr. John Bernardo
National Tuberculosis Association

Dr. Susan Huang
Asian Health Services

Mr. John Seggerson
Stop TB USA

Glossary of Acronyms

3HP	Three-month, once-weekly Isoniazid/Rifapentine
AA/NHOPIs	Asian American, Native Hawaiian and Other Pacific Islanders
AAPCHO	Association of Asian Pacific Community Health Organizations
AAPIs	Asian American/Pacific Islanders
ACA	Affordable Care Act
ACET	Advisory Council for the Elimination of Tuberculosis
AHS	Asian Health Services
AMD	Advanced Molecular Detection
CDC	Centers for Disease Control and Prevention
CHAC	CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment
CHARN	Community Health Applied Research Network
CHC	Community Health Center
CoAg	Cooperative Agreement
CSTE	Council of State and Territorial Epidemiologists
DFO	Designated Federal Officer
DGMQ	Division of Global Migration and Quarantine
DTBE	Division of Tuberculosis Elimination
EHRs	Electronic Health Records
EPC	Evidence-Based Practice Center
FBPs	Foreign-Born Persons
FDA	U.S. Food and Drug Administration
FOA	Funding Opportunity Announcement
FPL	Federal Poverty Level
FQHCs	Federally Qualified Health Centers
FTE	Full-Time Equivalent
GDF	Global Drug Facility
HHS	U.S. Department of Health and Human Services
HRSA	Health Resources and Services Administration
IGRAs	Interferon Gamma Release Assays

INH	Isoniazid
IOM	Institute of Medicine
IRPB	International Research and Program Branch
IUATLD	International Union Against TB and Lung Disease
KQs	Key Questions
LEP	Low English Proficiency
LTBI	Latent TB Infection
M.tb	*Mycobacterium tuberculosis*
MDR-TB	Multidrug-Resistant TB
MMWR	*Morbidity and Mortality Weekly Report*
MOHs	Ministries of Health
NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
PCSI	Program Collaboration and Service Integration
RPT	Rifapentine
RTMCCs	Regional Training and Medical Consultation Centers
RVCT	Report of Verified Case of Tuberculosis
SLDs	Second-Line Drugs
SNP	Single Nucleotide Polymorphism
TA	Technical Assistance
TB	Tuberculosis
TBESC	Tuberculosis Epidemiologic Studies Consortium
TBNC	TB Nurse Consultant
TBNCM	TB Nurse Case Management
TBTC	Tuberculosis Trials Consortium
TSTs	Tuberculin Skin Tests
USAID	U.S. Agency for International Development
USG	U.S. Government
USPSTF	U.S. Preventive Services Task Force
WGS	Whole-Genome Sequencing
WHO	World Health Organization