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

Advisory Council for the Elimination of Tuberculosis
December 6-7, 2011
Atlanta, Georgia

Record of the Proceedings

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ATTACHMENT 1

List of Participants

(*Note:* The Designated Federal Official conducted a roll call on December 6 and 7, 2011 and verified the presence of a quorum with voting members and *ex-officio* members for ACET to conduct its business on both days of the meeting.)

ACET Members
Mr. Shannon Jones III, Chair
Dr. Eric Brenner
Dr. Marcos Burgos
Dr. Jane Carter
Dr. Gail Cassell
Dr. Susan Dorman
Dr. Christine Hahn
Dr. Masahiro Narita
Dr. Barbara Seaworth

ACET Designated Federal Official
Dr. Hazel Dean, NCHHSTP Deputy Director

ACET *Ex-Officio* Members
Dr. William Baine (Agency for Healthcare Research and Quality)
Ms. Sarah Bur (Federal Bureau of Prisons)
Dr. Amy Bloom (U.S. Agency for International Development) [via teleconference]
Dr. Richard Ehrenberg (National Institute for Occupational Safety and Health)
Dr. Mamodikoe Makhene (National Institute of Allergy and Infectious Diseases) [via conference call]
Dr. James Mancuso (Alternate, Department of Defense)
Dr. Gary Roselle (Department of Veteran Affairs)
Dr. Diana Schneider (Department of Homeland Security)
Dr. Theresa Watkins-Bryant (Health Resources and Services Administration)

ACET Liaison Members
Dr. Robert Benjamin (National Association of County and City Health Officials)
Mr. David Bryden (Alternate, RESULTS)
Ms. Catherine Cairns (Alternate, Association of State and Territorial Health Officials)
Dr. Charles Daley (Alternate, American Thoracic Society)
Dr. Frances Downes (Association of Public Health Laboratories)
Dr. Mayleen Ekiek (Pacific Island Health Officers Association)
Ms. Cornelia Jervis (Treatment Action Group)
Dr. Susan Ray (Infectious Disease Society of America)
Dr. Lee Reichman (American College of Chest Physicians)
Dr. Litjen Tan (American Medical Association)
Dr. Lornel Tompkins (National Medical Association)
Dr. Charles Wallace (National Tuberculosis Controllers Association)
Ms. Maria Teresa Zorrilla (Mexico Section, U.S. Mexico Border Health Commission)

CDC Representatives
Dr. Kevin Fenton, NCHHSTP Director
Dr. Kenneth Castro, DTBE Director
Mr. Gustavo Aquino
Dr. Victor Balaban
Dr. José Becerra
Ms. Shannon Burse
Ms. Elizabeth-Ann Chandler
Dr. Terence Chorba
Ms. Ann Cronin
Dr. Andrew Hill
Ms. Jennifer Hnuath
Dr. Christine Ho
Dr. Michael Iademarco
Dr. John Jereb
Dr. Sasi Jonnalagadda
Dr. Awal Khan

Ms. Ann Lanner
Dr. Philip LoBue
Mr. Elvin Magee
Dr. Joan Mangan
Ms. Eva Margolies
Dr. Suzanne Marks
Dr. Sundari Mase
Dr. Beverly Metchock
Dr. Jerry Mazurek
Mr. David Montgomery
Dr. Mary Naughton
Dr. Thomas Navin
Ms. Beverly Devoe Patton
Mr. Joseph Scavotto
Ms. Margie Scott-Cseh
Ms. Neha Shah
Dr. Angela Starks
Ms. Riley Steiner
Mr. Phillip Talboy
Ms. Frances Tyrrell
Dr. Benjamin Truman
Dr. Andrew Vernon
Dr. Wanda Walton
Mr. Terry Wheeler
Ms. Pei-Chun Wan
Dr. Meghan Weems

Members of the Public

Ms. Kendra Cufle (Member of the Public)
Ms. Sue Etkind (National Tuberculosis Controllers Association)
Dr. Michael Fleenor
Dr. Jennifer Flood (National Tuberculosis Controllers Association)
Mr. Phillip Griffin (National Tuberculosis Controllers Association)
Ms. Denise Ingman (National Tuberculosis Controllers Association)
Ms. Eileen Napolitano (Stop TB USA)
Ms. Carol Pozsik (National Tuberculosis Controllers Association)
Dr. Randall Reves (Denver Public Health)
Bruce Tidwell (Member of the Public)
Mr. John Seggerson (Stop TB USA)
Dr. Jon Warkentin (National Tuberculosis Controllers Association)

ATTACHMENT 2

Glossary of Acronyms

ACET	Advisory Council for the Elimination of Tuberculosis
AHRQ	Agency for Healthcare Research and Quality
APHL	Association of Public Health Laboratories
ART	Antiretroviral Therapy
ASD	Alternate Service Delivery
CDC	Centers for Disease Control and Prevention
CHCs	Community Health Centers
CoAg	Cooperative Agreement
DGMQ	Division of Global Migration and Quarantine
DOS	Department of State
DST	Drug Susceptibility Testing
DSTDP	Division of STD Prevention
DVH	Division of Viral Hepatitis
EDN	Electronic Disease Notification
FLDs	First-Line Drugs
FOA	Funding Opportunity Announcement
HHS	Department of Health and Human Services
HRD	Human Resource Development
HRSA	Health Resources and Services Administration
IDSA	Infectious Disease Society of America
IGRAs	Interferon Gamma Release Assays
INH	Isoniazid
LTBI	Latent TB Infection
M.tb	*Mycobacterium Tuberculosis*
MDDR	Molecular Detection of Drug Resistance
MDR-TB	Multidrug-Resistant TB
NACCHO	National Association of County and City Health Officials
NCET	National Coalition to Eliminate Tuberculosis

NCEZID	National Center for Emerging and Zoonotic Infectious Diseases
NHAS	National HIV/AIDS Strategy
NTCA	National Tuberculosis Controllers Association
NTIP	National Tuberculosis Indicators Project
NTP	National Tuberculosis Program
P&C	Prevention and Control (TB)
PCSI	Program Collaboration and Service Integration
PIHOA	Pacific Island Health Officers Association
PITCA	Pacific Island Tuberculosis Controllers Association
PrEP	Pre-Exposure Prophylaxis
PWP	Prevention with Positives
RIF	Rifapentine
RTMCCs	Regional Training and Medical Consultation Centers
SDH	Social Determinants of Health
SLDs	Second-Line Drugs
TAG	Treatment Action Group
TBESC	Tuberculosis Epidemiologic Studies Consortium
TBTC	Tuberculosis Trials Consortium
TBTIs	TB Technical Instructions
TRUST	Restructuring the U.S. TB Program
TST	Tuberculin Skin Test
USAPI	U.S.-Affiliated Pacific Islands
USBP	U.S.-Born Persons/Populations
USPSTF	U.S. Preventive Services Task Force
WHO	World Health Organization
XDR-TB	Extensively Drug-Resistant TB

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ADVISORY COUNCIL FOR THE ELIMINATION OF TUBERCULOSIS
December 6-7, 2011
Atlanta, Georgia

Minutes of the Meeting

The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP) Division of Tuberculosis Elimination (DTBE) convened a meeting of the Advisory Council for the Elimination of Tuberculosis (ACET). The proceedings were held on December 6-7, 2011 in Building 8 of CDC's Corporate Square Campus, Conference Room A/B/C, in Atlanta, Georgia.

Opening Session: December 6, 2011

Hazel Dean, ScD, MPH
Deputy Director, NCHHSTP
Centers for Disease Control and Prevention
ACET Designated Federal Official

Dr. Dean conducted a roll call to determine the ACET voting members, *ex-officio* members and liaison representatives who were attending the meeting in person and via teleconference. She verified that the voting members and *ex-officio* members constituted a quorum for ACET to conduct its business on December 6, 2011.

Dr. Dean called the meeting to order at 8:40 a.m. and welcomed the participants to the proceedings. She announced that ACET meetings are open to the public and all comments made during the proceedings are a matter of public record. She reminded the ACET voting members of their responsibility to identify individual potential conflicts of interest and recuse themselves from participating in these matters.

Dr. Dean opened the floor for introductions. The list of participants is appended to the minutes as Attachment 1.

NCHHSTP Director's Report

Kevin Fenton, MD, PhD, FFPH
Director, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

Dr. Fenton covered the following topics in his Director's report to ACET. At the agency level, the CDC leadership team had two recent personnel changes. Ms. Sherri Berger was appointed as the Chief Operating Officer and Dr. Katherine Lyon Daniel is serving as the Acting Associate Director for Communication.

The FY2011 budget was extremely challenging for CDC. The $740 million reduction in the budget authority accounted for an 11% decrease compared to the FY2010 funding level. The Prevention and Public Health Fund replaced some of these resources, but this funding stream will be at risk in FY2012 and thereafter. As a result, CDC expects its base allocations to decrease further in the future.

CDC currently is operating under a continuing resolution until December 16, 2011. For FY2012, the Senate proposal would allocate $7 billion to CDC. The proposed resources reflect a 2.5% increase (or $174 million) above the FY2011 funding level. The three key areas of the Senate proposal are highlighted below.

The first area is a $5.77 billion base budget, overall increases for NCHHSTP and the National Center for Immunization and Respiratory Diseases, and level funding for the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID). The second area is $848 million through the Affordable Care Act/Prevention Public and Public Health Fund to support CDC's immunization activities, epidemiology and laboratory capacity, healthcare acquired infections initiatives, and infectious disease screening activities (e.g., viral hepatitis). The third area is the elimination of the block grant.

For FY2012, the House proposal would allocate $6 billion to CDC. The proposed resources reflect a 13% decrease (or $863 million) below the FY2011 funding level. The three key areas of the House proposal are highlighted as follows. The first area is the elimination of the Prevention and Public Health Fund. The second area is the return of the block grant with funding of $100 million. The third area is decreases to all three infectious disease centers that would be below the FY2011 level. These reductions would range from $49 million to $73 million in each center. Both the Senate and House proposals present tremendous challenges for CDC to allocate funding to state and local health departments to provide even the most basic public health services.

In October 2011, CDC released its new "Framework for Preventing Infectious Diseases: Sustaining the Essentials and Innovating for the Future." CDC developed the framework with three overarching elements: (1) strengthen fundamental public health capacity, including infectious disease surveillance, laboratory detection and epidemiologic investigation; (2) identify and implement high-impact public health interventions to reduce infectious diseases; and (3)

develop and advance policies to prevent, detect and control infectious diseases. The CDC Infectious Disease Framework is available at www.cdc.gov/oid/framwork.html.

At the National Center level, the Division of Adolescent and School Health (DASH) will be added to NCHHSTP in FY2012. The new addition will allow NCHHSTP to focus on adolescent and youth programming. Changes in NCHHSTP's leadership include the following appointments: Acting Associate Director for Health Equity (Dr. Ramal Moonesinghe), Associate Director for Science (Dr. Benedict Truman), and Acting Associate Director for Laboratory Science (Dr. Edwin Ades). NCHHSTP is engaged in a recruiting process at this time to permanently fill the acting positions in early 2012.

NCHHSTP made several accomplishments in FY2011 to advance the prevention and control of infectious diseases. The Division of HIV/AIDS Prevention (DHAP) implemented the National HIV/AIDS Strategy (NHAS) and published new data that reported stable HIV incidence of ~50,000 new cases in the United States per year. However, these data showed substantial and significant increases in new HIV infections among gay men, particularly those of color.

CDC released a new funding opportunity announcement (FOA) totaling >$370 million to support HIV prevention activities conducted by state and local health departments. The overarching goal of this funding is to completely align HIV resources with the epidemic over the next five years. DHAP expanded its HIV testing initiative and began exciting new research on the efficacy of pre-exposure prophylaxis (PrEP).

The Division of Viral Hepatitis (DVH) began implementation of the HHS Viral Hepatitis Action Plan and the new CDC Viral Hepatitis Strategic Plan. The large Viral Hepatitis Action Coalition with public and private partners was expanded. Emphasis was placed on recommendations by the CDC Advisory Committee on Immunization Practices to focus on new approaches for hepatitis B vaccination in the United States. Screening guidelines for hepatitis C infection were revised.

The Division of STD Prevention (DSTDP) collaborated with the World Health Organization (WHO) on emerging challenges related to gonococcal antimicrobial resistance. Dr. Gail Bolan was appointed as the new Director of DSTDP and is leading the division's reorganization and development of new strategic priorities. The 2012 STD Treatment Guidelines were recently released. The "2012 Get Yourself Tested" Campaign was launched.

DASH released school health policy reports and groundbreaking data to better characterize youth risk behaviors in the United States, including risks among the young lesbian/gay/bisexual/ transgender population in school settings. CDC released a new five-year FOA to provide better support to non-governmental organizations across the country to conduct HIV, STD and pregnancy prevention initiatives among youth. DASH developed and disseminated guidance to schools on the role of social determinants of health (SDH) in family involvement and school connectedness to improve the health of youth.

NCHHSTP released its 2010-2015 Strategic Plan in February 2010 to articulate its vision, overarching goals and strategies to guide programs. The six cross-cutting goals of the

NCHHSTP Strategic Plan support the disease-specific strategic plans developed by each division. Dr. Fenton highlighted NCHHSTP's key accomplishments in FY2011 for each of the six cross-cutting goals.

For the prevention through healthcare goal, NCHHSTP convened the "Prevention Through Healthcare: Enhancing Health Departments' Preparedness and Response" Consultation in June 2011. The consultation provided a forum for ~100 public health professionals to help CDC identify changes in healthcare delivery that may affect health department activities and propose strategies for health departments to better respond to these changes.

NCHHSTP collaborated with the Centers for Medicare and Medicaid to inform state health departments about extending Medicaid to low-income TB patients. NCHHSTP strengthened its existing partnership with the Health Resources and Services Administration (HRSA) to update the Prevention with Positives (PWP) Guidelines, more strongly focus on "Treatment as Prevention" initiatives, and expand HIV, STD and hepatitis screening in Federally Qualified Health Centers (FQHCs).

For the program collaboration and service integration (PCSI) goal, NCHHSTP developed guidelines for data security and confidentiality standards for state and local health departments to remove barriers to sharing data across infectious disease programs. NCHHSTP convened a PCSI grantee meeting for the six funded jurisdictions to share best practices in addressing syndemics through PCSI. The grantees are now conducting PCSI demonstration projects. NCHHSTP developed a new "Atlas Tool" to display integrated HIV, STD, TB and viral hepatitis data on its website.

For the health equity goal, NCHHSTP sponsored a supplement to *Public Health Reports* that focused on data systems and their use in addressing SDH. NCHHSTP held a Health Equity Symposium in August 2011 with >300 CDC employees in attendance. The symposium focused on the use of data to inform and shape public health policy, practice and research. NCHHSTP developed specific health equity language to include in all FOAs.

For the global health protection and systems strengthening goal, NCHHSTP released results of a clinical trial that showed efficacy of a supervised 12-dose regimen for latent TB infection (LTBI). NCHHSTP collaborated with WHO to estimate the global congenital syphilis burden and respond to gonococcal antimicrobial resistance. NCHHSTP participated in the HIV Prevention Trials Network 052 Study that showed early initiation of antiretroviral therapy for HIV-positive heterosexuals led to reductions in transmission. NCHHSTP published study results on PrEP for heterosexual couples in Botswana.

For the partnerships goal, NCHHSTP collaborated with numerous partners to launch health communications and social marketing campaigns, including the new "Testing Makes Us Stronger" Campaign to increase HIV testing among African American gay and bisexual men in the United States. The "KNOW MORE HEPATITIS" Campaign is under development. The "Get Yourself Tested" Campaign resulted in a 10% increase in STD testing in clinics.

NCHHSTP's new disease-specific strategic initiatives include coordination with partners on implementation of the NHAS and collaboration with partners on the Viral Hepatitis Action Plan. NCHHSTP is continuing its public/private partnerships with the National Viral Hepatitis Action Coalition and the Chlamydia Resource Exchange.

For the workforce development and capacity building goal, NCHHSTP increased staff participation in the Employee Viewpoint Survey compared to the previous year. The survey is designed to determine the happiness, health, well-being and satisfaction of government employees. NCHHSTP's new activities to improve employee morale, engagement and performance have resulted in tangible improvements. The NCHHSTP Strategic Plan can be viewed at www.cdc.gov/nchhstp/publications.

NCHHSTP introduced new strategic initiatives in FY2011 to enhance HIV, hepatitis, STD and TB prevention efforts. More integrated and holistic approaches were promoted to improve PCSI, address structural and social determinants of health, and promote sexual health in the United States.

NCHHSTP focused on high-impact prevention for the first time to emphasize the effectiveness and cost-effectiveness of interventions; understand and address social, structural and political contexts; prioritize populations and interventions; determine the feasibility of full-scale implementation; identify coverage of target populations; strengthen interaction, combination and targeting of interventions; and enhance implementation and program science. NCHHSTP leveraged wider health system transformation through the Affordable Care Act, health information technology, electronic health records, Prevention Through Healthcare, and expanded collaborations with federal partners.

NCHHSTP designed these strategic approaches to focus on packages of interventions, synergies and antagonisms across interventions. The combination, differential uptake and sustainability of interventions are integrated into these approaches. Interventions that modify social determinants of morbidity are included. Planning, modeling and research are included in required and achievable coverage or "reach" of the interventions. The new approaches also are designed to help NCHHSTP better prioritize evaluation and operational research on implementation of interventions. Issues related to expanding resources, mobilization and advocacy are considered as well.

CDC recently issued the "New Hope for Stopping HIV" *Vitalsigns* Report in conjunction with World AIDS Day. The report emphasized the importance of HIV testing and medical care with the following data: 1.2 million persons in the United States are living with HIV; 1 in 5 HIV-infected persons have no knowledge of their status; and only 1 in 4 HIV-infected persons (or 28%) receives the care needed to keep the virus under control.

CDC also published data on the number and percentage of HIV-infected persons engaged in care as well as antiretroviral therapy (ART) prescriptions during the preceding 12 months among HIV-infected adults who received medical care by age, race/ethnicity and sexual risk behavior. The *Vitalsigns* report is available at www.cdc.gov/vitalsigns.

ACET advised CDC to more strongly focus on the large number of HIV-infected persons who are not on ART. The members noted that CDC's recent data show poor performance in the United States of diagnosing, enrolling and retaining HIV-infected persons into care and treatment. In its new focus on high-impact prevention, ACET urged CDC to prioritize this population to suppress viral loads.

In response to ACET's comments and suggestions, Dr. Fenton emphasized the critical need to take a systems approach in suppressing viral loads among HIV-infected persons in the United States. He was aware that the level of viral suppression among HIV-infected persons in the United States is estimated to be ~19% compared to ~50%-60% in the United Kingdom.

Dr. Fenton noted that CDC is collaborating with HRSA and other federal partners to advance in this direction. These ongoing activities include scaling-up HIV testing and linkages to care; more strongly focusing on PWP initiatives; and revising the HIV Treatment Guidelines to reflect new data and knowledge on antiretroviral safety and efficacy.

DTBE Director's Report

RADM Kenneth Castro, MD
Assistant Surgeon General, U.S. Public Health Service
Director, Division of Tuberculosis Elimination/NCHHSTP
Centers for Disease Control and Prevention

Dr. Castro covered the following topics in his Director's report to ACET. DTBE branches co-chaired the "Restructuring the U.S. TB Program" (TRUST) Workgroup. A detailed overview of this new initiative is scheduled on the agenda.

DTBE partnered with the National TB Controllers Association (NTCA) to recommend a formula to distribute CDC's cooperative agreement (CoAg) funds for TB prevention and control activities, including laboratory support, in all 50 states, 10 large cities, and 8 territories and freely associated states. The breakdown of the proposed formula is an 80% needs-based component (e.g., TB prevention and control activities, laboratory support, and continued support to the Regional Training and Medical Consultation Centers (RTMCCs)) and a 20% performance-based component.

DTBE participated in a meeting of a Food and Drug Administration (FDA) advisory panel in June 2011 that recommended reclassification of devices to detect *Mycobacterium tuberculosis* (*M.tb*) and associated resistance to Class II. The next step in this process will be to draft special controls guidance.

DTBE made a presentation to the CDC Office of Infectious Diseases Board of Scientific Counselors entitled, "National Tuberculosis Laboratory Experience: Increasing Access to Molecular Diagnostic Testing in the United States." In January 2012, DTBE expects to expand

its Molecular Detection of Drug Resistance (MDDR) services by offering a rapid test for resistance in patient specimens in addition to the current comprehensive service on isolates.

DTBE allocated a one-time $3 million supplement to the Association of Public Health Laboratories (APHL) in FY2010 to increase patient access to molecular diagnostic testing in 56 jurisdictions. More laboratories are expected to provide access, while others are planning changes to their existing testing algorithms and methodologies. DTBE will release an FOA in the spring of 2012 to support operational and laboratory systems research to examine increased efficiencies for nucleic acid amplification testing (NAAT) and drug susceptibility testing (DST).

DTBE completed year 1 of the 2011-2012 TB survey component in the National Health and Nutrition Examination Survey. The final survey results will be available in early 2013. Under its Surveillance Data Quality Assurance Training Program, DTBE has trained 75 state and county TB program personnel in four 2-day sessions. DTBE will develop and distribute print and web-based materials for staff that was unable to attend the training program in person. DTBE contributed to NCHHSTP's new Atlas Tool to display TB surveillance data for public use. The TB data are expected to be incorporated into the tool by February 2012.

DTBE provided support and technical assistance to three recent TB outbreak investigations: (1) two outbreaks on an American Indian reservation in July 2011; (2) an outbreak that began in 2007 and grew to 28 cases in September 2011 because contacts were not treated for LTBI in an Illinois homeless shelter; and (3) an outbreak among residents and staff in a long-term care facility in Alaska in November 2011.

A joint CDC/state workgroup is compiling best practices for the effective use of genotyping. This resource will highlight ideal activities for CDC, state and local TB programs. Cluster investigation training modules and tools were pilot tested during an NTCA conference. The focus of this initiative is to develop webinars and training tools that can be shared via electronic media. DTBE is using its Tuberculosis Genotyping Information Management System to develop a "watch list" to monitor for known genotypes of concern. New clusters that may represent potential outbreaks will be categorized as "high," "medium" or "no" alerts and will be distributed via e-mail notification.

DTBE will soon publish Tuberculosis Trials Consortium (TBTC) Study 26 on the success of the 12-dose regimen of 3 months of once-weekly isoniazid and rifapentine (INH-RIF). Guidelines on the new regimen will be concurrently published in the *New England Journal of Medicine* and the *Morbidity and Mortality Weekly Report* (*MMWR*). The joint CDC/U.S. Army study was recently published on diagnostics for LTBI.

Several presentations were made during the 2011 International Union Against Tuberculosis and Lung Disease Conference that offered encouragement on the progress of new and novel compounds in the mouse model in terms of shortening a regimen for treatment of drug-susceptible and drug-resistant TB. Efforts are underway to update guidance on interactions of rifamycins and HIV drugs. CDC participated in a workshop in November 2011 sponsored by the Bill and Melinda Gates Foundation "Critical Path to a TB Regimen" Initiative.

DTBE's recent communications, education and training activities include printing the 5th Edition of the *Core Curriculum on Tuberculosis: What the Clinician Should Know*. Copies of the Core Curriculum would be distributed to ACET during the meeting. DTBE developed and conducted the "Quality Assurance for Tuberculosis Surveillance Data Training Course." DTBE currently is pilot testing the "Contact Investigation and Interviewing Course." DTBE will soon post the "TB 101 for Healthcare Workers" online course on the CDC website. DTBE is now developing a TB website in Spanish.

DTBE held the 2011 TB Education and Training Network Conference with attendance by 175 participants. DTBE utilized Facebook and Twitter to market the release of the new TB surveillance report. New staff joined DTBE to replace vacancies in the Communications, Education and Behavioral Studies Branch: Dr. Joan Mangan (Behavioral Scientist) and Ms. Jamala Best (Webmaster).

DTBE prepared numerous communication materials to publicize the new 12-dose regimen for LTBI. These materials include a "Dear Colleague" letter; external key messages to distribute to partners; a video podcast in English and Spanish; matte articles targeting the general public and healthcare professionals; a new feature on the CDC.gov website in English and Spanish; social media tactics (e.g., Twitter and Facebook); updates of 10 fact sheets, web pages, slide sets and prepared responses for CDC INFO; and a press release, media statement and message box.

DTBE will release recommendations for using the INH-RIF regimen with direct observation to treat latent *M.tb* infection in a coordinated publication on December 8-9, 2011. The publication will include peer-reviewed study results and guidelines. The guidelines were developed based on evidence from three treatment trials and input from an external expert consultation DTBE held in April 2011. PREVENT TB was the largest of the three treatment trials with 8,000 patients. The communication plan for the guidelines was designed with a multi-prong strategy, including pre-release announcements to partners, online informational supplements and media messages. Post-marketing surveillance of the new LTBI regimen is underway.

ACET congratulated DTBE for developing a communication plan to quickly release and publicize the guidelines on the new LTBI regimen. However, some members were disappointed that DTBE did not provide advance notice of the guidelines in order for state and local TB programs to answer questions by the media and initiate planning efforts.

Dr. Castro was aware that the need to rapidly publish the guidelines on the new LTBI regimen did not allow DTBE to notify TB programs of the recommendations in advance. However, he confirmed that DTBE's communication plan for the guidelines will help TB programs to answer questions by the media, particularly related to the availability of RIF. DTBE leadership also will be available to assist TB programs in this regard.

Update by the Division of Global Migration and Quarantine (DGMQ)

Mary Naughton, MD, MPH
Medical Officer, Immigrant, Refugee and Migrant Health Branch/DGMQ
Centers for Disease Control and Prevention

Dr. Naughton covered the following areas in her update to ACET. The top immigrant source countries in FY2010 were Mexico, Dominican Republic, Philippines, China, India, Vietnam, Haiti, Bangladesh, Pakistan and Jamaica. The top 10 countries for U.S. refugee arrivals by nationality in FY2011 were Burma, Bhutan, Iraq, Somalia, Cuba, Iran, Eritrea, Democratic Republic of the Congo, Ethiopia and Ukraine. There were 56,422 refugees from all source countries in FY2011, but the Department of State (DOS) expects the number of U.S. refugee arrivals to increase to ~70,000 in FY2012.

To date, CDC has implemented Culture and Directly Observed Therapy (DOT) TB Technical Instructions (TB TIs) in 35 countries, including China, Philippines, Vietnam, Mexico, India, Bangladesh, Malaysia, Thailand and Nepal. At this time, 68% of immigrants and >67% of refugees are being screened with the Culture and DOT TB TIs. This coverage includes refugees from Burma and Bhutan. CDC visited several countries in FY2011 to plan or maintain the quality of implementation, including China, Thailand, Vietnam, Malaysia, South Korea, India, Bangladesh, Burma (2012 implementation), and several countries in Central/South America and Africa..

CDC hosted two Panel Physician Training Summits in Bangkok, Thailand and Lima, Peru in 2011 with broad representation by several countries (206 attendees from 46 countries), including physicians from the International Organization for Migration and consular officers. CDC plans to expand TB TI implementation to additional countries in FY2012, including Canada, Cameroon, , Burma, and El Salvador, Peru, and Honduras., , CDC will sponsor another Panel Physician Training Summit in Istanbul, Turkey in March 2012. The ACET/NTCA evaluation of the Culture and DOT TB TI implementation will be held at the Dominican Republic panel site in the summer of 2012.

CDC's rationale for expanding the TB TIs to El Salvador in FY2012 is two-fold. First, El Salvador is the 11th largest source country for immigrants and accounted for 10,555 arrivals to the United States in FY2010. . El Salvador is the largest Central or South American immigrant source country overall. Second, El Salvador accounted for 116 TB cases reported in the United States in 2010 and worldwide is the 12th largest source country for TB. El Salvador has three panel sites in San Salvador.

The National TB Program (NTP) Director in El Salvador, Dr. Julio Garay Ramos, attended the Panel Physician Training Summit in Peru and has assumed an active coordinating role with panel physicians. Immigrants will be screened according to the Culture and DOT TB TIs beginning on January 1, 2012. The National Laboratory will perform cultures and DST, while the NTP will provide DOT at five sites. A Culture and DOT TB TI implementation plan has been

developed that is specific to El Salvador to clearly delineate roles and responsibilities of each entity. CDC will circulate El Salvador's plan for other countries to use as a model.

DOS is shifting to paperless medical examination forms. DOS is developing an electronic system for visa applicants through the Consular Electronic Application Center (CEAC). CEAC will include a module to capture medical examination information electronically. DGMQ is collaborating with DOS to electronically transfer medical examination information from CEAC into the CDC Electronic Disease Notification (EDN) System. DOS hopes to pilot certain non-medical aspects of CEAC beginning in 2012. Timeframes for the development of the medical examination module and subsequent linkage with the EDN System are being established.

The Chicago Quarantine Station conducted a successful intervention to increase the rate of follow-up for arrivals to Illinois with TB classifications. Local health departments that received contact information for arriving immigrants who had TB classifications were four times more likely to initiate follow-up examinations. Efforts are underway to explore expanding Chicago's system to other quarantine stations across the country.

Dr. Naughton provided clarification in response to ACET's specific questions. The discussion topics included:

- protocols to determine and notify state and local TB programs of the number of refugees arriving to specific localities in the United States each year to improve preparedness;
- the number and capacity of testing sites and the National Laboratory in El Salvador;
- requirements in the Culture and DOT TB TIs for TB contacts to be identified; and
- the possibility of allowing Former Soviet Union countries to participate in CDC's future training courses, particularly those related to the treatment of multidrug-resistant TB (MDR-TB).

Update on NCHHSTP's PCSI Activities

Gustavo Aquino, MPH
Associate Director for Program Integration, NCHHSTP
Centers for Disease Control and Prevention

Mr. Aquino covered the following topics in his update to ACET. NCHHSTP defines "PCSI" as a mechanism for organizing and blending interrelated health issues, activities, and prevention strategies to facilitate comprehensive delivery of services that are based on five principles: appropriateness, effectiveness, flexibility, accountability and acceptability.

NCHHSTP defines the "program collaboration" component of PCSI as a mutually beneficial and well-defined relationship between two or more programs, organizations or organizational units to achieve common goals. Collaborations have the capacity to:

- broaden the mission of member organization and help these groups to develop more comprehensive strategies;
- help develop wider public support for issues;
- increase the influence that individuals, communities and institutions have over policies and practices;
- minimize duplication of serves and increase the efficiency with which resources are used;
- increase participation from diverse constituencies;
- exploit new resources in a changing environment;
- increase accountability and strengthen planning and evaluation capacity; and
- increase the ability of local organizations and institute to respond better to the needs and aspirations of their constituents.

NCHHSTP defines the "service integration" component of PCSC as a distinct method of service delivery that provides persons with seamless services from multiple programs or areas within programs without repeated registration procedures, waiting periods or other administrative barriers. Service integration has the capacity to combine interrelated prevention services rather than delivering these services independently. These critical benefits include:

- providing prevention service providers with greater flexibility when responding to changing disease epidemics;
- building upon existing program infrastructures of multiple programs (e.g., human, information technology or financial);
- lowering the total cost of service provision; and
- maximizing prevention opportunities to meet the needs of communities and populations at risk for multiple infections.

NCHHSTP designed PCSI to modernize prevention responses. The traditional public health approach included vertical programs, a focus on infections, limited connectivity, clinical interventions, and a highly specialized and targeted approach. PCSI's syndemic approach recognizes interactions, focuses on the client, connects specialties, uses a network approach, adopts a holistic approach, and emphasizes structural interventions.

NCHHSTP obtained input from key stakeholders to establish three priority areas for PCSI. Integrated surveillance enhances the quality and sharing of data across programs. Integrated training ensures a more holistic approach to health is practiced in state and local health departments, community-based organizations, health clinics and other venues. Integrated services provide a multi-level approach to prevention services and interventions for individuals and communities.

PCSI is a cross-cutting goal in the 2010-2015 NCHHSTP Strategic Plan. NCHHSTP created an internal matrix to measure performance of the PCSI goal at five levels. Programmatic flexibility will be expanded to facilitate PCSI at the client level. Surveillance systems, policies, standards and procedures will be aligned to ensure surveillance data are accessed and used for integrated public health interventions, programmatic planning and evaluation.

Opportunities for integrated training and cross-training will be identified and promoted across NCHHSTP and jurisdictions. Support systems, policies, structures and activities will be implemented, maintained and evaluated to enhance PCSI. PCSI-related research and evaluation will be conducted to identify best practices.

In addition to the internal matrix, NCHHSTP also implemented other internal activities to further institutionalize PCSI. These activities include bimonthly meetings with Division Directors, the PCSI Workgroup, quarterly Project Officer meetings, Surveillance Workgroup, Drug User Workgroup, Health Equity Workgroup, Corrections Workgroup, and Men Who Have Sex With Men Workgroup.

NCHHSTP has made a number of notable accomplishments since the initial PCSI consultation was held in August 2007. In June 2008, a PCSI training meeting was convened. In April, October and December 2009, a meeting was held with national partners to accelerate PCSI implementation; the PCSI evaluation plan was developed; and a white paper was published. In April-June 2010, the PCSI FOA was released; six PCSI demonstration sites were funded; a PCSI webinar was held; and a consultation was convened with external partners to obtain feedback on draft data security and confidentiality guidelines. In June 2011, a literature review on PCSI was completed.

PCSI funding was ~$4.4 million in FY2011 with the following breakdown: CoAgs (71%), intramural funds (26%), and contractual services (1%). PCSI played an integral role in reducing cuts to the TB budget. Since 2008, NCHHSTP has added PCSI language to FOAs in categorical programs within all four divisions: DTBE, DVH, DHAP and DSTDP.

DTBE is leading NCHHSTP's PCSI efforts to strengthen innovation and integration in the Pacific Islands, particularly related to the tremendous TB and syphilis burden. To support this effort, an integrated FOA will be developed and released to reduce current reporting requirements from 45 to 4 goals, decrease current required activities from 236 to 86, and reduce the number of annual, interim and financial progress reports from 12 to 3.

NCHHSTP funded six sites to conduct PCSI demonstration projects in San Francisco, Texas, New York City, North Carolina, Houston, Philadelphia and Washington, DC. The grantees are funded to develop PCSI models to strengthen collaboration, expand service integration, identify PCSI priorities, assess existing service integration, use surveillance data to identify syndemics, determine operational barriers to PCSI, develop methodologies to improve PCSI, and evaluate best practices. The inclusion of TB is a requirement of the PCSI demonstration projects.

NCHHSTP will soon release *Data Security and Confidentiality Guidelines for HIV/AIDS, Viral Hepatitis, STD and TB Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action*. The publication is intended to achieve three major objectives. Minimum standards will be established to ensure the appropriate collection, storage, sharing and use of data across surveillance and program areas for NCHHSTP.

The new guidelines will replace current recommendations for HIV surveillance programs and establish standards for viral hepatitis, STD and TB programs. Minimum standards will be

established to allow for increased use of HIV surveillance data for public health action. The new data security and confidentiality guidelines also will promote flexibility of new technology in the field and in tele-work settings, designation of an overall responsible party, and a self-certification process.

The Atlas Project is one of the newest components of PCSI. The purpose of this tool is to provide an interactive and unified platform to access HIV, STD, TB and viral hepatitis data in order to meet the analytical and data dissemination needs of NCHHSTP, its national, state and local partners, and the general public. NCHHSTP initially will launch the Atlas Project with HIV and STD data, but TB and viral hepatitis data will be added in the future.

NCHHSTP plans to issue a call for papers for programs to describe their local experiences with PCSI. The selected manuscripts will be published as a supplement in *Public Health Reports* in January 2012. Authors will be allowed to submit their manuscripts in an analytic or descriptive format and outline implications for policy and practices. The overarching goal of the manuscripts will be to advance scientific knowledge and report findings of public health research and policy related to PCSI.

Dr. Mayleen Ekiek is the ACET liaison representative for the Pacific Island Health Officers Association. She was pleased that NCHHSTP is targeting its PCSI activities to the Pacific Islands, particularly since the same staff coordinates HIV and STD programs in these countries. However, she was uncertain about the feasibility of implementing an integrated FOA in the Pacific Islands due to staff shortages.

Dr. Ekiek advised NCHHSTP to ensure that its PCSI guidance strongly emphasizes the need for all TB cases to be screened for HIV in Pacific Island countries. NCHHSTP guidance also should inform patients in the Pacific Islands of their ability to opt-in or opt-out of HIV screening. She hoped that NCHHSTP would resolve confidentiality issues in order to retain HIV data on STD reporting forms in the Pacific Islands.

Dr. Fenton was aware that programs typically have a desire to return to categorical line items when federal funding is decreased. However, he emphasized that PCSI has numerous benefits for TB elimination, particularly in the current era of severe budget cuts. He clarified that NCHHSTP's overarching intent is to use PCSI to identify opportunities for collaboration, leverage resources, and strengthen partnerships to advance health impact across the nation.

Dr. Fenton informed ACET that NCHHSTP would conduct a mid-course review in FY2012 to determine the current status of PCSI, the accomplishments of this initiative since 2007, priority needs of partners at the local level, and future directions of PCSI. To guide the mid-course review, he confirmed that NCHHSTP would solicit feedback and recommendations from its external partners in HIV, STD, TB and viral hepatitis.

Dr. Castro highlighted the critical need for NCHHSTP to shift the focus of PCSI from program collaboration and service integration to actual outcomes of interest (e.g., an increase in identifying TB cases, a decrease in the national TB rate, and an increase in curing TB patients).

Update by the TB Elimination Workgroup

Masahiro Narita, MD, FCCP
Director, TB Control Program
Public Health-Seattle and King County
ACET Member & TB Elimination Workgroup Chair

Dr. Narita covered the following topics in his update on the workgroup's activities. ACET charged the workgroup with formulating recommendations in response to three questions: (1) Should TB elimination be retained as a national goal? (2) If yes, by when and how? (3) If not, what should be the new national goal?

The rationale for the workgroup's charge is summarized as follows. In 1989, CDC and ACET issued an *MMWR* publication, *A Strategic Plan for the Elimination of Tuberculosis in the United States*. The Strategic Plan established a national TB elimination goal of a case rate of <1/1 million population by 2010 and an interim target of 3.5/100,00 population by 2000. This goal was not met due to the resurgence of TB and emergence of MDR-TB.

In 1999, ACET issued a follow-up *MMWR* publication, *Tuberculosis Elimination Revisited: Obstacles, Opportunities and a Renewed Commitment*, to reaffirm its call for the elimination of TB in the United States. In 2000, the Institute of Medicine (IOM) published a report, *Ending Neglect: The Elimination of Tuberculosis in the United States*, that suggested elimination of TB might be feasible by 2035 if a number of recommendations were implemented to accelerate the decline in TB cases from 7% to 10% annually.

In 2009, Stop TB USA published *A Call for Action on the Tuberculosis Elimination Plan for the United States* to reemphasize that this worthy goal could be achieved with the implementation of dramatic improvements in TB control strategies. WHO published its Stop TB Strategy with a global target of eliminating TB as a public health concern by 2050 (e.g., <1/1 million population). In 2010, the European Centre for Disease Prevention and Control accepted the WHO global target as the target for the European Union in its report, *Progressing Toward Tuberculosis Elimination*. A 1999 *MMWR* publication described numerous options for a TB elimination goal: control, elimination of disease or infections, eradication or extinction.

Dr. Narita highlighted the workgroup's recommendations in response to its charge. <u>One</u>, should TB elimination be retained as a national goal? The workgroup's response to this question is "yes" based on the following rationale. TB elimination is a worthy and achievable goal. The U.S. national goal should be aligned with the global goal by WHO and the European Union. A clear and consistent goal would help to increase the engagement of patients, public health workers, the community and policymakers.

<u>Two</u>, if yes, by when and how? The workgroup's response to this question is "by 2050" based on the following rationale. Alignment between the U.S. national goal and the global goal by WHO and the European Union would reflect synergy and promote a simple message of global coordination. Mathematical models suggest that a TB rate of <1/1 million population among

U.S.-born persons/populations (USBP) is achievable by 2050. However, these same models indicate that TB elimination would occur much later among foreign-born persons/populations (FBP).

The workgroup recommended several strategies on "how" to retain TB elimination as a national goal. Investments should be sustained or augmented to develop more efficient and effective tools and interventions for TB disease and LTBI. Prevention of the progression of LTBI to TB disease is now the most important determinant of success in achieving TB elimination. A new call is needed for additional research investments in TB prevention (e.g., better and simpler LTBI diagnostic tools, shorter and safer LTBI treatment options, or an effective vaccine, particularly among FBP).

These strategies cannot be implemented at the expense of current TB control efforts that need to be sustained. Moreover, TB control and prevention efforts overlap in some areas (e.g., prevention of transmission from active cases in homeless, substance abuse, HIV-infected and other high-risk groups).

The role of TB transmission between groups (e.g., from FBP to at-risk USBP or from homeless to non-homeless persons) should be analyzed and described. The role of an aging population that has a concomitant increase in co-morbid conditions (e.g., diabetes and immunosuppressive treatments) should be analyzed and described. The influence of the perception of "fatigue" in consistently not meeting previous TB elimination targets should be explored.

Interim goals and milestones to measure progress should be established. National objectives and performance indicators that are described in the National TB Indicators Project (NTIP) should be reexamined on the basis of updated science and epidemiology. Indicators that have been associated with local program success should be determined. Annual progress on meeting targets should be documented in the Annual TB Surveillance Summary, *Reported Tuberculosis in the United States*.

Critical assessments should be conducted every 5 to 10 years to determine national progress in meeting the TB elimination targets. The assessments should be designed to generate a "call for action" if the nation fails to meet its performance targets; facilitate a review of strategies; and periodically boost advocacy efforts. Opportunities that will be made available by the Affordable Care Act should be incorporated at several levels. Coordination should be strengthened among new partners for diagnosis and treatment of LTBI. The workgroup is collaborating with the ACET Affordable Care Act Workgroup in this effort.

ACET commended the workgroup on recommending a set of clear, concise and concrete strategies to achieve the national TB elimination goal of 1/1 million population by 2050. The members made several comments and suggestions for the workgroup to consider in refining this guidance.

- The workgroup should revise some of its recommended strategies to emphasize the critical importance of engaging communities in achieving the national TB elimination goal.

- The workgroup should discuss and explore whether the focus on USBP to achieve the national TB elimination goal by 2050 might have an unintended consequence of increasing stigma and health disparities in the large FBP in the United States. Messages to the public on this issue will need to be thoughtfully and sensitively framed. Moreover, the workgroup should coordinate its efforts with those of the ACET Racial/ Ethnic Disparities Workgroup to issue integrated recommendations on TB elimination in FBP and other racial/ethnic groups.
- The workgroup should consider the possibility of recommending LTBI or TB infection as a reportable disease as an additional strategy to achieve the national TB elimination goal.
- The workgroup should make specific recommendations on TB elimination along the U.S.-Mexico border due to the extremely high incidence of disease in this population.

Dr. Fenton noted that the workgroup's thoughtful and deliberate recommendations on TB elimination could be used as models in ongoing elimination efforts for syphilis, perinatal hepatitis B and perinatal HIV. However, he encouraged the workgroup to formulate additional guidance on strengthening Congressional interest and political will in TB elimination. Due to the tremendous success in reducing national TB rates, interest in TB investments has decreased over time.

Update by the TB Second-Line Drug Shortage Workgroup

Barbara Seaworth, MD
Medical Director, Heartland National TB Center
ACET Member & TB Second-Line Drug Shortage Workgroup Chair

Dr. Seaworth covered the following topics in her update on the workgroup's activities. Drug shortages are part of a larger problem in the United States and globally. Shortages of all drugs nearly tripled from 61 in 2005 to 178 in 2010. Of the current drug shortages, 132 involve sterile injectable drugs. Several groups convened the Drug Shortage Summit in November 2010 to identify reasons for the lack of key medications, increase advocacy for drug shortages, and determine solutions to this important problem.

These groups included the American Society of Health Systems Pharmacists, American Society of Oncology, American Society of Anesthesiologists, and Institute for Safe Medication Practices. The groups released several publications that provided a comprehensive review of the problem. TB drug shortages include both first-line drugs (FLDs) and second-line drugs (SLDs): RIF, INH tablets, Rifabutin, Amikacin, Levofloxacin injections, Streptomycin, Kanamycin, Capreomycin, Ethionamide and Cycloserine.

In an effort to determine the extent of the drug shortage problem, NTCA administered a survey in 2010 to 61 TB control programs. Of 33 programs that responded to the survey, the major problems reported were the high expense of drugs (62%), delays in starting therapy (58%),

overall challenges (33%), lapses or interruptions in treatment (32%), and use of less than an optimal regimen (26%).

Human resources costs for staff to acquire and ensure TB patients have necessary medications have increased to $216 million annually (or an increase of 9 person-hours per week). U.S. hospitals currently spend $200 million to purchase more expensive TB medications. The cost of TB medications also has increased over time (e.g., $11.70 for a 1-gram vial of Capreomycin in 2007 versus $137.00 in 2010).

Recent data show that quality and manufacturing issues account for 43% of current drug shortages. These problems include contamination of glass and metal containers, shortages of active pharmaceutical ingredients, increased reliance on foreign ingredients and resources, vulnerability of sterile injectables, just-in-time manufacturing and inventory, supplies with "short dates," and difficulties in ramping up production due to sole-source manufacturers. Economic issues with low-margin profits and restrictions of drugs due to investigational use also play an important role in TB drug shortages.

In addition to the private sector, the federal government also is taking actions to address the TB drug shortage problem. FDA partners with manufacturers to track current shortages of all medically necessary drugs, including those for TB, and publicly display this information on its website. FDA encourages voluntary reporting by manufacturers, considers extending the expiration deadline for certain drugs, and authorizes importation of drugs from other countries.

President Obama signed an Executive Order in October 2011 to broaden requirements for manufacturers to report discontinuation of drugs, expedite the FDA regulatory review process, and mandate reporting of any price gouging, stockpiling or hoarding of drugs to the Department of Justice. Both the House and Senate introduced bills to require manufacturers of certain drugs to notify the HHS Secretary if any drugs would be discontinued or interrupted.

Several partners are collaborating with the federal government to address problems related to TB SLDs and the broader issue of TB drug shortages. The American Thoracic Society (ATS) is partnering with the U.S. Senate to incorporate a directive into the FY2012 Health Spending Bill that would emphasize the national drug shortage of TB medications and other barriers to treatment.

The Infectious Disease Society of America (IDSA) Board of Directors has been notified of and is waiting for further information on TB drug shortages in the United States. This group may highlight this issue in its "Bad Bugs-No Drugs" Report. The Scientific Advisory Committee of the TB-HIV Global Advocacy Center and the Stop TB MDR Workgroup are aware of and are willing to support this issue. These partners drafted a problem statement and fact sheet that were distributed to ACET for review.

CDC responded to a Congressional inquiry at the request of ATS and the Treatment Action Group (TAG) and also has been extensively engaged in the workgroup's activities to explore potential solutions. The possibility has been raised of CDC serving as a coordinator to facilitate better access to TB drugs. CDC's potential functions in this effort include serving as a central or

regional stockpile or reinstating its Drug Service Program. However, the previous program was limited to potentially fatal diseases (e.g., botulism and tularemia) and would need to be modified to address TB drug shortages.

Dr. Seaworth concluded her update by highlighting the workgroup's proposed solutions to address the shortage of TB drugs in the United States. Advocacy should be strengthened to ensure the impact on public health is recognized far beyond individual patient outcomes. A national or regional MDR-TB Drug Repository should be developed. Second-line TB drugs should be registered with the federal Orphan Drug Program or another initiative to provide tax credits or other financial incentives to manufacturers.

Additional insurance should be offered to cover expensive TB SLDs. The process of acquiring Clofazamine should be streamlined to increase access to this drug. For example, a central Institutional Review Board could be established to decrease the current 6- to 8-week delay for TB programs to complete paperwork to acquire Clofazamine. A protocol should be developed for all TB programs to qualify for federal 304B pricing and obtain less expensive TB drugs.

ACET commended the workgroup on proposing solid solutions to address the extremely complex issue of TB drug shortages in the United States. The members were pleased that awareness of this problem is increasing at the Congressional level, particularly with the new White House Executive Order and the newly-established TB Congressional Caucus. Moreover, language was incorporated into the FY2012 Senate bill to emphasize the need for FDA and other federal partners to accelerate the development of new TB diagnostics.

The ACET members made several comments and suggestions for the workgroup to consider in strengthening this guidance.

- The workgroup should advise CDC to convene a meeting with manufacturers to begin identifying practical solutions to address the cost of and access to SLDs in the field. CDC should extensively engage TAG in convening the meeting with manufacturers.
- The workgroup should review and compile lessons learned from high-burden MDR-TB countries outside of the United States and apply these global best practices to address TB drug shortages in the United States.
- The workgroup should recommend the development and distribution of standardized forms, templates or toolkits to assist TB programs in acquiring Clofazamine.
- The workgroup should review the Orphan Drug Act that was passed in the 1980s with multiple advantages and incentives to drug manufacturers to make drugs more widely available.
- HRSA will soon launch a series of webinars with guidance for programs to secure a contract under the 340B Drug Pricing Program. Dr. Theresa Watkins-Bryant is the ACET *ex-officio* for HRSA. She made a commitment to facilitate a direct linkage between NTCA and 340B Program staff in HRSA. She also planned to obtain a response to ACET's questions regarding barriers to local programs receiving 340B pricing. Local programs that receive direct funding from states rather than federal agencies are ineligible for 340B pricing.

- The workgroup should review lessons learned by the Global Drug Facility and Green Light Committee. These groups are charged with providing quality-assured drugs at the global level for the treatment of MDR-TB. These groups also have had high-level discussions with all manufacturers of TB drugs in the world. The global experiences with TB drug shortages are valuable and could be used to inform the problem in the United States.
- The workgroup should determine whether SLDs can be secured from WHO and make recommendations accordingly.

Dr. Castro was pleased that the workgroup recommended multiple approaches to address the complex problem of TB drug shortages in the United States. In response to one of the recommendations, he announced that CDC's Drug Service Program is still operational and is housed in NCEZID. The program maintains a formulary of investigational and licensed drugs and biologics that are distributed to approved physicians for the prevention, control or treatment of rare, tropical or exceptional diseases. Dr. Castro noted that if ACET passed a consensus resolution, DTBE would explore the possibility of using the Drug Service Program to address the TB drug shortage problem.

Dr. Fenton agreed with Dr. Castro's comments, but he made two additional suggestions to address the broader drug shortage problem in the United States beyond TB. First, leadership in DTBE and the other NCHHSTP divisions should brief Dr. Thomas Frieden, Director of CDC, and Dr. Rima Khabbaz, Deputy Director of the Office of Infectious Diseases on the drug shortage problem for all infectious diseases covered by NCHHSTP. Second, ACET should invite a CDC senior official to the next meeting to describe the agency's programmatic strategy to address drug shortages for NCHHSTP's infectious diseases.

PANEL PRESENTATION: FUTURE DIRECTION OF TB CONTROL AND ELIMINATION IN THE UNITED STATES

A panel of speakers presented a series of updates and overviews describing the future direction of TB control and elimination in the United States. The presentations are summarized below.

Progress Report on the 2000 IOM "Ending Neglect" Recommendations

Randall Reves, MD, MSc
Medical Director, Denver Public Health Department
Former Chair, Stop TB USA

Dr. Reves reported on the progress to date in implementing the IOM recommendations on TB elimination in the United States, but he first presented a series of TB case studies. In case 1, the Denver TB Control Program recently was notified of acid-fast bacillus (AFB) that was growing on sputum collected from a patient who was hospitalized for 8 days. The patient died after being sent to home hospice for progressive pulmonary fibrosis. The gene probe showed

that the patient was susceptible to FLDs and had *M.tb*, smear-negative sputum and tracheal aspirate. The contact investigation identified 4 of 8 adults with LTBI, but none of the 6 children had infection.

In case 2, a female patient 62 years of age who was born in Mexico was first seen in 1997 in an FQHC with a history of stroke, hypertension and lung fibrosis. The patient was followed by primary care and specialty clinics through 2010 and had no prior record of a tuberculin skin test (TST). TB was "ruled out" because the TST that was performed 10 days before the patient's death showed negative AFB sputum smears.

The death of this patient most likely was preventable. The patient was a candidate for evaluation of inactive TB and treatment due to her birth in Mexico and the presence of parenchymal fibrotic lesions. Although TB was ruled out on the basis of a negative TST and smears, empirical treatment may have been effective because <50% of pulmonary TB smears are positive. Prior documentation of LTBI before hospital admission also may have altered treatment of the patient.

In case 3, a U.S.-born male 2 years of age was asymptomatic, but had a positive TST. The child's mother had been hospitalized with recurrent pneumonia, cavitary nodules on computed tomography, and AFB-positive sputum smears. The child was treated as a clinical TB case and his congenital urinary tract abnormalities were corrected.

In case 4, a female patient 31 years of age who was born in Mexico had multiple bouts of pneumonia for the past 2 years. The patient presented to a clinic 5 years earlier and was referred to the health department on the basis of a positive TST. The patient had a normal x-ray and did not return to the TB clinic to start INH after the birth of her fifth child. The patient was hospitalized with pneumonia 2 years prior and had a negative TST. The patient and her 2-year old child were later diagnosed with TB, but the primary care provider had no knowledge of the previous TST that was positive.

Cases 3 and 4 demonstrate that U.S.-born children with foreign-born parents are at increased risk for acquiring TB from family members. However, challenges arise in timely diagnosing important events that are relatively rare. Delays in diagnosis and treatment of TB lead to ongoing transmission. Preventable TB cases continue to occur, even in FQHCs, due to failures in diagnosing and treating TB infection in populations at increased risk for TB. These cases also emphasize the critical need to improve the medical record system and more extensively engage primary care providers and FQHCs in TB diagnosis and treatment.

In terms of the status of TB elimination in the United States, the 2010 goal established by ACET in 1989 was not met. In 2000, the IOM recommended an annual decline in TB cases of 10% to achieve TB elimination by 2035, but this goal also is unlikely. TB is expected to be a disease exclusively in minorities in 42 years. The >10% drop in TB cases and rates in 2009 did not start a new trend. Based on TB rates in 2000-2008, the projected year for TB elimination is 2107.

The IOM recommendations are still valid, but have not been fully implemented. For goal 1, control has been maintained despite the decline. For goal 2, the decline has not been

accelerated by increasing targeted testing and treatment of LTBI. For goal 3, research was expanded to develop new diagnostics, treatment and prevention tools, but implementation has been limited. For goal 4, U.S. involvement in global TB control has been increased. For goal 5, public support has been mobilized and sustained, but success in this area has been modest.

Efforts focused on targeted testing and treatment for LTBI in the United States also have been limited. ATS and CDC published guidelines in 2000. The 2006 Sterling study and the 2010 Horsburgh study were conducted under the Tuberculosis Epidemiologic Studies Consortium (TBESC). The studies reported that public health, correctional settings, refugee clinics and shelters accounted for 95% of LTBI treatment. Pediatric settings, Community Health Centers (CHCs) and the private sector had minimal involvement in LTBI treatment. Of persons with LTBI, 17% declined to start treatment and 53% who started treatment failed to complete their regimens.

Emphasis needs to be placed on whether the engagement of all U.S. medical care providers, professional organizations and community organizations in TB prevention is possible. Interferon gamma release assays (IGRAs) are recommended for BCG-vaccinated patients, but issues related to costs and logistics still need to be addressed.

Shorter regimens for LTBI treatment are currently being used. For example, some jurisdictions use rifampin in place of INH because treatment can be completed more readily with fewer adverse effects. CDC will soon issue guidance on the new INH-RIF once-weekly/three-month regimen for LTBI. Guidelines and record systems need to be developed for risk assessment, testing and treatment and made available to providers to inform decision-making.

Data have been produced to show the cost of treating TB in the United States. The total treatment cost for drug-susceptible TB per individual is $4,000 for DOT and $19,000 for hospitalization. Each year in the United States, TB accounts for 1,200 deaths before diagnosis or during treatment. The total treatment cost for MDR-TB per individual ranges from $28,217 to ~$1.3 million.

The total treatment cost for extensively drug-resistant TB (XDR-TB) is >$600,000, excluding hospitalization. A large patient series showed that the XDR-TB death rate is >40%. The 2010 Miller study estimated that the total societal cost of TB is $367,000 per case with disability accounting for 35% and transmission accounting for 47%. The benefits of achieving the U.S. TB elimination goal by 2035 include 253,000 fewer active TB cases, 15,200 fewer TB-associated deaths, and $1.3 billion less in treatment costs. However, the total societal costs are not considered in these estimates.

Stop TB USA issued a Call to Action to renew and expand the commitment to TB elimination, but the document was not intended to rewrite the IOM recommendations. Instead, the Call to Action emphasized the need for stakeholder involvement; described specific action plans to implement the IOM recommendations; and identified several groups that will need to be engaged to achieve TB elimination in the United States.

Dr. Reves highlighted some of the action plans described in the Stop TB USA Call to Action. A commitment should be made to implementing the IOM recommendations. A periodic review should be conducted to determine progress toward TB elimination. New timelines and interim goals should be established for TB elimination. An infrastructure should be developed and funding should be leveraged to enable Stop TB USA to collaborate with partners to generate political will for TB elimination.

The federal funding gap should be addressed by independently assessing the effectiveness of increased funding levels authorized in the Comprehensive Tuberculosis Elimination Act of 2007. The new dollars could accelerate the development and implementation of new tools for the diagnosis, treatment and prevention of TB. However, the funds were authorized, but have not been appropriated to date. A number of groups should be engaged to make a commitment to TB elimination (e.g., policymakers at all levels of government, the public health sector, medical practitioners, professional societies, community-based organizations and voluntary organizations). Minimal progress has been made on these action plans over the past year.

Overall, TB cases and deaths continue to occur due to limited LTBI diagnosis and treatment. The benefits of TB elimination would be even more compelling if societal costs are considered. The potential role of the Affordable Care Act in accelerating TB elimination remains unclear. New tools have been developed since 2000, but barriers to implementation persist. Because Stop TB USA is a voluntary organization, its role in the national TB elimination effort remains limited.

Progress Report on Implementing the Stop TB USA Five-Year Plan

Eileen Napolitano
Deputy Director, New Jersey Medical School Global Tuberculosis Institute
Chair-elect, Stop TB USA

Ms. Napolitano reported on the progress toward implementing the Stop TB USA five-year plan for TB elimination. Stop TB USA is exclusively organized for public health, scientific and educational purposes related to the elimination to TB in the United States. The vision and mission of Stop TB USA are to eliminate TB as a public health problem in the United States and strengthen TB prevention, care and control in the United States in collaboration with CDC.

The overarching goal of Stop TB USA is to create a social movement for public awareness, community empowerment and policy action. Stop TB USA established four key objectives to achieve this goal. Resources will be mobilized and actively supported for TB elimination in the United States at national, state and local levels.

A channel of scientific and public health knowledge will be provided for policymakers and the public on the status of TB elimination at global, national, state and local levels. Policymakers and the public will be educated on the need for sustaining community public health activities for TB elimination, including the development of new tools. A framework will be provided for

increasing community participation in the national TB elimination effort with an emphasis on building awareness in and participation of at-risk populations.

The National Coalition to Eliminate Tuberculosis (NCET) was organized in 1992 through a grant from the Robert Wood Johnson Foundation with 83 individuals representing the 58 founding organizations. NCET was reorganized in November 2002 with a new governance structure, bylaws and goals aimed at implementing the IOM recommendations. NCET leadership, advocacy partners and CDC unanimously agreed to rename NCET to Stop TB USA to further emphasize the global TB elimination effort.

Stop TB USA held a retreat in September 2010 to review and strengthen its mission, bylaws and activities. A five-year plan of action was developed at that time to guide Stop TB USA toward achieving its goals. Progress toward meeting these goals is summarized below.

Goal 1 is to revise the bylaws. Stop TB USA voted to approve the new bylaws during its annual partnership meeting in June 2011. The mission and objectives were strengthened. A Coordinating Board was established to replace the previous Steering Committee. Officer positions were expanded to include a secretary and treasurer. A Nominating Committee will be convened in early 2012 to nominate candidates for the new officers of secretary and treasurer and identify organizations and individuals to serve on the Coordinating Board.

Goal 2 is to develop a Patients' Forum to engage patients in the partnership activities of Stop TB USA. Stop TB USA established a workgroup to support this effort. Priorities were identified and a mechanism was developed for patients to discuss problems and challenges, exchange information, and create and support opportunities for patients to advocate for TB care and treatment. The Patients' Forum was used as a resource for two patient members to receive media training, participate in World TB Day activities, and share their personal experiences at regional meetings and training events. However, Stop TB USA is aware that implementation of patient educational and support activities may require a more dynamic website.

Goal 3 is to develop workgroups to fully engage partner organizations and members in activities. Stop TB USA will form more workgroups after members of the Coordinating Board have been appointed, but initial recommendations have been made to form a Communications Workgroup and a workgroup to develop a collaborative approach for CHCs to focus on TB prevention in high-risk populations. The Patients' Forum could assist programs in engaging at-risk communities, building trust and gaining access to these populations.

Goal 4 is to formalize the Stop TB USA Secretariat within ATS to further mobilize resources to create a 501(c)(3) organizational structure. This structure will increase Stop TB USA's capacity to fundraise and support its organizational activities. Stop TB USA received a small foundation grant to support the Patients' Forum, but a previous grant for partial support of an Executive Director requires matching funds. ATS developed a process to earmark a portion of its member donations to Stop TB USA.

Stop TB USA's ongoing activities include the production of *A Call for Action on the Tuberculosis Elimination Plan for the United States*; maintenance of advocacy and communications tools

(e.g., Stop TB Wire and the *TB No Longer a Problem* Compendium); participation in World TB Day activities; and support of Patients' Forum initiatives.

Stop TB USA plays several roles in the national TB elimination effort. Critical issues related to the care, control and elimination of TB in the United States are identified. TB program challenges resulting from diminishing resources and restructured programs are identified. Potential solutions to problems are identified in collaboration with national, state and local partners. Advocacy efforts are targeted to solutions and resources to address these challenges. Partners are engaged at all levels, including TB patients, their families and communities, to mobilize necessary and appropriate resources.

Stop TB USA faces several challenges to achieve its goals in the national TB elimination effort. The completely voluntary organization has limited resources, no funded infrastructure support, and an Executive Director position that is entirely unfunded. Stop TB USA successfully developed the Call to Action, new bylaws and related strategies, but has been unable to advance to broad implementation due to lack of resources.

Organizations are becoming more disengaged due to the lack of staff to sustain Stop TB USA. Stop TB USA will be severely limited in its scope, unable to fulfill its mission and incapable of achieving the objectives outlined in the bylaws without a supported infrastructure, a funded part-time Executive Director position at a minimum to sustain and expand activities, establishment of a 501(c)(3) organizational structure, and ability to raise needed funds.

Overall, necessary resources for Stop TB to sustain and grow its organization will become more important as the shift is made from TB prevention to eventual elimination. These resources also are needed for Stop TB USA to fully engage its partners, support individuals and communities most affected by TB, support the efforts of TB programs at all levels, engage policymakers, and encourage political interest in TB.

Ms. Napolitano concluded her update by asking ACET to formally approve a resolution to CDC. The resolution should request funding of $100,000 to Stop TB USA for staff, an improved website, and utilization of state-of-the-art communication tools.

Overview of the TRUST Report: TB Prevention and Control Component

Terence Chorba, MD, DSc, FACP
Chief, Field Services and Evaluation Branch/DTBE
Centers for Disease Control and Prevention

Dr. Chorba presented an overview of the TB prevention and control (P&C) component of the TRUST Report. He pointed out that the report was distributed to ACET for review. The workgroup was convened in March 2011 and disseminated the TRUST Report to NTCA and APHL in May 2011. The original report was revised based on feedback submitted by partners. DTBE distributed its response document to partners in November 2011.

Dr. Chorba summarized the planning assumptions, comments by partners, and DTBE's response to the 7 focus areas of the TRUST Report.

Focus area 1 is TB CoAgs and TB P&C funds. The workgroup highlighted 3 key planning assumptions in this section. In a transition phase, CDC should continue to assist state TB programs in maintaining a minimum public health infrastructure to control TB. Core activities include TB surveillance, treatment of TB disease and high-risk LTBI cases, case reporting, contact investigations, and laboratory services. CoAg recipients ideally would have a reasonable amount of time to transition from their current CDC funding stream to new budget lines and resources.

The workgroup proposed several options based on the planning assumptions. For option 1, 25% of all TB P&C CoAg line item amounts would be cut during the transition phase. A base amount would be established for low and medium morbidity areas. The remaining balance would be redistributed to high morbidity areas based on the funding formula.

For option 2, TB surveillance data would be used to fund P&C programs with the highest total morbidity that collectively report 50% of the national TB morbidity (e.g., New York City and New York State, Los Angeles and the state of California, Florida and Texas). For option 3, TB surveillance data would be used to fund P&C programs with the highest total morbidity that collectively report 75% of the national TB morbidity.

For option 4, the current P&C funding formula would be used to accelerate to 100% the funding for FY2013 for all programs based on certain variables. "No hold harmless" language would be included in this option. For option 5, any funding reductions would be distributed across all DTBE line items. Based on current line item allocations, each line item percentage of the overall DTBE budget would be reduced proportionally.

NTCA agreed with full and accelerated implementation of the formula, but emphasized the need to maintain core capacity in each state because states are legally required to control TB. NTCA strongly agreed with a "shared approach" by spreading the impact of reduced funds across all DTBE line items.

DTBE's response to NTCA's comments on focus area 1 is outlined as follows. Some of the proposed options are not desirable, but remain an alternative consideration if severe budget cuts are necessary. The preference for the "shared approach" will be taken into consideration. Recent recommendations from the Prevention and Control Workgroup and Laboratory Funding Formula Workgroup will be used to inform an equitable method to distribute funds across jurisdictions for the next funding cycle. Acceleration of the implementation of the funding formula method will be explored with attention given to maintaining core capacity in each program area.

Focus area 2 is TB cluster and outbreak response and emergency preparedness. The workgroup highlighted 5 key planning assumptions in this section. A mechanism should be developed to provide and protect emergency supplemental funding if CoAg funds to programs

decrease. An identifiable "TB program partner" should be retained in each jurisdiction to respond to outbreaks or emergencies. The current TB program model should be viewed as unrealistic and not necessarily supportable in any given jurisdiction.

The increasing need to collaborate with frontline public health nurses, providers and epidemiologists who primarily have non-TB responsibilities should be anticipated. An assumption should be made that a reduction in CoAg funds to state and local health departments would result in less effective TB P&C efforts in those jurisdictions and may lead to increased efforts to respond to outbreaks.

NTCA recognized the importance for CDC to have safety net capacity. An outbreak team may be as effective with fewer personnel and different skill sets or professional training. DTBE should assess whether supplemental funding or direct assistance after an outbreak has been effective in TB control. A genotyping initiative should be maintained, but the investment should not be increased. The information is of some value, but is not timely in the current situation.

CDC Headquarters should support increased emphasis on remote technical assistance options. Skills of local HIV/STD colleagues are utilized in TB outbreak investigations in many states and should be expanded. Flexibility should be maintained in awarding supplemental funding amounts and deploying CDC Headquarters staff to state and local health departments for certain periods of time.

DTBE's response to NTCA's comments on focus area 2 is outlined as follows. A formal cost-effectiveness evaluation is appropriate for emergency funding or direct assistance. The utility of genotyping has been demonstrated in the literature and in states that actively use these data, but timeliness has been a barrier to broader and more effective use.

DTBE considers its current staff to be sufficient for this activity and does not see the need for additional resources. DTBE will continue to solicit suggestions on ensuring that jurisdictions with outbreaks occurring later in the fiscal year are not denied emergency funding due to depletion of funds earlier in the fiscal year.

Focus area 3 is support for the TB Laboratory Network. The workgroup highlighted 2 key planning assumptions in this section. NTP is supported by multiple activities that in turn support the two principle components of TB control and laboratory activities. Emphasis is placed on process rather than specific solutions. A detailed overview will be presented on the laboratory component of the TRUST Report.

Focus area 4 is TB program monitoring and evaluation. The workgroup's key planning assumption in this section was that 4 components are critical to TB program monitoring and evaluation: NTIP, TB program capacity, internal DTBE capacity, and operational research.

NTCA considered NTIP to be the most important component of TB program monitoring and evaluation and emphasized the need to perform this activity at the national level. NTIP reports were viewed as valuable tools. However, further development of NTIP should be discontinued

until an evaluation is conducted on the current resources of programs to perform these functions.

Program evaluation most likely will continue to be a core function for programs. The value of technical assistance by the Program Evaluation Team is unclear. This function should be evaluated before efforts are made to expand in this area. Accurate and timely surveillance data are a state function that cannot be assured by any amount of funding at the DTBE level.

DTBE's response to NTCA's comments on focus area 4 is outlined as follows. DTBE reserves the ability to review current indicators, remove those that add no value, and add indicators based on a vote by the Steering Committee with emphasis on reducing the reporting burden on programs.

The Program Evaluation Team and Field Operation Team maintain strong collaborative efforts in developing an evaluation plan with local evaluation focus points. These efforts focus on intended program users who have the responsibility of applying and implementing evaluation findings. Operational research activities are programmatically relevant and proximally and distally linked with national goals and objectives.

Focus area 5 is continued support of the RTMCCs. The workgroup's key planning assumption in this section was that 2 components are critical and integral in any strategy to prevent, control and eliminate TB in the United States: maintenance of a well-trained workforce and human resource development (HRD), training and education among health department staff and other healthcare providers.

NTCA generally supported retaining the current number, structure and function of RTMCCs. NTCA emphasized the importance of assuring a genuine linkage between RTMCCs and TB programmatic issues and accountability. The approach of "pass-through" funding from RTMCCs to programs was found to be less important.

New models of RTMCC governance should be considered (e.g., a consortium of constituent TB controllers who would provide input and approve annual RTMCC work plans). The formula each RTMCC has for products and training should be adapted to address diverse needs across the United States. Webinars should be held to target specific audiences. CDC field staff should not be assigned to RTMCCs and a new RTMCC should not be added.

DTBE's response to NTCA's comments on focus area 5 is outlined as follows. RTMCCs are advised to base efforts and products according to the needs identified by regional stakeholders and DTBE guidance. DTBE is in favor of removing currently specified health department affiliations and agrees that RTMCCs should be linked to public health programs.

CoAg language advises RTMCCs to establish a Regional Advisory Committee to obtain guidance and input on their work plans. DTBE agrees with NTCA's suggestion not to pursue adding a new RTMCC or exclusively assign field staff to RTMCCs at this time. DTBE reserves the right to change the number of RTMCCs depending on responses to the FOA and if the best interests of NTP and public health warrant such a change.

Focus area 6 is TB research. The workgroup highlighted 2 key planning assumptions in this section. National TB control efforts should continue to benefit from TB programmatic research to investigate changes to TB epidemiology; assure desired performance of new drugs, diagnostics and vaccines; and identify and test new approaches to TB P&C. Funds to support necessary research activities through TBTC and TBESC should remain, even if reduced, unless the Consortia were required in the future to sustain core functions of surveillance, outbreak investigations, and guidelines and policy development.

NTCA noted that efficiencies could be gained by combining administrative functions of TBTC/ TBESC. Academic institutions are critical for conducting research. Programmatically relevant research requires the funding and participation of health departments, but programs are not adequately integrated in these efforts. Reduced scopes in work should be supported for all research contracts. A meeting of experts and stakeholders should be convened to discuss TB research enterprises.

NTCA agreed that capacity should be developed in the context of health economics, but a large new infrastructure should not be supported. DTBE and/or RTMCCs should spearhead the development, testing and training of using economics tools. Increased support for TB research is not tenable. Investments in access to and adoption of new TB diagnostic tools by public health laboratories are more important.

DTBE's response to NTCA's comments on focus area 6 is outlined as follows. Long-term improvements in CDC's costs may be driven by funding health departments that could subcontract with academic investigators. Increased engagement with health departments is necessary for optimal targeting and translation of research. Representation by NTCA, APHL and health departments should be integrated into the existing program of monitoring and consultation for TBTC/TBESC.

DTBE will solicit health economics expertise to identify additional capacity that is needed in this area. Investments in access to and adoption of new diagnostic stools are paramount. End-of-year funding in FY2010 and FY2011 was directed at improving the TB Laboratory Network with an emphasis on increasing access to diagnostic testing.

Focus area 7 is international engagement. The workgroup highlighted 2 key planning assumptions in this section. International engagement is critical to the domestic TB elimination plan. FBP account for 7,000-8,000 TB cases per year in the United States in addition to a number of MDR-TB cases. A CDC-wide workgroup and the CDC Center for Global Health drafted a strategy for CDC's international engagement in TB.

NTCA was unable to provide extensive comments on this section because a summary of DTBE's resources for international engagement was not available. However, NTCA recognized the potential impact of international engagement by DTBE on domestic TB P&C efforts. Strategies that would leverage external resources for international engagement should be considered.

DTBE's response to NTCA's comments on focus area 7 is outlined as follows. DTBE strives to leverage non-domestic resources for international TB efforts. In an effort to coordinate and organize CDC's international efforts, this issue has been prioritized at the level of the CDC Office of the Director. If DTBE develops a summary of the use of its resources for international engagement, the document will be distributed to partners for review and comment.

In addition to the specific focus areas of the TRUST Report, the partners also submitted general comments. NTCA posed overarching questions regarding the restructure of the U.S. TB Program: (1) What is the difference between a uniquely "federal" and "state" role? (2) What components of NTP are most effective in advancing TB control? (3) What is missing from, but should be part of NTP?

NTCA described several resources from CDC that add value to programs: timely and up-to-date guidelines and statements, support for front-line TB control activities, and laboratory testing. APHL pointed out that the 4 RTMCCs receive nearly the same amount of funding as all 64 CoAg laboratories, but do not provide training for laboratories.

DTBE's response to the general comments is outlined as follows. Long-range strategic planning requires accurate definitions of the unique role of the federal government in supporting TB control, components of NTP that are most effective in advancing TB control, and unfilled gaps. The Funding Formula Workgroup will examine questions related to cost-savings.

CDC must continue to provide state and local programs with timely and up-to-date guidelines, support for the National Public Health Laboratory Network, and frontline TB P&C activities. DTBE acknowledges APHL's observations regarding training and relative levels of funding. However, RTMCCs traditionally have focused on non-laboratory education and communication that are specific to TB control.

NTCA made suggestions to address gaps in several areas: "state" versus "city" funding, the "funding floor" in various jurisdictions, the speed in which changes in the CoAg funding stream would occur, the ability of states to leverage federal dollars, HRD funding, the role of program consultants, the affiliation and scope of services of RTMCCs, and epidemiologic forecasting.

Update by the TB Prevention and Control Funding Formula Workgroup

Phillip Griffin
Past President, National TB Controllers Association
Co-Chair, TB Prevention and Control Funding Formula Workgroup

Mr. Griffin presented an update by the TB Prevention and Control Funding Formula Workgroup. NTCA and DTBE formed joint workgroups to initially develop the funding formula in 2005 and review and modify the funding formula in 2008. The workgroup was reconvened in 2011 in anticipation of funding reductions.

The workgroup's charge addressed four major activities: (1) evaluate the current formula elements and weights; (2) assess the current funding structure in large cities, hold-harmless jurisdictions, U.S. territories (e.g., Puerto Rico and the Virgin Islands) and U.S.-affiliated Pacific Islands (USAPI); (3) asses the pace of current implementation; and (4) develop a mechanism to incorporate performance measure funding for a portion of allocations.

The 2008 workgroup developed the current funding formula: 30% to incident cases, 35% to U.S.-born minorities and FBP, 15% to smear-positive pulmonary cases, 5% to TB/HIV co-infection, 5% to MDR-TB cases, 5% to substance abuse, and 5% to homeless. The 2011 workgroup included representation by NTCA and DTBE as co-chairs, TB program staff from low, medium and high incidence states, TB program staff from large cities, DTBE branches and APHL.

Mr. Griffin noted that the workgroup's "recommendations" actually reflect suggestions proposed by the diverse membership during its discussions rather than consensus or official statements to DTBE. Key outcomes of the workgroup's discussions on specific components of the funding formula are summarized below.

For HRD funding, the workgroup was in favor of retaining the existing structure. Although funding is not adequate, the flexibility of these dollars is extremely useful. Required attendance at the annual TB Education Training Network (ETN) Conference should be evaluated to determine the need and value of this initiative for all programs, particularly small programs that no longer provide training. Elimination and redistribution of these funds to larger TB P&C efforts would be of little gain. An approach of changing the funding stream based on different tiers of morbidity would not add much universal value due to the limited amount of funds that are being considered.

For hold harmless programs, the workgroup was in favor of eliminating this category. However, the workgroup emphasized the need for no program to be funded at less than $65,000 plus an HRD allocation. Expectations of certain program outputs should be adjusted to be aligned with reduced funding and program capacity.

The workgroup considered a base funding level of $65,000 and application of the funding formula on top based on minimum case counts of 10, but this proposed approach may lead to broader per case disparity. The workgroup also considered floor funding of $100,000, but this approach was abandoned because funds would be diverted from high morbidity areas.

For large city programs, the workgroup was in favor of retaining historical funding for these jurisdictions. The 100% formula distribution in the future will eliminate funding disparities. Large cities and states with large cities should be given the option of submitting joint grant applications at their discretion.

For U.S. territories and USAPI, the workgroup was in favor of establishing a "carve-out" with a separate funding formula for these jurisdictions. Similar to programs in U.S. states and large cities, the carve-out for U.S. territories and USAPI should be aligned with the percentage of the total morbidity and adjusted accordingly. The funding formula should be designed to address

the infrastructure capacity and special needs of these programs. The workgroup proposed a funding carve-out of 3.5% because U.S. territories and USAPI account for ~3.5% of TB cases in the United States.

In terms of the overall funding formula, the workgroup was in favor of retaining all of the current data elements, but some changes were suggested. A new data element should be added for immigrants and refugees who arrive to the United States with "B-status" applications (e.g., suspected TB cases or new arrivals who need further evaluation). The new element should be weighted at 5%. This change would cause a 5% reduction in the weight associated with U.S.-born minorities/FBP. The MDR-TB data element should be changed to "rifampin resistant TB" to address treatment issues and associated costs for programs.

The workgroup considered other data elements to the funding formula (e.g., economic factors, binational morbidity and contact investigation activities). The workgroup eventually agreed that these proposed data elements should not be incorporated into the funding formula due to the lack of reliable data sources to support these changes.

Based on its discussions, the workgroup proposed the following funding formula: 30% to incident cases, 30% to U.S.-born minorities and FBP, 15% to smear-positive pulmonary cases, 5% to TB/HIV co-infection, 5% to rifampin-resistant cases, 5% to substance abuse, 5% to homeless, and 5% to EDN arrivals.

In terms of implementation, the workgroup discussed the possibility of all programs immediately and fully shifting to the proposed formula. On the one hand, some workgroup members expressed concern that a 100% shift may adversely impact current infrastructures and cause a negative impact on progress toward TB elimination. On the other hand, other workgroup members recognized that further delay in implementation of the TB funding formula may impact additional progress in some high burden jurisdictions.

The workgroup proposed the following implementation schedule to resolve this dilemma: 40% base funding and 60% formula funding in 2013; 30% base funding and 70% formula funding in 2014; 20% base funding and 80% formula funding in 2015; 10% base funding and 90% formula funding in 2016; and 0% base funding and 100% formula funding in 2017.

In consideration of the continuing shift in TB epidemiology nationwide and ever-changing trends within TB control jurisdictions, the 5-year cohort of data that would be used in the formula calculations and reflect this dynamic over time is reasonable. For example, both 2013 and 2014 funding would be based on 2006-2010 data; both 2015 and 2016 funding would be based on 2008-2012 data; and 2017 funding would be based on 2010-2014 data.

In terms of performance measures, the workgroup agreed that two performance-driven funding measures should be established and account for 20% of total funding allocated to programs. The largest proportion of performance funding (or 75%) should be targeted to completion of treatment within two years, excluding rifampin-resistant cases. The remaining 25% of performance funding should be determined by culture-positive TB cases and completion of DST for INH, RIF and emthambutol.

If the workgroup's proposed performance funding had been implemented in 2011, ~$14.6 million would have been redistributed (e.g., ~$11 million for DST and ~$3.6 million for completion of treatment). The workgroup identified a number of complicating factors in calculating the proposed performance funding and emphasized the need to answer several questions.

- What happens to funds that programs do not earn?
- If measures are not met, is it a sign of lack of resources?
- In the spirit of CoAg funds, what is DTBE's role and responsibilities in ensuring programs meet the performance measures?
- Should the performance measures be determined annually or based on an average of a proportion of years?
- What steps should be taken to address the disconnect between cause and impact as a result of delays in the availability of data?
- What strategies should be implemented to address the small number of TB cases in low incidence areas?
- What mechanisms should be incorporated if performance measures are entirely out of the control of the program?

The workgroup proposed several suggestions to address some of these issues. If a program does not meet a performance-driven funding measure, DTBE should restrict and redirect "unearned" funding into other activities of the same program to improve its capacity to meet the target in the future. DTBE should take this action in consultation and collaboration with the program. Before discussions are held on the 2018 funding cycle, DTBE should evaluate and report to NTCA the impact of linking a portion of TB program funding to the selected performance measures to determine success, added value or additional burden.

In terms of reported TB data, the workgroup recommended that DTBE and programs jointly review all data variables prior to final calculations and distribution of the funding formula. This mechanism should be used to assure accurate distribution of funding to programs and improve the presentation of DTBE's national data reports. The workgroup made this recommendation due to concerns regarding differences between TB data at DTBE and program levels.

Overall, the workgroup made strong efforts to be as transparent as possible in its deliberations. The meeting minutes, discussion points, potential scenarios, and other key outcomes of both the 2008 and 2011 workgroups are available on the NTCA website at http://tbcontrollers.org.

Overview of the TRUST Report: Laboratory Component

Frances Pouch Downes, DrPH
Laboratory Director, Michigan Department of Community Health
ACET Liaison, Association of Public Health Laboratories

Angela Starks, PhD
Microbiologist, Laboratory Capacity Team/DHQP
Centers for Disease Control and Prevention

Drs. Downes and Starks presented an overview of the laboratory component of the TB CoAg. CDC has awarded TB CoAgs to laboratories since 1992 to support laboratory upgrades and enhancements. The 64 grantees include all 50 states, the District of Columbia, 6 large cities, and 6 USAPI. The funding level was $7.4 million FY2011. The original emphasis of the CoAgs in 1992 was to improve laboratory performance through the use of rapid methodologies (e.g., fluorescence microscopy and liquid culture).

Since 1992, the grantees have focused on the intent of the CoAg funds to upgrade and enhance rapid turnaround times and develop a strong integrated laboratory system in collaboration with numerous partners (e.g., clinicians, TB control programs and other public health laboratories). The FY2005 awards were determined using a historical base and a formula calculation that included the number of TB cases for which the laboratory provided a result (e.g., NAAT, culture, identification, DST or referral for genotyping). The new workload-based formula in FY2011 incorporated multiple variables as a result of recommendations by the 2008 Laboratory Funding Formula Workgroup.

To fulfill its charge of reviewing the funding intent and formula, the workgroup focused on options for maximizing efficiencies to support the Laboratory Network. All options proposed by the workgroup would retain direct laboratory-based funding due to the essential need for laboratory services for TB control and elimination efforts. The workgroup considered a restructuring option that would incorporate regionalization of services as described in the TRUST Report. The workgroup's recommendations addressed several critical issues and were aligned with responses to the TRUST Report by other partners.

The workgroup took several actions to meet its charge. The existing formula, redistribution schedule and funding floor were reviewed in light of potential budget reductions, the evolving role of public health laboratories, and declining test volumes in some jurisdictions. The workgroup conducted its activities in parallel to the TB Prevention and Control Workgroup and held regular teleconferences in July-October 2011. The minutes of the teleconferences were routinely posted on the APHL website to assure transparency. The workgroup included representation by laboratories with low, medium and high testing volumes, NTCA, APHL and DTBE.

The workgroup considered 5 key questions as the basis for formulating its recommendations. One, should DTBE retain the intent of laboratory funding to upgrade and enhance services? Two, does the current TB laboratory funding formula need modification? Three, should a performance indicator be incorporated into the funding formula? Four, is the current funding amount for the laboratory component sufficient for sustaining investments in expanding access to molecular diagnostics? Five, should the formula include a mechanism to support and encourage regional testing rather than testing in every state?

In terms of the intent of laboratory funding, the workgroup considered the historical intent of upgrading and enhancing TB laboratory services and recommended a change in the language to "strengthen and enhance TB laboratory services." The proposed change reflects an understanding of laboratories implementing many new technologies that have now become core services. The CoAg should encourage the exploration and incorporation of best technologies and practices for strengthening laboratory systems.

The workgroup recommended retention of the current formula elements with some modifications to weights and changes in calculations for elements focused on direct detection (e.g., NAAT). In the proposed laboratory funding formula, 10% would be allocated based on the total number of specimens; 10% would be equally allocated to laboratory systems across jurisdictions; and the remaining funds would be allocated on a per patient basis: TB cultures inoculated (15%), isolates received for identification (15%), NAAT of clinical specimens (25%), and DST for FLDs (25%).

The workgroup determined the base amount for NAAT based on the number of patients for whom clinical specimens would be received. The remaining funds would be distributed based on the number of patients who were found to be positive as a result of direct detection of *M.tb*.

The workgroup recommended redistribution with 60% of each award determined by the laboratory funding formula beginning in FY2013 with a 10% increase each year. With this approach, 100% of formula-based funding would be met in 2017. The workgroup's position was that jurisdictions would benefit from a gradual redistribution for management of funding increases or decreases. The workgroup was in favor of maintaining the $35,000 floor to ensure no U.S. laboratory receives less than this amount. Funding for USAPI laboratories should remain level.

In terms of performance indicators for the TB laboratory funding formula, the workgroup discussed the fact that CDC receives useful data from a number of different sources (e.g., the National Tuberculosis Surveillance System, CoAg progress reports, surveys, and the Model Performance and Evaluation Program) to better understand the performance of the Laboratory Network. Turnaround times are the primary component in assessing laboratory performance.

In 1993, CDC established its current recommendations regarding turnaround times primarily on the basis of implementation of a fluorescent acid-fast stain and liquid culture. As a result, a comprehensive assessment and update of these indicators are needed at this time. The workgroup recommended an assessment of the current indicators along with the selection and incorporation of a relevant and evidence-based performance element into the funding formula by 2015.

The workgroup expressed numerous concerns about the performance indicators, including differences in patient populations across regions, diverse disease presentations (e.g., extra-pulmonary versus pulmonary TB), and difficulties in transporting specimens that impact turnaround times, but are beyond the control of laboratories.

The workgroup reviewed alternate service delivery (ASD) models and raised several questions regarding proficiency as the volume for some laboratory tests continues to decline. The workgroup was aware that shared services, regionalization or ASD models could prove to be cost-effective and safeguard quality, but data are lacking on these systems.

The workgroup did not adopt an "all or nothing" approach because ASD models may be better suited to low-volume, highly specialized tests (e.g., DST). The workgroup noted that not all laboratories need to provide the same services, but access to reference level services is needed by all laboratories. The workgroup also examined redirection of funding from laboratories with low-volume testing for DST to higher volume testing centers.

The workgroup encountered difficulties in establishing a threshold for ASD models because low-volume laboratories currently use CoAg funds for personnel support primarily rather than DST reagents. The impact of the redirection of funds on the ability to provide support to grant-funded full-time equivalents is unknown. Operational research is needed to examine the feasibility of consolidated approaches.

The workgroup abandoned its proposed directed approach and agreed to advocate for voluntary consideration of referrals for laboratories that perform first-line DST for <50 patients per year. The workgroup was not in favor of redirecting CoAg funds and recommended the establishment of testing centers (e.g., Centers of Excellence) to perform first-and second-line DST and rapid MDDR. Each center would perform these services at an estimated cost of $165,000 per year.

In FY2011, CDC awarded supplemental funding to APHL in the amount of ~$300,000 to support pilot approaches toward increased consolidation or regionalization of certain laboratory tests (e.g., DST or molecular testing). The pilot will include an evaluation of cost, volume, proficiency and systems issues that will be critical for identifying effective models in consolidating laboratory services.

CDC expects that a limited number of awards will be made for joint applications submitted by state and local public health laboratories. However, this approach is complimentary to current efforts by the CDC Laboratory Science, Policy and Practice Program Office to improve increased efficiencies.

The workgroup considered the need for increased support to public health laboratories in light of continued funding constraints. The intent of laboratory CoAg funds historically has focused on upgrading services (e.g., liquid culture and fluorescence microscopy), but laboratories began to implement rapid technologies for direct detection of TB and provide MDDR services at an additional expense.

Although no new funds were allocated to the laboratory component of the TB CoAg, this source provided the majority of funds to fully implement genotyping. Anecdotal experiences reported to CDC confirmed that funds increasingly are being utilized to maintain core services. In response to the TRUST Report, both NTCA and APHL recommended an increase in overall support for the laboratory component of the TB CoAg.

The workgroup also recommended an additional $2.5 million to support the laboratory component of the TB CoAg. This amount was determined based on the mean number of patients for whom DST was performed as a surrogate for detectable TB cases in 2008 and 2009. The cost was estimated at $100 per test. The workgroup emphasized that the additional funding would be critical for sustaining DTBE's investment in NAAT methods. Many public health laboratories were able to implement these methods as a result of the supplemental award to APHL in FY2010.

The workgroup viewed rapid technologies as a part of a comprehensive testing menu to continue progress toward TB elimination. DTBE recently awarded another supplemental grant to APHL in the amount of ~$400,000 to conduct operational studies to evaluate effective testing algorithms and assess the performance of molecular assays in low incidence settings. This initiative potentially could lead to cost efficiencies in laboratories.

Overall, the workgroup primarily followed the TRUST process in issuing its recommendations. The historical intent of the laboratory component of TB CoAg funds should be modified to strengthen laboratory systems. The laboratory formula that recently was implemented in FY2011 only needs minor modifications. A phased evidence-based approach is needed to incorporate performance indicators into the funding formula after an evaluation is conducted.

Examination and implementation of ASD models is needed in some cases. Increased support is needed for the laboratory component of the TB CoAg. DTBE will collaborate with the CDC Procurement and Grants Office to write new language for inclusion in the FY2013 FOA. DTBE will collaborate with partners to develop a communication and dissemination plan on the laboratory recommendations.

Leadership Response to the TRUST Report Recommendations

RADM Kenneth Castro, MD
Assistant Surgeon General, U.S. Public Health Service
Director, Division of Tuberculosis Elimination/NCHHSTP
Centers for Disease Control and Prevention

Dr. Castro provided DTBE's leadership response to the TRUST Report recommendations. In terms of general issues, DTBE's primary goal will be to protect core public health functions (e.g., monitoring and evaluation, policy development, assessment and research). DTBE will continue its strong focus on crucial partnerships (e.g., public health departments, laboratories, FQHCs and other elements of the healthcare delivery system).

DTBE will fully embrace PCSI as a key component in implementing the recommendations. DTBE will take actions to shift to an outcomes-oriented approach. DTBE is not supportive of a regional approach to TB control at this time because TB is a communicable disease and remains a local issue. Most notably, regional TB centers could not replace the essential function of local TB programs in conducting contact investigations.

In terms of the specific recommendations by the TB P&C Workgroup, "MDR-TB" should not be changed to "rifampin resistant TB" in the funding formula. DTBE heavily depends on funding to specifically address the well-established, well-known and publicly recognized brand of "MDR-TB." DTBE agrees with the HRD recommendations and fully supports the suggestion to eliminate the hold harmless category.

DTBE is in favor of a minimum funding amount to all TB P&C programs, but this threshold should be $100,000 rather than the workgroup's proposed level of $65,000. The threshold will be needed for local surveillance activities, monitoring and evaluation, and oversight capacity. DTBE supports the option for states and large cities in those states to submit joint grant applications at some point in the future, but this suggestion is not feasible at this time.

DTBE agrees with the recommendation for a carve-out of funds to U.S. territories and USAPI. DTBE endorses the recommendation to expand the TB funding formula by adding immigrants and refugees who arrive to the United States with "B-status" applications. DTBE agrees that an incremental approach is needed to shift to the TB funding formula to avoid unintended consequences and adverse impacts to programs, but the proposed schedule for 100% implementation in 2017 is too long. The funding formula should be phased-in at 60% in 2013, 80% in 2014, and 100% in 2015.

DTBE agrees that data cohort years should be incorporated into the formula calculations, but the time frames should be shortened to 2 or 3 years rather than 5 years. DTBE fully supports the performance-based funding measures, but consideration will be given to replacing the DST indicator with a validated and more meaningful indicator in the future (e.g., rapid laboratory turnaround times).

DTBE agrees that consistent with the spirit of the CoAg, technical assistance should be provided to programs before punitive measures are taken if performance measures are not met. However, DTBE's position is that the program's use of resources should be restricted until the deficiencies are corrected. To ensure transparency, DTBE fully supports the recommendation for NTCA to evaluate the impact of the performance measures.

In terms of specific recommendations by the Laboratory Workgroup, DTBE agrees with the TB funding formula overall, but the time frames should be shortened to be the same as the P&C funding formula. DTBE fully supports the recommendation to establish two new Centers of Excellence at an estimated cost of $330,000 per year. DTBE "approves" the allocation of an additional $2.5 million to the laboratory component of the TB CoAg, but the ability to leverage these new dollars is not possible at this time.

Dr. Castro thanked the workgroups for their diligent efforts in formulating thoughtful and deliberate recommendations. As the CDC Federal Advisory Committee, he asked ACET to provide DTBE with comments, suggestions and formal guidance on the workgroups' reports.

Kevin Fenton, MD, PhD, FFPH
Director, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention

Centers for Disease Control and Prevention

Dr. Fenton provided NCHHSTP's leadership response to the TRUST Report recommendations. He noted that DTBE's efforts to realign TB resources with the epidemic are similar to activities in other parts of NCHHSTP. Similar to TB, the realignment of resources for HIV, hepatitis and STD prevention will increase accountability and advance toward better measurement.

Dr. Fenton clarified that decisions to take action on ACET's recommendations will be made at high levels of NCHHSTP leadership, CDC Office of the Director, and HHS Office of the Secretary. He made a commitment to support ACET's guidance to the extent possible, but he noted that NCHHSTP would thoroughly review the intended and unintended consequences of changes in the TB funding formula. For example, low incidence jurisdictions most likely would face the most difficult impacts.

Dr. Fenton joined Dr. Castro in thanking DTBE, NTCA and APHL for establishing strong partnerships to develop the recommendations and propose creative solutions.

ACET Discussion on the Panel Presentation

Shannon Jones III, ACET Chair
Acting Director, Public Health and Community Services, City of Austin/Travis County
Texas Health and Human Services Department

Mr. Jones facilitated ACET's discussion on the series of presentations that were made regarding the future direction of TB control and elimination in the United States. The panel of speakers provided additional details on their respective presentations in response to ACET's specific questions. The discussion topics included:

- the need for a national effort to advocate for TB resources with multiple entities (e.g., Stop TB USA, TAG, other external partners, practicing physicians and TB patients);
- key messages advocacy organizations should convey to policymakers and other partners on the critical need for additional TB resources;
- the integration of global and domestic TB activities by focusing on core public health functions (e.g., accurate and timely diagnosis of TB, prevention of transmission through curative treatment, and protection of contacts);
- the need to maintain the NTCA meeting as an annual event despite limited resources;
- CDC's efforts to reduce intramural expenditures (e.g., travel, staffing, conference attendance, non-performing programs, and under-funded activities with no significant impact);
- evaluation of the performance-based funding measures to determine their effectiveness;
- allocation of TB control dollars to urban cities that would not classify as "large" programs to better address health disparities;
- DHAP's more aggressive pace (e.g., 5 years) in realigning its HIV prevention funds compared to DTBE;

- the need to collect solid data on binational TB cases to provide to decision-makers;
- strategies to maintain the infrastructure and expertise in the field to respond to TB outbreaks in low-incidence areas;
- the possibility of conducting intensive surveillance in border states of infants born to mothers with TB from Mexico who cross to the United States to give birth;
- activities by the U.S.-Mexico Border Health Commission to prioritize TB; and
- potential roles and high-level testing activities of the 2 new Centers for Excellence.

ACET thanked the panel for making outstanding and informative presentations on the future direction of TB control and elimination in the United States. ACET also joined Drs. Castro and Fenton in thanking the workgroups for their tremendous efforts in developing solid guidance. ACET's comments and suggestions on the panel presentation are outlined below.

- Limited TB resources should be targeted to programs that will have the most significant impact in providing medications to patients. Of 1% of patients who are newly diagnosed with MDR-TB, only 50% are treated. In South Africa, 88% of XDR-TB strains are untreatable with existing drugs. Of all XDR-TB cases in South Africa, 80% occur in persons with no prior history of contact with patients with drug-resistant TB. These types of compelling data should be packaged and distributed to the media and general public. Professional societies (e.g., ATS, IDSA and the American Society for Microbiology) also should be engaged to broadly convey TB messages from CDC. This approach would be the best use of leveraging resources and knowledge.
- DTBE should not require TB grantees to attend the annual TB ETN conference and the National Program Manager's meeting due to limited resources. Webinars, video conferencing and other technology should be utilized to reduce travel costs of programs.
- The proposed approach of linking a portion of TB funding to performance indicators is of concern due to the potential for detrimental rather than constructive outcomes for some programs. This issue will be particularly problematic if programs began to subsume core and proven activities (e.g., DOT and contact investigations) by documenting indicators.
- Urgent TB disease control statistics should be included in the funding formula as a factor in determining allocations to programs. For example, a patient dies from TB every other day in California, Florida, Georgia, Illinois and Texas. However, these high-incidence states have been disproportionately funded for a long period of time.
- TB along the U.S.-Mexico border is a major public health problem, but CDC does not appear to prioritize this issue based on its funding allocations. The burden of TB is extremely high within the four U.S. states that face the Mexico border (e.g., Arizona, California and New Mexico and Texas). With the exception of a few binational projects, virtually no action has been taken to curtail Mexico-born persons with TB who routinely travel between the two countries and tremendously impact the incidence of TB in the United States.
- Programs will not have sufficient flexibility to respond to a rapid or dramatic change in TB epidemiology based on the proposed data cohort years for formula calculations. For example, the workgroup proposed the use of 2006-2010 data in 2013-2014. ACET's formal resolutions should support Dr. Castro's suggestion to shorten the data cohort years to 2 or 3 years rather than the proposed 5-year time frame.

- NTCA recommended the retention of a genotyping initiative, but was not in favor of increasing the investment in this area due to lack of timeliness. However, genotyping is a viable TB control tool and resources for this effort should not be eliminated. Instead, an investigation should be conducted to determine the rationale for the lack of timeliness in genotyping and resolve these issues.
- ACET should formulate recommendations specifically to address the extremely high rates of TB in USAPI citizens. Unlike refugees and immigrants from other countries, USAPI citizens are free to travel to the United States with no screening requirements or other restrictions.

With no further discussion or business brought before ACET, Mr. Jones recessed the meeting at 5:15 p.m. on December 6, 2011.

Opening Session: December 7, 2011

Hazel Dean, ScD, MPH
Deputy Director, NCHHSTP
Centers for Disease Control and Prevention
ACET Designated Federal Official

Dr. Dean conducted a roll call to determine the ACET voting members, *ex-officio* members and liaison representatives who were attending the meeting in person and via teleconference. She verified that the voting members and *ex-officio* members constituted a quorum for ACET to conduct its business on December 7, 2011.

Dr. Dean called the meeting to order at 8:55 a.m. and welcomed the participants to the proceedings. She announced that ACET meetings are open to the public and all comments made during the proceedings are a matter of public record. She reminded the ACET voting members of their responsibility to identify individual potential conflicts of interest and recuse themselves from participating in these matters.

Shannon Jones III
Acting Director, Public Health and Community Services, City of Austin/Travis County
Texas Health and Human Services Department
ACET Chair

Mr. Jones asked the participants to join him in a moment of silence to honor Mr. Daniel Reyna. Mr. Reyna passed away on July 29, 2011 and previously served as ACET's *ex-officio* member for the HHS Office of Global Affairs.

Mr. Jones announced that the agenda would be slightly modified because some ACET members did not have sufficient time to prepare their resolutions for the upcoming business session. To address this concern, the 30-minute time period for a follow-up discussion on the

workgroup reports would be replaced with a break. The ACET members could use this time to meet in small writing groups to develop and refine their respective resolutions.

Update by the Affordable Care Act (ACA) Workgroup

Barbara Seaworth, MD
Medical Director, Heartland National TB Center
ACET Member & Affordable Care Act Workgroup Chair

Dr. Seaworth covered the following topics in her update on the workgroup's activities. The workgroup was charged with identifying strategies to utilize ACA to improve care for TB patients. The workgroup initially identified 5 key problems to guide its discussions. One, with the exception of services to high-risk children, the current ACA language and guidance documents fail to mention TB P&C. Two, without inclusion of TB language, providers will have no financial incentive to provide services.

Three, delayed diagnosis and treatment may lead to sicker patients, increased medical costs and ongoing transmission. Four, opportunities are not maximized to promote a medical/public health model that recognizes the critical importance of a public/private collaboration and assures a safety net for persons who fail to access care. Five, the importance of TB treatment is not adequately recognized in the National TB Agenda. The workgroup's position is that TB treatment is the only means of preventing the disease. Moreover, TB should be included in the diseases covered by ACA because treatment is prevention.

The American Academy of Pediatrics strongly advocated for the inclusion of language in ACA to provide preventive care for children through a recommendation by HRSA. ACA language addresses primary prevention of diseases through vaccines, but does not address prevention of diseases through treatment. The Medicaid expansion language includes a limited reference to high-risk children as well.

Omnibus Budget Reconciliation Act of 1993 includes language on TB that covers prescribed drugs; services by physicians, outpatient hospitals, rural health clinics and FQHCs; laboratory and x-ray services, including those to confirm the presence of TB infection; case management services; and DOT and other services, with the exception of room and board, to improve adherence. However, state Medicaid programs have the option of covering these preventive measures.

The U.S. Preventive Services Task Force's (USPSTF) Grade A and B recommendations are included in ACA preventive services and are offered without cost sharing to an individual patient. Although these recommendations typically are targeted to screening that impacts large populations, USPSTF issued a Grade A recommendation in 2008 for screening of syphilis in all pregnant women. At that time, <500 congenital syphilis cases were reported in the United States.

USPSTF also has issued treatment recommendations (e.g., aspirin to prevent cardiovascular disease for men and women, fluoride for children, folic acid for pregnant women, iron supplementation in children <6 years of age who are at risk of deficiency, and topical medication to the eyes of newborns to prevent gonorrhea). USPSTF has made no recommendations on TB and defers to CDC on this issue. As a result, CDC's screening recommendations for TB are not covered under ACA. Routine HIV testing is a Grade A recommendation for persons at high risk or those seen in high-risk settings.

ACA recognizes the essential role of CHCs. The opportunity for public/private collaboration may provide all TB patients with direct access to a provider. The current system is unable to achieve this goal. The TB community must outreach to and partner with CHCs for direct patient services. Public health must maintain the three core functions of assessment, policy development, and assurance that patients are identified and properly treated.

ACET published recommendations in the *MMWR* in 1995 outlining the essential components of TB P&C and screening for TB and TB infection in high-risk populations. ACET identified the top 3 priorities as identifying and treating active TB; locating and screening TB contacts and providing treatment if appropriate; and screening high-risk populations and providing treatment to TB-positive persons.

The workgroup identified roles and responsibilities to retain these essential components. Health departments should be responsible for overall planning and policy of TB control activities; adherence-related activities, including confinement; infection control and contact investigations; drug resistance surveillance; and data analysis and program evaluation. Community providers and partners should be responsible for screening and treatment of TB infection, clinical consultative services, management of TB cases and suspects, and training and education.

Dr. Seaworth summarized the workgroup's preliminary solutions to utilizing ACA to improve the care of TB patients. TB should be separated from other population-based screening activities. For purposes of ACA, TB should be viewed as the evaluation and management of individuals with known or likely exposure to infectious TB because treatment is the only means of prevention in this patient population. The overarching goal is to provide treatment for the benefit of both the individual patient and public health.

Advocacy and funding for TB should be increased within NCHHSTP and across CDC. The workgroup was aware that one of the major challenges is the low profile of TB even within NCHHSTP. For example, screening and prevention of HIV and hepatitis are emphasized in the "Framework for Preventing Infectious Diseases: Sustaining the Essentials and Innovating for the Future" that CDC released in October 2011. However, the framework briefly mentions TB in only two areas: (1) the use of RTMCCs as an approach to limit acquired drug resistance and (2) advancement of strategies to enable co-treatment of frequently associated conditions (e.g., HIV, STDs and TB).

Efforts should be made to nominate an expert with a public health background to serve on USPSTF and include TB screening as a Grade A or B recommendation. Partnerships should be established to gain support for the concept that treatment of TB actually is prevention. After

the workgroup contacted the National Association of County and City Health Officials (NACCHO), this group drafted a letter to support this concept.

"Latent" in the context of TB infection should be de-emphasized because this word promotes a false sense of security that LTBI is of no concern. Some states have already replaced "LTBI" with "TB infection" in their guidance documents and communication materials. Emphasis should be placed on the continuum of TB (e.g., exposure, infection and disease) in some high-risk populations. Most notably, 60% of children <1 year of age will progress to active TB disease. Other vulnerable populations that may progress to life-threatening TB disease in a short period of time include patients on TNF-alpha blocker medications, transplant patients and diabetics.

Ongoing efforts to include coverage of all TB services in ACA should be continued. Advocacy should be targeted to two major areas: (1) a safety net for persons with TB who will not qualify for care under ACA (e.g., undocumented persons) and (2) an encounter with a qualified provider for all persons who are TB suspects.

William Baine, MD
Senior Medical Advisor, Center for Outcomes and Evidence
Agency for Healthcare Research and Quality
ACET Ex-Officio Member

Dr. Baine made some clarifying remarks regarding the workgroup's recommendations on USPSTF. The Agency for Healthcare Research and Quality (AHRQ) provides funding and support to USPSTF. However, USPSTF has statutory autonomy and does take instructions or directives from AHRQ. He noted that before TB screening can become a Grade A or B recommendation for inclusion in ACA, USPSTF must first conduct a comprehensive and rigorous evidence review. Based on the results of the evidence review, USPSTF then decides whether to recommend a preventive service as Grade A, B, C, D or I statement.

As an interim solution to the ongoing efforts to change the legislation, Dr. Fenton raised the possibility of USPSTF issuing a clear statement of ratification on CDC's recommendations. For example, USPSTF merely deferred to CDC on TB screening without issuing a formal position statement.

Dr. Baine confirmed that he would explore Dr. Fenton's suggestion if CDC and ACET provided him with draft language. However, he pointed out that a statement by USPSTF ratifying CDC's recommendations still would not be sufficient for TB screening to be covered under ACA. Dr. Castro noted that the newly-established TB Congressional Caucus might be the most appropriate body to address the legislative aspects of including TB screening in ACA.

ACET's comments and suggestions on the workgroup's preliminary recommendations are outlined below.

- A precedent should be considered in which USPSTF deferred authority to the CDC Advisory Committee on Immunization Practices (ACIP) for coverage of vaccines. In this model, for example, USPSTF would defer authority to ACET for coverage of TB

screening. This approach would be much less contentious and controversial than the workgroup's recommendation to include TB screening in ACA. However, legislation still would need to be changed because unlike ACIP, ACET's recommendations are not required to be funded.

- ACET should compile solid evidence for TB prevention and treatment in a usable format for USPSTF and decision-makers. CDC's voluminous guidelines should be streamlined to identify and focus on only the specific aspects of TB treatment, case prevention and cost-savings that should be recommended. For example, cost data have been produced that suggest TB treatment is more effective than cervical cancer screening in prolonging life and saving costs. USPSTF's treatment recommendations are extremely specific (e.g., gonorrhea treatment of newborns and cervical cancer screening). The evidence base for USPSTF to issue TB treatment recommendations also must be distilled and focused accordingly.
- CDC recently released the TB Control Statement, but this publication and other guidance documents should be reviewed and updated to emphasize that treatment is prevention for TB and other communicable diseases without an effective vaccine. Consideration also should be given to changing the title of the document to the "TB Prevention and Control Statement." Moreover, "treatment is prevention" should be the theme for World TB Day.
- Policymakers should be informed and educated that unlike Ryan White dollars for HIV treatment and care, no federal funding is allocated to the treatment of TB or LTBI. However, states should be informed of the ability to use Medicaid for LTBI treatment of refugees. All newly-arrived refugees are covered by Medicaid for 8 months.
- Efforts should be made to contact and develop relationships with the decision-makers who serve on USPSTF to begin taking concrete action steps toward initiating an evidence review, grading TB screening as an A or B recommendation, and including this preventive service in ACA.
- Consideration should be given to expanding the existing HRSA recommendation in ACA to provide preventive services to high-risk children to include populations at high risk for TB. This approach may be easier and faster than USPSTF's lengthy evidence review process to grade a preventive service.
- The possibility should be explored for NACCHO, the Association of State and Territorial Health Officials and other professional associations to advocate for all state Medicaid programs to adopt the ACA preventive services.
- The workgroup should align its recommendations with the 10 essential public health services that were defined by CDC and other public health agencies at state and local levels. These services are well established, widely recognized and broadly accepted by the public health community.
- The workgroup should take caution in recommending that all TB suspects have an encounter with a provider, particularly in the absence of solid data to demonstrate the effectiveness and practicality of this intervention. Most notably, access to providers is particularly challenging for TB patients in rural areas.
- ACET should formalize and promote some of the workgroup's recommendations that may have a positive impact when TB funding decisions are made. For example, workloads of health departments that are not reflected in TB incident cases should be documented (e.g., screening of TB contacts and evaluation of persons identified as TB

suspects through laboratory testing). The HIV model should be replicated in which "latent" would be dropped from "TB infection" and emphasis would be placed on the number of TB-infected persons in the country. The term "LTBI" should be changed because the language is a disservice to patients and the broader TB community. Compelling messages should be framed to combat the false sense of security that has occurred due to the declining trends in TB. National success in this area has led Congress, policymakers, the media, the general public and even some providers to believe that TB is no longer a public health problem in the United States. These messages should be developed to clearly articulate the meaning of "LTBI" and describe the critical need to continue to focus on LTBI. Consideration should be given to making LTBI a state reportable condition to increase its importance to policymakers and facilitate the development of tangible goals. Mr. Griffin informed ACET of a "real-world" example on this issue that can be documented with solid data. After he replaced "LTBI" with "TB infection" on the reportable disease list in 2004, the Kansas Tuberculosis Control Program has seen a 60% decline in TB infection, a 55% reduction in active TB disease, and an increase in funding over the past 7 years.

- ACET should take caution in de-emphasizing "latent" in the context of TB infection for public relations purposes. LTBI is biologically different than HIV infection. Instead, emphasis should be placed on making LTBI a state reportable condition, describing the epidemiology of LTBI, and documenting populations in which conversions occur.

Dr. Fenton advised the workgroup to expand the responsibilities of health departments in the essential components of TB P&C with more cross-cutting, strategic and networking activities (e.g., providing collaborative and integrated opportunities and exploring strategic partnerships with the private sector, homeless shelters and other entities to make more efficient use of limited resources).

Dr. Fenton strongly supported the workgroup's recommendation to de-emphasize "latent" in the context of TB infection. He was aware that the global success in decreasing HIV incidence would not have been achieved if HIV infection was characterized as "latent HIV infection." Although 11 million Americans are infected with TB, the word "latent" decreases the sense of urgency. In its future discussions, Dr. Fenton encouraged ACET to explore political issues, the epidemiology and science of TB or other reasons that make the TB community reluctant to de-emphasize "latent" in the context of TB infection.

In response to Dr. Fenton's comments, Dr. Castro confirmed that DTBE, ATS and IDSA would discuss this issue. These groups are continuing to update the TB Diagnosis and Treatment Statement.

ACET Business Session

Shannon Jones III, ACET Chair
Acting Director, Public Health and Community Services, City of Austin/Travis County
Texas Health and Human Services Department

Mr. Jones opened the business session and called for ACET's discussion and formal action on the following topics.

TOPIC 1: A motion was properly placed on the floor and seconded by Drs. Jane Carter and Marcos Burgos, respectively, for ACET to approve the previous meeting minutes. ACET **unanimously approved** the June 7-8, 2011 Draft Meeting Minutes with no changes or further discussion.

TOPIC 2: Mr. Jones announced that he received a formal response from HHS Secretary Kathleen Sebelius regarding ACET's annual TB report. In a letter dated June 10, 2011, Secretary Sebelius confirmed that she would ask Dr. Howard Koh, Assistant Secretary for Health, to be available for a face-to-face briefing with ACET to discuss specific aspects of the report. She was particularly interested in ACET's recommendations regarding collaboration with the Department of Homeland Security, efforts to address special populations, and the need for programmatically relevant research.

Mr. Jones, Dr. Dean and Dr. Castro have been attempting to schedule the meeting with Dr. Koh before the next ACET meeting. After the date is confirmed, Mr. Jones and CDC will solicit volunteers from ACET to attend the meeting. Secretary Sebelius' letter was distributed to ACET for review.

TOPIC 3: Dr. Mayleen Ekiek is the liaison representative to the Pacific Island Health Officers Association (PIHOA). She reported that the 6 USAPI countries include the Commonwealth of the Northern Mariana Islands, Guam, Republic of Palau, Republic of Marshall Islands, Federated States of Micronesia, and American Samoa.

USAPI Health Ministries and departments founded PIHOA in 1987 as a non-profit corporation to provide a regional voice for the 6 USAPI jurisdictions; serve as a cross-border forum for developing solutions, adopting policy and improving funding sources; and function as a primary venue for health collaborators where population centers are isolated. PIHOA closely collaborates with WHO, CDC and the Secretariat of the Pacific Community to coordinate policy and resources.
Dr. Ekiek presented PIHOA's six recommendations for ACET's consideration and formal action during the next meeting. One, TB funding should be increased in USAPIs. The region is the most vulnerable to TB and could be a significant source of TB and MDR-TB transmission in the United States if not appropriately resourced.

Two, effective strategies should be supported to ensure rapid availability of SLDs because these drugs are extremely costly. Three, the development of a long-range plan should be supported to build capacity both locally and regionally. Potential components of the plan include the CDC-sponsored Pacific Island Tuberculosis Controllers Association (PITCA), Serial Epi-Aids and deployment of CDC staff to the field.

Four, the development of overall data and surveillance capacity should be supported with long-term placement of DTBE staff in USAPIs, including an epidemiologist or public health advisor. HHS should support this recommendation as a long-term solution for effective communicable

disease surveillance in USAPIs. ACET should explicitly identify the development of cross-cutting epidemiologic and data capacity across USAPIs as a desirable outcome and prerequisite to effective TB control.

Five, assistance should be provided to develop local laboratory capacity. PIHOA has partnered with the Guam Department of Public Health and Social Services in the development of a Level 2 laboratory over the next two years. The governor of Guam has committed $1.2 million to this project. HHS should be encouraged to make this project a priority. ACET should explicitly identify the development of local and regional laboratory capacity for both Level 1 and 2 laboratory needs.

Six, strategies should be explored that fully meet TB training needs in USAPIs and more effectively strengthen the overall core public health and educational capacity in USAPIs. The Associate of Science Degree in Public Health Program recently was initiated at the College of Federated States of Micronesia. Similar programs are planned for Palau and the Republic of Marshall Islands. However, these programs are in jeopardy because Congress will eliminate funding. An alternative is to rely on periodic and standalone workshops, but these initiatives rarely provide credit or contribute to a degree. ACET should consider the impact and desirability of this approach in long-term TB capacity building.

In preparation of revisiting the recommendations Dr. Ekiek presented during the next meeting, ACET advised PIHOA to consider collaborating with CDC, PITCA, American Lung Association and other partners to conduct a comprehensive TB program review in USAPIs.

TOPIC 4: Dr. Dean announced that ACET traditionally has held 3 face-to-face meetings per calendar year in Atlanta. Due to budget constraints, however, NCHHSTP leadership is exploring the possibility of shifting to a 2-meeting schedule with a combination of face-to-face and webinar/teleconference meetings.

ACET extensively discussed the pros and cons of retaining the 3-meeting schedule versus shifting to a new 2-meeting schedule. ACET members concurred with the shift to a 2-meeting schedule with a combination of face-to-face and webinar/teleconference meetings to reduce the burden on DTBE's budget. However, several ACET members were uncertain of the ability of Dr. Dean, as the Designated Federal Official, to verify the presence of a quorum at all times during a webinar or teleconference.

The ACET members described their previous experiences in which other Federal Advisory Committees were required to rescind formal resolutions because the participants on webinars or teleconferences did not constitute a quorum. Moreover, a webinar/teleconference would not allow ACET to meet in small writing groups to develop or refine proposed resolutions.

To address this dilemma, ACET proposed the following schedule to account for CDC's budget constraints, while attempting to meet its need to continue to meet 3 times per calendar year.

- Meeting 1: Traditional face-to-face meeting in Atlanta in or around March

- Meeting 2: Webinar/teleconference meeting in or around June with updates only and no business session for ACET to propose formal resolutions
- Meeting 3: Traditional face-to-face meeting in Atlanta in or around October.

Dr. Jane Carter is an ACET member and chair of the ACET Meeting Workgroup. During ACET's first face-to-face meeting in 2012, she would present the workgroup's recommendations on the potential format and topics of a face-to-face versus a webinar/teleconference meeting. She hoped that the workgroup's guidance would allow ACET to feel comfortable in shifting to a 2-meeting schedule in 2013.

TOPIC 5: Dr. Gail Cassell is an ACET member and chair of the NTP Workgroup. During the next meeting, she would present the workgroup's first formal report to ACET. In the interim, however, she outlined the workgroup's proposed strategy. The workgroup proposes to conduct a review of TB case rates by high, medium and low incidence states. Alternatively, the workgroup may conduct the review of the domestic NTP by making site visits to regions based on case frequency. The workgroup expects that 6-8 weeks will be needed to develop questions and criteria to conduct the review. The workgroup will distribute the proposed process to ACET for review and comment.

ACET advised the workgroup to closely collaborate with RTMCCs if the review will be conducted by region, use DTBE's surveillance and laboratory data, and categorize programs by frequency of MDR-TB cases. The workgroup also was advised to replicate WHO's existing process and tools that are used to conduct TB program reviews. ACET encouraged the workgroup to solicit external expertise to conduct the review and consult with NTCA to clearly define a "functioning" TB program.

TOPIC 6: The following motion was properly placed on the floor and seconded by Drs. Jane Carter and Masahiro Narita, respectively. "ACET recommends that DTBE provide Stop TB USA with support in the form of funding for a part-time Executive Director; technical support for website enhancement; and technical support to result in a 501(c)(3) application to support activities. ACET recommends that a Public Health Prevention Specialist Fellow potentially evaluate technical support to Stop TB USA. ACET proposes support to Stop TB USA in the amount of $100,000 annually for a period of five years with the eventual aim of Stop TB USA having fiscal independence at that time." **ACET unanimously approved the resolution.**

TOPIC 7: The following motion was properly placed on the floor and seconded by Drs. Jane Carter and Barbara Seaworth, respectively. "ACET recommends that DTBE adopt all 5 of the DTBE/APHL recommendations presented to ACET by the Laboratory Workgroup." **ACET approved the resolution by a majority vote with Dr. Eric Brenner abstaining and Drs. Susan Dorman and Christine Hahn opposing.**

TOPIC 8: The following motion was properly placed on the floor and seconded by Drs. Jane Carter and Barbara Seaworth, respectively. "ACET recommends that DTBE de-emphasize the term "latent" in future publications and statements with immediate notification to any writing groups and emphasize the continuum of infection to disease." **The resolution was withdrawn.** Dr. Eric Brenner will draft new language and reintroduce the motion at the next meeting.

TOPIC 9: The following motion was properly placed on the floor and seconded by Drs. Jane Carter and Christine Hahn, respectively. "ACET recommends that DTBE recommend to the Council of State and Territorial Epidemiologists to discuss with states the inclusion of TB infection in the list of state reported conditions." **The resolution was withdrawn.** The motion will be refined and reintroduced at the next meeting.

TOPIC 10: The following motion was properly placed on the floor and seconded by Drs. Jane Carter and Susan Dorman, respectively. "ACET recommends that DTBE (1) use GRADE criteria to review all TB studies over the past 20 years for acceptance in the USPSTF A/B recommendations, including IGRA and new short-course regimens; (2) summarize the cost-effectiveness of screening coupled treatment as prevention; and (3) pursue the process of including TB as a USPSTF recommendation." **ACET unanimously approved the resolution.**

TOPIC 11: The following motion was properly placed on the floor and seconded by Drs. Barbara Seaworth and Christine Hahn, respectively. "ACET recommends that DTBE develop a proposal to assure timely and affordable access to TB drugs for all patients throughout the country." **ACET unanimously approved the resolution.**

TOPIC 12: The following motion was properly placed on the floor and seconded by Drs. Barbara Seaworth and Christine Hahn, respectively. "ACET recommends that DTBE collaborate with ACET to define the burden of binational TB disease, determine the investment needed for binational TB control and elimination, and revisit this issue at the next meeting." **ACET unanimously approved the resolution.**

TOPIC 13: The following motion was properly placed on the floor and seconded by Drs. Masahiro Narita and Jane Carter, respectively. "ACET recommends that DTBE collaborate with ACET and Stop TB USA to publish an updated statement in the *MMWR* regarding the goal of eliminating TB in the United States." **ACET unanimously approved the resolution.**

TOPIC 14: The following motion was properly placed on the floor and seconded by Drs. Masahiro Narita and Christine Hahn, respectively. "ACET recommends that CDC harmonize TB testing cooperative agreements and contracts to reduce the shipping burden on state and local public health laboratories and improve the turnaround time." **ACET approved the resolution by a majority vote with Dr. Barbara Seaworth abstaining and Drs. Susan Dorman and Christine Hahn opposing.**

TOPIC 15: The following motion was properly placed on the floor and seconded by Drs. Eric Brenner and Susan Dorman, respectively. "ACET recommends that DTBE consider adding an item during the next revision of the Report Verified Case of TB to ascertain whether or not the TB case has a prior history of incarceration." **ACET unanimously approved the resolution.**

TOPIC 16: Mr. Jones opened the floor for ACET's discussion on restructuring the U.S. TB Program. Due to time constraints, Dr. Castro emphasized that DTBE first needs feedback from ACET on the TB funding formula because the new language must be submitted to the CDC

Procurement and Grants Office by the spring of 2012. He noted that ACET's comprehensive discussion on the TRUST Report could be placed on a future agenda.

ACET was not in favor of additional resources being targeted to increasing capacity for CDC to respond to outbreaks. States that perform TB control and investigate TB outbreaks currently have this expertise and also have the ability to utilize RTMCCs. ACET agreed with Dr. Castro's suggestion to increase the minimum funding amount to all TB P&C programs from the proposed level of $65,000 to $100,000.

ACET extensively discussed the unintended and negative consequences of immediately shifting to the TB funding formula at 100% (e.g., a loss of $4 million to the New York City TB Program) versus implementing a tiered approach. Overall, ACET was pleased with DTBE's strong efforts to assure transparency and collaborate with external partners in all aspects of developing the TB funding formula.

TOPIC 17: Mr. Jones led ACET in a review of topics to place on future ACET agendas:

- DTBE: Update on TB P&C efforts along the U.S.-Mexico border, including the role of the U.S.-Mexico Border Health Commission in this effort
- DTBE: Update on TBESC Task Order 23, "National Study of Determinants of Early Diagnosis, Prevention and Treatment of Tuberculosis in the African American Community"
- NCHHSTP Office of Health Equity: Progress report on implementing ACET's previous health disparities recommendations
- APHL/Laboratory Procurement Supply Office: Overview of the Laboratory Efficiency Initiative
- WHO, Green Light Committee and Stop TB USA: Update on changes in global activities to effectively treat MDR-TB
- RESULTS: Overview of the new advocacy tool and communication materials for children with TB and LTBI
- ACET: Discussion of strategies for TB to be more visible and prominent at the next International AIDS Conference in the summer of 2012 (e.g., broader representation by ACET and submission of abstracts to the conference by ACET members and other TB experts in the field)
- DTBE: Progress report on implementation of ACET's previous resolutions
- DTBE: Overview of the DTBE budget for TB control
- ACET: Updates by the 2 remaining workgroups (e.g., NTP Workgroup and ACET Meeting Workgroup)
- DTBE: Update on TB P&C efforts in federal penitentiaries and local jails
- ACET: Comprehensive discussion on the TRUST Report

Public Comment Session

Phillip Griffin
Director, Kansas Tuberculosis Control Program

Mr. Griffin reported that errata for the Infection Control Guideline are larger than the actual document. CDC has promised to reprint the guideline for two years, but this action has not been taken to date.

Phillip Talboy
Deputy Director, Division of Tuberculosis Elimination
Centers for Disease Control and Prevention

Mr. Talboy confirmed that DTBE and MMWR staff are making every effort to revise and release the Infection Control Guidelines.

Barbara Seaworth, MD
Medical Director, Heartland National TB Center
ACET Member

Dr. Seaworth reported that ACET's BCG guideline was submitted for CDC clearance, but the document was removed from the publication queue due to the absence of a methods section.

Closing Session

The 2012 ACET meetings were tentatively scheduled on March 6-7, 2012 (face-to-face), June 5-6, 2012 (webinar/teleconference call) and October 2-3, 2012 (face-to-face). The ACET members will be polled via e-mail to confirm these dates.

The participants joined Mr. Jones in applauding Ms. Margie Scott-Cseh, the ACET Committee Management Specialist, for her continued leadership in providing outstanding administrative and logistical support for the ACET meetings. The participants applauded Mr. Jones for his excellent role as chair.

With no further discussion or business brought before ACET, Mr. Jones recessed the meeting at 2:18 p.m. on December 7, 2011.

I hereby certify that to the best of my knowledge, the foregoing Minutes of the proceedings are accurate and complete.

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Date

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Shannon Jones III
Chair, Advisory Committee for the Elimination of Tuberculosis