

**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  
June 7-8, 2011  
Atlanta, Georgia**

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**DRAFT Record of the Proceedings**

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## ATTACHMENT 1

### List of Participants

(Note: The Designated Federal Official conducted a roll call on June 7 and 8, 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. Iram Bakhtawar  
 Dr. Eric Brenner  
 Dr. Marcos Burgos  
 Dr. Jane Carter  
 Dr. Gail Cassell  
 Dr. Christine Hahn  
 Dr. Masahiro Narita  
 Dr. Barbara Seaworth

#### ACET Designated Federal Official

Dr. Hazel Dean, NCHHSTP Deputy Director

#### ACET Ex-Officio Members

Dr. Naomi Aronson  
 (Department of Defense)  
 Dr. William Baine (Agency for Healthcare  
 Research and Quality)  
 Dr. Amy Bloom (U.S. Agency for  
 International Development)  
 Dr. John Halpin (National Institute for  
 Occupational Safety and Health)  
 Dr. Warren Hewitt (Substance Abuse and  
 Mental Health Administration)  
 Dr. Mamodikoe Makhene (National Institute  
 of Allergy and Infectious Diseases)  
 [via conference call]  
 Dr. Gary Roselle  
 (Department of Veteran Affairs)  
 Dr. Diana Schneider  
 (Department of Homeland Security)  
 Dr. Theresa Watkins-Bryant (Health  
 Resources and Services Administration)  
 [via conference call]

#### ACET Liaison Members

Dr. Robert Benjamin (National Association  
 of County and City Health Officials)  
 Dr. Mayleen Ekiek (Pacific Island Health  
 Officers Association)

Mr. Phillip Griffin (National Tuberculosis  
 Controllers Association)  
 Ms. Cornelia Jervis  
 (Treatment Action Group)  
 Ms. Jennifer Maurer  
 (RESULTS Educational Fund)  
 Dr. José Montero (Association of State and  
 Territorial Health Officials)  
 Dr. Edward Nardell (International Union  
 Against Tuberculosis and Lung Disease)  
 Dr. Susan Ray (Infectious Disease  
 Society of America)  
 Dr. Lee Reichman  
 (American College of Chest Physicians)  
 Ms. Rachel Stricof (Association of  
 Professionals of Infection Control  
 and Epidemiology, Inc.)  
 Dr. Litjen Tan  
 (American Medical Association)  
 Dr. Michael Tapper (Society for Healthcare  
 Epidemiology of America)  
 Dr. Lornel Tompkins  
 (National Medical Association)

#### CDC Representatives

Dr. Rima Khabbaz, CDC Deputy Director  
 Dr. Kenneth Castro, DTBE Director  
 Ms. Ijeoma Agulefo  
 Dr. José Becerra  
 Dr. Stuart Berman  
 Dr. Terence Chorba  
 Ms. Ann Cronin  
 Ms. Mollie Dowling  
 Ms. Maria Fraire  
 Ms. Judy Gibson  
 Ms. Peri Hopkins  
 Dr. John Jereb  
 Mr. John Kastenbauer  
 Dr. Awal Khan  
 Ms. Ann Lanner  
 Dr. Philip LoBue

Ms. Eva Margolies  
Dr. Suzanne Marks  
Dr. Sundari Mase  
Dr. Beverly Metchock  
Mr. Mark Miner  
Ms. Kathy Meyer  
Dr. Thomas Navin  
Dr. Gloria Oramasionwu  
Ms. Bonnie Plikaytis  
Dr. Drew Posey  
Mr. Joseph Scavotto  
Ms. Margie Scott-Cseh  
Ms. Sarah Segerlind  
Mr. Brian Sizemore  
Mr. Phillip Talboy  
Ms. Tonya Thrash  
Dr. Elsa Villarino  
Dr. Wanda Walton  
Ms. Pei-Chun Wan

Mr. Terry Wheeler

**Members of the Public**

Dr. John Bernardo (Stop TB USA)  
Mr. Frank Coviello (Polymedco, Inc.)  
Ms. Sue Etkind (National Tuberculosis  
Controllers Association)  
Dr. Jennifer Flood (National Tuberculosis  
Controllers Association)  
Ms. Ruth Noro  
(Tuberculosis Trials Consortium)  
Ms. Carol Pozsik (National Tuberculosis  
Controllers Association)  
Ms. John Seggerson (Stop TB USA)  
Dr. Charles Wallace (National Tuberculosis  
Controllers Association)  
Dr. Jon Warkentin (National Tuberculosis  
Controllers Association)

## ATTACHMENT 2

### Glossary of Acronyms

ICE	Immigration and Customs Enforcement
ACET	Advisory Council for the Elimination of Tuberculosis
ACIP	Advisory Committee on Immunization Practices
APHL	Association of Public Health Laboratories
APRC	Annual Percentage Rate Change
ATS	American Thoracic Society
BSC	Board of Scientific Counselors
CDC	Centers for Disease Control and Prevention
CHCs	Community Health Centers
CLIA	Clinical Laboratory Improvement Amendments
CMS	Centers for Medicare and Medicaid Services
CoAg	Cooperative Agreement
DASH	Division of Adolescent and School Health
DGMQ	Division of Global Migration and Quarantine
DHAP	Division of HIV/AIDS Prevention
DOT	Directly Observed Therapy
DSTD	Division of STD Prevention
DTBE	Division of Tuberculosis Elimination
DVH	Division of Viral Hepatitis
FBPs	Foreign-Born Persons/Populations
FDA	Food and Drug Administration
FOA	Funding Opportunity Announcement
FQHCs	Federally Qualified Health Centers
FTEs	Full-Time Equivalents
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
HAIs	Healthcare-Associated Infections
HBV	Hepatitis B Virus
HHS	Department of Health and Human Services
HIE	Health Information Exchange
HIT	Health Information Technology
HRSA	Health Resources and Services Administration
ID	Infectious Disease
IGRAs	Interferon Gamma Release Assays
INH	Isoniazid
IOM	Institute of Medicine
LTBI	Latent TB Infection
<i>M.tb</i>	<i>Mycobacterium Tuberculosis</i>
MDDR	Molecular Detection of Drug Resistance
MDR-TB	Multidrug-Resistant TB
MIRU	<i>Mycobacterium</i> Interspersed Repetitive Units
NAAT	Nucleic Acid Amplification Testing
NCCDPHP	National Center for Chronic Disease Prevention and Health Promotion
NHANES	National Health and Nutrition Examination Survey

NHAS	National HIV/AIDS Strategy
NIH	National Institutes of Health
NTCA	National Tuberculosis Controllers Association
NTGS	National TB Genotyping Services
NTIP	National Tuberculosis Indicators Project
NTP	National Tuberculosis Program
NTP	National Tuberculosis Program
OEU	Outbreak Evaluation Unit
OID	Office of Infectious Diseases
PCSI	Program Collaboration and Service Integration
PHLs	Public Health Laboratories
PPACA	Patient Protection and Affordable Care Act
Prevention Fund	Prevention and Public Health Fund
RTMCCs	Regional Training and Medical Consultation Centers
RVCT	Report Verified Case of TB
SaTScan	Statistical Geospatial Scan
SDH	Social Determinants of Health
SLD	Second-Line Drug
Spoligotyping	Spacer Oligonucleotide Typing
TB GIMS	Tuberculosis Genotyping Information Management System
TBESC	Tuberculosis Epidemiologic Studies Consortium
TBTC	Tuberculosis Trials Consortium
TSTs	Tuberculin Skin Tests
USBPs	U.S.-Born Persons/Populations
USPSTF	U.S. Preventive Services Task Force
VNTR	Variable Number Tandem Repeat
WHO	World Health Organization
XDR-TB	Extensively Drug-Resistant TB

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**ADVISORY COUNCIL FOR THE ELIMINATION OF TUBERCULOSIS  
June 7-8, 2011  
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**DRAFT 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 June 7-8, 2011 in Building 8 of CDC's Corporate Square Campus, Conference Room A/B/C, in Atlanta, Georgia.

**Opening Session: June 7, 2011**

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

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 conference call. She verified the presence of a quorum with voting members and *ex-officio* members for ACET to conduct its business on June 7, 2011. The list of participants is appended to the minutes as [Attachment 1](#).

Dr. Dean called the meeting to order at 11:00 a.m. and welcomed the participants to the proceedings. She clarified that the June 2011 ACET meeting was published in the *Federal Register* with an official start time of 11:00 a.m. on June 7, 2011 to accommodate an orientation session for the new members and an annual training session for the returning members.

Dr. Dean announced that ACET meetings are open to the public and all comments made during the proceedings are a matter of public record. ACET members should be mindful of potential conflicts of interest identified by the CDC Management Analysis and Services Office and recuse

themselves from participating in discussions or voting on issues in which they have a real or perceived conflict.

Dr. Dean asked the participants to join her in welcoming four new ACET members and three new liaison representatives:

- Eric Brenner, MD; Medical Epidemiologist, South Carolina Department of Health and Environmental Control
- Marcos Burgos, MD; Medical Director, Tuberculosis Program, New Mexico Department of Health and University of New Mexico School of Medicine
- Jane Carter, MD; Associate Professor (Teaching Scholar), Alpert School of Medicine at Brown University
- Gail Cassell, PhD; Visiting Professor, Harvard University, Department of Global and Social Medicine
- Mayleen Ekiek, MD; liaison to the Pacific Island Health Officers Association
- José Montero, MD, MPH; liaison to the Association of State and Territorial Health Officials
- Susan Ray, MD; liaison to the Infectious Disease Society of America

Dr. Dean announced that the four new members replaced four former members: Dr. Michael Fleenor (Chair), Dr. Ana Lopez-de Fede, Mr. Joseph Kinney and Ms. Sirlura Taylor. On behalf of CDC and ACET, Dr. Dean thanked the four former members for their outstanding service and contributions to CDC and the broader TB prevention and control community.

Dr. Dean highlighted other changes in the ACET membership:

- Shannon Jones III, Acting Director of Public Health and Community Services, City of Austin/Travis County, Texas Health and Human Services Department. Mr. Jones was reappointed as the ACET Chair.
- Masahiro Narita, MD, FCCP; Director, TB Control Program, Public Health-Seattle and King County, Associate Professor, Division of Pulmonary and Critical Care, University of Washington. Dr. Narita's term was extended for an additional two years.

Dr. Dean announced that for the current meeting, Mr. Phillip Griffin would serve as the alternate liaison to the National Tuberculosis Controllers Association (NTCA) on behalf of Ms. Kimberly Field. Dr. Dean asked the participants to join her in welcoming several guests who were in attendance: Dr. John Bernardo (Stop TB USA), Dr. Jennifer Flood (NTCA), Dr. Charles Wallace



## Report from CDC Deputy Director for Infectious Diseases

### **Rima Khabbaz, MD**

CDC Deputy Director for Infectious Diseases  
Director, Office of Infectious Diseases (OID)  
Centers for Disease Control and Prevention

Dr. Khabbaz began with a report on CDC's FY2011 budget. CDC's current budget reflects a reduction of 11% (\$740 million) below the FY2010 budget. The FY2011 budget includes \$200 million in statutory reductions specified by Congress and an additional \$500 million that CDC had to apply through various programmatic reductions and eliminations. In making these decisions, CDC took into account key agency priorities. A summary of CDC's budget is available at [www.cdc.gov](http://www.cdc.gov).

Each of the three infectious disease (ID) national centers—NCHHSTP, the National Center for Immunization and Respiratory Diseases, and the National Center for Emerging and Zoonotic Infectious Diseases—sustained budget cuts to their programs, including a \$4 million cut for DTBE. In addition, reductions in emergency preparedness funds administered by the CDC Office of Public Health Preparedness and Response will cause significant decreases, including reductions in cooperative-agreement funding to state and local health departments, and will affect several ID programs which receive preparedness funding.

The FY2011 cuts are partially offset by other funds, including the Prevention and Public Health Fund of the 2010 Patient Protection and Affordable Care Act. Funded ID activities include efforts to eliminate healthcare-associated infections (HAIs), strengthen the immunization infrastructure, and enhance information technology capacity as part of the Epidemiology and Laboratory Capacity for Infectious Diseases program.

More budget cuts are expected if Congress approves the President's FY2012 budget request. Despite these extensive budget cuts, CDC is committed to maximizing public health impact, maintaining the focus on national priorities, and sustaining critical programs.

Dr. Khabbaz next informed ACET about recent activities of the OID Board of Scientific Counselors (BSC). Mr. Shannon Jones is ACET's liaison representative on the board. During its most recent meeting in May 2011, the BSC proposed potential strategies to help transition CDC's ID programs during a time of healthcare changes and budget constraints. The BSC discussed current and potential changes in healthcare, opportunities to advance ID prevention, and the important need to retain core ID capacity and activities. The BSC meeting minutes will be available to the public on CDC's website.

Dr. Khabbaz also announced that OID is finalizing a framework document to help guide CDC's ID activities and collective public health action. OID widely distributed the draft framework in the fall of 2010, solicited broad input from across CDC and from the BSC and other external partners, and revised the document based on input received. OID plans to publish an abbreviated version of the framework, and post the full document on CDC's website.

Dr. Khabbaz next described efforts related to CDC's "Winnable Battles"—a series of targeted efforts that use known, effective strategies to achieve measurable results against high-burden diseases within a short period of time. Identified by CDC Director Dr. Thomas Frieden and other CDC leaders, these efforts include three strategies related to infectious diseases: reducing HIV infections, reducing HAIs, and reducing foodborne diseases. Dr. Khabbaz stated that she would let Dr. Dean discuss in her update CDC's work to implement the National HIV/AIDS strategy to reduce HIV infections, but would speak briefly on efforts to reduce HAIs and foodborne diseases.

To advance progress toward reducing HAIs—which data show are mostly preventable—CDC is closely collaborating with federal and state partners in a variety of activities, including expansion of the agency's National Healthcare Safety Network (NHSN), CDC's primary source for facility-based information on HAIs. Hospitals can access the CDC web-based system at no charge to support their activities to reduce HAIs. More than 4,000 hospitals are currently using the system. NHSN will also be used to track the progress of the Partnerships for Patients initiative, launched in May 2010 by HHS Secretary Kathleen Sebelius.

Dr. Khabbaz then highlighted some of CDC's work to reduce foodborne diseases. She noted that today, the agency would be releasing a report on food safety in *Vital Signs*, a CDC publication featuring a different important public health topic each month. Dr. Khabbaz also noted that CDC has been directed to conduct two activities as part of the Food Safety Modernization Act, signed into law earlier this year. First, CDC is directed to strengthen national and state surveillance for foodborne illnesses through improved efforts to collect, analyze, and share data. Second, CDC is directed to establish five integrated food safety centers of excellence at state health departments to identify and implement best practices in foodborne disease surveillance and serve as resources for public health professionals. However, the legislation did not allocate resources for CDC to conduct the new food safety activities.

Dr. Khabbaz next invited ACET members to attend the eighth International Conference on Emerging Infectious Diseases on March 11-14, 2012, at the Hyatt Regency Atlanta. Since 1998, this biennial meeting has brought together approximately 2,500 public health professionals from around the world to encourage the exchange of scientific and public health information on a broad range of global emerging ID issues. The conference continues to serve as a helpful and unique forum to convene domestic and international groups to address these issues. Each division in the three ID national centers is represented on the Scientific Program Committee for the conference. The 2012 conference is being planned with various plenary sessions and panel discussions that are timely and relevant to the field.

Dr. Khabbaz concluded her report by thanking the ACET members for continuing to take time from their busy schedules to provide CDC and HHS with sound advice on efforts to prevent, control, and eliminate TB.

## NCHHSTP Deputy Director's Report

### Hazel Dean, ScD, MPH

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

Dr. Dean covered the following topics in her Deputy Director's report to ACET. At the agency level, Congress passed CDC's continuing appropriation funding on April 14, 2011 through the remainder of FY2011. The continuing resolution included a cut of \$740 million from the FY2010 budget in addition to a 0.2% rescission across all programs. The budget cut translates to a decrease of ~12% in CDC programs that will be effective during the last 5.5 months of FY2011.

Dr. Dean presented a chart illustrating CDC's organizational structure. Dr. Thomas Frieden is the Director of CDC, Dr. Ilena Arias is the Principal Deputy Director of CDC, and Dr. Rima Khabbaz is the Deputy Director of OIG that houses NCHHSTP.

CDC issued the *CDC Health Disparities and Inequalities Report-United States 2011* in January 2011 at [www.cdc.gov/mmwr/pdf/other/su6001.pdf](http://www.cdc.gov/mmwr/pdf/other/su6001.pdf). The report highlights health disparities by sex, race/ethnicity, income, education, disability status and other social characteristics. In March 2011, CDC announced the availability of \$34.17 million for states and local jurisdictions participating in the National Public Health Improvement Initiative. This effort supports activities to accelerate public health accreditation readiness activities; performance management and improvement practices; and the development of evidence-based policies and practices.

The President's FY2012 budget proposes a transfer of funds from the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) to NCHHSTP. With this change, HIV funding and prevention activities from the Division of Adolescent and School Health (DASH) will be shifted to NCHHSTP in accordance with the President's FY2012 budget request.

NCCDPHP proposed a reorganization plan to ensure that the transfer of funds will strengthen coordination between HIV school health and other prevention programs to optimize support for the National HIV/AIDS Strategy (NHAS). DASH's non-HIV school health activities will be housed in a new NCCDPHP division. NCCDPHP intends to complete the reorganization plan by the end of FY2011.

At the National Center level, NCHHSTP's FY2011 operating budget is \$1.076 billion. NCHHSTP received a \$27.7 million increase in its budget authority to support NHAS, but also sustained a \$30.4 million decrease from the PPACA Prevention Fund. NCHHSTP's overall budget cut of \$2.8 million reflects a \$4 million decrease for TB activities and a \$1.2 million increase for domestic HIV activities.

The FY2012 President's budget requests ~\$1.2 billion for domestic HIV/AIDS, viral hepatitis, STD and TB activities at CDC. The request includes \$30.4 million from the PPACA Prevention Fund; an increase of \$58.3 million in base appropriations to achieve NHAS priority actions; a

transfer of \$40 million from NCCDPHP for HIV school health activities; an additional \$6.7 million targeted to STD prevention for men who have sex with men; and an additional \$5.2 million to implement the Institute of Medicine's (IOM) recommendations related to chronic viral hepatitis and associated liver cancer.

Dr. Dean presented a chart illustrating NCHHSTP's organizational structure. Dr. Kevin Fenton is the Director of NCHHSTP and Dr. Hazel Dean is the Deputy Director. NCHHSTP's four divisions are DTBE (Dr. Kenneth Castro, Director); the Division of HIV/AIDS Prevention (DHAP) (Dr. Jonathan Mermin, Director); Division of Viral Hepatitis (Dr. John Ward, Director); and Division of STD Prevention (DSTDP) (Dr. Gail Bolan, Director).

Dr. Bolan was named as the Director of DSTDP in December 2010. She previously was Chief of the STD Control Branch at the California Department of Public Health and Director of the California STD/HIV Prevention Training Center. Dr. Bolan began her public health career as a CDC Epidemic Intelligence Service Officer.

Dr. Dean highlighted NCHHSTP's recent accomplishments that are directly responsive to its Strategic Plan priorities. For the "prevention through health care" goal, NCHHSTP and the Health Resources and Services Administration (HRSA) are collaborating on integrating health department programs and Community Health Centers (CHCs). NCHHSTP is exploring the possibility of using Beacon community data in its programs. NCHHSTP is collaborating with the Centers for Medicare and Medicaid Services (CMS) to address quality and coverage of service.

For the "Program Collaboration and Service Integration" (PCSI) goal, NCHHSTP held a PCSI grantee meeting on March 31-April 1, 2011. The purpose of the meeting was for the grantees to share best practices and lessons learned from their experiences with PCSI implementation. The intent of the funding opportunity announcement (FOA) is to increase collaboration among programs and integrate prevention, testing and treatment services. The six demonstration sites represented at the PCSI grantee meeting were state and local health departments in the District of Columbia, New York City, North Carolina, Philadelphia, San Francisco and Texas.

NCHHSTP recently completed an in-depth review of the existing PCSI literature to identify gaps. The findings of the literature review will be posted on the PCSI website in June 2011. NCHHSTP revised the Data Security and Confidentiality Guidelines to harmonize protocols, unify procedures, and reach consensus on the guidelines across NCHHSTP's four divisions and its funded state and local health departments.

For the "healthy equity" goal, the NCHHSTP Office of Health Equity developed health equity and social determinants of health (SDH) language that was incorporated into all NCHHSTP FOAs in FY2011. NCHHSTP will release three documents related to health equity in the summer of 2011: (1) the SDH guidance document for surveillance systems, (2) the 2010 SDH Activities Report, and (3) the second *Public Health Reports* supplement on SDH and data systems.

NCHHSTP released a new FOA with an application deadline of May 31, 2011 to build a national coalition to enhance STD/HIV prevention through promotion of a holistic approach to health and wellness. The new program is designed to support efforts to improve the health of populations

disproportionately affected by HIV/AIDS, viral hepatitis, STDs and TB by maximizing the health impact of public health services, reducing disease prevalence, and promoting health equity as outlined in NHAS.

For the “global health protection and systems strengthening” goal, NCHHSTP and the CDC Center for Global Health designated a Global TB Liaison to coordinate cross-center and agency-wide TB control efforts. NCHHSTP collaborated with the Stop TB Partnership to provide training for healthcare professionals in countries with a high TB burden. NCHHSTP initiated operational research on congenital syphilis and assigned staff to serve on the World Health Organization (WHO) Steering Committee for Global Elimination of Congenital Syphilis.

For the “partnerships” goal, NCHHSTP hosted a pre-conference session at the Council of State Government’s “Reducing Health Disparities in STIs and HIV” National Conference. NCHHSTP continued its communications activities that were initiated in 2010 to develop and collect evaluation data on communications products. NCHHSTP continued to build public-private partnerships through joint efforts with the CDC Foundation and the National Viral Hepatitis Roundtable.

For the “workforce development and capacity building” goal, NCHHSTP launched its Ambassador Program in October 2010 with 16 employees who were new to the federal government. NCHHSTP created a blog, website and other communications products to engage its workforce and also launched the monthly “NCHHSTP Learn @ Lunch Career Development” series. NCHHSTP collaborated with the Office of Diversity to develop and implement diversity training for senior leaders in June and July 2011 followed by training of staff in DHAP.

NCHHSTP published its FY2010 Annual Report highlighting its activities related to NHAS, the decline in TB disease, new efforts to mobilize communities and promote health equity, and the HHS/NCHHSTP collaboration on developing the Hepatitis Action Plan. The Annual Report is available at [www.cdc.gov/nchhstp/Publications/index.htm](http://www.cdc.gov/nchhstp/Publications/index.htm).

At the Division level, the Division of HIV/AIDS Prevention (DHAP) is conducting a series of activities to commemorate 30 years of fighting the HIV/AIDS epidemic. An online community blog was launched at <http://hivstory.ning.com>. On June 10, 2011, CDC will broadcast the first of a nine-part lecture series, “HIV/AIDS: 30 Years of Leadership and Lessons.” The series will feature moderated conversations with leaders describing defining moments that changed the course of the epidemic. DHAP will convene the National HIV Prevention Conference on August 14-17, 2011 in Atlanta.

The Division of Viral Hepatitis (DVH) was extensively involved in the development of the “HHS Action Plan for the Prevention, Care and Treatment of Viral Hepatitis.” The action items include identifying individuals with viral hepatitis and referring these persons to care; improving surveillance of viral hepatitis; eliminating mother-to-child transmission of hepatitis B virus (HBV); and achieving universal hepatitis A and B vaccination for vulnerable populations. The HHS Action Plan is available at [www.hhs.gov/ash/initiatives/hepatitis](http://www.hhs.gov/ash/initiatives/hepatitis).

The Division of STD Prevention (DSTDP) released an FOA with an application deadline of April 20, 2011 to fund community approaches to reduce STDs. The grantees will be funded to reduce STD rates by providing chlamydia and gonorrhea screening, treatment and partner treatment to 50% of women in publicly funded family planning and STD clinics nationwide.

DSTDP released its "Legal/Policy Toolkit for Adoption and Implementation of Expedited Partner Therapy" in January 2011 to assist states in analyzing laws and policies on this issue. DSTDP's partners in developing the toolkit include the Arizona State University College of Law and CDC Public Health Law and Policy Program. DSTDP expects to release the 2011 STD Laboratory Guidelines in the summer of 2011.

Dr. Dean noted that she did not highlight DTBE's recent activities because DTBE leadership and staff would present updates throughout the meeting. She concluded her Deputy Director's report by informing ACET of upcoming events in 2011. The National TB Controllers Conference will be held on June 15-17, 2011 in Atlanta. NCHHSTP will convene the "Prevention Through Health Care: Enhancing Health Department Preparedness and Response" Consultation on June 20-21. NCHHSTP is continuing to develop its Sexual Health White Paper and will publish new HIV incidence data later in 2011.

ACET thanked Drs. Khabbaz and Dean for their informative and comprehensive Deputy Directors' reports for OID and NCHHSTP, respectively. The ACET members advised CDC to identify efficiencies in three key areas due to its significant 11% budget cut in FY2011.

- NCHHSTP received a \$27.7 million increase in its budget authority to achieve the NHAS goals for domestic HIV/AIDS. NCHHSTP should use PCSI as a mechanism to leverage a portion of these dollars for TB prevention and control activities, particularly to address TB/HIV co-infection.
- CDC has made minimal progress to date in using teleconferences, webinars and other technologies to decrease travel costs to meetings and national conferences. For example, some state grantees used their cooperative agreement (CoAg) funds at a cost of ~\$1,500 for each traveler to attend CDC's 45<sup>th</sup> National Immunization Conference in March 2011. CDC must make stronger efforts to reduce travel expenditures in light of its tremendous 11% budget cut. In addition to using technologies more routinely, CDC also should consider convening annual national conferences on a biennial basis.
- OID has a new, but unfunded legislative mandate to conduct food safety surveillance and establish five new Food Safety Centers of Excellence. OID and all other parts of CDC should develop and maintain a record of its unfunded mandates, particularly since additional budget cuts are anticipated in FY2012. Clear documentation of unfunded mandates is a powerful tool for agencies to obtain new dollars for new activities.

Mr. Phillip Griffin (NTCA alternate liaison) noted that the "National TB Controllers Conference" was re-branded in 2009 as the "National Tuberculosis Conference" to engage and include public health laboratory professionals and other audiences beyond TB controllers. He asked CDC to ensure that its web links to future conferences reflect the revised name.

Dr. Gail Cassell (ACET voting member) noted that CDC's budget for antimicrobial resistance sustained a cut for all diseases. She advised ACET to strengthen its focus on TB antimicrobial resistance by inviting the American Society for Microbiology to serve as a new liaison representative. This group could serve as a valuable resource in providing TB-related microbiologic expertise and advocating for funding of TB antimicrobial resistance issues at the highest levels of government.

## DTBE Director's Report: Challenge to ACET

### **RADM Kenneth Castro, MD**

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

For the benefit of the new members, Dr. Castro explained that his Director's reports typically are structured to provide ACET with brief updates on recent TB prevention and control activities conducted by DTBE and its branches. However, this report would solely focus on DTBE's challenge to ACET to address the following question: "How should the National Tuberculosis Program (NTP) be configured to accomplish its elimination goal?"

Dr. Castro covered the following topics in his Director's report to assist ACET in providing advice to DTBE on this issue. The "1989 National Strategic Plan to Eliminate Tuberculosis from the United States" established a TB elimination goal of  $\leq 1$  TB case/million population by 2010, but this goal was not met. ACET ratified and recommitted its efforts in 1999 to reach the TB elimination goal. The 2000 IOM report, *Ending Neglect: The Elimination of Tuberculosis in the United States*, was published with five key recommendations to make progress in this area.

During its December 2006 meeting, ACET expressed grave concerns that shrinking federal dollars would make TB elimination less likely. ACET raised the possibility of the HHS Secretary renaming DTBE as the "Division of Tuberculosis Control." However, ACET ultimately advised DTBE to strengthen its focus on reaching the national TB elimination goal. Stop TB USA leveraged DTBE's modeling expertise to publish a TB Elimination Plan in 2010. The plan estimated that eliminating TB by 2035 would result in 253,000 fewer TB cases, 15,200 fewer TB-related deaths, and \$1.3 billion less in TB treatment costs based on 2006 dollars.

DTBE's vision is a "nation and world free of TB." DTBE's mission is to promote health and quality of life by preventing, controlling, and eventually eliminating TB from the United States and by collaborating with other countries and international partners in controlling global TB. DTBE ratified and updated its mission statement in January 2011. DTBE's 2008 Strategic Plan prioritized five areas that were ratified in January 2011:

1. Prevent new cases of *Mycobacterium tuberculosis* (*M.tb*) infection and disease by locating and curing all persons with TB.

2. Reduce TB in foreign-born persons/populations (FBPs) residing in or traveling to the United States.
3. Reduce TB in U.S. racial/ethnic minority populations by measuring and addressing SDH.
4. Reduce the impact of multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB) domestically and globally.
5. Reduce HIV-associated TB domestically and globally.

CDC data of its annual TB budget from FY1990-FY2010 show a 61% reduction in purchasing power compared to FY1994. The annual budgets are based on adjusted 1990 dollars using the Consumer Price Index for Medical Care.

Dr. Castro asked ACET to consider “change factors” in two categories to provide advice to DTBE on configuring NTP to accomplish its elimination goal given CDC’s FY2011 and FY2012 budget cuts. The change factors in category 1 are challenges and threats to NTP:

- budgetary constraints;
- weakened programs;
- second-line drug (SLD) shortages;
- an increase in the percentage of TB among FBPs;
- the increasing role of SDH in U.S.-born persons/populations (USBPs);
- FDA approval of new diagnostic tools and drugs;
- the need to address latent TB infection (LTBI);
- the role of TB co-morbidities;
- the need to improve the translation of science to programs; and
- diagnostic delays that continue to contribute to ongoing TB transmission.

The change factors in category 2 are opportunities for NTP:

- PPACA if this legislation is not repealed;
- an increase in CMS coverage for TB;
- a stronger role in TB by HRSA-funded Federally Qualified Health Centers (FQHCs);
- the role of universal genotyping in enhancing knowledge of transmission dynamics to interrupt the transmission of disease;
- same-day diagnosis (e.g., the automated Cepheid Xpert® MTB/RIF diagnostic test that can identify *M.tb* and resistance to rifampin);
- short-course LTBI treatment with demonstrated efficacy (e.g., clinical trial data showing comparable efficacy between a three-month regimen of once-weekly isoniazid (INH)/rifapentine (RPT) and a nine-month regimen of INH); and
- continued support for global TB prevention and control by leveraging U.S. President’s Emergency Plan for AIDS Relief resources from other agencies (e.g., U.S. Agency for International Development and the Office of the U.S. Global AIDS Coordinator).

Dr. Castro articulated a more specific and concrete charge for ACET to revise and update the TB elimination targets and measures of success for FY2011 and FY2012. DTBE’s rationale for



asking ACET to undertake this effort is based on the failure to meet the 2010 target date for TB elimination. Moreover, DTBE's modeling data show that the elimination goal of 1 case/1 million would not be achieved until the 22<sup>nd</sup> century at the current rate of decline of ~3.8% per year.

Dr. Castro asked ACET to aim for ambitious, but realistic targets in fulfilling its charge. For example, the elimination goal of 1 case/1 million could be established by 2050. Interim targets should be considered as well (e.g., 1 case/100,000 by 2020, 5 cases/million by 2030, 2.5 cases/million by 2040, no more TB deaths/no more transmission, or a specific LTBI target).

DTBE convened a workgroup to consider the feasibility of developing a quantitative measure of recent TB transmission; identify interim targets for the elimination of TB transmission; and calculate the number of cases and deaths averted. DTBE charged the National TB Indicators Project Workgroup with reexamining its targets in light of current developments. ACET should consider these issues in its deliberations.

Dr. Castro also asked ACET to consider seven critical and core functions in proposing changes to NTP. DTBE obtained preliminary input on restructuring NTP during a consultation with external partners on June 6, 2011. The seven major issues are:

- retention of DTBE's 68 CoAgs for grantees to focus on core program functions;
- retention of surge capacity for cluster investigations, outbreak response and emergency preparedness activities;
- continued support for the Public Health Laboratory Network;
- retention of program monitoring and evaluation;
- continued funding to Regional Training and Medical Consultation Centers (RTMCCs);
- the need for the U.S. government to continue to protect the important and relevant role of research to TB programs; and
- CDC's continued role in global TB control without weakening domestic TB control. Recent CDC data show that FBP's still account for 60% of TB cases in the United States.

ACET emphasized the need to form a new workgroup or engage in extensive discussions during future meetings to fully address the complexities related to configuring NTP to achieve its elimination goal given current and future budget cuts. In the interim, however, several ACET members made comments and suggestions in response to DTBE's charge.

- DTBE should take advantage of existing opportunities to accelerate progress on TB/HIV co-infection. For example, HRSA-funded clinics are required to report on LTBI testing and treatment. DTBE should determine whether a portion of CDC's \$27.7 million increase for HIV prevention could be leveraged to offer highly antiretroviral therapy to TB patients who are newly diagnosed with HIV. The TB community also should make stronger efforts to provide HIV testing and referral services to all persons diagnosed with TB.
- DTBE proposed an interim target of elimination of recent TB transmission, but this target might not be feasible due to the "silent" period between patients reactivating old infection and becoming infectious. Because reactivation cases transmit TB disease during the

silent period, DTBE should reconsider asking ACET to provide guidance on the interim target of eliminating recent transmission.

- DTBE should conduct and validate a systematic root cause analysis of every TB death to analyze TB-associated deaths as preventable adverse events. In addition to focusing on epidemiologic characteristics of patients, the root cause analysis also should identify existing systematic failures in the diagnostic and treatment course of TB patients and determine areas of improvement. In response to this suggestion, Dr. Flood reported that the Tuberculosis Epidemiologic Studies Consortium is currently conducting an analysis to compare >1,000 TB patients who did and did not die in the United States. The study focuses on the contribution of TB to morbidity and modifiable factors. Preliminary data show that TB contributed to many patient deaths.

In response to ACET's comments and suggestions regarding funding for TB/HIV co-infection, Dr. Castro explained that Congressional language requires a portion of HIV prevention dollars to be used to address TB/HIV co-infected patients. DTBE has received funding for this effort since the 1990s and was given \$9.6 million in FY2010. NCHHSTP leadership assured Dr. Castro that resources for TB/HIV co-infection would be retained. In terms of leveraging a portion of CDC's new HIV prevention dollars for TB/HIV co-infection, Dr. Castro confirmed that DTBE would submit proposals to NCHHSTP to justify this funding request.

## Forecasting U.S. Trends and Challenges in TB

### **José Becerra, MD, MPH**

Chief, Data Management and Statistics Branch, DTBE  
Centers for Disease Control and Prevention

Dr. Becerra presented DTBE's recent modeling results and data to analyze and forecast TB trends in the United States. The annual percentage rate change (APRC) of TB incidence in the United States decreased from 7.3% in 2000 to 3.8% in 2008. Based on the 2008 APRC of 3.8%, 100 years would pass before the TB elimination goal of 1 case/1 million was achieved. An APRC of 8.8% and new diagnostic tools, new and shorter treatment, and a new TB vaccine would be needed to eliminate TB by 2050.

USBPs are the only subgroup that is close to achieving the TB elimination goal in the 21<sup>st</sup> century at the current rate of decline of ~3.8% per year. Non-Hispanic whites, blacks, Asians and Hispanics would not achieve the TB elimination goal until the 22<sup>nd</sup> century. DTBE's 2009 data showed that the decrease in TB incidence rates was well below the expected predicted interval.

DTBE designed a TB transmission dynamics model to compare outcomes when interventions are performed at different times of the disease transmission process. The model assumed a baseline year of 2000 and 16,000 TB cases. The model showed that LTBI accounted for 12,000 cases and dominated the trend. The 12,000 LTBI cases could be tested and treated, progress to TB disease, or result in death.

The model also showed that recent TB infection accounted for the remaining 4,000 cases. These cases potentially could come into contact with a susceptible population of 270 million persons. If these cases are not controlled with early detection and treatment, outbreaks could occur. Based on 2000 National Health and Nutrition Examination Survey (NHANES) data, an estimated prevalence of 2 million infections accounted for the vast majority of TB cases.

DTBE's deterministic and compartmental TB transmission dynamics model stratifies populations by U.S.-born or foreign-born status as well as by age groups. The model was calibrated based on overall national incidence levels and population projections using 2000-2008 data. DTBE designed the model to be as simple and useful as possible to assess the relative impact of interventions on time to elimination.

The national elimination goal would be achieved by 2107 or 2108 based on the current rate of decline of ~3.8% per year. However, the incorporation of baseline TB incidence projections into the model up to the year 2060 shows that elimination would not be achieved in foreign-born arrivals due to LTBI in this population. Similar results were seen when an interim target of elimination of TB transmission was incorporated into the model.

If the model increased chronic LTBI treatment by 5%, 10% or 15% per year, elimination would be achieved only in USBPs assuming that the proportion of LTBI among FBPs was 20%. Similar results were seen when the proportion of LTBI among FBPs was decreased to 10% or 5%. All of the mathematical calculations incorporated into the model showed that without achieving elimination in FBPs, elimination would not be achieved in the United States as a whole. The model showed that elimination could only be achieved in FBPs by decreasing the proportion of LTBI to 0% in this population (*i.e.*, screening and treating all FBPs upon arrival to the United States).

DTBE reached several conclusions based on the modeling data and results. The prevention of progression from LTBI to TB disease is the most important determinant for TB elimination provided that TB control efforts are sustained in the United States. The constant flow of LTBI cases among FBPs does not allow the model to predict elimination in this specific subgroup. FBPs account for 60% of TB cases in the United States and have a substantial impact on overall estimates of U.S. incidence. The ability to achieve TB elimination in the United States within the current century will require new LTBI diagnostic tools, shorter and safer TB treatments, and an effective vaccine, particularly among current and newly-arrived FBPs.

Dr. Becerra concluded his overview by asking ACET to consider the modeling data and results to provide advice on three key questions. First, is the target of achieving elimination of TB disease by 2050 feasible and realistic? Second, should alternate elimination targets other than 1 case/1 million be considered for different subgroups (e.g., USBPs versus FBPs)? Third, should interim elimination goals be established given that new tools have the ability to measure TB clusters and recent transmission?

ACET commended DTBE on developing a solid TB transmission dynamics model to analyze and forecast TB trends in the United States. Several members made comments in response to

the questions Dr. Becerra posed to ACET. In response to question 1, some ACET members found the goal of achieving elimination of TB disease by 2050 to be unrealistic based on the modeling data. The members further noted that the goal could be achieved if research dollars were targeted to enhancing diagnostic tools and improving LTBI detection and treatment.

In response to question 2, some ACET members supported DTBE's proposal to establish different elimination targets for USBPs and FBPs. In response to question 3, some ACET members expressed concern about DTBE's proposal to establish an elimination goal that would solely focus on TB transmission. The members pointed out that the tremendous pool of LTBI cases is extremely important to address.

The ACET members made other suggestions for DTBE to consider in enhancing and refining its TB transmission dynamics model.

- DTBE should redesign the model to show completion of therapy with or without directly observed therapy (DOT). DOT is administered to increase treatment success and prevent relapses of TB disease, but many state health departments are unable to conduct DOT due to declining resources. DTBE should present the modeling data to funders of state TB programs to show the impact of decreased dollars for DOT.
- DTBE should redesign the model to account for TB/HIV co-infection.
- DTBE should provide state and local TB programs with a software version of the model that would include with a user-friendly interface. This tool would allow programs to enter local data into the model to project trends of TB disease, MDR-TB and LTBI in their respective jurisdictions.
- DTBE should review modeling efforts that were published in the *New England Journal of Medicine* as a resource in refining its TB transmission dynamics model. The study reported data regarding the impact of assistance the United States provides to other countries with large immigrant populations to address their TB problems.
- DTBE designed the model with minimal emphasis on TB re-infection due to the extremely small number of these cases in the United States. However, the model should focus more on this issue because immigrants who reside in the United States routinely travel to their countries of origin and have the potential for re-infection during visits to other parts of the world with a high prevalence of TB.
- DTBE should redesign the model to show increasing strains of drug-resistant TB that are likely to return to the United States. Data show that only one-half of 1% of newly-diagnosed MDR-TB cases has been treated since 1998. These data suggest that untreated cases are spreading TB infection in communities across the country.
- DTBE should use its modeling data to perform a cost-effectiveness analysis of U.S. TB trends. DTBE should use these data to present a strong case to support investments in new tools that will have a dramatic impact on U.S. capacity to control TB disease and infection in the future.

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## OVERVIEW OF CDC's TB PREVENTION AND CONTROL CORE FUNCTIONS

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A panel of DTBE leadership made two presentations describing CDC's CoAgs to support TB prevention and control core functions in the United States.

### National TB Program Capacity and the National TB Indicators Project

#### **Terence Chorba, MD, MPH, DSc**

Chief, Field Services and Evaluation Branch, DTBE  
Centers for Disease Control and Prevention

Dr. Chorba reported that NTP has a domestic goal to eliminate TB in the United States to  $\leq 1$  case/million and a global goal to contribute to reductions in the global incidence and mortality of TB by 50% each. CDC established five domestic and global priorities for NTP in 2009-2010: interrupt transmission of *M.tb* by preventing future cases of infection and disease; reduce TB in FBPs; reduce TB in racial/ethnic minority populations; mitigate or reduce the impact of MDR-/XDR-TB; and reduce HIV-associated TB.

CDC administers NTP's six core activities: develop national policies and guidelines, serve as a national reference laboratory, maintain a national TB registry, be responsible for overseas screening of immigrants and refugees, provide a national resource for training and education, and conduct epidemiologic, operational and clinical research.

DTBE uses CoAgs to allocate categorical funding to four RTMCCs and 68 programs in all 50 states, the District of Columbia and 9 other large cities, and 8 U.S.-affiliated jurisdictions: Puerto Rico, the Virgin Islands, Guam, Federated States of Micronesia, Palau, American Samoa, Republic of the Marshall Islands, and the Commonwealth of the Northern Mariana Islands.

At this time, DTBE's state CoAgs expressly stipulate that federal resources should not be used to supplant state resources. The CoAgs do not require maintenance of a level of effort or state-based matching funds. TB control programs submitted data to DTBE in November 2010 that indicated CoAgs support 1,249 full-time equivalents (FTEs) in state and local TB programs and an additional directly-funded 74 FTEs who perform TB testing in public health laboratories.

NTP's TB control functions at the national level include providing staff in state and local TB programs: 33 public health advisors in 27 locations and 8 field medical officers in 7 locations. NTP's other functions at the national level include oversight, leadership or participation in the Tuberculosis Trials Consortium, Tuberculosis Epidemiologic Studies Consortium, National Genotyping Service, laboratory research, and NHANES.

NTP's TB control functions at the state level include developing policies and guidelines, funding TB control activities, providing training, technical assistance, oversight and evaluation,

supporting public health laboratory functions, conducting surveillance, and serving as the public health authority on state TB control efforts.

NTP's TB control functions at the local level include case management, contact investigations, collaboration with private medical providers, DOT and other direct medical care at sites, TB surveillance and program evaluation. Because CDC's "constitution" does not specifically mention public health, states are responsible for the diagnosis, treatment and prevention of TB disease. As a result, states must invite CDC to participate in these efforts.

NTP's TB control functions at the global level are designated to the CDC Division of Global Migration and Quarantine (DGMQ). Panel physicians in countries of origin oversee screening of immigrants and refugees as well as interstate and international movement of TB patients.

Key TB control strategies have been established for the United States: case finding and case management with monitoring of outcomes, contact investigations, diagnosis and treatment of LTBI in high-risk persons, and prevention of TB in congregate settings and healthcare facilities. DTBE recognizes that resources for two key TB control strategies (e.g., LTBI treatment and diagnosis and TB prevention in congregate settings and healthcare settings) will immediately decline in the current era of federal budget constraints.

DTBE acknowledges the critical role of the private sector in advancing TB prevention and control core functions in the United States. Most TB patients (or 55%) receive some level of care in the private sector, but the impact of managed care and PPACA is not clear at this time. Certain public health services (e.g., provision of DOT and contract tracing) will remain in the public sector.

Due to budget constraints, DTBE established a goal to redistribute and align all funds with data-driven epidemiologic needs based on 2004-2013 data. DTBE's current funding formula reflects a 45% redistribution of funds based on a five-year average of Report Verified Cases of TB (RVCT) data from 2004-2008 with the following weighted factors: incident cases (40%), U.S.-born minorities (15%), foreign-born persons (15%), Class A/B1/B2 immigrants (10%), TB/HIV co-infection (5%), MDR-TB (5%), substance abuse (5%), and homeless persons (5%). The funding formula reflects burden-based rather than performance-based budgeting.

The most significant challenges in national TB program capacity include the erosion of federal and state TB budgets, losses in human resources and proficiency, a smaller workforce of private medical providers and public health professionals, and fiscal constraints. Funding for the TB CoAgs will be decreased and certain aspects of regionalization will be increased as a result of decreased TB morbidity and mortality.

Tension exists between achieving the TB elimination goal before funding is eliminated. The rate of decline in TB cases has slowed over time. Racial/ethnic minorities continue to have a disproportionate burden of TB disease. The percentage of TB cases among FBPs continues to increase. TB/HIV co-morbidity and antimicrobial resistance continue to be problematic. Institutional memory for TB treatment has decreased, while drug resistance and the complexity of cases have increased.

Dr. Chorba explained that the National TB Indicators Project (NTIP) is a web-based performance monitoring system based on existing data sources. Indicator reports are intended to inform progress toward national objectives in 15 high-priority categories; focus program evaluation efforts; and provide performance targets as benchmarks for assessment. TB programs that are funded through CoAgs began using NTIP in 2010 to report their progress toward reaching the national objectives.

DTBE established national TB program objectives and performance targets in 12 areas for grantees to reach by 2015: completion of treatment, TB case rates, contact investigations, laboratory reporting, treatment initiation, sputum culture conversion, data reporting, universal genotyping, recommended initial therapy, known HIV status, evaluation of immigrants and refugees, and sputum-culture reporting. Grantees use five existing data sources to report their progress in NTIP: RVCT, the Electronic Disease Notification System for immigrants and refugees, TB Genotyping Information Management System, Aggregate Reports of Program Evaluation for contacts, and U.S. Census data.

To integrate NTIP into program practice, an evaluation team and field consultants compile best practices and lessons learned for implementation in other jurisdictions when targets are met. When targets are not met, the evaluation team and field consultants develop an evaluation plan to understand barriers and challenges, provide evaluation updates and complete the evaluation. The program refines its activities based on these findings and implements improvements. Progress toward achieving the national objectives is monitored in all TB programs.

Overall, NTIP is intended to reinforce national priorities; measure progress and the impact of interventions using existing data; help identify priorities for program improvement, reporting and technical assistance; facilitate evidence-based practices; and enhance collaboration among partners at all levels. Although NTIP is extremely valuable at the national level, low incidence states have relatively little need for NTIP at the state level.

## **Update on the Current and Future Role of the TB RTMCCs**

### **Wanda Walton, PhD**

Chief, Communications, Education and Behavioral Studies Branch, DTBE  
Centers for Disease Control and Prevention

Dr. Walton reported that CDC currently funds four RTMCCs to focus on domestic TB issues: New Jersey Medical School Global TB Institute (Newark, New Jersey); Southeastern National TB Center (Gainesville, Florida); Heartland National TB Center (San Antonio, Texas); and Curry International TB Center (San Francisco, California).

DTBE developed indicators to measure the performance of RTMCCs in conducting their scope of work. RTMCCs must allocate 70%-80% of their resources and effort to education and training to increase human resource development in TB programs. Of these resources, 50%

must be allocated to training courses and technical assistance with the following annual requirements: a minimum of 230 training hours, training to a minimum of 350 participants with an in-person format or 500 participants with distance-based learning technology, 6 mini-fellowships (*i.e.*, individualized training experiences), and a minimum of 40% of offsite training courses.

The remaining 20%-30% of education and training resources must be allocated to developing TB educational and training products (e.g., manuals and training courses for use by other groups). RTMCCs must allocate the remaining 20%-30% of their total CoAg funding and effort to medical consultation.

Each RTMCC covers a defined region of the country and is responsible for conducting needs assessments to identify training and medical consultation needs for their respective regions. Each RTMCC receives ~\$1.4 million annually to conduct activities and is affiliated with a state or large-city TB program and a university. However, CDC awards CoAg funds directly to the TB program rather than the RTMCC.

Since 2005, RTMCCs have provided >4,400 hours of training to 44,484 participants with in-person or web-based formats, 152 mini-fellowships, and 12,619 medical consultations. Other achievements by RTMCCs include the development of educational products based on identified needs or gaps that consider both regional and national audiences. The products are accessible in various formats (e.g., print, electronic and video) and are available free of charge whenever possible. The RTMCC Products Page at <http://sntc.medicine.ufl.edu/RTMCCProducts.aspx> provides access to 164 TB products and archived webinars.

In its ongoing planning process regarding the future role of RTMCCs in light of diminishing resources, DTBE obtained input from partners and reached agreement on several assumptions. Retention of a well-trained workforce is critical to TB elimination in the United States. As TB control programs face funding decreases and loss of staff, maintenance of human resource development and training and education to health department staff and other healthcare providers will be imperative and an integral part of any strategy to prevent, control and eliminate TB. RTMCCs will continue to focus on activities that contribute to the elimination of TB in the United States and provide services to meet existing needs.

In the interest of time, Dr. Walton did not present the restructuring options DTBE has proposed for RTMCCs. However, she informed ACET that the options and scenarios were described in their entirety in the slide set. The options outlined the advantages, disadvantages or unknown outcomes if DTBE reduced, maintained or increased the current level of support to RTMCCs.

Dr. Walton asked ACET to consider and provide guidance on a number of overriding questions to help CDC clearly define the future role of RTMCCs in light of funding constraints.

1. Should the requirement to fund RTMCCs through an existing state or large-city TB CoAg be removed? This option would remove RTMCCs from the overall guidance of front-line TB programs.



2. Should CDC continue to provide CoAg funds for human resource development to TB programs? This option would allow RTMCCs to continue to build state and local capacity for training and education.
3. Should CDC expand or increase annual training requirements for RTMCCs? This option would broaden training to include private providers and HRSA-funded CHCs, but RTMCCs would still include TB programs in providing training to these groups to ensure accuracy, feasibility and acceptance.
4. Should CDC market the availability of medical consultation services provided by RTMCCs? This option might bypass state or large-city TB programs and increase the use and cost of these services to programs.
5. Should DTBE medical officers and public health advisors be placed in RTMCCs?
6. How many RTMCCs should CDC support? For example, should the number of RTMCCs be reduced to three, maintained at four or increased to five?
7. What strategies should be implemented to address training, education and medical consultation needs along the U.S. Border?
8. What strategies should be implemented to address training and education needs of laboratorians?

Mr. Phillip Griffin (NTCA alternate liaison) made a clarifying comment in response to Dr. Chorba's overview of NTIP. He noted that TB programs have been reporting on their progress toward achieving the national objectives well before 2010 and the official rollout of NTIP in 2008.

ACET was gravely concerned about the severe impact of funding cuts on national TB program capacity. The members asked DTBE to consider the following issues in its ongoing discussions and efforts to realign the TB funding formula.

- DTBE should redistribute funding to TB programs to align with both epidemiologic needs and performance. The development of stronger NTIP indicators would play a critical role in this effort. For example, the evaluation of immigrants and refugees is one of the 12 NTIP program objectives. However, consensus has not been reached on meeting this performance target because the number in this population has not been determined to date.
- DTBE should expand RTMCC training and education to include physicians and mid-level providers who are contracted by companies that operate medical units of correctional facilities and regularly evaluate TB transmission in these settings. These companies typically are not qualified to ensure that contracted medical providers have appropriate expertise or knowledge to detect, manage or treat TB cases in correctional settings.
- DTBE should make strong efforts to maintain TB control dollars for continued support of liaisons between health departments and correctional facilities in the United States. At this time, ~250 local jails house detainees in the custody of Immigration and Customs Enforcement (ICE) and >1,800 local jails house U.S. Marshals Service prisoners. The funding cuts will severely jeopardize the ability of health departments to support local jails in providing an array of TB services (e.g., direct care to detainees and prisoners, contact investigations, technical guidance, policy development, clinical management and sputum collection). In its ongoing discussions to realign the TB funding formula, DTBE should consider binational and transnational cases that are managed by border states,

but are not counted in the national surveillance system. Federal funding for TB case management that is outside the authority of any U.S. state or local jurisdiction also should be raised during DTBE's discussions of the TB funding formula. For example, federal funding would be needed if no state resources were available to manage a newly-arrived foreign-born MDR-TB case.

- CDC/DGMQ oversees interstate and international movement of TB patients, but persons born in U.S.-affiliated Pacific Islands are not included in these efforts. Because these individuals have no screening requirements or other restrictions and are free to travel between their countries of origin and the United States, the burden of TB in this population is not documented. DTBE should engage the Pacific Island Health Officers Association to obtain input on potential strategies to address this issue.

### **Update on TB Surveillance, Genotyping and the Outbreak Evaluation Unit (OEU)**

#### **Thomas Navin, MD**

Chief, Surveillance, Epidemiology and Outbreak Investigations Branch, DTBE  
Centers for Disease Control and Prevention

Dr. Navin reported on recent scientific advances in three areas that provide a foundation for early outbreak detection. The first scientific development is genotyping, which allows for the identification of genetically related organisms, which in turn allows the identification of genotype clusters of TB cases.

DTBE has organized the Outbreak Evaluation Unit to coordinate the response to potential outbreaks. OEU is comprised of five DTBE organizational units: Office of the Director; Surveillance, Epidemiology and Outbreak Investigations Branch; Communications, Education and Behavioral Studies Branch; Laboratory Branch; and Field Services and Evaluation Branch.

OEU's current inputs include requests by local TB programs for assistance on potential outbreaks. OEU's current outputs include tabling an issue to gather more information, conducting Epi-Aids to better understand the epidemiologic subtleties of the problem and propose recommendations, and possibly offering programmatic support to provide surge capacity.

DTBE is aware of three major drivers of change that currently affect TB outbreak capacity at federal and state levels. State budget cuts are impacting the number of outbreaks, decreasing the ability of states to detect outbreaks, and reducing their capacity to respond to outbreaks. DTBE's outbreak detection capabilities are increasing. Additional data collection to evaluate the cost-effectiveness of a new approach is a critical need at both federal and state levels.

DTBE's response to the drivers of change includes applying insights learned during research projects to defining the appropriate inputs for OEU, improving existing abilities to provide surge capacity, and providing a safety net. DTBE is currently taking steps to broaden the OEU inputs and outputs. The inputs are being expanded to include alarms to detect potential TB outbreaks.

The outputs are being expanded to include alerts, in-person or telephone consultations, onsite technical assistance visits by senior epidemiologists over multiple days, and long-term assistance for outbreaks.

The second scientific development is the linkage between genotyping data and surveillance data. The function of TB genotyping is to examine tiny DNA variations to determine genetic relatedness of TB strains from different patients. TB genotyping is only performed on culture-positive cases. CDC launched the National TB Genotyping Service (NTGS) in 2004 for states to submit TB isolates for genotyping. Although 83% of culture-positive TB cases in the United States had a TB genotype result as of 2009, DTBE's goal is to increase TB genotyping to 94%. CDC funds two TB genotyping laboratories in California and Michigan, and the CDC laboratory serves as an overflow facility.

NTGS uses two polymerase chain reaction methods for genotyping: spacer oligonucleotide typing (spoligotyping) and mycobacterial interspersed repetitive units (MIRU). These methods provide laboratories with capacity to determine TB transmission with a great deal of specificity. CDC launched the Tuberculosis Genotyping Information Management System (TB GIMS) in March 2010 as a secure web-based application to manage, disseminate, and analyze genotype data. As of March 2011, TB GIMS contained >55,000 patient records with genotype and surveillance results. TB GIMS currently has 457 registered users.

The primary functions of TB GIMs are to receive genotype results from genotyping laboratories, link genotype results to patients' surveillance data, provide standardized reports and maps of genotype clusters, and compare demographic, clinical and risk characteristics of patients in genotype clusters. TB genotype data are used to better understand and confirm a suspected chain of transmission when an epidemiologic link is established between cases of active TB.

Genotypes from related cases are expected to match, while unexpected genotype matches can signal an alert to unsuspected chains of transmission. Discordant genotypes among persons with suspected transmission links can signal a misclassification and avert a potential outbreak investigation.

"Genotype clusters" are defined as two or more patients with matching TB genotypes in the same place. The "clustering rate" in a population is used as a key measure and often serves as a surrogate for the rate of recent transmission. The Moonon, *et al.* study was submitted for publication and estimated recent tuberculosis transmission in the United States based on genotype and geospatial scanning clusters in three geographic units of analysis.

The study identified the U.S. clustering rates as 77% at the national level, 57% at the state level, and 39% at the county level. The study showed that the U.S. clustering rate was 23% when the statistical geospatial scan (SaTScan) was used to define clustering. Dr. Navin believes that the 23% genotype clustering rate is the best estimate of recent TB transmission in the United States at this time.

TB genotyping has a number of practical applications beyond identifying recent transmission, such as detecting false-positive TB cultures, distinguishing between relapse and re-infection,

confirming known epidemiologic links, finding previously unknown epidemiologic links, detecting outbreaks and defining their scope, and monitoring outbreak transmission over time.

The third scientific development is utilization of genotype and surveillance data to predict, detect, and analyze TB outbreaks. DTBE's current outbreak detection algorithm is based on four characteristics: the genotype cluster, geography, time and risk factors. DTBE plans to refine these outbreak detection methodologies in the future. Genotyping will be improved from spoligotyping plus a MIRU12 match to spoligotyping plus a MIRU24 match. Active research is exploring the potential role of whole-genome analysis.

The three-year time window will be reduced to two years and the new CUSUM analysis will be applied to focus more on time in addition to geography. Risk factors will be improved by shifting from a case-by-case analysis to automated algorithm. In terms of geography, however, DTBE is uncertain at this time whether SaTScan can be automated in the future for use with TB GIMS.

DTBE tested its future outbreak detection algorithm by using TB GIMS data from an actual outbreak in a homeless shelter. The local TB program noted the problem in the second quarter of 2009 after case 7, but TB GIMS would have signaled an alert in 2008 after case 3. Another analysis showed that for 6 of 8 TB outbreaks DTBE investigated in 2008-2009, SaTScan would have raised an alert from 2 to 42 months earlier than local programs (or a median of 8 months).

Previous analyses of TB outbreaks were based on situations in which local programs were overwhelmed and requested assistance from DTBE. Moreover, previous analyses of TB clustering were based on prevalent clusters at the national level. DTBE has started to improve its analytic ability by examining all incident TB clusters in the TB GIMS database and analyzing changes over time.

New clusters that began in 2006 were examined to determine characteristics that were associated with extreme growth by the end of 2009. For purposes of this analysis extreme growth was defined as 6 or more TB cases in the same area that represented statistically significant geospatial clustering.

Of 349 clusters in this analysis, 17 clusters showed extreme growth. DTBE applied TB GIMS data from the homeless shelter outbreak in an effort to predict outcomes of the 17 clusters with extreme growth. Of 10 clusters with similar characteristics to the homeless shelter outbreak, 80% showed extreme growth.

DTBE's outbreak detection analysis emphasized the need to strike an appropriate balance between taking action well before an outbreak is underway and not issuing alerts for "false" outbreaks. However, DTBE is aware that early outbreak detection is not sufficient. Consensus is needed among all participants to issue an alert for potential outbreaks and implement the best interventions for specific situations. An appropriate balance is needed between new activities, interventions and initiatives versus the struggle of TB programs to meet current needs. Other critical needs include adequate surge capacity to respond to outbreaks, a solid safety net, and compelling prevention-effectiveness data to make a strong case to decision-makers about the importance of TB outbreak detection.

DTBE identified several principles to guide the development of its updated TB outbreak response plan. Actions will be taken in accordance with CDC's core values of accountability, respect and integrity. DTBE will acknowledge its role as a guest of host jurisdictions. Collaborations will be fostered and expertise will be built within and outside of CDC. Surge capacity will be provided when requested.

Research will be applied to improve practice. Consensus will be built among stakeholders on when early intervention is warranted. Existing capacity to detect TB outbreaks will be confirmed and enhanced. Prevention-effectiveness measures will be built into genotyping and outbreak detection. Current inputs will be expanded to include outbreak detection alerts internally and institutionalize a relatively theoretical framework.

Current outputs will be expanded with alerts, consultations, technical assistance, Epi-Aids and long-term assistance to increase the flexibility of responses. Alerts will be institutionalized externally to increase the knowledge of partners about DTBE's data on TB clusters. Efforts will be made to prepare for increased requests for support.

## **Update on the TB Laboratory System and Core Functions**

### **Bonnie Plikaytis, MS**

Deputy Chief, Laboratory Branch, DTBE  
Centers for Disease Control and Prevention

Ms. Plikaytis reported that the DTBE Laboratory Branch conducts its three core functions with the Reference Laboratory Team, Laboratory Capacity Team and Applied Research Team. The "services" function includes the Molecular Detection of Drug Resistance (MDDR) Service, drug susceptibility testing, the Supranational Reference Laboratory, oversight of 65 CoAgs, and consultation and technical assistance.

The "partnerships" function includes education and training, operational research, policy development, laboratory systems, and collaborative efforts with federal partners, academia, public health laboratories (PHLs), NTCA and the Association of Public Health Laboratories (APHL). The "research" function includes applied, operational and translational research (e.g. molecular genetics of drug resistance, genotyping and human genetics, and immunology and cell biology).

CDC awarded contracts to two laboratories in California and Michigan to perform the NTGS functions using spoligotyping and the MIRU variable number tandem repeat (VNTR) platform with 24 loci. Because capacity is based on the national incidence of TB, the two laboratories collectively process ~10,000 isolates per year. NTGS forms the basis for TB GIMS surveillance data and is used by state TB control programs, CDC and PHLs. NTGS assists in investigations of TB outbreaks and possible false-positive results, including laboratory cross-contamination. The cost of NTGS is ~\$117 per isolate.

DTBE conducted research to develop, validate and implement MDDR as a referral service for isolates in compliance with the Clinical Laboratory Improvement Amendments (CLIA). DTBE deployed the MDDR Service nationally in September 2009 to provide rapid and preliminary guidance for the selection of an initial MDR-/XDR-TB regimen. The MDDR Service uses 9 loci to detect resistance to 7 classes of drugs.

The MDDR Service is being used by 40 states at this time and has captured 50% of MDR-TB isolates in the United States. The average turnaround time for the MDDR Service is two days compared to 28 days for growth-based methods. DTBE is currently validating phase II of the MDDR Service to include clinical specimens for testing of INH and rifampin resistance. DTBE hopes to rollout phase II of the MDDR Service at the end of the summer in 2011.

DTBE has identified several laboratory imperatives for NTP. Accurate, reliable and prompt TB services must be provided. Laboratory services must be coordinated with healthcare providers and public health authorities that care for TB patients. Policy guidance must be offered to make prompt and informed case management decisions and eliminate transmission of TB disease. New tools must be developed in the following framework to accelerate elimination: research and development, efficient deployment and implementation, ongoing operational research for evaluation and systems improvement, and continual development of policy and guidance.

DTBE serves on the Federal TB Task Force's Diagnostics Workgroup to engage public and private partners in exploring models and strategies to expedite the development of new tools. The workgroup will hold the "TB and HIV Diagnostics in Adult and Pediatric Populations" Workshop on June 28-30, 2011. The workshop will focus on research and development, implementation and evaluation of new tools in pediatric populations.

FDA will convene a public meeting of the Microbiology Devices Panel of the Medical Devices Advisory Committee on June 29, 2011. The panel will discuss and make recommendations on a possible reclassification of TB diagnostics. Industry views the current Class 3 status of TB diagnostics as an impediment to seeking FDA approval for new diagnostics. CDC is engaged with the AIDS Clinical Trials Group in an effort to evaluate the Cepheid Xpert® MTB/RIF assay. Registered data collected from this study will be presented to FDA for approval.

In terms of national laboratory capacity, CDC provides \$7.6 million annually to 64 U.S. jurisdictions through CoAgs for laboratory enhancement based on a consensus-driven and workload-based formula. In FY2010, DTBE used an APHL supplement for programmatic intervention to allocate one-time funding of \$3 million to PHLs to increase patient access to molecular diagnostics for the detection of TB and drug-resistant TB.

Similar to other parts of DTBE, the Laboratory Branch also is in the planning stage of aligning the NTP budget with TB elimination goals. The FY2011 funding allocations for laboratory enhancement include a 55% distribution based on prior funding and a 45% distribution based on the formula. Of the funds allocated to laboratories according to the formula, the total number of specimens received accounts for 5%; the per patient basis accounts for 80% (15% for TB cultures inoculated, 15% for isolates received for identification, 25% for nucleic acid

amplification testing [NAAT] of clinical specimens, and 25% for drug susceptibility testing of first-line drugs) and 15% for laboratory systems.

The National Laboratory System includes ~1,500 public and private laboratories that provide some level of mycobacteriology service. CDC-funded PHLs receive ~300,000 specimens annually, but this estimate most likely would increase to millions with the inclusion of specimens from private laboratories. The major components of the National Laboratory System include a well-trained and knowledgeable workforce; provision of an external quality assurance program for PHLs (e.g., the CDC Model Performance Evaluation Program); and evidence-based technical guidance DTBE develops in collaboration with federal partners, APHL and the Clinical Laboratory and Standards Institute.

DTBE is aware of several challenges that must be addressed to advance national laboratory capacity. The existing legal and regulatory framework adds complexity to the National Laboratory System in terms of providing services in certain local jurisdictions. Issues related to the laboratory infrastructure and logistics are expensive, particularly the requirement to maintain a BSL-3 facility in each TB laboratory and the transportation of specimens between local providers and PHLs. The laboratory network depends on rapid referral of specimens and timely requests from local laboratories and providers.

Because PHLs may be the sole provider of mycobacteriology services in low-incidence states, elimination of funding in these areas would result in a disruption of services. Decreased funding to PHLs would require these dollars to be replaced with state resources or contracts. The ability to maintain proficiency in low-volume laboratories would be uncertain. Data-driven guidance is needed before laboratory services are consolidated to ensure positive outcomes. PPACA aims to improve access, but the role of this legislation in addressing laboratory services is unclear. Many PHLs do not have a mechanism or infrastructure to receive payment from a third-party payer.

### **Update on the Role of the U.S. TB Program in Global TB Control**

#### **RADM Kenneth Castro, MD**

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

Dr. Castro presented the update on behalf of Dr. Eugene McCray, Chief of the DTBE International Research and Programs Branch, who was unable to attend the ACET meeting. At the agency level, CDC follows the “2011-2015 Global Plan to Stop TB” that was developed and published by the Global Stop TB Partnership. Dr. Castro represents CDC on the Federal TB Task Force’s U.S. Government Workgroup to Address Global TB, the Global Stop TB Partnership Coordinating Board, and the WHO TB Technical Advisory Group.

Dr. Frieden recently expressed his interest in CDC developing a unified policy to address global TB and designated a TB Coordinator to make recommendations on investing resources in

CDC's global research agenda. The TB Coordinator will be accountable for agency-wide global TB activities and will be evaluated in one year to determine whether the intended outcomes were met. This effort is an attempt to address the IOM's recommendation in 2000 that called for the U.S. government to become directly involved in global TB control. CDC data show that FBPs account for ~60% of U.S. TB cases. If the evaluation shows that the TB Coordinator was unsuccessful, Dr. Frieden most likely will reorganize CDC's global TB activities.

At the division level, DTBE invests ~\$1.4 million to address TB in high-burden countries that impact the number of foreign-born cases in the United States, primarily from U.S.-Mexico border states. The goal of these resources is to improve detection, follow-up and completion of TB therapy regardless of whether the patient is on the U.S. or Mexico side of the border. DTBE uses the binational referral and counter-referral system that is provided by Cure TB and TB Net in this effort.

DTBE collaborates with other CDC divisions and global partners to reduce the importation of TB from the Philippines and Vietnam and also to address HIV-associated TB in sub-Saharan Africa. The major outcomes of these efforts include:

- overseas screening and the management of TB cases before immigrants are issued visas to enter the United States;
- a demonstration project of a regimen to reduce TB in latently infected HIV patients with low CD4 counts;
- an evaluation of operational research for a TB screening algorithm in HIV-infected persons in Cambodia, Thailand and Vietnam; and
- the development of evidence-based policy guidance that has been promulgated in other parts of the world.

DTBE's global partners fund operational research training and have created a training module for providers who address TB in high-burden countries that need programmatic improvements. DTBE leveraged resources from its global partners to deploy CDC staff to China, India, Kenya and Thailand and provide subject-matter expertise on TB in these countries. DTBE is providing technical support to implement infection control precautions and improve capacity in this area at the global level.

DTBE is continuing to provide technical assistance and staff support to revitalize the TB program in Haiti following the devastating earthquake in 2010. Overall, CDC is interested in aligning its domestic and global TB activities for mutual benefit and welcomes guidance from ACET in achieving this goal.

### **Update on CDC's Role in Clinical, Epidemiologic and Laboratory TB Research**

A panel of DTBE leadership made two presentations describing CDC's history, role and current activities in conducting clinical, epidemiologic and laboratory TB research.



**Elsa Villarino, MD, MPH**

Tuberculosis Trials Consortium Project Officer, DTBE  
Centers for Disease Control and Prevention

Dr. Villarino presented an update on CDC's TB research conducted by the Tuberculosis Trials Consortium (TBTC). The major functions of NTP are to develop and disseminate national policies and guidelines, serve as the National Reference Laboratory, maintain the National TB Registry, serve as a national resource for training and education, and conduct epidemiologic, operational and clinical research.

DTBE conducts research in four areas: (1) clinical trials to evaluate new, safer, stronger or faster treatment for latent and active TB disease; (2) epidemiologic studies to assess risk factors and new interventions; (3) laboratory science (e.g., diagnostics, genotyping, immunology, rapid detection of drug resistance, and bacterial and human genetics); and (4) outbreak investigations and program evaluation.

The global investment in TB research increased from \$357 million to \$614 million from 2005-2009. However, the five-year total is only 50% of the amount called for in the WHO 2006-2015 Global Plan to Stop TB. The updated 2011-2015 Global Plan calls for a doubling of these resources. Investments in TB research in 2009 were \$206 million from the National Institutes of Health (NIH), \$114 million from the Gates Foundation, and \$18.5 million from CDC (external funding only).

The purchasing power of CDC's TB budget has dropped by 57% since FY1994 when adjusted by 1990 dollars using the Consumer Price Index for Medical Care. Funding for TBTC was renewed in 2009 for a ten-year period and will decrease by 22% in 2011. DTBE hopes funding for TBTC will remain level for the remainder of the project cycle.

TBTC was initially funded in 1993 to conduct one trial and was formally reorganized in 1997. Formal bylaws and policies were established in 1998. TBTC is housed in the Clinical Research Branch and the Data and Coordinating Center is located at CDC. Each TBTC site is funded to conduct research through contracts or memoranda of understanding and must have links to local TB control programs to recruit patients for studies.

CDC leadership conducts annual reviews of TBTC sites, while an expert panel conducts periodic external reviews every five years. TBTC's mission is to conduct programmatically relevant clinical, laboratory and epidemiologic research concerning the diagnosis, clinical management and prevention of TB infection and disease. TBTC's organizational structure includes a Steering Committee, oversight groups and workgroups to conduct, prioritize and ensure the quality of research. TBTC is comprised of 9 international and 11 domestic sites.

Study 22 was the first TBTC study that was conducted in 1995-2000 and tested a once-weekly regimen of RPT for continuation phase therapy. Outcomes from Study 22 led to the inclusion of RPT in a new LTBI treatment regimen. Study 26 was recently submitted for publication. The study included 8,000 patients and compared a nine-month INH regimen versus a 12-week INH/RPT regimen for LTBI treatment. The Study 26 results showed that the new 12-week INH/RPT

regimen had equal efficacy and less toxicity than the INH regimen in treating LTBI. Protocols are currently being drafted and funding is being procured to implement six new TBTC studies later in 2011.

DTBE and its partners have made several notable accomplishments to date through TBTC research. TBTC's 9 major clinical trials and 15 sub-studies have enrolled >12,000 patients and volunteers. TBTC studies have resulted in 25 publications in peer-reviewed journals and >100 presentations, posters and abstracts at national and international scientific, bioethics and social science conferences. These topics have included pharmacokinetic evaluations of drugs and drug interactions. *Nature Medicine* cited TBTC Study 27 as one of the 20 most important TB papers published in the past three years.

DTBE recognizes that the success of TBTC is largely due to partners and researchers in the private sector, academia, government, non-governmental organizations, and TB clinics in health departments. TBTC's major partners include FDA, the National Institute of Allergy and Infectious Diseases, Global Alliance for TB Drug Development, Foundation for Innovative New Diagnostics, Johns Hopkins Center for Tuberculosis Research, commercial drug manufacturers and patients worldwide.

Dr. Villarino concluded that research advances with multiple new candidate drugs, promising new diagnostics and improved strategic approaches to TB control represent a promise to significantly impact TB control in the next decade. As a result, investments in TB research should be continued and strengthened.

ACET was impressed by TBTC's outstanding accomplishments, tremendous productivity and meaningful research, particularly the exciting new results of Study 26 demonstrating the efficacy of a shorter LTBI treatment regimen.

**Thomas Navin, MD**

Chief, Surveillance, Epidemiology and Outbreak Investigations Branch, DTBE  
Centers for Disease Control and Prevention

Dr. Navin presented an update on CDC's other TB research initiatives. Research area 1 is the Tuberculosis Epidemiologic Studies Consortium (TBESC). The first ten-year cycle of TBESC was recently completed. Of 32 studies conducted over this period of time, 2 were cancelled and 30 will complete data collection by September 2011. One TBESC study evaluated the timing of TB among contacts by interval from the initiation of treatment in TB patients. The study showed that a remarkable number of TB cases were identified at the time of the contact investigation.

DTBE will focus on LTBI in the next ten-year cycle of TBESC. The major study will be a prospective comparison of tuberculin skin tests (TSTs) and interferon gamma release assays (IGRAs) in diagnosing LTBI and predicting progression from LTBI to TB disease. Sub-studies of the major study will focus on an assessment of LTBI treatment and an evaluation of strategies to ensure LTBI treatment acceptance and completion.

CDC released the RFP for the TBESC re-competition on May 5, 2011 with a deadline to submit proposals by June 17, 2011. Applicants were required to submit two proposals to document their (1) qualifications for TBESC membership and ability to perform all research studies and (2) ability to participate in the major study involving the evaluation of TSTs and IGRAs.

Research area 2 is NHANES. DTBE and the CDC National Center for Health Statistics signed an intra-agency agreement in August 2010 to use NHANES data for TB research over a two-year survey period from January 2011 to December 2012. DTBE incorporated 10 TB questions into NHANES and added TST and IGRA questions to the laboratory portion of the survey. The skin test methodology is identical to the one that was utilized in the 1999-2000 survey and will be used to compare TST and IGRA reactivity rates. Other laboratory tests added to NHANES include a complete blood count, lipids, HIV, hemoglobin A1c and vitamin D.

CDC administers NHANES in 10 U.S. locations annually to a representative population of non-institutionalized persons  $\geq 6$  years of age. Several subpopulations are over-sampled: Hispanics (25%), African Americans (25%), Asians (14%) and other low-income groups (13%). For the TB component, DTBE assures the quality of data and expects to receive the NHANES results for analysis in late 2012.

The goals of DTBE's TB research with NHANES data are three-fold: (1) obtain the first national estimate of LTBI in a representative sample of the U.S. population since 2000; (2) simultaneously assess reactivity rates with TST and the QuantiFERON®-TB Gold test in the diagnosis of TB infection; and (3) evaluate the correlation between LTBI and less understood risk factors (e.g., vitamin D levels).

Research area 3 is laboratory research. DTBE's laboratory research activities cover five major areas. Studies to make more accurate and rapid diagnosis of TB drug resistance account for 50% of DTBE's laboratory research. The remaining 50% includes operational studies to improve the National Laboratory Network System (30%), research to improve genotyping (10%), laboratory science, in cooperation with Clinical Research Branch, to support the TBESC's human genetics epidemiologic study (5%), and immunology and cell biology research to advance TB vaccine development and contribute to improved diagnosis of LTBI (5%).

DTBE's laboratory operational research projects are designed to address issues to strengthen the National Laboratory Network from a systems perspective. Implementation of this function critically relies on close coordination and communication among CDC, APHL, public health authorities, healthcare providers, and public health, commercial and clinical laboratories that perform TB testing services.

DTBE and APHL recently administered the "National TB Laboratory Services Survey" in a joint effort to characterize existing TB testing capacity in U.S. laboratories. The survey questions focused on quality improvement, access, responsibilities and locations of TB testing, referral patterns, testing volume, turnaround times and various technical issues. DTBE and APHL will use the survey results to develop and prioritize a list of future operational research projects.

DTBE's laboratory drug resistance research projects are designed to conduct basic science studies of molecular resistance mechanisms to fill gaps in NIH-funded research. DTBE performed translational research to create a platform in which suspected MDR-TB isolates were genetically tested for first-line and second-line drug resistance. DTBE used the research results to design a validation study that complies with CLIA.

After DTBE deploys the MDDR Service nationally, discordance between results for molecular and growth-based drug susceptibility tests will be examined to improve both methods. DTBE initiated phase II research and development to create an expanded platform to test sputum specimens for INH and rifampin resistance. DTBE will evaluate the MDDR Service to identify more efficient and effective approaches.

DTBE's laboratory research projects to improve genotyping are designed to identify optimal mechanisms and provide surveillance data to the broader TB control community. DTBE's research has strengthened capacity to advance from using restricted fragment length polymorphism and spoligotyping methods to the 24-loci MIRU-VNTR platform.

DTBE is attempting to address four key questions to improve genotyping. Is additional discriminatory power needed to optimize public health impact? What approaches should be taken to conduct new, more efficient and cost-saving technologies? What strategies should be implemented to improve laboratory data analysis? What is the role of new technological advances?

DTBE is aware that the next generation of sequence platforms undoubtedly will provide alternative approaches to genotyping and routine/whole-genome sequencing and also will offer the potential for simultaneous identification of organisms, prediction of drug resistance and useful epidemiologic typing. The burden of data analysis, costs and other barriers is decreasing, but operational research and research regarding data analysis and interpretation continues to be a critical need.

With no further discussion or business brought before ACET, Mr. Jones recessed the meeting at 5:19 p.m. on June 7, 2011.

### Opening Session: June 8, 2011

**Hazel Dean, ScD, MPH**  
Deputy Director, NCHHSTP  
Centers for Disease Control and Prevention

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 conference call. She verified the presence of a quorum with voting members and *ex-officio* members for ACET to conduct its business on June 8, 2011. Dr. Dean reconvened the meeting at 8:35 a.m.

Dr. Dean announced that ACET meetings are open to the public and all comments made during the proceedings are a matter of public record. ACET members should be mindful of potential conflicts of interest identified by the CDC Management Analysis and Services Office and recuse themselves from participating in discussions or voting on issues in which they have a real or perceived conflict.

## **Overview of the Role of CDC and ACET in the Development of TB Evidence-Based Policies, Guidelines and Recommendations**

### **Philip LoBue, MD, FACP, FCCP**

Associate Director for Science, DTBE  
Centers for Disease Control and Prevention

Dr. LoBue explained that DTBE makes strong efforts to issue evidence-based guidelines, but some recommendations are based on expert opinion with little or no evidence. DTBE and its partners have released guidelines since 2000 covering nearly all aspects of TB control and elimination, including treatment of TB disease and LTBI, diagnosis of TB with NAAT and IGRA, contact investigations, and TB control in high-risk settings (e.g., healthcare settings and correctional facilities).

Multiple entities can propose topics to develop TB guidelines, such as DTBE, ACET, professional societies, or ad hoc groups with interest in a particular issue. The development of TB guidelines typically is driven by new scientific information that can alter policy, but a systematic and coordinated review and decision-making process is lacking at this time.

TB guidelines can be developed by CDC alone, CDC and ACET, CDC and NTCA or other external partners, or professional societies with CDC as a partner. ACET's role in TB guidelines has ranged from no involvement to endorsement of a product solely developed by CDC, active participation and endorsement of a product developed by CDC, or development and endorsement of a product through a joint CDC/ACET workgroup.

DTBE is aware that no process or criteria have been clearly defined to identify entities to develop TB guidelines. From a historical perspective, however, professional societies typically have led the development of clinical-based guidelines. The development of other guidelines appears to be based on legacy. For example, the previous approach most likely would be used to update guidelines on the same topic or create new guidelines for a similar topic.

DTBE recognizes that its methodology for evaluating evidence and grading recommendations is quite variable and does not use a standardized system (e.g., Grading of Recommendations Assessment, Development and Evaluation (GRADE), U.S. Preventive Services Task Force (USPSTF), U.S. Public Health Service, or the Infectious Diseases Society of America). However, some guidelines are not well suited to using these methodologies because the

recommendations are based on expert opinion or experience, do not have a strong evidence base from randomized controlled trials, and should be described as “best practices.”

The use of methodologies to evaluate evidence and grade recommendations typically is at the discretion of writing committees unless an outside partner mandates the use of a specific method. Most notably, the American Thoracic Society (ATS) now requires the use of GRADE to evaluate its guidelines. GRADE was initially created to evaluate therapeutic interventions, but the method was expanded to assess diagnostics. However, GRADE might not be particularly useful for evaluating process and organizational recommendations.

In the GRADE-mandated process, ATS has adopted to evaluate its guidelines, the Microbiology, Tuberculosis and Pulmonary Infections Assembly must formally approve all applications that are submitted once per year. The period of time between approval of a proposal and publication of guidelines typically is several years. ATS’s GRADE-mandated process for evaluation of guidelines is more formal and systematic, but less flexible. This process might limit DTBE’s ability to be responsive to new TB developments.

DTBE must consider the ongoing development of CDC policy in creating a new process for TB guidelines and recommendations. CDC formed an internal workgroup to provide advice on approaches to develop evidence-based guidelines. The workgroup noted that several CDC programs currently use modified versions of GRADE. A guidance document is being drafted at this time with proposed practices and minimum standards for guidelines. The workgroup has emphasized its strong focus on transparency in developing guidelines and clearly documenting the direct path between the collection of evidence and formulation of recommendations.

In the interim of CDC issuing an agency-wide policy, Dr. LoBue asked ACET to provide advice to DTBE during a future meeting on important issues that should be addressed in the future development of evidence-based TB recommendations and guidelines.

1. Should DTBE shift from its current ad hoc approach to a more systematic, formal and standardized approach in developing TB guidelines? What would be the resource implications of convening expert panels to evaluate evidence under the GRADE system? What strategies should be implemented to strike an appropriate balance between formality and flexibility? For example, DTBE would adversely impact the TB prevention and control community if guidelines were published three years after data were collected from a study.
2. What are appropriate roles of various entities (e.g., CDC, ACET, NTCA and professional societies) in developing TB guidelines?
3. Should DTBE use the GRADE system or other prescribed methodologies to evaluate TB evidence? If yes, what steps should be taken to implement the expensive and resource-intensive GRADE system in developing TB guidelines? What approaches should be taken to assess expert opinions, best practices or other categories of evidence that are not easily addressed by GRADE-type methodologies? GRADE is a process-oriented system that is not designed to evaluate rigorous evidence.
4. Should DTBE create a formal vetting or application process for guideline proposals similar to the planning committee process ATS established with the Microbiology,

Tuberculosis and Pulmonary Infections Assembly? If yes, what steps should DTBE take to integrate this approach into existing processes? What components should be included in the application process?

5. Should DTBE create and institutionalize a formal process to review existing guidelines at regular time intervals? If yes, what would be the appropriate time interval?
6. What actions should DTBE take to achieve maximum responsiveness and flexibility of guidelines in a systematic process? Should a web-based “living document” approach be implemented to assure easy and rapid revisions and allow for updates to individual sections rather than the entire document?

ACET agreed that at a future meeting, the topic of developing TB policies, guidelines and recommendations would be revisited to provide detailed responses to the questions Dr. LoBue posed. In the interim, several ACET members made suggestions for DTBE to consider in its ongoing efforts to create a process for the development of evidence-based TB guidelines and recommendations.

- DTBE should review the Agency for Healthcare Research and Quality’s National Guideline Clearinghouse as an additional model in developing evidence-based policies, guidelines and recommendations.
- DTBE should consult with the CDC Advisory Committee on Immunization Practices (ACIP) to obtain input and insights on its adoption of a modified GRADE approach.
- DTBE should invite a meta-analyst to make a presentation at a future ACET meeting to describe the technology involved with formulating TB guidelines and recommendations.
- DTBE should formally adopt the web-based living document approach to provide TB controllers with the best tools as quickly as possible. Providers are forced to use outdated guidelines to treat their TB patients because updates are made to entire documents rather than individual sections as needed. The living document approach would have been helpful in updating key sections of the TB Treatment Guidelines with recent evidence-based data. However, DTBE should develop clear and transparent criteria to ensure updated sections of guidelines are evidence-based. An effective and formal strategy also should be devised to publicize the availability of updates.
- DTBE should formally adopt a process to systematically and periodically update guidelines that are perceived to be “outdated.” A statement should be included in these updates to inform readers that the existing guidelines were reviewed, no new evidence was produced, and no changes were made to the recommendations.
- HHS is currently examining evidence-based practice at the department level due to the great deal of variability among HHS agencies in defining the burden of evidence. DTBE and ACET should engage appropriate HHS representatives in a discussion on this issue.

## Update on NCHHSTP's Prevention Through Healthcare Activities

### **Stuart Berman, MD, ScM**

Senior Advisor to the Director of NCHHSTP  
Centers for Disease Control and Prevention

Dr. Berman presented an update on NCHHSTP's recent prevention through healthcare activities to enhance preparedness and response capacity of health departments. NCHHSTP will convene a consultation on June 20-21, 2011 in Atlanta with several overarching aims. The impact of changes in the healthcare system on service delivery will be discussed. The implications of these changes for state and local health departments related to NCHHSTP's HIV, TB STD and viral hepatitis prevention programs will be described.

Activities and strategies that are most important to public health and anticipated emerging situations will be identified. Next steps for NCHHSTP and health departments will be prioritized to facilitate responses to challenges and opportunities. The responsibilities and roles of health departments are likely to change over the next few years.

NCHHSTP's care-based services are critical to its mission. DTBE's care-based services include the diagnosis and treatment of active and latent TB. DVH's care-based services include screening of pregnant women, immunization of neonates and management of exposed newborns, HBV immunization of at-risk adults, and identification and treatment of chronic hepatitis.

DSTD's care-based services include access to care for persons with STD symptoms, chlamydia and gonorrhea screening of young women, intensive behavioral counseling for at-risk persons, and management of syphilis. DHAP's care-based services include HIV screening and testing, risk assessment and behavioral counseling for at-risk persons, and linkage to and retention in care as well as assurance of undetectable viral loads in HIV-positive persons.

The consultation will serve as a forum to focus on several important drivers of change in prevention through healthcare initiatives. The first driver of change is increased availability of preventive services without cost sharing. Many of NCHHSTP's prevention services will be covered without cost sharing due to USPSTF's A/B recommendations or ACIP's recommended immunizations. These services include syphilis, chlamydia and gonorrhea screening, HBV screening of pregnant women, STD counseling, HIV testing among at-risk populations, cervical cancer screening, and HPV and HBV vaccination. USPSTF deferred TB screening to CDC.

The second driver of change is expansion of Medicaid coverage and CMS's new agency-wide focus. The expansion of Medicaid will affect service delivery in STD clinics. In 2014, coverage will be extended to adults <65 years of age with incomes up to 133% of the Federal Poverty Level. STD clinic patients primarily are low-income males, many of whom may be covered by Medicaid in the future. STD clinics are a source for ~30% of chlamydia and gonorrhea cases among males.



The expansion of Medicaid may provide clients with more options for care beyond STD clinics. Moreover, STD clinics may no longer serve as facilities of “last resort.” Fiscal pressures will be problematic for the maintenance of STD clinics. Under PPACA, Medicaid may support a substantial increase in STD screening among women as part of family planning.

The expansion of Medicaid will affect service delivery to HIV-infected persons. In AIDS Drug Assistance Programs, >75% of clients are males and >75% are below 200% of the Federal Poverty Level. Many of these clients may be eligible for Medicaid. The expansion of Medicaid also may reduce fiscal pressure on some HIV programs and AIDS Drug Assistance Programs by allowing for an increase in antiretroviral therapy coverage. Increases in eligibility may be greatest in areas of the country with the highest STD/HIV rates (e.g., the Southeast). The provision of HIV care may change and would impact care to TB patients in primary care settings.

The third driver of change is the tremendous investment in health information technology (HIT). The Meaningful Use program offers incentives to eligible professionals and hospitals to adopt electronic health records and electronic laboratory reporting of results. The HIT investment will provide health departments with better data and may facilitate increases in efficiency, but resources are limited for health departments to adopt electronic health records. The investment in health information exchange (HIE) is designed to rapidly build capacity to exchange health information across the healthcare system both within and across states.

Louisiana has bridged public health and healthcare delivery with bi-directional HIE data about patients who needed contact and follow-up. HIV, STD and TB programs and Louisiana State University hospitals participated in this effort. Other states are using HIE as a source of reporting data to decrease costs and improve efficiency. A paper was published in *Pediatrics* in February 2011 documenting the use of HIE data by the Indianapolis Regenstrief System to assess chlamydia screening coverage by race.

The fourth driver of change is expansion of HRSA-funded CHCs. The expansion of CHCs may serve as the default safety net of providers depending on the specific locality. CHCs also may emerge as principal primary care providers for low-income and marginalized populations that often are at increased risk for TB, STDs and HIV.

The expansion of CHCs may decrease the need for health departments to provide direct care, particularly in light of state fiscal situations. Relationships between health departments and CHCs are formed on an ad hoc basis rather than on a formal or structural basis. CDC and HRSA can do more to facilitate relationships between CHCs and health departments across NCHHSTP’s four diseases. This issue will be a key topic of discussion during the consultation.

At the state level, Massachusetts adopted a statewide plan in 2006 to provide near universal health insurance coverage (97% of citizens). But the 2008 economic crisis resulted in the complete elimination of the \$1.2 million STD services line item that funded STD clinics, requiring STD be provided elsewhere.

The fifth driver is changes in systems of care. Threats to health departments include less direct service, reduced funding, less need to fund screening and other areas, and other facilities outside of public health taking the lead for prevention services. Opportunities for health departments to address these threats include collaborating with CHCs to provide continuous services; taking advantage of HIT to increase efficiency and implement new strategies to conduct business; and addressing broader issues by playing a central role in assuring the quality, coverage and effectiveness of systems. In new systems of care, accountable care organizations may need to involve health departments to help link fragmented entities of the healthcare system.

Dr. Berman concluded his overview by providing ACET with more details on the June 20-21, 2011 consultation. Plenary sessions will be held for the four NCHHSTP divisions to describe their missions, activities and challenges related to healthcare reform. Health departments will describe their experiences, assistance needed in the field, collaborations with CHCs, potential new opportunities with HIT, and interactions with primary care providers.

The first series of breakout sessions will be multidisciplinary with NCHHSTP staff and external partners across all four divisions. These sessions will focus on the drivers of change: taking advantage of HIT, collaborating with CHCs, identifying new opportunities with the expansion of Medicaid and addressing billing issues, and interacting with private and primary care providers. The second series of breakout sessions will be disease-focused between the four divisions and their external partners. The invited participants will represent CDC and its federal partners, state and local health departments, professional organizations and academia.

### **Ann Cronin**

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

Ms. Cronin announced that DTBE's partners met with a Congressional committee consultant in November 2010. The purpose of the meeting was to determine the rationale for TB programs not taking advantage of the Omnibus Budget Reconciliation Act of 1993 that expands eligibility of services to TB patients. Congress enacted the legislation during the TB resurgence to eliminate all barriers to TB treatment.

For states that elect to implement the TB option of the law, TB programs can bill Medicaid for prescribed drugs; case management and other services to encourage completion of TB regimens with prescribed drugs by outpatients, including DOT services; and physician, x-ray, laboratory, clinical and FQHC services. However, the law excludes room and board of TB patients. At this time, only nine states are implementing the TB option.

NTCA administered a survey to its membership regarding implementation of the TB option and compiled the following responses. The TB option has more disadvantages than incentives. The TB option adds burden to current workloads. TB programs have minimal control in their states regarding services covered under Medicaid. TB programs that proposed implementation of the TB option in the past were met with resistance. TB programs that billed for Medicaid-eligible services would not be reimbursed.

To address these issues, CDC and the CMS Chief of Enrollment will hold a session during the National Tuberculosis Conference on June 16, 2011. CDC and CMS will use this session to clearly describe the TB option, eligibility criteria, and enrollment instructions to minimize the burden on TB programs. In the future, CDC and CMS hope to collect solid data to demonstrate to states the cost benefits of implementing the TB option by recovering federal dollars.

ACET was pleased that CDC and CMS are making a joint effort to encourage more states to take advantage of the TB option of the Omnibus Budget Reconciliation Act of 1993. However, several members urged the agencies to simplify this process to increase implementation among states.

ACET also asked CDC and CMS to address enormous barriers to states that use the TB option to provide treatment and care to patients. Most notably, legal contracts do not allow hospitals to charge co-pays to some payers and not charge co-pays to other payers. Patients must pay their full deductibles before insurance pays for services. The ability to bill Medicaid for payment of TB drug and diagnostics is extremely difficult.

ACET expressed concern about the omission of TB from PPACA, particularly since TB has no effective vaccine and individual interventions cannot be taken to prevent transmission of an airborne disease. ACET urged CDC to make a solid argument to USPSTF to rate TB treatment with an A or B recommendation for inclusion in PPACA with the justification that primary prevention for TB is locating, treating and curing cases.

ACET made two additional suggestions for CDC to consider in its prevention through healthcare initiatives. First, DTBE should review and replicate the HIV model due to its success in using Medicaid to provide treatment to persons at high risk. Innovative strategies are a critical need because Medicaid and PPACA will not serve the large immigrant population that is at increased risk for TB.

Second, CDC should ask CMS to authorize a Medicaid waiver for TB in a clearly defined local jurisdiction. The purpose of this project would be to reimburse the demonstration site for TB Medicaid-eligible services, provide benefits to the patient population, and collect solid data to show cost benefits to the state in implementing the TB option. Data from the demonstration project could be given to the HHS Secretary to justify inclusion of TB in the PPACA Essential Health Benefits Packages. Efforts should be made to engage AARP to support the TB Medicaid benefit since seniors account for the vast majority of Medicaid dollars.

Dr. Berman responded to ACET's suggestion to include TB in PPACA. He advised ACET to provide input to the HHS Secretary on including TB in the PPACA Essential Health Benefits Package. He also encouraged ACET to regularly review the *Federal Register* to obtain notice on public comment periods for drafts of PPACA public laws.

## ACET Business Session

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 Iram Bakhtawar, respectively, for ACET to approve the previous meeting minutes. **ACET unanimously approved the November 2-3, 2010 Draft Meeting Minutes with no changes or further discussion.**

**TOPIC 2:** A motion was properly placed on the floor and seconded by Drs. Jane Carter and Barbara Seaworth, respectively, for ACET to formally approve the "Recommendations for Prevention and Control of Tuberculosis Among Foreign-born Persons in the United States." ACET's approval would be contingent upon DTBE revising the "Correctional and Detention Facilities" subsection (page 31) and the U.S. Marshals Service reviewing these changes for accuracy prior to publication. **ACET unanimously approved the motion.**

**TOPIC 3:** A motion was properly placed on the floor and seconded by Drs. Christine Hahn and Jane Carter, respectively, for ACET to formally approve "Prevention Measures for Reduction of Multidrug Resistant and Extensively Drug Resistant TB Risk in U.S. Healthcare Workers and Volunteers Serving in High Risk International Settings." ACET's approval would be contingent upon DTBE deleting the header for the unwritten "Future Directions and Needed Research" subsection and Dr. Seaworth adding new text on the importance of early treatment to decrease TB transmission. **ACET unanimously approved the motion.**

ACET applauded Drs. Barbara Seaworth and Elsa Villarino for their outstanding leadership and efforts over a long period of time in developing and revising these guidelines.

**TOPIC 4:** A motion was properly placed on the floor and seconded by Drs. Iram Bakhtawar and Masahiro Narita, respectively, for ACET to formally adopt the new *Advisory Council for the Elimination of Tuberculosis Policies and Procedures Manual*. **ACET unanimously approved the motion.**

**TOPIC 5: ACET agreed to establish a new "Second-Line Drug Shortage Workgroup."**

*Membership:* Barbara Seaworth (chair), Jane Carter and Gail Cassell (ACET), Cornelia Jervis (Treatment Action Group), John Bernardo (Stop TB USA), Jennifer Flood (NTCA), Edward Nardell (International Union Against TB and Lung Disease), Ann Cronin and Sundari Mase (CDC/DTBE)

*Charge:* Address the suggestions ACET made on the SLD shortage problem during the November 2010 meeting (pages 37-38 of the minutes). For example, DTBE should publish Dr. Flood's presentation on challenges in obtaining SLDs in the United States as an expert opinion from the TB community. ACET should write a letter to Dr. Donald Berwick, Administrator of CMS, to describe the serious SLD shortage problem.

**TOPIC 6: ACET agreed to establish a new "TB Elimination Workgroup."**

*Membership:* Eric Brenner, Marcos Burgos, Jane Carter and Masahiro Narita (ACET), Naomi Aronson (Department of Defense), Edward Nardell (International Union Against TB and Lung Disease), José Becerra and Thomas Navin (CDC/DTBE)

*Charge:* Formulate recommendations in response to three questions: Should TB elimination be retained as a national goal? If yes, by when and how? If not, what should be the new national goal?

**TOPIC 7: ACET agreed to establish a new “National TB Program Workgroup.”**

*Membership:* Iram Bakhtawar and Gail Cassell (ACET), Lee Reichman (American College of Chest Physicians), Charles Wallace (NTCA), Mamodikoe Makhene (National Institute of Allergy and Infectious Diseases), Susan Ray (Infectious Disease Society of America), Litjen Tan (American Medical Association), John Bernardo (Stop TB USA), Cornelia Jervis (Treatment Action Group), Terence Chorba and Michael Iademarco (CDC/DTBE)

*Charge:* Propose strategies to reconfigure NTP to accomplish its goals in light of current and future budget reductions.

**TOPIC 8: ACET agreed to establish a new “Affordable Care Act Workgroup.”**

*Membership:* Susan Dorman, Masahiro Narita and Barbara Seaworth (ACET), Theresa Watkins-Bryant (HRSA), Ann Cronin and John Halpin (CDC/DTBE/National Institute for Occupational Safety and Health)

*Charge:* Identify opportunities to use PPACA to make further progress on achieving the TB elimination goal in the United States.

**TOPIC 9: ACET agreed to establish a new “ACET Meeting Workgroup.”**

*Membership:* Shannon Jones, Jane Carter and Christine Hahn (ACET), Lornel Tompkins (National Medical Association)

*Charge:* Propose strategies to improve the organizational structure, productivity and efficiency of ACET meetings, particularly the business session. ACET suggested a number of potential strategies for the workgroup to consider in its discussions.

- ACET meetings in their entirety should serve as business meetings. Updates should be shortened to provide ACET with sufficient time to extensively discuss the topic, propose formal motions or resolutions, and call for a vote at the end of each presentation that will require formal action. This approach would provide ACET with an opportunity to provide more meaningful and relevant advice to the CDC Director and HHS Secretary.
- The business session should be held on day 1 of the meeting to ensure that a quorum is maintained for ACET to conduct its business.
- Updates should be sent to ACET electronically in advance of meetings as background materials in preparation of discussing and formally voting on action items. This approach would allow ACET to use its face-to-face meetings more efficiently.
- The meetings should be restructured to allow time for members, *ex-officios*, liaisons and CDC staff to meet in small groups to discuss complex or pressing TB issues.
- The agenda items should be selected based on ACET’s charter to provide expert advice and recommendations to the CDC Director and HHS Secretary on TB-related issues.
- Both days of the meeting should be restructured for the morning sessions to be devoted to updates and the afternoon sessions to be devoted to business items.

- Updates should be aligned with topics that will require a formal vote by ACET. External experts should be invited to make presentations on these issues as needed.
- The meetings should be restructured to allow ample time for liaisons to provide their expertise, guidance and support to CDC on the National TB Program from an advocacy perspective.
- The agendas should be reorganized to make better use of ACET's time during meetings, particularly since the number of annual meetings has been reduced from three to two. This goal could be achieved by extending meetings to two full days and limiting the number of updates to only those that will require ACET's formal action. Consideration also should be given to convening ACET business meetings via conference call to account for the reduction in face-to-face meetings from three to two annual meetings.

**TOPIC 10:** Dr. Seaworth noted a disconnect in the meeting minutes between important guidance ACET provides after each update versus resolutions or recommendations ACET formally adopts during the business session. She was concerned about CDC's lack of follow-up on suggestions ACET makes following updates (e.g., ACET's input to DTBE on the MDDR Service during the November 2010 meeting).

Mr. Phillip Talboy, Deputy Director of DTBE, made clarifying remarks in response to Dr. Seaworth's concern. DTBE created a document to track and monitor the status of all of ACET's recommendations, resolutions and endorsements that were fully or partially implemented, withdrawn or not implemented. The tracking document was distributed to ACET for review.

In response to Mr. Jones' suggestion, Mr. Talboy confirmed that DTBE would provide ACET with the current version of the tracking document prior to each meeting. DTBE also would present annual updates on its efforts to respond to and take action on ACET's formal recommendations made in the current calendar year.

**TOPIC 11:** Mr. Jones noted that Dr. Michael Fleenor, former Chair of ACET, wrote a letter to the HHS Secretary dated July 6, 2010 along with a report of ACET's activities from 2006-2010. The letter and report were distributed to ACET for review. The participants joined Mr. Jones in acknowledging Dr. Fleenor's outstanding leadership during his tenure as the ACET Chair.

Because the HHS Secretary did not respond to Dr. Fleenor's letter and report, ACET raised the possibility of communicating with other senior-level officials and entities that would have a greater impact on its TB recommendations (e.g., Dr. Howard Koh, HHS Assistant Secretary for Health, Trust for America's Health and FDA).

**TOPIC 12:** Dr. Gail Cassell proposed the following resolution. "ACET should establish a new workgroup to address CDC's role in global TB control with an emphasis on drug-resistant TB. The workgroup should be charged with formulating recommendations to ensure that U.S. involvement in global TB control activities do not dilute or adversely impact TB prevention, control and elimination efforts in the United States."

**ACET did not make a motion to formally adopt the proposed resolution.** ACET agreed to establish a broader "Global TB Control Workgroup" that would include the charge and

membership of the Second-Line Drug Shortage Workgroup: Jane Carter, Gail Cassell and Barbara Seaworth (ACET), Cornelia Jervis (Treatment Action Group), John Bernardo (Stop TB USA), Jennifer Flood (NTCA), Edward Nardell (International Union Against TB and Lung Disease), Ann Cronin and Sundari Mase (CDC/DTBE). However, Dr. Cassell noted that the name, membership and charge of the new workgroup most likely would change to reflect its expanded focus on both global TB control issues and the SLD shortage problem.

**TOPIC 13:** Dr. Barbara Seaworth proposed the following resolution. “Given the reduced budget for the Division of Tuberculosis Elimination, be it resolved that ACET requests CDC to assess the public health benefits, cost and effectiveness of the National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention supported activities (e.g., Program Collaboration and Service Integration and Social Determinants of Health) and demonstrate how these activities support TB elimination efforts and impact TB morbidity.”

A motion was properly placed on the floor and seconded by Drs. Christine Hahn and Jane Carter, respectively, for ACET to formally approve the resolution. **ACET passed the motion by a majority vote of 7 to 1 with Dr. Eric Brenner in opposition.**

**TOPIC 14:** Dr. Jennifer Flood proposed the following resolution. “ACET recommends that the Division of Tuberculosis Elimination proactively work toward leveraging additional resources and funding through collaborative efforts across NCHHSTP, particularly as it relates to the Patient Protection and Affordable Care Act and national prevention initiatives.”

A motion was properly placed on the floor and seconded by Drs. Marcos Burgos and Barbara Seaworth, respectively, for ACET to formally approve the resolution. **ACET unanimously approved the motion.**

**TOPIC 15:** Dr. Iram Bakhtawar proposed the following resolution. “Because of imminent fiscal pressures and the 2012 projected budget reductions, ACET advises the Division of Tuberculosis Elimination to continue to work with ACET through partners (e.g., APHL, NTCA and Stop TB USA) to collaborate and reach consensus on a strategic national approach based on the understanding that all TB is local. Investments should be guided by an assessment of the greatest impact toward achievement of the goal of TB elimination in the United States. This process will require expeditious action with a proposal to ACET at the fall 2011 meeting.”

A motion was properly placed on the floor and seconded by Drs. Masahiro Narita and Gail Cassell, respectively for ACET to formally approve the resolution. **ACET unanimously approved the motion.**

**TOPIC 16:** Dr. Iram Bakhtawar proposed the following resolution. “WHEREAS, there is a large latent TB infection (LTBI) population; and WHEREAS the prevention of progression from LTBI to TB disease is the most important determinant for TB elimination; and WHEREAS, identification and testing of targeted high-risk populations are proven to be important to eliminate TB; ACET recommends that DTBE identify and collaborate with organizations (e.g., American Diabetes Association) with responsibility for mandating Healthcare Effectiveness Data Information Set (HEDIS) or Meaningful Use requirements to include LTBI testing in the treatment in diabetes.”

A motion was properly placed on the floor and seconded by Drs. Masahiro Narita and Barbara Seaworth, respectively, for ACET to formally approve the resolution. **The motion was withdrawn and replaced with an agenda item.** Dr. Castro would designate DTBE staff to meet with staff in the CDC Division of Diabetes Translation. The purpose of the meeting would be to better understand the overlapping epidemics of TB and diabetes to inform ACET's development of evidence-based recommendations on this issue. Dr. Castro would invite staff in the Division of Diabetes Translation to attend the next ACET meeting.

**TOPIC 17:** Dr. Masahiro Narita proposed the following resolution. "ACET recommends that the treatment of TB disease be included in the Patient Protection and Affordable Care Act for funding." The rationale for the proposed resolution is that TB is an airborne disease and has no effective vaccine.

**ACET did not make a motion to formally adopt the proposed resolution.** ACET agreed that the new Affordable Care Act Workgroup would be charged with addressing this issue.

**TOPIC 18:** Dr. Diana Schneider proposed the following resolution. "ACET recommends that CDC invite the U.S. Marshals Service (USMS) to serve on ACET as a new *ex-officio* member." The rationale for the proposed resolution is that prisoners in the custody of USMS are housed in >1,800 local jails nationwide. However, the roles and responsibilities for TB management, care and treatment of USMS prisoners are not clearly defined at the local level, particularly for undocumented persons.

A motion was properly placed on the floor and seconded by Drs. Jane Carter and Gail Cassell, respectively, for ACET to formally approve the resolution. **ACET passed the motion by a majority vote of 6 to 2 with Drs. Iram Bakhtawar and Barbara Seaworth in opposition.**

**TOPIC 19:** Dr. Eric Brenner proposed the following resolution. "ACET recommends sending a letter to the HHS Secretary urging HHS to maintain funding needed for national TB elimination efforts in accordance with its commitment that was made over 20 years ago." The letter should outline the following points to support ACET's recommendation.

- CDC made a commitment in 1989 to achieve the vision of eliminating TB as a public health problem in the United States. Accordingly, the CDC "Division of Tuberculosis Control" subsequently was renamed as the "Division of Tuberculosis Elimination."
- Subsequent funding and extraordinary cooperative federal, state and local efforts sustained over the past two decades have led to an all-time low national incidence of 3.4/100,000 TB cases in 2010.
- The low rate achieved points the way to TB elimination in coming decades with efforts supported by a suite of new tools (e.g. the use of IGRAs to diagnose LTBI, the possibility of treating LTBI in 12 weeks, and rapid laboratory detection of drug-resistant TB) that recently have become available and whose impact will be achieved only through continued availability of resources.
- WHO may appropriately continue to focus on TB control in high-incidence developing countries at a global level. By virtue of its achievements over the past two decades, the



United States is now in a position to serve as a model for lower-incidence industrialized countries as they embark on their own TB elimination efforts.

- These recent achievements and continued national and international progress toward eventual elimination in the future are now threatened by a loss of TB control funds in state and local health departments where front-line TB control work is actually performed and often has significant funding from CDC.

A motion was properly placed on the floor and seconded by Drs. Marcos Burgos and Jane Carter, respectively, for ACET to formally approve the resolution. **ACET tabled the motion until the next meeting.** Dr. Brenner would collaborate with DTBE staff to draft and circulate the letter to ACET for review and discussion prior to calling for a formal vote at the next meeting. During this time, efforts would be made to obtain external input from advocates and partners and identify other potential recipients of the letter (e.g., high-level officials in HHS other than the Secretary and the Office of Management and Budget).

### Public Comment Session

Mr. Jones opened the floor for public comments; no participants responded.

### Closing Session

The next ACET meeting would be held on November 1-2, 2011 or the first week of December 2011. Ms. Margie Scott-Cseh, the ACET Committee Management Specialist, would poll the members via e-mail to determine the exact date.

With no further discussion or business brought before ACET, Mr. Jones adjourned the meeting at 2:19 p.m. on June 8, 2011.

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

\_\_\_\_\_  
Date

\_\_\_\_\_  
Shannon Jones  
Chair, Advisory Committee for the  
Elimination of Tuberculosis