

**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
November 27-28, 2007
Atlanta, Georgia**

Record of the Proceedings

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ATTACHMENT 1

List of Participants

ACET Members

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Dr. Richard Fluck
Mr. Shannon Jones III
Mr. Joseph Kinney
Dr. Ana Lopez-De Fede
Dr. Masahiro Narita
Dr. Barbara Seaworth

Designated Federal Official

Dr. Kenneth Castro,
Executive Secretary

Ex-Officio and Liaison Members

Dr. William Baine (Agency for Healthcare
Research and Quality)
Dr. Amy Bloom (U.S. Agency for
International Development)
Ms. Fran DuMelle
(American Thoracic Society)
Dr. Joseph Goldenson
(National Commission on
Correctional Healthcare)
Dr. Debra Horensky (Association of
Public Health Laboratories)
Dr. Robert Kim-Farley
(National Association of County and
City Health Officials)
Dr. Michael Leonard, Jr. (Infectious
Disease Society of America)
Dr. Bonita Mangura (American College of
Chest Physicians)
Dr. Edward Nardell
(International Union Against
Tuberculosis and Lung Disease)
Ms. Susan Perez
(Treatment Action Group)
Ms. Carol Pozsik (National Tuberculosis
Controllers Association)
Mr. Dan Reyna (Department of
Health and Human Services)

Amb. Eleazar Benjamin Ruiz y Avila
(U.S.-Mexico Border Health
Commission)
Dr. Diana Schneider (Department of
Homeland Security)
Ms. Rachel Stricof (Association for
Professionals in Infection Control and
Epidemiology)
Dr. Litjen Tan
(American Medical Association)
Dr. Theresa Watkins-Bryant
(Health Resources and
Services Administration)

CDC Representatives

Dr. Francisco Averhoff
Mr. Jose Becerra
Dr. Ann Buff
Ms. Kristen Clingler
Ms. Ann Cronin
Dr. Hazel Dean
Ms. Susan DeLisle
Ms. Judy Gibson
Dr. Richard Goodman
Ms. Theresa Harrington
Ms. Natalie Hundley (CDC Contractor)
Dr. John Jereb
Dr. Dolly Katz
Ms. Ann Lanner
Dr. Phillip LoBue
Dr. Beverly Metchock
Dr. Drew Posey
Dr. John Ridderhof
Mr. Dan Ruggiero
Ms. Margie Scott-Cseh
Dr. Andrew Vernon
Dr. Elsa Villarino
Dr. Wanda Walton
Ms. Kai Young

**Guest Presenters and
Members of the Public**

Mr. Antonino Catanzaro (National
Tuberculosis Curriculum Consortium)
Ms. Jennifer DeYoung
(Government Accountability Office)

Ms. Karen Doran
(Government Accountability Office)
Dr. John Seggerson (Stop TB USA)
Ms. Donna Wegener
(Southeastern National TB Center)

ATTACHMENT 2

Acronyms Used In These Meeting Minutes

AAs	— African Americans
ACET	— Advisory Council for the Elimination of Tuberculosis
ACIP	— Advisory Committee on Immunization Practices
ATS	— American Thoracic Society
BHC	— Border Health Commission (U.S.-Mexico)
BSC	— Board of Scientific Counselors
CAP	— Community-Acquired Pneumonia
CBOs	— Community-Based Organizations
CCID	— Coordinating Center for Infectious Diseases
CDC	— Centers for Disease Control and Prevention
CLSI	— Clinical and Laboratory Standards Institute
DGMQ	— Division of Global Migration and Quarantine
DHAP	— Division of HIV/AIDS Prevention
DHS	— Department of Homeland Security
DNB	— Do Not Board
DOT	— Directly Observed Therapy
DST	— Drug Susceptibility Testing
DTBE	— Division of Tuberculosis Elimination
FBPs	— Foreign-Born Persons
FBWG	— Foreign-Born Workgroup
FDA	— Food and Drug Administration
FTBTF	— Federal TB Task Force
GAO	— Government Accountability Office
GAP	— Global AIDS Program
HCWs	— Healthcare Workers
HHS	— Department of Health and Human Services
ICE	— U.S. Immigration and Customs Enforcement
IDSA	— Infectious Disease Society of America
IGRA	— Interferon Gamma Release Assay
IHRs	— International Health Regulations
INH	— Isoniazid
IoM	— Institute of Medicine
IOM	— International Organization for Migration
IUATLD	— International Union Against Tuberculosis and Lung Disease
LTBI	— Latent TB Infection
MOAs	— Memoranda of Agreement
MDR-TB	— Multi-Drug Resistant TB
MIC	— Minimum Inhibitory Concentration
<i>MMWR</i>	— <i>Morbidity and Mortality Weekly Report</i>
MOX	— Moxifloxacin
<i>M.tb</i>	— <i>Mycobacterium Tuberculosis</i>
NCET	— National Coalition for the Elimination of Tuberculosis

NCHHSTP	—	National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
NCPDCID	---	National Center for Prevention, Detection, and Control of Infectious Diseases
NIH	—	National Institutes of Health
NTCA	—	National Tuberculosis Controllers Association
NTCC	—	National Tuberculosis Curriculum Consortium
QFT-G	—	QuantiFERON-Gold
PART	—	Program Assessment Rating Tool
PCSI	—	Program Collaboration and Service Integration
PEPFAR	—	President's Emergency Plan for AIDS Relief
RTMCCs	—	Regional Training and Medical Consultation Centers
SLDs	—	Second-Line Drugs
TBESC	—	TB Epidemiologic Studies Consortium
TBETN	—	TB Education and Training Network
TBTC	—	TB Trials Consortium
TBTE	—	TB Training and Education
TIs	—	Technical Instructions
TSA	—	Transportation Security Administration
TST	—	Tuberculin Skin Test
TTCC	—	Transnational Tuberculosis Continuity of Care Workgroup
USAID	—	U.S. Agency for International Development
WHO	—	World Health Organization
XDR-TB	—	Extensively Drug-Resistant TB

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**ADVISORY COUNCIL FOR THE ELIMINATION OF TUBERCULOSIS
November 27-28, 2007
Atlanta, Georgia**

Minutes of the Meeting

The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP) Division of Tuberculosis Elimination (DTBE) convened a meeting of the Advisory Council for the Elimination of Tuberculosis (ACET). The proceedings were held on November 27-28, 2007 at CDC's Corporate Square Offices, Conference Room A/B/C in Atlanta, Georgia.

Opening Session

Dr. Michael Fleenor, Chair of ACET, called the meeting to order at 8:39 a.m. on November 27, 2007. He welcomed the attendees to the proceedings and opened the floor for introductions. The list of participants is appended to the minutes as [Attachment 1](#).

Dr. Kenneth Castro, Director of DTBE and Executive Secretary of ACET, announced that ACET meetings are open to the public and all comments made during the proceedings are a matter of public record. He pointed out that ACET members should be mindful of potential conflicts of interest identified by the CDC Committee Management Office and recuse themselves from participating in or voting on these discussions.

Update on NCHHSTP Activities

Dr. Hazel Dean, Acting Deputy Director of NCHHSTP, covered the following areas in her update. The NCHHSTP Office of the Director accomplished several goals in FY'07. Clear leadership priorities and goals were established. A consultation was held and a green paper was produced to articulate NCHHSTP's vision of Program Collaboration and Service Integration (PCSI). NCHHSTP formed eight cross-cutting workgroups to achieve three programmatic

imperatives. A web page on lesbian, gay, bisexual and transgender health was launched on the CDC web site. New cross-center leadership groups were established. NCHHSTP gained new resources and minimized the loss of resources resulting from its reorganization.

Dr. Dean was pleased to announce that NCHHSTP programs received the highest rating of “effective” in the Office of Management Budget Program Assessment Rating Tool (PART) evaluation. PART defines “effective” programs as those that are well managed, set ambitious goals, achieve results and improve efficiency. Only one or two other CDC programs have achieved this status to date. Additional information about NCHHSTP’s effective rating can be obtained from the “ExpectMore.gov” web site.

Dr. Dean explained that NCHHSTP is governed and guided by CDC’s goals and strategic imperatives, shared leadership values, and three programmatic imperatives. To “reduce health disparities,” NCHHSTP will help eliminate health disparities and improve the health of populations that are disproportionately affected by HIV/AIDS, viral hepatitis, STDs, TB, and other related diseases and conditions. NCHHSTP’s target populations in this imperative include racial/ethnic minorities, women, incarcerated persons, sexual minorities, and other persons disproportionately affected by these diseases and conditions.

NCHHSTP accomplished several goals in FY’07 to reduce health disparities. Key consultations and strategies were launched at the division level, such as the “Heightened National Response for Reducing the HIV/AIDS Epidemic in the African American (AA) Community” and the “Consultation on STDs in the AA Community.” Three cross-center workgroups were formed to focus on health disparities, corrections, and men who have sex with men. NCHHSTP used a social determinants of health framework to initiate the development of a white paper to address TB, HIV, STD and viral hepatitis.

NCHHSTP issued its first integrated report on health disparities on November 20 2007, entitled *Health Disparities in HIV/AIDS, Viral Hepatitis, Sexually Transmitted Diseases and Tuberculosis in the United States: Issues, Burden and Response*. The comprehensive report provides a retrospective review of CDC’s 2002-2004 surveillance data of these diseases, examines programs that CDC created to respond to reducing health disparities, and highlights CDC’s future direction in this area. The public can download the report from the CDC web site.

To advance the “PCSI initiative,” NCHHSTP will organize and blend interrelated health issues and separate activities and services to maximize public health impact through new and established linkages to facilitate the delivery of services. NCHHSTP acknowledges that integration should be focused at the field or client level where the interface between the system and consumer occurs.

NCHHSTP accomplished several goals in FY’07 to advance the PCSI initiative. The NCHHSTP Director and senior staff made a number of site visits to obtain feedback on PCSI from state and local programs. NCHHSTP underwent an internal organizational realignment to support PCSI. “Leaders-to-leaders” meetings were convened with other federal agencies.

NCHHSTP held a PCSI consultation in August 2007 with >125 external and internal stakeholders. A number of key objectives were established for the participants. Advice would be given to NCHHSTP on the development of PCSI activities over the next five years. Assistance would be provided in establishing PCSI priorities. Strategies for CDC to implement to strengthen its PCSI efforts as well as those at the local level would be identified. The consultation resulted in the development of a PCSI green paper.

NCHHSTP's Surveillance and Strategic Information Workgroup held a meeting in August 2007 to begin developing the first cross-center high-level surveillance summary. The report will examine intersections and overlaps between epidemics and also will include a special emphasis section on AA men. Overall, external partners and other parts of CDC and have expressed tremendous support of NCHHSTP's PCSI initiative.

To "maximize global synergies," NCHHSTP will promote interdependent programmatic relationships between its divisions that are global in nature. The goals of this imperative are to ensure active collaboration between NCHHSTP divisions, take full advantage of opportunities for leveraging NCHHSTP and CDC resources, and maximize health impact. NCHHSTP will actively pursue and seek input on international program development and public health research, foster robust internal and external partnerships, and commit to novel and participatory approaches for implementation and dissemination.

NCHHSTP accomplished several goals in FY'07 to maximize global synergies. An intra-center collaborative meeting, a leadership retreat, and the CDC's Director's regional leadership meeting were convened. A Global Antenatal Workgroup was developed and led by the Global AIDS Program (GAP). Global efforts on extensively drug-resistant TB (XDR-TB) and multidrug-resistant TB (MDR-TB) were mobilized through the leadership of DTBE. Implementation of the President's Emergency Plan for AIDS Relief (PEPFAR) was continued. Although 1.1 million patients are under treatment at this time, PEPFAR has treated 2 million dying patients with lifesaving antiretroviral therapy to date.

Dr. Dean noted that \$30 million was appropriated to the Coordinating Center for Infectious Diseases (CCID) in FY'07 to address emerging infectious diseases. An internal competitive process was instituted to support critical CCID programs. CCID's funding to NCHHSTP in FY'07 included \$1.8 million to DTBE to (1) upgrade drug susceptibility testing (DST) and genotyping laboratory equipment; (2) increase capacity to detect TB outbreaks; and (3) expand the portfolio of drugs available to TB control programs.

Dr. Dean summarized NCHHSTP's other developments, personnel changes and budget in FY'07. The CCID Board of Scientific Counselors (BSC) made a number of recommendations to NCHHSTP on antimicrobial resistance during its meeting in March 2007. NCHHSTP met with a BSC workgroup in October 2007 to obtain guidance on strategic information gathering for health impact.

NCHHSTP appointed a new Associate Director for Program Integration, Associate Director for Science, and Associate Director for Communications. Interviews are underway to permanently fill the position of the NCHHSTP Deputy Director at the beginning of 2008.

The FY'07 domestic HIV, viral hepatitis, STD and TB prevention budget totaled \$1 billion. CDC anticipates that PEPFAR's budget will increase in FY'08. The President vetoed the FY'08 Labor-HHS budget bill that called for \$18.4 million for the hepatitis program (an increase of ~\$1 million above FY'07); \$704.2 million for domestic HIV prevention activities, including \$53.3 million for the HIV testing initiative; flat funding for the STD program; \$146.5 million for the domestic TB program (an increase of ~\$12 million); and \$121.5 million for GAP via the CDC budget. CDC is operating under a continuing resolution through December 14, 2007.

DTBE Director's Report

Dr. Castro covered the following areas in his update. CDC's surveillance report of TB cases in the United States was distributed to ACET for review. The report particularly emphasized surveillance of persons who met the "XDR-TB" case definition as defined by initial DST from 1993-2006. New York City and 13 states accounted for 48 reported cases. DTBE used a portion of its FY'07 emerging infectious disease funding to provide additional resources to California, Florida, New York and Texas to enhance surveillance of persons with MDR-TB and ensure that isolates are genotyped and submitted for second-line DST.

DTBE provided epidemiologic support, gave technical assistance or was directly involved in a variety of TB, MDR-TB and XDR-TB outbreak investigations both domestically and internationally in 2006-2007. The settings of these outbreaks included a Navy aircraft carrier, prison, community and organ transplants.

Several new TB Epidemiologic Studies Consortium (TBESC) studies were approved for FY'07: (1) TB in AAs; (2) use of the QuantiFERON-TB Gold (QFT-G) test in contact tracing; (3) use of QFT as an initial screening tool for U.S.-bound immigrants and feasibility of follow-up in the United States; (4) evaluation of a new social network analysis tool; and (5) an ethnographic study of TB among Karen-Burmese refugees who reside in Thailand and have been slated for resettlement in the United States by the Department of State.

A number of recommendations were made to DTBE following the external peer review of TBESC. DTBE should not reduce the TBESC budget any further. Productivity and the emphasis on TBESC-wide studies should be increased. Delays in TBESC activities should be reduced. Processes for funding and research project selection should be improved. Performance reviews of TBESC sites and investigators should be conducted on a regular basis. Use of a central Institutional Review Board should be emphasized. TBESC-wide policies for authorship, data access and other issues should be clearly defined.

DTBE is implementing a long-term planning process to clearly articulate key elements of the current TBESC model, including continuation of the external peer review process; development of agreed upon protocols; enhancement of an adequate data management component; capacity to ensure the completion of projects; consensus building to establish an agenda and identify

priorities; and input from ACET, academic researchers, health departments and other key stakeholders.

The TB Trials Consortium (TBTC) completed Study 28. The phase 2 trial randomized 433 persons who were given either isoniazid (INH) and a moxifloxacin (MOX) placebo or MOX and an INH placebo. The primary endpoints of Study 28 are summarized as follows. The 5% difference that was seen in the eight-week sputum conversion favored the MOX arm, but this result was not statistically significant. The study population showed excellent tolerability of the MOX regimen. Results that were driven by liquid culture findings required TBTC to reevaluate previous studies. The difference with solid media was ~3%, but might slightly increase as TBTC completes its validations.

Two other studies were developed with a Study 27 design in which MOX was used in place of ethambutol. The 17%-18% difference that was seen favored MOX on solid media. Virtually all expected associations were seen in Study 28, such as a faster conversion with lower grade smear, less extensive disease, no cavitation, more pre-treatment, higher body weight, female gender and HIV positive. Contamination rates were not elevated and decontamination procedures were within acceptable standards. DNA fingerprint was used to match ~13 pairs from the Uganda site. Overall, DTBE expects Study 28 to provide an opportunity to include a larger laboratory component as additional clinical trials are conducted in the future.

DTBE convened its annual TB Program Managers Course in October 2007 with 36 participants who were selected by local health departments. A contact investigation course for South Pacific in New Caledonia was piloted in October 2007. This new activity is being designed for territories to expand contact investigations beyond current efforts to only detect household contacts with disease.

Dr. Castro testified before a Congressional committee in October 2007 regarding efforts to eliminate TB, including MDR-/XDR-TB in the United States. He and other DTBE staff made several presentations to a number of groups on XDR-TB, participated in the Stop TB Coordinating Board meeting, and attended the 38th World Conference on Lung Health.

Dr. Castro provided a breakdown of DTBE's FY'07 expenditures of \$142.8 million: 64% for TB prevention, control and laboratory support; 15% for DTBE and field expenses; 13% for TB elimination research; 4% for Regional Training and Medical Consultation Centers (RTMCCs); 2% for partnerships and communications; and 2% for research support. DTBE expects that its provisional funding will be ~\$146.5 million in FY'08 and plans to solicit guidance from ACET on using these resources.

DTBE has identified a number of unmet needs in TB to target its future funding. Most notably, MDR-/XDR-TB should be addressed. Support should be provided to limit the erosion of core programs. Laboratory systems should be updated. Proficiency and expertise should be developed and retained. Research capacity should be scaled-up by evaluating epidemiologic trends and program improvements through PCSI and national TB indicators. Advancements should be made in promising and groundbreaking new tests to rapidly detect the presence of drug

resistance. The performance, safety and efficacy of new diagnostics and regimens should be evaluated. Global improvements should be made in program and research.

Dr. Castro announced that in response to ACET's previous recommendation, Cardinal Naomi Aronson accepted DTBE's invitation to serve as a new *ex-officio* member for the Department of Defense. Dr. Castro would attend an entrance interview by the Government Accountability Office (GAO) later in the day. During the interview, GAO would obtain information on the response by CDC and other agencies to two cases of MDR-/XDR-TB patients who traveled between the United States and other countries. Dr. Castro confirmed that he would brief ACET on key outcomes from the GAO interview at a future meeting.

Update on NCHHSTP's PCSI Initiative

Ms. Susan DeLisle, Associate Director for Program Integration in NCHHSTP, provided an update on PCSI. NCHHSTP is focusing on PCSI at this time in response to a strong demand by grantees. External stakeholders that implement public health programs have long recognized the difficulty in using a siloed approach to provide integrated services and address the needs of clients. In addition to the demand by grantees, NCHHSTP is also advancing PCSI due to overlapping social determinants of health and epidemiology, such as TB and HIV.

NCHHSTP's primary goal in PCSI is to facilitate seamless interface among NCHHSTP programs at the client level. The focus is not on organizational or structural integration per se. Appropriateness, flexibility, effectiveness, accountability and acceptability are identified as five principles for successful PCSI. A literature review was conducted to compile input on integration from domestic programs over the past ten years. NCHHSTP also made joint site visits to community-based organizations (CBOs), local public health agencies and community planning groups in 3 areas of the country and recommendations on PCSI from these joint site visits are posted on the CDC web site in site visit reports.

To identify priorities for PCSI, an external consultation was convened in August 2007 with >125 external and internal stakeholders. Key objectives of the consultation were for NCHHSTP to receive advice on the development of priority PCSI activities over the next five years; establishing short- and long-term priorities for PCSI; identifying strategies for CDC to implement and strengthen its own PCSI efforts as well as those at the local level. To develop the external consultation, a planning committee was established with representation from key stakeholder organizations. Specific criteria were established and a peer selection process was used to identify non-CDC members to ensure diversity and equity across HIV, TB, STD and viral hepatitis during the PCSI consultation. Criteria included: large and small programs both in funding and population; integrated and non-integrated programs based on both structure and service delivery; urban and rural states; and cities and states with both high and low morbidity.

The external participants represented 40 project areas or jurisdictions throughout the country. Other participants of the PCSI consultation included, ACET, RTMCCs, the National Tuberculosis Controllers Association (NTCA), National Association of County and City Health

Officials (NACCHO), CDC staff from each NCHHSTP division, other federal agencies, non-federal partners, CBOs, and state surveillance coordinators from each program.

Key questions were developed for the external consultation to address barriers, gaps and recommendations that had been identified through joint site visits, literature review or in pre-meeting input received by >50 programs.

The external participants identified the top three priority opportunities for PCSI and recommended specific actions for each area. The top three priorities were (1) integrated surveillance and data efforts; (2) integrated funding; and (3) workforce development and training.

Recommended activities for each priority were: (1) integrated surveillance and data efforts, participants recommended that surveillance reports should be integrated; standards should be developed for data sharing; guidelines should be created for integrated data with common demographics, variables and definitions; a gold standard should be developed to address confidentiality issues; surveillance programs should be designed to be effective with and across programs. (2) integrated funding commitments, participants recommended integrative program announcements should be developed; collaborative efforts should be undertaken for program announcements and post-award management; incentives for state and federal funding; in-kind funds or required matching funds should be provided to support integration; funding at the CDC level should be reprioritized; reporting and evaluation components should be incorporated into integrated funding; funds should be allocated to support pilot or demonstration projects. (3) workforce development and training, participants recommended flexible funding should be provided for training; integrated and comprehensive guidelines should be developed; program announcements should include a common language and objectives to address NCHHSTP's diseases; training centers should be required to have integrated training curricula.

The NCHHSTP Federal Workgroup reviewed the activities recommended by the external participants and used the list to identify the top six priorities for PCSI from a federal perspective. These priorities were: guidelines for integrated surveillance data and integrated data reporting; assessing the current level of integration; funding integration and evaluation projects; collaboration on funding announcements and post-award management; exploring internal and authority issues surrounding flexible funding; and training on integration to project officers. The federal workgroup disagreed with recommendations that "required" programs to take certain actions, but agreed that the activities were possible to accomplish over the next 1-3 years.

Ms. DeLisle described the next steps to further advance the PCSI initiative. The presentations, report, green paper and other materials related to the PCSI consultation will be posted on the CDC web site. By the spring of 2008, NCHHSTP will publish its PCSI Action Plan for 2008 and an NCHHSTP White paper. On an ongoing basis, NCHHSTP will continue to engage partners, incorporate PCSI into national meetings and develop opportunities for sharing promising practices.

Dr. Ana Lopez-De Fede, an ACET member, attended the PCSI consultation on behalf of ACET. She presented key action items for ACET to consider. NTCA should coordinate with CDC to assess state TB control programs and document the level of PCSI at client, state program and community levels. The assessment should measure the level of service integration among these programs, evaluate services as a whole, and pinpoint those services that are collaborating well. The assessment also should probe whether existing funding arrangements are optimizing, facilitating or hindering integrated service delivery as measured by increased efficiency and improved health outcomes.

TB funding initiatives should include pilots of integration efforts that are appropriate from both epidemiological and programmatic perspectives. Evaluation measures should be developed and standardized across sites. Findings from the assessment should be reported to ACET for the development of strategic efforts that identify benefits and opportunities for program integration activities while engaging stakeholders and mobilizing resources.

ACET thanked NCHHSTP for presenting comprehensive updates on its ongoing activities. Several members made suggestions for NCHHSTP to consider as these initiatives are refined in the future.

- NCHHSTP should take caution in recommending treatment of HIV/TB co-infected patients in an integrated program due to infection control concerns at the client level.
- NCHHSTP should ensure that programs have knowledge of the language and terminology of other programs during collaboration and integration efforts. NCHHSTP should develop and provide programs with an alphabetized list of acronyms that are commonly used in the HIV, TB, STD and viral hepatitis fields.
- DTBE should conduct surveillance of transplant-associated TB infections and issue guidance based on the surveillance data.
- NCHHSTP should administer surveys and conduct focus groups at the national level to identify appropriate strategies to better meet the needs of affected and infected clients.
- DTBE should collect national data to determine the frequency of XDR-TB cases occurring in the United States. For example, local data show that XDR-TB cases are occurring in some areas with a low incidence of TB due to limited capacity of these jurisdictions to treat MDR-TB.
- NCHHSTP should develop rigorous evaluation measures and indicators because solid data on PCSI from an infectious disease standpoint are lacking at this time.

TB Legislative Update

Ms. Fran DuMelle, the ACET liaison to the American Thoracic Society (ATS), explained that CDC commissioned the Institute of Medicine (IoM) to analyze TB elimination in the United States. The IoM published a report, entitled *Ending Neglect*, in 2000, but no actions were taken to implement the recommendations on TB elimination. As a result, the National Coalition for the Elimination of Tuberculosis (NCET) held a consultation with CDC, other federal agencies, non-governmental organizations, and Congressional committees and offices.

Participants of the consultation thoroughly reviewed five key policy recommendations outlined in the IoM report: (1) maintain control while adapting to declining incidence; (2) speed the decline and advance toward elimination through targeted testing and treatment of latent TB infection (LTBI); (3) develop new tools; (4) increase U.S. engagement in global TB control; and (5) mobilize support and measure progress.

Based on a review of the IoM policy recommendations, the participants agreed to address several issues. Adequate funding should be maintained, including categorical funding at the federal level. Resources should be provided to maintain excellence in TB services. Resources for research should be increased for the development of new diagnostic tools, LTBI treatments and a vaccine. Involvement in global TB control should be increased.

The participants collaborated with Congressional staff in developing two legislative approaches to address the IoM policy recommendations and key issues. The "Comprehensive TB Elimination Act" was created as a mechanism to maintain excellence in TB services and increase resources for research. The bill called for ACET to make recommendations on the development, revision and implementation of a comprehensive plan to eliminate TB in the United States. The bill further required the HHS Secretary to develop new tools for the elimination of TB and the Federal TB Task Force (FTBTF) to make recommendations on the development of a plan for the creation of these tools. The bill authorized \$300 million to CDC and \$100 million for new tools.

The bill was introduced in the House in March 2007 with 41 co-sponsors and in the Senate in June 2007 with 13 co-sponsors. A Senate committee passed the bill in November 2007 and a House committee is expected to review the bill in early 2008. The report for the bill is currently being written.

The "Stop TB Now Act" was created as a mechanism to increase involvement in global TB control. Policy language in the bill emphasized that the major objective of the foreign assistance program of the United States is to control TB. The bill called for priority to be given to activities described in the World Health Organization (WHO) Stop TB Strategy, including expansion and enhancement of directly observed therapy (DOT) coverage and use of international standards for TB care and treatment of persons with TB/HIV and MDR-/XDR-TB. The bill further called for assistance to be provided to WHO and the Stop TB Partnership. The bill authorized \$400 million to the U.S. Agency for International Development (USAID) in 2008-2009 and \$70 million to CDC in 2008-2009.

The bill was introduced in the House in March 2007 with 106 co-sponsors and in the Senate in March 2007 with 14 co-sponsors. The bill was passed by both Senate and House committees in October and November 2007, respectively, and has been placed on the Senate legislative calendar.

Ms. DuMelle concluded that several actions would need to be taken after the bills are authorized and appropriated. ACET would need to engage in a comprehensive planning process, while FTBTF would need to develop a research plan. Moreover, USAID would need to create a solid strategy to allocate additional resources from the Stop TB Now Act.

Update by the ACET Foreign-Born Workgroup (FBWG)

Dr. Dolly Katz, of DTBE, reported that FBWG was formed in response to ACET's unanimous agreement to revise CDC's "Recommendations for Prevention and Control of Tuberculosis Among Foreign-Born Persons" (FBPs). ACET acknowledged that the outdated foreign-born guidance document was developed in 1998 and did not include more recent data. FBWG is updating the guidance document with recommendations in nine major areas: a new screening algorithm, critical program elements, special issues for health departments, laboratory issues, special FBPs, critical partners, education and training resources, policy recommendations, and future research needs.

Dr. Katz noted that with the exception of the pediatrics section, the FBWG members have approved outlines and completed first drafts of each section. FBWG's editing subgroup will begin to revise each section. The *Morbidity and Mortality Weekly Report (MMWR)* approved the overall outline and committed to placing the updated foreign-born guidance document in the publication queue for the spring of 2008.

Update on Implementation of the 2007 TB Technical Instructions (TIs)

Dr. Drew Posey, of the CDC Division of Global Migration and Quarantine (DGMQ), was pleased to announce that DGMQ and the International Organization for Migration (IOM) appointed and stationed new professional staff members in the field to assist in the implementation of the TIs. CDC finalized and posted the TIs on its web site in August 2007.

The 2007 TIs for TB screening and treatment are based on countries with WHO TB incidence of $\geq 20/100,000$. The major changes between the 1991 and 2007 TIs are summarized as follows. For children 2-14 years of age, a tuberculin skin test (TST) is required and a chest x-ray (CXR) is also required for those with a TST ≥ 5 mm. A CXR is required for all applicants ≥ 15 years of age. Applicants with HIV or a history, physical examination or CXR that is suggestive of TB are required to provide three sputum specimens for both smear and culture. DST is required for positive isolates. DOT must be administered in accordance with guidelines developed by ATS, CDC and the Infectious Disease Society of America (IDSA) until therapy is completed.

TI implementation began in April 2007 in Thailand for Burmese refugees and in October 2007 in Mexico and the Philippines. The start date for TI implementation in Vietnam has been delayed because the laboratory will not begin operations until December 2007. TI implementation is expected to be launched in Nepal for Bhutanese refugees in January 2008 with an IOM laboratory and DOT program. This resettlement will include $\geq 60,000$ refugees over the next several years.

Efforts are underway to implement the TIs in Malaysia for Burmese Chin refugees as soon as possible. The 1991 TB TIs were used to screen 4,662 Burmese Chin refugees in FY'07, but physicians detected 32 culture-positive cases and two imported TB cases. The IOM will administer DOT in Malaysia, but laboratory options are being determined at this time. This resettlement will include 7,000 refugees during FY'08-09. In addition to TI implementation in FY'08, the Philippines screening program will be evaluated as well. DGMQ is collaborating with DTBE to arrange for experts from ACET, NTCA and other groups to assist in the evaluation.

Dr. Posey summarized data based on TB indicators CDC developed following the resettlement of Burmese refugees in Mae La, Thailand from April-September 2007. Of 9,899 refugees screened, 17% had an abnormal CXR. Of 114 refugees with pulmonary TB disease, 103 were diagnosed through screening. Of these 103 cases, 62% were smear-negative/culture-positive and 11% were smear-negative/culture-negative.

During pre-departure screening, Class B1 TB applicants in Mae La, Thailand received a physical examination, chest radiograph and three additional sputum smears within three weeks of departure. No cases were detected with the pre-departure screening process. Of 91 isolates with DST, 85% were pan-susceptible and only 2% had MDR-TB. However, both MDR-TB cases were treated for TB disease prior to screening.

In terms of laboratory indicators, contamination rates for mycobacteria growth indicator tubes decreased from 34.3% in April 2007 to 10% in August 2007. However, Dr. Posey asked ACET to thoroughly review the laboratory indicators and provide input to the TB Technical Instruction Workgroup about the performance of the laboratory and potential areas of improvement.

Dr. Posey outlined CDC's observations and lessons learned in implementing the 2007 TIs for TB screening and treatment. Implementation of the TIs is achievable, but requires patience, determination and creativity. Regular visits of approximately every three to four months are needed at sites during the preceding 12-16 months. Efforts to build culture and DST capacity are easier than efforts to develop DOT programs. TI implementation contributes to global control of TB.

All DOT programs are not equally created, particularly with individual perspectives of "DOT" on the one hand and "self-administered therapy" on the other hand. Use of WHO regimens by national TB programs is not as rigorous as the ATS/CDC/IDSA guidelines and other standards for drug-resistant cases. Some programs have limited drug availability, human resources, drug distribution systems or private enterprises. DGMQ will continue to consult with DTBE to develop creative solutions that will be specific to various countries.

ACET commended the laboratory efforts that have been made to reduce contamination, particularly the reduction of smear-negative/culture-positive cases from 14.2% to 2.8% from April-August 2007. However, some members were concerned that smear-negative/culture-negative cases increased from 85.8% to 97.2% during this same period of time. Dr. Posey confirmed that he would continue to provide ACET with regular updates on the implementation and evaluation of the TB TIs.

Overview of the Use of Homeland Security Tools for Public Health Purposes

Dr. Francisco Averhoff, of DGMQ, provided an overview of using Department of Homeland Security (DHS) tools for travel restriction and border identification. Routine public health tools include education, hygiene, surveillance and investigation, treatment, vaccination, and isolation and quarantine. However, the XDR-TB patient who traveled by air from the United States to other countries provided CDC with an opportunity to more closely collaborate with DHS in developing additional public health tools, such as the “do not board” (DNB) list, Border lookouts, and data requests for contact investigations.

Dr. Averhoff described two travel restriction laws that can be applied to protect public health. Section 361 of the Public Health Service Act requires the apprehension, examination and conditional release to prevent introduction, transmission and spread of communicable diseases. The law applies to communicable diseases from foreign countries into the United States as well as from one state or possession into another. The law has no state preemption and protects the *habeas corpus writ*.

The Aviation and Transportation Security Act of 2002 provides more direct authority by allowing the Transportation Security Administration (TSA) to take necessary actions to mitigate threats to aviation security, including denial of boarding to persons who pose a public health threat. Despite this law, active TB cases that crossed the Border by air dramatically increased from July 2006 to June 2007. Moreover, data collected from 2005-2007 showed that persons with TB traveled by air to the United States on an originating flight from Africa or Asia and a connecting flight in Europe.

Although law enforcement agencies are responsible for implementing DHS tools to protect public health, DGMQ provides stewardship of this program. Public health tools historically have focused on travelers with TB, but these mechanisms also could be applied to measles and other infectious diseases. DTBE’s draft algorithm to evaluate infectiousness has been shared with NTCA.

Dr. Averhoff provided additional details about the DNB list that is managed by the TSA Office of Intelligence. The requirement prohibits an individual, including any U.S. citizen or alien, from boarding an aircraft that is inbound, outbound or within the United States. The “do not fly” list is aimed at protecting civil aviation and the United States from acts of terrorism and is different from the DNB list. Persons on the do not fly list are not included on the DNB list.

Canada and Mexico are notified of every DNB action and are provided with detailed information on each case. Other international notifications are made as necessary. State and local health departments review the DNB list at least every 30 days to evaluate whether an individual should be removed from the list based on an absence of infection. Removal from the DNB list requires no more than 24 hours and does not result in residual adverse effects to the patient.

Specific criteria have been established to place an individual on the DNB list. A reason exists to believe the individual is infectious or likely to become infectious with a disease that should be quarantined. Available evidence supports concerns regarding non-compliance by the patient or an inability to locate the patient. The patient has capacity to obtain a ticket for air travel. Documentation exists that the patient will attempt to fly on a common air carrier. This evidence includes a record of a purchased airline ticket, a ticket reservation, or an admission of intent to travel by commercial aircraft, relative or acquaintance.

The approval process to place persons on the DNB list requires several steps. Quarantine stations, through state or local health departments, submit requests to DGMQ. DGMQ convenes a conference call with state and local health officials, local quarantine staff and DTBE to review the DNB criteria for the patient in question. If a determination is made that an infectious patient is at risk of traveling against advice, CDC leadership approves placement on the DNB list or lookout.

CDC sends the DNB request to DHS along with the patient's clinical background, identifying information, and reasons to support the belief that the patient is at risk of flying. DHS shares CDC's DNB information with TSA and informs CDC in less than 24 hours that the patient has been placed on the DNB list. After receiving confirmation from DHS, CDC contacts and advises local health authorities to inform patients of their placement on the DNB list.

Dr. Averhoff reported that of CDC's 17 DNB requests for persons with known or suspected infectious TB since May 2007, 10 are currently active. Additional requests were discussed, but were not processed because CDC and state and local health departments reached consensus that such a measure did not meet DNB criteria and would not advance public health.

Dr. Averhoff concluded his presentation with a summary of several issues that need to be addressed to improve the DNB process. Airline personnel have not been given clear instructions on effectively handling infectious individuals who are attempting to check-in for a flight. Criteria to remove persons from the DNB list are not clearly defined. Arrangements by local and state authorities to facilitate social needs and other areas of care might pose barriers to patients receiving and adhering to treatment.

A local or state health department will exercise its legal options to restrict the patient's movement if appropriate. CDC should make certain requests on behalf of the patient, such as a visa extension and a request to waive fees or penalties for changing travel dates. Solid strategies should be developed to more widely and formally publicize the availability of the DNB list to state and local health departments.

Dr. Castro added that as these outstanding issues are clarified over the next few months, DTBE would use "TB Notes," "Dear Colleague" letters and other venues to inform groups other than quarantine stations about the DNB list, including health organizations, NACCHO and the Council of State and Territorial Epidemiologists. Dr. Averhoff confirmed that he would provide an update at a future ACET meeting as information about the DNB list is more broadly disseminated and implemented.

Update on TB Control in the U.S.-Mexico Border Region

Dr. Diana Schneider, the ACET *ex-officio* member to DHS, covered the following areas in her update. ACET passed a resolution in March 2007 with three overarching goals. First, emergency funding would be requested to continue trans-border case management activities of CureTB and TBNet and also to maintain TB continuity of care for mobile populations.

Second, necessary activities and infrastructure for trans-border TB case management would be maintained and enhanced. These activities would include the TB health card, electronic health records, staff and resources, and other innovative strategies to facilitate data sharing across jurisdictional boundaries and healthcare systems. Third, a mechanism would be created to account for all trans-border TB cases managed in the United States for determination of federal funding, regardless of nationality.

The Transnational Tuberculosis Continuity of Care Workgroup (TTCC) was established in 2002 to address continuity and completion of TB treatment for U.S. Immigration and Customs Enforcement (ICE) detainees. The TTCC Workgroup later formed a Legal Subgroup and also expanded its scope to include general TB control issues affecting the U.S.-Mexico Border region. Data collected in 2005 showed that the case rate of pulmonary TB was 14.3/100,000 in Mexico compared to 4.8/100,000 in the United States.

Dr. Schneider outlined key recommendations of the TTCC Workgroup. Border entities should include recommendations from the TTCC Workgroup in their respective strategic action agendas. A forum should be convened to facilitate clarification and understanding of applicable laws and regulations in the four U.S. Border states and Mexico regarding infectious diseases of public health significance.

Mechanisms should be developed to address cross-jurisdictional, binational and international TB case management. A mechanism should be created to facilitate information management. A clearinghouse of public health legal information should be established. A mechanism should be developed to count the total case burden of all TB cases that are managed by state and local TB control programs. The TTCC Workgroup also provided specific details for each of the six recommendations.

The TTCC Workgroup considered several legal issues pertaining to its recommendations. In the United States, local jurisdictions and states have authority to compel isolation, quarantine, detention and court-mandated case management. State statutes vary based on an ongoing

public health threat, contagiousness of the patient or non-adherence to treatment. A court order may only extend, while applicable criteria apply. Required admissible evidence and processes for admitting evidence in a court of a competent jurisdiction also vary by state. The scope of inclusion varies with regard to non-state residents, non-U.S. citizens, undocumented persons, and temporary residence in the state. Legal restrictions exist on sharing information, resources and mutual aid.

At the federal level, federal public health isolation authorities are limited to the patient's initial entry into the United States; patients who move between states or are a probable source of infection to others who will be moving between states; and patients in a communicable or pre-communicable stage if the disease is likely to cause a public health emergency if transmitted to others.

The CDC Director can determine whether measures taken by public health authorities of any state or possession are insufficient to prevent the spread of any communicable diseases to any other state or possession. No federal facility exists for isolation under federal administrative orders. Limited federal resources are available for prolonged isolation under administrative orders. In terms of U.S. immigration, ICE's authority to detain is to facilitate immigration proceedings and deportation. Statutory limitations exist regarding the duration of custody pre- and post-issuance of a final order of removal.

The TTCC Workgroup considered several resource issues pertaining to its recommendations. Use of legal authorities requires the commitment of state and local funds for treatment and related costs. States may have restrictions on the use of state funds for treatment of undocumented persons or individuals who temporarily reside in the state. ICE detainees and federal inmates may be detained in any state. Detainees may or may not have previous ties to the community in the location where they are housed.

The TTCC Workgroup considered several operational issues pertaining to its recommendations. Secure and specialty medical facilities in the United States are scarce and might require legal agreements to accept patients from other states. No federal facility exists for isolation under administrative orders. Federal resources for prolonged isolation under administrative orders are limited.

The TTCC Workgroup considered additional border security issues. U.S. Customs and Border Protection processes and provides instructions for the lookout list. The lookout list applies to all persons crossing the border and patients with contagious or suspected contagious infectious diseases. The GAO investigation of the interagency response to two highly publicized incidents involving MDR-/XDR-TB patients who traveled between countries is underway.

The United States, Canada and Mexico signed the Security and Prosperity Initiative on November 1, 2007 for the three governments to provide assistance during a public health emergency; cooperate in improving preparedness and emergency response efforts; and coordinate in efforts to address global health, border health, health security, laboratory testing, diagnosis and treatment, epidemiologic investigations, and infectious disease control.

Dr. Schneider announced that a TB Legal Forum was held in October 2007 to address cross-jurisdictional legal issues among U.S. border states. Participants included CDC, DHS, NTCA, U.S.-Mexico Border Health Commission (BHC), a Native American liaison, and representatives of TB control programs and state legal counsel in Arizona, California, New Mexico and Texas.

State and tribal statutes and regulations were extensively discussed during the TB Legal Forum. New Mexico statutes are general to threatening communicable diseases, while Arizona, California and Texas statutes are TB-specific. Processes to initiate legal action vary by state, but all of the represented states at the TB Legal Forum require documented failure to comply with the initial legal order.

Texas has restrictions on using state funds for persons who temporarily reside in the state. Public health authorities in Arizona, California and New Mexico do not have residency restrictions. Criteria for utilizing court-mandated isolation and case management differ among states. Tribal nations do not have their own laws and may follow federal laws. Indian Health Service statutes are extremely broad. The Navajo Nation adopted the Health Commitment Act of 2006 to provide a mechanism for the health commitment of individuals for treatment in the least restrictive setting.

Specialized facilities and mechanisms to transfer patients out of state were discussed during the TB Legal Forum. Texas is the only state in the Southwest region with a publicly-funded medical facility for court-mandated isolation and treatment, while other states use criminal detention facilities. As a result, a recommendation was made during the TB Legal Forum to develop mechanisms to foster regionalization.

Legal agreements have been established for cross-jurisdictional use of the Texas Center for Infectious Disease to transfer patients between the Navajo Nation and the New Mexico state government and between the New Mexico and Texas state governments. Arizona has a mechanism to transfer patients out of state, but California has no expressed authority for out-of-state transfers of patients.

The International Health Regulations (IHRs) were discussed during the TB Legal Forum. The IHRs are implemented under domestic laws for each country, require a response on a time-sensitive basis, and impose requirements for sharing information between member countries. The United States implements the IHRs under principles of federalism.

Issues related to U.S. immigration, detention and removal were extensively discussed during the TB Legal Forum. Efforts are made to promote continuity of care for TB patients who are undergoing deportation proceedings. Most patients are deported before treatment is completed and many patients are deported before case confirmation. Some patients who do not continue or interrupt treatment might return to the United States.

Some participants at the TB Legal Forum expressed a desire for patients to remain in ICE custody until treatment completion. However, several problems with this approach were noted, including ethical concerns, inconsistency with the community standard of providing treatment in

the least restrictive setting, and violation of civil liberties. Moreover, ICE authority to detain is incident to removal. Statutory limits exist on the duration of ICE custody.

Stays of removal can be considered in exceptional circumstances, such as a lack of capacity in the country of nationality to treat MDR-TB and no assurance of continued custody. A patient could be released to the community if a stay is granted. ICE might require another security setting. Resource and operational barriers to jurisdictions accepting patients into their care exist. ICE cannot pay for services for persons not in custody.

Dr. Schneider summarized key recommendations that were made during the TB Legal Forum. A binational legal forum should be held with Mexican counterparts. Meetings with the TB Legal Forum should continue and a web site should be created to facilitate ongoing communication. Border health partner organizations and entities involved in preparedness and other issues regarding infectious diseases of public health significance should be engaged in this effort. Cross-jurisdictional agreements and considerations of legal issues with regard to least restrictive standards should be reviewed.

Legal language for TB to be considered as an active infectious disease of public health importance until cured should be supported. Interstate and binational legal issues that need further study should be identified. The ability of tribal governments to have full participation TB legal determinations should be supported. Tribal inclusion in border TB control activities and planning should be promoted. Mechanisms should be developed to share information across state and national borders. Epidemiologic surveillance initiatives should be expanded to the ten U.S.-Mexico border states.

Binational case management and collaborations on contact investigations should be promoted. The ability to transfer patients in federal custody to state or local public health jurisdictions for treatment and case management should be reviewed. Mechanisms to delay deportation of patients with active TB until treatment is completed should be considered. Resource limitations should be addressed. All TB cases that are managed in funding determinations should be counted.

Dr. Schneider concluded that the TTCC Workgroup has made progress in identifying key issues, making recommendations and determining priorities. She and Dr. Fleenor have discussed the possibility of establishing a new ACET Border TB Workgroup and inviting ACET members to serve on the existing TTCC Workgroup.

Update on Stop TB USA

Dr. Schneider announced that a retreat was held in August 2007 to provide input to NCET. NCET was renamed to "Stop TB USA" to redefine its membership on the global Stop TB Partnership and provide a recognized brand for mobilizing partners in the TB elimination effort. A process and timeline were identified for mobilization efforts.

The participants made a number of recommendations during the retreat. A TB Elimination Plan Workgroup should be formed to assess progress toward elimination, update the plan with partners and establish a new goal. A Launch Workgroup should be formed to develop the branding, create a communications strategy, and launch Stop TB USA at the International Union Against Tuberculosis and Lung Disease (IUATLD) North America Region meeting in February 2008.

The participants acknowledged that several actions have been taken over the past decade regarding TB elimination, including the initial proposed plan in 1989; establishment of NCET in 1991 in response to the TB resurgence; publication of the IOM report in 2000; updated guidance in 2005; and the upcoming foreign-born recommendations in 2008. However, the participants emphasized the need for an updated TB elimination plan at this time to achieve the five major goals outlined in the IOM report, *Ending Neglect*.

The participants also noted that an updated TB elimination plan might strengthen mobilization efforts, enhance ATS administrative support to NCET, increase resources, and engage more partners as a result of the more recent focus on foreign-born persons. More emphasis also might be placed on the IOM recommendation to mobilize and sustain public support and commitment for eliminating TB and regularly measuring progress toward achieving this goal. The TB Elimination Plan Workgroup will continue to meet on a regular basis, launch Stop TB USA, and present the updated TB elimination plan in May 2008.

Ms. DuMelle advised ACET to thoroughly review the priorities established by the TTCC Workgroup to determine whether formal recommendations should be made to the HHS Secretary. For example, these priorities might assist ACET in providing language for the amendment to the domestic TB bill that calls for CDC to update quarantine provisions.

Dr. Schneider acknowledged two concerns raised by ACET members. First, Stop TB USA does not appear to have a strong focus on domestic priorities, particularly TB in U.S.-born AAs, in updating the TB elimination plan. Second, state TB controllers who need extensive knowledge of QFT-G testing and other TB issues as a result of large foreign-born populations in their respective states are not engaged in U.S.-Mexico Border activities. For example, Mexico has largely attributed to population increases of 700% in some counties in the Southeast region since the last census data. These jurisdictions need education and training to take advantage of lessons learned from U.S.-Mexico Border activities.

Dr. Schneider made two suggestions to address these concerns. First, ACET should recommend persons to serve on workgroups that Stop TB USA will establish in the future to write and review the updated TB elimination plan. This approach would ensure that ACET's priorities are reflected. Second, persons with an interest in joining the TTCC Workgroup are welcome.

Dr. Fleenor confirmed that during the business session on the following day, ACET would revisit cross-jurisdictional legal issues for TB control along the U.S.-Mexico Border to determine whether formal recommendations should be made.

Update on RTMCC Activities

Mr. Dan Ruggiero, of DTBE, provided a federal perspective on interactions between the Regional Training and Medical Consultation Centers (RTMCCs) and state and local TB control programs. In 2005, CDC established three RTMCCs replacing what was previously known as TB Model Centers in New Jersey, New York City and San Francisco to strengthen the public health infrastructure and respond to the TB epidemic at that time. The state-of-the-art RTMCCs provided innovations in TB treatment and established a foundation for new research in TB control.

Based on 11 years of experience with the Model Centers, CDC decided to take a new direction in meeting unmet needs in training, education and medical consultation. CDC also recognized the need to expand and redistribute the geographical locations of the RTMCCs. The New Jersey and San Francisco RTMCCs were retained in the new organizational structure and two new RTMCCs were established in San Antonio, Texas and Gainesville, Florida in 2005. CDC considered a number of factors in selecting the new geographical distribution, including TB morbidity in each region, characteristics of the populations served, and the distribution of programs.

CDC established the following mission for the RTMCCs. Human resource development for TB control and prevention would be increased through education and training activities. Capacity for appropriate TB medical evaluation and management would be increased. CDC instructed each RTMCC to devote 50% of its budget to training courses and technical assistance, 30% to product development, and 20% to medical consultation. CDC also encouraged each RTMCC to closely collaborate with state and local TB control programs.

CDC advised the RTMCCs to conduct business with three guiding principles. One, TB programs would be the customers, recipients and active participants in the service delivery of training and medical consultation by the RTMCCs. Two, RTMCCs would be held accountable for the delivery of training, education and medical consultation services to state and local TB programs across the country. Three, CDC would provide guidance, technical assistance and facilitation to the RTMCCs. CDC formed a four-member project team to assist the RTMCCs in meeting these goals.

The RTMCCs performed a needs assessments in 2005 and used these results to interact and communicate with TB programs through a number of venues, including a web site, regular e-mail communications, quarterly newsletters, conference calls, an advisory committee, regional and national meetings, the CDC TB Education and Training Network (TBETN), and NTCA. In 2006, the RTMCCs provided 1,119 training hours; trained 7,126 healthcare workers (HCWs); conducted 24 mini-fellowships; provided technical assistance on 194 occasions; developed or revised 39 new or existing products; disseminated 3,850 existing products online; and provided 1,720 medical consultations to physicians, nurses, HCWs and other groups.

Other accomplishments of the RTMCCs to date include the completion of needs assessments for all TB project areas. Moreover, four national web-based seminars were conducted. Linkages were established and activities were integrated with HIV/AIDS and STD Training Centers.

Mr. Ruggiero announced that CDC conducted a structured evaluation to assess interactions, communications and service delivery of the RTMCCs to TB programs. On the one hand, most respondents reported positive interactions with the RTMCCs and valued the expertise of the RTMCCs in training and consultation. TB programs also reported that the RTMCCs met their priority needs and provided useful medical consultation services.

On the other hand, respondents reported an increased demand for the following activities: courses on popular topics, advanced courses for experienced staff, onsite courses, web-based seminars, laboratory training of program staff, resources for medical consultations, printed copies of materials, a web page to identify and access all available RTMCC products, and more advance notice for staff to plan for, budget and attend courses.

Mr. Ruggiero pointed out that CDC would produce a report with a summary of the evaluation results, but all of the RTMCCs have been given preliminary outcome data from the evaluation in the interim. The evaluation report and needs assessment reports would be distributed to ACET to assist the members in providing formal guidance to CDC to improve the RTMCCs.

Mr. Ruggiero informed ACET that CDC would convene an RTMCC summit in 2008 to determine future directions, establish priorities, and identify the necessary level of funding for the 2010-2015 cycle. In addition to the RTMCCs, CDC, ACET, NTCA, TB controllers and other partners would be invited to attend the summit.

Ms. Donna Wegener, of the Southeastern National TB Center, represented all four of the RTMCCs. She provided a field perspective on partnerships among the RTMCCs, state TB programs and other agencies. In addition to the formal mission and guiding principles that CDC established for the RTMCCs, the RTMCCs also play a role in responding to regional needs with a flexible approach; using resources to create technologically innovative products; maximizing partnership opportunities, developing creative strategies; and establishing collaborative opportunities.

The RTMCCs provide numerous training opportunities through regional web-based seminars to address unique local and regional needs and also to disseminate information to a wide audience. However, the RTMCCs recognized the need to provide national web-based seminars to more broadly address topics of interest, such as MDR-/XDR-TB, legal interventions in TB control, effective laboratory and program partnerships, management of TB/HIV co-infected patients, and practical applications for genotyping in TB control.

Each RTMCC offers core courses in program management, clinical intensives or updates, contact investigations, interviewing skills, case management, and TST train-the-trainer courses. The RTMCCs provide region-specific educational activities through onsite training in partnership with states or project areas. The RTMCCs leverage existing state and local resources to

provide this need-based training. Training audiences for the RTMCCs include TB program staff and public/private healthcare providers.

In addition to these successes, the RTMCCs also are facing a number of training challenges, including staff turnover and the great demand for courses. For example, some RTMCCs are required to close registration for full courses despite continued requests from states or regions for traditional or web-based training. Moreover, TB programs are continuing to identify training needs for new content, such as high-risk populations and advanced courses.

Each RTMCC has established a hotline or warm line to provide TB programs with access to medical consultation and additional expertise or resources if required. The RTMCCs implemented the hotlines and warm lines in collaboration with states to support and reinforce state TB programs. At this time, the RTMCCs are advancing toward systematic data collection to create a medical consultation database system with a national focus. The system will be used to train, educate and mentor TB consultants in the future.

Each RTMCC convenes web-based case conferences on either a monthly or bimonthly basis with a state or regional focus. The case conferences are designed in a collaborative fashion with an educational format. The RTMCCs also partner with state TB programs to hold ad hoc complex case conferences with multiple care providers. To provide medical consultation, RTMCCs convene annual face-to-face meetings, network with states and public/private providers, and mentor TB program staff.

In addition to TB programs, the RTMCCs also have established partnerships with a number of agencies and organizations. Training sessions to various TB controller associations are held in conjunction with regional meetings that include guest speakers. These training sessions have allowed the RTMCCs to exhibit information, enhance networking opportunities, and offer continuing education and continuing medical education credits.

Training sessions to AIDS Education and Training Centers have allowed the RTMCCs to provide TB clinical updates to staff and explore opportunities to sponsor joint training sessions. These training sessions also have provided the RTMCCs with an opportunity to develop specific products, such as web-based or archived lectures on HIV/TB co-infection and the diagnosis and treatment of LTBI in HIV-infected patients.

Training sessions to STD/HIV Prevention Centers have allowed the RTMCCs to provide TB clinical updates to staff, offer technical assistance, facilitate meeting planning, and explore opportunities for joint training sessions on contact investigations and interviewing skills. Training sessions to the American Lung Association have allowed the RTMCCs to convene state-specific TB summits and develop the *Teachback Training Guide* and other products.

Training sessions to academic health centers have allowed the RTMCCs to provide medical consultation services through grand rounds and web-based case conferences. These training sessions also have resulted in the development of subcontracts to solidify partnerships for product development and training opportunities. The RTMCCs have established a number of partnerships with other professional associations and CBOs as well.

Ms. Wegener concluded that in 2008 and beyond, the RTMCCs would strengthen existing activities, enhance partnerships, identify unmet needs, and establish new collaborations. In the future, the RTMCCs also would focus on creative solutions, innovative partnerships, additional resources and other potential enhancements.

ACET made two key suggestions for CDC to consider in improving the RTMCCs in the future. First, the development of skill sets for epidemiologists who are involved in TB control should be emphasized in the future direction of the RTMCCs. Another future priority of the RTMCCs should be the translation of epidemiologic and clinical trial research. This approach would help to advance innovations from concepts to actual products in the field, such as genotyping, social network analyses and national TB indicators.

Second, the RTMCCs should formally engage other partners during the strategic planning process for the 2010-2015 funding cycle, such as the U.S.-Mexico BHC. Strong collaborations also should be established with the Homeless Clinicians Network, state-based primary care associations, and other entities funded by the Health Resources and Services Administration that serve patients who are at risk for TB infection or active disease. The RTMCCs should broaden its partnerships and audiences by making presentations at conferences or other events sponsored by these groups.

Update on the National Strategic Plan for TB Training and Education

Dr. Wanda Walton, of the DTBE Communications, Education and Behavioral Studies Branch, covered the following areas in her update. The 1999 Strategic Plan for TB Training and Education (TBTE) underscored the importance of maintaining efforts against TB in the United States; emphasized the need for comprehensive TBTE programs; and noted the significance of coordinating TBTE resources and identifying areas of highest need.

The 1999-2003 TBTE Strategic Plan was designed to avoid duplication of services, anticipate diminishing TB resources, coordinate TBTE resources, and identify areas of highest need. CDC funded the Francis J. Curry National TB Center to serve as the secretariat in providing administrative and logistical support for this voluntary effort. DTBE and three Model TB centers coordinated the planning process and established six workgroups to develop the strategic plan.

The 1999-2003 TBTE Strategic Plan resulted in the development of several five-year goals. Collaboration with key agencies, training organizations and global partners would be built, strengthened and maintained. Access to and availability of TBTE resources would be developed, improved and maintained. Knowledge, skills and practices tailored to local epidemiological circumstances would be improved and sustained. Financial resources for TBTE would be identified and mobilized.

Following the development of the 1999-2003 TBTE Strategic Plan, an implementation committee was formed to review progress of the six workgroups, discuss follow-up actions and decide next steps. Quarterly status reports were developed and shared to hold organizations

and individuals accountable to the TBTE Strategic Plan. Each status report was formatted with a stated goal, objectives, current status, accomplishments to date, planned action steps, noted problems and additional comments.

The 1999-2003 TBTE Strategic Plan resulted in the development of a TBTE Network, the "TB Educate" listserv, a web site with TBTE resources, and national attention, recognition and support for TBTE. Moreover, the 2000 IOM report on TB elimination in the United States recommended full funding of the TBTE Strategic Plan to promote a well-trained medical workforce and educated public.

The 2004-2008 National Strategic Plan for TB Training and Education was developed to update and replace the 1999-2003 TBTE Strategic Plan. The Francis J. Curry National TB Center utilized existing funds to coordinate the 2004-2008 National Plan and post the document on its web site to serve as a national planning resource. Although 50 U.S. and international experts representing a variety of agencies and organizations were involved in the development of the 2004-2008 National Plan, no additional funding was provided for monitoring and evaluation.

The 2004-2008 National Plan retained the same goals as the 1999-2003 TBTE Strategic Plan, but strategic objectives, desired outcomes, strategies and potential responsible entities for implementation were described as well. However, this approach did not identify specific accountability and funding for the 2004-2008 National Plan.

Despite this limitation, recent progress has been made in TBTE. The four funded RTMCCs were charged with provided training and building capacity in TB programs. For the first time, TBTE was recognized and funded as a TB core activity in the 2005-2010 cooperative agreement. Focal points for training were identified for TB programs in each state and large city. Annual human resource development plans were provided for each TB program. TBETN has grown with a current membership of 679 persons and 197 registrants for the August 2007 conference.

CDC acknowledged the need to apply lessons learned from the first two strategic plans to develop a new National Strategic Plan for TB Training and Education for 2009-2013. The 2009-2013 National Plan will be consistent with the purpose of any strategic plan to engage stakeholders, secure consensus, and promote coordinated action that leads to results. The 2009-2013 National Plan also will meet current TBTE needs, such as promoting a shared understanding of challenges; facilitating a forum for new voices; providing an opportunity for collaboration; prioritizing greatest needs; emphasizing the ongoing importance of TBTE in a time of shrinking resources; and supporting and enabling TB elimination in the United States. In developing the 2009-2013 National Plan, efforts will be made to avoid overburdening persons in terms of time and resources.

CDC has established a stepwise strategic planning process to develop the 2009-2013 National Plan. The vision and mission statement will be defined with a hierarchy of goals. A "strengths, weaknesses, opportunities and threats" analysis will be conducted based on desired goals. Actions and processes will be formulated to attain the goals. Consensus-based processes will

be implemented. An evaluation will be performed to determine success, identify barriers and focus on other needs.

Dr. Walton noted that now is an opportune time to develop the 2009-2013 National Plan due to existing collaborative opportunities. Most notably, Stop TB USA will launch its initiative and develop an updated TB elimination plan. The National Tuberculosis Curriculum Consortium (NTCC) has reached new audiences in wider venues. CDC will convene a summit in 2008 with a number of partners to discuss and plan for the future of the RTMCCs. The establishment of a TBETN Workgroup has been proposed to guide the development and implementation of the 2009-2013 National Plan.

CDC will lead the development of the 2009-2013 National Plan in close collaboration with the RTMCCs. However, CDC acknowledges that a number of partners will need to be engaged in this effort, including NTCA, ACET, Stop TB USA, state health departments, professional organizations and federal agencies.

ACET made several suggestions for CDC to consider during its ongoing efforts to develop the 2009-2013 National Plan.

- CDC should extensively engage additional partners during the development and implementation of the 2009-2013 National Plan, such as schools of public health and professional associations that represent general practitioners.
- CDC should thoroughly review the two previous strategic plans during the development of the 2009-2013 National Plan to identify accomplishments.
- CDC should design the 2009-2013 National Plan to include 16 national TB program objectives and indicators that DTBE developed in conjunction with state TB partners.

Update on NTCC Activities

Dr. Antonino Catanzaro, of the University of California-San Diego, explained that the National Institutes of Health (NIH) funded NTCC to strengthen the teaching of TB to undergraduate students of nursing, medicine and allied health, including public health. He pointed out that more information on NTCC could be obtained at www.ntcc.ucsd.edu.

Following his presentation on NTCC at the previous ACET meeting, Dr. Catanzaro learned that NIH had performed an assessment of the state of TB education in the United States and had no interest in expanding NTCC's current focus to include pulmonary and infectious disease fellows. NIH explained that a broader scope for NTCC would require a completely new application and external review process. However, NIH expressed more interest and flexibility in expanding NTCC's scope to the international arena. NIH welcomed formal communications with ACET to discuss this issue in more detail.

Dr. Catanzaro reported that he made two initial efforts after his conversation with NIH to begin expanding TB teaching to the international arena. In preparation of the IUATLD meeting in Cape Town, he contacted TB teachers at all six schools of medicine in South Africa. The South

African teachers expressed a great deal of interest in NTCC's educational programs and products. Initial plans were made to form an organizing committee to advance this activity.

Dr. Catanzaro noted that certain actions would need to be taken to expand NTCC to South Africa. The NTCC materials would need to be modified for specific local needs because South Africa is an extremely high-burden country with TB case rates of $\geq 1,000/100,000$, extensive drug resistance and limited resources. A planning grant would need to be awarded to convene appropriate stakeholders, recruit a pool of investigators, identify common needs, establish educational modalities and determine priorities.

Dr. Catanzaro informed ACET that a professor from Argentina expressed a great deal of interest in having NTCC's educational materials translated into Spanish. An expansion of NTCC to Latin American countries would greatly benefit the United States because Mexico and other Spanish speaking countries account for the majority of foreign-born TB cases domestically.

Dr. Catanzaro concluded that he was interested in obtaining ACET's support of NTCC in general as well as its endorsement to expand NTCC to the international arena. He believed that NTCC's products could make a significant impact on the education of medical students in high-burden countries. NTCC also could play an important role in U.S. government efforts to impact the global TB problem. He announced that NTCC would convene its last annual meeting in San Diego, California to review its products.

ACET was disappointed about NIH's lack of interest in expanding NTCC to include pulmonary fellows, infectious disease fellows and internal medicine graduates. Several members suggested strategies to overcome this challenge.

- Partnerships should be established with ATS, IDSA and other professional societies to provide TB training to pulmonary and infectious disease fellows because these graduates are expected to be experts in the field.
- Certification and re-certification processes for all practicing physicians should be used as venues to require knowledge in public health areas.
- Experiences and lessons learned during NTCC's history should be compiled and widely distributed to Historically Black Colleges and Universities and other academic institutions that were not a part of the program. This approach would broaden the pool of medical students who receive TB education.
- The international expansion of NTCC should include medical schools in Western European countries. Similar to South Africa and Latin American countries, Western European countries also have low indigenous rates and account for foreign-born TB cases in the United States.

Dr. Fleenor confirmed that during the business session on the following day, ACET would revisit this agenda item to determine whether a formal recommendation should be made on NTCC.

Update on the Public Health Law Review

Dr. Richard Goodman, of the CDC Public Health Law Program, explained that CDC is considering options to improve understanding of the status and sufficiency of state laws for TB control and prevention in the setting of progressively emerging drug-resistant TB. He described six key issues that have implications for public health laws and TB control in the United States.

1. What is the sufficiency of state TB laws to support TB prevention and control strategies, particularly in the setting of continually emerging drug resistance?
2. What are the legal impediments to operational plans and activities?
3. To what extent are existing legal authorities for controlling TB understood and effectively applied?
4. To what extent do state legal regimens for TB control comport with 21st century principles of public health ethics and, with due process, protections for liberty, autonomy and privacy interests?
5. What information do practitioners need to implement TB control laws?
6. What legal issues and considerations exist for coordinating TB control activities across different jurisdictions?

Coordination of multi-jurisdictional efforts is another important legal issue in TB control. Case management, including treatment and monitoring, is further complicated when a TB patient travels to another jurisdiction. However, application of TB control legal authorities must be coordinated. Several options are available to achieve coordination, such as enacting uniform laws or negotiating and executing memoranda of agreement (MOAs). MOAs can cover several issues, such as screening for the level of infectiousness prior to travel, infection control during travel, responsibility for continuity and completion of treatment and management, and costs after travel.

Dr. Goodman announced that ACET's recommendations on TB control laws in the United States were published in the *MMWR* in 1993. Following the July 2007 ACET meeting, CDC considered three strategies to update the 1993 guidance. Dr. Goodman summarized and requested ACET's feedback on the three proposed options.

For option 1, regulatory and statutory laws in all 50 states that expressly relate to TB control through state and local health departments only would be reviewed and characterized. The study of these laws would cover TB testing, screening, DOT, compulsory treatment, quarantine and isolation. The laws would be organized by public health powers, public health duties and limits on powers. Exclusions or limitations to this approach would include general laws related to communicable disease control; relevant local, tribal and international laws; attorney general opinions and MOAs; and relevant legal issues, such as privacy and anti-discrimination laws.

For option 1(a), express laws for TB control would be studied in a smaller sample of 25 key states. Other government entities and private sector partners would be included in addition to state and local health departments. Additional functions would be covered in the study, such as privacy, discrimination, case management and inter-jurisdictional controls. Options 1 and 1(a) would have the same limitations, but a bias might arise in option 1(a) because characterizations

and conclusions would be based on a sample size of 25 states only. In terms of logistical issues, CDC would select the 25 sample states in consultation with DTBE and ACET. CDC would use a cooperative agreement with Georgetown Law Center to conduct legal research for option 1 or 1(a).

For option 2, a handbook on TB control laws would be developed. The audiences of the handbook would include public health practitioners who are active in TB control at local, state and tribal levels as well as their legal counsel. The handbook would focus on pertinent local, state and tribal laws and essential information on federal and international laws, such as the IHRs. The handbook would be available in print and electronic formats, but an instructional PowerPoint presentation also would be created for education and training purposes.

The provisional content of the handbook would include six major sections: principles of public health practice for TB control; a general legal framework for disease control; communicable disease control law; TB control law; legal controversies in TB control law; and TB control law in practice. The first section would be primarily targeted to attorneys.

For option 3, a scenario-based tabletop exercise would be conducted to examine and understand the sufficiency of state laws in relation to evolving developments in TB, such as contagiousness in smear-negative/culture-positive patients and the static nature of antimicrobial options in the face of increasing resistance. The hypothetical scenario would be designed for TB controllers, state and local personnel who have basic communicable disease control responsibilities, providers who treat and manage TB patients, court staff, and other groups that are impacted by TB control laws.

Implementation of the tabletop exercise would be modeled after the recent “social distancing law” project. This initiative was conducted in 13 states by using a scenario to test the sufficiency of laws that restrict the movement of persons in the event of an influenza pandemic. The tabletop exercise could be conducted at professional meetings to increase knowledge of TB control laws.

Several ACET members made suggestions in response to Dr. Goodman's request for input on the proposed options for the public health law review.

- Option 1 should be selected as the approach for the public health law review. This strategy would serve as a solid initial step in allowing states that do not have existing laws to replicate models from other states and adopt TB control laws. Option 1 also would provide information about commonalities in TB control laws among states.
- Reporting and investigation should be included as two additional functions to cover in option 1. For example, TB control programs are frequently asked about statutes that mandate reporting and allow state and local health departments to investigate and review medical records.
- Option 1 should include a review and characterization of case laws surrounding documented TB laws on record. This approach would help to address different interpretations of a TB state law at the local level.

- An additional option should be considered in which a model law for TB control would be developed. This approach could provide explicit guidance, criteria and language for states to use in writing, interpreting and implementing consistent laws.
- Consideration should be given to updating the 1993 handbook by asking states to submit TB legislation that has been revised since this time.
- Outdated Indian Health Service laws, tribal codes and applicable federal laws should be thoroughly reviewed and incorporated into the option 1 study.

Update on Second-Line DST Guidelines

Dr. John Ridderhof, Associate Director for Laboratory Science of the National Center for Prevention, Detection, and Control of Infectious Diseases (NCPDCID), presented interim policy guidance on DST of second-line anti-TB drugs. The document was developed in response to the serious public health threat from MDR-/XDR-TB, the emergence and spread of epidemics, specific challenges in high HIV settings, and the urgent need for scale-up and diagnosis and treatment. Data show that <5% of MDR-TB cases worldwide are diagnosed or detected due to the lack of laboratory capacity.

Several actions need to be taken to effectively address XDR-TB. Most notably, laboratory services for adequate and timely diagnosis of MDR-/XDR-TB should be strengthened. Infection control should be introduced or expanded, particularly in high HIV prevalence settings. A number of constraints are associated with second-line drugs (SLDs), including technical complexities, instability of drug powders *in vitro*, variable methodologies, lack of correlation with clinical response, minimal laboratories with technical capacity, cross-resistance issues, and inconsistent results due to critical drug concentrations versus minimum inhibitory concentrations (MIC) of the drug.

The Green Light Committee saw an urgent need to develop general programmatic guidance on SLD-DST to provide countries with information on validated technologies, cross-resistant issues, limitations in interpreting DST results, and drugs that can be reliably tested. In response to this observation, a technical workgroup was formed with representation by CDC, WHO, the Stop TB Partnership and other groups. The interim policy guidance has been broadly reviewed.

Dr. Ridderhof reviewed key sections of the interim policy guidance. An explicit statement of the problem is included in the document. Due to the delay with conventional DST results, results might not accurately reflect bacterial populations at the time of sputum collection. Sole reliance cannot be placed on DST results to guide treatment design. Rapid DST methodologies are still in development, in the early validation stage, or in the early field demonstration phase. No rapid DST methodologies have been developed for SLD-DST. No studies have systematically evaluated all available DST methods for all available SLDs or assessed a large number of clinical isolates for microbiological and clinical endpoints.

The document outlines several factors that have hampered policy development. SLD-DST is technically complex. Only a minimal number of global laboratories have the required capacity and expertise to perform SLD testing. Conventional liquid and solid media are still widely used. Most of the newer techniques still require adequate validation. Testing differs among epidemiological settings. All SLDs are not available in all countries.

The document describes reliability and reproducibility and issues. Reliability and reproducibility are relatively good for aminoglycosides, polypeptides and fluoroquinolones, but are limited or have not been proven for other SLDs. Moreover, no methodologies have been developed to test some SLDs. A correlation between *in vitro* SLD-DST results and clinical treatment response has not been established to date.

The document extensively covers cross-resistance issues. Cross-resistance was previously considered to be complete for fluoroquinolones. However, limited evidence suggests possible enhanced clinical benefits with low MICs, improved biochemical structures, and a theoretical reduction in the selection of resistant mutants. Clinical efficacy remains to be confirmed in controlled clinical trials. Cross-resistance for aminoglycosides and cyclic polypeptides is complex and contradictory. Genotypes associated with resistance were found to overlap. A clear association was seen between *in vitro* drug resistance and specific molecular mutations. A generalization of resistance based on one drug might be misleading.

Dr. Ridderhof explained that the technical workgroup agreed to use a semi-quantitative ranking system to categorize the recommendations in one of five groups. Category I had the strongest evidence base with extensive published studies, while Category V had the weakest evidence base with no published studies. The group 1 drugs included the first-line regimen; the group 2 drugs included aminoglycosides; and the group 3 drugs included fluoroquinolones.

The technical workgroup did not recommend routine DST for the group 4 and 5 drugs. The recommendation was not intended to imply that laboratories with current capability terminate testing, but caution was advised in using *in vitro* DST results alone to guide treatment design or adjustment. The technical workgroup recommended rapid rifampin testing in high-risk settings for screening, including areas with a high burden of HIV. Conventional DST was noted as the gold standard.

The technical workgroup agreed on the following hierarchy for DST: INH and rifampin in step 1; ethambutol, streptomycin and pyrazinamide in step 2; and amikacin, kanamycin, capreomycin, ofloxacin or the fluoroquinolone of choice in the treatment strategy in step 3. The technical workgroup noted that steps 1 and 2 or steps 2 and 3 could be merged if indicated.

Dr. Ridderhof summarized next steps in this initiative. The SLD-DST policy guidance document will be posted on the WHO web site. A draft SLD-DST technical manual will be discussed during meetings in Cape Town, South Africa. The laboratory chapter in the WHO guidelines will be finalized. The Stop TB Coordinating Board endorsed the Global Laboratory Initiative. Efforts will be made for CDC and other U.S.-based organizations to massively scale-up technical capacity and provide technical guidance.

Overview of CDC's Model Performance Evaluation Program (MPEP)

Dr. Ridderhof explained that CDC established MPEP in 1994 to send drug-resistant and susceptible TB isolates to laboratories, assist with the transition to rapid DST methods, and assess laboratory performance. MPEP is a voluntary and confidential program of 140 U.S. and non-U.S. participant laboratories. Isolates are shipped biannually with four TB strains and one non-tuberculous mycobacteria strain to assist in improving education and standards. The MPEP laboratories often test and report SLDs, but rarely include SLD resistant strains. CDC collects, analyzes, disseminates and posts MPEP results on its web site in an aggregate report.

Data collected from the June 2006 shipment showed that of the 108 MPEP laboratories in the United States, 30 tested at least one SLD, nine tested all six SLDs, and 16 tested kanamycin and/or amikacin, fluoroquinolones and capreomycin. CDC is currently considering whether all of the U.S. MPEP laboratories need to test this number of SLDs or if SLD testing should be consolidated in some laboratories. MPEP and other U.S. laboratories use standards developed by the Clinical and Laboratory Standards Institute (CLSI).

Dr. Ridderhof described several actions that should be taken to improve laboratory capacity in the United States. A systems approach should be implemented to strengthen referral, reporting and standardization of practices for primary drugs and SLDs. The turnaround time for testing should be optimized. Guidance on SLDs should be updated, including the use of rapid molecular testing for DST. Operational research should be performed on SLD methods and algorithms.

Dr. Ridderhof announced that an expert panel meeting would be held in December 2007 to improve DST for the detection and control of MDR-/XDR-TB. The participants would include a broad range of practice, program and clinical experts. The objectives of the meeting are summarized below.

Recommendations would be provided on updating the 2003 CLSI standard on susceptibility testing for mycobacteria with an emphasis on SLD testing practices. Guidance would be provided on developing national strategies to assure access to rapid and comprehensive SLD testing in selected referral laboratories. Quality standards and existing proficiency testing for DST would be reviewed. Guidance would be provided on laboratory and program level practices to assure the accuracy of testing at all levels. Guidance would be provided on priorities for operational research to improve current practices and promote implementation of methods and algorithms for the rapid detection of drug resistance.

Several ACET members made suggestions for the technical workgroup to consider in refining the SLD-DST policy guidance document.

- Collaborations should be established with global laboratory networks for polio and other diseases to include these groups in the global laboratory initiative for TB.

- The DST hierarchy should only be recommended with extensive caveats due to the potential for this guidance to cause further drug resistance.
- The SLD-DST policy guidance document should mention the ability of reference laboratories to validate and implement rapid DST that has not been approved by the Food and Drug Administration (FDA).
- Resources that public health laboratories would need to implement the SLD-DST policy guidance should be considered. Most notably, new laboratory tests are becoming cost-prohibitive because compliance with the Clinical Laboratory Improvement Amendments must still be maintained. A national referral system should be established to address resource limitations of public health laboratories.

With no further discussion or business brought before ACET, Dr. Fleenor recessed the meeting at 5:20 p.m. on November 27, 2007.

Update on the CCID BSC

Dr. Fleenor reconvened the ACET meeting at 8:39 a.m. on November 28, 2007 and reported on key outcomes from the BSC meeting that was held in early November 2007. The BSC operates with workgroups that represent each of the CCID centers and make recommendations on specific topics. The BSC has greatly improved its operational structure to function in a more comprehensive manner across centers and identify synergies between the CCID program areas.

During the previous BSC meeting, the NCHHSTP divisions and GAP made presentations on HIV, STD, TB, viral hepatitis and PEPFAR in the context of NCHHSTP's impact evaluation. NCHHSTP conducted the outcome research project to assess the impact of its activities. Dr. Fleenor commended DTBE for an excellent presentation on the development of a TB monitoring system to determine impact and track progress. DTBE reported that the system is being designed with indicators to inform progress, focus program evaluation efforts, and provide performance targets as a benchmark for assessment. The BSC unanimously endorsed DTBE's program monitoring dashboard approach.

Dr. Phillip LoBue, of DTBE, mentioned that some BSC members were disappointed with the compact agenda because all four NCHHSTP divisions and GAP make presentations at each BSC meeting. The BSC members pointed out that this format has limited the time for discussions and the formulation of solid recommendations. Dr. LoBue agreed that CDC should convene more conference calls during the meeting planning process to better balance the agenda with presentations and BSC discussion periods.

Dr. Castro added that laboratories should be extensively engaged in PCSI efforts at federal, state and local levels to assist in strengthening national public health laboratory capacity. He noted that enhancement of public health laboratory capacity with TB as an important component would be an important issue for the BSC to discuss at a future meeting. Because laboratory

issues cut across all CCID centers, Dr. Castro believed that the BSC could serve as a mechanism to begin integrating laboratories into existing PCSI efforts.

Dr. Dean conveyed that the need to decrease the number of recommendations to each center also was discussed during the BSC meeting. As the largest CCID center, this issue is particularly challenging to NCHHSTP. To resolve this problem, the possibility was raised of each NCHHSTP division posing only two questions to the BSC. This approach also might provide more time for the BSC to have discussions and formulate recommendations.

Dr. Fleenor encouraged the ACET members to provide him with additional topics that he could propose during the next BSC meeting in May 2008. He planned to reiterate this request during ACET's business session.

Update on the XDR-TB Investigation

Dr. Ann Buff, of DTBE, explained that the objectives of the contact objectives were to determine the source of the index patient's *Mycobacterium tuberculosis* (*M.tb*); define the extent of *M.tb* transmission; prioritize contacts for screening and evaluation including family, friends, coworkers, HCWs, airline passengers and crew; and determine factors associated with a TST conversion or positive interferon gamma release assay (IGRA) test result.

Final results of the close contact evaluation are summarized as follows. All six family members identified in the original close contact investigation had negative TST or QFT-G results in the second round of testing. Of 20 additional friends, family members and coworkers identified as contacts, 18 had negative TST results in both rounds of testing; one had a negative clinical evaluation, a prior positive TST result, and a history of LTBI treatment in the past; and one had a positive TST and QFT-G result at initial testing, a negative clinical evaluation and a negative CXR. CDC believed that the positive result in the contact likely represented previous LTBI rather than recent transmission based on interviews of both the patient and contact. However, with current technologies, CDC was unable to determine if this represented recent or remote transmission.

Final results of the HCW evaluation are summarized as follows. Of ten HCWs, seven were involved in the patient's bronchoscopy procedure; nine had negative baseline TST results and negative QFT-G results eight weeks post-exposure; and one had a negative clinical evaluation and a history of prior LTBI and treatment.

Of 272 passengers on the flight with the index patient who were identified as U.S. citizens or residents, 26 were seated within two rows of the patient and were characterized as "high priority." All 26 high-priority passengers were contacted and 25 were evaluated. The remaining 246 passengers were characterized as "low priority." Of 244 low-priority passengers who were contacted, 224 were evaluated with at least one round of testing and five declined testing.

Results of the high-priority passengers who completed the first round of testing are summarized as follows. Of these 23 passengers, 20 had negative TST results; one had a negative clinical evaluation and a history of LTBI; and two had positive TST results initially using a ≥ 5 mm cutoff. Both of these passengers were born outside of the United States. Demographics of the high-priority passengers included 69% U.S.-born, 38% male, and a median age of 46 years with a range of 9-73 years.

The 20 high-priority passengers who initially had negative TST results formed the denominator for the second round of TST testing to determine conversion status. All 20 of these high-priority passengers completed a second round of evaluation and had negative TST results. Two passengers had only one evaluation eight weeks post-exposure and both were TST negative.

Results of the low-priority passengers who completed the first round of testing are summarized as follows. Of these 214 passengers, eight had positive TST results; 193 had negative TST results; and 13 had prior positive TST results with negative clinical evaluations. Of the eight passengers with positive TST results, three were born outside of the United States. Five low-priority passengers refused testing.

Demographics of the low-priority passengers included 81% U.S.-born, 54% male, and a median age of 45 years with a range of 0-83 years. CDC expects ~3%-5% of U.S.-born adults to have a positive TST result on screening based on national surveillance data and a ≥ 10 mm cutoff.

The 193 low-priority passengers who initially had negative TST results formed the denominator for the second round of TST testing to determine conversion status. Of 176 low-priority passengers who completed the second round of testing, 169 had negative TST or QFT-G results and seven had positive TST results. Ten passengers had only one round of testing at least eight weeks post-exposure, and all were TST negative. Seven low-priority passengers refused a second round of screening.

Of the seven low-priority passengers with positive TST results, five were born outside of the United States. Six passengers had negative chest radiographs with no signs or symptoms of TB disease on clinical evaluation and one had a known radiographic abnormality consistent with prior TB disease. This passenger is currently being treated for TB. CDC believes that the seven positive TST results represent boosting rather than recent transmission.

Dr. Buff summarized several conclusions that were reached following the contact investigation. The index patient has primary MDR-TB, but the source of *M.tb* is unknown. No evidence was seen of *M.tb* transmission to close contacts, HCWs or high-priority passengers. The most common factor associated with a TST conversion was birth outside of the United States. All agencies involved in the contact investigation agreed to share data with WHO for analysis and dissemination. WHO convened a formal workgroup to revise the *2006 TB and Air Travel Guidelines* to strengthen the guidance and clarify roles and responsibilities, particularly in light of the new IHRs.

ACET commended CDC and its partners on conducting a comprehensive contact investigation. An ACET member advised CDC to issue a statement about the relative importance of the XDR-TB investigation to coincide with the publication of WHO's revised *TB and Air Travel Guidelines*. This approach could emphasize the need for additional resources to address MDR-/XDR-TB.

Dr. Fleenor confirmed that during the business session, efforts would be made to revisit the XDR-TB investigation to determine whether ACET should formulate policy recommendations.

Update by the ACET TB in African American Workgroup (AAWG)

Mr. Shannon Jones III is an ACET member and chair of the AAWG. He reported on AAWG's activities following the previous ACET meeting. ACET charged AAWG with addressing disparity issues related to the AA population and developing a strategic plan of action. Mr. Jones presented data to demonstrate the disproportionate burden of TB among AAs in the United States, particularly in the Southeastern part of the country. He also showed data to emphasize the importance of service integration due to the high rates of HIV/TB co-morbidity in the AA population.

Mr. Jones explained that AAWG formed three subgroups to fulfill its charge, but the entire AAWG identified several key issues for action. Emphasis should continue to be placed on the contribution of social status and stigma to TB. These factors include (1) educational impacts on TB health literacy and disparities; (2) epidemiological impacts of segregation, unstable housing, poverty, employment and other aspects of socioeconomic status; (3) the impact of incarceration on TB in AA communities; and (4) the impact of key social institutions, such as churches, neighborhood associations, barbershops and beauty salons, on TB prevention and control in AA communities.

A number of factors that result in poor outcomes for AAs with TB should be acknowledged, such as stage of diagnosis, social and environmental issues, competing financial needs, distrust of the medical establishment, and the role of diabetes, hepatitis, substance abuse, HIV/AIDS and other chronic or co-morbid conditions. Government funding should be allocated to implement community-based interventions and strengthen partnerships with TB control programs that address TB in AA communities. However, challenges in implementing targeted outreach and prevention activities should be considered.

Mr. Jones summarized recommendations by the "Research Subgroup." AAWG's key issues for action should be reviewed for clarification and feasibility. Resources should be allocated to DTBE to develop an annual report and a blueprint to guide strategic efforts. DTBE should present the annual report to ACET with a summary of the status, activities and successes related to TB in the AA community and a description of efforts to measure progress in this area. The annual report also should include policy recommendations within a proposed blueprint to guide funding allocations, infrastructure development, training and outreach efforts. The target date of the report should be August 2008.

Mr. Jones summarized recommendations by the "Community Awareness and Outreach Subgroup." Culturally appropriate standards of care should be created and promoted with input from targeted medical providers in AA communities with high TB incidence. Primary care and

public health systems should be used in this effort. Social workers, health educators, nutritionists, outreach workers and other social service agency personnel should be reimbursed for participating in TB outreach activities.

Councils or advisory boards should be established in states with the highest TB rates among AAs, particularly in the Southeastern part of the country. Members of these groups should reflect health and social issues of the community and attempt to achieve three key goals. Community awareness of critical healthcare issues should be raised by increasing the number of AA communities that are targeted for TB awareness, enhancing knowledge about TB among prospective clients, and offering strategies to access care. Public/private partnerships should be established to address multiple needs of at-risk AA TB patients and reduce overlapping services. Community and faith-based organizations and leaders should be engaged as gatekeepers to the AA community.

Television and radio commercials on TB and HIV disparities among AAs should be created. The “asthma bus” should be used as a model to solicit funding for a “TB bus” to augment awareness about TB disparities in the AA community. TB awareness efforts should be incorporated into the “Take Your Loved One to the Doctor” campaign. AA celebrities who can become the face for TB awareness in the AA community should be recruited, such as Tom Joyner and Sugar Ray Leonard whose father died of TB. Dr. Helena Gayle, of the Gates Foundation, should be contacted to discuss potential collaborations on TB disparities in the AA community. HIV should be used as a “hook” in this effort.

Mr. Jones summarized recommendations by the “Protocols and Guidelines Subgroup.” Opportunities for training and dissemination of information to AA providers should be maximized. For example, the National Medical Association’s convention in July 2008 could be used to display a TB booth, distribute TB educational materials to each participant, and convene a workshop session on TB.

A toolkit should be developed for AA physicians, nurse practitioners, nurses, physician assistants, dentists, dental hygienists and other providers who care for AA patients. The toolkit should be developed in both print and electronic formats to highlight disparities and risk factors for AA patients. The toolkit should include CDC’s TB awareness materials for both patients and providers, such as patient-centric posters to be displayed in waiting rooms and examining rooms, patient fact sheets, information on TST and LTBI, referral criteria, and CDC’s TB diagnostic, screening and treatment algorithms for active TB disease and LTBI.

Mr. Jones acknowledged the outstanding efforts of the other AAWG members in formulating the recommendations. He conveyed that AAWG planned to place a formal motion on the floor during the business session for ACET’s vote.

Dr. Dean clarified that opportunities are available at three different levels for AAWG to advance its recommendations. At the division level, the Division of HIV/AIDS Prevention (DHAP) has completed most of the activities recommended by AAWG for HIV among AAs. DTBE and DHAP could collaborate in replicating these models for TB among AAs. At the center and coordinating center levels, DTBE could be used as a mechanism to advance AAWG’s

recommendations through its representation on both the NCHHSTP Health Disparities Workgroup and the CCID Health Disparities Council.

Several ACET members made suggestions for AAWG to consider in refining its guidance.

- AAWG should recommend additional funding and education for jails to perform prophylaxis with INH due to the high prevalence of TB and LTBI among incarcerated AAs.
- AAWG should recommend a partnership with the Congressional Black Caucus as an additional tool in community awareness and outreach.
- AAWG should consider collaborating with FBWG due to the similarities between culturally appropriate approaches for AA and foreign-born populations. Communication and coordination between the two groups would result in broader input and increased synergy.

Update on the ATS/IDSA Guidelines for Community-Acquired Pneumonia (CAP)

Dr. Michael Leonard, Jr., the ACET liaison to IDSA, recalled that several ACET members expressed concern during the previous meeting on the updated ATS/IDSA guidelines for the management of adults with CAP. ACET's major concern with the guidelines related to increased use of fluoroquinolones in treating CAP and the implications of this guidance for TB. The use of monotherapy fluoroquinolones has been shown to delay TB diagnosis and induce resistance after an extremely short course.

Dr. Leonard announced that he and three other physicians representing professional societies wrote a joint letter to IDSA and ATS to express these concerns. The letter by Dr. Leonard and the other physicians dated August 30, 2007 and IDSA's response dated October 10, 2007 were distributed to ACET for review. In its response, IDSA advised ATS, CDC and IDSA to emphasize the delay in TB diagnosis and increased drug resistance associated with fluoroquinolones in the joint statement on the diagnosis of TB the three groups are currently developing.

Dr. Leonard's position was that ATS and IDSA would not incorporate a black box warning into the guidelines or take further actions to address these concerns. He requested ACET's input on next steps in this effort. For example, a grassroots campaign could be launched in which professional societies would inform TB consultants about problems in using fluoroquinolones in treating CAP. Moreover, NTCA could be used as a mechanism to initiate a national effort of contacting medical consultants and local communities.

ACET recognized that responding to professional societies was outside its purview to advise the HHS Secretary and the CDC Director. However, several members made suggestions to widely publicize concerns related to the use of fluoroquinolones in treating CAP.

- A fact sheet should be developed as an attachment to the ATS/IDSA guidelines or an editorial in a peer-reviewed journal.
- Laboratory data published in the *MMWR* and anecdotal data of fluoroquinolone resistance in the community should be compiled and distributed to emphasize the importance of not using fluoroquinolones to treat CAP.
- The physicians should submit their letter to the peer-reviewed journals of ATS and IDSA to ensure that targeted communities are aware of concerns regarding fluoroquinolones in the treatment of CAP. ACET could endorse and issue a formal statement of support of the letter.

Update by the ACET BCG Workgroup (BCGWG)

Dr. Edward Nardell is an ACET Liaison member of the BCGWG. He reported on BCGWG's activities following the previous ACET meeting. BCGWG identified several problems to support the need to revisit CDC's BCG guidelines to specifically address the protection of U.S. students, trainees, researchers and HCWs in foreign settings who are at high risk for MDR-/XDR-TB. Transmission of MDR-/XDR-TB to visitors in high prevalence settings has been well publicized. Interest is growing in global health among U.S. undergraduate, graduate and medical students, residents, fellows, nurses and researchers.

Exposure to *M.tb* infection among immunologically naïve persons is increasing. Personal protection from respirators is important, but limited. Minimal or no infection control is available onsite. Students, residents, fellows or workers who travel abroad are at risk of MDR-/XDR-TB transmission. Although HIV, hepatitis and other diseases pose a risk, the airborne risk of MDR-/XDR-TB merits special focus in a guideline.

A number of interventions are available to address these problems. Education should be provided to increase awareness of risk and personal risk factors. Unnecessary or excessive exposure should be avoided. Pre-/post-travel TST or IGRA testing should be administered. Fit testing should be performed for respirator use. Infection control measures should be upgraded at local sites if possible. Suggested LTBI treatment should be given. BCG vaccination should be administered.

Several reasons support the rationale for BCG vaccination. Most U.S. students, residents and researchers are immunologically naïve about TB. Reliance cannot be placed on local infection control measures. Personal protection cannot be continuously used. The traditional argument that BCG vaccination will result in a loss of TST is no longer relevant with the emergence of IGRAs. No proven treatment is available for LTBI due to MDR-/XDR-TB. Treatment of active MDR-/XDR-TB is toxic and not uniformly successful.

ACET and CDC's Advisory Committee on Immunization Practices (ACIP) published a joint statement on BCG in the *MMWR* in 1996. A number of studies also have been conducted to demonstrate BCG efficacy. CDC sponsored a meta-analysis that estimated BCG protection at 50% with a range of 0%-80% depending on the setting. The study showed geographic

variability in BCG efficacy with most effectiveness outside tropical areas and in healthy populations. BCG efficacy was not found to correlate with an ability to produce a positive TST result. Because new vaccines are under development and most likely will not be available for many years, new data are not expected to be generated for some time.

The majority of evidence on BCG has focused on preventing disseminated disease in children. Limited data have been produced in adults, but the theory is that BCG should provide some protection through cell mediated immunity-mediated accelerated granuloma formation. The BCG mechanism is expected to be analogous to prior *M.tb* infection. However, BCG protection is incomplete because exogenous reinfection occurs even after previous *M.tb* infection. Solid evidence has been produced to demonstrate less TB among HCW contacts who were purified protein derivative-positive prior to exposure.

Data collected from Brazil suggested less MDR-TB transmission to BCG-vaccinated household contacts of MDR-TB cases. The cohort in the Brazil study included 64 culture-confirmed MDR-TB patients in Rio de Janeiro. TB disease developed in 17 of 218 previously healthy close contacts for a fairly high case rate of 1.6/100,000. Susceptibility patterns were identical to those of the index case in 46% of cases. Patterns of resistance were different in 31% of cases. Susceptibility to all drugs was seen in 23% of cases. Risk factors for TB among contacts included male gender, persons ≥ 15 years of age, non-white race, and previous BCG vaccination.

The TICE-BCG strain is only available in the United States and is administered percutaneously. Other manufacturers are unlikely to seek FDA approval due to the limited market. BCG has been widely used throughout the world and has resulted in the production of a wealth of data. Detailed reviews are available on BCG's adverse effects and uncommon local reactions at the site. However, the major concern with BCG has been dissemination in immunocompromised children. The use of BCG in children without HIV testing was previously controversial. HCWs were given pre-vaccination HIV counseling and testing.

BCG efficacy does not correlate with an ability to produce a positive TST result. TST is commonly used to establish a "take." The possibility of using pre-/post-TST vaccination to identify TST should be explored. The use of IGRAs to test for recent infection post-exposure independent of BCG should be considered as well. BCG vaccination is not readily available in the United States. The true availability of vaccine and administration kits should be determined. Capacity should be strengthened to administer BCG to persons traveling abroad. Personnel, university health services and TB clinics should be trained in BCG application.

Data should be gathered on BCG by developing a national registry to monitor its use and track adverse reactions. Formal follow-up of BCG recipients should be explored as well as persons who declined vaccination due to efficacy, acceptance or side effects. Data collection also should focus on relative rates of IGRA conversion and post-vaccination active TB.

Dr. Nardell concluded that BCGWG would present its proposed action items for ACET's formal consideration during the business session.

CDC announced that ACIP's Adult Immunization Workgroup has agreed to address BCG in the revision of the 1997 recommendations on HCW immunization. ACIP anticipates that completion of this effort will require at least one year and has expressed an interest in collaborating with ACET on revising and disseminating the recommendations.

ACET Business Session

Dr. Fleenor entertained a motion for ACET to approve the previous meeting minutes. A motion was properly placed on the floor and seconded by Mr. Jones and Dr. Fluck, respectively, for ACET to accept the previous minutes. ACET **unanimously approved** the July 10-11, 2007 Draft Meeting Minutes with no changes or further discussion.

Dr. Fleenor opened the floor for ACET members to propose recommendations or resolutions that should be considered for formal action.

Issue 1. Dr. Leonard acknowledged the difficulty in ACET formulating guidance to ATS and IDSA on the use of fluoroquinolones in TB due to its charter to advise the HHS Secretary and CDC Director rather than professional societies. Dr. Leonard and other physicians who wrote a letter to ATS and IDSA would continue their grassroots efforts to educate physicians about the use of fluoroquinolones and subsequent problems associated with TB. The physicians would use NTCA and the American Medical Association as mechanisms in the grassroots efforts.

The following motion was properly placed on the floor and seconded by Drs. Seaworth and Fluck, respectively. ACET should advise CDC to gather data on single drug treatment of TB and publish these cases in the *MMWR*. A commentary on the dangers of this approach should accompany the publication.

Several ACET members made suggestions to amend the motion. The article should be submitted for publication to peer-reviewed journals that target primary care physicians in addition to the *MMWR*. The content of the article should describe the frequency of fluoroquinolone resistance at the national level. The following information should be published in the *MMWR*: (1) a case report of a recent occurrence of fluoroquinolone resistant-TB in the context of TBTC Study 28; (2) data from other studies; (3) and an editorial to raise concerns about the use of fluoroquinolones for CAP as a first-line drug and also to advise persons to consider using alternatives to this regimen.

ACET **unanimously approved** the original motion with no further discussion.

Issue 2. The following motion was properly placed on the floor and seconded by Dr. Lopez-De Fede and Mr. Jones, respectively:

Whereas, the ACET African American TB Workgroup has made a series of recommendations to address TB disparities in the AA community, the Workgroup recommends that ACET endorse its recommendations by requesting the following:

(1) DTBE should endorse the elimination of TB in the AA community as a priority across all units of the division.

(2) DTBE should commit to the development of a strategic plan with the allocation of resources, personnel and funding, targeted objectives, and measurable outcomes that address the recommendations of the Workgroup.

(3) DTBE should report on the development on such a strategic plan with implementation strategies, a timeline and its linkages to the work of NCHHSTP's initiatives addressing health disparities in the AA community at the March 2008 ACET meeting.

ACET **unanimously approved** the motion with no further discussion.

Issue 3. The following motion was properly placed on the floor and seconded by Drs. Fluck and Seaworth, respectively:

(1) CDC should perform or commission a systematic review of the literature on BCG efficacy, specifically the ability of BCG to protect adults.

(2) CDC should update recommendations on the use of BCG in conjunction with ACIP.

(3) CDC should develop guidance on the indications, contraindications, procurement, and side effects management for this indication.

(4) CDC should attempt to monitor the use of BCG for this indication, its safety and possible efficacy, including biomarkers if they correlate with protective immunity.

(5) CDC should focus on and gather more information on the efficacy of the TICE-BCG strain that is available in the United States.

ACET extensively discussed the motion, but was unable to reach consensus on all six components. ACET **withdrew** the motion.

The following motion was properly placed on the floor and seconded by Drs. Seaworth and Flood, respectively. CDC should update recommendations regarding the use of BCG, specifically for healthcare workers traveling to countries and working in settings with a high risk of MDR-TB or XDR-TB. This update should include a review of the recent literature.

ACET **unanimously approved** the motion with no further discussion.

Issue 4. The following motion was properly placed on the floor and seconded by Drs. Fleenor and Fluck, respectively:

Whereas, education about TB is an important component to TB control and elimination to build competence and also to providers to recognize and successfully treat TB, ACET recommends:

- (1) an ongoing comprehensive review of professional and community educational activities related to TB, including activities of RTMCCs and NTCC, and to retain and fund best practices;
- (2) greater efforts to explore opportunities to expand beyond the current scope of educational outreach to clinicians to include policymakers, TB controllers and the community;
- (3) identification of priority audiences for TB educational activities that are directed to reducing infection and disease in the highest prevalence populations (e.g., African American and foreign-born groups);
- (4) assurance of continued focus on educational product development that includes easily accessible web-based modalities along with written or other recorded information;
- (5) funding priority to programs that most completely address trends in TB in various risk groups; and
- (6) incorporation of an evaluation of program successes in any funding of said programs.

ACET **passed the motion by a majority vote** with no further discussion.

ACET agreed that TB education efforts should be coordinated among CDC, NIH and other groups involved in education.

Other Issues. Dr. Barbara Seaworth should represent ACET on the Transnational TB Continuity of Care Workgroup. **[Unanimously approved]**

CDC should evaluate a sample of key state and local statutory, regulatory and subsequent case laws on TB to develop model legislation based on these findings. **[Unanimously approved]**

ACET should comment on the proposed Stop TB USA Plan for the Elimination of TB. Mr. Shannon Jones should represent ACET on workgroups that will be established to write and review the updated TB elimination plan. **[General agreement]**

The BSC should address laboratory issues as its theme during the next meeting in May 2008. **[General agreement]**

ACET should designate members to participate in laboratory and program reviews of DGMQ's evaluation of the Philippine TB program. Drs. Charles Nolan and Sarah Royce have already expressed an interest in participating in this activity. ACET members with an interest in serving on the laboratory and programs reviews should contact Dr. Castro. **[General agreement]**

Dr. Fleenor led ACET in a review of future agenda items that were raised over the course of the meeting.

- Status report on ACET's previous correspondence with the HHS Secretary.

- Update by Dr. Castro on the GAO study on the interagency response to the MDR-/XDR-TB cases.
- Update on the second part of the TB budget redistribution plan in the context of FY'08 funding.
- Update on the TB funding formula.
- Update on steps to improve laboratory capacity in the United States.
- Update on nucleic acid amplification test laboratory guidelines.
- Presentation on a community/federal government collaborative model of optimizing the role of the community in TB elimination.
- Update on Mexican Border security and new healthcare facility issues.
- Update on drug resistance surveillance in Mexico and CDC's implementation report.
- Update on TB education in medical and nursing schools.
- Progress report on developing a TB Healthcare Effectiveness Data and Information Set indicator.
- Presentation by Dr. Paul Farmer on TB control in Haiti.
- Update by FDA on new TB nucleic acid diagnostics and guidelines.
- Update on the revised TB testing policy in New York City jails.
- Update on CDC's accreditation efforts and their effects on TB control.
- Update on mandatory DOT in health departments.
- Presentation by Dr. Gary Simpson on national TB isolates and genomics archives.
- Update on NCHHSTP's PCSI initiative.
- Progress report by DTBE on its strategic planning initiative.
- Presentation by DTBE on trends and challenges of TB incidence in urban metropolitan cities, including a clear definition of minimal staffing standards for local TB programs.

Closing Session

The next ACET meeting would be held on March 26-27, 2008. With no further discussion or business brought before ACET, Dr. Fleenor adjourned the meeting at 1:15 p.m. on November 28, 2007.

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

Date

Michael E. Fleenor, M.D., M.P.H.
Chair, Advisory Council for the
Elimination of Tuberculosis