

**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  
March 26-27, 2008  
Atlanta, Georgia**

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**Record of the Proceedings**

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## ATTACHMENT 1

### List of Participants

#### ACET Members

Dr. Michael Fleenor, Chair  
Dr. Jennifer Flood  
Dr. Richard Fluck  
Mr. Joseph Kinney  
Dr. Masahiro Narita  
Dr. Barbara Seaworth  
Ms. Sirlura Taylor

#### Designated Federal Official

Dr. Kenneth Castro,  
Executive Secretary

#### Ex-Officio and Liaison Members

Dr. Naomi Aronson  
(Department of Defense)  
Dr. William Baine (Agency for Healthcare  
Research and Quality)  
Dr. Amy Bloom (U.S. Agency for  
International Development)  
Mr. Jim Cobb (National Tuberculosis  
Controllers Association)  
Dr. Richard Ehrenberg (National Institute  
for Occupational Safety and Health)  
Dr. Fred Gordin  
(American Thoracic Society)  
Dr. Michael Leonard, Jr. (Infectious  
Disease Society of America)  
Dr. Edward Nardell  
(International Union Against  
Tuberculosis and Lung Disease)  
Dr. Lee Reichman (American College of  
Chest Physicians)  
Dr. Gary Roselle  
(Department of Veteran Affairs)  
Dr. Diana Schneider (Department of  
Homeland Security)  
Dr. Litjen Tan  
(American Medical Association)  
Dr. Theresa Watkins-Bryant  
(Health Resources and  
Services Administration)

#### CDC Representatives

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Greg Andrews  
Francisco Averhoff  
Sarita Chattinger  
Ann Cronin  
Hazel Dean  
Heather Duncan  
Teresa Durden  
Judy Gibson  
Richard Goodman  
Natalie Hundley (CDC Contractor)  
Kashef Ijaz  
Paul Jensen  
John Jereb  
Dolly Katz  
Curi Kim  
Ann Lanner  
Phil LoBue  
Harriette Lynch  
Suzanne Marks  
Sundari Mase  
Michael Melneck  
Thomas Navin  
Eric Pevzner  
Drew Posey  
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Thomas Shinnick  
Wanda Walton  
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Laurina Williams

#### Guest Presenters and Members of the Public

Phil Griffin (National Tuberculosis  
Controllers Association)  
Carol Pozsik (National Tuberculosis  
Controllers Association)  
Lewis Radonovich  
(Department of Veterans Affairs)  
Randall Reves  
(Denver Public Health Department)  
Max Salfinger (Florida Department of  
Health)  
John Seggerson (Stop TB USA)

## 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
AFB	— Acid Fast Bacilli
APHL	— Association of Public Health Laboratories
BSC	— Board of Scientific Counselors
CCID	— Coordinating Center for Infectious Diseases
CDC	— Centers for Disease Control and Prevention
CDPH	— California Department of Public Health
CS	— Civil Surgeons
CSTE	— Council of State and Territorial Epidemiologists
CXR	— Chest X-Ray
DGMQ	— Division of Global Migration and Quarantine
DHS	— Department of Homeland Security
DNB	— Do Not Board
DOS	— Department of State
DOT	— Directly Observed Therapy
DST	— Drug Susceptibility Testing
DTBE	— Division of Tuberculosis Elimination
EDN	— Electronic Disease Notification
FBPs	— Foreign-Born Populations/Persons
FBWG	— Foreign-Born Workgroup
FDA	— Food and Drug Administration
FSWG	— Field Staff Workgroup
GLC	— Green Light Committee
HAART	— Highly-Active Antiretroviral Therapy
HCWs	— Healthcare Workers
HHS	— Department of Health and Human Services
HPGs	— Health Protection Goals
HRSA	— Health Resources and Services Administration
ICE	— U.S. Immigration and Customs Enforcement
IGRA	— Interferon Gamma Release Assay
IHRs	— International Health Regulations
IMP	— Immigrant and Migrant Populations
INH	— Isoniazid
IoM	— Institute of Medicine
IOM	— International Organization for Migration
IT	— Information Technology
IUATLD	— International Union Against Tuberculosis and Lung Disease
LTBI	— Latent TB Infection
MDR-TB	— Multi-Drug Resistant TB
MMWR	— <i>Morbidity and Mortality Weekly Report</i>

MSAs	— Metropolitan Statistical Areas
<i>M.tb</i>	— <i>Mycobacterium Tuberculosis</i>
MTD	— <i>M.tb</i> Direct Test
NAAT	— Nucleic Acid Amplification Test
NACCHO	— National Association of County and City Health Officials
NCET	— National Coalition for the Elimination of Tuberculosis
NCHHSTP	— National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
NTCA	— National Tuberculosis Controllers Association
NTIP	— National TB Indicators Project
NTP	— National TB Program (Mexico)
NTSS	— National TB Surveillance System
QFT-G	— QuantiFERON-Gold
OD	— Office of the Director (CDC)
PCR	— Polymerase Chain Reaction
PCSI	— Program Collaboration and Service Integration
PHAs	— Public Health Advisors
RIF	— Rifampin
RTMCCs	— Regional Training and Medical Consultation Centers
SLDs	— Second-Line Drugs
TBESC	— TB Epidemiologic Studies Consortium
TBTC	— TB Trials Consortium
TEP	— TB Elimination Plan
TIs	— Technical Instructions
TST	— Tuberculin Skin Test
USCIS	— U.S. Customs and Immigration Services
WHO	— World Health Organization
XDR-TB	— Extensively Drug-Resistant TB

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**ADVISORY COUNCIL FOR THE ELIMINATION OF TUBERCULOSIS  
March 26-27, 2008  
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 March 26-27, 2008 in Building 8 of 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 8:30 a.m. on March 26, 2008. 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.

**NCHHSTP Director's Report**

Dr. Kevin Fenton covered the following areas in his update. Dr. Julie Gerberding, Director of CDC, testified on February 27, 2008 before the House Committee on Foreign Affairs and the Subcommittee on Africa and Global Health. Her testimony served as CDC's response to drug-resistant TB both globally and in the United States.

Dr. Gerberding emphasized a number of key points during her Congressional testimony. TB control in high-burden HIV settings is important. New tools for TB prevention, treatment and diagnosis are needed. Partners in the TB community need to closely collaborate. TB training and sustained support are needed both in the United States and abroad.

Dr. Gerberding also testified on March 5, 2008 before the House Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies. Her testimony focused on health protection and the role of public health in the health system transformation. Dr. Gerberding provided several examples of CDC's achievements in key health protection goal areas during her Congressional testimony.

Dr. Fenton reminded ACET that CDC developed a set of four overarching health protection goals (HPGs): (1) "Healthy People in Every Stage of Life;" (2) "Healthy People in Healthy Places;" (3) "People Prepared for Emerging Health Threats; and (4) "Healthy People in a Healthy World." The HPGs serve as cross-cutting and cross-agency strategic priorities; provide a framework for achieving health protection and health equity; and will inform CDC's activities and priorities at agency, center and division levels. The HPGs also will help CDC to achieve its mission "to promote health and quality of life by preventing and controlling disease, injury and disability."

CDC is now reviewing Goal Action Plans that were developed to introduce key focus areas for public health action, describe the current disease burden, highlight CDC's response and achievements to date, and provide recommendations to maximize health impact. In FY'08, all CDC coordinating centers, centers and divisions will be asked to perform portfolio reviews to critically assess various programs and projects and align these efforts and resources with the HPGs.

CDC will use the portfolio review process as a mechanism to provide partners and stakeholders with a better understanding of health-related activities and investments across the agency. CDC is undertaking this effort to transition from its traditional disease-oriented focus to a broader focus on healthy populations and places. CDC is currently developing methodologies to ensure that the portfolio review process is conducted in a consistent and efficient manner. The HPGs are available for review on CDC's web site.

Dr. Fenton announced that the CDC Office of the Director (OD) was reorganized to reduce its budget by at least 15%; eliminate the Office of Chief of Staff; appoint an Associate Director for Management; and relocate some OD staff to program offices they support. Only essential vacancies will be filled in CDC OD.

Dr. Fenton described two key documents that NCHHSTP recently developed. The "NCHHSTP FY'07 Annual Business Report" will be released in April 2008. The overarching goal of the report is for NCHHSTP to be more transparent and accountable to partners and the general public by widely publicizing its activities, investments and performance. The report highlights NCHHSTP's key accomplishments, budget items, priorities, and performance indicators for disease trends, quality of services and organizational excellence. The report is available for review on the NCHHSTP web site.

The “Program Collaboration and Service Integration (PCSI) Consultation Report” is a compilation of key recommendations that were made during the PCSI consultation in August 2007 with >100 partners and CDC staff. The consultation was held for NCHHSTP to obtain guidance on its PCSI strategy over the next five years. The report is available for review on the CDC web site.

Dr. Fenton summarized a number of activities that NCHHSTP will prioritize in FY’08. Several documents will be published, including (1) a PCSI policy paper and research priorities; (2) an integrated surveillance report and guidelines; and (3) a green research paper on using a social determinants framework to accelerate the reduction of infectious disease health disparities. NCHHSTP will widely disseminate the publications for public comment by ACET and other advisory committees, state and local health departments, and other partners.

A national mobilization effort on PCSI will be developed and launched. Meta-leadership for prevention across federal agencies will be heightened. External communications with partners will be strengthened. All of the divisions will continue joint efforts to complete the “NCHHSTP 2020 Strategic Plan” and explore strategies to meet upcoming challenges related to prevention services over the next five to ten years. Opportunities will be identified to strengthen strategic partnerships to accelerate prevention.

Dr. Fenton will continue his PCSI site visits to TB, HIV, STD and viral hepatitis programs in the rural United States, territories and other jurisdictions to explore opportunities to enhance health protection and maximize programmatic investments. His upcoming PCSI site visits include programs in Arizona and New Mexico in April 2008 in partnership with the Indian Health Service; the Navajo and Tohono O’Odham Nations as well as state and local programs; and programs in the rural Southeast to focus on PCSI implementation.

Dr. Fenton reminded ACET that NCHHSTP established eight cross-cutting workgroups to collaborate more effectively across divisions with a holistic approach. The workgroups are focusing on surveillance and strategic information, program integration, health measurement, health disparities, men who have sex with men, drug users, global perinatal issues, and corrections. NCHHSTP recently completed a first-year review of six of the workgroups and concluded that the workgroups have added tremendous value to both existing and new activities. NCHHSTP will use the workgroups to develop integrated guidelines and policy papers on the eight focus areas.

Dr. Fenton was pleased to announce that two senior staff positions were filled after the previous ACET meeting. Dr. Hazel Dean is the new NCHHSTP Deputy Director and Dr. Sal Butera is the new Associate Director for Laboratory Sciences. Efforts are underway to advertise both internally and externally to fill the position of the Associate Director for Health Disparities. Dr. Fenton encouraged ACET to provide him with names of potential candidates.

Dr. Fenton conveyed that the “2<sup>nd</sup> Annual TB Walk” was held in Atlanta on March 22, 2008 in recognition of World TB Day with >600 participants. The National Tuberculosis Controllers Association (NTCA) and other partners sponsored, organized and planned the event and played

a critical role in its success. The Annual TB Walk will continue to add tremendous value to CDC's TB prevention efforts.

ACET expressed concern regarding the dismal TB budget. The members were disheartened that CDC's FY'08 budget did not include a significant increase in TB funding, particularly in light of unprecedented opportunities to develop new drugs and short-course regimens; the tremendous disparity between budgets for TB research and smallpox, anthrax and other diseases; and the current burden of multidrug-resistant and extensively drug-resistant (MDR-/XDR-TB) globally.

ACET advised NCHHSTP to include "information technology (IT) support" as an additional priority in FY'08 due to the national shift to use electronic health records and other technologies to enhance disease reporting. The members noted that this effort would be extremely important to assist states with limited IT capacity, expertise and resources to refine and overhaul existing data systems, incorporate new technologies, and more effectively report and manage cases in the future. The members also emphasized the need for information to be provided to physicians in real time to properly manage patients with XDR-TB.

In response to ACET's first comment, Dr. Fenton understood their concern that CDC's FY'08 budget did not include a robust increase in TB funding. However, he confirmed that DTBE is currently exploring strategies to apply the small increase in TB funding to maximize impact and focus on key priorities. He noted that Dr. Castro would provide more details on the TB budget during his update.

In response to ACET's second comment, Dr. Fenton explained that IT is a priority at all levels throughout CDC. At the agency level, Dr. Gerberding has commissioned a number of workgroups and leadership groups to specifically focus on the future of surveillance and strategic information. At the center level, NCHHSTP is identifying approaches to leverage IT to more effectively and efficiently provide preventive services over the next five to ten years.

At the coordinating center level, the Coordinating Center for Infectious Disease (CCID) has acknowledged that CDC is not keeping pace with technological advances to improve the characterization and management of infectious disease epidemics. The CCID Board of Scientific Counselors (BSC) is in the process of formulating guidance to CDC on strategic information issues, including IT development and infrastructure as well as the critical need for stronger investments in this area.

CCID has invited colleagues across CDC to meet with infectious disease leaders to discuss effective strategies to advance IT. Dr. Fenton advised the meeting planners to include this topic as a CDC presentation and ACET discussion during the next meeting. The agenda item should cover CCID's investments to strengthen the IT and strategic information infrastructure for infectious diseases.

Dr. Castro added that after CDC retires the TB Information Management System, states would have at least four different IT options, including commercially available software. He agreed with Dr. Fenton's suggestion to devote a considerable amount of time during the next meeting to

CDC's ongoing IT activities and investments. He also asked ACET to be prepared to provide guidance to CDC on this issue.

Dr. Fenton responded to two questions posed by the ACET members. In terms of ongoing efforts to forecast or mitigate PCSI costs to local and state TB programs, NCHHSTP is currently compiling studies and collecting cost data from the peer-reviewed literature on integration activities. NCHHSTP has no plans at this time to invest in any new projects or studies to demonstrate the cost burden or implications associated with PCSI because this initiative does not have a separate line item.

NCHHSTP will build on best practices that are currently being conducted across the country, such as California's recommendation for HIV testing of TB patients. NCHHSTP also will use the PCSI white paper to encourage programs to review existing guidance on integration and identify opportunities to improve performance on these recommendations.

With respect to current activities to address changes in CDC's leadership after the 2008 Presidential election, CDC is convening a series of seminars with leadership groups across the agencies to discuss issues related to the transition. This effort is focusing on (1) enhancing and institutionalizing organizational changes that have been implemented under Dr. Gerberding's leadership; (2) creating solid transition plans; (3) refining organizational structures; (4) strengthening budgets; and (5) training leaders in preparation of the transition.

The new Administration will have the most significant impact on Dr. Gerberding's position as the Director of CDC, but the transition process is not expected to result in further ramifications across CDC at the center and division levels.

### **DTBE Director's Report**

Dr. Castro covered the following areas in his update. In 2007, DTBE and the White House Policy Coordinating Committee jointly explored the possibility of developing a "Presidential TB Initiative." The committee eventually decided against taking further action on this activity due to the absence of new resources. However, DTBE plans to renew this effort by emphasizing that TB is the only one of three diseases funded by the Global Fund without a Presidential Initiative.

Dr. Castro announced that DTBE convened senior management retreats in January and February 2008 to articulate and align its division goals to CDC's overarching agency goals. The retreats resulted in DTBE reaffirming (1) a domestic goal to eliminate TB in the United States to  $\leq 1$  case/million population and (2) a global goal to contribute to reductions in global incidence and mortality by 50% each.

The retreats also provided DTBE with an opportunity to identify five division-wide domestic and global priorities for 2008-2009: (1) interrupt transmission of *M. tuberculosis*; (2) reduce TB in foreign-born populations (FBPs); (3) reduce TB in racial/ethnic minority populations with a focus on African Americans (AAs); (4) mitigate or reduce the impact of MDR-/XDR-TB; and (5) reduce

HIV-associated TB, particularly in the context of President's Emergency Plan for AIDS Relief activities.

Dr. Castro explained that DTBE would be expected to continue to perform 12 core functions regardless of its priorities:

1. Surveillance, including drug susceptibility testing (DST) and periodic surveys.
2. Program support for case identification, contact investigations and completion of therapy, including preparedness and outbreak response and care and treatment in collaboration with Regional Training and Medical Consultation Centers (RTMCCs).
3. Program evaluation with the National TB Indicators Project (NTIP).
4. Laboratory diagnostic services and research support for outbreak investigations, programs and clinical research.
5. Applied research to develop and evaluate new tools and interventions for diagnosis, treatment and prevention and also to assist programs in conducting activities in a smarter and more efficient manner.
6. Data management, statistical and IT support in collaboration with internal CDC partners.
7. Provision of personnel salaries, travel, equipment and supplies.
8. Workforce and professional development and the development and evaluation of training and educational materials in collaboration with RTMCCs.
9. Web- and print-based education, risk and media communications.
10. Evidence-based policy development.
11. External expert consultation and advice from ACET, BSC and ad hoc groups.
12. Cultivation of relevant external partnerships and internal collaborations with CDC centers, institutes and offices.

Dr. Castro reported that the latest provisional data from World TB Day showed 13,293 persons were diagnosed with TB in 2007 for a case rate of 4.4%. The rate of decline slowed in a statistically significant manner from an annual percent change of 7.3% in 1993-2000 to 3.8% in 2000-2007. DTBE recently performed modeling to forecast the TB epidemic and evaluate the impact of various interventions. Key findings of the analysis are outlined below.

If the current rate of decline is maintained, 100 years would be required to reach the TB elimination goal. An 8.8% decline would be needed each year to reach the TB elimination goal by 2050. An increase from ~90% to ~95% in the proportion of persons who effectively and successfully completed treatment of TB disease would result in reaching the TB elimination goal 13 years earlier.

An increase from ~65% to ~90% in effectively and successfully treating a proportion of persons with latent TB infection (LTBI) would result in a 13-year gain in the elimination curve. By combining these two efforts, the TB elimination goal would be reached 22 years earlier. DTBE also modeled the impact of a new TB vaccine with efficacy and coverage rates of 75% and 90%. DTBE plans to use results of the analysis to justify the allocation of resources and demonstrate specific interventions that would have the most significant impact.

Dr. Castro explained that DTBE staff participated in a variety of activities to raise awareness about TB in support of World TB Day on March 24, 2008. An article was published in the *Morbidity and Mortality Weekly Report (MMWR)* to describe TB trends in the United States in 2007. Media interviews were given during site visits to the Pacific Island TB Controllers Association. World TB Day communication and education resources included a web page with links to resources; data, statistics and other features on the DTBE and CDC web sites; posters, an e-card and graphical web buttons; and the "CDC Connects" article. Additional information on World TB Day was included in the meeting packets for ACET to review.

Dr. Castro provided details on DTBE's FY'07 and FY'08 budgets. Congress appropriated ~\$143 million for TB in FY'08. With the Congressional rescission of 1.747% (or ~\$2.5 million), CDC actually received ~\$140 million. Prior to allocating funds to DTBE, CDC further reduced the appropriation of ~\$140 million by deducting expenses for individual learning accounts, PHS Evaluation transfers, Small Business Innovative Research, the Strategic Business Unit, and CCID's Strategic Science and Program Unit. The FY'08 TB budget does not include one-time funding of ~\$1.8 million that DTBE received from the Emerging Infectious Disease Program in FY'07 to initiate a response to XDR-TB.

For the FY'08 TB budget, DTBE was directed to pass on the Congressional rescission of ~\$2.5 million to all grantees and contractors. DTBE will use its existing system to evaluate new initiatives and proposals that could be supported with a modest amount of new funds. DTBE hopes this approach will assist in mitigating the impact of the Congressional rescission. Dr. Castro planned to update ACET on the TB budget during the next meeting.

Dr. Castro reviewed other developments that occurred in DTBE after the previous ACET meeting. An expert group that provides scientific advice to the TB Trials Consortium (TBTC) recently emphasized the need to present the TBTC research portfolio to ACET for comment and input. An inventory of DTBE-funded projects and other activities is currently being updated. DTBE will use the inventory to inform its portfolio management efforts and will distribute the document to ACET during the next meeting. Four senior public health advisors (PHAs) were relocated to fill various positions in DTBE.

The ACET members made several suggestions for DTBE to consider in its ongoing efforts to conduct, support and provide leadership for TB elimination activities.

- DTBE should provide leadership in expanding the current focus to accelerate the decline. In addition to new TB tools, emphasis also should be placed on stronger capacity and optimal use of new tools to minimize drug resistance and enhanced ability to rapidly apply new tools to program practice. DTBE should include this language in program announcements and require TB grantees to target cooperative agreement dollars to address these issues over time with effective and evidence-based interventions.
- DTBE should collect more solid data and revise its models to systematically capture TB patients who are not regularly counted in data systems, such as persons who present to local and state programs for treatment and do not meet the case definition of “incident TB.”
- DTBE should strongly endorse the concept of regionalizing TB reference laboratories and specialized care centers throughout the country. DTBE should widely vet this initiative through ACET, NTCA and other partners. This effort will be a critical step for states to increase access to laboratories and new tools.
- DTBE should invite Drs. James Kim or Michael Porter to a future ACET meeting to discuss the actual science involved with effectively implementing new TB tools.
- DTBE should provide leadership in emphasizing the critical need for infection control with new TB tools in addition to diagnosis and treatment. This focus will be particularly important to the global response to drug-resistant TB.

#### **Update by the DTBE Field Services and Evaluation Branch (FSEB)**

Dr. Kashaf Ijaz, Chief of FSEB, provided an update on FSEB’s strategic direction. The vision statement of FSEB is to have no new transmission of TB in the United States. FSEB’s organizational structure includes two Field Operations Teams, a Program Evaluation Team, and a Medical Consultation Team.

FSEB is responsible for facilitating the management of most core program activities and managing TB cooperative agreement funds to 68 programs in all 50 states, the District of Columbia and nine other cities, and U.S. territories and commonwealths. FSEB’s ten program consultants provide technical assistance to state and local TB programs. PHAs are temporarily assigned to offer technical and program support. Supplemental funds are awarded to programs whenever possible to support outbreaks and provide follow-up to Epi-Aids.

Since September 2007, FSEB has held a series of strategic planning retreats with the Field Staff Workgroup (FSWG), Program Evaluation Team and program consultants. Additional retreats are planned with medical officers and PHAs in the field in April-May 2008. To inform the strategic planning retreats, FSEB administered questionnaires and convened meetings either in person or by telephone with the branch staff both at headquarters and in the field.

The TB controllers emphasized the need for FSEB to enhance communications by convening monthly conference calls with the FSWG and medical officers in the field; distributing DTBE staff meeting minutes to the field; and providing regular updates to them. In response to another recommendation made by the program consultants, FSEB developed an algorithm for site visits conducted by to program consultants. FSEB will also collaborate with the Mycobacteriology Laboratory Branch to conduct joint site visits.

Dr. Ijaz provided descriptions of FSEB's key components. The FSWG is represented by PHAs in the field and serves as a conduit to enhance communications among DTBE, its branches and ~50 field staff. The FSWG held a retreat in September 2007 to establish criteria for field assignments, including infrastructure, active TB transmission or morbidity, the need for TB control capacity building, career development and training, and issues that are critical to DTBE's mission. During the retreat, the FSWG also developed a strategy to sustain PHA assignments at different position levels; reviewed the site visit algorithm; explored approaches to increase the benefit and value of year-end PHA reports; and discussed temporary duty assignments to efficiently deploy PHAs during or after an outbreak.

The mission of the FSEB TB program consultants is to collaborate with state and local TB control programs to provide TB programmatic expertise, guidance and leadership and optimize TB prevention, control and elimination efforts in the United States. A retreat was held with the program consultants in January 2008. During the retreat, the program consultants established priorities, specifically discussed NTIP, explored strategies to incorporate TB genotyping into program practice, and provided suggestions on the FY'10 redistribution formula.

The mission of the Program Evaluation Team is to provide guidance and expertise to TB programs and DTBE in developing and implementing evaluation activities for maximizing effectiveness. A retreat was held with the team in February 2008 and the same issues were covered as those during the program consultants' retreat. However, the team also discussed the ongoing evaluation of regionalization projects to obtain best practices and lessons learned and explored approaches to improve aggregated reports for program effectiveness.

Dr. Ijaz highlighted FSEB's major partnerships. FSEB has established several collaborations across DTBE's branches to participate in various activities, including an RTMCC Team, NTIP, outbreak detection and response, and the binational project. In terms of collaborations with NCHHSTP, FSEB has been actively participating in the PCSI initiative to support DTBE's priority of TB/HIV activities. FSEB plans to conduct joint site visits and release joint program announcements in collaboration with other NCHHSTP divisions.

FSEB collaborates with TB controllers by convening regular conference calls with NTCA, obtaining external guidance from ACET, consulting with the RTMCCs, and is currently participating on two joint DTBE/NTCA workgroups. The TB Cooperative Agreement Formula Workgroup is comprised of representatives from states with high, medium and low TB incidence, large cities, laboratories and all DTBE branches. The workgroup is currently reviewing the TB redistribution formula, analyzing various weights and variables, and will

recommend modifications, deletions or other revisions for the FY'10 funding allocations or the entire formula.

The workgroup is exploring the possibility of revising the redistribution formula based on changing TB Epidemiology. The formula variables should be justified and measurable based on data reported to DTBE via surveillance systems. The workgroup plans to complete the review and submit a draft to the CDC clearance process by October 2008 in preparation of the FY'10 program announcement.

The TB Public Health Laws Workgroup is currently reviewing express TB control laws of states to implement a scenario-based assessment of the understanding and sufficiency of TB control laws. The workgroup will develop a model act on state and local TB control and produce a *TB Control Law Handbook*.

Dr. Ijaz announced that a summit would be held on April 2-4, 2008 to evaluate the future role of RTMCCs in six key areas:

- Identifying and addressing changing needs for medical consultation and training and developing strategies to best meet these needs.
- Developing new education and training products based on CDC guidelines and scientific research.
- Translating research findings into operational practice.
- Assisting TB programs to build human resource capacity at both state and local levels.
- Collaborating with other organizations and training centers to enhance PCSI in delivering medical consultation and training.
- Providing direct patient management and consultation.

ACET commended FSEB on its outstanding efforts to collaborate and regularly communicate with TB controllers through NTCA. However, some members emphasized the critical need for FSEB to streamline the process of reassigning PHAs to fill vacancies in Miami, Florida and other large cities.

In terms of the TB redistribution formula, ACET advised FSEB to include epidemiologic factors in its review and exclude previous political decisions if these issues are not relevant in the current environment. ACET also recommended that FSEB establish partnerships with the Health Resources and Services Administration (HRSA) Area Health Education Centers because many of these facilities are located in medical centers.

In response to ACET's question regarding linkages between the RTMCCs and other training bodies, Dr. Ijaz explained that TB is not included in the activities of HRSA's four training centers. However, the RTMCCs have started to attend meetings of the HRSA training centers to emphasize the need to incorporate a TB focus. Moreover, representatives of HRSA training centers will be invited to attend the upcoming RTMCC Summit. Another external consultation will be held later in 2008 to discuss collaborative efforts among TB, STD and HIV/AIDS centers of excellence or training centers.

Dr. Fleenor confirmed that ACET would have an extensive discussion during its next meeting on revisions to the TB redistribution formula.

### Update on Stop TB USA Activities

Dr. Randall Reves is the Medical Director of the TB Control Program at the Denver Public Health Department. He provided an update on Stop TB USA activities. The TB Elimination Plan (TEP) Workgroup has continued to meet on a regular basis with representation by ACET, CDC, NTCA and other groups to revise the TEP. The International Union Against Tuberculosis and Lung Disease (IUATLD) North America Region held a meeting in February 2008 to launch Stop TB USA in collaboration with partners from the United States, Canada, Mexico and the Global Stop TB Partnership.

The TEP Workgroup was charged with conducting three key activities: (1) review progress toward meeting the national TB elimination goal in the United States as recommended by the Institute of Medicine (IoM) in 2000; (2) identify barriers to meeting the TB elimination goal; and (3) determine specific action steps to achieve TB elimination in the United States.

The TEP Workgroup held a retreat in August 2007 to present a draft of the updated TEP for the United States, including specific recommendations to achieve goals and leverage support from partners. The retreat resulted in the establishment of a Plan Workgroup to update the TEP and a Launch Workgroup to launch both the TEP and Stop TB USA.

Dr. Reves outlined key suggestions that were made during the retreat. On the one hand, the TEP Workgroup noted that the updated TEP should not be designed as a detailed scientific document; a lengthy reference document for public health use; or a replication of previous well-written plans, such as ACET's 1989 and 1999 recommendations, the IoM *Ending Neglect* report in 2000 or the 2005 report on TB control in the United States.

On the other hand, the TEP Workgroup acknowledged that the updated TEP should include a revised timeline because the 2010 goal would not be achieved. A new timeline of 2025 was proposed. The TEP Workgroup also pointed out that the updated TEP should be based on recommendations in prior plans; reviewed, supported and valued by necessary partners; linked to the Global Stop TB Partnership; and supplemented with cost estimates for implementing specific recommendations.

Dr. Reves summarized the history and current status of the TEP. The TEP Workgroup approved the charge to the writing group and the outline for the updated TEP in January 2008. Additional writers, consultants and reviewers were also identified in January 2008 to develop four sections of the outline. A draft of the "Overview" section was submitted to the TEP Workgroup in February 2008. Writers for other sections of the updated TEP are continuing to meet by conference call.

The overview section raises a number of key points to provide a rationale to update the TEP. The goal of 300 reported TB cases/year (or 1 case/1 million population) cannot be achieved by 2010. More than 70 years would be needed to eliminate TB with an annual decrease of 3.8%. The global impact of TB/HIV drug resistance has become more significant over time. Recent data show that LTBI prevalence is 19% in FBPs and 1.8% in U.S.-born populations.

Current studies indicate that LTBI treatment is limited, even in public health settings. New tools have been developed, but capacity is not sufficient at this time to implement these technologies. Awareness of TB elimination is lacking among policymakers and the public. Funding and resources have decreased to accomplish mobilization for TB elimination.

Writers and CDC consultants are developing sections to address the following issues in the updated TEP: background and overall progress, TB in U.S.-born populations, TB in FBPs, TB in low-incidence areas, and TB partners. Each section of the updated TEP will describe progress, barriers and recommendations both in general terms and for specific populations. Partners that should be engaged in implementing the TEP will be identified as well.

The TEP Workgroup expects to complete the updated TEP by May 31, 2008 and present the document during an upcoming NTCA conference. To achieve this goal, the TEP Workgroup will use the concise and frank overview as a road map for the other sections. Moreover, the TEP Workgroup has sustained its energy and is continuing to meet challenges of other commitments. A consultation will be held for the TEP Workgroup to receive input from partners that will play a critical role in implementation. The Launch Workgroup has been extensively engaged in these efforts.

Dr. Reves reported on the North America Stop TB USA meeting that was held in February 2008. The key discussion topics included the transition from the National Coalition for the Elimination of Tuberculosis (NCET) to Stop TB USA; the Global Stop TB Partnership; Stop TB activities in Canada and Mexico; advocacy, communication and social mobilization efforts; the timeline and activities of the TEP Workgroup; and strategies to launch the updated TEP. Presentations from the meeting are available for review on the British Columbia Lung Association web site.

Dr. Reves concluded his presentation by requesting ACET's input on four key issues: (1) the progress and focus on updating the TEP; (2) potential reviewers for the updated TEP, particularly partners that will be critical to implementation; (3) future activities of the Launch Workgroup; and (4) the venue for presenting the updated TEP. He clarified that ACET's feedback on item 2 is a critical need for the TEP Workgroup at this time, but guidance on the other three issues could be given at a later date.

Dr. Fleenor confirmed that ACET would have a more detailed discussion on potential reviewers for the updated TEP on the following day. In the interim, the ACET members made a number of suggestions for the TEP Workgroup to consider in its ongoing efforts to update the TEP.

- The TEP Workgroup should expand its charge of "identifying barriers to meet the TB elimination goal" to include "interrupting TB transmission," particularly since DTBE has incorporated this issue into its vision statement.

- The TEP Workgroup should engage more community-based organizations that specifically focus on TB to ensure wider endorsement of the updated TEP.
- DTBE should invite Dr. Marcos Espinal to the next ACET meeting to make a presentation on the Global Stop TB Partnership and suggest strategies to establish and maintain an ongoing dialogue with ACET in implementing the updated TEP.
- The TEP Workgroup should outreach to the Gates Foundation to leverage funding for implementation of the updated TEP because this organization is extensively involved in global TB and other advocacy efforts.

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

Dr. Drew Posey, of DGMQ, announced that Dr. Greg Armstrong, formerly the Asia/Europe Team Leader in the Immigrant, Refugee, and Migrant Health Branch, has accepted the position of Epidemiology Branch Chief in the Division of Viral Diseases at CDC. Dr. John Painter is the new Asia/Europe Team Leader. DGMQ is currently implementing a new screening algorithm overseas for U.S.-bound immigrants and refugees. The new algorithm includes requirements for *Mycobacterium tuberculosis* (*M.tb*) cultures, DST, and directly-observed therapy (DOT) based on U.S. standards for persons identified with TB disease.

An article that was published in the *MMWR* on March 21, 2008 contained a “Notice to Readers” announcing the revision of technical instructions (TIs) for TB screening and treatment. The TB TIs are available for review on the CDC web site and include a map of the geographical locations of populations that are being screened with the new TB TIs. Since last fall, DGMQ has implemented the TB TIs for refugee populations in Nepal, Kenya, Tanzania and Turkey. The volume of these refugee populations is expected to total 16,500 persons, but the Department of State (DOS) plans to resettle 50,000-7000 refugees in FY’08.

From February-March 2008, DGMQ implemented the TB TIs in additional immigrant populations in Botswana, Lesotho, Mozambique, Namibia, South Africa, Swaziland, Turkey and Vietnam. With the exception of Turkey and Vietnam, all of these immigrants will receive medical examinations in South Africa.

DGMQ is currently implementing the TB TIs in China, the Dominican Republic, Ethiopia, Kenya, Malaysia and Tanzania with a total projected volume of >80,000 immigrants and refugees. DGMQ’s current implementation of the TB TIs also includes the resettlement of Iraqi refugees due to DOS’s plan to resettle 12,000 Iraqi refugees from Egypt, Iraq, Jordan, Lebanon, Syria, Turkey and Kuwait in FY’08. DGMQ is collaborating with DOS officials to establish a panel site in Baghdad, obtain a baseline assessment of the existing capacity of panel physicians in these countries, and assist in implementing the TB TIs in these regions.

The TB TI Workgroup recently convened a conference call and emphasized the need to disseminate information on unique situations in certain countries. For example, the Ministry of Health in China does not have a well-organized system to deliver DOT to TB patients. The law

states that persons diagnosed with TB in China are eligible to receive free treatment at their location of birth. In the Dominican Republic, first-line DOT is adequate, well organized, supported by solid documentation, and consistent with the regimen used in the United States. However, MDR-TB therapy is centralized due to limited resources. Patients are prioritized in the Dominican Republic and some have died while waiting to begin therapy.

Despite these challenges, DGMQ is pleased that efforts are underway to increase awareness of the TB TIs and enhance in-country collaborations. Most notably, the National Leprosy and Tuberculosis Control Programme recognized the International Organization for Migration (IOM) DOT program in Eastleigh (Nairobi), Kenya as the best-managed DOT program in the district and the second best DOT program throughout Kenya. Panel physicians in Mexico recently presented their experiences in implementing the new TB TIs during the 2008 IUATLD North American Region meeting.

Dr. Posey reported on three key activities that are underway for DGMQ to make further progress in implementing the TB TIs. First, implementation of the TB TIs will be evaluated at an immigrant site in response to external guidance that was provided during the 2007 review of the IOM screening program in Thailand. Saint Luke's Extension Clinic in the Philippines was selected as the site and is the largest panel site in the world. In FY'06, the clinic processed 43,684 immigrant visa entrants. The Philippines accounted for 3,205 (or 47%) of Class B TB arrivals to the United States. The Philippines began screening with the 2007 TB TIs on October 1, 2007.

The goals of the Philippines assessment will be to provide a thorough evaluation of the Saint Luke's TB program and inform DGMQ and DTBE on implementation activities. The evaluation will be conducted from May 26-June 2, 2008 by three external representatives of the TB community.

Second, DGMQ is refining the electronic disease notification (EDN) system due to its regulatory responsibility to provide information to receiving health departments of arriving aliens or refugees with a notifiable condition. The EDN system is designed to replace the outdated paper-based Immigrant and Migrant Populations (IMP) system; provide health departments with access to data recorded from DS forms and scanned overseas; and give health departments an electronic system to record and assess outcomes of domestic follow-up and evaluation.

The EDN system was introduced in March 2006, is currently used by 32 states, and will be launched in the near future to all remaining states. The data entry function is centralized at DGMQ. The EDN and IOM systems were interfaced in January 2008 to electronically transmit refugee data and minimize data entry requirements. As of December 31, 2007, 43,065 records were entered into the EDN system. However, states with Class B1 or B2 TB cases and follow-up evaluations in the United States have generated an extremely low rate of return in terms of entering these data in the EDN system.

DGMQ's immediate goals for the EDN system are to expand data entry capacity, terminate data entry through the IMP system among five remaining quarantine stations, and improve ability to

analyze data. DGMQ has been collaborating with DTBE to refine the EDN system and will also raise this issue during the NTCA EDN Workgroup conference call on March 27, 2008.

Third, DGMQ revised the civil surgeon (CS) TIs with input from DTBE and the broader U.S. TB community. The most significant changes to the CS TIs include clarifying the requirement for mycobacterial cultures and updating the guidance on LTBI. Previous delays within the U.S. Customs and Immigration Services (USCIS) in implementing the CS TIs have been resolved. The new CS TIs will become effective on May 1, 2008. States will be notified and will also be able to obtain updated information on implementing the CS TIs from the CDC and USCIS web sites.

### **Update by the DTBE Surveillance, Epidemiology and Outbreak Investigations Branch (SEOIB)**

Dr. Thomas Navin, Chief of SEOIB, provided an update on SEOIB's strategic research review. DTBE's 2008-2009 priorities are to interrupt TB transmission, reduce TB in FBPs, reduce TB in racial/ethnic minority groups, mitigate MDR-/XDR-TB, and reduce HIV-associated TB. DTBE's epidemiologic research agenda covers diagnostics for active TB and LTBI; studies of overseas screening and recent immigrants; LTBI treatment; TB in AAs; contact investigation evaluation; and pediatric TB, including foreign-born children.

To support DTBE's research agenda and priorities, TB Epidemiologic Studies Consortium (TBESC) dollars of ~\$16 million have been allocated to six large studies addressing contact investigations and immunogenetics, regionalization, FBPs, LTBI treatment, interferon gamma release assay (IGRA) versus tuberculin skin testing (TST), and outbreak detection and genotyping. Smaller TBESC studies with cohorts of 10 persons have cost \$350,000 on average.

The TBESC research agenda has been well aligned with funding, while research funding has been well aligned with DTBE's priorities. However, the current research portfolio is extremely broad and a recommendation was made during a recent external review of TBESC to narrow the focus of the research agenda. The expert panel also advised SEOIB to take advantage of the breadth of TBESC, increase nationally representative research and consider the future impact of research.

SEOIB has taken a number of actions in response to the external guidance that was provided by the expert panel. A process to focus the TBESC research agenda was proposed in which six to eight potential research agenda topics would be drafted, narrowed to two to four topics in the first cut, and reduced to one to two topics in the final cut. Proposals would be developed for all of the potential research topics, but the future TBESC research agenda would focus on the final cut of one to two topics. SEOIB acknowledges the importance of narrowing the research focus of TBESC, while maintaining flexibility to address new research questions that arise in the future.

Dr. Navin described the scope of three potential topics that could be included in the TBESC research agenda. "To interrupt TB transmission," findings from TBESC studies on contact

investigations, outbreak detection and regionalization would be used to develop, implement and evaluate improved contact and outbreak investigation guidelines to reduce the rate of recent transmission.

“To reduce TB in FBPs,” findings from TBESC studies on the foreign-born, LTBI treatment and TST versus IGRA would be used to develop, implement and evaluate improved overseas and domestic LTBI screening and treatment to reduce the rate of TB in FBPs. “To reduce TB in racial/ethnic minority groups,” findings from TBESC studies on the foreign-born, strategies to overcome barriers and TB in AAs would be used to develop, implement and evaluate improved guidelines for the prevention of TB in racial/ethnic minority groups to reduce the rate of TB in these populations.

Dr. Navin explained that decisions must be made on TBESC’s new research focus before the end of 2009 because the current ten-year contract ends in 2011. The new contract would provide an opportunity to establish strategic partnerships, but new TBESC partners might be identified in 2010 if possible. Dr. Navin conveyed that during future meetings, he would provide updates and solicit ACET’s input on TBESC’s new research agenda.

Dr. Fleenor made a note to keep TBESC’s new research direction as an ongoing agenda item. He confirmed that at a future meeting, ACET would provide formal recommendations on this issue to assist SEOIB in the decision-making process.

### **Update by the Foreign-Born Workgroup (FBWG)**

Dr. Dolly Katz, of DTBE, reported on FBWG’s activities since the previous ACET meeting. FBWG is revising CDC’s 1998 “Recommendations for Prevention and Control of Tuberculosis Among Foreign-Born Persons” to 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 TB programs, laboratory issues, special FBPs, critical partners, education and training resources, policy recommendations, and future research needs.

FBWG has approved outlines and completed drafts for all sections of the guidance document, conducted the first round of editing for five sections, and completed the editing process on one section. The editing process includes initial and final editing of each section by one of three FBWG members and comments on each section by the entire FBWG membership. FBWG hopes to present the draft guidance document to ACET during the fall meeting in 2008.

Dr. Katz presented the format of the “special issues for TB programs” section. To describe a specific program element that all health departments should have, programs will be advised to develop epidemiologic profiles of FBPs with TB. A chart will be provided to inform programs of the types of data that should be collected, such as the number of TB cases and the TB rate per 100,000 population by region and country; Class B notifications; the percentage of FBPs

evaluated and treated for TB; and the number of TB cases diagnosed or treated, but not counted.

The chart will identify sources to collect data, such as the report of a verified case of TB, Census Bureau, CDC and local TB programs. The chart will outline specific uses of these data, such as the identification of groups for testing, outreach, resource allocation, program evaluation, advocacy for medical services, and the quantification of otherwise unrecorded workloads for health departments.

A case study of Tibetans in New York City will be provided to illustrate the usefulness of surveillance. In 2005-2006, three XDR-TB cases were identified in New York City clinics among Tibetans who recently arrived from India or Nepal. The data analysis showed that an average of 22 cases per year were diagnosed in this population at a rate of 561/100,000.

An example will be provided to illustrate potential steps involved in conducting surveillance of FBPs. New York City faced problems in conducting surveillance of TB in Tibetans because Tibet is not officially recognized as a country. New York City clinics took a number of actions to overcome this challenge. Enhanced surveillance for Tibetans was performed by:

- Asking FBPs about their Tibetan heritage.
- Modifying the data abstraction form to include a question on Tibetan heritage.
- Compiling and distributing a list of common Tibetan names to clinic staff.
- Maintaining a central registry of Tibetan TB cases.
- Performing rapid susceptibility on all acid fast bacilli (AFB) positive smears of Tibetans.
- Outreaching to the Office of Tibet, community organizations and community gatherings.

### **Update on the TB and Air Travel Contact Investigation**

Dr. Curi Kim, of DGMQ, provided an update on the U.S. experience with contact investigations involving TB and air travel in 2006-2007. The U.S. approach to conduct passenger contact investigations occurs at two levels. First, CDC is notified about a TB case and then determines whether the case meets World Health Organization (WHO) criteria to conduct a contact investigation. CDC obtains and distributes passenger contact information to state and foreign public health authorities through secure mechanisms.

Second, local health jurisdictions (are forwarded contact information from state health departments) and foreign public health authorities locate and evaluate passenger contacts, and report results to CDC on a voluntary basis. With the passive data collection process, CDC submits a written request with the initial notification and asks for information on the outcomes of the investigation. CDC does not contact the health jurisdiction again.

With the active data collection process, CDC calls health jurisdictions that did not submit a report after the initial request and asks for information on the outcomes of the investigation. To date, CDC has only used the active data collection process for four highly-contagious and drug-resistant cases. CDC provides a list of specific data we ask the health departments to report to us; however, the detail and completeness of the data reported varies by health department. Despite these tools, the quality and completeness of data vary among health departments.

From July 2006-December 2007, 87 cases were reported to CDC that met WHO criteria for contact investigations. Of 68 index cases reported in 2007, 88% were culture-confirmed or had a positive nucleic acid amplification test (NAAT); 90% were AFB-positive on sputum smear; 44% had cavitation on chest x-ray (CXR); 47% were susceptible to isoniazid (INH) and rifampin (RIF); 12% were resistant to INH or RIF; and 9% had MDR-TB.

Dr. Kim summarized the results of contact investigations that were conducted from January 1-November 30, 2007. Of 2,062 passenger contacts, 77% had locator information and 12% had TB evaluation results that were reported to CDC. Of 249 TB evaluation results reported to CDC, 10% had TB test results and 2% had a known prior positive result. Of 206 passenger contacts with TB test results, 76% had a negative TST and 24% had a positive TST.

Of 49 passenger contacts with positive TST, 88% had risk factors reported for previous infection and 10% had no reported risk factors. The presence or absence of risk factors was not addressed in the remaining 2% of cases. A “negative” TST was defined as testing at least eight weeks after the flight and a TST <5 mm or a negative QuantiFERON-Gold (QFT-G) TB test. A “positive” TST was defined as testing any time after the flight and a TST  $\geq$ 5 mm or a positive QFT-G test.

Dr. Kim reviewed CDC’s major conclusions and recommendations based on its experience with contact investigations of airline travelers with TB. Efforts to obtain outcome data for passenger contacts of TB cases are challenging due to difficulties in collecting accurate locator information, reliance on other groups to locate and evaluate passenger contacts, a voluntary reporting system, and differences in the quality of reported data.

Active data collection from health jurisdictions significantly yields more data than passive data collection, but the information is still incomplete, inconclusive and cannot be used to assess the risk of TB transmission during air travel. The increase in reports of TB cases during air travel following high-profile events suggests a reporting bias and baseline under-reporting.

Notification of persons who are potentially exposed to TB during air travel is a public health responsibility. Routine collection of outcome data is important, but this effort does not provide quality data and is not useful for developing policy and guidelines. Collaborative efforts are needed internationally to create protocols for additional research, data collection and analysis, and dissemination of outcome data to better clarify the risk of TB transmission during air travel.

The ACET members made a number of suggestions for CDC to consider in refining TB contact investigations of passengers in the future.

- CDC should reconsider using the 5 mm cutoff for negative or positive TST because this measure will result in over-diagnoses and an increase in the false-positive rate. CDC should apply a 10 mm cutoff to measure negative or positive TST.
- CDC should compile and provide local TB programs with models, best practices and innovative strategies on reporting notification of persons who are potentially exposed to TB during air travel. These tools would be extremely beneficial because notification, data collection and data reporting are resource-intensive to local TB programs that have other competing priorities.
- CDC should reconsider its prioritization of TB contact investigations of airline passengers, particularly in light of limited resources. For example, modeling was recently performed on airline transmission of TB and showed that this setting was not particularly high risk compared to buses, subways and other modes of transportation. Moreover, the significant amount of time and resources that public health officials and field staff are devoting to TB transmission during air travel is only in response to two recent high-profile events. CDC should design an efficient study with cost-effectiveness data and sufficient power to obtain more solid evidence that will inform policy and determine feasibility.
- CDC should use data that have been collected to date to perform sensitivity analyses of worst case, average and best case scenarios. Probabilistic data from these analyses should be compiled to guide TB contact investigations of passengers in modes of transportation other than air travel.
- CDC should revise its notification process to ask transportation carriers rather than health departments to contact passengers about potential TB transmission and provide contact information to local health departments. During this time, CDC should update its web site with details on the event.

### **Update on the Investigation of the International Traveler with MDR-TB**

Dr. Francisco Averhoff, of DGMQ, described CDC's experience in investigating a high-profile event in which an MDR-TB patient traveled internationally by air. The investigation began in January 2007 when a lesion was detected on the lungs of the patient. The patient was diagnosed with TB and eventually MDR-TB during an initial workup and subsequent testing in April 2007. The patient expressed an interest in traveling to Europe, but the state and local health departments advised the patient against traveling in a written letter.

Because an official isolation order was not issued, the patient traveled abroad in May 2007. CDC contacted and informed the patient about efforts that were underway for repatriation to the United States or administration of appropriate evaluation and treatment in Italy. The patient departed Italy, traveled to other countries by airplane, returned to the United States, and was eventually contacted again by telephone. The patient presented to a hospital in the United States and was placed in isolation and reevaluated. An official isolation order was issued and CDC escorted the patient to Atlanta on May 28, 2007 for treatment.

CDC detected four major flaws in this event and identified opportunities to improve future investigations of travelers with TB. The first flaw was that the patient boarded an international flight and departed the United States. Opportunities to correct this deficiency include perceiving a patient as a flight risk; immediately issuing an isolation order; clearly defining responsibilities of state, local and federal agencies; and raising awareness within state, local and federal agencies of federal capabilities to limit travel.

A number of public health tools are available to take advantage of these opportunities, including education and hygiene; surveillance and investigation; treatment and vaccination; local, state and federal isolation and quarantine orders; and "lookout" and "do not board" (DNB) travel restrictions.

The second flaw was that CDC encountered difficulties in locating the patient in Europe. Opportunities to correct this deficiency include the implementation of International Health Regulations (IHRs) that were in effect as of July 17, 2008; federal protocols to track outbound case patients; and federal protocols to notify countries.

The third flaw was that the patient boarded another international flight and returned to North America. Opportunities to correct this deficiency include the implementation of IHRs; earlier notification and recognition of an event by CDC leadership; increased federal coordination among HHS, CDC and the Department of Homeland Security (DHS); and enhanced international coordination.

The fourth flaw was that despite a lookout, the patient entered the United States by the Canadian land border. Opportunities to correct this deficiency include the implementation of IHRs; earlier federal coordination between HHS and DHS; and a revision to DHS protocols that would not allow protocols at the Canadian border to be overlooked.

From May 2007-February 2008, 24 persons were added to and 16 persons were removed from the DNB list due to their infectiousness status or adherence to regulations. The countries of citizenship of the 24 persons who were added to the DNB list included the United States, India, Vietnam, Mexico, dual U.S./Russian citizenship, Japan, Thailand, Ethiopia, Ecuador, the Dominican Republic, El Salvador, Taiwan, Mauritania, the Philippines, Kenya and China.

Dr. Averhoff reviewed CDC's major lessons learned in conducting the investigation of an international traveler with MDR-TB. The event highlighted breaches in national security and focused less on public health. Reliance was placed on personal relationships to manage the patient prior to travel, but this approach resulted in delays in the timely use of federal tools and international notification.

State and local agencies have authority for isolation and quarantine, but federal authority can supplement state and local authority. Primacy is given to state and local health departments with no preemption. Federal authority exists to prevent air travel. For example, the Transportation Security Administration can take necessary actions to mitigate threats to transportation security and aviation, including TB and other public health threats.

International coordination is critical among involved countries, WHO and the European Centre for Disease Prevention and Control. Interstates and ports of entry have federal quarantine and isolation authority and also serve as DGMQ's "eyes and ears" for quarantine. However, this authority was enforced only after the patient entered the United States. The public good should be balanced with restrictions on the individual by using the least restrictive means and repatriating U.S. citizens.

Dr. Averhoff summarized CDC's next steps to improve future investigations of airline travelers with MDR-TB. WHO's TB guidelines on air travel will be revised with input from DGMQ and DTBE to strengthen international collaborations. Feedback will be solicited from ACET and a variety of other partners to increase awareness of this issue and widely disseminate information on tools that are available to respond to these types of events. Collaborative efforts will be undertaken with DHS to refine federal protocols. A process will be developed to repatriate persons with infectious diseases and strike a balance between individual versus societal responsibility.

Dr. Fleenor confirmed that during the business session on the following day, ACET would discuss the possibility of making a formal recommendation for DGMQ, DTBE and the CDC Coordinating Office for Terrorism Preparedness and Emergency Response to collaborate in targeting emergency preparedness resources to contact investigations involving TB and air travel.

### **Update on CDC's Activities to Address Public Health Law and TB Control**

Dr. Richard Goodman, of the CDC Public Health Law Program, explained that the overall goal of the public health law and TB control initiative is to strengthen understanding among practitioners and other groups regarding the status and sufficiency of state laws for TB control and prevention in the setting of progressively emerging drug-resistant TB. CDC will conduct three major activities to build on ACET's 1993 recommendations on TB laws.

Activity 1. Express laws for TB control within selected states and local jurisdictions will be reviewed and characterized. The goal of this activity will be to examine, organize and characterize legislative, regulatory or judicial case law across 26 select jurisdictions that expressly relate to the control of TB, MDR-TB or XDR-TB cases through state or local health departments, other governmental actors and private-sector partners. The jurisdictions will include 24 states and up to two local jurisdictions, such as New York City or Philadelphia.

The findings of the review and characterization of TB laws in the 26 jurisdictions will be used to inform the development of a model act on state and local TB control and a practice-directed handbook; prepare and nationally disseminate a full report on patterns, gaps and options for strengthening and harmonizing TB control laws; and serve as a resource for ACET to review the 1993 recommendations and consider future reviews or guidance.

A template will be used to organize the TB control laws in six categories: (1) prevention of TB cases, including general preventive measures; (2) identification of TB cases, including

measures to confirm cases through screening, examination and reporting; (3) management of TB cases, including measures to manage confirmed cases through investigation, treatment and other specific tools; (4) safeguarding of rights, including measures to protect the rights of patients through due process, confidentiality, anti-discrimination and religious exemptions; (5) special populations, including TB control measures and laws targeting specific groups; and (6) additional TB provisions that are not otherwise covered in the other five categories.

Activity 2. A model act on state and local TB control will be developed by using information obtained through the review of state laws. The model act will serve as a tool for state and local public health officials, policymakers, legislators and other groups to use in reviewing and potentially strengthening laws for preventing and controlling TB in their individual jurisdictions.

The Centers for Law and the Public's Health will conduct several activities to develop the model act on state and local TB control. A study of state TB laws will be completed on May 15, 2008. An initial blueprint of the model act will be prepared and disseminated to select subject matter experts and partners for preliminary review on June 1, 2008.

During the NTCA meeting on June 12, 2008, a presentation will be made on the suite of TB law activities and a breakout session will be convened for participants to review and provide feedback on the model act blueprint. The blueprint will be finalized on August 15, 2008 based on input submitted by the experts. The initial draft of the model act will be completed on October 15, 2008. The model act will be substantially revised on November 30, 2008 based on feedback submitted by the experts. The final model act will be completed on December 19, 2008.

Activity 3. A *TB Control Law Handbook* will be created to improve understanding of and competency in applying these laws. The target audiences of the handbook will include public health practitioners who are active in TB control at local, state and tribal levels as well as their legal counsel. The handbook will focus on pertinent local, state and tribal laws and essential information on federal and international laws, such as the IHRs. The handbook will be available in print and electronic formats, but an instructional PowerPoint presentation will also be created for education and training purposes.

The handbook will be structured with six major sections: the 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.

Several ACET members made suggestions for CDC to consider in its ongoing efforts to develop the model act on state and local TB control.

- A clear distinction should be made between "regular TB" versus "MDR-/XDR-TB" and "MDR-TB" versus "drug-susceptible TB," particularly in the context of the period of isolation when a patient is not infectious. This language would be extremely helpful to state and local programs. To date, CDC has not released

clear or specific guidance recommending that MDR-TB patients should not be released from isolation until three negative cultures are obtained.

- Inter- and cross-jurisdictional issues should be covered to provide a legal framework for TB patients who are moved while in the custody of public health legal authorities.
- The “special populations” section should include undocumented persons, temporary visitors to the United States, and hospice or end-of-life patients who refuse TB treatment.
- The model act should be accompanied by case studies to illustrate the actual application of TB control laws in various jurisdictions throughout the country.

Ms. Heather Duncan, of DTBE, described a process for ACET to provide feedback on a regular basis as the model act on state and local TB control is being developed. Mr. Joseph Kinney is representing ACET on the Public Health Law and TB Control Workgroup. He should be used as the point of contact for ACET to submit additional comments on the model act or propose names of other experts who should review and provide input on the draft. The initial blueprint of the model act will be completed on June 1, 2008 and distributed to ACET at that time. CDC will provide updates during ACET’s remaining two meetings in 2008.

Dr. Fleenor noted that Dr. Masahiro Narita and Ms. Sirlura Taylor volunteered to serve on the workgroup. He would have an offline discussion with Mr. Kinney to determine whether a conference call should be convened with CDC to discuss the workgroup’s next steps.

## Overview of TB-Related Death Data

**Federal Perspective.** Ms. Suzanne Marks, of DTBE, provided a federal perspective on collecting TB-related death data. “TB diagnosed at death” and “death during TB treatment” are the two variables that are reported to the National TB Surveillance System (NTSS) on TB-related deaths. TB diagnosis at death includes patients who were on one anti-TB drug prior to death because TB disease was not suspected and were diagnosed with TB after death. For example, patients who were on INH treatment for LTBI and were later found to have TB would fall in this category.

Ms. Marks reviewed a number of studies on the “TB diagnosis at death” variable. NTSS data from 2005 showed that TB diagnosis at death accounted for 2% of all TB cases. The number of TB diagnoses at death decreased from 667 in 1997 to 293 in 2005. By race/ethnicity, the percent decline in TB diagnoses at death among AAs, whites and Latinos was greater than the overall percent decline in the total number of TB cases for these populations. For Asians, there was an overall average annual percent increase in TB diagnosed at death of 2%.

A study was published in 1991 with 1985-1988 NTSS data. Of 4,373 cases during this period, TB diagnosis at death accounted for 5.1%. The major risk factors were older age, AA or Latino race/ethnicity, and miliary, meningeal or peritoneal forms of TB. A study is currently being conducted with 1997-2005 NTSS data, but California does not report HIV testing to CDC and

was excluded from the study. There were 948 cases of TB diagnosed at death during this period, accounting for 1.3% of all cases. The major risk factors were older age, HIV co-infection, U.S.-born status, being AA, and male.

A study that is in press used 1998-2003 NTSS data to analyze TB diagnosis at death among HIV-infected persons in ten metropolitan statistical areas (MSAs) with the greatest number of TB/HIV cases. The results of the study are outlined below.

The risk of TB diagnosis at death ranged from three to eight times greater in HIV-infected TB patients than HIV-uninfected TB patients at 9 of the 10 sites. The unadjusted risk of TB diagnosis at death was nearly five times greater in HIV-infected TB patients than HIV-uninfected persons. TB patients diagnosed at death were nearly three times as likely to have unknown HIV status. HIV-infected TB patients  $\geq 65$  years of age were nearly four times more likely than younger patients to be diagnosed at death. HIV-infected TB patients in three MSAs were one to three times more likely to be diagnosed at death than patients in other MSAs.

HIV-infected TB patients, Latinos, FBPs and those in one MSA were half as likely to be diagnosed at death than patients without these characteristics. For TB patients who are diagnosed at death, more data need to be collected on HIV status, substance abuse, incarceration and long-term care residence. The association between HIV and TB diagnosis at death suggests that access to health care might be a problem for these persons.

Ms. Marks reviewed a number of studies on the "death during TB treatment" variable. NTSS data from 2005 showed that deaths during TB treatment accounted for 6% of all TB cases. The number of deaths during TB treatment decreased from 1,759 in 1997 to 816 in 2005. By race/ethnicity, the percent decline in deaths during TB treatment among AAs, whites, and Latinos was greater than the overall percent decline in the total number of TB cases for these populations. For Asians, there was an average annual percent increase in TB deaths during treatment of 0.3%.

A study is currently being conducted with 1997-2005 NTSS data. 4,465 deaths during TB treatment occurred, accounts for 6.2%. The major risk factors were older age, HIV co-infection, MDR-TB, long-term care residence, U.S.-born status, Latino race/ethnicity, sputum smear-positive, extrapulmonary-only TB, injection drug use, being male and being culture-positive.

An autopsy would need to be performed to verify whether TB was the cause of death. However, this type of verification is challenging because autopsies have declined from 41% in 1961 to 5%-10% in the mid-1990s. Autopsies are expensive, not reimbursed, and are no longer required for hospital accreditation. Moreover, physicians often do not request autopsies and efforts to obtain consent for an autopsy from family members are difficult.

A study that was published in 2002 showed that 22% of a 1997 TB/HIV cohort died. Sputum smears and other clinical information at the time of death were used to demonstrate that 44% of these deaths were due to TB. A TBTC study used 1995-1998 data to show that 7% of a cohort died during TB treatment. Death certificates, autopsies and clinical information were used to demonstrate that TB was the cause of one death. Multiple risks were found to be associated

with a greater risk of death during TB treatment. The risk factors for death in this study included cancer malignancy, HIV, daily alcohol use, unemployment and older age.

Ms. Marks explained that DTBE uses National Center for Health Statistics data to report the number of TB-related deaths in the "*Reported Tuberculosis in the United States*" annual report. In 2005, 646 TB-related deaths were reported and accounted for 58% of all deaths identified in NTSS. DTBE's new study to examine TB mortality was funded in FY'08 and will include both a descriptive cohort and a nested case-control phase.

**State Perspective.** Dr. Jennifer Flood is an ACET member and Chief of the Surveillance and Epidemiology Section of the TB Control Branch in the California Department of Public Health (CDPH). She provided a state perspective on collecting TB-related death data in California. CDC's 1995 guidance on the essential components of a TB prevention and control program was extremely useful for the field. CDC advised programs to analyze each death caused by TB; determine whether the death could have been prevented; and use the findings from the review to develop and implement new policies to reduce the number of preventable deaths.

Since the release of CDC's 1995 guidance, CDPH has been attempting to answer a number of key questions: (1) What is the frequency and trend of TB deaths in California? (2) What are the characteristics of persons who die from TB? (3) Is TB a cause of death or a contributor in persons dying with TB? (4) Can future TB-related deaths be averted? CDPH used the state TB case registry, the California "Adverse Treatment Outcome Study," and TB death investigation data as sources to address these issues.

Dr. Flood summarized TB-related death data that have been collected in California. The number of deaths among persons with TB declined in California from 1997-2006, but no changes were observed in the proportion of TB diagnoses at death or death during TB treatment. The TB case fatality ratio of ~8.5%-9.5% exceeds other communicable diseases. Data were collected on persons who were diagnosed with TB, but had a delay in starting therapy. The data showed that a large percentage of TB patients died within one month of beginning treatment.

Data collected from 2000-2005 showed that older age >65 years and HIV co-infection were major patient characteristics of TB-related deaths in California. In terms of TB-related deaths in California by race/ethnicity, white TB patients were over-represented, AA TB patients were slightly over-represented, and Asian and Latino TB patients were under-represented. A disparity was seen in the TB case fatality ratio among AAs 45-64 and ≥65 years of age in California. By age, a disparity was seen among whites 26-44 years of age due to a high proportion of HIV-infected TB cases.

Data showed that ~50% of the HIV population in California was on highly-active antiretroviral therapy (HAART) as of 2005. The introduction of HAART was strongly associated with a four-fold decrease in TB incidence among HIV-infected persons from 13.5% to 7.9% and a dramatic decline in the case fatality ratio among AIDS/TB cases from 30% to 12.5% from 1996-2005.

Dr. Flood described a number of activities that were conducted in California to address TB-related deaths. CDPH launched the “Adverse Treatment Outcome Study in 18 high-morbidity jurisdictions throughout California from 1996-1997. The study showed that disseminated or pulmonary disease plus extrapulmonary disease, AIDS, renal disease, diabetes and cancer were all associated with TB death. Persons who had ever received DOT were much less likely to die. Only 3% of persons who died from TB had legal orders served. These findings indicated that interventions, provider oversight or contact with a health department might be factors in preventing TB-related deaths.

CDPH developed a “death assessment tool” in response to concerns expressed by local TB programs in California regarding TB-related deaths. The local programs requested assistance from CDPH in evaluating the preventability of TB deaths. CDPH conducted a search, but was unable to locate a systematic tool to examine the causes of TB deaths or contributing factors. As a result, CDPH formed a workgroup to create the death assessment tool.

CDPH designed the tool to systematically assess the contribution of TB to death; evaluate prevention opportunities for each TB-related death; use information from missed opportunities to develop interventions and guide public health actions in preventing future deaths; and improve outcomes for all TB patients over time. CDPH used five major data sources to assess death: public health medical records; provider records; outpatient, hospital or institutional records from long-term care and correctional facilities; laboratory, imaging and autopsy reports; and death certificates.

CDPH developed an algorithm and established criteria to assign the contribution of TB to death in five categories: “definitely,” “possibly,” “unlikely,” “definitely not,” and “unknown” TB-related. For example, the “definitely TB-related” category included persons who died from complications of pulmonary or pleural TB, specific consequences to the site of extrapulmonary TB disease, an adverse event associated with TB medication, or a peri-procedural death.

CDPH piloted the death assessment tool in four counties in the San Francisco Bay area from January 2005-June 2006. The random sample included 20 TB-related deaths from a total cohort of 54 cases that were *M.tb* culture-positive or pathology-positive. Of the 20 sample cases, 16 were categorized as “definitely” or “possibly” TB-related deaths and four were categorized as “definitely not” TB-related deaths. Prevention opportunities were missed in 13 of the 16 TB-related deaths.

CDPH categorized the 13 TB-related deaths with missed prevention opportunities in three groups. “Case detection” accounted for 64% of missed prevention opportunities, including provider diagnostic and reporting delays, patient diagnostic delays and laboratory reporting delays. “Case management” accounted for 33% of missed prevention opportunities, including failures to initiate DOT, inadequate continuity of care, and insufficient monitoring and management of adverse medication effects. “Treatment” accounted for 25% of missed prevention opportunities, including delays in treatment initiation, inappropriate regimens, and laboratory delays in reporting drug susceptibility.

Dr. Flood gave examples of three cases from the 13 TB-related deaths with missed prevention opportunities. Case 1 was a patient 42 years of age with hernia repair, a history of liver disease, an AFB-positive tissue stain and pathology consistent with TB. Treatment was not initiated until two weeks following positive culture and more than four weeks after the positive stain and pathology results were obtained. A hepatic-sparing regimen was not started and the patient died from hepatic failure less than three weeks after treatment initiation. TB was not mentioned on the death certificate.

Case 2 was a previously healthy patient 81 years of age from China with no co-morbidities. The patient presented with cough, a 50-pound weight loss and an abnormal CXR. The patient was initially treated for pneumonia, but the radiology report noted that TB should be considered after the CXR showed no improvement. An AFB smear was ordered two weeks later and was found to be positive. TB treatment was initiated more than one month following the abnormal CXR that was suggestive of TB. The patient died of disseminated TB.

Case 3 was a patient 50 years of age from the Philippines who presented with weight loss and a cough for more than six months. The patient's underlying condition of diabetes was well controlled. Despite multiple visits to a private provider with complaints of persistent cough, the patient died from massive hemoptysis before TB was diagnosed.

Dr. Flood reviewed a number of interventions that TB control programs in the San Francisco Bay area have implemented in response to TB-related deaths in California. Feedback on delayed diagnoses and case management errors has been given to private providers. Oversight of TB patients during hospitalization has been intensified.

Health departments have strengthened transfer of care while moving TB patients. Educational interventions have been conducted to target key provider populations. Assurances have been made to administer DOT for complicated and severe TB cases. Recurrent TB control gaps that contribute to deaths have been addressed in local, state and national guidelines.

Despite the success of these activities, CDPH has identified a number of limitations in interventions for TB-related deaths. Efforts to develop a systematic approach to examine the cause of death are challenged by limited available information, such as the lack of records of events preceding death, autopsy records and complete diagnostic workup preceding death. Surveillance data do not readily measure healthcare disparities, socioeconomic inequities or barriers to access. A larger representative sample has not been compiled to date to confirm and generalize findings on the contribution of TB to death and missed prevention opportunities.

Dr. Flood summarized the major conclusions from California's experience in responding to TB-related deaths. Over the past decade, 3,727 TB-related deaths have occurred among California residents. Each year, ~65 TB cases are dead at diagnosis or die before starting TB therapy. The proportion of persons with TB who die in California ranges from 8%-9% and is no longer declining. TB death disparities have been observed among racial/ethnic groups.

The primary patient characteristics of TB-related deaths in California include older age, HIV, co-morbidities and extensive TB disease. Current surveillance data do not capture the reasons for

TB-related deaths or demonstrate whether these deaths are preventable. Key opportunities are being missed to prevent TB-related deaths, such as oversight of care by private providers and administration of DOT. Care by private providers was found to be a strong predictor of TB-related deaths in California.

The pilot of the California death assessment tool showed that TB was a major contributor to deaths in the majority of deaths reviewed in the systematic investigation. However, public health gaps also might have contributed to many TB-related deaths. Interventions at local, state and national levels might be informed by a systematic assessment of missed opportunities for the prevention of TB-related deaths. Data have shown that TB-related deaths are costly in terms of hospitalizations and the value of lost lives.

Dr. Flood concluded her presentation by asking ACET to provide input on three key questions to assist programs in making progress on addressing TB-related deaths. First, should the magnitude of TB-related deaths, disparities and potential prevention opportunities prompt action or follow-up at this time? Second, should the broader TB control community undertake different efforts at this time? Third, what is ACET's role in supporting CDC's efforts to better understand TB-related deaths?

The discussion period was devoted to Ms. Marks and Dr. Flood responding to ACET's questions regarding federal and state studies, data collection efforts and other activities to bring attention to TB-related deaths. ACET commended CDC and CDPH for providing leadership on this issue. Dr. Fleenor confirmed that during a future meeting, ACET would formulate guidance to advance current efforts to address TB-related deaths.

With no further discussion or business brought before ACET, Dr. Fleenor recessed the meeting at 5:11 p.m. on March 26, 2008.

### **Update on NAAT Research**

Dr. Fleenor reconvened the ACET meeting at 8:33 a.m. on March 27, 2008 and yielded the floor to the first presenter.

Dr. Max Salfinger is the State Laboratory Director of the Bureau of Laboratories at the Florida Department of Health and a representative of the Association of Public Health Laboratories (APHL). He explained that the mission of APHL is to safeguard the public's health by strengthening public health laboratories in the United States and across the world.

APHL was established more than 50 years ago as a non-profit 501(c)(3) organization to advance laboratory systems and practices and promote policies that support health communities. APHL's membership includes state and local public health laboratories, environmental laboratories and other groups that conduct testing of public health significance.

Significant milestones in the history of molecular technologies include the introduction of DNA in 1953, release of the polymerase chain reaction (PCR) assay in 1986, a description of the RIF drug-resistant gene in 1993, and Food and Drug Administration (FDA) approval of the first NAAT in 1995. From 1993-2000, FDA approved four NAATs and CDC published NAAT guidance in the *MMWR*.

Dr. Salfinger summarized a CDC investigation that emphasized the importance of NAAT. The index case was 22 years of age, HIV-negative, and was traveling from Los Angeles to Chicago on AMTRAK in January 1996. A sputum smear was collected from the passenger, submitted to a regional hospital and found to be AFB-positive. An additional sputum smear collected from the passenger was fast-tracked to the public health laboratory and was found to be positive based on the *M.tb* Direct (MTD) and AccuProbe tests.

DST results were available the following day, but the passenger died ten days later. The Löwenstein-Jensen slant from the first specimen was submitted for DST from the regional hospital 24 days later. The investigation showed that DST results were obtained one month quicker by fast-tracking the specimen to the public health laboratory instead of using regular channels. Despite the fact that this case occurred 12 years ago, NAAT still has not been implemented in every state laboratory.

Dr. Salfinger reviewed the results of several NAAT studies. In terms of TB control and new assays, genotyping and IGRA are much more widely used and have been given more resources than NAAT. However, the availability of the MDR assay provides an opportunity to combine NAAT and the drug-resistant component. A study was published in 2005 to demonstrate a reduction in the turnaround time for laboratory diagnosis of pulmonary TB by routine use of NAAT. Of 797 patients in the study, 81 had TB. The study showed that in a two-day turnaround time, NAAT sensitivity was 90% and specificity was 100%.

A study has been submitted for publication on the removal of TB suspects from respiratory isolation to determine the efficiency of a single sputum NAAT compared to serial smears. Of 494 patients in the study, 46 had TB. The study showed that additional time was needed to wait for a culture and obtain additional information to release a patient from respiratory isolation.

A study was published in 2008 on the implementation of rapid molecular screening for MDR-TB in a high-volume public health laboratory in South Africa. In this setting, the TB incidence was 932/100,000, the rate of TB/HIV co-infection was 28.2%, and the MDR-TB rate was 0.9% in newly diagnosed persons and 3.9% in previously treated patients. The study included testing of 536 specimens. Without using the PCR assay, culture and DST results were obtained three days to six weeks later in this setting.

The New York State laboratory conducted a study to develop and implement a real-time PCR assay for rapid identification of *M.tb* complex DNA from clinical specimens. For purposes of the study, IS6110 was used as the target and all members of the *M.tb* complex were detected, validated and approved by the New York State Clinical Laboratory Evaluation Program.

In comparing real-time PCR and the MTD test, the study found real-time PCR to be superior in terms of specificity, cost, ease of use, the potential for contamination, and the amount of time involved. The MTD test is cross-reactive with *Mycobacterium terrae* and *Mycobacterium celatum*; costs \$20 more than real-time PCR; requires intensive hands-on time; uses an open rather than a closed system; takes ~2-4 more hours to run than PCR due to the need for repeat testing; and will miss at least 10% of persons with TB.

The U.S. market penetration of the BACTEC 46 TB System to diagnose TB dramatically increased from 1980-1995. However, some laboratories are still not routinely using liquid media. In Washington State, recurring MTD funding was successfully leveraged in response to a large TB outbreak of >70 cases among homeless persons in Seattle. Many cases were AFB smear-negative and culture-positive. Access to radiology services was geographically limited.

TB controllers in Seattle and Washington State expressed the need for a tool to rapidly detect active TB cases. Public health leadership was engaged from state and local health departments and a CDC Epi-Aid. The Washington State legislature approved recurring funding of \$97,000 per year for MTD testing.

Based on a mathematical model with ~13,000 new TB cases per year in the United States and ~13 suspects for one TB cases, the screening population would be 169,000 patients. On the basis of 200,000 tests with reagent rentals at four sites, the cost of MTD testing would be \$10.16 per test. This model demonstrates that MTD testing should be expanded to the entire country and should not be restricted to individual hospitals and local jurisdictions.

Dr. Salfinger emphasized the need for a paradigm shift. Most notably, NAAT should be independent of and separate from smear results. This approach would resolve shipping issues and maximize DNA extraction for molecular assays. A two-tiered screening approach would use NAAT for positive smear results in tier 1 and an MDR assay in tier 2.

Dr. Salfinger clarified that the proposed paradigm shift was not meant to advocate for discontinuing traditional diagnostic smear microscopy, culture or solid liquid. Instead, the proposal should be used to consider specific circumstances in which NAAT and the drug-resistance assay would be helpful in addressing clinical situations.

Dr. Salfinger described APHL's ongoing activities to strengthen the focus on NAAT. APHL established a workgroup with representation by six states and the CDC laboratory to review the TB portfolio beginning in April 2008. APHL will use CDC funding to convene an expert consultation to discuss NAAT-related issues, develop an algorithm to rapidly launch NAAT as the standard of care, and ensure that local, state and hospital laboratories have access to the latest technologies. Dr. Salfinger offered to provide an update on APHL's NAAT activities during a future ACET meeting.

To guide the discussion, Dr. Castro asked ACET to consider whether data are sufficient at this time to rapidly advance toward the use NAAT throughout the country.

Dr. Fleenor confirmed that ACET would revisit the issue of NAAT during the business session to prioritize its future activities. However, ACET would not make formal recommendations on this issue until Dr. Salfinger provided an update on the outcomes of APHL's expert consultation on NAAT.

In the interim, the ACET members made three key suggestions for APHL to consider during its workgroup meeting and expert consultation on NAAT.

- APHL and DTBE should collaborate to provide leadership in changing the current laboratory structure to make the paradigm shift that Dr. Salfinger proposed. For example, NAAT screening validates the need to regionalize TB services.
- APHL should ask DTBE to advise programs to ship specimens to laboratories that perform genotyping and include initial testing for INH and RIF resistance. This approach would eliminate the need to ship specimens to a second laboratory because genotyping would be performed and results on INH and RIF resistance would be immediately obtained.
- APHL should extensively engage TBTC and TBESC in its NAAT activities. This strategy should be used to urge the two consortia to incorporate laboratory issues into TB research and strengthen the national and DTBE research agendas.

### **Overview of the Public Health Service (PHS) Drug Abuse Program Guidelines**

Dr. Eric Pevzner, of DTBE, reported on CDC's ongoing efforts to develop PHS guidelines for the prevention and control of HIV/AIDS, viral hepatitis, STDs and TB among persons using illicit drugs. He noted that this activity is consistent with NCHHSTP's PCSI initiative to organize and blend interrelated health issues, separate activities and services to maximize public health impact through new and established linkages between programs and facilitate service delivery.

DTBE established a multidisciplinary Drug Use Workgroup to compile the best data to formulate evidence-based recommendations for the PHS guidelines and distribute a useful document to the field. The workgroup hopes the guidelines will reinvigorate collaborations because the current practice of addressing drug use among persons with TB in isolation has resulted in significant challenges and has not been effective in making progress toward TB elimination.

CDC has lead responsibility in PHS to draft the initial version of the guidelines, but HRSA, the National Institute on Drug Abuse, and the Substance Abuse and Mental Health Services Administration will be extensively involved in reviewing and providing input on the document. The workgroup also plans to disseminate the draft PHS guidelines in early 2009 to ACET, NTCA and other partners for review and comment.

Dr. Pevzner summarized the six major sections of the PHS guidelines:

- An “introduction” to describe the challenges of drug use in NCHHSTP’s disease focus areas. For example, drug use is a barrier to TB control due to its role in delays in health-seeking behavior, increased infectiousness, a stronger likelihood of drug resistance, prolonged transmission, and limited opportunities to initiate, adhere to and complete treatment.
- A “methodology” section to describe actions that were taken to develop the PHS guidelines.
- A section on the “epidemiology of drug use and NCHHSTP diseases.” The workgroup is challenged in writing this section because solid data have not been produced to date to demonstrate the burden of TB among persons who use illicit drugs in the United States.
- A section on “diagnosis, treatment and evidence-based behavioral interventions.” The workgroup has engaged NTCA to obtain lessons learned and experiences on programmatic activities that states have conducted to address drug use among persons with TB.
- A section on “prevention strategies.”
- A section on “recommendations” to provide advice on the best strategies to integrate existing and new guidelines.

ACET noted that the PHS guidelines will focus on disease prevention and control among “illicit” drug users only. However, several members advised DTBE to also include recommendations for alcoholics and abusers of prescription drugs in the guidelines. Most notably, these two groups do not transmit TB through blood and would require different interventions than injection drug users. The ACET members also pointed out that the guidelines should be used to improve current capacity to screen for TB in drug rehabilitation programs. These efforts should be linked to local TB program activities.

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

Dr. Diana Schneider is the ACET *ex-officio* member to and a Senior Epidemiologist in the U.S. Immigration and Customs Enforcement (ICE). She covered the following areas in her update. The pulmonary TB rate in 2005 was 14.3/100,000 in Mexico compared to 4.8/100,000 in the United States. Data collected in 1996-2007 showed that TB case rates were higher in border counties in Texas compared to the remainder of the state.

A number of key issues impact TB control in Mexico. Cases are under-reported. The public health workforce and primary care providers need training to facilitate early case detection. Treatment norms in Mexico do not require culture for diagnosis. Training is needed to develop and enhance laboratory capacity and skills to improve the quality of AFB smears and perform culture testing and DST at the local level. Access to second-line drugs (SLDs) in Mexico is limited and monitoring of SLDs is not always appropriate.

Experts in the United States typically provide clinical consultation to Mexico for MDR-TB and other medically complex cases. DOT coverage in Mexico generally does not meet U.S.

standards and is inadequate due to the administration of drugs in health centers and the lack of transportation. TB control along the Mexico-Guatemala border is a significant problem in Mexico and has implications for the United States.

In addition to issues that affect TB control in Mexico only, a number of problems also have an impact on both the United States and Mexico, such as MDR-/XDR-TB diagnosis and treatment; bridge case management; continuity of care; challenges in the binational transportation of specimens, reagents and drugs between the United States and Mexico; inadequate laboratory capacity for culture testing and DST in Mexico; the erosion of U.S. funding for binational programs; and cross-border surveillance.

Other binational challenges in TB control include different case definitions between the United States and Mexico for "smears," "TST," "cultures" and "clinical diagnoses." Efforts to share information between the two countries are problematic from both legal and logistical perspectives. Legal, immigration and multi-jurisdictional issues arise at federal, state and tribal levels when TB patients are voluntarily or involuntarily moved between the United States and Mexico.

The growing immigrant population of Mexicans throughout the United States has increased morbidity in U.S. geographical areas where TB previously was uncommon. Projections show that ~25% of the total U.S. population will be of Latino descent by 2050. In border counties in Texas, nearly 85% of the population is Latino at this time.

Dr. Schneider described other key issues that impact TB control in the U.S.-Mexico Border region. For "MDR-/XDR-TB treatment in Mexico," Mexico has capacity to treat MDR-TB cases only in a few areas in collaboration with binational programs. However, the United States typically provides SLDs. TB patients in areas with no binational program are often unable to begin treatment and are instructed to travel to the United States for treatment. Inadequate DOT coverage is a barrier to securing SLDs through the Green Light Committee (GLC). TB drugs are readily available over-the-counter in Mexico and are not rigorously controlled.

The National TB Program (NTP) in Mexico currently has amikacin, kanamycin, prothionamide, ciprofloxacin and linezolid, but these drugs are not linked to the adequacy of DOT. As a result, the NTP is planning to procure capreomycin, para-amino salicylic acid and cycloserine as SLDs and will purchase these drugs commercially in 2008 for ~60 patients. The NTP will submit an application to the GLC in 2009 to administer these drugs to all patients. In Mexico, the State Drug Resistance Committee reviews all cases and a National Advisory Group on Drug Resistance approves the regimen for a specific patient.

For "MDR-/XDR-TB treatment in Guatemala," ~3% of TB cases are MDR-TB. GLC approval of drugs in Guatemala is pending. Resources are expected to be allocated before the end of 2008 to treat 15 patients. Guatemala has procured drugs from Peru to treat four MDR-TB patients at this time. No legal authorities exist in the country to compel isolation or hospitalization. The Global Fund Project has been approved in Guatemala to provide financial support to families while patients are hospitalized.

MDR-/XDR-TB cases in Mexico and Central America have had an effect on California, Texas and other U.S. states. For example, Mexican-born TB patients in California are twice as likely to have TB and AIDS than non-Mexican-born persons. Although several projects have been initiated to improve binational treatment of MDR-TB, funding is needed by both the United States and Mexico to develop and sustain infrastructure changes to treat MDR-TB in the Mexico border region. Existing infrastructures will be lost if U.S. funding is diverted to other priorities as a result of domestic budget cuts.

To develop and enhance infrastructures, stable and comprehensive funding must be targeted to education and training, clinical support, DOT, transportation, access to monitoring tools for adverse reactions or side effects, and access to culture testing, DST and drug levels in limited situations.

For “cross-border transportation and customs issues,” the development of policies and practices to support collaborative cross-border TB projects is a top priority. Processes to transport laboratory specimens from Mexico to the United States and transport medications, reagents and supplies from the United States to Mexico are an urgent need. These processes should reflect the working hours of public health programs, transportation costs and implementation of the same policies throughout the border region.

For “ICE detainees,” patients may be repatriated before culture results are known. This practice has raised ethical considerations regarding continued detention of a patient while waiting for laboratory results. ICE can request a stay of removal for MDR-TB and other medically complex patients who are unable to receive adequate treatment in their country of nationality to remain in the United States during the completion of therapy. However, these patients may be released from ICE custody before repatriation and may have no relationships in the community. Case management and costs may become the responsibility of the local or state health department because federal resources are not allocated if the patient is no longer in ICE custody.

For “immigration and repatriation issues,” some jurisdictions have asked to deport patients who are receiving care in the community. These requests have been made in response to MDR-TB, non-adherence and other case management challenges, the burden on local TB program budgets, no additional sources of funding, a mandate by the governor, or restrictions on the use of government funds for undocumented persons or those who are only temporarily residing in the jurisdiction.

Dr. Schneider reported on the “Bridge Case Management Project” that is jointly conducted by CureTB and TB Net. This initiative was designed to provide binational referrals to TB patients who migrate between the United States and Mexico. The state of California currently provides ~\$132,000 to support staff salaries and a toll-free telephone number for patients to call from any location in the United States or Mexico. However, California’s 10% budget cut has reduced the CureTB workforce to only two staff. Ongoing funding to support these two staff members and the toll-free telephone number is a critical need to sustain the project.

TB Net provides TB referrals to any country for any patient who moves between the United States and another country. TB Net is supported by fundraising efforts, a one-time allocation of

\$50,000 from San Diego County cooperative agreement dollars, and ICE funds specifically for ICE detainees. The state of Texas discontinued its cooperative agreement dollars to TB Net in 2007. TB Net's major expenses include staff salaries, communications activities and a toll-free telephone number. Overall, current funding is not sustainable for either CureTB or TB Net.

Despite the barriers to funding, legal issues and capacity in the border region, Dr. Schneider was pleased to report that binational TB programs in Arizona, California, New Mexico and Texas are making tremendous efforts to address TB control and provide services to high-risk patients in the border region. The activities of these programs include capacity building for long-term sustainability, treatment of MDR-TB patients, binational referrals, provision of a safety net for patients from other areas through Sister Cities programs, processing of a limited number of specimens for TB surveillance and treatment, and capacity to train microbiologists to perform DST.

The binational TB programs have expressed needs in a number of critical areas to strengthen the overall programs, such as more active participation of Mexican public health authorities, increased DOT coverage in Mexico to secure GLC applications for SLDs, enhanced laboratory capacity in Mexico, better use of Binational TB Cards in Mexico, and development of a secure data network to facilitate information sharing.

In an effort to address legal issues in the border region, Mexico and Chihuahua will convene TB legal forums in March and May 2008. Moreover, a binational TB legal forum has been proposed to be held in late 2008 or early 2009 to address legal barriers to effective TB case management of patients who cross the border and identify legal mechanisms to compel isolation and adherence. Other topics that will be covered during the binational TB legal forum include non-adherence, information sharing, transportation of biologics and drugs across the border, contact investigations, and the lack of enforceable isolation laws in Mexico.

Overall, Dr. Schneider emphasized that TB control in the United States would benefit from improved TB control in Mexico and other Latin American countries. However, existing structures and binational efforts for TB control in the border region are useful, but are inadequate due to the lack of sustainable funding for binational and cross-border programs.

The political border is an artifact from a public health perspective due to the transient nature of TB patients in the border region. MDR-/XDR-TB treatment is unavailable in most of Mexico and Latin America. Laboratory capacity and supplies to perform culture testing and DST are an urgent need. Cross-jurisdictional issues and other legal barriers need to be addressed.

The ACET members made three key suggestions that should be considered to improve TB control in the U.S.-Mexico Border Region.

- CDC should establish two strategic priorities at this time to strengthen TB control along the border: (1) drug resistance and (2) continuity of care, via CureTB, to TB patients who move from the United States to Mexico. These two priorities would make the best use of the U.S. TB investment in Mexico.

- CDC should use Homeland Security Presidential Directive 21 because this mandate gives CDC explicit responsibility for surveillance in the context of national security. This mechanism might play a significant role in leveraging sustainable funding for the surveillance and reporting components of TB control across the United States.
- Binational TB programs should be advised to replicate “community-based DOT” that has been successfully implemented in Africa, Asia and other countries. This model uses an in-country clinic or health department to supervise community volunteers who provide support and monitor patients to ensure adherence to and completion of therapy.

### Update by the BCG Workgroup (BCGWG)

Dr. Barbara Seaworth is a member on both ACET and BCGWG. She reported on BCGWG's recent activities to determine whether BCG vaccine should be given to prevent TB in healthcare workers (HCWs) in high-risk settings overseas. CDC published guidelines in the *MMWR* in 1996 that recommended the use of BCG for HCWs in the United States with exposure to TB in certain settings and for children with continuous exposure to MDR-TB.

A number of factors played a role in the rare implementation of CDC's 1996 BCG guidelines. The efficacy of BCG is highly variable. BCG is not readily available and interferes with the interpretation of TST. The U.S. experience with BCG is limited. Infection control measures are effective in stopping TB transmission in the United States.

ACET identified several reasons to review CDC's 1996 BCG guidelines. TB epidemiology changed as a result of the increasing incidence of MDR-TB and the emergence of XDR-TB. Humanitarian efforts and university research programs increasingly support activities of HCWs, volunteers, students and other persons who travel to high-risk areas of the world. The implementation of infection control measures is inadequate or incomplete to document TB transmission to HCWs and patients in facilities or in areas with a high prevalence of HIV infection.

IGRA is now available as a diagnostic tool to identify LTBI and eliminate concerns regarding false-positive results due to BCG. The Tice vaccine is not likely to be the most immunogenic. New guidelines should be written with sufficient flexibility to allow for the use of a better vaccine if one becomes available in the future. Capacity to monitor the side effects of BCG vaccination is weak. Resources are not sufficient to collect data on persons who received BCG vaccination.

To address these issues, ACET established BCGWG with the following charge. New literature related to BCG efficacy would be reviewed. Recommendations would be formulated for HCWs, volunteers and students who travel to work in areas of the world with an increased incidence of MDR-/XDR-TB and absent or incomplete implementation of infection control measures.

To begin fulfilling its charge, BCGWG performed an extensive literature review of studies that have been produced since 1996. A reanalysis of data from a 1994 meta-analysis of 26 studies was published in 2000. The study showed that BCG reduced the risk of TB by 50% and decreased the incidence of both pulmonary and extrapulmonary TB. Age at vaccination was not found to predict BCG efficacy. Adults were included in several of the selected papers.

A long-term evaluation of a randomized and placebo-controlled study of American Indians and Alaska Natives was published in 2004. The study showed that BCG reduced the risk of pulmonary and extrapulmonary TB in adults by 52% and had an efficacy rate of 44% in preventing death in this population since 1948. The risk reduction was estimated to persist for 50-60 years.

A retrospective review of TB infection rates in a population of nearly 1,000 persons in Turkey with household TB exposure was published in 2005. The study showed that BCG was associated with a 24% relative risk reduction for LTBI. However, an editorial was published in 2006 that questioned variations in the degree of exposure and other results of the study. The editorial noted that persons in the study who sought BCG vaccination for their children would have more health-seeking behaviors for TB symptoms.

A study was published that examined contacts of MDR-TB patients. The study demonstrated a decreased risk in the incidence of TST positivity in persons who received BCG vaccination. However, the study design had a major flaw because nearly 50% of patients had the same susceptibility results as the source. This finding indicated ongoing transmission in the community.

Dr. Seaworth reviewed BCGWG's preliminary observations and recommendations. Guidance will be provided on using IGRA to diagnose LTBI and performing a risk assessment based on the WHO "4<sup>th</sup> Report of the Global Project." CDC's 1996 BCG guidelines for HCWs and children in the United States will not be addressed. BCGWG's new recommendations will be limited to persons who travel to high-risk settings overseas.

Available data do not support the development of definitive recommendations either in favor of or against the use of BCG vaccination for the protection of contacts and HCWs against MDR-/XDR-TB. As a result, BCGWG's recommendations will be based on expert opinion. The guidance will note the risk of exposure to MDR-/XDR-TB, the lack of data to support the effectiveness of LTBI treatment due to MDR-/XDR-TB, and the availability of IGRA to allow for diagnosis of LTBI despite BCG.

BCGWG will describe five situations in which BCG vaccination could be recommended. Persons who request BCG vaccination have no evidence of LTBI or active TB disease. The destination of the traveler has a high percentage of TB patients who are infected with *M.tb* strains or MDR-/XDR-TB. Transmission to HCWs is likely. Comprehensive infection control precautions have not or cannot be fully implemented in the destination of the traveler. Personal protective equipment and education on its use have been provided.

BCGWG will emphasize that BCG vaccination should not be required for any HCW. Counseling regarding the risks and benefits of BCG and LTBI treatment should be provided. An initial TB risk assessment should be performed of the traveler's destination. An initial evaluation should be conducted to exclude LTBI or TB disease in the traveler. Education should be provided on infection control strategies that may limit the intensity of exposure. The traveler should be fit-tested for a personal respirator mask, provided with a mask and educated on its use.

BCG vaccination should be administered at least eight weeks prior to travel when possible to allow for the development of an immune response following TB exposure. An evaluation should be conducted with TST and IGRA eight weeks after BCG vaccination and should be repeated with a medical assessment two months after the traveler returns to the United States. A CXR should be taken and a referral to an expert in the treatment of MDR-TB should be given if the medical assessment shows TB signs and symptoms.

A mechanism should be developed to gather information from persons who receive BCG vaccination, such as a national BCG registry or a data collection protocol within state and local health departments, CDC or academic institutions. Support and partnership of BCGWG's efforts should be leveraged from the following groups: CDC/DGMQ, TB controllers, academic institutions, the Infectious Diseases Society of America, American Thoracic Society, and the CDC Advisory Committee on Immunization Practices (ACIP).

The ACET members made a number of suggestions for BCGWG to consider in its ongoing efforts to develop the BCG recommendations.

- Explicit guidance should be provided to address persons with a prior history of BCG vaccination.
- Collaborations should be established with travel medicine clinics in developing the BCG guidance because these facilities will play a key role in implementing the recommendations. Travel medicine clinics also could assist in stockpiling and securing access to the BCG vaccine and compiling data from travelers.
- Language regarding "TST" should be deleted from the recommendations.
- The recommendation for the traveler to be fit-tested for a personal respirator mask, provided a mask and educated on its use should be revised to clarify that these actions should be taken at the time of BCG vaccination.
- Caution should be taken in recommending fit-testing for students, residents and other persons who travel to high-risk settings overseas. This guidance might discourage travelers from obtaining BCG vaccination and does not clearly explain that respirators cannot be worn in all high-risk areas.
- New language should be added to address HCWs who might be exposed to immunocompromised populations that can transmit TB to others. The guidance should advise HCWs in these settings to avoid direct patient contact to circumvent the possibility of transmitting a live attenuated vaccine.

Dr. Castro confirmed that DTBE would attempt to place BCGWG's same presentation on the next ACIP agenda. He clarified that the BCG recommendations would be issued as joint ACET/ACIP guidance and would need vetting and formal endorsement from both advisory committees.

Dr. Litjen Tan, ACET's liaison member to the American Medical Association, offered to facilitate this effort due to his membership on ACIP's Adult Vaccination Workgroup. Dr. Seaworth added that BCGWG also has made initial contacts to ACIP to inform the membership of ongoing efforts to develop the BCG 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 Dr. Fluck and Ms. Taylor, respectively, for ACET to accept the previous minutes. ACET **unanimously approved** the November 27-28, 2007 Draft Meeting Minutes with no changes or further discussion.

Dr. Fleenor pointed out that during the previous meeting, Ms. Sue Perez, ACET's liaison member to the Treatment Action Group, requested an update on communications between ACET and the HHS Secretary from 2003 to the present. Due to time constraints and Ms. Perez's absence at the current meeting, ACET agreed to replace the update with a brief summary in the minutes. Dr. Fleenor noted that his entire PowerPoint presentation was distributed in the meeting packets and also would be available from DTBE upon request.

The timeline of communications between ACET and the HHS Secretary is summarized below:

- Spring/fall 2003–ACET: Two letters with requests to add TB to the HHS list of disparities and begin HHS-wide discussions on this issue. HHS Secretary: No response.
- 2005–ACET: A letter to express concerns about TB in FBPs and emphasize the need for coordinated federal funding. HHS Secretary: A commitment to continue collaborations with various groups to address ACET's concerns.
- March 2006–ACET: A letter to highlight important issues regarding TB in minority groups and emphasize the need for a national dialogue on health disparities. Dr. Gerberding: Advice to ACET to meet with the HHS Deputy Assistant Secretary for Minority Affairs.
- December 2005–ACET: A letter in support of additional resources to evaluate new TB drugs. HHS Secretary: A commitment to establish a subcommittee within the Federal TB Task Force to explore synergies between HHS agencies in advancing research opportunities.
- March 2006–ACET/NCET: A joint letter calling for urgent funding to support the U.S. TB elimination plan. Dr. Gerberding: A commitment to consider this issue in the President's 2008 budget.
- December 2006–ACET: A letter with a special and urgent request for an FY'07 appropriation to address the emergence of XDR-TB in the United States. Dr. Gerberding: A commitment to include the elimination of TB and XDR-TB as CDC's highest priorities in FY'08.

Dr. Fleenor led ACET in a review of three business items that could be easily resolved without an extensive discussion or a formal resolution. ACET's **general agreement** on the three items is outlined below.

1. ACET agreed that Drs. Flood and Narita would represent ACET on APHL's expert consultation on NAAT. Dr. Castro confirmed that DTBE would coordinate with APHL to assure ACET's representation on this activity.
2. ACET agreed that the Council of State and Territorial Epidemiologists (CSTE) TB medication survey would be placed on a future agenda before providing input or formally endorsing the document. The presentation would cover two key areas: (1) current data on the rigor, accuracy and completeness of TB surveillance and (2) programs that are reporting anti-TB medications at this time.
3. ACET agreed that its suggestions to the DTBE Drug Use Workgroup to include alcohol in the draft PHS guidelines on the prevention and control of TB and other infectious diseases among persons using illicit drugs would serve as a formal statement.

Dr. Fleenor led ACET in a review of four business items that would require more substantive discussion and perhaps formal resolutions.

Item 1. Dr. Castro proposed a process to advance BCGWG's activities. Dr. Seaworth's presentation could be repeated at a future ACIP meeting. A small writing group could be formed with representation by ACET and ACIP to use BCGWG's findings to draft the BCG guidance. This effort could be incorporated into monthly conference calls of the ACIP Adult Vaccination Workgroup. After ACET and ACIP formally endorsed and vetted the BCG recommendations, the guidance could be published in the *MMWR* as a "Notice to Readers." Dr. Castro emphasized that the guidance would be much more powerful and credible as a joint ACET/ACIP statement.

Several ACET members expressed concern that ACIP's potential disagreement with the draft BCG recommendations could ultimately result in the release of different guidance from two CDC advisory committees and confusion in the field. Other ACET members made two key suggestions for BCGWG to consider in its ongoing efforts.

First, a formal decision analysis should be performed to identify compelling evidence to support key variables of BCG, such as the level of resistance and efficacy of the vaccine. Second, formal endorsement of the BCG recommendations should be limited to ACET and ACIP only. Several liaison members noted that efforts to widely vet the guidance with professional societies would result in the need to respond to numerous comments and a delay in releasing the statement. However, professional societies would have the option of writing an editorial to voice concern or disagreement after the joint ACET/ACIP statement was released.

ACET resolved item 1 with a motion that was properly placed on the floor and seconded by Drs. Seaworth and Fluck, respectively. BCGWG should collaborate with ACIP on developing a joint

ACET/ACIP statement on the use of BCG vaccine in travelers to high-risk areas overseas. ACET **unanimously approved** the motion.

Item 2. Dr. Castro reported that the National Association of County and City Health Officials (NACCHO) expressed an interest in participating in TB control activities. He asked ACET to consider whether NACCHO should be invited to serve as formal liaison member to facilitate long-term strategic partnerships and highlight the importance of local health departments in implementing CDC's guidance.

ACET resolved item 2 with a motion that was properly placed on the floor and seconded by Drs. Narita and Seaworth, respectively. DTBE should invite a NACCHO representative to serve as a formal liaison member. ACET **unanimously approved** the motion.

Item 3. Dr. Castro asked ACET to consider adopting the following resolution. DTBE would be advised to pursue discussions with CDC on leveraging emergency preparedness dollars to conduct TB investigations that might have implications for both emergency preparedness and TB. DTBE would conduct the investigations in collaboration with DGMQ to improve the existing body of knowledge on TB transmission during commercial air travel.

On the one hand, some ACET members were uncomfortable in approving the resolution due to the following reasons. TB resources are limited and should not be invested in additional research on TB transmission on airplanes. The resolution proposes to use emergency preparedness dollars, but DTBE's TB expertise, time and personnel resources would still be required to conduct the investigations. Moreover, other areas in TB have a more compelling need to be addressed than TB transmission during air travel. Sufficient data have been collected to now shift the focus to TB transmission in modes of transportation other than airplanes.

On the other hand, some ACET members supported the resolution because responsibility for the investigations would be shared between CDC's TB and emergency preparedness resources and would benefit efforts at national, state and local levels.

ACET resolved item 3 with **general agreement** on the following process. A conference call would be convened with an ACET quorum to discuss the proposed resolution in more detail and address concerns raised by the members. The proposed resolution would be tabled at this time and placed on the June 2008 meeting for a formal vote.

Item 4. ACET did not support making a formal statement or recommendations at this time on the isolation guidelines for MDR-/XDR-TB.

ACET resolved item 4 with **general agreement** on the following process. A presentation would be made on the isolation guidelines during the June 2008 meeting to highlight two key issues: (1) a description of challenges in the decision-making process of removing a patient from isolation and (2) a review of available surveillance data.

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

- Update by Dr. Salfinger on APHL's NAAT activities. (Fall 2008 or early 2009 meeting)
- Update by DTBE on the TB redistribution formula. (Dr. Narita volunteered to represent ACET on the weekly one-hour conference calls of the TB Cooperative Agreement Formula Workgroup each Wednesday beginning at 3:00 p.m. EST.)
- Update by DTBE on the draft PHS guidelines on drug use in TB.
- Update by BCGWG on the BCG guidance document.
- Briefings by DTBE on the SAGE Report, TB training activities, RTMCC projects and TB research.
- Report on CDC's progress in responding to ACET's previous resolutions.
- Update on TB health disparities: (1) an overview of the updated inventory of DTBE-funded projects to illustrate projects that focus on health disparities and (2) a presentation by the NCHHSTP Health Disparities Workgroup.
- Overview of CCID's investments in IT and strategic information activities for infectious diseases.
- Update on CDC's public health law and TB control activities.
- Presentation by Drs. James Kim or Michael Porter on the science involved with effectively implementing new TB tools.
- Presentation by Dr. James Lawlor, of the Homeland Security Council, regarding his leadership in developing a Presidential TB Initiative. (This presentation will depend on Dr. Lawlor's availability because he is scheduled to leave this position in April 2008.)
- Presentation on the CSTE TB medication survey.
- Presentation on the isolation guidelines for MDR-/XDR-TB.
- Extensive presentation on national TB performance and the essential functions and standards for various public health efforts:
  - Trends and challenges of TB incidence in urban metropolitan cities, including a clear definition of minimal staffing standards for local TB programs.
  - CDC's accreditation efforts and their impact on TB control.
  - Mandatory DOT in health departments.
  - New set of TB indicators and results of the nation's performance in achieving these measures for DOT, treatment completion, disparities and other issues.
  - Results of DTBE's modeling activities to forecast the TB epidemic and evaluate the impact of various TB control interventions.

## Closing Session

ACET applauded Dr. Fleenor's outstanding efforts in chairing a flexible meeting that allowed for CDC's informative updates and ACET's extensive discussions. The next ACET meeting would be held on June 17-18, 2008.

With no further discussion or business brought before ACET, Dr. Fleenor adjourned the meeting at 1:51 p.m. on March 27, 2008.

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 Committee for the  
Elimination of Tuberculosis