

**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 2-3, 2010  
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. Christine Hahn  
 Mr. Shannon Jones III  
 Mr. Joseph Kinney  
 Dr. Ana Lopez-de Fede [via conference call]  
 Dr. Masahiro Narita  
 Dr. Barbara Seaworth  
 Ms. Sirlura Taylor

**ACET Designated Federal Official**

Dr. Hazel Dean, NCHHSTP Deputy Director

**ACET Ex-Officio and Liaison Members**

Dr. Naomi Aronson  
 (Department of Defense)  
 Dr. William Baine (Agency for Healthcare  
 Research and Quality)  
 Dr. Robert Benjamin (National Association  
 of County and City Health Officials)  
 Dr. Charles Daley  
 (American Thoracic Society)  
 Ms. Linda Danko  
 (Department of Veterans Affairs)  
 Dr. Edward Desmond (Association of  
 Public Health Laboratories)  
 Mr. Phillip Griffin (National Tuberculosis  
 Controllers Association)  
 Dr. Joe Goldenson (National Commission  
 on Correctional Health Care)  
 Dr. John Halpin (National Institute for  
 Occupational Safety and Health)  
 Mr. Warren Hewitt (Substance Abuse and  
 Mental Health Administration)  
 Dr. Michael Leonard, Jr. (Infectious  
 Disease Society of America)  
 Dr. Edward Nardell (International Union  
 Against Tuberculosis and Lung Disease)  
 Ms. Susan Perez (Treatment Action Group)  
 Dr. John Redd (Indian Health Service)  
 Mr. Dan Reyna  
 (HHS Office of Global Health Affairs &  
 the U.S.-Mexico Border Health  
 Commission)

Ms. Rachel Stricof (Association of  
 Professionals of Infection Control  
 and Epidemiology, Inc.)  
 Dr. Litjen Tan  
 (American Medical Association)  
 Dr. Lornel Tompkins  
 (National Medical Association)  
 Secretary Clemente Villalpando  
 (Mexico Section, U.S.-Mexico Border  
 Health Commission)  
 Dr. Theresa Watkins-Bryant (Health  
 Resources and Services Administration)

**CDC Representatives**

Dr. Kenneth Castro, DTBE Director  
 Mr. Gustavo Aquino  
 Dr. Lori Armstrong  
 Dr. Sapna Bamrah  
 Dr. Jose Becerra  
 Dr. Terence Chorba  
 Ms. Ann Cronin  
 Ms. Beverly DeVoe  
 Ms. Carol Friedman  
 Ms. Jennifer Han  
 Mr. Andrew Heetderks  
 Dr. Dolly Katz  
 Ms. Ann Lanner  
 Dr. Sundari Mase  
 Dr. Jerry Mazurek  
 Mr. Michael Melneck  
 Ms. Beverly Metchock  
 Ms. Tamara Miller  
 Dr. Patrick Moonan  
 Dr. Tony Moulton  
 Dr. Thomas Navin  
 Ms. Bonnie Plikaytis  
 Dr. Krista Powell  
 Dr. Drew Posey  
 Ms. Sandy Price  
 Ms. Margie Scott-Cseh  
 Mr. Daniel Stier  
 Mr. Phillip Talboy  
 Ms. Melisa Thombley  
 Mr. Paul Tribble  
 Dr. Elsa Villarino

Dr. Wanda Walton  
Dr. Jessie Wing  
Dr. Carla Winston

**Guest Presenters and  
Members of the Public**

Dr. Richard Brostrom (Commonwealth of  
the Northern Mariana Islands)  
Mr. James Elkins (Texas Department of  
State Health Services)

Ms. Kimberly Field (National Tuberculosis  
Controllers Association)  
Ms. Belinda Haerum (Association of State  
and Territorial Health Officials)  
Ms. Carol Poszik (National Tuberculosis  
Controllers Association)  
Mr. John Seggerson (STOP TB USA)  
Ms. Roylinne Wada  
(U.S. Department of the Interior)

## ATTACHMENT 2

Glossary of Acronyms

ADAP	AIDS Drug Assistance Program
AMA	American Medical Association
ART	Antiretroviral Therapy
ASTHO	Association of State and Territorial Health Officials
ASU	Administrative Services Unit
CGH	Center for Global Health
CIC	Citizenship and Immigration Canada
DHAP	Division of HIV/AIDS Prevention
DoD	Department of Defense
DSTDP	Division of STD Prevention
EOC	Emergency Operations Center
FOAs	Funding Opportunity Announcements
GAP	Global AIDS Program
GHESKIO	Haiti Group for the Study of Kaposi's Sarcoma and Opportunistic Infections
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
ID-TV/HIV	"Improving Diagnosis of TB in People with HIV" Study
IHS	Indian Health Service

IPT	Isoniazid Preventive Therapy
NCEZID	National Center for Emerging and Zoonotic Infectious Diseases
NCIRD	National Center for Immunization and Respiratory Diseases
NCMHHD	National Center on Minority Health and Health Disparities
NGO	Non-Governmental Organization
NMA	National Medical Association
OD	Office of the Director
OID	Office of Infectious Diseases
RDS	Rapid Diagnostic Service
SAMHSA	Substance Abuse and Mental Health Service Administration
SDH	Social Determinants of Health
SLDs	Second-Line Drugs
TCID	Texas Center for Infectious Disease
TDSHS	Texas Department of State Health Services
USPHLs	U.S. Public Health Laboratories
XDR-TB	Extensively Drug-Resistant TB

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**ADVISORY COUNCIL FOR THE ELIMINATION OF TUBERCULOSIS  
March 2-3, 2010  
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 2-3, 2010 in Building 8 of CDC's Corporate Square Offices, Conference Room A/B/C in Atlanta, Georgia.

**Opening Session**

Dr. Hazel Dean, Deputy Director of NCHHSTP and Designated Federal Official of ACET, called the meeting to order at 8:30 a.m. on March 2, 2010. She welcomed the attendees to the proceedings and particularly recognized Dr. Susan Dorman, a new ACET member. Dr. Dorman replaced Dr. William Burman, whose term expired on June 30, 2009. Dr. Dean noted that Dr. Dorman was unable to attend the meeting, but her biographical sketch was included in the meeting packets.

Dr. Dean highlighted other changes in ACET's membership. Dr. Charles Daley replaced Dr. Fred Gordin as the liaison to the American Thoracic Society. Lt. Jennifer Chang, *ex-officio* to the Division of Immigration Health Services (DIHS), is no longer with this agency. Efforts are underway to identify a new DIHS *ex-officio*. Ms. Kimberly Field is the President-elect of the National Tuberculosis Controllers Association (NTCA) and would replace Mr. Phillip Griffin as the NTCA liaison after the June 2010 ACET meeting.

Dr. Dean recognized the alternate *ex-officios* and liaisons who were attending the current meeting. Dr. Robert Benjamin would serve as the alternate liaison to the National Association of County and City Health Officials (NACCHO) for Dr. Robert Kim-Farley. Ms. Linda Danko would serve as the alternate *ex-officio* to the Department of Veterans Affairs for Dr. Gary Roselle. Dr. John Halpin would serve as the alternate *ex-officio* to the National Institute for

Occupational Safety and Health for Dr. David Weissman. Dr. John Redd would serve as the alternate *ex-officio* to the Indian Health Service for Dr. James Cheek.

Dr. Dean acknowledged two guest speakers, Ms. Roylinne Wada (U.S. Department of the Interior) and Dr. Richard Brostrom (Commonwealth of the Northern Mariana Islands), who would make follow-up presentations on TB control in the U.S. Affiliated Pacific Islands. Dr. Dean also noted that Ms. Belinda Haerum, of the Association of State and Territorial Health Officials (ASTHO), was in attendance.

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

Dr. Dean reminded the members that ACET made two suggestions during the October 2009 meeting to help the new "African American TB Elimination Strategy Workgroup" refine its charge. First, DTBE should be advised to implement ACET's previous recommendations whenever possible in addressing TB in the African American (AA) community. Second, DTBE should be urged to design research projects to identify barriers to making further progress in decreasing the gap in TB health disparities in the AA community.

In response to ACET's second suggestion, Dr. Dean pointed out that the July 2, 2004 edition of the *Morbidity and Mortality Weekly Report (MMWR)* included a paper entitled "Racial Disparities in Tuberculosis: Selected Southeastern States, 1991-2002." The paper was included in the meeting packets and stratified data by various demographic factors, including geographic area, gender and age.

Dr. Michael Fleenor, Chair of ACET, joined Dr. Dean in welcoming the attendees to the meeting. He noted that in response to ACET's previous suggestions, the agenda was modified to provide ACET with more time to discuss formal motions placed on the floor and give CDC more concrete guidance during the business session on the following day.

Dr. Fleenor opened the floor for introductions. Dr. Barbara Seaworth is an ACET member and the Medical Director of the Tuberculosis Education Center at the Texas Center for Infectious Disease (TCID). She conveyed that an overview of TCID's Southwest Regional TB Hospital in Texas would be presented during the meeting. Dr. Seaworth confirmed that she would refrain from voting if ACET placed any motions on the floor for this agenda item.

No other voting members declared any conflicts of interest for the record that were pertinent to the published agenda for the March 2-3, 2010 ACET meeting. The list of participants is appended to the minutes as Attachment 1.

## NCHHSTP Director's Report

Dr. Dean presented the update on behalf of Dr. Kevin Fenton, Director of NCHHSTP, who was unable to attend the meeting. At the agency level, Dr. Thomas Frieden, Director of CDC, recently announced several appointments to the Office of Director (OD) Leadership Team as part of CDC's organizational improvement.

Dr. Ileana Arias was named as the Principal Deputy Director. Dr. Janet Collins was named as the Associate Director for Program. Dr. Harold Jaffe was named as the Associate Director for Science. Ms. Donna Garland was named as the Associate Director for Communication. Mr. Andrew Rein was named as the Associate Director for Policy. Mr. William Nichols was named as the Chief Operating Officer. Dr. Kevin DeCock was named as the Director of the Center for Global Health.

Dr. Rima Khabbaz was named as the Deputy Director for Infectious Diseases. Dr. Robin Ikeda was named as the Deputy Director for Noncommunicable Diseases, Injury and Environmental Health. Dr. Steven Thacker was named as the Deputy Director of the Office of Surveillance, Epidemiology and Laboratory Services. Dr. Judith Monroe was named as the Deputy Director of CDC and Director of the Office of State, Tribal, Local and Territorial Support.

Recruiting efforts are underway to permanently appoint senior-level staff for the two remaining acting positions on the CDC OD Leadership Team: Director of the Office of Diversity Management and Equal Employment Opportunity and Director of the Office of Public Health Preparedness and Response.

The new Office of Infectious Diseases (OID) supports CDC's infectious disease activities. OID houses NCHHSTP, the National Center for Immunization and Respiratory Diseases (NCIRD), and the new National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) (reflecting the consolidation of the National Center for Preparedness, Detection and Control of Infectious Diseases and the National Center for Zoonotic, Vector-Borne and Enteric Diseases). National Center Directors in OID hold biweekly meetings to discuss cross-cutting issues.

CDC is continuing its active role in the U.S. government response to the devastating earthquake in Haiti. Most notably, CDC is closely collaborating with its sister agencies in HHS as well as other federal and international agencies to help communities in Haiti recover from the earthquake. As of February 23, 2010, 323 CDC staff members were engaged in the emergency response. Of these staff members, 23 were deployed to Haiti and 18 NCHHSTP staff members were participating in the response effort.

At the National Center level, Dr. Fenton recently announced two key changes in senior-level positions within NCHHSTP OD. Dr. John Douglas was named as the Chief Medical Officer and will assume this new position on March 22, 2010. Dr. Douglas's seven-year tenure as the Director of the Division of STD Prevention (DSTDP) will be invaluable in leading and enhancing NCHHSTP's involvement in planning for health reform, developing and strengthening

NCHHSTP's community prevention portfolio, and coordinating sexual health activities and other major cross-cutting health initiatives.

In his new role, Dr. Douglas will closely collaborate with NCHHSTP leadership, internal partners in other CDC centers, HHS operational divisions and other federal agencies to provide executive-level guidance to NCHHSTP. Dr. Kathleen Walsh will serve as the Acting DSTDP Director until a permanent replacement is appointed.

Dr. Stuart Berman, of DSTDP, was named as the Senior Advisor to the Director of NCHHSTP. In his new role, he will help to improve overall program performance by strengthening performance management, quality improvement and data integration across NCHHSTP. Dr. Berman also will spearhead activities for NCHHSTP's prevention priorities through health care.

Other key changes in NCHHSTP's organizational structure are outlined as follows. The Global AIDS Program (GAP) will be relocated from NCHHSTP to the new CDC Center for Global Health (CGH). However, the governance of GAP in terms of its existing structure, mission, programmatic relationships and budget will not be changed. The relocation of GAP will provide new and exciting collaborations as CGH is established.

The dissolution of the Coordinating Centers has resulted in staff being aligned back to NCHHSTP OD and divisions and four new teams joining NCHHSTP OD: the Informatics Team, Web Team, Communications Team from the National Center for Health Marketing, and Extramural Research Team.

Staff from the Coordinating Center for Infectious Diseases (CCID) Strategic Business Unit Teams that supported NCHHSTP has been realigned to NCHHSTP OD as the new "Administrative Services Unit" (ASU). The ASU Chief reports to the NCHHSTP Management Officer, but the ASU team structure has not changed due to business services the "High Performing Organization" is required to provide to CDC until the end of 2011.

The Board of Scientific Counselors (BSC) that was formed to advise the four National Centers in CCID will meet in May 2010 to discuss its future role and next steps. However, CDC leadership has informed the three National Centers in OID (*i.e.*, NCHHSTP, NCIRD and NCEZID) that no plans have been made at this time to disband the BSC due to the outstanding advice and valuable guidance the BSC provides to CDC.

NCHHSTP released its 2010-2015 Strategic Plan on February 26, 2010. The Strategic Plan articulates a vision, overarching goals and strategies to guide and enhance NCHHSTP's programs to prevent HIV/AIDS, viral hepatitis, STDs and TB. The Strategic Plan clearly states the NCHHSTP vision of "a future free of HIV, viral hepatitis and TB" and outlines the NCHHSTP mission to prevent, control and eliminate disease, disability and death from HIV, viral hepatitis, STD and TB in the United States and through global partnerships.

The Strategic Plan describes six priority areas for NCHHSTP to achieve its vision and mission: prevention through healthcare, program collaboration and service integration (PCSI), health equity, global health protection and systems strengthening, partnerships, and workforce

development and capacity building. Detailed explanations are given for specific goals under each of the six priority areas.

The Strategic Plan recognizes the dynamic interplay of factors that continues to drive HIV, viral hepatitis, STD and TB both domestically and globally. The Strategic Plan provides an overarching framework for NCHHSTP to develop and implement disease-specific prevention strategies; leverage opportunities to strengthen collaborations within and outside of CDC; and identify new, reinvigorated and productive partnerships.

NCHHSTP acknowledges the need for openness and flexibility while obtaining additional input, experience and perspectives on the Strategic Plan. Similar to the Strategic Plan, NCHHSTP also will publish its FY2009 Annual Report on the CDC website in the near future. The Strategic Plan was distributed to ACET in the meeting packets and also is available on the CDC website at [www.cdc.gov/nchhstp/publications](http://www.cdc.gov/nchhstp/publications).

CDC's FY2010 budget was signed into law on December 16, 2009. The domestic TB budget of \$144.3 million reflects an increase of \$398,000 over the FY2009 level, but funding remained relatively flat overall. The domestic HIV prevention budget received an increase of \$36 million to be allocated to the Expanded HIV Testing Initiative, PCSI, HIV surveillance and prevention with HIV-positive persons. The STD budget received an increase of \$1.5 million to expand efforts to prevent STD-related infertility. The viral hepatitis budget received an increase of nearly \$900,000 to identify persons with chronic viral hepatitis.

Dr. Kenneth Castro, Director of DTBE, noted ACET's concerns regarding the much smaller increase for TB in the FY2010 budget compared to NCHHSTP's other disease areas. He explained that CDC has no control or authority over funding directly appropriated by Congress.

Dr. Castro also responded to ACET's concerns regarding unintended consequences as a result of the relocation of GAP from NCHHSTP to CGH. He announced that he met with Dr. Kevin DeCock, Director of CGH, to explore strategies to maintain and improve the strong focus on global HIV-associated TB. Based on this discussion, Dr. Castro did not believe the relocation of GAP would lead to less emphasis or resources on TB globally. However, he confirmed that periodic updates on GAP's activities would be made during ACET meetings.

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

Dr. Castro covered the following areas in his update. From August 2009 to February 2010, 21 DTBE staff members were deployed to respond to and support CDC's novel influenza A virus (H1N1) activities. Estimates show that DTBE provided 615 cumulative full-time equivalent days for the fall/winter H1N1 response.

Similar to other parts of CDC, DTBE also has been engaged with the Department of Defense (DoD) and other federal partners in the public health response to the Haiti earthquake. DTBE established a "Haiti Desk" to coordinate communications among CDC, the Haiti TB Program,

Pan American Health Organization and other groups to provide guidance to first responders, states and persons returning from Haiti.

DTBE assignments for the Haiti response included Dr. Castro's one-week detail to the CDC Emergency Operations Center (EOC), the deployment of two staff members to Port-au-Prince, and the deployment of a DTBE Branch Chief to EOC in a leadership role. The World Health Organization (WHO) estimates that the TB case rate in Haiti is 306/100,000 compared to the U.S. rate of 4.2/100,000.

The "16<sup>th</sup> Meeting of the International Task Force for Disease Eradication" on January 12, 2010 included two major TB presentations. Dr. Andrew Hill, of DTBE, presented a mathematical model for projecting TB trends in the United States. The model illustrated a constant disease progression rate for foreign-born persons (FBP) and a decreasing disease progression rate for U.S.-born persons (USBP).

Dr. Hill emphasized three major points based on the mathematical model of TB trends in the United States. The prevention of progression from latent TB infection (LTBI) to TB disease is the most important determinant for TB elimination so long as TB control efforts are sustained in the United States. The model demonstrates that recruitment of LTBI into the foreign-born compartment implies no "disease-free equilibrium" based on a foreign-born endemic threshold of >1 per million even if all TB transmission stopped. TB elimination in the United States within this century will require new LTBI diagnostic tools and shorter and safer LTBI drugs or an effective vaccine, particularly among both current and newly settled FBP.

Dr. Hill described both short- and long-term plans to refine the mathematical model of TB trends in the United States. The model will be further calibrated. A glossary will be included to clearly describe epidemiologic concepts and parameters of the model. An age structure will be incorporated with data stratified by race/ethnicity. Factors related to heterogeneous mixing and re-infection will be explored. A cost-effectiveness analysis will be added.

The second TB presentation focused on the Cain, *et al.* study that was published in the *New England Journal of Medicine* in February 2010. The overarching goal of the "Improving Diagnosis of TB in People with HIV" (ID-TB/HIV) Study was to identify the best approach to TB screening and diagnosis in a cohort of 2,000 persons with HIV in Cambodia, Thailand and Vietnam. Each patient received the gold standard TB evaluation of culture of six to seven specimens. Standardized data were collected from the patient's medical history, including signs and symptoms of TB. CD4 testing, a complete blood count and chest radiography were performed on each patient as well.

Of the study participants, 15% had culture-confirmed TB. The sensitivity of chronic cough was 22%-33%. The sensitivity of a combination of cough or fever of any duration or night sweats for at least three weeks was 93% with a negative predictive value of 97%. The likelihood of TB was very low among HIV-infected persons who denied having cough, fever or night sweats in Cambodia, Thailand and Vietnam.

The key findings of the ID-TB/HIV Study are summarized as follows. Chronic cough should not be used as the sole basis for TB screening. Patients with none of the three symptoms can be safely started on isoniazid preventive therapy (IPT) and antiretroviral therapy (ART) if indicated. Scale-up of access to liquid culture or potentially other rapid diagnostic tests are urgently needed.

The ID-TB/HIV Study also resulted in major policy implications. CDC and WHO led a meta-analysis of screening studies in 2009 that confirmed the findings of the ID-TB/HIV Study in Southeast Asia. The outcomes of the CDC/WHO meta-analysis will result in a change to global policy within the next few months. Regional and country policies also have been modified or will be changed in the near future.

DTBE presented a study during the International Union Against Tuberculosis and Lung Disease Conference in December 2009. The four-year study evaluated six versus 36 months of IPT for HIV-positive persons in Botswana. The cohort included ~1,000 patients per study arm.

The key findings of the study are summarized as follows. Tuberculin skin test (TST)-positive/HIV-infected persons who received 36 months of IPT had a 92% reduction in TB compared to those who received six months of IPT. TST-negative persons did not appear to benefit from 36 months of IPT. ART was additive to IPT in preventing TB in all HIV-infected persons. No increase in incident isoniazid-resistant TB cases was observed.

DTBE submitted the Interferon Gamma Release Assay (IGRA) Guidelines to the *MMWR* copy editor for publication in the near future. The TB Trials Consortium is continuing three major studies. Study 30 is evaluating a single dose of linezolid for multidrug-resistant TB (MDR-TB). Although the study is nearing its conclusion in Durban, opportunities are being investigated to initiate this effort in other sites. Study 26 is evaluating a three-month regimen of isoniazid (INH)/rifapentine (RPT) for LTBI treatment. Analyses of the study are being planned and results are expected to be produced in late 2010 or early 2011.

Study 29 is evaluating the use of a daily RPT regimen in a phase 2 trial. Plans are underway to conduct a phase 3 trial of a daily RPT regimen to shorten the total duration of therapy. A collaborative pharmacokinetic study of a daily RPT regimen was initiated at Johns Hopkins. New collaborations between the TB Trials Consortium and AIDS Clinical Trial Groups sponsored by the National Institutes of Health (NIH) are being explored, but a partnership for Study 26 already has been formed.

DTBE developed a wide range of communication materials and educational resources in both English and Spanish for World TB Day on March 24, 2010. The materials include posters, e-cards, web graphical buttons, *MMWR* articles, a message box, and a data and statistics feature. All materials are available on the CDC website at [www.cdc.gov/tb/events/WorldTBDay](http://www.cdc.gov/tb/events/WorldTBDay). DTBE will host an event on World TB Day at the CDC Global Communications Center with Drs. Frieden, Fenton, Collins and Margaret Chan of WHO as the keynote speakers. The event will include a tour of the TB laboratory and a reception to commemorate the occasion.

DTBE will celebrate the 10<sup>th</sup> anniversary of the TB Education and Training Network in a joint conference with the TB Program Evaluation Network on August 10-12, 2010 in Atlanta. The theme of the conference will be “*TB Education, Training and Evaluation: Fitting the Pieces Together.*” Three HHS agencies (CDC, the Food and Drug Administration (FDA), and the National Institute of Allergy and Infectious Diseases) will co-sponsor a public workshop on June 7-8, 2010 in Silver Spring, Maryland to engage public and private partners in advancing the development of diagnostic tests and biomarkers for TB.

The workshop will respond to suggestions by the external peer review panel for the DTBE Mycobacteriology Laboratory Branch as well as recommendations by the Federal TB Task Force to develop strategies for expedited discovery, evaluation and implementation of diagnostic tests and biomarkers for TB. The goals of the workshop will be engage public and private partners, identify intellectual and procedural gaps, and explore models and strategies.

DTBE was involved in three field investigations from October 2009 to March 2010: an outbreak of MDR-TB in the Republic of Marshall Islands; a multi-state outbreak of eight TB cases with the same genotype pattern in Bureau of Prisons facilities; and a public health response to the unexpected decline in reported TB cases in multiple states in 2009.

Between 2008 and 2009, the reported TB case count decreased by 10.6% and the TB rate decreased by 11.4%. Decreases in reported TB cases included a 14.8% reduction in USBP and a 10.5% reduction in FBP. The substantial decrease represents the greatest reduction in

data to determine the potential for and specific factors related to underreporting of TB cases in 2009. However, a preliminary review has shown that the decline is approximately equal across U.S.-born whites, AAs and Hispanics.

ACET reiterated its longstanding request for an update on the reprinting of the Infection Control Guidelines errata. The members pointed out that DTBE still has not responded to this request to date. Dr. Castro clarified that DTBE completed and submitted the errata to the *MMWR*, but the documents are still in the publication queue at this time.

ACET advised DTBE to review re-infection data from the Botswana trial to consider the implications and importance of re-infection and disease progression in existing models.

### **Update on the Healthcare Infection Control Practices Advisory Committee (HICPAC)**

Ms. Rachel Stricof is the ACET liaison to both HICPAC and the Association of Professionals of Infection Control and Epidemiology, Inc. She described two major topics that are currently being addressed by both ACET and HICPAC.

For topic 1, HICPAC formed a workgroup to update the 1998 Healthcare Personnel (HCP) Infection Prevention and Control Guideline. The updated guideline will include three major

sections. The “baseline and routine practices” section will cover pre-employment immunization, annual screening and testing, booster and annual immunizations, and education. The “special HCP populations” section will cover immunocompromised and pregnant HCP. The “specific infectious diseases” section will cover TB, meningitis and pertussis.

The HICPAC workgroup identified potential research questions in four areas to inform the update of the 1998 HCP infection control guideline: respiratory protection for infections transmitted by the airborne route; the best method for screening for TB (*i.e.*, TST versus IGRA); best practices for pregnant HCP; and best practices for influenza immunization.

Because the updated HCP infection control guideline will link to existing guidance documents, HICPAC discussed the need for recommendations by ACET, the CDC Advisory Committee on Immunization Practices (ACIP) and other groups to be available in an electronic format. Most notably, HICPAC expressed a strong interest in reviewing ACET’s recommendations on guidelines for travelers as soon as possible. HICPAC agreed on the need to link or integrate its updated HCP infection control guideline to ACET’s guidelines for travelers.

The next steps for the HICPAC workgroup in updating the 1998 HCP infection control guideline will be to identify its full membership and external experts; search medical databases and websites for relevant guidelines and narrative reviews; and refine the potential research questions in collaboration with the University of Pennsylvania Health System Center for Evidence-Based Practice.

For topic 2, HICPAC expressed ongoing concern related to the implications of MDR-TB and extensively drug-resistant TB (XDR-TB) globally on infection control in the United States. Dr. Peter Cegielski is the Team Leader for Drug-Resistant TB in DTBE. His presentation to HICPAC during the February 2010 meeting covered the definitions of MDR-/XDR-TB, the global distribution of disease, data from the 2006 *MMWR* article on XDR-TB, and the 2006 Gandhi and Moll, *et al.* study that showed an extraordinarily high mortality rate of 98% from XDR-TB in KwaZulu-Natal, South Africa.

At the conclusion of Dr. Cegielski’s presentation, HICPAC agreed that the emergence of highly drug-resistant TB and the potential for transmission in U.S. healthcare settings would not require immediate changes to current infection control guidelines at this time. However, HICPAC confirmed that this issue would be periodically revisited to determine whether guidelines should be updated at some point in the future.

Dr. Castro announced that Dr. Dixie Snider, Senior Advisor to the Director of CDC, recently asked DTBE to provide subject matter expertise to the Division of Healthcare Quality Promotion in designing a clinical trial to evaluate a head-to-head comparison of N95 and surgical masks and appropriately perform a randomization scheme. Dr. Castro identified a number of DTBE experts to respond to Dr. Snider’s request.

Dr. Seaworth pointed out that the published literature has a lack of scientific data to guide recommendations regarding return-to-work practices or discontinuation of isolation for HCP with TB. Dr. Castro agreed with Dr. Seaworth that no data are available at this time to provide direct

evidence to support recommendations in this area. He raised the possibility of ACET asking HICPAC to conduct further research to obtain the most recent available data. For example, recent publications from San Francisco, British Columbia and the Netherlands suggest that smear-negative/culture-positive persons have been implicated as a source of prevalent TB cases at a rate of ~16%-17%.

Dr. Fleenor's position was that due to the lack of evidence on return-to-work practices or discontinuation of isolation for HCP with TB, ACET should discuss this issue in more detail at a future meeting. In the interim of ACET's follow-up discussion, Ms. Stricof confirmed that she would convey Dr. Castro's suggestion for HICPAC to conduct additional research in this area. She asked CDC to provide ACET with the current HCP infection control guideline in preparation of the discussion.

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

Dr. Drew Posey, of the DGMQ Immigrant, Refugee and Migrant Health Branch, reported on DGMQ's ongoing activities related to site visits to Haiti and China, implementation of the 2007 TB Technical Instructions (TBTIs) for immigrants and refugees entering the United States, and screening requirements for the use of culture and directly observed therapy (DOT).

The TB case rate of 306/100,000 is extremely high in Haiti compared to the U.S. rate of 4.2/100,000. Haiti is the seventh largest source country for immigrants to the United States and accounted for 15,127 immigrants and 1,180 asylees who were examined overseas prior to U.S. arrival in FY2008. Overseas screening with the 2007 TBTIs was initiated in Haiti on September 26, 2009.

Panel physicians with three private practices in Port-au-Prince are responsible for TB screening in Haiti. Two of the three panel physician practices perform DOT. The Haiti Group for the Study of Kaposi's Sarcoma and Opportunistic Infections (GHESKIO) is a non-governmental organization (NGO) that is responsible for cultures in Haiti.

DGMQ, DTBE and officials from Citizenship and Immigration Canada (CIC) conducted a joint site visit to Haiti on February 22-27, 2010. Canada receives 3,000 Haitian immigrants each year. The overarching purpose of the joint site visit was to evaluate panel physicians and assess their capabilities in order to continue using cultures and DOT in immigration screening in Haiti. During the joint site visit, CDC and CIC networked with the CDC country office, the National Tuberculosis Program (NTP) and the National Laboratory in Haiti.

CDC and CIC reached the following conclusions during the joint site visit in Haiti. The panel physician capabilities are intact in terms of physical structures, chest radiographs, serologic testing, vaccinations and capacity to meet volume demands. In terms of cultures, the GHESKIO laboratory was severely damaged in the earthquake.

Because no other culture facilities are available in Haiti, the panel physicians began shipping specimens to the panel physician laboratory in the Dominican Republic. A team was deployed on March 1, 2010 to assess the capacity of the laboratory and panel site operations in the Dominican Republic to handle the volume of specimens shipped from Haiti.

In terms of DOT, medications are readily available in Haiti and panel physician operations will continue. Collaborations with NTP will be maintained to ensure that U.S. TB regimens are used for Haitian immigrants applying for resettlement to the United States. Canada will begin requiring cultures and DOT based on the U.S. TB screening and treatment program.

With respect to the China site visit, China is the third largest source country for immigrants to the United States and accounted for 32,151 arrivals in FY2008. China also is the first largest source country for adoptees and accounted for 3,001 foreign adoptions in FY2009. In an effort to implement culture and DOT requirements, laboratories were established in Beijing, Fuzhou, Guangzhou, Jiangmen and Shanghai.

Australia, Canada, New Zealand and U.S. officials (with representation by CDC) will initiate an intergovernmental site visit to China beginning on March 3, 2010. The three non-U.S. countries are interested in using culture and DOT programs that have been implemented for the United States. During the site visit, the intergovernmental partners will meet with the China NTP to share data on TB rates and the origin of TB cases and also to foster collaborations by utilizing the laboratory network.

The Guangzhou International Healthcare Center and the Fujian Provincial Hospital are the two largest panel sites in China based on volume. DGMQ issued an update to the 2007 TBTIs in October 2009 with a set of indicators for panel physicians to use as a guide in routinely reporting data to CDC. The Guangzhou and Fuzhou sites used these indicators to report preliminary data to CDC.

Preliminary data from Guangzhou as of January 21, 2010 and preliminary data from Fuzhou as of February 26, 2010 showed that 4,549 persons were screened in Guangzhou and 1,847 persons were screened in Fuzhou. Laboratory results of 14 TB cases in Guangzhou showed a change from three smear-positive/culture-positive cases to eight smear-negative/culture-positive cases. The rate of culture-positive cases was 240/100,000 in Guangzhou and 110/100,000 in Fuzhou.

Preliminary data on drug susceptibility testing (DST) in Guangzhou and Fuzhou showed that most isolates were pan-susceptible. However, Guangzhou reported its first MDR-TB case as of January 21, 2010. DGMQ collected data to provide the China NTP with a map illustrating the cities of origin for TB cases that presented to the Guangzhou site.

DGMQ's implementation of the 2007 TBTIs currently represents 53% of immigrants and >50% of refugees from 27 countries. However, DGMQ will increase the reach of the TBTIs in 2010 to include Ghana, Guatemala, Nigeria, Nepal, India, Thailand, South Korea, Indonesia and Malaysia. Of all these countries, implementation of the TBTIs will have the largest impact in India.

DGMQ's training summit in India on January 13-15, 2010 was extremely successful with representation by 70 panel physicians. DGMQ's other major activities in 2010 will include panel physician training in Ghana on March 16-18, 2010 and in the Dominican Republic on May 3-5, 2010. DGMQ and DTBE will jointly sponsor the ACET/NTCA evaluation of the Vietnam TB Program in the summer of 2010.

The 2005 Schwartzman, *et al.* study was published in the *New England Journal of Medicine* and focused on TB control in the United States and overseas screening. The study emphasized that improvements in overseas screening for immigrants and refugees prior to U.S. arrival can have a significant impact. Overall, the 2007 TBTIs have played a critical role in the decline of TB in the United States. However, DGMQ recognizes the need to continue to share data, strengthen partnerships and establish new relationships to make further progress in TB control in source countries for immigrants and refugees.

ACET commended DGMQ on its extraordinary progress in implementing the 2007 TBTIs over the past three years. Several ACET members were particularly impressed that implementation of the TBTIs currently represents the majority of immigrants and refugees in over 25 countries. Other ACET members applauded DGMQ on its ambitious goal of implementing the TBTIs in nine additional countries in 2010.

### **Update on the Program Collaboration and Service Integration (PCSI) Initiative**

Mr. Gustavo Aquino is the Associate Director for Program Integration in NCHHSTP. He explained that a number of factors accelerated NCHHSTP's momentum in developing and implementing the PCSI initiative. HIV/AIDS, STD, TB and viral hepatitis are "syndemics" because these diseases have a synergistic interaction. HIV, STD and viral hepatitis share common risk factors in terms of modes of transmission. STDs increase the risk for HIV, while HIV is the greatest risk factor for progression to TB disease. The clinical course and outcomes of concurrent diseases can be deadly.

NCHHSTP's initial step in formalizing the PCSI initiative was to issue a green paper in 2007 to stimulate debate and launch a consultative process with a diverse group of internal and external partners. Following the release of the green paper, NCHHSTP convened an external consultation with ACET members and other key stakeholders at local, state and national levels to refine and expand the PCSI concept.

Based on extensive input from the consultative process, NCHHSTP published a PCSI white paper in December 2009 representing the collective viewpoints of NCHHSTP leadership and staff as well as local, state and national partners. The white paper serves as a CDC policy document that outlines a strategic vision for PCSI and clearly defines and articulates a framework to conceptualize PCSI.

Mr. Aquino summarized the definitions of PCSI. PCSI is a structural intervention to enhance the prevention and control of HIV/AIDS, STD, TB and viral hepatitis in the United States. PCSI is based on small changes in approaches to deliver services and offer the potential to maximize prevention opportunities. PCSI is a mechanism to organize and blend interrelated health issues, activities and prevention strategies to facilitate comprehensive delivery of services.

Mr. Aquino noted that NCHHSTP created PCSI with five core principles. The “appropriateness” principle ensures that the integration of prevention services is logical and appropriate from epidemiologic, programmatic and contextual perspectives. The “effectiveness” principle ensures that limited prevention resources will not be wasted on ineffective or unproven interventions and settings. Grantees will be advised to monitor the effectiveness of PCSI and track the yield of new diagnoses resulting from service integration.

The “flexibility” principle ensures that more effective settings or services are identified and an appropriate response is provided for new trends in disease epidemiology, changes in the demographics of target populations or advances in technology. For example, advances in HIV rapid testing and CDC’s new guidelines on routine HIV testing will have implications for HIV STD, TB and viral hepatitis clinical settings. The “accountability” principle ensures that capacity exists to monitor key aspects of combined prevention services. The “acceptability” principle ensures that PCSI is appropriately packaged to be accepted by diverse groups, including HIV/AIDS, STD, TB and viral hepatitis program staff, service providers and clients.

Mr. Aquino described the two components of PCSI that are intended to improve public health. “Program collaboration” is a mutually beneficial and well-defined relationship between two or more programs, organizations or organizational units to achieve common goals. “Service integration” is a distinct method of service delivery that provides persons with seamless services from multiple programs without repeated registration procedures, waiting periods or other administrative barriers.

NCHHSTP designed the service integration component of PCSI with three distinct levels. Level 1, “non-integrated services,” focuses on prevention, treatment or care services provided for a single condition (*i.e.*, HIV/AIDS, viral hepatitis, STD or TB) by a single program. Level 2, “core integrated services,” focuses on the integration of two or more CDC-recommended prevention, treatment or care services across HIV/AIDS, STD, TB or viral hepatitis infections. Level 3, “expanded integrated services,” focuses on the integration of multiple prevention, treatment and care services for HIV/AIDS, STD, TB and viral hepatitis into general health and social services.

NCHHSTP has made a strong commitment to PCSI and will explore opportunities across the HIV/AIDS, STD, TB and viral hepatitis program areas to implement naturally synergistic approaches to collaboration and wisely utilize resources. NCHHSTP plans to achieve this goal by applying data from the four individual epidemics to identify opportunities to intervene in the transmission of multiple infections.

NCHHSTP has informed its HIV/AIDS, STD, TB and viral hepatitis grantees that the PCSI white paper is a CDC policy document. As a result, NCHHSTP has strongly encouraged its grantees to take specific actions in five areas to implement PCSI. One, grantees should adopt PCSI as a

strategic imperative at the state, local health department, agency, clinic or unit level. Grantees should identify PCSI priorities for their individual jurisdictions. Two, grantees should obtain a clear political commitment to PCSI and PCSI-related activities at the local level.

Three, grantees should identify an appropriate senior organizational leader to serve as the “PCSI champion” at the local level. Grantees should form a PCSI Coalition with representation by the HIV/AIDS, STD, TB and viral hepatitis program areas, but substance abuse, corrections and other settings with similar target populations should be engaged whenever possible.

Four, grantees should assess and articulate strategies for PCSI to improve service delivery at the local level. In this effort, grantees should use available evidence to understand the intersection and overlap among HIV/AIDS, STD, TB and viral hepatitis in local populations. Moreover, grantees should increase their knowledge of ongoing collaborations and the extent to which integrated services are offered locally.

Five, grantees should support evidence-based practices in the adoption and implementation of PCSI and evaluate the impact of PCSI on behavioral and health outcomes for populations at risk for HIV/AIDS, STD, TB and viral hepatitis. Mr. Aquino informed ACET that additional details on PCSI are available at [www.nchstp/program\\_integration.shtml](http://www.nchstp/program_integration.shtml).

Mr. Warren Hewitt is the ACET *ex-officio* to the Substance Abuse and Mental Health Service Administration (SAMHSA). He described a key barrier at the federal level to truly achieving program collaboration and service integration. The White House Office of National AIDS Policy held several town hall meetings across the country to obtain input from national organizations and other stakeholders in developing the National HIV/AIDS Strategy.

One of the most frequent concerns expressed during the town hall meetings was that although CDC, SAMHSA and the Health Resources and Services Administration (HRSA) address the same target populations, community-based organizations are challenged by responding to different funding, data reporting and other requirements from the three HHS agencies. The stakeholders emphasized the critical need to eliminate regulatory or statutory barriers at the federal level to adopt a seamless approach and a common funding stream across all three HHS agencies.

Dr. Dean confirmed that she would convey Mr. Hewitt’s comments to Dr. Fenton due to his role as the CDC representative on the HHS Assistant Secretary for Health HIV Principal’s Group. Dr. Dean noted that SAMHSA is represented on this group as well.

Dr. Castro agreed with Mr. Hewitt’s comments regarding the difficulty in truly achieving program collaboration and service integration at the federal level. His position was that PCSI has been a “philosophically appealing” concept, but no concrete models with demonstrated effectiveness in collaborating programs and integrating services have been produced to date. Dr. Castro noted failures in previous PCSI efforts (*i.e.*, block grants domestically and programs in Malawi and Zambia internationally) due to an abandonment of outcomes and accountability. He indicated that HIV/AIDS, STD, TB and viral hepatitis programs should develop rigorous indicators to measure actual implementation of PCSI.

Mr. Griffin agreed with the remarks by Mr. Hewitt and Dr. Castro that virtually no changes or improvements have been made at the federal level in collaborating programs and integrating services since NCHHSTP introduced PCSI in 2007. From a TB perspective, he pointed out that one of the most significant challenges was the exclusion of TB from PCSI activities and the need for TB controllers to educate NCHHSTP divisions outside of DTBE about TB.

Mr. Griffin conveyed that NCHHSTP's recent funding opportunity announcements (FOAs) contain clear guidance to help grantees to implement PCSI. However, NCHHSTP has not fully embraced PCSI or increased internal collaborations and communications. Most notably, DTBE and the Division of HIV/AIDS Prevention still require grantees to report the same data in different formats with no increase in funding for the additional burden.

Mr. Griffin clarified that HIV/AIDS, STD, TB and viral hepatitis grantees in the field have a long and successful history of collaborating. However, he explained that NCHHSTP is making the overall PCSI process more difficult by issuing more guidance and requirements rather than engaging grantees as partners to simplify and streamline data reporting and other components of the PCSI process.

Mr. Aquino thanked Mr. Griffin for providing his valuable perspective from the field on PCSI. He offered to provide an update at a future ACET meeting on changes that have been made in collaborating programs and integrating services as a result of PCSI. For example, NCHHSTP issued newly integrated recommendations for partner services for HIV and STDs; new guidelines for integrating HIV in clinical settings; and an FOA to fund the integration of HIV in various settings. Dr. Fleenor confirmed that Mr. Aquino would be placed on a future ACET agenda for an update.

The ACET members made two key suggestions for NCHHSTP to consider in refining the PCSI initiative. First, NCHHSTP should develop and distribute a guidance document to grantees that provides clear direction on situations, settings or scenarios in which program collaboration or service integration would be necessary or appropriate.

Second, NCHHSTP should explore the possibility of identifying a staff member from the Division of HIV/AIDS Prevention (DHAP) to serve as an *ex-officio* to ACET. HIV/AIDS representation on ACET would enhance PCSI efforts and also would improve bi-directional communication between DTBE and DHAP. In the interim, NCHHSTP should respond to ACET's previous request to receive regular updates on the inclusion of TB screening as part of CDC's Expanded HIV Testing Initiative.

## Overview of NCHHSTP Health Equity Activities

Dr. Dean presented the overview on behalf of Dr. Kathleen McDavid Harrison, Director of the NCHHSTP Office of Health Equity, who was unable to attend the meeting. She reminded ACET of NCHHSTP's vision in the Strategic Plan, "a future free of HIV, viral hepatitis and TB," and the

NCHHSTP mission to prevent, control and eliminate disease, disability and death from HIV/AIDS, viral hepatitis, STD and TB in the United States and through global partnerships.

NCHHSTP identified health equity as one of six priority areas to achieve its vision and mission. This goal focuses on reducing health disparities in HIV/AIDS, viral hepatitis, STD and TB through three key objectives. Science will be advanced in identifying and eliminating health disparities by defining and pursuing a science-based approach. Partners and stakeholders will be mobilized to promote health equity and social determinants of health (SDH). Key SDH will be identified and addressed for programs to reduce health disparities. Appropriate plans will be developed and advanced to address SDH through NCHHSTP's scientific initiatives.

NCHHSTP uses two definitions to guide its health equity activities. CDC's operational definition of health equity is the fair distribution of health determinants, outcomes and resources within and between segments of the population regardless of social standing. The WHO Commission on Social Determinants of Health defined SDH as the range of personal, social, economic and environmental factors that determine the health status of individuals or populations.

In December 2008, NCHHSTP hosted the "Addressing Social Determinants of Health: Accelerating the Prevention and Control of HIV/AIDS, Viral Hepatitis, STD and TB" External Consultation. Four priority areas were identified during the consultation: policy, research and evaluation, data systems, and capacity building for prevention. Findings from the consultation helped to form an SDH strategy with clear goals, objectives and implications for NCHHSTP's activities in 2009 and beyond. Key recommendations from the consultation were incorporated into the NCHHSTP 2009-2015 Strategic Plan. The published consultation report is available on the CDC SDH website at [www.cdc.gov/socialdeterminants](http://www.cdc.gov/socialdeterminants).

Dr. Dean highlighted NCHHSTP's accomplishments in health equity in 2009. Dr. McDavid Harrison was hired as the Associate Director for Health Equity. The Office of Health Disparities was renamed to the "Office of Health Equity" to reflect the expanding U.S. and global role in the larger task of eliminating health inequalities within and between populations as well as inequities stemming from broader environmental, political and social contexts.

The CDC Social Determinants of Health Website was launched as an information source, point of contact and sharing portal for national and international stakeholders with an interest in addressing SDH. Two calls for papers were released for Public Health Report Supplements. The Public Health Reports special journal issue, *Addressing Social Determinants of Health in HIV/AIDS, Viral Hepatitis, Sexually Transmitted Diseases and Tuberculosis*, will be published in the summer of 2010. The second Public Health Reports special journal issue, *Use of Data Systems and Social Determinants of Health*, will be published in the summer of 2011.

An assessment of NCHHSTP's surveillance systems was completed to identify SDH variables that had been collected. The goal of this effort was to provide guidance throughout NCHHSTP on SDH measures to routinely monitor and identify linkages to data sets to obtain key SDH variables.

Dr. Dean described NCHHSTP's ongoing health equity projects. The *NCHHSTP 2009 Social Determinants of Health Activities Report* will be completed in the near future. A number of awareness-building products are being developed and will be included in the health equity communications plan. These resources include a glossary of terms regarding health equity and SDH; an SDH fact sheet with frequently asked questions; and a brief SDH and health equity training slide set. SDH and health equity language is being developed and will be included in future NCHHSTP FOAs. Statistical methods are being developed to model SDH using American Community Survey data.

An SDH white paper is being completed that will serve as an official set of science-based revise proposals for policy development to address disparities in HIV/AIDS, viral hepatitis, STD and TB. The white paper will include an SDH framework; program activities for targeting root and often ecological causes and disparities; and suggest methods to maximize the use of federal and other resources to reduce health disparities using an SDH framework.

The SDH white paper is organized into nine sections. Section 1 is the executive summary. Section 2 is the introduction and includes the objectives, summaries of the PCSI green paper and SDH External Consultation, definitions and a literature review. Section 3 describes the SDH approach and outlines the SDH rationale, framework and vision (*i.e.*, awareness, engagement and actions for SDH that are incorporated into NCHHSTP's daily policies, practices and activities).

Section 4 describes four components to incorporate the SDH approach into NCHHSTP's activities: research and science (*i.e.*, a research agenda and measurement guidance for surveillance systems); communication (*i.e.*, a comprehensive communications plan and an enhanced web presence); policy (*i.e.*, SDH language in FOAs and a prioritization of investments to reduce health inequities using SDH approaches); and programs (*i.e.*, structural and social determinants in prevention activities).

Section 5 describes activities for partners to consider, including research, communications, policy, programs, capacity building and partnerships. Section 6 describes monitoring and evaluation of SDH (*i.e.*, accountability measures to ensure that activities are conducted according to the SDH plan). Sections 7-9 are the conclusions, references and appendices.

Dr. Dean requested ACET's input on the draft outline of the SDH white paper, particularly section 4 (the plan to incorporate the SDH approach into NCHHSTP's activities) and section 6 (monitoring and evaluation of SDH). NCHHSTP plans to complete the document in July 2010. NCHHSTP intends to develop the white paper for state and local partners to tailor the document to meet their specific needs, but CDC has no additional resources at this time for implementation at the local level. However, NCHHSTP will provide technical assistance upon request. The draft outline was provided to ACET in the meeting packets.

ACET made two key suggestions for NCHHSTP to consider in refining its health equity portfolio. First, NCHHSTP should expand the key target audiences of the SDH white paper to include the American Medical Association (AMA) and other professional associations. These organizations could play an important role in widely distributing the white paper and leveraging social science

expertise on a broader national scale. For example, AMA, the National Medical Association (NMA), National Hispanic Physicians Association and >55 other national organizations serve on the Commission to End Healthcare Disparities. ACET advised NCHHSTP to collaborate with the Commission to identify synergies in ongoing and future health equity activities.

Second, NCHHSTP should carefully reconsider using the WHO definition of SDH as a framework to guide its health equity activities. Some members believed the definition is vague and does not reflect the importance of SDH. In response to this suggestion, Dr. Dean pointed out that an extensive body of research and documentation, models and other inputs provide a strong rationale for the development of the WHO definition of SDH. She offered to provide ACET with links to these documents.

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

Dr. Dolly Katz, of DTBE, reported on FBWG's progress in revising the 1998 "Recommendations for Prevention and Control of Tuberculosis Among Foreign-Born Persons." Data showed a large gap in TB case rates between USBP and FBP in the United States from 1993-2008. The most successful TB control strategies in the United States focus on recent transmission only, including early diagnosis and treatment of TB disease as well as screening and treatment of recently infected contacts. Minimal efforts to widely implement targeted testing and treatment of LTBI have played a major role in consistently higher rates of TB in FBP compared to USBP.

Due to the ongoing disparities in TB case rates, a new approach is needed for TB control in FBP. Most TB cases in FBP are due to reactivation of infection acquired prior to U.S. arrival rather than recent transmission. Moreover, the 6.9 million FBP with LTBI must be addressed to achieve TB elimination. The most important change between the 1998 and updated guidelines is the recommendation for every individual living in the United States who was born in a TB-endemic country to be screened at least once for TB.

Dr. Katz highlighted other key recommendations in the updated guidelines. Screening should be performed to identify cases of active TB earlier; provide treatment for LTBI and prevent future cases; and educate patients who are not treated. TB screening at least once of every individual living in the United States who was born in a TB-endemic country should be performed as part of routine health maintenance for persons seeking medical care in primary care settings.

Evidence suggests that IGRA is the preferred screening method for most FBP due to the higher specificity of this technology in persons who have received BCG vaccination. However, the current FBP guidelines recommend TST if a laboratory is not available to perform IGRA or the physician is not comfortable in using IGRA. FBP who should be treated for LTBI include recent arrivals who have lived in the United States for less than five years as well as FBP who are  $\leq 35$  years of age, live in institutional or congregate settings, or have diabetes, HIV/AIDS or other standard risk factors for disease progression.

For FBP with no standard risk factors, individual treatment decisions should be made based on a discussion between the physician and patient regarding the risks and benefits of preventive treatment and the likelihood of the patient completing treatment. For example, the physician should consider alcoholism, homelessness or visits to TB-endemic countries as factors in deciding whether to administer treatment.

If a decision is made not to administer treatment to FBP, the physician should educate the patient about the symptoms of TB, discuss the risk of developing disease, explain potential changes in the risk for TB if the risk profile of the patient changes, and document the patient's medical record with the reason treatment was not administered.

Dr. Katz described FBWG's next steps in finalizing the updated guidelines on TB prevention and control in FBP. Editing of the document will be completed and the supporting sections will be assembled. Revisions to the guidelines will be presented to ACET during the June 2010 meeting for review and input. The final draft will be submitted to the CDC clearance process in August 2010.

Dr. Katz noted that ACET was provided with a table on the number of FBP who entered the United States in 2006 by category and the contribution of each category of FBP to TB cases. The table illustrates that immigrants and refugees/asylees were screened for TB upon U.S. entry and accounted for 37% of TB cases among FBP in 2006.

By contrast, undocumented persons and FBP with temporary visas (*i.e.*, students, tourists, and FBP in the United States for business or work) were not screened for TB upon U.S. entry and accounted for 46% of TB cases among FBP in 2006. The table emphasizes the need to screen other categories of FBP for TB beyond immigrants and refugees/asylees. The table will be included in the updated guidelines. Other resources will be provided in the guidelines as well, including links to the TBTIs, guidelines on TB treatment and maps of TB-endemic countries.

Several ACET members made suggestions for FBWG and DTBE to consider in finalizing and disseminating the updated guidelines on TB prevention and control in FBP.

- The guidelines should provide recommendations on situations in which FBP should not be screened for TB (*i.e.*, those who have lived in the United States for more than five years, are older than 35 years of age and have no risk factors for TB).
- The guidelines should be distributed to the American Thoracic Society (ATS), American College of Chest Physicians and similar professional associations to ensure that the pulmonary community has an opportunity to review, provide input and endorse the document prior to broad dissemination.
- DTBE should extensively engage AMA, other professional associations, communities, academic institutions and other NGOs in outreach efforts. This approach will help to ensure that concrete guidance and resources are provided to the local medical community (*i.e.*, private providers, health departments and institutions) on appropriate steps to take when foreign-born patients test positive for TB or LTBI.
- The table on the contribution of specific foreign-born categories to TB cases should be revised to place the relative proportion or rate of TB in each foreign-born group in the

proper context. For example, FBP with temporary visas account for the vast majority of U.S. arrivals, but their relative contribution to TB cases is <20%. As a result, the current focus on screening immigrants and refugees/asylees for TB is appropriate.

Based on ACET's comments, Dr. Castro agreed that a plan is needed to widely disseminate the updated FBP guidelines to diverse target audiences for review, input and endorsement prior to publication in the *MMWR*. As a member of both ATS and the Infectious Disease Society of America, for example, Dr. Castro would distribute the guidelines to these organizations. DTBE would make efforts to engage HRSA-funded community health centers with large Asian and Hispanic patient populations as well as a host of professional associations, including AMA, NMA and the American Academy of Pediatrics.

### **Update on the Menu of Suggested Provisions for State TB Prevention and Control Laws**

Ms. Melisa Thombly, of DTBE, provided a status report on the menu of suggested provisions CDC developed for state TB prevention and control laws. In the summer and fall of 2009, CDC conducted research on TB prevention and control statutes and regulations in all 50 states, the District of Columbia and New York City. CDC created categories based on these research findings, the 1993 *MMWR* article on state TB control laws, and current issues in TB prevention and control. CDC reviewed and categorized TB control laws or general communicable disease control laws in each state, the District of Columbia and New York City.

CDC reorganized, modified and condensed the initial 136 pages of the menu to develop a rough draft of TB prevention and control provisions. The goal of this effort was to capture the types of provisions that might be considered as "best practices" for possible inclusion in state TB control or general communicable disease control codes and also to provide a continuum of optional provisions within each type.

On February 4-5, 2010, DTBE and the CDC Public Health Law Program held the "Developing a Menu of Suggested Provisions for State TB Prevention and Control Laws" Workshop. The purpose of the workshop was to develop a "Menu of Suggested Provisions for State TB Prevention and Control Laws" to assist U.S. states and localities in preventing and controlling TB.

The workshop participants included legal counsel to state and local health departments, TB program directors and staff, CDC staff from various operating units, NTCA, ASTHO and NACCHO. Prior to the workshop, the participants were asked to carefully review and analyze provisions found within each category in preparation of providing input to CDC regarding gaps, corrections or improvements to the proposed language.

CDC charged the workshop participants with providing input in response to three key questions: (1) Are the selected provisions in fact "best practices?" (2) Are any of the suggested provisions in the document inadvisable or unnecessary and should be deleted or modified? (3) Should

other types of provisions be included in the Menu? Over the course of the workshop, the participants reviewed and analyzed each section of the draft Menu, provided substantive input to CDC, and made a number of recommendations on revising the draft Menu.

The participants also discussed problematic issues experienced by TB programs in various states. Key discussion topics during the workshop included whether provisions should be in statutes, rules or regulations; refinement or modification of the reporting and due process sections; whether TB prevention and control measures should be implemented by administrative order or court order; whether resource limitations should be considered in the Menu; and inter-jurisdictional issues and transportation. CDC believed that the brainstorming sessions and substantive input provided during the workshop added tremendous value to the overall process of drafting the Menu.

Ms. Thombley conveyed that CDC is now requesting ACET's input on two of the three questions that were posed during the workshop: (1) Are any of the suggested provisions in the document inadvisable or unnecessary and should be deleted or modified? (2) Should other types of provisions be included in the Menu? Based on input from ACET and the workshop participants, CDC will revise the draft Menu, draft descriptive notes for each section, circulate the revised draft Menu to the workshop participants for final review, and produce and disseminate the final draft. CDC will make strong efforts to complete the final draft of the Menu by the NTCA meeting in June 2010.

Ms. Thombley informed ACET that a number of TB law-related resources are available on both the CDC and NTCA websites. These resources include the report on state TB control laws in 25 jurisdictions; *Tuberculosis Control Laws and Policies: A Handbook for Public Health and Legal Practitioners* and the companion PowerPoint slide set; *CDC Scenario-Based Assessment: Understanding and Sufficiency of State TB Control Laws* and the companion PowerPoint slide set and User's Guide; and the *Express Tribal TB Control Laws Report*.

ACET commended CDC on convening an outstanding workshop. Several members committed to providing Ms. Thombley with detailed comments on the draft Menu in writing. In the interim, other ACET members made suggestions for CDC to consider in revising the draft Menu.

- The Menu should be revised to include tribal health codes and provisions for Indian lands.
- The Menu might be confusing for state TB controllers because the document appears to serve as both a compilation of existing state laws and a model act. To minimize confusion, sources of the suggested provisions in the Menu should be identified. This approach would help TB controllers to obtain additional information from states and confirm that a suggested provision has been tested and vetted, particularly for provisions in the Menu CDC has modified.
- New language should be included at the beginning of the Menu to explicitly state that the document is a compilation of existing state laws and is not intended to serve as a model act or promote best practices.
- The Menu should be thoroughly reviewed to delete outdated practices or provisions that would be difficult for states to adopt. Examples of suggested provisions that should be

modified or deleted include: “Local health authorities shall transcribe from the original reports information necessary.” “Reports must be made by telephone.” “A written report shall be submitted.” “If a physician is not in attendance, it shall be the duty of the head of a private household to report.” The ACET members noted that local health authorities utilize electronic methods and no longer “transcribe” data from original reports. Many states provide local authorities with flexibility to report data by various methods other than by telephone or in a written format (*i.e.*, electronic or web-based reports). Most states would not implement a law requiring private citizens to report a suspected communicable disease if a physician is not in attendance.

- Correctional facilities should be included as an additional setting in item (B) of the “checklist of signs and symptoms” under the screening procedures section.
- Efforts should be made to include language in the Menu for “unresolved issues” at the local level. For example, one of the suggested provisions recommends committing a TB patient with a history of alcohol or other drug abuse for emotional health care or detoxification prior to TB treatment. However, most institutions would not act on this provision due to the potential infectiousness of the patient. Physicians are not given an opportunity to obtain culture and sensitivity information from specimens submitted to pathology laboratories. The possibility should be explored of requiring pathology specimens that resemble granulomas to be sent to microbiology laboratories.
- The Menu should reference CDC’s existing guidelines that recommend nucleic acid amplification testing (NAAT) as the standard of practice in certain defined situations.

### Update by the BCG Workgroup

Dr. Barbara Seaworth is an ACET member and chair of the workgroup. She reported that the Workgroup convened its last conference call on February 16, 2010. She provided an update on the Workgroup’s progress in developing the “TB Prevention and Control Measures for U.S. Health Care Workers and Volunteers Serving in High-Risk Settings for Exposure to *Mycobacterium Tuberculosis*” Guidelines.

ACET and ACIP published joint guidelines in 1996 on the use of BCG in the following situations: (1) prevention of TB in children continuously exposed to MDR-TB and (2) prevention of TB in HCP in the United States when a high percentage of TB patients are infected with MDR-TB; transmission of drug-resistant TB to HCP and subsequent infection are likely; and infection control measures are implemented, but are not successful in preventing TB transmission.

In 2008, ACET began considering the need to review and update the 1996 BCG vaccine guidelines due to a number of factors. TB epidemiology changed globally based on WHO estimates in 2007 of 500,000 MDR-TB cases, 50,000 XDR-TB cases, and only ~1% of cases treated in accordance with WHO standards. Through humanitarian efforts and university research programs, HCP, researchers, volunteers and students increasingly travel to and work in TB-endemic areas with the potential for TB exposure leading to LTBI and TB disease.

The incidence of MDR-/XDR-TB often is fueled by HIV. Implementation of infection control measures has been found to be inadequate or incomplete in high-risk settings overseas. Transmission of TB disease has been documented in healthcare facilities among both HCP and patients. The current availability of IGRA as a diagnostic tool for LTBI eliminates concerns regarding false-positive TST results due to BCG.

Based on its original charge from ACET to draft guidelines addressing BCG only, the workgroup planned to co-sponsor a meeting with ACIP in the spring of 2008. In June 2008, however, ACIP informed the workgroup of its lack of interest in supporting ACET's BCG guidelines due to the paucity of data. As a result, ACET modified the charge in March 2009 and advised the workgroup to broaden the scope of the guidelines and describe BCG as only one option for HCP and volunteers who travel to TB-endemic areas.

Dr. Seaworth highlighted the sections the workgroup has proposed to include in the guidelines:

- Overview of the current epidemiology of MDR-/XDR-TB.
- Information on humanitarian volunteers, HCP and other groups that travel to TB-endemic areas to work.
- A discussion of the risk for TB among HCP.
- Information on IGRA and its utility in the diagnosis of LTBI.
- Information on BCG vaccination as one of several proposed interventions (*i.e.*, an update on the risks and efficacy of the current BCG vaccine, information on obtaining BCG vaccine, and a detailed description on administering BCG vaccine).
- Guidance on the management of HCP and humanitarian volunteers at risk (*i.e.*, screening for *Mycobacterium tuberculosis (M.tb)* infection prior to travel, education, fit-testing with a personal respirator, infection control strategies in low-resource countries with suggestions on minimizing personal risk, BCG risks and benefits, and evaluation upon return to the United States with recommendations for LTBI treatment if newly positive by TST or IGRA and considerations to risk for exposure to drug-resistant TB.

Dr. Seaworth conveyed that the workgroup needs ACET's input in four key areas to continue revising and refining the guidelines.

1. What should be the strength of the BCG recommendations (*i.e.*, a "reasonable option" or "possibility")?
2. Should an industry representative be engaged as an external consultant to enhance the workgroup's knowledge of the ability to obtain and administer BCG vaccine? For example, the industry representative could provide the workgroup with information in the following areas: general availability of the Tice vaccine due to changes in ownership of the manufacturer, availability of the puncture device to administer the vaccine, and FDA approval of percutaneous delivery of the current Tice vaccine.
3. What is the best approach to address respiratory protection? For example, should the guidelines include a recommendation to "wear respiratory protection?"
4. What is the best approach to address management of LTBI due to presumed MDR-TB or XDR-TB? For example, should the guidelines include a recommendation to "seek consultation with an expert?" Should the 1992 *MMWR* article on ethambutol,

pyrazinamide and fluoroquinolones be included as possible treatment options as well as the need to follow patients from both clinical and radiographical perspectives for 24 months?

Dr. Seaworth pointed out that the draft guidelines were provided to ACET in the meeting packets. The workgroup will continue to edit and shorten the document to meet its target publication date of December 2010.

The ACET members made a number of comments and suggestions in response to Dr. Seaworth's request for input on the four questions.

- On the one hand, several ACET members believed BCG should be recommended as a "possibility" or a "reasonable option" due to the lack of evidence to support a "strong" recommendation. On the other hand, some ACET members believed BCG should be a "moderately strong" recommendation because uptake of the vaccine will be minimal if the guidance is diluted as a "reasonable option."
- The guidance document on MDR-TB treatment developed by the Francis J. Curry National Tuberculosis Center should be referenced in addition to the 1992 *MMWR* article on possible treatment options. The Curry Center document contains strong language on treating MDR-TB contacts.
- To provide more concrete guidance on question 4, a case-control study should be conducted to identify the number of MDR-TB cases among U.S. workers and volunteers abroad.
- A registry should be developed to collect data and perform surveillance on TB cases among U.S. HCP, volunteers and students who travel abroad to TB-endemic areas. The registry would serve as a valuable source of information for the future. However, roles and responsibilities for funding the registry as well as collecting and maintaining data should be clearly defined. To divide the costs of the registry, CDC could partner with the Department of Defense, employee health groups, or infectious disease and pulmonary fellows in medical schools to collect data, evaluate and monitor specific cohorts of persons who travel to TB-endemic areas.
- The "provision of BCG" section recommends administering BCG ~6 months before the onset of travel. The guidelines also should advise practitioners on actions to take when persons present for BCG vaccination less than six months prior to travel.
- The target audience of "students" should be clearly defined to clarify whether the guidelines are directed to medical students only or students at all colleges and universities who travel to TB-endemic areas for work or study.
- The guidelines should be revised to change the term "preventive therapy" to "LTBI treatment."
- The guidelines should provide recommendations on properly covering TB lesions with a bandage when travelers work in TB-endemic areas with high-risk populations.

Dr. Castro emphasized the need to implement a more systematic approach (*i.e.*, the "Grading of Recommendations, Assessment, Development and Evaluation" (GRADE) system) when ACET guidelines are developed. He explained that the GRADE system evaluates the evidence basis

for the strength of recommendations and could be utilized to resolve ACET's dilemma regarding the strength of evidence on BCG vaccination.

Based on the discussion, Dr. Castro noted that ACET reached agreement in the following areas. BCG should be described as only one option in the toolbox. The guidelines should explicitly state that BCG vaccination does not assume protection from TB. The contraindications of BCG vaccination should be clearly described, particularly for HIV-infected persons and cancer patients who travel abroad. Dr. Castro advised ACET to apply the underlying principles of the GRADE system to address the four questions posed by the workgroup.

Dr. Fleenor pointed out that although the discussion resulted in several useful suggestions, ACET did not reach consensus or general agreement on the four questions Dr. Seaworth posed. As a result, he confirmed that the four questions would be revisited during the business session on the following day for ACET to provide the workgroup with more concrete advice on the next steps in revising and refining the guidelines.

In preparation of the business session, Dr. Fleenor asked ACET to review the draft guidelines, consider the workgroup's request for input on the strength of the BCG recommendations, and make efforts to clearly distinguish between an "evidence base" and "expert opinion" for recommendations in the guidelines.

### **National Tuberculosis Controllers Association's (NTCA) Vision on Regionalization**

Mr. Phillip Griffin is the ACET liaison to and the President of NTCA. He reviewed several developments that led to the current focus on regionalization. Prior to 2008, the lack of support from CDC for hospitalizations and medication costs was a source of frequent frustration at state and local levels despite constant reminders that were issued on CDC's public health mission to "prevent." Moreover, conflicts arose around the unique role of TB prevention and control because treatment issues are a primary component of elimination goals.

In late 2007 and early 2008, DTBE requested NTCA's assistance in ACET's new Model Law Project and the Northeast TB Controllers submitted a Call to Action around regionalization issues, particularly hospitalization and patient care. To fulfill these charges, the Regionalization of Care Committee and TB Model Law Committee were formed. However, a number of issues were not clearly defined in these efforts, such as confining, paying for, transporting and placing a TB patient in another jurisdiction as well as addressing a vast array of different public health structures between different jurisdictions.

A decision was made to focus on legal issues first within the Model Law Project in an effort to resolve these challenges, but the new direction was problematic as well. Most notably, initial drafts of the Model Law Act were unacceptable because the authors appeared to have no interest in partnering with the public health community, ACET and other TB experts, and TB controllers in the field. As a result of these differences, the project was abandoned and converted to the "TB Law Menu" Project.

Because the change from the Model Law Project to the new TB Law Menu Project led to further delays, a decision was made to reconvene the Regionalization of Care Committee. However, the committee continued to struggle with identifying effective strategies to develop a system of regionalized care in light of multiple legal obstacles. As a potential resolution, Regional Training and Medical Consultation Center (RTMCC) representatives made a passionate presentation, issued a challenge to the broad TB community, and proposed a formal resolution during the National Tuberculosis Conference in June 2009.

The conference participants were challenged to take action in the following areas. Serious discussions should be held on mechanisms that will be needed to preserve the TB public health infrastructure. Resources that will be needed to perform TB control at local, regional or other levels should be determined. Existing resources, proper legal authority and available procedures should be identified to assure access to expert care for all persons. The possibility of the RTMCCs acting as a broker in this effort should be considered. Adequate funding for the TB public health infrastructure should be maintained, including the establishment of unique funding streams for particular threats to the public's health.

The following statements were articulated in support of the formal resolution. Improvements in TB control in the United States during recent years are a source of pride. Paradoxically, however, these improvements have reinforced inherent difficulties and frustrations in providing TB care. These frustrations have documented a well-known fact that despite exceptional TB control efforts, extraordinary efforts to eliminate TB disease not only will place great financial burden on the system, but also will invariably fail in 5% of TB patients.

The failure of TB elimination efforts in 5% of TB patients will pose a monumental challenge to state and local TB control programs. Domiciliary treatment as the only option is reluctantly acknowledged. The fact that 5% of TB patients invariably has no means of support for their care remains essential for the public good.

The conference participants were asked to endorse two components of the formal resolution: (1) the concept of a referral network to ensure access to expert care, including hospitalization in inpatient facilities where the most difficult 5% of TB patients can receive treatment and management of their disease and (2) a funding mechanism (*i.e.*, a Medicare waiver) recognizing the critical nature of such patient care to protect the public's health and seek to achieve cure for individual patients.

The formal resolution led to a great deal of discussion, debate and dissent among the conference participants due to the lack of preparation and forewarning, multiple unresolved issues, and concerns and dissatisfaction regarding the timing of the proposal. As a collective body, the conference participants ultimately did not pass or take action on the formal resolution. However, the conference participants agreed that actions would need to be taken and additional details would need to be addressed. This issue was presented to ACET during the July 2009 meeting and then deferred back to NTCA.

Mr. Griffin described NTCA's actions on regionalization since the July 2009 ACET meeting. NTCA renamed the "Regionalization of Care Committee" to the "Patient Care Committee" to focus on broader issues beyond regionalized care, such as specialized care, funding, access regardless of means or status, jurisdictional authority, and federal roles and responsibilities in regionalization.

NTCA broadened the narrow scope of "regionalized care" to its vision on "access to care for all TB patients." NTCA convened a consultation in September 2009 in Washington, DC with the National Association of State and Territorial AIDS Directors and RESULTS to explain the position on regionalization by the TB community, clarify TB-specific regionalization issues, obtain input on successes and challenges in regionalization by the AIDS community, and enhance collaboration between the TB and AIDS communities in regionalization.

During the consultation, NTCA articulated the most pressing issues the TB community is facing at this time: access to TB medications for MDR-/XDR-TB patients; provision of available and accessible specialized regional inpatient facilities for complex or non-adherent TB patients; maintenance of TB expertise and the public health infrastructure; the role of regionalization in healthcare reform; and the potential use of federal options across jurisdictional lines (*i.e.*, a Medicaid or Medicare waiver).

NTCA also discussed key topics during the consultation: development of the AIDS Drug Assistance Program (ADAP) as a potential model for regionalization; the need to locate a "second home" for TB in another HHS agency that has a mission focused on care and treatment; the need to obtain better estimates based on documented facts of the cost to treat MDR-/XDR-TB; the need to obtain better estimates on the percent of MDR-/XDR-TB cases compared to the percent of the budget required to care for this population; the need to develop and widely disseminate fact sheets to build advocacy efforts; the need to place a "foot in the door" and then expand efforts from this point; and effective strategies to overcome challenges or obstacles related to timing in the context of the national landscape of the economy.

NTCA is taking steps to address a number of issues to advance its vision on regionalization. Recruitment efforts are underway to replace the chair of the Patient Care Committee. However, TB control leaders across the country are extremely challenged in undertaking advocacy roles at this time due to declining resources. NTCA acknowledges that its vision on regionalization must be broad and attempt to strike a balance between persons who appear to have a special interest versus those who have less to gain, but fully understand the impact.

Regionalization issues will have universal impact regardless of morbidity, but differences between low-morbidity and high-morbidity areas must be recognized. Flexibility must be a key component of regionalization as well. An appreciation of multiple models of care is essential. The "whole patient" must be the center of any discussions on regionalization.

Mr. Griffin summarized NTCA's future actions to advance its vision on regionalization. Mr. Griffin was appointed as the new chair of the Patient Care Committee. He will initiate strategy sessions, but his responsibilities in this position will be limited until after he completes his tenure as the NTCA President over the next two months.

NTCA will create fact sheets on the needs of regionalization by collecting data to develop state profiles; gathering information to identify “Centers of Excellence” in collaboration with the RTMCCs; and obtaining cost estimates of regionalization based on research or well-documented studies. The first arm of the strategy will be to approach HRSA to seek a funded second-line stockpile of medications that would be accessible through programs as a resource of last resort.

NTCA will continue partnering with the Advocacy Committee to seek full funding of the Comprehensive TB Elimination Act of 2008. NTCA will meet with Dr. Howard Koh, Assistant Secretary of HHS, after requests for the second-line stockpile of medications have been formulated and refined with a strong basis. NTCA will solicit partnerships with drug companies similar to those that were established for ADAP. The Treatment Action Group will be asked to assist NTCA in making comparisons to 340B pricing.

NTCA will strengthen collaborations with partners in Washington, DC to increase its visibility. NTCA will approach Dr. Seiji Hayashi, Chief Medical Officer for the HRSA Bureau of Primary Health Care, to explore the development and implementation of pilot projects with community health centers to compensate for the decay in the public health infrastructure.

Overall, regionalization is an extremely complex issue. Limited resources, the economic recession and Congressional challenges are severely impacting progress. The vast majority of regionalization activities are being conducted on a voluntary basis. Many TB leaders across the country may be unable to participate in regionalization activities until state statutes or policies are changed. Centers of Excellence are sound concepts, but efforts to remain patient-focused and consider multiple cultural issues increase challenges.

Mr. Griffin confirmed that he would make periodic updates to ACET on NTCA’s progress in advancing its vision on regionalization. For bi-directional communication, he raised the possibility of an ACET member serving as a liaison to the Patient Care Committee. Dr. Seaworth volunteered to represent ACET on the Patient Care Committee, but she asked whether her position as the Medical Director of an RTMCC would serve as a conflict of interest.

Dr. Fleenor explained that because Dr. Seaworth would provide regular reports to ACET and would not make recommendations on ACET’s behalf, her role in an RTMCC would not serve as a conflict of interest. Mr. Hewitt also volunteered to serve on the Patient Care Committee.

ACET applauded NTCA on its vision to provide access to care for all TB patients and its approach to the complex issue of regionalization. Several ACET members suggested additional partners for NTCA to engage in this effort and proposed other actions to assist NTCA in making progress on regionalization.

- NTCA should include state and local health departments as additional partners in its vision on regionalization.

- NTCA should ask CDC to identify facilities across the country that can serve as Centers of Excellence in addressing the 5% of TB patients who are most difficult and complex to treat.
- NTCA should contact Dr. Kyu Rhee, Chief Public Health Officer of HRSA, due to his strong interest in issues related to regionalization.
- NTCA should make efforts to better understand the different cultures and structures of various federal agencies to leverage a broad range of expertise. For example, the focus on cultural competency, low English proficiency and TB stigma by a number of HRSA bureaus could be valuable in advancing NTCA's vision on regionalization. SAMHSA's current activities with the same patient populations as CDC and HRSA could be helpful in regionalization efforts as well.
- NTCA's vision on regionalization should take into account the burden of undocumented persons and other foreign-born groups on TB caseloads across the country.
- NTCA should continue to closely partner with the RTMCCs to ensure that medical consultation is provided for the management of TB patients in communities.
- NTCA should explore the possibility of developing "regionalized" partnerships based on drug resistance. For example, patient populations with drug resistant-TB and STDs would be similar.
- NTCA should collaborate with the American Hospital Association to collect survey data on hospitals that would be willing to devote beds to complex or non-adherent TB patients.
- NTCA should outreach to private foundations to leverage funding for regionalization in a public-private partnership. For example, Kaiser and the Robert Wood Johnson Foundation are strong proponents of patient populations with important risk factors for TB (*i.e.*, HIV and substance abuse).
- NTCA should carefully consider the problems with regionalization, particularly in rural areas or small states. Most notably, the isolation of TB patients in another jurisdiction or state disrupts families. Moreover, hospital staff members in the treating jurisdiction typically have no knowledge of available support systems for ambulatory care in the source community.

Dr. Castro emphasized the need to demonstrate a compelling case for developing a funding source for TB care and treatment that would be similar to the Ryan White Care Act for HIV/AIDS care and treatment. He advised NTCA to solicit guidance from Timothy Westmoreland due to his instrumental role and expertise during the resurgence of TB.

Dr. Dean encouraged NTCA to form partnerships with non-traditional groups, such as the NIH National Center on Minority Health and Health Disparities (NCMHHD). The TB patient population would be consistent with NCMHHD's mission to reduce health disparities in minority communities. NCMHHD also funds Centers of Excellence. Dr. Dean further advised NTCA to approach Dr. Garth Graham, Deputy Assistant Secretary for Minority Health in the HHS Office of Minority Health, to explore synergies in regionalization between the two groups.

## Overview of the New Texas Center for Infectious Disease (TCID)

Mr. James Elkins is the Hospital Director of the Texas Department of State Health Services (TDSHS). He provided an overview of the new TCID that will achieve TDSHS's vision of establishing a Southwest Regional TB Hospital in Texas. Mr. Elkins began his presentation by showing a series of photographs illustrating both the old and new TCID facilities.

TCID will serve as a "virtual" hospital for San Antonio, Tyler and other hospitals in Texas. New construction, fees and renovations to existing buildings totaled \$34 million. The cost to build the new 60,000-square foot patient care facility totaled \$26.7 million. TCID's annual operating budget is \$9.7 million. All patient care furnishings and equipment in the new TCID facility will be new. The Texas Constitution requires counties to bear the costs for care and treatment of patients.

TDSHS is exploring the possibility of acquiring a recreational vehicle for TCID to assure air quality and avoid paying for a motel room or air transportation when moving TB patients. Fences around the new TCID facility control access to the campus and are not necessarily intended to confine patients to an area. Each patient room in the new TCID facility is private, large, air-isolated to 12 air changes per hour, and has a private toilet and shower.

Energy conservation measures are installed in utility systems. Four day rooms, large televisions, a walking trail and outside patios are fenced for patient use. The recreation, radiology, physical fitness, laboratory, cardiopulmonary care and dining rooms are in one of three other contiguous buildings on the campus.

TCID is authorized to treat persons with a proven diagnosis of complicated TB. TCID patients are persons with the most complicated TB cases identified through referral sources. TCID treats 4%-6% of patients with TB in Texas who are unable or unwilling to be managed in the community and whose hospitalization is indicated for the two-month to two-year duration indicated to cure disease.

TDSHS provides a variety of services to TCID patients other than medical care. A psychologist, substance abuse counselor and social workers are available to patients during the period of treatment. For patients with an interest in obtaining their general educational development diplomas, TDSHS has reached agreements with community programs to provide this service. Patients who participate in the work program on the TCID campus are paid for their work. TDSHS also has reached agreements with employers for patients who are employed to continue working during the course of care and treatment.

TCID serves as a resource to accept patients from other states. TCID is accredited by the Joint Commission and certified by Medicare as a long-term acute care hospital. However, more acute services are contracted. TCID is the designated hospital for court-ordered/quarantined TB treatment for cases in which a patient's non-adherence to TB medication regimens has proven to be a threat to public health or safety. TCID is one of four clinics in Texas that is

contracted through TDSHS and the U.S. Public Health Service to treat patients for Hansen's disease.

State legislation provides TDSHS with authority to enter into an agreement with an agency of another state that is responsible for the care of residents with TB in the other state. The legislation further states that residents of the other state with TB may be admitted to a state chest hospital subject to the availability of appropriate space after the needs of eligible TB and chronic respiratory disease patients who are residents of Texas have been met. The other state is responsible for paying all costs of hospitalization and treatment of patients admitted under the agreement at the current rate of \$965 per day.

Mr. Elkins announced that the new TCID facility would begin operations in July 2010. He confirmed that TDSHS would make efforts to collect and publish data on the experiences, lessons learned, outcomes and best practices of the new TCID. He invited ACET and DTBE to attend the ribbon-cutting ceremony for the new TCID facility in August 2010.

ACET congratulated TDSHS on achieving its vision of a Southwest Regional TB Hospital in Texas with the establishment of the new TCID facility. Several ACET members hoped "TCID-like" facilities would be built in other parts of the country for wider delivery of services for complex or non-adherent TB cases.

### **Update on the DTBE Laboratory Flagship Project**

Ms. Bonnie Plikaytis is the Acting Chief of the DTBE Mycobacteriology Laboratory Branch (MLB). She provided an update on the DTBE laboratory flagship project for the rapid detection of drug-resistant TB in high-risk persons. The three components of the project are rapid diagnostic service (RDS) for U.S. public health laboratories (USPHLs); evaluation of RDS; and point-of-care molecular testing in conjunction with U.S.-Mexico binational TB control projects.

Of the three components of the project, MLB is responsible for judiciously providing RDS to USPHLs. RDS will be targeted to "high-risk patients" defined as persons previously treated for TB, persons with contact with a known drug-resistant case, or persons who remained culture-positive after three months of treatment. MLB also will provide RDS on a case-by-case basis. RDS will be available for NAAT-positive specimens and molecular testing for INH and rifampin resistance. The targeted turnaround time for MLB to issue a report will be two days from receipt of the specimen. MLB will initiate a reflex protocol for culture followed by first- and second-line DST for specimens that are found to be positive for TB.

To provide USPHLs with RDS, MLB will follow the successful model of the TB Genotyping Program. MLB selected the RDS platform based on the following criteria: sensitivity and specificity, scalability, ease of implementation, and the amount of information obtained from the assay. Based on these criteria, MLB considered three platforms: molecular beacons, high resolution melt analysis with nucleic acid probes and DNA pyrosequencing.

MLB extensively reviewed the advantages and disadvantages of all three options and ultimately selected DNA pyrosequencing as the RDS platform. MLB's review showed that molecular beacons and nucleic acid probes met only one of six criterion, while DNA pyrosequencing met five of six criteria: good predictive values for resistance, capacity to know exact mutations, the absence of false-positive results due to silent mutations, the ability to easily add additional loci for more drugs, and cost-effectiveness. However, FDA has not approved commercial assays for molecular beacons, nucleic acid probes or DNA pyrosequencing.

After selecting DNA pyrosequencing as the RDS platform, MLB established a timeline for implementation. In the spring of 2010, instruments and supplies will be acquired, protocols and algorithms will be developed, and select USPHLs will be engaged to obtain specimen sediments to be utilized for development and validation. In the summer of 2010, MLB will train personnel on use of the instruments and develop assays.

In the fall of 2010, MLB will validate the assay and develop standardized language for data to be reported to CDC. In early 2011, MLB will offer RDS to USPHLs to be utilized by the TB control programs. In the future, MLB anticipates issuing a competitive FOA for the selection of one or two USPHLs to prepare for the establishment of regional services in early 2012.

ACET made two key suggestions for MLB to consider in providing RDS to USPHLs. First, MLB should explore the possibility of allowing states to submit specimens to laboratories that perform both genotyping and RDS. A "one-stop" source would be extremely beneficial to states. Moreover, states have well-established relationships with their genotyping laboratories.

Second, MLB should develop a plan for USPHLs to prioritize the processing of specimens in order of most to least importance. This approach will help USPHLs control requests submitted by TB controllers, laboratories and other groups. In response to this suggestion, Ms. Plikaytis confirmed that a clear protocol for shipping specimens will be developed similar to the services MLB provides for TB isolates. Instructions on the types of specimens that will be eligible for RDS will be provided as well. RDS as well as its usage and impact will be rigorously evaluated as part of the laboratory flagship project.

With no further discussion or business brought before ACET, Dr. Fleenor recessed the meeting at 5:15 p.m. on March 2, 2010.

### **Update on TB Control in the U.S.-Affiliated Pacific Islands (USAPIs)**

Dr. Dean reconvened the ACET meeting at 8:32 a.m. on March 3, 2010 and yielded the floor to the first presenter.

A panel of DTBE staff and guest speakers presented a series of updates on ongoing TB prevention and control efforts in the USAPIs. The updates are summarized below.

**Dr. Richard Brostrom** is the Public Health Medical Director of the Commonwealth of the Northern Mariana Islands (CNMI) Department of Public Health. He presented 2009 data to illustrate the TB burden in the USAPIs. Chuuk accounted for 25 of 38 MDR-TB cases. Of 422 contacts, Ebeye accounted for 173, Chuuk accounted for 121, Majuro accounted for 106, Guam accounted for 12 and Pohnpei accounted for 10.

Chuuk, Majuro and Guam accounted for 363 of 421 TB cases in the USAPIs in 2009. The TB case rate ranged from 59-421/100,000 in Guam, Pohnpei, Ebeye, Chuuk and Majuro. The number of cases reported in 2009 reflected an extremely high TB burden in the USAPIs, but underreporting was still a major issue based on data submitted for the CDC Epi-Aid investigations.

**Dr. Krista Powell**, of DTBE, described the federal response to MDR-TB in the Republic of the Marshall Islands (RMI). In April 2009, CDC and its USAPI partners conducted a TB program review in RMI that revealed an outbreak of six MDR-TB cases since 2004. In August 2009, the RMI Ministry of Health requested onsite epidemiologic assistance from CDC to investigate the MDR-TB cases. Limited resources to conduct contact investigations of the MDR-TB cases and an inadequate supply of second-line drugs (SLDs) to treat these cases severely limited RMI's response capacity.

In October 2009, a joint CDC/WHO Epi-Aid Team joined the investigation in RMI and learned that 10 confirmed and suspected MDR-TB cases had occurred since 2004. At the start of the investigation, no patients had completed adequate treatment for MDR-TB. Of the 10 cases, two patients with active TB are undergoing adequate treatment at this time, nine patients had diabetes, and five patients without epidemiologic links received previous TB treatment, indicating acquired resistance. RMI is a vulnerable region that will play a critical role in the growing emergence of MDR-TB without improvements in TB control. However, the full burden and trends in the epidemiologic curve of MDR-TB in RMI are uncertain at this time.

The ongoing contact investigation revealed no additional cases, but only 43% of 279 contacts identified have been evaluated to date. Of 119 contacts that were evaluated, 36 (or 30%) had positive TST results. At this time, 20 household contacts reside in the United States. The work burden of the contact investigation was enormous because each patient averaged 60 household contacts due to overcrowding.

Dr. Powell described actions that have been taken following the MDR-TB investigation in RMI. CDC, the U.S. Department of Interior (DOI) and other partners allocated funding to RMI to hire additional staff to provide DOT, effectively treat MDR-TB cases, and conduct contact investigations of all smear-positive and MDR-TB cases. The RMI government demonstrated a political commitment to TB control by changing public health laws to restrict free travel of persons with infectious TB.

CDC made two additional site visits to RMI to continue providing onsite technical assistance for active case-finding. CDC funded a two-year operational research project to conduct active surveillance of contacts of MDR-TB cases and follow patients who received treatment for drug-resistant infection. CDC is continuing its collaborations with WHO and other USAPI partners for

capacity-building in RMI. DOI sustained political support for TB control in the USAPIs by allocating \$1.4 million to the MDR-TB response in RMI.

**Dr. Sapna Bamrah**, of DTBE, described the federal response to MDR-TB in the Federated States of Micronesia (FSM). After the incident case of MDR-TB was identified in Chuuk, FSM in December 2007, CDC was asked to conduct an Epi-Aid investigation in April 2008 due to the discovery of four MDR-TB cases that resulted in three deaths.

Of 11 additional cases identified in 2008, five patients were deceased and six patients were being treated with FSM's first supply of SLDs in a newly-constructed isolation ward with nine beds. Before LTBI treatment could be administered to contacts identified during the investigation, 10 additional MDR-TB cases were diagnosed and admitted to the new isolation ward to begin therapy with SLDs. At that time, a 12-month DOT regimen was administered to 75 contacts to treat LTBI.

Of 27 MDR-TB cases that were identified in Chuuk from 2007-2009, seven patients are deceased and 20 are currently receiving treatment with SLDs. One of the 20 patients admitted to the isolation ward to begin therapy is a general medical ward nurse who was caring for an acid-fast bacilli-smear/culture-positive patient who was later diagnosed with MDR-TB. MDR-TB treatment of patients in the first cohort will be completed in six months.

The epidemiologic curve of MDR-TB is beginning to decline, but the Chuuk TB staff will continue to address both existing and new patients for quite some time. By comparison to U.S. states, the number of MDR-TB cases in Chuuk was second to California in 2008 and fourth to California, Florida, New York and Texas based on more recent preliminary data.

The number of pan-susceptible TB cases in Chuuk is increasing as well. Most notably, TB treatment of 153 cases in Chuuk in 2009 reflected a 28% increase from 2008 due to improved surveillance, the presence of TB staff and DOT workers in the community, and stronger trust and rapport within the TB program.

Dr. Bamrah described actions that have been taken following the MDR-TB investigation in Chuuk. Chuuk achieved its first priority to improve overall TB care by providing DOT to 100% of all active MDR-TB and pan-susceptible TB cases. CDC, DOI and other partners allocated funding to Chuuk to hire additional staff to administer and assure adherence to DOT; admit 20 MDR-TB cases to the new isolation ward to begin an effective nine-month treatment regimen; and provide 12 months of DOT to treat LTBI in patients at most risk for developing MDR-TB. As of January 2010, 82 patients had completed the 12-month DOT regimen.

CDC made >10 additional site visits to Chuuk to continue to provide onsite technical assistance for active case-finding and LTBI treatment. CDC funded an operational research project to conduct active surveillance of contacts of MDR-TB cases and follow patients who received treatment for drug-resistant infection. CDC also funded a pharmacokinetic study on the use of fluoroquinolones in the treatment of contacts.

CDC is continuing its collaborations with WHO and other USAPI partners for capacity-building in Chuuk. DOI sustained political support for TB control in the USAPIs by allocating \$1.9 million to the MDR-TB response in FSM. These efforts have led to TB medical staff in Chuuk and other providers across the region increasing their knowledge of MDR-TB and sharing lessons learned.

**Ms. Roylinne Wada** is the Field Office Manager for the DOI Office of Insular Affairs. She reported that DOI allocated Compact funding to support the MDR-TB outbreak responses in RMI and Chuuk, FSM. The special one-time funding is in addition to operating grants DOI awards to RMI and FSM and will be available until expended. For the MDR-TB outbreak responses, DOI awarded a \$1.9 million grant to Chuuk, FSM in October 2008 and a \$1.4 million grant to RMI in February 2010. A portion of the \$1.4 million grant to RMI will be allocated to assure adherence to DOT and strengthen primary and secondary care.

DOI acknowledges that special Compact funding will not be a reliable source for future TB control efforts in the USAPIs. The prospect for continued availability of these funds is dim because DOI takes \$600,000 each year from annual financial assistance and deposits these dollars into trust fund accounts for the country. Moreover, inflation adjustments that DOI returns to countries are not substantial and account for the only “new” dollars awarded.

Special Compact funding for the MDR-TB outbreak responses reflects dollars that were redirected from other areas rather than new funds. For example, DOI was required to de-obligate funds, defer planned infrastructure projects for health and education, or decrease funds in other sectors supported by the Compact. DOI’s position is that a better solution would be to champion and support sustainable improvements in prevention and control infrastructure and management systems.

Ms. Wada explained that Chuuk’s annual operating budget of ~\$8.4 million covers a population of ~54,000 persons, while RMI’s annual operating budget of \$16 million covers a population of ~53,000 persons. DOI will integrate some costs for TB staffing into the regular budgets of Chuuk and RMI. This strategy will allow Chuuk and RMI to fund nurses, DOT workers, contact tracers and a physician for one year, but funds from local sources will need to be identified thereafter. Alternatively, Chuuk and RMI will need to incorporate these services into their existing budgets.

Dr. Castro emphasized the need to thoroughly review microbial virulence studies to address the unusually high attack rate in persons with confirmed MDR-TB in the USAPIs. He also advised the USAPI partners to collaborate with the CDC Division of Diabetes Translation, particularly since nine of 10 MDR-TB cases in RMI had diabetes as an underlying or concurrent condition. This partnership could be used to conduct research to demonstrate that diabetics in extremely poor communities in the USAPIs are immunocompromised for TB.

ACET commended CDC, DOI, the Chuuk and RMI TB programs, and other partners in their outstanding TB prevention and control efforts in the USAPIs, particularly in light of extremely limited resources.

Dr. Fleenor noted that Dr. Brostrom was scheduled to conclude the panel presentation by requesting ACET's formal action on a series of proposed resolutions to address important TB prevention and control issues in the USAPIs. Due to time constraints, Dr. Fleenor confirmed that the business session would be modified for Dr. Brostrom's presentation and ACET's deliberations on the proposed resolutions.

## Overview of the CDC/DTBE Response to the Haiti Earthquake

**Mr. Paul Tribble**, of DTBE, reported that the massive earthquake in Haiti on January 12, 2010 reflected the worst destruction in the history of the Port-au-Prince area. The Haiti government currently estimates that the earthquake resulted in 222,5000 deaths, injuries to 300,000 persons and displacement of >1 million persons. The public health infrastructure was severely damaged based on the complete destruction or major damage to buildings housed in the National TB Program (NTP) and the National Public Health Laboratory.

CDC received an initial report stating that TB laboratory equipment, reagents and supplies in Haiti were destroyed, but follow-up reports confirmed the supply of TB medications and TB case registers were intact. However, the earthquake resulted in the interruption of treatment to >7,000 TB patients in Haiti.

Mr. Tribble was assigned as the DTBE point of contact to the Haiti response with assistance from Vidya Venkataramanan. The CDC Emergency Operations Center (EOC) appointed two liaisons to the Haiti response as well. DTBE established a "Haiti Desk" to coordinate communications among CDC, the Haiti TB Program, Pan American Health Organization and other groups. The purpose of the Haiti Desk is two-fold: (1) provide assistance and guidance to first responders, states and persons returning from Haiti and (2) facilitate the detection and treatment of TB among Haitians both in the United States and Haiti.

Estimates show that 28,093 repatriates (*i.e.*, U.S. citizens and legal permanent residents) lived in Haiti at the time of the earthquake, but the vast majority of these persons were repatriated back to the United States. Other populations affected by the earthquake in Haiti included ~800 orphans who were evacuated to the United States and >500 medical evacuees (*i.e.*, persons whose injuries could not be adequately addressed in Haiti).

The vast majority of medical evacuees were sent to Florida, but some of these persons arrived in Atlanta. Of >300 new immigrant applications submitted since the earthquake, 130 are pending. However, the panel physician process in Haiti of applying for an immigrant visa and undergoing a medical examination has resumed normal operations.

DTBE published a series of guidelines on the CDC website targeted to three key groups: responders (in an effort to identify earthquake survivors with TB), healthcare facilities, and relief workers and other groups traveling to Haiti for the emergency response. DGMQ issued recommendations targeted to the initial domestic screening of Haitian orphans and parents

adopting children from Haiti. DGMQ also publicized frequently asked questions for earthquake survivors with an interest in transporting their pets from Haiti to the United States.

DTBE deployed staff to both Haiti and the CDC EOC in Atlanta to support the response to the Haiti earthquake. These staff included a medical officer, epidemiologist, laboratory specialist, acting incident manager and co-lead of the infectious disease team. To date, no DTBE personnel have been assigned to Haiti to specifically address TB issues.

Dr. Thomas Frieden, Director of CDC, solicited Dr. Castro's expertise to issue the following urgent recommendations to the NTP in Haiti to address TB prevention and control issues. Any laboratory equipment, reagents and supplies damaged during the earthquake should be replaced. CDC, WHO or other partners should be used to assure backup to the National Public Health Laboratory in Haiti. An adequate supply, stockpile and efficient distribution of anti-TB drugs should be confirmed and maintained.

Partnerships should be established with NGOs with an active role in TB control to develop strategies for rapidly identifying and restoring treatment to ~7,000 persons in the Port-au-Prince area who were receiving TB treatment prior to the earthquake in Haiti, particularly patients who were receiving MDR-TB care. Screening of TB symptoms at residential encampments and other congregate settings should be considered. The status of ongoing TB and HIV services should be assessed to ensure the continuity of ART at TB facilities and also to assure TB screening in HIV-infected persons under care.

Dr. Frieden also called on Dr. Castro's advice to issue the following ongoing recommendations to the NTP in Haiti. TB surveillance, outbreak detection and response capacity should be strengthened. Monitoring of treatment adherence should be considered to facilitate adoption of the 2010 WHO recommendations for use of rifampin in the continuation phase of TB treatment. TB screening and care of U.S. immigrant visa applicants from Haiti should be coordinated with overseas panel physicians.

**Dr. Castro** reported that DTBE's contribution to the public health response to the earthquake in Haiti will be relatively limited in the short term. The majority of immediate support will come from three major sources: (1) public health laboratories to diagnose various diseases; (2) surveillance to identify diseases with the potential for devastating outbreaks (*i.e.*, water-, food- and vector-borne diseases); and (3) expertise in injuries and disabilities due to the large proportion of the Haitian population that will require orthopedic care, amputations or reassembly of limbs.

Dr. Castro was aware that TB, HIV and malaria would be major public health issues in post-earthquake Haiti in the future, but DTBE is currently focusing on the immediate need to address the interruption of treatment to >7,000 TB patients in Haiti. However, the exact number of the TB-affected population is unknown because Haiti has never participated in a TB drug-resistant survey. For example, WHO "guesstimates" the MDR-TB rate to be ~1.8%, while studies in the published literature estimate the MDR-TB rate to be 20% in previously treated persons in Haiti. Other data estimate that ~23% of TB patients in Haiti are co-infected with HIV.

Dr. Castro described actions that will be taken to strengthen public health in post-earthquake Haiti. The NTP in Haiti has heavily relied on NGOs to conduct TB prevention and control activities to date, but the earthquake will allow the NTP to enhance its approach to improve public health through solid governance in-country and strong political commitment. DTBE will advise the NTP to administer a TB drug-resistant survey to obtain more solid data on MDR-TB rates throughout Haiti. Efforts are underway at CDC to develop plans to regularly review the status of public health in Haiti six months, one year and five years post-earthquake.

### Update on DTBE's Surveillance Activities

Dr. Thomas Navin is Chief of the DTBE Surveillance, Epidemiology and Outbreak Investigations Branch. He announced that DTBE's article in the March 19, 2010 edition of the *MMWR* for World TB Day would show an unprecedented decrease in the number of TB cases reported to date. Due to the historic decline in the number of TB cases, DTBE is attempting to identify problems in its surveillance systems.

Dr. Navin emphasized that the surveillance data he would present are provisional as of February 26, 2010 and contain unknown variables with the potential to change in the future. Moreover, the provisional surveillance data have not been rigorously vetted in accordance with CDC's normal four-month review process before being released to the public.

Dr. Navin's summary of the provisional surveillance data reported to CDC is outlined as follows. Percent changes in total TB cases by state between 2008 and 2009 were -39% reported by one state; -28.4% to -19.3% reported by six states; -15.5% to -0.1% reported by 11 states; and 2% to 12.3% reported by six states. Texas was the only state that reported no percent change in total TB cases between 2008 and 2009. Low-burden and high-burden states had similar declines in total TB cases over this same time period.

By population, declines in TB rates were 11.4% overall, 14.8% in USBP and 10.5% in FBP. The percent decline in TB cases among FBP by years in the United States at the time of diagnosis between 2008 and 2009 ranged from -25.3% based on <2 years in the United States to -6.9% based on >10 years in the United States. Between 2008 and 2009, differences in the percent decline in TB cases among FBP by years in the United States at the time of diagnosis were minimal when the data were stratified by Hispanics and non-Hispanics.

FBP who lived in the United States less than one year at the time of TB diagnosis and were from countries that had not implemented the 2007 TBTIs as of January 2009 accounted for more counted TB cases. By race/ethnicity, the percent decline in reported TB cases between 2008 and 2009 ranged from -8.5% to -15.1% in Hispanics and non-Hispanic Asians, blacks and whites. Between 2008 and 2009, the percent decline in reported TB cases in these four-racial/ethnic groups broadly ranged from -15.5% to 5.7% in USBP and -4.4% to -13.7% in FBP.

DTBE's comparison of 2008 and 2009 provisional data indicated a phenomenon in early-year reporting. However, the 2009 provisional data reported to CDC did not account for the expected

3.8% decline in TB cases per year or the normal seasonal variation in cases. DTBE incorporated these two factors into a model and observed a dramatic change in TB cases in January 2009 that was unprecedented in the previous 10 years.

DTBE conducted two data analyses in an effort to determine factors that might have played a role in the percent decline in TB cases between 2008 and 2009. DTBE initially focused on three major data management changes that occurred in January 2009. CDC introduced the revised Report Verified Case of TB (RVCT) form that allowed states to report uncounted TB cases. The shift from the Tuberculosis Information Management System (TIMS) to the new National Electronic Disease Surveillance System (NEDSS) allowed counties to report data directly to CDC. States switched from TIMS to new software systems (*i.e.*, NEDSS Base System (NBS), Maven, eRVCT or state-generated systems).

The first data analysis did not allow DTBE to definitively conclude that the percent decline in TB cases was actually associated with changes in data management systems. For example, provisional case counts in two formats only differed by 12 cases (*i.e.*, 11,552 TB cases based on verbal reports from TB surveillance coordinators versus 11,540 TB cases based on electronic reports). TB counts declined -10.6% overall, -11% among TIMS users, -8.6% among eRVCT users, and -6.7% among NBS users. TIMS was CDC's data management system prior to 2008, but showed the largest percent decline in TB cases among current users.

DTBE's second data analysis focused on a potential association between the recession and the percent decline in TB cases from 2008 to 2009. The analysis showed a weak relationship between the percent decline in TB cases over the one-year time period and the impact of the number of TB staff positions lost in 2009 on states reporting >100 TB cases.

Because the data analyses did not result in definitive answers, DTBE collaborated with NTCA to identify other factors that potentially played a role in the percent decline in TB cases between 2008 and 2009. DTBE and NTCA identified several possible theories: under-diagnosis of TB, under-reporting or delayed reporting within public health in which counties have not yet notified states of TB cases, under-reporting to public health by commercial laboratories, improved TB control efforts, and shifts in demographic groups.

A number of actions are being taken to obtain more concrete answers on the percent decline in TB cases between 2008 and 2009. NTCA developed and disseminated a survey to all funded TB sites. DTBE is expanding its National TB Surveillance System data analyses to include data from states, counties and metropolitan statistical areas. DTBE is collecting data from additional sources, such as mortality data, the National Center for Health Statistics data set and pharmacy databases. DTBE launched an Epi-Aids with Georgia serving as the first site. DTBE is currently making efforts to provide technical assistance to states.

by March 5, 2010. At this time, 24 fully complete and 28 partially complete surveys have been returned to NTCA.

Based on preliminary responses to the NTCA survey, demographic changes related to refugee resettlements in the United States were cited as the primary reason for the percent decline in TB cases between 2008 and 2009. Other factors reported by TB controllers included the need to redirect staff to focus on H1N1 activities, less emphasis on contact investigations, a decrease in the number of clinical TB cases, concerns related to TB diagnoses by providers, and confusion regarding reporting ability. Overall, responses to the survey will provide DTBE and NTCA with observational data from the field on potential reasons for the unexpected decline in reported TB cases.

ACET made a number of comments and suggestions for DTBE to consider in its ongoing data analyses to determine potential reasons for the percent decline in TB cases between 2008 and 2009.

- DTBE should utilize the Indian Health Service (IHS) database in its ongoing data analyses because this system has no economic barriers to persons seeking care. The inclusion of TB diagnoses in IHS's national data system would allow comparisons of reporting trends between the Native American and general U.S. populations. Dr. John Redd, the alternate *ex-officio* to IHS, offered to assist DTBE in these efforts.
- DTBE should expand its data analyses to determine whether reporting problems in the private sector contributed to the percent decline in TB cases between 2008 and 2009.
- DTBE should review data on both counted and uncounted TB cases reported to CDC prior to 2009. For example, over-counting or duplicate counting could have occurred before 2009, particularly since TB patients frequently move to different states during treatment. The TB funding formula might have played a role in over-counting cases before 2009 as well. Because CDC does not require named reporting or other identifiers, no mechanism exists to confirm whether a TB case was counted more than once.
- DTBE should clearly articulate the disclaimers, caveats and uncertainties associated with the percent decline in TB cases between 2008 and 2009. Most notably, the upcoming *MMWR* article on the unprecedented decrease in the number of TB cases should outline limitations of the data and explicitly state that conclusions regarding a true decline cannot be reached at this point. The *MMWR* article also should strongly advise the TB community against using the data as a basis for placing less emphasis on current TB prevention and control efforts. DTBE's careful messaging will be particularly important from an advocacy perspective because the President's budget request to Congress includes a \$1.2 million decrease for DTBE.

### ACET Business Session

Dr. Fleenor announced that the regular format of the business session would be modified to ensure ACET reached agreement on one major topic before the meeting was adjourned. He

reminded ACET that the four questions the BCG Workgroup posed on the previous day resulted in diverse perspectives and a broad range of suggestions and comments with no resolution by the members.

To ensure consensus was reached on the BCG Workgroup's questions, Dr. Fleenor explained that the ACET members would meet in two small subgroups based on their respective positions. Dr. Christine Hahn would lead a subgroup of ACET members who believed "BCG vaccine should be considered" due to the lack of evidence to support a strong recommendation.

Dr. Edward Nardell would lead a subgroup of ACET members who believed "BCG vaccine should be recommended as an option" to increase uptake among U.S. travelers to TB-endemic countries. After the small subgroup meetings, Drs. Hahn and Nardell would present the outcomes of their respective groups to assist ACET in providing more concrete guidance and direction to the BCG Workgroup.

Dr. Fleenor opened the business session and called for ACET's formal action on the following topics.

**TOPIC 1:** A motion was properly placed on the floor and seconded by Ms. Sirlura Taylor and Mr. Joseph Kinney, respectively, for ACET to approve the previous meeting minutes. ACET proposed three changes to the minutes.

- Page A1.1: Change the title of "Dr." Linda Danko (alternate *ex-officio* to the Department of Veterans Affairs) to "Ms." Linda Danko in the list of participants.
- Page 9: Change "IoM" to "IOM." [*Editor's Note:* "IoM" was used as the acronym for the Institute of Medicine to distinguish between DGMQ's use of the acronym "IOM" for the International Organization for Migration.]
- Page 12: Change Dr. Jennifer Flood is a "former ACET meeting" to "former ACET member."

ACET **unanimously approved** the October 27-28, 2010 Draft Meeting Minutes with the changes noted for the record with no further discussion.

**TOPIC 2:** Dr. Brostrom proposed resolutions for ACET to consider in addressing the following TB prevention and control issues in the USAPIs.

Issue 1 is to "improve program funding for the USAPIs." CDC funding is needed to support an evaluation of MDR-TB. The prospect of continued program improvement funding from DOI is dim. FSM and RMI are high-burden jurisdictions that receive allocations from the Global Fund. Appropriate prioritization of TB at the local level as well as sustainable funding from the United States and WHO are lacking. The proposed resolution for issue 1 is to readjust the national TB cooperative funding formula to increase funds to the most vulnerable areas in the USAPIs.

Issue 2 is to "support access to SLDs in the USAPIs." Medications cannot be procured with CDC's TB cooperative agreement funds. RMI and FSM experience considerable waiting times for SLDs that cause prolonged exposure to household contacts and clinical staff. The USAPIs

need logistical and technical assistance with a maintenance supply of SLDs. The proposed resolution for issue 2 is to leverage separate funding outside of CDC for management of a modest “stockpile” of SLDs in the USAPIs. However, CDC funding could be added to support a pharmacist as well as storage and management of SLDs.

Issue 3 is to “increase education and training opportunities.” Pacific Islands TB Controllers Association (PITCA) meetings are the primary educational tools for TB control programs in the USAPIs. PITCA’s efforts have led to remarkable advances in local technical capacity. The proposed resolution for issue 3 is to continue to support PITCA’s essential capacity building meetings. No further action by ACET is requested.

Issue 4 is to “support the regional reference laboratory.” The private contracted laboratory in Hawaii is performing extremely well as the regional reference laboratory for TB smear and culture. However, the caseload is rapidly expanding; the number of drug-resistant TB cases has sharply increased; and the availability of beacon testing is critical at times. The proposed resolution for issue 4 is to continue to support funding for the contract laboratory in the USAPIs. No further action by ACET is requested.

Issue 5 is to “support research for best practices in the USAPIs.” The development of TB guidelines for patients with diabetes is underway. The Francis J. Curry National Tuberculosis Center used USAPI data to convene a TB/diabetes webinar for U.S. TB control programs with participation by USAPI representatives. CDC is involved with the TB/diabetes study that was initiated in Kirbati. Diabetes was added as a risk factor to the online “EPIanywhere.net” surveillance tool. The USAPIs were represented at a recent TB-Union Workgroup on TB/diabetes.

Initial data are available for treatment of TB infection in MDR-TB contacts in FSM and RMI. DTBE allocated funding for TB Leads to conduct pharmacokinetic studies in order to determine appropriate treatment doses of fluoroquinolones in children undergoing treatment for MDR-TB infection. The proposed resolution for issue 5 is for ACET to support a national initiative to evaluate the effect of diabetes on TB incidence and outcomes and also to support continued involvement in USAPI research initiatives.

Issue 6 is to “support improved regional surveillance through EPIanywhere.net.” The web-based program is currently available for all jurisdictions in the USAPIs to report TB cases online. This tool improved surveillance in FSM and RMI and showed a rapid rise in case counts in several jurisdictions. The proposed resolution for issue 6 is to provide additional support with “TB 101” courses and onsite surveillance training in FSM and RMI and also to support efforts to increase surveillance personnel in RMI. No further action by ACET is requested.

Issue 7 is to “develop a TB screening plan for H-2 workers (*i.e.*, seasonal and agricultural workers) in Guam.” Estimates show that up to 15,000 overseas workers who primarily would come from the Philippines and would not need a physical examination are expected in Guam to build new military base housing. Based on CNMI’s experience, >100 additional TB cases can be anticipated in the first two years and would result in a 50%-60% increase in the caseload of the Guam health department. The proposed resolution for issue 7 is to provide guidance to

Guam for appropriate TB screening of H2 workers in Guam and strongly consider placement of an experienced TB public health advisor in Guam.

Issue 8 is to “increase the regional presence of the United States/CDC in the USAPIs.” The duties of the Hawaii TB Branch Chief was expanded as follows: coordinate TB surveillance activities in the USAPIs; coordinate TB-related guidelines in the USAPIs in consultation with PITCA; and serve as an onsite expert TB medical consultant during site visits to the USAPIs or for program interventions. The proposed resolution for issue 8 is to support a U.S./CDC “boots on the ground” presence in the USAPIs. No further action by ACET is requested.

ACET was uncomfortable in taking formal action on some of the resolutions proposed for the USAPIs. Concerns expressed by several ACET members in three major areas are outlined as follows. First, some resolutions appear to be “micromanagement” issues that are not within the scope of ACET’s charter to provide advice and recommendations to the HHS Secretary and CDC Director on the elimination of TB in the United States.

Second, the resolution to readjust the TB funding formula would require CDC to reduce dollars allocated to U.S. states. Moreover the DTBE/NTCA FY2010 Formula Workgroup agreed that the USAPIs would not be included in the TB funding formula due to extreme differences in TB prevention and control issues between the United States and the USAPIs. As a resolution to this issue, CDC acted on NTCA’s appeal over the past year and increased the “funding floor” of USAPIs to \$100,000 where appropriate. As a result, only one USAPI with three TB cases is not receiving the \$100,000 funding floor at this time.

Third, to address the proposed resolution to provide guidance to Guam, a formal request should be submitted to DoD to include TB screening in the defense contract for H2 workers in Guam. In this case, TB screening would be more appropriate by DoD rather than CDC because the H2 workers will be contracted to build military base housing in Guam. In response to ACET’s suggestion, Dr. Brostrom clarified that H2 workers will be hired by private companies and will be under the jurisdiction, control and authority of the Guam health department rather than DoD.

In follow-up to this issue, ACET raised the possibility of engaging the Occupational Safety and Health Administration by defining TB screening of H2 workers in Guam as labor migration or worker safety and health issues. ACET also suggested charging the public health advisor in Guam with responsibility for providing guidance to the Guam health department on TB screening of H2 workers.

Similar to ACET’s hesitation in formally approving some of the proposed resolutions, Dr. Castro also expressed concerns. He noted that accountability, roles and responsibilities to implement the proposed activities were not clearly defined. Moreover, some resolutions (*i.e.*, readjusting the TB funding formula) might result in unintended consequences. Dr. Castro made a number of comments for ACET to consider before voting on the proposed resolutions.

Before launching a national initiative to evaluate the effect of diabetes on TB incidence and outcomes, a smaller project should be piloted in the USAPIs. Solid data and evaluation outcomes from the pilot project could be used to justify implementation of a national initiative

with possible funding from the National Institute of Diabetes and Digestive and Kidney Disease along with support from the CDC Division of Diabetes Translation.

DTBE is already considering and discussing potential approaches to place an experienced TB public health advisor in Guam to address issues in the USAPIs. DGMQ must be engaged in TB screening of H2 workers in Guam because medical screening is only mandated for persons who apply to enter the United States as immigrants or refugees. As a result, TB screening of persons who arrive in Guam as H2 workers would be legally challenged. However, solid data on the disease burden in Guam and a strong evidence basis to support the expectation of >100 additional TB cases in Guam in the first two years could be used to justify the potential benefit of screening H2 workers for TB.

To develop and manage a stockpile of second-line TB drugs in the USAPIs, efforts should be made to leverage CDC's existing capacity in delivering antiretroviral drugs to the USAPIs for H1N1. Moreover, actions taken after the earthquake in Haiti could be replicated in which TB controllers across the country would be asked to donate TB drugs to the USAPIs on an emergency basis while efforts are made to develop and maintain a more secure stockpile of SLDs over time. Overall, opportunities should be explored to solicit resources from the U.S. Agency for International Development to support the proposed TB prevention and control activities in the USAPIs.

At the conclusion of the discussion, Dr. Fleenor called for votes on the proposed resolutions for TB prevention and control in the USAPIs as five separate items rather than one set of issues.

Mr. Shannon Jones III properly placed a motion on the floor for ACET to approve proposed resolution 1: "Readjust the national TB cooperative funding formula to increase funds to the most vulnerable areas in the USAPIs." **The motion failed due to the lack of a second from an ACET voting member.**

Mr. Shannon Jones III properly placed a motion on the floor for ACET to approve proposed resolution 2: "ACET to support a national initiative to evaluate the effect of diabetes on TB incidence and outcomes." **The motion failed due to the lack of a second from an ACET voting member.**

ACET did not vote on proposed resolution 3: "Strongly consider placement of an experienced TB public health advisor in Guam." Dr. Castro informed ACET that DTBE is currently considering and discussing strategies to take action in this area.

A motion was properly placed on the floor and seconded by Mr. Shannon Jones III and Dr. Barbara Seaworth, respectively, for ACET to approve proposed resolution 4: "Provide guidance to Guam for appropriate TB screening of H2 workers in Guam." **ACET passed the motion with a majority vote of 5 in favor and 2 opposed.**

Dr. Fleenor conveyed that the next steps in ACET's formal adoption of this resolution would be for DTBE to present an update on its progress in providing guidance to Guam during the June

2010 ACET meeting. He reminded DTBE that suggestions were made to engage DGMQ and DoD in this effort.

A motion was properly placed on the floor and seconded by Ms. Sirlura Taylor and Dr. Barbara Seaworth, respectively, for ACET to approve proposed resolution 5 AS REVISED: "ACET to support DTBE's efforts to explore a mechanism to provide SLDs to USAPIs in a timely manner." **ACET unanimously passed the motion with no further discussion.**

Dr. Fleenor concluded Topic 2 of the business session by presenting ACET's formal resolution on TB prevention and control efforts in the USAPIs that would be forwarded to the Director of CDC.

WHEREAS, U.S.-Affiliated Pacific Island (USAPI) jurisdictions have recently demonstrated excellent and sustainable improvement in several key areas of TB control;

WHEREAS, more than 15,000 H2 workers from the Philippines are expected to arrive in Guam over the next two years for infrastructure development of the Guam Military Buildup;

THEREFORE, be it resolved that the Advisory Council for the Elimination of Tuberculosis (ACET) unanimously recommends that the Director of the Centers for Disease Control and Prevention (CDC):

1. Provide guidance to Guam for appropriate TB screening of H2 workers in Guam.
2. Acknowledge ACET's support of efforts by the CDC Division of TB Elimination to explore a mechanism to provide second-line drugs to USAPIs in a timely manner.

**TOPIC 3:** Dr. Nardell reported that the two ACET subgroups reached agreement on three of the four questions posed by the BCG Workgroup.

- **ACET unanimously agreed** that an industry representative should be asked to assure availability of BCG vaccine if this product is recommended.
- **ACET unanimously agreed** that the guidelines should recommend the use of respiratory protection.
- **ACET unanimously agreed** that the best approach to address management of LTBI due to presumed MDR-/XDR-TB would be to leverage existing expertise rather than formulate new recommendations. Most notably, the guidelines should reference the 1992 *MMWR* article on ethambutol, pyrazinamide and fluoroquinolones as possible treatment options.

Dr. Hahn reported that the two subgroup meetings did not result in ACET agreeing on the most contentious issue related to the strength of the BCG recommendations. Her subgroup was in favor of revising the existing "Provision of BCG" section on page 10 of the guidelines: "BCG vaccination of health professionals, students or volunteers who work in high-risk settings should be considered as a reasonable option after an evaluation of the risk ...". Dr. Hahn's subgroup

also supported adding a new sentence to clarify that the recommendations were based on expert opinion supported by currently available data.

Dr. Nardell's subgroup agreed on the following language: "For otherwise healthy U.S.-born humanitarian workers and scholars likely to be exposed to MDR-TB in resource-limited settings who are baseline TST or IGRA-negative, a single dose of an FDA-approved BCG vaccine is recommended as an option for this limited indication unless contraindicated."

The ACET members engaged in further discussion on whether BCG vaccine "should be considered" or "recommended as an option" in the guidelines. **ACET unanimously agreed that the guidelines should recommend BCG vaccine as an option.**

In addition to the four questions posed by the BCG Workgroup, the ACET members also were divided on whether the guidelines should generically recommend referring persons who convert to TB disease to an expert for consultation or if more specific guidance with options should be provided. **ACET agreed by a majority vote that the guidelines should provide specific recommendations with options for persons who convert to TB disease.**

**TOPIC 4:** No ACET members proposed additional suggestions or revisions to the draft outline of the NCHHSTP Social Determinants of Health White Paper.

**TOPIC 5:** Dr. Fleenor would write a letter to extend a formal invitation for a staff member from the Division of HIV/AIDS Prevention to serve as an *ex-officio* to ACET to strengthen PCSI efforts. The letter also would raise the possibility of an ACET member serving as a liaison to the CDC/HRSA CDC Advisory Committee on HIV and STD Prevention and Treatment.

**TOPIC 6:** Dr. Fleenor would collaborate with Drs. Castro and Dean to identify specific topics to address when HHS Secretary Kathleen Sebelius attends an ACET meeting. The ACET members were asked to submit potential topics to Dr. Fleenor for consideration in developing the agenda.

**TOPIC 7:** Dr. Fleenor announced that as part of its charter, ACET is charged with producing a report to the HHS Secretary every two years on the status of DTBE achieving the goal of TB elimination in the United States. Dr. Fleenor's term would end after the June 2010 meeting, but he would begin developing the TB elimination status report to ensure that ACET maintains the momentum in fulfilling its charge during the change in leadership.

The report would highlight ACET's extensive review and vetting of the STOP TB document and DTBE's implementation of ACET's formal resolutions over the past four years related to TB elimination. Dr. Fleenor would present the draft TB elimination status report during the next ACET meeting and describe next steps for ACET's new leadership.

A motion was properly placed on the floor and seconded by Mr. Shannon Jones III and Dr. Barbara Seaworth, respectively, to convene the June 2010 in Washington, DC with Secretary Sebelius as a keynote speaker. Dr. Fleenor's presentation of the TB elimination status report to

Secretary Sebelius would serve as the cornerstone of the meeting. **ACET unanimously passed the motion with no further discussion.**

Ms. Stricof announced that the Centers for Medicare and Medicaid Services recently published a paper in the *Federal Register* on the meaningful use of certified electronic health records. She urged DTBE, ACET and the broader TB community to be involved in initial discussions regarding the design and development of standards, codes and minimum data elements for this technology to ensure that public health and TB control are integrated into certified electronic health records. She pointed out that the deadline for comments on the *Federal Register* notice is March 15, 2010.

### Public Comment Session

Dr. Fleenor opened the floor for public comments; no participants responded.

### Closing Session

Three dates were proposed for the next ACET meeting in 2010: June 1-2, June 2-3, or June 29-30. Ms. Margie Scott-Cseh, Committee Management Specialist for ACET, would poll the members by e-mail to confirm the exact date of the next meeting.

With no further discussion or business brought before ACET, Dr. Fleenor adjourned the meeting at 2:15 p.m. on March 3, 2010.

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

\_\_\_\_\_  
Date

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