DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Division of Tuberculosis Elimination

Advisory Council for the Elimination of Tuberculosis
December 4-5, 2012
Atlanta, Georgia

Record of the Proceedings

Table of Contents

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Division of Tuberculosis Elimination

Advisory Council for the Elimination of Tuberculosis
December 4 – 5, 2012
Atlanta, GA

Minutes of the Meeting

The US Department of Health and Human Services (HHS) 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) on December 4 and 5, 2012, in Building 8 of CDC's Corporate Square Campus, Conference Room A/B/C, in Atlanta, Georgia.

Call to Order, Welcome, and Roll Call: December 4, 2012

Shannon Jones III
Deputy Director
City of Austin/Travis County Health Human Services Department
ACET Chair

Mr. Jones called the meeting of ACET to order at 8:38 am on Tuesday, December 4, 2012. He welcomed the meeting participants, especially the new members of ACET. He reminded ACET members and presenters to be timely in their presentations, questions, and responses and to adhere to the meeting protocol. He asked ACET members to begin crafting their resolutions for the next day's business meeting in order to maximize their time.

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

Dr. Dean reminded the group that all ACET meetings are open to the public, and all comments made during the proceedings are a matter of public record. She asked ACET members to be mindful of potential conflicts of interest identified by the CDC Committee Management Office (CMO), and instructed them to recuse themselves from participating in voting or discussion on matters with which there are conflicts of interest. She then requested that ACET members declare any conflicts of interest. Dr. Jane Carter declared that she is the sitting president of the International Union Against Tuberculosis and Lung Disease. No other conflicts were declared.

Dr. Dean welcomed and introduced the following new ACET members:

- Barbara Cole, RN, MSN, PHN
- Robert C. Horsburgh, Jr., MD, MUS

She then welcomed new ACET liaison and *ex officio* members and ACET alternates:

- Jon Warkentin, MD, is a new ACET liaison representative representing the National Tuberculosis Controllers Association (NTCA).
- James Mancuso, MD, DrPH, US Department of Defense (DoD) attended the meeting on behalf of Dr. Naomi Aronson.
- Dr. Linda Danko was present on the telephone on behalf of Dr. Gary Roselle with the US Department of Veterans Affairs (VA).
- Lisa Delaney was in attendance, replacing Dr. Jon Halpin with the National Institute for Occupational Safety and Health (NIOSH).
- Eddie Hedrick, BS, MT (ASCP), CIC, is a new ACET liaison representative representing the Association for Professionals in Infection Control and Epidemiology (APIC).
- Jennifer Rakeman, PhD, is a new ACET liaison representative from the Association of Public Health Laboratories (APHL).

Dr. Dean noted other updates regarding ACET membership:

- Dr. Litjen Tan is leaving the American Medical Association (AMA). A new ACET liaison from AMA will be identified.
- Dr. Catherine D. Torres is no longer representing the Association of State and Territorial Health Officials (ASTHO). ASTHO will name a replacement.

Dr. Dean conducted a roll call of ACET members, *ex officio* members, and liaison representatives. She established that a quorum was present.

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention Program Progress Reports

DTBE Director's Report

RADM Kenneth Castro, MD
Director, Division of Tuberculosis Elimination / NCHHSTP
Centers for Disease Control and Prevention

Dr. Castro acknowledged the work of DTBE staff in contributing materials for the Director's Update to ACET. He reported the following personnel changes within DTBE:

- Senior Public Health Advisors Greg Andrews and Joe Scavotto have retired.
- Dr. Elsa Villarino has accepted a position in Mexico with CDC's Division of Global Migration and Quarantine (DGMQ).
- Dr. Heather Menzies has accepted a position with the Division of Global HIV/AIDS (DGHA) in Namibia)
- Dr. Brian Baker has accepted a position in Los Angeles County.
- Lindsay Kim is now in the Respiratory Diseases Division.

- Dr. Sarita Shah was an Epidemic Intelligence Service (EIS) Officer with DTBE and has returned to DTBE in the International Research and Programs Branch (IRPB).
- Dr. David Yost is a new medical officer with DTBE in Puerto Rico.
- Ms. Nydia Palacios is a Public Health Associate in Houston.
- Curtis Allen is the new Webmaster in DTBE's Communications, Education, and Behavioral Studies Branch (CEBSB)
- New EIS Officers are Drs. Niki Alami, Chimeremma Nnadi, and Courtney Yuen.

Five Tuberculosis Regional Training and Medical Consultation Centers (TB RTMCCs) have been funded for a five-year funding cycle from January 2013 through 2018, pending the availability of funds. The centers are:

- Curry International Tuberculosis Center (CITC) in San Francisco, California
- Heartland National Tuberculosis Center (HNTC) in San Antonio, Texas
- Mayo Center for Tuberculosis in Rochester, Minnesota
- New Jersey Medical School Global Tuberculosis Institute (GTBI) in Newark, New Jersey
- Southeastern National Tuberculosis Center (SNTC) in Gainesville, Florida

The awards call for a reconfiguration of the states that are serviced by the RTMCCs. The centers' primary activities include continuing to provide training and technical assistance to increase human resource development. The US faces a significant challenge in retaining the repository of expertise in tuberculosis (TB) as cases decline. The centers will also develop TB educational materials and products and provide medical consultations to TB programs and medical providers anywhere in the US.

DTBE has updated the Core Curriculum on TB, which will be available both online and in print in early 2013. The updates include 2011 surveillance data; the new 12-dose regimen for latent TB infection (LTBI); the new smear classification table, and minor corrections to the 2011 edition.

The TB Program Manager Course has been available for several years. DTBE has developed methods for conducting a needs assessment on the course and will apply those results to reconfigure it. The next course will take place in January 28 – February 1, 2013, at CDC's Global Communications Center (GCC).

The TB Education and Training Network (TB ETN) and TB Program Evaluation Network (TB PEN) held their conference in Atlanta, Georgia, in September 2012. Efforts to link the ETN and PEN have been successful. The next ETN/PEN Professional Development Workshop will be held in June 2013 and will focus on the development of education, training, and evaluation skills as well as providing network opportunities and highlighting education, training, and evaluation activities.

Regarding surveillance, December 31, 2012 marks the end of the two-year collection of LTBI data from the National Health and Nutrition Examination Survey (NHANES). The last collection of LTBI data from NHANES occurred in 1999 – 2000. The NHANES sample is comprised of non-institutionalized persons. Collection of data on institutionalized persons needs to take place in another manner. The final data will be released in the third quarter of Fiscal Year (FY) 2013.

The National Tuberculosis Indicators Project (NTIP) will continue to collect data that will be used for the funding formula. The TB burden, or needs-based formula, will continue at least until 2013. That formula is 80% needs-based and 20% performance-based. This program is the first at CDC to include a performance element in the formula. This new approach is promising, but DTBE is mindful of potential unintended consequences and a desire to reward programs that are doing well.

Ongoing TB cluster and outbreak investigations include sites in:

- Jacksonville, Florida, in a homeless community
- Dallas, Texas, in a corrections setting
- North Dakota, in a Tribal Nation

DTBE continues to provide monitoring and investigative services of instances of severe hepatitis associated with the 12-dose regimen for LTBI. The division will review the results of recently-completed investigations. An internal medical board assesses the objective information and adjudicates the likelihood that the hepatitis was associated with the regimen.

Version 2.0 of CDC's Molecular Detection of Drug Resistance (MDDR) Service started in January 2012. The service accepted specimens in addition to isolates. The service has been operative since September 2009 and has achieved over 1000 referral submissions as of November 2012. In cooperation with APHL, regional training targeting clinical service laboratorians is occurring in Pennsylvania and New Mexico and is planned in Los Angeles. The training focuses on specimen processing, handling, and transport; Acid-Fast Bacilli (AFB)-smear microscopy; and biosafety. DTBE initiated a cooperative research effort with the National Institute of Allergies and Infectious Diseases (NIAID) at the National Institutes of Health (NIH) to better understand the ability to reliably test for pyrazinamide (PZA) resistance. PZA has a pivotal role as new regimens for drug-susceptible and drug-resistant TB are developed.

The Tuberculosis Epidemiologic Studies Consortium (TBESC) has been reconfigured with a new focus on LTBI. A pilot study from July – September 2012 enrolled 460 persons from 10 partner sites. The participants are 85% foreign-born and 9% HIV-positive, with a median age of 28. Overall, 45% of the participants are positive on more than one diagnostic test for TB: 41% are Tuberculin Skin Test (TST) positive, 26% are QuantiFERON-TB test (QFT) positive, and 16% are T-SPOT® positive. It is critical to understand LTBI if TB is to be eliminated.

Dr. Castro summarized clinical research activities of interest. Study 26 was a randomized trial that established the efficacy of the 12-dose regimen for LTBI consisting of a three-month, once-weekly regimen of isoniazid and rifapentine. The study continues to enroll HIV-infected individuals and children. Preliminary data were presented during the International AIDS Conference (IAC) in July 2012, and during the Infectious Diseases Society of America (ISDA) Conference in October 2012. Planning is ongoing for a possible Phase Three rifapentine trial and for a possible Phase Two novel regimen in drug-susceptible TB.

presentations have been proposed for the Conference on Retroviruses and Opportunistic Infections (CROI) in Atlanta in 2013.

DTBE is preparing for World TB Day activities in March 2013. The activities will be consistent with the World Health Organization's (WHO) theme.

The FDA's Anti-Infective Drugs Advisory Committee (AIDAC) reviewed and approved an application for the approval of bedaquiline in persons with multi-drug resistant TB (MDR-TB). It is unclear what FDA will do, as there are questions about the safety of bedaquiline. If the risks are outweighed by the benefits of having access to the drug for persons who really need it, then guidelines will need to be developed for its potential use in the US. Dr. Castro hopes to work with FDA to gather information to engage in scenario-based planning. DTBE is prepared to collect and monitor data on the safety of bedaquiline, as called for by AIDAC. DTBE will also be able to collect isolates and monitor for the emergence of resistance to bedaquiline. Further, DTBE and CDC will continue to support WHO and global policy for the use of new drugs. Additional issues will emerge as new agents are reviewed. One of the side effects of these new drugs is the promulgation of the electrocardiographic QT segment. The risk of arrhythmias is possible, but has not yet been seen. When drugs with similar QT promulgations are added, there are possible unintended consequences, and all of the partners are aware of the need to be cautious as they proceed in providing access to new drugs.

Discussion Points

In response to a question from ACET, Dr. Castro said that the status of clearance of foreign-born guidelines has been a source of frustration. He hopes to have a meeting with the CDC Office of the Associate Director for Science (OADS) to address policy concerns. CDC is cautious because of potential repercussions at sister agencies. There are also concerns about unintended consequences and immigration issues.

ACET noted that bedaquiline was approved for use in patients with MDR-TB. There are great opportunities in the US to monitor the development of resistance, to use appropriate diagnostics before beginning treatment, and to monitor treatment. The opportunity to establish guidelines that could be applied in other countries is unique, and CDC's leadership role is important.

ACET expressed concern about supply problems for patients with MDR-TB and about the possibility of losing the effectiveness of these drugs rapidly, given the global situation with MDR-TB.

Dr. Castro replied that AIDAC was considering the potential approval of the new anti-TB drug under FDA's Subpart H "accelerated clause" that allows them to consider drugs for life-threatening conditions based on limited efficacy data. AIDAC underscored the need to continue to collect data in Phase Three studies. FDA does not have to accept the recommendations of the committee. Dr. Castro agreed with the importance of striking a balance between making a useful drug available to people who need it and limiting the possibility of "drug anarchy" that gives rise to drug resistance. He agreed that the US is in a position to provide leadership. The AIDAC and members of the public at the meeting acknowledged that any actions of the US are likely to guide what other countries do. It is important to move forward cautiously to avoid possible consequences, such as misuse of the drug in areas where drug resistance is more common.

NCHHSTP Director's Update

Kevin Fenton, MD, PhD, FFPH
Director, NCHHSTP
Centers for Disease Control and Prevention

Dr. Fenton welcomed ACET to Atlanta. He announced that he had tendered his resignation to CDC and would leave the agency at the end of 2012 to take on a new role in the United Kingdom. He thanked ACET for its service and leadership over the years and noted the leadership of Mr. Shannon Jones, ACET Chair.

Several leadership changes are taking place across CDC, including the following:

- ❑ As of January 2, 2013, Dr. Rima Khabbaz will serve as the Acting Director of NCHHSTP.
- ❑ Dr. Anne Schuchat is serving as Acting Director of the Center for Global Health (CGH) following the departure of Dr. Kevin De Cock.
- ❑ Dr. Denise Cardo is Acting Director of the Office of Surveillance, Epidemiology, and Laboratory Services (OSELS).
- ❑ Dr. Melinda Wharton is the Acting Director of the National Center for Immunization and Respiratory Diseases (NCIRD).

Dr. Tom Frieden, CDC Director, is moving rapidly to ensure that the leadership positions are filled as quickly as possible.

Regarding CDC's budget, Dr. Fenton reported that the federal government is operating under a Continuing Resolution (CR) through March 27, 2013. The CR does not address the January 2, 2013 sequester mandated by the 2011 Budget Control Act. CDC is mindful of the "fiscal cliff" and of difficult decisions that may be required if sequestration takes place.

As part of World AIDS Day, CDC focused on HIV among youth and an "AIDS-free Generation." A *Vital Signs* publication shared new data focusing on the increasing concentration of HIV among youth in the US. Nearly one in four new HIV infections in the US occur in people ages 13 through 24. Approximately 1000 new HIV infections occur among young people every month, and the majority of infections occur in youth men who have sex with men (MSM). Nearly half of the infections occur in young African Americans. Approximately 60% of HIV-infected youth do not know that they are HIV-infected and are not maximally benefitting from treatment.

Dr. Fenton shared updates from NCHHSTP. The center includes five large divisions and strives to be "more than the sum of its parts." The NCHHSTP Director's role includes encouraging and supporting strong science, program, and policy in each of the divisions, as well as ensuring a comprehensive, holistic, and integrated approach across the divisions. The center focuses on six key areas to promote this approach.

Program Collaboration and Service Integration (PCSI): The center has released new guidelines on data security and confidentiality standards for infectious diseases to remove the barriers to sharing and using data across disease lines. The guidelines are available at http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf.
The center has considered new, Internet-based tools to increase the public's access to data: http://www.cdc.gov/nchhstp/atlas/.

NCHHSTP has released an integrated Pacific Island Funding Opportunity Announcement (FOA) to remove burdens to reporting. The center collaborated on a *Morbidity and Mortality Weekly Report* (*MMWR*) summarizing guidelines and recommendations from multiple HHS agencies on integrated approaches to the prevention and control of infectious diseases among persons who use drugs illicitly. The report can be viewed at http://www.cdc.gov/mmwr/pdf/rr/rr6105.pdf. Last month, the center held a consultation on the future of surveillance systems for HIV, STDs, TB, and viral hepatitis as part of preparations for health reform in the US. Their efforts are also part of considering new ways to work across disease borders.

Promoting health equity and reducing health disparities: The center is assuring that language addressing social and structural determinants of health is integrated in in all new NCHHSTP FOAs and incorporated into the culture of the center's grantees at the local level. NCHHSTP contributes to the science of health equity and social and structural determinants of health. The center published a special Public Health Reports Supplement focused on data systems and their use in monitoring and tracking social and structural determinants of health. The center created and enhanced Web-based tools and holds webinars and symposia for internal staff and external partners.

Prevention through healthcare: As the center considers implementation of the Affordable Care Act (ACA) and how programs will need to change to take advantage of the act, personnel in each division focus on aspects of prevention through healthcare and ACA implementation. These issues are of particular concern in TB, as programs determine how to work with primary care and how to ensure that critical TB programmatic functions are not lost in the transformation of the health system. CDC and NCHHSTP are moving forward proactively on these issues.

Leveraging strategic partnerships to accelerate health impact: The center has released a range of social marketing campaigns to educate the American public and providers, as well as to target information to groups at greatest risk. Campaigns have focused on STD awareness and testing, HIV awareness, and hepatitis. Other strategic initiatives include coordination with other federal agencies on the implementation of the National HIV/AIDS Strategy (NHAS) and the Viral Hepatitis Action Plan. In TB, groups such as the NTCA are examples of important partners for creative and strategic work in the era of health reform. A number of important public-private partnerships are making great strides in viral hepatitis and offer lessons for TB prevention efforts. The CDC Foundation is an example of how these partnerships can conduct work in research, policy, and social marketing.

Global health protection and health systems strengthening: The Global AIDS Program is not housed at NCHHSTP, but all of the center's divisions have strong international and global health portfolios.

Workforce development and capacity building are important directions for the center to meet new challenges and to work with the external public health workforce to prepare them for the ACA. Innovative work in this area includes implementing a coaching and leadership initiative to build a new generation of leaders and to "deepen our leadership bench" within the center.

Dr. Fenton then offered disease-specific updates from the center. The Division of HIV/AIDS Prevention (DHAP) has developed and awarded the next five-year cycle of the HIV Prevention Fund. These resources are aligned with the NHAS, and awards are based on the geographic burden of HIV. Experience in TB prevention informed the alignment of HIV funding with current disease epidemiology. Grantees at the local level are investing in the highest-impact activities, such as HIV testing and linkage to care, condom promotion and scale-up, policy intervention, and prevention initiatives. The center and division are more directive in how resources are targeted and used at the local level. A new funding opportunity called Care and Prevention in the United States (CAPUS) was released and awarded in the fall of 2012. This project uses CDC resources through the Minority HIV/AIDS Initiative (MAI) to assess the treatment and care capacity for HIV in the US, and to learn how to use prevention dollars to increase the number of individuals who are diagnosed, linked to care, and who maintain their care and virus suppression. Further, the project will consider how to use these resources to address social and structural drivers influencing the cascade of HIV in the US.

The Division of Adolescent and School Health (DASH) has moved to NCHHSTP, enabling the center to focus on sexual health "from cradle to grave" and to enhance school health. The division has been working on resources for schools in parent engagement and on releasing new data on HIV, STDs, and pregnancy prevention and education in schools. The data show trends in secondary schools and opportunities for enhancing youth programs as well as areas of concern in youth sexual health.

The Division of Viral Hepatitis (DVH) has developed its portfolio tremendously in the past year. New recommendations for hepatitis C screening were developed and released, recommending that all individuals born between 1945 and 1965 should receive one-time screening for viral hepatitis. The United States Preventive Services Task Force (USPSTF) recently released recommendations that are in slight conflict with the CDC recommendations. NCHHSTP will work to harmonize the recommendations. The first National HIV/Hepatitis Testing Day was held in 2012, and the division received funds from the Prevention and Public Health Fund to scale up hepatitis screening and to fund new social marketing campaigns for viral hepatitis.

The Division of STD Prevention (DSTDP) has been grappling with emerging highly drug-resistant gonorrhea globally and preparing for this type of resistance in the US. Many activities have focused on provider awareness and engagement, community awareness and engagement, and working with NIH and other federal agencies to ensure that they are prepared for the emergence and the next pipeline of drugs for managing gonorrhea in the US. The division is creating new global and domestic partnerships and engaging in social marketing.

The IAC was held in the US this year for the first time in 20 years. NCHHSTP had a strong presence at the conference, partly due to strong leadership from CDC scientists, policy staff, and partners.

In conclusion, Dr. Fenton noted that the new Associate Director for Health Equity at NCHHSTP is Wayne A. Duffus, and the new Associate Director for Informatics is Thomas Sukalac. The leadership cadre of the center is strong.

Discussion Points

ACET thanked Dr. Fenton for his support over the years and wished him the best in the future.

ACET commented on the discrepancy between different federal agencies' recommendations regarding hepatitis C. Dr. Fenton answered that NCHHSTP would work with USPSTF to present additional evidence in the hope of harmonizing the recommendations for hepatitis screening in the US.

In response to a question from ACET regarding assessing the effectiveness of social marketing campaigns, Dr. Fenton said that public health in general grapples with the evaluation of social marketing. All of CDC's campaigns have a strong, evidence-based approach from the design phase through the implementation phase. Before campaigns are released nationally, CDC conducts formative research to ensure that the messages are correct. The process includes a stepwise approach to successively implementing and evaluating pilot phases of the campaigns so that when they are released, the messages are correct and appropriately targeted. Because CDC uses a variety of channels, the evaluation strategies depend on the channel. For instance, it is possible to track hits on websites and social media channels such as Twitter. Using social and digital media enables them to assess first-, second-, and third-generation conversations that the campaigns stimulate. CDC also uses its population-based surveys to assess awareness of the campaigns.

Meeting attendee Julie Higashi, President of the California TB Controllers Association, asked about the status of the USPSTF evaluation of screening and treatment for TB infection.

Dr. Castro said that resources have been identified to conduct the review required by USPSTF. DTBE hopes that the data will support a Class A or Class B recommendation for screening persons at high risk of disease progression and of having LTBI. It is important to be engaged with USPSTF to create a timeline for this work. The recommendations will be for screening, not for treatment of TB infection.

Dr. Christine Ho added that securing the necessary funding is good news. Their next steps will be to generate the question for the USPSTF to consider. The task force will then review the literature and begin its deliberations.

Global TB Control

CDC's Efforts on Global TB Control

Patricia M. Simone, MD, CAPT, USPHS
Principal Deputy Director, CGH
Centers for Disease Control and Prevention

Dr. Simone provided ACET with an update on CDC's Efforts on Global TB Control and Prevention. She explained that TB activities take place in multiple divisions across CDC, including in DTBE, NCHHSTP, in Division of Global Migration and Quarantine (DGMQ), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), (both under the Office of Infectious Diseases (OID) and in the Division of Global HIV/AIDS (DGHA) and the Division of Global Disease Detection and Emergency Response (DGDDER), both part of The Center for Global Health (CGH).

In 2011, Dr. Tom Frieden appointed a coordinator for CDC's global TB activities. The Acting Coordinator, Dr. Harold Jaffe, reported to the CGH Director and the Director of the Office of Infectious Diseases (OID).

An external peer review to provide an objective assessment of CDC's global TB activities was implemented in June 2012. The report was released in October 2012. A panel of 14 TB experts from a variety of organizations assembled to conduct the review. The two-day forum included an overview of mandates and activities of the four main CDC divisions with global TB control responsibility and themed discussions in the following five areas:

- Program implementation and evaluation
- Operations research
- Epidemiological and clinical research
- MDR-TB and infection control
- Strengthening laboratory and diagnostic capacity

The panel noted a number of strengths in its report. CDC was commended for being a global leader and valued partner and for having passionate commitment to global TB control. The panel also noted CDC's accomplishments and substantial range of activities with a small workforce and limited budget.

The review revealed many of CDC's unique assets in the area of global TB control. These assets include core competencies such as epidemiology and disease surveillance; public health policy and guideline development; laboratory diagnostics; implementation and operational research; design and execution of public health projects; and expertise in key public health areas. CDC also has extensive experience providing technical assistance to US states and in other countries. CDC has close working relationships with key partners, such as Ministries of Health (MOHs); international organizations, such as WHO and the Pan American Health Organization (PAHO); and other US government agencies. CDC has substantial presence in the field, especially in CDC Country Offices and in the Global Disease Detection (GDD) Regional Centers. The review panel noted CDC's strong research collaborations with NIH, the Kenya Medical Research Institute, Tuberculosis Trials Consortium (TBSC), and many other groups.

The report included the following five major findings:

- As an agency, CDC lacks a clear vision or strategy for global action on TB.
- Better coordination and communication is needed among relevant CDC divisions, which will improve strategic planning and decision-making and inform the optimal use of limited resources.
- CDC's proven ability to form effective partnerships is particularly important during a time of limited resources.
- CDC's field presence is a major resource for providing technical assistance to MOHs and other partners.
- The mutually-reinforcing relationship between CDC's domestic and international TB activities is a special strength.

The review panel made a number of recommendations, including focusing on the impact that CDC is trying to achieve and how CDC's efforts will contribute to the global plan to stop TB.

- CDC should develop a forward-looking, agency-wide Global TB Strategy that prioritizes two to three focus areas.
  - The strategy should include the application of core competencies to a range of TB issues, including epidemiology and disease surveillance, research and research training, laboratory training and infrastructure development, infection control, and translating evidence-based policies to action.
  - The strategy should also consider factors that drive the TB epidemic: HIV/AIDS, diabetes mellitus, and MDR-TB.
  - The strategy should address TB in vulnerable populations, such as children and mobile populations.

- CDC should identify and implement a mechanism for increasing internal coordination and communication, specifically around planning, priority-setting, and leveraging limited resources.

- CDC should continue to seek out new partnerships which leverage CDC's core competencies. The panel specifically suggested expanding to research organizations and working with MOHs to foster public-private partnerships.

- CDC should maintain close relationships between its global and domestic TB activities.

- CDC should conduct an agency-wide review to define, evaluate, and optimize the provision of on-site technical assistance related to global TB control. The technical assistance provided should align with the strategy that is developed, and the capacity development activities should be better coordinated. Input from the field is important in this work.

Dr. Simone reviewed CDC's next steps. They have hired a Global TB Coordinator, Dr. Susan Maloney. She will report to the Director of CGH and the Director of OID. They are responsible for supporting her as she works to strengthens internal coordination and communication mechanisms. A draft Global TB Strategy has been generated and will be reviewed and refined to address the panel's findings and recommendations. CDC will review current funding streams and projects and look for ways to synergize and optimize leveraging of resources. They will identify additional funding sources and partners and monitor progress towards addressing the review findings.

Dr. Simone asked ACET for comments about the review and whether they agree with the recommendations. She also asked if ACET had additional recommendations.

Discussion Points

ACET hoped that CDC might serve as the "conscience" of TB global policy, especially given what is known about aerosol transmission, the realistic burden of drug-resistant TB, and what needs to be done quickly. CDC is in a unique position to drive and to correct global policy, particularly related to MDR in China and South Africa.

ACET pursues TB elimination in the US while recognizing the impact of global TB control on the US. ACET supported the review panel's recommendation that CDC develop a clear vision or strategy for global action for TB elimination.

ACET asked about opportunities to work with professional societies and other groups regarding the reauthorization of the President's Emergency Plan for AIDS Relief (PEPFAR) approaches. Decision-makers may not appreciate the realities of how MDR is being managed and handled. It is not allowable for ACET members to do this work on behalf of ACET, but it is permissible outside their capacity as ACET members.

In response to a question from ACET regarding the relationship between global and domestic TB efforts, Dr. Simone said that there have been discussions regarding the benefits and disadvantages associated with "lumping" and "splitting" different groups. There are limitations imposed by Congressional funding which do not make it feasible to make organizational changes. For now, CDC will coordinate domestic and global TB work at a high level with a clear strategy. They will evaluate this approach and determine whether it should be changed.

ACET asked for DTBE's comments on the review panel's findings and recommendations.

Dr. Castro replied that DTBE appreciates the work that went into the review panel's report. The recommendations call on CDC to focus attention on TB while acknowledging that resources are limited. CDC needs to define its unique contribution to the global sphere of TB control, as opposed to duplicating what others are doing well. This work requires coordination with partners, including MOHs and other professional groups, leveraging not only PEPFAR assets, but also Global Fund assets. About 16% to 17% of global TB investments come from the Global Fund, and about 85% of the investments are from the nations themselves. Those investments should be used as effectively as possible. CDC seeks input from external groups and seeks to bring all of the groups that work in global TB together. Groups that prevent the importation of TB and the DGDDER are improving diagnostic capacity. In that framework, it may be possible to develop a mechanism for diagnosing all respiratory diseases.

Dr. Simone added that there are reasons to be optimistic about the report, and moving in the direction of the panel's recommendations will bring CDC closer to where it wants to be. There is good will among the groups that work together as well as the understanding that working together better will have benefits.

Dr. Edward Nardell, an ACET liaison representative from the International Union Against TB and Lung Disease, commented on criticism of the scale-up of the number of people placed in treatment for MDR-TB and whether WHO has taken the right approach. He asked about CDC's role as a collaborator with WHO and as a critic of its global policy.

Dr. Simone replied that CDC often supports WHO while "pushing," for critical assessments and discussions of proposed disease control approaches and strategies, and she anticipated a similar approach in the case of MDR. CDC's strategy is to complement the work of its partners and to use its strengths to achieve the biggest impact.

Ms. Cornelia Jervis, an ACET liaison representative from the Treatment Action Group (TAG), said that many important global conversations will occur in the coming year, given the reauthorization of PEPFAR and the future of the Global Fund. Last year, the President's Budget cut $.5 billion from the PEPFAR budget, but the future is uncertain at this point, given the possibility of sequestration. It is not clear whether the administration will move away from PEPFAR toward a different blueprint strategy, or whether the administration will pursue another reauthorization. She asked about the timeline and process for creating CDC's Global TB Strategy, given these issues.

Dr. Simone answered that the timeline is relatively short, but they are not "starting from scratch." They will work quickly, recognizing that an appropriate framework will be needed as other issues are addressed. Secretary of State Hillary Clinton is stepping down, and the leadership of the Office of the US Global AIDS Coordinator (OGAC) is not clear.

Dr. Castro added that representatives from CDC participate on the Global Stop TB Partnership Coordinating Board and are helping to develop a global vision for TB elimination. It is important to determine how CDC can contribute to that larger effort rather than to see the agency as a separate entity. He agreed that CDC's science and data can help "push the envelope beyond the status quo," aligning their work with other global efforts. Global partners in TB are developing targets beyond 2015, and efforts at CDC will be informed by that process.

Division of Global Migration and Quarantine Update

Update on Technical Instruction Site Visit for the Dominican Republic

Jon Warkentin, MD, MPH
President, NTCA
ACET Liaison Representative

Dr. Warkentin reported on the evaluation of the implementation of the 2007 TB Technical Instructions (TTI) in the Dominican Republic (DR). The multidisciplinary evaluation team spent eight days in the DR. The team included CDC representatives from DGMQ and DTBE and a representative from the Health Protection Agency in the United Kingdom, as well as external experts. The project was based in Santo Domingo and included visits to clinics and a baseball stadium. The DR has a diverse population, including persons of European, South American, and African origin. The incidence is high there, with approximately 6% of TB cases being MDR-TB.

The team had two objectives, which were to: 1) provide recommendations to the Consultorios de Visa (CdV) and the DR National TB Program (NTP) related to the screening, diagnosis, and treatment of TB among US-bound immigrants; and 2) provide recommendations to CDC's DGMQ and DTBE for improving the effectiveness and practical implementation of the 2007 TTI for screening and treatment.

The 1991 TTI were updated in 2007 and have been implemented in many countries around the world. In the updated protocol, persons between the ages of 2 and 14 receive a TST. If the test is negative, the person can travel within six months. If the test is positive, the person is given a chest x-ray. If the chest x-ray is normal, then the person is evaluated as B2 LTBI and can travel within six months.

All persons age 15 and over receive a chest x-ray. If the chest x-ray is normal and the TST is negative or not required, then the person can travel within six months. If the person's history, an examination, or a chest x-ray suggests TB or HIV infection, then the person undergoes three sputum smears and cultures for *Mycobacterium tuberculosis*. This approach allows for treatment before the person comes to the US. If the smears and cultures are negative, then the person can travel within three months. If treatment is required, then the treatment must be completed before the person travels, and the person has three months to travel from the completion of treatment.

The evaluation team utilized several methods, including the following:

- ❑ Many site visits to the CdV, Consulate Section, DOT site, and hospital
- ❑ Daily team strategy meetings
- ❑ Site observations
- ❑ Chart reviews of LTBI, TB, and MDR-TB cases
- ❑ Radiograph reviews of pediatric and adult x-rays
- ❑ A data review
- ❑ Interviews

The team concluded that the DR is operating a model site. The site is designed for high volume of as many as 50,000 applicants per year, and for minimal patient wait time. More applicants can be seen if the need arises. The process includes efforts to prevent fraud, such as ensuring that patients enter the grounds early; installing security cameras; training clinicians to look for signs of fraud; including a cafeteria within the compound; and investing in high-quality staff and providing them with opportunities for innovation.

Another strong element of this site is its commitment to patient education. Videos are shown in the waiting area, and weekly sessions are held on LTBI and on the consulate process. Each patient receives a data CD with his or her chest x-ray and paperwork. Additionally, paperwork is delivered directly to the Consulate's Office. The radiography system at the site is outstanding and includes two different digital units. Images are presented in real time to the full-time, on-site radiologists. The images can be interpreted immediately, and immediate intervention for abnormal chest x-rays is possible.

Pediatric TST placement and reading is well-done at the site. The immunization process is also well-done. Sputum and gastric aspirate collection is another strong aspect of the site. Infection control is generally managed well, and the site has an active partnership with a private laboratory which is committed to new technology. The team concluded that there is adequate case management of pan-sensitive TB cases, and the linkage to the NTP is growing. LTBI treatment and DOT are provided in community centers. The site was impressive in the area of information technology (IT) and in its plan for an electronic medical records (EMR) system.

The panel also identified areas of concern. The site has seen a decrease in culture-confirmed TB cases, and it is not clear why, as the transportation process and other processes appear to be sound. The team offered suggestions regarding the management of MDR-TB cases by the NTP. Five cases of MDR-TB were detected in the DR in 2011, and none have been detected so far in 2012. It is not clear why there has been a decrease in case detection of MDR-TB, since 6% of TB cases in the DR have historically been MDR-TB.

Overall, the facility is excellent, but minor recommendations regarding infection control were noted. The team was concerned about the possibility that the evaluations of patients are inconsistent, as patients move through the facility quickly. The team specifically pointed out the importance of ascertaining pertinent medical history and symptoms during the physical examination. Tracking specimens in the laboratory, particularly cultures, is critical.

The team was also troubled by an apparent delay in initiation of treatment by the NTP. Further, there is room for improvement in the management of TB cases by the NTP, including side effects, monitoring, and delayed response to treatment. Panel physicians make decisions about individual cases, and they rely on the data provided to them. If they do not receive detailed clinical information from the NTP, they cannot be certain that a patient received full treatment. The team suggested the development of a method for providing this documentation consistently.

Overall, the team concluded that CdV is a model for efficient, high-quality TB screening, particularly in high volume, for immigrants to the US. The team reported that CdV will benefit from additional quality assurance processes and infection control protocols, and appropriate staff training on those processes and protocols. Collaboration with the NTP is encouraging, but there is room for growth.

Dr. Warkentin acknowledged the support and cooperation of staff at CdV and in the DR. He asked ACET for feedback on the site and on the panel review process in terms of whether the process is reproducible and under what circumstances, and how long it will take.

Discussion Points

In response to a question from ACET about LTBI at CdV, Dr. Warkentin said that treatment for LTBI does not occur in the DR; rather, the diagnosis is made through the program in the DR and patients are encouraged to visit the health department in the US with their documentation for additional evaluation and treatment. CdV provides ample opportunities for patients to ask questions about the overall visa process. The education about LTBI itself is somewhat lacking, and the evaluation team encouraged CdV to utilize CDC products.

ACET commented on the process from the perspective of the immigrants, and asked how the panel physicians have expanded and whether there is a limit to the amount of money that they pay into the system. There should be regulation to ensure that the sites are not-for-profit and that their compensation is balanced with what patients receive.

Dr. Mary Naughton (CDC/DGMQ) answered that immigrants pay for their screening, while the US government pays for refugee screening. Individual consulate sections set the amount that panel physicians charge. Generally, rates are higher for adults than for children, and vaccinations are charged separately. The compensation for panel physicians tends to mirror the expenses in each country. CDC is primarily interested in the quality of care. They also consider how much panel physicians put back into their practice, including investments in equipment and personnel. The site in the DR has quality facilities and long-term personnel. CdV encourages innovative ideas among the personnel.

ACET remarked that the funding of this site is dependent on a fee-for-service structure and wondered about its sustainability.

In response to questions from ACET about the relationship of CdV and the NTP and the potential for CdV to strengthen the NTP, Dr. Christine Ho (CDC/DTBE) answered that when CdV determines that a patient needs treatment, the patient is referred to the NTP, which manages the treatment. The treatment is free. DOT takes place at all NTP sites and is provided to all in the DR who need it. One or two DOT sites have received supplemental funding from CdV, as the sites have provided DOT training to nurses and radiologists. Those efforts strengthen the NTP, and more can be done in the areas of drug-resistant cases and cases in which patients are not able to take the standard treatment regimen.

Dr. Warkentin added that SNTC has a relationship with the NTP, and there is potential to build on that relationship to provide education.

Dr. Naughton commented that CdV is forward-looking in its relationship with the NTP. In addition to sponsoring the DOT sites, they have a larger program through which personnel in the NTP are trained. CdV has facilities and equipment that are not available throughout the NTP, and they nurture their relationship with NTP. NTP will not accept results from a private laboratory, which may delay treatment. They are working on a mechanism for accrediting or certifying a private laboratory.

Dr. Susan Ray, an ACET liaison representative from the Infectious Disease Society of America, commented that the program seems to work well. She asked if the evaluation team chose to visit this site because they knew it works well, and how much better it works than programs in other countries.

Dr. Naughton answered that the program in DR has been one of the largest programs for screening immigrants coming into the US. This site visit is the fifth that has taken place. Other visits have focused on immigrant and refugee sites, primarily in Asia. In the past, sites that have a large impact on the US have been chosen. Generally, the visits are to sites that perform fairly well.

Dr. Andrew Vernon (CDC/DTBE) recalled that some years ago, WHO's drug-resistance surveillance reported a high rate of MDR-TB in the DR; however, the evaluation team reported a lower-than-expected rate of MDR. He asked about a consultation that DTBE provided to the NTP. He also noted a proposed study of drug resistance patterns in immigrants to the US to indicate resistance patterns in countries for which good data are not available.

Dr. Warkentin said that the data regarding MDR-TB prevalence in the DR is old. It would be useful to have more current information, but there are issues associated with the quality of the drug sensitivity testing at the national laboratory. Until that work improves, valid data are not likely.

Health Equity Update

Update on Health Equity Activities

Wayne A. Duffus, MD, PhD
Associate Director, Office of Health Equity / NCHHSTP
Centers for Disease Control and Prevention

Dr. Duffus presented ACET with an overview of health equity-related activities at NCHHSTP. The Office of Health Equity (OHE) has three objectives, which are to advance science in identifying and eliminating disparities; mobilize partners to promote health equity and social determinants of health; and identify and address key social determinants of health.

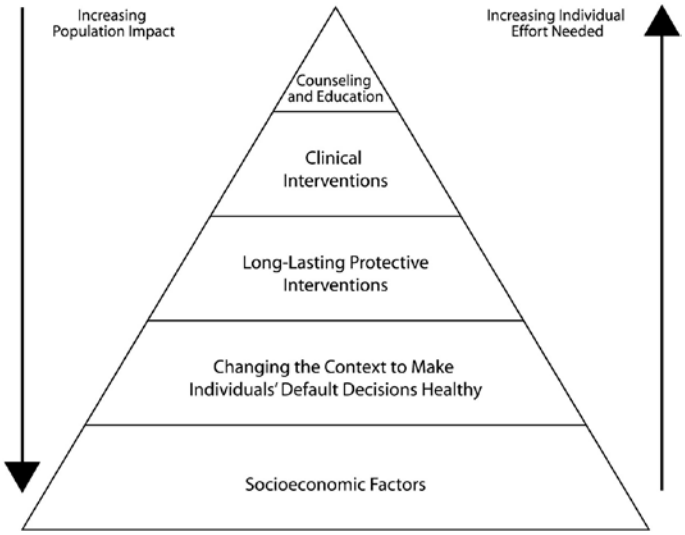
One definition of "health equity" is "optimal health for all, and no one is disadvantaged from achieving this potential because of his or her socially determined circumstance." Every person in every community deserves equal access to good health. The opposite of health equity is health inequity, which is defined as a "difference or disparity in health outcomes that is systematic, unfair, and avoidable."

In order to ensure that everyone has a chance to have optimal health, it is important to adopt a holistic approach to reduce rates of HIV, viral hepatitis, STDs, TB, and other diseases. This approach includes understanding and addressing the relationships between health outcomes and individual and behavioral factors, as well as environmental and social factors such as education, housing, access to employment, and transportation. WHO states that health equity cannot be achieved without addressing the social determinants of health. Health inequity results from differences in the general social, political, and economic conditions in which people live. These conditions are the social determinants of health.

Dr. Duffus shared data from the Robert Wood Johnson (RWJ) Foundation Commission to Build a Healthier America. The data indicate that for both men and women, more education often means longer life. Further, adult life expectancy increases with increasing income. Lower income generally means worse health. Racial or ethnic differences in health status are also evident. Poor or fair health is much more common among black and Hispanic adults than among white adults.

OHE adopted the WHO framework for social determinants of health to understand HIV inequalities. Many conditions in the model, such as homelessness and residential segregation, are common among the populations that NCHHSTP serves and have a negative impact on outcome. For instance, residential segregation can affect access to care or to high-quality care. Fresh fruits and vegetables may not be available. Homeless and incarcerated populations see higher rates of mental health and substance abuse issues.

A five-tier pyramid illustrates the different impacts of different public health interventions:



Interventions at the lower levels of the pyramid tend to be more effective because they reach broad segments of society and require less individual effort. Efforts directed at socioeconomic factors, located at the base of the pyramid, include poverty reduction, improved education, and improved access. The next tier on the pyramid includes interventions change the context so that an individuals' default decision will be healthy. Examples of these interventions are fluoridated water, salt iodization, and elimination of trans-fats. Long-lasting interventions on the next tier are one-time or infrequent interventions that do not require clinical care, such as immunizations. They tend to reach individuals as opposed to populations. Clinical interventions make up the next tier of the pyramid. These interventions require little contact, but are limited by access or a requirement of strict adherence. Interventions in this category include efforts aimed at diseases such as hypertension, hyperlipidemia, and diabetes. At the peak of the Health Impact Pyramid is counseling and education-based interventions. These interventions tend to be the least effective because they require more participation by individuals and require ongoing behavioral change. Examples of these interventions are increased physical activity and improved diet. Despite their relative lack of effectiveness, educational interventions are often the only available strategies and they can still have considerable impact.

Dr. Duffus explained the organizational structure for health equity within NCHHSTP. The OHE works collaboratively with each division. DHAP and DSTDP each have individual offices of health equity as part of their structures. All of the divisions contribute to a center-wide health equity workgroup, and additional workgroups meet periodically to share ideas and programs toward achieving the goals of health equity.

OHE was established in 2003 and was formerly named the Office of Health Disparities. Every year since 2005, the office has hosted a Lunch and Learn Lecture Series with the goal of advancing the science of health equity. The office has held internal consultations on social determinants of health, which have led to a published document.

The office conducted work on African Americans and TB. They also conducted a review of NCHHSTP surveillance systems for social determinants of health variables and hosted Health Equity Symposia in 2010 and 2011. OHE had peer-reviewed journal articles, three Public Health Reports Supplements, and presents at specialist and general public health meetings.

NCHHSTP utilizes policy approaches to achieve health equity. Health equity is an overarching goal in the center's strategic plan. A 2010 White Paper highlighted public health approaches to eliminate health disparities in HIV, viral hepatitis, STDs, and TB in the US. Additionally, all FOAs include health equity and social determinants of health language and guidance.

Another goal of NCHHSTP is to identify and address key social determinants of health for programs. Communication products focus on social determinants of health. OHE is developing a Social Determinants of Health Model Language Project to avoid NCHHSTP staff with examples of how to discuss potentially stigmatizing messages and to introduce concepts regarding social determinants of health and disparities in health outcomes.

In order to accomplish its mission, OHE and NCHHSTP have identified key partners in the federal government, academic institutions, and fellowship programs. Their partners help focus on expanding the pool of racial and ethnic minority students who view public health as a top career choice, public health ethics and health equity, sexual health, incorporating a health equity focus in curriculum development, and disease-specific issues.

Discussion Points

ACET appreciated the update on health equity activities at NCHHSTP, particularly on the progress over the years. Federal partners such as the White House and the Health Resources and Services Administration (HRSA) work with Historically Black Colleges and Universities (HBCU) as well as Hispanic and other institutions on the goal of expanding the pool of racial and ethnic minority students who view public health as a top career choice. There are opportunities for collaboration with other Offices for Health Equity in other federal agencies.

Dr. Duffus agreed, indicating that one of his goals is to reach out to assess what needs to be done in this area. He noted a successful fellowship program with Morehouse College.

Dr. Dean added that as an agency, CDC is active with minority fellowship programs. NCHHSTP hosts the Summer Fellow Forum and helps participants see the value in how their college majors intersect with public health. NCHHSTP is actually involved in workforce development programs and building a racially diverse public health workforce.

ACET asked whether the slides from RWJ exaggerated the differences in health outcomes among different social determinants of health.

ACET noted that in Japan, collaborations between social and health departments are common and strong, and the collaborations affect how people think about TB and its elimination.

Regarding the Health Impact Pyramid, ACET observed that most CDC funding tends to support activities on the upper levels of the pyramid, such as counseling and education and clinical interventions, as opposed to efforts that may have greater impact. ACET asked about efforts to work with other agencies to address the socioeconomic factors at the bottom of the pyramid, or whether CDC was taking a standalone approach, identifying the factors but not reacting to them.

Dr. Dean said that over the last five years, NCHHSTP has systematically examined its programs to incorporate a social determinants of health approach. They have reached out to their federal partners, and the work is not conducted "in a vacuum." The center catalogued its programs to determine where they are already incorporating social determinants of health, and to identify areas where the approach needs to be incorporated. NCHHSTP's FOAs include language pertaining to social determinants of health, and grantees incorporate the approach. NCHHSTP is looked on as a model within CDC in adopting the approach and in moving the science of social determinants of health forward and into public health practice.

Eileen Napolitano, an ACET liaison representative from Stop TB USA, asked about recent articles in terms of the language utilized to describe persons who have TB. She wondered about links between that project and social determinants of health.

Dr. Castro acknowledged that the field of TB control has used language that is programmatically oriented and is not friendly to the individual, such as referring to patients as "suspects" and using terms with pejorative connotations. These problems are being addressed while interacting with standardized definitions.

TB in the African-American Community: Updates from DTBE Health Equity Workgroup

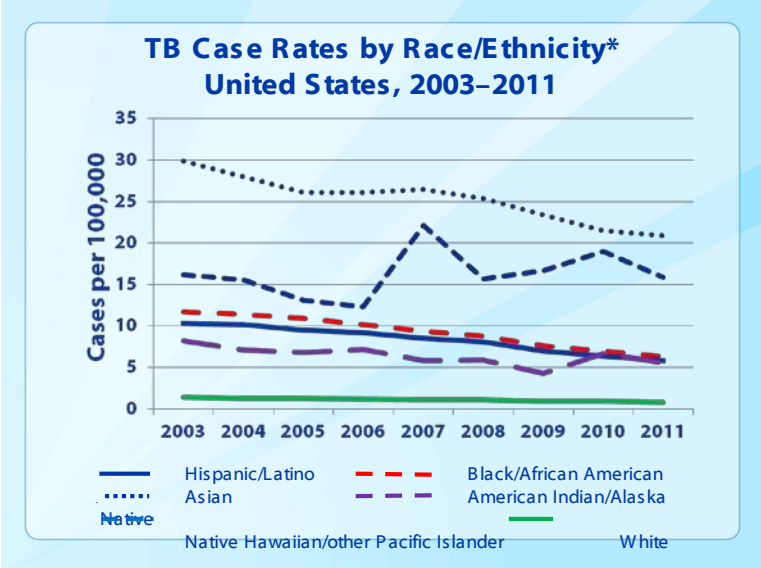
RADM Kenneth Castro, MD
Director, Division of Tuberculosis Elimination / NCHHSTP
Centers for Disease Control and Prevention

Dr. Castro explained that the DTBE Health Equity Workgroup was formed after ACET expressed interest in it in 2003. DTBE, ACET, and others held an awareness-raising workshop, followed by a summit in 2006. That work resulted in the creation of training and educational materials. The informant interviews indicated that TB is not frequently mentioned in conversations about social determinants of health or health disparities. DTBE and the workgroup have continued this work and engaged with other entities.

Awal Khan, PhD
Health Scientist, DTBE
NCHHSTP/OID/CDC

Dr. Awal Khan presented updates from the DTBE Health Equity Workgroup. One of DTBE's five priority areas is to reduce TB in racial and ethnic populations, and another is to reduce TB in foreign-born populations.

In 2011, a total of 10,528 TB cases were reported in the US. The case rate is 3.4 TB cases per 100,000 population, but in the 13 states, the rate is higher than 3.4 per 100,000. They represent 67% of all TB cases reported in the US. The following table depicts TB case rates by race and ethnicity in the US from 2003 – 2011:



In 2003, the TB case rate among African Americans was 11.7 per 100,000. In 2011, the rate was 6.3 per 100,000, showing a rate decline of approximately 46%. Case rates declined similarly in the Hispanic and Latino populations. Rates among Asians decreased approximately 30%, and rates in American Indian, Alaska Native, Native Hawaiian, and other Pacific Islander populations varied but have experienced an overall decrease.

In 2011, 84% of all TB cases were among racial and ethnic minorities, especially in Asians, African Americans, and Hispanic and Latino populations. Among US-born cases, African Americans represent 39% of TB cases. African Americans represent 13% of foreign-born TB cases. Most of the foreign-born TB cases are in Asian and Hispanic populations. White populations account for 5% of the foreign-born TB cases and 33% of the US-born TB cases. Overall, African Americans have the highest proportion of TB cases.

From 2003 to 2011, TB case rate ratios among African American and white populations remained essentially stable. However, the case rate ratio among Asians has risen. The ratio of US-born African American to US-born white case rates also remained steady until 2009. From 2009 to 2001, there is a steady decline in that rate ratio.

Dr. Khan described efforts to reduce TB rates among African Americans, including partnership initiatives. The Working Together to Stop TB (WTST) Toolkit is a product of TBESC Study 11. The toolkit was developed by SNTC to help TB programs address the issues of TB disparities in local African-American communities, and it was pilot tested in areas where TB presents in higher rates in the African American population. Its objectives are to raise awareness of TB among African Americans; foster collaboration among community groups, minority health programs, and public health regarding TB in African Americans; and help TB programs conduct TB forums.

The pilot study with SNTC began in 2011. Nine sites were selected to pilot test the WTST toolkit. SNTC conducted two webinars to train site facilitators, and about 20 participants received on-site training for site facilitators in Atlanta in April 2011. Three additional webinars followed the on-site training.

The goal of the pilot project was to train facilitators to plan, implement, and evaluate TB educational forums within high burden African-American communities. The participants came from all over the country. They applied their training to develop partnerships in their local areas. About 14 community engagement and leadership initiatives have resulted from the training. The participants have held health events and health education trainings. They have also created steering committees and raised local awareness through newsletter articles, newspaper articles, and proclamations. SNTC plans to continue to follow up with the sites.

Dr. Khan described the DTBE Health Equity Workgroup, which includes representation from all seven branches of the division and the Office of the Director. Its main goal is to promote opportunities for collaboration working across DTBE branches and with the NCHHSTP divisions. The workgroup holds a monthly meeting, and recently reorganized and has achieved a series of accomplishments.

In collaboration with other branches within DTBE, the workgroup developed a fact sheet about TB in African Americans and Blacks. A fact sheet for the Hispanic population has been developed and is in the clearance phase, and a new website has been developed. The workgroup presented DTBE activities at an NCHHSTP "Lunch and Learn" in coordination with other presentations on TB treatment and prevention among African Americans compared to whites, "causes of the cause" as African Americans and Asians are disproportionately affected by TB, and risk factors for TB among US-born and foreign-born populations. The workgroup also cataloged all TB projects and activities related to health equity and social determinants of health. Finally, DTBE has provided direct assistance to states with TB outbreaks among African-Americans.

The Health Equity Workgroup has brainstormed about how to assess the causes of disparities among racial and ethnic minorities, and how to better understand the causes of racial disparities. The workgroup includes persons with extensive experience in these issues. After the March 2012 ACET meeting, it was decided that an ACET member would participate on the DTBE Health Equity Workgroup, and Dr. Khan thanked ACET members Dr. Narita, Mr. Jones, and Dr. Warren Hewitt for occasional participation of the monthly conference calls.

Discussion Points

ACET commented on the CDC-funded Enhanced Comprehensive HIV Prevention Planning and Implementation Program (ECHIPP) cities, seven of which are included in the data from cities with high rates of TB cases over 100,000 population. It will be important to consider racial and ethnic populations in those cities, particularly for TB.

ACET commented on the relevance of residential segregation and isolation for African Americans. A recent article from Johns Hopkins examined public health disparity issues and racial segregation, and other authors have also considered the issue.

ACET suggested that the Health Equity Workgroup and its ACET participants should meet on a more consistent basis to pursue a stronger agenda.

ACET applauded DTBE's understanding of the need to advance activities as they articulate the activities' objectives and expected impact, and measure the impact.

ACET asked whether participation in WTST is limited to programs that are funded by CDC, or whether others such as primary care associations and other HRSA-funded programs could expand their reach. HRSA uses knowledge management portals to disseminate information and for training purposes. When WTST is evaluated, it could be included in these portals.

Ms. Gail Burns-Grant (CDC/DTBE) answered that WTST involves other partners. When the project began, states identified local partners. The training session in Atlanta included representation from non-governmental organizations (NGOs) and community-based organizations (CBOs). Other participants included infection control nurses. These partners are vital to the success of the project.

Dr. Warkentin shared his experience in Tennessee, noting that forums are useful ways to bring people together, but a spark must be ignited that will result in follow-up, community action, and engagement in the long-term. Public health programs must have resources for these activities. Regarding the epidemiological data, he asked whether the African American morbidity and mortality data had been stratified by HIV status and age. He also asked about the status of Task Order 23.

Dr. Khan replied that Mr. Elvin Magee conducted an analysis of risk factors, including socioeconomic factors, homelessness, incarceration, and behavioral risk factors such as alcohol. The analysis also included HIV and how those risk factors affect the TB case rate among US- and foreign-born African Americans. There will be an update when this analysis is complete. An update on the status of Task Order 23 was presented on October 22, 2012. The report is being prepared.

Dr. Nardell pointed out that groups that are at risk for one thing are often at risk for many things. Efforts to make communities aware about TB may not have impact, given other risks and issues such as diabetes, hypertension, obesity, smoking, and others. He wondered about creative ways to package TB with other concerns so that it is more realistic to expect people to become aware of TB.

Dr. Khan replied that DTBE is pursuing the idea of understanding the disparities and underlying causes of TB, such as socioeconomic and behavioral issues that contribute to TB cases among racial and ethnic minorities. Then, they create an action plan and approach based on the Health Impact Pyramid. There are great opportunities to understand disparities and to understand the factors that affect racial and ethnic minorities.

Ms. Burns-Grant (DTBE, CDC) said that there will be an evaluation of WTST. The participants who obtained training in Atlanta have identified partners in their local programs in areas such as diabetes, hepatitis, HIV, and others. There is a holistic approach to addressing patients and clients at the community level, and the different groups are learning more about each other and crafting messages together to educate target audiences regarding disease.

Ms. Suzanne Marks (DTBE, CDC) said that within the last month, guidelines for integrated services were released. It is important to determine how best to implement those guidelines.

Dr. Robert Benjamin, an ACET liaison representation from the National Association of City and County Health Officials (NACCHO), reflected on how to communicate messages to impacted populations. Although TB is not one of CDC's Winnable Battles, at least three of the six battles could be linked to TB: HIV, tobacco, and obesity/diabetes. PCSI is purported to make these

connections, but he was not certain that the linkages have been given enough emphasis. He suggested that they "grab onto the coattails" of the priorities that are relevant to TB and ensure that TB advocates are included in the messaging.

Mr. Jones acknowledged the positive trends indicated in the data presented by Dr. Khan.

ACET Workgroup Updates

Mr. Jones explained that several workgroups were formed to support ACET operations and to make recommendations as part of the ACET mission.

National TB Program Workgroup

Gail H. Cassell, PhD
Visiting Professor, Harvard University
Chair, ACET National TB Program Workgroup

Dr. Cassell thanked the participants on the National TB Program Workgroup. They have focused on understanding the group's broad charge. In a conference call, Dr. Castro asked the group to provide recommendations in the following three areas:

- The level of support to health departments to carry out their TB prevention and control activities, including laboratory needs, the funding formula for the distribution of resources, and the administration of cooperative agreements in a time of constrained resources
- Surveillance, especially taking advantage of new methodologies and applying molecular tools to enhance outbreak investigations
- The research portfolio, including laboratory research, specifically focused on the state and local levels

The workgroup needed a definition of the current status of TB control programs, the resources available, and a better understanding of the research portfolio. In particular, the workgroup sought to understand how the CDC portfolio might synergize with the portfolio of NIAIP, or how their efforts could synergize at the state and local levels. Detailed information is necessary in order to address their three areas of concern and to make concrete recommendations in three requested areas:

- Is the focus of the TB control programs appropriate?
- What gaps need attention?
- Should any aspects of the programs be discontinued?

The workgroup held several conference calls and one face-to-face meeting with CDC staff, and heard background information as well as information on existing programs and a summary of the NIAID portfolio. There is no duplication between the portfolios, but there are opportunities for continued synergy not only in research, but also related to the regulatory approval of new molecular tests, such as GeneXpert, and of monitoring and approval of new drugs.

One strategy for accomplishing the workgroup's charge will be to compare high-burden and low-burden states: California, Texas, New York, New Jersey, Florida, and Illinois. The states were chosen in consultation with CDC staff. The workgroup is exploring the possibility that Texas can serve as a model for their review process. Texas has a unique program, and the state has considerable needs and challenges associated with its 1200-mile border and its diverse population. Texas also has a genotyping unit and close interactions with the Mexican TB Control Program. Those relationships are unique, but can also serve to illustrate a number of important aspects of TB control in the US. The workgroup will also collect data from existing databases and from a broad survey of the state TB programs. They hope to conduct site visits in the other states which might represent the extremes of TB control in the US.

The site visit to Texas could include learning about the structure of the TB program at the central office in Austin. The visit could then "branch out" to the structure of the health regions, including local TB programs in the Houston area and in the border programs. Other sites could include the Immigration and Customs Enforcement (ICE) Detention Center and centers for children and women, as well as correctional facilities.

The workgroup's next steps are to arrange site visits in a timeframe so that they can complete their report for the June 2013 ACET meeting. Dr. Barbara Seaworth, ACET member, and Dr. Jeffrey Starke have been asked to serve as consultants to this process. Officials in Texas are excited at the prospect of a site visit. New members of ACET will also be asked to participate, as the workgroup is relatively small, and they hope to take advantage of the expertise of all ACET members and liaisons.

Discussion Points

Mr. Jones, ACET chair, explained that ACET workgroups are given one year to complete their assignment. This workgroup's term will be complete in March 2013, and they may need to seek a six-month extension in order to generate recommendations. Dr. Cassell said that the workgroup would seek input from ACET before making final recommendations, so it is reasonable to request an extension.

ACET thanked Dr. Cassell for the update. Last year, Dr. Castro asked ACET to address questions in three areas: the National TB Program, the ACA, and TB elimination goals. ACET hoped that they would be mindful of the diversity of TB control and elimination in the US. It is important that the ACET workgroups work synergistically to address multiple aspects of TB control.

ACET recommended that the site visit to Texas include detention settings, correctional facilities, and local jails along the southern border of the state. These facilities house mixed populations of local inmates, US Marshal Service prisoners, and ICE detainees. Some of these facilities are large, and they will be different from facilities that are managed by the federal government. Texas has one of the highest rates of TB cases that are diagnosed in correctional facilities. Further, it is important to consider the continuum from screening to evaluation of patients in correctional facilities. Much of this evaluation takes place at local hospitals, and there can be breakdowns in the evaluation of patients for TB.

Dr. Cassell observed that the use of molecular diagnostics and faster approaches could make a significant difference in controlling TB in correctional facilities and detainee populations. She agreed with the importance of considering local hospitals, the variability in follow-up, and the opportunity for missed cases.

Dr. Marcos Burgos, ACET member and member of the National TB Program Workgroup, added that NTCA is developing a survey pertaining to the National TB Program. That data will be important to take into account.

Dr. Warkentin explained that the NTCA will duplicate a survey from 2010. It is a "TB Control and Prevention Capacity Assessment." Data will be collected from all 50 states, including TB controllers in large cities and at other levels below the state level. NTCA is committed to finding resources for the analysis, as they know anecdotally from their membership that TB programs at the local level have suffered due to decreased resources during the recession.

Dr. Warkentin asked for elaboration on the idea of Texas as a model.

Dr. Cassell clarified that it is impossible to conduct a thorough review of every state TB program. Therefore, the workgroup will select for review programs that are extremes; that is, illustrative of high burden and illustrative of lesser burden. The workgroup has also discussed challenges associated with the large number of pediatric cases that are potentially undiagnosed and not tracked. Houston, Texas, sees a high number of these types of deliveries. Further, Texas is attractive as a model due to its high TB burden and because of its links to laboratories and the potential for considering new molecular techniques for addressing outbreaks.

Dr. Nardell said that Massachusetts has had universal healthcare in place for some time. As TB cases decline, the state will transition to a different kind of care. At a retreat on December 14, 2012, a group of primary care providers and thought leaders will consider a different structure for TB control. As the ACET workgroup considers states to visit, he suggested that the transition to different structures under low-prevalence conditions and universal health insurance should be on the agenda.

Dr. Cassell replied that these issues are important, especially given the lack of experience and expertise of individuals that may see patients with TB.

Dr. Maria Teresa Zorrilla, an ACET liaison representative from the US-México Border Health Commission, spoke about the Bi-National Joint Declaration of the Texas Department of State Health Services of the US and the Secretariat of Health of the State of Coahuila of the United Mexican States. This statement focuses on bi-national, collaborative work on TB control at the US-México border. She shared the document with ACET.

Dr. Napolitano asked about the process of the proposed site visits. For instance, would different groups visit the states and use a standardized assessment tool so that the results of the visits will be comparable? She noted that while the proposed site visit states have high burdens and lesser burdens, there are no areas with low burden.

Dr. Cassell replied that they may need an additional state with a low burden. The workgroup will use processes and tools developed by WHO in order to standardize the review. Because the workgroup is relatively small, additional people will be asked to participate. Beginning with the review of Texas will allow them to determine the feasibility of conducting more site visits and what will be required to conduct the reviews.

Dr. Castro clarified that the workgroup is proposing to engage in an in-depth case study using Texas as a convenient location, not necessarily because it is representative. Texas brings the opportunity to address border concerns, bi-national issues, laboratory concerns, and issues of TB in incarcerated populations. Texas houses one of the five RTMCCs. While the site visit will yield information only about Texas, the information gathered will inform future steps. Additional data will come from the NTCA assessment tool. The work is important and necessary, but the visits are costly and labor-intensive, and teams will need to divide across large geographical areas to address different themes.

Dr. Warkentin noted that the organization of public health varies among states. The case studies should document how public health is structured in each state, given that state health departments have different relationships with counties and sometimes with regional entities. Understanding the environment in which these programs exist will be important in drawing conclusions from the reviews.

ACET Corrections Workgroup

Jane E. Carter, MD
Associate Professor/Teaching Scholar, Alpert School of Medicine at Brown University
Chair, ACET Corrections Workgroup

Dr. Carter explained that the ACET Corrections Workgroup was formed after the March 2012 ACET meeting. They have met for the last six months and would present their recommendations.

Sarah Bur, RN, MPH
Infection Control Consultant, Federal Bureau of Prisons
ACET *ex officio* Member

Ms. Bur listed the workgroup members and explained the workgroup's charge, which was to provide a set of recommendations to the Secretary of HHS and CDC regarding the development of a national strategy for improving prevention and control of TB in correctional facilities.

The US has the highest incarceration rate in the world, with approximately 2.3 million people incarcerated. The "epidemic of incarceration" in the US began in 1980 with changes in drug laws, the institutionalization of the mentally ill, and mandatory minimum sentencing. The risk of TB in jails and prisons is four to five times greater than for the general population. The rates vary based on location and are higher along the US-México border. Outbreaks continue to occur in correctional settings, posing a threat for widespread TB transmission. Rates of TB treatment completion are significantly lower among active TB cases diagnosed in correctional facilities than among non-incarcerated populations, and only 50% of foreign-born inmates complete treatment. The "2006 CDC Guidelines for Prevention and Control of Tuberculosis in Correctional and Detention Facilities" provide detailed, relevant, and comprehensive guidance, but have not been fully implemented by correctional and detention facilities.

Given that correctional settings provide opportunities to turn the tide for these concerning TB trends, the Correction Workgroup offered several recommendations.

CDC should consider making TB prevention and control in correctional settings a priority focus to improve TB case detection; reduce TB case rates; increase TB treatment completion rates among TB cases identified while incarcerated; prevent TB transmission in these settings; and expand treatment of latent TB infection to prevent future TB cases.

The "2006 CDC Guidelines for the Prevention and Control of TB in Correctional and Detention Facilities" recommend that every health department should have a Correctional TB Liaison. In many health departments, that role is critically important to support jails and prisons to implement comprehensive TB control and prevention programs. There are strong models for these relationships across the country, especially in California. With input from partners, the Corrections Workgroup created a recommendation that DTBE make an addition to the TB Cooperative Agreement language: "TB prevention and control in correctional and detention facilities is a high national priority. Each Cooperative Agreement recipient will designate a correctional liaison and provide a brief summary report of activities in the interim and final progress reports."

Regarding surveillance, a Report of Verified Case of Tuberculosis (RVCT) is collected when TB is diagnosed in a correctional facility. This data could be used more creatively, and more in-depth analysis could be conducted. Therefore, the workgroup recommends that DTBE develop a plan for using TB surveillance data as a programmatic tool to identify burden of disease in correctional settings and the need for proactive interventions and special studies. The workgroup also recommends that DTBE publish a brief annual summary of trends in TB in correctional and detention facilities. The workgroup also recommends that DTBE add a question to the RVCT to address the patient's history of incarceration.

Many challenges are associated with TB case detection in correctional settings. These challenges are inter-related; for instance, as the workforce retires, the level of TB expertise in local community hospitals is disappearing. There are also issues with the use of rapid testing, which is recommended for persons in high-priority settings such as prisons. These tests are often not available in local hospitals. Algorithms are needed for returning inmates with suspected pulmonary TB to the general inmate population.

Continuity is also a concern for foreign-born inmate patients with TB. The workgroup recommends that DTBE conduct state-specific analyses of the low rates of TB treatment completion among persons incarcerated at diagnosis. The workgroup also recommends that DTBE evaluate the effectiveness of transnational referral programs and explore long-term funding for them. DTBE should explore the possibility of establishing a central system to obtain completion of treatment information from foreign countries for patients who have moved or been repatriated outside the US. Finally, DTBE should identify successful programs for improving continuity of care and TB treatment completion for TB cases identified in correctional facilities. Information about these effective models should be disseminated.

Regarding education, the workgroup recommends that DTBE coordinate with the RMTCCs on strategies to identify and meet the TB learning needs of correctional administrators, health care providers and infection control personnel, law enforcement and correctional officers, and inmates. The workgroup also recommends that the division conduct a needs assessment and develop, disseminate, and evaluate educational tools. It is important that correctional healthcare providers know "the rules of TB," because it is not feasible to educate every local infectious disease physician and pulmonologist.

The workgroup also created recommendations concerning the treatment of LTBI. The 12-week isoniazid/rifapentine regimen has great potential in the corrections population and to improve treatment completion. Currently, completed treatment consists of 76 directly-observed doses. Introduction of the 12-week regimen is beginning at six pilot sites through the Federal Bureau of Prisons (FBOP), and they are cautious about co-morbidities, especially with hepatitis C.

TB funding is declining, and it is important that DTBE partner with key stakeholders to leverage existing and future resources for TB prevention and control in correctional and detention facilities. For example, PCSI funds could address infectious disease in corrections. Emergency preparedness funds could be used to strengthen the airborne infection isolation capacity in prisons and jails. The workgroup recommended partnering with HIV/Viral Hepatitis/Diabetes organizations, as well as organizations and programs that work with immigrant populations. Finally, national correctional organizations are powerful potential partners.

Regarding coordination, the workgroup recommended that DTBE strengthen the coordination and oversight of TB prevention and control in correctional and detention facilities in partnership with state TB programs. Work has begun in this area, but it could be strengthened. The work can include developing ongoing collaborative partnerships with national and regional correctional organizations to advance TB education and prevention and control efforts. A great deal of correctional healthcare is contracted to large corporations. There is potential for partnering with those providers. A full-time staff member at CDC may be needed to coordinate these activities.

Corrections is a complicated field with many perspectives, settings, and issues. Public health needs to understand this field and the overall context of correctional health in order to prevent and control TB in corrections settings. In 2009, NCHHSTP hosted a national external consultation entitled Correctional Health" Expanding the Reach of Prevention. One of the major recommendations from that consultation was to establish a CDC Office for Correctional Health." The workgroup recommended that ACET recommend that the CDC Director consider establishing an Office of Correctional Health to provide national leadership and assure that all CDC centers operationalize correctional health priorities in programs and guidelines.

Discussion Points

ACET commented on an ongoing case in the state of Alabama that may have impact on the recommendations that ACET makes. The case involves a group of HIV inmate patients who were being discriminated against because of segregation in the prison. The final rendering of the Supreme Court could set a precedent for prison health.

Regarding private correctional healthcare providers, ACET commented that some have been culpable for failure to provide proper care. They have been the subject of litigation concerning access to care. They may not be optimal partners; however, federal, state, and local entities all contract with for-profit companies to incarcerate inmates. There may be concerns about the TB programs in these facilities, and they may not provide the highest standard of care or live up to their contractual obligations, but they could still be valuable partners. Additionally, private organizations will not be able to supply the best care if they do not have good guidelines.

ACET noted that HIV programs at CDC also have concerns about the incarcerated population and their care. An inter-center discussion at CDC, and perhaps beyond CDC, may be needed to discuss prison health. PCSI may not be the best approach.

Because the proposed resolution is lengthy, ACET suggested that the Corrections Workgroup create a summary of the resolution, including specific deliverables, on which ACET can vote.

ACET asked about engagement with the community of inmates, who could be interested in these issues and could be powerful allies. Ms. Bur replied that in her experience, inmates are often the first in the setting to know about a TB case in their midst. Promoting LTBI in this population will require education of the general inmate population as well.

Dr. Ray congratulated the workgroup on their accomplishments and supported their comprehensive results. She commented that ACET's discussion about TB in African Americans at the meeting thus far had not addressed how incarceration contributes to those rates. Funding directed toward addressing the problem of TB in the African American population in the US should be cognizant of the link to incarceration. She commented on the human rights violations associated with incarcerating persons from a certain race at disproportionate rates, and then with not protecting their health. Issues of disparities and social determinants of health are prominent in issues of TB in corrections.

Dr. Castro commented on the outrage of prison guards in New York State after an officer died of MDR-TB, which led to action. A key group of allies will be the people who work at correctional facilities, as their own health is affected.

Dr. Nardell said that while it is important to have comprehensive guideline for TB control in prisons, it is also important to develop a succinct core message. Rather than focusing on isolation rooms, the focus should be on active case-finding, rapid diagnosis, and referral to appropriate therapy.

Second Line Drug Shortages Update

Ann M. Cronin
Associate Director for Policy and Issues Management / DTBE
Centers for Disease Control and Prevention

Ms. Cronin provided ACET with an update on shortages of drugs used for TB treatment. The cornerstone of TB prevention is an effective drug supply and management system. In addition, it is critical to have a regular, uninterrupted supply of all essential anti-TB drugs. Patients with TB must receive appropriate treatment until they are cured.

Drug shortages are currently a pervasive problem throughout many areas of health care. In 2010, NTCA conducted a nationwide survey to understand this problem and its impact on TB control in the US. The results of the survey indicated that shortages and other barriers to receiving medicine are hindering consistent access to second line drugs. Interruptions can lead to adverse patient outcomes through delays in treatment initiation; substitution with other, potentially more toxic or less effective, medications; relapse; and treatment failure. Drug shortages also can lead to higher degrees of drug resistance and transmission of drug-resistant TB.

TB controllers report that the following drugs are in short supply: Amikacin, Capreomycin, Clofazimine, Cycloserine, Ethionamide, INH (isoniazid) 300, Linezolid, PAS (4 aminosalycitic acid), and Rifapentine (for treatment of latent TB infection). Many of these drugs have a sole manufacturer. When a manufacturer decides that it is no longer in their interest to produce the TB drug, this may result in the drug being completely unavailable, as is the case with kanamycin. Drug shortages are difficult for patients and providers and can threaten the public's health.

DTBE approaches drug shortages in several ways. Staff physicians consult with TB programs when shortages are identified. TB controllers frequently work together to get the drugs that the need, but the work is time-consuming and disruptive to patients. DTBE can provide evidence of the impact of drug shortages and drug costs. An upcoming *MMWR* article will address these issues. (This was published January 18). DTBE is collaborating with FDA to show where the drugs are in short supply and to help disseminate information to the TB controllers. Stockpiling drugs is another potential option, although procurement, storage and distribution of the drugs would be complex.

DTBE has drafted a protocol that would allow CDC to hold the Investigational New Drug (IND) for Clofazimine. This approach will not answer all of the problems of drug shortages, but it may reduce the administrative burden on TB programs. Clofazimine has a long history of safe and effective use for leprosy and MDR-TB. The manufacturer, Novartis, ceased distribution and marketing of Clofazimine in 2004. Novartis still manufactures the drug but releases it to the National Hanson's Disease Programs for release to individual patients. Any other indications require single patient INDs, which are administered by the FDA. The FDA considers treatment of MDR-TB as a qualifier for an emergency IND. The process requires review by an Institutional Review Board (IRB) within five days of administration of the drug.

If DTBE holds this IND, it could enable faster access to Clofazimine for patients who have limited options for TB treatment, including individuals with multi-drug resistant (MDR) TB or extensively-drug resistant TB (XDR TB), or individuals who have functional MDR TB because they are unable to tolerate other medications.

The protocol is not designed to answer research questions, and patients are referred to the program. In the IND process, the treating physician will identify the candidate and inform DTBE of the eligibility criteria for the candidate. The physician will obtain consent from the patient and submit the appropriate FDA forms. The physician will also monitor the patient while in treatment, consult with DTBE, and assure confidentiality. DTBE's role in the process is to verify patient eligibility and to inform the CDC IRB of the patient's enrollment. DTBE will also consult with the treating physician, monitor adverse events, and report them to the FDA. CDC will manage a data system for keeping track of adverse events and assure patient confidentiality.

Ms. Cronin acknowledged the work of Dr. Jennifer Flood (California Department of Public Health); Dr. Sundari Mase (CDC/DTBE); Dr. Neha Shah; and ACET liaison representative from TAG, Ms. Cornelia Jervis.

Ms. Jervis will hold a Federal Advocacy Meeting on January 18, 2013, in Washington, DC. This meeting will assemble the different groups that have been working on this issue and to share their advocacy strategies as well as the broader effects of drug shortages, such as administrative costs. The meeting will also educate stakeholders from FDA and Congress about the issues. They hope to begin to develop a multifaceted advocacy campaign that addresses the issues and how to work together as a coalition. TAG is funding some meeting attendees from TB control programs. Additionally, TAG staff members are working with manufacturers to lower the price of Rifapentine. Their advocacy work includes working with TB controllers and providers to develop cost-reducing strategies. Other groups are engaging in advocacy work to address drug shortages.

Discussion Points

ACET asked about tracking of the lack of availability of drugs and whether the information is widely available. A historical record of the magnitude of this problem would be useful.

Ms. Cronin replied that the FDA maintains a website on all current drug shortages. CDC keeps internal records of the drugs that have been unavailable in the past, and for how long.

In response to a question from ACET about the possibility of an IND for Kanamycin, Ms. Cronin answered that while Kanamycin is licensed for use in the US, it is not manufactured in the US and is not available. It is not clear whether Kanamycin is a good candidate for an IND. FDA was not supportive of the importation of the drug in discussion thus far, based on information they had on the firm that manufactures it.

Dr. Castro said that options beyond the IND have been considered. CDC Director Dr. Frieden suggested that DTBE explore the possibility of importing drugs that are produced for the Global Drug Facility, but that are not available in the US. It may be possible to have an IND for Kanamycin and import it from Japan, but the FDA must be satisfied with their manufacturing processes. This problem is larger than TB, as exemplified by the President's October 2011, Executive Order to the FDA to address chronic shortages of prescription drugs. CDC learns about shortages from the states, and no forecasting system is foolproof. CDC is willing to consider other methods for meeting needs.

ACET commented on efforts to work with manufacturers to lower the cost of drugs. This approach may cause the drugs to disappear from the market. In the case of TB drugs, payment is not meeting the manufacturers' costs. Lowering the costs may discourage them further. Producing some drugs is equivalent to losing money for drug companies that could be devoting the same capital and personnel resources into a more profitable drug.

Ms. Cronin said that there are two sides to the drug shortage problem: the drug cost, and the drug availability. Any proposed solution to the problem has limitations. The development process for drugs that will not be highly profitable is another concern.

ACET noted that the issue is complicated because some of the drugs are expensive, and some are not. Some of the drugs are needed by many people, and some are needed by a few people. It is important to distinguish between "no profit" for drug manufacturers and "not enough profit" for manufacturers. The GDF is assuring that each drug has at least two manufacturers. Further, drug shortages can also be due to problems in supply chain management, not just production. The states are not able to employ a drug management system that allows them to forecast appropriately.

ACET recognized that the patients affected by these shortages are frequently underrepresented. They must be aware of the public health impact associated with TB transmission in the community.

ACET said that the Secretary of HHS could be encouraged to explore options in the area of the profitability of uncommonly-used drugs.

In response to a question from ACET, Ms. Cronin said that CDC is not currently utilizing the Orphan Drug Act to address the problem; however multiple approaches should be considered. The ACA does not address this issue.

Ms. Jervis said that the childhood cancer community has coalesced to generate advocacy around many issues. Their approach has brought focus to their issues, and TAG hopes to learn from them.

Dr. Sundari Mase (CDC/DTBE) said that there is not a systematic method for collecting information on drug shortages. The information comes from state and local programs. Drug shortages are not necessarily nationwide, but could be an instance of a problem with a pharmacy or a distributor.

Ms. Jervis added that many states will reject the Medicaid expansion. The ACA is an important step forward, but it is not clear whether states will take advantage of all it has to offer.

Dr. Benjamin agreed that the issue is broader than TB, and that manufacturers are likely to cease production of a drug when reimbursements decrease. During the H1N1 pandemic, the government guaranteed purchase of the vaccine. He asked whether the US has a national formulary or national "essential drug list." If such a list existed, as it does for bioterrorism, then the government could assure a market for those essential drugs.

TB/HIV Collaborations

The Epidemiology of TB-HIV in the United States

Taraz Samandari, MD, PhD
Division of HIV/AIDS Prevention / NCHHSTP
Centers for Disease Control and Prevention

Dr. Samandari provided ACET with an update on U.S. HIV testing among TB patients; HIV prevalence in TB patients; TB incidence after antiretroviral therapy (ART); TB mortality among persons living with HIV; and LTBI in persons living with HIV.

Last year, PAHO sent CDC a survey to ascertain how well the HIV and TB Divisions work together at the national level. The collaboration between DHAP and DTBE is adequate. In the US, 1.2 million people are infected with the HIV virus, and 50,000 new cases are reported every year. In contrast, TB cases are declining. Of the TB cases, less than 700 are co-infected with HIV.

There has been an increase in the number of TB patients who are tested for HIV. A significant increase in 2010-2011 is attributed to new reporting by states that were not previously reporting HIV test results. African American TB patients were more likely to have HIV testing than other racial and ethnic groups. However, injection drug users, non-injection drug users, inmates, and alcohol abusers were less likely to be offered HIV testing. Some people refused HIV testing, particularly Asians, 15 to 24 year olds, 45 to 64 year olds, non-Hispanic whites, and foreign-born persons. Among persons of all ages, the percentage with HIV test results increased from 67% in 2010 to 82% in 2011. Among persons 25 to 44 years of age, reporting of HIV test results increased from 75% to 90% from 2010 through 2011.

States or territories that had more than 100 TB cases and less than 75% testing of their TB cases for HIV were Indiana, Marshall Islands, Massachusetts, and New Jersey. States with more than 200 cases and 75 - 84% HIV testing rates were Arizona, California, Florida, New York State, New York City, Pennsylvania, and Texas.

In 2011, there were 10,528 total TB cases, and 8,683 of them received HIV tests. Of those tested, 672 cases (6% of total TB cases) were HIV-infected. The prevalence of HIV in TB-infected patients is declining over time. In 1993, 29% of TB cases were HIV-infected. The rate of HIV infection among TB patients of all ages has remained at approximately 6% since 2008. The rate is 10% among patients aged 25 to 44. Puerto Rico has the highest proportion of HIV-infected TB cases; however, the total number of TB cases is 40. Florida also has a high proportion of HIV co-infected TB patients at 18%. Other states with high proportions (10.5-13.4%) include the District of Columbia, Tennessee, New Hampshire, the Republic of Palau, Connecticut, New York City, Nebraska, and New Jersey.

ART has revolutionized the longevity, survival, and well-being of HIV-infected persons. It also reduces the risk of TB. Patients receiving antiretroviral therapy (ART) had a relative TB risk of 0.2 in early U.S. studies when compared to HIV-infected patients who did not receive ART. Since then this statistic has been confirmed.

DHAP significantly contributes data to the North American AIDS Cohort Collaboration on Research and Design (NA-ACCORD). Data from this cohort in a recent publication showed the incidence of TB in HIV-infected persons receiving ART. Because of the relatively low incidence of TB in HIV-infected persons receiving ART in the U.S., the authors of the article incorporated multiple cohorts to conduct their analysis. The group of cohorts included 37,845 persons, and 145 were diagnosed with TB after ART initiation. The risk of TB was highest in the first three months of ART, suggesting that screening may not have been performed when people were enrolled into the study. A multivariate analysis concluded that factors independently associated with TB risk included low CD4 count (under 200), black race, other non-white race, Hispanic ethnicity, and history of injection drug use.

Data from the HIV Cohorts Analyzed Using Structural Approaches to Longitudinal Data (HIV-CAUSAL) collaboration were published in 2012. This study includes 12 cohorts from the US, Canada, and European countries. It followed 65,121 individuals, of whom 712 developed TB over 28 months. The incidence of TB was three cases per 1000 person-years, or 0.3%. The study determined that ART helps everyone, except those with a CD4 count below 50 and those who are over the age of 50.

A group in Tennessee developed a marginal structural model analysis and published their conclusions in 2012. Their study included 4534 HIV-infected patients who initiated ART and identified 34 cases of TB. The highest risk in this group was in the first six months of starting ART. After correcting for the CD4 count, it became clear that the response to ART is the most important factor, i.e., it is key that the CD4 count rises on ART. This is consistent with reports from settings endemic for TB and that also have high rates of HIV, such as South Africa: the duration of ART is not as important as the increase in CD4 count to minimize TB incidence.

Dr. Samandari turned to case fatality in TB-HIV patients. Data published by CDC in a 2012 *MMWR* examine mortality from 1993 through 2006. In 1993, 8% of TB cases who were not infected by HIV died. In 2006, 5% of those cases died. HIV-infected persons who have TB had a 41% mortality in 1993, and that rate declined to 20% in 2006. The wide availability of ART has had a beneficial effect. Nevertheless the 20% proportion seems high for the U.S. and may be due to delays in diagnosis and/or treatment initiation.

A group of researchers from DTBE assessed case fatality in smear-negative TB-HIV patients in the U.S. In contrast to high mortality rates among smear-negative TB-HIV cases in resource constrained setting, in the U.S. persons who are smear-negative have lower mortality rates than smear-positive TB-HIV cases. The researchers suggested that this difference is due to the increase culture confirmation of disease in the US, whereas resource-constrained settings utilize a smear for TB diagnosis. Patients in the U.S. are probably given treatment earlier in the course of their disease.

A number of important clinical trials have recently been concluded regarding the use of ART during TB treatment. In March 2012, HHS issued the following updates to the guidelines for opportunistic infections:

- Patients with a CD4 count of less than 50 who have TB should initiate ART within two weeks of starting TB treatment.
- Patients with a CD4 count of more than 50 with clinical disease of major severity should initiate ART within two to four weeks of starting TB treatment.

- Patients without severe disease with CD4 counts of over 50 may delay ART beyond the two- to four-week period, but should start ART within eight to twelve weeks of TB treatment initiation.

DHAP conducts the Medical Monitoring Project, which is a cross-sectional study of persons who are HIV-infected and are in care. Between 2007 and 2008, the study gathered data on the participants to learn whether they received a TST to assess latent TB infection in these HIV-infected persons. Two thousand and eight participants received a TST, and almost 8% of them had a positive TST. The risk for having a positive TST was twofold higher for people who were more than 35 years old, those who used non-injection drugs other than marijuana, for African Americans compared to whites, for Hispanics compared to whites, and for those who had received public assistance in the last 12 months.

US surveillance statistics from 1993 through 2010 indicate that 44% of persons with active TB were TST positive at the time of TB diagnosis. Among the TB patients who were also HIV-infected, only 19% had positive TSTs. The TST is less sensitive in people with active TB who are HIV-infected, and many more of them had negative TST results, as opposed to those who were HIV-negative. Treatment for positive TST in HIV-infected patients is daily isoniazid for nine months. HIV-infected persons not receiving ART are eligible for the recently recommended 12-dose isoniazid-rifapentine regimen.

Discussion Points

Referring to the survey request from PAHO regarding coordination between TB and HIV in the US, ACET asked for additional comments regarding DTBE's and DHAP's perceptions of the coordination of HIV and TB care.

Dr. Castro said that coordination of care is highly variable. The two programs are not brought together consistently, but HIV clinics have policies in place to avoid transmission of TB. There is room for improvement. He commented that the statistics in the presentation regarding the proportion of TB patients who were not offered HIV testing came from CDC surveillance data. There is no record of an HIV test. It may have been offered, but it is not offered to the TB registry. It is not clear whether the results reflect tests that were not offered, or tests that were offered but not reported.

Dr. Samandari said that often, people in North America who are TST positive do not necessarily receive, or complete, treatment for latent TB infection. Ms. Suzanne Marks (CDC/DTBE) said that the new HIV recommendations are for "opt-out" testing. The standard of care is to be tested, but patients can refuse. This recommendation will reduce the number of tests that are not offered, and will probably reduce the number of refusals. A study which is in clearance addresses the use of nucleic acid amplification (NAA) for diagnosis of TB disease. This approach is cost-saving in HIV-infected populations.

ACET asked whether the data on the prevalence of HIV among TB patients are stratified by race and ethnicity. There is a significantly larger number of TB cases among US-born African Americans.

Dr. Samandari said that in his experience in DHAP, there is a problem with rates of HIV increasing among African American MSMs. In some communities, incidence rates are as high as any in Africa. Given that the community is also at increased risk of incarceration, it is important to pay close attention to HIV infection within the prison system, especially in the Southeast, where HIV incidence is high.

Dr. Castro said that in the TB outbreaks and clusters that DTBE helps local health departments investigate, they have seen populations of homeless, US-born African Americans with an HIV co-infection rate of 10% to 15%. They should learn how to better address these issues.

ACET said that the "HIV world" has been concerned with poor performance with the cascade. There are possibilities for tri-infection with hepatitis C in populations such as injection and non-injection drug users and homeless populations. This issue is critical for developing sustained viral suppression. They should be attentive to these possibilities, as those who are dually infected may not be adherent to ART.

Ms. Marks said that a recent study, which is in clearance, was conducted in California, where they have increased their interim testing in the two years since they began reporting HIV status. In a 2008 study, approximately half of TB/HIV patients had a diagnosis of HIV at TB diagnosis or afterwards. It is not possible to prevent TB/HIV without knowing HIV status at an earlier time. One study achieved consistent HIV testing of contacts in New York City; however, the testing is not conducted in most places and is not specified in HIV testing recommendations. A footnote in the recommendations states that HIV tests should be administered to suspects, patients, and contacts, but the recommendation states that HIV tests should be administered to those who start TB treatment. Other studies have examined TB/HIV and mortality and the need to collect data on CD4 status as well as ART in the RVCT.

No additional comments or questions were presented by ACET or other meeting participants. Mr. Jones adjourned the meeting for the day at 4:20 pm.

Call to Order / Roll Call: December 5, 2012

Shannon Jones III
Deputy Director
City of Austin/Travis County Health Human Services Department
ACET Chair

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

Mr. Jones called the second day of the ACET meeting to order at 8:35 am on Thursday, December 5, 2012.

Dr. Dean reminded the participants that all ACET meetings are open to the public, and all comments made during the proceedings are a matter of public record. She called roll of those present and on the telephone and established a quorum.

Mr. Jones reminded ACET members to provide their proposed resolutions to the meeting technicians so that they would be available for the business session of the meeting.

Dr. Castro directed ACET's attention to data from Dr. Tom Navin regarding HIV status for TB patients stratified by race and ethnicity, as well as a document from Dr. Zorrilla on the bi-national TB initiative.

TB Detection

Update on Outbreak Prevention

Juliana Grant, MD, MPH
Lead, Molecular Epidemiology Activity
Surveillance, Epidemiology, and Outbreak Investigations Branch / DTBE
Centers for Disease Control and Prevention

Dr. Grant provided ACET with an update on a project concerning early intervention with potential TB outbreaks. From 2002 through 2011, CDC investigated approximately 40 outbreaks involving 647 cases and 32 deaths. The actual number of outbreaks is likely much higher. It is relatively rare for states to request or need CDC assistance, and there is variation in reporting of outbreaks. One high-incidence jurisdiction had three CDC-investigated outbreaks during 2005 through 2011. That jurisdiction identified 57 outbreaks during that time frame.

With limited data, it is difficult to estimate the magnitude and impact of TB outbreaks in the US. One outbreak in a homeless population in 2010 involved 24 cases. One estimate for the cost of that outbreak was approximately $10 million in total costs, including healthcare. The health department estimated a cost of $200,000 for housing support, food, transportation, and treatment.

DTBE has begun to address the issue of whether outbreaks can be predicted. Dr. Tom Navin and others developed an outbreak prediction algorithm, which was based on a retrospective analysis of small TB genotype clusters, using incident clusters of three cases. The process excluded endemic genotypes and focused on brand-new clusters, representing recent transmission. The process monitored the clusters for growth in size over 24 months. The researchers examined a number of factors, including geospatial concentration; time; and clinical, social, demographic, and ecologic risk factors to identify characteristics associated with growth into an outbreak. "Outbreak" was defined as at least six cases and a classification as an outbreak by the state TB program.

The algorithm identified 146 new genotype clusters of three cases, of which 11% became outbreaks. The analysis divided the clusters into three categories: high risk, medium risk, and low risk. High-risk clusters were those in which one or more cases among the first three cases detected had excess alcohol use, homelessness, illicit drug use, or incarceration at diagnosis and the third case occurred within 5.3 months of the first case, indicating rapid initial growth. Of these cases, approximately 53% became outbreaks. Medium-risk clusters were those in which one or more cases among the first three cases detected had excess alcohol use, homelessness, illicit drug use, or incarceration at diagnosis, with no time characteristic as in the high-risk category. Of these cases, 12% became outbreaks. Low-risk clusters had no social risk factors or time characteristics associated with them, and 1% of them became outbreaks.

The researchers assessed a number of risk factors, including HIV status, other clinical issues such as chronic disease, immunosuppresion, social crowding, socioeconomic status, and others. All of the factors were associated with outbreaks, but the risk factors listed in these categories were the most predictive of a small cluster becoming a future outbreak.

This work indicates that it is possible, to some degree, to predict when outbreaks are going to occur. The next question is whether outbreaks can be prevented. Prevention of outbreaks fundamentally relies on good, routine TB control. However, other novel approaches or targeted interventions with small clusters could also prevent outbreaks.

There are challenges associated with outbreak prevention. The small genotype clusters at high risk of becoming outbreaks are relatively rare. Fewer than 10 of these clusters occur per year in the US, and they occur in different states. Six genotype clusters that meet the high-risk criteria for the algorithm were identified in 2012, and these are spread among five different states. Therefore, it is challenging to develop targeted interventions. Further, testing whether interventions work would require broad support, including contributions from the national program; commitment from CDC, state, and local programs; and substantial resources.

Given those challenges, the branch developed an Outbreak Prevention Feasibility Project. The goals of the project are to modify the algorithm for prospective use, as the original algorithm was developed on retrospective data; develop a detailed intervention protocol; and determine the resources needed to intervene.

In modifying the algorithm for prospective use, it is clear that the time window to intervene with the clusters is likely small. The median time from the third to the sixth case is 5.5 months. The prediction algorithm is based on genotype data linked to RVCT data, and the median time from specimen collection to linking to genotype data is 2.5 months. Time spent linking data is time lost to intervene. The feasibility project is focusing on how to modify algorithm to maximize the time window to detect clusters with unlinked cases and in the absence of surveillance data.

The researchers are taking a “kitchen sink” approach with the intervention protocol; that is, there are many intervention activities that are applied to large clusters and outbreaks, and they could be applied to smaller clusters as well. An example of an approach is the active use of social media in the investigation. Dedicating staff to the cluster and working actively to engage the community are other strategies. Other approaches include Interferon-Gamma Release Assays (IGRAs), incentives and enablers for cases and contacts, shorter treatment regimens, and other new and innovative approaches.

It is critical to monitor resources in the feasibility project because it is important to understand how much it might cost to expand the effort nationally. Factors to consider include the number of personnel devoted to the effort; travel costs; costs associated with the use of incentives and enablers; medications and laboratory costs; and other costs. The resources should be monitored over the entire time frame of the project, which is expected to be 6 to 12 months after the cluster is detected.

Dr. Grant posed the following questions to ACET about the feasibility project:

- ❑ Is the project an efficient use of division resources?
- ❑ How should this project be prioritized relative to other projects?
- ❑ What other issues or questions should be addressed during the project to ensure that its results are useful in the future?

Discussion Points

ACET thanked Dr. Grant for the presentation and encouraged CDC to apply other lessons learned from the feasibility project. Other lessons could be learned from local jurisdictions which used to be considered low-incidence that have slashed resources and are now seeing increased TB deaths. This project could help illuminate what happens when resources are decreased.

Dr. Grant agreed and hoped that ACET could continue to provide input into the project. CDC does not conduct the interventions "on the ground," so they must be applicable and useful for local jurisdictions. CDC will determine the resources needed to support them.

ACET supported conducting the feasibility project and suggested that the project also consider costs to other institutions and organizations involved in the investigation, such as detention facilities and shelters. Investigations are significant for their operations.

ACET noted that while there are costs associated with outbreaks, there is also income associated with healthcare costs and hospitalization, for instance.

Dr. Grant said that the cost estimates were generated by state and local programs and that the $10 million includes costs associated with patient care. Income to hospitals is a critical part of health economics analysis, and the estimates were intended to gain insight into the impact of the outbreak.

In response to a question from ACET, Dr. Grant said that the algorithm will be applied when the third case in a cluster is detected, so it will be possible to differentiate between high-risk and medium-risk clusters early in the process. The analysis did not consider large clusters of 15 or more cases, but some of those clusters would be in the high-risk category. In addition to predicting outbreaks, the branch hopes to learn what predicts certain genotypes becoming endemic in certain areas. With additional data, they could create an "extreme risk" category for the clusters that may grow to 30 or more cases.

ACET advised that the project should focus on the "greatest bang for the buck;" that is, focus on the large, high-risk clusters.

ACET expressed surprise that it only takes 2.5 months to link a specimen to the RVCT. It may be possible to shorten the time even more and intervene earlier by focusing on the clusters with the significant risk factors, such as alcohol use, corrections, and homelessness. It could also be beneficial to focus on clusters in certain locations, such as big cities and correctional facilities. Dr. Grant noted that the 2.5 month time frame for linking is a median time. There was a range among the states.

In modifying the algorithm for practical use, Dr. Grant said that they might consider looking at clusters of two cases if they have the significant risk factors. Risk factors such as geography and ecological characteristics such as crowding and socioeconomic status are associated with outbreaks, but were not as strongly as the other characteristics included in the algorithm.

ACET said that a retrospective analysis could include interviews with teams that investigated the outbreaks to learn about the degree to which the variables in the algorithm make sense. For instance, homelessness with a diagnosis of mental illness may be more important than homelessness alone. Further, homelessness is different in different jurisdictions. Another facet of the issue could be whether the person was in a shelter in the last 30 to 60 days as opposed to people who have not been in a shelter. It may be necessary to refine the parameters of illicit drug use to consider dependence or other factors in order to further pinpoint the high-risk category.

Regarding assessing resources, ACET suggested that the researchers consider a structured methodology for evaluating cost-benefit questions associated with outbreak prevention.

Dr. Grant said that having additional data, such as information about shelters, would be very useful, but the project is limited to a national surveillance data set and to the variables that are routinely collected. It may be possible to further stratify data that are collected at the state or local levels.

ACET said that the algorithm is a model way to use routinely-collected information to go beyond a description of an event to a predictive tool.

ACET commented that the data set uses the TST, and there may be concerns about its sensitivity and specificity, which lead to concerns about its predictive value. More information may be needed.

ACET said that the algorithm mines a data set with a certain outcome to build a predictive model. Often, part of the data set is used to develop the model, and then the remaining part of the data set is used to test the model. In order to be validated, the model may need to be tested against data that was not used to generate the model, perhaps by going forward in time or by using data from other sources.

Dr. Grant said that the published manuscript includes more details. It is possible to test for sensitivity and specify in the algorithm. Additional validation of the algorithm is needed; however, using the information to guide interventions is also critical. She asked how to balance those needs to refine and develop the science and to put the model to work with interventions.

Dr. Grant agreed and said that the intent of the project is to support staff at state and local programs that are devoted to investigating and intervening with this cluster. If additional resources are needed to hire or fund additional people, then that factor will be taken into account. Staff will need to have experience in TB, which is one of the challenges associated with implementing interventions.

In response to a question from ACET, Dr. Grant said that at the county level in the US, approximately 25% to 30% of TB cases are in a genotype cluster. Approximately 60% to 70% of those are in genotype clusters of two or three cases.

In response to a question from ACET, Dr. Grant said that the algorithm considered race, ethnicity, and US-born or foreign-born status. The majority of factors that are classically associated with TB transmission, including cavitary disease, were associated with the development of an outbreak, but were not as strongly associated as the risk factors that were identified in the time frame.

ACET said that the needs for each population in each outbreak are different, and the appropriate interventions are also different.

Dr. Grant indicated that one of the branch's goals is to create a comprehensive list of tools, methods, approaches, and strategies that could be used in an intervention. That list can serve as a toolbox to help local officials intervene in their areas and to gather evidence to support the use of different methods.

Dr. Benjamin said that if the model is proven to be sensitive and specific, it will be a useful tool at the local level. Often, by the time CDC learns about a cluster, "things have already gotten out of hand." Regarding resources needed for interventions, with erosion of funds at the local level, it is not likely that staff will be able to be dedicated to the effort.

Post-Deployment TB in the US Military

James Mancuso, LTC, MC
Walter Reed Army Institute of Research
ACET Liaison Representative, Department of Defense

Dr. Mancuso provided a report to ACET on post-deployment TB in the US Military. He pointed out that the views expressed in the presentation were his and did not reflect the official policy or position of the Department of the Army, DoD, or the US Government.

He shared case studies of TB in the US military. The first case is a classic example of TB acquired during deployment. The patient was a 49-year-old Intensive Care Unit (ICU) nurse with a Combat Support Hospital (CSH) in 2008. She was born in the US, but her parents were born in México. She was TST negative prior to deployment and took direct care of TB patients. Post-deployment, her TST was 15mm and she had TB symptoms and a positive culture. This case is the only case of deployment-associated transmission of which Dr. Mancuso was aware.

The next case developed TB during deployment. The patient was a 24-year-old male reservist with pleural effusion in Iraq. He was sent to Walter Reed for evaluation. He was placed on TB medication. The pulmonologist concluded that he was at "low suspicion" for TB and discontinued the medication. Four weeks later, slow-growing TB was identified. An investigation revealed that the patient had been in contact with an active TB case two years prior. His TST was 15mm before deployment, but he did not receive an x-ray. Genotyping on the patient and his contacts confirmed the transmission before deployment to Iraq. Genotyping is part of the standard of care.

Historically, TB in the military is a reflection of TB in the US source population. TB in the military was common during World War I because it was common in the US. There were few methods to screen for TB at that time. A clinical examination was used, but it was not effective. Screening during World War II and Korea included a chest x-ray. The only military group at higher risk of TB than the general US population was prisoners of war (POWs).

TSTs were instituted in the Vietnam era. A study of the incidence of active TB and prevalence of TST reactors in US Navy recruits from 1950 through 2006 shows a correlation with the general US population. The TST does not predict risk of activation among military personnel as it once did. There have been some "pseudoepidemics" of TST conversion since the 1980s, but no evidence of active transmission was found. A number of false positives were attributed to errors in TST administration, reading, and documentation, as well as to a lack of documentation of prior positives and cross-reactions with *non-tuberculous mycobacteria* (NTM). Performing TSTs during deployment is not optimal, and there are doubts about the usefulness of TST.

The DoD has considered active TB rates in recent years to detect possible increases in active TB. The military began documenting reportable medical events and notifiable events in a high-quality way in 1998. The rate of confirmed active pulmonary TB in the military is low at less than one per 100,000 per year. The rate is lower than the rate in the general US population, which is to be expected, given the relative health of the military population.

No increases in TB cases were observed after large-scale deployments to Iraq and Afghanistan in 2001 and 2003, despite the number of TST conversions. The military suspected a high number of false positives in TSTs. Using a set of common assumptions about the prevalence of LTBI and performance characteristics of the TST, a value of about 21% positive predictive value (PPV) in this population was determined.

A case-control study examined risk factors for those who develop active TB. Risk factors during and prior to service were considered. The most important risk factors were those prior to service, including foreign birth and racial and ethnic groups. Deployment was not a significant risk factor; however, being stationed in Korea was a risk factor. Approximately 30,000 to 50,000 US military are stationed in Korea, and some Korean nationals are imbedded with the service there. Korea is moderately endemic for TB. Also, service members have contact with Korean nationals in a way that they do not typically have contact with nationals in other deployment sites.

The military screening policies for TB include targeted testing after deployment to reduce unnecessary testing. The policies are available at http://www.pdhealth.mil/tuberculosis.asp#nm. Each branch of the service also utilizes a questionnaire that addresses possible contacts with active TB cases and high-risk groups such as refugees, hospitals, prisons, and other local or national populations. Most service members have contact with local populations in some form.

An evaluation of the TB exposure assessment portion of the post-deployment survey completed on a unit of soldiers returning from Iraq in 2008 showed that those who indicated "moderate or greater" exposure to TB had a lower risk of having a positive TST. A provider assessment was no more effective at assessing TB exposure. Better predictors of positive TST were foreign birth and race, which exist prior to accession and are unlikely to be related to deployment. Another approach used at Fort Stewart, Georgia utilized a consultation with a healthcare provider in order to better target the testing. Even with the consultation, 34.8% of the personnel were tested.

Dr. Mancuso concluded that the most important risk factors for active and LTBI exist prior to entry into the service. Thus far, few cases of active TB are a result of deployment. The risk for LTBI after deployment is uncertain. The military has observed discordance between TST and IGRA methods in the deployment setting, and they are still over-testing. Current targeting

methods can be improved, and the current screening questions yield too many positives and are a poor discriminator.

In the future, the US military hopes to conduct a high-quality study of infection risk after deployment and to better define risk factors for targeted testing. Other future directions include assessing the confounding exposures to NTM during deployment, to conduct follow-up studies in collaboration with the VA, to update policies, and to provide clinical practice guidelines (CPG).

Dr. Mancuso requested ACET's input regarding the following:

- ❑ How to improve the US military's TB control program
- ❑ The gaps in knowledge which are most important to address
- ❑ Collaborations that should be explored
- ❑ How to update policies and provide CPG

Discussion Points

ACET thanked Dr. Mancuso for the informative presentation and for his service.

ACET said that one of the US military's main goals is to protect its population from developing TB. This work presents a great opportunity to learn about the prevalence of TB infection in a large population and could be extremely useful if the data are collected and published.

ACET observed that different branches of the service have different approaches to screening for TB, such as different questionnaires and asked whether a uniform preventive medicine policy applies to the entire military population.

Dr. Mancuso answered that there are universal testing policies, and each of the three services test for TB, but there is movement toward targeted testing at accession. All three services conduct testing based on their screening questionnaires, but there is variability in the implementation of the tests and the manner in which the questions are answered. There is also variability in the locations where the tests are administered. For instance, the highest rates of TST conversion were among a group in Hawaii. The reason for this difference is unknown.

Regarding a question from ACET about how to follow up on exposures to cases when personnel are sent to multiple posts, Dr. Mancuso answered that the US military's data systems are good, but there are limitations to the data.

ACET commented on the improvement in military TB control and gaps in knowledge. It appears that there is good TB control and understanding in the areas where the military is active. The gaps in knowledge could occur when the military is deployed to new areas that present different TB risks and are issues of readiness to understand and react to those risks in a timely way.

ACET asked whether the TB screening as personnel return from deployment is part of a larger "machinery" of screening that involve other diseases and exposures.

Dr. Mancuso answered that redeployment is a seven-day cycle. The tests include the TST as well as tests for HIV. There is a battery of questionnaires and a health assessment, which has a mental health focus as well as assessment for other exposures.

Regarding gaps in knowledge, Dr. Mancuso said that he struggles with why more TB is not observed, based on the TST data. All of the TST results cannot be false positives or prior positives that were not documented. Alternatively, perhaps the military is doing a better job at preventing TB than they think they are. The lack of TB could be due to the relative health of the population, so that TB disease does not progress. The VA is not reporting an increase in TB currently, but an increase is possible in the future if risk is being postponed.

Given that the IGRA and TSTs do not correlate well, ACET suggested examining the role of Vitamin D.

In response to an observation from ACET regarding the high relative risk for foreign-born soldiers, Dr. Mancuso said that the data quality is fairly poor. Some soldiers report having a first-time positive TST, but the result is not in their military records. The military defers to the CDC for guidance on the tests to administer, and the QFT, IGRA, and TST are considered equally acceptable. Testing becomes logistically challenging when personnel are screened in high numbers. Serial testing can be problematic with any tests, but especially with QTF and not knowing the significance of the conversion in this population.

ACET suggested that the follow-up studies not only work with the VA, but also reach the veterans who are in homeless shelters, prisons, or otherwise may not be likely to seek care at the VA. Those people may be at greater risk for TB.

ACET asked about "fleet testing" in the Navy and whether fleets that port in high-risk areas are tested. The submarine service could be a critical group to be tested.

Dr. Mancuso replied that the Navy used to conduct annual testing of personnel on ships, and in 2009 they moved to targeted testing. They perform annual screening with a questionnaire as opposed to post-deployment testing. Persons who endorse an exposure on the questionnaire move to testing. The Navy has historical experience with outbreaks on ships.

In response to a question from ACET about dependent testing, Dr. Mancuso replied that there is no strong mechanism for detecting LTBI in dependents, but they do track active TB in dependents. A 2011 Army cohort review yielded ten cases, two of which were active. The cohort included approximately 500,000 people. The population is geographically dispersed and has variation in risk factors.

The Future of ACET and Elimination of TB in the US: A Conversation

Jon Warkentin, MD, MPH
President, NTCA
ACET liaison representative

Dr. Warkentin reviewed the ACET Policies and Procedures, which were finalized in 2011. The document outlines a charge that is broader than TB, stating that the council, in accordance with its charter, will:

- Conduct, encourage, cooperate with, and assist other appropriate public authorities, scientific institutions, and scientists in the conduct of research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases, and other impairments; and

- ❑ Assist states and their political subdivisions in preventing and suppressing communicable diseases and other preventable conditions, and in promoting health and well-being.

The document also states that ACET shall, in accordance with the Comprehensive TB Elimination Act, provide advice and recommendations regarding the elimination of TB to the Secretary of HHS; the Assistant Secretary for Health; and the CDC Director. The Council shall make recommendations regarding policies, strategies, objectives, and priorities; address the development and application of new technologies; provide guidance and review on CDC's TB Prevention Research portfolio and program priorities; and review the extent to which progress has been made toward eliminating TB.

Regarding nomination for membership on ACET, the policies and procedures indicate that individuals chosen for membership on the Council should have significant expertise in TB control, public health, academia, and/or TB research, including cross-cutting knowledge and experience in the various components of the TB control. ACET members offer unique perspectives, and the strength of ACET is in those different perspectives.

ACET utilizes work groups to extensively review research data and develop options for recommendations for presentation to the full Council for their deliberation. The work groups are used as a resource for gathering, analyzing, and preparing information for ACET, which will discuss and deliberate the information presented and make a consensus decision in an open, public meeting.

Potential topics for ACET consideration can be suggested by anyone, but are most often proposed by ACET members, CDC program staff, TB Controllers, NTCA, researchers, and other partners. Approximately six to ten weeks prior to an upcoming meeting, the Designated Federal Officer (DFO) sends an email to ACET members, CDC staff, other government agency staff, and other partners requesting potential agenda items. Included in the email are previously suggested topics or a list of topics based on action or follow-up items from the last meeting. During the business session of the meeting, the Chair develops a list of potential topics based on discussions from that meeting. This approach may be a missed opportunity for *ex officio* ACET members or liaison representatives to suggest agenda items.

Dr. Warkentin offered observations from his perspective as a state TB controller and his experience with regional TB programs and NTCA. Budget cuts have been taking place at federal, state, and local levels for several years. Domestic TB control programs are threatened. Restructuring of state health departments challenges the continuity of TB program initiatives. Additionally, the "graying and retiring" of experienced TB control and prevention leaders and practitioners is leading to loss of knowledge and skills in the workforce. TB programs cannot compete financially to hire replacements with expertise, or to hire replacements at all.

There is a lack of access to new drugs for the treatment of TB disease. The FDA's quick action on new drugs is heartening, but there is a need for new, safe, and effective TB treatment regimens. The ACA is bringing a rapidly changing healthcare services environment. Public health has a unique role in the new environment, but it must be protected as more elements of the ACA are implemented.

Some TB-related guidelines are outdated and have not kept pace with scientific developments in diagnostics and treatment. Results and findings from many studies from TBESC-1 have not been published and are not available to first-line TB controllers and prevention practitioners. It is critical to translate research into practice, and the process must be accelerated. The impact of the fiscal cliff and consequences of sequestration during the current federal fiscal year will affect CDC and the states, but it is unknown. Finally, it is unclear whether there is a national commitment to the mission of domestic TB elimination.

Dr. Warkentin presented questions for ACET to consider:

- ❑ Is ACET meeting its objectives?
- ❑ Does the structure of ACET meetings, such as the selection of topics and updates generated by DTBE, mitigate against ACET productivity?
- ❑ Are ACET motions and decisions based on scientific rigor?
- ❑ Are ACET work groups given clear mandates and expected outcomes with deadlines that are relevant to the charge given to ACET?
- ❑ What are the priorities of ACET?
- ❑ How can ACET function more efficiently and effectively, and whose responsibility is it?
- ❑ With domestic TB control and prevention capacity threatened, what can and will ACET do?

He thanked Mr. Jones, Dr. Castro, Mr. Phil Talboy, Dr. Fenton, and Ms. Carol Pozsik and the NTCA Executive Committee.

Discussion Points

ACET responded that the questions posed in the presentation are valuable, and ACET should address them, perhaps as part of the agenda for their next meeting.

ACET can best contribute strategic advice. It would be valuable to see DTBE's strategic plan as well as the strategic plan for the federal government, which may be outdated.

The questions have arisen in the past, and one of the most important questions is whether elimination is still valuable as a strategy and whether ACET's purpose is still viable. ACET has a specific charge to report to the HHS Secretary, which they should do on a systematic basis. Because of the range of expertise and perspectives on ACET, the council should advise DTBE on future directions. It is difficult to offer that advice when the meetings consist of many presentations. Dr. Warkentin observed that the agenda lacks focus and a prioritization of issues. The presentations are interesting and relevant, but they may create structural problems for the effectiveness of ACET.

There was discussion regarding the way that ACET's charge is written, which indicates a charge broader than just TB. TB does not exist in a vacuum, and more co-infections with HIV and hepatitis are emerging.

The mission of ACET is very broad, and it is possible to lose track of its mission. Prioritizing the immediate, important needs, such as the loss of TB control at the local level, will help them focus.

ACET observed a level of activity, engagement, and enthusiasm at this meeting that had not been evident at prior meetings.

Dr. Castro said that if they do not address these issues, they will be "driven into extinction." TB elimination is threatened by growing complacency and other factors. They must bridge "the ambition gap" and expect to eliminate TB. They have the tools and know what needs to be done. The feasibility project presented by Dr. Grant represents an approach to enhance CDC's ability to predict and prevent cluster growth. They are obligated to try new methods. The voice of ACET should be clear in the Chair's report to the Secretary of HHS and share the concern about the threat of not making TB elimination a priority. If ACET desires to engage in strategic planning and thinking, perhaps a future meeting should be in a "mini-retreat" format with a facilitator. There was support for the idea of a "retreat" for ACET.

There was agreement that ACET should inform the HHS Secretary that this is not the time to cut TB funding. Several recent HHS strategies have focused on prevention, but there has been no mention of infectious disease prevention. The Secretary could also be urged not to forget about infectious diseases.

ACET noted that Assistant Secretary for Health, Dr. Howard Koh, is interested in a number of infectious disease issues that can be linked to TB. The ACET Chair's report is sent to the HHS Secretary, and she will respond to it. After the last report, she designated Dr. Koh as ACET's "point person." Representatives met with him in January 2012, and he was interested in TB issues.

Many presentations at ACET meetings have addressed DTBE's priorities. The division will have to distribute funding cuts and it is important to look at how funds are distributed to local programs, relative to the rest of the division's work. Work "on the ground" has led to TB elimination in some areas of the country. It is critical to preserve that basic TB function.

A major role for ACET is to support the creation and sustaining of political will. TB elimination will not be possible unless it is set as a goal. Diseases and issues such as hospital-acquired infections, HIV, and hepatitis B have strong groups of consumers who have advocated for themselves. TB patients do not have a similar advocacy voice.

Another component of TB elimination will be engagement with the medical community.

Dr. Nardell hoped for clarity regarding the roles of ACET liaison representatives as opposed to the legal members of the council. The liaison representatives represent organizations that are partners in the effort of TB elimination, but the structure may not utilize them to the fullest.

Ms. Jervis suggested that liaison representatives could be given action steps or issues to build on the ACET meeting priorities.

Dr. Warkentin said that funding decisions are also made at state levels where there is no commitment to TB control and prevention. All of the efforts are funded by federal dollars, and there should be a means for allocating those funds. Some states, however, have made a strong commitment to TB prevention and control.

Ms. Napolitano observed that ACET "preaches to the choir." The meetings include active discussions, but action may need to come from DTBE as ACET speaks to higher levels of the US government. She suggested that a workgroup learn about other federal advisory committees that have been successful at reaching high levels of government and impacting outcomes to learn how they have made their inroads and built political will. Stop TB USA works with various TB programs to identify patients that could be a "voice for TB." They are also developing a patient forum and working with other partners, such as TAG, to build a voice for TB across the states.

Mr. Jones agreed that ACET often discusses its purpose, accomplishments, and operations. The political structure dictates how ACET operates. For instance, the roles and responsibilities of liaison representatives, ACET members, and ACET *ex officio* members are clearly outlined. They can discuss changing them, but cannot change them themselves. An ACET workgroup was created previously to discuss the structure of ACET meetings and how to ensure that they are meaningful. One of the issues discussed was the number of updates and reports. They may hamper the council's operations, but they are often requested by ACET. He supported the idea of a retreat, if it is allowable. ACET meetings are required to be public. He also supported the idea of determining how to implement the ideas and questions posed by Dr. Warkentin and the subsequent dialogue; however, he emphasized that ACET will have to commit to any recommended changes. His report to the HHS Secretary can include some of the limitations they have identified. Each member of ACET needs to ensure that they will be consistent in implementing any proposed changes.

ACET Membership Input for Biennial Report to the Secretary of HHS

Shannon Jones III
Deputy Director
City of Austin/Travis County Health Human Services Department

Mr. Jones explained that every two years, the Chair of ACET provides a report to the Secretary of HHS regarding the activities, recommendations, and resolutions of the council over the past two years. The report may include policy recommendations made by ACET, concerns and issues, program evaluation and implementation issues regarding DTBE, clinical research recommendations, and funding recommendations.

Mr. Jones will review ACET's recommendations and resolutions since 2010 and identify priorities that should be highlighted in the report to the Secretary. He requested that ACET review that document and a matrix of ACET's activities and achievements and share items and issues that should be highlighted. Other areas, such as strategic thinking, and future directions, can also be addressed. The report will be sent in June 2013, and ACET will have one meeting in the interim, at which additional recommendations may be made. He hoped to vet the report with the ACET membership before it is submitted to the Secretary, but it must be done in a timely manner.

Discussion Points

In response to a comment form Dr. Julie Higashi, a participant from the California TB Controllers Association, Mr. Jones agreed that timeliness is important and noted that the report must be vetted and sent through CDC, which takes time. June 2013 is likely to be too late, but if ACET members share their feedback by the end of January 2013, it will be possible to complete the report faster.

ACET added that the major regulations for ACA are in process, and an update on the status of the benefit structures and whether they include TB would be helpful.

Dr. Castro said that a group within DTBE is monitoring that process. They have determined what needs to be done about TB at various stages of ACA implementation. For example, as a larger proportion of the population will be ensured with access to the Federally Qualified Health Centers (FQHCs), CDC will work with HRSA and other partners to ensure that the FQHCs are prepared in the area of TB control. Some key public health functions will never be covered by a private provider or insurer, such as outbreaks, DOT, or contact investigations. These functions should be protected in a persuasive and justifiable manner.

Mr. Jones added that the states impacted by TB are probably less likely to participate in the health insurance exchanges. Those states, many of them in the South, may not necessarily continue support for public health activities. The report to the Secretary could include those points.

One of the critical steps in implementing the ACA is the regulatory process. There will be an opportunity to comment on the Notice of Proposed Rule Making (NPRM). That time will be critical for feedback on TB issues and inclusion. HHS will recalibrate the rules according to the comments received.

Business Session

Shannon Jones III
Deputy Director
City of Austin/Travis County Health Human Services Department
ACET Chair

Topic 1
A motion was properly placed on the floor by Dr. Jane Carter and seconded by Dr. Masahiro Narita to approve the minutes from the June 5, 2012 ACET meeting in Atlanta, Georgia, and via teleconference. **ACET unanimously approved the motion**, with Ms. Barbara Cole and Dr. C. Robert Horsburgh abstaining.

Topic 2
Mr. Jones reviewed upcoming meeting dates for ACET. He reminded ACET that at a previous meeting, it was agreed that their meeting schedule would include two in-person meetings and one Webinar per year. There was discussion concerning future ACET meeting formats and scheduling:

- Dr. Castro proposed that the March 2013 ACET meeting be in-person and in the "facilitated retreat" format that was previously suggested to engage in strategic thinking and planning. The meeting will conform to requirements of the Federal Advisory Committee Act (FACA). The deliberations could inform the ACET Chair's report to the HHS Secretary. The ACET Webinar could take place in June.
- Dr. Dean noted that four members of ACET, including the chair, will rotate off of the council in June 2013. An evaluation was sent to ACET members after the first Webinar last year, and most members found it to be generally useful and cost-effective, despite some "quirks."
- The possibility of holding an ACET meeting in Washington, DC, was raised, perhaps near the time of the Federal TB Task Force meeting. Dr. Castro said that a date for the Federal TB Task Force meeting has not been set, but it will likely take place in the first quarter of 2013. Planning and coordinating two separate meetings with two separate agendas is challenging. There are also cost implications to meeting in DC.
- There was discussion about the potential difficulties associated with transitioning to a new Chair via a Webinar in June. If the June meeting were held in-person, then the December meeting would be a Webinar, which may be a resource strain in one fiscal year.
- Ms. Napolitano said that Stop TB USA developed and released an update of the TB Elimination Plan of the United States on World TB Day 2010. It may be a worthwhile document to review in advance of the next ACET meeting.
- Dr. Castro proposed that ACET not develop another plan to eliminate TB. In 1999, ACET published a recommitment to the goal of eliminating TB. A similar document might be a way forward.

ACET indicated agreement with holding the March 2013 "retreat" meeting in person and holding the Webinar in June 2013.

Topic 3

ACET discussed agenda items for the next meeting and for future meetings. The March 2013 ACET meeting will focus on the "big picture" of how ACET operates and its future. Other topics may be addressed in the Business Session, or moved to the June or December meeting.

- It was proposed that no other items be discussed at the March 2013 meeting to ensure progress on ACET's strategic direction.
- It was also proposed that a small portion of the March 2013 could be devoted to updates from DTBE. Mr. Jones agreed and suggested that those updates could be reserved for the Business Session of the meeting, with limited time allocated for them.
- ACET suggested utilizing a standard format for written updates and reports, as opposed to presentations.
- ACET requested information about racial disparity in TB, particularly etiology in the African American community and how to target efforts.
- The discussions at the March 2013 meeting will be informed by the ACA and how it relates to TB.
- If ACET reissues its 1999 statement committing to TB elimination in the US, it should incorporate the context of the global TB problem.

- Dr. Zorrilla requested that a future ACET agenda item focus on the bi-national agreement between the US and México regarding cooperation in the Texas-Coahuila Border Tuberculosis Initiative and on other activities of the US-México Border Health Commission. The future operations of ACET may change as a result of the March 2013 meeting, but the issue may be included in the June 2013 or December 2013 meeting.

Mr. Jones asked Dr. Carter, who previously chaired the ACET Agenda Workgroup, to chair a workgroup to plan the agenda for the March 2013 meeting. Dr. Carter agreed and noted that most of the membership of the original Agenda Workgroup has rotated off of ACET, so it will need to be repopulated. ACET members Dr. Marcos Burgos and Ms. Barbara Cole agreed to participate on the workgroup, as did ACET liaison representatives Dr. Robert Benjamin, and Dr. Jon Warkentin. The workgroup was charged to work with DTBE staff to formulate the agenda for the March 2013 ACET, incorporating the points raised in Dr. Jon Warkentin's presentation. The group will also ensure that background information and documents will be made available to ACET members in advance of the meeting.

Topic 4
A motion was properly placed on the floor by Dr. Marcos Burgos and seconded by Dr. Jane Carter to extend the timeline of the ACET National TB Program Workgroup for six months beyond its scheduled expiration, to September 2013, with appropriate funding allocated for the program review.

- ACET supported refining the objectives of the workgroup but expressed concern about funding for the site review.
- Dr. Castro suggested that rather than extending the workgroup, ACET might consider putting a moratorium on its activities until after the retreat in March 2013, which may being more clarity. Additionally, it is awkward to approve an undisclosed budget figure. The work proposed by the workgroup is important and should get back on track, but the March retreat may help redefine the workgroup's scope and role, perhaps leading to a new charge or reconstituted agenda.
- Dr. Warkentin said that NTCA could not support the workgroup unless its objectives and methods are more defined. Extending funds to support site visits that may not be generalizable to the broader mission of TB control in the US is not worth the investment.

Dr. Burgos agreed with the suggestions and withdrew the motion. He asked that the topic be discussed during the Business Session of the next ACET meeting. Dr. Carter agreed to withdraw the motion.

Topic 5
Mr. Jones said that Dr. Fenton has had discussions with his counterpart with the Public Health Agency of Canada (PHAC) regarding the value of having PHAC participation on ACET. For the purposes of this motion, Mr. Jones allocated the Chair to Dr. Jane Carter.

A motion was properly placed on the floor by Mr. Shannon Jones and seconded by Ms. Barbara Cole to include PHAC as a liaison member of ACET, with the approval of the HHS and consistent with all other liaison membership. **ACET unanimously approved the motion**. There were no abstentions.

- ACET asked about funding for a non-American liaison representative to attend ACET meetings. Dr. Dean answered that CDC does not fund all liaisons.

- ACET asked about other federal advisory committees that have non-American liaisons. Dr. Dean replied that international representatives participate on the Board of Scientific Counselors (BSC) for OID. The participation has been invaluable. PHAC also participates on the Healthcare Infection Control Practices Advisory Committee (HICPAC).
- There was discussion regarding the benefit to PHAC of its participation on ACET, and of the value of PHAC to ACET. DTBE's counterparts in Canada have spoken to them about the 3HP regimen. The cross-fertilization and added voice and perspective will be useful. Also, Canada's new guidelines for TB control are being published. Canada's focal concerns in TB are TB among the foreign-born and TB in First Nations. PHAC is eager for CDC's input on contact investigations, prevention of TB, surveillance systems, and TB control for First Nations, as the Indian Health Service (IHS) has been relatively successful in that area. Canada has been more successful in their efforts for TB control in immigrants, due to their healthcare tracking systems.
- There was discussion about other "neighbors" to the US that could be valuable additions to ACET's deliberations. The March 2013 retreat is an opportunity to discuss other entities to augment ACET. Criteria or policies for joining ACET could be discussed.

Topic 6

Mr. Jones assumed the role of Chair. The following motion was properly placed on the floor by Dr. Eric Brenner and seconded by Dr. Susan Dorman:

"Whereas:

1) Essential components of tuberculosis prevention and control programs in the United States were last described 17 years ago; and
2) Though many elements of TB control have remained unchanged during that time, a number of specific technical and operational components have either changed or need to be usefully refined; and since
3) epidemiologic realities (decline in national TB incidence to < 5.0 per 100,000); new federal, state and local TB budget constraints (related to recession and other factors); and impending new health-care system realities (e.g. related to provisions of the Affordable Care Act) dictate that core components of state and local TB programs need to be reviewed; and since
4) failure of state and local programs to explicitly assure their ability to carry out core TB control functions would (a) jeopardize the gains made in TB control in the since 1993, and (b) would risk rendering illusory the goal of progressive elimination of tuberculosis in the United States in the coming decades;

Be it therefore resolved that in the coming year ACET should:

1) Review, reaffirm and redefine as necessary the core components of TB prevention and control programs in accordance with the evolving realities described above;
2) Utilize any useful existing work (e.g. such as that done by US local jurisdictions and/or the International TB community in the last decade) to define such components;
3) Request the collaboration of partners including the CDC DTBE and the NTCA in this task; and
4) Disseminate a description of these components to state and local jurisdictions as guides to the explicit standards to be met in their TB program management, prevention and control activities.

"ACET efforts on this task may be referred to as: 'Recasting Core TB Program Components in a period of Epidemiologic, Financial, and Healthcare System change.'" **ACET unanimously approved the motion.** Dr. Jane Carter abstained.

- There was confusion about this suggested document versus the Bacille Calmette-Guerin (BCG) vaccination paper that was created by ACET members. If a document is created by ACET, the document review system makes it challenging for DTBE to participate. Some of the documents created by ACET are technical in nature; however, the BCG document is a policy statement that is appropriate for ACET.
- Dr. Dean clarified that previous ACET discussions focused on the CDC clearance process and how it might modify a document. Representatives from CDC's Management Analysis and Services Office (MASO) advised ACET that a document produced by the council should not be subjected to the *MMWR* criteria or be published as an *MMWR* document. ACET has had several documents in development, but they have not been submitted to the *MMWR*.
- Dr. Castro added that CDC has looked carefully at their compliance with FACA. In the past, documents were developed jointly; however, ACET is required to have an independent voice. Therefore, ACET cannot publish in the *MMWR*, which is a product of CDC. ACET should still move forward with documents, but they will be disseminated in other venues.

Topic 7
The following motion was properly placed on the floor and seconded by Dr. Jane Carter and Ms. Barbara Cole, respectively:

"Whereas TB in corrections represents a serious threat to TB elimination in the US, ACET recommends that the DTBE prioritize TB in corrections by strengthening: coordination of prevention and control in corrections and detention facilities; the Cooperative Agreement to require the identification of a correctional liaison in each jurisdiction; surveillance; TB case detection; continuity of care; education; treatment of LTBI; and funding. In addition, ACET recommends the establishment of a CDC Office of Correctional Health which will provide cross-cutting evaluation and support of the health needs of corrections to include, but not be limited to, TB."

Dr. Carter explained that the motion refers to a longer document created by the Corrections Workgroup. The supporting document is included with this report as Attachment #3. There was discussion regarding creating an Office of Correctional Health at CDC:

- ACET observed that issues such as hepatitis, mental health, TB, and other issues facing the corrections population are addressed in different areas throughout CDC. An Office of Correctional Health might be a good approach to handle all of these concerns efficiently as they affect the corrections population, but CDC currently operates within a disease-specific structure, and it is not clear how the proposed office would interact with it.
- Dr. Dean added that CDC's Office of Minority Health and Health Equity (OMHHE) focuses on special populations such as the incarcerated population.
- Dr. Carter answered that the workgroup reviewed different statements and documents regarding healthcare in corrections and concluded that the number of cross-cutting issues in that population and the fact that DTBE does not have the resources to dedicate a staff member to TB in corrections merited the creation of an office within CDC to

coordinate across centers that could be funded by the different offices that address the myriad issues in the population.

- There is no coordination for corrections healthcare issues; for instance, an infection control nurse at a local jail has no single resource for guidance. There is no coordination to ensure that "corrections" is included as a component of grants and cooperative agreements, nor is there coordination among substance abuse, TB, mental health, and other concerns. The proposed office at CDC will coordinate among CDC programs, not provide oversight of local jurisdictions.

There was discussion regarding the difference between local jails, state and federal prisons, and other detention settings. They have different chains of command, accountability, and connections to local public health. The linkages occur well in some areas of the country, and less well in other areas. More people in public health need to understand the distinctions between the different types of facilities and sectors. Nationwide, about 2000 local jails house federal prisoners, inmates, and detainees in addition to their local inmates. There is, therefore, federal interest in local facilities.

There was discussion regarding separating the motion as written into two separate motions:

- Dr. Lornel G. Tompkins, an ACET liaison representative from the National Medical Association (NMA) observed that local and county jails are under the local public health jurisdictions, and actions at the federal level do not impact them directly. While the motion, as written, aimed to bring many corrections issues under one "umbrella," the local levels are guided by local funding streams and state priorities. She suggested creating two separate motions so that it can be determined whether an Office of Corrections at CDC is feasible without potentially hindering the goals of the first part of the resolution.
- CDC Office of Corrections could facilitate coordination at the local level, and there is value to bringing more coordination to the corrections system and health departments.
- It is important to have additional discussion about coordination of correctional health issues, particularly regarding the role of OMHHE.

Dr. Carter and Ms. Cole withdrew the motion as written and separated it into two motions. The motion to create a CDC Office of Correctional Health would be tabled until a later date.

With the supporting document, the following motion was properly placed on the floor and seconded by Dr. Jane Carter and Ms. Barbara Cole, respectively: "Whereas TB in corrections represents a serious threat to TB elimination in the US, ACET recommends that the DTBE prioritize TB in corrections by strengthening: coordination of prevention and control in corrections and detention facilities; CoAg agreement to require the identification of a correctional liaison in each jurisdiction; surveillance; TB case detection; continuity of care; education; treatment of Latent TB; and funding." **ACET unanimously approved the motion.**

Topic 8

Dr. C. Robert Horsburgh properly placed the following motion on the floor. It was seconded by Dr. Jane Carter.

"The Advisory Council for the Elimination of Tuberculosis advises the Secretary of Health and Human Services to direct the FDA to facilitate importation of WHO-qualified second-line tuberculosis drugs. Distribution of such drugs should be managed by the CDC under IND for treatment of persons with drug-resistant TB or persons with drug-susceptible TB who are intolerant to first-line agents." ACET unanimously approved the motion. The following ACET members abstained from the vote: Ms. Barbara Cole and Dr. Susan Dorman.

- More should be learned about the WHO pre-qualification and qualification guidelines and process. The gap between WHO pre-qualification and FDA standards is significant. Dr. Horsburgh agreed that the quality standards are different; however, people with MDR-TB in the US should be able to get the same drugs that people in other countries can get.
- There are serious concerns about imported drugs and cancer treatment. However, WHO ensures that the drugs are not counterfeit and monitors drug activity.
- Dr. Nardell and others expressed concern that this resolution may not be the appropriate mechanism for making second-line drugs available. It was suggested that a small group of representatives from ACET discuss approaches to this problem directly with FDA.
- It is important to be clear about FDA's process for approving drugs from logistical and regulatory perspectives. A representative from FDA should participate in ACET meetings, and it may be prudent to have a meeting with them before passing the resolution.
- Dr. Castro said that the FDA Globalization Act of 2009 addresses good importer practices and guidance. It will be possible for ACET to stimulate a conversation with FDA to learn how the Act could be used to facilitate access to these drugs. He agreed that it is important to have an FDA representative present at ACET meetings as *ex officio*.
- There was concern that the resolution was not specific enough, as the problems occur in specific situations when there are drug shortages or when people are intolerant of the drugs that are available.
- Ms. Jervis said that these issues would be addressed at TAG's upcoming advocacy meeting on January 18th, at which FDA will be present.

Topic 9

The following motion, titled *Diagnosis and Treatment of TB Disease and Infection Should be Considered as Essential Health Benefits for All*, was properly placed on the floor by Dr. Susan Dorman and seconded by Ms. Barbara Cole:

"Whereas tuberculosis (TB) is a communicable disease spread through the air,

"Whereas antimicrobial treatment is effective in curing most forms of active TB disease, antimicrobial treatment of TB infection is effective secondary prevention for infected individuals, and treatment of active TB disease serves as primary TB prevention for the community and protects public health,

"Whereas the Affordable Care Act (ACA) will provide a medical home and expand access to primary care in the U.S., but services for diagnosis and treatment for TB infection and disease are not presently included in the description of essential health benefits covered under the ACA,

"Whereas it is recognized that a proportion of the population will not have a medical home and will be provided with clinical care by local health departments and other safety net providers,

"Whereas the ACA does not address the public health functions (including but not limited to TB surveillance and reporting, assessment and management of contacts to infectious TB cases, and formulation of population health policy driven by local epidemiology) that have been demonstrated to be critical for TB control,

"Be it now resolved that ACET recommends that diagnosis and treatment for TB infection and disease be recognized as essential health benefits." **ACET unanimously approved the motion.** There were no abstentions.

- There was discussion regarding whether the last bullet should include the phrase, "as essential health benefits under the ACA." The group that wrote the resolution did not include the phrase because diagnosis and treatment for TB should be essential health benefits, regardless of the ACA.
- Dr. Warkentin said that NTCA supports this motion, which has been overdue. This issue is time-critical and should move to the HHS Secretary quickly.

Topic 10
The following motion, titled *Targeted Screening and Treatment of TB Infection should be evaluated ASAP for inclusion as a USPSTF Grade A or B Prevention Activity*, was properly placed on the floor and seconded by Ms. Barbara Cole and Dr. C. Robert Horsburgh, respectively:

"Whereas progress has been made in the control of TB in the US, TB morbidity and TB mortality represent an ongoing public safety risk. Although the US is considered a country with low rates of TB, transmission of TB continues.

"Screening and treatment of groups at risk for TB infection and disease are our only forms of prevention. There is no effective vaccine to prevent TB infection. Many people who are immunocompetent are able to effectively keep TB infection, the form of TB that is not contagious, under control. However the development of a medical condition like diabetes, HIV, cancer, need for immunosuppressive medical therapy, or simply the aging process, can cause the TB infection to progress to active TB disease. These individuals with TB infection represent the reservoir of future active cases, and benefit the most from intervention.

"Targeted screening and treatment of TB infection must expand to non-public health settings to move TB elimination forward. Local public health programs need to support providers in non-public health settings to develop the ability to effectively diagnose and treat TB infection. This skill should become part of the routine armamentarium for general prevention in the primary care setting.

"Targeted screening and treatment for TB infection in patients at risk for progression should be graded by the USPSTF as a prevention activity. Patients would not need to worry about cost sharing and proceed with treatment. This strategy would be highly beneficial in areas of the US with high rates of TB infection, and move TB elimination forward in the US.

"Therefore, let it be resolved that ACET recommend to CDC and the Secretary of HHS that targeted screening and treatment of TB infection be evaluated by USPSTF as a prevention measure." **ACET unanimously approved the motion.** There were no abstentions.

- Dr. Tompkins suggested removing a sentence in the resolution referring to reimbursement to providers, thereby removing reimbursement as a motivation for physicians or care providers to participate in the diagnosis and treatment of TB. Ms. Cole and Dr. Horsburgh agreed with the amendment.
- Dr. Castro said that USPSTF independently ascertains the evidence base for grading prevention activities. He suggested revising the resolution verbiage accordingly to remove specific references to Grade A or B.
- Dr. Castro suggested uncoupling screening and treatment in the resolution, as USPSTF typically rates screening, such as mammography, but does not address treatment.
- Dr. Dorman replied that the group that created the resolution feels that treatment should remain in the statement, because treatment of individuals with TB infection is prevention for others.
- USPSTF defers to CDC regarding screening for TB. The problem is the legislation that ties reimbursement to whether an activity is approved by USPSTF. One solution could be legislation to bridge the gap of issues that USPSTF does not directly address.
- The resolution focuses on patients at high risk, such as diabetics and HIV-infected persons, who are at greater risk for progression of TB disease.

Public Comment

Shannon Jones III
Deputy Director
City of Austin/Travis County Health Human Services Department
ACET Chair

At 2:26 pm, Mr. Jones opened the floor for public comment. No comments from the public were offered.

Meeting Adjournment

Shannon Jones III
Deputy Director
City of Austin/Travis County Health Human Services Department
ACET Chair

Mr. Jones asked the chair of each of the workgroups that prepared resolutions to share the approved resolutions with him within two weeks so that he can forward them in a memo to the HHS Secretary. He also asked for any additional verbiage to support the resolution.

Mr. Jones encouraged ACET members, *ex officios*, and liaison representatives to come to the March 2013 meeting ready to participate in a strategic effort, being mindful of the realities of their position as a federal advisory committee. ACET members, *ex officios*, and liaison representatives will all need to commit to the process and to any recommended changes.

Dr. Castro observed a renewed sense of vibrancy on ACET and hoped that they would capitalize on that energy. He proposed that the individuals who self-identified to participate in planning for the March 2013 retreat join on a telephone call the next week.

With no additional comments or questions posed, Mr. Jones adjourned the meeting at 2:29 pm.

Certification

I hereby certify that, to the best of my knowledge and ability, the foregoing minutes of the December 4 - 5, 2012, meeting of the Advisory Council for the Elimination of Tuberculosis, CDC are accurate and complete.

_____ _____

Date

Shannon Jones III
Chair, Advisory Council for the
Elimination of Tuberculosis, CDC

Attachment #1: Meeting Participants

Note
Dr. Hazel Dean, ACET Designated Federal Officer, conducted roll calls on December 4 and 5, 2012, at the beginning of each day's proceedings and when the group reconvened from breaks. She verified the presence of a quorum of ACET voting members and *ex officio* members sufficient for ACET to conduct its business on both days of the meeting.

ACET Members
Mr. Shannon Jones III, Chair
Dr. Eric Brenner
Dr. Marcos Burgos
Dr. Jane Carter
Dr. Gail Cassell (via telephone)
Ms. Barbara Cole
Dr. Susan Dorman
Dr. C. Robert Horsburgh, Jr.
Dr. Masahiro Narita

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

ACET *ex officio* Members
Dr. William B. Baine (Agency for Healthcare Research and Quality)
Dr. Amy Bloom (US Agency for International Development)
Ms. Sarah Bur (Federal Bureau of Prisons)
Ms. Linda Danko (alternate, Department of Veterans Affairs) (via telephone)
Ms. Lisa Delaney (alternate, National Institute for Occupational Safety and Health)
Dr. Diana Elson (US Immigration and Customs Enforcement)
Dr. J. Nadine Gracia (Office of Minority Health, HHS) (via telephone)
Dr. Warren W. Hewitt, Jr. (Substance Abuse and Mental Health Administration)
Dr. Momodikoe Makhene (National Institute of Allergy and Infectious Diseases) (via telephone)
Dr. James Mancuso (alternate, Department of Defense)
Ms. Tiffany Moore (US Marshals Service)
Dr. Theresa Watkins-Bryant (Health Resources and Services Administration)

ACET Liaison Members
Dr. Robert Benjamin (National Association of City and County Health Officials)
Dr. Mayleen J. Ekiek (Pacific Island Health Officers Association)
Dr. Joe Goldenson (National Commission on Correctional Health Care)
Mr. Eddie Hedrick (Association for Professionals in Infection Control and Epidemiology)
Ms. Cornelia Jervis (Treatment Action Group)
Ms. Eileen Napolitano (Stop TB USA)
Dr. Ed Nardell (International Union Against TB and Lung Disease)
Dr. Jennifer Rakeman (Association of Public Health Laboratories)
Dr. Susan M. Ray (Infectious Disease Society of America)
Dr. Lornel Tompkins (National Medical Association)
Dr. Jon Warkentin (alternate, National Tuberculosis Controllers Association)
Dr. Maria Teresa Zorrilla (US-México Border Health Commission) (via telephone)

CDC Representatives

Dr. Kenneth Castro, Director, Division of Tuberculosis Elimination, NCHHSTP
Dr. José Becerra
Mr. Stephen Benoit
Dr. Stewart Berman
Dr. Terence Chorba
Ms. Ann Cronin
Dr. Wayne Duffus
Dr. Kevin Fenton, Director, NCHHSTP
Ms. Smita Ghosh
Ms. Judy Gibson
Dr. Juliana Grant
Dr. Christine Ho
Dr. Michael Iademarco
Dr. John Jereb
Dr. Awal Khan
Ms. Ann Lanner
Dr. Susan Maloney
Dr. Sundari Mase
Mr. James Miner (CDC/FMO)
Ms. Brittany Moore
Dr. Tom Navin
Ms. Melissa Pagaoa
Dr. Drew Posey
Ms. Amy Pulver
Dr. Taraz Samandari
Dr. Salaam Semann
Ms. Maria Fraire Sessions
Dr. Patricia Simone
Ms. Margie Scott-Cseh
Mr. Philip Talboy
Dr. Andy Vernon
Ms. Pei-Chun Wan
Dr. Kai Young

Members of the Public

Ms. Kendra Cox (Cambridge Communications)
Mr. Dack Dalrymple (Dalrymple & Associates)
Dr. Mike Fleenor (Jefferson County Department of Health)
Dr. Julie Higashi (California TB Controllers Association)
Mr. William Murtaugh (Association of Public Health Laboratories)
Ms. Carol Pozsik (National Tuberculosis Controllers Association)
Mr. John Seggerson (Stop TB USA)

Attachment #2: Acronyms Used in This Document

Acronym	Expansion
ACA	Affordable Care Act
ACET	Advisory Council for the Elimination of Tuberculosis
ACIP	Association for Professionals in Infection Control and Epidemiology
AFB	Acid-Fast Bacilli
AIDAC	Anti-Infective Drugs Advisory Committee
AMA	American Medical Association
APHL	Association of Public Health Laboratories
ART	Antiretroviral Therapy
ASTHO	Association of State and Territorial Health Officials
BCG	Bacille Calmette-Guerin (vaccination)
BSC	Board of Scientific Counselors
CAPUS	Care and Prevention in the United States
CBO	Community-Based Organization
CDC	Centers for Disease Control and Prevention
CdV	Consultorios de Visa
CEBSB	Communications, Education, and Behavioral Studies Branch
CGH	Center for Global Health
CITC	Curry International Tuberculosis Center
CMO	Committee Management Office
CPG	Clinical Practice Guidelines
CR	Continuing Resolution
CROI	Conference on Retroviruses and Opportunistic Infections
CSH	Combat Support Hospital
DASH	Division of Adolescent and School Health
DFO	Designated Federal Officer
DGDDER	Division of Global Disease Detection and Emergency Response
DGHA	Division of Global HIV/AIDS
DGMQ	Division of Global Migration and Quarantine
DHAP	Division of HIV/AIDS Prevention
DoD	(United States) Department of Defense
DOT	directly observed therapy
DR	Dominican Republic
DSTDP	Division of STD Prevention
DTBE	Division of Tuberculosis Elimination
DVH	Division of Viral Hepatitis
ECHPP	Enhanced Comprehensive HIV Prevention Planning and Implementation Program
EIS	Epidemic Intelligence Service
EMR	Electronic Medical Records
FACA	Federal Advisory Committee Act
FBOP	Federal Bureau of Prisons
FDA	(United States) Food and Drug Administration
FOA	Funding Opportunity Announcement
FQHC	Federally Qualified Health Center
FY	Fiscal Year

Acronym	Expansion
GCC	Global Communications Center
GDD	Global Disease Detection
GDF	Global Drug Facility
GTBI	New Jersey Medical School Global Tuberculosis Institute
HAART	Highly Active Antiretroviral Therapy
HHS	(United States) Department of Health and Human Services
HICPAC	Healthcare Infection Control Practices Advisory Committee
HIV	Human Immunodeficiency Virus
HIV-CAUSAL	HIV Cohorts Analyzed Using Structural Approaches to Longitudinal Data
HNTC	Heartland National Tuberculosis Center
HRSA	Health Resources and Services Administration
IAC	International AIDS Conference
ICE	Immigration and Customs Enforcement
ICU	Intensive Care Unit
IGRAs	Interferon-Gamma Release Assays
IHS	Indian Health Service
IND	Investigational New Drug
INH	Isoniazid
IOM	Institute of Medicine
IRB	Institutional Review Board
IRPB	International Research and Programs Branch
ISDA	Infectious Diseases Society of America
IT	Information Technology
LTBI	Latent Tuberculosis Infection
MAI	Minority HIV/AIDS Initiative
MASO	Management Analysis and Services Office
MDDR	Molecular Detection of Drug Resistance (Service)
MDR-TB	multidrug-resistant tuberculosis
MMWR	*Morbidity and Mortality Weekly Report*
MOH	Ministry of Health
MSM	Men who have sex with men
Mtb	*Mycobacterium tuberculosis*
NAA	Nucleic Acid Amplification
NAA	nucleic acid amplification
NA-ACCORD	North American AIDS Cohort Collaboration on Research and Design
NACCHO	National Association of City and County Health Officials
NCEZID	National Center for Emerging and Zoonotic Infectious Diseases
NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
NCIRD	National Center for Immunization and Respiratory Diseases
NGO	Non-Governmental Organization
NHANES	National Health and Nutrition Examination Survey
NHAS	National HIV/AIDS Strategy
NIAID	National Institute of Allergies and Infectious Diseases
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
NMA	National Medical Association
NPRM	Notice of Proposed Rule Making

Acronym	Expansion
NTCA	National Tuberculosis Controllers Association
NTIP	National Tuberculosis Indicators Project
NTM	*Non-Tuberculous Mycobacteria*
NTP	National Tuberculosis Program
OADS	Office of the Associate Director for Science
OGAC	Office of the US Global AIDS Coordinator
OID	Office of Infectious Diseases
OMH	Office of Minority Health
OMHHE	Office of Minority Health and Health Equity
OSELS	Office of Surveillance, Epidemiology, and Laboratory Services
PAHO	Pan American Health Organization
PCSI	Program Collaboration Service Integration
PEPFAR	President's Emergency Plan for AIDS Relief
PHAC	Public Health Agency of Canada
POW	Prisoner of War
PPV	Positive Predictive Value
PZA	Pyrazinamide
QFT	QuantiFERON-TB test
RTMCC	Regional Training and Medical Consultation Centers
RVCT	Report of Verified Case of Tuberculosis
RWJ	Robert Wood Johnson (Foundation)
SNTC	Southeastern National Tuberculosis Center
STD	Sexually Transmitted Disease
TAG	Treatment Action Group
TB	Tuberculosis
TB ETN	Tuberculosis Education and Training Network
TB PEN	Tuberculosis Program Effectiveness Network
TB RTMCCs	Tuberculosis Regional Training and Medical Consultation Centers
TBESC	Tuberculosis Epidemiologic Studies Consortium
TBTC	Tuberculosis Trials Consortium
TST	Tuberculin Skin Test
TTI	Tuberculosis Technical Instructions
US	United States
USPSTF	United States Preventive Services Task Force
VA	(United States) Department of Veterans Affairs
WHO	World Health Organization
WTST	Working Together to Stop TB
XDR-TB	Extensively Drug-Resistant Tuberculosis

Attachment #3: Supporting Document for ACET Corrections Workgroup Resolution

ACET Corrections Workgroup
Proposed Resolution (12/4/12)

WHEREAS

- The U.S. has the highest incarceration rate in the world with approximately 2.3 million people incarcerated;
- The risk of TB in jails and prisons is 4-5 times greater than for the general population;
- Outbreaks continue to occur in correctional settings posing a risk for widespread TB transmission;
- Rates of TB treatment completion are lower among active TB cases diagnosed in correctional facilities than among non-incarcerated populations (73% vs. 86%) with only 50% of foreign born inmates completing treatment; and
- The 2006 CDC Guidelines for Prevention and Control of Tuberculosis in Correctional and Detention Facilities, while providing detailed and comprehensive guidance, have not been fully implemented by correctional and detention facilities.

THEREFORE

Given that correctional settings provide opportunities to turn the tide for these concerning TB trends, ACET recommends that CDC consider making TB prevention and control in correctional settings a priority focus to:

- Improve TB case detection;
- Reduce TB case rates;
- Increase TB treatment completion rates among TB cases identified while incarcerated;
- Prevent TB transmission in these settings; and
- Expand treatment of latent TB infection to prevent future TB cases.

It is proposed that CDC consider the following measures to strengthen the implementation of the 2006 CDC Guidelines for the Prevention and Control of TB in Correctional and Detention Facilities.

ACET Corrections Workgroup Proposed Resolution	
Coordination	Division of TB Elimination (DTBE): • Strengthen the coordination and oversight of TB prevention and control in correctional and detention facilities in partnership with state TB programs. • Conduct a formal evaluation to assess the need for a full-time staff person to coordinate these activities. • Develop ongoing collaborative partnerships with national and regional correctional organizations to advance TB education and prevention and control efforts (e.g., American Correctional Association, National Commission on Correctional Health Care, National Institute of Corrections, American Jail Association, American Sheriff's Association, Coalition of Correctional Health Authorities, Society of Correctional Physicians, correctional health care corporations).
Correctional Liaison role defined in the TB Cooperative Agreement	DTBE incorporate into the new TB Cooperative Agreement the following proposed language: *"TB prevention and control in correctional and detention facilities is a high national priority. Each Cooperative Agreement recipient will designate a correctional liaison and provide a brief summary report of activities in the interim and final progress reports. Each jurisdiction should determine local priorities for the TB correctional liaison utilizing the National TB Controllers Association (NTCA) Public Health TB Corrections liaison model duty statement as a guide (available at: http://tbcontrollers.org/docs/CoreCompetencies/Corrections042209_0710.pdf"*
Surveillance	DTBE: • Develop a plan for using TB surveillance data as a programmatic tool to identify burden of disease in correctional settings and the need for interventions and special studies. • Publish a brief annual summary of trends in TB in correctional and detention facilities that is made widely available and promoted for use by state TB programs to make data driven decisions about resource allocation. • Add a question to the Report of Verified Case of Tuberculosis the next time it is updated: "history of incarceration in the last (one or) two years"
TB Case Detection	• DTBE identify methods to improve TB screening, case detection and medical management of persons with suspected TB. • Emphasize the appropriate use of rapid testing in the diagnostic evaluation of persons in the legal custody of a law enforcement agency. • Develop algorithms for returning inmates with suspected pulmonary TB to the general inmate population.
Continuity of Care	DTBE: • Conduct state specific analyses of the low rates of TB treatment completion among persons incarcerated at diagnosis and work with state and local health departments to plan to improve completion rates. • Evaluate the effectiveness of CURE-TB and TB-NET for transnational TB referral s and explore long term funding. • Explore the possibility of establishing a central system to obtain completion of treatment information from foreign countries for patients who have moved or been repatriated outside the U.S. • Identify successful programs for improving continuity of care and TB

ACET Corrections Workgroup Proposed Resolution	
	treatment completion for TB cases identified in correctional facilities and disseminate information about these effective models.
Education	DTBE instruct the Regional Training & Medical Consultation Centers and the appropriate DTBE Branches to coordinate on strategies to identify and meet the TB learning needs of correctional administrators, correctional health care providers and infection control personnel, law enforcement/correctional officers, and inmates. • Conduct a needs assessment • Develop, disseminate and evaluate educational tools • Develop TB competency assessment tools for correctional health care providers • Collaborate with correctional partners to identify methods to assure that correctional health care providers and infection control staff receive TB education and that there is a means to demonstrate TB competency.
Treatment of Latent TB Infection	DTBE identify ways to expand treatment of latent TB infection in correctional facilities (including expanded use of the 12-week isoniazid/rifapentine regimen).
Funding	DTBE partner with key stakeholders to leverage existing and future resources for TB prevention and control in correctional and detention facilities (e.g., funding and resources from Program Collaboration and Services Integration activities, emergency preparedness programs, HIV/viral hepatitis/diabetes-related organizations, programs working with immigrant populations, and national correctional organizations).
Establish CDC Office of Correctional Health	ACET recognizes that prevention and control of TB in corrections and law enforcement settings occurs in a larger correctional health context that includes other communicable diseases, substance abuse, mental health, and chronic diseases, infection control, and occupational health. In March 2009, the National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention hosted a national external consultation entitled Correctional Health- Expanding the Reach of Prevention. One of the major recommendations from that consultation was to establish “an Office for Correctional Health to help integrate data collection, programs, and service support for chronic and infectious disease prevention.” ACET recommends that the CDC Director consider establishing an Office of Correctional Health to provide national leadership and assure that all Centers operationalize correctional health priorities in programs and guidelines. • Provide national leadership on the scope and complexity of the U.S. law enforcement, corrections, detention, and community corrections systems and their intersection with health and public health; • Develop relationships with key national and regional law enforcement and corrections agencies, e.g., American Correctional Association, American Jail Association, National Commission on Correctional Health Care, National Institute of Corrections, National Sheriffs Association, Association of State Correctional Administrators (ASCA), Coalition of Correctional Health

ACET Corrections Workgroup Proposed Resolution	
	Authorities, Society of Correctional Physicians, private corrections management organizations, private correctional health care organizations; • Assist CDC Centers with operationalizing correctional health priorities within CDC programs and addressing needs in relevant guidelines; • Provide technical assistance to state and local public health correctional liaisons and to state, local, and federal corrections and law enforcement agencies; • Assist CDC Centers with identifying appropriate corrections and law enforcement indicators in surveillance systems; • Assist CDC Centers in developing training and educational materials related to health and public health associated with corrections and law enforcement; • Provide technical assistance and resources to promote continuity of care for individuals that move between correctional facilities, law enforcement agencies, and communities.