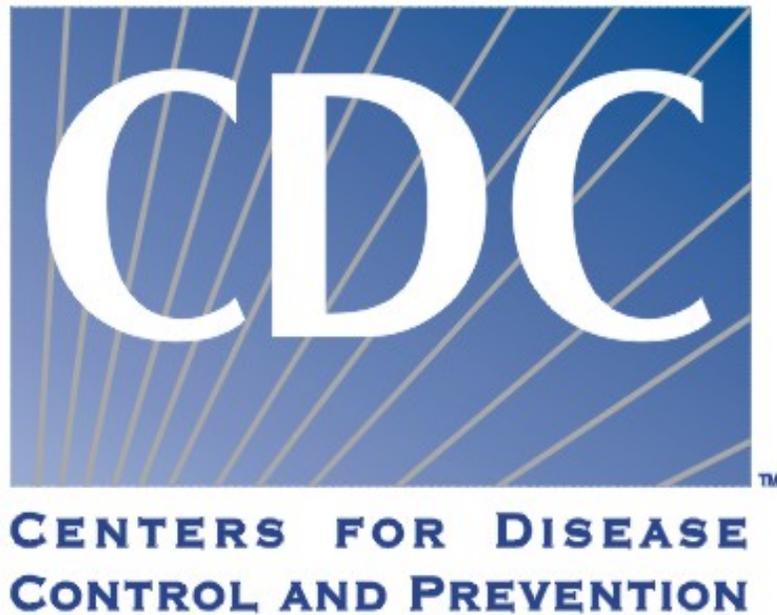


**ADVISORY COUNCIL FOR THE ELIMINATION OF TUBERCULOSIS
CENTERS FOR DISEASE CONTROL AND PREVENTION**



**JUNE 4 - 5, 2013
ATLANTA, GEORGIA**

DRAFT Summary of the Proceedings

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**Advisory Council for the Elimination of Tuberculosis
Centers for Disease Control and Prevention (CDC)**

**8 Corporate Square
Conference Room 1 A/B/C
Atlanta
June 4, 2013**

AGENDA

8:30 Call to Order and Welcome Dr. Hazel Dean
Mr. Shannon Jones

8:35 Roll Call Dr. Hazel Dean

DTBE Strategic Vision for 2015 and the Future

8:45 DTBE Strategic Vision for the Future Dr. Kenneth Castro

9:30 Q's and A's

TB Prevention and Control in Changing Healthcare Environment

9:45 Redefining the Essential Components of an Effective TB Program Dr. Jon Warkentin

10:15 Q's and A's

10:45 BREAK

10:50 TB as it Relates to Affordable Care Act/
Implementation of ACA Dr. Christine Ho

11:20 Q's and A's

12:00 Lunch on your own

1:00 U.S. Preventive Services Task Force / Assessing
Evidence for Treatment of LTBI as Prevention Dr. Christine Ho

1:20 Q's and A's

1:30 Internal ACET Discussions Mr. Shannon Jones
Resolutions

Drug/Diagnostic Shortages Update

2:50	Drug/Diagnostic Shortages - Field Perspective	Dr. Jennifer Flood
3:00	CDC Activities around Drug/Diagnostic Shortages	Dr. Sundari Mase
3:10	Federal TB Task Force – Drug Shortages Report	Dr. Sundari Mase
3:15	An update of the Diagnostics Work Group of the Federal TB Task Force	Dr. Michael Iademarco
3:30	Q and A's	
3:45	Break	
4:00	Task Order 18 Update and Recommendations	Dr. Wendy Thanassi
4:30	Q's and A's	
4:45	TB Corrections Update	Dr. Jane Carter/Sarah Bur
5:00	Wrap-Up Discussion	Shannon Jones
5:30	Meeting Adjourned	

**Advisory Council for the Elimination of Tuberculosis
Centers for Disease Control and Prevention (CDC)**

**8 Corporate Square
Conference Room 1 A/B/C
Atlanta
June 5, 2013**

AGENDA

8:30 Call to Order Dr. Hazel Dean
Mr. Shannon Jones

8:35 Roll Call Dr. Hazel Dean

TB in the Homeless

8:45 HRSA perspectives on the Homeless Dr. Seiji Hayashi

9:00 Healthcare for the Homeless Mr. John Lozier

9:15 Qs and As

U.S./Mexico Border Health

9:45 TB efforts along the U.S./Mexico Border Mr. Paul Dulin

10:10 Q's and A's

10:30 BREAK

Business Session

10:45 Motion to accept minutes of March 5, 2013 meeting Mr. Shannon Jones
Dates for next ACET meeting
-December 3-4, 2013

Potential Business Items

10:55 **Potential Business Items:** Mr. Shannon Jones
-Strategy for First and Second Line Drug Shortages
-Number of meetings – reduce to 1 in person and 2
webinars
-Number of Liaisons and Ex-Officios
-Travel of Liaisons and Ex-Officios

Continuation of Potential Business Items:

- Future dates for the ACET meetings
- Future Agenda Items / What are Priority issues for ACET?
- Other Business

12:00	Boxed Lunch	
12:25	Continuation of Business Items	
2:05	Potential agenda topics for the next meeting	Mr. Shannon Jones
2:20	Public Comment	
2:30	Meeting Adjourned	

**ADVISORY COUNCIL FOR THE ELIMINATION OF TUBERCULOSIS
CENTERS FOR DISEASE CONTROL AND PREVENTION
8 Corporate Square
Conference Room 1 A/B/C
Atlanta
June 4-5, 2013**

DRAFT Minutes of Meeting

The Centers for Disease Control and Prevention (CDC), National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP) Division of Tuberculosis Elimination (DTBE) convened a meeting of the Advisory Council for the Elimination of Tuberculosis (ACET) on June 4-5, 2013, in Building 8 of CDC's Corporate Square Campus, Conference Room A/B/C, in Atlanta, GA.

TUESDAY, JUNE 4, 2013

CALL TO ORDER AND WELCOME

Shannon Jones, III

ACET Chair, Deputy Director, City of Austin/Travis County Human Services Department

Mr. Jones called the meeting of the ACET to order, at 8:40 AM on Tuesday, June 4, 2013. The proceedings were turned over to Dr. Hazel Dean, for announcements and roll call.

Hazel D. Dean, ScD. MPH

Deputy Director, NCHHSTP, CDC, 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 requested that ACET members declare any potential conflicts of interest to be noted for the record.

Dr. Dean welcomed the following individuals:

- Dr. Edward Desmond, sitting in for Liaison Representative Dr. Jennifer Rakehan of the Association of Public Health Laboratories
- Dr. David Trump, Liaison Representative for the Council of State and Territorial Epidemiologists (CSTE)

- Dr. Gudelia Rangel, Acting Liaison Representative to replace Dr. Zorrilla, Former Executive Secretary of the U.S.-Mexico Border Health Commission
- Dr. Paul Dulin, sitting in for both the U.S.-Mexico Board of Health Commission
- Dr. Edward (Howard) Najoo, Liaison Representative from the Public Health Agency of Canada
- Mr. David Bryden, Liaison Representative replacing Ms. Jennifer Maurer from RESULTS

The following ACET Members will rotate off, as of June 30, 2013:

- Mr. Shannon Jones, III, ACET Chair
- Dr. Masahiro Narita, ACET Member
- Dr. Barbara Seaworth, ACET Member
- Dr. Susan Dorman, ACET Member

A nomination package was submitted to the CDC CMO on January 17, 2013 to replace the above-mentioned members.

Dr. Dean conducted a roll call of members, ex officio members, and liaison representatives. Quorum was present and no conflicts of interest were declared.

Mr. Shannon Jones

Mr. Jones welcomed participants to the meeting and acknowledged the presence of Acting Center Director, Dr. Rima Khabbaz. Dr. Khabbaz greeted the committee and provided brief comments. The division is making progress in identifying a permanent center director. Individuals are currently being vetted. In addition, CDC is under significant budgetary constraints due to the sequestration and budget reductions. Not only have activities and programs been affected but also travel, which has restricted some staff from participating in meetings. Yet, there is still exciting work occurring in DTBE.

Individuals participating via the phone were asked to identify themselves. The following were present:

- Ms. Cornelia Jervis, Treatment Action Group
- Ms. Demetria Gardner, Management Analysis and Services Office (MASO)
- Mr. Eddie Hedrick, Association for Professionals In Infectious Control and Epidemiology
- Dr. Mamodikoe Makhene, National Institutes of Health
- Dr. Sheldon Morris, Food and Drug Administration (FDA)
- Ms. Caroline Freeman, Occupational Safety and Health Administration (OSHA)

Observers were also given the opportunity to introduce themselves. [See Attachment #1 for a full list of attendees.]

DTBE STRATEGIC VISION FOR 2015 AND THE FUTURE

DTBE Strategic Vision for the Future

Dr. Kenneth Castro

Director, DTBE

Dr. Castro's presentation outlined the 2015 strategic vision, for DTBE. The DTBE webpage, www.cdc.gov/tb/about/strategicplan.htm, highlights the strategic plan and lays out the priorities, goals, and core functions of DTBE. Also included are overviews of past activities, plans, and reports. The strategic planning sessions were started back in 1989. Public Law 110-392 authorizes the division through 2013. In examining the law, gaps between what was authorized and what has been received from Congress can be easily identified; therefore, Congress is considering redrafting Public Law 110-392.

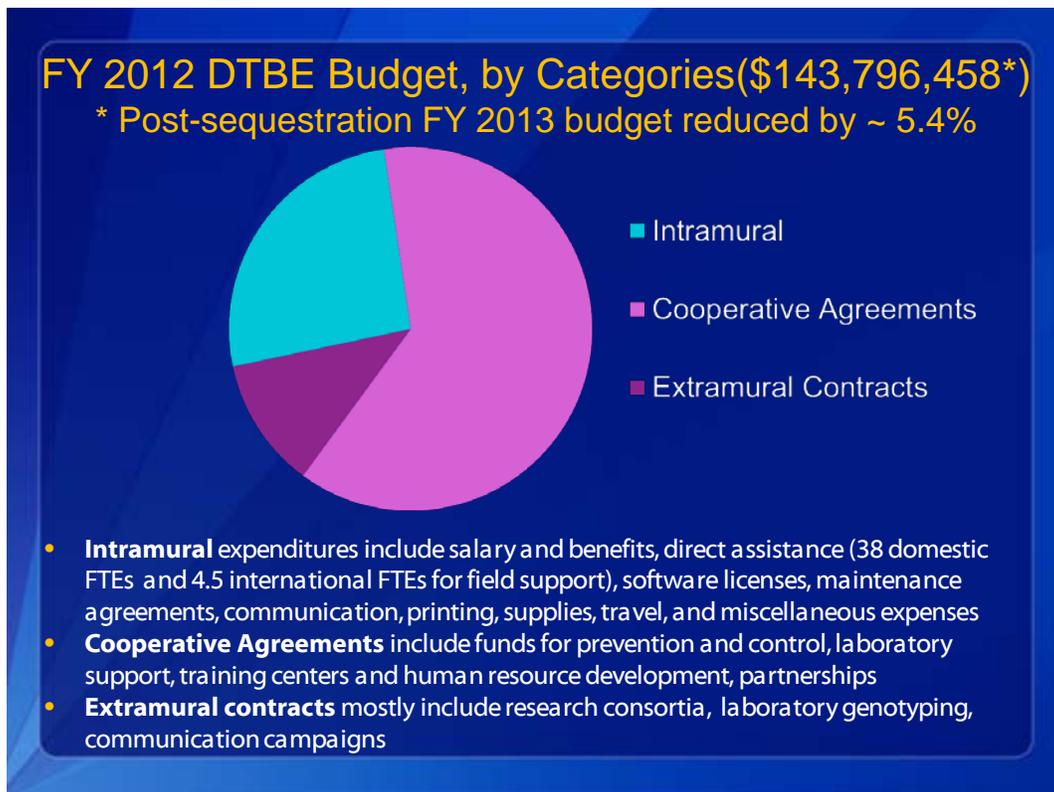
DTBE's vision is a nation and world free of TB. The mission is to promote health and quality of life by preventing, controlling, and eventually eliminating tuberculosis from the United States, and by collaborating with other countries and international partners in controlling global tuberculosis. The priorities are to prevent new cases of infection and disease with s; find and cure all persons with TB disease; reduce tuberculosis in foreign-born persons residing in, or traveling to, the United States; reduce TB in U.S. racial and ethnic minority populations; reduce impact of multidrug-resistant and extensively drug-resistant TB in the U.S. and abroad; and reduce HIV-associated TB in the U.S. and internationally. Many of the priorities were developed, because of the work in Africa, through the President's Emergency Plan for AIDS Relief (PEPFAR).

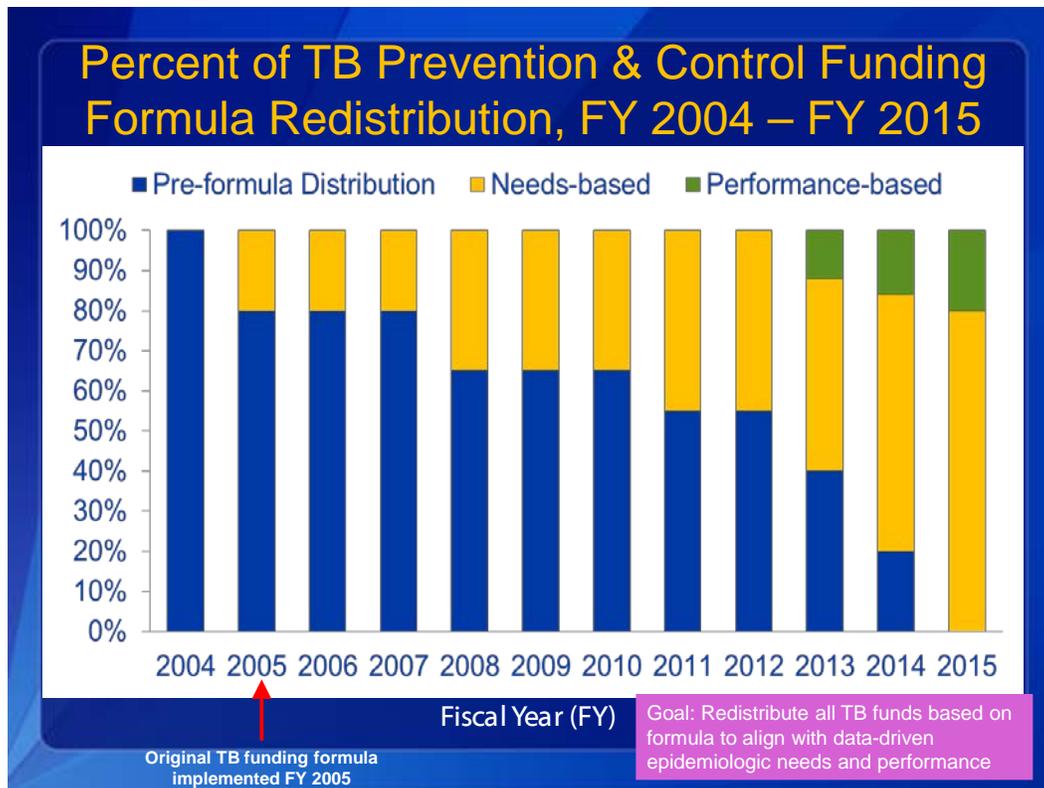
Several core functions have been identified for the division. They are as follows:

- Conduct routine surveillance (including drug susceptibility surveillance) and periodic surveys
- Provide funding and technical assistance to state and local programs for case finding, contact investigation, and completion of treatment, and support care and treatment with assistance from Regional Training and Medical Consultation Centers (RTMCC)
- Support intramural infrastructure (salaries, travel, equipment and supplies) required for maintaining subject-matter expertise in TB
- Guide preparedness and outbreak investigation responses
- Conduct program evaluation (e.g., National TB Indicators Project)
- Provide laboratory diagnostic services, research and build/maintain capacity
- Provide data management, statistical, and IT support

- ❑ Obtain external expert consultation and advice to ensure that research and program activities are responsive to emergent public health concerns
- ❑ Conduct critical, programmatically relevant operational research to develop and evaluate new tools/interventions for diagnosis, drug treatment, prevention and control of TB (to help programs work more effectively and more efficiently)
- ❑ Develop and evaluate evidence-based training and educational materials, policies, and guidelines to ensure competency in TB diagnosis, drug treatment, laboratory capacity, and programmatic prevention and control
- ❑ Develop education, risk, and media communications (web and print based) to aid in preparedness and public awareness of TB prevention and control
- ❑ Cultivate strategic partnerships (e.g., Stop TB USA, NTCA, ATS, IDSA, AAP, APHL, affected individuals and their families), across other federal agencies (FTBTF), US-MX Binational Commission, NHCHC*,NCCHC*, global Stop TB Partnership

Below is a pie chart and graph, which were presented to illustrate the budget and funding for DTBE.





About three quarters of the budget goes to cooperative agreements and extramural contracts. Over time, the division has worked diligently to make the funding follow the epidemiology of TB. By working with partners, an agreement was met to redistribute funding. Funding has shifted starting in 2013 and a performance-based component has been added, which looks at completion of therapy and the number of culture positive individuals who have drug susceptibility tests. The hope is to redistribute 60% of the budget by 2013, 80% by 2014, and all budgetary assignments to be formula-based by 2015.

There are several challenges or threats to the 2013-2015 efforts. Some of the challenges include budget sequestration and mandated reductions, weakened programs, outbreak response capacity, and drug shortages. However, there are also several opportunities for DTBE, like the Affordable Care Act (ACA) coverage for TB services, U.S. Prevention Services Taskforce (USPSTF) to review TB screening guidelines, increases in federally-qualified and community health centers, and a universal genotyping role in targeting prevention and control efforts.

The proposed strategic vision for tuberculosis is to retain optimistic goal of TB elimination (≤ 1 case/million) in U.S. and advance global prevention and control; bridge implementation, knowledge, and ambition gaps, and focus activities to address specific “change factors”. Much of the work was started earlier and in May 2011, the *Restructuring the U.S. Tuberculosis Program Work Group Report*

was shared with ACET. The work group ratified the broad areas of work that DTBE undertakes and determined that the division needed to retain the cooperative agreements. Program relevant research and global/international activities was also endorsed, and there was an acknowledgement of the need to the support workforce (subject matter experts, SMEs).

Dr. Castro gleaned lessons learned from the *Smallpox and Its Eradication* document. Some of those lessons were outlined for the committee.

1. Political commitment, coordination, and implementation
 - Decision by 1959 WHA, ratified in 1966 WHA with new resources
2. Special program
 - Specifically targeted (cessation of mass vaccination), time-limited
 - Adapted to local epidemiology and different local conditions
 - Identify and address set-backs
3. Defined objectives and goals
 - Complete disease reporting and nil incidence
 - Discover cases and contain outbreaks within 2 weeks
4. Quality control and program management
 - Network of professional staff: “many thousands of health staff received training in the execution of vaccination programs and in field epidemiology”
5. Research
 - Better methods for quality vaccine production and targeted delivery
6. Certification, Costs

Dr. Castro has taken the above lessons and applied them to TB elimination, which result in the following outline of activities:

1. Political commitment, coordination, and implementation
 - Reauthorize and resource PL110-392
 - Develop and nurture strategic alliances (including affected persons)
2. Special program (demonstrate added value to PPACA)
 - Active case finding adapted to local epidemiology, targeted contact investigations, work with federally-qualified health centers (FQHC), shelters, corrections, refugee programs, recent immigrants (students, workers), electronic lab records. Focus on universal diagnosis and cure
 - Provide timely and robust emergency outbreak response capacity
 - Rely on molecular genotyping to target contact investigations, informed by infectious periods and exposed cohorts
 - “Allocate resources where needed,” such as high-burden areas, for targeted screening of high risk groups; cease mass screening of all students, teachers, healthcare workers (HCW)

- Develop early warning system and mechanisms to prevent commodity shortages (drugs, lab and other diagnostic tests)
 - Align domestic work in support of global TB prevention and control
3. Defined objectives and goals
 - Complete disease reporting and incidence of $\leq 1/\text{million}$
 - Define interim measures
 - Targeted testing and treatment of high-risk groups with LTBI (HIV-infected, persons on TNF-alpha inhibitors, recent immigrants from high-burden countries)
 4. Quality control and program management
 - Network of trained professional staff with subject-matter expertise
 - Identify and address set-backs by reliance on, and refinements of, indices in NTIP
 5. Research
 - Invest in new tools research (i.e., same-day diagnosis of disease and LTBI, drug resistance, and short course Rx for disease and LTBI)
 6. Certification, Costs
 - Calculate averted cases, cost savings, and societal benefits

The above activities has caused the division to consider revising and updating the tuberculosis targets and measures in order to achieve ambitious but realistic goals that will aid in achieving its mission. The division should aim for elimination of ≤ 1 case/million by 2050 and develop interim targets, like 1/100,000 by 2020, 5/million by 2030, 2.5/million by 2040 or maybe even zero TB deaths. In order to eliminate recent transmissions, DTBE should develop quantitative measure of recent transmission and identify interim targets for elimination of transmission. In addition, it should calculate cases and deaths averted, as a metric.

Dr. Castro concluded the presentation by posing several questions to ACET that the division needs guidance around:

- Is the national comprehensive TB elimination framework appropriate and relevant to attain maximal impact?
 - What proportion of CDC resources should support future program (prevention and control) laboratory, RTMCC, human resource development, research, global work?
 - Continue with formula funding plans in near future?
- Recommendations for program monitoring and improvement?
- Recommendations for outbreak response capacity?
- What type of research should be supported by CDC?
- Is the alignment of domestic and global work appropriate? Recommended revisions?

The floor was then opened for discussion.

Dr. Baine did not notice any new activities proposed for Priority 3, which is to reduce tuberculosis in U.S. racial and ethnic minority populations. Dr. Castro said a number of racial and ethnic populations are supported with funding. Beyond that, DTBE needs to better understand the social determinants of health that are accounting for disparities. Although TB incidences have decreased, there still exists a significant gap for minorities, and that needs to be addressed. Better collapsed approaches are also needed for homeless shelters and correctional facilities.

Dr. Horsburgh noted the proposal to the USPSTF has the potential to be extremely cost effective by providing funding to perform one of the major interventions and incentivize physicians to carry out the intervention. Yet, the materials indicate that the proposal is at risk. Dr. Castro was pleased to report that the proposal would be funded. Atlanta Human Resources Center (AHRC) is funding \$125,000 and DTBE \$375,000. Once, DTBE knew its budget, the proposal was the first thing funded.

Dr. Reichman urged DTBE to make very evident the activities that it is doing well. The outbreak response is an example of an activity that should be spotlighted. Stop TB USA shows an average of two or three outbreaks per week in the United States, and the outbreaks do get media attention. The media attention would provide a platform to bring awareness to ongoing TB threats from international cases. DTBE staff should learn to respond to these opportunities, which can offer the U.S. realistic pictures of TB in 2013. Dr. Castro agreed with Dr. Reichman's thought, but he has found that local health departments do not want to draw attention, in that regard. The biggest misconception in this country is that TB is a disease of the past. This is why it is key to continue to work with affected populations to give them a voice and a platform. More over, when DTBE meets with CSTE, state, and territorial health departments, rarely is TB on the agenda because health departments are doing pretty well in those efforts. Health departments should be encouraged to celebrate their work, which can help to dispel the belief that TB is no longer a threat for the United States.

Dr. Hewitt made a comment in regards to Dr. Castro's smallpox correlation. Tuberculosis elimination needs to be a politicized activity by people outside of CDC, who have a stake. Public health is more political than it was 20 years ago, and will continue to become more political, if the tension between acute care and primary care continues to become grayer. He hopes the Affordable Care Act would address that. On the subject of social determinants, the Substance Abuse and Mental Health Administration (SAMHA) found that it did not have the resources to address the social determinants of health that drive the issues in racial and ethnic populations. In addition, that fact should be put into context; moreover, activities should be identified to bring about immediate impact. Agencies like HUD and others, who also have a stake, should be engaged.

Mr. Jones asked Dr. Castro to speak on emergency response where cooperative agreements may not be implemented and efforts to address social determinants of health if cooperative agreements were reprioritize among states. Dr. Castro replied in any jurisdiction where the annual incidence of TB is less than 10 per year, DTBE could consider working with other partners. The division could also redistribute funding in order to fund partners who are more pluripotential, so that in the event of a cluster of TB threats, there is ready access to call for help and for CDC to mobilize as well as other partners. Surveillance, he noted, should never stop. He would personally enter cases by hand if needed because the moment surveillance stops, decision makers are given an opportunity to make excuses for not supporting efforts and providing resources. He welcomed input on how to modify and move forward. If data shows that DTBE is not moving in the right direction, it will reassess and try again.

Dr. Benjamin suggested lessons learned should also be gleaned from HIV efforts as well and Ms. Levin highlighted the need for more coordination with correctional facilities and detention centers, with a focus on the transient issues. Dr. Castro agreed that efforts have fallen significantly in that area and should be strengthened.

Dr. Baine asked where is the evidence that all the determinants are social and what is the prevalence required in the U.S. population to have a lower threshold for positivity and screening. Dr. Castro answered the data that support the various threshold have to do with retest probability. U.S-born populations are more likely to have a positive skin test because of a cross reactor non-TB bacteria or a false positive reactor. That is why the thresholds were changed. The thresholds were put into place before Dr. Castro's time in the division. He suggested the necessity for population-specific thresholds.

Dr. Andy Vernon provided some statistics to ACET concerning incarceration. Internal analysis shows that the best predictor of failure to complete treatment is being diagnosed while incarcerated; more so than being homeless or a racial or ethnic minority. Twenty-five percent of U.S. cases diagnosed while incarcerated fail to complete treatment at all.

TB PREVENTION AND CONTROL IN CHANGING HEALTHCARE ENVIRONMENT

Redefining the Essential Components of an Effective TB Program

Dr. Jon Warkentin

President, National Tuberculosis Controllers Association (NTCA), State TB Control Officer, Tennessee

Dr. Warkentin reviewed the Morbidity and Mortality Weekly Report (MMWR) entitled *Essential Components of a Tuberculosis Prevention and Control Program*, which he attributes to playing a major role in his work, in Tennessee

when he was an administrator for the TB program. The report was published on September 8, 1995 and comprised the recommendations of ACET, at that time.

The purpose of the document was to provide a national standard for the assessment of individual TB control programs by TB control program managers, policymakers, and other persons evaluating TB programs. It was also to assist local programs in obtaining and maintaining adequate resources for TB control activities, define the essential components of a TB control program, and emphasize the importance:

- ❑ Prioritizing TB control activities (3 strategies)
- ❑ Coordinating care with other health-care providers, facilities, and community organizations; and
- ❑ Using alternative approaches to TB control, e.g.:
 - The expanded use of directly observed therapy
 - Targeted screening and prevention programs to high-risk populations, and
 - Adoption of current recommendations for the treatment of TB

Although the size and structure of TB control programs vary according to each community's specific needs, TB control program managers should attempt to incorporate each of the core components into program activities. However, the question is where is it done that way. It does happen in some areas but still certain essential components are no longer feasible. How have sociopolitical changes influenced the application of this recommendation in state and local health departments' TB programs?

Dr. Warkentin provided an outline derived from the Essential Components document. Below is the outline he uses to guide his work and shares with his staff.

- I. Overall planning and policy
 - A. Overall TB control strategy and written policies and procedures
 - B. Advising local institutions and practitioners
 - C. Appropriate laws and regulations to support TB control activities
 - D. Adequate and appropriate staff to conduct TB control activities
 - E. Adequate funding to conduct TB control activities
 - F. Networks with community groups
- II. Managing persons who have disease or who are suspected of having disease
 - A. Clinical services
 - B. Developing a treatment plan
 - C. Clinic services
 - D. Promoting adherence
 - E. Referral system for other medical problems

- F. Clinical consultative services
 - G. Inpatient care
 - H. Confinement capability
 - I. Infection control
 - J. Coordinating care with other health-care providers and facilities
- III. Identifying persons who have clinically active TB
- A. Diagnostic methods
 - B. Case finding
 - C. Contact investigation
- IV. Identifying and managing persons infected with *Mycobacterium tuberculosis*
- A. Close contacts of persons known or suspected to have TB
 - B. Persons infected with HIV
 - C. Persons who inject illicit drugs or other locally identified high-risk substance users (e.g., crack cocaine users)
 - D. Persons who have medical risk factors known to increase the risk for disease if infection occurs
 - E. Residents and employees of high-risk congregate settings (e.g., correctional institutions, nursing homes, mental institutions, other long-term residential facilities, shelters for the homeless)
 - F. Health-care workers who serve high-risk clients
 - G. Foreign-born persons, including children, recently arrived (within 5 years) from countries that have a high TB incidence or prevalence
 - H. Some medically underserved, low-income populations, as defined locally
 - I. Infants, children, and adolescents exposed to adults in high-risk categories
- V. Laboratory and diagnostic services
- A. Chest radiograph and interpretation
 - B. Mycobacteriology laboratory
 - C. Diagnostic services to assess drug toxicity
 - D. HIV testing and counseling
- VI. Data collection and analysis
- A. Case reporting
 - B. TB registry
 - C. Protection of confidentiality
 - D. Drug resistance surveillance
 - E. Data analysis and program evaluation
- VII. Training and education
- A. Staff training
 - B. Education for health-care providers and members of the community

The outline has helped his agency to develop a scope of services for metro programs and serves as an auditing tool based on each of the components. They have also developed a 72-point action plan and set measurable objectives using each of the components. This helps to tie in performance metrics and assists in making programs more effective.

Dr. Warkentin suggests revisiting the document in light of technology, epidemiology and sociopolitical changes. The outline can highlight:

- What needs to be updated?
- Are there additional components needed?
- How is public health practice changing at the state and local level?
- What is the federal (CDC/DTBE) role?
- What should ACET do?

There have been numerous changes in technology, like internet, social media, mobile communication devices, data management, genotyping, molecular drug sensitive testing, etc, but what has not changed are things like, TB Vaccine, HRZE (antituberculosis drug), and isoniazid (INH) as the leading treatment for infections.

Epidemiology changes include U.S. total TB cases at a historical low, proportions of foreign born cases increasing, HIV/TB co-infections are somewhat stable, and multi-drug and extreme-drug resistance (MDR, XDR) globally are rampant, but MDR-TB in the U.S. is low. What have not changed are issues like cases of TB in correction facilities, homelessness, drug abuse, and alcoholism.

There have been several sociopolitical changes. Dr. Warkentin listed the following:

- Post-911 era: Mtb as a potential BT threat, prioritization of public funds for “security”
- National economy: robust economy to worst recession since the 1930’s to slow “recovery”
- Focus on deficit reduction
- Progressive and additive budget cuts to PH at local, state and national levels
- Restructuring of state health departments challenges continuity of TB program initiatives
- ACA - Rapidly changing health-care services environment, shifting organizational roles
- Evolving details and impact of “sequestration” for FY2013, FY2014 and beyond
 - o Cuts to “Cooperative Agreements” and contracts with states, big cities, partner organizations, domestic research consortia
- Unclear national commitment to the goal of domestic TB elimination (DHHS, CDC, DTBE?)

- ❑ Shortages of anti-TB drugs and biologics: INH, Tubersol, Aplisol, injectables, third-line drugs
- ❑ “The cycle of neglect” --- again?!

Moving ahead, there is an urgent need to define and claim the roles of public health in local, state, and national TB control and prevention. The division needs to assess the relevance of the 1995 Essential Comments document and update areas in light of changes since its inception and identify new components needed. It is also necessary to update the TB prevention and control guidelines, define the role of CDC/DTBE with regard to assessment and policy development, and determine if there is a new national TB prevention and control paradigm emerging.

Dr. Warkentin referenced another smallpox model that could be used called *On Fire, the Fight to Eradicate Smallpox* by Bill Fahgee. It too contains lessons learned that should be examined to locate some parallels and points of divergence for TB work. He offered a word of caution that the model needs to be evaluated, thought through thoroughly, and discussed with partners before plunging into a new paradigm. A list of several potential partners was presented.

Before closing, he acknowledged several individuals who helped with the presentation.

Mr. Jones opened the floor for discussion.

Dr. Dorman fully supported the idea of revising the document and said ACET has a very clear and necessary role in helping to advise DTBE as ACA becomes implemented. She pondered if the goal of TB elimination, considering the current sociopolitical condition, should be what ACET and DTBE strive for and maybe reengaging the topic would be useful. Dr. Warkentin has also pondered the same thoughts. Social determinants of health are key to dealing with this issue but are very resource-dependent.

Dr. Levin’s comments were around the homeless and drug-using population. Expecting treatment without providing management of the addiction at the same time is unrealistic. There need to be collaboration between TB control programs and providers, who work with addiction. This could increase compliance, if services were offered together. Dr. Hewitt added that drug use has changed and therefore assumptions of drug use should be revisited, as well. The number of drug injectors has declined, and there are new methods of drug use. Changes can also be seen in the homeless population makeup. These are additional elements in the document that should be updated. Dr. Warkentin also included the growing number of veterans some of which are receiving organ transplants. Dr. Desmond recalled there was no mention of genotyping in the document, nucleic acid amplification (NAA), or molecular detection of drug resistance. He went on to say genotyping requires that the state public labs acquire the cultures.

There is a role for the TB control program to ensure cultures are acquired, that good regulations are in place, and follow-up occurs. He expressed disappointment in the nucleic acid amplification testing and how poorly it has penetrated into routine practices. TB programs could also encourage the use of NAA testing among clinicians. Dr. Warkentin responded many hospitals ship their specimens to large labs out of state, which puts reflex testing with NAA up in the air. There is delay in culture confirmation and drug sensitivity testing, which are both avoidable. Dr. Elson said, when culture results do become available, they should be conveyed back to where the person is at that time not where they were collected. This would help with the transient issues.

Dr. Burgos called TB a disease of poverty, which is not talked about in the document. Poverty has increased recently in the United States, and although TB is not affecting the U.S. right now, down the line it can become a problem causing increasing occurrences. A study of how poverty affects TB rates in the future should be studied.

Dr. Baine expressed concern over drugs that are found to be economical possibly not being available in the future due to shortages.

Ms. Bur noted changes in correctional facilities, which have seen inmate populations more than doubled, since the creation of the document. The document should have a section on corrections and the roles of TB control in correctional facilities. Dr. Elson agreed and added into the list changes in the complexity of local jails and detention centers. Patients in those institutions are often referred to emergency rooms, where they are sometimes not evaluated properly. Dr. Warkentin replied the amount of for-profit correctional facilities is something different from what was seen in 1995, as well as continuity of care while incarcerated. All those things need to be explored in the new document.

Dr. Doshi inquired if Dr. Warkentin knew the cost of treating a person with active TB and if it differed depending on the individual's ethnicity. Ms. Marks provided some statistics. Including the half, which are hospitalized, the average cost is about \$17,000 per drug susceptible case, \$131,000 per MDR case, and \$430,000 per XDR case. There is a very wide variability on those cases due to co-infections.

Dr. Roselle noted there was no reference to collaborating with the general population of internist, pulmonary doctors, etc. There's always mention of "Public Health" in meetings but no one speaks to "public health" and vice versa when he attends infectious disease meetings. Nevertheless, never is it more important for the groups to collaborate in light of ACA. There is a reluctance of interaction. Doctors think that Public Health is bothering them unless they are desperate and Public Health cannot figure out why doctors are not taking care of business. The result is a self-fulfilling prophesy. Therefore, he suggested partnership start with clinicians, doctors, etc. Dr. Warkentin agreed and saw the problem to be an

uphill battle. What further complicates the matter is finding someone to provide education to both the groups.

Ms. Cole said to consider establishing a type of memorandum of understanding (MOU) with providers, in light of decreasing resources. This will counteract fragmentation. Dr. Castro agreed with Ms. Cole and said currently dialysis care is using similar practices. Ms. Cole suggested that under the ACA, TB clinics could be designated as essential service providers.

Mr. Jones before closing for a break, made a change in the agenda. The resolution discussion would be move to later in the day so that elements from other presentations, such as drug shortages could be included. The members concurred with Mr. Jones' suggestion. He asked members to prepare their resolutions over the break.

He group reconvened at 11:05 AM. Dr. Dean took role and quorum was present.

TB as it Relates to Affordable Care Act/Implementation of ACA

Dr. Christine Ho

Medical Officer, DTBE, CDC

Dr. Ho's presentation was entitled The Impact of Patient Protection and Affordable Care Act on Tuberculosis. The purpose of the presentation was to dissect the Affordable Care Act into simple terms, describe its impact on TB control, the role of TB programs, and how programs could strategically leverage opportunities presented by the law to ensure TB services.

The ACA now allows adult children 26 and under to be covered by parents' plans, which will account for 3.1 million newly covered individuals. It also will expand coverage to many currently uninsured persons. Because of expanded coverage:

- Uninsured non-elderly will drop by 20 million in 2015
- Medicaid is expanded to individuals with incomes below 133% the federal poverty level (FPL) for participating states
- Enrollment for private insurance plans will be available through the Marketplace, or Exchanges (+13 million)
- Employer and non-group coverage (-5 million)

It also offers new consumer protections and choices. ACA generally prohibits denial of coverage based on pre-existing conditions and rescission (dropping coverage retroactively). It bans lifetime and annual coverage limits, puts restrictions on out-of-network ER usage, and expands consumers' rights to appeal denials.

States have the opportunity to expand Medicaid eligibility to adults ages 19 – 64 with incomes up to 133% of the (FPL) (\$15,282/year for an individual,

\$31,322/year for a family of 4) and 100% federal funding through 2016, 90% thereafter. States have no deadline for implementing the expansion. There will be one streamlined application for Medicaid and private health plans in the Marketplace and a shift to a simplified way of calculating income to determine Medicaid/CHIP eligibility. This calculation is known as the Modified Adjusted Gross Income (MAGI). There will be the opportunity for employers and individuals to directly compare plans through the Exchange, or Marketplace.

There will still be 44 million people in 2014 not covered by ACA. In 2015, there will be 37 million and 31 million in 2016. Therefore, there will still be a need for safety-net services. Areas of convergence should be identified between covered services under ACA and the essential components of a TB prevention control program in order to leverage opportunities to maximize population health.

Prior to healthcare reform, States could add Medicaid eligibility for TB patients. Now, states have the option to extend Medicaid eligibility to low-income persons infected with TB. Dr. Ho provided a list of covered TB-related services, which include:

- Prescribed drugs
- Physicians' services (includes outpatient hospital services, rural health clinic services, and Federally Qualified Health Center (FQHC) services)
- Laboratory and X-ray services
- Clinic and FQHC services
- Case management services
- Services (other than room and board) designed to encourage completion of outpatient regimens, including services to directly observe the intake of prescribed drugs.

Currently, nine states have elected to provide this benefit, including Arizona, California, Connecticut, Louisiana, Montana, New York, Oklahoma, Utah, and Wyoming. Receipt of matching federal dollars for treating eligible TB patients could alleviate budget difficulties for some states.

Individuals will be enrolled through the "Marketplace". The Marketplace (or insurance exchanges) will use a website for qualified individuals and qualified employers to directly compare private health insurance options also known as Qualified Health Plans (QHPs). The Marketplace provides the advantage of directly comparing QHPs based on price, benefits, quality, and other factors. It also helps enhance competition in the health insurance market and increases affordability through premium tax credits and cost sharing reductions. Moreover, it ensures quality through requiring that QHPs must meet basic standards, including quality standards, consumer protections, and access to an adequate range of clinicians. In addition, the Marketplace makes costs clear by providing information about prices and benefits in simple terms consumers can understand, so they do not have to guess about the cost.

The law requires the following services to be covered without cost-sharing for non-grandfathered individual and small group plans as well as Medicaid expansion plans:

- ❑ United States Preventive Services Task Force (USPSTF)
 - All preventive services with an 'A' or 'B' grade recommendation
 - LTBI screening of high risk persons had an 'A' grade in 1996
 - 2002 recommendations deferred to CDC, ungraded
 - Ungraded, LTBI screening not covered without cost-sharing
- ❑ Advisory Council on Immunization Practices (ACIP) and Health Resources and Services Administration (HRSA)-supported recommendations
 - TB testing for “children at high-risk for TB”

What the law does not state is what additional specific services will or will not be covered. Coverage of specific services will be determined state-by-state. States previously established benchmark plans and set the minimum requirements for a plan. They must include these 10 areas (also referred to as the 10 Essential Health Benefits):

1. Ambulatory patient services
2. Emergency services
3. Hospitalization
4. Maternity and newborn care
5. Mental health and substance use disorder services, including behavioral health treatment
6. Prescription drugs
7. Rehabilitative services and devices
8. Laboratory services
9. Preventive and wellness services and chronic disease management
10. Pediatric services, including oral and vision care

The law requires that QHPs offered through Marketplaces include in their networks essential community providers, where available, that serve predominately low-income, medically-underserved individuals. Centers for Medicare and Medicaid Services (CMS) regulations provide that a QHP issuer must have a sufficient number and geographic distribution of essential community providers (ECPs), where available, to ensure reasonable and timely access to a broad range of such providers. The Health Resources and Services Administration (HRSA) identified ECPs, which include providers eligible for the 340B program. TB programs can be a member of an accountable care organization; they can also identify additional hospitals, clinics, practices that evaluate and diagnose TB suspects and cases; and ensure these facilities are designated as ECP.

Dr. Ho provided an example of Urban County A TB cases:

- ❑ Foreign-born cases
 - Mix of newly arrived and settled immigrants or refugees

- Medical services through the refugee clinic, federally qualified health center (FQHC), or other community providers
- ❑ US-born cases
 - Concentrated in an area with shelters and treatment facilities
 - One FQHC and several non-profit clinics serve this area
- ❑ Options to optimize TB screening and evaluation:
 - Non-profit clinic affiliates with an accountable care organization (academic medical center, consortium) and bill for services
 - TB program partners with FQHC and refugee clinics to do TB screening and evaluation, those clinics bill for services
 - TB clinic gets 340B or FQHC status and bills for services

The Meaningful Use Rule is an incentive designed to get physicians and clinicians to utilize electronic health records. It is also another way to track performance. To collective incentives, providers must use structured fields and clinical decision support tools. They must report clinical quality measures and communicate relevant health information to patients. Lastly, providers must provide patients the ability to view their health information and provide a summary of care record for transitions and/or referrals.

There is a stage in Meaningful Use, where providers will be required to select quality measures to report on. As an example, new or updated HIV measures in the endorsement process include: percent of patients seen at least once during 12-month period with suppressed VL; percent of patients seen at least once during 12-month period on ART; percent of patients with a visit every 6 months over 24 months; and percent of patients with gap in care over a 12-month period.

Clinical decision support (CDS) is a process for enhancing health-related decisions and actions with pertinent, organized clinical knowledge and patient information to improve health and healthcare delivery. The systems provide prompts to the provider for retention/re-engagement in care; patient self-care and treatment adherence; data collection and bi-directional reporting and communicating; and performance measurement and improvement

What may also be impacted by the ACA is billing. Right now, the health departments provide services to clients regardless of ability to pay. There will now be other options available. Option 1 is the health departments continue to provide clinical services to clients. For insured clients, health departments may bill those health plans for services. In Option 2, the insured patients can receive services from non-health department providers. The health department in that option cares for the uninsured clients only, but with that option, they are not able to ensure quality services for outside providers.

Several billing resources exist that can be considered for TB such as:

- ❑ National Center for Immunization and Respiratory Diseases (NCIRD) American Recovery and Reinvestment Act-funded billing project

- ❑ 2012 NTCA Billing roundtable session
- ❑ CDC and billing activities
- ❑ American Health Insurance Plan (AHIP) has 3-part billable project to support sites (not known whether this will need MOU or workaround)
 - Contracting
 - Coding
 - Credentialing
- ❑ National Association of City and County Officials (NACCHO) developed a billing toolkit

There is a continued role for public health under the ACA for populations most at risk for TB, such as non US-born, racial or ethnic minorities, homeless, and persons affected by alcohol or substance abuse, who have limited access to health care. Ongoing transmission, outbreaks, and drug resistance can result, if contacts of infectious patients are not located and provided preventive therapy or if persons with TB disease are not treated completely. Guarantees for inherently governmental public health services were not the goal of the law, and the Affordable Care Act expansion will not substantially decrease the need for these services by CDC and health department partners.

There are several ways to leverage TB services in the community, like studying each state's benchmark, or alternative plan (upon which the minimum required coverage is based) to address what is and is not covered. Addition suggests are to identify health plans that serve populations at high-risk for TB and working with those plans directly to cover TB-related patient services (such as LTBI treatment). Other recommendations would be to identify providers that serve individuals at high-risk for TB; explore partnership with these providers, and survey future education and quality assurance opportunities in these settings.

The floor was opened for discussion.

Dr. Hewitt asked if TB drugs were included in the formularies and if cost sharing was included in prescription drugs. Dr. Ho said it could be, under the alternative plan, and it is only for preventative services that have an A or B grade, under USPSTF or ACIP, and that do not have cost sharing. He went on to ask how individuals not under the expansion would be treated. Dr. Berman replied cost sharing does not address treatment. Cost sharing is relevant for the individual plans. Screening may be covered but treatment may not in some plans. Alternative plans are going to vary. State plans do not have to be exact replications but do have to be equal in actuarial value. Dr. Hewitt said cost sharing is part of the reality in some states and therefore empirically it will be a barrier to care. There cannot be continuity of care if cost sharing is imposed on individuals who may not be able to pay. Dr. Ho said programs might be able to broker with plans to overcome that barrier. Dr. Hewitt proposed ACET examine the issue. Dr. Dorman agreed and asked for Dr. Ho and her team's guidance on

identifying ways for ACET to play a meaningful role on the matter. Dr. Berman said there are many possibilities and shared responsibility may be the solution.

Dr. Horsburgh asked how the HIV/AIDS quality measures get decided upon and put into the program. He also reminded ACET that CDC did identify quality measures for TB and perhaps those should be revisited. Dr. Berman did not see the Meaningful Use requirements as being the answer. Only in Meaningful Use 3 is there any look at performance. Medicaid has new measures where they are interested in performance levels and that would be a good place to look. The question is how to use quality community measures in an effective way, lobby for them, and then figure out ways to use those measures outside of the provider realm. Dr. Ho suggested foreign-born patients, who have been in the United States for awhile, as a possible group. Those individuals tend to go to private providers and may offer a role for the QHPs.

Dr. Narita felt public health should retain the responsibility of care for infectious TB cases, in order to protect the public. Dr. Ho said it would be a local decision. She also suggested that ACET consider changing the term essential components, which may be confused with essential health benefits.

Dr. Castro noted in the case of TB, states have public health laws and statutes in place to detain TB-positive individuals, if they have exhausted all means in getting them to seek treatment. However, he wondered how situations would be handled if a person were fiscally unstable and cannot afford care. He suggested ACET consider those types of scenarios in its deliberations.

Dr. Tompkins made ACET aware of the existing state of the health information exchange (HIE), which is not available currently. Providers and health departments cannot communicate with one another's systems causing silos and duplication of treatments and efforts. Collaboration should be encouraged between local health departments, hospitals, providers, etc by opening access to one another's systems to reduce duplication. Dr. Ho said part of the requirements for Meaningful Use is having an IT structure that is be to able talk across systems. Dr. Tompkins agreed with Dr. Ho, but she was referring to the actual implementation. The capability is there for all systems that meet Meaningful Use, but the health information exchange still has not occurred. Dr. Berman chimed in and said all HIEs are different in every place; therefore, the business models are different, and it is important that health departments can be part of the system.

Going back to measurements, he also reminded ACET that no measurements would be given anywhere, if it were not National Quality Forum (NQF) endorsed. The only TB measure that is NQF-endorsed is testing among HIV positive patients. There is no stand-alone measure for TB. This is an area that needs to be worked on.

Dr. Trump inquired, with Medicaid expansion, has there been discussion among programs of how to approach funding for TB control programs for states that don't adopt Medicaid expansion and does it go under the funding formula for the TB program in the future. Dr. Ho was not sure. Dr. Trump said it should be considered.

Dr. Doshi suggested ACET look to the Louisiana Public Health Information Exchange, for an example of HIE. An alert has been implemented for HIV-positive people that will help them to be linked back into care, if they have not been seen for some time by a physician. There are also examples of where public health links to community providers. With ACA, primary care doctors feel more burden is being put upon them, but the true expertise to handle TB are in the public health field. DTBE needs to encourage more partnerships between physicians and public health. She concluded by asking how does ACA work for incarcerated individuals. Dr. Ho said they are not covered.

Dr. Iademarco asked if the state has a public health law, does that trump what needs to be included under ACA. Dr. Ho responded treatment of diseases is not stipulated by ACA, so treatment will continue to be handled by the states. Dr. Iademarco then suggested the use of public health laws to address the gaps in fundamentals.

Mr. Jones before adjourning the meeting for a lunch suggested ACET consider appointing a group to look at ACA over time and the impact it has on TB control efforts as well some of the other programs in the center, who also touch TB.

The meeting was reconvened at 1:19 PM. Dr. Dean took role and quorum was present. Mr. Jones again reviewed the agenda.

U.S. Preventive Services Task Force /Assessing Evidence for Treatment of LTBI as Prevention

Dr. Christine Ho

Dr. Ho's second presentation was on the role of USPSTF in Latent TB Infection (LTBI) testing and treatment. The healthcare reform requires coverage of certain preventive services. These services pertain to individual and small group plans, Medicaid expansion plans, and must be offered without cost-sharing. It covers all preventive services with an 'A' or 'B' grade recommendation from USPSTF, as well as the Advisory Council on Immunization Practices (ACIP) and Health Resources and Services Administration (HRSA)-supported recommendations.

TB testing for children at high risk for TB is covered under ACIP and HRSA recommendations. Moreover, USPSTF recommendations for LTBI screening of high risk person had an 'A' grade in 1996. In 2002, USPSTF recommendations for LTBI testing were deferred to CDC recommendations, ungraded.

The USPSTF is an independent group of national experts in prevention and evidence-based medicine. The taskforce puts recommendations forward about clinical preventive services based on a unique systematic method. The LTBI screening was declined by the USPSTF topic prioritization work group in past years because of duplication of efforts by federal agencies. A joint-agency review was approved for this fiscal year, but budgetary impacts on funding have stalled the process. The topic may not come up for review again and joint funding from AHRQ might not be available either; thus, the interagency agreement did go through last week. A funding announcement will be coming this summer.

The USPSTF assigns letter grades to signify the strength of each of its recommendations based on evidence supporting the benefits of the service.

- A - strongly recommend
- B - recommend
- C - neither recommending for or against
- D - recommending against
- I - insufficient evidence to recommend for or against the service.

The development of a topic recommendation takes 2-3 years, and 1-2 topics are selected each year. Topics that meet criteria are prioritized according to public health importance and potential for a recommendation to affect clinical practice.

There have been other communicable diseases that have gone through the taskforce review. USPSTF uses the GRADE approach, which is an evidence-based, systematic approach which places greater weight and emphasis on randomized control trials. Public health studies frequently rely on observational cohort trial design. The strength of the recommendation also depends on diagnostic tests, risks, and benefits of treatment. Under the new USPSTF recommendations, HIV screening, for all ages 15-65, received a grade of A and hepatitis C screening, for the general population, a grade of D.

The costs of treatment for services are not dictated by the USPSTF grade. Reimbursement of LTBI treatment and co-pay requirements are determined by each state's alternative benchmark plan. The HRSA-commissioned IOM reviewed preventative services and determined that they are necessary for women's health and well-being and should be considered in the development of comprehensive guidelines for preventative services for women. Dr. Ho pondered if there could be something similar for vulnerable populations or communicable diseases.

The floor was opened for discussion.

Dr. Makhene asked if cost sharing is only applicable when there is a Grade A. Dr. Ho responded preventative services that have an A or B grade are covered without cost sharing.

Dr. Horsburgh thought CDC was going to prepare the application but an FOA has been designated. He asked if there are groups skilled at carrying out that process. There are also other taskforces who are grading the same thing, so wondered could there be duplication. Dr. Ho said the USPSTF study is completely separate and related to ACA. CDC had to guarantee the systematic review was not duplicated by the current IDSA and ATS guideline workgroups or anywhere else. CDC reached out to the LTBI Treatment Group, IDSA, and ATS to ensure that there was no overlap or duplicate services. The original plan was for CDC to have more control over what questions were posed, but that has changed. By having this jointly funded, CDC can sit in to make sure the review is going in the right direction but cannot influence the questions. Therefore, Dr. Horsburgh concluded this would be a limited competition of those who have the skills. Dr. Ho affirmed his assumption. A set of research questions will be identified, and CDC can then share those questions with its partners.

Ms. Cole wondered how the D rating against testing for hepatitis C related to screening the baby boomers born between 1945-1965. There seemed to be a contradiction. Dr. Ho agreed and the Hepatitis Division is currently working on the problem. CDC's recommendation is for a certain cohort born in those years, and the recommendation they were trying to attain was for the general population. Dr. Berman said it is under consideration and not a final. Hopefully by springtime more data will have been accumulated. Dr. Ho added USPSTF would not re-review a topic unless there is new evidence.

Dr. Narita wondered if LTBI screening methods can include both skin testing and interferon- γ release assay (IGRA) and whether the study to recommend should be based on each individual test. Dr. Ho said it would have to be chosen through the evidence practice centers; although DTBE could suggest it. Other new regimens could also be added to the list as well.

Dr. Warkentin thanked DTBE for providing funding for the review in spite of the tough economic times.

DRUG/DIAGNOSTIC SHORTAGES UPDATE

Drug/Diagnostic Shortages - Field Perspective

Dr. Jennifer Flood

Chief, TB Control Branch, CDC

President-Elect, National TB Controllers Association (NTCA)

About two years ago, Dr. Flood gave a presentation to ACET with the same title and now wanted to update the committee on the current state of TB drug availability. Some things have changed and some have remained the same. What have not changed are the essential components of the National TB Program. ACET endorsed the recommendation to ensure that patients who have

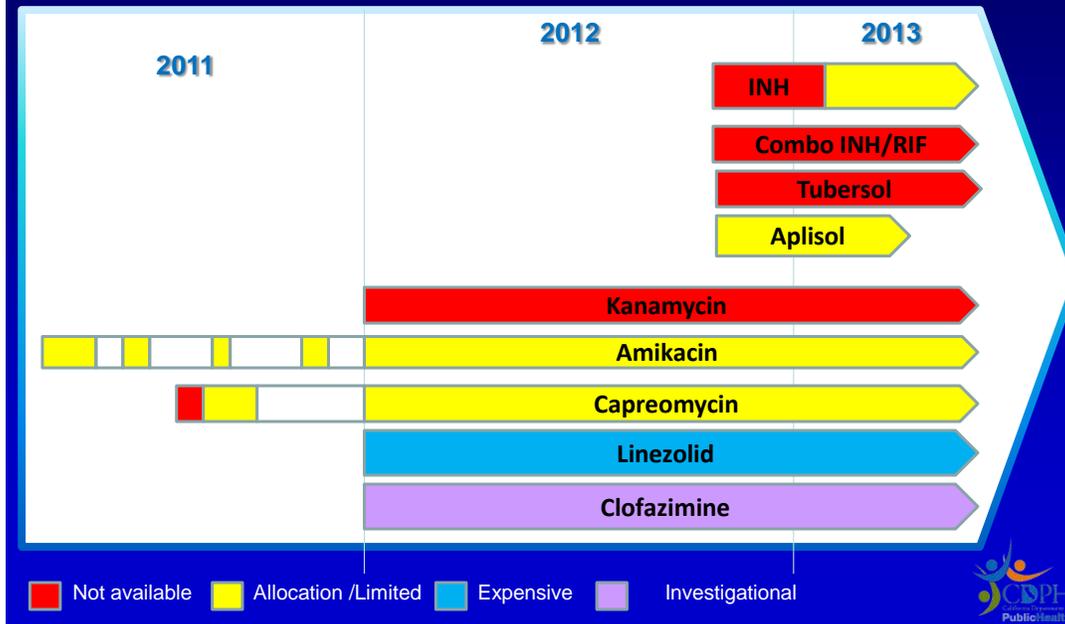
TB receive appropriate treatment until they are cured and to treat patients without consideration of their ability to pay. The International Standards says there should be an uninterrupted and sustained supply of anti-TB drugs. Other components of the National TB Program include a reliable system of procurement and distribution of anti-TB drugs and that anti-TB drugs should be available free of charge both because patients are poor and may not be able to afford them and because treatment has benefits to society.

Surveys show that 81% of U.S. programs report difficulties accessing second line drugs for MDR patients. Ninety percent reported adverse outcomes, such as treatment delays, inadequate regimens, and treatment interruptions. Shortages have occurred with eight anti-TB drugs to date. Dr. Flood recounted a case of MDR TB in an infant and father. Shortages of capreomycin and amikacin led to a delay in treatment initiation. The infant, who had severe meningitis and hydrocephalus, was placed in serious danger.

In addition, hundreds of drugs outside of TB have experienced some shortages. Included in that is INH and tubersol. Between 2011 and 2013, in the U.S., 79% of individuals had difficulty obtaining INH. Programs lost or turned away patients with indications for treatment. TB contacts delayed access to INH and thousands of healthcare workers went without testing for months. In addition, alternatives are not always palliative to institutions because of cost restraints.

While there have been a number of acute shortages of INH and tubersol, others are reoccurring and chronic, and when medications were brought back into the market, they were delayed. Dr. Flood presented the illustration below.

Interruptions in anti-TB medications 2011- 2013



Drug stock-outs are not an unfamiliar scenario. About 18% of countries surveyed by the World Health Organization (WHO) reported interrupted supply of first-line drugs and 15% reported interruptions in supplies of second-line drugs. The United States stands with the nations without a secure drug supply.

Articles have been recently written on the issue. Charity Thoman wrote an article about drug shortages. The article was entitled *U.S. Doctors Shouldn't Have to Beg for TB Drugs*, and was published on May 30, 2013.

Large co-pays and the high price tag for many second and third line drugs are an issue. There are escalating costs for first-line drugs and tuberculosis skin test (TST) solution -- rather a price gouging. INH has increased 30 times its original price and Aplisol over 5 times over its original price during the tubersol shortage.

There is a lot of hope for bedaquilline, a new drug, but it is very costly to public health because it requires an upfront purchase of the entire 6-month course. ACET needs to think of ways to overcome this barrier.

Drug resistance has increased in the U.S., which raises concern. Drug susceptibility trends, according to U.S. surveillance data, show increasing resistance to INH, pyrazinamide (PZA), and MDR treatments. The questions the division needs to have addressed are:

- What strategy will work to meet national program basic element of continuous drug supply; and
- How will we get there?

This issue is garnering more attention. There have been some white papers created on the subject of drug shortages. In addition, at the Treatment Action Group Summit in Washington, D.C. 2013 the question was asked by C. Toman, “Can the model be one where patient/public safety becomes the paramount, most powerful driving force?”

There are models to consider: DHHS has the Vaccines for Children Program. There is also the Canadian TB Procurement and Supply and the Global Drug Facility. Many lessons can be learned from these programs. Moreover, leadership and experience can be garnered, from CDC and HHS, on vaccine supply programs, influenza drugs, and HIV drugs. If can be done for those programs, it can be done for TB. Dr. Flood said the focus of discussions should be on finding ways to prevent drug shortages versus just reacting to them. There needs to be a move to prevention, which requires a systematic strategy and prioritizing of public good. The goal is not to return to past outcomes.

The NTCA has developed a set of recommendations for CDC. They are to support a continuous and affordable drug supply by:

- Intensifying actions to prevent drug shortages
- Establishing a dedicated team
- Partnering with HHS, FDA, GDF and health departments
- Building on existing models, like the vaccine program
- Pursuing national procurement and distribution, and
- Supporting needed regulatory changes

Dr. Flood concluded by reminded ACET that several years ago it was not until several people died from fungal meningitis that the nation reacted. It should not take the same before the nation becomes more proactive concerning TB.

CDC Activities around Drug/Diagnostic Shortages

Dr. Sundari Mase

Medical Team Lead, Field Services and Evaluation Branch, DTBE, CDC

Dr. Mase continued the drug shortage discussion. Her presentation focused on the CDC strategies for securing adequate supplies for patients. U.S. TB patients and TB programs have experienced recurring difficulty accessing first and second line TB drugs and are now also experiencing a Tuberculin Skin Test reagent shortage. In addition to shortages, other barriers include climbing costs, multi-step processes for procurement, out-of-reach costs for uncovered patients, and stress on programs.

Dr. Mase provided some background on shortages. She re-reviewed information presented by Dr. Flood about the essential components of a National TB Program. Access to uninterrupted, top quality, anti-TB drugs is DTBE's priority. There have been barriers to treatment caused by several drugs from 2011-2013. Dr. Mase presented a list of drugs currently affected.

- Amikacin
- Capreomycin
- Clofazimine
- Cycloserine
- Ethionamide
- INH (isoniazid) 300 mg: not currently available
- Linezolid
- PAS (4 amino-salicylic acid)
- Rifamycins
- EMB
- Rifamate

Shortages are contributed mainly to problems with manufacturing, which may include non-specific discoloration of product, glass shards, metal filings, fungal or other contaminants, especially an issue with injectable drugs. Other reasons for shortage includes delays in manufacturing and/or shipping, active pharmaceutical ingredient (API) shortages, and increasing demand outpacing supply. Challenges can also be attributed to issues outside of manufacturing, like passive surveillance/reporting, short-dated medications, single sources for some drugs, lengthy procurement process for certain drugs, manifestations of market forces, like hoarding, price increases and gouging, and market abandonment.

The results of these shortages are delays in treatment or procedures and rationing or restriction of drugs. There is also a need to use less effective alternative drugs, which have had the occurrences of medications errors and adverse events. Other consequences include increases in drug costs, increases in ancillary costs, more staff time dedicated to drug procurement, and labor costs for these activities.

The impacts of shortages are also felt by patients, programs, and providers. TB programs have lost credibility and cannot meet core functions. There is the chance that TB disease manifestations may worsen. Patients may acquire further drug resistance, and there could be increases in TB transmission. The failed ability to respond to outbreaks will make for the perfect storm.

CDC responded by actively tracking and reporting on other pharmaceutical shortages. There have been six publications since December 2012 related to TB drug shortages. State and local programs were altered in December 2012 to let them know the extent of the problem and to provide guidance. A few months ago to assess the impact of the lack of INH, a survey was conducted. More than 50%

of programs reported significant shortage of INH. In mid-January 2013, CDC was notified that VersaPharm would not have INH until 2014. CDC, FDA, and Teva worked together to provide an emergency allocation for state and local programs. In addition, two national webinars on INH and Tubersol were presented.

The Federal TB Taskforce Meeting was convened on Monday, April 8, 2013. At the meeting, Dr. Chorba discussed current TB drug and pharmaceutical shortages. Short and long term solutions were identified. The short-term solutions included:

- Establish a monitoring and early warning system
 - Use CDC's Countermeasure Tracking Systems to track availability of pharmaceuticals and to respond to shortages in a timely manner
- Formal designation of TB in the United States as a disease covered under the Orphan Drug Act
- Establish regulatory requirements for early notification to FDA of potential shortages and of plans for product discontinuations
- Offer financial incentives (e.g., tax credits) to drug makers to produce specific drugs in shortage

Also identified were proactive, long-term solutions, such as

- Create a national or regional TB drug repository
- Accelerate review of requests for importation of quality assured drugs from the TB Global Drug Facility (GDF),
- Form a strong regulatory and inspection network with other countries
- Establish a qualified manufacturing partner program for drugs used for diseases that pose a public health threat, such as essential pharmaceutical list

A week or two ago the division was asked to put together a white paper on stock-outs. Recommendations in the document were to create an early warning system for TB drug or pharmaceutical stock-outs. The document also spoke to a centralization distribution of TB drugs, by identifying distributors to maintain a certain level of TB drugs and obtain drugs from foreign manufacturers, when unavailable in the United States. It also addressed improving timeliness of reporting of drug shortages by drug suppliers.

This issue is not going to go away and will require further discussion. Participation of CDC, FDA, and other federal agencies in addressing this issue is paramount. DTBE in its capacity of overseeing the National TB Program's prevention and control activities needs to consider undertaking a new role, and the division welcomed ACET's recommendations on how to move forward.

Dr. Mase concluded the presentation by providing the FDA website address regarding drug shortages as well as its email address designated to this issue:

- <http://www.fda.gov/drugs/drugsafety/drugshortages/ucm050792>

□ drugshortages@fda.hhs.gov

An Update of the Diagnostics Work Group of the Federal TB Task Force

Dr. Michael Iademarco

Captain, U.S. Public Health Service
Chief, Laboratory Branch

Dr. Iademarco provided a brief update from the Diagnostic Work Group of the Federal TB Taskforce. The taskforce is comprised of individuals from CDC, FDA, and the National Institute of Allergy and Infectious Disease (NIAID). The update was focused on diagnostic laboratories, which was also highlighted in the February 13, 2009 edition of the MMWR.

The first issue presented was the diagnostic delays, for NAA tests. The delay was a significant factor in 27 CDC-investigated outbreaks between 2002–2008. In 2009, public health laboratories (PHLs) performed NAA testing for *M. tuberculosis* for 14% of TB suspects. Cautious guidelines were released in 1996 and 2000 due to the limited evidence of programmatic effectiveness, and in 2009, CDC updated the NAA testing guidelines. The January 16, 2009 MMWR said, “NAA testing should be performed on at least one respiratory specimen from each patient with signs and symptoms of pulmonary TB for whom a diagnosis of TB is being considered but has not yet been established, and for whom the test result would alter case management or TB control activities.”

Issues with NAA are not the only reason for delays, in TB testing. It has been estimated that 28% of patients with negative sputum smears and positive sputum cultures are not started on treatment until culture results are available. A liquid culture for *M. tuberculosis* can take weeks to grow. In addition, it has been found that 72% of PHLs meet benchmark of identifying *M. tuberculosis* within 21 days of specimen receipt. All of this underscores the need for rapid and accurate testing for TB diagnosis, especially if the acid-fast bacilli (AFB) smear shows negative. Currently, there are no FDA-approved molecular tests to detect drug resistance.

Within the last few years, two conferences have helped to build momentum around these matters. In June 2010, The Advancing the Development of Diagnostic Tests and Biomarkers for Tuberculosis meeting was held, and a year after, in June 2011, a workshop on TB and HIV Diagnostics in Adult and Pediatric Populations was convened.

The Diagnostic Work Group, at its last meeting, reviewed progress made since 2011. Several activities have occurred. There was the establishment of the FDA and NIH co-sponsored clinical trial specimen bank to aid in biomarker discovery. Also occurring was a joint activity between CDC and NIH on improving diagnostic testing for pyrazinamide resistance. CDC and NIH also coordinated with WHO for moving research and development to field demonstration for molecular

detection of drug resistance. Meanwhile, the FDA has worked on policy efforts for devices that detect *M. tuberculosis* and related drug resistance. CDC, the Tuberculosis Trials Consortium (TBTC), NIH, and the AIDS Clinical Trials Group (ACTG) collaborated on a U.S. Expert study to contribute to FDA registration, and another major step was the Diagnostics Research Forum, which was a collaboration between NIH, the Bill and Melinda Gates Foundation (BMGF), and CDC.

As a result of the work groups analysis, there have been three meetings related to PZA and poor drug susceptibility testing.

- May 2011, NIH, Essentiality of PZA
 - Outcome: “PZA has potent sterilizing activity and is a highly important drug in current anti-tuberculosis combination therapy. Unfortunately, while PZA-resistant TB has been increasing worldwide, rapid and reliable diagnostic tools for the detection of PZA-resistant TB are still unavailable. This presents a major barrier for treatment, especially for multidrug-resistant and extensively drug-resistant disease. PZA is the least understood anti-TB drug due to its complex mechanisms of action and obstacles in establishing animal models for PZA testing Hafner.”
- December 2011, CDC PZA Day
 - Outcome: CDC presented information on the surveillance of PZA resistance, experience in providing clinical microbiologic service, and preliminary results on approaches to improve drug susceptibility testing for PZA. A series of concrete actions steps were laid out for the various federal agencies to strengthen internal U.S. government interaction.
- September 2012, NIH “Demystifying PZA—Challenges and Opportunities”
 - Outcome: “Topics included mechanisms of action; drug resistance and associated testing; combination therapy; and toxicity. This meeting was the pre-step to the announcement of a NIH-sponsored “TB Diagnostics Research Forum”

After the September 2012 meeting, the work group identified a set of next steps. One is to understand molecular markers of resistance for fluoroquinolone (FQ) and other important drugs. Other steps include pediatric TB diagnostics, standardization of laboratory processes for clinical trials, improved platforms for rapid resistance testing beyond rifampin, and MDDR for surveillance internationally.

The floor was opened for questions.

Ms. Bur expressed concern over issues with NAA, from correctional facilities, being refused by state labs. According to Dr. Iademarco, the taskforce works with lab directors, in the states, to answer questions and provide technical assistance. A more detailed dialogue is needed to clarify and dissect the matter,

in order to identify easy wins and low-hanging fruits. Dr. Elson suggested preparing guidance, in general, for the detention systems, as opposed to just facilities, which will help with transient issues and duplicative testing.

Dr. Dorman wondered if there was anything, further that ACET could do. She was not sure if this was the time for ACET to be reengaged with resolutions. Dr. Castro felt there was a benefit from ACET endorsement, which encourages DTBE to move ahead. However, DTBE will not wait for ACET before it takes action. It will use every tactic available to ensure success.

Drs. Flood and Mase have put forward recommendations. They asked if ACET uncovers any gaps to please notify them.

Dr. Horsburgh said CDC should take the lead in this. He would want to set up something new and felt existing mechanism should be employed. Dr. Baine suggested the use of a mechanism that was more radical related to national products. The government, he felt, should acquire manufacturing capabilities. Dr. Flood was in agreement; however, Dr. Mase felt existing mechanisms should be examined. Dr. Baine replied that public health would be “crazy” to think it was someone else’s responsibility to fund drug manufacturing. Dr. Reichman added TB’s history is replete with incidences of slow response. If there are new technologies, they should be utilized. Dr. Flood said the biggest barrier is money, even if you have alternatives.

After the break, roll was taken and quorum was present. Mr. Jones, again, reviewed the agenda

Ms. Suzanne Marks read, for the record an addendum for Task Order 27, which was made available online, as of May 22. It read as follows:

The Health-System Benefits and Cost-effectiveness of using M. Tuberculosis Direct NAA Testing to Diagnosis Tuberculosis Disease in the United States.

Potential Audience: Tuberculosis and infectious disease clinicians and health economists.

Key Message: The M. tuberculosis Direct (MTD) NAA test improved diagnostic accuracy and timeliness, and reduced unnecessary respiratory isolation, treatment, and contact investigation. It was cost savings in patients with HIV, recent homelessness, or substance abuse, but in others.

Talking Points:

1. Improvements in diagnosis of TB disease are needed, since sputum-smear microscopy detects less than half of TB patients.
2. For patients suspected of having pulmonary TB, the CDC has recommended since 1996 that nucleic acid amplification testing be

- conducted on at least one respiratory specimen if sputum-smear positive, and since 2009 if sputum-smear negative.
3. The U.S. Food and Drug Administration approved an enhanced MTD in 1999 for both smear-positive and smear-negative specimens.
 4. Individual providers, hospitals, and laboratories determine its use. However, the nucleic acid amplification testing is not used universally.
 5. Data on its programmatic benefits and cost-effectiveness might influence its use.
 6. The study evaluates the use, effectiveness, health system benefits, and cost-effectiveness of MTD nucleic acid amplification testing from the largest known cohort of patients suspected of pulmonary TB reported in 2008-2010 from multiple U.S. sites.
 7. Compared with no MTB, we found:
 - a. Improved diagnostic accuracy for all patients
 - b. Reduced time to TB diagnosis in smear-positive/MTD(+)
 - c. Reductions in medical procedures and respiratory isolation for smear-positive/MTD(-) patients without TB
 - d. 1.5 fewer months of unnecessary and potentially toxic TB medications in MDT(-) patients without TB
 - e. Fewer contact investigations initiated for smear-positive/MTD(-) patients without TB
 - f. Cost savings per additional patient with HIV or homelessness diagnosed without TB or excluded with TB, and per smear-negative patient with substance abuse to exclude TB
 8. Study results provide a baseline for newer molecular TB disease diagnostics, such as Xpert.

Task Order 18 Update and Recommendations

Dr. Wendy Thanassi

National Lead, Tuberculosis, Veterans Health Administration Office of Public Health, Occupational Health Strategic Healthcare Group,
Chief, Occupational Health, VA Palo Alto Healthcare System
Assistant Clinical Professor, Emergency Medicine, Stanford Medical Center

Dr. Thanassi presented results and reversions from work completed by the Interferon Gamma Release Assay (IGRA) Sounding Board. The board also presented a set of resolutions to be considered. [See Day 2, Resolutions section.]

IGRAs have several uses in practice. Both the 2010 CDC and the 2008 American College of Occupational and Environmental Medicine (ACOEM) guidelines support IGRA use as an alternative to TST in serial testing. The adoption of IGRA is growing, principally in healthcare worker (HCW) screening programs. The IGRAs offer both advantages and challenges in serial testing. The management of variability around the dichotomous cut-point poses

significant challenge, but multiple protocols are emerging to prevent over-treatment based on transiently positive results.

There is a lot of talk of reversions in the literature with regard to IGRAs. One, in particular, appeared in the *CHEST* December 2012 issue. It stated, “It is now clear that a simplistic definition of conversion (i.e. change from negative to positive) is no longer acceptable from a programmatic perspective. Additionally, given the high rates of reversions, it may be necessary to routinely repeat the IGRA in a recent convertor before decisions are made about preventive therapy. Until future iterations of guidelines address these issues, occupational health programs must ... not rely on dichotomous (yes/no) results...” But there were no guidelines for next steps. Therefore, in June 2012, the IGRA Sounding Board produced a set of objectives to “[address} variability around the cut-point in serial IGRA testing.” During the meeting, the board heard presentations regarding the high number of positive results and reversions observed in serial testing. They also discussed testing algorithms. Consensus of opinion helps to guide programs using IGRAs in serial testing, and the board is considering national guidance on IGRAs.

The board is co-chaired by Dr. Kenneth Castro and Dr. Charles Daley. Participants on the board are from organizations, like CDC, the TB Epidemiologic Studies Consortium (TBESC) Taskforce, ACOEM, APHL, and tuberculosis experts with research findings or extensive experience using IGRAs.

Dr. Thanassi presented two study designs that were presented at the board's meeting. The first was the TBESC Study Design - Task Order 18, which was a multi-center longitudinal study of serial testing in HCWS comparing IGRAs and TST. The study was performed in South Central, Rocky Mountain, Mid-Atlantic, and New England, among 2,500 HCW participants. It examined QuantiFERON-TB test (QFT), TSPOT and TST over 0, 6, 12 and 18 month durations. The study found that compared with TST, baseline testing with an IGRA reduces LTBI diagnoses by 80% among BCG-vaccinated. This ultimately showed cost savings and incremental benefits. It also demonstrated that prior TST could boost IGRA results, mostly in the TST positive. The effects last approximately 6 months. Positive result percentage was similar on all three tests, but with poor agreement. The following result percentages were seen:

- ❑ 5.2% TST
- ❑ 4.9% QFT
- ❑ 6.0% TSPOT
- 1.4% positive by all three tests

This begs the question of why there is such poor agreement. These numbers were just over the cut point.

Ultimately, the TBESC Task Order 18 exhibited conversions and reversions occurred with all 3 tests, but significantly more often with IGRAs.

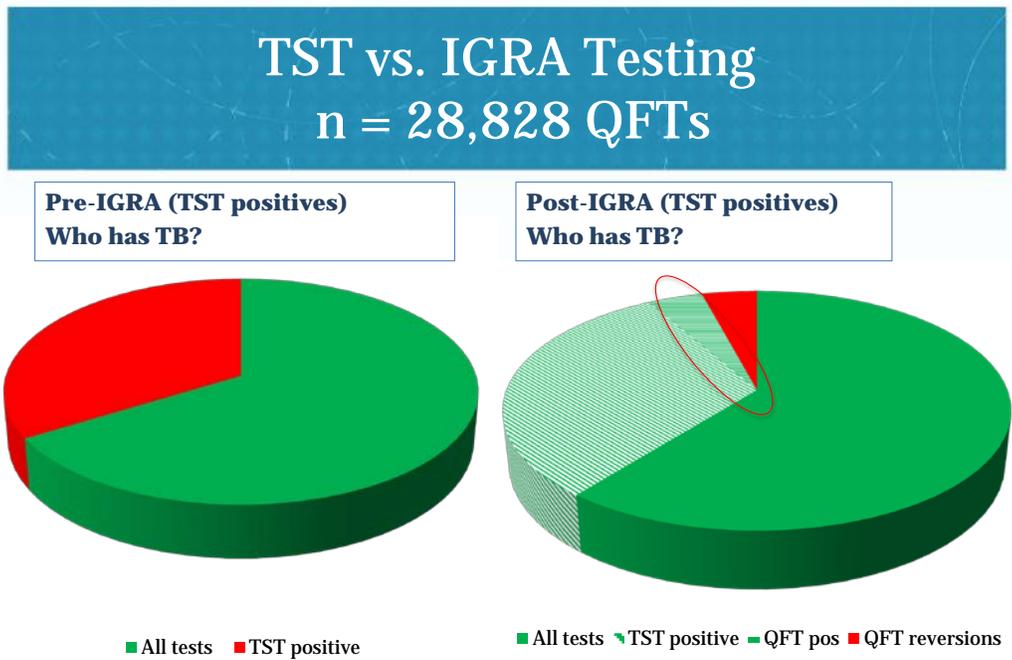
Conversion rates:	TSPOT	8.3 %
	QFT	6.1 %
	TST	1.0 %

Most IGRA conversions do not represent true change in infection status. Conversions with IGRAs occurred most frequently with quantitative results that were close to the cut-point, and almost 75% of IGRA conversions were transient. Therefore, strategies for discerning “true” IGRA conversions are needed. Until then, caution should be used in interpreting a single, newly positive test in a low-risk HCW.

The second study was called the Palo Alto Model – A Retest Zone, which was a multi-center statistical analysis to predict QFT reversions versus consistently positive result. The study was conducted in VA Palo Alto Health Care System (VAHCS), University of Illinois at Chicago (UIC), and the Cleveland Clinic. The method used to analyze was the Receiver Operating Characteristic analysis, which is a statistical method that differentiates similar appearing groups based on attributes. Participants were as follows:

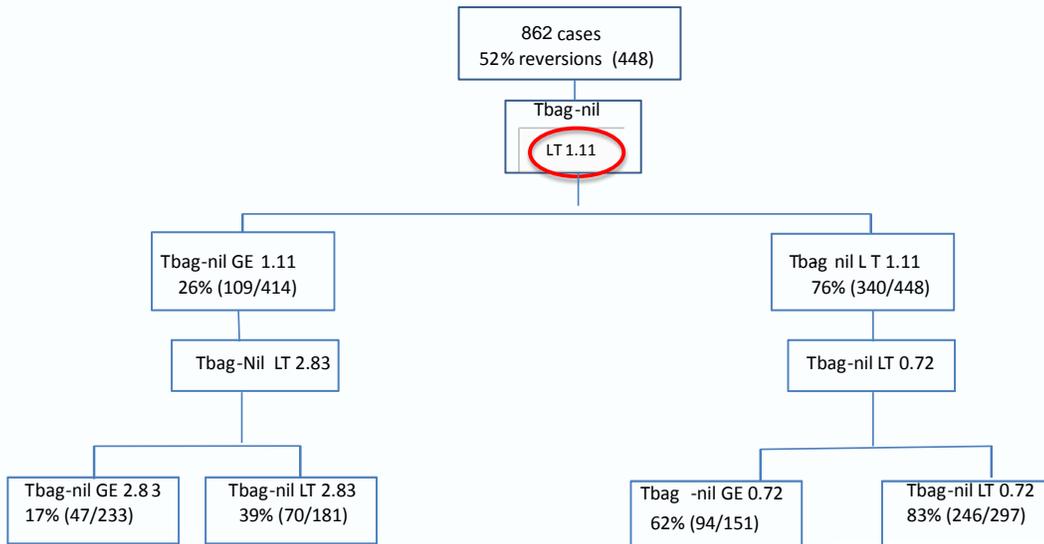
862 serially tested HCWs with positive QFT
 29,000 tests, 14,000 HCWs, 9.6% positive,
 52% reversions

The following pie chart, flow chart, and graph were presented in relationship to the study.

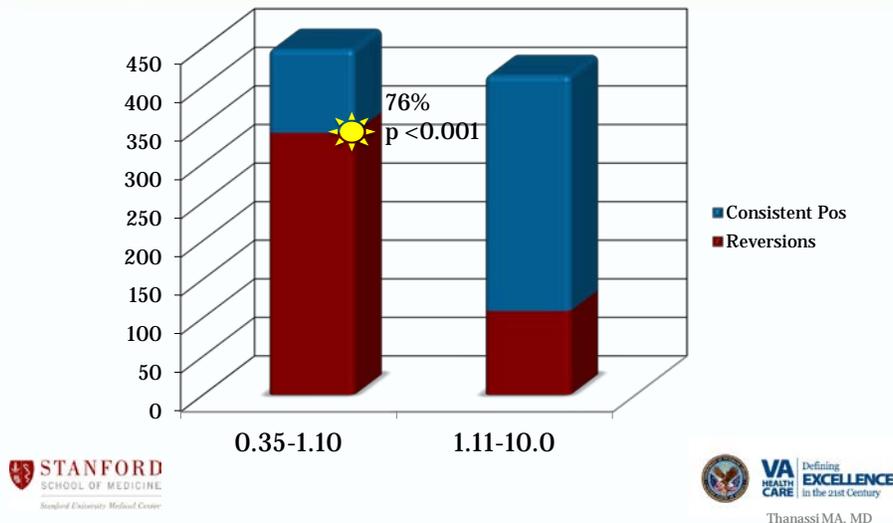


Retesting Zone Results for 3 Sites

n=862 US HCWs; p<0.001



Reversions at <1.11 IU/ml, $p < 0.001$ n's per Category, n = 862 HCWs



The result was a reversion rate of 76%. Retesting can be done as soon as the next day. The board's data was presented to Dr. Castro and was published in *Pulmonary Medicine's* December 2012 issue.

The Palo Alto Model is the largest study of IGRA positive U.S. HCWs to date representing HCWs across the U.S. The retesting zone consistent with 3 sites and with 7 sites validates CDC recommendation for quantitative reporting, algorithms that are currently improvised (OH), and ideal retesting zone at <1.1 IU/ml. Therefore, this should be a considered regiment. Additional analysis can add to future algorithms.

At the conclusion of the board one year ago, it was determined that IGRA testing of low risk persons causes transient, low-positive results that may not represent infection. A retesting strategy for low risk HCWs is needed to clarify QFT conversion. The board also established that *"there was unanimous consensus that national guidance, led by the CDC, is needed to formulate an optimal strategy or set of systematic approaches to address the unexpected high rates of positive IGRA results in the serial testing of low risk persons."* This guidance was felt to be urgent because providers and laboratories are faced with the issues of conversions and reversions on a daily basis. The summary of the June 2012 meeting was published in the *Infection Control and Hospital Epidemiology*, Volume 34, No.6 (June 213), pp. 623-630.

Dr. Thanassi asked ACET to consider the following:

- ❑ Serial testing of low-risk adults in a low-prevalence setting leads to high levels of reversion, with 77% of those testing between 0.35 and 1.1 IU/ml reverting on retest.
- ❑ Identification of a QDT retesting zone prevents misdiagnosis and treatment of LTBI without compromising sensitivity.

Therefore, CDC guidance in interpreting quantitative IGRA results in low-risk adults is requested, particularly recommendation for a QFT IGRA retesting zone in the low-risk adult.

- ❑ Establishment of a working group to identify algorithms for testing and treating based on quantitative IGRA results,
- ❑ Recommendation that quantitative IGRA interpretation be included in the next revision of the MMWR.

The floor was opened for questions.

Dr. Ekiek queried if island nations should utilize the recommendations, since they are experiencing difficulty accessing tubersol. Dr. Thanassi suggested the use of IGRA, which will relieve the burden of possibly exposing false-positive individuals. She suggested that Dr. Ekiek speak with Ms. Eva Margolies on the matter.

Dr. Baine asked about the effects of IGRAs on vitamin D levels. She replied the issue has been taken into consideration, when the analysis is performed on individuals who revert. If there was a vitamin D influence, it was quite small.

Dr. Narita felt the data underscores the need to revise the guideline.

Dr. Burgos asked for an update on T-spot, since it has different measurements. Dr. Thanassi said the test has built into it a borderline zone. The European cutoff is dichotomous to the board's number of six. The reversions with T-spot were higher compared to IGRAs. The data should be examined carefully. Dr. Horsburgh wondered if Dr. Dorman's group could quantify the results with another test. Dr. Thanassi said the issue has been addressed with statisticians; however, since this is not a probability issue, the results would be valid and independent. This would be a different draw on a different day. Their interferon gamma may be different between those two days. Drs. Thanassi and Horsburgh agreed to talk more offline about testing.

Dr. Seaworth said ACET's recommendations should specify IGRA for low risk individuals only. Healthcare workers, she said, are not the only people who have reversions. Dr. Thanassi would defer to ACET for a definition of low risk.

Dr. Trump suggested ACET also look at the guidance in partnership with OSHA and determine if they should be doing all the testing for low risk individuals.

TB Corrections Update

Ms. Sarah Bur, Ms. Diana Fortune and Ms. Lauren Lambert gave a combined presentation on corrections. Dr. Jane Carter's portion of the presentation displayed three TB case studies. The case studies exemplified what could go wrong in corrections.

Case study one was related to drug-resistant TB mismanagement. An Immigration and Customs Enforcement (ICE) detainee, who tested positive for M. tuberculosis on a culture, was placed in a detention center, on November 2012. The inmate was started on a regiment of rifampin, isoniazid, pyrazinamide, and ethambutol (RIPE) and moved to a local detention center in Texas. After two months, PZA and ethambutol were discontinued. The inmate then entered a federal bureau of prisons (BOP) facility in March of 2013. It was determined that the culture obtained at the ICE was INH-resistant. The inmate is now at risk for cultivated MDR TB. A follow-up on this case study showed that there might be hope for this individual. GeneExpert did show sensitivity to rifampin.

The second study presented was a case of diagnostic delay. An individual was detained at a local Texas detention center, in October 2012, who was symptomatic at intake. The detainee tested TST negative, but in December 2012 showed an abnormal chest radiograph that was said to have pneumonia. The individual was moved to another detention center in February 2012 still symptomatic (coughing) and was shortly thereafter moved to a BOP facility in March. An AFB smear, as well as an NAAT, reflected a positive result for M. tuberculosis. As a result, a contact investigation had to be conducted at three facilities. The preliminary results at the BOP documented 6/25, 24% TST conversions. There is no data as of yet from the other two facilities.

The final case also related to diagnostic delays. A 26-year old female was in custody at a private Arizona prison in October 2012. The female also briefly stayed at a Nevada correctional facility, where it was reported she coughed relentlessly but was not examined. She was then placed in a BOP on March 15, 2013, resided there until May 10, and was never examined for the cough, which continued. It was not until an interview was conducted that it was discovered that the persistent coughing had started in October 2012. On May 10, a chest radiograph showed bilateral disease with cavitations. There have been 47-documented TST converters. Below are the percentages presented:

- 18% conversion rate on housing unit
- >10% conversion rate on adjacent housing unit
- >10% conversion rate at work site

An investigation is now underway, in Arizona and Nevada.

Ms. Diana Fortune did second part of the presentation, which was an update on the National Tuberculosis Controllers Association/National Tuberculosis Nurse

Coalition (NTNC) Corrections Committee. The committee's mission is to improve TB recognition, prevention, and control in correctional facilities. The committee has designed its work plan for 2012/2013, and it can be found on the NTCA website, at http://www.tbcontrollers.org/ntca-2/committees/corrections/#.Uau_oJxnerg.

The committee is made up of 48 members from the following agencies:

- State and Local TB Program
- DTBE
- RTMCCs
- ICE
- BOP
- U.S. Marshalls
- Local Correctional Facilities
- TB Net
- CURE TB

They are hoping to increase the number of correctional agencies, particularly individuals with management responsibilities.

The committee has formed three Work Groups to help it accomplish its mission: Surveillance for Action, Education and Training, and TB Liaison. The work groups are chaired by Carla Chee (AZ), Ann Sittig (MN) and Barbara Vassell (TX), and Ellen Murray (SE National TB Center) respectively.

The purpose of the surveillance group is to enhance surveillance reporting among TB cases in correctional facilities and to use data for public health decision making and actions toward the ultimate goal of eliminating TB. To date, the work group has accomplished the following:

- The DTBE Surveillance Team completed a slide set for 1993–2011 Corrections data. The NTCA work group assisted in review of slides.
 - o Posted to NTCA website
 - o E-mailed to State TB Correctional Liaisons
- The work group developed a draft recommendation to clarify the RVCT correctional facility variable in the CDC instructional manual.
- The work group requested an analysis from the CDC to review national reporting completeness of the correctional facility variable.

The Education and Training Work Group's mission is assuring that targeted education regarding TB and corrections are available for health departments and correctional partners. They are currently developing a central repository of educational tools and ensuring that they are accessible to public health and correctional partners. The desire is to vet current materials, determine gaps for future educational tool development, and develop domain name to increase recognition and awareness. They also will promote collaboration between public health and corrections by presenting at educational conference on a national, state, and local level. The following individuals will present:

- Phil Griffin (KS)
- Barbarah Brissett (Houston)
- Sarah Bur (BOP)
- Ellen Murray (SE NTC)

Lastly, the Corrections TB Liaison Work Group's objectives are to expand the awareness of the challenges of TB in correctional facilities through collaborative efforts with the larger corrections committees and develop corrections liaisons for resources and link with experts in all aspects of corrections. The work group's accomplishments include a listing of all Correctional Liaisons for the United States and its territories. The list is posted on the NTCA website. It has been utilized to send out notice of INH and Tubersol shortages, in Jan 2013 and to send TB Correctional Surveillance slide set, in May 2013. The work group has also performed a needs assessment questionnaire of the TB Correctional Liaisons and in conjunction with the RTMCCs are developing an on-line TB correctional liaison training.

The committee will have an abstract/poster of its accomplishments showcased at the corrections annual meeting, on Wednesday, from 12:45 PM to 2:00 PM. New members are always welcomed to join. There will also be a breakout session, at the annual meeting on Wednesday, at 3:45 PM. The goal of the breakout is to examine a variety of strategies and models of collaborations between public health and correctional partners and to discuss incorporating IGRAs into the correctional setting.

The final portion of the presentation was presented by Ms. Lauren Lambert, who gave an update on the DTBE Corrections Work group. The mission of the work group is to enhance the prevention, control, and treatment of LTBI and TB associated with correctional facilities. The work group has performed activities in response to the eight resolutions, for correctional facilities, put forward by ACET, which relate to coordination, correctional liaison defined in TB CoAG, surveillance, TB case detection, continuity of care, education, treatment of LTBI, and Funding.

Activities related to each of the resolutions are as follows:

Coordination	
DTBE	Status

<input type="checkbox"/> Strengthen the coordination and oversight of TB prevention and control in correctional and detention facilities in partnership with state TB programs.	Fully-initiated
<input type="checkbox"/> Conduct a formal evaluation to assess the need for a full-time staff person to coordinate these activities.	Partially Initiated
<input type="checkbox"/> Develop ongoing collaborative partnership with national and regional correctional organizations to advance TB education and prevention and control efforts	Partially-Initiated

Correctional Liaison Defined in TB CoAG

DTBE incorporate into the new 2015 TB Cooperative Agreement the following proposed language:	Status
<input type="checkbox"/> “TB prevention and control in correctional and detention facilities is a high national priority. <input type="checkbox"/> Each Cooperative Agreement recipient will designate a correctional liaison and provide a brief summary report of activities in the interim and final progress reports. <input type="checkbox"/> Each jurisdiction should determine local priorities for the TB correctional liaison utilizing the NTCA Public Health TB Corrections liaison model duty statement as a guide.”	Partially-initiated

Surveillance

DTBE	Status
<input type="checkbox"/> 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	Partially-initiated

studies.	
<ul style="list-style-type: none"> <input type="checkbox"/> 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. <input type="checkbox"/> 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.” 	<p>Partially-initiated</p> <p>Not initiated but on the agenda. The work group is overcoming some funding issues.</p>

TB Case Detection

DTBE	Status
<ul style="list-style-type: none"> <input type="checkbox"/> Identify methods to improve TB screening, case detection, and medical management of persons with suspected TB. <input type="checkbox"/> Emphasize the appropriate use of rapid testing in the diagnostic evaluation of persons in the legal custody of a law enforcement agency. <input type="checkbox"/> Develop algorithms for returning inmates with suspected pulmonary TB to the general inmate population. 	<p>Partially-initiated</p> <p>Partially-initiated</p> <p>Although not initiated some states have been able to develop algorithms.</p>

Continuity of Care

DTBE	Status
<ul style="list-style-type: none"> <input type="checkbox"/> 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. <input type="checkbox"/> Evaluate the effectiveness of CURE-TB and TB-NET for transnational referrals and explore long-term funding. 	<p>Partially-initiated</p> <p>Partially-initiated</p>

<ul style="list-style-type: none"> <input type="checkbox"/> 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. 	Not initiated
<ul style="list-style-type: none"> <input type="checkbox"/> Identify successful programs for improving continuity of care and TB treatment completion for TB cases identified in correctional facilities and disseminate information about these effective models. 	Partially-initiated

Education

DTBE instruct the RTMCCs and the appropriate DTBE branches to coordinate strategies to identify and meet TB learning needs of correctional administrators, correctional health care providers , infection control personnel, law enforcement/correctional officers, and inmates.	Status
<ul style="list-style-type: none"> <input type="checkbox"/> Conduct a needs assessment. 	Not initiated
<ul style="list-style-type: none"> <input type="checkbox"/> Develop, disseminate and evaluate educational tools. 	Partially-initiated
<ul style="list-style-type: none"> <input type="checkbox"/> Develop TB competency assessment tools for correctional health care providers. 	Partially-initiated
<ul style="list-style-type: none"> <input type="checkbox"/> 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. 	Partially-initiated

Treatment of LTBI

DTBE	Status
Identify ways to expand treatment of latent TB infection in correctional facilities (including expanded use of the 12-week INH and Rifapentine regimen).	Partially-initiated

Funding

DTBE	Status
<p><input type="checkbox"/> 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).</p>	<p>Partially-initiated</p>

Ms. Lambert concluded by providing a snapshot of CDC accomplishments. The DTBE Corrections Work Group has been established and surveillance corrections slide set posted. “Predictors of failure in timely TB treatment completion” was published in the *International Journal of Tuberculosis and Lung Disease*, 2012 Edition. Educational materials and training for Corrections Liaisons are being created and Molecular Epidemiology Activity is developing methods to identify corrections-related TB clusters. There have been posters and presentations given at conferences and meetings about TB in corrections. She concluded her presentation by emphasizing that TB in Corrections is a priority for DTBE.

The floor was opened for questions.

Mr. Jones thanked DTBE for the work they have moved on in regards to ACET’s recommendations. The board had no questions related to the presentation.

The board moved to working on two proposed resolution. The first was presented by Dr. Dorman. It was developed in partnership with the TB Action Group and read as follows:

Recommendation to revise proposed DTBE FY 2014 budget allocations in response to sequestration-mandated reductions

The members of the Advisory Council for the Elimination of Tuberculosis (ACET),

Determined to eliminate tuberculosis (TB) in the United States;

Conscious of fiscal constraints and the need to allocate limited resources wisely in a period of nascent economic recovery;

Voicing the concern of TB patients, healthcare providers and TB-affected communities regarding the long duration and serious

toxicities of current therapeutic regimens and the urgent need to develop shorter, more efficacious, and better-tolerated therapies;

Seriously concerned that proposed budget allocations to the Centers for Disease Control and Prevention (CDC) Department of Tuberculosis Elimination (DTBE) under federally mandated sequestration will delay these necessary scientific and clinical advances;

Alarmed especially that the proposed budget allocation will severely curtail meaningful research in this area carried out by the Tuberculosis Trials Consortium (TBTC), the world's premier TB research consortium that has been 19 years in the making, as well as the Tuberculosis Epidemiologic Studies Consortium (TBESC);

Recalling that Public Health Law No. 110.392 encourages the Secretary of Health to “give priority to programmatically relevant research so that new tools can be utilized in public health practice;”

Further recalling that that Public Health Law encourages the Secretary of Health to carry out, directly or through grants, “research and development and related activities to develop new tools for the elimination of TB, including drugs, diagnostics, vaccines and public health interventions;”

Recognizing that programmatic relevance and public health impact sit at the heart of the TBTC's scientific missions, as well as that of the TBESC;

Recognizing also the strong programmatic value of TBTC and TBESC research, which has led to the recent development of a 3 month regimen for LTBI treatment and ongoing efforts to develop a 4 month treatment regimen for TB disease, advances which will increase the acceptability and cost-effectiveness of TB treatment and can be expected to contribute materially to our ability to eliminate TB in the US;

Have agreed, as follows:

For the fiscal year 2014 budget, we encourage the Secretary to preserve the research component of the DTBE.

Dr. Dorman put the resolution forward and a motion for ACET consideration. The motion was seconded by Dr. Horsburgh. The floor was then opened for discussion.

Ms. Jervis alerted the committee to Treatment Action Group's recent advocacy work related to the 13% reduction in budget to CDC. A series of meetings have begun, as well as usage of social media to bring about attention to the matter. She encouraged ACET to approve the resolution. .

Dr. Narita asked the committee if the item proposed on the resolution is the one item the committee wants to emphasize and if ACET is intending to suggest a shift of priorities. Dr. Horsburgh agreed. The idea is not to pit on side of TB against the other. The intent is to preserve the research function. The language should encourage the Secretary of Health to restore the 2013 cuts to the research components and preserve it in the future. The committee edited the document to Drs. Narita and Horsburgh's suggestions.

Drs. Roselle and Brenner suggested an annex page with a list of the accomplishments be added, for the purpose of Congress. After some grammatical edits, the following resolution was reread into the record, as a motion:

Recommendation to revise proposed DTBE FY 2014 budget allocations in response to sequestration-mandated reductions

The members of the Advisory Council for the Elimination of Tuberculosis (ACET),

Determined to eliminate tuberculosis (TB) in the United States;

Conscious of fiscal constraints and the need to allocate limited resources wisely in a period of nascent economic recovery;

Voicing the concern of TB patients, healthcare providers and TB-affected communities regarding the long duration and serious toxicities of current therapeutic regimens and the urgent need to develop shorter, more efficacious, and better-tolerated therapies;

Seriously concerned that proposed budget allocations to the Centers for Disease Control and Prevention (CDC) Department of Tuberculosis Elimination (DTBE) under federally mandated sequestration will delay these necessary scientific and clinical advances;

Alarmed especially that the proposed budget allocation will severely curtail meaningful research in this area as carried out by the Tuberculosis Trials Consortium (TBTC), the world's premier TB research consortium, and the Tuberculosis Epidemiologic Studies Consortium (TBESC);

Recalling that Public Health Law No. 110.392 “Comprehensive Tuberculosis Elimination Act” Section 317E No. 2 encourages the Secretary of Health and Human Services to “give priority to programmatically relevant research so that new tools can be utilized in public health practice;”

Further recalling that Public Health Law No. 110.392 encourages the Secretary of Health and Human Services to carry out, directly or through grants, “research and development and related activities to develop new tools for the elimination of tuberculosis, including drugs, diagnostics, vaccines and public health interventions;”

Recognizing that programmatic relevance and public health impact sit at the heart of the scientific missions of the TBTC and TBESC;

Recognizing also the strong programmatic value of TBTC and TBESC research, which has led to the recent development of a 3 month regimen for LTBI treatment and ongoing efforts to develop a 4 month treatment regimen for TB disease, advances which will increase the acceptability and cost-effectiveness of TB treatment and can be expected to contribute materially to our ability to eliminate TB in the US;

Have agreed, as follows:

For the fiscal year 2014 budget, we encourage the Secretary of Health and Human Services to rescind the FY2013 cuts and preserve the research component of the DTBE.

The motion was seconded by Dr. Horsburgh. Mr. Jones called for a vote. The committee voted to **unanimously accept** the resolution.

WRAP-UP DISCUSSION **Shannon Jones**

Mr. Jones concluded the meeting with instructions for submitting the remaining resolutions for Day Two. After some brief housekeeping notes, the meeting was adjourned.

MEETING ADJOURNED

WEDNESDAY, JUNE 5, 2013

CALL TO ORDER

Mr. Shannon Jones called Day Two's meeting to order at 8:31 AM. Dr. Hazel Dean conducted the roll call and quorum was present. After briefly reviewing the day's agenda, the meeting promptly began with presentations.

TB IN THE HOMELESS

HRSA Perspectives on the Homeless

Dr. Seiji Hayashi

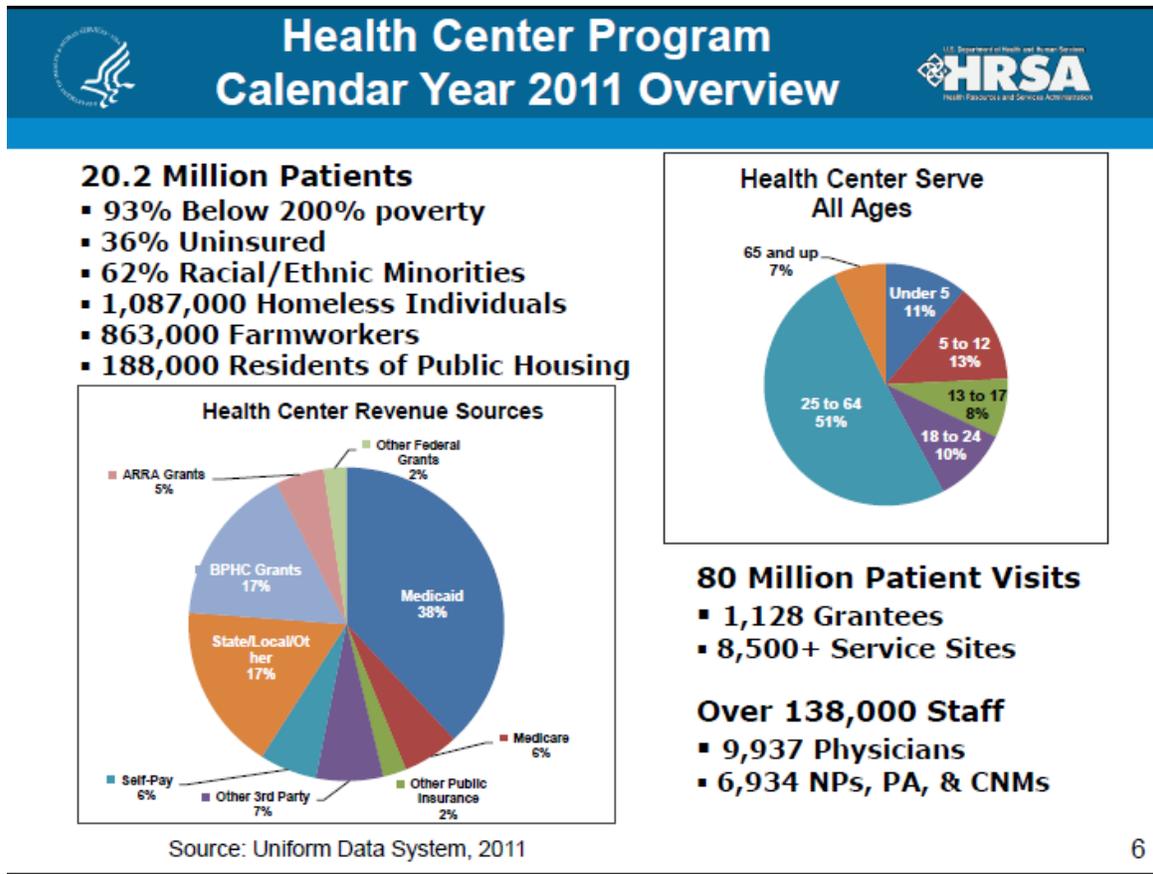
Chief Medical Officer, Bureau of Primary Health Care, HHS

The mission of the Bureau of Primary Health Care (BPHC) is to improve the health of the Nation's underserved communities and vulnerable populations by assuring access to comprehensive, culturally competent, quality primary health care services. The Health Center Program was authorized under section 330 of the Public Health Service (PHS) Act.

Federal support for health centers began in 1965. The grant programs established were for not-for-profit private or public entities, in all states and territories. The Federally Qualified Health Center (FQHC) established under the program was through CMS designation. Dr. Hayashi was careful to point out that FQHCs are not the same as a community health center; although they have some common characteristics.

Requirements must be fulfilled to be considered a Health Center Program. It must be located in or serve a high-needs community and governed by a community board composed of a majority of health center patients, who represent the population served. It must also provide comprehensive primary health care services, as well as supportive services that promote access to health care. Programs must provide services available to all on a sliding-fee scale and meet other performance and accountability requirements regarding administrative, clinical, and financial operations.

There are about 9,000 clinics around the U.S., and 1200 organizations funded by the program. The pie charts below were presented to illustrate ages served and revenue sources.

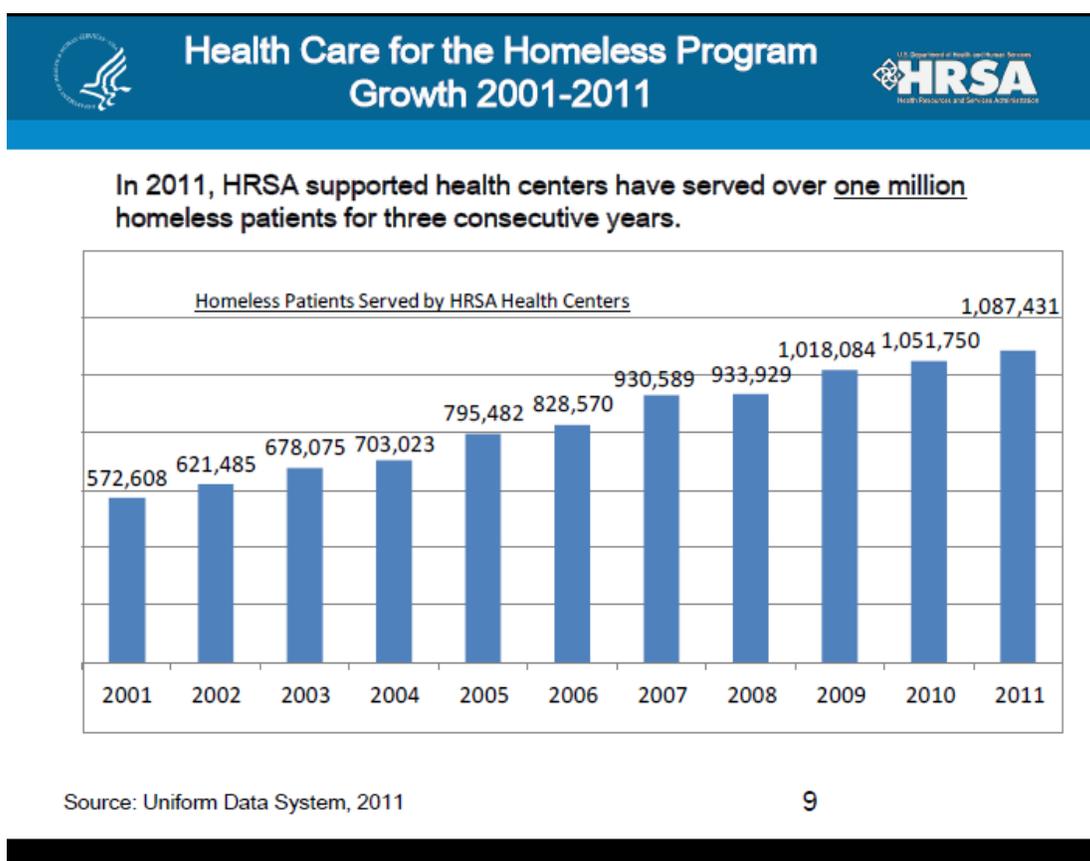


A snapshot of the 2011 Health Center Program's workforce was presented. Below is a table detailing the workforce composition.

Total 138,403		Staff	Mental 4,486		Health
Physicians 9,936			<input type="checkbox"/> Psychiatrists 401 <input type="checkbox"/> Clinical Psychologists 403 <input type="checkbox"/> Clinical Social Workers 1,394 <input type="checkbox"/> Other Licensed MH 1,006 <input type="checkbox"/> Other MH 1,282		
<input type="checkbox"/> Family/General P. 5,034 <input type="checkbox"/> Internal Med 1,607 <input type="checkbox"/> Pediatrics 2,010 <input type="checkbox"/> Ob/Gyn 979 <input type="checkbox"/> Other MD/DO 306					
Nurse 4,186		Practitioners	Substance 874		Abuse
Physician 2,194		Assistants	Pharmacy 2,999		
Certified 553	Nurse	Midwives	Vision 298		
			<input type="checkbox"/> Ophthalmologists 30 <input type="checkbox"/> Optometrists 134 <input type="checkbox"/> Other Vision Care Staff 134		
Nurses 11,854			Other 977		Professional
Other 17,711		Med	Program 12,504	Enabling	Services
Lab/X-ray 2,778			<input type="checkbox"/> (Case Managers, Education, Outreach, Transport, etc.)		
Dental 10,338			Other 4,256		Program/Services
<input type="checkbox"/> Dentists 3,096 <input type="checkbox"/> Hygienists 1,285 <input type="checkbox"/> Assistants 5,957			Patient 23,596	Support	Staff
			Management 13,875	and Support	Staff
			Fiscal 9,261	and Billing	Staff
			IT 2,180		Staff
			Facility 3,547		Staff

The goal of the Health Center Program is to provide comprehensive care.

The Health Care for the Homeless Program (HCH) was authorized under section 330(h) of the Public Health Service (PHS) Act. The Homeless Program affords individuals and families experiencing homelessness with high-quality, comprehensive, primary health care services and innovative programs and outreach. In addition to the primary health care, substance abuse services are required to be available and provided, if needed. In 2011, 825,295 patients had over 4 million encounters with the program. At that time, 221 HCH grantees were located in the 50 states, DC, and Puerto Rico. The following chart was presented to illustrate the growth in the number of homeless persons served by the program between 2001 and 2011.



Below are some statistics pertaining to Health Care for Homeless Program:

- 221 HCH grantees in all 50 states, DC, and Puerto Rico
- 825,295 patients served at HCH grantees (1,087,431 total homeless patients served at Health Centers)
- 90.4% below 100 percent poverty level
- 62.4% uninsured
- 27.7% enrolled in Medicaid or SCHIP
- 47.1% from racial/ethnic minority group

A table was also provided showing the number of patients diagnosed among all grantees and also by HCH grantees. For tuberculosis, 6,816 people were diagnosed over all the grantees. Of that number, 1,265 were diagnosed by an HCH grantee. Some individual may be underreported due to co-morbid conditions. What the table illustrated was that HCH patients were sicker and poorer.

The Bureau of Primary Health Care Quality Strategy has five activities and approaches: Policies and Programs, Funding, Technical Assistance, Data and Information, and Partnerships and Collaboration. The aim is provide better care and affordable care and produce healthy people and communities. To achieve this a stepwise approach has been adopted. It includes access, comprehensive services, and integrated care all within an integrated health system.

The Bureau's work is a collaborative effort and depends on technical assistance resources like:

- ❑ National and state-based support for training and technical assistance:
 - National Cooperative Agreements
 - State/Regional Primary Care Associations
 - State Primary Care Offices
- ❑ Federal TA Support:
 - Project Officer
 - TA Calls/Trainings
 - Onsite Consultant Support
 - BPHC TA Website

More information regarding BPHC technical assistance can be found at <http://www.bphc.hrsa.gov/technicalassistance/index.html>.

Healthcare for the Homeless

Mr. John Lozier

Executive Director, National Health Care for the Homeless Council

The National Health Care for the Homeless Council is a 28-year old non-profit based in Nashville, Tennessee comprised of 125 organizational members and greater than 2,000 individual members from the HCH Clinicians' Network, National Consumer Advisory Board, and Respite Care Providers' Network. The mission of the Council is to eliminate homelessness by ensuring comprehensive health care and secure housing for everyone.

In order to achieve its mission, the Council strives to create and disseminate knowledge regarding the interaction of inadequate housing and poor health. It also works to maintain active relationships with a broad range of service providers, consumer and advocacy groups, academic institutions, and public officials, in the United States and internationally. It promotes clinical practices and public policies that will improve the health status of people without homes or

at risk for homelessness. Lastly, it demonstrates its commitment to human rights and adherence to its Founding Principles in its activities, governance structure, internal policies, and external partnerships.

The Council considers itself to be a human rights organization and pulls its principles from Article 25, the Universal Declaration of Human Rights, which says everyone has the right to a standard of living adequate for the health and well-being of oneself and one's family, including food, clothing, housing, and medical care.

The Council provides services such as technical assistance and training, research, policy analysis and advocacy, and peer support. More information about the Council's service can be found at www.nhchc.org.

The Council tries to address the social determinants of health. Social determinants of health, for the homeless, cause a ripple effect. Poor health causes homelessness. Homelessness causes poor health, and homelessness complicates treatment. The homeless experience excessive morbidity. All conditions are 3 to 6 times the rate of the general public. These individuals also experience premature mortality, with a life expectancy 30 years less than the general public.

Mr. Lozier presented statistics to compare and contrast the condition of the U.S. in the 1980s compared to now. In the 1980s, there was an increase in homelessness due to the recession experienced under President Reagan's administration. There was:

- 10% unemployment, 15% poverty
- 75% reduction in HUD budget
- Mental health deinstitutionalization
- Baby boomers reaching adulthood
- Traumatized veterans
- Appearance of AIDS
- 12.9% un-insurance (1987)

The parallels of 2013 are very similar. The numbers show:

- 7.5% unemployment, 15% poverty
- Housing crisis reaches middle class
- Behavioral health care insufficiency
- Boomer's children reaching adulthood
- Traumatized veterans
- 50,000 new AIDS cases per year
- 15.7% un-insurance

The Council has learned that housing is health care. Therefore, the Council has taken on an initiative called Housing First. The Council believes the first priority is to provide individuals with a home and then fix the other confounders of

homelessness. Individuals tend to do better and adhere to treatment if their housing status is stable.

Health Care for the Homeless has practice models, which are patient-centered and trauma-informed, with multi-disciplinary teams that can address many issues. The outreach orientation creates access to care, and the systems perspective is, again, to address the social determinants. Grantee organizations span several expertise, such as:

- Community Health Centers
- Migrant Health Centers
- Farmworker Health Centers
- Public Health Departments
- Hospitals
- Other Community Organizations

The HCH provide TB screening for shelter admission and provide a great deal of education and training. Some of the HCHs provide radiology services and engage in treatment efforts. They also try to support outbreak investigations.

Medicaid Expansion is now a state option. Everyone less than or equal to 138% of FPL or \$15,500 are federal match 100% for the first 3 years, with access to care. Most states in the Southeast and Southern Midwest have opted not to expand. Under ACA, eligibility determination does not require individuals to have:

- No home address
- MAGI—IRS
- Citizenship/residency—SSA
- Online, in person, by telephone, on paper
- Annual re-determination

Navigators are provided to assist individuals through the new ACA plan and assisters are funded through the marketplaces.

ACA has requirements for outreach. The law requires states “establish procedures for outreach and enrollment activities to vulnerable and underserved populations” (ACA §2201)

- Children
- Unaccompanied homeless youth
- Children and youth with special health care needs
- Pregnant women
- Racial and ethnic minorities
- Rural populations
- Victims of abuse or trauma
- Individuals with mental health or substance-related disorders
- Individuals with HIV/AIDS

In order to continue the work of the Council, which includes assisting in TB control efforts, several things will have to be considered. Health Centers will need to continue to increase their capacity. It needs to be remembered that essential community provider inclusion in panels is not guaranteed. Also, more very poor people will have Medicaid, which will increase primary care relationships and will need to include substance abuse treatment. He also asked ACET to remember that housing is health care.

The floor was opened for discussion.

Dr. Levin said, according to the map, health care centers are lacking in the Mexico-U.S. border region. Dr. Hayashi replied the number of health centers reflect the populations in that area. However, what is concerning is the number of places, where healthcare centers do not exist, like the Rocky Mountain area. Additional funding is being provided for those communities, but the caveat is the grant selection process, which is competitive. HHS is looking for ways to ensure those areas do get the HCHs they need.

Dr. Thanassi asked how Mr. Lozier's council reduces reduplication of efforts with other government agencies, when addressing the homeless population and if they coordinate with other agencies. He replied the council is very lean and tries to leverage as many additional resources as possible through leadership, so a lot of collaboration takes place between the council and government agencies. There has been, for example, much collaboration with the VA because of the overwhelming needs of the veterans, and there is plenty of work to go around.

Dr. Castro said there is a vast array of FQHCs or look-a-likes. The concern is proficiency in expertise to sufficiently diagnosis and treats TB. He doubted they would be found in all of those centers. He suggested DTBE partner with the program to make sure those expertise are available. DTBE could also assist in recruiting health centers, which are resisting change, to make sure the right and appropriate services are provided. Dr. Hayashi welcomed the opportunity. Health centers also require guidance on quarantine matters. Health centers are utilized by children and others, who could be at risk of catching TB from patients presenting to the center for treatment or diagnosis. Mr. Lozier also welcomed the opportunity to work in collaboration with DTBE. Transport issues are an area they need assistance with for homeless individuals, who are not able to access an HCH in close proximity.

U.S./MEXICO BORDER HEALTH

TB efforts along the U.S./Mexico Border

Mr. Paul Dulin

Director, Office of Border Health

Delegate of the Secretary, New Mexico Department of Health to the U.S.-Mexico Border Health Commission

TB is one of the top priorities of the U.S.-Mexico Border Health Commission (BHC). The BHC established the U.S.-Mexico TB Consortium and Legal Forum as a medium for addressing TB issues in the border region. In 2010 and 2011, the BHC convened two annual meetings of the U.S.-Mexico TB Consortium and Legal Forum, which consisted of presentations in a conference setting. In 2012, the annual meeting was changed into a workshop format, with work groups formed around three major themes:

- Legal issues limiting effective TB treatment
- Continuity of care in the binational border region
- MDR-TB (this was the first meeting to address clinical issues)

U.S. law gives the right to detain an individual for refusal of treatment. In Mexico, there is a statute to isolate the patient, but if the patient refuses treatment, the Human Right Laws, which says the patient can refuse treatment, trumps the statute.

Members of the TB Consortium come from both the United States and Mexico. Below is a list of agencies that are part of the Consortium.

United States

- U.S. Section of the BHC
- CDC/DTBE and DGMQ
- DHS/ICE
- DOJ/BOP and USMS
- Regional and State TB programs and Legal Counsels of TX, NM, AZ, CA
- Border county TB programs of TX, CA and AZ
- Heartland National TB Center
- Migrant Clinicians Network
- Cure-TB
- PAHO US-MX Border Field Office

Mexico

- Mexican Section of the BHC
- Federal Secretariat of Health Mycobacterium Program and Legal Affairs
- Secretariat of Foreign Affairs Consulates in border region
- National Migration Institute
- TB Programs and Legal Counsels of State Health Secretariats of TAM, NL, COH, CHIH, SON, and BC

At the 3rd Annual Meeting of the U.S.-Mexico Border TB Consortium, three binational work groups were established. The TB Legal Issues deal with public health law regarding treatment of non-compliant TB patients and U.S. states' statutes and precedents to ensure treatment. Continuity of Care's looks at continuity of treatment for patients under TB therapy being deported to Mexico or transferred to the Mexican authorities. The Binational Consultative Network of MDR-TB Experts is a forum created for binational consultation on treatment and formularies for drug resistant patients. A series of action items were proposed

for each work group and presented to ACET in the form of resolutions. [See Resolutions under the Business Section.]

The 4th Annual Meeting of the U.S.-Mexico Border TB Consortium work group breakouts convened for the first full day. Presenters provided foundational material for discussion. A list of tasks was presented to each work group based on action items proposed the previous year. Each work group prepared a three-year operational plan to implement activities related to their respective action items. The work groups also named co-chairs to serve as focal points for convening quarterly virtual meetings and compiling deliverables.

One of the products to be developed by the TB Legal Issues Work group is a “Guidebook of Legal Procedures to Facilitate Management of TB Patients in the U.S.-Mexico Border Region” (with emphasis on treatment of non-compliant TB patients). The guidebook will be produced in collaboration with the legal counsels of selected U.S. and Mexican State Health Departments, DHS/ICE, and Mexico Health Secretariat. The Co-Chairs are Polly Price, Professor of Law and Associated Faculty, Emory University (U.S.) and Lic. Agustín Herrera, Director, Human Rights and Health Law Investigation, Mexico Secretariat of Health (MX).

Actions for the Continuity of Care Work group include creating uniform standards for meet and greet transfers of TB patients deported to Mexico by DHS/ICE, DOJ/BOP and USMS, as well as local and state detention facilities. The standards will deal with reception, as well as aligning follow-up and continuity of care in Mexico through the Mexican Consulates, National Migration Institute, and local and state health jurisdictions. They will then be disseminated to the TB Controllers in the United States. A third party evaluation of all binational TB programs will be conducted and the definition of a binational case (U.S.-Mexico) will be determined. The Co-Chairs are Diana Elson, DrPh, Chief, Epidemiology, DHS-ICE/ERO/ IHSC, Dept. of Homeland Security (U.S.) and Dr. Martin Castellanos Joya, Director, National Mycobacterium Program, Mexico Ministry of Health (MX).

Lastly, the Binational Consultative Network of MDR-TB Experts developed agreements on convening and consultation procedures among state and federal authorities. Meetings will be scheduled and assembled possibly quarterly and include select members at the regional level to review cases. The work group will identify and share resources [This does not imply that the U.S. will fund all resources to Mexico.] and develop training of clinicians in MDR-TB treatment strategies and formularies, through national TB training centers, and virtual technologies. Co-Chairs will be appointed by their respective federal TB programs. A matrix has been developed to explain the work plan.

The following recommendations from the BHC were presented to ACET. These recommendations were also used to formulate the resolution.

- ❑ Embrace the efforts of the U.S.-Mexico Border TB Consortium and support the implementation of its work plans as a basis to resolve binational TB issues
- ❑ Consider advising the Secretary of HHS to support alignment of the priorities and strategies of ACET, NTBC, CDC and the OGA/U.S.-Mexico Border Health Commission with those of the Consortium for TB management in the border region
- ❑ Consider advising the Secretary of HHS to reach out to her counterpart Secretary of Health in Mexico to advocate for Mexico's continued participation in the TB Consortium and support to implement the work groups operational plans
- ❑ Consider advising the Secretary of HHS to allocate additional funding and technical assistance to support activities included in the TB Consortium Work Group Operational Plans

Dr. Seaworth said without some medication resources, it would be hard to move forward on specialized and individualized treatment of XDR cases. Finding a way to support the resources would be the smartest strategy.

Dr. Elson felt lessons learned from the correctional presentation yesterday made it evident that education is needed for local health departments and law enforcement, on continuity of care for inmates. It would also help law enforcement to be able to identify potential TB cases in their populations.

Dr. Dorman requested further information on CDC's roles and its interaction with the Consortium. Mr. Dulin informed the binational program is funded largely on the U.S. side, partially by CDC. One of the issues the Consortium is trying to resolve is consistency. In silos, everyone has developed its own practices and standards. The Consortium is creating common standards to address treatment processes, sovereignty issues, and create a more systematic and evidence-based practice for the programs.

Dr. Castro said Mexico should be providing resources, as well, to address this issue. From the TB side, DTBE could recruit TB coordinators at CDC. They may be helpful, as well as others at CDC, who could leverage activities. Mr. Dulin felt the partnership with PAHO was a missed opportunity. The commission could have done more to align work plans in 2008. There was a request at the Border Governors Conference for governors to meet with PAHO, but it never came to fruition; therefore, PAHO facilitated the connections themselves.

Dr. Elson said an additional complexity is the Consortium focuses on individuals in the border areas, but there are no efforts to support treatment at their homes. When deported individuals return home, some further mechanism should be employed to ensure treatment is received. Another point to remember is that Mexicans are not the only people who cross the border, and the same issue applies for those individuals as well.

The meeting was called to order at 11:01 AM, after a break. Dr. Dean conducted a roll call and determined that quorum was present.

BUSINESS SESSION: MOTION TO ACCEPT MINUTES OF MARCH 5, 2013 MEETING

ACET members, ex officio members, and liaison representatives were all provided a copy of the minutes from the March 5, 2013 meeting held in Atlanta, GA, via webinar. Only members were permitted to vote on the minutes. Mr. Jones asked for a motion to accept the minutes from the March meeting, as presented and provided to the members. A motion was placed by Ms. Barbara Cole and seconded by Dr. C. Robert Horsburgh, Jr. Ms. Cole requested a status update on the Letter to the Secretary of Health. Mr. Jones is in the process of finalizing the letter. He has received all requested supplementary reports from the members. He will complete the letter before his term ends, at the end of the month. He will then turn the letter over to DTBE for it to be vetted through MASO. From that point, MASO will forward the letter to the Secretary of Health. Copies of the letter will be distributed to the members, ex officio members, and others. No further discussion was requested by members. **ACET unanimously approved the motion**, with no members abstaining.

Forms were provided to members, who had travel orders to participate in the meeting. The forms are to be submitted no later than five working days from the close of the meeting. Forms should be emailed to VIM7@cdc.gov, attention Maureen McDermott. Ms. McDermott's information was also displayed on the overhead projector, at the conclusion of the meeting.

POTENTIAL BUSINESS ITEMS

Number of Meetings - Reduce to One In-Person and Two Webinars

Dr. Dean provided information on a recommendation to reduce the number of meetings to one in-person meeting and two webinars. The request was made due to budget constraints that are being experienced across the agency. The Directors Committee has also adopted the new meeting schedule to one in-person meeting and webinars. The new proposed meeting schedule was placed before ACET for discussion.

Number of Liaisons and Ex Officio Members

Regarding the number of liaisons and ex-officio members, more clarity is needed; therefore, Dr. Dean passed over this portion of the meeting and moved to travel.

Travel of Liaisons and Ex-Officio Members

Due to budget constraints, the Committee Management Office has advised ACET to discuss eliminating the cost of travel for liaisons and ex-officio members. If agencies and organizations cannot bear the brunt of travel cost, the Office is asking for those expenses to be eliminated. Ex Officio members were asked to speak with their agencies about picking up those expenses, or ex officio members could participate, in the meetings, via conference call.

Mr. Jones then opened the floor for discussion.

Dr. Reichman felt the comments were very necessary; but the American College of Chest Physicians has no interest in tuberculosis. He will provide the college with a copy of the minutes, once they are approved, but he was very certain that the college would not want to pay for his travel. He felt DTBE would need to determine if it was important to continue to foster relationships. He pledged to participate by phone if he was not able to physically attend. Dr. Elson's agency also has travel restrictions but she committed to attending via the phone, as well.

Dr. Castro responded that it is very appropriate to have CDC to support travel, but due to budget constraints, drastic decisions had to be made. CDC, in fact, has suspended all staff travel to conferences, for the remainder of the calendar year. Since quorum is essential to conduct a meeting, CDC will be looking at other methods and technologies, like webinars, that can solve the problem. Once funding has returned to normal, travel again will be supported by CDC.

Dr. Dorman concurred with both Dr. Reichman's and Dr. Castro's comments but was concerned about the lessening in meeting quality, as well as the outputs. Dr. Benjamin also believed that in-person meetings yielded better productivity and that DTBE should do as much as possible to preserve in-person meetings.

ACET members made some cost-saving suggestions. Dr. Burgos suggested putting ACET meetings closer to the NTCA meetings and maybe that would provide some savings to the member's agencies, if they did have to pay for travel. Ms. Levin observed that 21 of those in attendance were from Washington, D.C. She proposed that CDC come to Washington, D.C. and believed the change would also provide a cost savings because it would eliminate hotel and food costs.

That option had already been considered according to Mr. Jones. Dr. Castro and Dr. Dean have run some numbers and found that it is worth reconsidering that option. The Federal Tuberculosis Taskforce Meeting occurs in Bethesda, MD at NIH facilities because a majority of its members lives in that area. He felt it would be worth writing a letter to the Secretary of Health to consider this option. DTBE will do an official cost comparison. The option may prevent several key individuals at CDC, from attending. Dr. Baine advised DTBE to speak to the Healthcare Infection Control Practices Advisory Committee (HICPAC), who has also reduced their number of meetings and have been for some time. They may have some cost-savings estimates that they could share. He also did not believe

that his agency would support paying the cost for him to attend ACET meetings, as they already do not support his trips to HICPAC meetings.

Ms. Bur suggested using the Corrections Work Group model, which has proven to be efficient and is leading to real change. Members of the work group met on the phone to achieve its mission. She felt the current fiscal constraints were an opportunity for DTBE to figure out a way to do things differently, such as using small work groups to do more intensive work via the telephone. The process would also yield more well prepared and thought-out material. Mr. Jones concurred with Ms. Bur's comments. Meetings should be used to advance policies, said Mr. Jones, and not just to hear presentations of updates. He suggested the new chair and the Agenda Review Committee move to that type of process. Ms. Cole agreed with Mr. Jones' suggestions and felt subcommittees could be assign to certain task, and at the in-person meetings, present their outcomes to be vetted by ACET. Any updates could be submitted in the form of reports versus presentations.

Dr. Reichman asked DTBE to forward a communicate either from Dr. Dean, Dr. Frieden, or the Secretary of Health explaining why participation was important enough that members' agencies should support travel expenses.

Mr. Jones, before closing discussion on the travel topic, again recommended ACET continue to talk about ideas on how to conduct future meetings. Dr. Carter was heading a work group, who was examining options to overcome this problem. The Agenda Committee was one of the outputs from the work group. The second recommendation from the work group was to use in-person meetings for advancing policy and only hear updates that were essential. More specificity is needed on what day one of the meeting will entail and leaving day two for business only. Therefore, he queried the committee and asked if it felt another similar work group should be put together, who can decide the components of a typical meeting.

Dr. Narita said the complexity of some resolutions demanded discussion among the committee and DTBE to gain more understanding. Mr. Jones said a possible agenda item could be a report on what actions have been taken, since the resolution.

Dr. Horsburgh, Jr. did not feel a new work group was warranted. The Agenda Committee could take on that role. Mr. Jones directed the Agenda Committee to meet soon and to make sure deliverables are focused on policy type of discussion, in light of what has been discussed at this meeting.

Dr. Castro reminded the Committee of the rule, which says members may not rotate off the committee until a replacement member has been identified.

Dr. Roselle observed the current meeting format and found it to be backwards. Most meetings he has attended handle business on day one and leaving day two for presentations. The business decisions that ACET makes demand that the group be energized so that it may weigh in on very important topics. As it is now, business is conducted on the second day and members are either exhausted or disengaged or have to leave early to catch flights back home, which threatens quorum. Mr. Jones charged the Agenda Committee to put future meetings in Dr. Roselle's prescribed format.

Dr. Benjamin proposed using a webinar just before the in-person meeting to present any background information or updates. In-person meetings could contain discussion of what was learned through the webinar, as well as, to conduct the business session. Mr. Jones also added the suggested format to the Agenda Committee's charge. Dr. Baine hoped that members would come to the meeting prepared by being sure to review any pre-presented information so rich discussions could occur.

Dates for next ACET meeting -December 3-4, 2013

Mr. Jones said the anticipation was to have a meeting in October and December. The October meeting would be a webinar and the December meeting would be the annual. Mr. Jones asked if the October webinar was needed or should the committee just defer to the December meeting.

Dr. Castro thought Dr. Benjamin's suggestion should be employed and to use the October meeting as the webinar for updates and presentations, which can guide policy discussions at the December meeting. Ms. Scott-Cseh will provide dates for the October webinar. The December meeting will be on the 3rd and 4th.

Ms. Bur will facilitate efforts to find one location for all D.C. attendees to gather for the October webinar. The same process will happen for Atlanta but no one was identified to head those efforts.

The committee stopped, momentarily, to pick up lunch and continued the meeting over a working lunch. A roll call was taken to ensure quorum was present.

INTERNAL ACET DISCUSSIONS Resolutions

The Committee reviewed six resolutions. The first was presented by Ms. Cole entitled TB Screening for H-1B Work Visa Applicants, which was a collaboration among the California Tuberculosis Controllers Association (CTCA), the National Association of City and County Health Officials (NACCHO), and the National Tuberculosis Controllers Association (NTCA). The resolution was brought forth in light of the Immigration Bill that is before Congress. The collaborative felt it

important to look at H-1B work visa applicants. Work visa applicants may work up to three years and in some cases up to six. The resolution proposes screening recommendations for this population.

Ms. Cole read the resolution.

TB Screening of H1B Work Visa Applicants

WHEREAS the Immigration Bill currently before Congress proposes to increase the number of H1B work visas from the current 65,000 to approximately 180,000 applicants yearly,

WHEREAS there is currently no requirement for H1B work visa applicants or their families, to receive any health screening prior to migration to the United States,

WHEREAS many H1B work visa applicants come from countries with high prevalence of tuberculosis (TB) and drug resistant TB,

WHEREAS ACET recommends that health screening for Tuberculosis and other communicable diseases for all H1B work visa applicants and any family members planning to migrate to the United States under the H1B visa program be implemented overseas, by approved Panel Physicians, in compliance with the current Technical Instructions, prior to travel to the United States.

WHEREAS ACET further recommends that the cost of the overseas, pre-migration screening of the H1B work visa applicant and any family member(s) planning to migrate under this program, be borne by the company sponsoring the H1B work visa applicant, and that prohibitions/restrictions on travel/migration be the same as applies to current immigrants based on health screening.

Be it now resolved that ACET recommends that:

- 1. H1B work visa applicants be screened for TB and other communicable diseases in compliance with the current Technical Instructions prior to travel to the United States.***
- 2. CDC informs HHS Secretary Sibelius of this resolution and recommends that she take appropriate action to inform congressional members working on the Immigration reform bill.***

Mr. Jones asked for a second to accept the resolution. The motion was seconded by Dr. Seaworth. The floor was opened for discussion.

Dr. Brenner asked for the verbiage “prior to issuance of H-1B visa” be added to the resolution and delete travel to the U.S. The change was made throughout the document where needed. The additional verbiage “implemented overseas, by approved Panel Physicians, or in the U.S. by Civil surgeons, in compliance with the current Technical Instructions” was also added.

Ms. Napolitano supported the resolution on behalf of Stop TB USA. Dr. Trump also supported the resolution on behalf of the Council for State and Territorial Epidemiologists (CSTE).

Dr. Narita asked if the resolution would void a decision made by his agency to test anyone who plans to stay in the United States for more than six months. Ms. Cole replied the resolution stands on its on and would not.

Dr. Elson asked if the resolution would restrict travel for individuals who are screened in the United States and found to have TB. According to the Technical Instructions, those individuals would have to remain in the country of origin until they completed treatment without the waiver. Dr. Levin thought the model used in Australia would work, in this case. In the model, any individuals found positive with latent or active TB are treated in Australia at the government’s expense. Ms. Cole said the United States would handle active cases as normal and intervene. Dr. Narita reminded the group that the process the resolution proposes will cause increases in H-1B, H-2B, and H-3B.

After a few additional minimal changes, Ms. Cole re-read the resolution.

TB Screening of H-1B Work Visa Applicants

WHEREAS the Immigration Bill currently before Congress proposes to increase the number of H-1B work visas from the current 65,000 to approximately 180,000 applicants yearly,

WHEREAS there is currently no requirement for H-1B work visa applicants or their families, to receive any health screening.

WHEREAS many H-1B work visa applicants come from countries with high prevalence of tuberculosis (TB) and drug resistant TB,

WHEREAS ACET recommends that health screening for Tuberculosis and other communicable diseases for all H-1B work visa applicants and any family members prior to issuance of a H-1B visa be implemented overseas, by approved Panel Physicians, or in the U.S. by Civil surgeons, in compliance with the current Technical Instructions.

WHEREAS ACET further recommends that the cost of screening of

the H-1B work visa applicant and any family member(s) be borne by the company sponsoring the H-1B work visa applicant, and that prohibitions/restrictions on travel/migration be the same as applies to current immigrants based on health screening.

Be it now resolved that ACET recommends that:

- 1. H-1B work visa applicants be screened for TB and other communicable diseases in compliance with the current Technical Instructions prior to issuance of H-1B visa.**
- 2. CDC informs HHS Secretary Sebelius of this resolution and recommends that she take appropriate action to inform congressional members working on the Immigration reform bill.**

Dr. Seaworth seconded the resolution. **ACET unanimously approved the motion**, with no members abstaining. Dr. Cole gave special thanks to Dr. Benjamin, who was first to propose the resolution.

Dr. Seaworth presented two resolutions. The first was regarding bedaquiline. Dr. Seaworth read the resolution.

Bedaquiline, the first new class of drug to be approved for treatment of tuberculosis in over 50 years, was granted accelerated approval by the FDA in December 2012. On January 15, 2013 the CDC held a consultancy with external experts to develop guidelines for the use of this drug. These guidelines have passed through CDC clearance. ACET recommends that they be published immediately in the MMWR in order to provide guidance to programs and providers to ensure proper use of the drug in the correct patient populations, and to ensure proper monitoring.

Mr. Jones suggested the paragraph be split into two paragraphs starting at ACET. He then called for a second to the motion. Dr. Narita seconded the motion. The floor was opened for discussion.

Dr. Brenner asked if the resolution was proposed for the record or out of fear that the MMWR publication may be delayed. Dr. Seaworth said the cue for MMWR publications is very long and the resolution was part of what FDA instructed the company to do, which was to work with CDC to develop guidelines for the use of the drug. The drug is not yet available, and the resolution could expedite the process. Dr. Castro said the guidelines have been written and cleared by the Office of the Associate Director at CDC. Because of the cue in the MMWR, it would not be published until late October or November.

Ms. Cole supported the resolution but felt the cost would be a barrier because the manufacturer has mandated that 188 tablets must be purchased upfront, with a cost of approximately \$23,000. Dr. Castro advise Ms. Cole to reach out to the Treatment Action Group (TAG) or other outside advocates to bring the issue to the forefront.

Dr. Horsburgh, Jr. proposed that CDC put the resolution online, prepublication. Dr. Castro said it could be a plan-B effort or ACET could amend the resolution to say if immediate publication is not evident in the foreseeable future, consider posting online. Verbiage was added to the resolution as Dr. Castro prescribed.

Dr. Dorman asked if the guidelines has been vetted through the CDC process. Dr. Castro was pretty certain that the guidelines have been shared. The guidelines, however, are not co-authored by the expert panel according to the Federal Advisory Committee Act (FACA) Rules. Dr. Seaworth added that, as one of the consultants who was part of the development of the guidelines, comments were not shared with consultants. Dr. Baine advised adding the verbiage “ACET recommends that if immediate publication of the guidelines for using bedaquiline”.

Dr. Reichman felt the new drug alert was just as important as a new side effect publication and wondered if new drugs follow the same precedence. Dr. Castro replied the drug would be announced in some shape or form even if it did not make immediate publication in the MMWR.

Since physicians are not able to write prescriptions for bedaquiline, Dr. Tompkins wondered how the resolution would help. Dr. Seaworth had a patient who started on the drug in April and is still going through the Compassionate Use Process. The availability of the drug is resting on Janssen Therapeutics identifying a distributor and putting in place mechanisms for distribution. A consultation with experts is also still needed and extent guidelines for use labeling process has not occurred. Dr. Castro believed those were the only issues preventing physicians from writing prescriptions for the drug. Dr. Seaworth’s understanding was that guidelines and a registry was delaying the process. Dr. Castro will check with Dr. Mase for more information.

After a few minor edits, Dr. Seaworth re-read the resolution.

Bedaquiline, the first new drug to be approved for treatment of tuberculosis in over 50 years, was granted accelerated approval by the FDA in December 2012. On January 15, 2013 the CDC held a consultancy with external experts to develop guidelines for use of this drug. These guidelines have passed through CDC clearance.

ACET recommends that if immediate publication of the bedaquiline guidelines in the MMWR cannot accomplished, then they should be

published on line in order to provide guidance to programs and providers to ensure proper use of the drug in the correct patient populations, and to ensure proper monitoring.

The motion was seconded by Dr. Horsburgh, Jr. **ACET unanimously approved the motion**, with no members abstaining.

Dr. Seaworth then presented her second resolution. The resolution was developed in conjunction with Dr. Burgos and Mr. Dulin to support the work plan developed by the U.S.-Mexico Border TB Consortium.

Whereas the burden of tuberculosis is higher in the U.S.-Mexico Border Region than in any other region of either Mexico or the U.S.;

Whereas the U.S.-Mexico border region is an area with a high prevalence of drug-resistant TB that can easily be transmitted to persons in the US.;

Whereas, the U.S.-Mexico Border TB Consortium was established under the auspices of the U.S.-Mexico Border Health Commission, and whose members have developed a three-year operational work plan to implement a series of actions aimed at reducing barriers to successful treatment of TB in the binational border region;

Be it resolved that ACET embraces the efforts of the U.S.-Mexico Border TB Consortium and supports the implementation of its work plan as a basis to resolve binational TB issues and

Recommends that:

(1) CDC continue to identify opportunities to address tuberculosis control efforts along the U.S.-Mexico Border and

(2) Advises the Secretary of Health and Human Services reach out to her counterpart Secretary of Health in Mexico to advocate for Mexico's continued participation in the TB Consortium and support to implement the work group's operational plans and to allocate additional funding and technical assistance to support activities included in the TB Consortium Work Group Operational Plan.

Mr. Jones asked if items in the "be it resolve" section would be incorporated into the body of the resolution. The Secretary, according to Dr. Seaworth, was being asked to support the efforts and not CDC. Mr. Jones asked for a second to the motion. Dr. Burgos seconded the motion. The floor was opened for discussion.

Dr. Elson felt it was more appropriate for ACET to advise the Secretary, since it is part of the ACET Charter and to remove “allocate funding” because that is a function of Congress.

Dr. Narita asked if the statement in the first sentence was supported by data. Dr. Seaworth confirmed it to be accurate. Dr. Baine made minor editing suggestions.

With no further discussions, Mr. Jones asked Dr. Seaworth to re-read the resolution proposed.

Whereas the burden of tuberculosis is higher in the U.S.-Mexico Border Region than any other region of either Mexico or the U.S.;

Whereas the U.S.-Mexico border region is an area with a high prevalence of drug-resistant TB that can easily be transmitted to persons in the US.;

Whereas, the U.S.-Mexico Border TB Consortium was established under the auspices of the U.S.-Mexico Border Health Commission, and whose members have developed a three-year operational work plan to implement a series of actions aimed at reducing barriers to successful treatment of TB in the binational border region;

Be it resolved that ACET embraces the efforts of the U.S.-Mexico Border TB Consortium and supports the implementation of its work plan as a basis to resolve binational TB issues and

Recommends that:

(1) CDC identify opportunities to address tuberculosis control efforts along the U.S.-Mexico Border and

(2) the Secretary of Health and Human Services reach out to her counterpart Secretary of Health in Mexico to advocate Mexico’s continued participation in the TB Consortium and support implementation of the operational plan and

(3) the Secretary of Health and Human Services recommend allocation of additional resources and technical assistance to support activities included in the TB Consortium Work Group Operational Plan.

Mr. Jones called for a second. Dr. Burgos seconded the motion. **ACET unanimously approved the motion**, with no members abstaining.

Dr. Dorman presented the Drug Shortage Resolution. The resolution was developed, in consultation with Drs. Jennifer Flood and Sundari Mase to strengthen their activities, in ensuring a continuous and affordable supply of anti-tuberculosis drugs. Dr. Dorman read the resolution.

Recommendations to ensure a continuous and affordable supply of anti-tuberculosis drugs

The members of the Advisory Council for the Elimination of Tuberculosis (ACET),

Determined to eliminate tuberculosis (TB) in the United States;

Cognizant of the actions taken to date by the Centers for Disease Control and Prevention (CDC) Department of Tuberculosis Elimination (DTBE) to assess the extent and impact of shortages of anti-tuberculosis drugs;

Seriously concerned that the shortage of anti-tuberculosis drugs persists without resolution;

Alarmed especially that the shortage presently encompasses isoniazid, a critical component of the standard regimen for treatment of tuberculosis;

Recognizing that longer-term strategies to prevent shortages are required in addition to the ongoing drug-by-drug stopgap measures

Have agreed, as follows:

We encourage the Secretary of Health and Human Services to support activities towards ensuring a continuous and affordable supply of anti-tuberculosis drugs. Consideration should be given to establishment of a dedicated team to address this issue, intensification of activities to prevent drug shortages, and pursuit of regulatory changes that will facilitate a stable drug supply. Strong consideration should be given to pursuit of a centralized procurement and distribution system for anti-tuberculosis drugs.

The resolution was in concordance with a white paper developed by Drs. Flood and Mase' team.

Mr. Jones suggested the language "we recommend" be replaced by "we encourage". He then asked for a second to the motion. Dr. Seaworth seconded the motion. The floor was opened for discussion.

Dr. Seaworth felt the resolution was a step in the right direction for MDR drugs. She reported on the model used for Texas, which has a central procurement for INH, and, therefore, the state experienced no drug shortages. Pharmacies were made aware of potential drug shortages long before CDC announced them and had developed strategic plans to dealing with the matter. A notice was provided in a recent Lancet article, which said the Global Drug Facility provided data showing a significant decrease in cost of TB drugs, since developing a single procurement agency to purchase drugs.

Dr. Warkentin thought it would have been helpful, if Drs. Flood and Mase provided the white paper to the ACET prior to the committee making a decision; albeit, he felt there would be broad support for the resolution. Dr. Seaworth said her understanding was the paper was proposed but has not been written. Dr. Castro confirmed it is being worked on.

Dr. Dorman noted biologics were not included in the resolution, which was by intent, since the real issue is drugs.

With no further discussion and a motion properly seconded by Dr. Seaworth, **ACET unanimously approved the motion**, with no members abstaining. The resolution will read as follows:

Recommendations to ensure a continuous and affordable supply of anti-tuberculosis drugs

The members of the Advisory Council for the Elimination of Tuberculosis (ACET),

Determined to eliminate tuberculosis (TB) in the United States;

Cognizant of the actions taken to date by the Centers for Disease Control and Prevention (CDC) Department of Tuberculosis Elimination (DTBE) to assess the extent and impact of shortages of anti-tuberculosis drugs;

Seriously concerned that the shortage of anti-tuberculosis drugs persists without resolution;

Alarmed especially that the shortage presently encompasses isoniazid, a critical component of the standard regimen for treatment of tuberculosis;

Recognizing that longer-term strategies to prevent shortages are required in addition to the ongoing drug-by-drug stopgap measures

Have agreed, as follows:

ACET recommends that the Secretary of Health and Human Services support activities towards ensuring a continuous and affordable supply of anti-tuberculosis drugs. Consideration should be given to establishment of a dedicated team to address this issue, intensification of activities to prevent drug shortages, and pursuit of regulatory changes that will facilitate a stable drug supply. Strong consideration should be given to pursuit of a centralized procurement and distribution system for anti-tuberculosis drugs.

Dr. Horsburgh, Jr. presented the ACA Resolution to ACET. It reads as follows:

Whereas the Affordable Care Act (ACA) offers unprecedented opportunity to increase insurance coverage, access to care, and to increase healthcare quality, providing critical services to uninsured and high-risk populations will remain challenging;

Whereas the focus to date in ACA to address chronic diseases is warranted given the burden and cost associated with them, it will be important to assure that efforts to prevent transmission of communicable diseases, such as tuberculosis (TB), which can threaten a community's well-being, are not compromised by changes in care systems;

Therefore, ACET urges the Secretary of Health and Human Services to require that CDC, CMS, HRSA, and other relevant federal agencies work together to develop an operational framework for assuring the ongoing adequacy of the safety net for addressing communicable diseases of public health significance.

Mr. Jones called for a second to the motion. Ms. Cole seconded the motion. The floor was opened for discussion.

Dr. Narita felt it admirable to include other communicable disease but wondered if the focus should remain solely on TB. The committee was queried the committee for comments. Dr. Burgos and Ms. Cole believed the wording TB and other communicable disease should be used, since TB is the charge of ACET. Mr. Dulin asked for the insertion of the Assistant Secretary for Preparedness and Response (ASPR), as an additional agency, since the agency is also a major player in communicable disease outbreaks. Dr. Baine again offered minimal edits.

With no further discussion and a motion properly seconded by Dr. Narita, **ACET unanimously approved the motion**, with no members abstaining. The resolution will read as follows:

Whereas the Affordable Care Act (ACA) offers unprecedented opportunity to increase insurance coverage, access to care, and healthcare quality, providing critical services to uninsured and high-risk populations will remain challenging;

Whereas the focus to date in ACA to address chronic diseases is warranted given the burden and cost associated with them, it will be important to assure that efforts to prevent transmission of tuberculosis (TB) and other communicable diseases, which can threaten a community's well-being, are not compromised by changes in care systems;

Therefore, ACET urges the Secretary of Health and Human Services to require that CDC, CMS, HRSA, ASPR, and other relevant federal agencies work together to develop an operational framework for assuring the ongoing adequacy of the safety net for addressing TB and other communicable diseases of public health significance.

Ms. Cole presented the reformatted ACET Resolution presented, from day one. It read as follows:

ACET Resolution

WHEREAS, accurate TB testing of medium- and high-risk persons is essential to TB elimination in the US, and

WHEREAS, the accuracy and positive predictive value of any assay decreases significantly in populations with low prevalence of TB infection, and

WHEREAS, Interferon Gamma Release Assay (IGRA) reversion has been commonly observed and frequently reported in low-risk (unexposed) healthcare workers undergoing serially testing, and

WHEREAS, false-positive results can lead to unnecessary medical evaluation or treatment, and

WHEREAS, it is recognized that the low-risk individuals should not be undergoing such TB testing, and

WHEREAS, over testing of low-risk persons can lead to misdiagnosis and waste of national healthcare dollars, so

BE IT RESOLVED, that ACET advises the CDC to convene an expert working group to urgently address the following by priority:

1. *Management guidelines to address the variability observed in serial testing using IGRAs among low risk or unexposed adults, who are included in a mandatory TB screening program*
2. *Stratification guidelines for HCWs based on the levels of TB exposure for the purpose of determining the need for serial testing*
3. *Consideration of a retesting zone for low risk or unexposed individuals undergoing TB screening currently recommended by state law or local, state and national TB guidelines.*

Mr. Jones called for a second to the motion. It was seconded by Dr. Seaworth. The floor was opened for discussion.

Dr. Burgos expressed concerns over the amount of false positives associated with IGRAs and suggested the proposed team, of experts recommended in the resolution, make the stratification of the guidelines. The issue, he felt, was outside of the expertise of the ACET. Dr. Dorman concurred with Dr. Burgos and believed the scope of what ACET was to recommend was unclear. Should the focus be on healthcare workers or should the vision be more broader? Dr. Narita thought the context of how TB experts was expressed sounded more like a partnership with an occupational workforce. Ms. Bur believed it is becoming unethical to treat bacilli Calmette-Guerin (BCG)-vaccinated individuals, who test positive on a PPD.

Mr. Desmond said the public health department works with IGRAs and are very often asked to make an interpretation, which puts the health department in an awkward situation. Therefore, he strongly supports the formation of the proposed working group and looked forward to its recommendations.

Dr. Warkentin said the statement in bullet three must be based on the science and any scientific gathering around the issue or development of guidelines not be subject to a group convened by one of the manufacturers. Furthermore, the second bullet puts into questioning the guidelines published in 2005 regarding testing of healthcare workers. What may need to occur, he suggested, is a revision to the 2005 guidelines, in light of new technologies.

Dr. Thanassi thanked Mr. Desmond for his comment and concurred with his opinions. She also thanked Dr. Warkentin for suggesting that the proposed panel be independent of any industry influence. Dr. Thanassi reminded the group that the resolution was crafted, in part, due to the findings she presented on day one. ACET, she said, was the perfect mechanism to make recommendations regarding healthcare workers not being stratified. Ms. Cole said the committee would look at the issues, but an expert panel should make the decisions.

Dr. Narita preferred that healthcare worker still be spelled out. Ms. Cole felt that leaving the resolution to read among low risk or unexposed adults, would still encompass that group. Mr. Desmond suggested the addition of “consideration” be added to bullet two and three

Dr. Brenner pondered if it would be easier for DTBE to conduct the panel in-house versus turning to outsiders. Dr. Castro said DTBE would use its normal approach by turning to experts and not convening panel on its own.

Dr. Baines once more made minimal edits.

Ms. Cole reread the revised document. The document read as follows:

ACET Resolution

WHEREAS, accurate TB testing of medium- and high-risk persons is essential to TB elimination in the US, and

WHEREAS, the accuracy and positive predictive value of any assay decreases significantly in populations with low prevalence of TB infection, and

WHEREAS, Interferon Gamma Release Assay (IGRA) reversion has been commonly observed and frequently reported in low-risk (unexposed) healthcare workers undergoing serially testing, and

WHEREAS, false-positive results can lead to unnecessary medical evaluation or treatment, and

WHEREAS, it is recognized that the low-risk individuals should not be undergoing such TB testing, and

WHEREAS, over testing of low-risk persons can lead to misdiagnosis and waste of national healthcare dollars, so

BE IT RESOLVED, that ACET advises the CDC to convene an expert working group to urgently address the following:

- 1. Management guidelines to address the variability observed in serial testing using IGRAs among low risk or unexposed adults, who are included in a mandatory TB screening program*
- 2. Consideration of Stratification guidelines for HCWs based on levels of TB exposure for the purpose of determining the need for serial testing*

3. *Consideration of a retesting zone for low risk or unexposed individuals undergoing TB screening currently recommended by state law or local, state and national TB guidelines.*

The motion was seconded by Dr. Seaworth. **ACET unanimously approved the motion**, with no members abstaining.

Dr. Dorman introduced a letter proposed by Ms. Bur to the Secretary of Health and Human Services highlighting the necessity of preserving capacity for treatment at both the individual and public health level for TB. Dr. Dorman suggested that the letter should be circulated among ACET for revisions and edits offline and then sent forward through the appropriate mechanisms. Dr. Dean made the committee aware that ACET is not allowed to conduct ACET business offline but that it could convene a work group. Therefore, Dr. Dorman therefore made the motion that ACET convene a work group to develop a letter directed to the Secretary of the Department of Health and Human Services addressing more largely the potential impact of funding cuts on TB programs. Ms. Cole seconded the motion. Mr. Jones opened the floor for discussion.

Dr. Narita suggested the addition of Dr. Frieden's name to the letter. Dr. Dorman said the work group would be responsible for determining additions and then ACET could review the revisions and edits at the October meeting.

With no further discussion, Mr. Jones called for a vote. **ACET unanimously approved the motion**, with no members abstaining. Mr. Jones appointed Drs. Dorman and Horsburgh, Jr. to form the committee and present the finalized document at the October meeting.

CONTINUATION OF POTENTIAL BUSINESS ITEMS:

Special recognition and plaques were presented to members rotating off the committee, by Dr. Dean, with the exception of Dr. Dorman, who will stay on the committee until a replacement has been identified.

Dr. Horsburgh, Jr. reminded ACET of Dr. Warkentin's request to look at the Essential Components of the Prevention Control Program statement and to consider updating it. He wondered if a work group should be convened to examine the document. Mr. Jones suggested the topic be submitted to the Agenda Review Committee, as a possible item for the October meeting. Dr. Castro clarified his understanding of Dr. Horsburgh's request, which was to either convene a working group to have already examined the document and report its findings at the next meeting or have the Agenda Review Committee consider it as an item to be added to the agenda.

Dr. Brenner made the motion that ACET put together a work group to address revising the Essential Components of the Prevention Control Program

document. The motion was seconded by Dr. Horsburgh, Jr. **ACET unanimously approved the motion**, with no members abstaining.

Mr. Jones asked for volunteers for the work group. Drs. Brenner, Burgos and Ms. Cole volunteered to be a part of the work group.

Ms. Cole asked if resolutions could be shared once they have passed. She would attend an upcoming meeting and would like to present the resolution. Dr. Dean replied the meeting is open to the public; therefore, it should not present a problem.

Mr. Jones solicited the committee for additional items to be considered for the Agenda Committee. The following were proposed.

- IGRAs and the changing landscape with an emphasis on correctional facilities
- Understanding the timeframe for reviewing and updating previous recommendations to develop a current set of guidance. What is up to date? What needs to be changed? What is the timeline and work plan of ACET for advancing changes?
- Essential Components and funding reductions
- More transparency in forthcoming guidelines with representation from appropriate groups, like NTCA
- Screening and Management of TB in Foreign-Born Populations and Prevention of TB in Humanitarian Workers guidance documents
- Ways for ACET to update existing policies and address new policies

Dr. Trump inquired about missing minutes on the website. To DTBE's knowledge, the website did contain all the approved minutes, but staff will make sure any missing items are made available.

PUBLIC COMMENT

The floor was open for public comments. Mr. Jerry (Mazverk) commended the committee on a job well done. No other comments were expressed.

MEETING ADJOURNMENT

Dr. Dean conducted a final roll call. Quorum was present.

Mr. Jones thanked all the participants for joining and helping to facilitate a productive meeting. He also thanked ACET for allowing him to serve the committee, as Chair, and wished other members leaving the committee much success, in their roles. Ms. Scott-Cseh and her staff were acknowledged and shown appreciation, for their hard work.

With no additional comments or questions posed, Mr. Jones adjourned the meeting at 2:19 PM.

CERTIFICATION

I hereby certify that, to the best of my knowledge and ability, the foregoing minutes of the June 4-5, 2013, 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 June 4-5, 2013, at the beginning of the meeting and when the group reconvened from breaks. She verified the presence of a quorum for ACET voting members and ex officio members sufficient for ACET to conduct its business.

ACET Members

Mr. Shannon Jones III, Chair
Dr. Eric Brenner
Dr. Marcos Burgos
Ms. Barbara Cole
Dr. Susan Dorman
Dr. C. Robert Horsburgh, Jr.
Dr. Masahiro Narita
Dr. Barbara Seaworth

ACET Designated Federal Officer

Dr. Hazel Dean, NCHHSTP Deputy Director

ACET Ex Officio Members

Dr. Naomi Aronson (Department of Defense, Uniformed Services)
Dr. William B. Baine (Agency for Healthcare Research and Quality)
Ms. Sarah Bur (Federal Bureau of Prisons)
Dr. Rupali Doshi (HIV/AIDS Bureau)
Ms. Lisa Delaney (alternate, National Institute for Occupational Safety and Health)
Mr. Paul Dulin (sitting in for Dr. Antonio Falcon)(U.S.-Mexico Border Health Commission)
Ms. Caroline Freeman (Office of Biologic Hazards)
Dr. Diana Elson (US Immigration and Customs Enforcement)
Dr. J. Nadine Garcia (Office of Minority Health, HHS)
Dr. Warren W. Hewitt, Jr. (Substance Abuse and Mental Health Administration)
Dr. Momodikoe Makhene (National Institute of Allergy and Infectious Diseases)
Ms. Tiffany Moore (United States Marshals Service)
Dr. Sheldon Morris (Food and Drug Administration)
Dr. Gary Roselle (Department of Veteran Affairs)
Dr. David Weissman (National Institute for Occupational Safety and Health)

ACET Liaison Members

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

Mr. Eddie Hedrick (Association for Professionals in Infection Control and Epidemiology)
Ms. Cornelia Jervis (Treatment Action Group)
Dr. Ilse Levin (American Medical Association)
Ms. Eileen Napolitano (Stop TB USA)
Dr. Edward Desmond (Association of Public Health Laboratories)
Dr. Susan M. Ray (Infectious Disease Society of America)
Dr. Lee Reichman (Global Tuberculosis Institute)
Dr. Lornel Tompkins (National Medical Association)
Dr. David Trump (Council of State and Territorial Epidemiologists)
Dr. Jon Warkentin (alternate, National Tuberculosis Controllers Association)

CDC Representatives

Dr. Kenneth Castro, Director, Division of Tuberculosis Elimination, NCHHSTP
Mr. Glen Christie
Ms. Margie Scott-Cseh
Mr. Philip Talboy
Ms. Wanda Walton
Dr. Beverly Metchock
Dr. John Jereb
Dr. Michael Iademarco
Dr. Eugene McCray
Dr. Andy Vernon
Ms. Susan Robinson
Ms. Michelle Russell
Mr. Angel Roca
Ms. Ann Lanner
Dr. Salaam Semaan
Dr. Krista Powell
Dr. Drew Posey
Ms. Anne Marie France
Mr. Mark Miner
Ms. Amera Khan
Ms. Kim Young
Dr. Tom Navin
Ms. Suzanne Marks
Mr. Gustavo Aquino
Dr. John Douglas
Ms. Angela Starks
Ms. Maria Fraire Sessions
Dr. Christina Ho
Mr. Jerry Mazvach
Mr. Weigong Zhou
Dr. Awal Khan
Ms. Brandy Peterson
Dr. Stuart Berman

Ms. Haley Stolp
Ms. Michele Pearson
Ms. Rozina Kassam
Ms. Lauren Lambert
Ms. Maureen McDermott
Ms. Demetria Gardner
Ms. Reque Miranda
Ms. Rebekah Turner
Ms. Aril Adiqu
Ms. Alison Footman
Ms. Adren Heathers
Ms. Smita Wosh
Ms. Ann Lamar
Ms. Eva Margolies
Mr. Bob Pratt

Members of the Public

Ms. Catherine Cairns (Association of State and Territorial Health Officials)
Ms. Candrea Cherry (Marshall Service)
Ms. Denise Dodge (VA Department of Health)
Dr. Michael Fleenor (Jefferson County Department of Health)
Dr. Wendy Thanassi (Veterans Health Administration)
Dr. Jennifer Flood (National Tuberculosis Controllers Association)
Ms. Donna Wegner (National Tuberculosis Controllers Association)
Mr. John Lozier (National Health Care for the Homeless Council)

Attachment #2: Acronyms Common to the Division of Tuberculosis Elimination

Acronym	Expansion
ACA	Affordable Care Act
ACET	Advisory Council for the Elimination of Tuberculosis
ACIP	Association for Professionals in Infection Control and Epidemiology
ACTG	AIDS Clinical Trials Group
AFB	Acid-Fast Bacilli
AIDAC	Anti-Infective Drugs Advisory Committee
AMA	American Medical Association
APHL	Association of Public Health Laboratories
ART	Antiretroviral Therapy
ASPR	Assistant Secretary for Preparedness and Response
ASTHO	Association of State and Territorial Health Officials
BCG	Bacille Calmette-Guerin (vaccination)
BMGF	Bill and Melinda Gates Foundation
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	Consulorios 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
CTCA	California Tuberculosis Controllers Association
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
FQ	Fluoroquinolone
FQHC	Federally Qualified Health Center
FY	Fiscal Year
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
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
NHCHC	National Health Care for the Homeless Council
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
NTCA	National Tuberculosis Controllers Association
NTIP	National Tuberculosis Indicators Project
NTM	Non-Tuberculous Mycobacteria
NTNC	National Tuberculosis Nurse Coalition
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
PHL	Public Health Laboratory
POW	Prisoner of War
PPD	Purified Protein Derivative
PPV	Positive Predictive Value
PZA	Pyrazinamide
QFT	QuantiFERON-TB test
RIPE	Rifampin, Isoniazid, Pyrazinamide, and Ethambutol
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
TBRTMCCs	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
VHA	Veterans Health Administration
WHO	World Health Organization
WTST	Working Together to Stop TB
XDR-TB	Extensively Drug-Resistant Tuberculosis