

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



**Virtual Meeting of the
Advisory Council for the Elimination of Tuberculosis
April 16, 2019**

Record of the Proceedings

TABLE OF CONTENTS

| | <u>Page</u> |
|--|-------------|
| Minutes of the Virtual Meeting | 1 |
| Opening Session..... | 1 |
| DTBE Director’s Report..... | 3 |
| Overview of TB Care for ICE Detainees | 5 |
| NCHHSTP Director’s Report..... | 9 |
| Electronic Case Reporting (eCR) and the Digital Bridge | 12 |
| Overview of the Infrastructure and Mechanisms to Develop, Update, and Maintain HIV Guidelines | 13 |
| Congregate Settings Workgroup Closeout Report..... | 15 |
| Update by the Essential Components Workgroup | 16 |
| Update by the TB Drug Supply Workgroup | 17 |
| Update by the LTBI Workgroup..... | 19 |
| Child and Adolescent Workgroup Closeout Report | 21 |
| ACET Business Session | 21 |
| Business Item 1: Approval of Previous ACET Meeting Minutes | 21 |
| Business Item 2: ACET’s Draft Report to the HHS Secretary—2019 | 22 |
| Business Item 3: ACET’s Feedback on the Effectiveness of Video Conferencing..... | 23 |
| Business Item 4: ACET’s Response to the “Public Charge” Rule | 23 |
| Business Item 5: Advice Requested from ACET..... | 24 |
| Business Item 6: Future Agenda Items..... | 25 |
| Public Comment Session | 26 |
| Closing Session | 26 |
| Attachment 1: Participants’ Directory | 28 |
| Attachment 2: Glossary of Acronyms..... | 31 |



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

**ADVISORY COUNCIL FOR THE ELIMINATION OF TUBERCULOSIS
April 16, 2019**

Minutes of the Virtual Meeting

The U.S. Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC), National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP), Division of Tuberculosis Elimination (DTBE) convened a virtual meeting of the Advisory Council for the Elimination of Tuberculosis (ACET). The proceedings were held on April 16, 2019 beginning at 10:00 a.m. EST.

ACET is formally chartered under the Federal Advisory Committee Act (FACA) to provide advice and recommendations to the HHS Secretary, HHS Assistant Secretary for Health, and CDC Director regarding the elimination of tuberculosis (TB). The charter authorizes ACET to make recommendations regarding policies, strategies, objectives and priorities; address the development and application of new technologies; provide guidance and review on CDC's TB Prevention Research portfolio and program priorities; and review the extent to which progress has been made toward TB elimination.

Information for the public to attend the virtual ACET meeting via webinar or teleconference was published in the *Federal Register* in accordance with FACA regulations and rules. All sessions of the meeting were open to the public (*Attachment 1: Participants' Directory*).

Opening Session

Hazel Dean, ScD, DrPH (Hon), MPH, FACE

Deputy Director, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
ACET Designated Federal Officer (DFO)

Dr. Dean conducted a roll call to confirm the attendance of the ACET voting members, *ex-officio* members, and liaison representatives. She announced that ACET meetings are open to the public and all comments made during the proceedings are a matter of public record. She informed the ACET voting members of their responsibility to disclose any potential individual

and/or institutional conflicts of interest for the public record and recuse themselves from voting or participating in these matters.

| ACET Voting Member (Institution/Organization) | Potential Conflict of Interest |
|---|---|
| Ana Alvarez, MD, FAAP (University of Florida, College of Medicine) | No conflicts disclosed |
| Lisa Armitige, MD, PhD (Heartland National Tuberculosis Center) | No conflicts disclosed |
| Robert Belknap, MD (Denver Metro Tuberculosis Control Program) | No conflicts disclosed |
| Barbara Cole, RN, MSN, PHN (Riverside County Department of Public Health) | No conflicts disclosed |
| Jennifer Flood, MD, MPH (California Department of Public Health) | No conflicts disclosed |
| David Horne, MD, MPH (University of Washington School of Medicine) | No conflicts disclosed |
| Robert Horsburgh, Jr., MD, MUS (Boston University School of Public Health) | No conflicts disclosed |
| Lixia Liu, PhD, MP, (ASCP), D(ABMM) (New Mexico Department of Health) | Recipient of federal funding from CDC for the TB Cooperative Agreement (CoAg) |
| Jeffrey Starke, MD (Baylor College of Medicine) | Member of the Otsuka Pharmaceutical Company Data Safety Monitoring Board for pediatric studies of Delamanid |
| Zelalem Temesgen, MD (Mayo Clinic Center for Tuberculosis) | No conflicts disclosed |

Dr. Dean confirmed that the 21 voting members and *ex-officio* members in attendance constituted a quorum for ACET to conduct its business on April 16, 2019. She called the proceedings to order at 10:00 a.m. EST and welcomed the participants to the virtual ACET meeting.

Dr. Dean made several announcements regarding the changes that have occurred in ACET's membership since the previous meeting in December 2018.

- The participants were asked to welcome two new ACET members to their first meeting.
 - Letha Healey, MD is the Chief Medical Officer for the Office of Training Capacity and Development, Division of Domestic HIV Programs at the Health Resources and Services Administration (HRSA), HIV/AIDS Bureau. She was designated as ACET's new *ex-officio* member for HRSA.
 - Daphne Ware, PhD is the Clinical Services Director of the Mississippi Public Health Laboratory. She was designated at ACET's new liaison representative to the Association of Public Health Laboratories.
- CDC sent a letter to the National Association of County and City Health Officials with a request to identify a new liaison representative to replace Dr. Robert Benjamin. Dr. Benjamin is now serving on ACET as a liaison to Stop TB USA.
- CDC sent a letter to the HHS Office of Minority Health with a request to identify a new *ex-officio* member to replace Dr. Matthew Lin.

- CDC sent a letter to the Agency for Healthcare Research and Quality, dated August 16, 2018, with a request to identify a new *ex-officio* member to replace Ms. Kali Crosby.
- CDC sent a letter to the HHS Office of Global Affairs, dated August 25, 2018, with a request to identify a new *ex-officio* member for the U.S. Section of the U.S.-Mexico Border Health Commission.

Barbara Cole, RN, MSN, PHN, ACET Chair

TB Controller

Riverside County (California) Department of Public Health

Ms. Cole also welcomed the participants to the virtual ACET meeting. She noted that the final agenda for the April 16, 2019 meeting was distributed to the members with a few minor changes. She concluded her opening remarks by reviewing the key agenda items.

DTBE Director's Report

Kathryn Koski, MEd, MPH

Deputy Director, Division of Tuberculosis Elimination

Centers for Disease Control and Prevention

Carla Winston, PhD, MA

Associate Director for Science, Division of Tuberculosis Elimination

Centers for Disease Control and Prevention

Ms. Koski and Dr. Winston presented the DTBE Director's report to ACET in the absence of Dr. Philip LoBue. They covered three key topics in the update: (1) the President's FY2020 proposed budget; (2) provisional 2018 TB surveillance data for the United States; and (3) the status of recent TB guidelines.

CDC's FY2019 BUDGET

The President's FY2020 proposed budget for domestic TB activities reflects a level appropriation of approximately \$135 million and the realignment of approximately \$7 million to the Center for Global Health for international TB activities. The President's FY2020 proposed budget is awaiting Congressional appropriation bills.

PROVISIONAL 2018 TB SURVEILLANCE DATA

The provisional 2018 TB data for the United States that were reported to the CDC National TB Surveillance System as of February 11, 2019 are highlighted as follows. The TB case count decreased from 9,094 cases in 2017 to 9,029 cases in 2018 (or a reduction of 0.71 percent over the past year). The associated TB incidence rate decreased from 2.80 cases per 100,000 people in 2017 to 2.76 cases per 100,000 people in 2018 (or a reduction of 1.33 percent over the past year).

The number of TB cases in the United States has decreased over time from 11,095 cases in 2010 to 9,029 cases in 2018. The TB incidence rate in the United States also has decreased over time from 3.59 cases per 100,000 people in 2010 to 2.76 cases per 100,000 people in 2018. Both the TB case count and TB incidence rate reported in 2018 reflect the lowest numbers reported in U.S. history. However, the average annual decline in the TB incidence rate

has slowed from 4.75 percent per year from 2018-2013 to 1.65 percent per year from 2014-2018.

The states with the highest number of reported TB cases in 2018 were California (2,091 cases), Texas (1,129 cases), New York (750 cases), and Florida (591 cases). These four states have consistently accounted for over 50 percent of all TB cases reported in the United States for the past 20 years.

TB incidence rates by state, including the District of Columbia, were categorized into three groups in 2018: (1) less than or equal to 1.4 cases per 100,000 people (the 2020 national target); (2) greater than 1.4 cases, but less than 2.8 cases per 100,000 people (the national rounded rate); and (3) greater than or equal to 2.8 cases per 100,000 people (above the national average). TB incidence rates that exceeded the national average in 2018 ranged from 2.8 to 8.5 cases per 100,000 people in 11 states: Alaska, California, the District of Columbia, Florida, Hawaii, Maryland, Massachusetts, Minnesota, New Jersey, New York, and Texas.

TB incidence rates by country of birth have declined in both U.S.-born people/populations (USBP) and non-USBP from 1993-2018. However, the proportion of TB cases among non-USBP has been steadily increasing since 1993. USBP accounted for 29.5 percent of TB cases in 2018, while non-USBP accounted for 69.5 percent of cases. By race/ethnicity, Native Hawaiian/Pacific Islanders, American Indians/Alaska Natives, and non-Hispanic Blacks accounted for the highest TB incidence rates among USBP in 2018. Asians, Native Hawaiian/Pacific Islanders, and non-Hispanic Blacks accounted for the highest TB incidence rates among non-USBP in 2018.

By congregate settings, the percentage of TB cases in 2017 was 4.1 percent among people who reported homelessness, 3.3 percent among people in correctional facilities, and 1.6 percent among residents of long-term care facilities. The percentage of TB cases with HIV co-infection decreased to 8.6 percent among people 25-44 years of age and 5.3 percent among people of all ages. Of 128 multidrug-resistant TB (MDR-TB) cases reported in 2017, non-USBP accounted for 110 cases. Of MDR-TB cases, 26 self-reported a prior history of TB. Non-USBP accounted for all three extensively drug-resistant TB cases reported in 2017. Of these cases, one self-reported a priority history of TB.

TB GUIDELINES

The draft *Healthcare Personnel TB Screening and Testing Guidelines* were presented to ACET in April 2018 and have since been cleared and accepted by the *Morbidity and Mortality Weekly Report (MMWR)* for publication in May 16, 2019. The draft *Drug-Resistant TB Treatment Guidelines* were presented to ACET in December 2018 and have been peer reviewed by the professional society co-authors. The CDC clearance process will be initiated after the peer review process is completed. The draft *Latent TB Infection Treatment Guidelines* were presented to ACET in December 2018 and will undergo a review by the National Tuberculosis Association (NTCA) and the CDC clearance process.

Overview of TB Care for ICE Detainees

CAPT Diana Elson, DrPH, MA

ICE Health Service Corps
Public Health, Safety, and Preparedness Unit
ACET *Ex-Officio* Member

Dr. Elson presented an overview of TB care for U.S. Immigration and Customs Enforcement (ICE) detainees and the flow of detainees through U.S. Department of Homeland Security (DHS) custody.

- For people who are apprehended by and are in custody of the U.S. Customs and Border Protection (CBP), a law enforcement officer or agent conducts a health interview at the border patrol station or port of entry. If the border station has medical staff on-site, a medical assessment is conducted if the person is less than 18 years of age and for adults if findings are observed during the health interview. Basic and acute medical care or a referral is provided to community hospitals. These findings are reported to the local and/or state health department by health care staff at the point of care.
- ICE processing is conducted for administrative immigration proceedings and removal. People who are in ICE custody are detained in detention facilities that are for single adults or family units. The intake process includes medical and mental health screening, including; TB screening; routine health care also includes a health assessment within 14 days; sick calls; and chronic, dental, and mental health care.
- Interior apprehension occurs after local, state, or federal criminal charges are resolved by other criminal justice system.
- Some people may be apprehended by CBP, processed by ICE at the border, and given a notice to appear in immigration court without being detained by ICE in a detention facility; these people may be released until their final disposition of “release” or “removal.”

The types of facilities within the ICE detention health care system are highlighted below.

- A service processing center is owned by the government and staffed by a combination of federal and contract employees. The medical authority for these facilities is the ICE Health Service Corps (IHSC).
- A contract detention facility is owned by a private company and contracted directly with the government. The medical authority for these facilities is IHSC, a private facility operator, or a subcontracted medical authority.
- An intergovernmental service agreement (IGSA) is operated by state/local governments or a private company that has contracted with the state/local government. These facilities might house detainees, prisoners, and inmates for multiple law enforcement agencies. The medical authority for these facilities is a local jurisdiction, private facility operator, or subcontracted medical authority.
- A dedicated IGSA only houses ICE detainees. The medical authority for these facilities is IHSC, a local jurisdiction, private facility operator, or subcontracted medical authority.

- A family residential center allows families to remain together while awaiting their proceedings. The medical authority for these facilities is IHSC, a private facility operator, or subcontracted medical authority.
- A U.S. Marshals Service (USMS) intergovernmental agreement (IGA) allows ICE to utilize an existing USMS IGA. The medical authority for these facilities is a local jurisdiction, private facility operator, or subcontracted medical authority.
- A USMS contract detention facility is a private facility contracted with USMS. The medical authority for this single facility is a private facility operator or subcontracted medical authority.
- The Federal Bureau of Prisons operates and manages three facilities. A staging facility is used for staging purposes. The medical authority for these facilities is IHSC.

IHSC is the medical authority for 22 detention and staging facilities that account for approximately 16,000 detainees per day on average. IHSC official guidance is intended for IHSC-staffed medical clinics. IHSC staff is responsible for IHSC protocols, policies, and clinical care. Local jurisdictions, private facility operators, or subcontracted medical authorities are responsible for approximately 200 local jails and detention facilities that account for approximately 30,000 detainees per day on average. These facilities frequently house detainees, inmates, prisoners for multiple jurisdictions and law enforcement agencies. The facility's medical authority is responsible for its protocols, policies, and clinical care.

All facilities that house ICE detainees longer than 72 hours operate under a set of ICE detention standards. These health systems rely on community resources for specialty referrals and hospitalizations. Because each facility has a limited number of respiratory isolation cells, community hospitals and local health departments are critical partners in evaluating and managing detainees. Each facility is accountable to contracts and IGSA's that designate a specific set of ICE detention standards. These standards are available on the ICE Detention Management website.

IHSC implements CDC's guidance in four major areas to ensure the successful management of TB care for detainees in custody in its 22 facilities.

- Prompt screening is performed for the identification of TB disease, airborne infection isolation, and clinical management. The tuberculin skin test (TST) or interferon gamma release assay (IGRA) is used in the screening protocol. ICE has designated the use of a chest x-ray (CXR) to test for TB disease as a best practice. All patients with positive single view CXRs will have two to three views to confirm. If two or three view CXRs are negative, the detainee will be released to general population without further evaluation except if the single view finding was in the upper lobe.
- Early management and treatment are provided to ensure appropriate care for the patient as well as to prevent transmission to other detainees, staff, and the public in the United States and foreign communities. IHSC developed a rigorous algorithm for suspected and confirmed pulmonary TB cases, including (1) detainees in the initial management phase who require no further work-up and can be cleared for placement in the general population or travel and (2) detainees with symptoms at screening and radiographic findings. Providers review all abnormal upper lobe single view and abnormal confirmatory CXR reports (i.e., two to three views) against Appendix B in the TB screening and early management algorithm.

- Release planning leverages established relationships with federal, state, local, and community partners and to ensure clear and frequent communication.
- Contact investigations often involve multiple facilities and jurisdictions.

IHSC issues official guidance, clinical guidelines, and public health actions for TB care for implementation in the 22 detention and staging facilities where IHSC operates the medical clinic. The intake screening process frequently includes a CXR as the primary method of TB screening. Airborne infection isolation is available onsite or at a local hospital. IHSC also has developed protocols for housing detainees in the general population after initial evaluation and/or empiric management for TB. Local jurisdictions, private facility operators, or subcontracted medical authorities that are the medical authority for approximately 200 local jails and detention facilities implement their internal protocols. The intake screening process typically relies on a TB skin test (TST) as the primary TB screening method. Airborne infection isolation is available onsite or at the hospital. Hospital discharge is usually accepted as clearance for housing in the general population without scrutiny.

For facilities with medical staffing, IHSC conducts TB surveillance, reports TB to and collaborates with local/state health departments, refers TB patients to CDC's CureTB Program for transnational linkage to care. The IHSC TB Coordination and Care Team conducts active surveillance with clinical and public health interventions. The team proactively reviews CXR, pharmacy, and TB case management systems; provides infectious disease consultations; and reviews patients who are released from ICE custody on a weekly basis. Health departments and CDC CureTB are notified of patients who are released or removed from ICE custody.

TB reporting by local jurisdictions, private facility operators, or subcontracted medical authorities is conducted by the local/state health department. Notifications to IHSC of ICE detainees with TB who are housed in facilities without IHSC medical staffing and referrals to CDC CureTB occur occasionally but not routinely.

Many facilities are capable of TB management, such as screening, isolation, further diagnostics, and empiric treatment. However, most facilities heavily rely on community medical resources if airborne infection isolation capabilities are not available onsite. Facility providers frequently often will follow hospital or community provider recommendations. Detainees, staff, and communities remain at risk when patients return to detention facilities with incomplete management and are housed in the general detention population. Community collaborations depend on effective communications regarding the high incidence of TB disease among ICE detainees and the high risk of transmission in congregate settings. Among ICE detainees, clinical suspicion of TB can still be high with an asymptomatic patient and/or a patient with other than apical or cavitary findings on CXR.

Based on recent surveillance data of IHSC's 22 facilities, the incidence of TB disease was found to be high among ICE detainees. From May 1, 2017-May 6, 2018, 124,818 unique ICE detainees were screened via CXR. The TB incidence among this population was estimated at 94.5 per 100,000 people based on confirmed culture-positive and culture-negative TB disease. The TB incidence of 46.5 per 100,000 people was still extraordinarily high based on microbiologically-confirmed TB disease by a nucleic acid amplification test (NAAT) or culture-positive test.

Of 118 patients with confirmed TB disease from May 1, 2017-May 6, 2018, 76 percent were asymptomatic; 37 percent had a negative test for TB infection based on TST or IGRA and could have been missed by conventional screening; 32 percent had a negative test for infection and were asymptomatic; 81 percent had all respiratory specimens that were negative for acid-fast bacillus (AFB) on smear microscopy and could have been inappropriately “ruled out for TB” with no treatment; and 52 percent had negative cultures for *Mycobacterium tuberculosis* (MTB) complex and could have had treatment stopped or entirely delayed.

Of 57 patients with culture-confirmed TB disease from May 1, 2017-May 6, 2018, 28 percent had a negative test for TB infection based on TST or IGRA; 23 percent had a negative test for TB infection and were asymptomatic; 25 percent had all respiratory specimens that were negative for AFB on smear microscopy and a positive NAAT result; and 31 percent had all respiratory specimens negative for AFB on smear microscopy and a negative NAAT result. Of 18 patients with positive MTB culture results, 88 percent were smear-negative, NAAT-negative, and asymptomatic. Of 52 patients with negative MTB culture, smear, and NAAT results, 83 percent were asymptomatic.

The IHSC surveillance data showed that asymptomatic TB disease is common among ICE detainees. Of patients who had negative AFB, negative NAAT, and positive culture results, nearly 90 percent were asymptomatic. These patients are at highest risk for improper clinical management because active TB disease is not suspected. Of patients with AFB-positive results, more than 33 percent were asymptomatic.

ACET published recommendations in the May 16, 2003 edition of the *MMWR*, “Post-Detention Completion of Tuberculosis Treatment for Persons Deported or Released from the Custody of the Immigration and Naturalization Service (INS) – United States, 2003.” ACET found that issues of security and law enforcement are integral to the completion of treatment involving people who are ineligible for legal admission into the United States under immigration law. ACET also emphasized the need for interagency coordination to ensure the completion of treatment for people being evaluated or treated for TB.

IHSC follows CDC/ACET recommendations to facilitate linkage to care. For care within the United States, notification is provided to local health departments, including intended addresses and telephone numbers, of detainees who are released from custody. However, IHSC is only able to provide notification about the release status of patients who are reported to IHSC. For care outside of the United States, the CDC Division of Global Migration and Quarantine CureTB Program facilitates transnational referrals. CureTB Program staff facilitate linkage to foreign national and local TB programs through telephone interviews; verify addresses and telephone numbers in the country of nationality and United States; and link patients to care in the countries of nationality. This service is supported through an ICE-CDC interagency reimbursable working agreement.

Public health authorities could provide assistance in several areas to support optimal facilitate TB care for ICE detainees. IHSC recommends that health jurisdictions ascertain which law enforcement agencies that have legal custody of patients by obtaining the agency identification number as well as the complete name and date of birth of the patient. Collaborations are established with the facility’s medical staff and local hospitals to provide appropriate initial clinical management; ensure the patient is non-contagious prior to placement in the general detention population; and communicate the initial and final laboratory results to the facility and law enforcement agency medical staff. It is important to keep in mind that detention facility

medical staff may be operationally distinct from the law enforcement agency's health services program; it is essential to communicate and collaborate with both entities.

Health jurisdictions should communicate and collaborate with the law enforcement agency's health service program and the facility's medical staff. Referrals should be facilitated to CDC CureTB to link detainees to care outside of the United States. Health jurisdictions should collaborate with all partners on contact investigations within and across jurisdictions to improve multijurisdictional coordination of contact investigations related to patients who originate in federal custody.

Overall, TB management in detention facilities that house ICE detainees is a complex issue and may require more conservative management than traditional approaches. Appropriate TB care for this population is vitally important for the health of the population in custody and the surrounding communities. Moreover, the specific congregate setting, transfers of patients, and contacts across jurisdictions must be considered and anticipated. Strong public health/community partnerships are a critical component of TB care for ICE detainees.

ACET DISCUSSION: TB CARE FOR ICE DETAINEES

Dr. Elson provided additional details on the following topics in response to ACET's questions.

- Protocols for pediatric TB screening and care, for children who are detained in ICE family residential centers with at least one adult parent.
- IHSC's use of Language Line Services and local interpreters to clearly communicate with detainees in their native languages during medical encounters.

IHSC collaborated with NTCA in 2018 to develop and distribute TB screening guidance to assist providers in community hospitals and local detention facilities that house ICE detainees.. The guidance document covers the evaluation of patients, criteria that warrant a high index of suspicion for TB, and a checklist to return patients to the general detention population. The guidance document is available for review on the NTCA website.

In response to Ms. Cole's request, Dr. Elson offered to provide the ACET members with a list of non-IHSC facilities in each state that house ICE detainees. Ms. Cole raised the possibility of local and state TB programs using the list to reach out to medical staff in these facilities.

Ms. Cole clarified that Dr. Elson's overview solely focused on TB care for ICE detainees. Due to ACET's strong interest, however, TB screening and care for unaccompanied minors who are placed in the custody of the HHS Administration for Children and Families, Office of Refugee Resettlement would be placed on the next agenda.

NCHHSTP Director's Report

Jonathan Mermin, MD, MPH (RADM, USPHS)

Director, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

Dr. Mermin covered several topics in the NCHHSTP Director's report to ACET. The \$135 million request in the fiscal year (FY) 2020 President's budget for CDC to support TB-related activities is the same as the FY2019 funding level. The FY2020 President's budget for CDC

also proposes funding to support two NCHHSTP's initiatives: "Ending the HIV Epidemic" (\$140 million) and "Addressing the Infectious Disease Consequences of the Opioid Epidemic" (\$58 million).

CDC recently published the *2017 U.S. State and City TB Report: Contacts Completing Latent TB Infection Treatment (LTBI)*. The report showed indicators to evaluate progress toward TB elimination. Based on CDC's 2018 preliminary TB surveillance data, 9,029 TB cases were reported in the United States in the previous year. The national average in 2016 was 77.5 percent and the 2020 national target was established at 81 percent. The data showed that 23 states and four cities met or exceeded the 2020 national target; four states and two cities did not meet the 2020 national target, but were above the national average; and 23 states and three cities did not meet the 2020 national target and also were below the national average.

CDC developed a [module on TB whole-genome sequencing](#) (WGS) to provide state and local TB programs with important tools and information, including case studies and future plans. WGS is used to investigate cases of recent TB transmission.

CDC and Medscape collaborated to produce a TB expert video commentary to provide physicians and other healthcare providers/professionals (HCP) with information on the updated LTBI treatment recommendations. The video was released in December 2018 and featured Dr. Philip LoBue, Director of DTBE.

CDC released the *2019 HIV Prevention Progress Report* that presented annual targets and results for 21 key indicators in the most recent data year. The report showed that no progress has been made for the following indicators: prevent new HIV infections by reducing non-sterile injections; improve health outcomes for people living with HIV by (PLWH) reducing homelessness; and reduce HIV-related disparities and health inequities in the Southern United States.

CDC published a new *VitalSigns*[™] report in March 2019 to emphasize the ability of HIV treatment to prevent transmission. The data showed that approximately 80 percent of new HIV infections in the United States in 2016 were transmitted from nearly 40 percent of PLWH who either had no knowledge of their positive HIV status or had received a diagnosis, but were not receiving HIV care. The new *VitalSigns*[™] report featured the following data to highlight the power of testing and treatment to end the HIV epidemic in the United States:

- 15 percent of PLWH who had no knowledge of their positive HIV status accounted for 38 percent of new transmissions;
- 23 percent of PLWH who had knowledge of their positive HIV status, but were not receiving care accounted for 43 percent of new transmissions;
- 11 percent of PLWH who were in care, but were not virally suppressed accounted for 20 percent of new transmissions; and
- 51 percent of PLWH who were taking HIV medications and were virally suppressed accounted for 0 percent of new transmissions.

CDC hosted the National HIV Prevention Conference in March 2019 with more than 3,000 attendees. The theme of the conference, "Getting to No New Infections," focused on the latest advancements, accomplishments, and strategies in HIV prevention; highlighted dynamic approaches to HIV prevention; and generated rich discussions of HIV initiatives.

A CDC study reported that transgender students experience health disparities. Based on a CDC survey from 19 state and urban school districts, an average of 1.8 percent of high school students identify as transgender. The survey also found that transgender students are more likely than cisgender students to report substance use, suicide risk, and being victims of violence. The study was published in the January 25, 2019 edition of the *MMWR*.

CDC is continuing its efforts to control hepatitis A virus (HAV) outbreaks in multiple states. As of March 18, 2019, the affected states reported more than 15,000 cases that have resulted in over 140 deaths and over 8,400 hospitalizations (or 56 percent). The HAV outbreaks primarily are affecting people who inject drugs and/or are experiencing homelessness. CDC issued a Health Alert Network update on the HAV outbreaks on March 25, 2019. CDC recommended that public health departments, healthcare providers, and other partners who serve affected populations launch a rapid and effective public health response. CDC also recommended vaccination for people who are experiencing homelessness.

A new analysis by CDC, Emory University, and University of Albany researchers estimates the prevalence of hepatitis C virus (HCV) ranges from 0.45 percent to 2.34 percent across states. States with the highest rates are affected by the opioid crisis, people with a history of chronic HCV infection, or increased levels of injection drug use. A map with the estimated number of people living with HCV from 2013-2016 is available at the [HepVu website](#).

A CDC analysis found that drug use among heterosexuals with syphilis has more than doubled over the past five years. The primary and secondary syphilis rate increased from 5.5 cases per 100,000 people in 2013 to 9.5 cases per 100,000 people in 2017 (or 73 percent). The CDC analysis also found that drug use, including methamphetamine, injection drugs, and heroin, more than doubled among heterosexual men and women with syphilis during this period. Data indicate that epidemics of heterosexual syphilis transmission and drug use are intersecting.

ACET DISCUSSION: NCHHSTP DIRECTOR'S REPORT

Dr. Mermin provided additional details on two issues related to TB funding in response to ACET's questions.

- Opportunities to apply a portion of the proposed \$140 million appropriation for CDC's new "Ending the HIV Epidemic" initiative to TB.
- The impact of transferring \$7 million to the Center for Global Health on domestic TB activities.

Dr. John Hellerstedt is the ACET liaison representative for the Association of State and Territorial Health Officials. He reported that the Texas Department of State Health Services requested and obtained additional funding to combat TB by expanding its existing programs. Texas used the new funding to conduct more TB surveillance, increase contact investigations, provide more medications to TB patients, and increase capacity in the San Antonio State Chest Hospital. In response to Ms. Cole's request, he agreed to make a presentation to ACET on the impact of Texas's additional TB funding at the local level.

Electronic Case Reporting (eCR) and the Digital Bridge

William Mac Kenzie, MD

Deputy Director for Science

Center for Surveillance, Epidemiology, and Laboratory Services

Centers for Disease Control and Prevention

Dr. MacKenzie presented an overview of TB eCR and the Digital Bridge. The 1988 Thacker and Berkelman study defined public health surveillance as “the ongoing systematic collection, analysis, and interpretation of data, closely integrated with the timely dissemination of these data to those responsible for preventing and controlling disease and injury.” An eCR is defined as “the automated generation and transmission of case reports from the electronic health record (EHR) to public health agencies for review and action.”

An eCR adds value in several areas, such as providing more complete, accurate data in real time; facilitating early detection and earlier intervention; improving outbreak detection, response, and recovery; diminishing the burden of HCPs and meeting public health needs; and linking health care to population health. The four components of an eCR include reporting across four domains: HCPs, EHRs, intermediary platforms, and public health. However, the Reportable Condition Knowledge Management System (RCKMS) within an intermediary platform can differ in each state.

The Council of State and Territorial Epidemiologists (CSTE) drafted a list in September 2015 of the minimum data elements to include in an electronic initial case report (eICR), such as provider, patient, facility, and clinical information. However, eICR data must exist in the EHR and be used for all conditions in all jurisdictions. An eCR begins with care as routinely documented in an EHR. The provider documents the diagnosis and orders laboratory testing. Documentation of the laboratory result is generated. Standard codes are associated with documentation and are used to trigger an initial case report.

The RCKMS is a logic-based decision support service that is maintained on an intermediary services platform with three components. Public health agencies enter their local reporting requirements into an authoring interface. The decision support service adjudicates each eICR against appropriate jurisdictional requirements to determine reportability. The RCKMS also includes a knowledge repository. The reportability response can include information from public health back to clinical care regarding the report of the condition, jurisdictions that are receiving the report, additional relevant information (e.g., treatment guidelines or local context), or a request for supplemental data. An implementation guide for the Clinical Document Architecture-based reportability response was balloted in May 2017.

The public health community, professional societies, the health care industry, and vendors serve as Digital Bridge partners to standardize the eCR field. The partners agreed that their initial focus would be to collaboratively develop an interoperable, multi-jurisdictional, consistent, nationwide, and sustainable eCR approach. The initial projects would be implemented at five sites by December 2018 using a standard technical framework. The initial conditions to be evaluated with eCR would include chlamydia, gonorrhea, pertussis, salmonella, and Zika virus. The Digital Bridge partners also established several guiding principles to launch standardized use of eCR:

- Embrace partnership and enterprise solutions.

- Maintain a seamless approach for providers and implement a simple process for health information technology developers.
- Use existing standards for the standards-based approach.
- Promote long-term thinking beyond communicable diseases.
- Avoid perfectionism by focusing on the need to “implement,” “evaluate,” and “evolve.”
- Obtain feedback to collect useful information.
- Address obvious issues, such as legal and sustainability issues.

At this time, the Digital Bridge partners have successfully implemented eCR in two large jurisdictions and gathered over four months of data on the five conditions. However, HCV has since been added as a sixth condition. The Digital Bridge demonstration sites include Houston, Utah, New York City, New York State, California, Michigan, and Kansas. The eCR evaluation report is pending publication.

To scale-up eCR nationally, jurisdictions will author the RCKMS rules. Onboarding documents and processes will be created and tested by the health care industry and public health agencies. Technical assistance will be provided to state, tribal, local, and territorial partners. Cohorting will be performed when feasible. Health care reporters will be onboarded and conditions will be expanded. For diseases that are not currently reportable, partnerships will be developed with CSTE and states to establish national case definitions and trigger codes for priority conditions. Collaborations will be launched with stakeholders to make priority conditions reportable in states.

CDC acknowledges that the LTBI coding list is incomplete at this time. The recommended ICD-10 code for LTBI is R76.1, “abnormal reaction to tuberculin test.” Additional LTBI codes are listed below:

- Mantoux-positive: SNOMED-CT 268376005
- Inactive TB: SNOMED-CT 11999007
- TB Intradermal test: LOINC 45323-3 and multiple other codes
- IGRA-QuantIFERON Gold: LOINC 53704-3 and multiple other codes

Overview of the Infrastructure and Mechanisms to Develop, Update, and Maintain HIV Guidelines

John Brooks, MD

Medical Epidemiologist, Division of HIV/AIDS Prevention
Centers for Disease Control and Prevention

Dr. Brooks presented an overview of the infrastructure and mechanisms to develop, update, and maintain HIV Guidelines. The Office of AIDS Research Advisory Council (OARAC) is a federal advisory committee for the National Institutes of Health (NIH) Office of AIDS Research (OAR). OARAC reports its findings to the OAR Director on the planning, coordination, and evaluation of research and other HIV/AIDS activities conducted or supported by NIH. OARAC convenes workgroups to write, review, and update HHS guidelines for the prevention and treatment of HIV/AIDS. OARAC is responsible for five major HIV-related guidelines:

- Antiretroviral Therapy (ART) Guidelines for Adults and Adolescents

- Prevention and Treatment of Opportunistic Infections (OIs) in Adults and Adolescents
- ART Guidelines for Children
- Prevention and Treatment of OIs in Children
- Prevention of Perinatal HIV Transmission

Workgroups that are convened by OARAC specify processes to develop and maintain guidelines in the Introduction sections. The guidelines are developed with a standard template that uses a tabular format in a transparent manner. The Introduction sections cover several specific areas:

- Goals/purpose of the guidelines
- Intended audience (e.g., clinicians) and scope of the guidelines (e.g., U.S. context)
- Panel membership (e.g., eligibility, selection process, and terms of the members)
- Management of financial disclosures and conflicts of interest of the members
- Funding source
- Evidence collection and grading systems (via a detailed table)
- Methods for synthesizing data and formulating recommendations
- Plans to update the guidelines
- Process to manage public comments

The development processes of the guidelines are extensively detailed in a table format:

- where to locate the roster and disclosures of the panel;
- mandatory information for panel members to disclose;
- how disclosures are documented;
- examples of “acceptable evidence” (e.g., peer reviewed publications, conference abstracts, or press releases/agency notices);
- how new evidence is identified;
- the frequency of appraising the evidence;
- data synthesis and the formulation of recommendations, including any voting procedures used for the guidelines;
- details on rating the recommendations;
- details on the occurrence of scheduled or unscheduled updates; and
- how and where to submit public comments.

Rating schema are adapted to the available science to document the strength and quality of evidence for each recommendation. The strength of the recommendation is rated as “strong,” “moderate,” or “optional.” The quality of the evidence is rated as “I,” “II,” or “III” based on the types of trials/studies conducted or expert opinion.

Each section of the guidelines has a writing group with a subject group lead. For example, the Adult OI Guidelines include 22 sections that were led by five executive co-editors from NIH, CDC, the Infectious Disease Society of America (IDSA), and the HIV Medical Association (HIVMA). The guidelines reflected input by more than 110 contributors of whom over 50 percent were unconflicted. Various approaches are implemented to recruit and target contributors based on subject-matter expertise for the guidelines, such as public announcements posted on the IDSA, HIVMA, and *AIDSinfo* websites or direct outreach.

Contributors are appointed for three-year terms with consideration of diversity and succession planning. For the Adult OI Guidelines, for example, the sections are divided by pathogen or pathogen group. The subject group lead distributes quarterly literature reviews and arranges conference calls to discuss the need to update or revise the guidelines. Each section is dated to indicate when it was last reviewed and when it was last updated (i.e., changes were deemed warranted and made to the last version). The subject group leads participate with guideline leadership on quarterly calls. The immediacy of the revision depends on the clinical impact of changes to the guidelines.

The OARAC workgroups are managed through an NIH contract. The guidelines are “living documents” that can be flexibly reviewed and updated. The NIH contract covers the costs of convening the workgroup calls and/or in-person meetings; managing the review and update of sections; editing, proofing, and maintain control of each version; hosting the website; and creating and disseminating mobile applications for both Apple and Android users. The *AIDSinfo* resources also provide information for people who are interested in volunteering to participate in HIV/AIDS clinical trial.

Data on usage of and updates to the guidelines are presented at each quarterly OARAC meeting. This information allows OARAC members to monitor real-time on-line access to the guidelines. Usage data also can help to inform the prioritization of updates. Dr. Brooks presented screen shots of the *AIDSinfo* website and mobile applications.

ACET DISCUSSION: HIV GUIDELINES INFRASTRUCTURE

In response to Ms. Cole’s question regarding opportunities to include TB guidelines in the existing NIH contract, DTBE staff agreed to initiate this discussion with their NIH colleagues. She was particularly interested in transforming TB guidelines as “living documents” that can be updated with more flexibility and more rapidly disseminated.

Congregate Settings Workgroup Closeout Report

Lisa Armitige, MD, PhD

Medical Consultant, Heartland National Tuberculosis Center
University of Texas Health Center at Tyler
ACET Member & Workgroup Chair

Dr. Armitige presented the closeout report for the Congregate Settings Workgroup. During its previous meetings, the ACET members raised three key points regarding TB in congregate settings. First, incarcerated people frequently are overlooked during discussions on TB disparities and health equity of racial/ethnic groups. Second, the disproportionate incarceration of racial/ ethnic minorities should be used as an opportunity to improve TB control with a stronger focus on health equity, particularly due to availability of the short-course regimen of isoniazid/rifapentine for three months (3HP). Third, this population should be extensively engaged in all discussions of TB disparities

ACET voted to establish the Congregate Settings Workgroup with a charge of exploring health inequities and other concerns related to homeless and incarcerated populations and presenting its findings to the full ACET membership. To fulfill its charge, the workgroup recruited a diverse group of ACET liaisons, *ex-officio* members, and external experts, including representation by the Federal Bureau of Prisons, ICE, and U.S. Marshals Service.

The Congregate Settings workgroup devoted an extensive amount of time to addressing two major concerns. First, the roles and responsibilities for TB contact investigations of prisoners who are transferred between jurisdictions are uncertain and not clearly defined. Based on feedback by DTBE staff and ICE officials, efforts are underway at CDC and within local jurisdictions to fill this gap. Second, representation by the corrections community has been lacking in some of CDC's new documents, such as the updated 3HP guidelines, the 2020 Report of Verified Case of Tuberculosis, and the 2020 TB funding formula. Based on a suggestion by Dr. LoBue, DTBE staff could conduct a literature review and publish an *MMWR* article with updated data on TB in congregate settings. The workgroup members also proposed specific revisions to include in these TB documents.

In December 2018, the workgroup acknowledged that only one rather than two ACET members were serving. Moreover, none of the workgroup members raised any additional concerns that should be addressed. ACET also did not provide the workgroup with an expanded charge. Based on these factors, the members agreed that the charge has been fulfilled and the workgroup should be dissolved at this time.

ACET DISCUSSION: CONGREGATE SETTINGS WORKGROUP

Dr. Elson was aware that both the workgroup and ACET members have raised the possibility of developing standards for TB screening and care in ICE detention facilities across jurisdictions. However, she clarified that TB clinical practice guidelines in correctional settings might be more effective than standards, particularly for large detention management companies.

Ms. Cole thanked Dr. Armitige for her excellent leadership of the Congregate Settings Workgroup. She also thanked the workgroup members for their outstanding contributions and strong support of this important topic. She confirmed that ACET would periodically revisit issues related to TB in congregate settings. Based on Dr. Elson's comments, for example, ACET's discussion of the existing TB clinical practice guidelines would be placed on the December 2019 agenda. The outcomes of this discussion would be used to determine whether the workgroup should be reconvened in the future with a new charge.

Based on a suggestion by Dr. Bodnar, Ms. Cole agreed to specifically solicit input from Dr. Robert Morris, the ACET liaison representative for the National Commission on Correctional Health, to inform the discussion.

Update by the Essential Components Workgroup

Barbara Cole, RN, MSN, PHN, ACET Chair

TB Controller

Riverside County (California) Department of Public Health

Ms. Cole reported that the workgroup completed the updated *Essential Components of a Public Health Tuberculosis Prevention, Control, and Elimination Program: Recommendations of the Advisory Council for the Elimination of Tuberculosis (ACET) and the National Tuberculosis Controllers Association (NTCA)* document. However, she entertained a motion for ACET to formally approve submitting the document to CDC/DTBE for possible publication in the *MMWR*. She clarified that the workgroup reconvened in January 2019 to change the authorship of the document, but no changes were made to the content.

| Action | Description |
|-------------------------|--|
| Chair's call for a vote | Ms. Barbara Cole properly placed a motion on the floor for ACET to approve forwarding the April 16, 2019 version of the Essential Components document to CDC with its request to submit the document to CDC/DTBE for possible publication in the <i>MMWR</i> . Dr. Robert Horsburgh seconded the motion. |
| Outcome of the vote | The motion was unanimously approved by 10 ACET voting members. |
| Next steps | The April 16, 2019 version of the Essential Components document will be forwarded to CDC/DTBE with ACET's request to submit the document to the <i>MMWR</i> for possible publication. |

Update by the TB Drug Supply Workgroup

Jennifer Flood

Chief, Tuberculosis Control Branch
 California Department of Health Services
 ACET Member & Workgroup Chair

Advice requested from ACET by the TB Drug Supply Workgroup:
 1. What are the most critical next steps to ensure a continuous, affordable anti-TB drug supply?

Dr. Flood presented an update on the recent activities of the TB Drug Supply Workgroup. The workgroup is charged with (1) identifying and discussing strategies to ensure an uninterrupted drug supply for treating TB disease and LTBI and (2) addressing manufacturing, procurement, distribution, and pricing challenges that contribute to shortages and access to needed drugs. The workgroup will report its findings to ACET for consideration. ACET will submit the workgroup's recommendations to CDC.

The TB Drug Supply Workgroup developed a risk profile table to guide its discussions.

| RISK PROFILE OF ESSENTIAL ANTI-TB DRUGS | | | | |
|---|---------------------|-------------------|----------|---|
| TB Drug | Single Manufacturer | New Higher Demand | Shortage | Access Difficulty*/ Ongoing Challenges |
| Intravenous INH | ✓ | | | Interruptions in the supply |
| Rifapentine | ✓ | ✓ | ✓ | Cost for patient, including copays, and clinics |
| Bedaquiline | ✓ | ✓ | | Cost for uninsured and insured |
| Moxifloxacin | ✓ | | | |
| Clofazimine | ✓ | ✓ | | Investigational new drug only and new procurement process |
| Cycloserine | ✓ | ✓ | ✓ | Shortage |
| Intravenous Streptomycin | ✓ | | | |

| RISK PROFILE OF ESSENTIAL ANTI-TB DRUGS | | | | |
|---|---------------------|-------------------|----------|--|
| TB Drug | Single Manufacturer | New Higher Demand | Shortage | Access Difficulty*/ Ongoing Challenges |
| Delamanid | | | | Over one month for compassionate use |

*Impaired access: lengthy process for patient assistance and barriers for those who are unable to afford the medication.

The TB Drug Supply Workgroup thoroughly reviewed and discussed the specific challenges related to access to Clofazimine (CFZ). In addition to the Institutional Review Board documents and the consent process, Novartis also requires TB programs to sign a non-negotiable letter of agreement to receive CFZ. The letter outlines strict terms and conditions.

- All adverse events, including non-serious events and beneficial effects, must be reported to the Novartis online system.
- Novartis reserves the right to access data and other work products relating to the use of CFZ as well as to utilize all data resulting from the use of its product for all purposes, including submission to regulatory agencies, marketing, and/or sales of any therapeutic agent or formulation.
- Results of the use of CFZ cannot be reported via conferences, publications, or presentations without prior review by Novartis.
- Novartis reserves the right to delete information and delay a CFZ publication or presentation for up to 45 days.
- TB programs must accept all liability stemming from the use of CFZ.

The challenges to accessing CFZ has impacted several areas. Most notably, delays of over six weeks for patients to start the drug have been reported. The amount of time is significant for the physician, TB program, and county counsel to create a contract. This process must be restarted if the patient relocates.

The TB Drug Supply Workgroup has explored several potential solutions to address these issues. Concept 1 would be to include Bedaquiline (BDQ) in the national stockpile. The rationale for this concept is based on BDQ's placement on the CDC and World Health Organization essential anti-TB medicine list. Moreover, BDQ is now a key first-line drug for MDR-TB and is used for the resistance or intolerance of other drugs. The demand for BDQ and its sole manufacturer create conditions for a shortage.

Based on recent research, the contents of the stockpile can be modified. The estimated need of BDQ is at least 100 courses per year. The cost would be approximately \$200,000 if BDQ is acquired through the Global Drug Facility (GDF), but the price would be much higher if the drug is not purchased through the GDF. The next steps to support Concept 1 would be to create a budget and identify possible funding sources. The TB drug stockpile currently is supported by Combating Antibiotic-Resistant Bacteria (CARB) funding.

Concept 2 is to access TB drugs through the GDF and use BDQ as a pilot project. The rationale for this concept is the GDF's role as a high functioning centralized procurement source that receives U.S. funds for the supply of drugs for multiple nations. Moreover, a pooled procurement process would address several existing challenges. Based on recent research,

most drugs on the essential medicine list are available through the GDF, but only a limited number of these drugs have been approved by the U.S. Food and Drug Administration (FDA).

BDQ is an FDA-approved drug, but a label change is needed by the manufacturer for drugs provided to the GDF. The next steps to support Concept 2 would be to access BDQ through the GDF if funds are identified and encourage the manufacturer to make a label change. The current CoAg process would be used to distribute BDQ during a shortage.

The benefits of a centralized drug supply/pooled procurement include monitoring the national supply and demand; ensuring a continuous supply; decreasing prices paid by governmental organizations; and improving efficiency, particularly as the number of TB cases decrease. Moreover, the current decentralized system does not allow for monitoring the national supply and demand. The next steps would be to examine responses to the FDA *Federal Register* proceedings and its Drug Shortages Task Force; determine whether CARB funding can be sustained and increased for the TB drug stockpile; and determine whether funds for the drug supply can be appropriated through the Comprehensive TB Act as described in ACET's December 2018 letter to the HHS Secretary.

Concept 3 is to replicate Louisiana's model, "The Journey Toward Eliminating Hepatitis C." Louisiana solicited offers; selected one of three manufacturers; and signed a contract for a hepatitis subscription model. Louisiana will make a one-time payment to the manufacturer to receive drugs at one price for an entire population of HCV patients in the state for a specified period of time. The next steps to support Concept 3 would be to convene a conference call with Louisiana to better understand the HCV model; evaluate whether this process could be nationally scaled up for TB; and determine whether a multi-state process or regional contracts would be more feasible.

The TB Drug Supply Workgroup is continuing to monitor FDA's *Federal Register* notice on September 10, 2018 to request comments on its public meeting, "Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions." The workgroup's next steps will be to draft its summary report. The report will (1) articulate the existing challenges of patients and programs in accessing TB treatment drugs; (2) outline priority recommendations for HHS and CDC; and (3) propose action steps for resolving challenges. The summary report will specifically address concerns related to an uninterrupted supply, drug pricing, manufacturing problems, and distribution shortages. The workgroup will present the draft report to ACET and obtain feedback during the August 2019 meeting and present the finalized report with recommendations to HHS and CDC during the December 2019 meeting.

Update by the LTBI Workgroup

Jeffrey Starke, MD

Professor of Pediatrics, Baylor College of Medicine
Texas Children's Hospital
ACET Member & Workgroup Co-Chair

Jennifer Flood

Chief, Tuberculosis Control Branch
California Department of Health Services
ACET Member & Workgroup Co-Chair

Advice requested from ACET by the LTBI Workgroup:

1. What is ACET's reaction to the approach and preliminary findings of the LTBI Workgroup?

Dr. Starke reported that the LTBI Workgroup has convened several conference calls since its establishment and formal charge by ACET. To guide its deliberations, the workgroup drafted the following framework with six major topics and proposed several examples to address for each topic.

1. Identify and engage individuals at risk and their providers
 - Groups of patients with increased risk of infection
 - Groups of patients with increased risk of progression to disease
 - Providers for higher risk patients: private practice and small groups; HMOs and PPOs; and providers for refugees, immigrant populations, homeless populations, and correctional institutions
2. Increase testing of at-risk individuals
 - Recommendation to be tested at least once
 - Choice of test: encourage the use of IGRAs over TST, particularly for people with previous BCG vaccination
 - Standardize recording of results in the medical record
3. Increase treatment of infected individuals
 - Availability of multiple regimens
 - Encourage the use of 3HP and four months of rifampin (4R)
 - Lower price and increase access to rifapentine to allow for self-administered therapy versus directly-observed therapy
4. Measure the success and outcomes of LTBI testing and treatment scale-up (LTBI surveillance and quality improvement)
 - Develop effective LTBI surveillance, including completion of adequate treatment
 - Standardize recording in the EHR
 - Quality improvement measures that are effective for maintenance of certification initiatives
5. Secure new resources to support TB prevention
 - For CDC
 - For state and local health departments
 - For basic and operational/applied research
6. Develop effective communications to support topics 1-5
 - Branding, e.g., "New tests, new [much shorter and easier] treatment regimens"
 - Examine and learn from other similar efforts, e.g., HIV, hepatitis B, STDs
 - Identify potential partners, including the possibility of linking to existing efforts
 - Create materials in both paper and electronic formats

The next steps of the LTBI Workgroup will be to use the framework and examples and draft a report with references. In addition to the workgroup presenting the draft report with its findings and recommendations, the members also plan to develop an article for publication in the *MMWR*.

Dr. Flood was extremely pleased by the excellent participation and strong contributions of the LTBI Workgroup members and external SMEs. She confirmed that the workgroup's products would inform the development of a roadmap for TB elimination in the United States.

Child and Adolescent Workgroup Closeout Report

Jeffrey Starke, MD

Professor of Pediatrics, Baylor College of Medicine
Texas Children's Hospital
ACET Member & Workgroup Chair

Dr. Starke presented the closeout report for the Child and Adolescent Workgroup. The workgroup was established to address modern methods of treatment and diagnosis of LTBI in children and adolescents. The workgroup fulfilled its charge with the harmonization of recommendations by CDC and the American Academy of Pediatrics. These guidelines recommend expanded use of IGRAs, 4R, and 3HP and also include a permissive recommendation for self-administration of these regimens in children.

The Child and Adolescent Workgroup has acknowledged that virtually no progress has been made on the development of child-friendly TB formulations. However, multi-drug TB formulations are available for and disbursed to children in other countries. Because the members agreed to integrate any outstanding child/adolescent issues into the activities of the LTBI Workgroup, the workgroup will be dissolved at this time.

ACET Business Session

Barbara Cole, RN, MSN, PHN, ACET Chair

TB Controller
Riverside County (California) Department of Public Health

Ms. Cole opened the Business Session and facilitated a review of old and current business items that warrant ACET's formal action at this time, additional discussion, or requests for future agenda items.

Business Item 1: Approval of Previous ACET Meeting Minutes

A motion was properly placed on the floor by Dr. Lisa Armitige and seconded by Dr. Jeffrey Starke for ACET to approve the previous meeting minutes.

ACET approved the Draft December 11-12, 2018 Meeting Minutes with no changes or further discussion.

Business Item 2: ACET's Draft Report to the HHS Secretary—2019

Ms. Cole presented the following outline that she would use as a guide to draft the 2019 ACET report to the HHS Secretary. She asked the ACET members to provide input on any additions, deletions, or other revisions that should be considered. She planned to present the draft report during the December 2019 meeting for ACET's review and formal approval.

I. Introduction

- A. Overview of Legal Basis for CDC Advisory Council for Elimination of Tuberculosis (ACET)

II. Background

- A. Brief Overview of the Current TB Trends in the United States (based on CDC data)
- B. Overview of the Institute of Medicine (IOM) Report

III. ACET's 2018 Accomplishments

- A. Chair's Summary of ACET Guidance

IV. Summary of the ACET Workgroups (description of the focus and current progress for each of the five workgroups)

- A. Essential Components of a TB Prevention, Control, and Elimination Program Workgroup
- B. TB Drug Supply Workgroup
- C. Congregate Settings Workgroup
- D. Child and Adolescent Workgroup
- E. LTBI Workgroup

V. Priorities for Moving the United States Toward TB Elimination

- A. Maintaining the Public Health Infrastructure
- B. Discussion about progress on the goals outlined in the IOM Report
- C. Intermittent Drug Shortages
- D. TB in Congregate Settings (emphasis on corrections and homeless populations)
- E. TB along the U.S.-Mexico Border

F. Targeted testing of individuals at risk for progression from LTBI to active TB (focus on tip of the iceberg)

G. TB Research

Dr. Flood suggested rearranging the priorities for TB elimination in Section V by order of importance. She proposed the top three priorities as subsection A (maintaining the public health infrastructure); subsection F (targeted testing of individuals at risk for progression from LTBI to active TB); and subsection G (TB research).

Business Item 3: ACET's Feedback on the Effectiveness of Video Conferencing

Ms. Cole acknowledged the technical difficulties in the video conferencing capabilities for the current meeting. In response to Ms. Cole's question, Dr. Dean confirmed that CDC has not changed its policy for ACET to convene one in-person meeting and two webinars during each fiscal year.

- Dr. Flood reiterated that the webinars are not as effective as ACET's in-person meetings. Most notably, the inability of the workgroups to present their activities to ACET on an ongoing basis and engage in a robust discussion is a problematic approach.
- Dr. Horsburgh raised the possibility of CDC using a video conferencing platform other than Adobe Connect to convene the webinars.
- Dr. Elson asked the committee management staff to use a standard format to name the PowerPoint slide sets and other documents that are distributed to the ACET members for the webinars. This approach would help the participants to quickly and easily the document that is being presented.

Business Item 4: ACET's Response to the "Public Charge" Rule

Ms. Cole reminded ACET that during the December 2018 meeting, the members took a formal vote and approved sending a letter to the HHS Secretary to express concerns regarding DHS's Proposed Rule, "Inadmissibility on Public Charge Grounds." She led ACET in a review of the draft letter.

Dear Mr. Secretary:

The Advisory Council for the Elimination of Tuberculosis (ACET) is charged with providing advice and recommendations regarding the elimination of Tuberculosis (TB) in the United States to the Secretary of HHS; the Assistant Secretary of HHS; and the Director of the Centers for Disease Control and Prevention (CDC). Evaluating and treating individuals with infectious TB is essential for preventing transmission to others, in addition for the health of the individual.

The members of ACET are writing you in response to the U.S. Department of Homeland Security's (DHS) Proposed Rule "Inadmissibility on Public Charge Grounds." We are concerned of its potentially negative impact on the health of

individuals who are concerned about this rule and thus do not present for tuberculosis care. Any action taken by the Federal Government that would prevent, hinder, or discourage people who are within the United States from seeking services for tuberculosis care would constitute a significant threat to the public health of the United States. Therefore, ACET respectfully requests the HHS Secretary to advise DHS and other relevant departments of this potential risk to public health.

Dr. Benjamin informed ACET that the public comment period on DHS’s proposed rule closed on December 10, 2018. The submission of over 100,000 responses set a record for a public comment period for a *Federal Register* notice. The current Administration has not yet announced its decision on whether DHS’s proposed rule will be formalized as a Presidential Executive Order and executed.

| Action | Description |
|-------------------------|---|
| Chair’s call for a vote | Dr. Ana Alvarez properly placed a motion on the floor for ACET to approve the draft “Public Charge” letter to the HHS Secretary as outlined above. Dr. Robert Horsburgh seconded the motion. |
| Outcome of the vote | The motion was unanimously approved by 10 ACET voting members. |
| Next steps | The draft letter will be finalized, placed on ACET letterhead, signed by Ms. Cole, and submitted to the HHS Secretary. |

Business Item 5: Advice Requested from ACET

Ms. Cole presented a table with the advice that the presenters requested from ACET during the December 2018 meeting. She led ACET in a review of these topics to determine whether any further action is needed.

| ADVICE REQUESTED FROM ACET | |
|--|---|
| Topic | Action |
| DTBE-Funded Demonstration Project on LTBI Testing and Treatment | Ms. Cole referenced the guidance that ACET provided to DTBE. ACET agreed that no further action is needed. |
| DTBE’s Communication Messaging and Campaigns | Ms. Cole referenced the guidance that ACET provided to DTBE. ACET agreed that no further action is needed. |
| FDA Drug Shortages Task Force | ACET voted and approved the submission of a letter to the HHS Secretary regarding the TB drug supply. ACET agreed to revisit this issue after Ms. Cole receives the response from the HHS Secretary. |
| LTBI Treatment: Insights from Immunology Studies and Opportunities for Collaboration | Ms. Cole referenced ACET’s discussion with the guest presenter. ACET agreed that no further action is needed. |
| LTBI Guidelines | Ms. Cole referenced the guidance that ACET provided to DTBE. ACET agreed that no further action is needed. |

| ADVICE REQUESTED FROM ACET | |
|--|---|
| Topic | Action |
| Draft Drug-Resistant TB Treatment Guidelines | Ms. Cole referenced the guidance that ACET provided to DTBE. ACET agreed that no further action is needed. |
| New LTBI Workgroup Charge | ACET voted and approved a new charge for the LTBI Workgroup. ACET agreed that no further action is needed. |

In response to Ms. Cole's question regarding the current process to document and monitor ACET's advice, Dr. Armitige's position was that this standing agenda item is effective and should be maintained.

Business Item 6: Future Agenda Items

Ms. Cole confirmed that the Agenda Setting Workgroup will convene a teleconference to draft an agenda based on the topics ACET proposed over the course of the meeting. The draft agenda will be circulated to ACET for review in advance of the August 2019 meeting.

| Presenter | Agenda Item |
|---|--|
| Dr. Robert Morris (ACET Liaison) | Overview by the National Commission on Correctional Health |
| To Be Determined | Overview of TB prevention, treatment, and care of unaccompanied minors in HHS custody |
| Dr. John Hellerstedt (ACET Liaison) | Overview of successful strategies implemented by the Texas Department of State Health Services with its additional TB funding |
| DTBE | Update on TB whole-genome sequencing |
| Ms. Suzanne Marks and/or NEEMA Grant Recipients | Update on efforts to model the domestic TB epidemic and priority interventions that can lead to TB elimination in the United States <ul style="list-style-type: none"> ➤ Dr. Flood noted that this presentation should focus on the progress to date and recent publications by the three grant recipients of the NCHHSTP Epidemiologic and Economic Modeling Agreement (NEEMA): Emory University, Harvard University, and the University of California, San Francisco. |
| Dr. Ed Cox (Director, FDA Office of Antimicrobial Products) | Overview by the FDA Drug Shortages Task Force |

| Presenter | Agenda Item |
|--|--|
| ACET Membership | <p>Follow-up discussions: (1) potential strategies to include the development and revision of TB guidelines in NIH's existing contract for HIV guidelines and (2) the replication of efforts for TB that have been successful in increasing funding and advocacy for HIV and STDs at federal, state, and local levels.</p> <ul style="list-style-type: none"> ➤ Dr. Mermin announced that DTBE staff reached out to colleagues at NIH during the previous break to begin discussing topic 1. NIH confirmed that Ms. Kathryn Koski, Deputy Director of DTBE, will be provided with contact information for AIDSinfo staff. However, he noted that both the advantages and disadvantages of this proposed approach will need to be carefully considered, such as the strength, capacity, and resources of the existing AIDSinfo infrastructure versus the potential for TB guidelines to be diluted within the AIDSinfo system. He confirmed that DTBE would report the key outcomes of its discussions with NIH during the August 2019 ACET meeting. |
| Dr. Robert Redfield | <p>Overview of the CDC Director's priorities and/or areas of interest to advance toward TB elimination</p> <ul style="list-style-type: none"> ➤ Based on Dr. Redfield's availability, Ms. Cole will attempt to schedule his presentation for the December 2019 ACET meeting. |
| Dr. Jennifer Flood Drs. Jennifer Flood/Jeffrey Starke | <p>Update by the ACET TB Drug Supply Workgroup Update by the ACET LTBI Workgroup</p> |
| ACET Membership | <p>Discussion of existing TB clinical practice guidelines</p> <ul style="list-style-type: none"> ➤ ACET will use the outcomes of this discussion to determine whether to reconvene the Congregate Settings Workgroup with a new charge. |

Public Comment Session

No members of the public provided comments for ACET's consideration.

Closing Session

The next two ACET meetings will be held on August 20, 2019 (webinar) and December 10-11, 2019 (in-person meeting in Atlanta).

Ms. Margie Scott-Cseh, the ACET Committee Management Specialist, will poll the members via email to determine their availability and confirm the dates of the next two meetings.

With no further discussion or business brought before ACET, Ms. Cole adjourned the meeting at 3:30 p.m. on April 16, 2019.

CHAIR'S CERTIFICATION

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

Date

Barbara Cole, RN, MSN, PHN
Chair, Advisory Council for the
Elimination of Tuberculosis



Attachment 1: Participants' Directory

ACET Members Present

Ms. Barbara Cole, Chair
Dr. Ana Alvarez
Dr. Lisa Armitige
Dr. Robert Belknap
Dr. Jennifer Flood
Dr. David Horne
Dr. Robert Horsburgh, Jr.
Dr. Lixia Liu
Dr. Jeffrey Starke
Dr. Zelalem Temesgen

ACET Ex-Officio Members Present

Dr. Naomi Aronson
U.S. Department of Defense

Dr. Amy Bloom
U.S. Agency for International Development

Dr. Ulana Bodnar
U.S. Department of Justice

Ms. Sarah Bur
Federal Bureau of Prisons

Dr. Karen Elkins
U.S. Food and Drug Administration

Dr. Diana Elson
U.S. Department of Homeland Security
U.S. Immigration and Customs Enforcement

Dr. Letha Healey
Health Resources and Services
Administration, HIV/AIDS Bureau

Dr. Jonathan Iralu
Indian Health Service

Dr. Mamodikoe Makhene
National Institute of Allergy and Infectious
Diseases, National Institutes of Health

Mr. Stephen Martin
National Institute for Occupational Safety
and Health

Dr. Gary Roselle
U.S. Department of Veteran Affairs

ACET Ex-Officio Members Absent

Dr. Anthony Campbell
Substance Abuse and Mental Health
Services Administration

Dr. Thomas Nerad
U.S. Department of Labor/Occupational
Safety and Health Administration

ACET Liaison Representatives Present

Dr. Shama Ahuja
Council of State and Territorial
Epidemiologists

Dr. Robert Benjamin
National Association of County and City
Health Officials

Mr. David Bryden
RESULTS

Ms. Diana Fortune
National Tuberculosis Controllers
Association

Dr. John Hellerstedt
Association of State and Territorial Health
Officials

Dr. Robert Morris
National Commission on Correctional
Health

Dr. Ameer Patrawalla
American College of Chest Physicians

Ms. Susan Rappaport
American Lung Association

Dr. Susan Ray
Infectious Disease Society of America

Dr. Randall Reves
International Union Against TB and Lung
Disease

Ms. Susan Ruwe
Association for Professionals in Infection
Control and Epidemiology

Dr. Daphne Ware
Association of Public Health Laboratories

ACET Liaison Representatives Absent

Dr. Fran du Melle
American Thoracic Society

Dr. Mayleen Ekiek
Pacific Island Health Officers Association

Dr. Ilse Levin
American Medical Association

Mr. Surajkumar Madoori
Treatment Action Group

Dr. Howard Njoo
Public Health Agency of Canada

Dr. Gudelia Rangel
Mexico Section, U.S.-Mexico Border Health
Commission

Dr. Michael Tapper
Society for Healthcare Epidemiology of
America

Dr. Lornel Tompkins
National Medical Association

Mr. Bobby Watts
National Health Care for the Homeless
Council

ACET Designated Federal Officer

Dr. Hazel Dean
NCHHSTP Deputy Director

CDC Representatives

Dr. John Brooks
Dr. Deron Burton
Dr. Terence Chorba
Ms. Ann Cronin
Mr. Justin Davis
Dr. Nikolas DeLuca
Dr. Neela Goswami
Mr. Lon Gross
Ms. Carla Jeffries
Dr. Awal Khan
Ms. Maureen Kolasa
Ms. Kathryn Koski
Dr. Adam Langer
Dr. William Mac Kenzie
Ms. Allison Maiuri
Ms. Suzanne Marks
Dr. Jonathan Mermin
Mr. Roque Miramontes
Dr. Ranell Myles
Dr. Thomas Navin
Mr. Gibril Njie
Ms. Margie Scott-Cseh
Dr. Andrew Vernon
Dr. William Walker
Dr. Carla Winston

Guest Presenters/ Members of the Public

Dr. Brent Gibson
National Commission on Correctional
Health Care

Ms. Erin Laird
National Association of County and City
Health Officials

Ms. Clarisse Tsang
Arizona Department of Health Services

Ms. Donna Wegener
National Tuberculosis Controllers
Association



Attachment 2: Glossary of Acronyms

| Acronym | Definition |
|---------|--|
| 3HP | Three Months of Isoniazid/Rifapentine |
| 4R | Four Months of Rifampin |
| ACET | Advisory Council for the Elimination of Tuberculosis |
| AFB | Acid-Fast Bacillus |
| ART | Antiretroviral Therapy |
| BDQ | Bedaquiline |
| CARB | Combating Antibiotic-Resistant Bacteria |
| CDC | Centers for Disease Control and Prevention |
| CFZ | Clofazimine |
| CoAg | Cooperative Agreement |
| CSTE | Council of State and Territorial Epidemiologists |
| CXR | Chest X-Ray |
| DFO | Designated Federal Officer |
| DHS | U.S. Department of Homeland Security |
| DTBE | Division of Tuberculosis Elimination |
| eCR | Electronic Case Reporting |
| EHR | Electronic Health Record |
| eIRC | Electronic Initial Case Report |
| FACA | Federal Advisory Committee Act |
| FDA | U.S. Food and Drug Administration |
| FY | Fiscal Year |
| GDF | Global Drug Facility |
| HAV | Hepatitis A Virus |
| HCP | Healthcare Providers/Professionals |
| HCV | Hepatitis C Virus |
| HHS | U.S. Department of Health and Human Services |
| HIVMA | HIV Medical Association |
| HRSA | Health Resources and Services Administration |
| ICE | U.S. Immigration and Customs Enforcement |

| Acronym | Definition |
|-------------|--|
| IDSA | Infectious Disease Society of America |
| IGA | Intergovernmental Agreement |
| IGRA | Interferon Gamma Release Assay |
| IGSA | Intergovernmental Service Agreement |
| IHSC | ICE Health Services Corps |
| INS | Immigration and Naturalization Service |
| LTBI | Latent Tuberculosis Infection |
| MDR-TB | Multidrug-Resistant Tuberculosis |
| <i>MMWR</i> | <i>Morbidity and Mortality Weekly Report</i> |
| MTB | <i>Mycobacterium tuberculosis</i> |
| NAAT | Nucleic Acid Amplification Test |
| NCHHSTP | National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention |
| NEEMA | NCHHSTP Epidemiologic and Economic Modeling Agreement |
| NIH | National Institutes of Health |
| NTCA | National Tuberculosis Controllers Association |
| OAR | Office of AIDS Research |
| OARAC | Office of AIDS Research Advisory Council |
| OIs | Opportunistic Infections |
| PLWH | People Living With HIV |
| RCKMS | Reportable Condition Knowledge Management System |
| SMEs | Subject-Matter Experts |
| TB | Tuberculosis |
| TST | Tuberculin Skin Test |
| USBP | U.S.-Born People/Populations |
| USMS | U.S. Marshals Service |
| WGS | Whole-Genome Sequencing |
| WHO | World Health Organization |