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

Virtual Meeting of the
Advisory Council for the Elimination of Tuberculosis
December 9-10, 2025

Record of the Proceedings

TABLE OF CONTENTS

Table of Contents

US DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Division of Tuberculosis Elimination

ADVISORY COUNCIL FOR THE ELIMINATION OF TUBERCULOSIS
December 9-10, 2025

Minutes of the Meeting

The United States (US) Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC), National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP, the Center), Division of Tuberculosis Elimination (DTBE) convened a virtual meeting of the Advisory Council for the Elimination of Tuberculosis (ACET). The proceedings were held on December 9-10, 2025 beginning at 12:11 PM Eastern Time (ET) on December 9, 2025 and 12:05 PM on December 10, 2025.

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 the 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 of 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.

December 9, 2025 Opening Session

Lynn Sosa, MD
Director of Infectious Disease and State Epidemiologist
Connecticut Department of Public Health
ACET Chair

Carla Winston, PhD, MA
Associate Director for Science
Division of Tuberculosis Elimination
National Center for HIV, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention
ACET Designated Federal Officer

Marah E. Condit, MS
Public Health Analyst, Advisory Committee Management
Office of Policy, Planning, and Partnerships
National Center for HIV, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention

Dr. Sosa called the meeting to order at 12:13 PM ET on December 9, 2025. Marah Condit provided meeting ground rules. She noted that members of the public would have an opportunity to provide comments during the second day of the meeting at 2:05 PM ET. Dr. Winston welcomed participants and conducted a roll call to confirm the attendance of ACET voting members, *ex-officio* members, and liaison representatives. She explained that ACET meetings are open to the public and all comments made during the proceedings are a matter of public record. She reminded ACET voting members of their responsibility to disclose any potential individual and/or institutional conflicts of interest (COI) for the public record and recuse themselves from voting or participating in these matters.

ACET Voting Member Institution/Organization	Potential Conflict of Interest
Rajita Bhavaraju, PhD, CHES Rutgers, The State University of New Jersey	No conflicts
Adithya Cattamanchi, MD University of California- Irvine	No conflicts
Lisa Chen, MD University of California, San Francisco	No conflicts
Andrea Cruz, MD, MPH Baylor College of Medicine	No conflicts
William Glover, PhD, D(ABMM), MT(ASCP) North Carolina Department of Health and Human Services	No conflicts
Kelly John Holland, MD Lynn Community Health Center	No conflicts
Kathleen A. Ritger, MD, MPH Chicago Department of Public Health	No conflicts
Lynn Sosa, MD Connecticut Department of Public Health	No conflicts
Shu-Hua Wang, MD, PharmD, MPH&TM, FIDSA College of Medicine, The Ohio State University	No conflicts

Dr. Sosa conducted the roll call, which confirmed that the 16 voting and *ex-officio* members in attendance constituted a quorum for ACET to conduct its business on December 9, 2025. The roll was called subsequent to each break and lunch, with a quorum established each time throughout the day.

Dr. Winston expressed gratitude and bid farewell to Dr. Chen, who extended her ACET term for an additional 180 days and for whom this was the last ACET meeting, and to Dr. Stout, who rotated off of ACET at the end of his term in June 2025. She welcomed the following new members, *ex officios*, and liaisons:

Members

- ❑ Andrea Tania Cruz, MD, MPH Professor (tenured); Chief of Research Sections of Pediatric Emergency Medicine and Pediatric Infectious Diseases, Baylor College of Medicine
- ❑ Shu-Hua Wang, MD, PharmD, MPH&TM, FIDSA; Professor of Medicine (tenured); Internal Medicine Department, Division of Infectious Diseases; College of Medicine, The Ohio State University

Ex Officio

- ❑ Gayathri S. Kumar, MD, C-IAYT; CAPT, United States Public Health Service; Chief Medical Officer, HHS Office of Minority Health, HHS Office of Assistant Secretary for Health (OASH)

Liaison

- ❑ David Lewinsohn, MD, PhD; Stop TB USA Coordinating Board, Voting Member; Professor of Medicine, Oregon Health Sciences University

Dr. Sosa reviewed and commenced the agenda.

NCHHSTP Director's Report

Renáta D. Ellington, PhD, MSEd, MCHES
Acting Director, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, CDC
Centers for Disease Control & Prevention

Dr. Ellington provided the NCHHSTP Director's Report, beginning with leadership announcements. Prior to becoming the NCHHSTP Director, Dr. Ellington joined CDC as a Project Officer in the Division of HIV Prevention (DHP) in 2005, became DHP's Community Based Organization (CBO) Program Lead in 2009, and the Associate Deputy Director of DHP Prevention Programs in 2015 serving as the lead for the development of the Ending the HIV Epidemic (EHE) Initiative Notice of Funding Opportunity (NOFO). In April 2020, Dr. Ellington became the DHP Deputy Director of Program Management and Operations. She joined the NCHHSTP Center Leadership team in 2024 as the Deputy Director for Management, Operations, Communications, and Policy. Dr. Phil LoBue retired on June 22, 2025 as DTBE Director after 26 years of dedicated service to the elimination of TB and CAPT Deron Burton became the new DTBE Director.

NCHHSTP prioritizes cost-effective and scalable programs, policies, and research to achieve the greatest impact in terms of HIV, viral hepatitis, STDs, and TB. The strategies NCHHSTP utilizes to accomplish these goals are to: 1) maximize use of surveillance and other data to drive program improvement; 2) support scientific discovery, implementation research, and evaluation of interventions; 3) increase collaboration and service integration; 4) promote prevention,

detection, and treatment through healthcare delivery systems; 5) promote protective systems and policies and increase knowledge and adoption of healthy behaviors; and 6) use guidelines to improve public health.

NCHHSTP allocates approximately 76% of its total budget to extramural funding, a majority of which supports state and local health departments and community organizations. NCHHSTP focuses on high-impact prevention activities promoting efficient and effective use of resources, such as: 1) investing in prevention, testing, and linkage to care; 2) preparing for and responding to epidemics and outbreaks; 3) expanding the use of public health and clinical data; 4) developing guidelines and trainings for healthcare providers; and 5) educating the public, partners, and key populations. This table reflects NCHHSTP's total budget and breakdown among activities:

Budget Activity/ Description	FY24 Enacted	FY25 Continuing Resolution Enacted*	FY26 President's Budget (proposed)*
Domestic HIV/AIDS	$1,013,712	$1,013,712	$0
School Health – HIV	$38,081	$38,081	$0
Elimination Initiative **(non-add)**	$220,000	$220,000	$0
Viral Hepatitis	$43,000	$43,000	N/A
Sexually Transmitted Infections	$174,310	$174,310	N/A
Tuberculosis (TB)	$137,034	$137,034	N/A
Infectious Disease and Opioids	$23,000	$23,000	N/A
Consolidated Funding for Viral Hepatitis, STI, TB and IDO	N/A	N/A	$300,000
TOTAL NCHHSTP	**$1,391,056**	**$1,391,056**	**$300,000**

The fiscal year 2026 (FY26) President's Budget proposes a decrease in NCHHSTP's total budget of almost $1.1 billion and consolidates funding for viral hepatitis, sextually transmitted infections (STIs), TB, and infectious disease and opioid epidemic (IDO) activities into a single consolidated proposed grant program with a budget of $300 million. This represents approximately $77.3 million decrease across those 3 funding lines. The FY26 President's Budget also proposes eliminating the domestic HIV program, but allocates $220 million for the Ending the HIV Epidemic (EHE) program that is proposed to transition to the Administration for a Healthy America (AHA).

To provide a snapshot of the numbers across NCHHSTP and DTBE overall, over 39,000 people were diagnosed with HIV and 1.1 million people in the US were living with diagnosed HIV in 2023. Hepatitis B (HepB) and Hepatitis C (HepC) are the leading causes of liver cancer in the US. HepC is the most common bloodborne infection, with more than 2.4 million people infected. Over 660,000 people are infected with HepB. More than 2.4 million cases of chlamydia, gonorrhea, and syphilis were reported in 2024. There were over 3,900 cases of congenital Syphilis (CS), including 279 cases of CS stillbirths and neonatal/infant deaths. Up to 13 million people in the US have latent tuberculosis infection (LTBI) and are at risk for developing TB disease.

When we talk about our work to all of our partners, we focus on how saving lives saves money. Along these lines, here are a few of our realized and aspirational outcomes of our surveillance and prevention efforts. Between 2012 and 2022, approximately 27,900 HIV infections were prevented, which saved an estimated $15.1 billion in lifetime medical costs. Implementing the proposed "National Hepatitis C Elimination Initiative" would save an estimated $6.6 billion within 10 years. At the current level of sexually transmitted infection (STI) prevention funding, CDC would prevent over 1.6 million STIs (syphilis, gonorrhea, and chlamydia) and 761 STI-attributable HIV infections over the next 5 years, saving $781 million in direct lifetime medical costs. From 1995-2023, US TB control efforts averted up to 549,000 cases of TB and up to $26 billion in medical and societal costs. Prevention is cost-effective. For instance, the lifetime treatment cost for HIV per person is approximately $554,000. The lifetime cost to treat CS disease per person is $28,500. The cost of 1-time treatment for HepC is estimated to be $25,200 ($7,500 to $75,000). Treating LTBI prevents TB disease and is cost-effective. The cost to treat one person with LTBI is $400 to $1,300. The cost to treat one person with drug-susceptible TB is $25,000. The cost to treat one person with multidrug-resistant TB (MDR-TB) is $60,000 to $114,000 using the new short-term regimen), while the cost to treat one person with extensively drug-resistant TB is $128,000 to $316,000 using the new short-term regimen.

To highlight a few programs we are implementing throughout the Center, the "Policy as a Public Health Intervention Cooperative Agreement PS23-0009" funds Temple University and the National Network of Public Health Institutes (NNPHI) to do comprehensive legal epidemiology, legal mapping, and establish a national resource center to provide tailored technical assistance (TA) that equips public health decisionmakers with evidence-based tools to reduce morbidity and mortality related to HIV, viral hepatitis, STDs, and TB. Within this cooperative agreement, recently completed products include the National Alliance of State and Territorial AIDS Directors (NASTAD) *State Reporting Requirements for Negative HIV and HCV Test Results,*[1] which clarifies state and territorial requirements for reporting negative HIV and HCV test results, an area in which obligations are often unclear. The aim of this resource is to close that gap by supporting health departments, laboratories, and healthcare providers (HCP) in understanding their legal obligations related to public health reporting, while strengthening HIV and HCV surveillance systems nationwide. The National Association of County and City Health Officials (NACCHO) *Point-of-Care Testing for Sexually Transmitted Infections Toolkit*[2] outlines available point-of-care tests (POCTs) for STIs and their regulations, benefits, limitations, and considerations for test use. NASTAD's *Pharmacist Authority to Provide Viral Hepatitis Prevention, Testing, and Treatment Services*[3] outlines viral hepatitis in the US, pharmacist scope

[1] https://nastad.org/resources/state-reporting-requirements-negative-hiv-and-hcv-test-results
[2] https://www.naccho.org/uploads/downloadable-resources/POCT-TOOLKIT-2025_Final.pdf
[3] https://nastad.org/resources/pharmacist-authority-provide-viral-hepatitis-prevention-testing-and-treatment-services

of practice, collaborative practice agreements (CPAs), reimbursement for pharmacist clinical services, and prior authorization requirements for HepC treatment.

Turning to division updates, the Division of STD Prevention (DSTDP) released *Sexually Transmitted Infections Surveillance, 2024 (Provisional)*[4] in September 2025. This report provided 2024 provisional data showing that the overall STI burden remains substantial, but signs of progress continue. Provisional data were released due to CDC migrating the National Notifiable Disease Surveillance System (NNDSS) data to the One CDC Data Platform (1CDP). Because of this, CDC has proposed a reconciliation and publication of the 2024 NNDSS case surveillance data to allow state health departments and CDC more time to onboard to 1CDP. CDC knows it is extremely important to release all data in a timely manner because local and state programs depend upon these data to inform local STI prevention efforts. In 2024, the combined number of cases of chlamydia, gonorrhea, and syphilis declined 9% from 2023—down for a third consecutive year. However, there were still more than 2.2 million reported STIs in 2024. The total rate of primary and secondary syphilis among reported cases by sex and year in the US from 2015 to 2024 was about 12.2 per 100,000 population. Primary and secondary syphilis cases declined for the second year in a row, down 22% since 2023. While it is important to recognize the successes, there is still work to be done.

In terms of trends in CS cases and rates of primary and secondary syphilis and syphilis of all stages among women aged 15–44 years, CS increased for the 12th year in a row, approximately 3,900 cases of CS were reported in the US or about 109.6 per 100,000 live births—nearly a 700% increase since 2015. To address this debilitating infectious disease, it is imperative to address syphilis among women of reproductive age and their partners. Some of the missed opportunities to address CS during pregnancy are due to a combination of individual- and system-level barriers to timely syphilis testing and treatment. Individual-level barriers may include lack of insurance and substance use disorder (SUD), while some of the system-level barriers may include limited healthcare access or insufficient care. Additionally, benzathine penicillin G (BPG) is the only recommended treatment for syphilis during pregnancy. BPG must be administered by trained professionals 1 or 3 times spaced over a period of 7 to 9 days. For the last several years, the US has experienced shortages and there is only 1 manufacturer approved for BPG at this time. As a result, CDC is encouraging priority actions for clinicians and health departments to help ensure an adequate supply of BPG and prioritize this drug to treat pregnant women with syphilis and babies with CS.

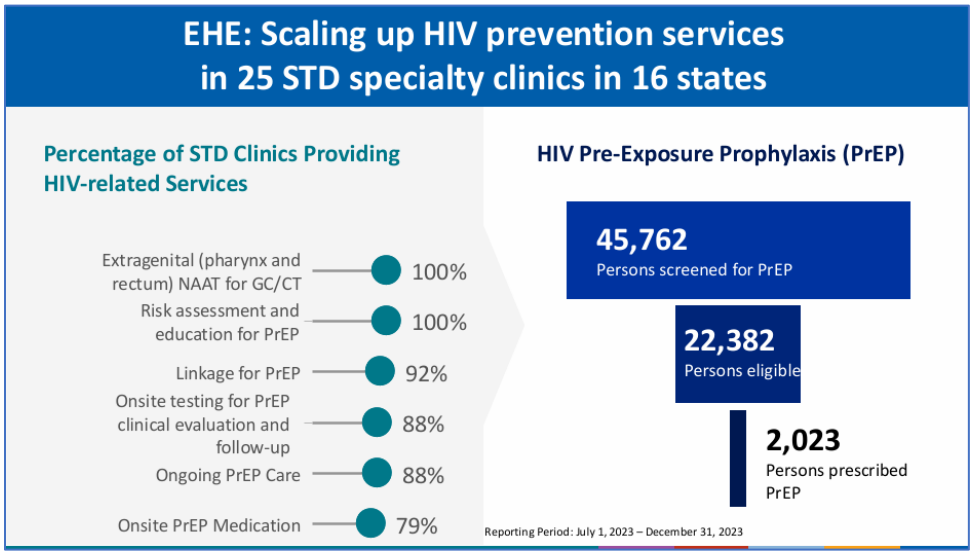
Over the past 15 years, CDC-funded state and local STI programs prevented 6.4 million cases of syphilis, gonorrhea, and chlamydia and 2,520 STI attributable HIV infections, saving $2.7 billion in lifetime direct medical costs. In 2023, 6,239 potential cases of congenital syphilis were averted with potential cost savings of $168.5 million in direct medical costs. CDC-funded STI prevention programs support rapid identification and follow-up of pregnant women with syphilis to help avert potential CS cases. While making strides, CDC knows there is more the agency can do with its partners.

Moving to DHP updates, 1.2 million persons in the US were living with diagnosed and undiagnosed HIV. Among these persons, 87% knew their status in 2022, 83% diagnosed with HIV were linked to care within a month, and 67% diagnosed with HIV were virally suppressed at the most recent viral load test. To summarize HIV incidence in 2022,[5] over 38,000 people

[4] https://www.cdc.gov/sti-statistics/annual/index.html
[5] State level HIV prevention profiles: https://www.cdc.gov/hivpartners/php/state-hiv-profiles/index.htm

received an HIV diagnosis, with 81% of new HIV infections in men, with gay and bisexual men accounting for the majority; 40% of all new infections among persons aged 25-34; and a decrease in new infections by 30% among persons aged 13-24 years. Black persons had the largest number of new infections, accounting for 37% of all new infections. Of the new infections among females, 47% were among Black females. The South had the largest numbers of new infections, accounting for more than 52% of all diagnoses. Of new HIV infections, 67% were among gay, bi-sexual, and other men who have sex with men (MSM). For the first time among MSM, Hispanic/Latinos accounted for the most new infections in 2022.

The foundation of the CDC and HIV prevention strategy includes diagnosing all people with HIV as early as possible; treating people with HIV rapidly and effectively to reach sustained viral suppression; preventing new HIV transmission using proven interventions, including Pre-Exposure Prophylaxis (PrEP); and responding quickly to potential HIV outbreaks to get the needed prevention services to the people who need them. EHE allowed for the scaling up of prevention services in 25 STD specialty clinics in 16 states. Through EHE, CDC has the opportunity to integrate the delivery of services to the public to address related infections. This approach recognizes commonalities across HIV, viral hepatitis, STDs, and TB to develop streamlined capacities that can be shared across programs. One example of success is scaling up HIV prevention and care services in STD specialty clinics, which is depicted here:



To provide highlights from the Division of Viral Hepatitis (DVH), there are approximately 660,000 Americans living with hepatitis B virus (HBV) and 2.4 million Americans living with hepatitis C virus (HCV). In 2023, there were more than 86,000 estimated infections. There are many newly reported chronic infections each year, with 17,650 HBV and 101,000 HCV.[6] Tools are available to eliminate viral hepatitis as a public health threat in the US, including vaccines for HepA and HepB and a curative treatment for HepC. However, far too many new infections still occur, and people experience consequences of these diseases. Left untreated, chronic HBV and HCV infections can lead to liver damage, liver cancer, and death. HepA and HepB are vaccine-preventable, HepB is treatable, and HepC is curable. CDC recently updated its viral hepatitis screening, testing, and vaccination guidelines. The *Updated Recommendation for Universal*

[6] Bixler et al, Hepatology Communications, 2023; Bradley et al, Hepatology, 2024; Lewis et al, CID, 2023; www.hepatitis.uw.edu

Hepatitis B Vaccination in Adults Aged 19–59 Years — United States, 2024[7] includes recommendations for universal HepB vaccination for adults 19–59 years of age, including pregnant persons and adults ≥60 years of age with risk factors for HepB.

CDC works with health departments to prevent, detect, and rapidly respond to viral hepatitis outbreaks. The DVH provides TA to partners, which include person-to-person transmission, foodborne, community, healthcare-associated, corrections-associated, and transplant-associated outbreaks. The CDC Viral Hepatitis Lab is the only lab that provides computational analysis of sequence data to identify and characterize viral hepatitis outbreaks. Since 2020, the Laboratory Branch has supported more than 80 outbreaks throughout the US.

CDC is partnering with the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) to increase the availability of viral hepatitis point-of-care (POC) diagnostics. In June 2024, FDA cleared a fingerstick POC hepatitis C Ribonucleic Acid (RNA) test for use in Clinical Laboratory Improvement Amendment (CLIA)-waived settings. This new POC test allows for same-day diagnoses and rapid treatment initiation. It also has the potential to significantly improve HCV and treatment rates in high-impact settings where people seek care. In November 2025, NIH in collaboration with FDA, began solicitation for a POC hepatitis B surface antigen (HBsAg) test for HBsAg diagnostics.

DTBE Director's Update

Deron Burton, MD, JD, MPH (CAPT, USPHS)
Director, Division of Tuberculosis Elimination
National Center for HIV, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention

CAPT Burton provided updates on the work of DTBE in terms of staffing changes, FY26 budget, TB program and laboratory cooperative agreement, final 2024 surveillance report, and science. With regard to staffing, CAPT Burton has been serving as the DTBE Director since earlier in 2025. Prior to becoming DTBE Director, he served as the Acting Director of the National Center on Birth Defects and Developmental Disabilities (NCBDDD), Director of the Division of Blood Disorders and Public Health Genomics (DBDPHG) within NCBDDD, and NCHHSTP's Deputy Director. Previously, he worked in DTBE's Clinical Research Branch (CRB) as the Methodology and Analysis Team Lead and in DTBE's former International Research and Programs Branch (IRPB) as the Technical Lead for Childhood TB. He was fortunate to overlap as the DTBE Director with Dr. LoBue, who retired in June 2025 after 26 years of service with DTBE, with his first role having been as a CDC Field Medical Officer in San Diego before moving to Atlanta headquarters.

[7] Sandul AL, Rapposelli K, Nyendak M, Kim M. Updated Recommendation for Universal Hepatitis B Vaccination in Adults Aged 19–59 Years — United States, 2024. MMWR Morb Mortal Wkly Rep 2024;73:1106. DOI: http://dx.doi.org/10.15585/mmwr.mm7348a3

Concerning funding, under the current Continuing Resolution (CR), DTBE is funded at prorated FY24 appropriation levels until January 30, 2026. DTBE's FY24 appropriation was about $137 million. Generally, under a CR, agencies may not start new activities that were not previously funded by Congress. DTBE continues its 40-year partnership of providing funds to complement state and local efforts to reduce TB morbidity and mortality. CDC funds 60 state, local, and territorial health departments through a Cooperative Agreement (CoAg) for Tuberculosis Programs and Laboratories for the project period 2025-2029 to carry out TB prevention and control activities, case management and contact investigations, evaluation and data reporting, laboratory services, and human resources development. The goal of this 5-year CoAg is to prevent local TB transmission and progression of LTBI to TB disease. The continuation funds for this CoAg are expected to go out January 1, 2026. In FY25, the TB CoAg awards totaled over $70 million, representing about 50% of DTBE's budget.

Following preliminary 2024 tuberculosis annual surveillance report data released in March 2025, CDC will be publishing the website *Reporting Tuberculosis in the United States: 2024* on its website later in December 2025. The report will describe cases of TB disease reported to CDC during 1993–2024. This report also will include new tables of recent TB transmission and new content describing large outbreaks in the US. The 2024 data from the National Tuberculosis Surveillance System (NTSS) show that the US has achieved a 56% decrease in TB cases and a 68% decrease in the TB incidence rate since 1989, the year that the US first committed to the goal of eliminating TB, resulting now in one of the lowest TB incidence rates in the world.

In addition to TB programs support and data updates, DTBE staff have continued with scientific accomplishments in 2025. The Tuberculosis Epidemiologic Studies Consortium-III (TBESC-III) has been in its third iteration since 2021. At the December 2024 ACET meeting, CDC gave a presentation about TBESC-III describing the consortiums focus on primary care settings, the baseline LTBI care cascade, and ongoing interventions to enhance LTBI testing and treatment. The TBESC-III Study concludes in 2026 and will estimate intervention effects on the LTBI care cascade and will include cost analyses. The NCHHSTP Epidemiologic and Economic Modeling Agreement (NEEMA) is a CoAg funded by the center for projects across the center. DTBE's subject matter experts (SMEs) are currently contributing to 2 NEEMA projects, one of which is to assess the clinical costs of TB diagnosis and care using the Massachusetts All Payers Claims Database and the other to survey TB patients in participating jurisdictions about out-of-pocket costs, time, and lost work or income related to their experiences with TB.

With regard to ACET recommendations updates, this table provides an overview of updates since the last ACET meeting in December 2024:

Recommendation	Update
Define the key components of an effective public health TB workforce in the United States.	CDC included a workforce needs assessment in the 2025 TB elimination Co Ag requirements. TB programs will report workforce information after year one, with information expected in 2026.
Review the data analysis and recommendations presented in the NTCA Guidelines for Respiratory Isolation and Restrictions to Reduce Transmission of Pulmonary Tuberculosis in Community Settings.	CDC workgroup to review recommendations met through April 2025. Activities of the workgroup were suspended pending capacity and revised procedures for establishing guidelines.
Explore a mechanism for accessing the Global Drug Facility (GDF) for procurement of TB drugs and diagnostics in shortage or otherwise not available in the United States.	CDC previously explored the GDF mechanism for the procurement of TB drugs and diagnostics in the United States. CDC will continue to monitor for relevant changes in domestic policy.
Invite the Health and Human Services (HHS) Supply Chain and Resilience Coordinator to attend an ACET meeting.	HHS has undergone restructuring this past year, this position was eliminated in May 2025.

Regarding ACET's recommendation that CDC explore existing resources and tools that can be used to develop a standard and sustainable process for evaluation and periodic assessment of the public health TB workforce, in the new TB Elimination and Laboratory CoAG, recipients are required by the end of Year 1 to provide data to be used in a national TB workforce assessment. Specifically, recipients must provide: A) a list of current positions with titles and percent full-time equivalent (FTE), filled and vacant; and B) a list of additional desired positions with titles and percent FTE that are believed necessary to fully execute the program's elimination plans. The first reporting of this information is expected in 2026.

In terms of ACET's recommendation that CDC review the data analysis and recommendations presented in the *NTCA Guidelines for Respiratory Isolation and Restrictions to Reduce Transmission of Pulmonary Tuberculosis in Community Settings* in regard to existing CDC guidelines and policies related to TB isolation, CDC formed a workgroup (WG) to review underlying data, systematic reviews, and recommendations. The WG determined clinical and population questions and methodological considerations for updating guidelines. This WG met biweekly through April 2025, after which time activities were suspended pending workforce capacity within the agency and revised CDC procedures for establishing guidelines.

ACET also recommended that CDC explore a mechanism for accessing the Global Drug Facility (GDF) for procurement of TB drugs and diagnostics in shortage or otherwise not available in the US. CDC previously explored the GDF mechanism for the procurement of TB drugs and diagnostics in the US. At this time, regulatory barriers persist that make the GDF procurement mechanisms inaccessible in the US. CDC will continue to monitor for any relevant changes in domestic policy that might bear on this issue. Finally, ACET recommended that CDC formally invite the Health and Human Services (HHS) Supply Chain and Resilience Coordinator to attend an ACET meeting. HHS has undergone restructuring this past year. As a part of that effort, HHS ended the Supply Chain and Resilience Coordinator position in May 2025 because funding that originally was designated for those activities had expired.

ACET Discussion: NCHHSTP & DTBE Directors' Presentations & ACET Recommendations

Acknowledging the current staffing levels and challenges, such as losing all of the educational and communications staff, Dr. Sosa asked CAPT Burton what they see as the greatest challenge for DTBE to address and asked Dr. Ellington whether there are opportunities for sharing resources across NCHHSTP.

Dr. Burton indicated that DTBE branches are continuing their core activities. DTBE is operating in a lean posture for staffing. Each branch is having to prioritize the most important activities with limited staffing.

Dr. Ellington responded that internally, NCHHSTP is always working collaboratively to share expertise and resources among its divisions. There are discussions underway about how best to leverage expertise to continue to support all areas of the Center moving forward.

Dr. Sosa inquired as to whether there are any plans for a TBESC-IV.

CAPT Burton reported that there are no plans in place for IV at this point. TBESC-III is winding down, so plans moving forward after TBESC-III's conclusion are still to be determined.

Dr. Chen expressed understanding of the limitations regarding CDC's response to ACET's past recommendations, but emphasized the importance of taking advantage of any opportunities to leverage the GDF as the fastest route to gaining access to drugs for domestic TB. It is unlikely that commercial manufacturers will be interested in entering the domestic marketplace because it is not advantageous to them. Given that the marketplace is not going to drive this and the GDF may be one of the best solutions, she implored CDC to continue to look for possible opportunities.

CAPT Burton emphasized that CDC recognizes the importance of the issues pertaining to drug shortages. The GDF has been considered for some time now, but has not proven at this point to be a quick solution given the regulatory barriers, including that most of the drugs available through the GDF are not FDA-approved. FDA approval would need to be considered for manufacturers to make drugs available in the US. The value proposition for that is up to manufacturers to decide. In terms of a procurement mechanism for the GDF, the President signed an order withdrawing the US from the World Health Organization (WHO), so an alternative procurement mechanism would need to be identified to work with the GDF at this point. DTBE is monitoring a number of lingering issues and will continue to look for any opportunities.

Mr. Cummins pointed out that the issue programs are experiencing now is not necessarily availability, but the high price of drugs—especially for isoniazid (INH). Another option for which a precedent was set in the past was that Uniting for Ukraine (U4U) funds could be used to purchase medication. While U4U was a unique funding mechanism, perhaps exploring that option as a way to purchase TB medications would help some programs that may be having to forego the use of INH due to pricing.

CAPT Burton responded that over the last year, CDC has been hearing a lot about the price of INH being a barrier for programs. CDC's procedures do not allow the funding that DTBE provides to jurisdictions to be used for medication purchases. While this is a continuing topic of discussion, the broader market issues are going to remain a challenge while waiting to see how manufacturers will address the issues moving forward.

Regarding one of the goals of the CoAG funding to decrease local transmission, Dr. Ritger asked how the workforce assessments that grantees would be submitting will be used to inform issues that impact the ability of state and local health departments to decrease local transmission and whether there are plans to publish this information.

CAPT Burton indicated that the workforce assessment is responding to what DTBE has heard from ACET and others that the workforce and expertise are thin within programs in terms of addressing outbreaks and being proactive in engaging communities around LTBI prevention activities. Given that a robust workforce is needed to implement these activities, the assessments will help DTBE understand the programs' capacities and how DTBE's partnership with those programs through the CoAg and other avenues might help to meet those needs and support activities on the ground. While he was not aware of any discussions about an intent to publish the findings, decisions on dissemination strategies will be made after review of the information.

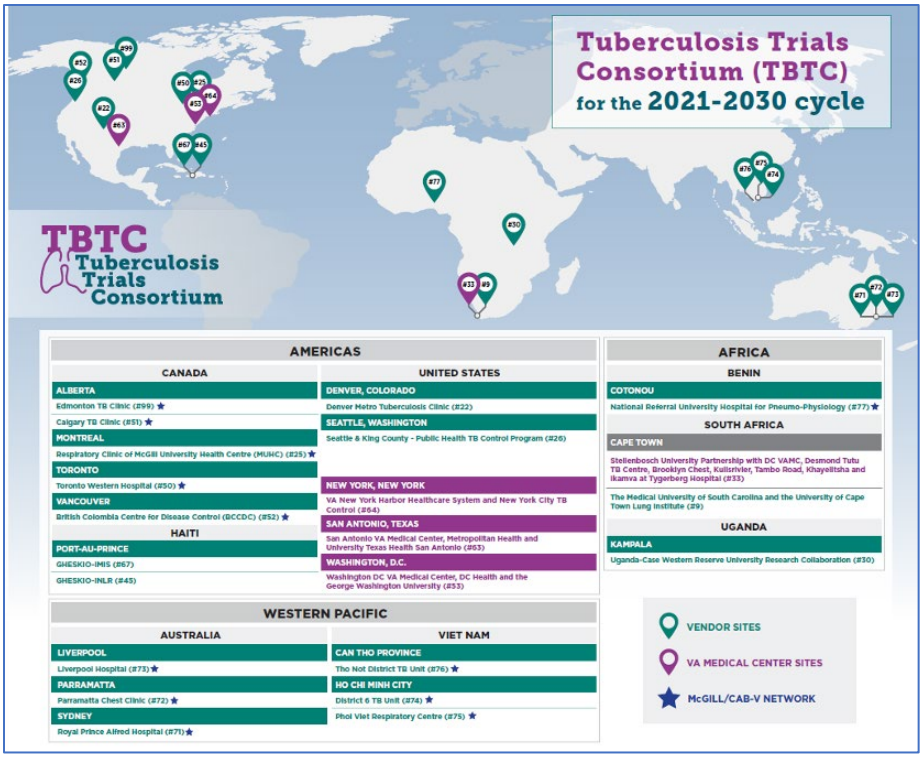
Tuberculosis Trials Consortium (TBTC) Update

Wendy Carr, PhD
Branch Chief, Clinical Research Branch
Division of Tuberculosis Elimination
National Center for HIV, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention

Dr. Carr indicated that TBTC was established in 1993, with a mission "to conduct programmatically relevant clinical, laboratory, and epidemiologic research concerning the diagnosis, clinical management, and prevention of tuberculosis infection and disease."

During the past 3 decades, TBTC has conducted 16 major trials and studies (not counting several sub-studies), and has cumulatively enrolled over 17,000 participants. TBTC has been through several configurations of research sites over the last 30 years that have been marked by the awarding of new contracts. The last competition for a new 10-year cycle was in 2021, which also included significant changes to the consortium. TBTC currently has 21 sites in 8 countries, with 13 in low TB incidence settings (US, Canada, and Australia) and 5 in high TB incidence settings (Haiti, South Africa, Uganda, Vietnam, and Benin). TBTC's portfolio of trials includes both LTBI and active TB treatment trials. All sites have the capacity for these 2 types of studies, although active TB studies are harder to enroll in low incidence settings and the number of participants is usually low.

This graphic includes a map and lists TBTC research sites for the 2021-2030 cycle that are funded through individual contracts (shown in green) or as part of a sub-network through the Veterans Affairs (VA) Interagency Agreement (IAA):



Each clinical trial is designed in a series of steps or phases that are designed to answer certain questions. Phase I investigates whether the treatment is safe, with testing in a small group of people (20–100) for the first time. The purpose of Phase I is to determine safety and dosage. Phase II studies whether the treatment works, with testing in a larger group of people (100–300). The purpose of Phase II is to determine efficacy and identify side effects. Phase III focuses on whether a treatment is better than what is already available, with testing in large groups of people (1,000–3,000), the purpose of Phase III is to confirm efficacy, monitor adverse reactions (AEs), and compare with standard or similar treatments. TBTC has conducted trials in all 3 phases and is currently conducting a Phase II trial and a Phase III trial. The following table highlights the recently completed and ongoing TBTC studies:

Study	Phase	Topic	Status
S31/A5349	**III**	**4-month daily rifapentine (RPT) regimens for active Drug Sensitive TB**	**Completed** Secondary analyses ongoing
S31PK	Sub-study	Pharmacokinetics (PK)/pharmacodynamics (PD) TB drugs	Analysis *Many published*
S31PG	Sub-study	Pharmacogenetics and PK, drug response, and safety	Analysis
S31A	Sub-study	M. tuberculosis RNA transcriptomic expression profiling in sputum	Analysis
S31B	Sub-study	Novel biomarkers to shorten TB treatment	Analysis
S31 Adolescents	Sub-study	Adolescent recruitment, enrollment, and retention	*Published*
S35	**I/II**	**Novel pediatric formulation RPT PK/safety for LTBI**	Analysis
S35A	Sub-study	Acceptability of pediatric formulation RPT	Analysis
S37/ASTERoiD	**III**	**6-weeks daily RPT for LTBI**	**Enrolling**
S38/CRUSH-TB	**IIC**	**Novel short-course BMZ-based regimens for DS TB**	**Fully Enrolled** (Wave 1)

The 2 largest TBTC trials thus far, Studies 26 and 31, have been landmark achievements of TBTC and were both Phase III trials. Study 26 on LBTI enrolled over 9,000 participants and established the new short regimen for LTBI known as 3HP. Study 31 resulted in the new 4-month rifapentine/moxifloxacin regimen for treatment of active TB disease. Study 31/A5349 is completed, but several secondary analyses are ongoing. Among the many unique features of Study 31, there was collection of pharmacokinetic (PK) samples from nearly every participant, as well as pharmacogenetic samples. PK and pharmacodynamics (PD) papers have been published. A pharmacogenetic sub-study that is in the late stages is assessing whether there are human genetic components that affect PK/PD TB drugs. There also are 2 biomarker studies (31A and 31B). The adolescent sub-study (S31 Adolescents) focused on requirement, enrollment, and retention of adolescents in clinical trials and is now published. Study 35 and Study 37/ASTERoiD (Assessment of the Safety, Tolerability, and Effectiveness of Rifapentine) are both LTBI studies using RPT and Study 38/CRUSH-TB (Combination Regimens for Shortening Tuberculosis Treatment) is an active TB treatment trial, which Dr. Carr discussed in more detail.

Study 35 was an open-label, single arm, exposure-controlled dose-finding pediatric Phase I/II study with a primary objective to evaluate the PK safety and tolerability of RPT given in a mango-flavored water-dispersible formulation in a fixed-dose combination with INH. An RPT-only formulation also was used to ensure appropriate dosing. Treatments were given once weekly for 12 weeks to children 0─12 years of age for whom LTBI treatment was indicated, including children living with HIV. The sample size was 72 participants enrolled in 4 consecutive age cohorts: 4─12 years, 2─4 years, 12─24 months, and 0─months. Study 35 had an adaptive design because enrollment was paused at pre-specified points in the study to analyze the PK data during the interim analysis that was used to determine whether the dose needed to be adjusted to ensure that the children were receiving an amount of drug that was comparable to that in adults since children metabolize drugs differently. Enrollment began with the 2 oldest cohorts, paused for analysis, resumed, and then enrolled the youngest 3 cohorts. This study is completed and publications are underway and pending. This study was very important because it provided confirmation of the correct dose for pediatric populations, and results have been used to inform guidelines.

Study 37/ASTERoiD is a large label, multi-center, Phase III randomized controlled non-inferiority clinical trial with 2 arms, which compares the safety and efficacy of a 6-week regimen of daily rifapentine (6wP, experimental arm) to a 12–16-week regimen of any of the short-course rifamycin-based treatment (3HP, 3HR, or 4R standard of care, control arm). The study is currently enrolling, with a sample size goal of 3,400. Current enrollment is 1,426 (as of 21 November 2025). An amendment to Study 37 was approved in 2022 that expanded enrollment to sites in high TB incidence settings, so there are now 20 sites open for enrollment in both low and high incidence settings in North America, Australia, Africa, and Asia, including the following:

North America
- US: Denver, Seattle, Washington DC (2), New York City (2)
- Canada: Montreal, Toronto, Calgary, Vancouver, Edmonton
- Haiti: Port-au-Prince

Australia
- Sydney (3)

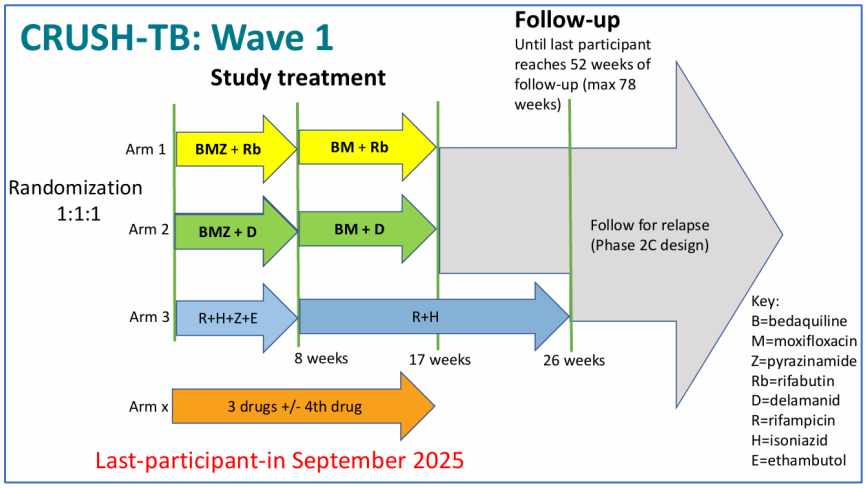
Africa
- Benin, Uganda, South Africa

Asia
- Vietnam: Ho Chi Minh City (2)

Study 37 has reached a great milestone in which the first interim safety analysis can be conducted, with 224 participants in each arm having had sufficient time elapsed to have completed study treatment. The primary safety endpoint is drug discontinuation due to adverse drug reaction (ADR) associated with 6wP and the rifamycin-based comparator arm (3HP, 3HR, or 4R). The estimated completion date for this analysis is the fourth quarter of 2025. The analysis will be reviewed by the Data and Safety Monitoring Board (DSMB) in an unblinded manner to provide recommendations to the investigators as they remain blinded to the results.

A recent protocol amendment was approved to add PK component thanks to an NIH merit award grant to collaborator Dr. Kelly Dooley at Vanderbilt University Medical Center (VUMC). This amendment and PK work will allow enrollment of populations who have not been previously included, pregnant women and children under 12 years of age, and to learn more about other at-risk populations such as older persons, persons living with HIV, and adults with high BMI—populations who are under-enrolled in clinical trials. This component will be implemented using a staged approach. Sparse PK will be conducted among all Study 37 participants who consent and semi-intensive PK will be conducted among select populations (pregnant women and children) at the sites that have the capacity to implement this component. After completing the semi-intensive PK and confirming optimal dose and safety in those populations, the trial will then be open fully to all populations and sparse PK will continue throughout the trial. In addition, a quality-of-life component is being added to assess participant health-related quality of life during treatment and treatment acceptability. This amendment has been approved by the CDC Institutional Review Board (IRB) and sites are currently submitting for local IRB approvals. With the 2 years of follow-up required, the last participant is projected to be enrolled in December 2027, reaching the last participant completion in December 2029.

Study 38/CRUSH is an active TB treatment trial and is designed as a Phase IIC study to assess the safety and efficacy of 4-month bedaquiline (B), moxifloxacin (M), and pyrazinamide (Z) or BMZ-based regimens to a 6-month standard of care (HRZE) among adult and adolescent patients with drug-susceptible pulmonary TB. This is an open-label, multi-center, randomized, 3-arm adaptive trial. The sample size is 288 participants, with 96/arm, and is now fully enrolled at 292 participants. An important aspect of Study 38 is that it is designed to be adaptive so that arms can be added for new regimens that show promise in pre-clinical and early-phase clinical trials, with concurrent enrollment of an equal number of controls. This graphic depicts the design of CRUSH-TB Wave 1:



Initially, there have been 3 arms with randomization 1:1:1 into the control or one of the investigational regimens shown in yellow and green. The 2 investigational arms have BMZ backbone plus a 4th drug of rifabutin (Rb) in Arm 1 and delamanid (D) in Arm 2. The experimental treatment will be given for 17 weeks and the control arm is the standard HRZE regimen given for 26 weeks. Participants will be followed up to 78 weeks or until the last enrolled participant completes 52 weeks post-randomization, whichever comes first. The adaptive design in which additional arms can be added is shown in orange and have been termed "waves." Notably, the last participant was enrolled in September 2025. Research Sites in S38/CRUSH-TB include the following:

Sites with Completed Enrollments (6)

- Cape Town, South Africa
- Kampala, Uganda
- Port-au-Prince INLR, Haiti
- Port-au-Prince IMIS, Haiti
- Can Tho Province, Vietnam
- Seattle, US

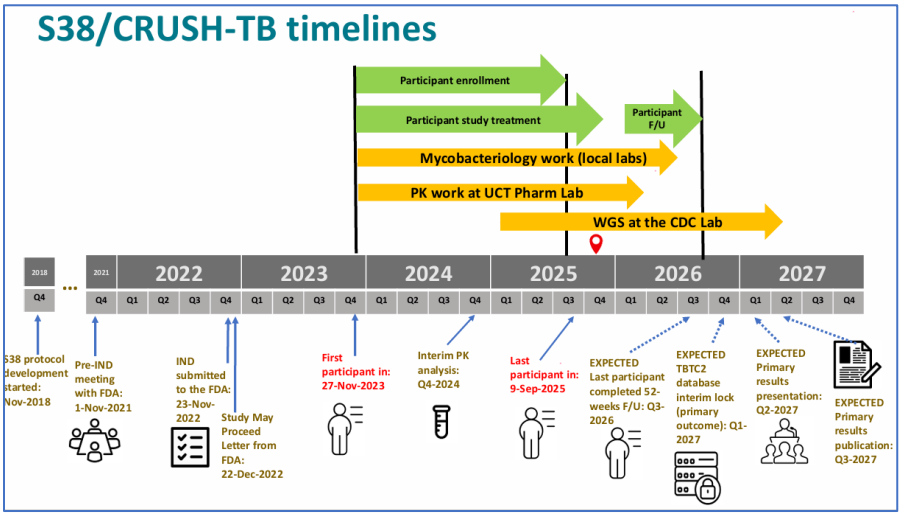
Sites Open but no Enrollments Yet (1)

- Montreal, Canada

Sites Preparing to Open for Enrollment (2)

- Vancouver, Canada
- New York, US

While the site in Montreal was open for enrollment, it did not enroll any participants due to the low active TB incidence. The 2 sites in Vancouver and New York have worked through most of the site opening requirements and hopefully will open in future waves, but are limited by the challenges and costs of acquiring bedaquiline (BDQ) in Canada and the US. To share a few study design highlights, dosing is done 7 days per week with at least 5 of those 7 days under directly observed therapy (DOT). Participants have serial microbiology and safety monitoring, including electrocardiograms (ECGs) that are done with the Kardia Mobile device (AliveCor). Sparse PK sampling will be done in all participants and intensive PK sampling has been completed in some participants. This intensive PK was designed to allow an interim analysis of drug interaction between BDQ and Rb. The trial includes a novel biomarker called the R/S ratio (rRNA ratio). Follow-up will occur until last participant is 52 weeks post-treatment completion, with a maximum of 78 weeks. This graphic shows the timelines of Study 38/CRUSH-TB:



Since Study 38/CRUSH-TB is an adaptive trial, amendment Wave 1A was created that will use the same regimens as Wave 1. However, the inclusion criteria have been modified to focus on priority populations who are often under-enrolled in TB clinical trials (e.g., adolescents, persons living with HIV, older adults, and persons with diabetes). In addition, protocol changes were made to enhance the collection of tolerability data pertaining to low-grade adverse events (AEs) and to incorporate questionnaires to capture participant-reported outcomes. The protocol for Wave 1A has been approved by the CDC IRB and is currently under review by local site IRBs, with the hope to start early in 2026. Wave 2 was envisioned to involve the addition of new regimens. While there is not yet a decision on the regimens for Wave 2, the Pre-clinical Design and Clinical Translation of TB Regimens (PReDiCTR) Consortium that is funded by NIH is evaluating new regimens as part of their work to accelerate new TB treatments. The PReDiCTR Consortium has identified several promising regimens for which TBTC would need to work with manufacturers and asset owners to be able to include them in Wave 2 of Study 38/CRUSH-TB.

ACET Discussion: TBTC Consortium Update

Dr. Holland acknowledged and thanked Dr. Carr for sharing highlights of Studies 37 and 38, especially with regard to the exciting inclusion of populations who are not typically enrolled in these trials and tend to seek shorter courses and obtain feedback from participants on quality-of-life impact.

Dr. Cattamanchi asked whether full TBTC funding would be available through the period ending in 2031, or if reductions in budget are anticipated moving forward.

Dr. Carr responded that this is difficult to answer. Contracts are funded through option years that are exercised each calendar year and are currently funded through the end of 2025. In terms of being able to exercise that option for 2026, TBTC is awaiting the Office of Acquisition Services (OAS) to confirm that. Given that the studies are funded year by year, TBTC will have to work with NCHHSTP and DTBE in terms of how that would look for the consortium.

Reported TB Disease in the United States 1993–2024

Jonathan Wortham, MD, (CDR, USPHS)
National Tuberculosis Surveillance System
Division of Tuberculosis Elimination
National Center for HIV, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention

CDR Wortham highlighted TB disease in the Us from 1993 through 2024, with data updated as of July 10, 2025. As a reminder, the TB elimination threshold is approximately 335 cases or <1 case per 1,000,000 persons. In 1992, there were 26,673 TB cases reported in the US for an incidence rate of 10.4 per 100,000 people. While TB cases and incidence rates have declined since 1992, the annual rate of decline has been inadequate to achieve TB elimination goals. TB cases and incidence rates declined considerably in 2020, coinciding with the coronavirus disease 2019 (COVID-19) pandemic. TB cases subsequently rose in 2021, 2022, and 2023. In 2024, a total of 10,388 TB cases were reported for an incidence rate of 3.1 cases per 100,000 people. This represented the fourth consecutive year of case counts, a 7.9% increase in case counts, and a 6.9% increase in rate compared with 2023. Except for 2015, annual case counts and incidence rates declined every year during 1993 to 2020. Since that sharp decline, there have

been increases in both case counts and incidence rates. While there was an increase in 2024, it was less than the percentage increase in rates during 2023 compared to 2022.

As in past years, 4 US states combined reported approximately half of all US TB cases in 2024. These include California 20% (n=2,109); Texas 12% (n=1,279); New York, including New York City, 10% (n=1,083); and Florida 6% (n=675). These states are the most populous states in the US, but represent only about a third of the US total population. In 2024, 12 states and the District of Columbia (DC) had higher incidence rates than the national rate of 3.1 cases per 100,000 persons. Alaska had the highest rate at 12.3/100,000 followed by Hawaii (8.1); California (5.3); New York, including New York City (5.5); Texas (4.1); DC (4.7); Arkansas (3.9); Kansas (3.8); New Jersey (3.6); Massachusetts (3.6); Maryland (3.5); Minnesota (3.3); and Washington (3.2). In terms of the TB incidence rates and cases per 100,000 people by age, incidence rates were higher amongst adults compared with children <15 years of age. Among persons ≥15 years of age, the incidence rates increase with age. In 2024, people ≥65 years of age had the highest TB incidence rate and children ages 5–14 years of age had the lowest incidence rate. Incidence increased in 2024 compared with 2023 for all age groups except for people ≥65 years of age.

Regarding TB cases and incidence rates broken down by origin of birth, most reported TB cases occurred amongst non-US-born people. Approximately 77.2% of cases occurred among non-US-born people. The percentage of cases among non-US-born people has increased gradually over time during the past decade from 66.8% in 2014 to 77% in 2024. Looking at the percentage of TB cases among non-US-born people by the number of years since initial arrival in the US prior to diagnoses, most cases (51.3%) in 2024 among non-US-born people were among those who had been in the US for at least 5 years. Almost a quarter (~24%) of TB cases among non-US-born people occurred among those who had arrived in the US less than 1 year prior to diagnosis. In terms of TB incidence rates by origin and race/ethnicity, TB incidence rates were higher for every race/ethnicity group in 2024 among non-US-born people compared with US-born people except for those who identified as American Indian or Alaska Native (AI/AN). Among non-US-born people with TB disease, people who identified as Native Hawaiian or Other Pacific Islander (NHPI) had the highest incidence rate, followed by persons of more than one race.

Among people who had social and behavioral risk factor information available and were at least 15 years of age, the most common risk factor reported was being a current or former tobacco smoker (31%) followed by ever experiencing homelessness (9%), history of ever being incarcerated (9%), non-injecting drug use (8%), experiencing homelessness within the past 12 months prior to TB diagnosis (7%), excess alcohol use (7%), incarceration within the past 12 months prior to TB diagnosis (4%), resident of a long-term care facility (LTCF) (2%), and injecting drug use (1%).

The 2024 annual TB surveillance report includes estimates of recent transmission for the first time since 2021 based on an updated method that incorporates whole genome sequencing (WGS) data. The percentage of TB cases attributed to recent transmission by year and genotyping method for 2015–2024 were estimated using GENType-based estimates for 2015–2021 and whole-genome multilocus sequence typing (wgMLST)-based estimates for 2020–2024. Based on conventional genotyping, GENType with polymerase chain reaction (PCR)-based methods, the percentage of cases attributed to recent transmission declined from 14.2% in 2015 to 12.4% in 2021. The updated estimate for 2021 based on the WGS method was 12.8%. After a decline in 2022 to 10.9%, the estimated percentage of cases attributed to recent transmission increased to 11.9% in 2023 and 12.7% in 2024. Looking at a map showing the number of TB cases attributed to recent transmission in the US from 2023–2024 using these methods, 15 counties reported >20 cases, 22 report 11 to 20 cases, 370 reported 1 to 10 cases, and 810

reported zero cases. The remaining 1,903 counties have no genotype cases that could be evaluated for recent transmission during this time period. The takeaway is that using this method to attribute cases to recent transmission, there is significant heterogeneity with respect to whether cases are recent transmission and recent TB incidence.

In terms of the percentage of TB cases attributed to recent transmission by origin of birth in the US for 2023–2024, the percentage of genotyped TB cases attributed to recent transmission among US-born people (33%) was nearly 5 times the percentage among non-US-born people (7%). The remaining 67.1% of genotyped cases among US-born people and 93.3% among non-US-born people were not attributed to recent transmission. These could represent transmission more than 2 years before diagnosis or transmission outside of the US. The percentage of TB cases attributed to recent transmission by selected risk factors in the US for 2023–2024 was higher than the national average of 12% for people reporting non-injecting drug use (33%), injecting drug use (29%), incarcerated (24%), excess alcohol use (22%), experiencing homelessness (20%), current or former smoker (15%), and HIV co-infection (15%). The percentage of TB cases attributed to recent transmission was lower than the national average among people with non-HIV immunosuppression (9%) and diabetes mellitus (8%).

To highlight select characteristics of new large outbreaks, defined by ≥10 cases related by recent transmission during a 3-year period, of TB reported in the US in 2024, there were 6 large outbreaks ranging in size from 10 to 64 cases each. The median age of people in each outbreak ranged from 6 years of age to 37 years of age. At least 50% of cases occurred in US-born people in 5 of 6 outbreaks, and 1 outbreak predominantly involved people who reported experiencing homelessness and using alcohol to excess or drugs.

ACET Discussion: Reported TB Disease in the US 1993–2024

Referring to the map of the number of TB cases attributed to recent transmission in the US for 2023–2024 (slide 13), Dr. Thanassi expressed confusion about why Kansas did not light up more on recent transmission for this timeframe when so many active cases were determined there.

CDR Wortham responded that in general, certain criteria must be met to be included as a case of recent transmission. The first is that pediatric cases are less likely to be genotyped, so those cases cannot generally be attributed to recent transmission, even though it is recognized that those cases are recent transmissions. Pediatric cases are less likely to be attributed to recent transmission on the algorithm because they are not likely to be genotyped or culture-confirmed. In non-genotyped cases in general, when a health department is diagnosing people who have abnormalities on chest X-ray (CXR) but do not have a positive genotype, that could be another situation in which cases are not able to be attributed to recent transmission using this algorithm. However, from a clinical and public health standpoint, it is known that they are attributable to recent transmission. The goal is to become really good at estimating recent transmissions. The reason it has been possible to release some data this year is because some state and local health partners helped use the sequencing and their local epidemiological data to create an algorithm that is as accurate as it can be for a diverse set of states and communities that represent the US. This goal is close to being achieved with the genotyped cases and being able to change some of the parameters that were used with the PCR-based algorithms. There are some initiatives in place to try to do that for non-genotyped cases and potentially for pediatric cases so that going forward, it may be possible to include more groups of cases than can be included now. Some of the Kansas outbreak surveillance data includes epidemiologic data even if they are not attributed to recent transmission because of the genotyping aspects, which is how they can know that.

CAPT Rhodes said she was surprised with the 24% for corrections, because she finds it difficult to know if a transmission is recent. A lot of times they find cases when people come in. It is unclear when foreign-born people entering corrections were exposed since they usually have poor histories. She knows that CDC gets some genotyping data on corrections patients from labs that are drawn on the outside. She asked whether new transmission data were coming only from new transmissions, which are potentially under-reported. She found the 24% to be high because new transmissions are very hard to determine in correctional settings. In the federal system and for immigration, everyone is tested when they come in with tuberculin skin tests (TSTs) and CXRs if they are symptomatic. She wondered how that is being determined at the state-level as well.

CDR Wortham referred to Slide 15, Percentage of TB Cases Attributed to Recent Transmission by Selected Risk Factors, United States, 2023–2024, noting that this deals again with the recent transmission algorithm, so these are genotyped cases. CDC has been receiving isolates and getting genotyping results from samples that are coming from correctional facilities and is aware of a number of outbreaks that have occurred in those facilities. At least some of that 24% is a result of that. They also are aware of a number of smaller outbreaks in communities within prison systems in which the patient in the transmission chain presents to the local jail where TB is identified, so they count as being incarcerated at diagnosis, but their transmission may or may not be occurring within that facility. A higher percentage of those are among US-born people and may not be the population CAPT Rhodes is thinking about.

Mr. Watts inquired as to how the homeless information was collected, pointing out that how the question is asked will determine how likely people are to classify themselves as homeless or experiencing homelessness in the past. The definition is complicated, so he asked what, if any, definition is used. The federal government uses at least 3 different definitions in different agencies.

CDR Wortham asked to follow up with the definition used in their RVCT trainings. In interacting with a number of partners at the state and local levels, they have responded a couple of different ways in their responses to this question. One said that if someone does not have a home address to which something can be mailed, those patients may be coded as experiencing homelessness. CDR Wortham followed up post-meeting with the exact terminology in the 2020 RVCT instruction manual for which he provided a copy of page 32. These instructions give some examples and scenarios, but state that a person experiencing homelessness could be a person who has “no fixed, regular, and adequate nighttime residence” as well as a people “in unstable housing situations.” As he said during the meeting, they know that there might be some variability in reporting homelessness in actual public health practice, but hope that all will consider the RVCT instruction manual when submitting TB case reports. Page 32 of the full 2020 RVCT instructions follows:[8]

[8] https://www.cdc.gov/tb/media/pdfs/Report-of-Verified-Case-of-Tuberculosis-RVCT.pdf

Option *(select one)*	Description
No	Patient does **not** have this risk factor.
Yes	Patient has this risk factor.
Unknown	It is unknown whether the patient has this risk factor.

Definitions:

Diabetic

The American Diabetes Association (American Diabetes Association. *Dia Care*. 2014;37:S81-S90) has established the following criteria for a diagnosis of diabetes:

- Hemoglobin A1c ≥6.5%, **or**
- Fasting (defined as no caloric intake for ≥8 hours) plasma glucose ≥126 mg/dL (7.0 mmol/L), **or**
- 2-hour plasma glucose ≥200 mg/dL (11.1 mmol/L) during an oral glucose tolerance test, as described by the World Health Organization, **or**
- In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose ≥200 mg/dL (11.1 mmol/L)

Persons who do not meet the above criteria only because they are currently receiving treatment for diabetes should still be reported as diabetic.

Homeless

A person experiencing homelessness may be an individual who has:

1. No fixed, regular, and adequate nighttime residence, **and**
2. A primary nighttime residence that is
   a. A supervised publicly or privately operated shelter designed to provide temporary living accommodations, including welfare hotels, congregate shelters, and transitional housing for the mentally ill, **or**
   b. An institution that provides a temporary residence for individuals intended to be institutionalized, **or**
   c. A public or private place not designated for, or ordinarily used as, a regular sleeping accommodation for human beings.

A **person experiencing homelessness** may also be defined as a person who has no home (e.g., is not paying rent, does not own a home, and is not steadily living with relatives or friends). Persons in unstable housing situations (e.g., alternating between multiple residences for short stays of uncertain duration) may also be considered homeless.

A **person experiencing homelessness** may be a person who lacks customary and regular access to a conventional dwelling or residence. Included as homeless are persons who live on streets or in nonresidential buildings. Also included are residents of homeless shelters and shelters for battered women. Residents of welfare hotels and single room occupancy hotels could also be considered homeless. In the rural setting, where there are usually few shelters, a homeless person may live in nonresidential structures, or substandard housing, or with relatives. *Homeless* does not refer to a person who is incarcerated or in a correctional facility.

Dr. Ritger observed that the 2023–2024 timeframe is impacted by the new arrivals and the artificiality of migrants being bussed and moved by plane from the US Southern border to interior cities. Chicago was on the receiving end of that. She asked whether the algorithm takes into account time since US arrival. Chicago identified many co-incident cases and that they may genotype match, but do not represent local transmission for their jurisdiction. Many exposures could have occurred along the way in the route from South America, through Central America, at the US Southern border while waiting to cross or in shelters in other jurisdictions. She wondered how the artificiality of the situation of such a number of new arrivals at one time was adapted to or assessed in some way.

CDR Wortham indicated that WGS has allowed for more specific identification of clustering. Clusters of cases have been seen amongst recently arrived people, and sometimes with a very close genetic relationship through WGS in a number of states who arrived from countries in Central and South America. The approach has been to reach out to local programs when this is observed, primarily to ensure that this did not represent transmission in some shared institution on the US side of the border and, if it did, to consider how to collaborate with state and local partners to work with the appropriate federal partner to ensure that proper infection controls are in place to prevent the transmission. In practice, that has been difficult because partners have reported that it can be challenging to elicit details about the person's journey in real clinical public health practice. There have been patients in several states who have TB with genetic isolates that are very close. Another aim is to ensure that the patients actually have TB, given that an alternate scenario is laboratory contamination at a commercial laboratory someplace where several states submit samples. People who were recently arrived are not attributed to recent transmission, so it is not a concern as much with the algorithm because it is designed around identifying recent transmission within the US.

Dr. Ritger said she worries about some local jurisdictions being tagged as having high levels of local transmission when it may not truly represent that. Adding to Mr. Watts' comments about homeless persons, Chicago coded new arrivals as homeless because they were moved into migrant shelters the city set up. She thinks that also contributes to the increase in Chicago's homeless percentage during this timeframe.

CDR Wortham followed up post-meeting with more details about the algorithm. TB cases among non-US–born people reported within 100 days of US entry are not attributed to recent transmission in both the old (based on PCR-based genotyping) and current (based on WGS-based genotyping) algorithms. For each case, the current algorithm also looks for a plausible source case with the following characteristics:

a. A culture-confirmed, genotyped TB case whose isolate has a matching genotype (i.e., whole-genome multilocus sequence type) AND is within 5 single nucleotide polymorphisms (SNPs) after wgSNP analysis;
b. Reported within the 2-year period before diagnosis;
c. ZIP codes of residence within 100 miles;
d. Occurs in a patient ≥10 years old;
e. Reported infectious form of TB (i.e., pulmonary or laryngeal)
f. Report date must be after US arrival date if the case being evaluated is non-US–born

If a plausible source case is found, the case is considered attributable to recent transmission. In the validation study, the results of which they hope to publish soon, which considered epidemiologic and molecular (i.e., genotyping and wgSNP) data, the algorithm's accuracy was approximately 96%. CDR Wortham welcomed any further questions TB programs have concerning these data.

Dr. Bhavaraju requested additional information about the definition used for "non-US-born" and the rationale behind not just looking at birthplace. It looked like someone would be US-born if they had one parent who is a US citizen, but not if the parents are not US citizens.

CDR Wortham responded that this does not represent a change from what has been done previously. Anyone born within the US is considered US-born and anybody eligible for US citizenship at birth would be considered US-born. For instance, someone born in Germany to a US service member stationed there would be considered US-born. He acknowledged that this definition has caused some confusion.

Dr. Thanassi noted that she was in attendance representing the American College of Occupational Medicine (ACOM) as their liaison. ACOM is happy to be able to look at the Online Tuberculosis Information System (OTIS). While OTIS allows them to parse out the people who have TB by occupation, this is only possible by the occupations that are collected. Occupations collected prior to 2024 included healthcare worker (HCW), correctional care, and migratory agricultural. That collection of occupations comprises only about 6% of the TB cases occurring among employed people. Public health has done a wonderful job of reducing HCW TB by implementing great interventions in public health. However, it is known in the occupational health field that there is a great deal of transmission in other occupations. In 2023 or 2024, the RVCT started collecting occupation as a text file. She asked whether any efforts are being made to determine other areas that should be considered for workplace transmission. It is known anecdotally that this is occurring in other workplaces, but it would be helpful to understand where to find these data so that occupational medicine physicians can do better.

CDR Wortham indicated that occupational variables were added in the 2020 RVCT that was implemented in many places for the year 2023. There have been challenges in putting those data into a usable form for the types of analyses Dr. Thanassi mentioned. It is one thing to identify outbreaks, which can be done through molecular methods and working with state and local public health partners, but that is not all of the transmission. It would be wonderful to be able to assess groups who have increased risk based on their occupations, but there are challenges to that, such as getting data into useable form. There also have been some unanticipated challenges in terms of personnel this year, but CDC will work to make those data as useable as possible as fast as possible.

Given that NHPI have the highest TB among non-US-born and US-born populations and considering that 8% with diabetes is among cases where TB was attributed to recent transmission, Ms. Shinagawa (AAPCHO/TEA) indicated that they are hearing from their partners in the Pacific that diabetes was a risk factor for TB. She wondered what proportion of the 8% is attributable to NHPIs.

CDR Wortham indicated that he could run that analysis and report back to the ACET. The numbers among NHPI are relatively small compared to some of the other racial groups, so small changes numbers such as due to an outbreak, can result in substantial increases in the rate but would have a much smaller impact in some of the other groups. He reported post-meeting that in 2024, 251 people diagnosed with TB disease identified as NHPI. Among those, 185 (74%) were 15 years of age or older. Diabetes was reported for 64 (35%) of 185 NHPI who were 15 years of age or older. [Note: It was later clarified that the 8% with diabetes is among cases where TB was attributed to recent transmission].

Dr. Goswami asked how the transition from GENType to wgMLST affects the ability to see trends and outbreaks in cases attributed to recent transmission.

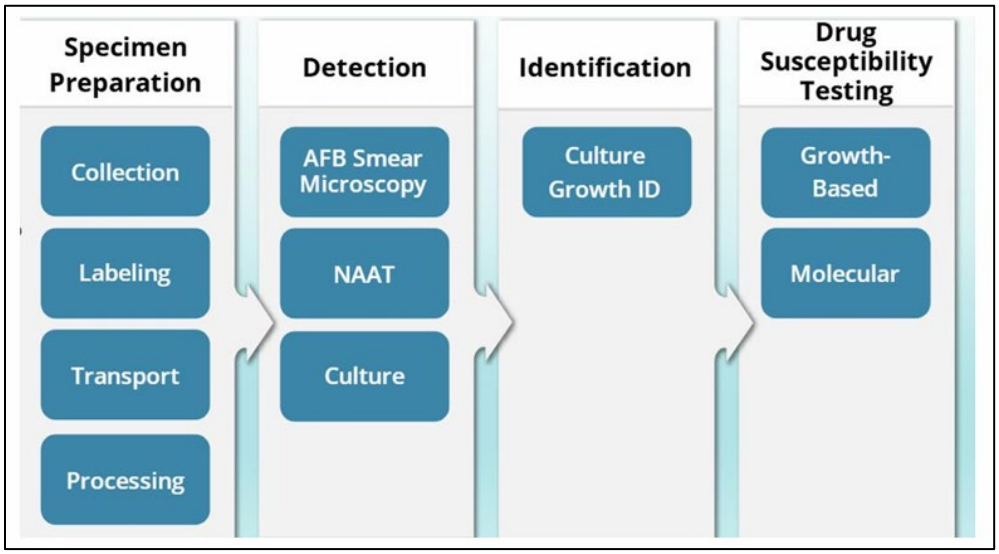
CDR Wortham indicated that WGS has been performed since 2018, from many of which a wgMLST can be obtained. There is certainly an ability to look back several years. The advantages of the WGS methods for outbreak detection are great because it is possible to look at the molecular level and cover about 90% of the genome, which provides the ability to be much more specific. Some of the outbreaks on the older technology might have broken up into subclusters, which can be helpful for state and local partners because instead of trying to find connections between cases with the WGS data that are further apart genetically, they can focus in on those groups. He proposed that since there are 7 years of WGS-based genotyping, the need for looking back to the PCR-based GENTypes should be relatively rare. Part of the purpose of the overlapping period of using both GENType to wgMLST was to address this specific concern. If a program does find itself in those circumstances, he invited them to contact him for assistance.

Dr. Sosa added that their jurisdiction has seen a huge benefit to breaking out some of the older clusters they had with WGS.

Changes in TB Diagnostics in the United States

Angela M. Starks, PhD
Chief, Laboratory Branch
Division of Tuberculosis Elimination
National Center for HIV, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention

Dr. Starks discussed testing workflow and evolving needs, as well as challenges and opportunities across the US TB diagnostics landscape. As a reminder, the testing workflow includes specimen preparation, detection, identification, and drug-susceptibility testing as illustrated in this graphic:[9]



The goal of the laboratory is to provide timely and accurate results across this TB testing workflow. There are a number of areas in which extensive research and development are being conducted, along with areas that continue to experience some challenges. TB testing needs to continue to evolve in the following areas:

- Technological advancements
- Improvements in scientific understanding, especially as it relates to the predictive value of molecular results for susceptibility and resistance prediction
- New drugs and treatment regimens
- Interest in alternative specimen types other than sputum
- Needs for testing access nearer to patients
- Interest in multi-disease platforms
- Drive for shorter turnaround times to reduce diagnostic delays
- Workforce and infrastructure needs

[9] https://www.aphl.org/programs/infectious_disease/tuberculosis/Understanding_TB_Lab_Test_Nurses/story.html

Beginning with a discussion of molecular methods from the global arena and those in the US, diagnostic tests for TB include nucleic acid amplification tests (NAATs). A NAAT is a molecular test used to detect the nucleic acid, typically deoxyribonucleic acid (DNA), of *Mycobacterium tuberculosis* complex (MTBC) in a clinical sample (e.g., sputum). It involves amplification of MTBC-specific targets to improve sensitivity and is intended to provide rapid results more quickly than culture. There are numerous diagnostics in the global pipeline that are in early, late, or commercialized phases. Some tests also include detection of drug resistance. It is an exciting time in terms of the research and development aspects of the global pipeline. NAATs available globally include the following:[10]

- Xpert MTB/RIF® and Xpert MTB/RIF Ultra®
- Ultra- TrueNat MTB® and TrueNat MTB Plus®
- TB-LAMP®, an isothermal amplification process that might be more relevant for limited resource settings
- Abbott Realtime MTB® and MTB RIF/INH®
- BD MAX MDR-TB®
- Bruker-Hain FluroType MTBDR®
- Roche Cobas MTB® and MTB-RIF/IN®

One of the appealing aspects of NAATs is that some also include the capacity to detect drug resistance.

The only FDA-approved commercial NAAT in the US is the Xpert MTB/RIF® assay developed by Cepheid. This assay provides rapid results for identification of MTBC and mutations associated with RIF resistance. It is used on a platform that can be used for testing of other pathogens. It is an older generation test with lower sensitivity and some issues with false positive calls for RIF resistance. About 20% of the samples DTBE receives with a call for RIF resistance detected with this assay are shown to be a silent mutation by DNA sequencing. A silent mutation is where there is a change in the DNA sequence but not a subsequent substitution in the amino acid sequence. These mutations do not actually result in RIF resistance.

There is a limited market for Xpert MTB/RIF®, given that the newer generation Ultra technology is available and used globally. However, Xpert MTB/RIF Ultra® is not currently available in the US. There are some differences in terms of Xpert MTB/RIF® and Xpert MTB/RIF Ultra® in that Ultra utilizes melt curve technology to detect MTBC and RIF resistance and includes targets IS6110 and IS1081 in addition to *rpo*B. Some benefits of the Ultra assay are that it seems to be better in reducing resistance calls for silent mutations due to the revision in the technology and algorithm. It also has a lower limit of detection (16 cfu/ml) than that observed with the use of the Xpert MTB/RIF® assay.

There also is increasing interest in the use of alternative specimen types for TB testing, given that sputum can be difficult to obtain. Alternative specimen types could be easier and non-invasive for collection, have the potential to increase access to testing, possibly could improve time to diagnosis, and reduce some of the safety concerns with sputum collection. One of the areas of interest is in testing of cell-free RNA or DNA that would be released by damaged or dying cells, primarily through collection of urine or blood samples. There have been a number of reports in literature exploring the potential of cell-free DNA to be used as a diagnostic or host

[10] https://www.treatmentactiongroup.org/wp-content/uploads/2025/02/2024_pipeline_tb_diagnostics_final.pdf)

response biomarker[11] to detect TB disease, latent infection, and possibly for monitoring treatment response. Cell-free DNA that would be released from *Mycobacterium tuberculosis* also are described in the literature.[12] A lot of these technologies are either metagenomic or clustered regularly interspaced short palindromic repeat (CRISPR)-based diagnostics. Studies continue to assess the performance and potential of these assays for earlier diagnosis and usefulness for monitoring treatment response. One assay that has recently had some media attention is a CRISPR-based TB blood test from IntelliGenome.[13] This test was given FDA Breakthrough Device Designation program recognition.[14] This program recognizes medical devices that offer more efficient treatment or diagnosis for life-threatening or irreversibly debilitating conditions, prioritizing these devices for faster FDA review and authorization to expedite for development and market entry.

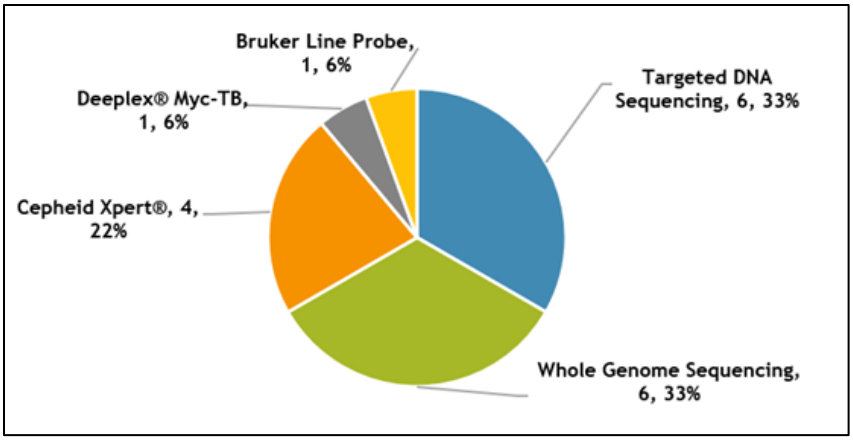
Numerous molecular tests for detection of drug resistance are in early, late, or commercialized phase globally, including but not limited to the following:[15]

- Xpert MTB/XDR® (isoniazid, ethionamide, fluoroquinolones, and second-line injectables)
- Line Probe Assays: Nipro Genoscholar PZA-TB II®, Bruker GenoType MTBDRplus® ver 2.0, & Nipro NTM+MDRTB II®
- DNA sequencing including targeted next generation sequencing (specific areas of the genome) and whole genome sequencing (examining most of the genome for prediction of susceptibility and/or resistance)

Globally accessible targeted next generation sequencing (tNGS) assays are available in the US for research use only (RUO). The Deeplex® Myc-TB (Genoscreen, France) detects resistance to rifampicin, isoniazid, pyrazinamide, ethambutol, fluoroquinolones, bedaquiline, linezolid, clofazimine, amikacin, and streptomycin. This assay relies on deep sequencing of a 24-plex amplicon and probes 18 drug-resistance targets. The AmPORE-TB® (Oxford Nanopore Diagnostics, United Kingdom) detects resistance to rifampicin, isoniazid, fluoroquinolones, linezolid, amikacin, and streptomycin. This assay relies on sequencing of a 27-plex amplicon and probes 24 drug-resistance targets. A number of laboratories are evaluating these tests.

In terms of the status of US molecular susceptibility testing, data from CDC's Model Performance Evaluation Program (MPEP) March 2025 panel[16] indicated that 18 (36%) of 56 participating laboratories (public health, clinical, commercial, and federal) reported use of molecular methods. This program involves sending out 5 isolates of *Mycobacterium tuberculosis* with different resistances to allow for voluntary participation for performance evaluation of laboratories in the US that perform susceptibility testing for *Mycobacterium tuberculosis*. The following pie chart illustrates that a lot of the testing in the 18/56 laboratories was reported to be either tDNA sequencing or WGS:

[11] https://www.nature.com/articles/s41467-024-49245-6
[12] https://pmc.ncbi.nlm.nih.gov/articles/PMC11874688/; and https://www.sciencedirect.com/science/article/pii/S2405579424000081
[13] https://intelligenome-us.com/crispr-tb-benchtop-assay
[14] https://www.biospace.com/press-releases/intelligenome-receives-fda-breakthrough-device-designation-for-crispr-tb-blood-test
[15] Treatment Action Group 2024 TB Diagnostics Pipeline Report: https://www.treatmentactiongroup.org/wpcontent/uploads/2025/02/2024_pipeline_tb_diagnostics_final.pdf
[16] https://www.cdc.gov/tb/php/laboratory-information/model-performance-evaluation-program.html



There has been an increase in evaluation and implementation across laboratories that are performing susceptibility testing and use of these types of assays. In comparison to the same timeframe in the MPEP 2021 report,[17] only 17% of respondents indicated that they had some use of molecular susceptibility testing. Although there are some limitations in terms of commercially available FDA-approved products, laboratories are developing and evaluating performance of laboratory-developed tests (LDTs) for these types of methods and assays in their own settings. That is probably represented in these data as well, not just those that might be commercially available as RUOs.

Moving to phenotypic methods, many are aware of the challenges experienced with pyrazinamide (PZA) susceptibility testing in the US and globally. Susceptibility testing for PZA is typically included as part of the first-line panel for *Mycobacterium tuberculosis* isolates. In late 2023/early 2024, numerous laboratories reported issues with quality control (QC) failures and noted an increase in PZA false-resistance over and above what they normally would observe in their laboratories. At that time, there was work with the Association of Public Health Laboratories (APHL) to collect lot numbers and report issues to the manufacturer, Becton Dickinson (BD), in early 2024. At that time, a number of public health, clinical, and commercial laboratories suspended testing for PZA due to these concerns.

Unfortunately, the BD BACTEC™ and MGIT™ 960PZA test kits were unavailable from July 18, 2024 through late September 2024. BD issued a communication that they identified a corrective action and began to release new lots of PZA susceptibility testing kits that they deemed at that time to be suitable for use. Shortly thereafter, some laboratories again began to report challenges and issues with the new lots that were issued. BD issued another medical device correction in September 2025 as the implemented corrective action from May 2024 might not have fully resolved the issue and further investigation was warranted. Of note, BD issued a communication in November 2025 indicating that there is now a resumption of production and release of a modified version of the PZA susceptibility testing kits. There has been a change to the Instructions for Use (IFU) to indicate that days post-positivity that inoculum can be prepared is now 3–5 days only and adjustment of product shelf life from 18 to 13 months.

[17] https://stacks.cdc.gov/view/cdc/114749

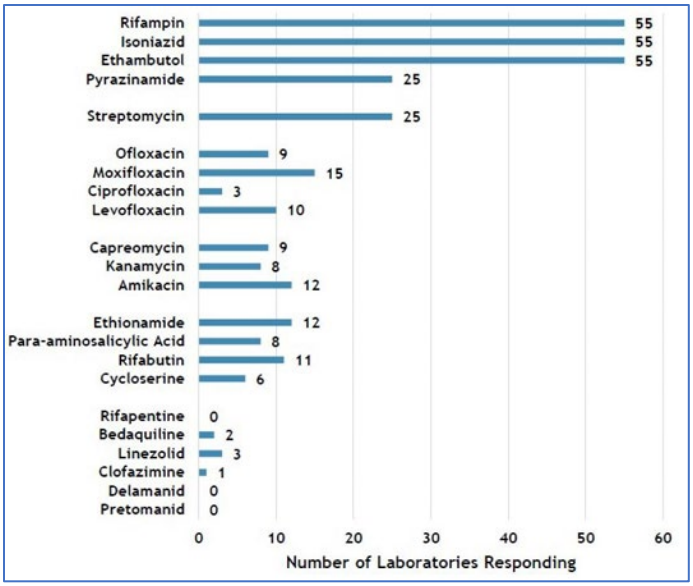
Given the challenges that were experienced over that timeframe with phenotypic testing for PZA, there was a great deal of interest in molecular testing for PZA. PZA is a prodrug that is converted to its active form by pyrazinamidase encoded by *pnc*A. It is known that mutations in *pnc*A that disrupt pyrazinamidase activity result in PZA resistance. It also is known that mono-PZA resistance is rare except for *Mycobacterium bovis*, which has intrinsic resistance due to a specific *pnc*A mutation. National data from 2018-2022 comparing WGS data and reported PZA phenotypic data revealed that mutations in *pnc*A were found to have a 96% sensitivity and 94% specificity for predicting PZA phenotypic resistance in MDR-TB patients. In collaboration with the APHL, CDC set up a network of laboratories that assisted with testing to perform molecular susceptibility testing for PZA. This network continues to operate and be supported while the new test kits are being rolled out for the laboratories that may still have a need while they are working through the evaluation process. Approximately 20 states currently submit isolates to the National Public Health Laboratory (PHL) Drug Susceptibility Testing (DST) Reference Center at the California Microbial Diseases Laboratory (MDL). Those submitters will continue to receive services through that reference center. For other laboratories that may have challenges with accessing phenotypic susceptibility testing for PZA, there is a network of laboratories shown in the following table, which includes CDC's Molecular Detection of Drug Resistance (MDDR) service:

Laboratory	States	POC
CA MDL	California, Hawaii, Minnesota, and Nevada + All states currently submitting to National PHL DST Reference Center	cdphtbdst@cdph.ca.gov
DTBE/LB	Alabama, Connecticut, Georgia, Illinois, Indiana, New Jersey, North Dakota, Ohio Oregon, and Wisconsin	tblab@cdc.gov
FL BPHL	Florida and North Carolina	Patrick.valois@flhealth.gov
TX DSHS	Arizona, Arkansas, Louisiana, Missouri, Tennessee, Texas, Virginia, and West Virginia	Jan.owen@dshs.texas.gov
Wadsworth	Delaware, Maryland, Massachusetts, Michigan, Pennsylvania, New York, Washington (state) and Washington DC	tb_wgs@health.ny.gov

The table includes each laboratory, the states that are assigned to them, and the point of contact to whom they can reach out to coordinate in terms of testing that may be needed. CDC's MDDR service continues to be available to all jurisdictions when a need for assessment or evaluation of other drug resistances may be needed.

Another issue that has been encountered in terms of phenotypic susceptibility testing is that there has been limited access to susceptibility testing for new and repurposed drugs. Figure 5 includes data from CDC's March 2025 MPEP report[18] and breaks down antituberculosis drugs tested by growth-based method among the 55 participating laboratories in that particular panel, which is shown below:

[18] https://www.cdc.gov/tb/php/laboratory-information/model-performance-evaluation-program.html



Note that when examining second-line drugs and newer and repurposed drugs toward the bottom of the figure, access to susceptibility testing for these drugs is limited.

There are no FDA- approved commercial assays for this purpose, and testing currently requires validation as an LDT. The knowledge base for optimal ways to perform growth-based and molecular testing for some of these drugs continues to grow, but more needs to be learned. However, testing is recommended before initiating use of treatment regimens such as BPaL/BPaLM. Testing is currently limited to 3 US laboratories, but there soon will be 4 laboratories. CDC's National TB Reference Laboratory has plans in place to implement this testing for bedaquiline, clofazimine, linezolid, and pretomanid beginning early in 2026.

There is also an increasing interest in use of broth microdilution for susceptibility testing of MTBC for determination of minimum inhibitory concentrations (MICs). A benefit of this format is that it allows for evaluation of different drugs at different concentrations to provide quantitative levels of resistance. MIC is the lowest concentration of drug that inhibits visible growth, which provides more granularity. The challenge is that formal consensus breakpoints are not established for all drugs, so providing a categorical result as with use of a critical concentration in terms of determination of resistance or susceptibility is not always possible. However, work is being done globally in terms of evaluation of an optimized plate design and standardized methodologies for performing this type of testing.

As a later breaker, CDC has newly deposited de-identified WGS sequencing data for 28,850 samples in the National Center for Biotechnology Information (NCBI) BioProject PRJNA1237251 that became available as of 9/8/25.[19] These data are from culture-confirmed cases from 2018–2022. There are some limited meta-data associated with the data in this BioProject that include growth-based susceptibility results for rifampin, isoniazid, ethambutol, and pyrazinamide, the year the case was counted, the region of birth, and the site of TB disease.

[19] https://www.ncbi.nlm.nih.gov/bioproject/?term=PRJNA1237251

Dr. Starks summarized that the US is limited by the number of FDA-approved assays in the US. However, laboratories are continuing to evaluate ROUs or LDTs—especially for molecular susceptibility testing. It is an exciting time during which a lot is being learned. Hopefully, the knowledge base will continue to advance.

ACET Discussion: Changes in TB Diagnostics in the US

Dr. Sosa asked Dr. Starks to share her thoughts about potential stool testing for TB among pediatric patients.

Dr. Starks replied that it has value. In some of the studies she has reviewed it seems like, especially in pediatric cases, the performance could be pretty good. It is also exciting to think about some of the studies examining tongue swabs or cheek swabs. There is variable performance in some of the results, but this could be quite exciting in terms of advancements for those types of specimens—especially for pediatric cases. This is not something CDC is looking at right now.

On behalf of a colleague, Dr. Chen asked whether the data CDC is submitting to the NCBI BioProject will be used in the next version of the WHO mutation catalog.

Dr. Starks said she did not have any information regarding whether that would be used for any updates for the mutation catalog. It is in the public domain, so it is there and available if the WHO has interest in this.

Dr. Cattamanchi commented that in the next month or so, WHO is expected to endorse a new class of near-POC tests using sputum and tongue swabs. Those tests also are unlikely to be available in the US, although they are a tenth of the cost of the Xpert assay and provide results in half the time. It is important to continue to emphasize to HHS and CDC in that the US is going to be behind without better tools and diagnostics that can be used at the POC, including making diagnostics more accessible for people who are unable to produce sputum. This is known to be a major issue for the elderly and children. The issue of FDA approval impacts both treatments and diagnostics.

Dr. Ritger asked whether CDC will provide specific recommendations for state public health laboratories regarding the resumptions of the BD kits for PZM testing or if that is strictly a local decision. Related to that regards whether these reference laboratories will still be available for sequencing if the kits prove to be successful. It has been challenging at the program level to determine which laboratory will be performing which test and whether they should be awaiting a CDC report to be released.

Dr. Starks responded that at this time, CDC does not have any plans to offer specific guidance on resumption of the susceptibility test kits. CDC is working closely with its partners at the APHL to monitor as laboratories are starting to bring testing back online and evaluate how well that is going. That is one of the reasons CDC is hoping for the near-term to continue support of the *pnc*A sequencing network she mentioned. How long that support will stay in place is not known at this time, but at least for the near-term while the evaluations are taking place, CDC will keep the network supported. Hopefully, the new lots will be successful.

Biennial Letter Workgroup (BLWG) Update

Lynn Sosa, MD
Director of Infectious Disease and State Epidemiologist
Connecticut Department of Public Health
ACET Chair

Dr. Sosa provided an update from the Biennial Letter Workgroup (BLWG), for which she serves as Chair and which consists of all of the currently active ACET Special Government Employee (SGE) members. As a reminder, the BLWG was formed to research and evaluate the current status of TB elimination in the US and to draft the biennial letter to HHS on this topic, as required by the ACET Charter. The focus of the workgroup is to: 1) evaluate the status of recommendations from the previous biennial letter submitted to HHS in 2023; 2) engage with ACET members on the current status of TB elimination in the US; and 3) to draft a new biennial letter with updated data and provide findings, observations, and outcomes for review and vote by the full ACET.

The Terms of Reference (TOR) for the BLWG was finalized in July 2025. The BLWG had a planning meeting in August 2025 and a meeting on September 22, 2025 that included presentations and discussions with Donna Wegener and Jason Cummins, MPH from the National Tuberculosis Coalition of America (NTCA); Janice Louie, MD, MPH, Medical Director for TB Prevention and Control from the San Francisco Department of Public Health (SFDPH); and Kristin Bertrang, RN, MSN, Tuberculosis Program-DHHS Program Specialist RN, Nebraska Department of Health and Human Services (Nebraska DHHS). The BLWG also had a discussion on December 3, 2025.

The BLWG sent a State of TB Survey to ACET liaison and *ex-officio* members with the following questions:

1. What are the most critical TB related programs or activities that your organization or stakeholders conduct?
2. What are the potential impacts if those programs or activities are not supported?
3. Have those TB related programs or activities been affected by changes in the federal government or other changes?
4. If yes, what activities or programs are being prioritized? How has the scope of work changed?
5. Do you have any vignettes or stories you would like to share that demonstrate positive impact of your work or negative impact of any recent changes?

In addition, the BLWG posed the following questions to DTBE:

1. What is the current funding level for DTBE in the CR and also in the proposed budget for FY 2026?
2. Is there any budget for research (e.g., TBESC, others) in the current budget and if so, what is it?

Responses to the survey were received from the Pacific Island Health Officers Association (PIHOA), Department of Health and Social Affairs, Association of State and Territorial Health Officials (ASTHO), Stop TB USA, APHL, and We are TB. Based on the information received from the survey and the discussion they had in September, the BLWG has been working on a draft biennial letter, which has 3 themes: 1) strengthening the TB workforce at all levels keeps everyone safe; 2) addressing rising drug costs keeps everyone healthy; and 3) maintaining research for TB testing and treatment makes our country stronger.

For ACET discussion, Dr. Sosa outlined the requests for inclusion in the biennial letter. Typically, the letter includes a background about ACET and its charge, a description of the current state of TB in the US, highlights of the accomplishments of ACET's work, and the specific requests for priorities and how HHS can help further the goal of TB elimination in the US. Based on the discussions, these are the requests the BLWG put forward for discussion during this session:

1. Restore domestic funding for the CDC's Division of TB Elimination to $173 million per year which would be equivalent to the 2014 funding level when adjusted for inflation and determine a sustainable funding model necessary to maintain the required public health infrastructure and account for rising costs. The proposal to combine TB funding with sexually transmitted disease and viral hepatitis funding in the President's budget will not provide the minimum resources needed to combat the surge of TB in our country.

2. Immediately identify ways to bring approved TB drugs into the US via FDA authorization for temporary importation, similar to what was done with lentocillin and extencilline during the penicillin G shortage to address increasing syphilis cases. This effort should include pediatric formulations and combination drugs.

3. As directed in the President's Executive Order 13944, update the essential medications list to include all first-line medications for treating drug-sensitive and drug-resistant TB: isoniazid, rifampin, rifabutin, pyrazinamide, ethambutol, rifapentine, bedaquiline, pretomanid, moxifloxacin, levofloxacin, linezolid.

4. As directed in the President's Executive Order 13944, identify strategies to incentivize pharmaceutical companies to manufacture drugs for the US market.

5. As outlined above, fund DTBE to enable the full support of another cycle of TBESC in 2026 and ensure the full funding of TBTC for the entirety of the current funding cycle through 2030.

ACET Discussion: BLWG Update

Dr. Lewinsohn expressed concern about what ACET just heard with respect to diagnostics and treatment. The US is growing further and further behind on diagnostic capabilities. He suggested that ACET push for approval of novel and exciting diagnostics as part of the effort, especially in terms of children and other vulnerable populations.

Dr. Sosa requested feedback from ACET directly related to the feedback the BLWG heard as part of its efforts.

Dr. Patil asked whether any immediate steps are being taken to alleviate the shortage of drugs, particularly given that some of the planned activities may take months to years. The cost of INH is approximately $300 per bottle. If this price continues, drugs will not be available to treat

patients. A timeline is needed in terms of planning for budgets next year as well.

Dr. Sosa replied that she did not have detailed understanding about how the US was able to get the importation of drugs except that this is the best example of how issues with drug shortages have most recently been addressed. ACET heard during this and the last meeting that the GDF is not an option at this point. This certainly needs to be figured out now and she invited ideas about other resources that ACET could suggest for HHS to explore. The idea was to at least include an option that has been used relatively recently.

Dr. Thanassi asked why the 2014 funding level was selected.

Dr. Sosa indicated that this was a request included in a previous biennial letter, which was somewhat out of convenience and because that was the year that the global TB budget was separated from the domestic budget. While her original thought was to go back to the same year when there was similar incidence, the DTBE budget at that time had global and domestic TB combined. In the spirit of working with a new HHS Secretary who may not have seen this information before, this seemed like a convenient place to begin.

Dr. Thanassi asked whether the budget was increased in 2018. Perhaps looking at the middle of this administration in a similar situation would be more than 2014.

Dr. Sosa said the 2018 budget could be reviewed. If there was level funding, it would represent an overall decrease. Her understanding was that for the last 5 or more years, the funding was flat, which is essentially a decrease because the budget did not keep up with inflation.

Ms. O'Brien noted that the advocacy coalitions such as the TB Round Table that We Are TB is a part of have been using $195 million instead of $173 million. There are increased numbers to back this up, and this would match the appropriations work in March. Some of the factors used to determine $195 million were the flat budgets over numerous years, increased costs for TB programs throughout the country, and TB cases becoming more complicated to treat. The factors are delineated in all of We are TB's materials. She offered to provide more specific information at a later time if needed.

Dr. Sosa replied that while more specific numbers were not needed at this time, the BLWG wants to include references and a good rationale for why a specific number might be included.

Mr. Cummins added that with respect to rising drug costs and availability of drugs, he encouraged making a recommendation to DTBE to explore the option of restocking the stockpile. It has been said that there are no plans for restocking when the stockpile is depleted because of the rising costs. Along the same lines, there was discussion about incentivizing manufacturers. That is important given the lack of availability of diagnostics in the US and the US growing increasingly behind. When Xpert MTB/RIF sunsets, the US will be left in the lurch. The US needs the availability of drugs and diagnostics that are being used around the world—sometimes in settings with lower case rates than the US.

Dr. Rowlinson indicated that as the ACET liaison for the APHL, she wanted to address some of the issues with diagnostics and to reiterate what they heard about the issues associated with the limitations on clinical and public health laboratories to perform testing. If an assay is available for RUO, laboratories potentially can use it as a LDT. However, there are several assays that cannot be used as ROUs to develop as a LDT. A good example of that is the Cepheid Expert MTB/RIF Ultra assay. There have been many conversations with the Cepheid about this, but FDA wants clinical trial data from the US. There are limited data for Cepheid to try to get this through FDA approval. Encouraging or incentivizing manufacturers will not be helpful if they are not able to collect the data FDA requires for authorizing a product. She asked whether there is an option to advocate for FDA to accept data from clinical trials outside the US to get these products authorized in the US. This pertains to the MTB/RIF Ultra assay, as well as all of the other assays Dr. Starks discussed that are coming to market. The US is going to be hampered because these will not be available domestically.

Dr. Sosa noted that this was not necessarily the main theme the BLWG heard from the survey. They heard a lot about costs of drugs and workforce. Not to say that FDA test and diagnostic approval is not important, but the ACET has spent a lot of time on this in the last couple of years. That may be another reason that this did not rise to the top. The goal is to focus the requests in the letter and make it shorter so that it has the best reception and the best opportunity to be read and absorbed.

Dr. Glover emphasized that they should avoid submitting the identical letter every year and should consider ways to include some of these issues, but make it differ from previous letters.

Dr. Sosa agreed, noting that there were 5 areas in the last letter and diagnostics were included. While the goal was to focus on 3 overarching areas, she thought diagnostics could be included in the research part of the letter.

Dr. Glover proposed that if diagnostics are included, perhaps a solution should be suggested as well. Instead of the solution being to ask for FDA clearance with limited data, perhaps there is an investigational device exemption or use that would allow the US to implement the technology in order to provide US data to the FDA at the same time information is being collected.

Dr. Sosa added that perhaps an example can be included for a test that FDA has approved that is not available in the US and describe the special circumstances—similar to the example for treatment. Again, it is important to provide as much concrete information as possible in this letter.

Dr. Holland suggested somehow incorporating the idea about tests that are being manufactured in the US but that are not approved for use in the US.

Ms. Lovinger indicated that some test manufacturing is being done in Maine. She will check with her team to find out which ones.

Dr. Cattamanchi added that Cepheid's Xpert MTB/RIF Ultra is manufactured in Sunnyvale, California. Abbott is a US company that manufactures Determine™ TB LAM Ag, but it is not available in the US.

Dr. Holland thought Dr. Carr's presentation on TBTC re-emphasized how important this is and made the case for keeping TBESC in the letter.

Dr. Sosa recapped the ideas/suggestions that arose during the discussion, noting that the BLWG would need to incorporate these into the letter, ACET would need to vote on the next iteration of the letter, and the letter would need to be finalized and submitted by the end of the year:

- Potentially increase the requested budget for DTBE to $195 million, for which Ms. O'Brien offered to provide some numbers and justification
- Potentially restocking the stockpile while other avenues for addressing drug shortages and pricing are addressed since that will take a while
- The need to include a request in regard to diagnostics, with a focus on the issue of the US falling behind in diagnostics and the lack of availability of diagnostics in the US even though there are many more tests to which other countries have access, highlighting that the FDA will not approve diagnostics without clinical data from the US even though some of them are manufactured in the US

Dr. Wang recalled that the point Dr. Rowlinson made regarded FDA allowing the use of data from outside of the US for diagnostic approval, especially data from European studies. The crux of the issue is that there are tests approved by WHO that are being used outside of the US that should be allowed to be used in the US. While she liked the idea of the example of tests manufactured in the US, she was not clear whether that should be the only argument.

Dr. Rowlinson added that several of these assays are not only WHO-approved, but also are Conformité Européenne (CE)-marked, which means they have been authorized for use in the European market. The US is seriously behind that as well. It would be beneficial if FDA would at least consider using data from the CE-marked assays to inform US authorization. She wondered whether ACET needed a mechanism through which to have that discussion with FDA. Perhaps the first step is to determine who to talk to at FDA.

Dr. Sosa pointed out that this is slightly different. ACET certainly can consider asking FDA to talk to them about mechanisms for approving tests and what might be needed to explore other potential avenues, in addition to including in the letter that ACET wants HHS to work with FDA to prioritize this as part of their response to ACET's letter.

Dr. Rowlinson clarified that the mechanisms are known, but FDA should be asked what they need to make an exception for infectious diseases like TB that are not that common and for which the clinical data will never be sufficient under the current processes.

Dr. Chen suggested adding in the third bullet to ensure additional research funding for domestic trials of newer diagnostics for US cohorts to meet FDA's criteria to support bringing these diagnostics to the US market.

Dr. Glover noted that FDA has a humanitarian device exemption (HDE) pathway for devices for rare diseases or conditions affecting less than 250,000 people in the US, which might be a good example. This is a streamlined review with a fee waiver, less stringent effectiveness data requirements, and a focus on the probable benefits of the device.

Dr. Rowlinson pointed out that in the case of Cepheid's Xpert MTB/RIF Ultra, one of the challenges would be that a lot of clinical and public health laboratories currently use that assay for screening, release of patients from airborne isolation, and not just diagnostics. Even though the number of infections is lower, that may be a sticking point for use of the HDE. For a company like Cepheid to make money on an assay in the US, they would want people to be using it for release of patients rather than to diagnose.

Dr. Glover emphasized that this is why the conversation is needed. He said he was looking for a device other than COVID because a lot of exemptions were made for that which unlikely to happen again because it was a unique situation.

Dr. Sosa clarified that while they do not need to state which diagnostics because there are many on the list, she liked the idea of giving concrete examples. From her perspective, she would rather give options. If the issue is that there is not enough domestic data and that is not going to change anytime soon, consideration should be given to other options for approving diagnostics.

Dr. Rowlinson pointed out that while she is just one person and this is a broader question that has to be put before the broader community, having access to Ultra would be a priority and at the same time asking FDA about pathways for other tests in the pipeline. Cepheid has committed to continuing to provide the US with Expert MTB/RIF, but the US is the only country in the world using that cartridge. Thus, she worries about its future. Her priority would be getting Ultra as soon as possible.

Dr. Glover agreed about Ultra, but he wondered if perhaps they could frame the example in terms of categories of diagnostic tests. For instance, Dr. Starks categorized her presentation by assay methods. They could state, “This is one example, but there are other examples of tests in the pipeline or that already exist but are not available in the US for which the same strategy could be used.”

Dr. Gayle agreed that while there does not need to be an emphasis on a specific test, presenting features that an alternative test would need is one way to describe the functions a test would have to perform. One of the functions would be susceptibility testing in addition to just diagnostics in order to make the system more resilient to fluctuations in medication access or changes in the epidemiology of resistant strains. It is known indirectly which tests are capable of doing that, especially if it is mentioned that this is within the spectra of the Expert MTB/RIF test potentially being sunsetted despite the assurances of the manufacturer.

Ms. O’Brien indicated that she located a report with a breakdown from 2002 that she would submit to Ms. Condit to share with the group to help inform the discussion.

Day 1 Wrap-Up and Adjourn

With no further business posed, Dr. Winston officially adjourned the first day of the meeting at 3:55 PM ET. The ACET stood in recess until 12:00 PM ET on December 10, 2025.

December 10, 2025 Opening Session

Lynn Sosa, MD
Director of Infectious Disease and State Epidemiologist
Connecticut Department of Public Health
ACET Chair

Carla Winston, PhD, MA
Associate Director for Science
Division of Tuberculosis Elimination
National Center for HIV, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention
ACET Designated Federal Officer

Marah E. Condit, MS
Public Health Analyst, Advisory Committee Management
Office of Policy, Planning, and Partnerships
National Center for HIV, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention

Dr. Sosa called the meeting to order at 12:05 PM ET on December 10, 2025. Ms. Condit provided meeting ground rules and noted that members of the public would have an opportunity to provide comments at 2:05 PM ET. Dr. Winston reminded everyone that ACET meetings are open to the public and that all comments made during proceedings are a matter of public record. She also reminded the ACET members to be mindful of their responsibility to disclose any potential COI, as identified by the CDC Committee Management Office, and to recuse themselves from voting or participating in discussions for which they have a conflict. Dr. Sosa conducted a roll call to confirm attendance of the ACET voting members, *ex-officio* members, and liaison representatives. The roll call confirmed that the 16 voting and ex-officio members in attendance constituted a quorum for ACET to conduct its business on December 10, 2025. No new COIs were declared, and quorum was maintained throughout the meeting.

Recap of Day 1

Lynn Sosa, MD
Director of Infectious Disease and State Epidemiologist
Connecticut Department of Public Health
ACET Chair

Dr. Sosa recapped the first day of the meeting, emphasizing that the ACET had a robust and productive first day. She expressed appreciation for the presentations they heard from CDC on various activities at NCHHSTP and DTBE, the presentation of TB epidemiology data, and the presentation on TB diagnostics. There was a good discussion about the various areas the ACET should consider for inclusion in the Biennial Letter, which would continue later in the afternoon. She then commenced the agenda for the day.

Patient-Centered Experience and Care

Ed Zuroweste, MD
TB Medical Consultant
Pennsylvania Department of Health

Dr. Zuroweste expressed appreciation for the invitation to present to the ACET on a very important current concept in TB now. In terms of why he felt like he was an early adapter to the new isolation guidelines, these differ from other guidelines in terms of including TB experts, a medical ethicist, and TB survivors. To him, the credibility of this type of guideline for those who are practicing on the frontlines was very important. In addition to being the TB Medical Consultant for the Pennsylvania Department of Health, he also runs 8 of the county TB clinics and is a frontline TB provider. He shared 2 examples of how these guidelines provided guidance for treatment of a couple of their patients early on. Within a week of the guidelines being published, he had a 28-year-old landscaper from Central America who was living paycheck-to-paycheck whose employer needed him during the busiest landscaping time in Pennsylvania. Dr. Zuroweste was able to see the patient on a Wednesday, start him on treatment that day, and he was able to return to work the next Monday. The patient was NAAT-positive with minimal disease and his RIF was sensitive on his Xpert and missed only 3 days of work, which for him and his employer was very important. The second example was about a week later when a 15-year-old presented whose father had pan-sensitive TB, with a fair amount of confidence that he got TB from his father. The patient was a recent immigrant to the US who had just started high school about a month before this. Dr. Zuroweste was able to get him back to school within 5 days of starting his treatment, which means he missed very little school and was very impactful for him. He needed the education and the contact investigation did not call attention to him as a possible TB contact because he was only out of school for a few days. These are just 2 examples of how these isolation guidelines have impacted him as a provider and, more importantly, the people who are living with TB.

Renee Purdy
TB Survivor
We Are TB

Ms. Purdy expressed gratitude to ACET for inviting her to share her story. While her experience is her own, she believes there are similarities and differences between other TB survivors. She lives in the Bay Area, is a Nationally Board-Certified teacher who teaches first grade, has been a Type 1 diabetic since she was 14 months old, was born in the US, is English-speaking, is a mom to a wonderful 9-year-old, and is super active. Her TB story began in Fall 2022 when she received a letter from the county indicating that there had been a case of TB at her school, but that she was not a direct contact. At the time, she did not realize there was still TB in the US and did not know anything about it. She asked her Principal if she had possibly come in contact and was told that she did not because the student was in a different grade level. While she coaches different things at the school, she had not come into contact with the student. Prior to December 3, 2022, she was living her life. She coached the girls running team, finished a 5K with no problem, traveled to Minnesota to spend Thanksgiving with her family, and was feeling great.

On December 3rd, she took her 6-year-old daughter to see “Frozen the Musical,” which she found ironic because Elsa sends ice to her sister and it spreads. That was the first day she knew something was wrong, but little did she know something was spreading inside of her. On the way home from that matinee, an overwhelming sense of tiredness came over her that made her think she might have to pull over on the freeway. When she arrived home, her daughter spiked a fever and began throwing up and she spiked a fever. They took COVID and influenza tests and thought they had a virus. Her daughter recovered a few days later and returned to school. While she improved, she had a sense that something was wrong. On December 9th, she had a call with her HCP. She asked for a CXR thinking that perhaps she had pneumonia. The doctor agreed to a CXR if she would provide a urine sample. Ms. Purdy got the CXR that day and the technician immediately offered to walk her back to urgent care, so she skipped the urine sample because she knew something was wrong from the CXR. She was seen by urgent care the next morning who asked whether she knew if she had come into contact with anyone with TB or had traveled. She then remembered and showed them the letter from the county, but they said there was no way she had TB and that it must be a unique case of pneumonia. They sent her home with 2 antibiotics.

Her motherly instinct caused her to call her daughter’s father to say she did not think their daughter should be with her. Her daughter went to her dad’s house where she stayed for the next few months. Ms. Purdy started the antibiotics and while she was not getting worse, she was not getting better. She returned to the doctor on December 14th, at which point she was having night sweats and losing weight. Her QuantiFERON Gold TB test (QFT) came back on December 17th confirmed positive and she began treatment on December 22nd. That entire process was very overwhelming, and she feels lucky that she was able to catch it so quickly and the doctor listened to her instincts. The county health representative came out to sign all of the paperwork and told her she would be in isolation for 5 days to 2 weeks. Because she is a very goal-oriented person, she was convinced she could do this. The 2 weeks came and went, but her test would not convert. She was at a level 4, had cavitation, her symptoms were improving, but she would not convert. That was during the Christmas season, so she spent the holiday not being able to see her daughter, by herself, without family. Around New Year’s, she hit rock-bottom because when she asked for a timeline for getting out of isolation, no one knew. She had a friend who was sick with influenza for 3 weeks along with her whole family, but they were together. Her friend talked about how hard it had been and she told her to imagine that times 4 being by herself not seeing anyone. Each day Ms. Purdy was in isolation, it magnified the experience.

She felt so alone and so unseen. In the early part of the new year, her family became very concerned about her mental health. She reached out to a counselor she had a couple of years before that when going through a divorce, who said her parents, sister, and friend had called her to express their concern that Ms. Purdy might be suicidal. The counselor told her she was to call everyone back to tell them that she was not suicidal but was horribly sick and totally alone. At this point, she also found and joined the We Are TB support group, which was the first time she felt seen. There were finally people who could understand what she was going through and could tell her whether the symptoms and side-effects from the medications were normal. She was released from isolation on Valentine’s Day, when she and her daughter celebrated Christmas. Ms. Purdy’s total isolation was about 80 days. She had a lot of side-effects from some of the medications during that time and her entire treatment took 3 regimens to complete. During that time, she saw her county representative 2 times when she came to fill out paperwork. Her infectious disease doctor would check in, but it was scary because she was having a lot of side-effects and could not reach anyone regularly. Her infectious disease doctor was incredible, but she was only part-time. Whenever she called the county, she rarely got a response.

When she left isolation, she went to the mountains to celebrate and played UNO. Her daughter accused her of cheating because she could not tell the difference in the color of the cards. Because she had been in isolation by herself for so long, she did not realize she had become color-blind because she was used to seeing the exact same things every day. Plus, no one had come by to check her eyes during that time. She did not realize that this was a side-effect. She scheduled an appointment with her ophthalmologist whose first question regarded whether she was on ethambutol. During the beginning of isolation, she could not have gone anywhere because she was so ill. By the end of the isolation, she was running 5Ks again and had great energy, but the mental effects of that time period still haunt her. They moved this Fall to a new place because the memories from the last place were too strong for her. Every time she got a cold, influenza, or COVID, she would find herself feeling like she was in isolation again. The financial impact of that time period also still haunts her. As a teacher, she used all of her leave time. Each year since then, she has had to pay out-of-pocket for substitutes when she or her daughter get sick.

ACET Discussion: Patient-Centered Experience and Care

Dr. Sosa thanked Dr. Zuroweste and Ms. Purdy for sharing their experiences and explained that one of the reasons ACET wanted to talk about this during this meeting was in order to focus on making the experience better for all patients. While it makes sense that the initial period of diagnosis and everything that goes into that are probably heightened, ACET wanted to hear about the whole experience. From the bottom of her heart, she expressed empathy for Ms. Purdy who was treated for a year, which is longer than most TB patients. It is important for the ACET to hear about the whole experience so they can think as a group about where to focus to make improvements. She agreed with Dr. Zuroweste that these guidelines have been important in terms of spurring that discussion. Everybody who works in TB is very dedicated to and invested in their relationships with and care of their patients. These guidelines have been important in highlighting the discussion about being more patient-centered and not necessarily applying the same algorithm to everybody. It is important to recognize that everybody's experience is unique. She posed the following questions to start the discussion: 1) What was your experience with TB diagnosis and treatment, for which Ms. Purdy provided a good picture; 2) What were the major social, medication, mental, and physical health issues that you face; 3) What kinds of data do you think are necessary to guide improvements in the TB patient experience; 4) What support is needed that patients could benefit from?; and 5) What would you tell ACET members and health providers what you want us to focus on and think about?

In terms of the major social, medication, mental, and physical health issues that she faced, Ms. Purdy emphasized that being isolated for that long was hard for people to understand. It was almost like when the world was shut down with COVID because it was 80 days, but the difference was that no one else experienced it and everyone else's lives went on. She also was super ill, so even her re-entry into society was very challenging. She finally converted and got out of isolation on Valentine's Day, booked a reservation at a restaurant for her and her daughter, but felt awkward ordering and was overwhelmed by all of the people in the restaurant. She felt like she had forgotten how to act socially. Though she wanted so much to connect with people, she also was overwhelmed by the sheer number of people when she visited Costco. It took a while to re-integrate, but she had a neighbor of Indian origin who brought her lunch with particular spices every day and offered her encouragement. As mentioned earlier, the We Are TB group was huge for mental health. It would have been helpful to have mental health providers who were experienced with isolation, but she was paying out-of-pocket. She did have a phenomenal therapist, who had to consult with others to help her understand how to work with Ms. Purdy on this. The medications were brutal. Not only did she have the color-blindness, but

also had drug-induced hepatis and had to switch drugs and was not permitted to exercise any longer. By the end of the year, she was double-booted and her Achilles tendons were barely hanging on. With every step, she was afraid she was going to rupture one. Just 3 weeks ago, she stepped back on a tennis court for the first time since before her diagnosis because her tendons are now at a point that she can push off. She is joining a league again for the first time since 2022. Her eyes have recovered and the physical side-effects from the drugs are finally leaving her system. She does think her experience with her county health department is an anomaly compared to others. Her representative treated her more like a box to check, met with her only 2 times in a year, and did not try to establish a relationship with her.

Dr. Zuroweste pointed out that the isolation guidelines have opened up more dialogue with the individuals who are suffering from TB so that now they are having many more shared decision-making with patients, at least where he is. They have always tried to engage in patient-centered medical care and he is a family doctor, so he has always felt that he should deal with patients on that level. Now he is seeing that all of the clinicians are much more open to shared decision-making. For example, they have a person who is struggling just like Ms. Purdy did with the medications and they are having to switch him to the potential of BPaL (bedaquiline, pretomanid, and linezolid) or BPaLM (bedaquiline, pretomanid, linezolid, and moxifloxacin), which is 6 months. The alternative was 12 to 15 months of 4 other drugs. The clinician decided to discuss this with the patient and have shared decision-making, and the patient decided not to do the shorter course. He wanted to do the longer course because he was more comfortable with those medications. This is just another example of clinicians actually listening to patients, the survivors, and having them direct clinicians in decision-making, which is very healthy for everyone. The guidelines have opened that up more, because everybody is individual and the guidelines are complicated. The 2 examples he shared earlier were people who had minimal disease and they were not drug-resistant, so within 5 days of starting medication he could return them out of isolation completely and felt very comfortable doing that. However, there are other cases that are much more complicated that are not getting out of isolation in 5 days. At least there is now a mechanism of discussing those scenarios with the patients.

Dr. Sosa noted that she works in Connecticut and they adopted the guidelines pretty early as well. She has tried to explain to their staff and the local health department that it is part of the trust-building process with the patient not to treat them all the same. Part of the challenge is that everybody across the spectrum of healthcare is very busy and it is sometimes easier to just apply the rules. Acknowledging from the beginning that every patient is different is one way to build relationships with patients. Every part of a patient's TB experience is going to be unique and it cannot be assumed that there might be the same resources for everyone. For instance, having better health department support throughout her illness could have changed Ms. Purdy's experience.

Ms. Purdy understood that she could not be around others and she was dealing with many factors. However, even when she was back functioning in terms of her diabetes not requiring as much insulin, gaining weight, eating, and running 5K, she was still in isolation for another month. Even at her most contagious, she did not transmit TB to anyone. That last stretch was so damaging to her social and mental health and the trauma that still lingers from that. She is all about keeping other people safe and would have felt horrible if she had transmitted TB, but those tests were not converting.

Dr. Sosa asked Ms. Purdy to provide more advice or suggestions about the challenges she had in terms of coming out of isolation, talking to people about TB, and what would have been helpful. This is a long process and people do not necessarily know about TB.

Ms. Purdy said she was very direct with her class when she returned. She lived in one county and taught in another, so 2 counties were involved. The county where she taught hosted some informational sessions and to answer questions, which she thought were helpful for the school population. The more people who are educated on TB, the better. She has tried to educate her friends and encouraged them all to get tested. She reached out to every person she had come into contact with to let them know. She is an educated white woman and American citizen, so the stigma she experienced was probably different from others. People were bewildered that she had gotten such a thing, and just hearing about her struggle and TB has created some additional advocates. Even now years later, her friends do not understand the main issue of isolation. Everyone knows what COVID, influenza, and cancer are. A lot of people in her community did not have any sense about TB. While they wanted to be supportive, they just did not know enough.

Dr. Zuroweste added that it is always assumed that there is going to be a lot of stigma, so they have to talk to each person. He had another young man who was in high school who was born outside the US so he discussed his concern that when the young man returned to school there would be stigma, especially among his friends. The patient said it was not a problem because he had told everybody that he had TB. In fact, he ended up infecting several of his closest friends. But he said it was almost like a badge of honor for them that he infected them and he was not feeling persecuted at all. Again, this is talking to an individual patient. Everybody is different. All of his friends were born outside the US, they knew more about TB and that they needed to have preventive treatment, and they all came in and all were treated. This illustrates the importance of not assuming anything.

Dr. Sosa asked Ms. Purdy to expand on her experience with HCP in terms of whether there was someone who did really well and someone who did not.

Ms. Purdy stressed that her infectious disease doctor has been phenomenal, other than being part-time and not necessarily quickly reachable. She continues to have a great relationship with her infectious disease doctor, who was very encouraging, provided referrals for the tendon issues, and now uses her as a thought partner. The flipside was the county representative who saw her as a checkbox and never asked a question about who Ms. Purdy is as a person. She was a compliant patient who had access to food because she could order groceries and had family sending her food and she took her medications, so she ticked all of the boxes for the case worker. Another issue is how the TB impacts not only the patient, but also everyone around the patient. Her daughter was 6 years old at the time and she said she wondered every day when she would be able to see her mom again. She stagnated academically from the day her mom went into isolation until she came out, and is now more clingy. The lasting impacts for her daughter have been significant. Her students that year also were without a consistent teacher for months and were just coming out of COVID, so it was hard for them as well. Her family felt horrible guilt that they could not be with her and did not know how to support her.

Dr. Sosa asked Dr. Zuroweste to talk about what data would be helpful to have.

Dr. Zuroweste said it is a process they are going through right now with the isolation guidelines. They are using the same checklist Baltimore is using, which is very helpful. The guidelines are very flexible, so everyone needs to discuss them as they go along and try to get some consistency whenever possible. Pennsylvania has only done a couple of things that are strict. One is that if someone is in isolation for 2 weeks, the nurses or clinicians have to contact them and tell why the patient is still in isolation. That is a fairly stringent guideline for his group. People also have to go through the checklist that was developed by Baltimore and go through all of the steps, which is very helpful in terms of trying to decide when people can leave isolation. What is needed now with this particular set of guidelines is more discussion about how people are dealing with it and when they are having difficulty getting people back to work or their lives. The reason NTCA decided to create the guidelines themselves and not wait for the CDC to change the guidelines was because they heard from survivors that isolation was very difficult and took a huge toll on then. Oftentimes it is very complicated to decide when someone can leave isolation. A teacher going back to first grade or someone returning to the NICU with newborn babies would be a totally different situation that would have to be considered carefully, especially if they were still 2 or 3 plus on their smears. It is known that smears are not an accurate description of when somebody should be out of isolation, but it certainly weighs heavily on clinicians—especially if it is unclear whether there is any drug-resistance at all or the person is not absorbing the medications and not getting a good level. It really depends on how the patient is doing. He would love to have patients like Ms. Purdy because she listens to and understands her body. She knew at a certain point that she was back to where she should be, was healthy, and was doing better. Why was she still being isolated? More information is still needed moving forward in making these guidelines as simple as possible, while still individualizing every person. This makes it difficult because clinicians like standardization and being able to put people in boxes. Too bad because it is better for the survivors.

Dr. Bhavaraju pointed out that there have been discussions about cuts in funding, insufficient staffing, and how that impacts providers. However, it is important not to forget the providers need to offer support. Ms. Purdy's story reminded her that this also impacts the patients. In addition to the contact investigation in Ms. Purdy's school, she asked whether there was a larger investigation conducted around her and if so, what the experience felt like. She observed that Ms. Purdy is educated, well-spoken, and advocates. However, in other situations there is no one to do that.

Ms. Purdy said she thinks that a lot of people who implement guidelines do not understand how schools work. The initial patient was in her own class, but children tend to be moved around to reading groups, math groups, and other areas. Only the one group in the child's main classroom was tested. At some point somewhere in that school, she came into shared space with that child. She is a Type 1 diabetic and no one could find another Type 1, so it was difficult to ascertain how her experience was different. When she was diagnosed, she put a ton of pressure on her county because she demanded that they test all first graders. The county did set up testing at the school, but it was a lot of work for them. That would not have happened if she had not been a strong advocate, along with some parents who also advocated strongly. The contact investigation also went back to look at the initial patient to determine where they may have missed something. They did find others from the initial contact who had LTBI who were able to get treated and it never turned active.

CAPT Rhodes indicated that the Federal Bureau of Prisons (BOP) has no guidance on releasing from isolation, though she continues to try to acquire that guidance. There is not shorter guidance for a congregate setting like prisons, so they have to work on this as the next step. Unfortunately, they have to utilize the longer isolation guidance because these are congregate

settings and patients have to be sent back there. She appreciated Ms. Purdy's thoughts on how socially and mentally impacting isolation is. When inmates go into isolation, they get 30-minute checks. When she was working in the institution, she would tell the officers they were not on punishment and to make sure the patient got their commissary and property. That does not always happen. To just stick patients in a cell with nothing mirrors how Ms. Purdy felt. When she is among brilliant minds like ACET, she advocates for figuring out how to reduce time in isolation in congregate settings. They also want to protect the rest of the institution so that TB does not spread to others, but they also do not want to put mental strain on patient inmates they are treating for TB. CAPT Rhodes said she was so sorry about what Ms. Purdy experienced and thanked her for sharing her perspective, which solidified how much these guidelines are needed for congregate settings.

Ms. Purdy said she recalled thinking a lot about how her isolation must be what it felt like to be in prison, except that no one laid eyes on her for months. Even in jail, someone would have laid eyes on her regularly.

Dr. Holland thanked Ms. Purdy for sharing her experience and perspective, which hit on every point ACET has talked about. He acknowledged that some people who have had such an experience never want to think about it again, but she came before ACET and relived her experience to help push the needle forward. He expressed admiration and appreciation for her courage in sharing her journey.

Ms. Purdy said that she would not wish this experience on anyone, but she also feels like having a voice can help the experience be different for others. One story she tells is that her daughter had a pet Guinea pig when she was diagnosed with TB. A couple of weeks into isolation, the Guinea pig started appearing ill. She called every vet in the Bay Area, all of whom told her that the Guinea pig could not get TB. However, she watched the Guinea pig get increasingly worse. She finally called the University of California Davis Veterinary school who told her that Guinea pigs could not get TB. Oakland Zoo put her through to the veterinarian who said they absolutely could get TB and are very susceptible. Now 1 person said they could and 40 people said they could not. She called Johns Hopkins Research on TB and the person actually answered the phone. She conveyed that she had been in isolation about 50 days and that the Guinea pig appeared to be dying in front of her eyes. He told her that they used to use Guinea pigs for testing because they are the most susceptible to getting TB. Not only was she in isolation, but also she was in isolation with an animal who died of the same thing. She relates it to Tom Hanks and Wilson the volleyball in that she watched her only companion die of the exact same thing.

Dr. Chen said it was lovely to hear Dr. Zuroweste's voice and that Ms. Purdy is a TB hero in the West and is greatly appreciated for agreeing to participate in so many speaking events. She said she wanted to give voice to the ongoing theme that increasingly more people are echoing in that Ms. Purdy's story beyond magnifying what isolation can do also magnifies the conversation that is needed about more tolerable regimens. More data collection is needed in clinical trials on tolerability and the side-effects, even the lower side-effects, which make regimens so intolerable and have to be switched all of the time. Having solid data can help to support shared decision-making.

Dr. Zuroweste added that he is thankful for the new isolation guidelines and now they need to move forward with analyzing how things are going as the guidelines are rolled out in terms of how effective the guidelines are; whether the states are really using the guidelines at the county and state levels; whether survivors are doing better, especially in terms of mental health; and if the guidelines are resulting in the desired outcomes.

Ms. Purdy urged the ACET to make sure the new guidelines are being adopted, and she hopes that no one has to experience the prolonged isolation like she did because it is very cruel. She also encouraged giving consideration to the mental health services patients who are in extended isolation should receive.

Dr. Gayle asked whether performance measures have been formulated yet for the isolation guidelines, or if ACET could propose this in the letter.

Dr. Sosa was not aware of any performance measures for the guidelines. The existing performance measures are focused on treatment of the patient and meeting certain benchmarks as a whole, such as starting treatment at a certain time, obtaining isolates for genotyping patients, et cetera. Part of the challenge is that these are NTCA guidelines, which are great, but they are not CDC guidelines, which creates some challenges. As they heard the day before, a previous recommendation was for CDC to consider how they could more formally adopt the NTCA guidelines or align the NTCA guidelines with some of the older guidelines, such as guidelines for congregate settings. There are some barriers to that because of how the NTCA guidelines came about in a different way than previous guidelines.

Mr. Cummins thanked Dr. Zuroweste and Ms. Purdy for their presentations and insight. He agreed that the national guidelines were not really operational guidelines. Some work toward or play into the traditional release from isolation, such as treatment initiation within 7 days of specimen collection. In terms of the suggestion about adding benchmarks, this is probably not possible. TB programs across the country would have to set those and could provide them to CDC in their annual reports.

Public Comment

Lornel Tompkins, MD
National Medical Association
Pulmonary Specialist/Primary Care

Dr. Tompkins said she was wondering, particularly given the presentations they heard earlier and knowing that public health departments are severely challenged with personnel and funding, if there is a way that the ACET could encourage more outreach—particularly in settings that are less well-resourced. Perhaps there is a way to use partnerships with medical associations; The Divine Nine,[20] one of the most influential networks in African American higher education and community leadership; and other public social conscious organizations that have outreach capabilities to educate them to help increase TB awareness and ensure access for others who are in the position of Ms. Purdy in long-term isolation.

[20] https://blackownedentrepreneur.com/the-divine-nine-a-complete-guide-to-americas-black-greek-organizations/

L. Masae Kawamura, MD
Retired TB Controller, San Francisco (1996-2011)
Member, National Tuberculosis Controllers Association

Dr. Winston noted that Dr. Masae Kawamura submitted a public comment in advance that was shared pre-meeting with the ACET members, which Dr. Chen read into the record:

November 17, 2025

L. Masae Kawamura, MD
263 Molino Ave
Mill Valley, California 94941

Advisory Council for the Elimination of Tuberculosis (ACET)
Centers for Disease Control and Prevention
Atlanta, GA

Subject: Domestic Strengthening of Tuberculosis (TB) Case Finding and Prevention Needed Now: A Model to Follow

Dear Members of the Advisory Council,

As a retired TB clinician, TB controller, educator, and concerned citizen, I am writing to share my perspective on the policy and implementation gaps needed to address the rising rates of TB in the U.S. and a return to the road of TB elimination.

The TB incidence in the United States is increasing after nearly 3 decades of steady decline, reversing hard-won progress toward elimination. TB rates have exceeded pre-pandemic levels for 2 years in a row, (3.0 cases per 100,000 in 2024 per CDC). Even more concerning, the increased rates are not focal but spread across 34 states and the District of Columbia, many of which were considered low-incidence areas. As ACET is well aware, reactivation of TB is considered the driving factor for TB in the US, which comes from an estimated 13 million people with TB infection (TBI) reservoir and accounts for 80% or more (in some states), of all active TB found in the US.

The reversal in trends reveals the fragility and gaps in our health systems and policies, despite having a comprehensive set of TB policies addressing persons at risk for TB or TB infection in the US. Outbreaks in congregate worksites with community spread point to new OSHA requirements needed for certain industries, or by expanding migrant CDC TB screening/Treatment policies to include working (and student) visa holders. More importantly, however, the national implementation gap and lack of adoption of the Services Task Force (USPSTF) recommendations for latent tuberculosis infection (LTBI) screening are hindering TB prevention, asymptomatic TB case finding, and further reduction in TB incidence.

The 2016 USPSTF guidelines were celebrated as a huge step forward by US TB Controllers because they nationally addressed TB screening and prevention of adults at the primary care level, where most at-risk individuals seek routine services. It was a milestone to reach and begin eliminating the enormous TBI reservoir responsible for TB reactivation. However, we are far from nationwide adoption of these important guidelines, and TB screening and prevention remain fragmented, especially in primary care, where competing screening priorities exist. To blame are gaps in the current USPSTF Guidance, including a lack of specificity for implementation in

primary care workflows, such as systems-level integration of electronic health record prompts, alignment of insurance coverage, and state-level surveillance for reporting, follow-up, and linkage to care or treatment completion. As a result, adoption has been absent or inconsistent. TB testing is more often reactive rather than based on guidelines, and community clinicians remain unaware of them, leaving the cycle of TB reactivation to manifest unabated.

The good news is that California took a landmark step by enacting AB2132 into law on September 29, 2024, adding new sections to the California Health and Safety Code. It requires primary care providers and clinics to:

1. Offer TB screening to all adults over age 18 at increased risk during routine care
2. Ensure confirmatory testing and documentation in the medical record
3. Provide or refer for preventive treatment when indicated
4. Align with existing public health reporting systems for monitoring outcomes.

This legislative model creates a state-backed infrastructure for sustained TB screening and prevention by linking public health, health systems, and clinicians in a coordinated approach. It also operationalizes the USPSTF recommendations in a way that is measurable and enforceable, rather than advisory.

Given the current TB trends, lack of significant or consequential implementation of current USPSTF guidance, I respectfully urge ACET to

1. Review California's AB2132 with CDC as a potential model for national replication
2. Recommend that CDC and HHS:
    I. Formally engage with USPSTF to review and strengthen the current recommendations of universal screening of persons at risk for TB by providing a framework for implementation, including:
        - Integration of electronic health records (EHR) -based clinical decision support for the cascade of care from testing to completion of preventive treatment
        - Systematic coverage and reimbursement for testing and preventive treatment (currently implicit, not explicit)
    II. Encourage states to enact legislation modeled on AB 2132, embedding TB screening in primary care through health regulations or quality measures.
    III. Support development of model rules and funding mechanisms (e.g., cooperative agreements, HRSA block grants) that assist states in implementing these recommendations.

TB elimination in the U.S. will not be achieved without addressing the gap between public health and primary care. Strengthening the USPSTF recommendation and promoting AB 2132-like legislation nationwide would transform TBI management from a discretionary service into a standard of care, preventing thousands of future TB cases and deaths, while getting the US back on track toward TB Elimination.

Thank you in advance for your leadership and for considering this proposal. As a former member (1996-2006), and chair of ACET (2003-2006), I would welcome the opportunity to contribute to ACET's deliberations on better integrating TB screening and prevention into the U.S. health system. Please call upon me if needed.

Respectfully,

L. Masae Kawamura, MD
Retired TB Controller, San Francisco (1996-2011)
Member, National Tuberculosis Controllers Association

Business Session

Lynn Sosa, MD
Director of Infectious Disease and State Epidemiologist
Connecticut Department of Public Health
ACET Chair

During this session, Dr. Sosa facilitated a review of business items that warranted ACET's formal action and allowed time for additional discussion and/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. Cattamanchi and seconded by Dr. Chen to accept the minutes from the December 2024 ACET meeting. With no further discussion or changes, the motion to accept the minutes as written carried unanimously with no abstentions or opposition.

Business Item 2: Biennial Letter

Dr. Sosa indicated that based on the previous day's discussion, she made a couple of minor changes to the draft letter and added a few items for consideration as follow:

- Existing Request 1: This was a major change in which the request for funding for DTBE was increased to $225 million, which aligns with what other organizations are using.

- Proposed Request 6: As outlined above, fund DTBE to enable restocking of the TB medication stockpile to ensure access to critical TB medications while other recommendations are pursued to address drug shortages and increased drug prices.

- Proposed Request 7: Ensure additional funding for domestic TB trials to have data to support approval of TB diagnostics not currently available in the US.

- Proposed Request 8: Direct FDA to leverage approval pathways not currently utilized for TB diagnostics and susceptibility testing including, but not limited to, the humanitarian device exemption (HDE).

Noting that the way in which the requests appear in the letter can be dealt with later, Dr. Sosa explained that the main vote for this session would be to achieve consensus for the specific requests.

ACET Discussion: Biennial Letter

To better understand how the decisions for the final requests in the letter were developed, comments are captured within the request under which they were made:

Requests 1-5: As Presented for Discussion

- There was some discussion about whether each funding request should be separate, but it was not clear whether the request should be in the background and justification or if all of the requests should be combined as one of the bullets in the body of the letter.
- Request 1 is about overall funding and Request 5 is referenced backwards "as referenced above."
- Should Request 4 have incentives only? There was agreement on just "incentivizing."
- ACET members supported the change to the $225 million in Request 1 for the DTBE budget, recognizing that having consistency with other organizations sends an important message.
- For Request 5, consider adding the sentence, "Ensure funding to expand the scope of TBTC trials to include diagnostics in the US." It was noted that manufacturers typically fund diagnostics trials, and also that manufacturers do not have sufficient incentive to invest funding in trials. Also noted was that clinical trials are expensive and the funding request for DTBE may not be sufficient to do both.
- Instead of adding the sentence, "Ensure funding to expand the scope of TBTC trials to include diagnostics in the US," consider adding a sub-bullet to Request 5 reading, "provide additional funding to expand the scope of TBTC trials to include evaluation of diagnostics not currently available in the US."
- Consider adding 2 sub-requests under Request 5 reading:
    a. Provide additional funding to expand the scope of TBTC trials to include evaluation of diagnostics not currently available in the US.
    b. Direct FDA to provide ~~leverage~~ approval pathways for TB diagnostics and susceptibility testing for which there are data outside the US. ~~, including but not limited to, the humanitarian device exemptions (HDE).~~
- Following several revisions, it was suggested that Request 5 remain as it was originally and that the language be moved to Request 6.

Proposed Request 6: *Enable Restocking of the TB Medication Stockpile*

- DTBE specified on a call earlier in the morning that the ability to have a stockpile at DTBE was specifically approved to enable the ability to address shortages of critical drugs.
- This bullet could be misconstrued in that the stockpile is intended to address programs' needs if they cannot afford the drugs. Programs would not have access to this stockpile due to affordability.
- When the stockpile is about to expire, CDC has released the stock to programs that apply for it, which is a different circumstance.
- Perhaps delete "and increased drug prices" in terms of replenishing the stockpile.
- Understanding all of that, there have never been allocations dedicated to funding the stockpile. At the same time, ACET wants to ensure that DTBE has enough money so that there is the opportunity to fund the stockpile. The concern is that at the current funding levels, there will not be an opportunity to have funds that could be used for the stockpile. Perhaps ending the bullet after "critical TB medications" would be best, given that this is really what the bullet is about.
- Either an additional justification could be added to this bullet, or this ask could be blended into the first bullet. However, there are a few requests for funding so this potentially could be separate items as well.

- Consider leaving Request 5 as it is and revising Request 6 to read, “Direct FDA to provide approval pathways for TB diagnostics and susceptibility testing for which there are data outside of the US” and include a sub-bullet stating, “Provide additional funding to expand the scope of TBTC trials to include evaluation of diagnostics not currently available in the US.”
- The data outside the US are not just from sporadic research. Other countries have approved use. There are European- and WHO-approved data.
- The diagnostics could be listed out as was done in the drugs request. However, new tests will come down the pipeline so it could be limiting to list test.
- Perhaps FDA could suggest some examples of tests that are most amendable to receiving approval. This might be a useful invitation to the next ACET meeting rather than making it a part of the Biennial Letter.
- Categories of tests could be suggested with an example for each (low complexity molecular assays, moderate complexity molecular assays, targeted sequencing assays).
- Following several suggested revisions and movement of the sub-bullets from Request 5 to Request 6, the proposed language for Request 6 was suggested to read, “Direct FDA to provide approval pathways for TB diagnostics and susceptibility testing which are approved for use outside the US based on clinical data generated primarily outside the US. Examples include but are not limited to low complexity molecular assays (Xpert MTB/RIF Ultra), moderate complexity molecular assays (BD MAX MDR TB Assay), and targeted sequencing assays (Deeplex). A sub-bullet would read, “Until such a pathway is available, provide additional funding to expand the scope of TBTC trials to include domestic evaluation of TB diagnostics not currently available in the US.” This eventually became Request 7 in the final iteration of the package.

Proposed Request 7: Additional Funding for Domestic TB Trials to Support Approval of Domestic TB Diagnostics

- It is important to make this clearer so that whoever is reading it understands why ACET is making this request.
- This pertained to FDA not approving the use of certain diagnostics in use globally for the US because there are no or insufficient data with US participants.
- It seems like what ACET is asking is for TBTC trials to include treatment and evaluation of diagnostics not available in the US. It is about adding that to the mandate of TBTC and providing the necessary funding to do that, in addition to evaluating trials. Both aspects need to be captured. TBTC is the network that conducts trials, so ACET is recommending that TBTC focus on diagnostics and receive adequate funding to do that.
- Perhaps “funding” could be removed and the focus could be placed on requesting that TBTC trials include evaluation of diagnostics.
- Request 5 specifically refers to TBTC funding.
- Consider adding a sub-bullet reading, “TBTC trials should include not just treatment but also diagnostics and receive funding to do that.” This concept was moved to Request 5.
- There was a suggestion to move Request 7 *before* Request 5.

Proposed Request 8: Direct FDA to Leverage Approval Pathways Not Currently Utilized for TB Diagnostics

- Perhaps Proposed Requests 7 and 8 could be combined into a single bullet for TBTC.
- There was some opposition to combining Proposed Requests 7 and 8 just for TBTC because there are others who can generate novel tests not currently available in the US.
- The goal of Request 8 is really to implore FDA to accept data from outside of the US, from smaller studies, and from other alternative pathways to support approval of diagnostics for use in the US that already are being used globally.

- Consider revising this Request to read, “Direct FDA to provide guidance regarding existing approval pathways not currently utilized by TB diagnostic manufacturers that could be leveraged to ensure that the latest or advanced TB diagnostics are available for use in the US.” The HDE pathway might be too restrictive. This would place the onus on the FDA to review the existing pathways and suggest the one they think will be more applicable, and then ask them to provide funding to expand the scope if a pathway is not available. Add to this suggested revision, “for which there are data outside the US.”
- It is not clear that the FDA fully understands how much the US relies on LTDs in this field. It should be pointed out to FDA someplace in the letter that some of these kits are manufactured in the US, yet are not approved for use in the US. Perhaps this could be highlighted in the background or justification for why ACET is making that request.
- Consider language stating, “Direct FDA to provide guidance on existing approval pathways for TB diagnostic manufacturers.”
- Maybe this is about directing FDA to provide a pathway to TB diagnostics manufacturers that involves being able to obtain approval with limited data or data outside of the US. If that is not possible, then FDA should direct funding to TBTC to collect the data. It is not really providing guidance. ACET is directing FDA to let TB diagnostic manufacturers know whether/how there is a pathway through which they can obtain approval for use in the US.
- Take out “limited data” because that can be open to interpretation. Instead say, “for which there are data outside of the US.”
- FDA is typically given authority by Congress to have pathways. If there are no approved pathways, it may take longer, but the onus should be on FDA to figure it out.
- Perhaps include 2 sub-requests under Request 5.
- Consider eliminating Request 8 because it was incorporated and move Request 7 up.

Vote #1: Biennial Letter

A motion was properly placed on the floor by Dr. Ritger and seconded by Dr. Chen to remove the language in Proposed Request 6 reading, “while other recommendations are pursued to address drug shortages and increased drug prices.” With no further discussion or changes, the vote to accept this change carried unanimously with no abstentions or opposition.

Vote #2: Biennial Letter

A motion was properly placed on the floor by Dr. Cattamanchi and was seconded by Dr. Holland to approve the full package of requests proposed for inclusion in the Biennial Letter. The vote to accept this motion was carried unanimously, with no abstentions or opposition. The final package of requests included in this motion/vote read as follows:

1. Increase domestic funding for the CDC’s Division of TB Elimination (DTBE) to $225 million per year and determine a sustainable funding model necessary to maintain the required public health infrastructure and account for rising costs. The proposal to combine TB funding with sexually transmitted disease and viral hepatitis funding in the President’s budget will not provide the minimum resources needed to combat the surge of TB in our country.

2. Immediately identify ways to bring approved TB drugs into the United States via FDA authorization for temporary importation, similar to what was done with lentocillin and extencilline during the penicillin G shortage to address increasing syphilis cases. This effort should include pediatric formulations and combination drugs.

3. Update the essential medications list to include all first-line medications for treating drug-sensitive and drug-resistant TB: isoniazid, rifampin, rifabutin, pyrazinamide, ethambutol, rifapentine, bedaquiline, pretomanid, moxifloxacin, levofloxacin and linezolid.

4. Incentivize pharmaceutical companies to manufacture TB drugs for the United States market.

5. As outlined above, fund DTBE to enable restocking of the TB medication stockpile to ensure access to critical TB medications.

6. As outlined above, fund DTBE to enable the full support of another 5-year cycle of TBESC in 2026 and ensure the full funding of TBTC for the entirety of the funding cycle through 2030.

7. Direct FDA to provide approval pathways for TB diagnostic and susceptibility tests which are approved for use outside the United States based on clinical data generated primarily outside the United States. Examples include but are not limited to low complexity molecular assays (Xpert MTB/RIF Ultra), moderate complexity molecular assays (BD MAX™MDR-TB Assay), and targeted sequencing assays (Deeplex®-Myc TB).

    a. Until such a pathway is available, provide additional funding to expand the scope of TBTC trials to include domestic evaluation of TB diagnostics not currently available in the United States.

Business Item 3: Advice from ACET

December 2025 ACET Recommendations	Action
1) <u>Biennial Letter</u>	ACET voted unanimously on the following language to be included in the Biennial Letter: 1. Increase domestic funding for the CDC's Division of TB Elimination (DTBE) to $225 million per year and determine a sustainable funding model necessary to maintain the required public health infrastructure and account for rising costs. The proposal to combine TB funding with sexually transmitted disease and viral hepatitis funding in the President's budget will not provide the minimum resources needed to combat the surge of TB in our country. 2. Immediately identify ways to bring approved TB drugs into the United States via FDA authorization for temporary importation, similar to what was done with lentocillin and extencilline during the penicillin G shortage to address increasing syphilis cases. This effort should include pediatric formulations and combination drugs. 3. Update the essential medications list to include all first-line medications for treating drug-sensitive and drug-resistant TB: isoniazid, rifampin, rifabutin, pyrazinamide, ethambutol, rifapentine, bedaquiline, pretomanid, moxifloxacin, levofloxacin and linezolid. 4. Incentivize pharmaceutical companies to manufacture TB drugs for the United States market. 5. As outlined above, fund DTBE to enable restocking of the TB medication stockpile to ensure access to critical TB medications.

December 2025 ACET Recommendations	Action
	6. As outlined above, fund DTBE to enable the full support of another 5-year cycle of TBESC in 2026 and ensure the full funding of TBTC for the entirety of the funding cycle through 2030. 7. Direct FDA to provide approval pathways for TB diagnostic and susceptibility tests which are approved for use outside the United States based on clinical data generated primarily outside the United States. Examples include but are not limited to low complexity molecular assays (Xpert MTB/RIF Ultra), moderate complexity molecular assays (BD MAX™MDR-TB Assay), and targeted sequencing assays (Deeplex®-Myc TB). a. Until such a pathway is available, provide additional funding to expand the scope of TBTC trials to include domestic evaluation of TB diagnostics not currently available in the United States.

Business Item 5: Agenda Topics

Topics put forth for consideration as future ACET agenda topics:

- Provide more detailed information pertaining to the 2024 surveillance data, such as delving into these data further to try to better understand why cases have become increasingly complex. Thus far, this has been largely observation and gut feeling. Perhaps there is a way to look into these and other data (death data) to tell a more compelling story about these increases, such as whether there are more deaths among these cases beyond what would be expected; whether there are more deaths among infants and children and/or migrants; why there are increases in MDR-TB and how BPaL and BPaLM treatments are going in the field, particularly with regard to the shortened course and cost ($20,000 per bottle for a full course); and why there are upticks in INH resistance.
- Consider requesting a presentation from California State regarding the early impact of Law AB2132, early lessons learned, and whether it would be something to consider on a more widespread basis.
- There are many questions for FDA, particularly regarding diagnostics. Perhaps FDA could provide more concrete answers on potential pathways to approval and previous pathways utilized.
- More information about patient-centered care and shared decision-making would be interesting. We Are TB and others are thinking more deeply about how to bring shared decision-making into practice. Many patients are health illiterate and do not know much, if anything, about TB. Having those discussions and input into their own care can be difficult because they do not know much and often just trust whatever their doctor says. A lot of research committees and development committees have incorporated survivors' perspective in the development of research and in ongoing oversight, which could be informative for ACET in terms of hearing about this experience from research groups who have successfully incorporated survivor input in their clinical and diagnostic trials. Advocating for more research like this could come from ACET. Treatment Action Group is engaging Community Advisory Boards (CABs) in research and could be a resource.
- More information about 1HP and LTBI would be interesting. Workplace infection is a very under-recognized phenomenon. Occupational health physicians are with their workers all of the time and are seeing higher rates in healthcare and other jobs. Better testing on hire and

continuing to emphasize access to short-course therapy would offer a more concentrated avenue to work on elimination. It would be beneficial to hear about research, papers, patient reception, access to short-course, pricing, efficacy, rebound, et cetera.
- More insight would be helpful into TB patients who are dealing with multiple health concerns, such as those articulated by Ms. Purdy, in terms of managing additional conditions.
- Sub-clinical TB is getting a lot of attention right now.
- Novel diagnostic testing was discussed during the TB Consultants meeting that would be interesting to hear about in terms of what has been approved recently and what is in the pipeline.

Topics put forth for consideration during previous ACET meetings:

- An update on the TB workforce would be beneficial. There is a survey in the field now that could inform this if results are available by the June 2026 ACET meeting.
- The public health infrastructure was discussed previously in terms of what will be happening with the new TB cooperative agreement and trying to collect some information and touch on the laboratory.
- Drug shortages will continue to be a topic, so ideas for who should be invited to a future ACET meeting to talk about drug shortages would be helpful.
- Potentially continue work on congregate settings (nursing homes, shelters, corrections).
- Discuss pregnancy in terms of severe disease and female genital urinary TB.
- It would be beneficial to hear about post-TB sequelae in terms of how that is a burden and impacts healthcare in the US.

Closing & Adjourn

Lynn Sosa, MD
Director of Infectious Disease and State Epidemiologist
Connecticut Department of Public Health
ACET Chair

Carla Winston, PhD, MA
Associate Director for Science
Division of Tuberculosis Elimination
National Center for HIV, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention
ACET Designated Federal Officer

Dr. Sosa lamented that the end of this meeting was sad in that it was Dr. Chen's last meeting. She expressed appreciation for Dr. Chen's service and emphasized that she would be missed on ACET. The Biennial Letter will be finalized over the next couple of weeks, which is exciting. The next ACET meeting is proposed to be June 16-17, 2026, which potentially could be in-person.

Dr. Winston thanked everyone for their participation, great discussions, and engagement. She offered gratitude to Dr. Sosa and Ms. Condit for making this one of the smoothest ACET meetings, and all of the members, *ex officios*, liaisons, presenters, and technical support staff.

With no further discussion or business brought before ACET, Dr. Winston officially adjourned the meeting at 3:52 PM on December 10, 2025.

Chair's Certification

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

Date	**Lynn Sosa, MD, Chair** **Advisory Council for the Elimination of Tuberculosis**

Attachment 1: Participant Directory

ACET Members Present
Dr. Lynn Sosa, Chair
Dr. Rajita Bhavaraju
Dr. Adithya Cattamanchi
Dr. Lisa Chen
Dr. Andrea Tania Cruz
Dr. William Glover, II
Dr. Kelly John Holland
Dr. Kathleen Ritger
Dr. Shu-Hua Wang

ACET Members Absent
N/A

ACET *Ex-Officio* Members Present
Dr. Britt Gayle
Health Resources and Services Administration

Dr. Sheena Harris
Agency for Healthcare Research and Quality

Dr. Jonathan Iralu
Indian Health Service

CAPT Gayathri S. Kumar
Health HHS Office of Assistant Secretary for Health

CAPT Tara Rhodes
Bureau of Prisons

ACET *Ex-Officio* Members Present (continued)
Dr. Kevin Taylor (Alternate)
Department of Defense/US Army

Dr. David Weissman
National Institute for Occupational Safety and Health

ACET *Ex-Officio* Members Absent
Dr. Naomi Aronson
Department of Defense

Dr. Amy Bloom
US Agency for International Development

Dr. Mamodikoe Makhene
National Institutes of Health

ACET Liaison Representatives Present
Deborah Brown
American Lung Association

Mr. Jeffrey Caballero
Association of Asian Pacific Community Health Organizations

Mr. Jason Cummins
National Tuberculosis Coalition of America

Dr. Charles Daley (Alternate)
American Thoracic Society

Dr. Jonathan Golub
International Union Against TB and Lung Disease, North America Region

ACET Liaison Representatives Present (continued)

Mr. Tenzin Kunor
RESULTS

Dr. David Lewinsohn
Stop TB USA

Ms. Elizabeth Lovinger
Treatment Action Group

Ms. Kate O'Brien
We are TB

Dr. Naveen Patil
Association of State and Territorial Health Officials

Dr. Marie-Claire Rowlinson
Association of Public Health Laboratories

Dr. Wendy Thanassi
American College of Occupational and Environmental Medicine

Mr. Andrew Tibbs
Council of State and Territorial Epidemiologists

Dr. Lornel Tompkins
National Medical Association

Mr. Bobby Watts
National Healthcare for the Homeless Council

Dr. David Weber
Society for Healthcare Epidemiology of America

ACET Liaison Representatives Absent

Dr. Mayleen Ekiek
Pacific Island Health Officers Association

Dr. Amee Patrawalla
American College of Chest Physicians

ACET Liaison Representatives Absent (continued)

Dr. Susan Ray
Infectious Disease Society of America

Dr. Sylvie Stacy
National Commission on Correctional Health

ACET Designated Federal Officer

Carla Winston, PhD, MA
Associate Director for Science
DTBE, NCHHSTP, CDC

Federal Representatives

Sandy Althomsons
Kimberly Boim
Martha Boisseau
Kevin Borden
Jessica Brown
Mayra Garcia Brown
Kia Bryant
Deron Burton
Beth Butler
Wendy Carr
Kristina Cesa
Terence Chorba
April Cobos
Marah Condit
Tracy Dalton
Justin Davis
Renata Ellington
Erica Figueroa
Vanessa Fong
Neela Goswami
Leslie Hausman
Andrew Hill
David Huang
Matthew Josey
Gayathri Kalla
LeiAnn Keuth
Kathryn Koski
Ekaterina Kurbatova
Adam Langer
Emily Maass
Joan Mangan
Erin Miller
Scott Nabity
Sherry Owen
Diane Padron

Federal Representatives (continued)

Sandy Price
Claire Sadowski
Audilis Sanchez
Kim Skrobarcek
Angela Starks
Michelle Van Handel
Kathleen Weitzner
Kathryn Winglee
Jonathan Wortham

Guest Presenters

Ed Zuroweste, MD, TB Medical Consultant
Pennsylvania Department of Health

Renee Purdy, TB Survivor
We Are TB

Members of the Public

Nisha Ahamed
Kiley Ariail
Sherrie Arnwine
Bob Belknap
Kristin Bertrang
Jolie Black
Joseph Burzynski
Mukta Deia
Traci Dreiling
Lisa Edgerton-Johnston
Libby Enriquez
Prakasj Ganesh
Katelynne Gardner-Toren
Kimberly Gladfelter
Michelle Gomez
Anna Hippchen
Colleen Hoehn
Karin Hopkins
Bobbi Jo Hurst

Members of the Public (continued)

Jason Jones
Shereen Katrak
Chris Keh
Mark Kirkpatrick
Claire Leback
Andrea Liptak
Quentin Mazzaferro
Jordan McBride
Eno Mondesir
David Moskowitz
Sonal Munsiff
Pamela Nelson
Patrick Nosko
Amy Painter
Mary Raschka
Marco Salerno
Chibo Shinagawa
Amelia Slaichert
Cherie Stafford
Katie Stinebaugh
Alison Stratton
Cynthia Tschampl
Stephanie Wallace
Donna Wegener

Attachment 2: Glossary of Acronyms

Acronym	Definition
1CDP	One CDC Data Platform
ACET	Advisory Council for the Elimination of Tuberculosis
ACOM	American College of Occupational Medicine
ADR	Adverse Drug Reaction
AE	Adverse Event
AHA	Administration for a Healthy America
AI/AN	American Indian or Alaska Native
AMD	Advanced Molecular Detection
APHL	Association of Public Health Laboratories
ASTERoiD	Assessment of the Safety, Tolerability, and Effectiveness of Rifapentine
ASTHO	Association of State and Territorial Health Officials
BD	Becton Dickinson
BDQ	Bedaquiline
BMI	Body Mass Index
BPaL	Bedaquiline, Pretomanid, and Linezolid
BPaLM	Bedaquiline, Pretomanid, Linezolid, and Moxifloxacin
BPG	Benzathine Penicillin G
BMZ	Bedaquiline, Moxifloxacin, and Pyrazinamide
CBO	Community-Based Organization
CDC	Centers for Disease Control and Prevention
CE	Conformité Européenne
CEBSB	Communications, Education, and Behavioral Studies Branch
CLIA	Clinical Laboratory Improvement Amendment
CoAg	Cooperative Agreement
COI	Conflict of Interest
COVID-19	Coronavirus Disease 2019
CPA	Collaborative Practice Agreement
CR	Continuing Resolution
CRB	Clinical Research Branch
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
CRUSH-TB	Combination Regimens for Shortening Tuberculosis Treatment
CS	Congenital Syphilis
CXR	Chest X-Ray

Acronym	Definition
DBDPHG	Division of Blood Disorders and Public Health Genomics
DC	District of Columbia
DFO	Designated Federal Official
DHP	Division of HIV Prevention
DNA	Deoxyribonucleic Acid
DOGE	Department of Government Efficiency
DOT	Directly Observed Therapy
DSMB	Data and Safety Monitoring Board
DST	Drug Susceptibility Testing
DSTDP	Division of STD Prevention
DTBE	Division of Tuberculosis Elimination
ECG	Electrocardiogram
EHE	Ending the HIV Epidemic
ET	Eastern Time
FACA	Federal Advisory Committee Act
FDA	(United States) Food and Drug Administration
FY	Fiscal Year
GDF	Global Drug Facility
HBsAg	Hepatitis B Surface Antigen
HCP	Healthcare Providers/Professionals
HCV	Hepatitis C Virus
HDE	Humanitarian Device Exemption
Hep	Hepatitis
HHS	(United States) Department of Health and Human Services
HIV	Human Immunodeficiency Virus
IAA	Interagency Agreement
IDO	Infectious Disease and Opioid Epidemic
IFU	Instructions for Use
INH	Isoniazid
IRB	Institutional Review Board
IRPB	International Research and Programs Branch
LDT	Laboratory Developed Test
LTBI	Latent Tuberculosis Infection
LTCF	Long-Term Care Facility
MDDR	Molecular Detection of Drug Resistance
MDL	Microbial Diseases Laboratory
MDR-TB	Multidrug-Resistant Tuberculosis
MIC	Minimum Inhibitory Concentration
MPEP	Model Performance Evaluation Program
MSM	Men who have Sex with Men
MTBC	*Mycobacterium Tuberculosis* Complex

Acronym	Definition
NAAT	Nucleic-Acid Amplification Test
NACCHO	National Association of County and City Health Officials
NASTAD	National Alliance of State and Territorial AIDS Directors
NCBDDD	National Center on Birth Defects and Developmental Disabilities
NCBI	National Center for Biotechnology Information
NCHHSTP, the Center	National Center for HIV, Viral Hepatitis, STD and TB Prevention
Nebraska DHHS	Nebraska Department of Health and Human Services
NEEMA	NCHHSTP Epidemiologic and Economic Modeling Agreement
NHPI	Native Hawaiian or Other Pacific Islander
NICU	Neonatal Intensive Care Unit
NIH	National Institutes of Health
NMA	National Medical Association
NNDSS	National Notifiable Diseases Surveillance System
NNPHI	National Network of Public Health Institutes
NOFO	Notice of Funding Opportunity
NTCA	National Tuberculosis Coalition of America
NTSS	National TB Surveillance System
OD	Office of the Director
PCP	Primary Care Providers
PCR	Polymerase Chain Reaction
PHL	National Public Health Laboratory
POC	Point-of-Care
POCT	Point-of-Care Tests
PReDiCTR	Pre-clinical Design and Clinical Translation of TB Regimens
PrEP	Pre-Exposure Prophylaxis
QC	Quality Control
RUO	Research Use Only
PIHOA	Pacific Island Health Officers Association
PWID	People Who Inject Drugs
PWTB	People With TB
PZA	Pyrazinamide
QA/QC	Quality Assurance/Quality Control
QFT	QuantiFERON
Rb	Rifabutin
RCT	Randomized Controlled Trial
RIF	Rifampin
RNA	Ribonucleic Acid
RPT	Rifapentine
RVCT	Report of Verified Case of TB
SFDPH	San Francisco Department of Public Health
SGE	Special Government Employee

Acronym	Definition
SME	Subject Matter Expert
SNP	Single Nucleotide Polymorphisms
STD	Sexually Transmitted Diseases
STI	Sexually Transmitted Infections
SUD	Substance Use Disorder
TA	Technical Assistance
TB	Tuberculosis
TBESC	Tuberculosis Epidemiologic Studies Consortium
TBTC	Tuberculosis Trials Consortium
TEA	Tuberculosis Elimination Alliance
TOR	Terms of Reference
TST	Tuberculin Skin Tests
tNGS	Targeted Next Generation Sequencing
UCSF	University of California, San Francisco
US	United States
VA	Veteran Affairs
VUMC	Vanderbilt University Medical Center
WG	Workgroup
wgMLST	Whole-Genome Multilocus Sequence Typing
WGS	Whole Genome Sequencing
WHO	World Health Organization

Attachment 3: Biennial Letter

ACET

Advisory Council for the Elimination of Tuberculosis

December 23, 2025

The Honorable Robert F. Kennedy, Jr.
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mister Secretary:

We are writing to you today to update you on the current status of tuberculosis (TB) in the United States and request assistance from HHS in making Americans healthy against TB.

In 1989, US Public Law Act [42 USC 247b-6(f) (section 2(b)), Public Law 101-368 (section 317E of the Public Health Services Act)], as amended, established the Advisory Council for the Elimination of Tuberculosis (ACET) as a Congressionally mandated advisory body to provide guidance to the Secretary, US Department of Health and Human Services (HHS), the Assistant Secretary for HHS, and the Director, Centers for Disease Control and Prevention (CDC), regarding elimination of TB in the United States.

ACET is formally chartered under the Federal Advisory Committee Act to (a) make recommendations regarding policies, strategies, objectives, and priorities; (b) address development and application of new technologies; (c) provide guidance and review regarding CDC's TB Prevention Research portfolio and program priorities; and (d) review the extent to which progress has been made toward TB elimination.

Background

TB is an airborne disease that is spread when someone with TB coughs, speaks, sings, or does anything that puts TB bacteria into the air where anyone close by can breathe it in. Anyone can get TB, and it affects people in all geographic areas of the country. After years of declines, TB disease has increased steadily over the last five years in the United States, with the number of cases reported in 2024 similar to the number reported in 2011. Thirty-four states and the District of Columbia reported increases in TB case counts and rates from 2023 to 2024. Sadly, in 2022, 572 died due to TB or TB related causes.[i] The United States was only ranked 16th after Greece for the lowest number of TB cases in the world in 2022.[ii]

Importantly we can treat people infected with TB bacteria (called latent TB infection or LTBI) before they get sick, which can prevent not only illness but also further transmission of the disease. Treating LTBI doesn't just save lives, it saves money. One analysis of TB prevention efforts for the years 1995–2014 showed that as many as 300,000 persons were prevented from developing TB disease and $14.5 billion in costs were avoided.[iii] These cost savings have only continued to accumulate over the last decade.

How HHS Can Help

Over the last few months, we have surveyed the people that work on TB everyday including physicians, nurses, laboratorians and state and local health department staff. The stories they have told us depict a TB infrastructure in crisis. There are fewer experienced and knowledgeable staff available to help patients, regular drug shortages, more expensive medications, and fewer resources and advances to handle the increasing number of TB cases. We are writing to implore that you prioritize TB to make America safe, healthy and strong.

Strengthening the TB workforce at the local, state and federal level keeps everyone safe

Due to retirements, burnout and the inability to hire new staff, the TB workforce has been shrinking. While this loss of expertise and experience is affecting everyone, the loss is most felt in our rural states. We heard from multiple states in the heartland that have only one full time equivalent, and sometimes less, managing all the TB cases in the state. Without local TB expertise, some people have to travel multiple hours to see a physician and sometimes, the only option is a telehealth appointment with a provider in another state. As health departments are forced to prioritize their work, these increased pressures will mean that some activities will not be done, including routine contact investigations that identify people who have been exposed and could be treated for LTBI before they get sick. Not being able to do this work will mean TB will continue to spread across our country.

State and local health departments rely on CDC not just for funding but for laboratory testing, medical consultation and other technical assistance, especially for outbreaks. In addition to getting funding to health departments directly interacting with patients, it is critical to ensure the infrastructure at the federal level is maintained as well. CDC supports public health laboratories to provide TB testing including identification, drug sensitivity testing and whole genome sequencing that can rapidly diagnose patients and find outbreaks. The country is also reliant on TB medical experts at CDC including the CDC laboratory and the CDC-funded regional TB Centers of Excellence that are the safety net for managing complex drug-resistant cases and preventing further spread.

Investing in the TB workforce is critical for preparing for future pandemics. The skills that TB staff have are transferable to other diseases and conditions. People that work on TB have assisted with emergencies such as measles and influenza. Maintaining and strengthening the TB workforce ensures the foundation for response to all future infectious disease outbreaks.

Addressing rising drug costs keeps everyone healthy

The availability of TB drugs and the quickly rising costs of these drugs are a major challenge and have been a priority for ACET for many years. In addition to our last biennial letter dated 6/27/2023, ACET has brought attention to the issue of drug availability and cost to the HHS Secretary in a letter dated 5/23/23 and another 2/13/2025 for which we have not received a response. The pressure for cheaper and more easily available TB drugs has only increased. These pressures are multifactorial. Many of the drugs used to treat TB are specific to TB and have only one manufacturer. One important example is isoniazid (INH), one of the four main drugs used in the standard treatment for TB disease and also an effective drug for treating LTBI. In 2023, the cost of INH was 0.06 cents/tablet. When the company that used to make INH was bought by another company, the cost of INH in 2025 rose to $3.72/tablet. For the average TB patient, the price of this one drug for their entire treatment course has increased from $10.80 to $670. This dramatic price increase affects the ability to ensure treatment for all patients, endangering the health of everyone.

While there have been important breakthroughs in shortening the length of effective treatment for TB patients from 6–9 months to as short as 4 months, the lack of availability of these medications makes these shorter regimens out of reach. Rifapentine is one of the drugs that can be used to shorten TB disease treatment to 4 months and, in combination with INH, reduce the time for LTBI treatment to 3 months. Rifapentine has been in shortage since March 2020 per the FDA website,[iv] hampering efforts to fully implement these shorter course regimens. Even more alarming is the shortage of rifampin, the cornerstone drug for TB treatment. The loss of this drug would inevitably lead to patients not being treated or being incompletely treated, contributing to the increase in multidrug-resistant TB.

Maintaining research for TB testing and treatment makes our country stronger

The US has long been a leader in TB research including identifying shorter course regimens for drug-resistant TB and developing new diagnostics. CDC has two vital flagship research consortia, the TB Epidemiologic Studies Consortium (TBESC) and the TB Trials Consortium (TBTC). Since 2001, TBESC has been working to find novel approaches to specifically advance TB elimination in the United States. The current TBESC cycle has been focused on the treatment of LTBI in primary care settings, which directly impacts everyone seeking care in the United States. TBESC has been the driving force behind the adoption of new

drugs that allow people with LTBI to complete their treatment in shorter periods of time. TBTC has existed since the early 1990s, created at a time when our country was experiencing a dramatic increase in TB cases, similar to now. Both of these consortia must continue to ensure our country can tackle the increasing burden of TB and maintain the country's ongoing leadership in TB research and innovation.

Diagnosis is another area that is critical to rapid and efficient treatment of TB patients. For the past 20 years, the availability of a rapid molecular test that can detect both the TB bacteria and resistance to the most effective drug against TB within a few hours has been a key contributor to the downward trends in TB. This test is in danger of being discontinued by the manufacturer which would be a catastrophe for the health and safety of Americans. While there are at least six different rapid diagnostic tests for TB available worldwide, this is the only FDA approved test available in the United States. More must be done to encourage and support the approval of rapid molecular tests for TB in the United States and to ensure they are available to our country's healthcare providers and patients. Not doing so puts the country farther behind the rest of the world.

ACET respectfully makes the following requests:

1. Increase domestic funding for the CDC's Division of TB Elimination (DTBE) to $225 million per year and determine a sustainable funding model necessary to maintain the required public health infrastructure and account for rising costs. The proposal to combine TB funding with sexually transmitted disease and viral hepatitis funding in the President's budget will not provide the minimum resources needed to combat the surge of TB in our country.
2. Immediately identify ways to bring approved TB drugs into the United States via FDA authorization for temporary importation, similar to what was done with lentocillin and extencilline during the penicillin G shortage to address increasing syphilis cases. This effort should include pediatric formulations and combination drugs.
3. Update the essential medications list to include all first-line medications for treating drug-sensitive and drug-resistant TB: isoniazid, rifampin, rifabutin, pyrazinamide, ethambutol, rifapentine, bedaquiline, pretomanid, moxifloxacin, levofloxacin and linezolid .
4. Incentivize pharmaceutical companies to manufacture TB drugs for the United States market.
5. As outlined above, fund DTBE to enable restocking of the TB medication stockpile to ensure access to critical TB medications.
6. As outlined above, fund DTBE to enable the full support of another 5-year cycle of TBESC in 2026 and ensure the full funding of TBTC for the entirety of the funding cycle through 2030.

[iii] Castro, et al. Int J Tuberc Lung Dis. 2016 July ; 20(7): 926–933. doi:10.5588/ijtld.15.1001.
[iv] Food and Drug Administration. (2025 December 23). FDA Drug Shortages. https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Rifapentine%20Tablet,%20Film%20Coated&st=c

Attachment 4: NCD Response CMS

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S3-02-01
Baltimore, Maryland 21244-1850

January 16, 2025

Lynn Sosa, MD
Chair
Advisory Council for the Elimination of Tuberculosis (ACET)
lynn.sosa@ct.gov

Dear Dr. Sosa:

We acknowledge that we have received ACET's letter and thank you for requesting that the Centers for Medicare & Medicaid Services (CMS) open a national coverage determination (NCD) for latent tuberculosis infection (LTBI) screening using interferon gamma release assays (IGRAs) for Medicare and Medicaid recipients. I am responding on behalf of the Secretary. We appreciate ACET's role in working towards eliminating tuberculosis and improving the health outcomes of people with Medicare.

As you mentioned, CMS has received a request to open an NCD for LTBI screening. As reflected on the NCD Dashboard,[1] we accepted the request; however, we have not been able to act on this request at this time due to our internal capacity restraints. CMS indicated in the August 2013 Federal Register Notice that, "[i]n the event that we have a large volume of NCD requests for simultaneous review, we prioritize these requests based on the magnitude of the potential impact on the Medicare program and its beneficiaries and staffing resources."[2]

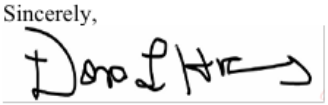
Our delay in opening a consideration is not meant to minimize the importance of this request; it only reflects the limitations of our available resources. This topic will be considered in the future as we prioritize the requests for NCDs. Additional information regarding the Medicare NCD process is available on the CMS Coverage website at: https://www.cms.gov/Medicare/Coverage/DeterminationProcess.

We appreciate the council's commitment to improving access to LTBI screening and greatly value their input.

[1] https://www.cms.gov/files/document/ncddashboard2024.pdf
[2] 78 Fed. Reg. 48164, 48168 (Aug. 7, 2013).

We will keep your letter and the information you provided on file and will contact you with any updates. Please have your staff contact Rachel Katonak, Policy Analyst, Coverage and Analysis Group, CMS Center for Clinical Standards and Quality, at Rachel.katonak@cms.hhs.gov if you have additional questions or concerns.

Sincerely,



Dora L. Hughes, M.D., M.P.H.
Acting Director,
Center for Clinical Standards and Quality
Chief Medical Officer
Centers for Medicare & Medicaid Services

Attachment 5: ACET Drug Shortages Letter

ACET

Advisory Council for the Elimination of Tuberculosis

February 13, 2025

The Honorable Robert F. Kennedy, Jr.
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Kennedy:

The Advisory Council for the Elimination of Tuberculosis (ACET) provides 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 CDC. We are writing in follow up to our letter from May 30, 2023 to request your assistance with addressing critical issues regarding TB medication and access in the United States.

Domestic and international drug shortages have impaired timely access to the first line medications used as key elements of regimens to prevent and treat TB. The lack of consistent access to TB medications hampers clinical management of identified cases and impairs efforts to prevent transmission. This gap in clinical care compounds health disparities and compromises relationships with communities, many of whom have a history of negative interactions with the medical and public health systems.

CDC's Division of Tuberculosis Elimination (DTBE) has developed a national stockpile of TB medications and has shared a list of practical solutions to address shortages in a 2023 Dear Colleague Letter. [1] While this is helpful, we need more concrete and sustainable solutions. At this time, we make these three specific recommendations, approved at the ACET meeting in June 2024, which would improve availability of TB treatment in the US:

1. We suggest addition of the four most common oral TB drugs, specifically isoniazid, rifampin, pyrazinamide and ethambutol (including the most frequently used formulations and strengths) to the FDA Essential Medications List. This list was developed to "ensure sufficient and reliable, long-term domestic production of these products, and to minimize potential shortages." Inclusion on the list would prioritize protection of TB medications during shortages and supply chain challenges.

[1] https://www.cdc.gov/tb/php/dear-colleague-letters/2023-tb-drug-shortages.html

2. We strongly encourage exploring a mechanism for accessing the Global Drug Facility for procurement of TB drugs and diagnostics in shortage or otherwise not available in the US.

   The Global Drug Facility [2] (GDF) was established in 2001 to facilitate access to high quality TB medications and diagnostic tests. Significant funding for the GDF comes from the United States Agency for International Development. The GDF was generally developed and intended for distribution of TB medications to low- and middle-income countries; the United Nations General Assembly in 2018 encouraged all nations to procure TB medications and diagnostics from the GDF. There are a number of high-income countries that now use the GDF extensively or on a case-by-case basis for TB drug and diagnostic access.

   While many of the supplies in the GDF are not FDA licensed, they go through a rigorous quality assurance process defined and are audited by WHO. The GDF has delivered TB medications valued at over $200 million in 2023. [3] While we recognize the hurdles to using the GDF for all US TB medications and diagnostics, we propose that a process be established to pilot access to pediatric TB formulations not licensed in the US through the GDF. Children in much of the rest of the world receive pleasant tasting dispersible formulations which are tailored to pediatric doses and tastes. These well studied and well tolerated formulations are not available in the US. Since toddlers and infants are more likely to develop the most severe forms of TB, including meningitis, improving access to pediatric formulations via the GDF should be prioritized.

3. We formally invite the HHS Supply Chain and Resilience Coordinator to attend one of our biannual ACET meetings to learn firsthand about the challenges of TB drug shortages and work with ACET to develop solutions.

ACET is committed to working collaboratively with HHS agencies in facilitating a path forward for addressing this important issue.

Sincerely,

Lynn Sosa, MD
ACET Chair

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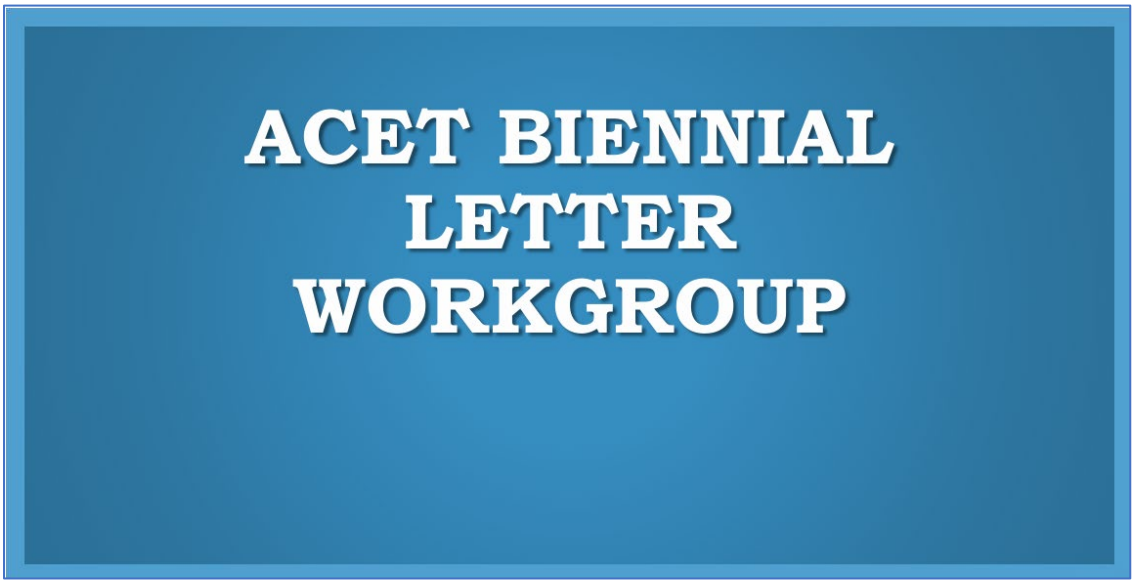
[2] https://www.stoptb.org/facilitate-access-to-tb-drugs-diagnostics/global-drug-facility-gdf
[3] https://www.stoptb.org/gdfs-results

Cc:
Jonathan H. Mermin, MD, MPH; Director, National Center for HIV, Viral Hepatitis, STD and TB Prevention
Philip LoBue, MD; Division of Tuberculosis Elimination Director, National Center for HIV, Viral Hepatitis, STD and TB Prevention
Carla Winston, PhD, MA; Designated Federal Officer, Advisory Council for the Elimination of Tuberculosis
ACET Members

Attachment 6: Workgroup Slides



MEMBERSHIP

- Membership

- Lynn Sosa (WG Chair)
- Andrea Cruz
- Adithya Cattamanchi
- Rajita Bhavaraju
- Lisa Chen
- Kelly Holland
- Kathleen Ritger
- William Glover
- Shu-Hua Wang
- Marah Condit (CDC, DFO)

2

SCOPE

Scope

The BLWG is being formed to research and evaluate the current status of TB elimination in the U.S. and to draft the biennial letter to HHS on this topic, as required by the ACET Charter. The focus of the workgroup is to: 1) evaluate the status of recommendations from the previous biennial letter submitted to HHS; 2) engage with ACET members on the current status of TB elimination in the US; and 3) to draft a new biennial letter with updated data and provide findings, observations, and outcomes for review and vote by the full ACET.

3

MEETING SCHEDULE

- July 2025 – Terms of Reference was finalized
- August 6, 2025 – Planning meeting
- September 22, 2025 – Presentation and Discussion
  - Donna Wegener and Jason Cummins, MPH; NTCA
  - Janice Louie, MD, MPH; Medical Director TB Prevention and Control, San Francisco Department of Public Health
  - Kristin Bertrang, RN, MSN; Tuberculosis Program-DHHS Program Specialist RN, Nebraska Department of Health and Human Services
- December 3, 2025 – Member Discussion

4

DATA COLLECTION

- State of TB survey sent to ACET Liaison and Ex-Officio Members
- What are the most critical TB related programs or activities that your organization or stakeholders conduct?
- What are the potential impacts if those programs or activities are not supported?
- Have those TB related programs or activities been affected by changes in the federal government or other changes?
- If yes, what activities or programs are being prioritized? How has the scope of work changed?
- Do you have any vignettes or stories you would like to share that demonstrate positive impact of your work or negative impact of any recent changes?

- **Questions posed to DTBE**
- What is the current funding level for DTBE in the CR and also in the proposed budget for FY 2026?
- Is there any budget for research (e.g. TBESC, others) in the current budget and if so, what is it?

5

FINDINGS

- Responses to survey were received from the Pacific Island Health Officers Association, Department of Health and Social Affairs, Association of State and Territorial Health Officials, Stop TB USA, APHL, and We are TB

6

THREE THEMES TO BIENNIAL LETTER

- **Strengthening the TB workforce at all levels keeps everyone safe**
- **Addressing rising drug costs keeps everyone healthy**
- **Maintaining research for TB testing and treatment makes our country stronger**

7

REQUESTS FOR INCLUSION IN BIENNIAL LETTER

- Restore domestic funding for the CDC's Division of TB Elimination to $173 million per year which would be equivalent to the 2014 funding level when adjusted for inflation and determine a sustainable funding model necessary to maintain the required public health infrastructure and account for rising costs. The proposal to combine TB funding with sexually transmitted disease and viral hepatitis funding in the President's budget will not provide the minimum resources needed to combat the surge of TB in our country.

8

REQUESTS FOR INCLUSION IN BIENNIAL LETTER

- 2. Immediately identify ways to bring approved TB drugs into the U.S. via FDA authorization for temporary importation, similar to what was done with lentocillin and extencilline during the penicillin G shortage to address increasing syphilis cases. This effort should include pediatric formulations and combination drugs.

- **As directed in the President's Executive Order 13944**

- **3. Update the essential medications list** to include all first-line medications for treating drug-sensitive and drug-resistant TB: isoniazid, rifampin, rifabutin, pyrazinamide, ethambutol, rifapentine, bedaquiline, pretomanid, moxifloxacin, levofloxacin, linezolid

- 4. Identify strategies to incentivize pharmaceutical companies to manufacture drugs for the US market.

9

REQUESTS FOR INCLUSION IN BIENNIAL LETTER

- 5. As outlined above, fund DTBE to enable the full support of another cycle of TBESC in 2026 and ensure the full funding of TBTC for the entirety of the current funding cycle through 2030.

10

THANK YOU