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 13-14, 2022

Record of the Proceedings

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ADVISORY COUNCIL FOR THE ELIMINATION OF TUBERCULOSIS
December 13-14, 2022

Minutes of the Virtual 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 13-14, 2022 beginning at 10:00 a.m. Eastern Time (ET).

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 13, 2022 Opening Session

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

Deron Burton, MD, JD, MPH (CAPT, USPHS)
Acting Director, National Center for HIV, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control & Prevention
ACET Designated Federal Officer (DFO)

Robert Belknap, MD
Acting Director, Public Health Institute at Denver Health
ACET Chair

Ms. Condit called the meeting to order at 10:05 AM ET on December 13, 2022 and provided meeting ground rules. She noted that members of the public would have an opportunity to provide comment during the second day of the meeting at 4:45 PM. CAPT Burton welcomed participants and conducted a roll call to confirm the attendance of ACET voting members, *ex-officio* members, and liaison representatives. He explained that ACET meetings are open to the public and all comments made during the proceedings are a matter of public record. He reminded ACET voting members of their responsibility to disclose any potential individual 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
Amina Ahmed, MD Levine Children's Hospital at Carolina Medical Center	No conflicts
Robert Belknap, MD Public Health Institute at Denver Health	No conflicts
Lisa Chen, MD University of California, San Francisco	No conflicts
David Horne, MD, MPH University of Washington School of Medicine	No conflicts
Lixia Liu, PhD, MP, (ASCP), D(ABMM) Indiana State Department of Health	No conflicts
Ann Loeffler, MD Multnomah County Oregon	No conflicts
Lynn Sosa-Bergeron, MD Connecticut Department of Public Health	No conflicts
Kristine Steward-East Advocate for Tuberculosis	No conflicts
Jason Stout, MD, MHS Duke University Medical Center	No conflicts
Zelalem Temesgen, MD Mayo Clinic Center for Tuberculosis	No conflicts

The roll call confirmed that the 21 voting and *ex-officio* members in attendance constituted a quorum for ACET to conduct its business on December 13, 2022. The roll was called subsequent to each break and lunch, with a quorum established each time throughout the day.

Dr. Burton thanked the following outgoing members for their service on ACET over the last 4 years and for extending 180 days past their term to support the Council:

- Dr. Zelalem (Zami) Temesgen
- Dr. David Horne
- Dr. Lixia Liu

He thanked CAPT Edith Lederman, the ACET's *ex-officio* from the Department of Homeland Security's (DHS's) Immigrations and Customs Enforcement (ICE), for her service in the Public Health Service (PHS) and on ACET. He then welcomed the following new members to the ACET:

Ex-Officios

- CDR Tara Rhodes, Bureau of Prisons (BOP)
- Dr. Laura Sessums from the Agency for Healthcare Research and Quality (AHRQ)

Liaison Members

- Council of State and Territorial Epidemiologists (CSTE): Andy Tibbs, MPH, Team Lead of Epidemiology, Surveillance and Research at the Massachusetts Department of Public Health
- Association of State and Territorial Health Officials (ASTHO): Dr. Natasha Bagdasarian, Chief Medical Executive at the Michigan Department of Health and Human Services
- RESULTS: Colin Puzo Smith, Director of Communications and Expansion

Elizabeth Lovinger, Treatment Action Group (TAG), was unable to attend this meeting. Kendall Martinez-Wright, Government Relations and Policy Associate for TAG served in her stead. Dr. Karen Elkins, Food and Drug Administration (FDA), was able to attend for only half of the day and unofficially appointed Sherry Kurtz to represent FDA for the remainder of the meeting.

CAPT Burton reminded everyone that the ACET Charter is renewed every 2 years and will be renewed on March 15, 2023.

Dr. Belknap welcomed members and participants, extending his gratitude to those who were ending their terms and expressing his hope that the next meeting in June 2023 would be in-person.

NCHHSTP Director's Report

Deron Burton, MD, JD, MPH (CAPT, USPHS)
Acting Director, National Center for HIV, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control & Prevention
ACET Designated Federal Officer (DFO)

CAPT Burton noted that the permanent NCHHSTP Director who normally provides this update, Dr. Jonathan Mermin, has been deployed as the Lead for CDC's Mpox response activities. While Dr. Mermin is away, CAPT Burton is serving as the Acting Director and provided the NCHHSTP update for this meeting. NCHHSTP envisions a future free of HIV, viral hepatitis, STIs, and tuberculosis. To achieve this, they work every day to prevent infections, morbidity, mortality, health inequities, and stigma associated with these infections. NCHHSTP believes that to be effective in this mission, they must embody core values in all activities internally as an organization and through its external collaborations.

NCHHSTP recently released its 2022-2026 Strategic Plan[1] that details the Center's overarching goals to: 1) reduce incidence of HIV, Viral Hepatitis, STIs, and TB; 2) reduce morbidity and mortality of HIV, Viral Hepatitis, STD, and TB infections; 3) reduce disparities and promote health equity; and 4) achieve organizational excellence. In addition, the Strategic Plan outlines three guiding principles for the center: 1) high-impact prevention; 2) cross-sector collaboration; and 3) embedding equity principles in all aspects of the NCHHSTP's work. NCHHSTP has six strategies to achieve its goals: 1) maximize the 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 and policy to improve public health.

At the agency level, the CDC Director's announcement to move CDC forward is an opportunity to identify lessons learned from the COVID-19 pandemic and to take action to modernize CDC to consistently deliver expert public health information and guidance to Americans in real-time. This means not only finding opportunities for realigning certain parts of the organization, but also prioritizing CDC's organizational culture and authorities toward more timely action so that CDC science reaches the public in an understandable, accessible, and implementable manner. As Dr. Walensky leads CDC through implementing changes, she also wants to find ways to work collaboratively with the agency's partners to modernize CDC's ability to respond to emerging public health threats.

NCHHSTP is excited to announce a new funding opportunity, CDC-RFA-PS-23-0009, that was recently published to grants.gov titled *Advancing Policy as a Public Health Intervention to Reduce Morbidity, Mortality, and Disparities in HIV, Viral Hepatitis, STDs, and Tuberculosis*.[2] This two-component funding opportunity aims to strengthen the ability of leaders who make decisions in public health to identify and implement evidence-based policy interventions that will save lives, save money, reduce health disparities, and protect adults and youth from HIV, viral

[1] https://www.cdc.gov/nchhstp/strategicpriorities/
[2] https://www.grants.gov/web/grants/view-opportunity.html?oppId=341540; https://www.cdc.gov/nchhstp/funding/pphi/

hepatitis, STDs, and TB. NCHHSTP thinks this work is critical to its collective syndemic approach to reducing morbidity, mortality, and death from these infections. The components of the Notice of Funding Opportunity (NOFO) include: 1) leveraging legal epidemiology methods to examine laws and policies over time and performing critical analyses to understanding the effect of laws and policies on health and economic outcomes; and 2) providing robust legal and policy technical assistances (TA) to support leaders who make decisions in public health as they navigate complex issues unique to their jurisdictions and proactively create publicly accessible TA tools and resources. NCHHSTP hopes to award this NOFO in Spring 2023. This 5-year program will be funded at a minimum of $750,000 per budget year per component, totaling $1.5 million per budget year across both components and $7.5 million across the life of the program. Application details and deadlines can be found on the grants.gov site.[3]

CAPT Burton provided a few updates from NCHHSTP programs. From the Division of HIV Prevention (DHP), he highlighted a few recent Ending the HIV Epidemic (EHE) programmatic achievements. CDC distributed 100,000 free to the consumer HIV self-test kits to populations disproportionately affected by HIV, including transgender women and racial and ethnic minority communities. Health departments in EHE jurisdictions conducted almost 250,000 HIV tests, of which 1000 people received a new diagnosis of HIV. More than 140,000 HIV-negative persons were identified through testing efforts in EHE areas, of which 64% were screened for pre-exposure prophylaxis (PrEP). Of the 76% found to be eligible, 27% were prescribed PrEP. Also, 108 syringe services programs (SSPs) were supported in EHE jurisdictions. Of these, 57 are fixed locations and 51 are mobile or outreach locations. In over 200 instances, real-time data have allowed CDC grantees to quickly direct resources to communities that need them most by identifying and addressing gaps in services.

To highlight a few recent releases of note, CDC published a new HIV Surveillance Report on May 24, 2022 titled, *Diagnoses of HIV Infection in the United States and Dependent Areas 2020,*[4] and a new HIV supplemental surveillance report titled, *Monitoring Selected National HIV Prevention and Care Objectives By Using HIV Surveillance Data United States and 6 Dependent Areas, 2020.*[5] These reports show that the annual number of HIV diagnoses in 2020 were 17% lower than 2019. However, the steep reduction in diagnoses in 2020 is likely due to disruptions in clinical care services due to the pandemic; patient hesitancy; and shortages in HIV testing, reagents, and materials. In September 2022, CDC also published two HIV surveillance reports that feature quality of life indicator data. The Medical Monitoring Project Data Tables Report is a special report that was created specifically to support the September 2022 release of the *National HIV/AIDS Strategy Federal Implementation Plan* (*NHAS Federal Implementation Plan*).[6] This special Medical Monitoring Project (MMP) report contains a table for each quality-of-life indicator, which include self-rated health, unmet needs for mental health services, hunger and food insecurity, unemployment, unstable housing and homelessness, and HIV stigma. CDC released an Issue Brief titled, *Issue Brief: Highlighting the Role of Status Neutral HIV Care and Service Delivery: Eliminating Stigma and Reducing Health Disparities.*[7] A status neutral approach to HIV-related service delivery aims to deliver high-quality, culturally-affirming health care and services at every engagement, supporting optimal health for people with and without HIV.

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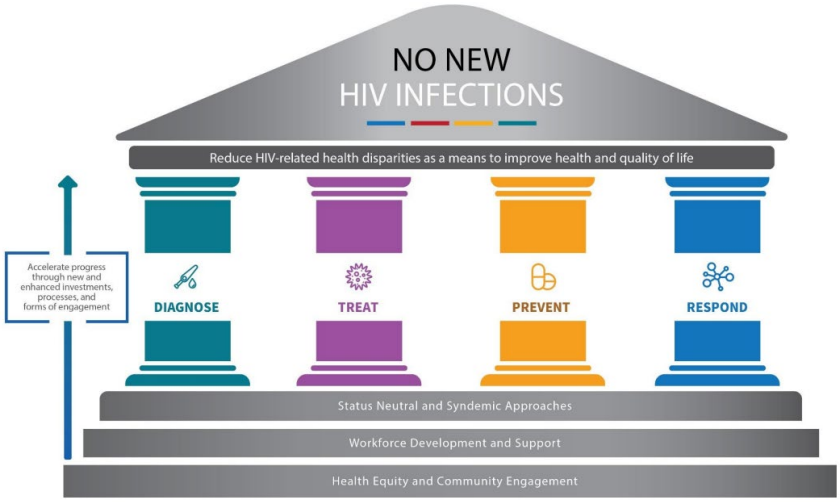
[3] https://www.grants.gov/web/grants/view-opportunity.html?oppId=341540; https://www.cdc.gov/nchhstp/funding/pphi/
[4] https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-33/index.html
[5] https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-27-no-3/index.html
[6] https://files.hiv.gov/s3fs-public/2022-09/NHAS_Federal_Implementation_Plan.pdf
[7] https://www.cdc.gov/hiv/policies/data/status-neutral-issue-brief.html

In October 2022, DHP released the *Division of HIV Prevention Strategic Plan Supplement: An Overview of Refreshed Priorities for 2022-2025.*[8] This new *Strategic Plan Supplement* builds on the goals and objectives in the existing 2017-2020 Plan by articulating some key priorities that DHP wants to accelerate to advance HIV prevention progress. To inform development of this supplement, the DHP held 18 listening sessions across health departments, directly and indirectly funded community-based organizations (CBOs), and policy partners. The DHP's Strategic Framework is a visual framework to accompany its *Strategic Plan Supplement*, representing how the EHE in the US Initiative pillars integrate with other priorities like health equity and community engagement, supports the way DHP delivers its work, and identifies room for continuous innovation and advancement across the 4 focus areas with EHE:



Drivers for how to implement a scientific and programmatic portfolio to reach HIV prevention goals include health equity and community engagement, which aims to address how racism, homophobia, transphobia, and stigma significantly exacerbate the health disparities experienced within the communities that DHP serves and also considers how DHP can expand its engagement with communities and increase the number and diversity of its partnerships. In addition, there is a focus on workforce development and support in order to strengthen the workforce operations to meet the demands of DHP's programmatic and scientific portfolio. Finally, the status neutral and syndemic approaches highlight the need for a bold and comprehensive delivery method for HIV prevention, as well as a whole person approach to this work. It also incorporates the idea of collectively addressing intersecting conditions and social determinants of health (SDOH) to result in better HIV prevention and care outcomes by prioritizing the whole person.

Next, a few updates from NCHHSTP's Division of Adolescent and School Health (DASH). Recent data from CDC[9] illustrate the mental health crisis adolescents experienced during the pandemic. More than 1 in 3 (37%) students reported poor mental health during the pandemic. Nearly half (44%) felt so sad and hopeless that they could not do their regular activities for at least 2 weeks during the prior year, which are markers for depression. About 20% (2 in 10) seriously considered attempting suicide and nearly 1 in 10 (9%) attempted suicide in the past year. These numbers are extremely concerning. As discussed during the June 2022 ACET

[8] https://www.cdc.gov/hiv/division-of-hiv-prevention/strategic-plan/index.html
[9] Adolescent Behaviors and Experiences Survey, 2021

meeting, not all students are experiencing the mental health impacts of the pandemic equally. CDC data confirm that LGBTQ (Lesbian, Gay, Bisexual, Transgender, and Queer/Questioning) students were disproportionately impacted, including nearly 2 in 3 LGBQ students reporting experiencing poor mental health. LGBTQ students also were more than three times as likely to have attempted suicide in the past year. However, there is good news. The power that enhancing safe and supporting learning environment in schools has on improving health outcomes is known. Despite the challenges that they face, schools and districts have worked hard to keep students healthy and connected to their schools and communities during the pandemic.

CDC's newly released *School Health Profiles* report[10] shows how schools implemented policies and practices to promote connectedness during the COVID-19 pandemic. It is known that strategies like gender and sexuality alliances, identifying safe spaces, prohibiting harassment, and professional development for educators make schools safer and more supportive and improve adolescent health and wellbeing. In schools that CDC funds to implement these activities, improvements are seen in mental health outcomes for all youth. Schools are a critical venue to increase feelings of connectedness for all students, including LGBTQ students. These data[11] reflect the efforts schools made to keep students connected during this time, as well as much more is needed to support school connectedness for LGBTQ youth. The data show that 97% of middle and high schools prohibit harassment of LGBTQ students and 80% identified safe spaces for LGBTQ youth. However, only 44% of middle and high schools have a Gay-Straight Alliance (GSA) and only 30% of middle and high schools report training staff on how to support LGBTQ students. It is important that CDC continue to focus on fostering supportive school environments for LGBTQ youth as this may be an area where schools have the risk of becoming less inclusive within the current environment.

Now moving to updates from NCHHSTP's Division of STD Prevention (DSTDP). CDC released new preliminary 2021 STD surveillance data in September 2022. The data[12] suggest that STDs continued to increase during the second year of the COVID-19 pandemic, with nearly 2.5 million cases of chlamydia, gonorrhea, and syphilis reported. This reflects a 4.4% increase since 2020. While STIs are increasing across many groups, the preliminary data show that disparities in STIs continue to exist. For chlamydia, gonorrhea, and syphilis, Black/African American persons and American Indian/Alaska Native (AI/AN) persons consistently have the highest rates. Rates for Black/African American persons are 6 to 8 times higher than for White persons, depending on the infection. Rates for AI/AN persons are 4 to 8 times higher than for White persons.

In September 2022, DSTDP published its new *Division of STD Prevention Strategic Plan 2022-2026*.[13] The plan's six goals outline a comprehensive approach to maximize the impact of STI prevention programs, policies, and science. Furthermore, the goals align with the National STI Strategic Plan to: 1) prevent new STIs; 2) improve the health of people by reducing adverse outcomes of STIs; 3) accelerate progress in STI research, prevention, and technology; 4) reduce STI-related health disparities and health inequities; 5) achieve integrated and coordinated efforts to address the STI epidemic; and 6) enhance and support an effective internal workforce.

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[10] https://www.cdc.gov/healthyyouth/data/profiles/pdf/2020/CDC-Profiles-2020.pdf
[11] Kaczkowski, W., Li, J., Cooper, A. C., & Robin, L. (2022). Examining the Relationship Between LGBTQ-Supportive School Health Policies and Practices and Psychosocial Health Outcomes of Lesbian, Gay, Bisexual, and Heterosexual Students. LGBT health, 9(1), 43–53. https://doi.org/10.1089/lgbt.2021.0133
[12] https://www.cdc.gov/std/statistics/2021/default.htm
[13] https://www.cdc.gov/std/dstdp/dstdp-strategic-plan-2022-2026.htm

CDC continues to identify priority areas for STI research. In May 2022, national STI experts met for a two-day meeting to develop a national research agenda for STI prevention and treatment over the next five years. The following four key areas were identified, which are that research is needed to: 1) understand point of care (PoC) and self-tests dissemination, impact, outcomes, most effective integration into existing care, surveillance impact, and cost implications; 2) better understand the etiology of STI syndromes, and screening and treatment options and outcomes; 3) improve understanding of the outcomes and impact at the individual and population levels for STI screening; and 4) develop STI vaccines.

CDC also is investing $9 million in several projects to innovate STI testing and service delivery. $6.5 million has been allocated for STD testing innovations projects that include development of rapid PoC syphilis diagnostic tests and direct molecular detection of syphilis tests at Chembio Diagnostics, University of Maryland, and University of Washington. To increase access to STI and HIV services and care, five jurisdictions have been awarded $875,000 to develop projects to leverage pharmacies. Illinois, Massachusetts, Mississippi, and Oklahoma received $2 million in supplemental funding to implement interventions that will decrease congenital syphilis by supporting a multi-sector response to syphilis in 1 to 2 high morbidity areas.

Finally, updates from NCHHSTP's Division of Viral Hepatitis (DVH). In September 2022, CDC released its *Viral Hepatitis Surveillance Report: United States, 2022*[14] and *2022 Viral Hepatitis National Progress Report*[15] in fully digital formats. Some highlights from the reports include that the number of Hepatitis A (Hep A) reported in 2020 decreased 47% from 2019, which marks the first year the incidence of Hep A has decreased after 5 consecutive years of increasing incidence. To date, 24 of 37 affected states have declared an end to their Hep A outbreaks. For Hepatitis B (Hep B), a 32% decrease was observed in reported cases from 2019 to 2022. After 10 years of stable rates, this abrupt decline should be interpreted with caution in the context of the COVID-19 pandemic. In contrast, the number of reported Hepatitis C (Hep C) cases increased 16% from 2019 to 2020, consistent with ongoing increases over the past decade. However, a new, more sensitive case definition for acute Hep C was introduced in 2020, which could have contributed to increased reporting. After several years of declining rates of age-adjusted Hep B- and Hep C-related mortality, both rates increased. Again, these results should be interpreted with caution in the context of the COVID-19 pandemic. In 2020, the US experienced an overall increase in age-adjusted mortality due to the COVID-19 pandemic, which could have impacted reported numbers for viral hepatitis-related deaths as well.

CDC embarked on a project to create dashboards for viral hepatitis, which will improve capacity at the jurisdictional level to monitor, analyze, and disseminate viral hepatitis data for public health action. Leveraging CDC's Data Collection and Integration for Public Health Event Response (DCIPHER) platform, the new secure HepSEE Dashboard began in March 2022. Prototypes were prepared in July 2022, and it is expected that the full version will be available to pilot in January 2023.

[14] https://www.cdc.gov/hepatitis/statistics/2020surveillance/index.htm
[15] https://www.cdc.gov/hepatitis/policy/npr/2022/overview.htm

In September 2022, CDC began its first program dedicated to funding SSPs. This 5-year program will increase access to harm reduction services for people who use drugs and prevent Hep C, Hep B, HIV, and other infectious diseases and complications associated with injection drug use. CDC issued two awards totaling $7.7 million in the first project year to RTI International and the National Alliance of State and Territorial AIDS Directors (NASTAD) through the Strengthening Syringe Services Programs (CDC-RFA-PS22-2208) Cooperative Agreement. RTI International will use its funds to support a national network of SSPs and oversee implementation and use of an annual national survey of SSPs' capacity and service delivery. NASTAD will use its funds to expand the reach of SSPs working across the US to prevent the infectious consequences of injection drug use and overdose through harm reduction services.

In August 2022, CDC released a new *Vital*signs™ reporting that only about 1 in 3 people overall who are diagnosed with Hep C and who are continuously insured initiated direct acting antivirals within 1 year of diagnosis.[16] The number was even lower at 1 in 4 among Medicaid recipients. The report found further reductions among Medicaid recipients, including a 23% additional reduction in timely Hep C treatment initiation among Medicaid recipients living in states with treatment eligibility restrictions and up to a 27% reduction among persons with a reported race other than white. To ensure all people with Hep C receive treatment, the *Vital*signs™ calls for elimination of Hep C treatment eligibility restrictions, expansion of the number of primary care providers (PCP) treating Hep C, provision of treatment in places whether people with Hep C already receive care (e.g., primary care clinics, substance use disorder treatment centers, and correctional facilities), and promotion of best practices for providers to offer simplified testing and treatment.

ACET Discussion

Dr. Belknap asked whether CAPT Burton could share more about the timeline for the potential restructuring, whether there will be an opportunity for outside partners to provide input, and anything that the ACET might expect to change as it relates to TB.

CAPT Burton indicated that CDC Moving Forward is currently in full swing. As part of the process, there have been a number of listening sessions and direct calls to external partners to gather input for CDC to consider as part of the Moving Forward process. That work has been ongoing for a number of months and is now moving into a phase in which the agency is considering recommendations from inside and outside the organization to formulate potential organizational changes, as well as changes in processes within the organization to implement beneficial changes. When final decisions have been made about structural and process-oriented changes, those will be shared more broadly.

Dr. Belknap asked whether CDC funds research activities and consortia in the other branches within STI, HIV, or hepatitis similar to what is done for TB with clinical trials and epidemiology networks.

[16] www.cdc.gov/vitalsigns/hepc-treatment

CAPT Burton indicated that the agency does fund research consortia in other environments. NCHHSTP's DSTDP has been interested in developing a research consortium that is modeled on the Tuberculosis Trials Consortium (TBTC) in many respects in terms of borrowing lessons learned from how TBTC is organized and how it functions to set and execute research priorities. That consortia is being developed now within the DSTDP and there may be other locales across the agency that have similar activities as well.

Dr. Belknap recalled previous ACET discussions regarding challenges with the clearance process for getting science out quickly. That was a high priority during COVID-19 in terms of the speed at which information was being made available. Assuming that would be a part of the Moving Forward discussion, he asked whether CAPT Burton could share any additional information.

CAPT Burton pointed out that a core piece of the discussions regards how the agency can provide its scientific information in a timelier way, with more effective communication that is understandable, action-oriented, and implementable in real-time. There are many conversations underway within the agency about how to improve CDC communications. Some of that has to do with updates to the agency's clearance processes to make them more streamlined, improve the use of processes to speed up the internal review timeline, and ensure that products entering the clearance process are already in a form that will allow them to move through. Other aspects of the agency's communication processes are being discussed as part of Moving Forward. Final decisions on the CDC Moving Forward portfolio changes are still underway. He will be able to share more once the final decisions and changes are released.

Dr. Roselle observed that there seems to be prohibition for self-collection of oral and anal gonorrhea and chlamydia testing.

CAPT Burton indicated that he would follow up with colleagues in the DSTDP and provide more information on Dr. Roselle's observation at a later time.

DTBE Director's Update

Philip LoBue, MD, FACP, FCCP
Director, Division of Tuberculosis Elimination
National Center for HIV, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention

Dr. LoBue updated ACET on nitrosamine impurities, drug shortages, TB Centers of Excellence for Training, Education, and Medical Consultation (COEs) re-competition, final 2021 surveillance report, the TBTC scientific retreat, and a US Preventive Services Task Force (USPSTF) latent tuberculosis infection (LTBI) recommendation. He reminded everyone that the first 2 topics were requested but would be fairly brief, given that there is not a lot of new information on nitrosamine impurities or drug shortages. In August 2020, the FDA announced that there was a finding of nitrosamine impurities in both rifampin and rifapentine that were above the usually acceptable limits of 0.16 ppm and 0.1 ppm, respectively. The issue with these impurities is that they are potentially carcinogenic. At the time, a decision was made that the FDA would set higher limits of these impurities in those 2 drugs in order to keep them flowing in the US market. The new temporary acceptable limits were set at 5 ppm and 14 ppm, respectively. The plan was to work with companies to determine whether there were ways to alter the manufacturing process and lower the amounts of impurities. In October 2020, the limit for rifapentine was

raised again to 20 ppm in order to keep that drug available. In January 2021, testing results were released for different formulations of rifampin and rifapentine published by FDA, which conformed to limits the FDA had set. CDC has seen no new information since January 2021. The drugs are still available. While there are some supply issues, they are not related to this issue as far as CDC is aware.

There have been persistent issues in terms of drug shortages for rifapentine and rifampin. Rifapentine has a single manufacturer. There have been intermittent shortages that started in March 2020. Per the manufacturer, the cause for this was an inability to meet increasing global demand. Per the FDA website, there remains a shortage of rifapentine. The ability to obtain this drug has been mixed geographically and temporally. Sometimes people have no trouble getting and other times have trouble. While the problem persists, CDC is not aware of anything new other than the larger global demand that the manufacturer has been unable to keep up with at different times. The rifampin shortage began in December 2021 per the FDA. It is important to understand that this has occurred in a setting where there has been a substantial loss of manufacturers over the last several years. It was not that long ago that there were 5 manufacturers, but now there are only 2 manufacturers. One manufacturer has indicated that they currently have a normal supply, while the other has indicated that they have limited quantities because they have had difficulty obtaining the active ingredient. When CDC has rifampin, they are making it available to programs. As it becomes available in increments, CDC will allow programs that have cooperative agreement to request the drug per the mechanism that has been used in the past. The agency currently has approximately 1,700 bottles of rifampin that are slated to go out and has ordered a little over 9,000 bottles from the stockpile.

Moving on to the TB Centers of Excellence for Training, Education, and Medical Consultation. The overall goal of these centers is to support domestic TB control and prevention efforts with a focus on 2 major activities, which are to: 1) increase knowledge, skills, and abilities for TB prevention and control through communication, education, and training activities; and 2) improve sustainable evidence-based TB clinical practices and patient care through the provision of expert medical consultation. These centers are funded in 5-year cycles, with the current funding cycle ending at the end of December 2022. The announcement for the new 5-year funding for 2023-2027 was released in 2022, for which competitive selection has been completed. The 4 sites selected include the following:

- Southeastern National TB Center* (SNTC) in Gainesville, Florida
- Curry International TB Center* (CITC) in San Francisco, California
- Global TB Institute* (GTBI) in Newark, New Jersey
- Mayo Clinic Center for Tuberculosis (MCCT) in Rochester, Minnesota

The first 3 were funded sites during prior funding period (2018-2022). While the MCCT was not funded in the prior cycle, they have been funded previously.

The final 2021 US TB surveillance report,[17] *Reported Tuberculosis in the United States, 2021*, became available online November 29, 2022. Provisional data were reported in March 2022 in the *MMWR* and Dr. LoBue presented them during the June 2022 ACET meeting. There was little difference in the final TB case count of 7882 versus a case count of 7860 in the provisional data. The final rate of 2.4 per 100,000 did not change from the provisional data. The final report

[17] https://www.cdc.gov/tb/statistics/reports/2021/default.htm

includes a lot more data than in the *MMWR* published in March, with the final report containing 54 tables, 2 figures, and a slide set with 68 slides. The report is completely electronic online, and the communications and surveillance groups have worked to make it as easy and interactive as possible.

In terms of the TBTC Scientific Retreat, some issues are still being worked out. As a reminder, the TBTC's mission is to conduct programmatically relevant research concerning the diagnosis, clinical management, and prevention of tuberculosis infection and disease. In March 2021, CDC announced the sites for the research cycle that goes through December 2030. However, much of the TBTC's work was paused because of the COVID-19 pandemic and then slowly restarted over the last year and a half or so. Following the beginning of a new funding cycle and with TBTC activities getting back to normal, internal and external leadership felt this was an opportune time to reassess TBTC's strategic direction. For that reason, the group held a strategic retreat on November 29-30, 2022. The expected outcomes from this retreat were to identify priorities for the TBTC scientific agenda through 2029 and develop a strategic plan with concrete steps for addressing these priorities. The group met these outcomes at a high level, but also recognized that there are a lot of details around these areas that need to be worked out. For that reason, they formed 5 workgroups to address the priority areas.

As a reminder, the USPSTF is an independent, volunteer panel of national experts in disease prevention and evidence-based medicine. They work to improve the health of people nationwide by making evidence-based recommendations about clinical preventive services. They are convened by the AHRQ. The USPSTF reviews its recommendations every 5 years to determine whether any changes are needed. Their 2021 draft recommendation for LTBI appears to be unchanged from the 2016 final recommendation. The population is asymptomatic adults at increased risk of LTBI and the recommendation is screening for latent TB infection in populations at increased risk. Importantly, they mention that the pathway to benefit is that persons who screen positive for LTBI receive follow-up and treatment. That is given a Grade B recommendation, which the USPSTF Grading table puts into context:

Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer or provide this service for selected patients depending on individual circumstances.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

The definition of "populations at increased risk for LTBI" is based on increased prevalence of active disease and increased risk of exposure. This includes: 1) persons who were born in, or are former residents of, countries with increased TB prevalence; and 2) persons who live in, or have lived in, high-risk congregate settings (e.g., homeless shelters or correctional facilities). This does not include populations that may be considered standard care as part of disease

management or indicated prior to the use of certain medications (e.g., HIV infection, other immunosuppression), given that the USPSTF considers such populations outside their scope and refers to recommendations by other organizations for these populations. They say that this type of screening and testing would be part of the management of these conditions. They mention that clinicians can consult their local or state health departments for more information about populations at risk in their community since local demographic patterns may vary across the US. Dr. LoBue indicated that the draft USPSTF recommendation would be available for Public Comment until December 27, 2022 and that comments would be accepted through the USPSTF website.

ACET Discussion

Dr. Stout commented that he is particularly interested in the drug shortage issue, which feels like playing "whack a mole" for a long time. This seems like it fits into the large context of antibiotic shortages in the US, such as the current amoxicillin suspension for pediatrics. It appears that the underlying issue relates to the economics of antibiotics, because curing people does not make a lot of money. There are commonalities across many disease areas in terms of advocacy and what needs to be done. Therefore, he was interested to know what CDC and perhaps other agencies are doing to combine efforts with other interested groups to try to advocate for policy change or maybe rethink how antibiotics are supplied in the US broadly as part of the context of TB drug shortages.

Dr. LoBue said that he could not speak for the agency as a whole, but within the TB drug issues they certainly have made people aware through the center and at the higher level of the Deputy Director of Infectious Diseases (DDID). Until the recent issue with moxifloxacin, he did not think that they had been hearing from a lot of people other than DTBE and DSTDP over penicillin. It has become more of an issue recently not only with amoxicillin, but also beyond antibiotics with simple drugs like Tylenol being in shortage. The financial aspects are certainly true with drugs that people take for a limited time versus a lifetime. There is the issue of products being generic, which takes away the profit margin. On top of that, there have been newer issues recently related to supply chain that are outside of the profit margin. They have spent a lot of time over the years talking to the FDA, different types of stockpiles, and manufacturers but have not gotten very far in finding easy solutions to this. He agreed that it has reached a point in which it would be good to have a more concerted efforts, because these issues occur with many types of drugs—even cancer drugs. They will continue to bring these issues up to determine whether there is a better way to address them.

Dr. Ahmed said she assumed that children were left out of the USPSTF recommendation because of the rates of TB being low.

Dr. LoBue indicated that children were left out because the USPSTF makes recommendations for adults.

Dr. Sosa-Bergeron noted that the American Academy of Pediatrics (AAP) has the LTBI screening recommendation for children.

Dr. Benjamin asked whether the US would consider development of a National Essential Drug Formulary that guarantees supply of identified essential drugs as is done in many less economically advantaged countries.

Dr. LoBue said the only efforts he is aware of is the stockpiling of certain drugs for emergency situations.

Dr. Belknap recalled that ACET had a Drug Shortages Working Group in the past. Perhaps there could be a larger strategic approach to this, keeping ACET more narrowly focused on TB. There are the currently available drugs and some newer drugs that are available and being used, but that are challenging to get. He asked whether there was an approach that the ACET could continue to discuss and/or pursue to make the drugs available, easier for programs, and more equitable for patients. It appears that the timeliness of access depends upon where someone is.

Dr. LoBue emphasized that part of the problem is that it is not one thing. Even if some sort of central procurement and distribution system that might mitigate against other issues related to how some programs get their drugs through middlemen who may or may not be dependable. For the manufacturers who do not make many drugs, having a distribution system is irrelevant. There are problems now in that manufacturers are making the drugs, but the distribution systems do not work. There have been times when plenty of drugs are available, but certain programs could not get them because for whatever reason, the private distribution system was not working the way it should. The economics of it are a major issue for manufacturers so they either drop out of the market or do not really care if a drug that is not that profitable is down on their assembly line. Distribution and supply chain issues sometimes may be affected by economics, but sometimes it is other issues like COVID-19. While there may be various solutions, they are well beyond anything DTBE can do other than raising the issue to higher levels.

Dr. Chen recognized that while CDC is now maintaining a stockpile, especially of rifampin, the volume is not high, but the acuity and complexity are high in cases that cannot get bedaquiline in a timely way. She wondered whether any thought had been given to keeping a small central supply of bedaquiline and somehow getting reimbursed.

Dr. LoBue pointed out that the problem with bedaquiline is the expense. With limited funds, they are trying to do the most they can with it. If they start buying very expensive drugs, there will not be very much. There is an FDA Task Force on Drug shortages report.[18] Three years ago, the FDA assembled this Task Force at the behest of Congress and developed this report. During that period, they took comments and DTBE provided comments. He thought the National Tuberculosis Controllers Association (NTCA) also may have had an opportunity to provide comments. The Task Force identified a number of the causes discussed, but 3 years later the problems are continuing, either because the solutions proposed were not implemented or were not the correct solutions. Either way, the problem has not been fixed. His personal opinion is that some of the solutions definitely would help, but he does not think it is comprehensive in terms of the solutions that are needed—including things that were suggested at the time that did not make it into the report.

Dr. Belknap stressed that 3 years is a lifetime in terms of the pandemic timeline, so this may have “fallen off the radar.” This is still an important topic. The Council had a good discussion around it and should continue to emphasize that it either did not work or did not happen.

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[18] https://www.fda.gov/drugs/drug-shortages/report-drug-shortages-root-causes-and-potential-solutions

Dr. Stout asked at what level the process of addressing antimicrobial drug shortages for TB have to occur (e.g., advocacy for legislation, regulatory, et cetera) to make a more concerted effort. Trying to address individual shortages has not proven to be a great strategy. While he understands there is not a big fix for all of this, the Infectious Diseases Society of America (IDSA) has engaged in some advocacy to push for some measures to hedge against drug shortage issues. A division-level intervention is not going to be very effective due to lack of resources.

Dr. LoBue stated in his opinion, it probably would require legislation. He does not think that any authority exists within any specific agency to fix the multiple issues that occur. Once there was legislation, the coordination would have to be at least at the department level at HHS or the White House.

Dr. Benjamin noted that decades ago, the State of Massachusetts manufactured biologicals that the state determined were essential by the state.

Dr. Belknap asked whether the DTBE has a similar strategic plan approach as the one described by CAPT Burton for HIV elimination, or if there is an effort to align work across NCHHSTP's various divisions.

Dr. LoBue indicated that each division has a strategic plan and they make a conscious effort to align those with the NCHHSTP's plan. The divisions' strategic plans are reviewed by the center to ensure that they do align. One of the major roles of the center is work across divisions, which is done through various workgroups and other ways of aligning the work—usually around certain issues. One example has to do with testing in primary care settings for all of the diseases.

Electronic Data Systems for Overseas Medical Evaluations

Deborah Lee, MPH
Lead, Migration Health Information Nexus
Immigrant, Refugee, and Migrant Health Branch
Division of Global Migration and Quarantine
Centers for Disease Control and Prevention

Ms. Lee discussed the landscape in terms of the background and authority for the Division of Global Migration and Quarantine (DGMQ) authority to do its work; an overview of its systems overseas and domestic; a review of the Afghan response and related projects; and some of the takeaways from the past decade and a half that she has been in this field. The basis of DGMQ's regulatory authority includes the Federal Quarantine Regulations 1798 that requires prevention of international and interstate disease; the Immigration & Nationality Act 1968 that requires medical screening and vaccinations; and the Refugee Act 1980 that requires notification and provision of medical data, and meeting arrivals at the port of entry. In terms of estimated international arrivals and status adjusters during 2019, there were 30,000 refugees; over 1,000,000 immigrants; and over 180,000,000 non-immigrant admissions comprised of 4,000,000 temporary workers and their families and 1,900,000 student visas; and over 600,000

status adjusters.[19]

For a brief history of the DGMQ's notification databases, there were two systems in the 1990s, the Alien Information System (AIS) and the Information of Migrant Population (IMP) system. Partial pieces of the overseas medical records were entered into a database and the Quarantine Officers did a lot of the collecting, entering, and mailing out of the notifications. In the mid-2000s, the DGMQ embarked on centralizing the system with the Electronic Disease Notification (EDN) system and an ability to access the medical records by health departments and health partners through and the Secure Access Management System (SAMS) through a secure firewall. This has allowed them to provide summaries. The EDN provides immigrant and refugee arrival notification and health information to US health partners. There are over 130,000 notifications per year to over 1500 US health partners and over 500 jurisdictions. Medical exam data transfer has been simplified in many ways. Overseas processes are still paper-based for non-immigrants, Diversity Visa applicants, and parolees (except Afghan). Those data are collected at the port of entry. Major advancements have been made in electronic data collection in terms of immigrants and refugees. Immigrant applicants apply online through Form DS260, which sits in the system and is pulled in when the immigrant goes to a physician overseas. The structured data goes to DGMQ, a pdf goes to the Department of State, and DGMQ is notified when the immigrant arrives in the US. The status adjustment is still a paper-based process that is completed by US Citizenship and Immigration Services (USCIS). DGMQ does not have access to the USCIS records.

eMedical, a collaboration that DGMQ started about 5 years ago with the Department of State, is an electronic processing system for immigration medical examinations that uses form DS-7794. The system was developed by the Australian Department of Home Affairs. It is used by Australia, Canada, New Zealand, and the US. eMedical has been used by over 750 panel physicians in 377 clinics in over 160 countries. Panel physicians who perform required medicals for multiple countries can use a single system. Overseas medical data is transmitted electronically from eMedical to the CDC staging database and then to EDN. It is used only for immigration visa applicants, excluding Diversity type immigrant visa applicants. Technical instructions are built into eMedical. Some of the benefits of using eMedical are that it improves data quality (i.e., align business rules with CDC's Technical Instructions); improves timeliness of notifications to health departments (i.e., from 2 weeks to 2 days); improves follow-up of persons with admissible TB condition classifications; reduces lost/illegible paper forms; reduces the risk of fraud, and eliminates the need for panel physicians to burn CDs with chest x-ray images. There is an ability with the EDN system for health departments to engage in TB follow-up.

Operation Allies Welcome (OAW) was established following the collapse of Afghanistan in 2021. Afghans were moved to lily pads and then resettled to 8 US Safe Havens. There was a limited requirement for vaccinations and medical screening, with information recorded on the I-693 form. They quickly rallied to try to figure out how to get this this medical screening information to US health partners. Project ARMS was a complex pivoting operation that leveraged existing processes and partnerships. While there is a data entry platform for all of these systems, it was behind a CDC firewall, so they had to leverage federal partners and different systems. The systems component was a very small portion of the operation, collaborating with the Department of Homeland Security (DHS) and the Department of Defense (DoD). The project was CDC-funded but contracted by the Department of State. CDC provided the logistical

[19] https://www.dhs.gov/sites/default/files/publications/immigration-tatistics/yearbook/2019/yearbook_immigration_statistics_2019.pdf

operations and had to look at the medical screening, adapt an overseas process domestically, and enter it back into an overseas form. They worked with the Department of State to have an expedited approval to use the overseas eMedical system, with an agreement with USCIS to be able to share the I-693 so that it can be entered. In terms of an examiner, CDC had to work with civil surgeons who are part of the DoD and contractors doing the data entry. The forms had to be pivoted to portions of the USCIS form and entered into a Department of State system. Then CDC had to create systems to be able to enter the information into a digital form, and manually provide that to health departments while adjusting the eMedical system.

The rationale for not using existing systems is that there is a systematic process to the system development. CDC does have systems now that can be used with the eMedical system. CDC was able to adjust a functionality in which the requirements were removed that came from the Department of State in terms of the demographic information. Then the rest of the information is familiar and fairly easy for entry. That information comes into CDC's system and then goes into the EDN system. Currently, CDC's informatics team is creating a web-based data entry platform. For about 4 months or so, they had to use a homegrown system that the Digital Service Office was able to create. They made a form exactly like the I-693 form in which the fields were mapped so that it could be utilized. This form is still available for use.

The key takeaways are that electronic systems were established to collect immigration medical information. Additional visa classes will need Office of Management and Budget (OMB) approval for use, such as the Diversity immigrant visas that represent all most 8% of immigrant visas. There is no electronic system to collect domestic medical information from civil surgeons. One of the biggest pieces to this puzzle is having federal partners champion the effort to make things electronic.

ACET Discussion

For this discussion, ACET was asked to consider the following questions:

1. *What recommendations can ACET make to HHS to improve EMR systems for both overseas and domestic medical information tracking?*
2. *What next steps and improvements to EMRs should CDC consider?*

Dr. Belknap asked whether there is a mechanism by which the performance and metrics related to how information is fed in and gets to local jurisdictions. While his sense was that there has been great improvement over time, he wondered how often there was missing information or missing digital x-rays and if there is a way to track this.

Dr. Lee said that for the refugee population, there is a routine assessment of all records that should have been received from the Department of State. This has been tricky with the Afghans since some could have entered the US and elected benefits later, so they get cued into the Department of State system. Typically, the assessment is done on a bimonthly basis. The assessment is tricky for immigrants as well if there is paper collected by the quarantine system. The denominator in terms of the panels using eMedical have been very helpful. There is a huge portion of diversity that are not being used. There are proxies in terms of TB indicator metrics that help, but it still has been the health departments and heath partners notifying DGMQ when records are missed. While it is a very small percentage in the totality of things, it is still significant enough and noticeable if a partner calls in to say that records are missing. There has been tremendous improvement over her 15 years in this division, but there is more to improve.

Dr. Liu noted that during the time of OAW, the Indiana state laboratory and other commercial laboratories were involved. She asked how the multiple sources of laboratory testing results were migrated and incorporated into the DGMQ system.

Dr. Lee said that the OAW project arm or the first phase of movement was done in the Safe Havens was a huge effort. The laboratory results were not entered into the DGMQ system and probably were obtained later. There was a lot of pivoting. Boxes were being moved to a facility in Texas where they had to chase down records and collaborate with the USCIS. The USCIS was focused primarily on the 693 forms, but only a few sections of the forms were entered or available (e.g., TB, vaccine, physical history). The laboratory data were not available for the DGMQ system. In terms of the overseas medicals being done, the division adjusted the forms to be able to enter the (interferon-γ release assay (IGRA)) results onto the forms. Those were implemented in 2022. They asked panels in the past to upload those, but some do and some do not. Now they are required to have those on the form.

Dr. Ahmed asked whether international adoptees fall into the algorithm under “immigrants” or somewhere else. This is a population she struggles with in terms of their paperwork, which should be sitting somewhere in the state but often is not. The parents bring part of the paperwork with them, but she is not sure whether it is complete.

Dr. Lee indicated that the immigrant visa class is represented by 8 or so subclasses and adoptees is one of them. Special immigrants is another. The largest is family-based. They are required to have those entered into the eMedical system. For adoptees who have to be moved quickly for whom culture results are not available but who meet other health requirements, there is an ability to have those portions be available later. The DGMQ has asked panels to submit those so that the adoptee can get to their final location more quickly. If an adoptee is not in the system, the DGMQ is happy to check where the gaps are.

Dr. Chen congratulated the DGMQ, recognizing that it is a huge deal and takes several years to set up an electronic system like this. She recalls how many hours she has spent looking at reviews for people coming in for their B classification, and this is so much better. Much has been learned over the last couple of years with the Afghan influx and now with the large influx of Ukrainian arrivers. She asked whether there is flexibility built into the system in the event of another urgent situation with rapid standing up of medical arrival sites in military institutions. Having worked with panel physicians directly with program sites, there appears to her to be a gap in that panel sites gather a lot of information at the beginning of someone’s path toward immigration but then one piece of critical information that is missing is where to find that person. US programs have a hard time tracking people, so she wondered if there is a way to insert a reconfirmation before the last clearance of where people can be contacted in the US.

Dr. Lee confirmed that Dr. Chen’s questions resonate with what the DGMQ has heard from partners. The panel is asked to enter an address into the system and made that a requirement earlier in the year. At the ports of entry, Customs and Border Protection (CBP) Officers are updating addresses and transmitting them to DGMQ. There are a lot of people who come to the US with a company that has a common address, but they are not actually going to that location. People are living with their families and moving on, so DGMQ does not have the ability to update those records. That is a serious concern for which there needs to be a collaboration with other federal agencies that will help get that information. The ability to scale up rapidly is possible if the pathway is followed. In the last year with the various emergency evacuations with the Ukrainians, medical screening was not required. The systems are the easiest component, but it is hard if the policy and collaboration are not in place. The collection of this information is

really overseen by other agencies. DGMQ is providing the medical and technical instructions and has federal responsibility, but approval and so forth comes from CDC's partners.

Dr. Belknap asked Dr. Lee to share DGMQ's priorities for future improvements or next steps as advancements to continue to move this work forward.

Dr. Lee indicated that one of the challenges with their partners, such as the Department of State, is that she has been working with federal officers who rotate every couple of years. Her hope is that the current new liaison will stay longer to help champion the additional pieces to the eMedical component, which is adding the diversity visas into the eMedical system. There is no OMB approval for this. In terms of systems, there probably does not need to be any updates. However, if the Department of State wants to collect that, they probably need to do some rewiring on their side. That is the most immediate advancement DGMQ wants to move forward with, as well as getting the parolees or other populations who are using the DS forms. They made a request for this, which is still with OMB. Trying to clear out as much paper as possible is something Dr. Lee is likely to be doing until she retires. There is some exciting work happening now in terms of the digital x-rays with machine learning (ML) projects. In terms of location, it is hard to hear partners say that they cannot find people so DGMQ hopes to open up collaboration with USCIS to determine what can be done. This will be a process and will take time, but the USCIS has a high rotating staff as well.

Dr. Belknap asked whether Dr. Lee foresees moving the status adjuster process that is on paper to electronic in the near future.

Dr. Lee said that DGMQ has been asking USCIS what it will take to get these records digitized and are hoping to get some traction in the next few months. They developed a module to enter the information that could be adapted, have shown the proof of concept that it is available, but need a champion on the other side to see it through.

Dr. Belknap asked the members to consider what recommendations ACET can make to CDC and HHS to improve electronic medical record (EMR) systems for overseas and domestic medical information tracking.

Dr. Chen supported ACET endorsing the effort that Dr. Lee described about moving the civil surgeon into the mix so that it moves faster.

Dr. Loeffler noted that based on the gaps, the care that is being given to these individuals seems suboptimal. Systems-wise, she would think that having a mechanism for ACET to help DGMQ by identifying the gaps so their teams could pick the things they could work on easily versus the larger more aspirational ideas.

Dr. Lee indicated that DGMQ has been working closely with the NTCA as well on little things that need to be fixed. There also are some bigger issues and the DGMQ would be happy to receive any comments and continue to move forward where they can.

Dr. Loeffler asked whether there is a user guide that someone who is new at this could access. For example, the person she collaborates with every week on the Refugee & Immigration Alliance who are coming into her county seems to know everything. However, she is going on maternity leave.

Dr. Lee indicated that the user guide for the system could be provided to Dr. Loeffler and ACET.

In terms of who is or is not in the system from a bigger group population, they can share her slides. There is a lot of piecemealing occurring. Primarily immigrants and refugees should be in the system. They hope everyone is in the system based on paper, but they are still working through that. She indicated that she would be happy to email Dr. Loeffler directly as well.

Dr. Belknap asked whether Dr. Lee knows at a high level what the amount of loss to follow-up or inability to contact and complete the initial evaluation is in terms of the contact information not being adequate to make that connection.

Dr. Lee indicated that while she did not have that information offhand, it does go into the National Tuberculosis Indicators Project (NTIP) as well. They can try to get that information.

Given how interlinked EHRs are becoming in the US, particularly with Epic and PowerShare, Dr. Stout asked whether there is any consideration of making some of the data in EDN interface with any of the common US EHRs. It would be very attractive for providers when they see patients like this to have access to those records to be able to take care of them, recognizing that this is a huge task.

Dr. Lee emphasized that this is an incredibly huge task. They have been "picking the scab" currently with the vaccine records for refugees in terms of getting those into immunization registries, learning what it means to be interoperable, having all the data be translated to national standards, and then working through an immunization gateway within NCIRD. The EHR highway is looking like one of the directions they are moving toward as well, with the hope that early in 2023 they will start connecting DGMQ's records to states. This is currently being done through the Public Health Information Network Messaging System (PHINMS) transport system, which is older, and Data Downloads. They know they need something common and standard, which is having the information in Health Level Seven (HL7) and then having it go through a transport mechanism like an Ivy Gateway. They would love to explore the opportunity to have the full records go into EHRs. Right now their immediate look is at the Ivy Gateway, which is an interesting process.

Dr. Loeffler asked whether the DGMQ posts or shares the health metrics of the groups of recent refugees, especially Afghans and U4U population.

Dr. Lee indicated that these are available for Afghans who are going through the immigration process. The U4U is outside of scope for the DGMQ, so they are not requiring medicals from her team in terms of TB. If they go outside the pathway, it is somewhat tricky. The important thing is that it emphasizes the Phase 1 of the Afghan resettlement. The other federal partners and CDC as well were able to learn a lot from Phase 1, so all of the screening is happening overseas and movement is done by the Department of State in an organized way, so those records should be in the system.

TB Diagnostics in the US Market

Jennifer L. Rakeman, PhD
Senior Director, Medical Affairs
Public Health Programs, Cepheid

Dr. Rakeman provided a brief background of Cepheid and Cepheid technology, described the Cepheid TB Test Menu, provided further details about 3 tests that are available on the Cepheid

platform (Xpert® MTB/RIF*, Xpert® MTB/RIF^ Ultra, and Xpert® MTB/XDR^),[20] and discussed how to get some of those tests into the US Market. In terms of background, Cepheid is very much a global company. They have a presence around the globe in more than 100 countries; manufacturing sites in the US, Sweden, and India; office locations in 17 countries around the world; and Headquarters in Sunnyvale, California.

In terms of getting tests set up, which generally is very easy for the user. The complexity happens within the cartridge itself. The instrument is very easy to use and can run different types of tests simultaneously. For TB testing, the sample preparation is slightly more complicated because specimens are added to a sample reagent. This is important because the sample reagent inactivates TB, so it makes the rest of the testing safe and able to be done on the bench versus in a Biosafety Level (BSL)-3 setting. The inactivated sample is then added to the cartridge, the cartridge goes into the instrument, the instrument can read the QR code on the front of the cartridge, and uses that to determine what assay file to run to test appropriately for that particular assay. The cartridge has a number of chambers inside that hold reagents when the cartridge is manufactured. There is a valve body and a plunger that moves up and down based on the assay definition file, which moves liquid through the different chambers. Nucleic acid extraction, sample preparation, all the steps to set up a polymerase chain reaction (PCR), additions of primers and probes, and master mix happen within the cartridge in those different chambers. The reaction mix for the PCR reaction goes out into a think reaction tube that sticks out of the back of the cartridge. When it goes into the module, that tube goes between plates that allow for rapid heating and cooling to go through the PCR reaction, which is why the PCR reactions can be relatively fast. The instruments come in a variety of sizes from 2 modules up to 16 modules. There also are floor models that can hold up to 48 and 80 modules. All of the modules are exactly the same and can run any of the tests on the Cepheid menu.

A variety of tests are on the Cepheid menu that are available now or will be launched in the future in the US under IVD, as shown in the following table:

	Respiratory	HAI & Other Infectious Diseases	Blood Virology, Women's Health, & Sexual Health	TB & Emerging Infectious Diseases	Oncology & Human Genetics
23 Tests Available Now*	Xpress CoV-2/Flu/RSV *plus*#†	MRSA NxG	Xpress Group B Strep	MTB/RIF	BCR-ABL Ultra
	Xpress CoV-2 *plus*#†	SA Nasal Complete	Group B Strep LB XC	Ebola†	Thrombophilia (FII & FV)
	Xpress Flu/RSV#	MRSA/SA Blood Culture	Chlamydia/Gonorrhea		
	Xpress Strep A#	MRSA/SA SSTI	Trichomonas		
	Xpress Flu#	Carba-R	Xpress Multiplex Vaginal Panel		
		Norovirus			
		Enterovirus			
		C. difficile			
		vanA			
6 Launches 2022–24^	Respiratory Panel‡^^	GI Panel‡**	Xpress Chlamydia/Gonorrhea	Monkeypox	Insight Breast Cancer
				Hemorrhagic Fever Panel	
11 Launches 2025+^		Carba-R XC‡	Hepatitis C Fingerstick	Tropical Fever Panel	ALL (BCR-ABL p190)
		Candida auris			AML (NPM1 Mutation)
		Meningitis/Encephalitis Panel			AML (IDH1/2)
					AML (FLT3-ITD)
					AML (FLT3-TKD)
					APL (PML-RARA)

* US-IVD. *In Vitro* Diagnostic Medical Device. Visit cepheid.com for more details.
^ Products in development. Not for use in diagnostic procedures. Not reviewed by any regulatory body. Products in development are subject to change and target menu is subject to revision.
# *In vitro* diagnostic device for use in Moderate Complexity or CLIA waived settings.
† These tests have not been FDA cleared or approved. These tests have been authorized by FDA under an EUA for use by authorized laboratories; Xpert Xpress CoV-2 *plus* has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. Xpert Xpress CoV-2/Flu/RSV *plus* has been authorized only for the simultaneous qualitative detection and differentiation of nucleic acids from SARS-CoV-2, Influenza A, Influenza B, and respiratory syncytial virus (RSV), and not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
‡ Run on GeneXpert® systems equipped with 10-color modules.
** **GI Panel**: *Campylobacter*, STEC (Shiga toxin 1), STEC (Shiga toxin 2), *Salmonella*, *Shigella*/EIEC, *Yersinia enterocolitica*, *Vibrio parahaemolyticus*, *Vibrio cholerae*, *Giardia lamblia*, *Cryptosporidium*, Norovirus
^^ **Respiratory Panel**: Adenovirus, Coronavirus, SARS-CoV-2, Human Metapneumovirus, Rhinovirus/Enterovirus, Parainfluenza, Flu A, H1N1 2009, Flu B, RSV, *Bordetella pertussis*, *Bordetella parapertussis*, *Mycoplasma pneumoniae*, *Chlamydophila pneumoniae*
AML: acute myeloid leukemia, **APL**: acute promyelocytic leukemia, **CNS**: central nervous system, **GI**: gastrointestinal, **HAI**: healthcare-associated infections, **LB**: Lim Broth, **MTB**: *Mycobacterium tuberculosis*, **NG**: Neisseria gonorrhoeae, **RIF**: rifampin, **SA**: *Staphylococcus aureus*, **SSTI**: skin and soft tissue, **XC**: extended coverage

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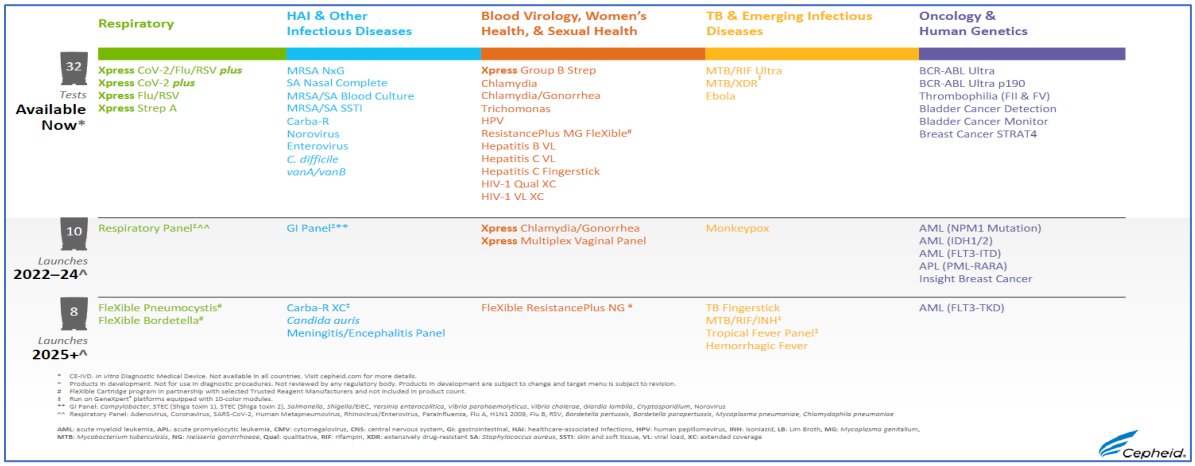
[20] *US-IVD. In Vitro Diagnostic Medical Device; ^CE-IVD. In Vitro Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

This table shows the CE-IVD tests available, or the additional tests available outside the US on this menu that are available now and will be launched in the future:



	Respiratory	HAI & Other Infectious Diseases	Blood Virology, Women's Health, & Sexual Health	TB & Emerging Infectious Diseases	Oncology & Human Genetics
32 Tests Available Now*	Xpress CoV-2/Flu/RSV *plus* Xpress CoV-2 *plus* Xpress Flu/RSV Xpress Strep A	MRSA NxG SA Nasal Complete MRSA/SA Blood Culture MRSA/SA SSTI Carba-R Norovirus Enterovirus *C. difficile* *vanA/vanB*	Xpress Group B Strep Chlamydia Chlamydia/Gonorrhea Trichomonas HPV ResistancePlus MG FleXible# Hepatitis B VL Hepatitis C VL Hepatitis C Fingerstick HIV-1 Qual XC HIV-1 VL XC	MTB/RIF Ultra MTB/XDR‡ Ebola	BCR-ABL Ultra BCR-ABL Ultra p190 Thrombophilia (FII & FV) Bladder Cancer Detection Bladder Cancer Monitor Breast Cancer STRAT4
10 Launches 2022–24^	Respiratory Panel‡^^	GI Panel‡**	Xpress Chlamydia/Gonorrhea Xpress Multiplex Vaginal Panel	Monkeypox	AML (NPM1 Mutation) AML (IDH1/2) AML (FLT3-ITD) APL (PML-RARA) Insight Breast Cancer
8 Launches 2025+^	FleXible Pneumocystis# FleXible Bordetella#	Carba-R XC‡ *Candida auris* Meningitis/Encephalitis Panel	FleXible ResistancePlus NG #	TB Fingerstick MTB/RIF/INH‡ Tropical Fever Panel‡ Hemorrhagic Fever	AML (FLT3-TKD)

* CE-IVD, *in Vitro* Diagnostic Medical Device. Not available in all countries. Visit cepheid.com for more details.
^ Products in development. Not for use in diagnostic procedures. Not reviewed by any regulatory body. Products in development are subject to change and target menu is subject to revision.
# FleXible Cartridge program in partnership with selected Trusted Reagent Manufacturers and not included in product count.
‡ Run on GeneXpert® platforms equipped with 10-color modules.
** GI Panel: *Campylobacter*, STEC (Shiga toxin 1), STEC (Shiga toxin 2), *Salmonella*, *Shigella*/EIEC, *Yersinia enterocolitica*, *Vibrio parahaemolyticus*, *Vibrio cholerae*, *Giardia lamblia*, *Cryptosporidium*, Norovirus
^^ Respiratory Panel: Adenovirus, Coronavirus, SARS-CoV-2, Human Metapneumovirus, Rhinovirus/Enterovirus, Parainfluenza, Flu A, H1N1 2009, Flu B, RSV, *Bordetella pertussis*, *Bordetella parapertussis*, *Mycoplasma pneumoniae*, *Chlamydophila pneumoniae*

AML: acute myeloid leukemia, **APL:** acute promyelocytic leukemia, **CMV:** cytomegalovirus, **CNS:** central nervous system, **GI:** gastrointestinal, **HAI:** healthcare-associated infections, **HPV:** human papillomavirus, **INH:** isoniazid, **LB:** Lim Broth, **MG:** *Mycoplasma genitalium*, **MTB:** *Mycobacterium tuberculosis*, **NG:** *Neisseria gonorrhoeae*, **Qual:** qualitative, **RIF:** rifampin, **XDR:** extensively drug-resistant **SA:** *Staphylococcus aureus*, **SSTI:** skin and soft tissue, **VL:** viral load, **XC:** extended coverage

Cepheid.

Accurate diagnosis, reduced diagnostic delay, appropriate treatment, and linking more patients to care are needed to address TB. The different types of TB include susceptible TB (DS-TB), rifampan-resistant TB (RR-TB), multi-drug resistant TB (MDR-TB) that are resistant to isoniazid and rifampin, pre-XDR-TB that are resistant to isoniazid and/or rifampin plus fluoroquinolone, and XDR-TB that have additional resistance. Continued innovations in TB diagnostics have occurred across time in Cepheid. In 2010, the initial MTB/RIF test that is currently available in the US was launched. At this time, the instruments went from a 4-color to a 6-color. Additional colors essentially mean that there are additional numbers of targets that can be detected in the test. In 2017, the MTB/RIF Ultra was launched. That test is somewhat faster than the MTB/RIF, with results in less than 80 minutes versus 110 minutes. It introduced the ability use melt curve analysis in addition to real-time PCR analysis within the cartridge. In 2020, the MTB/XTR cartridge was launched, which went from a 6-color instrument to 10-color that allows for more flexibility and ability to detect targets within the assay.

The Xpert® MTB/RIF target is the *rpoB* gene. There are 5 molecular beacons that detect mutations within the rifampin-resistance determining region (RRDR). Bringing this test onboard helps to decrease the amount of time it takes for a patient to get appropriate treatment with regard to RIF. A negative Xpert® MTB/RIF test can help get patients out of isolation and a positive test allows patients to be diagnosed and potentially start appropriate treatment on the same day or within a few days of initial sample collection versus being reliant on culture and phenotypic analysis, which can take many more weeks. In terms of the performance of this test versus culture, the overall sensitivity and specificity of MTB/RIF tests are very good. In smear positive, the sensitivity and specificity are better than in smear negative. That is related to the fact that a smear positive sample generally has a higher bacillary load than a smear negative. In terms of detecting drug susceptibility for RIF, the sensitivity and specificity are very good. In terms of the negative predictive value of the test, 1 negative result means that there is a 99.7% chance that the patient will be culture negative and 2 negative results from 2 different specimens are 100% correlate with a negative culture. A negative test is very important because it can help get patients out of isolation and keep them from getting treatment for a long time that is not helping because they do not actually have TB.

The Xpert® MTB/RIF Ultra includes additional RIF resistance determining mutations and additional sensitivity. Like the Xpert® MTB/RIF, the Xpert® MTB/RIF Ultra test's intended use is to be run on unprocessed sputum samples or concentrated sediments prepared from induced or expectorated sputum samples. Both tests run on the same systems; have similar kit configurations; the process for preparing specimens, loading them into the cartridge, and putting in into the instrument are all the same; and kit storage and stability are the same. A laboratory that can run an MTB/RIF can run an MTB/RIF Ultra. The tests are different in multiple areas. There are 5 probes in MTB/RIF in *rpoB*. In MTB/RIF Ultra, there are 4 *rpoB* probes and 2 multi-copy targets, *IS1081 & IS6110*, with 2 probes to detect that. The PCR chamber size went from a 25µL to 50µL tube, with the additional volume helping to increase the sensitivity. The limit of detection (LoD) is about 10-fold better on the RIF/Ultra. The detection methods are somewhat different, with some advances in the technology of the molecular methods for the MTB/RIF Ultra test. The MTB/RIF Ultra test is faster, which can mean that there can be more turnaround and throughput on an instrument as well as getting faster results to patients. The impact of the MTB/RIF Ultra test is similar in that it can help get patients out of isolation sooner and/or get them on appropriate treatment sooner.

In terms of interpretation of the Xpert® MTB/RIF Ultra, there are both *rpoB* targets and insertion sequence targets that are in multi-copy. Assuming that the cartridge passes its initial control, which is the Probe Check Control (PCC), the test looks at the insertion sequence results first. Those are multi-copy targets, so they are somewhat more sensitive. If those targets are positive, the algorithm will look at the *rpoB* targets. If only 1 *rpoB* target is detected, that probably means that there is a very low concentration of TB in the specimen. The result is then reported out at MTB trace detected and no RIF resistance information is given. This just means that while it is positive, it is very low positive. If multiple *rpoB* targets are detected, the result is reported out as MTB detected with a semi-quantitative result. Then melt curve analysis is used to determine RIF resistance. Now to go through some performance data.

The first evaluation of the MTB/RIF Ultra[21] showed that as predicted, the LoD is about 10-fold better with the MTB/RIF Ultra versus the MTB/RIF. The MTB/RIF Ultra test performs well. There is an increase in sensitivity of 13%, particularly in smear-negative specimens with the MTB/RIF Ultra versus the MTB/RIF. That relates back to the increase in sensitivity for that test in general and has to do with the trace result. Similarly, the MTB/RIF Ultra performs better than the MTB/RIF in a TB and HIV endemic setting.[22] The key findings in this study were that MTB/RIF Ultra had lower LoD for TB compared to MTB/RIF, MTB/RIF Ultra has a higher sensitivity in HIV-infected persons than MTB/RIF, MTB/RIF Ultra was 6% more sensitive than MTB/RIF in smear-negative samples, MTB/RIF Ultra had a lower MTB Trace Detected readout in HIV uninfected persons of 2.7% compared to 9.6% in HIV infected persons, and a minority of samples comprised MTB Trace Detected readout, which may represent a false-positive signal in those with previous TB. The added insertion sequence targets that are multi-copy are driving the increase in sensitivity of the test. A systematic review showed essentially the same data.[23]

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[21] Chakravorty S, et al,2017. The New Xpert MTB/RIF Ultra: Improving Detection of Mycobacterium tuberculosis and Resistance to Rifampin in an Assay Suitable for Point-of-Care Testing.

[22] Esmail A, et al. Comparison of Xpert MTB/RIF (G4) and Xpert Ultra, including trace readouts, for the diagnosis of pulmonary tuberculosis in a TB and HIV endemic setting. International Journal of Infectious Diseases, 2020.

[23] Zifodya JS, et al. Xpert Ultra versus Xpert MTB/RIF for pulmonary tuberculosis and rifampicin resistance in adults with presumptive pulmonary tuberculosis. Cochrane Database Syst Rev. 2021 Feb 22;2:CD009593. https://pubmed.ncbi.nlm.nih.gov/33616229/

The Xpert® MTB/XDR test is meant as a reflex test after MTB is detected, so it adds information on resistance to 6 additional drugs (e.g., isoniazid, ethionamide, fluoroquinolones, amikacin, kanamycin, and capreomycin). This is intended to be a reflex text that is run on unprocessed or concentrated sputum samples, or it can be run on positive Mycobacteria Growth Indicator Tube™ (MGIT™) culture from sputum samples that previously have been tested and determined to be positive for MTB. This test takes about 90 minutes, so it is somewhat slower than the Ultra and a little bit faster than the MTB/RIF. It runs on the same instruments and requires a 10-color system, which are now being introduced in the US. This test was endorsed by the World Health Organization (WHO) in February 2021. In terms of the diagnostic pathway, if the Xpert® MTB/RIF Ultra is positive, regardless of whether the specimen was detected to be RIF resistant or susceptible, the test would reflex to an Xpert® MTB/XDR. That helps cover mono-INH, which there is plenty of in the US, as well as other MDR-TB strains that are RIF sensitive. Within the same day, running these 2 tests in tandem can provide drug resistance information for 7 drugs. The MTB/XDR also can be used on a specimen that was negative initially but then grew in MGIT™ culture. The positive MGIT™ can be run on the test in order to get drug susceptibility information that same day rather than waiting additional weeks to get a phenotypic drug susceptibility testing (DST) test result completed.

The LoD for the MTB/XDR test is closer to the range of the MTB/RIF LoD at around 136 CFU/mL for unprocessed sputum or 86 CFU/mL for sediment. The Ultra LoD is lower because of the additional multi-copy target numbers in that test. Regarding the clinical performance of the MTB/XDR test, retrospective specimens had high sensitivity and specificity. The one outlier was ethionamide sensitivity versus phenotypic DST. The reason for that is that the test is designed to detect only resistance based on *inhA* promoter mutations. Data from prospective specimens are very similar. Clinical performance in positive MGIT™ culture isolates is comparable to sputum and looks very good. For the most part across the board, there is concordance of the Xpert® MTB/XDR test with existing TB tests for detecting MTB, with a few outliers. Data from a paper on the performance of the MTB/XDR test[24] demonstrated equivalent LoD to MTB/RIF and showed good detection of mutations. In addition, there was detection of hetero-resistance at different percent mixes of resistant and susceptible strains.

With regard to getting into the US market, MTB/RIF is available in the US. However, the CE-IVD product is being discontinued in May 2023. The US IVD product will continue to be available in the US, China, Japan, and India. For the MTB/RIF Ultra and MTB/XDR tests, data are only available from outside the US. No US clinical trials have been performed on those tests to date. It is clear that there is a public health and clinical need for rapid molecular diagnostics to detect TB and resistance markers in patients, and to get the results as soon as possible to get patients appropriately treated. Relatively speaking, the incidence of TB is low in the US and the incidence of MDR TB and XDR TB is even lower. However, a clinical trial in the US would need to be very lengthy in order to get enough positives to have the data required by the FDA to bring the test to market as a US IVD test. This raises the following key questions in terms of potential creative ways to get beyond the barriers of conducting a clinical trial and obtaining sufficient data in the US for an FDA submission:

[24] Georghiou S. B, et al, Analytical performance of the Xpert MTB/XDRR assay for tuberculosis and expanded resistance detection, Diagnostic Microbiology & Infectious Disease, 2021. https://doi.org/10.1016/j.diagmicrobio.2021.115397

1. Could an FDA approval pathway that enables use of ex-US performance data be accessed?
2. Could an accelerated review model for assessment be utilized, such as an Independent Test Assessment Program model?
3. Could MTB/RIF Ultra and/or MTB/XDR be made available as a diagnostic test to address public health need in public health laboratories following a model similar to the CDC Laboratory Response Network (LRN)?

ACET Discussion

For this discussion, ACET was asked to consider the following questions:

1. What are recommendations to HHS on addressing the barriers presented by Cepheid?

Dr. Shereen Katrak asked about the possibility of MTB/RIF false positivity in the setting of nontuberculous mycobacteria (NTM). They have always found the test to be extremely specific; however, they have a new case in which it seems likely that an MTB/RIF test was falsely positive in the setting of mycobacterium avium complex (MAC). She is happy to give more details, but notably, only a single Xpert® MTB/RIF was positive with Ct values of 29.9-32.8 out of >6 specimens, including BAL. The reports they have seen of false positive MTB PCRs in the setting of NTMs mostly predate use of Xpert®.

Dr. Rakeman emphasized that the specificity of that test is very high, so there have not been very many false positives. She would be happy to discuss that particular case offline to go over what may have happened. That is a great question for Cepheid Customer Service, because those types of questions would then get shunted over to the Cepheid Medical & Scientific Affairs Team. They have not seen reports of false positives with NTM in general.

Dr. Horne requested a ballpark estimate as to the number of participants that would be needed in a clinical trial in the US for FDA submission.

Dr. Rakeman indicated that she would have to request this information from the biostatistics team. Given the low incidence, the FDA likes to see at least some of the clinical trial data based in the US with US patients and have it be prospective data. It would take a fair amount of time in order to get enough positives to meet that requirement.

Dr. Horne asked whether a clinical trial would have to be performed in suspects or if for the XDR tests, it could include patients known to have drug resistance and then see the performance in that sample compared to patients who are known to not have drug resistance.

Dr. Rakeman indicated that they would take this type of question to the FDA through a pre-submission process to get input on how many of those types of patients would be acceptable in a clinical trial. That test is meant to be used as a reflex, so the question would pertain to whether they could start with an unknown patient versus a patient who already is known to have drug resistant TB.

Dr. Loeffler said she would start with the stance of getting to “yes” and figuring out what it takes between FDA, Cepheid, teams of people who recruit patients, and all of the international trials being conducted using US institutions and US clinicians. She also stressed that high-quality sputum is required for positive culture and a nucleic-acid amplification test (NAAT).

Noting that an FDA liaison was present, Dr. Chen asked whether a full clinical trial would be needed in the US to compare 2 different versions of a diagnostic test or if it could be verified in a US study in a smaller set of programmatic cases and within stored specimens.

Dr. Elkins (FDA) indicated that neither she nor any of her colleagues could comment at all on an example that involves an individual manufacturer's potential submission. In this kind of case, generalizing to all in vitro diagnostics is also not useful. As Dr. Rakeman mentioned, this is the kind of conversation that would occur between the sponsor and the FDA in a pre-submission discussion based on available data, goals, stated uses, et cetera. They cannot be generalized and discussed in this type of setting.

Dr. Chen pointed out that as an advisory committee, the ACET is looking for ways to identify high need areas for the domestic audience. She asked how the ACET could appropriately advocate for or be involved in prioritizing movement for diagnostics of concern with the FDA.

Dr. Elkins said it is important to remember that discussions with the FDA begin with the sponsor who owns the technology and intellectual property, has the best view of what their product or diagnostic is most appropriate for, and so forth. In the US capitalistic system, sponsors "drive the bus" for starting those conversations. She supposed that could be described as ACET advocating to the sponsors, but the FDA responds directly to the data submitted by sponsors. She explained that her area of expertise and regulatory authorities are in biological, vaccine, and blood products, so she is not as up to speed with the exact process used for the diagnostics side of FDA, which is handled by a different center. In general, sponsors come to the FDA before submitting an actual application and frame a number of questions, provide pertinent data or information that they have on hand, and that informs the discussion. The FDA then responds to the questions as best they can, depending upon what the sponsor has submitted to them. A sponsor may ask for guidance on future activities. A common response may be that it is too soon to be able to have a good discussion, but it depends upon what a sponsor already has available at that point in the conversation.

Dr. Belknap expressed appreciation for Dr. Elkins helping the ACET understand the limitations on being able to comment on a specific product and/or manufacturing. The ACET's interest is in trying to figure out how to bridge the gap between what the FDA is able/allowed to do, the sponsor, and the ACET's representation of patients, providers, and communities. He thought what they were hearing, and what he would support as well from a program perspective, was that if there are data needs that a partnership with Cepheid could help to generate, they need to know what data would be needed to help move this forward. He also wondered if it has to be different patients or if testing the technology, if specimens could be collected (stored or otherwise) from the same patient with known resistance and tested in different lots, machines, et cetera and validate it in the US in multiple laboratories.

Dr. Narita noted that the definition of XDR-TB changed last year and new drugs are on the horizon, so he wondered whether there is anything in the pipeline to address this.

Dr. Rakeman indicated that the XDR cartridge was released in 2020, so it is already 3 years old. It was several years in the making to even get to that point. An issue with any sort of drug resistant type of test is that once the test is launched, it already is out of date. Cepheid is considering how that test can be updated continually to make sure that it continues to work and brings in new drugs into the test. Questions about how to pull specimens and patients into trials would have to be taken to the FDA, given that this is not the traditional way clinical trials are conducted. Regarding what would be needed in terms of other specimen types, other drugs, et

cetera, there are existing Ultra and XDR tests that may not be the best fit for the US. Her question would regard the wish list and how to quickly get to something closer to the “perfect” test, considering the timeline to develop and perform the clinical trial work to get the test registered in the US.

Dr. Stout said that as he was thinking about the presentation and comments, it occurred to him that in the US market, the marginal difference in terms of diagnostic utility between the Xpert® and the Xpert® Ultra is probably fairly small in terms of the number of people who will be diagnosed quicker. Looking at Cepheid’s marketing strategy, the US market seems like a very small share. Right now, the company is basically having to produce a different product and will keep the discontinued product going in the US market. If this plays out well, somebody will conduct the research study necessary for the FDA to approve the Ultra in the US. That would be great, but he wondered whether there are plans to continue to produce the RIF indefinitely for US use if that does not happen.

Dr. Rakeman indicated that the plan is to ensure that there is a test available in the US. The MTB/RIF would not be discontinued in the US unless there is something available to replace that.

Dr. Ahmed emphasized that children should not be forgotten. While there are not a lot of cases among children in the US, in terms of returns because they are largely smear negative, a lot more information is acquired percent-wise proportionally for children than for adults. That would be on her wish list because if they send a sample to the state for Xpert® because it is not FDA cleared, that goes to Florida, so the results get reported out from Florida as opposed to North Carolina, which causes delays.

Dr. Belknap said he thought that this may have to do with the fact that the Florida laboratory validates the results internally.

Dr. Loeffler noted that ACET has talked previously about legislative change that would allow for the unidirectional flow of requests to FDA to be modified, which may be required in this case. She expressed appreciation for the reminder of the statutes that require the process of the sponsor taking a product to the FDA. While they do not have to talk about money or capitalism, if there truly is a monetary barrier to an entity taking something to the US market, perhaps legislation could be changed that could allow for the ACET to be enlisted by an entity to be their advocate. That is, could the ACET be a part of taking something to the FDA and being a part of creative thinking that would ask these questions. She wondered what Australia, New Zealand, and Western European countries are doing.

Dr. Belknap reminded everyone that the ACET’s role is to provide advice to the CDC and the HHS. In terms of partners and liaisons, the NTCA is probably the better partner for what Dr. Loeffler described in terms of working with Cepheid on the wish list and trying to move this forward, which is probably outside the scope of the ACET. However, the ACET’s job as he sees it is to raise these questions and try to figure out what might be paths forward. These are not new questions.

In terms of what other countries are doing, Dr. Rakeman indicated that regulatory registration outside of the US is very complicated and she is not the expert in that. However, many of those countries are either able to use tests that have CE-IVD or they have their own in-country registration. European countries are using an CE-IVD product and New Zealand and Australia are able to use the CE-IVD mark to register tests in those countries as well.

Regarding a question about the cost difference in general of the MTB/RIF versus MTB/RIF Ultra cartridge in the US, Dr. Rakeman indicated that this would be determined as the test was being developed and moving through market. She would assume that the pricing would be similar to other tests that are as similarly complicated as the Ultra test.

Dr. Liu asked whether the same instrument used for MTB/RIF can be used for the MTB/XDR as well, given that it has more channels now.

Dr. Chen's wish list would be the improved performance of the Ultra test but minimum H, R, FQ test that will help expand new DS-TB regimens. She also wondered whether there other disease advantages to laboratories investing in the 10-color machines in anticipation of someday having XDR cartridges.

Dr. Rakeman indicated that the MTB/XDR requires a 10-color module. One of the barriers is that the 10-color module just received FDA approval for the US, so it just launched in the US the previous week. There will be a period of time during which the modules will start to be swapped with different customers across the country. It is the same instrument, but each individual module can be swapped. Theoretically, an instrument could be running a 6-color module next to a 10-color module. A test that requires 10 colors could be run only in the 10-color module, but a 6-color test could be run in a 10-color module. Moving forward, development of tests in the pipeline that are planned to launch in the US will require the 10-color modules. The goal is eventually to have all of the modules switched over to 10-color.

Dr. Loeffler commented that some emerging data suggest improved sensitivity for Ultra vs MTB/RIF for pediatrics. From impending posting of Drug Resistant Guide, among 213 pediatric patients in Kampala, Uganda, Xpert Ultra (not yet available in the US) had 92% sensitivity for microbiologically-confirmed TB among smear-positive individuals and 40% among those who were smear negative. She also asked for email follow-up on other specimens.

In terms of email follow-up for other specimens, Dr. Rakeman indicated that the quick answer is that the number of specimens available is very small, even to be able to do an in-laboratory validation for some of those. That is a challenge, so the start will be with sputum. The potential to add additional specimen types on-label will go back to the FDA in the pre-submission type questions and availability of enough specimens to get enough data for that to be on-label via FDA.

CDC Support for TB Screening in the Uniting for Ukraine Response

Terence Chorba, MD, DSc, FACP, FIDSA
Chief, Field Services Branch
Division of TB Elimination
National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

Dr. Chorba described the United for Ukraine (U4U) Program. On May 21, 2022, President Biden signed into law emergency supplemental appropriations that included funds for medical support, screening, and other public health activities related to populations displaced from Ukraine. These appropriations included CDC funding of $54,000,000 for medical support, screening, and other public health activities related to populations displaced from Ukraine. The program is a

pathway for at least 100,000 Ukrainian citizens who have fled their country because of Russian aggression in the past year to come to the US and stay temporarily for a 2-year period of parole. Ukrainians participating in the program must meet specific health requirements, including vaccinations and TB testing.

As of November 29, 2022, talking points prepared at the DHS have included the following figures:

- Since the launch of U4U on April 25, 2022, USCIS has received 175,000 supporter applications (Form I-134, Declaration of Financial Support) that have been filed for consideration.

- Once a supporter has been approved, the Ukrainian beneficiary may apply for travel authorization to the US. To date, approximately 123,000 beneficiaries have been approved for travel.

- To date, almost 88,000 Ukrainian beneficiaries have been paroled into the US through the U4U program.

In the U4U program, parolees are required to undergo testing with a TB-specific IGRA and subsequent TB diagnostic studies as needed. Parolees are also required to be vaccinated for several other infections (measles, polio, COVID). The applicants for parole are instructed to seek medical care and to record the completion of health requirements for vaccinations and TB testing by submitting a “Vaccination Attestation Form.” On July 14, 2022, the US DHS extended the time period for completing the TB requirement from 14 days to 90 days. To support this effort, in August 2022, DTBE awarded nearly $8 million in supplemental funding under CDC-RFA-PS20-2001 in FY22 to currently funded states, cities, and territories, including their public health laboratories, for screening, evaluation, and treatment of LTBI and TB disease among Ukrainians paroled into the US. These dollars were emergency supplement appropriation funds made available for assistance for the U4U program for the fiscal year that ended in September 2022. The funds were in addition to and separate from the funds that CDC had previously awarded to the 61 jurisdictions (e.g., 50 states, 9 large cities, and 2 Atlantic territories) that fall under that cooperative agreement on January 1, 2022. To allocate funding in as efficient a manner as possible, CDC/DTBE developed a funding formula to distribute the funds to all 61 recipients that was based on the number of sponsors and TB morbidity and mortality for each state.

CDC will award an additional $19.4 million that will be announced in FY23 as a second supplement to TB control programs in support of U4U. That approach will allow grantees to use these supplemental funds to purchase medications and pursue strategies and activities within the 61 project areas that fall under that same cooperative agreement. The goals of the U4U supplemental funding are to: 1) expand ongoing TB prevention, control, and laboratory services for addressing the care of U4U parolees; 2) prevent transmission of MTB; 3) prevent the progression of LTBI to TB disease; and 4) ensure rapid and reliable TB laboratory services. In terms of evaluation, the only quantitative data systematically gathered across jurisdictions that could reflect U4U activity would be: 1) aggregate numbers of TB cases in the National Tuberculosis Surveillance System (NTSS) among persons born in the Ukraine; and 2) Aggregate Reports for TB Program Evaluation (ARPE) data being gathered specifically for U4U testing. Because the IGRA testing and TB screening that will occur for the U4U program are not happening beyond the US borders, parolee data will not be entered into the EDN system.

In terms of how the first $8 million U4U funds were allocated in FY22, monies were accorded as programmatic funds (90%; $7.2 million) and laboratory funds (10%; $0.8 million). For programmatic funds, the funding formula was based on estimated numbers of Ukrainian arrivals (70%) by zip code of residence of the sponsors, and on an NTSS 3-year pre-COVID average (2017-2019) of TB morbidity (30%) for each jurisdiction. Each program received a $10,000 base in programmatic funding. Laboratory funds were allocated to the 58 laboratory recipients of cooperative agreement funds by a parallel funding formula. Each program received $7,500 base laboratory funding. For the remaining $19.4 million to be allocated in FY23, monies will be accorded as programmatic funds (90%; $17,460,000) and laboratory funds (10%; $1,940,000). For the programmatic funds, the funding formula will be based on estimated numbers of Ukrainian arrivals by zip code of residence of the sponsors. Each program will receive $25,000 in base programmatic funding. Laboratory funds will be allocated to the 58 laboratory recipients of cooperative agreement funds by a parallel funding formula. Each program will receive $10,000 in base laboratory funding. DTBE has produced a webpage that includes the information on the NOFO for FY23.

Based on previous experience, data from the WHO indicate prevalence rates of MDR-TB or rifampin-resistant TB among persons with culture-confirmed TB in Ukraine to be about 33%. Data from CDC indicate prevalence rates of MDR-TB or rifampin-resistant TB among Ukrainians with culture-confirmed TB in the US to be about 13%. When Ukrainian parolees are being examined for possible TB disease, microbiological testing should include rapid molecular methods for detecting drug resistance. TB disease must be excluded before any regimen for treating LTBI is started.

DTBE also has been involved in supporting communications and education aspects of the program and has developed an online toolkit[25] for health departments that incudes ready-made materials health departments can use or adapt to reach Ukrainian arrivals, their sponsors, and private and community healthcare providers. Resources currently include patient education resources in Ukrainian and Russian, links to U4U resources from key partners, information for TB programs, and information for arrivals and sponsors. The toolkit will be updated with additional resources and information as needed and requested. A contract also will be awarded by the end of December 2022 for additional planned communication and outreach support. The purpose of this award is to develop, design, and implement TB communications and education communications and outreach efforts for arrivals from Ukraine in 3 to 4 select jurisdictions receiving a high number of Ukrainian arrivals. The project objectives are to: 1) encourage and facilitate testing and treatment for LTBI and TB disease among people arriving from Ukraine through community outreach and education; and 2) develop and disseminate culturally- and linguistically-appropriate TB communication and education materials of health departments, healthcare providers, and community organizations to serve people arriving from Ukraine and their US-based supporters.

On October 12, 2022, the US DHS announced a new process allowing Venezuelan nationals and their immediate family members to come to the US. No emergency supplemental appropriations have been allotted to cover medical support, screening, and other public health activities related to populations displaced from Venezuela, although the medical requirements and schedules are the same as in the U4U program. The process offers a way for Venezuelan

[25] https://www.cdc.gov/tb/programs/unitingforukraine.htm

nationals outside of the US and lacking US entry documents to be considered, on a case-by-case basis, for advance authorization to travel to the US and a temporary period of parole for up to 2 years. The program currently has a ceiling of 24,000 parolees, unlike the U4U program that has no absolute ceiling.

To summarize, under U4U, parolees are required to undergo IGRA testing and subsequent TB diagnostic studies as needed. DTBE is administering approximately $27.4 million in TB-specific U4U support to the 61 PS20-2001-funded jurisdictions ($8 million in FY22 and $19.4 in FY 23), with 90% of this funding being distributed as programmatic funding and 10% as laboratory funding. The anticipated number of 100,000 U4U parolees has been surpassed. DTBE has been and will be engaged in development and updating of additional resources and information as needed and requested. A contract will be awarded for development, design, and implementation of TB and education communications and outreach efforts for arrivals from Ukraine. The anticipated number of 24,000 parolees in the Venezuelan humanitarian relief program has been surpassed as well. Although the TB screening requirements of that program are the same as those for U4U, no TB-specific funding has been made available to CDC to pass to programs or laboratories.

ACET Discussion

For this discussion, ACET was asked to consider the following questions:

1. *How can CDC use the second round of funding to further this project?*

Dr. Belknap asked whether there are any restrictions on the funds that are being made available to support infrastructure to support specific testing. For example, could a jurisdiction that is receiving and caring for these individuals have limited access to molecular testing, could the funds be used for boosting infrastructure to provide that knowing that it would help beyond just the Ukrainian arrivals.

Dr. Chorba responded that the funding must be used for the Ukrainian arrivals, but there is no follow-up on the expenditure of the funds in that regard. Specifically for laboratory funding, he deferred to Dr. LoBue.

Dr. LoBue added that more generally, DTBE understands that regardless of what jurisdictions are purchasing (e.g., additional laboratory services, medications, testing, personnel time, et cetera), it is impossible to predict exactly what will be needed. Therefore, DTBE's guidance was that it is better to purchase more and have excess than not to have enough. There are no restrictions on the populations among whom excess doses can be used. In particular, they emphasized that medication and testing materials should not be allowed to expire if they can be used on someone else who is not Ukrainian.

Dr. Belknap asked whether there is any possibility of an expansion of the funds so that they could be used for the Venezuelan arrivers as well, and who controls those decisions.

Dr. LoBue indicated that Congress controls that decision, given that they appropriate the funds. While a jurisdiction cannot say that they are going to create a program for Venezuelans, if they end up with excess capacity for the Ukrainians, the funds certainly can be used for that purpose.

CDC Recommendations for Use of Video Directly Observed Therapy During Tuberculosis Treatment in the United States

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Dr. Mangan shared the CDC recommendation for the use of video-supported directly observed therapy (vDOT) during TB treatment in the US. The current US clinical practice guidelines recommend DOT as the standard of care. This, combined with the increased use of vDOT in practice, especially during the pandemic, as well as published experience with vDOT and the results of the recent randomized trial in New York City (NYC) by CDC, supported the development of guidelines for vDOT. CDC/DTBE established an internal workgroup to create these guidelines. As a point of clarification, vDOT allows individuals undergoing TB treatment the opportunity to use video-enabled phones, tablets, or computers to remotely interact with health workers in real-time (synchronous) or through recorded (asynchronous) videos. CDC reviewed published evidence on vDOT compared with in-person DOT for TB treatment adherence, completion, and microbiologic resolution. The intent is to publish the guidelines as a policy note in the *MMWR* and provide supplemental information via the www.cdc.gov/tb webpage in the format of frequently asked questions.

The information Dr. Mangan shared reflects the efforts of the Writing Team representing the various branches across the DTBE. The Writing Team put forth a concerted effort to develop the guidelines in a timely manner. They began developing the protocol and proposal in March 2022. The literature search and data abstraction were conducted between May-July 2022. The Writing Team began drafting the guidance in June 2022 and had a version ready for external review in early September 2022. The draft Policy Note was sent out to reviewers in September and received comments back in October 2022. Edits were made and the drafted FAQs were expanded in response to comments. The updated Policy Note was sent to the DTBE leadership in November 2022 and was being presented to the ACET during this session for comments. The goal is to submit the Policy Note into clearance in December 2022 and hope to see it published by late Winter or early Spring of 2023.

Before the Writing Team's work got underway, the following 4 reviews that assessed technology interventions for TB treatment were identified:

- Truong CB, Tanni KA, Qian J. Video-Observed Therapy Versus Directly Observed Therapy in Patients With Tuberculosis. Am J Prev Med. 2022;62(3):450-458. doi:10.1016/j.amepre.2021.10.013

- Ridho A, Alfian SD, van Boven JFM, et al. Digital Health Technologies to Improve Medication Adherence and Treatment Outcomes in Patients With Tuberculosis: Systematic Review of Randomized Controlled Trials. J Med Internet Res. 2022;24(2):e33062. Published 2022 Feb 23. doi:10.2196/33062

- Ngwatu BK, Nsengiyumva NP, Oxlade O, et al. The impact of digital health technologies on tuberculosis treatment: a systematic review. Eur Respir J. 2018;51(1):1701596. Published 2018 Jan 11. doi:10.1183/13993003.01596-2017

- Alipanah N, Jarlsberg L, Miller C, et al. Adherence interventions and outcomes of tuberculosis treatment: A systematic review and meta-analysis of trials and observational studies. PLoS Med. 2018;15(7):e1002595. Published 2018 Jul 3. doi:10.1371/journal.pmed.1002595

Notably, 2 systematic studies published in 2018 identified the same studies and 2 more published in 2022 identified the same studies as those published in 2018. The primary focus of all 4 systematic reviews was medication adherence and 3 of the 4 also sought to assess the impact of technology on treatment completion and smear culture conversion. Looking at the most recent reviews from 2022, Ridho and colleagues combined vDOT, text reminders, and medication monitoring boxes for comparison with in-person DOT. The second review by Truong and colleagues focused solely on vDOT compared with in-person DOT and performed a meta-analysis to assess treatment adherence, treatment completion, and microbiologic resolution. This published meta-analysis was used as supporting evidence and the starting point for an updated literature review.

Turning to the methods used for guideline development, this table delineates the study eligibility criteria:

Study Eligibility

	Included	Excluded
Populations	• Studies involving persons of any age, any sex, and from any country with a diagnosis, or suspected diagnosis, of tuberculosis, including pulmonary disease, extrapulmonary disease, and drug resistant tuberculosis.	• Persons undergoing TB treatment while in an inpatient setting. • Persons who require anti-TB medications administered through injection, thereby making use of electronic or video DOT unworkable.
Interventions	• Studies in which the intervention of interest involved use of a videophone or video-enabled electronic device (e.g., mobile phones, tablets, computers) to conduct directly observed therapy.	• Use of SMS, MEMS Caps, electronic pill boxes, or sensors embedded into pills to monitor treatment adherence in lieu of in-person meetings.
Comparisons	• Studies in which the comparator was directly observed therapy conducted via in-person meetings in an outpatient or community setting.	• Self-administered therapy • Studies that lack a control or referent group will be excluded.
Setting	• Outpatient settings such as health department clinics, TB or DOT clinics, and community-based settings such as pharmacies, schools, workplaces, and patient's homes.	• In-patient • Institutional settings (e.g., Detention center, prisons) • Medically supervised residential setting (e.g., Rehabilitation center, nursing home)
Study Design	• Randomized controlled trials • Case-control studies • Prospective and retrospective cohort studies	• Case studies • Case reports

The primary outcome of interest included medication adherence. This can be defined as a dichotomous measure meaning that patients were considered adherent if they were observed taking >80% of prescribed doses or not, or as a continuous measure meaning that a proportion of observed doses were divided by total prescribed doses. Secondary outcomes included treatment completion and treatment outcome (e.g., microbiologic resolution as demonstrated by sputum smear conversion and/or improved radiology/imaging studies).

As noted, the systematic review and meta-analysis by Truong and colleagues became the jumping off point that was supplemented by studies published in late-2021 to mid-2022. The Writing Team mirrored the approach that was used by Truong et al. and the Community Preventive Services Task Force (CPSTF) to rate the quality of evidence and formulate the

recommendations. One departure from this approach was that the CPSTF specifies that only studies conducted in a World Bank-designated high-income country be included. Given the dearth of data, the criteria were expanded to include studies conducted in upper-middle income countries.

To summarize the Truong et al. systematic review and meta-analysis, 9 studies were included in the systematic review. It is important to note that the outcomes of interest were not consistently defined or reported across all studies. Therefore, the authors conducted a series of meta-analyses that included 4 studies for medication adherence, 3 studies for the proportion of doses observed, 3 studies for treatment completion, and 3 studies for microbiological resolution. Only 2 of the 9 studies examined LTBI treatment. Therefore, the focus of the Policy Note is on the treatment for TB disease.

Based on the inclusion criteria described earlier, 2 members of the Writing Team served as reviewers of articles collated through a literature review that was conducted with the assistance from CDC librarians. Reviewers screened article abstracts for exclusion criteria and then independently abstracted data from the retained articles. The updated literature review yielded 5 articles published after the meta-analysis by Truong and colleagues. As shown in the following table, 2 of the 5 articles were obtained as supporting evidence and 3 were excluded, 2 of which did not include a comparison group and 1 of which reported previously published data included in the meta-analysis by Truong:

The "New" Studies

Author	Perry ✓	Burzynski ✓	Doltu ☒	Kumwichar ☒	Peinado ☒
Journal	International Journal of Tuberculosis & Lung Disease	JAMA Network Open	Journal of Infection in Developing Countries	JMIR FORMATIVE RESEARCH	Revista Medica Herediana
Title of Manuscript	***Real-world implementation of video-observed therapy in an urban TB program in the United States***	***In-Person vs Electronic Directly Observed Therapy for Tuberculosis Treatment Adherence: A Randomized Noninferiority Trial***	***Short and long-term outcomes of video observed treatment in tuberculosis patients, the Republic of Moldova***	***Development of a Video-Observed Therapy System to Improve Monitoring of Tuberculosis Treatment in Thailand: Mixed-Methods Study***	***Tratamiento supervisado por video VDOT en pacientes con tuberculosis pulmonar de un Centro de Salud de Lima. Estudio piloto***
Published Year	2021	2022	2021	2021	2022
Country	USA	USA	Moldova	Thailand	Peru
Objective	To assess the reach and effectiveness of vDOT for TB treatment under routine conditions in Alameda County, CA	To determine whether electronic DOT can attain a level of treatment observation as favorable as in-person DOT	To compare adherence and short and long-term TB treatment outcomes for TB patients who experienced asynchronous Video Observed Treatment (aVOT) during an RCT vs. patients on in-person DOT in the RCT and those found in national TB register who were eligible for, but not enrolled in the RCT	The objectives of this study were to describe how the VOT system was designed and to identify potential system improvements.	To report the characteristics of the implementation process of the video supervised treatment (VST) of patients with pulmonary tuberculosis in a first level health care center of the Social Security in Peru
Study design	Prospective Observational Study	Randomized Controlled Trial - a 2 arm, 2-period crossover, noninferiority trial with initial randomization to electronic or in-person DOT at the time outpatient tuberculosis treatment began	Retrospective Cohort	Non-comparative Observational	Non-comparative Observational
NOTES	**Include**	**Include**	**Do not include.** *Adherence data was reported earlier and is reiterated*	**Do not include.** The manuscript focuses on describing the system used and procedures for patients. No comparison data to ipDOT	**Do not include.** No comparator group

As noted, the retained articles were reviewed with the same quality assessment tools used in the published meta-analysis. Specifically, the Revised Tool for Assessing Risk of Bias in Randomised Trials (RoB-2) was used. Looking at this table, the exclamation marks denote some concern was noted for the study by Ravenscroft et al. as this team did not provide information about the process used to conceal allocation during randomization. A concern also was noted with the study by Burzynski et al. as the authors reported deviations arose from the intended intervention, specifically in that participants broke randomization assignments and these deviations occurred more amongst participants randomized to the study arm undergoing vDOT first, followed by in-person DOT:

	Randomization Process	Deviation from intended interventions	Missing outcomes data	Measurement of the outcomes	Selection of reported result	Overall
Studies included in Published Meta-Analysis						
Ravenscroft (2020)	!*	+	+	+	+	!
Story (2019)	+	+	+	+	+	+
Guo (2020)	+	+	+	+	+	+
Study identified through Literature Search						
Burzynski (2022)	+	!**	+	+	+	!

+ Low risk of Bias
! Some concern

* The Study by Ravenscroft et al. did not provide information about allocation concealment process during randomization

**The study by Burzynski et al reported deviations arose from the intended intervention (participants broke randomization assignment and these deviations occurred more often among participants randomized to the study arm undergoing video DOT first, followed by in-person DOT

The Newcastle-Ottawa Scale (NOS) and AHRQ National Quality Standards (NQS) were used to assess bias in the cohort studies. As illustrated by this table, the lack of an asterisk denotes that some concerns of potential bias arose from the non-exposed cohort or those patients receiving in-person DOT and the adequacy of the follow-up for some studies. Based on the assessments, studies considered to have a risk of bias by one tool could grade better with the other tool. The exception was the study by Lam et al:

Risk of Bias Assessment for Cohort Studies Using the Newcastle-Ottawa Scale and Agency for Healthcare Research and Quality Standards

	Studies included in Published Meta-Analysis					Literature Search
Selection	**Guo (2020)**	**Lam (2018)**	**Garfein (2018)**	**Chuck (2016)**	**Wade (2012)**	**Perry (2021)**
Representativeness of exposed cohort	*	*	*	*	*	*
Selection of the nonexposed cohort	---	---	---	---	---	*
Ascertainment of exposure	*	*	*	*	*	*
Absence of outcome of interest at start of study	*	*	*	*	*	*
Comparability	---	---	*	---	**	---
Outcomes						
Assessment of outcome	*	*	*	*	*	*
Length of follow-up	*	*	*	*	*	*
Adequacy of follow-up of cohorts	---	---	---	*	---	---
Overall	7	5	6	7	7	6
Newcastle-Ottawa Scale for Assessing Quality	Good / Low Risk of Bias	Low / High Risk of Bias	Moderate Risk of Bias	Good / Low Risk of Bias	Good / Low Risk of Bias	Moderate Risk of Bias
Agency for Healthcare Research and Quality Standards	Poor / High Risk of Bias	Poor / High Risk of Bias	Good / Low Risk of Bias	Poor / High Risk of Bias	Good / Low Risk of Bias	Good / Low Risk of Bias

Newcastle Ottawa Scale:
≥7 points: Good
6 points: Moderate
≤5 points: Poor

Newcastle Ottawa Scale converted into the Agency for Healthcare Research and Quality Standards:
Good quality: 3 or 4 stars in selection domain AND 1 or 2 stars in comparability domain AND 2 or 3 stars in outcome/exposure domain
Fair quality: 2 stars in selection domain AND 1 or 2 stars in comparability domain AND 2 or 3 stars in outcome/exposure domain
Poor quality: 0 or 1 star in selection domain OR 0 stars in comparability domain OR 0 or 1 stars in outcome/exposure domain

Looking at the evidence for the outcome of treatment adherence, the meta-analysis by Truong et al., the randomized controlled trial (RCT) by Burzynski, et al., and the prospective observational study by Perry et al. examined the proportion of medication doses observed by TB program staff. The meta-analysis defined treatment adherence as “observation of ≥80% or more of prescribed doses.” The RCT by Burzynski, et al. and the observational study by Perry et al. defined adherence as “the observed proportion of total prescribed doses.” Both the meta-analysis and observational study found greater adherence among patients on vDOT compared with patients on in-person DOT. Notably, the observational study by Perry et al. focused on doses taken Monday through Friday. Per program practice, if a patient using vDOT missed a weekday dose and submitted additional videos on the weekends, these were included in the

weekly adherence count, which potentially biased results in favor of vDOT. The RCT found that vDOT was as effective as in-person DOT by achieving observed doses.

Regarding the evidence for the outcome of treatment completion, the meta-analysis by Truong et al. defined treatment as the "patient did not prematurely stop treatment or was not lost to follow-up" and the observational study by Perry et al. defined completion as "treatment completion and success were based on ingesting a set number of target doses." Treatment completion was similar among patients on vDOT and in-person DOT. The RCT by Burzynski et al. did not evaluate treatment completion.

The meta-analysis by Truong et al. and the observational study by Perry et al. reported results for the outcome of microbiologic resolution, which is a principal prognostic indicator for TB treatment response. The meta-analysis results were based on radiography and negative sputum smear in the last month of treatment and on ≥1 previous occasion among patients who were sputum smear positive at the beginning of treatment. Data from this analysis indicate more favorable outcomes with vDOT. The observational study reported microbiologic resolution as the mean days to culture conversion among patients who were sputum smear positive at the beginning of treatment. In this study, microbiologic resolution was similar between patients on vDOT and in-person DOT. With the cross-over design, the RCT by Burzynski et al. did not evaluate microbiologic resolution.

In terms of the updated recommendations, missed doses of medication or treatment interruptions can lead to suboptimal drug concentrations, acquired drug resistance, longer treatment times, TB treatment failure, and recurrence. For these reasons, CDC continues to recommend DOT as the standard of care for all persons prescribed TB treatment. CDC updates this recommendation to include vDOT as equivalent to in-person DOT. This update of CDC recommendations is based on evidence that vDOT is associated with a higher proportion of medication doses being observed and similar proportions of TB treatment completion and microbiologic resolution when compared with in-person DOT. These data, combined with research that has demonstrated vDOT can conserve time and costs for patients and programs, improve patient satisfaction with DOT, and provide opportunities to monitor adherence when in-person DOT is not feasible, illustrate the utility of vDOT to sustain patient care and treatment.

The following considerations are also added to the guidelines:

- Decisions regarding the use of vDOT or in-person DOT during TB treatment are best made when healthcare providers and patients work in partnership to discuss the potential benefits and drawbacks of both DOT approaches.

- Topics to address in shared decision-making discussions include the patient's healthcare needs, social conditions, preferences, regular access to video-enabled devices and the internet, reimbursement (as appropriate), confidentiality, and privacy as well as program capacities and provider preferences.

- For patients taking injectable medications, experiencing circumstances that they and their providers decide would benefit from additional monitoring, or unable to use vDOT technology, in-person DOT is likely the best option for care.

- To date, few RCTs and cohort studies of vDOT have been conducted. Studies have been heterogenous with respect to video type (synchronous vs. asynchronous) and location of in-person DOT (clinic vs. community).

- Additionally, published studies have been conducted in urban and suburban settings, in locations with broad internet availability.

- Thus, additional evaluation of vDOT implementation in more diverse settings and with diverse populations will expand the current knowledge base.

- Moreover, technology has evolved rapidly over the past decade. This evolution likely will continue, adding to the evidence and further informing best practices for the use of vDOT in supporting patients in their treatment adherence.

In terms of the implications for public health practice, vDOT can assist health department TB programs to meet the US standard of care for patients undergoing tuberculosis treatment, while using resources efficiently. As noted in the timeline shared earlier, once the guideline was drafted, it was sent for external review by TB subject matter experts (SMEs). Reviewers provided a variety of perspectives and included the following representation:

- Former patient
- High, medium, and low TB incidence settings
- Various geographic areas of the US
- Public Health Nurses
- TB Program Leaders (Managers, Directors, Administrators)
- Persons responsible for coordinating video DOT
- Persons who have led projects evaluating video DOT

No comments were received that were critical of vDOT. However, experts were not selected based on known opinions. The majority of comments received from the experts addressed vDOT operations and topics to include in the supplemental materials. With the release of the guidelines, there will be a webpage with supplemental content in the form of FAQs. The questions and answers address the topics of: DOT, vDOT Logistics, Implementation Challenges, Education and Training for Patients and Staff, Patient Safety, Patient-Centered Care, Incentives and Enablers Appropriate for Patients Undergoing Treatment with vDOT, Surveillance/Reporting, Costs and Cost Savings, Reimbursement for vDOT, and Privacy/Confidentiality.

There are a few topics that the Writing Team considered to be beyond the scope of the guidelines and supplemental materials, including the following:

- Costs of standing up a vDOT program
- Regulations/laws surrounding vDOT and telemedicine
- Comparison with other digital tools, such as pill bottles with medication event monitoring systems (MEMS), electronic pill boxes, and sensor-embedded pills
- Use of artificial intelligence (AI)
- Environmental benefits

The next steps are to address comments received from the ACET as appropriate, finalize the supplemental information, submit the materials for clearance, publish the guideline in the *MMWR*, and work on disseminating the guidelines.

ACET Discussion

For this discussion, ACET was asked to consider the following items:

1. *CDC requests comments regarding accuracy and comprehensiveness of the summarized evidence, the practicality and clarity of the recommendation and accompanying considerations.*

Dr. Belknap recalled that assessing adverse events (AEs) was not one of the objectives, but he wondered if there was any discussion about including patient experience and patient preferences as part of the review specifically or if it was considered to be outside of the scope.

Dr. Mangan emphasized that both topics are very important and are addressed in the supplemental materials. There is not a lot of data on these topics, such as from RCTs, that can be drawn on to include in a Policy Note. That information will continue to evolve, so including it into the supplement material will allow for easy updates as more data become available.

Dr. Narita indicated that the Tuberculosis Control Clinic/Public Health-Seattle & King County at Harborview has been using asynchronous vDOT for years and they love it. On the other hand, in-person DOT is done for a couple of weeks practically speaking to make sure that they transition patients.

Dr. Mangan directed Dr. Narita to look at the study by Burzynski at al. that came out on the *Journal of the American Medical Association* (*JAMA*) open network at the beginning of 2022. One thing that was somewhat different about this study compared to some of the others in the literature, patients frequently would have to demonstrate good adherence for a period of time before they would be offered vDOT. What was different in the Burzynski at al. study was that the NYC Department of Health (DOH), which had used that policy themselves, made the decision that they would allow patients to start on vDOT as soon as they were enrolled in the study and were starting outpatient treatment. The results of the study show that the vDOT and in-person did well, which shows that patients potentially could be brought right onto vDOT. That study also allowed patients to choose between synchronous or asynchronous videos, both of which were available in the study. In terms of policies programs adopt, it is beneficial to show patients, let them practice, and offer support. The FAQs acknowledge that different programs use different approaches, and each program will have to determine what works best for them.

Dr. Ahmed asked what the lower limit of age would be for the guidelines. North Carolina has allowed vDOT for adolescents. She does not have any objections to using it in younger children, but it likely would work better with a dyad (e.g., the mother and child are both being treated). Some lead-in with dyads would help to ensure that the mother or father can actually administer the medications. They have allowed vDOT on a case-by-case basis for younger children. She and Dr. Stout recalled allowing vDOT down to 12 years of age, though they could not recall offhand whether they officially established a lower limit. Even before COVID-19, they were conducting virtual or telemedicine through the school system. A lot of asthma care is being delivered that way. There is no reason that vDOT could not be done through the school system as well.

Dr. Mangan indicated that the guidelines themselves do not specify a lower limit. Pediatric populations are very important. The Burzynski study allowed patients as low as the age of 12 years, but patients that young were not enrolled in the study. There are not a lot of data by age in the literature at this point. This is one of the gaps in the published literature to date, which illustrates that additional evaluation needs to be done. When the Writing Team got into the considerations, they felt strongly that there needed to be a shared decision-making discussion to address patient and provider preferences. Regarding conducting vDOT through the schools system, she indicated that when she was at the University of Alabama Birmingham (UAB), they conducted studies online with elementary school children who went into the system to report their peak flow results and any symptoms. The children, who were from the inner-city and were quite young, adapted to this pretty well. There was an adult in the room who could address any struggles.

Dr. Loeffler said that she is not opposed vDOT for pediatrics, though she could not recall a time when they used it. She would support doing this on a case-by-case basis, depending upon the person delivering the DOT and their interest. Once families get used to the concept, they love having someone come in to support them.

Dr. Stout observed that the review was rigorous, evidence-based, and comprehensive. It is nice that the guidelines finally will catch up with what everyone has been doing for the last 3 or so years. It also speaks to the lag between clinical practice, standards, and guidelines. He wondered whether more thought should be given to how to accelerate the process of developing guidelines for practices that already are being used.

Dr. Mangan agreed and emphasized that when this group got started, they moved relatively quickly in the grand scheme of things to push this out because they realized they were coming out of the gate somewhat late. Having the data from NYC was beneficial.

Dr. Loeffler noted that the use of the CPSTF approach to assess the findings and quality of evidence was an amazing tool in the right setting.

Dr. Belknap added that there are very few things that work well as a one-size-fits-all and this is not that. It is great to have this flexibility in the right setting.

TB Elimination Alliance (TEA) Update

Overview

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Dr. DeLuca began with an overview of the Tuberculosis Elimination Alliance (TEA). In terms of background, the importance of the dual approach to TB elimination in the US is well-known. Achieving TB elimination requires maintaining and strengthening current TB control priorities, while expanding testing and treatment for people with LTBI. In the US, TB control and prevention traditionally has been a function of state and local public health departments. Many of those at risk for TB infection and TB disease who need to be tested and treated receive care

from private health care providers and community health centers. It is important to engage and educate healthcare providers, health care agencies, and organizations who serve communities at risk.

In an effort to expand and build relationships with community stakeholders, the TEA was created. The TEA is a national partnership of community leaders dedicated to increasing knowledge, testing, and treatment of TB and LTBI among communities at risk for TB. The goals of the TEA are to: 1) conduct outreach to communities most affected by TB; 2) increase awareness and understanding of LTBI testing and treatment strategies; 3) share resources and best practices among providers; and 4) develop partnerships to scale existing initiatives. The TEA was launched in October 2019. It is based on the CDC DVH model to support Hep B United. The TEA is funded through a CDC Center for State, Tribal, Local, and Territorial Support (CSTLTS) cooperative agreement titled, "Strengthening Public Health Systems and Services Through National Partnerships to Improve and Protect the Nation's Health." The first meeting of TEA members in July 2020 was convened virtually due to the COVID-19 pandemic. It is important to recognize that this entire initiative was funded, launched, and grew in the context of the pandemic.

In terms of leadership and organization, the TEA is led by the Asian and Pacific Islander American Health Forum (APIAHF), with support from the Association for Asian Pacific Community Health Organizations (AAPCHO), Hepatitis B Foundation, and Stop TB USA. The 15 current members represent community health centers, CBOs, public health agencies, academic institutions, and other partners.[26]

Regarding TEA expansion and growth, there was outreach and support for Asian American, Native Hawaiian, and Pacific Islander communities in 2019-2021. This involved recruitment of up to 20 TEA member organizations serving Asian American, Native Hawaiian, and Pacific Islander communities. During this time period, 10 "mini-grants" were funded each year for community-based activities. In addition, CDC hosted an Annual TB Summit for all partners and others in the TB prevention and control community. CDC was able to do all of this for about $310,000 per year. In 2022, the TEA received additional funding from the DTBE to expand to include non-US-born Hispanic and Latino communities and US-born African American communities. This involved the recruitment of up to 10 TEA member organizations serving non-US-born Hispanic and Latino communities and US-born African American communities. Mini-grant, summit, training, and technical assistance opportunities were expanded as well. The CDC funding was increased to $610,000 per year. Notably, not all mini-grant awardees are TEA members and summits involve a much broader group of people.

[26] https://tbeliminationalliance.org/

TEA Activities

Jeffrey B. Caballero, MPH
Executive Director, AAPCHO
National Co-Lead, TB Elimination Alliance

Mr. Caballero indicated that AAPCHO[27] is a national membership association of community organizations serving predominantly Asian American and Native Hawaiian/Pacific Islander populations. AAPCHO has 34 members across the country, 30 of which are Federally Qualified Health Centers (FQHCs) that serve the majority of foreign-born Asian American and Native Hawaiian/Pacific Islander populations. In terms of transparency, prior to this cooperative agreement experience, Mr. Caballero said he was fortunate many years ago to have had another experience with CDC TB when AAPCHO was a recipient in 1993 of a 5-year LTBI cooperative agreement to help develop LTBI relationships between community health centers and local health departments. He was hired right out of graduate school to serve as the Program Coordinator of that project during which he was fortunate to gain experience from TB Controllers and health department folks from across the country.

The TEA is a national partnership of community leaders dedicated to eliminating TB and LTBI inequities among Asian American and Native Hawaiian/Pacific Islander populations through education, raising awareness, and innovation. The TEA's vision is healthy communities free of TB. The TEA's strategic pillars include collaboration and partnerships, community engagement, access to testing and treatment, provider education, and research and data. The intent of the TEA's initial outreach was to help strengthen and develop partnerships between local coalitions engaging in LTBI work. This was inspired by a model that AAPCHO also has been a part of that Mr. Caballero helped co-found in partnerships with the Hep B Foundation, which is Hep B United. Toward that end, the Hep B Foundation was invited to be part of the Steering Committee in order to work on building this relationship and building the capacity for communities need to address the disparities that are being encountered by Asian American and Native Hawaiian/Pacific Islander specific to TB and Hep B. The partnership was needed to ensure that there was an SME in TB and to have that expertise be grounded in advocacy work that is needed to help lift up and increase support for TB.

In addition to developing the mission and vision, the coalition helped to identify potential coalition members to be engaged in moving the agenda forward, develop and implement the mini-grant program, and identify TB elimination champions among this group of individuals. In addition to the 5 pillars, the TEA developed 4 goals, which are to: 1) conduct outreach to under-served Asian American and Native Hawaiian/Pacific Islander communities with the highest TB burden; 2) increase awareness and understanding of culturally and linguistically appropriate LTBI and TB treatment and testing strategies; 3) share resources and best practices among providers; and 4) develop partnerships to scale these initiatives.

The 2020 Summit was solely TB-focused and was titled, "Eliminating TB Together." This was not exactly the kind of summit that had been envisioned when funding was awarded in 2019. It was the TEA's first venture into a virtual summit, which went fairly well. In 2021 and 2022, the TEA partnered with Hep B United, which is a well-established coalition that existed 10 years

[27] AAPCHO's TB & LTBI Needs Assessment of Community Health Centers: https://aapcho.org/addressing-tuberculosis-and-latent-tuberculosis-infection-screening-testing-and-treatment-needs-among-community-health-centers-serving-asian-americans-native-hawaiians-and-pacific-islanders-sept/

prior to TEA and supports networks in more than 36 cities across the country. The partnership with them in convening the virtual summits over the last 3 years has helped the summit and participation grow. During this short time frame, the participant numbers have nearly doubled each year. More organizations and geographic areas have become involved in the summits, so it has been good tool in helping to identify potential new partners in the future. The summits[28] have offered a tremendous opportunity to help highlight some of the many grantees who have developed some promising programs. Doing this across the TB and Hep B practices at the community level has been rewarding in terms of the kinds of experiences and interactions that have occurred among CBOs, health departments, and Centers of Excellence that have been involved in this program.

In addition to CDC resources utilized for the TEA, AAPCHO also has been leveraging its other national partnerships and is a cooperative agreement grantee of the Health Resources and Services (HRSA). Over the last 2 years, Mr. Caballero has been conducting TB Learning Collaboratives that are focused on LTBI implementation. There also have been opportunities to conduct webinars with the TB Centers of Excellence to help ensure that community partners around the country are aware of the resources that are available. There also has been a promising response to the summits in the last 2 years, during which Dr. Carolyn Wester from DVH and Dr. Philip LoBue from DTBE have spoken. This offered communities opportunities that they have never had in terms of hearing directly from the leadership of DVH and DTBE. Mr. Caballero also had the honor of being invited to present during the last NTCA conference in Palm Springs. Their relationship is continuing to mature with the TBCB and the NTCA, and they are looking forward to being able to identify some shared local champions in the upcoming project year.

As mentioned earlier, TEA was blessed to have its award budget increased. Mr. Caballero shared the list of 2022-2023 Mini-Grantee Cohort recipients of the additional TEA funds for the Year 5 expansion goals. These 14 grantees are located in Guam, Minnesota, Nevada, California, Georgia, Oregon, Alaska, Colorado, Arkansas, and Massachusetts and include the following recipient organizations:

- Southland Integrated Services, Inc.
- Saint Paul - Ramsey County Public Health
- Todu Guam Foundation, Ltd.
- Healthy Asians & Pacific Islanders Medical Center
- Home of Helping Hand, Inc.
- Vietnamese American Cancer Foundation
- Micronesian Islander Community
- Polynesian Association of Alaska
- San Diego County, dba Champions for Health
- Colorado Alliance for Health Equity
- Arkansas Coalition of Marshallese
- La Maestra Community Health Centers
- Southeast Asian Coalition of Central Massachusetts, Inc.
- Asian Pacific Health Foundation

[28] 2022 Hep B United/TB Elimination Alliance Annual Summit Recordings: https://www.youtube.com/playlist?list=PLfd5PeQY3Bl14UTLA_U-rKLNzbrcg-kln

These grantees had a total mini-grant award of about $310,000. Half of the award has gone to the mini-grant programs in communities. Of the organizations listed, 5 included the intension of expanding the target population beyond Asian American and Native Hawaiian/Pacific Islander communities. The purpose for implementing this particular set of the expansion was critical in order to make sure that the grantees that were selected could still receive the type of support that AAPCHO and APIAHF can provide them on the national level while they expand their target populations to non-US-born Hispanic and Latino communities and US-born African American communities. AAPCHO, APIAHF, and the Steering Committee are looking to national partner organizations to help lift up the awareness around TB and the populations who are at risk. AAPCHO and APIAHF want to build these national partnerships so that they will have a similar level of support for local organizations that also are serving these other high-priority populations. They will be reaching out to these organizations over the next few months and hope to convene an Equity Council that will help guide future programming. The hope is that there will be an additional round of this cooperative agreement in order to keep growing and cultivating this type of community-centered approach to TB and LTBI programming. To that end, they are reaching out to ACET and other communities to ask for recommendations of candidate organizations that serve non-US-born Hispanic and Latino communities and US-born African Americans to reach out to determine whether there are opportunities to cultivate this type of support.

An example of a mini-grant that has the capacity to expand is La Maestra Family Clinic, Inc., which is a FQHC with over 30 years of experience serving low-income, uninsured, and underinsured communities in the Central, South, and East Regions of San Diego County, California. This organization currently operates 18 primary care and behavioral health sites, 10 dental suites, 3 school-based sites, 2 mobile medical and dental units, and a state-of-the-art mobile mammography coach. According to clinic data, La Maestra has grown from serving 15,870 patients in 2003 to 39,943 patients in 2021. La Maestra's "TB Education and Testing in San Diego's Vulnerable Communities" project aims to:1) raise awareness about the link between LTBI and TB disease, address misperceptions, decrease stigma, and encourage and facilitate testing and treatment for LTBI and TB; 2) increase awareness of the recommended shorter treatment regimen for LTBI; and 3) encourage providers to test and treat LTBI among at-risk populations. The organization will achieve this through a multidisciplinary team of health education staff, physicians, and a hepatologist. The team will utilize its existing culturally and linguistically appropriate LTBI and TB education, training and community engagement resources and activities that resonate with high priority AA, NH, PI, non-US born Hispanic/Latino, and US born African American communities.

TEA Mini-Grant Program

Maria Fernanda Gutierrez, MPH
Program Manager, APIAHF National
Co-Lead TB Elimination Alliance

Ms. Gutierrez indicated that she is a Steering Committee member of the TEA based in Washington, DC, representing the APIAHF.[29] She was fortunate enough to join the TEA in Fall 2021. Prior to this role, she served as a 2019 CDC Public Health Associate Program (PHAP) Associate based at the California Department of Public Health California Tuberculosis Control Branch (TBCB) working in outbreak prevention and control. The APIAHF provides advocacy

[29] https://www.apiahf.org/press-release/tuberculosis-elimination-alliance-awards-mini-grants-to-expand-latent-tuberculosis-infection-and-tuberculosis-testing-screening-treatment-and-prevention/

and technical assistances primarily to CBOs that serve Asian Americans and Pacific Islanders. She provided more details about the TEA Mini-Grant Program, emphasizing that it is truly remarkable to see some of the tangible impacts that TEA has achieved over the last 3 years. She spent this portion of the presentation providing more granularity about the metrics and sharing some of the impacts that TEA required from its partners. TEA has been privileged to support 40 grants across the US and US-affiliated Pacific Islands. To date, TEA has awarded over half a million dollars to support A/AA and NH/PI serving community programs, clinics, and academic centers focused on treating, preventing, and eliminating TB. TEA is incredibly grateful for the support from federal partners, and they thought it was important to show how these funds are being utilized at the community level, why these resources are needed, how they have generated positive outcomes, and perhaps learn how they should respond to these issues moving forward.

Over 70% of these resources were allocated toward staffing. This makes sense, especially reflecting on some of the realities faced nationally in the wake of COVID-19. At the height of the outbreak, there was not appropriate infrastructure, funding mechanisms, or workforce available to respond to this crisis. Therefore, it was necessary to rely on unusual tactics like deferring the responsibility to hospitals and local health departments. They fairly quickly realized that not only was this not sustainable, but also it was not reaching vulnerable, usually ethnic minority populations with limited English proficiency, who were at most risk of contracting, spreading, and disproportionately dying from the disease. There was not enough time to repair those relationships with community members and oftentimes partners who were deployed were not adequately trained or well-versed in the local context of these populations. What they have learned and continue to see from the data is that one of the most crucial elements for the success of these efforts is having the right people such as nurses, technicians, translators, outreach coordinators, data analysts, program managers, and culturally representative leaders to show up and do the work. This is why it makes sense that over two-thirds of all mini-grant funds were allocated to finance capacity, while another 14% was utilized to purchase microphones, tents, chairs, software licenses, print materials—all of the infrastructure needed to build a village that was dedicated and prepared to provide the necessary resources to community members in locations where they need them to be, in the languages that need to be provided, and with the people who they trust to supply it. This is a reality that TB has continued to highlight, and that COVID-19 more recently has re-emphasized.

There are not enough national coalitions working directly with ethnic minority organizations or non-profit agencies on initiatives like the ones being funded through TEA. An important lesson to take from these metrics is that mobilizing communities, especially marginalized populations, is expensive. It is incredibly complex and is unfortunately under-funded at various levels. However, when performed intentionally with community priorities at the center, much more can be accomplished in a much more cost-effective manner than continuing to “shoot in the dark.” This is one of the key drivers to TEA’s success over time. Careful consideration and resources have been allocated to finding local gatekeepers to champion these efforts and uplift communities’ narratives. Performing outreach and education is much more complicated than just printing out flyers. It can mean having the need to fill one’s car and drive 45 miles to facilitate a screening event that the community can access. It can mean weeks and months of recruiting hard-to-reach community members to agree to participate in surveys or needs assessments that will be used to train healthcare providers in the future. It is in that intentional distribution of resources, infrastructure, and personnel that TEA was able to reach the kind of metric pulled from its yearly reports dating from October 2020 through February 2022. While these are preliminary data, TEA’s mini-grantees have been able to reach over 4400 people cumulatively in just shy of a year or so. Close to 500 of those were providers, nurses, and

community health workers (CHWs) who participated in trainings, workshops, webinars, and/or quality improvement projects to help improve their provider capacity and TB and LTBI knowledge. Over half of the 4400 were community members, patients, and at-risk persons who were offered culturally and linguistically relevant LTBI education or were referred for evaluation and treatment during these outreach engagement, screening, and education events.

It is also important to recognize and acknowledge some of the challenges mini-grantees encountered throughout this journey. What was learned from this cohort is that there were some key barriers, some acute and some systemic, the predominance of barriers were related to the byproducts of the pandemic. COVID-related restrictions, delays, and apprehensions limited group activities, recruitment efforts, and enrollment of program participants. For most of the country, the ever-changing circumstances and shifting priorities that emerged from the pandemic made it challenging for partners to build out their interventions to scale. Some of the reported barriers included community members not being able to connect through Zoom or feeling uncomfortable in virtual settings, which made it hard to provide steady outreach, education, and risk awareness. Other challenges included hiring and sustaining bilingual CHWs from various ethnic backgrounds when there already was a national shortage of providers. Even finding culturally representative experts or well-respected leadership to help create trust in the community was an added obstacle—not that this is not already inherently demanding, but it is especially so when it is compounded with forces that are beyond anyone's control.

This lends itself to some of the other physical and technical challenges like the increase in prices for QuantiFERON®-TB (QFT) blood test, which created several limitations for programs focused on increasing access to treatment and testing. About 20%of recipients who prioritized treating or testing in their workplans reported an increase in diagnostic expenses due to the inflated QFT prices. Rather than purchasing 100 tests at $20, they could only acquire 27 tests at $73 with the available funds. Another 30% or so of recipients reported enduring challenges associated with TB and LTBI stigma, which is something that has been echoed throughout all 3 years of TEA's programming. TB/LTBI misconceptions, misinformation, and taboos continue to persist among community members and even providers. This breeds a cascade of related barriers that proliferate fear, misunderstanding, and hesitancy by community members. One of the programs reported that even the introduction to blood tests versus traditional skin tests in the community was problematic. The impression of drawing vials of blood can discourage many from receiving screening, even when they are at greater risk. It should be noted that the top 4 reported barriers did not include language access among these metrics, but that would still be a Tier 1 issue if not for COVID, along with the retention of providers and other CHWs who were hired for these projects. These barriers point to the sheer need, concerted amount of effort, and infrastructure dollars required to provide comprehensive, culturally and linguistically appropriate TB and LTBI education for A/AA and NH/PI communities and other ethnic minority groups.

Despite these limitations, TEA's partners were able to leverage their communities' assets and rise up to the challenge. These are some of the pictures the mini-grant recipients captured during their funding period. Even in such perilous times, these organizations continued to show up every single day for their communities. While TEA wants to be transparent about the uncertainties grantees faced, they also wanted to spotlight some of the leaders because these are the people who need to be recruited at the frontlines and the local leaders who should be included in the national response effort or other state TB elimination plans. These are the outcomes that happen at the local level when state and national TB programs collaborate and partner with partner and community organizations. While this is only a partial capture of the work that has been done, TEA continues to feel incredibly honored by, proud of, and inspired by its partner organizations for continuing to further TEA's mission and uplift communities:

To provide a more detailed example of what is meant by “culturally and linguistically appropriate interventions,” Ms. Gutierrez highlighted one of TEA’s long-term partners, the Vietnamese American Cancer Foundation (VACF), by sharing a snapshot of their 2021-2022 TB Free Orange County project. An important piece of information to recognize about this community is that the TB case rate among Asians is 5 times higher than the rate for Hispanics. In 2021, the TB case rate among Asians was 16/100,000. In Orange County, 2 in 3 TB cases occurred among Asians and 44.9% of those were from Vietnam. To mitigate that statistic, the VACF program has been focusing on increasing TB and LTBI awareness, testing and treatment, and performing a variety of culturally appropriate interventions to educate the community and help them learn about their TB status. For example, they produced a series of weekly TB education radio shows on an ethnic station that is very popular in the community and has a standard listenership of over 60,000 people on a usual 5:30 PM broadcast. The VACF also performed a lot of their other outreach through other communication channels that their priority population utilizes to hear the news and obtain health information, including Facebook. This was in addition to distribution of in-language flyers, newsletters, and other social media products that featured well-known and trusted stakeholders to help champion these educational activities and attract the attention of community members toward a topic that is still highly stigmatized.

The VACF also collaborated with local churches and temples to facilitate on-site TB screening events on the weekends and even included other comprehensive health services like COVID-19 vaccines and Hep B and C screening with bilingual healthcare providers to attract more community members. For those who could not make it to the screening events on the weekends, VACF partnered with local laboratories to triage testing referrals so these community members could get their tests done at one of the other 10 locations throughout the county. In 6 to 7 months, the VACF was able to educate 360 high risk community members through webinars, language group sessions, or one-on-one health education sessions. Throughout the project, they successfully screened 144 community members. That is 80 or so more members than the aim at the beginning of the project. When communities’ needs are not acknowledged directly and their lived experiences are not respected, it proliferates a collective sense of fear,

misunderstanding, and discrimination that prevents communities of color from seeking healthcare, trusting their providers, or adhering to treatment and follow-up care that is impractical or inconsiderate of their life circumstances. This is a perfect example of what happens when intentional program activities are curated and infrastructure dollars are channeled to provide resources that will be accessed, understood, and respected by high-risk community groups.

The TEA is approaching its final year of programmatic funding. Thanks to the ongoing support of TEA's federal partners, they have been given the honorable duty to offer expanded services and mini-grant funds to other high-risk populations that are disproportionately affected by TB disease, including non-US-born Hispanic and Latino communities and US-born African American communities. TEA's objective has been and will continue to be a focus on empowering the voices of Asian American and Native Hawaiian and Pacific Islanders, while also thriving to establish a mutual ownership and lasting partnership with Asian American and Native Hawaiian and Pacific Islanders organizations that are focused on TB health equity efforts that serve all communities' needs. As champions for health equity in TB, TEA's priorities for the next 6 months until funding ends and moving forward is to continue to further examine the scope of the problem and learn about the lived experiences of these expansion populations, because it is only through careful initiations and conversations that TEA as a coalition will be able to know what kind of resources the non-US-born Hispanic and Latino communities and US-born African American communities need. These other high-risk populations must be approached in an equitable and sustainable way moving forward into the next funding cycle or at least for the next decade. Ultimately, TEA's objective is to seek, build, and sustain genuine partnerships with other minority communities who also have been systemically vulnerable to this disease throughout history. The recruitment strategy has to be intentional, so Ms. Gutierrez encouraged community gatekeepers and nationally representative leaders from these expanded populations who may be in the audience to join TEA in this effort so that they can learn from each other and move forward with a shared ownership of these priorities by emailing TEA@aapcho.org.

The TEA coalition has had an incredible journey forged by the minds of many dedicated leaders. That vision continues to be uplifted by the hands of TEA's local community partners. The act of achieving health equity is an ultra-marathon that requires patience to learn, discipline to invite others, tenacity to enable to communities, and most importantly representative leadership to advocate for better outcomes, better policies, better resources, and improved visibility. As they move forward with the expansion, the hope is to continue to achieve TEA's mission to achieve TB elimination priorities among underserved communities of color. They encouraged those in the audience and other national leaders to feel empowered to reach out and collaborate with TEA in order to learn from each other to help create healthy communities free of TB.

ACET Discussion

For this discussion, ACET was asked to consider the following items:

1. *What are ACET recommendations for CDC on the future of this collaboration:*
    - *Feedback on the proposed expansion of the TB Elimination Alliance.*
    - *Additional partners, groups, or organizations for engaging in current or future expansion efforts?*

Dr. Belknap asked what lessons learned might be carried forward with the expansion, with hopefully being able to move away from virtual meetings and being able to do more in person.

Mr. Caballero said they have thought about how they would have done things differently without COVID, but he also has recently started to ask himself what they have been able to do *because* of COVID. One of the project sites in one of the largest health center programs in the country did not have CHWs that did outreach until COVID. The CHWs who started working on COVID most recently started to transition their work and are engaged in support work for TEA, including outreach and education for TB now. This health center is now learning how CHWs have a new outreach role that has enhanced their clinical program because COVID introduced CHWs to them. When those CHWs needed something to do aside from COVID, TB was something this clinic had prioritized. Many more community organizations have resources to have CHWs now. He wonders how many of the CHWs would be around later in communities when COVID dollars begin to be reduced. There also is a large HRSA CHW workforce program that has hired over 400 CHWs across the country. It is known that about half of them will not be sustained by their community organizations once COVID funds are gone. However, many community organizations have learned the benefits of CHWs and are asking TEA to help them find opportunities to retain them given the enhanced visibility and credibility that they have to champion on behalf of their communities.

Dr. DeLuca said that one thing that has been neat to see is how great organizations enter the fold who are working day in and day out with the populations that DTBE and the TB prevention and control community see as being at high-risk for TB. He did not think TB was even on the APIAHF's radar screen and this is a group that works with the target populations, given that there were a host of other issues. Even partnering with APIAHF at a macro level has brought more attention to TB. To see the VACF take on TB when their mission is primarily elsewhere is exciting. That said, one of the things they asked ACET members is that as they are trying to bring others into the fold, such as organizations that serve non-US-born Hispanic and Latino communities and US-born African American communities, many organizations are tapped out and spread thin because of COVID. There have been some challenges trying to reach these organizations to recruit and engage them, beyond even the mini-grants. They would love to hear from ACET members about how to reach out and engage them in the TEA partnership.

Dr. Benjamin pointed out that diabetics who are infected with TB have a 3 times greater risk of progressing from infection to active disease. He wondered how screening for TB could be included in routine care of diabetes patients as has been done successfully with Hepatitis. Involvement of the American Diabetes Association (ADA) and a policy emanating from them are needed.

Mr. Caballero observed that these questions are emerging, given the prevalence of this disease in the Asian American and Hawaiian/Pacific Islander communities. These discussions are beginning to occur among clinical champions across the country.

Dr. DeLuca did not recall that comorbid conditions such as HIV and diabetes would be included in the new LTBI recommendations. They often hear cited that there is not enough evidence, but in the field, people are seeing this and know that is important. This was a major topic at the recent Pacific Islander TBCA meeting. DTBE would like to hear from ACET about how to bring further attention or additional studies to this topic.

Dr. Belknap commented that it is incredibly challenging to try to figure out how to get TB high enough on a priority list when there are so many other competing and seemingly more urgent issues. The fact that TEA has been able to do this speaks volumes.

Justina Novak with Washington State TB indicated that they have tried working with the Washington Diabetes Association, but there are many co-morbidities that seem to keep bumping Washington State TB off of the Washington Diabetes Association's radar.

Dr. Narita emphasized the importance of elevating TB and LTBI but wondered what the selling point is to make sure the this is an important element of health.

Dr. Chen added that Dr. Narita's question went back to the folks who just spoke to them in terms of the lessons learned and the turning point that has gotten them interested and changed their minds about taking this on. For example, what made the difference with the oncology group? That is fabulous.

Ms. Gutierrez pointed out that from its inception, the TEA model integrated a multidisciplinary perspective on how to approach TB. They have been alluding to the fact that perhaps other chronic diseases have been stealing the limelight so to speak in many facets of infrastructure and capacity. Groups recognized at the end of the day that there is a common goal involved in all of this, so consideration should be given to how TB can become more involved with other divisions, even at CDC, outside of Hep B, and having that trickle into the local and state levels. The VACF prioritized TB because there was a recognition of the need and how there could be more comprehensive services that could be cost-effective and still could address their priority areas along with other high-risk disease this population is experiencing.

Mr. Caballero added that AAPCHO and APIAHF are organizations that have existed for 35 plus years. As national organizations, they have taken a leadership role in terms of advocacy for Asian Americans, Native Hawaiians, and Pacific Islanders. For many of their member and partner organizations, community empowerment is a critical component. Their efforts to build community capacity like this contribute to that type of community power-building. Folks want to be a part of that and they want to see themselves as contributing to their communities in that way as well, beyond the clinical capacity that they are able to deliver.

Dr. DeLuca emphasized that having both AAPCHO and APIAHF leading this effort has been key. In addition, instead of asking people to do more with less, they are asking them to do more with a little bit. These are truly mini-grants and many grant opportunities open the door for people to get some small amount of funding to try innovative ideas. It has been really lucky to also have identified advocates or cheerleaders within the organizations to move these efforts forward.

Dr. Belknap suggested that seemingly where they need to start is in finding the AAPCHO and APIAHF organizations that serve the expansion populations. Historically, there has been a "chicken and egg" approach that has begun with getting medical associations on board and then using them to try to leverage communities. The approach TEA has taken to empowering communities is probably the better approach. Then if associations are hearing that communities want this, then they will follow. That is probably a more successful type of strategy.

Dr. Chen stressed that COVID funds are already starting to sunset. There have been many successful community groups that have engaged in COVID outreach among these target audiences that are looking for the next thing. This is exactly the right time to engage with people

who have shown that they have a successful community outreach model that worked for COVID that could dovetail those lessons right into a short-term mini-grant for TB.

Public Comment

No public comments were provided.

Day 1 Recap

Robert Belknap, MD
Acting Director, Public Health Institute at Denver Health
ACET Chair

Dr. Belknap expressed gratitude to everyone who attended the ACET meeting throughout the long day and then provided a recap. There was a helpful discussion, though without resolution, on the issues of drug shortages and the need to continue conversations and perhaps circle back to some publications by the FDA 3 years ago. He noted that this conversation would arise again on the second day of the meeting during the working group updates in terms of the recommendations the ACET may want to make and include in the biennial letter. They heard a nice summary of the past, present, and future of the EDN systems and goals. A possible area for which the ACET may be able to provide some support would be to encourage the USCIS to advance the process by moving away from paper forms to the use of electronic systems. Cepheid described the barriers to bringing newer diagnostics within their portfolio to the US market. While the ACET did not provide any specific recommendations for HHS or CDC on this topic, hopefully they provided some useful feedback to Cepheid around strategies that the company could take forward to work with important partners in the US who are interested in this subject. In addition, the ACET heard updates pertaining to the Ukrainian arrivals and the ample funding that has been made available to support those efforts for TB programs. They also heard about an adjacent group that does not have funding, but has need for anticipated arrivers from Venezuela. Helpful updates were provided on video DOT and the progress that has been made, as well as a comprehensive review of the upcoming guidelines. Finally, the ACET heard from the TEA on the great work that they have been doing with the communities most impacted to increase interest, awareness, and advocacy for TB prevention.

With no further business posed, the meeting was adjourned at 4:06 PM ET. The ACET stood in recess until 10:00 am ET on December 14, 2022.

December 14, 2022 Opening Session

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

Deron Burton, MD, JD, MPH (CAPT, USPHS)
Deputy Director, National Center for HIV, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control & Prevention
ACET Designated Federal Officer (DFO)

Ms. Condit called the meeting to order at 10:00 AM ET on December 14, 2022 and provided meeting instructions. CAPT Burton welcomed participants to the second day of the ACET meeting. He then conducted a roll call to confirm attendance of the ACET voting members, *ex-officio* members, and liaison representatives. He reminded everyone that ACET meetings are open to the public and that all comments made during proceedings are a matter of public record. He informed 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. The roll call confirmed that the 19 voting members and *ex-officio* members in attendance constituted a quorum for ACET to conduct its business on December 14, 2022. No additional COIs weredeclared and quorum was maintained throughout the meeting.

Working Group Updates

ACET TB Workforce Work Group

Robert Belknap, MD
ACET Chair, TB Workforce WG Chair
Acting Director, Public Health Institute at Denver Health Denver Public Health

Jason E. Stout, MD, MHS
TB Workforce WG Member
Infectious Disease Specialist
Duke University Medical Center

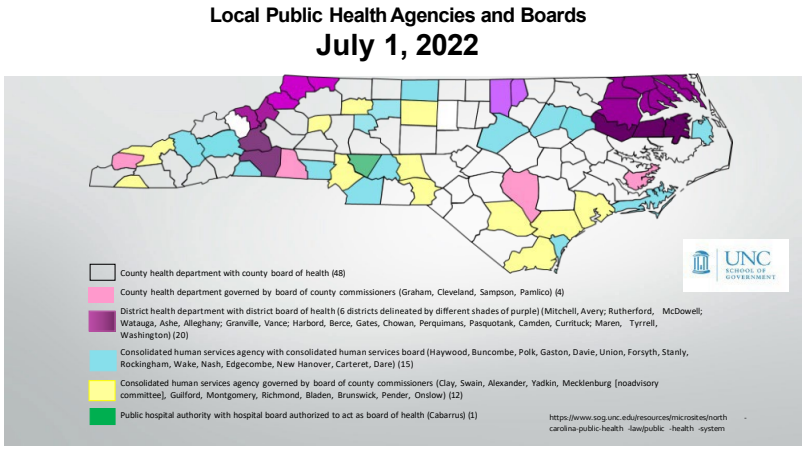
Dr. Belknap reminded everyone that during the last ACET meeting, there were discussions and concerns were raised about the US TB workforce due to COVID-19 redeployment, burnout, decreased funding, and pending retirements. The ACET TB Workforce WG was charged with determining what is known about the current and future status of the US TB workforce. Dr. Belknap was designated as the Chair and the members include Jason Stout, Zelalem Temesgen, Kristine Stewart-East, and Amina Ahmed. The WG has met 3 times since its establishment in June 2022.

One of the pieces of information the WG reviewed was an assessment conducted by the TB COEs at the beginning of the previous funding cycle in 2018. There were almost 1500

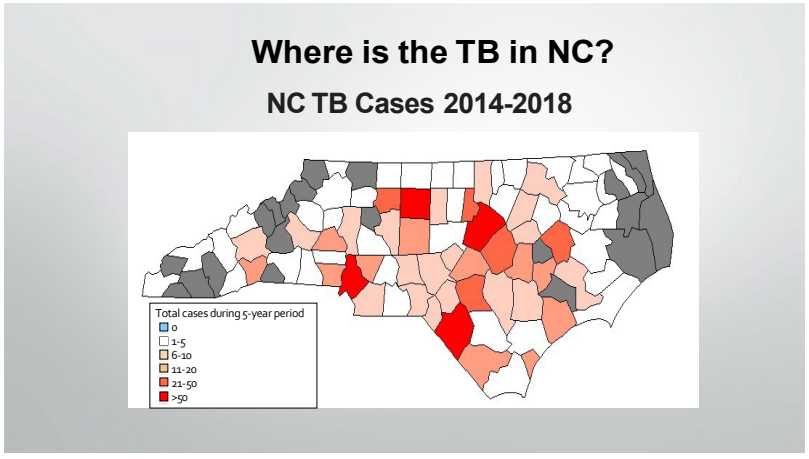
responses, the majority (73.8%) of which were from health departments. Some information also was provided by hospitals, community health centers, laboratories, and private practice. The profession of the majority (70.4%) of respondents was nurses (all types), with physicians making up just short of 10% and epidemiologists making up just 4%. In terms of the people responding and their years of working in TB, about 30% had been working 1 to 5 years. The biggest group (44%) were people who had been working in TB for more than 10 years.

The WG found this to be helpful information to inform at least what was known in 2018 about the make-up of the workforce and the distribution, but they also recognized that this was not as helpful in terms of understanding anything about the impact and outcomes from the pandemic may be on the current TB workforce. Dr. Stout shared some work that he and others did in North Carolina around the TB workforce there.

Dr. Stout described a North Carolina survey that was commissioned to try to understand the public health nursing TB WG. North Carolina has 100 counties, 79 of which have their own health departments or equivalent, and 21 of which are consolidated into district health departments for multiple counties as illustrated by this map:



To overlay cases on the above map, the following map shows where TB cases were in North Carolina from 2014-2018:



In the center, 3 of the dark red counties are Wake, Gilford, and Mecklenburg. These 3 counties have the large urban centers of Raleigh, Greensboro, and Charlotte respectively. At the bottom most part of the map is Robison County, which has a lot of social disadvantage.

The purpose of the WF survey was to: 1) understand the current public health TB nursing workforce; and 2) anticipate changes in and plan for the next 5 years. The survey was sent out online to nurses at the health departments in July 2022. Results were compiled and the initial presentation was in August 2022. There were significant issues with incomplete responses and failure to understand some of the questions. For example, some health departments would provide 2 responses to the same questions and those 2 responses would differ. Therefore, another query was performed in October 2022 and tentative results were recompiled in November 2022. Notably, this tentatively recompiling is still incomplete.

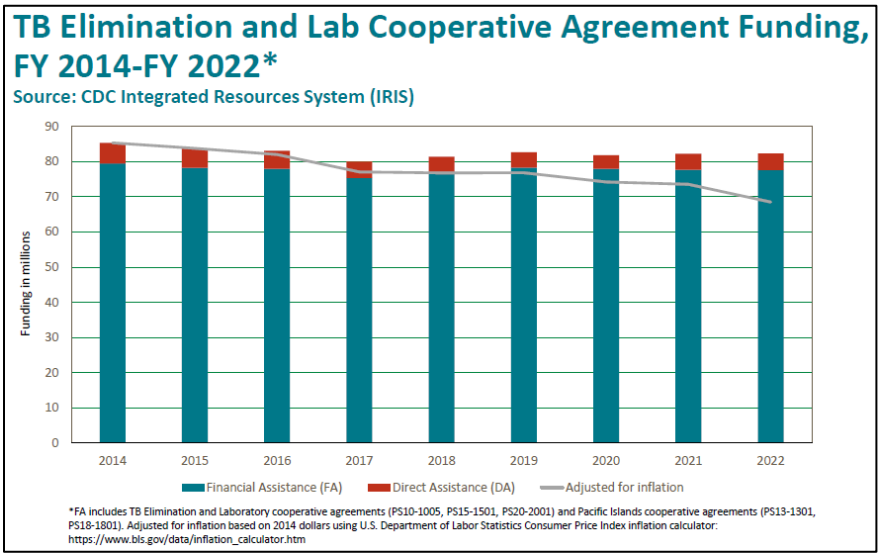
This time, 67 responses were received. Given that there were 3 duplicate responses with inconsistent answers, a total of 64 out of 85 counties or districts responded. There were 8 fulltime TB nurses in Charlotte/Mecklenburg, but most counties had a single TB nurse. Among 53 respondents, 21% stated that the part-time nurses summed to at least 1 FTE. This means that basically, a little piece of a nurse is doing all of the TB work in most health departments. The survey also asked respondents to indicate the number of years of experience in public health/TB for every public health nurse in the TB program. The average in public health was about 8 to 10 years, with a wide range spanning from less than a year to 33 years. This was similar for the average in TB. Similar to the COE survey, this group has 1 to 3 years of experience or more than 10 years of experience.

Respondents were asked how many TB nurses anticipate leaving the local TB program in the next 5 years. The total was about 30%, but at least 1 TB nurse was going to anticipate leaving the local TB program in most jurisdictions. Remember that in most jurisdictions, there is only 1 TB nurse. Respondents were asked to rate their perceived level of support related to TB duties. To provide some background on this, North Carolina is a Home Rule state, which means that each county is responsible primarily for taking care of its public health business, including TB. The state TB program provides support and plays a consultative role. Each county is supposed to have a TB provider. In the larger counties that may be a fulltime person or someone who is dedicated to TB, but in many of the smaller counties there is a physician who is TB in name only who signs orders but defers any complex treatment decisions. That is the context of this survey. On this scale, 1 is the lowest possible level of support and 10 is the highest. Support for Manager/Supervisor was overall pretty good at an average of 8.3, but there was quite a range from 3 to 10. The average support from TB Providers was good at 8.6, but the range was 1 to 10. In the State TB Program, the average was 9 but the range was 5 to 10.

In terms of issues to be addressed, it was surprisingly challenging to get responses. Part of the issue is that the people providing the responses were too busy doing the work to answer a survey like this, even though it was a very brief survey. The investigators are still individually contacting health departments to try to get responses that were not provided. They also are still trying to sort out analysis of staffing to case ratios and experience to case ratios. They also are very much interested in understanding barriers to recruiting and retaining PH nurses. They have some early interventions. For instance, some people from the TB Program are going to nursing schools to speak with people who are going to be new nursing graduates to generate interest in public health and TB work.

Dr. Belknap indicated that one of the other pieces of information the WG was seeking was to understand the funding for cooperative agreements through DTBE and how that has changed over the last decade or so. Looking at the funding amounts overall from 2010-2020, there was a decrease between 2012-2013. A variety of factors affected those changes that occurred. There were changes to/enforcement of contract severability rules that reduced funding flexibility and resulted in a shortfall of about $6 million. Sequestration resulted in a greater than $7 million reduction to the TB budget. The Pacific Islands cooperative agreement was consolidated at the NCHHSTP level, so $2.7 million in TB funding was carved out and moved to contracts.

Looking at these funding amounts in this bar chart adjusted for inflation between 2014-2022, the funding amounts are decreased, but only slightly until they are adjusted for inflation factors:



With the adjustment, it is clear to see that the funding amount has effectively decreased from roughly $85 million in terms of purchasing power to less than $70 million in purchasing power. The overwhelming majority of the funding is allocated to financial assistance of funding that goes out to jurisdictions versus the direct assistance of deployment of CDC staff to support programs.

TB nurses are vital to the work that is done and comprise a large proportion of people working in TB nationwide, as depicted in the COE and North Carolina surveys. In terms of what is known about nursing and the future of nursing, nursing is the nation's largest healthcare profession. Of the 4.2 million RNs nationwide, 84.1% are employed in nursing. The federal government projects that over 203,000 new RN positions will be created each year from 2021-2031. RNs are in high demand in a variety of areas: private practices, health maintenance organizations, public health agencies, primary care clinics, home health care, nursing homes, minute clinics, outpatient surgical centers, nursing school-operated clinics, insurance and managed care companies, schools, mental health agencies, hospices, the military, industry, nursing education, and healthcare research. As seen and experienced as an impact of the pandemic, the demand for nurses increased. In concordance with that, so did the salaries. For public health agencies to be able to compete with other groups who also are seeking nurses is becoming increasingly challenging from a salary perspective.

Key takeaway points from the TB Workforce WG are, first to define what is meant by “TB workforce” that is intentional about all of the positions/groups that make up a TB workforce (e.g., nurses, physicians with expertise in TB, disease intervention specialists, outreach workers, contact investigators, supporting staff, laboratorians, CHWs, community partners who are vital to progress in TB elimination, et cetera). Second, to standardize the process for ongoing, periodic assessments of the US TB workforce. Perhaps this could be done through a collaboration between the DTBE, COEs, and the NTCA. The WG had some email communications with the NTCA but was not able to connect with them. Certainly, the NTCA thinks deeply about this issue and how to assess it. They conducted a capacity survey in 2012 and a survey of sites in 2021 around what was occurring acutely with redeployments in response to the pandemic. One of the ideas that was raised in the WG was whether something could be incorporated into cooperative agreement reporting that includes workforce, with an eye toward a process that is standardized and occurs on a regular basis. The WG also felt that there need to be some estimates of the funding required to sustain the current TB workforce, including retention, training, recruitment, and funding to achieve TB elimination in the US.

ACET Discussion

Dr. Stout observed that the situation is going to be that funding for elimination of the disease is going to be eliminated before the disease is eliminated. The TB workforce probably should be considered from the perspective of the broader public health nursing workforce that can be employed for TB or at least cross-trained in TB. That makes a lot of sense because it is very clear that the need in public health is not going away with all of the emerging and re-emerging threats with vaccine-preventable diseases and everything else. He wonders if there might be more success with the ask if the ACET combines forces with other similar public health groups, perhaps within CDC and elsewhere, to encourage nurses to go into public health in general. Having more public health nurses benefits everyone, but the narrow appeal for more TB nurses is probably going to fall flat since TB cases are declining. Interventions are certainly needed to sustain the medical and nursing sides, but in terms of making the appeal for more people to go into TB, this request needs to be fairly broad.

Dr. Ahmed agreed and stressed that they need to “strike while the iron is hot.” Hopefully people learned from COVID-19 and Mpox that the health department workforce is needed.

Dr. Chen noted that NPR had a recent article about how fewer new trainees are choosing infectious disease. The gist of the article is that public health does not pay well enough and there it has been a burnout couple of years. Part of ACET’s advice might be that the DTBE consider looking at this as a central part of the survey and that in the long-run, survey questions should be asked that can be tracked over time. She like the suggestion of adding something into the routine cooperative agreement reporting in terms of the most meaningful baseline metrics that would be helpful to inform planning and education around what is occurring.

Dr. Belknap agreed that there needs to be better data and a broader strategy around this. CDC awarded $5 billion in public health infrastructure funding. He hopes and expects that jurisdictions have included in their applications the need to sustain and rebuild the public health nursing workforce as part of that. He worries that without some intentionality around raising the general awareness about some of the specialty training needs of someone to do TB nursing, that could get lost. In their role as ACET, they must consider how to advance what is needed for TB control and progress toward elimination and how to do that in the context of recognizing that the public health workforce and public health nursing really need a strategic approach to future growth and sustainability.

Dr. Horne suggested obtaining nursing representation as well to help address this problem.

Tara Rhodes from the BOP indicated that she is a Corrections Nurse, which also is a part of public health. She feels like it is getting better, but the lack of exposure to different types of public health is a problem. Most nursing programs have a public health course, but there are many avenues into public health so it is difficult to cover all of the different areas that a nurse could go into in one class in one semester of nursing school. Pay is another issue, especially when nurses are starting out or for those who received extra pay during COVID-19.

Dr. Sosa-Bergeron said that her understanding was that a good proportion of the $5 billion in public health infrastructure funding had to go to local health departments, which is another place they can focus. The value of public health nurses certainly was made clear during the pandemic. She is hopeful that more local health departments will maintain their nurses. Part of this relates to people even knowing what is available. For example, their local health department had someone do a nursing rotation there who had retired from corrections and is now becoming a nurse. They could capitalize on that type of exposure.

Dr. Belknap agreed that attracting people by giving them exposure has a great chance of success, because public health is not going to be competitive with other areas of nursing in terms of pay. What typically attracts people to public health is that they get exposed, it is mission-driven, and they get to work with other people who are passionate about caring for people and communities that often are under-served.

Dr. Sosa-Bergeron emphasized that public health is more flexible than shift work and allows for a normal work schedule.

Dr. Loeffler pointed out that there could be opportunities to engage with the 20% of nurses who have left the workforce. She loves that a lot of her nurses have medical/surgical experience.

Dr. Stout agreed that it would be a good strategy to try to attract later-career nurses who have significant experience but may be looking for a change.

Dr. Belknap commented that this has been their experience in Denver as well. They have 3 nurses, all of whom were not new graduates entering public health. A couple of them are later in their careers and like the idea of change. There is a degree of autonomy to the work that they do that is different from shift work in areas where the work may be more prescribed.

Dr. Narita asked whether there is a way the cooperative agreement contracts could encourage or facilitate local collaboration as a means of helping to sustain an effective TB workforce in an area or region.

Dr. Chen asked whether there are best practice nurse to case ratios for TB.

Dr. Belknap said he was not aware of that or whether anyone has assessed the case ratio distribution across jurisdictions. He would expect that similar to what Dr. Stout presented, it is pretty wide. In small rural areas there may be only 1 nurse who spends a part of her time on TB and there may be 1 case per year or every few years. In urban areas where there is more concentration, there is likely to be more patients.

Heidi Behm from NTCA commented that there are programs in the US which are starting to address the staffing/case ratios for TB. Virginia comes to mind.

Dr. Loeffler suggested that as the need is measured in TB work, more nuanced measurements are needed for the complexity of cases and value of LTBI identification/treatment in a given community.

Heidi Behm from NTCA indicated that she is an RN. In many rural areas in particular, the salaries are far too low and the RNs have to wear too many hats.

Susan Ruwe, who is an RN, asked how recruitment is done and how to advertise for job openings. She also noted that as a later career nurse, she could not afford the pay cut.

Dr. Belknap said he suspects that the approach to recruitment is highly variable depending upon the area of the country.

Dr. Ahmed noted that another group to "advertise" to would be APPs. They often are not exposed to public health, but it would broaden options for them, especially if some have aspirations for more leadership roles.

Vote

Dr. Belknap requested that the group return to the recommendations, come to agreement as a group, and take a vote on what the ACET might want to recommend as an outcome of this WG. The following high-level recommendations were proposed:

1. **ACET recommends that CDC define the key components of an effective public health TB workforce in the US.**

2. **ACET recommends that CDC develop a standard process for evaluation and periodic assessment of the US public health TB workforce.**

3. **ACET recommends that CDC consider a cost analysis to sustain the current TB workforce to achieve TB elimination in the US.**

A motion was properly placed on the floor by Dr. Horne and seconded by Dr. Ahmed to accept the recommendations as proposed. With no further discussion or changes, the motion to accept the recommendations as written carried unanimously with no abstentions or opposition.

ACET Biennial Working Group

Robert Belknap, MD
ACET Chair, TB Workforce WG Chair
Acting Director, Public Health Institute at Denver Health

Dr. Belknap reminded everyone that the ACET Biennial Working Group was charged with drafting the key priorities to include in the next biennial letter, due in June 2023, for discussion with ACET. Dr. Belknap was designated as the Chair and the members include Lynn Sosa-Bergeron, Lixia Liu, David Horne, Ann Loeffler, and Lisa Chen. The process included reviewing recent prior letters that were sent from the ACET to HHS and conducting a survey of ACET

member groups and liaisons to identify the priorities of those key partners. This WG has met 5 times since its establishment in June 2022.

In terms of recent prior letters, the most recent of which was in June 2021, recommendations focused on the following key areas:

- Provide financial resources for TB prevention
- Provide mandatory coverage of diagnosis and treatment of LTBI by CMS
- Remove barriers to no-cost sharing
- Increase CDC and NIH research funding
- Remove barriers to TB/LTBI treatment for persons incarcerated or recently released
- Strengthen HHS support for addressing TB in congregate settings and transnationally
- Establish a Presidential TB Elimination Initiative

To summarize the major current challenges, there have been decreases in the TB workforce and expertise; increases in the complexity of cases in people with TB; real and functional reductions in CDC funding; inequities in the access to care for early diagnosis, prevention, and treatment; and an inability to access the newest diagnostic tests and medications. The ACET Biennial Working Group tried to narrow its focus and develop more specific recommendations as best they could, which resulted in the following:

1. Strengthen the TB public health infrastructure:

    - COVID-19 has caused a redirection of TB staff resulting in delayed case management, contact investigation, and TB prevention activities.

    - Restore funding for TB programs that is adjusted annually to account for usual inflation. Additional funding is needed for TB elimination.

    - Support CDC efforts in data modernization, including the seamless sharing of data for people newly arriving in the US or moving between states and jurisdictions.

2. Expand equitable access to all jurisdictions for diagnostic testing and treatment:

    - Increase communication efforts to close the knowledge gap for providers and available testing.

    - Ensure that medications needed to treat TB are available to all people in the US regardless of where they live, the state and local jurisdictional funding, or their insurance:
        - Includes newer drugs such as bedaquiline, pretomanid, and linezolid.
        - Includes formulation of approved drugs that are available outside the US such as pediatric friendly formulations (many adults would also benefit).

    - Ensure that molecular diagnostic tests keep pace with treatment expansion:
        - Access to the best available tests (ex. GeneXpert® Ultra and MTB/XDR)
        - Include molecular resistance for unique specimen types (pleural fluid, spinal fluid, stool, tissue).

3. Expand access to TB prevention for patients with the highest need:

    - HHS designating LTBI evaluation and treatment as a covered service in Medicare and Medicaid.

    - Centers for Medicare and Medicaid Services to establish a mandatory national coverage determination for LTBI testing and treatment and to develop a metric for evaluating performance.

    - Remove barriers to no-cost sharing for treating persons with LTBI – needs more specifics.

4. Address TB in priority populations to increase equity:

    - Meet people where they are.

    - Increase access to testing and preventive treatment for people who:
        - Have lived outside the US
        - Are incarcerated or have been recently released from a correctional setting
        - Are experiencing homelessness
        - Are uninsured
        - Vulnerable populations, including black, indigenous, and people of color (BIPOC)

5. Increase investments in TB research (clinical and basic):

    - HHS to increase basic and translational science funding to the NIH and CDC for the diagnosis and treatment of TB infection and disease.

ACET Discussion

Dr. Belknap indicated that if the ACET could agree on the priority areas and the general language, the ACET Biennial Working Group can refine that language outside of the meeting. They just could not add anything, such as another priority. If they need to add something, then they would need to present again during the June ACET meeting.

Lornel Tompkins, Liaison for the National Medical Association (NMA), suggested specifically including vulnerable communities when listing areas for outreach, such as minority, Native Americans, et cetera. A lot of times, that gets lost in translation or is assumed. Those are communities for which access has been a problem. The majority of TB cases within the US are occurring in the African American community.

Dr. Belknap indicated that this would fit under Recommendation 4 regarding priority populations. He asked whether BIPOC would capture this or if the categories should be spelled out for black, indigenous, and people of color (BIPOC). There was agreement that this would be acceptable.

Dr. Liu suggested that for Recommendation 2, perhaps they could ask CDC to facilitate the connection between what is available and the gap related to communication.

Dr. Belknap said that for the purpose of the letter, they would not call out specific test platforms or manufacturers. Instead, they make a broad recommendation around ensuring that the best available tests are accessible.

Dr. Loeffler recalled that they talked about “competency” for all public health “TB workforce” to be aware of advanced laboratory resources available to clients in their jurisdictions. She is learning new surprising things all of the time. She just learned about what appears to be a home grown Xpert MTB type test for tissue. People need a ready resource to see what is available. Therefore, people who do not do TB quite as much or are not as up to date on molecular tests could have that available for their clients.

Dr. Belknap agreed that this is needed, but emphasized that the recommendation should be broader than just awareness of what is available in a jurisdiction. There needs to be an intentional effort to ensure that the best tests and medications are available uniformly in all jurisdictions and that there are no barriers to accessing them.

Dr. Loeffler pointed out that if they start by defining what is available to everybody, they may see where the big gaps are. California has amazing resources.

Dr. Belknap suggested that language could be captured in a sub-bullet regarding the awareness of current availability and gaps. Certainly, a part of addressing and ensuring availability is understanding what actually is available.

Dr. Loeffler suggested wording this as “work toward” instead of “ensure,” which is never going to happen. She preferred more realistic wording.

Dr. Belknap noted that the WG did not do a lot with Recommendation #5. This was in previous recommendations, so they kept it.

Dr. Loeffler suggested adding more specificity about what would be most impactful. Perhaps mention a few things that would have high impact because of new science emerging or new vulnerable populations.

Vote

The ACET agreed in principle with the high-level numbered priority topic areas for recommendations and in general on the language that supports them, with the following edits:

#2: Change “ensure” to “expand” all jurisdictions have equitable access to diagnostic testing
#2: Add “increase communication efforts to close the knowledge gap for providers”
#4: Add “vulnerable populations, people of color, and indigenous populations” and perhaps use “BIPOC”

A motion was properly placed on the floor by Dr. Stout and seconded by Dr. Sosa-Bergeron to accept the high-level topics/recommendations as proposed, with the proposed edits incorporated. With no further discussion or changes, the motion to accept the recommendations as written carried unanimously with no abstentions or opposition.

ACET Business Session

Robert Belknap, MD
Acting Director, Public Health Institute at Denver Health
ACET Chair

Dr. Belknap opened the Business Session and facilitated a review of old and current business items that warranted ACET's formal action and allowed time for additional discussion and requests for future agenda items.

Business Item 1: Approval of Previous ACET Meeting Minutes

A motion was properly placed on the floor by Dr. Sosa-Bergeron and seconded by Dr. Stout to accept the minutes from the June 21-22, 2022 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: Advice from ACET Workgroup Activities

Dr. Belknap reminded the members that one of ACET's responsibilities is to provide advice to HHS and the CDC. Together they reviewed advice requested from ACET on Working Group Activities, e DOT Guidelines, TEA, and CDC Support for U4U.

Vote: TEA
A motion was properly placed on the floor by Dr. Loeffler and second by Dr. Sosa-Bergeron for **CDC to continue to provide funding and support for the work of the TEA, evaluate the impact, and compile and disseminate best practices.** With no further discussion or changes, the motion carried unanimously with no abstentions or opposition.

Business Item 3: Resolution Related to Drug Shortages

Drs. Belknap and Sosa-Bergeron presented a draft resolution related to drug shortages, which read as follows subsequent to discussion and proposed edits by the full ACET:

> Resolution:
>
> **Therefore, ACET respectfully requests that the Secretary of Health and Human Services prioritize developing a robust process for evaluating the root causes of barriers to acquiring and distributing medications broadly in the US:**
>
> - **Prioritize continuous and equitable access to TB medications and other medications for diseases of public health importance.**
> - **Investigate root causes of shortages and develop solutions to ensure timely access and treatment for TB and other diseases of public health importance.**

Vote: Resolution Related to Drug Shortages

A motion was properly placed on the floor by Dr. Ahmed and seconded by Dr. Stout to accept the resolution as proposed. With no further discussion or changes, the motion carried unanimously with no abstentions or opposition.

December 2022 Topics	Action
1) **Electronic Data Systems of Overseas Medical Evaluations**	• DGMQ has been working closely with the NTCA. There also are some bigger issues and the DGMQ would be happy to receive any comments and continue to move forward where they can. • The EHR highway is looking like one of the directions they are moving toward, projecting early in 2023 to begin to start connecting DGMQ's records to states. This is currently being done through the Public Health Information Network Messaging System (PHINMS) transport system, which is older, and Data Downloads. The need is to have Health Level Seven (HL7) and then having it go through a transport mechanism like an Ivy Gateway. • ACET requested real-time feedback on the new immigration/refugee process to answer these outstanding questions: are providers able to see images and obtain notes, are some states better served than others, can we consider somehow moving towards alignments with EMRs, are international adoptees being captured?
2) **TB Diagnostics in the US Market**	• NTCA is probably the better partner for working with Cepheid on the wish list and trying to move this forward, which is outside the scope of the ACET.
3) **vDOT Guidelines**	• No Action by ACET; guidelines were well-received.
4) **TB Elimination Alliance (TEA)**	• CHWs who started working on COVID most recently started to transition their work and are engaged in support work for TEA, including outreach and education for TB now. Many community organizations have resources to have CHWs now. It is known that once COVID dollars sunset CHW will not be sustained by their community organizations. However, many community organizations have learned the benefits of CHWs and are asking TEA to help them find opportunities to retain them given the enhanced visibility and credibility that they have to champion on behalf of their communities. • ACET Discussed focusing efforts by comorbidities such as diabetes and HIV. • ACET noted the approach TEA has taken to empowering communities is a better approach to TB outreach than what has historically been done.
5) **CDC Support for U4U**	• There was not a specific ask with regard to this topic. ACET is supportive of this effort, but there did not seem to be any votes necessary at this time. • One of the needs in terms of the EDN is moving USCIS along. ACET is supportive of any efforts that HHS and CDC can make to continue and accelerate the movement to digitized TB records.

December 2022 Items Voted Upon	Action
1) **Biennial Letter Working Group**	• ACET agreed in principle with the high-level numbered priority topic areas for recommendations and in general on the language that supports them. They voted unanimously to accept the 5 priority areas, with the proposed edits incorporated.

2) **TB Workforce Working Group**	• ACET voted unanimously to accept the recommendations proposed by the TB Workforce Workgroup:
	  • ACET recommends that CDC define the key components of an effective public health TB workforce in the US.
	  • ACET recommends that CDC develop a standard process for evaluation and periodic assessment of the US public health TB workforce.
	  • ACET recommends that CDC consider a cost analysis to sustain the current TB workforce to achieve TB elimination in the US.

3) **TB Elimination Alliance (TEA)**	• ACET voted unanimously to recommend that. CDC continue to provide funding and support for the work of the TEA, evaluate the impact, and compile and disseminate best practices.

4) **Resolution Related to Drug Shortages**	• ACET voted unanimously to accept the proposed resolution to HHS:
	  • ACET respectfully requests that the Secretary of Health and Human Services prioritize developing a robust process for evaluating the root causes of barriers to acquiring and distributing medications broadly in the US:
	  • Prioritize continuous and equitable access to TB medications and other medications for diseases of public health importance.
	  • Investigate root causes of shortages and develop solutions to ensure timely access and treatment for TB and other diseases of public health importance.

Business Item 4: Future Agenda Items

Due to time constraints, Dr. Belknap indicated that future agenda topics would be sought outside the meeting.

Closing & Adjourn

Robert Belknap, MD
Acting Director, Public Health Institute at Denver Health
ACET Chair

Deron Burton, MD, JD, MPH (CAPT, USPHS)
Acting Director, National Center for HIV, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control & Prevention
ACET Designated Federal Officer (DFO)

Dr. Belknap expressed appreciation to the ACET members for their time and discussion during this helpful and productive meeting. He offered special thanks to Marah Condit and Becca Pope Alley for keeping them organized leading up to this meeting and throughout the 2 days of the meeting.

CAPT Burton echoed Dr. Belknap's sentiments that this was a fantastic ACET meeting. He thanked all of the members, *ex officios*, liaisons, other participants, and the support team who worked behind the scenes to make this a smooth and successful meeting. He announced that the June 20-21, 2023 ACET meeting would be hybrid, which would allow for the opportunity to attend the meeting in-person in Atlanta or virtually. The second meeting for the year will be December 12-13, 2023.

With no further discussion or business brought before ACET, the meeting was officially adjourned at 12:00 pm on December 14, 2022.

Chair's Certification

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

Date

Robert Belknap, MD, Chair
Advisory Council for the Elimination of Tuberculosis

Attachment 1: Participants' Directory

ACET Members Present

Dr. Robert Belknap, Chair
Dr. Amina Ahmed
Dr. Lisa Chen
Dr. David Horne
Dr. Lixia Liu
Dr. Ann Loeffler
Dr. Lynn Sosa-Bergeron
Kristine Steward-East
Dr. Jason Stout
Dr. Zelalem Temesgen

ACET *Ex-Officio* Members Present

Dr. Naomi Aronson
US Department of Defense

Dr. Amy Bloom
US Agency for International Development

Dr. Karen Elkins
Food and Drug Administration

Dr. Jonathan Iralu
Indian Health Service

Dr. Edith (Edie) Lederman
US Immigration and Customs Enforcement

Dr. Lawrence Kline
US Section, US-Mexico Border Health Commission

Stephen Martin
National Institute for Occupational Safety and Health

CDR Tara Rhodes
Federal Bureau of Prisons

Dr. Gary Roselle
Department of Veteran Affairs

Dr. Laura Sessums
Agency for Healthcare Research and Quality

Dr. Mamodikoe Makhene
National Institutes of Health

ACET *Ex-Officio* Members Absent

Dr. Ronald Wilcox
Health Resources and Services Administration

CAPT David Wong
Office of Minority Health

ACET Liaison Representatives Present

Dr. Shama Desai Ahuja
Council of State and Territorial Epidemiologists

Dr. Natasha Bagdasarian
Association of State and Territorial Health Officials

Dr. Robert Benjamin
Stop TB USA

Heidi Behm
National Tuberculosis Controllers Association

Valerie Adelson
American Thoracic Society

Dr. Jonathon Golub
International Union Against TB and Lung Disease

Colin Puzo Smith
RESULTS

Dr. Masahiro Narita
National Association of County and City Health Officials

Susan Ruwe
Association for Professionals in Infection Control and Epidemiology

Dr. Sylvie Stacy
National Commission on Correctional Health

Dr. Lornel Tompkins
National Medical Association

Kendall Martines-Wright
Treatment Action Group

Dr. Amee Patrawalla
American College of Chest Physicians

Dr. Susan Ray
Infectious Disease Society of America

Andrew Tibbs
Association of State and Territorial Health Officials

Dr. Mayleen Ekiek
Pacific Island Health Officers Association

ACET Liaison Representatives Absent

Susan Rappaport
American Lung Association

Dr. Ilse Levin
American Medical Association

Dr. Howard Njoo
Public Health Agency of Canada

Dr. Gudelia Rangel
Mexico Section, US-Mexico Border Health Commission

Dr. David Weber
Society for Healthcare Epidemiology of America

Dr. Daphne Ware
Association of Public Health Laboratories

ACET Designated Federal Officer

CAPT Deron Burton
NCHHSTP Acting Director

CDC Representatives

Rebeccann Pope Alley
Derek Armstrong
Garrett Asay
Elvy Barroso
Kevin Borden
Misty Carlson
Elise Caruso
Kathy Chapuran
Terry Chorba
Jenna Colliflower
Marah Condit
Kelly Curtis
Amanda Dam
Nickolas DeLuca
Felicia Dworkin
Kiara Everett
Mari Galvis
Maryam Haddad
Savannah Harrelson
Kay Hendricks
Nicolas Jarboe
John Jereb
Stephanie Johnston
Hannah Jordon
Kathryn Koski
Ekaterina Kurbatova
C. Kin Lam
Adam Langer
Deborah Lee
Philip LoBue
Autumn Logsdon
Marissa Ly
Allison Maiuri
Joan M. Mangan
Suzanne Marks
Luc Marzano
Susan McClure
Meredith Moore

CDC Representatives (continued)

Selma Moore
Pat Nosko
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Attachment 2: Glossary of Acronyms

Acronym	Definition
AAPCHO	Association of the Asian Pacific Community Health Organizations
ACET	Advisory Council for the Elimination of Tuberculosis
ADA	American Diabetes Association
AE	Adverse Event
AHRQ	Agency for Healthcare Research and Quality
AI	Artificial Intelligence
AI/AN	American Indian/Alaskan Native
AIDS	Acquired Immunodeficiency Syndrome
AIS	Alien Information System
APIAHF	Asian and Pacific Islander American Health Forum
ARPE	Aggregate Reports for TB Program Evaluation
ASTHO	Association of State and Territorial Health Officials
BDQ	Bedaquiline
BIPOC	Black, Indigenous, and People of Color
BOP	Federal Bureau of Prisons
BPaL	Bedaquiline, Pretomanid, and Linezolid
BSL	Biosafety Level
CBO	Community-Based Organization
CBP	Customs and Border Protection
CDC	Centers for Disease Control and Prevention
CHWs	Community Health Workers
CITC	Curry International TB Center
COE	Centers of Excellence
COI	Conflict of Interest
CPSTF	Community Preventive Services Task Force
CSTE	Council of State and Territorial Epidemiologists
CSTLTS	Center for State, Tribal, Local, and Territorial Support
CXR	Chest X-Ray
DASH	Division of Adolescent and School Health
DC	District of Columbia
DCIPHER	Data Collection and Integration for Public Health Event Response

Acronym	Definition
DDID	Deputy Director of Infectious Diseases
DFO	Designated Federal Official
DGMQ	Division of Global Migration and Quarantine
DHP	Division of HIV Prevention
DHS	Department of Homeland Security
DoD	Department of Defense
DOT	Directly Observed Therapy
DST	Drug-Susceptibility Testing
DSTDP	Division of STD Prevention
DTBE	Division of Tuberculosis Elimination
DVH	Division of Viral Hepatitis
EDN	Electronic Disease Notification
eDOT	Electronic Directly Observed Therapy
EHE	Ending the HIV Epidemic
EHR	Electronic Health Record
EMR	Electronic Medical Record
ET	Eastern Time
FACA	Federal Advisory Committee Act
FDA	(United States) Food and Drug Administration
FQHCs	Federally Qualified Health Centers
GSA	Gay-Straight Alliance
GTBI	Global TB Institute
HBV	Hepatitis B Virus
HCP	Healthcare Providers/Professionals
HCV	Hepatitis C Virus
Hep	Hepatitis
HHS	(United States) Department of Health and Human Services
HIV	Human Immunodeficiency Virus
HL7	Health Level Seven
HRSA	Health Resources and Services
ICE	Immigration and Customs Enforcement
IDSA	Infectious Diseases Society of America
IGRA	Interferon-γ Release Assay
IMP	Information of Migrant Population
IND	Investigational New Drug
INH	Isoniazid
JAMA	*Journal of the American Medical Association*
LGBQ	Lesbian, Gay, Bisexual, and Queer/Questioning
LGBT	Lesbian, Gay, Bisexual, and Transgender
LHD	Local Health Department
LoD	Limit of Detection

Acronym	Definition
LRN	Laboratory Response Network
LTBI	Latent Tuberculosis Infection
MAC	Mycobacterium Avium Complex
MCCT	Mayo Clinic Center for Tuberculosis
MDR-TB	Multidrug-Resistant Tuberculosis
MEMS	Medication Event Monitoring Systems
MGIT	Mycobacteria Growth Indicator Tube
ML	Machine Learning
MMP	Medical Monitoring Project
MMWR	*Morbidity and Mortality Weekly Report*
MPOX	Monkeypox
MTB	Mycobacterium Tuberculosis
NAAT	Nucleic-Acid Amplification Test
NASTAD	National Alliance of State and Territorial AIDS Directors
NCHHSTP	National Center for HIV, Viral Hepatitis, STD and TB Prevention
NCIRD	National Center for Immunization and Respiratory Diseases
NH/PI	Native Hawaiian and Pacific Islander
NHAS	National HIV/AIDS Strategy Federal Implementation Plan
NIH	National Institutes of Health
NMA	National Medical Association
NOFO	Notice of Funding Opportunity
NQS	National Quality Standards
NTCA	National Tuberculosis Controllers Association
NTIP	National Tuberculosis Indicators Project
NTM	Nontuberculous Mycobacteria
NTSS	National Tuberculosis Surveillance System
NYC	New York City
OAW	Operation Allies Welcome
OMB	Office of Management and Budget
PCC	Probe Check Control
PCP	Primary Care Providers
PCR	Polymerase Chain Reaction
PHAP	Public Health Associate Program
PHINMS	Public Health Information Network Messaging System
PrEP	Pre-Exposure Prophylaxis
QFT	QuantiFERON®-TB Blood Test
RCT	Randomized Controlled Trial
RoB-2	Revised Tool for Assessing Risk of Bias in Randomised Trials
RPT	Rifapentine
RRDR	Rifampin-Resistance Determining Region
SME	Subject Matter Expert

Acronym	Definition
SNTC	Southeastern National TB Center
SSP	Syringe Services Programs
STI	Sexually Transmitted Infections
TA	Technical Assistance
TAG	Treatment Action Group
TB	Tuberculosis
TBCB	California Tuberculosis Control Branch
TBTC	Tuberculosis Trials Consortium
TEA	Tuberculosis Elimination Alliance
U4U	United for Ukraine
US	United States
USCIS	United States Citizenship and Immigration Services
USG	United States Government
USPHS	United States Public Health Service
USPSTF	United States Preventive Services Task Force
VACF	Vietnamese American Cancer Foundation
vDOT	Video-Supported Directly Observed Therapy
WG	Working Group
WHO	World Health Organization
XDR-TB	Extensively Drug-Resistant TB