

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



**Virtual Meeting of the
Advisory Council for the Elimination of Tuberculosis
August 21, 2018**

Record of the Proceedings

TABLE OF CONTENTS

	<u>Page</u>
Minutes of the Virtual Meeting	1
Opening Session.....	1
NCHHSTP Director’s Report.....	4
DTBE Director’s Report.....	8
Update on TB Prevention Research.....	11
DHAP’s Strategy of Adopting HIV Treatment as Prevention (TasP).....	15
Update on DTBE’s Concept of Operations for LTBI Surveillance	19
Update by the Child and Adolescent Workgroup.....	23
Update by the Essential Components Workgroup.....	24
Update by the TB Drug Supply Workgroup	24
Update by the LTBI Workgroup.....	24
ACET Business Session	24
Business Item 1: Approval of Previous ACET Meeting Minutes	25
Business Item 2: ACET Letter to the HHS Secretary	25
Business Item 3: NTCA Collaborative Workgroup on Training Centers and Consultation	25
Business Item 4: CDC Office of Infectious Diseases Board of Scientific Counselors	25
Business Item 5: Advice Requested from ACET.....	26
Business Item 6: Future Agenda Items.....	27
Public Comment Session	29
Closing Session	29
Attachment 1: Participants’ Directory.....	30
Attachment 2: Glossary of Acronyms.....	33



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**ADVISORY COUNCIL FOR THE ELIMINATION OF TUBERCULOSIS
August 21, 2018**

Minutes of the Virtual Meeting

The U.S. Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC), National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP), Division of Tuberculosis Elimination (DTBE) convened a virtual meeting of the Advisory Council for the Elimination of Tuberculosis (ACET). The proceedings were held on August 21, 2018 beginning at 10:00 a.m. EST.

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

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

Opening Session

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

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

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

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

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

Dr. Dean confirmed that the 18 voting members and *ex-officio* members in attendance (or their alternates) constituted a quorum for ACET to conduct its business on August 21, 2018. She called the proceedings to order at 10:03 a.m. EST and welcomed the participants to the virtual ACET meeting.

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

- The participants were asked to join Dr. Dean in welcoming the new ACET members and alternates who were attending the meeting on behalf of their absent colleagues.

New ACET Members

- Dr. Robert Belknap, Medical Director
Denver Metro Tuberculosis Control Program, Denver Public Health
- Dr. David Horne, Associate Professor
University of Washington School of Medicine
- Dr. Lixia Liu, Director, Scientific Laboratory Division
New Mexico Department of Health
- Dr. Zelalem Temesgen, Executive Director, Department of Internal Medicine
Mayo Clinic Center for Tuberculosis

New ACET Ex-Officio Members

- Dr. Jonathan Iralu, Chief, Clinical Consultant for Infectious Diseases
Indian Health Service
- Dr. Thomas Nerad, Office Director, Biological Hazards
U.S. Department of Labor/Occupational Safety and Health Administration

New ACET Liaison Representatives

- Ms. Diana Fortune, President
Representing the National Tuberculosis Controllers Association (NTCA)
- Dr. John Hellerstedt, Texas Department of State Health Services
Representing the Association of State and Territorial Health Officials
- Ms. Susan Ruwe, Senior Infection Preventionist, Carle Foundation Hospital
Representing the Association for Professionals in Infection Control and
Epidemiology

Alternates

- CMDR Julie King; Attending for Ms. Sarah Bur, Federal Bureau of Prisons
 - Dr. Samuel Wu; Attending for Dr. Matthew Lin, U.S. Department of Health and
Human Services, Office of Minority Health
- CDC sent a letter to the HHS Office of Global Affairs with a request to identify a new *ex-officio* member for the U.S. Section of the U.S.-Mexico Border Health Commission.
 - CDC sent a letter to the Health Resources and Services Administration (HRSA) with a request to identify a new *ex-officio* member to replace Dr. Deborah Parham Hopson who retired from HRSA on April 30, 2018.
 - CDC is seeking a qualified candidate to be considered for ACET membership for a four-year term. The candidate should be an individual who has had TB disease or is the parent of a child who has TB disease. CDC is encouraging ACET members to nominate interested candidates who meet these qualifications and submit the following information to Ms. Margie Scott-Cseh, the ACET Committee Management Specialist (zkr7@cdc.gov), by September 30, 2018:
 - Candidate's name and affiliation
 - Candidate's basis for nomination (e.g., experience, education, and position served)
 - Written confirmation of the candidate's interest in membership (e.g., the candidate's address, telephone number, email address, and current curriculum vita or résumé)

In response to Dr. Horsburgh's question, Dr. Dean will confirm whether ACET members are required to be U.S. citizens. She will report her findings to assist ACET and NTCA members who are interested in nominating potential candidates for the upcoming vacancy.

Barbara Cole, RN, MSN, PHN, ACET Chair

TB Controller

Riverside County (California) Department of Public Health

Ms. Cole also welcomed the participants to the virtual ACET meeting. She reviewed the agenda and confirmed that several recurring topics would be presented during the meeting:

updates by the NCHHSTP and DTBE Directors, updates by the ACET workgroups, and the Business Session. She also pointed out that three presentations by CDC staff were placed on the agenda in direct response to ACET's previous requests.

NCHHSTP Director's Report

Jonathan Mermin, MD, MPH (RADM, USPHS)

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

Dr. Mermin covered several topics in the NCHHSTP Director's report to ACET. NCHHSTP recently announced the addition of new staff in the Office of the Director: CMDR Deron Burton (Associate Director for Health Equity and Director of the Office of Health Equity) and Ms. Rachel Powell (Associate Director for Communication Science).

NCHHSTP updated AtlasPlus with several new indicators. The user-friendly online tool can be used to access core surveillance information on NCHHSTP's four diseases of interest: HIV, viral hepatitis, STDs, and TB. The new indicators are outlined below.

- *New social determinants of health indicators*
 - Uninsured
 - Less than a high school education
 - Rural, suburban, or urban residence
 - Below federal poverty level
 - Vacant housing

- *New HIV indicators*
 - Linkage to care
 - Receipt of HIV care
 - Viral suppression
 - Estimated incidence
 - Estimated prevalence (diagnosed and undiagnosed)
 - Percentage of people persons diagnosed HIV infections among all people living with HIV (PLWH) infection

[AtlasPlus](#) is available to the public.

NCHHSTP recently updated its [Pregnancy and HIV, Viral Hepatitis, STD, and TB Prevention Website](#). The updated website includes the latest data on pregnancy and HIV, viral hepatitis, STDs, and TB infection and prevention; describes the implications of these diseases for pregnant women and newborns; highlights CDC's activities in these areas; and provides information on screening guidelines for health care providers.

NCHHSTP recently hosted a site visit to CDC that was organized by the Federal AIDS Policy Partnership (FAPP). The visitors included leaders from 22 FAPP partner organizations that are involved in HIV/AIDS, viral hepatitis, STDs, and TB prevention, and/or adolescent health. The site visit included an overview of NCHHSTP's priorities and activities as well as tours of the TB, HIV, STD, and viral hepatitis laboratories.

DTBE recently updated CDC's 2011 recommendations on the use of three months of isoniazid/rifapentine (3HP) to treat latent TB infection (LTBI). The updated recommendations are targeted to people over two years of age, people with LTBI and HIV/AIDS, and people being treated by directly observed therapy (DOT) or self-administered therapy. The recommendations are available on the CDC.gov website and highlights four major benefits of the 12-dose regimen for LTBI: prevents TB disease, saves money, results in higher treatment completion, and is convenient for patients. DTBE was pleased to note that CDC's updated recommendations are supported by research conducted by the Tuberculosis Trials Consortium (TBTC) and reflects extensive input from ACET and expert consultation.

The Division of Adolescent and School Health (DASH) released the *CDC 2017 National Youth Risk Behavior Survey (YRBS) Results and Trend Report*. DASH conducts the YRBS on a biennial basis with a nationally representative sample of schools across the country. DASH uses YRBS data to monitor risk behaviors and other important health issues among high school students in the United States. The 2017 YRBS and *Trend Report* covered the 10-year period of 2007-2017 and reported the following key outcomes.

- Fewer U.S. high school students are having sex and using drugs, but too many students are still at risk for HIV and STDs.
- Of all U.S. high school students included in the 2017 YRBS, 1 in 7 reported ever misusing prescription opioids.
- Condom use declined from 58 percent to 54 percent.
- A decrease was observed in racial/ethnic disparities in terms of sexual initiation.
- Sexual risk behaviors have declined in some U.S. high school students:
 - Those having sex declined from 46 percent in 2001 to 40 percent in 2017.
 - Those with four or more lifetime partners declined from 14 percent to 10 percent.

DASH announced the grant recipients of CDC's five-year CoAg, "Promoting Adolescent Health Through School-Based HIV Prevention." The average funding request of \$80,265 was awarded to the following recipients to support school-based surveillance: 31 state education agencies, 19 state public health agencies, 28 local education agencies, one territorial agency, and one tribal agency. The average funding request of \$313,554 was awarded to 28 local education agencies to support school-based HIV/STD prevention. Funding also was awarded to six non-governmental organizations to provide technical assistance (TA) and capacity building. The programmatic components of the CoAg are expected to reach 2.2 million students.

The Division of Viral Hepatitis (DVH) issued a [surveillance report](#) that showed a 44 percent increase in hepatitis A virus (HAV) cases due to two large outbreaks associated with food. DVH led CDC's response to a multi-state HAV outbreak among people reporting drug use or homelessness. From January 2017 to April 2018, more than 4,000 HAV infections were reported to CDC. The CDC health advisory that was released in June 2018 recommended vaccinations for people at increased risk. CDC implemented its Incident Manager Structure in July 2018 to support states with HAV outbreaks.

The DVH surveillance report also showed that the reported number of hepatitis B virus (HBV) cases decreased by 5 percent from 2015 and the reported number of hepatitis C virus (HCV) cases increased by 22 percent from 2015. The national opioid crisis primarily was responsible for the increase in HCV cases.

The Advisory Committee on Immunization Practices recommended a new two-dose HBV vaccine for adults. The recommendation for the use of Heplisav-B was published in the April 20, 2018 edition of the *Morbidity and Mortality Weekly Report (MMWR)*. The vaccine is available for adults 18 years of age and older. Heplisav-B represents the first new HBV vaccine in the United States in more than 25 years and is the only two-dose HBV vaccine for adults.

The Division of HIV/AIDS Prevention (DHAP) is leading CDC's new Act Against AIDS initiative, "[Transforming Health: Patient-Centered HIV Prevention and Care](#)." The new campaign provides materials for health care providers to deliver HIV care to transgender patients, increase HIV testing, promote HIV prevention strategies, and help transgender people enroll in and remain in care. The campaign also includes information for transgender people on HIV prevention therapy.

DHAP awarded \$14.6 million to 20 health departments to enhance CDC's high-impact HIV prevention demonstration projects. The grant recipients will use their funds to develop demonstration projects to enhance and expand high-impact HIV prevention and surveillance strategies. The grant recipients will implement the following strategies:

- Improve pre-exposure prophylaxis (PrEP) use and adherence for specific groups and geographic areas, such as Black and Latino men
- Implement interventions to address social and structural factors
- Use innovative methods, such as molecular epidemiology, to limit HIV cluster growth
- Expand access to medical care through telemedicine

The CDC National Prevention Information Network (NPIN) and Emory University jointly developed and released a national directory of health care service providers who offer PrEP. The directory includes more than 1,800 public and private PrEP providers. The NPIN also released a PrEP locator widget to locate providers by zip code.

DHAP recently issued the *HIV Monitoring Report* with 2016 surveillance data from the United States and 40 jurisdictions. The report showed an increase in HIV viral suppression. Most notably, 85.5 percent of PLWH knew their status in 2015; 75.9 percent of newly diagnosed people were linked to medical care; and youth and people who inject drugs were less likely to be virally suppressed.

The Division of STD Prevention (DSTDP) released CDC's new Notice of Funding Opportunity (NOFO) to health departments to strengthen STD prevention and control. The project period of the new five-year CoAg will be from 2019-2023. Of the total estimated \$95 million that will be awarded to 59 health departments, the individual grant recipients will receive funding ranging from \$300,000 to more than \$7 million based on their burden of disease and other factors. The health departments will use their grants to conduct various activities:

- Conduct STD surveillance
- Respond to STD outbreaks
- Identify and link people and their partners who have STDs to care and treatment
- Promote screening, diagnosis, and treatment among providers
- Develop partnerships to support STD prevention and control
- Analyze data for program improvement

DSTDP published an article in the April 17, 2018 edition of the *MMWR* that reported gonorrhea patients received CDC's recommended treatment to prevent antimicrobial resistance. The CDC STD Surveillance Network (SSuN) found that 81 percent of patients with gonorrhea received CDC's recommended treatment of dual therapy to help prevent the emergence of antimicrobial resistance. Patients who were treated in STD, family planning, and reproductive health clinics were more likely to receive dual therapy than those who visited urgent care, hospital emergency rooms, or private providers.

ACET DISCUSSION: NCHHSTP DIRECTOR'S REPORT

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

- Reports to CDC of waning HAV or HBV vaccine efficacy due to the increase in the number of viral hepatitis cases and the aging population.
- The ability of CDC's surveillance system to document the impact of the national opioid epidemic on TB patients.
- The extent to which CDC's SSuN data are nationally representative.
- The large disparity between NCHHSTP's release of NOFOs for health department-based demonstration projects that focus on HIV versus those for TB.

ACET GUIDANCE

- Dr. Reves advised CDC to consider the possibility of adding two key questions to the YRBS. (1) "Have you lived in a country in Asia, Africa, or Latin America for at least three months?" (2) "If so, have you had a test for TB or been treated for TB infection?"

NCHHSTP leadership provided follow-up remarks to some of ACET's questions and suggestions. Dr. Mermin confirmed that new questions can be added to the YRBS, but CDC initiates this process by first piloting and testing any proposed variables in specific jurisdictions. CDC also must be mindful of the extent to which self-reported data from high school students will be accurate. He planned to engage DTBE and DASH leadership to discuss expanding the YRBS with more TB-related questions.

Dr. LoBue explained that because the HIV budget is approximately five times larger than the TB budget, DHAP has more flexibility to spend funds on demonstration projects than DTBE. DTBE also has minimal discretionary funding because its budget primarily is set aside for CoAgs with state and local TB programs, the TB laboratory, the two TB research consortia, and internal operating costs. The release of NOFOs for health department-based demonstration projects that focus on TB would require DTBE to transfer funds from another area, particularly the extramural TB CoAg program. Moreover, DTBE's previous efforts to conduct TB programmatic and epidemiologic demonstration projects were unsuccessful due to the inability to hold grant recipients accountable for these initiatives.

Dr. LoBue noted that the Tuberculosis Epidemiologic Studies Consortium (TBESC) is similar to a demonstration project in some areas because the competitive funding supports collaboration between academia and health departments. For example, the TBESC investigators are beginning to focus on innovation related to LTBI.

DTBE Director's Report

Philip LoBue, MD

Director, Division of Tuberculosis Elimination
Centers for Disease Control and Prevention

Dr. LoBue covered four key areas in the DTBE Director's report to ACET: (1) CDC's fiscal year (FY) 2019 budget, (2) "Primary Care and Public Health: Partners in Prevention" meeting; (3) high-level TB meetings; and (4) ICD-10 Coding Workgroup.

CDC's FY2019 BUDGET

The new fiscal year will begin on October 1, 2018. Based on the House and Senate draft appropriations for FY2019, DTBE will receive level funding of approximately \$142 million.

"PUBLIC HEALTH AND PRIMARY CARE: PARTNERS IN PREVENTION MEETING"

NCHHSTP convened the Partners in Prevention meeting on May 7-8, 2018 with representatives from multiple primary care professional societies, including the American College of Physicians, American Academy of Pediatrics (AAP), American Academy of Family Physicians, American Academy of Physician Assistants, and American Association of Nurse Practitioners. The key discussion topics included HIV, viral hepatitis, STD, and LTBI screening.

The insightful perspectives and extensive guidance on LTBI screening that the participants provided to DTBE during the Partners in Prevention meeting are highlighted below.

- Primary care providers (PCPs) continue to have misconceptions regarding LTBI. The interferon gamma release assay (IGRA) as a solution to minimize the number of false-positive test results for the *Bacillus Calmette-Guérin* (BCG) vaccine is not widely known. Moreover, providers have limited knowledge on the use of short-course regimens as a solution to decrease hepatotoxicity with isoniazid (INH).
- Opportunities should be leveraged to widely educate providers. Professional societies can use their newsletters and other educational media to support this effort.
- The lack of a performance measure (e.g., breast cancer screening in women 50-74 years of age) related to reimbursement remains a major barrier to TB prevention.
- A more focused approach is needed for LTBI. For example, efforts to address LTBI should be targeted to healthcare facilities with predominantly high-risk clients, such as Federally Qualified Health Centers (FQHCs).

DTBE currently is exploring strategies to maintain the momentum of the Partners in Prevention meeting. Most notably, DTBE will effectively engage professional societies and other groups to build and sustain a strong, large-scale partnership between the public health and primary care communities that focuses on TB prevention. DTBE will draft a Partners in Prevention proposal that will emphasize the need to engage TB controllers as a key partner. NTCA already is contributing to the partnership by developing educational products to assist PCPs in administering 3HP to their patients.

HIGH-LEVEL TB MEETINGS

The United Nations General Assembly High-Level Meeting (UN HLM) on Tuberculosis will be held in New York City on September 26, 2018 to reach agreement on cooperation measures and solutions on important global issues among Heads of State and governments. The U.S. representative has not yet been determined, but is expected to be a high-level HHS official,

such as the HHS Secretary. The modalities resolution describes the framework of the UN HLM meeting and has been published as outlined below.

- *Meeting theme:* “United to end tuberculosis: an urgent global response to a global epidemic”
- *Opening segment:* Statements from UN and World Health Organization (WHO) leadership
- *Plenary session:* Statements by member states and observers
- Panels with multiple stakeholders to discuss two key topics:
 - Accelerating comprehensive response through access to affordable prevention, diagnosis, treatment, and care to end the TB epidemic
 - Scaling up sufficient and sustainable national and international financing and implementation for service delivery, innovation, and research
- *Closing segment:* Summary of the meeting
- *Expected outcome:* A concise and action-oriented political declaration that will be agreed to in advance by consensus through intergovernmental negotiations [currently under negotiation]
- *Additional feature:* An interactive civil society hearing to obtain external input as part of the preparations for the UN HLM was held in June 2018 in New York City.

The “Preventing TB to End TB” meeting will be held in conjunction with the UN HLM. The meeting will be coordinated by the CDC Center for Global Health and sponsored by the CDC Foundation. The meeting will focus on the strategies and benefits of TB preventive treatment (TPT) (i.e., LTBI testing and treatment) in high and low burden countries. The HHS official who will represent the United States government (USG) at the meeting has not yet been determined. The key components of the USG meeting are highlighted below.

Meeting Themes

- Acknowledging the critical role TPT implementation plays in achieving national and global END TB targets
- Designating TPT as a core national public health prevention measure
- Prioritizing investments in the systems, people, and commodities needed for wide-scale adoption of TPT and innovations in the field
- Accelerating research to identify better and shorter TB regimens and diagnostics
- Systematically sharing innovations, experiences, and outcomes in implementing TPT to enhance partnerships and monitor progress toward implementation

Draft Agenda

- Opening remarks
- Perspectives from civil society and the community
- “Setting the Stage: The Critical Role of TPT in Ending TB”
- Panel Discussion: “Progress, Opportunities, and Challenges and Future Plans for Scaling up TPT within National TB Epidemic Control and Elimination Efforts”
 - The panels will be represented by two high-incidence countries and one low-incidence country (United States).
- Perspectives from international partners and donors
- Open Discussion
- Closing

ICD-10 CODING WORKGROUP

The CDC National Center for Health Statistics (NCHS) Coordination and Maintenance Committee accepted the DTBE/NTCA ICD-10 Coding Workgroup's proposal that was presented at its September 2018 meeting. The committee will review, comment, and make recommendations on the proposal. The proposal also will be published in the *Federal Register* for public comment from mid-September to mid-November 2018. Final approval on revisions to the ICD-10 codes will be made through the HHS clearance process.

The ICD-10 Coding Workgroup determined and NCHS strongly recommended the need for clinicians to be educated on the use of ICD-10 codes. The workgroup is considering the development of a tool for clinicians to use the revised codes in the field. Pending final approval, the workgroup will undertake this effort in collaboration with the DTBE Communications, Education and Behavioral Science Branch and/or the CDC-funded TB Centers of Excellence (COEs) for Training, Education, and Medical Consultation Centers of Excellence. The tool will be housed on the CDC.gov website, disseminated in presentations at conferences, or displayed at an educational "roadshow."

Dr. LoBue concluded his update by presenting a table to illustrate the modifications and new codes that the workgroup has proposed for the ICD-10 codes.

Proposed Modifications

ICD-10	Current Code	Proposed Modification
Z22.7	Latent tuberculosis	Add two inclusion terms: 1. Latent tuberculosis infection 2. LTBI Use additional codes R76.11 or R76.12 to identify positive test for tuberculosis infection
Z11.1	Encounter for screening for respiratory tuberculosis	Add one inclusion term: 1. Encounter for screening for active tuberculosis disease
Z86.11	Personal history of tuberculosis	Personal history of active tuberculosis disease

Proposed New Codes

ICD-10 Number	Current Code	Proposed Modification
Z11.7	N/A	Encounter for testing for latent tuberculosis infection
Z86.15	N/A	Personal history of latent tuberculosis infection
Z09.0	N/A	Encounter for follow-up examination after completed treatment for latent tuberculosis infection

R76.11: Non-specific reaction to the tuberculin skin test (TST) without active tuberculosis

R76.12: Non-specific reaction to cell-mediated immunity measurement of gamma interferon antigen response without active tuberculosis

ACET GUIDANCE

Dr. Flood noted that the U.S. Preventive Services Task Force (USPSTF) recommends TB screening of two high-risk groups: Medicaid beneficiaries and non-U.S.-born people/populations (USBPs). She raised the possibility of DTBE developing a performance measure for PCPs in FQHCs to be reimbursed for TB screening of these two populations.

In response to Dr. Starke's question, Dr. LoBue confirmed that he will determine whether AAP has been invited to attend the upcoming USG meeting, "Preventing TB to End TB," to represent the pediatric community. He also informed ACET that NCHHSTP likely will be represented on the UN Delegation for the UN HLM meeting in September 2018.

Update on TB Prevention Research

Andrew Vernon, MD, MS

Chief, Clinical Research Branch
Division of Tuberculosis Elimination
Centers for Disease Control and Prevention

Advice requested from ACET by DTBE:

1. What are ACET's general comments regarding the current plan to advance toward testing the six-week TB regimen of daily rifapentine (RPT)?
2. What are ACET's comments on the utility and importance of including a four-week arm of the INH/RPT regimen?
3. What are ACET's thoughts on the relevance of the results of Study A5279 to the developed country setting?
4. Should any lessons learned from Study A5279 influence the design and/or implementation of the ASTERoID trial?

Dr. Vernon presented an overview of recently completed and upcoming TB prevention studies.

BRIEF RIFAPENTINE-ISONIAZID EFFICACY FOR TB PREVENTION (BRIEF-TB)/ AIDS CLINICAL TRIALS GROUP (ACTG) STUDY A5279

ACTG reported the results of its large TB prevention trial in PLWH in high-burden settings (i.e., BRIEF-TB/Study A5279). TBTC, TBESC, and the Medical Research Council (MRC)-United Kingdom will soon launch a large TB prevention trial primarily in people without HIV in low-burden settings. Because the choices of a TB regimen are different between the two trials, DTBE is interested in informing ACET and seeking its counsel regarding the influence of one trial on the other.

The hypothesis of Study A5279 was that four weeks of daily INH and RPT (1HP) would be non-inferior to nine months of INH for preventing TB in PLWH. The primary objective of the study was to compare the efficacy of the 1HP regimen with a nine-month daily regimen of INH (9H) for the prevention of TB in adults and adolescents with HIV infection. Study A5279 was a multi-center, randomized, open-label Phase III clinical trial with a cohort of 3,000 PLWH 13 years of age and older, and no evidence of active TB.

The primary endpoint of Study A5279 was the incidence rate of active TB, TB death, or death due to an unknown cause. The secondary endpoints included safety and tolerability, all-cause and non-TB mortality, adherence to the treatments, pharmacokinetics and drug-drug

interactions of RPT/INH with Efavirenz (EFV) and Nevirapine (NVP), and rate and pattern of antibiotic resistance.

Study A5279 was designed as a non-inferiority trial. In a prior 3HP trial with four arms in Soweto, South Africa, the TB rate was determined to be 1.77 per 100 person-years. The cohort in the Soweto trial was not on ART and had a median CD4 count of approximately 500. The TB rate for the control group in Study A5279 was expected to be 2 per 100 person-years. The non-inferiority margin was defined at 1.25 per 100 person-years (or 62.5 percent of the control event rate). Based on the use of a one-sided significance level of 0.025, the study power was estimated at 90 percent. The study aimed for a total sample size of 2,596 with adjustment for 10 percent loss to follow-up.

The participants in Study A5279 were required to meet one of two criteria: (1) TST reactivity of 5 mm or more and/or a positive IGRA or (2) residence in a high TB burden area as defined by “a prevalence of TB of 60 or more cases per 100,000 population.” The study participants were stratified by CD4 count and the use of antiretroviral therapy (ART) at entry in the study. Only an EFV- or NVP-based ART regimen was permitted while the study participants were on RPT. The duration of the study was three years (or 156 weeks) after enrollment of the final participant.

Among the 3,000 participants in Study A5279, the baseline characteristics were equally balanced between 1,504 people who received the 9H regimen in the control arm and 1,496 people who received the 1HP regimen in the experimental arm:

- By age: 28-43 years of age with a median age of 35 years
- By gender: males (46 percent) and females (54 percent)
- By race/ethnicity: White non-Hispanics (1 percent), Black non-Hispanics (66 percent), Hispanics (24 percent), and Asian/Pacific Islanders (8 percent)
- By history of prior TB: 6 percent
- By CD4 count: less than 100 (2 percent); 100 through less than or equal to 250 (11 percent); and greater than 250 (87 percent)
- Of the 50 percent of participants on ART at entry in the study, viral load was undetectable (80 percent) and detectable (20 percent).

The 3,000 participants in Study A5279 were categorized by high- and low-burden settings to determine their baseline TST and IGRA results. Of 2,905 participants in the high-burden group, 21 percent had positive TST results, 69 percent had negative TST results, and 10 percent had no TST results at entry. Of 95 participants in the low-burden group, 40 percent had positive TST results, 55 percent had negative TST results, and 4 percent had no TST results at entry. Of the 95 participants in the low-burden group, 74 percent had positive IGRA results, 2 percent had negative IGRA results, and 22 percent had no IGRA result. The IGRA results from the low-burden sites included 91 participants from the United States and four participants with no documentation of a positive TST or IGRA.

In terms of the regimens administered in Study A5279, the participants in the control arm received the 9H regimen for 36 weeks (300 mg of daily INH). The participants in the experimental arm received the 1HP regimen for four weeks (450 or 600 mg of RPT, depending on the weight of the participant, plus 300 mg of daily INH) and no treatment in weeks 5-36. The participants also received 25 mg of vitamin B6 with each dose of INH.

In terms of the primary endpoints of Study A5279, the major events are highlighted below:

- 33 primary endpoints in the 9H arm and 32 in the 1HP arm
- 14 confirmed active TB cases in the 9H arm and 18 in the 1HP arm
- 10 probable active TB cases in the 9H arm and 11 in the 1HP arm
- 2 deaths related to TB in the 9H arm and 0 in the 1HP arm
- 7 deaths from an unknown cause in the 9H arm and 3 in the 1HP arm
- Overall incidence of the combined endpoint per 100 person-years: 0.67 in the 9H arm and 0.65 in the 1HP arm.
- Brazil and the United States were the only two of 10 countries in the study with no primary endpoint events.

In terms of baseline covariates observed in Study A5279, the incidence rates among participants with CD4 counts of 250 or less were 1.275 in the 9H arm and 1.931 in the 1HP arm. The incidence rates among participants with negative or missing IGRA or TST results were 0.585 in the 9H arm and 0.576 in the 1HP arm. The incidence rates among participants with a positive IGRA or TST result were 0.967 in the 9H arm and 0.903 in the 1HP arm.

In terms of Grade 3 or higher adverse events reported in Study A5279, the number of participants who had any white blood cell-related hematologic event were 18 in the 9H arm and 36 in the 1HP arm. The number of participants who had any liver/hepatic event were 42 in the 9H arm and 28 in the 1HP arm. The number of participants who had any neurological event were 30 in the 9H arm and 14 in the 1HP arm.

The results of Study A5279 led to the following conclusions. The 1HP regimen was found to be non-inferior to 9H for preventing the composite endpoint of TB, TB death, or death from an unknown cause in adults and adolescents with HIV infection. The rates of TB were higher in people with positive TST or IGRA results and those with low CD4 counts of 250 or less. Compared to the 9H regimen, the rates of endpoints were higher in people with low CD4 counts of 250 or less who received 1HP.

Safety was found to be good and relatively similar in both arms overall. However, hematologic toxicity was higher with the 1HP regimen, while liver toxicity and neurotoxicity were higher with the 9H regimen. Treatment completion was excellent in both arms, but better with the 1HP regimen. The authors concluded that the 1HP regimen is a highly effective, ultra-short course regimen for the prevention of TB in PLWH. The regimen can contribute to improvements in global control of TB and should be studied in other high-risk groups.

Overall, Study A5279 represents a significant achievement. The success of the trial provides strong support for the presumption that the 1HP regimen is non-inferior to 9H in preventing the defined composite outcome in the study population of PLWH who live in high-burden and low-resource settings. However, several issues have been identified related to the applicability of the study results to high-resource settings, such as the United States and the United Kingdom. These issues have influenced the design of the TBTC and TBESC study in the United States and the United Kingdom that is intended for a different epidemiologic setting and will involve a different study population.

ASSESSMENT OF THE SAFETY, TOLERABILITY, AND EFFECTIVENESS OF RIFAPENTINE GIVEN DAILY FOR LTBI (ASTEROID)/STUDY 37

Study 37 will compare six weeks of daily RPT to an arm of a 12- to 16-week regimen of a rifamycin-based treatment for latent *Mycobacterium tuberculosis* (MTB) infection to assess

safety, tolerability and effectiveness. The following issues of interest were considered in the designs of both Studies A5279 and 37.

- The mouse model data were open to differing interpretations.
- The setting for Study A5279 was one of high TB burden with the likely occurrence of active transmission.
- The characteristics of the cohort in Study A5279 were significant: negative TST results (80 percent), HIV positive (100 percent), and not on effective ART at entry (50-60 percent).
- The composite endpoint of TB and death did not include all deaths. The determination of cause of death in low-resource settings can be difficult. The Study 37 team considers TB and death to be distinct and separate endpoints.
- Toxicity is likely to be lower with only one instead of two drugs.
- A regimen without INH will likely be useful against INH-resistant TB.
- The 1HP regimen was found to be less effective in people with low CD4 counts.
- The ability to distinguish new infection from reactivation is difficult in high-burden settings.

Study 37 will be a randomized, controlled, open-label non-inferiority trial. The test regimen will be six weeks of daily RPT at a dose of 600 mg/day with food. The comparison arm will be 12- to 16-weeks of a rifamycin-based treatment (3HP once weekly, 3HR daily, or 4R daily). The study participants will include people 12 years of age and older who have positive TST or IGRA results and are at high risk for progression to TB. People with rifamycin intolerance and rifamycin-resistant source cases will be excluded from the study.

The study participants primarily will include HIV-seronegative people, but PLWH will be eligible as well. The participants will be recruited in low TB incidence countries (the United States and the United Kingdom). The non-inferiority margin will be 4 percent for safety and 0.75 percent for effectiveness. The sample size will be 560 people per arm (or 1,120 participants in total) for safety and tolerability and 1,700 per arm (or 3,400 participants in total) for effectiveness.

Several issues were considered to support the rationale for continuing the current design from Study A5279 to Study 37. Tolerability and safety were found to be of paramount importance for the treatment of LTBI and widespread rollout. A single drug regimen will involve fewer pills and can be administered even with INH resistance. RPT alone likely will be safer than the combined regimen of INH/RPT.

Data from multiple studies were reviewed on Grade 3 or higher adverse events that were reported with various TB regimens. Data from the mouse model of LTBI demonstrated a higher relapse risk after four weeks of treatment with RPT or INH/RPT compared to six to eight weeks of treatment. In low TB incidence settings, sub-clinical or asymptomatic TB will be less likely than in high TB incidence settings, particularly in non-PLWH. TB re-infection will be unlikely. TB drug resistance rates will be low, especially to rifamycins.

DTBE arranged three other presentations of data from Study A5279 following the presentation at the Conference on Retroviruses and Opportunistic Infections in March 2018: (1) to the Study 37 Protocol Team in mid-March 2018, (2) at CDC in April 2018, and (3) at the TBTC meeting in May 2018. The protocol team decided to continue with the current study design and establish a workgroup to assess the possibility of adding an arm of a four-week regimen of INH/RPT in the

future. The ideal time to include the arm will be after safety and tolerability data have been collected on 1,120 participants in Study 37.

ACET DISCUSSION: TB PREVENTION RESEARCH

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

- The protocol of selecting study participants in the context of their LTBI status and their risk of progression to active TB disease.

ACET GUIDANCE

- The ACET members were in favor of the current plan to advance toward testing the six-week regimen of daily RPT, but some caveats were included in their support.
 - Dr. Horne noted that the four-week INH/RPT regimen was shown to be effective in PLWH, but he still had questions on whether this arm should be tested.
 - Dr. Horsburgh pointed out that the four-week INH/RPT regimen is under-powered to draw definitive conclusions, but the preliminary data are important and suggest the regimen is effective.
- Dr. Starke reported that in a previous study in which INH was given to children with HIV infection, INH showed no difference in health outcomes compared to placebo. He advised the protocol team of Studies A5279 and 37 to review these data because the controversial pediatric study has been extensively used to show the lack of effectiveness of INH. However, other parts of the pediatric community believe that data from the study were inaccurately analyzed. Moreover, a new analysis of the pediatric study could help to convince clinicians in the United States of the efficacy of the treatment regimens in Studies A5279 and 37.

Ms. Cole concluded the discussion by summarizing ACET's general guidance to DTBE regarding Studies A5279 and 37. The protocol team should advance toward testing the six-week regimen of daily RPT, but the four-week INH/RPT regimen should only be added based on good outcomes.

DHAP's Strategy of Adopting HIV Treatment as Prevention (TasP)

Cynthia Lyles, PhD

Associate Deputy Director, Behavioral and Social Science
Division of HIV/AIDS Prevention
Centers for Disease Control and Prevention

Dr. Lyles presented an overview of DHAP's efforts in translating the science of TasP into communication messages. ART is a powerful tool to prevent and treat HIV infection. ART also has the capacity to significantly improve the health of PWH and decrease the risk of HIV transmission. ART prevents HIV transmission through sex, injection drug use, and mother-to-child transmission. TasP is a prevention strategy that effectively uses ART to reduce viral load and decrease HIV infectiousness, which leads to preventing HIV transmission.

The science behind TasP for preventing the sexual transmission of HIV is well documented in the literature. The HIV Prevention Trials Network (HPTN) 052 study was a landmark study that documented the efficacy of treatment to prevent sexual transmission of HIV. The randomized controlled trial examined both the health and prevention benefits of early versus delayed

ART. The study followed 1,763 HIV-discordant couples that primarily were heterosexual. The interim analyses of the HPTN 052 study (Cohen, *et al. New England Journal of Medicine*, 2011) reported a 96 percent reduction in the risk of sexual transmission of HIV among heterosexual HIV-discordant couples with early versus delayed ART. The majority of participants in the early treatment arm were virally suppressed and reported condom use.

In 2016 and 2018, four more recently published studies examined whether a person with HIV, who was on treatment and virally suppressed, could sexually transmit HIV to an HIV-negative sex partner. All four studies reported no linked HIV transmissions among HIV-discordant couples when the HIV-positive partner was virally suppressed. The studies followed both heterosexual and men who have sex with men (MSM) couples that reported condom-less sex and no PrEP use. The combined studies reflected over 2,600 couple-years of follow-up time and over 125,000 condom-less sex acts.

The combined HIV transmission risk of three of the four studies [PARTNER, Opposites Attract, and PARTNER2] was estimated at 0.0 per 100 couple-years of follow-up for both any sex (among HIV-discordant heterosexual and MSM couples with a virally suppressed HIV-positive partner) and anal sex (among MSM couples with a virally suppressed HIV-positive partner). The research studies showed that effective treatment prevented any and all sexual transmission of HIV within the couples.

DHAP acknowledges the challenges with implementing TasP in the field. The effectiveness of TasP depends on PWH achieving and maintaining viral suppression, but up to six months can be required to become virally suppressed when starting ART. The majority of PWH in care are virally suppressed at their last test (approximately 80 percent), but less PWH maintain viral suppression over 12 months (approximately 66 percent). Increased viral load will occur if PWH miss too many doses or discontinue ART. TasP does not protect against other STDs.

DHAP communicates messages for TasP to prevent the sexual transmission of HIV. DHAP communicates various types of information, including complex scientific findings; prevention methods and their effectiveness; and approaches to collaborate with stigmatized and marginalized populations to raise awareness and build capacity to adopt and implement prevention strategies. DHAP also communicates information to diverse audiences, including the general audience, higher-risk consumers (e.g., PWH and people at high risk for HIV), providers and prevention partners, and capacity-building and TA providers.

DHAP uses several different modalities to communicate information, including consumer educational campaigns, online risk reduction tools and resources, intervention tools, training and implementation materials, and programmatic guidance. Overall, the process of effectively communicating to all audiences to maximize the impact of the science in the field is complex and challenging.

DHAP's early communication messages regarding TasP were based on the 2011 Cohen, *et al.* study of the HTPN 052 findings and were similar to messages from other HHS agencies. DHAP informed its audiences that TasP is an effective strategy for preventing the sexual transmission of HIV. Examples of DHAP's early messages are as follows: "Consistent ART greatly reduces the chance of transmitting HIV" or "If taken the right way, every day, ART can dramatically reduce the chance of transmitting HIV to sex partners."

HHS, CDC, and several other HHS agencies updated their communication messages regarding TasP as part of a cross-federal agency workgroup. Based on the more recently published studies in 2016 and 2018, HHS released its core prevention message for TasP: “People with HIV who take HIV medicine as prescribed and get and keep an undetectable viral load have *effectively no risk* of transmitting HIV to their HIV-negative sexual partners.” The HHS workgroup also endorsed the terminology of “negligible risk.”

Other groups outside of HHS also are communicating the evidence on HIV risk. The author of the PARTNER2 study made the following statement: “We can’t say it’s zero risk, but it’s effectively zero. You could keep studying this forever, but I think the question is now settled.” The Prevention Access Campaign launched “U=U” (Undetectable equals Untransmittable). The U=U campaign is extremely popular and supported by the HIV-positive community.

DHAP conducted message testing of HHS’s core prevention message for TasP to obtain feedback. In-depth interviews were conducted with 88 HIV-positive and at-risk participants. A short description of the science and the core prevention message for TasP were presented. The terminology of “effectively no risk”, “negligible risk”, and other alternative wording were included. Many participants found the science to be new information and many did not believe the information, particularly HIV-negative people.

The terminology of “negligible risk” was the least motivational wording for positive change and the most difficult for the participants to understand. The terminology of “effectively no risk” ranked in the middle of all phrases that the participants rated. DHAP concluded that “effectively no risk” may be acceptable terminology for some audiences, but better options should be explored for its specific consumer audiences, particularly PWH and people who are at greatest risk for HIV.

DHAP recognizes the need to address several key challenges to improve its TasP communication messages for consumer audiences. The lack of understanding or disbelief about the science could affect acceptance of the messages. Rejection of the messages could affect motivations and informed decision-making. Specific audiences have different information needs and receive, process, and react to information differently. Consumer audiences need more plain-language messages to ensure maximum comprehension and acceptance. Consumer audiences also need more support to implement positive change.

DHAP’s next steps in delivering TasP messages will be to accelerate communication efforts regarding the benefits of TasP to consumers and providers. Funds recently were awarded to accelerate dissemination efforts, raise awareness, and increase support for and broaden the implementation of TasP in the field among both consumers and providers. Message testing research will continue to be conducted with consumers. Alternative communication messages will be evaluated and identified to clearly explain the benefits of TasP to consumers at highest risk. Strategies will be identified to improve comprehension and reduce barriers to the acceptance of messages.

ACET DISCUSSION: DHAP’S STRATEGY OF ADOPTING HIV TASP

Dr. Lyles provided additional details on the following topics in response to ACET’s questions.

- The extent to which the terminology of “effectively no risk” has been accepted by the provider audience.

- The extent to which sex partners of PWH have received and accepted DHAP's TasP communication messages.
- The potential advantages and disadvantages of joint HIV and TB TasP messages.

ACET GUIDANCE

- Several members recalled that ACET's previous request to USPSTF to issue a recommendation on TB TasP was not well received. The members raised the possibility of ACET using the more recently published studies on HIV TasP in 2016 and 2018 as models to submit an updated request to USPSTF. Dr. Horsburgh offered the following language as an example of a TasP message to include in ACET's request to USPSTF: "Treatment of TB infection prevents progression to active TB disease and transmission." He pointed out that unlike the Ryan White HIV/AIDS Program for the care and treatment of HIV, TB has no equivalent funding mechanism. As a result, he expressed a strong interest in TB TasP partnering with and leveraging the success of HIV TasP, particularly since TB is the single largest cause of death in PWH globally. He also emphasized the need for USPSTF to broaden its perception of primary prevention for diseases that have no effective vaccine, such as HIV and TB.
- Dr. Belknap noted that the replication of techniques used in TB contact investigations for HIV might offer an additional opportunity for synergy between HIV and TB TasP. However, the replication of HIV TasP messaging for TB would be extremely challenging due to cultural, language, and other issues that are unique to people who have or are at risk for TB.

The NCHHSTP staff made several comments in follow-up to ACET's discussion.

- Dr. Lyles clarified that DHAP has not considered submitting a request to USPSTF to issue a recommendation on HIV TasP, but this issue can be discussed in more detail with colleagues. She pointed out that the [Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV](#) currently recommend ART for all PWH for both individual health benefits and for preventing HIV transmission. Both recommendations have A1 ratings:
 - Antiretroviral therapy (ART) is recommended for all individuals with HIV, regardless of CD4 T lymphocyte cell count, to reduce the morbidity and mortality associated with HIV infection (A1).
 - ART is also recommended for individuals with HIV to prevent HIV transmission (A1).
- Dr. LoBue reminded ACET that USPSTF decided against issuing a recommendation on TB TasP less than two years ago. He was uncertain whether ACET's submission of an updated request at this time would lead to a different outcome.
- Ms. Suzanne Marks, of DTBE, emphasized the need for NCHHSTP to communicate combined TasP messages rather than disease-specific TasP messages. For example, "HIV treatment prevents the progression of TB." "LTBI treatment prevents TB disease."
- Dr. Nikolas DeLuca, of DTBE, informed ACET that DTBE will soon initiate message testing of its TB-related communication materials and products.

Ms. Cole concluded the discussion by confirming that ACET's original request to USPSTF on issuing a recommendation on TB TasP and USPSTF's response would be revisited at a future meeting.

Update on DTBE's Concept of Operations for LTBI Surveillance

Adam Langer, DVM, MPH, DACVPM

Surveillance Team Lead, Division of Tuberculosis Elimination
Centers for Disease Control and Prevention

Advice requested from ACET by DTBE:

1. What are ACET's general comments in reaction to the presentation?
2. What are ACET's comments on the conclusions of the internal DTBE workgroup on LTBI prevalence estimation methods?
3. What is ACET's feedback on the plans for implementation of a case-based LTBI surveillance system?
4. What are ACET's thoughts on the identified key issues to resolve, including any additional issues that need to be considered?

Dr. Langer presented an update on DTBE's Concept of Operations (ConOps) for LTBI surveillance. The Society for Epidemiology in TB Control, with input from CDC, developed a standard LTBI surveillance case definition. The case definition was adopted by the Council of State and Territorial Epidemiologists in 2017 and accepted by CDC in 2018 for publication on the CDC.gov website.

"Clinical criteria" in the LTBI surveillance case definition include one of three requirements for patients: (1) no signs or symptoms compatible with TB disease; (2) no chest imaging abnormalities consistent with TB; or (3) microbiologic testing that is negative for the MTB complex and TB disease has been clinically ruled out. "Laboratory criteria" in the LTBI surveillance case definition include one of two requirements for patients: (1) positive TST or (2) positive IGRA.

DTBE established an internal workgroup to evaluate LTBI prevalence estimation methods following NCHHSTP's data-driven review in 2018. The advantages and limitations of the data sources that the workgroup reviewed and considered in this effort are summarized below.

The National Health and Nutrition Examination Survey (NHANES) is a population-based national survey that includes the ability to identify people who meet the LTBI surveillance case definition. NHANES has an established sampling methodology that can generate national prevalence estimates every other year. Because the NHANES sample represents a broad cross-section of the U.S. population, a large proportion of individuals who are considered to be low-risk for LTBI are included. However, the concern with NHANES is that current diagnostic tests overestimate LTBI prevalence, particularly in low-risk populations. To address the overestimation issue, future NHANES cycles will limit LTBI testing to non-USBP with a much higher prevalence of LTBI.

Back-calculation methods from national TB disease surveillance data assumed a reactivation rate from LTBI to TB disease of 0.1 percent per year that will allow for calculations of an estimate of LTBI prevalence from TB disease incidence data. Back-calculation methods also allow for stratified LTBI prevalence estimates based on TB disease surveillance data. Of two similar approaches to this calculation that have been proposed, one is in press and one has been submitted to the CDC clearance process. Analyses are ongoing to validate the effectiveness of these approaches in estimating LTBI prevalence in the United States.

Commercial billing databases maintain comprehensive and large datasets on public (e.g., Medicare and Medicaid) and private (e.g., commercial insurance) payer claims for medical services. None of the databases consistently use diagnosis codes for LTBI, but procedure codes for TB infection testing can be combined with prescription claims for LTBI-specific treatment regimens to develop estimates of LTBI. However, the concern with commercial billing databases is the accuracy of data due to their primary function to maximize reimbursement rather than ensure the integrity of data. Moreover, risk factor data generally are not available for patients. The datasets likely include many low-risk persons and have the potential to generate a large number of false-positive results.

De-identified laboratory data only apply to IGRA testing. QuantiFERON data potentially are available from large clinical laboratories, such as LabCorp and Quest. T-Spot data are available directly from the test manufacturer. No risk factor data are available for QuantiFERON from clinical laboratories. Limited risk factor data are available for T-Spot. No process has been developed to identify and eliminate TB disease cases from de-identified laboratory datasets.

Contact investigation databases include DTBE's Aggregate Reports for Program Evaluation (ARPE). The aggregate data are limited to contacts of TB disease cases only. The ARPE also includes denominator data for calculations of rates among contacts. Although contacts are a high-risk group, other high-risk groups are not represented in the ARPE.

Immigrant/refugee health databases include CDC's Electronic Disease Notification (EDN) System. The EDN System maintains data on the outcomes of TB evaluations for Class B immigrants/refugees. Class B immigrants/refugees are a high-risk group, but are not necessarily representative of an overall high-risk population. Class B only includes a portion of all immigrants/ refugees. The EDN System does not include visitors, tourists, students, undocumented people, and others who are not seeking legal permanent residency in the United States.

De-identified electronic health record (EHR) data are the most promising large data source for LTBI surveillance, but the sources for these data are fairly limited and expensive. "Country of birth" is rarely included as a variable in these datasets, but "preferred language" can be used as a proxy. Other demographic and risk factor data often are available.

The DTBE workgroup reached several conclusions in its review of the available data sources for LTBI surveillance. The ability to distinguish between "high-risk" and "low-risk" populations for LTBI is critical to generating reliable LTBI prevalence estimates given the predictive value of available tests for TB infection. The current design of NHANES requires further exploration of methods to correct for the inclusion of large numbers of low-risk people in the LTBI survey.

Back-calculation methods based on TB disease surveillance are the most promising data source for generating accurate LTBI prevalence estimates at state and county levels and by specific demographic characteristics. Most other large data sources have limited usefulness at this time. De-identified EHR data have the potential to be useful provided that sufficient risk factor data are available.

DTBE is continuing to characterize the epidemiology of LTBI cases using sampling methods. The collection of data on all LTBI cases in the United States is not a feasible approach. At this time, 16 states (or 31 percent) treat LTBI as a reportable condition, but more states are planning to add LTBI in the near future. Although no immediate plans have been made to make LTBI a

nationally notifiable condition, voluntary reporting to CDC from a substantial portion of the United States is possible. The establishment of national reporting standards is critical at this time before LTBI reporting becomes widespread.

DTBE's TB Latent Infection Surveillance System (TBLISS) will be operational by 2020 to accept LTBI case reports. The TBLISS form is a subset of the Report of Verified Case of Tuberculosis (RVCT). Questions that are specific to TB disease will be omitted in the TBLISS form, while LTBI-specific treatment questions will be included. Only a small number of questions will be required to submit the TBLISS report.

Specific data elements will need to be collected to ensure alignment with the LTBI surveillance case definition. Risk factor data also will need to be gathered to distinguish between low- and high-risk populations within the dataset. TBLISS will be designed to be scalable by using CDC's existing national TB surveillance informatics infrastructure. Reporting areas can be easily added to TBLISS as more states decide to participate over time. TBLISS will be integrated with the Surveillance for TB Elimination Management System (STEMS) application.

TBLISS will be designed to accept all of the RVCT data elements as listed below. However, the proposed TBLISS core data elements are marked below with an asterisk.

- Administrative Information*
- Reporting Address*
- Date of Birth
- Sex at Birth
- Race/Ethnicity
- Country of Origin*
- U.S. Residency*
- Initial Reason Evaluated for TB
- TST/IGRA & Culture Results*
- Chest Imaging Results*
- Risk Factors
 - Diabetes Status
 - HIV Status
 - Primary Occupation/Industry
 - Homeless/Incarcerated/Long-Term Care Facility
 - Substance Use
 - Immunocompromised
 - Travel History
- Epidemiologic Investigation
- Treatment & Outcome Information*

STEMS is a web-based LTBI case management system that is hosted at CDC, but is designed for use in clinics at no charge. STEMS will have the ability for users to submit LTBI case reports to TBLISS. STEMS will include a new contact investigation management module. The ideal candidates for STEMS deployment include TB clinics without an existing EHR system and jurisdictions with an interest in avoiding manually extracting LTBI case data from another system to enter into TBLISS. STEMS will be expanded in the future to add case management functions for TB disease and LTBI.

DTBE's next steps in its ConOps for LTBI surveillance will be to resolve several key issues.

- Which methods/data sources should be used to estimate LTBI prevalence at each geographic level? How often should these estimates be updated?
- Which existing data sources might also be useful for characterizing LTBI epidemiology beyond prevalence estimates?
- What approaches can be taken to avoid introducing systematic or analytic biases in TBLISS sampling?
- If or when should LTBI be made a nationally notifiable condition?
- What efforts can be made with current resources? Which additional activities should be prioritized if additional resources become available in the future?

ACET DISCUSSION: DTBE'S CONOPS FOR LTBI SURVEILLANCE

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

- Methodologies that can be used to conduct a risk-based assessment of LTBI.

ACET GUIDANCE

- Dr. Starke pointed out that one component of an ideal surveillance system is to improve and increase testing of high-risk people. He encouraged DTBE to design TBLISS to maintain data on low-risk people who become at risk for LTBI due to inappropriate testing or other factors.
- Dr. Hellerstedt fully supported DTBE's proposal of including "country of origin" rather than "country of residence" as one of the TBLISS core data elements. He explained that "country of residence" is difficult to determine for binational TB patients because their place of residence frequently changes in a short period of time.
- Dr. Ahuja encouraged DTBE to focus on collecting data on contacts as a starting point in TBLISS. Contacts are an extremely high-risk group that needs to be followed, particularly since 1 percent of contacts develop active TB disease. She emphasized the need to obtain solid data on contacts before efforts are made to expand to other components of LTBI surveillance.
- Dr. Reves noted that some states and large universities require LTBI testing of all international students. Moreover, several healthcare personnel (HCP) are non-USBPs at baseline LTBI testing. He advised DTBE to collect data from these existing datasets as an additional source to evaluate LTBI prevalence and populate TBLISS.
- Dr. Liu suggested a potential change to the LTBI surveillance case definition. "Microbiologic testing that is negative for the MTB complex" is one of the clinical criteria, but this requirement should be relocated to the laboratory criteria.
- Dr. Starke advised DTBE to identify any existing datasets that are available on the prevalence of people in the United States who have received the BCG vaccine and their testing outcomes. This information would help DTBE to better determine the proportion of LTBI testing results that are false-positive.
- Dr. Flood pointed out that CDC and states have capitalized on extracting EHR and electronic laboratory reporting (ELR) data on immunizations from private sector databases and entering this information into registries. Because a large proportion of LTBI testing occurs in the private sector, she raised the possibility of CDC providing national leadership to support this effort. To date, the Centers for Medicare & Medicaid Services has not included TB in its Meaningful Use funding to capture LTBI through EHR/ELR systems. The EHR/ELR systems that currently track vaccination uptake and

outcomes could be used as a model to capture LTBI treatment outcomes through EHR/ELR systems at the national level. This resource would be extremely helpful in minimizing the workload of TB controllers in the field.

Dr. Mermin's position was that outcome data of people who were diagnosed with LTBI would be a tremendously important feature of TBLISS. The design of TBLISS to be representative of a proportion of patients who were treated for LTBI would provide extremely helpful data to DTBE, such as the drugs used for treatment and adherence rates.

Dr. Langer thanked NCHHSTP leadership and the ACET members for their thoughtful comments and suggestions. He conveyed that the ACET members should feel free to submit additional guidance on DTBE's ConOps for LTBI surveillance after the meeting. In the interim, he made several remarks in follow-up to ACET's discussion.

- In response to Dr. Mermin's comments, Dr. Langer confirmed that TBLISS will be designed to capture a number of important outcome data elements, such as the specific regimen used for LTBI treatment of each patient and the length of time each patient was followed. Moreover, the revised RVCT form includes new questions on whether the patient was previously diagnosed with LTBI and, if so, the patient's TBLISS state case number. The new questions will allow the RVCT to be linked to the TBLISS record of the patient's LTBI history.
- In response to Dr. Starke's suggestion, Dr. Langer confirmed that TBLISS will be designed to identify potential patterns of inappropriate testing of low-risk people in specific jurisdictions, clinical settings, and other areas. DTBE will "flag" these areas to ensure that training and education are provided.
- In response to Dr. Hellerstedt's comments, Dr. Langer announced that DTBE will develop and disseminate guidance to state and local partners as part of the rollout of the revised RVCT. DTBE is considering the addition of several new questions to assist TB controllers in the field to obtain more accurate information from their binational TB populations, such as "Which country do you spend more nights in?" or "Where do you consider home?"
- In response to Dr. Flood's suggestion, Dr. Langer confirmed that DTBE leadership will explore the possibility of developing an EHR/ELR system to capture LTBI treatment outcomes.

Update by the Child and Adolescent Workgroup

Jeffrey Starke, MD

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

Dr. Starke reported that AAP published the *Red Book*® in May 2018. He was pleased to announce that the *Red Book*® is well aligned with CDC's recent guidance on LTBI treatment. He thanked CDC for helping to harmonize the two sets of recommendations.

Update by the Essential Components Workgroup

Barbara Cole, RN, MSN, PHN, ACET Chair

TB Controller

Riverside County (California) Department of Public Health

Ms. Cole reported that the *Essential Components of a Public Health Tuberculosis Prevention, Control, and Elimination Program: Recommendations of the Advisory Council for the Elimination of Tuberculosis (ACET) and the National Tuberculosis Controllers Association (NTCA)* document is still undergoing the CDC clearance process. She hoped CDC would approve the document for publication in the *MMWR* in October 2018.

Update by the TB Drug Supply Workgroup

Barbara Cole, RN, MSN, PHN, ACET Chair

TB Controller

Riverside County (California) Department of Public Health

Ms. Cole reported that the TB Drug Supply Workgroup convened its most recent meeting on July 9, 2018 to address several key issues, including problems related to obtaining specialty drugs and strategies to advance the workgroup's revised charge. She was pleased to announce that Dr. Flood has agreed to serve as the new workgroup chair.

Update by the LTBI Workgroup

Jeffrey Starke, MD

Professor of Pediatrics, Baylor College of Medicine

Texas Children's Hospital

ACET Member & Workgroup Co-Chair

Dr. Starke reported that the LTBI Workgroup has not yet convened a meeting. However, his position was that the workgroup's inability to hold a meeting to date will be beneficial in terms of building a more concise framework. Most notably, the workgroup will be informed by Dr. Langer's update on DTBE's ConOps for LTBI surveillance. Moreover, Dr. Thomas Navin, Chief of the Surveillance, Epidemiology, and Outbreak Investigations Branch, has provided the workgroup with a comprehensive summary of DTBE's ongoing activities related to LTBI.

For the benefit of the new members, Dr. Starke explained that the LTBI Workgroup is charged with exploring whether ACET should issue a statement on current approaches to LTBI and assisting DTBE with its ongoing LTBI activities. He encouraged the new ACET members with an interest in joining the workgroup to notify Ms. Scott-Cseh (zkr7@cdc.gov). The workgroup will convene a conference call within the next two weeks.

ACET Business Session

Barbara Cole, RN, MSN, PHN, ACET Chair

TB Controller

Riverside County (California) Department of Public Health

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

Business Item 1: Approval of Previous ACET Meeting Minutes

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

ACET approved the Draft April 17, 2018 Meeting Minutes by a majority vote of 9 members in favor and 1 abstention (Dr. Robert Belknap) with no changes or further discussion.

Business Item 2: ACET Letter to the HHS Secretary

Ms. Cole announced that ACET's letter to HHS Secretary Alex Azar II and the report of ACET's key activities from 2016-2018 were submitted on July 6, 2018. The letter concluded with her request to meet with the HHS Secretary or the Assistant Secretary for Health. She will provide an update to ACET after the Office of the HHS Secretary submits a response. The letter and report were distributed to ACET for review.

Business Item 3: NTCA Collaborative Workgroup on Training Centers and Consultation

Ms. Cole returned to ACET's previous resolution that endorsed the formation of an external workgroup with representation by ACET, DTBE, NTCA, and the TB COEs to examine new and innovative modalities for the delivery of TB medical consultation services. She acknowledged that agreement was reached to table this update until DTBE announces the awards to the TB COEs under the re-competed CoAg. She planned to revisit this agenda item at the December 2018 ACET meeting.

Business Item 4: CDC Office of Infectious Diseases Board of Scientific Counselors

Ms. Cole presented an update in her role as the ACET liaison to the CDC Office of Infectious Diseases, Board of Scientific Counselors (BSC). The BSC convened its most recent meeting on May 2-3, 2018. Updates and overviews were provided by various workgroups and centers, including the Center for Global Health. Dr. Mermin provided an update on NCHHSTP's activities. Dr. Robert Redfield, the CDC Director, presented his areas of particular interest and priorities for CDC: disease elimination (particularly HIV and hepatitis), influenza, opioids, and global health protection.

Ms. Cole requested input on inviting Dr. Redfield to attend the in-person ACET meeting in December 2018 to share his vision for TB elimination. Based on background information and guidance provided by Dr. Mermin on the most appropriate and effective next steps, ACET agreed on the following plan of action.

- As the ACET Chair, Ms. Cole will send a written letter of invitation to Dr. Redfield to attend the in-person ACET meeting in December 2018 and share his vision for TB elimination. Although Dr. Redfield did not specifically identify TB as a priority for CDC, TB can be included in his priority area of disease elimination.
- ACET will draft a specific list of topics to address with Dr. Redfield. The potential agenda items include:
 - ACET’s request in its July 6, 2018 letter to the HHS Secretary to “establish a focus on domestic TB elimination within the Executive Branch by forming a Presidential TB Elimination Initiative.”
 - Opportunities to incorporate TB elimination in some geographic areas and other types of population as part of Dr. Redfield’s priority area of disease elimination.
 - ACET’s recommendations on DTBE pursuing other aspects of CDC’s existing TB research agenda.

Business Item 5: Advice Requested from ACET

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

ADVICE REQUESTED FROM ACET	
Topic	Action
Revision of the RVCT for 2020	Dr. LoBue reported that DTBE considered ACET’s advice and currently is piloting a draft of the 2020 RVCT to obtain feedback from TB controllers in the field. Ms. Cole confirmed that ACET would revisit this issue after DTBE completes the pilot and finalizes the 2020 RVCT. ACET agreed that no further action is needed at this time.
Updated Recommendations for TB Screening and Testing of U.S. Healthcare Personnel	Dr. LoBue reported that CDC and NTCA currently are reviewing the updated HCP recommendations. Ms. Cole confirmed that ACET would revisit this issue after CDC and NTCA finalize, clear, and approve the updated HCP recommendations for dissemination. ACET agreed that no further action is needed at this time.
Specific Topics to be Addressed by the TB Drug Supply Workgroup	Ms. Cole reported that the workgroup currently is addressing the cost of bedaquiline. The workgroup will invite a speaker to discuss the requirements of the 340B Drug Pricing Program after HRSA appoints a new <i>ex-officio</i> member. ACET agreed that no further action is needed at this time.

ADVICE REQUESTED FROM ACET

Topic	Action
Revised TB Technical Instructions (TIs)	<p>Ms. Cole reported that the CDC Division of Global Migration and Quarantine (DGMQ) issued a table on August 14, 2018 to compare the old and revised TB TIs. The revised TIs will become effective in October 2018. The key changes are highlighted below.</p> <ol style="list-style-type: none"> 1. The use of IGRA in applicants 2-14 years of age in all countries with WHO's estimated TB incidence rate of 20 or more cases per 100,000 population. 2. Inclusion of the new Class B0-TB Pulmonary (i.e., applicants who were diagnosed by or presented to a panel physician while on TB treatment and successfully completed DOT under supervision). 3. The requirement for an IGRA to be performed for all applicants 2 years of age and older. 4. The requirement for civil surgeons to report LTBI testing results to state or local jurisdictions. <p>ACET agreed that no further action is needed.</p>

Dr. Starke clarified that the third revision in the TB TIs cited the 2015 *Red Book*® rather than the 2018 *Red Book*®. The 2018 *Red Book*® recommends the use of IGRA in children as young as 2 years of age, but points out that some experts use IGRA in even younger children. He confirmed that he would send an email to Ms. Cole with this correction to be forwarded to Dr. Joanna Regan, of DGMQ, who is leading CDC's effort to revise the TB TIs.

Business Item 6: Future Agenda Items

Ms. Cole confirmed that the Agenda Setting Workgroup will convene a teleconference to draft an agenda based on the topics ACET proposed over the course of the meeting. The draft agenda will be circulated to ACET for review in advance of the December 2018 meeting.

Presenter	Agenda Item
Dr. Philip LoBue Dr. Peter Davidson	Status report on ACET's previous resolution that endorsed the formation of an external workgroup to examine new and innovative modalities for the delivery of TB medical consultation services. [Note: This update will continue to be tabled until DTBE announces the awards of the TB COEs under the re-competed TB CoAg.]
Dr. Philip LoBue	Updates to include in the DTBE Director's Report: <ul style="list-style-type: none"> ➤ Key outcomes on piloting the revised RVCT. ➤ Updated recommendations on TB screening and testing of U.S. HCP. ➤ Education that will be offered to PCPs to implement the modified and new ICD-10 codes in the field. ➤ Current status of DTBE's information campaign to reach PCPs to publicize the USPSTF recommendations on LTBI screening and treatment as well as DTBE's efforts to monitor the implementation of the recommendations by PCPs.
Ms. Lauren Lambert (DTBE) Ms. Jennifer Cochran (Massachusetts Department of Public Health)	Overview of the DTBE-funded demonstration project on launching LTBI testing and treatment at the Lynn Community Health Center in Lynn, Massachusetts.
Mr. Jeff Caballero	[Rescheduled agenda item]: Overview of successful TB prevention activities by the Association of Asian Pacific Community Health Organizations, particularly in the area of stigma reduction.
Dr. Robert Redfield	Overview of the CDC Director's priorities and/or areas of interest for TB. <ul style="list-style-type: none"> ➤ If Dr. Redfield is unable to attend, the time should be devoted to key outcomes from the upcoming high-level TB meetings in New York City in September 2018. The speaker should be a current participant of the U.S. Mission or an NTCA member who attended the high-level TB meetings.
Dr. Nikolas DeLuca	Update by the DTBE Communications, Education, and Behavioral Studies Branch: <ul style="list-style-type: none"> ➤ ACET's discussion and recommendations on TB messaging. ➤ The most recent recommendations by ACET/CDC to USPSTF on TB TasP and USPSTF's response two years ago.
DASH and DTBE	Update on efforts to add TB-related questions to the YRBS.
ACET Membership	Follow-up discussion topics: <ul style="list-style-type: none"> ➤ Potential strategies to fund new demonstration projects for TB. [TB controllers in the field will need to be surveyed to provide input on using part of their programmatic funds from the TB CoAg to support the new demonstration projects.] ➤ Potential approaches to develop a TB performance measure for PCPs.

Public Comment Session

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

Closing Session

The next ACET meeting will be held in person in Atlanta on December 11-12, 2018. Ms. Scott-Cseh will poll the members via email to determine their availability and confirm the date.

With no further discussion or business brought before ACET, Ms. Cole adjourned the meeting at 2:50 p.m. EST on August 21, 2018.

CHAIR'S CERTIFICATION

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

Date

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



Attachment 1: Participants' Directory

ACET Members Present

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

ACET Ex-Officio Members Present

Dr. Ulana Bodnar
U.S. Department of Justice

Ms. Kali Crosby
Agency for Healthcare Research and Quality

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

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

Dr. Jonathan Iralu
Indian Health Service

CMDR Julie King
Federal Bureau of Prisons
(Alternate for Ms. Sarah Bur)

Mr. Stephen Martin
National Institute for Occupational Safety and Health

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

Dr. Samuel Wu
U.S. Department of Health and Human Services, Office of Minority Health
(Alternate for Dr. Matthew Lin)

ACET Ex-Officio Members Absent

Dr. Naomi Aronson
U.S. Department of Defense

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

Ms. Sarah Bur
Federal Bureau of Prisons

Dr. Anthony Campbell
Substance Abuse and Mental Health Services Administration

Dr. Matthew Lin
U.S. Department of Health and Human Services, Office of Minority Health

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

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

ACET Liaison Representatives Present

Dr. Shama Ahuja
Council of State and Territorial
Epidemiologists

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

Ms. Diana Fortune
National Tuberculosis Controllers
Association

Dr. John Hellerstedt
Association of State and Territorial Health
Officials

Mr. Surajkumar Madoori
Treatment Action Group

Dr. Robert Morris
National Commission on Correctional
Health

Dr. Randall Reves
International Union Against TB and Lung
Disease

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

ACET Liaison Representatives Absent

Mr. David Bryden
RESULTS

Dr. Fran du Melle
American Thoracic Society

Dr. Mayleen Ekiek
Pacific Island Health Officers Association

Dr. Ilse Levin
American Medical Association

Dr. Howard Njoo
Public Health Agency of Canada

Dr. Ameer Patrawalla
American College of Chest Physicians

Dr. Jennifer Rakeman
Association of Public Health Laboratories

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

Ms. Susan Rappaport
American Lung Association

Dr. Susan Ray
Infectious Disease Society of America

Dr. Michael Tapper
Society for Healthcare Epidemiology of
America

Dr. Lornel Tompkins
National Medical Association

Mr. Bobby Watts
National Health Care for the Homeless
Council

ACET Designated Federal Officer

Dr. Hazel Dean
NCHHSTP Deputy Director

CDC Representatives

Ms. Ann Cronin
Mr. Justin Davis
Dr. Nikolas DeLuca
Dr. Neela Goswami
Dr. Maryam Haddad
Dr. Awal Khan
Ms. Maureen Kolasa
Ms. Kathryn Koski
Dr. Adam Langer
Rebecca Levine, Esq.
Dr. Philip LoBue
Dr. Cynthia Lyles
Ms. Suzanne Marks
Dr. Jonathan Mermin
CAPT Roque Miramontes
Dr. Thomas Navin
Mr. James Nowicki

CDR Melanie Ross
Ms. Margie Scott-Cseh
Dr. Andrew Vernon
LCDR Laura Vonnahme
Ms. Kai Young

**Invited Guests/
Members of the Public**

Dr. Brent Gibson
National Commission of Correctional Health
Care

Ms. Donna Wegener
National Tuberculosis Controllers
Association

Dr. Jennifer Shuford
Texas Department of State Health Services



Attachment 2: Glossary of Acronyms

Acronym	Definition
1HP	Four Weeks of Daily Isoniazid and Rifapentine
3HP	Three Months of Isoniazid/Rifapentine
9H	Nine Months of Daily Isoniazid
AAP	American Academy of Pediatrics
ACET	Advisory Council for the Elimination of Tuberculosis
ACTG	AIDS Clinical Trials Group
ARPE	Aggregate Reports for Program Evaluation
ART	Antiretroviral Therapy
ASTERoiD	Assessment of the Safety, Tolerability, and Effectiveness of Rifapentine Daily
BCG	<i>Bacillus Calmette-Guérin</i>
BRIEF-TB	Brief Rifapentine-Isoniazid Efficacy for TB Prevention
BSC	Board of Scientific Counselors
CDC	Centers for Disease Control and Prevention
CoAg	Cooperative Agreement
COEs	Centers of Excellence
ConOps	Concept of Operations
DASH	Division of Adolescent and School Health
DFO	Designated Federal Officer
DGMQ	Division of Global Migration and Quarantine
DHAP	Division of HIV/AIDS Prevention
DOT	Directly Observed Therapy
DSTD	Division of STD Prevention
DTBE	Division of Tuberculosis Elimination
DVH	Division of Viral Hepatitis
EDN	Electronic Disease Notification
EFV	Efavirenz
EHR	Electronic Health Record
ELR	Electronic Laboratory Record
FACA	Federal Advisory Committee Act
FAPP	Federal AIDS Policy Partnership

Acronym	Definition
FQHCs	Federally Qualified Health Centers
FY	Fiscal Year
HAV	Hepatitis A Virus
HBV	Hepatitis B Virus
HCP	Healthcare Personnel
HCV	Hepatitis C Virus
HHS	U.S. Department of Health and Human Services
HPTN	HIV Prevention Trials Network
HRSA	Health Resources and Services Administration
IGRA	Interferon Gamma Release Assay
INH	Isoniazid
LTBI	Latent Tuberculosis Infection
<i>MMWR</i>	<i>Morbidity and Mortality Weekly Report</i>
MRC	Medical Research Council
MSM	Men Who Have Sex With Men
MTB	<i>Mycobacterium tuberculosis</i>
NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
NCHS	National Center for Health Statistics
NHANES	National Health and Nutrition Examination Survey
NOFO	Notice of Funding Opportunity
NPIN	National Prevention Information Network
NTCA	National Tuberculosis Controllers Association
NVP	Nevirapine
PCPs	Primary Care Providers
PLWH; PWH	People Living With HIV; People With HIV
PrEP	Pre-Exposure Prophylaxis
RPT	Rifapentine
RVCT	Report of Verified Case of Tuberculosis
SSuN	STD Surveillance Network
STEMS	Surveillance for TB Elimination Management System
TA	Technical Assistance
TasP	Treatment as Prevention
TB	Tuberculosis
TBESC	Tuberculosis Epidemiologic Studies Consortium
TBLISS	TB Latent Infection Surveillance System
TBT	Tuberculosis Preventive Treatment
TBTC	Tuberculosis Trials Consortium
TIs	Technical Instructions
TST	Tuberculin Skin Test
U=U	Undetectable Equals Untransmittable

Acronym	Definition
UN HLM	United Nations High-Level Meeting
USBP	U.S.-Born People/Populations
USG	U.S. Government
USPSTF	U.S. Preventive Services Task Force
WHO	World Health Organization
YRBS	Youth Risk Behavior Survey