Roadmap for Advancing TB Elimination in the United States through Scale up of Testing and Treatment of Latent TB Infection

Recommendations of the Advisory Council for the Elimination of Tuberculosis (ACET)

Prepared by: ACET Latent Tuberculosis Infection Workgroup

Summary
This statement from the Advisory Council for the Elimination of Tuberculosis updates the strategy to eliminate tuberculosis (TB) in the United States (2, 7). The report provides new recommendations to prevent TB, specifically through focus on identifying individuals at risk and testing and treating latent TB infection (LTBI). To scale up testing and treatment of latent TB infection, recommendations include: 1) identifying and engaging individuals at risk and their providers, 2) encouraging prevention using focused, effective testing and treatment strategies, 3) developing streamlined LTBI surveillance and monitoring systems to measure and optimize outcomes and 4) securing new funding to support these new activities. Effective communication strategies and outreach to affected communities and healthcare providers are crucial components for success of each strategy. Research to improve diagnostics and treatment and advance vaccine development will also be essential to reach TB elimination.

BACKGROUND/INTRODUCTION
The Advisory Council for the Elimination of Tuberculosis (ACET) provides advice and recommendations regarding the elimination of tuberculosis to the Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC). The ACET Latent Tuberculosis Infection (LTBI) Workgroup was established to develop a strategy document with concrete recommendations to address latent tuberculosis infection (LTBI) with the goal of ultimately eliminating tuberculosis (TB) within the United States.

This report provides a major update to the 1989 Strategic Plan publication (7). In the past 2 decades, the epidemiology of TB in the US has changed. To date, strategies to control TB in the United States have focused on rapidly finding and treating patients with active TB disease and testing and treating their contacts with minimal focus on the larger reservoir of persons with latent TB infection.

Today untreated LTBI is the main generator of new TB cases in the US and is responsible for a significant slowing in the decline of TB disease. Persons with LTBI are not ill and have no clinical evidence compatible with TB disease, but can become sick in the future and develop active disease. In 2014, the World Health Organization published guidance for the scale up of LTBI testing and treatment in low incidence countries. In addition, in 2016, the US Preventive Services Task Force (USPSTF) released findings calling for routine LTBI testing and treatment of non-US-born (non-USB) adults and those residing in congregate settings (27), yet these recommendations are only slowly being adopted. These recent recommendations emerged in tandem with the introduction of a more accurate test for LTBI (the interferon-ɣ release assays [IGRAs]) and shorter, safer treatment regimens for LTBI (9, 16). In addition, expansion of healthcare access has created new opportunities for care of populations at high-risk for LTBI and development of TB disease. While these opportunities can help us advance to TB elimination,

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the need for strategies to promote widespread adoption of LTBI testing and treatment requires update of the TB elimination roadmap. Scaling up prevention efforts by improving our ability to conduct LTBI testing and treatment and measure LTBI outcomes is the focus of this strategy document.

While modeling studies have suggested we cannot make substantial progress toward eliminating TB without an LTBI-focused approach (10), the barriers to LTBI scale-up must first be addressed. Individuals with LTBI feel well and may be unaware of their risk of developing TB disease and the benefit of testing and treatment, resulting in minimal patient-driven demand for testing and treatment. Although many non-USB persons are in routine care, LTBI risk assessment and testing are often overlooked by clinicians because of competing health priorities and a knowledge gap related to TB/LTBI. Many healthcare providers are unaware of the USPSTF LTBI recommendations and are unclear about who to test and treat; they also are unfamiliar with the new and better tests, and the shorter and safer drug regimens for treating LTBI. Across healthcare settings, there are currently few systems to help busy physicians with LTBI testing and treatment; most electronic health records do not include TB risk factor questions as a part of routine health maintenance screening and changing electronic health records (EHRs) to include elements important for TB risk assessment, such as country of birth, is not straightforward. Public health department resources for LTBI testing and treatment are often meager, and there has been no unified effort to promote LTBI testing and treatment scale-up to community providers who care for large volumes of high-risk patients. Lack of designated funding and effective local, regional and national TB prevention initiatives and LTBI awareness campaigns have impeded public health department action. Finally, the complementary roles of public health departments and primary care providers in TB prevention have not been well-articulated. As a result, many national and community-based organizations that support high-risk patients are not yet fully focused on the need for, and benefits of, TB prevention.

Most patient and provider education about LTBI and TB disease has come from health departments and academia. While these sources have provided valuable information, they have not always been effective. New active strategies are needed that reach out to the target populations, address the needs and concerns of high-risk individuals and their healthcare providers and provide practical action steps that will lead to engagement in LTBI care. It will be essential to engage key community partners both to design new strategies, produce culturally tailored materials and motivate at-risk individuals to seek appropriate testing and treatment. Community-based and medical professional organizations play an important role in this process. Providers in all settings need to be empowered to identify and evaluate their clients at risk for LTBI (22). Finally, while education is necessary, it also important to develop a marketing approach tailored to specific high-risk groups of patients and providers to encourage engagement and action.

Healthcare access poses an additional barrier for many individuals who would benefit from TB prevention services. Patients who are at risk for TB may not be in care or may experience prohibitive out-of-pocket costs for LTBI assessment and treatment (e.g., IGRA testing, medical evaluation, chest radiograph, and medications). Most public and private healthcare settings have limited budgets for LTBI diagnostics and treatment. Although many healthcare settings routinely screen patients for infections such as HIV and Hepatitis B and C, many fewer routinely assess for LTBI and there usually is no synergy between these screening activities even though many patients are at risk for all of these infections. Many Federally Qualified Health Centers (FQHCs) that provide care to high-risk clients do not have

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adequate funding for LTBI testing and treatment. Health departments have been unable to focus on LTBI because of the absence of designated funding and the need to prioritize attention on TB disease. With TB disease waning in much of the country, many healthcare providers lack experience and knowledge about TB and LTBI, especially of the newer tests and treatment regimens, and the essential step of excluding TB disease prior to LTBI treatment. Systems for supporting adherence of patients throughout treatment, particularly in community healthcare settings, are typically undeveloped. Finally, the return on investment and future savings incurred by LTBI testing and treatment by reducing future costly disease has not yet ignited activity.

To measure progress in expanding LTBI testing and treatment, LTBI monitoring and surveillance are critical activities to target and evaluate the success of public health interventions. Local and nationwide LTBI surveillance and monitoring systems are needed that support data flow among varied healthcare settings, local and state health departments, and the CDC. LTBI is an asymptomatic condition that can be detected only through diagnostic testing (the tuberculin skin test [TST] or IGRA) and through the exclusion of active disease via chest imaging. Ironically, while many high-risk individuals go unevaluated, much of the testing for LTBI in the US currently is done through administrative or employment testing of low-risk populations. Although LTBI is reported in some areas, public health agency resource constraints limit the proportion of LTBI reports that can be investigated.

At both local and national levels, monitoring the success of interventions is critical. A major impediment to adoption of LTBI testing and treatment in healthcare settings is that there is no national requirement for quality improvement of LTBI testing and treatment or no required national LTBI performance metrics. There is a clear need for measuring LTBI burden over time and establishing a system for monitoring LTBI practices and outcomes. Several first steps that will allow better measurement of LTBI testing and treatment have occurred in the U.S: 1) minimum data elements for LTBI surveillance (26, 19) have been established, 2) informatics infrastructure (Tuberculosis Latent Infection Surveillance System [TBLISS]) has been developed and 3) a growing number of states now mandate LTBI reporting and 4) the National Health and Nutrition Examination Survey (NHANES) LTBI testing has also provided key estimates of LTBI in the US. Establishing national metrics for federally funded clinical settings, disseminating tools for tracking LTBI care steps, and supporting data exchange will help spur further progress.

METHODS

In January 2018, ACET convened a workgroup comprised of ACET members and subject matter experts to review existing evidence on strategies to achieve TB elimination and approaches for LTBI testing and treatment scale-up. A review of both program experience and the published literature was synthesized on strategies to accelerate the decline of TB cases in the US. The most recently published LTBI testing and treatment recommendations of the Institute of Medicine, USPSTF and CDC were considered. Experiences of US health departments in TB elimination planning and successful LTBI testing and treatment programs were analyzed.

Both current epidemiology and published modeling studies forecasting results of specific interventions were reviewed. Published reports on the facilitators and barriers for identifying and engaging high-risk populations and establishing systems for successful testing and treatment were examined.

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While prior US TB strategic plans have emphasized diagnosis, treatment and contact investigation for individuals with TB disease as the top priorities for TB elimination, these ACET recommendations highlight the new, additional priority of LTBI testing and treatment in high-risk persons to prevent TB disease as an equally important and necessary strategy to achieve further TB case decline. Building on USPSTF recommendations published in 2016 (27), the recommendations in this document can be applied by the CDC and state and local health departments in partnership with medical care settings, industry, and community organizations.

FINDINGS/RECOMMENDATIONS

There are four major activities required for scaling up LTBI testing and treatment in the United States: 1) identify and engage individuals at-risk and their providers; 2) increase testing of at-risk individuals and increase treatment of infected individuals; 3) measure outcomes of LTBI testing and treatment scale-up, and 4) secure funding for these TB disease prevention activities. Effective outreach, communication, education and partnership are crucial cross-cutting components for implementing these activities. Two additional high-priority interventions include research to improve diagnosis and treatment of LTBI and policies that implement targeted testing and treatment of LTBI in adult migrants before arrival in the US. To support each activity, ACET recommends the actions described below:

Identify and engage individuals at risk and their providers

Community outreach

1) Launch a marketing strategy targeted at public and community-based organizations to raise awareness about who is at risk for LTBI and TB disease and who needs testing, and to create demand for testing in healthcare settings:

- Engage community organizations to endorse/encourage TB screening
- Provide web-based tools for the public to determine individual risk ("Know Your TB Status/Risk"), to locate testing sites by zip code and to generate a risk assessment record for individuals to keep and to trigger testing by their healthcare provider
- Develop community-specific and culturally competent messages and education tools for specific patient groups at risk for TB

2) Use evidence-based strategies tailored to settings and risk groups to bring people at risk into care for testing and treatment

3) Build on and HIV/Hepatitis B and C/Sexually Transmitted Disease screening initiatives to replicate successful models of how to motivate patients and providers through engagement, linkage to care, testing (e.g., blood draw/chest radiograph) and treatment

4) Work with homeless organizations to implement risk-based testing and treatment

Provider outreach

5) Engage medical professional organizations to endorse/encourage TB screening

6) Identify and disseminate a list of provider groups and health plans serving large numbers of non-USB individuals to local health departments so they can focus their LTBI testing and treatment scale-up efforts

7) Encourage LHDs to engage with providers to communicate with local high-risk groups and give them the tools to do this effectively; as an example, academic detailing has been successful and used to outreach to clinicians on focused topics

8) Disseminate efficient models of LTBI risk-based testing and treatment work flows and protocols to clinics serving high risk patients

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Increase LTBI testing and treatment with the most effective tools

1) Initiate an awareness campaign to educate and disseminate effective tools for providers including:
- Methods for effectively communicating to patients about the need for LTBI testing and
- treatment
- Simple educational products about risk assessment (including who to test among non-USB
- populations), testing and treatment
- Recommendations about additional key risk groups warranting testing (e.g.,
- immunocompromised, contacts)
- Messages that explain the USPSTF recommendation
- Information about use of new short-course regimens
- Steps for ruling out TB disease before beginning LTBI treatment
- Steps for reporting LTBI to their jurisdiction, if mandated

2) Disseminate adherence strategies, for example, treatment support networks for patients, tailored case management strategies for specific patient groups, electronic Directly Observed Therapy (eDOT) strategies and electronic telemedicine follow-up models

3) Support documentation of treatment completion within healthcare systems, including adding an ICD-11 code for treatment completion documentation and ensure that patients have these records as they move across health systems and locations

4) Incentivize healthcare providers and plans to perform routine risk assessment to identify high-risk patients, including simple EHR tools to determine individual risk, including test order sets
- Engage companies that provide EHRs to develop capacity for recording, using and analyzing TB
- risk factors including country of birth
- Disseminate standardized elements for TB risk assessment, testing, and treatment for EHR
- systems and support EHR user networks for systematic changes

5) Facilitate outreach to and provide incentives for populations and their providers undergoing required testing (status adjusters) to promote linkage to and completion of treatment

6) Initiate a program for pre-departure LTBI testing and treatment for adults who are migrating to the US

7) Describe roles of local, state, federal, health department and health care providers for TB prevention

8) Build consultative capacity within public health departments, regional centers and the CDC Centers of Excellence for access by community providers and organizations

Measure success and outcomes of LTBI testing and treatment scale-up

1) Establish national, state and local LTBI surveillance systems that, to the extent feasible, exchange data among healthcare settings, state and local health departments, and the CDC to measure and improve outcomes of LTBI testing and treatment
- Define the core elements and approaches for simple effective LTBI surveillance and monitoring systems
- Determine and incorporate the needs and capabilities of local/state health departments for successful surveillance
- Engage public health and community providers in the system design and implementation
- Create systems that respond to healthcare setting, local and state needs and feasibility constraints

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- Implement laboratory reporting of the TB blood test results (IGRAs) for surveillance purposes as an important first step

2) Establish and track simple national, state and local quality improvement and performance metrics that measure (1) the percent of non-USB tested for LTBI, (2) the percent of LTBI treatment completion for those who test positive and (3) the percentage of active TB cases meeting criteria for potentially being preventable (e.g. were at known risk and not tested and/or not offered treatment)

- Work with the Health Resources and Services Administration (HRSA) and Centers for Medicare and Medicaid Services (CMS) to establish national performance measures
- Include these measures in the CMS Adult and Child Core Set and Medicare Quality Improvement requirements
- Assess whether risk criteria were met for testing

3) Work with state and local health departments to launch rigorous evaluation and improvement of newcomer testing and treatment (status adjusters and persons with TB B-notification)

Secure TB prevention funding for education, testing, treatment, surveillance and research

1) Establish private and public partnerships involving philanthropy, industry, governmental, and nongovernmental
health organizations for a national TB prevention/elimination initiative

2) Identify new funding streams to offset patient financial burden for the uninsured, as well as those insured with high co-pays

- Recommended strategies include making testing available for free, supporting a USPSTF review of LTBI treatment as prevention activity so that both testing and treatment have cost-sharing removed, and dissemination of financial analyses of the return on investment of LTBI testing and treatment to policymakers and health plans
- Ancillary actions that could remove financial barriers for programs and patients include allowing use of federal cooperative agreement funds for LTBI treatment and stimulating drug manufacturers to lower costs

3) Create a budget and secure funding for LTBI surveillance system

- Funding support should include electronic DOT/telemedicine adherence and follow-up to ensure treatment completion and create efficiency through electronic case reporting directly from electronic health records

4) Support research to advance needed tools

- While intensifying TB prevention through increased LTBI testing and treatment is an important step toward TB elimination, ending TB will require novel interventions; even though LTBI diagnostics and treatment regimens and our understanding of LTBI have improved, they are far from perfect
- Ongoing investment in research is critical to reach elimination and the workgroup identified five of the eight research priorities articulated by WHO (28) as the most critical to advance our ability to prevent TB in the US

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Recommended Priorities for Research

1. Define the rate of progression to active TB among those with LTBI generally and for specific subgroupsto inform the risk/benefit ratio of LTBI testing and treatment to aid clinical decision-making
2. Develop more predictive diagnostics to identify those with LTBI who will progress to TB disease
3. Conduct trials to assess effective shorter treatment options
4. Identify interventions that promote treatment adherence and prevent attrition during the LTBI care cascade
5. Identify the most cost-effective approaches and populations to focus screening testing and treatment

DISCUSSION

The expected impact of these new policy recommendations, if fully adopted, will be a successful expansion of LTBI testing and treatment and prevention of TB disease for those at risk. Modeling results have predicted that with a 4-fold to 8-fold increase in targeted testing and treatment using the most effective tools (e.g., IGRA and short course treatment regimens) (11), we can realize a substantial reduction of TB cases in the US and achieve pre-elimination targets (10). These tools provide us with the opportunity to save lives and reduce TB-related costs, morbidity, and deaths.

Useful lessons can be gleaned from the successful national "Know Hepatitis B Campaign" developed by CDC and the Hep B United coalition (14). The challenges for hepatitis B prevention were addressed by reaching Asian Americans for testing in their communities, in their language and with trusted leaders. The plan for accomplishing this was through partnerships with Asian American organizations, CDC funding of a cooperative agreement and providing linkage to care and integrating hepatitis B with other important conditions. Similarly, progress in ending HIV has occurred through federal commitment and funding. The national LTBI initiative can build on and learn from these successes.

In addition to domestic expansion of LTBI testing and treatment, advancing policy and action outside the US in parallel is crucial. Successfully addressing and reducing TB globally in high-burden countries is a critical component for elimination of this disease. In addition, policies should promote testing and encourage referral for LTBI treatment of immigrants applying for permanent residency during health examinations done before US entry and at the time of visa status change in the US. The current overseas requirement for pre-departure screening of immigrants should be expanded to include those requesting student, worker, and extended tourist visas with the goals of TB case detection as well as diagnosis for LTBI with encouragement of LTBI treatment (22). LTBI diagnosis and treatment can be successful and efficient with new tests and short-course treatment. While many activities must occur in parallel, prioritizing and staging actions to advance TB elimination may be needed in the context of limited resources. The workgroup recommended tackling the following high-priority interventions first, shown in the following graphic.

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High-Priority Interventions

1. Create a visible national TB prevention and elimination plan focused on LTBI testing and treatment
2. Secure funding and partnerships for CDC and health department-led activities and stimulatesupport needed by community organizations and persons at risk and healthcare providers
3. Launch marketing strategy targeted at public and community-based organizations to raise awareness of who is at risk for LTBI and TB disease and to create demand for testing in healthcaresettings public and community based organizations
4. Disseminate evidence-based strategies tailored to risk groups and settings to bring people at riskinto care for testing and treatment
5. Disseminate efficient models and tools for LTBI risk-based testing and treatment in clinical settings(e.g., template for systematic approach to LTBI care cascade steps, workflows, protocols, EHR triggers)
6. Facilitate outreach to and provide incentives for newcomers (status adjusters and those with B-notification) who test positive to promote linkage to and completion of treatment
7. Establish and track simple national state and local quality improvement and performance metricsto stimulate improvement
8. Specifically, establish measure in CMS Child and Adult Core set which will be required of federally funded providers/clinics (FQHCs, Medicaid, and Medicare healthcare providers)
9. Work with state and local health departments to launch rigorous evaluation and improvement ofnew comer testing and treatment (e.g., status adjusters and TB B-notifications)
10. Support a prioritized LTBI research agenda advancing 2-3 high impact studies in next 5 years

High-Priority Interventions: Future Steps

1. Create streamlined exchange of LTBI data for monitoring and action across healthcare settings,local and state health departments and CDC.
2. Initiate a program for adult pre-departure LTBI testing and treatment building on the Vietnampilot experience
3. Implement new research findings that can lead to faster adoption of best practices and speed TBdecline

CONCLUSION

Substantial progress has been made in reducing tuberculosis in the United States, but the decline has stalled, with persistent morbidity, cost and transmission of TB. A commitment to achieve TB elimination is crucial for progress and requires effective partnerships across diverse organizations and health system components. TB decline can be accelerated by a robust investment in targeted testing and treatment of latent TB infection added to strong core TB infrastructure for TB disease diagnosis and treatment. In parallel, global TB prevention efforts and research are vital to realizing TB elimination.

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Summary Recommendations

- Resource and commit to a national TB elimination plan
- Engage and motivate providers and health systems
- Outreach to high-risk populations
- Conduct research to advance tools for LTBI testing and treatment
- Measure and improve outcomes of the LTBI care cascade

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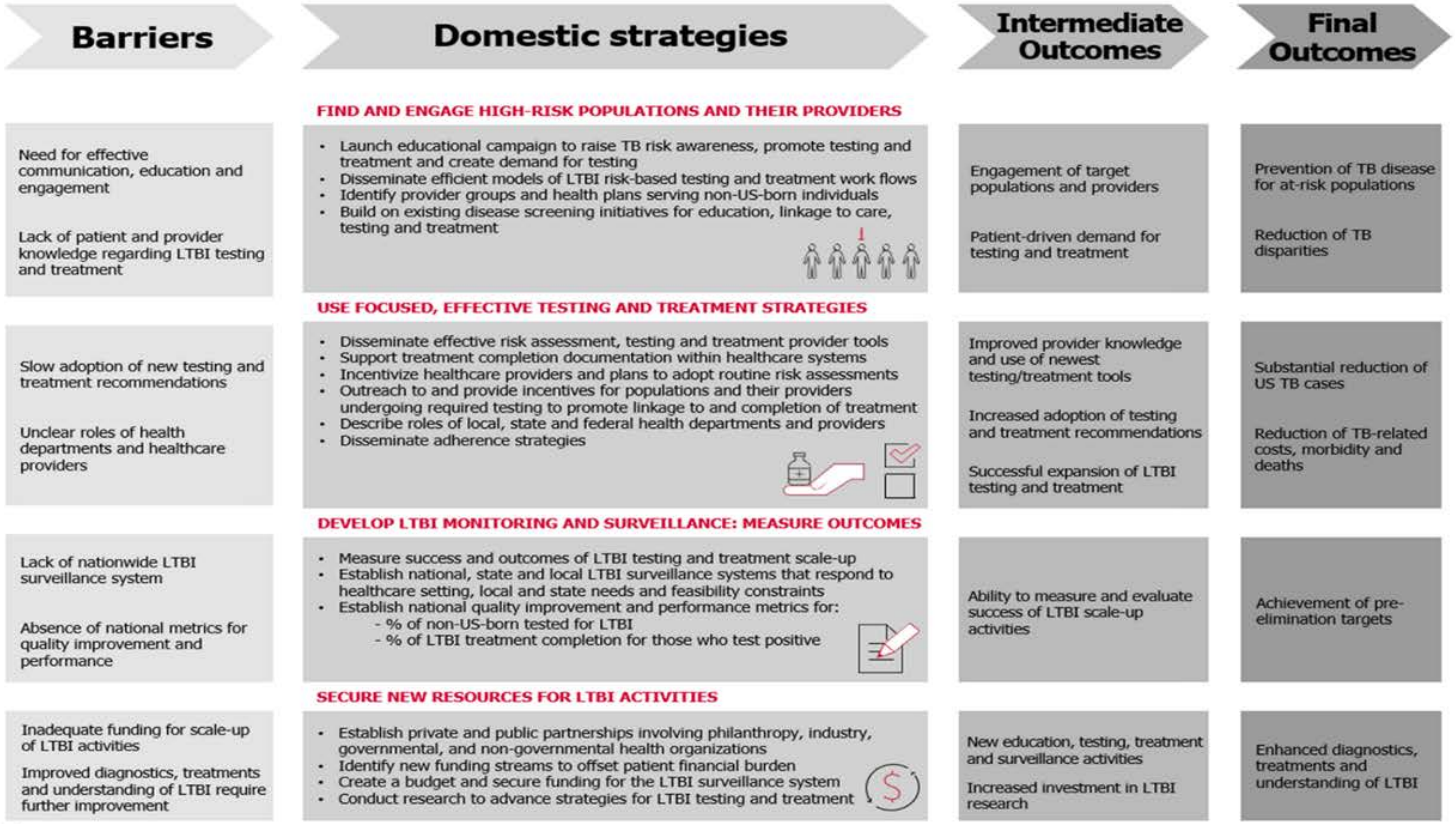
LTBI TESTING AND TREATMENT SCALE-UP ROADMAP



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