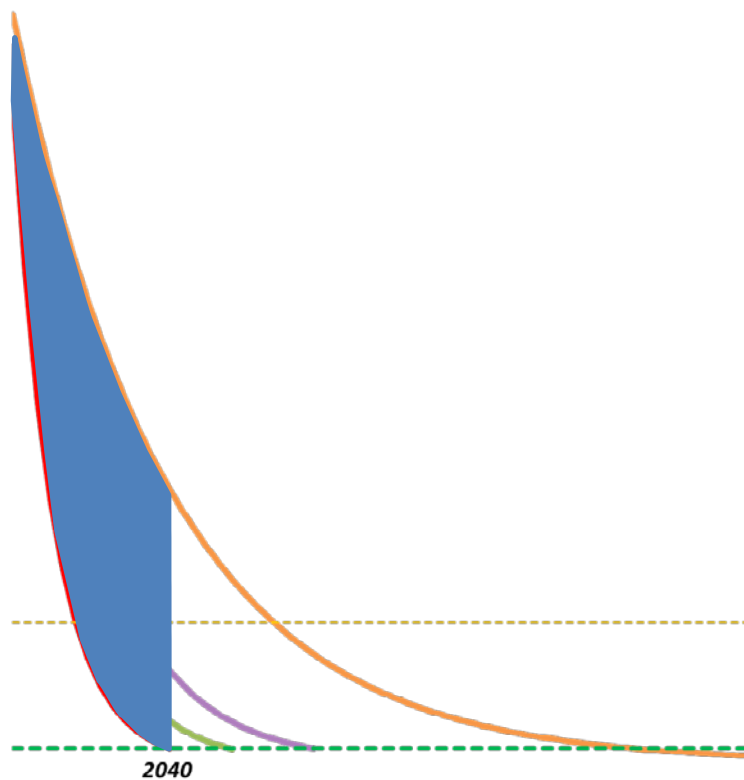


California Tuberculosis Elimination Plan 2016–2020

A Five-Year Action Plan



July 2016

California Tuberculosis Elimination Advisory Committee



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Preface

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I. Executive Summary

California has had a steady decline in tuberculosis (TB) disease, but this trend has slowed significantly since 2000 and appears to have slowed further since 2013. Public health departments have been successful in curtailing transmission of TB in California, and now most new TB cases in California result from longstanding latent TB infection (LTBI) that, in many persons, progresses to active TB disease. There are an estimated 2.4 million persons with LTBI in California. This reservoir of TB infection must be addressed to achieve a further reduction in TB disease.

Several advances make it timely to pursue elimination of TB¹ in California: a new short-course drug regimen for LTBI with very high treatment completion rates; the interferon-gamma release assay blood tests now available have fewer false positive results in foreign-born persons; the Affordable Care Act has expanded access to health care; national and international organizations are now focused on elimination and LTBI prevention; and the U.S. Preventive Services Task Force has issued draft recommendations for TB screening which will eliminate out of pocket payment for these services.

In early 2015, a scientific task force met and developed technical recommendations for high impact interventions to achieve TB elimination. Using the task force recommendations as a framework, the California TB Elimination Advisory Committee (CTEAC) was convened in December 2015 to create a detailed five-year action plan. The CTEAC membership is comprised of TB controllers and medical and public health experts. CTEAC met with stakeholders to develop an action plan through systematic, facilitated discussion of each task force recommendation. CTEAC developed action steps for implementation of the task force recommendations and interventions.

The five-year action plan outlines the necessary steps to reach elimination of TB in California by the year 2040. The specific focus of the plan is to ensure the identification and treatment of individuals with LTBI in California who are likely to progress to TB disease. This plan is designed to facilitate collaboration among public health TB programs and private and public partners toward the common goal: a California free of TB. The audience for this plan includes public health practitioners, clinical providers, health plan administrators, policymakers, community organizations and coalitions and other partners in the public and private sectors that serve populations at risk for TB.

¹ The World Health Organization defines TB elimination as less than one case of TB disease per million population. This translates to an elimination target of 39 cases per year in California. In 2015 there were over 2000 TB cases reported in California.

The California Tuberculosis Elimination Plan proposes actions in California during the five-year period, 2016-2020. The actions, listed in the table below, address each step for engaging populations at risk for LTBI through testing and treatment. The action steps—many of which are in progress—outline processes to ensure that at-risk populations are tested and treated with the most effective tools and that there is a tracking system in place to monitor testing and treatment completion. In addition, the steps call for effective communication with both providers and the public about TB prevention opportunities available through intensifying LTBI testing and treatment activities for high risk populations. CTEAC identified partners to engage and resources needed to make TB elimination possible. This action plan provides concrete steps to galvanize progress to reach TB elimination by 2040 in California. Success is possible through ongoing commitment of partners statewide.

California Tuberculosis Elimination Plan, a Five-Year Action Plan, 2016 – 2020

Recommendation 1: Find and engage persons and populations at high risk for TB and their providers in California

Intervention 1A: Use epidemiologic profiles to identify populations at high risk for TB and the providers who serve them

Action Steps

1. Create epidemiologic profiles of populations at high risk for TB to aid prevention efforts
2. Provide epidemiologic profiles and maps of high risk populations and their providers to local health departments to determine potential partners for TB prevention
3. Identify health care providers who are most frequently serving individuals who develop TB disease
4. Identify providers for populations at high risk by reviewing the languages spoken by medical providers, available from the Medical Board of California website

Intervention 1B: Ensure that country of birth is included as a data element for electronic health records across care settings

Recommendation 1: Find and engage persons and populations at high risk for TB and their providers in California

Action Steps

1. Systematically ensure that country of birth, an important risk factor, is added as a data field to electronic health records and medical care intake and charting
2. Request that electronic health record developers modify existing software systems to include a country of birth data field and include as part of the standard demographic package in new systems
3. Include a country of birth data field in TB-specific Confidential Morbidity Reports used for reporting TB suspected cases and known cases

Recommendation 2: Apply focused and effective strategies for TB testing in California

Intervention 2A: Prioritize testing for LTBI in foreign-born persons from countries with an elevated TB rate; the immune compromised; and contacts to TB cases, by encouraging use of the California TB risk assessment tool

Action Steps

1. Use education and outreach to stimulate healthcare providers' use of the California TB risk assessment tool
2. Incorporate the risk assessment questionnaire into electronic health records
3. Identify and disseminate Medi-Cal and Medicare codes for reimbursement for conducting a TB risk assessment
4. Harmonize the child, adult and specialized versions of the TB risk assessment tools
5. Standardize the TB risk assessment performed for school entry throughout the state
6. Implement effective marketing strategies to encourage providers and health systems to adopt the TB risk assessment tool
7. Ensure official endorsement of the TB risk assessment tool by the highest levels of public health
8. Encourage health care system administrators to require that their providers complete TB risk data fields and tie to quality improvement initiatives
9. Develop a metric and track the adoption and use of the risk assessment tool

Intervention 2B: Ensure that California health care providers use interferon gamma release assays for testing individuals who previously received bacille Calmette-Guerin (BCG) vaccine

Recommendation 2: Apply focused and effective strategies for TB testing in California

Action Steps

1. Update and widely disseminate guidelines to community providers to recommend that interferon-gamma release assays should be used for testing individuals who have been vaccinated with BCG
2. Engage private sector patient assistance programs, health plans and manufacturers to provide interferon-gamma release assays at lowest cost
3. Ensure that health plan utilization reviews assess use of interferongamma release assays

Intervention 2C: Reduce TB testing in low risk populations

Action Steps

1. Eliminate requirements for screening employees in settings where the risk of TB transmission is low
 2. Align the Child Health and Disability Prevention Program TB screening protocol with risk-based testing for K-12 school entry
 3. Implement a process to monitor and update TB screening laws as TB epidemiology and tools change overtime
 4. Bring the CalOSHA annual screening regulations for health careworkers into alignment with federal guidance on preventing TB transmission in health care facilities
-

Recommendation 3: Optimize treatment for LTBI

Intervention 3A: Maximize initiation and completion of treatment for LTBI

Action Steps

1. Develop and disseminate educational materials on LTBI treatment to providers serving populations at high risk for TB
2. Develop strategies to ensure that individuals at high risk for disease progression who are already being screened are starting and completing LTBI treatment
3. Educate providers on the most effective ways to communicate the importance of LTBI treatment completion to patients
4. Develop strategies to support treatment monitoring and/or adherence
5. Establish provider incentives for recording LTBI diagnosis and LTBI treatment completion
6. Conduct outreach to populations at high risk to provide education about the need for testing and treatment for LTBI

Intervention 3B: Promote use of the shortest effective LTBI treatment regimens

Action Steps

1. Promote access to effective short-course regimens to all who need them
2. Ensure that pharmacy formularies provide easy access to drugs used in short-course LTBI regimens

Intervention 3C: Increase access to adherence technologies to enhance completion of treatment for LTBI

Action Steps

1. Use data to provide feedback to providers and health care systems on provider performance on LTBI testing and treatment
 2. Disseminate models on best practices for improving patient LTBI treatment monitoring and completion
 3. Expand access to and use of electronic directly observed therapy reminder and tracking technologies
-

Recommendation 4: Develop strong and effective partnerships to eliminate TB in California

Intervention 4A: Create and strengthen prevention partnerships that involve public and non-public health providers

Action Steps

1. Implement local health department strategies to stimulate health care provider testing and treatment of LTBI in populations at high risk
2. Create public-private partnerships to assist providers to complete each step of the TB prevention and treatment cascade
3. Identify and train community health workers and former TB patients to educate communities and individuals at high risk about the need for testing and treatment for LTBI

Intervention 4B: Stimulate and incentivize community providers who serve populations at high risk to make testing for and treatment of LTBI routine

Action Steps

1. Encourage health systems to implement routine quality improvement activities that assess completion of steps of LTBI testing and treatment
2. Educate civil surgeons to ensure that patients with LTBI are referred for or receive and complete treatment
3. Identify methods to recognize providers who excel at ensuring LTBI treatment completion
4. Create a pilot demonstration project to replicate the British LTBI care provider incentive process

Intervention 4C: Remove existing financial barriers to LTBI testing and treatment for both patients and providers

Action Steps

1. Collect data about the LTBI burden in California and utilize these data to communicate resource needs for LTBI testing and treatment
 2. Make testing and treatment for LTBI a routinely covered benefit of health plans to eliminate barriers created by out-of-pocket expenses
 3. Communicate and disseminate to health plan administrators the return on investment for the testing for and treatment of LTBI
-

Recommendation 5: Create an effective communication plan to promote testing for and treatment of LTBI to health providers and the community in California

Intervention 5A: Develop, implement and evaluate a simple, clear communication strategy focusing on testing for and treatment of LTBI, targeted to both public and private providers

Action Steps

1. Identify medical societies and groups for targeted messages about testing for and treatment of LTBI
2. Develop compelling messages for health care systems to focus on foreignborn populations and other risk groups for TB testing
3. Create an LTBI educational toolbox with resources for communicating to providers serving populations with high TB infection rates
4. Promote LTBI testing and treatment at key conferences to providers who serve populations at high risk
5. Identify industry and philanthropic organizations that can fund development of resources for communicating about new LTBI diagnostics and treatment

Intervention 5B: Develop, implement and evaluate a simple, clear communication strategy focusing on testing for and treatment of LTBI for the general public

Action Steps

1. Collaborate with a marketing expert to create public communication strategies for populations at high risk
 2. Use social media tools to disseminate LTBI testing and treatment messages to the public
 3. Develop a group of TB patients and representatives to disseminate LTBI testing and treatment messages to the public and policymakers
 4. Conduct outreach to engage key populations at high risk for TB to promote LTBI screening
-

Recommendation 6: Develop and implement a surveillance system for reporting, tracking and evaluating LTBI in California

Intervention 6A: Establish systematic mechanisms for reporting LTBI and tracking populations through the LTBI testing and treatment steps

Action Steps

1. Assess the feasibility of making LTBI a reportable condition in California (including the development of a mandate)
2. Develop a standardized definition of LTBI
3. Explore using existing systems for reporting LTBI (laboratory reporting of interferon-gamma release assays) and for tracking LTBI treatment and outcomes
4. Identify initial and ongoing funding to support LTBI reporting and treatment
5. Develop performance measures for LTBI testing and treatment
6. Facilitate electronic transfer of LTBI testing and treatment information between electronic health records and LTBI reporting systems
7. Pilot an LTBI reporting system before conducting a statewide rollout

Recommendation 7: Secure sufficient resources for implementing the California TB Elimination Plan

Intervention 7A: Ensure that both public and private providers have the capacity to adequately test and treat all patients at high risk for TB

Action Steps

1. Ensure an adequate and continuous supply of drugs to treat LTBI, especially those drugs needed for short-course therapy
2. Ensure that clinical and programmatic TB guidelines for California are up-to-date and are widely disseminated; develop and disseminate new ones, as necessary
3. Coordinate with TB training organizations to ensure that training curricula for public and private providers are relevant, up-to-date and being implemented for the highest priority audiences
4. Create an inventory of LTBI testing and treatment best practices for dissemination to public and private partners

Intervention 7B: Acquire new funding to ensure sufficient resources to eliminate TB in California

Recommendation 7: Secure sufficient resources for implementing the California TB Elimination Plan

Action Steps

1. Seek funding from the Centers for Disease Control and Prevention for intensifying LTBI screening, testing and treatment activities
 2. Secure private foundation and industry funding to support California TB Coalition infrastructure and initial support for demonstration projects, innovations and intensification of current activities
 3. Strengthen the public health infrastructure so that electronic health records and electronic laboratory reporting capacity exists across local public health departments
 4. Identify ongoing resources to support LTBI reporting and treatment
-

II. Background

The report, “Ending Neglect: The Elimination of Tuberculosis in the United States” published in 2000 by the Institute of Medicine, stated that to reach tuberculosis (TB) elimination, the 10-15 million people in the U.S. living with latent TB infection (LTBI) must be identified and treated.¹ As a result, both federal and state TB programs recognized the need to intensify targeted testing and treatment of LTBI while maintaining control of active TB disease. In 2010, the non-governmental organization Stop TB USA contributed to this momentum with a national action plan to guide planning for TB elimination and a proposal that states create their own specific elimination plans.²

As the first step to create a California elimination plan, a scientific task force met in May 2015 to develop recommendations to reach TB elimination (Appendix B). The California TB Elimination Task Force determined that addressing the reservoir of LTBI is essential for reaching elimination. The Task Force reviewed the scientific body of evidence about strategies for engaging, testing and treating populations at risk for TB exposure and

The CTEAC vision, “reach TB elimination in California by 2040,” provided a clear charge for the committee and its partners.

progression to disease. Their findings were that the most effective tools and scientific strategies should be used, that the simplest messages should be disseminated and that LTBI testing and treatment should be made routine in primary care practice, as well as in the public health sector.

The task force noted several opportunities that make it timely to advance a plan for elimination in California:

1. New short-course treatment regimens have demonstrated very high treatment completion rates
2. Interferon-gamma release assays reduce false positive result rates for foreign-born persons vaccinated with bacille Calmette-Guerin (BCG)
3. Expanded access to health care with the Affordable Care Act
4. New national and international engagement and focus on TB elimination
5. U.S. Preventive Services Task Force draft recommendations allow for TB screening at no cost to individuals

Following the Task Force report, the California TB Elimination Advisory Committee (CTEAC) met in December 2015 with a new goal: to create a five-year statewide TB elimination action plan. CTEAC, comprised of TB controllers and other public health experts, is an ad hoc committee that was established in 1992 to advise the California state health department director on TB control at the height of the TB resurgence in the 1990s. The California TB Elimination Task Force 2015 recommendations served as the framework for the CTEAC elimination plan discussions. The CTEAC vision, “reach TB elimination in California by 2040,” provided a clear charge for the committee and its partners.

The CTEAC membership met with 24 organizational partners to identify potential action steps for each of the Task Force recommendations. The partners represented stakeholders from numerous organizations that provide health care services and organizations that work with Californians at high risk for TB, including representatives from: federally-qualified health centers, Kaiser Permanente, ethnic medical societies, the state Medi-Cal program, state and county public health and corrections agencies, the Mexico National TB Prevention and Control Program, the Centers for Disease Control and Prevention, Stop TB USA, state and national TB controllers associations, a Regional TB Training and Medical Consultation Center and a former TB patient. The professional and geographic diversity of the partners provided a broad perspective to identify action steps for TB elimination.

The formation of the California TB Coalition was a significant outcome of the CTEAC meeting. Coalition members include CTEAC meeting participants and will be expanded to include additional representatives from organizations with a vested interest in TB elimination. The California TB Coalition embraces a common goal of a TB-free California and serves a primary role of organizing partners in activities to advance elimination.

The World Health Organization defines TB elimination as less than one case of TB disease per million population. This translates to an elimination target of 39 cases per year in California. There is much work to be done: in 2015 there were over 2000 TB cases reported in California. The California TB Elimination Plan outlines 16 interventions for achieving elimination in California by the year 2040. These interventions address the original six Task Force recommendations with an additional seventh recommendation. For each intervention, action steps are described, along with a timeline for implementation (Section IX, pp. 53-55). Numerous collaborators are proposed for the implementation of this plan, including local health departments, the California Department of Public Health, health maintenance organizations and other health care systems, private provider networks and community health organizations. It is hoped that leadership from these groups can help to stimulate or intensify their respective LTBI diagnostic and treatment activities.

Partners and resources

CTEAC members and partners identified potential collaborators and resources needed to implement all interventions. The overall strategy calls for all partners to act in concert for collective impact to make TB elimination possible. Both the public and private sectors have important roles in the implementation of this plan. The California Department of Public Health TB Control Branch is a key partner and has a leadership role in statewide TB elimination efforts. Local health departments, community providers and the Centers for Disease Control and Prevention all have critical roles in plan implementation. Efforts and resources mobilized by diverse public and private sector partners will help ensure that elimination can be realized. See Table 1 in Section VI (pp. 44-46) and Table 2 in Section VII (pp. 48-49) for partnerships and resources needed for implementing the interventions in this plan.

III. How to Use this Plan

Purpose

The purpose of this plan is to outline actions that can be taken to ensure that the large population of Californians who have LTBI are evaluated and successfully treated. It is expected that these actions will prevent TB disease in individuals and accelerate the time to TB elimination in California. Intensifying targeted testing and treatment of LTBI must occur in parallel to ongoing TB disease testing and treatment efforts by strong public health departments. It is critical that the detection of TB disease be timely, that treatment be effective and that contact investigations are completed. It is only with strong health departments that the core functions of TB control can be maintained while TB prevention activities expand to hasten progress towards elimination.

Intended Audience

This plan, which outlines the steps to take to achieve TB elimination, was developed by CTEAC, an ad hoc stakeholder body that provides information to the Director of the California Department of Public Health. The audience of the plan includes public health practitioners, clinical providers, health plan administrators, policymakers, community organizations and coalitions and other partners in the public and private sectors that serve populations at risk for TB. Ultimately the plan is intended to benefit all Californians as efforts to make California TB free will be of benefit to everyone. The plan will be used by CTEAC and collaborators to implement and monitor progress on specific actions steps to reach elimination.

Key Concepts

TB prevention. While many activities are needed to control and reduce TB disease, the term “TB prevention” as used in this report, specifically refers to targeted testing and the treatment of LTBI. The term can also be used to describe other activities that contribute to TB disease prevention, including, but not limited to, early detection and treatment of TB; isolation of patients with infectious TB; TB case contact investigation; BCG vaccination; and environmental controls for preventing transmission of *Mycobacterium tuberculosis*. In this action plan, “TB prevention” primarily refers to preventing LTBI from reactivating, leading to TB disease.

Geographic focus of the plan. This plan describes actions that can take place within California. While national and international policies and activities strongly influence TB disease trends in the state, the primary focus of this plan is what can be accomplished in California within a five-year period.

Innovations and research. Many recent advances and innovations, such as LTBI diagnostic and treatment regimens and technologies, are central to this plan. However, it is understood that much research is needed to improve current methods for LTBI testing and treatment. While ongoing research is crucial, it is outside the scope of this plan.

IV. Tuberculosis Epidemiology, Control and Prevention in California

Epidemiology of TB and LTBI in California

TB is a communicable disease that is caused by a bacterium, *Mycobacterium tuberculosis*. When a person becomes infected with *M. tuberculosis*, the bacteria are usually contained by the immune system and remain dormant in the lungs; this condition is called “latent TB infection” (LTBI). Approximately one-third of the world’s population has LTBI. This condition is not infectious, nor does it create any symptoms. Most people do not even know that they have LTBI.

Overall, 2.4 million California residents are estimated to have LTBI; approximately three quarters of them were born outside the United States.

In approximately 10% of people with LTBI, the TB infection will progress. In these people the TB bacteria will multiply and spread inside their bodies, creating an infectious form of the condition, referred to as “TB disease” or “active TB,” which usually creates symptoms in the person. If left untreated, TB disease is life-threatening and is a leading killer among infectious diseases worldwide.

While LTBI is common worldwide, and TB disease is life-threatening, treatment for both LTBI and TB is available. LTBI can be treated so it does not progress to TB disease, and TB can be treated so the patient is cured and no longer infectious or symptomatic. While tools for diagnosis and treatment are available, barriers to identifying and treating both conditions exist worldwide. Barriers in California include limited experience in the diagnosis and treatment of LTBI and TB disease among most health care providers.

California TB and LTBI risk profile

California is home to a large, diverse population that represents the highly mobile global community. Ten million individuals, or 26% of California’s population of 39 million, were born outside the U.S., many from regions with an elevated TB burden. Additionally, over 11 million individuals enter California from outside the U.S. each year. An example of this diversity is that 50% of California’s 10 million children under age 18 have a foreign-born parent. Adding to this population with potential exposure to TB earlier in their lives is the large and growing elderly population comprised of two million residents who are 75 years old or older. Many U.S.-born and foreign-born individuals exposed to TB in childhood have

chronic medical conditions that increase their risk of progressing to TB disease. Overall, 2.4 million California residents are estimated to have LTBI; approximately three quarters of them were born outside the U.S.

TB trends and patient characteristics

For more than two decades, the rate of TB disease declined steadily in California. In 2015, the TB rate among U.S.-born residents was 1.4 per 100,000 and among foreign-born residents it was 16.5 per 100,000. More recently, this decline has slowed. During 1992-2000 there was an average 5.6% annual decline whereas during the most recent decade, the average annual case decline was 3.4%. Despite the overall decrease in TB disease, the TB case rate in 2015 was 5.5/100,000, which is the lowest case rate ever recorded in California history and the third highest in the nation, behind Alaska and Hawaii, contributing 22% to the national TB burden.

TB disease affects population groups in California unevenly. In 2015, only 6% of the cases of TB in California were reported in the non-Hispanic white population, which made up 38% of the state population. In contrast to TB case rates among non-Hispanic whites, the rates are 22-fold higher among Asians and nearly five times higher among Hispanics and blacks. These disease disparities also reflect the diverse countries of origin of California's TB cases.

The top five countries of origin for patients with TB disease in California have remained constant over this 20-year period, with Mexico, the Philippines, Vietnam, China and India contributing 77% of California's foreign-born cases. The majority of these TB cases occur in those who have been in California for many years. At least 75% had been in the U.S. six years or longer at the time of TB diagnosis. Nearly half of TB cases are among foreign-born residents who enter the U.S. with immigrant or refugee status and are screened for TB disease (but not LTBI) before entering the

U.S. The other half of foreign-born TB cases are in persons who are not screened for LTBI or TB disease pre-entry to the U.S. This group includes individuals with worker, student or tourist visas, and a large proportion is undocumented.

In 2015, the median age of TB patients was 54 years, and approximately one-third of TB patients had at least one medical co-morbidity, e.g., diabetes mellitus, end stage renal disease, anti-tumor-necrosis-factor therapy or other treatment with immunosuppressive drugs, solid organ transplantation, HIV infection or other immunosuppressive condition.

These co-existing conditions increase the risk of progression to TB disease from asymptomatic and non-infectious LTBI.

Four-fifths of TB disease in California results from progression of previously acquired infection to active disease. Another 13% is from recent transmission within California communities; and 7% is imported, i.e., from new arrivals who are diagnosed with TB disease within one year of arrival in the U.S. Finally, a very small percentage, less than 1% of TB disease, may be generated as a result of relapse of previously treated disease or from re-infection.

Tuberculosis Control and Prevention in California

Each of California's 61 local health departments is responsible for overseeing the care of TB patients, responding to and preventing TB transmission in its community, and preventing TB in individuals at high risk. Local health departments perform these functions through direct patient care and/or partnerships with community providers, including hospitals, health maintenance organizations, federally qualified health centers and other community clinics, private physician networks and individual providers.

TB control programs are supported by funding from federal, state and local governments. The percentage of each government's contribution varies for each local health department. Three large health departments in California—Los Angeles, San Diego and San Francisco—and the state TB control program have cooperative agreement funding from the Centers for Disease Control and Prevention, Division of TB Elimination. The majority of resources for TB control for local health departments come from their county level governments, which cover approximately 65% of TB program budgets. Medi-Cal (the Medicaid program in California) is a key payer of coverage for Californians with TB and LTBI.

The state TB control program provides technical assistance, resources, outbreak assistance, and consultation on diagnosis and management of drug resistant TB and guidance on TB control and prevention efforts. The state program collects, interprets and disseminates surveillance data. Local health departments carry out TB control and prevention activities, including surveillance, epidemiology and direct services to individuals with, and at risk for, TB infection and disease within their geographic area. Community providers have an essential role in the management of patients with both TB disease and LTBI.

Testing and treatment for LTBI

Health care providers use one of two methods for diagnosing LTBI: either the tuberculin skin test or interferon-gamma release assays; both are in widespread use in California. Consistent with Centers for Disease Control and Prevention guidelines, because of increased specificity (99% vs. 85%)³ especially in individuals who have been vaccinated with BCG, interferon-gamma release assays are recommended over the tuberculin skin test for use in foreign-born populations—the overwhelming majority of whom received BCG vaccine at birth in their home countries.

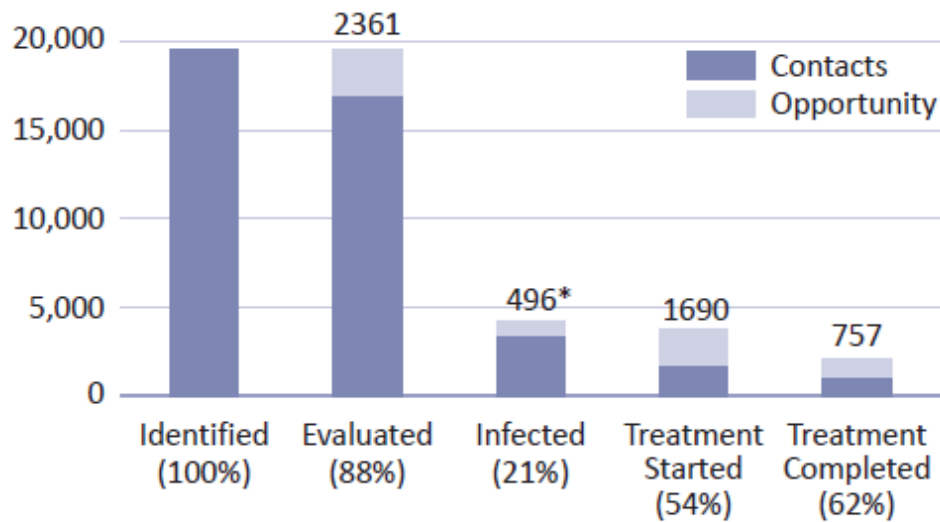
TB screening programs in California are currently in place and cover an estimated 1.7 million individuals each year. The populations screened—which include teachers, employees and volunteers in schools; health care workers; and correctional inmates, parolees and employees—have varying risks of TB. Programs in place to screen populations at higher risk of TB include testing of individuals that are recent contacts to a known TB case; new immigrants arriving in the U.S. who had an abnormal chest radiograph during

their overseas exam (B-notification arrivers); and individuals who apply to adjust their immigration status from a temporary to a permanent status (status adjusters). The majority of individuals tested each year in California have a low risk for TB, and many are re-tested annually without acquiring any new risk to justify repeat testing. Initial and re-testing of low risk populations use limited resources needed for effective TB control and prevention and can result in false-positive tests, unneeded treatment and adverse treatment effects.

Despite the longstanding availability of treatment for LTBI and the newer treatment and testing methods, getting individuals through each step of testing and treatment for LTBI has been challenging. California's local health departments and private provider partners perform testing and treatment for LTBI, but have variable success in getting all patients at high risk through the full LTBI testing and treatment cascade.

The LTBI treatment and prevention steps (TB prevention cascade, see figure below) involve engaging and testing individuals with a high risk for TB, identifying individuals who should be tested for LTBI, and starting and completing LTBI treatment in those individuals. At each step, patients and prevention opportunities can be lost. For example, only a small proportion of populations at high risk of LTBI receive a TB skin test or interferon-gamma release assay. In 2012, 88% of identified contacts to sputum smear-positive pulmonary TB cases were completely evaluated, but only 54% of those identified with LTBI started treatment, and only 62% of those who started actually finished their full course of treatment. Attrition of contacts at each step is shown in the figure below. Rates of treatment completion are expected to improve considerably as more local health departments adopt the new shorter treatment regimens (i.e., three or four-month). Increasing success at each step of the cascade will have a substantial impact on California's ability to achieve TB elimination.

TB Prevention Cascade for Contacts California, 2012



* Estimated based on proportion infected among those evaluated

Health care services and payer sources

In California, health care services for TB are provided through a complex health care delivery system, which can impede consistent implementation of LTBI testing and treatment activities. Among the 61 local health departments in California, just 21 reported 95% of all TB cases in California in 2010-2014. Eighteen of these 21 local public health departments have dedicated TB clinics that provide direct patient care. Sixty-four percent of patients with TB disease in 2010-2012 received the majority of their TB care in a public health department clinic. Patients who do not receive their care in a public clinic receive care in the private sector, or have care provided jointly by both private providers and a public health clinic.

The TB knowledge and skills of providers in the health care system vary, depending on their level of experience and concentration of TB in their areas. Despite the array of health delivery systems and providers, there are some larger ones that serve populations at risk, including Kaiser Permanente, federally-qualified health centers and primary care doctors who serve indigent patients, including those on Medi-Cal. Two large health maintenance organizations, Kaiser Permanente Northern California and Kaiser Permanente Southern California, provided care for 11% of all reported culture-confirmed TB patients in California during 2007-2011.

The TB knowledge and skills of providers in the healthcare system vary, depending on their level of experience and concentration of TB in their areas.

The California Department of Health Care Services oversees 23 full-scope Medi-Cal Managed Care plans, the Medi-Cal Fee for Service program, and a number of other programs such as the Child Health and Disability Prevention program; together these plans and programs help to serve a sizeable patient population that may be at risk for TB.

If a patient with TB meets specific criteria, he/she can be enrolled in Medi-Cal, which covers TB diagnosis, treatment and case management expenses. Local health departments can bill Medi-Cal for reimbursement and use the county indigent fund to pay for care. A remaining gap in payment for TB services is for undocumented immigrants, of which 500,000 are estimated to have LTBI and who comprise roughly 15-25% of patients with TB disease in California.⁴

The federal Affordable Care Act presents opportunities for health departments to promote TB elimination: many more individuals at high risk are insured; and screening for LTBI has been designated by the U.S. Preventive Services Task Force as a screening with a B rating. With this designation, these services for testing and treating for LTBI will not require out-of-pocket payments by patients, creating a new opportunity for ensuring that all individuals at high risk are provided critical TB prevention services.⁵

TB Elimination in California

The World Health Organization defines TB elimination as <1 case of TB disease/ million, which translates to an elimination target of 39 cases per year in California. In 2015, 2,137 TB cases were reported in California. While TB control efforts successfully reduced TB disease to below the epidemic threshold of <100 cases/ million in 2000, the current case count is still four times higher than the pre-elimination target and 50 times higher than the elimination target. To reach elimination in the state by 2040, a 14% annual decline in TB cases will need to occur.⁶ To create a TB free California in the near future, bold thinking and actions are needed.

| Definition | Rate | CA Cases | Target Year |
|-----------------------|-------------------------|--------------|-------------|
| End of TB epidemic | <100 cases/million | 3,880 | achieved |
| Current status | 56 cases/million | 2,137 | 2015 |
| Pre-elimination | <10 cases/million | 388 | 2025 |
| Elimination | <1 case/million | 39 | 2040 |

There are several compelling reasons to intensify efforts to eliminate TB. The fact that California has experienced a consistent decline in TB cases and TB mortality since the height of the TB resurgence in the 1980s is just one. Epidemiologic evidence suggests that recent transmission of TB is at a nadir, and the percentage of TB among recent arrivers has declined by 50% since overseas screening and treatment was improved in 2007.^{7,8} This significant improvement, in addition to two major technological advances (better screening tests for TB

and short-course LTBI treatments), creates new opportunities to prevent TB by focusing on reducing the size of the LTBI reservoir in California.

Adding to the rationale that the time is right for California to focus on TB elimination, there is substantial evidence that TB prevention is cost-effective.^{9,10} The overall human and economic consequences of persistent TB disease in California are the most compelling reasons to pursue elimination. If not prevented, TB disease can result in hospitalization, disability and most important, premature death. Over half of individuals diagnosed

with TB are hospitalized for treatment or disease complications, and the death toll is daunting. In California, one in 10 diagnosed with TB disease dies of their disease, either during therapy or before they have had an opportunity for treatment. If the annual rate of case decline observed during 2005–2014 (approximately 4% per year) continues, by 2040 there will have been approximately 3,700 deaths due to TB in California. Individuals' inability to work and loss of income due to TB disease affects their families, and leads to an overall depreciation in their quality of life.

To reach elimination in the state by 2040, a 14% annual decline in TB cases will need to occur.

V. Action Steps for the Interventions to Eliminate Tuberculosis

This action plan was developed with the following hierarchy: it starts with the recommendations and then provides interventions and action steps for each recommendation. There are one to three interventions for each recommendation, then a number of concrete action steps with activities to support each intervention. Six recommendations were developed in May 2015 by the California TB Elimination Task Force and collectively include 14 interventions; a seventh was added by CTEAC.

Recommendation 1: Find and engage persons and populations at high risk for TB and their providers in California

Identification of individuals at highest risk for TB disease and their health care access points (e.g., their providers) is a first step in detecting LTBI and preventing it from developing into TB disease. Specific strategies to reach the diverse populations will vary with the specific population and the venue of care. An initial approach is for health departments to utilize epidemiologic profiles created by the state health department that describe the populations at high risk in their jurisdictions—and their health care providers—and then focus strategies on finding and engaging both groups in LTBI testing and treatment activities.

To identify foreign-born individuals from countries with elevated TB rates systematically, a standardized data element that captures country of birth in the electronic health record (EHR) is necessary. A patient's country of birth noted in the EHR would help health care providers to assess this important risk of TB exposure more easily and provide a decision point for TB testing. To engage and locate persons who do not access health care will also be needed and will be addressed as the plan is implemented.

Expected Outcomes

- Local health departments, in partnership with state and community providers, can identify the size and location of groups at high risk for LTBI and TB disease and their health care access points to focus TB testing efforts
- A descriptive profile of who provides medical care to populations that are at high risk for LTBI and TB disease is available from the California Department of Public Health for local

health departments to target education and outreach promoting LTBI testing and treatment

- Electronic health records with fields for patient birthplace facilitate successful risk-based LTBI screening

Intervention 1A: Use epidemiologic profiles to identify populations at high risk for TB and the providers who serve them

Local health jurisdiction TB programs and the California Department of Public Health TB Control Branch should use surveillance data and public data sets to create and use epidemiologic profiles to identify populations at highest risk for LTBI and disease. These profiles should include geographic location of residence, points where each population receives care, and the primary care medical providers who serve the target populations. This specific information will enable health departments and community providers to identify the size and location of groups at high risk and allow health departments to identify access points and to focus their education,

outreach and testing efforts. It will also aid more efficient targeting of health care providers, health plans and medical practices that serve the groups that will benefit most from targeted testing and treatment for LTBI.

A patient's country of birth in the electronic medical record would help health care providers to assess [the] important risk of TB exposure more easily and provide a decision point for TB testing.

Action steps

1. Create epidemiologic profiles of populations at high risk for TB to aid prevention efforts
2. Provide epidemiologic profiles and maps of high risk populations and their providers to local health departments to determine potential partners for TB prevention
3. Identify health care providers who are most frequently serving individuals who develop TB disease
4. Identify providers for populations at high risk by reviewing the languages spoken by medical providers, available from the Medical Board of California website

Intervention 1B: Ensure that country of birth is included as a data element for electronic health records across care settings

Every primary care electronic health record should include a standardized data field to document country of birth to facilitate identification of patients born in countries with elevated TB rates. While providers often ask about country of birth to determine potential TB exposure risk and to trigger testing, there is no standardized place to document this risk factor. The key criteria to prompt testing are: 1) birth in a country other than the U.S., Canada, Australia, New Zealand or western and northern Europe; 2) current or planned patient immunosuppression; and 3) close contact with an infectious TB case at any time. Most electronic health records include fields for clinical conditions, but fields for birthplace and TB contact information infrequently exist.

Action steps

1. Systematically ensure that country of birth, an important risk factor, is added as a data field to electronic health records and medical care intake and charting
2. Request that electronic health record developers modify existing software systems to include a country of birth data field and include as part of the standard demographic package in new systems
3. Include a country of birth data field in TB-specific Confidential Morbidity Reports used for reporting TB suspected cases and known cases

Recommendation 2: Apply focused and effective strategies for TB testing in California

Public and private health care resources for LTBI testing need to be utilized efficiently. However, current practice in California includes testing of many low risk populations. The main reason for excess testing is a body of California statutes that require testing of certain populations historically at high risk but that are no longer considered to be high risk for TB. Routine testing of some low risk populations persists, with health care workers being the single largest group; they are re-tested annually regardless of exposure risk and represent a high volume of testing that could be shifted to risk-based testing, as is recommended by the Centers for Disease Control and Prevention.

To make progress toward TB elimination, California's largest population at risk for TB, individuals from countries with elevated TB rates, should be tested with the most specific diagnostic test available, interferon-gamma release assays. These tests to detect LTBI are more specific than TB skin tests and do not yield false-positive results from BCG vaccination. The Centers for Disease Control and Prevention recommends use of

New policies and simple assessment tools are needed to ensure that only populations at high risk are routinely tested for LTBI...

the interferon-gamma release assay over the tuberculin skin test for foreign-born populations. New policies and simple assessment tools are needed to ensure that only populations at high risk are routinely tested for LTBI and that the appropriate testing methodologies are utilized for specific populations.

Recommendations from the newly revised national LTBI guidelines to be published by the American Thoracic Society, the Centers for Disease Control and Prevention and the Infectious Diseases Society of America are expected to emphasize the focus on foreign-born populations as a critical risk group for testing and treatment for LTBI. The U.S. Preventive Services Task Force 2016 recommendation highlights testing and treatment of persons born outside the U.S. as a major risk group to target for TB screening and now enables LTBI testing and treatment services to be provided without out-of-pocket costs to individuals. A TB risk assessment tool for screening California adults developed in 2015 is available to aid providers to identify who should be tested for LTBI. Additional collaborative work is needed to incorporate the tool into electronic health records.

Expected outcomes

- Only populations at high risk are tested for LTBI
- Primary care providers in both the public and private sectors routinely use a standardized TB risk assessment tool to identify patients at high risk to test for LTBI
- Interferon-gamma release assays have replaced tuberculin skin tests to test people vaccinated with BCG, particularly individuals born in countries with an elevated TB rate

Intervention 2A: Prioritize testing for LTBI in foreign-born persons from countries with an elevated TB rate; the immune compromised; and contacts to TB cases, by encouraging use of the California TB risk assessment tool

More than 75% of TB cases in California develop in persons previously exposed and infected years ago who may have been living with LTBI for many years before they progress to TB disease. To speed the decline of TB and move toward TB elimination, all individuals in California born in countries with an elevated TB rate should be tested, and, if infected, treated for LTBI. Scaling up the identification and treatment of LTBI in this population will reduce TB disease, deaths and their associated costs.

Action steps

1. Use education and outreach to stimulate healthcare providers' use of the California TB risk assessment tool
2. Incorporate the risk assessment questionnaire into electronic health records
3. Identify and disseminate Medi-Cal and Medicare codes for reimbursement for conducting a TB risk assessment
4. Harmonize the child, adult and specialized versions of the TB risk assessment tools

5. Standardize the TB risk assessment performed for school entry throughout the state
6. Implement effective marketing strategies to encourage providers and health systems to adopt the TB risk assessment tool
7. Ensure official endorsement of the TB risk assessment tool by the highest levels of public health
8. Encourage health care system administrators to require that their providers complete TB risk data fields and tie to quality improvement initiatives
9. Develop a metric and track the adoption and use of the risk assessment tool

Intervention 2B: Ensure that California health care providers use interferon-gamma release assays for testing individuals who previously received BCG vaccine

Widespread use of interferon-gamma release assays for testing people who have been immunized with BCG (mostly non U.S.-born) populations in accordance with CDC recommendations will avoid false positive tuberculin skin test results from BCG vaccination. Reducing false positives also reduces unneeded treatment of individuals without true infection and prevents adverse effects of treatment occurring in those without infection who did not need treatment.

Action steps

1. Update and widely disseminate guidelines to community providers to recommend that interferon-gamma release assays should be used for testing individuals who have been vaccinated with BCG
2. Engage private sector patient assistance programs, health plans and manufacturers to provide interferon-gamma release assays at lowest cost
3. Ensure that health plan utilization reviews assess use of interferon-gamma release assays

Intervention 2C: Reduce TB testing in low risk populations

To reduce false positive tests and avoid treatment of individuals without true infection, routine testing of low risk individuals should be minimized. Screening and testing guidelines should clearly outline who should be tested for TB. The use of a very simple risk assessment form to support provider decisions about testing is available. Screening of low risk populations should be limited to testing those with new exposure risk. State and local mandates should be updated to be consistent with current epidemiology and tools.

Action steps

1. Eliminate requirements for screening employees in settings where the risk of TB transmission is low
2. Align the Child Health and Disability Prevention Program TB screening protocol with risk-based testing for K-12 schoolentry
3. Implement a process to monitor and update TB screening laws as TB epidemiology and tools change over time
4. Bring the CalOSHA annual screening regulations for health careworkers into alignment with federal guidance on preventing TB transmission in health care facilities

Recommendation 3: Optimize treatment for LTBI

At the current rate of decline, an estimated 25,000 cases of TB in California will occur between 2015 and 2040 that could be avoided with intensified LTBI targeted testing and treatment efforts. LTBI treatment completion is a key step to avoid these preventable cases. However, despite the longstanding availability of LTBI treatment, only about 50% of individuals that start LTBI treatment complete their regimens. Recently, short-course treatment regimens have become available to reduce the length of treatment from nine months to three or four months. With these short-course treatments, completion rates have improved from 50% to over 80%. Shorter regimens are key to maximizing LTBI treatment completion rates and successfully preventing TB.

In order for these new regimens to be widely implemented, there needs to be increased public and private sector provider awareness on the use and benefits of these regimens. To facilitate broad adoption of the 12-dose regimen (three months isoniazid and rifapentine) and the four month rifampin regimen, treatment formularies should include these regimens. Access to LTBI treatment without impediments needs to be facilitated.

To further improve TB treatment adherence, increased education and training efforts for building public health capacity are needed to ensure monitoring and support for patients on treatment for LTBI. These activities, provided through case management approaches, can be supported by nursing and pharmacy. Lastly, TB control and prevention can emulate the successful strategies employed to ensure treatment adherence in HIV and hepatitis Ccare.

Expected outcomes

- All individuals with LTBI who will benefit from LTBI treatment will start and complete an optimal regimen to prevent progression to TB disease
- Providers of populations at high risk for LTBI are aware of and familiar with the shortest effective LTBI treatment regimens and utilize adherence technologies to support their patients
- Less transmission of *Mycobacterium tuberculosis* occurs due to improved TB testing and LTBI treatment strategies and shrinking of the pool of persons at risk for progression to TB disease

Intervention 3A: Maximize initiation and completion of treatment for LTBI

Higher completion rates for LTBI treatment are needed to provide benefit for both individuals and populations. Strategies to maximize the treatment of groups at high risk that are already being tested should be utilized and broadly disseminated.

Action steps

1. Develop and disseminate educational materials on LTBI treatment to providers serving populations at high risk for TB
2. Develop strategies to ensure that individuals at high risk for disease progression who are already being screened are starting and completing LTBI treatment
3. Educate providers on the most effective ways to communicate the importance of LTBI treatment completion to patients
4. Develop strategies to support treatment monitoring and/or adherence
5. Establish provider incentives for recording LTBI diagnosis and LTBI treatment completion
6. Conduct outreach to populations at high risk to provide education about the need for testing and treatment for LTBI

Intervention 3B: Promote use of the shortest effective LTBI treatment regimens

Historically, patient completion of LTBI treatment has been limited in large part because the regimens for LTBI treatment were lengthy. Recently, two shorter regimens have been evaluated and recommended by Centers for Disease Control and Prevention guidelines (a three-month regimen of 12 once-weekly doses of isoniazid/rifapentine (3HP) and four months of daily rifampin (4R)). Economic evidence shows that these regimens are cost-effective when compared to the longer traditional isoniazid regimens because treatment completion is more likely.¹⁰

Action steps

1. Promote access to effective short-course regimens to all who need them
2. Ensure that pharmacy formularies provide easy access to drugs used in short-course LTBI regimens

Intervention 3C: Increase access to adherence technologies to enhance completion of treatment for LTBI

Innovative technologies, such as dose-enhancing packaging, electronic directly observed therapy, mobile phone text reminders and incentives, have been shown to greatly improve completion of treatment rates in individuals with TB disease.^{11,12} These technologies can be used to promote adherence to LTBI treatment, and use of these strategies for LTBI treatment

should be evaluated.

Action steps

1. Use data to provide feedback to providers and health care systems on provider performance on LTBI testing and treatment
2. Disseminate models on best practices for improving patient LTBI treatment monitoring and completion
3. Expand access to and use of electronic directly observed therapy reminder and tracking technologies

Recommendation 4: Develop strong and effective partnerships to eliminate TB in California

To achieve TB elimination, TB experts at the local and state levels in California will need to collaborate with organizations and individuals that share a common vision of a TB-free California. These partnerships will extend across both the public and private sectors and include local and state level public health programs, health care organizations, providers, non-profit organizations, public health laboratories and other agencies that provide health and social services to populations at high risk for TB. The California TB Coalition, with members from both the public and private sectors (including CTEAC members), will mobilize to work with health care organizations and industry to ensure that populations at high risk for TB have access to the most up-to-date LTBI screening and treatment protocols.

Expected outcomes

- Effective partnerships encompassing both the public and private sectors provide the means for ensuring that populations at high risk will benefit from targeted testing and LTBI treatment strategies. Private providers are motivated to ensure that appropriate populations are tested and treated for LTBI.
- Populations at high risk do not encounter financial barriers for LTBI testing and treatment services.
- The California TB Coalition mobilizes partners and other stakeholders to secure sufficient partner engagement to leverage existing and new resources to achieve TB elimination.

Intervention 4A: Create and strengthen prevention partnerships that involve public and non-public health providers

To promote LTBI testing and treatment among provider communities, these activities should be described as a benefit to community health, in addition to individual health. Strategies can be implemented to change current provider practices and make these services routine.

Action steps

1. Implement local health department strategies to stimulate health care provider testing and treatment of LTBI in populations at high risk
2. Create public-private partnerships to assist providers to complete each step of the TB prevention and treatment cascade
3. Identify and train community health workers and former TB patients to educate communities and individuals at high risk about the need for testing and treatment for LTBI

Intervention 4B: Stimulate and incentivize community providers who serve populations at high risk to make testing for and treatment of LTBI routine

Educational and marketing interventions focused on community providers who see high risk populations may help stimulate their compliance with LTBI testing and treatment guidelines. To make progress toward TB elimination, rationale and motivation should be strong for providers to prioritize and engage patients at each step of LTBI testing and treatment to ensure that populations at high risk for TB are tested and treated. These incentives must be accompanied with a clear message to providers emphasizing the imperative to test and treat for LTBI.

Action steps

1. Encourage health systems to implement routine quality improvement activities that assess completion of steps of LTBI testing and treatment
2. Educate civil surgeons to ensure that patients with LTBI are referred for or receive and complete treatment
3. Identify methods to recognize providers who excel at ensuring LTBI treatment completion
4. Create a pilot demonstration project to replicate the British LTBI care provider incentive process

Intervention 4C: Remove existing financial barriers to LTBI testing and treatment for both patients and providers

Because of the community health protection provided by identifying and treating LTBI, there should be no cost to patients for receiving LTBI services. To achieve TB elimination in California, coverage for LTBI services should be for all persons at risk, regardless of immigration status.

Action steps

1. Collect data about the LTBI burden in California and utilize these data to

communicate resource needs for LTBI testing and treatment

2. Make testing and treatment for LTBI a routinely covered benefit of health plans to eliminate barriers created by out-of-pocket expenses
3. Communicate and disseminate to health plan administrators the return on investment for the testing for and treatment of LTBI

Recommendation 5: Create an effective communication plan to promote testing for and treatment of LTBI to health providers and the community in California

The relatively new technologies in use to test for and treat LTBI require clear and easily implemented practice guidance. Current guidelines are complex, and some apply to California only while others are national. New streamlined and readily usable California guidelines are needed along with a communication plan to promote both public and private providers' adoption of the newest testing and treatment strategies. In particular, the availability of the California TB risk assessment tool should be communicated to providers and disseminated broadly.

In addition, the roughly 2.4 million people in California infected with TB should be aware that they have LTBI. They should know that their risk of developing TB disease creates a possibility that they can later transmit it to friends, family and co-workers. A distinct communication strategy should be targeted specifically to these populations at high risk.

Expected outcomes

- Public and private providers are aware of and have access to simple and clear LTBI screening, testing and treatment guidelines
- Public awareness about LTBI is widespread and individuals at high risk for LTBI know their infection status

Intervention 5A: Develop, implement and evaluate a simple, clear communication strategy focusing on testing for and treatment of LTBI, targeted to both public and private providers

A comprehensive communication strategy that focuses on testing for and treatment of LTBI for providers will promote the use of consistent, clear and simple guidelines for these activities, which can then be more easily incorporated into routine primary care practice.

Action steps

1. Identify medical societies and groups for targeted messages about testing for and

treatment of LTBI

2. Develop compelling messages for health care systems to focus on foreignborn populations and other risk groups for TB testing
3. Create an LTBI educational toolbox with resources for communicating to providers serving populations with high TB infection rates
4. Promote LTBI testing and treatment at key conferences to providers who serve populations at high risk
5. Identify industry and philanthropic organizations that can fund development of resources for communicating about new LTBI diagnostics and treatment

Intervention 5B: Develop, implement and evaluate a simple, clear communication strategy focusing on testing for and treatment of LTBI for the general public

A comprehensive communication strategy for the general public that focuses on testing for and treatment of LTBI will promote broad awareness and will encourage individuals at high risk for TB to learn their status and, when necessary, start and complete LTBI treatment. This communication strategy will also reach policymakers and funders who could make decisions about funding and promotion of LTBI testing and treatment initiatives.

Action steps

1. Collaborate with a marketing expert to create public communication strategies for populations at high risk
2. Use social media tools to disseminate LTBI testing and treatment messages to the public
3. Develop a group of TB patients and representatives to disseminate LTBI testing and treatment messages to the public and policymakers
4. Conduct outreach to engage key populations at high risk for TB to promote LTBI screening

Recommendation 6: Develop and implement a surveillance system for reporting, tracking and evaluating LTBI in California

The State of California requires that cases of TB disease be reported to the local health departments and the local health departments, in turn, report to the state health department. While some reporting of LTBI is required, either by local health departments or as a statewide mandate, these reports are restricted to

A cohesive reporting system for individuals with LTBI is needed to reach elimination.

subsets of populations, e.g., some newly arriving immigrant and refugee groups, children's LTBI status through the immunization registry and aggregate reporting for contacts to TB cases. A cohesive reporting system for individuals with LTBI is needed to reach TB elimination. Without such a system, the California TB Control Program and local health departments will be unable to monitor the epidemiology of LTBI and guide appropriate efforts for testing and treatment. A system allowing ongoing tracking of patients through testing and treatment for LTBI could improve TB prevention and facilitate measurement of progress toward TB elimination. Such a system should include electronic laboratory reporting as well as bidirectional information flow between the LTBI system and provider electronic health records in order to track whether patients are starting and completing treatment. Rather than creating an entirely new system, adapting existing surveillance systems may be most feasible. However, any new or modified reporting and tracking system must place minimal burden on busy providers and health departments. Complementary indicators of TB risk assessment, testing and treatment completion will be important to track and improve these critical activities by provider groups.

Currently, local health departments may not be using electronic health records or have the capacity for electronic laboratory reporting. For LTBI reporting to become a reality this capacity needs to be improved.

Expected outcomes

- Identification and treatment of LTBI is tracked via a reporting system that includes an electronic link to the laboratory
- Electronic systems are in place to evaluate whether LTBI patients are starting and completing treatment

Intervention 6A: Establish systematic mechanisms for reporting LTBI and tracking populations through the LTBI testing and treatment steps

To improve TB prevention efforts and reach TB elimination, it will be essential to track diagnoses of LTBI and completion of treatment. Systems are needed to measure progress and set clear benchmarks to ensure that public health and community providers are reaching populations at high risk for TB and getting individuals through LTBI treatment.

Action steps

1. Assess the feasibility of making LTBI a reportable condition in California (including the development of a mandate)
2. Develop a standardized definition of LTBI
3. Explore using existing systems for reporting LTBI (laboratory reporting of interferon-gamma release assays) and for tracking LTBI treatment and outcomes
4. Identify initial and ongoing funding to support LTBI reporting and treatment
5. Develop performance measures for LTBI testing and treatment
6. Facilitate electronic transfer of LTBI testing and treatment information between electronic health records and LTBI reporting systems
7. Pilot an LTBI reporting system before conducting a statewide rollout

Recommendation 7: Secure sufficient resources for implementing the California TB elimination plan

Successful public health campaigns need sufficient resources to support the strategies, action steps and partnerships for implementation. For TB elimination, specific resources are required, including sufficient diagnostic tools and treatment; supportive legislation and policies; provider and TB program staff knowledge and skills; and financial support. Some of these ingredients are available in California,

The large LTBI reservoir is responsible for most of the new TB cases in California.

but there is need for additional resources, including clear guidelines for LTBI medical practice; expanded public health infrastructure to support new surveillance systems and innovative technologies, e.g., electronic directly observed therapy; mobile phone text reminders; ongoing human resource development; and policies that will ensure that individuals at high risk for TB receive optimal preventive care. Multiple sources of prevention dollars, including new ones from the private sector, will help to ensure success of the elimination plan.

Expected outcomes

- Local TB programs have both the human and financial resource capacity to sufficiently conduct necessary interventions for reaching TB elimination
- Both public and private providers are knowledgeable and skilled in assessing patients' TB risk and assuring that those with LTBI are appropriately treated
- Adequate resources exist for providing services for evaluating risk, testing and treatment for LTBI of all individuals at high risk for TB
- Health disparities among California's populations are decreased because sufficient resources exist for TB control and prevention

Intervention 7A: Ensure that both public and private providers have the capacity to adequately test and treat all patients at high risk for TB

Progress on TB elimination in California will require a significant investment to increase the state's public and private providers' capacity to ensure individuals at high risk for LTBI are tested and, when relevant, complete treatment. The large LTBI reservoir is responsible for most of the new TB cases in California. Most persons with LTBI in California are untreated. Strategic and collaborative planning for use of scarce resources will be necessary to adequately strengthen

the capacity of TB program staff, private providers and other individuals and organizations that can impact TB prevention through LTBI testing and treatment.

Action steps

1. Ensure an adequate and continuous supply of drugs to treat LTBI, especially those drugs needed for short-course therapy
2. Ensure that clinical and programmatic TB guidelines for California are up-to-date and are widely disseminated; develop and disseminate new ones, as necessary
3. Coordinate with TB training organizations to ensure that training curricula for public and private providers are relevant, up-to-date and being implemented for the highest priority audiences
4. Create an inventory of LTBI testing and treatment best practices for dissemination to public and private partners

Intervention 7B: Acquire new funding to ensure sufficient resources to eliminate TB in California

Evidence exists that savings are gained from an investment in TB prevention.^{9,13} Intensified TB prevention actions as well as new ones will be required. Ongoing TB prevention activities outlined in this action plan will need to be sustained until TB elimination is reached.

Action steps

1. Seek funding from the Centers for Disease Control and Prevention for intensifying LTBI screening, testing and treatment activities
2. Secure private foundation and industry funding to support California TB Coalition infrastructure and initial support for demonstration projects, innovations and intensification of current activities
3. Strengthen the public health infrastructure so that electronic health records and electronic laboratory reporting capacity exists across local public health departments
4. Identify ongoing resources to support LTBI reporting and treatment

VI. Partners Needed for Tuberculosis Elimination

Eliminating TB in California will need to be a multi-faceted effort requiring well-coordinated partnerships. Numerous organizations and individuals will need to be involved to ensure successful implementation. Partner collaborations will reduce duplication of efforts, ensure the sustainability of current efforts and expand the collective “reach” of participating partners for the delivery of TB prevention services.¹⁰

A key partner in the statewide TB elimination effort is the California TB Controllers Association (CTCA), a network of TB public health experts working to control and eliminate TB—many of its active members are also CTEAC members. CTCA members are largely TB controllers, program managers and other clinicians who comprise the leadership in local health department TB control programs. These individuals, and the programs they represent, will be at the front line when implementing many of the action steps in this plan. CTCA members’ expertise and their collaboration with elimination partners will be a critical component of successfully implementing this plan.

Another key partner for plan implementation is the California Department of Public Health TB Control Branch. The TB Branch supports local TB programs through consultation, technical assistance, education, training and resources. The TB Branch is conducting many of the activities outlined in this plan and will continue to play an important leadership role during the plan implementation.

The California TB Coalition is an important group for successful action plan implementation. The Coalition will be expanded to include other key collaborators, such as the California Association of Health Plans, Local Health Plans of California, the California Primary Care Association and organizations representing refugee health and California-Mexico border health.

Table 1 (pp. 44-46) identifies potential partners for each of the plan’s 16 interventions. A large dot in a partner’s column signifies the organization (or type of organization) that will be a likely lead for some or all of the action steps outlined for a specific intervention. A small dot signifies the organization (or type of organization) that will be a partner in carrying out some of the intervention’s action steps. Many of the activities led by stakeholders listed below are already in progress. Specific leads for each action step outlined will be identified by CTEAC.

| Intervention | CTEAC and TB Coalition (Proposed Partner) | TBCB-CDPH (Proposed Partner) | Other state agencies (Proposed Partner) | CDC (Proposed Partner) | Local health departments (Proposed Partner) | CTCA-CCLHO (Proposed Partner) | Curry International TB Center (Proposed Partner) | Primary care providers and groups (Proposed Partner) | Health Plans (Proposed Partner) | CBOs and advocacy groups (Proposed Partner) | Industry (Proposed Partner) | Other (Proposed Partner) |
|---|---|------------------------------|---|------------------------|---|-------------------------------|--|--|---------------------------------|---|-----------------------------|--------------------------|
| 2A: Prioritize testing for LTBI in foreign born persons from countries with an elevated TB rate; the immune compromised; and contacts to TB cases, by encouraging use of the California TB risk assessment tool | | ● | * | | * | ● | * | * | * | * | | * |
| 2B: Ensure that California health care providers use interferon-gamma release assays for testing individuals who previously received bacille Calmette-Guerin (BCG) vaccine | | ● | * | | * | ● | * | * | * | * | * | * |
| 2C: Reduce TB testing in low risk populations | | ● | * | | * | ● | * | * | * | | | * |
| Recommendation 3: Optimize treatment for LTBI | | | | | | | | | | | | |
| 3A: Maximize initiation and completion of treatment for LTBI | | * | * | | ● | ● | * | ● | ● | * | * | * |

| Intervention | CTEAC and TB Coalition (Proposed Partner) | TBCB-CDPH (Proposed Partner) | Other state agencies (Proposed Partner) | CDC (Proposed Partner) | Local health departments (Proposed Partner) | CTCA-CCLHO (Proposed Partner) | Curry International TB Center (Proposed Partner) | Primary care providers and groups (Proposed Partner) | Health Plans (Proposed Partner) | CBOs and advocacy groups (Proposed Partner) | Industry (Proposed Partner) | Other (Proposed Partner) |
|--|---|------------------------------|---|------------------------|---|-------------------------------|--|--|---------------------------------|---|-----------------------------|--------------------------|
| 3B: Promote use of the shortest effective LTBI treatment regimens | | ● | * | * | ● | ● | ● | * | * | * | * | * |
| 3C: Increase access to adherence technologies to enhance treatment of completion for LTBI | | * | | | ● | ● | | * | * | | ● | |
| Recommendation 4: Develop strong and effective partnerships to eliminate TB in California | | | | | | | | | | | | |
| 4A: Create and strengthen prevention partnerships that involve public and non-public health providers | ● | * | | | * | ● | * | | | | | |
| 4B: Stimulate and incentivize community providers who serve populations at high risk to make testing for and treatment of LTBI routine | * | * | | | * | * | | ● | ● | | | |

| Intervention | CTEAC and TB Coalition (Proposed Partner) | TBCB-CDPH (Proposed Partner) | Other state agencies (Proposed Partner) | CDC (Proposed Partner) | Local health departments (Proposed Partner) | CTCA-CCLHO (Proposed Partner) | Curry International TB Center (Proposed Partner) | Primary care providers and groups (Proposed Partner) | Health Plans (Proposed Partner) | CBOs and advocacy groups (Proposed Partner) | Industry (Proposed Partner) | Other (Proposed Partner) |
|---|---|------------------------------|---|------------------------|---|-------------------------------|--|--|---------------------------------|---|-----------------------------|--------------------------|
| 4C: Remove existing financial barriers to LTBI testing and treatment for both patients and providers | ● | * | * | * | * | ● | | | ● | * | | |
| Recommendation 5: Create an effective communication plan to promote testing for and treatment of LTBI to health providers and the community in California | | | | | | | | | | | | |
| 5A: Develop, implement and evaluate a simple, clear communication strategy focusing on testing for and treatment of LTBI, targeted to both public and private providers | ● | * | * | | * | ● | * | | | * | | * |
| 5B: Develop, implement, and evaluate a simple, clear communication strategy focusing on testing for and treatment of LTBI for the general public | ● | | | | | * | | | | | | ● |

| Intervention | CTEAC and TB Coalition (Proposed Partner) | TBCB-CDPH (Proposed Partner) | Other state agencies (Proposed Partner) | CDC (Proposed Partner) | Local health departments (Proposed Partner) | CTCA-CCLHO (Proposed Partner) | Curry International TB Center (Proposed Partner) | Primary care providers and groups (Proposed Partner) | Health Plans (Proposed Partner) | CBOs and advocacy groups (Proposed Partner) | Industry (Proposed Partner) | Other (Proposed Partner) |
|---|---|------------------------------|---|------------------------|---|-------------------------------|--|--|---------------------------------|---|-----------------------------|--------------------------|
| Recommendation 6: Develop and implement a surveillance system for reporting, tracking and evaluating LTBI in California | | | | | | | | | | | | |
| 6A: Establish systematic mechanisms for reporting LTBI and tracking populations through the LTBI testing and treatment steps | | ● | * | * | * | ● | | * | * | | * | * |
| Recommendation 7: Secure sufficient resources for implementing the California TB Elimination Plan | | | | | | | | | | | | |
| 7A: Ensure that both public and private providers have the capacity to adequately test and treat all patients at high risk for TB | ● | ● | * | * | ● | ● | ● | ● | ● | ● | ● | * |

| Intervention | CTEAC and TB Coalition (Proposed Partner) | TBCB-CDPH (Proposed Partner) | Other state agencies (Proposed Partner) | CDC (Proposed Partner) | Local health departments (Proposed Partner) | CTCA-CCLHO (Proposed Partner) | Curry International TB Center (Proposed Partner) | Primary care providers and groups (Proposed Partner) | Health Plans (Proposed Partner) | CBOs and advocacy groups (Proposed Partner) | Industry (Proposed Partner) | Other (Proposed Partner) |
|--|---|------------------------------|---|------------------------|---|-------------------------------|--|--|---------------------------------|---|-----------------------------|--------------------------|
| 7B: Acquire new funding to ensure sufficient resources to eliminate TB in California | ● | ● | | ● | * | ● | | | | ● | ● | * |

KEY: CTEAC=California TB Elimination Advisory Committee; TBCB/CDPH: TB Control Branch of the California Department of Public Health; CDC=Centers for Disease Control and Prevention; CTCA/CCLHO: California TB Controllers Association/California Conference of Local Health Officers; CBOs=community based organizations

(1) Includes private providers and providers working in federally-qualified health centers and other community clinics

(2) These include a variety of types of health plans, such as Medi-Cal Managed Care, Medi-Cal Fee for Service plans and commercial plans (both employer-provided and through Covered California)

VII. Resources Needed to Reach Tuberculosis Elimination

Various types of resources will be needed for successful implementation of this TB elimination plan, including: training and education to build TB program staff and community provider capacity; intensification of elimination activities already occurring; current and new partnerships; and simple, precise messaging for dissemination. Ultimately, the success of this plan will depend on its stakeholders acting in concert for collectively impacting the TB elimination trajectory.

Table 2 below provides an overview of the resources identified by CTEAC members to ensure sufficient investment in promoting TB prevention through intensified LTBI testing of and treatment for high-risk populations. This list is likely to grow as CTEAC and the California TB Coalition members modify and/or identify new components of the elimination action plan.

Table 2: Resources required for implementing TB elimination interventions

| Intervention | Epidemiologic data and GIS* (Resource required) | Surveillance systems (Resource required) | New practice guidelines (Resource required) | Academic expertise (Resource required) | IT expertise and vendors (Resource required) | Marketing expertise (Resource required) | Industry (Resource required) | Private grants (Resource required) | TB patients (Resource required) | New TB prevention public funds (Resource required) | Other (Resource required) |
|---|--|---|--|---|---|--|---------------------------------|---------------------------------------|------------------------------------|---|------------------------------|
| 1A: Use epidemiologic profiles to identify populations at high risk for TB and the providers who serve them | * | * | | * | | | | | | * | |
| 1B: Ensure that country of birth is included as a data element for electronic health records across care settings | * | * | | | * | | | | | | * |

| Intervention | Epidemiologic data and GIS* (Resource required) | Surveillance systems (Resource required) | New practice guidelines (Resource required) | Academic expertise (Resource required) | IT expertise and vendors (Resource required) | Marketing expertise (Resource required) | Industry (Resource required) | Private grants (Resource required) | TB patients (Resource required) | New TB prevention public funds (Resource required) | Other (Resource required) |
|---|--|---|--|---|---|--|---------------------------------|---------------------------------------|------------------------------------|---|------------------------------|
| 2A: Prioritize testing for LTBI in foreign-born persons from countries with an elevated TB rate; the immune compromised; and contacts to TB cases, by encouraging use of the California TB risk assessment tool | * | | * | | | * | | | | * | |
| 2B: Ensure that California health care providers use interferon-gamma release assays for testing individuals who previously received bacille Calmette-Guerin (BCG) vaccine | | | * | | | * | * | | | | |

| Intervention | Epidemiologic data and GIS* (Resource required) | Surveillance systems (Resource required) | New practice guidelines (Resource required) | Academic expertise (Resource required) | IT expertise and vendors (Resource required) | Marketing expertise (Resource required) | Industry (Resource required) | Private grants (Resource required) | TB patients (Resource required) | New TB prevention public funds (Resource required) | Other (Resource required) |
|---|--|---|--|---|---|--|---------------------------------|---------------------------------------|------------------------------------|---|------------------------------|
| 2C: Reduce TB testing in low risk populations | | | * | | | * | | | | | * |
| 3A: Maximize initiation and completion of treatment for LTBI | | | * | | | * | * | | | | * |
| 3B: Promote use of the shortest effective LTBI treatment regimens | | | * | | | * | * | | | | |
| 3C: Increase access to adherence technologies to enhance completion of treatment for LTBI | | | | * | | * | * | | | | |
| 4A: Create and strengthen prevention partnerships that involve public and non-public health providers | * | | * | | | | * | * | | * | |

| Intervention | Epidemiologic data and GIS* (Resource required) | Surveillance systems (Resource required) | New practice guidelines (Resource required) | Academic expertise (Resource required) | IT expertise and vendors (Resource required) | Marketing expertise (Resource required) | Industry (Resource required) | Private grants (Resource required) | TB patients (Resource required) | New TB prevention public funds (Resource required) | Other (Resource required) |
|---|--|---|--|---|---|--|---------------------------------|---------------------------------------|------------------------------------|---|------------------------------|
| 4B: Stimulate and incentivize community providers who serve populations at high risk to make testing for and treatment of LTBI routine | | | * | | | * | * | | | * | |
| 4C: Remove existing financial barriers to LTBI testing and treatment for both patients and providers | | | | | | | * | * | | * | * |
| 5A: Develop, implement and evaluate a simple, clear communication strategy focusing on testing for and treatment of LTBI, targeted to both public and private providers | | | * | | | * | * | * | * | | |

| Intervention | Epidemiologic data and GIS* (Resource required) | Surveillance systems (Resource required) | New practice guidelines (Resource required) | Academic expertise (Resource required) | IT expertise and vendors (Resource required) | Marketing expertise (Resource required) | Industry (Resource required) | Private grants (Resource required) | TB patients (Resource required) | New TB prevention public funds (Resource required) | Other (Resource required) |
|---|--|---|--|---|---|--|---------------------------------|---------------------------------------|------------------------------------|---|------------------------------|
| 5B: Develop, implement and evaluate a simple, clear communication strategy focusing on testing for and treatment of LTBI for the general public | | | | | | * | | * | * | | * |
| 6A: Establish systematic mechanisms for reporting LTBI and tracking populations through the LTBI testing and treatment steps | | * | * | | * | | | | | * | |

| Intervention | Epidemiologic data and GIS* (Resource required) | Surveillance systems (Resource required) | New practice guidelines (Resource required) | Academic expertise (Resource required) | IT expertise and vendors (Resource required) | Marketing expertise (Resource required) | Industry (Resource required) | Private grants (Resource required) | TB patients (Resource required) | New TB prevention public funds (Resource required) | Other (Resource required) |
|--|--|---|--|---|---|--|---------------------------------|---------------------------------------|------------------------------------|---|------------------------------|
| 7A: Ensure that both public and private providers have the capacity to adequately test and treat all patients at high risk for TB patients at high risk for TB | * | * | * | * | * | | * | * | | * | * |
| 7B: Acquire new funding to ensure sufficient resources to eliminate TB in California | * | * | * | | | * | * | * | | * | * |

*GIS= geographic information systems

VIII. Implementation and Evaluation Plan

To ensure that this action plan is monitored and kept up to date, by June 30, 2016, CTEAC will establish an evaluation process to monitor the plan implementation. The Committee will meet bi-annually to review progress made on each of the action steps and will modify the steps and/or the implementation timing for each one. The CTEAC leadership will develop an evaluation plan to measure success for a number of key action steps to measure the success of implementation by identifying and addressing gaps. The biannual assessments and the evaluation findings will be shared with the California TB Coalition members for feedback. Finally, CTEAC leadership will follow cases of incident TB disease to assess progress to elimination.

IX. Implementation Timeline

Recommendation 1: Find and engage persons and populations at high risk for TB and their providers in California

| Action Steps | Year(s) |
|--|---------|
| Intervention 1A: Use epidemiologic profiles to identify populations at high risk for TB and the providers who serve them | |
| 1. Create epidemiologic profiles of populations at high risk for TB to aid prevention efforts | 2016 |
| 2. Provide epidemiologic profiles and maps of high risk populations and their providers to local health departments to determine potential partners for TB prevention | 2016 |
| 3. Identify health care providers who are most frequently serving individuals who develop TB disease | 2016-20 |
| 4. Identify providers for populations at high risk by reviewing the languages spoken by medical providers, available from the Medical Board of California website | 2016-20 |
| Intervention 1B: Ensure that country of birth is included as a data element for electronic health records across care settings | |
| 1. Systematically ensure that country of birth, an important risk factor, is added as a data field to electronic health records and medical care intake and charting | 2016-19 |
| 2. Request that electronic health record developers modify existing software systems to include a country of birth data field and include as part of the standard demographic package in new systems | 2016-18 |
| 3. Include a country of birth data field in TB-specific Confidential Morbidity Reports used for reporting TB suspected cases and known cases | 2016-20 |

Recommendation 2: Apply focused and effective strategies for TB testing in California

| Action Steps | Year(s) |
|---|---------|
| Intervention 2A: Prioritize testing for LTBI in foreign-born persons from countries with an elevated TB rate; the immune compromised; and contacts to TB cases, by encouraging use of the California TB risk assessment tool | |

| Action Steps | Year(s) |
|---|---------|
| 1. Use education and outreach to stimulate healthcare providers' use of the California TB risk assessment tool | 2017-18 |
| 2. Incorporate the risk assessment questionnaire into electronic health records | 2016-20 |
| 3. Identify and disseminate Medi-Cal and Medicare codes for reimbursement for conducting a TB risk assessment | 2016-18 |
| 4. Harmonize the child, adult and specialized versions of the TB risk assessment tools | 2016 |
| 5. Standardize the TB risk assessment performed for school entry throughout the state | 2016-18 |
| 6. Implement effective marketing strategies to encourage providers and health systems to adopt the TB risk assessment tool | 2016-20 |
| 7. Ensure official endorsement of the TB risk assessment tool by the highest levels of public health | 2016 |
| 8. Encourage health care system administrators to require that their providers complete TB risk data fields and tie to quality improvement initiatives | 2019-20 |
| 9. Develop a metric and track the adoption and use of the risk assessment tool | 2016-18 |
| Intervention 2B: Ensure that California health care providers use interferon-gamma release assays for testing individuals who previously received bacille CalmetteGuerin (BCG) vaccine | |
| 1. Update and widely disseminate guidelines to community providers to recommend that interferon-gamma release assays should be used for testing individuals who have been vaccinated with BCG | 2016-17 |
| 2. Engage private sector patient assistance programs, health plans and manufacturers to provide interferon-gamma release assays at lowest cost | 2016-17 |
| 3. Ensure that health plan utilization reviews assess use of interferon-gamma release assays | 2017-18 |
| Intervention 2C: Reduce TB testing in low risk populations | |
| 1. Eliminate requirements for screening employees in settings where the risk of TB transmission is low | 2016-18 |
| 2. Align the Child Health and Disability Prevention Program TB screening protocol with risk-based testing for K-12 school entry | 2016-18 |
| 3. Implement a process to monitor and update TB screening laws as TB epidemiology and tools change over time | 2016-20 |
| 4. Bring the CalOSHA annual screening regulations for health care workers into alignment with federal guidance on preventing TB transmission in health care facilities | 2017-20 |

Recommendation 3: Optimize treatment for LTBI

| Action Steps | Year(s) |
|---|---------|
| Intervention 3A: Maximize initiation and completion of treatment for LTBI | |
| 1. Develop and disseminate educational materials on LTBI treatment to providers serving populations at high risk for TB | 2016-18 |
| 2. Develop strategies to ensure that individuals at high risk for disease progression who are already being screened are starting and completing LTBI treatment | 2016-20 |
| 3. Educate providers on the most effective ways to communicate the importance of LTBI treatment completion to patients | 2016-20 |
| 4. Develop strategies to support treatment monitoring and/or adherence | 2016-20 |
| 5. Establish provider incentives for recording LTBI diagnosis and LTBI treatment completion | 2016-18 |
| 6. Conduct outreach to populations at high risk to provide education about the need for testing and treatment for LTBI | 2017-20 |
| Intervention 3B: Promote use of the shortest effective LTBI treatment regimens | |
| 1. Promote access to effective short-course regimens to all who need them | 2016-20 |
| 2. Ensure that pharmacy formularies provide easy access to drugs used in short course LTBI regimens | 2016-17 |
| Intervention 3C: Increase access to adherence technologies to enhance completion of treatment for LTBI | |
| 1. Use data to provide feedback to providers and health care systems on provider performance on LTBI testing and treatment | 2017-20 |
| 2. Disseminate models on best practices for improving patient LTBI treatment monitoring and completion | 2016-18 |
| 3. Expand access to and use of electronic directly observed therapy reminder and tracking technologies | 2016-20 |

Recommendation 4: Develop strong and effective partnerships to eliminate TB in California

| Action Steps | Year(s) |
|---|---------|
| Intervention 4A: Create and strengthen prevention partnerships that involve public and non-public health providers | |
| 1. Implement local health department strategies to stimulate health care provider testing and treatment of LTBI in populations at high risk | 2016-20 |
| 2. Create public-private partnerships to assist providers to complete each step of the TB prevention and treatment cascade | 2017-20 |

| Action Steps | Year(s) |
|---|---------|
| 3. Identify and train community health workers and former TB patients to educate communities and individuals at high risk about the need for testing and treatment for LTBI | 2017-20 |
| Intervention 4B: Stimulate and incentivize community providers who serve populations at high risk to make testing for and treatment of LTBI routine | |
| 1. Encourage health systems to implement routine quality improvement activities that assess completion of steps of LTBI testing and treatment | 2016-18 |
| 2. Educate civil surgeons to ensure that patients with LTBI are referred for or receive and complete treatment | 2016-20 |
| 3. Identify methods to recognize providers who excel at ensuring LTBI treatment completion | 2017-18 |
| 4. Create a pilot demonstration project to replicate the British LTBI care provider incentive process | 2017-19 |
| Intervention 4C: Remove existing financial barriers to LTBI testing and treatment for both patients and providers | |
| 1. Collect data about the LTBI burden in California and utilize these data to communicate resource needs for LTBI testing and treatment | 2016 |
| 2. Make testing and treatment for LTBI a routinely covered benefit of health plans to eliminate barriers created by out-of-pocket expenses | 2016-18 |
| 3. Communicate and disseminate to health plan administrators the return on investment for the testing for and treatment of LTBI | 2016-18 |

Recommendation 5: Create an effective communication plan to promote testing for and treatment of LTBI to health providers and the community in California

| Action Steps | Year(s) |
|---|---------|
| Intervention 5A: Develop, implement and evaluate a simple, clear communication strategy focusing on testing for and treatment of LTBI, targeted to both public and private providers | |
| 1. Identify medical societies and groups for targeted messages about testing for and treatment of LTBI | 2016-20 |
| 2. Develop compelling messages for health care systems to focus on foreign born populations and other risk groups for TB testing | 2016-20 |
| 3. Create an LTBI educational toolbox with resources for communicating to providers serving populations with high TB infection rates | 2017-19 |
| 4. Promote LTBI testing and treatment at key conferences to providers who serve populations at high risk | 2016-20 |

| Action Steps | Year(s) |
|---|---------|
| 5. Identify industry and philanthropic organizations that can fund development of resources for communicating about new LTBI diagnostics and treatment | 2016-17 |
| Intervention 5B: Develop, implement and evaluate a simple, clear communication strategy focusing on testing for and treatment of LTBI for the general public | |
| 1. Collaborate with a marketing expert to create public communication strategies for populations at high risk | 2017 |
| 2. Use social media tools to disseminate LTBI testing and treatment messages to the public | 2017-20 |
| 3. Develop a group of TB patients and representatives to disseminate LTBI testing and treatment messages to the public and policy makers | 2016-18 |
| 4. Conduct outreach to engage key populations at high risk for TB to promote LTBI screening | 2017-20 |

Recommendation 6: Develop and implement a surveillance system for reporting, tracking and evaluating LTBI in California

| Action Steps | Year(s) |
|---|---------|
| Intervention 6A: Establish systematic mechanisms for reporting LTBI and tracking populations through the LTBI testing and treatment steps | |
| 1. Assess the feasibility of making LTBI a reportable condition in California (including the development of a mandate) | 2016-17 |
| 2. Develop a standardized definition of LTBI | 2017-19 |
| 3. Explore using existing systems for reporting LTBI (laboratory reporting of interferon-gamma release assays) and for tracking LTBI treatment and outcomes | 2017-19 |
| 4. Identify initial and ongoing funding to support LTBI reporting and treatment | 2017-19 |
| 5. Develop performance measures for LTBI testing and treatment | 2016-19 |
| 6. Facilitate electronic transfer of LTBI testing and treatment information between electronic health records and LTBI reporting systems | 2018-19 |

Recommendation 7: Secure sufficient resources for implementing the California TB Elimination Plan

| Action Steps | Year(s) |
|---|---------|
| Intervention 7A: Ensure that both public and private providers have the capacity to adequately test and treat all patients at high risk for TB | |
| 1. Ensure an adequate and continuous supply of drugs to treat LTBI, especially those drugs needed for short-course therapy | 2016-20 |
| 2. Ensure that clinical and programmatic TB guidelines for California are up-to-date and are widely disseminated; develop and disseminate new ones, as necessary | 2016-20 |
| 3. Coordinate with TB training organizations to ensure that training curricula for public and private providers are relevant, up-to-date and being implemented for the highest priority audiences | 2016-20 |
| 4. Create an inventory of LTBI testing and treatment best practices for dissemination to public and private partners | 2016-17 |
| Intervention 7B: Acquire new funding to ensure sufficient resources to eliminate TB in California | |
| 1. Seek funding from the Centers for Disease Control and Prevention for intensifying LTBI screening, testing and treatment activities | 2016-20 |
| 2. Secure private foundation and industry funding to support California TB Coalition infrastructure and initial support for demonstration projects, innovations and intensification of current activities | 2016-20 |
| 3. Strengthen the public health infrastructure so that electronic health records and electronic laboratory reporting capacity exists across local public health departments | 2016-20 |
| 4. Identify ongoing resources to support LTBI reporting and treatment | 2016-19 |

X Next Steps for Plan Implementation

To effectively begin implementation of the California TB Elimination Action Plan, CTEAC has identified the following activities as next steps:

| Activity | Who | By When |
|--|-------------------------|----------------------|
| 1. Prioritize action steps for implementation in first two years of plan | CTEAC/CTCA/CDPH | Summer 2016 |
| 2. Identify and recruit organization leads for prioritized action steps | CTEAC/CTCA | Summer 2016 |
| 3. Recruit new partners to collaborate in plan implementation | CTEAC/CTCA/TB Coalition | Summer and Fall 2016 |
| 4. Conduct outreach to engage key populations at high risk for TB to promote LTBI screening | CTEAC | Summer 2016 |
| 5. Secure ongoing support for TB coalition activities | CTEAC/CTCA/TB Coalition | Summer 2016 |
| 6. Collaborate with public and private health plans to develop health plan metrics that stem from public health indicators | CTEAC/CTCA/CDPH | Fall 2016 and beyond |

XI. How to Support this Plan

The successful implementation of this action plan can be achieved with the participation and coordinated efforts of a diverse group of stakeholders. The 61 local health departments, the California Department of Public Health TB Control Branch, public health associations (e.g., CTCA), health plan administrators, advocacy and patient survivor groups and many others, including the public, have roles to play.

Listed below is a sampling of the many ways the plan can be supported through these partnerships. A number of the activities listed below, and outlined in the action steps, describe activities already being implemented. Many are not new, but may require intensification to make progress toward elimination.

Local health department TB control programs

- Conduct outreach to and education of providers and the community focused on LTBI testing and treatment
- Ensure LTBI testing and treatment (if infected) of immigrants and refugees who have undergone pre-immigration TB screening for LTBI
- Work with civil surgeons, community health center staff and other private providers serving foreign-born populations to raise their awareness about the potential for LTBI and TB, reduce delays in diagnosis, and intensify targeted testing and treatment programs for LTBI
- Increase access to adherence technologies to enhance LTBI follow-up and treatment completion
- Build strong TB prevention partnerships with public and private providers
- Support community-based LTBI testing and treatment programs for populations at high risk

California Department of Public Health TB Control Branch

- Create and disseminate epidemiologic profiles of populations at high risk for LTBI and TB disease and the providers who serve them
- Work with partners to facilitate the modification of electronic health records to include a new field to capture country of birth
- Promote among partners the most effective strategies for testing populations at high risk for TB
- Establish systematic mechanisms for reporting LTBI and tracking treatment

outcomes

- Prevent loss of core TB control capacity; work to increase or sustain resources to maintain core TB programs
- Continue to provide local assistance to health departments, including support for TB prevention activities
- Provide technical assistance for intensifying LTBI targeted testing and treatment activities
- Collaborate with CTEAC, the California TB Coalition and stakeholders to fully implement the California TB Elimination Action Plan

California TB Controllers Association and other networks of public health communicable disease providers

- Create and disseminate new guidelines on best practices for testing and treating populations at high risk for LTBI
- Propose a legal framework for reporting individual cases of LTBI to local and state health departments
- Build effective partnerships to promote TB elimination across California
- Participate in the development of communication strategies focused on LTBI testing and treatment for both providers and the public

Primary care providers or community health centers providing care to populations at high risk

- Make the diagnosis and treatment of LTBI a priority activity
- Utilize the TB risk assessment tool to identify patients at high risk for LTBI
- Become educated about optimal practices for testing and treating patients at risk for LTBI and/or request clinical consultation from public health departments
- Maximize LTBI treatment initiation and completion in high risk patients who have LTBI
- Educate patients at high risk about the need for testing and treatment for LTBI
- Provide clear recommendations for treatment of individuals with LTBI

Health systems and health plans

- Collaborate with the California Department of Public Health, the Department of Health Care Services and Covered California to ensure that the United States Preventive Services Task Force TB screening recommendations are implemented by health plans
- Communicate to providers the critical importance of LTBI treatment initiation and completion in patients at high risk for TB

- Create incentives for providers who use the TB risk assessment tool to identify patients who need to be tested
- Implement tracking systems in electronic health records and health plan protocols that identify patients at risk who need testing and patients with LTBI who need treatment

Advocacy groups and community-based organizations

- Work in partnership with the California TB Coalition to reduce existing financial barriers for TB prevention services for populations at high risk
- Create simple TB prevention messages for dissemination to policymakers and populations at high risk

Pharmaceutical industry

- Ensure a sufficient supply of new drugs, especially rifapentine, to meet demand
- Develop less complex LTBI regimen preparations for adults and children
- Offer reduced rates for regimens as incentives for providers who prescribe short course treatment
- Ensure robust patient assistance programs for LTBI treatment

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XIII. Appendices

Appendix A: Glossary of Terms

Affordable Care Act: The Patient Protection and Affordable Care Act, commonly called the Affordable Care Act, expands Medicaid coverage to millions of low-income Americans through a federal statute that required a significant overhaul of the U.S. health care system. The Affordable Care Act was enacted to increase the quality and affordability of health insurance, lower the uninsured rate by expanding public and private insurance coverage, and reduce the costs of health care for individuals and the government.

Bacille Calmette-Guerin (BCG) vaccine: A vaccine used to prevent disseminated TB disease in children. Use of interferon-gamma release assays to test for TB infection are preferable for use with BCG-vaccinated individuals to avoid the false positive results that can occur with the TB skin test.

California Immunization Registry (CAIR): The California statewide immunization registry with 10 regional CAIR affiliates throughout the state. CAIR ensures the secure electronic exchange of immunization records to support the elimination of vaccine-preventable diseases.

California Reportable Disease Information Exchange (CalREDIE): A computer application created by the California Department of Public Health for web-based disease reporting and surveillance.

Contact investigation: A process performed (usually by health department staff) to identify people who have had contact with a person with TB disease, assess them for LTBI and TB disease, and provide, when appropriate, treatment for LTBI or TB disease. This is a priority activity which is critical for preventing future cases of TB.

Interferon-gamma release assay (IGRA): Whole-blood tests that can aid in diagnosing *Mycobacterium tuberculosis* infection. The tests do not differentiate LTBI from TB disease. Unlike the tuberculin skin test, only a single patient visit is required to conduct the test, results are available in 24 hours and prior BCG vaccination does not cause a false-positive interferon-gamma release assay test result.

Latent tuberculosis infection (LTBI): Individuals with LTBI carry *Mycobacterium tuberculosis*, the organism that causes TB, but do not have TB disease; they are asymptomatic and non-infectious. Individuals with LTBI usually have a positive reaction to the tuberculin skin test and have a positive interferon-gamma release assay blood test.

LTBI reservoir: The population of individuals who have LTBI but have not yet progressed to

TB disease.

Private providers: A general term that refers to a wide range of clinicians that provide care to patients in private practice settings (e.g., private practice groups, health maintenance organizations)

Surveillance: Ongoing systematic collection, analysis, and interpretation of health data essential to the planning, implementation, and evaluation of public health practice, closely integrated with the timely dissemination of these data to those who need to know in public health programs

TB elimination: An epidemiologic term defined as <1 TB case per million population. For California in 2015, this translates to an elimination target of 39 annual cases.

TB prevention and care cascade: Involves public health departments and providers reaching and testing individuals at risk for TB, identifying those who should be treated for LTBI, and starting and completing LTBI treatment in those individuals. At each step, patients and prevention opportunities could be lost.

Tuberculin skin test (TST): A skin test to determine whether a person has LTBI. The test is administered by injection of a small amount of tuberculin fluid under the skin of the forearm. The individual must return within 48 to 72 hours after the test is placed to have a trained health care worker look for and measure a reaction on the arm.

Tuberculosis: An infectious disease caused by the bacterium *Mycobacterium tuberculosis*. The bacteria usually attack the lungs, but TB bacteria can attack any part of the body such as the kidney, spine, and brain. If not treated properly, TB disease can be fatal.

Appendix B: California Tuberculosis Elimination Task Force Report

Report of the California Tuberculosis Elimination TaskForce Meeting

May 11, 2015
Berkeley, California

Funding provided by the California HealthCare Foundation



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Executive Summary

A scientific task force to recommend strategies for the elimination of tuberculosis (TB) in California was established in 2015. This group met on May 11, 2015, and identified six groups of interventions needed to reach TB elimination in California by 2040. The recommendations will be used by stakeholders in the fall of 2015 to develop a statewide TB elimination action plan.

The Task Force called out the urgent need for simple and clear guidance to both public and private providers regarding populations to test and methods to use for latent TB infection (LTBI) testing and treatment. This guidance should include promoting the use of: 1) TB epidemiologic profiles by health departments and routine use of risk assessments by providers; 2) a unified focus on testing the major high-risk population of foreign-born residents; 3) the more specific assays such as the interferon-gamma release assay (IGRAs) for testing of the foreign-born with bacille Calmette-Guerin (BCG) vaccination; and 4) the shortest, most effective treatment regimens for treating LTBI. A key recommendation was that TB prevention must extend beyond public health settings and be included in primary care services that should be made accessible to all Californians, regardless of their ability to pay or their immigration status. They also recommended that new guidance be straightforward, user-friendly and be disseminated via a robust statewide communication strategy to both providers and the public.

The Task Force members highlighted several topics that will benefit from further detailed discussion for implementation. These areas include the process for staging the statewide TB elimination effort (broad implementation vs incremental steps); whether some subgroups among the foreign-born merit intensified LTBI testing; and how implementation, reporting and monitoring of individual LTBI status should occur.

The Task Force recommendations to reach TB elimination in California by 2040 are presented in the table on the following page.

Recommendations of the California TB Elimination Task Force, May 2015

1. Find and engage persons and populations at risk for LTBI

- Create epidemiologic profiles of populations at high-risk for TB infection and disease and the providers who serve them
- Include foreign birth and country of birth as data elements for electronic medical records in all care settings

2. Testing

- Focus testing on foreign-born persons in California from moderate and high prevalence countries
- Use IGRAs for testing foreign-born (BCG-vaccinated) persons
- Reduce testing of low-risk populations

3. Treatment

- Maximize treatment initiation and completion for LTBI in high-risk populations that already undergo routine testing
- Promote use of the shortest effective LTBI treatment regimens
- Increase access to adherence technologies to enhance follow-up and treatment completion

4. Create partnerships and remove barriers

- Implement prevention partnerships that encompass both public and non-public health providers
- Stimulate and incentivize community providers who serve high-risk populations to make TB prevention routine in primary care
- Remove existing financial barriers for TB prevention services for both patients and providers

5. Communication

- Develop and implement a simple, clear TB prevention communication strategy

6. Reporting, tracking, and evaluation

- Create systematic mechanisms for reporting LTBI and tracking populations through TB prevention steps
- Create or modify existing systems for measuring, monitoring and evaluating LTBI testing and treatment outcomes

Background and Purpose

An estimated 2.5 million Californians have latent infection with *Mycobacterium tuberculosis*—most are unaware of their infection and are untreated. Since tuberculosis (TB) disease and transmission are at a nadir and TB transmission from persons with active TB is now limited, a great public health opportunity exists in California to shrink the pool of latent TB infection (LTBI). Innovations in diagnosis and treatment of LTBI, as well as the expansion of health care coverage, now make it possible to more effectively advance TB prevention. Models suggest that expansion of treatment of LTBI can reduce the magnitude of TB disease substantially, averting TB deaths, new transmission and TB-related costs. In addition, broader efforts are planned as global and national organizations are committing to TB prevention and elimination.

On May 11, 2015, the California TB Elimination Task Force was convened to explore how best to seize the opportunity to eliminate TB in California. This Task Force was a collaboration of the California Department of Public Health (CDPH), the University of California, San Francisco, and the California TB Controllers Association. Funding for this effort was provided by the California HealthCare Foundation. Task Force members were subject matter experts in public health, TB disease and latent infection, infectious disease epidemiology, health economics, communicable disease control and implementation science. The Task Force meeting objective was to identify strategies for achieving elimination of TB in California by 2040. The following questions were posed: 1) What bundle of interventions will enable California to reach TB elimination most quickly? 2) What strategies should be pursued if new resources become available?

CDPH provided background materials to the task force members relevant to TB elimination in California in advance of the meeting. Meeting presentations included an overview of California TB epidemiology and facets of a TB elimination model. TB prevention cascade elements were presented as the framework for the intervention bundle. These elements include: 1) finding and assessing individuals at risk for LTBI; 2) testing for LTBI and completing treatment in persons with LTBI; and 3) systems that support these steps. Large group discussions were followed by deliberations on specific interventions, culminating in a recommended intervention bundle to advance TB elimination in California.

Assumptions for the Task Force Consultation

The Task Force was asked to make recommendations for achieving TB elimination in California based on the following assumptions: 1) the task force will focus on interventions within California rather than global or national interventions; 2) for TB elimination to occur in California, an action plan must address reducing the number of persons with undiagnosed and untreated latent TB infection; 3) current tools available at the time of the meeting will be considered for interventions when making recommendations for elimination. Any new tools developed between now and the target year 2040 could further speed up elimination; 4) global conditions such as immigration into the U.S., international TB case rates, and U.S. healthcare delivery will remain stable; 5) sufficient resources and political advocacy will be available to support the interventions and strategies recommended to reach elimination; 6) strong partnerships will be in place to reach elimination; 7) current global and research investments currently underway will continue to be funded and be ongoing; and 8) current levels of TB control in California will remain the same, with a stable public health infrastructure. Case finding, treatment, and investigation efforts will continue and the average annual number and complexity of outbreaks will not change.

TB Elimination Thresholds

The World Health Organization has defined the thresholds for pre-elimination and elimination of TB. Listed below are the numbers of TB cases that would meet each of these thresholds based on the current California population:

| Definition | Rate | CA Cases | Target Year |
|-----------------------|-------------------------|--------------|-------------|
| Current status | 56 cases/million | 2,145 | 2014 |
| Pre-elimination | <10 cases/million | 388 | 2025 |
| Elimination | <1 case/million | 39 | 2040 |

Epidemiology of Tuberculosis and TB Infection in California

When designing public health interventions to accelerate the time to TB elimination, California's population has specific characteristics that need to be considered. The state is home to a large, diverse population representing the highly mobile global community. Ten million persons, or 26% of California's population of 39 million, were born outside the U.S., many from a region with a high TB burden. Additionally, over 11 million persons enter California from outside the U.S. each year. An example of this diversity is that half of California's 10 million children (under age 18) have a foreign-born parent. Adding to this population at risk for TB is the large and growing elderly population comprised of two million residents who are 75 years old or older. Many U.S.-born and foreign-born

persons exposed to TB in childhood are part of this elderly group and have chronic medical conditions that increase their risk of TB progression. Overall, 2.5 million California residents are estimated to have LTBI; 2 million of those with TB infection are foreign-born and 500,000 are U.S.-born.

TB trends

For more than two decades, the rate of TB has steadily declined in California. In 2014, the TB rate among the U.S.-born was 1.6 new cases per 100,000 and among the foreign-born it was 16.1 per 100,000. More recently, this decline has slowed. During 1992–2000 there was an average 5.6% annual decline whereas during the most recent decade, the average annual case decline was 3.4%. Despite the slowing decrease in TB disease, 2,145 cases were reported in 2014, representing the lowest case count in California history but still the largest in the nation.

TB patient characteristics

The top five countries of origin for foreign-born patients with TB in California has remained constant over this 20 year period with Mexico, Philippines, Vietnam, China and India contributing 75% of California's foreign-born cases. However, the face of TB has changed. Compared to 1994, TB patients in 2014 are now older (median age 51 years), more likely to be foreign-born (78%), and more likely to have co-existing medical conditions. During 2010-2014, 32% of TB patients had at least one of the following medical co-morbidities: diabetes mellitus, end stage renal disease (ESRD), anti-tumor necrosis factor alpha therapy or other treatment with immunosuppressive drugs, solid organ transplant recipient, HIV infection, or another immunosuppressive condition.

In contrast to previous decades, TB in Californians is now less likely to be found among persons who are homeless, incarcerated or substance-using. Those with TB in California are now also less likely to be co-infected with HIV (4%). When HIV/TB disease does occur, it is most often found in the foreign-born (60%).

Of note, the majority of TB disease among the foreign-born occurs in those who have been in California for many years. At least 75% have been in the U.S. six years or longer at the time of TB diagnosis. Half of TB cases among foreign-born residents enter the U.S. with immigrant or refugee status and are screened for active TB, but not LTBI, before entering the U.S. The other half, which includes persons with worker, student or tourist visas, and the undocumented, is not required to have pre-entry TB screening.

How is TB disease generated in California?

The vast majority of TB in California, 75.5%, is from reactivation of remotely acquired infection. Another 17% is from recent transmission within California communities, and 7.5% is "imported," i.e., from new arrivers who are diagnosed with active TB disease within one year of arrival in the U.S. Finally, a very small percentage, less than 1%, may be generated as a result of relapse of previously treated

disease or from re-infection.

Tuberculosis Control and Prevention in California

The role of health departments and community providers

Each of California's 61 local health departments is responsible for overseeing the care of TB patients, responding to and preventing TB transmission in the community, and preventing TB in persons at high risk. Local health departments perform these functions through direct patient care and/or partnerships with community providers, including hospitals, health maintenance organizations, federally qualified health centers and other community clinics, private physician networks, and individual providers.

The role of the state TB control program is to provide technical assistance, resources on outbreak response, consultation on diagnosis and management of drug resistant TB, and guidance on TB control and prevention efforts. The state program monitors TB control by collecting and interpreting surveillance data. Local health departments are the front line workers in TB control efforts. Community providers are an important source for care of patients with both TB disease and latent infection.

Testing for LTBI

Both tuberculin skin tests (TST) and interferon-gamma release assays (IGRAs) are in widespread use in California for diagnosing LTBI. Consistent with CDC guidelines, because of increased specificity (99% vs. 85%)¹ especially in persons who have been vaccinated with BCG, IGRA is preferentially recommended for use in foreign-born populations. A variety of screening programs occur in California covering an estimated 1.7 million persons each year (figure), but these populations have varying risks of TB. Programs in place to screen populations at higher risk of TB include testing of persons that are recent contacts to a known active TB case, new immigrants arriving in the U.S. who had an abnormal chest radiograph during overseas exam (B-notification arrivers), and persons who apply to adjust their immigration status from a temporary to a permanent status (status adjusters). The majority of persons tested each year in California have a low risk for TB infection.

Who is being tested for LTBI in California now?

| Group | Estimated Number Tested Annually | TB Risk |
|-------------------------|----------------------------------|---------------|
| Recent contacts | 17,000 | High |
| HIV infection | 18,000 | High |
| B-notification arrivers | 5,000 | High |
| Refugees | 8,000 | High |
| Status adjusters | 105,000 | Moderate-High |
| Healthcare workers | 1,443,000 | Low |

| Group | Estimated Number Tested Annually | TB Risk |
|----------------------|----------------------------------|---------|
| State prison inmates | 130,000 | Low |
| Others | ? | Varied |
| Total | 1,726,000 | |

Sources include: California Department of Corrections, United States Department of Homeland Security, and California Department of Public Health: TB Control Branch, Office of Statewide Health Planning and Development, and Refugee Health Program.

Health care for TB

TB care is delivered through a complex health care delivery system in California. Among the 61 local health departments, just 21 reported 95% of all TB cases in California in 2010–2014. At least 18 of these 21 local public health departments have categorical TB clinics that provide direct patient care. Sixty-four percent of TB patients in 2010-2012 received the majority of their TB care in a public health department clinic. Patients who do not receive their care in a public clinic receive care in the private sector, or have care provided jointly by both private provider(s) and a public health clinic. A single large health maintenance organization, Kaiser Permanente, provides care for 14% of all reported culture-confirmed TB patients in California.

Health insurance for TB care

If a TB patient meets criteria, he/she can be enrolled in Medi-Cal (the Medicaid program in California) which covers TB diagnosis, treatment and case management expenses. Local health departments can bill Medi-Cal for reimbursement. A remaining gap in payment for TB care is for undocumented immigrants—who are estimated to comprise 15-25% of patients with active TB in California—and for 500,000 persons who have LTBI.²

Foreign-born residents not only have an increased risk of TB, but many are not able to access health insurance or make co-payments for medical care. A 2006 study of foreign-born TB patients revealed that 144 patients (55%) in a California sample of 262 had household incomes of less than \$30,000. Forty-one percent of patients did not have health insurance when their TB symptoms started.³

Affordable Care Act

The federal Affordable Care Act (ACA) presents both opportunities and challenges for health departments to build partnerships with private providers. For TB control, the opportunity is that many more high-risk persons will be insured; but, screening and treatment for LTBI has not yet been designated as a U.S. Prevention Services Task Force “essential health benefit.” In the absence of this designation, these public health activities require patient co-pays, providing a barrier to ensuring that all high-risk individuals are provided critical TB prevention services.⁴

California regulations and policies

California has strong public health regulations that support TB control and prevention. Evidence of active TB disease in an individual must be reported by laboratories and providers to the local health department, and each case of active TB must be reported to the state TB registry, with follow-up information documenting treatment. Hospitals that provide care to an individual with active TB must provide a written discharge plan, outlining follow-up care and referral of the patient. The local health officer is responsible for approving the hospital plan prior to patient discharge. This process ensures uninterrupted transition of patient care, minimizing potential loss to follow-up and other resultant adverse outcomes (e.g., transmission within the community, development of drug resistance). The California penal code mandates annual TB screening of inmates, and TB case and aggregate LTBI reporting to the California TB Control Branch. Other screening mandates include teacher risk-based testing and annual tests of health care workers and students. Specific screening policies for many populations vary by jurisdiction and institution.

Funders of TB control in California

TB control programs are supported by funding from federal, state, and local governments. The percentage of each government's contribution varies for each local health department. Three large county health departments—Los Angeles, San Diego, and San Francisco—and the state TB control program have cooperative agreement funding from the Centers for Disease Control and Prevention Division of TB Elimination. The majority of resources for TB control for local health departments come from their county-level governments which cover approximately 65% of TB program budgets. Medi-Cal is a key payer of coverage for Californians with TB and LTBI.

TB Elimination in California: Why Now?

Two major technological advances create new opportunities to efficiently prevent TB: the new short course LTBI treatment which greatly enhances rates of regimen completion and a relatively new TB test, IGRA, that reduces false positive results. Additionally, with the expansion of health care access, an estimated 800,000 new foreign-born adults were enrolled in Medi-Cal after implementation. Finally, recent commitments to TB elimination by national and global organizations contribute to new opportunities for elimination in California.

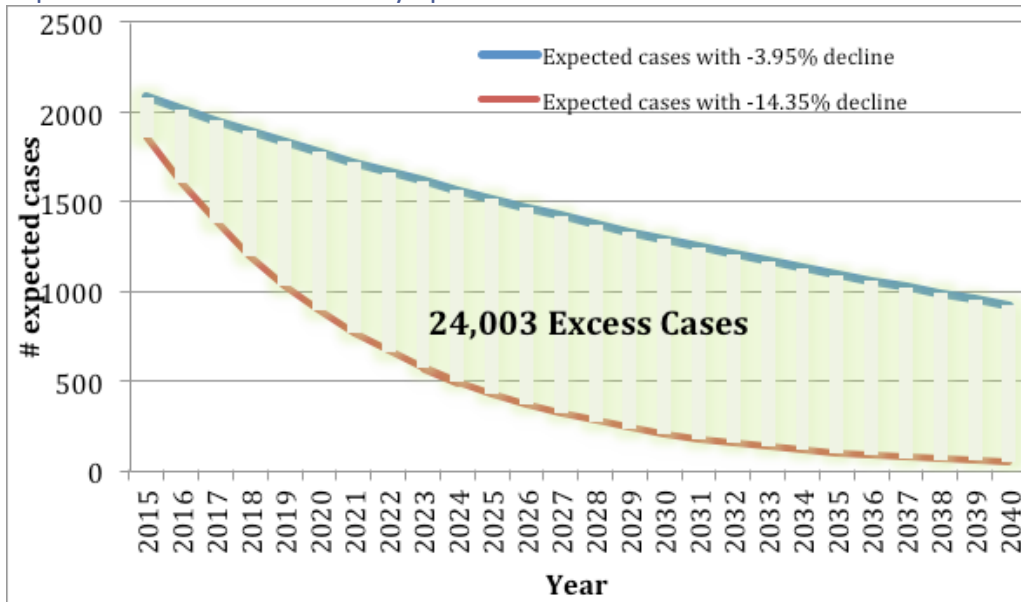
The Value of TB Elimination

The human and economic consequences of persistent TB disease in California are the most compelling reasons to pursue elimination—TB elimination is of great value to both individuals and to society. If not prevented, TB disease may result in hospitalization, disability and most important, premature death across the age spectrum. Over half of

persons diagnosed with TB are hospitalized for treatment or disease complications, and the death toll is daunting. In California, one in ten diagnosed with TB dies, either during therapy or before they have had an opportunity for treatment. At the current rate of case decline (3.95% per year), by 2035 there will have been approximately 2,900 deaths due to TB. A TB patient's inability to work and loss of income due to TB illness affects their families, and an overall depreciation in quality of life is common. Protection of the health of the public and overall reduction of costs by eliminating TB as a source of illness benefits all populations in California. Direct patient costs for a TB case in California average \$31,000 for drug susceptible TB and \$115,000 for MDR TB, but can range substantially above \$1 million for certain patients.⁵

In 2014, the estimated direct cost for TB cases in California for 2014 was \$51 million. Additional costs to society arise from secondary transmission of disease and the resultant costs and productivity losses. Increasing efforts now to increase the annual rate of decline to 14.35% instead of the current 3.95% could avert 24,000 cases by 2040, saving more than \$600 million, and preventing approximately 1,200 excess deaths due to TB. The CDC has estimated that every \$1 of investment in TB prevention would result in a \$12.08 return to society.⁶

Expected Cases in California by Specific TB Decline Rates



Source: CDPH TB Control Branch April 2015

Cost-effectiveness of Newer LTBI Treatment Regimens

TB prevention has been limited in large part because the regimens for latent TB infection treatment are lengthy. Recently, two shorter regimens have been evaluated and recommended by CDC guidelines: 3 month regimen of 12 weekly doses of INH/rifampin (3HP) and 4 months of rifampin (4R). The economic evidence that has accumulated shows that these regimens are cost-effective when

compared to the longer traditional INH regimens, mainly because the likelihood that a person will complete a 12 dose or 4 months of daily medicine is much higher than the likelihood of completing 9 months of daily INH. When TB disease prevention and medication completion rates are taken into account, both 4R and 3HP were less costly than INH for 9 months in persons who were TB contacts.⁷ The 3HP regimen was less costly and more effective than all regimens among patients at high risk of TB disease and for persons who are known to have low completion rates. The economic benefits increase further when 3HP can be given without directly observed therapy. Overall, studies have demonstrated that the shorter duration of LTBI treatment regimens of 3HP and 4R were cost-effective compared with 9 months of INH.^{7,8}

Recommendations for Reaching TB Elimination in California

Task Force members recommended six groups of interventions to help California achieve TB elimination. Interventions span the major steps within the TB prevention care cascade and provide systems level support to these steps. Each of the recommended interventions is described in detail below.

1. Find and engage individuals and populations at risk for LTBI

- **Create epidemiologic profiles of populations at high-risk for TB infection and disease and the providers who serve them.** Local health jurisdiction TB programs and the state TB program should use surveillance data and public datasets to create statewide and local epidemiologic profiles to identify target populations to guide community providers. These profiles should include geographic location of residence, points where care can be accessed, and primary medical providers. The target populations are those persons at risk for LTBI and progression to TB disease. This specific information will allow health departments and community providers to identify the size and location of high-risk groups and allow health departments to identify access points and to focus testing efforts. It will also enable more efficient targeting of providers, health plans and practices that provide care to the groups most in need of TB prevention.
- **Include foreign birth and country of birth as data elements for electronic medical records in all care settings.** Every primary care electronic medical record (EMR) should include country of birth. Providers need to ask about birthplace/country of origin to determine potential TB exposure risk and to trigger testing. Other disease prevention efforts may also benefit (e.g., hepatitis B). Movement to risk-based screening will require data to be systematically collected with prompted questions on TB risk with country of birth being one of the most important risk factors.

2. Testing

- **Focus testing on foreign-born persons in California from moderate and high prevalence countries.** To achieve progress toward TB elimination all persons born in countries with TB prevalence >20/100,000 should be tested and treated for LTBI. Prioritizing testing of subgroups within this foreign-born population may be necessary as an initial strategy in some settings. However, focusing exclusively on persons with co-morbidities is not likely to achieve elimination and unnecessarily complicates screening messages to providers. Supporting this statement, in California, only one third of TB cases have a co-morbid condition identified, leaving the majority without a factor that promotes disease progression. The World Health Organization defines medium TB prevalence as >20 cases/100,000 and high prevalence as >100cases/100,000. Countries within Africa, Asia/Pacific, Eastern Europe (including Russia), and Latin America (including Mexico) have moderate or high TB prevalence.
- **Use interferon-gamma release assays (IGRAs) for testing foreign-born (BCG-vaccinated) individuals.** Widespread adoption of IGRAs for the foreign-born population will avoid the false positive skin test results from BCG vaccination. Reducing false positives also reduces unneeded treatment of persons without true infection. In addition, blood tests have the added advantage of allowing for electronic laboratory reporting of results for surveillance purposes.
- **Reduce testing of low-risk populations.** To reduce false positive tests and treatment of persons without true infection, routine testing of low-risk persons should be minimized. Screening and testing guidelines should clearly outline who should be tested for LTBI. The use of a very simple risk assessment tool to support provider decisions about testing is needed. Complicated and tiered decision algorithms that create barriers for use should be avoided. Low-risk populations being routinely screened, such as health care workers, should be limited to testing those with new exposure risk.

3. Treatment

- **Maximize treatment initiation of LTBI and completion of treatment in highrisk populations that already undergo testing.** Higher completion rates for LTBI treatment are needed to provide benefit for both individuals and populations. Strategies to maximize the treatment of high-risk groups that are already being tested should be utilized. Specific populations routinely tested but with suboptimal treatment completion rates include contacts of TB patients, immigrants with B-notification (new arrivers with TB condition (B1, B2) flagged on U.S. entry), and status adjusters (immigrants applying for permanent U.S. residency).
- **Promote use of the shortest effective LTBI treatment regimens.** The length of LTBI treatment has been a major barrier to uptake of TB prevention by providers and patients. Clinicians need to become familiar with the 12 dose isoniazid-rifampentine and four-month rifampin regimens and use them routinely. Greater use of these regimens, which are shorter in length than therapy solely with isoniazid, will help to “normalize” LTBI treatment and integrate it into routine practice. Shorter regimens are also a key ingredient to maximize LTBI treatment completion rates.

- **Increase access to new innovative adherence technologies to enhance follow-up and treatment completion.** Innovative technologies, such as dose enhancing packaging, video directly observed therapy, cell phone text reminders, incentives, and other novel interventions should be made more accessible in order to facilitate treatment adherence. Robust evaluation of these new methods should be prioritized. Additionally, TB control and prevention leaders should take advantage of the lessons learned from treatment adherence advances now occurring in HIV and hepatitis C care.

4. Create partnerships and remove barriers

- **Implement prevention partnerships that encompass both public and non-public health providers.** To promote TB prevention among provider communities, TB disease and its prevention should be described as an issue that encompasses public and community health, not solely individual health. Strategies can be implemented to change current provider practices, making TB prevention routine. These could include leveraging existing systems by addressing TB risk in primary care assessments, developing tools and educational opportunities for providers, and engaging with medical specialty societies that care for patients who are at risk for reactivation (e.g., nephrology, transplant surgery). In addition, health departments need to coordinate with private provider partners to disseminate public health messages to increase awareness in at risk communities.
- **Motivate community providers who serve high-risk populations to make TB prevention routine in primary care.** Incentives should be offered to providers at each step of the TB prevention care cascade to ensure that at risk populations are tested and treated. Private providers should be engaged and motivated through diverse types of incentives. In the United Kingdom, providers receive financial incentives for each step of the TB prevention care cascade. Incentives must be accompanied with a clear message to providers focused on the imperative to test and treat for TB. Promoting development of a Health Plan and Employer Data Information Set (HEDIS) or similar indicator for LTBI screening can also ensure that appropriate LTBI testing would be accomplished, as was the case with chlamydia in 2000. The most feasible and effective incentives should be identified and pursued.
- **Remove existing financial barriers for TB prevention services for both patients and providers.** For patients, there should be no cost for TB prevention and care services. TB services should be provided at no cost to patients because of the community protection provided by individual treatment. To remove LTBI testing and treatment financial barriers (e.g., loss of revenue to capitated plans), partnership with key entities, including Covered California, the state health insurance marketplace, Medi-Cal Managed Care and other health insurance providers is required. To achieve TB elimination in California, coverage for all who need TB services must be ensured,

including undocumented persons.

5. Communication

- **Develop and implement a simple, clear TB prevention communication strategy.** A comprehensive TB prevention communication strategy for both providers and the wider community is needed and will be a critical component of any successful campaign for elimination in California. For providers, a strategy that promotes clear and simple guidelines for screening, testing, and treatment of LTBI should be implemented. For community members, the message should be that every person should know his/her TB risk and get tested if at risk. A comprehensive TB prevention communication strategy must also reach policymakers and funders. This public messaging, which will create demand for TB screening, should occur following provider education and capacity building so that providers are ready and clear about testing and treatment recommendations.

6. Reporting, Tracking, and Evaluation

- **Create systematic mechanisms for reporting LTBI and tracking populations through TB prevention steps.** To improve TB prevention and reach TB elimination, it is essential to track LTBI identification and treatment. A system must be developed for LTBI reporting that includes an electronic link to the laboratory report. To develop a surveillance system, individual TB contact reporting may be a place to start. It will be important to provide incentives to providers to ensure timely reporting. The IGRA blood tests allow for an automated electronic result and therefore facilitate the ease of electronic LTBI reporting. Interfaces with other communicable disease reporting mechanisms are needed. Possible use of the California Reportable Disease Information Exchange (CalREDIE) and the California Immunization Registry should be investigated. The system should place minimal burden on providers and health departments.
- **Create or modify existing systems for measuring, monitoring, and evaluating LTBI testing and treatment outcomes.** To assure that public health and community providers are reaching at risk populations and getting persons through LTBI treatment, systems need to be developed to measure progress and set clear benchmarks. Mechanisms to measure LTBI prevalence in key populations and measure performance at each prevention step of testing and treatment completion are needed. Systems for monitoring should build on existing electronic systems.

Areas of Discussion

A number of areas of the Task Force discussion require further consideration to plan implementation. These key issues are outlined below. The TB elimination action plan to be developed in the fall of 2015 should continue to review and address these issues. The purpose of the resulting TB elimination action plan will be to resolve questions, engage key stakeholders on feasibility, resources and strategy, and provide details on implementation of the recommendations.

As Task Force members deliberated on specific interventions, one area of discussion focused on whether the best approach to eliminate TB in California is a simple expansive and bold approach or one which implements smaller, stepwise elements. One line of thinking was that a serious elimination effort should be large and aggressive, rather than have options that chip away at morbidity reductions among small groups or with more minor interventions. Alternatively, there may not be a single unifying large scale intervention given currently available tools and the absence of a vaccine. Another common perspective favored staged elimination targets that highlight disparities across populations that have reached elimination versus those who have not.

Both large scale and smaller approaches require targets to be set to measure progress toward pre-elimination. A system could be developed to monitor progress and to trigger notification about locations and populations for whom pre-elimination benchmarks have been reached. The initial focus could be on halving cases, then addressing pre-elimination, followed by elimination. An advantage of an approach with successive and local measurements is that it provides opportunities for public health departments to identify and address population disparities throughout each stage of case decline.

Much discussion focused on who should be targeted for screening and testing. While the majority of Task Force members agreed that screening should be focused on foreign-born persons from moderate and high morbidity countries, and completion of treatment should be emphasized for these high-risk individuals, population subsets were identified as having priority for testing as well, such as those with co-morbidities and certain groups with specific types of visas. However, Task Force members ultimately concluded that the overarching need was a unified and simplified focus on testing all foreign-born, leaving room for public health departments to intensify focus on foreign-born subsets, as needed.

There was agreement that LTBI should become a monitored condition which is reported in some format, however there was extensive discussion on the mechanism for how to do so and what type of surveillance system should be used. There was agreement that a thoughtful strategic approach to reporting should minimize burden. Electronic reporting of laboratory results could help streamline a potentially cumbersome process.

Task Force members engaged in a lengthy discussion about the balance of toxicity and benefit of treatment for TB infection for individuals. Specifically, older persons who may be more likely to suffer adverse events associated with medications often have co-morbidities that pose increased progression risk for TB disease. At the same time, their advanced age reduces longer term benefit from TB prevention. To address this concern, the TB prevention strategy should state that the decision to test and treat for LTBI must routinely consider individual circumstances and that individualizing treatment decisions is especially important for elderly patients. Life expectancy and lifetime benefit yielded by LTBI treatment for individuals should be a consideration in the testing and treatment decision.

The U.S. Preventive Services Task Force (USPSTF) recommendations do not currently include a recommendation on LTBI testing and treatment in adults, although USPSTF recommendations for TB screening are expected in 2015. Task Force members acknowledged that this current gap leaves most clinicians without a clear directive, and, coupled with discomfort with TB regimens, leaves many

persons untested and untreated. TB control programs need to develop ways to promote acceptance and reduce fear regarding treatment among providers and patients. LTBI treatment with rifamycin-based regimens is not more toxic than many other U.S. Preventive Task Force A/B recommended treatments, such as statins for lowering blood cholesterol levels. This message should be an integral piece in the TB prevention communication strategy.

All Task Force members agreed that, to reach TB elimination, LTBI testing and treatment must be integrated into primary care in addition to intensifying capacity in local health departments able to service high-risk populations, including contacts and new immigrants. All providers need education and simple tools to appropriately assess risk, and test and treat individuals. Public health TB programs should be available to provide services to complex patients or provide assistance to providers when patients have complex circumstances.

Task Force members largely agreed that a national policy to legally require TB evaluation of immigrants and refugees with a B-notification upon arrival in the United States would enhance evaluation rates. Pre-immigration LTBI testing should also be considered. In addition, a large contingency felt new policies that require or incentivize testing of those with worker or student visas are also needed. It will be useful to further examine the numbers and risk of these groups and the impact on TB elimination progress.

Outstanding Questions

In addition to specific areas of discussion, questions arose during the Task Force meeting that merit further information gathering and analysis. A number of these are described below. Ongoing research will help inform implementation of the Task Force recommendations.

Among newly arriving migrants, which sub-populations justify the most focus? What are the annual population totals, distribution and access points for TB testing and treatment? What is the LTBI prevalence in each of the subpopulations? How do the dynamics at the U.S.-Mexico border impact the potential for TB elimination in California?

What is the best estimate for risk to progression in each population? How important is this number? Is it much lower than 5-10% lifetime risk?

Who are the major providers for persons from high-risk populations throughout the state? Which populations are not accessing a regular source of care prior to TB diagnosis? How many high-risk individuals are insured and uninsured? Where and when do the uninsured access TB care? How can their providers be engaged in prevention?

How can a systematic and efficient approach to TB prevention be developed across the complex health care provider types and payer sources within California? How can providers in the public and private sectors efficiently reach those at risk, and carry out testing and treatment with minimal attrition? How can treatment outcomes be maximized for those high-risk patients who are routinely

tested and likely to benefit from treatment, particularly those new arrivals with B-notifications, status adjusters, TB case contacts, and other high-risk groups?

How can birthplace/country of origin (foreign-born status) become an electronic medical record field throughout California medical settings to enable recognition of TB risk? How can the relatively few electronic medical record developers be motivated to include new data fields in their software products? How can birthplace also become an element in a monitoring system for TB prevention?

How can LTBI reporting effectively measure and track testing, treatment, and prevalence over time in different populations throughout California? How can LTBI reporting be accomplished without undue burden on providers and health departments? How can it provide a monitoring mechanism to ensure those at risk are diagnosed and successfully complete treatment? What is needed from a monitoring system? How can LTBI reporting become integrated within other systems so it is not a stand-alone system?

Can annual health care worker re-testing be halted in health care settings with low transmission risk? What TB test conversion data and healthcare worker data can inform this policy? How can California more closely adopt national guidance on healthcare worker testing?

Conclusion

The Task Force recommended multiple interventions that would enhance progress toward the goal of reaching TB elimination in California. These interventions were informed by evidence where it exists; however, some recommendations without definitive data were necessarily based on the expertise of the Task Force and conceived as pragmatic interventions.

Among the recommendations, there were several unifying messages that emerged from the meeting. First and foremost, to reach TB elimination in California, clear and simple messages for screening, testing and treating LTBI must be developed. Also important, a robust communication strategy must be implemented statewide to facilitate providers' use of new guidance and to communicate with populations at high-risk for LTBI.

New TB prevention guidance should provide clear information on who to screen and test for LTBI, and on the use of IGRAs for detection in BCG-vaccinated populations. Use of the short-course LTBI regimens, together with new technologies to enhance adherence, should be emphasized. Effective strategies to improve the public health sector's ability to partner with community providers should be developed and implemented. Scaled incentives should be provided to both providers and patients to ensure appropriate testing and treatment. Cost-sharing and other barriers for LTBI treatment must be removed so that all individuals, including the undocumented, have access to full care. Lastly, a reporting and monitoring system must be put in place that measures that individuals at risk are progressing through LTBI testing and treatment.

The initiative to eliminate TB in California will continue through the work of a stakeholder group that will tackle implementation questions related to the Task Force recommendations. This group

will be convened in December 2015 to deliberate over the actions and resources required for implementing each recommendation and to create a comprehensive action plan.

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