

Report of the California Tuberculosis Elimination Task Force Meeting

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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 (IGRA) for testing of the foreign-born with 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 below.

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 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?

<u>Group</u>	<u>Estimated number tested annually</u>	<u>TB risk</u>
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
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.

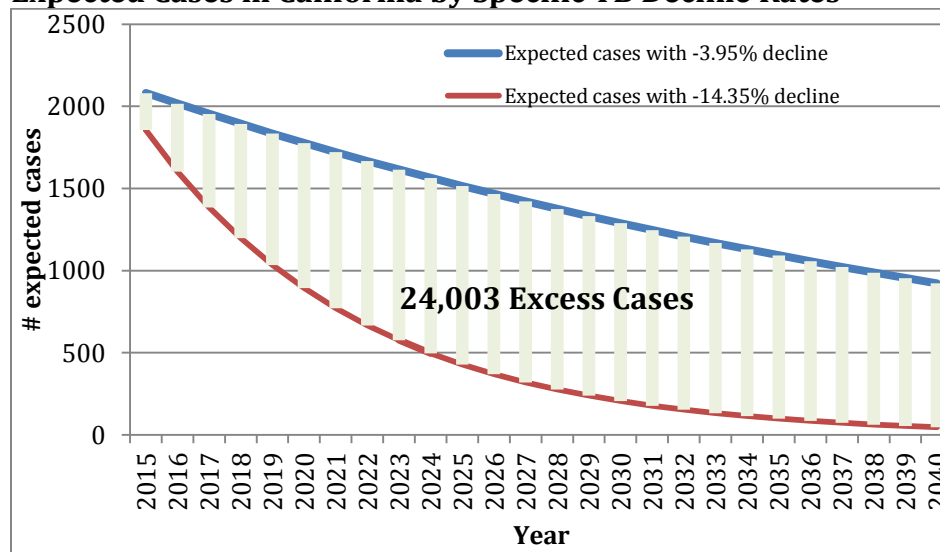
The Value of TB Elimination

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 Centers for Disease Control and Prevention (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/rifapentine (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 high-risk 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-rifapentine 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 modifying 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.

References

1. Mazurek GH, Jereb J, Vernon A, LoBue P, Goldberg S, Castro K; IGRA Expert Committee; Centers for Disease Control and Prevention (CDC). Updated guidelines for using Interferon Gamma Release Assays to detect Mycobacterium tuberculosis infection – United States, 2010. *MMWR Recomm Rep.* 2010 Jun 25;59(RR-5):1-25.
2. Oh P, Barry P, Flood J. Estimates of the proportion of active and latent tuberculosis borne by undocumented persons in California. 2013 Spring California Tuberculosis Controllers Association Meeting: San Jose, CA, USA: May 29, 2013.
3. Oh P, Pascopella L, Robsky K, Salcedo K, Benjamin R, Low J, Carson M, Moser K, Kawamura M, Grinsdale J, Higashi J, Flood J. Immigration visa status and identification of foreign-born tuberculosis cases in California. 43rd California Tuberculosis Controllers Association Educational Conference: San Francisco, CA, USA: April 30-May 1, 2009.
4. Balaban V, Marks SM, Etkind SC, Katz DJ, Higashi J, Flood J, Cronin A, Ho CS, Khan A, Chorba T. Tuberculosis Elimination Efforts in the United States in the Era of Insurance Expansion and the Affordable Care Act. *Public Health Rep.* 2015 Jul-Aug;130(4):349-54.
5. Oh P, Pascopella L, et al. Direct Costs of Treating and Managing Active Tuberculosis Disease in California, 2013. Submitted manuscript 2015.
6. Marks S, Cronin A, Lobue P. Centers for Disease Control and Prevention. *The Value of TB Elimination in the United States*. Publication in progress. 2015 Nov.
7. Shepardson D, Marks SM, Chesson H, Kerrigan A, Holland DP, Scott N, Tian X, Borisov AS, Shang N, Heilig CM, Sterling TR, Villarino ME, MacKenzie WR. Cost-effectiveness of a 12-dose regimen for treating latent tuberculous infection in the United States. *Int J Tuberc Lung Dis* 2013 Dec;17(12):1531-7
8. Holland DP, Sanders GD, Hamilton CD, Stout JE. Costs and Cost-effectiveness of four treatment regimens for latent tuberculosis infection. *Am J Respir Crit Care Med* 2009 Jun 1;179(11): 1055-60