

**OCCUPATIONAL SAFETY AND HEALTH
STANDARDS BOARD**

BOARD STAFF'S REVIEW OF THE PETITION

Petition File No. 563
Kenneth Cutler, MD, MPH



Submitted By: David Kernazitskas, MSPH, CIH, CSP

Title: Senior Safety Engineer

Date: June 26, 2017

Introduction

The Occupational Safety and Health Standards Board (Board) received a petition dated January 12, 2017, from Kenneth Cutler, MD, MPH, President of the California Conference of Local Health Officers (CCLHO) (Petitioner). The Petitioner requests that the Board amend Title 8 Section 5199 Aerosol Transmissible Diseases to allow Tuberculosis (TB) testing in health care facilities as determined by a risk assessment of the facility, instead of the current requirement to provide testing “at least annually to all employees in sites that are subject to the standard.”

Labor Code Section 142.2 permits interested persons to propose new or revised regulations concerning occupational safety and health and requires the Board to consider such proposals and to render its decision no later than six months following their receipt. In accordance with Board policy, the purpose of this evaluation is to provide the Board with relevant information upon which to base a reasonable decision.

History

Section 5199 Aerosol Transmissible Diseases was adopted by the Board in May 2009 with the intent of protecting employees from both existing and emerging infectious disease threats. The present petition is the first request received by the Board in relation to changing the frequency of required TB testing.

Reason Given for the Petition

The Petitioner requests that the Board change the requirement in Section 5199 for employers to provide annual TB tests to “all healthcare workers in California.” Instead, the Petitioner requests a provision where the necessary frequency of testing is “guided by an assessment of the exposure risk in an individual facility.”

The Petitioner refers to a Centers for Disease Control (CDC) document “Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Setting, 2005” as a basis for the recommendation. The Petitioner also insists that excessive testing of health care workers (HCW) can lead to negative health effects, which harm “is not offset by the benefit of treatment for true TB infection.”

National Consensus Standard

The CDC published the document “Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Setting, 2005” as an update to a 1994 version of the same document. According to the CDC,

The guidelines were issued in response to 1) a resurgence of tuberculosis (TB) disease that occurred in the United States in the mid-1980s and early 1990s, 2) the documentation of several high-profile health-care-associated (previously termed "nosocomial") outbreaks related to an increase in the prevalence of TB disease and human immunodeficiency virus (HIV) coinfection, 3) lapses in infection-control practices, 4) delays in the diagnosis and treatment of persons with infectious TB disease, and 5) the appearance and transmission of multidrug-resistant (MDR) TB strains.¹

The guidelines provide recommendations to health-care facilities for providing risk-based TB testing to employees. The updated recommendations reflect “shifts in the epidemiology of TB, advances in scientific understanding, and changes in health-care practice that have occurred in the United States during the preceding decade.” The document was developed to “maintain momentum and expertise needed to avert another TB resurgence and to eliminate the lingering threat to HCWs.”²

Federal OSHA Standards

Federal OSHA does not have a comprehensive regulation on aerosol transmissible diseases equivalent to Section 5199.

Division of Occupational Safety and Health (Division) Report

In its May 23, 2017 evaluation, the Division recommends that the Board deny the Petitioner’s requested change. The Division points out that “Section 5199 only requires [latent TB infection (LTBI)] testing of employees with occupational exposure to aerosol transmissible diseases and does not require testing of all employees in the health care industry.” The evaluation concludes saying that “Cal/OSHA believes that the existing regulation [Section 5199] provides sufficient flexibility to employees regarding participation in LTBI testing, maximizes the benefits to employees and the facility of periodic testing, and minimizes and potential negative impacts.”

¹ From the Summary section of the online version of “Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Setting, 2005.”

<https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm>

² Ibid.

Staff Evaluation

Board staff participated in a conference call with the Petitioner and other subject matter experts³ on June 12, 2017, to discuss the Petition. When staff asked the attendees about the annual TB testing requirements of other regulations (i.e. Title 22, etc.), they responded that Section 5199 is the most restrictive testing requirement for HCW. They pointed out that Title 22 provides the local health officer the flexibility to adjust the TB testing frequency according to risk-based strategies.

Board staff inquired about data suggesting that HCW have a higher rate of TB infection (6.4 cases / 100,000 population) than the rate in the general population in California (5.5 / 100,000). The group explained that the perceived increased rate is explained by the larger proportion of HCW that are foreign born when compared to the proportion in the general population. When controlling for foreign born versus US-born HCW, the TB rates are about the same, they said.

Five-Year Action Plan

In July, 2016, the University of California, San Francisco, the California Tuberculosis Controllers Association, and the California Department of Public Health (CDPH) published the “California Tuberculosis Elimination Plan 2016-2020: A Five-Year Action Plan.” The Executive Summary of the plan provides the following:

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.⁴

³ In addition to the Petitioner, the conference call was attended by: Julie Higashi, MD, PhD, Director, TB Control Program, Los Angeles County Department of Public Health; Robert Kim-Farley, MD, MPH, Director, Communicable Disease Control and Prevention, Los Angeles County Department of Public Health, and Chair, Communicable Disease Control and Prevention Committee;

Leah Northrop, MPA, MAIS, Executive Administrator, California Conference of Local Health Officers, California Department of Public Health;

Julie Vaishampayan, MD, MPH, Health Officer, Stanislaus County, and President, California Tuberculosis Controllers Association.

⁴ “California Tuberculosis Elimination Plan 2016-2020: A Five-Year Action Plan”, page 1. Available here: <https://archive.cdph.ca.gov/programs/tb/Documents/TBCB-TB-Elimination-Plan-2016-2020.pdf>.

The stated goal of the plan is to eliminate TB in California by the year 2040. “TB Elimination” is defined by the World Health Organization as less than one case of TB per one million population. According to its authors, California needs to have 39 or fewer TB cases per year to meet its goal. They point out that in 2015, more than 2,000 TB cases were reported in California.

The plan outlines several steps necessary to achieve its goal and requests an ongoing commitment of stakeholders statewide to be successful. In discussing the testing and treatment of LTBI, the document states, “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.”

The authors point out that “Among the 61 local health departments in California, just 21 reported 95% of all TB cases in California in 2010-2014.” In support of targeted testing, the second recommendation in the plan is to “Apply focused and effective strategies for TB testing in California.” The plan calls for efficient use of LTBI testing resources, stating:

*[C]urrent 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 Prevention⁵. (emphasis added)*

As one of its “action steps” to reduce TB testing in low risk populations, the plan says that “State and local mandates should be updated to be consistent with current epidemiology and tools.” Item four in the list states:

4. Bring the CalOSHA annual screening regulations for health care workers into alignment with federal guidance on preventing TB transmission in health care facilities⁶

2007 Position Letter from CDPH, Occupational Health Branch

A February 28, 2007, letter to Tony Paz, MD, President, California Tuberculosis Controllers Association (Attachment 1), served as one of the documents relied upon for the 2009 adoption of Section 5199, and mentioned in Section 6.0 of the Division evaluation. The letter was sent by the Occupational Health Branch of the CDPH (then

⁵ Ibid. Recommendation 2: Apply focuses and effective strategies for TB testing in California, page 28.

⁶ Ibid. Intervention 2C: Reduce testing in low risk populations, page 30.

the California Department of Health Services) and provided commentary regarding California's adoption of the 2005 CDC guidelines. At the time, CDPH recommended against adopting the CDC guidelines, preferring "that health care facilities in California continue to perform annual TB tests."

In a follow up email request for comment from CDPH on its current position regarding the 2007 letter, James Watt, MD, MPH, Chief, Division of Communicable Disease Control, Center for Infectious Disease, CDPH, stated the following:

Since 2007, the epidemiology of tuberculosis has changed and there are new technologies available for testing for tuberculosis infection. In addition, CDPH has analyzed current data on tuberculosis in health care workers to provide insight into the risk of nosocomial transmission. As a result, CDPH is in the process of developing a new position on tuberculosis testing in health care workers.

The 2007 letter that you reference below does not reflect the current assessment of this issue by CDPH.

Conclusion

In an effort to support the public health community's goal of eliminating TB infection in California, Board staff believes there is merit to further discussion on the issue of required annual TB testing for all HCW with occupational exposure.

Recommendation

Consistent with the foregoing discussion, Board staff believes the Petitioners' request should be granted to the extent that the Division be requested by the Board to convene an advisory committee discussing amendments to Section 5199 and "[Bringing] the CalOSHA annual screening regulations for health care workers into alignment with federal guidance on preventing TB transmission in health care facilities." The Petitioner and other subject matter experts should be extended an invitation to participate in the advisory committee deliberations.



California
Department of
Health Services

SANDRA SHEWRY
Director

State of California—Health and Human Services Agency
Department of Health Services



ARNOLD SCHWARZENEGGER
Governor

February 28, 2007

Tony Paz, MD
President, California Tuberculosis Controllers Association
American Lung Association of California
424 Pendleton Way
Oakland, CA 94621

Dear Dr. Paz:

The Occupational Health Branch (OHB) of the California Department of Health Services (CDHS) strives to improve worker health and safety through a program of public health activities including surveillance, worksite investigations, hazard evaluation, and development of policy recommendations. In October 2006, the CDC *Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Healthcare Settings, 2005* (CDC Guidelines) prompted the CDHS Tuberculosis Control Branch to request OHB to render a written opinion regarding reducing the frequency of tuberculosis (TB) tests in health care workers (HCWs). CDHS OHB recommends that health care facilities in California continue to perform annual TB tests. We further recommend that facilities that are considering reducing the frequency of TB testing perform both a community and an institutional risk assessment as described below, and obtain the approval of the local health officer as required by Title 22 of the California Code of Regulations (CCR).

Summary of CDC Guidelines

The CDC Guidelines recommend that each health-care setting conduct initial and ongoing (preferably annual) evaluations of the risk for transmission of *M. tuberculosis*. This includes reviewing the “community profile of TB disease in collaboration with the state or local health department” and consulting “the local or state TB-control program to obtain epidemiologic surveillance data necessary to conduct a TB risk assessment for the health-care setting.” This multi-step risk assessment is recommended to determine the types of administrative, environmental, and respiratory-protection controls needed for a health-care facility (page 9).

The CDC Guidelines define three risk classifications of health-care settings that guide TB testing frequency: low-risk, medium-risk, or potential ongoing transmission.

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Appendix C of the CDC Guidelines states that the classification of patient treatment facilities into low- and medium-risk categories is determined by the annual number of TB patients treated at the facility. CDC recommends that the classification of low-risk should be applied to settings in which a risk assessment has determined that HCWs will “never be exposed to persons with TB disease or to clinical specimens that might contain *M. tuberculosis*.” The classification of medium-risk is to be applied to settings in which the risk assessment has determined that HCWs may be exposed to “persons with TB disease or to clinical specimens that might contain *M. tuberculosis*.” CDC recommends baseline two-step tuberculin skin testing (TST) or blood assay for *M. tuberculosis* (BAMT) for all HCWs upon hire. However, annual testing with TST or BAMT is recommended only for medium-risk facilities. HCWs in low-risk facilities are not required to be in a serial testing program following baseline testing on initial hire. If there is evidence of ongoing transmission of TB, more frequent testing of HCWs is required, regardless of the setting.

Justification for OHB Recommendations

OHB considered the following criteria in formulating recommendations for frequency of TB testing in California HCWs:

1. California’s tuberculosis case incidence rate remains among the highest in the nation. The risk of TB transmission in California is high primarily because of its large immigrant and other high-risk populations. Cases are often misdiagnosed at the initial treating facility. This may result in erroneous classification of a health-care setting into a low-risk category, latent exposures of HCWs, and delayed case detection. The risk in HCWs is apparent; 83 (3%) of the state’s 2,903 TB cases reported in 2005 were health care workers. (Note that surveillance data don’t differentiate whether the infection was acquired occupationally or in the community.)
2. Less frequent testing of HCWs may result in delayed detection of TST and BAMT conversions if an exposure didn’t trigger a complete contact investigation. Delayed detection of conversions results in lost opportunities for timely and effective therapy to prevent active TB from developing. If less frequent testing results in delays in diagnosis of cases of active disease in health care workers, TB can spread in the facility and community.
3. The majority of health-care facilities in California (60%) have less than 200 beds. The CDC Guidelines require only three TB cases a year for these small facilities to be classified as medium-risk and to result in annual testing requirements (Appendix C). One missed TB case can result in a facility being incorrectly classified into a

4. low-risk category, potentially resulting in exposure and disease among multiple HCWs and patients.
5. Historical data show that populations served by a health-care facility vary with management changes. Given the frequent management shifts recently observed among California facilities, variations in the patient population may result in rapidly shifting TB risks which may not be reflected in the facility risk classification. Health care workers also may be employed by several facilities, not all of which may be "low risk."
6. Failure to conduct periodic TB testing in workers at a health-care setting classified as low-risk may give HCWs a false sense that the facility and its workers are not at risk for TB. Since the risk of TB is high throughout most of the state and since the risk may change depending on population and worker migration, HCWs should be aware that they may always be at risk of TB exposure.
7. Title 22 CCR gives the local health officer the ability to approve less than annual TB testing among HCWs in acute care hospitals. Specifically, Ch 1 §70723 (b) (3) states:

"Less frequent testing for tuberculosis, but never less than every four years, may be adopted as hospital policy when documented in writing as approved by the Infection Control Committee, the medical staff and the health officer of the health jurisdiction in which the facility is located."

Title 22 CCR also allows flexibility in TB testing frequency among HCWs who work in psychology clinics (Ch 7.2 §75335) and psychiatric health facilities (Ch 9 §77121).

The following types of health-care settings are required to perform annual TB testing of HCWs according to Title 22: acute psychiatric hospitals, skilled nursing facilities, intermediate care facilities, home health agencies, primary care clinics, intermediate care facilities for the developmentally disabled, chemical dependency recovery hospital, and correctional treatment centers.

Based on the above criteria, OHB recommends the following:

1. Health-care facilities should protect HCWs from work-related TB infections by: a) assessing the number of patients with TB treated annually at the facility, and b) assessing the TB incidence in the community annually. These two components of the TB risk assessment must be performed annually according to procedures outlined in the 2005 CDC Guidelines. Corrective actions suggested by the risk assessment should be implemented and documented. The assessment and corrective actions must be reviewed and approved by the local health officer.
2. HCWs are best protected by annual TB screening; this allows for early detection and treatment and results in decreased morbidity and improved prognosis in the event of disease.
3. Acute care hospitals that demonstrate both low TB risk at the facility and low incidence in the community and that wish to lengthen the interval of TB screening among HCWs must obtain the approval of the local health officer. The interval of TB screening should be no less frequent than every two years, so that conversions can be detected (defined as a change within 24 months from negative to positive test for latent TB infection).
4. Acute care hospitals that elect to perform HCW TB screening biannually should notify the California Department of Health Services, Licensing and Certification District Office in their jurisdiction of their decision process and document that the decision was made with the approval of the local health officer.
5. Psychology clinics and psychiatric health facilities that demonstrate both low TB risk at the facility and low incidence in the community and that wish to lengthen the interval of TB screening among HCWs, must obtain the approval of the local health officer. The interval of TB screening should be no less frequent than every two years. Facilities that elect to perform biannually HCW TB screening must inform the CDHS Licensing and Certification Program of their decision process and must document that the decision was made with the approval of the local health officer.
6. Health-care settings that are required by Title 22 CCR to perform annual TB testing of HCWs may not decrease testing frequency at this time.

In summary, to optimize early case detection and treatment outcome, OHB recommends annual TB screening of HCWs. Health-care facilities (acute care hospitals, psychology clinics, and psychiatric health facilities) that wish to perform less frequent screening must perform institutional and community risk assessments and must obtain the approval of the local health officer. These facilities must perform TB

Tony Paz, MD
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screening of HCWs at least every two years. Please contact Dr. Rupali Das at (510) 620-5763 if you have any questions.

Sincerely,

Rupali Das, MD, MPH
Public Health Medical Officer
Occupational Health Branch

Barbara Materna, PhD, CIH, Chief
Occupational Health Branch

cc: See next page

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