CDPH/CTCA Joint Guidelines

Guidelines for the Assessment of Tuberculosis Patient Infectiousness and Placement into High and Lower Risk Settings

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I. Preface

The following Guidelines have been developed by the California Department of Public Health (CDPH), Center for Infectious Diseases, Tuberculosis Control Branch (TBCB), and the California TB Controllers Association (CTCA). These Guidelines provide statewide recommendations for tuberculosis (TB) control in California. If these Guidelines are altered for local use, then the logo should be removed and adaptation from this source document acknowledged.

No set of guidelines can cover all individual situations that can and will arise. When questions arise on individual situations not covered by these guidelines, consult with your local TB Controller or the CDPH, TBCB. As mandated by state law (California Health and Safety Code, Section 121361), all decisions regarding the discharge or transfer of TB patients from health care facilities must be made by the local health officer (LHO) or designee of the jurisdiction in which the facility is located.

II. Background

One of the cornerstones of tuberculosis (TB) control is preventing TB transmission and the development of secondary TB cases. TB transmission has been documented in a variety of high risk settings, including health care facilities (HCFs), skilled nursing facilities (SNFs), correctional institutions, congregate living sites for HIV-infected persons, residential drug treatment facilities, and homeless shelters. This guideline was originally published in 1997 and was entitled *Guidelines for the Placement or Return of TB Patients into High Risk Housing, Work, Correctional or In-Patient Settings.*[1] The aim was to provide guidance for the safe placement of TB patients into high risk settings in California. The guideline underwent revision in 2009 following work that better defined characteristics associated with ongoing infectiousness after the initiation of appropriate anti-TB therapy[2-9] and following publication of updated guidelines from the Centers for Disease Control and Prevention (CDC). It was also expanded to include recommendations for the safe placement of TB patients into lower risk settings.

This current version reflects shifts in the epidemiology of TB in California and diagnostic advances. The guideline continues to be in accordance with recommendations made by the three most recent national guidelines published by the CDC addressing patient infectiousness- Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings (2005)[10], Prevention and Control of Tuberculosis in Correctional and Detention Facilities (2006)[11], and Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis (2005).[12]

Because of the robust data on the value of an induced specimen, we are recommending that at least one of the three specimens should be induced, if

sputum induction is available. To conform to the CDC recommendations, the number of days on anti-TB therapy for AFB sputum smear negative patients to be considered non-infectious is five days.

Although there is evidence that patients with multidrug-resistant TB (MDR TB) on effective treatment become non-contagious quickly,[13] because the transmission of MDR TB infection has more serious potential consequences for contacts, a more stringent set of criteria for release from isolation of these patients is warranted, and reflected in these guidelines.

The following guideline first defines risk-related and pertinent TB-related terms and outlines considerations for determining the risk of *Mycobacterium tuberculosis* (*M. tb*) transmission. The latter sections provide criteria for infectiousness and placement in high and low risk settings, criteria for discharge or transfer of TB cases and suspects from health care facilities, and considerations for home isolation. The document does not focus on the release of hospitalized patients from negative pressure isolation.

III. Objectives

These guidelines have been developed to reduce the risk of TB transmission by:

1. Defining uniform criteria for patient non-infectiousness which should be assessed before placing patients in settings in which the risk of transmission and/or secondary TB cases is high.
2. Defining uniform criteria for patient non-infectiousness for placement of patients in settings in which the risk of both transmission and secondary TB cases is lower.

IV. Risk Definitions: Settings, Disease Progression, and Drug Resistance

1. High risk setting[a]

a. A residential or work setting in which others will share air with the TB patient and which is characterized by one or more of the following factors:
   i. A large number or high density of persons.
   ii. Presence of persons at high risk of progression to active TB disease (see IV. 3. below).
   iii. The presence of persons who have not been previously exposed to the TB patient.

[a] Determination of risk should be done by the local TB control program

2. Lower risk setting[b]

All settings should be considered high risk until an assessment has been done by the local TB control program.

a. A residential setting not characterized as high risk, and:
   i. No other persons will share the air with the TB patient; OR
   ii. Other persons who will share the air with the TB patient are not at increased risk for progression to TB disease infected (see IV.3. below); OR
   iii. All persons at increased risk of progression to TB disease if infected, including all children under the age of five years, who will share the air with the TB patient have been previously exposed to the TB patient, have had a complete medical evaluation and have been started on therapy, including window period treatment for presumed LTBI (TB1),[12] as appropriate.

b. A work setting not characterized as high risk, and in which no contacts are known or reasonably expected to be at increased risk of progression to TB disease if infected.

3. Persons at increased risk of progression to TB disease if infected[12]

a. Children < 5 years of age.

b. Persons with medical conditions associated with an increased risk of progression to active TB disease, including:

   i. HIV infection (including persons at increased risk for HIV infection who have not been tested).
   ii. Diabetes mellitus, especially if insulin dependent or poorly controlled.
   iii. End-stage renal disease.
   iv. Injection drug use, if HIV status unknown.
   v. Cancer of the head and neck.
   vi. Immunosuppressive treatment, including chronic corticosteroids, anti TNF agents, post-transplant therapy and cancer chemotherapy.
   vii. Other diseases characterized by immunosuppression, such as lymphoma or leukemia.
   viii. Intestinal bypass or gastrectomy.
   ix. Low body weight (> 10% below ideal body weight).
   x. Chronic malabsorption.
   xi. Malnutrition and clinical situations associated with rapid weight loss.
   xii. Silicosis.

[b] Determination of risk should be done by the local TB control program

4. **Persons at increased risk of MDR TB**[14]

   a. Contact to an MDR TB case.

   b. Current TB treatment with evidence of treatment failure.

   c. Prior TB treatment since 1970 (Exception: relapse of disease following completion of adequate therapy by Directly Observed Therapy (DOT) for an episode of pan-susceptible disease).

   d. Immigration from or recent extended travel to a country with a high incidence (> 2%) of MDR TB among cases from that country diagnosed in California.[c] Data on MDR cases by country of origin is provided in the "Report on Tuberculosis in California".[d]

Persons at increased risk of MDR TB:

- Contact to an MDR TB case.
- Current TB treatment with evidence of treatment failure.
- Prior TB treatment, unless DOT.
- Immigration from, or recent extended travel to, a country with a high incidence of MDR TB.
- Other risk groups identified by the state or local health department.

V. Definition of Terms

1. **Acid Fast Bacilli (AFB) smear negative**: any respiratory specimen which is negative for AFB.[15]

2. **Acid Fast Bacilli (AFB) smear positive**: any respiratory specimen positive for AFB by microscopy. Because fluorescent (auramine-rhodamine [A-R]) staining is potentially prone to artifact, if an AFB smear is positive on A-R, it is strongly recommended to confirm with Ziehl-Neelson (Z-N) staining. Because infectiousness has been associated with degree of smear positivity, and persons who are A-R positive but Z-N negative have low

[c] Current data on the risk of MDR TB in US TB Cases, by Country of Origin, are available from the CDC, Division of TB Elimination (DTBE) (www.cdc.gov/tb)

[d] Current data on California epidemiologic groups at increased risk for MDR-TB are available from the CDPH, TBCB (510-620-3000) (www.cdph.ca.gov/Programs/CID/DCDC/Pages/TBCB.aspx)

numbers of AFB on smear, these persons can be considered smear negative for determining infectiousness.

3. **Direct genetic test for drug resistance:** direct test for mutations associated with isoniazid (INH) and/or rifamycin (RIF) resistance, for example, the gene pyrosequencing, or line probe assay. Cepheid Xpert ® MTB/RIF tests for RIF resistance only.

4. **Drug susceptibility test (DST)**: phenotypic drug susceptibility test in liquid or solid media.

5. **MDR TB**: confirmed TB disease resistant to INH and RIF based on the results of drug susceptibility testing (DST), or a direct genetic test (unless discordant with subsequent phenotypic DST).

6. **Nucleic acid amplification test (NAAT)**: a test that detects, via the amplification of specific nucleic acid sequences, the presence of *M. tuberculosis (M. tb)* complex in clinical specimens. Examples include MTD® (approved for smear positive and smear negative specimens), and Cepheid Xpert® MTB/RIF. Some labs use a homebrew PCR for *M. tb* complex identification.[36,41]

7. **Positive culture for *M. tb***: liquid or solid media with growth of AFB identified as *M. tb or M. tb complex,* except for *the BCG strain of Mycobacterium bovis.*

8. **Preliminary positive AFB culture**: liquid or solid media with growth of AFB, identification pending.

9. **Respiratory specimen**: sputum, induced sputum, broncho-alveolar lavage, biopsy of tissue from the respiratory tract (not including pleura).

10. **Sputum specimen**[e,16-23]: spontaneous or induced sputum specimen of at least 2 ml (not saliva). Some labs will not accept a specimen less than 5

[e] For patients, unable to produce a spontaneous specimen, sputum induction using hypertonic saline should be performed. Because AFB smear positivity is increased significantly by induction compared with simple expectoration, when available an induced specimen is preferred.25 If sputum induction is unsuccessful, an alternative method of sampling such as bronchoscopy should be considered if clinically warranted. Gastric aspirates can be useful for obtaining cultures, especially in children, but are prone to false positive smears due to acid fast stomach organisms. An induction attempt that does not yield an adequate specimen ("dry" induction) may be considered equivalent to an adequate specimen that is smear and culture negative at the discretion of the TB Controller.

ml. In some situations, even a scant specimen if it is true sputum should be processed.[24]

VI. General Considerations for Determining the Risk of TB Transmission and the Development of Secondary TB Cases

The following factors should be considered in determining the risk of, and consequences of transmission.

1. **The patient's infectiousness**[9,10,12,26] **positively correlates with the following factors:**

   a. Disease in the lungs, airways or larynx.

   b. Presence of cough

   c. Presence of a positive AFB smear in the sputum.[f]

   d. Extent of infiltration on chest radiograph.

   e. Cavitation on chest radiograph.

   f. Failure of the patient to cover the mouth and nose when coughing.

   g. Inappropriate or short duration of chemotherapy.

   h. Non-adherence to chemotherapy.

   i. Poor clinical or bacteriologic response to therapy.

For assessing patient infectiousness (except for MDR TB), sputum specimens may be collected ≥ 8 hours apart. At least one should be early AM, induced, collected by broncho- alveolar lavage, or collected post-bronchoscopy.

2. **The probability that exposed persons, if infected, will develop active disease** (See IV.3)

3. **The potential for transmission of *M. tb* in the environment** [27]

   a. Environmental factors which increase the risk of transmission include:

      i. Potential of others sharing air with the case (either in the same room or via the building ventilation system). Use of HEPA filtration or

[f] Transmission of TB by AFB smear-negative cases prior to treatment can occur and is well-documented. Consequently, in certain circumstances, the determination of infectiousness may require the application of more stringent criteria, specifically; consistently negative sputum cultures (at least two consecutive respiratory specimens).

ultraviolet germicidal irradiation (UVGI) may reduce the risk.[28-31]

ii. Poor supply of fresh air.[10]

iii. Larger number and higher density of persons in the setting.[27]

iv. Longer duration of time spent in the setting.

b. Transmission of *M.tb* has been documented in a variety of settings. At a minimum, the following types of settings, should be considered high risk:

i. Health care facilities[10]

ii. Correctional facilities[11]

iii. Drug treatment residential facilities[32]

iv. Other congregate living sites, especially sites housing persons at increased risk of progression to TB disease if infected (see IV.3), including homeless shelters [33], board and care facilities, and residential treatment facilities[34]

v. Public living accommodation, including single room occupancy hotels[35], if air is shared in common areas or through the building ventilation system.

4. Drug resistance of the patient's TB isolate

VII. Criteria for Evaluating Placement in High and Lower Risk Settings

1. The TB clinical and bacteriological status of the patient as well as the environment must be considered when evaluating the risk of transmission of TB to others

2. Results of nucleic acid amplification tests (NAAT) may be used in placement decisions; three specimens should always be collected for AFB smear and culture.

3. Suggested criteria to assist in the decision-making process are delineated in tables 1 and 2. Placement decisions are made at the discretion of the local TB Controller.

Table 1. Criteria for Evaluating Placement in a HIGH RISK SETTING[g]

Category	Lab Criteria[h,i]	Treatment Criteria[j]
TB suspected	AFB smear negative x 3 **OR** NAAT negative x 2[h] **OR** AFB smear positive **AND** NAAT negative x 2 (ideally done on the same specimens)[h]	No minimum number of days of TB treatment required
TB suspected or known • AFB smear negative **OR** NAAT negative x 2 (without smear results) **OR** AFB smear negative **AND** NAAT positive • No MDR TB risk factors	AFB smear negative x 3 Obtain direct genetic test, if available and not already done, for rifampin resistance	≥5 daily doses of appropriate TB treatment taken and tolerated **AND** Clinical improvement
TB suspected or known • AFB smear positive **AND** NAAT positive **OR** NAAT positive (without smear results) • No MDR TB risk factors	AFB smear negative x 3 Obtain direct genetic test, if available and not already done, for rifampin resistance	≥14 daily doses of appropriate treatment for TB, preferably by directly observed therapy (DOT), taken and tolerated **AND** Clinical improvement.
TB suspected or known At increased risk for MDR TB (see section IV.4)	Obtain direct genetic test, if available and not already done, for Rifampin resistance **OR** If direct genetic test unavailable, while phenotypic DST for rifampin is pending, either criteria for patients with known MDR TB or criteria for patients not at increased risk of MDR TB may be applied, at the discretion of the local TB controller.	≥14 daily doses of appropriate treatment for TB, preferably by directly observed therapy (DOT), taken and tolerated **AND** Clinical improvement

Table 1 (cont)

Known MDR TB case (see section IV.4)	AFB smear negative x 3 **AND** At least 2 consecutive negative sputum cultures without a subsequent positive culture **OR** If subsequent AFB smear positive after 3 negative AFB smears, a clinical assessment has been performed and determined to most likely not represent viable *M. tb.*	≥14 daily doses of appropriate treatment for TB, preferably by directly observed therapy (DOT), taken and tolerated **AND** Clinical improvement

[g] See risk definitions in section IV.

[h] Three consecutive respiratory specimens, including at least one early AM or induced sputum, or broncho-alveolar lavage (BAL), collected at least 8 hours apart. If available, induced sputum is preferred. If bronchoscopy is done, a post-bronchoscopic sputum specimen obtained at least 8 hours post-bronchoscopy should be included as one of the 3 specimens. The quality of sputum smear must be verified before smear negative status is confirmed, especially if cavitary disease is present. A concentrated specimen with fluorescent microscopy is preferred.

[i] If using a NAAT other than Xpert, the NAAT should be assessed for inhibitors on a positive AFB smear and negative NAAT. Ideally NAAT should be performed on a smear positive specimen if available.

[j] For definition of "appropriate" treatment refer to the most recent CDC TB treatment guidelines.

Table 2. Criteria for Evaluating Placement in a LOWER RISK SETTING[k]

Category	Lab Criteria[l,m]	Treatment Criteria[n]
TB suspected	AFB smear negative x 3 **OR** NAAT negative x 2 [l] **OR** AFB smear positive and NAAT negative x 2 (ideally done on the same specimens) [l]	No minimum number of days of TB treatment required
TB suspected or known • AFB smear negative **OR** NAAT negative x 2 (without smear results) **OR** AFB smear negative **AND** NAAT positive • No MDR TB risk factors	AFB smear negative x 3	At least one dose of appropriate TB treatment taken and tolerated
TB suspected or known • NAAT positive (without smear results) **OR** AFB smear positive **AND** NAAT positive • No MDR TB risk factors	Bacteriologic response to therapy (progressively decreasing degree of smear positivity)	≥14 daily doses of appropriate treatment for TB, preferably by directly observed therapy (DOT), taken and tolerated **AND** clinical improvement
TB suspected or known At increased risk for MDR TB (see section IV.4)	Obtain direct genetic test, if available for rifampin resistance **OR** If direct genetic test not available, while phenotypic DST for rifampin is pending, either criteria for patients with known MDR TB or criteria for patients not at increased risk of MDR TB may be applied, at the discretion of the local TB controller.	≥14 daily doses of appropriate treatment for TB, preferably by directly observed therapy (DOT), taken and tolerated **AND** clinical improvement
Known MDR TB case (see section IV.4)	AFB smear negative x 3	≥14 daily doses of appropriate treatment for TB, preferably by directly observed therapy (DOT), taken and tolerated **AND** clinical improvement

[k] See risk definitions in section IV. Three consecutive respiratory specimens, including at least one early AM or induced sputum, or broncho-alveolar lavage (BAL), collected at

least 8 hours apart.

[l] If available, induced sputum is preferred. If bronchoscopy is done, a post-bronchoscopic sputum specimen obtained at least 8 hours post-bronchoscopy should be included as one of the 3 specimens. The quality of sputum smear must be verified before smear negative status is confirmed, especially if cavitary disease is present. A concentrated specimen with fluorescent microscopy is preferred.

[m] If using a NAAT other than Xpert, the NAAT should be assessed for inhibitors on a positive AFB smear and negative NAAT. Ideally NAAT should be performed on a smear positive specimen if available.

[n] For definition of "appropriate" treatment refer to the most recent CDC TB treatment guidelines.

VIII. Discharge or Transfer of Patients with Suspected or Known TB from Health Care Facilities

California Health and Safety Code (HSC), Section 121361, requires that a health facility shall discharge or transfer a person known or suspected to have active TB disease *only after notification and a written treatment plan is received and approved* by the local health officer (LHO) of the jurisdiction in which the health facility is located. This authority is often delegated by the LHO to the local TB Controller.

1. The written treatment plan shall include the following elements (HSC Section 121362):
    a. Verified patient address (or address of the receiving facility);
    b. Name and contact information of the medical provider who has specifically agreed to provide medical care;
    c. Clinical information used to assess the patient's infectiousness; and
    d. "Any other information required" by the LHO.
2. When reviewing the written treatment plan, the LHO or designee should take into consideration risk factors for MDR TB, infectiousness of the patient, and the type of setting the patient is entering or returning to using the criteria in section VII to guide decision-making. In addition, before a discharge or transfer can be approved:
    a. Arrangements should be in place for continuation without interruption of an appropriate, prescribed course of TB medication, preferably by DOT;
    b. For patients returning home, a home evaluation, including an in-person home visit, should be completed by the local TB program and documented. All contacts at increased risk of progression to TB disease, if infected (see IV.3.), should be

medically evaluated for TB and started on appropriate therapy, including window period treatment for presumed LTBI (TB1).[12] The patient or guardian must agree to abide by home isolation instructions (see section IX.);

c. The patient's ability to ambulate and perform all activities of daily living should be appropriate for the discharge setting;

d. Special medical needs (e.g., hemodialysis, cancer treatment), transportation to source of medical care, cooking, shopping, laundry and other issues that might present barriers to adherence with home isolation, or risk of transmission of TB to previously unexposed persons, especially new contacts at increased risk for progression to TB disease if infected (see IV.3.), should be addressed.

IX. Home Isolation

Prior to meeting the criteria for placement as outlined in the above tables. TB patients may be placed in *home isolation*. To be placed in home isolation the following criteria should be met:

1. The patient should have been started on a standard multidrug anti-TB treatment regimen;

2. No infants, children <5 years, or persons with HIV or other severely immunocompromising conditions live in the household OR if present, they are on appropriate LTBI treatment or window period treatment for presumed LTBI;

3. All immunocompetent household members have been previously exposed to the patient; and

4. The patient is willing to follow the restrictions imposed by the local TB control program.

Parameters for home isolation need to be clarified with the patient and other residents. This should include conditions for entry of persons into the environment, circumstances where the patient may leave the residence, and precautions within the residence (separate room, etc.). Special precautions for attendance at medical appointments should be clarified with the provider seeing the patient and the patient. Patients in home isolation may not work until they meet the criteria appropriate for their work setting. Patients who do not adhere with the conditions of home isolation may be served a public health legal order to remain in home isolation (HSC Section 121365[g]) and may be prosecuted if they violate such an order (HSC Section 120280).

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X. Acknowledgements

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