CONNECTICUT
PUBLIC HEALTH

STANDARDS OF CARE FOR PATIENTS WITH SUSPECTED AND CONFIRMED TUBERCULOSIS IN CONNECTICUT

Connecticut Department of Public Health
Tuberculosis Control Program
Hartford, Connecticut
July 2024

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ACRONYMS

AFB	Acid-fast bacilli
ATS	American Thoracic Society
AII	Airborne infection isolation
CBC	Complete blood count
CDC	Centers for Disease Control and Prevention
DOT	Directly observed therapy
DPH	Connecticut Department of Public Health
eDOT	Electronic directly observed therapy
HIPAA	Health Insurance Portability and Accountability Act
HIV	Human immunodeficiency virus
IGRA	Interferon gamma release assay
LHD	Local health department or district
LTBI	Latent TB infection
MDR TB	Multidrug-resistant TB
NAA	Nucleic acid amplification
RIPE	Rifampin, isoniazid, pyrazinamide, ethambutol
RIR	Respiratory isolation restrictions
SOC	Standards of Care
SPHL	Connecticut State Public Health Laboratory
TB	Tuberculosis
TST	Tuberculin skin test
XDR TB	Extensively drug resistant TB

INTRODUCTION

In 2008, the Connecticut Department of Public Health (DPH) Tuberculosis (TB) Control Program (DPH TB Control Program) in collaboration with the Connecticut Advisory Committee for the Elimination of Tuberculosis (CACET) first developed and adopted standards of care (SOC) for patients suspected of and subsequently diagnosed with drug-susceptible TB in Connecticut. These SOC have since been updated periodically based on national standards developed by the Centers for Disease Control and Prevention (CDC) and its partner organizations and advisory groups[1–6], in collaboration with local and state public health officials.[7–8] These Connecticut SOC are intended to provide guidance for clinicians, hospitals, local health departments and districts (LHDs), and state TB control and state regulatory officials.

This 2024 SOC is presented in two Sections. *Section I* presents a summary of responsibilities that DPH TB Control Program, Providers, and LHDs hold for the evaluation, diagnosis, and treatment of TB and LBTI. *Section II* presents numbered Standards of Care concerning diagnosis, treatment, and infection control for TB.

SECTION I. RESPONSIBILITIES FOR TB PREVENTION AND CONTROL

A. DPH TB Control Program Responsibilities

- Provide medical consultation about TB disease and latent TB infection (LTBI).
- Facilitate QuantiFERON testing, acid fast bacillus (AFB) smear, nucleic acid amplification (NAA), culture, and drug susceptibility testing at no cost at the Connecticut State Public Health Laboratory (SPHL).
- Provide guidance and technical assistance to LHDs with a focus on the identification and evaluation of contacts of patients with pulmonary TB.
- Provide reimbursement opportunity for eligible TB-related diagnostic tests, medical visits, and treatment including directly observed therapy (DOT) or electronic DOT (eDOT) for patients with TB disease and LTBI who are uninsured or underinsured and do not qualify for other programs (e.g., TB Medicaid Program).
- Provide resource materials and educational opportunities about TB disease and LTBI.
- Receive TB surveillance and follow-up care reports; maintain surveillance databases for TB disease and LTBI.

B. Provider Responsibilities

- Providers and laboratories are required to notify the DPH TB Control Program and LHD immediately by phone, followed by a written report within 12 hours when TB disease is strongly suspected in a patient, usually when treatment is initiated or when there is radiologic or microbiologic evidence of TB disease.[9]
- Clinical management of a patient with TB includes monitoring treatment through to completion. The provider initiating treatment for TB assumes this responsibility unless clinical management has been formally transferred to another provider.

B. Provider Responsibilities *(continued)*

- Additional notification to the DPH TB Control Program is required immediately if:
  - therapy is stopped for medical or any other reason,
  - patient is not adherent to treatment or appointments,
  - patient is lost to follow-up,
  - patient has persistently positive acid-fast bacilli (AFB) culture results after two months of treatment, or
  - patient moves to another jurisdiction.
- Providers who care for persons at risk for TB should maintain proficiency in the diagnosis and treatment of TB. They should confer with the DPH TB Control Program regarding treatment whenever needed.
- Providers should offer opt-out human immunodeficiency virus (HIV) testing to all patients with TB disease and LTBI.
- Providers should also offer Hepatitis B and C testing for patients, especially those at increased risk for these infections.
- Diabetes screening (e.g., fasting glucose or Hgb A1C) is highly encouraged, especially for patients at risk.

1. TB Diagnosis
   - A negative tuberculin skin test (TST) or interferon gamma release assay (IGRA) result should not be used to eliminate the possibility of active TB disease.[1]
   - Most patients being evaluated for pulmonary TB disease usually only need a chest radiograph to make a presumptive diagnosis of TB and for monitoring response to treatment. A computerized tomography of the chest can be ordered for patients in whom other diagnoses are being considered.
   - At least three sputum specimens (spontaneous or induced, preferably one early morning specimen) at least eight hours apart should be submitted from patients with suspected pulmonary TB for AFB sputum-smear and mycobacterial culture. Ideally, two of these specimens should be submitted for NAA testing.
   - Specimens other than sputum should be considered only if sputum cannot be obtained.
   - A negative NAA test should not be considered as definitive evidence against TB disease in a patient with TB symptoms.
   - An HIV test should be performed for all TB patients.
   - The diagnosis of culture-negative TB or intra-thoracic TB in children and adults is usually a clinical diagnosis.
2. TB Treatment and Discharge Plans
   - For most patients with a definite or presumptive diagnosis of TB, four antituberculosis drugs, isoniazid, rifampin, pyrazinamide, and ethambutol (RIPE) should be started after specimens are collected for microbiologic examination but before cultures are finalized unless resistance is suspected. If resistance is suspected, the DPH TB Control Program should be consulted for treatment recommendations.
   - All persons with TB must have a treatment plan approved by the local health director in the patient's town of residence, as required by state law.[7] For hospitalized patients, this plan must be made and approved before discharge from the hospital. Clinicians should initiate coordination of the discharge process with the LHD as early as possible during the patient's hospitalization to facilitate timely discharge.

B. Provider Responsibilities *(continued)*

2. TB Treatment and Discharge Plans *(continued)*

- The plan must include treatment by DOT, performed in-person or using real-time eDOT applications.
- Patients should be actively monitored for adherence and adverse events related to treatment with a minimum of a monthly office visit until therapy is completed. Adherence monitoring should include notation of cumulative and interval counts of the number of doses received by DOT or eDOT.
- Consultation with an expert is highly recommended for all patients co-infected with HIV and patients with drug resistant TB. Medical consultation is available through the DPH TB Control Program or the Rutgers Global Tuberculosis Institute.

3. TB Infection Control

- Most TB patients do not need to be hospitalized and can be safely maintained in Respiratory Isolation Restrictions (RIR) at home. Home RIR should be considered for individual patients in consultation with the LHD responsible for the patient.
- AFB smear status alone should NOT be used to determine the length of RIR for patients in the community.
- Patients with confirmed or suspected drug susceptible TB who reside in community settings and are not hospitalized can be released from RIR back to routine activities when the following criteria have been met:
  - the patient has been on five days of appropriate antituberculosis treatment, and
  - tolerance to antituberculosis drugs has been demonstrated, and
  - the patient has demonstrated adherence to the medication regimen.
- **Individual patient circumstances may dictate longer periods of RIR.**
- Patients with confirmed or suspected TB in inpatient settings should be isolated in an AII (airborne infection isolation, e.g., negative pressure) room **while they require ongoing hospitalization** until they:
  - have three consecutive negative AFB sputum smear results, each collected in 8 to 24-hour intervals, with at least one being an early morning specimen, and
  - have received standard multidrug antituberculosis treatment (minimum of two weeks) and
  - have demonstrated clinical improvement.
- It is imperative that discussions regarding discharge from the hospital are initiated as early as possible with the LHD where the patient resides so that **medically stable patients can be transitioned to an appropriate community setting as soon as possible.**

C. LHD Responsibilities for TB Patient Case Management

- LHDs retain the authority and responsibility for the case management of all TB disease patients in their jurisdiction, regardless of provider type or site of disease.[8]
- TB case management includes the following minimum activities:
  - Review TB Surveillance Report and interview all new patients regardless of site of disease in a timely manner (usually within three working days).

C. LHD Responsibilities for TB Patient Case Management *(continued)*

- TB case management includes the following minimum activities *(continued)*:
  - Approve appropriate discharge plans for hospitalized patients and treatment plans for non-hospitalized patients.
  - Ensure timely and thorough contact investigations are performed for infectious TB patients.
  - Ensure medical treatment, follow-up, and adherence, including DOT and eDOT.
  - Regularly monitor changes and updates to patient treatment plans.
  - Follow patients until TB treatment is completed.

SECTION II. STANDARDS OF CARE FOR TB DISEASE

1. Standards for Providers

Standard 1.1 Reporting to the DPH TB Control Program and the LHD

A case of TB disease, regardless of anatomic site, is a reportable condition to DPH.[7] All providers and laboratories must immediately report patients having suspected or confirmed TB disease by telephone to the DPH TB Control Program (860-509-7722) followed by a written report within 12 hours of suspicion of disease. Cases should also be reported to the LHD where the patient resides. Case should be reported, even if definitive culture results are not known, if there is microbiologic (e.g., positive AFB smears, positive NAA) or radiologic evidence of TB. Cases should be reported by completing all pages of the Tuberculosis Surveillance Report Form.

Standard 1.2 Assumption of Care and Appropriate Monitoring of Patients

Any healthcare provider treating a patient for TB assumes an important public health responsibility. To fulfill this responsibility, the provider must be capable of providing care through the completion of treatment. This includes seeing patients at least monthly and sending the Tuberculosis Treatment and Follow-up Care Report Form to both DPH and the LHD. If a provider is unable to do this for the full course of treatment, they should facilitate and formally transfer care of the patient to another provider.

No patient may be denied care because of their inability to pay for their TB care.[10] Providers should refer to the CT DPH TB website for information on how to obtain medications for patients or for reimbursement procedures for TB-related services.

Patients have a legal right to be provided with medical interpretation. Providers must ensure certified medical interpretation services are available if the preferred language of the patient is a language other than the provider speaks.

- The minimum recommended schedule for medical follow-up is as follows:
  - After the initial appointment, patients should have clinical evaluations by the provider at least monthly. Consider a visit two weeks after the initial visit for patients with extensive or severe disease and those with TB disease resistant to rifampin.
  - The Tuberculosis Treatment and Follow-Up Care Report should be completed monthly and sent to DPH.

1. Standards for Providers *(continued)*

Standard 1.2 Assumption of Care and Appropriate Monitoring of Patients *(continued)*

- If the patient is still an inpatient at one month after starting therapy, consider further evaluation that includes a chest radiograph if one has not been done since admission as well as checking sensitivities if that hasn't been done.
- For patients with pulmonary disease, sputum samples should be obtained for AFB smear and culture at least monthly after initiation (day 1) of treatment (a minimum of two specimens within the first 60 days of treatment, including a sample at around days 55–59) to document culture conversion (two negative sputum cultures for AFB). Duration of treatment may change if a patient remains culture positive two months after treatment initiation.
- Routine measurements of hepatic and renal function and CBC are not necessary during treatment unless patients have baseline abnormalities or are at increased risk of hepatotoxicity or other side effects (e.g., hepatitis B or C virus infection, excessive alcohol use).

- Patients taking ethambutol should be questioned regarding possible visual disturbances including blurred vision or scotoma at baseline and at each monthly visit. Baseline and monthly visual acuity (Snellen test) and color discrimination tests should be performed. Patients with abnormal findings should be referred to an ophthalmologist.
- Providers are responsible for notifying LHD by phone in a timely manner when changes have been made to the patient's medication regimen as well as by faxing the Tuberculosis Treatment and Follow-Up Care Report to the LHD.
- Follow up chest radiographs should be obtained at two months to help assess response to treatment and at end of treatment as a baseline.
- Patients with persistently positive AFB culture results after two months of medications, with or without symptoms, should be evaluated carefully to identify the cause of the delayed response in consultation with the DPH TB Control Program. Patients who have positive cultures after four months of treatment are considered treatment failures and should have therapy modified in consultation with an expert.
- Additional notification to the DPH TB Control Program and the LHD is required when:
  - therapy is stopped for medical or any other reason,
  - a patient is nonadherent to treatment or appointments,
  - a patient is lost to follow-up,
  - the patient has persistently positive AFB culture results after two months of treatment, or
  - the patient moves to a new jurisdiction.

Standard 1.3 Maintain Proficiency in TB Diagnosis and Treatment

It is expected that healthcare providers who care for patients at risk for TB disease maintain proficiency in the diagnosis and treatment of TB. Opportunities for TB education are available both through webinars and in person trainings throughout the year in the region through a variety of resources.[11]

Medical consultation is available through DPH or the Regional Training and Medical Consultation Center at the Rutgers Global TB Institute. Providers are highly encouraged to seek consultation whenever needed, especially at the beginning of treatment.

1. Standards for Providers *(continued)*

Standard 1.3 Maintain Proficiency in TB Diagnosis and Treatment *(continued)*

Consultation with DPH should be actively sought for all the following situations: HIV coinfection, drug resistance, children ≤5 years old, and pregnancy.

Standard 1.4 HIV Testing

Given the strong interaction between TB and HIV and the importance and impact that HIV infection and treatment has on TB, all patients with TB disease, regardless of age, should be routinely tested for HIV infection.[12, 13] It is also recommended that all patients with LTBI receive HIV testing. Since July 2011, general consent for medical procedures is sufficient for HIV testing and there is no requirement to sign a specific consent form for HIV testing.[14]

Standard 1.5 Hepatitis and Diabetes Testing

Many TB patients are also at risk for hepatitis; in addition, the medications used to treat TB can be hepatotoxic. It is recommended that patients be offered testing for Hepatitis B and C (e.g., Hepatitis B surface antigen, Hepatitis B core IgM antibody, and Hepatitis C antibody) when appropriate, and especially when risk factors are present. Consideration should be given to testing at risk individuals for past hepatitis B infection (e.g., Hepatitis B surface antibody and core IgG) and vaccinating patients for hepatitis B when appropriate.

In addition, diabetes is an important co-morbidity that can impact TB patients' treatment. Screening for diabetes (fasting glucose or hemoglobin A1c) should be performed for: patients over the age of 35, patients with pre-diabetes, patients with a history of gestational diabetes, and overweight or obese adults with risk factors (e.g., first-degree relative with diabetes, high risk race/ethnicity, history of cardiovascular disease, hypertension, low HDL or high triglycerides, history of polycystic ovary syndrome, physical inactivity, or condition associated with insulin resistance such as acanthosis nigricans).[1,15]

2. Standards for TB Diagnosis

Standard 2.1 "Think TB"

All persons with otherwise unexplained productive cough lasting three weeks or more or other signs and symptoms suggestive of TB should be evaluated for TB, especially those with a TB risk factor. TB risk factors may be found in the Connecticut TB Risk Assessment and User Guide.

Standard 2.2 Chest Radiography

Chest radiography is the initial imaging modality of choice for evaluating a patient with suspected pulmonary TB. Computerized tomography is usually not required for diagnosis but might be done if other conditions are being considered in the differential diagnosis (e.g., cancer).

Standard 2.3 Collection of Specimens and Microbiologic Testing

All persons with chest radiographic findings suggestive of TB disease should have three sputum specimens submitted for microbiological examination, ideally, before therapy is started. This includes AFB smear, NAA testing (at least two), and culture. Adults and children suspected of having pulmonary TB who are capable of producing sputum should have sputum specimens collected 8–24 hours apart. At least one early morning specimen should be obtained.

2. Standards for TB Diagnosis *(continued)*

Standard 2.3 Collection of Specimens and Microbiologic Testing *(continued)*

In patients who are not producing sputum spontaneously, induction of sputum using aerosolized hypertonic saline should be attempted in an AII setting, if possible, and any specimen resulting from an induction should be sent for AFB smear, NAA, and culture; such specimens should be labeled "induced sputum". Sputum induction can almost always yield a specimen; even if specimens appear watery, they should be submitted for testing. DPH and LHDs can assist in the collection of induced sputum for non-hospitalized patients. Directions and guidance for the collection of induced sputum are available.[16]

In the rare event that sputum induction is unsuccessful, bronchoscopy should be considered for adults and adolescents. Sputum collection should be considered after a bronchoscopy procedure. One bronchoscopy specimen can usually be substituted for one of three sputum specimens in the assessment of a patient.

Children who cannot produce sputum should have three gastric aspirates performed for culture and drug susceptibility testing.

Treatment for persons suspected of having TB disease should be continued until AFB cultures are finalized (six to eight weeks after collection). Even if cultures are negative, some patients might be treated for culture-negative pulmonary TB (see Standard 3.6).

Standard 2.4 Nucleic Acid Amplification (NAA) Testing

NAA testing is recommended for all patients with suspicion of TB. NAA testing should be performed on two sputum specimens for a patient as part of the initial diagnostic evaluation.[4] An NAA positive result on an AFB positive sputum smear is presumed TB unless proven otherwise. A negative NAA result on an AFB negative sputum smear should not be used to rule out TB disease in a patient with TB symptoms. NAA positive specimens that did not include rapid molecular drug susceptibility testing for rifampin with or without isoniazid should be referred for NAA testing that includes rapid molecular drug susceptibility testing.[4]

NAA testing that can detect rifampin resistance is available through the SPHL should not be used to monitor response to treatment in TB patients. [16–18]

Patients with **two** sputum specimens with negative NAA testing performed *might* be able to be released from AII if suspicion for TB disease is low.[16]

Standard 2.5 TST/IGRA Testing

A tuberculin skin test (TST) or interferon gamma release assay (IGRA) is not a necessary test to diagnose TB disease. A negative TST or IGRA should never be used to rule out TB disease in a patient with clinical signs and symptoms of TB.[1]

Standard 2.6 HIV Testing

All patients with suspected or confirmed TB disease, regardless of age or site of disease, should be tested for HIV. [13] Testing should ideally be opt-out testing. Informed consent is not required for HIV testing in Connecticut. [14]

2. Standards for TB Diagnosis *(continued)*

Standard 2.7 Radiographic Findings of Previous TB Disease

Patients with parenchymal or fibrotic lesions should not be classified as "old" healed TB based on a single imaging study of the lungs. Either a negative full diagnostic evaluation including sputum cultures, or two stable chest radiographs taken at least six months apart in the absence of symptoms are needed.

Patients for whom the clinician has a high suspicion of TB disease, especially those with abnormal chest radiographs, should undergo evaluation as detailed in Standards 2.3 and 2.4. Appropriate treatment should be started and continued until cultures are finalized. Some patients with negative cultures might be treated for culture-negative TB (see Standard 3.6).[1]

Standard 2.8 TB in Children[19]

The diagnosis of pulmonary or intrathoracic (e.g., adenopathy) TB in children with negative sputum smears should be based on the finding of chest radiographic abnormalities consistent with TB and a risk factor for exposure to TB (e.g., a history of exposure to an infectious patient, previous residence and/or travel to a high TB incidence country, or evidence of LTBI (e.g., positive TST or IGRA result). For such patients, obtain specimens by gastric washings or sputum induction for culture and drug susceptibility testing.

3. Standards for TB Treatment

Standard 3.1 Treatment Regimen

All patients (including those with HIV infection) who have not been treated previously should receive a nationally recommended first-line treatment regimen using DOT. [1] If no concerns for drug resistance, the intensive treatment phase (first eight weeks) should start with daily (five to seven days per week) RIPE, along with pyridoxine (vitamin B6). Dosages of medications are based on CDC recommendations; adults and children weighing more than 40 kg should be given the standard dosages of medications.[1]

- Once sensitivities are known, ethambutol can be stopped if the organism is found to be susceptible to isoniazid, rifampin, and pyrazinamide. For drug susceptible TB, these three drugs are continued for a total intensive phase of eight weeks. Regimens should be given daily (five to seven days per week) whenever possible; intermittent treatment three times a week with DOT should be reserved for situations where daily DOT cannot be done.
- The continuation phase (four months for most patients) consists of isoniazid and rifampin given daily or intermittently (three times a week), with a preference for daily treatment, until a total of six months of therapy is achieved or longer if there have been interruptions in treatment.
- For patients with pulmonary cavitary lesions on chest radiograph and positive culture results at two months of treatment (including a sputum obtained at about days 55–59), the continuation phase with isoniazid and rifampin should be extended for an additional three months (i.e., a continuation phase of seven months duration, total of nine months of therapy).[1] For patients whose initial treatment phase did not include pyrazinamide, the continuation phase should be extended by three months for a total of nine months of therapy. [1]

3. Standards for TB Treatment *(continued)*

Standard 3.1 Treatment Regimen *(continued)*

- Additional factors to be considered in deciding to prolong treatment in patients with either cavitation or positive culture at two months (but not both) might include: being >10% below ideal body weight; being an active smoker; having diabetes, HIV infection, or any other immunosuppressing condition; or having extensive disease on chest radiograph or slow response to treatment. Intermittent treatment (three times a week) in these patients should only be considered with caution and reserved for situations where daily DOT cannot be performed.
- In patients with HIV infection, therapy should be daily (five to seven days per week). Intermittent treatment (three times a week) in these patients should only be considered with caution. It is strongly recommended that patients be referred to an expert in treating HIV/TB coinfection.[1]
- Never add one drug to a failing treatment regimen. Contact the DPH TB Control Program for medical consultation if any drug resistance is detected.
- After consultation with DPH TB Control Program, consideration can be given to an initial four-month rifapentine-moxifloxacin regimen providing patient meets CDC criteria for this regimen and rifapentine supply is adequate.[20]
- Fluoroquinolones should be used with caution in the treatment of presumed community-acquired pneumonia in patients with a risk factor for TB. Fluoroquinolones are active against *Mycobacterium tuberculosis* complex and may cause transient improvement in persons with TB misdiagnosed as community-acquired pneumonia, potentially leading to delayed diagnosis and continued transmission.[21, 22]
- Fluoroquinolones generally should not be added to the standard TB regimen or used to replace a drug in the standard TB regimen unless there is isoniazid resistance specifically or a concern for other drug resistance. **If there is a concern for drug resistance, call the DPH TB Control Program for consultation.**

Standard 3.2 Treatment of TB in children

The same empiric regimen as outlined above for adults (RIPE) should be prescribed in appropriate doses for children with TB.

- A shortened four-month treatment regimen consisting of an intensive phase of RIPE, followed by a two-month continuation phase of isoniazid and rifampin can be considered for children between three months and 16 years of age who have nonsevere presumed drug susceptible TB (confined to one lobe without cavitation), or isolated intrathoracic adenopathy.[19]
- Children with more extensive TB such as those with cavitary disease, miliary TB, complex pleural effusion, or significant airway obstruction, are not candidates for this abbreviated regimen.
- After consultation with the DPH TB Control Program, consideration can be given to use of a four-month rifapentine-moxifloxacin regimen for children >12 years (and > 40 kg) who have severe or nonsevere TB. Children treated with this regimen must meet CDC criteria and supply of rifapentine must be adequate.
- Recommendations concerning treatment of extrapulmonary TB in children can be found elsewhere.[19]

3. Standards for TB Treatment *(continued)*

Standard 3.3 Treatment Interruption

Treatment phase (i.e., intensive vs. continuation), duration of prior treatment, and bacteriologic status of the patient are considerations when treatment has been interrupted. Treatment interruptions of more than 14 days should be discussed with the DPH TB Control Program.

Guidelines for management of treatment interruptions can be found in the following Table 6 from the ATS/CDC/IDSA TB treatment guidelines.[1]

Table 6. Management of Treatment Interruptions [a]

Time Point of Interruption	Details of Interuption	Approach
During intensive phase	Lapse <14 days	Continue treatment to complete planned total number of doses (as long as all doses are completed within 3 months)
	Lapse ≥ 14 days	Restart treatment from the beginning
During continuation phase	Received ≥80% of doses and sputum was AFB smear negative on initial testing	Further therapy may not be necessary
	Received ≥80% of doses and sputum was AFB smear positive on initial testing	Continue therapy until all doses are completed
	Received 80% of doses and accumulative lapse is <3 months in duration	Continue therapy until all doses are completed (full course), unless consecutive lapse is >2 months
		If treatment cannot be completed within recommended time frame for regimen, restart therapy from the beginning (ie, restart intensive phase, to be followed by continuation phase) [b]
	Received <80% of doses and lapse is ≥3 months in duration	Restart therapy from the beginning, new intensive and continuation phases (ie, restart intensive phase, to be followed by continuation phase)

Abbreviation: AFB, acid-fast bacilli.

[a] According to expert opinion, patients who are lost to follow-up (on treatment) and brought back to therapy, with interim treatment interruption, should have sputum resent for AFB smear, culture, and drug susceptibility testing.

[b] The recommended timeframe for regimen, in tuberculosis control programs in the United Statesand in several European countries, is to administer all of the specified numberof doses for the intensive phase within 3 months and those for the 4-month continuation phase within 6 months, so that the 6-month regimen is completed within 9 months.

3. Standards for TB Treatment *(continued)*

Standard 3.4 Directly Observed Therapy (DOT)

DOT is the standard of care for all patients with TB disease regardless of background, profession, or socioeconomic status and should be used for all weekday doses during therapy. Please see details in Standard 5.4 below concerning LHD responsibilities for DOT and eDOT. Providers should work with LHDs to ensure DOT or eDOT is established upon initiation of treatment or at time of discharge from hospital or other congregate setting.

Standard 3.5 Co-infection with HIV

All patients with TB and HIV coinfection should be evaluated by a provider familiar with HIV treatment and considered for antiretroviral therapy if the patient has not yet been started on antiretroviral treatment.[1] Appropriate arrangement for access to antiretroviral drugs should be made for HIV patients. Initiation of treatment for TB disease should not be delayed.

Given the complexity of concurrent administration of antituberculosis treatment and antiretroviral therapy, immediate consultation with a provider who is expert in treatment of TB and HIV coinfection is recommended for management of concurrent treatment for HIV infection, regardless of which disease appeared first.

Standard 3.6 Assessing Drug Resistance

An assessment of the likelihood of drug resistance, based on history of prior treatment, exposure to a possible source patient having a drug-resistant organism, and the prevalence of drug resistance in the country from which the patient originated, should be obtained for all patients.

- Notify the DPH TB Control Program whenever drug resistance is a concern.
- Patients who fail treatment or who have persistently positive cultures (after two months of appropriate therapy) should always be assessed for possible drug resistance.
- For patients in whom drug resistance is likely, culture and drug susceptibility testing for RIPE should be performed promptly, and second-line drug susceptibility testing should be strongly considered. The SPHL can facilitate the testing of specimens for drug resistance at CDC and other public health laboratories.

Standard 3.7 Smear-Negative Pulmonary TB and Culture-Negative TB[1]

The early diagnosis of sputum smear-negative, NAA negative pulmonary TB should be based on the following criteria:

- The patient has a risk factor for infection with *Mycobacterium tuberculosis*.
- Clinical course and chest radiography findings are consistent with TB.
- The patient has at least three negative sputum AFB smears and NAA testing is negative on at least two of these samples (including at least one early morning specimen).
- Sputum cultures are obtained with results pending.
- There are no alternative diagnoses that have been confirmed and would explain the findings.

Smear-negative patients who ultimately have negative cultures might be considered to have culture-negative TB if there is clinical improvement while on the standard four drug TB treatment regimen and improvement on chest radiograph (or computerized tomography of the chest if done as part of the initial work-up) after two months of treatment. If these criteria are met, the patient can be continued on isoniazid and rifampin for two more months (i.e., four months total) to complete therapy for culture-negative TB.

4. Standards for TB Infection Control

Note: These standards apply to patients with TB disease sensitive to the usual regimen of TB drugs. For patients with multidrug-resistant TB (MDR TB), consult with the DPH TB Control Program for guidance on infection control in all setting types.

Standard 4.1 Infection Control for Pulmonary TB Patients in the Community [5, 6]

- Many TB patients do not need to be hospitalized and can be safely maintained in respiratory isolation restrictions (RIR) at home. See Standards 5.1-5.5 below for necessary activities to determine if a household is appropriate for home RIR for the patient. The situation may be dynamic, and risk should be assessed on an ongoing basis.
- Release from RIR in the community setting should be conditioned on the following:
  - at least five days of standard antituberculosis treatment,
  - ability to tolerate antituberculosis medications,
  - anticipated adherence to antituberculosis medications.

These general criteria apply to patients regardless of their AFB smear status (positive or negative); AFB smear status alone should NOT be used to determine the length of RIR for patients in the community.

- Additional considerations that may warrant longer RIR are: [5]
  - Possible MDR TB or XDR TB,
  - High initial bacterial burden (i.e., laryngeal TB),
  - Likely exposure of immunocompromised persons or young children if patient released from isolation too soon (see Standard 5.3 below concerning evaluation of these contacts),
  - Crowded or poorly ventilated living conditions,
  - Lack of or slow clinical response to treatment, or
  - Use of regimen other than RIPE.
- Level of RIR (moderate or extensive) will be determined by the LHD in conjunction with the DPH TB Control Program based on individual patient circumstances.[5]

Standard 4.2 Airborne Infection Isolation (AII) in Congregate Settings

Patients with suspected TB in congregate settings (e.g., hospital, correctional facility, long-term care facility) should be segregated immediately in an AII room until deemed non-infectious. CDC minimally recommends the infection control measures below. [2, 6, 23]

- Every effort should be made to **initiate and coordinate plans for early discharge of medically stable patients with the LHD as soon as possible.** At the time of discharge the patient would then be managed according to criteria for release from RIR as outlined in Standard 4.1.
- Patients who have a positive AFB sputum smear result (without an NAA result pending or available), a positive NAA result, or are smear negative but TB is highly probable, should start on standard multidrug antituberculosis treatment using four drugs (assuming resistance is not a consideration) and remain in an AII room.
- Hospitalized patients begun on treatment for strongly suspected or confirmed TB disease who require ongoing hospitalization (e.g., not clinically ready for discharge) should remain on AII while they are hospitalized until they have:
  - three consecutive negative AFB sputum smear results, each collected at 8–24-hour intervals, with at least one being an early morning specimen, and
  - received standard multidrug antituberculosis treatment (for a minimum of two weeks), and
  - demonstrated clinical improvement.

4. Standards for TB Infection Control *(continued)*

Standard 4.2 Airborne Infection Isolation (AII) in Congregate Settings *(continued)*

- Individuals in other congregate settings should be managed using the same criteria as for hospitalized patients. [23]
- Most children under the age of 10 with TB disease are not considered contagious. Children who are not coughing and have negative AFB smears do not require an AII room. [19] Exceptions would include children with cavitary lesions, positive AFB smears, laryngeal TB, extensive pulmonary infiltrates, and infants with congenital TB undergoing procedures involving the airway. Policies and procedures should be in place to evaluate children with suspected pulmonary TB for infectiousness (e.g., cough, infiltrate, or cavitation on chest radiograph). Discussion with hospital infection preventionists and the DPH TB Control Program is recommended on a case-by-case basis.
- To protect hospital staff and other patients from undiagnosed source TB cases, adult and adolescent family, household members, and friends visiting children hospitalized with TB should be screened at least with a symptom check and, if symptomatic, a chest radiograph before being allowed to visit the child.[19]

5. Standards for Local Health Department TB Patient Case Management

Standard 5.1 Legal Authority for Responsibility and Management of TB Patients

Connecticut General Statute §19a-265 outlines the legal authority for the care and management of TB patients.[8] LHDs retain the authority and responsibility for the case management of all TB patients in their jurisdiction, regardless of provider type or site of disease.

Standard 5.2 Treatment and Discharge Plans

Patients who are evaluated, diagnosed, or treated for suspected TB disease require a plan for the continuation of treatment. *Treatment plans* are used for those for whom treatment was initiated on an outpatient basis. *Discharge plans* are used for those for whom treatment was initiated in a congregate setting (e.g., hospital, correctional facility, long-term care facility). Plans should be developed in collaboration with the LHD of the town where the patient is being discharged to. The plan should include:

- the treatment regimen and date of initiation of treatment,
- the name of the person or agency providing DOT,
- obstacles to adherence,
- patient contact information,
- the name and contact information of the provider, and
- the date and time of follow up appointment with community provider.

The patient will need an adequate supply of medication to last until initial outpatient TB follow up. The patient should not be discharged until the local health director or their designee discusses, approves, and signs the discharge plan, along with the treating clinical provider and the patient.[6] A TB Discharge/Treatment plan template is available from the DPH TB Control Program.

5. Standards for Local Health Department TB Patient Case Management *(continued)*

Standard 5.2 Treatment and Discharge Plans *(continued)*

Every effort should be made to discharge medically stable patients from the hospital as early as possible. Patients may be discharged home on RIR while still potentially infectious or started on TB treatment on an outpatient basis if they have a specific treatment plan including DOT/eDOT that has been approved by the local health director (or their designee). Such patients should have stable housing, and there should be no risk of exposing uninfected persons who are at high risk for progressing to TB disease (e.g., children aged younger than five years, persons infected with HIV, other immunocompromised persons). Until the patient is deemed noninfectious, they should not have visitors who have not been previously exposed to TB.

If the preferred language of the patient is a language other than that spoken by LHD or DOT staff, certified medical interpretation services should be utilized.

Standard 5.3 Contact Investigations for Infectious TB Patients [24]

LHDs are responsible for ensuring that a contact investigation is performed for all infectious TB patients; this includes patients with pulmonary, laryngeal, and pleural TB. Every new TB patient, regardless of site of disease, should have at least one interview, ideally in person, within three working days of notification of the case to the LHD. This might mean interviewing a patient in the hospital. Contacts who do not know their HIV status should be offered HIV testing.

Contacts identified and the outcomes of their evaluation should be documented on a Contact Investigation Worksheet which must be returned to the DPH TB Control Program. There are two phases of Contact Investigation and reporting:

- First-round Contact Investigation Worksheets should be returned within 60 days of case notification with most contact investigations completed.
- Final, completed Contact Investigation Worksheets (i.e., with all screening, radiography, and treatment information) should be sent to the DPH TB Control Program within 90 days of case notification.

DPH TB Control Program staff are available to advise about contact investigations, especially those that involve contacts outside of the jurisdiction of the LHD for the patient and workplace investigations.

Persons identified as having significant contact with an infectious patient should be evaluated with an IGRA or TST followed by a chest radiograph if IGRA or TST is positive. If signs or symptoms of TB are present in a contact with a positive IGRA or TST and chest radiograph findings are abnormal, additional tests will be needed to complete an evaluation for active TB disease.

Identifying and evaluating high-risk contacts should be the first priority in a contact investigation. This group includes children younger than five years old and immunocompromised adult contacts; these contacts should be evaluated and managed consistent with national and state recommendations. [4, 19, 24] This includes both an IGRA or TST and a chest radiograph.

5. Standards for Local Health Department TB Patient Case Management *(continued)*

Standard 5.3 Contact Investigations for Infectious TB Patients [24] *(continued)*

- If both results are negative, the high-risk contact should be placed on appropriate prophylaxis until the incubation period is complete and a repeat IGRA or TST has been performed at eight to ten weeks.
- The same test method should be used for each test to allow for comparison of test results.
- Treatment can be discontinued in children younger than five whose second TB test is negative.
- Immunocompromised patients whose second TB test is negative should be evaluated for the possibility of active TB and continued for a full course of treatment for LTBI.
- The decision to complete a full course of treatment in immunocompromised patients may be modified based on evidence of extent of transmission estimated from contact investigation.[3]
- Patients who wish to return to a home setting with these high-risk contacts should not do so until the contacts have completed their initial evaluation and started prophylactic therapy.

Non-high-risk contacts with an initially negative IGRA or TST result should have the same test repeated eight to ten weeks after exposure has ended. If the test result converts to positive, they should be managed as any other individual with LTBI.3 Contacts with a positive IGRA or TST should be reported to both the LHD and DPH TB Control Program on the Tuberculosis Contact Investigation Worksheet and offered treatment for LTBI unless contraindicated.

Standard 5.4 Promoting Adherence and Directly Observed Therapy (DOT)

TB control entails a case management team that includes the patient, the provider, and the LHD. To foster and assess adherence, a patient-centered approach to drug treatment, based on mutual respect between the patient and the provider, should be developed for all patients.

DOT is the standard of care for all patients and should be used for all doses during therapy. DOT is recommended for all patients regardless of background, profession, or socioeconomic status.

DOT can be performed either in-person or electronically via video using a variety of different devices (e.g., computer/laptop, tablet, mobile phone). DOT is the observation of a patient ingesting the TB medications in person. eDOT is the observation of a patient ingesting the TB medications in real time (i.e., not recorded) via an electronic application such as FaceTime or WhatsApp. eDOT is an option for all patients for ensuring medication adherence. Consult the DPH TB Control Program for recommended applications for eDOT.

A written record (DOT Log) of all medications given, bacteriologic response, and adverse reactions should be maintained for all patients, regardless of the type of DOT being performed.

- The number of doses taken by the patient defines treatment completion.
- Documentation of each dose should be done by the person providing DOT and be available to the clinician at each visit.

Based on availability, the DPH TB Control Program can provide measures such as incentives (e.g., grocery gift cards) and/or enablers (e.g., bus fare) to promote adherence for individual TB patients.

5. Standards for Local Health Department TB Patient Case Management *(continued)*

Standard 5.5 Monitoring Treatment and Adverse Drug Effects

The LHD is responsible for monitoring TB cases and contacts who are receiving services (e.g., DOT). LHD activities include, but are not limited to:

- ensuring adherence to DOT and medical visits and addressing nonadherence, when necessary,
- questioning patients about possible adverse effects at each appointment and dose by DOT,
- communicating with healthcare providers for treatment updates or about adverse events,
- maintaining appropriate documentation (e.g., DOT logs),
- collecting follow up AFB sputum cultures at least monthly until two negative cultures are obtained (including one sent no earlier than at about days 55-59). Specimens can be sent to the SPHL using the Clinical Test Requisition form (unless previously obtained and sent by provider),
- obtaining completed TB Follow-up Treatment Report Forms from the provider responsible for the patient's TB care, and
- facilitating follow-up chest radiographs at two months to help assess response to treatment and at end of treatment as baseline.

All patients should be monitored for clinical and microbiologic response to therapy. Patients with pulmonary and/or laryngeal TB should have sputum AFB smear and culture obtained at minimum monthly after initiation of treatment (i.e., at least two specimens in the first 60 days of treatment, one of which should be obtained at about days 55–59) until two sputum cultures are negative to monitor for microbiologic response to treatment and determine length of treatment.

Patients with persistently positive AFB culture results after two months of treatment, with or without symptoms, should be evaluated carefully, in consultation with the DPH TB Control Program, to identify the cause of the delayed response. Patients who have positive cultures after four months of treatment are considered treatment failures and should have therapy modified in consultation with an expert.

In patients with extrapulmonary TB and in children, the response to treatment is best assessed clinically.

SUMMARY

Treatment of TB is complex and requires a multidisciplinary approach with providers working together with local and state health department staff to ensure successful infection management. The above Standards delineate expectations for all involved in the care of patients with TB in Connecticut and should serve as a framework for successful management of patients with TB in Connecticut.

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APPENDICES

CT Public Health Resources

1. Tuberculosis Surveillance Report - tb_initsurvreptform_20230412.pdf (ct.gov)
2. Tuberculosis Treatment and Follow-Up Care Report - tb-treatmentfuform_20230412.pdf (ct.gov)
3. TB Risk Assessment Questionnaire (English and Spanish) - tb-risk-assessment-and-user-guide.pdf (ct.gov)
4. Discharge/Treatment Plan Template - https://portal.ct.gov/-/media/dph/tuberculosis/discharge-plan-template.pdf\
5. Lab requisition - clintestreq_ol9b_fill-up1-10-24.pdf (ct.gov)
6. AFB testing description - dcts-afb-clinical-specimen-2023-09-20.pdf
7. NAA Guidelines for DPH lab - mtb-naat-request-form-ctdph-lab-0418.pdf-]
8. Referred culture Mycobacteria for ID - dcts-afb-referred-culture-2023-09-25.pdf
9. QuantiFERON Gold Test - clin-dir-serv-quantiferon-tb-gold-plus_1-5-2024.pdf (ct.gov)
10. Mycobacteria testing services guide - dph-labs-mycobacteriology-testing-services-guide-200422-for-web-rev-09292022.pdf
11. Directly observed therapy log - https://portal.ct.gov/dph/tuberculosis/tuberculosis-forms

Other Resources

1. CDC - https://www.cdc.gov/tb/
2. Rutgers Global Tuberculosis Institute - https://globaltb.njms.rutgers.edu/