

Implementing Directly Observed Therapy for the Treatment of Tuberculosis

Purpose

The standard of care for the treatment of tuberculosis (TB) is directly observed therapy (DOT). This practice ensures that persons with TB are treated until cured and allows the TB nurse or healthcare worker to closely monitor the person for medication side effects. The Texas Department of State Health Services (DSHS) Tuberculosis and Hansen's Disease Unit (TB Unit) reaffirms its commitment to the use of DOT by providing the necessary resources for its implementation.

The purpose of this document is to outline standards when implementing DOT for persons on therapy for TB disease and known or suspected TB infection (known as directly observed preventive therapy [DOPT]). It is also intended for licensed healthcare providers outside of health departments and for patients to understand recommendations surrounding DOT use in Texas.

Indications for DOT

The TB Unit recognizes direct observation as a key strategy in TB elimination and case management. DOT is:

1. Required for all persons with suspected or confirmed active TB disease.
2. Required for contacts to persons with infectious TB that are resistant to isoniazid and or rifampin.
3. Recommended for children under age five with TB infection.

When DOT is required but not implemented, the licensed healthcare provider must document in the medical record extremely unusual circumstances that prevent its use.

Household contacts to a person with infectious TB and other contacts with TB infection who are at high risk of progression to TB disease are to be treated by DOPT as resources permit. Preference for treatment of TB infection by DOPT for contacts to a person with infectious TB should be given in the following order:

1. Contacts aged < 5 years.
2. Contacts with HIV infection or other conditions that weaken immune response.
3. Contacts with a documented change in TB screening tests, from a negative to a positive result.
4. Contacts who might not complete treatment because of social or behavioral impediments (e.g., alcohol addiction, chronic mental illness, injection-drug use, unstable housing, or unemployment).

Other persons who are recommended treatment for TB infection may be treated by self-administered therapy (SAT) as determined by the local health department/public health regional (L/PHR) TB program.

Defining DOT in Practice

DOT is the act of providing the anti-tuberculosis medication directly to the patient and observing the patient ingest the medication(s) as prescribed. The DOT process considers several steps and often involves more than one staff member to ensure the person with TB disease or infection receives adequate treatment.

DOT can occur in various settings such as a clinic, a home, place of employment, a hospital, a jail, or any other agreed-upon setting established between the DOT provider and patient.

To avoid misconceptions, the following are examples of what is **NOT** DOT:

- Allowing a family member or friend to supervise and observe a patient taking the prescribed medication without the DOT provider being present.
- Allowing a parent or guardian to administer medication to a child or adolescent without the DOT provider being present.
- Allowing an inmate in a correctional institution to swallow a dose of medication without observation.
- Leaving medications at the patient’s home when the patient is not present.
- Leaving medications at the patient’s bedside in a hospital, nursing home, or another medical facility without observing ingestion.
- Dispensing medications and “verifying” ingestion by performing a weekly pill count.
- Permitting medical professionals (e.g., physicians and nurses) to self-administer their medications.

Advances in technology and the use of mobile phones, computers, or tablets with video capabilities have provided additional tools for DOT administration in the form of electronic directly observed therapy (eDOT). Video-enabled directly observed therapy (VDOT) is a form of eDOT and may be used as an alternative for some patients needing direct observation of therapy. See the *Resources* section, below, for more information.

Who Can and Cannot Provide DOT?

DOT can be provided by a licensed or unlicensed person after being trained according to the L/PHR’s parameters.

Table 1. Who Can/Cannot Provide DOT?

Who Can Provide DOT	Who Cannot Provide DOT
<ul style="list-style-type: none"> • Trained licensed or non-licensed employees or contractors of L/PHRs. • Employees of institutions responsible for the TB care of their residents, in collaboration with the L/PHRs. 	<ul style="list-style-type: none"> • A family member when not in the presence of a DOT provider. • Individuals who are not able to demonstrate their knowledge of TB as specified in a DOT training section.

DOT Training

A DOT provider should demonstrate to their supervisor or the nurse responsible for the management of the TB patient at a minimum the following:

- Ability to list at least five symptoms of active TB disease.
- Ability to name medications commonly prescribed for the initial and continuation phases of TB treatment.
- Ability to visually identify each medication they will deliver to the patient.
- Demonstrate understanding or describe each adverse drug reaction listed on the [TB-206 Tuberculosis Directly Observed Therapy Log \(TB 206 DOT Log\)](#).
- Demonstrate understanding of L/PHR procedures related to DOT.
- Ability to describe when they must wear an N-95 respirator during a DOT visit.
- Demonstrate the correct procedure for donning an N-95 respirator and performing a fit-check.

Verifying Medications Prior to DOT

Medication verification involves multiple steps and ideally more than one member of the TB care team. Duplicate verification ensures the correct medication is provided to the correct patient, minimizing opportunities for medication errors. This is an important step in the DOT process. Programs that have a pharmacy technician may have a three-step verification process: pharmacy to nurse care manager to DOT provider, all ensuring the correct medications are given to the correct patient.

Table 2. Nurse and DOT Provider Responsibilities to Verify TB Medications:

Nurse Responsibilities	DOT Provider Responsibilities
<ul style="list-style-type: none"> • The nurse is responsible for preparing medications for delivery. • The nurse should verify that the medications indicated on the dose packet or bottle are identical to the medications listed on the medication orders. • The nurse should verify the following regarding the patient’s allotted medication(s): <ul style="list-style-type: none"> ○ Verify the patient’s name and date of birth (DOB). ○ Verify dose packet label by visually matching each medication and number of pills or capsules to ensure they are correct. ○ Verify medication is not/will not expire prior to the DOT date. 	<ul style="list-style-type: none"> • If this is the DOT provider’s first visit to the patient, ask the patient to state his/her name and DOB; for a child, have the parent or guardian identify the child. • The DOT provider must verify the patient receiving DOT matches the patient’s correct name/DOB on the medication order and DOT packet label. • Prior to handing the DOT packet to the patient, the DOT provider should verify the following: <ul style="list-style-type: none"> ○ Visually check that medications in the packet match the medications on the label, both type and dose. ○ Medications are not expired at the time of dosing.

Screening Prior to DOT

Prior to each DOT dosing, the DOT provider should screen the patient for TB symptoms and signs or symptoms of medication toxicity.

TB Symptoms Screening

- If a patient on treatment for active TB disease reports a new, resumed, or worsening of TB symptoms, the DOT provider must advise the nurse upon returning to the clinic or by phone if the provider will not return to the clinic that day.
- If a patient on treatment for TB infection reports symptoms of active TB disease, the DOT provider is to call the nurse for instructions **before** giving the DOT dose. When a dose of medication for TB infection is withheld because of symptoms of active TB disease, do not restart medication without an order from a licensed healthcare provider.

Medication Toxicity

- The DOT provider must ask the patient at each visit all the medication toxicity questions before the patient ingests medication to determine if the patient is having possible side effects to the TB medications. The TB 206 DOT Log provides the list of side effects of the various anti-TB medications. Document answers on the TB-206 DOT Log or equivalent.
- If the patient reports any conditions noted with a double asterisk on the TB-206 DOT Log, do not give the medication. The DOT provider shall call the nurse immediately for instructions.
- When a dose of medication is withheld because of symptoms of medication toxicity or adverse drug reactions, do not restart medication without a licensed healthcare provider order.

Documenting the DOT Visit

DOT requires timely and accurate documentation to ensure the patient completes adequate TB disease and infection treatment. Document in the following way:

- Use the [TB-206 Tuberculosis Directly Observed Therapy Log](#) or equivalent to document doses of medication provided by DOT.
- The DOT provider signature and/or initials on the TB-206 confirms the provider:
 - Asked all questions on the toxicity screen on the TB-206;
 - delivered the medication to the patient; and
 - observed the patient taking the medications
- The patient initials on the TB-206 DOT Log means that the patient ingested the medication on the date indicated and that the dose was properly identified as DOT or self-administered therapy (SAT).

- For scheduled DOT doses not given or missed:
 - DOT provider documents on the TB-206 DOT Log;
 - DOT provider informs the nurse of the missed DOT dose; and
 - The nurse documents in patient's medical record progress notes, the recommendations to DOT provider, and missed DOT dose.
- As the completion of the therapy date approaches, the DOT provider will coordinate the exact date of closure with the nurse. The DOT provider will document the drug stop date for TB disease on the TB-400B and for TB infection on the TB- 400A (or equivalent). The stop date is the actual day the last dose is taken.

Process for Providing DOT

This process ensures that the DOT provider, TB nurse case manager, the licensed healthcare provider, and patient understand the parameters surrounding DOT.

DOT Medications

- All dose packets must be labeled (including the patient's name) by the nurse or authorized pharmacy staff. If the packet is not properly labeled, the DOT provider should return the dose pack to the nurse or pharmacy for proper labeling.
- Medications must be stored in a safe place (not accessible to children) and protected from prolonged exposure to light or extreme temperatures (either hot or cold). Do not leave medications in a car for prolonged periods of time. Return undeliverable medications to the clinic for storage.
- Some liquid TB medications may need to be refrigerated. Isoniazid (INH) liquid should not be refrigerated. The nurse should consult the drug insert or a trusted drug book for proper storage instructions and relay these instructions to the DOT provider.
- Each time a liquid medication is given, the liquid medication container should be inverted and shaken several times for proper mixing.

Delivery of DOT Medication

- Safety is a priority for all DOT providers. Unsafe conditions or threats made to the DOT provider should be reported to the supervisor or nurse as soon as possible so that steps may be taken to protect the safety of the DOT provider or other arrangements may be made to provide TB care for the patient.
- The patient should be observed continuously from the time the medication packet is given to the patient until the medication is completely ingested. (Have the patient get a glass of water before giving them the packet of medication.) The DOT provider should observe the patient ingesting the medication in every DOT dose pack and should never leave a DOT pack to be taken later. Some health departments deliver extra packets of medication for weekends and

holidays, but these are not considered DOT doses and are counted as SAT.

- It is important that the patient ingests all medications in a single day's dose packet during one DOT visit to assure appropriate response to therapy. Medications must be taken on the schedule prescribed for maximum efficacy. If a patient is unable to ingest the entire dose (because of the number of pills, etc.), notify the nurse immediately.
- Hand each patient or parent/guardian the appropriate dose packet or medication bottle for the patient to open.
- Licensed nurses who are providing DOT through a contractual arrangement with a health department may administer the medication according to the terms of their license.
- Personnel without a nursing license are not allowed to provide DOT from bottles, nor pour pills out of packets, nor crush pills, nor mix pills with food or liquids unless a supervising physician has delegated to them those acts under the provisions of the Texas Occupations Code, Chapter 157, §157.001.
- The DOT provider will notify the clinic nurse if the patient is not found at the agreed time and place and will document the missed appointment on the TB-206 DOT Log. Follow-up instructions to DOT providers are to be documented by the clinic nursing staff in the patient's medical record progress notes.
- The nurse must notify the licensed healthcare provider if the patient misses the equivalent of one week of medication. Hospitalization or court-order management may be needed to complete therapy.

DOT Incentives

- The use of incentives is recommended and should be used as available to reward patient adherence to treatment.

Persons Affected

- Employees of DSHS and local health departments that are responsible for the management of persons with active TB disease and TB infection.
- Employees of DSHS and local health departments that are responsible for dispensing medications used to treat TB disease and TB infection.
- Contractors or employees of L/PHRs that are responsible for providing directly observed therapy to persons with active TB disease or TB infection.
- Patients on treatment for TB disease or TB infection.
- Prescribing physicians and licensed healthcare providers.

Responsibilities

- The licensed healthcare provider is responsible for determining if the patient is to receive medications by DOT. If a patient with suspected or confirmed TB disease will not receive medications by DOT, the licensed healthcare provider must

document in the patient's medical record the extremely unusual circumstances that led to this decision.

- The nurse case manager is responsible for explaining DOT to the patient, coordinating with the assigned DOT provider, informing the DOT provider of any changes in medication orders, and implementing the individual treatment goals as outlined by the licensed healthcare provider.
- It is the responsibility of the nurse, pharmacist, or locally determined designee in charge of medications to process them for use for DOT and keep a log of medications distributed to the DOT provider.
- It is the responsibility of the DOT provider to coordinate with the nurse case manager and with the patient so that the licensed healthcare provider orders for DOT are implemented and appropriately documented.
- It is the responsibility of the patient to meet the DOT provider at the agreed time and place for each dose of medication or to notify the DOT provider so that alternate arrangements can be made.
- It is the responsibility of the TB program manager or the nurse case manager to ensure their DOT providers are trained prior to providing DOT.

Resources

- Two Centers for Disease Control and Prevention (CDC) supporting resources on eDOT are [CDC eDOT for Active TB Disease](#) and [CDC TB eDOT Toolkit](#).
- The DSHS TB Unit website provides recommendations for implementing VDOT. Refer to [DSHS Video-Enabled Directly Observed Therapy](#).

Definitions

DOT – directly observed therapy is the act of providing the anti-tuberculosis medication directly to the patient and observing the patient ingest the medication(s) as prescribed for the treatment of TB or TB infection.

eDOT – electronic DOT. An alternative method to in-person DOT in which a patient is remotely observed (e.g., over a smartphone) taking his or her TB medications.

Licensed Healthcare Provider - a licensed healthcare provider (physician assistant, advanced practice nurse, physician) who is responsible for the care of the client. The licensed healthcare provider may be another provider who is providing care for the client in the medical community or it may be the authorizing physician if the client does not have another provider.

TB Disease – a condition caused by Mycobacterium tuberculosis complex that can affect any part of the body, but usually affects the lungs. The general symptoms are fever, night sweats, weight loss, and fatigue. Pulmonary TB symptoms may include productive cough and/or coughing up blood. Extrapulmonary TB may include pain or other symptoms related to the site of the disease.



TB Infection- a condition characterized by a positive reaction to a tuberculin skin test, the absence of symptoms of active TB disease, and a chest x-ray that is not suggestive of active TB disease.

VDOT- video-enabled DOT. The use of synchronous or asynchronous technology to observe DOT.