

 <p>Directly Observed Therapy for Active TB Disease and Latent TB Infection</p>	Policy Number	TB-5001
	Effective Date (<i>original issue</i>)	September 6, 1995
	Revision Date (<i>most recent</i>)	June 26, 2008
	Subject Matter Expert (<i>title</i>)	Manager, Infectious Disease Intervention and Control Branch
	Approval Authority (<i>title</i>)	Manager, Infectious Disease Control Unit
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1.0 Purpose

The purpose of this policy is to assure that all patients in Texas with tuberculosis (TB) or patients with latent TB infection (LTBI) that meet specific criteria receive the recommended doses of anti-tuberculosis medication prescribed by the physician for the successful completion of treatment. This policy also assures that children who are less than 5 years of age and a contact to a known TB case receive medications as prescribed by the physician.

2.0 Policy

It is the standard of care in Texas that all persons with suspected or confirmed active TB disease receive their medications by directly observed therapy (DOT) unless their physician documents in the medical record extremely unusual circumstances that prevent the use of DOT. Scientific literature supports this policy and the Texas Department of State Health Services (DSHS) reaffirms its commitment to the use of DOT by providing the necessary resources to implement it in unusually difficult and costly situations. Without exception, patients with confirmed or suspected resistance to isoniazid and/or rifampin, must be on DOT.

If treatment is prescribed for latent TB infection (LTBI) for a contact to a TB case with resistance to isoniazid and rifampin, treatment must be by DOT. Household contacts of cases and other contacts with LTBI and a high risk of progression to TB disease are to be treated by DOT as resources permit. Preference for treatment of LTBI by DOT for contacts to cases should be given in the following order: 1) contacts aged <5 years, 2) contacts with HIV infection or other conditions that limit immune response to TB, 3) contacts with a documented change in tuberculin sensitivity from a negative to a positive result, and 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 recent contacts and persons with LTBI of unknown origin may receive treatment by self-administered medication.

3.0 Definitions

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

TB – tuberculosis is a disease 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.

LTBI – latent TB infection is 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.

4.0 Persons Affected

Employees of DSHS and local health departments that are responsible for the management of persons with active TB disease and LTBI
Employees of DSHS and local health departments that are responsible for dispensing medications used to treat TB disease and LTBI
Contractors or employees of DSHS and local health departments that are responsible for providing directly observed therapy to persons with active TB disease or LTBI
Patients on treatment for TB disease or LTBI
Prescribing physicians

5.0 Responsibilities

- 5.1 The prescribing physician 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 physician must document for the patient's medical record the extremely unusual circumstances that led to this decision.
- 5.2 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 physician.
- 5.3 It is the responsibility of the nurse in charge of medications to process them for use for DOT and keep a log of medications distributed to the DOT provider.
- 5.4 It is the responsibility of the DOT provider to coordinate with the nurse case manager and with the patient so that the physician's orders for DOT are implemented and appropriately documented.
- 5.5 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.
- 5.6 It is the responsibility of the TB program manager or the nurse case manager to assure that their DOT providers are trained prior to providing DOT.

6.0 Procedures

- 6.1 Who can provide DOT
 - A. Trained licensed or non-licensed employees of local and regional health departments
 - B. Trained contractors to local or regional health departments
 - C. Employees of institutions responsible for the TB care of their residents
- 6.2 Who cannot provide DOT
 - A. Family members
 - B. Individuals who are not able to demonstrate their knowledge of TB as specified in 6.3
- 6.3 Training
 - A. Providers of DOT should demonstrate to their supervisor or the nurse responsible for management of the TB patient at least the following knowledge:
 1. Ability to list at least 5 symptoms of active TB disease.
 2. Ability to name the medications most commonly prescribed for the initial and continuation phases of TB treatment.
 3. Ability to identify each medicine they will deliver after visual inspection of the pill.
 4. Demonstrate understanding or otherwise describe each potential adverse drug reaction listed on the TB-206 Tuberculosis Directly Observed Therapy Log.
 5. Demonstrate understanding of local or regional health department procedures related to DOT.
 6. Ability to describe when they must wear an N-95 respirator during a visit for DOT.
 7. Demonstrate the correct procedure for donning an N-95 respirator and performing a fit-check.
- 6.4 Verification of Correct Patient and Correct Medication
(To be done each time DOT is provided.)

- A. 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.
- B. The nurse should verify that the medication(s) in the dose packet match what is listed on the dose packet label (visual check for correct pills or capsules and correct number of pills or capsules in packet), or correct bottle of medication is being taken to the patient.
- C. The DOT provider must be sure that the patient is the correct patient listed on the medication orders. If this is the DOT provider's first visit to the patient, ask the patient to state his name, for a child, have the parent or guardian identify the child.
- D. The DOT provider must verify that the dose packet or bottle of medication indicates the patient's correct name. (Is this the right dose packet for this patient?)

6.5 Adverse Drug Reaction Screening Questions

- A. The DOT provider must ask the patient at each visit all the screening questions on the TB-206 **before** the patient ingests medication to determine if the patient is having possible side effects to the TB medications. Document answers on the TB-206.
- B. If the patient reports any conditions noted with a double asterisk on the TB-206, do not give the medication. The DOT provider shall call the nurse case manager immediately for instructions. When a dose of medication is withheld because of symptoms of adverse drug reaction, do not restart medication without a physician order.
- C. If a patient on treatment for LTBI reports symptoms of active TB disease, call the nurse for instructions before giving the DOT dose. When a dose of medication for LTBI is withheld because of symptoms of active TB disease, do not restart medication without a physician order.
- D. If a patient on treatment for active TB disease reports a resumption or worsening of symptoms, advise the nurse upon return to the clinic or by phone if the provider will not return to the clinic that day.

6.6 General Information for Providing DOT

- A. The patient should be observed continuously from the time the packet of medication is given to the patient until the medication is actually 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 self administered therapy.)
- B. It is important that the patient is able to ingest all medications in a single day's dose packet during one DOT provider home 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.
- C. 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.
- D. Hand each patient the appropriate dose packet or medication bottle for the patient to open.
- E. 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.
- F. 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.
- G. Medications must be stored in a safe place (not accessible to children) and protected from prolonged exposure to light or temperature extremes (either hot or cold). Do not leave medications in a car for prolonged periods of time. Return undeliverable medications to the clinic for storage.

- H. Some liquid TB medications may need to be refrigerated. INH liquid should not be refrigerated. Every time liquid medication is given, the patient or responsible adult should invert and shake the liquid medication several times for proper mixing. The nurse should consult the drug insert or Physicians' Desk Reference for proper storage instructions and relay these instructions to the DOT provider. If a child is on liquid medication, the DOT provider must observe the parent or responsible adult pour the appropriate amount of the liquid medication needed and observe the parent or responsible adult give it to the child.
- I. 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.
- J. The use of incentives is recommended and should be used as available to reward patient adherence to treatment.

6.7 Documentation of DOT

- A. Use the TB-206 Tuberculosis Directly Observed Therapy Log to document doses of medication provided by DOT. Local health departments may develop and use a similar form as long as it provides at least as much information as the TB-206.
- B. When the DOT provider signs or initials the Directly Observed Therapy Log, it means that the provider asked all the questions on the toxicity screen on the TB-206, delivered the medication to the patient, and observed the patient taking the medications.
- C. When the patient initials the Directly Observed Therapy Log, it means that the patient ingested the medication on the date indicated and that the dose was properly identified as DOT or Self Administered.
- D. As completion of therapy approaches, the DOT provider will coordinate the exact date of closure with the nurse case manager. The drug stop date documented on the TB-400 is the actual day the last dose is taken.

6.8 Doses of DOT not Delivered as Scheduled

- A. 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. Follow-up instructions to DOT providers are to be documented by the clinic nursing staff in the patient's medical record progress notes.
- B. The nurse must notify the physician if the patient misses the equivalent of one week of medication. Hospitalization or court-order management may be needed to complete therapy.

6.9 What is not DOT?

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

7.0 Revision History

Date	Action	Section
9/6/1995	New	
8/28/1997	Revised	
6/26/2008	Revised	