POLICY AND PROCEDURE	
SUBJECT/TITLE:	Directly Observed Therapy for Latent Tuberculosis Infection and TB Disease
SCOPE:	All staff in the Ben Franklin TB Program
CONTACT PERSON & DIVISION:	Maureen Murphy-Weiss, Ben Franklin TB Program
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PURPOSE

The intent of this document is to assure that all Franklin County residents with tuberculosis (TB) disease and selected persons with latent TB infection (LTBI) receive directly observed therapy (DOT) for the recommended number of doses of anti-tuberculosis medication prescribed by the clinician. Successful completion of treatment reduces the risk of acquired drug resistance and relapse, and mitigates the risk of TB transmission in the community.

POLICY

In Franklin County, selected persons with LTBI at high risk for disease progression, and all persons with suspected or confirmed TB disease receive treatment using DOT. DOT is defined as the supervised swallowing of self-administered medications. Guidance published by the Centers for Disease Control and Prevention (CDC), and the Ohio Department of Health (ODH) support this policy. The Ben Franklin TB Program reaffirms its commitment to the use of DOT by providing the necessary resources to implement the intervention. In extremely unusual circumstances DOT may not be possible. Such situations are well documented in the medical record and in the state surveillance record.

Initially, DOT is provided through in-person, face to face contact, however, ongoing DOT may be provided via electronic technology known as electronic directly observed therapy (eDOT). Methods of DOT will be mutually agreed upon by the patient, nurse case manager and DOT provider.

BACKGROUND

In-person DOT is considered the global standard of care and has proven to be an effective method for monitoring TB treatment adherence until completion. Declining public health resources and improvements in technology have allowed local TB prevention and control programs to develop cost-effective strategies to maintain established standards, while continuing to support patient adherence to appropriate and complete treatment regimens. A strategy used by TB programs across the nation is to observe patients taking their medication in their home, school, work place or other location via electronic technology. Observation may occur in real time or by video submission using an electronic device. These procedures are known as eDOT.

GLOSSARY OF TERMS

1. **DOT** – directly observed therapy is the act of providing anti-tuberculosis medication and supervising the swallowing of self-administered anti-tuberculosis medication by a patient diagnosed with confirmed or suspected TB disease.
2. **DOT Provider** - licensed or non-licensed employee of Columbus Public Health (CPH) trained to provide in-person or electronic directly observed therapy (DOT).
3. **EHR –** electronic health record
4. **LTBI –** latent TB infection
5. **MAR** – medication administration record. For the purpose of clarity, the term MAR in the TB program means the electronic record detailing doses of self-administered anti-TB medication given by DOT.
6. **MDR** - multi drug-resistant tuberculosis
7. **MRN –** medical record number
8. **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. Extra-pulmonary TB may include pain or other symptoms related to the site of the disease.
9. **eDOT** – electronic directly observed therapy DOT via electronic technology, in real time or by video, using a computer, tablet or cell phone.
10. **eDOT provider -** licensed or non-licensed employee of CPH trained to provide eDOT
11. **XDR** - Extensively drug-resistant tuberculosis

PROCEDURES

I. DOT Responsibilities

A. If a patient with suspected or confirmed TB disease will not receive medications by DOT, the treating clinician must document the circumstances surrounding the decision. The Ben Franklin TB Program Medical Director, or designee, will contact the provider to discuss the circumstances and educate the provider on TB treatment standards.
B. 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 clinician.
C. The nurse case manager and/or nursing supervisor will maintain a log of medications received from internal or external pharmacies.
D. The nurse case manager will verify and document all medication packets or bottles for accuracy prior to placing the medication in the designated pick-up area for the DOT provider.
E. The DOT provider will coordinate with the nurse case manager and with the patient to ensure the clinician's orders for DOT are implemented and appropriately documented.
F. The DOT provider will provide instructions to the patient for situations where he or she is unable to meet at the agreed upon location or time for DOT.
G. The TB case management nursing supervisor and program manager will assure DOT providers are properly trained prior to providing DOT.

II. Who Can Provide DOT:

A. Licensed or non-licensed CPH employees trained to provide DOT.
B. A trained healthcare provider under the guidance of CPH/TB program. In some situations, home care agencies, correctional facilities, schools and other facilities may assist or provide DOT.

III. Who Cannot Provide DOT

A. Family members; or
B. Any untrained CPH employee; or
C. Any non-CPH employee not trained to provide DOT.

IV. Training

A. DOT provider will demonstrate to their supervisor or responsible nurse case manager the following knowledge:
   1. Ability to name the medications most commonly prescribed for the initial and continuation phases of TB treatment;
   2. Demonstrate understanding of state and local procedures related to DOT;
   3. Ability to collect required patient information at each visit;
   4. Ability to describe when an N-95 respirator is required;
   5. Demonstrate the correct procedure for donning and doffing an N-95 respirator; and
   6. Perform a N-95 fit-check.

V. Verification of Correct Patient and Correct Medication

A. Prior to placing medications in the designated DOT medication pick-up area, the nurse case manager will:
   1. Verify the medications listed on the pill packet or bottle label are identical to medication orders.
   2. Verify that medication(s) in the pill packet or bottle match the label (visual check for correct pills or capsules, and correct number of pills or capsules).
   3. Verify the name, MRN, bottle date and expiration date on each pill packet or bottle of medication.
B. The DOT provider will verify the 10 rights listed below at the time of every DOT encounter. If any of these rights are violated, the DOT provider will stop the process and consult with the responsible case manager, supervisor or department manager.
   1. Right patient;
   2. Right MRN;
   3. Right order;
   4. Right medication;
   5. Right dose;
   6. Right time;
   7. Right route;
   8. Right medication label;
   9. Right reason for giving;
   10. Right documentation
      a) Successful in-person DOT will be documented in the designated MAR at the time of service, or by the end of the business day in situations where documentation cannot be completed.
C. At each DOT encounter, the provider will:
   1. Verify the patient’s name, and date of birth
      a) For a child, the parent or guardian can identify the child.
   2. Verify the medication packet or bottle is correctly labeled.
   3. Verify the patient has not taken any TB medications on the same day as the DOT encounter.

VI. General Information for Providing DOT

A. The DOT provider will use an interpreter for every patient who requires or requests this service.
B. The DOT provider will ask the patient about changes in non-TB related medications, side effects and/or other client concerns regarding TB medications or treatment.
C. The DOT provider will observed the patient continuously from the time the packet or bottle is opened until all medication is actually ingested.

D. Medications must be taken on the schedule prescribed for maximum efficacy. If a patient is unable to ingest the entire dose, the DOT provider will notify the nurse case manager immediately.
   1. All pill packets or bottles must be labeled properly by the authorized pharmacy staff and/or registered nurse case manager. If the packet or bottle is not properly labeled, the DOT provider should return the medication to the nurse case manager or pharmacy, and obtain a properly labeled packet or bottle.
   2. The DOT provider will deliver the appropriate pill packet or bottle to the patient.
   3. Personnel without a nursing license are not permitted to pour pills out of packets or bottles, nor crush pills, nor mix pills with food or liquids.
   4. Medications must be stored in a safe place not accessible to children.
   5. Medication must be protected from prolonged exposure to light or extreme temperatures (either hot or cold).
   6. Medications may not be left in a car for prolonged periods of time.
   7. Undeliverable medications must be returned to the clinic for storage. Staff members may not take medications home.
   8. Some liquid TB medications require refrigeration.
      a) Isoniazid (INH) liquid should not be refrigerated.
      b) Every time liquid medication is administered, the patient or responsible adult should invert and shake the liquid medication several times for proper mixing.
      c) The nurse case manager should verify proper storage instructions contained in the drug insert and/or with the pharmacist. Explicit instructions will be given to the DOT provider.
      d) If a child is prescribed liquid medication, the DOT provider must observe the parent or responsible adult pouring the appropriate amount of the liquid medication into a measuring spoon, cup or food, and then observe the parent or responsible adult give it to the child.
      e) If the medication is mixed with food or a beverage, the child must ingest all of the food or beverage before completing the visit.
   9. Unsafe conditions or threats made to the DOT provider should be reported to the supervisor or nurse case manager as soon as possible. Other arrangements may be made to provide TB care for the patient.
   10. The use of enablers or incentives is recommended and should be used when barriers are encountered. Enablers and incentives have been shown to improve patient adherence to treatment.

VII. <u>Documentation of DOT</u>

A. Successful in-person DOT will be documented in the designated MAR at the time of service, or by the end of the business day in situations where documentation cannot be completed.
B. Unsuccessful attempts for DOT will be documented in the EHR by the end of the next business day.
C. The nurse case manager will be notified of missed medication doses by the end of the business day.
D. As completion of therapy approaches, the DOT prescribing clinician will coordinate the exact date of treatment completion with the nurse case manager.
E. The drug stop date documented on the MAR and the EHR is the actual day the last dose of TB medication is taken.

VIII. <u>Doses of DOT Not Delivered as Scheduled</u>

The nurse case manager must notify the nursing supervisor if the patient misses the equivalent of one week of medication.

A. Patient specific interventions will be developed to improve adherence.
B. The clinician will be notified if the patient misses six or more consecutive doses of TB medication.
C. Hospitalization or court-ordered management may be initiated to complete therapy.

IX. <u>What is Not DOT?</u>

A. Allowing a family member or friend to observe ingestion of 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 ingest a dose of medication without observation.
D. Leaving medications at any location when the patient is not present.
   1. Medication delivery or pick up for patients that submit videos for eDOT is allowable if arrangements are made with the patient, responsible person accepting delivery and the nurse case manager.
   2. Medication delivery or pick-up is not considered DOT and should not be documented as such.
E. Leaving medication at the patient's bedside in a hospital, nursing home or other medical facility without observing ingestion.
F. Permitting medical professionals (e.g., clinicians and nurses) to self-administer their own TB medications.
G. Dispensing medication and "verifying" ingestion by performing a weekly pill count. Medications taken using this method are not considered DOT.

X. eDOT Eligibility Criteria

Providers must consider the individual circumstances of each case to determine whether a patient is a candidate for eDOT. The following criteria are offered as suggested guidelines when considering a candidate for eDOT.

A. Inclusion
   1. Patient accepts the TB diagnosis, is motivated and understands the need for TB treatment.
   2. Patient has been released from isolation.
   3. Patient agrees to participate in eDOT and understands his or her responsibilities if technical failures occur.
   4. Patient agrees to and completes training on how to use the eDOT application and equipment.
   5. Patient is able to demonstrate how to properly use the eDOT equipment.
   6. Patient has received in-person, face-to-face DOT for a minimum of 2 weeks with 100% compliance.
   7. Parental consent is obtained if the patient is younger than 18 years old.
   8. Patient can accurately identify each medication and the accurate dosage (number of tablets).
   9. Patient has access to video equipment that allows for confidential communications, regardless of housing status.
B. Exclusion
   1. Patient is considered at risk for poor adherence and cause is well documented in the EHR.
C. Reasons to discontinue eDOT
   1. Patient requests in-person DOT.
   2. Patient has an adverse reaction to TB medication and requires close monitoring.
   3. Patient can no longer accommodate use of eDOT equipment in a confidential setting.
   4. Patient consistently misses TB medical appointments or consultations and/or ingests <80% of scheduled eDOT medication doses.

XI. eDOT Process

eDOT providers will:

A. Train the patient in the use of eDOT equipment and procedures.
B. Use an interpreter for every patient that needs or requests this service.
C. Activate the eDOT at the scheduled times if synchronous eDOT is used.
D. Confirm the identity of the patient using established platform criteria.
E. For synchronous eDOT, assesses the patient for adverse drug reactions prior to observing medication ingestion. If side effects are voiced, the eDOT provider will notify the case manager and the medications will be held until prescribing clinician provides new or updated orders.

F. For asynchronous eDOT, where the patient selects "no side effects" and then proceeds to take medication, and then verbalizes side effects, the eDOT provider will notify the case manager immediately. The case manager will contact the patient to gather additional assessment data, and the medications will be held until prescribing clinician provides new or updated orders.
G. Observe the patient showing each pill prior to ingestion.
H. Observe the patient placing the pills in their mouth after showing the pill(s) and then drinking clear liquid.
    1. If an asynchronous method is used, beverages should be contained in a clear glass or bottle.
I. Observe the patient open mouth after ingesting pills to show the eDOT provider that the pills were swallowed.
J. Confirm the time and date for the next eDOT if synchronous method is used.
K. Complete required documentation in the EHR and MAR.

XII. <u>eDOT Provider Responsibility:</u>

A. Document each patient encounter as directed by CPH/TB Program policy.
B. In case of device technical failure, make a home/field visit to provide in-person DOT.
C. Provide regular, in person nurse assessments (weekly, biweekly or monthly). This will be determined by the nurse case manager and the clinician.
D. Timely delivery of medication bottles and/or packets.
E. Provide patient with instructions and training on how to use the eDOT applications/equipment.
F. Provide patient with information about who to call with questions or if there is a problem that requires assistance from CPH staff.
G. The eDOT provider will conform to all applicable legal provisions regarding the protection of patient information to ensure patient confidentiality and compliance with HIPAA regulations.

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APPENDICES

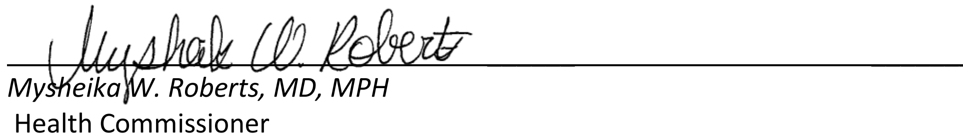
N/A

REFERENCE FORMS

N/A

SIGNATURES

I have reviewed this document and endorse it as an official CPH Policy and Procedure:



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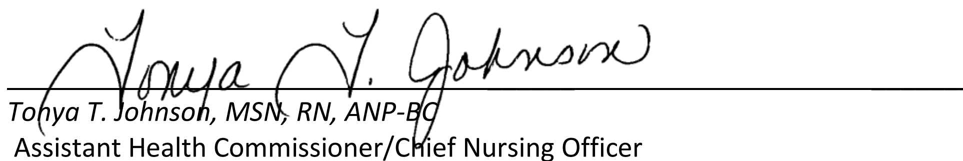

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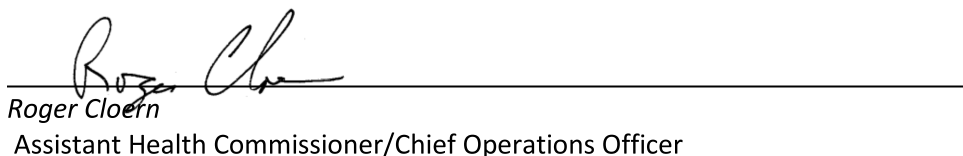

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