

PROCEDURES FOR DIRECTLY OBSERVED THERAPY (DOT)

- I. **TITLE:** Procedures for providing directly observed therapy to clients with active TB, high-priority TB suspects, and high-risk clients with latent TB infection (LTBI).
- II. **TYPE OF STANDARD:** Service
- III. **OUTCOMES:**
 - A definition of Directly Observed Therapy (DOT) and establishment of the role of DOT as a Standard of Care in the management of TB clients.
 - Uniform statewide procedures for the use of DOT for the treatment of clients with active tuberculosis disease and latent tuberculosis infection (LTBI).
 - Priorities for the use of DOT among the various classes of tuberculosis clients.
 - Administrative procedures for safeguarding medications, recognizing adverse reactions of medications, and reporting any adverse circumstances to the TB Nurse Case Manager (NCM) who is responsible for care of the client.
 - Guidelines for maintaining confidentiality and documenting services provided, reactions, and related information.
- IV. **PERSONNEL:** The following subsections address the classes of personnel who may perform the referenced activities within the constraints of their practice acts and protocols.
 1. Responsibility for Identifying Persons to be placed on DOT: M.D., D.O., P.A., A.R.N.P., Nurse Case Manager
 2. Supervision of DOT: NCM
 3. Client Education: M.D., D.O., P.A., A.R.N.P., NCM, R.N., L.P.N., Disease Intervention Specialist (DIS), DOT Technician, Health Services Representative (HSR)
 4. Provision of DOT: NCM, R.N., L.P.N., DIS, DOT Technician, HSR
- V. **COMPETENCIES:**

County Health Department (CHD) TB care providers must have demonstrated knowledge of the principles and concepts related to effective TB control. Each health care worker (HCW) providing DOT should receive classroom training in basic TB, anti-TB drugs and their side effects, interviewing techniques, and effective documentation. Ideally, the HCW providing DOT should be trained by the nurse case manager and should work with the nurse case manager and/or an experienced DOT worker in the field. Health care workers responsible for DOT activities should also be familiar with:

1. Florida Statute 392 and Chapter 64D-3 related to tuberculosis control, Technical Assistance Guidelines issued by the Bureau of TB and Refugee Health, CHD policies, internal operating procedures and other local policies and procedures, confidentiality, and case management of tuberculosis cases.
2. All sections of the current edition of the Centers for Disease Control and Prevention (CDC) "Core Curriculum on Tuberculosis - What the Clinician Should Know" and other appropriate CDC and American Thoracic Society (ATS) tuberculosis guidelines.

VI. DOT POLICIES AND PROCEDURES

1. **Definition of DOT.** Directly Observed Therapy is a component of case management that helps to ensure that clients adhere to therapy. DOT means that a health care worker personally watches the client swallow each dose of TB medication. DOT ensures an accurate account of how much medication the client took. It also provides a mechanism for the early detection of medication adverse reactions or non-adherence. DOT may be prescribed for clients with active TB disease, high-priority TB suspects or high-risk clients with LTBI based on the priorities listed below. DOT may be given in the home, the clinic, at the worksite, under a bridge, at school or in any other convenient and acceptable location. For clients housed in institutions such as jails, nursing homes or hospitals, DOT is administered by the institution's staff. The decision to place a client on DOT is made by the attending physician with consultation from the NCM.

However, DOT is not just providing medication. DOT involves front line interaction with the client. The HCW has the opportunity to make a genuine contribution not only to the client's physical health but also his or her well-being. Frequently, the HCW will identify social service or personal needs that could interfere with completion of treatment. Helping the client resolve these problems not only helps achieve program outcomes but it also helps the client find the assistance needed with their problems. Establishing a close relationship with the client may serve other purposes as well, such as helping assure the HCW's personal safety while performing outreach duties. The client can sometimes become the "protector" of the HCW, warning him or her when the area is unsafe or keeping drug dealers or others from bothering the health care worker. DOT is not just a technical task but sometimes becomes an act of compassion and caring. DOT also provides an opportunity to follow-up with contact investigations.

Language and cultural barriers continue to be an issue when providing DOT services. Federal law (Title VI: Prohibition Against National Origin Discrimination as It Affects Persons with Limited English Proficiency) requires that interpreters and translated documents be provided for non-English speaking clients. The Florida Department of Health and Florida Department of Children and Family Services provide interpreter and document translation services for all county health departments and these services should be utilized when providing DOT for a non-English speaking client. For additional information, visit the following web link: http://dohiws.doh.state.fl.us/Divisions/Equal_Opp/Email_links/Limited_English_Proficiency_Requirements_10302002.doc.

2. **Expected Outcomes.** The current state goal is for at least 80% of active TB clients to receive treatment via DOT.
3. **Policy on DOT.** Directly Observed Therapy is the standard of care for all persons receiving treatment for suspected and active TB disease. Certain high-risk, high-priority LTBI clients should also be placed on DOT. Resource limitations do not permit every client to be placed on DOT. Therefore, the Bureau has established priorities as guidelines for the use of DOT.
4. **DOT Priorities.** The following categories of clients, in priority order, should be placed on DOT:

- a. Any client with active multi-drug resistant TB disease
 - b. Children under five years of age with active TB disease
 - c. High-priority contacts to active TB cases who can be provided with DOT for LTBI including children on “window” prophylaxis at the same time the index case receives DOT
 - d. Any active TB disease client who is known to be non-adherent or who is at high risk for non-adherence such as persons who miss appointments
 - e. Substance abusers and homeless persons receiving treatment for active disease
 - f. Persons receiving a short-course therapy for LTBI (**must** be given via DOT).
 - g. Other high-priority contacts to active TB cases, e.g., HIV+ contacts
 - h. Children under five years of age with LTBI
 - i. Any other persons designated by the attending physician or nurse case manager
5. **DOT Counseling.** The HCW who provides DOT to a given client is responsible for establishing rapport with the client. This includes arranging a time and place for DOT that meets the needs of both client and the HCW, having the Notice of Counseling for Directly Observed Therapy, DH 1184, signed, reviewed with the client by the NCM, and placed in the client’s medical record. The HCW also reinforces counseling and education provided by the NCM.
6. **Health Care Worker Responsibilities for Medications.** HCWs who provide DOT are responsible for obtaining medications from the CHD pharmacy or the nurse case manager in accordance with local CHD procedures and following local security procedures to keep medications safe for DOT performed outside the TB Clinic. The HCW should always check to determine that the medications match the medication orders and that the medication is given to the correct client. HCWs do **not** administer (“pour”) medications unless they are licensed to administer medications. The HCW gives the bottles or packages containing medications to the client to take as prescribed, and the HCW observes the ingestion and swallowing of the medications. The HCW also maintains possession of the medications. Clients requiring weekend doses must be provided individual prepackaged medications. Prepackaged, individual dose medications are available from the State of Florida Pharmacy in Tallahassee.
7. **Documentation.** The HCW is responsible for documenting all medications taken by each client on the TB Directly Observed Therapy Log, DH 2110 after returning to the clinic. This DOT log form is recommended for use in documenting DOT. It provides complete client identification, a medication schedule, medications the client is receiving, a place for the client to initial that the medications were provided, space for recording each time medication is observed to be taken, recording of possible side effects, and other relevant information. Document additional information about the DOT visit in the medical record, if necessary. The original copy when completed should be placed in the medical record. In addition, other local guidelines for documentation should be followed.
8. **Observation and Reports.** During all client encounters, education concerning TB is to be reinforced. The HCW should identify any unanswered questions, educational needs, or social needs and report these observations to the NCM for follow up. The HCW should also be alert for signs and symptoms of adverse

medication reactions that should be brought to the attention of the NCM. These signs include evidence of hepatitis such as nausea, loss of appetite, vomiting, persistently dark urine, yellowish skin, malaise, unexplained elevated temperature for more than 3 days, or abdominal tenderness. Other symptoms suggesting drug reaction include bleeding tendency, easy bruising, blood in urine, or flu-like symptoms. **If there is any suggestion of an adverse medication reaction, the HCW should withhold the medication and report the adverse reactions immediately to the NCM for evaluation.**

The HCW should also report any failure of DOT or incident out of the ordinary to the NCM and document the incident in the client's record.

VII. CONFIDENTIALITY. Client confidentiality is a critical element in the TB control process. All HCWs are expected to maintain a professional attitude, show respect for the client and above all to protect the client's confidentiality. Measures include, but are not limited to, not revealing the reason for visiting a client to others, providing medications in a manner that does not call attention to the client, not leaving messages for clients who miss a DOT appointment that compromise confidentiality, and similar measures.

VIII. INCENTIVES AND ENABLERS. The Bureau supports the use of incentives and enablers as an adjunct to the DOT program. Incentives and enablers may take many forms but all share a common purpose. They are given to encourage clients to complete the full course of therapy. Incentives and enablers do not take the place of a good provider-client relationship, but may help build the relationship.

It is important also to remember the objective in using incentives and enablers. Incentives and enablers are designed to achieve completion of therapy, a TB program purpose. Incentives and enablers are not intended to provide special occasion gifts or charity to a client.

REFERENCES

1. Centers for Disease Control and Prevention. (2003). *Treatment of Tuberculosis*. Atlanta Georgia.
2. Centers for Disease Control and Prevention. (2000). *Core Curriculum on Tuberculosis, What the Clinician Should Know*. Atlanta, GA.