



## CDHS/CTCA JOINT GUIDELINES Directly Observed Therapy Program Protocols in California



The following guidelines have been developed by the Executive Committee of the California Tuberculosis Controllers Association in consultation with the California Department of Health Services, Tuberculosis Control Branch. These guidelines are official State Recommendations and have been endorsed by the California Tuberculosis Controllers Association.

Directly Observed Therapy (DOT) is utilized to insure that a person who has been prescribed medications to treat tuberculosis (TB) disease or to prevent TB disease after infection takes all medication correctly to complete a prescribed course of therapy. DOT is administered in this way to:

- ▼ Prevent further transmission of infection and disease
- ▼ Prevent development of drug resistance

These Guidelines represent the compilation of protocols and experience from several jurisdictions within California. It is recognized that each jurisdiction will need to develop policies and protocols with consideration of local resources, disease level, geography, and agency capability.

### Definition of DOT

- I. Directly Observed Therapy (DOT) is a technique of TB treatment which requires a staff person to assist patients with taking medications prescribed to treat TB disease in order to insure that the entire course of medication is taken in the correct dose, at the correct time and for the complete period of therapy. Direct observation of preventive therapy is referred to in most jurisdictions as DOPT. For purposes of this document, both types of direct observation will be referred to as DOT.
- II. Given adequate training and supervision, DOT may be provided by:
  - A. Nurses
  - B. Physicians
  - C. Outreach workers
  - D. Staff of community-based organizations or clinics
  - E. Employers
  - F. Drug or alcohol treatment staff
  - G. School staff
- III. DOT may take place in various settings:
  - A. Clinics

- B. Community-based organization sites
- C. Drug or alcohol treatment programs
  
- D. Home
  
- E. Work
  
- F. School
  
- G. Additional locations:
  1. Any other location which is convenient for both the patient and DOT worker
  2. A physician's office, clinic, or a combination of sites with cooperative efforts
  3. Many jurisdictions use a clinic/field combination. The clinic model requires a patient who is willing to be cooperative and report to a clinic or office site to obtain medication.

IV. DOT delivery

- A. May be delivered two, three or five times a week
  
- B. If the person is on a daily dose, the protocol should include a plan for provision of weekend doses.

V. The DOT worker is assisting and observing the patient with self administration of medication by delivering, observing and aiding the patient in taking medication which has been prescribed by a physician. The DOT worker is not dispensing or furnishing medication. It is important that all persons involved in this program understand the value of the DOT worker and the legal limitations of this assisting person (see **Legal Issues**).

**Determination of Risk**

- I. Those at risk for non-adherence to therapy and in need of DOT include persons of various lifestyles, health status, cultural practices, economic status and educational level. It is incumbent on each jurisdiction to determine which categories of risk are important for assessment in that particular jurisdiction. The following list represents categories of people at risk for non-adherence:
  - A. History of alcohol or drug abuse
  - B. Adolescents
  - C. Homeless/shelter resident
  - D. Non-adherence with TB medications, present or past

- E. History of previous TB treatment
  - F. History of being in correctional facility
  - G. Major psychiatric disorder/memory or cognitive disorder
  - H. Poor or nonacceptance of TB diagnosis
  - I. Poor compliance during initial medical management
  - J. Slow sputum conversion or slow clinical improvement
  - K. Clinical deterioration while on TB therapy
  - L. Adverse reaction to TB medications
  - M. Too ill to self manage
  - N. Children needing therapy whose parents are in any of the above categories
  - O. Drug resistant TB
- II. Information regarding previous non-adherence with therapy or risk of non-adherence may be obtained from the following sources (see **Appendix E** for examples of information/intake forms):
- A. Initial intake interview with patient
  - B. Medical record
  - C. Referral document and referral source
  - D. Community agencies with whom the patient is in contact
  - E. Family or significant other(s)
  - F. Basic needs assessment

### **Legal Issues**

- I. Legal authority to enforce compliance with DOT is addressed in the California Health and Safety Code Section 121365 [Gotch] (see **Appendix A**). This section allows the Health Officer to issue an order requiring the person who has active TB, and who is unwilling or otherwise unable to follow a prescribed course of therapy, to complete an appropriate prescribed course of medication for TB through DOT.
- II. Statements regarding who may provide prescribed medications is covered in the Business and Professions code, the California Health and Safety Codes and in the Nursing Practice Act. Each

jurisdiction should consider consultation with county counsel or other legal authorities to ensure that protocols are developed in accordance with these laws (see **Appendices B and C**).

- III. Protocols concerning the administration of medication to children need to be carefully drafted. This section should explain the assistive and supportive role of the DOT worker to the parent or guardian. The DOT worker may not always be directly observing the very young child self administering medications, but may be assisting/observing the parent or guardian in giving the medication.

**Job Specifications - minimum qualifications (see Appendix D)**

- I. Knowledge of the community. DOT workers should be familiar with:
  - A. Health and social services provided in the community
  - B. Geography of the region (how to find specific places in the community)
  - C. Population groups to be served
  - D. Community resources
- II. Communication skills
  - A. Essential to understand and be respectful of the culture of the person served
  - B. Special skills are necessary when serving patients who are homeless, substance abusers, or otherwise disenfranchised
  - C. Needs to accept and be accepted by the people being served
- III. Language skills
  - A. DOT staff should either speak the language(s) of the population served or have the ability to work with an interpreter in serving the population.
  - B. In hiring workers to provide DOT, it is very helpful to have workers who are bilingual in one of the major secondary languages on the community. This will allow the worker to speak directly with the patient and will promote better direct communication with the patients.
- IV. Education
  - A. High school diploma or GED is needed.
  - B. Experience in outreach, community service, or a medical setting is helpful but not essential.

**Duties of the DOT Worker**

- I. Duties of the DOT worker will differ according to the level of education and skill of each worker. The basic responsibility of the worker is to insure safety, accuracy and completeness of therapy.

Duties include:

- A. Monitoring patient for complaints of untoward effects of medication
- B. Observing/monitoring for possible signs of non-adherence (i.e. not swallowing medication)
- C. Delivering of prescribed medication to patient
- D. Checking to insure that correct number of pills is being prepared to take
- E. Observing patient swallowing correct number of pills
- F. Checking physicians orders and discussing/assisting case manager with instruction to patient regarding regimen changes
- G. Reporting patient problems to case manager and/or physician as soon as noted
- H. Assisting patient with completion or regimen, including laboratory test or x-ray, transportation, referring to needed resources such as additional health care, social service, and housing.
- I. Charting that medications have been taken and any other pertinent finding to complete adequate documentation for the service/observation that has taken place (see **Appendix E**)

## **Training**

- I. Training for the DOT provider needs to be ongoing throughout employment. However, training needs and skills level of each worker should be assessed initially and training for each worker on basic skills and assessed knowledge gaps must be completed before beginning DOT provision (see **Appendix F**).
  - A. Review of CDC information modules or individual jurisdiction training modules on (It is suggested that periodic tests be held to assess knowledge gaps and need for additional training during this time):
    - 1. TB disease and infection
    - 2. TB disease transmission
    - 3. TB disease prevention
    - 4. How to deliver DOT
    - 5. Interaction with other health care workers on the DOT team
    - 6. CPR/emergency response training
    - 7. Community resources available for patients.
  - B. Field safety training which includes information on resources available to assist with potentially

threatening situations should be included as part of the initial training of all DOT workers.

- C. Field training includes joint visits with the PHN or case manager, experienced DOT providers and the unit supervisor.
  - 1. The ‘buddy’ visits with an experienced DOT provider should be for at least two weeks or a minimum of 4 visits, with assessment of skills level and need for additional joint visits at the end of that time.
  - 2. Supervisory visits should be made at least one time a month with the new worker for the first six months to assess skills level and training needs and then every six months on a continuing basis or more often as needed.
- D. Ongoing training should include:
  - 1. Updates at least every six months with disease review
  - 2. Field visits with case manager
  - 3. Participation in training through outside agencies
  - 4. Participation in the DOT case conferences to enhance skills level
  - 5. To promote quality assurance, a plan for formal review of performance and recording on a regular basis should be written into the program protocol. Quality assurance should be an ongoing part of this program through:
    - a. Chart review
    - b. Supervision visits
    - c. Case management meetings
- E. Pediatric DOT delivery should be recognized as an area in which the DOT worker will need special training regarding:
  - 1. Potential problems
  - 2. Medication measurement
  - 3. Working in a supportive and assistive role with parents and guardians

## **Supervision**

- I. The job title of persons doing direct supervision will differ in various jurisdictions depending on personnel classifications and program needs.
  - A. Categories of supervisors may also vary and may include:
    - 1. TB case managers

2. Social workers
  3. PHNs
  4. MDs
  5. Senior DOT workers
- B. Medical supervision must be available at all times for oversight of medically related tasks/problems to insure patient safety.
- II. Joint supervisory visits on a regular basis are necessary to insure safety of the DOT worker's practice and correct/safe management of the patient's treatment regimen. Visits should be made as frequently as necessary to assess the worker's ability to provide DOT safely and independently.
- III. Case conferences need to be held on at least a bi-weekly basis for case review, training and supervision.
- A. Conferences should:
1. Include all DOT team members: MD, PHN, DOT worker, case manager, etc.
  2. Check all patients on DOT briefly for present or developing problems with regimen
  3. Delete patients who are no longer on DOT
  4. Ideally include:
    - a. Thorough review of each new patient on DOT
    - b. Review of patients who have medication changes
    - c. Review of any patient with problems from medication or compliance
  5. Develop plans for correction of any problems
  6. Develop record of the problems/findings at the time of the conference to ensure continuity of care and quality assurance review.

### **Case Load Determination**

- I. Case load will differ greatly with each worker and the geographic characteristics of the area served as well as the factors listed below. Establishing a relationship between the DOT worker and patient has proven to be an extremely important part of encouraging compliance and the success of the program. These relationships should be encouraged by allowing enough time in the case load assignment for a few minutes of interaction, observation and information gathering between the worker and the patient.
- II. The following factors should be assessed to determine the case load for each worker:
- A. Worker skill and experience

- B. Geography (spread of the cases)
  - C. Acuity, and need for assistance/supervision of each patient
  - D. Site/location of the DOT program (clinic or field)
  - E. Safety for the worker (e.g. should workers go in teams)
  - F. Time available for field visits
- III. Workers in jurisdictions now doing DOT carry a case load ranging 7 - 18 patients in an 8 hour day. Case load assignments are based on consideration of the above factors.

### Support Services

- I. Patients should keep all clinic appointments while on DOT and the DOT worker can encourage this on each visit.
  - A. If resources allow, it is helpful for the DOT worker to be present in the clinic to assist with patient education and to promote continuity of care.
  - B. The clinic visit may include laboratory tests, sputum tests and a chest x-ray.
  - C. The physician needs to communicate any new orders for the DOT patient to the worker during or after the clinic.
  - D. The DOT worker needs to check the chart for new orders and assist the patient in obtaining any testing which has not already been done.
- II. Incentives are helpful in encouraging compliance with the DOT program. If this is possible they need only be small items or whatever can be afforded.
  - A. A questionnaire to patients is useful in determining items which patients will find most useful and desirable.
  - B. Juice, coffee, cheese crackers, or a donut, as well as small personal items such as combs or shampoo have been well received (see **Appendix G** for a sample patient survey list).
- III. Case conferences are an integral part of every DOT program, and are a chance to give and get team support, new ideas and solve problems.
 

With the DOT team working together, information exchanged in these meetings has proven essential for:

  - A. Continuity of care.
  - B. Patient safety.

- C. Coordination of services.
- D. Resolution of patient care problems.

### **Encounter Forms**

- I. Ease of use by the DOT provider is a main factor when developing forms to be used in DOT.
  - A. The form should not require assessment by the worker, but should be a simple question and answer system to include patients response to questions about medication side effects and other problems which the patient perceives (see **Appendix E**).
  - B. Training workers in the use of the form and the need for immediate notification of supervisor/MD of any problems noted is essential.
- II. Charting will vary in jurisdictions according to program design, needs and personnel. A check list form of charting for the DOT worker with a review of possible side effects and medications delivered will ensure complete information gathering by the worker and save time.
- III. Charting case conference findings may be included in the patient record or as a separate section of the program documentation.
  - A. Case conference notes, progress note, problems discussed and the plan for corrective action will be included.
  - B. These records need to be readily available for quality review.

**NOTE:** No set of guidelines can cover all individual directly observed therapy situations which can and will arise. Thus, when questions on individual situations not covered by these guidelines do arise, consult with your local health department Tuberculosis Control Program for further information.