# NURSING DIRECTIVE

**Subject: Direct Observed Therapy (Medication Administration)**

**SECTION:** Standards of Care

**SUMMARY**

The process of providing directly observed tuberculosis chemotherapy in the community setting is the responsibility of the nurse case manager with assistance from the outreach worker, community health worker or other assigned health department personnel.

**BACKGROUND**

Directly observed therapy (DOT) is the expected case management strategy and should be considered in all tuberculosis (TB) cases, regardless of the source of medical care. DOT is considered the standard of care by the Centers for Disease Control and Prevention (CDC) and the Virginia Department of Health (VDH). DOT may be used for others undergoing treatment of LTBI per clinical team discretion.

## PROCEDURE/DIRECTIVE:

### Initiation of Therapy

1. The clinician will prescribe the course of treatment for the client. The treatment plan may originate in either the private sector or within VDH. The nurse case manager is responsible for reviewing the treatment regimen and orders (e.g., appropriate drugs, appropriate dosage for weight, appropriate duration) and alerting the clinician of any discrepancies that may exist with the regimen. If discrepancies are unresolved, the TB nurse case manager shall immediately consult with the district nurse manager or health director for resolution of the issues.

2. The pharmacist or clinician is responsible for dispensing each medication into a container labeled for the client. The prescription label must include the name, address, and telephone number of the dispensing pharmacy; the date of dispensing; name of the prescriber; client; and drug; and directions for use.

Where appropriate, cautionary statements (e.g., take with food) should be included on the label.

3. With rare exceptions, all TB drugs for individuals undergoing treatment for TB by DOT will be dispensed from the state pharmacy in daily dose packages containing required prescription labeling information. Exceptions to this packaging are medications that require refrigeration, special light protection, injectables, and prescriptions filled by non-VDH pharmacies.

    a. Packets may or may not be provided by the state pharmacy in light-resistant containers with approved child safety closures for storage within local health departments (LHDs). LHDs must ensure proper, safe storage of DOT packets until delivered to the client.

    b. Generally, packets should not be stored in the home. If packets are stored in the home, the drugs must be in tight, light-resistant containers with approved child safety closures. The client may request his/her drugs not be placed in child-resistant containers; however, the client must sign either the back of the prescription paper or some other form documenting this request. A copy of the same must be filed in the client record.

4. Drugs not packaged in daily administration packets must be dispensed in standard prescription bottles that are tight, light-resistant containers with approved child safety closures. Storage of the bottles in the home is not recommended. However, if the bottles are to be stored in the home, the client may request his/her drugs not be placed in child-resistant containers; however, the client must sign this VDH form documenting this request. A copy of the same must be filed in the client record.

5. VDH and local drug handling and storage procedures regarding release and return of medications for client delivery and DOT must be followed.

6. DOT medications may not be repackaged except by a pharmacist or clinician. The VDH outreach worker/unlicensed worker, once in the home, may not repackage DOT medications from the original prescription containers.

    a. If changes are made to medications, any remaining daily dose packets shall be returned to the state pharmacy for corrected dosing. LHD personnel cannot adjust medication in the daily dosing packets. An exception is the medication repackage of several days of medication with relabeling by an authorized health department clinician. Staff shall follow labeling requirements as outlined above.

   b. If medications are changed due to side effects or toxicity and drugs are being restarted one at a time over a period of time, consider ordering medications in bottles until the regimen is again stabilized.

7. The health director may authorize staff other than nurses to transport the refill to the client's home. Follow VDH and local drug handling and storage procedures regarding release and return, if necessary, of medications. If the client voices any concerns or has questions concerning the refill, unlicensed staff should not leave the refill. All client questions concerning medications must be referred to appropriate licensed medical staff.

8. The delegating public health registered nurse (RN) must monitor the performance of delegated tasks and ensure appropriate documentation. It is also the responsibility of the delegating nurse to ensure that doses are taken and observed as ordered. Refer to the Office of Community Health Services Nursing Directive Delegation of Nursing Tasks to Unlicensed Personnel Dispensing and Delivering Medications in Health Departments for additional guidance.
   a. The outreach worker/unlicensed individual must operate under the health district's adopted plan for delegation. The outreach worker/unlicensed individual must use the Directly Observed Therapy Log to document each client encounter.

9. All staff, including unlicensed staff, may assist in medication administration in the home setting if the client is unable to do this on his/her own.

10. Although not legally authorized to administer medications, it is the responsibility of the outreach worker/unlicensed worker to observe the client removing the medication(s) and ingesting the prescribed dose from the labeled containers, assuring the correct number of tablets/capsules are removed and ingested.

11. If weekend/holiday doses are needed and medications are not routinely stored in the home, the nurse or outreach worker/unlicensed worker will either leave the correct number of daily packets, the client-labeled medication bottles, or observe the client remove the correct number of pills for self-administration. If medications are removed for weekend administration, the medications must be stored in tight, labeled, light-resistant containers.

12. Every dose of medication must be accounted for and documented in the DOT Log. This includes DOT, self-administered or the combination of the two. Refer to the VDH Guidelines – Tuberculosis Recommendations for Determination of Completion of Treatment and VDH Guidelines for TB record and form use.

13. Documentation of observed doses should occur in the client record on the DOT Log on the actual day the dose was ingested. Districts may choose to maintain a separate, working DOT field record for each client, which includes the current active DOT Log, client demographic/locator information and progress notes, to facilitate daily documentation. Completed DOT Log forms and associated progress notes must be incorporated into the main, permanent client record on a monthly basis or sooner if the records are complete.

14. During each DOT visit, the nurse or outreach worker/unlicensed worker observing the medication dose shall ask the client if they experienced side effects or have other concerns related to treatment.

    a. If concerns or potential medication side effects are discussed by the client, the outreach worker/unlicensed personnel will immediately contact the TB nurse case manager, or other nurse if the case manager is unavailable, to report the issues prior to ingestion of the dose.

    b. Licensed health department personnel will follow agency guidelines regarding reporting side effects and potential toxicity to clinicians.

    c. The appropriate check boxes for side effect monitoring will be completed daily on the DOT log. Progress notes shall be used to document additional information and observations.

## Video Enhanced Therapy

1. Video enhanced therapy (VET) is an alternative to DOT for selected clients in Virginia to ensure client adherence to treatment of tuberculosis disease. See Recommendations for Video Enhanced Therapy for more information on when VET is appropriate.
2. To request a VET platform account, email tuberculosis@vdh.virginia.gov

## Scheduling of Doses

1. Treatment regimens for tuberculosis may involve medications being prescribed for daily, twice weekly, thrice weekly, or weekly administration. For clients with certain medical conditions such as renal disease, dosing requirements vary. In these instances, consultation shall be sought to ensure proper client treatment.

a. **Daily doses** - given either five (5) or seven (7) days per week.
    i. A daily dose can be considered as a DOT dose only if observed by a health department employee or other previously arranged observer who is not a family member.
    ii. If feasible, daily doses should be given at approximately the same time each day.

b. **Intermittent doses –** Higher drug dosages are used with intermittent treatment for tuberculosis, and giving the doses too closely together may result in the client experiencing side effects or medication toxicity.
    i. **Twice weekly Doses -** given two (2) times per week.
        1. When scheduling twice weekly doses, a minimum of two days without medication should occur between scheduled doses.
        2. Twice weekly dosing should be scheduled on a Monday/Thursday or Tuesday/Friday schedule.

    ii. **Thrice weekly doses** – given three (3) times a week
        1. When scheduling thrice weekly doses, a minimum of one day without medication should occur between scheduled doses.
        2. Thrice weekly dosing should be scheduled on a Monday/Wednesday/Friday schedule. Individuals on thrice weekly dosing due to dialysis may need an alternate schedule as DOT for some drugs must be done *after* dialysis is completed.

c. **Once weekly doses** – given one (1) time per week. Ideally, weekly doses should be given on the same day each week.

d. **Legal holiday and weather-related closures**
    i. Holiday Considerations
        1. For clients with TB disease resistant to two (2) or more first line anti-TB drugs, DOT/medication will not be missed for legal holidays unless approved by the health director and/or treating clinician.
        2. Selected clients may be able to self administer on major holidays such as Thanksgiving, Christmas, and New Year's Day; however, if at all possible, there should be phone communication with the client to foster adherence.

3. Longer holiday periods, such as Thanksgiving and Christmas require planning to avoid unnecessary treatment interruptions.

ii. Weather –related Closures
   1. Plan ahead for weather-related events, if possible.
   2. Deliver extra packets if snow, ice or hurricane closure is anticipated.
   3. Discuss communication plan with client.
   4. If at all possible, there should be phone communication with the client during the weather-related closure to foster adherence.
   5. Plan for potential communication disruptions. Have a back-up plan such as the client taking the medication at a pre-determined time if s/he has not had a telephone call or visit by the predetermined time.
   6. Resume DOT within 72 hours if conditions permit.

iii. Follow Appendix A for planning alternative DOT schedules during legal holiday and weather-related closures.

## Evidence Base

Centers for Disease Control and Prevention. (2023). Treatment of TB Disease. Treatment for TB Disease | TB | CDC

Centers for Disease Control and Prevention (2021). Core Curriculum on Tuberculosis: What the Clinician Should Know. Core Curriculum on Tuberculosis: What the Clinician Should Know (cdc.gov)

Va. Code § 54.1-3408 – Virginia Drug Control Act

Va. Code § 32.1-50 – Examination of persons suspected of having active tuberculosis disease; reporting; report forms; report schedule; laboratory reports and required samples.

Virginia Department of Health. (2022) Guidelines for Determination of Completion of Tuberculosis Treatment. Virginia Department of Health, Division of Disease Prevention

Virginia Department of Health. (2022) Division of Pharmacy Services. Policy and Procedures Manual for the Operation of Alternative Drug Delivery Sites.

Virginia Department of Health. (2019). Recommendations for Tuberculosis Record and Form Use. Virginia Department of Health, Division of Disease Prevention.

Virginia Department of Health (2019). TB Nurse Case Management Clinical Pathway. Virginia Department of Health, Division of Disease Prevention.

Williams PM, Pratt RH, Walker WL, Price SF, Stewart RJ, Feng PI. Tuberculosis — United States, 2023. MMWR Morb Mortal Wkly Rep 2024;73:265–270. DOI: http://dx.doi.org/10.15585/mmwr.mm7312a4

Virginia Department of Health (2015). Delegation of Nursing Tasks to Unlicensed Personnel Dispensing and Delivering Medications in Health Departments. Virginia Department of Health, Office of Community Health Services.

## Directive Comments and Feedback

Comments and feedback regarding this directive should be directed to the Director, Public Health Nursing (804) 864-7014.

## APPENDIX A

## Direct Observed Therapy Dosing Schedule Reference

| Dosage frequency | Typical scheduling | Minimum time between doses | Maximum time between doses | Comments |
|---|---|---|---|---|
| Daily | 5-7 days/wk. | 12 hours | 72 hours | |
| Once weekly | 1 time per wk. | 72 hours | Must conform to requirements for completion within specified time period | Minimum time interval between doses should occur no more than 1-2 times during entire course of treatment |
| Twice weekly | M/TH or TU/F | 48 hours | 96 hours | In rare circumstances, may do 36 hr. minimum. (No more than 1-2 times during entire course of treatment) |
| Three times weekly | M-W-F | 36 hours | 72 hours | |