**Virginia Department of Health**
**Tuberculosis and Newcomer Health**
**Recommendations for Determination of Completion of Treatment for Active or Suspected Tuberculosis Disease**

In 2016, the American Thoracic Society (ATS), the Centers for Disease Control and Prevention (CDC), and the Infectious Diseases Society of America (ISDA) published new treatment guidelines for drug susceptible tuberculosis. The VDH Tuberculosis (TB) Program concurs with the treatment guidelines of the ATS, CDC, and ISDA.

This document provides recommendations on calculating adequate treatment for those under care for active tuberculosis. Completion of therapy is no longer based on the number of actual months alone. The number of doses and their frequency must be calculated to determine if an adequate amount of treatment has been taken. In order to assist local districts and case managers in determining if patients have completed an adequate course of therapy, VDH TB Program has prepared the following recommendations and instructions.

1. The selection of an appropriate individual regimen is based on a number of individual patient characteristics, a discussion of which can be found in the ATS, CDC, and ISDA treatment guidelines.

2. Definitions
    - DOT – Directly Observed Therapy. Every dose of medication is observed by a health care worker.
    - Self – All doses are self-administered, or less than ½ observed by health care worker.
    - DOT/self – More than ½ of doses are observed by health care worker, with the remainder of the doses self-administered.

3. For patients on self-administered therapy, only 7 day per week regimens may be used. All intermittent treatment regimens (i.e. 5 day per week, twice weekly, or thrice weekly require DOT). Self-administration is not permitted with intermittent regimens.

4. Ideally, all treatment regimens should be completed within the specified timeframes, i.e. 6-month regimens within 6 months and 9-month regimens within 9 months. In situations where there are treatment interruptions due to drug intolerance or non-adherence, the following recommendations should be used. If the patient fails to complete treatment within the extended timeframes, treatment should be restarted from the beginning.

5. All standard 6-month regimens should be completed within 9 months with the 2-month initial phase completed within 3 months and the 4-month continuation phase completed within the final 6 months. All standard 9-month regimens should be completed within 12 months with the 2-month initial phase completed within 3 months and the 7-month continuation phase completed within the remaining 9 months.

6. For non-standard treatment regimens due to drug resistance or intolerance, there are no "initial" or "continuation" phases to treatment. Dose count starts from the beginning of appropriate treatment and continues to the end of treatment.

7. The number of doses required for completion of any regimen varies with the frequency of the regimen selected. Many individuals may have varying administration frequencies during any phase of their treatment. Determining completion of treatment will be a calculation reflecting number of doses divided by frequency of administration equaling weeks to assure that treatment was adequate.

8. VDH TB concurs with the ATS/CDC/ISDA position of DOT as the standard of care for all individuals on treatment for active or suspected active TB in Virginia. If limited resources do not permit universal DOT, patients with the following conditions/circumstances are considered a priority for DOT.
    - Smear positive, pulmonary tuberculosis
    - Treatment failure or relapse
    - Drug resistance
    - HIV infection
    - Previous treatment for TB disease or latent TB infection
    - Current or prior substance abuse
    - Psychiatric illness
    - Memory impairment
    - Previous non-adherence to therapy
    - TB in child or adolescent

9. Video Enhanced Therapy (VET) may be an option for selected clients. Refer to the VDH TB recommendations for Video Enhanced Therapy for additional information.

10. In instances where DOT is not selected by the health department or local provider, documentation of the reason for self-administration should be placed in the chart along with actions taken by the health department, including health director review and approval of treatment plans as mandated by Virginia's TB Control statutes. (§ 32.1-50.1)

11. When DOT is not used, the health department should obtain a written certification of compliance from the physician managing the care. In this statement the physician should certify the number of weeks that the patient received each drug. Activities by the case manager to monitor adherence such as pill counts, monitoring pharmacy pick-ups etc. are also appropriate to monitor patients for whom DOT is not provided. **The health department is ultimately responsible for assuring that a complete course of treatment has been achieved.**

12. For patients on DOT, VDH TB encourages the use of the 5day/week regimen for the daily treatment schedule. Regimens with self-administered medications on weekends are discouraged.

13. Regardless of whether medications were provided for self-administration on weekends and holidays, only M-F weekday doses will be counted toward dose counts for completion of therapy.

14. Every dose of medication should be accounted for and documented, whether by DOT, VET, or self-administration. For patients on self-administration, acceptable documentation may include a progress note discussing the patient's self report of compliance or documentation concerning pill counts, pharmacy refill pick-up, etc.

15. In instances when the patient is admitted to a residential facility (i.e. hospital, jail, etc), the district will need to assess the quality of the medication delivery system at that facility to determine if doses provided will count towards completion of therapy. If these doses are counted towards the completion of therapy totals, copies of medication administration records must be obtained.

16. If transitioning daily dosing to intermittent dosing, it is recommended to have 24 hours between the daily and the intermittent dose. During holidays when DOT is not possible, the client should self-administer the dose that was scheduled.

17. For patients on non-standard regimens due to drug resistance or drug intolerance, VDH-TB should be consulted regarding the length of treatment required for adequate completion of therapy.
    - **DOT is required for all non-standard treatment regimens.**
    - **Prior to the discontinuance of treatment**, all individuals on treatment using a regimen that does not contain a rifamycin must be reviewed by VDH TB and one of the TB Clinical Consultants. Refer to the recommendations regarding treatment for active/suspected tuberculosis whose regimen did not contain a full course of a rifamycin for additional information.

**Doses Required for Completion of Initial Phase of Treatment**
(Isoniazid/Rifamycin/Pyrazinamide/Ethambutol regimens only. Not for use with second line drugs)

| Regimen | Days per week | Total doses | Number of weeks |
|---|---|---|---|
| Daily | 7 days per week | 56 | 8 |
| | 5 days per week | 40 | 8 |
| Two weeks daily, then twice weekly | 7 days/week for 2 weeks, then two times per week | 14 daily doses, then 12 twice weekly doses (26 total doses) | 8 |
| Two weeks weekday daily, then twice weekly | 5 days /week for 2 weeks, then two times per week. | 10 weekday daily doses, then 12 twice weekly doses (22 total doses) | 8 |
| Thrice weekly | 3 times per week | 24 | 8 |

| **Doses Required for Completion of Continuation Phase of Treatment (26 week/6 month regimen)**<br>(Isoniazid/Rifamycin regimens only. Not for use with second line drugs) | | | |
|---|---|---|---|
| **Regimen** | **Days per week** | **Total doses** | **Number of weeks** |
| Daily | 7 days per week | 126 | 18 |
| | 5 days per week | 90 | 18 |
| Thrice weekly | 3 days per week | 54 | 18 |
| Twice weekly | 2 days per week | 36 | 18 |

| **Doses Required for an Extra Three Months of Treatment**<br>(Use for any regimen when treatment is extended for an additional 3 months) | | | |
|---|---|---|---|
| **Regimen** | **Days per week** | **Total doses** | **Number of weeks** |
| Daily | 7 days per week | 91 | 13 |
| | 5 days per week | 65 | 13 |
| Thrice weekly | 3 days per week | 39 | 13 |
| Twice weekly | 2 days per week | 26 | 13 |

Reference

Official American Thoracic Society/Centers for Disease Control and Prevention/Infectious Diseases Society of America Clinical Practice Guidelines: Treatment of Drug-Susceptible Tuberculosis. CID 2016: 63. https://www.cdc.gov/tb/publications/guidelines/pdf/clin-infect-dis.-2016-nahid-cid_ciw376.pdf