

PROTOCOL FOR TREATMENT OF TUBERCULOSIS USING DIRECTLY OBSERVED THERAPY

Background

Directly observed therapy (DOT) is when a trained health care worker or other designated individual (excluding a family member) provides the TB medication and watches the patient swallow every dose. When used in an individual with latent TB infection (LTBI), the process is referred to as directly observed preventive therapy (DOPT). The Center for Disease Control (CDC) and the World Health Organization (WHO) strongly recommend using a patient-centered case management approach for the treatment of TB, which includes using DOT and DOPT when treating patients for TB.

We do DOT/DOPT because:

- We cannot predict who will take medications as directed, and who will not. People from all social classes, educational backgrounds, ages, genders, and ethnicities can have problems taking medications correctly.
- Studies show that 86-90% of patients receiving DOT complete therapy, compared to 61% for those on self-administered therapy.
- DOT helps patients finish TB therapy as quickly as possible, without unnecessary gaps.
- DOT helps prevent TB from spreading to others.
- DOT decreases the risk of drug-resistance resulting from erratic or incomplete treatment.
- DOT decreases the chances of treatment failure and relapse.

DOT is especially critical for patients with drug-resistant TB, HIV-infected patients, children and those on intermittent treatment regimens.

Requirements

Patients with active TB disease: Directly observed therapy is the standard of care for ALL patients being treated for active TB disease in West Virginia and is required by WV State Code 64CSR76. The patient must receive daily (5x week) DOT, unless they are prescribed an intermittent treatment regimen in which case DOT is done on the days they take the medication. **ONLY DOT doses count towards the completion of treatment dose count.**

Patients with latent TB infection: (see each specific regimen for DOPT requirements)

1. *12-week INH/Rifapentine* – ALL doses must be DOPT, no exceptions.
2. *4-month daily Rifampin* – Initial doses must be DOPT to ensure the patient understands how to take the medication. After the Local Health Department nurse is comfortable

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with the patient's tolerance of the medication and their ability to comply with treatment, medication can be dispensed and self-administered.

3. *9-month daily INH* - Initial doses must be DOPT to ensure the patient understands how to take the medication. After the Local Health Department nurse is comfortable with the patient's tolerance of the medication and their ability to comply with treatment, medication can be dispensed and self-administered.
4. For any patient who refuses to begin or chooses to stop treatment for latent TB infection, a Refusal of Treatment Form (TB-102) must be documented and kept in the patient's chart and submitted to WV Tuberculosis Elimination Program (WV TBEP). If the patient is under 5 years of age, a Treatment Refusal for High-Risk Children (TB-103) must be completed and kept in the patient's chart and submitted to WV TBEP.

Video Directly Observed Therapy (VDOT) may be used to observe the DOT doses using videophones or video enabled electronic devices. VDOT is useful for selected patients to minimize travel burden and provide a convenient patient centered approach to care. VDOT may be used for treating active TB disease patients or latent TB infection (LTBI) patients. For a patient to be eligible for VDOT a minimum of 2 weeks of in-person DOT should be done to assess the patient for eligibility of VDOT. Consider the individual circumstances for each patient to determine if VDOT is appropriate, please refer to the WV Protocol for Video Directly Observed Therapy to help determine eligibility and next steps for VDOT.

Monitoring Patients on TB Treatment

Just like with any other medication there is also risk of adverse drug reactions with TB medication. These adverse drug reactions range from mild reactions such as rash and nausea to life threatening severe reactions such as seizures and hepatotoxicity. Patients on treatment for active TB disease or latent TB infection should be made aware that they need to report any signs and symptoms of adverse drug reactions to their health care provider immediately.

This includes but are not limited to:

- Unexplained anorexia, nausea or vomiting, dark urine, or yellowing of skin or eyes
- Persistent paresthesia (tingling, numbness, or burning) of hands or feet
- Persistent weakness, fatigue, fever, or abdominal tenderness
- Rashes or any persistent itching
- Easy bruising or bleeding
- Blurred vision or changed vision
- Or anything else that is not considered normal for them

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To help monitor for adverse drug reaction as well as to monitor the effectiveness of the treatment regimen the WV TBEP requires that certain things be monitored on a regular basis.

Active TB disease monitoring for drug susceptible TB

(Please note that the following list is for Rifampin, Isoniazid, Pyrazinamide and Ethambutol (RIPE). If the patient is on a different regimen other than RIPE WV TBEP will make you aware of this when the medication is prescribed by the doctor.)

- Assessment for any signs of adverse drug reactions through patient interviews should be done with DOT.
- Liver function tests (LFT's) are done every month while the patient is on treatment and one month after treatment is completed.
- Chest x-rays are done every month (or according to physician's orders) to monitor patient's response to treatment.
- Sputum specimens are obtained for 3 consecutive days at least monthly until negative conversion is documented to monitor treatment response. For details refer to the standing order for sputum collection at <http://www.dhhr.wv.gov/oeps/tuberculosis/Pages/StandingOrders.aspx>.
- Ishihara color blindness test and a visual acuity test are done monthly while the patient is on Ethambutol to check for any visual disturbances the medication may cause.

Note: After completion of treatment, active TB cases need to be followed with serial chest x-rays every 6 months for a period of 2 years.

Latent TB Infection monitoring

- Assessment for any signs of adverse drug reactions through patient interviews should be done with DOPT.
- Liver function tests (LFT's) are done every month while the patient is on treatment and one month after treatment is completed.

All patients (active and latent) must have liver function tests performed a minimum of 1 week after treatment completion to document normal levels prior to being discharged from TB Clinic.

When A Patient Has to Travel While on Treatment

Sometimes during treatment, the patient may have to travel to another state or another county. When this happens WV TBEP should be notified as soon as possible before the travel so that a plan can be put into place to ensure there are no interruptions to the patient's

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treatment. Depending on the length of travel and the patient's compliance and medication tolerance, it may be possible for them to self-administer the doses while traveling in some circumstances. When this is not an option, an Interjurisdictional Transfer Form (IJF) needs to be filled out and sent to WV TBEP so that they can send it to the receiving jurisdiction (state, county or country) so that DOT or DOPT may continue and there are no interruptions to the patient's treatment regime. The following information is needed for the IJF:

- Information on where the patient is going. This includes the address and contact information for where the person is staying (hotel, private residency, etc.).
- Dates of travel when they plan on leaving and when they expect to be return if they are coming back.
- A copy of the DOT or DOPT record along with a list of medication and doses of medication.
- A copy of the most recent labs obtained on the patient (LFT's, smears, cultures, PCR test, etc.)
- A copy of the most recent x-ray report done on patient.
- A copy of the nurse's notes on the patient
- And any other pertinent information from the patient's chart that you feel is important to provide care to the patient.

This information should be faxed to the WV TBEP at (304) 558-1825 and then call WV TBEP at (304) 558-3669 to inform us of the travel.

The WV TBEP will contact the receiving jurisdiction and make them aware of the patients travel to their area. The contact information for your organization will be given to the receiving state or county and they may contact you with any questions regarding the patient's treatment.

Managing Care for a Patient Being Treated by a Private Health Provider

The WV TBEP provides medication and medical monitoring for the treatment of active tuberculosis and latent tuberculosis infection free of charge to prevent the spread of TB in West Virginia and ensure that patients receive appropriate and cost-effective treatment. This is an effective way to provide the patient with individualized care, patient education and it promotes adherence and treatment completion. ALL active TB disease cases must be followed by the Local Health Department, even if management of care is being provided by someone other than WV TBEP.

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LTBI patient do have the right to be treated by their private health care provider instead of WV TBEP, medication and medical monitoring will not be provided for them unless their private provider is willing to consult with WV TBEP medical staff and collaborate on treatment decisions. This patient would then be subject to the same guidelines for DOT/DOPT and monitoring as described above. A patient may not just come to the local health department with a prescription for TB medications from a private provider and have the medication provided by the health department.