

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

Directly observed therapy is the standard of care for all treatment of TB in West Virginia. The WV Division of Tuberculosis Elimination (WV DTBE) requires that ALL patients identified with active TB disease, latent TB infection or requiring window post exposure prophylaxis must receive DOT or DOPT respectively.

Patients with active TB disease: Must receive daily (5x week) DOT, unless prescribed an intermittent treatment regimen in which case DOT is done on the days they take the medication. All doses during treatment course must be DOT.

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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 (approx. 1-2 weeks). After LHD nurse is comfortable with the patient's tolerance of the medication and their ability to comply with treatment, a modified DOPT (i.e. self-administration) can be implemented. The nurse may contact the WV DTBE and request modified DOPT be implemented.
3. *9-month daily INH* - Initial doses must be DOPT (approx. 1-2 weeks). After LHD nurse is comfortable with the patient's tolerance of the medication and their ability to comply with treatment, a modified DOPT (i.e. self-administration) can be implemented. The nurse may contact the WV DTBE and request modified DOPT be implemented.

For any patient who refuses to begin or chooses to stop treatment, a Refusal of Treatment Form (TB-102) must be documented and kept in the patient's chart and submitted to WV DTBE. 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 DTBE.

Monitoring Patients on TB Treatment

Just like with any other medication there are also risk for 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

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

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Active TB disease monitoring for drug susceptible TB

(Please note that the following list is for Isoniazid, Rifampin, Ethambutol and Pyrazinamide. If the patient is on a different regimen other things may need monitored regularly. The WV DTBE 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 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 follow up.

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 the WV DTBE should be notified as soon as possible before the

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travel so that a plan can be put into place to ensure there are no interruptions to the patient's 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 by the WV DTBE and sent to the receiving state or county 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 DTBE at (304) 558-1825 and then call WV DTBE at (304) 558-3669 to inform us of the travel.

The WV DTBE will contact the receiving state or county 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 DTBE 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.

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However, should a patient choose to be treated by their private health care provider instead of WV DTBE, medication and medical monitoring will not be provided for them unless their private provider is willing to consult with WV DTBE 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.