

WV Tuberculosis Elimination Program Standards of Care Protocol for Active Tuberculosis Disease

WV Tuberculosis Elimination Program's (WV TBEP) Mission

The mission of the WV TBEP is to eliminate tuberculosis in West Virginia. This will be accomplished by assuring compliance with effective TB strategies, by all WV TBEP clinics providing consistent quality standard of care, and by coordinating the efforts of private providers with public health when providing care to TB patients.

Standards of Care for all WV TBEP Clinics for Active TB Disease

(A suspect case is to be treated as an active case until active TB is ruled out)

I. Intensive Phase of Active TB Case- Day 1 to 8 weeks

1. Once the LHD is first made aware of the case they need to obtain all the needed records from the reporter for the case. This includes:
 - a. A history and physical.
 - b. Demographic information.
 - c. Any radiographical procedure reports.
 - d. All lab results that were done pertaining to the diagnosis and where any specimens have been sent.
 - e. A complete list of home medications. This list should also include any medication started for the treatment of active TB.
 - f. Whether the case is still in the hospital or if they have been discharged.
 - i. If the case is still in the hospital find out if the case is in negative air flow isolation and if airborne precautions have been implemented. Also, inquire about an expected discharge date and inform them that the Local Health Department will need to be notified when the case gets discharged.
 - ii. If the case has been discharged inquire about where they were discharged and obtain a discharge summary.
2. Call WV TBEP to verbally report the case within 24 hours.
 - a. All documentation obtained about the case should be faxed to (304) 558-1825.
 - b. Consult WV TBEP regarding any questions or findings.
3. Fill out all the initial forms that are needed for reporting. All forms can be found on the WV OEPS/Tuberculosis website.
Link to forms: https://oeps.wv.gov/tuberculosis/pages/tb_forms.aspx .

WV Tuberculosis Elimination Program Standards of Care Protocol for Active Tuberculosis Disease

The initial forms are:

- a. TB-34 Individual Active TB Reporting Form- this form is used to report the case to WV TBEP and we in turn use it to report the information to the CDC. It should be faxed in as soon as possible. The form needs to be as complete as possible; all information is required by CDC.
 - b. TB-80 Diagnostic Clinic Form- this form is used to set up a diagnostic clinic. The form is to be filled out completely and faxed to WV TBEP. All active cases are to be seen in clinic monthly during treatment and this form should be faxed in every time a clinic needs to be scheduled. All active TB cases are managed by WV TBEP, however.
 - i. Once this form is received by WV TBEP, someone will be in contact with dates and times for clinic.
 - c. TB-104 Risk Assessment Form- this form is to assess the cases risk factors for TB.
 - d. TB-18 Drug Supply Inventory and Order Form - this form is used to order the medication that will be used for treatment and some other medical supplies.
 - e. TB 109 Clinical Pathway for Managing an Active TB Case- this form is used to document when each task is done during treatment.
4. Develop a plan for doing Directly Observed Therapy (DOT). It is in the WV Reportable Disease Rule that TB medication must be done by DOT. To complete treatment a case must complete a set number of DOT doses, the total number is dependent on what the regimen is and how long they are required to take the medication. Therefore, it is very important to begin DOT as soon as possible once a case has been identified. Please refer to the Treatment Protocol for information on how DOT is to be done, by whom it is to be done and why it is to be done. There are two different forms that will need to be used for DOT. These forms are:
- a. TB-107 DOT Treatment Record- this form is used to document every dose given by DOT and to keep a recorded total of how many doses the case receives. This record will be faxed to WV TBEP at the end of treatment.
 - b. TB-150 Workers Log- this form is for billing purposes. WV TBEP is able to provide some reimbursement to the Local Health Departments for the time the nurse spends conducting DOT for TB cases. Please refer to the WV TBEP DOT/DOPT Reimbursement Breakdown for more details.
5. Contact the case and inform them of our role in their care for active TB. Work with the case and WV TBEP on setting up a date and time for clinic. It is very important that once

WV Tuberculosis Elimination Program Standards of Care Protocol for Active Tuberculosis Disease

- a case is out of the hospital, we get them transferred to the care of the WV TBEP clinician.
6. During the initial clinic the case will get to talk to the clinician. WV TBEP has developed an order set that is to be used during clinic by the clinician.
 - a. For the counties with contracted clinicians the order set is to be filled out and faxed to WV TBEP after each clinic. This is required to help WV TBEP stay in the loop with the clinical care of the case.
 - b. For the counties that will be seen by the WV TBEP clinician an order sheet will be filled out during clinic and faxed to county after clinic.
 7. The following is a list of things that need to be done for all active cases:
 - a. Provide HIV counseling and testing if not already done. If it has been done find out where and obtain a copy of the results.
 - b. Provide Hepatitis C and Hepatitis B testing if not already done. If it has been done find out where and obtain a copy of the results.
 - c. Do any confirmatory testing if not already done. If it hasn't been done, obtain a state funded IGRA for anyone over the age of 2, for cases under 2 years old place a PPD. If testing has been done find out where and obtain a copy of the results.
 - d. Obtain baseline labs. These include the following:
 - i. CBC- this is only done at the initiation of treatment unless ordered more frequently by the clinician.
 - ii. CMP- this is only done at the initiation of treatment unless ordered more frequently by the clinician.
 - iii. Hepatitis B and C- this is just done once during treatment.
 - iv. HIV- this is just done once during treatment.
 - v. And any other lab the clinician will need to properly care for the case.
 - e. Obtained a chest xray. Contact WV TBEP to schedule a date and time for this to be done. A chest xray will be done every month during treatment until discontinued by the clinician. Clinicians should only discontinue chest x-rays once they have seen significant clinical improvement or stabilization on the films.
 - f. Obtain baseline vision acuity testing and color blindness testing. This will be done monthly while the case is taking Ethambutol.
 - g. Obtain the initial weight of the case. The weight is to be obtained monthly while the case is on treatment.
 - h. 3 consecutive days sputum needs to be collected and sent to the Office of Laboratory Services (OLS) for Acid Fast Bacilli (AFB) smear and culture testing.

WV Tuberculosis Elimination Program Standards of Care Protocol for Active Tuberculosis Disease

Collect the first one during clinic and then provide the case with 2-3 more sputum containers with instruction on how to collect and what to do with the specimen once it is obtained. If the case cannot produce sputum contact WV TBEP to see what should be done next.

- i. Information on how often sputa samples need to be obtained during treatment can be found under Standing Orders for Sputum Collection.
 - ii. Please refer to the Health Care Worker Sputum Collection Instructions for instructions on how to properly collect, store and ship the sputum.
 - iii. Please give the case the Patient Sputum Collection Instructions sheet on how to properly collect and store the specimen.
- i. Educate the case on TB medications, hepatotoxicity and the side effects that they can cause. Provide contact information for the health department so that they know how to contact someone with any questions or concerns about treatment.
 - i. Read and review the Medication Fact Sheet for each medication the case is on and provide them with a copy. Link to Medication Fact Sheets: https://oeeps.wv.gov/tuberculosis/pages/tb_lhd.aspx.
 - ii. Review with them the Treatment Plan for Active Tuberculosis prior to consents being signed.
 - iii. Have the case read and sign the TB-106 Consent for Treatment form.
 - iv. Fill out the TB-50 Medication Dispensing Record. This form is used to track the information about the medication such as the medication name, strength, lot number and expiration date. This form should be filled out each time new medication is dispensed to the case.
 - j. Administer their medication by DOT and document in the TB-107 DOT Treatment Record.
 - k. Explain to them how DOT is done and why it is done. Take this time to discuss what time is best to do the DOT and schedule the DOT visits.
 - l. Talk to them about clinic and let them know that they will be scheduled with the clinician to be evaluated and to check their progress once a month.
 - m. Obtain the information for the contact investigation. To help with this document the findings on the TB-1001 Contact Sheet. Once completed the Contact Sheet should be faxed to WV TBEP. Please refer to the MMWR Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis for help in determining a contacts risk level. West Virginia's definition of a Close Contact is

WV Tuberculosis Elimination Program Standards of Care Protocol for Active Tuberculosis Disease

a person who has had prolonged, intense, or frequent contact - on average eight hours or more per week of exposure - with a patient with active TB disease during the infectious period.

8. For the rest of the Intensive phase:
 - a. Continue daily DOT.
 - b. Assess for adverse drug reactions and hepatotoxicity and contact WV TBEP or the clinician with any findings.
 - c. Continue monitoring the LFT's and fax them to WV TBEP to be put in the case file.
 - i. LFT- these are done monthly to monitor for hepatotoxicity during treatment unless ordered more frequently by the clinician. Refer to the Standing Order for Hepatotoxicity at this link on how to interoperate the lab results: https://oeeps.wv.gov/tuberculosis/pages/tb_lhd.aspx.
 - d. Continue monthly clinic visits with the clinician.
 - i. For counties with contracted clinicians continue to fax the TB-80 Diagnostic Clinic Form and the order set even if there are no changes to WV TBEP monthly.
 - e. Continue monthly chest x-rays until discontinued by the clinician.
 - f. Continue monthly vision acuity testing and color blindness testing until one month after Ethambutol is stopped.
 - g. Continue sputum collection per standing orders.
 - h. Follow the schedule of the Clinical Pathway.
 - i. Continue the contact investigation until everyone has been tested at least 8 weeks post exposure to the case.
 - j. Observe for sputum conversion.
 - k. Obtain copy of drug sensitivity testing.
 - l. Obtain any missing information for the TB-34 Individual TB Reporting form and fax it to WV TBEP.

II. Continuation Phase- Week 9-Completion of treatment

1. Sputum conversion should have occurred by now.
 - a. If it hasn't, contact WV TBEP to discuss a plan of action.
 - b. If it has be sure to document the date of conversion.
2. For the Continuation Phase continue the following:
 - a. Daily DOT as ordered by the clinician.

WV Tuberculosis Elimination Program Standards of Care Protocol for Active Tuberculosis Disease

- b. Sensitivity testing results should be complete, and a copy sent to WV TBEP.
 - c. Assess for adverse drug reactions and hepatotoxicity and contact WV TBEP or the clinician with any findings.
 - d. Continue monitoring the LFT's and fax them to WV TBEP to be put in the case file.
 - e. Continue monthly clinic visits with the clinician until the completion of treatment.
 - f. Continue monthly vision acuity testing and color blindness testing if the case is still on Ethambutol.
 - g. Follow the schedule of the Clinical Pathway.
3. At the completion of treatment notify WV TBEP of the date the medication was stopped and fax in a copy of the completed DOT record for a dose count to be done.
 4. Obtain LFT's 1 week after completion of treatment and fax to WV TBEP.
 5. WV TBEP will send a discharge order and a copy of the Completion of Treatment letter that will need to be filled out.
 6. Go over the discharge orders with the case.
 7. All active TB cases will receive chest x-rays every 6 months for 2 years.
 8. The case should be instructed not to receive another TB test and why. When necessary, they should provide a copy of the completion of treatment letter and a risk assessment should be completed instead and if necessary, a chest xray should be done.
 9. Provide the case with a **COPY** of the Completion of Treatment Letter and fax a completed copy to WV TBEP.
 10. Fax a copy of the completed Clinical Pathway to WV TBEP.
 11. Fill out a cohort review form and fax it to WV TBEP.