

IV. Diagnosis and Treatment of TB Disease

A. Diagnosis

Individuals with suspected TB disease should receive a medical evaluation that includes:

1. Medical and social history (e.g., the TB Epidemiological Record – DHHS 1030)
 - a. Recent exposure – exposure within the past two years;
 - b. Signs and symptoms of TB disease – unexplained productive cough greater than three weeks of duration, anorexia, unexplained weight loss, fever, night sweats or hemoptysis;
 - c. Previous infection – if individual has taken adequate preventive therapy, TB disease is less likely;
 - d. Previous disease – if individual has taken inadequate regimen or compliance was poor, TB disease is likely to reoccur;
 - e. Risk factors – evaluate risk factors for developing disease (**see Chapter II**);
 - f. HIV infection – individuals with latent TB infection and HIV have a high risk of progression to active TB disease; provide HIV counseling and testing for everyone regardless of age (**see Chapter V for the diagnosis and treatment of TB in HIV positive persons**); or
 - g. Possible pregnancy – refer for pregnancy testing if indicated.

2. Tuberculin Skin Test (TST) or Interferon Gamma Release Assay (IGRA)
 - a. Obtain documented TST mm reading **or** administer TST and record mm reading **or** documented IGRA test result **or** obtain IGRA results; IGRA/TST is recommended but not required if the individual is known to be *M. tuberculosis* culture positive.
 - b. A positive IGRA/TST may support the diagnosis of TB disease but does not distinguish latent TB infection from active TB disease. A negative IGRA/TST does not exclude the possibility of TB disease.

3. Chest x-ray
 - a. A posterior-anterior (PA) view of the chest is the standard radiograph for adults
 - b. Children < 5 years of age need a posterior-anterior view and a lateral view chest x-ray.
 - c. Reactivation TB disease in immunocompetent adults usually occurs in the apical and posterior segments of the upper lobe or in the superior segments of the lower lobe.
 - d. Individuals suspected of having TB disease **at any site** should have a chest x-ray and sputum smear/culture (if able to provide specimens) to rule out pulmonary involvement.

4. Bacteriology
 - a. Three sputum specimens should be obtained with an interval of at least eight hours between specimen collections. At least one of these specimens should be an early morning specimen. After the initial three sputum specimens, collect two sputum specimens every two weeks for smear and culture until two consecutive sputum cultures are negative (culture conversion).

- b. All initial specimens from any source should have cultures performed.
- c. Drug susceptibility testing should be done on all initial isolates.
- d. Patients who have received prior TB treatment or who come from countries with relatively high rates of drug resistance (most TB-endemic countries can be considered in this category) are recommended to get a specimen (either smear-positive sputum or isolate from a positive culture) sent to the Centers for Disease Control and Prevention for molecular detection of drug resistance. This must be coordinated through the state lab.

B. Airborne Precautions and/or Home Isolation

1. Transmission of TB is dependent upon four factors:
 - Number and/or viability of bacilli expelled in air (index case characteristics);
 - Susceptible host (contacts);
 - Environment (shared air); and
 - Duration and/or frequency of exposure (time).

2. Individuals newly suspected of having pulmonary or laryngeal TB are considered infectious and should be managed using airborne precautions with no new persons exposed until the following conditions have been met:
 - a. Individuals who are initially sputum smear positive should be maintained in negative pressure isolation while in the hospital or restricted to their home until:
 - Two sputum specimens (induced or natural) are collected, with a minimum interval of eight hours between specimens are found to be smear negative for AFB, and no other specimens in the same calendar week (Sunday to Saturday) are AFB smear-positive
 - They have been compliant on TB medicine to which the organism is judged to be susceptible: and
 - They show evidence of clinical improvement.
 - b. Individuals initially sputum smear negative should be maintained in negative pressure isolation while in the hospital until they have been compliant on tuberculosis medications to which the organism is judged to be susceptible and there is evidence of clinical improvement on treatment. In the inpatient setting, a minimum of two weeks of tuberculosis treatment is generally recommended for a patient with smear-negative, presumed drug-sensitive pulmonary tuberculosis prior to discontinuing respiratory isolation.
 - c. Individuals needing respiratory precautions may be discharged to their home regardless of sputum smear status with instructions to remain in the home, avoid exposing anyone other than already exposed household members and to avoid contact with infants and young children and immunocompromised individuals. The local health department will advise when the precautions can be lifted based on length of treatment and sputum smear status.
 - d. It is critical that a person with positive smears not be permitted to return to an institutional or congregate setting, a setting with children under 5 years of age, or a setting where immunocompromised individuals are located. An outdoor work environment may be permissible in some circumstances; this first needs to be discussed with the nurse consultant.
 - e. Persons with suspected or known active pulmonary or laryngeal TB who are initially sputum smear negative and who will be managed at home (not in

the hospital) do not require respiratory isolation once they have been started on tuberculosis treatment.

C Diagnostics for suspected TB in children

- Consultation with a pediatric infectious diseases specialist is strongly recommended when TB in a child is suspected. See chapter I for contact information or call your TB Nurse Consultant for assistance in making this contact.
- If the source case is unknown or the isolate is not available from the source case, obtain specimens from the child via gastric aspirate (**see Chapter XII for procedure**), BAL, sputum collection or tissue biopsy if extra-pulmonary disease is suspected.
- If the source case is known, obtain the susceptibility test results to assure effective treatment.
- If resistance is suspected in the source case or child, obtain specimens from the child for mycobacterial cultures.
- Consider a lumbar puncture to rule out meningeal tuberculosis for any child <4 years old with TB; a lumbar puncture is strongly recommended in children <2 years of age with suspected TB even in the absence of neurological symptoms.
- Any child with suspected TB and neurological symptoms should undergo prompt evaluation by a physician, preferably a pediatric infectious disease physician, a lumbar puncture, and an MRI of the brain with contrast.
- Hospitalized pediatric TB suspects and cases should be managed in accordance with specific pediatric infection control policies. Parents or guardians should be evaluated for TB disease early in the hospital stay.
- "Children younger than 10 years of age with primary tuberculosis rarely are contagious because their pulmonary lesions are small (paucibacillary disease), cough is not productive, and few or no bacilli are expelled." (American Academy of Pediatrics. *Tuberculosis*. In: Pickering LK, ed. Red Book: 2006 Report of the Committee on Infectious Diseases, 27th ed. Elk Grove Village, IL: American Academy of Pediatrics, 2006: 680.

D. Treatment

1. Standards of TB Disease Management

- a. Patients treated for pulmonary or extra-pulmonary TB should be examined by a physician, physician's assistant or nurse practitioner:
 - Within the first four weeks after presumptive or confirmed TB diagnosis;
 - Any time during treatment if there are signs or symptoms of significant drug toxicity;
 - Any time there is an indication that the patient is not responding to therapy; and
 - During the final month of therapy.

The exam should focus on signs and symptoms of pulmonary and extra-pulmonary disease at baseline, and resolution of such findings at the end of therapy.

- b. Suspects of any age should have an HIV test. This information is essential to ensure adequate and appropriate treatment.
- c. Isoniazid (INH), rifampin (RIF), pyrazinamide (PZA), plus ethambutol (EMB) is the standard initial four-drug regimen for all HIV-negative non-pregnant individuals.
- d. Prior to initiating any TB therapy, review all medications the individual is taking and assess for potential drug interactions. If medications used to treat other conditions are adjusted to account for interactions with TB treatment, it is critical to readjust them to former doses once TB medications are stopped.
- e. TB treatment orders must specify the name of the drug, dosage, frequency, route and length of treatment.
- f. Standing orders may not be used for drug treatment orders when treating active tuberculosis.
- g. The initial clinical assessment should include a listing of all other medical conditions and medications, as well as information about other providers involved in the patient's medical care (particularly the primary care provider). For example, a patient with TB and diabetes should have, at a minimum, the following data collected:
 - Primary care provider name and contact information (if patient has a primary care physician)
 - Most recent hemoglobin A1c value and date collected
 - List of known complications of diabetes (nephropathy, retinopathy, neuropathy)
- h. Patients with medical conditions besides TB who do not have an identified primary care provider should be assisted to find a primary care provider early in TB treatment
- i. Regular communication with other providers involved in the patients' care is an important aspect of TB disease management. At a minimum, communication with the primary care provider should occur at the beginning and end of TB treatment.
- j. **Any variation (drugs, dosage, or length of treatment) from the NC recommended regimens is to be discussed with the attending physician and the TB Nurse Consultant or the TB Control Program physician.**
- k. All TB drug dosages should be calculated according to mg/kg body weight and rounded up to the next available dose supplied by the manufacturer, not to exceed maximum safe dosage for each drug; **(see dosage table later in this chapter).**
- l. Adjust weight-based dosage as weight changes; All patients should be weighed monthly.

- m. All tuberculosis medications should always be administered at the same time (no split doses and all TB drugs simultaneously).
- n. **Directly observed therapy (DOT) is the standard of care for the management of TB disease and is required by law (10A NCAC 41 A .0205 (e)).** Video DOT may be used when appropriate. See more information regarding video DOT in Chapter IX.
- o. Never add a single drug to a failing regimen.
- p. Every patient must be assessed at least monthly for adverse reactions and the findings documented (DHHS 2810).
- q. If response is slow or sub-optimal (failure to convert sputum cultures at the end of 10 - 12 weeks of treatment and/or lack of improvement in initial symptoms), contact your TB Nurse consultant. The individual should be evaluated for adherence, drug absorption, and drug resistance; treatment may need to be prolonged
- r. The standard length of treatment for uncomplicated pan-sensitive TB is a minimum of six months (26 weeks) and at least four months (18 weeks) of treatment following sputum culture conversion (whichever is longer)
- s. **If it is necessary to use second line TB drugs during treatment, the expertise of the TB Control Program physicians should be utilized.**
- t. Conversion date is defined as the date of the first sputum specimen collected that does not grow *Mycobacterium tuberculosis* with no subsequent sputum cultures demonstrating growth of *M. tuberculosis*; if subsequent cultures are found to be positive, this negates the conversion.
- u. If an individual is unable to produce sputum** and the attempt to collect a specimen is made under nursing supervision with clear documentation of the effort in the record, this may be considered a “clinical” conversion.

An attempt to collect an induced sputum by nebulizer should be made if a natural sputum specimen cannot be obtained **(see Chapter XII for procedure).
- v. TB medications in healthcare facilities or institutional/congregate settings should be administered daily by direct observation whenever treating disease.
- w. All suspected or confirmed TB cases must be reported to the regional TB Nurse Consultant using the North Carolina Electronic Disease Surveillance System (NCEDSS) within seven days of the patient being identified as a suspect.

- x. See variations in the length of treatment under specific regimens found in the remainder of this chapter.
- y. The physician should review all lab results and the medical record should indicate that the physician reviewed the lab results.
- z. When a patient is treated for active tuberculosis with rifampin, isoniazid, pyrazinamide, and ethambutol for eight weeks and active tuberculosis is ruled out, the patient can be considered adequately treated for latent TB infection.
- aa. If pyrazinamide cannot be used during the initial phase, do not use intermittent therapy and extend therapy to treat for a total of 39 weeks.

2. Standard Regimen for Adults \geq 12 yr. with Pulmonary TB

- a. The **intensive phase** (8 weeks) is intended to rapidly reduce the number of tubercle bacilli in the body. This phase consists of four-drug therapy:
 - INH, RIF, PZA, EMB, daily DOT for 8 weeks (56 doses, 40 of which must be directly observed);
 - If local program resources make daily therapy logistically unfeasible during the first two months, an alternative is to treat with daily DOT for 2 weeks (14 doses, of which 10 must be directly observed), followed by thrice-weekly DOT (**dose must be increased for intermittent therapy**) for 6 weeks (18 thrice-weekly doses).
 - Patients with HIV infection, positive sputum smears, and/or cavitory disease should be given highest priority for daily therapy during the intensive phase
 - **If PZA is not included in the initial regimen, the first eight weeks of treatment must be administered by daily DOT;**
 - If PZA is not included in the regimen within the first 2 weeks of treatment or PZA is contraindicated, a minimum of **nine months** of INH and RIF is required. (two months of PZA at the beginning of treatment is required for a six-month regimen to be effective);
 - Discontinue PZA after eight weeks if
 - the organism is fully susceptible to INH and RIF and the patient is tolerating both drugs or
 - if the initial cultures were negative and the individual is clinically improving
 - Discontinue EMB when either
 - drug susceptibility testing on the initial positive culture indicates that the organism is fully susceptible to INH and RIF and these drugs will remain in the regimen or
 - at eight weeks when an individual with negative cultures is determined to be improving clinically and tolerating the remaining drugs.

- b. The **continuation phase** (18 weeks) is intended to eliminate the smaller number of organisms that persist. If treatment is not continued long enough, some bacilli may survive and cause TB disease later.
 - For most patients, this should consist of isoniazid and rifampin thrice weekly DOT for 18 weeks (54 thrice-weekly doses).
 - Patients with HIV infection, positive acid-fast smears, and/or cavitary disease on plain chest radiographs are recommended to receive daily therapy for 18 weeks (with DOT given 5 days in 7, equal to 90 daily DOT doses) if local program resources permit.
- c. For patients who are initially sputum culture positive, two sputum specimens must be collected every two weeks after treatment is initiated until two consecutive sputum specimens have converted to culture-negative.
- d. If the patient has a cavity on initial x-ray **and** fails to convert two sputum specimens to negative within 60 days of starting treatment (based on the collection date), treatment must be extended for a total of nine months (**continuation phase of 31 weeks**).

3. Regimen for Pregnant Women

- INH, RIF, and EMB daily for eight weeks DOT (initial phase) followed by 31 weeks of INH and RIF (if fully susceptible) The first eight weeks of medicine must be administered on a daily basis since PZA is not routinely used during pregnancy
 - Continuation phase should ideally be administered daily, and must be administered daily if the patient is immunocompromised, smear-positive, or has a cavity on CXR. Thrice-weekly therapy is acceptable for other patients.
 - Discontinue EMB when initial culture results confirm it to be susceptible to INH and RIF – or at eight weeks if the initial cultures were negative **and** the individual is clinically improving.
- a. **PZA** is not routinely used in the United States in HIV-negative pregnant women because its effect on the fetus is unknown. However, for severe cases of TB or on advice of a NC TB Medical Consultant, PZA may be used in pregnancy.
 - b. **Streptomycin** should not be used when treating pregnant women because it interferes with the development of the ear and may cause congenital deafness.
 - d. Vitamin B6 should be given due to the risk for peripheral neuropathy in pregnancy.
 - e. INH, RIF and EMB all cross the placenta, but these drugs have not been demonstrated to have teratogenic effects on the fetus.
 - f. Small concentrations of TB medications in breast milk do not produce toxicity in the nursing newborn; therefore, breast-feeding should not be discouraged. (**see Chap. III regarding breast-feeding and B₆**).

4. Regimen for Infants and Children (<12 yr.)
- a. Refer to special diagnostics on page one of this chapter when TB in a child is suspected and obtain consultation from a pediatric infectious disease specialist.
 - b. Treatment of suspected central nervous system (CNS) TB should include corticosteroids in addition to the standard TB drugs.
 - c. **Initial phase** (8 weeks) is intended to rapidly reduce the number of tubercle bacilli in the body. This phase consists of:
 - INH, RIF, PZA, and EMB, daily DOT for eight weeks (56 doses, 40 of which must be directly observed).
 - Use EMB with caution for children who are unable to be vision-tested
 - c. **Continuation phase** is intended to eliminate the smaller number of organisms that persist. If treatment is not continued long enough, some bacilli may survive and cause TB disease later. The duration of the continuation phase in children depends on the extent of disease:
 - For children with nonsevere disease the duration of the continuation phase is 8 weeks (40 directly observed daily doses with self-administered doses on weekends). Nonsevere pulmonary or peripheral lymph node disease is defined as meeting all of the following criteria:
 - All respiratory samples and gastric aspirates are AFB smear-negative
 - Lung infiltrate confined to one lobe
 - No cavities on chest radiograph
 - No clinically significant airway obstruction
 - No evidence of miliary, abdominal, bone, meningeal, or congenital tuberculosis
 - Weight ≥ 3 kg
 - An alternative acceptable regimen for children with nonsevere disease consists of a continuation phase of 18 weeks with thrice-weekly dosing (54 directly observed doses).
 - For children who do not meet criteria for nonsevere disease the duration of the continuation phase is 18 weeks. Daily therapy (90 directly observed daily doses) is preferred but thrice-weekly therapy (54 directly observed daily doses) is acceptable with approval from the state TB medical director or state TB pediatric medical consultant.
 - Discontinue EMB when initial cultures results confirm the TB organism is susceptible to INH and RIF or at eight weeks if the initial culture results were negative **and** the child is clinically improving; and

- Discontinue PZA after eight weeks if the organism is fully susceptible to INH and RIF and the patient is tolerating both drugs or after eight weeks if the initial cultures were negative and the individual is clinically improving.
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- e. Infants and children with meningeal, bone/joint or miliary TB should receive a minimum of 9-12 months of treatment.
 - f. If PZA is not included in the first eight weeks, the initial phase of treatment must be administered by daily DOT and the regimen must be extended to nine months.
 - g. Infants and children should be weighed monthly and drug dosages adjusted accordingly.
 - h. Children weighing more than 40 kg should be dosed as adults.
 - i. Chest x-rays of children with hilar adenopathy may not become normal for two to three years after treatment. A normal chest x-ray is not required to consider treatment complete.
5. Regimen for HIV-negative Non-Pregnant Adults with Smear and Culture Negative Pulmonary TB
 - a. Treatment consists of INH, RIF, PZA, and EMB for eight weeks. (56 daily doses, 40 of which must be directly observed) At the completion of eight weeks of treatment, discontinue PZA and EMB and continue with INH and RIF thrice-weekly for a total of 16 weeks of treatment (24 additional thrice-weekly doses) **(if HIV-positive, treat for a total of 26 weeks; see Chapter V for further information).**
 - b. Obtain a chest film after two months of treatment. If there is no improvement on x-ray, consult the physician regarding a possible change in the diagnosis.
 - c. If the source case is known to have drug resistant TB, refer to the regimens for resistant TB in this chapter.
 6. Regimen for Adults with Extra-pulmonary Tuberculosis

Individuals with TB disease at any site should have a chest x-ray and sputum specimens for smear/culture (if able to produce sputum) done during the diagnostic phase to rule out pulmonary involvement.

 - a. Extra-pulmonary TB can be treated with the same drug regimens and for the same length of time as pulmonary TB (standard six-month regimen - 26 weeks) with the following exceptions:
 - Meningeal/CNS TB should be treated for 9-12 months based on response to treatment;

- Bone/joint TB should be treated for 6-9 months based on response to treatment; and
 - If there are questions regarding a prescribed treatment regimen, please consult with the N.C. TB Control Program.
- b. Corticosteroids can be beneficial in improving survival in patients with TB meningitis, particularly if administered early in the course of disease. They should be administered in most cases of TB meningitis according to the current ATS/CDC/IDSA guidelines:
- TB meningitis: The recommended regimen is dexamethasone in an initial dose of 8 mg/day for children weighing less than 25 kg and 12 mg/day for children weighing 25 kg or more. This dose should be continued for one week, with a gradual tapering down each week for the next 5 weeks, with discontinuation after 6 weeks. Adults with severe disease (grade II or III, corresponding to Glasgow Coma Scale scores below 15 or with focal neurologic signs) should receive the following dexamethasone regimen:
 - 0.4 mg/kg daily for 1 week, followed by
 - 0.3 mg/kg daily for 1 week, followed by
 - 0.2 mg/kg daily for 1 week, followed by
 - 0.1 mg/kg daily for 1 week, followed by
 - 4 mg daily for 1 week, followed by
 - 3 mg daily for 1 week, followed by
 - 2 mg daily for 1 week, followed by
 - 1 mg daily for 1 week, then stop
 - Adults with less severe disease (grade I, corresponding to Glasgow Coma Scale score of 15 and no focal neurologic signs) should receive the following dexamethasone regimen:
 - 0.3 mg/kg daily for 1 week, followed by
 - 0.2 mg/kg daily for 1 week, followed by
 - 0.1 mg/kg daily for 1 week, followed by
 - 3 mg daily for 1 week, followed by
 - 2 mg daily for 1 week, followed by
 - 1 mg daily for 1 week, then stop
7. Rifapentine (RPT) Option for Treating HIV-negative Adults \geq 18 years old
- a. Once weekly INH and RPT is no longer recommended for general use in treating active TB.
8. Treatment of *M. bovis* Including BCG Strain
- a. If *M. bovis* is isolated from urine specimens following intravesical BCG treatment, treatment may not be necessary; clinical consultation with a physician who has experience in management of BCG should be sought.
- b. If *M. bovis* is isolated from pulmonary specimens following intravesical BCG treatment, the patient should receive treatment for tuberculosis disease.

- c. If you receive a positive *M. tuberculosis complex* culture report on an individual who has been treated with BCG for bladder cancer, notify your nurse consultant.
- d. *M. bovis* is always resistant to PZA.
- e. Use INH and RIF for the initial regimen and treat for nine months (39 weeks) using daily administration during the first eight weeks.
- f. Remember that *M. bovis* is one of the organisms found in the *Mycobacterium tuberculosis complex* (**see Chapter 12, Laboratory Services**). If drug susceptibility testing shows mono-resistance to PZA, the disease is likely due to *M. bovis*; the genotype information can be used to determine if it is the BCG strain.
- g. If a specimen is found to be *M. bovis*, BCG strain this is not counted as a communicable disease and is not reported as a TB case.

E. Drug Resistant TB

1. Patients who are resistant to TB drugs will need an alternative regimen. The alternative regimen should be discussed with a state TB Medical Consultant on a case-by-case basis.
2. Primary resistance occurs when resistant tubercle bacilli are isolated before any TB drugs are administered. Patients with risk factors for primary resistance should have an early specimen (smear-positive sputum or positive culture) sent for molecular detection of drug resistance (MDDR testing). Risk factors for primary resistance are:
 - a. Exposure to a TB patient who has drug-resistant TB disease;
 - b. Being from a country with a high prevalence of drug resistance (foreign-born from Latin America, the Caribbean, Eastern Europe, Asia, or Africa); and
 - c. Member of a population with ≥ 4 percent resistance to INH
3. Acquired resistance occurs when resistant tubercle bacilli are isolated during treatment or isolated from those who have been treated in the past. Risk factors for acquired resistance are:
 - a. Individuals who do not follow their prescribed treatment schedule;
 - b. Inadequate or inappropriate drug regimen; and
 - c. Malabsorption (can lead to sub-therapeutic serum drug levels).
4. Regimens for INH Resistance or Intolerance (**Consult with a State TB Medical Consultant**)
 - a. Individuals on an initial regimen of INH, RIF, PZA, and EMB:
 - Discontinue INH; continue to treat with RIF, PZA, and EMB for a total of six months (26 weeks). A fluoroquinolone (moxifloxacin or

levofloxacin) should generally be added to this regimen, particularly in cases of extensive disease.

- b. Individuals on an initial regimen of INH, RIF, and EMB (no PZA):
 - Discontinue INH; continue to treat with RIF and EMB;
 - A fluoroquinolone (moxifloxacin or levofloxacin) may be added to this regimen, particularly in cases of extensive disease
 - The initial phase (the first eight weeks) must be administered by daily DOT); and
 - Treat for a minimum of 12 months.
 - c. Individuals on initial regimen of INH and RIF:
 - Repeat susceptibility studies;
 - Discontinue INH and continue RIF; and
 - Add PZA and EMB to the regimen if susceptible to these two drugs and then treat for six months (26 weeks) with the three drugs. A fluoroquinolone (moxifloxacin or levofloxacin) should be added to this regimen, particularly in cases of extensive disease.
5. Regimen for RIF Resistance or Intolerance (**Consult with a State TB Medical Consultant**)
- a. Individuals on initial regimen of INH, RIF, PZA, and EMB:
 - Discontinue RIF;
 - Continue to treat with INH, PZA and EMB daily during the initial phase (the first eight weeks);
 - Strongly consider adding a fluoroquinolone to this regimen and
 - After the initial phase continue INH and EMB (+/- fluoroquinolone) daily or intermittently
 - Treat for a total of 18 months (78 weeks).
6. Regimen for PZA Resistance or Intolerance (**Consult with a State TB Medical Consultant**)
- a. An "*M. tuberculosis* complex" isolate that is PZA monoresistant is likely to be *M. bovis* (which is always PZA resistant). *M. bovis* can be acquired through unpasteurized milk or cheese, and, if the site of disease is pulmonary, can be contagious to others.
 - b. Individuals on an initial regimen of INH, RIF, PZA and EMB:
 - Discontinue PZA and EMB if sensitive to RIF and INH;
 - Treat with INH and RIF for nine months (39 weeks); and
 - The initial phase (the first eight weeks) must be administered by daily DOT.
7. Multi-Drug Resistant TB (MDR-TB) (**Consult with a State TB Medical Consultant**)
- a. MDR-TB is resistant to both INH and RIF and may also be resistant to other first or second line drugs.

- b. Treatment must be individualized and prolonged based on medication history and susceptibility studies.
- c. Give at least four medications to which the organism is susceptible.
- d. The regimen should continue until sputum conversion is documented, followed by at least 12 months of treatment.
- e. Only daily therapy is used in the treatment of MDR-TB.
- f. **The N.C. TB Control Program should be consulted regarding the treatment regimen whenever treating an MDR-TB case.**

F. Pyridoxine (B₆)

1. Peripheral neuropathy is associated with INH but is uncommon at dosages of 5 mg/kg of body weight.
2. Patients with the following conditions in which neuropathy is common should receive B₆ 25 mg. daily or 50 mg twice or thrice weekly:
 - Diabetes mellitus;
 - Average alcohol use of >three drinks per day;
 - Malnutrition;
 - HIV infection;
 - Pregnancy; and
 - Seizure disorder.
3. Pyridoxine (B₆) is recommended for exclusively breastfed infants and for children and adolescents on milk and meat and deficient diets; children with nutritional deficiencies, including all symptomatic HIV-infected children:
 - Dosage for infants and children (contact physician for order): 1 mg/kg body weight (maximum 25mg daily).
4. Individuals that develop peripheral neuropathy while taking daily B₆ should have their B₆ dose doubled. If neuropathy is not resolved within two weeks, consult the physician.
5. Individuals on dialysis should be given B₆ 50mg on the same schedule as INH

G. Dosing for Adults with Reduced Renal Function (creatinine clearance <30ml/min) on Hemodialysis¹

1. Medications should be given after hemodialysis on the day of dialysis (dialysis is normally done three times a week).
 - a. Monitoring of serum drug concentrations should be considered to ensure adequate absorption and to assist in avoiding toxicity.
 - b. Ethambutol is difficult to manage in renal insufficiency and therefore is used less often, usually only when resistance is an issue.

- c. There is no clinical evidence for using 250 mg of cycloserine daily; there should be careful monitoring for evidence of neurotoxicity.

Isoniazid	No change
Rifampin	No change
Pyrazinamide	25-35 mg/kg thrice weekly (not daily)
Ethambutol	20-25 mg/kg thrice weekly (not daily)
Levofloxacin	750-1000 mg thrice weekly (not daily)
Moxifloxacin	No change
Cycloserine	250 mg daily or 500 mg thrice weekly
Ethionamide	No change
PAS	No change
Streptomycin	15 mg/kg twice or thrice weekly (not daily)
Capreomycin	15 mg/kg twice or thrice weekly (not daily)
Kanamycin	15 mg/kg twice or thrice weekly (not daily)
Amikacin	15 mg/kg twice or thrice weekly (not daily)
Linezolid	No change
Bedaquiline	No change
Clofazimine	No change

¹ Nahid P et al, Official American Thoracic Society/Centers for Disease Control and Prevention/Infectious Disease Society of America Clinical Practice Guidelines: Treatment of Drug-Susceptible Tuberculosis. *Clinical Infectious Diseases* 2016; 63(7): e147-195.

H. Directly Observed Therapy and Counting Doses

1. **Directly Observed Therapy (DOT) is the standard of care for the management of TB disease and is required by law (10A NCAC 41 A .0205 (e)).**
2. Directly Observed Therapy (DOT) is the documented actual observation of medication ingestion by a health care worker (HCW). This specifically excludes family members and significant others. Video DOT may be used when appropriate. See guidance about video DOT later in this chapter.
3. Document each DOT dose on the back of the Tuberculosis Drug Record (DHHS 1391).
 - a. When DOT is delegated to a health care worker outside the health department, the TB nurse retains ultimate responsibility for documenting the monthly patient assessment (regardless of who observed the medication ingestion) and for patient management.
 - b. Document the observer's understanding and willingness to:
 - Assume responsibility for actual observation of ingestion;
 - Document ingestion of TB drugs;
 - Report to PHN any patient complaints;
 - Notify PHN immediately when dose(s) are missed; and
 - Request relief from DOT responsibility if does not wish to continue.
4. Daily DOT must be administered Monday through Friday. Unit doses may be self-administered on weekends; five DOT doses are considered a DOT week.

5. Thrice weekly DOT requires a physician's order to increase the dosage and is administered on a Monday/Wednesday/Friday schedule.
6. Thrice weekly dosages should not be given to the patient to self-administer. If the patient must self-administer, such as, during a vacation, daily dosing should be given to the patient to self-administer.
7. Twice weekly DOT scheduling should be adjusted for holidays so that both doses can be given by DOT that week; it is permissible to give both twice weekly doses at least 48 hours apart if holidays require doing so.
8. In order to ensure that all doses are administered by DOT, please make up any self-administered doses (except weekends) with a DOT dose; this will allow for 100 percent DOT when reporting to the TB Control Program using the CDC Follow Up 2 form and will ensure adequate treatment.
9. How to count doses:
 - During intensive phase, count DOSES. To complete 8 weeks of intensive phase, the patient must ingest 40 doses directly observed. If more than two consecutive weeks are missed during intensive phase, counting must restart at zero doses received.
 - During continuation phase, count WEEKS. A week of therapy can count toward completion of treatment under the following circumstances:
 - If the patient is receiving daily therapy, at least five daily doses of therapy are observed (four doses is acceptable if a holiday falls during that week and the patient is self-medicating on weekends also)
 - If the patient is receiving therapy three times weekly, if three doses were observed during the week and each dose was separated from the next dose by at least a day
 - If the patient is receiving therapy three times weekly, up to two weeks may be counted in which only two doses were received, as long as those doses were at least 72 hours apart
 - If more than three consecutive months (12 weeks) are missed in the continuation phase, the entire course of treatment must be started over from the beginning

I. North Carolina Video Directly Observed Therapy Policies and Procedures

Purpose:

To provide guidelines for the use of video directly observed therapy (video DOT) by public health providers in North Carolina. Video DOT is defined as the use of remote video (e.g. streaming video using a service such as Skype or Facetime) by a **healthcare worker** to observe a patient ingesting medication.

Policies:

- 1) Public health staff may use video DOT to supervise ingestion of medications for selected patients with active or latent tuberculosis who meet the inclusion criteria listed below

- 2) For TB control/program purposes, video DOT is considered equivalent to in-person directly observed therapy
- 3) Patient adherence with video DOT should be continuously monitored, and if any concerns arise there should be a low threshold to resume conventional directly observed therapy
- 4) Monthly in-person monitoring visits will be conducted by the local health department TB nurse

Policy:

Administrative Requirements

The following administrative requirements must be met prior to initiation of video DOT:

- 1) Signed order by the attending public health/tuberculosis physician
- 2) Signed treatment agreement

Technological Requirements

- 1) Patient must have a working mobile phone with videophone (e.g. Facetime) capability that can interface with corresponding technology at the local health department OR
- 2) Patient must have a working computer with broadband internet connectivity and a webcam capable of transmitting sound and video

Patient Selection

Video DOT may be offered to adult (18 and over) patients with active TB that meet the following criteria:

- 1) Good response to treatment, as judged by the treating clinician. Examples of a good response would be decreasing degree of sputum smear positivity and/or improved signs and symptoms.
- 2) Motivated to complete treatment with psychosocial support to attain this goal.
- 3) No prior problems with missed DOT doses, missed appointments, or nonadherence.
- 4) Patient has demonstrated successful swallowing of all pills within a five-minute period.
- 5) No treatment interruptions due to medication toxicity or intolerance.
- 6) Stable residence and living conditions.
- 7) Able to communicate directly with TB program staff using appropriate language skills
- 8) Patient must be able to clearly identify by name and quantity each drug as it is ingested while provider maintains a clear view of the patient's face and mouth.
- 9) There is no known resistance to any of the first-line anti-tuberculous drugs (isoniazid, rifampin, pyrazinamide, or ethambutol); if drug resistance is identified the state nurse consultant should be contacted regarding whether continued VDOT is appropriate.
- 10) In-person DOT is strongly recommended for at least the first 14 doses of treatment for most patients with pulmonary TB, particularly smear-positive TB. Patients with latent TB may be offered Video DOT at the start of latent TB treatment at the discretion of the patient and treating clinician.

Video DOT Procedure

- 1) Patient and public health provider will establish a standing video DOT appointment time and contact procedure that is mutually convenient prior to initiation of video DOT.

- 2) Patient will be informed that video DOT is voluntary and may be discontinued (with resumption of face-to-face DOT) at any time at the discretion of the patient or provider.
- 3) Patient and public health provider will test the video connection prior to administration of the first video DOT dose. For a mobile phone setup, this should consist of a test video call between the patient and provider while the patient is in the clinic. For a home computer setup, this should consist of a test video call at a time mutually convenient for the patient and provider.
- 4) Key elements to be verified during the test call:
 - a. Video is of adequate quality to observe pills and to visualize the patient's open mouth
 - b. Patient and public health provider have correct mutual contact identifiers (e.g. phone numbers, Skype ID, etc.)
- 5) Video DOT should not be initiated until a successful test call has been conducted
- 6) The patient should be advised to perform video DOT in a private location to preserve confidentiality. Confirmation of the confidentiality of the setting by the video DOT provider is strongly recommended at the beginning of the first few calls, at a minimum. If others are present in the room, the provider should confirm that the patient wants to proceed with video DOT while those individuals are present in the room.
- 7) A successful video DOT call should consist of the following elements:
 - a. Provider verifies the identity of the patient by visual recognition
 - b. Provider visualizes the pills to be taken and verifies that the doses and medications are correct
 - c. Provider directly visualizes the patient swallowing all of the pills
 - d. After the last pill is swallowed, patient will display the empty mouth on the video to verify that no pills remain in the mouth
 - e. Provider will speak with the patient for at least 30 seconds after ingestion of the last pill as a second check that no pills remain in the mouth. The patient should speak during this time and reciting a standardized phrase (e.g. the alphabet) is encouraged.
 - f. Provider will document the DOT visit in NCEDSS per standard procedure
- 8) If the patient wishes to discuss private information with the healthcare provider via video DOT, the provider should remind the patient that video DOT (like telephone and internet communication) is not completely secure and confirm that the patient wishes to proceed with the discussion via video DOT. Other means of communication (e.g. telephone, face-to-face) should always be offered if the patient prefers these to video DOT.
- 9) Patients should be provided no more than a thirty-day supply of medication, and a face to face visit should occur on at least a monthly basis. Medications should be provided labeled in appropriate containers in accordance with NC Pharmacy regulations.

J. Monitoring

1. Baseline Evaluation

- a. The TB Nurse needs to visit the patient either in the hospital or in the home as soon as possible after notification to establish a working relationship.

- b. Obtain medical history using the TB Epidemiological (EPI) Record (DHHS 1030).
- c. Complete a baseline evaluation using the Tuberculosis Flow Sheet (DHHS 2810).
- d. Obtain a signed TB Treatment Agreement (**see sample agreement later in this chapter**). Include the following in the document:
 - Treatment regimen and frequency;
 - Required monitoring e.g. x-rays, sputum, lab work, appointments; and
 - Other requirements pertinent to the situation.
- e. If infectious, advise the patient to remain at home, exclude outside visitors and wear a mask to medical appointments until s/he becomes non-infectious as determined by the health department.
- f. Collect supervised sputum regardless of prior pulmonary or pleural specimens obtained elsewhere. Provide individual with two additional containers for collection of consecutive early morning specimens to be sent to the State Laboratory. (**refer to Chapter IX for procedure**).
- g. Have patient identify persons at risk for exposure and possible infection and prepare a list of contacts for tuberculin skin testing or IGRA testing.
- h. Obtain documented TST mm reading **or** administer TST and record mm reading **or** documented IGRA test result **or** obtain IGRA and record results; IGRA/TST is recommended but not required if the individual is known to be *M. tuberculosis* culture positive.
- i. Draw blood or obtain laboratory results for those ≥ 15 years old including:
 - Hepatic function panel;
 - Serum creatinine; and
 - CBC with platelet.
- j. Consult physician if any baseline laboratory test is abnormal; if within normal limits, no further testing is necessary unless the patient has evidence of toxicity.
- k. All children and adults should have HIV testing done or results documented.
- l. Individuals taking Ethionamide or p-Aminosalicylic acid (PAS) should have baseline thyroid function tests.
- m. Individuals taking Streptomycin, Amikacin, Kanamycin, or Capreomycin should have BUN and Creatinine monitored at baseline.
- n. Individuals taking Capreomycin should have potassium and magnesium monitored at baseline.

- o. Baseline visual acuity (Snellen) and color perception testing (red/green-Ishihara test) on individuals to be treated with ethambutol.
 - p. Perform baseline hearing/ataxia testing on individuals to be treated with streptomycin (SM), Capreomycin, Kanamycin, and Amikacin using screening audiometry and tandem gait test (heel-to-toe in a straight line for four-six steps).
 - q. Calculate and verify each prescribed medication dosage. Calculate on the lower figure in the range and round up to the next available dose supplied by the manufacturer; any dosage within the therapeutic range is acceptable.
 - r. If the specimen submitted is NAAT positive (i.e. PCR positive) or culture positive for *M. tuberculosis* and the patient is at high risk for drug resistance (previously treated for TB, a contact to a drug resistant case or is from a country with a high incidence of drug resistant TB) have the state lab submit an isolate to the CDC for Molecular Detection Drug Resistance (MDDR) testing.
2. Follow-up monitoring
- a. Complete the Tuberculosis Flow Sheet (DHHS 2810) monthly.
 - b. Make a home visit to:
 - Further identify personal and socioeconomic barriers to treatment adherence; and
 - Re-interview to ensure all contacts have been identified.
 - c. Obtain a set of two consecutive early morning sputum specimens every two weeks (if diagnostic specimen was sputum), until cultures convert to negative. **Supervise the collection of one specimen in each set.**
 - d. Check visual acuity (Snellen) and color perception (red/green, Ishihara test) **monthly** while individual is taking EMB. Report any changes in visual acuity or color perception to the TB physician.
 - e. Individuals taking ethionamide or p-aminosalicylic acid (PAS) should have thyroid function monitored monthly
 - f. Individuals taking Streptomycin, Amikacin, Kanamycin, or Capreomycin should have BUN and Creatinine monitored at least weekly.
 - g. Individuals taking Capreomycin should have potassium and magnesium monitored monthly.
 - h. Individuals taking linezolid should have a complete blood count monitored weekly.
 - i. Perform hearing acuity using screening audiometry and tandem gait test (heel-to-toe in a straight line for four-six steps) monthly while individual is taking SM, capreomycin or amikacin, or kanamycin. Report any

changes in audiometric screening or tandem gait testing to the TB physician.

- j. Obtain monthly hepatic function panel for the following individuals:
 - Abnormal baseline hepatic function;
 - Pregnant or up to 3 months postpartum;
 - Those with symptoms of adverse reactions;
 - Persons taking potentially hepatotoxic drugs;
 - Persons with chronic active hepatitis B or those with hepatitis C;
 - Chronic or binge use of alcohol; and
 - Persons with HIV infection.

- k. Consult physician anytime hepatic function testing results are abnormal.

- l. If the patient does not clinically improve and/or sputum cultures do not convert from positive to negative within 10-12 weeks:
 - Arrange for patient to be evaluated by a physician or mid-level provider;
 - Repeat susceptibilities testing on latest positive MTB sputum culture if cultures are still positive at 10-12 weeks;
 - Consult with regional TB nurse consultant regarding serum drug levels. Information regarding serum drug levels may also be found in chapter IX; and
 - Consult with the state TB medical clinician to discuss serum drug level results, appropriate dosing of TB medicines, and length of therapy.

- m. Review at least monthly for hepatotoxicity and other drug reactions:
 - Nausea;
 - Vomiting;
 - Loss of appetite;
 - Dark urine (cola color);
 - Yellow skin or sclera;
 - Malaise;
 - Abdominal tenderness;
 - Unexplained fever lasting three days or more;
 - Unexplained abdominal bloating;
 - Rash;
 - Pruritus;
 - Paresthesias of the hands or feet;
 - Bruising;
 - Flu-like symptoms; and
 - Abnormal bleeding.

- n. If the individual exhibits signs or symptoms of possible toxicity:
 - Temporarily stop the medications.
 - Do lab work appropriate to symptoms.
 - Contact the prescribing physician to discuss symptoms, lab results, and any needed changes in the treatment plan.
 - Patients with confirmed or strongly suspected TB should not remain off all TB medications for much longer than a week. Consultation

with one of the State TB physicians should be initiated if there is any question or delay in finding an acceptable treatment regimen

- o. Obtain a chest x-ray after two months of treatment if pre-treatment culture results were negative. If no improvement on x-ray, consult physician regarding possible change in original diagnosis.
- p. Obtain a chest x-ray during the final two weeks of therapy on all individuals with pulmonary and pleural TB disease. This provides a comparison film for future reference. **Length of treatment should not be based on end of treatment chest x-ray results.**
- q. The patient should be evaluated by the referring physician, primary care provider or health department TB physician in the final weeks of treatment.
- r. Discharge the individual from service after providing education and instructions to return if symptoms occur. A record of completion of TB treatment should be given to the patient to keep as part of his personal medical record.

ACTIVITY	WHEN ACTIVITY IS NEEDED
Home visit	At baseline and as needed
Clinical assessment	At baseline and monthly
Sputum samples	Obtain initially, then two specimens every two weeks
Chest x-ray	At baseline and two weeks before ending therapy. Also obtain if the initial sputum cultures are negative to determine if this is a clinical case.
TST or IGRA	At baseline
Hepatic Function Panel	At baseline. Monthly thereafter if at risk for hepatotoxicity and anytime symptoms suggest hepatotoxicity.
CBC for adults	At baseline. Weekly thereafter if patient is taking linezolid.
Creatinine for adults	At baseline
HIV for adults and children	At baseline
Vision Screening while on EMB	At baseline and monthly
TST or IGRA for Contacts to Case	As baseline and eight weeks after last exposure

K. TB Drug Adverse Reactions

Evaluation of all adverse reactions should include a hepatic function panel to rule out hepatotoxicity and consultation with the prescribing physician.

Common Adverse Reactions to First-Line TB Drugs

Adverse Reactions	Signs and Symptoms	Lab Test	Usual Causes
Dermatitis	pruritus, rash, hives, fever		PZA, RIF, INH, rarely EMB
Hepatitis	anorexia, nausea, vomiting, fatigue, dark urine, jaundice	ALT, AST, Bilirubin	INH, RIF, PZA, rarely EMB
GI upset	anorexia, nausea, vomiting, epigastric pain		PZA, RIF
Peripheral neuropathy	numbness or paresthesia's of feet and hands		INH
Joint signs and symptoms	pain, swelling, tenderness, heat, redness	Uric Acid	PZA, RIF
Renal signs and symptoms	hematuria, uremia	Serum Creatinine	RIF
Hematologic manifestations	leukopenia, thrombocytopenia	CBC with platelets	RIF, INH, PZA, RBT, EMB
Uveitis	inflammation of the iris, choroid and sub-scleral layer of the eye		RBT
Optic neuritis	decrease in vision and/or loss, color blindness		EMB

For more information about adverse reactions and drug interactions for 1st and 2nd line tuberculosis drugs, see Nahid P et al. Official American Thoracic Society/Centers for Disease Control and Prevention/Infectious Disease Society of America Clinical Practice Guidelines: Treatment of Drug-Susceptible Tuberculosis. Clinical Infectious Diseases 2016; 63(7): e147-195. This document is available on line at <http://cid.oxfordjournals.org/content/63/7/e147>

1. Rash

- a. If the rash is minor and or manifested primarily by itching, the medical provider may treat with antihistamines which may provide symptomatic relief.
- b. If the rash is petechial, it may be due to rifampin induced thrombocytopenia. Stop TB medicines and contact TB physician. Obtain order for CBC with diff and platelets and a hepatic function panel and report results to TB physician as soon as possible. If rifampin is discontinued due to thrombocytopenia notify regional nurse consultant.

- c. If there is a generalized erythematous rash, particularly if associated with fever and/or mucous membrane involvement, stop all drugs immediately and notify physician.
- d. If patient experiences swelling of the face, throat or difficulty breathing, call 911 and activate emergency services immediately.

2 Nausea/vomiting and other GI distress

- a. Obtain a hepatic function panel to rule out hepatotoxicity.
- b. If no hepatotoxicity is present, the provider should consider the use of an anti-nausea medicine 30 minutes before the TB medications are administered or offer TB drugs with food.

3. Hepatotoxicity

- a. If signs and symptoms of hepatotoxicity are **present**:
 - Temporarily stop medications;
 - Draw hepatic function panel;
 - Contact the prescribing physician to discuss symptoms and lab results and any needed changes in the treatment plan;
 - The prescribing physician should refer to the hepatotoxicity flowchart at the end of chapter III; and
 - Contact the regional TB Nurse Consultant if ALT>3 times the upper limit of normal (ULN) or the bilirubin is > 2.5.
- b. If signs and symptoms of hepatotoxicity are **not present**, manage individuals according to hepatotoxicity flowchart at the end of chapter III.
- c. Hepatitis due to other causes needs to be ruled out using appropriate serologies i.e., HBsAg, antiHBc-IgM, HAV IgM, HCV.
- d. Changes to a standard four drug TB regimen (INH, RIF, EMB, PZA) must be approved by a state TB medical consultant.

L. Reintroduction of TB Medication for Hepatotoxicity

- 1. **Stop all TB medications if lab work is abnormal and consult physician.** Patients with confirmed or strongly suspected TB should not remain off all TB medications for much longer than a week. Consultation with one of the State TB physicians should be initiated if there is any question or delay in finding an acceptable treatment regimen.
- 2. Monitor liver enzymes until level reflects a continuing decrease before restarting any TB drugs (ideally ALT< 2x ULN).
- 3. Reintroduce drugs in the following order (see protocol below):
 - ethambutol (EMB) and rifampin (RIF).
 - isoniazid (INH).
 - pyrazinamide (PZA).

- PZA is reintroduced only if individual has not completed the initial eight weeks of PZA.
 - EMB is reintroduced at a full therapeutic dose if drug susceptibilities are not yet available and the drug is needed for the initial treatment regimen.
4. Monitor liver enzyme levels weekly and evaluate results before adding another drug to the regimen.
 5. Because reintroduction takes approximately three weeks, for patients with extensive or severe disease, it may be prudent to give at least two non-hepatotoxic TB drugs during this time, e.g., EMB and a fluoroquinolone (moxifloxacin or levofloxacin).
 6. Contact North Carolina Tuberculosis Control for assistance in determining the appropriate length of therapy once reintroduction of drugs is complete and therapeutic dosages are achieved.

M. Suggested Flow Chart for Reintroducing TB Medications (daily administration)

Week #1:

Dose #1	EMB (full dose), RIF 600 mg
Dose #2	EMB, RIF 600 mg
Dose #3	EMB, RIF 600 mg.
Dose #4	EMB, RIF 600 mg
Dose #5	EMB, RIF 600 mg

Draw hepatic function panel

Week #2:

Dose #6	EMB, RIF 600 mg, INH 300 mg
Dose #7	EMB, RIF 600 mg, INH 300 mg
Dose #8	EMB, RIF 600 mg, INH 300 mg
Dose #9	EMB, RIF 600 mg, INH 300 mg
Dose #10	EMB, RIF 600 mg, INH 300 mg

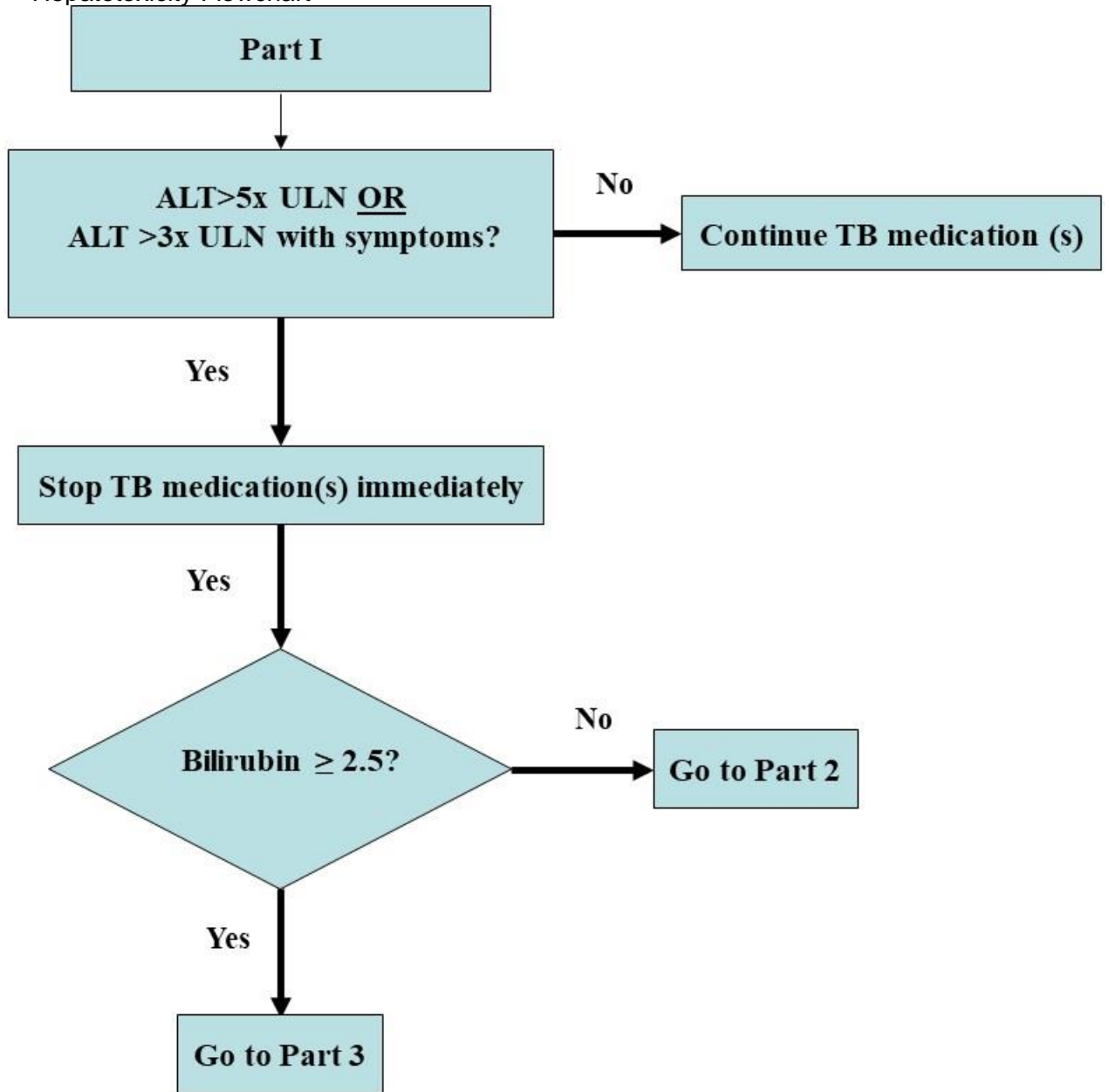
Draw hepatic function panel

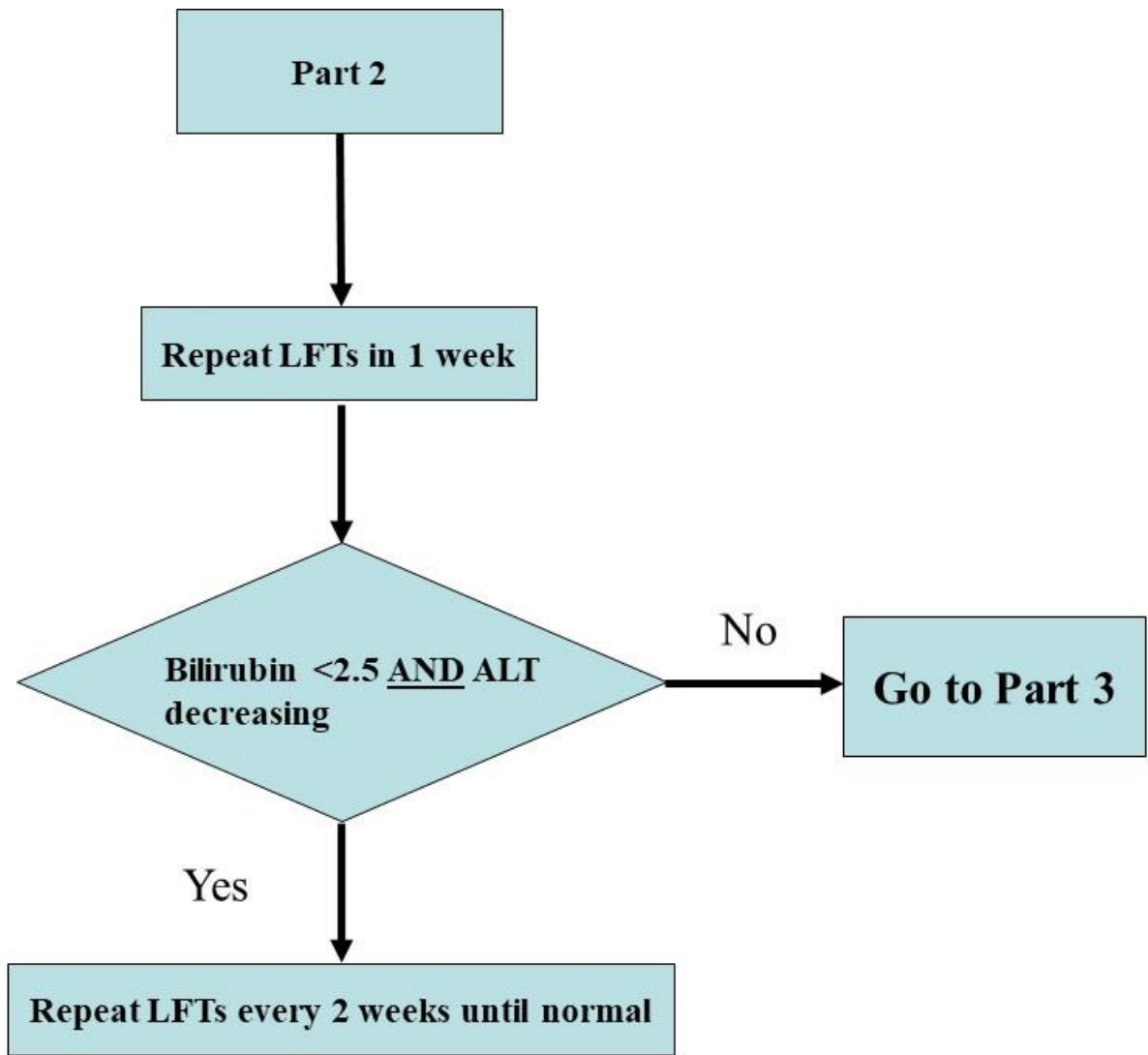
Week #3:

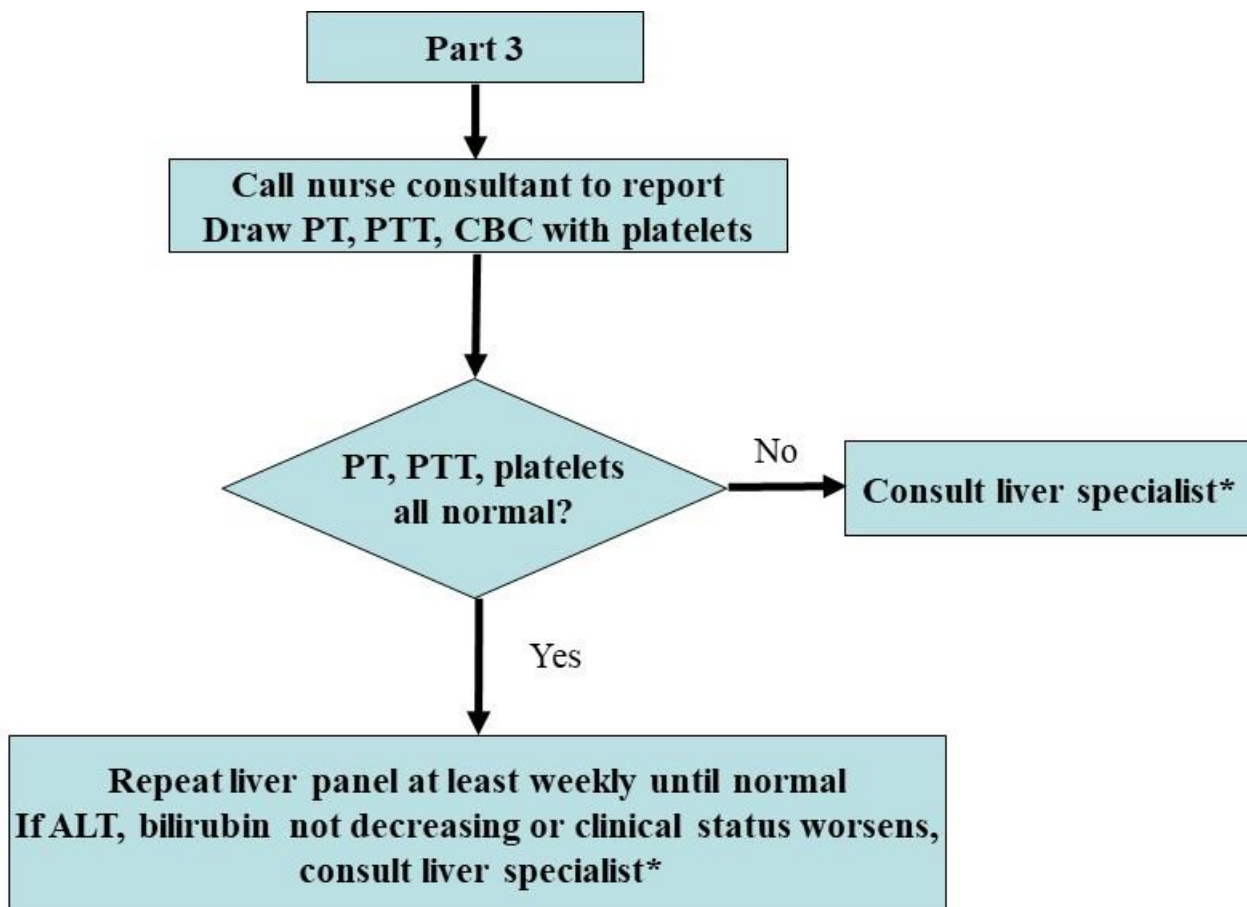
Dose #11	EMB, RIF 600 mg, INH 300 mg, PZA 500 mg
Dose #12	EMB, RIF 600 mg, INH 300 mg, PZA 1000mg
Dose #13	EMB, RIF 600 mg, INH 300mg, PZA 1500 mg
Dose #14	EMB, RIF 600 mg, INH 300mg, PZA full dose
Dose #15	EMB, RIF 600 mg, INH 300mg, PZA full dose

Draw hepatic function panel

N. Hepatotoxicity Flowchart







O. Reporting Cases

1. When a suspected or confirmed TB case is identified, a reporting tool wizard must be completed in NCEDSS then assigned to the regional TB nurse consult for review within seven business days of the case being reported. When a TB case is confirmed, a RVCT question summary wizard must be completed in NCEDSS and assigned to the regional TB nurse consultant. This should be completed within 12 weeks of the person starting TB medication. See below for descriptions of confirmed cases.
 - a. Laboratory confirmed cases
 - Isolation of *M. tuberculosis* complex from a clinical specimen. The use of rapid identification techniques for *M. tuberculosis* performed on a culture from a clinical specimen, such as DNA probes and high-pressure liquid chromatography (HPLC), is acceptable under this criterion.
 - Demonstration of *M. tuberculosis* from a clinical specimen by nucleic acid amplification (NAA) test. NAA tests must be accompanied by cultures of mycobacterial species. However, for surveillance purposes, CDC will accept results obtained from NAA tests approved by the FDA and used according to the approved product labeling on the package insert, or a test produced and validated in accordance with applicable FDA and Clinical Laboratory Improvement Amendments (CLIA) regulations.
 - Demonstration of acid-fast bacilli (AFB) in a clinical specimen when a culture has not been or cannot be obtained or is falsely negative or contaminated; historically this criterion has been most commonly used to diagnose TB in the postmortem setting.
 - b. Clinical case definition– In the absence of laboratory confirmation of *M. tuberculosis* complex after a diagnostic process has been completed, persons must have **all** of the following criteria for clinical TB:
 - Evidence of TB infection based on a positive tuberculin skin test result or positive interferon gamma release assay for *M. tuberculosis*.
 - One of the following:
 - Signs and symptoms compatible with current TB disease, such as an abnormal chest radiograph or abnormal chest computerized tomography scan or other chest imaging study; or
 - Clinical evidence of current disease (e.g., fever, night sweats, cough, weight loss, hemoptysis).
 - Current treatment with two or more anti-TB medications.
 - c. A final diagnosis should be made by the TB clinician, in conjunction with the treating physician if indicated, within two months of initiating therapy.
 - d. Submit the Report of Verified Case of TB (RVCT) and Follow Up 1 report in NCEDSS to the TB Nurse Consultant for your county when drug susceptibilities are known and within three months of initiating treatment.

2 Special Reporting Situations

- a. Immigrants, refugees, permanent resident aliens, border crossers, and foreign visitors
 - Immigrants and refugees who are examined after arriving in the United States and diagnosed with clinically active TB requiring anti-TB medications should be counted by the locality of their current residence at the time of diagnosis regardless of citizenship status.
 - Border crossers and permanent resident aliens who are diagnosed with TB and plan to receive anti-TB therapy from a locality in the United States for 90 days or more should be counted by the locality of current residence.
- b. Out-of-state or out of area residents
 - A person's TB case should be counted by the locality in which he or she resides at the time of diagnosis. TB in a person who has no address should be counted by the locality that diagnosed and is treating the TB. The TB control officer should notify the appropriate out-of-state or out-of-area TB control officer of the person's home locality to (1) determine whether the case has already been counted to avoid "double counting;" and (2) agree on which TB control office should count the case if it has not yet been counted.
- c. Migrants and other transients
 - Persons without any fixed U.S. residence are considered to be the public health responsibility of their present locality and their TB case should be reported and counted where diagnosed.
- d. Federal facilities (e.g., military and Veterans' Administration facilities)
 - Cases in military personnel, or dependents, or veterans should be reported and counted by the locality where the persons are residing in the United States at the time of diagnosis and initiation of treatment. However, if military personnel or dependents are discovered to have TB at a military base outside the United States but are referred elsewhere for treatment (e.g., a military base located within the United States), the TB case should be reported and counted where treated and not where the diagnosis was made.
- e. Indian health services
 - TB should be reported to the local health authority (e.g., state or county) and counted where diagnosed and treatment initiated. However, for a specific group such as the Navajo Nation, which is geographically located in multiple states, health departments should discuss each case and determine which locality should count the case.
- f. Correctional facilities (e.g., local, state, federal, and military)
 - Persons who reside in local, state, federal, or military correctional facilities may frequently be transferred or relocated within and/or between various correctional facilities. TB in those persons should be reported to the local health authority and counted by the locality where the diagnosis was made and treatment plans were initiated.

- g. Peace Corps, missionaries, and other citizens residing outside the United States
 - TB in persons diagnosed outside the United States should not be counted. TB in these persons should be counted by the country in which they are residing regardless of their plans to return to the United States for further work-up or treatment.
- h. If TB recurs (relapse) in an individual **and** if more than 12 months have elapsed since the individual completed treatment, the recurrence is considered a separate episode and should be counted as a new case.
- i. If the case is lost to follow-up but is then located and restarted on treatment, this is not a separate episode; the RVCT Follow Up 2 form should be updated to reflect a new Reason Therapy Stopped and Date Stopped when the person completes treatment or has another outcome.
- j. Notify the state of residence or state to which a NC case is moving using the Interjurisdictional TB Notification Form (**see Chapter X for instructions and form**); a copy of the form should be placed in the patient's record.
- k. Forward information regarding cases with residence in another North Carolina county to the appropriate county for case counting.
- l. Obtain assistance from the N.C. TB Control when making international referrals.

P. Death Certificates

1. Review and investigate death certificates that list TB as a cause of death or contributing condition. Count as a TB case if confirmed and not previously reported.
2. If TB was not the cause of death, ask the physician to amend the death certificate as follows:
 - a. Attending physician completes Supplemental Report of Cause of Death (**DHHS 2263**);
 - b. Original DHHS 2263 is forwarded to Vital Records in Raleigh;
 - c. One copy is kept at health department; and
 - d. One copy is sent to Register of Deeds in the county where the individual died.

Q. Sample TB Treatment Agreement (Also Found in the Print Documents in NCEDSS)

TB TREATMENT AGREEMENT

Patient Name: _____ DOB _____ Date: _____

Patient Address: _____ Health Department: _____

I, _____, understand I have suspected or confirmed tuberculosis and have been prescribed by a physician to treat this disease. If my disease goes untreated, there may be serious results:

- my illness may last longer or become more severe.
- I may spread TB to others.
- I may develop and spread drug-resistant TB.
- I can die from TB.

The _____ County Health Department has the responsibility of being sure I complete treatment for my tuberculosis and do not give tuberculosis to others. To help me complete TB treatment, the health department will:

- supply all my TB medications, x-rays, and laboratory testing free of charge.
- discuss with a physician any problems relating to my disease.
- observe me take each dose of medicine.
- see me at least monthly to evaluate for any side effects to my TB medications.

To complete my treatment and protect my family, friends and co-workers I will:

- give sputum samples when asked.
- keep all appointments for medical testing and x-rays.
- be at the agreed-upon location to take my TB medication.
- tell the health care worker whenever I plan to change my address or location.

Visit Day(s): _____ Time: _____ Location: _____

If a scheduled visit falls on a holiday, the health care worker will work with me to make an adjustment in my schedule.

I have read this agreement and understand the following **(initial on line)**:

_____ Taking TB medication is very important.

_____ I am responsible for the four tasks listed above.

_____ I have been told to stop taking my medication and call my doctor and the health department if I have any side effects.

_____ If I fail to complete these tasks, legal action can be taken to make sure I complete my TB treatment.

_____ I have been given the North Carolina TB Control program's pamphlet, "TB and You" which lists the possible side effects of tuberculosis medicines. These possible side effects have been explained to me. I will inform the TB nurse of any problems that I may have regarding any physical complaint or possible side effects to the tuberculosis medications.

Patient Signature and Date

Witness Signature and Date

R. Sample TB Treatment Agreement (Spanish)

COMPROMISO DE TRATAMIENTO DE TUBERCULOSIS

Nombre del paciente: _____ Fecha de nacimiento _____

Fecha de hoy: _____

Dirección del paciente: _____ Departamento de Salud:

Yo, _____, entiendo que se sospecha o se ha confirmado que tengo tuberculosis, y que un médico me ha recetado medicamentos para tratar esta enfermedad. Si no se trata mi enfermedad, esto puede ocasionar graves resultados:

- mi enfermedad puede prolongarse más o agravarse
- puedo contagiar la tuberculosis a otras personas
- puedo desarrollar una tuberculosis resistente a los medicamentos y contagiar esta a otros
- puedo fallecer por causa de la tuberculosis

El Departamento de Salud del condado _____ es responsable por asegurarse de que yo complete mi tratamiento contra la tuberculosis y de que no contagie la tuberculosis a otras personas. A fin de ayudarme a completar mi tratamiento contra la tuberculosis, el Departamento de Salud:

- me proporcionará todos los medicamentos contra la tuberculosis, las radiografías y los análisis clínicos en forma gratuita
- consultará con un médico todos los problemas relacionados con mi enfermedad
- me observará tomar todas las dosis de medicamentos
- me verá por lo menos una vez al mes para evaluarme en cuanto a cualquier efecto secundario de los medicamentos contra la tuberculosis

A fin de completar mi tratamiento y proteger a mi familia, mis amistades y mis compañeros de trabajo, yo:

- entregaré las muestras de esputo cuando me lo soliciten
- acudiré a todas las citas para los exámenes médicos y las radiografías
- me presentaré en el lugar acordado para tomar mis medicamentos contra la tuberculosis
- informaré al trabajador de salud cada vez que piense cambiar de domicilio o de localidad

Día(s) de visita: _____ Hora: _____ Lugar: _____

Si una visita programada cae en día festivo, el trabajador de salud coordinará conmigo para hacer un ajuste en mi programa de medicamentos.

He leído este compromiso y entiendo lo siguiente (**Escriba sus iniciales sobre cada una de las líneas.**)

_____ Es muy importante que yo tome los medicamentos contra la tuberculosis.

_____ Soy responsable por realizar las cuatro tareas indicadas anteriormente.

_____ Se me ha indicado que deje de tomar los medicamentos y llame a mi médico y al departamento de salud si tengo algún efecto secundario.

_____ Si no cumplo con realizar esas tareas, puede tomarse una acción legal en mi contra para asegurar que complete mi tratamiento contra la tuberculosis.

_____ Me han entregado el panfleto «La tuberculosis y usted» del Programa de Control de la Tuberculosis de Carolina del Norte, el cual indica los posibles efectos secundarios de los medicamentos contra la tuberculosis. Se me han explicado los posibles efectos secundarios. Informaré a la enfermera de tuberculosis acerca de cualquier problema que tenga que esté relacionado con malestar físico o con posibles efectos secundarios de los medicamentos contra la tuberculosis.

Firma del paciente y fecha

Firma del testigo y fecha

S. First-Line TB Drugs for Treating Active Tuberculosis

Drug	Doses in mg/kg (Maximum Dose) is listed in parenthesis			
	Daily		Twice or thrice weekly	
	Children (<15 years)	Adults	Children (<15 years)	Adults
INH	10 - 15 (300mg)	5 (300mg)	20 - 30 (900mg)	15 (900mg)
RIF	15 - 20 (600mg)	10 (600mg)	15 - 20 (600mg)	10 (600mg)
RBT Rifabutin	5 (300 mg)	5 (300 mg)	5 (300 mg)	5 (300 mg)
PZA	30-40 mg (2000 mg) Round up to the next available dose	See Suggested doses in table below	50 (4000 mg)	See Suggested doses in table below
EMB	20 mg (2500mg) round up to the next available dose	See Suggested doses in table below	50 (2500 mg)	See Suggested doses in table below

The following guidelines[‡] should be used to determine the appropriate dosing for PZA and EMB in adults:

Suggested **pyrazinamide** doses, using whole tablets, for adults weighing 40-90 kg

Weight in kg (estimated lean body wt)	40 - 55 kg (88 to 121 lbs)	56 - 75 kg (123 to 165 lbs)	76 - 90 kg (167 to 198 lbs)
Daily, mg (mg/kg)	1000 (18.2 - 25)	1500 (20.0 - 26.8)	2000 ¹ (22.2 - 26.3)
Twice weekly, mg (mg/kg)	2000 (36.4 - 50.0)	3000 (40 - 53.6)	4000 ¹ (44.4 - 52.6)
Thrice weekly, mg, (mg/kg)	1500 (27.3 - 37.5)	2500 (33.3 - 44.6)	3000 ¹ (33.3 - 39.5)

¹ Maximum dose regardless of weight

Suggested **ethambutol** doses, using whole tablets, for adults weighing 40-90 kg

Weight in kg (estimated lean body wt)	40 - 55 kg (88 to 121 lbs)	56 - 75 kg (123 to 165 lbs)	76 - 90 kg (167 to 198 lbs)
Daily, mg (mg/kg)	800 (14.5 - 20.0)	1200 (16.0 - 21.4)	1600 ¹ (17.8 - 21.1)
Twice weekly, mg (mg/kg)	2000 (36.4 - 50.0)	2800 (37.3 - 50.0)	4000 ¹ (44.4 - 52.6)
Thrice weekly, mg (mg/kg)	1200 (16.0 - 21.4)	2000 (26.7 - 35/7)	2400 ¹ (26.7 - 31.6)

¹ Maximum dose regardless of weight

[‡] Nahid P et al, Official American Thoracic Society/Centers for Disease Control and Prevention/Infectious Disease Society of America Clinical Practice Guidelines: Treatment of Drug-Susceptible Tuberculosis. *Clinical Infectious Diseases* 2016; 63(7): e147-195..

- INH and RIF can be obtained in syrup formulations for pediatric use. PZA and EMB come in tablet form only. Tablets of INH, PZA, and EMB can be divided and crushed for patients

unable to swallow pills. RIF comes in capsules (150 and 300 mg) that can be opened and sprinkled over food Dosing for children can be calculated as follows:

Tablets: To calculate number of kg, divide individual's weight by 2.2. (1 kg = 2.2 lbs.). Multiply weight in kg by recommended mg per kg based on daily or twice weekly regimen.

Syrup: To calculate number of kg, divide individual's weight by 2.2. (1 kg = 2.2 lbs.). Multiply weight in kg by recommended mg per kg based on daily or twice weekly regimen. INH syrup concentration is generally 10 mg/cc, and RIF syrup concentration is generally 20 mg/cc, but this should always be confirmed with the pharmacy.

T. Clinical Pathway for Managing Tuberculosis Suspects/Cases

CLINICAL PATHWAY FOR MANAGING TUBERCULOSIS SUSPECTS/CASES	NAME _____ ID # _____ DOB _____
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VISIT	INITIAL AND DATE AFTER COMPLETING EACH TASK	INITIAL	DATE
Day 1	Obtain medical history including recent exposure, previous infection, risk factors, signs, symptoms & duration of symptoms of TB disease. Use Tuberculosis Epidemiologic Record (DHHS 1030).		
	Collect and send sputum specimen for AFB smear & culture. Provide patient with two more sputum containers and give instructions on how to obtain a sputum specimen. If unable to get a specimen provide or schedule induction.		
	Place PPD or obtain IGRA/ Obtain weight/ Perform baseline visual acuity testing for red-green color blindness if taking EMB/ Complete flow sheet -DHHS 2810.		
	Provide HIV counseling and testing. If HIV positive get CD4 count and assure patient is in HIV care. Obtain baseline test/results for hepatic function panel, creatinine, CBC, platelet count, as ordered. If streptomycin is used, also need baseline BUN and audiogram. Second-line drugs need additional monitoring.		
	Provide educational information about TB, including TB Booklet with contact phone numbers and plan for future care including need for monthly clinic visits to see physician or nurse/have patient sign TB Treatment Agreement.		
	Obtain a posterior-anterior view chest x-ray plus lateral if < 5 yr		
	Discuss TB medications/side effects/hepatotoxicity/DOT/		
	Obtain prescriptions for standard four drug regimen (RIF, INH, PZA, EMB) and administer first dose of daily DOT. All meds should be given at the same time. Set up schedule for daily DOT. Document DOT on Tuberculosis Drug Record (DHHS 1391).		
	Begin contact investigation.		

Day 2	Obtain sputum smear results in the afternoon if the State Lab received the specimen this am. Obtain second sputum specimen.		
	Continue contact investigation and daily DOT		
	Review chest x-ray report/chest x-ray film with physician		
Day 3	Read PPD on day 2 or 3 and record results in chart.		
	Obtain sputum smear/NAA results and third sputum specimen.		
	Continue contact investigation and daily DOT.		
Day 5-14	Continue daily DOT.		
	Continue educating patient and contacts about TB.		
	Continue contact investigation.		
	Report initial findings about case to the TB nurse consultant using the reporting tool wizard in N.C. EDSS within seven business days.		
VISIT	INITIAL AND DATE AFTER COMPLETING EACH TASK	INITIAL	DATE
Week 3			
	Obtain two sputum specimens for smear and culture every two weeks until there are two consecutive negative cultures. Isolation can be discontinued after getting two consecutive negative smears.		
Week 4	Complete monthly assessment (DHHS 2810). If there are side effects, hold meds, draw appropriate labs and consult physician.		
	Obtain monthly hepatic function panel on high risk individuals.		
	Continue DOT.		
Weeks 5 to 7	Contact State Lab for sensitivity results if these have not yet been obtained. If sensitive to all medications, ask physician to discontinue EMB. If any resistance, consult physician.		
	Continue collection of q 2 wk sputum specimens until culture negative x 2.		
	Continue DOT.		
Week 8	Complete monthly assessment. (DHHS 2810) If there are side effects, hold meds, draw appropriate labs and consult physician.		
	Obtain monthly hepatic function panel on high risk individuals.		
	Discontinue PZA after eight weeks if fully sensitive.		
	Cultures and susceptibility results should be final. If initial culture is positive this should be reported as a TB case by completing a RVCT wizard in NCEDSS and assign to TB nurse consultant.		
	If cultures are negative consult with physician about diagnosis. Obtain a chest x-ray. If decision is made to treat as a culture negative case of TB based on improved symptoms and chest x-ray, continue RIF and INH for a total of 16 weeks of therapy.		
	For most patients, therapy can begin thrice weekly. This should consist of isoniazid and rifampin thrice weekly (dosage will change) DOT for 18 weeks (54 thrice-weekly doses). It is recommended that patients with HIV infection, positive acid-fast sputum smears, and/or cavitory disease on plain chest radiographs continue daily therapy until completion.		
	Repeat PPD's for contacts that were negative initially.		

Week 9 to 11	Continue DOT and collection of sputum specimens if still culture positive.		
Week 12	Complete monthly assessment (DHHS 2810). If there are side effects, hold meds, draw appropriate labs and consult physician.		
	Obtain monthly hepatic function panel on high risk individuals.		
	Assess for response to treatment. If response (clinical or bacteriological is slow or sub-optimal consult TB Nurse Consultant. Treatment should be lengthened to include at least four months (18 weeks) of treatment following sputum conversion. If the patient does not convert sputum cultures to negative by eight weeks and had a cavity on the initial x-ray, treatment should be extended to nine months.		
Clinical Pathway for Managing Tuberculosis Suspects/Cases Page 3		Name _____	
		DOB _____	

VISIT	INITIAL AND DATE AFTER COMPLETING EACH TASK	INITIAL	DATE
Week 13 to 15	Continue DOT, and collection of every two weeks sputum specimens until culture negative x two.		
Week 16	Complete monthly assessment (DHHS 2810). If there are side effects, hold meds, draw appropriate labs and consult physician.		
	Obtain monthly hepatic function panel on high risk individuals.		
	Continue DOT.		
Week 17 to 19	Continue DOT.		
Week 20	Complete monthly assessment (DHHS 2810). If there are side effects, hold meds, draw appropriate labs and consult physician.		
	Obtain monthly hepatic function panel on high risk individuals.		
	Continue DOT.		
Week 21 to 23	Continue DOT.		
Week 24 to 25	Complete monthly assessment (DHHS 2810). If there are side effects, hold meds, draw appropriate labs and consult physician.		
	Obtain monthly hepatic function panel on high risk individuals.		
	Continue DOT.		
	Obtain end-of-treatment chest x-ray for a comparison film for future reference for all pulmonary cases unless treatment is going to be extended		
	Schedule patient to receive end of treatment evaluation by a physician or mid-level provider		
Week 26	Complete final week of DOT if treatment was not lengthened due to missed doses, slow sputum conversion, or resistance.		
	Complete Certificate of Completion for TB Treatment card and give to patient along with instructions to return to clinic if symptoms of TB occur.		
	Complete RVCT follow-up 2 wizard in NCEDSS and assign to TB nurse consultant.		

Initials	Signature

U. Tool for Reporting Suspected or Confirmed TB Cases to TB Nurse Consultant
Within 7 Business Days of Notification

Date Report Faxed/Called _____ Date Suspect reported to county _____
County _____ Nurse _____
Patient's Name: _____ Gender _____ Race _____
Address: _____
DOB: _____
AFB Smear results: _____ Culture Results: _____
Specimen Source/Collection Date _____ Pulmonary _____ Extra-pulmonary _____
PPD results: _____ IGRA results: _____
HIV status _____ Date tested _____
Chest x-ray results: _____

Drugs/Dosages: Date started: _____ Weight _____

INH _____ mg	Daily _____	Bi-weekly _____
Rifampin _____ mg	Daily _____	Bi-weekly _____
PZA _____ mg	Daily _____	Bi-weekly _____
EMB _____ mg	Daily _____	Bi-weekly _____
Other _____ mg	Daily _____	Bi-weekly _____

Medical or Population Risk Factors:

Potential Drug Interactions:

Symptoms and Duration:

Contact Investigation Status (describe progress of CI, and areas of high risk, such as, children, nursing homes, schools, HIV positive contacts, etc); indicate if no contact identified

Have baseline labs been drawn? Yes ____ No ____

If HIV+: CD4 level _____ Date of most recent test _____

If diabetic: HbA1c (date): _____

Additional Comments:

V. Sample Standing Orders for Suspect/Confirmed TB Cases

Sample Standing Order Example: Suspect or Known Tuberculosis

Assessment: All PHN's employed or contracted by the agency that have completed a TB program orientation and have been appropriately trained in agency protocols shall evaluate for signs and symptoms of tuberculosis and obtain tests. The PHN will initiate this standing order if a patient reports or the medical record indicates he/she has two or more findings listed under subjective and objective.

1. **Subjective Findings:**

- a. Night sweats;
- b. Shortness of breath;
- c. Chest pain;
- d. Appetite loss; and/or
- e. Unexplained fatigue.
- f. Unexplained productive cough for greater than three weeks;
- g. Hemoptysis;
- h. Unexplained weight loss;
- i. Unexplained fever

2. **Objective findings:**

- a. Positive tuberculin skin test or Positive IGRA;
- b. Abnormal chest x-ray indicated by a TB clinician and/or radiologist.
- c. Positive acid-fast bacillus (AFB) smear.

Plan of Care:

1. **Implementation:**

- a. Place a tuberculin skin test (TST) or draw blood for an IGRA (Interferon Gamma Release Assay) unless there is a documented previous positive TST or IGRA.
- b. Obtain three natural or induced sputum specimens on three consecutive days, preferably early morning specimens, and send for AFB smear, culture, and susceptibility.
- c. Continue obtaining two sputum specimens for AFB smear and culture every two weeks until there are two consecutive negative sputum culture results reported.
- d. Obtain a posterior-anterior (PA) chest x-ray on persons \geq 5 years of age.
- e. Obtain both a PA and lateral view on children under the age of 5 years.
- f. Obtain an HIV test and if the individual is \geq 12 years old also obtain the following:

- i. Liver function panel;
 - ii. Serum creatinine; and
 - iii. CBC with differential (platelets).
- g. If during TB treatment the patient complains of signs and symptoms consistent with hepatotoxicity, such as nausea, vomiting, loss of appetite, dark (tea or cola colored) urine, malaise, abdominal discomfort, or yellow skin or sclera, hold TB medications, and draw hepatic function panel.
- h. If during the treatment the patient reports signs and/or symptoms of immunologic reactions such as fever, easy bleeding or bruising, or low hemoglobin (< 13.5 for men, < 12.5 for women, and < 11 for children (between 5 years but less than 12 years), draw CBC with platelets and consult physician.
- i. Obtain hepatic function panel monthly for the following individuals:
 - i. Has abnormal baseline hepatic function;
 - ii. Pregnant or up to three months postpartum;
 - iii. Those with symptoms of hepatotoxicity;
 - iv. Persons taking potentially hepatotoxic drugs;
 - v. Persons with chronic active hepatitis B or C;
 - vi. Persons who report any alcohol intake while taking TB medications;
 - vii. Persons with HIV infection.

2. Nursing Action:

- a. Review with, and have the patient sign the TB Treatment Agreement if TB treatment is ordered.
- b. Ensure that there is documentation of an exam by a physician or mid- level provider within the first four weeks of initiation of TB therapy.
- c. Ensure that physician reviews laboratory results and documents this per the agency policy on reviewing laboratory results. (Agency should list the name of this policy here)

3. Criteria for Calling the Physician:

- a. If the patient develops side effects from the medications such as, nausea, vomiting, loss of appetite, dark urine, jaundice, malaise, abdominal discomfort, skin rash, fever, easy bleeding or bruising, or low hemoglobin (< 13.5 for men, < 12.5 for women, and < 11 for children (between 5 years but less than 12 years) occur.
- b. If the patient becomes pregnant.
- c. Anytime laboratory results are abnormal.
- d. If additional orders are needed.
- e. If drug resistance is reported.
- f. If sputum cultures are still positive after taking TB medications for eight weeks.
- g. If the patient's clinical condition worsens.
- h. If there is any question about whether to carry out the standing order call the physician.

4. Follow-up:

- a. Follow-up with the physician for treatment orders after initial evaluation is complete.
- b. Evaluate the patient monthly using the Tuberculosis Flow Sheet (DHHS 2810).
- c. Recalculate medication dosage monthly after weighing.
- d. Ensure that there is documentation of an exam by a physician or mid- level provider within the last four weeks of TB therapy.
- e. Obtain end of treatment chest x-ray if the patient has pleural or pulmonary TB.

Resources: NC TB Control Program Policy Manual 2012 edition.

Legal Authority: Nurse Practice Act, G.S. 90-171.20 (7) (f) & (8) (c)

Date written: _____

Approved by: _____

Date: _____

Approved by: _____

Date: _____

Approved by: _____

Date: _____