

### III. TB INFECTION (TBI)

#### MODULE OUTLINE

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## 1. STANDARDS OF PUBLIC HEALTH PRACTICE

- III-1. All patients being evaluated for TB infection (TBI) have a clinical exam that includes a chest X-ray (CXR), physical exam and appropriate lab tests (if indicated).
- III-2. Persons diagnosed with TBI have HIV testing prior to initiation of TBI treatment unless the patient specifically chooses to “opt-out” of HIV testing.
- III-3. Persons <18 years of age who are diagnosed with TBI receive directly observed preventive therapy (DOPT) throughout the course of treatment.
- III-4. For daily TBI treatment regimens, only a one (1) month supply of TBI medication is dispensed monthly. A physician order is required and is included in the patient’s chart if greater than one (1) month of medication is dispensed.
- III-5. Before monthly medication is re-supplied, patients are assessed by a public health nurse (PHN) for signs/symptoms of adverse effects of medication. If medication is re-supplied, the PHN documents all information on the PH-2040.
- III-6. If a patient has stopped TBI medication or has not picked up a medication re-supply for less than two (2) months, the PHN carefully assesses for signs/symptoms of active TB. If the assessment for sign/symptoms of TB is negative, the PHN may restart the TBI medication. If there are sign/symptoms of TB disease, the TB clinician is notified for further orders.
- III-7. If a patient has stopped TBI medication or has not picked up a medication re-supply for greater than two (2) months, the TB clinician re-evaluates the patient in TB clinic (including a clinical exam and CXR) prior to restarting medication.
- III-8. Treatment for TBI is recommended for all eligible patients who are diagnosed with TBI.
- III-9. TBI treatment is not started until all diagnostic tests are finalized.
- III-10. For each patient placed on TBI treatment, the following treatment information is documented in the medical record by the TB clinician: drug name(s), dosage, frequency of dose and planned duration of therapy.
- III-11. Completion of TBI treatment, including the appropriate number of doses given within the allotted timeframe, is documented in the patient medical record.

## 2. DEFINITION OF TBI

### TB Infection (TBI)

Tuberculosis infection (TBI) is an asymptomatic state in persons who are infected with *Mycobacterium tuberculosis* (M. tb). TBI is detected as a result of skin testing (TST) or obtaining a blood test (IGRA) among persons with risk factors for TB disease. While not everyone with TBI will develop TB disease, about 5% to 10% of infected people will develop active TB disease if not treated. Treatment of TBI is essential to controlling and eliminating TB disease in the U.S. It substantially reduces the risk that persons infected with *M. tuberculosis* will progress to TB disease.

**Table III-1** describes the differences between TBI and TB disease.

**Table III-1: Differentiating between TB Infection and TB Disease**

TB Infection (TBI)	TB Disease
<ul style="list-style-type: none"> <li>• Has a small amount of TB bacteria in his/her body that are alive, but inactive</li> </ul>	<ul style="list-style-type: none"> <li>• Has a large amount of active TB bacteria in his/her body</li> </ul>
<ul style="list-style-type: none"> <li>• Cannot spread TB bacteria to others</li> </ul>	<ul style="list-style-type: none"> <li>• May spread TB bacteria to others</li> </ul>
<ul style="list-style-type: none"> <li>• Does not feel sick, but may become sick if the bacteria become active in his/her body</li> </ul>	<ul style="list-style-type: none"> <li>• May feel sick and may have symptoms that include:                             <ul style="list-style-type: none"> <li>○ Cough lasting ≥ 2-3 weeks</li> <li>○ Pain in the chest</li> <li>○ Coughing up blood or sputum</li> <li>○ Weakness or fatigue</li> <li>○ Weight loss</li> <li>○ No appetite</li> <li>○ Chills</li> <li>○ Fever</li> <li>○ Night sweats</li> </ul> </li> </ul>
<ul style="list-style-type: none"> <li>• Usually has a TB skin test or TB blood test reaction indicating TB infection</li> </ul>	<ul style="list-style-type: none"> <li>• Usually has a TB skin test or TB blood test reaction indicating TB infection</li> </ul>
<ul style="list-style-type: none"> <li>• Has a normal chest x-ray</li> </ul>	<ul style="list-style-type: none"> <li>• May have an abnormal chest x-ray</li> </ul>
<ul style="list-style-type: none"> <li>• Sputum smears and cultures are negative</li> </ul>	<ul style="list-style-type: none"> <li>• Sputum smears and cultures may be positive</li> </ul>
<ul style="list-style-type: none"> <li>• Should consider treatment for TBI to prevent TB disease</li> </ul>	<ul style="list-style-type: none"> <li>• Needs treatment for TB disease</li> </ul>
<ul style="list-style-type: none"> <li>• Does not require respiratory isolation</li> </ul>	<ul style="list-style-type: none"> <li>• May require respiratory isolation</li> </ul>
<ul style="list-style-type: none"> <li>• Not a TB case</li> </ul>	<ul style="list-style-type: none"> <li>• A TB case</li> </ul>

Reference:

1. CDC. Core Curriculum on Tuberculosis: What the Clinician Should Know, 2013 (adapted). <http://www.cdc.gov/tb/education/corecurr/pdf/chapter2.pdf>
2. CDC. Questions and Answers about Tuberculosis, 2014 (adapted). <http://www.cdc.gov/tb/publications/faqs/pdfs/qa.pdf>

**3. CLINICAL EVALUATION**

**History**

Medical History

Before TBI treatment is considered, a medical history is to be conducted to:

- Determine the patient’s preferred language, use interpreter if needed (Patient’s family or friends should not be used to interpret);
- Review the patient’s TB Risk Assessment Tool (TB RAT) for any pertinent data including:
  - Risk for progression to active TB disease
  - Symptoms suggestive of TB disease

- Prior treatment of TB/TBI
- HIV risk factors, if any, which may include:
  - Engaging in anal, vaginal, or oral sex with men who have sex with men, multiple partners, or anonymous partners without using a condom
  - Injecting drugs or steroids where needles/syringes are shared
  - Having a sexually transmitted infection, such as syphilis, genital herpes, chlamydia, gonorrhea, bacterial vaginosis, or trichomoniasis
  - Having a previous diagnosis with hepatitis, tuberculosis, or malaria
  - Exchanging sex for drugs or money
  - Having been exposed to the virus as a fetus or infant before or during birth or through breastfeeding from a mother infected with HIV
  - Receiving a blood transfusion or clotting factor in the U.S. anytime from 1978 to 1985
  - Engaging in unprotected sex with someone who has any of the previously listed risk factors

Reference:

1. National Institute of Allergy and Infectious Diseases  
<http://www.niaid.nih.gov/topics/hivaids/understanding/pages/riskfactors.aspx>
  - Identify conditions associated with chronic or previous liver disease (i.e., viral hepatitis, cirrhosis). Determine if patient has any current symptoms suggestive of liver disease (anorexia, dark urine, jaundice, scleral icterus, etc.)
  - Determine if patient has any current symptoms suggestive of underlying neurological disease (numbness or tingling of hands or feet, dizziness, confusion, etc.)
  - Identify any significant family history of disease, especially chronic liver or kidney disease, diabetes, TB, etc.
  - Determine if there are any co-morbidities that are a contraindication to TBI treatment or are associated with an increased risk of adverse effects from treatment
  - Obtain a thorough review of systems, considering the possibility of extrapulmonary TB or other symptoms that could affect TBI treatment or adherence
  - Determine possible pregnancy and identify current birth control method (female patients only). For women of child-bearing age, obtain the date of last menstrual period. If pregnancy is suspected (e.g., due to unexplained missed menstrual period or lack of birth control use), perform a pregnancy test
  - Determine current or past substance abuse including injecting drug use, non-injecting drug use, and alcohol use (**Refer to Module II. Screening and Testing for Infection for more information on alcohol use**). Assessing current or past substance abuse includes:
    - Injecting drug used
    - Non-injecting drugs used (illegal and legal)
    - Type(s) of alcoholic beverage(s)
    - Number of alcoholic drinks per day/week
    - Drinking habits (i.e., binges)

- Obtain information about current and previous drug therapy (prescription, over-the-counter [OTC], herbal supplements, or home remedies); document all medications in chart
- Identify all allergies, including any previous or current adverse reactions to medications

### Social History

Obtain a social history that focuses on issues that may affect the ability to contact or monitor the patient, such as:

- Lack of telephone
- Lack of available transportation, and/or
- Unstable residence

Also assess for barriers that may affect the patient's ability to adhere to treatment, such as:

- Patient's work schedule
- Medication side effects
- Co-existing medical conditions
- Frequent or anticipated travel
- Lack of financial resources
- Lack of social support system

### Physical Examination

All patients being evaluated for TB infection (TBI) have a clinical exam that includes a chest X-ray (CXR), physical exam and appropriate lab tests (if indicated) (**Standard of Public Health Practice III-1**). TBI treatment cannot be started on patients unless active TB disease (including extrapulmonary disease) has been specifically ruled out by the clinician.

The physical exam, at a minimum, may include these elements:

- Weight
- Skin for jaundice (yellowing)
- Eyes for icterus (yellowing)
- Lymph nodes for adenopathy (swollen or tender)
- Heart and lung for abnormalities
- Abdomen for tenderness, liver abnormalities, or ascites (fluid)
- Extremities for edema (swelling)
- Other stigmata of chronic liver disease (spider angiomas, palmar erythema, gynecomastia, etc.)

Consider the possibility of extrapulmonary TB and expand the exam if indicated, especially for children and HIV-infected persons.

For a patient that refuse a physical exam, the refusal should be documented in the patient's chart and education provided about the importance of receiving a full evaluation.

## Radiography

A chest radiograph to rule out pulmonary TB disease is indicated for all persons being considered for treatment of TBI. If a chest radiograph (CXR) is unable to be performed at the Health Department (HD) TB clinic, alternate arrangements must be made for the patient to receive the chest radiograph at another location. A Prior Authorization (PA) form must be sent to the C.O. requesting approval for this service.

- Adults should have a screening Posterior-Anterior (PA) film or both PA and lateral views. Arrangements can be made with local healthcare facilities to have over reads done at the request of the clinician.
- Children <5 years should have both a PA and lateral CXR. Arrangements can be made with local healthcare facilities to have over reads done at the request of the clinician.
- Pregnant women who have a positive TST or IGRA should have a CXR (with appropriate shielding) as soon as feasible, even during the first trimester of pregnancy, due to the risk for progression and/or congenital TB. The clinician may opt to do the CXR after the patient is >12 weeks pregnant.
- Persons who have TBI or radiographic evidence of prior TB disease should not have repeat chest radiographs performed routinely. Repeat radiographs are not needed unless symptoms or signs of TB disease develop or a clinician recommends a repeat chest radiograph.

Examples of radiographic evidence of prior TB include:

- 1) Dense pulmonary nodules, with or without visible calcification, in the upper lobes;
- 2) Smaller nodules, with or without fibrotic scars, in the upper lobes, frequently accompanied by upper lobe volume loss; and
- 3) Nodules or fibrotic lesions with well-demarcated, sharp margins.

Most persons with radiographs that show only pleural thickening or isolated calcified pulmonary nodules do **not** require sputum AFB smear or culture.

## References:

1. CDC. Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection. MMWR 2000; 49 (No. RR-17).  
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4906a1.htm>
2. CDC. Latent Tuberculosis Infection: A Guide for Primary Health Care Providers, CDC 2013. <http://www.cdc.gov/tb/publications/LTBI/diagnosis.htm>
3. CDC. Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings. MMWR 2005; 54 (No. RR-17).  
<http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf>
4. CDC. Core Curriculum on Tuberculosis: What the Clinician Should Know, 2013.  
<http://www.cdc.gov/tb/education/corecurr/default.htm>
5. Current TB Nursing Protocol

## **Laboratory Tests**

Sputum examination is not indicated for most persons being considered for treatment of TBI. However, sputum collection is indicated under the following circumstances:

- If the patient has symptoms of active TB that include:
  - Cough  $\geq$ 2-3 weeks with or without sputum production
  - Coughing up blood (hemoptysis)
  - Chest pain
  - Loss of appetite
  - Unexplained weight loss
  - Night sweats
  - Fever
  - Fatigue
- The CXR has any abnormalities consistent with TB disease; or the patient has a chest radiograph suggestive of old fibrotic lesions thought to represent previous TB disease.

Obtain **three (3)** consecutive sputum specimens, collected on different days, submitted for Acid Fast Bacilli (AFB) smear and culture. If the patient cannot easily mobilize sputums for an adequate specimen, an induced sputum should be collected. If sputum collection is indicated as above, treatment for TBI should be **deferred** until the final culture results are reported as negative, and the patient has no sign/symptoms of active TB disease. If the patient is considered a TB suspect, **refer to Module IV: TB Disease**.

## **Reference:**

1. CDC. Core Curriculum on Tuberculosis: What the Clinician Should Know, 2013.  
<http://www.cdc.gov/tb/education/corecurr/default.htm>

The following lab tests are indicated for patients diagnosed with TBI prior to initiation of treatment:

- HIV testing (if not already obtained), unless patient chooses to “opt-out” of HIV testing (**Standard of Public Health Practice III-2**)
- Pregnancy test for females, if indicated
- **CMP and CBC** with platelets and without differential for patients with:
  - Chronic liver disease (hepatitis B or C, cirrhosis)
  - An initial evaluation suggestive of liver disorder
  - Immunosuppression (HIV, etc.)
  - Pregnancy and those in the immediate post-partum period (i.e., those within 3 months after delivery)
  - Regular alcohol use

Baseline monitoring may be considered on an individual basis for persons taking other medications or with chronic medical conditions.

## **Diagnosis of TB Infection**

Criteria for the clinical diagnosis of TBI include the following elements:

- A positive TST or IGRA
- A normal radiograph
- No symptoms consistent with TB disease
- A negative sputum culture (if obtained)
- Clinical exam with no findings suggestive of pulmonary or extrapulmonary TB disease

#### 4. TREATMENT OF TB INFECTION

##### Patient Education

When discussing the risks and benefits of treatment, it is important to explain that:

- Germs in the body may begin to multiply and cause active disease
- Certain individuals are at especially high risk for progression to TB disease, including persons with recent TB infection, persons with certain medical conditions, and those taking medication that may alter the immune system
- Completion of treatment for TBI can reduce the risk of TB disease by up to 90%
- Treatment decisions are based on the results of scientific research
- TBI is treated with one or two drugs, whereas TB disease initially requires four drugs
- Consequences of stopping and re-starting medication

Patient education and documentation may also consist of:

- Specific drug dosage and frequency of medication
- Signs and symptoms of possible drug adverse effects (**Refer to Tool III-1: Drug Information Sheets**).
- Instructions to stop TBI medications and immediately contact the health department if adverse effects occur
- How to contact the health department, including holidays, and weekends, if side effects develop
- Agreement of patient to take the medication correctly as prescribed if directly observed preventive therapy (DOPT) is not indicated
- Agreement of parent or legal guardian to ensure that the medication is taken correctly, as prescribed if DOPT is not indicated
- Instruct that only one-month supply of TBI medication will be dispensed at a time for self-administered regimens
- Need to return to the health department and/or TB clinic for monthly medication refill visits
- Notify the health department TB nurse if the patient plans to move or travel from the area
- Importance of disclosing any other medications (prescription, OTC, or home remedies), and the use of alcohol and any illicit drugs to the TB nurse

**Table III-2** identifies certain groups that are at high risk of developing TB disease once infected.

**Decision Making**

TBI treatment should **only** be prescribed if the CXR is **normal**, without evidence of any findings consistent with TB disease. TBI treatment should be considered for patients who:

- Have been evaluated to rule out active TB disease (pulmonary or extrapulmonary)
- Are willing and able to complete a full course of therapy
- Are available to be clinically monitored during the full course of treatment (that is, not about to leave the country, etc.)
- Have no medical contraindications to treatment, such as severe liver disease or drug hypersensitivity

**Table III-2. High-Priority Candidates for TBI Treatment**

<b>Groups Who Should Be Given High Priority for TBI Treatment</b>	
<b>People who have a positive IGRA result or a TST reaction of 5 or more millimeters</b>	<b>People who have a positive IGRA result or a TST reaction of 10 or more millimeters</b>
<ul style="list-style-type: none"> <li>• HIV-infected persons**</li> <li>• Recent contacts of persons with infectious TB disease**</li> <li>• Persons with fibrotic changes on chest radiograph consistent with prior TB disease</li> <li>• Organ transplant recipients</li> <li>• Persons who are immunosuppressed for other reasons (e.g., taking the equivalent of &gt;15 mg/day of prednisone for one month or longer, taking TNF-<math>\alpha</math> antagonists, etc.)</li> </ul>	<ul style="list-style-type: none"> <li>• Recent arrivals to the U.S. (&lt;5 years) from high-prevalence countries</li> <li>• Injection drug users</li> <li>• Residents and employees of high-risk congregate settings (e.g., correctional facilities, nursing homes, homeless shelters, hospitals, or other health care facilities), etc.</li> <li>• Mycobacteriology laboratory personnel</li> <li>• Persons with medical conditions that increase the risk for progression to TB disease, including silicosis, diabetes mellitus, chronic renal failure, certain types of cancer (e.g., leukemia and lymphomas, or cancer of the head, neck or lung), gastrectomy or jejunioileal bypass, and weight loss of at least 10% below body weight</li> <li>• Children &lt;5 years of age; or children and adolescents exposed to adults in high-risk categories</li> </ul>

\*\*In certain circumstances, people in these categories may be given TBI treatment even if they do not have a positive TST or IGRA result.

**References:**

1. CDC. Core Curriculum on Tuberculosis: What the Clinician Should Know, 2013. <http://www.cdc.gov/tb/education/corecurr/default.htm> (adapted)

2. CDC. TB Elimination: Treatment Options for Latent Tuberculosis Infection, 2011.  
[http://www.cdc.gov/tb/publications/factsheets/treatment/LTBI\\_treatment\\_options.pdf](http://www.cdc.gov/tb/publications/factsheets/treatment/LTBI_treatment_options.pdf)  
(adapted)

In Tennessee public health clinics, persons without any risk factors should **not** be tested for TBI. Testing should be targeted to groups at high risk for TBI and TB disease. However, if a person without any risk factors is tested and has a positive IGRA result or TST reaction that is  $\geq 15$  mm, he/she should be evaluated for TBI treatment once TB disease is excluded.

### **Regimen Options**

There are several treatment regimens available for the treatment of TBI (**Table III-3**). Providers should choose the appropriate regimen based on:

- Drug susceptibility results of the presumed source case (if known);
- Co-existing medical conditions;
- Potential for drug-drug interactions;
- Priority for completion of TBI treatment;
- Logistical feasibility; and
- Patient preference

### **Selection of Treatment Regimen**

Treatment for TBI is recommended to all eligible patients who are diagnosed with TBI (**Standard of Public Health Practice III-8**). Considerations before beginning treatment for TBI:

- TBI treatment is not started until all diagnostic tests are finalized (**Standard of Public Health Practice III-9**)
- History of Bacillus Calmette-Guerin (BCG) vaccine should not affect the decision to treat a high-risk person with a positive TST or IGRA (i.e., ignore BCG history if from a high-risk country)
- Consider the risk of treatment toxicity in all patients (i.e., substance abuse, liver disease, other medications that may affect the liver, etc.)
- Consider potential drug interactions, especially with rifampin/rifabutin and medications for HIV or concurrent use of dilantin and INH
- Active hepatitis and end-stage liver disease are contraindications to the use of INH
- The two (2)-month rifampin-pyrazinamide (2RZ) regimen for TBI is no longer recommended by the Centers for Disease Control and Prevention (CDC) and should not be used

**Table III-3: Drug Regimens for the Treatment of TBI**

Regimen	Drug/Duration	Interval	Minimum Doses	Comments
#1	Isoniazid (INH) 9 months	Daily	<b>270</b> within 12 months	<ul style="list-style-type: none"> <li>The preferred regimen is daily treatment for 9 months</li> <li>Recommended regimen for people with HIV, for children, and for people with chest radiograph findings suggestive of previous TB</li> </ul>
		Twice weekly	<b>76</b> within 12 months	<ul style="list-style-type: none"> <li>DOPT <b>must</b> be used with twice weekly dosing</li> </ul>
#2	Isoniazid (INH) 6 months	Daily	<b>180</b> within 9 months	<ul style="list-style-type: none"> <li><b>Not</b> recommended for people with HIV, for children, or for people with chest radiograph findings suggestive of previous TB</li> </ul>
		Twice weekly	<b>52</b> within 9 months	<ul style="list-style-type: none"> <li>DOPT <b>must</b> be used with twice weekly dosing</li> </ul>
#3	Rifampin (RIF) 6 months	Daily	<b>180</b> within 9 months	<ul style="list-style-type: none"> <li>Children must receive <b>180</b> daily DOT doses within 9 months</li> </ul>
#4	Rifampin (RIF) 4 months	Daily	<b>120</b> within 6 months	<ul style="list-style-type: none"> <li>Used for persons who cannot tolerate INH or have been exposed to INH-resistant TB</li> <li>May be useful to enhance compliance in targeted testing setting or for other high-risk adults who are unlikely to complete 6-9 months of INH</li> <li>Adults must receive <b>120</b> daily doses within 6 months</li> </ul>
#5	Isoniazid (INH)- Rifapentine (RPT) (aka "3HP") 12 weeks	Once weekly	12 within 16 weeks	<ul style="list-style-type: none"> <li>Recommended as an equal alternative to 9 months of daily INH for otherwise health patients aged <math>\geq 2</math> years who: <ul style="list-style-type: none"> <li>Were recently in contact with infectious TB</li> <li>Have conversion from negative to positive on an indirect test for infection (i.e., TST or IGRA)</li> <li>Have radiographic findings of healed pulmonary TB</li> </ul> </li> <li>The 12-dose regimen can be considered for other groups when it offers practical</li> </ul>

				<p>advantages, such as completion within a limited timeframe</p> <ul style="list-style-type: none"> <li>• Must be administered by DOT</li> <li>• <b>Not</b> recommended for: <ul style="list-style-type: none"> <li>○ children &lt;2 years of age</li> <li>○ previously completed an adequate treatment course for TB disease or TB infection</li> <li>○ has a combination of symptoms and/or signs suggestive of active TB disease (pulmonary or extra-pulmonary)</li> <li>○ regardless of chest X-ray result, HIV-infected patients taking ART (HIV expert consultation is required)</li> <li>○ patients who are contacts with known or presumed INH or RIF-resistant <i>M. tuberculosis</i>, pregnant women, or women expecting to become pregnant within the treatment period or currently in immediate post-partum period (<math>\leq 3</math> months since delivery)</li> <li>○ allergy to rifamycins or isoniazid, underlying liver disease with elevated baseline transaminases (ALT or AST) <math>\geq 3</math> X the upper limits of normal (ULN) with or without symptoms, or low platelet count (<math>&lt; 140</math>k/ul)</li> <li>○ unable or unlikely to adhere to a once-weekly plan for DOT for 12 weeks</li> </ul> </li> </ul>
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Reference:

1. CDC. Core Curriculum on Tuberculosis: What the Clinician Should Know, 2013. <http://www.cdc.gov/tb/education/corecurr/default.htm> (adapted)

#### TBI Regimen #1: 9-Month Isoniazid (INH)

- Considered optimal treatment
- To be adequately treated, a patient must receive a minimum of 270 doses administered within 12 months
- The preferred regimen for children 2-11 years of age is nine (9) months of daily INH
- For patients receiving a twice weekly regimen of INH, 76 doses administered within 12 months is considered adequate therapy

#### TBI Regimen #2: 6-Month Isoniazid (INH)

- Provides substantial protection against developing TB disease but is less protective than the nine (9)-month regimen
- Is acceptable if the patient is unable to complete the nine (9)-month regimen with the exception of:
  - Children
  - Immunosuppressed persons
  - Persons with evidence of previous TB on chest radiograph
- To be adequately treated, a patient must receive a minimum of 180 daily doses administered within nine (9) months
- For patients receiving a twice-weekly regimen, 52 doses administered within 9 months is considered adequate therapy

#### TBI Regimen #3: 6-Month Rifampin (RIF)

- May be used for children and adolescents who cannot tolerate INH or have been exposed to INH-resistant TB
- Must be given daily
- To be adequately treated, a patient must receive a minimum of 180 doses within nine (9) months

#### TBI Regimen #4: 4-Month Rifampin (RIF)

- Alternative for persons who cannot tolerate INH or have been exposed to INH-resistant TB
- Must be given daily
- To be adequately treated, a patient must receive a minimum of 120 daily doses administered within six (6) months
- In some situations in which RIF cannot be used because of interactions with ART, rifabutin (RBT) may be used

#### TBI Regimen #5: 12-Week Isoniazid (INH)-Rifapentine (RPT) (aka “3HP”)

- Recommended as an equal alternative to nine (9) months of daily self-administered INH
- Must be given by DOT
- Recommended for otherwise healthy patients aged  $\geq 2$  years who have a predictive factor for greater likelihood of developing TB, which includes:
  - Recent exposure to infectious TB

- Conversion from negative to positive on an indirect test for infection (i.e., TST or IGRA)
- Radiographic findings of healed pulmonary TB
- Can be used for HIV-infected patients who are otherwise healthy and are not taking antiretroviral medications
- Not recommended for:
  - children <2 years of age
  - previously completed an adequate treatment course for TB disease or TB infection
  - has a combination of symptoms and/or signs suggestive of active TB disease (pulmonary or extra-pulmonary), regardless of chest X-ray result
  - HIV-infected patients taking ART (HIV expert consultation is required)
  - patients who are contacts with known or presumed INH or RIF-resistant *M. tuberculosis*
  - pregnant women, or women expecting to become pregnant within the treatment period or currently in immediate post-partum period ( $\leq 3$  months since delivery)
  - allergy to rifamycins or isoniazid, underlying liver disease with elevated baseline transaminases (ALT or AST)  $\geq 3$  X the upper limits of normal (ULN) with or without symptoms, or low platelet count ( $< 140$ k/ul)
  - unable or unlikely to adhere to a once-weekly plan for DOT for 12 weeks. Doses have to be separated by five (5) days to be counted
- Patient must receive 12 doses within 16 weeks

**Refer to Appendix D for the TTBEF “3HP” Protocol**

**TBI Treatment Regimens for Specific Situations**

Children and Adolescents

Children <5 years of age who are close contacts to an adult with infectious TB should receive treatment for TBI even if the initial TST result is negative and following timely exclusion of TB disease by chest radiograph, symptom review, and clinical examination. This is called “window” prophylaxis (**Refer to Module VII. Case Finding and Contact Investigation**).

The recommended treatment regimen for children and adolescents is nine (9) months of INH. Person <18 years of age who are diagnosed with TBI receive directly observed preventive therapy (DOPT) throughout the course of treatment (**Standard of Public Health Practice III-3**). Patients will be allowed to self-administer if parents refuse DOPT (DOPT can be provided by a trained school nurse to accommodate the patient, if necessary).

Rifampin may be used as an alternative regimen in those patients who cannot tolerate INH or have been exposed to INH-resistant TB.

### HIV-Infected Persons

TBI treatment regimens of HIV-infected persons should be provided in consultation with an expert in the management of HIV and TB. A nine (9)-month regimen of daily INH is considered optimal treatment for HIV-infected adults with TBI. In HIV-infected persons, INH may be administered together with nucleoside reverse transcriptase inhibitors (NRTIs), protease inhibitors, or non-nucleoside reverse transcriptase inhibitors (NNRTIs).

For HIV-infected persons who cannot tolerate INH or have been exposed to INH-resistant TB, an alternative regimen is four (4) months of RIF. RIF should not be used in HIV-infected persons being treated with some combinations of ART. In some situations in which RIF cannot be used because of interactions with ART, rifabutin (RBT) may be used.

Most protease inhibitors and delavirdine should not be administered together with RIF. Rifabutin with appropriate dose adjustments can be used with protease inhibitors and NNRTIs (except delavirdine).

HIV-positive patients with TBI should be prescribed the four (4) month-RIF regimen only if strict adherence to therapy is likely. Poor adherence could lead to rifampin resistance.

HIV-infected persons who are receiving antiretroviral therapy (ART) should not take the 12-dose regimen of INH-RPT (3HP) (HIV expert consultation is required). However, HIV-infected persons who are otherwise healthy and are not receiving ART can be considered for the 12-dose regimen.

### Persons with Fibrotic Lesions

Persons who have a chest radiograph suggestive of old fibrotic lesions thought to represent previous TB disease should be treated for TBI if they have:

- A positive IGRA result, or TST reaction (induration)  $\geq 5$ mm;
- No symptoms of infectious TB disease; and
- No history of treatment for TB disease.

**Table III-4: Drug Regimens for the Treatment of TBI for Persons with Fibrotic Lesions**

Regimen	Drug/Duration	Interval	Minimum Doses	Comments
#1*	Isoniazid (INH) 9 months	Daily	270	Provide TBI treatment for patients who have a chest radiograph suggestive of old fibrotic lesions thought to represent previous TB disease and <ul style="list-style-type: none"> <li>• A positive IGRA result or TST reaction (induration <math>\geq</math>5 mm)</li> <li>• No symptoms of infectious TB disease</li> <li>• No history of treatment for TB disease</li> <li>• Three negative sputum smears and cultures</li> </ul>
		Twice weekly	76	
#2	Rifampin (RIF) 4 months	Daily	120	

\*Preferred

Persons with radiographic evidence suggestive of healed, primary TB disease (i.e., calcified solitary pulmonary nodules, calcified hilar lymph nodes, and apical pleural capping) are not at increased risk for TB disease. **Refer to Table III-4 for acceptable treatment options for persons with fibrotic lesions.**

Reference:

1. CDC. Core Curriculum on Tuberculosis: What the Clinician Should Know, 2013. <http://www.cdc.gov/tb/education/corecurr/default.htm> (adapted)

Contacts of Persons with Multidrug Resistant TB (MDR TB)

If a person is a contact of a patient with multidrug resistant TB (MDR TB), the risk of progressing to MDR TB disease should be considered for recommending treatment for TBI.

Consultation from the TTEBP Medical Director should be obtained prior to initiation of treatment. In general, contacts to MDR TB, PZA and EMB or PZA and a fluoroquinolone (Levaquin, moxifloxacin or gatifloxacin) for 6-12 months is recommended depending upon the specific drug sensitivity of the presumed *M. tuberculosis* strain causing TBI.

After appropriately ruling out active TB disease, immunocompetent contacts who have received a diagnosis of TB infection attributable to MDR TB exposure should be clinically monitored for two (2) years after exposure. Regardless of whether the patient is treated for TBI, such monitoring should include screening for symptoms of active TB and a focused clinical evaluation at 6, 21, 18, and 24 months. At the clinician’s discretion, repeat chest X-ray and sputum collection may be warranted.

Also, immunocompromised or immunosuppressed contacts to MDR TB, with or without a positive test for TB infection, should be similarly monitored at 6, 12, 18, and 24 months, with a low threshold for repeating the chest X-ray and sputum collection by induction.

Pregnancy and Breastfeeding

INH administered either daily or twice weekly is the preferred regimen for the treatment of TBI in pregnant women. Consult with the TTBE Medical Director on TBI treatment for pregnant women who are intolerant of INH or likely to be infected with an INH-resistant strain of *M. tuberculosis*.

For women who are at high risk for progression from TBI to TB disease, especially those who are HIV-infected or diabetic, TBI treatment should not be delayed on the basis of pregnancy alone, even during the first trimester. TB disease must be excluded through a symptom review and chest radiograph prior to the initiation of TBI treatment.

Breastfeeding is not contraindicated when a mother is being treated for TBI. The amount of INH in the mother’s breast milk is inadequate to either harm or benefit an infant. Breast-fed infants of mothers who take INH should receive supplemental pyridoxine (B<sub>6</sub>). The 12-dose regimen of INH-RPT (3HP) is not recommended for pregnant women or women expecting to become pregnant women during the treatment period, or in the immediate post-partum period (≤ 3 months since delivery). **Refer to Table III-5 for drug regimens for treatment of TBI for women who are pregnant or breastfeeding.**

**Table III-5: Drug Regimens for the Treatment of TBI in Pregnancy or Breastfeeding**

Regimen	Drug/Duration	Interval	Minimum Doses	Comments
#1	Isoniazid (INH) 9 months	Daily	270	<ul style="list-style-type: none"> <li>Do not delay initiation of therapy based on pregnancy alone, even during the first trimester for women who are at high risk for progression from TBI to TB disease, especially those who are HIV-infected or diabetic</li> <li>Breastfeeding is not contraindicated when a mother is being treated for TBI</li> <li>The amount of INH provided in the mother’s breast milk is inadequate to either harm or benefit an infant</li> <li>Breastfeeding infants whose mothers are taking INH should receive supplemental pyridoxine (vitamin B<sub>6</sub>)</li> <li>Twice-weekly regimen must be administered by DOPT</li> </ul>
		Twice weekly	76	

Reference:

1. CDC. Core Curriculum on Tuberculosis: What the Clinician Should Know, 2013. <http://www.cdc.gov/tb/education/corecurr/default.htm> (adapted)

Persons Initially Suspected of Having Active TB Disease but Dispositioned as TBI

- Patients who begin multi-drug therapy for suspected pulmonary TB but are subsequently determined not to have active disease should complete at least two (2) months of a TB disease medication regimen
- For suspected cases of active TB that have been on four (4)-drug therapy for six (6) weeks and are ruled out as active cases of TB (i.e., cultures for acid-fast bacilli [AFB] are negative, and chest radiographs are unchanged after six (6) weeks of an appropriate regimen for TB disease), TBI therapy can be considered complete with an additional:
  - two (2) weeks of INH, RIF, and PZA **or**
  - 2.5 months of RIF only **or**
  - 7.5 months of INH only

**Adverse Effects of TBI Medication**

**Table III-6** describes possible adverse reactions to medications used to treat TBI. For adverse reaction information on the 3HP regimen, **refer to Appendix D for the TTBE “3HP” Protocol.**

**Table III-6: Common Adverse Reactions to TBI Drugs**

Caused by	Adverse Reaction	Signs and Symptoms	Significance of Reaction*
Any drug	Allergic	<ul style="list-style-type: none"> <li>• Skin rash</li> </ul>	May be serious or minor
INH RPT	Hepatic toxicity	<ul style="list-style-type: none"> <li>• Abdominal pain</li> <li>• Abnormal liver function test results</li> <li>• Dark urine</li> <li>• Fatigue</li> <li>• Fever for three (3) or more days</li> <li>• Flu-like symptoms</li> <li>• Lack of appetite</li> <li>• Nausea</li> <li>• Vomiting</li> <li>• Yellowish skin or eyes</li> <li>• Tingling or numbness in hands or feet</li> <li>• Dizziness</li> </ul>	Serious
INH	Nervous system toxicity	<ul style="list-style-type: none"> <li>• Dizziness; tingling or numbness around the mouth; mental status changes</li> </ul>	Serious
	Peripheral neuropathy	<ul style="list-style-type: none"> <li>• Tingling sensation in hands and/or feet</li> </ul>	Serious

RIF	Bleeding problems	<ul style="list-style-type: none"> <li>• Easy bruising</li> <li>• Slow blood clotting</li> </ul>	Serious
	Discoloration of body fluids	<ul style="list-style-type: none"> <li>• Orange urine, sweat, or tears</li> <li>• Permanently stained soft contacts</li> </ul>	Minor
	Drug interactions	<ul style="list-style-type: none"> <li>• Interferes with certain medications such as birth control pills, birth control implants, and methadone treatment</li> </ul>	May be serious or minor
	Sensitivity to the sun	<ul style="list-style-type: none"> <li>• Frequent sunburn</li> </ul>	Minor

\*Patients should stop medication for serious adverse reactions and consult a clinician immediately. Patients can continue taking medication if they have minor adverse reactions.

Reference:

1. CDC. Core Curriculum on Tuberculosis: What the Clinician Should Know, 2013. <http://www.cdc.gov/tb/education/corecurr/default.htm> (adapted)

Contraindications to tuberculosis medications can be found at:

<http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf>

**Clinical and Laboratory Monitoring**

Clinic Visits

TBI patients will be seen in the HD monthly to be evaluated by a TB nurse for:

- Adherence to the prescribed regimen;
- Signs and symptoms of TB disease; if signs and symptoms are present, patient should be evaluated by a clinician and treatment changes should be made, as indicated; and
- Signs and symptoms of adverse effects to TBI medication, especially hepatic toxicity (**Refer to Table III-6**).

Monthly Re-Supply of Medication:

- If on a daily TBI treatment regimen, the patient will return to clinic for a one (1) month TBI medication re-supply visit. A physician order is required and is included in the patient’s chart if greater than one (1) month of medication is dispensed (**Standard of Public Health Practice III-4**).
  - If patient is going out of town for an extended period, consult with TB clinic regarding dispensing more than a one-month supply of medication
  - If patient is buying medication, obtain name of pharmacy and monitor monthly pick-up
- Before monthly medication is re-supplied, patients are assessed by a public health nurse (PHN) for sign/symptoms of adverse effects of medication. If the medication is re-supplied, the PHN documents all information on the Drug Screening and Monitoring

Record form PH-2040 (**Standard of Public Health Practice III-5**). (**Refer to Tool III-2 Drug Screening and Monitoring Record**)

- Ask patient about new medications (prescription, OTC, home remedies)
- Provide laboratory monitoring if indicated by clinical evaluation or physician order
- Contact patient if appointment not kept

For patients receiving any of the treatment regimens for TBI, follow-up laboratory monitoring is not routinely indicated for most patients, but may be ordered at the provider's discretion.

Routine laboratory monitoring during therapy is only indicated when:

- Baseline measurements are abnormal
- Patient has symptoms of adverse reactions or
- Persons are at risk for liver toxicity (e.g., underlying liver disease, taking other medications metabolized by the liver)

Asymptomatic mild elevations serum levels of aminotransaminases (AST/ALT) are expected with INH use and do **not** require that treatment be stopped. TBI therapy should be stopped at least temporarily and the patient evaluated by a clinician if liver enzymes (AST/ALT) exceed upper limit of normal (ULN):

- by three (3) times with symptoms **or**
- by five (5) times without symptoms **or**
- bilirubin is over the ULN at any level

Decisions to restart INH should be made carefully. If liver enzymes increase on therapy, inquire about concurrent use of alcohol or other medications or substances that may be contributing to elevated enzymes.

If patient has stopped TB medication or has not picked up a resupply for:

- Less than 2 months, the public health nurse (PHN) carefully assesses for signs/symptoms of active TB. If the assessment for signs/symptoms of TB is negative, the nurse may restart the TB medications. If there are signs and symptoms of TB disease, the TB clinician is notified for further orders (**Standard of Public Health Practice III-6**).

If TBI therapy is deferred for **> two (2)** months for any reason (i.e., until after pregnancy, after completion of rehab, patient returns from travel, etc.), or the patient has stopped TB medication or has not picked up medication re-supply for greater than two (2) months, the TB clinician re-evaluates the patient in TB clinic (including a clinical exam and CXR) before restarting medication (**Standard of Public Health Practice III-7**).

If TB disease is again ruled out and the TBI treatment interruption is:

- Less than three (3) months, TBI therapy can be restarted to complete the remaining amount of doses.
- Greater than three (3) months, and the patient is willing to be compliant with TBI therapy, treatment can be restarted as a new course of TBI treatment.

### **Documentation of Completion of Therapy for TBI**

For each patient placed on a TBI treatment, the following information is documented in the medical record by the TB clinician: drug name(s), dosage, frequency of dose and planned duration of therapy (**Standard of Public Health Practice III-10**). Completion of a full course of TBI treatment is the most-effective way to ensure the patient will not develop active TB and to prevent community transmission of TB. Completion of therapy should be based on the actual number of doses taken (**Refer to Table III-3**). Completion of TBI treatment, including the appropriate number of doses given within the allotted timeframe, is documented in the patient medical record (**Standard of Public Health Practice III-11**).

- 1) 9-month course of INH: **270** doses should be given within 12 months (or **76** doses if twice-weekly DOPT given)
- 2) 6-month course of INH: **180** daily doses should be given within 9 months, if longer duration of INH (9 month) cannot be completed
- 3) 6-month course of Rifampin: **180** daily DOPT doses must be given within 9 months for children
- 4) 4-month course of Rifampin: **120** daily doses should be given within 6 months for adults
- 5) 12-week course of Isoniazid-Rifapentine (aka “3HP”): **12** DOT doses should be given within 16 weeks.

Upon TBI treatment completion, patients should:

- Receive documentation of TST or IGRA result, medication taken (including medication name, dosage and frequency), and dates of treatment initiation and completion (**Refer to Appendix T – Completion of Treatment Template**);
- Be instructed to present this documentation when they are required to be tested for TB;
- Be re-educated about the signs and symptoms of TB disease and advised to seek medical attention if these occur;
- Be advised that treatment for TBI greatly reduces the risk of progression to TB disease, but does not entirely eliminate it; and
- Be informed that no further follow-up is required unless TB symptoms or other evidence of active disease are present.

Patients who cannot or will not take treatment for TBI are generally not followed clinically for reactivation of TB. Periodic clinical exams and periodic CXRs have not been shown to be effective in detecting TB reactivation before symptoms develop and are **not** recommended for most patients. **Annual follow-up CXR for TBI patients will not be provided by the health department, even if required for employment.**

For the patient that will not or cannot take TBI treatment:

- Provide the patient with a record of their positive TST or IGRA, and ensure understanding of the test’s significance; and
- Instruct to seek medical care if the patient develops any unexplained, persistent symptoms suggestive of TB disease, and to remind their provider of their positive TST or IGRA status.

5. **TOOLS**

III-1: Drug Information Sheets

III-2: Drug Screening and Monitoring Record

# **Tool III-1: Drug Information Sheets**

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# What You Need to Know About Your Medicine for Latent Tuberculosis (TB) Infection

## ISONIAZID

You have been given medicine to treat your latent TB infection. You do not have TB disease and cannot spread TB to others. This medicine will help you **PREVENT** getting TB disease.

### While on this Medicine:

- Tell your doctor or nurse if you have questions or concerns with the medicine.
- Go to your planned clinic visits.
- Discuss any alcohol use with your doctor. Alcohol use may cause side effects.
- Tell your doctor about all other medicines you are taking.
- Be sure to tell your other doctors that you are being treated for latent TB infection.
- Take all of your medicine as you were told by your TB doctor or nurse.
- Some people find that the medicine affects them less when taken with food.

### Tips to Help You Take Your Medicine:

- ✓ Take your medicine at the same time every day.
- ✓ Set an alarm reminder for the time you should take your medicine.
- ✓ Ask a family member or friend to remind you.
- ✓ Use a pillbox.
- ✓ Put a reminder note on your mirror or refrigerator.
- ✓ Use a calendar to check off the day when you take your medicine.

### Latent TB Infection Medicine Schedule:

(Providers: Indicate the appropriate schedule, days and number of pills)

Medicine	Schedule	Days	Number of pills per day	Length of time
Isoniazid	<input type="checkbox"/> Daily	Every day		9 months
	<input type="checkbox"/> Twice Weekly*	M T W Th F S Sun		

Your doctor may have you take vitamin B6 with your medicine.

**Note:** When isoniazid is to be taken 2 times a week, it should be given by directly observed therapy (DOT).\*

**IF YOU FORGET TO TAKE YOUR MEDICINE: If it is still the same day, take the dose as soon as you remember. If the day has passed, skip the missed dose and take your next scheduled dose — do not take 2 doses at the same time.**

### NOTES

Name of my doctor:  
Name of my clinic:  
Telephone number of my clinic:



### Watch for these Possible Problems:

**STOP** taking your medicine right away **AND** call your TB doctor or nurse if you have any of the problems below:

- Less appetite, or no appetite for food
- An upset stomach or stomach cramps
- Nausea or vomiting
- Cola-colored urine or light stools
- Rash or itching
- Yellowing skin or eyes
- Tingling or numbness in your hands or feet

### \*Directly Observed Therapy (DOT)

You will meet with a health care worker to take your medicine. This plan is called directly observed therapy.

DOT can help you in several ways.

- The health care worker helps you to remember to take your medicine.
- You will complete your treatment as soon as possible.
- The health care worker will make sure you are not having problems with the medicine.

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# Lo que usted necesita saber sobre sus medicamentos contra la infección de tuberculosis (TB) latente

## ISONIAZIDA

Usted recibió medicamentos para tratar la infección de tuberculosis latente que contrajo. Usted no tiene la enfermedad de tuberculosis y no se la puede transmitir a otras personas. Estos medicamentos ayudarán a **PREVENIR** que contraiga la enfermedad de tuberculosis.

### Mientras tome este medicamento:

- Dígales a su médico o enfermera si tiene preguntas o preocupaciones acerca del medicamento.
- Acuda a las visitas clínicas planificadas.
- Dígale a su médico si tomó cualquier cantidad de alcohol porque el consumo de alcohol puede producir efectos secundarios.
- Infórmele a su médico de todos los demás medicamentos que esté tomando.
- Asegúrese de decirles a sus otros médicos que está recibiendo tratamiento contra la infección de tuberculosis latente.
- Tome todos sus medicamentos de la manera en que se lo indique su médico especialista en tuberculosis o la enfermera.
- A algunas personas los medicamentos las afectan menos cuando los toman acompañados de comida.

### Consejos para ayudarlo a que se tome su medicamento:

- ✓ Tómelo a la misma hora todos los días.
- ✓ Póngase una alarma que le recuerde la hora a la que debe tomar su medicamento.
- ✓ Pídale a un familiar o amigo que le recuerde.
- ✓ Utilice un pastillero.
- ✓ Ponga una nota de recordatorio en su espejo o refrigerador.
- ✓ Utilice un calendario para marcar los días en los que se tome su medicamento.

### Calendario de medicamentos contra la infección de tuberculosis

**latente:** (Proveedor: Indique la frecuencia adecuada, el día y el número de pastillas)

Medicamento	Frecuencia	Día	Número de pastillas al día	Duración
Isoniazida	<input type="checkbox"/> Diariamente	Todos los días		9 meses
	<input type="checkbox"/> Dos veces a la semana*	L M M J V S D		

Su médico puede indicarle que tome vitamina B6 con su medicamento.

**Nota:** Cuando la isoniazida se deba tomar 2 veces a la semana, se debe administrar bajo terapia de observación directa (DOT).\*

**SI SE OLVIDA DE TOMAR SU MEDICAMENTO:** Si todavía es el mismo día, tome la dosis tan pronto como se acuerde. Si ya pasó el día, sátese la dosis que olvidó y tome la siguiente según el calendario, pero no tome 2 dosis al mismo tiempo.

#### NOTAS:

Nombre de mi médico:

Nombre de mi clínica:

Número de teléfono de mi clínica:



### Ponga atención a estos problemas posibles:

**DEJE** de tomar su medicamento de inmediato y llame a su médico especialista en tuberculosis o a la enfermera si tiene alguno de los siguientes problemas:

- Pérdida o disminución de su apetito por la comida
- Cólicos o malestar estomacales
- Náuseas o vómitos
- Orina de color de la Coca Cola o heces claras
- Sarpullido o picazón
- Piel y ojos amarillentos
- Hormigueo o adormecimiento en las manos o en los pies

### \*Terapia de observación directa (DOT)

Usted se reunirá con un profesional de la salud para tomar su medicamento. Este plan se llama terapia de observación directa (\*DOT, por sus siglas en inglés).

La DOT puede ayudarlo de varias maneras.

- El profesional de la salud le ayuda a acordarse de tomar su medicamento.
- Usted completará su tratamiento lo más pronto posible.
- El profesional de la salud se asegurará de que usted no esté teniendo problemas con el medicamento.

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# What You Need to Know About Your Medicine for Latent Tuberculosis (TB) Infection

## RIFAMPIN

You have been given medicine to treat your latent TB infection. You do not have TB disease and cannot spread TB to others. This medicine will help you **PREVENT** getting TB disease.

### While on this Medicine:

- Tell your doctor or nurse if you have questions or concerns with the medicine.
- Go to your planned clinic visits.
- Discuss any alcohol use with your doctor. Alcohol use may cause side effects.
- Tell your doctor about all other medicines you are taking.
- Be sure to tell your other doctors that you are being treated for latent TB infection.
- Take all of your medicine as you were told by your TB doctor or nurse.
- Some people find that the medicine affects them less when taken with food.

### Tips to Help You Take Your Medicine:

- ✓ Take your medicine at the same time every day.
- ✓ Set an alarm reminder for the time you should take your medicine.
- ✓ Ask a family member or friend to remind you.
- ✓ Use a pillbox.
- ✓ Put a reminder note on your mirror or refrigerator.
- ✓ Use a calendar to check off the day when you take your medicine.

### Latent TB Infection Medicine Schedule:

(Providers: Indicate the appropriate number of pills)

Medicine	Schedule	Number of pills per day	Length of time
Rifampin	Daily		4 months

Your doctor may have you meet with a health care worker to take your medicine. This plan is called directly observed therapy (DOT).

**IF YOU FORGET TO TAKE YOUR MEDICINE: If it is still the same day, take the dose as soon as you remember. Do not take 2 doses at the same time.**

### NOTES

Name of my doctor:

Name of my clinic:

Telephone number of my clinic:



### Watch for these Possible Problems:

**STOP** taking your medicine right away **AND** call your TB doctor or nurse if you have any of the problems below:

- Less appetite, or no appetite for food
- An upset stomach or stomach cramps
- Nausea or vomiting
- Cola-colored urine or light stools
- Easy bruising or bleeding
- Rash or itching
- Yellowing skin or eyes
- Severe weakness or tiredness
- Fever
- Head or body aches
- Dizziness

**NOTE:** It is normal if your urine, saliva, or tears become orange-colored. Soft contact lenses may become stained.

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# Lo que usted necesita saber sobre sus medicamentos contra la infección de tuberculosis (TB) latente

## RIFAMPICINA

Usted recibió medicamentos para tratar la infección de tuberculosis latente que contrajo. Usted no tiene la enfermedad de tuberculosis y no se la puede transmitir a otras personas. Estos medicamentos ayudarán a **PREVENIR** que contraiga la enfermedad de tuberculosis.

### Mientras tome este medicamento:

- Dígales a su médico o enfermera si tiene preguntas o preocupaciones acerca del medicamento.
- Acuda a las visitas clínicas planificadas.
- Dígale a su médico si tomó cualquier cantidad de alcohol porque el consumo de alcohol puede producir efectos secundarios.
- Infórmele a su médico de todos los demás medicamentos que esté tomando.
- Asegúrese de decirles a sus otros médicos que está recibiendo tratamiento contra la infección de tuberculosis latente.
- Tome todos sus medicamentos de la manera en que se lo indique su médico especialista en tuberculosis o la enfermera.
- A algunas personas los medicamentos las afectan menos cuando los toman acompañados de comida.

### Consejos para ayudarlo a que se tome su medicamento:

- ✓ Tómelo a la misma hora todos los días.
- ✓ Póngase una alarma que le recuerde la hora a la que debe tomar su medicamento.
- ✓ Pídale a un familiar o amigo que le recuerde.
- ✓ Utilice un pastillero.
- ✓ Ponga una nota de recordatorio en su espejo o refrigerador.
- ✓ Utilice un calendario para marcar los días en los que se tome su medicamento.

### Calendario de medicamentos contra la infección de tuberculosis

**latente:** (Proveedor: Indique el número adecuado de pastillas)

Medicamento	Frecuencia	Número de pastillas al día	Duración
Rifampicina	Diariamente		4 meses

Su médico puede indicarle que se reúna con un trabajador de la salud para tomar su medicamento. Este plan se llama terapia de observación directa (DOT, por sus siglas en inglés).

**SI SE OLVIDA DE TOMAR SU MEDICAMENTO: Si todavía es el mismo día, tome la dosis tan pronto como se acuerde. No tome 2 dosis al mismo tiempo.**

#### NOTAS:

Nombre de mi médico:

Nombre de mi clínica:

Número de teléfono de mi clínica:



### Ponga atención a estos problemas posibles:

**DEJE** de tomar su medicamento de inmediato y llame a su médico especialista en tuberculosis o a la enfermera si tiene alguno de los siguientes problemas:

- Pérdida o disminución de su apetito por la comida
- Cólicos o malestar estomacales
- Náuseas o vómitos
- Orina de color de la Coca Cola o heces claras
- Moretones frecuentes o hemorragia
- Sarpullido o picazón
- Piel y ojos amarillentos
- Debilidad o cansancio extremos
- Fiebre
- Dolor de cabeza o dolores en el cuerpo
- Mareos

**NOTA:** Es normal si su orina, saliva o lágrimas se vuelven color naranja. Los lentes de contacto blandos se pueden manchar.

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# What You Need to Know About Your Medicine for Tuberculosis Infection (TBI)

## ISONIAZID and RIFAPENTINE

You have been given medicine to treat your TB infection. You do not have TB disease and cannot spread TB to others. This medicine will help you **PREVENT** getting TB disease.

### Remember to Keep Your Weekly Visits:

You will meet with a health care worker weekly to take your medicines. This plan is called directly observed therapy (DOT).

DOT can help you in several ways.

- The health care worker helps you to remember to take your medicines.
- You will complete your treatment as soon as possible.
- The health care worker will make sure you are not having problems with the medicines.
- During your weekly meetings, this person can answer your questions. You can also talk about any concerns you have.

### While on this Medicine:

- ✓ Tell your doctor or nurse if you have questions or concerns with the medicine.
- ✓ Go to weekly visits.
- ✓ Discuss any alcohol use with your doctor. Alcohol use may cause side effects.
- ✓ Tell your doctor about all other medicines you are taking.
- ✓ Be sure to tell your other doctors that you are being treated for TB infection.
- ✓ Some people find that the medicines affect them less when taken with food.

### TB Infection Medicine Schedule:

(Providers: Indicate the appropriate day and number of pills)

Medicine	Schedule	Day	Number of pills per day	Length of time
Isoniazid & Rifapentine	Once weekly	M T W Th F S Sun		3 months (12 weeks)

Your doctor may have you take vitamin B6 with your medicine.

#### NOTES

Name of my doctor:

Name of my clinic:

Telephone number of my clinic:



### Watch for these Possible Problems:

**STOP AND** call your TB doctor or nurse right away if you have any of the problems below:

- Less appetite, or no appetite for food
- An upset stomach or stomach cramps
- Fever
- Head or body aches
- Nausea or vomiting
- Cola-colored urine or light stools
- Easy bruising or bleeding
- Rash or itching
- Yellowing skin or eyes
- Severe weakness or tiredness
- Tingling or numbness in your hands or feet
- Dizziness

**NOTE:** It is normal if your urine, saliva, or tears become orange-colored. Soft contact lenses may become stained.

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# Lo que usted necesita saber sobre sus medicamentos contra la infección de tuberculosis (TBI)

## ISONIAZIDA Y RIFAPENTINA

Usted recibió medicamentos para tratar la infección de tuberculosis latente que contrajo. Usted no tiene la enfermedad de tuberculosis y no se la puede transmitir a otras personas. Estos medicamentos ayudarán a **PREVENIR** que contraiga la enfermedad de tuberculosis.

### No se olvide de sus visitas semanales:

Usted se reunirá con un profesional de la salud cada semana para tomar sus medicamentos. Este plan se llama terapia de observación directa (DOT, por sus siglas en inglés).

La DOT es útil por varias razones:

- El profesional de la salud le ayuda a acordarse de tomar sus medicamentos.
- Usted completará su tratamiento lo más pronto posible.
- El profesional de la salud se asegurará de que usted no esté teniendo problemas con los medicamentos.
- Durante sus reuniones semanales, esta persona puede responder a sus preguntas y usted también podrá hablar acerca de cualquier preocupación que tenga.

### Mientras tome este medicamento:

- ✓ Dígales a su médico o enfermera si tiene preguntas o preocupaciones acerca del medicamento.
- ✓ Vaya a las visitas semanales.
- ✓ Dígale a su médico si tomó cualquier cantidad de alcohol porque el consumo de alcohol puede producir efectos secundarios.
- ✓ Infórmele a su médico de todos los demás medicamentos que esté tomando.
- ✓ Asegúrese de decirles a sus otros médicos que está recibiendo tratamiento contra la infección de tuberculosis.
- ✓ A algunas personas los medicamentos las afectan menos cuando los toman acompañados de comida.

### Calendario de medicamentos contra la infección de

**tuberculosis:** (Proveedor: Indique la fecha adecuada y el número de pastillas)

Medicamento	Frecuencia	Día	Número de pastillas al día	Duración
Isoniazida y Rifapentina	Una vez a la semana	L M M J V S D		3 meses (12 semanas)

Su médico puede indicarle que tome vitamina B6 con su medicamento.

#### NOTAS:

Nombre de mi médico:

Nombre de mi clínica:

Número de teléfono de mi clínica:



### Ponga atención a estos problemas posibles:

**DETÉNGASE** y llame a su médico especialista en tuberculosis o a la enfermera de inmediato si tiene alguno de los siguientes problemas:

- Pérdida o disminución de su apetito por la comida
- Cólicos o malestar estomacales
- Fiebre
- Dolor de cabeza o dolores en el cuerpo
- Náuseas o vómitos
- Orina de color de la Coca Cola o heces claras
- Moretones frecuentes o hemorragia
- Sarpullido o picazón
- Piel y ojos amarillentos
- Debilidad o cansancio extremos
- Hormigueo o adormecimiento en las manos o en los pies
- Mareos

**NOTA:** Es normal si su orina, saliva o lágrimas se vuelven color naranja. Los lentes de contacto blandos se pueden manchar.

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention  
Division of Tuberculosis Elimination



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# **Tool III-2**

## **Drug Screening and Monitoring Record**

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