Latent Tuberculosis Infection
A Quick Guide to Case Management

DOH TB Program
Table of Contents

Introduction ....................................................................................................................................... 2

Diagnosing Latent TB Infection Flow Chart ....................................................................................... 3

Section One: Diagnosing TB Infection .................................................................................................. 4
  How to Interpret a Tuberculin Skin Test Reaction ............................................................................. 5
  Labs Available to Perform IGRA Testing ............................................................................................ 7
  TB Testing Risk Assessment Form .................................................................................................... 9
  Tuberculosis Laboratory Diagnostics Summary ................................................................................. 11

Section Two: Initiating Treatment ..................................................................................................... 12
  Recommended Drug Regimens for Treatment of LTBI ...................................................................... 13
  Consent for LTBI Treatment ............................................................................................................ 16

Section Three: Case Management ..................................................................................................... 18
  LTBI Case Management: Monthly Patient Assessment ..................................................................... 19-20

Section Four: Dispositioning the Patient ........................................................................................... 22
  Tuberculosis Treatment Summary ................................................................................................... 23

Section Five: Additional Resources .................................................................................................. 24
Introduction

This guide is intended for providers who care for individuals who have or may be at risk for latent tuberculosis infection (LTBI). LTBI is the presence of *Mycobacterium tuberculosis* in the body without signs and symptoms, or radiographic or bacteriologic evidence of tuberculosis (TB) disease.

In the United States, an estimated 9-14 million people have LTBI. Without treatment, approximately 5-10% of persons with LTBI will progress to TB disease at some point in their lifetime unless LTBI therapy is initiated. Identifying and treating those at highest risk for TB disease will help move toward elimination of the disease.

This document is not meant to be used as a substitute for the comprehensive guidelines published by the Centers for Disease control and Prevention (CDC) and by Washington State Department of Health (DOH), but rather as a ready and useful reference that highlights the main points of those guidelines.

In this document you will find summarization of the main topics related to LTBI diagnosis and case management, links to useful tools and resources, as well as sample forms that can be modified for use by your facility.
Diagnosing Latent TB Infection

Perform TB test (TST or IGRA)

- TB test Positive
  - Obtain chest radiograph
    - Radiograph Abnormal*:
      - Obtain laboratory diagnostics (sputums)**:
        - Sputums Positive for TB disease***: Treat for active TB disease
        - Sputums Negative for TB disease: Treat for LTBI
  - Radiograph Normal: Treat for LTBI

- TB test Negative
  - Collect 3 sputums for AFB smear, culture, and nucleic acid amplification testing (NAAT).
  - Notify the local health department and consult and/or refer patient to them for treatment.

*Consider notifying/consulting with local health department.
** Collect 3 sputums for AFB smear, culture, and nucleic acid amplification testing (NAAT).
*** Notify the local health department and consult and/or refer patient to them for treatment.
Section One: Diagnosing TB Infection

Tests for TB Infection

_Tuberculin Skin Test (TST)_

The tuberculin skin test is administered intradermally using the Mantoux technique by injecting 0.1 ml of 5 TU purified protein derivative (PPD) solution. If a person is infected, a delayed-type hypersensitivity reaction is detectable 2-8 weeks after infection. The reading and interpretation of TST reactions should be conducted within 48 to 72 hours of administration by a trained health care professional.\(^i\)

Online training on administration of the TST using the Mantoux method is available at: [http://www2c.cdc.gov/podcasts/player.asp?f=3739](http://www2c.cdc.gov/podcasts/player.asp?f=3739)

Key Points

- Almost everyone can receive a TST, including infants, children, pregnant women, people living with HIV, and people who have had a BCG vaccination. People who had a severe reaction to a previous TST should not receive another TST.\(^ii\)
- The TST should not be performed on a person who has written documentation of either a previous positive TST result or treatment for TB disease.\(^i\) Once positive, a TST will likely always react positive on subsequent testing.
- Interpretation of the TST result is the same for persons who have had BCG vaccination.\(^i\)
- A positive TB test indicates that a person has been infected with TB, but does not differentiate between latent and active TB.\(^ii\)
### How to Interpret a Tuberculin Skin Test Reaction

<table>
<thead>
<tr>
<th>Induration Size</th>
<th>Considered Positive In:</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 mm or more</td>
<td>- HIV-infected persons</td>
</tr>
<tr>
<td></td>
<td>- Recent contacts of a person with infectious TB disease</td>
</tr>
<tr>
<td></td>
<td>- Persons with fibrotic changes on chest radiograph consistent with prior TB</td>
</tr>
<tr>
<td></td>
<td>- Organ transplant recipients</td>
</tr>
<tr>
<td></td>
<td>- Persons who are immunocompromised for other reasons (e.g., taking equivalent of &gt; 15 mg/day of prednisone for 1 month or more or those taking TNF-alpha antagonists)</td>
</tr>
<tr>
<td>10 mm or more</td>
<td>- Foreign-born persons from countries with a high TB incidence or prevalence (e.g., most countries in Africa, Asia, Latin America, Eastern Europe, the former USSR, or from refugee camps)</td>
</tr>
<tr>
<td></td>
<td>- Injection drug user’s</td>
</tr>
<tr>
<td></td>
<td>- Residents and employees in high-risk, congregate settings (e.g., correctional institutions; long-term residential care facilities, such as nursing homes, mental institutions, etc.; hospitals and other healthcare facilities; homeless shelters; and refugee camps)</td>
</tr>
<tr>
<td></td>
<td>- Mycobacteriology laboratory personnel</td>
</tr>
<tr>
<td></td>
<td>- Persons with other medical conditions that increase the risk of TB disease (e.g., diabetes, chronic renal failure or on hemodialysis, head and neck cancer)</td>
</tr>
<tr>
<td></td>
<td>- Children younger than 4 years of age, or children and adolescents exposed to adults in at high risk for TB disease</td>
</tr>
<tr>
<td>15 mm or more</td>
<td>- Persons with no known risk factors for TB</td>
</tr>
</tbody>
</table>
BCG Vaccine

The BCG vaccine is currently used in many parts of the world where TB is common to protect infants and young children from serious, life-threatening disease. BCG vaccination is not recommended in the U.S. The question of the effect of BCG vaccine on TST results often causes confusion. TST reactivity caused by BCG vaccine generally wanes with the passage of time, but periodic skin testing may prolong (boost) reactivity in vaccinated persons. A history of BCG vaccination is not a contraindication for tuberculin skin testing or treatment for LTBI in persons with positive TST results. TST reactions should be interpreted regardless of BCG vaccination history.

Interferon-Gamma Release Assays (IGRAs) use *M. tuberculosis* specific antigens that do not cross react with BCG and therefore, do not cause false positive reactions in BCG recipients.

*Interferon – Gamma Release Assays (IGRAs)*

Like the TST, IGRAs are used to determine if a person is infected with *M. tuberculosis*. The QuantiFERON®- TB Gold In-Tube test (QFT-GIT), and T-SPOT.®-TB are the two available IGRA tests. The advantages of IGRAs include that they are unaffected by BCG and most environmental mycobacteria, and that a positive and negative control is built into the test which minimizes false positive and negative results.

For more information on QFT-GIT and T-SPOT see: www.quantiferon.com and www.tspot.com

Key Points

- Blood samples must be processed within 8-16 hours.
- Blood samples must be collected using specific tubes and collection technique.
- Limited data exist on use in children younger than 5 years of age.
- IGRAs do not cross react with BCG vaccine.
- Once positive, an IGRA will likely always react positive on subsequent testing.
### Labs Available to Perform IGRA Testing

<table>
<thead>
<tr>
<th><strong>Evergreen Hospital</strong></th>
<th><strong>Providence St. Peter Hospital Clinical Laboratory</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>12040 NE 128th St</td>
<td>413 Lilly Road NE</td>
</tr>
<tr>
<td>Kirkland, WA 98034</td>
<td>Olympia, WA 98506</td>
</tr>
<tr>
<td>Ph: 425-899-3900</td>
<td>360-493-5181</td>
</tr>
<tr>
<td>Fax: 425-899-3901</td>
<td></td>
</tr>
</tbody>
</table>

**Group Health**  
Locations throughout Washington. Click on link to find the nearest medical center.

**LabCorp-Northwest Region**  
Locations throughout Washington. Click on link to find the nearest laboratory.

**Overlake Hospital Medical Center**  
1135 116th Ave NE Ste 170  
Bellevue, WA 98004  
425-688-5106

**Paclab Network Laboratories**  
Click on link to find the nearest laboratory.  
425-688-9274

**PAML – Pathology Associates Medical Laboratories**  
110 W Cliff Ave  
Spokane, WA 99204  
PAML Client Services (statewide):  
800-541-7891  
Bellevue/Seattle: 888-472-2522  
Olympia: 888-910-6156  
Fax: 509-924-0002  
Courier Services: 800-541-7891

**Providence Everett**  
916 Pacific Avenue  
Everett, WA 98201  
425-261-2000

**Public Health – Seattle and King County**  
325 Ninth Ave  
Seattle, WA 98104  
Ph: 206-744-8950  
Fax: 206-731-8963

**Quest Diagnostics**  
1737 Airport Way S, Suite 200  
Seattle, WA  
1-866-697-8378

**Seattle Children’s**  
4800 Sand Point Way NE  
Seattle, WA 98105  
866-987-2000 (Toll Free)

**Tacoma General Hospital (Laboratories Northwest)**  
1003 South 5th – 4th Floor  
Tacoma, WA 98405  
253-403-1187

**Tri-Cities Laboratory**  
7131 West Grandridge Blvd.  
Kennewick, WA 99336  
509-736-0100

**UW Medical Center**  
1959 NE Pacific St  
Seattle, WA 98195  
206-598-6131  
UW MC Fax 206-598-7937  
Harborview Fax: 206-744-4850
Selecting a Test to Detect TB Infection

- IGRAs are the preferred method of testing for:
  -- Groups of people who have poor rates of returning to have the TST read
  -- Persons who have received BCG vaccine

- TST is the preferred method for testing for:
  -- Children under the age of 5 years

- Either TST or IGRA may be used without preference for other groups that are tested for LTBI.

For more information on selecting a test for TB infection please see:

http://www.cdc.gov/mmwr/pdf/rr/rr5905.pdf

Key Point

- Routine testing with both TST and IGRAs is NOT recommended.

At the time of testing the person should be evaluated for risk of TB infection and disease, symptoms of TB disease, and any TB history such as prior positive TB tests and completion of TB therapy. A thorough risk assessment will help in choosing a testing method, interpreting TB test results, and provide useful information regarding potential treatment options.

The following form is an example TB risk assessment form:
TB Testing Risk Assessment Form

Name: __________________________ Last First MI

Birthdate: __________ Age: _______ Male: ☐ Female: ☐ Phone #: __________________________

Address: __________________________ City: __________ State: _______ Zip: __________

TB History

Documentation of Prior TB Test: Yes ☐ No ☐ Date: __________ Result: __________________________

Documentation of Prior TB Treatment Completion: Yes ☐ No ☐

Symptoms

☐ None ☐ Cough ☐ Hemoptysis (blood in sputum) ☐ Fever ☐ Night Sweats ☐ Unusual Fatigue

☐ Weight Loss ☐ Anorexia (loss of appetite) ☐ Dyspnea (shortness of breath) ☐ Chest Pain ☐ Hoarseness

If yes to any of the above, please specify for how long: __________________________

Risk Assessment

Medical Risk:

☐ HIV + ☐ + TST ☐ Abnormal CXR ☐ IV drug use/substance abuse ☐ Diabetes

☐ Steroid/immunosuppressive medication ☐ Chronic Renal Failure ☐ Cancer/Leukemia

☐ Pulmonary Silicosis ☐ Intestinal Bypass Surgery ☐ Age <5yrs ☐ TB Exposure

Population Risk: (Live or work in)

☐ Homeless Shelter ☐ Prison/Jail ☐ Healthcare Facility ☐ Nursing Home ☐ Foreign Born

TB Testing

Current Medications: __________________________ Recent Vaccinations: Yes ☐ No ☐

TST Date: _______ Time: _______ Read Date: _______ Result (mm): _______ Positive: ☐ Negative: ☐

PPD Solution Lot #: __________________________

Consent

☐ I consent to a TB test for tuberculosis for myself.

OR

☐ I consent to a TB test for tuberculosis for my child, _____________________________.

Signature: __________________________ Date: __________________________
Follow-up for Positive TB Test

*Chest Radiograph*

All persons with a positive TB test should receive a chest radiograph. Chest radiographs help differentiate between LTBI and pulmonary TB disease.¹

Key Points

- Persons > 5 years of age should have a posterior-anterior view radiograph.
- Children under 5 years of age should have both posterior-anterior and lateral views.
- Periodic follow-up radiographs are not indicated regardless of whether treatment is completed except in unusual circumstances (e.g., contacts to patients with drug resistant TB).¹

Radiographic findings suggestive of active TB include:

- Air-space opacity or consolidation, often referred to as air-space disease
- Interstitial opacity
- Nodules or masses
- Thoracic lymphadenopathy
- Pulmonary cysts or cavities
- Pleural space abnormalities

For more information on TB Chest Radiology see:

*Sputum Examination*

Sputum examination is indicated for persons with positive TB test results and either an abnormal chest radiograph or the presence of respiratory symptoms (even when the chest radiograph is normal).¹

Key Points

- Three consecutive sputums should be collected 8-24 hours apart with one being an early morning sputum.
- Specimens should be refrigerated until sent to the laboratory.
- Order an Acid Fast Bacilli (AFB) smear and culture on each specimen.
- Nucleic Acid Amplification testing (NAAT) may be ordered through the Washington State Public Health Lab (WAPHL). Contact WAPHL at 206-418-5473 for ordering information.
<table>
<thead>
<tr>
<th><strong>Tuberculosis Laboratory Diagnostics Summary</strong></th>
</tr>
</thead>
</table>
| **AFB Smear** | • Tests for the presence of any mycobacterium  
• Results available within 24 hours  
• Provides clue to potential infectivity  
• Does not differentiate between live and dead mycobacterium  
• Performed in most laboratories |
| **AFB Culture** | • Gold standard for diagnosing TB  
• Results typically available in 2-8 weeks  
• Only detects live mycobacterium  
• Performed at WAPHL, Harborview, SeaKing PHL, PAML, UW, and commercial labs |
| **Species Identification** | • Performed automatically on positive cultures to determine the type of mycobacterium present (ex. M.tb, M. avium, M. gordonae)  
• One of the following methods is used to identify the species:  
  o DNA Probe (AccuProbe)  
  o Hsp65 sequencing  
  o High Performance (or Pressure) Liquid Chromatography (HPLC) |
| **Nucleic Acid Amplification Test (NAAT)** | • Detects TB DNA  
• Performed after AFB smear, if ordered (more sensitive on smear positive specimens)  
• A positive NAAT is considered a confirmed case of TB  
• A negative NAAT does not rule out TB  
• Results available in 24-72 hours  
• Does not differentiate between live and dead mycobacterium  
• Two methods for NAA testing include:  
  o Polymerase Chain Reaction (PCR) performed at WAPHL  
  o Hsp65 Sequencing performed at UW |
| **Drug Sensitivity Testing** | • First-line (SIRE and usually PZA) performed automatically, using MGIT instrument, on culture positive specimens  
• Available within 30 days of culture positive result  
• Performed at Harborview, PAML, or WAPHL  
• Second-line performed at WAPHL or CDC using plate or Agar Proportion Method, if first-line resistance detected |
| **Drug Resistance Mutation Detection** | • Detects common mutations located within specific regions of TB DNA  
• Performed when requested on NAAT or culture positive specimens  
• Two methods for detecting mutations include:  
  o Drug Resistance Screening by Sequencing (DRSS) performed at WAPHL  
  o Molecular Detection of Drug Resistance (MDDR) performed at CDC  
• Detected mutation does not always mean total resistance to the drug(s) |
| **Genotyping** | • Performed automatically on culture positive specimens  
• Determines the strain of TB and whether it matches other strains of TB  
• Performed by a CDC contracted lab in Michigan |

Acronyms: Washington State Public Health Lab (WAPHL), Seattle and King County Public Health Lab (SeaKing PHL), Pathology Associates Medical Laboratory (PAML), University of Washington (UW), Centers for Disease Control and Prevention (CDC), Streptomycin, Isoniazid, Rifampin, Ethambutol (SIRE), Pyrazinamide (PZA)
Section Two: Initiating Treatment

**Decision to Treat**

The decision to initiate or forego treatment for LTBI should be made by weighing a person’s risk for progression to active TB disease, risk for potentially harmful side effects from the medication, and likelihood of patient adherence. The following tool may help you estimate the risk of active TB for persons with a TST reaction > 5mm and/or a positive IGRA: [http://tstin3d.com/en/calc.html](http://tstin3d.com/en/calc.html)

**Key Points**

- There is no age cutoff for LTBI treatment
- Never begin treatment for LTBI until active TB disease is ruled out

**Choosing a LTBI Treatment Regimen**

Each LTBI treatment regimen differs regarding risk for side effects, drug-drug interactions, and length of treatment. With this in mind, an appropriate regimen should be chosen after considering a person’s health status, other medications prescribed, and life circumstances.

The following printable pocket guide describes the different LTBI Treatment Regimens:
**RECOMMENDED DRUG REGIMENS FOR TREATMENT OF LTBI**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Interval/Duration</th>
<th>Adult, &gt;25Yrs, Dosage (max)</th>
<th>Pediatric, &lt;15Yrs, Dosage (max)</th>
<th>Criteria for Completion</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>INH*</td>
<td>Daily for 9 mos.</td>
<td>5 mg/kg (300mg)</td>
<td>10-20 mg/kg (300mg)</td>
<td>270 doses within 12 mos.</td>
<td>DAILY INH PREFERRED FOR ALL PERSONS Not indicated for persons exposed to INH-resistant TB</td>
</tr>
<tr>
<td></td>
<td>Twice-weekly for 9 mos.</td>
<td>15mg/kg (900mg)</td>
<td>20-30 mg/kg</td>
<td>76 doses within 12 mos.</td>
<td>• DOT must be used with twice-weekly dosing</td>
</tr>
<tr>
<td>RIF</td>
<td>Daily for 4 mos.</td>
<td>10 mg/kg (600mg)</td>
<td>10-20 mg/kg (600mg)</td>
<td>120 doses within 6 mos.</td>
<td>For contacts of patients with INH-resistant, RIF-susceptible TB or when shorter course treatment is preferred In HIV-infected persons, protease inhibitors or NNRTIs should not be administered concurrently with RIF</td>
</tr>
<tr>
<td></td>
<td>Daily for at least 6 mos.</td>
<td>15mg/kg (900mg)</td>
<td></td>
<td>180 doses within 9 mos.</td>
<td></td>
</tr>
<tr>
<td>INH/ RPT</td>
<td>Once weekly for 12 wks.</td>
<td>Rifapentine: 10-14kg=300mg 14.1-25kg=450mg 25.1-32kg=600mg 32.1-49.9kg=750mg (900mg) INH: 15mg/kg (900mg)</td>
<td>Only for &gt;12yr Rifapentine: 10-14kg=300mg 14.1-25kg=450mg 25.1-32kg=600mg 32.1-49.9kg=750mg (900mg) INH: 15mg/kg (900mg)</td>
<td>11 or 12 doses within 16 wks.</td>
<td>• DOT must be used with this regimen Do not use in children &lt;2, or for HIV-infected patients receiving ARV therapy, or for pregnant women, or for persons exposed to INH or Rif-resistant TB INH is preferred for children 2-11, however, this regimen may considered when completion of 9 months of INH is unlikely and the risk of TB disease is great</td>
</tr>
</tbody>
</table>

**Abbreviations:** INH=isoniazid, RIF=rifampin, RPT=rifapentine, NNRTIs=non-nucleoside reverse transcriptase inhibitors, ARV=antiretroviral, DOT=directly observed therapy, mos.=months, wks.=weeks

*isoniazid for six months can be considered a complete course of LTBI therapy; however, it is not indicated for persons with HIV infection or fibrotic lesions, or for children, or for persons exposed to INH-resistant TB

---

**Drug Information**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Adverse Reactions</th>
<th>Contraindications</th>
<th>Monitoring</th>
<th>Patient Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>INH</td>
<td><em>Hepatitis</em></td>
<td>Patients infected with presumed INH-resistant strain</td>
<td>Clinical monitoring is essential. Liver function monitoring is appropriate if given with other hepatotoxic medications or if there are symptoms of hepatotoxicity. Monitor concentrations of phenytoin or carbamazepine.</td>
<td>• May take with food</td>
</tr>
<tr>
<td></td>
<td><em>Peripheral neuropathy</em></td>
<td></td>
<td></td>
<td>• Avoid alcohol</td>
</tr>
<tr>
<td></td>
<td><em>Hypersensitivity reactions</em></td>
<td>Other reactions, including optic neuritis, arthralgias, CNS changes, drug-induced lupus, headache, diarrhea, and cramping. <strong>Note:</strong> Pyridoxine (B6) supplements are also recommended for pregnant and breast feeding women, breast-feeding infants, children and adolescents on milk- and meat-deficient diets, children who experience parasitases while taking INH, and those with HIV infection</td>
<td></td>
<td>• Avoid antacid within one hour of taking INH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Call doctor right away if:</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Loss of appetite for a few days</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Tiredness, weakness</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Stomach pain, nausea, or vomiting</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Numbness or tingling in fingers or toes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Blurred vision, eye pain</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Yellow skin or eyes or dark-colored urine</td>
</tr>
<tr>
<td>RIF/ RPT</td>
<td><em>Many drug interactions</em></td>
<td>Rifamycin allergy; due do drug interactions, may be contraindicated with concurrent use of certain drugs (ARVs, anticoagulants, methadone, oral hypoglycemics).</td>
<td>Liver function monitoring is appropriate if given with other hepatotoxic medications or if there are symptoms of hepatotoxicity; monitor drug concentrations of interacting medications</td>
<td>• Best taken without food</td>
</tr>
<tr>
<td></td>
<td><em>Orange staining of body fluid</em></td>
<td></td>
<td></td>
<td>• Avoid wearing soft contact lenses</td>
</tr>
<tr>
<td></td>
<td><em>Rash and pruritus</em></td>
<td></td>
<td></td>
<td>• RIF decreases effectiveness of oral hormone-based birth control methods</td>
</tr>
<tr>
<td></td>
<td><em>GI upset, flu-like syndrome</em></td>
<td></td>
<td></td>
<td><strong>Call doctor right away if:</strong></td>
</tr>
<tr>
<td></td>
<td><em>Hepatotoxicity</em></td>
<td></td>
<td></td>
<td>Unusual tiredness or loss of appetite</td>
</tr>
<tr>
<td></td>
<td><em>Hematologic abnormalities</em> (thrombocytopenia, hemolytic anemia)</td>
<td></td>
<td></td>
<td>Severe abdominal upset</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fever or chills</td>
</tr>
</tbody>
</table>

*Routine monthly monitoring of liver function tests (LFTs) not generally indicated, except in the following circumstances: Abnormal LFT at baseline, Chronic liver disease, HIV infection, Risk for hepatic disease, including other potentially hepatotoxic drugs (e.g., anti-convulsants or over-the-counter drugs, e.g., acetaminophen), Regular alcohol use, Pregnancy or immediate postpartum

**Medication should be withheld and patients evaluated if:**

- Transaminase levels >3 times upper limit of normal in presence of symptoms
- Transaminase levels >5 times upper limit of normal in asymptomatic patient

**Pediatrics:** If children taking LTBI treatment develop hepatitis, seek other causes. Discontinue LTBI treatment in cases of symptomatic hepatitis, noting transaminase levels stated above
Key Points

- Intermitent therapy (anything other than seven days per week) should be administered by directly observed therapy (DOT), meaning a trained health care provider observes the person swallowing each dose of medication
- HIV + persons on antiretroviral therapy should not be dosed intermittently and should not be placed on Rifampin
- Use of liquid Isoniazid in children may cause diarrhea. Crushing the tablets is a common alternative

For additional information on TB drugs, side effects, and contraindications see: http://www.currytbcenter.ucsf.edu/tbdruginfo/

Several drug-interaction tools are available online (both free and paid versions). A suggested program is Lexi-Comp available at: http://www.lexi.com/institutions/products/pda/lexi-drugs-lexi-interact/http://uptodate.com

Baseline Laboratory Monitoring

Baseline laboratory testing (measurements of serum AST, ALT and bilirubin) are not routinely necessary unless the patient has any of the following factors:

- Liver disorders
- History of liver disease (hepatitis B or C, alcoholic hepatitis, or cirrhosis)
- Regular use of alcohol
- Risks for chronic liver disease
- HIV infection
- Pregnancy or the immediate postpartum period (within 3 months of delivery)
- Intake of additional hepatotoxic medications

Patient Education and Consent

Upon initiating treatment it is important that the patient fully understand the benefits and risks of LTBI therapy. Patient education should include:

- basic disease process (LTBI vs TB disease)
- basis for their LTBI diagnosis (TB test result, x-ray result, etc.)
- rationale for medication in the absence of symptoms or radiographic abnormalities
- possible side effects of the medication
- stop taking treatment and seek medical attention immediately if symptoms of hepatitis develop
For resources and additional information on TB patient education see: http://ethnomed.org/patient-education/tuberculosis

Once the patient has been informed of the benefits and risks of LTBI therapy and agrees to start treatment, it is important to obtain documentation of the patient’s agreement. The following form is an example of a treatment consent form:
Consent for LTBI Treatment

The following has been explained to me:

• Tuberculosis (TB) can spread through the air and be breathed in by anyone causing them to become infected with TB.
• My blood test and x-ray determined that I have been infected with TB.
• My TB infection does not cause me to feel sick and I cannot spread TB to others.
• My TB infection is treated with 4-9 months of TB antibiotics, taken daily, with monthly clinical check-up’s.
• Without treatment, I have a 10% chance of developing active TB disease sometime in my life.
• If I develop active TB disease I may feel sick and spread TB to others.
• It is important that I finish my entire course of TB antibiotics to minimize my risk of developing active TB disease.
• It is my responsibility to come to the clinic, in person, monthly to refill my TB antibiotic and be evaluated for side effects of the medications. If I cannot keep my appointment I will notify the clinic to reschedule my appointment.
• I realize that a friend or family member will not be allowed to pick up my medication for me.
• I agree to communicate with a nurse if I have any side effects or problems with TB medications, if I develop any signs or symptoms of TB (cough, fever, night sweats, losing weight), and if I stop taking the medication.
• If I have dark urine, yellowing skin or eyes, or experience other side effects of the medication, I will stop taking the medication and seek medical care right away.
• I have had the opportunity to ask questions and have my questions answered.

☐ I refuse to take treatment for my TB infection but will notify my doctor or the TB program if I experience: cough lasting more than 3 weeks, blood in my sputum, unexplained loss of weight, night sweats, fevers, or unusual tiredness.

☐ I agree to be treated for my TB infection.

☐ I have received a copy of this document.

__________________________________________  ____________________________
Client or Guardian’s Signature                  Date
Special Situations

HIV-Infected Individuals

- HIV-infected individuals should be treated with a 9-month regimen of INH.
- Rifampin is contraindicated in HIV-infected persons being treated with certain combinations of antiretroviral drugs. For more information see: http://www.cdc.gov/tb/publications/guidelines/TB_HIV_Drugs/recommendations03.htm and http://www.currytbcncenter.ucsf.edu/ltbihiv/

Pregnancy

- Use a shield to when performing a chest radiograph to rule out TB disease
- After TB disease is excluded wait until 2-3 months post partum to initiate treatment unless the woman is HIV-infected or a recent contact to an infectious case
- Isoniazid is the preferred drug and supplementation with 10-25mg/d of pyridoxine (vitamin B6) is recommended

Breastfeeding

- Supplementation with 10-25 mg/d of pyridoxine (vitamin B6) is recommended for nursing women and for breastfed infants

Infants and Children

- Infants and children under 5 years of age with LTBI have been recently infected and, therefore, are at high risk for progression to disease
- Risk of INH-related hepatitis in infants and children is minimal
- Directly observed therapy (DOT) should be considered
Section Three: Case Management

Patient Monitoring

In Washington State, to ensure safe and efficacious treatment for LTBI, the patient should be seen by the health care provider who is managing their treatment monthly. This visit should include clinical monitoring, laboratory testing (if needed), and ongoing patient education.

Clinical Monitoring

The following assessment form is an example of a documentation tool for use during the patients monthly visits. This form is meant to be printed double sided:
LTBI Case Management: Monthly Patient Assessment

Are you having any of the following symptoms?

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>☐</td>
<td>☑</td>
</tr>
</tbody>
</table>

I have answered the above list of questions to the best of my knowledge.

X Patient/ Parent Signature: ___________________________ Date: ___ / ___ / ___

☐ Monthly patient assessment form not completed. See progress notes and/or TB clinic record.

Office Use Only:
Patient Name: ___________________________ Birthdate: ________ Visit #: ________ Date: ___ / ___ / ___
NURSE TO COMPLETE THIS SECTION:

NURSING ASSESSMENT:

- Intake assessment completed (see form)
- No jaundice
- Skin is clear
- Patient is taking medication as directed.
- No change in meds since last visit
- No change in health status since last visit
- Negative for S/S of active TB disease
- Using appropriate birth control
- Questionnaire was reviewed, no concerns identified.

NURSING INTERVENTIONS:

- Interpreter used per request or need
- Hepatic function panel obtained
- Hold medication
- TB Medical Consultant notified
- Recommended PYRIDOXINE to medication regimen
- Switched medication
- Changed dosage of medication
- End of tx education and documentation given
- Checked new Rx/herb/vitamin for drug interactions
- Pregnancy test obtained
- Referred to Inland Imaging - CXR
- Obtained sputum for AFB smear and culture
- Other: __________________________
- Transferred pt to: __________________

- Obtained Weight
- Next appointment scheduled for one month or ______________
- Medication started/refill given
- Completed medication

Nurse Signature ___________________________ Date ___________________________
**Laboratory Testing**

Routine periodic retesting is only recommended for persons who had abnormal baseline results and other persons at risk for hepatic disease. Laboratory testing is also recommended if patients have symptoms suggestive of hepatitis. AST or ALT elevations up to 5 times normal can be accepted if the patient is free of hepatitis symptoms, and up to 3 times normal if there are signs or symptoms of liver toxicity.
Section Four: Dispositioning the Patient

Determining Treatment Completion

When determining treatment completion, both the number of doses and number of months should be considered. If the patient cannot complete the required number of doses within the maximum amount of time then treatment is not considered complete and should be restarted or discontinued.

The following chart is a tool to assist in determining treatment completion:

<table>
<thead>
<tr>
<th>Drug(s)</th>
<th>Typical Duration</th>
<th>Frequency</th>
<th>Total doses required</th>
<th>Maximum time to complete</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isoniazid (INH)</td>
<td>9 months</td>
<td>Daily</td>
<td>270</td>
<td>12 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Twice weekly</td>
<td>76</td>
<td>12 months</td>
</tr>
<tr>
<td></td>
<td>6 months</td>
<td>Daily</td>
<td>180</td>
<td>9 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Twice weekly</td>
<td>52</td>
<td>9 months</td>
</tr>
<tr>
<td>Rifampin (RIF)</td>
<td>4 months</td>
<td>Daily</td>
<td>120</td>
<td>6 months</td>
</tr>
<tr>
<td>Isoniazid (INH) and Rifapentine (RPT)</td>
<td>3 months</td>
<td>Once weekly</td>
<td>11-12</td>
<td>4 months</td>
</tr>
</tbody>
</table>

Documentation

Patients should receive documentation of TST or IGRA results and treatment completion that includes name, dates, chest radiograph results, and dosage and duration of medication. The patient should be instructed that he or she should present this documentation any time future testing is required.

The following form is an example of treatment completion documentation:
Tuberculosis Treatment Summary

Date of report:

Name: Date of birth:

<table>
<thead>
<tr>
<th>QuantiFERON-Gold TB Test</th>
<th>TB Skin Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>Date</td>
</tr>
<tr>
<td>Reading</td>
<td>Reading</td>
</tr>
</tbody>
</table>

**Imaging**

<table>
<thead>
<tr>
<th>Initial Imaging Date</th>
<th>Type of Imaging</th>
<th>Reading</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Follow-up Imaging Date</th>
<th>Type of Imaging</th>
<th>Reading</th>
</tr>
</thead>
</table>

**AFB Microbiology**

<table>
<thead>
<tr>
<th>1st AFB Smear + Date:</th>
<th>1st AFB Culture + Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>or N/A</td>
<td>or N/A</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1st AFB Smear – x 3 Date:</th>
<th>1st AFB Culture – Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>or N/A</td>
<td>or N/A</td>
</tr>
</tbody>
</table>

**Medication History**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosage</th>
<th>First Dose</th>
<th>Last Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isoniazid (INH)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rifampin (RIF)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethambutol (EMB)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pyrazinamide (PZA)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Treatment Complete: ☐**  **Treatment Not Complete: ☐**

If you have further questions regarding your Tuberculosis treatment, please contact the XXX-XXX-XXXX.
**Education**

Providers should re-educate patients about the signs and symptoms of TB disease and advise them to contact the medical provider if he or she develops any of these signs or symptoms. Patients should also be reminded that their TB test will likely always be positive despite completing treatment and to avoid additional TB testing by showing documentation of completing treatment.

**Section Five: Additional Resources**

**TB Contacts**

*State*
http://www.doh.wa.gov/AboutUs/ProgramsandServices/DiseaseControlandHealthStatistics/InfectiousDisease/TuberculosisStaff.aspx

*Local*
http://www.doh.wa.gov/AboutUs/PublicHealthSystem/LocalHealthJurisdictions.aspx

**References**


For persons with disabilities, this document is available on request in other formats. To submit a request, please call 1-800-525-0127 (TDD/TTY call 711).