Use of New Treatment Protocols for Latent TB Infection in Corrections

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Disclosures
NONE
OBJECTIVES

- Define Active TB and LTBI
- How diagnosis of LTBI is determined
- Review management of LTBI
- Discuss treatment options for LTBI
- Share management protocols of LTBI in NCDPS
- Discuss treatment of LTBI in NCDPS
Mycobacterium Tuberculosis

**Tuberculosis: a world wide concern**

- According to the CDC, nearly 1/3 of the world’s population is chronically infected with latent Tuberculosis (LTBI)
  - Nearly 9 million people worldwide became sick with active tuberculosis in 2011
- In the United States active Tuberculosis has been on the decline
  - A total of 9,945 Tuberculosis cases were reported in the United States in 2012
    - Lowest number since reporting begin in 1953
    - 63% in foreign-born persons
Tuberculosis (TB) is a disease caused by a germ called *Mycobacterium tuberculosis* that is spread from person to person through the air. TB usually affects the lungs, but it can also affect other parts of the body, such as the brain, the kidneys, or the spine. When a person with infectious TB coughs or sneezes, droplet nuclei containing *M. tuberculosis* are expelled into the air. If another person inhales air containing these droplet nuclei, he or she may become infected. However, not everyone infected with TB bacteria becomes sick. As a result, two TB-related conditions exist: latent TB infection (LTBI) and TB disease (active TB).
Latent TB Infection

Definition

- Infected with Mycobacterium tuberculosis
- Asymptomatic
- No evidence of disease
- Only sign of TB infection
  - Positive skin test
  - Positive blood test
Basis of LTBI Diagnosis

- medical history
- TST or IGRA result
- chest radiograph
- physical examination
- sputum examinations (in some cases)
Goal in Diagnosis

- Exclude presence of TB disease
  - Adequate treatment
  - Avoid drug resistance
Diagnosis of LTBI

Available testing methods for *M. tuberculosis* infection:

- Mantoux tuberculin skin test (TST)

- Blood tests known as interferon-gamma release assays (IGRAs):
  - QuantiFERON®-TB Gold test (QFT-G)
  - QuantiFERON®-TB Gold In-Tube (QFT-GIT)
  - T-SPOT
Mantoux Tuberculin Skin Test (1)

- TST is administered by injection
- Tuberculin is made from proteins derived from inactive tubercle bacilli
- Most people who have TB infection will have a reaction at injection site
Mantoux Tuberculin Skin Test

0.1 ml of 5 tuberculin units of liquid tuberculin are injected between the layers of skin on forearm

HCW administering Mantoux TST
Mantoux Tuberculin Skin Test

- Forearm should be examined within 48 - 72 hours by HCW

- Reaction is an area of **induration** (swelling) around injection site
  - Induration is measured in millimeters
  - Erythema (redness) is not measured

Only the induration is measured
Interpretation of TST reaction depends on size of induration and person’s risk factors for TB
Mantoux Tuberculin Skin Test
Interpreting the Reaction

Induration of $\geq 5$ mm is considered positive for:

- People living with HIV
- Recent close contacts of people with infectious TB
- People with chest x-ray findings suggestive of previous TB disease
- People with organ transplants
- Other immunosuppressed patients

Give these high priority for LTBI treatment
Mantoux Tuberculin Skin Test
Interpreting the Reaction

- Induration of \( \geq 10 \text{ mm} \) is considered a positive reaction for:
  - People who have recently come to U.S. from areas where TB is common
  - People who inject drugs
  - People who live or work in high-risk congregate settings
  - Mycobacteriology laboratory workers

**Give these high priority for LTBI treatment**
Mantoux Tuberculin Skin Test
Interpreting the Reaction

Induration of ≥ 10 mm is considered a positive reaction for:
- People with certain medical conditions that increase risk for TB
- Children younger than 4 years old
- Infants, children, or adolescents exposed to adults in high-risk categories
Mantoux Tuberculin Skin Test
Interpreting the Reaction

- Induration of $\geq 15$ mm is considered a positive reaction for people who have no known risk factors for TB
Mantoux Tuberculin Skin Test
Factors that Affect the Reaction
Mantoux Tuberculin Skin Test
False-Positive Reaction

Factors that can cause people to have a positive reaction even if they do not have TB infection:

- Infection with non-tuberculous mycobacteria
- BCG vaccination
- Administration of incorrect antigen
- Incorrect measuring or interpretation of TST reaction
Mantoux Tuberculin Skin Test

BCG Vaccine

- People who have been vaccinated with BCG may have a false-positive TST reaction

- However, there is no reliable way to distinguish between reaction caused by TB infection or by BCG vaccine

- Individuals should always be further evaluated if they have a positive TST reaction
Mantoux Tuberculin Skin Test
False-Negative Reaction

Factors that can cause false-negative reactions:

- Anergy
- Recent TB infection (within past 8 – 10 weeks)
  - It can take 2 – 8 weeks after TB infection for body’s immune system to react to tuberculin
- Younger than 6 months of age
- Recent live-virus (e.g., measles or smallpox) vaccination
- Incorrect method of giving the TST
- Incorrect measuring or interpretation of TST reaction
Mantoux Tuberculin Skin Test

Any patient with symptoms of TB disease should be evaluated for TB disease, regardless of his or her skin test reaction.
TB Testing Programs

- Many health care facilities have TB testing programs
  - Employees and residents are periodically given TSTs or IGRAs

Testing programs:
- Identify people who have LTBI or TB disease and give them treatment
- Determine whether TB is being transmitted in facility
TB Testing Programs

- Employees and/or residents are given TSTs or IGRAs when they first enter facility
  - If person is negative, they may be retested at regular intervals thereafter
  - Tested yearly in NCDPS (employees & inmates)

CDC Module 3
TB Test Conversion

Definition:

A change from negative to positive result and \( \geq 10 \text{ mm} \) increase in induration, within a 2 year interval
TB Test Conversions

Persons whose TST or IGRA result converts from negative to positive:
- have probably been infected with *M. tuberculosis*
- may be transmitting TB throughout facility
To Treat or Not Treat LTBI

- Evaluate individual’s risk of developing TB disease
- Assess level of commitment to complete treatment
- Determine resources available to ensure adherence
Why Treat LTBI?

PREVENTING TB BY TREATING LTBI IS A CORNERSTONE OF THE U. S. STRATEGY TO ELIMINATE TB.
Treatment of LTBI
Patient Management

- Discuss benefits and risks of treatment
- Review medication side effects
- Emphasize importance of adherence
- Identify potential barriers to adherence
- Establish plan to ensure adherence
Who to Screen for LTBI
High Risk Populations

- Close contacts of a person with infectious TB.
- Immigrants from countries with high rates of TB.
- People who live or work in places where TB is more common, such as homeless shelters, migrant labor camps, prisons, jails, hospitals, and some nursing homes.
- Medically underserved and low-income populations.
- Children exposed to high-risk adults.
- People with chest radiographs showing healed TB.
- Patients with HIV, silicosis, malnutrition, renal failure, or other conditions placing them at higher risk for active TB.
- Patients on chronic immunosuppressive drugs.
- Injection drug users.

The CDC discourages testing of people at low risk for infection.
Differentiating Between Latent TB Infection and TB Disease

**LTBI**
- No symptoms or physical findings suggestive of TB disease.
- TST or IGRA result usually positive.
- Chest radiograph is typically normal.
- If done, respiratory specimens are smear and culture negative.
- Cannot spread TB bacteria to others.
- Should consider treatment for LTBI to prevent TB disease.

**TB Disease**
- Symptoms may include one or more of the following: fever, cough, chest pain, weight loss, night sweats, hemoptysis, fatigue, and decreased appetite.
- TST or IGRA result usually positive.
- Chest radiograph is usually abnormal. However, may be normal in persons with advanced immunosuppression or extrapulmonary disease.
- Respiratory specimens are usually smear or culture positive. However, may be negative in persons with extrapulmonary disease or minimal or early pulmonary disease.
- May spread TB bacteria to others.
- Needs treatment for TB disease.
LTBI to TB

5% - 10% LTBI
- Develop active disease
- Greatest risk for reactivation:
  - Weakened immune system
  - Recent TB infection

½ develop TB within 2-year period

Groups at high risk:
- Recent skin test converters (within the past 2 years)
- Young children. (Infants have a 40% chance of progressing to active disease, and children are more likely to develop life-threatening forms of TB).
- Immigrants from countries with high rates of TB (within the first 5 years after immigration)
LTBI to TB
High Risk Clinical Conditions

- HIV/AIDS (10% annual risk of developing active TB)
- Diabetes mellitus
- Underweight (more than 10% below normal)
- Chronic kidney disease, esp. hemodialysis patients
- Gastrectomy or jejunoilial bypass
- Silicosis
- Head and neck cancer
- Solid organ transplant recipients
- Prolonged use of immunosuppressive drugs (prednisone 15 mg/day > 1 month, TNF-alpha antagonists)
- Leukemia or lymphoma
- Chest X-rays with evidence of prior TB
- Injection drug users
## Treatment Regimens for LTBI

<table>
<thead>
<tr>
<th>Drugs</th>
<th>Duration</th>
<th>Interval</th>
<th>Minimum doses</th>
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</thead>
<tbody>
<tr>
<td>Isoniazid</td>
<td>9 months</td>
<td>Daily</td>
<td>270</td>
</tr>
<tr>
<td>Isoniazid</td>
<td>6 months</td>
<td>Daily</td>
<td>180</td>
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<tr>
<td>Isoniazid and Rifapentine</td>
<td>3 months</td>
<td>Once weekly*</td>
<td>12</td>
</tr>
<tr>
<td>Rifampin</td>
<td>4 months</td>
<td>Daily</td>
<td>120</td>
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</tbody>
</table>
Isoniazid (INH)

- Very effective
- Use for 9 months: 90% protection against LTBI progression to active TB
  - Use for 6 months
    - Offers adequate treatment of LTBI
    - Recommended when 9 months cannot be completed
    - 70% protection against LTBI progression to active TB
- Preferred regimen
  - for HIV infected persons taking antiretroviral therapy
  - for children aged 2-11 years of age
- Recommend using same weekly schedule (T, F or M, Th)
- Given as DOT
Rifampin

- Use only if:
  - Intolerance to INH develops
  - Contraindication for INH use
  - Person is close contact to an INH resistant TB case
- May not be given twice weekly
Isoniazid (INH) and Rifapentine (RPT)

- Administered once weekly x 12 weeks (long half life of RPT)
- Complete doses within 16 weeks
- Missed doses administered up to 72 hours before next dose
- Particularly good option for those unlikely to complete longer treatment regimens
- Use same day of week for administration (Tuesday or Thursday)
- Given as DOT
Rifapentine

- December, 2011 - Approved by CDC for DOT treatment of LTBI
- Three large clinical studies
- Largest in NEJM: Concluded that the combination 3-month regimen was as effective as standard 9-month isoniazid regimen
- Offered another option for treatment
In NCDPS, Rifapentine prescribed for **NEWLY** diagnosed Latent TB Infection (LTBI) patients **since June 1st, 2013**

Providers must evaluate patients individually for appropriateness of treatment

**NOT** recommended for:

1. patients with HIV / AIDS taking antiretroviral treatment;
2. patients presumed to be infected with INH or RIF-resistant Mycobacterium TB;
3. Pregnant or expect to become pregnant during treatment
4. Patients with porphyria – use with caution
5. Patients with liver disease / abnormal liver function tests - Use with caution and careful monitoring
Rifapentine

Must be used in conjunction with one other antituberculosis drug

- Isoniazid (INH) 900 mg x 12 weeks will be prescribed with rifapentine
  - Isoniazid is supplied as 100mg and 300mg scored tablets

- Vitamin B₆ is usually taken with INH because INH will deplete Vitamin B₆

Administer rifapentine, INH, and B₆ at the same time
**Rifapentine**

- **12 week regimen** for Latent Tuberculosis Infection (LTBI), given **once a week**
  - Promotes better compliance and completion of treatment

- **DOSAGE** = **Rifapentine 900mg weekly**, administer **SIX 150mg tablets by mouth**
  - Rifapentine (RPT) is formulated as 150 mg tablets packed in blister packs
  - Keep sealed until administered
Pharmacy will dispense 24 tablets of Rifapentine 150mg every 28 days

Nursing will need to REQUEST refills monthly for rifapentine, INH, and B_{6}
Use of Rifapentine / INH

CDC Recommendations

Equal alternative to 9 months of INH for the following:

- Contacts
- Recent converters
- Old, healed (Class IV) TB
- Adults and children greater than / equal to (≥) 12 years old
- Can be used in children 2 – 11 yrs old on “case by case” basis
- HIV+ if healthy and on NO Antiretroviral (ARV) – must consult with ID provider
- Should be given by DOT (required in DPS Health Services)
- Should NOT be used in pregnant women
Rifapentine

- May take with or without food
  - If patient complains of stomach upset, may take with food
- No alcohol – increases risk of liver damage
- May interfere with hormone-based birth control
  - Counsel patient and refer to provider
Prolonged use may result in a **fungal** or **bacterial infection** such as *C-difficile* and *Pseudomembranous colitis*

- Use with caution in patients with **porphyria**, may cause exacerbation
  - Porphyria – a buildup of chemicals called porphyrins, typically affects the nervous system, or skin, or both
COMPLIANCE is necessary for successful drug therapy

- DOT administration

- After each dose is administered, document on the MAR the **number of the dose**
  - All 12 doses must be documented
Warning / Precautions

- **Missing doses** – for **ANY single** missed dose – licensed nurse is to counsel patient, document education provided, and notify provider

- Med Techs will notify the licensed nurse **immediately** for any missed doses or inmate reports of side effects

- If a weekly **dose is missed** due to court or outside medical appointments, it **may be given on another day, IF** there is **at least 72 hours before** the next scheduled dose
Warning / Precautions

Monitoring

- **Baseline lab tests** – liver function tests that include AST, ALT, Alkaline phosphate, and total bilirubin, and complete CBC with platelets

- Seen **monthly** by Chronic Disease Nurse

- **Due to potential for hepatic impairment**
  - liver function tests **prior to therapy**
  - **every 4 weeks during** therapy, more frequently as indicated
Monitoring

- Providers should order lab tests and frequency with original medication order
  - Ensure provider has reviewed all lab tests
- Discontinue with signs of liver disease
Warning / Precautions

- **Red/Orange discoloration:** urine, feces, saliva, sweat, tears, skin, tongue, teeth, cerebral spinal fluid

- Can cause **permanent discoloration** to soft contact lenses, clothing, dentures
**Warning / Precautions**

- Pregnancy: Do NOT take this medicine if pregnant
  - Potential birth defects – cleft palates, right aortic arch, delayed ossification, increase ribs, underdeveloped ovaries, foot deformities, congenital abnormality of the eyeball, irregularities of ossified facial tissues
  - Decreased fetal weight, increased stillborns, and decreased gestational survival
Seen by Chronic Disease Nurse monthly

Consult pharmacy for medication interactions

Note the following medication interactions:

- INH increases blood levels of phenytoin (Dilantin®) and disulfiram (Antabuse®)
- Rifapentine decreases blood levels of many drugs including oral contraceptives, warfarin, sulfonylureas, and methadone

If the patient is on Rifapentine and submits a Sick Call request with complaints of adverse effects, the patient needs to be seen by the nurse at no cost
Interacting Medications

- Antiarrhythmics (eg, disopyramide, mexiletine, quinidine, tocainide)
- Antibiotics (eg, chloramphenicol, clarithromycin, dapsone, doxycycline, fluoroquinolones such as ciprofloxacin)
- Anticoagulants, oral (eg, warfarin)
- Antifungals (eg, fluconazole, itraconazole, ketoconazole)
- Artemether/lumefantrine
- Barbiturates
- Benzodiazepines (eg, diazepam)
- Beta blockers, calcium channel blockers (eg, diltiazem, nifedipine, verapamil)
- Bortezomib
- Brentuximab
- Corticosteroids
- Cardiac glycoside preparations
- Clofibrate
- Oral or other systemic hormonal contraceptives
- Elvitegravir
- Haloperidol
- HCV protease inhibitors (eg, boceprevir, telaprevir)
- HIV protease inhibitors (eg, indinavir, ritonavir, nelfinavir, saquinavir see indinavir interaction above)
- Oral hypoglycemic agents (eg, sulfonylureas)
- Immunosuppressants (eg, cyclosporine, tacrolimus)
- Levothyroxine
- Lurasidone
- Narcotic analgesics (eg, methadone)
- Praziquantel
- Progestins
- Quinine
- Ranolazine
- Rilpivirine
- Reverse transcriptase inhibitors (eg, delavirdine, zidovudine)
- Rivaroxaban
- Sildenafil
- Theophylline
- Tricyclic antidepressants (eg, amitriptyline, nortriptyline)
- Tyrosine kinase inhibitors (eg, axitinib, crizotinib)
Patient Education

- Indication for treatment
  - Latent TB Infection

- Importance of compliance
  - Decreases the risk of drug resistance

- Side effects – Sick Call request for any signs and/or symptoms of adverse effects
  - No co-pay for Sick Call visit related to Rifapentine adverse effects

- Routine blood testing every 4 weeks and as indicated

- No alcohol – increases chance of liver damage

- May interfere with hormone-based birth control
Potential Side Effects

- Dizziness or light-headed when sitting, standing, or lying down
- Decreased appetite or no appetite for food
- Stomach upset, nausea, or vomiting
- Stomach pain or stomach cramps
- Pain in lower chest or heartburn
Potential Side Effects

- Flu-like symptoms with or without fever
- Severe tiredness or weakness
- Fever or chills
- Severe diarrhea or light colored stools
- Brown, tea colored, or cola-colored urine
- Skin or whites of eyes appear yellow
Potential Side Effects

- Skin rash and itching
- Unexplained bruising
- Nosebleeds, bleeding from gums or around teeth
- Shortness of breath
- Pain or tingling in hands, arms, or legs
Patient Education

- Instruct patient to contact Facility Medical Unit for ANY signs and/or symptoms of adverse side effects

- Document patient education provided, and patient understanding
Procedure for Implementation of INH/Rifapentine in NCDPS

1. Research
2. Education of staff
3. Work with Pharmacy to get medication
4. Notification to providers (memo dated
5. Policy Revisions
6. Monitoring of activity
7. Information to State Public Health
North Carolina Department of Public Safety  
Health Services  
Community TB Referral

Complete this form and forward copy to the local health department in county where inmate is to be released 14 days prior to release.

1. PPD Skin Test
   Date:  
   Result:  

2. Chest X-ray (attach copy of report)
   _______ Within Normal Limits
   _______ Abnormal

3. LFT (attach copy of report)
   _______ First
   _______ Last
   Patient's weight: _______ lb
   Date:  

4. HIV test results
   _______ Date:  

5. TB Medication: (attach copy of physician's order for medications and ALL applicable MARs for duration of treatment while in the custody of DPS.)

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<th>Dosage</th>
<th>Start Date</th>
<th>Route</th>
<th>How Often</th>
<th>End Date</th>
<th>Special Instructions</th>
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<td>Other Specify</td>
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TO:  
(County / District Health Dept)  
FROM:  
(Prison Name and Number)

________________________________________

(AAddress)

RE:  
Patient Name:  
Race:  
Sex:  
Social Security #:  
Birth Date:  
Address:  

The above named individual has been instructed to follow-up with the Health Department TB Program. The above information extracted from patient’s medical records.

Completed By:  
Date:  
Title:  
Date Sent:  
Mailed:  
Faxed:  

Telephone #  

(County / District Health Dept)  
FROM:  
(Prison Name and Number)

________________________________________

(AAddress)
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<th>Culture Results</th>
<th>Date Reported</th>
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</tbody>
</table>
| Chest X-rays
| Date | Position | Results |
|      |          |         |
|      |          |         |
|      |          |         |
| LFT (other)
| Date | Test  | Normal | Abnormal | Comments |
|      |       |        |         |          |
|      |       |        |         |          |
|      |       |        |         |          |
Current NCDPS Experience

- Impact on staff
- Number of treatments
- Completed INH/Rifapentine
- Side Effects
- Follow-up
Recommendations for Use of an Isoniazid-Rifapentine Regimen with Direct Observation to Treat Latent *Mycobacterium tuberculosis* Infection

*Weekly*

*December 9, 2011 / 60(48):1650-1653*

Preventing tuberculosis (TB) by treating latent *Mycobacterium tuberculosis* infection (LTBI) is a cornerstone of the U.S. strategy for TB elimination. Three randomized controlled trials have shown that a new combination regimen of isoniazid (INH) and rifapentine (RPT) administered weekly for 12 weeks as directly observed therapy (DOT) is as effective for preventing TB as other regimens and is more likely to be completed than the U.S. standard regimen of 9 months of INH daily without DOT. This report provides CDC recommendations for using the INH-RPT regimen. The new regimen is recommended as an equal alternative to the 9-month INH regimen for otherwise healthy patients aged ≥12 years who have LTBI and factors that are predictive of TB developing (e.g., recent exposure to contagious TB). The new regimen also can be considered for other categories of patients when it offers practical advantages. Although the INH-RPT regimen was well tolerated in treatment trials, monitoring for adverse effects is recommended. Severe adverse effects should be reported to the Food and Drug Administration (FDA) and CDC.
References


- *Recommendations for use of isoniazid-rifapentine regimen with direct observation to treat latent mycobacterium tuberculosis infection.* Dec 9, 2011. retrieved from [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6048a3.htm?s_cid=mm6048a3_w#Box1](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6048a3.htm?s_cid=mm6048a3_w#Box1)


- Individual prescribing information for rifapentine and isoniazid.
Recommendations for Use of and Isoniazid-Rifapentine Regimen with DOT to Treat LTBI; CDC Morbidity and Mortality Weekly Report; December 9, 2011/60(48); 1650 -1653

Self-study Modules on Tuberculosis; Module 3: Targeted Testing and the Diagnosis of Latent TB Infection and TB Disease; Centers for Disease Control and Prevention Division of Tuberculosis Elimination 2010

Acknowledgements

- NCDPS Infectious Disease Clinicians
- NCDPS Pharmacy
- NCDPS Nursing Education
- North Carolina Public Health – TB Division