Nicoletta A. Turner-Foster, MD
Medical Officer

U.S. Department of Justice
Federal Bureau of Prisons
Federal Correctional Institution
P.O. Box 38
Fort Dix, New Jersey 08640

December 18, 2011

The Honorable Carolyn N. Lerner
Special Counsel
Office of Special Counsel
1730 M. Street, N. W., Suite 218
Washington, D.C. 20036-4505

Re: OSC File No. DI-11-2109

I submit this letter to comment on the report prepared by Mr. Scott Schools, the Associate Deputy Attorney General. His report was generated in response to my "allegations that employees were responsible for a violation of a law, rule, or regulation, gross mismanagement, and a substantial and specific danger to public health and safety at the Department of Justice, Federal Bureau of Prisons (BOP), Federal Correctional Institution; Fort Dix, New Jersey".

After, reviewing the aforementioned report, I noticed some areas that require further comment for clarity.

In section I entitled "The Predicate for the Investigation", it is documented in the report, "The whistleblowers stressed that several months is an unacceptably long time to wait for laboratory testing and results for patients requiring medical evaluations." It was and continues to be my practice to schedule the patient's lab collection one (1) month prior to his next clinic visit (clinic visits are supposed to occur every 6 months). In theory, this would allow one (1) month for the lab to be collected. However, usually the lab collection did not occur prior to the clinic visit. The lab collection usually did not occur six months or even a year after the scheduled lab collection date.

In section III entitled "Summary of Evidence Obtained from the Investigation", it is documented in the report, "The physicians are responsible for chronic care clinics (CCC), and their caseloads range from 435 to 530 in number." This is an understatement. In addition to evaluating 10 patients a day (the number of patients a physician is required to evaluate a day increased from 8 to 10 during the investigation on the lab collections) the physicians have other responsibilities. The physicians are responsible for providing the final impression and treatment plan for all

emergent/urgent clinical care. The physicians perform concurrent visits (clinical patient encounter performed concurrently by a mid-level practitioner (physician assistant or nurse practitioner) and a physician). The physician has numerous administrative responsibilities. He or she must review and cosign all off shift BEMR entries made by the mid-level practitioners. He or she must review and cosign: (1) laboratory results, (2) radiology reports (x-rays, MRIs, CT scans), (3) EKGs, or (4) subspecialist's impressions and recommendations. He or she must develop an impression and a diagnostic or treatment plan for the aforementioned reviewed documents when appropriate.

It is important to clarify the responsibilities of the physician so that the environment in which the physician evaluates the patient is evident. Also in section III, it is documented, "The doctors did not always review lab documentation when examining patients to determine if there were outdated tests that had not been completed. There were a number of duplicate tests ordered for the same patients. For example, if the initial test was determined to be outdated a new test was ordered. In some cases the initial test, no longer in the prescribed time frames, would not be cancelled and would still show as pending."

As the responsibilities of the physician continue to increase the time to address these issues remains constant. Consequently the time, the physician has to evaluate the patient and to document the encounter, continues to decrease. There are four main screens in BEMR. First, is the subjective screen which is where the patient's history and subjective complaints are documented. Next, is the physical exam screen which is where any physical findings or pertinent lab results are documented. The third screen is the diagnosis screen which is where the patient's diagnoses are entered. The fourth and last screen is the plan screen which is where the physician/clinician orders medication, x-rays, labs, consultations with subspecialists, and schedules other on site orders like Optometry visits, EKGs, pain clinics, etc…

When the physician clicks on the lab tab, BEMR only shows lab orders back to a certain date; it will not typically show the physician or the clinician lab orders from two or three years ago. Also, the physician or the clinician may not even think to look greater than 1 year back to determine if labs were ordered but not collected. Who would expect that labs would not be collected for more than one year after the scheduled collection date?

Also documented in section III is the term "duplicate tests ordered for the same patient". This term does not accurately describe the ordered lab. The labs on the "pending lab collection roster" (that initiated this investigation) were labs were scheduled for collection by the clinicians but, these lab collections did occur. I was instructed to review of approximately 30 lab collections that I ordered (that were identified as potential duplicate lab orders by health information technicians). I did not confirm any duplicate orders. For example, I evaluated a patient in clinic on 01/01/2008 and, I scheduled a lab collection on 06/01/2008. The patient returned on 07/01/2008 but, the lab collection scheduled for 06/01/2008 did not occur. I did not reorder the same labs. If I required labs in addition to the lab collection I scheduled for 06/01/2008 then I would order only the additional labs required.

The lab collection date was not changed. It is recommended by the Federal Bureau of Prisons (FBOP) Clinical Practice Guidelines (CPGs) that certain diagnoses be monitored via lab collections. In addition, medications used to treat certain diagnoses i.e. diabetes and high cholesterol require monitoring of the patient's kidney and/or liver function via lab collections. So, if the lab was not collected 6 months, 12 months, or more after the scheduled collection date, then it appears that the expectation outlined in this report is that the uncollected should be discontinued and reordered.

This expectation is unacceptable to me. To discontinue and reorder the lab I ordered 6 months or 1 year ago could imply that I did not need the lab collection on the scheduled date or worse, it could appear as if I was not monitoring the patient's diagnoses for 6 or 12 months. Both of those implications are inaccurate. I ordered the lab collection because I need to monitor the patient's diagnoses and, I need to monitor the patient for side effects of medications. It is possible that I ordered the lab collection to diagnose a patient with diabetes, HIV, Hepatitis C, etc…

The foot note at the bottom of page 6 of the report documents, "Although Turner-Foster acknowledged a long past due date, she put a 5 month due date on her lab order, suggesting no urgency." Certainly, the lab collection is not urgent; however, I did not intend nor did I expect that the lab collection would not occur for 6 to 12 months after the scheduled collection date.

Some of the documentation in section III generated more questions for me than answers. For example, why wasn't Ms. Johnson, the lab technician trained by a FBOP staff member? Mrs. Palmisano is the least senior health information technician in the Health Service Department. Why wasn't one of the more experienced health information technicians testimony sited? Why didn't Dr. Lopez de LaSalle (the Clinical Director), Commander Baker (the Health Service Administrator), Ms. Zickefoose (the Warden), Regional nor Central Clinical Oversight know the "true magnitude and scope of the problem"? The Heath Service Administration had access to a pending lab roster prior to the preparation of the following memorandums.

Documented in section III entitled "The investigation revealed numerous efforts to resolve the problems of overdue laboratory requests: In a December 18, 2009 memorandum, titled "BEMR House Keeping" and addressed to all clinical staff, LaSalle notes, "Make sure you discontinue old labs, duplicate labs, labs which do not follow the schedule you have assigned for your patient. A March 8, 2010 memorandum from CD LaSalle and HSA Steve Spaulding with a subject line "BEMR Housekeeping" advised all Clinical Staff, "In the process of reviewing your case, if you note the service has already been provided, or is no longer indicated, please remove from the scheduler and indicate in the comment box why the service was cancelled." It was also noted, "Before you order labs, look to make sure someone else has not ordered the same labs.""

The memorandums titled "BEMR Housekeeping" instructed clinicians to review lab requests without the patient and to decide if the lab request could be deleted. I submit that ideally, the clinician should evaluate the patient prior to deciding if the ordered labs are still needed. At the very least the clinician would need to review the chart of the patient for each lab order to essentially guess if the lab order is still required. Also, as I mentioned earlier deleting labs that

were ordered for example in 2008 then reordering the same labs in 2011 could lead to inaccurate implications.

Also, in section III it is documented multiple times that the health service administration and the executive staff attempted to hire lab technicians; however, it was noted that an appropriate candidate could not be found. However, during this investigation three lab technicians were located and hired. There are now four lab technicians at FCI FTD.

In section IV entitled "Violation or Apparent Violation of Law, Rule or Regulation" it is documented that "the investigation revealed no violation of law, rule or regulation by not conducting medical laboratory test in a timely manner. ...While we recognize the potential risks posed to the inmates as a result of untimely laboratory test, we do not believe management's actions or inaction rose to the level of "gross mismanagement."

Gross mismanagement is defined as actions or situations arising out of management ineptitude or oversight leading to major violations of Workforce Investment Act (WIA) processes, regulations, or contract grant provisions that could severely hamper the accomplishments of the program goals. I do not fully understand this definition. Therefore, I will not comment on if the health service administrative staff's mismanagement meets the definition of "gross mismanagement".

I realize that the Associate Deputy Attorney General's report was generated from information obtained during an investigation solely on the specific allegation that "FCI Fort Dix employees did not timely collect samples for medically ordered laboratory diagnostic tests, including blood, stool, and urine samples, which in turn caused delays in receiving results that were needed for medical diagnoses". However, I feel obligated to put the issue of lab collection into perspective.

At this point, I have to digress to November 1, 2007, when the US Department of Justice FBOP Federal Correctional Institution at Fort Dix gave me a letter of proposal through the Clinical Director at that time, Dr. John Chung, that I be suspended for 30 calendar days for my alleged failure to follow proper medical procedures and for my alleged failure to provide adequate medical care. (Appendix 1) Specifically, the charges were:

1. *"On April 19, 2005, while on duty as an attending physician, you treated an inmate for Latent Tuberculosis Infection (LTBI). Agency's Clinical Practice Guidelines provide procedures for initiating an Isoniazid Prophylaxis regimen based on positive Protean Purified Derivative (PPD) readings for Latent Tuberculosis Infection (LTBI), yet you failed to order the required baseline liver function tests prior to providing INH treatments to this inmate. You were made aware of the Bureau's Clinical Practice Guidelines through Continuing Professional Education in November 2002 for PPD and in April 2003 for TB. Your actions described above constitute a violation of this procedure."*
2. *"On April 19, 2005, while on duty as an attending physician, you treated an inmate for Latent Tuberculosis Infection (LTBI). Agency's Clinical Practice Guidelines provide procedures for initiating an Isoniazid Prophylaxis regimen based on positive Protean Purified Derivative (PPD) readings for Latent Tuberculosis Infection (LTBI), yet you*

failed to ensure a baseline CXR was ordered for the inmate. You were made aware of the Bureau's Clinical Practice Guidelines through Continuing Professional Education in November 2002 for PPD and in April 2003 for TB. Your actions described above constitute a violation of this procedure."

3. *"On August 1, 2005, while on duty as an attending physician, you provided follow-up treatment for an inmate with Latent Tuberculosis Infection (LTBI). Agency's Clinical Practice Guidelines provide procedures for initiating an Isoniazid Prophylaxis regimen based on positive Protean Purified Derivative (PPD) readings for Latent Tuberculosis Infection (LTBI), yet you failed to order the required baseline liver function tests prior to providing INH treatments to this inmate. You were made aware of the Bureau's Clinical Practice Guidelines through Continuing Professional Education in November 2002 for PPD and in April 2003 for TB. Your actions described above constitute a violation of this procedure."*

This patient complained of abdominal pain on 10/28/2005 and on 11/04/2005. It was documented by the Physician's Assistant that the patient stated he had a KUB and a lab collection on 10/31/2005. However, the lab results were not available for review until after the patient had been transferred to the community hospital on 11/13/2005. The lab results were reviewed by me on 11/16/2005 and a duplicate lab result report was reviewed by Dr. Chung on 11/29/2005.

Of note, the FBOP sustained the charges against me because I failed to follow the Federal Bureau of Prisons Clinical Practice Guidelines dated December 2004. The FBOP CPGs did not say that prior to initiating Isoniazid for LTBI liver function tests must be checked. The FBOP CPGs dated December 2004 were as follows, "All inmates should have baseline liver transaminases measured and should be subsequently monitored for signs and symptoms of hepatitis and other medication side effects".

Of note, the FBOP dismissed the fact that the Assistant Health Service Administrator at the time, Mr. Tushar Patel, wrote the following email to all clinical staff on 01/21/2005, "Please be advised that Hepatitis B and C profiles and LFTs are not ordered routinely unless there is history and medical evaluation is completed during sick call, chronic care clinic or during physical examination. Please do not order Hepatitis Profile or Liver Function Test on a routine basis for inmates with a history of positive PPD". (Appendix 2)

The FBOP guidelines for the treatment of LTBI differ from those of the CDC. The Centers for Disease Control and Prevention's Latent Tuberculosis Infection: A Guide for Primary Health Care Providers (last updated November 24, 2010) documents the following. "Physical examination and medical history, which includes obtaining information about previous positive results of a test for TB, previous treatment for LTBI or TB disease, and a risk assessment for liver disease, are indicated for an individual with positive test results. Written documentation of a previously positive TST or IGRA result is required; a patient's verbal history is not sufficient." In addition the CDC documents the following, Baseline laboratory testing (measurements of serum AST, ALT, and bilirubin) are not routinely necessary. Laboratory testing at the start of

LTBI therapy is recommended for patients with any of the following factors:

Liver disorders

History of liver disease (e.g., hepatitis B or C, alcoholic hepatitis, or cirrhosis)

Regular use of alcohol

Risks for chronic liver disease

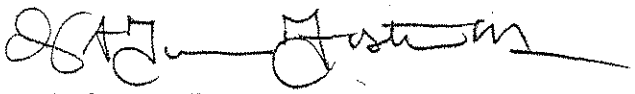
HIV infection

Pregnancy or the immediate postpartum period (i.e., within 3 months of delivery)" (Appendix 3)

In conclusion, on November 7, 2011 the Department of Justice concluded that management's actions failed to violate a law, rule, or regulation by not conducting medical laboratory tests in a timely manner. However, on November 1, 2007, the FBOP sustained charges that I failed to order the required baseline liver function tests prior to LTBI treatment initiation. Furthermore, the FBOP ruled that my failure to follow the FBOP CPGs constituted a "violation of this procedure".

I submit that the FBOP constituted a violation of the procedure of following their CPGs. The failure of Central Office Clinical Oversight, Regional Office Clinical Oversight, The Warden, The Associate Warden over Health Services, the Clinical Director, and the HSA to recognize the severity of the lab backlog prevented me and other clinicians from following the CPGs for at least 2 years. In fact, the FBOP inhibited the physicians/clinicians from evaluating the patients according to the FBOP CPGs. Consequently, patient safety was compromised.

Sincerely,



Nicoletta A. Turner-Foster, MD

U.S. Department of Justice
Federal Bureau of Prisons
Federal Correctional Institution
P.O. Box 38
Fort Dix, NJ 08640

November 1, 2007

Nicoletta Turner-Foster
Medical Officer
Federal Correctional Institution
Fort Dix, New Jersey 08640

Dear Dr. Turner-Foster:

This is notice that I propose that you be suspended for a period of 30 calendar days for Failure to Follow Proper Medical Procedures and Failure to Provide Adequate Medical Care, violations of the Standards of Employee Conduct which you acknowledged receipt of March 23, 2004, and receive training annually.

Charge I: Failure to Follow Proper Medical Procedures

Specification A: On April 19, 2005, while on duty as attending Physician, you treated inmate Register Number for a positive Protean Purified Derivative (PPD) readings for Latent Tuberculosis Infection (LTBI). Agency's Clinical Practice Guidelines provides procedures for initiating an Isoniazid (INH) prophylaxis regimen based on positive PPD readings for LTBI, yet you failed to order the required baseline liver function tests prior to providing INH treatments for inmate You were made aware of the Bureau's Clinical Practice Guidelines through Continuing Professional Education in November 2002 for PPD and in April 2003 for TB. Your actions described above constitute a violation of this procedure.

Specification B: On August 1, 2005, while on duty as attending Physician, you provided follow-up treatment to inmate Register Number for a positive Protean Purified Derivative (PPD) readings for Latent Tuberculosis Infection (LTBI) of April 14, 2005. Agency's Clinical Practice Guidelines provides procedures for initiating an Isoniazid (INH) prophylaxis regimen based on positive PPD readings for LTBI, yet you failed to order the required baseline liver function test during your follow-up examination of INH treatments for inmate You were made aware of the Bureau's Clinical Practice Guidelines through Continuing Professional Education in November 2002 for PPD and in April 2003 for TB. Your actions described

above constitute a violation of this procedure.

Specification C: On April 19, 2005, while on duty as attending Physician, you provided treatment to inmate Register Number for a positive Protean Purified Derivative (PPD) readings for Latent Tuberculosis Infection (LTBI) of April 14, 2005. Agency's Clinical Practice Guidelines provides procedures for initiating an Isoniazid (INH) prophylaxis regimen based on positive PPD readings for LTBI, yet you failed to ensure a baseline Chest X-ray was ordered for inmate You were made aware of the Bureau's Clinical Practice Guidelines through Continuing Professional Education in November 2002 for PPD and in April 2003 for TB. Your actions described above constitute a violation of this procedure.

Providing health care and services to inmates is the primary responsibility of the institution's Health Services Department, and of your position as a Medical Officer. Following proper medical procedures is a basic standard-of-care both necessary and required. Failure to follow proper medical procedures for any inmate, could lead to more serious, life-threatening situations. In particular, regarding this inmate, your failure to follow proper medical procedures may have contributed to the liver cancer based on your failure to recognize Chronic Hepatitis B infection found during a subsequent liver biopsy and hepatitis profile of this inmate. Therefore, your failure to follow proper medical procedures brings into question your ability to make sound medical decisions, and cannot be tolerated.

Charge II: Failure to Provide Adequate Medical Care

Specification A: On April 19, 2005, while on duty as attending Physician, you prescribed an Isoniazid (INH) prophylaxis regimen for inmate Register Number for a positive Protean Purified Derivative (PPD) readings for Latent Tuberculosis Infection (LTBI) without accessing the inmate's baseline liver function test. Agency's Clinical Practice Guidelines provides procedures for treating LTBI, yet you failed to order the required baseline liver function test prior to providing INH treatments for inmate You were made aware of the Bureau's Clinical Practice Guidelines through Continuing Professional Education in November 2002 for PPD and in April 2003 for TB. Your actions described above constitute a violation of this procedure.

Specification B: On August 1, 2005, while on duty as attending Physician, you followed up with an Isoniazid (INH) prophylaxis regimen for inmate Register Number for a positive Protean Purified Derivative (PPD) readings for Latent Tuberculosis Infection (LTBI) without accessing the inmate's baseline liver function test. Agency's Clinical Practice Guidelines provides procedures for treating LTBI, yet you failed to

order the required baseline liver blood test prior to providing INH treatments for inmate You were made aware of the Bureau's Clinical Practice Guidelines through Continuing Professional Education in November 2002 for PPD and in April 2003 for TB. Your actions described above constitute a violation of this procedure.

Specification C: On April 19, 2005, while on duty as attending Physician, you provided treatment to inmate Register Number for a positive Protean Purified Derivative (PPD) readings for Latent Tuberculosis Infection (LTBI) of April 14, 2005. Agency's Clinical Practice Guidelines provides procedures for initiating an Isoniazid (INH) prophylaxis regimen based on positive PPD readings for LTBI, yet you failed to ensure a baseline Chest X-ray was ordered for inmate You were made aware of the Bureau's Clinical Practice Guidelines through Continuing Professional Education in November 2002 for PPD and in April 2003 for TB. Your actions described above constitute a violation of this procedure.

You admit in your affidavit, dated February 8, 2006, that on April 19, 2005, upon your initial examination of inmate Register you were aware that the base line blood tests (liver function tests) and chest X-rays were not ordered. In addition, you admit that on August 1, 2005, when you reexamined inmate Register you once again noticed that the base line blood tests (liver function tests) and chest X-rays were not ordered yet. On both occasions you administered the INH prophylaxis to him for the treatment of Latent Tuberculosis Infection (LTBI) without verifying a negative chest X-ray, and acceptable liver function test to rule out any contraindications to treatment existed.

The Federal Bureau of Prison's, Clinical Practice Guidelines, Management of Tuberculosis, dated December 2004, states "Although baseline liver transaminases are not routinely recommended prior to initiating Latent Tuberculosis Infection (LTBI) treatment in general population, screening is recommended for federal inmates, because of the high incidence of substance abuse and associated liver disease among incarcerated populations. If liver transaminases are elevated, liver function tests should be assessed." In addition, the Drug Information Handbook, 13th Edition, concerning Isoniazid (INH) states under Warnings and Precautions, "Use with caution in patients with renal impairment and chronic liver disease. Severe and sometimes fatal hepatitis may occur or develop at anytime or after many months of treatment. In addition, it states under Monitoring Parameters, "Periodic liver function tests monitoring for prodromal signs of hepatitis."

As a medical doctor treating inmates you have the responsibility to ensure you achieve a reasonable and accepted medical standard-of-care in the management of inmate care . You prescribed INH

prophylaxes prior to evaluating this inmate's laboratory studies, thus exposing him to potential serious side-effects. In addition, you failed to review chest X-rays to ensure this inmate did not have an active Tuberculosis Infection. Because you failed to order and review laboratory tests and a chest X-ray, you were unable to properly determine to be sure that the inmate was not active for the Tuberculosis Infection and rule out contraindications for INH treatment. Your lack of proper management care may have contributed to the liver cancer found on subsequent biopsy of this inmate. Also, you did not know that the inmate had Hepatitis B infection. Should you have checked the liver function tests, you might not have prescribed the INH treatment to this inmate. By not initiating appropriate laboratory evaluation of the positive PPD test readings you could not determine that Inmate Belandres liver function was acceptable to treat. Your inability to properly administer medical care to the inmate demonstrates that you cannot be relied upon to carry out the duties and responsibilities of your position.

The Warden will make the final decision on this proposal. You may reply to the Warden orally, in writing, or both orally and in writing. Your reply may include affidavits or other supporting documents. Any reply which you make must be received by the Warden within fifteen working days from the date you receive this letter. Consideration will be given to extending this time limit if you submit a written request, to the Warden, stating your reasons for desiring more time. No final decision on this proposal will be made until after your reply, if any, is received and considered. Your present duty and pay status are not affected by this letter.

You have the right to a representative of your choice to assist you in the preparation and presentation of any reply you may wish to submit. You and your representative, if your representative is an employee of this institution, will be allowed a reasonable amount of official or work time to review the materials, upon which this action is based, and present a reply. To obtain copies of the materials, if copies have not already been provided, please contact the Employee Services Department.

Should you have any questions or need assistance in this matter, contact Christine Dynan, Employee Services Manager, extension 110.

Sincerely,

John W. Chung
Clinical Director

I have received the original and one copy of this letter.

Signature _____ Date 11·1·2007

From: Tushar Patel
To: docs; PA
Date: 1/21/2005 2:55:52 PM
Subject: Ordering Hepatitis Profile and LFT's

Please be advised that Hepatitis B and C profiles and LFT's are not ordered routinely unless there is a history and medical evaluation is completed during sick call, chronic care clinic or during physical examination.

Please DO NOT order Hepatitis Profile or Liver Function Test on a routine basis for inmates with a history of positive PPD. If the inmate has a positive PPD, you need to refer him in PPD Clinic. If there is an indication for INH Prophylaxis, it will be ordered by the Clinician. If inmate is at high risk from a previous risky behavior, i.e. intravenous drug use, multiple sex partners, a thorough history and physical must be documented prior to ordering Hepatitis Profile and a follow-up must be provided after the results.

Ordering the labs and not providing follow-up for abnormal labs is risky and can lead to a malpractice lawsuit. Please feel free to contact me if you have any questions regarding this matter. Thank you.

Tushar B. Patel, CCHP, ACHE
Assistant HSA
FCI Fort Dix, NJ 08640
609-723-1100, X778

November 14, 2007

Guide for Primary Health Care Providers: Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection 2005

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Treatment of Latent TB Infection

Treatment Regimens

Using an adaptation of the U.S. Public Health Service (USPHS) rating system, CDC and ATS have rated LTBI treatment regimens based on the strength of recommendation and the quality of the evidence that supports that recommendation (see Table 4).

Table 4: Treatment Regimens

Drug/Dose	Frequency/ Duration	Rating*(Evidence)†	
		HIV negative	HIV positive
Preferred Regimen			
Isoniazid Adult: 5 mg/kg Children: 10-20 mg/kg Maximum dose 300 mg	Daily x 9 months	A (II)	A (II)
Alternate Regimens			
Isoniazid Adult: 15 mg/kg Children: 20-40 mg/kg Maximum dose 900 mg	Twice weekly x 9 months§	B (II)	B (II)
Isoniazid Adults: 5 mg/kg Maximum dose 300 mg	Daily x 6 months	B (I)	C (I)
Isoniazid Adults: 15 mg/kg Maximum dose 900 mg	Twice weekly x 6 months§	B (II)	C (I)
Rifampin Adults: 10 mg/kg Children: 10-20 mg/kg Maximum dose	Daily x 4 months	B (II)	B (II)

600 mg				

Note:
A regimen of rifampin and pyrazinamide for the treatment of LTBI should generally not be offered due to risk of severe adverse events.

In situations in which rifampin cannot be used (e.g., HIV-infected persons receiving protease inhibitors), rifabutin may be substituted.

* Strength of the recommendation: A = preferred regimen; B = acceptable alternative; C = offer when A and B cannot be given

† Quality of the supporting evidence: I = randomized clinical trials data; II = data from clinical trials not randomized or from other population

§ Intermittent regimen must be provided via directly observed therapy (DOT), i.e., health care worker observes the ingestion of medication

Special Considerations in the Treatment of LTBI

Contacts

Contacts are those with recent, prolonged exposure to a person with known or suspected infectious TB (i.e., pulmonary or laryngeal TB with positive sputum smear). They should be evaluated immediately for TB disease and LTBI. If the TST is positive, the guidelines below should be followed. Those who have negative TST reactions should be retested in 8–10 weeks. **However, treatment should be initiated in TST-negative children ≤ 5 years of age (note: some TB control programs may use a different age cutoff) and in immunocompromised persons of all ages; this should be continued until the results of the second test and other medical evaluation are known.** This treatment is known as "window prophylaxis" and accounts for the time period immediately after exposure when a TST may remain negative.

- If person is exposed to known *drug-susceptible* TB or drug susceptibility is unknown:
  - Positive TST result → treat regardless of age with isoniazid (INH) for 9 months preferred
  - Negative TST result → retest in 8 –10 weeks
- If person is exposed to known *isoniazid-resistant* TB:
  - Positive TST result → treat for 4 months with rifampin (RIF)
  - Negative TST result → retest in 8–10 weeks
- If person is exposed to known *multidrug-resistant* TB (MDR TB):
  - Positive TST result → An expert in the treatment of multidrug-resistant TB should be consulted.
  - Negative TST result → retest in 8–10 weeks
- In general, TST-positive contacts with a documented history of prior adequate treatment for LTBI do not need to be re-treated. Re-treatment may be indicated for persons at high risk of becoming re-infected and progressing to TB disease (e.g., immunocompromised persons)

HIV-infected Individuals

- HIV-infected individuals should be treated with a 9-month regimen of INH.
- Rifampin (RIF) is contraindicated in HIV-infected persons being treated with certain combinations of antiretroviral drugs. In those cases, rifabutin may be substituted for RIF (see CDC website at http://www.cdc.gov/tb for guidelines for the use of rifamycins and protease inhibitors or nonnucleoside reverse transcriptase inhibitors).
- If TST result is negative, treat if person has recent, prolonged exposure to infectious TB or if there is ongoing risk for exposure.

Pregnancy

- Consider immediate treatment for LTBI if the woman is HIV-infected or recent contact, and monitor
- In the absence of risk factors, wait until after the woman has delivered to avoid administering unnecessary medication during pregnancy
- INH daily or twice weekly (using DOT) is preferred regimen
- Supplementation with 50 mg of pyridoxine (vitamin B6) is recommended

Breastfeeding

- Breastfeeding is not contraindicated in women taking INH
- Supplementation with 50 mg of pyridoxine (vitamin B6) is recommended for nursing women and for breastfed infants
- Amount of INH in breast milk is inadequate for treatment of infants exposed to TB

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, children, and adolescents is minimal
- Routine monitoring of serum liver enzymes is not necessary
- DOT should be considered

Additional Notes of Importance

- Old fibrotic lesions can represent previous TB disease. Persons with TST result of ≥ 5 mm of induration and no active disease should be treated for LTBI.
- Calcified solitary pulmonary nodules, calcified hilar lymph nodes, and apical pleural capping represent healed primary *M. tuberculosis* infection and do not increase the risk of TB disease. Persons should not receive treatment

unless other risk factors are present.

Adverse Effects of Drugs Used to Treat LTBI

Many health care providers have concerns about treating patients for LTBI. These concerns are generally related to the length of treatment and the potential side effects of isoniazid (INH). As with any treatment, the physician must weigh the risks and benefits for each individual. Obtaining a detailed and accurate medical history and updating information at frequent intervals will detect persons who require close monitoring and aid the physician in determining the most appropriate course of action. In addition, CDC guidelines, drug package inserts, and other authoritative medical sources should be consulted whenever there is a question about side effects or drug-drug interactions.

The sections that follow discuss some of the adverse effects of isoniazid and rifampin, as well as recommendations for monitoring during treatment and for assessing and ensuring adherence.

Possible adverse effects of INH

- Asymptomatic elevation of serum liver enzyme concentrations occurs in 10%–20% of people taking INH. Increased enzyme concentrations can be accepted at up 5 times the upper limit of normal for patients who are free of hepatitis symptoms, if the serum bilirubin concentration is in the normal range. Liver enzyme concentrations usually return to normal even when treatment is continued.
- Clinical hepatitis occurs in 0.1% to 0.15% of people taking INH, and is more common when INH is combined with other agents. Factors that may increase either these rates or the severity of hepatitis include alcohol consumption, underlying liver disease or risks for liver disease, and the concurrent use of other medications which are metabolized in the liver. Symptomatic hepatitis is rare in patients younger than 20 years of age, but severe and fatal cases have been reported, and younger patients should be monitored clinically with the same precautions as older patients.
- Peripheral neuropathy occurs in less than 0.2% of people taking INH at conventional doses, and is more likely in the presence of other conditions associated with neuropathy such as diabetes, HIV, renal failure, and alcoholism. Pyridoxine (vitamin B6) supplementation is recommended in such conditions or to prevent neuropathy in pregnant or breastfeeding women.

Possible adverse effects of rifampin (RIF)

- Hepatotoxicity, evidenced by transient asymptomatic hyperbilirubinemia, may occur in 0.6% of persons taking

RIF. Hepatitis is more likely when RIF is combined with INH.

- Cutaneous reactions, such as pruritis (with or without a rash), may occur in 6% of persons taking RIF. It is generally self-limited and may not be a true hypersensitivity; continued treatment may be possible.
- Gastrointestinal symptoms such as nausea, anorexia, and abdominal pain are rarely severe enough to discontinue treatment.
- Orange discoloration of body fluids is expected and harmless, but patients should be advised. Soft contact lenses may be permanently stained.
- RIF interacts with a number of drugs, causing drug-drug interactions. It is known to reduce concentrations of methadone, warfarin, oral contraceptives, and phenytoin.
- RIF is contraindicated, or should be used with caution, in HIV-infected individuals being treated with certain protease inhibitors (PIs) or nonnucleoside reverse transcriptase inhibitors (NNRTIs). In this situation, rifabutin may be substituted.

Patient Monitoring and Education During Treatment

To ensure safe and efficacious treatment for LTBI, the provider should periodically assess the patient's progress. This evaluation involves the following:

Laboratory Testing

- Baseline laboratory testing (measurements of serum AST, ALT, and bilirubin) at the start of LTBI therapy is recommended for patients with any of the following factors:
  - Liver disorders
  - History of liver disease (e.g., 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 (i.e., within 3 months of delivery)
- Baseline testing can be considered on an individual basis, especially for patients taking other medications for chronic medical conditions.
- After baseline testing, routine periodic retesting is recommended for persons who had abnormal initial results and other persons at risk for hepatic disease.
- At any time during treatment, whether or not baseline tests were done, laboratory testing is recommended for patients who have symptoms suggestive of hepatitis (e.g., fatigue, weakness, malaise, anorexia, nausea, vomiting, abdominal pain, pale stools, dark urine, chills) or who have signs of jaundice. Patients should be instructed, at the start of treatment and at each monthly visit, to stop taking treatment and to seek medical attention

immediately if symptoms of hepatitis develop and not to wait until a clinic visit to stop treatment.
- 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.

Clinical Monitoring

- Patients should visit the health care provider who is managing treatment on a monthly basis for
  - Brief physical assessment for signs of hepatitis
  - Assessment of adherence
  - Review of symptoms of possible adverse drug reactions or interactions
- Patients taking INH or RIF who experience possible adverse reactions should be advised to stop medication and consult their physician immediately

Patient Education

- Explain the disease process and rationale for medication in absence of symptoms or radiographic abnormalities
- Review the importance of completing treatment for LTBI
- Discuss possible side effects of LTBI medications such as
  - Fever
  - Unexplained anorexia
  - Dark urine (color of coffee or cola)
  - Icterus
  - Rash
  - Persistent paresthesia of hands and feet
  - Persistent fatigue or weakness lasting 3 or more days
  - Abdominal tenderness, especially in right upper quadrant
  - Easy bruising or bleeding
  - Arthralgia
  - Nausea
  - Vomiting
- Discuss management of common side effects and the need to report to physician

Assessing Adherence

Many variables affect a patient's adherence to the medication regimen for treatment of LTBI. Episodes of nonadherence should be detected and addressed as soon as possible. Some examples of barriers to adherence are noted in the section that follows.

Office-Related Variables

- Long waiting time for appointment and referrals
- Long waiting time in provider's office
- Inconvenient office hours

- Complicated telephone system (not "user-friendly")

Patient-Related Variables

- Misinformation about topics such as
  - The TST; for example, a positive TST result thought to be normal or common in all foreign-born persons
  - Differences between injections, vaccines, and TST
  - The words "positive" and "negative"
  - Transmission and prevention
  - Safety of family and friends around someone with LTBI
- Residential instability
- Lack of financial resources
- Poor access to health care
- Stigma associated with tuberculosis
- Co-existing medical conditions

Treatment Variables

- Visits for administering, reading, and counseling between TST and QFT
- Complexity and duration of treatment
- Medication side effects
- Obtaining refills
- Frequency of office visits

Techniques to Improve Adherence

- Collaborate with local health department to provide
  - DOT, especially if intermittent therapy is desirable or if patient is high risk (e.g., HIV infected or TB contact)
  - Case management to coordinate care and services
  - Free or low-cost medication
  - Incentives (rewards for adherence)
    - Grocery store or restaurant vouchers
    - Nutritional supplements
    - Movie tickets
  - Enablers (to overcome barriers)
    - Free van transportation or bus tickets
    - Effective patient education
- Provide patient education and instructions in patient's primary language
- Reinforce patient education at each visit
- Ensure confidentiality
- Suggest or provide patient reminders such as pill box, calendar, timer

Posttreatment Follow-Up

- Patient should receive documentation of TST or QFT results and treatment completion that includes name,

dates, chest radiograph, and dosage and duration of medication. The patient should be instructed that he or she should present this document any time future testing is required.

- Patient should be re-educated about the signs and symptoms of TB disease and told to contact his or her medical provider if he or she develops any of these signs or symptoms.
- Regardless of whether the patient completes treatment for LTBI, serial or repeat chest radiographs are not indicated unless the patient develops signs or symptoms suggestive of TB disease.

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Management of Tuberculosis

December, 2004

(Federal Bureau of Prisons - Clinical Practice Guidelines)

Clinical guidelines are being made available to the public for informational purposes only. The Federal Bureau of Prisons (BOP) does not make any promises or warrant these guidelines for any other purpose, and assumes no responsibility for any injury or damage resulting from the reliance thereof. Proper medical practice necessitates that all cases are examined on an individual basis and treatment decisions are patient-specific.

Management of Tuberculosis
December, 2004
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1. Purpose

The Federal Bureau of Prisons Clinical Practice Guidelines for the Management of Tuberculosis (TB) provide recommendations for the treatment of federal inmates with TB infection and disease and for the management of contacts to infectious TB cases.

2. Epidemiology, Transmission and Natural History

TB incidence in the United States decreased during the past decade largely as a result of more intensive TB control efforts. Nevertheless, TB control remains a public health priority for correctional systems, since TB outbreaks continue to occur in U.S. jails and prisons. Furthermore, a significant proportion of TB cases in the U.S. occur among persons who are over-represented in certain jails or prisons, including racial/ethnic minority populations, persons with human immunodeficiency virus (HIV) infection, and persons born in countries with high rates of TB.

M. tuberculosis, the organism that causes TB, is transmitted through airborne respiratory *droplets when an individual with active pulmonary TB coughs, sneezes, speaks or sings.* Transmission of *M. tuberculosis* depends on the length of time and frequency of the exposure, the degree of contagiousness of the infected person, the environment and airflow in which the exposure occurred, and the intensity of the contact with the TB organism itself. Infection with *M. tuberculosis* usually requires prolonged contact with an infectious case in an enclosed space. The majority of infected persons never develop active TB, but rather develop a latent TB infection (LTBI).

The most significant risk factor for LTBI is country of origin. The general U.S. population has an estimated TB infection rate of only 5 to 10%, whereas foreign born populations have an average estimated TB infection rate of 52%, with rates varying widely throughout the world. Other risk factors for infection with TB include injection drug use, being a resident or employee in congregate settings such as prisons and jails, health care facilities and homeless shelters, and most notably being a known contact of an active TB case. On average, 30% of household contacts to infectious TB cases have a positive tuberculin skin test (TST).

Approximately 5% of infected persons develop active TB disease during the first year or two after infection. In another 2-5%, disease will develop later in their lives. Certain medical conditions increase the risk that TB infection will progress to disease, the most important of which is HIV infection. *Appendix 1 (Tuberculosis Risk Factors)* lists conditions associated with a higher risk of TB disease, including evidence of prior TB disease on chest radiograph (CXR), injection drug use, history of organ transplant, immunosuppressive therapy, diabetes mellitus, and chronic renal failure.

3. Screening

Screening for TB in correctional facilities involves both ongoing surveillance for active TB disease and detection of latent TB infection. Early detection and isolation of inmates with suspected pulmonary TB is critical to prevent widespread TB transmission. Identification of latent TB infection provides an opportunity for providing treatment to prevent future development of TB disease.

TB Symptom Screening

At intake, all inmates should be systematically screened for TB symptoms. The following questions should be asked:

1. *Have you ever been treated for tuberculosis (TB)?*
2. *Have you had a cough for more than 3 weeks?*
3. *Are you coughing up blood?*
4. *Have you recently lost weight?*
5. *Do you have frequent fevers or night sweats?*

Inmates who have symptoms suggestive of TB disease should receive a thorough medical evaluation, including a TST, a chest radiograph, and, if indicated, sputum examinations; and be isolated in a negative pressure isolation room (NPIR) if TB is suspected.

Chest Radiograph Screening

All HIV infected inmates should have a CXR performed at intake, in addition to the intake TB symptom screen and a tuberculin skin test.

Some facilities, which house inmates with a high incidence of TB, may conduct routine CXR screening of all inmates entering the prison. Decisions about use of routine CXR screening should be made in coordination with the Warden, Regional and Central Office HSD staff.

Tuberculin Skin Testing

The TST is an approved method for diagnosing *M. tuberculosis* infection in persons who do not have TB disease. Persons with LTBI usually are asymptomatic, often unaware of past exposures to TB, and yet they are at future risk of developing infectious TB. Screening high risk populations, such as inmates, and providing treatment for those with latent TB infection, is therefore an important public health measure.

The TST has a specificity of approximately 99% in populations that have no other mycobacterial exposures or BCG (Bacillus Calmette Guerin) vaccination. However, the specificity decreases where cross-reactivity with other mycobacteria is common. Tuberculin skin testing guidelines are outlined in *Appendix 2 (Tuberculin Skin Testing Guidelines)*.

- **Indications for tuberculin skin testing:** Inmates should be evaluated for TB infection with a TST in accordance with BOP policy and Centers for Disease Control and Prevention (CDC) guidelines. Inmates with a history of a negative TST or unknown status should be tested for LTBI in accordance with Bureau policy and the following indications:
  - *upon incarceration:*
    (Note: TST documentation during the past year from local detention centers is acceptable for TB screening purposes. However, repeat TST is recommended for *inmates who have been transferred from local detention centers that are located in* regions of the country with higher rates of TB. For BOP inmates who are transferred frequently to and from local jails, testing should be repeated as recommended by the evaluating clinician, but no more than quarterly.)
  - as part of annual screening;
  - if active TB disease is clinically suspected (and TST status unknown), and
  - as part of a TB contact investigation.
- **Special considerations**
  - Reported prior positive TST: A self-reported, prior positive TST without a millimeter reading is not a contraindication to repeat testing unless either a severe reaction (e.g., swollen, blistering reaction) has been documented or described by the inmate or a credible history of treatment for LTBI has been provided. Inmates with a documented positive TST, measured in millimeters, should not be tested repeatedly.
  - Pregnancy is not a contraindication to tuberculin testing.
  - BCG vaccination is not a contraindication to tuberculin testing. TST reactivity resulting from BCG vaccination does not correlate with protection against TB. Since there is no reliable method for distinguishing tuberculin reactions caused by BCG from those caused by infection with *M. tuberculosis*, persons with a positive TST with a history of BCG vaccination should be considered infected with *M. tuberculosis*.
  - Anergy testing is not medically indicated as a component of tuberculin skin testing for inmates. HIV infected and other immunosuppressed persons may not mount an immune response to the TST, however, anergy testing does not help determine whether a person will have an adequate cellular immune response to PPD tuberculin.
  - QuantiFERON® is a recently licensed blood test for the detection of TB infection. After evaluating available data on its specificity and sensitivity, the Bureau of Prisons has decided to not recommend general use of QuantiFERON®, pending results of ongoing studies and development of subsequent generations of the test.
- **Administering and reading TSTs**
  - Training: TSTs should only be performed by health care workers who have had formal training in administering, reading and interpreting the test. If the Mantoux TST

is placed or read incorrectly, the results may be inaccurate.

  - Product information: Only BOP Purified-protein tuberculin solution should be used. Tuberculin should never be transferred from one container to another to minimize reduction in potency by adsorption. Skin tests should be administered as soon as possible after the tuberculin syringe has been filled. The tuberculin test solution should be refrigerated (not frozen) and stored in the dark as much as possible (exposure to strong light should be avoided). Multi-puncture tests (Tine®) are poorly standardized and should not be administered.
  - Administration: The TST should be administered by the Mantoux method via intradermal injection of 0.1 ml of purified protein derivative (PPD) tuberculin containing 5 tuberculin units (TU) into the volar or dorsal surface of the forearm, using a disposable tuberculin syringe. Other areas may be used, but the forearm is the preferred site for testing. A skin area away from superficial veins and free of lesions should be selected. A 5 mm sense white wheal should appear at the injection site. If this does not appear, replace the test at least 2 inches away from the initial injection site. Gloves are optional for administering TSTs and can be used on a case by case basis. Wash hands before and after placing and reading a TST. Alcohol based hand *sanitizer can be used.*
  - Reading: The TST should be read by a trained health care worker 48 to 72 hours after injection. A positive reaction can be measured up to one week after testing and is considered valid; however, readings after 72 hours tend to underestimate the true size of induration. A negative reaction read after 72 hours is invalid and the test should be repeated. The test is "read" by measuring the largest diameter of the indurated area (palpable swelling) on the forearm in millimeters (mm). The diameter of the induration should be measured transversely to the long axis of the forearm for standardization purposes. Erythema (redness) without induration is not significant. The TST results should always be documented in millimeters, not as positive or negative. If there is no reaction (or just erythema), record "0 mm".
- **Interpreting skin test reactions:** Two end-points for defining a positive TST are indicated in correctional facilities based on risk factors for TB infection and TB disease in infected inmates.
  - **Positive tuberculin test:**
    - 5 millimeters or greater with the following concurrent conditions:
      - Close contact to an active TB case
      - HIV co-infection, HIV risk factors and unknown HIV status
      - Other immunosuppressed conditions
      - Systemic corticosteroids (equal to prednisone 15 mg for 1 month or more)
      - History of organ transplantation or other immunosuppressive therapy
      - Fibrotic changes on chest radiograph suggestive of inactive pulmonary TB
      - Radiographic or clinical findings suggesting active TB
      - Persons taking anti-TNF alpha drugs (e.g., infliximab)

- **10 millimeters or greater:** all other inmates

All inmates with a TST of 5 millimeters of induration or greater should be referred for a CXR and promptly evaluated by a physician for evidence of active TB disease and consideration for LTBI treatment, if indicated.

- **TST reactors vs. convertors:** A TST "reactor" is anyone who has a positive TST. A TST convertor is one whose TST has increased 10 mm or more in a 2 year period. A TST convertor has a higher risk of developing TB disease.

- **Booster phenomenon and two-step testing:** Certain individuals infected with *M tuberculosis* will have a negative TST when tested many years after their initial infection. This skin test, however, may stimulate or "boost" the immune system's ability to react to tuberculin and cause a positive reaction to subsequent tests. This booster phenomenon can be induced more than a year after an initial test.

Two-step testing is a technique used to help distinguish between "boosted" reactions and reactions due to new infections. Consideration should be given to doing "two-step testing" for the following newly sentenced inmates at high risk for boosting who have not received a TST in the last year, and for whom repeated annual testing is anticipated:

- Inmates over 50 years of age;
- Foreign born inmates;
- Inmates with a history of BCG vaccination; and
- Other inmates as medically indicated with suspected previous exposures to *M tuberculosis*.

Two-step testing is performed as follows. If the initial TST reaction is negative, a second test is placed 1 to 3 weeks later. If the second test is also negative, the person is considered uninfected. Any subsequent positive test would be considered new infection (skin test conversion). However, if the second test is positive, the person should be classified as infected (but not a convertor) and be managed accordingly.

4. Treatment of Latent Tuberculosis Infection

Baseline Evaluation

- Medical history should include risk factors for TB (*Appendix 1*), prior treatment for TB or LTBI, review of preexisting medical conditions that may complicate treatment, review of current medications with attention to potential drug interactions, and review of symptoms of active TB disease, hepatitis, liver disease, and pregnancy.

- **Targeted examination** should be performed by a clinician for systemic signs of active TB disease (e.g., fever, weight loss, pulmonary findings) and for signs of hepatitis.

- **Chest radiographs:** The treatment of LTBI should never be initiated until active TB disease has been eliminated as a potential diagnosis with a posterior-anterior CXR and documented negative assessment for signs and symptoms of TB. A CXR is "good" (for the purpose of ruling out TB prior to starting treatment of LTBI) for 3-6 months in HIV seronegative persons and 1 month in HIV-positive persons.

- **Pregnancy:** A CXR should be done immediately utilizing lead shielding, even during the first trimester for pregnant women who are:
  - presenting with symptoms suggestive of TB disease;
  - *HIV-positive (TST positive or negative) and had close contact to a TB case,*
  - TST positive and are a close contact to a smear positive or cavitary case.

  A CXR should be performed for lower risk TST positive pregnant women after the first trimester, utilizing lead shielding.

- **Liver transaminases:** ALT (SGPT) or AST (SGOT) and other laboratory tests should be obtained as clinically indicated. Although baseline liver transaminases are not routinely recommended prior to initiating LTBI treatment in the general population, screening is recommended for federal inmates, because of the high incidence of substance abuse and associated liver disease among incarcerated populations. If liver transaminases are elevated, liver function tests (e.g., bilirubin) should also be assessed.

- HIV counseling and testing is strongly recommended for all TST positive persons (if not done previously) since HIV co-infection significantly increases the risk of developing active TB.

- **Sputum evaluation** is not routinely indicated for persons being considered for LTBI *treatment. Inmates* with CXRs suggestive of old healed TB, however, should provide 3 consecutive sputum samples (if producible), on different days for AFB smear and culture studies to screen for active TB disease. Inmates with HIV infection, and respiratory symptoms or unexplained fever or weight loss, should also have sputums submitted for bacteriologic cultures, since active TB disease in immunocompromised hosts is often difficult to diagnose.

If sputum smears and cultures are negative and the inmate's symptoms or radiographic findings can not otherwise be clinically explained, further diagnostic evaluations (e.g., bronchoscopy) for active TB disease should be considered. During the diagnostic evaluation, empiric treatment for active TB disease can be considered on a case by case basis depending on the inmate's symptoms and radiographic findings. **Single drug treatment of LTBI should never be instituted while an evaluation for active TB disease is being pursued.**

Indications for Treatment of LTBI

Clinical indications for the treatment of LTBI are based on the inmate's TST reaction in millimeters, *the relative risk of developing TB disease*, and risk factors for drug side effects. Treatment of LTBI should be considered for all TST positive inmates (see *Appendix 2*) regardless of age, when no medical contraindications to treatment exist, and previous adequate

treatment has not been provided, while giving the highest priority to the following inmates:

- **Highest priority for treatment for LTBI**
  - **HIV co-infection** is the most significant risk factor for the development of active TB; therefore co-infected TST-reactors are a very high priority for effectively treating LTBI. Similarly, patients on immunosuppressive therapy, a history of organ transplantation with immunosuppression, or chronic steroid usage should also receive priority treatment for LTBI.

  - **Recent convertors:** Inmates whose TST has increased 10 millimeters or more within the past 24 months, are at relatively high risk for developing TB and thus are high priority candidates for LTBI treatment.

  - **Other high risk medical conditions:** Concurrent conditions that increase the risk of TB disease include in part, abnormal CXR consistent with old healed TB, injection drug use history, hematologic or reticuloendothelial neoplasms, chronic renal failure, diabetes mellitus (insulin dependent), gastrectomy and other specific conditions resulting in nutritional deficiencies, head and neck malignancies, and silicosis

- **Detention facilities:** Inmates in detention centers should ordinarily not be prescribed LTBI treatment if their anticipated incarceration is uncertain or is less than several months unless any of the following high priority indications have been identified: HIV co-infection or other immunocompromised condition, close contact of an active TB case, or recent convertor status.

Treatment Regimens

Two treatment regimens for LTBI have been recommended by the CDC as enumerated in *Appendix 3 (Treatment Regimens for Latent Tuberculosis Infection)*. The anti-tuberculosis medications used in these regimens differ in their dosages, potential toxicities, and monitoring requirements. Ingestion of ALL doses of medication for treatment of LTBI will *be directly* observed via pill line. The 2 standard options for treatment of LTBI are outlined below.

Medication administration should be documented using the *Federal Bureau of Prisons Tuberculosis Preventive Treatment Program Medication Administration Record*. All doses should be administered in unit doses and directly observed. Effective determination of treatment completion is based upon doses taken rather than time elapsed.

- **Isoniazid (INH) - 6 to 9 months** by mouth is the preferred treatment regimen for LTBI and should be prescribed unless other medical or logistical reasons warrant an alternative regimen. **Nine months of isoniazid should be administered for all HIV co-infected inmates** and, whenever feasible, for all other inmates. INH can be administered daily or twice weekly.
  - **Twice weekly: 15 mg/kg (maximum 900 mg), twice weekly, at least 2 days apart**
    Total doses: 9 months = 78 doses
    6 months = 52 doses

  - **Daily: 5 mg/kg (maximum 300 mg), daily (at physician discretion)**
    Total doses: 9 months = 270 doses
    6 months = 180 doses

  Pyridoxine should ordinarily be prescribed concurrently with isoniazid, usually as 50 mg per dose of isoniazid. Pyridoxine helps prevent neuropathy and other isoniazid-related side effects in at-risk populations.

Drug interactions between isoniazid and phenytoin increase the serum concentrations of both drugs; therefore serum levels of phenytoin should be monitored monthly and adjusted as necessary for patients taking both medications.

- **Rifampin (RIF) - 4 to 6 months**, administered daily, is an acceptable alternative treatment regimen for LTBI, particularly for individuals who will not remain incarcerated long enough to complete a longer course of treatment. Efficacy data for this regimen are not as strong as for isoniazid; therefore isoniazid is the preferred regimen. Rifampin interacts with many drugs, including anti-retroviral drugs and coumadin and may reduce the effectiveness of these and other drugs. The prescribing clinician and pharmacy staff should review drug interactions carefully whenever prescribing rifampin. Dosing is as follows:
  - **Daily: 10 mg/kg (maximum 600 mg) (cannot be administered intermittently)**
    Total doses: 4 months = 120 doses
    6 months = 180 doses (preferred with HIV co-infected)

- **Rifampin / Pyrazinamide:** The use of rifampin and pyrazinamide for treatment of LTBI is not recommended due to unacceptable rates of hepatotoxicity with that regimen.

- **MDR-TB contacts:** Consultation with a TB expert is recommended when treating contacts of persons with MDR-TB.

Completion of LTBI treatment must be determined by counting doses of medication taken, not solely by duration of treatment, since missed doses may occur.

Special Considerations

- **Contraindications:** Treatment of LTBI should *not* be initiated if contraindications to treatment exist, including but not necessarily limited to the following:
  - **Radiologic or clinical evidence of active TB disease.**

  - Symptoms or signs of active hepatitis or other medical conditions that would complicate treatment. Some experts recommend that isoniazid be withheld if a patient's transaminase level exceeds 3 times the upper limit of normal (if associated with symptoms) and 5 times the upper limit of normal if the patient is asymptomatic. Inmates with significant elevations in liver transaminases should be considered for LTBI treatment only if at high risk of developing active TB disease. Consultation with a physician with expertise in treating LTBI is recommended.

- *History of adverse reactions to medications prescribed for LTBI.*

- **HIV co-infection:** Persons with HIV infection and LTBI are at significant risk of developing active TB disease and are therefore considered priority candidates for treatment. When prescribing isoniazid for treatment of LTBI, 9 months of treatment is recommended. Inmates with HIV infection who are close contacts of a person with infectious TB disease should be considered for treatment regardless of TST results.

- **Pregnancy:** Pregnancy itself does not significantly influence the pathogenesis of TB or the risk of LTBI progressing to active TB disease; therefore treatment of LTBI with isoniazid is not routinely recommended during pregnancy. Daily or twice weekly isoniazid for 6-9 months should be prescribed 1-2 months following delivery in most cases. Pregnant women in high risk of developing TB disease (e.g., positive TST and history of close contact to an active TB case, recent converters, or have concurrent HIV infection or other immunosuppressive conditions) should be considered for isoniazid treatment of LTBI during pregnancy with close monitoring for hepatitis. No harmful effects on the fetus have been observed with isoniazid therapy.

- **Old TB:** Inmates with abnormal CXRs suggestive of prior TB infection should be evaluated on a case by case basis in consultation with physicians experienced in diagnosing TB. Calcified solitary pulmonary nodules, calcified hilar lymph nodes, and apical pleural capping usually represent primary healed TB rather than active TB disease. Treatment of LTBI in persons with evidence of primary healed TB depends on the patient's history, TST results, and risk factors for TB disease. Persons with old fibrotic changes on CXR suggestive of previous infection with TB, a positive TST of ≥ 5 millimeters, without evidence of active disease and no history of treatment for TB should be considered for treatment of LTBI. If the person can produce sputum, sputum examination is warranted to rule out active TB disease prior to initiating treatment of LTBI in persons with fibrotic changes on CXR. In some symptomatic cases, clinicians may elect to initiate treatment for TB disease while awaiting sputum culture results for *M. tuberculosis*.

- **BCG vaccination:** A history of BCG vaccination, with or without a BCG scar, should be ignored as a factor in deciding to offer treatment.

Monitoring Treatment

- **Inmate counseling:** Inmates should be counseled by health care staff about the importance of adherence to every dose of treatment for LTBI. Pharmacy staff and other health care staff as appropriate should educate inmates about potential drug side effects, especially the signs and symptoms of hepatitis, and the reason for pyridoxine co-administration. Group counseling or other structured educational efforts should be considered for inmates who refuse treatment for LTBI when treatment is clearly indicated.

- **Monitoring drug side effects:** The risk of hepatitis from isoniazid is low, but may be increased in older persons (≥ 50 years of age), women, and during the third trimester of

pregnancy and the postpartum period. Inmates should be interviewed monthly by a health care provider for symptoms of anorexia, nausea, vomiting, dark urine, scleral rash, persistent paresthesias of the hands and feet, fatigue or weakness lasting 3 or more days, abdominal pain, easy bruising or bleeding, and arthralgias. Inmates who are nonadherent to treatment or who report symptoms suggestive of an adverse drug reaction or a serious drug side effect should have medications held and be immediately referred to a clinician for further evaluation.

All inmates should have baseline liver transaminases measured and should be subsequently monitored for signs and symptoms of hepatitis and other medications side effects. Monitoring liver transaminases is not routinely recommended during treatment of LTBI. However, liver transaminases, and liver function tests as necessary, should be monitored periodically, for the following inmates:

- significant elevations in baseline liver transaminases;
- chronic liver disease from alcohol, viral hepatitis or other etiologies;
- concurrently prescribed other potentially hepatotoxic drugs;
- history of previous adverse reactions to the medications used in treating LTBI; and
- pregnant women.

Treatment for LTBI should ordinarily be discontinued if liver transaminases exceed 3 times the upper limit of normal if associated with symptoms and 5 times the upper limit of normal if the inmate is asymptomatic.

The most important measure to prevent severe hepatitis is to stop TB medications as soon as the symptoms occur.

Evaluation of drug side effects for inmates receiving treatment for LTBI should be documented using the *Federal Bureau of Prisons Side Effect Interview and Monitoring Form for LTBI* (available in both English and Spanish). The form requires the inmate's signature upon the initiation of treatment. Health care staff should read the form to illiterate inmates. The form should ordinarily be maintained by pharmacy or nursing staff, made available to clinicians for review, and a copy placed in the inmate's medical record at the completion or discontinuation of treatment.

- **Clinician follow-up care:** Routine follow-up clinician evaluations during treatment of LTBI should be scheduled on a case by case basis as determined by the responsible physician. Inmates with baseline elevations of liver transaminases or other complicating medical conditions should be followed closely. CXRs, other than baseline, are not indicated during treatment of LTBI, unless symptoms of TB disease develop during treatment.

- **Interruption or discontinuation of treatment:** Inmates failing to complete a treatment regimen for LTBI on 3 or more occasions should be evaluated on a case by case basis to determine if additional retreatment efforts are clinically prudent based on the inmate's risk factors for TB disease, previous cumulative doses of administered treatment, and anticipated adherence to therapy.

The following practical decision rule should be applied when considering therapy for inmates

who have stopped taking their medications for LTBI or have had therapy interrupted for medical reasons:

- *If 30% or fewer doses have been missed within the intended treatment period, then add doses onto the end of treatment.*

- *If greater than 30% of doses have been missed, then restart therapy.*

In either situation, when therapy is reinstituted after an interruption of more than 2 months, a medical examination to rule out active TB is indicated.

- **Chest radiographs:** Annual chest radiographs are not ordinarily indicated for inmates with a positive TST. Inmates who decline treatment for LTBI, or have treatment discontinued because of drug side effects, nonadherence, or other reasons, should be monitored in accordance with the following:

  - semi-annual CXRs and clinician evaluations for symptoms and signs of pulmonary TB, indefinitely, for inmates with HIV infection (or unknown HIV serostatus) or other immunosuppressive conditions, and

  - semi-annual CXRs and clinician evaluations for symptoms and signs of pulmonary TB for a 2 year period for HIV seronegative inmates who are recent converters or close contacts of active TB cases.

- **Documentation of treatment regimen:** Treatment of LTBI should be documented by the responsible physician and other health care staff as appropriate using the *Federal Bureau of Prisons Treatment Record for Latent Tuberculosis*. The form should be maintained in the inmate's medical record and documentation updated:

  - at the baseline evaluation and initiation of treatment;
  - whenever treatment is interrupted or discontinued; and
  - at the completion of treatment.

Inmates who refuse treatment for LTBI should sign a refusal form in their medical record, documenting their declination of treatment.

5. Diagnosis of Active Tuberculosis Disease

The expedient diagnosis of contagious TB is critical for providing effective treatment and for preventing TB transmission in the correctional setting. Diagnosis of active TB disease is summarized in *Appendix 4 "Components of a Tuberculosis Diagnostic Work Up"* and includes a medical history, physical exam, TST (unless prior positive TST or TB is already culture confirmed), CXR and bacteriology.

Diagnostic Issues

Although many inmates with active TB disease are symptomatic with a positive TST and characteristic abnormal CXRs (upper lobe/cavitary lesions), correctional health care providers

should maintain a high index of diagnostic suspicion for TB and be alerted to the following:

- **A negative TST does not rule out active TB:** The TST is not a sensitive test for detecting TB disease. An estimated 25% of patients with active TB disease will have a negative (0 millimeter) TST, particularly if immunocompromised.

- **Inmates with active TB disease may appear healthy and deny symptoms.**

- **Culture-negative pulmonary TB:** Negative AFB smears and cultures do not rule out a diagnosis of pulmonary TB. Patients with abnormal CXRs and symptoms compatible with TB should be treated presumptively. Individuals on anti-tuberculosis treatment with CXR improvement and negative cultures are considered to have culture-negative TB.

- **Important risk factors for TB are foreign birth**, HIV infection, alcoholism, chronic renal failure, diabetes mellitus, neoplastic diseases, and drug abuse.

- **Extrapulmonary TB** can occur in nearly any organ of the body and should always be considered when an inmate presents with a fever or infection of unknown etiology that does not respond to routine antibiotic therapy. Extrapulmonary TB is usually more difficult to diagnose than pulmonary TB. Presentations may include lymphadenitis (painless swelling of one or more lymph nodes), pleuritis, pericarditis, renal disease (mild dysuria / hematuria / flank pain/ sterile pyuria), skeletal disease (arthritis / bone pain / bone deformities), meningitis, peritonitis, and epididymitis. At any site, evidence of necrotizing or caseating granulomas on pathology report is presumed to be indicative of TB unless proven otherwise. Co-existent pulmonary disease should be ruled out in all cases of extrapulmonary disease.

Medical History and Physical Exam

- **Medical history** should focus on history of TB exposure, prior TST results, prior TB infection or disease. Demographic information should include country of origin, occupation, incarceration history and other factors that might increase the person's risk of TB. Evaluating health care providers should assess medical conditions that increase the risk for developing TB (*Appendix 1*) and assess patients for TB symptoms, such as fever, weight loss, cough for greater than 3 weeks, hemoptysis and chest pain.

- **Physical examination** is not useful for confirming or ruling out a TB diagnosis but can provide valuable information on the extent of TB disease and presence of relevant co-morbid conditions.

Chest Radiograph Manifestations of TB

Below are listed typical radiographic features of pulmonary TB.

- **Location:** apical and/or posterior segment of right upper lobe, apico-posterior segment of

left upper lobe or superior segment of either lobe. (Reactivation pulmonary TB commonly presents with cavitary upper lobe disease.)

Infiltrates: fibronodular, *variable* confluence and cavitation.

Cavities: thick, *nonuniform*, irregular walls; *air fluid levels uncommon.*

- Volume: progressive, often rapid loss of volume with the involved segment(s) or lobe(s).

- Adenopathy: hilar adenopathy common in HIV infected persons and young children.

Sputum Pulmonary TB, however, may exist even when the CXR is completely normal or mildly abnormal, particularly with HIV co-infection. With advanced HIV infection, other atypical presentations of active TB disease are common, including lower lung zone infiltrates without cavities, and intrathoracic lymphadenopathy without pulmonary infiltrates.

Diagnostic Microbiology

- Specimen collection: Self-induced sputum specimens collected from TB suspects should be obtained in a sputum induction booth or in an NPIR by health care pro-vider wearing adequate personal respiratory protection. Patients should be instructed prior to coughing that nasopharyngeal discharge and saliva are not sputum, rather the specimen material sought is brought up from the lungs after a deep productive cough. Where specimens are acceptable, a series of at least 3 specimens should be collected on separate days and transported to the laboratory as soon as possible. A State laboratory or other reliable TB laboratory recommended by the State Health Department should be utilized.

If the patient is unable to produce sputum, sputum induction can be performed utilizing an aerosol of sterile hypertonic saline produced by an ultrasonic nebulizer. Sputum induction should be performed either in an NPIR or in a community-based medical facility where adequate infection control measures can be ensured. If pulmonary TB disease is suspected, but sputum specimens can not be obtained, more invasive diagnostic procedures such as bronchoalveolar washes or transbronchial biopsies should be considered.

- Laboratory Examination:
  - AFB smears can be processed and reported within hours of receiving a sputum specimen and thus provide a rapid diagnostic tool for detecting *M. tuberculosis*. An estimated 50%-80% of persons with pulmonary TB have positive sputum smears, however, *AFB smear* positivity does not confirm the diagnosis of pulmonary TB. Furthermore, AFB smears are not specific for *M. tuberculosis*, since the presence of other nontuberculous mycobacteria can also result in *AFB smear* positive sputums. Negative AFB smears do not rule out active TB disease.

  - AFB cultures: All clinical specimens suspected of containing *M. tuberculosis* should be inoculated onto culture media. Culturing is more sensitive than microscopy. (AFB

smear positivity), allows for the precise identification of the mycobacterial species, and permits drug susceptibility testing and genotyping. Laboratory contamination resulting in false positive *M. tuberculosis* cultures) should be suspected when the specimen is AFB smear negative, has a single positive culture, a low colony count on conventional media and a clinical presentation uncharacteristic of TB.

- Drug susceptibility testing should be performed on all positive cultures for *M. tuberculosis*. The use of broth systems for culturing mycobacteria should be utilized whenever possible, since this method permits more rapid detection of organisms (1-3 weeks) than solid media (4-8 weeks).

- Nucleic acid amplification tests can detect *M. tuberculosis* within hours and are useful for the rapid diagnosis of TB disease in certain clinical situations. Confirmatory bacterial cultures and sensitivities should also be obtained regardless of the results of nucleic acid amplification (NAA) testing. Two licensed tests are available: MTD® and Amplicor®. A positive direct amplified test in conjunction with an AFB positive or negative smear is highly predictive of TB disease. A negative NAA with an AFB *positive smear indicates* that the AFB are probably non-tuberculous mycobacteria. In the absence of clinical symptoms, these results may lend the clinician to discontinue isolation and anti-TB treatment; moreover, there may be no need for a contact investigation. The diagnosis in such a case will depend on the overall clinical picture, clinical judgment, and repeat testing by either NAA or other methods of growth and detection. A negative direct NAA test on an AFB smear negative specimen has no clinical relevance.

DNA Fingerprinting

DNA fingerprinting (genotyping) of the organism is indicated for investigating possible TB outbreaks or laboratory contamination in consultation with state health departments and Central Office HSD.

Reporting Suspected / Confirmed Tuberculosis Cases

Any inmate diagnosed with suspected or confirmed TB who is placed on multi-drug TB treatment should be promptly reported to Regional and Central Office HSD and to the local health department in the jurisdiction where the facility is located. TB suspects should be reported, even if there is no laboratory confirmation of the case.

6. Treatment of Tuberculosis Disease

The goal of TB treatment is to interrupt TB transmission, prevent acquisition of drug resistance and cure the patient. Any deviations to the standard regimen are rarely indicated. Recommended TB treatment regimens and drug doses are outlined in *Appendix 5 (Standard Tuberculosis Treatment Regimen), Appendix 6 (First-Line Tuberculosis Drug Doses), and Appendix 7 (Tuberculosis Treatment Regimens - Special Situations).* The following general principles should be adhered to when treating confirmed or suspected TB patients.

General Principles

- Four-drug initial therapy is routinely recommended for all inmates with a clinical or bacteriologic diagnosis of TB disease. The initial use of 4 drugs is essential to minimize the *development of further drug resistance.*

- Never treat active TB with a single drug.

Never add a single drug to a failing TB *treatment* regimen.

- All TB medications should be administered by directly observed therapy (DOT) to ensure adherence to the prescribed treatment regimen and reduce the emergence of resistant disease. DOT means watching the inmate swallow each dose of TB medication.

Such consultation: A physician consultant with TB treatment expertise and the local or state health department should be consulted for any of the following TB cases:
- culture for sputum cultures to convert to negative following 2 months of therapy.
- *resistance to rifampin* with or without resistance to other drugs, and
- HIV co-infection, drug intolerance, pregnancy, or other situations requiring deviation from a standard treatment regimen.

Standard Tuberculosis Treatment Regimen

Standard TB *treatment* occurs in 2 phases and is outlined in *Appendix 5*

- Initial phase
The initial phase consists of 8 weeks of isoniazid (INH), rifampin (RIF), pyrazinamide (PZA), and ethambutol (EMB) and is administered daily for 2 weeks; then therapy is switched to twice weekly *for an additional 6 weeks.*

- Continuation phase
The continuation phase consists of 18 weeks of INH and RIF administered twice weekly.

Never switch to a 2 drug regimen of isoniazid and rifampin *before* drug sensitivities confirm non-resistant TB.

All TB medications should be prescribed according to the inmate's weight *(Appendix 6)* and adjusted appropriately with weight changes. In certain cases in which MDR-TB is suspected, alternative treatments with 4 or more drugs may be indicated in consultation with a TB expert and the local or state health departments. TB treatment regimens may require adjustments *once drug susceptibility tests become available. Modifications* to the standard treatment regimen are necessary in the special situations outlined below.

Special Situations

- Culture-negative, pulmonary TB: Clinical and/or radiographic improvement following empiric treatment for pulmonary TB with negative cultures is strongly suggestive of culture-negative pulmonary TB. Misdiagnosis should be considered. If the clinical response to treatment is satisfactory, treatment for culture-negative TB can usually be discontinued after a total of 16 weeks. HIV infected persons and those with cavitation should be treated with a *full 6 months* of therapy.

- Extrapulmonary TB: Extrapulmonary TB is generally treated using the same drug regimens as pulmonary TB. Treatment is generally extended for bone and joint disease (6 to 9 months) and TB meningitis (9 to 12 months) with the ultimate duration of treatment determined *on an individual basis based upon clinical response.* Serial bacteriologic evaluations may be limited by disease location; therefore the response to treatment must be judged on the basis of clinical, and where applicable, radiologic findings.

- HIV co-infection: Persons with TB complicated by HIV co-infection usually respond adequately to the standard, recommended 6 month TB treatment regimen. However, drug side effects are more frequent and bacteriologic response may be less satisfied, necessitating careful monitoring and, when necessary, extended treatment.
  - *CD4+ T-cells < 100/mm³*: An alternative, more intensive regimen is sometimes recommended for patients with HIV infection and a low CD4+ T-cell count because persons in this category have experienced higher than expected rates of relapse with standard rifampin resistant TB during treatment. Standard TB drugs should be prescribed (INH, RIF, PZA, EMB for 2 months, followed by INH, RIF for 2 months), but they should be administered either daily or thrice (3x) weekly.

  - Anti-retroviral therapy: Treatment of TB patients with HIV infection already taking antiretroviral medications is particularly complicated and warrants consultation with a HIV/TB expert. In general, HIV co-infected persons who are taking antiretrovirals when diagnosed with TB should continue them. When anti-retrovirals are medically indicated, their initiation generally should be postponed for 2 to 8 months after starting TB treatment due to pill burden and potential side effects. Protease inhibitors and non-nucleoside reverse transcriptase inhibitors interact with drugs (rifampin and rifabutin) potentially affecting drug selection and dosing for both TB and HIV medications. Treatment recommendations for the treatment of HIV co-infected TB patients on anti-retroviral therapy change rapidly. Consult a CDC website with regularly updated information about TB/HIV drug interactions, regimen options, and

dosage adjustments: www.nlm.gov/medlineplus/druginformation.html and www.fda.gov/medwatch/safety/2004/safety04.htm.

- *Immune reconstitution:* TB disease and its associated systemic symptoms may be paradoxically exacerbated when persons with HIV co-infection are simultaneously treated with highly effective antiretroviral regimens, resulting in immune reconstitution with increased T-lymphocytes and enhanced cytotoxic activity against *M. tuberculosis*. If signs of clinical worsening on treatment occur, such findings should be attributed to a paradoxical reaction only after a thorough evaluation has excluded other possible causes. Changes in anti-TB or antiretroviral therapy are rarely necessary in persons with paradoxical reactions.

- Cavitary TB with positive cultures at 2 months: Patients who present with cavitary disease and whose sputum cultures remain positive after 2 months have been demonstrated to have very high rates of relapse; therefore, it is recommended that the continuation phase in such patients be extended by 3 months for a total treatment of 9 months.

- Renal insufficiency and end-stage renal disease: Renal insufficiency complicates the management of TB because some anti-tuberculosis medications are cleared by the kidneys. Management may be further complicated by the removal of some anti-tuberculosis agents on hemodialysis. For patients with a creatinine clearance of < 30 ml/minute or who are on renal dialysis, the alterations in dosing and frequency outlined in *Appendix 6* should be utilized. For patients on hemodialysis, medications should be given 3 times per week after dialysis.

- Drug resistance and intolerance: Consultation from a TB expert should be sought when treating TB complicated by either drug resistance or intolerance. Generally recommended treatment regimens for drug resistance or intolerance are outlined in *Appendix 7*.

Monitoring Treatment

All inmates with active TB disease should be monitored at least monthly by a physician to evaluate the clinical response to therapy and monitor side effects to medications. Baseline laboratory studies, TB medication regimens, and monitoring of adverse reactions should be in accordance with the parameters outlined in *Appendix 8 (Monitoring for Tuberculosis Treatment Response and Adverse Reactions)* and the following guidelines:

- Bacteriologic conversion: Inmates with sputum cultures positive for *M. tuberculosis* should have 3 adequate morning sputum cultures obtained monthly until sputum cultures convert to negative. Inmates who can not voluntarily provide a sputum sample at a BOP facility should have sputum induction performed in an NPR or should be sent to an appropriate community health care facility. A final sputum culture should be obtained at the completion of successful treatment as a reference culture (if the patient can produce a sputum). Sputum cultures positive for *M. tuberculosis* after 2 months of drug treatment may indicate ineffective therapy. Repeat drug sensitivities should be obtained to evaluate for resistant disease. Inmates with TB disease who do not respond to standard drug

therapy by 2 months of treatment may be nonadherent to their medication regimen or may have malabsorption, drug interactions, or other problems resulting in subtherapeutic serum drug levels. Persons with chronic gastrointestinal disease (e.g., Crohn's disease or HIV-related diarrhea) are particularly at risk for drug treatment failure. Serum drug levels should be obtained to document the adequacy of medication delivery for inmates with known malabsorption or who fail to respond to TB treatment.

- Radiographic monitoring: CXRs should be obtained at baseline, at the completion of therapy, and during treatment (when clinically indicated). Patients with suspected pulmonary TB and negative sputum cultures at 2 months should have a repeat CXR at 2 months. CXR improvement on treatment is indicative of culture-negative TB.

- Monitoring for drug-induced hepatitis: Three of the first line TB medications, INH, RIF and PZA can cause drug-induced liver injury. Liver transaminases should be obtained at baseline. Symptom screening for hepatitis (nausea, vomiting, abdominal pain, fatigue) should be reviewed at least monthly and medications generally stopped if they occur.

Monthly monitoring of liver enzymes should be considered for inmates with the following conditions:

- baseline liver transaminases greater than the upper limit of normal;
- chronic liver disease from alcohol, viral hepatitis or other etiologies;
- other potentially hepatotoxic drugs prescribed; and
- pregnancy.

Moderate asymptomatic increases in AST or ALT levels occur in nearly 20% of patients treated with the standard 4-drug regimen and does not indicate hepatic injury. In the absence of symptoms, therapy should NOT be altered because of these modest asymptomatic AST or ALT elevations, but the frequency of clinical and laboratory monitoring should be increased. However, if at any point liver transaminases are greater than 3 times normal (with symptoms) or greater than 5 times normal (without symptoms) hepatotoxic drugs should be stopped immediately and the patient evaluated carefully. Liver function studies should be obtained. Screening tests for HAV, HBV, and HCV infections should be obtained in noninmune patients. Once the liver enzymes return to normal, the person should be rechallenged with TB medications, in consultation with a TB expert.

- Monitoring for other TB drug toxicities: Baseline complete blood count, platelets and uric acid should be obtained in addition to LFTs. Thrombocytopenia is a rare toxicity associated with rifampin. Elevated uric acid can occur with pyrazinamide but rarely necessitates a change in regimen. Visual acuity (Snellen) and red-green color vision (Ishihara) should be assessed at baseline and monthly thereafter for inmates treated with ethambutol due to the risk of optic neuritis. For patients on prolonged treatment with ethambutol, optometry or ophthalmology evaluations are indicated every 3 months. Baseline and monthly creatinine and audiograms are indicated for inmates receiving streptomycin or other aminoglycosides due to the risk of nephrotoxicity and ototoxicity.

7. Contact Investigations

The goal of a TB contact investigation is both to identify other active cases of TB (cases) and to identify and completely treat individuals with new latent TB infection, particularly those at high risk for developing disease. The identification of a potentially infectious TB case in a correctional facility should always provoke a rapid response because of the potential for widespread TB transmission. Numerous outbreaks of TB have been reported in prisons and jails, especially among HIV infected inmates. A prompt public health response can prevent a TB outbreak.

The decisions involved in planning and prioritizing contact investigations in correctional facilities are seldom clear-cut and benefit from multi-disciplinary, team input. Shortly after the case is diagnosed, the Clinical Director and Health Services Administrator should convene a team of professionals who will plan the contact investigation. Ideally the team should include infection control staff, medical, nursing and custody. Contact investigations should also involve Regional and Central Office HSD staff. Generally, the local health department should also be consulted while conducting contact investigations in accordance with pre-established bilateral arrangements.

Transmission Factors

The following characteristics of the index case, contacts and exposure influence the likelihood that TB transmission will occur.

- Index case characteristics: When an index case has either cavitation on CXR or AFB smear positive respiratory specimens there is a much higher risk of TB transmission than if neither of those characteristics are present.

- Contact characteristics:
  - Immunosuppression: HIV infection is the greatest single risk factor for progression to TB disease in infected persons. Therefore, HIV infected contacts should receive the highest priority for evaluation even if they had shorter duration of exposure than other contacts. Persons receiving prolonged therapy with corticosteroids or other immunosuppressive agents should also be considered high priority for investigation.

  - Age: Young children (age < 4) are at high risk for development of active TB disease and should be evaluated promptly. When an inmate identifies a young child (age < 4) as a community contact, a health department referral should be made immediately.

- Characteristics of the exposure:
  - Air volume: The volume of air shared between an infectious TB patient and susceptible contacts is an important determinant in the risk of TB transmission. The larger the air space, the more infectious particles are distributed and the less likely they are of being inhaled.

  - Ventilation: Ventilation is an important factor in the risk of airborne transmission of disease. Exposures in confined air systems with little or no ventilation have been associated with increased TB transmission. The space where airborne infection spreads includes all space sharing the same air. Thus if air circulates from the room occupied by an infectious patient and other rooms, these occupants will also be exposed.

  - Duration of exposure: Even though transmission of TB can occur following a brief exposure, the likelihood of infection following exposure to an infectious patient is related to the frequency and duration of exposure. However, it is exceedingly difficult to know what constitutes a significant duration of exposure for any given contact in any given environment. Priority should be given first to inmates and employees who sustained the most exposure to the index case.

Decision to Initiate a Contact Investigation

The decision to initiate a contact investigation should be based upon the characteristics of the presenting case of TB. Contact investigations should be conducted in the following circumstances:

- Suspected or confirmed pulmonary, laryngeal or pleural TB; and
  - Cavitary disease on CXR or
  - Positive AFB smears (sputum or other respiratory specimens)
  Note: If the sputum smear is positive and a nucleic acid amplification test is negative then TB is unlikely and a contact investigation may not be necessary.

- Suspected or confirmed pulmonary (non-cavitary) or pleural TB and
  - Negative AFB smears (sputum or other respiratory specimens)
  A more limited investigation should be conducted for smear negative cases.

Contact investigations are generally not indicated for extrapulmonary TB cases (except for laryngeal and pleural) without pulmonary involvement.

Note: In some patients with pulmonary TB, it may not be possible to collect sputum samples, and other types of respiratory specimens (e.g., those from bronchoscopy) may be collected. In this situation, AFB smear and mycobacterial culture results from the bronchoscopy or other respiratory specimen should be used as a surrogate for sputum in determining the need for and priority of the contact investigation. However, if the patient can produce sputum, it should always be collected and the result used to guide the investigation.

Prioritizing and Structuring the Contact Investigation

Unfortunately, there is no simple formula for deciding which contacts to screen in a correctional facility contact investigation. However, there are several basic principles around which the contact investigation team should make decisions about structuring the investigation.

- **Promptly screen and initiate treatment for LTBI for all contacts with HIV infection** *(regardless of duration/intensity of exposure).*

Screen an identified group of contacts who are at highest risk for infection (i.e., greatest duration of exposure or concentrated exposure in a confined space).

- **Calculate the infection rate.**

- **Decide about how to structure investigation based upon the infection rate.**

If there is no evidence of transmission, then the investigation should generally stop. If there is evidence of transmission, the investigation generally is expanded incrementally to groups with less exposure until there is a group screened with minimal or no evidence of transmission.

Ideally, decisions about structuring the contact investigation should be made cooperately with the contact investigation team, seeking expert opinion from the state or local health department, as needed. Sometimes it is necessary to screen a convenience sample first. For example, in jail investigations, many contacts may have been already released and the only accessible contacts available to screen are those who remain incarcerated. If a significant number of high priority contacts can not be fully evaluated, then a wider contact investigation may be indicated.

Focus should be placed on identifying the highest risk contacts, completely screening them and providing a full course of treatment of LTBI for those who are infected. In general, avoid mass screening of all those who had any contact with the index case. Such wide-scale investigations divert attention away from the high priority activities necessary to interrupt TB transmission *in the facility, i.e., complete screening and appropriate treatment of the contacts* who are most likely to have become infected. Very rarely is an index case so infectious that wide-scale expansion of the contact investigation is necessary.

Medical Evaluation of Contacts

The medical evaluation required depends upon both the HIV status of the contact and prior TST results.

- **All contacts** should be personally interviewed for symptoms of active TB and HIV testing encouraged (if status unknown). Symptomatic inmates should receive a CXR and complete medical evaluation by a physician regardless of TST status and should be isolated in an NPIR if contagious TB is suspected by CXR or clinical findings. All other asymptomatic inmate contacts do not require isolation. HIV testing should be recommended for all inmate contacts with unknown HIV status.

- **Prior TST positive inmates** *(who are HIV seronegative or unknown): Asymptomatic, HIV seronegative, prior TST positive inmates need no further follow-up.* If HIV status is unknown, inmates should be tested for HIV infection

- **HIV seropositive inmates:** HIV seropositive contacts should be carefully interviewed for symptoms, have a CXR performed, and **initiate a complete course of treatment for LTBI** *(once active TB has been ruled out).* Treatment should be initiated even for those with a history of prior treatment for LTBI or active disease because of the possibility of re-infection. Those with a history of a negative TST should have a TST placed at baseline and again in 8 to 10 weeks. The results of the TST will not effect treatment decisions, but provide important information for the whole contact investigation.

- **Prior TST negative inmates** *(HIV seronegative).* Mandatory tuberculin skin testing of all previously TST negative inmate contacts should be conducted at baseline (unless previously tested within 1 to 3 months of exposure) and repeated 8 to 10 weeks from the last contact with the source case. TST converters (TST ≥ 5 mm) should be prescribed treatment for LTBI unless medically contraindicated. If inmate contacts refuse medically indicated isoniazid prophylaxis they should be monitored by CXRs every 6 months for 2 years if HIV seronegative; and every 6 months indefinitely if HIV seropositive.

Contact Investigation Stepwise Procedures

See Appendix 10 (Tuberculosis Contact Investigation Checklist)

- **(1) Notify correctional management officials:** Identification of a TB case in a correctional setting can be alarming for inmates, correctional staff, and the community. Promptly notify the Warden, through appropriate chains of command, that a TB case has been identified in the institution so that briefing and educational efforts can begin. Subsequently notify Regional and Central Office HSD staff.

- **(2) Clinical assessment of case:** *A clinical assessment of the case and case interview* should be accomplished within one working day for inmates with AFB smear positive respiratory specimens or cavitary CXRs and within 3 days for all others. The assessment should include a medical evaluation and retrospective chart review to help establish duration of symptoms. The following available data should be collected: history of previous exposure to TB, onset and history of TB symptoms (cough, fever, night sweats, weight history, i.e., documented weight loss), CXR reports, prior TST results, bacteriology results (AFB smears, cultures, susceptibilities), nucleic acid amplification tests, HIV status, and other medical risk factors *(Appendix 1)*

- **(3) Case interview:** The case should be interviewed as soon as possible, probing about TB symptom history with a particular focus on duration of cough. Prompt with questions associating cough with particular holidays and events. Also interview the patient for common places of daily activity, and to identify direct contacts to the index case particularly those who were not merely within the housing unit. Those who were incarcerated during the infectious period should be interviewed for community contacts. The inmate should be specifically questioned about contact with individuals with HIV infection or young children (age ≤ 4). Obtain locating information for community contacts. The case should be re-interviewed for contacts within 7 to 14 days.

- **(4) Determine the infectious period:** The infectious period is determined to identify how far back in time to go for investigating contacts. The infectious period should be determined as follows:
  - **Generally:** onset of cough or 12 weeks prior to TB diagnosis (whichever is longer).
  - **Exception:** 4 weeks prior to date of suspected TB diagnosis if no TB symptoms and AFB smear negative and non-cavitary CXR.

- **(5) Convene a contact investigation team:** Clearly identify a team leader, the roles and responsibilities of each team member, and establish a schedule of regular meetings with written minutes. Develop a communication plan and a plan for handling contact investigation data.

- **(6) Update correctional management officials**, including the Warden, Regional staff, and Central Office HSD staff, regarding the strategy for beginning the contact investigation.

- **(7) Obtain index case inmate traffic history:** Obtain the dates and locations of where the TB case was housed during the infectious period. Also obtain work and education assignment history.

- **(8) Tour exposure sites:** *A tour should be conducted of each place the suspect TB case was housed and worked during the infectious period. The assistance of a facility engineer is often necessary to help characterize the ventilation system.* The following information should be collected for each site: the number of inmates who are housed together at one time, the housing arrangement (e.g., cells vs. dorms), the general size of the air space, the basics of the ventilation system (recirculated air?), the pattern of daily inmate movement (eating, working, recreating), and the availability of data on other inmates housed at the same time as the index case.

- **(9) Prioritize contacts:** Group contacts based upon their duration/intensity of exposure. Those with the most exposure and those who are HIV infected or immunosuppressed *(regardless of duration of exposure)* are considered highest priority.

- **(10) Develop contact lists:** Obtain rosters of inmate and employee contacts from each location and research their current location. Generate lists of exposed contacts grouped by their current location, i.e., remaining incarcerated, transferred, released

- **(11) Conduct a medical record review on each high priority contact:** Record TST history, CXR history, history of treatment for latent TB infection, HIV status and other high risk medical conditions, reported respiratory symptoms and country of origin.

- **(12) Initiate medical evaluation of contacts** by first evaluating contacts with HIV infection. Both inmates and employees who are considered high priority contacts should be evaluated per guidelines for medical evaluation of contacts (above).

- **(13) Referral for contact evaluation** should be made to the local health department for inmate contacts who have been released or transferred to another facility.

- **(14) Determine the infection rate by exposure site:** *The infection rate is calculated by* dividing the number of inmates with TST conversions by the total number of skin tested inmates. If the initial contact investigation indicates that significant transmission of TB infection has occurred to other inmates or correctional staff, the contact investigation should be expanded to contacts with less exposure to the index case. The decision about whether or not to expand the investigation should be guided by the contact investigation team, in consultation with state or local health department investigators and the Central Office HSD

- **(15) Follow-up TSTs** *should be done at least 8 weeks after exposure to the index case* ended. A record search should be done to determine current location of inmate contacts, testing conducted for inmates and employees, and referrals made for those in need of a follow-up TST who have been either released or transferred.

- **(16) Determine the infection rate** from the second round of testing and if there is need to expand the investigation

- **(17) Write a summary report:** Briefly summarize the circumstances of the investigation, what occurred and the results of the investigation including associated cases and infection rates and forward through your Warden to the Regional and Central Offices HSD.

8. Infection Control Measures

Early Detection

The most important measure to prevent TB transmission in a correctional facility is to maintain a high index of suspicion for TB. Early identification and isolation of TB cases is critical to prevent further TB transmission. *Most TB outbreaks reported from correctional facilities have* involved a highly infectious case who remained undetected for a prolonged period.

All inmates should be screened for TB symptoms at intake. They should be counseled during orientation to the institution, and when appropriate during clinical evaluations, to recognize and promptly report symptoms of TB disease, and to participate in baseline and annual skin testing to screen for TB infection. Inmates should be advised of the importance of completing treatment for either TB disease or LTBI if diagnosed. Inmates should be counseled that certain risks and conditions such as HIV infection, diabetes, chronic renal failure, injection drug use history, and close contact with someone who is sick with infectious TB, all pose a greater risk for getting TB disease.

Isolation

- **Initiation:** Inmates with suspected TB should be promptly isolated in an NPIR. Inmates with suspected or confirmed active TB disease should be managed while incarcerated in accordance with BOP policy. If AFB smears are negative, but TB is suspected based on the clinical presentation and CXR findings, the inmate should be housed in an NPIR during initial

diagnosis and treatment. The inmate should be instructed to cover his or her mouth when coughing or sneezing.

- Respiratory protection: Inmates should be managed using airborne precautions and personal respiratory protection designed to prevent transmission of *M. tuberculosis*. All persons entering an NPIR or transporting an infectious patient in a closed space should wear appropriate respiratory protection, in accordance with BOP policy and OSHA recommendations. The minimal acceptable form of respiratory protection to protect against transmission is an N-95 respirator.

- Maintenance of negative pressure isolation rooms: Inmates should be managed in an NPIR in accordance with BOP policy and current CDC recommendations on ventilation and air change rates per hour for TB isolation. The CDC recommends that verification of negative pressure of the NPIR be checked and recorded daily *while isolation of a suspected or confirmed TB case is in effect*. Monthly verification of negative pressure should occur at all other times. Traffic control and measures to contain airflow within the NPIR room such as keeping all doors closed except for entering and exiting should be maintained. The same routine daily cleaning procedures used in other rooms in the facility should be used to clean TB isolation rooms. If a detergent germicide is used for routine cleaning, a hospital grade, EPA approved germicide/disinfectant that is not tuberculocidal can be used.

Transport

During transport, a potentially infectious inmate should be instructed to wear a surgical mask (without an exhalation valve). Movement of the inmate should be limited to those situations where movement is required for medical or security purposes. If the TB suspect is in a confined space, e.g., emergency vehicle, others in the vehicle should wear respiratory protection.

Discontinuation of Isolation

Inmates with contagious TB disease should be assigned to an NPIR room until no longer infectious. Isolation is ordinarily maintained until all 3 of the following parameters are achieved:

- treatment with a 4 drug regimen per treatment guidelines or other equally effective regimen has been administered for at least 2 weeks by DOT, and

the inmate shows clinical evidence of improvement; and

- three consecutive sputum smears are negative (at least 8 hours apart including one early morning specimen).

- Special Situations:
  - AFB smear negative TB suspects: If sputum smears are all initially negative without

secretary disease and the inmate is clinically improving, isolation in an NPIR room can be discontinued after 7 days of TB treatment on a case by case basis, in consultation with the Medical Director.

- Suspected or confirmed drug resistance: If drug resistance is suspected, isolation should be continued until drug sensitivities are documented, appropriate treatment has been initiated (based upon the pattern of drug resistance identified), the patient has had 3 negative AFB smears, and there is evidence of clinical improvement. It may take several weeks to obtain drug sensitivities. If multi-drug resistance is identified (defined as resistance to at least isoniazid and rifampin) then isolation should be continued until reports of 3 negative cultures are obtained.

- TB suspects discharged from a community hospital: When TB suspects have been isolated in a community hospital and are being discharged back to a correctional facility, they should not be accepted back into general population until they meet all 3 of the standard criteria for discontinuing isolation: 3 negative AFB smears, on an appropriate treatment regimen for at least 2 weeks and evidence of clinical improvement. If the patient is initially AFB smear negative and TB is suspected, on a case by case basis, the inmate can be accepted back into general population after 7 days of TB treatment.

- Engineering controls following discharge of a patient from an NPIR: The room *should be appropriately purged of airborne contaminants* before the room is used to house another inmate or is occupied without the use of protective respiratory protection. Clearance times should be based on CDC guidelines on "Air changes per hour and time in minutes required for removal efficiencies of airborne contaminants." *MMWR*, Vol. 43, RR-13, table 53-1, page 72, (i.e., if an isolation NPIR has been determined to provide 12 air changes per hour, it will take approximately 35 minutes to remove air contaminants to achieve the 99 removal efficiency rate of 99.9% and prevent transmission to others).

9. Discharge Planning

Inmates receiving treatment for LTBI or TB disease should have their treatment plan coordinated with community providers by the time of release to help ensure continuity of care and maintain public health. All inmates with active TB disease should have a specific plan for continuing treatment with the receiving state health department and local community public health providers. Specific referrals for community-based treatment of LTBI should be coordinated and secured when feasible. The treating physician and other health care providers can improve continuity of care for inmates upon release by initiating the following:

- coordinating release planning with case managers and community corrections staff in accordance with BOP policy;

- providing counseling to ensure the inmate understands importance of adherence to treatment and specific instructions for seeking care upon release;

- securing consent for release of medical information in accordance with BOP policy; and

- supplying TB medications in accordance with BOP policy.

Appendix J1 (Tuberculosis Pre-Release Checklist) specifies the steps involved in ensuring continuity of care. Utilize the National TB Controller Association *"Interjurisdictional Tuberculosis Notification"* form (found at www.naca-tb.org) for referring those on treatment for active disease or LTBI or contacts in need of following. State health departments will channel TB referrals to the appropriate local health departments. Links to all the state health departments can be found at the CDC website:
http://www.cdc.gov/nchstp/tb/pubs/tbcontrol.htm.

The BOP facility should *notify* the health department if the inmate is an Immigration and Customs Enforcement (ICE) detainer, and include the date the detainee will be transferred to ICE, Alien (A) number, country of origin and contact information (address, telephone, relative, etc.).

For inmates who are foreign nationals, CURE-TB and TBNet are U.S.-based referral programs that assist mobile patients to access and complete TB treatment. CURE-TB, operated by the San Diego County Health and Human Services Agency's TB Control Program, focuses on patients crossing the U.S.-Mexico border. TBNet, operated by the nonprofit Migrant Clinicians Network in Austin, Texas, specializes in migrant populations in the United States, including parolees. The programs are working together and with INS to assist detainees in continuing TB treatment on release from custody. These referral programs can be accessed as follows:

CURE-TB: www2.sdcounty.ca.gov/hhsa/announcements/CURETBbrochure.pdf
TBNet: www.migrantclinician.org/network/tbnet

10. TB Program Management

The Clinical Director and Health Services Administrator should work collaboratively to ensure that BOP TB policy and these Management of Tuberculosis Clinical Practice Guidelines are fully implemented. Particular attention should be focused on ensuring the following:

- TB symptom screening at intake is occurring according to BOP policy;

- TB suspects are contained and evaluated for contagious TB;

- All inmates with TB disease are treated in accordance with recommended guidelines;

- Contacts to TB cases receive appropriate evaluation and follow-up;

- Annual tuberculin skin testing of inmates is timely and data are evaluated to detect *unrecognized transmission of M. tuberculosis*;

- Inmates are treated for LTBI in accordance with recommended guidelines; and

- TB case reports and referrals are made to health authorities as appropriate.

Strategic measures should be monitored in order to assess the *effectiveness of the TB program*, such as the following:

- TST Conversion Rate:
  Number of inmates or staff TST converters identified through annual tuberculin skin testing over defined time period.

  ÷ (divided by)

  Number of inmates or staff tuberculin tested during the same time period

- Completion of Isoniazid (INH) Therapy:
  Number of inmates completing bi-weekly isoniazid therapy for LTBI during this reporting quarter. (Completion criteria for bi-weekly isoniazid therapy include the following: at least 52 doses if HIV seronegative or 78 doses if HIV seropositive.)

  ÷ (divided by)

  Number of inmates previously started on treatment for LTBI who should have completed treatment during this reporting period.

Definitions

Acid-fast bacilli (AFB) are bacteria that retain certain dyes after being washed in an acid solution. Most acid-fast bacilli are *mycobacteria*. When AFB are seen on a stained smear of sputum or other clinical specimen, a diagnosis of TB should be suggested, however, the diagnosis of TB is not confirmed until a culture is grown and identified as *M. tuberculosis*.

Airborne exposure is the condition of being subjected to an infectious agent that could have a harmful effect in airborne transmission events. A person exposed to *M. tuberculosis* does not necessarily become infected.

Airborne precautions are protective measures used in patient rooms and situations to prevent the spread of infections that can be transmitted by aerosols created with infectious agents that remain suspended in the air when indoors over a period of time. Precautions include the wearing of appropriate personal respiratory protection (i.e., high efficiency particulate air (HEPA) or N-95 respirators) for persons who come in direct contact with infectious aerosols, the isolation of infectious patients/inmates in a private room with monitored, negative air pressure, and the implementation of necessary engineering controls in rooms, duct, and perimeter portals entering the isolation rooms.

Anergy is the inability of a person to react to skin test antigens even if the person is infected with the organisms tested because of immunosuppression.

BCG is Bacillus Calmette-Guerin vaccinations used in many parts of the world to prevent development of TB disease.

Booster phenomenon occurs when persons (especially older adults) many years after initial infection with *M. tuberculosis* have a negative reaction to an initial skin test, followed by a positive reaction to a subsequent skin test. The second positive reaction is caused by a boosted immune response, indicating latent TB infection.

Clearance time is the time between the discharge of an inmate isolated for TB precautions in a negative pressure isolation room and the arrival of another inmate or other personnel who will occupy the room without the use of airborne precautions.

Clinician is a physician or mid-level provider.

Contact is a person who has shared the same air with a person who has infectious TB for a sufficient amount of time to allow possible transmission of *M. tuberculosis*.

Culture is the process of growing bacteria in the laboratory so that organisms can be identified.

Delayed-type hypersensitivity (DTH) reaction is a cellular immunologic response caused by lymphokines released from T cells that have been sensitized by prior infection with a specific antigen.

Directly observed therapy (DOT) of latent TB infection (LTBI) and TB disease is the unit dose administration of TB medications to an inmate by a clinician, nurse, pharmacist, or specially trained staff, under direct observation of ingestion of each dose.

Drug susceptibility tests are the laboratory tests that determine whether the TB bacteria *cultured from a patient are susceptible or resistant to various anti-tuberculosis drugs.*

Index case is the initial person who has suspected or confirmed infectious TB who may have been in contact with other persons while sharing the same air space for a sufficient amount of time to allow possible transmission of *M. tuberculosis*.

Intradermal is within the layers of skin.

Latent tuberculosis infection (LTBI) is a condition in which a relatively small number of living tubercle bacilli (*M. tuberculosis*) are present in the body but are not multiplying or causing clinically active disease. Although persons with LTBI usually have positive tuberculin tests, they have no symptoms or other objective evidence of TB disease and are not infectious to others. Persons with LTBI, however, have a lifelong risk for developing active TB disease.

Mantoux method is the most reliable method of TST, involving the intradermal injection of PPD-tuberculin into the forearm with a needle and syringe.

Multi-drug resistant TB (MDR-TB) is active TB caused by *M. tuberculosis* organisms that are resistant to more than 1 anti-tuberculosis drug; in practice, often refers to organisms that are resistant to both isoniazid and rifampin with or without resistance to other drugs.

Mycobacterium tuberculosis (*M. tuberculosis*) is the mycobacterial species that is the primary cause of active TB disease in the United States.

Negative pressure isolation room (NPIR) is a room designed for the isolation of persons with contagious TB disease that has adequate directional airflow, air exchanges, and exhaust that reduce transmission of *M. tuberculosis*, in accordance with Centers for Disease Control and Prevention guidelines.

Personal respiratory protection is the use of respirators to protect a person from the transmission of airborne infectious agents. Particulate respirators indicated for protection against *M. tuberculosis* are selected and worn based on recommendations from the Centers for Disease Control and Prevention and certification criteria from the National Institute for Occupational Safety and Health (NIOSH).

Positive (TST) is the induration measured in millimeters that develops after the intradermal injection of PPD-tuberculin, indicative of previous infection with *M. tuberculosis*. The extent of induration that determines a positive test depends on the medical history and risk factors of the person being tested in accordance with the following BOP policy:

- ≥ 5 millimeters = positive for:
  - Close contact to an active TB case
  - HIV co-infection, HIV risk factors and unknown HIV status
  - Other immunocompromised condition
    Systemic corticosteroids equal to prednisone 15 mg for 1 month or more)
  - History of organ transplantation or other immunosuppressive therapy
  - Fibrotic changes on chest radiograph suggestive of inactive pulmonary TB
  - Radiographic or clinical findings suggesting active TB
  - Persons taking anti-TNF alpha drugs (e.g., infliximab)

- ≥ 10 millimeters = positive for all other inmates and correctional staff

Purified protein derivative (PPD) tuberculin is the most common agent used for tuberculin skin testing to evaluate the *likelihood that a person is infected with M. tuberculosis.*

Recent conversion is an individual who has a negative tuberculin skin-test reaction that increases in reaction size by ≥ 10 millimeters (mm) within a period of 2 years, which is suggestive of recent infection with *M. tuberculosis*.

Smear (AFB smear) is the laboratory technique for visualizing mycobacteria. The specimen is smeared onto a slide and stained, then examined using a microscope. A large number of mycobacteria seen on an AFB smear from a person with TB usually indicates infectiousness. However, a positive smear is not diagnostic of TB, because acid-fast organisms other than *M. tuberculosis* may be seen on an AFB smear.

Surgical mask is a disposable paper-type mask used to prevent respiratory secretions from the person wearing the mask from entering into the air. Surgical masks should be worn by visitors or suspected infectious TB patients during transport.

Tuberculosis disease is a clinically active disease caused by organisms of the Mycobacterium tuberculosis complex, which are sometimes referred to as tubercle bacilli. Symptoms of TB disease depend on the site of active disease. Pulmonary TB, *the most common form of TB*, is characterized by chronic cough, hemoptysis, and chest pain. General symptoms of TB include fever, chills, night sweats, malaise, loss of appetite, and weight loss.

Two-step testing is baseline tuberculin testing that, if negative, is repeated to reduce the future likelihood of misranking a boosted reaction for a new infection with *M. tuberculosis*. If the initial baseline tuberculin skin test result is classified as negative, a second test is repeated 1 to 3 weeks later. If the reaction to the second test is positive, it represents a boosted reaction indicating old latent TB infection. If the second test result is also negative, the person is classified as not infected with *M. tuberculosis*.

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Appendix B: TB Risk Factors

Risk Factors for TB Infection:	Risk Factors for TB Disease (if infected)
• Close contacts to infectious TB cases	• HIV infected persons
• Injection drug user	• *TST conversion / recently infected*
• Residents/Employees of:	• Fibrotic changes on chest x-ray consistent with old-healed TB
- prisons and jails - long term care facilities - hospitals and long term care facilities - homeless shelters	• Injection drug users
• Mycobacteriology laboratory personnel	• Certain clinical conditions:
• Children exposed to high risk adults	- organ transplant recipient - immunosuppressant therapy (equivalent to ≥ 15 mg prednisone/day for ≥ 1 month) - anti-TNF alpha therapy (e.g., infliximab) - silicosis - diabetes mellitus - chronic renal failure - leukemia / lymphomas - carcinomas of head, neck, lung - underweight (> 10% under ideal weight) - gastrectomy / jejuno-ileal bypass

Appendix C: Tuberculin Skin Test (TST) Criteria

Screening Criteria	TST negative reasons: - upon interpretation (can indicate result from local jails*) - annually - when TB is suspected - as part of TB contact investigation	
Prior TST Positives	Self-reported "previously positive" skin test reactions or multipuncture readings are not a contraindication to repeat testing unless history of a severe reaction or definite history of treatment for latent TB infection. If documented history of positive TST, do not repeat.	
Placement	- Specific training for placing and reading tests should be obtained. - Only BCG formulary tuberculin should be used. Keep refrigerated. Store in dark. - Skin tests should be administered as soon as possible once syringe is filled. - 0.1 ml (5 TU) tuberculin injected intradermally in volar or dorsal surface of forearm - Tense white wheal (≥ 5 mm) should appear. If not repeat at least 2 inches away.	
Reading	- 48 to 72 hours after placement - read palpated induration (not redness) - measure transversely to the long axis of the forearm - for an induration record "0 mm"	
TST Cut-Points	5 mm	- Close contact to an active TB case - HIV co-infection (HIV risk factors and unknown status or other immunocompromised condition) - Systemic corticosteroids, treatment for organ transplantation, or other immunosuppressive therapy (equivalent to ≥15 mg prednisone per day for greater than 1 month) - Fibrotic chest radiograph changes suggestive of inactive TB - Clinical or radiographic findings suggestive of active TB - Anti-TNF alpha drugs (e.g., infliximab)
	10 mm	all other persons
Two - Step Testing	Consider for newly employed persons at risk for boosting (age > 50, foreign-born, BCG history) who have not had a TST in last year. Procedure: Test as usual. If negative, repeat in 1 to 3 weeks. Positive second test considered "boosted" (or baseline positive), not a TST conversion.	
BCG	Vaccine used in many countries to prevent severe TB disease in young children. Not a contraindication for TST. Ignore history of BCG when interpreting TST results.	
Pregnancy	Not a contraindication for tuberculin skin testing.	

* Consider repeating if inmate has come from jurisdictions with higher TB rates.

Appendix D: Treatment Regimens for Patients with Tuberculosis Infection

Regimen	Dosing	Comments / Side Effects	Monitoring (INH/RIF)
Isoniazid (INH) 6 to 9 months 9 months for HIV seropositive and preferred for all others	Twice Weekly 15 mg/kg (max. 900 mg) 6 mos: 52 doses 9 mos: 78 doses Daily 5 mg/kg (max. 300 mg) 6 mos: 180 doses 9 mos: 270 doses	**Comments:** Offer 6 months if 9 months not feasible. If 6 months not feasible, consider alternative regimen. - *Give pyridoxine (B6) 50 mg* per dose of INH to prevent INH-associated peripheral neuropathy (may increase if neuropathy occurs). **Side Effects:** - anorexia - nausea / vomiting - *dark urine* - icterus - rash - paresthesias (hands or feet) - fatigue/weakness > 3 days	**Baseline:** CXR to rule out active TB if CXR suggestive of old healed TB, should obtain 3 consecutive sputums (if possible). Obtain baseline hepatic enzymes (ALT and AST). Bilirubin - LFTs if baseline hepatic enzymes elevated. - HIV testing is routine for TST positive inmates. **Ongoing:** Monitor for signs and symptoms of drug side effects routinely.
Rifampin (RTF) 4 months 6 months for HIV seropositive	Daily only 10 mg/kg (max. 600 mg) 4 mos: 120 doses	**Comments:** Efficacy data are not as strong as for isoniazid and therefore isoniazid is preferred. Rifampin has numerous drug interactions including with anti-retroviral drugs and coumadin and often reduces the effectiveness of other drugs. **Side Effects:** - hepatitis - fever - thrombocytopenia - GI upset - colors body fluids orange; stains contact lenses.	Monitoring ALT/AST not routinely necessary, but inclicated periodically if: - baseline LFTs significantly increased - chronic liver disease - pregnancy - taking other hepatotoxic drugs

Clinical Notes:
- ALWAYS rule out active TB prior to starting treatment for LTBI.
- *To prevent severe hepatitis, STOP the medications immediately if hepatitis symptoms occur. Monitor for side effects monthly. Instruct inmates to report any of the following signs to treating provider: anorexia, nausea, vomiting, GI upset, dark urine.*
- Consult a TB expert for treatment of contacts to multi-drug resistant TB.
- Refer to clinical guidelines: "Indications for LTBI treatment" and "Special Considerations" referral to Old TB, HIV Co-infection, And Pregnancy.
- Non-compliance in therapy:
  If < 50% of doses missed, continue therapy. If ≥ 50% of doses missed, restart therapy.

Appendix 2 — Components of a Tuberculosis Diagnostic Work-Up

Medical History	TB history: history of TB exposure, prior tuberculin skin tests, prior TB infection or disease, risk factors for drug resistant TB (history of *incomplete treatment*, foreign birth, incarceration) Demographics: country of origin, occupation, incarceration history and other factors which might increase the person's risk of TB Medical conditions: conditions which increase risk for developing TB if infected (*Appendix B*) or may affect ability to tolerate TB treatment. TB symptom history: fever, weight loss, cough > 3 weeks duration, hemoptysis, chest pain.
Physical Exam	Cannot be used to confirm or rule out a TB diagnosis, but can provide valuable information about the person's overall health status
Tuberculin Skin Test	Tests can be negative in the presence of active disease or HIV infection. TST not needed if disease already confirmed with a positive culture.
Chest Radiograph	Posterior/anterior view initially; others as appropriate.
HIV	Test for HIV infection *and if infected*, obtain *CD4 + T-cell count* and viral load.
Bacteriology	AFB smear: indicates mycobacteria (may or may not be TB) AFB culture: indicates mycobacterial growth (*may or may not be TB*) MTB culture: indicates growth of *M.tuberculosis* MTB complex: indicates 1 of 4 mycobacterial organisms including TB (presume TB) Susceptibility Testing: should be done on all positive MTB cultures Nucleic Acid Amplification: AFB smear positive or negative AND NAA positive: presume TB AFB smear positive and NAA negative: generally presume TB is ruled out AFB smear negative and NAA negative: result not clinically relevant Always confirm with culture. DNA fingerprinting (genotyping): useful in suspected outbreaks to help determine if TB cases are related. Contact local health department.
Histology	Pathology reports indicating caseating or necrotizing granuloma are presumed to be *TB until proven otherwise*.

Appendix 5 — Standard Tuberculosis Treatment Regimen - 6 months

Initial Phase - 2 months	Continuation Phase - 4 months
Drugs: INH, RIF, PZA, EMB	Drugs: INH, RIF
2 weeks daily then 6 weeks twice weekly (14 doses)	18 weeks twice weekly (36 doses)

INH = isoniazid, RIF = rifampin, PZA = pyrazinamide, EMB = ethambutol

Clinical Notes:

- Do not await confirmation of TB diagnosis to start treatment.
- Report suspected or confirmed cases to local health department
- Ingestion of all drug doses should be directly observed by a health care worker.
- Pyridoxine (B_6) 50 mg should be administered with each dose of TB medication to prevent INH-associated peripheral neuropathy.
- Ethambutol can be discontinued once susceptibilities to INH, RIF and PZA are known.
- Do not switch to 2 drugs until susceptibilities to both INH and RIF has been demonstrated (culture positive cases only).
- Drugs prescribed twice weekly should be administered 2 to 5 days apart.
- See *Appendix 8* for recommended baseline and monthly medical monitoring.
- Immediately begin discharge planning, particularly if release is anticipated during treatment.

* Refer to *Appendix 7* for the following exceptions to the standard regimen:
- culture-negative TB
- HIV infection
- pregnancy
- drug resistance
- failure to convert sputum cultures in 2 months
- bone/joint TB
- TB meningitis

Appendix 6 — Daily & Intermittent Dosing Guidelines for Adults

Drug	Daily	Twice (2x) Weekly	Thrice (3x) Weekly
Isoniazid	5 mg/kg (300 mg)	15 mg/kg (900 mg)	15 mg/kg (900 mg)
Rifampin	10 mg/kg (600 mg)	10 mg/kg (600 mg)	10 mg/kg (600 mg)
Rifabutin	5 mg/kg (300 mg)	5 mg/kg (300 mg)	5 mg/kg (300 mg)
Pyrazinamide	15-30 mg/kg (2000 mg)	50-70 mg/kg (4000 mg)	50-70 mg/kg (3000 mg)
Ethambutol	15-25 mg/kg (1600 mg)	50 mg/kg (4000 mg)	25-30 mg/kg (2400 mg)

Renal Insufficiency (creatinine clearance < 30 ml / min.)[1]

Isoniazid	5 mg/kg (300 mg)	***	15 mg/kg (900 mg)
Rifampin	10 mg/kg (600 mg)	***	10 mg/kg (600 mg)
Pyrazinamide	***	***	25-35 mg/kg (3000 mg)
Ethambutol[2]	***	***	15-25 mg/kg (1600 mg)

INH = isoniazid, RIF = rifampin, PZA = pyrazinamide, EMB = ethambutol, RBT = rifabutin
*** = Do not use

[1] Dosing for PZA and RNB based upon 1994 Centers for Disease Control recommendations (CDC/ATS/IDSA: Treatment of tuberculosis and tuberculosis infection in adults and children. *Am J Respir Crit Care Med* 1994; 149:1359-1374). More recent (2003) CDC recommendations (ATS/CDC Treatment of tuberculosis. *Am J Respir Crit Care Med* 2003; 167:603-662) have PZA and EMB dosing on less than weight-based basis requiring a separate weight calculation and does not result in significant changes in dosing from the previous recommendations.

Start with administered 15 mg/kg to reduce the risk of ocular toxicity. The use of 25 mg/kg should be reserved for patients requiring retreatment or drug resistant TB.

[2] For patients on hemodialysis, administer medication 3 times weekly after dialysis using renal insufficiency dosing above.

Appendix 7 — Tuberculosis Treatment Regimens - Special Situations

Category	Months	Comments
Positive CXR & Culture (+) after 2 mos.	9	If initial CXR shows cavitation and sputum remain culture positive after 2 months of TB treatment, the continuation phase (INH and RIF) should be extended an additional 3 months for a total 9/9 months of treatment
Culture negative TB	6	For persons with suspected pulmonary TB who have negative cultures but clinical or roentgenographic improvement, the continuation phase can be discontinued at 2 months for a total of 6 months of treatment. Exception: if HIV seropositive or circumstances or CXR argue for 9 months.
Bone/Joint TB	9	Extend standard therapy to a total of 9 months.
CNS TB	9 to 12	For TB meningitis, extend standard therapy for a total of 9 to 12 months. Adjunctive dexamethasone are recommended. Consult a TB expert.
HIV	usually 6	*CD4+ T-cells < 100/mm³*: Due to increased risk of acquired rifamycin resistance, give daily or thrice (3x) weekly. *CD4+ T cells ≥ 100/mm³*: standard dosing. *Antiretroviral therapy*: If taking ARV, reevaluate if TB diagnosis continue them. When antiretrovirals are modified, even slightly, these guidelines generally should be presumed for 2 to 3 months after starting TB treatment. Patients on protease inhibitors and non-nucleoside inhibitors may need medication adjustment because of drug interactions with rifamycin. Consult an HIV/TB expert. Consult www.cdc.gov/nchstp/tb/TB_HIV_Drugs/Table.htm
Pregnancy	9	Treat without delay. Start with INH, RIF, EMB (not PZA). Discontinue EMB once INH and RIF susceptibilities known. Continue INH + RIF. Give equivalent of pyridoxine 50 mg/day (unless known to already be taking the equivalent as a prenatal vitamin)
Renal Disease	6	If creatinine clearance < 30 ml/min. or on renal dialysis, after dosing. If on hemodialysis, give thrice (3x) weekly after dialysis after dosing per *Appendix 6*.
Drug-Resistance and Intolerance - Treatment Regimens Lacking:		
INH	6	Once resistance to INH is known or INH intolerance identified, discontinue INH and continue RIF, PZA and EMB for the duration of therapy.
RIF	9 to 12	For rifampin resistance or intolerance, treat for 12 months with INH, PZA, EMB and a fluoroquinolone. An injectable agent (e.g., streptomycin) for the first 2 months should be considered for more extensive disease or if shorter duration of therapy desired (9 months).
PZA	9	For PZA resistance or intolerance, treat for 9 months with INH and RIF.
INH / RIF	18 to 24	Multiple drug resistant (MDR-TB). Must be closely managed in consultation with a TB expert utilizing multiple drugs to which organism is sensitive.

Appendix 3: Monitoring for Tuberculosis Treatment Response and Adverse Reactions

	Baseline	Monthly	Comments
TB Treatment Response			
Chest Radiographs	PA/ Lateral		After initial CXR only repeat if clinically indicated. With suspected culture negative TB perform a CXR at 2 months to evaluate for CXR improvement. For pulmonary cases, a CXR should be obtained at treatment completion.
Sputums	3 consec daily	1	Obtain 3 monthly until culture conversion documented. Treatment is extended if culture conversion documented after 4 months of treatment. If patient can produce sputum at the end of treatment obtain sputums.
Vital Signs/ Weight	X	X	Weight and temperature are often a critical measure of treatment response
TB Signs and Symptoms	X	X	Check for cough, hemoptysis, chest pain, fever, night sweats, fatigue, malaise.
Adverse Reactions			
Blood Work	X	varies	*Baseline liver function tests, uric acid and complete* blood count including platelets. Monthly liver function tests should be done only for those with: - abnormal baseline liver function tests - development of hepatitis symptoms - HIV infection - history of heavy alcohol use, liver disease or chronic hepatitis
Vision	X	while on EMB	While on ethambutol, check visual acuity (Snellen) and color vision (Ishara). If on EMB greater than 3 months, evaluation by an ophthalmologist is required.
Signs and Symptoms	X	X	Check for nausea, vomiting, abdominal pain, decreased appetite, jaundice, dark urine, rash/ itching, joint pains, tingling extremities.

Appendix 9: Dosage Chart for Tuberculosis Drugs (mg)

Weight		Weight Adjusted Dosages (mg/kg)								
lb	kg	5 mg/kg	10 mg/kg	15 mg/kg	20 mg/kg	25 mg/kg	30 mg/kg	40 mg/kg	50 mg/kg	70 mg/kg
77	35	175	350	525	700	875	1050	1400	1750	2450
88	40	200	400	600	800	1000	1200	1600	2000	2800
99	45	225	450	675	900	1125	1350	1800	2250	3150
110	50	250	500	750	1000	1250	1500	2000	2500	3500
121	55	275	550	825	1100	1375	1650	2200	2750	3850
132	60	300	600	900	1200	1500	1800	2400	3000	4200
143	65	325	650	975	1300	1625	1950	2600	3250	4550
154	70	350	700	1050	1400	1750	2100	2800	3500	4900
165	75	375	750	1125	1500	1875	2250	3000	3750	5250
176	80	400	800	1200	1600	2000	2400	3200	4000	5600
187	85	425	850	1275	1700	2125	2550	3400	4250	5950
198	90	450	900	1350	1800	2250	2700	3600	4500	6300
209	95	475	950	1425	1900	2375	2850	3800	4750	6650
220	100	500	1000	1500	2000	2500	3000	4000	5000	7000
231	105	525	1050	1575	2100	2625	3150	4200	5250	7350
242	110	550	1100	1650	2200	2750	3300	4400	5500	7700

Appendix 10: Tuberculosis Contact Investigation Checklist

After identification of a TB case or suspect, the inmate should be immediately isolated, medically evaluated and, if appropriate, treatment initiated. The case should be immediately reported to the local or state health department. The contact investigation steps outlined below may overlap in time. As soon as close contacts are identified, they should be promptly evaluated.

✓	Date	Task
		1. Notify correctional management officials
		2. Clinical assessment of case (including retrospective chart review): - previous exposure to TB - history of TB symptoms (cough, fever, nightsweats, etc.) - weight history - chest radiographs - tuberculin skin test - bacteriology (AFB smear/culture/susceptibilities), nucleic acid amplification tests - HIV status - other medical conditions
		3. Case interview. *Interview in 1 day for AFB smear positive or cavitary cases* or in 3 days for other cases. Re-interview in 7 to 14 days. Interview for: - TB symptom history / onset of symptoms - close contacts in correctional facility and community (if relevant)
		4. Determine infectious period. Generally: onset of cough or 12 weeks prior to TB diagnosis—whichever is longer. Exception: if no TB symptoms and AFB smear negative and non-cavitary, then 4 weeks prior to suspected TB.
		5. Convene contact investigation team (corrections and health department) - identify team leader, roles and responsibilities of team members - develop plan for managing contact investigation data - develop investigational priorities
		6. Update correctional management officials including the Warden, Regional, and Central Office BSD staff regarding contact investigation strategy.
		7. Obtain index case's traffic history during/travel/school locations during infectious period).
		8. Tour exposure sites (where case frequented during infectious period) - number of inmates housed together - general size of airspace - housing arrangements (cells/dorms) - availability of data on inmates housed at same time - ventilation - heating/air conditioning system (recirculated air?) - pattern of daily inmate movement (cafeteria, general areas)

Appendix 11: Tuberculosis Contact Investigation Checklist (Page 2)

✓	Date	Task
		9. Prioritize contacts. Group contacts based upon duration of exposure and/or intensity of exposure. Those with the most exposure and HIV infected contacts (regardless of duration of exposure) are considered highest priority.
		10. Develop contact list. Obtain rosters of highest priority employee and inmate contacts and research their current location. Generate lists of exposed contacts grouped by their current location (currently incarcerated, transferred, and released).
		11. Conduct medical record review for highest priority contacts as follows - prior TST / CXR results / dates - history of treatment for latent TB infection or TB treatment - HIV status - other high risk medical conditions
		12. Initiate contact medical evaluation (employees and inmates). HIV infected contacts should be evaluated as soon as possible.

		- ALL contacts: Interview for TB symptoms and encourage HIV testing if status unknown. If TB symptoms, perform CXR and medical evaluation and isolation as an NPIR if TB suspected.
		- Prior TST positives (HIV seronegative or unknown):
		  - offer HIV counseling and testing
		  - no further follow-up unless symptomatic
		- HIV seropositives (regardless of prior TST result):
		  - do symptom review, TST (if prior TST negative) and chest radiograph
		  - initiate complete course of treatment for LTBI after active TB ruled out (regardless of prior treatment for LTBI or active TB)
		- Baseline TST negatives (HIV seronegative or unknown):
		  - do symptom review, TST
		  - CXR (if TST is positive)

		13. Referral for contact evaluation (for releasing/transferred inmates).
		14. Determine infection rate by exposure site. Infection rate = # whose TST has converted from negative to positive divided by # tested. Calculate rates separately for U.S. born and foreign born inmates. Decide whether or not to expand investigation beyond highest priority contacts
		15. Follow-up tuberculin skin testing - 8 wks weeks after exposure ended
		- recent search to determine current location of inmates - limited testing of employees and inmate contacts who remain incarcerated - refer released/transferred inmates for follow-up TST
		16. Determine infection rate and need to expand investigation
		17. Write a summary report and submit through wardens to Regional and Central Offices

Appendix 12. Interagency TB Disease Checklist

Appropriate discharge planning and referrals are critical for inmates receiving treatment for TB disease or LTBI and for identified contacts of a TB case in need of evaluation. Continuation of release and referral processes should take place to assist the inmate in making the transition to the community. Maintain necessary care, and to protect the public health.

✓	Date	Task
		1. Determine release/transfer destination: Anticipated Date: ___/___/___ __halfway house __community by supervision (i.e., USPO) __other jurisdiction (agency) __full release (i.e., treatment) __other country __FCI, Berlin; Contact information: name, address, phone number, state number, referrals, FAX, etc.
		2. Obtain a signed release of medical information (i.e., BP-S021), as needed.
		3. Complete *"Interjurisdictional Tuberculosis Notification"* can be obtained at www.naccho.org). Send form and other necessary information to the next provider of services, the state TB program where inmate is going and state TB program. Also utilize this form for referral to the functional referral program. Cure TB, VA Net, etc.). State TB program contact information: www.cdc.gov/mmwr/pdf/wk/mm5551.pdf.
		3. Request dispensation of medication supply based on current treatment: Required treatment (DOT) according to BOP policy on supply-fill on: __ A. Community correctional facility placement __ B. Other jurisdiction (i.e., state transfer, other agency, etc.) __ C. Release and referred for required treatment through a community provider, public health referral or other community resource
		4. Provide inmate education on: __ *Current TB treatment medications, doses, frequency, durations* __ Potential side effects __ Consequences of nonadherence __ Follow-up clinical appointment: Date: ___/___/___ Time: _____ Location/address: Contact name, telephone no.
		5. Health departments notified: RECEIVING state / local health department(s): Date: ___/___/___ Contact name/telephone/FAX: TRANSFERRING system state / local health department(s): Date: ___/___/___ Contact name/telephone/FAX:
		Treating Clinician and Supervising Physician Signature: Date File copy of supporting documentation(s) in medical record.

Appendix 12. Tuberculosis Educational Resources

TB Guidelines

The following Centers for Disease Control guidelines are available at: www.cdc.gov/nchstp/tb/pubs/mmwrhtml/Maj_guide/List_categories.htm.

Diagnosis
ATS/CDC. Diagnostic standards and classification of tuberculosis in adults and children (2000)

Targeted Testing and Treatment of Latent TB Infection
ATS/CDC. Targeted tuberculin testing and treatment of latent tuberculosis infection (2000)

CDC Update: Adverse event data and revised American Thoracic Society/Centers for Disease Control recommendations against the use of rifampin and pyrazinamide for treatment of latent tuberculosis infection--United States (2003)

TB Treatment
ATS/CDC. Treatment of TB (2003)

CDC. *Notice to readers*: Updated guidelines for the use of rifamycins for the treatment of TB among HIV-infected patients taking protease inhibitors or nonnucleoside reverse transcriptase inhibitors (2004)

Infection Control
CDC. *Guidelines for preventing transmission of Mycobacterium TB in health-care facilities* (1994)

Educational Materials

Centers for Disease Control and Prevention

TB Education and Training Resource Guide, 2003. This comprehensive 256 page resource guide which provides access to a broad range of TB educational material can be obtained through: www.edcpin.org/scripts/tbfguide/tbre.asp

Division of TB Elimination Educational and Training Materials Order Sheet. (www.cdc.gov/nchstp/tb/pubs/tbfactsheets/2500ffl.pdf). A large variety of TB training materials directed at both patients and providers can be ordered, including a "Think TB" wall chart, Mantoux Tuberculin Skin Testing Training, etc.

Self-Study Modules on TB, 1999-2000. This award-winning on-line course for health care providers can be accessed through: www.ahrpo.cdc.gov/nhanrtm/modules/Default.htm.

Appendix 12. TB Educational Resources (Page 2)

Charles P. Felton National TB Center
www.harlemtbcenter.org

The Charles P. Felton National TB Center has developed a number of pocket cards for managing latent TB infection and training materials for clinicians.

Francis J. Curry National TB Center
www.nationaltbcenter.edu

The Francis J. Curry National TB Center has developed a number of helpful materials including a "Contact Investigation in a Work-site Toolbox" and "TB Infection Control Plan for Labs Template" (2003). The pdf template provides all the necessary components of a pdf TB control plan.

New Jersey Medical School National TB Center
www.umdnj.edu/tbcweb

The New Jersey Medical School National TB Center has developed a wide array of materials on diagnosing latent TB infection, TB treatment (including curbs antihepatitis treatment recommendations), case management and TB education.

National Institute for Occupational Safety and Health (NIOSH)

"NIOSH Respiratory Protection Program in Health Care Facilities - Administrator's Guide" can be found at http://www.cdc.gov/niosh/pdfs/99-143.pdf

NIOSH Approved Disposable Particulate Respirators (N 95) list can be obtained at: http://www.cdc.gov/niosh/topics/respirators/disp_part/

Training Opportunities

The 5 training centers listed above all also provide training opportunities which can be accessed through their WEB sites.

National Jewish Medical and Research Center

National Jewish offers an extraordinary 4-day intensive TB course for clinicians, "The Denver TB Course". For more information see: http://nationaljewish.org/diseases.aspx