TUBERCULOSIS

Federal Bureau of Prisons

Clinical Guidance

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WHAT'S NEW IN THIS DOCUMENT?

This 2020 version of the BOP Clinical Guidance on Tuberculosis contains the following changes to the version issued in 2015.

LATENT TB INFECTION (LTBI)

- Consult with the Regional Quality Improvement/Infection Prevention & Control (QI/IPC) Consultant regarding the appropriate LTBI regimen to prescribe for inmates at high risk for TB disease who have a projected release date less than 12 weeks hence.
- A complete blood count (CBC) is no longer recommended as a baseline test prior to starting the isoniazid-rifapentine (INH-RPT) 12-week, 12 dose LTBI regimen.
- Inmates who arrive while currently on monotherapy with INH should generally be switched to the INH-RPT regimen unless they have less than 3 months of treatment remaining of a 9-month INH regimen.
- 12-week INH-RPT is contraindicated for *HIV-infected inmates* on antiretroviral therapy, **EXCEPT** for those on efavirenz- or raltegravir-based regimens in combination with abacavir/lamivudine or tenofovir disoproxil fumarate/emtricitabine.
- Prior to starting a *TNF-alpha inhibitor drug*, patients should be screened for LTBI with a tuberculin skin test (TST) and/or an interferon gamma release assay (IGRA). The BOP recommends screening within 4 weeks prior to starting the treatment. Treatment for LTBI should be started at least one to two weeks, with consideration given to completing LTBI treatment altogether, prior to starting a TNF-alpha inhibitor drug.
- Increased emphasis is placed upon counting doses rather than time elapsed to document treatment completion. The BOP recommends recording final treatment dose counts in the treatment completion note and the note resolving the health problem.
- LTBI treatment with INH-RPT should be completed within 16 weeks.

DIAGNOSIS OF ACTIVE TB

- A TB Hospital Letter (included in *Appendix 11*) is designed to inform hospital providers of the needed elements for a diagnostic work-up for active TB.
- The 2016 CDC guidelines on TB diagnosis recommend sputum induction rather than flexible bronchoscopic sampling for patients who are unable to produce sputum or for whom expectorated sputum is AFB-smear negative. (See *Appendix 5*.)
- The Huff Cough Technique may improve the quality of sputum collected. (See *Appendix 5*.)
- It is usually necessary to specifically request that a nucleic acid amplification test (NAAT) be performed in addition to AFB sputum smears and cultures. For some private labs, it is necessary to specifically request that AFB cultures be performed in addition to AFB smears.
- Inmates with suspected TB should be screened for diabetes with either a fasting serum glucose or a hemoglobin A1C.
- In the context of large TB contact investigations, where there is evidence of significant TB transmission, molecular tests for both INH and rifampin resistance should be requested through the state TB program in order to guide selection of the appropriate LTBI treatment regimen for contacts to a TB case.

TREATMENT OF ACTIVE TB

- The guideline for drug dosing, as provided in *Appendix 6b*, has been simplified.
- Very strong emphasis is placed on counting TB treatment doses rather than time elapsed to determine completion of treatment. A TB Treatment Dose count chart is provided in *Appendix 6b*.
- The recommended strategy for managing asymptomatic, TST positive inmates with chest radiographs suggestive of TB disease is to obtain sputa and start presumptive RIPE (rifampin, isoniazid, pyrazinamide, ethambutol) treatment.
- Review of the Medication Administration Records by the TB case manager is recommended at least **WEEKLY** to assess for medication compliance.
- Suspected active TB is now reportable within BOP by utilizing the Reportable Infectious Disease (RID) System.
- Guidance regarding treating *active TB in HIV-infected patients* not yet on ART has changed. In patients with CD4 counts < 50 cells/mm3, ART should be initiated as soon as possible, but within 2 weeks of starting TB treatment. In patients with CD4 counts ≥ 50 cells/mm3, initiate ART within 8 weeks of TB therapy initiation. In the uncommon situation in which an HIV-infected patient does not receive ART during tuberculosis treatment, CDC recommends extending the continuation phase with INH and RIF an additional 3 months (for a total of 9 months of therapy).
- Sputum culture conversion is achieved with two (previously three) consecutively negative cultures while on TB treatment.
- Guidance is included on rechallenge of TB drugs for active TB treatment in inmates with evidence of *hepatotoxicity*.
- A new *Table 1, Management of Treatment Interruptions*, has been added at the end of Section 6, Treatment of Tuberculosis Disease.

CONTACT INVESTIGATION

- HIV testing is always recommended for identified contacts to a TB case.

INFECTION CONTROL

- *Appendix 10*, *Instructions for Transport and Hospital Escort Staff for Inmates with Suspected or Confirmed TB*, provides detailed guidance on respiratory protection.
- The criteria for discontinuation of isolation (*Appendix 7*) has been revised and simplified.

TABLE OF CONTENTS

1. PURPOSE

The Federal Bureau of Prisons (BOP) *Clinical Guidance for Tuberculosis* provides recommendations for the treatment of federal inmates with tuberculosis (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 two decades. However, TB prevention and control remains a high 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 foreign countries that have high rates of TB. **The rate of TB in correctional facilities is four to five times greater than in the U.S. population as a whole.**

TRANSMISSION: *Mycobacterium 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 persons who become infected with M. tuberculosis never develop active TB.*

RISK FACTORS FOR LATENT TB INFECTION (LTBI): Persons with LTBI are usually identified with a positive tuberculin test, have no symptoms of TB disease, and are not infectious to others—but are at lifelong risk for developing active TB disease.

- **The most significant risk factor for LTBI is country of origin.** The general U.S. population has an estimated TB infection rate of only 5–10%; foreign-born populations have an average estimated TB infection rate of 32%, 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).

RISK FACTORS FOR ACTIVE TB DISEASE: Approximately 5% of infected persons develop active TB disease during the first year or two after infection. In another 2–5%, the 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**.
- **Diabetes** is an increasingly important risk factor for active TB. Diabetics have a 2–3 times higher risk of developing active TB if infected, compared to people without diabetes.

➔ *Appendix 1, Tuberculosis Risk Factors, lists conditions associated with a higher risk of TB disease.*

3. SCREENING

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

INTAKE TB SYMPTOM SCREENING

All inmates (including all holdover inmates) should be systematically screened for TB symptoms as part of intake screening. For non-English speaking inmates, it is critical that TB symptom screening questions be asked through an interpreter (either in-person or via language line).

TB QUESTIONS

BOP Electronic Medical Record (BEMR) Intake Health Screen

- History of previous disease?
- Blood-tinged sputum?
- Night sweats?
- Weight loss?
- Fever?
- Cough?

CHEST RADIOGRAPH SCREENING

INTAKE CHEST X-RAYS (CXRS)

CXRS AT INTAKE: The following categories of inmates should have a CXR at intake.

➔ *Inmates with symptoms should have both a posterior-anterior (PA) AND a lateral CXR. For asymptomatic inmates, a PA view is sufficient.*

- Inmates reporting TB symptoms (especially a cough for 2–3 weeks), regardless of TST results
- TST-positive inmates
- All HIV-infected inmates

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

CXRS DURING PREGNANCY*:*

- **For pregnant women at a higher risk for developing active TB disease (as listed below)**, a CXR using lead shielding should be done *immediately*, even during the first trimester. Higher-risk scenarios include the following:
  - Presenting with symptoms suggestive of TB disease
  - HIV-positive (TST-positive or negative) and had close contact to a TB case
  - TST-positive and a close contact to a smear-positive or cavitary case
- **For lower risk TST-positive pregnant women**, a CXR using lead shielding should be performed *after* the first trimester.

SCREENING FOR LATENT TB INFECTION

While persons with LTBI are usually asymptomatic and often unaware of past exposures to TB, they are at risk of developing infectious TB. Screening high-risk populations such as inmates and providing treatment for those with LTBI are important public health measures.

➔ *Currently there are **TWO TYPES OF METHODS** approved by the U.S. Food and Drug Administration (FDA) for testing for LTBI—the tuberculin skin test (TST) and interferon-gamma release assays (IGRAs) blood tests. These methods, and their use in the BOP, are discussed in the next two sections.*

TUBERCULIN SKIN TEST (TST)

The TST is an approved method for diagnosing *M. tuberculosis* infection in persons who do not have TB disease. Below is a discussion of indications, special considerations, administering and reading the TST, interpreting results, and two-step testing.

➔ *Guidelines for tuberculin skin testing are summarized in Appendix 2.*

★ ***TSTs have been demonstrated to be "false negative" in 25% of active TB cases.***
★ ***A negative TST does not rule out the possibility of active TB.***

INDICATIONS FOR TUBERCULIN SKIN TESTING

Inmates should be evaluated for TB infection with a TST, in accordance with BOP policy and the indications discussed below.

➔ *See also the discussion of Special Considerations Regarding the TST on the next page.*

ACTIVE TB DISEASE IS CLINICALLY SUSPECTED: Tuberculin skin testing should be performed if active TB is clinically suspected and the inmate's TST status is unknown.

INTAKE SCREENING:

A baseline TST will be obtained on all new intakes to the BOP, regardless of TST results from other detention facilities/systems or an inmate's history of a prior positive TST, **with the following exceptions:**

- The inmate has documentation of a prior positive TST while incarcerated within BOP.
- The inmate has a history (either by self-report or clinically documented) of a severe reaction to a TST (e.g., a swollen, blistering, vesiculated reaction). It is recommended that an IGRA be drawn.
- Inmates in holdover status, with a TST result (negative or positive) from a non-BOP detention facility.
  - ➔ *It is critically important that **HOLDOVER INMATES** receive a TB symptom screen at intake.*
- There is a unique reason not to repeat a TST (as approved by the Regional Medical Director) such as repeated admissions from local detention facilities over a short period.

FOR FOREIGN-BORN INMATES: Consider performing two-step tuberculin skin testing for foreign-born inmates who have not been tested in the previous 12 months. A self-report of being tested within the last year is a sufficient reason not to perform a two-step test.

➔ *See Booster Phenomenon and Two-Step Testing at the end of the section on TSTs.*

ANNUAL SCREENING: Tuberculin skin testing should be performed annually unless there is documentation of a prior positive TST or history of active TB disease.

TB CONTACT INVESTIGATION: Tuberculin skin testing should be done for contacts of an inmate determined to have active TB.

➔ *See Medical Evaluation of Contacts under Section 7, Contact Investigations.*

SPECIAL CONSIDERATIONS REGARDING THE TST

PREGNANCY: Pregnancy is not a contraindication to tuberculin skin testing.

BACILLUS CALMETTE-GUERIN (BCG) VACCINATION: BCG vaccination is not a contraindication to tuberculin testing. TST reactivity resulting from BCG vaccination does not correlate with protection against TB. Persons with a history of BCG vaccination whose TST is positive should be considered infected with *M. tuberculosis*.

ADMINISTERING AND READING TSTS

TST TRAINING: TSTs should only be performed by health care workers who have had formal skills training in administering, reading, and interpreting the test. If the TST is placed or read incorrectly, the results may be inaccurate. The BOP has developed a TST training program including on-line training and skills assessment.

PRODUCT HANDLING:

- Only BOP Formulary tuberculin solution should be used.
- Skin tests should be administered as soon as possible after the tuberculin syringe has been filled. Tuberculin should not be drawn up in advance of testing. The reason for this is that tuberculin adsorbs to the plastic of the syringe; if syringes are drawn up in advance the amount of tuberculin administered may be reduced by adsorption.
- The tuberculin test solution should be refrigerated (not frozen) and stored in the original box, in the dark. Exposure to strong light should be avoided.

ADMINISTRATION OF THE TST:

- The TST should be administered by the Mantoux method, which consists of intradermal injection of 0.1 ml of PPD tuberculin containing 5 tuberculin units (TU) into the volar or dorsal surface of the forearm, using a disposable tuberculin syringe. The left forearm is the preferred site for testing. A skin area away from superficial veins and free of lesions should be selected.
- A 5 mm tense 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:

- The TST should be read by a trained health care worker 48–72 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 in millimeters (mm) the largest diameter of the indurated area (palpable swelling) on the forearm. The diameter of the induration should be measured transversely to the long axis of the forearm.
- 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

TST CUT-POINTS:

Two cut-points for defining a positive TST are indicated in correctional facilities, based on risk factors for TB infection and TB disease in infected inmates (5 mm for inmates with specific risk factors and 10 mm for all others).

➔ *See "TST Cut-Points" in Appendix 2, Tuberculin Skin Testing Guidelines.*

TST REACTORS VS. CONVERTORS:

- A **TST REACTOR** is anyone who has a positive TST. A **TST CONVERTOR** is a TST reactor whose TST has increased at least 10 mm or more in a two-year period or at least a 5 mm increase in a person who is a known contact to a TB case.
- This distinction is important because TST convertors have a higher risk of developing TB disease in the two years following infection and are considered high priority for LTBI treatment.

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.

Consider TWO-STEP TESTING (see box below) for newly sentenced inmates in the following categories who are at high risk for boosting (if they have not received a TST in the last year and if repeated annual testing is anticipated):

- Foreign-born inmates
- Inmates with a history of BCG vaccination
- Other inmates as medically indicated with suspected previous exposures to *M. tuberculosis*

TWO-STEP TUBERCULIN SKIN TESTING PROCEDURE

- Place a TST.
- If the initial TST reaction is negative, a second test is placed 1–3 weeks later.
  - If the second test is *negative*, the person is considered uninfected. (Any subsequent positive test would be considered new infection)
  - If the second test is *positive*, the person is a TST reactor (but not a TST convertor) and managed accordingly. (See *Interpreting Skin Test Reactions* above.)

➔ *If an inmate received a TST in the last year this is considered equivalent to a two-step test and a second "step" test is not needed.*

INTERFERON-GAMMA RELEASE ASSAYS (IGRAS)

Interferon-gamma release assays are whole-blood tests that can aid in diagnosing *M. tuberculosis* infection. Two main types of IGRAs have been approved by the FDA and are commercially available:

- **QuantiFERON®-(QFT)**
- **T-SPOT®.TB test (T-Spot)**

IGRAs measure a person's immune reactivity to *M. tuberculosis*. White blood cells from most persons that have been infected with *M. tuberculosis* will release interferon-gamma (IFN-g) when mixed with antigens (substances that can produce an immune response) derived from *M. tuberculosis*. To conduct the tests, fresh blood samples are mixed with antigens and controls.

★ **Similar to the TST, IGRAs test for TB infection. They are NOT tests for active TB disease.**
★ **In 10–25% of active TB cases, IGRAs have been demonstrated to be "false negative." A negative IGRA does not rule out the possibility of active TB.**

THE USE OF IGRAS IN THE BOP

Currently, the routine use of IGRAs for screening purposes in the BOP is NOT recommended.

- The use of IGRAs may be considered in the diagnostic work-up of inmates with suspected active tuberculosis, particularly when the TST result is negative. They also may be considered for use in inmates with questionable TST results with prior approval of the Regional Medical Director.
- Some inmates may enter BOP with documentation of prior IGRA results. These results (positive or negative**)** should be considered as evidence of the presence or absence of LTBI.
- Record of a prior positive IGRA test should be considered as evidence of LTBI, i.e., equivalent to a positive TST. There is generally no reason to perform a TST to confirm it.
- Use the appropriate problem code in BEMR for inmates with a positive IGRA.

ADVANTAGES OF IGRAS OVER THE TST

- Only a single patient visit is required to conduct the test.
- Results can be available within 24 hours.
- IGRAs do not "boost" the response measured by subsequent tests.
  ➔ *See discussion of booster phenomenon with TSTs.*
- Prior BCG vaccination does not cause a false-positive IGRA result.

DISADVANTAGES OF IGRAS COMPARED TO THE TST

- Blood samples must be carefully processed in the timeframe defined by the manufacturer.
- Errors in collecting or transporting blood specimens can decrease the accuracy of IGRAs.
  ➔ *It is critically important to carefully follow the manufacturer's instructions for handling specimens and timing of shipments.*
- Tests may be expensive.

OTHER CONSIDERATIONS REGARDING IGRAS

- IGRA interpretations are based on the amount of IFN-g that is released or on the number of cells that release IFN-g.
- IGRAS, as with TSTs, should be used as an aid in diagnosing infection with *M. tuberculosis*.
  - **POSITIVE** test result – suggests that *M. tuberculosis* infection is likely.
  - **NEGATIVE** result – suggests that infection is unlikely.
  - **INDETERMINATE** result – indicates an uncertain likelihood of *M. tuberculosis* infection.
  - **BORDERLINE** test result (T-Spot only) – also indicates an uncertain likelihood of *M. tuberculosis* infection.

4. LATENT TUBERCULOSIS INFECTION (LTBI)

All inmates with a positive TST or IGRA should be clinically evaluated, have a CXR to rule out active TB, and be considered for treatment of LTBI. Treatment substantially reduces the likelihood that a person with LTBI will develop active TB in the future.

Currently there are several options for treatment of LTBI. The BOP has adopted the 12-week, 12-dose regimen of isoniazid (INH) and rifapentine (RPT) as the standard BOP treatment for LTBI, to be utilized unless there are contraindications for its use.

➔ *See Appendix 3a, Standard Treatment for Latent TB Infection.*

BASELINE EVALUATION FOR LTBI

> ★ ***The treatment of LTBI should NEVER be initiated until active TB disease has been eliminated as a potential diagnosis.***

A diagnosis of LTBI (positive TST or IGRA) requires that active TB disease be excluded by medical evaluation that includes assessment of the following:

- **TB SIGNS AND SYMPTOMS:** Cough, fever, night sweats, weight loss, hemoptysis.
- **CXR:**
  - A posterior-anterior (PA) view is sufficient in asymptomatic inmates; a lateral should also be performed if there is any suspicion for active TB.
  - In the asymptomatic inmate, a CXR must be performed within 14 days of identifying the positive TST or IGRA.
  - For the purpose of ruling out TB in asymptomatic persons prior to starting treatment for LTBI, a CXR is "good" for six months in HIV-seronegative inmates and for one month in HIV-positive inmates.
  - CXRs, other than baseline, are not indicated during treatment of LTBI unless symptoms of TB disease develop during treatment.
    - ➔ *See discussion of CXRs during pregnancy under "Chest Radiograph Screening," Section 3.*
- **MEDICAL HISTORY** should include review of the following:
  - Risk factors for TB (*see Appendix 1, Tuberculosis Risk Factors).*
  - Prior treatment for TB or LTBI.
  - Preexisting medical conditions that may complicate treatment.
  - Symptoms of active TB disease, hepatitis, liver disease, and pregnancy.
  - Current medications, with attention to potential drug interactions. There are significant drug interactions with RPT, including some drugs for which RPT is contraindicated.
    - ➔ *See Appendix 3a for a list of these drugs.*
- **TARGETED EXAMINATION** should be performed by a clinician for systemic signs of active TB disease, as well as signs of hepatitis.
- **HIV TESTING** shall be performed on an opt-out basis for all inmates with a positive TST or IGRA (unless previously tested for HIV), since HIV co-infection significantly increases the risk of developing active TB.
- **DETERMINE PROJECTED RELEASE DATE TO ASSESS ELIGIBILITY FOR TREATMENT.**
  - **IN GENERAL,** LTBI treatment is not prescribed for inmates whose projected release date is sooner than the anticipated completion of the 12-week INH-RPT treatment regimen, or whose projected release date is unknown. Pretrial inmates and inmates in holdover status should ordinarily not be prescribed LTBI treatment.
    - ➔ *See discussion of **EXCEPTIONS** in box on next page.*

★ **EXCEPTIONS: Inmates with the following RISK FACTORS should be started on LTBI treatment regardless of their expected duration of incarceration:**

- HIV co-infection or other immunocompromised condition
- Close contacts with an active TB case who are TST convertors
- Recent TST convertor (10 mm or more increase in reaction size within two years)

➔ *These high-risk inmates with a projected release date of less than 12 weeks hence should be started on LTBI treatment. Consult Regional QI/IPC Consultant regarding whether to start the 12-week INH-RPT or the 9-month INH regimen.*
(See Appendix 3b for details on the 9-month INH regimen.)

➔ *See also Section 9, Discharge Planning for inmates who will require continuation of treatment after release.*

- **BASELINE LABORATORY TESTS** prior to initiating LTBI treatment:
  - **TESTING FOR HCV INFECTION** is recommended for all inmates and should be performed if not previously tested in the BOP. Screening for hepatitis B infection is recommended if risk factors are present.
  - **ALT AND AST:** Obtain for all inmates being considered for LTBI treatment. If liver transaminases are elevated, liver function tests (e.g., bilirubin) should also be assessed.
  - **SPUTUM EVALUATION** is not routinely indicated for persons being considered for LTBI treatment. However, for inmates with CXRs suggestive of old healed TB, sputum (if producible) should be obtained to screen for active TB disease: AFB smear, nucleic acid amplification test (NAAT), and culture.
    ➔ See *Old Healed TB vs. Active TB in Section 5 for guidance on evaluating and treating inmates with evidence of old healed TB*.

INDICATIONS FOR TREATMENT OF LTBI

Clinical indications for the treatment of LTBI are based on the inmate's TST reaction in millimeters or a positive IGRA, the relative risk of developing TB disease, and risk factors for drug side effects. Treatment of LTBI should be considered for all TST-positive or IGRA-positive inmates, regardless of age—when no medical contraindications to treatment exist, and previous adequate treatment has not been provided. BCG vaccination history should be ignored.

Give highest priority for LTBI treatment to inmates who have an increased risk of developing active TB disease:

- **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 LTBI treatment.
- **DIABETES MELLITUS** which increases risk of TB disease by 2–3 fold.
- **OTHER IMMUNOSUPPRESSIVE CONDITIONS OR THERAPY:** Inmates on immunosuppressive therapy (including a history of organ transplantation with immunosuppression, on chronic steroid therapy, or those on TNF-alpha inhibitor therapy) should receive priority treatment for LTBI.
- **RECENT CONVERTORS:** Inmates whose TST has increased 10 mm or more within the past 24 months (and close contacs whose TST has increased 5 mm or more) are at relatively high risk for developing TB, and are therefore high-priority candidates for LTBI treatment.
- **ABNORMAL CXR (OLD HEALED TB):** See *Old Healed TB vs. Active TB* in *Section 5*.
- **OTHER HIGH-RISK MEDICAL CONDITIONS:** See *Appendix 1*, which lists conditions associated with a higher risk of TB disease.

TREATMENT REGIMENS FOR LTBI

★ **MEDICATION LOOK-ALIKE /SOUND-ALIKE ALERT** ★

Do not confuse **Rifapentine (RPT)** (*used for treatment of LATENT TB infection*) with **Rifampin (RIF)** or **Rifabutin (RBU/RBT)** (*used for treatment of ACTIVE TB disease*).

- **The BOP adopted use of the INH-RPT regimen as the standard regimen for LTBI treatment** in 2015 because of demonstrated high completion rates and the logistical advantages of this 12-dose, 12-week treatment regimen. Treatment with the 12-dose regimen should be completed within 16 weeks.
- **DRUG INTERACTIONS:** Like all rifamycins, RPT induces activity of the cytochrome P-450 system, resulting in drug interactions with substrates of this enzyme system—warfarin, hormonal contraceptives, antiretroviral agents, anti-HCV agents, methadone, sulfonylureas (oral hypoglycemic), and anti-epileptic drugs.

  ★ **There are various contraindications to rifapentine (RPT). See list in** *Appendix 3a*.

- **ALTERNATIVE REGIMENS:** If 12-week INH-RPT is contraindicated or adverse effects occur on the regimen, consideration can be given to utilizing alternative regimens for LTBI treatment, including 9-month INH (administered twice weekly) and 4-month rifampin (administered daily).
- **FOR ALL LTBI REGIMENS:**
  - All doses of medication must be directly observed by a health care provider.
  - Determination of treatment completion is based on counted doses administered, NOT time elapsed. Completed doses should be documented in BEMR.

➔ *See Appendix 3a, Standard Treatment for LTBI, and Appendix 3b, Alternative Regimens for Treatment of LTBI, for specific recommendations regarding contraindications, medication dosing, drug interactions, summary of side effects, etc.*

SPECIAL CONSIDERATIONS IN TREATING LTBI

INMATES ARRIVING WHILE ON INH MONOTHERAPY

It is recommended that inmates who arrive on monotherapy with INH be switched to the 12-dose, 12-week INH-RPT regimen, unless they have less than 3 months of treatment remaining of a 9-month regimen.

TREATMENT REFUSALS

Inmates who refuse treatment for LTBI should sign a refusal form to be kept in their medical record, documenting their declination of treatment; the LTBI "Prophy" Problem Code should be revised. Group counseling or other structured educational efforts should be considered for inmates who refuse treatment for LTBI when treatment is clearly indicated.

(Discussion continues on the next page.)

MONITORING INMATES WHO REFUSE TREATMENT:

Two categories of inmates who refuse treatment for LTBI—or have treatment discontinued because of drug side effects, nonadherence, or other reasons—should be monitored in accordance with the following:

- **Inmates with HIV infection (or unknown HIV status), or who are on TNF-alpha inhibitor drugs or immunosuppressive therapy for organ transplantation, and with TST > 5mm:** Semi-annual CXRs and clinician evaluations for symptoms and signs of pulmonary TB performed indefinitely for HIV-infected inmates with a CD4+ T cell count < 200 cells/mm^3.
- **HIV-seronegative inmates who are recent convertors or close contacts of active TB cases:** Semi-annual CXRs and clinician evaluations for symptoms and signs of pulmonary TB; performed for a 2-year period. (*See Interpreting Skin Test Reactions for description of recent convertor*.)

➔ *Both of the above groups should be educated at the time of their symptom assessment about the importance of promptly reporting to health services if they develop TB symptoms, especially a persistent cough.*

CONTRAINDICATIONS TO LTBI TREATMENT

Treatment of LTBI should not be initiated if contraindications to treatment exist. Contraindications to LTBI treatment include, but are 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.
  - ➔ *Inmates with significant elevations in liver transaminases should be considered for LTBI treatment only if they are at high risk of developing active TB disease. Consult with Regional/Central Office.*
- History of adverse reactions to medications prescribed for LTBI.

HIV CO-INFECTION

➔ ***12-week INH-RPT treatment for LTBI is contraindicated for HIV-infected inmates on antiretroviral therapy except for those on efavirenz- or raltegravir-based regimens, in combination with abacavir/lamivudine or tenofovir disoproxil fumarate/emtricitabine. The 9-month INH treatment is recommended instead.***

- Persons with HIV infection and LTBI are at significant risk of developing active TB disease and are therefore considered priority candidates for treatment.
- Inmates with HIV infection who are close contacts of a person with infectious TB disease should be considered for treatment, regardless of TST results.
- Inmates with HIV infection who have respiratory symptoms, unexplained fever, or weight loss, should also have sputum submitted for bacteriologic cultures, since active TB disease in immunocompromised hosts is often difficult to diagnose.

PREGNANCY

➔ ***RPT is contraindicated in 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 is not routinely recommended during pregnancy.
- In most cases, LTBI treatment should be prescribed 1–2 months following delivery.
- Pregnant women at high risk of developing TB disease (e.g., positive TST and history of close contact to an active TB case; recent convertors; or concurrent HIV infection or other immunosuppressive conditions) should be considered for INH treatment of LTBI during pregnancy, with close monitoring for hepatitis. No harmful effects on the fetus have been observed with INH therapy.

OLD HEALED TB

➔ *See Section 5, Diagnosis of Active TB Disease, for discussion of the diagnostic work-up of inmates with radiographic presentations that may represent old healed TB.*

BCG VACCINATION

A history of BCG vaccination, with or without a BCG scar, should be ignored as a factor in deciding whether to offer treatment for LTBI.

CONTACTS TO MULTIPLE DRUG RESISTANT TB (MDR-TB)

Consultation with the Regional/Central Office Infection Prevention and Control Program is important when treating contacts of persons with MDR-TB.

TNF-ALPHA INHIBITOR DRUGS (TUMOR NECROSING FACTOR ALPHA ANTAGONISTS)

TNF-alpha inhibitor drugs, a class of immunosuppressive drugs used for treatment of inflammatory conditions such as psoriasis and rheumatoid arthritis, are associated with increased risk of TB disease.

Prior to starting treatment with a TNF-alpha inhibitor, patients should be screened for LTBI with a TST and/or IGRA:

- The BOP recommends that this screening be done no more than 4 weeks prior to starting treatment.
- **For inmates with a positive TST (cut-point of > 5mm), a positive IGRA, or a previous diagnosis of LTBI without completed treatment for LTBI:** Treatment for LTBI should be initiated at least one to two weeks prior to starting the TNF-alpha inhibitor. Consideration should be given to completing the full course of LTBI treatment before starting the TNF-alpha inhibitor, if clinically appropriate..

➔ *See the list of TNF-alpha inhibitor drugs in Appendix 1 (right-hand column).*

MONITORING LTBI TREATMENT

➔ *Guidelines for monitoring LTBI treatment are summarized in Appendix 3c, Treatment for LTBI: Baseline and Ongoing Monitoring.*

CLINICIAN EVALUATIONS

- At a minimum, patients on treatment for LTBI should be evaluated by a physician or qualified advanced practice provider at the initiation of treatment, when signs and symptoms of adverse reactions occur, and whenever treatment is interrupted.
- Inmates with baseline elevations of liver transaminases or other complicating medical conditions should be followed closely.

INMATE COUNSELING

Inmates should be counseled by health care staff about the importance of adherence to every dose of treatment for LTBI, potential drug side effects, signs and symptoms of hepatitis and the reason for pyridoxine (vitamin B6) co-administration.

BASELINE/ONGOING LABORATORY TESTS

All inmates on LTBI treatment should have baseline liver transaminases measured. ALT and AST should be monitored periodically for inmates with risk factors for hepatotoxicity,

Treatment for LTBI should ordinarily be discontinued under the following circumstances:

- Liver transaminases exceeding three times the upper limit of normal, if the inmate has symptoms of hepatitis.
- Liver transaminases exceeding five times the upper limit of normal, if the inmate is asymptomatic.

MONITORING DRUG SIDE EFFECTS

- All inmates on LTBI treatment require regular monitoring:
  - Inmates on 12-week INH-RPT shall be monitored for adverse effects weekly.
  - Inmates treated with 9-month INH or 4-month RIF shall be monitored monthly.
- Monitoring shall be recorded in the BEMR Latent TB flow sheet. For inmates on INH-RPT, additional questions should be asked during the weekly visits with the responses recorded in the Comments section of the BEMR flowsheet.

  ➔ *See adverse reactions in Appendix 3c.*
- **At each encounter, patients should be instructed in their preferred language to seek medical attention immediately** if they have fever, yellow eyes, dizziness, rash, or aches—or greater than one day of nausea, vomiting, weakness, abdominal pain, or loss of appetite. LTBI treatment (regardless of regimen) shall be withheld while the cause of symptoms is being determined and the inmate is referred to a clinician for further evaluation.

DOCUMENTATION OF TREATMENT REGIMEN

Treatment of LTBI should be documented utilizing the appropriate problem code in the electronic medical record.

- *Drug treatment completion is measured in terms of total number of doses ingested, NOT the amount of time elapsed. To be considered treatment complete, at least 11 of the weekly doses must be taken within a 16-week timeframe. The number of completed doses should be documented in the electronic health record.*

STRATEGIES FOR A SUCCESSFUL LTBI TREATMENT PROGRAM

The following BEST PRACTICES were reported to be effective in a pilot evaluation of the 12-week INH-RPT regimen in the BOP:

- **One health care professional was dedicated to oversee the program** and conducted the weekly symptom reviews and administered medication. This health care worker was selected on the basis of available staff resources at the institution (e.g., nurse, infection control staff, pharmacist, advanced practice provider). Thus, inmates received ongoing individual support from one health professional for promoting compliance and completing the regimen.
- **Weekly call-outs were used to structure the INH-RPT clinics** rather than via pill-line. The weekly call-out system resulted in groups of inmates waiting together to be seen, resulting in the formation of informal support groups for completing the regimen.
- **Pilot sites frequently started the inmates on INH-RPT in cohorts** to facilitate efficient tracking of the baseline evaluations and lab monitoring. This approach also allows for educational efforts to be provided to groups of inmates who are all starting the regimen at the same time.

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. The diagnosis of TB disease frequently requires expert medical consultation, which can be accessed through the Regional/Central Office Infection Prevention and Control Consultants.

➔ *Guidelines for the diagnostic work-up of patients with suspected TB are summarized in step 1 of Appendix 4, TB Case Management Checklist.*

DIAGNOSTIC ISSUES

Although many inmates with active TB disease are symptomatic and have a positive TST and a characteristically abnormal CXR (upper lobe/cavitary lesions), many other cases of active TB may not be so obvious. Correctional health care providers should maintain a high index of diagnostic suspicion for TB and be alert to the following:

- **Inmates with active TB disease may appear healthy and deny symptoms.**
- **Important risk factors for TB** are foreign birth, HIV infection, alcoholism, chronic renal failure, diabetes mellitus, neoplastic diseases, TNF-alpha inhibitor drugs, and drug abuse.
- **A negative TST or IGRA does NOT rule out active TB.**
- **Negative AFB smears from sputum or bronchoscopy specimens do NOT rule out active TB.**
- **Negative AFB cultures in persons with abnormal CXRs consistent with TB do NOT rule out TB.**
  ➔ *See Culture-Negative Pulmonary TB in Section 6. See also Appendix 6c, Tuberculosis Treatment Regimens in Special Situations.*
- **Fluoroquinolones (e.g., ciprofloxacin, levofloxacin, moxifloxacin) are highly effective drugs for treating active TB.** In general, fluoroquinolones should be avoided when active TB is in the differential diagnosis because it can confuse the diagnostic work-up. For example, it is impossible to determine if clinical improvement on the fluoroquinolone is related to improvement of symptoms caused by TB or caused by another problem, i.e., community-acquired pneumonia.
- **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.
- **Evidence of necrotizing or caseating granuloma on pathology report is presumed to be indicative of TB unless proven otherwise.**

MEDICAL HISTORY AND PHYSICAL EXAM

Inmates who present with signs and symptoms of TB or an abnormal CXR consistent with TB should be evaluated by a physician or advanced practice provider. The physical examination is not useful for confirming or ruling out a TB diagnosis, but can provide valuable information on the extent of TB disease, signs of extrapulmonary TB, and the presence of relevant co-morbid conditions.

➔ *Components of the medical history are summarized in Step 1 of Appendix 4, TB Case Management Checklist.*

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.)
- **INFILTRATE:** Fibronodular, coalescence or consolidation, pneumonia, miliary.
- **CAVITIES:** Thick, moderately irregular walls; air-fluid levels are 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 in young children).
- **PLEURAL EFFUSION:** More common in persons with recent TB infection.

➔ *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

It is recommended that, if possible, sputum specimens for AFB be sent to a public health laboratory in the state where the facility is located. Each institution should contact the public health laboratory in their state and determine whether this is feasible. The institution should a priori acquire appropriate specimen containers and lab slips, and determine procedures for specimen submission.

The CDC recommends sputum induction rather than flexible bronchoscopic sampling for patients who are unable to produce sputum. The CDC recommends that postbronchoscopy sputum specimens be collected from all adults with suspected pulmonary TB who undergo bronchoscopy.

➔ *Detailed recommendations on sputum collection, sputum induction, and associated infection control measures are provided in Appendix 5, Sputum Collection/Induction Procedures.*

AFB SMEARS

- 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*.
- AFB smears are not specific for *M. tuberculosis*, since the presence of other nontuberculous mycobacteria can also result in positive AFB smears.

  ➔ *Negative AFB smears from sputum or bronchoscopy DO NOT rule out active TB disease.*

NUCLEIC ACID AMPLIFICATION TESTS (NAATS)

- Sometimes referred to as "rapid tests" or "PCR tests," NAATs can detect *M. tuberculosis* within hours and are useful for the rapid diagnosis of TB disease in certain clinical situations.
- A NAAT should be performed on at least one respiratory specimen from each patient for whom a diagnosis of TB is being considered, but has not yet been established.

(Discussion of NAATs continues on the next page.)

- It is usually necessary to specifically request that this test be performed.
- Confirmatory bacterial cultures and sensitivities should also be obtained, regardless of the results of the NAAT.
- Interpretation of NAAT Results:
  - In AFB smear-positive patients, a negative NAAT makes TB disease unlikely.
  - In AFB smear-negative patients with an intermediate to high level of suspicion for disease, a positive NAAT can be used as presumptive evidence of TB disease, BUT a negative NAAT cannot be used to exclude pulmonary TB.

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. Once a positive AFB culture is obtained, it requires identification to determine if it is *M. tuberculosis* or another type of acid-fast bacteria.
- 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.
- If a private lab is used, it may be necessary to specifically request "AFB culture," in addition to an "AFB smear."

  ➔ *Negative cultures do NOT rule out active TB in a person whose CXR is consistent with active TB (with or without TB symptoms) and for whom there is no alternative diagnosis. See Culture-Negative Pulmonary TB in Section 6.*

DRUG SUSCEPTIBILITY TESTING

- Drug susceptibility testing should be performed on all cultures positive for *M. tuberculosis*.
- For culture-positive patients, do NOT switch from the initial 4-drug phase of treatment to two drugs UNTIL AFTER receipt of drug susceptibilities indicating drug sensitivity. Seek consultation from Regional/Central office staff if drug resistance is identified.

RAPID TESTS FOR DRUG RESISTANCE

- Rapid tests for drug resistance are available and should be requested from local or state health departments for inmates with suspected tuberculosis who are AFB smear-positive and who have risk factors for drug resistance—such as history of previous treatment for active tuberculosis or born in parts of the world with high rates of multiple drug-resistant TB (especially Eastern Europe, Asia, and Africa).
- In the context of large TB contact investigations where there is evidence of significant TB transmission, molecular tests for both INH and rifampin (RIF) resistance should be requested through the state TB program in order to guide selection of the drug regimen for treatment of LTBI in contacts to the TB case.

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 the Regional/Central Office Infection Prevention and Control Program.

OLD HEALED TB VS. ACTIVE TB: A DIAGNOSTIC CHALLENGE

The evaluation of inmates with abnormal CXRs suggestive of prior TB disease is complex and often requires expert consultation. Given the high-risk congregate settings in our prisons, inmates with radiographic findings suggestive of TB require a more aggressive work-up than might be indicated in the community.

DIAGNOSIS

Old healed TB presents a different radiologic appearance from active TB. In the BOP, this presentation is most often encountered in foreign born inmates. Dense pulmonary nodules, with or without visible calcification, may be seen in the hilar area or upper lobes. Smaller nodules, with or without fibrotic scars, are often seen in the upper lobes, and upper-lobe volume loss often accompanies these scars.

Asymptomatic inmates with abnormal CXRs suggestive of previous infection with no history of treatment are at increased risk for active TB and should be further evaluated. Obtain a TST if no result is available. Sputum examination obtained in an AII room is warranted to rule out active TB disease. Obtain three consecutive sputum samples, at least eight hours apart, including one early morning specimen. One of those tests should be a NAAT, if available.

- Attempt to obtain CXR films from at least 6 months previously and have them compared with current films. If the radiographic presentation is stable, then this effectively rules out active TB.
- If sputum smears and NAAT are negative, and the inmate's symptoms or radiographic findings cannot otherwise be clinically explained, further diagnostic evaluations (e.g., CT scan or bronchoscopy) for active TB disease should be considered. TB expert consultation, including review of chest radiographs by TB experts, can be accessed through the Regional/Central Office Infection Prevention and Control Program.

➔ *The criteria for discontinuation of isolation are outlined in Appendix 7.*

The recommended strategy for management of the TST positive and/or IGRA positive, asymptomatic inmate with an abnormal CXR suggestive of prior disease, whose sputum smears and NAAT are negative, and for whom there is no alternative diagnosis to explain the pulmonary abnormality is to start presumptive treatment, as follows:

- Start presumptive treatment for active TB with daily 4-drug RIPE treatment (rifampin, isoniazid, pyrazinamide, and ethambutol).
- If cultures all come back negative, then a CXR is repeated after 56 doses. If the CXR is improved, then this is considered "culture-negative TB," and treatment is continued for an additional 8–18 weeks. (See *Culture Negative Pulmonary TB* in *Section 6.*)
- If the CXR is unchanged, then the 56 doses of RIPE is considered equivalent to 9 months of INH, and should be coded as "complete LTBI treatment."

EXTRAPULMONARY TB

Extrapulmonary TB is usually more difficult to diagnose than pulmonary TB. Presentations may include fever, lymphadenitis (painless swelling of one or more lymph nodes), pleural effusion, pleuritis, pericarditis, renal disease (mild dysuria/hematuria/flank pain/sterile pyuria), skeletal disease (arthritis/bone pain/bone deformities), meningitis, peritonitis, and epididymitis.

- Patients suspected of having extrapulmonary TB should also undergo a CXR to rule out pulmonary TB.
- Sputum for AFB should routinely be collected for persons who are suspected of having extrapulmonary TB.
- Evidence of necrotizing or caseating granuloma on pathology reports from any site is presumed to be indicative of TB, unless proven otherwise. It is generally treated with a standard 6-month TB treatment regimen.

REPORTING SUSPECTED/CONFIRMED TUBERCULOSIS CASES

Any inmate diagnosed with suspected or confirmed TB should be promptly reported to the Regional and Central Office—and to the local health department in the jurisdiction where the facility is located—utilizing the *BP-A0665 Tuberculosis Case/Suspect and Referral Form*. Cases are reported within the BOP by uploading the *BP-A0665* form into the Reportable Infectious Disease (RID) System.

- Inmates with suspected TB should be reported, even if there is no bacteriologic confirmation of the case.
- The *BP-A0665* form shall be filed as a flow sheet in the electronic medical record. This form is designed to be updated as additional information becomes available, with the updates posted in BEMR.
- At the completion of treatment the form should be completed summarizing the outcome, i.e., treatment completed, released, TB ruled-out, and again filed in BEMR and the RID System. This final update of the form provides a concise summary of the TB diagnosis and treatment for future reference.
- If a Witness Security (WITSEC) case is diagnosed with active TB, this should be reported first to the Inmate Monitoring Section of the Correctional Programs Branch—prior to reporting the case to local health authorities.

6. TREATMENT OF TUBERCULOSIS DISEASE

★ **The GOALS OF TB TREATMENT are 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 6a, Standard Tuberculosis Treatment Regimen – 6 months

Appendix 6b, First-Line Tuberculosis Drug Dosing andDose Counts

Appendix 6c, Tuberculosis Treatment Regimens in Special Situations

GENERAL PRINCIPLES

The following principles should be adhered to when treating confirmed or suspected TB patients:

- **Four-drug DAILY therapy is routinely recommended initially** for all inmates with a clinical or laboratory diagnosis of TB disease. Standard 4-drug "RIPE" treatment consists of rifampin, isoniazid, pyrazinamide, ethambutol *PLUS* vitamin B6 (pyridoxine).
- **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.*
- **Seek expert consultation through Regional/Central Office** in the following circumstances:
  - Failure of sputum cultures to convert to negative, following 56 doses of therapy.
  - Resistance to rifampin, with or without resistance to other drugs.
  - HIV co-infection, drug intolerance, pregnancy, or other situations requiring deviation from a standard treatment regimen.

STANDARD TUBERCULOSIS TREATMENT REGIMEN

★ **Treatment should be DAILY throughout, unless there are contraindications to daily treatment—such as renal insufficiency.**

★ **Standard TB treatment occurs in two phases, the INITIAL PHASE and the CONTINUATION PHASE, as outlined in *Appendix 6a*.**

★ **COMPLETION of TB treatment phases is based on counting the TOTAL NUMBER OF DOSES ingested, and NOT the time elapsed since treatment started.**

INITIAL PHASE ("RIPE" TREATMENT)

- **The INITIAL PHASE consists of 8 weeks (56 daily doses)** of rifampin (RIF), isoniazid (INH), pyrazinamide (PZA), and ethambutol (EMB), and is commonly referred to as "**RIPE**" treatment.
- The initial use of four drugs is essential to minimizing the risk of further development of drug resistance in inmates whose disease may be drug-resistant.
- All TB medications should be prescribed according to the inmate's weight and adjusted appropriately with weight changes (weight can increase significantly after initiation of TB treatment).
  ➔ *See Appendix 6b, First-Line Tuberculosis Drug Dosing and Dose Counts.*
- The initial phase is completed after completing all 56 recommended doses.

➔ ***Do not switch to the CONTINUATION PHASE** until drug susceptibility tests confirm that the TB organism is sensitive to both INH and RIF and the inmate has received 56 daily doses of pyrazinamide.*
***EXCEPTION:** When an inmate's cultures are negative at 8 weeks (after 56 doses) and the inmate is being treated for culture-negative TB.*

CONTINUATION PHASE (RIF AND INH)

The **INITIAL PHASE** (56 RIPE doses) is followed by the **CONTINUATION PHASE**, which consists of 18 weeks of RIF and INH administered daily (126 counted doses).

➔ ***TOTAL DOSE COUNT at end of treatment is RIPE 56 doses PLUS 126 doses of RIF and INH.***

SPECIAL SITUATIONS IN TREATING ACTIVE TB

Modifications to the standard treatment regimen may be necessary in certain special situations, as outlined below.

➔ *The treatment recommendations in the **SPECIAL SITUATIONS** discussed below are summarized in Appendix 6c.*

CULTURE-NEGATIVE PULMONARY TB

- Inmates with (1) **CXR evidence** of active TB (with or without symptoms), (2) a positive **TST** (in this case > 5mm) or **IGRA**, and (3) negative **AFB smears** should be started on **STANDARD RIPE TREATMENT** for active TB.
  - ➔ *Expert review of chest radiographs should be obtained to determine whether the patient's CXR shows evidence of active TB.*
- If after starting on treatment, all **AFB cultures** are negative, then a CXR is repeated after 56 doses of daily RIPE treatment.
  - ➔ *The CXR request should specify request for a comparison with the initial CXR to assess for radiographic improvement.*
  - ▸ **IF CXR OR CLINICAL IMPROVEMENT → INDICATIVE OF CULTURE NEGATIVE TB**

    If the CXR shows improvement or the patient shows symptomatic improvement on RIPE treatment, then this is considered to be diagnostic for **CULTURE-NEGATIVE PULMONARY TB**. The PZA and EMB should be discontinued, and the INH and RIF should be continued for an additional 56 doses (8 weeks).
    - ➔ *In other words, treatment for culture negative TB consists of an 8-week (56-dose) initial ("RIPE") phase and an 8-week (56-dose) continuation phase of RIF and INH.*

    EXCEPTION: In the case of culture-negative pulmonary TB with HIV infection, or cavitation on CXR, the continuation phase of treatment (RIF and INH) should consist of 126 doses (18 weeks) following the initial 56 doses of RIPE treatment.
  - ▸ **IF NO CXR IMPROVEMENT → CONSIDERED TO BE COMPLETE LTBI TREATMENT**

    If after 56 doses there is no improvement in the CXR, then RIPE treatment is discontinued. The 56 doses of RIPE treatment is considered to be complete treatment of LTBI (equivalent to 9 months INH or 12 weeks INH-RPT) and the inmate should be coded in BEMR to indicate that.

★ **CULTURE-NEGATIVE PULMONARY TB is considered to be a form of active TB and is reportable to the health department.**

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 duration of treatment determined individually, based upon clinical response. Serial bacteriologic evaluations may be limited by disease location; therefore, treatment response must be judged on the basis of clinical and/or radiographic findings.

➔ ***Inmates with a diagnosis of extrapulmonary TB should always be assessed for evidence of pulmonary TB, including sputum for AFB.***

HIV CO-INFECTION

HIV infection significantly increases the risk of progression from latent to active TB disease. The CD4 cell count influences both the frequency and severity of active TB disease. Active TB also negatively affects HIV disease. It may be associated with a higher HIV viral load and more rapid progression of HIV disease.

Active pulmonary or extrapulmonary TB disease in HIV-infected inmates requires prompt initiation of TB treatment. Management of HIV-related tuberculosis is complex and requires consultation from experts in the management of both HIV disease and tuberculosis. The treatment of active TB disease in HIV-infected patients should follow the same general principles guiding treatment for individuals without HIV.

- **All HIV-infected patients taking antiretroviral therapy (ART)** with the diagnosis of active TB should be started on TB treatment immediately, while continuing ART.
- **If the HIV-infected patient is not yet on ART**, it should be initiated under the following guidelines:
  - In patients with CD4 counts < 50 cells/mm^3, ART should be initiated as soon as possible, but within 2 weeks of starting TB treatment.
  - In patients with CD4 counts ≥ 50 cells/mm^3, initiate ART within 8 weeks of TB therapy initiation
  - **EXCEPTION:** In patients with HIV infection and tuberculous meningitis, the best time to start ART is not known with certainty because of the severe complications from meningitis; however, there is also a higher rate of severe adverse drug-related complications when ART is started early. Consultation with an expert is recommended in such situations.
  - In the uncommon situation in which an HIV-infected patient does not receive ART during tuberculosis treatment, the CDC recommends extending the **CONTINUATION PHASE** with INH and RIF an additional 3 months (i.e., a continuation phase of 7 months in duration, corresponding to a total of 9 months of therapy) for treatment of drug-susceptible pulmonary tuberculosis.

COMBINING ART AND TB REGIMENS: Despite pharmacokinetic drug interactions, a rifamycin (rifampin or rifabutin) should be included in TB regimens for patients receiving ART, with dosage adjustment if necessary. ART regimens should be assessed with particular attention to potential pharmacokinetic interactions with rifamycins. The patient's regimen may need to be modified to permit use of the optimal TB treatment regimen.

- Use only rifabutin with protease inhibitors.
- If rifampin is used:
  - Efavirenz-based regimens have the least drug interactions.
  - If raltegravir is used, increase dose to 800 mg twice daily.
  - If dolutegravir is used, increase dose to 50 mg twice daily. Avoid if INSTI resistance is present.

➔ *See drug interaction tables for antimycobacterials (rifampin and rifabutin) at: https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/367/overview*

(Discussion of HIV Co-Infection continues on the next page.)

IMMUNE RECONSTITUTION/PARADOXICAL REACTION: The term **IMMUNE RECONSTITUTION INFLAMMATORY SYNDROME (IRIS)** describes a collection of inflammatory disorders associated with paradoxical worsening of preexisting infectious processes following the initiation of ART in HIV-infected individuals. Preexisting infections in individuals with IRIS may have been previously diagnosed and treated, or they may be subclinical and later unmasked by the host's regained capacity to mount an inflammatory response.

- This inflammatory reaction is usually self-limited, especially if the preexisting infection is effectively treated. However, long-term sequelae and fatal outcomes may rarely occur, particularly when neurologic structures are involved.
- Although it is reasonable to perform studies looking for unmasked subclinical opportunistic infection, the diagnosis of IRIS is generally one of exclusion. Investigations to rule out the possibility of drug reaction, patient noncompliance, persistently active infection and/or drug resistance are usually warranted before concluding that IRIS is present.
- Most patients with IRIS develop symptoms within one week to a few months after the initiation of ART. Treatment for the underlying pathogen should generally be started or continued in patients who develop IRIS. Corticosteroids or NSAIDS may help decrease the inflammatory response in some patients with IRIS. The decision to use corticosteroids should be individualized and should take into account the risks of therapy.

CAVITARY TB WITH POSITIVE CULTURES AFTER 56 DOSES

Very high rates of relapse have been reported in patients who present initially with cavitation on chest radiograph and whose sputum cultures remain positive after 56 doses of RIPE treatment. Therefore, it is recommended that the **CONTINUATION PHASE** (RIF/INH) in such patients be extended to 7 months, for a total of 9 months of treatment (56 RIPE doses plus 217 RIF/INH doses).

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 via hemodialysis.

- For patients with a creatinine clearance of <30 ml/minute or who are on renal dialysis, the alterations in dosing and frequency are outlined in the 2016 CDC guidance on *Treatment of Drug Susceptible Tuberculosis (Table 12)*, available at: *https://academic.oup.com/cid/article/63/7/e147/2196792*.
- For patients on hemodialysis, medications should be given 3 times per week—after dialysis.

DRUG RESISTANCE AND INTOLERANCE

Consultation with the Regional/Central Office Infection Prevention and Control Program should be sought when treating TB that is complicated by drug resistance or drug intolerance.

➔ *Generally recommended treatment regimens for drug resistance or intolerance are outlined in Appendix 6c.*

MULTIPLE DRUG-RESISTANT TB (MDR-TB), defined as resistance to at least isoniazid and rifampin, can generally be treated successfully with a prolonged treatment regimen if managed appropriately.

In some parts of the world, **EXTENSIVELY DRUG RESISTANT TB (XDR-TB)** is increasingly common. XDR-TB is defined as resistance to isoniazid and rifampin plus resistance to any fluoroquinolone and at least one of three injectable second-line drugs (i.e., amikacin, kanamycin, or capreomycin). XDR-TB, an emerging global pathogen associated with very poor treatment outcomes, requires expert consultation.

MONITORING TREATMENT

All inmates with active TB disease should be monitored at least monthly to evaluate the clinical response to therapy and to monitor side effects of medications.

- *Baseline laboratory studies, TB medication regimens, and monitoring of adverse reactions should be in accordance with parameters outlined in Appendix 4, TB Case Management Checklist.*
- *Document monitoring of TB cases utilizing the Active TB Montoring in BEMR.*

CLINICIAN EVALUATION

- At a minimum, patients on treatment for active TB disease should be evaluated by a physician or qualified advanced practice provider (with physician review) at initiation of treatment; at ~2 months of treatment; if signs and symptoms of adverse reactions or lack of clinical response; whenever treatment is interrupted; at treatment completion; and monthly throughout treatment if drug resistant TB, drug intolerance or HIV co-infection.
- Inmates with baseline elevations of liver transaminases or other complicating medical conditions should be followed closely.

BASELINE LABS

Tests include an HIV Ab test, ALT/AST, bilirubin and uric acid, and a CBC and platelets. Testing for HCV infection is recommended for all inmates and should be performed if not previously tested in the BOP. Screening for hepatitis B infection is recommended if risk factors are present. A fasting serum glucose or hemoglobin A1C should be obtained because of the increased risk of development, presentation, and progression of active TB associated with diabetes mellitus.

BASELINE VISION TESTS

Optic neuritis is a rare adverse effect of ethambutol. The risk of optic toxicity is higher at higher doses given daily. Start with EMB 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.

- *A Snellen (visual acuity) and Ishihara (red-green color vision test) should be performed prior to initiating treatment with ethambutol.*

MONITORING FOR ADVERSE REACTIONS / CLINICAL RESPONSE TO TREATMENT

Monitoring and documentation of signs and symptoms of clinical response and adverse reactions should be conducted weekly initially and then monthly in a BEMR Active TB Monitoring Clinical Encounter.

BACTERIOLOGIC CONVERSION

➔ *See Appendix 5, Sputum Collection/Induction Procedures. Sputum should be obtained in an airborne infection isolation room (AIIR). Lacking an AIIR, another option is to obtain these specimens outdoors if this can be accomplished discretely. If necessary, sputum should be induced.*

- **Inmates who are initially AFB sputum smear positive should have 3 consecutive adequate sputum specimens (for both smear and culture) collected weekly after starting treatment** (obtained 8 hours apart, including one early morning specimen)**—**until AFB smears convert to negative (3 consecutive negative smears)**—**so that inmates can be released from isolation as soon as possible.
- **All cases should have 3 consecutive adequate sputum specimens (for both smear and culture) collected monthly after starting treatment** (obtained 8 hours apart, including one early morning specimen), until cultures convert to negative. Once 2 consecutive cultures are negative, no further sputum testing is necessary.
- **Sputum cultures positive for *M. tuberculosis* after two months of drug treatment may indicate ineffective therapy.**
  - Repeat drug sensitivities should be obtained for those patients who fail to convert sputum cultures to negative within two months.
  - Inmates with TB disease who do not respond to standard drug therapy by the end of two months of treatment may be nonadherent to their medication regimen, or they 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 (in consultation with the Central Office Infection Prevention and Control program) 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 and at the completion of therapy. The purpose of the CXR at the completion of treatment is to serve as a baseline for future comparisons.
- CXRs are only obtained during treatment if clinically indicated.
- Patients with suspected pulmonary TB and negative sputum cultures should have a repeat CXR after 56 doses of treatment (to include comparison with the baseline CXR). CXR improvement is indicative of culture-negative TB.

  ➔ *See Culture-Negative Pulmonary TB in Section 6.*

MONITORING FOR DRUG-INDUCED HEPATITIS

Three of the first-line TB medications (RIF, INH, 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 should be stopped if they occur.

➔ ***Monthly monitoring of liver enzymes should be conducted for inmates with risk factors for hepatotoxicity.*** (*See Appendix 4, step 13.*)

- Moderate asymptomatic increases in AST or ALT levels occur in nearly 20% of patients treated with the standard 4-drug RIPE regimen and do 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 should be evaluated carefully. Liver function studies should be measured.
- **The following is the American Thoracic Society (2016) guidelines for RECHALLENGE:**
  1. After ALT returns to less than two times the upper limit of normal, rifampin may be restarted with or without ethambutol.
  2. After 3 to 7 days, isoniazid may be reintroduced, subsequently rechecking ALT.
  3. If symptoms recur or ALT increases, the last drug added should be stopped.
  4. For those who have experienced prolonged or severe hepatotoxicity, but tolerate reintroduction with rifampin and isoniazid, a rechallenge with pyrazinamide may be hazardous. In this circumstance, pyrazinamide may be permanently discontinued, with treatment extended to 9 months of isoniazid and rifampin.

  ➔ *Contact Regional/Central Office Infection Prevention and Control to access expert consultation on **RECHALLENGES**.*

MONITORING VISUAL ACUITY (WHILE ON ETHAMBUTOL)

For patients treated with ethambutol, visual acuity (Snellen) and red-green color vision (Ishihara) should be assessed at baseline, and monthly thereafter. For patients on prolonged treatment with ethambutol, supplementary optometry evaluations are indicated every three months. Patients with visual changes should have ethambutol stopped and be evaluated by an ophthalmologist.

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.
- Baseline and monthly creatinine and audiograms are indicated for inmates receiving streptomycin or other aminoglycosides, due to the risk of nephrotoxicity and ototoxicity.

MANAGING TREATMENT INTERRUPTIONS

The CDC recommends the following strategy for managing treatment interruptions to active TB treatment, as shown in **TABLE 1** below.

TABLE 1. MANAGEMENT OF TREATMENT INTERRUPTIONS*

TIME POINT OF INTERRUPTION	DETAILS OF INTERRUPTION	APPROACH
DURING INITIAL PHASE	Lapse is <14 days in duration	Continue treatment to complete planned total number of doses (as long as all doses are completed within 3 months).
	Lapse is ≥14 days in duration	Restart treatment from the beginning.
DURING CONTINUATION PHASE	Received ≥80% of doses and sputum was AFB smear negative on initial testing	Further therapy may not be necessary.
	Received ≥80% of doses and sputum was AFB smear positive on initial testing	Continue therapy until all doses are completed.
	Received <80% of doses and accumulative lapse is <3 months in duration	Continue therapy until all doses are completed (full course), unless consecutive lapse is >2 months. If treatment cannot be completed within recommended time frame for regimen, restart therapy from the beginning (i.e., restart initial phase, to be followed by continuation phase).**
	Received <80% of doses and lapse is ≥3 months in duration	Restart therapy from the beginning, new initial and continuation phases (i.e., restart initial phase, to be followed by continuation phase).

ABBREVIATION: AFB = acid-fast bacilli.

* According to expert opinion, patients who are lost to follow-up (on treatment) and brought back to therapy, with interim treatment interruption, should have sputum resent for AFB smear, culture, and drug susceptibility testing.

** The recommended time frame for regimen, in tuberculosis control programs in the United States and in several European countries, is to administer all of the specified number of doses for the initial phase within 3 months and those for the 4-month continuation phase within 6 months, so that the 6-month regimen is completed within 9 months.

ADAPTED FROM:
Nahid P, Dorman SE, Alipanah N, et al. Official American Thoracic Society/Centers for Disease Control and Prevention/Infectious Diseases Society of America clinical practice guidelines: treatment of drug-susceptible tuberculosis. *Clin Infect Dis*. 2016;63(7):e147–e195,Table 6. Available at: https://academic.oup.com/cid/article/63/7/e147/2196792

7. CONTACT INVESTIGATIONS

STEPWISE PROCEDURE FOR CONTACT INVESTIGATION

GOALS: The goals of a TB contact investigation are to:

1. Identify other active cases of TB (rare); and
2. Identify and completely treat individuals with new LTBI, particularly those at high risk for developing the disease.

The identification of a pulmonary or laryngeal 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.

MULTIDISCIPLINARY APPROACH: 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 the Health Services Administrator should convene a team of professionals who will plan the contact investigation. Ideally, the team should include staff from infection control, medical, nursing, and custody. Large contact investigations should also involve Regional and Central Office staff. Generally, the local health department should also be consulted during contact investigations.

➔ *A stepwise approach to managing a TB contact investigation is outlined in Appendix 8, Tuberculosis Contact Investigation—Checklist. It is recommended that the contact investigation team review and utilize this checklist as a guide when planning and implementing a TB contact investigation.*

TRANSMISSION FACTORS

The characteristics of the index case, the contacts, and the exposure all affect the likelihood of TB transmission.

1. **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 is present. If the inmate has been coughing for a prolonged period of time, there is also a higher risk of TB transmission.
2. **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.

     ➔ *Groups of contacts who are likely to benefit from a full course of presumptive treatment (regardless of TST results) are those with HIV infection, those taking immunosuppressive therapy for organ transplantation, and those taking TNF-alpha inhibitor drugs.*

   - **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 child (age ≤ 4) as a community contact, a health department referral should be made immediately because of the potentially life-threatening consequences of undetected TB in a young child.

3. EXPOSURE CHARACTERISTICS:

- **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 to be inhaled.
- **VENTILATION:** Ventilation is a key factor in the risk of airborne transmission of TB.
  - Exposures in confined air systems with little or no ventilation have been associated with increased TB transmission.
  - The spread of airborne infection extends to all space sharing the same air. Thus, if air circulates from the room occupied by an infectious patient into other rooms, the occupants of these other rooms will also be exposed.
- **DURATION OF EXPOSURE:** Even though transmission of TB can occur from a brief exposure, the likelihood of infection from exposure to an infectious patient is related to the frequency and duration of exposure. It is impossible to know what constitutes a significant duration of exposure for a given contact in a particular environment before conducting contact screening. Priority should be given 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 on the characteristics of the presenting TB case.

- **CONTACT INVESTIGATIONS should be conducted** for index cases in the following circumstances:
  1. **Suspected or confirmed pulmonary, laryngeal, or pleural TB and …**
     - Cavitary disease on CXR ***or***
     - Positive AFB smears (of sputum or other respiratory specimens)
  2. **Suspected or confirmed pulmonary (non-cavitary) or pleural TB, with AFB-negative smears** (of sputum or other respiratory specimens). A more limited investigation should be conducted for symptomatic AFB smear-negative cases.

- **CONTACT INVESTIGATIONS are generally NOT indicated** for extrapulmonary TB cases (except for laryngeal and pleural) without pulmonary involvement.

➔ *If the patient can produce sputum, it should always be collected and used to guide the investigation. However, in some patients with pulmonary TB, it may not be possible to collect sputum samples. In such cases, other types of respiratory specimens (e.g., those from bronchoscopy) may be collected and tested as a surrogate for sputum in determining the need for and priority of the contact 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 to guide the contact investigation team in making decisions about structuring the investigation:

- ★ **Promptly screen and initiate treatment for LTBI for all close contacts infected with HIV, taking immunosuppressive therapy for organ transplantation, or taking TNF-alpha inhibitor drugs.**
- ★ **Screen an identified group of contacts who are at highest risk of being exposed to infection (i.e., greatest duration of exposure, or concentrated exposure in a confined space).**
- ★ **Calculate the infection rate for each group of exposed persons (i.e., cell-mates, dorm-mates, co-workers, and exposed employees working in a dorm).**
- ★ **Decide how to structure the investigation based on the infection rates.**

DECIDING WHEN AND WHERE TO EXPAND THE INVESTIGATION

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 everyone who has had any contact with the index case.**

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

There is no formula for determining if an infection rate is "significant" and therefore merits expanding the investigation. The unique circumstances surrounding an investigation must be taken into account and evaluated in relation to calculated infection rates. Ideally, decisions about structuring the contact investigation should be made by the contact investigation team as a whole, seeking expert opinion from the Regional/Central Office and the state or local health department, as needed.

Sometimes, it is necessary to first screen a **CONVENIENCE SAMPLE.** For example, in jail investigations, many contacts may have already been released, and the only easily accessible contacts available for screening are those who remain incarcerated.

Rarely is an index case so infectious that wide-scale expansion of the contact investigation is necessary. Wide-scale investigations divert attention away from the high priority activities needed 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.

MEDICAL EVALUATION OF CONTACTS

The medical evaluation required depends on the contact's immune status and TST results.

➔ *HIV testing is ALWAYS recommended for inmate contacts with unknown HIV status.*

1. All contacts should be interviewed for symptoms of active TB and to encourage HIV testing (if status is unknown).

- Symptomatic inmate contacts should receive a CXR and complete medical evaluation, regardless of TST status. Symptomatic inmates should be isolated in an AIIR if CXR or clinical findings suggest contagious TB.
- Asymptomatic inmate contacts do not require isolation.

2. Close contacts of infectious TB cases who are HIV seropositive, taking immunosuppressive therapy for organ transplantation, or taking TNF-alpha inhibitor drugs should generally initiate a complete course of treatment for LTBI—after ruling out active TB by symptom review and CXR.

- Treatment should be initiated regardless of TST results, 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 8–10 weeks. The results of the TST, while not affecting treatment decisions, provide important information for the overall contact investigation.

3. Inmate contacts with a prior negative TST, and who are HIV-seronegative, require a TST and TB symptom screen initially and again 8–10 weeks after exposure ended.

- Mandatory tuberculin skin testing of all previously TST-negative inmate contacts should be conducted at baseline (unless previously tested within 1–3 months of exposure) and repeated 8–10 weeks from the last contact with the source case.
- TST convertors (TST ≥ 5mm) should be prescribed treatment for LTBI unless medically contraindicated.
- If inmate contacts refuse medically indicated treatment of LTBI, they should be monitored with a CXR and symptom screen:
  - Every 6 months for 2 years, if HIV seronegative
  - Every 6 months indefinitely, if HIV-seropositive and CD4 < 200 cells/mm^3 or on anti-TNF-alpha inhibitor drugs or immunosuppressive therapy for organ transplantation.

4. Asymptomatic inmate contacts with a prior positive TST, and who are HIV-seronegative or whose HIV status is unknown, should receive a TB symptom screen initially and again 8–10 weeks after exposure ended.

- If HIV status is unknown, inmates should be tested for HIV infection.

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 involve a highly infectious case of TB with a persistent cough that remains undetected for a prolonged period of time.**
>
> ★ **It is the responsibility of all correctional facility staff to identify inmates with a chronic cough and refer them to Health Services.**

INMATE SCREENING AND COUNSELING: All inmates should be screened for TB symptoms at intake. They should be counseled at orientation—and during clinical evaluations when appropriate—to recognize and promptly report possible symptoms of TB disease. They should be encouraged to participate in baseline and annual skin-testing to screen for TB infection. If diagnosed with either TB disease or LTBI, inmates should be advised about the importance of completing their treatment. Inmates should be counseled that certain risks and conditions—such as HIV infection, taking TNF-alpha inhibitor drugs, 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 if they become exposed to it.

AIRBORNE INFECTION ISOLATION

- **INITIATION:**
  - Inmates with suspected TB should be promptly isolated in an airborne infection isolation room (AIIR)—formerly known as a negative pressure isolation room (NPIR). In accordance with CDC guidelines, the room should have been validated within the previous year.
  - Prior to placing inmate in an AIIR, assure that there is negative pressure in the room by performing a "tissue test." Place a singly-ply tissue under the closed door of the room to see if it is drawn under the door, thereby demonstrating negative pressure.
  - The inmate should be instructed to cover his or her mouth when coughing or sneezing.
  - Inmates should remain isolated until they meet the criteria for discontinuation of isolation.

    ➔ *See Appendix 7 , for criteria for discontinuation of airborne infection isolation.*

- **RESPIRATORY PROTECTION:** Inmates should be managed using airborne precautions and personal respiratory protection designed to prevent transmission of *M. tuberculosis*.
  - All persons entering an AIIR or transporting an infectious patient in a closed space should wear appropriate respiratory protection, in accordance with BOP policy and OSHA recommendations.

(Discussion of respiratory protection continues on the next page.)

- The minimal acceptable form of respiratory protection to protect against TB transmission is an N-95 respirator mask.
- Respirators should only be utilized in the context of a fit-tested OSHA-compatible respiratory protection program, including medical evaluation, fit-testing, and training.
- In accordance with OSHA regulations, persons wearing respirators cannot have facial hair that interferes with the respirator seal.

- **MONITORING INMATES IN ISOLATION:** Inmates should be seen by a health care provider daily while isolated, with the visit documented in the medical record.

- **PRECAUTIONS WHEN INMATES LEAVE ISOLATION ROOM:** If inmates need to leave the AII room before isolation is discontinued they should wear a surgical mask while outside the room or during transport.

- **ISOLATION DISCONTINUATION:**
  - Inmates with suspected TB should remain in airborne infection isolation until they meet criteria for discontinuation of isolation (see *Appendix 7*).
  - Assess weekly to determine if the inmate meets criteria for discontinuation of isolation.
  - If isolation extends beyond 14 days, hold weekly case conferences to assess plan for assuring that isolation is discontinued as soon as possible.

- **CLEARANCE TIME FOR AIIRS:** 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. BOP AIIRs should not be entered without respiratory protection until two hours after they have been exited by a patient with an airborne infectious disease.

TRANSPORT

➔ *See Appendix 10, Instructions for Transport and Hospital Escort Staff for Inmates with Suspected or Confirmed Infectious TB for detailed instructions regarding transport of inmates outside of an AIIR.*

- When a potentially infectious inmate is being transported outside an AIIR, the inmate should be instructed to wear a surgical mask.
- Movement of the inmate should be limited to those situations where movement is required for medical or security purposes.

9. DISCHARGE PLANNING

Discharge planning begins as soon as a suspected case of active TB is identified. Inmates should be placed on Medical Hold (in SENTRY and BEMR) to prevent transfer to another facility during TB diagnosis and treatment. Inmates who are diagnosed with TB in detention or holdover facilities can be moved to another BOP facility once isolation is discontinued and the patient is stabilized, assuring appropriate communication about the patient with the receiving facility. 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 to maintain public health.

☑ **Check the Projected Release Date.** If the date precedes the anticipated date of TB treatment completion, then begin discharge planning immediately.

☑ **Determine where the inmate is likely to go upon release**, e.g., deportation, return to home, etc.

☑ **The *BP-A0665* form serves as both a TB case report form and as referral form.** All available information about the TB diagnosis and treatment should be recorded on the form.

☑ **All inmates with active TB disease should have a specific plan** for continuing treatment via an international referral program or state health department.

☑ **For inmates who will be deported**, CURE-TB assists mobile patients to access and complete TB treatment. This agency generally conducts telephone interviews to refer inmates for care after deportation. Utilize the completed ***BP-A0665*** form for referrals to CURE-Tb after obtaining informed consent, as appropriate.

- *CURE-TB is a collaboration between CDC's Division of Global Migration and Quarantine (DGMQ) and the County of San Diego's Tuberculosis Control Program. Information about CURE-TB is available at: https://www.cdc.gov/usmexicohealth/curetb.html*

☑ **Inmates who will be released in the United States should have referrals made to state health departments where your BOP facility is located, using the *BP-A0665* form.** The health department is responsible for assuring interstate notifications.

- *For a list of state TB programs, see the National TB Controller's Association website, "State, Big City, and Territory TB Contacts" at* : *http://www.tbcontrollers.org/community/statecityterritory/#.VhOpKivjJ5o*

☑ **Provide counseling** to ensure that the inmate understands the importance of adherence to treatment and receives specific instructions for seeking care upon release.

☑ **Supply TB medications** to the inmate in accordance with BOP policy.

10. TB PROGRAM MANAGEMENT

The Clinical Director and Health Services Administrator should work collaboratively to ensure that BOP policy, this *Tuberculosis* Clinical Guidance, and the requirements of the OSHA Respiratory Protection Standard (1910.134) are fully implemented.

TB CASE MANAGEMENT

➔ *See Appendix 4, TB Case Management Checklist for a detailed overview of case management responsibilities.*

A TB Case Manager (usually the Infection Prevention and Control Coordinator) is recommended for each suspected or confirmed case of tuberculosis. The role of the TB Case Manager includes the following:

- Assure that the TB case/suspect is appropriately reported to the Regional and Central Office via the Reportable Infectious Disease (RID) System and to the local health department using the ***BP-A0665*** form.
- Track the diagnostic work-up.
- Assure that the inmate is appropriately isolated.
  - ➔ *See Appendix 7, for criteria for discontinuation of airborne infection isolation.*
  - ▸ Assure that the inmate is not released from isolation and returned to general population until he or she has met the criteria for release from isolation.
  - ▸ Assure that the inmate is assessed daily while isolated, with documentation in BEMR.
  - ▸ Assure that inmates are released from isolation *as soon as* criteria is met.
- Assure that the inmate is placed on Medical Hold (in both BEMR and SENTRY) until TB treatment completed or TB is ruled out.
  - ➔ *Inmates who are diagnosed with TB in detention or holdover facilities can be moved to another BOP facility once isolation is discontinued and the patient is stabilized, assuring appropriate communication about the patient with the receiving facility.*
- Coordinate with the local pharmacist to assure that drug treatment/dosing is appropriate.
- Communicate with the health department and hospital infection control practitioner.
- Assure that appropriate monitoring occurs—including laboratory, monthly symptom screen, visual acuity/color vision screening while on ethambutol, monthly sputum specimens, etc.
- Assure that there is weekly assessment of compliance with treatment. At least monthly, count and summarize the number of doses ingested for each treatment phase.
- Coordinate the TB contact investigation, if indicated.
- Immediately start release planning if the inmate's projected release date is prior to the projected TB treatment completion date or if the projected release date is unknown.
  - ➔ *See Section 9, Discharge Planning.*
- Ensure that health problem codes are updated appropriately in the electronic medical record.

(Discussion of TB Case Management continues on the next page.)

- Regularly update the ***BP-A0665*** form with new information regarding the TB case, and post the updates in the electronic medical record.
  - A final version of the report shall be completed, summarizing the outcome and filed in the electronic medical record and uploaded into the RID System so that the history of the diagnostic work-up and treatment is accessible for future reference.

TUBERCULOSIS EXPOSURE CONTROL PLAN

Each facility will develop a **TB EXPOSURE CONTROL PLAN** that defines facility-specific procedures to fulfill policy and regulatory requirements shall be completed and updated annually. The facility's Infection Prevention and Control Committee shall review at least annually the facility's compliance with its Tuberculosis Exposure Control Plan.

Particular attention should be focused on ensuring the following:

- TB symptom screening at intake is occurring according to BOP policy.
- TB suspects are isolated 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.
- TB case reports and referrals are made to health authorities as appropriate.

PROGRAM EVALUATION

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

- Annual TST conversion rate (inmates and staff).
- Completion of treatment for latent TB infection.

DEFINITIONS

NOTE: *Terms used in* "SMALL CAPS" *within a definition are listed elsewhere in this section with their own 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 suspected; 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 if airborne transmission occurs. A person exposed to *M. TUBERCULOSIS* does not necessarily become infected.

AIRBORNE PRECAUTIONS are protective measures used for patients/inmates and situations to prevent the spread of infections that can be transmitted by airborne contact 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., N-95 respirator) for persons who come in direct contact with infectious airspace; the isolation of infectious patients/inmates in a private room with monitored, negative air pressure; and the implementation of necessary engineering controls to inform, direct, and protect persons entering the isolation rooms.

AIRBORNE INFECTION ISOLATION ROOMS (AIIR) are rooms designed to prevent AIRBORNE EXPOSURE. Formerly called a NEGATIVE PRESSURE ISOLATION ROOM (NPIR), an AIIR is a single-occupancy, patient-care room used to isolate persons with suspected or confirmed infectious TB disease. Environmental factors are controlled in AIIRs to minimize the transmission of infectious agents that are usually spread from person-to-person by droplet nuclei associated with coughing or aerosolization of contaminated fluids. AIIRs should provide negative pressure in the room (so that air flows under the door gap into the room), an air flow rate of 6–12 ACH, and direct exhaust of air from the room to the outside of the building or recirculation of air through a HEPA filter.

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.

ANTIGENS are substances that can produce an immune response, especially the production of antibodies.

TNF-ALPHA INHIBITOR DRUGS (tumor necrosing factor alpha antagonists) are immunosuppressive drugs utilized for treatment of inflammatory conditions such as psoriasis and rheumatoid arthritis. They have been demonstrated to increase the likelihood of TB disease in those infected with TB who start on those drugs.

➔ *See the right-hand column in Appendix 1 for a list of these drugs.*

BCG (BACILLUS CALMETTE-GUERIN) are 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 (LTBI).

CLEARANCE TIME is the time between the discharge of an inmate isolated for airborne precautions in an AIIR and the arrival of another inmate or other person(s) who will occupy the room without the use of airborne precautions.

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 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) is the practice of administering a unit dose of TB medication to an inmate by a clinician, nurse, pharmacist, or specially trained staff member who directly observes 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.

IGRA is the acronym for interferon-gamma release assay, a type of whole-blood test that can aid in diagnosing *M. TUBERCULOSIS* infection.

➔ *See the discussion of Interferon-Gamma Release Assays in Section 3, Screening.*

IMMUNE RECONSTITUTION INFLAMMATORY SYNDROME (IRIS) describes a collection of inflammatory disorders associated with paradoxical worsening of preexisting infectious processes following the initiation of ART in HIV-infected individuals.

➔ *See discussion* under *HIV Coinfection in Section 6.*

INDEX CASE is the initial person with 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*. This person is sometimes called the SOURCE CASE.

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 tuberculin skin testing, involving the intradermal injection of PPD-tuberculin into the forearm with a needle and syringe.

MTB is an abbreviation for *MYCOBACTERIUM TUBERCULOSIS*

MULTI-DRUG RESISTANT TB (MDR-TB) is active TB caused by *M. TUBERCULOSIS* organisms that are resistant to at least isoniazid and rifampin, with or without resistance to other drugs.

MYCOBACTERIUM TUBERCULOSIS (MTB) COMPLEX is a term frequently seen on laboratory reports for positive AFB cultures. The complex includes *M. tuberculosis* and four other TB-causing mycobacteria: *M. bovis*, *M. africanum*, *M. canetti*, and *M. microti*. A report indicating MTB complex is generally considered to be confirmation of tuberculosis and an indication for treatment for TB disease.

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) was the former nomenclature for a room designated for the isolation of patients with contagious TB disease, with adequate directional airflow, air exchanges, and exhaust. The new name is an AIRBORNE INFECTION ISOLATION ROOM (AIIR).

NUCLEIC ACID AMPLIFICATION TESTS (NAAT), also sometimes referred to as *rapid tests* or *PCR tests*, identify genetic material unique to MTB directly in clinical samples. Detecting *M. TUBERCULOSIS* (MTB) complex with traditional laboratory culture methods takes one to eight weeks; however, direct molecular methods using nucleic acid amplification can detect MTB genetic material directly from specimens within three to five hours.

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 (CDC) and certification criteria from the National Institute for Occupational Safety and Health (NIOSH).

PURIFIED PROTEIN DERIVATIVE (PPD) tuberculin is the agent used for tuberculin skin testing (TST) to evaluate the likelihood that a person is infected with *M. TUBERCULOSIS*.

RECENT CONVERTOR is an individual who has a prior negative TST reaction that increases in reaction size with the current test by >10 millimeters (mm) within a period of two years, or a 5 mm incease in known contacts to a TB case; this is suggestive of recent infection with *M. TUBERCULOSIS*.

RIPE is an acronym for the standard, initial four-drug therapy: **R**ifampin, **I**soniazid, **P**yrazinamide, and **E**thambutol.

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 known or suspected infectious TB patients during transport or awaiting isolation.

TUBERCULOSIS DISEASE is a clinically active disease caused by MYCOBACTERIUM TUBERCULOSIS 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.

TST is the acronym for *tuberculin skin test*.

➔ *See discussion of the Tuberculin Skin Test in Section 3, Screening.*

TWO-STEP TESTING is baseline tuberculin testing that, if negative, is repeated to reduce the future likelihood of mistaking a boosted reaction for a new infection with *M. TUBERCULOSIS*. If the initial baseline TST result is classified as negative, a second test is repeated one to three 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*.

XDR-TB (extensively drug resistant TB) is defined as TB that is resistant to isoniazid and rifampin *plus* resistant to a fluoroquinolone AND resistant to at least one of three second-line injectable drugs, i.e., capreomycin, kanamycin or amikacin. It is an emerging global pathogen associated with very poor treatment outcomes.

REFERENCES

TB AND CORRECTIONS

Centers for Disease Control and Prevention. Prevention and control of tuberculosis in correctional and detention facilities: recommendations from CDC. *MMWR*. 2006;55(No. RR-09):1–53. Available at: http://www.cdc.gov/mmwr/PDF/rr/rr5509.pdf

EPIDEMIOLOGY

Bur S, Golub JE, Armstrong JA, et al. Evaluation of an extensive tuberculosis contact investigation in an urban community and jail. *Int J Tuberc Lung Dis*. 2003;7(Suppl 3):S417–S423. Available at: http://www.ingentaconnect.com/content/iuatld/ijtld/2003/00000007/A00312s3/art00017

Centers for Disease Control and Prevention. Drug-susceptible tuberculosis outbreak in a state correctional facility housing HIV-infected inmates – South Carolina, 1999–2000. *MMWR*. 2000;49(46):1041–1044. Available at: http://www.cdc.gov/mmwR/preview/mmwrhtml/mm4946a1.htm

Centers for Disease Control and Prevention. *Trends in tuberculosis, 2018*. Centers for Disease Control and Prevention website. Published October 29, 2019. Available at: https://www.cdc.gov/tb/publications/factsheets/statistics/tbtrends.htm

Centers for Disease Control and Prevention. Tuberculosis transmission in multiple correctional facilities – Kansas, 2002–2003. *MMWR*. 2004;53(32):734–738. Available at: http://www.cdc.gov/MMWR/preview/mmwrhtml/mm5332a2.htm

Jones TF, Craig AS, Valway SE, Woodley CL, Schaffner W. Transmission of tuberculosis in a jail. *Ann Intern Med*. 1999;131:557–563. Available at: http://www.ncbi.nlm.nih.gov/pubmed/10523215

World Health Organization. *TB Burden Estimates*. World Health Organization Web site, Programmes/Tuberculosis (TB). Available at: http://www.who.int/tb/country/data/download/en/index.html. Accessed December 30, 2019.

DIAGNOSIS AND TREATMENT

American Thoracic Society and Centers for Disease Control and Prevention. Targeted tuberculin testing and treatment of latent tuberculosis infection. *Am J Respir Crit Care Med*. 2000;161:S221–247. Available at: http://www.cdc.gov/mmwr/PDF/rr/rr4906.pdf

Borisov AS, Morris SM, , Njie GJ, et al. Update of recommmendations for use of once-weekly isoniazid-rifapentine regimen to treat latent *Mycobacterium tuberculosis* infection. *MMWR*. 2018;67:723–726. Available at: https://www.cdc.gov/mmwr/volumes/67/wr/mm6725a5.htm?s_cid=mm6725a5_w

Centers for Disease Control and Prevention. Notice to readers: revised definition of extensively drug-resistant tuberculosis. *MMWR*. 2006;55(43):1176. Available at: http://www.cdc.gov/MMWR/preview/mmwrhtml/mm5543a4.htm

Centers for Disease Control and Prevention. Recommendations for use of an isoniazid-rifapentine regimen for direct observation to treat latent *Mycobacterium tuberculosis* infection. *MMWR*. 2011;60(48):1650–1653. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6048a3.htm

Centers for Disease Control and Prevention. Tuberculosis associated with blocking agents against tumor necrosis factor-alpha – California, 2002–2003. *MMWR*. 2004;53(30):683–686. Available at: *http://www.cdc.gov/mmwr/PDF/wk/mm5330.pdf*

Centers for Disease Control and Prevention. Updated guidelines for the use of nucleic acid amplification tests in the diagnosis of tuberculosis. *MMWR*. 2009;58(01):7–10. Available at: *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5801a3.htm?s_cid=mm5801a3_e*

Centers for Disease Control and Prevention. Updated guidelines for using interferon gamma release assays to detect *Mycobacterium tuberculosis* infection – United States, 2010. *MMWR*. 2010;59(No RR-5):1–25. Available at: *http://www.cdc.gov/mmwr/PDF/rr/rr5905.pdf*

Cystic Fibrosis Foundation. Coughing and Huffing. Cystic Fibrosis Foundation (website). Available at: *https://www.cff.org/Life-With-CF/Treatments-and-Therapies/Airway-Clearance/Coughing-and-Huffing/.* Acceessed December 30, 2019.

Department of Health and Human Services. AIDS INFO. Guidelines for the use of antiretroviral agents in adults and adolescents with HIV. Drug-drug interactions. Department of Health and Humans Services Website. Available at: *https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/367/overview*. Accessed December 30, 2019.

Lewinsohn DM, Leonard MK, LoBue PA, et al. Official American Thoracic Society/Infectious Diseases Society of America/Centners for Disease Control and Prevention clinical practice guidelines: diagnosis of tuberculosis in adults and children. *Clinical Infectious Diseases 2017;64:111-115.* Available at: https://www.thoracic.org/statements/resources/tb-opi/diagnosis-of-tuberculosis-in-adults-and-children.PDF

Nahid P, Dorman SE, Alipanah N, et al. Official American Thoracic Society/Centers for Disease Control and Prevention/Infectious Diseases Society of America clinical practice guidelines: treatment of drug-susceptible tuberculosis. *Clin Infect Dis. 2016;*63:e147-e195. Available at: *https://academic.oup.com/cid/article/63/7/e147/2196792I*

New York City Department of Health and Mental Hygiene. *Tuberculosis: Clinical Policies & Protocols Manual*, 4th Edition, 2008. Available at: *https://www1.nyc.gov/site/doh/health/health-topics/tb-hosp-manual.page*

Saukkonen JJ, Cohn DL, Jasmer RM, et al. An official ATS Statement: hepatotoxicity of antituberculosis therapy. *Am J Respir Crit Care Med*. 2006;174:935–952. Available at: *https://www.thoracic.org/statements/resources/mtpi/hepatotoxicity-of-antituberculosis-therapy.pdf*

Schmit KM, Lobato MN, Lang S, Wheeler S, Kendig NE, Bur S. High completion rate for 12 weekly doses of isonizid and rifapentine as treatment for latent *Mycobacterium tuberculosis* infection in the Federal Bureau of Prisons. *J Public Health Manag Pract*. 2019;25;e1–e6. Available at: *https://phpa.health.maryland.gov/OIDPCS/CTBCP/CTBCPDocuments/2019%20Annual%20Meeting/High_Completion_Rate_for_12_Weekly_Doses_of.18.pdf*

Sterling TR, Villarino ME, Borisov AS, et al. Three months of rifapentine and isoniazid for latent tuberculosis infection. *N Engl J Med*. 2011;365:2155–2166. Available at: *https://www.nejm.org/doi/full/10.1056/NEJMoa1104875*

INFECTION CONTROL AND CONTACT INVESTIGATIONS

California Department of Public Health and California TB Controller's Association. Guidelines for the assessment of tuberculosis patient infectiousness and placement into high and lower risk settings. Published 2017, Available at: *https://ctca.org/wp-content/uploads/2018/11/InfectiousnessOctober2017.pdf*

Centers for Disease Control and Prevention. Guidelines for environmental infection control in health-care facilities: recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). *MMWR*. 2003;52(No. RR-10):1-42. Available at: *http://www.cdc.gov/MMWR/PDF/rr/rr5210.pdf*

Centers for Disease Control and Prevention. Guidelines for the investigation of contacts of persons with infectious tuberculosis: recommendations from the National Tuberculosis Controllers Association and CDC. *MMWR*. 2005;54(No. RR-15):1–47. Available at: *http://www.cdc.gov/mmwr/pdf/rr/rr5415.pdf*

Centers for Disease Control and Prevention. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care settings, 2005. *MMWR*. 2005;54(No. RR-17):1–140. Available at: *http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf*

DISCHARGE PLANNING

Centers for Disease Control and Prevention. United States-Mexico Public Health. CureTB. Centers for Disease Control and Prevention website. Available at: *https://www.cdc.gov/usmexicohealth/curetb.html.* Accessed: September 14, 2017.

APPENDIX 1. TUBERCULOSIS RISK FACTORS

RISK FACTORS FOR TB INFECTION	RISK FACTORS FOR TB DISEASE (IF INFECTED)

• Close contacts to infectious TB cases
• Foreign born from high-incidence countries*
• Injection drug users
• Residents/employees of:
  ➢ Prisons and jails
  ➢ Long-term care facilities
  ➢ Hospitals and long-term care facilities
  ➢ Homeless shelters
• Mycobacteriology laboratory personnel
• Children exposed to high-risk adults
	• HIV infected persons
	• TST convertors/recently infected
	• Fibrotic scarring on chest x-ray, consistent with old-healed TB
	• Injection drug users
	• Certain clinical conditions:
	  ➢ Organ transplant recipient
	  ➢ Immunosuppressant therapy (equivalent to 15 mg prednisone/day for 1 month)
	  ➢ TNF-alpha inhibitor therapy, for example:
	  ○ Adalimumab (Humira®),
	  ○ Certolizumab (Cimzia®)
	  ○ Etanercept (Enbrel®),
	  ○ Golimumab (Simponi®),
	  ○ Infliximab (Remicade®)
	  ➢ Silicosis
	  ➢ Diabetes mellitus
	  ➢ Chronic renal failure
	  ➢ Leukemia/lymphomas
	  ➢ Carcinomas of head, neck, lung
	  ➢ Underweight (>10% under ideal weight)
	  ➢ Gastrectomy/jejuno-ileal bypass

* **For information about TB incidence rates by country, see:** World Health Organization (home page on the internet). Global Tuberculosis Report. Available from: *http://www.who.int/tb/publications/global_report/en/*	

APPENDIX 2. TUBERCULIN SKIN TESTING GUIDELINES

SCREENING CRITERIA	TST negative inmates: • Upon incarceration within the BOP ➔ **EXCEPTION:** *If an inmate is in holdover status and has documentation of a negative TST in the last year while incarcerated, then that TST is considered valid for screening purposes.* • Annually • When TB is suspected • As part of TB contact investigation	
PRIOR POSITIVE TST	A baseline tuberculin skin test (TST) should generally be obtained on all new intakes to the BOP—regardless of an inmate's reported history of a prior positive TST—with the following exceptions: • Prior documentation of positive TST while inmate was incarcerated within BOP • History of a severe TST reaction, e.g., swollen, blistering (vesiculated) reaction • In holdover status and has documentation of a positive TST or IGRA ,and a negative CXR.	
PLACEMENT	• Specific training for placing and reading tests should be obtained. See *Administering and Reading TSTs* in Section 3. • Only BOP formulary tuberculin should be used. • Keep refrigerated, in original box, and store in the dark. • Skin tests should be administered as soon as possible after syringe is filled. • 0.1 ml (5 TU) tuberculin should be injected intradermally in the volar or dorsal surface of the forearm. • Tense white wheal (≥5 mm) should appear. *If not, replace at least 2 inches away.*	
READING	• Read 48 to 72 hours after placement. • Read palpated induration (not redness). • Measure transversely to the long axis of the forearm (across the forearm). • For no reaction, 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 scarring on CXR suggestive of inactive TB. • Clinical or radiographic findings suggestive of active TB. • TNF-alpha inhibitor drugs (i.e., infliximab, etanercept, adalimumab, certolizumab and golimumab).
	≥10 mm	All other inmates and correctional staff
TWO-STEP TESTING	Consider two-step testing for newly sentenced, foreign born inmates who have not had a TST in the last year. ***Procedure:*** Test as usual. If negative, repeat in 1 to 3 weeks. A positive reaction on the second test is considered a boosted skin test reaction (that is a baseline TST positive) and ***NOT*** a TST conversion. ➔ *If the inmate received a TST in the last year, this is considered equivalent to a two-step test and a second test is NOT needed.*	
BCG	BCG vaccine is used in many countries to prevent TB disease in young children and is not a contraindication for a TST. Ignore BCG history when interpreting TST results.	
PREGNANCY	Not a contraindication for tuberculin skin testing.	

APPENDIX 3A. STANDARD TREATMENT FOR LATENT TB INFECTION

ISONIAZID (INH) AND RIFAPENTINE (RPT)

12-week, once-weekly INH-RPT is the standard LTBI treatment regimen in the BOP. It should be utilized to treat LTBI unless there are contraindications for its use.

MEDICAL HISTORY

- Risk factors for TB
  ➔ See *Appendix 1*.
- Prior treatment for TB/LTBI
- Signs and symptoms of active TB (cough, fever, night sweats, weight loss)
- Review of CXR result
- Review of symptoms of hepatitis and liver disease
- Review of preexisting medical conditions

REVIEW CURRENT MEDICATIONS—especially those listed below, which have drug interactions with RPT and may be contraindicated or require closer monitoring.

Warfarin (Coumadin)

Antiepileptic drug therapy
- Phenytoin*
- Phenobarbital
- Carbamazepine
- Clonazepam

Calcium channel blockers, including:
- Amlodipine
- Diltiazem
- Felodipine
- Isradipine
- Nicardipine
- Nifedipine
- Nisoldipine
- Verapamil

Sulphonylureas (oral hypoglycemics), including:
- Glipizide
- Glyburide
- Glimepiride
- Chlorpropamide
- Tolbutamide

Clarithromycin/erythromycin

Anti-rejection medications

Azole antifungals

HIV antiretroviral therapy

Hepatitis C treatment

CONTRAINDICATIONS:

- Suspected/confirmed active TB
- Anticipated duration of incarceration is less than 12 weeks, unless high-risk for TB.
- Source case known to have TB organism resistant to RIF or INH
- HIV infection on ART (**EXCEPTION:** Efavirenz- and raltegravir- based regimens in combination with abacavir/ lamivudine or tenofovir disoproxil fumarate/emtricitabine.)
- Hepatitis C treatment
- Pregnancy
- Warfarin
- Phenytoin
- Hypersensitivity INH or rifamycins (rifampin, rifabutin)

DOSING GUIDELINES: Isoniazid (INH)

Kg	Pounds	INH Dose
≤ 40	≤ 88	15 mg/kg*
≥40	≥88	900 mg (three 300mg tabs)

INH is formulated as 100 mg and 300 mg tablets.
* Round up to the nearest 100 mg.

DOSING GUIDELINES: Rifapentine (RPT)

Kg	Pounds	RPT Dose
25.1–32	55–70	600 mg
32.1–49.9	71–109	750 mg
≥ 50	≥ 110	900 mg (max) (six 150mg tabs)

Rifapentine is formulated as 150 mg tabs (keep sealed until use in blister packs).

Pyridoxine (Vitamin B-6). Administer 50 mg once weekly with each dose of INH-RPT. If patient has peripheral neuropathy, increase dose to 100 mg once weekly with INH-RPT

ADVERSE EFFECTS:

- **Possible hypersensitivity reactions** occur in ~4% of patients including: fever, chills, headache, fatigue, red eyes, dizziness, urticaria, pruritis, musculoskeletal pain, and/or petichiae, and rarely hypotension.
- Hepatoxicity
- Thrombocytopenia
- Rifapentine turns urine and tears orange.

ALERT If patients present with fever, yellow eyes, dizziness, rash, or aches or greater than 1 day of nausea, vomiting, weakness, abdominal pain, or loss of appetite, then LTBI treatment should be withheld while the cause of symptoms is being determined.

BASELINE AND ONGOING MONITORING: See *Appendix 3c*.

APPENDIX 3B. ALTERNATIVE REGIMENS FOR TREATMENT OF LATENT TB INFECTION

<table>
<tr><th colspan="3">9-MONTH ISONIAZID (INH)</th></tr>
<tr><th>REGIMEN</th><th>DOSING</th><th>COMMENTS</th></tr>
<tr><td>9 month regimen</td><td>Twice-Weekly:
15 mg/kg
(max: 900 mg)
76 doses

Daily:
5 mg/kg
(max: 300 mg)
270 doses</td><td>Alternative regimen if 12-week INH-RPT is contraindicated. Prescribe 9-month INH if LTBI treatment is indicated (e.g., contact to TB case), and inmate has a short length of stay.

Give pyridoxine (B6) 50 mg daily per dose of INH to prevent INH-associated peripheral neuropathy (may increase pyridoxine to 100 mg if neuropathy occurs or if there is a prior diagnosis of neuropathy).

ADVERSE EFFECTS

• Hepatic enzyme elevation
• Hepatitis
• Peripheral neuropathy
• Mild central nervous system effects</td></tr>
<tr><th colspan="3">DAILY RIFAMPIN (RIF)</th></tr>
<tr><th>REGIMEN</th><th>DOSING</th><th>COMMENTS</th></tr>
<tr><td>• 4 months

• 6 months for HIV-seropositive</td><td>Daily Only:
10 mg/kg
(max: 600 mg)
4 months= 120 doses

6 months= 180 doses</td><td>Alternative regimen if INH is contraindicated or adverse reaction is suspected due to INH. Efficacy data are not as strong as for isoniazid; therefore, isoniazid is preferred.

Rifampin has numerous drug interactions – see list on Appendix 3a for drug interactions with rifapentine (RPT).

ADVERSE EFFECTS

• Rash
• Hepatitis
• Fever

• Thrombocytopenia
• Flu-like symptoms
• Orange-colored body fluids (urine, tears)</td></tr>
</table>

APPENDIX 3C. TREATMENT OF LTBI: BASELINE AND ONGOING MONITORING

ALWAYS rule out TB disease with a CXR & symptom screen prior to starting LTBI treatment.			
	12-week INH-RPT*	**9-month INH***	**4-month RIF***
Baseline chest radiograph (PA) (within 6 mos.; 1 mo. if HIV-infected)	X	X	X
Place on Medical Hold (BEMR/SENTRY)	X		
BASELINE LABS			
HIV [1]	X	X	X
HbsAg [1] and Anti-HCV [1]	X	X	X
ALT/AST (obtain bilirubin if elevated)	X	X	X
LAB MONITORING			
For inmates with the following hepatic risk factors, obtain ALT/AST after 4 wks of treatment & periodically thereafter: Abnormal baseline ALT/AST, HIV infection, chronic liver disease (due to alcohol/viral hepatitis/other causes), other hepatotoxic drugs prescribed, pregnancy, history of adverse reaction to LTBI. ➔ ***Discontinue LTBI treatment if ALT or AST is greater than 3 times the upper limit of normal (if associated with symptoms) and greater than 5 times the upper limit of normal (if no symptoms).***			
BASELINE/ONGOING SCREENING FOR ADVERSE REACTIONS (recorded in BEMR Latent TB Flow Sheet)			
	INH-RPT Weekly	**INH Monthly**	**RIF Monthly**
Numb hands/feet	X	X	X
Headache	X	X	X
Seizure	X	X	X
Vision decrease	X	X	X
Memory loss	X	X	X
Appetite loss	X	X	X
Nausea/vomiting	X	X	X
Yellow skin or eyes	X	X	X
Fatigue	X	X	X
Weight loss	X	X	X
Abdominal pain	X	X	X
Brown urine	X	X	X
Diarrhea [2]	X		X
Dizziness [2]	X		X
Fever or chills [2]	X		X
Rash or hives [2]	X		X
Sore muscles or joints [2]	X		X
[1] *Only obtain HIV, hepatitis B, and hepatitis C serologies if they were not previously obtained in the BOP. Testing for HCV infection is recommended for all inmates. Screening for hepatitis B infection is recommended if risk factors are present.* [2] *Record in the "Comments" section of the BEMR Latent TB Flow Sheet.*			
Count doses to date and record in BEMR Latent TB Flow Sheet "Comments"	X	X	X
TOTAL DOSES FOR COMPLETION	12 weekly	76 twice-weekly	120 daily (180 if HIV)
Clinician Evaluation			
Inmates should be clinically evaluated by the responsible physician/advanced practice provider as follows: treatment initiation, if signs and symptoms of adverse events and whenever treatment is interrupted .			
Treatment Completion			
To complete INH-RPT treatment regimen, at least 11 doses should be ingested within a 16-week time period.			
* ***INH*** *= isoniazid,* ***RPT*** *= rifapentine,* ***RIF*** *= rifampin*			

APPENDIX 4. TB CASE MANAGEMENT CHECKLIST

*This checklist is meant to guide BOP clinicians and Infection Prevention & Control (IP&C) Coordinators in the management of inmates with suspected TB disease (i.e., symptoms of TB disease and/or an abnormal CXR consistent with TB). The **16 STEPS** do not necessarily need to take place in numerical order, and may occur simultaneously.*

☐ 1. Conduct initial clinical assessment. (Physician/Advanced Practice Provider)

a) Tuberculin skin test. Also consider QuantiFERON or T-Spot if TB is suspected and TST is negative.

ALERT: *TST is "false negative" in 25% of persons diagnosed with TB disease.*

ALERT: *A negative TST or IGRA does not rule out TB disease.*

b) Obtain chest x-ray (posterior-anterior (PA) and lateral views if TB is suspected).

- The chest x-ray must be obtained as soon as possible if symptoms of TB disease.
- If TB symptoms, request STAT CXR reading. If possible, the ordering clinician should also provide a "wet reading" (immediate impression). Forward reports to the Clinical Director.

ALERT: *In HIV infected patients with TB disease, the TST and/or CXR may be negative (or the CXR may have an atypical presentation).*

c) Evaluate for TB signs and symptoms—cough of two or more week's duration and systemic symptoms (e.g., night sweats, fever, chills, unexplained weight loss, fatigue, anorexia, hoarseness).

ALERT: *Inmates with TB disease may appear healthy and deny symptoms.*

d) Obtain weight and compare to previous weights.

e) Obtain medical history, including:

- **TB history:** History of TB exposure, prior TST or IGRA, prior TB infection or disease.
- **Risk factors for TB infection**: Country of origin, history of injection drug use, incarceration, homelessness or long term care.
- **Medical conditions that increase the risk for developing TB disease, if infected:**
  - HIV infection
  - TST conversion in previous 2 years
  - Fibrotic scarring on chest x-ray, consistent with old-healed TB
  - Diabetes mellitus
  - Chronic renal failure
  - Injection drug use
  - Organ transplant recipient
  - Immunosuppressant therapy (equivalent to 15 mg prednisone/day for 1 month)
  - TNF-alpha inhibitor therapy (e.g.,
    - adalimumab (Humira®),
    - certolizumab (Cimzia®)
    - etanercept (Enbrel®),
    - golimumab (Simponi®),
    - infliximab (Remicade®)
  - Silicosis
  - Leukemia/lymphomas
  - Carcinomas of head, neck, lung
  - Underweight (>10% under ideal weight)
  - History of gastrectomy/jejuno-ileal bypass
- **Risk factors for multiple drug resistant (MDR) TB:** Prior TB treatment, immigration from or extended travel to a country with a high incidence of MDR-TB.

f) Physician or advanced practice provider shall perform physical examination.

g) Baseline laboratory tests: HIV, fasting CMP (comprehensive metabolic panel), uric acid, CBC with platelets. Testing for HCV infection is recommended for all inmates and should be performed if not previously tested. Screening for hepatitis B infection is recommended if risk factors are present.

☐ 2. Notify health services and correctional leadership.

Immediately notify institution leadership about suspected TB case. If transport to a hospital for isolation is indicated, then advise regarding the need for N-95 fit-tested officers for transport. If wearing an N-95 respirator, facial hair cannot interfere with the respirator seal.

☐ 3. Initiate respiratory protection and isolation.

- **Inmates with suspected TB should be placed in an airborne infection isolation room (AIIR)** immediately (either in the facility or transported to a community hospital).
  - While awaiting isolation, the inmate must wear a surgical mask. Replace mask if it becomes wet or torn.
  - Place inmate in low traffic area until he/she can be isolated.
  - Fit-tested staff must wear an N-95 respirator mask when in contact with the patient.
- **Determine where inmate will be isolated.**
  - **If facility has an AAIR:**
    - Was room validated in last year? (If not, send inmate to hospital.)
    - Monitor AIIR daily while in use (tissue test daily for negative pressure).
    - Assure that inmate is seen *daily* while isolated, with clinical encounter documented.
  - **If facility does not have an AIIR, then transport inmate to a local hospital for isolation and diagnostic evaluation:**
    - Inmate wears surgical mask. Staff wear fit-tested N-95 respirator mask.
    - Contact hospital Emergency Department and Infection Prevention staff to notify them of case & establish point of contact.
    - Send the TB Hospital Letter (*Appendix 11*) to the hospital, customized with clinical information about the inmate.

☐ 4. Report TB suspect case.

Report suspected TB cases within one working day (utilizing the *BP-A0665 form*) to:

- **Regional/Central Office** (uploading ***BP-A0665*** form into Reportable Infectious Disease (RID) System).
- **Local Health Department** (The *BP-A0665* form can substitute for health department report form.)
- **Scan form and updates into BEMR Documents Manager** ("Flowsheet" labeled "TB Report").

☐ 5. Participate in TB case management teleconference.

Schedule conference call with Regional QM Coordinator to review plan of care (especially facilities that rarely diagnose TB). Consider including facility health services leadership and executive staff.

☐ 6. Collect sputum specimens.

- **Obtain three sputum specimens** (see *Appendix 5, Sputum Collection Procedures*)**:**
  - At least 8 hours apart, including at least one early AM specimen using Huff Cough Technique.
  - If necessary, induce sputum (see *Appendix 5*).
  - If possible, use your local/state health department lab for specimens.
  - Sputum request should include: AFB smears, cultures, and nucleic acid amplification (NAAT/PCR/DNA) test.
  - A bronchoscopy specimen may be substituted for one sputum specimen. If bronchoscopy is done, obtain sputum after bronchoscopy.
- **Obtain sputum smears & NAAT/PCR results** (~24 hours).

ALERT: *Negative AFB smears from sputum or bronchoscopy do NOT rule out active TB!!*

☐ 7. Place on Medical Hold.

Place on Medical Hold in both BEMR and SENTRY.

☐ 8. Conduct vision tests prior to TB treatment initiation.

Vision tests (required for ethambutol): Snellen (visual acuity) and Ishihara (color vision plates)

☐ 9. Initiate TB Treatment.

- **4-drug daily Rifampin/Isoniazid/Pyrazinamide/Ethambutol (RIPE) *plus* pyridoxine (vitamin B6) 50 mg** with each dose. See *Appendix 6a* and *Appendix 6b* for prescribing information.
  - *If a different regimen is prescribed, contact Regional/Central Office to discuss.*
- **Check with pharmacist to assure correct weight-based doses for pyrazinamide/ethambutol.**
  - ***All medication doses must be directly observed. Place on pill line.***
  - ***Completion of treatment is based upon number of COUNTED DOSES ingested, NOT on the amount of time elapsed.*** See *Appendix 6b*.

☐ 10. Initiate Discharge Planning.

Determine Projected Release Date (PRD). Immediately begin release planning if inmate's PRD is before anticipated treatment completion. See *Section 9, Discharge Planning*.

- *The updated BP-A0665 form is used as the referral form for inmates who are releasing before the TB diagnostic work-up or treatment is complete.*

☐ 11. Initiate contact investigation, if indicated.

See *Section 7* and *Appendix 8* to determine if contact investigation is indicated. Consult with Regional Quality Improvement/Infection Prevention & Control Consultants.

☐ 12. Assess if isolation can be discontinued.

Regularly determine if isolation can be discontinued (see criteria in *Appendix 7*). If isolation extends greater than 14 days, hold weekly case conferences to assure that isolation is discontinued AS SOON AS POSSIBLE.

☐ 13. Clinician Evaluation

At a minimum, patients on treatment for active TB disease should be evaluated by a physician or qualified advanced practice provider (with physician review) at:

- Initiation of treatment
- At ~2 months of treatment
- If signs and symptoms of adverse reactions or lack of clinical response
- Whenever treatment is interrupted
- At treatment completion
- Monthly throughout treatment if drug resistant TB, drug intolerance or HIV co-infection

Inmates with baseline elevations of liver transaminases or other complicating medical conditions should be followed closely.

☐ 14. Monitor for medication compliance, treatment response, and adverse reactions.

Monitor weekly for the first few weeks, and then at least monthly. Utilize the clinical encounter for Active TB Monitoring in BEMR to record results of monitoring.

- **TB symptom review:** Coughing, coughing up blood, fever, night sweats, chest pain
- **Adverse Reactions:** Nausea, abdominal pain, vomiting, dark urine, decreased appetite, fatigue, headache, joint pain, memory loss, nausea, numbness in hands/feet, rash/itching, seizure, vision decrease, yellow skin or eyes.
- **Weight:** Assess for weight gain if weight loss occurred initially.
- **Bacteriology:** Obtain sputum specimens in AIIR or outside.
  - If initially AFB sputum smear positive, then obtain 3 sputum specimens weekly until 3 consecutive negative AFB smears.
  - Obtain 3 sputum specimens monthly at least 8 hours apart, including at least one early morning sputum, until at least 2 consecutive negative cultures (culture conversion).
    - ➔ See *Appendix 6c* if culture positive after 56 doses of RIPE.
  - Obtain all smear, NAAT, culture reports. Record results on the *BP-A0665* form with the lab accession numbers.
  - For culture-positive patients, obtain drug susceptibility reports.
- **ALT/AST: Perform monthly if any of the following risk factors:**
  - Abnormal baseline ALT/AST; HIV; chronic liver disease (due to alcohol/viral hepatitis/other causes); other hepatotoxic drugs prescribed; pregnancy; history of adverse reaction to TB medications
- **Vision (only while on Ethambutol):** Monthly Snellen and Ishihara. For patients on ethambutol for more than 3 months, vision should be assessed every 3 months by an optometrist.
- **Chest Radiograph (CXR):**
  - Ongoing CXR monitoring is done only if clinically indicated.
  - If AFB cultures are negative at 6-8 weeks, then obtain CXR after 56 doses of treatment. Request CXR comparison with prior CXRs.
    - ➔ See *Section 6*, *Culture-Negative TB*.
- **Medication Monitoring:**
  - At least weekly, review medication administration records to assess medication compliance.
  - At least monthly, count and record total doses to-date.
  - Do not switch to two drugs (INH/rifampin) until drug susceptibility is known and pyrazinamide has been given for a total of 2 months (56 doses). ***EXCEPTION:*** culture-negative TB
- **Update *BP-A0665 TB Case/Suspect Report & Referral Form*.**
  As additional information becomes available (e.g., new labs, susceptibility reports, dose counts at completion of treatment phases), update form & scan updates into BEMR. Upload into RID System.

☐ 15. Complete final steps after treatment completion.

- **Discontinue Medical Hold.**
- **Obtain end-of-treatment CXR** (to serve as a baseline CXR for future comparisons).
- **Perform final dose count** (record in clinical encounter and *BP-A0665* form).

☐ 16. Complete and file final updated *BP-A0665* form.

Update form with all available information and file in Documents Manager and upload into RID System. If the inmate has left the facility make arrangements for the form to be scanned into the BEMR.

➔ ***This final BP A0665 form update is a critically important record tracing the history of the patient's diagnostic work-up and treatment for TB, to be available for future reference.***

APPENDIX 5. SPUTUM COLLECTION / INDUCTION PROCEDURES

INFECTION CONTROL

SPUTUM EXPECTORATION OR INDUCTION for acid-fast bacilli (AFB) smear and culture should be performed in an airborne infection isolation room (AIIR). Facilities that lack AIIRs should have a local protocol for referral and safe transport of tuberculosis (TB) suspects to local hospital until the criteria for discontinuing isolation is met (see *Appendix 7*).

Inmates who are undergoing TB treatment, and who have met the criteria for discontinuation of isolation, should have three sputa obtained monthly—either in an AIIR or, if locally feasible, outdoors.

The 2016 CDC guidelines on TB diagnosis recommend **SPUTUM INDUCTION,** rather than flexible bronchoscopic sampling, for patients who are unable to produce sputum or for whom expectorated sputum is AFB smear negative.

EXPECTORATED SPUTUM COLLECTION PROCEDURE

- Collection of early morning specimens is preferred because of the overnight accumulation of secretions; however, you may collect specimens at any time for patients who have a deep cough that is readily productive. Taking a hot shower immediately prior to sputum collection can sometimes aid in sputum production.
- Sputum should be collected under direct observation. If the inmate is able to perform on their own, staff should exit the AIIR and observe from view window (if available); otherwise, staff should keep the respirator on and supervise the inmate. Keep the AIIR door closed.
- Equipment needed:
  - Wide-mouthed sterile container with a screw-top lid or a container provided by the lab
  - Lab slip
  - Cup of water, tissues
  - For staff: Respirator (N-95 or higher) and gloves
- Before the procedure, have the inmate remove any dentures and rinse mouth well with water (or drink water) to remove food particles and bacteria.
- Instruct the patient to breathe deeply and cough from deep down in the lungs. Instruct them that saliva and upper respiratory secretions are not sputum and are not acceptable specimens. The **HUFF COUGH TECHNIQUE** below can improve specimen quality.

HUFF COUGH PROCEDURE

1. Sit up straight with chin tilted slightly up and mouth open.
2. Take a slow, deep breath to fill lungs about three quarters full.
3. Hold breath for two or three seconds.
4. Exhale forcefully, but slowly, in a continuous exhalation to move mucus from the smaller to the larger airways.
5. Repeat this maneuver two more times, and then follow with one strong cough to clear mucus from the larger airways.

Adapted from Cystic Fibrosis Foundation, 2019

- Assess the adequacy of the specimen. Specimen should consist a minimum of 3 ml (and ideally 5-10 ml) ml of thick, mucoid sputum, and not saliva or nasal secretions (i.e., a thin, clear sample is not acceptable).
- Patients who have difficulty producing sputum should undergo sputum induction (see next page).

SPUTUM INDUCTION PROCEDURE

SPUTUM INDUCTION is a procedure for obtaining sputum from patients who have difficulty producing it spontaneously. In this procedure, patients inhale a mist of nebulized, sterile normal saline that irritates their airways, causing them to cough and produce respiratory secretions.

- Sputum induction must be ordered by a physician and supervised by a trained staff member.
- Sputum induction must be performed in a functioning AIIR or sputum induction booth.
- Additional equipment for obtaining an induced sputum include:
  - Nebulizer and table to support nebulizer
  - Disposable tubing with cup and lid
  - Sterile normal saline
- Prepare the equipment:
  - Place sterile normal saline in the nebulizer chamber to the level marked on the chamber.
  - Place a small amount of normal saline in the cup portion of the disposable nebulizer tubing.
  - Insert the cup into the nebulizer.
  - Test to make sure the nebulizer is functional by turning it on and checking to see whether it produces a mist.
- Prepare the patient:
  - Explain the purpose of the procedure.
  - Orient the patient to the nebulizer and demonstrate how it works.
  - Provide water in a disposable cup and explain that drinking it will help with the procedure.
- Provide the patient with these instructions:
  - Inhale the aerosol by taking 3 or 4 deep, slow breaths through the mouth without placing his/her mouth on the tubing.
  - Cough vigorously (if coughing does not start spontaneously).
  - Cover their mouth with a tissue when coughing unless expectorating into the sputum container.
  - Continue trying to cough and to expectorate after inhaling the mist.
  - Expectorate all sputum into the sputum container.
  - Cover the sputum container tightly after collecting about 1 tablespoon of sputum.

INFECTION CONTROL PRACTICES

- Wear respirator when in the room with the patient. Wear gloves when handling specimens.
- Always wash hands with soap and water before procedures and after handling specimen containers.

SAMPLE LABELING, HANDLING, AND TRANSPORT

- Labeling:
  - In the presence of the patient, label the side of the specimen collection container to include: name of the inmate, registration number, date of birth, and date and time of collection.
  - Lab slip should include inmate identifiers, facility name and address, and the reason for exam (i.e., active TB suspect, TB chemotherapy follow-up).
  - Aerosol induced sputum samples should be clearly labeled as “induced sputum.”
  - On the lab slip, also record the visual appearance of the sample, including the color (e.g., white, green, red, or brown), the consistency (e.g., thick and mucoid), and the amount (ml).
- Place the sample in a biohazard bag. Refrigerate the sample until transported.
- Preferably on the day of collection, transport or mail the sample to the laboratory, by airmail or overnight courier.

Adapted from: New York City Department of Health and Mental Hygiene, Bureau of Tuberculosis Control. Tuberculosis Policies and Protocols, 4th Edition, March 2008.

APPENDIX 6A. STANDARD TUBERCULOSIS TREATMENT REGIMEN – 6 MONTHS

INITIAL PHASE 2 MONTHS*	CONTINUATION PHASE 4 MONTHS*	TOTAL DOSES
DRUGS: RIF, INH, PZA, EMB (RIPE) • 8 weeks daily therapy • **TOTAL:** 56 **COUNTED DOSES**	**DRUGS: RIF, INH** • 18 weeks daily therapy • **TOTAL:** 126 **COUNTED DOSES**	**56 DOSES RIPE** **+ 126 DOSES RIF& INH** **182 TOTAL DOSES**
PYRIDOXINE (Vitamin B6) 50 mg should be administered with **EACH** dose of TB medication to prevent INH-associated peripheral neuropathy.		

➔ *Medication doses are weight-based.*

➔ *All doses are administered once daily (no divided doses).*

KEY: RIF = rifampin, **INH** = isoniazid, **PZA** = pyrazinamide, **EMB** = ethambutol

CLINICAL NOTES:

- Do not wait for confirmation of TB diagnosis to start treatment.
- Report suspected or confirmed cases to Regional and Central office via the RID System and to the local health department using *BP-A0665* form.
- Ingestion of all drug doses should be directly observed by a health care worker.
- For culture positive cases, do not switch to two drugs (RIF/INH only) until susceptibility to both INH and RIF has been demonstrated .
- See *Appendix 4* for recommended baseline and monthly medical monitoring.

*** EXCEPTIONS:**

Refer to Appendix 6c for the following exceptions to the standard regimen:

- HIV infection
- Pregnancy
- Drug resistance
- Failure to convert sputum cultures in 2 months (after 56 doses)
- Bone/joint TB
- TB meningitis

APPENDIX 6B. FIRST-LINE TUBERCULOSIS DRUG DOSING AND DOSE COUNTS

TB DRUG DOSING (MG) BY WEIGHT					
LB	**KG**	**RIF**	**INH**	**PZA**	**EMB**
88–120	**40–55**	600	300	1000	800
121–165	**56–75**	600	300	1500	1200
166–198+	**76–90+**	600	300	2000	1600

KEY: RIF = rifampin, **INH** = isoniazid, **PZA** = pyrazinamide, **EMB** = ethambutol

➔ *For dosing with renal insufficiency/dialysis, see Table 12 in CDC guidance on Treatment of Drug Susceptible Tuberculosis*: *https://academic.oup.com/cid/article/63/7/e147/2196792*

TB TREATMENT – DOSE COUNT CHART	
INITIAL PHASE	**TOTAL DOSES**
RIPE (RIF, INH, PZA, EMB) Initial Phase = 8 weeks	56 daily doses
CONTINUATION PHASE	**ADDITIONAL DOSES // TOTAL DOSES***
CULTURE NEGATIVE TB (4-MONTH TREATMENT) (RIF, INH) Continuation Phase = 8 additional weeks (Total treatment = 16 weeks)	56 *additional* daily doses // Total 112 doses
STANDARD 6-MONTH TREATMENT (RIF, INH) Continuation Phase = 18 additional weeks (Total treatment = 26 weeks)	126 *additional* daily doses // Total 182 doses
9-MONTH TREATMENT (RIF, INH) Continuation Phase = 31 additional weeks (Total treatment = 39 weeks)	217 *additional* daily doses // Total 273 doses
12-MONTH TREATMENT (RIF, INH) Continuation Phase = 44 additional weeks (Total treatment = 52 weeks)	308 *additional* daily doses // Total 364 doses
* **TOTAL DOSES** = **INITIAL PHASE** doses **PLUS** additional doses during **CONTINUATION PHASE**	

APPENDIX 6C. TUBERCULOSIS TREATMENT REGIMENS IN SPECIAL SITU=-0IONS

SITUATION	MONTHS OF RX*	COMMENTS
Cavitary CXR & Culture (+) after 2 mos.	9	If initial CXR shows cavitation and sputa remain culture positive after 56 doses of RIPE treatment, the continuation phase (INH and RIF) should be extended an additional 3 months (lasting 7 months instead of 4 months), for a total of 9 months of treatment. **DOSES:** RIPE = 56 plus RIF/INH = 217
Culture-negative TB	4	For persons with suspected pulmonary TB who have negative cultures, but clinical or radiographic improvement after 56 doses, the continuation phase (INH and RIF) is 8 additional weeks. **DOSES:** RIPE=56 plus RIF/INH=56 **EXCEPTION:** If HIV seropositive or cavitation on CXR, then the continuation phase is 18 additional weeks. **DOSES:** RIPE=56 plus RIF/INH=126
Bone/Joint TB	9	Extend standard therapy to total 9 months. **DOSES:** RIPE = 56 plus RIF/INH = 217
CNS TB	9 to 12	For TB meningitis, extend standard therapy for a total of 9 to 12 months. Adjunctive dexamethasone use is often recommended. Consult Regional/Central Infection Prevention & Control.
HIV Co-Infection	usually 6	Treatment of HIV co-infected TB patients should be provided in consultation with an HIV/TB expert. Refer to *HIV Co-Infection*, in Section 6. Patients on protease inhibitors and non-nucleoside inhibitors may need medication adjustments because of drug interactions with rifampin. Consult DHHS HIV guidelines on drug-drug interactions: *https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/284/pi-drug-interaction* **NOTE:** In the rare instance that inmate is not treated with ART, TB treatment is extended to 9 months.
Pregnancy	9	Start with INH, RIF, and EMB (not PZA). Discontinue EMB once INH and RIF susceptibility known. Continue INH and RIF. Give equivalent of pyridoxine 50 mg/day (unless already in prenatal vitamin). Contraindicated: Streptomycin, Amikacin, Fluoroquinolones. **DOSES:** RIF/INH/EMB=56 plus INH/RIF 126
Renal Disease	6	If creatinine clearance <30 ml/min. or on renal dialysis, alter dosing. If on hemodialysis, give 3 times weekly after dialysis, on the same day as dialysis. (For dosing, see Table 12 in CDC guidance on *Treatment of Drug Susceptible Tuberculsosis*: *https://academic.oup.com/cid/article/63/7/e147/2196792*)
TREATMENT REGIMENS FOR DRUG RESISTANCE OR INTOLERANCE		
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. **NOTE:** If low level INH resistance is detected some clinicians will continue INH.
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 a shorter duration of therapy (9 months) is desired.
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 the organism is sensitive.
***** If not listed under **COMMENTS**, see **DOSE COUNTS** in *Appendix 6B*. **KEY: RIF** = rifampin, **INH** = isoniazid, **PZA** = pyrazinamide, **EMB** = ethambutol		

APPENDIX 7. CRITERIA FOR DISCONTINUATION OF AIRBORNE INFECTION ISOLATION AND RETURN OF AN INMATE WITH SUSPECTED TB TO GENERAL POPULATION

The following criteria must be met before a BOP inmate who is diagnosed with suspected or confirmed TB can be returned to the general inmate population. This criteria applies to inmates hospitalized in a community hospital or being worked up for TB in a facility airborne infection isolation room (AIIR).

DIAGNOSTIC WORK-UP

The TB diagnostic workup should include three sputum specimens for acid fast bacilli (AFB):

- Collected at least 8 hours apart, including at least one early morning specimen.
- Test for AFB smear and culture
- Request a nucleic acid amplification test (NAAT/PCR) for at least one test.

→ *If a bronchoscopy is performed, then bronch specimen can serve as one of the specimens. Obtain a sputum after bronchoscopy (significantly higher yield for AFB).*

Important Clinical Notes	• Negative AFB smears from sputum & bronchoscopy do NOT rule out active TB. • In general, avoid use of fluoroquinolones (e.g., ciprofloxacin, levofloxacin) if TB is in differential diagnosis. They are highly effective agents against TB and can confuse the diagnostic work-up.

CRITERIA FOR DISCONTINUATION OF ISOLATION / RETURN TO GENERAL INMATE POPULATION

Before an inmate can be returned to general population, the inmate must EITHER …

1. Have an alternative, non-contagious diagnosis that clearly explains the pulmonary abnormality.

OR

2. Meet one of the **CRITERIA FOR DISCONTINUATION OF ISOLATION** listed below:

IF AFB & CXR RESULTS …	AND	IF NAAT…	THEN, CRITERIA FOR DISCONTINUATION OF ISOLATION ARE …
If AFB smear neg x 3 AND Non-cavitary CXR	**AND**	- Neg ***OR*** - Pos ***OR*** - Not done	• At least 5 days of RIPE[a] treatment ***AND*** • If symptomatic, then definite clinical improvement [b]
If AFB smear neg x 3 AND Cavitary CXR	**AND**	- Neg ***OR*** - Pos ***OR*** - Not done	• At least 14 days of RIPE[a] treatment ***AND*** • If symptomatic, then definite clinical improvement [b]
If AFB smear positive	**AND**	- Neg	• Obtain expert consultation through Regional/Central Office Infection Prevention & Control
If AFB smear positive	**AND**	- Pos ***OR*** - Not done	• At least 14 days of RIPE[a] treatment ***AND*** • If symptomatic, then definite clinical improvement [b] ***AND*** • Subsequent negative AFB smears x 3

CRITERIA FOR DISCONTINUATION OF ISOLATION FOR MDR-TB

1. Three consecutively negative sputum smears and no subsequent positive smear; ***AND***
2. At least 14 daily directly observed doses of treatment for MDR-TB taken and tolerated; ***AND***
3. Evidence of clinical improvement [c]; ***AND***
4. At least 2 consecutive negative sputum cultures without a subsequent positive culture.

[a] **RIPE** = rifampin (RIF), isoniazid (INH), pyrazinamide (PZA), ethambutol (EMB)
[b] **Clinical Improvement** = i.e., resolution or significant reduction in cough if inmate initially presents with a cough; improved sense of well-being; weight gain if prior weight loss
[c] **MDR-TB** = multiple-drug resistant TB (TB resistant to at least INH and RIF)

Adapted from: California Department of Public Health. Guidelines for the Assessment of Tuberculosis Patient Infectiousness and Placement into High and Lower Risk Settings (2017).
Available from: *https://ctca.org/wp-content/uploads/2018/11/InfectiousnessOctober2017.pdf*

APPENDIX 8. TUBERCULOSIS CONTACT INVESTIGATION – CHECKLIST

After identification of a TB case or suspected case, the inmate should be immediately isolated, medically evaluated, and (if appropriate) treated.

- The case should be immediately reported to the local or state health department.
- The contact investigation steps outlined below may overlap in time.
- Close contacts should be evaluated promptly.

√	Date	Task
		1. Notify correctional management officials.
		2. Perform clinical assessment of the TB case (including retrospective chart review): • Previous exposure to TB • TB risk factors (*Appendix 1*) • History of TB symptoms (cough, fever, night sweats, etc.). Weight history • Chest radiographs • TST/IGRA • Bacteriology (AFB smear/culture/susceptibilities), nucleic acid amplification tests • HIV status • Other medical conditions
		3. Interview case. For AFB smear-positive or cavitary cases, interview within 1 day; for all others, interview within 3 days. Re-interview in 7–14 days. Interview for: TB symptom history/onset of symptoms and close contacts in correctional facility and community (if relevant). See *Appendix 9, TB Contact Investigation Interview*.
		4. Determine the infectious period to determine how far back in time to go for investigation of TB contacts. • Generally: 12 weeks before symptom onset or first positive findings consistent with TB disease, 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 (include institution & regional health services & custody staff). • Identify team leader; identify 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 staff, and Central Office staff) regarding contact investigation strategy.
		7. Obtain index case traffic history (housing/work/school locations during infectious period). SENTRY pp37 (Housing = QTR, Education = EDU, Work = WRK).
		8. Tour the exposure sites (where case frequented during infectious period) with the facility HVAC (heating/ventilation/air conditioning) personnel and assess: • Number of inmates housed together • General size of airspace • Housing arrangements (cells/dorms) • Availability of data on inmates housed at same time • Ventilation: HVAC system (Recirculated air? Where does air move?) • Pattern of daily inmate movement (cafeteria, general areas)

Appendix 8, TB Contact Investigation – Checklist (page 1 of 2)

√	Date	Task
		9. Prioritize contacts. • Contacts who are HIV-infected, on TNF-alpha inhibitor treatment or immunosuppression for organ transplant are the highest priority contacts regardless of duration of exposure. • Otherwise prioritize contacts based upon duration and/or intensity of exposure. • Immediately refer to the health department the names of community contacts who are young children or who are HIV infected.
		10. Develop contact lists. 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). **NOTE:** The Office of Infection Prevention & Control can obtain lists of historic contacts upon request. Sample spreadsheets to manage data can be found on HSD/Infectious Disease Sallyport page.
		11. Conduct a medical record review of each high priority contact, to collect: • Prior TST and CXR results • History of treatment for latent TB infection or TB treatment • HIV status • Other high risk medical conditions
		12. Initiate medical evaluation of contacts (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. Isolate in an AIIR if TB is suspected. • **Prior TST positives** (HIV seronegative or unknown): ➢ Offer HIV counseling and testing and assess for symptoms at baseline & 8 weels after exposure ended. ➢ Do symptom review at baseline and 8 weeks after exposure ended. • **HIV-infected, TNF-alpha inhibitor, or organ transplant on immunosuppression therapy** (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 and TST at baseline and 8 weeks after exposure ended. • **Obtain CXR** if TST is positive.
		13. Make referrals for contact evaluation for inmates who are transferred or released in conjunction with Regional/Central Office.
		14. Determine the infection rates by exposure sites. • Infection rate = total # skin tested, divided by # whose TST has converted from neg to pos. • Calculate rates separately for U.S. born and foreign born inmates. • Decide whether or not to expand investigation beyond highest priority contacts.
		15. Conduct follow-up tuberculin skin testing. Perform at 8 or more weeks *after exposure ended.* • Perform record search in Sentry to determine current location of inmates. • Conduct 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 (see *Step 14* above).
		17. Write a summary report; submit through Warden to Regional and Central Offices.

Appendix 8, TB Contact Investigation – Checklist (page 2 of 2)

APPENDIX 9. TB CONTACT INVESTIGATION INTERVIEW

Purpose: The goal of interviewing the index case in a contact investigation is to gain the information needed for:

(1) establishing the infectious period; and

(2) identifying potential contacts.

Overview:

- It is critically important that time be spent establishing trust with the inmate before conducting the interview, and making sure that the inmate understands the purpose of the contact investigation. Use an interpreter if needed.
- The following questions should be used to guide the contact investigation interview. Depending on the inmate's responses, additional questions may be asked as follow-up on their answers.
- The inmate should be re-interviewed in 1–2 weeks to gain additional information and validate the answers.
- **DO NOT file interview documentation in the inmate's medical record.**

TB Patient Name: _____ **Registration #:** _____ **Facility Intake Date:** _____

Interviewer Name: _____ **Interview Date:** _____

1. Review the TB diagnosis with the inmate:

☐ Assess inmate's knowledge of the condition.

☐ Describe TB, how it is diagnosed and treated, and the treatment plan.

☐ Describe how TB is transmitted (airborne).

☐ Discuss the need to identify potentially exposed contacts.

2. Ask about the inmate's TB history:

a. Have you known anyone with a diagnosis of TB? ☐ YES ☐ NO. IF YES, where and when?

_____

b. Have you ever had a positive TB skin test? ☐ YES ☐ NO. IF YES, where and when?

_____

c. Have you ever been diagnosed with or treated for TB? ☐ YES ☐ NO. IF YES, where and when?

_____

3. Ask about the inmate's other medical history:

What other medical conditions do you have?

4. Ask about the inmate's history of TB symptoms:

YES	NO	Have you had any of the following symptoms?	IF X, how long have you had them? When did they start?
		Cough?	
		Coughing up blood?	
		Fever?	
		Chills?	
		Night sweats?	
		Unexplained weight loss?	___ pounds in ___ weeks
		Chest pain?	
		Hoarseness?	
Likely date of symptom onset: __/__/___			

TB Contact Investigation – Interview Questions (page 1 of 3)

5. Ask about the inmate's TB risk factors:

YES	NO	Please answer the following questions:	When? Where?
		Were you born outside the U.S.?	
		Have you traveled outside the U.S.?	
		Have you ever been homeless?	
		Have you ever used drugs? Which ones?	
		How much alcohol do you drink?	
		Before this incarceration, were you ever incarcerated?	

6. If symptoms began prior to incarceration, ask:

a. Where were you living? _____

b. Who were you living with? _____

7. Ask: Since __/__/___ (3 months before symptom onset) …

YES	NO	Have you been in the same room with:	Who? Where?
		Any infants or young children?	
		Anyone known to be HIV-infected?	

8. Please describe your previous day-to-day activities at this facility:

Time of Day	Daily Activities
Morning	
Mid-Day	
Afternoon	
Evening	

9. Ask: Has this been your pattern during the period since __/__/___ (3 months before symptom onset), or has the way you spend your time changed in any way?

Same	Changed	How and when did your daily pattern change?

10. Ask: Please tell me if you have been involved in any of the following activities …

YES	NO	Activity	Where?	When?	With whom?
		Watching TV?			
		Playing cards or games?			
		Religious services?			
		Recreation or sports?			
		Work?			
		Education?			
		Library?			
		Other?			
		Other?			

11. Ask: Who are your close friends that you spend time with? Are there any others whom you've spent time with that you would be concerned about getting exposed to TB?

12. Ask: Since __/__/___ (3 months before symptom onset), have you had any visitors? ☐ YES ☐ NO

Visitor Name	When Visited	Locating Information

13. Ask: Since __/__/___ (3 months before symptom onset), have you had lawyer visits? ☐ YES ☐ NO

Lawyer Name/Info	When Visited

14. Ask: Are there any staff members that you have had close contact with? ☐ Yes ☐ NO

Staff Name	Type of Contact

15. Ask: Is there any other information that might help identify anyone else you've been in contact with? Is there anyone else who you're concerned could have become infected with TB by being near you?

16. Ask: Do you have any questions about TB or the plans for your medical care?

APPENDIX 10. INSTRUCTIONS FOR TRANSPORT AND HOSPITAL ESCORT STAFF FOR INMATES WITH SUSPECTED OR CONFIRMED TB

Following is a one-page, printable checklist with detailed guidance on **RESPIRATORY PROTECTION** while escorting, transporting, and providing custody for inmates with suspected or confirmed infectious TB.

Instructions for Transport and Hospital Escort Staff for Inmates with Suspected or Confirmed Infectious TB

Preparing Inmate for Transport

- ☐ Instruct the inmate to wear a surgical mask over his or her mouth and nose. The mask will help to prevent TB germs from being released into shared air. The inmate should not wear an N-95 respirator mask.
- ☐ Prior to transport, the inmate should be placed in a low-traffic area and should wear the surgical mask.
- ☐ Escorting staff should instruct the inmate not to remove the surgical mask at any time outside the airborne infection isolation ("AII") room.
- ☐ Bring enough surgical masks for the inmate to wear for the entire journey.

Preparing Staff for Transport/Hospital Custody

- ☐ Only staff who have been fit-tested for an N-95 respirator mask in the last 12 months can transport or provide hospital escort for inmates with suspected infectious TB.
- ☐ Obtain sufficient supply of the appropriate brand, model, and size respirators for each of the staff involved in transport and hospital custody (as determined during annual fit-testing). See **NOTE** below under "hospital Custody."
- ☐ In accordance with OSHA regulations, the use of N-95 respirators is prohibited for any staff member who has facial hair that comes between the sealing surface of the face piece and the face of the wearer, because it is impossible to get a sufficient face seal.
- ☐ Each time the staff person puts on the respirator mask, a seal check must be performed to assure appropriate fit before exposure to the inmate. Printable seal check instructions are available at: *https://www.cdc.gov/niosh/docs/2018-130/pdfs/2018-130.pdf?id=10.26616/NIOSHPUB2018130*. Video instructions on performing a seal check are available at: *https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/donningdoffing.html*

Transport by Vehicle

- ☐ Inmates with suspected TB should not be transported with other inmates who do not have TB.
- ☐ Transport staff must wear N-95 respirator masks throughout the transport in accordance with OSHA regulations.
- ☐ Ventilation system should bring in as much outdoor air as possible. Set fan to high.
- ☐ DO NOT place air on recirculation mode.
- ☐ Upon conclusion of the vehicle's use, it is recommended that the vehicle be aired out for at least one hour before being used again.
- ☐ Respirators/masks can generally be disposed of in regular trash after use. If contaminated with blood or body fluids, they should be disposed of in a biohazardous waste container.

Hospital Custody Staff

- ☐ There needs to be an adequate supply of N-95 respirator masks for hospital escort staff in the appropriate make, model, and sizes. **NOTE:** The respirator masks supplied at the hospital may be a different type/size than the ones used for fit-testing in this institution. If so, they should not be used.
- ☐ All hospital escort staff must wear N-95 respirator masks whenever entering an "AII" room at the hospital. Officers who are stationed in the anteroom (small room located before the "AII" room), who are required to maintain custody for more than a few minutes, must wear an N-95 respirator mask. In accordance with OSHA regulations, the use of N-95 respirators is prohibited for any staff member who has facial hair that comes between the sealing surface of the face piece and the face of the wearer, because it is impossible to get a sufficient face seal.
- ☐ It is recommended that hospital escort staff continue the use of an N-95 respirator mask (even if the hospital has discontinued their use) until otherwise directed by the facility Clinical Director or designee. It is recommended that hospital escort staff notify their supervisor if the use of respirators has been discontinued by the hospital so that the supervisor can contact the Clinical Director with this information.

APPENDIX 11. TB HOSPITAL LETTER

This Appendix contains a two-page, printable TB Hospital Letter designed for use when an inmate with suspected TB is referred to a hospital with AII facilities for a clinical work-up.

Institution: _____

Federal Bureau of Prisons (BOP)

Date: ___/___/___

Inmate Last Name: _____ First:_____ DOB: ____/____ /____

Inmate Register Number: _____-_____

Dear Hospital Health Care Provider:

We have referred this BOP inmate to you for airborne infection isolation (AII) and a clinical work-up for suspected tuberculosis (TB) because we lack an available AII room in this facility. Clinical information includes:

Tuberculin Skin Test date: ____/____/____ ____ mm **Symptoms:** None

Cough x __ weeks Hemoptysis Fever Chills Night sweats Weight loss ___ lbs in ___ wks

CXR date ____/_____/_____ **Result:** _____

_____

Other:_____

To safely return this inmate to our congregate prison setting, the following criteria *must be met*:

(1) Active TB Treatment

- **If initially sputum AFB smear negative x 3 and noncavitary CXR** then ***5 days*** of weight-based **r**ifampin, **i**soniazid, **p**yrazinamide and **e**thambutol plus B6 (RIPE+B6) *with* evidence of clinical improvement (if initially symptomatic)
- **If initially sputum AFB smear positive or cavitary CXR** then 3 negative smears and a minimum of ***14 days*** of RIPE+B6 treatment *with* evidence of clinical improvement.

OR

(2)* Documentation of a confirmed *alternative diagnosis* that explains the pulmonary abnormality

* ***Important Note:*** *"Pneumonia" cannot serve as an alternative diagnosis UNLESS there is clinical improvement on antibiotic treatment that does not include a fluoroquinolone (e.g., levofloxacin, ciprofloxacin, moxifloxacin) because fluoroquinolones effectively treat active TB—confusing the diagnostic evaluation.*

A checklist for the TB clinical work-up is included on the following page. Please note that BOP inmates who are diagnosed with active TB are often both asymptomatic and sputum AFB smear negative. With our aggressive TB screening program we typically diagnose inmates early in the course of their TB disease process.

Thank you for your assistance!

If you have additional questions or concerns please reach out to me, the referring provider:

Name: _____ Position: _____Phone: _____ ***or***

Name: _____ Position: _____Phone: _____

Checklist for Return of Federal Inmate Being Evaluated For Suspected Tuberculosis

Inmate Last Name: _____ First:_____ DOB: ____/____ /____

Inmate Register Number: _____-_____ Institution: _____

Important:

Correctional Officers must wear a fit-tested N-95 respirator in the airborne infection isolation room and anteroom (if there is one) until airborne infection isolation is discontinued in consultation with the BOP physician.

The following is required to safely return an inmate to the congregate prison setting.

- ☐ **Report suspected TB case** to the local health department.
- ☐ **Obtain 3 sputum specimens** (induced if patient is asymptomatic) that are negative for AFB smear
  - ➢ **Specimens may be collected 8–24 hours apart**
  - ➢ **1 specimen may be from bronchoscopy but the other 2 should be from separate sputum collections**
    (*Note*: Bronchoscopies are often not necessary to rule in TB. If bronchoscopy is performed, it is recommended that sputums for AFB be obtained *after* bronchoscopy because they have higher yield post-bronchoscopy.)
  - ➢ It is preferred that 1-2 sputum tests for *M. tuberculosis* NAAT (nucleic acid amplification test) also known as TB PCR also be performed.
- ☐ **TB skin test** [TST (PPD)] unless obtained at BOP facility **or** **interferon gamma release assay** [IGRA (QFT gold, T-spot)]
- ☐ **HIV screen**
- ☐ **Baseline CBC, LFTs, creatinine**
- ☐ **Either of the following:**
  - ☐ **Active TB Treatment:**
    - ☐ ***If initially AFB smear negative x 3 and noncavitary CXR:*** Weight-based 4-drug therapy of **r**ifampin, **i**soniazid, **p**yrazinamide, and **e**thambutol plus **B6** (RIPE+B6) *x* ***5 days*** with clinical improvement (if initially symptomatic).
    - ☐ ***If initially AFB positive or cavitary CXR:*** Weight-based RIPE+B6 *for a* ***minimum of 14 days*** in addition to 3 negative, consecutively collected AFB smears.

  OR

  - ☐ **Documentation of a confirmed, non-contagious *alternative diagnosis* that explains the pulmonary abnormality**