APPENDICES

APPENDIX A: INTERNATIONAL CLASSIFICATION OF TUBERCULOSIS[1]

CLASS	TYPE	DESCRIPTION	FOLLOW-UP ACTION
0	No history of TB exposure; Not infected	• Negative result on IGRA or TST • No history of TB exposure • No evidence of LTBI or disease	None
I	TB exposure; No evidence of TB infection or disease	• History of exposure to person with *M. tuberculosis* • Negative result on IGRA or TST (given at least 8 to 10 weeks after exposure [post-window period])	None
II	TB infection; No disease	• Positive results on IGRA or TST • No clinical or radiographic evidence of active TB disease • Calcified granuloma on CXR • Negative bacteriological studies (smears and cultures) for TB if performed	Classify as contact, medical, population, or administrative risk Treat for LTBI, if indicated
III	Current TB disease	• Positive culture for *M. tuberculosis* and/or • Clinical, bacteriological, or radiographic evidence of current active TB • With or without a positive result on IGRA or TST	Treat for TB disease
IV	Previous TB disease	• Positive result on IGRA or TST • History of active TB in past or abnormal but stable or fibrotic radiographic findings • Negative bacteriologic studies (if done) • No clinical or radiographic evidence of current active TB disease	Conduct patient evaluation and consider re-treatment, as indicated
V (high)[2]	Current TB disease suspected	• Current TB symptoms[3] • Diagnosis pending • Expected to be Class III	Conduct patient evaluation and reclassify patient within two months
V (low)[2]	Previous TB disease suspected	• Diagnosis pending • Expected to be Class IV or abnormality unrelated to TB	Conduct patient evaluation and reclassify patient within two months

Adapted from: *Centers for Disease Control and Prevention. (2013). Core curriculum on tuberculosis: what the clinician should know. Atlanta, Georgia: United States Department of Health and Human Services; Centers for Disease Control and Prevention; National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention; Division of Tuberculosis Elimination. Retrieved from https://www.cdc.gov/tb/education/corecurr/pdf/corecurr_all.pdf.*

1. The International Classification of TB has been modified for use by BTBC. 2. The division of Class V into "high" or "low" categories is intended to improve case management and is specific to the BTBC; it is not part of the International Classification of TB. 3. Current TB symptoms or CXR findings consistent with active TB.

Abbreviations Used: BTBC=Bureau of Tuberculosis Control; CXR=chest radiograph; IGRA=interferon gamma release assay; LTBI=latent tuberculosis infection; *M. tuberculosis*=*Mycobacterium tuberculosis*; NYC=New York City; TB=tuberculosis; TST=tuberculin skin test

APPENDIX B: TUBERCULOSIS RISK ASSESSMENT TOOL

This tool helps you identify asymptomatic adults and children at risk for latent tuberculosis infection (LTBI).

- Do not repeat testing unless there are new risk factors since the last test for TB infection.
- Do not treat for LTBI until active TB disease has been excluded.[1]

Testing for TB infection[2] is recommended if your patient meets ANY of the below criteria:

○ **HAVE THEY LIVED WITH OR SPENT TIME WITH ANYONE WHO HAD OR MAY HAVE HAD TB?**

Notify the New York City Department of Health and Mental Hygiene (NYC Health Department) if your patient has had close contact with anyone with TB disease. Call the **TB HOTLINE** at **(844) 713-0559**, available 24 hours a day, seven days a week.

○ **DO THEY HAVE HIV/AIDS, CANCER, OR AN IMMUNE DISORDER?**

Immunosuppression[3] includes the following: HIV infection, cancer, prolonged corticosteroid use (equivalent to 15 milligrams/day or more of prednisone for one month or more), other immunosuppressive treatments (for example, TNF- α antagonists, JAK Inhibitors, IL-1 receptor antagonists, chemotherapy, organ transplant medications).

○ **WERE THEY BORN OUTSIDE OF THE U.S. IN A HIGH TB INCIDENCE AREA, SUCH AS AFRICA, ASIA, MEXICO, CENTRAL OR SOUTH AMERICA, THE CARIBBEAN, OR EASTERN EUROPE, OR HAVE THEY TRAVELED TO OR LIVED IN A HIGH TB INCIDENCE AREA FOR MORE THAN ONE MONTH?**

If your patient was born outside of the U.S. in a high TB incidence area —or—traveled or lived outside the U.S. for one consecutive month or more in a high TB incidence area, they may be at greater risk of infection.

If the TB test result is positive and TB disease is ruled out,[1] treatment for LTBI is recommended.

1. Evaluate, by medical history and physical examination, all people with TB symptoms, positive TB test results or abnormal chest radiographs (CXRs) consistent with TB disease. Following NYC Health Code Article 11, report all people with potential or confirmed TB disease and children younger than 5 years of age diagnosed with LTBI to the NYC Health Department. For more information, visit: www.nyc.gov/health/tb.
2. Interferon Gamma Release Assays (IGRAs) are preferred for people age 2 years and older, particularly those who have previously received the Bacille Calmette-Guérin (BCG) vaccine since IGRAs do not cross-react with BCG; some experts recommend using IGRAs for people of all ages.
3. IGRA results may be indeterminate and may need to be repeated. IGRA results may be negative and unless indicated by clinical judgment (for example, clinical suspicion of TB disease, immunosuppression), no further evaluation is needed.

APPENDIX C: ADMINISTERING THE TUBERCULIN SKIN TEST

FIRST STEPS:

1. Gather your equipment
   - Gloves
   - Alcohol pads or alternative skin cleanser
   - Disposable 26-gauge syringe needle
   - Tuberculin syringe (do not pre-draw tuberculin into syringes prior to test)
   - Purified protein derivative (PPD)
   - Sharps container
2. Check PPD vial's expiration/opening date
3. Explain to patient why test is being done and how it will be performed

PREPARATION:

1. Wash hands and put on gloves
2. Place patient's arm on a flat surface, exposing the volar (inside) surface of the forearm
3. Locate site for the injection (two to four inches below elbow, where no scars, bumps or veins are located)
4. Clean the injection site with an alcohol swab
5. Wipe the top of the PPD vial with a second alcohol swab and place the vial on a flat surface
6. Prepare the syringe by inserting it into the vial. Inject 0.1 milliliters (ml) of air into the airspace in the vial. Do not inject air into the PPD solution. Invert the vial, keeping the needle tip below fluid level. Pull back on the plunger of the syringe and draw slightly more than 0.1 ml of PPD solution. Remove the syringe from the vial and tap the syringe lightly to dispel air bubbles. Hold the syringe point up and expel air and/or excess fluid, leaving exactly 0.1 ml of PPD solution in the syringe
7. Return the PPD vial to the refrigerator when not in use and place on a cooling pad when in use

INJECTION:

1. Stretch the skin of the injection site with the thumb of the non-dominant hand (e.g., left hand for right-handed persons)
2. Hold the syringe between the thumb and forefinger of the dominant hand (e.g., right hand for right-handed persons) with the bevel of the needle pointing upward
3. Insert the needle intradermally (just under the top layer of skin) at a 5°-15° angle
4. Inject the PPD solution slowly. A firm resistance should be felt as the tuberculin solution enters the skin. Ensure that the entire needle bevel lies just under the skin
5. Release the stretched skin and remove the needle from the injection site (DO NOT RECAP). Discard the syringe immediately in a sharps container

6. Ensure that a discrete skin elevation (wheal), six to 10 mm in diameter, has been formed (measure wheal using a tuberculin skin test [TST] ruler). If the injection angle was too deep, no wheal will appear. If the angle was too shallow, fluid may leak. Be sure to check for leakage at the insertion site.
7. Repeat injection two inches (five cm) from site, or on opposite arm, if wheal is smaller than six mm or if less than 0.1 ml was injected (both tests need to be documented; [see below]). If, after a second injection, the wheal is still less than six mm or not enough fluid is injected, clinic staff should speak with a supervisor

POST-INJECTION:

1. Educate the patient on the possible reactions to the TST (e.g., mild itching, swelling, irritation)
2. Instruct patient not to rub, scratch, or put an adhesive bandage or lotion on the test site. The area may be washed and patted dry
3. Document the test in the patient's chart (including second test if done)
4. Schedule reading date and explain the importance of the patient returning for reading in 48 to 72 hours

READING THE TUBERCULIN SKIN TEST REACTION:

The test result should be read only by a trained healthcare worker. Patients should never be allowed to read their own reaction.

1. Read the result 48 to 72 hours after administering the test. A test result that has a palpable induration can still be read up to 96 hours
2. Inspect the injection site for raised areas. Palpate the arm for a hard, dense, and raised area known as an induration. Feel the edges of the induration with the index finger
3. Mark the two edges of the induration with a dot, using a black, watermark pen, if available
4. Measure the induration (not redness) at its widest point transversely, from one marked edge to the other, using a flexible TST ruler. If the reading is between two points, the lower value should be used. Swollen areas, if they feel hard (but not red areas), should be palpated and included in the measurement
5. Record the size in mm and not simply as "positive" or "negative." If there is no induration, record the result as "00 mm"
6. Interpret the reaction as positive or negative based on both the size of the induration and the individual's risk factors. (See *Table 2.4: Criteria for Determination of a Positive Tuberculin Skin Test Result.*)
7. Explain the meaning of a positive or negative reaction to the individual and refer for follow-up evaluation, if needed. Provide appropriate literature
8. Document results in the patient's chart

APPENDIX D: THE USE OF BACILLE CALMETTE-GUÉRIN VACCINE

Bacille Calmette-Guérin (BCG) vaccine[1] is a live, attenuated strain of *Mycobacterium bovis* (*M. bovis*). In most parts of the world, BCG vaccine is used routinely to prevent serious complications of tuberculosis (TB), such as miliary TB and central nervous system (CNS) TB, in infants and children and in healthcare workers with frequent exposure to individuals with infectious TB disease.

Although the evidence is conflicting, a large body of research indicates that BCG vaccination does not completely prevent TB infection or pulmonary TB disease. Some studies suggest that BCG vaccination lessens the likelihood of disseminated TB and TB meningitis, especially in infants.

In the United States, BCG vaccination is not recommended routinely for children or used as a control strategy against TB. Specifically, it is not recommended as a general preventive strategy for healthcare workers because it complicates the interpretation of tuberculin skin test (TST) reactions and because it has not been proven effective in preventing TB infection.

BCG is not recommended for children or adults with human immunodeficiency virus (HIV) infection; HIV testing must be performed before BCG is administered. Similarly, active TB disease must be ruled out before BCG can be given. Nonetheless, BCG vaccine may be considered in very specific circumstances. These circumstances include instances in which infants and children are close household contacts of an individual with persistently untreated or ineffectively treated smear-positive TB disease, especially MDR-TB.

As of January 2018, TICE BCG (Manufacturer: MERCK) is available through Cardinal Health as a special order item. All requests for BCG must be discussed with the Bureau of Tuberculosis Control (BTBC); BTBC can be contacted via the TB Hotline at 844-713-0559.

1. INDICATIONS AND CONTRAINDICATIONS FOR BACILLE CALMETTE-GUÉRIN VACCINE

Before deciding to give BCG vaccine to a contact of an individual with persistently untreated or ineffectively treated smear-positive TB disease, every effort should be made to (1) ensure that the inadequately treated individual with infectious TB disease is treated properly, and (2) separate the individual with TB and the exposed contact(s).

If this is not possible, giving BCG vaccine may be considered if the contact meets **ALL** of the following criteria:

- The contact has a negative test for TB infection
- The contact is repeatedly exposed to an individual with persistently untreated or ineffectively treated smear-positive multidrug resistant TB (MDR-TB)
- The contact does not have HIV infection (in some situations, however, BCG vaccine may be given to infants who have a positive HIV antibody as below)

BCG vaccine should **NOT** be given to the following individuals:

- Persons with a documented history of a positive reaction to a test for TB infection
- Persons with HIV infection or persons who are otherwise immunosuppressed

There have been no reports of harmful effects of BCG vaccine on the fetus. Nevertheless, giving BCG vaccine should be avoided in pregnant patients, unless there is an unusual risk of unavoidable exposure to infectious MDR-TB.

2. SPECIAL CONSIDERATIONS FOR INFANTS

At least two other factors must be weighed before a decision is made to give BCG vaccination to a newborn or infant younger than nine months old:

- Because an infant may not be able to mount a cellular immune response to infection with *Mycobacterium tuberculosis* (*M. tuberculosis*), a TST may not be a reliable indicator of infection. Thus, there may be instances where an infant with a negative TST may receive BCG vaccine even though they may be infected with *M. tuberculosis.*
- The blood of some infants born to mothers with HIV infection may show the presence of HIV antibodies for a number of months after birth, even if the infant is not infected with HIV. Because HIV infection cannot be excluded in this situation, BCG vaccine could be considered only if the infant is otherwise healthy, especially if the evaluation of other close contacts reveals a high rate of documented TST conversions and if all other efforts to prevent transmission have failed. Such an infant needs to be followed by a specialist until HIV infection is ruled out based on the most current recommendations.

3. EVALUATION AND FOLLOW-UP

- An individual who is being considered for BCG vaccination who cannot document a history of a previous positive TST reaction should have a TST, using five tuberculin units of purified protein derivative (PPD). A blood-based test is not recommended.
- An individual who is being considered for BCG vaccination should be offered HIV counseling and testing if they have risk factor(s) for HIV infection.
- If the individual being considered for BCG vaccination is an infant or child, the parent or legal guardian must be interviewed and must agree. This must be documented in the chart.
- Eight weeks after the administration of BCG vaccine, the individual should have a repeat TST performed to document any reaction. If the contact's TST is less than five millimeters (mm), the BCG vaccination should be repeated.
- There is no evidence that revaccination with BCG later in life affords any additional protection and therefore revaccination is not recommended.

NOTE: Product names are provided for identification purposes only; their use does not imply endorsement by the New York City Health Department.

APPENDIX E: INSTRUCTIONS FOR PERFORMING SPUTUM INDUCTION

Sputum induction is the procedure for obtaining sputum from patients who have difficulty producing it spontaneously. In this procedure, patients inhale a mist of nebulized, sterile water (many facilities use hypertonic saline), which irritates their airways, causing them to cough and produce respiratory secretions.

EQUIPMENT

In order to appropriately and safely conduct sputum induction, the following equipment is required:

- A room, booth, or enclosed area that meets environmental control standards for high-risk procedures, including:
  - Negative air pressure relative to other areas (air flow must be from the corridor into the sputum induction room or booth; from there it should be exhausted to the outside or appropriately filtered and safely discharged by a mechanical ventilation system)
  - 12 or more complete air changes per hour
  - For rooms, ultraviolet germicidal irradiation (UVGI) must be used

All Bureau of Tuberculosis Control (BTBC) sputum induction rooms are fully equipped with the following:

- Nebulizer and table to support nebulizer
- Disposable tubing with cup and lid
- Sterile sputum collection jar, properly labeled
- Mycobacteriology forms
- Clear plastic biohazard specimen bag and paper bag
- Paper tissues and bag for disposal of tissues
- Sterile water
- Distilled water
- Solution of 10% bleach, 90% water
- Disposable gloves
- Disposable drinking cups

PREPARING EQUIPMENT AND THE SPUTUM INDUCTION ROOM

Once all equipment has been collected, BTBC staff prepare the room and supplies as follows:

- Assemble and organize the following equipment in quantities sufficient for the anticipated number of patients to be seen that day:
  - Sputum jars
  - Plastic biohazard bags and brown paper bags
  - Disposable plastic nebulizer tubing with cup and lid
  - Sterile water
  - Distilled water
  - 10% bleach solution, mixed at the start of the shift in an amount sufficient for that shift only
  - Disposable drinking cups

- Check that the ultraviolet light and exhaust fan are on and functional
- Prepare the nebulizer:
  - Inspect it for cleanliness
  - If necessary, wipe the nebulizer surfaces with 10% bleach solution
  - Place distilled water in the nebulizer chamber to the level marked on the chamber
  - Place a small amount of sterile water 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
- Before beginning sputum induction:
  - Label the sputum jar in pencil with the patient's name and address, and the date
  - Place the completed Mycobacteriology form in the lab slip pocket of a biohazard bag with the patient's name facing out
- Include the TB Registry number of patients with confirmed TB disease or signs and symptoms consistent with TB disease on the mycobacteriology form

PREPARING THE PATIENT

The attending BTBC staff member prepares the patient for sputum induction:

- Explain the purpose of the procedure
- Orient the patient to the nebulizer and demonstrating how it functions
- Show patient the sputum jar and instruct them not to open the jar until ready to expectorate into it and to close the jar tightly as soon as the specimen is collected
- Provide sterile or bottled water and ask the patient to rinse their mouth prior to the procedure
- Explain not to begin the sputum induction procedure until the staff member has left the room and the door is firmly closed
- Telling the patient to:
  - Inhale the aerosol by taking three or four deep, slow breaths through the mouth without placing their mouth on the tubing (the patient is not to demonstrate deep breathing during the instruction)
  - Cough vigorously if they do not cough spontaneously in response to the mist
- Ask the patient to cover their mouth with a tissue when coughing unless expectorating into the sputum jar
  - Continue trying to cough and to expectorate after inhaling the mist
  - Expectorate all sputum into the sputum jar, without spilling it outside the jar
  - Cover the jar tightly after 5-10 milliliters (ml) of sputum from deep in the lung are in the jar

- Place sputum specimens in the biohazard bag, then the brown paper bag, and give the plastic to the TB clinic staff
- Stay in the sputum induction room, remaining in the anteroom until coughing has completely stopped
- Shut the door after leaving the sputum induction room

ROLE OF TUBERCULOSIS CLINIC STAFF DURING THE INDUCTION PROCEDURE

BTBC staff remain near, but not inside, the sputum induction room during the procedure in order to be available to assist patients if necessary and to ensure that patients remain in the sputum induction room until coughing has stopped. If a staff member must enter the sputum induction room during the procedure, a properly fitted, National Institute for Occupational Health and Safety (NIOSH)-approved respirator (e.g., respirator type N95) is worn.

HANDLING OF SPECIMENS

While in the sputum induction room or booth, patients place the sputum jar in the Ziploc section of the biohazard bag and put the biohazard bag in a brown paper bag. The patient gives the brown paper bag to clinic staff, who place the bag in the refrigerator until it is delivered to the laboratory.

- BTBC staff put on a properly fitted, NIOSH-approved N95 particulate respirator and disposable gloves before entering the sputum induction room
  - The respirator is not removed until after leaving the room
  - The door is closed after entering the sputum induction room
- BTBC staff remove nebulizer tubing with cup and lid and discard it into the disposal bag for biohazardous waste
- BTBC staff wipe the nebulizer and table surfaces clean with a 10% bleach solution and discard any litter in the treatment area
- Staff remove gloves, wash hands, and prepare the equipment for the next patient

SPUTUM INDUCTION ROOM CLEARANCE TIMES

Each sputum induction room has an individually calculated clearance time that is determined by the size of the room, the air changes per hour (ACH), and the air mixing factor. NYC Health Department TB clinic sputum induction rooms' clearance times are as follows:

- **Corona TB Clinic:** 15 minutes
- **Fort Greene TB Clinic:** 10 minutes
- **Morrisania TB Clinic:** 15 minutes
- **Washington Heights TB Clinic (3rd Floor):** 13 minutes
- **Washington Heights TB Clinic (2nd Floor):** 15 minutes

Clearance times are determined by qualified Bureau staff and calculated as follows:

- Determine the cubic volume of the room: **Cubic volume = length x width x height**
- Calculate ACH: **ACH = (cubic feet per minute x 60) / cubic volume**
- Determine air mixing factor: Isol-Aide sputum induction booths/rooms have an effective mixing factor of 1.81 as determined by the manufacturer.
- Extrapolate clearance time from Centers for Disease Control and Prevention's "Guidelines for Preventing the Transmission of *Mycobacterium Tuberculosis* in Health-Care Facilities, 2005," available at **www.cdc.gov**

CARE OF ROOM AND NEBULIZER AT THE END OF THE DAY

At the end of the day, staff restore the nebulizer and the sputum induction room as follows:

- Before entering the sputum induction room, wait at least 10 minutes after the last patient leaves
- Put on disposable gloves and a properly fitted, NIOSH-approved particulate respirator prior to entering
- Close the door after entering
- Remove and discard the nebulizer tubing with cup and lid
- Empty the nebulizer chamber
- Clean the nebulizer chamber and all exposed surfaces with a 10% bleach solution and wipe the chamber dry
- Discard the bleach solution
- Remove and discard the disposable gloves and wash hands
- Leave the ultraviolet light and the fan on
- Remove the personal N95 particulate respirator after leaving the room

APPENDIX F: POTENTIAL DRUG INTERACTIONS WITH ISONIAZID AND RIFAMYCIN MEDICATIONS

DRUG INTERACTIONS WITH RIFAMYCIN MEDICATIONS[1]

DRUG INTERACTION	EFFECTS
Angiotensin Converting Enzyme Inhibitors	Decreases angiotensin converting enzyme levels
Angiotensin Receptor Blockers	Decreases angiotensin receptor blocker levels
Antianxieties	Decreases antianxiety effect
Anticoagulants	Decreases anticoagulants effect
Antidepressants (TCA)	Decreases antidepressant effect
Antiplatelet Agents	Increases antiplatelet effect
Antipsychotics	Decreases level of antipsychotic and may increase clearance of some
Azole Antifungals	Decreases azole antifungal effect
Beta-Blockers	Decreases beta blockade; RIF has more of an effect than RBT
Barbiturates	Decrease barbiturate effect
Benzodiazepines	Decreases benzodiazepines effect that undergo oxidative oxidation
Calcium Channel Blockers	Decreases calcium channel blocker effect
Chloramphenicol	Decreases chloramphenicol effect
Contraceptives	Decreases contraceptive effect
Corticosteroids	Marked decrease in steroid effect
Cyclosporine	Decreases cyclosporine effect, increases RIF effect
Delavirdine	Marked decrease in delavirdine effect
Digoxin	Decreases digoxin effect; decreases RIF level
Dilantin	Decreases dilantin effect
Dipeptidyl Peptidase IV Inhibitors	Decreases dipeptidyl peptidase IV inhibitor effect
Efavirenz	Slight decrease in efavirenz effect
Glipizide and Metformin	Decreases glipizide effect, no effect on metformin
Glyburide and Metformin	Decreases glyburide effect, no effect on metformin
Haloperidol	Decreases haloperidol effect
HMC CoA Inhibitors (Statins)	Decreases statin levels
Macrolide antibiotics	Decreases macrolide effect; increases RBT toxicity
Meglitinide Analogue	Decreases meglitinide analogue
Methadone	Decreases methadone effect
Protease Inhibitors	Marked decrease in activity of protease inhibitors, increases RIF effect
Sitagliptin and Metformin	May decrease sitagliptin levels, no effect on metformin
Sulfonylurea	Decreases sulfonylurea effect

DRUG INTERACTIONS WITH ISONIAZID

DRUG INTERACTION	EFFECTS
Acetaminophen	Increases hepatotoxicity
Alcohol	Increase incidence of hepatitis; possible decreased INH effect
Anticoagulants	Increases anticoagulant effect
Benzodiazepine	Increases benzodiazepine toxicity
Carbamazepines	Increases toxicity of both carbamazepines and INH
Disulfiram (Antabuse)	Potential for psychotic episodes
Halpendol	Increases halpendol toxicity
Hypoglycemics	Monitor glucose, decreases effect (may cause hyperglycemia)
Ketoconazole	Decreases ketoconazole effect
Phenytoin	Increases phenytoin toxicity
Theophylline	Increases theophylline toxicity

Adapted from: Heartland National TB Center. Tuberculosis Medication Drug and Food Interactions. Retrieved from www.heartlandntbc.org/assets/products/tuberculosis_medication_drug_and_food_interactions.pdf.

1. Rifabutin is a weaker inducer of the cytochrome P450 system, potentially interacting with some of the same medications as RIF

Abbreviations Used: CNS=central nervous system; RBT=rifabutin; RIF=rifampin; TB=tuberculosis

APPENDIX G: DOSAGES, ADVERSE REACTIONS, AND MONITORING FOR FIRST-LINE MEDICATIONS USED TO TREAT TUBERCULOSIS*

DRUG *ROUTE OF ADMINISTRATION* MODE OF ACTION	DAILY DOSE [MAX]	THREE TIMES PER WEEK DOSE [MAX]	TWO TIMES PER WEEK DOSE [MAX]*	MAJOR ADVERSE REACTIONS	RECOMMENDED REGULAR MONITORING	COMMENTS
INH *Oral/ Intramuscular* Bactericidal	Children: 10-15 mg/kg Adults: 5 mg/kg [300 mg]	Children: 20-30 mg/kg Adults: 15 mg/kg [900mg]	Children: 20-30 mg/kg Adults: 15 mg/kg [900mg]	Hepatic enzyme elevations, hepatitis, rash, peripheral neuropathy, CNS effects, increased phenytoin levels, possible interaction with disulfiram (Antabuse®)	• Monthly clinical evaluation • LFTs[1]	• Vitamin B6 (pyridoxine) 25 mg/day may decrease peripheral neuritis and CNS effects and should be used in patients who are abusing alcohol, pregnant, breastfeeding infants on INH, malnourished, or who have HIV infection, cancer, chronic renal or liver disease, diabetes, or pre-existing peripheral neuropathy • Aluminum-containing antacids reduce absorption • Drug interactions with several agents
RIF *Oral/Intravenous* Bactericidal	Children: 10-20 mg/kg Adults: 600 mg (range: 8-12 mg/kg) [600 mg]	Children: 10-20 mg/kg Adults: 600 mg (range: 8-12 mg/kg) [600 mg]	Children: 10-20 mg/kg Adults: 600 mg (range: 8-12 mg/kg) [600 mg]	Hepatic enzyme elevations, hepatitis, rash, fever, thrombocytopenia, influenza-like syndrome, reduced levels of many drugs, including methadone, warfarin, hormonal forms of contraception, oral hypoglycemic agents, theophylline, dapsone, ketoconazole, PIs and NNRTIs	• Monthly clinical evaluation • CBC including platelets and LFTs as indicated[1]	• Orange discoloration may occur in contact lenses and body secretions such as tears and urine • Patients receiving methadone will need their methadone dosage increased, by an average of 50%, to avoid opioid withdrawal • Interaction with many drugs leads to decreased levels of the co-administered drug • May make glucose control more difficult in people with diabetes • Contraindicated for patients taking most PIs and NNRTIs • Patients should be advised to use barrier contraception
RBT[2] *Oral* Bactericidal	Children: 5 mg/kg Adults: 5 mg/kg [300 mg]			Rash, hepatitis, fever, neutropenia, thrombocytopenia, reduced levels of many drugs, including PIs, NNRTIs, dapsone, ketoconazole and hormonal forms of contraception	• Monthly clinical evaluation • CBC including platelets and LFTs as indicated[1]	• Orange discoloration may occur in contact lenses and body secretions, such as urine and tears • If taken concurrently with PIs or NNRTIs, adjust dose of RBT and monitor for decreased ART activity and for RBT toxicity • Contraindicated for patients taking single PI, ritonavir/saquinavir, or delaviridine based ART regimens • Methadone dosage generally does not need to be increased • Patients should be advised to use barrier contraception

APPENDIX G: DOSAGES, ADVERSE REACTIONS, AND MONITORING FOR FIRST-LINE MEDICATIONS USED TO TREAT TUBERCULOSIS (CONTINUED)*

DRUG *ROUTE OF ADMINISTRATION* MODE OF ACTION	DAILY DOSE [MAX]	THREE TIMES PER WEEK DOSE [MAX]	TWO TIMES PER WEEK DOSE [MAX]*	MAJOR ADVERSE REACTIONS	RECOMMENDED REGULAR MONITORING	COMMENTS
PZA *Oral* Bacteriostatic	Children: 35 mg/kg (range: 30-40 mg/kg) Adults: 25 mg/kg (range: 20-30 mg/kg) [2000 mg for children and adults]	Children: 50 mg/kg (range: 40-60 mg/kg) Adults: 35 mg/kg (range: 30-40 mg/kg [3000 mg for children and adults]	Children: 50 mg/kg (range 40-60 mg/kg) Adults: 50 mg/kg (range 40-60 mg/kg) [3500 mg for children and adults]	GI upset, hepatotoxicity, hyperuricemia, gout (rarely), arthralgias, rash	• Monthly clinical evaluation • LFTs as indicated[1]	• Hyperuricemia can be used as indicator of adherence • Treat increased uric acid only if symptomatic • May complicate management of diabetes mellitus • Allopurinol increases level of PZA by inhibiting xanthine oxidase resulting in failure of allopurinol to lower serum uric acid
EMB *Oral* Bacteriostatic	Children: 20 mg/kg (range: 15-25 mg/kg) [1500 mg] Adults: 15-25 mg/kg [2000 mg]	Children: 50 mg/kg [2500 mg] Adults: 30 mg/kg (range: 25-35 mg/kg) [2800 mg]	Children: 50 mg/kg [2500mg] Adults: 45 mg/kg (range: 40-50 mg/kg) [3600 mg]	Decreased red-green color discrimination, decreased visual acuity, skin rash	• Monthly clinical evaluation • Check color vision and visual acuity monthly	• Optic neuritis may be unilateral; check each eye separately. If possible, avoid in children too young to undergo vision testing • If patient develops visual complaints, refer for prompt ophthalmologic evaluation. May need to discontinue EMB while awaiting evaluation
SM *Intramuscular/ Intravenous* Bactericidal	Children: 15-20 mg/kg Adults: 15 mg/kg [1000 mg]	Children: 25-30 mg/kg Adults: 15 mg/kg [1000 mg]	Children: 25-30 mg/kg Adults: 15 mg/kg [1000 mg]	Auditory toxicity, renal toxicity, hypokalemia, hypomagnesemia	• Monthly clinical evaluation • Audiometry, renal function, electrolytes, including magnesium	• Ultrasound and warm compresses to injection site • Patients with decreased renal function may require the 15 mg/kg dose to be given only 3 times per week to allow for drug clearance

Source: 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 Oct 1;63(7):e147-e195.

* All toxicities are not listed here. Full prescribing information should be checked in the package insert or pharmacology texts. Use of brand names is for informational purposes only and does not imply endorsement by the New York City Health Department.

♦ Daily or three times per week therapy are the preferred treatment regimens compared to twice weekly therapy.

1. LFTs are indicated if baseline is abnormal or patient has risk factors for toxicity.

2. Not FDA-approved for the treatment of TB.

Abbreviations Used: ART=antiretroviral therapy; ATS=American Thoracic Society; CBC=complete blood count; CDC=Centers for Disease Control and Prevention; CNS=central nervous system; DOT=directly observed therapy; EMB=ethambutol; FDA=Food and Drug Administration; GI=gastrointestinal; HIV=human immunodeficiency virus; IDSA=Infectious Disease Society of America; INH=isoniazid; IUATLD=International Union against Tuberculosis and Lung Disease; kg=kilograms; LFT=liver function test; mg=milligrams; NNRTI=non-nucleoside reverse transcriptase inhibitors; PI=protease inhibitors; PZA=pyrazinamide; RBT=rifabutin; RIF=rifampin; SM=streptomycin; TB=tuberculosis; WHO=World Health Organization

APPENDIX H: DOSAGES, ADVERSE REACTIONS, AND MONITORING FOR ADDITIONAL MEDICATIONS USED TO TREAT TUBERCULOSIS*

DRUG *ROUTE OF ADMINISTRATION* MODE OF ACTION	DAILY DOSE [MAX]	MAJOR ADVERSE REACTIONS	RECOMMENDED REGULAR MONITORING	COMMENTS
AK *Intramuscular/ Intravenous* Bactericidal	Children: 15–30 mg/kg Adults: 15 mg/kg [1000 mg]	Auditory toxicity, renal toxicity, vestibular toxicity (rare), hypokalemia, hypomagnesemia	• Monthly clinical evaluation • Audiometry, renal function, electrolytes, including magnesium	• Ultrasound and warm compresses to injection site may reduce pain and induration • PICC line may need to be used • AK levels are commercially available and should be followed • Patients with decreased renal function may require 15 mg/kg dose to be given only 2-3 times per week to allow for drug clearance
BDQ *Oral* Bactericidal	Children: 5 years of age and older weighing 15-29 kg: 200 mg x 2 wks, then 100 mg 3x/wk x 22 wks Children weighing > 30 kg: Dose same as adults Adults: 400 mg x 2 wks, then 200 mg 3x/wk x 22 wks	QT prolongation, hepatotoxicity, nausea, loss of appetite, abdominal pain, arthralgia, hemoptysis, rash	• Monthly clinical evaluation • Complete blood count, chemistry including K^{+}, Ca^{+2}, Mg^{+2}, and LFTs • FDA requires monitoring EKG at baseline then at 2 wks, 12 wks, and 24 wks	• Approved for pulmonary MDR-TB • Part of combination regimen for MDR-TB • Duration is 24 wks total; longer duration could be considered on a case-by-case basis especially when there are limited treatment options • BDQ's half-life is 4-5 months; consider discontinuing BDQ 4–5 months prior to discontinuing other drugs in the treatment regimen to reduce or avoid an extended period of exposure to low levels of BDQ • Should not be used with CYP3A4 inducers, i.e., rifampin and efavirenz • There may be cross resistance between BDQ and CFZ • Can be taken with food • Must be given under DOT • For children who cannot swallow, disperse tablets in water and mix with beverage or soft food or crush the tablet and mix with soft food
CFZ *Oral* Bactericidal	Children: Limited data, but doses of 2-5 mg/kg/day have been given Adults: 100 mg	Pink or red discoloration of skin and body fluids discoloration; gastrointestinal intolerance; hepatotoxicity; photosensitivity; rash, pruritus, dry skin, ichthyosis; retinopathy; severe abdominal symptoms, bowel obstruction, gastrointestinal bleeding	• Monthly clinical evaluation • Baseline and monthly EKGs to assess QT interval • Monitor complete blood count, chemistry including K^{+}, Ca^{+2}, Mg^{+2}, and LFTs	• Needs an IND from the FDA and coordination with Novartis • Skin discoloration is reversible but may take a long time • Can prolong the QT interval especially if given with BDQ and other QT prolonging agents • Each dose should be taken with food and on DOT • There may be cross resistance between BDQ and CFZ
CM *Intramuscular/ Intravenous* Bactericidal	Children: 15–20 mg/kg Adults: 15 mg/kg [1,000 mg]	Auditory, vestibular, and renal toxicity; eosinophilia, hypokalemia, hypomagnesemia	• Monthly clinical evaluation • Audiometry, renal function, electrolytes, including magnesium	• Ultrasound and warm compresses to injection site may reduce pain and induration • Patients with decreased renal function may require 15 mg/kg dose to be given only 2-3 times per week to allow for drug clearance

APPENDIX H: DOSAGES, ADVERSE REACTIONS, AND MONITORING FOR ADDITIONAL MEDICATIONS USED TO TREAT TUBERCULOSIS (CONTINUED)*

DRUG *ROUTE OF ADMINISTRATION* MODE OF ACTION	DAILY DOSE [MAX]	MAJOR ADVERSE REACTIONS	RECOMMENDED REGULAR MONITORING	COMMENTS
CS *Oral* Bacteriostatic	Children: 15–20 mg/kg Adults: 500–1000 mg, divided doses [1000 mg]	Psychosis, seizures, headache, depression, suicide, other CNS effects, rash, increased phenytoin levels	• Monthly clinical evaluation • Assess and monitor mental status	• Increase gradually, checking serum levels • Pyridoxine hydrochloride (vitamin B6) may decrease CNS effects (use 50 mg for each 250 mg of CS)
ETA *Oral* Bacteriostatic	Children: 15–20 mg/kg Adults: 500–1000 mg, divided doses [1000 mg]	Nausea, vomiting, diarrhea, abdominal pain, bloating, hepatotoxicity, hypothyroidism (especially when administered with PAS), metallic taste	• Monthly clinical evaluation • LFTs (if baseline abnormal) • Thyroid function periodically, especially if also on PAS	• Antacids/anti-emetics and lying supine for 20 minutes after dose may help tolerance • Start with 250 mg daily and increase as tolerated
LFX[1] *Oral/Intravenous* Bactericidal	Children: 6 months to under 5 years of age: 10 mg/kg two times per day 5 years and older: 10 mg/kg once per day Adults: 500–1000 mg in one dose	Nausea, vomiting, diarrhea, abdominal pain, tremulousness, insomnia, headache, dizziness, lightheadedness, photosensitivity, tendonitis, tendon rupture, possible hypo- and hyperglycemia hypersensitivity	• Monthly clinical evaluation • Monitor blood sugar	• Our clinical experience shows safety with long-term use • Dose should be adjusted to 3 times per week in renal failure
LZD *Oral/intravenous* Bacteriostatic[2]	Children: Under 12 years of age: 10-15 mg/kg per day, based on weight 12 years of age and older: 10 mg/kg [600 mg/day] Adults: 600 mg	Myelosuppression, hemolytic anemia, peripheral and optic neuropathy, nausea, vomiting, diarrhea, LFT elevations, tongue discoloration	• Monthly clinical evaluation, BP, screening for optic and peripheral neuropathy • Complete blood count initially 1-2 wks, then monthly, chemistry, and LFTs	• Available in an oral suspension 100mg/5ml • Drug-drug interactions with tyramine containing foods (e.g., cured meats), SSRIs, and MAOIs • Risk of serotonin syndrome • Can cause lactic acidosis
MFX[1] *Oral/Intravenous* Bactericidal	Children: 10-15 mg/kg Adults: 400 mg[3]	Similar to LFX	• Monthly clinical evaluation • Monitor blood sugar	• More active than LFX against *M. tuberculosis*. • Avoid in patients with prolonged QTc interval and those receiving class Ia or III antiarrhythmic agents

APPENDIX H: DOSAGES, ADVERSE REACTIONS, AND MONITORING FOR ADDITIONAL MEDICATIONS USED TO TREAT TUBERCULOSIS (CONTINUED)*

DRUG *ROUTE OF ADMINISTRATION* MODE OF ACTION	DAILY DOSE [MAX]	MAJOR ADVERSE REACTIONS	RECOMMENDED REGULAR MONITORING	COMMENTS
PAS *Oral* Bacteriostatic	Children: 200-300 mg/kg total (usually divided 100 mg/kg given two times per day) Adults: 4000 mg two times per day [12,000 mg]	Nausea, vomiting, diarrhea, abdominal pain, hypersensitivity, hepatoxicity, hypothyroidism (especially when administered with ETA), decreased digoxin levels, increased phenytoin levels, PAS levels decreased by diphenhydramine	• Monthly clinical evaluation • Thyroid function periodically especially if also on ETA	• Begin gradually and increase dosage as tolerated • May cause hemolytic anemia in patients with glucose 6-phosphate dehydrogenase deficiency
Pretomanid *Oral* Bactericidal	Children: Not established Adults: 200 mg per day for 26 wks	Optic and peripheral neuropathy, myelosuppression, hepatotoxicity[4]	• Monthly clinical evaluation • Baseline and monthly EKGs to assess QT interval[5] • Monitor complete blood counts, chemistry including K^{+}, Ca^{+2}, Mg^{+2}, and LFTs • Monitor for visual changes and neuropathy	• Pretomanid must be used in combination with BDQ and LZD for treatment of pulmonary XDR-TB and treatment intolerant or nonresponsive MDR-TB (BPaL regimen); regimen must be given as specified[6] • Pretomanid is contraindicated in patients for whom BDQ and/or LZD are contraindicated • Most of the adverse reactions observed in the BPaL regimen were noted when pretomanid was given with BDQ and LZD and may be attributed to those drugs • Tablets should be taken whole and can be given with food • Should not be used with CYP3A4 inducers, i.e., rifampin and efavirenz • Avoid organ anion transport substrates (OAT3) • Testicular atrophy and male infertility in animal studies

Source: Nahid P, Mase SR, Migliori GB, et al. Treatment of drug-resistant tuberculosis. An Official ATS/CDC/ERS/IDSA Clinical Practice Guideline. Am J Respir Crit Care Med. 2019;200(10):e93-e142.

* All toxicities are not listed here. Full prescribing information should be checked in the package insert or pharmacology texts. Use of brand names is for informational purposes only and does not imply endorsement by the New York City Health Department.

1. Although FQNs are not approved for use in children in most countries, the benefit of treating children with MDR-TB with a FQN may outweigh the risk in many instances. 2. May be bactericidal when combined with other agents in the treatment of MDR-TB. 3. Higher MFX doses have been used safely when the isolate is resistant to ofloxacin and the minimum inhibitory concentration for LFX or MFX suggests higher doses may overcome resistance. Higher doses also are used in cases of malabsorption. 4. List of adverse reactions when pretomanid is used combined with LZD and BDQ. 5. When used in combination with BDQ and LZD, the BDQ package insert recommends EKGs at baseline, and then at 2, 12, 24 wks after starting medications. Some experts recommend monthly EKG monitoring. 6. BPAL regimen: pretomanid 200 mg orally x 26 wks, BDQ 400 mg orally x 2 wks, then 200 mg 3x/wk for 24 wks, and LZD 1200 mg orally for 26 wks, with dose adjustments after the first month.

Abbreviations Used: AK=amikacin; BDQ=bedaquiline; BTBC=Bureau of Tuberculosis Control; CFZ=clofazimine; CM=capreomycin; CNS=central nervous system; CS=cycloserine; ETA=ethionamide; FQN=fluoroquinolone; kg=kilograms; LFX=levofloxacin; LZD=linezolid; MAOI=monamine oxidase inhibitors; *M. tuberculosis*=*Mycobacterium tuberculosis*; MDR-TB=multidrug-resistant tuberculosis; MFX=moxifloxacin; mg=milligrams; PAS=para-aminosalicylic acid; PICC=peripherally inserted central catheter; SSRI=selective serotonin reuptake inhibitors; TB=tuberculosis; wk=week; XDR-TB=extensively drug-resistant tuberculosis

APPENDIX I: THE USE OF ANTI-TUBERCULOSIS DRUGS AND PREGNANCY, BREASTFEEDING, TUBERCULOSIS MENINGITIS, AND RENAL AND HEPATIC FAILURE[1]

DRUG	SAFETY IN PREGNANCY[2]	SAFETY IN BREASTFEEDING	CNS PENETRATION[3]	DOSAGE IN RENAL INSUFFICIENCY[4]	DOSAGE IN HEPATIC INSUFFICIENCY
Isoniazid	Has been used safely[3]	Safe	Good (20-100%)	No change[5]	No change, but use with caution
Rifampin	Has been used safely (isolated reports of malformations)	Safe	Fair (inflamed meninges) (10-20%)	No change	No change, but use with caution
Rifapentine	Safety not established	No data	Not established	Not established; Use with caution	No change, but use with caution
Rifabutin	Use with caution (limited data on safety)	No data	Good (30-70%)	No change	No change, but use with caution
Pyrazinamide	Recommended by WHO (not FDA)	Moderately safe	Good (75-100%); Use with caution	Decrease dosage; Increase interval; Use with caution	No change, but use with caution
Ethambutol	Has been used safely	Safe	Inflamed meninges only (20-30%)	Decrease dosage; Increase interval[4]	No change
Aminoglycosides (streptomycin, kanamycin, amikacin)	Avoid[6] (associated with ototoxicity in fetus)	Safe	Poor[7] (10-20%)	Decrease dosage; Increase interval[4,8]	No change
Capreomycin	Avoid[6] (limited data on safety)	No data	Poor (10-20%)	Decrease dosage; Increase interval[4,8]	No change
Levofloxacin	Use if benefit outweighs risk	Moderately safe	Good (70-80%)	Increase interval	No change, but use with caution
Moxifloxacin	Use if benefit outweighs risk	Moderately safe	Good (70-80%)	No change, but use with caution	No change, but use with caution, esp-ecially with severe hepatic insufficiency
Cycloserine	Use with caution (limited data on safety)	Moderately safe	Good (50-100%)	Decrease dosage; Increase interval[4,5]	No change
Ethionamide	Do not use (premature labor, congenital malformation)	No data	Good (100%)	No change, but use with caution	No change, but use with caution

APPENDIX I: THE USE OF ANTI-TUBERCULOSIS DRUGS AND PREGNANCY, BREASTFEEDING, TUBERCULOSIS MENINGITIS, AND RENAL AND HEPATIC FAILURE (CONTINUED)[1]

DRUG	SAFETY IN PREGNANCY[2]	SAFETY IN BREASTFEEDING	CNS PENETRATION[3]	DOSAGE IN RENAL INSUFFICIENCY[4]	DOSAGE IN HEPATIC INSUFFICIENCY
Para-aminosalicylic acid	Has been used safely	Moderately safe	Inflamed meninges only	No change, but use with caution	No change, but use with caution
Linezolid	Use only if the potential benefit justifies the risk	Limited data	Good (30-70%)	No change, but use with caution[4]	No change, but use with caution
Bedaquiline	Use only if the potential benefit justifies the risk	Limited data; if needed, monitor infants for signs of BDQ toxicity	Limited data	No change, but use with caution	No change, but use with caution
Clofazimine	Use only if the potential benefit justifies the risk	Should not be used unless clearly indicated	Limited data	Limited data	Limited data
Pretomanid[9]	No data	No data	No data	No data	No data

1. This table presents a consensus of published data and recommendations.

2. As with all medications given during pregnancy, anti-TB medications should be used with extreme caution. The risk of TB to the fetus far outweighs the risk of most medications. Data are limited on the safety of anti-TB medications during pregnancy.

3. Steroid treatment appears to improve outcome in TB meningitis, particularly in patients with altered mental status.

4. If possible, monitor serum drug levels of patients with renal insufficiency.

5. Supplement with pyridoxine hydrochloride (vitamin B6), 25 mg per day for INH, 50 mg per day for each 250 mg per day of cycloserine.

6. If an injectable medication must be used during pregnancy, streptomycin is the preferred agent if the organism is susceptible.

7. Has been used intrathecally: efficacy not documented.

8. If possible, avoid injectable agents in patients with reversible renal damage.

9. Pretomanid is used as part of a regimen that includes linezolid and bedaquiline.

Abbreviations Used: CNS=central nervous system; FDA=Food and Drug Administration; mg=milligrams; TB=tuberculosis; WHO=World Health Organization

APPENDIX J: RECOMMENDATIONS FOR PATIENTS TO ASSIST WITH TAKING TUBERCULOSIS MEDICATIONS

DRUG	RECOMMENDATION
Isoniazid	• Avoid alcohol and acetaminophen-containing medications • Take 1 hour before or 2 hours after meals • May take with small snack if needed • Take 1 hour before or 2 hours after antacids • Supplement Vitamin B6 as needed (25-50 mg) • Avoid food and drinks that contain tyramine including hard cheeses, smoked or cured meats, and soy products
Rifampin	• Avoid alcohol • Take 1 hour before or 2 hours after meal • May take with small snack if needed • Take 1 hour before antacids
Ethambutol	• May be taken with food
Moxifloxacin and Levofloxacin	• Take 2 hours before or after aluminum-, magnesium-, or calcium-containing antacids; iron; vitamins; sucralfate; milk-containing products; and food supplements
Pyrazinamide	• May be taken with food
Ethionamide	• Avoid alcohol • Take with or after meals
Amikacin	• Increase fluid intake, if allowed
Streptomycin	• Increase fluid intake, if allowed • May affect the taste of food
Capreomycin	• May need to increase intake of foods high in potassium, if instructed • Increase fluid intake, if allowed
Para-aminosalicylic acid	• Take with or immediately following meals • Increase fluid intake • Take with yogurt, applesauce, or acidic foods
Cycloserine	• Avoid alcohol • Supplement vitamin B6 as directed
Linezolid	• May be taken with food • Avoid food and drinks that contain tyramine including hard cheeses, smoked or cured meats, and soy products • Do not use with pseudoephedrine, selective serotonin reuptake inhibitors, and other antidepressants

Adapted from: *Heartland National TB Center. Tuberculosis Medication Drug and Food Interactions.* Retrieved from www.heartlandntbc.org/assets/products/tuberculosis_medication_drug_and_food_interactions.pdf.

APPENDIX K: PROCEDURES FOR THERAPEUTIC DRUG MONITORING

Therapeutic drug monitoring (TDM) should be done when there is a clear indication for it. Routine monitoring of antituberculosis drug levels is not recommended in clinical practice. The significance of low serum levels of antituberculosis drugs in relation to clinical response has not been demonstrated. Studies have shown that as many as 60% of tuberculosis (TB) patients had low serum levels of isoniazid or rifampin. However, the clinical response to TB therapy did not differ in those with low drug levels when compared to those with normal levels.

Nonetheless, some patients will fail to respond to antituberculosis treatment despite documented adherence to the medications and absence of drug resistance. Some of these patients may have malabsorption syndromes that prevent them from achieving therapeutic levels of these drugs. Diseases such as human immunodeficiency virus (HIIV) infection, cystic fibrosis, diabetes, and sprue have been implicated in malabsorption of antituberculosis drugs.

A select number of patients with drug susceptible TB will therefore require drug level testing at some point during their treatment for tuberculosis. Patients with drug-resistant TB are more likely to require drug level testing.

In order to optimize the treatment of patients with TB while maintaining the highest levels of sound medical practice, the Bureau of Tuberculosis Control (BTBC) recommends that TDM be used in the following circumstances:

- Lack of clinical response (i.e., culture conversion) while on appropriate drugs and doses, on directly observed therapy (DOT) for at least two months and in the absence of drug resistance
- Lack of clinical response from second-line drugs with a narrow therapeutic window, such as cycloserine, when alternative drugs are limited, and when plans are in place to increase the dose of the drug should levels be low
- Patients with few effective drugs in their regimen, in order to optimize the effect of available drugs
- Lack of clinical response (i.e., lack of culture conversion at two months) in a patient with known or suspected malabsorption syndrome
- Patients with renal insufficiency and who have multidrug-resistant tuberculosis (MDR-TB) or are on certain drugs such as ethambutol
- Patients who relapse with active TB despite appropriate therapy

If drugs levels are low and doses are increased, clinical monitoring should be used to judge the response; repeat TDM should only be done when there is no clinical response after a reasonable amount of time.

Patients with pansensitive, cavitary, or otherwise very extensive disease tend to have a delayed clinical response to treatment even when adherence is documented (under DOT). In most cases these patients will respond if given enough time, usually in the third month of therapy. All patients with a delayed response (i.e., lack of culture conversion at two months) should be treated for nine months instead of six months.

In order to obtain accurate TDM results, BTBC staff must adhere strictly to the guidelines on specimen procurement and handling. Failure to do so will lead to inaccurate results, which may ultimately harm the patient. The following sections delineate procedures for obtaining and handling specimens for TDM.

PHYSICIANS

1. Request New York State (NYS) Clinical Laboratory Evaluation Program (CLEP) pre-approval for TDM through the Office of Medical Affairs, who will fax the NYS non-permitted lab test request to NYS CLEP. Approval is usually received within 1-2 days of submission of the request at the BTBC and the Bureau of Public Health Lab (PHL).
2. Schedule blood drawing on Monday or Tuesday to ensure delivery of the specimen to the Advanced Diagnostic Laboratories National Jewish Health (ADx-NJH) by Thursday. Since the serum must be frozen immediately after centrifugation, arrange immediate delivery of the serum on dry ice to the PHL if a freezer is unavailable at the chest center.
3. Order blood drawing for approximately 2 hours after an observed dose of antituberculosis medications for most medications. When testing levels for linezolid, blood should be drawn just before ingestion of the scheduled dose to obtain the trough level. After the observed ingested dose, blood should be drawn again in 2 hours to obtain the peak level. Additional information on the number of hours after administration of the drug/s dose to collect peak concentration is available on the ADx-NJH Pharmacokinetics Laboratory Requisition (https://www.nationaljewish.org/NJH/media/ADX/Requisitions/ADx700-Pharmacokinetics_Req_10-2018.pdf).
4. For most drug assays, continue all other antituberculosis medication as usually given. For streptomycin, inquire if patient is taking ampicillin and record this on ADX-NJH Pharmacokinetic Laboratory requisition.

PHLEBOTOMISTS

1. Communicate with PHL at (212) 447-6745 to inform them about the scheduled blood draw for TDM at the clinic and to arrange dry ice for specimen delivery back to the PHL.
2. Complete ADX-NJH pharmacokinetic laboratory requisition and PHL requisition to accompany the serum sample to the PHL.
3. Draw blood 2 hours or as applicable after an observed dose of anti-tuberculosis medication(s). Use two 5mL serum separator tubes (SST) or Northwell Lab gold top tubes to draw 5 mL of blood in each tube for one drug assay. Allow blood to clot for 30 minutes before centrifuging specimen to separate serum from cells. Label the cryovial to be used for aliquoting serum with the patient's name, DOB, the date and time of the blood draw, and the name of the drug(s) to be assayed.
4. Centrifuge blood tubes and aliquot serum from each 5mL tube into a separate 2 mL labeled cryovial. ADx-NJH requires at least 2mL of serum per test. Allow room for expansion of the serum inside the tube.

5. Freeze serum in the cryovial immediately and contact PHL to have the frozen serum picked up and transported to them on dry ice.

BUREAU OF PUBLIC HEALTH LABORATORY

1. At PHL, the sample will be frozen overnight at −70° C; the next day it will be packed in dry ice and labeled as specified in full compliance with the shipper and guidelines on handling of dry ice and potentially infectious materials. The ADx-NJH Pharmacokinetic Laboratory requisition sent with the specimen will be included in the shipping package.
2. PHL staff will call the shipper to pick up and deliver the samples.

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1. TDM reports will be delivered from ADx-NJH to the BTBC Office of Medical Affairs. Assays may require up to seven business days for completion.
2. ADx-NJH will bill the BTBC and the bill will go directly to Internal Accounting.
3. The Office of Medical Affairs will notify the staff taking care of the patient of the results. The results will be attached in the surveillance system and the electronic medical record.

APPENDIX L: INITIAL PATIENT INTERVIEW TOPICS

1. Educate the patient about tuberculosis (TB), debunking any misconceptions about the disease. The case manager should determine the most appropriate educational intervention and provide appropriate literature. The educational content should include information about:
   - TB transmission and pathogenesis
   - Preventing TB
   - Distinguishing infection from disease
   - How drug resistance develops
   - Length of treatment needed for sensitive vs. drug-resistant TB (DR-TB)
   - Standard TB medications, including names, dosages, actions, and side effects
   - Directly observed therapy (DOT) program and free New York City (NYC) Health Department services for TB
2. Establish long-term plans for treatment (including DOT).
3. Determine whether the patient will stay in NYC during TB treatment.
4. Inquire about contacts and emphasize to the patient why it is important that contacts be identified and evaluated as soon as possible.
5. Establish a trusting relationship, as this determines how well the patient views the role of the case manager and the healthcare establishment.
6. Obtain and document locating information and agree with the patient on a mode of communication (e.g., cell phone, home/work number, significant other). Identify who will always know where to find the patient.
7. Educate family and identified contacts about TB and the importance of getting evaluated.
8. Assess social needs such as access to social services to resolve issues with child care, housing, employment, substance abuse, and (if appropriate) legal or immigration issues (tell the patient that all services are provided irrespective of immigration status) and refer patient to social worker.
9. If the patient is diagnosed with TB while in a hospital, plans for follow-up care upon discharge must be initiated at the onset of hospitalization and not on the day before discharge. These plans must address issues that will ensure adherence with the treatment regimen.

APPENDIX M: DIRECTLY OBSERVED THERAPY AGREEMENT FORM

NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Dave A. Chokshi, MD MSc
Commissioner

BUREAU OF TUBERCULOSIS CONTROL (BTBC)
DIRECTLY OBSERVED THERAPY (DOT) AGREEMENT FORM

For Office Use Only:

Patient Name:_____

EMR ID (DOHMH): _____ TB Registry ID: _____

Patient's telephone number: ( ) _____ VDOT telephone number: ( ) _____

This is an agreement between the Bureau of Tuberculosis Control and _____to enroll into the Directly Observed Therapy program for: [ ] myself or [ ] _____ of who I am the legal guardian.

It has been explained to me that the most effective way to treat and prevent tuberculosis (TB) is by taking prescribed anti-TB medication and having a trained health care worker observe the ingestion of all oral medication doses. This observation can be done face to face or virtually by the use of a video-enabled device also known as video DOT (VDOT).

PATIENT/GUARDIAN AGREEMENT

I am enrolling [ ] myself [ ] my ward (e.g. minor child) in:

(1) Face to Face DOT: (a) _____ clinic (b) _____community

(2) Video DOT: (a) _____live video (LVDOT) (b) _____Recorded video (RVDOT)

Therefore, I, _____, agree to the following:
Name of patient /guardian

- I will take or ensure that _____(ward) takes his/her medication under direct observation either face to face in the clinic or the community or by video-enabled device, e.g., phone, tablet, or computer, in my home or secure location of my choice.
- I will or ensure that _____(ward) attends <u>all</u> clinic appointments until the doctor tells me that treatment is completed or is removed from the DOT program.
- If I or _____(ward) cannot make an appointment, I will call to reschedule it as soon as I know I cannot make it:
  - For VDOT appointments, I will call: _____ at _____
    Name of VDOT supervisor Telephone Number
  - For Chest Center appointments, I will call: _____ at _____
    Name of Clinic Nurse Telephone Number
  - For home/community provider appointments, I will call: _____ at _____
    Name of DOT case manager Telephone Number
- I understand that I may transfer between DOT options at any time during the course of the treatment.

APPENDIX M: DIRECTLY OBSERVED THERAPY AGREEMENT FORM (CONTINUED)

- If I or _____ (ward) attends a DOHMH clinic and enrolled in VDOT and decides to withdraw for any reason, I will immediately return unused medication to the clinic so that a new treatment plan can be made by my doctor. I will not give (ward) medication on my own without permission from the treating physician or designee.

Participants who selected VDOT, please initial beside each statement below to indicate that you understand and agree:

- If using my own equipment:
  _____ I understand that standard rates apply. I understand that the DOHMH is not responsible for any data, wireless, or other charges that may occur due to the use of the free VDOT software.

- If I am loaned a DOHMH videophone equipment:
  _____ I understand that the videophone equipment is the property of the DOHMH, and I am responsible for its care, maintenance, and return to the DOHMH upon completion or discontinuation of the VDOT program.

  _____ I will only use the equipment for VDOT and for communication directly related to my TB care.

BUREAU OF TUBERCULOSIS CONTROL (BTBC) AGREEMENT

I have explained the importance of TB treatment and DOT to the patient/guardian. Therefore,

I, _____, as a representative of the BTBC, agree to the following:
Name/title of Nurse/Case Manager/DOT Observer

- BTBC staff will meet _____ at _____AM/PM in person or by video conferencing.
  Name of Patient/ward

- BTBC staff will notify the patient and or guardian as quickly as possible if there is a scheduling conflict by phone at:
  _____ or _____.
  Home Number Mobile Number

- BTBC staff will assist the patient in maintaining his/her DOT and clinic appointments.

- BTBC staff will respond to all questions, concerns, and needs raised by the patient or guardian to the best of his/her capacity, including referrals for social services.

By signing below, we agree to be responsible for the above statements:

_____ Date____/____/____
Signature of Patient/Guardian

_____ Date____/____/____
Signature of Case Manager/DOT Observer/Nurse

If you have any questions, concerns, suggestions or complaints about any aspect your care, please contact:

_____ at _____
Name/Title Telephone Number

Last updated: March 2019

APPENDIX N: HOME ISOLATION AGREEMENT

NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Dave A. Chokshi, MD MSc
Commissioner

HOME ISOLATION PATIENT AGREEMENT

I _____ acknowledge that I have active infectious tuberculosis,
(Patient's full name)
and that I must separate myself from others in order to prevent other from being exposed to my tuberculosis disease.
I have discussed this agreement with _____
(Full name of DOHMH employee)
a _____ at the Department of Health and Mental Hygiene
(Job title)
(DOHMH), who has answered my questions about home isolation fully to my satisfaction. I further acknowledge that if I am unable or unwilling to observe any of the conditions of this agreement, while my tuberculosis remains infectious, I represent a danger to the health of others and I am subject to removal to a hospital for respiratory isolation either voluntarily or by order of the Commissioner of Health.

In return for being allowed to remain in my home while my tuberculosis is infectious, I agree to all of the following conditions.

- I will take all my prescribed anti-tuberculosis medications in a program of daily directly observed therapy (DOT) as directed by my physician or the Commissioner of Health.
- I will entertain no visitors in my home and will not visit other persons' home.
- I will cover my mouth and nose whenever I cough, sneeze, or hack while indoors or outdoors in the presence of other people.
- I will not use any public (bus, train, taxi, subway, airplane) or private (automobile) transportation unless absolutely necessary to obtain medical attention, and then only using the mask which my physician has prescribed for me.
- I will not visit enclosed public spaces such as theaters, shopping malls, department, supermarket or other stores; but I may spend time in open spaces such as parks, backyards or public streets which are not crowded.
- I will not care for or spend time with children of any age or work outside my home without permission from my physician and the DOHMH.
- I will not leave New York City for any reason without the DOHMH and my physician's permission and under such conditions as are prescribed.
- I have received a copy of the instructions entitled "Instructions for Patients with Potentially Infectious TB"
- Any additional conditions:

_____
_____
_____

If I have any further questions about how to comply with this agreement, I will telephone
_____ at _____
(Full name and title of contact person at DOHMH) (Telephone number with area code)

Date: _____ _____
(Patient's signature)

Date: _____ _____
(Staff signature)

Revised: July 2006

APPENDIX O: INSTRUCTIONS FOR PATIENTS WITH POTENTIALLY INFECTIOUS TB

NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Dave A. Chokshi, MD MSc
Commissioner

Instructions for patients with potentially infectious TB

You are being discharged from the hospital although your sputum tests indicate that you may still infect other people with TB or you are advised to be evaluated as an outpatient while you may have infectious TB.

You are being discharged because you said that either you live alone or will be going back to a living arrangement where the other people living there are healthy and wish to have you home. We are required by law to notify them that they have been exposed to TB and to evaluate them.

You may have been placed on medication to treat TB already or are waiting to start medications after you have been evaluated as an outpatient.

The following instructions will help reduce the spread of TB germs to other people and you should follow them carefully:

- If you return to a home that has other people, you should always:
  - Limit the time spent in common household areas (such as bathroom or kitchen) and keep your bedroom door closed
  - Wear a surgical mask when spending time in a space that is also used by others to reduce the number of TB germs that you put in the air when you cough or talk.
- You should always cover your mouth when coughing or sneezing
- You should not be around infants, young children or, to the best of your knowledge, persons who have weakened immunity such as people with HIV/AIDS. (If there are young children at home, you may still be discharged to the home if the children have been evaluated for latent TB infection and are on "preventive" medication, as determined by their physician)
- You should participate in a program of directly observed therapy (DOT), about which you have been educated by an employee of the NYC health department
- You should avoid going to public places or return to work or school until your doctor, working with the health department, says it is OK for you to do so
- You should keep your doctor's or clinic appointments to ensure that treatment for TB is not interrupted
- Some of these restrictions will be removed once your physician, along with the health department, determines that you are no longer infectious
- Your TB treatment and DOT will continue even after these restrictions are removed.

Following these instructions will help in limiting the spread of TB germs to your family and others. If you have questions about your treatment please call your physician or health department at 311.

You can also find more information about TB on our website at nyc.gov/health/tb.

APPENDIX P: INFORMATION FOR PERSONS WHO LIVE WITH PATIENTS WITH TB

NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Dave A. Chokshi, MD MSc
Commissioner

Information for persons who live with patients with TB

A family member or someone in your household was recently diagnosed with or is suspected of having active TB. TB is a preventable and treatable disease. TB is transmitted through the air when a patient with the disease coughs or sneezes without covering his or her mouth. People with the active form of the disease must take their medication and must follow certain rules to prevent the spread of TB germs to people they live or work with. ***We are required by state law to inform you of this information.***

If there are children in your home they should be evaluated by their doctor and they should be placed on "preventive" therapy if appropriate. They can also be evaluated and treated at the health department's chest centers.

If a family member or someone in your household has been diagnosed with TB:

- You should get tested to see if you have already been infected with the germs that cause TB
- If you have been infected with the germs that cause TB, you should have a medical evaluation and a chest x-ray to make sure that you have not progressed to active TB
- If you have TB infection, you should take medicine to prevent the development of active TB.
- **The member of your household with TB should stay at home until his or her physician and the health department says he/she can go out.**
- He/she should not go to work or school during this time period and should avoid going to any public areas during this time period.
- Please assist the TB patient by doing their errands, such as grocery shopping.
- Your household member with TB should cover his/her mouth with a tissue whenever he/she coughs or sneezes; he/she should put the used tissue in the regular garbage.
- When around other people, the patient should wear a surgical mask that covers the nose and mouth.
- While at home, limit your contact with the TB patient as much as possible; the patient should sleep in a separate room until advised by their physician.
- It is OK to share eating utensils (spoons, forks, cups or glasses) and other household items.

Following these instructions will help in limiting the spread of TB germs to your family and others.
If you have questions about your treatment please call your physician or health department at 311.
You can also find more information about TB on our website at nyc.gov/health/tb.

APPENDIX Q: NEW YORK CITY HEALTH DEPARTMENT UNIVERSAL REPORTING FORM

NYC Health

New York City Department of Health and Mental Hygiene

Universal Reporting Form

To report an **immediately notifiable** disease or condition, an outbreak among three or more persons or an unusual manifestation of any disease or condition, or any newly apparent or emerging disease or syndrome, call the Provider Access Line at **866-692-3641**.

Diseases and conditions in green and marked with * are **immediately notifiable**; those marked with † are immediately notifiable if case meets the risk group criteria on page 2. Report by calling **866-692-3641**.

For all other diseases and conditions, report using Reporting Central online via NYCMED at **www.nyc.gov/health/nycmed**, mail this form to the NYC Department of Health and Mental Hygiene, 42-09 28th Street, CN-22, Long Island City, NY 11101, or call **866-692-3641** for the appropriate fax number.

Go to **www.nyc.gov/health/diseasereporting** for more information.

Patient Information

Patient Last Name	First Name	Middle Name	DATE OF REPORT
Patient AKA: Last Name	AKA: First Name	AKA: Middle Name	_____/_____/_____
Age / Date of Birth _____/_____/_____	Country of Birth	Social Security Number	DATE OF DIAGNOSIS
If patient is a child, Guardian Last Name	Guardian First Name	Guardian Middle Name	_____/_____/_____
Medical Record Number	Medicaid Number		DATE OF ILLNESS ONSET
Patient Home Address	City / State / Zip Code		_____/_____/_____
Country	Borough: ☐ Manhattan ☐ Bronx ☐ Brooklyn ☐ Queens ☐ Staten Island ☐ Unknown ☐ Not NYC		
Email Address	Mobile Phone	Home Phone	☐ Homeless

Sex: ☐ Male ☐ Female ☐ Transgender MTF ☐ Transgender FTM ☐ Unknown

Race: ☐ Black ☐ White ☐ American Indian/Alaska Native ☐ Native Hawaiian/Pacific Islander ☐ Asian ☐ Other: _____ ☐ Unknown

Ethnicity: ☐ Hispanic ☐ Non-Hispanic ☐ Unknown

Is patient alive? ☐ Yes ☐ No ☐ Unknown
If no, date of death: _____/_____/_____

Is patient pregnant? ☐ Yes ☐ No ☐ Unknown
If yes, due date: _____/_____/_____

Is case suspected to be due to healthcare associated transmission? ☐ Yes ☐ No ☐ Unknown

Was patient admitted to hospital? ☐ Yes ☐ No ☐ Unknown
Admission date: _____/_____/_____
Discharge date: _____/_____/_____

Is patient a newborn infant? ☐ Yes ☐ No ☐ Unknown
If yes, name of hospital where infant was born _____
Name of facility where infant's mother obtained prenatal care _____

Foreign travel

Countries _____ **Date returned to U.S.** _____/_____/_____

Other Information

REPORTER	Name of Person Reporting Disease	Email address	Phone	
	Name of Facility of Person Reporting Disease	National Provider Identifier (NPI) Code	Permanent Facility Identifier (PFI) Code	
	Facility Street Address	City	State	Zip Code
FACILITY	Name of Hospital/Healthcare Facility Providing Care for Patient	Facility National Provider Identifier (NPI) Code	Permanent Facility Identifier (PFI) Code	
	Facility Street Address	City	State	Zip Code
LAB	Name of Testing Laboratory	Phone	CLIA Number	
	Laboratory Street Address	City	State	Zip Code
PROVIDER	Name of Provider Caring for Patient	National Provider Identifier (NPI) Code	Fax	
	Email address	Phone	Mobile	
	Provider Street Address	City	State	Zip Code

Form PD-16 (Rev. 3/2017)

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APPENDIX Q: NEW YORK CITY HEALTH DEPARTMENT UNIVERSAL REPORTING FORM (CONTINUED)

Patient Last Name	First Name	Medical Record Number

Diseases and conditions in green and marked with * are immediately notifiable; those marked with † are immediately notifiable if case meets the risk group criteria at the bottom of the page. Report by calling **866-692-3641**.

For all other diseases and conditions, report using Reporting Central online via NYCMED at **www.nyc.gov/health/nycmed**, mail this form to the NYC Department of Health and Mental Hygiene, 42-09 28th Street, CN-22, Long Island City, NY 11101, or call **866-692-3641** for the appropriate fax number.

Go to **www.nyc.gov/health/diseasereporting** for more information.

- ☐ **Amebiasis†**
- ☐ **Anaplasmosis** (Human granulocytic anaplasmosis)

  Animal bite – see Environmental Conditions section on page 3. See rabies if potential for exposure.
- ☐ **Anthrax***
- ☐ **Arboviral infections,** acute*

  Specify which virus: _____
  If Chikungunya, Dengue, West Nile, Yellow Fever or Zika report as such.
  Attach copies of diagnostic laboratory results if available.
- ☐ **Babesiosis**
- ☐ **Botulism***
  ○ Foodborne ○ Infant ○ Wound
- ☐ **Brucellosis***
- ☐ **Campylobacteriosis†**

  Carbon Monoxide poisoning* – see Poisonings section on page 3

  Chancroid – see STD section on page 4
- ☐ **Chikungunya**

  Chlamydia – see STD section on page 4
- ☐ **Cholera***

  Creutzfeldt-Jakob disease – see Transmissable spongiform encephalopathy
- ☐ **Cryptosporidiosis†**
- ☐ **Cyclosporiasis†**
- ☐ **Dengue**
  Attach copies of dengue diagnostic laboratory results if available.
- ☐ **Diphtheria***

  Drownings – see Environmental Conditions section on page 3
- ☐ **Ehrlichiosis** (Human monocytic ehrlichiosis)
  If human granulocytic anaplasmosis report as anaplasmosis.
- ☐ **Encephalitis**
  If Jul.1–Oct. 31 consider and test for West Nile virus. If due to another reportable disease (e.g. Lyme, West Nile, arbovirus), report under the other disease.
- ☐ **Escherichia coli** O157:H7 infection†

  Falls from windows – see Environmental Conditions section on page 3
- ☐ **Food poisoning** in a group of 2 or more individuals*
- ☐ **Giardiasis†**
- ☐ **Glanders***

  Gonorrhea – see STD section on page 4

  Granuloma inguinale – see STD section on page 4
- ☐ **Haemophilus influenzae** (invasive disease)†

  Test type:
  ○ Culture ○ Antigen
  ○ PCR ○ Gram stain
  ○ Other _____

  Specimen Source:
  ○ Blood ○ CSF ○ Unknown
  ○ Other _____

  Specify Serotype:
  ○ Type B ○ Not typeable
  ○ Not tested ○ Unknown
  ○ Other _____
- ☐ **Hantavirus disease***
- ☐ **Hemolytic uremic syndrome**

FOR ALL HEPATITIS REPORTS

Jaundice ○ Yes ○ No ○ Unknown
ALT (SGPT) value:_____ ○ Unknown
Lab reference range:_____ ○ Unknown

- ☐ **Hepatitis A†**
  Total Ab to Hepatitis A is NOT reportable.
  IgM anti-HAV: ○ Pos ○ Neg ○ Unknown
- ☐ **Hepatitis B†**
  Report at least one positive hepatitis B test result. Total Ab to Hepatitis B is not reportable.
  IgM anti-HBc: ○ Pos ○ Neg ○ Unknown
  HBsAg: ○ Pos ○ Neg ○ Unknown
  HBeAg: ○ Pos ○ Neg ○ Unknown
  HBV Nucleic Acid: ○ Pos ○ Neg ○ Unknown

  If IgM is positive, describe symptoms and risk in comments box on last page.

  Hepatitis B in pregnancy
  Report cases in Reporting Central or fax IMM-5 form to 347-396-2558. For more information, call 347-396-2403.
- ☐ **Hepatitis C†**
  Check all that apply:
  ○ EIA pos
  ○ HCV Nucleic Acid (e.g.PCR) pos

  Is this an acute infection?
  ○ Yes
  ○ No
  ○ Unknown

Herpes, neonatal – see STD section on page 4

HIV/AIDS
Report using the New York State Provider Report Form (PRF). Call 518-474-4284 for forms or 212-442-3388 for more information.

Influenza
- ☐ Suspected novel viral strain with pandemic potential (e.g., avian H5N1 or H7N9)*
- ☐ Death in a child aged 18 or younger

Lead poisoning – see Poisonings section on page 3

- ☐ **Legionellosis†**

  Specify positive test:
  ○ Culture ○ Urine antigen
  ○ DFA ○ Serology
  ○ NAAT or PCR
- ☐ **Leprosy** (Hansen's disease)
- ☐ **Leptospirosis**
- ☐ **Listeriosis†**
- ☐ **Lyme disease**

  Erythema migrans present?
  ○ Yes ○ No ○ Unknown
- ☐ **Lymphocytic choriomeningitis virus**

  Lymphogranuloma venereum – see STD section on page 4
- ☐ **Malaria†**

  Select at least one of the following:
  ○ falciparum ○ vivax ○ malariae
  ○ ovale ○ undetermined

  Complete Foreign Travel section on page 1.
- ☐ **Measles** (rubeola)*
- ☐ **Melioidosis***
- ☐ **Meningitis,** bacterial

  Specify bacteria identified _____
- ☐ **Meningococcal disease,** invasive (including meningitis) *

  Test type/Specimen source:
  ○ Blood culture ○ CSF culture
  ○ Antigen test from CSF ○ Gram stain
  ○ PCR ○ Other _____
- ☐ **Monkeypox***
- ☐ **Mumps†**
- ☐ **Paratyphoid fever†**
- ☐ **Pertussis** (whooping cough)†
- ☐ **Pesticide poisoning** - see Poisonings section on page 3
- ☐ **Plague***

  Poisoning – see Poisonings section on page 3
- ☐ **Poliomyelitis***
- ☐ **Psittacosis**
- ☐ **Q Fever***
- ☐ **Rabies** and **exposure to rabies*** – see animal bites in Environmental Conditions section on page 3
- ☐ **Ricin poisoning***
- ☐ **Rickettsialpox**
- ☐ **Rocky Mountain spotted fever**
- ☐ **Rubella** (German measles)*
- ☐ **Rubella syndrome,** congenital
- ☐ **Salmonellosis†**

  Serogroup: _____
  If due to Salmonella typhi or paratyphi, select Typhoid or Paratyphoid Fever.
- ☐ **Severe or novel coronavirus** (e.g., SARS or MERS-CoV)*
- ☐ **Shiga-toxin** producing Escherichia coli (STEC) infection†
- ☐ **Shigellosis†**
- ☐ **Smallpox** (variola)*
- ☐ **Staphylococcal enterotoxin B poisoning***
- ☐ **Staphylococcus aureus,** vancomycin intermediate (VISA) and resistant (VRSA)*

  Source: _____
  MIC (µg/ml): _____
- ☐ **Streptococcus** (Group A and B) invasive†

  Specify Source: ○ Blood ○ CSF ○ Unknown
  ○ Other, Specify:_____

  Syphilis, including congenital – see STD section on page 4
- ☐ **Tetanus**
- ☐ **Toxic shock syndrome**
- ☐ **Trachoma**
- ☐ **Transmissible spongiform encephalopathy** (Creutzfeldt-Jakob disease and variants)

  Testing done: _____
  (e.g. 14-3-3 on CSF, brain biopsy, autopsy, EEG/MRI)
- ☐ **Trichinosis**

  Tuberculosis – see Tuberculosis section on page 3
- ☐ **Tularemia***
- ☐ **Typhoid fever†**
- ☐ **Vaccinia disease** (adverse events associated with smallpox vaccination)*
- ☐ **Vibrio species,** non-cholera

  Specify species:_____
- ☐ **Viral hemorrhagic fever***
- ☐ **West Nile** fever and viral neuroinvasive disease (e.g., meningitis and encephalitis)

  Attach copies of diagnostic laboratory results if available.
- ☐ **Yellow fever***

  Attach copies of diagnostic laboratory results if available.
- ☐ **Yersiniosis,** non-plague†
- ☐ **Zika**

*Report suspected and confirmed cases immediately to 1-866-692-3641 †If case meets any of the risk group criteria below, report immediately to 1-866-692-3641

Risk Groups for Disease Exposure/Transmission Complete this section for diseases marked with † and if case meets any criteria, report it immediately to 1-866-692-3641.

Patient works in:
☐ Childcare ☐ Health care facility ☐ Long-term care facility/Nursing home ☐ Clinical/Research laboratory
☐ Unknown ☐ Food service ☐ Correctional facility ☐ Position with routine animal contact ☐ Other _____

Patient attends/resides in:
☐ Assisted living facility ☐ School ☐ Dormitory ☐ Long-term care facility/nursing home
☐ Unknown ☐ Correctional facility ☐ Shelter ☐ Day care/group baby-sit ☐ Other congregate living facility (specify: _____)

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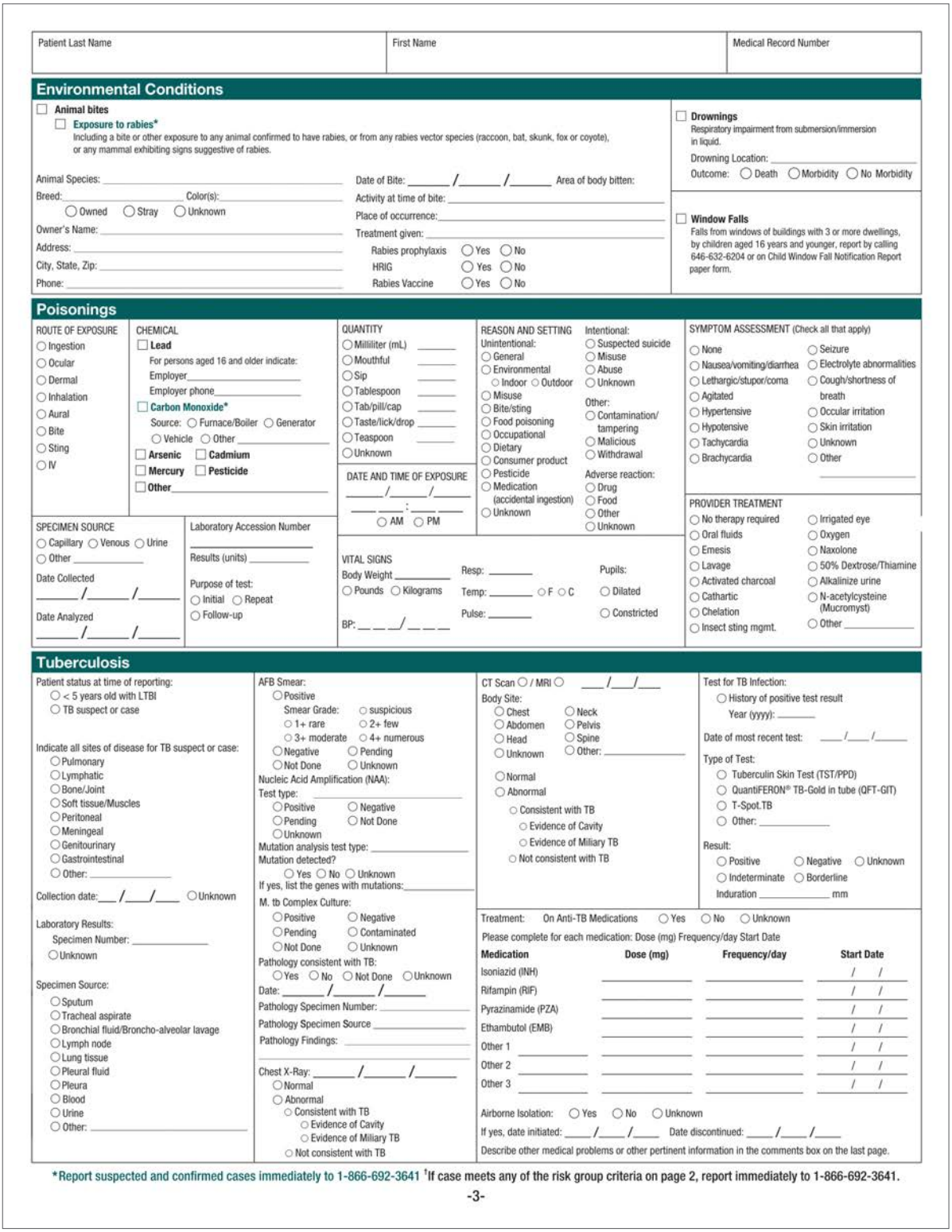
APPENDIX Q: NEW YORK CITY HEALTH DEPARTMENT UNIVERSAL REPORTING FORM (CONTINUED)



Patient Last Name | First Name | Medical Record Number

Environmental Conditions

☐ **Animal bites**

☐ **Exposure to rabies***
Including a bite or other exposure to any animal confirmed to have rabies, or from any rabies vector species (raccoon, bat, skunk, fox or coyote), or any mammal exhibiting signs suggestive of rabies.

Animal Species: _____
Breed: _____ Color(s): _____
○ Owned ○ Stray ○ Unknown
Owner's Name: _____
Address: _____
City, State, Zip: _____
Phone: _____

Date of Bite: ____/____/____ Area of body bitten:
Activity at time of bite: _____
Place of occurrence: _____
Treatment given: _____
Rabies prophylaxis ○ Yes ○ No
HRIG ○ Yes ○ No
Rabies Vaccine ○ Yes ○ No

☐ **Drownings**
Respiratory impairment from submersion/immersion in liquid.
Drowning Location: _____
Outcome: ○ Death ○ Morbidity ○ No Morbidity

☐ **Window Falls**
Falls from windows of buildings with 3 or more dwellings, by children aged 16 years and younger, report by calling 646-632-6204 or on Child Window Fall Notification Report paper form.

Poisonings

ROUTE OF EXPOSURE
○ Ingestion ○ Ocular ○ Dermal ○ Inhalation ○ Aural ○ Bite ○ Sting ○ IV

CHEMICAL
☐ **Lead**
For persons aged 16 and older indicate:
Employer_____
Employer phone_____
☐ **Carbon Monoxide***
Source: ○ Furnace/Boiler ○ Generator ○ Vehicle ○ Other _____
☐ **Arsenic** ☐ **Cadmium** ☐ **Mercury** ☐ **Pesticide** ☐ **Other**_____

QUANTITY
○ Milliliter (mL) _____ ○ Mouthful _____ ○ Sip _____ ○ Tablespoon _____ ○ Tab/pill/cap _____ ○ Taste/lick/drop _____ ○ Teaspoon _____ ○ Unknown

DATE AND TIME OF EXPOSURE
____/____/____
____ : ____
○ AM ○ PM

REASON AND SETTING
Unintentional:
○ General ○ Environmental ○ Indoor ○ Outdoor ○ Misuse ○ Bite/sting ○ Food poisoning ○ Occupational ○ Dietary ○ Consumer product ○ Pesticide ○ Medication (accidental ingestion) ○ Unknown
Intentional:
○ Suspected suicide ○ Misuse ○ Abuse ○ Unknown
Other:
○ Contamination/tampering ○ Malicious ○ Withdrawal
Adverse reaction:
○ Drug ○ Food ○ Other ○ Unknown

SYMPTOM ASSESSMENT (Check all that apply)
○ None ○ Nausea/vomiting/diarrhea ○ Lethargic/stupor/coma ○ Agitated ○ Hypertensive ○ Hypotensive ○ Tachycardia ○ Brachycardia ○ Seizure ○ Electrolyte abnormalities ○ Cough/shortness of breath ○ Occular irritation ○ Skin irritation ○ Unknown ○ Other _____

PROVIDER TREATMENT
○ No therapy required ○ Oral fluids ○ Emesis ○ Lavage ○ Activated charcoal ○ Cathartic ○ Chelation ○ Insect sting mgmt. ○ Irrigated eye ○ Oxygen ○ Naxolone ○ 50% Dextrose/Thiamine ○ Alkalinize urine ○ N-acetylcysteine (Mucromyst) ○ Other _____

SPECIMEN SOURCE
○ Capillary ○ Venous ○ Urine ○ Other _____
Date Collected ____/____/____
Date Analyzed ____/____/____

Laboratory Accession Number _____
Results (units) _____
Purpose of test:
○ Initial ○ Repeat ○ Follow-up

VITAL SIGNS
Body Weight _____ ○ Pounds ○ Kilograms
BP: ___ ___/___ ___
Resp: _____
Temp: _____ ○ F ○ C
Pulse: _____
Pupils:
○ Dilated ○ Constricted

Tuberculosis

Patient status at time of reporting:
○ < 5 years old with LTBI ○ TB suspect or case

Indicate all sites of disease for TB suspect or case:
○ Pulmonary ○ Lymphatic ○ Bone/Joint ○ Soft tissue/Muscles ○ Peritoneal ○ Meningeal ○ Genitourinary ○ Gastrointestinal ○ Other: _____
Collection date: ___/___/___ ○ Unknown

Laboratory Results:
Specimen Number: _____
○ Unknown

Specimen Source:
○ Sputum ○ Tracheal aspirate ○ Bronchial fluid/Broncho-alveolar lavage ○ Lymph node ○ Lung tissue ○ Pleural fluid ○ Pleura ○ Blood ○ Urine ○ Other: _____

AFB Smear:
○ Positive
Smear Grade: ○ suspicious ○ 1+ rare ○ 2+ few ○ 3+ moderate ○ 4+ numerous
○ Negative ○ Pending ○ Not Done ○ Unknown
Nucleic Acid Amplification (NAA):
Test type: _____
○ Positive ○ Negative ○ Pending ○ Not Done ○ Unknown
Mutation analysis test type: _____
Mutation detected?
○ Yes ○ No ○ Unknown
If yes, list the genes with mutations: _____
M. tb Complex Culture:
○ Positive ○ Negative ○ Pending ○ Contaminated ○ Not Done ○ Unknown
Pathology consistent with TB:
○ Yes ○ No ○ Not Done ○ Unknown
Date: ____/____/____
Pathology Specimen Number: _____
Pathology Specimen Source _____
Pathology Findings: _____

Chest X-Ray: ____/____/____
○ Normal
○ Abnormal
○ Consistent with TB
○ Evidence of Cavity
○ Evidence of Miliary TB
○ Not consistent with TB

CT Scan ○ / MRI ○ ___/___/___
Body Site:
○ Chest ○ Abdomen ○ Head ○ Unknown ○ Neck ○ Pelvis ○ Spine ○ Other: _____
○ Normal
○ Abnormal
○ Consistent with TB
○ Evidence of Cavity
○ Evidence of Miliary TB
○ Not consistent with TB

Test for TB Infection:
○ History of positive test result
Year (yyyy): _____
Date of most recent test: ___/___/___
Type of Test:
○ Tuberculin Skin Test (TST/PPD)
○ QuantiFERON® TB-Gold in tube (QFT-GIT)
○ T-Spot.TB
○ Other: _____
Result:
○ Positive ○ Negative ○ Unknown
○ Indeterminate ○ Borderline
Induration _____ mm

Treatment: On Anti-TB Medications ○ Yes ○ No ○ Unknown
Please complete for each medication: Dose (mg) Frequency/day Start Date

Medication	Dose (mg)	Frequency/day	Start Date
Isoniazid (INH)			/ /
Rifampin (RIF)			/ /
Pyrazinamide (PZA)			/ /
Ethambutol (EMB)			/ /
Other 1			/ /
Other 2			/ /
Other 3			/ /

Airborne Isolation: ○ Yes ○ No ○ Unknown
If yes, date initiated: ___/___/___ Date discontinued: ___/___/___
Describe other medical problems or other pertinent information in the comments box on the last page.

*Report suspected and confirmed cases immediately to 1-866-692-3641 †If case meets any of the risk group criteria on page 2, report immediately to 1-866-692-3641.

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APPENDIX Q: NEW YORK CITY HEALTH DEPARTMENT UNIVERSAL REPORTING FORM (CONTINUED)

Patient Last Name	First Name	Medical Record Number

Sexually Transmitted Diseases

For All STD Reports

As of the date of this report,

Were any of this patient's sex partners notified of possible exposure to an STD? (Check all that apply)
- ◯ Yes, our office notified the partner(s)
- ◯ Yes, the patient was asked to notify partner(s)
- ◯ No
- ◯ Unknown

Did you provide treatment for any of this patient's partners? (Check all that apply)
- ◯ Yes, I saw the sex partner(s) in my office
- ◯ Yes, I gave extra medication for ___(#) partner(s)
- ◯ Yes, I wrote a prescription for ___(#) partner(s)
- ◯ Yes, some other way (specify):_____
- ◯ No
- ◯ Unknown

Is the patient on pre-exposure prophylaxis (PrEP) to prevent HIV infection?
- ◯ Yes, started PrEP at time of current STD diagnosis
- ◯ Yes, already on PrEP at time of current STD diagnosis
- ◯ No
- ◯ Unknown

Please indicate gender of sexual partners in the past year: (Check all that apply)
- ◯ Males
- ◯ Females
- ◯ Transgender Male to Female
- ◯ Transgender Female to Male
- ◯ Unknown

☐ **Chancroid**
Specify type of specimen:
◯ Penile ◯ Vaginal ◯ Endocervical ◯ Anorectal ◯ Oropharyngeal ◯ Other: _____
Specimen collection date: ____/____/____
Treatment: _____
Treatment date: ____/____/____ ◯ Unknown

☐ **Granuloma inguinale**
Specify type of specimen:
◯ Penile ◯ Vaginal ◯ Endocervical ◯ Anorectal ◯ Oropharyngeal ◯ Other _____
Specimen collection date: ____/____/____
Treatment: _____
Treatment date: ____/____/____ ◯ Unknown

☐ **Lymphogranuloma venereum**
Clinical Presentation (Check all that apply)
◯ Proctitis ◯ Lymphadenopathy ◯ Buboe ◯ Skin lesion ◯ Other: _____
Specimen collection date: ____/____/____
Treatment: _____
Treatment date: ____/____/____ ◯ Unknown

Syphilis Test Types: (Check all that apply)

1. Serologic tests for syphilis

A. Non-treponemal Test
◯ RPR ◯ Reactive ◯ Non-reactive
Titer _____
◯ VDRL ◯ Reactive ◯ Non-reactive
Titer _____
Specimen collection date: ____/____/____

B. Treponemal Test
◯ TP-PA/MHA-TP ◯ Reactive ◯ Non-reactive
◯ FTA ◯ Reactive ◯ Non-reactive
◯ Treponemal IgG ◯ Reactive ◯ Non-reactive
Specimen collection date: ____/____/____

2. Cerebrospinal fluid tests
◯ CSF VDRL ◯ Reactive ◯ Non-reactive
◯ CSF FTA ◯ Reactive ◯ Non-reactive
◯ Other Test: _____ Result _____
Specimen collection date: ____/____/____
◯ Elevated CSF protein ◯ Yes ◯ No
◯ Elevated CSF leukocytes ◯ Yes ◯ No
Specimen collection date: ____/____/____

3. Organism visualization
◯ Darkfield ◯ Positive ◯ Negative
◯ Other Test: _____ Result _____
Specimen collection date: ____/____/____

☐ **Chlamydia** (CT)
Specify type of specimen:
◯ Endocervical ◯ Urethral ◯ Anorectal ◯ Oropharyngeal ◯ Urine ◯ Other: _____
Specify test type:
◯ Culture ◯ Nucleic acid amplification ◯ Nucleic acid hybridization ◯ EIA ◯ DFA ◯ Other: _____
Specimen collection date: ____/____/____
Treatment: _____
Treatment date: ____/____/____ ◯ Unknown

☐ **Herpes, neonatal**
Herpes simplex virus infection in infants aged 60 days and younger.
◯ Clinical diagnosis
◯ Lab confirmed diagnosis
◯ Culture ◯ PCR ◯ Other _____
Herpes type: ◯ Type 1 ◯ Type 2 ◯ Not typed
Clinical Syndrome (Check all that apply)
◯ Skin, eye, mucous membrane infection
◯ CNS involvement
◯ Disseminated disease
Herpes lesions present?
◯ Yes, anatomic site _____
◯ No
◯ Unknown
Specimen collection date: ____/____/____
Treatment for infant: _____
Treatment date: ____/____/____ ◯ Unknown
Mother's Name: _____
Mother's DOB: ____/____/____
Birth Hospital _____
Mother's Labor and Delivery Medical Record No: _____

☐ **Syphilis****
Stage:
◯ Congenital
◯ Primary, chancre present (Check all that apply)
◯ Penile ◯ Vaginal ◯ Endocervical ◯ Anorectal ◯ Oropharyngeal ◯ Other: _____
◯ Secondary (Check all that apply)
◯ Alopecia ◯ Condylomata ◯ Mucous patches ◯ Rash
◯ Early Latent
no symptoms, infection ≤ 1 year duration
◯ Late Latent
no symptoms, infection of > 1 year duration
◯ Tertiary, gumma or cardiovascular
Neurologic symptoms present?
◯ Yes ◯ No ◯ Unknown
Ocular symptoms present?
◯ Yes ◯ No ◯ Unknown
Otic symptoms present?
◯ Yes ◯ No ◯ Unknown
Treatment – list medication and dosage below:
_____
_____
_____
Treatment date: ____/____/____ ◯ Unknown
Continue to next column

☐ **Gonorrhea*** (GC)
Specify type of specimen:
◯ Endocervical ◯ Urethral ◯ Anorectal ◯ Oropharyngeal ◯ Urine ◯ Other: _____
Specify test type:
◯ Culture ◯ Nucleic acid amplification ◯ Nucleic acid hybridization ◯ Other: _____
Specimen collection date: ____/____/____
Treatment 1*: _____ mg/gram
Treatment 2*: _____ mg/gram
Treatment date: ____/____/____ ◯ Unknown

* For uncomplicated gonococcal infections of the cervix, urethra, anorectum or pharynx, CDC recommends dual therapy (irrespective of concurrent chlamydial infection) using BOTH Ceftriaxone 250mg IM AND Azithromycin 1g PO.

** Licensed health care providers can access current and historical syphilis test results and treatment information in the New York City Syphilis Registry to inform the diagnosis and management of syphilis in their patients. For more information, see the Syphilis Registry check at: http://www1.nyc.gov/assets/doh/downloads/pdf/std/hcp-syphilis-registry-check.pdf, or call 347-396-7201

Comments:

APPENDIX R: REPORT OF PATIENT SERVICES FORM

NYC Health

Bureau of Tuberculosis Control
42-09 28th Street, Box 72
Long Island City, N.Y. 11101
844-713-0559/ FAX: 844-713-0557

REPORT OF PATIENT SERVICES

Please print firmly and legibly

By law this form must be submitted for every monthly visit of patients with active tuberculosis.

TB Registry Number _____ Social Security Number ___ ___ _____ Chart Number _____

Patient Name: _____ (Last) _____ (First) _____ (M.I.)

Address _____ Apt. # _____ Zip Code _____

Daytime Phone ( ) ___ _____ Evening Phone ( ) ___ _____ Date of Birth ____ (Month) / ____ (Day) / ____ (Year)

❑ If patient missed appointment, check here and go to box at bottom of page. (Date of missed appointment ____ (Month) / ____ (Day) / ____ (Year))

TB Site of Disease (check all that apply):

- ❑ Pulmonary
- ❑ Other (Specify)
- ❑ Pleural _____
- ❑ Lymphatic _____
- ❑ Meningeal _____

Latest chest X-ray: ____ (Month) / ____ (Day) / ____ (Year)

- ❑ Normal
- ❑ Abnormal-noncavitary (including adenopathy)
- ❑ Abnormal-cavitary

Findings: _____

If prior films available; is this film

- ❑ Stable ❑ Worsening ❑ Improving

Most recent bacteriology:

Date specimen collected: ____ (Month) / ____ (Day) / ____ (Year)

Source of Specimen: _____

Smear:	Culture:
❑ Positive	❑ Positive
❑ Negative	❑ Negative
❑ Pending	❑ Pending

If culture positive:

❑ M.tb ❑ Other _____

Was susceptibility ordered? ❑ Yes ❑ No

Medications prescribed at this visit?

❑ Yes ❑ No Reason: _____

Medication regimen changed this visit?

❑ Yes ❑ No Reason: _____

Is patient on Directly Observed Therapy?

❑ Yes ❑ No Reason: _____

Frequency of DOT:

- ❑ Daily
- ❑ 2x per week
- ❑ 3x per week
- ❑ 5x per week
- ❑ once a week

Drugs and dosages:

❑ INH ____ mg	❑ RIF ____ mg	❑ PZA ____ mg
❑ EMB ____ mg	❑ SMN ____ mg	❑ PAS ____ mg
❑ Ethio ____ mg	❑ CYC ____ mg	❑ Kana/AMI ____ mg
❑ RPT ____ mg	❑ Levo ____ mg	❑ Capreo ____ mg
❑ RBT ____ mg	❑ Other ____	❑ MOXI ____ mg

Services provided
Check all that apply:

- ❑ Doctor visit
- ❑ Nurse visit
- ❑ X-ray
- ❑ Sputum sample
- ❑ Audiometry
- ❑ Liver enzymes
- ❑ Vision testing
- ❑ Other

Date of this visit: ____ (Month) / ____ (Day) / ____ (Year) Date of next visit: ____ (Month) / ____ (Day) / ____ (Year)

Management Course/Outcome:

- ❑ Completed treatment
- ❑ Expired – was cause of death TB? ❑ Yes ❑ No
- ❑ Moved/transferred (where): _____
- ❑ Rehospitalized (where): _____
- ❑ Other _____

M.D. Name: _____ M.D. License # _____

Facility: _____ Prepared by: _____ Phone: ( ) ___ _____

TB 65 (Rev. 11/11)

COPIES: White–DOHMH; Yellow–Chart; Pink–Clinic Records

APPENDIX S: HOSPITAL DISCHARGE APPROVAL FORM

NYC Health

NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE
BUREAU OF TUBERCULOSIS CONTROL

HOSPITAL DISCHARGE APPROVAL REQUEST FORM

Please complete this form in entirety and fax to 844-713-0557 (toll-free)

SECTION A: Patient Contact Information

Patient name: _____ DOB: ____/____/____ (mm/dd/yyyy)

Tel. #: (1) (____)_____–_____ (2) (____)_____–_____

Address: _____ Apt.: _____ City: _____ State: _____ Zip: _____

Emergency contact name: _____ Relationship to patient: _____ Tel. #: (____)_____–_____

SECTION B: Discharge Information

Discharging facility: _____ Discharging facility tel. #: (____)_____–_____

Address: _____ Fl.: _____ City: _____ State: _____ Zip: _____

Patient medical record #: _____ Date of admission: ____/____/____ (mm/dd/yyyy) Planned discharged date: ____/____/____ (mm/dd/yyyy)

Discharged to: ☐ Home (if not the same address as above, fill in address below)

☐ Shelter ☐ Skilled nursing facility ☐ Jail/Prison ☐ Residential facility ☐ Other facility

Name of facility: _____ Tel. #: (____)_____–_____

Address: _____ Apt./Fl.: _____ City: _____ State: _____ Zip: _____

Is patient scheduled to travel outside of NYC? ☐ Yes ☐ No If yes, specify date/destination: _____

SECTION C: Patient Follow-Up Appointment

Patient follow-up appointment date: ____/____/____ (mm/dd/yyyy)

Physician assuming care: _____ Tel. #: (____)_____–_____ Cell. #: (____)_____–_____

Address: _____ City: _____ State: _____ Zip: _____

Potential barriers to TB therapy adherence: ☐ None ☐ Adverse reactions ☐ Homelessness

☐ Physical disability (*specify*) _____ ☐ Medical condition (*specify*) _____

☐ Substance use (*specify*) _____ ☐ Mental disorder (*specify*) _____ ☐ Other _____

SECTION D: Laboratory Results

Dates of three most recent acid fast bacilli (AFB) smears	Specimen source	Acid fast bacilli (AFB) smear results
____/____/____	_____	☐ Positive Grade: _____ ☐ Negative
____/____/____	_____	☐ Positive Grade: _____ ☐ Negative
____/____/____	_____	☐ Positive Grade: _____ ☐ Negative

SECTION E: Treatment Information

Date TB therapy initiated: ____/____/____ (mm/dd/yyyy) Interruption in therapy? ☐ Yes ☐ No If yes, state the reason and duration of the interruption? _____

TB medications at discharge: ☐ INH ____ mg ☐ RIF ____ mg ☐ PZA ____ mg ☐ EMB ____ mg ☐ SM ____ mg ☐ Vitamin B_6 ____ mg

☐ Injectables (*specify*) _____ ☐ Other TB meds (*specify*) _____

Frequency: ☐ Daily ☐ 2x weekly ☐ 3x weekly ☐ Other _____

Was a central line (i.e. PICC) inserted on the patient? ☐ Yes ☐ No

Number of days of medications supplied to patient at discharge _____ Patient agreed to be on DOT? ☐ Yes ☐ No

Print name of individual filling out this form: _____ Date: ____/____/____ (mm/dd/yyyy)

Name of responsible physician at the discharging facility: _____ License #: _____

Signature of responsible physician at the discharging facility: _____ Tel. #: (____)_____–_____

COMPLETED BY THE HEALTH DEPARTMENT **BTBC NUMBER:** _____

Discharge approved: ☐ Yes ☐ No Action required before discharge: _____

Reviewed by: _____ (NAME OF HEALTH OFFICER/DESIGNEE) Date: ____/____/____ (mm/dd/yyyy)

TB 354 (11/10)

APPENDIX S: HOSPITAL DISCHARGE APPROVAL FORM (CONTINUED)

Guidelines for How to Complete and Submit the Mandatory TB Hospital Discharge Approval Request Form (TB 354)

As of June 16, 2010, Article 11 of the New York City Health Code mandates health care providers to obtain approval from the New York City Department of Health & Mental Hygiene (DOHMH) before discharging infectious TB patients from the hospital.

Discharge of an Infectious (sputum smear positive) Tuberculosis Patient

Health care providers must submit a Hospital Discharge Approval Request Form (TB 354) at least 72 hours prior to the anticipated discharge date. The DOHMH will review the form and approve or request additional information before the patient can be discharged from the health care facility.

Weekday (non-holiday) Discharge: The written discharge plan should be submitted by fax to the Bureau of TB Control between 8am-5pm. Bureau of TB Control staff will review the discharge plan and, within 24 hours, notify the provider of approval or inform the provider of any additional information/actions required for approval prior to discharge.

Weekend and Holiday Discharge: All arrangements for discharge should be made in advance when weekend or holiday discharge is anticipated.

For detailed information about hospital admission and discharge of TB patients, please refer to the New York City DOHMH Bureau of TB Control Policies and Protocols manual available online at http://www1.nyc.gov/site/doh/health/health-topics/tb-hosp-manual.page

Instructions for Completing the Hospital Discharge Approval Request Form (TB 354)

Section A Patient contact information: Provide the patient's contact information including patient's name, a verified address and telephone numbers. In addition, include a name of an emergency contact, the contact's relationship to the patient and the contact's verified phone number.

Section B Discharge information: Provide the name and phone number of the discharging facility, the medical record number of the patient at the facility, date the patient was admitted, planned discharge date, and the location to which the patient is being discharged. If the patient will be discharged to a location other than the patient's address listed in Section A, a facility name (if applicable), address and phone number must be provided. If the patient plans to travel, provide the date and destination.

Section C Patient follow-up appointment: Provide the patient's follow-up appointment date, as well as the name and contact information of the provider who is assuming patient care. Check all potential obstacles that may affect TB therapy adherence.

Section D Laboratory results: Report the results of the three most recent acid fast bacilli (AFB) smears including the date of specimen collection, specimen source, and AFB smear results and/or grade.

Section E Treatment information: Fill in the date TB treatment was initiated. If there were any treatment interruptions, indicate the reason and number of days treatment was stopped. Check the box next to each prescribed drug and state dosages for each drug. Write in drugs and dosages for drugs not specified. Specify the treatment frequency by checking one of the three boxes, or writing in a different treatment schedule. State whether the patient will have a central line inserted at the time of discharge. If TB medication will be supplied to the patient at discharge, write the number of days for which the medication will be supplied. State whether the patient agreed to be on directly observed therapy (DOT).

After Section E, the name of the person completing the form should be printed and the authorized physician at the discharging facility must print and sign their name, and provide their medical license number and telephone number.

Forms should be faxed to the DOHMH at 844-713-0557 (toll-free).

If you have questions about completing the form, please call 311 and ask to speak to a Bureau of TB Control physician.

To fulfill State requirements for communicable disease reporting, health care providers must report all suspected or confirmed TB cases to the DOHMH via Reporting Central (formerly Universal Reporting Form (URF)). Instructions for reporting a case of TB can be found at http://www1.nyc.gov/site/doh/providers/reporting-and-services/hcp-urf.page

NOTE: A discharge approval request form does not substitute required case reports.

TB 354 (11/10)