TUBERCULOSIS AND HANSEN'S DISEASE UNIT

BINATIONAL TUBERCULOSIS PROGRAM MANUAL FISCAL YEAR 2025

TEXAS Health and Human Services
Texas Department of State Health Services

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Table of Contents

Appendices

Figures

Tables

Glossary of Terms

COEFAR

Comités Estatales de Fármacorresistencia
A state committee in Mexico that ensures patients with drug-resistant (DR) tuberculosis (TB) are properly diagnosed, treated, and managed based on Mexico's National TB guidelines. Per Mexico's federal guidance, each state in Mexico must maintain a COEFAR to address drug-resistant TB.

COFEPRIS

Comisión Federal para la Protección contra Riesgos Sanitarios
A regulatory body of the Mexican government to regulate a variety of health-related products in Mexico, including food safety, pharmaceutical drugs, medical devices, organ transplants, and environmental protection. This regulatory body is equivalent to the United States (U.S.) Food and Drug Administration (FDA).

Texas Consulting Physician

A physician who has a valid and current license to practice in the State of Texas who acts in an advisory capacity to the binational TB (BNTB) program. This physician provides expert recommendations and may provide oversight to the BNTB program to ensure Texas standards of care are followed for patients enrolled in the BNTB Program.

Dictamen

A formal document provided by the COEFAR and GANAFAR to the requesting health department in Mexico which includes recommendations to treat patients.

doTBal

A two-phased fixed combination of medication dosages available in Mexico consisting of isoniazid, rifampin, ethambutol, and pyrazinamide in the intensive phase, and isoniazid and rifampin in the continuation phase.

GANAFAR

Grupo Asesor Nacional en Fármacorresistencia
A federal committee composed of Mexico's national TB director, the *Instituto Nacional de Referencia Epidemiológica* (InDRE) mycobacterial laboratory manager,

physicians belonging to different health institutions in Mexico with experience managing DR-TB, and a bioethics representative of the National Human Rights Commission. The GANAFAR responsibilities include:

- Promoting compliance in guiding patient care with DR-TB,
- Reviewing all difficult to treat cases of TB,
- Advising COEFAR on any issues related to DR-TB,
- Reviewing, recommending, and ratifying documents previously approved by COEFAR,
- Updating national TB guidelines,
- Supporting the national TB program in training staff on DR-TB management, and
- Operating as a gateway to access new TB medications such as delamanid and bedaquiline.

Green Light Committee

A committee established by the World Health Organization (WHO) in January 2000 which provides access to affordable, high-quality, second-line TB medications for the treatment of multi-drug resistant (MDR-TB). Mexico may request medications from this committee to treat MDR-TB.

Incentives and Enablers

These are methods employed by TB programs to facilitate adherence to TB treatment. Incentives are small rewards given to the patient and may include gift cards or food vouchers. Enablers help the patient complete therapy or show up for DOT appointments. This may include transportation vouchers.

Official Mexican Norma

Referred to as the Norma Oficial Mexicana for the prevention and control of TB in Mexico. It is the official TB guidelines outlining Mexico's standards to prevent, detect, diagnose, and treat TB and latent TB infection (LTBI). It also includes control measures to protect public health. See guidelines here: NOM-006-SSA@-2013.

Patient-Physician Relationship

A patient-physician relationship exists when a physician serves a patient's medical needs. Generally, the relationship is entered into by mutual consent between physician and patient (or surrogate). However, a limited patient-physician relationship may be created without the patient's (or surrogate's) explicit

agreement. Such as when a physician provides emergency care or provides care at the request of the patient's treating physician. In circumstances like these, the patient's (or surrogate's) agreement to the relationship is implicit. Read more about patient-physician relationships here.

Regional Mycobacteriology Program

Colloquially known as the "National," "Nacional," "Regional," or "Jurisdicción" Program. The local regional mycobacteriology programs within each Mexican state ensure each patient with TB receive comprehensive care and full access to quality diagnosis and treatment. This program refers patients to the BNTB Program if specific criteria are met. Note: The federal program's official name is the National Program for the Prevention and Control of TB, and the state program is known as the State Mycobacteriology Program.

Secretaría de Salud

Also referred to as Secretariat of Health and is a department in the Mexican government responsible for social services and other aspects of health and human services in Mexico.

Shadow Chart

A system to include components of a full patient medical record at a different location where the original medical record is housed.

Treating Physician

A physician who is responsible for the overall care of a patient and who provides medical treatment and evaluation to a patient. The treating physician has an ongoing relationship with the patient known as a patient-physician relationship.

Rifampin mono-resistance (RR-TB)

Resistance to rifampin, a first-line TB drug; this type of DR-TB is treated similarly to multi-drug resistant TB (MDR-TB).

Multi-drug resistant (MDR-TB)

Resistance to at least rifampin and isoniazid.

Pre-extensively drug resistant (Pre-XDR-TB)

MDR-TB, plus resistance to one of the second-line injectable agents (amikacin, capreomycin, kanamycin) *or* a fluoroquinolone.

Extensively drug resistant (XDR-TB)

MDR-TB, plus resistance to one of the second-line injectable agents (amikacin, capreomycin, or kanamycin) **and** a fluoroquinolone **OR** MDR, plus resistance to a fluoroquinolone, and BDQ or linezolid.

I. Introduction

The Binational TB Program (BNTB) is within the Department of State Health Services (DSHS) Tuberculosis and Hansen's Disease Unit (Unit). It is a formal partnership between Texas and Mexico to address TB along the Texas-Mexico border. The program consists of physicians, nurses, managers, and coordinators in Texas working in close collaboration with physicians and nurses in Mexico to provide direct outpatient care services to eligible patients. Established in 1991, the goal of the program is to reduce transmission of TB along the Texas-Mexico border to protect public health in Texas.

The purpose of the BNTB program manual is to describe the origins of the program and provide guidance to BNTB program sites to implement consistent TB prevention and care practices. While BNTB programs must follow the minimum standards of care outlined in this document, the treating physician should write patient specific orders. Programs will collaborate with partners in Mexico to ensure procedures in both countries are followed.

The BNTB Program follows the guiding principles, mission, and vision of DSHS and the Secretariat of Health in Mexico, including standards set forth by the Unit. The BNTB programs are to use the most current version of the manual and have systems in place to implement program activities.

II. Background

Among all the states in the United States (U.S.), Texas shares the longest stretch of border with Mexico, spanning 1,254 miles from the Gulf to El Paso. It is joined by twenty-eight international bridges and border crossings, including two dams, one hand-drawn ferry, and twenty-five additional crossings that allow commercial, vehicular, and pedestrian traffic. According to the Bureau of Transportation Statistics, 86,913,296 people crossed legally into Texas from Mexico through Texas International Ports of Entry in 2023. Of that number, there were 15,834,545 pedestrians, while 64,127,033 crossed in personal vehicle passengers. However, millions come to the U.S. each year by other means[1]. According to the Center for Immigration Studies, there are an estimated 11.35 million undocumented immigrants in the U.S. as of January 2022. While the exact number of illegal crossings via the Texas/Mexico border is not known, this does suggest a "floating" population.

Beyond the social, political, and economic impact of immigration, there is also a public health impact. Tuberculosis is among the most significant infectious disease concern along the Texas/Mexico border. Both Texas and Mexico acknowledge cities along this border have a higher incidence of TB, which was pivotal in the combined decision to establish the BNTB program.

The first BNTB program Juntos was formally established in 1991 with Texas Department of Health, Public Health Region (PHR) 9/10, El Paso Department of Public Health and the Mexican Secretariat of Health with both countries agreeing to work together in El Paso-Ciudad Juarez, Chihuahua, Mexico. The Los Dos Laredos Program was established in 1993 with cooperative agreements between the Laredo Public Health Department in Laredo and Nuevo Laredo, Tamaulipas, Mexico. Two years later in 1995, the Grupo Sin Fronteras Program was formally established between Texas Department of Health PHR 11 and the Mexican Secretariat of Health in Tamaulipas, Mexico incorporating its work between the two largest bordering cities in the area specifically Brownsville-Matamoros, Tamaulipas and McAllen-Reynosa, Tamaulipas. In 2010 the newest program, Esperanza y Amistad, was established between Texas DSHS PHR 8 and the Secretariat of Health in Coahuila, Mexico working in Del Rio-Ciudad Acuña, Coahuila, and Eagle Pass-Piedras Negras, Coahuila, Mexico.

[1] Border Crossing Data Release 2023. Bureau of Transportation Statistics. www.bts.gov/newsroom/border-crossing-data-annual-release-2023.

Table 1: Binational TB Program Border Cities

BNTB Program	Established	Texas Border	Mexico Border	Mexico State
Juntos	1991	El Paso	Juarez	Chihuahua
Los Dos Laredos	1993	Laredo	Nuevo Laredo	Tamaulipas
Grupos Sin Fronteras	1995	Brownsville McAllen	Matamoros Reynosa	Tamaulipas Tamaulipas
Esperanza y Amistad	2010	Eagle Pass Del Rio	Piedras Negras Acuña	Coahuila Coahuila

III. Map, Organizational Structure, and Directory

There are four Mexican states bordering Texas: Tamaulipas, Nuevo Leon, Coahuila, and Chihuahua. The BNTB Program operates six Mexican-based clinics spanning three Mexican states, managed by four TB programs in Texas border cities.

Figure 1: Location of Binational TB Programs along the Texas-Mexico Border

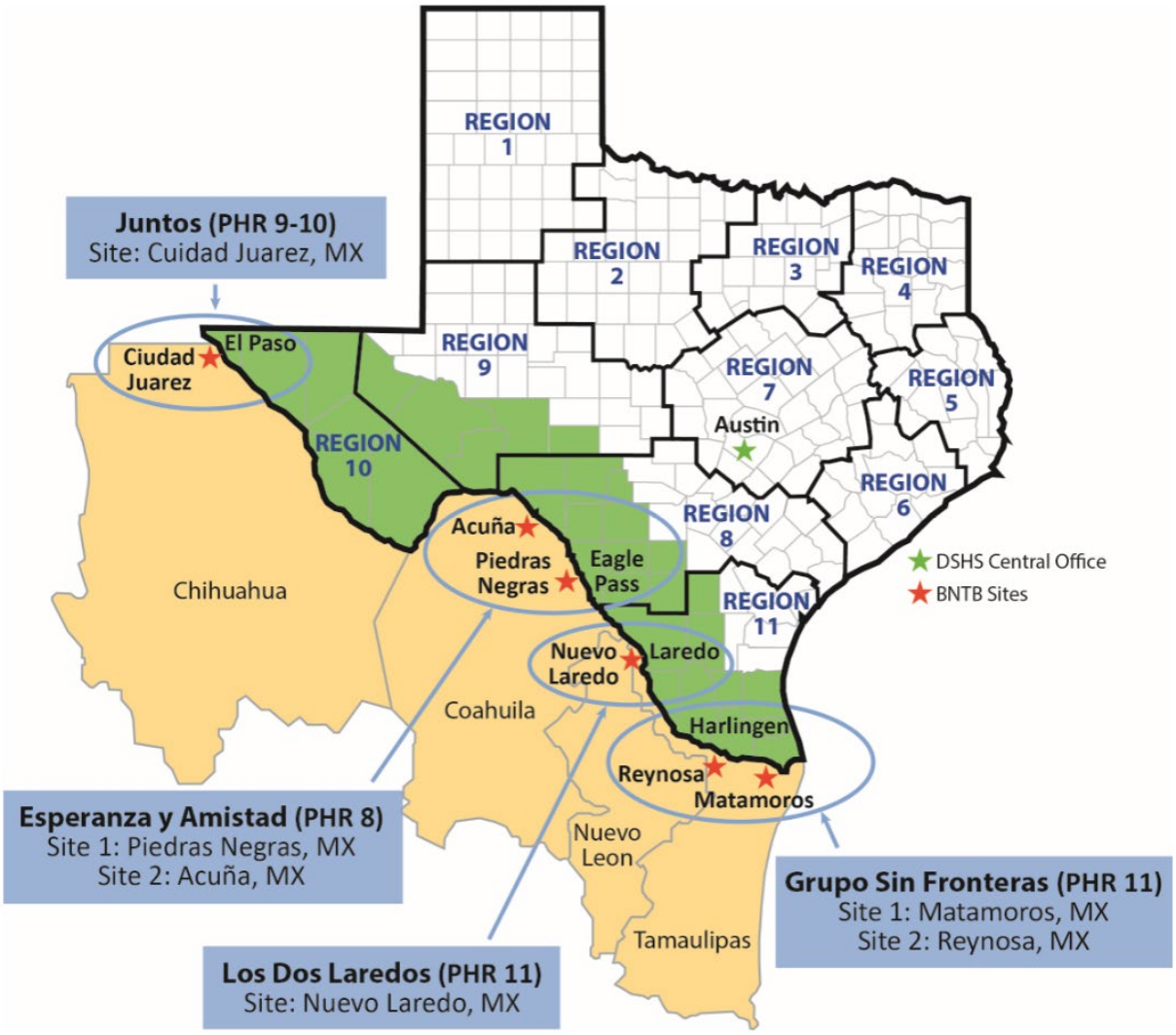


FIGURE 2 outlines the BNTB program structure. Roles and responsibilities are described in Chapter VII. ROLES AND RESPONSIBILITIES.

Figure 2: Binational TB Program Structure

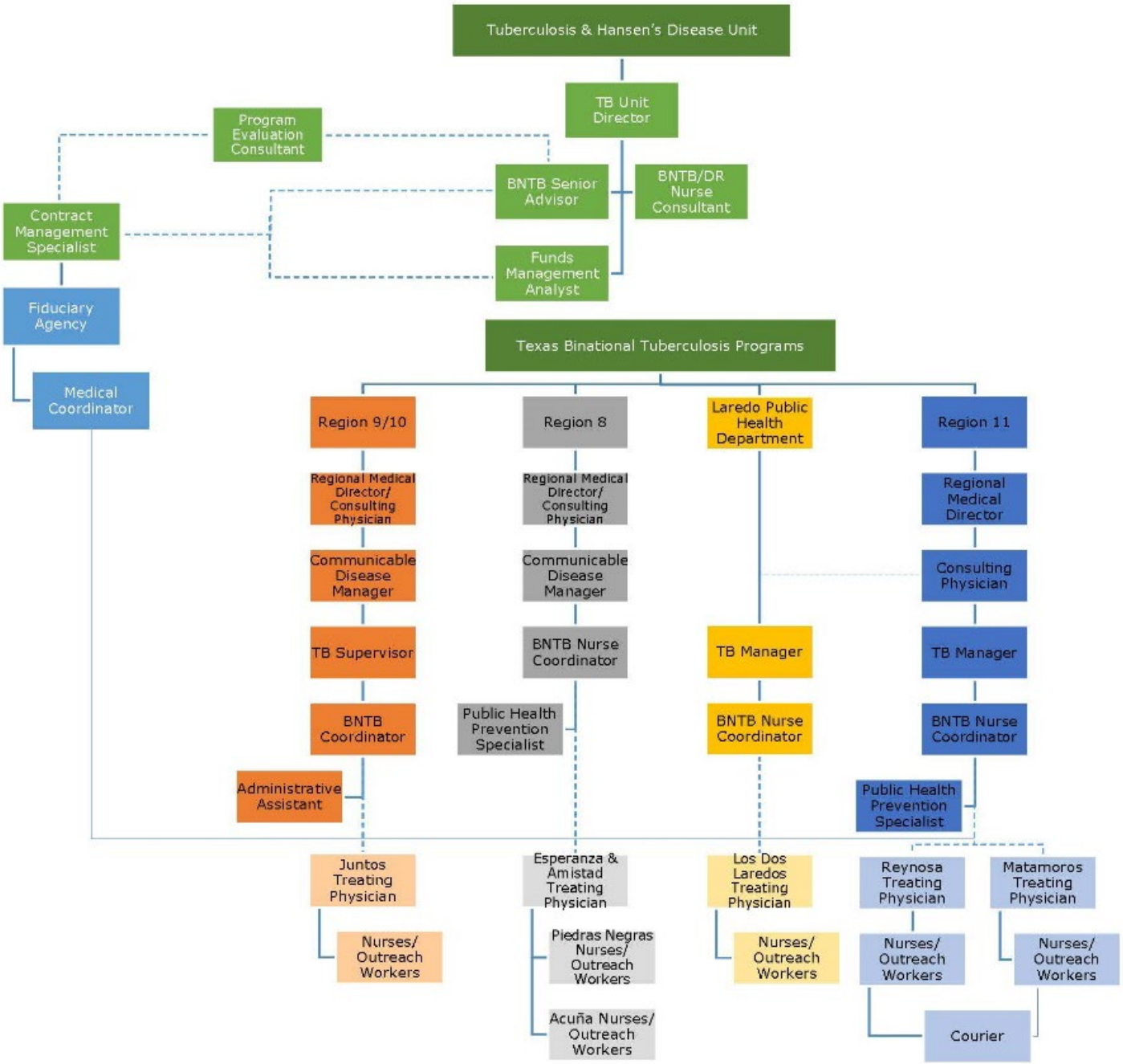


Table 2: Binational TB Program Contact Information

Esperanza y Amistad DSHS PHR 8 *Sites:* Piedras Negras, Coahuila, México Ciudad Acuña, Coahuila, México	1593 Veterans BLVD Eagle Pass, Texas 78852 Phone: 830-758-4274 Fax: 512-206-3949 Tuberculosis.region8@dshs.texas.gov
Grupo Sin Fronteras DSHS PHR 11 *Sites:* Matamoros, Tamaulipas, México Reynosa, Tamaulipas, México	601 W Sesame Drive Harlingen, Texas 78550 Phone: 956-444-3244 956-444-3205 956-421-5574 Fax: 956-444-3295
Juntos DSHS PHR 9/10 *Site:* Ciudad Juárez, Chihuahua, México	401 E Franklin, Suite 210 El Paso, Texas 79901 Phone: 915-834-7792 Fax: 915-834-7722 HSR9-10.CDReporting@dshs.texas.gov
Los Dos Laredos Laredo Public Health Department *Site:* Nuevo Laredo, Tamaulipas, México	2600 Cedar Ave Laredo, Texas 78040 Phone: 956-727-6974 956-795-4911 Fax: 956-724-5789

IV. Program Eligibility, Referrals and Approval

Eligibility

To be eligible for BNTB services, a patient must have known or suspected TB disease, be a contact to someone with known or suspected TB disease, and meet at least one of the following criteria:

A. Has dual residency in the U.S. and Mexico.

   1. Proof of resident card (green card) is required.

B. Lives in Mexico and has contacts on both sides of the Texas border during infectious period.

   1. Proof of Texas address can be verified using DSHS approved address verification database (e.g., Accurint).

C. Is referred from the U.S. for treatment follow-up in Mexico.

Referrals

Programs must ensure resources are available to manage patients prior to accepting them into the BNTB program. Programs will follow the steps outlined in APPENDIX B: PROCESS FOR ENROLLMENT when accepting a patient into the BNTB program. These patients should be managed in partnership and collaboration with the TB program in Mexico. The following forms should be used when referring a patient to the BNTB program:

A. Form BN-200 will be submitted to the BNTB program from programs in Mexico requesting admission into the program prior to receiving care in the Texas BNTB program.

B. An Interjurisdictional TB Notification (IJN) Form will be submitted for patients with suspected or confirmed TB, a TB contact or person with LTBI who needs continuity of care within a BNTB program who have moved from or to a jurisdiction in Texas or the U.S. See APPENDIX N: INTERJURISDICTIONAL COMMUNICATION for activities related to IJN.

Approval

Programs will follow a tiered approval process when accepting patients into the BNTB program. The detailed process is outlined in APPENDIX B: PROCESS FOR ENROLLMENT and states the following:

A. The BNTB program in Mexico will review form BN-200 for criteria eligibility.

B. The treating physician in the BNTB program in Mexico, BNTB coordinators, managers, and consulting physician will review and collaboratively accept or decline entry into the program.

C. The BNTB program in Mexico will send their decision to accept or decline the patient to the Regional Mycobacteriology Program.

D. A copy of the BN-200 will be kept in the patient's medical record in Mexico and the Texas shadow chart.

V. Stewardship and Accountability

General Requirement

The BNTB programs, with the fiduciary agency, will implement a comprehensive TB program and manage resources effectively focusing on stewardship and accountability. The BNTB programs in Mexico are an extension of the L/RHD TB programs and receive assistance from them.

Accounts for TB services (i.e., video directly observed therapy (VDOT), Quest account numbers, DSHS laboratory requisitions or any requisition containing Unit billing information, etc.) cannot be shared with entities outside the program. The U.S. BNTB program staff must ensure program services are delivered in a manner consistent with DSHS standards. This includes ensuring the appropriate evaluation, treatment, and management of program-eligible patients. Patients should be managed according to standards of care outlined in this document with consideration to the TB Mexican Norma. Collaboration among Texas consulting physicians, Mexico's treating physician and the Regional Mycobacteriology Program must occur to successfully deliver patient care services.

Activities

A**. The BNTB programs will:**

1. Provide care and make recommendations in evaluating, diagnosing, treating, and monitoring patients with suspected or confirmed TB disease or LTBI who meet program eligibility to receive services.
2. Collaborate with the Regional Mycobacteriology Program in Mexico on patients referred to the BNTB program for treatment for LTBI or disease and start treatment as directed by the BNTB treating physician.
3. Provide a written agreement to the Regional Mycobacteriology Program in each Mexican state describing the shared roles and responsibilities in the delivery and co-management of TB services between the BNTB program and the TB program in Mexico, see APPENDIX C: CO-MANAGEMENT OF PATIENTS AGREEMENT.
4. Maintain a complete shadow chart at the BNTB program in Texas on patients managed in the program.
5. Comply with medication and record keeping, and completion of TB-206a, as required by 340B, regardless of the administration location.

6. Document plan of care between the BNTB program and Mexico in the medical record, specifying each program's responsibilities.
7. Adhere to Mexico's reporting requirements for all program-eligible patients. This will include sharing treatment recommendations with the TB program in Mexico.
8. Develop a plan to prepare for unforeseen circumstances (e.g., hurricanes, border closures due to increased violence in the area, etc.). Programs should consider the event including medication allowance to patients during these events (e.g., five to seven days of self-administered medications or video directly observed therapy (VDOT).
9. Provide contact investigation (CI) services outlined in Chapter XII. Conduct and Manage a TB Contact Investigation.
10. Treat contacts according to the standards of care outlined in Chapter IX. Management of Patients with Latent TB Infection, including Patients on Window Prophylaxis.
11. Send and receive referrals for patients needing care from regional and local TB programs in the U.S. and Mexico for TB case management purposes.
12. Report to the Regional Mycobacteriology Program in each Mexican state, referrals received from the Migrant Clinicians Network/Health Network (formerly TB Net), CureTB, detention centers, and correctional facilities.
13. Develop a process for continuity of care for referrals received including but not limited to Immigration Customs Enforcement (ICE), Cure TB, U.S. Marshalls, etc. A process should be outlined at each program site.
14. Obtain formal consults from a Texas DSHS-Recognized TB Medical Consultant upon identification of a drug-resistant case of TB and for patients outlined in Appendix D: Medical Consultation Process.
15. Submit Unit-designated reports in accordance with established deadlines and schedules, by DSHS-approved mechanisms.
16. Enter all program-eligible patients in the Notifiable Electronic Disease Surveillance System (NEDSS). See Chapter XVIII. Reporting Requirements for time requirements.
17. Apply appropriate administrative, environmental, and respiratory controls to prevent exposure and transmission of TB.

18. Provide professional education, training, and orientation to contracted BNTB program staff working in Mexico to perform duties that align with DSHS and BNTB program standards of care outlined in this manual.
19. Respond to medical records requests per local or regional policies.
20. Maintain medical records as required by General Provisions Article VIII, "Records Retention," and by Texas Administrative Code Title 22, Part 9, Chapter 165, §165.1, or by your local and regional record retention policy, whichever has a longer retention policy.
21. Collaborate with the fiduciary agency to maintain accurate and concise records such as time and mileage reports for all staff working in Mexico, daily clinical activities, and that patient medical records are equivalent to DSHS standards of care.
22. Comply with confidentiality and security standards.
23. Perform self-auditing activities to assess clinical care services and reporting practices to achieve program objectives including conducting cohort reviews.
24. Collaborate with the fiduciary agency to conduct annual performance reviews of each BNTB contracted employee annually or when any clinical issues arise that need immediate attention.
25. Perform continuous quality improvement activities to achieve performance indicators. Outcome measures will reflect performance during each calendar year. The BNTB program performance indicators align with DSHS Texas TB Program's Performance Measures outlined in TABLE 12: TEXAS TB PERFORMANCE MEASURES.
26. Obtain on an annual basis, a permit from the Centers for Disease Control and Prevention (CDC) to legally import biological specimen into the U.S., Track and document each specimen transported into the U.S. See APPENDIX J: BIOLOGICAL SPECIMEN TRANSPORTATION for details.
27. Track and document each specimen transported into the U.S. See APPENDIX K: SAMPLE BIOLOGICAL SPECIMEN MANIFEST.

VI. Local Binational Tuberculosis Program Procedures

General Requirement

The BNTB programs will maintain procedures that align with the Unit's standards of care. The BNTB program procedures should not conflict with established Unit requirements and guidelines. Unit standards and procedures are published in this manual and available on DSHS TB website, texastb.org.

Activities

A. Develop and implement written procedures that meet the standards of care outlined in Chapter VIII. STANDARDS OF CARE. The following services are outlined in this manual and serve as minimum requirements:

1. Criteria to receive TB services
2. Enrollment to receive TB services
3. Treatment and management of LTBI
4. Treatment and management of suspected or active TB disease
5. Treatment and management of drug-resistant TB disease
6. Treatment and management of contacts to patients with TB disease
7. Contact investigation services
8. Transportation of biological specimens
9. Second-line medications
10. Sputum collection
11. Directly observed therapy
12. Infection control for TB
13. Case review
14. Cohort review
15. Reporting
16. Surveillance

B. BNTB program staff in Texas and Mexico must review and sign APPENDIX A: ATTESTATION OF REVIEW OF BNTB MANUAL within 30 days of hire. Existing BNTB staff in Mexico must submit a signed copy to the fiduciary agency within 30 days of the start of each new fiscal year which begins September 1.

1. It is recommended that BNTB program staff in Texas and Mexico review the BNTB program manual and procedures annually with the BNTB program coordinator, all BNTB program staff, nurse consultants, and any

additional licensed or unlicensed staff. This may occur in a one-day in-service to ensure all staff understand the requirements.

C. Ensure written procedures are easily accessible to all staff responsible for TB prevention and care activities in English and Spanish.

D. Revise procedures as appropriate to conform with DSHS standards and best practices.

VII. Roles and Responsibilities

General Requirement

The BNTB programs and contracted staff must deliver services in an efficient and competent manner. This chapter outlines the roles and responsibilities for programs and staff involved in the delivery of BNTB program services.

A. **The Unit will:**

1. Oversee BNTB program activities.
2. In all communication with the Mexico treating physician, include the local or regional program manager, the BNTB coordinator, and the RMD or consulting physician.
3. Provide expert nursing consultation.
4. Develop standards for TB prevention, care, and program management in collaboration with BNTB programs.
5. Use the Annual Progress Report (APR) and the Contract Management Section (CMS) reports to monitor and evaluate programs' progress towards meeting performance objectives to determine effectiveness and compliance with essential TB prevention and care standards.
6. Monitor BNTB programs' reports and ensure reports are submitted to the Unit by established deadlines.
7. Communicate with DSHS Pharmacy Unit and the BNTB programs to ensure availability of medications to treat TB disease and LTBI.
8. Provide laboratory support for diagnostic purposes.
9. Serve as a liaison with CDC, the fiduciary agency, and other federal and state partners.
10. Maintain and distribute the most current version of the BNTB Program Manual in English and Spanish.
11. Serve as repository for TB data reported to DSHS.
12. Collect and analyze reports from BNTB programs to satisfy grant requirements.
13. Serve as a point of contact for inter-jurisdictional transfers. Patients transferring to and from a BNTB program and a U.S. TB program will have an inter-jurisdictional notification (IJN) submitted to the Unit.
14. Promote security and confidentiality standards for TB data exchanges through trainings, and communication.
15. Prepare and report aggregate data to CDC.

16. Oversee molecular epidemiology practices, provide technical assistance to investigate transmission patterns, cluster events, and prepare TB epidemiological reports.
17. Provide technical assistance to BNTB programs for accurate submission of TB data; and
18. Lead the development and implementation of quality assurance (QA) procedures and activities involved in the delivery of BNTB program services.

B. **The fiduciary agency will:**

1. Ensure the medical coordinator works with BNTB programs to adhere to program standards and expectations outlined in the BNTB Manual, notify the contracted physician and nurses in Mexico on changes in the BNTB program manual that impact their practice and ensure the attestation page is signed yearly.
2. Prepare contracts, hire, and select staff to maintain services at the four DSHS BNTB programs in Mexico. Each site in Mexico must maintain the following staff to provide services:
   a) Physician with a current and valid medical license to practice medicine in Mexico;
   b) Nurse(s) with a current and valid license to practice nursing in Mexico;
   c) Outreach worker(s) to perform field investigations and provide directly observed therapy (DOT) as needed;
   d) Staff responsible for transporting biologicals or other items needed to the BNTB sites in Texas; and
   e) Radiology services to perform, read and interpret chest x-rays.
3. Conduct interviews for new hires in collaboration with the Texas-based BNTB program manager or supervisor. The BNTB program manager may designate a staff member in the Texas-based program to serve on the interview panel.
4. Ensure programs have adequate telecommunication services, office and medical supplies, and office space to perform daily activities.
5. Collaborate with the medical coordinator to ensure all contracted clinical staff are mask fit tested and trained upon hire and annually in using N95 respirators (or its equivalent).

6. Ensure direct clinical care staff are screened for TB upon hire and annually when indicated.
7. Schedule annual site visits to each BNTB site in Mexico to ensure adherence to program standards outlined in the BNTB manual and submit written results to the Unit.
8. Conduct annual performance reviews of each BNTB clinical employee in Mexico and submit findings to CMS.
9. Maintain collaboration with DSHS and each BNTB program site in Mexico and Texas to ensure program needs are met.
10. Notify the Unit immediately of any situation that may affect the BNTB program operations.
11. Notify the Unit of any publication, presentation, or abstracts regarding the BNTB programs in Mexico. The agency should share materials with the Unit.
12. Provide payment to subcontractors in Mexico in accordance with Unit-approved budget.
13. Request and review weekly time and mileage reports from staff in Mexico bi-monthly.
14. Submit a complete and accurate APR by the established deadline; and
15. Monitor budget expenditures and submit fiscal reports by established deadlines for activities involved in the delivery of BNTB program services.

C. **It is the role of the regional or local BNTB program manager or supervisor to:**

1. Read, understand, and follow procedures outlined in the BNTB manual.
2. Supervise the BNTB staff in Texas only.
3. Develop and revise local BNTB program procedures. These procedures should not contradict procedures and expectations outlined in the BNTB program manual.
4. Assign a nurse to oversee nurse case management activities if the BNTB coordinator is not a nurse.
5. Participate in the annual review and revision of the BNTB program manual and submit updates to the Unit by the targeted deadline.
6. Communicate with the fiduciary agency and the Unit, understanding when to engage one or both.

7. Communicate any of the following routinely with the fiduciary agency: any concerns regarding contractors' performance in Mexico; hiring and selecting contract staff in Mexico, coordinating courier services and other issues as arise.
8. Elevate concerns within one business day to the Unit when there are situations that impact program operations.
9. Communicate with the Unit routinely on the following: presentations (for review and approval), changes in TB personnel, and updates on program activities.
10. Review and approve presentations, publications or abstracts in collaboration with regional or DSHS leadership.
11. May assist the fiduciary agency to contract with a radiology service to perform x-rays for cases and contacts residing in Mexico.
12. Collaborate, as needed, with the fiduciary agency to ensure courier services are available to transport specimens to the U.S.
13. Ensure DSHS data security and confidentiality procedures are maintained and arranged for contracted staff in Mexico to obtain DSHS or LHD email addresses.
14. Will collaborate with the fiduciary agency in hiring and selecting contracted staff in Mexico; and
15. Notify the Unit of any changes in personnel in the Texas BNTB Program, including new hires. Submit the Notice of Change in TB Personnel to TBProgram@dshs.texas.gov.

D. **It is the role of the Texas consulting physician to:**

1. Articulate to the treating physician in Mexico, U.S. treatment guidelines for TB disease and infection, and provide treatment recommendations as requested. According to Health and Safety Code Title 3-Occupational Code 151.002 A-12, Texas consulting physicians are licensed to practice in Texas. If a Texas consulting physician's licensure does not extend to Mexico, they are unable to act as the treating physician for patients receiving care in Mexico.
2. Coordinate with the Mexico physician to ensure medical consultation occurs as outlined in APPENDIX D: MEDICAL CONSULTATION PROCESS. "Curbside consultation" is discouraged, and complete information must be provided to a DSHS-recognized medical consultant when medical

consultation is requested. Consultation recommendations should be provided in writing to the Mexico treating physician.
3. Participate and submit recommendations in writing on monthly case review conferences as needed.

E. **It is the role of the BNTB Program Coordinator* to:**

1. Read, understand, and follow procedures outlined in the BNTB manual and sign attestation annually.
2. Collaborate with the treating physician in Mexico, the program manager, and, in some instances, the Texas consulting physician to accept or decline referrals based on available resources. Submit written responses to the BNTB program in Mexico. See APPENDIX B: PROCESS FOR ENROLLMENT.
3. Assign work to contracted nursing staff providing services in Mexico.
4. Participate in annual reviews of the BNTB manual in collaboration with the BNTB program manager and submit updates to the DSHS BNTB nurse consultant and BNTB program manager by targeted deadline.
5. Perform nurse case management oversight activities according to Unit standards and CDC's guidelines:
   a) Directly observed therapy (DOT)and/or VDOT.
   b) Contact investigations.
   c) Medication dispensing.
   d) Documentation of patient care to include baseline and monthly toxicity assessments.
6. Maintain complete shadow chart with up-to-date progress notes and applicable TB forms (or their equivalent) at the Texas BNTB program site.
7. Coordinate the completion of necessary documentation with both Texas and Mexico when second-line medications are requested.
8. Ensure medications are ordered, received, and delivered.
9. Inspect medications for accuracy in regimen and dosage prior to delivery to nurse in Mexico; if the coordinator is not a nurse, then a nurse must be assigned to verify medications.
10. Schedule and lead monthly case reviews with Mexico's treating physician, nurses, and Texas consulting physicians.

11. Ensure all documents are received and placed in order prior to submitting for consultation to the Texas consulting physician or a DSHS-recognized medical consultant.
12. Prepare and present educational programs in English and Spanish on services provided by the BNTB Program. Presentations must be approved by the BNTB manager and the Unit. Once approved, they can be shared with nurses in Mexico for presentations in Mexico.
13. Ensure BNTB patient data is entered in NEDSS by the assigned regional or LHD staff. See APPENDIX M: GUIDELINES FOR RESPONDING TO THE UNIT'S SURVEILLANCE REQUESTS.
14. Review and revise the federal budget impacting their program (this excludes Mexico's budget) in coordination with the BNTB program manager and Unit.
15. Collaborate with health officials in Mexico and local TB programs in their jurisdiction on patients referred to the BNTB program.
16. Complete, and submit annual reports to the fiduciary agency by scheduled deadline.
17. Meet and communicate on a regular basis with Mexico's BNTB staff and Mexico's health officials to discuss caseload and administrative issues.
18. Conduct cohort reviews as specified in the Cohort Review Process, outlined in APPENDIX I: COHORT REVIEW PROCESS.
19. Maintain an up-to-date line-list of patients in the BNTB program and submit a copy to the Unit's TB nurse consultant as requested.
20. Review time and mileage reports from nurses and physicians in Mexico on a bi-monthly basis for accuracy on patient workload and submit to the fiduciary agency for approval and payment.
21. Assist, as needed, the fiduciary agency to contract with one person to transport specimens to the U.S. including obtaining CDC import permit, See APPENDIX J: BIOLOGICAL SPECIMEN TRANSPORTATION.

*Note: If the BNTB program coordinator is not a licensed registered nurse, defer to the manager/supervisor to assign a nurse to perform nurse case management oversight for nursing activities.

Binational TB Programs in Mexico

A. **The BNTB contracted staff in Mexico will:**

1. Maintain communication with Texas-based BNTB program staff on patient management activities.
2. Communicate with the fiduciary agency and the Texas-based BNTB program staff to maintain appropriate personnel to perform clinical care services and outreach activities, including but not limited to:
   a) Physician services
   b) Nurse case management
   c) Directly observed therapy or VDOT
   d) Contact investigation
   e) Referrals and updates
   f) TB education
   g) Reporting
   h) Collection and transport of laboratory specimens
3. Perform work in accordance with Chapter VIII. STANDARDS OF CARE.

B. **It is the role of the BNTB medical coordinator to:**

1. Participate in maintaining an up-to-date, comprehensive bilingual BNTB manual, complete with standards of care and established best practices across all BNTB programs.
2. Read, understand, and follow procedures outlined in the BNTB manual and sign attestation annually.
3. Collaborate with the fiduciary agency and each BNTB coordinator to ensure each BNTB program contractor completes an annual review of the program manual.
4. Ensure consistent delivery of clinical practices among all BNTB program clinics in Mexico.
5. Oversee the work performed by all DSHS-supported contractors and vendors in Mexico to ensure adherence to U.S. TB regulations, quality assurance, safety standards, and standard of care for patients.
6. Assist in implementing new TB diagnostic technologies and treatment at each BNTB program site upon approval by DSHS.
7. Communicate and collaborate with BNTB programs' treating physicians on a regular basis to provide guidance as appropriate to facilitate positive and productive relationships with local jurisdictional colleagues.

8. Participate in annual program evaluations at each BNTB program in Mexico.
9. Participate in interviews of new hires and ensure there is collaboration with the Texas-based BNTB program for participation.
10. Participate in training new hires as requested.
11. Conduct annual performance reviews of each BNTB program staff member in Mexico in collaboration with BNTB Texas program coordinator.
12. Maintain standardized job descriptions for all clinical contractors and prepare formal agreements with all clinical vendors in collaboration with DSHS Central Office and Regional program.
13. Function as a back-up as needed to conduct clinical assessments for the diagnosis and treatment of TB and provide direct medical care services, including services for drug-sensitive and drug-resistant cases, at any of the BNTB program sites in accordance with DSHS approved clinical standards and Mexico's legal and clinical standards.
14. Attend relevant trainings and conferences to remain up to date with the developments and best practices in the prevention and treatment of TB.
15. Communicate with the BNTB Texas-based program and the Unit on any updated laboratory testing capabilities in Mexico.
16. Perform other duties as assigned that align with TB prevention and control services.

C. **It is the role of the treating physician in Mexico to:**

1. Read, understand, and follow procedures outlined in the BNTB manual and sign the attestation annually.
2. Review and be familiar with both standards of care for treatment and prevention of TB in the U.S. and Mexico as outlined in Chapter VIII. STANDARDS OF CARE.
3. Perform initial and follow-up assessments with suspected or confirmed TB disease and LTBI and document in the patient's medical record.
4. Communicate and coordinate patient's medical care with primary physicians in Mexico, and the Texas consulting physician and/or the regional medical director (RMD) when needed.
5. Order and interpret appropriate diagnostic tests.
6. Provide clear direction to contracted nursing staff on expectations of assessment: how often patients should be seen in the clinic, how often

orders will be signed, and the method staff will use to communicate with the treating physician.

7. Submit information to the Texas consulting physician, as needed, to ensure adequate treatment recommendations are received from a DSHS-recognized TB medical consultant for DR-TB and/or challenging cases. See APPENDIX D: MEDICAL CONSULTATION PROCESS.
8. Review all documents prior to submission for consultation to ensure correct and up to date information are submitted.
9. Provide written orders for medication regimens to include dosage, route, and frequency. If verbal orders are given to the nurse, document orders in the patient's medical record within one week of providing the verbal order.
10. Review, initial, and date laboratory results and other diagnostics tests.
11. Document and include progress note in the medical record at least monthly for each patient on treatment for TB disease.
12. Accurately complete patient care documents and provide them to the nurses who will send to the BNTB coordinator to maintain a complete shadow chart at the Texas BNTB office. The treating physician will review and sign patient orders prior to submitting to the nurses and BNTB coordinator.
13. Ensure patients with DR-TB, young children with TB, or other high-risk individuals are managed according to the U.S. standards of care for treatment.
14. Provide TB education to patients and family members to include prevention and transmission, disease process, and consequences of inadequate treatment.
15. Participate on monthly case review conferences with the regional or local BNTB program.
16. Participate in BNTB program conferences, meetings, in-service trainings, and seminars.
17. Coordinate with the appropriate TB state and/or local physician in Mexico for the approval, procurement of second-line medications and seek required involvement of the COEFAR and/or GANAFAR when applicable; a letter of approval, 'DICTAMEN,' is needed to receive medications through the Federal TB program in Mexico. The process to acquire a 'DICTAMEN' for BDQ and clofazimine (CFZ) is required to be

initiated when these medications are recommended for treatment as every effort should be made to obtain these medications from Mexico.

18. Ensure recommendations by the DSHS-recognized medical consultant for the treatment of drug-resistant patients are shared with the National TB Program and the COEFAR and/or GANAFAR.
19. Ensure medications recommended for DR-TB patients are consistent with U.S. treatment guidelines. If not, collaboration between Mexico physicians and Texas physicians should occur to reach a consensus on the best treatment option for the patient. If an agreement cannot be reached, the consulting physician in Texas and the treating physician in Mexico will determine if the patient may or may not be served by the BNTB program.
20. Collaborate with the TB program in Mexico to ensure Mexico can provide some, if not all, second-line medications. U.S. medications may be used in the interim until the BNTB program in Mexico receives medications from Mexico.
21. Participate on quarterly meetings with Mexico's Binational Committee, as needed.
22. Perform TB education activities to health care providers within the service area to increase program awareness and promote referrals to the BNTB Program.
23. Communicate with the BNTB Program medical coordinator in Mexico any concerns affecting the daily operations of the BNTB program site.
24. Ensure all documents and results are shared with referring physicians in Mexico to comply with Mexico's disease reporting and surveillance procedures.
25. Maintain a log of daily work activities and mileage and submit to the BNTB program coordinator and the fiduciary agency bi-monthly, see APPENDIX P: SAMPLE IN-SERVICE AND TRAINING ROSTER and TIME AND MILEAGE REPORT.

D. **It is the role of the Nurses in Mexico to:**

1. Read, understand, and follow procedures outlined in the BNTB manual and sign the attestation annually.
2. Perform duties in a professional manner to provide nursing and administrative services as assigned by the BNTB coordinator and the BNTB program manager.

3. Perform duties within the assigned contracted hours.
4. Complete medical and social history TB-202a or equivalent to include initial signs and symptoms with date of assessment.
5. Ensure patients have current written medical orders from the treating physician.
6. Conduct physical, developmental, and mental health assessments of patient health needs and perform applicable nursing interventions; communicate findings and results with the treating physician in a timely manner.
7. Ensure patients are started on an adequate treatment regimen and administer medications as prescribed by the treating physician.
8. Ensure patients are assessed according to Unit standards, see Chapter XX. Conduct Continuing Quality Improvement (CQI) Activities, Table 12: Texas TB Performance Measures.
9. Maintain complete medical records (including all required forms) and submit copies to the BNTB coordinator. Records should be reviewed by the treating physician for accuracy prior to submitting to the BNTB coordinator. See Appendix F: Binational TB Program Clinical Care Forms.
10. Document in the medical record, all patient encounters including phone calls, clinic visits and/or home visits.
11. Perform monthly toxicity examinations and document in the patient's medical record. This includes responses to any abnormalities noted (i.e., document what the nurse did to address the abnormality); do not administer medications to patients if toxicity screening is not done and notify the treating physician.
12. Maintain a process to respond to medication toxicity and other concerns reported by the patient.
13. Provide DOT or VDOT to all patients as prescribed by the treating physician in alignment with DSHS program standards of care. Document all doses taken, missed, or self-administered on TB-206b or its equivalent. See Appendix H: Directly Observed Therapy (DOT) Procedure.
14. Use appropriate measures to ensure patients complete adequate therapy. If patient does not complete adequate therapy, document all interventions taken to return patient to therapy.
15. Collect sputum for patients with suspected TB following Appendix G: Sputum Collection Procedure.

16. Assist the treating physician and the BNTB coordinator in gathering all pertinent information to submit for medical consultation.
17. Provide education to all patients on TB prevention, transmission, disease process, treatment, and the consequences of inadequate treatment.
18. Educate health care providers and community-based organizations within the service area to increase awareness of TB and promote referrals to the BNTB Program.
19. Educate patients on possible medication side effects, conditions under which medications should be stopped, the need to prevent pregnancy (if applicable) and when to seek immediate medical attention.
20. Provide referrals for medical evaluations as needed.
21. Correctly label, document and correctly package specimens according to program shipping requirements, including having a list of items transported to Texas. See Appendix K: Sample Biological Specimen Manifest.
22. Coordinate the transport of biological specimens for acid-fast bacilli testing to DSHS laboratory. Collaborate with the BNTB program manager and the BNTB coordinator for transportation schedule.
23. Transport equipment and supplies to and from Texas and Mexico's BNTB program sites.
24. Provide BNTB program coordinator with information needed to prepare reports for clinical and funding purposes.
25. Participate in BNTB program conferences, meetings, in-service trainings, and seminars.
26. Maintain a detailed log of daily work activities and mileage. Submit the completed log to the BNTB program coordinator and the fiduciary agency on bi-monthly basis. See Appendix P: Sample In-Service and Training Roster.
27. Participate in monthly case management conferences and quarterly cohort reviews.
28. Perform other duties as assigned that align with TB prevention and control services.

VIII. Standards of Care

General Requirement

This chapter outlines the minimum standards of care for patients undergoing evaluation and treatment for TB services within the BNTB programs. The intended audience for these standards is authorized staff working in the BNTB programs in Texas and in Mexico.

Patients in the BNTB program will receive outpatient treatment and care that align with standards of care in the U.S. while taking into consideration the Mexican TB Norma for the treatment and prevention of TB.

Activities

A. BNTB programs must review, be familiar with, and readily access recommendations within the following documents:

1. Official American Thoracic Society/Centers for Disease Control and Prevention/Infectious Diseases Society of America Clinical Practice Guidelines: Treatment of Drug-Susceptible Tuberculosis. Clinical Infectious Diseases (2016), 63 (7): e147-e195. cdc.gov/tb/publications/guidelines/pdf/clin-infect-dis.-2016-nahid-cid_ciw376.pdf.
2. Official American Thoracic Society/Infectious Diseases Society of America/Centers for Disease Control and Prevention Clinical Practice Guidelines, Clinical Infectious Diseases, Diagnosis of Tuberculosis in Adults and Children. (2016), 64 (2):111-115. https://academic.oup.com/cid/article/64/2/e1/2629583.
3. Provisional CDC Guidance for the Use of Pretomanid as part of a Regimen (Bedaquiline, Pretomanid, and Linezolid [BPAL]) to Treat Drug-Resistant Tuberculosis Disease. CDC, 2022. cdc.gov/tb/hcp/treatment/bpal.html.
4. Guidelines for the Treatment of Latent Tuberculosis Infection: Recommendations from the National Tuberculosis Controllers Association and CDC, 2020. cdc.gov/mmwr/volumes/69/rr/pdfs/rr6901a1-H.pdf.
5. Testing and Treatment of Latent Tuberculosis Infection in the United States, 3rd Edition, 2023: A Clinical Guide for Health Care Providers and

Public Health Programs. https://tbcontrollers.org/resources/tb-infection/clinical-recommendations/.
6. Updated Guidelines for Using Interferon Gamma Release Assays to Detect *Mycobacterium tuberculosis* Infection — United States, 2010. MMWR. 2010; 59(5):1-25. cdc.gov/mmwr/preview/mmwrhtml/rr5905a1.htm?s_cid=rr5905a1_e.
7. Treatment of Drug-Resistant Tuberculosis, An Official ATS/CDC/ERS/IDSA Clinical Practice Guideline: Executive Summary (2019). American Journal of Respiratory and Critical Care Medicine, 2019. https://www.atsjournals.org/doi/full/10.1164/rccm.201909-1874ST.
8. Recommendations for Use of an Isoniazid-Rifapentine Regimen with Direct Observation to Treat Latent *Mycobacterium tuberculosis* Infection. Treatment of Drug-Resistant Tuberculosis. An Official ATS/CDC/ERS/IDSA Clinical Practice Guideline. American Journal of Respiratory and Critical Care Medicine (2019) https://www.atsjournals.org/doi/full/10.1164/rccm.201909-1874ST.
9. Update of Recommendations for Use of Once-Weekly Isoniazid-Rifapentine Regimen to Treat Latent *Mycobacterium tuberculosis* Infection | (2018) MMWR. cdc.gov/mmwr/volumes/67/wr/pdfs/mm6725a5-H.pdf.
10. American Academy of Pediatrics. Committee on Infectious Diseases. (2023). Red Book: Report of the Committee on Infectious Diseases. Red Book, 33rd edition. American Academy of Pediatrics (AAP) https://publications.aap.org/redbook/book/755/Red-Book-2024-2027-Report-of-the-Committee-on.
11. Screening and Testing for HIV, Viral Hepatitis, STD & Tuberculosis in Pregnancy (2024). cdc.gov/pregnancy-hiv-std-tb-hepatitis/php/screening/.
12. An Official ATS Statement: Hepatotoxicity of Antituberculosis Therapy. Am J Respir Crit Care Med. 2006; 174:935-952. https://www.thoracic.org/statements/resources/mtpi/hepatotoxicity-of-antituberculosis-therapy.pdf.
13. Core Curriculum on Tuberculosis: What the Clinician Should Know. 7th Edition. CDC (2021). cdc.gov/tb/media/Core_Curriculum_TB_eBook.pdf.

14. Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis. MMWR 2005; 54(RR15): 1-55. CDC (2021). cdc.gov/mmwr/preview/mmwrhtml/rr5415a1.htm.
15. Official Mexican Standard NOM-006-SSA2-2013, for the Prevention and Control of Tuberculosis (2013) https://www.cndh.org.mx/sites/default/files/doc/Programas/VIH/Leyes%20y%20normas%20y%20reglamentos/Norma%20Oficial%20Mexicana/NOM-006-SSA2-2013.pdf.
16. Mexico's Guide for the Care of People with Drug-Resistant Tuberculosis. http://www.cenaprece.salud.gob.mx/programas/interior/micobacteriosis/descargas/pdf/guia_tb_mfr_ok.pdf.

Minimum Standards of Care

A. **Provide Patient-Centered Care in an Outpatient Setting**

1. Provide culturally competent education and care using preferred language, age and literacy level when discussing TB pathology, transmission, treatment options and plan of care.
2. Identify barriers to care and develop strategies to meet individual patient needs. This may include a plan for incentives and enablers and the coordination of ancillary support services. Programs should collaborate with the fiduciary agency for allocated funds to support incentives and enablers.
3. Develop a DOT patient-centered care plan. VDOT should be considered for all eligible patients. Refer to https://www.dshs.texas.gov/sites/default/files/IDCU/disease/tb/forms/DOCS/VDOT-ClientAgreement.doc.

B. **Prioritize Referrals and Screening for TB Disease and Latent TB Infection**

1. Assess program capacity to manage patients prior to accepting a patient into the program.
2. Perform interferon gamma release assay (IGRA) testing.
   a) Per the American Academy of Pediatrics Redbook, 2023rd edition: "Either TST or IGRA testing is acceptable for children of any age". Both the TST and IGRA are unreliable in infants who are four to six months of age or younger. Screening test results, especially in young children, should be interpreted in conjunction with epidemiology risk factors and clinical assessment.

b) If phlebotomy is refused, the patient may receive a tuberculin skin test (TST), or as otherwise specified by the treating physician. Consideration should be given to results despite BCG vaccine.
c) IGRAs are provided at no cost to BNTB programs by the Unit.
d) TST supplies (e.g., syringes and tuberculin purified protein derivative [PPD]) should be ordered from DSHS Pharmacy using the pharmacy ordering system.
e) Programs shall not order or distribute TST or IGRA supplies to sites, organizations, or clinics outside the BNTB program. The TST or IGRA must be administered only to patients referred and accepted into the BNTB program.

3. Consider repeating an IGRA when the initial IGRA result is indeterminate, borderline, or invalid, and a reason for testing persists.
   a) If an IGRA is to be repeated, a new blood sample should be used. In such situations, a repeated test from a new blood sample usually provides interpretable results.
   b) If a second test result is reported as indeterminate, borderline, or invalid, consult with the treating physician whether a TST or CXR should be ordered.

C**. Radiology**

1. Every program must have radiology services available through a contracted facility.
2. Every patient under 18 years of age or diagnosed with HIV infection will have a posterior/anterior (PA) and lateral chest x-ray (CXR) when undergoing evaluation for TB infection or disease, or when a CXR is recommended; patients aged 18 years or older will have a PA CXR.

D. **Location-Appropriate Isolation and Transmission-Based Precautions**

1. Every patient with known or suspected TB disease will be advised to remain in respiratory isolation as appropriate for the setting. If home-based isolation is initiated, ensure the patient has a surgical mask and remains separated from others. Document in the medical record the date the patient is placed in isolation and the date of release from isolation.
2. A nurse may only release a patient from isolation after written instructions are received by the treating physician. All activities done to

ensure patient's compliance with respiratory isolation should be documented in the patient's medical record.

3. Every patient who arrives at the TB clinic and infectiousness is unknown will be given a surgical mask to wear.
4. BNTB Mexico staff will use fit-tested N-95 respirators (or equivalent) in situations that pose a risk of exposure to TB disease and when providing patient care to patients on isolation.
5. BNTB Mexico direct-care staff should screen for TB yearly. See Chapter XVI: Infection Control Procedures for details. Results should be made readily available to the medical coordinator to review yearly.

E. **Laboratory Testing**

1. Laboratory testing such as IGRA, acid fast bacilli (AFB) smears, AFB cultures, nucleic acid amplification test (NAAT), and molecular detection for drug-resistance (MDDR) are only available for eligible patients accepted into the program.
2. Every patient for whom sputum is collected, one (ideally the first) sample should be sent for NAAT, unless there is documentation of a polymerase chain reaction (PCR) that tests for rifampin (RIF) resistance or unless drug susceptibilities are known.
3. Every patient with TB disease will have documentation of culture conversion. Culture conversion is documented by the first negative culture in a series of previously positive cultures, when all subsequent culture results remain negative.
4. Every patient with TB disease must be monitored for smear and culture conversions. Submit consultation as indicated in Appendix D: Medical Consultation Process.
5. Every program should obtain supplies necessary to induce sputum (i.e., portable nebulizers) as program resources allow.

F. **Nursing Assessments**

1. Every patient receiving medication for TB disease or LTBI will have at minimum, a baseline and monthly nursing assessment to include a nursing physical exam and toxicity screening documented in the medical record.
   a) Toxicity screening must be documented on TB-205a or TB-702a for patients on second-line medications or their equivalent.

b) Toxicity screenings must be done according to the patient's drug regimen.

2. Every patient on treatment for LTBI must have documentation in the medical record of all communication with the licensed nurse. Documentation will include at a minimum:
   a) Medication refill information, including drug name, dosage, lot number, and expiration date of medication; and
   b) Response to toxicity questions and notes on refill coordination.

G. **Physician Assessments**

1. Every patient on treatment for TB disease must receive an in-person physical examination by the Mexico treating physician at initial diagnosis. Subsequent examinations should be done as outlined in Chapter X. Management of Patients with Suspected or Confirmed Tuberculosis or as determined by the treating physician or as recommended by the consulting physician. All examinations should be clearly documented in the medical record.
2. The Mexico treating physician will review and sign the medical record when orders are updated or revised.
3. Every patient on treatment for LTBI will have a physical evaluation by the Mexico treating physician as outlined in Chapter IX. Management of Patients with Latent TB Infection, including Patients on Window Prophylaxis.
4. For patients with LTBI receiving treatment, the Mexico treating physician will review and document in the medical record as outlined in Chapter IX. Management of Patients with Latent TB Infection, including Patients on Window Prophylaxis.

H. **Directly Observed Therapy (DOT)**

1. Initiate DOT within one week of acceptance into the BNTB program or within one week of treatment orders.
2. Only Mexico BNTB program staff administer DOT to patients.
3. Nurses and outreach workers will have written orders from the BNTB treating physician prior to administering medications to patients.
4. Every patient on treatment for TB disease will be treated for the duration of treatment via DOT whether in person or by VDOT.

a) VDOT should be considered for all eligible patients and may be utilized when patients are recommended for DOT. See DSHS Video-Enabled Directly Observed Therapy Required and Recommended Activities Manual (Spanish).
b) When using Scene (formerly known as Emocha), adjust patient language under the profile tab. The application translates to the language selected.

5. Every contact to a case of MDR-TB, if treatment is recommended for LTBI or on window prophylaxis, will be treated via DOT or VDOT.
6. Every patient on isoniazid (INH) and rifapentine (3HP) may be treated by self-administration at the discretion of the treating physician and with a written order.
7. Every patient under age five is recommended to have DOT or VDOT for LTBI, including those on window prophylaxis.
8. When doTBal cannot be used, all DOT medications will be ordered via the DSHS Pharmacy medication ordering system.

I. Children and Pediatrics Age 17 and Younger

1. Every child younger than five years of age who is undergoing evaluation for LTBI or TB disease will have a physical examination by a physician, pediatrician, or licensed clinician.
2. If the guardian refuses therapy for a patient aged 17 years and younger and for whom treatment is recommended for LTBI, the guardian shall sign the TB-415a indicating refusal. The guardian receives a copy, and a copy is saved in the Mexico BNTB medical record and Texas shadow record. Refer patients back to the reporting entity.

J. Completing Adequate Therapy

1. DOT is the standard of care; therefore, every patient will ideally finish therapy as specified by the ordering physician with 100% of doses taken by DOT/VDOT.
2. At minimum, when closure at 100% DOT is not possible, Class 3 patients will have at least 80% of treatment completed by DOT/VDOT at closure. Physicians should ensure the patient has responded to therapy and has received adequate therapy prior to closure.

3. Patients eligible to complete treatment within 12 months must complete therapy within 365 days or less. See TABLE 12: TEXAS TB PERFORMANCE MEASURES for exclusions.
4. If patient stops treatment before completing the recommended regimen, close the medical record and document the reason for closure in the medical record. Write any recommendation for follow-up treatment by the treating physician in the medical record. Refer the patient back to the reporting entity and share follow-up recommendations with them.

K. **Contact Investigations (CI)**

1. Programs will perform CI by screening high priority contacts of suspected or confirmed pulmonary, pleural, or laryngeal TB disease.
2. Initial interviews are conducted by contracted staff in Mexico within three working days of being notified of a patient with suspected or confirmed TB disease.
3. Every sputum smear-positive case will have at least three contacts identified.
4. Every contact refusing evaluation for LTBI, including patients needing evaluation for window prophylaxis, will be informed of the implications regarding their decision. Complete TB-230a documenting patient's refusal and obtain their signature. A copy will be given to the patient and a copy saved in the patient's Texas and Mexico medical records.

L. **Case Conferences and Cohort Reviews**

1. Monthly case conferences will be held to review ATS class 3, and ATS class 5 patients on treatment. These should be done with both the Texas BNTB program, the BNTB program staff in Mexico and the Regional Mycobacteriology Program within each jurisdiction in Mexico. BNTB programs may determine if separate case conferences are held with Mexico's Regional Mycobacteriology Program.
2. BNTB Programs will conduct case reviews of contacts on treatment at the discretion of the Mexico treating physician and/or the Texas consulting physician.
3. Cohort reviews will be conducted quarterly in accordance with Unit standards. See APPENDIX I: COHORT REVIEW PROCESS.

IX. Management of Patients with Latent TB Infection, including Patients on Window Prophylaxis

General Requirements

This chapter outlines minimum activities that must be performed when initiating treatment and providing medical case management for contacts with LTBI. These are not standing delegation orders (SDOs), and nurses must ensure written or verbal orders are received by the treating physician prior to carrying out orders. SDOs may be available at the local or regional health department of each BNTB site and may extend to the BNTB program. If these are adopted for use in the BNTB clinics in Mexico, staff must sign and acknowledge the SDOs.

Active TB disease should always be ruled out prior to deciding to treat a patient for LTBI.

Patients eligible for treatment for LTBI including window prophylaxis are:

A. Contacts to known TB cases who have a positive IGRA or TST, a normal chest x-ray, and no signs and symptoms of active TB; and

B. Contacts who are immunocompromised and/or younger than 5 years old who have a negative IGRA or TST, a normal CXR, and no signs or symptoms of active TB, and in whom a second-round TB screening test will be performed (these patients qualify for window prophylaxis until the second test can be repeated).

Activities

A. **Administrative**

1. Create a medical record for each patient with LTBI and/or who require window prophylaxis. Medical records will be organized with clear division of sections as determined locally. All entries in the medical record should be signed, dated, and in chronological order with no blank spaces in the progress notes. A line should be drawn through open spaces. Medical records kept at the clinic in Mexico and shadow chart retained in the Texas program will include at minimum, the following:
   a) TB-400A-sp -Report of Case and Patient Services
   b) TB-202a - TB Initial Health Risk Assessment/History
   c) TB-205a - TB Toxicity Assessment

d) TB-206b - Directly Observed Therapy Log
e) 12-14198a – Patients on 3HP - Dosing and Symptom Monitoring Log
f) Progress Notes
g) BN-200- *Forma de Referido* (referral form) if applicable

2. Obtain general consents and disclosures for treatment.
   a) DSHS General Consent and Disclosure (L-36a)
   Microsoft Word - General Consent Form _04-2010_.doc (texas.gov)
   b) DSHS Consent to Release Confidential Medical Information (Spanish L-30a)
   c) Disclosure and Consent for LTBI Therapy (TB-415a)

B. **Initial Assessment by Nurse in Mexico**

1. Complete an initial health risk assessment/history TB-202a or the equivalent, to include signs, symptoms, risk factors, a list of current medications, and all medical history.
2. Obtain weight, height, and document in the medical record.
3. Perform baseline toxicity checks on all patients and document on the TB-205a or its equivalent.
4. Perform baseline laboratory tests, as ordered by the physician. For patients aged 12 years and older, screen for HIV using an approved laboratory-based HIV immunoassay.
5. Educate and assess the patient's understanding of the disease, medications, expectations of treatment, and compliance to achieve completion of preventive therapy.
6. Submit copies of the medical record to the BNTB coordinator to maintain an up-to-date shadow chart, initially, monthly and at closure or anytime changes are made to the treatment regimen.

C. **Assessment by the Physician in Mexico**

1. Perform and document an initial physical examination on all patients with LTBI, including those who qualify for window prophylaxis. Follow-up physical evaluations should also occur anytime the patient experiences medication toxicity requiring medications to be held.
   a) High-risk contacts in whom window prophylaxis is recommended should receive a physical examination, radiology, and begin therapy as soon as possible, not to exceed 14 days of identification. Refer to Chapter XII for details.

2. Evaluate and assess the patient anytime there is concern for medication toxicity. There should be clear documentation in the patient's medical record of physician evaluation and steps taken to address medication toxicity.
3. Submit a consultation request to the Texas consulting physician anytime clinical guidance is needed or as outlined in APPENDIX D: MEDICAL CONSULTATION PROCESS.
4. Write orders for treatment using the TB-400A-sp or equivalent and provide a copy to the nurse for administration of medication. Ensure a copy is provided to the BNTB coordinator to be kept in the shadow chart.

D. **Texas Consulting Physician**

1. Provide consultation recommendations in writing for patients with LTBI as outlined in APPENDIX D: MEDICAL CONSULTATION PROCESS or as requested by the Mexico treating physician.

E. **Chest X-rays (CXR)**

1. Perform a CXR on all patients with a positive IGRA or TST identified through a contact investigation prior to initiating treatment for LTBI. An initial CXR is also required for patients eligible for window prophylaxis, regardless of IGRA or TST results.
2. Perform posterior/anterior (PA) CXR on adults aged 18 years or older and, PA and lateral (LA) for those less than 18 years of age or patients with HIV infection at minimum.
3. Physicians may write patient specific orders that extend beyond the minimum recommendations.
4. Perform a CXR on contacts who are exposed to a person with known or suspected TB regardless of IGRA or TST results. This includes the following contacts:
   a) Children less than five years of age;
   b) Persons who are HIV positive;
   c) Persons with other immunocompromised conditions or receiving immunosuppressive therapy; or
   d) Persons exhibiting signs and symptoms of active TB disease.
5. Shield pregnant females with a lead apron over the abdomen.

6. Perform a CXR on contacts with a documented history of LTBI who never received treatment prior to initiating treatment.
7. Perform a follow-up CXR before continuing treatment for LTBI or window prophylaxis for the following:
   a) Patients who exhibit symptoms suggestive of TB disease,
   b) Patients, who prior to initiation of therapy, did not start treatment for LTBI within one month of the initial CXR showing no abnormalities suggestive of TB disease and are at high risk of progression to active TB disease,
   c) Patients who have an interruption in treatment for LTBI longer than one month during the first two months of treatment and are at high risk of progression to active TB disease (see list below). Otherwise, reimaging is not necessary unless the patient has symptoms consistent with active TB disease,
   d) Other patients who are not at high risk of progressing to active TB who have not started treatment for LTBI within six months of initial CXR showing no abnormalities suggestive of TB disease, and
   e) Other patients who are not at high risk of progressing to active TB disease who have an interruption of treatment for LTBI and needs to be re-started on medications.

The following patients with LTBI are at high-risk of progressing to active TB disease:

1. Children younger than five years of age
2. Patients who have HIV infection or at risk for HIV infection
3. Patients who have an immune compromising condition or other clinical condition that is associated with progression to active TB (such as substance abuse, silicosis, underweight by more than 5%, diabetes, chronic renal failure, gastrectomy, jejunoileal bypass, solid organ transplantation, and head and neck cancer)
4. Patients receiving immunosuppressive therapy
5. Patients within groups having high rates of TB transmission [homelessness, injection drug users] or within groups who work or reside with people who are at high risk for TB in facilities or institutions [hospitals, homeless shelters, correctional facilities, nursing homes, residential homes for those with HIV]

6. Patients* without TB signs and symptoms who have a documented change in TB screening test results from a negative to a positive, and other patients who have been recently infected with TB (such as close contacts of a person with infectious TB disease, patients who have immigrated from areas of the world with high rates of TB).
7. Patients* with pulmonary fibrotic lesions seen on CXR (presumed to be from prior, untreated TB).

**Do not delay treatment if obtaining a CXR on these patients. If needed, start therapy while awaiting CXR coordination.*

F. **Laboratory Tests**

1. Physicians may write patient specific orders that extend beyond the minimum recommendations.
2. Screen all patients aged 12 years and older for HIV risk factors and offer an HIV test.
3. Screen for diabetes patients aged 12 years and older unless the patient has the appropriate documented diabetes test results from a specimen collected within the last 14 days. Obtain a copy of the results and document in the patient's medical record.
   a) Screen using, at minimum, a fasting blood glucose for patients with known or suspected diabetes.
   b) Screen using, at minimum, a random blood glucose for non-diabetic patients.
4. Perform the following laboratory tests on patients receiving treatment for LTBI (including patients on window prophylaxis) age 18 or older under the following circumstances as ordered by the treating physician:
   a) Perform the following blood chemistry tests at <u>baseline</u>:
      i. Measure aspartate transaminase (AST), alanine transaminase (ALT), total bilirubin (T Bil), alkaline phosphatase (Alk Phos), and albumin for all patients starting treatment for LTBI who have risk factors for potential hepatotoxicity or other complications, including but not limited to:
         (a) Pregnant patients
         (b) Female patients during the first 3 months postpartum
         (c) Patients with or at risk for hepatitis B virus (HBV), hepatitis C virus (HCV), or other liver disorders

(d) Patients with other comorbidities or chronic medical conditions
(e) Patients who use alcohol or recreational drugs (orally or by injection)
(f) Patients with HIV infection/AIDS
(g) Patients on medications that affect or are excreted by the liver

ii. Complete blood count (CBC) if starting on a rifamycin.

b) Perform the following blood chemistry tests monthly:
i. Measurements of AST, ALT, T Bil, and/or Alk Phos if the baseline result is abnormal.
ii. CBC if patient will be taking a regimen that includes a rifamycin if the baseline CBC is abnormal.
iii. Measurements of AST, ALT, T Bil, and Alk Phos for patients with risk factors for hepatotoxicity or other complications, including but not limited to:
(a) Pregnant patients
(b) Female patients during the first three months postpartum
(c) Patients with or at risk for HBV, HCV, or other liver disorder
(d) Patients with other comorbidities or chronic medical conditions
(e) Patients who use alcohol or recreational drugs (orally or by injection)
(f) Patients with HIV infection/AIDS
(g) Patients on medications that affect or are excreted by the liver

c) Perform the following blood chemistry tests as needed:
i. Measurement of AST, ALT, T Bil if:
(a) AST, ALT and/or bilirubin level exceeds more than three times the upper limit of normal in the presence of symptoms, or
(b) AST, ALT levels exceed more than five times the upper limit of normal with or without symptoms, or
(c) Bilirubin exceeds two times the upper limit of normal.
ii. Measurement of complete metabolic panel (CMP) and CBC if signs and symptoms of hepatotoxicity are present, including nausea and vomiting.

iii. If at any time during treatment the patient has signs and symptoms of liver toxicity, the treating physician should be notified, medications should be held, and the treating physician should provide further instructions/orders to the nurse.

5. For patients younger than 18 years of age, consider performing blood chemistry tests if they have any of the following conditions:
   a) Chronic medical conditions,
   b) On chronic medications,
   c) Increased body mass index (BMI),
   d) Pregnancy,
   e) Disseminated disease, or
   f) Who report substance use.

   Alkaline phosphatase varies in children depending on growth cycles; therefore, considerations should be made for interpreting pediatric laboratory values.

G. **Treatment**

1. The treatment of patients with LTBI or those on window prophylaxis should be consistent with the following:
   a) Guidelines for the Treatment of Latent Tuberculosis Infection: Recommendations from the National Tuberculosis Controllers Association and CDC, 2020. cdc.gov/mmwr/volumes/69/rr/pdfs/rr6901a1-H.pdf.
   b) Testing and Treatment of Latent Tuberculosis Infection in the United States, 3rd edition, 2023. https://www.tbcontrollers.org/resources/tb-infection/clinical-recommendations/.
   c) Update of Recommendations for Use of Once-Weekly Isoniazid-Rifapentine Regimen to Treat Latent *Mycobacterium tuberculosis* Infection. MMWR cdc.gov/mmwr/volumes/67/wr/mm6725a5.htm?s_cid=mm6725a5_w.
   d) Regional or Local TB SDOs, if applicable.
2. The treating physician should use clinical judgment when deciding to treat a contact with LTBI if the index case does not have drug susceptibility test results. The following should be taken into consideration:

a) Decision to accept into the BNTB program;
b) Index case's response to treatment; and
c) Risks versus benefits of treatment.

3. Treatment for TB infection should begin within one month of identification. Refer to letter **E. X-rays** in this chapter for indications when a repeat CXR may be necessary.
   a) High risk contacts in whom window prophylaxis is recommended to begin therapy as soon as possible, but no later than 14 days of identification.
4. The treating physician must provide written orders for LTBI ensuring the appropriate weight-based dosages are calculated for each patient.
   a) If verbal orders are given to the nurse, the physician should return within one week and sign the verbal order.
5. The nurses in Mexico and the BNTB coordinator should review the most recent TB medication orders and ensure appropriate weight-based doses are ordered. Keep a copy in the Texas shadow chart. Nurses in Mexico will ensure the patient updates and signs a medication consent to reflect current drug regimens. Give a copy to the patient and keep a copy in the patient's medical record.
6. Patients refusing treatment for LTBI, including patients recommended for window prophylaxis, will be counseled regarding the benefits to therapy and risk for not taking treatment. Complete the TB 240A documenting the patient's refusal and obtain their signature. A copy will be given to the patient and a copy saved in the patient's Texas and Mexico medical record.
7. Remind female patients on a rifamycin of the effect of the medication on hormonal contraceptive method.
8. DOT is recommended until completion of therapy for the following patients:
   a) Contacts to multi-drug resistant (MDR) TB, pre-extensively drug-resistant (pre-XDR) TB, or extensively-drug resistant (XDR) TB.
   b) Children aged less than five years should be highly considered for DOT.
   c) Intermittent regimens (self-administration) may be considered on select patients on 3HP if specified by the treating physician. Mechanisms to ensure adherence to treatment must be in place.

9. Window prophylaxis is strongly recommended for the following patients:
   a) Children younger than five years of age.
      i. Note: Children less than six months old should continue window prophylaxis until they undergo a repeat TST at six months of age.
   b) Patients with HIV infection*
   c) Patients receiving immunosuppressive therapy for organ transplantation*
   d) Patients taking TNF-α inhibitors*

   **Patients in this category are likely to progress to TB disease. Therefore, a complete course of treatment for LTBI should be completed if the TB screening test was administered ≥ 8 weeks after the end of the exposure and the TST or IGRA result remains negative.*

H**. Completion of Therapy for LTBI**

Rifamycin-based regimens are the preferred regimen because of their effectiveness, safety, and high treatment completion rates.

1. Below are the minimum number of doses required, and the corresponding time frame for acceptable completion of therapy.
   a) <u>INH/RPT (3HP)</u> = Preferred regimen strongly recommended for adults and children aged > 2 years of age, including HIV-positive persons, as drug interactions allow.
   b) 12 doses (minimum of 11 doses acceptable) administered in no fewer than 12 weeks (but no more than 16 weeks). Doses must be separated by ≥72 hours to be counted.
   c) <u>4 months of RIF (4R)</u> = Strongly recommended for HIV-negative adults and children of all ages.
      i. 7 days per week for 120 doses taken within 6 months, OR
      ii. 5 days per week for 90 doses administered by DOT within 6 months.
   d) <u>3 months of INH and RIF (3HR)</u> = Preferred treatment for adults and children of all ages and for HIV-positive persons as drug interactions allow.
      i. 7 days per week for 90 doses taken within 4 months.
   e) <u>6 months of INH daily (6H)</u> =
      i. 7 days per week for 180 doses taken within 9 months, OR

ii. 5 days per week for 129 doses administered by DOT within 9 months.

f) 6 months of twice-weekly INH (6H) (by DOT ONLY) =
   i. Twice weekly for 52 doses administered by DOT within 9 months.

g) 9 months of INH daily (9H) =
   i. 7 days per week for 270 doses taken within 12 months, or
   ii. 5 days per week for 195 doses administered by DOT within 12 months.

h) 9 months of twice-weekly INH (9H) (by DOT ONLY) =
   i. Twice weekly for 76 doses administered by DOT within 12 months.

2. For persons treated empirically for TB disease for two months with at least INH, RIF, and pyrazinamide (PZA) and are subsequently determined to have LTBI, this regimen can be considered an effective and complete treatment of LTBI.

I. Interruptions of Therapy for LTBI

If the minimum number of doses cannot be completed within the maximum time frame allowed, as described above: H. COMPLETION OF THERAPY for LTBI, treatment should be restarted. Contact the treating physician for instructions.

J. Monitoring

1. Educate and monitor patients monthly for signs and symptoms of medication toxicity and provide monthly face-to-face clinical assessments and document.
2. Document and report any signs and symptoms of medication toxicity to the physician immediately and document on TB-205a or equivalent.
3. Obtain a clinical evaluation with the treating physician as soon as possible if signs and symptoms of toxicity occur. Take appropriate steps as ordered by the treating physician and as designated below:
   a) Conduct laboratory tests as ordered.
   b) Instruct patient to stop medication, if indicated.
   c) Instruct the patient to follow the following precautions: avoid medications that contain acetaminophen (Tylenol) and avoid alcohol.

The nurse should review all medications the patient takes, including over-the-counter medications. Educate on adequate fluid intake.

d) If medication is not restarted, educate patient on signs and symptoms of active TB, and instruct to report for re-evaluation.
e) If medication is restarted, continue to monitor monthly and issue medication in accordance with the physician's orders.

4. Document and report any abnormal laboratory results to the treating physician for review.
5. Patients taking rifabutin (RBT), should receive baseline and monthly clinical monitoring. Inquire about eye pain, overall vision changes, and/or sensitivity to light.

K. **Review and Close Medical Record**

1. The treating physician in Mexico will review and document in the patients' medical record at the following intervals:
   a) Initially,
   b) At closure, and
   c) Anytime medications are held or changed.
2. Close the patient's medical record using the following dispositions:
   a) Completed adequate therapy; indicate the number of months on medication and number of months recommended
   b) Deceased (Cause of death)
   c) Moved out of state/country
   d) Lost to follow-up
   e) Patient chose to stop
   f) Adverse drug reaction
   g) Provider decision - pregnant, non-TB, or
   h) Other
3. Report to the referring entity closure disposition.

X. Management of Patients with Suspected or Confirmed Tuberculosis

General Requirement

This chapter outlines minimum activities to perform when initiating treatment and providing outpatient medical case management for patients with suspected or confirmed TB. These are not SDOs, and programs must ensure the nurse receives written or verbal orders from the treating physician to carry out orders. The BNTB clinics in Mexico may adopt SDOs at the local or regional health department TB program. If the BNTB clinics in Mexico adopt them, staff must sign and acknowledge the SDOs.

When patients are referred to the BNTB program from Mexico's Regional Mycobacteriology TB Program for outpatient TB services, routine communication is required to provide case management updates to ensure compliance with disease reporting and surveillance guidelines in Mexico and to support the co-management of patients.

Activities

A. **Administrative**

1. Collaborate with Mexico's Nacional TB Program to provide outpatient case management, DOT, radiology, laboratory, medications, nursing, and physician services as needed.
2. Create a medical record for each patient with suspected or confirmed TB disease. Medical records will be organized with clear division of sections as determined locally using forms in Appendix F: Binational TB Program Clinical Care Forms, or their equivalent. All entries in the medical record are signed, dated, and in chronological order with no blank spaces in the progress notes. A line should be drawn through open spaces. Medical records kept at the clinic in Mexico and shadow chart retained in the Texas program will include at minimum, the following:
   a) TB-400A-sp - Report of Case and Patient Services
   b) BNTB-400B – Report of Case and Patient Services
   c) BNTB-201a - Case Management Plan for Outpatient Care
   d) TB-202a - TB Initial Health Risk Assessment/History
   e) TB 203a - Education/Counseling Record

f) TB-205a - TB Toxicity Assessment
g) TB-206b - Directly Observed Therapy Log
h) TB-231a - Bacteriology Monitoring
i) TB-411a - Disclosure and Consent Drug Therapy TB (Spanish)
j) TB-700 - Series for drug-resistant patients
k) Progress Notes
l) BN-200- *Forma de Referido* (referral form) if applicable

3. Obtain general consents and disclosures for treatment.
   a) DSHS General Consent and Disclosure (L-36a) Microsoft Word - General Consent Form _04-2010_.doc (texas.gov)
   b) DSHS Consent to Release Confidential Medical Information (Spanish L-30a) Autorización para Revelar Información Confidencial (texas.gov)
   c) Disclosure and Consent for LTBI Therapy (TB-415a)

B. **Infection Control**

1. Screen each patient evaluated at the clinic for signs and symptoms of TB and mask appropriately. The nurse should use a fit-tested N-95 respirator (or equivalent) when evaluating patients with suspected or confirmed with TB disease. A surgical mask should be provided to the patient.
2. Adhere to all standard precautions, including bloodborne and respiratory precautions when participating in TB clinical services.
3. BNTB staff working directly with infectious patients should have TB testing and screening done at least yearly.

C. **Initial Assessment by the Nurse in Mexico**

1. Collect and send information to the BNTB program coordinator for review and acceptance or denial into the program. See APPENDIX B: PROCESS FOR ENROLLMENT.
2. Conduct initial interviews and develop a case management plan within five business days of the patient referred and accepted into the BNTB program. Document on the BNTB-201a or equivalent.
3. Complete TB-202a or equivalent to include symptoms, risk factors, and a list of current medications.

4. Perform an appropriate nursing examination to include current weight, body mass index (BMI) and height and document in the patient's medical record.
5. Administer an IGRA test if the patient has suspected or confirmed TB disease, and there is no documentation of receiving a screening test. If the patient is unable to receive an IGRA or refuses phlebotomy, administer a TST.
6. Perform baseline toxicity checks on all patients and document using the TB-205a or equivalent or TB-702a for drug-resistant patients.
7. Educate and assess the patient's understanding of the disease, medications, laboratory tests, expectations of treatment, isolation, and compliance to achieve a cure.
8. Ensure a TB-411a or equivalent is signed and dated any time TB treatment is initiated, changed, or when a new medication is added.
9. Ensure initial assessment and physical examination are done by a physician in Mexico.

D. **Assessment by Mexico's Treating Physician**

1. Perform an in-person physical examination on patients suspected or confirmed with TB disease at the following intervals:
   a) Initially,
   b) Monthly,
   c) At end of two months of treatment (eight weeks of therapy or upon completion of initial phase if greater than eight weeks),
   d) At closure; and
   e) Anytime toxicity signs or symptoms develop requiring medications to be held.
2. Determine if the patient can be treated with doTBal or if doTBal should continue if already started. See M, USE OF DOTBAL FOR DRUG-SUSCEPTIBLE TB DISEASE for criteria when doTBal may be used or refer to the Official Mexican Normas for treatment guidelines.
   a) If treatment is adequate and no adjustments are needed based on the standards of care, complete and sign the BNTB-400B with treatment regimens. Send a copy to the BNTB coordinator to be kept in the Texas shadow chart.
   b) For patients that cannot take doTBal alone and need an individualized treatment regimen to either augment doTBal or to

replace entirely, the BNTB treating physician may complete and sign the BNTB-400B. Send a copy to the BNTB coordinator to be kept in the Texas shadow chart.

3. Follow the consultation indications and process outlined in APPENDIX D: MEDICAL CONSULTATION PROCESS.
4. Sign all treatment regimen orders using the BNTB-400B or equivalent. Provide a copy to the nurse prior to administration of medications. Send a copy to the BNTB coordinator to be kept in the Texas shadow chart.
5. Document patient's status monthly either on BNTB-400B or progress note, and provide a copy to the BNTB coordinator.

E. **Texas Consulting Physician**

1. Provide consultation recommendations in writing to the treating physician in Mexico, as requested.
2. Coordinate CFZ enrollment. Refer to Chapter XIV MANAGEMENT OF MEDICATIONS AND MEDICATION AVAILABILITY.

F. **Chest X-rays**

1. Perform PA and LA CXRs for patients <18 years of age or patients with HIV infection at minimum. Perform PA for patients ≥18 years.
2. Physicians may write patient specific orders that extend beyond the minimum recommendations.
3. Perform CXR without delay on pregnant patients being evaluated for active TB disease. Perform CXR with appropriate shielding, even if in the first trimester, if indicated.
4. Conduct chest x-rays at least, at minimum, in the following intervals:
   a) At baseline,
   b) Upon completion of two months of therapy, and
   c) At or near completion of therapy.
5. Follow-up chest x-rays are not needed for the following:
   a) If a previous chest x-ray (baseline or at two months) is normal,
   b) The patient is diagnosed with extrapulmonary TB disease, and pulmonary TB is ruled out, as evidenced by normal CXR results and negative AFB sputum results if sputum was collected.
6. Send chest-x-rays for interpretation with results reviewed by the treating physician.

G. **Sputum Collection**

1. Collect and send sputum specimens to DSHS laboratory only if the BNTB program accepted the patient into care.
2. Send specimens to DSHS laboratory in Austin or South Texas Laboratory (STL) for processing.
   a) Use appropriate requisitions required by DSHS laboratory.
   b) Use best practices for submitting sputum specimens. This should be as soon as possible or no longer than one week from collection if kept refrigerated.
   c) Transport specimens to the laboratory on cold packs to preserve the specimen as long as possible.
3. Collect three consecutive sputum specimens (for all patients) – ideally 24 hours apart, but at minimum eight hours apart, ideally with no more than 96 hours between the first and the third sputum specimen collection - with at least one specimen collection observed and one collection in early morning. Sputum collection must occur within seven days before (preferable to) seven days after medication start date. Copies of the sputum results will be kept in both the main medical record in Mexico and shadow chart in Texas.
   a) Submit three sputum specimens for AFB smear and culture results.
      i. The DSHS laboratory will perform drug susceptibility testing (DST) reflexively on the initial *M. tb* culture positive specimen.
      ii. The DSHS laboratory will repeat the DST if the patient is still *M. tb* culture-positive three months or more after the initial specimen collection date, or upon physician request. NOTE: the DSHS laboratory reports fluoroquinolone susceptibilities using ofloxacin testing.
   b) For all patients with no laboratory confirmation of a rapid test showing RIF resistance (i.e., GeneXpert), regardless of positive *M. tb* cultures, request NAAT on one of the first three diagnostic sputum specimens and label the initial specimens “1 of 3,” “2 of 3,” and “3 of 3” unless DST results are known. The laboratory will perform NAAT on only the most suitable specimen.
   c) For patients who have an initial AFB sputum smear positive result and the NAAT is negative, the DSHS laboratory will reflexively perform a second NAAT on a second AFB smear positive specimen if it is available.

i. Repeat NAATs will only be performed if that second specimen is AFB smear positive.
ii. If a second AFB sputum smear positive specimen is not available, contact the treating physician if a repeat NAAT is needed to develop a treatment plan.

4. For patients who have positive initial AFB smears at the time of diagnosis, collect three sputum specimens, with at least one specimen collected in early morning for AFB smear at least monthly until three consecutive specimens are negative on AFB smear.
5. For all patients, collect up to three sputum specimens, with at least one specimen collected in early morning, at least once a month until two consecutive specimens (at least one month apart) are negative on culture. (At this point, the patient has reached culture conversion).
6. For all patients with pulmonary disease, if possible, collect one final sputum specimen in the early morning for AFB culture at completion of therapy.
7. For patients with suspected or known extrapulmonary TB, make attempts to collect three sputum specimens ideally 24 hours apart, but at minimum eight hours apart.
   a) At least one sputum specimen collection should be observed with one collected in the early morning, even if the CXR is normal to exclude concomitant pulmonary disease.
   b) If gastrointestinal (GI) or genitourinary (GU) TB is suspected, collect stool or urine samples in addition to sputum (as above) and send for NAA test, AFB smear, and culture. In addition, submit any specimen collected on an extrapulmonary site, including cerebral spinal fluid (CSF), aspirates from a lymph node or pleural fluid, peritoneal fluid, and an aspirate from purulent collection or biopsy site for AFB smear, culture, and NAA. Coordinate with the receiving laboratory and contact DSHS state laboratory for submission criteria prior to shipping. See: http://www.dshs.texas.gov/lab/myco_home.shtm.

H. **Isolation**

1. Implement location appropriate isolation for patients suspected or confirmed to have TB disease. Every effort should be made to ensure patient complies with respiratory isolation restrictions as instructed by the nurse and/or physician in Mexico.
2. Apply the following for patients with suspected or confirmed drug-susceptible TB:
   a) If the patient has an AFB smear positive specimen, do NOT release from isolation until:
      i. The patient has three consecutive negative AFB sputum smears, collected in 8 to 24-hour intervals, and
         (a) Has symptomatic improvement; and
         (b) Has been on multi-drug therapy for TB for at least the equivalent of two weeks given as directly observed therapy (DOT); and
         (c) Has been completely adherent to DOT.
   b) Once the above criteria are met, the patient may be released from isolation, with physician orders and the date documented in the medical record.
   c) If the patient has never had an AFB smear-positive sputum or other respiratory specimens, do NOT release from isolation until:
      i. The patient has three consecutive negative AFB sputum smears collected in 8-to-24-hour intervals, and
         (a) Has symptomatic improvement; and
         (b) Has been on multi-drug therapy for TB for at least five days given as directly observed therapy (DOT); and
         (c) Has been completely adherent with DOT.
3. If the patient has positive AFB sputum smears and the last two consecutive sputum specimens return AFB culture-negative, they may be released from isolation with physician orders and if they meet the following criteria (*even if they remain smear-positive, as these likely represent dead organisms*):
   a) Have symptomatic improvement; and
   b) Have been adherent with multi-drug therapy for TB given as DOT.

I. **Laboratory**

1. Laboratory tests should be ordered by the treating physician on patients aged 18 or older with suspected or confirmed drug-susceptible TB.
2. Physicians may write patient specific orders that extend beyond the minimum recommendations.
3. Screen patients aged 12 years and older for HIV risk factors and offer an HIV test.
4. For patients aged 12 years and older screen for diabetes unless the patient has the appropriate documented diabetes test results from a specimen collected within the last 14 days. Obtain a copy of the results and document in the patient's medical record.
   a) Screen at minimum using a fasting blood glucose for patients with known or suspected diabetes.
   b) Screen at minimum using a random blood glucose for non-diabetic patients.
5. Perform the following blood chemistry tests at <u>baseline</u>:
   a) Measurement of CBC.
   b) Liver function tests to include at least: AST, ALT, T Bil, Alk Phos, albumin, and creatinine.
6. Perform the following blood chemistry tests <u>monthly</u>:
   a) Measurement of CBC if baseline result is abnormal.
   b) Measurements of AST, ALT, T Bil, and Alk Phos for patients whose baseline results are abnormal, and/or those with risk factors for hepatotoxicity or other complications, including but not limited to:
      i. Pregnant patients
      ii. Female patients during the first three months postpartum
      iii. Patients with or at risk for HBV, HCV, or other liver disorder
      iv. Patients taking medications for other comorbidities or chronic medical conditions that may affect the liver or kidneys
      v. Patients who use alcohol or recreational drugs (orally or by injection)
      vi. Patients with HIV infection/AIDS
      vii. Patients on medications that affect or are excreted by the liver.
7. Perform the following blood chemistry tests, as needed:
   a) Measurement of AST, ALT, and T Bil if:
      i. ALT or AST are more than three times the upper limit of normal in the presence of symptoms,

ii. ALT or AST are more than five times the upper limit of normal with or without symptoms, or
iii. Bilirubin exceeds two times the upper limit of normal.

b) Measurements of a CMP and a CBC if signs or symptoms are compatible with hepatotoxicity, including nausea or vomiting. Contact the treating physician. Hold the medications, and the treating physician should provide further instructions and orders to the nurse.
c) If at any time during therapy the patient has signs and symptoms of liver toxicity, notify the treating physician, hold the medications, and obtain an AST, ALT, T Bil, Alk Phos, and albumin with physician orders.
d) Therapeutic drug monitoring will be approved on a case-by-case basis after discussion with the treating or consulting physician and the BNTB nurse consultant.

8. Screen for Hepatitis B virus (HBV) using hepatitis B surface antigen (HBsAg) unless the patient has a previously documented positive HBV test result. If a negative result has been documented within the last 14 days, HBV testing does not need to be repeated. Obtain a copy of the negative or positive results and document in the patient's medical record.
   a) Patients with the following risk factors should be screened for HBV:
      i. All persons born in one of the following high-risk regions:
         (a) Western Pacific (includes China, Cambodia, Vietnam, the Philippines, Korea)
         (b) Africa (Democratic Republic of Congo, Ethiopia, Guinea, Kenya, Eritrea, Sierra Leone)
         (c) Southeast Asia (Bangladesh, Nepal, India, Myanmar/Burma)
         (d) Eastern Mediterranean (Afghanistan, Iraq, Kuwait, Pakistan, Yemen, Sudan, Syria)
      ii. Persons not vaccinated as infants
      iii. Persons with behavioral exposure to HBV (e.g., men who have sex with men, past or current injection drug users, history of incarceration)
      iv. Persons with liver disease or elevated ALT/AST of unknown etiology

v. Pregnant women
vi. Household contacts and sex partners of HBV-infected persons
vii. Persons with HIV

Additional information can be found at: https://wwwnc.cdc.gov/travel/yellowbook/2018/infectious-diseases-related-to-travel/hepatitis-b.

9. Screen for hepatitis C virus (HCV) using an FDA-cleared test for antibody to HCV (e.g., immunoassay, enzyme immunoassay (EIA) or enhanced chemiluminescence immunoassay (CIA) and, if recommended, a supplemental HCV test unless the patient has a previously documented positive HCV test result. If a negative result has been documented within the last 14 days, HCV testing does not need to be repeated. Obtain a copy of the negative or positive results and document in the patient's medical record.
   a) Patients with the following risk factors should be screened for HCV:
      i. Patients born during 1945 through 1965 (without prior ascertainment of HCV)
      ii. Current or past injection drug use, including those who injected once or a few times many years ago
      iii. History of incarceration
      iv. Have a certain medical condition, including persons:
         (a) Who received clotting factor concentrates produced before 1987
         (b) Who were ever on long-term hemodialysis
         (c) With persistently abnormal ALT levels (if known/previously documented)
         (d) Who have HIV infection
      v. Were prior recipients of transfusion or organ transplants, including persons who:
         (a) Were notified that they received blood from a donor who later tested positive for HCV infection
         (b) Received a transfusion of blood, blood components or an organ transplant before July 1992
      vi. Being born of a mother with HCV infection

vii. Intranasal drug use
viii. Receipt of an unregulated tattoo
ix. Other percutaneous exposures

Additional information can be found at: https://wwwnc.cdc.gov/travel/yellowbook/2018/infectious-diseases-related-to-travel/hepatitis-c.

J. **Monitoring**

1. Educate patient at baseline and monthly on signs and symptoms of drug toxicity and document on TB-205a and/or TB-702a for drug-resistant patients or equivalent.
2. Obtain monthly weights on patients. Weigh the patient the same way each time (i.e., shoes on or off, etc.). Calculate BMI.
   a) Pediatric patients may require weights more frequently as determined by the treating physician. Consideration should be given to very young children whose weight may increase more rapidly.
3. Monitor monthly for adherence to treatment and compliance to DOT.
4. Monitor and document smear and culture conversion as outlined in Section G. Sputum Collection in this chapter.
5. Perform clinical evaluations promptly when signs or symptoms of medication toxicity develop. Hold medications, contact the treating physician, and do not resume until orders are received to re-start medications by the physician.
6. Report and obtain guidance from the BNTB coordinator in addressing situations in which special circumstances arise, such as the provision of self-administered medication doses when a patient will have extended period without access to DOT/DOPT treatment, especially with regards to pediatrics or drug-resistant patients.
7. Perform baseline and monthly clinical monitoring for the following medications:
   a) If patient is taking ethambutol (EMB), include:
      i. Red/green color discrimination using Ishihara plates, and
      ii. Visual acuity using Snellen chart.
   b) If the patient is taking RBT, inquire about eye pain, overall vision changes, and/or sensitivity to light.
   c) If patient is taking high dose INH (adults 15mg/kg), include:
      i. Peripheral neuropathy screening.

K. **Treatment**

1. Physicians shall provide treatment consistent with the following guidelines:
   a) Official American Thoracic Society/Centers for Disease Control and Prevention/Infectious Diseases Society of America Clinical Practice Guidelines: Treatment of Drug-Susceptible Tuberculosis, 2016. cdc.gov/tb/publications/guidelines/pdf/clin-infect-dis.-2016-nahid-cid_ciw376.pdf.
   b) Official American Thoracic Society/Infectious Diseases Society of America/Centers for Disease Control and Prevention Clinical Practice Guidelines: Diagnosis of Tuberculosis in Adults and Children, *Clinical Infectious Diseases*, Volume 64, Issue 2, 15 January 2017, Pages e1–e33, https://doi.org/10.1093/cid/ciw694.
   c) American Academy of Pediatrics Red Book, Report of the Committee on Infectious Disease. 2024-2027, 33rd Ed. https://publications.aap.org/redbook/book/755/Red-Book-2024-2027-Report-of-the-Committee-on?autologincheck=redirected.
      - SHINE TB Regimen – American Academy of Pediatrics Red Book: 2021 – 2024 Report of the Committee on Infectious Diseases
   d) Official Mexican Standard NOM-006-SSA2-2013, for the Prevention and Control of Tuberculosis
   e) Regional or Local TB SDOs if applicable.
2. Develop a treatment plan within five business days of receiving an eligible patient into the program or within five business days of receiving treatment recommendations from the Texas consulting physician.
3. Continue patients on doTBal for drug-susceptible patients referred to the BNTB program who are responding to therapy.
   a) A BNTB-400B must be completed by the nurse case manager and treating physician in Mexico and a copy kept in the shadow chart.
4. The nurse shall review the most recent TB medication regimen ordered by the physician; a copy should be placed in the medical record including an updated medication consent form.
   a) Verify appropriate weight-based dosage calculations for all patients. For purposes of dosage calculations and treatment regimen selection, a patient is considered a child if the patient is less than 18 years of age and should receive pediatric weight-based dosing of medications.

5. Administer all regimen for TB disease via DOT or VDOT. Physicians will give orders for VDOT if the patient meets the criteria. See Video-Enabled Directly Observed Therapy, Required and Recommended Activities (texas.gov) for inclusion and exclusion criteria.
6. The treating physician will complete and sign BNTB-400B, at the start of treatment, at the end of two months of therapy, at the end of therapy and/or anytime there is a change in treatment.
7. Follow guidelines for completion of therapy for drug-susceptible TB disease using U.S. standards of care when doTBal is not used:
    a) Completion of therapy is based on the total number of doses administered (allowing for minor interruptions in therapy) not on the duration of therapy (months) alone.
    b) Six months (26 weeks) is generally the minimum duration of treatment; nine months (39 weeks) is recommended for patients with cavitation on initial chest radiograph and who remain culture positive at completion of two months of therapy. See 8, b. and c. below for more details.
    c) Daily dosing, five or seven days per week, throughout the course of therapy is preferred over intermittent dosing when treating under Texas standards of care and doTBal is not an option. Interventions to support seven days per week, including VDOT, should be arranged, when possible, as intermittent dosing is less efficacious and leads to higher rates of relapse. Patients may self-administer medications on weekends and/or holidays if seven days per week cannot be arranged.
8. Consider the following factors when determining to extend length of treatment:
    a) If PZA cannot be included throughout the initial phase of treatment (minimum of 40 doses given five days per week by DOT or 56 doses given seven days per week by DOT), or those with *M. bovis*, the continuation phase of treatment must be extended to seven months (31 weeks) for a total minimum duration of treatment of nine months (39 weeks).
        i. NOTE: *M*. *bovis* is naturally resistant to PZA. Infection with *M*. *bovis* or PZA-resistant *M. tb* requires a minimum of nine months (39 weeks) of treatment. Consultation is not required for *M*. *bovis*.

b) Patients with cavitation or extensive pulmonary TB disease on initial CXR and a positive culture result at the time of completing two months (8 weeks) of treatment are at substantially increased risk of relapse. The continuation phase for these patients is recommended to be prolonged to seven months (31 weeks), to complete a total treatment period of 9 months (39 weeks).
c) Additional factors may be considered when deciding to prolong treatment in patients even when cultures convert by two months if the patient has extensive disease and slow clinical response or underlying chronic disease that increases poor outcome or relapse (e.g., dialysis, TNF alpha therapy, malignancy, diabetes, or any other immunosuppressing condition).
d) The following extrapulmonary TB sites require a longer duration of treatment:
    i. Bone and joint: nine months (39 weeks) of treatment recommended
    ii. Meningitis: nine to twelve months (39-52 weeks) of treatment recommended
    iii. Disseminated/miliary TB in children with HIV: nine to twelve months (39-52 weeks) of treatment recommended
    iv. Any site that is slow to respond should be considered for prolongation of treatment

9. When a decision to treat culture-negative TB disease is considered, alternative diagnosis must be carefully assessed, and additional diagnostics may need to be undertaken for the patient.
    a) Culture-negative pulmonary TB is defined as symptomatic or radiographic improvement after two months of RIF, INH, PZA, and EMB (RIPE) treatment in a patient for whom the clinical suspicion for active TB disease is high, AFB cultures were collected and are negative, and an alternative diagnosis/etiology has not been found.
    b) For adult patients, because of a potential for INH-resistance, treatment should be continued with INH, RIF, and EMB for an additional two months to complete a total of four months (18 weeks) of treatment.
    c) For pediatric patients with no identifiable source case, treatment should be continued with INH, RIF, and EMB for an additional four

months (18 weeks) to complete a total of six months (26 weeks) of treatment.

d) EMB can be discontinued if the patient with culture-negative pulmonary TB is a contact to a case and the susceptibilities of that case are known and no resistance is detected.
e) For culture-negative extrapulmonary TB, the treating physician determines treatment recommendations, preferably in consultation with a Texas consulting physician.

10. Patients newly diagnosed with HIV who are not started on an anti-retroviral therapy (ART) during TB treatment, should receive at least eight months or longer of treatment for TB.
11. If RIF cannot be included in the treatment regimen, the minimum duration of treatment is 6-18 months (26-78 weeks). A medical consult is required.

L. **Interruption of Treatment**

The nurse case manager should carefully monitor and address treatment interruptions early on and report them to the treating physician. Consider the number of planned doses and the duration of therapy.

The following guidelines apply for interruption of treatment using U.S. standards of care:

1. When any interruption occurs during the initial phase of treatment for *less than 14 cumulative days, treatment can continue*.
   a) If the total initial phase of treatment is not completed in ten weeks, the treatment will need to be restarted. Contact the treating physician for instructions.
2. When any interruption occurs in the initial phase of treatment for *14 or more cumulative days*, the treatment regimen should be restarted. Contact the treating physician for instructions.
   a) If treatment is discontinued for drug intolerances, the patient must be on an adequate empiric regimen (RIP [RIF, INH, PZA], RIE [RIF, INH, EMB], or RPE [RIF, PZA, EMB]) for doses to count towards completion of therapy.
   b) If susceptibilities are known and there is no resistance to INH, RIF, or a fluroquinolone (FQN), either levofloxacin or moxifloxacin, then

once the patient is on both INH and RIF, or RIF and an FQN, doses can count towards completion of therapy.

3. If a patient misses a cumulative total of three months of doses during the continuation phase and completes less than 80% of doses in the continuation phase, treatment should be restarted.
   a) Collect three sputum specimens for AFB smear and culture and contact the treating physician for instructions.
4. If a patient misses a cumulative total of three months of doses during the continuation phase and completes 80% or more doses in the continuation phase, additional treatment may not be necessary.
   a) However, patients who initially had positive AFB sputum smears should receive additional therapy. Contact the treating physician.

M. **Use of doTBal for Drug-susceptible TB Disease**

Apply the following when using doTBal for drug-susceptible TB disease:

1. doTBal is provided by the Mexico Nacional TB Program if the patient does not require a complete individual treatment adjustment.
2. doTBal should not be used in the following circumstances:
   a) Drug-resistant TB,
   b) Patient is on medications that interact with RIF,
   c) Patient's weight is out of range for doTBal < 60kg and > 75kg, and/or
   d) Patient was referred to the BNTB program from the U.S. already on U.S. medications.
3. doTBal may be used if all the following criteria apply and the patient:
   a) Has drug-susceptible TB disease,
   b) Weighs between 60-75 kg,
   c) Has non-cavitary and non-extensive TB disease,
   d) Has baseline normal liver function tests,
   e) Is tolerating doTBal,
   f) Is HIV negative,
   g) Has no kidney disease,
   h) Is not on medications that interact with RIF, and/or
   i) Has not already started on US medications.
4. The treating physician should be familiar and up to date on treatment doses and regimens when using doTBal. Written orders should be given correctly and documented using the BNTB-400B or the equivalent.

a) Table 3: Initial Phase* - doTBal Regimen: Initial Phase and Table 4: Continuation Phase* - doTBal-S Regimen indicate the dosing, number of doses, and duration requirements for doTBal as indicated by the Norma Oficial Mexicana NOM-006-SSA2-2013.

5. The treating physician should ensure patients on doTBal receive adequate doses prior to stopping treatment as completing adequate therapy.

Table 3: Initial Phase* - doTBal Regimen

Rifampicina (R)	150 mg	600 mg
Isoniacida (H)	75 mg	300 mg
Pirazinamida (Z)	400 mg	1600 mg
Etambutol (E)	300 mg	1200 mg
*60 total number of doses required for initial phase Duration for initial dose is 10 weeks administered Sunday through Saturday.		

Table 4: Continuation Phase* - doTBal-S Regimen

Medications	Dosage per Pill	Recommended Dosage
Isoniacida (H)	400 mg	800 mg
Rifampicina (R)	300 mg	600 mg
**45 total number of doses required for continuation phase* *Duration for the continuation phase is 15 weeks (3.5 months) administered Monday, Wednesday, and Friday.*		

N. **Closing Patient's Record**

Close the patient's record and communicate to the referring entity once the patient reaches completion using the following dispositions:

1. Completion of adequate therapy
   a) Treatment completion within 12 months.
   b) Exceptions to completion of adequate treatment within 12 months apply if:
      i. Patient has RIF resistant TB (RR-TB), multi-drug resistant TB (MDR-TB), pre-extensively resistant TB (Pre-XDR TB) or extensively resistant TB(XDR-TB);
      ii. Patient is aged 14 or younger with miliary disease; or
      iii. Patient has meningeal disease.

2. Non-TB
3. Deceased
4. Moved out of the country
5. Lost to Follow-up (LTFU)
    a) Make three attempts and document them in the patient's medical record to contact the patient before considering a patient as LTFU, including:
        i. Calling the patient;
        ii. Visiting the patient's residence (when possible); and
        iii. Sending a postal mail notification of the need to follow-up with the TB program, if mail services are available in the area.

O. **Patient Travel**

Coordinate with the patient and other jurisdictions in Texas or Mexico when a patient on treatment for known or suspected TB intends to travel.

1. The decision to accept a patient's request to travel outside the managing BNTB program area must be carefully considered by the treating physician and the patient.
2. Known or presumed infectious patients will not travel commercially.
3. Many patients living in Mexico travel to work in Texas. Infectious patients should not be allowed to return to work until respiratory isolation is discontinued.
4. Follow APPENDIX N: INTERJURISDICTIONAL COMMUNICATION when coordinating travel.

P. **Requesting a Do Not Board (DNB)**

Request a Do Not Board (DNB) or Public Health Border Lookout (LO) consultation for any person with confirmed or suspected TB disease who plans to cross the U.S. border and/or board a commercial aircraft and is infectious or likely infectious, by emailing the DSHS epidemiology team at TBEPI@dshs.texas.gov. See APPENDIX O. DO NOT BOARD AND PUBLIC HEALTH LOOKOUT.

XI. Management of Patients with Drug-Resistant Tuberculosis

General Requirement

This chapter outlines minimum activities to be performed when managing a patient with DR-TB in the BNTB program. The BNTB programs will treat outpatient DR-TB according to U.S. standards of care in collaboration and mutual agreements with the Regional Mycobacteriology Programs.

Activities

A. **Identifying Patients at Risk for DR-TB**

1. Risk factors include:
   a) Previous episodes of TB treatment, usually incomplete treatment.
   b) Worsening clinical and/or radiographic findings while on TB treatment.
   c) Country of origin, history of residence in, or frequent travel to a region or country with a high prevalence of DR-TB.
   d) Exposure to a person with known (or highly suspected) infectious DR-TB.
   e) Exposure to people in congregate settings where DR-TB has been documented.
2. BNTB programs are made aware of DR-TB when:
   a) Rapid testing identified from a GeneXpert-NAAT, or other PCR indicates RIF resistance.
   b) DST results indicate resistance. Laboratory-confirmed drug resistance is defined as resistance to INH and/or RIF or to any drug other than streptomycin or PZA mono- resistance on drug susceptibility panel testing.
   c) Patient is reported with other laboratory results that indicate resistance including Molecular Detection of Drug Resistance (MDDR) or Whole Genome Sequencing (WGS) with RNA polymerase Beta Subunit (rpoB) mutations.

B. **Notify the Treating Physician**

Notify the treating physician immediately when DR-TB is suspected or confirmed.

C. **Seek Consultation**

1. See Appendix D: Medical Consultation Process upon initial suspicion or diagnosis of DR-TB and for a complete list of consultation requirements and recommendations.
2. At minimum, consultation with a DSHS-recognized TB medical consultant or regional medical director is required when:
   a) A patient has laboratory indications of drug resistance:
      i. Submit initial expert medical consultation within five business days of notification of suspected or confirmed drug resistance. This may be an informal notification while awaiting further test results or assessments. The purpose of the initial notification is to rapidly engage expert physician (s) and establish the right plan of care.
      ii. Follow with a formal consult when more results are available (e.g., MDDR results, updated bacteriology, radiology, other laboratories, or toxicity assessments).
   b) A patient is prescribed second-line TB medications for DR-TB;
   c) The treating physician requests MDDR testing;
   d) Any time treatment regimen changes are needed (e.g., adverse drug reaction or abnormal drug levels);
   e) A patient is approaching end of therapy and prior to stopping treatment; and
   f) A patient is a known contact to MDR-TB, Pre-XDR TB, or XDR-TB.

D. **Notify the BNTB Program Nurse Consultant**

Notify the BNTB Program nurse consultant when DR-TB is suspected or confirmed.

1. Notify the BNTB Program nurse consultant via email at TBClincalCareTeam@dshs.texas.gov within three business days of any consults submitted for RR-TB, MDR-TB, Pre-XDR-TB, or XDR-TB.

E. **Coordinate with DSHS Laboratory**

Coordinate with DSHS Laboratory to ensure appropriate diagnostic tests are ordered.

1. NAAT with GeneXpert is a rapid PCR test that identifies the presence of deoxyribonucleic acid (DNA) in the *M. tb* isolate as well as assesses for mutations consistent with RIF resistance.
    a) NAAT with GeneXpert should be performed on at least one respiratory specimen unless drug susceptibility tests are known.
    b) For non-respiratory specimens, coordinate with the laboratory for rapid testing if patient has risk factors for DR-TB.
2. If RIF resistance is detected, this may indicate resistance to additional first-line drugs; therefore, further testing would be indicated, such as an MDDR test.
3. The treating physician may request MDDR testing by coordinating with the BNTB coordinator and the Texas consulting physician to submit request.
4. DSTs are performed on positive *M. tb* cultures sent to the DSHS laboratory.
    a) If resistance to primary drugs (excluding PZA mono-resistance) is detected, DSHS laboratory will reflexively perform second-line drug panel testing and communicate directly with the submitter.
    b) Some second-line medications cannot be tested at the DSHS laboratory; therefore, programs should communicate directly with the laboratory to coordinate additional testing.
    c) If specimen was collected at an outside laboratory, coordination with the DSHS laboratory is recommended to ensure further testing is performed.
5. Outside laboratories or hospitals may also report resistance from rapid tests such as PCR; coordination with outside laboratories is recommended to ensure appropriate testing.

F. **Notify the Regional Mycobacteriology Program in Mexico**

Notify the Regional Mycobacteriology Program in Mexico and provide a copy of the consultation from the DSHS-recognized medical TB consultant of treatment recommendations. Consultation recommendations from a DSHS-recognized medical TB consultant should be provided to the COEFAR/GANAFAR to ensure U.S. treatment recommendations can be reviewed.

G. **Coordinate with Mexico for Medications**

Coordinate with Mexico on procurement of medications. TB medications from Mexico should be used whenever possible. See Chapter XIV. MANAGEMENT OF MEDICATIONS AND MEDICATION AVAILABILITY.

H. **Order Medications from DSHS Pharmacy**

While awaiting Mexico's response for assistance with medication procurement, order medications from DSHS Pharmacy. Ensure treatment regimen meet the U.S. standards of care for the management and treatment of DR-TB. See Chapter XIV. MANAGEMENT OF MEDICATIONS AND MEDICATION AVAILABILITY.

I. **Case Management and Treatment**

Develop a case management plan and treatment activities within ten business days of notification of drug resistance using clinical care forms specific to DR-TB. Use TB 700a series or their equivalent. The following should occur:

1. Chest X-Rays
   a) Perform PA CXRs for patients over age 18 years; PA and LA for patients younger than 18 years of age and patients with HIV. Physicians may write patient specific orders that extend beyond the minimum recommendations.
   b) Perform CXRs for patients with RR/MDR/Pre-XDR/XDR pulmonary TB, at minimum intervals:
      i. During treatment:
         (a) Initially,
         (b) Two months,
         (c) At six months, then
         (d) Every six months until completion of therapy or as recommended by the DSHS-recognized medical TB consultant.
      ii. Post-treatment:
         (a) Every six months for two years, accompanied with a TB signs and symptoms questionnaire, medical evaluation, and weight.
2. Sputum collection
   a) For patients with pulmonary RR/MDR-TB/Pre-XDR/XDR-TB collect sputum in the following intervals:

i. At least three consecutive sputum each month until AFB smear and culture conversion are documented.
ii. At least one sputum each month after culture conversion, until treatment is completed.
iii. At least one sputum every six months for two years after completion of therapy.

3. Isolation
   a) It is appropriate to be more cautious when releasing DR-TB patients from airborne isolation.
   b) For patients with suspected or confirmed RR/MDR/Pre-XDR/XDR-TB, release from isolation may be made in consultation with the Texas consulting physician or a DSHS-recognized medical TB consultant. Considerations to release from isolation include:
      i. Where the patient is being released to (i.e., congregate settings, household with small children, etc.).
      ii. Patient's response to therapy clinically, radiographically, and bacteriologically (some experts recommend two to three consecutive negative AFB sputum cultures prior to release from isolation).

   Refer to: guidelines_home_hospital_infectious_patients.pdf (heartlandntbc.org) and Drug-Resistant Tuberculosis: A Survival Guide for Clinicians, 3rd edition (ucsf.edu).

4. Laboratory
   a) In addition to laboratory requirements for drug-susceptible TB, additional laboratory tests are required for patients with RR/MDR-TB/Pre-XDR/XDR or any patient prescribed second-line medications as specified below for patients aged 18 years old or older.
   b) Perform the following blood chemistry tests and other laboratory at baseline:
      i. CBC and CMP.
      ii. A pregnancy test for females of childbearing age who are starting CFZ or on an aminoglycoside, commonly amikacin (AK).
      iii. For patients on bedaquiline (BDQ) and AK, include magnesium (Mg), which must be ordered in addition to the CMP.
      iv. For patients on ethionamide (ETA), BDQ, and para-aminosalicylic acid (PAS), include a thyroid-stimulating hormone (TSH) level.

v. Therapeutic drug monitoring 10–14 days after treatment initiated; perform the following:
(a) Linezolid (LZD) peak and trough. Trough is done right before next dose is administered. LZD peak should be done two hours post dose.
(b) Moxifloxacin peak level at two hours post dose.

c) Perform the following blood chemistry tests monthly:
i. CBC and CMP.
ii. For patients on BDQ, include magnesium.

d) Perform the following blood chemistry tests quarterly and as needed:
i. For patients on BDQ, ETA, or PAS, include measurement of TSH levels.

e) Perform the following as needed or per consultation:
i. CBC if moderate or severe anemia or other abnormalities present at baseline.
ii. Therapeutic drug monitoring.

5. Clinical Monitoring
a) Monthly assessments of medication toxicity specific to each medication are required and must be documented on TB-702a toxicity forms or equivalent.
b) Perform weights at every visit or more frequently as determined by clinical assessments.
c) Perform the following baseline and monthly clinical monitoring for medications as follows:
i. If patient is taking aminoglycosides (most commonly AK), include:
(a) Audiometry screening, and
(b) Vestibular screen.
ii. If patient is taking cycloserine (CS), include:
(a) A mental health assessment to include depression and anxiety screening questions.
(b) Ask if they are experiencing nightmares, hallucinations, aggression, or disorientation.
iii. If patient is taking CFZ, include:
(a) A mental health assessment to focus on depression symptoms.
iv. If patient is taking linezolid (LZD), include:
(a) Red/green color discrimination using Ishihara plates

(b) Visual acuity using Snellen chart, and
(c) Peripheral neuropathy screening.

v. If patient is taking BDQ, also known as Sirturo, include:
(a) ECG at baseline, two weeks after initiation of treatment and monthly. The treating physician should interpret the ECG within 24 hours of the ECG test or sooner.
- Perform ECG at the designated intervals (preferably Monday-Wednesday in case further interventions such as labs or consultations are needed).
- ECG should be performed at the same time of day each time. ECGs exhibit diurnal variation of up to +/- 75ms during a day.
- A patient with elevated QTc intervals should have one repeat ECG done ≥ 30 minutes apart to confirm the reading.
- Documentation of any symptoms* of prolonged QTc should be included when performing the ECG and results of both provided to the licensed healthcare provider. Ensure the licensed healthcare provider reviews the symptoms and ECG results within 24 hours of test, unless otherwise specified, and documents response in the medical record.

d) Respond to the following based on the ECG results:
i. If QTc is greater than 450 ms (in males) or greater than 470 ms (in females) and patient is asymptomatic*:
(a) Draw CMP plus magnesium, TSH, CBC.
(b) Contact the licensed healthcare provider to review ECG results within 24 hours.
(c) Perform weekly ECGs until normal or until licensed healthcare provider orders otherwise.

ii. If QTc is greater than 500 ms in males or females, and patient is asymptomatic*:
(a) Hold medications.
(b) Draw CMP plus magnesium, TSH, CBC.
(c) Contact the treating physician to review results within 24 hours.

(d) Request the treating physician consults cardiology or the Texas consulting physician for further guidance.
(e) Repeat ECG in 24-48 hours.
(f) Perform weekly ECGs until normal or the physician orders otherwise.
(g) Do not resume regimen until instructed by the treating physician.

iii. If QTc is greater than 450 ms (in males) or greater than 470 ms (in females) and patient is symptomatic*:
(a) Refer patient to the emergency department (ED)- ensure there is a referral form that the patient may present to the ED already reviewed by the treating physician which outlines at minimum: diagnosis, isolation status, current medications, baseline and current ECG results, symptoms, reason for referral to ED and TB physician contact information.
(b) Do not resume regimen until instructed by the treating physician.

iv. If QTc is greater than 60 ms above baseline and patient is asymptomatic*:
(a) Draw CMP plus magnesium, TSH, CBC.
(b) Contact the treating physician to review ECG results within 24 hours for recommendations.

*Symptoms of prolonged QTc include palpitations, tachycardia, light-headedness, fainting/syncope, chest pain, loss of consciousness, shortness of breath.

Considerations for the treating physician—Correcting the QT interval from ECG readings: The QTc interval is influenced by the heart rate (HR). At a HR of 60, QT = QTc using any of the formulas (Bazett, Fridericia, Framingham, or Hodges). As HR increases, the QTc increases. Most ECG machines in the US use the Bazett formula which at higher HR yields a more prolonged QTc than the Fridericia formula. It is recommended to use the Fridericia formula when calculating corrected QTc intervals as studies examining TB medications and QT prolongation used the Fridericia formula in their assessments and guidance. Consider online calculators (e.g., Corrected QT Interval (QTc) [mdcalc.com]) or manual calculations.

Refer to algorithms for monitoring and managing corrected QT prolongation in patients with DR-TB here:
Guidance on requirements for QTc measurement in ECG monitoring when introducing new drugs and shorter regimens for the treatment of Multi/Extensively Drug-Resistant Tuberculosis.
https://www.challengetb.org/publications/tools/pmdt/Guidance_on_ECG_monitoring_in_NDR_v2.pdf.

6. Treatment
   a) Physicians and nurses should be familiar with the U.S. standards of care for the treatment of DR-TB in the following documents:
      i. Treatment of Drug-Resistant Tuberculosis, An Official ATS/CDC/ERS/IDSA Clinical Practice Guideline: Executive Summary (2019). American Journal of Respiratory and Critical Care Medicine. https://www.atsjournals.org/doi/full/10.1164/rccm.201909-1874ST.
      ii. Provisional CDC Guidance for the Use of Pretomanid as part of a Regimen (Bedaquiline, Pretomanid, and Linezolid (BPaL) to Treat Drug Resistant Tuberculosis Disease (2022) Bedaquiline, Pretomanid, and Linezolid (BPaL). cdc.gov/tb/hcp/treatment/bpal.html?CDC_AAref_Val=https://www.cdc.gov/tb/topic/drtb/bpal/default.htm.
   b) When drug resistance is identified, BNTB programs should discontinue administering medications to which the patient is resistant. If treatment recommendations from a DSHS-recognized TB medical consultant and recommendations from the COEFAR/GANAFAR do not align, physicians both in Mexico and the U.S. should collaborate and come to a unified consensus for the best treatment regimen for the patient. If a unified consensus cannot be met, the last resort would be to decline treatment in the BNTB program.
   c) The treating physician will sign and complete the BNTB-400B, with treatment regimen, initially, at the end of two months of therapy, then every three months until the end of therapy or anytime there is a change in treatment.

d) Manage and treat patients in accordance with recommendations from a DSHS-recognized medical TB consultant and the Texas consulting physician and in collaboration with the Regional Mycobacteriology Program.
e) Develop a treatment plan within ten business days after receiving initial notification of drug-resistance and treatment recommendation from the expert medical consultant or RMD.
f) Seven days a week of observed dosing is optimal for patients treated for DR-TB. If that is not feasible, consider self-administration for weekend doses.
g) Initial and continuation phases are different for patients on treatment for DR-TB than for patients with drug-susceptible TB. The nurse case manager should carefully monitor treatment interruptions, as any missed doses are concerning and may impact treatment outcomes. Consultation may be necessary when interruptions occur. Please refer to article: *Addressing Bedaquiline treatment interruption in the treatment of drug-resistant TB.* https://pubmed.ncbi.nlm.nih.gov/35768912/.
h) Nurses should contact the treating physician when a patient on a DR-TB regimen misses an observed dose.

7. Communication
   a) Maintain communication with the BNTB Program nurse consultant, including but not limited to:
      i. Early notification of DR-TB patients, within three business days of suspected or confirmed DR-TB; and
      ii. Respond to case management inquiries in a timely manner or by the designated due date.

XII. Conduct and Manage a TB Contact Investigation

General Requirement

BNTB programs will conduct a CI for people with suspected (Class 5) or confirmed (Class 3) pulmonary, pleural, or laryngeal TB disease and evaluate, treat, and monitor their contacts. Programs will also screen high priority contacts identified from a U.S. managed case who are referred to the BNTB program.

In general, CIs are conducted the same whether the patient has drug-susceptible TB or drug-resistant TB. The goal of a CI is to find people exposed to TB who are likely to become infected or progress to TB disease to prevent further transmission.

Activities

A. **Initiate a CI or Source Case Investigation**

1. Conduct initial interviews within three working days of a patient being reported to the BNTB program with suspected or confirmed TB diagnosis.
   a) The interview should be done in the primary language of the patient or their representative (parent or guardian for young children or proxy for patients diagnosed at death or otherwise unable to be interviewed), using an interpreter if needed.
   b) Patients who are AFB sputum smear-positive and/or with chest radiography revealing cavitation must have the second interview seven days after the initial interview.
2. Visit the primary residence of a patient within three working days of initial report.
3. Visit additional sites where transmission may have occurred.
4. TB disease in children under the age of 5 years is a sentinel event of possible recent transmission from an adult in the child's social environment. Members of the child's household should be evaluated. Only one round of testing is required.

B. **Determine Infectious Period**

1. Determine infectious period using TB-425a (TB Infectious Period Calculation Worksheet).
2. The infectious period generally begins three months before the onset of symptoms see
3. TABLE 5: ESTIMATING THE INFECTIOUS Period.

4. Determine date in which contact was broken based on:
   a) date of physical separation from the index case; or
   b) date the index case is no longer considered infectious (i.e., date they are released from isolation).

C. **Prioritize all Contacts**

Prioritize all contacts into high, medium, or low categories see TABLE 6: GUIDELINES FOR PRIORITIZING CONTACTS.

1. Consider index case characteristics (e.g., site of TB disease, AFB sputum smear results).
2. Consider contact characteristics (e.g., aged 4 and younger, HIV status).
3. Calculate weekly and cumulative exposure hours.
   a) Contacts with greatest duration of time spent with the index case have the highest risk of exposure and should be tested first.
   b) Extend testing to other contacts with less exposure only if significant transmission is observed.
4. Consider exposure setting (e.g., size, indoors/outdoors, windows).
5. Do not initiate a CI without first prioritizing contacts.
6. Evaluate for LTBI based on the priority criteria outlined in TABLE 6: GUIDELINES FOR PRIORITIZING CONTACTS, regardless of mask use or physical distancing of contacts. Programs should continue to follow recommendations outlined in Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis issued by CDC.

Table 5: Estimating the Infectious Period

Index Case Characteristics						Infectious Period
TB Symptoms		AFB Sputum Smear (+) Result		Cavitary CXR		
Yes	No	Yes	No	Yes	No	
√			√		√	Three months before symptom onset or first positive finding* consistent with TB disease (whichever is longer)
√		√		√		Three months before symptom onset or first positive finding* consistent with TB disease (whichever is longer)
	√		√		√	Four weeks before the date of suspected TB diagnosis
	√	√		√		Three months before first positive finding* consistent with TB disease

*Abnormal CXR consistent with TB or bacteriology

Table 6: Guidelines for Prioritizing Contacts

Index Case Characteristic	Contact Prioritization
Pulmonary, laryngeal, or pleural TB • Cavitary lesion on CXR; *or* • AFB sputum smear positive	**HIGH PRIORITY** • All household contacts; *or* • Contact in a congregate setting (schools, correctional and detention facilities, etc.), *and* with significant frequency and duration of exposure **Any hours of exposure for:** • Children <5 years; *or* • Contact with medical risk factors (e.g., HIV, immune compromising condition); *or* • Contact exposed during specific medical procedures (bronchoscopy, sputum induction *or* autopsy). **MEDIUM PRIORITY** • Anyone 5–15 years who does not meet one of the high priority criteria; *or* • Contacts with significant frequency and duration of exposure. **LOW PRIORITY** • Only consider if expansion is warranted.
Suspected or confirmed pulmonary or pleural TB • Abnormal CXR consistent with TB disease; *and* • AFB sputum smear negative; *and* • Might be NAAT positive and/or AFB culture positive	**HIGH PRIORITY** • All household contacts; *and* • Contacts with significant frequency and duration of exposure. **Any hours of exposure for:** • Children <5 years; *or* • Contact with medical risk factors (e.g., HIV, immune compromising condition); *or* • Contact exposed during specific medical procedures (bronchoscopy, sputum induction *or* autopsy). **MEDIUM PRIORITY** • Contact in a congregate setting (schools, detention facilities, etc.); *and* • Contacts with significant frequency and duration of exposure. **LOW PRIORITY** • Only consider if expansion is warranted.

Adapted from Guidelines for the Investigation of Contacts of Persons with Infectious TB: Recommendation from the National TB Controllers Association and CDC and Guidelines for Using QuantiFERON®-TB Gold Test for Detecting Mycobacterium tuberculosis Infection, United States, Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, 54(RR-15), 2005.

D. Conduct Screenings

1. Conduct first and second round screenings.
2. Initiate screening for high priority contacts within seven working days of identification.

3. Initiate and complete first round screening within four weeks of identification.
4. Use TST if IGRA is contraindicated or patient refuses phlebotomy.
5. Avoid testing people with low risk of infection.
6. Perform a complete evaluation of all high priority TB contacts. A complete evaluation generally includes:
   a) A contact interview to obtain relevant medical history, including specific questions about symptoms of TB disease, previous positive IGRA or TST and/or previous treatment for TB disease or infection.
   b) Administration, reading and interpretation of a TST or IGRA.
   c) A chest radiography where indicated (refer to the DSHS SDOs); and/or
   d) Collection of sputum or other specimens for mycobacteriology testing for contacts suspected of having TB disease.
7. Apply the following to contacts with a previous positive IGRA or TST:
   a) Results must be documented. If not documented, administer a screening test.
   b) If documented prior adequate treatment, perform a symptom screen. If showing signs and symptoms of active TB disease, perform a chest x-ray.
   c) If did not start LTBI treatment or did not complete LTBI treatment, perform a symptom screen and chest x-ray.
8. Apply the following to contacts with previous TB disease:
   a) Previous positive TB disease must be documented. If not documented, administer a screening test.
   b) If contact has documented adequate previous treatment, perform a symptom screen. If showing signs and symptoms of active TB disease, perform a chest x-ray. If active TB disease is suspected, collection of sputum or other specimens for mycobacteriology is recommended (refer to Chapter X. Management of Patients with Suspected or Confirmed Tuberculosis).
9. Apply the following to contacts Lost to Follow-Up (LTFU)
   a) Make at least three attempts to contact a TB contact before considering them as LTFU, including:
      i. Calling the contact;
      ii. Visiting the contact's residence if safety is not a concern; and
      iii. Sending a postal mail notification of the contact's need to follow-up with the TB program if services are available in the area.

b) Document attempts in the progress notes of the contact's record.
c) Place certified mail notification receipt in the contact's record, if applicable.

10. Begin second round screening eight to ten weeks after break in contact or after the end of the index case's infectious period, whichever is first.
    a) Retest all contacts who's initial IGRA or TST results were negative after documented contact break with the index, including contacts started on window prophylaxis.
    b) Contacts whose IGRA or TST results are negative and asymptomatic at second round testing have received a complete evaluation.
    c) If a contact was identified after first round screening was initiated, they are still eligible for second round screening. Perform one test eight to ten weeks after break in contact for a complete evaluation.
11. For source case investigations, second round testing is not required.

E. **Consider CI Expansion**

Consider CI expansion if the infection rate is high or if TB transmission is detected see TB-460a, Expansion Analysis Checklist.

1. LTBI among high priority contacts indicates transmission.
    a) The Unit generally uses an infection rate of ≥ 20%. This percentage should be modified based on sentinel events and local data.
    b) An investigation should not be expanded without first reviewing screening results among high priority contacts.
2. Other indicators of transmission include:
    a) Positive tests in contacts aged four and younger,
    b) A change in TST or IGRA status from negative to positive among contacts between first and second-round testing; and
    c) Contacts diagnosed with TB disease.
3. As needed, request a consult with the Unit epidemiologists to discuss whether an expansion to low priority contacts is warranted. Submit consultation requests through GlobalScape and notify TBEpi@dshs.texas.gov.

F. **Conduct a Follow-up Investigation**

Conduct a follow-up investigation for TB isolates identified as *M. bovis*:

1. Ask about a history of consuming raw, unpasteurized dairy products or exposure to livestock.

2. If exposure to either is identified, investigate location of exposure if safety is not a concern.
3. If a Texas dairy or livestock area is identified, contact the Unit to determine if reporting to appropriate partner state agencies is warranted.

G. **Conduct Interviews**

Conduct interviews throughout the patient's treatment period.

1. For all contacts, document the date of identification and the date of break-in-contact with the index on TB-341a.
2. Re-interview patient one to two weeks after initial interview to obtain and/or clarify missing data. Consider using different interviewers.
3. Additional patient and contact interviews may be required when:
   a) Drug susceptibility results indicate drug resistance; or
   b) Genotyping results indicate patient is part of a cluster.

XIII. Managing Contacts to Confirmed or Suspected Tuberculosis Cases

General Requirements

BNTB programs will evaluate, treat, and monitor contacts to suspected or confirmed cases of pulmonary, pleural, or laryngeal TB disease as outlined in Chapter IX. Management of Patients with Latent TB Infection, including Patients on Window Prophylaxis. BNTB clinics in Mexico may adopt SDOs at the local or regional health department TB program. If the BNTB clinics in Mexico adopt these, staff must sign and acknowledge the SDOs.

Contacts referred to the BNTB program for outpatient treatment where Mexico manages the index case and for whom the drug susceptibility tests (DSTs) result is unknown, the BNTB program and the treating physician should use clinical judgment and consider the following prior to admitting patient into the program and determining treatment:

A. Age of patient
B. Symptomatology of the index case and response to therapy, if available
C. Risk of developing TB disease
D. Risk of drug toxicity (i.e., risk of treatment vs. benefits of treatment)
E. Patient's willingness to initiate and adhere to therapy.

Activities

A. **Evaluate High Priority Contacts**

Consider testing results of high priority contacts before addressing any medium or low priority contacts.

1. Conduct medical evaluations and screening tests for high-priority contacts. Use Form TB-460a, Expansion Analysis Checklist, to determine if CI should be expanded. If expansion of the CI is deemed necessary, evaluate medium-priority contacts before expanding to low priority contacts.
2. Face-to-face physician medical evaluation at diagnosis is preferable for initiation of treatment or resumption of medications.
3. Obtain chest radiography within 10 to 14 calendar days* if:

a) The initial IGRA or TST result is positive and no documented history exists of previous adequate LTBI or TB disease treatment;
b) If the patient has high risk for progression to active TB, regardless of previous history of LTBI or disease, and regardless of initial IGRA or TST result; or
c) If the patient reports signs and symptoms of TB regardless of IGRA or TST.

*TB programs with on-site radiograph equipment should obtain a chest radiography within ten calendar days.

4. Assess for TB disease if a contact tests positive and exhibits symptoms of TB disease or has chest radiography suggestive of TB disease.
5. If the IGRA or TST result is positive and the chest radiography is normal or TB disease has been ruled out, consider treatment for LTBI.
6. If a previously positive contact did not complete adequate treatment for LTBI, evaluate for TB disease, which includes a symptom review and a chest radiography. If there is no indication of disease, consider treatment for LTBI.
7. If a previously positive contact completed treatment for LTBI or disease, further treatment may not be required unless recommended by the treating physician. A complete evaluation for contacts that have documented previous adequate treatment requires a symptom screening.
8. Review and assess the completeness of the contact's medical evaluation.

B**. Consider DST Results**

Consider DST results of the index case when determining a contact's course of treatment.

1. Obtain a consult from a DSHS-recognized medical TB consultant for all contacts to MDR-TB, pre-XDR or XDR-TB cases who test positive for infection or are a candidate for window prophylaxis.
2. For contacts treated with INH in the past and are now exposed to an INH-resistant case, treatment with a rifamycin may be needed for the new exposure.
3. Provide DOT or VDOT for contacts to RR, MDR, pre-XDR or XDR-TB cases who are diagnosed with LTBI; consider VDOT as resources allow.

4. Evaluate for TB disease with a signs and symptoms questionnaire and a chest x-ray contacts to MDR-TB, pre-XDR or XDR-TB regardless of previous treatment.
5. Obtain a symptom screening and a CXR every six months for a period of two years (from the date of break in contact) for any contact exposed to MDR-TB, pre-XDR or XDR-TB cases with a positive TST or IGRA test, regardless of whether treatment was taken for LTBI.
6. Previous positive contacts who are now a contact to MDR-TB, pre-XDR, or XDR-TB regardless of previous treatment, evaluate for TB disease with a signs and symptoms questionnaire and a chest x-ray.
7. For contacts in which DSTs for the index case are unknown, the treating physician should closely review the records of the index case and their response to treatment prior to making a treatment recommendation.

C. Review for Treatment Regimens

Review Chapter IX. MANAGEMENT OF PATIENTS WITH LATENT TB INFECTION, INCLUDING PATIENTS ON WINDOW PROPHYLAXIS for treatment regimens that may be considered for these contacts.

1. Document completion of treatment on the appropriate reporting form such as TB-400A-sp or equivalent.
2. Document reason(s) medication was stopped if treatment was not completed.
3. Conduct minimum monthly reviews of adherence to treatment for LTBI.
4. Conduct minimum monthly reviews to identify adverse reactions to treatment for LTBI.
5. Hold medications and obtain a follow-up chest radiography before continuing treatment for LTBI for contacts receiving treatment for LTBI who develop signs and/or symptoms suggestive of TB disease.

D. Provide Window Prophylaxis and Manage High Risk Contacts

Managing high risk contacts requires identifying conditions that will impact treatment for either LTBI or TB disease.

1. Window prophylaxis is treatment for possible LTBI and should be provided until a complete evaluation is documented. It is provided to vulnerable contacts who:

a) Are at a high risk of progressing to severe forms of TB (e.g., TB meningitis);
b) Do not have current TB signs or symptoms, have a negative TB screening test and a CXR not consistent with TB on first-round screening; and
c) Are prophylactically treated for TB infection during a "window period" between their TB exposure until their second-round screening test can be confirmed with to ten weeks after their break in contact or last exposure.

2. The decision to provide window prophylaxis is based on the treating physician's evaluation of the patient, ensuring TB disease has been ruled out.
3. Complete evaluation for contacts under five years of age and contacts with HIV infection or other immunocompromising conditions; include a TST or IGRA, symptom screening, physical examination, and a chest X-ray.
4. Every effort should be made to begin window prophylaxis treatment as soon as possible, but no longer than 14 days of identification. Treatment should be provided by directly observed preventive therapy (DOPT) where possible.
5. Children under five, patients with HIV infection, patients receiving immunosuppressive therapy for organ transplant, and patients taking TNF-a inhibitors with a negative IGRA or TST examination and chest X-ray with unremarkable results should be offered window prophylaxis treatment until second round TB screening is performed.
   a) If the repeat TB screening test remains negative eight to ten weeks after break in contact to index case (beyond the window period), it is recommended that the following groups complete a full course of treatment for LTBI:
      i. Patients with HIV
      ii. Patients receiving immunosuppressive therapy for organ transplant
      iii. Patients taking TNF-α inhibitors
   b) If the repeat TB screening test remains negative eight to ten weeks after break in contact for children under the age of five years, treatment can be discontinued. Infants aged five months and

younger should continue window prophylaxis until they undergo a repeat TST or IGRA at six months.

E. Maintain Medical Record

Maintain a medical record for each person on treatment for LTBI, including those on window prophylaxis as outlined in Chapter IX. MANAGEMENT OF PATIENTS WITH LATENT TB INFECTION, INCLUDING PATIENTS ON WINDOW PROPHYLAXIS. Maintain a complete shadow chart in the Texas BNTB program.

XIV. Management of Medications and Medication Availability

General Requirements

This chapter outlines usage requirements of DSHS-purchased medications and the availability and indications for requesting medications from Mexico.

BNTB programs should establish a process with the Regional Mycobacteriology Programs in Mexico to provide medications when possible. Texas medications may be requested while awaiting procurement from Mexico or when needed to augment Mexico's treatment regimens.

DSHS purchases medications under the Federal 340B Drug Pricing Program to be used for outpatient TB services only. However, DSHS purchased medications can be used for existing BNTB patients when in-patient care is needed. When this occurs, the TB Unit must be notified. Programs must adhere to the DSHS 340B policy requirements when using state-purchased TB medications. Refer to https://www.dshs.texas.gov/pharmacy-unit/340b-drug-discount-program. Also refer to (hrsa.gov/opa/eligibility-and-registration/specialty-clinics/tuberculosis) for additional information on Federal 340B Drug Pricing Program requirements.

Activities

A**. Collaborate Between Programs**

Develop a pre-arranged agreement between the BNTB program in Mexico and Regional Mycobacteriology Program that details how to obtain medications. Discuss and outline roles and responsibilities of each program, including which program will provide medications and in which circumstances they cannot. BNTB programs should ensure medications are available to begin care following standards of care.

B. **Order and Distribute Medications**

The BNTB coordinator will oversee the ordering and distribution of DSHS medications to ensure that:

1. The BNTB program in Mexico accepted the patient into the program and assumed care for the patient.
2. The BNTB program established a medical record for the patient.
3. The BNTB program follows standards of care DOT or VDOT for outpatient use only, and there is clear documentation of treatment administration.

4. The BNTB program only administers 340B medications to patients enrolled in the BNTB outpatient program and only via DOT or VDOT, and document it on the TB-206b. TB-206b form is subject to random quarterly reviews by DSHS pharmacy as required by the 340 policy.
5. Once medications are received by the Texas BNTB program, the nurse coordinator or nurse assigned to oversee nurse case management activities, will review medications received against medication orders for accuracy prior to submitting to the TB clinic in Mexico for treatment of the patient.
6. Patients are not charged for medications.

C. **Follow Usage Recommendations for Mexico's First-Line Medications**

The following medications, when readily available in Mexico may be used in the BNTB program with physician orders and in collaboration with the Regional Mycobacteriology Program.

1. doTBal - Intensive Phase (*Fase Intensiva*)- combination pill given Monday through Saturday, see FIGURE 3 below.
2. doTBal-S - Continuation Phase (*Fase de Sostén*) –combination pill given Monday, Wednesday, and Friday, see FIGURE 4.

Figure 3: doTBal Initial Phase

Figure 4: doTBal-S Continuation Phase

D. **Adhere to Usage Requirements of DSHS Medications**

1. Prescriptions for non-controlled drug orders written by practitioners in the Mexican states can be filled by a Texas pharmacy. See Texas Administrative Code (state.tx.us). Therefore, BNTB treating physicians may write prescription drug orders to receive TB medications.
2. Follow DSHS-established procedures for TB medication inventory management.
   a) The BNTB coordinator will request medications from DSHS pharmacy and reconcile inventory through the DSHS medication ordering system.
   b) Inventory reconciliation must be done at minimum every 30 days in the ordering system. If not done, a new medication order will not be able to be placed. Programs may choose to complete an inventory reconciliation more frequently if desired.
   c) Limit medication orders to a one-month supply. DSHS Pharmacy typically fulfills orders within 24 hours of receipt.
   d) Set maximum stock levels no higher than a one-month average usage.
   e) Monitor and manage use of TB medications and testing supplies furnished by DSHS in accordance with first expiring/first-out (FEFO) principles of inventory control.
   f) Avoid waste by ordering packets for patients new to therapy with individual drugs to avoid waste (e.g., 10 packets of RIF, 10 packets of INH) to maximize usage.

3. Order medications for patients in individual/DOT packets or bulk bottles and ensure labeling requirements are met.
    a) Individual/DOT-packaged medications have a shorter expiration date than their original manufacturer expiration date, typically two to six months after packaging. Therefore, if one medication in the packet expires, the entire packet must be disposed.
    b) Order medication packets for self-administered therapy (SAT) or VDOT. These may be ordered in the same way as individual packets from the DSHS Pharmacy. If medications will be in the patient's possession, certain labeling requirements must be met for packaging (e.g., amber zip-closure bag) containing individual/DOT packets.
    c) The label should be prepared and affixed to the zip-closure bag by TB program staff providing medications to the patient. The label may be requested in Spanish (request only in one language) and must follow the instructions in FIGURE 5: SAMPLE MEDICATION LABEL FOR INDIVIDUAL/DOT PACKETS:
        i. The name and address of the medical director or physician who prescribed the drug;
        ii. The date the drug is delivered to the patient,
        iii. The patient's name; and
        iv. The name, strength, directions for use of the drug(s).

Figure 5: Sample Medication Label for Individual/DOT Packets

TB Program Name Here

123 Main St.
City, Tx 77000
Phone 123-456-7891

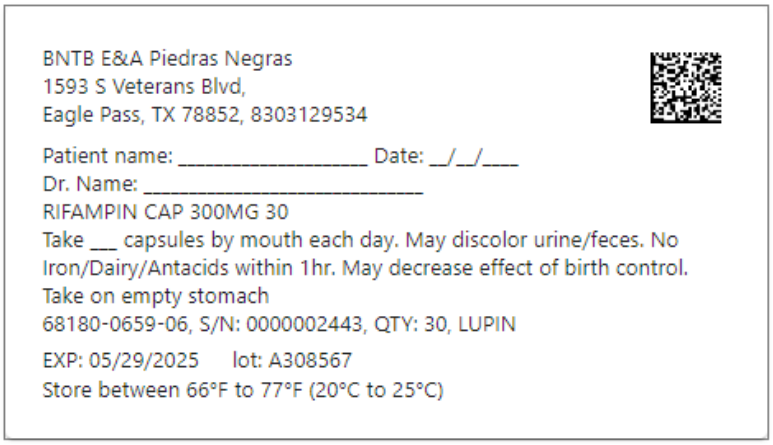
Date: 01/01/2023
Physician: John Watson, MD
Patient: Jane Doe

Medications: Rifampin 600mg, Isoniazid 300mg, Pyrazinamide 1000mg, Ethambutol 800mg, Pyridoxine 50 mg

Instructions: Take 2 packets each day

4. Refer to Terapia Directamente Observada por Video (texas.gov) when using VDOT for eligible patients.
5. Order medication bottles for patients with LTBI. These may be provided to the patient with the following labeling requirements as required by the Texas State Board of Pharmacy (TSBP), Texas Administrative Code (state.tx.us). See FIGURE 6.
    a) The label may be requested in Spanish, attached to bottles, and include:
        i. Name, address, and telephone number of BNTB Texas office,
        ii. Name and strength of drug; if generic, name of drug manufacturer or distributor,
        iii. Quantity,
        iv. Lot number; and
        v. Expiration date.
    b) The BNTB coordinator, if a nurse (if not a nurse, the BNTB program must designate a nurse), will ensure labeling directions include:
        i. Patient name,
        ii. Date medication is provided,
        iii. Physician name, and directions for use (per TSBP rules, incomplete directions for use may be present and if so, are to be completed by the authorized licensed nurse at time of provision).

Figure 6: Sample Medication Label for Bulk Bottles



Note: Label may vary as printing software is updated.

E. **Order Second-line Medications**

1. Second-line medications are not readily available in Mexico but may be procured after consultation and approval from the GANAFAR committee in Mexico. Access to these medications depends on the COEFAR's notification to the GANAFAR, the response from the GANAFAR, and whether they are in stock at Mexico's National TB Program. Medications not in stock require the GANAFAR to submit a request through the Green Light Committee, which may be a longer process.
   a) BNTB clinics in Mexico should coordinate with the TB program in their state and develop a plan to determine which medications they can procure in Mexico. Coordinate this plan with the COEFAR and GANAFAR.
   b) When a consultation is received from a DSHS-recognized TB medical consultant, the program may order medications in the interim from DSHS pharmacy pending approval from the COEFAR, GANAFAR, and the procurement of medication from Mexico. Do not delay patients' treatment pending medications from Mexico.
2. Consultation with either a Texas consulting physician or a DSHS-recognized medical TB consultant is required before ordering second-line medications, see APPENDIX D: MEDICAL CONSULTATION PROCESS.
   a) Order medications for patients in accordance with the treating physician orders, DSHS TB formulary and Unit requirements. See APPENDIX E: DSHS TB FORMULARY.
   b) Most second-line medications are available through the DSHS Pharmacy ordering system. Exceptions:
      i. BDQ (Sirturo)
         (a) Begin process to request medication from Mexico. Submit patient documentation to the Regional Mycobacteriology Program who will ask the COEFAR and the GANAFAR for medication support. Include with the documentation, the DSHS-recognized medical consultant's recommendations and a formal request for medications. Await the COEFAR and the GANAFAR Committee response.
         (b) While awaiting response from the COEFAR and GANAFAR, medications may be ordered from DSHS

Pharmacy Unit. Instructions are outlined in the Bedaquiline Ordering Guide.

(c) Once the GANAFAR reviews the case, they will provide a "Dictamen" to the Regional Mycobacteriology Program with their treatment recommendations. The Dictamen should be shared with the DSHS nurse consultant and uploaded to the patient's ID in the surveillance and reporting database.

ii. CFZ is an investigational drug only available in the U.S. through a Single Patient Investigational New Drug (SPIND) and may only be prescribed by Institutional Review Board (IRB) enrolled physicians, called investigators.

(a) Begin process to request medication from Mexico. Submit patient documentation to the Regional Mycobacteriology Program who will ask the COEFAR and the GANAFAR for medication support. Include with the documentation, the DSHS-recognized medical consultant's recommendations and a formal request for medications. Await the COEFAR and the GANAFAR Committee response.

(b) Once the GANAFAR reviews the case, they will provide a "Dictamen" to the Regional Mycobacteriology Program with their treatment recommendations. The Dictamen should be shared with the DSHS nurse consultant and uploaded to the patient's ID in the surveillance and reporting database.

(c) While awaiting response from the COEFAR and GANAFAR or if Mexico is unable to provide the medication, adhere to the following:

- Inform the Texas consulting physician that IRB enrollment is required; identify if the physician has access to CFZ through an IRB. NOTE: DSHS regional medical directors are investigators. Contact the Unit for coordination.
- Communicate with the IRB-enrolled CFZ prescriber or their designee for next steps in arranging patient

enrollment, IRB consent, medication ordering, and monitoring requirements.

Table 7: DSHS Second-Line Medications

Drug Type*	Name of Medication
Injectable Agents	amikacin
Fluoroquinolones	levofloxacin, moxifloxacin
Bacteriostatic Agents	bedaquiline, cycloserine, ethionamide, para-aminosalicylic acid (PAS), pretomanid
Other Oral Agents	clofazimine, linezolid
**Second-line medications include, but are not limited to these groups*	

F. **Medication Compounding**

Use medication compounding for select patient populations. The DSHS Pharmacy Unit performs medication compounding on Mondays, Tuesdays, and Wednesdays in the following situations:

1. When the patient requires a precise dose that is not commercially available (i.e., a dose of 250mg of RIF is ordered but capsules are only available as 150mg and 300mg).
2. When administrative attempts by the nurse have been exhausted (splitting or crushing tablet, disguising in foods, etc.) and compounding is seen as a last resort to supported medication administration.
3. When the physician provides a manual signature on the prescription and faxes the prescription to DSHS pharmacy. Manual signatures and faxed prescriptions are the legal requirements from the Texas Board of Pharmacy. Electronic signatures and emailed prescriptions are not accepted.

   Note: Some compounded medications must be kept refrigerated and have a shorter expiration period than DOT medications. Contact the DSHS Pharmacy Unit at (512) 776-7500 when compounding is needed and for storage recommendations.

G**. Reconcile Medication Inventory**

1. BNTB programs in Texas will do the following:
   a) Maintain a count of DSHS-purchased medications and supplies in both Texas and Mexico's BNTB sites.

b) Reconcile bulk inventory according to product and lot numbers listed in the DSHS medication ordering system at minimum every 30 days. Bulk medication inventory refers to bottles of medications and not medication packets.
c) Transfer of medication is not allowed to other binational clinics, Texas-based clinics (including clinics within the same health department system), or to another facility in Mexico or Texas. However, medication may be used on another eligible patient within the same clinic. If this occurs, reconcile the medication in the pharmacy ordering system and ensure there is documentation that the medication was provided to an eligible TB patient.
d) Only a BNTB program staff can administer DSHS TB medications. Giving medications to another facility to perform DOT or VDOT is in violation of 340B requirements.
e) Establish protocols and procedures internally for the disposal of expired or non-usable medications.
f) Coordinate with DSHS pharmacy staff to ensure TB orders comply with best practices.

2. Store all DSHS-purchased medications and supplies, at both BNTB programs in Texas and Mexico, properly and securely in accordance with the manufacturer's instruction.

H. **Auxiliary Medications**

1. The TB formulary includes auxiliary medications to support individualized patient care. They include but are not limited to:
   a) Anti-emetics,
   b) Corticosteroids, and
   c) Lidocaine.
2. To order auxiliary medications, consider the following options:
   a) The treating physician may write a prescription for the patient to fill at their own pharmacy.
   b) The managing BNTB program may coordinate with the patient's primary care provider to obtain medications.
   c) The treating physician may consider over-the-counter medications that the patient may choose to purchase.
   d) The BNTB program may request medication from the DSHS Pharmacy Unit when the above options have been exhausted. The

Unit reserves the right to request documentation of attempts to obtain auxiliary medications at any time.

XV. Professional Education and Workforce Competency

General Requirement

All new BNTB program staff shall receive professional education, training and orientation and current staff will receive ongoing education and training.

Activities

A. Ensure all persons operating under procedures of the BNTB program, have the requisite experience and/or training to deliver appropriate services.

B. Provide training and orientation to all employees involved in TB activities, including physicians, nurses, contact investigators, outreach workers, administration staff and other support staff.

1. Initial training includes 40 hours of TB training specific to job duties within 90 days of employment.
2. The following CDC courses are available in Spanish:
   a) CDC "Self-Study Modules on Tuberculosis" are available in Spanish and included as a required training for contract staff.
   CDC | TB | Self-Study Modules on Tuberculosis
   b) Internet course for TB-101
   CDC | TB 101 for Health Care Workers
   c) Podcast for Basic TB Facts
   Public Health Media Library (cdc.gov)
3. Core training topics for TB staff should include the following:
   a) Transmission and pathogenesis of TB
   b) Epidemiology of TB
   c) Diagnosis of LTBI and disease
   d) Treatment of LTBI and disease
   e) TB reporting and notifiable conditions
   f) Drug interactions and toxicity
   g) TB contact investigation
   h) Infectiousness and infection control
   i) Interviewing, investigating, and influencing techniques
   j) Directly observed therapy
   k) TB nurse case management for LTBI, TB disease, and DR-TB
   l) CDC TB surveillance and reporting

4. BNTB program staff in Texas must complete 16 hours of continuing education and contracted staff in Mexico must complete 10 hours of continuing education each calendar year relevant to each staff member's position.
5. The BNTB coordinator or administrating staff member should participate in the TB monthly conference calls or trainings.
6. Ensure monthly case management conferences and cohort reviews include education on TB case management.
7. Conferences and trainings are provided by DSHS PHRs, local health departments and the Unit. Additionally, specialized trainings are provided by Heartland National TB Center (Heartland) as well as other Centers of Excellence on:
   a) Nurse case management;
   b) Drug interactions and toxicity;
   c) Contact investigation for TB;
   d) Infection control measures;
   e) Patient adherence;
   f) Directly observed therapy; and
   g) Tuberculin skin testing practicum.

C. The fiduciary agency, its contracted staff, and the Texas BNTB program will maintain documentation of training for all employees and contracted staff.

1. Retain logs, see APPENDIX P: SAMPLE IN-SERVICE AND TRAINING ROSTER, for in-house trainings in accordance with local procedures include:
   a) Job titles;
   b) Training dates;
   c) Title of training or course; and
   d) Number of hours.
2. Retain copies of employee training certificates.
3. The BNTB treating physicians must have access to training records to verify those operating under their medical license have the requisite experience and training.
4. Notify the Unit of newly hired BNTB program staff in Mexico and Texas within 30 days of hire. The BNTB coordinator will submit the Notice of Change of TB Personnel form (TB Forms Resources | Texas DSHS) to TBProgram@dshs.texas.gov.
5. Educate external entities as needed and as resources allow.

a) Promote the BNTB program during these events on the services and support provided by the program.
b) Ensure advance written approval for any publication, presentation or abstracts regarding the BNTB program has been obtained from the Unit director and that the affected PHR and/or LHD in Texas have been notified.

6. Report trainings on the DSHS APR according to contract deadlines.
7. Maintain competency within the Texas BNTB staff to navigate NEDSS. BNTB program managers may choose to require certificates of training completion for each NEDSS training course.

XVI. Infection Control Procedures

General Requirement

The BNTB programs in Mexico in collaboration with the fiduciary agency will apply appropriate administrative, environmental, and respiratory controls to prevent exposure to and transmission of *M. tb*.

Activities

A. **Administrative Control Measures**

Administrative control measures reduce the risk of exposure to persons with infectious TB and may include the following activities:

1. Implement effective work practices for managing patients with TB disease and infection.
2. Ensure separation of infectious or potentially infectious patients from other patients in the clinic.
3. Ensure proper cleaning, sterilization, or disinfection of equipment and surfaces to prevent contamination.
4. Educate, train, and counsel health care workers, patients, and visitors about LTBI and disease.
5. Use posters and signs to remind patients and staff of proper cough etiquette and respiratory hygiene.
6. Screen direct-care staff for TB.
    a) The program must screen direct-care staff for TB upon hire and at least annually to monitor results, conversions, and signs and symptoms. If the screening test is positive, contractual staff will be referred to their primary care provider or the BNTB treating physician.
        i. IGRA is the preferred method for screening.
        ii. New hires with previous positives should present documentation of results and completion of adequate treatment for LTBI or TB disease. If no results are available, retesting is appropriate as determined by the program.
        iii. Any staff with signs and symptoms of TB disease should be referred for a complete medical evaluation regardless of test result.

b) Maintain documentation in accordance with local procedures and ensure they are readily available to the medical coordinator for yearly review.

7. Be familiar with CDC's recommendations for screening health care personnel (HCP) for TB found in the Centers for Disease Control and Prevention's (CDC's) document "Tuberculosis Screening, Testing and Treatment of U.S. Health Care Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC."

B. **Environmental Control Measures**

Environmental control measures prevent the spread and reduce the concentration of infectious respiratory particles (IRPs) of *M. tuberculosis,* these include:

1. Use local exhaust ventilation (e.g., hoods, tents, or booths) to contain and control the source of infection.
2. Use general ventilation to dilute and remove contaminated air.
3. Use high-efficiency particulate air (HEPA) filtration or ultraviolet germicidal irradiation (UVGI) to clean the air.
4. Control airflow to prevent the contamination of air in adjacent areas.
5. Properly install, operate, and maintain environmental control equipment.

C. **Respiratory Controls**

Respiratory controls consist of the use of personal protective equipment in situations that pose a high risk of exposure to TB disease and include the following:

1. Develop a procedure on respiratory protection, to include the type and size of respirators available to staff, routine inspection and maintenance, and appropriate use.
2. Contracted staff must receive fit testing upon hire, yearly and as needed if there is any change to physical facial structure.
3. Ensure masks are fitted properly on each staff.
4. Ensure N-95 respirators are used by staff that are in situations that pose a high risk of exposure to TB disease.
5. Educate patients on respiratory hygiene and the importance of cough etiquette and provide surgical masks as needed.

6. Perform droplet nuclei-producing procedures (e.g., sputum collection) outside in a location that protects patient confidentiality if an AIIR room or booth is unavailable.

XVII. Budget Management

General Requirement

The CDC funds BNTB programs through a cooperative agreement. CDC funds support Texas-based BNTB program staff, including services performed in Mexico through a contracted fiduciary agency.

The fiduciary agency is responsible for developing subcontracts to maintain clinical operations in Mexico, which includes hiring clinical staff; monitoring budget expenses; purchasing supplies; maintaining patient medical records at each clinic site in Mexico; and submitting required reports to DSHS by established deadlines.

The BNTB coordinator must perform the following activities to support the fiduciary agency:

A. Review and validate weekly time and mileage report, see APPENDIX P: SAMPLE IN-SERVICE AND TRAINING ROSTER, prior to submitting to the fiduciary agency for approval of payment vouchers of Mexico contractors for salaries, mileage, and other allowable reimbursements.
B. Work closely with the fiduciary agency to determine supplies needed at the clinic site in Mexico.

The BNTB program managers and coordinators in Texas must manage and monitor their own program budgets by accomplishing the following activities:

A. Review and revise federal budget.
B. Monitor budget expenditures for program operations.
C. Recommend budget revisions for program operations and obtain approval from the Unit.
D. Notify the Unit of any changes in personnel, including new hires.

Restricted Activities

The BNTB Program adheres to state and federal funding standards including funding restrictions and limitations.

A. **Activities in Mexico**

The fiduciary agency must ensure program activities in Mexico are coordinated as needed with appropriate government authorities and appropriate licenses, permits, or approvals are obtained.

B. **Limited English Proficiency**

The fiduciary agency must take reasonable steps to ensure patients with limited English proficiency have meaningful access to TB health services and there is effective communication between the service provider and the patient. To clarify existing legal requirements, HHS published "Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons." This guidance provides a description of the factors that recipients should consider in determining and fulfilling their responsibilities to individuals with limited English proficiency under Title VI of the Civil Rights Act of 1964.

C. **Limitations**

1. CDC Notice of Funding Opportunity restrictions that must be considered when developing the budget are:

    a) Recipients may use funds only for clinical services that align with the standards of care approved by Texas and Mexico.
    b) Recipients may use funds only for reasonable program purposes, including personnel, travel, supplies, incentives, enablers, and services.
    c) Recipients may not use funds to purchase furniture or equipment costing more than $500 U.S. Any proposed spending must be clearly identified in the budget and approved by the Unit director.
    d) Reimbursement of pre-award costs is not allowed.
    e) No funds can be used for:
        i. Publicity or propaganda purposes, for the preparation, distribution, or use of any material designed to support or defeat the enactment of legislation before any legislative body.
        ii. The salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative.
            (a) Recipients may not use funds for in-patient clinical care.
            (b) Recipients may not use funds to supplant state or local health department funds.
            (c) Recipients may not use funds to purchase medications for treatment.

2. Other activities that are not supported by federal or state funds include the following:
    a) Lobbying activities or costs,
    b) Non-grant supporting activities,
    c) Activities that do not follow standards consistent with state and local laws, and ethics,
    d) Activities that promote the legalization of any drug or other substance included in Schedule I,
    e) Meals and alcoholic beverages,
    f) Paying bad debts, fines, and penalties,
    g) Termination or suspension costs,
    h) Entertainment costs,
    i) Fundraising costs,
    j) Honoraria,
    k) Independent research and development costs,
    l) Invention, patent, or licensing costs,
    m) Land or building acquisitions, and
    n) Library services.

To learn more about the general terms and conditions of discretionary grants and cooperative agreement awards visit Department of Health and Human Services Grants Policy Statement**.** The document provides information about the grant process and its associated authorities and responsibilities.

XVIII. Reporting Requirements

General Requirement

Programs must report suspected and confirmed TB cases, contacts, and people diagnosed with LTBI to the Unit through reporting mechanisms outlined in this chapter based on established deadlines. Reporting may include responding timely to Unit requests and entering data into the TB electronic database known as the Notifiable Electronic Disease Surveillance System (NEDSS).

NEDSS is a CDC-developed integrated information system that helps local, state, and territorial public health departments manage reportable disease data and send notifiable disease data to the CDC. NEDSS allows for real time data entry; therefore, TB programs must adhere to the reporting timelines outlined in this chapter.

Reporting is essential for TB programs to:

A. Ensure case supervision;
B. Ensure completion of appropriate therapy;
C. Ensure completion of timely contact investigations; and
D. Analyze data to determine morbidity, demographic characteristics, and trends so that opportunities for targeted screening for disease or infection can be identified.

Activities

A thorough search of the database should always be conducted before creating investigations. If the patient search results in no matches, a Patient File must be created before creating the TB investigation. Refer to the *NEDSS Data Entry Guide* for reporting surveillance data for TB conditions at dshs.texas.gov/tuberculosis-tb/training/nedss.

BNTB programs will perform the following:

A. Create a **Tuberculosis RVCT 2020 investigation** in NEDSS within three business days of notification for the following, unless the investigation was already created by an electronic laboratory report (ELR):

    1. All persons being evaluated for TB;
    2. Persons named as a contact;

3. Persons suspected of having TB; and
4. Persons with confirmed TB disease.

B. Obtain and enter in NEDSS the initial TB intake information within seven days of notification for all suspected (ATS 5) and confirmed TB cases (ATS 3) (refer to: APPENDIX L: INTAKE INFORMATION).

1. If suspected of having TB, the initial ATS classification should be entered as ATS 5 - pending diagnosis, with the classification date.
   a) Within the 90-day period, all diagnostic tests for TB should be completed. Therefore, a patient should not be an ATS class 5 for more than 90 days (three months).
2. Once a TB diagnosis is made, the current ATS classification should be updated and entered as ATS class 3-*M. Tb* disease, clinically active, with the new classification date.
3. If TB is ruled out, update the ATS classification as applicable and enter the updated classification date (refer to: TABLE 8: AMERICAN THORACIC SOCIETY (ATS) TB CLASSIFICATIONS below).

Table 8: American Thoracic Society (ATS) TB Classifications

Classification	Description
0	**No M.TB exposure, Not TB infected**
1	**M.TB exposure, no evidence of TB infection**
2	**M.TB infection, no disease**
3	**M.TB infection, current disease**
4	**M.TB, no current disease**
5	**M. TB suspected, diagnosis pending**

C. Report in NEDSS all **active TB cases (ATS 3)** to the Unit within two business days after identification of a laboratory, confirmed TB case, or diagnosis of a clinical case of TB by creating a notification. Ensure all applicable information is entered for the Unit surveillance team to verify case criteria and count status. (Refer to: TABLE 9: CASE CRITERIA .)

1. When notifications are received, a TB surveillance case consultant will perform quality assurance (QA) and assign state case numbers (SCN).
   a) A recurrent TB case will be counted as a new case if the recurrence occurred *after* 12 months from the last known date when TB treatment was stopped from the previous episode.
   b) It will not be counted as a new case if the recurrence occurred *within*

12 months from the last known date when TB treatment was stopped.

2. Enter remaining TB case data in NEDSS as soon as the information is available, not to exceed seven days after information is obtained.
   a) Initial drug susceptibility test (DST) results should be manually entered in NEDSS on all culture-confirmed cases as soon as an initial susceptibility report is available, if not reported electronically.
   b) Treatment and case outcome information should be entered in NEDSS for all cases as soon as treatment is complete or treatment information is available, not to exceed seven days from therapy stop date.

Table 9: Case Criteria

Case Criteria
Laboratory Confirmed
• Isolation of M. tuberculosis from a clinical specimen, OR • Demonstration of M. tuberculosis complex from a clinical specimen by nucleic acid amplification test, OR • Demonstration of acid-fast bacilli in a clinical specimen when a culture has not been or cannot be obtained or is falsely negative or contaminated.
Clinical Case (Pulmonary or Extra-pulmonary)
Pulmonary Site of TB disease contains one or more of the following: Pulmonary, Pleural, or Lymphatic – Intrathoracic, and: • Positive TST or positive IGRA for *M. tuberculosis;* and • Chest imaging study, consistent with TB; and • Initial drug regimen, started on at least two anti-TB medications. Extra-pulmonary or both Pulmonary and Extra-pulmonary Site of TB Disease contains one of the following: Adrenal; All teeth, gums and supporting structures; Anal; Appendix; Blood; Blood vessel; Bone and joint; Bone marrow; Brain; Breast; Cardiac valve; Colon; Duodenal; Epiglottis and larynx; Esophageal; Extrahepatic duct; Eye and ear appendages; Fetus and embryo; Gallbladder; Heart; Jejunum and ileum; Lip; Liver; Lymphatic Other; Lymphatic Unknown; Meninges; Middle ear and mastoid cells; Mouth region; Nasal; Nasopharyngeal; Other; Pancreatic; Paranasal sinus part; Pericardial; Peritoneal cavity; Pharyngeal; Pituitary; Placenta, umbilical cord and implantation site;

Case Criteria
Rectum; Salivary gland; Skin; Spinal cord; Splenic; Stomach; Genitourinary system; Lymphatic system of axilla; Lymphatic system of neck; Nervous system; Subcutaneous tissue; Thymus gland; Thyroid and/or parathyroid; Tongue; Tonsil and adenoid; Trachea; and: • Positive TST or positive IGRA for *M. tuberculosis;* and • Signs and symptoms compatible with TB; and • Initial drug regimen – started on at least two anti-TB medications.
Clinical Case by Provider Diagnosis
• Autopsy Report – report must be provided; • Child recent contact to active TB case; • Considerable clinical improvement based on symptoms from onset after starting minimum two anti-TB medications; • Not done or negative TST/IGRA and considerable improvement on abnormal chest X-Ray/chest imaging; and • TB expert consult – documentation must be provided that may indicate the provider's rationale or findings for which the diagnosis was based.

D. Create an **LTBI investigation (TBLISS)** in NEDSS within three business days for known LTBIs only. An investigation should be created for the following populations with high-risk conditions if the client is being treated by the health department:

1. Foreign-born from high-incidence countries;
2. Newly arrived immigrants and refugees notified through EDN;
3. Unaccompanied children;
4. HIV-positive individuals; and
5. Health care workers with recent TST or IGRA conversion.

A thorough search of the database should be conducted before creating investigations. If the patient search results in no matches, a patient file must be created before creating the LTBI investigation. Refer to the *NEDSS Data Entry Guide* for reporting surveillance data for TB conditions for more information: dshs.texas.gov/tuberculosis-tb/training/nedss.

E. Obtain and enter in NEDSS the initial intake information within seven days of notification for known LTBI (ATS class 2). (Refer to: APPENDIX L: TB INTAKE

INFORMATION.)

F. Report **ATS class 2** investigations to the Unit within two business days of LTBI therapy start date by creating a notification.

   1. When notifications are received, a Unit TB surveillance case consultant will perform QA and assign an LTBI number.
   2. Complete information must be entered in NEDSS before an LTBI number will be assigned. (Refer to: APPENDIX L: INTAKE INFORMATION for required information.)
   3. Enter remaining LTBI data in NEDSS as soon as the information is available.
      a) Treatment and outcome information should be entered in NEDSS as soon as LTBI therapy is complete therapy information is available, not to exceed seven days from therapy stop date.

G. Maintain a digital or electronic log of all TB cases reported or counted in the jurisdiction by county and year with the following:
   1. Name
   2. Date of birth
   3. City/County address and jurisdiction
   4. Contact information
   5. Database investigation ID
   6. State Case Number (SCN)

H. Incorporate **quality assurance (QA) protocols and procedures** into surveillance activities.
   1. Respond to requests from the Unit to check any discrepancies between the jurisdiction's case count in NEDSS and the case count in the jurisdiction's log.
   2. Respond to requests within one week or five business days after receipt or within the timeframe included in the request. See APPENDIX M: GUIDELINES FOR RESPONDING TO UNIT'S SURVEILLANCE REQUESTS.
   3. Reclassify suspected TB cases as soon as data are available to classify as a confirmed TB case or as not a verified case of TB. This should not take longer than 90 days after the initial ATS class 5 classification.
   4. Satisfy requirements for QA for TB Surveillance data. (Refer to: TABLE 10: REQUIREMENTS FOR QA FOR TB SURVEILLANCE DATA.)

Table 10: Requirements for QA for TB Surveillance Data

Summary of CDC Requirements for Quality Assurance for TB Surveillance Data
TB programs will incorporate protocols and procedures into surveillance activities to ensure: • Case detection (finding, counting, and reporting all TB cases). • Data accuracy (accuracy of data abstracted from original patient records, registry data, and data entered in the TB surveillance and reporting database and transmitted to CDC). • Data completeness. • Timeliness; and • Data security and confidentiality. Develop written protocol for QA for TB surveillance data Develop and implement plans for continued improvement and ongoing monitoring. • Describe how each of the QA components (case detection, data accuracy, data completeness, data timeliness, data security, and confidentiality) is being conducted. Qualified Participants: • Unit Surveillance Team • Designated Staff, including TDCJ and Binational TB Programs

Source: Quality Assurance for Tuberculosis Surveillance Data: A Guide and Toolkit, 2013.

I. Adhere to reporting timelines for TB case reporting to the Unit. Refer to TABLE 11: TIMELINE FOR TB CASE REPORTING below.

Table 11: Timeline for TB Case Reporting

Action	Deadline
Report 2024 TB cases to the Unit Central Office	**January 10, 2025**
Finalize 2024 TB case data (all but case outcome)	**March 14, 2025**
Reconcile 2024 TB case data	**May 9, 2025**

J. Complete TB-340a and TB-341a, or Mass Contact Spreadsheet, within 90 days of initial source case report in NEDSS. The initial contacts' report requires the following:

1. Part A. Case or suspect case of TB Information
2. Part B. Interview and Exposure Site Information

a) For every sputum smear positive case, conduct at least two interviews seven days apart.
b) Provide reason if at least three contacts to sputum smear positive cases were not identified.
c) Provide reason if second interview was not conducted.
d) Provide reason if no contact investigation was conducted.

3. Part C. Contact Information
   a) Duration of exposure and setting
   b) HIV test results
   c) Priority status
   d) TST or IGRA test results
   e) CXR or other imaging date and interpretation
4. Verify that a complete evaluation was performed. A complete evaluation for the purposes of the CI Aggregate Report consists of a TST or IGRA result. If the result is positive, a CXR result and a diagnosis from a physician should be made with an ATS classification are required. If the result is negative, do not provide an ATS classification until a second TST or IGRA is performed 8-10 weeks after the contact's last exposure to the source case. Once the treating physician makes a diagnosis, (i.e., LTBI, TB suspected, closed-no evidence of LTBI, etc.) the ATS classification can be made and entered in NEDSS.
   a) Perform a symptom screen for an evaluation to be complete.
   b) Provide reason if evaluation was incomplete.
5. For contacts with LTBI, ATS class 2s, update NEDSS with contact follow-up information including:
   a) If treatment was recommended;
   b) If treatment was not recommended, provide reason;
   c) Treatment start date;
   d) Treatment stop date;
   e) If treatment was completed adequately; and
   f) If contact did not complete treatment adequately, provide reason.
6. Report contacts who develop active TB disease before submitting the subsequent contacts of those cases. Provide the linking RVCT number of their source case in NEDSS.

K. Report mass screenings (contact investigations > 50 contacts) when using DSHS-purchased supplies. Do not perform mass screenings without prior Unit approval.

1. List CIs that yield >=50 contacts on the DSHS TB Mass Contact Spreadsheet. Request the most recent version from DSHS TB Epidemiology before use.
2. Make every effort to educate and inform the "concerned individual" regarding the TB screening process to ensure TB epidemiologic principles are applied at each CI event.
3. Use sound epidemiologic principles at each CI event to ensure appropriate people are identified for screening and to determine specific environments in which transmission may have occurred.
    a) Mass screenings that are not epidemiologically guided, drain limited resources and yield minimal results.

L. Achieve National TB Indicator Project (NTIP) Objectives and Performance Targets. Texas BNTB programs are required to achieve each measure for CIs outlined in TABLE 12 TEXAS TB PERFORMANCE MEASURES. For a comprehensive list of NTIP objectives and targets see National TB Program Objectives and Performance Targets for 2025.

M. Report false-positive cases.

1. Determine the need for a false-positive investigation when a patient presents with a single-positive cultures or the licensed healthcare provider suspects the clinical presentation is not consistent with culture findings.
2. Initiate the false positive investigation and review other specimens associated with a false-positive case to ensure they are culture-negative. Contact the originating laboratory to determine the source of the false positive result (e.g., lab contamination vs. specimen collection error). Use genotyping and whole genome sequencing data to support the investigation.
3. Request assistance as needed. Complete the False Positive Investigation Worksheet or equivalent and submit it to TBEpi@dshs.texas.gov. Upon

conclusion, provide a summary of the investigation results to include in the patient record, if warranted.

4. Report any case closed as false positive to the Unit's Surveillance Team at TBHDSurveillance@dshs.texas.gov with documentation to justify change in case status (e.g., amended laboratory report, doctor's note, written medical consult, etc.) within 45 business days of closure.

N. Follow APPENDIX N: INTERJURISDICTIONAL COMMUNICATION for Interjurisdictional Notification (IJN) when transferring or reporting suspects, cases, or contacts to and from the BNTB program.

O. Report DR-TB by notifying the BNTB nurse consultant and entering information in the NEDSS within three business days of suspected or confirmed drug resistance.

1. Complete and submit updated information at minimum every 90 business days for all DR-TB cases until treatment completion in NEDSS.
2. Submit changes in case management, drug resistance patterns or residence in any DR-TB case within 72 hours of notification. Changes will be entered in NEDSS and the BNTB nurse consultant will be notified via email.

P. The fiduciary agency submits the completed APR and the program managers are responsible to submit the BNTB APR supplementary form to CMS once a year by the established contract deadline (first business day in April).

Q. Submit completed cohort review documents to the Unit in accordance with the listed cohort review period and submission schedule via GlobalScape. Notify the Continuing Quality Improvement (CQI) team by emailing CQIteam@dshs.texas.gov upon upload. See TABLE 13 in APPENDIX I: COHORT REVIEW PROCESS for schedule.

R. Follow Mexico's reporting requirements regarding their monitoring and surveillance reporting system.

1. BNTB programs will abide by the reporting requirements from the Regional Mycobacteriology Programs in Mexico to ensure reporting of contacts, patients suspected of TB and cases of TB are reported using their required documents and following their reporting time requirements.

XIX. Confidentiality and Security Standards

General Requirement

BNTB programs must evaluate and treat patients at BNTB clinics in Mexico. Open and maintain the official medical record at the BNTB clinic in Mexico. However, keep and maintain an up-to-date shadow chart in Texas in accordance with applicable state and federal security and confidentiality standards, policies and guidelines including, but not limited to:

- DSHS Program Policy
  302.001 Release of Tuberculosis (TB), Human Immunodeficiency Virus (HIV), Sexually Transmitted Disease (STD) and Viral Hepatitis Data | Texas DSHS
  2016.01 HIV/STD Section Confidential Information Security | Texas DSHS
  2011.01 Confidential Information Security | Texas DSHS
  2011.04 Breach of Confidentiality Response | Texas DSHS
- Federal
  Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action (cdc.gov)

Activities

A. Submit documentation of DSHS security and confidentiality training course to the Unit Security Officer within 30 days of hire.

B. Submit inquiries related to database access and security training to TBHIVSTD.AccountRequest@dshs.texas.gov.

C. Complete an annual refresher training course on confidentiality requirements/confidential information security within one year of having taken the previous confidentiality and security course.

D. Submit all appropriate documentation of confidentiality and security training to TB/HIV/STD Database Access Requests within ten (10) business days of completing each course.

E. Designate a TB program staff member to serve as the local responsible party (LRP) at the regional or local BNTB program in Texas.

F. BNTB program staff (Texas & Mexico) will work closely with their designated local responsible party (LRP) to ensure personally identifiable information is kept secure ensuring that records are maintained in a secure area when not in use, are not left in plain sight, and shredded with a cross-cut feature before disposal.

XX. Conduct Continuing Quality Improvement (CQI) Activities

General Requirement

BNTB programs will evaluate their performance in meeting key measures including their process to maintain a robust BNTB infrastructure.

Activities

A. Update protocols to support BNTB program performance evaluation and CQI activities.

B. Assess, evaluate, and determine compliance of TB programs

   1. Review the Annual Progress Report (APR) submitted by the BNTB programs.
   2. Provide feedback and recommendations to increase program performance and adherence to the BNTB manual.

C. Conduct quarterly cohort reviews in accordance with the DSHS Tuberculosis Cohort Review Process. See TABLE 13: COHORT PERIOD AND SUBMISSION SCHEDULE.

   1. Compare treatment completion and contact evaluation rates by cohort periods and years to assess program progress.
   2. Identify trends that support or hinder effective TB prevention and care activities.
      a) Identify outcomes that fall short of local, state and/or national performance objectives.
      b) Develop corrective action plans to improve outcomes.
   3. Complete the 12-14064a Cohort Review Summary and each individual presentation form. Submit summary and presentation forms along with a list of counted cases to the Unit via GlobalScape. Notify the CQI Team of the upload by emailing CQITeam@dshs.texas.gov.
   4. TB programs with fewer than six counted cases in a given year may conduct a yearly cohort review due by December 31 of the following year.

D. Perform routine case management review and document findings.

   1. Establish a case management or case review schedule.
   2. Identify deviations from established standards of care.

3. Address needed changes in treatment and case management.

E. Use Texas Performance Measures to assess progress toward achieving state objectives.

1. Identify TB program staff who need access to NEDSS. At minimum, this should include the TB program manager and binational TB coordinator.
2. Contact the Unit at TBProgram@dshs.texas.gov for information on obtaining access to NEDSS.

F. Meet the Texas TB Performance Measures. See TABLE 12: TEXAS TB PERFORMANCE MEASURES.

1. If a program's performance falls short of desired benchmarks, DSHS may (at its sole discretion) require additional measures to improve performance on a timeline set by DSHS.
2. Maintain documentation used to calculate performance measures as required by General Provisions Article VIII "Records Retention," and by Texas Administrative Code (state.tx.us), regarding retention of medical records.

Table 12: Texas TB Performance Measures

Performance Measure (PM)	Benchmark (%)				
	2025	2026	2027	2028	2029
PM 1: Newly reported TB cases must have an HIV test performed unless there is documented evidence of an HIV-positive result or the patient refuses. Exclude TB cases who: • are diagnosed at death; and/or • aged 11 and under at the time of diagnosis.	91	92.7	93.2	94	94.5
PM 2: All suspected and confirmed TB patients are placed on DOT any time during the course of treatment.* Exclude TB cases who: • are diagnosed at death; • are not recommended for treatment; and/or • have not started on treatment.	92	92.3	92.5	93	93.5
PM 3: Newly reported suspected and confirmed cases of TB are started on the standard four-drug regimen. Exclude TB cases who: • are diagnosed at death; • are not recommended for treatment; and/or • have not started on treatment.	94	94.2	94.4	94.7	95

Performance Measure (PM)	Benchmark (%)				
	2025	2026	2027	2028	2029
PM 4: Newly reported patients aged 12 and older for whom TB was identified in the pleura or other respiratory site must have sputum collected and tested for AFB smear and culture results.[†] Exclude TB cases who: • are diagnosed at death; • aged 12 years and under; and/or has a site of TB disease that is not respiratory.	94	94.7	95.7	96.6	97
PM 5: Newly reported cases of TB with AFB-positive sputum culture results must have documented conversion to sputum culture-negative within 60 days of initiation of treatment. Exclude TB cases who: • do not have a positive sputum culture; • are not started on treatment; • are diagnosed at death; • died within 60 days of initiating treatment; • moved outside the U.S. within 60 days of initiating treatment; and/or • not been on treatment for 60 days.	64	64.5	65	65.5	66
PM 6: Newly diagnosed TB cases that are eligible to complete treatment within 12 months must complete therapy within 365 days or less. Exclude TB cases who: • have TB in the central nervous system; • have TB in bone, joint, or skeletal system; • are diagnosed at death; • die before or during treatment; • are resistant to rifampin; • have meningeal TB disease; • are age 14 or younger with either miliary disease or a positive blood culture for TB; and/or • cases who moved outside of the U.S.	87	87.5	88	88.5	89
PM 7: Increase the proportion of culture-confirmed TB cases with genotyping result reported.	98.5	98.7	99	99	99
PM 8: TB cases with initial cultures positive for *M. tb* complex are tested for drug susceptibility with results documented in the medical record and in the TB Unit's designated surveillance and reporting database.	93	94	95	96	97
PM 9: Newly reported TB patients with a positive AFB sputum-smear result have a defined infectious period documented in the medical record and in the TB Unit's designated surveillance and reporting database.	91	91.5	92	92.5	93

Performance Measure (PM)	Benchmark (%)				
	2025	2026	2027	2028	2029
PM 10: Newly reported TB patients with a positive AFB sputum-smear result have at least three contacts evaluated as part of the contact investigation.	79	79.5	80	81.5	82
PM 11: Newly identified contacts identified through the contact investigation that are associated with a sputum AFB smear-positive TB case are evaluated for TB infection and disease.	69	69.5	70	70.5	71
PM 12: Contacts identified to an AFB smear positive patient and for whom TB infection was diagnosed must be **started** on treatment for TB infection within a week of diagnosis.	66	66.5	67	67.5	68
PM 13: Contacts identified to an AFB smear positive patient and for whom treatment was initiated for TB infection must **complete** treatment within the recommended time frame.	82	82.5	83	83.5	84
** CDC recommends treatment initiation for TB patients with positive AFB sputum-smear results within 7 days of specimen collection.* *† Report results to DSHS according to the surveillance reporting schedule.*					

G. Conducting on-site program reviews.

1. Conducting on-site reviews of BNTB clinics in Mexico
   a) The medical coordinator will conduct on-site reviews of all BNTB coordinator sites in Mexico based on a routine or targeted need using an approved on-site review tool.
   b) Once the site is selected, the fiduciary agency will coordinate logistics and provide formal notification that includes agenda, and selected list of medical chart identification numbers with the BNTB program in Mexico.
   c) During the visit, the medical coordinator will conduct medical chart reviews, interview staff, and observation of staff to complete the onsite review tool.
   d) The medical coordinator will prepare a final report detailing findings and specific recommendations to address non-adherence with standards of care outlined in the BNTB manual. The fiduciary agency will submit the audit report to CMS and CMS will provide a copy to the Unit.
   e) The Unit will review the audit report and provide feedback and recommendations to the fiduciary agency and affected program via CMS.

f) The fiduciary agency in collaboration with the BNTB program will have 60 days to submit a Corrective Action Plan (CAP) to CMS in response to the final report that addresses each recommendation with a timeline for completing TB activities for monitoring, implementation, and ongoing follow-up by the Unit. The Unit will confirm receipt of CAP and a follow-up visit will be scheduled the following fiscal year.

2. Conducting on-site reviews of BNTB programs in Texas.
   a) The Unit will conduct on-site reviews of the Texas BNTB sites based on routine or targeted need using an approved on-site review tool.
   b) Once the site is selected, the BNTB program manager and CQI team will coordinate logistics and provide formal notification that includes agenda, and selected list of medical chart identification numbers with the BNTB program.
   c) The CQI Team will notify the TB program with a formal notification that includes an agenda, a selected list of medical chart identification numbers, and the Onsite Review Tool (texas.gov).
   d) During the on-site visit, reviewers will conduct medical chart reviews, staff interviews, and observe staff performing TB activities to complete the onsite review tool.
      i. BNTB programs must ensure training records and medical chart documentation comply with guidelines in the BNTB manual (relevant chapters) for on-site reviews.
   e) The Unit will provide the BNTB program with a final report detailing findings and specific recommendations to address non-compliance with the BNTB manual.
   f) The BNTB program will submit a CAP in response to the final report that addresses each recommendation with a timeline for completing TB activities for monitoring, implementation, and ongoing follow-up by the Unit.

Appendix A: Attestation of Review of BNTB Manual

I, _____, have read and understand the Binational TB Program Manual provided by the Texas Department of State Health Services TB and Hansen's Disease Unit, Fiscal Year 2025.

I understand the information and agree to follow the instructions outlined in the Manual.

_____

Signature of Staff Date (MM/DD/YYYY)

Appendix B: Process for Enrollment

Patients may be referred to the BNTB program by the health department in Mexico, a health department in the U.S., or self-referred as a walk-in patient. Qualifications for enrollment into the BNTB program are outlined in Chapter IV. PROGRAM ELIGIBILITY, REFERRALS AND APPROVAL.

All patients referred to the BNTB program, unless the patient is a walk-in, will have a referral form of either a BN-200 *Forma de Referido* or an Interjurisdictional TB Notification (IJN) Form.

A decision to accept or decline entry into the BNTB will be made as a collaborative decision between the treating physician in Mexico, the BNTB coordinator, the BNTB program manager and in some instances the Texas consulting physician. The final decision to admit or decline a patient to the BNTB program should be made within ten (10) business days.

All documents containing protected health information (PHI) should be shared using a protected mechanism approved by DSHS such as GlobalScape.

Step 1 Initial Interview and Review for Enrollment

A. The **nurse in Mexico** will do the following:
   1. Review the referral form and ensure there is a binational link.
   2. Collect all medical records from the referring program. If needed, have the patient sign the L-30a.
   3. Consent for treatment.
   4. Open a patient medical record.
   5. Each patient with class II, III, or V will have a medical record with designated forms, or their equivalent as outlined in APPENDIX F: BINATIONAL TB PROGRAM CLINICAL CARE FORMS.
   6. Conduct a patient interview and collect data using the TB-202a or equivalent.
   7. Present documents to the BN treating physician in Mexico for review and approval to send to the BNTB coordinator for formal acceptance into the program.
   8. Send all documents to the Texas BNTB coordinator after review from the Mexico treating physician.

B. The **Mexico treating physician** will do the following:
   1. Determine if consultation from the Texas consulting physician or a DSHS recognized medical consultant is needed.
      a) Patients **not requiring** consultation.
         i. Review the BN referral form and all medical documents.
         ii. Approve or decline services into the program and document in the BN-200**.**
         iii. If patients meet the qualifications for care in the BNTB program, instruct the nurse to submit all documents to the BNTB coordinator for collaborative approval into the program.
         iv. Await response.

      b) Patients **requiring** consultation.
         i. Review the BN referral form and all medical documents.
         ii. Approve or decline services into the program and document in the BN-200.
         iii. Fill out the consultation template. Use Heartland Medical Consultation Form or the TB-242 DSHS TB Consultation Request Form or equivalent.
         iv. Instruct the nurse to submit all documents to the BNTB coordinator who in turn will ensure all documents are submitted to the consulting physician.
         v. Await response and treatment recommendations.

      c) For patients who do not meet the qualification to be served in the BNTB program, referrals or medical records do not need to be forwarded to the BNTB coordinator. The treating physician may refer the patient back to the Regional Mycobacteriology Program with a response documented on the BN-200.

C. The **BNTB coordinator** will do the following:

   1. Review the referral form for eligibility criteria and reason for enrollment and ensure the patient qualifies for enrollment into the BNTB program.
   2. For patients not requiring consultation, and in collaboration with the treating physician in Mexico, accept or decline the patient for enrollment.

3. For patients requiring a consultation, submit documents to the Texas consulting physician for review.
4. For all patients, if services cannot be provided in the BNTB program, clear documentation should be provided in the appropriate section of the BN-200 referral form.
5. Return the BN-200 form to the Mexico BN program with the response within three business days and retain a copy in the shadow chart in the Texas BN program.
   a) Attach medical consultation recommendations when applicable.
6. If U.S. medications are needed and treatment orders are received by the treating physician in Mexico, the BNTB Coordinator may now order medications from DSHS pharmacy. See Chapter XIV. MANAGEMENT OF MEDICATIONS AND MEDICATION AVAILABILITY.

D. The **Texas consulting physician** will do the following:
   1. Review all information submitted.
      a) The consulting physician may engage a DSHS-recognized medical consultant if needed regarding the case prior to deciding to accept or refuse entry into the BNTB program.
   2. For patients requiring consultation, collaborate with the program manager, the BNTB coordinator and the treating physician in Mexico to determine if the patient will be accepted into the program.
      a) If accepted, provide in writing treatment recommendations and plan of care. This will be shared with the BNTB coordinator who in turn will share with the BN treating physician in Mexico.
      b) The Texas consulting physician does not need to fill out or sign the TB-400A or BNTB-400B, this is done by the treating physician in Mexico, see Chapter XIV. MANAGEMENT OF MEDICATIONS AND MEDICATION AVAILABILITY for process.
      c) If enrollment to the program is declined, provide clear and detailed documentation of the decision to the BNTB program in Mexico by documenting in the BN-200.
      d) Instruct the BNTB coordinator to return all the following forms to the BNTB program in Mexico and ensure copies are kept in the shadow chart.
         i. BN-200
         ii. Written recommendations for treatment

Step 2 Initiate Treatment

A. The **treating physician in Mexico** will do the following after formal enrollment into the program:

1. Provide further orders for diagnostics and treatment as recommended in the consultation or as outlined in Chapter IX. Management of Patients with Latent TB Infection, including Patients on Window Prophylaxis or Chapter X. Management of Patients with Suspected or Confirmed Tuberculosis.
2. Notify the Regional Mycobacteriology Program in Mexico using the BN-200 of acceptance into the program.
3. Provide signed medication orders using the TB-400s or equivalent. Ensure a copy is provided to the BNTB coordinator to be kept in the Texas TB shadow chart.
4. For patients denied access into the program, submit a copy of the BN-200 form to the Regional Mycobacteriology Program in Mexico and include the reason patient was denied entry into the program.

B. The **Nurse in Mexico** will do the following after formal enrollment into the program:

1. Ensure written signed orders are received from the treating physician prior to initiating treatment.
2. Coordinate and communicate with the BNTB coordinator on medication procurement.
3. Once medications are received from the BNTB coordinator, the nurse in Mexico must check each individual patient's medication against the physician's orders to ensure the correct medication regimen and dosages are received prior to giving to the patient. See Chapter XIV. Management of Medications and Medication Availability.
4. Document all services performed in the medical record.
5. Submit required forms to the BNTB coordinator to be kept in the Texas shadow chart as outlined in Chapter IX. Management of Patients with Latent TB Infection, including Patients on Window Prophylaxis or Chapter X. Management of Patients with Suspected or Confirmed Tuberculosis.

Appendix C: Co-management of Patients Agreement

[INSERT DATE]

Dear [INSERT REGIONAL MYCOBACTERIOLOGY PROGRAM NAME, JURISDICTION #],

The Texas Department of State Health Services (DSHS) Binational (BN) Tuberculosis (TB) Program in the TB and Hansen's Disease Unit (Unit) oversees TB prevention and care services to reduce the burden of TB along the Texas-Mexico border.

The DSHS-funded BNTB clinic in [INSERT NAME OF CITY, STATE] in Mexico, is directed by the guiding principles, mission, and vision of DSHS and the Secretariat of Health in Mexico, including standards set forth by the Unit.

The Binational TB Program will provide the following TB services:

- ☐ Contract with a fiduciary agency to hire medical and nursing staff to provide services in Mexico. The current agency is [INSERT NAME HERE]
- ☐ Provide the Regional Mycobacteriology Program in Mexico, a formal written communication of acceptance or declining of a patient into the BNTB program.
- ☐ Ensure all referrals have a binational link as outlined in the BNTB manual, and that all health institutions in Mexico (i.e., IMSS, ISSSTE, etc.) first refer patients, including suspected patients of TB, to the Regional Mycobacteriology Program which in turn will validate the information and send a referral to the BNTB program.
- ☐ Submit index case information for contacts referred from the U.S./Texas to the Regional Mycobacteriology Program to meet Mexico reporting requirements.
- ☐ Request additional patient information from the Regional Mycobacteriology Program in a confidential and secure manner.
- ☐ Evaluate and treat patients following the standards of care outlined in the BNTB manual.
- ☐ Provide directly observed therapy (DOT) and/or video directly observed therapy (VDOT) to patients following the standards of care outlined in the BNTB manual and the DSHS VDOT Required and Recommended Activities document.
- ☐ Provide DSHS medications, in the interim, while awaiting a response from Mexico to acquire medications as applicable (i.e., doTBal, personalized treatments for drug-susceptible patients, and second-line medications for drug-resistant patients, bedaquiline, clofazimine, etc.).
- ☐ Submit diagnostic results and treatment recommendations back to the Regional Mycobacteriology Program on all patients accepted into the BNTB program to facilitate Mexico's reporting requirements to the National Tuberculosis Platform.
- ☐ Provide routine updates on patient management or contact evaluation activities until services are completed.
- ☐ Conduct an appropriate contact investigation following DSHS guidelines and treat contacts following the standards of care outlined in the BNTB manual.
- ☐ The following will be performed as recommended by the BNTB physician to meet both U.S. standards for care and Mexican National Standards.

1) Management and treatment of the following:
    - ✓ Contacts with TB infection (LTBI)
    - ✓ Suspected or active TB disease
    - ✓ Drug-resistant disease
    - ✓ Contacts with active TB disease
2) Collection and shipment of specimens to include:
    - ✓ Sputum, urine, or miscellaneous specimens collected for AFB testing
    - ✓ Laboratory tests
    - ✓ Radiology
3) Routine medical evaluations
4) TB education to patients and families on the prevention of TB transmission, the disease process, and the consequences of inadequate treatment.
5) Conduct TB education activities for health care providers within the service area to promote BNTB and patient referrals through the Regional Mycobacteriology Program.

☐ List other details as appropriate: *(i.e., Drug-resistant patients will only be monitored via DOT. VDOT is not allowed for drug-resistant patients referred from the Regional Mycobacteriology Program).*

The Regional Mycobacteriology Program will provide the following:

☐ Submit a referral using the BN200 form to the BNTB program for patients suspected or with active TB disease and/or contacts that meet the criteria to receive services as listed in the BNTB manual. Referrals should include any diagnostics collected in Mexico and any other pertinent patient documents.

☐ Verify that all patient information submitted by Health Institutes in Mexico is complete and accurate prior to referring to the BNTB program.

☐ Provide information for patients with a BN link (cases and/or contacts) to quickly identify possible contacts in the U.S. for timely investigation in both countries.

☐ Respond to requests for patient information securely and confidentially in a timely manner.

☐ Provide medications for patients who can continue doTBal as indicated by the BNTB program physician, respecting the Official Mexican Tuberculosis Standards (NOM-006-SSa2-2013).

☐ Coordinate with the COEFAR/GANAFAR for patients with drug-resistant TB as indicated by the Official Mexican Tuberculosis Standards (NOM-006-SSa2-2013) and request second-line medications.

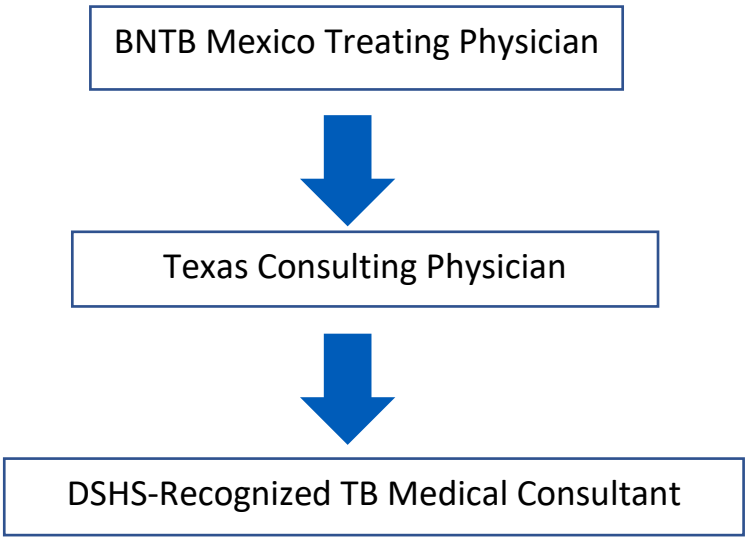
☐ Contact the BNTB program for copies of diagnostics, progress notes, and updates on patient status as needed.

In partnership,

[INSERT BNTB Program Name, Contact Information]

Appendix D: Medical Consultation Process

The BNTB programs shall follow the Unit's medical consultation process when submitting a request for consultation to either a Texas consulting physician or a DSHS-recognized TB medical consultant. The consultation process includes the following:



Not all patients in the BNTB program require a medical consultation. The BNTB treating physician in Mexico may determine if the patient is able to continue doTBal based on the patient's status (e.g., response to treatment, improved CXR, etc.) or if the patient only requires individual weight-specific doses to either replace doTBal or augment doTBal. In these situations, consultations are not required unless the treating physician determines the need or if the patient falls within one of the criteria listed below. Texas physicians do not need to sign the BNTB-400s for medications to be ordered from the DSHS pharmacy.

"Curbside Consultations" are strongly discouraged, and complete information must be submitted to the medical consultant for an objective assessment of the case to make the best recommendations.

Consultations required from a DSHS-recognized TB medical consultant will first be reviewed by the Texas consulting physician who will determine the need to elevate to a DSHS-recognized TB medical consultant unless otherwise specified within each program.

Consultation to the Texas Consulting Physician

Consultations with the Texas physician are required or recommended in situations described below.

A. Consultation to Texas consulting physician is **REQUIRED** when any of the following apply:

1. When INH cannot be used in a treatment regimen due to resistance, intolerance, or drug interaction.
2. Patients have serious forms of TB, e.g., disseminated, or meningeal TB.
3. Patient has a positive AFB sputum smear and/or positive sputum culture for *M. tb* after two months of appropriate therapy for TB disease.
4. Second-line medications are prescribed.
   a) RBT can be used interchangeably with RIF in patients with drug interactions. If RBT is used in place of RIF due to drug interactions, a consultation is not required.
   b) For children weighing less than 30kg needing RBT, a consultation is required.

B. Consultation to a Texas consulting physician is **highly RECOMMENDED** when:

1. Intermittent therapy is considered either in the initial or continuation phase including when doTBal is used.
2. Patient has HIV infection and is on or anticipates starting on antiretrovirals.
3. Patient's symptoms or CXR have not improved after the first two months of treatment.
4. Patient is under the age of five years.

Consultation process to a Texas consulting physician

1. The Mexico treating physician may communicate directly with the Texas consulting physician and explain the reason for a consult request. This can be done without first involving the BNTB coordinator. However, a consultation form must subsequently be completed and submitted to the BNTB coordinator. Use TB-242 DSHS Medical Consultation Request Form or the equivalent.

2. The nurses in Mexico will gather all medical documents and submit to the BNTB coordinator.
3. The BNTB coordinator will collect the following information and submit to the Texas consulting physician:
    a) Consultation form may be done by the physician in Mexico or the BNTB coordinator depending on the processes in place within each program.
    b) Complete clinical evaluation to include:
        i. History of present illness beginning with patient's initial presentation and proceeding chronologically up to the present time, noting any improvements since treatment initiation.
        ii. Prior history of TB exposure, infection, or disease.
        iii. TST or IGRA history and current dates and results.
        iv. Baseline and current chest x-rays/CT/other diagnostic imaging, written reports if possible, and pathology results. A disc of these should be sent if requested.
        v. Bacteriology smears and cultures - this may be submitted by including a log to show trends. MDDR and drug susceptibility reports should be shared when applicable.
        vi. Laboratory – HIV results with CD4 and viral load, baseline, and periodic laboratory monitoring results.
        vii. Medical history/medical and drug-resistant risk factors, social and individual risk factors for LTBI or disease.
        viii. Medication history – prescription, over the counter, folk, or herbal use.
        ix. Current weight, including weight changes in response to therapy.
        x. If there is history of hospitalization include admission history, physical exam findings, and hospital discharge summary.
4. The Texas consulting physician will review the documents and submit treatment recommendations in writing to the BNTB coordinator to be shared with Mexico's treating physician.
5. The Mexico treating physician will complete medication orders on the TB-400 and submit to the BNTB coordinator to order from DSHS pharmacy.

6. When consultation is obtained from a Texas consulting physician, BNTB clinics will provide a follow-up summary of the patient's status if requested by the Texas consulting physician.

Consultation to a DSHS-Recognized TB Medical Consultant

Consultation from a DSHS-recognized TB medical consultant is required or recommended in situations described below. Exceptions to a DSHS-recognized TB medical consultant may be granted if made by the DSHS Regional Medical Director (RMD). The RMD may request a consult from a DSHS-recognized TB medical consultant as needed. Consultants may be found at DSHS-Recognized Tuberculosis Medical Consultants | Texas DSHS.

A. Consultation to a DSHS-recognized TB medical consultant is **REQUIRED** when any of the following apply:

1. Patient has laboratory-confirmed drug resistance or is suspected to have drug-resistant TB. (Laboratory-confirmed drug resistance is defined as resistance to INH and/or RIF, or to any drug other than streptomycin on the drug susceptibility panel testing).
   a) An initial notification should occur within three days of laboratory test result showing DR-TB. Include all current known status to include details of the patient, test results, medications, and significant findings, until a more formal consult can be made. The purpose of the initial notification is to rapidly engage expert physician(s) and ensure the right plan of care is established.
   b) A formal consult should occur as soon as more test results are known, and a treatment plan has not yet been established.
   c) If the organism is identified as *M. bovis* with PZA monoresistance, a consultation is not required.
2. Patient with RR, MDR, Pre-XDR, or XDR TB, and
   a) Is reaching the end of treatment and prior to stopping treatment;
   b) Any treatment regimen changes are needed, i.e., adverse drug reaction or abnormal drug levels;
3. Patient is a contact to a case of MDR-TB, Pre-XDR-TB, or XDR-TB, unless otherwise communicated by the RMD or Texas Consulting Physician;
4. The treating physician is requesting MDDR testing;
5. When a rifamycin cannot be used due to intolerance or drug interactions in a regimen for active TB;

6. Patient has positive sputum cultures for *M. tb* after four months of appropriate therapy for TB disease and is a treatment failure;

B. Additional consultation is **highly RECOMMENDED** when a DR-TB patient:

1. Has a change in status;
2. Misses required screenings;
3. Exhibits signs of adverse drug reactions;
4. Is discharged from Texas Center for Infectious Disease (TCID); and/or
5. Any time the treating physician is concerned about the patient.

Consultation Process to DSHS-Recognized TB Medical Consultant

1. The Texas consulting physician, BNTB coordinator, or treating physician will ensure all documentation is in order prior to submitting information. This includes all documents identified in A.3.C.#1 and #2, Consultation Process to Texas Consulting Physician. If patient is drug resistant, include TB-700 TB Drug-O-Gram and Clinical Monitoring Overview or the equivalent as requested.
2. Requests to Heartland will be routed through the nurse consultants at Heartland who will review all documents submitted by the Texas consulting physician or BNTB coordinator and prioritize the request. The BNTB coordinator will request a status update from the Heartland nurse consultants of pending consultations by email or phone.
3. Submit all information and radiographs to:

HEARTLAND NATIONAL TB CENTER
2303 SE MILITARY DRIVE
SAN ANTONIO, TEXAS 78223

4. Once all information is received by Heartland, recommendations will be provided in writing back to the requestor. This may be done by email or as a formal consult request using the agency's letterhead. If no response is received within five business days, email the HTNC nurse consultant and request an update.
5. Place recommendations in the patient's clinic chart and a copy in the patient's shadow chart.

6. The Mexico treating physician will complete medication orders on the TB-400 and submit to the BNTB coordinator to order from the DSHS pharmacy.
7. When consultation is obtained from a DSHS-recognized TB medical consultant, BNTB programs will provide a follow-up summary of patient status as determined by the consulting physician.

Appendix E: DSHS TB Formulary

The following medications and supplies for outpatient TB management are available to BNTB programs. Place orders via DSHS Pharmacy Ordering System. For further assistance contact the DSHS Pharmacy at 512-776-7500.

Drug (Name Brand)	Item Description	Route	Comments
Amikacin	Vial	IM, IV	See Appendix D: Medical Consultation Process
Bedaquiline (Sirturo)	Tablet (Tab)	PO	See Appendix D: Medical Consultation Process
Clofazimine	Capsule (Cap)	PO	See Appendix D: Medical Consultation Process
Cycloserine (Seromycin)	Cap	PO	See Appendix D: Medical Consultation Process
Ethambutol (Myambutol)	Tab	PO	**First Line**
Ethionamide (Trecator)	Tab	PO	See Appendix D: Medical Consultation Process
Isoniazid	Solution (Solu)/Tab/Vial	PO, IM	**First Line**
Levofloxacin (Levaquin)	Solu/Tab/Vial	PO, IV	See Appendix D: Medical Consultation Process
Linezolid (Zyvox)	Suspension (Susp)/Vial	PO, IV	See Appendix D: Medical Consultation Process
Moxifloxacin (Avelox)	Tab/Vial	PO, IV	See Appendix D: Medical Consultation Process
Pretomanid	Tab	PO	See Appendix D: Medical Consultation Process*
Pyrazinamide	Tab	PO	**First Line**
Pyridoxine (Vitamin B-6)	Tab	PO	
Rifabutin (Mycobutin)	Cap	PO	**First Line**
Rifampin	Cap/Vial	PO, IV	**First Line**
Rifapentine (Priftin)	Tab	PO	**First Line**
Other Supplies			
Sterile Water for Injection	Vial	IM, IV	
Hypertonic saline (3%)	Vial	Nebulized	For sputum induction
Lidocaine (Xylocaine) 1% or 2%	Vial	IM, IV	
Pregnancy Tests	Test	NA	

Simple Syrup (Cherry flavor)	Bottle	PO	
X-ray envelopes	Envelopes	NA	
Syringes (1/2", 27 gauge)	Syringe	NA	
Tuberculin Skin Test (PPD)	Vial	SC	
Amber RX bottles	Vial	NA	For self-admin. DOT
Specimen Transport Boxes	Box	NA	Cardboard box for cold-box specimen shipping
Gel Pack	Gel Pack	NA	For cold-box specimen shipping
Auxiliary Medications			
Azithromycin (Zithromax)	Susp/tab/vial	PO/IV	See Chapter XIV. MANAGEMENT OF MEDICATIONS AND MEDICATION AVAILABILITY
Ondansetron	Tab/Orally dissolving tab	PO	See Chapter XIV. MANAGEMENT OF MEDICATIONS AND MEDICATION AVAILABILITY
Dexamethasone	Tab	PO	See Chapter XIV. MANAGEMENT OF MEDICATIONS AND MEDICATION AVAILABILITY
Promethazine	Tab	PO	See Chapter XIV. MANAGEMENT OF MEDICATIONS AND MEDICATION AVAILABILITY
Prednisone	Tab	PO	See Chapter XIV. MANAGEMENT OF MEDICATIONS AND MEDICATION AVAILABILITY
Prednisolone	Tab	PO	See Chapter XIV. MANAGEMENT OF MEDICATIONS AND MEDICATION AVAILABILITY
Lubriderm Advanced Lotion	Cream	External	For patients on Clofazimine ONLY
Lubriderm SPF 15	Cream	External	For patients on Clofazimine ONLY
Lidocaine/Prilocaine 2.5% cream SPF 30 and 50	Cream Cream	External External	See Chapter XIV. MANAGEMENT OF MEDICATIONS AND MEDICATION AVAILABILITY For patients on Clofazimine ONLY

Appendix F: Binational TB Program Clinical Care Forms

DSHS clinical care forms are available in Spanish for use in the BNTB Program. BNTB Programs will use the following forms or their equivalent:

A. Class II, and those on window prophylaxis (wp):

1. BNTB-400B Spanish Report of Case and Patient Services
2. TB-415a Consent LTBI Therapy
3. TB-202a TB Initial Health Risk Assessment/History
4. TB-205a Toxicity Assessment
5. TB-206b Directly Observed Therapy Log
6. TB-240a Refusal of Treatment for Latent Tuberculosis Infection (if applicable)
7. BN 200 Referral Form - when applicable
8. 12-14198a 3HP Dosing and Symptom Monitoring Log (if applicable)
9. General Consents:
   a) L36a General Consent and Disclosure
   b) L30a Authorization to Release Confidential Medical Information, when applicable

B. Class III, V:

1. TB-400A-sp Report of Case and Patient Services
2. BNTB-400B Spanish Report of Case and Patient Services
3. BNTB-201a Case Management Plan for Outpatient Care
4. TB-202a TB Initial Health Risk Assessment/History
5. TB-203a Education/Counseling Record
6. TB-205a Toxicity Assessment
7. TB 206b Directly Observed Therapy Log
8. TB-231a Bacteriology TB Control Log
9. TB-411a Disclosure and Consent Drug Therapy TB
10. BN-200 Referral Form
11. TB-700a-TB-705a series for drug-resistant patients
12. General consents:
    a) L36a General Consent and Disclosure
    b) L30a Authorization to Release Confidential Medical Information, when applicable

C. Contact Investigation:
    1. TB-208a Tuberculosis Contact Screening Form
    2. TB-340a Report of TB Contacts
    3. TB-341b Continuation of Report of TB Contacts
    4. 12-12062a Contact Investigation Worksheet
    5. TB-460a TB Contact Investigation Expansion Analysis Checklist
    6. TB-230a Contact Refusal Form (if applicable)
    7. TB-425a TB Infectious Period Calculation Sheet

D. Cohort Review:
    1. 12-14064a Cohort Review Presentation Form

E. VDOT
    1. 12-15760a Mobile Application
    2. 12-15761a VDOT Mobile Phone User Agreement
    3. 12-15762a VDOT Patient Participation Agreement
    4. 12-15763a Video DOT Medication Layout
    5. 12-15764a VDOT Patient Instructions

Appendix G: Sputum Collection Procedure

Staff in Mexico must adhere to all standard precautions, including bloodborne and respiratory precautions when participating in TB sputum collection procedures. Ensure that a physician order is available prior to sputum collection or that service is followed under an established Standing Delegation Order (SDO) by the regional or local program.

Procedure

1. Verify the patient meets the criteria for TB sputum collection and has been accepted into the BNTB program.
2. Ensure, to the extent possible, that the patient seen for TB sputum collection services is, in fact, who the person claims to be.
3. Obtain patient's consent and signature. Consent and signature should be obtained by the nurse responsible for the clinical management of the patient. Provide copies of DSHS Privacy Notice and applicable signed consent forms.
4. Explain to the patient, the TB sputum collection process. Discuss with the patient the risks and benefits of sputum collection. Provide the opportunity for the patient to ask questions.
5. Gather required supplies and prepare to collect the sputum sample.
    a) Label innermost tube with patient name and date of birth before obtaining TB sputum specimen and before giving container(s) to the patient for home sample collection. Provide the following instructions to the patient:
        i. Rinse mouth well with water to avoid contamination with food particles and mouth bacteria. Ideally, TB sputum specimen collection should occur before eating.
        ii. Inhale deeply two to three times and breathe out hard each time.
        iii. Cough deeply from the chest. A deeply coughed specimen is required (not saliva or nasal secretions).
        iv. Place the open container close to the mouth to collect the TB sputum specimen. The ideal specimen size is 5 to 10 mL, but 3 to 15 mL is acceptable.
        v. Avoid contaminating the inside of the container and lid by contact with the mouth or hand.
        vi. Close lid tightly and place into the TB sputum specimen bag.

vii. If the patient collects TB sputum specimens at home, instruct patient to store the TB sputum specimen(s) in a refrigerator until specimens are transported to clinic as soon as possible.
viii. If the patient is unable to produce an early morning sputum, suggest that he/she stand or sit in a steamy environment for 15 minutes after running hot water in the shower, if possible.

b) Supervise at least one (ideally the first) TB sputum collection to document that the patient demonstrates the correct technique.
   i. The first TB sputum specimen can be collected "on-the-spot" at the first patient encounter.
   ii. Three TB sputum samples should be collected at least eight hours apart.
c) If the patient is unable to produce an acceptable TB sputum specimen, follow the procedure below for TB sputum induction, if resources are available.
d) Once a TB sputum specimen is obtained, label and correctly package the specimen, according to shipping requirements.
   i. TB sputum specimens must be packed in triple containment with sufficient absorbent material enclosed to absorb the entire volume of liquid. The container used must meet current DOT and United States Postal Service regulations.
   ii. Complete the appropriate lab requisition G-MYCO form.
   iii. Specimens should be refrigerated.
   iv. Specimens should be transported to the U.S. on cold packs and shipped to the laboratory as soon as possible but no longer than one week.

TB Sputum Induction Procedure

1. Obtain and assemble the nebulizer tubing kit.
2. Attach one end of air tubing to the compressor unit and the other end to the nebulizer medication cup outlet.
3. With the machine turned off, prepare the nebulizer equipment as per package instructions. Add approximately 3 mL of sterile 0.9% sodium chloride (NaCl) solution to the nebulizer medication cup.

4. Instruct the patient to close lips around the mouthpiece and to breathe in and out slowly and deeply on the mouthpiece.
5. Turn compressor on and place mouthpiece into patient's mouth.
6. Encourage cough if no spontaneous coughing occurs.
7. Continue procedure until cough is stimulated, adding more sterile 0.9% NaCl solution as needed.
8. When a cough is stimulated, encourage its repetition several times to obtain an adequate specimen (at least 5 mL).
9. Upon completion, turn off the nebulizer.
10. Label and package the TB sputum specimen correctly and legibly. Mark lab requisition as "induced specimen".
11. Disassemble mouthpiece and disinfect nebulizer according to manufacturer instructions.
12. Document in the patient's medical record the procedure used to collect sputum, the amount and description of sputum collected and other circumstances affecting collection. (i.e., Patient instructed on collection of natural induction. Successfully observed patient collect 5 ml thick yellow secretions tinged with blood without difficulty. Patient given sputum containers to collect #2 and #3 at home and refrigerate after collection. Nurse will collect from patient at home on day #3.)

Appendix H: Directly Observed Therapy (DOT) Procedure

DOT is the standard of care for patients in the BNTB program outlined in Chapter VIII. STANDARDS OF CARE in this manual.

Staff providing DOT should be a contractor of the fiduciary agency and have undergone training for providing DOT including medication identification and toxicities.

Procedure

1. Verify the medication in the TB DOT packets and acknowledge receipt of the DOT packets. If the person providing DOT is not a nurse, ensure that a nurse has reviewed the DOT packets prior to providing to the patient.
2. Ensure, to the extent possible, that the person seen for TB DOT services is, in fact, who the person claims to be.
3. Provide your name and contact information to the patient.
4. Ensure that the patient's consent and signature have been obtained by the nurse responsible for the clinical management of the patient. If consent and signature have not been obtained, then obtain consent and signature in accordance with agency policy and provide copies of the DSHS Privacy Notice and applicable signed consent forms.
5. Determine safety prior to making a home visit. Consult with National program if there are any alerts for the area.
6. Arrive at the agreed upon place at the designated time with the patient's medication(s).
7. Document missed appointments on the Tuberculosis Directly Observed Therapy Log (TB-206b or their equivalent) when patient is not found at the agreed place at the agreed time.
    a) If unsafe conditions exist or if you feel threatened, leave as safely and quickly as possible. Immediately call 911, if necessary. Once you are in a safe place, notify your treating physician or the nurse responsible for the clinical management of the patient.
    b) Medications should not be left at the home or outside the home unless given directly to the patient.
8. Observe first dose of TB medications. First dose should be observed by a nurse or a physician. If the first dose of TB medication for the patient cannot be observed by a nurse or physician, immediately notify the nurse responsible for the clinical management of the patient.

9. Complete and sign the Patient/DOT Provider Agreement TB-206b or TB-704a for drug resistant patients upon initiation of TB DOT, and at the beginning of each month of TB DOT. Ensure patient signs and dates the form.
10. Complete the adverse reaction screening questions listed on the Tuberculosis Directly Observed Therapy Log TB-206b or TB-704a for drug resistant patients.
    a) If the patient reports any symptoms noted with a double asterisk or noted as adverse reactions, do not give the medication to the patient. Contact the nurse or treating physician responsible for the clinical management of the patient for instructions.
11. Provide the medication packet to the patient after the patient obtains a drink of water.
12. Observe the patient ingest all medications from each TB DOT dose packet. The patient should be observed continuously from the time the TB DOT dose packet(s) is given to the patient until all the medication is ingested. Never leave a TB DOT dose packet to be taken later unless the dose packet is for self-administration. Self-administered doses CANNOT be recorded as DOT.
13. If the patient is unable to ingest the entire dose, contact the treating physician responsible for the clinical management of the patient for instructions.
14. If the patient is suspected of not swallowing the medication, inspect the patient's mouth, including under the tongue.
15. If the patient is suspected of vomiting medication after the visit, wait 30 minutes before leaving the patient.
16. Document the dose of medication observed and place initials on the Tuberculosis Directly Observed Therapy Log TB-206b or TB-704a for drug resistant patients or their equivalent.
17. Request patient's initials as confirmation of the dose of medication observed on the Tuberculosis Directly Observed Therapy Log TB-206b or TB-704a for drug resistant patients.

Appendix I: Cohort Review Process

Cohort review is a systematic and retrospective review of the management of patients with TB disease and their contacts. A "cohort" is a group of TB cases counted over a specific period and in a defined geographic area. The review occurs after the cases are counted and within the time frame in which most cases are expected to complete treatment.

Cohort review is used as a tool to review and present patient outcomes and to monitor and evaluate program performance. At a cohort review, cases presented are:

A. Examined for the patient's clinical status
B. Adequacy of patient's regimen
C. Treatment adherence and completion
D. Results of the contact investigation.

Case Review is a systematic regular review of individual patient progress presented by the case manager. It is a fundamental component of case management and is an ongoing process for each patient. Plans should be made to immediately address any treatment and patient management concerns identified during a case review.

The Difference between Cohort Reviews and Case Reviews

Case reviews are real-time, ongoing and provide an opportunity to review individual patient specific care. They allow for immediate analysis of a patient's progress and plans to address any needed changes to treatment and management. As cohort reviews are a retrospective analysis of treatment outcomes, it provides an opportunity to review case data to address systemic programmatic concerns regarding the overall management of TB patients to improve patient care and programmatic performance and to promote efficiency.

Process

To promote consistent TB case management practices, program accountability and high TB evaluation and treatment completion rates, TB programs will hold quarterly cohort reviews. Cohort reviews are integral to TB prevention and care activities and provide a systematic retrospective review of the management of cases and contact investigations. DSHS public health regional TB programs will work with low

morbidity local health departments in their jurisdiction to implement cohort reviews.

Cohort Periods

Tuberculosis programs will schedule cohort reviews on a quarterly basis following the timelines identified in the following table:

Table 13: Cohort Period and Submission Schedule

Cohort Period cases counted in:	**Are reviewed and reported by:**
1st quarter (Jan 1 to Mar 31) current year	**March 31** of the following year
2nd quarter (Apr 1 to June 30) current year	**June 30** of the following year
3rd quarter (Jul 1 to Sep 30) current year	**September 30** of the following year
4th quarter (Oct 1 to Dec 31) current year	**December 31** of the following year

Cohort Teams

1. The cohort review process relies on the participation of various members involved in TB services at the program level. A cohort review should include at a minimum of the following participants:
   a) BNTB Regional or Local Program Manager/TB Supervisor
   b) BNTB Coordinator and/or Nurse Case Manager
   c) BNTB Nurse in Mexico
   d) BNTB Treating Physician

2. If available, the following participants should also be a part of the team:
   a) BNTB Texas Consulting Physician
   b) BNTB Manager/CDC Public Health Advisor
   c) BNTB Nurse Consultant
   d) BNTB Program Evaluation Consultant
   e) BNTB Data analyst or epidemiologist
   f) Contact investigator – if applicable
   g) DOT worker – if applicable

Reporting Requirements for Cohort Reviews

1. The Cohort Presentation Form shall be used to collect and present patient information during the cohort review meetings.
2. The Cohort Review Summary Form shall provide summarized and quantifiable data from all counted cases and associated contacts presented at each quarterly cohort review.
3. The Cohort Review List of Counted Cases shall be used to list counted cases presented at each quarterly cohort review.
4. Submit, by the dates identified in TABLE 13: COHORT PERIOD AND SUBMISSION SCHEDULE, the above forms using GlobalScape, or as specified by the Unit.

Cohort Review Resources

The following links provide information on cohort review models:

- The Centers for Disease Control and Prevention (CDC) Understanding the TB Cohort Review Process Instruction Guide, 2006.

Appendix J: Biological Specimen Transportation

Services

Quest, University of Florida Infectious Disease Pharmacokinetics Laboratory, and DSHS laboratories in Austin and Harlingen perform testing for patients undergoing evaluation for LTBI and TB disease. These tests and supplies include mycobacteriology, hematology, chemistry, and special tests. The list of tests performed at the laboratories can be found on the requisitions listed on the Laboratory Services Section - Testing Services[2].

CDC Import Permit

1. Each BNTB program coordinator is responsible for completing the necessary CDC forms to renew their permit to transport biological specimen from Mexico to the U.S. The following must be done to maintain a current permit to transport specimen to the U.S.:
   a) The CDC Import Permit Program (IPP) uses a secure electronic information system (eIPP) to conduct all program business.
   b) All CDC import permit applications must be submitted electronically using the eIPP system.[3]
   c) All applicants are required to have a Secure Access Management Services (SAMS) account to access the eIPP system to apply for a permit[4].
      i. Requestors with an existing SAMS account at CDC, that SAMS account must also be linked to the eIPP system.
      ii. If no other account exists in SAMS, an account will need to establish by submitting a new application, please contact the Help Desk by:
         (a) Filling out the online Customer Support Request Form or
         (b) Emailing your request to eIPPSupport@cdc.gov and include your
            - First and Last Name,

[2] Texas Department of State Health Services. Laboratory Services Section-Testing Services. 2024. dshs.texas.gov/laboratory-services/laboratory-services-section-testing-services.
[3] U.S. Centers for Disease Control and Prevention. eIPP Agents Training. 2020. cdc.gov/orr/ipp/docs/eIPP_training_bats_508.pdf.
[4] U.S. Centers for Disease Control and Prevention. SAMS Registration Process. 2020. cdc.gov/orr/ipp/docs/SAMS_Registration_Process_508.pdf.

- E-mail account that you want to be associated with SAMS, and
- Your organization.

d) Once you have SAMS credentials,
   i. Go to sams.cdc.gov
   ii. Login with your username (email) and your password
   iii. Your personal SAMS Landing page should load with the middle section shown as "My Applications."
   iv. Under "My Applications," note section called "Import Permit Program" with a link
   v. Select Link
      (a) This should open to the eIPP Login page.
   vi. Select SAMS to continue your authentication.
   vii. On acceptance, you will be brought to your entity's landing page.

2. There are two types of permits; select the “Permit to Import Biological Agents or Vectors of Human Disease.”
3. When applying, the BNTB Program Coordinator must be the “Primary Permittee” and should include the TB Program Manager as backup.
   a) Contact information must be accurate. If there are any concerns at the port of entry, Customs and Border Protection (CBP) will contact the Primary Permittee to corroborate the accuracy of the importation.
4. Multiple users may be added; select “Additional Authorized User” and add all nurses and courier as “Sender.”
   a) Make sure the name matches the legal name of the person.
   b) Inform the nurses and courier to always declare the importation and have extra copies of the permit and the specimen manifest to provide to CBP at the time of crossing.
      i. See Appendix K: Sample Biological Specimen Manifest.
5. Submit a copy to the Unit for record keeping.
6. At least a month before the current permit expires, use the eIPP renew button to update and submit the new request.
7. A permit is valid to import to a specific location. If you are transferring imported TB samples from the location listed on the permit, then the recipient should have a permit too. Please contact each lab’s safety officer to verify that their permit is up to date or contact the Unit for assistance.

For detailed instructions and additional information visit:[5] Applying for a CDC Import Permit or follow the Guidance on Completing Applications to Import Infectious Biological Agents, Infectious Substances, and Vectors (cdc.gov).

Shipping

1. The diagnostic specimens such as excreta, blood, and its components, as well as other tissues and fluids that are human materials being transported only for the purpose of diagnosis or investigation, are assigned as a Category B infectious substance (UN 3373). In accordance with the U.S. Department of Transportation's Hazardous Materials Regulations (and international organizations: International Air Transport Association Dangerous Goods Regulations; International Civil Aviation Organization; and Internationals Air Transport Association), Category B are low- or moderate-risk specimens. For safe transportation the package, label, and shipping should meet the following conditions: [6]
   a) Triple pack the specimens in the following:
      i. Leakproof primary receptacle; multiple primary receptacles should be individually wrapped or separated.
      ii. Leakproof secondary receptacle; and
      iii. Rigid or strong outer packaging
2. If specimen is a liquid, place sufficient absorbent material between the primary and secondary receptacle to absorb the entire contents so that, during transport, any release or leak of a liquid substance will not reach the outer packaging and will not compromise the integrity of the cushioning material.
3. Specimens must already be at desired temperature (e.g., frozen or refrigerated) prior to placing in box for transport.
   a) If shipping specimens at refrigerated temperature (2-8°C), include ice packs or gel packs outside of secondary container, add extra absorbent material, and note temperature handling conditions on rigid outer packaging.
4. When multiple fragile primary receptacles are placed in a single secondary packaging, they should be either individually wrapped or separated to prevent contact between them.

[5] U.S. Centers for Disease Control and Prevention. Applying for a CDC Import Permit. 2020. cdc.gov/orr/ipp/applications/index.htm.

5. Place a list of contents and paperwork between the secondary receptacle and outer packaging.
6. A biohazard symbol must be present on either the primary or secondary container.
7. Label outer package with:
   a) Proper shipping name: "Biological Substance, Category B" adjacent to the UN 3373 certification mark.
   b) Shipper and consignee identification (name, address, and telephone); and
   c) Package orientation arrows
8. FIGURE 7 BIOLOGICAL SUBSTANCE CATEGORY B PACKAGING SYSTEM outlines an example on how to pack and label specimens to prepare them for transporting to the U.S.[7] When specimens arrive in the U.S., they are sent to DSHS laboratory for AFB smears, AFB cultures and drug susceptibility testing.
9. Ensure the following when transporting specimens with a permit:
   a) Only people listed on permit are transporting specimens from Mexico to the U.S.,
   b) Food is not kept with specimens, and
   c) Personal stops are not done while transporting specimens.

Submitting to DSHS Lab

BNTB Program Coordinators may use the FedEx courier account supplied by the Unit to ship approved specimens to DSHS laboratories in Austin and Harlingen, as well as DSHS-contracted laboratories. Courier packages and supplies are available to programs and can be ordered through DSHS Pharmacy Inventory Tracking System.

A. Include with each specimen, a completed laboratory specimen submission form (G-MYCO for Austin's laboratory or F-40-B for South Texas laboratory) containing all pertinent patient information including specimen type and name of requesting physician.
B. Please see the Tuberculosis Specimen Shipping Guide for more details.[8]

[7] U.S. Department of Transportation. DOT Guide to Packaging Category B Diagnostic Samples. 2020. https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/2020-07/Guide%20to%20Packaging%20Cat%20B%20Diagnostic%20Samples%20Poster.pdf.

[8] Texas Department of State Health Services. Tuberculosis and Hansen's Disease Branch. Tuberculosis Specimen Shipping Guide. 2020. dshs.texas.gov/sites/default/files/IDCU/disease/tb/policies/TBSpecimenShippingGuide.pdf.

Figure 7: Biological Substance Category B Packaging System

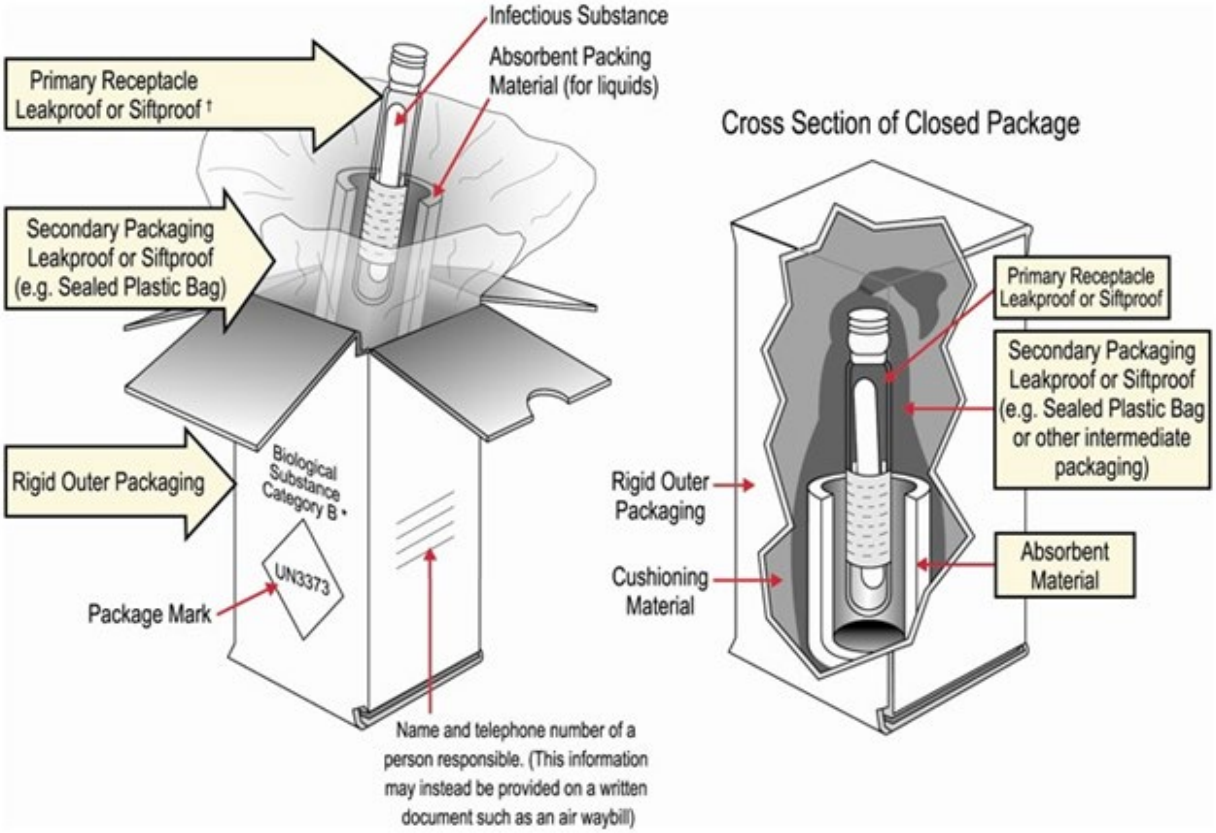


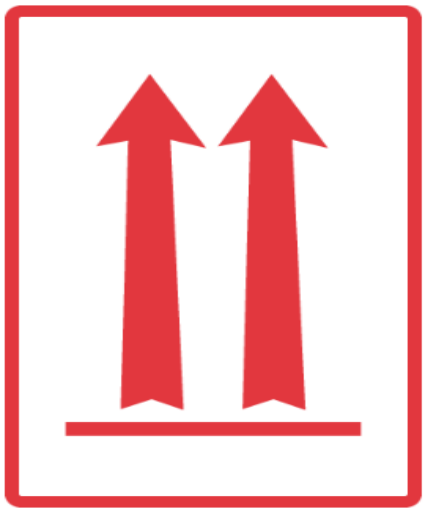
Image from CDC Packaging and Transporting Infectious Substances.[9]

[9] Association of Public Health Laboratories. QSA-2021-Pack-Ship-Guidance-Biological-Substances-Job-Aid. 2021. https://www.aphl.org/aboutAPHL/publications/Documents/QSA-2021-Pack-Ship-Guidance-Biological-Substances-Job-Aid.pdf.

Figure 8: Biological B Specimen Labeling/Marking

This label may be printed or ordered from *FedEx*.

Print this label and use it when shipping dry ice via *FedEx*.



Place an orientation label if contains

> 50 ml of liquid per primary container or if it contains dry ice.

Appendix K: Sample Biological Specimen Manifest

A list of specimens being imported into Texas should be provided to the U.S. Customs and Border Protection as part of the Customs Declaration 6059B. Please attach the list to the CDC Import Permit. Completed laboratory manifest or itemized invoices may be used as the importation manifest.

Manifest Example:

Texas Department of State Health Services
Tuberculosis and Hansen's Disease Unit
Binational Tuberculosis Program

Description of Article: Biological specimens of human origin for testing purposes to diagnose and treat tuberculosis (TB). Patients are enrolled in the Binational TB Program. Test will be performed at a Texas Department of State Health Services Laboratory.

CDC Permit #: _____ Total # of Specimens: _____ Commercial Value: $0.00

Number of specimens per type:

____ Sputum

____ Blood

____ Bronchial lavage

____ Excreta

____ Pleural effusion

____ Gastric fluid

____ Spinal fluid

____ Tissue

____ Urine

____ Other: _____

Samples are appropriately triple packed as UN 3373.

Appendix L: TB Intake Information

Obtain the following information at intake within seven days of notification for anyone being evaluated for TB (includes ATS class 2, 3, and 5). Not all information will be known at intake. Obtain the remaining information as soon as the patient has a confirmed TB diagnosis (*).

TB Intake Information	
Information as per NEDSS Investigation Tabs	**Description (please note that not all may be applicable to the BNTB programs)**
Patient Information	▪ Full name ▪ Date of birth ▪ Sex at birth ▪ If female, was patient pregnant at time of diagnostic evaluation? ▪ Physical address, city, county, Zip code with 4-digit extension (verified) ▪ Within/Outside city limits ▪ Census tract ▪ Ethnicity ▪ Race, extended race if Asian or Native Hawaiian or Other Pacific Islander
Case Information	▪ Jurisdiction ▪ Initial ATS ▪ Initial ATS classification date ▪ Current ATS classification 3* ▪ Current ATS classification 3 date* ▪ Date reported ▪ Case already counted by another reporting area ▪ If counted by another U.S. reporting area, state case number (SCN) ▪ If counted by another country, specify country
TB History	▪ Has the patient been previously diagnosed with TB disease or LTBI?
Tuberculosis	▪ Country of birth ▪ If country of birth is not U.S., date of first U.S. arrival. ▪ Eligible for U.S. Citizenship or Nationality at Birth ▪ Countries of Birth for Primary Guardian(s) (pediatric: <15 years old cases only) ▪ Country of usual residence ▪ If not U.S. reporting area, has patient been in U.S. for 90 days or more?

TB Intake Information	
Information as per NEDSS Investigation Tabs	**Description (please note that not all may be applicable to the BNTB programs)**
	▪ Status at TB diagnosis* ▪ Initial reason evaluated for TB ▪ Symptoms/start date ▪ Diabetic at diagnostic evaluation ▪ Current smoking status at diagnostic evaluation ▪ Resident of correctional facility at diagnostic evaluation? If yes, type of facility. ▪ Resident of long-term care facility at diagnostic evaluation? If yes, type of facility. ▪ Diagnostic Testing -Response required for each test type, indicate if Not Done. ▪ Chest Imaging -response required, indicate if Not Done.
TB Disease Only*	▪ Site(s) of TB disease* ▪ Therapy/start date
LTBI Only (ATS class 2 only)	▪ Therapy/start date

Appendix M: Guidelines for Responding to the Unit's Surveillance Requests

A. **Reply to Requests for Missing Report of Verified Case of TB (RVCT) Data**

1. During the 'crunch' period of **December-January** when the provisional year-end TB case count and World TB Day RVCT data is due to the CDC, TB case registrars should **respond to requests for missing RVCT data within three business days.**
2. During the 'crucial crunch' period of **February**-**March** when the *final* year-end TB case count and all RVCT variables are due to CDC, case registrars should **respond to requests for missing RVCT data within two business days.**
3. During the 'non-crunch' period of **April-November**, TB case registrars should **respond to requests for missing RVCT data within one week of request or five business days** to ensure missing RVCT data are collected and entered since these are needed for the funding formula, the Annual Progress Report, and National TB Indicators Project (NTIP) performance indicators. This prevents a last-minute rush for data entry during the crunch period.
   a) If the TB case registrar does not respond to the request for missing RVCT data within the request timelines, the surveillance case consultant will notify the PHR/LHD TB program manager to inform them of the request and ask for a response to the request within three business days.
   b) If the TB program manager does not respond to the request for missing RVCT data from the case consultant within three days of notification, the TB epidemiology and surveillance manager will contact the TB program manager requesting a response to the request.
   c) If the requested data is not entered after this request within five days of the initial notification to the TB program manager, the TB epidemiology and surveillance manager will inform the TB and Hansen's Disease Unit director. The TB and Hansen's Disease Unit director will notify the director of the PHR/LHD program.

Appendix N: Interjurisdictional Communication

BNTB Programs must ensure communication occurs with jurisdictions when a patient with an ATS classification of II, III, or V, and contacts travel or move to a U.S. jurisdiction and follow-up care is needed.

There are two types of communication channels:

A. Formal communication – using the National TB Controllers Association (NTCA) Interjurisdictional (IJN) form.
B. Informal communication – direct clinic to clinic phone calls, emails, or other forms of sharing patient information.

Activities

A**. When a patient plans temporary travel to the U.S.**

1. Plan, coordinate, and communicate informally (and formally when requested) with the receiving jurisdiction.
2. Within two business days that the BNTB program becomes aware of a patient's temporary travel plans (or has already traveled), identify the address where the patient will be/is staying. *Temporary travel is defined as 30 days or less to a U.S./Texas jurisdiction.*
3. Notify the Texas DSHS Unit's IJN Coordinator within two business days that the BNTB program becomes aware of the patient's travel plans that the patient will be in, or already is in, their jurisdiction temporarily and to determine which TB clinic in Texas should be contacted in case coordination of care may be needed. If the patient is moving to a non-Texas state, aside from notifying the Texas IJN Coordinator, also notify the state's IJN Coordinator. The list of IJN contacts for each state can be found at National Tuberculosis Controllers Association (tbcontrollers.org).
4. Coordinate the sharing of information as directed by the receiving jurisdiction. This includes sharing any medical records as requested.
   a) The receiving jurisdiction must be notified of any patient on treatment for active TB and as a courtesy, the BNTB program may want to provide details of a contact or person on treatment for LTBI.

b) The receiving jurisdiction will determine how best to coordinate care while the patient is in their jurisdiction.
c) If the BNTB program plans to keep the patient on VDOT, this courtesy notification must still be made.

5. Programs may provide up to 30 days' worth of medications for a patient on treatment for TB disease or LTBI. Anything longer than 30 days warrants formal communication as outlined below.

B. **When a patient plans a permanent move to the U.S., or when temporary travel plans change, or the travel is longer than 30 days**

1. Plan, coordinate, and communicate informally and formally with the receiving jurisdiction.
2. Within two business days that the BNTB program becomes aware of a patient's plan to move (or has already moved and will not be returning to Mexico), or remain in the U.S. longer than 30 days or when temporary travel plans change and assistance from the receiving state is needed, contact the Texas IJN coordinator (and another state's IJN coordinator if patient moved to a non-Texas state) to inform them of the patients move or intent to move to their jurisdiction or state.
3. Coordinate the sharing of information with the receiving local TB clinic as directed by the receiving state's IJN coordinator. This includes sharing of any medical records with the state and/or receiving local jurisdiction, and ideally a clinician-to-clinician phone call to share patient information and ensure continuity of care (i.e., a nurse-to-nurse handover).
4. Within one business day of notifying the receiving state, complete an IJN form, attach the completed IJN form and necessary medical records to the patient's event in NEDSS, update the address information and update the appropriate fields in NEDSS to reflect the move. The most recent IJN form is available at National Tuberculosis Controllers Association (tbcontrollers.org).
5. Notify the Texas IJN Coordinator by email that the IJN has been attached to NEDSS. The Texas IJN Coordinator's responsibilities include:

a) Sending the IJN form and medical records to the receiving jurisdiction or states TB program by fax and send follow up email to request receipt confirmation, and
b) Logging the IJN referral for tracking purposes

6. Follow-up with the receiving jurisdiction or state to ensure completion of therapy and document the patient's outcome in NEDSS.

C. **Accept IJN transfers from Texas/U.S. to Mexico**

1. When patients move to Mexico from a Texas jurisdiction or U.S. state, an IJN referral form and medical records will be sent to the DSHS Unit's Texas IJN Coordinator whose responsibility includes:
   a) Create an event in NEDSS;
   b) Log the IJN referral for tracking purposes;
   c) Attach the IJN referral and medical records to the event; and
   d) Send an email to the receiving jurisdiction within two business days of receipt of the IJN form.
2. When the referring state or jurisdiction requests follow-up information on the evaluation outcome or treatment outcome of the patient who moved from the U.S. to Mexico, the Texas IJN Coordinator will inform the receiving BNTB program of the request. The receiving BNTB program will communicate directly with the referring program within 1 week of the follow-up request – either by phone, email, or using the IJN Follow-up Form.
3. For contacts living in Mexico who were identified to an index case in the U.S., the referring jurisdiction will provide the index case susceptibilities when known and any other relevant information for Mexico to develop a proper treatment plan for the contact.

Appendix O. Do Not Board and Public Health Lookout

CDC has the authority to place an individual on a Do Not Board (DNB) list to prevent the spread of infectious disease. This includes preventing a person who may be considered infectious from receiving a boarding pass and traveling by commercial aircraft either departing from or entering in the U.S.

The Public Health Lookout (LO) ensures that a person placed on the DNB would be detected if attempts to enter the U.S. through any port of entry (e.g., seaport or land border crossing) or leave through an airport or seaport. The LO prompts government officials if a person on the list arrives in the U.S., so that the person can be evaluated and referred for additional public health follow-up if needed.

The DNB/LO are used for people with suspected or confirmed TB, including MDR-TB.

Case Criteria

CDC requires meeting specific criteria to initiate a DNB/LO. Individuals must meet the first criteria AND at least one of the subsequent three criteria:

The individual is known or reasonably believed to be infectious, or reasonably believed to have been exposed to a communicable disease and may become infectious **AND**

1. They are unaware of their diagnosis; or have been advised regarding diagnosis and are non-adherent with public health recommendations; or are unable to be located,
   OR
2. They are at risk of traveling on a commercial flight or traveling internationally by any means,
   OR
3. They need to be placed on DNB/LO list in response to a public health outbreak or to help enforce a public health order.

To request a DNB or LO consultation for any person with confirmed or suspected TB who plans to cross the U.S. border and/or board an airplane, email the DSHS epidemiology team at TBEpi@dshs.texas.gov.

Please complete and submit DSHS Form 12-12065 and copies of medical records, lab results, and radiology reports to the epidemiology team. The following information is required:

A. **Demographics**
   1. Patient name, date of birth, sex at birth, race, and ethnicity
   2. Physical Address (Mexico and if applicable, U.S. physical address), country of birth, passport number and issuing country, traveler's citizenship status in the U.S., i.e., legal permanent resident, visa-holder, fiancée, etc.
   3. Other information if available: email address and phone numbers (cell or landlines)

B. **Medical Evaluation**
   1. Reason evaluated for TB
   2. TB history, including but not limited to signs and symptoms of illness, date of symptom onset, and previous LTBI or TB disease
   3. Brief summary about concerns with compliance

C. **Treatment History**
   1. Current TB medication, including start dates
   2. Prior TB treatment history if any

D. **Laboratory**
   1. Sputum smears for acid-fast bacilli (AFB),
   2. NAA/probe or PCR with Xpert
   3. Culture
   4. MDDR or rapid drug resistance testing, if done
   5. Drug-susceptibility test (DST)

E. **Radiology**
   1. Chest radiograph (CXR) report, with date performed.
      a) Indicate the presence or absence of cavitation and the extent of disease.
   2. Chest CT report, if available
      a) Indicate the presence or absence of cavitation and the extent of disease.

F. **Travel**
   1. Intended dates of travel
   2. Intended method of travel
      a) Airline, flight number, departing and arriving airports, booking confirmation number for flights if available
      b) Usual Port of Entry for land border crossing

Follow-up

1. Once an initial call is held by the epidemiology team with the requesting program, a decision will be made to contact CDC if the patient meets the qualifications to be placed on the DNB/LO list.
2. Prior to scheduling a formal call with CDC, the L/RHD must have an interception plan in place which includes the following:
   a) Describe the steps that will be taken if the patient presents to board a plane or cross the border.
   b) Consider providing transportation if the patient needs hospitalization or isolation.
   c) Consider if the patient is intercepted during or outside regular business hours.
3. The Epidemiology Team will contact CDC and submit a formal request to review the case.
4. Once reviewed, CDC will schedule a call with all parties involved (DSHS Unit Director, Surveillance and Epidemiology Manager, Epidemiology Team Lead and Point of Contact, Clinical Care Team, L/RHD Case Manager, Nurse, Program Manager, Local Health Authority (LHA), and CDC travel restriction groups).
   a) The treating health department will provide a patient summary and any up-to-date information on the call.
   b) These calls do not guarantee the patient will be placed on the DNB/LO list. A decision will be made at the end of the call.
5. If the patient is placed on the DNB/LO list, CDC will send an official letter describing the DNB/LO and the responsibilities of the patient to the DSHS Epidemiology team. The letter will be attached to the NEDSS and the jurisdiction will be notified.
   a) CDC will mail written notification to the patient via FedEx, and a copy will be shared with the health department.
   b) The jurisdiction is responsible to share the letter with the patient.
6. The Epidemiology team will request routine/regular updates from the jurisdiction regarding the case's clinical and travel plan status.
7. If CDC elects not to place patient on the DNB/LO list, the Epidemiology team will continue to follow up with the jurisdiction until the request is closed.

Removing patients from DNB/LO list

To be removed from the list, the case must meet the criteria for non-infectiousness according to CDC Travel Restrictions Algorithm. The criteria for non-infectiousness are:

1. If there is no RIF resistance, criteria are based on smear and radiology
    a) AFB smear-positive OR cavitation on chest imaging
        i. 3 consecutive negative AFB smears, 10 doses of medication in 14 days via DOT, and continues medication through travel
    b) AFB smear-negative AND no cavitation on chest imaging
        i. 3 consecutive negative AFB smears, 5 doses of medication in 7 days via DOT, and continues medication through travel

    If there is at minimum RIF resistance, in addition to 10 doses of medication and negative smears, there must be two consistent negative cultures.

Appendix P: Sample In-Service and Training Roster

Topic: _____

Trainer/Educator: _____

Date: _____

Location: _____

Number of Hours: _____

Print Name	Signature

Appendix Q: Sample Weekly Time and Mileage Report

Name of Employee	Title	Binational Program

Date/ Day of week	Time of Visit/ Time of Activities		Starting point	Ending point	Activities Performed	Miles Traveled Km/Miles
	Start	End				
Example 5/12/2025 Monday	8:00 am	8:30 am	1234 Mockingbird Dr., Reynosa, Mexico	1819 Blueberry Lane Reynosa, Mexico	DOT, blood draw	7km/4.35 miles
5/12/2025 Monday	8:30 am	9:00 am	1819 Blueberry Lane, Reynosa, Mexico	Clinic address, Reynosa, Mexico	Traveled to clinic for the day	10km/6.2 miles
5/12/2025 Monday	9:00 am	5:00 pm	n/a	n/a	Phone calls, reviewed labs, pt. clinic visit x1, collected sputum, labs and provided DOT (detailed information here of days activities in clinic)	n/a
5/13/2025 Tuesday	8:00 am	5:00 pm	n/a	n/a	(Detailed information here of days activities in clinic)	n/a
					Total Km/miles	

Date:	Signature:

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