TEXAS
Health and Human Services

Texas Department of State Health Services

Binational Tuberculosis Program Manual

Tuberculosis and Hansen's Disease Unit

Created 8/31/2017

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Glossary of Terms

COEFAR (*Comités Estatales de Fármacorresistencia*) – A state committee in Mexico that ensures patients with drug-resistant tuberculosis (TB) are properly diagnosed, treated, and managed based on Mexico's National TB guidelines. Per 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 transplant, and environmental protection. This regulatory body is equivalent to the US Federal Drug Administration (FDA).

DOTBAL A fixed combination medication preparation available in Mexico that consists of Isoniazid, Rifampin, Ethambutol and Pyrazinamide.

GANAFAR (*Grupo Asesor Nacional en Fármacoresistencia*) – A federal committee composed of the National TB Director, the InDRE (Instituto Nacional de Referencia Epidemiológica) mycobacterial laboratory manager, physicians belonging to different health institutions in Mexico (with experience managing drug-resistant TB), and a bioethics representative of the National Human Rights Commission. The GANAFAR responsibilities include:

- promotes compliance in guiding patient care with drug-resistant TB;
- reviews all difficult to treat cases of TB;
- advising the COEFAR on any issue related to drug-resistant TB;
- reviewing, recommending and ratifying documents previously approved by the COEFAR;
- updating national TB Guidelines; and,
- supporting the national TB program in training staff on drug-resistant TB management.
- operates as a gateway to access new TB medications such as Delamanid and Bedaquiline

Secretaría de Salud Secretaria of Health also known as the Ministry of Health – A department in the Mexican government responsible for social health services and other aspects of health services in Mexico. The secretariat is a member of the Executive Cabinet and appointed by the President of the Republic.

I. Introduction

The Texas Department of State Health Services (DSHS) Binational Tuberculosis Program (BNTB) in the TB and Hansen's Disease Unit (Unit) provides TB prevention and care services along the Texas-Mexico border. The goal of the program is to reduce transmission of TB along the Texas-Mexico border to protect the public health in Texas. The BNTB program is directed by the guiding principles, mission and vision of DSHS and the Secretariat of Health including standards set forth by the Unit.

The purpose of the BNTB program manual is to describe the origins of the binational TB program and to guide program activities to maintain consistent TB prevention and care practices along the Texas-Mexico border. BNTB programs are required to use the most current version of the manual and have systems in place to guide program activities.

There are four BNTB programs serving the Texas-México border specifically, Juntos, Los Dos Laredos, Grupo Sin Fronteras and Esperanza y Amistad. Juntos serves the Texas-Mexico border cities of El Paso-Ciudad Juarez in the Mexico State of Chihuahua. Los Dos Laredos serves the Texas-Mexico border cities of Laredo-Nuevo Laredo which is in the State of Tamaulipas. Grupo Sin Fronteras serves the Texas-Mexico border cities of Brownsville-Matamoros, and McAllen-Reynosa. Both Mexico cities are in the State of Tamaulipas. Esperanza y Amistad serves the Texas-Mexico border cities of Del Rio-Ciudad Acuña, and Eagle Pass-Piedras Negras. Both cities are in the Mexico State of Coahuila.

II. Background

Texas and Mexico share the longest stretch of border of any state in the United States (U.S.) which is 1,254 miles long. It is joined by 28 international bridges and border crossings. This number includes two dams, one hand-drawn ferry, and 25 other crossings that allow commercial, vehicular and pedestrian traffic. According to the Bureau of Transportation Statistics, 45,677,223 people crossed legally into Texas from Mexico through Texas International Ports of Entry in 2020. Of that number, there were 9,644,413 pedestrians, while 35,203,891 crossed as personal vehicle passengers. This number does not include illegal crossings and suggests a "floating" population that shares infectious disease agents such as TB which is among the most significant infectious disease problems along the Texas-Mexico border. Both Texas and Mexico acknowledge that cities along the US/Mexico border have a higher incidence of TB, which was pivotal in the decision to collaborate and advocate 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 Health Department 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 City of Laredo 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; 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 the area of Del Rio-Ciudad Acuña, Coahuila and Eagle Pass-Piedras Negras, Coahuila, Mexico.

III. Map, Directory and Organizational Charts

Table 1. Location of Binational TB Programs along the Texas-Mexico Border

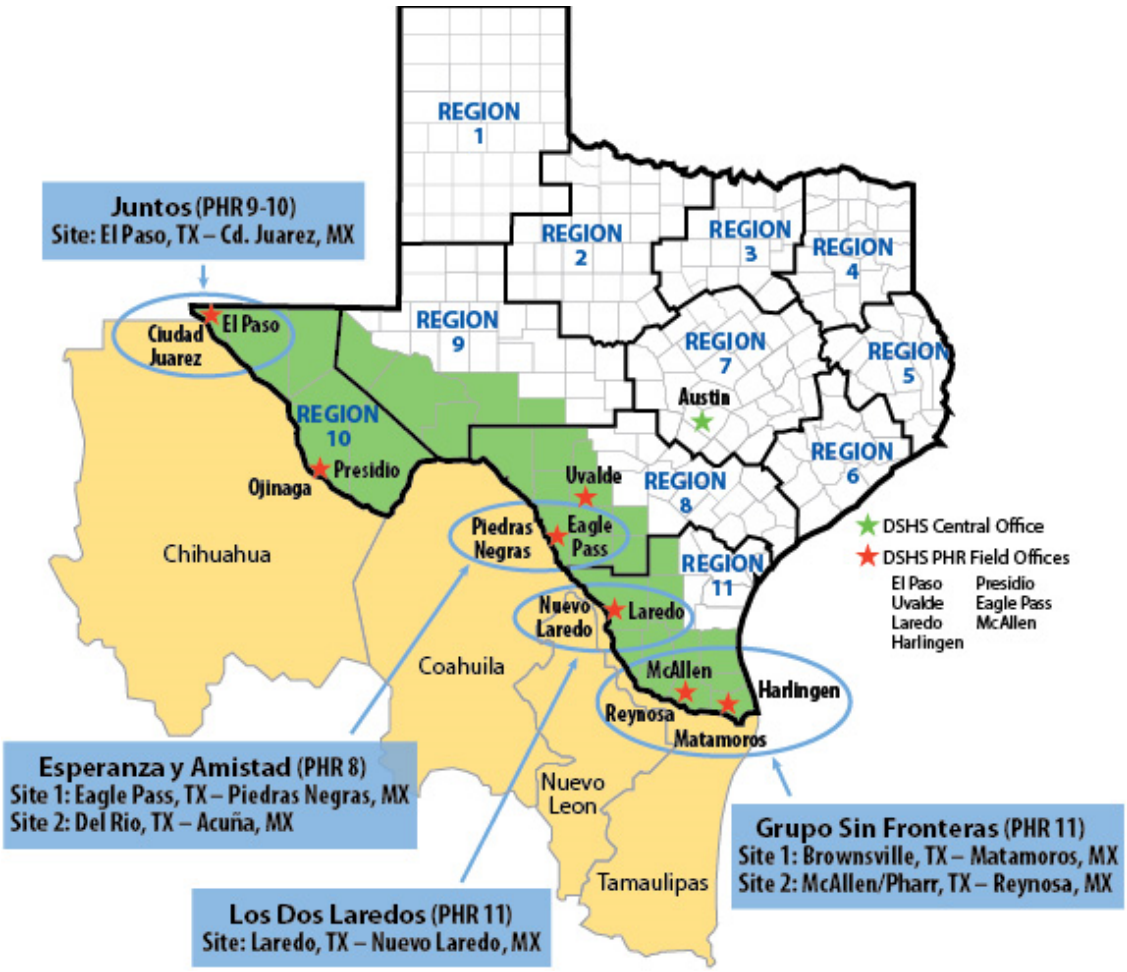
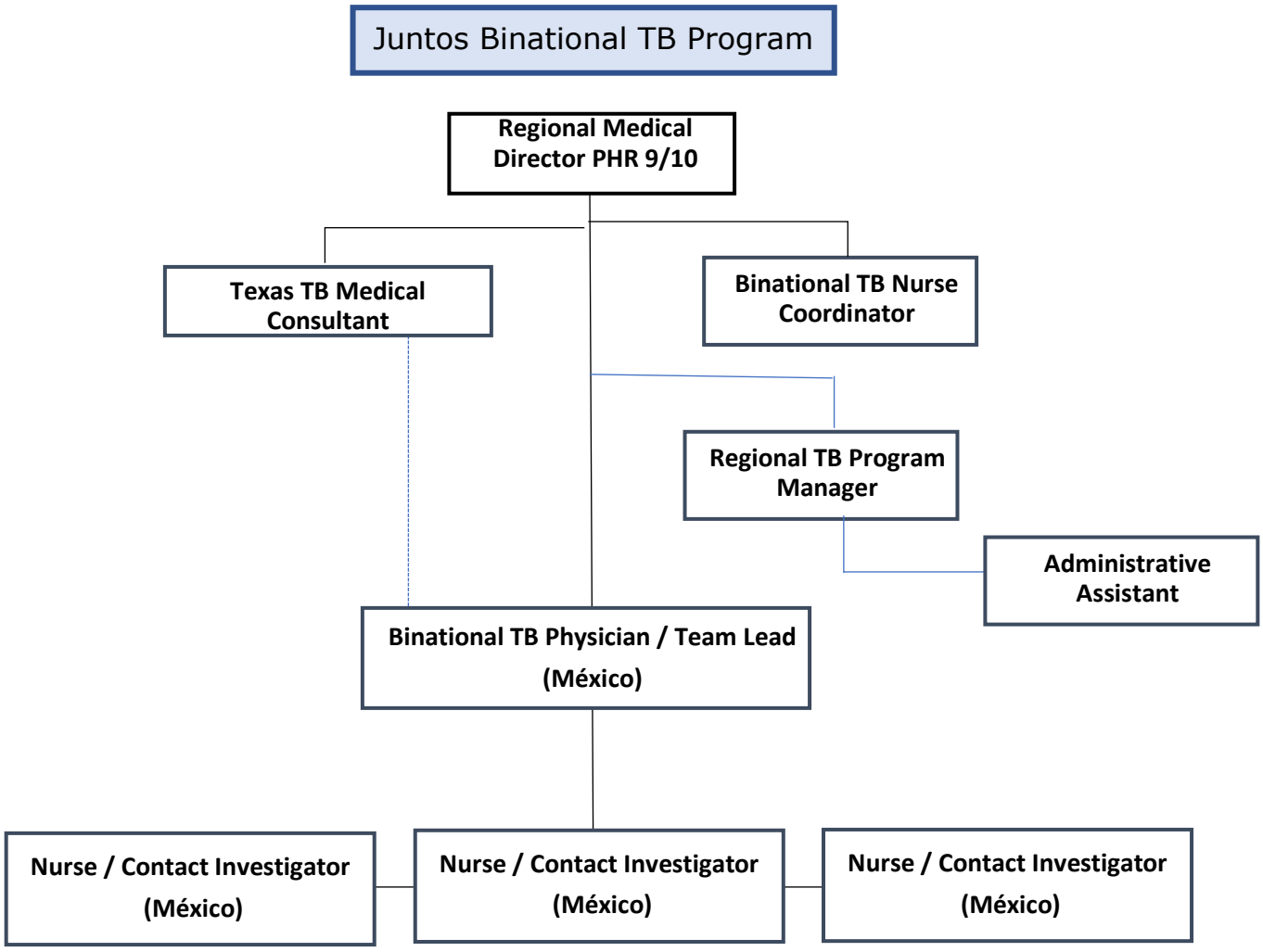
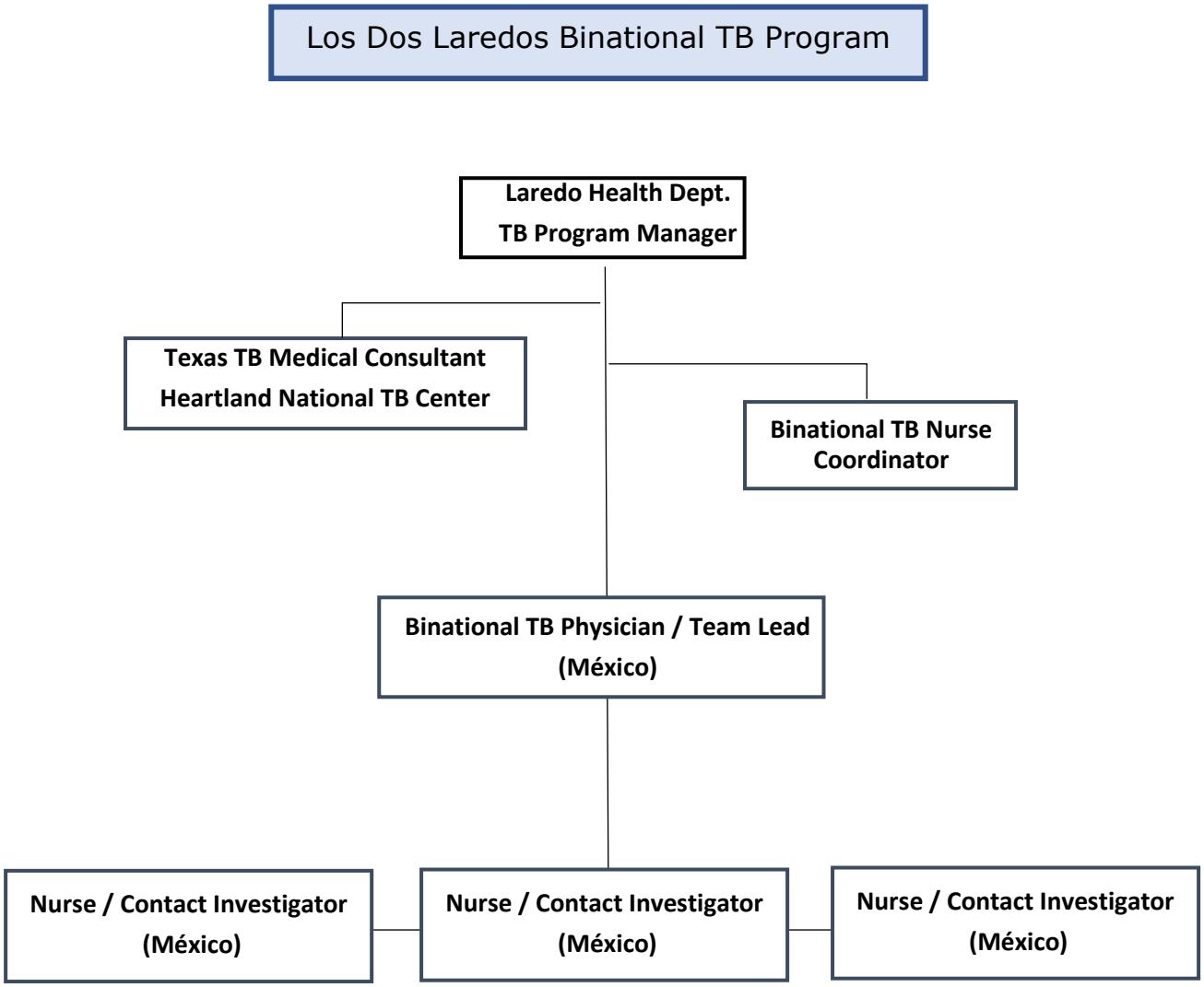


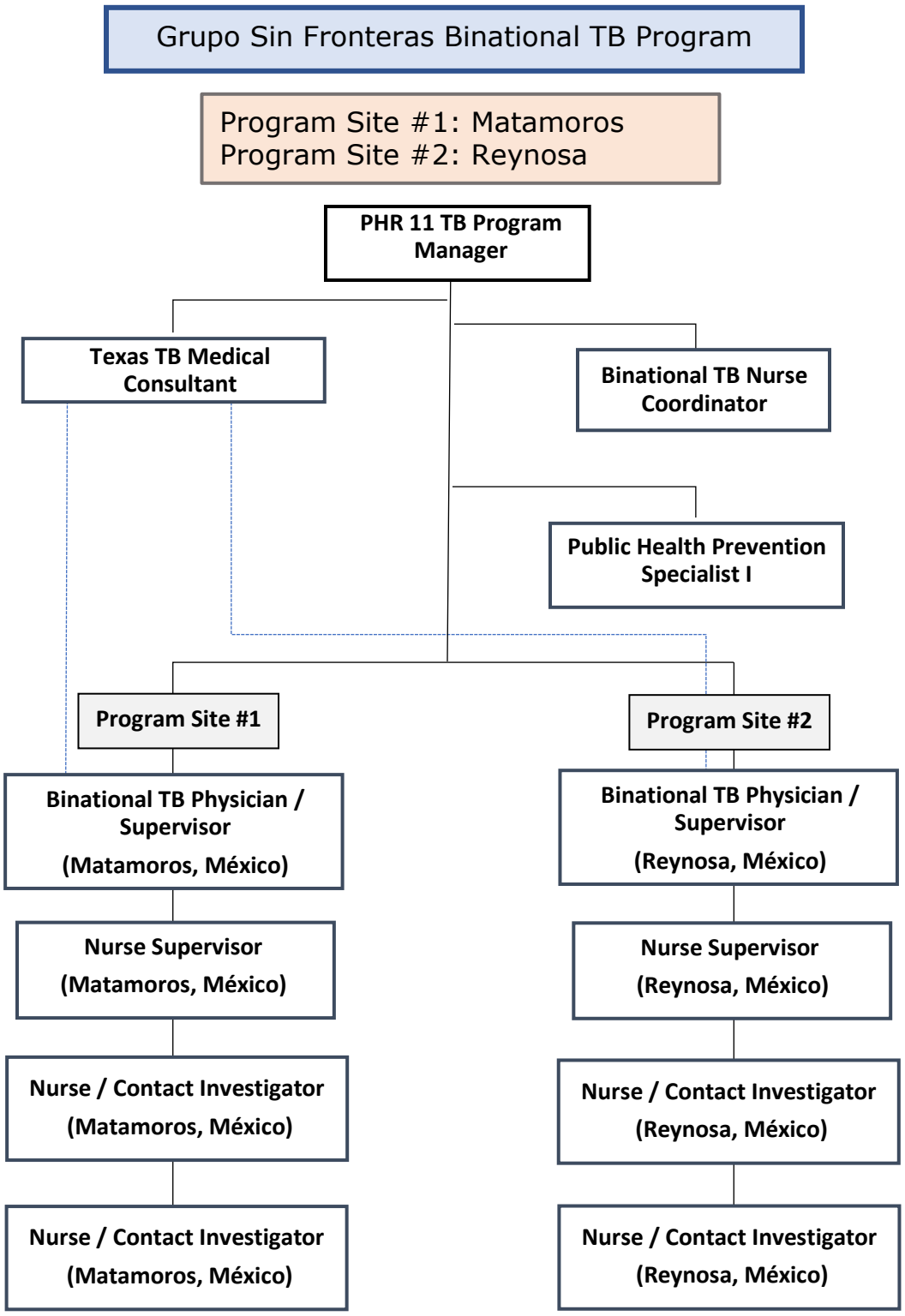
Table 2: Binational TB Program Contact Information

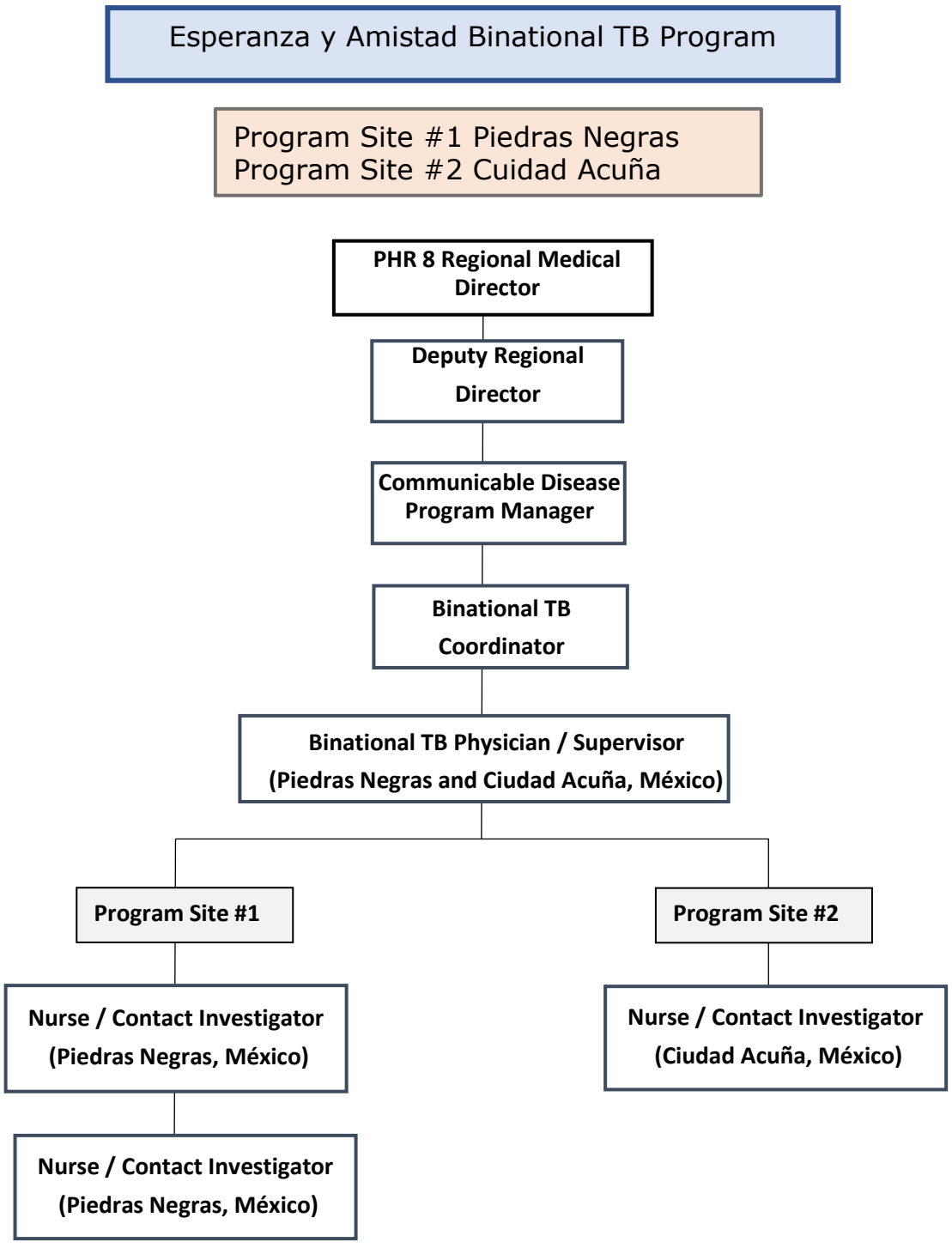
Contact Information	
Esperanza y Amistad Established 2010 Program Sites: Piedras Negras & Cd. Acuna, Coahuila México	**Glenda Lopez, Binational TB Coordinator** DSHS PHR 8 1593 Veterans Blvd., Eagle Pass, Texas 78852 Office: (830) 758-4274; Work Cell: (210) 779-7934 Email: glenda.lopez@dshs.texas.gov
Grupo Sin Fronteras Established 1995 Program Sites: Matamoros & Reynosa, Tamaulipas México	**Rebeca Muniz, R.N., Binational TB Coordinator** DSHS PHR 11 601 W. Sesame Drive, Harlingen, Texas 78550 Office: (956) 444-3215 Fax: (956) 444-3236 for confidential documents Email: rebeca.muniz@dshs.texas.gov
Juntos Established 1991 Program Site: Ciudad Juárez, Chihuahua México	**Laura Alvarez, MPH, BSN, RN, Binational TB Coordinator** DSHS PHR 9/10 401 E. Franklin, Suite 210 El Paso, Texas 79901 Office: (915) 834-7792; Fax: (915) 834-7722 Email: Laura.Alvarez1@dshs.texas.gov
Los Dos Laredos Established 1993 Program Site: Nuevo Laredo, Tamaulipas México	**Soraida Chapa, R.N., Binational TB Coordinator** City of Laredo Health Department 2600 Cedar, Laredo, Texas 78040 Office: (956) 795-6974 or (956) 795-4911; Fax: (956) 724-5789 Email: schapa@ci.laredo.tx.us

Table 3: Binational TB Programs' Organizational Charts




Los Dos Laredos Binational TB Program
Laredo Health Dept.
TB Program Manager
Texas TB Medical Consultant
Heartland National TB Center
Binational TB Nurse Coordinator
Binational TB Physician / Team Lead (México)
Nurse / Contact Investigator (México)
Nurse / Contact Investigator (México)
Nurse / Contact Investigator (México)


Grupo Sin Fronteras Binational TB Program
Program Site #1: Matamoros
Program Site #2: Reynosa
PHR 11 TB Program Manager
Texas TB Medical Consultant
Binational TB Nurse Coordinator
Public Health Prevention Specialist I
Program Site #1
Program Site #2
Binational TB Physician / Supervisor (Matamoros, México)
Nurse Supervisor (Matamoros, México)
Nurse / Contact Investigator (Matamoros, México)
Nurse / Contact Investigator (Matamoros, México)
Binational TB Physician / Supervisor (Reynosa, México)
Nurse Supervisor (Reynosa, México)
Nurse / Contact Investigator (Reynosa, México)
Nurse / Contact Investigator (Reynosa, México)


Esperanza y Amistad Binational TB Program
Program Site #1 Piedras Negras
Program Site #2 Cuidad Acuña
PHR 8 Regional Medical Director
Deputy Regional Director
Communicable Disease Program Manager
Binational TB Coordinator
Binational TB Physician / Supervisor (Piedras Negras and Ciudad Acuña, México)
Program Site #1
Program Site #2
Nurse / Contact Investigator (Piedras Negras, México)
Nurse / Contact Investigator (Piedras Negras, México)
Nurse / Contact Investigator (Ciudad Acuña, México)

IV. Criteria for Services and Referrals

Criteria

A client must meet one of the following criteria to receive services through the BNTB Program:

A. The client lives in Mexico with relatives in the U.S.;
B. The client has dual residency in the U.S. and Mexico;
C. The client has contacts on both sides of the border, in the U.S. and Mexico;
D. The client starts treatment in the U.S. but returns to live in Mexico; or
E. The client is referred from the U.S. for treatment or follow-up in Mexico.

Referrals

A. The BN-200 *Formato de Referencia (Referral Form)* will be submitted to the BNTB program from jurisdictions in Mexico when a client meets one of the qualifications listed above prior to receiving care in the Texas BNTB program.

B. U.S. Jurisdictions referring a new client to the BNTB program will submit a *TB-220* to the receiving BNTB program.

C. An Interjurisdictional TB Notification (IJN) Form will be submitted for clients with suspected or confirmed TB, a TB contact or person with TB infection who needs continuity of care within a BNTB program and/or moving to jurisdictions in Texas or U.S. *See Chapter XIII, Reporting* for activities related to IJN's.

V. Stewardship and Accountability

General Requirement

The BNTB programs will evaluate, diagnose, treat, and monitor clients with suspected or confirmed TB disease including their contacts who meet the criteria to receive services. BNTB programs will manage resources in a manner that focuses on stewardship and accountability.

The BNTB programs will:

A. provide care and make recommendations in evaluating, diagnosing, treating, and monitoring clients with suspected or confirmed TB disease or TB infection who meet the criteria to receive services;

B. consult with Mexico's health authority or the TB physician in Mexico on clients referred to the BNTB program for treatment of TB infection or disease and start treatment as directed by the treating physician;

C. provide contact investigation (CI) services by screening high priority contacts of individuals with possible or confirmed pulmonary, pleural or laryngeal TB disease. Screening is performed in accordance with the Texas Tuberculosis Work Plan Chapter VIII and IX;

D. screen high risk and high priority contacts identified from a U.S. managed case who are referred to the BNTB program. CI results are submitted to the managing U.S. TB program using the TB-340a. If additional cases are identified through the CI, treatment will be recommended by the BNTB physician and directly observed therapy (DOT) initiated by program staff;

E. coordinate with Mexico's TB Program to assist in CIs for clients meeting the criteria for services. When new cases of TB are identified through a CI, recommendations for care are provided to the referring TB program in Mexico;

F. prepare, send and receive referrals from regional and local TB programs in the U.S. and Mexico for TB case management purposes. BNTB programs also receive referrals from Mexico and the U.S. to conduct CIs on clients treated in the U.S.;

G. ensure that referrals received from Migrant Clinicians Network/Health Network (formerly TB Net), CURE TB, detention centers and correctional facilities are reported to the Mexican health authorities and investigated by program staff;

H. develop a safe process for continuity of care for referrals received from Immigrations Custom Enforcement (ICE) on detainees repatriated to a

jurisdiction in which the BNTB program is housed. A process is outlined at each program site;

I. develop and maintain TB surveillance mechanisms for early identification and reporting;

J. submit designated reports using established deadlines, schedules, and DSHS-approved mechanisms;

K. complete THISIS training courses and maintain timelines outlined in the TB Unit's THISIS Training and Implementation Plan (TIP);

L. obtain consults from a Texas DSHS-Recognized TB Medical Consultant upon identification of a drug resistant case of TB and when second-line medications are ordered according to the physician's recommendations;

M. apply appropriate administrative, environmental, and respiratory controls to prevent exposure and transmission of TB, to include providing necessary infection control supplies such as N95 masks to contracted direct-care TB staff and surgical masks to all clients with suspected or confirmed TB disease during the infectious period;

N. provide professional education, training and orientation for contracted BNTB program staff working in Mexico to perform duties in line with DSHS and BNTB program standards of care;

O. respond to medical records request. DSHS Office of General Counsel (OGC) is notified when clients request a copy of their medical records in the U.S. Copies of medical records are submitted to the requestor upon OGC's approval;

P. monitor local budget expenditures and maintain accurate, and concise records;

Q. comply with confidentiality and security standards;

R. perform self-auditing activities to assess clinical care services and reporting practices to achieve program objectives including cohort reviews;

S. collaborate with DSHS' contracted fiduciary agency to conduct annual performance review of each BNTB contracted employee;

T. 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 the Texas Tuberculosis Work Plan. *See Table 4*; and

U. 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., i.e.

sputum, cerebral spinal fluid, gastric washes and blood. *See Appendix A for details.*

Table 4: Texas TB Performance Measures

Performance Measure	Benchmark (%)
Newly reported cases of TB must have an HIV test performed, unless there is documented evidence of an HIV-positive result, or the client refuses.	91
All suspected and confirmed TB clients are placed on DOT at the start of treatment†.	92
Newly reported suspected and confirmed cases of TB are started on the standard four-drug regimen.	94
Newly reported clients ages 12 and older for whom TB was identified in the pleura or other respiratory site, must have sputum collected and tested for acid fast bacilli (AFB) smear and culture results*.	94
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.	64
Newly diagnosed cases of TB that are eligible to complete treatment within 12 months must complete therapy within 365 days or less. Exclude the following TB cases: • diagnosed at death; • who die during therapy; • who are resistant to rifampin (or intolerant to rifampin as the impact on treatment prolongation is the same); • who have meningeal disease; and	89

• who are younger than 15 years with either miliary disease or a positive blood culture for TB.	
Increase the proportion of culture-confirmed cases of TB with genotyping result reported.	99
Cases of TB with initial cultures positive for *M.tb* complex are tested for drug susceptibility with results documented in the medical record.	84
Newly reported TB clients with a positive AFB sputum-smear result have at least three contacts evaluated as part of the contact investigation.	94
Newly identified contacts identified through the contact investigation that are associated with a sputum AFB smear-positive cases of TB are evaluated for TB infection and disease.	80
Contacts identified to an AFB smear positive client and for whom TB infection was diagnosed must be started on treatment for TB infection within a week of diagnosis.	69
Contacts identified to an AFB smear positive client and for whom treatment was initiated for TB infection must complete treatment within the recommended time frame.	54

†The CDC recommends treatment initiation for TB clients with positive AFB sputum-smear results within seven days of specimen collection.

***Report results to the Unit according to surveillance reporting schedule**.

VI. Local Binational TB Program Procedures

General Requirement

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

Activities

A. Develop and implement written procedures that meet the standards of care outlined in *chapter IX* of this manual and the Texas TB Work Plan. Procedures should cover the following topics:

1. Criteria to receive services
2. Treatment and management of TB infection
3. Treatment and management of suspected or active TB disease
4. Treatment and management of contacts to clients with TB disease
5. Contact investigation services and implementation
6. Collection and shipment of specimens
7. Transportation of biologicals
8. Ordering second-line medications
9. Sputum collection
10. Directly observed therapy
11. Infection control for TB
12. Case review
13. Cohort review
14. Reporting
15. Surveillance

B. Ensure procedures are reviewed and signed annually by appropriate BNTB program staff.

C. It is recommended that BNTB program staff review the BNTB program manual and procedures annually together 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.

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

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

F. Submit title, table of contents and signature pages of procedures to the DSHS central office nurse consultant by October 14th of each year.

VII. Roles and Responsibilities

General Requirement

It is required that funded binational TB programs and contracted staff deliver services in an efficient and competent manner. This chapter outlines the roles and responsibilities for programs and staff involved in the delivery of binational TB services.

DSHS Central Office Responsibilities

A. The TB Unit will:

1. oversee BNTB program activities;
2. provide expert nursing consultation;
3. oversee and assist in the development and standardization of procedures for TB prevention and care in the BNTB programs;
4. monitor and evaluate program's progress towards performance objectives to determine effectiveness and compliance with essential TB prevention and care standards;
5. monitor BNTB programs' reports and ensure reports are submitted to the Unit by established deadlines;
6. communicate with DSHS Pharmacy Branch and the BNTB programs to ensure availability of medications to treat TB disease and infection;
7. serve as a liaison with the CDC and other federal and state partners;
8. develop and maintain contractual relationship with the fiduciary agency responsible for evaluating BNTB program services performed in Mexico; The fiduciary agency is responsible for hiring and terminating contracted BNTB program staff and providing salary payment to contracted staff;
9. maintain and distribute the most current version of the BNTB Program Manual;
10. serve as repository for TB data reported to DSHS;
11. collect and analyze reports from BNTB programs to satisfy grant requirements;
12. serve as a point of contact for inter-jurisdictional transfers. Clients transferring from a BNTB program to a US TB program will have an inter-jurisdictional notification (IJN) submitted to the Unit along with the receiving jurisdiction;
13. promote security and confidentiality standards for TB data exchanges;

14. prepare and report aggregate data to the CDC;
15. oversee molecular epidemiology practices, provide technical assistance to investigate transmission patterns and cluster events and prepare TB epidemiologic reports;
16. provide technical assistance to BNTB programs for accurate submittal of TB data;
17. assist with the development and implementation of quality assurance (QA) procedures and activities;
18. promote active surveillance activities; and
19. serve as the liaison for CDC's Division for TB Elimination (DTBE) surveillance team.

Binational TB Programs

A. The BNTB clinics in Mexico will:
   1. Maintain communication with DSHS and local health department TB program contacts to ensure program needs are met.
   2. Maintain appropriate staffing to deliver clinical care services. Each clinic will have the following staff:
      a. a physician with a current and valid 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 directly observed therapy (DOT) in accordance with Texas and Mexico's standards; and
      d. staff responsible for transportation of biologicals to DSHS PHRs or LHD.
   3. Maintain appropriate personnel to perform clinical care services and outreach activities to include but not limited to:
      a. physician services;
      b. nurse case management;
      c. directly observed therapy;
      d. contact investigation;
      e. referrals and updates;
      f. TB education;
      g. reporting; and
      h. collection and transport of laboratory specimens.
   4. Perform work in accordance with DSHS standards of care.

B. It is the role of the BNTB Program Manager to:

1. supervise the BNTB staff in the U.S.;
2. develop and revise local BNTB program procedures;
3. participate in the annual review and revision of the BNTB program manual and submits updates to the TB Unit by targeted deadline;
4. communicate and collaborate with the TB Unit on any situations that may affect the program, immediately;
5. review and revise federal budget specific to the US binational TB program, monitors budget and maintains accountability of BNTB program expenditures;
6. discuss with the designated fiduciary agency, concerns regarding contractors' performance in Mexico; and
7. collaborate with the fiduciary agency to contract with a radiology service entity to perform x-rays for cases and contacts residing in Mexico. Coordination for contracts should occur through the fiduciary agency.

C. It is the role of the BNTB Program Coordinator to:

1. assign work to contracted nursing staff providing services in Mexico;
2. participate in annual reviews of the BNTB program manual in collaboration with the BNTB program manager and submits updates to the DSHS nurse consultant;
3. notify the contracted physician in Mexico on changes in the BNTB program manual that impacts their practice. The BN coordinator must document that the physician received the most current version of the BNTB program manual;
4. perform nurse case management oversight activities according to DSHS Standards of Performance for the Prevention and Control of TB and CDC's guidelines:
   a. Directly observed therapy (DOT)
   b. Contact investigations
   c. Dispensing medications
   d. Documentation of patient care

   Note: If the BNTB program coordinator is not a licensed registered nurse, it is the responsibility of the local BNTB program manager to assign a licensed registered nurse to perform nurse case management oversight of work done by contracted nursing staff in Mexico;
5. ensure that a complete shadow chart is maintained with up-to-date progress notes and TB forms (or their equivalent) at the Texas BNTB program site;

6. schedule medical consultation sessions with DSHS designated medical consultants;
7. prepare and present educational programs in English and Spanish as it relates to services provided by the BNTB program;
8. manage BNTB program data entered in THISIS;
9. review and revise federal budget impacting the US binational regional or LHD TB program in coordination with the BNTB program manager and TB Unit;
10. collaborate with health officials in Mexico, and local TB programs in their jurisdiction on clients referred to the BNTB program;
11. complete, and submit annual reports to the Unit by scheduled deadline;
12. enroll and verify eligibility of clients referred for BNTB program services;
13. coordinate with physicians that all necessary documents are received for the use of second-line medications in Mexico;
14. ensure medications are ordered, received and delivered;
15. request supplies for each program site in coordination with the fiduciary agency;
16. meet/communicate on a regular basis with Mexico's BNTB staff and Mexico's health officials to discuss caseload and administrative issues;
17. conduct cohort reviews as specified in the Cohort Review Process, outlined in the *Texas TB Work Plan, Appendix N;*
18. ensure all contracted staff are trained to use N95 masks and fit tested upon hire and annually;
19. maintain an up-to-date line list of clients in the BNTB program and submit copy to the Unit's TB nurse consultant as requested;
20. coordinate with the fiduciary agency regarding hiring and selecting contracted staff. Notify the Unit of any changes in personnel, including new hires. Submit the *Notice of Change of TB Personnel*, dshs.texas.gov/IDCU/disease/tb/policies/TBPersonnelNotice.pdf to TBProgram@dshs.texas.gov; and
21. coordinate with the fiduciary agency to contract with one person, as needed, to transport specimen to the U.S.

D. It is the role of the Binational TB Program Clinical 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. work in collaboration with the BNTB coordinator to ensure each BNTB program contractor completes an annual review of the program manual;
3. ensure consistent delivery of clinical practices among all BNTB program clinics in Mexico;
4. 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;
5. help implement new TB diagnostic technologies and treatment at each BNTB program site upon approval by DSHS;
6. communicate and collaborate with BNTB program's treating physicians on a regular basis to provide guidance as appropriate to facilitate positive and productive relationships with local jurisdictional colleagues;
7. participate in annual program evaluations at each BNTB program in Mexico;
8. participate in training new hires;
9. conduct annual performance reviews of each BNTB program in Mexico;
10. maintain standardized job descriptions for all clinical contractors and prepare formal agreements with all clinical vendors in collaboration with DSHS;
11. act 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 DHS approved clinical standards and Mexico's legal and clinical standards;
12. attend relevant trainings and conferences to remain up to date with the developments and best practices in the prevention and treatment of tuberculosis; and
13. perform other duties as assigned.

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

1. review the most current version of the BNTB program manual and procedures annually. The BNTB coordinator will inform the treating physician on changes in the manual that impacts their practice and ensure that the physician receives the most current version of the BNTB program manual and procedures;
2. perform initial and follow-up assessments on clients with suspected or confirmed TB disease and TB infection and document in the client's

medical record;

3. coordinate and collaborate on the client's medical care with primary physicians in Texas and in Mexico, and with the Regional Medical Director (RMD);
4. order and interpret appropriate diagnostic tests;
5. ensure there is a process in place for staff to respond to medication toxicity and other client concerns when reported by the licensed nurse;
6. provide clear direction to contracted staff on expectations of assessment: how often clients should be seen in the clinic, how often orders will be signed, and how staff should communicate with the treating physician;
7. ensure medical consultation with a DSHS-Recognized TB medical consultant occurs when needed to ensure adequate treatment for DRTB and/or challenging cases. This will be done in coordination with the Texas physician (and not done by the nurse without written physician agreement);
8. document in the medical record for each client on treatment for TB disease at least monthly and provide a copy to the BN coordinator to be kept in the shadow chart;
9. ensure clients with DRTB, young children with TB, or other high-risk individuals are managed according to the standards of care for treatment outlined in the Texas TB Standing Delegation Orders;
10. provide TB education to clients and family members to include prevention and transmission, disease process, and consequences of inadequate treatment;
11. participate on monthly case review conferences with the BNTB program;
12. coordinate with the TB State Physician in Mexico for the approval of second-line medications and seek required involvement of COEFAR and/or GANAFAR if applicable; ensure medications recommended for drug resistant clients are in line with the COFEPRIS and México Guias (guidelines). If not, then a letter of approval, 'DICTAMEN', is needed to receive medication through the BNTB program. Currently, Bedaquiline is not included on Mexico's COFEPRIS list of approved medications;
13. participate on quarterly meetings with the Mexico Binational Committee;
14. perform TB education activities to health care providers within the service area to increase program awareness and promote referrals to the BNTB Program;

15. communicate with the BNTB Program Clinical Coordinator any concerns that may affect the daily operations of the BNTB program site; and
16. ensure all BNTB cases counted in Mexico are correctly reported to Mexico's TB surveillance reporting system known as Plataforma Única de Información.

F. 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;
2. coordinate with the Mexico physician to ensure medical consultation occurs with a DSHS recognized TB medical consultant for DRTB clients or for challenging cases; and
3. participate and submit recommendations in writing on monthly case review conferences as applicable.

G. It is the role of the Outreach Nurse to:

1. perform work in a professional manner to provide medical, programmatic and administrative services as directed by the BNTB coordinator and the BNTB program manager;
2. work full time to support program needs and is available to respond to individual program needs as directed;
3. ensure clients have current medical orders from the licensed provider;
4. conduct physical, developmental, and psychological assessments of client health needs and implement appropriate action;
5. administer and ensure clients are started on adequate therapy as prescribed by the licensed provider;
6. ensure clients are assessed per guidelines according to DSHS Standards of Performance for the Prevention and Control of TB and CDC's guidelines;
7. read, understand, and follow procedures outlined in the BNTB manual and sign annually;
8. ensure medical records are maintained, completed, and contain the appropriate forms or their equivalent. *See appendix B*.;
9. document all encounters appropriately when contact is made with the client either at the clinic site or during the home visit;
10. ensure monthly toxicity examinations occur. This includes documentation and responses to any abnormalities (i.e. document what the nurse did to address the abnormality);

11. notify the treating physician if toxicity screening does not occur. Medications should not be administered to clients if toxicity screening is not done;
12. provide DOT to all clients in accordance with the Mexican National Standards and the BNTB program procedures and document all doses taken, missed or self-administered using appropriate forms;
13. collect sputum for clients with suspected TB following *TB Sputum Collection Services Provided by Authorized Staff* procedures found at dshs.texas.gov/IDCU/disease/tb/policies/TB-SDO-SpututmCollection.pdf;
14. provide support and guidance to the Secretaria de Salud as needed in conducting CI of their identified TB clients or those with suspected TB;
15. provide TB education with regards to prevention and transmission to clients and family members to include disease process, treatment and the consequences of inadequate treatment;
16. support TB education activities to health care providers and community-based organizations within the service area to increase awareness and promote referrals to the BNTB Program;
17. instruct, counsel and assist clients in meeting their health care needs with regards to tuberculosis prevention and transmission;
18. educate clients on possible side-effects, conditions under which medications should be stopped, and the need to prevent pregnancy, if applicable;
19. provide referrals for medical evaluations as needed;
20. label and correctly package specimens according to program shipping requirements;
21. coordinate the transport of specimens. Collaborate with the BNTB Program Manager and the BNTB program staff for transportation schedule;
22. submit specimens to appropriate laboratory for processing;
23. transport equipment/supplies to and from Texas and Mexico's BNTB program sites as assigned;
24. assist BNTB program coordinator as requested in preparing reports for clinical and funding purposes;
25. participate in BNTB program conferences and in-service trainings, and seminars;
26. maintain a detailed log of daily work activities and mileage and submit to the BNTB program coordinator on a weekly basis, see appendix D, Weekly Time and Mileage Report;

27. participate in monthly case conference and quarterly cohort reviews; and
28. perform other duties as assigned.

VIII. Standards of Care

General Requirement

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

Minimum Standards and Service Availability

A. Screening for TB disease and TB infection

1. Interferon gamma release assays (IGRA) is the preferred screening test for clients two years and older. If phlebotomy is refused, the client may receive a tuberculin skin test (TST), or as otherwise specified by the treating physician.
    a. IGRAs are provided to BNTB programs via the Unit at no cost to the BNTB program.
    b. Tuberculin skin test (TST) supplies (e.g., syringes and tuberculin purified protein derivative) may be ordered from the DSHS Pharmacy Branch via the Inventory Tracking Electronic Asset Management System (ITEAMS). Programs may not order or provide TST for sites outside the BNTB program. For example, TST and IGRA supplies should not be provided to local providers in Mexico to facilitate TB screening of their clientele.
2. Clients age 13 and older should be offered an HIV test during screening for TB infection or disease.

B. Radiology

1. Every program must have radiology services available through a contracted facility.
2. Every client age under 18 will have a posterior/anterior (PA) and lateral chest x-ray (CXR) when undergoing evaluation for TB infection or disease, when CXR is recommended; clients 18 years or older will have a PA CXR.
3. Every client on treatment for TB disease with pulmonary involvement will have radiology in the following intervals:
    a. at baseline,
    b. at two months of appropriate treatment,
    c. at closure, and

d. as ordered by the treating physician.

4. Every client with rifampin resistant (RR), multi-drug resistant (MDR), pre-extensively drug resistant (Pre-XDR), or extensively drug resistant (XDR) pulmonary TB disease should receive a CXR and signs and symptoms check every 6 months for 2 years after completion of treatment.
5. Every client eligible for treatment for TB infection will have a baseline CXR to rule out active disease prior to staring therapy.

C. Airborne Infection Isolation (AII)

1. Every client diagnosed with an American Thoracic Society (ATS) class 3 or 5 will be placed in airborne infection isolation (AII) with date documented in the medical record unless criteria for release from isolation is met.
2. Clients released from airborne isolation will have the date of release documented in the medical record.
3. Every client who arrives at the TB clinic for services and infectiousness is unknown, will be given a surgical mask to wear.
4. BNTB Mexico staff will use N-95 respirators in situations that pose a high risk of exposure to TB disease.
5. A nurse may only release a client from airborne isolation after written instructions are received by the treating physician once criteria for release from isolation is met.

D. Sputum Testing and Culture Conversion

1. Every client for whom sputum is collected will have one (ideally the first) sample sent for Nucleic Acid Amplification Test (NAAT), unless there is documentation of a Polymerase Chain Reaction (PCR) that tests for rifampin resistance or unless drug susceptibilities are known.
2. Every client 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. In addition, all subsequent culture results must remain negative.
3. When culture conversion does not occur by three months of therapy, a consult will be requested from a DSHS-Recognized TB Medical Consultant.
4. Every program should obtain supplies necessary to induce sputum when indicated.

E. Nursing Assessments

1. Every client receiving medication for TB disease or TB infection 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 the *TB-205a* (or *TB-702a* for clients on second-line medications) or their equivalent;
    b. toxicity screenings must be done according to the patient's drug regimen
2. Every client on treatment for TB infection must have documentation of communication, in person, at least monthly by a licensed nurse. Documentation will include:
    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.

F. Physician Assessments

1. Every client on treatment for TB disease must receive a physical evaluation by the Mexico treating clinician at least once during therapy. This should be clearly documented in the medical record.
2. Texas consulting physicians must review and sign the medical record for clients with an ATS classification of 3 or 5 at minimum;
    a. Initially;
    b. at two months (8 weeks of therapy, or upon completion of initial phase if greater than 8 weeks);
    c. at 26 weeks of therapy;
    d. at closure;
    e. any time medications are held due to signs or symptoms of toxicity; and
    f. when orders are updated or need to be revised.
3. Every client on treatment for TB infection will have a Mexico physician's evaluation and review of the medical record with signature initially, at closure, and any time there is documentation of medication toxicity requiring medications held.

G. Directly Observed Therapy

1. Daily therapy is preferred (either 5x/week or 7x/week) to intermittent therapy where possible.
2. Every client on treatment for TB disease will be treated for the duration

of treatment via DOT whether in person or by enhanced video DOT (VDOT).

3. VDOT may be utilized by the BNTB Program when clients are recommended for DOT. See DSHS Video-Enabled Directly Observed Therapy Required and Recommended Activities Manual.
4. Every contact to a case of MDR-TB, if treatment is recommended for infection, will be treated via DOT as resources allow.
5. Every client on isoniazid and rifapentine (3HP) may be treated by self-administration at the discretion of the physician and with a written order,
6. Every client under age five is recommended to have DOT for TB infection.
7. When DOTBAL cannot be used, all DOT medications will be ordered via the Pharmacy Branch in DOT packets via ITEAMS.

H. Children and Pediatrics age 17 and younger

1. Every child younger than five years of age who is undergoing evaluation for TB infection or TB disease will have a physical exam by a physician, pediatrician, or clinician licensed in pediatrics upon initial evaluation.
2. Every client age 17 and younger who is recommended treatment for TB infection, whose guardians refuse therapy, will sign the *TB-415a* indicating refusal. A copy will be given to the guardian and a copy will be saved in the Mexico and Texas medical records.

I. Completing Adequate Therapy

1. DOT is the standard of care; therefore, every client will ideally finish therapy as specified by the ordering physician with 100% of doses taken by DOT.
2. At minimum, when closure at 100% is not possible, Class 3 clients will have at least 80% of treatment completed by DOT at closure.
3. Cases of TB that are eligible to complete treatment within 12 months must complete therapy within 365 days or less. See *Performance Measures Table 4* for exclusions.

J. Contact Investigations (CI)

1. Programs will perform CI by screening high priority contacts of possible or confirmed pulmonary, pleural or laryngeal TB disease.
2. Initial interviews are conducted by contracted staff in Mexico within three (3) working days of being notified of a client 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 TB infection, including clients needing evaluation for window prophylaxis, will be informed of the implications regarding their decision. Documentation of this will be done on the *TB-230a* and client will be asked to sign. A copy will be given to the client and a copy saved in the client's Texas and Mexico medical records.

K. Case Conferences and Cohort Reviews

1. Monthly case conferences will be held to review ATS class 3, and ATS class 5 clients on treatment. The following participants are required to attend:
    a. the BNTB program nurses,
    b. Mexico treating physician,
    c. U.S. consulting physician, and
    d. BNTB coordinator.
2. BNTB Programs will review 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 the DSHS *Tuberculosis Cohort Review Process* located in the Texas TB Work Plan, Appendix N.

IX. Professional Education and Workforce Competency

General Requirement

All new 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.gov/tb/esp/publications/guides/ssmodules/default.htm
      b. Internet course for TB-101
      cdc.gov/tb/esp/webcourses/tb101/default.htm
      c. Podcast for Basic TB Facts
      tools.cdc.gov/medialibrary/index.aspx#/media/id/304159
   3. Core training topics for TB staff include:
      a. transmission and pathogenesis of TB;
      b. epidemiology of TB;
      c. diagnosis of TB infection and disease;
      d. treatment of TB infection 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 TB infection, TB disease and drug resistant TB; and
l. CDC TB surveillance and reporting.

4. BNTB program staff and contracted staff in Mexico must complete 16 hours of continuing education each calendar year relevant to each staff member's position.
5. The BNTB coordinator and/or administrating staff member should participate in the monthly conference calls or trainings.
6. Ensure that 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 of Excellence on:
   a) Drug interactions and toxicity;
   b) Contact investigation for TB;
   c) Infection control measures;
   d) Client adherence;
   e) Directly observed therapy; and
   f) Tuberculin skin testing practicum.

C. Maintain documentation of training for all employees and contracted staff.
   1. Retain logs, *see Appendix C*, 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. Mexico treating physicians must have access to training records to verify that those operating under their medical license have the requisite experience and training.

CI. Notify the TB Unit of newly hired BNTB program staff within 30 days of hire. Submit the *Notice of Change of TB Personnel* form dshs.texas.gov/idcu/disease/tb/forms/ to TBProgram@dshs.texas.gov.

E. Provide support to educate external entities as needed and as resources allow.

1. Promote the BNTB program during these events on the services and support provided by the program.

F. Report trainings on the DSHS Annual Progress Report (APR).

G. Maintain competency within the Texas BNTB Texas staff in navigating THISIS, as per the THISIS Training and Implementation Plan (TIP). BNTB program managers may choose to require certificates of training completion of each THISIS training course.

X. Infection Control Procedures

General Requirement

The BNTB programs will apply appropriate administrative, environmental, and respiratory control measures to prevent exposure to and transmission of *M. tuberculosis.*

A. 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 clients with TB disease and infection.
    2. Ensure proper cleaning, sterilization, or disinfection of equipment and surfaces to prevent contamination.
    3. Educate, train, and counsel health care workers, clients, and visitors about TB infection and disease.
    4. Use posters and signs to remind clients and staff of proper cough etiquette and respiratory hygiene
    5. Test and evaluate clinic workers who are at higher risk for becoming infected with TB due to exposure to TB disease
        a. Contracted staff are required to be screened for TB upon hire and at least annually to monitor results and conversions. If the screening test is positive, contractual staff will be referred to their primary care provider or the BNTB program physician.
        b. Maintain documentation in accordance with local procedures.

B. Environmental control measures ensure that technologies are in place for the removal or inactivation of airborne *M. tuberculosis*. Programs should do the following:
    1. Ensure all environmental control equipment are properly installed, operated and maintained.
    2. Install Ultraviolet (UV) lights at each clinic site. Ultraviolet lights must be routinely inspected to maintain proper functionality.

C. 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 clients 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 client confidentiality if an AIIR room or booth is unavailable.

Recommendations for screening health care personnel (HCP) for TB can be 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."* These include performing a TB screening upon hire (baseline), and annually for *select* personnel with increased occupational risk for exposure to TB. Program personnel may qualify for annual TB screenings if they have direct contact with infectious TB patients, or if they share the same airspace with TB patients due to job duties or workspace.

XI. Budget Management

General Requirement

The BNTB programs are funded by the Centers for Disease Control and Prevention (CDC). Funding is allocated to the Unit through a cooperative agreement (COAG). The DSHS supports program services performed in Mexico through a fiduciary agency.

The fiduciary agency will monitor budget expenses in Mexico, maintain records and submit expenditure reports by the deadline specified in the fiduciary agency's *Statement of Work* to DSHS.

A. The BNTB program managers and coordinators will work collaboratively to manage and monitor their U.S. budgets to ensure the following activities:
    1. Review and revise federal budget for U.S. program operations.
    2. Monitor budget expenditures for U.S. program operations.
    3. Recommend budget revisions for U.S. program operations and obtain approval from the Unit.
    4. Prepare and/or approve payment vouchers of Mexico contractors for salaries/mileage and other allowable reimbursements by utilizing state voucher format prior to sending to the fiduciary agency for payment.
    5. Work closely with the fiduciary agency on ordering supplies for each program site in Mexico.
    6. Notify the Unit of any changes in personnel, including new hires.

XII. Reporting

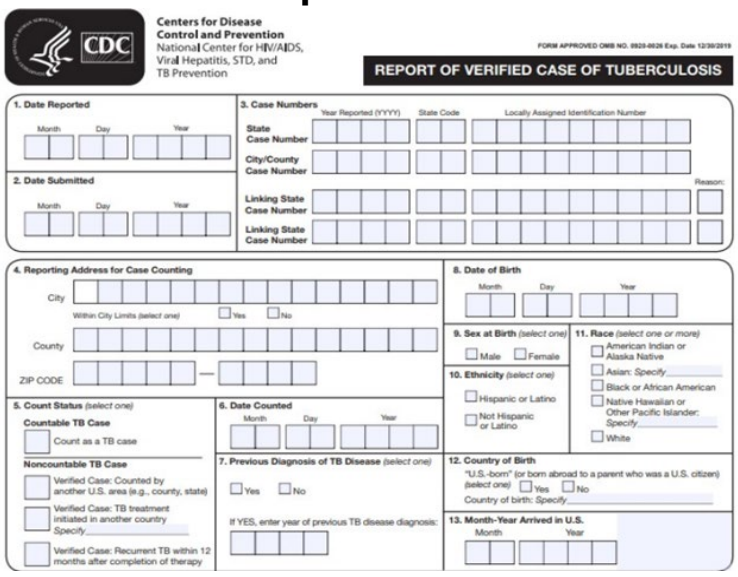
General Requirement

The BNTB programs must submit designated reports by established deadlines and schedules using DSHS-approved mechanisms to the Unit and contracted fiduciary agency. BNTB program managers must consolidate, verify and sign all TB case counts for the current calendar reporting year.

Activities

A. Report all ATS Class 3 cases in THISIS using the data elements in the CDC Report of Verified Case of TB (RVCT), Table 5, *Example of RVCT form*, within two business days after identification of a laboratory confirmed case of TB or diagnosis of a clinical case of TB. The RVCT form can be found at cdc.gov/tb/programs/rvct/default.htm.

Table 5: Example of a RVCT form



Centers for Disease Control and Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

REPORT OF VERIFIED CASE OF TUBERCULOSIS

1. Date Reported (Month, Day, Year)
2. Date Submitted (Month, Day, Year)
3. Case Numbers (Year Reported (YYYY), State Code, Locally Assigned Identification Number)
State Case Number
City/County Case Number
Linking State Case Number
Linking State Case Number
Reason:
4. Reporting Address for Case Counting
City
Within City Limits (select one) Yes No
County
ZIP CODE
5. Count Status (select one)
Countable TB Case
Count as a TB case
Noncountable TB Case
Verified Case: Counted by another U.S. area (e.g., county, state)
Verified Case: TB treatment initiated in another country Specify
Verified Case: Recurrent TB within 12 months after completion of therapy
6. Date Counted (Month, Day, Year)
7. Previous Diagnosis of TB Disease (select one) Yes No
If YES, enter year of previous TB disease diagnosis:
8. Date of Birth (Month, Day, Year)
9. Sex at Birth (select one) Male Female
10. Ethnicity (select one)
Hispanic or Latino
Not Hispanic or Latino
11. Race (select one or more)
American Indian or Alaska Native
Asian: Specify
Black or African American
Native Hawaiian or Other Pacific Islander: Specify
White
12. Country of Birth
"U.S.-born" (or born abroad to a parent who was a U.S. citizen) (select one) Yes No
Country of birth: Specify
13. Month-Year Arrived in U.S. (Month, Year)

1. Use the *Case Verification Form* to verify case criteria and count status. The form can be found at dshs.texas.gov/thsvh/thisis/files/CaseVerificationReport.pdf. Case criteria:
    a. Laboratory confirmed
    b. Clinical case (pulmonary or extra-pulmonary)
    c. Provider diagnosis

2. Enter the case's full first, middle and last name and the following minimum required RVCT data elements in THISIS at time of initial report:
   a. date reported;
   b. date of birth;
   c. race and ethnicity;
   d. country of origin, if not U.S.;
   e. laboratory and clinical data necessary to meet case definition as applicable;
   f. if diagnosed while in a facility or shelter, provide facility or shelter name; and
   g. initial drug susceptibility results, as applicable.
3. Enter remaining RVCT data elements in THISIS as required for National TB Indicator Project (NTIP) reporting and to fulfill federal cooperative agreements. See *Report of Verified Case of Tuberculosis, CDC Tuberculosis Surveillance Data Training*. U.S. Dept. of Health and Human Services, CDC, National Center for HIV/AIDS, Viral Hepatitis, STD and Tuberculosis, p 203, CDC, 2009. Note: CDC revised the current RVCT being used and the new RVCT variables will be implemented in THISIS in January 2022.
4. Enter RVCT Follow-Up 1 and 2 Report data in THISIS:
   a. Enter a completed Initial Susceptibility Report (RVCT Follow-Up 1) in THISIS on all culture-confirmed cases as soon as an initial susceptibility report is available.
   b. Enter a completed Case Completion Report (RVCT Follow-Up 2) in THISIS on all cases as soon as treatment completion or treatment outcome data is available.
   c. Provide a justification for any Follow-Up 2 reports submitted more than 90 days after medication stop date in RVCT comments.
   d. Provide the last date medication was given when treatment of the client stopped due to completion of adequate therapy, death, failure to locate, moved and/or 90 days' passage since last medication dose.
   e. Create a new EventID for a recurrent case of TB that occurs when the duration between the last known date when TB treatment stopped and the date when a new TB treatment regimen started is less than 365 days, but the event is not counted as a new case. A TB case that occurs more than 365 days between the last known date when TB treatment stopped and the date when a new TB treatment regimen started should have a new EventID and a new RVCT number and will be counted as a new case. Perform a new CI in both instances. Do not merge these events in THISIS if they appear on the deduplication workflow.

B. Report all ATS Class 5 (Suspected case of TB) in THISIS with the same data required of confirmed cases of TB. Update ATS Classification in THISIS within 90 days when clinical data is available to reclassify the patient.

C. Maintain a digital or electronic log of all cases in their jurisdiction by county and year reported or counted with the following:
    1. Name
    2. Date of birth
    3. City/County address and jurisdiction
    4. Contact information
    5. THISIS EventID
    6. RVCT number (also referred to as the state case number)

D. Complete Forms TB-340a and TB-341a, or Mass Contact Spreadsheet, within 90 days of initial source case report in THISIS. Enter the data from the forms in THISIS after THISIS training. The initial contacts' report requires the following:
    1. Part A. Case/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.
    3. Part C. Contact Information
        a. Duration of exposure and setting
        b. HIV test results
        c. Priority status
        d. TST/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 with an ATS classification are required. If the result is negative, perform a second TST or IGRA 8-10 weeks after the contact's last exposure to the source case.
        a. Perform a symptom screen for an evaluation to be complete.
        b. Provide reason if evaluation was incomplete.
    5. Update THISIS as "CI was indicated" = "Yes" if a contact investigation was initiated. If contact investigation was not initiated, provide reason.

6. Update THISIS 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
    f. If contact did not complete treatment adequately, provide reason
7. Update contacts' treatment outcome in THISIS no later than three months from the date the contact stopped treatment.
8. 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 THISIS.
9. List CIs that yields >=50 contacts on the DSHS TB Mass Contact Spreadsheet. Request the most recent version from DSHS TB Surveillance case consultants before use.

E. Report mass screenings (contact investigations > 50 contacts) when using DSHS TB Unit-purchased supplies. Do not perform mass screenings without prior TB Branch approval.
    1. Make every effort to educate and inform the "worried well" regarding the TB screening process to ensure TB epidemiologic principles are applied at each CI event.
    2. 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.
    3. Mass screenings that are not epidemiologically guided, drain limited resources and yield minimal results.

F. Achieve National TB Indicator Program (NTIP) Objectives and Performance Targets. Texas BNTB programs are required to achieve each measure for CIs outlined in *Table 4 Texas Performance Measures*, pg. 14 of this manual. For a comprehensive list of NTIP objectives and targets see cdc.gov/tb/programs/evaluation/indicators/.

G. Report false-positive cases.
    1. The DSHS TB Unit will assist TB programs' investigation of false positives either due to laboratory contamination or another misdiagnosis.
    2. Report any case closed as false-positive due to laboratory contamination or other reason to the TB Unit Epidemiology Team 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.
3. Review all other specimens associated with a false-positive case to ensure they are culture-negative.

H. Ensure timely communication occurs when a TB client needing follow-up, travels or moves to a U.S. jurisdiction. There are two types of communication channels:
1. Formal communication - using the National TB Controllers Association (NTCA) Interjurisdictional Notification (IJN) form.
2. Informal communication - direct clinic-to-clinic phone calls, emails, or other forms of sharing client information.

I. When a client plans <u>temporary</u> travel to the U.S.: Plan, coordinate, and communicate *informally* (and *formally* when requested) with the receiving jurisdiction.
1. Within two business days that the BNTB program becomes aware of a client's temporary travel plans (or has already traveled), identify the address where the client will be/is staying. Temporary travel is defined as 30 days or less to a U.S./Texas jurisdiction.
   Notify the U.S. IJN Coordinator within two business days that the BNTB program becomes aware of the client's travel plans that the client will be in, or already is in, their jurisdiction temporarily and to determine which TB clinic should be contacted in case coordination of care may be needed. The list of IJN contacts for each state can be found here: tbcontrollers.org/community/statecityterritory/
2. Coordinate the sharing of information *as directed by the receiving jurisdiction*. This includes sharing of any medical records as requested.
   a. The receiving jurisdiction must be notified of any client 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 TB infection.
   b. The receiving jurisdiction will determine how best to coordinate care while the client is in their jurisdiction.
   c. If the BNTB program plans to keep the patient on VDOT, this courtesy notification must still be made.
3. Programs may provide up to 30 days' worth of medications for a client on treatment for TB disease or TB infection. Anything longer than 30 days warrants formal communication as outlined below.

J. When a client plans a <u>permanent</u> move to the U.S., or when temporary travel plans change, or the travel is longer than 30 days: Plan, coordinate, and communicate *informally* <u>and</u> *formally* with the receiving jurisdiction.

1. Within two business days that the BNTB program becomes aware of a client'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 U.S. IJN coordinator to inform them of the client's move or intent to move to their jurisdiction or state.
2. 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 client information and ensure continuity of care (i.e., a nurse-to-nurse handover).
3. Within one business day of notifying the receiving state, complete an IJN form, attach the completed IJN form and necessary medical records to the client's event in THISIS, update the address information and update the appropriate fields in THISIS to reflect the move. The most recent IJN form is available at: tbcontrollers.org/docs/resources/IJN_Form_May2015.pdf.
4. Notify the DSHS TB Unit IJN Coordinator by email that the IJN has been attached to THISIS. The DSHS TB Unit IJN Coordinator's responsibilities include:
    a. Sending the IJN form and medical records to the receiving state's TB program by fax and send follow-up email to request receipt confirmation, and
    b. Logging the IJN referral for tracking purposes
5. Follow-up with the receiving state to ensure completion of therapy and document the patient's outcome in THISIS.

K. Complete and submit Form TB-400B on all newly diagnosed DR TB cases within five business days of notification to the TB Unit via GlobalScape.

1. Complete and submit updated Form TB-400B every 90 business days for all cases of DRTB until treatment completion.
2. Submit changes in case management, drug resistance patterns or residence for any DRTB case within 72 hours of notification.

L. Submit completed annual progress reports to the Unit.

M. Submit quarterly summary of cohort reviews to the TB Unit in accordance with the listed cohort review period and submission schedule via Globalscape. *See Table 6* for schedule.

Table 6: Cohort Periods and Submission Schedule

Cohort Review Periods and Submission Schedule	
Cohort period cases counted in:	**Are reviewed and reported by:**
First quarter (Jan 1 – Mar 31) current year	Mar 31 of the following year
Second quarter (Apr 1 – Jun 30) current year	Jun 30 of the following year
Third quarter (Jul 1 – Sep 30) current year	Sep 30 of the following year
Fourth quarter (Oct 1 – Dec 31) current year	Dec 31 of the following year

XIII. Confidentiality and Security Standards

General Requirement

It is required that all binational TB program clients are evaluated and treated in Mexico. The official medical record is opened and maintained in Mexico. However, an up-to-date shadow chart is kept in the U.S. and maintained in accordance with applicable state and federal security and confidentiality standards, policies and guidelines including but not limited to:

A. DSHS Program Policy 302.001, *Release of TB/HIV/AIDS and STD Data* dshs.texas.gov/hivstd/policy/policies/302-001.shtm
B. Federal HIV/AIDS Security and Confidentiality guidelines, cdc.gov/nchhstp/programintegration/docs/pcsidatasecurityguidelines.pdf;
C. DSHS Policy 2016.01, *TB/HIV/STD Section Confidential Information Security Procedures*, dshs.texas.gov/hivstd/policy/procedures/2016-01.shtm,
D. DSHS Program Policy 2011.01, *Confidential Information Security*, and dshs.texas.gov/hivstd/policy/policies/2011-01.shtm,
E. DSHS Program Policy 2011.04 *Breach of Confidentiality Response Policy*, dshs.texas.gov/hivstd/policy/policies/2011-04.shtm

Activities

A. DSHS staff submits documentation of DSHS security and confidentiality training course to the TB/HIV/STD (THS) 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 TBHIVSTD.AccountRequest@dshs.texas.gov within ten (10) days of completing each course.

E. Designate and identify a HIPAA Privacy Officer authorized to act on behalf of the BNTB program in developing and implementing requirements outlined in federal and state privacy laws.
F. Designate a TB program staff member to serve as the Local Responsible party (LRP).
G. 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.

Appendix A: Permit to Transport Category B Specimen

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 by each BNTB program coordinator to maintain a current permit to transport specimen to the U.S.:

A. Complete the CDC Application for Permit to Import Biological Agents or Vectors of Human Disease into the United States Form 0.752 (rev. Feb.2012) at least two to three months before the current permit expires. Review form for accuracy and completeness prior to mailing to the CDC.

   Note: The Permit to Import Infectious Biological Agents, Infectious Substances, and Vectors - Form: CDC 0728 (F13.40) REV. 4-13 is received by the program typically within two to four weeks of submitting an application to the CDC.

B. Provide a copy of the permit to the Customs and Border Protection (CBP) officer at the time of crossing, each time specimens are imported.

C. Submit to the Unit a copy of the renewed permit.

D. For more information, contact:

   Department of Health & Human Services, Public Health Service, Centers for Disease Control & Prevention, Office Health & Safety, MS A-46, Atlanta, Georgia, Phone: 404-718-2077, Fax: 404-718-2093 Email: importpermit@cdc.gov

Submitting Specimens to DSHS Lab:

For complete shipping and processing instructions see DSHS Specimen Shipping Guide.

Note: 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 client information including specimen type and name of requesting physician.

Table 7 outlines an example on how to pack and label specimens to prepare them for transporting to the U.S. When specimens arrive in the U.S., they are sent to DSHS laboratory for AFB smears, AFB cultures and drug susceptibility testing.

Table 7: Biological B Specimen Packing Visual

Category B – Biological substance (patient samples)

Definition – An infectious substance not in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure occurs.

Proper Shipping Name & UN Number: **UN3373 – Biological substance, category B**

Packaging

Primary container

Leak Proof

Cushioned if multiple fragile primaries

← Either must passed pressure test – 13.8 psi (air transport) →

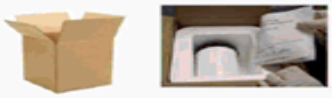
Absorbent between containers with liquids

Secondary container

Leak-proof

(Can be a small Biohazard bag)

Outer container



Sturdy box – passes drop tests (pass a 3.9 foot drop test)

Labeling / Markings (Be sure these do NOT overlap)

or

\+ Name, address, phone # of shipper and consignee (or on paperwork) +

\+

IF contains dry ice (Only needed for air shipments) Need "UN1845 Dry Ice" + Net quantity in Kg.
NOTE: New label to be used for dry ice as of October 1, 2015.

IF contains >50 mls of liquids per primary container or if contains dry ice

Appendix B: 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:

- **Class III, V**:
  - e. TB 400A Spanish Report of Case and Patient Services
  - f. TB 400B Spanish Report of Case and Patient Services
  - g. TB-202a TB Initial Health Risk Assessment/History
  - h. TB-203a Education/Counseling Record
  - i. TB-205a Toxicity Assessment
  - j. TB 206b Directly Observed Therapy Log
  - k. TB-231a Bacteriology TB Control Log
  - l. TB-411a Disclosure and Consent Drug Therapy TB
  - m. BN-200 Mexico Referral Form
  - n. TB-700a-TB-705a series for drug resistant clients
  - o. General consents:
    - L36a General Consent and Disclosure
    - ISP-01a - HIPPA privacy acknowledgement
    - L30a Authorization to Release Confidential Medical Information, when applicable

- **Class II, and those on window prophylaxis (wp)**:
  - p. TB-400B Spanish Report of Case and Patient Services
  - q. TB-415a Consent LTBI Therapy
  - r. TB-202a TB Initial Health Risk Assessment/History
  - s. TB-205a Toxicity Assessment
  - t. TB-206b Directly Observed Therapy Log
  - u. BN 200 when applicable
  - v. 12-14198a 3HP Dosing and Symptom Monitoring Log (if applicable)
  - w. General Consents:
    - L36a General Consent and Disclosure
    - ISP-01a - HIPPA privacy acknowledgement
    - L30a Authorization to Release Confidential Medical Information, when applicable

- **Contact Investigation**:
  - TB-208a Tuberculosis Contact Screening Form
  - TB-340a Report of TB Contacts
  - TB-341b Continuation of Report of TB Contacts

- 12-12062a Contact Investigation Worksheet
- TB-460a TB Contact Investigation Expansion Analysis Checklist
- TB-230a Contact Refusal Form (if applicable)
- TB-425a TB Infectious Period Calculation Sheet

❖ **Cohort Review**:

- 12-14064a Cohort Review Presentation Form

❖ **VDOT Forms**:

- 12-15760a Mobile Application
- 12-15761a VDOT Mobile Phone User Agreement
- 12-15762a VDOT Client Participation Agreement
- 12-15763a Video DOT Medication Layout
- 12-15764a VDOT Patient Instructions

Appendix C: Sample In-Service and Training Roster

Topic:

Trainer/Educator:

Date: Location:

Number of Hours:

Print Name	Signature

Appendix D: 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 *5/10/21 Monday*	*8 am*	*8:30 am*	*1234 Mockingbird Dr., Reynosa, Mexico*	*1819 Blueberry Lane Reynosa, Mexico*	*DOT, blood draw*	*7km/4.35 miles*
5/10/2021 Monday	*8:30 am*	*9 am*	*1819 Blueberry Lane, Reynosa, Mexico*	*Clinic address, Reynosa, Mexico*	*Traveled to clinic for the day*	*10km/6.2 miles*
5/10/2021 Monday	*9 am*	*5 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*
5/11/2021 Tuesday	*8 am*	*5 pm*	*n/a*	*n/a*	*(detailed information here of days activities in clinic)*	*n/a*
					Total Km/miles	

Date:	Signature: