



TEXAS
Health and Human
Services

**Texas Department of State
Health Services**

Texas Tuberculosis Work Plan



Tuberculosis and Hansen's Disease Unit

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I. Introduction

The Texas Tuberculosis (TB) Work Plan sets forth procedures established by the Texas Department of State Health Services (DSHS) Tuberculosis and Hansen's Disease Unit (TB Unit) to ensure all TB programs receiving state funding or in-kind support from DSHS public health regions (PHRs) achieve TB performance standards. The TB Work Plan:

- Serves as a prescriptive document to design and maintain a TB program;
- Outlines the expectations and responsibilities of all funded TB programs;
- Assures consistent TB prevention and care practices are applied throughout Texas; and
- Provides a blueprint to assess performance outcomes based on quality indicators.

Providing TB Services to Patients Regardless of Ability to Pay

Funded TB programs shall provide services without consideration of a patient's ability to pay. Local health department (LHD) TB programs requesting reimbursement for TB services should consider enrolling as a TB Medicaid Provider. To enroll, the LHD completes the *DSHS Medicaid Provider Application* located at, dshs.texas.gov/IDCU/disease/tb/forms/PDFS/TBMedicaidApplication.pdf and submits to the TB Unit for review and approval. Once approved, the TB Unit prepares an approval letter which the submitter must include in their submission to Texas Medicaid & Healthcare Partnership (TMHP) to begin the official Medicaid application process.

Funded TB programs shall not charge program-eligible patients for services supported by DSHS state and federal funds. Funded TB programs shall provide services to the following patients based on prioritization (See [Table 1. Prioritizing Evaluation for TB Services](#)):

- A. People with suspected or confirmed TB disease caused by *Mycobacterium tuberculosis* (*M. tb*) complex to include: *M. tb* and *M. bovis*. See dshs.texas.gov/IDCU/disease/tb/policies/EpiCaseCriteriaforTB.pdf.
 1. *Mycobacterium bovis*-*Bacille Calmette-Guerin* (*M. bovis*-BCG) is not reportable to the Centers for Disease Control and Prevention (CDC). BCG, an attenuated strain of *M. bovis*, is widely used as an adjunctive therapy for superficial bladder cancer. Intravesical administration of BCG has been associated with systemic infection. Disseminated infection due to *M. bovis* is otherwise uncommon. The decision to use state funded resources (i.e. medications and personnel) to treat *M. bovis*-BCG should only be considered after consultation with a DSHS-recognized TB medical consultant or Regional Medical Director (RMD).
 2. Patients who are closed as non-TB and identified as having *Mycobacterium avium* complex (MAC) or other nontuberculous mycobacteria (NTM) may not be treated using state-purchased



medications longer than 30 days. See [Form TB-409](#).

- B. Contacts to a person with suspected or confirmed TB disease
- C. Immigrants, including those referred to TB programs from the Electronic Disease Notification (EDN) System (*XI. Manage Electronic Disease Notification System and Other Foreign-Born Referrals.*)
- D. People at risk for developing TB disease (see [Table 1. Prioritizing Evaluation for TB Services](#) and *XII. Conduct Targeted Testing* for more information).



Table 1. Prioritizing Evaluation for TB Services

People who should be evaluated and treated by the TB program ROUTINELY	People who should be evaluated and treated by the TB program AS RESOURCES ALLOW	People who should NOT routinely be evaluated
• Anyone reported to the TB program in whom there is known or a suspicion of active TB disease. • Contacts to a person with known or suspected TB disease. • People reported to the TB program through the EDN, and immigrants from areas of the world with high rates of TB who are seeking permanent residence, after full evaluation from a Civil Surgeon.* • People reported to the TB program with a positive TB test <u>and</u> medical risk factors for developing TB disease, who do not have resources for medical care** outside the TB program. This most commonly includes but is not limited to people with HIV, on immunosuppressant medications or people taking tumor necrosis factor (TNF) alpha inhibitors. • Children aged 4 and younger with a positive TB test. • Children aged 5 and older with risk factors for TB exposure as identified on the <i>Tuberculosis Questionnaire for Children</i> (dshs.texas.gov/idcu/disease/tb/faqs/#students) and who have a positive TB screening test.	• Children aged 5 and older who have not been tested with a tuberculin skin test (TST) or interferon gamma release assay (IGRA) but who were referred for evaluation based on having risk factors listed on the <i>Tuberculosis Questionnaire for Children</i> and do not have resources for medical care** outside the TB program. • Groups with high rates of TB transmission*, such as homeless people, injection drug users and others in high risk congregate settings, as determined by epidemiological data to support testing and treatment. • People who work or reside with other people at high risk for TB in facilities or institutions such as hospitals, homeless shelters, correctional facilities, nursing homes and residential homes for those with HIV, as determined by epidemiological data to support testing and treatment*. • Other non-U.S.-born individuals not referred from EDN or a Civil Surgeon* seeking services for TB infection and who do not have resources for medical care** outside the TB program.	• People with no known risk factors for TB infection or progression to TB disease.
*refer to <i>XI. Manage Electronic Disease Notification System and Other Foreign-Born Referrals</i> **Resources for medical care include Medicare, Texas Health Steps providers, community sliding scale clinics and Federally Qualified Health Centers (FQHCs) that treat TB infection.		



TB Unit Responsibilities

The TB Unit, also referred to as central office, administers TB program services in accordance with Texas Health and Safety Code Chapter 31, Primary Health Care by allocating funds to LHDs and DSHS PHRs to perform TB prevention and care activities statewide. The TB Unit establishes core elements to design a funded TB program, prepares and maintains standards of care, and develops methods to deliver appropriate services. The TB Unit provides laboratory support, medications, testing supplies, courier transport, continuing quality improvement, epidemiological, nursing and medical consultation services to funded TB programs to enhance service delivery capacity.

The vision of the TB Unit is a Texas free of TB and the mission is to eliminate TB as a public health threat.

The TB Unit performing programmatic activities will:

- A. distribute funds to LHDs and PHRs to maximize the delivery of authorized services to eligible patients;
- B. monitor TB programs' budget expenditures on a quarterly basis. If annual expenditures are consistently below projected amounts, the budget may be decreased;
- C. provide expert nursing consultation;
- D. oversee binational TB program activities;
- E. develop standards for TB prevention and care in Texas;
- F. monitor and evaluate TB programs' progress towards performance objectives to determine effectiveness and compliance with essential TB prevention and care standards;
- G. provide technical assistance on TB prevention and care activities;
- H. work with the DSHS Pharmacy to ensure availability of medications and supplies to treat TB disease and infection;
- I. provide Texas-specific TB training directly or in collaboration with Heartland National TB Center (HNTC) and other partners;
- J. oversee molecular epidemiology practices and provide technical assistance to investigate transmission patterns and cluster events;
- K. oversee TB prevention and care in high risk populations, including correctional facilities, community corrections, homeless shelters, and other congregate settings;



- L. oversee targeted testing initiatives;
- M. develop and revise standards and regulations;
- N. serve as liaison with CDC and other federal and state partners;
- O. serve as point of contact for international activities involving TB prevention and care; and
- P. conduct continuing quality improvement (CQI) activities.

The TB Unit performing surveillance and reporting activities will:

- A. promote active surveillance activities among TB programs receiving state funding;
- B. collect and analyze reporting data entered into the TB, HIV, STD Integrated Systems (THISIS);
- C. serve as repository for TB data reported to DSHS;
- D. collect and analyze reports from TB programs to satisfy TB grant requirements;
- E. serve as point of contact for inter-jurisdictional patient transfers;
- F. promote security and confidentiality standards for TB data exchanges;
- G. prepare and report aggregate TB data to CDC;
- H. prepare TB epidemiologic reports;
- I. provide technical assistance to funded TB programs for accurate submittal of TB data to the TB Unit; and
- J. serve as liaison for CDC's Division for TB Elimination (DTBE) Surveillance Team.

Funded local and regional TB programs will:

- A. serve as the point of contact for hospitals, private laboratories and other reporting entities within jurisdiction;
- B. identify at least one designated and one back-up person at each TB program responsible for entering data into the THISIS database;
- C. verify American Thoracic Society (ATS) classifications based on current TB Epidemiology Criteria and Surveillance Definitions Guide for suspected and confirmed cases of TB and latent TB infection, before data entry;



- D. submit notifications and updates for confirmed cases to the TB Unit according to set schedules in the Case Verification question package of THISIS (answer “yes” to “case submitted to the TB Branch” and include date);
- E. serve as point of contact for intra/inter-jurisdictional patient transfers and update outcome within one week of receipt of the Interjurisdictional Notification (IJN) form;
- F. enter CI data into THISIS, as listed on [Form 340](#) and [Form 341](#) for evaluation of contacts and verify ATS classification for the TB Unit to prepare and report contact aggregate data to CDC;
- G. complete items in assigned workflows in THISIS or task those items to other staff within reporting jurisdiction;
- H. update local protocols to guide quality assurance (QA) activities;
- I. review TB epidemiologic reports provided by DSHS and provide feedback;
- J. submit requested data in adherence to reporting schedules;
- K. host or coordinate and document trainings based on RVCT and QA, the IJN process and THISIS;
- L. participate in monthly TB conference calls, THISIS calls, work groups, surveys and other meetings;
- M. request access to THISIS by following instructions on *Requesting New Access to a DSHS Database* at dshs.texas.gov/thsvh/account.shtm and submit THISIS issues via the THISIS helpdesk; and
- N. promote security and confidentiality standards for TB data exchanges and storage (see dshs.texas.gov/hivstd/policy/procedures/2016-01.shtm).

DSHS TB Unit, PHRs and LHDs must comply with the following regarding TB prevention and care activities:

- A. Texas References:
 - 1. DSHS, *Standing Delegation Orders and Standing Medical Orders for Tuberculosis Prevention and Control*, dshs.texas.gov/idcu/disease/tb/policies/#sdo
 - 2. DSHS, *Texas Tuberculosis Work Plan*, dshs.texas.gov/IDCU/disease/tb/policies/TBWorkPlan.pdf
 - 3. DSHS, *TB Unit Standards*, dshs.texas.gov/idcu/disease/tb/policies/
 - 4. DSHS, *TB Standards for Texas Correctional and Detention Facilities*, dshs.texas.gov/IDCU/disease/tb/policies/TBCorrectionalStandards.pdf
 - 5. DSHS, *Video-Based Directly Observed Therapy, Required and Recommended Activities*, dshs.texas.gov/IDCU/disease/tb/policies/TBVDOTPolicy.pdf



6. DSHS, *Binational TB Program Manual*,
dshs.texas.gov/IDCU/disease/tb/policies/TBBinationalProgramManual.pdf
 7. DSHS, *Epi Case Criteria for TB*,
dshs.texas.gov/IDCU/disease/tb/policies/EpiCaseCriteriaforTB.pdf
- B. CDC's Morbidity and Mortality Weekly Report (MMWR), ATS and Other State and Peer-Reviewed References:
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: Diagnosis of Tuberculosis in Adults and Children*, 2016.
cdc.gov/tb/publications/guidelines/pdf/cid_ciw694_full.pdf
 3. *Recommendations for Use of an Isoniazid-Rifapentine Regimen with Direct Observation to Treat Latent Mycobacterium tuberculosis Infection*, *MMWR*. 2011; 60(48):1650-1653.
cdc.gov/mmwr/preview/mmwrhtml/mm6048a3.htm
 4. *Update of Recommendations for Use of Once-Weekly Isoniazid-Rifapentine Regimen to Treat Latent Mycobacterium tuberculosis Infection*, 2018. cdc.gov/mmwr/volumes/67/wr/mm6725a5.htm
 5. *American Journal of Respiratory and Critical Care Medicine, Diagnostic Standards and Classification of Tuberculosis in Adults and Children*, Vol. 161, 1376-1395, 1999. cdc.gov/tb/publications/PDF/1376.pdf
 6. CDC, *Aggregate Reports for Tuberculosis Program Evaluation: Training Manual and User Guide*, 2005.
cdc.gov/tb/publications/pdf/arpes_manualsm1.pdf
 7. CDC, *Controlling Tuberculosis in the United States*, *MMWR*, Vol. 54 (RR12), 1-69, 2005. cdc.gov/mmwr/preview/mmwrhtml/rr5412a1.htm
 8. CDC, *Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis*, *MMWR*, Vol. 54 (RR15), 1-43, 2005.
cdc.gov/mmwr/indrr_2005.html
 9. CDC, *Guidelines for the Prevention and Treatment of Opportunistic Infections Among HIV-Exposed and HIV-Infected Children*, *MMWR*, Vol. 58 (RR11), 1-166, 2009. cdc.gov/mmwr/indrr_2009.html
 10. CDC, *IGRA Blood Test Fact Sheet*, 2016.
cdc.gov/tb/publications/factsheets/testing/igra.htm
 11. CDC, *Mycobacterium tuberculosis: Report of Verified Case of Tuberculosis (RVCT) Instruction Manual*, 2009.
cdc.gov/tb/programs/rvct/InstructionManual.pdf
 12. CDC, *Quality Assurance for TB Surveillance Data: A Guide and a Toolkit*.
 13. CDC, *Targeted Tuberculin Testing and Treatment of Latent TB Infection*



(LTBI), *MMWR*, Vol. 49 (RR6), 1-43, 2000.

[cdc.gov/mmwr/PDF/rr/rr4906.pdf](https://www.cdc.gov/mmwr/PDF/rr/rr4906.pdf)

14. CDC, *Tuberculin Skin Testing (TST) Fact Sheet*, 2016.

[cdc.gov/tb/publications/factsheets/testing/skintesting.htm](https://www.cdc.gov/tb/publications/factsheets/testing/skintesting.htm);

15. CDC, *Tuberculosis Surveillance Data Training Report of Verified Case of Tuberculosis (RVCT) Instruction Manual*, 2009.

[cdc.gov/tb/programs/rvct/InstructionManual.pdf](https://www.cdc.gov/tb/programs/rvct/InstructionManual.pdf)

16. CDC, *Update: Adverse Event Data and Revised ATS/CDC Recommendations against the Use of Rifampin and Pyrazinamide for Treatment of Latent Tuberculosis Infection – United States*, *MMWR*, Vol 52 (RR31), 735-739, 2003. [cdc.gov/mmwr/PDF/wk/mm5231.pdf](https://www.cdc.gov/mmwr/PDF/wk/mm5231.pdf)

17. Curry International Tuberculosis Center, *Drug-Resistant Tuberculosis: A Survival Guide for Clinicians*, Third edition.

currytbcenter.ucsf.edu/products/view/drug-resistant-tuberculosis-survival-guide-clinicians-3rd-edition

18. CDC, *Report of Expert Consultations on Rapid Molecular Testing to Detect Drug-Resistant Tuberculosis in the United States*.

[cdc.gov/tb/topic/laboratory/rapidmoleculartesting/](https://www.cdc.gov/tb/topic/laboratory/rapidmoleculartesting/)

C. Federal and state regulations and statutes, including but not limited to:

1. Texas Tuberculosis Code, Texas Health and Safety Code, Chapter 13, Subchapter B. statutes.capitol.texas.gov/Docs/HS/htm/HS.13.htm
2. Communicable Disease Prevention and Control Act, Texas Health and Safety Code, Chapter 81. statutes.capitol.texas.gov/Docs/HS/htm/HS.81.htm
3. Screening and Treatment for Tuberculosis in Jails and Other Correctional Facilities, Texas Health and Safety Code, Chapter 89. statutes.capitol.texas.gov/Docs/HS/htm/HS.89.htm
4. [Control of Communicable Diseases](#), Texas Administrative Code (TAC), Title 25, Part 1, Chapter 97, Subchapter A. sos.texas.gov/tac/index.shtml
5. [Tuberculosis Screening for Jails and Other Correctional Facilities](#), TAC, Title 25, Part 1, Chapter 97, Subchapter H. sos.texas.gov/tac/index.shtml
6. [Medical Records](#), TAC, Title 22, Part 9, Chapter 165, Rule §165.1. sos.texas.gov/tac/index.shtml



II. Program Stewardship and Accountability

General Requirement

TB programs will implement a comprehensive TB program and manage resources in an effective manner that focuses on stewardship and accountability. Accounts for TB services (i.e. Quest account numbers, ITEAMS accounts, therapeutic drug monitoring requisitions containing TB Unit billing information, etc.) cannot be shared with entities outside the health department.

TB programs will:

- A. implement a comprehensive TB prevention and care program;
- B. develop and maintain TB protocols;
- C. provide services to evaluate, treat and monitor patients with suspected or confirmed TB disease without consideration of a patient's ability to pay;
- D. initiate contact investigations (CIs);
- E. provide services to evaluate, treat and monitor contacts to suspected or confirmed cases of pulmonary, pleural or laryngeal TB disease without consideration of a patient's ability to pay;
- F. initiate court-ordered management when needed;
- G. provide treatment services for at-risk people diagnosed with TB infection without consideration of a patient's ability to pay;
- H. provide services to evaluate, treat and monitor Class A and B immigrants and refugees without consideration of a patient's ability to pay;
- 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. perform targeted testing based on epidemiologic assessments;
- L. serve as subject matter experts on screening recommendations for community partners including but not limited to licensed adult and child-care facilities;
- M. apply appropriate administrative, environmental and respiratory controls to prevent exposure to and transmission of TB;
- N. provide professional education, training and orientation for new TB program



- staff and maintain continuing education for current TB program staff;
- O. monitor budget expenditures and maintain accurate, concise records;
- P. comply with confidentiality and security standards;
- Q. monitor surveillance, reporting and case management activities in correctional facilities;
- R. perform self-auditing activities to assess clinical care services and reporting practices;
- S. perform continuous quality improvement activities to achieve Texas performance measures; and
- T. take THISIS training courses and maintain timelines outlined in the TB Unit's THISIS Training and Implementation Plan (TIP).



III. Conduct Overall Planning and Develop Protocols

General Requirement

TB Programs will develop and maintain protocols that align with the TB Work Plan and TB Unit standards. TB Unit standards and procedures are published on DSHS' TB website, texastb.org. Local and regional protocols must not contradict TB Unit requirements and guidelines.

Activities

- A. Develop and implement written protocols covering the following topics:
 - 1. Program administration
 - 2. Training
 - 3. Reporting
 - 4. Surveillance
 - 5. Infection prevention
 - 6. High risk population screening and evaluation
 - 7. Discharge planning and continuity of care
 - 8. Cohort review
 - 9. Program evaluation
 - 10. Laboratory testing for TB
 - 11. Case management
 - 12. Contact investigation
 - 13. Patient confidentiality and security
 - 14. Incident reporting
 - 15. Cluster and outbreak investigations
 - 16. False positive investigations
 - 17. Directly observed therapy
 - 18. Use of video enabled technology for directly observed therapy
 - 19. Sputum collection
 - 20. Emergency planning that would impact TB services (i.e. natural disasters that could disrupt DOT)
- B. Ensure written protocols are easily accessible to all staff responsible for TB prevention and care activities.
- C. Review protocols at least once every three years and revise as appropriate to conform to DSHS standards and best practices.



IV. Standards of Care for Tuberculosis Services

General Requirement

Tuberculosis programs will follow the minimum standards of care for patients receiving TB prevention and care services in Texas. The minimum standards, in accordance with the DSHS TB Work Plan and TB Unit [Standing Delegation Orders](#) (SDOs), are intended for authorized TB program staff working in LHDs and PHRs. Each TB program will have systems in place to ensure activities in this chapter are met.

Activities

A. Adopt and utilize SDOs.

1. The TB Unit is responsible for developing and updating SDOs that are consistent with national guidelines and recommendations from DSHS-recognized medical TB consultants.
 - a) TB programs may choose to adopt the DSHS SDOs or develop their own.
 - b) If TB programs develop local SDOs, they must meet the minimum standards outlined in the DSHS SDOs.
 - c) TB programs may add their name and logo to the DSHS SDOs. They may also elect to use the DSHS SDOs to develop local protocols.
2. Orders cannot be removed from the DSHS SDOs, but the reviewing physician may elect to add additional orders or modify the format.
3. TB Program staff authorized to carry out SDOs must sign attestation pages from the SDOs.
 - a) DSHS SDOs are revised yearly. The TB program manager and program staff should review SDOs after each release. This may occur via a one-day in-service training with staff to ensure a thorough understanding of the SDOs. In-service trainings are an ideal time to collect staff signatures.
 - b) Attestation pages must be kept at the health department and made available upon request by the TB Unit.
 - c) SDOs must be reviewed and signed by the current physician responsible for TB services (e.g., contracted TB physician, regional medical director, local health authority) at least yearly or when changes occur.

B. Provide patient-centered care.

1. Provide culturally competent care; consider preferred language, age and literacy level when discussing TB pathology, transmission, treatment options and plan of care. DSHS programs may use language services on the DSHS intranet (online.dshs.internal/translations/?terms=language+services). Local health departments must have translation services available.



2. Assess and identify variables that may impact patient's adherence to therapy. Consider court-ordered therapy as a last, not initial, resort to adherence to the treatment plan.
 3. Identify barriers to care and develop strategies to meet individual patient needs.
 4. Develop a DOT patient-centered plan. Consider limitations to travel and support the patient in DOT, using their preferred location and time where possible. Video-enabled DOT should be considered for eligible patients where possible. Refer to *DSHS Video-Enabled Directly Observed Therapy Required and Recommended Activities Manual* when using VDOT for eligible patients
dshs.texas.gov/IDCU/disease/tb/policies/TBVDPolicy.pdf
 5. Telemedicine may be considered for medical case management of patients evaluated by the TB program, as determined by the treating physician. If telemedicine is utilized, ensure the standards of care for TB are maintained. L/RHDs should develop written processes for how telemedicine is addressed based on local regulations and guidelines, and following Texas statute:
statutes.capitol.texas.gov/Docs/OC/htm/OC.111.htm
- C. Prioritize referrals and screen for TB disease and TB infection.
1. Any patient referred or seeking evaluation for TB at the TB program should be prioritized for services (see [Table 1. Prioritizing Evaluation for TB Services](#)).
 - a) Patients with known or suspected TB disease must be prioritized for evaluation within three business days of the report.
 2. Every patient aged two years and older who qualifies for services should be screened using an IGRA as the preferred TB screening test.
 - a) The TB Unit provides IGRAs at no cost to TB programs. IGRAs should only be used among populations described in this document.
 3. TSTs may be used for patients who qualify for services and are younger than two years or who refuse or cannot tolerate phlebotomy.
- D. Ensure the availability of radiology services.
1. Every program must have radiology services available, whether in-house or through a contract or local partnership.
- E. Implement location-appropriate isolation (home based or negative pressure air-borne infection isolation room [AIIR] if in-patient or in a congregate setting).
1. A nurse may place a patient in isolation by issuing the patient a TB control order signed by the local health authority.
 2. Patients released from isolation will have the date of release documented in the medical record. A nurse may release a patient from isolation after written instructions by the treating physician are issued



and once criteria for release from isolation are met. The treating physician may determine if the SDOs suffice for written instruction or if they prefer reviewing all requests before release from isolation.

F. Ensure the completion of specimen testing.

1. TB programs must have the capacity to obtain natural and induced sputum specimens when indicated.
2. TB programs that do not have sputum induction booths may purchase portable nebulizers using locally budgeted TB funds. Hypertonic solution for nebulization is available through the DSHS Pharmacy if 0.9% sodium chloride does not yield an adequate sample (see [Appendix H: DSHS TB Formulary](#)).
3. TB Programs must ensure that all specimens positive for *M. tb* by Nucleic Acid Amplification Test (NAAT) or polymerase chain reaction (PCR) are followed by culture and drug susceptibility testing. Ship at least one isolate, preferably the initial isolate to the DSHS Laboratory for genotyping.

G. Perform routine patient assessments.

1. Every patient on a medication regimen for TB disease or infection will have at minimum, a baseline and monthly nursing assessment with a physical exam and toxicity screening documented in the medical record.
2. Toxicity screening must be performed according to drug regimen.
3. Programs should ensure that the treating TB physician has reviewed and signed the medical record for patients with an ATS classification of 3 or 5 at the following intervals, at minimum:
 - a) upon treatment initiation;
 - b) at eight weeks of therapy or upon completion of the 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 or other reasons; and
 - f) as determined by the treating physician when orders are updated or need to be revised.
4. For patients receiving treatment for TB infection, there must be documentation of communication between a licensed nurse and patient at least monthly. Additional documentation must include:
 - a) a physical exam and/or toxicity screening; and
 - b) medication refill information, including drug name, dosage, lot number and expiration date provided to the patient or designee.

H. Provide directly observed therapy (DOT).

1. Every patient with an ATS classification of 3 or 5 will be placed on DOT for the duration of treatment, unless otherwise ordered by the treating physician.



- a) Daily therapy is preferred (either 5x/week or 7x/week) to intermittent therapy where possible.
 - b) DOT must be initiated as soon as possible, but no longer than one week of outpatient treatment initiation.
 2. Patients on isoniazid and rifapentine (3HP) may be treated by self-administration therapy (SAT) with a physician's order.
 3. DOT for TB infection is highly recommended for patients aged 4 and younger, as resources allow.
 4. DOT packets should be ordered through ITEAMS.
 5. If self-administration is needed temporarily to accommodate holidays, travel, or a patient moving out of Texas, programs may provide up to one month's worth of DOT packets. Any more than that should be pre-approved by the TB Unit. NOTE: the treating physician may determine how many doses of self-administration will "count" towards completion of adequate therapy, however DOT must be provided for at least 80% of the total treatment. Refer to *K. Ensure the completion of adequate therapy*, below.
 6. Video-enabled directly observed therapy (VDOT) may be utilized by TB programs when patients are recommended for DOT.
- I. Manage pediatric patients aged 17 and younger.
 1. The initial evaluation for TB disease or TB infection in patients aged 5 and younger will include a physical examination by a physician or other licensed clinician.
 2. If parents or guardians of patients aged 17 and younger decline treatment for TB infection, treating physician will provide a letter advising treatment.
 - a) A copy of the letter will be maintained in the patient's medical record.
 - b) The treating physician may consider additional steps such as a Child Protective Services (CPS) notification. See [Appendix A: Sample Letter for Child Window Prophylaxis](#) for sample correspondence.
- J. Seek expert consultation when indicated.
 1. Treatment for tuberculosis (TB) disease may become complicated in the presence of drug-resistance, age of the patient aged 17 years and younger, co-infection with HIV, or the presence of other medical issues. In these or other circumstances where expert recommendations are needed, seek consultation through DSHS recognized TB medical consultants. See dshs.texas.gov/disease/tb/consultants.shtm
 2. A list of required and recommended reasons for consultation is listed in the SDOs.
 3. When a consultation is required, the consultation and results (recommendations) must be kept in the medical record.



- K. Ensure the completion of adequate therapy.
 - 1. Ideally, every patient with TB disease will complete therapy as specified in the SDOs with 100% of doses taken by DOT.
 - 2. When closure at 100% is not possible, patients should have at least 80% of treatment for TB disease completed by DOT.
 - 3. TB cases eligible to complete treatment within 12 months must complete therapy within 365 days or less.
 - 4. Follow minimum doses for treatment completion of TB infection, as specified in the DSHS SDOs.
 - 5. If the above criteria are not met and the decision to close a case is made, reason for closure despite adequate therapy must be documented in the medical record, with recommendations for any follow-up made by the treating physician.

- L. Initiate contact investigations.
 - 1. Every respiratory TB case or suspect must have a CI initiated within three working days.
 - 2. Every acid-fast bacillus (AFB) smear positive sputum case must have at least three identified contacts.
 - 3. Submit an incident report to the TB Unit for mass or concerning CIs.
 - 4. Every contact will have a complete evaluation and be referred for treatment when indicated. Patients who decline a complete evaluation for TB infection, including patients needing evaluation for window prophylaxis, will be informed of the implications regarding their decision. Documentation of this communication will be kept in the patient's medical record (use [form TB 230](#) or equivalent).

- M. Clarify roles and responsibilities of TB program staff.
 - 1. It is the role of the TB program manager to:
 - a) ensure a process exists for assigning care to each new patient seeking services;
 - b) ensure a plan of care exists and documentation of shared roles of the TB program and community providers is included in the medical record; and
 - c) ensure patients and/or their guardians are given opportunities to comply with the treatment plan.
 - 2. It is the role of the TB physician to:
 - a) Review and sign SDOs upon assuming care for patients with TB and yearly;
 - b) work with the TB program manager to ensure staff understand SDOs and are provided the opportunity to ask clarifying questions;
 - c) ensure a process exists for responding to signs and symptoms of medication toxicity or other patient concerns when reported by the licensed nurse;
 - d) provide clear expectations to staff working under SDOs regarding the frequency of physician assessments, process of



- obtaining signed medical orders from the treating physician and communication with TB program staff; and
 - e) ensure a process exists for seeking medical consultation with a DSHS recognized TB medical consultant (i.e., coordination between TB physician and nurse).
3. It is the role of the physician writing orders for and managing the patient (if different from the physician who signs the SDOs) to:
- a) ensure all patients, especially patients with drug-resistant TB (DR TB), pediatric patients or other high-risk patients, are managed according to the standards of care for treatment as outlined in the SDOs.
4. It is the role of the nurse case manager to:
- a) ensure all patients have current medical orders from the licensed healthcare provider;
 - b) ensure patients are started on adequate therapy;
 - c) ensure routine assessment of patients per the TB Work Plan and SDOs are performed;
 - d) acknowledge and follow SDOs;
 - e) document assessments and monthly toxicity screenings, including documentation of interventions performed related to any abnormal findings; and
 - f) notify the treating physician if a required toxicity screening does not occur, as medications should not be administered to patients for which screening cannot be completed.



V. Manage Patients with Suspected or Confirmed Tuberculosis

General Requirement

It is the responsibility of the health department to ensure patients receive timely follow-up and, when indicated, treatment for TB. This follow-up should occur either directly or indirectly by the health department:

- Directly, through case management, DOT, radiology, laboratory, nursing, and physician services performed by the health department staff.
- Indirectly, through close collaboration with external medical partners (e.g., nursing homes, physicians' offices) when a direct provision of services is not performed by the health department. This collaboration includes establishing routine communication channels, delineation of duties, and frequent monitoring to ensure DSHS standards are maintained.

This chapter reflects all activities necessary for initiating and following patients with suspected or confirmed TB.

TB programs will:

- provide services to evaluate, treat and monitor patients with suspected or confirmed TB disease, regardless of ability to pay;
- ensure TB patients are appropriately managed, regardless of their jurisdiction; and,
- adhere to procedures outlined in the DSHS SDOs for Tuberculosis Prevention and Care.

Activities

- A. Collaborate with health care institutions, hospitals, long-term care facilities, private physicians and correctional facilities to ensure appropriate management and treatment of patients with suspected or confirmed TB disease. *It is the health department's responsibility to ensure standards of care are being followed regardless of where the patient is being managed.*
- B. Establish and maintain a medical record for each person with suspected or confirmed TB disease and document a plan of care on the [TB-201](#) or equivalent.
 1. Organize medical records according to locally determined chart order with sections clearly divided.
 2. Ensure all documents are securely attached to the medical record.
 3. Provide accurate and complete documentation.
 4. Date and sign all entries in the progress notes and draw a line through each blank section.
 5. Document in chronological order.



6. Draw a single line through errors and initial.
 7. Do not document outside the margins.
 8. Establish a locally approved list of abbreviations.
 9. The medical record should include at minimum the information that is asked on the following [DSHS forms](#) or equivalent¹:
 - a) TB 400A (Report of Case and Patient Services)-completed initially
 - b) TB 400B (Report of Case and Patient Services)-completed initially and updated when indicated
 - c) TB-201 (Case Management Plan for Outpatient Care)
 - d) TB-202 (Tuberculosis Health Assessment/History)
 - e) TB-203 (Education/Counseling Record)
 - f) TB-204 (Tuberculosis Forms/Literature Checklist)-this form may be modified with updated literature used locally
 - g) TB-205 (Toxicity Assessment)
 - h) TB-206 (DOT Log)
 - i) TB-700 Series (For patients on second-line medications)
 - j) L-36 (General Consent and Disclosure)
 - k) L-30 (Consent to Release Confidential Medical Information)
 - l) TB 409 (Acknowledgement of Understanding)
 - m) TB-410 (Order to Implement and Carry Out Measures for Patients with TB)
 - n) TB 411 (Disclosure and Consent for Drug Therapy)
- C. Coordinate discharge planning with in-patient facilities or correctional facilities for patients being released to outpatient care. The following discharge planning criteria should be met:
1. A specific plan exists for follow-up care, regardless of management facility.
 2. When possible, patients should be served the TB control order ([TB-410](#)) before being discharged or released to outpatient care.
 3. Patient is started on the standard multi-drug TB treatment regimen and DOT arranged.
 4. No infants or children aged four and younger or people with immunocompromising conditions are present in the household of an infectious patient (when possible).
 5. Patient is advised of travel restrictions while infectious.

¹*THISIS is not a medical record, however it contains elements of what is typically maintained in a medical record, as obtained from the listed TB forms. Data entry requirements in THISIS do not replace the need to maintain a patient's medical record. Therefore, to avoid duplicate entry, content from THISIS may be printed and saved in the medical record.*



- a) Except for healthcare-associated visits, direct patients to refrain from travel outside the home until patient has met criteria to discontinue AII.
 - b) Direct patients traveling for healthcare-associated visits to wear a surgical mask for the duration of travel and visit and notify the receiving agency before visit.
- D. Obtain acknowledgment and consent for treatment and care.
 - 1. Maintain signed consents and acknowledgements (DSHS or local equivalent) in the patient's medical record.
 - 2. If the patient moves to another jurisdiction, [Form TB-410](#) and acknowledgment/consent forms must be prepared by the receiving jurisdiction and submitted to the patient for signature.
- E. Develop a treatment and case management plan.
 - 1. Develop an initial treatment and case management plan for each patient **within one week of receiving the report of a new ATS class 3 or 5** and document on [Form TB-201](#) or equivalent.
 - a) TB programs must maintain oversight of patients receiving TB care from private providers outside the health department to ensure DSHS treatment standards are followed. State-purchased medications cannot be used to support a medication regimen that does not align with DSHS treatment standards.
 - b) Create a written agreement describing the shared roles and responsibilities in the delivery of TB care services between a private provider and the TB program.
 - (1) Present a written plan to the private provider and patient to ensure proper treatment, coordination of care and reporting.
 - (2) See [Appendix A: Sample Letter for Child Window Prophylaxis](#), [Appendix B: Sample Tuberculosis Program and Private Physician Agreement Letter](#), and [Appendix C: Sample Correspondence Letter for Patients Treated by Private or Community Providers](#) for sample correspondence.
 - 2. Facilitate the establishment of and identify a medical home for each patient. Regardless of patient's insurance status, identify community resources that serve patients, including indigent patients and the uninsured, and refer as appropriate. Referrals would include any findings made by the TB program that require medical intervention including but not limited to non-tubercular mycobacterium, diabetes, HIV. When applicable, provide referrals for patients needing primary or specialty clinical care:
 - a) Uninsured patients may be referred to FQHCs to ensure they have access to primary and specialty care (see dshs.texas.gov/chpr/fqhcmmain.shtm).



- b) Indigent patients may qualify for medical assistance in their county of residence (see hhs.texas.gov/services/health/county-indigent-health-care-program).
 - c) See *Appendix E: Additional Patient Services* for additional patient services.
- F. Implement initial infection prevention practices (see *XVI. Implement Infection Prevention Procedures* for more information).
 - 1. Place a surgical mask on patients who arrive at the clinic for TB services.
 - 2. Patients classified as class 3 or 5 based on the ATS classification system should be placed in location-appropriate isolation (air-borne infection isolation room [AIIR]) if in a congregate setting or respiratory isolation if home-based (refer to chapter 6 of the *Core Curriculum on Tuberculosis: What the Clinician Should Know, Seventh Edition* cdc.gov/tb/education/corecurr/pdf/CoreCurriculumTB-508.pdf). Maintain documentation in the medical record, unless criteria for release from isolation is met as outlined in the SDOs.
- G. Provide and document initial and ongoing patient education.
 - 1. Provide patient education on:
 - a) transmission and pathogenesis of TB;
 - b) means to decrease transmission and the need for infection control;
 - c) rationale for DOT;
 - d) seriousness and importance of completing treatment;
 - e) significance of conducting a complete and thorough CI;
 - f) protected health information (PHI);
 - g) adverse drug reactions and drug interactions of TB medications;
 - h) the need for patients to discuss adverse drug reaction symptoms and other treatment concerns with nurse case manager as soon as they occur;
 - i) consequences of non-adherence to treatment; and
 - j) unobserved specimen collection.
 - 2. Document initial and ongoing education and counseling on [Form TB-203](#) or equivalent.
- H. Conduct TB screening and evaluation in accordance with DSHS SDOs.
 - 1. Determine the appropriate TB screening method based upon:
 - a) patient age;
 - b) Bacillus Calmette-Guerin (BCG) status; and/or
 - c) other factors outlined in the SDOs.
 - 2. Conduct and document the medical evaluation.
 - a) Screen for TB signs and symptoms.
 - b) Collect patient medical and social history.
 - c) Conduct physical exam.



- d) Collect sputum specimens per SDOs and/or clinical specimens if warranted (see [Table 2. Types of Specimens Collected to Diagnose TB Disease](#)).
3. Screen for existing comorbid conditions (e.g., diabetes, HIV, hepatitis B and C, per SDOs). Collect the following diagnostic results and provide to treating provider for review and signature:
 - a) Baseline TB screening test results.
 - b) CXR (see [Table 3. Common Terminology Used on a Chest X-Ray Report](#)).
 - c) AFB smear results and bacteriology (see [Table 5. Acid Fast Bacilli Smear Classification Results](#)).
 - d) Drug susceptibility test (DST) results (see [Table 4. Drug Susceptibility Patterns](#)). Extended drug susceptibility testing must be performed on all isolates with resistance to first line agents (isoniazid, rifampin, and ethambutol).
 - e) Additional TB testing as needed for a diagnosis (see [Table 6. Tuberculosis Diagnostic Testing](#)).
4. Ensure shipment of initial isolate to DSHS Laboratory in Austin for genotyping regardless of the laboratory that performed acid fast bacilli (AFB) smear and culture tests.
5. Prepare a written TB control order for people with suspected (ATS class 5) or confirmed TB disease (ATS class 3).
 - a) Use [Form TB-410](#) or equivalent. This form is required even if patient refuses to sign. Note date and time provided to patient.
 - b) Prepare written control order in patient's preferred language, ideally within three days of classification.
 - c) Document in the medical record if an interpreter or guardian read the control order to patient before patient signed it.

Table 2. Types of Specimens Collected to Diagnose TB Disease

Diagnosis Type	Specimen Needed
Pulmonary or laryngeal TB	• Sputum (phlegm from deep in the lungs). • If a pulmonary TB diagnosis cannot be established with sputum collection, other procedures may be necessary (e.g., bronchoscopy, gastric aspiration. Laryngeal TB may be diagnosed from clinical signs and symptoms (i.e. hoarseness) or by biopsy.
Extra-pulmonary TB	• Anatomic sites include but are not limited to: ○ Urine ○ Cerebrospinal fluid ○ Pleural fluid ○ Pus or other aspirated fluid ○ Biopsy specimens ○ Blood (heparinized)

Adapted from *Controlling Tuberculosis in the United States: Recommendation from the American Thoracic Society, CDC, and Infectious Diseases Society of America*, by Centers for Disease Control and Prevention, 2005, *Morbidity and Mortality Weekly Report*, 54(RR-12).
[cdc.gov/mmwr/preview/mmwrhtml/rr5412a1.htm](https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5412a1.htm)



Table 3. Common Terminology Used on a Chest X-Ray Report

CXR Finding	Meaning
Consolidation	Often referred to as an ill-defined opacity
Cyst/cavity	Focal spaces or “holes” in the lung: both indicate the absence of lung tissue; a cavity being more likely to be TB, and generally indicative of greatest infectiousness
Fibrosis	May or may not be active disease and requires further evaluation
Granuloma	A small, calcified nodule, usually not indicative of active disease
Opacity	A circumscribed area that appears nearly white (i.e. denser) than its surroundings; may be parenchymal, pleural, within the chest wall or external to the patient
Lymphadenopathy	Enlarged lymph nodes seen as soft tissue densities: usually more indicative of active disease in a child
Miliary	Many tiny nodules resembling millet seeds scattered throughout
Nodule	Discrete opacity measuring two to 30 millimeters (mm) in diameter
Mass	Discrete opacity (nodule) greater than 30 mm in diameter; often indicative of a carcinogenic process

Table 4. Drug Susceptibility Patterns

Category	Sensitivity Patterns
Pan-sensitive	Sensitive to streptomycin, isoniazid, rifampin, ethambutol and pyrazinamide
Mono-resistant	Resistant to one first-line anti-TB drug only
Poly-resistant	Resistant to at least two first-line anti-TB medications (but not both isoniazid and rifampin)
Multi-drug resistant	Resistant to both isoniazid and rifampin
Pre-extensively drug-resistant	Resistant to isoniazid and rifampin, plus resistant to any fluoroquinolone or at least one of three injectable second-line drugs (such as amikacin, kanamycin or capreomycin)
Extensively drug-resistant	Resistant to isoniazid and rifampin, plus resistant to any fluoroquinolone and at least one of three injectable second-line drugs

Adapted from *Tuberculosis Nursing: A Comprehensive Guide to Patient Care, Second ed.*, National Tuberculosis Controllers Association, 2011.



Table 5. Acid Fast Bacilli Smear Classification Results

Quantity Reported*	DSHS Laboratory Quantitation	Smear Result	Infectiousness of Patient
4+/numerous (>9/field)	>10/field	Strongly positive	Probably very infectious
3+/few-numerous (1-9/field)	1-10/field or >10/field	Strongly positive	Probably very infectious
2+/few (1-9/10 fields)	<1/field or 1-10/field	Moderately positive	Probably infectious
1+/rare (1-9/100 fields)	<1/field	Moderately positive	Probably infectious
Actual number of AFB seen (no plus sign) (1-2/300 fields)	1 or 2 AFB seen on entire smear	Weakly positive [†]	Probably infectious
No acid-fast bacilli seen	No AFB seen on direct smear	Negative	Probably not infectious ^β

* Reporting methods may vary by laboratory. Check with your laboratory for specific interpretation.

[†] Laboratories may report these smear results as “doubtful” or “inconclusive” based on CDC guidelines.

^β Criteria for determining whether a patient may be considered noninfectious are discussed in Module 5: “Infectiousness and Infection Control” of the CDC’s *Self-Study Modules on Tuberculosis*.

Adapted from *Core Curriculum on Tuberculosis: What the Clinician Should Know, Sixth ed.*, Centers for Disease Control and Prevention, 2013; *Tuberculosis Nursing: A Comprehensive Guide to Patient Care, Second ed.*, National Tuberculosis Controllers Association, 2011.



Table 6. Tuberculosis Diagnostic Testing

Test* and Timeframe for Results	Definition	Purpose and Implications for Clinical Management
Acid-fast Bacilli (AFB) Smear <i>24 hours</i>	Mycobacteria that retain color after a fluorochrome staining. Under a microscope they appear rod-shaped and fluorescent.	• Presence may indicate TB disease but does not confirm a diagnosis, as some AFB are non-tuberculosis mycobacterium (NTM) disease. • The amount of AFB detected may correlate with infectiousness of a patient and the decrease in quantitation of AFB reported may be used to follow effectiveness of treatment (e.g. as treatment progresses, the number of AFB detected should decrease.) • Test results should be correlated with patient clinical and radiological findings. • Negative smears do not exclude TB disease.
AFB Culture and Identification <i>21 days (for most positive cultures) up to 6 weeks.</i> <i>NOTE: A specimen with a heavy M.tb load can be M.tb culture positive in 4 to 5 days.</i>	Test to identify viable M.tb organisms	• A positive culture confirms diagnosis of M.tb. • Culture results assist in monitoring response to treatment. • Positive results should be reported to the clinician as soon as possible. • Negative results should be used in correlation with the patient's clinical and radiological findings and treatment recommendations by the clinician. • Culture positive after 4 months of appropriate therapy is deemed as treatment failure. Consult required with a DSHS-recognized medical TB consultant.
Nucleic Acid Amplification Test (NAAT) <i>48 hours</i>	Used for rapid detection of M.tb DNA or RNA in patient specimen.	• Assists in the ability to rapidly diagnose or exclude M.tb. • While NAATs are more sensitive than AFB smear results, they do not replace AFB smear and/or culture results. • Does not distinguish between viable, disease-related organisms and nucleic acid persisting from prior disease. • Interpret results in the context of the clinical situation and AFB smear results. • Positive results should be communicated to the clinician immediately. • Negative results should be correlated with patient clinical and radiological findings in consultation with the treating clinician. • See algorithm for NAAT Interpretation and Response in SDOs.



Test* and Timeframe for Results	Definition	Purpose and Implications for Clinical Management
Polymerase Chain Reaction (PCR) <i>48 hours</i>	Testing technique used to amplify small segments of M.tb DNA in a specimen. PCRs are a type of NAA technique.	• Same as NAAT. • Rapid test to help identify M.tb more quickly than conventional culture methods. • Does not distinguish between viable, disease-related organisms and nucleic acid persisting from prior disease. • Ensure a culture is in progress. • Some clinicians request the cycle threshold (Ct) values, which provides the number of cycles necessary to detect the nucleic acid target of the PCR test. Collaborate with the laboratory to assist in obtaining these results when rifampin resistance is detected.
Cepheid GeneXpert Test (Xpert) commercial name is Cepheid MTB/RIF Assay <i>48 hours</i>	NAA test used for rapid diagnosis of TB disease and rifampin resistance on both AFB smear negative and smear positive specimens. The Xpert test is based on PCR technology that utilizes probes (A-E) that bind to different sections of the rpoB gene of M.tb DNA.	• Detects the presence of M.tb and the most common mutations in the rpoB gene that confer rifampin resistance. • Ensure an Xpert test is in progress as not all labs that perform NAA testing use the Xpert test that result in a rifampin result. • Ensure culture is in progress. • Interpret results along with clinical, radiographic, and other lab findings. • Obtaining and evaluating rifampin resistant Xpert results, including the Ct values and the probe results, should be guided by a consultation with a DSHS-recognized medical TB consultant. • If a mutation is detected, this mutation must be confirmed and identified by sequencing such as the MDDR testing. Not all mutations result in rifampin resistance.
Molecular Detection of Drug Resistance (MDDR)** <i>2 to 3 business days</i>	Test to identify mutations that may cause resistance to multiple groups of drugs.	• MDDR does not replace DSTs but assists the clinician with useful information to guide treatment when drug resistance to at least rifampin and/or isoniazid is known or suspected. • The presence of mutations is a way to rapidly and accurately detect potential drug resistance. • The absence of mutations decreases the likelihood of resistance but is not a guarantee of susceptibility.



Test* and Timeframe for Results	Definition	Purpose and Implications for Clinical Management
		- Results should be shared with the treating physician and a DSHS-recognized medical TB consultant. - See Appendix G: Requesting Molecular Detection of Drug Resistance (MDDR) Testing for criteria and submitting process.
Drug Susceptibility Testing (DST) <i>First-line DST: 17 days after positive MTB culture</i> <i>DSHS Austin Laboratory reports Isoniazid, both concentrations, and Rifampin at 11 to 14 days after positive M.tb culture</i>	Tests M.tb organism to determine susceptibility or resistance to specific drugs.	- Indicates if the patient's TB can be treated with first- line TB medications or not. - NOTE: the DSHS state laboratory in Austin will automatically test an initial positive culture for susceptibility to all first line anti-TB medications and ofloxacin. - Results are critical for patient management, treatment regimen and duration of therapy. - Ensure that DSTs are in progress if the AFB culture results are positive for M.tb. - Consult required with a DSHS recognized TB medical consultant if resistance to isoniazid and/or rifampin is identified.
Minimum Inhibitory Concentration (MIC)** <i>Varies 4-12 weeks</i>	Test using a series of drug concentrations. The result is the lowest concentration that inhibits bacterial growth.	- Some situations may require an MIC that is useful for clinical management of a patient. - Should be ordered and followed in close consultation with a DSHS recognized TB medical consultant.
TB Genotyping+ (GENType) <i>MIRU: 2 weeks</i> <i>Spoligotype: 1 month</i>	Examines the DNA of M.tb that caused disease in the patient. Genotyping is based only on 1% of the TB genome.	- Genotyping utilizes two types of tests, namely: MIRU and Spoligotype. This allows for comparison and establishes relatedness between M.tb isolates. - Can add value to conventional contact investigations and help aid in identifying links between cases. - Allows monitoring the progress toward eliminating TB transmission more accurately. - When combined with epidemiologic data, genotyping helps to identify persons with TB involved in the same chain of recent transmission and to distinguish between persons whose TB disease is a result of TB infection that was acquired in the past. - Ensure initial isolate has been submitted to DSHS laboratory for genotyping regardless of the laboratory that performed AFB smear and culture results.



Test* and Timeframe for Results	Definition	Purpose and Implications for Clinical Management
Whole Genome Sequencing+ ** (WGS)	Examines genetic relatedness of isolates by expanding coverage of the genome to approximately 90%.	- Can provide greater resolution than GENType for investigating recent transmission and can detect mutations (see also rpoB alert, below). - WGS results are accessed through TB GIMS. If not available, a request may be made by contacting TB Unit epidemiologists. - Whole-genome single nucleotide polymorphism analysis (wgSNP) comparison trees (the plots that explain how closely related isolates are from each other) are automatically performed on concerning clusters identified by the CDC. - Can be used to support false positive investigations, contact investigations and cluster investigations.
RNA polymerase Beta Subunit (rpoB) alert**	<i>rpoB</i> is a gene (not a test) found in the TB bacteria. Mutations in this gene can be associated with rifampin resistant TB.	- A rpoB alert means the patient is <i>likely</i> resistant to at least rifampin. - NOTE: rpoB genes are present in all MTBC isolates. The alert identifies a MUTATION was detected in this gene by WGS. The alert may not reflect routine DSTs. - CDC reports rpoB alerts to DSHS laboratory and PHR's and LHD's are made aware of rpoB alerts by the DSHS nurse consultant. - Notify the treating clinician immediately. - Consult with DSHS-Recognized Medical TB Consultant as soon as possible.
* Most tests are performed at the DSHS State Laboratory in Austin and/or South Texas and are available at most commercial laboratories. The DSHS State Laboratory will ship isolates to references labs when indicated. ** Performed at the Centers for Disease Control and Prevention (CDC) Reference Laboratory. +Performed at the Michigan Department of Health & Human Services Bureau of Laboratories and CDC.		

I. Initiate standard therapy as ordered.

1. Treatment for drug susceptible TB includes two phases:

- Initial treatment phase: isoniazid (INH), rifampin (RIF), ethambutol (EMB) and pyrazinamide (PZA) for the first eight (8) weeks or until susceptibilities are known.
- Continuation treatment: INH and RIF for the remaining months.

2. Provide DOT and document on [Form TB-206](#) or equivalent.

- DOT is the standard of care in Texas. Provide DOT to all patients with suspected or confirmed TB disease. Patients with suspected TB should continue DOT until TB is ruled out.



- b) Indicate clearly which medications are provided. Note any medication changes on the log and sign.
 - c) Document every directly observed dose of medication administered to the patient.
 - d) If a patient takes self-administered doses on the weekend, and/or holidays, do not count the number of weekend and holiday doses towards completion of therapy.
 - e) Document all self-administered doses and missed doses.
 - f) Pursue appropriate actions for missed DOT or clinic appointments, up to and including court-ordered management.
- J. Ensure patients are managed and respond to therapy.
 - 1. Monitor and document baseline and monthly adherence to treatment, response to treatment and medication side effects or adverse reactions.
 - 2. Conduct monthly follow-up laboratory tests and assessments in accordance with the SDOs; document results and subsequent interventions as necessary.
 - 3. Initiate a consult from a DSHS-recognized TB medical consultant as indicated.
 - a) Indicators for consultation are listed in the SDOs.
 - b) Consults from DSHS-recognized TB medical consultants are required for any patient with DR TB, as outlined in the SDOs.
 - c) See [Appendix F: Medical Consultation Templates](#) for medical consultation templates.
 - 4. Consider serum drug level testing for patients not responding adequately to therapy or patients with risk factors for poor absorption of medication. See *Therapeutic Drug Monitoring Process* at dshs.texas.gov/IDCU/disease/tb/forms/PDFS/TherapeuticDrugMonitoringProcess.pdf.
 - 5. Report any known or suspected TB-related death to the TB Unit within 48 hours while investigating if TB was the cause of death. Send an email to: TB.feedback@dshs.texas.gov without including PHI. If cause of death is TB per the death certificate, investigate events surrounding the death to determine if the death was preventable. Communicate findings with the TB Unit when requested.
- K. Close the patient's medical record using any one of the following dispositions:
 - 1. Completion of adequate therapy
 - a) Treatment completed within 12 months.
 - b) Exceptions to completion of adequate treatment within 12 months apply if:
 - (1) patient has RR, MDR or XDR TB;
 - (2) patient is aged 14 or younger with miliary disease; or
 - (3) patient has meningeal disease.
 - 2. Non-TB



3. Deceased
4. Moved out of country
5. Lost to Follow-Up (LTFU)
 - a) Make at least three attempts to contact a TB patient before considering a patient as LTFU, including:
 - (1) calling the patient;
 - (2) visiting the patient's residence; and
 - (3) sending a certified-mail notification of the patient's need to follow-up with clinic.
 - b) Document attempts in the progress notes of patient's medical record.
 - c) Place certified mail notification receipt in the patient's medical chart.
- L. Request a Do not Board (DNB) or Be on the Lookout (BOLO) consultation for any person with confirmed or suspected TB who plans to cross the U.S. border and/or board an airplane, by emailing the DSHS epidemiology team at TBepi@dshs.texas.gov.
 1. Placing an individual on a DNB list prevents him/her from receiving a boarding pass and travelling via commercial aircraft departing from or arriving in the U.S.
 2. The BOLO is a travel intervention tool that prompts a public health review of an individual if they attempt to enter the U.S. through land, sea, or airports of entry. It is indicated when an individual entering the U.S. needs to be put in contact with public health authorities to ensure appropriate management of a communicable disease. **Every person placed on the DNB list is automatically issued a BOLO.**
 3. All requests to place an individual on the DNB list are reviewed by DSHS and the CDC during a conference call with the requesting entity. The following criteria must be met for CDC to place someone on the DNB/Lookout list:
 - a) The case or suspect must be infectious or likely to become infectious during travel.
 - b) The case or suspect is unaware of, or is likely to be noncompliant with, public health recommendations against commercial air travel or travel outside the U.S. Evidence to support non-adherence includes disregard for isolation recommendations, violation of Control Order or signed treatment contract, or evidence that the individual has compelling reasons to travel before receiving clearance by the local/regional TB program.
 - c) The local/regional TB program must have reason to believe the person will attempt to fly on a commercial aircraft or leave the U.S., as supported by a history of frequent travel, record of ticket purchase, new ticket reservation, or stated intent to travel by commercial aircraft or outside the U.S. by the



individual, a relative, or another credible source.

d) Procedures for Do Not Board/ BOLO:

- (1) Seek consultation with TB Unit epidemiologists first to review criteria.
- (2) If criteria are met, the TB Unit will submit a Do not Board/ BOLO request to the CDC Regional Quarantine Station Officer and Division of Global of Migration and Quarantine (DGMQ) team.
- (3) The TB Unit will convene a meeting with the local/regional TB program, CDC and DGMQ team, treating physician, the Local Health Authority (LHA), and the nurse case manager.
- (4) The LHA will notify the DSHS TB Epidemiology team, CDC Regional Quarantine Station Officer and DGMQ in writing when agreed upon criteria for release from Do Not Board or BOLO requirements are met.



VI. Treatment of Drug-Resistant Tuberculosis

General Requirement

TB programs will participate in the TB Unit's DR TB monitoring program. The purpose of the DR TB monitoring program is to collect, analyze, describe and respond to data used in the prevention and care of DR TB in Texas. This includes monitoring:

- Rifampin mono-resistance (RR-TB);
- Multi-drug resistance (MDR-TB);
- Pre-extensively drug resistance (Pre-XDR TB); and
- Extensively drug resistance (XDR-TB).

Activities

- A. Identify patients at risk for DR TB. Risk factors include:
 1. previous episodes of tuberculosis treatment, usually incomplete treatment;
 2. worsening clinical and/or radiographic findings while on TB treatment;
 3. country of origin, history of residence in, or frequent travel to a region or country with a high prevalence of DR TB;
 4. exposure to a person with known (or highly suspected) infectious DR TB; and/or
 5. exposure to people in congregate settings where drug resistance has been documented.
- B. Seek consultation with a DSHS-recognized TB medical consultant upon initial diagnosis or suspicion of DR TB. Notify the TB Unit Nurse Consultant within 2 days for any consults submitted for RR-TB, MDR-TB, Pre-XDR TB or XDR-TB.
 1. TB programs are made aware of drug resistance when:
 - a) a patient presents with known risk factors for DR TB;
 - b) laboratory testing supports a DR TB diagnosis:
 - (1) Rapid testing identified from a GeneXpert-NAAT or other PCR indicates rifampin resistance;
 - (2) DST results indicate resistance. Laboratory-confirmed drug resistance is defined as resistance to isoniazid and/or rifampin or to any drug other than streptomycin or pyrazinamide mono- resistance on drug susceptibility panel testing; and/or
 - (3) patient is reported to the TB program with other laboratory results that indicate resistance including: Molecular Detection of Drug Resistance (MDDR) or Whole Genome Sequencing (WGS) with *rpoB* mutations.
 2. Consultation with a DSHS-recognized TB medical consultant is required when:



- a) a patient has laboratory indications of drug resistance.
 - (1) Consultation must occur within three days of laboratory notification.
 - b) a patient is prescribed second-line TB medications other than first-line drugs due to DR TB;
 - c) the treating physician is requesting molecular detection of drug resistance (MDDR) testing; and/or
 - d) patient is a contact to a case of MDR-TB, Pre-XDR-TB or XDR-TB.
3. Additional consultation is strongly recommended when a DR TB patient:
- a) has a change in therapy or change in status;
 - b) misses required screenings;
 - c) exhibits signs of adverse drug reactions;
 - d) is discharged from [Texas Center for Infectious Disease \(TCID\)](#); and/or
 - e) any time the treating physician is concerned about the patient's status.
- C. Coordinate with DSHS Laboratory to ensure appropriate diagnostic tests are ordered. See [Table 6. Tuberculosis Diagnostic Testing](#) for definition, purpose and clinical implications.
- 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 rifampin 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 lab for rapid testing if patient has risk factors for DR-TB
 - 2. If rifampin resistance is detected, this may indicate resistance to additional first-line drugs; therefore, further testing would be indicated, such as an MDDR test.
 - 3. Request MDDR testing when appropriate (see [Appendix G: Requesting Molecular Detection of Drug Resistance \(MDDR\) Testing](#)).
 - 4. DSTs² are run on positive *M. tb* cultures sent to the DSHS laboratory. If resistance to primary drugs (excluding pyrazinamide mono-resistance) is detected, DSHS laboratory will reflexively set up second-line drug panel testing and will communicate directly with the submitter. Some second-line medications cannot be tested at the DSHS laboratory; therefore, programs should communicate directly with the laboratory to coordinate additional testing. If specimen was collected at an outside laboratory, consultation with a DSHS-

² Although there are significant advantages offered by rapid molecular assays, growth-based susceptibility testing remains an integral diagnostic test to confirm molecular results. Both tests together provide the most complete information on the susceptibility of the isolate.



- recognized medical TB consultant is recommended to ensure further testing is performed.
5. Outside laboratories may also report resistance from rapid tests such as PCR; coordination with outside laboratories is recommended.
- D. Intervene when diagnostic tests indicate resistance if the patient is on therapy for drug-susceptible TB, such as rifampin, isoniazid, pyrazinamide and ethambutol (RIPE).
1. Consult with the treating physician.
 2. Consider holding current drug regimen when able (i.e. patient is medically stable).
 3. Request a medical consult from a DSHS-recognized medical TB consultant for continuation of care.³
- E. Consider admission and coordinate discharge with TCID.
1. Admission for initial stabilization may be an option but not required.
 2. Admissions should be coordinated with the TCID admissions nurse.
 - a) Submit admission requests to TCIDAdmissions@dshs.texas.gov. Upload supporting documentation to GlobalScape or THISIS for the TB admissions nurse to review.
 3. TCID discharge summaries are recommendations for care and should not be considered as physician orders.
 - a) TB programs are responsible for ensuring written orders are received for the patient from the local TB clinician, who may adopt the TCID orders in their entirety or make modifications after consultation from a DSHS-recognized medical TB consultant.
 - b) TB programs should ensure that the patient is carefully monitored at the local level.
- F. Order medications after consultation with a DSHS-recognized medical TB consultant and provide adequate therapy. (See *VII. Inventory Management of Medications and Supplies* for ordering details).
- G. Document case management and treatment activities on the TB Unit clinical care forms specific to DR TB ([TB 700 series](#)) or their equivalent. Monthly assessments of medication toxicity specific to each medication are required and must be documented on DSHS toxicity forms or equivalent.
- H. Submit reporting forms to the TB Unit Nurse Consultant as requested.
1. Submit changes in case management, drug resistance patterns or residence on DR TB case within 72 hours of notification in THISIS and notify the DR TB Nurse Consultant.

³ If the patient is hospitalized, request that the treating provider seek consultation with Heartland National TB Center.



- I. Maintain communication with the TB Unit Nurse Consultant, including but not limited to:
 1. submitting requests for information in a timely manner;
 2. responding to case management inquiries;
 3. outlining interventions taken to prevent or respond to medication toxicity; and
 4. participating in routine meetings or conference calls as requested.
- J. Manage patients in accordance to recommendations from a DSHS-recognized medical TB consultant and the treating physician for duration of therapy.



VII. Inventory Management of Medications and Supplies

General Requirement

TB programs will order and store DSHS-purchased supplies and medications in accordance with DSHS standards. DSHS purchases medications under the Federal 340B Drug Pricing Program. Therefore, medications may only be used for patients who qualify for TB services and shall not be distributed outside the TB program for use by patients for whom there is not a current medical record at the TB program site, such as jails or schools where the TB program is not overseeing care.

Activities

- A. Follow DSHS-established criteria for the use of TB program medications.
- B. Designate a staff member to oversee the ordering and management of DSHS-purchased medications to ensure that:
 - 1. medications are used for outpatient treatment of TB disease or TB infection only (including window prophylaxis);
 - 2. medications are used for patients who have a medical record established at the clinic providing the medication;
 - 3. the TB program supplying medications to the patient retains overall responsibility for the care of the patient;
 - 4. medications and supplies are used in a prudent manner and not distributed to entities for which TB programs do not provide treatment oversight;
 - 5. TB programs do not charge patients for medications or seek third-party reimbursement (including Medicaid reimbursement), as medications are provided to TB programs at no cost; and
 - 6. TB programs do not distribute or supply state-purchased medications to jails and other facilities in which the patients receiving the medications are not under the direct care of that TB program.
- C. Follow DSHS-established procedures for TB medication inventory management.
 - 1. Order TB medications and reconcile inventory through ITEAMS.
 - 2. Limit medication orders to a one-month supply, as the DSHS Pharmacy typically fulfills orders within 24 hours of receipt.
 - 3. Set maximum stock levels no higher than a one-month average usage.
 - 4. 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.
 - 5. Avoid waste by ordering packets for patients new to therapy with individual drugs to avoid waste (e.g. 10 packets of Rifampin, 10 packets of Isoniazid) to maximize usage.
- D. Order medications for patients in DOT packets or bulk bottles and ensure



labeling requirements are met.

1. Order medication for patients with known or suspected TB disease on DOT or those on directly observed preventative therapy (DOPT) for TB infection (including window prophylaxis) in DOT packets.
2. 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.
3. Order medication packets for SAT or VDOT. These may be ordered in the same way as DOT 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 DOT packets.
 - a) The label should be prepared and affixed to the zip-closure bag by TB program staff providing medications to the patient. The label must include (see [Figure 1. Sample Medication Label for DOT Packets](#)):
 - (1) the name and address of the medical director or physician who prescribed the drug;
 - (2) the date the drug is delivered to the patient;
 - (3) the patient's name; and
 - (4) the name, strength, directions for use of the drug(s).

Figure 1. Sample Medication Label for DOT Packets

TB Program Name HERE	
123 Main St.	
City, TX 77000	
Phone 123-456-7891	
01/01/2020	
John Watson, MD	
Jane Doe	
Medications:	Rifampin 600mg, Isoniazid 300mg, Pyrazinamide 1000mg, Ethambutol 800mg, Pyridoxine 50mg
Instructions:	Take 2 packets each day

4. Refer to *DSHS Video-Enabled Directly Observed Therapy Required and Recommended Activities Manual* when using VDOT for eligible patients (dshs.texas.gov/idcu/disease/tb/policies)
5. Order medication bottles for patients with TB infection. These may be provided to the patient with the following labeling requirements as required by the Texas State Board of Pharmacy (TSBP), Rule Title 22, Texas Administrative Code §291.93 (see [Figure 2. Sample Medication Label for Bulk Bottles](#)).
 - a) The label must be printed and attached to bottles for self-



administered medications and include:

- (1) name, address and telephone number of clinic;
 - (2) name and strength of drug; if generic, name of drug manufacturer or distributor;
 - (3) quantity;
 - (4) lot number; and
 - (5) expiration date.
- b) The authorized, licensed nurse will ensure the labeling directions include:
- (1) patient name;
 - (2) date medication is provided;
 - (3) physician name; and
 - (4) 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 2. Sample Medication Label for Bulk Bottles

DSHS Pharmacy Near You 123 Pharmacy Lane Pharmacy, TX 1231234 (512)555-5555		Date:
Name:	Exp:	01/01/19
Dr:	Lot:	111222
RIFAMPIN CAP 300 MG #60 Take ___ caps by mouth each day. Take 1 hour before or 2 hours after meals. May decrease effectiveness of birth control pills.		
VERSAPHARM STORE BELOW 86 DEGREES F.		
61748001860		

E. Order medications for patients in accordance with provider orders, the DSHS TB formulary (see [Appendix H: DSHS TB Formulary](#)) and TB Unit requirements. The following types of medications are available to TB programs:

1. First-Line Medications.
2. Second-Line Medications (see [Table 7. Second-Line Medications](#)):
 - a) Second-line medications may be ordered for:
 - (1) patients intolerant to first-line drugs;
 - (2) patients resistant to first-line drugs;
 - (3) patients with TB pathology requiring second-line medications (i.e. TB meningitis); and/or
 - (4) contacts to patients with resistance to first-line drugs who are recommended treatment for TB infection.
 - b) Consultation with a DSHS-recognized medical TB consultant is



required before ordering second-line medications unless the medication is listed as part of a TCID-discharge summary. TB programs may be required to show documentation of consultation at any time *upon request* by the TB Unit. TB programs should therefore attach written consultation notes to the THISIS event.

- c) Most second-line medications are available via ITEAMS.

Exceptions:

- (1) Bedaquiline (BDQ) is available through assistance programs (i.e. Johnson and Johnson Patient Assistance Foundation). Coordinate with the TB Unit Nurse Consultant to obtain medications from the DSHS Pharmacy for short-term use while other purchases are pending. See *Bedaquiline Ordering Guide*: dshs.texas.gov/idcu/disease/tb/forms/#drugresist
- (2) Clofazimine (CFZ) is an investigational drug that may only be prescribed by Institutional Review Board (IRB) enrolled physicians. If the patient received CFZ while at TCID, adhere to the following:
 - (i) Arrange clinical assessments every three months with TCID's prescribing physician to continue receiving CFZ.
 - (ii) Contact TCID for medication refill two weeks before running out of CFZ if it is not yet time for the patient's three-month visit.

For patients not started on CFZ at TCID, adhere to the following:

- (i) Inform the treating physician that IRB enrollment is required; identify if the physician has access to CFZ through an IRB.
- (ii) If the treating physician is unable secure CFZ through an established IRB, contact the TB Unit Drug-Resistant TB Monitoring Program Nurse Consultant for next-steps.

Table 7. Second-Line Medications

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



3. Auxiliary medications:

- a) Additional medications are available on the TB formulary to support individualized patient care. They include but are not limited to:
 - (1) anti-emetics;
 - (2) corticosteroids; and
 - (3) lidocaine.
- b) To order auxiliary medications, programs have the following options:
 - (1) The TB provider may write a prescription for the patient to fill at their own pharmacy.
 - (2) The managing TB program may coordinate with the patient's medical home to obtain the medications (this includes linking the patient to a FQHC or community clinic; ensure patient signs consents to share medical information).
 - (3) The provider may consider over-the-counter medications that the patient may choose to purchase.
 - (4) The managing program may request the medication via ITEAMS when the above options have been exhausted.
The TB Unit reserves the right to request documentation of attempts to obtain auxiliary medications at any time.

B. Mail medications to patients when in-person provision is not possible (see [Appendix I: Medication Mailing Processes](#)).

C. Request non-formulary medications and supplies when needed to directly support TB patient care.

- 1. The TB Unit convenes a Pharmacy and Therapeutics (P&T) Committee to maintain fiscally responsible ordering practices and to review requests for formulary additions⁴. Committee members include: the DSHS Infectious Disease Medical Officer or designee, DSHS Pharmacist(s), the Pharmacy Procurement Officer, TB Unit Nurse Administrator, and additional TB Unit or Regional and Local Health Operations representatives where necessary.
- 2. Any person may ask to add a medication or supply to the TB formulary. The request must include responses to the following questions; send an email to the TB Unit Nurse Administrator allowing 30 days to review and if approved, for the medication to be available:
 - a) What medication/medications are being requested (specify doses where applicable):

⁴ NOTE: The P&T Committee must consider state resources, scope and mission of TB Unit (the scope is the treatment of TB infection and disease, and the mission is to eliminate TB as a public health threat) and external availability of medications before adding medications or supplies to the TB formulary.



- b) Is this medication necessary for any TB patient or for a specific patient or population? Please specify.
- c) Is this medication vital for TB treatment? If yes, please specify.
- d) Without this medication, is there potential harm to the patient that could result in serious disability, hospitalization or death? If yes, specify.
- e) Is TB disease, TB infection or a TB medication the cause of the condition that the medication treats? If yes, please specify.
- f) Does literature support the need for this medication specifically for TB patients? If yes, please specify.
- g) Will this medication directly impact a patient's ability to be cured of TB? If yes, please specify.
- h) What monitoring is required while a patient is on this medication?
- i) Is this medication available over the counter or through other means in the community (i.e. primary care)? If no, please specify.
- j) Does providing this medication align with the scope (mission and vision) of the TB Unit?

D. Manage and monitor distribution of tubersol and TST supplies for:

1. Chapter 89 Correctional Settings:

- a) Distribute tubersol and syringes to correctional facilities meeting *Texas Health and Safety Code Chapter 89* requirements as needed (statutes.capitol.texas.gov/Docs/HS/htm/HS.89.htm)
- b) Manage and monitor supply requests received from Chapter 89 facilities by engaging in the following activities:
 - (1) Review the Correctional TB Screening Plan ([TB-805](#)) to determine if the facility lists the TB program as the entity to provide tubersol and TST supplies. If the Correctional TB Screening Plan does not list the TB Program as the entity that provides tubersol and TST supplies, the request must be denied, and the requestor notified. Chapter 89 facilities are required to maintain an updated and accurate Correctional TB Screening Plan.
 - (2) Review orders to ensure the facility is requesting a reasonable amount of supply to match their monthly averages (as noted on the monthly aggregate report) and reads a high majority of tests placed (>80%).
 - (3) Ensure inmates are screened appropriately and there is a limited amount of duplicate testing. The facility should only routinely test inmates who have not been screened in the past 12 months in previous bookings.
 - (4) Ensure the facility is not delinquent in submitting their monthly aggregate report to the TB program.



- (5) Ensure the facility has exhausted their current supply and does not have tuberculin stockpiled.
 - (6) Ensure the facility is only testing inmates who will likely remain at the facility for longer than 7 days.
 - c) Maintain an inventory of TST supplies provided to each correctional facility monthly.
 - d) Adjust quantity distributed based on trends in usage.
 - e) Halt distribution of TST supplies if monthly reports of usage are not provided by the receiving facility.
- 2. Community-based organizations serving high risk populations based on an environmental risk assessment:
 - a) Prepare and sign a memorandum of agreement for each entity determined by the TB program to receive TST supplies.
 - b) The memorandum of agreement should clearly explain the distribution, storage and reporting process including indicators that may halt or discontinue receiving TST supplies (including but not limited to yearly evaluation of treatment completion rates).
 - c) Distribute tubersol and syringes to community-based organizations when an epidemiologic assessment determines the selected facility is considered high risk for TB and targeted testing is a reasonable response to prevent a recurrence of TB disease transmission.
 - d) Maintain an inventory of TST supplies provided to each facility monthly.
 - e) Review monthly TST reports submitted by each targeted testing facility to determine use.
 - f) Adjust quantity distributed to targeted testing sites based on trends in usage.
 - g) Halt distribution of TST supplies if monthly reports of usage are not provided by the receiving facility.
- E. Avoid using or distributing state-purchased tubersol and TST supplies in populations or in settings not approved by the TB Unit. State-purchased tubersol and TST supplies are NOT approved for use in the following groups:
 - 1. Foreign born people from high prevalence countries aged two and older who do not refuse phlebotomy.
 - 2. Schools, hospitals or other congregate settings not identified for a targeted testing project (see [XII. Conduct Targeted Testing](#) for more information).
 - 3. Low-risk adults and children who are requesting testing for administrative reasons.



4. School-aged children⁵ who request testing for school.
- F. Reconcile medication inventory.
1. Maintain a count of DSHS-purchased medications and supplies.
 2. Reconcile bulk inventory according to product and lot numbers listed in ITEAMS no later than the seventh working day of each month. Bulk medication inventory refers to bottles of medications, as opposed to medication packets.
 3. Transfer products that have not been used in 6-9 months (or will not be used in 6-9 months) to another TB program where demand is greater.
 4. Record the transfer to another TB program facility as a "transfer order" by selecting the reason from the ITEAMS drop down list.
 5. Establish protocols and procedures for the disposal of expired/non-usable medications.
 6. Coordinate with ITEAMS inventory staff to ensure TB orders comply with best practices.
 7. Store all DSHS-purchased medications and supplies properly and securely in accordance with manufacturer's instructions.

⁵ The TB program should not be the primary source of TB testing in school-aged children. First, they should be referred for screening at their school or primary care office, an immunization clinic or to a Medicaid provider (Medicaid providers must follow TB screening guidelines under *Texas Health Steps*). If the child has no alternate resources for school screening, they may be tested with an IGRA if they present with risk factors for TB as evidenced by their answers to the [TB Questionnaire](#).



VIII. Conduct and Manage a TB Contact Investigation

General Requirement

TB 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. In general, contact investigations 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 the initial interview within three working days of a patient being reported to the TB program with suspected or confirmed TB diagnosis.
 - a) The interview should take place in the primary language of the patient or their representative (parent or guardian for young children or proxy for patients diagnosed at death), using an interpreter if needed. Document interpreter services on the [DSHS EF12-12062](#) CI Worksheet or equivalent.
 - 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 5 years old 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 using [Form TB-425](#) (*TB Infectious Period Calculation Worksheet*).
 1. The infectious period generally begins three months before the onset of symptoms (see [Table 8. Estimating the Infectious Period](#)).
 2. Determine date in which contact was broken based upon:
 - a) date of physical separation from the index case; or
 - b) date the index case is no longer considered infectious.
- C. Prioritize all contacts into high, medium or low categories (see [Table 9. 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 case have 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.

Table 8. 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

- D. Conduct first and second round screening.
 1. Initiate screening for high priority contacts within seven working days of identification.
 2. Initiate and complete first round screening within four weeks of identification.
 3. IGRA is the preferred testing method in Texas. TST may be used if IGRA is contraindicated or patient refuses phlebotomy.
 4. Avoid testing people with low risk of infection.
 5. A complete evaluation of a TB contact 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;



- 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 and/or those that are previous TB cases.
6. Contacts with a previous positive IGRA or TST
- a) Previous positive IGRA or TST results must be documented. If not documented, administer the screening test.
 - b) If with documented prior adequate treatment, perform a symptom screen. If with signs and symptoms, 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.
7. Contacts Lost to Follow-Up (LTFU)
- a) Make at least three attempts to contact a TB contact before considering them as LTFU, including:
 - (1) calling the contact;
 - (2) visiting the contact's residence; and
 - (3) sending a certified-mail notification of the contact's need to follow-up with the TB program.
 - b) Document attempts in the progress notes of contact's record.
 - c) Place certified mail notification receipt in the contact's chart.



Table 9. Guidelines for Prioritizing Contacts

Index Case Characteristic	Contact Prioritization
Pulmonary, laryngeal or pleural TB • Cavitory lesion on CXR; <i>or</i> • AFB sputum smear positive	High Priority • All household contacts; <i>or</i> • Contact in a congregate setting (schools, detention facilities, etc.); <i>and</i> with significant frequency and duration of exposure Any hours of exposure for: • Children <5 years; <i>or</i> • Contact with medical risk factors (e.g., HIV, immune compromising condition); <i>or</i> • Contact exposed during specific medical procedures (bronchoscopy, sputum induction <i>or</i> autopsy). Medium Priority • Anyone 5–15 years who does not meet one of the high priority criteria; <i>or</i> • 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; <i>and</i> • AFB sputum smear negative; <i>and</i> • Might be NAAT positive and/or AFB culture positive	High Priority • All household contacts; <i>and</i> • Contacts with significant frequency and duration of exposure. Any hours of exposure for: • Children <5 years; <i>or</i> • Contact with medical risk factors (e.g., HIV, immune compromising condition); <i>or</i> • Contact exposed during specific medical procedures (bronchoscopy, sputum induction <i>or</i> autopsy). Medium Priority • Contact in a congregate setting (schools, detention facilities, etc.); <i>and</i> • 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.



8. 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.
 9. For source case investigations, second round testing is not required.
- E. Consider CI expansion if the infection rate is high or if TB transmission is detected (see [Form TB-460](#), *Expansion Analysis Check-List*).
1. TB infection among high priority contacts indicates transmission.
 - a) The TB Unit generally uses an infection rate of $\geq 20\%$. 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 4 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 DSHS TB 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 for all 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.
 3. If a Texas dairy or livestock area is identified, contact the TB Unit to determine if reporting to appropriate partner state agencies is warranted.
- G. Notify the TB Unit of mass screenings or concerning CIs within 48 hours of meeting criteria.
1. Submit [Form EF12-12104](#) (*TB Incident Report*) or equivalent via GlobalScape for CIs involving:
 - a) ≥ 50 people identified for screening in a single location;
 - b) ≥ 25 people in a K-12 school; and/or



- c) media involvement.
 2. Seek consultation with TB Unit epidemiologists. Consultations should occur before testing is initiated.
 3. Submit timely written updates to the TB Unit as updates are available. These may include:
 - a) Bacteriologic or radiologic results
 - b) Environmental assessments
 - c) Contact prioritization
 - d) Screening dates
 - e) Screening methods
 - f) Evaluation results
 - g) Other relevant details
 4. Mass screenings using DSHS-purchased supplies should not be performed without prior TB Unit approval.
- H. 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 [Form TB-341](#).
 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.
- I. Coordinate CI activities with medical staff and administrators in congregate settings within the TB program's jurisdictions.
 1. Collect names and evaluation results of contacts in congregate facilities.
 2. Collect names and locating information for community contacts.
 3. Provide technical assistance and guidance when necessary.
 4. Consult DSHS epidemiology staff as needed.
- J. Conduct airline exposure screening based on notifications received from the TB Unit via the CDC Division of Global Migration and Quarantine (DGMQ).
 1. TB Unit epidemiologists will provide contact information for people exposed to an infectious TB case on an international flight.
 2. TB program staff will locate contacts and complete screening. Initiate evaluation of contacts within two weeks of notification.
 3. Complete the DGMQ TB CI Form and submit via GlobalScape to the TB Unit within a month of notification.



IX. Manage Contacts to Confirmed or Suspected Tuberculosis Cases

General Requirement

TB programs will evaluate, treat and monitor contacts to suspected or confirmed cases of pulmonary, pleural or laryngeal TB disease in accordance with current DSHS SDOs.

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 of high priority contacts. If the CI is expanded, evaluate medium-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 14 calendar days if:
 - a) the initial IGRA or TST result is positive and no history exists of a previously positive TB test; or
 - b) 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 and/or has an abnormal chest radiography.
 5. If the IGRA or TST result is positive and the chest radiography is normal and/or TB disease has been ruled out, consider treatment for TB infection.
 6. If a previously positive contact did not complete adequate treatment for TB infection, evaluate for TB disease, which includes a symptom review and a chest radiography. If there is no indication of disease, consider treatment for TB infection.
 7. Contacts to MDR-TB, pre-XDR or XDR-TB regardless if previously treated, **and** are under the age of 5 years, HIV infected or are immunocompromised, evaluate for TB disease with a signs and symptoms questionnaire and a chest x-ray.
 8. If a previously positive contact completed treatment for TB infection, further treatment may not be required unless recommended by the treating physician. A complete evaluation for contacts that completed previous adequate treatment requires a symptom screening.
 9. Review and assess the completeness of the contact's medical evaluation.
- B. Consider DST results of the index case in determining a contact's course of treatment.



1. All contacts to MDR-TB, pre-XDR or XDR TB cases who test positive for infection or are a candidate for window prophylaxis must receive a consult from a DSHS-recognized medical TB consultant.
 2. For contacts treated with INH in the past and are now exposed to an INH-resistant case, rifamycin may be needed for the new exposure.
 3. Provide DOT for contacts to MDR, pre-XDR or XDR TB cases who are diagnosed with TB infection; consider VDOT as resources allow.
 4. Any contact exposed to MDR-TB, pre-XDR or XDR TB cases with a positive TST or IGRA test should receive symptom screening and a CXR every six months for a period of two years (from the date of break in contact), including those who refuse TB infection treatment.
- C. Follow DSHS SDOs in determining treatment regimens.
1. Provide medications in accordance with DSHS SDOs.
 2. Document completion of treatment on the appropriate reporting form such as [Form TB-400A](#) or equivalent.
 3. Document reason(s) medication was stopped if treatment was not completed.
 4. Conduct minimum monthly reviews of adherence to treatment for TB infection.
 5. Conduct minimum monthly reviews to identify adverse reactions to treatment for TB infection.
 6. Contacts receiving treatment for TB infection who develop signs and/or symptoms suggestive of TB disease should have medications held and receive a follow-up chest radiography before continuing treatment for TB infection.
- D. Manage high risk contacts.
1. The decision to treat is based on a physician's assessment and diagnosis. Physicians for HIV-infected people may need results of smears, cultures or other rapid diagnostic procedures on appropriate specimens to differentiate between TB infection and active TB disease.
 2. Complete evaluation for contacts under five years of age include a TST or IGRA, symptom screening, physical examination, and a chest X-ray, regardless of symptoms. Children under five with a negative IGRA or TST examination and chest X-ray with unremarkable results should be offered treatment until a second TB screening is performed.
 3. 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 TB infection:
 - a) Patients with HIV
 - b) Patients receiving immunosuppressive therapy for organ transplant
 - c) Patients taking TNF- α inhibitors
 4. If the repeat TB screening test remains negative eight to ten weeks



after break in contact for children under the age of 5 years old, treatment can be discontinued. Infants 5 months and younger should continue window prophylaxis until they undergo a repeat TST at 6 months.

- E. Maintain a medical record for each person on treatment for TB infection, including those on window prophylaxis. The medical record should include at minimum the information outlined in the following [DSHS forms](#):
1. TB 400A (*Report of Case and Patient Services*) with "LTBI only" section completed
 2. TB-202 (*Tuberculosis Health Assessment/History*)
 3. TB-203 (*Education/Counseling Record*)
 4. TB-204 (*Tuberculosis Forms/Literature Checklist*) may be modified with updated literature used locally
 5. TB-205 (*Toxicity Assessment*)
 6. TB-206 (*DOT Log*) when applicable
 7. L-36 (*General Consent and Disclosure*)
 8. L-30 (*Consent to Release Confidential Medical Information*)
 9. TB 415 (*Disclosure and Consent for Drug Therapy TB Infection*)



X. Manage False Positive Investigations

General Requirement

TB programs will manage false positive investigations in accordance with local protocols and procedures. TB programs may initiate a false positive investigation independent of the TB Unit.

Activities

- A. Determine the need for a false positive investigation when:
 1. a single positive culture for *M. tb* exists for a patient; and/or
 2. the treating physician suspects the clinical presentation is not consistent with culture findings.
- B. Notify the local health authority if a false positive investigation is warranted.
- C. Consider consulting with a DSHS-recognized TB medical consultant.
- D. Initiate the false positive investigation.
 1. Complete the *False Positive Investigation Worksheet* (see dshs.texas.gov/IDCU/disease/tb/forms/DOCS/FPWorksheet.doc or equivalent).
 2. Contact the originating laboratory to determine source of false positive result (e.g., lab contamination vs. specimen collection error).
 3. Use genotyping and whole genome sequencing data to support the investigation.
 4. Upon conclusion, provide a summary of the investigation results to include in the patient record, if warranted.
- E. Request TB Unit assistance as needed.
 1. Submit a completed [False Positive Investigation Worksheet](#) with supporting documentation.
 2. The TB Unit will convene a meeting to discuss findings.
 3. The TB Unit will provide documentation to the requesting TB program summarizing investigation results and conclusions. This summary will only be offered if DSHS is engaged and coordinates the investigation.
 4. The TB Unit cannot provide treatment recommendations or confirm/refute the possibility of false positive culture results. TB is a clinical diagnosis and the patient's treatment plan should always be directed by clinical findings as determined by the licensed healthcare provider in conjunction with laboratory information.
- F. Report closed cases due to false positive results to the DSHS Surveillance Unit with supporting documentation (e.g., amended laboratory report, medical consultation, provider notes) justifying change in case status within 45 days of closure.



XI. Manage Electronic Disease Notification System and Other Foreign-Born Referrals

General Requirement

TB programs will screen and evaluate non-U.S. born persons referred to the health department for a TB evaluation. This includes accepting referrals from the Electronic Disease Notification (EDN) system.

Activities

- A. Prioritize referrals and evaluate the following non-U.S. born people for TB in accordance with DSHS SDOs:
1. People from countries with a high prevalence of TB, defined as countries with a TB rate ≥ 20 cases/100,000 (see World Health Organization, who.int/tb/country/data/profiles/en/ and Table 10. *Prioritizing Evaluation of TB Infection for Foreign Born People*);

Table 10. Prioritizing Evaluation of TB Infection for Foreign Born People

Category	Description	Medical Exam Site	How they are referred to the TB program
High Priority for Services Provided by the TB Program			
Refugees	A person who comes from another country after fleeing war, persecution or other reasons and are unwilling or unable to return to that country because of persecution or a well-founded fear of persecution because of race, religion, nationality, membership in a social group or political opinion.	Contracted local health departments that perform refugee health assessment activities	Referred by the local health department refugee health program. The TB Program is responsible for additional evaluation and treatment when indicated.
Immigrants Seeking Formal Permanent Residence	A person who comes from another country to live in the U.S. Citizens of foreign countries who would like to obtain permanent resident status in the U.S. must obtain visas (i.e. family, employment, fiancé and diversity-based such as "lottery" visas). travel.state.gov/content/travel/en/us-visas/immigrate.html	Regional or local health department	Referred through the EDN system; TB programs must perform a full evaluation.



Category	Description	Medical Exam Site	How they are referred to the TB program
Status Adjusters	People in the U.S. applying for adjustment of status to a permanent resident of the U.S.	Civil Surgeons domestically	Referred from a Civil Surgeon when: 1. there is suspicion of TB disease. 2. after a diagnosis of TB infection is made (Civil Surgeons are responsible for initial TB testing and CXRs when indicated). TB programs may offer treatment for TB infection.
Prioritize Based on Local Resources Available at the PHR or LHD			
Other Immigrants	Include migrants entering the U.S. with or without documentation.	N/A	Incidentally if evaluated by a clinician; may self-refer. Evaluate as resources allow.
Non-Immigrants	Tourists, students, specialty workers who obtain visas for non-permanent stays in the U.S.; these visas do not permit the person to live indefinitely in the U.S. They include Business (B-1), Tourism (B-2), Student (B, F, or M) Visas for temporary travel. travel.state.gov/content/travel/en/us-visas/tourism-visit/visitor.html	May be required for a medical exam at the discretion of the consular officer overseas or immigration officer at the U.S. port of entry.	Incidentally if evaluated by a clinician; may self-refer. Evaluate as resources allow.
Short-Term Transit	Transit (C) Visas for people traveling in immediate and continuous transit through the U.S. to another country. travel.state.gov/content/travel/en/us-visas/other-visa-categories/transit.html	N/A	Incidentally if evaluated by a clinician after interruption in travel and stay in U.S.; may self-refer. Evaluate as resources allow.

Adapted from: cdc.gov/immigrantrefugeehealth/exams/medical-examination-faqs.html

B. Evaluate immigrants with an A or B Classification referred from EDN System.

1. Use the EDN system to access records assigned to the TB program.
 - a) Identify at least two people to be assigned to retrieve notifications, enter evaluation and treatment on the TB Work Sheet and perform a final review of the TB Worksheet.
 - b) All funded TB programs must access EDN to view notification of immigrants' arrival in their jurisdiction and evaluate all class A



- and B immigrants assigned to their jurisdiction. Contact the TB Unit to get access to EDN.
- c) Notify the TB Unit when class A and B immigrants move. Provide the new location of the patient and CDC will initiate transfer in EDN to reassign all electronic information to the receiving jurisdiction.
2. Initiate an appropriate medical evaluation within 30 days of notification and document on the Follow Up Worksheet ([see Table 11. TB Follow-Up Worksheet](#)).
- a) Contact the patient within three working days of notification to schedule an evaluation.
- b) If a phone number is not available or if there is no response to the phone call within seven working days, send a letter to the home address listed in the EDN documents.
- c) If the only address listed is for a sponsor agency, contact the sponsor agency to verify the patient's address.
- d) If there is no response to the letter within ten working days from date sent, conduct a home visit.
- e) If all attempts to locate patient have failed, close the record and enter "lost to follow-up" on the EDN TB Follow Up Worksheet.
3. Complete the medical evaluation for all Class-B immigrants within 120 days of notification.
- a) Review all pre-departure medical records.
- b) Obtain a thorough medical history to include:
- (1) previous history of TB;
 - (2) signs and symptoms of TB disease;
 - (3) prior BCG vaccination;
 - (4) prior treatment TB treatment;
 - (5) prior diagnostic evaluation for TB; or
 - (6) history of family or household contact with a known person having a history of TB disease, treatment for TB disease or diagnostic evaluation suggestive of TB.
- c) Consider the following for children in this population:
- (1) A history of recurrent pneumonia, failure to thrive and/or recurrent or persistent fevers. Any of these should increase the provider's index of suspicion.
 - (2) Children experience higher rates of extrapulmonary TB disease, including meningitis and disease of the middle ear and mastoid, lymph nodes, bones, joints and skin.



Table 11. TB Follow-Up Worksheet

The TB Follow-Up Worksheet is used to document the initial evaluation of an arrival with a TB class condition. A complete evaluation requires a diagnosis, and when indicated, a treatment start date.	
Sections A & B	
Demographic & Jurisdictional Information	☐ Pre-populated
Section C	
Date of Initial U.S. Medical Evaluation	☐ Record date of initial evaluation.
IGRA or TST	☐ Administer TB screening test (IGRA or TST). ☐ Record date, brand and results of IGRA or TST used and interpretation (<i>for people with TB Class-B conditions or TB-related abnormalities on CXR, a TST of ≥ 5 mm is considered positive</i>). ☐ Record if a history of previous positive IGRA or TST.
U.S. Review of Pre-Immigration CXR	☐ Arrivals should bring their pre-immigration CXR film(s) or disk with them to exam. ☐ If the pre-immigration CXR is not available, mark "No." ☐ If the pre-immigration CXR did not have the patient's name and date of birth, mark "Not Verifiable." ☐ Record physician's interpretation of pre-immigration CXR. ☐ Do not copy overseas panel physician's interpretation of pre-immigration CXR into EDN follow-up worksheet (FUW).
U.S. Domestic CXR	☐ Record interpretation of CXR ordered by the medical director or consulting physician. ☐ Do not copy overseas panel physician's interpretation of pre-immigration CXR into EDN FUW. ☐ If your medical director or consulting physician does not perform a CXR, mark "No."



Comparison	☐ Compare pre-immigration CXR to U.S. CXR and chose one option that best represents your clinician's impression of the comparison. ☐ If the pre-immigration CXR is not available, mark "Unknown."
U.S. Review of Pre-Immigration Treatment	☐ Record interpretation of pre-immigration TB treatment based on review of patient-provided pre-immigration documents and information.
U.S. Microscopy/Bacteriology	☐ Collect specimen(s) for AFB smear and culture. Document specimen type, collection date and results. ☐ Report suspected pulmonary or extrapulmonary TB disease to TB Unit within one working day. Do not wait for culture confirmation.
Section D	
Evaluation Disposition Date	☐ Record date when medical director or consulting physician has completed the evaluation, if determined that the evaluation cannot be completed for one of reasons listed.
Evaluation Disposition	☐ If the evaluation was completed, check the box "Completed evaluation." Indicate whether treatment was recommended. If so, indicate whether for TB disease or TB infection. ☐ If the evaluation was initiated but not completed, check box "Initiated Evaluation/Not Completed." Select reason(s) why evaluation was not completed from list provided. Check all that apply and write or enter other reasons beside "Other, specify." ☐ If the evaluation was never initiated, check the box "Did not initiate evaluation." Choose the reason(s) why the evaluation was never initiated from the list provided. Check all that apply and write/enter other reasons beside "Other, specify."
Diagnostic	☐ Mark the box corresponding to the CDC diagnostic classification as listed. ☐ Treatment is inappropriate for diagnoses of Class 1 or 0. The EDN system will create an error message if treatment is recommended for either of these diagnoses. ☐ If diagnosis is Class 3, mark the site(s) of disease and contact Surveillance Unit to report. Contact TB Unit epidemiologist if assistance is needed completing section D4.



Section E (Complete this section only if treatment was recommended in question D2)	
U.S. Treatment Initiated	☐ If treatment was initiated, mark "Yes" and specify "for TB disease or TB infection." ☐ <i>Treatment must comply with CDC recommendations.</i> Patients diagnosed at Class 2 or Class 4 should receive treatment unless contraindicated. ☐ Consult the DSHS SDOs or TB Unit if uncertain which regimen to prescribe. ☐ Treatment for Class 3 should rely on DOT and be provided through the patient's local or regional TB program. ☐ If treatment was not initiated, mark "No" and specify the reason in the appropriate boxes. ☐ Check all that apply and enter other reasons next to "Other (specify)."
Treatment Start Date	☐ Specify date treatment was started (mm/dd/yyyy). ☐ Leave this section blank until treatment has stopped.
U.S. Treatment Completed	☐ Save the worksheet in EDN, but do not submit until treatment has completed or ended. ☐ Mark the appropriate box to indicate whether treatment was completed or if it is unknown whether treatment was completed. ☐ If treatment was not completed, mark "No" and specify the reason in the appropriate boxes. Check all that apply and enter other reasons next to "Other (specify)." ☐ If treatment was completed, specify the date next to "Treatment Completion Date" (mm/dd/yyyy). ☐ If treatment was initiated but not completed, specify the date treatment ended (date patient stopped taking treatment) next to "Treatment End Date" (mm/dd/yyyy).



XII. Conduct Targeted Testing

General Requirement

TB programs will identify high risk groups and congregate settings for which testing for TB infection and disease is justified. The goal for targeted testing is to identify, evaluate and treat populations at high risk for TB infection or at high risk for progressing to TB disease. TB programs will conduct targeted testing in accordance with DSHS standards.

Activities

- A. Develop a targeted testing plan to identify and treat population groups at high risk for exposure to TB or for developing disease once infected.
 1. Make a site selection only when an epidemiologic assessment determines the facility or group is considered high risk for TB and targeted testing is a reasonable response to prevent a recurrence of TB disease transmission.
 2. Identify the necessary resources for follow-up medical evaluation and treatment before initiating testing activities. Base decisions to conduct targeted testing on the ability to provide treatment services.
 3. Conduct TB testing activities *only* among high risk groups and/or settings. Unfocused population-based testing is not cost-effective and drains limited resources.
 4. A decision to test is a decision to treat.
 - a) Offer treatment for TB infection to patients regardless of age unless medically contraindicated, once TB disease has been excluded.
 - b) Document clinician's reason in the medical records as to why treatment was not recommended (e.g., alcohol addiction, drug abuse, mental illness, unstable housing, low-income, deportation, etc.).
 5. Base the decision to *continue* targeted testing by performing annual assessments, if not sooner to determine if the sites:
 - a) continue to have risk factors for TB, as determined by the risk assessment;
 - b) report high percentages of TB infection, as determined locally; and or
 - c) yield high rates of treatment completion (for example, over 80%).
 6. If selected sites do not show a continued epidemiologic need or do not yield locally determined rates of infection or treatment completion, the decision to discontinue routine targeted testing should be made.
- B. Document targeted testing activities.
 1. Submit *Congregate Settings Targeted Testing Monthly Report* (DSHS



Form EF12-14427 in [Word](#) or [Excel](#)) to the TB Unit no later than the second Friday of the month for testing from previous month via GlobalScape. Notify the Continuing Quality Improvement Team prior to sending report.

2. Track people who start and/or complete treatment for TB infection or TB disease.
3. Include targeted testing activities on the DSHS Annual Progress Report (APR).

C. Analyze local epidemiologic data to assess the need for targeted testing, particularly congregate settings.

1. Complete a TB risk assessment for congregate settings where a targeted testing project is being considered (see [Form TB-500](#)).
2. Targeted testing projects may be offered in medium or high-risk congregate settings to include:
 - a) homeless shelters;
 - b) nursing homes;
 - c) dialysis centers;
 - d) residential facilities;
 - e) social service programs for people with HIV;
 - f) drug and alcohol rehabilitation centers;
 - g) methadone centers; and
 - h) migrant farm worker camps.
3. Provide guidance to medium and high-risk facilities operating or starting a TB screening program.

D. Identify groups at risk for developing TB disease.

1. Evaluate the following at-risk populations for TB infection in accordance with DSHS SDOs:
 - a) Some medically underserved, low income populations defined locally as having an increased prevalence of TB disease
 - b) Residents of high-risk congregate settings
 - c) People who inject illicit drugs or other groups of high-risk substance users (e.g., injection drug users, heroin, etc.)
2. Complete the Targeted Tuberculin/IGRA Testing Screening Form (DSHS [Form TB-207](#)).
3. Conduct testing using TST or IGRA in accordance with DSHS-approved age requirements.

E. Assess effectiveness of targeted testing projects yearly based on:

1. TB infection yield;
2. likelihood of identifying infected people that will progress from TB infection to disease (risk classification); and
3. TB treatment completion rates.



XIII. Conduct Surveillance to Identify Unreported People with Suspected or Confirmed TB

General Requirement

Develop and maintain TB surveillance mechanisms for early identification and reporting.

Activities:

- A. Comply with the following:
 1. Designate at least one person with the ability to work on surveillance and case registry activities and at least one back-up person in their absence.
 2. Provide hardware and software necessary to conduct case registry activities (e.g., THISIS, access to web-based training and tools, GlobalScape access, access to WinZip or similar encryption software, etc.).
 3. Complete pre-requisite trainings (See *Appendix P: Case Detection, Accuracy, Completeness, Timeliness, Security and Confidentiality (DACTS) Audit Tool*).
 4. Maintain data security and confidentiality standards (see *XXIII. Confidentiality and Security Standards* for more information).
- B. Contact providers who deliver TB services to at-risk populations to increase case reporting at least quarterly.
- C. Educate and train providers and other key facilities on reporting.
 1. Provide education and training about TB reporting and surveillance to at least four of the following yearly:
 - a) Hospitals
 - b) HIV clinics
 - c) Homeless shelters
 - d) Drug rehabilitation facilities
 - e) Indigent care facilities
 - f) Kidney dialysis facilities
 2. Training must include but is not limited to TB case definition, when to report, how to report and Texas legal reporting requirements (see dshs.texas.gov/idcu/investigation/conditions/).
 3. Report training activities in the APR to the TB Unit.
- D. Communicate with HIV/STD or general surveillance program staff in the local and regional health departments to identify unreported HIV/TB co-infections at least quarterly.
 1. Maintain documentation of these activities.
 2. Report educational activities on the APR.



E. Conduct Case Investigations on Suspected TB Cases

1. Conduct investigations on suspected TB cases tasked by TB Program Surveillance within 24 hours of notification. TB Surveillance creates tasks in THISIS based on the following circumstances when RVCT data has not been submitted by TB Programs:
 - a) Culture confirmation for *M. tb* or *M. bovis* and all other species contained in *M. tb* complex from the Electronic Laboratory Reporting (ELR) System
 - b) Culture confirmation for *M. tb* or *M. bovis* from genotyping
 - c) Culture confirmation from the drug resistance program
 - d) EDN notification or referral or transfer of ownership
 - e) Vital statistics (death certificate) or a medical examiner's report
 - f) Hospital admission or discharge summary
 - g) Pharmacy records dispensing TB drugs
 - h) Infectious Disease Control Unit report of communicable disease
 - i) Receipt of an out-of-state IJN; provide status update within 30 days of notification
 - j) Initiation of a CI
 - k) Unreported source case identified
2. Track all laboratory results of AFB smears, NAAT and cultures within seven working days after collection date for AFB smears/NAAT and within six weeks for final AFB cultures.
3. Resolve the case verification status of all suspected TB cases in THISIS within 90 business days of notification from TB Surveillance. Suspected TB cases that are still pending verification in THISIS after 90 business days of notification are delinquent.



XIV. Reporting

General Requirement

TB programs must submit designated reports by established deadlines and schedules using DSHS-approved mechanisms. Managers must consolidate, verify and sign all case counts for the current calendar reporting year.

Activities

- A. Report all ATS Class 3 cases in THISIS using the data elements in CDC's Report of Verified Case of TB (RVCT), within two business days after identification of a laboratory confirmed TB case or diagnosis of a clinical case of TB. See cdc.gov/tb/programs/rvct/ for the current version of the RVCT.⁶
 1. Use the Case Verification Form to verify case criteria and count status: dshs.texas.gov/thsvh/thisis/files/CaseVerificationReport.pdf.
 - a) Case criteria:
 - (1) Laboratory confirmed
 - (2) Clinical case (pulmonary or extra-pulmonary)
 - (3) Provider diagnosis
 - b) Count status:
 - (1) Counted
 - (2) Not counted
 - (a) Out-of-state or country transfer
 - (b) Recurrent <365 days
 - (c) Binational
 - (d) Out-of-state contact investigation
 - (e) Out-of-state specimens processed in Texas
 - (f) *M. bovis* BCG
 2. Enter the minimum required RVCT data elements in THISIS at time of initial report:
 - a) Date reported
 - b) Full first, middle and last name
 - c) Date of birth
 - d) Race and ethnicity
 - e) Country of origin, if not U.S.
 - f) Date of entry into U.S.
 - g) Laboratory and clinical data necessary to meet case definition as applicable
 - h) Count status and date counted
 - i) Verification of Texas residency, including physical address, city, county, ZIP code with 4-digit code (within or outside city limits)

⁶ CDC revised the current RVCT and the new RVCT variables will be implemented in THISIS in January 2022.



- j) If diagnosed while in a facility or shelter, provide facility or shelter name
 - k) Initial drug susceptibility results, as applicable
- 3. Enter remaining RVCT data elements in THISIS as required for 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. Create a new Event in THISIS for recurrent TB cases. 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. 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. Perform a CI in both instances.
- 5. Enter RVCT Follow-Up I and II Report data in THISIS:
 - a) Enter a completed Initial Susceptibility Report (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 (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 patient stopped due to completion of adequate therapy, death, failure to locate, moved and/or 90 days' passage since last medication dose.
- B. Report all ATS Class 5 in THISIS with the same data required of confirmed TB cases. Update ATS Classification in THISIS 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 Event ID
 - 6. RVCT number (also referred to as the state case number)
- D. Complete Forms [TB-340](#) and [341](#), 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 Information
 2. Part B. Interview and Exposure Site Information
 - a) For every sputum smear positive case, conduct at least two different 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.
 6. Update THISIS as "CI was indicated" = "Yes" if a contact investigation was initiated.
 - a) If contact investigation was not initiated, provide reason
 7. 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
 8. Update contacts' treatment outcome in THISIS no later than three months from the date the contact stopped treatment.
 9. 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.
 10. CI that yields >49 contacts will be listed on the DSHS TB Mass Contact Spreadsheet. Request the most recent version from DSHS TB Surveillance case consultants before use.
- E. Achieve National TB Program Objectives and Performance Targets. See [Table 12. National TB Indicators Project \(NTIP\) Objectives and National Targets on](#)



Contact Investigation for more information on [National Tuberculosis Indicators Project \(NTIP\)](#) measures.

F. 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 (see *X. Manage False Positive Investigations* for more information).
2. Report any case closed as false-positive due to laboratory contamination or other reason to the TB Unit Surveillance 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.

Table 12. National TB Indicators Project (NTIP) Objectives and National Targets on Contact Investigation

Forms TB-340 and TB-341 Reporting Information	NTIP Objectives	U.S. 2025 Targets
Contact Elicitation	For TB patients with positive AFB sputum-smear results, increase the proportion who have contacts elicited.	100%
Examination and Evaluation	For contacts to sputum AFB smear- positive TB cases, increase the proportion who are completely examined for infection and disease.	94%
Treatment Initiation	For contacts to sputum AFB smear- positive TB cases diagnosed with latent TB infection, increase the proportion who start treatment.	92%
Treatment Completion	For contacts to sputum AFB smear- positive TB cases who have started treatment for TB infection, increase the proportion who complete treatment.	93%

G. Incorporate quality assurance (QA) protocols and procedures into surveillance activities.

1. Respond to requests from TB Unit case consultants to check any discrepancies between the jurisdiction's case count in THISIS and the case count in the jurisdiction's log.



2. Respond to tasks in THISIS within 14 days after receipt or within the timeframe requested in the task.
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. See [Table 13. Requirements for QA for TB Surveillance Data](#) below.

Table 13. 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, of registry data and of data entered onto the RVCT form and transmitted to CDC); • data completeness; • timeliness; and • data security and confidentiality. Develop written protocol for QA for TB surveillance data. • Describe how each of the QA components (case detection, data accuracy, data completeness, data timeliness and data security and confidentiality) is being conducted. Qualified Participants: • TB Unit Reporting and Surveillance • State-designated case registries including TDCJ and Binational Programs (29) • State-contracted counties Develop and implement plans for improvement.

Source: [Quality Assurance for Tuberculosis Surveillance Data: A Guide and Tool Kit, 2013](#)

- H. Review and submit designated reports received from jails that meet [Texas Health and Safety Code Chapter 89](#) requirements to the TB Unit via GlobalScape.
1. Submit monthly correctional TB screening reports within 15 business days of the following month.
 2. Collect *Monthly Correctional TB Report* (DSHS Form EF12-11462 in [Word](#) or [PDF](#)) and Positive Reactor Suspect/Case Report (DSHS [Form EF12-11461](#)) from jails and community corrections that meet Texas Health and Safety Code Chapter 89 requirements within five (5) business days of following month.
 3. Review reports for accuracy and completion. Provide guidance to jails and community corrections to complete the *Monthly Correctional TB Report*.



- I. 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 DR TB cases until treatment completion.
 2. Submit changes in case management, drug resistance patterns or residence in any DR TB case within 72 hours of notification.
- J. Complete and submit the APR using the TB Unit template to TBContractReporting@dshs.texas.gov once a year on April 15.
- K. Submit completed cohort review documents in accordance with the listed cohort review period and submission schedule (see *XXI. Conduct Continuing Quality Improvement Activities to Maintain a Robust Tuberculosis Program Infrastructure*) to the TB Unit via GlobalScape.
- L. Notify the TB Unit of concerning or mass screening CIs within 48 hours.
Concerning CIs involve:
 1. Locations of interest include but are not limited to academic institutions, day care centers, nursing homes, hospitals, correctional facilities (including community corrections), homeless shelters, airline exposures and other work settings.
 2. Submit completed TB Incident Form (DSHS [Form EF12-12104](#)) within 48 hours of event to the TB Unit via GlobalScape. The Incident Report Form is at texasTB.org.
 3. Contact a TB Unit epidemiologist to discuss:
 - a) clinical presentation of the patient;
 - b) medical and social history of the patient;
 - c) screening method and results including test dates (initial round of testing);
 - d) second round testing dates (planned);
 - e) radiologic and bacteriologic status including NAAT results;
 - f) infectious period;
 - g) contact investigation forms;
 - h) description of environmental assessment or planned environmental assessment;
 - i) incident command response plan;
 - j) results of epidemiologic assessment and next steps; and
 - k) other relevant details.
 4. Submit timely written updates to the TB Unit as updates are available (or as requested) that may include:
 - a) NAAT results;
 - b) environmental assessment to determine specific areas in which exposure occurred and the exposure period;
 - c) stratification of contacts by risk;
 - d) scheduled and actual dates of screening;



- e) screening methods (i.e. IGRA/TST);
 - f) evaluation results based on risk stratification (all high-risk contacts should be tested first to determine the need for expansion); and
 - g) other relevant details.
- 5. Submit a final epidemiologic update to the TB Unit after the investigation is closed.
- M. Report mass screenings (contact investigations $\geq$ 50 contacts) when using DSHS TB Unit-purchased supplies. Do not perform mass screenings without prior TB Unit 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.
- N. Conduct airline exposure screening based on notifications received from the TB Unit via the CDC Division of Global Migration and Quarantine (DGMQ).
 - 1. TB Unit epidemiologists will contact TB programs to provide the name and phone number of people exposed during the flight per the CDC DGMQ staff.
 - 2. TB programs must:
 - a) notify airline contacts and instruct them to report to their program site for TB screening;
 - b) screen contacts;
 - c) complete and submit the DGMQ TB Contact Investigation Form to the TB Unit Epi Evaluation Team via GlobalScape within ten (10) business days of notification; and
 - d) provide RVCT and contacts to surveillance staff for data entry into THISIS.
- O. Submit a report of adverse drug reactions resulting in hospitalization or death by completing the THISIS “Adverse Reaction” Question Package.
 - 1. Once complete, contact the DSHS pharmacy to notify them of the event (phone 512-776-7500). A DSHS pharmacist will review the information and contact the sender as needed to determine if a report to the Food and Drug Administration (FDA) is necessary.
 - 2. While the Adverse Reaction report is intended to inform the DSHS Pharmacy and TB Unit of the occurrence, it is the responsibility of the treating prescriber to intervene and make changes to regimens when indicated.



XV. Interjurisdictional Communication for People Traveling in and Out of State

General Requirement

TB programs must ensure communication occurs between jurisdictions when a patient with an ATS classification of 2, 3 or 5 and contacts needing follow-up, travel in and out of Texas.

There are two types of communication channels:

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

This chapter outlines circumstances when each type of communication should occur.

Activities

- A. Plan, coordinate, and communicate *informally* (and *formally* when requested) when a patient plans temporary travel out of state.
 1. Within two business days that a jurisdiction 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 in another state.**
 2. Notify the receiving state's IJN coordinator within two business days that the jurisdiction becomes aware of the patient's travel plans that the patient will be in, or already is in, their state temporarily and to determine which local jurisdiction or 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/
 3. Coordinate the sharing of information *as directed by the receiving state's IJN coordinator or receiving jurisdiction*. This includes sharing of any medical records as requested.
 - a) The receiving state must be notified of any patient on treatment for active TB and as a courtesy, a referring jurisdiction may want to provide details of a contact or person on treatment for TB infection.
 - b) The receiving state will determine how best to coordinate care while the patient is in their state.
 - c) If the referring jurisdiction plans to keep the patient on VDOT, this courtesy notification must still be made.
 4. Programs may provide up to 30 days' worth of medications for a



patient on treatment for TB disease or TB infection. Anything longer than 30 days warrants formal communication as outlined below.

- B. Plan, coordinate, and communicate *informally and formally* when a patient plans a permanent move out of state, or when temporary travel plans change, or the travel is longer than 30 days.
1. Within two business days that a jurisdiction becomes aware of a patient's plan to move (or has already moved and will not be returning to Texas), or remain in another state longer than 30 days, or when temporary travel plans change and assistance from the receiving state is needed, contact the state's IJN coordinator to inform them of the patient's move or intent to move to their state. The list of IJN contacts for each state can be found here:
tbcontrollers.org/community/statecityterritory/
 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 patient 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 patient'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.
- C. Accept IJN transfers from another state
1. When a patient moves to Texas from another state, an IJN referral form and medical records will be sent to the DSHS TB Unit IJN Coordinator whose responsibilities include:
 - a) Creating an event in THISIS for this patient;
 - b) Logging the IJN referral for tracking purposes;
 - c) Attaching the IJN referral/medical records to the event in THISIS, and
 - d) Sending a task through THISIS to the receiving jurisdiction in Texas within two business days of receipt of the IJN form.



2. When the referring state requests for follow-up information on the evaluation outcome or treatment outcome of the patient who moved from their state to Texas, the IJN Coordinator will inform the receiving jurisdiction's TB program in Texas of the request. The receiving TB program in Texas will communicate directly with the referring state within 1 week of the follow-up request - either by phone, email, or using the [IJN Follow-up form](#).

D. Process in-state transfers within Texas

1. When a patient plans to move (or has moved) from one jurisdiction to another jurisdiction within Texas, the referring jurisdiction will send an IJN with the patient's medical records within two business days of becoming aware of the move, by attaching them to the patient's event in THISIS, and communicate directly with the receiving jurisdiction to ensure appropriate continuity of care and follow-up of the patient.



XVI. Implement Infection Prevention Procedures

General Requirement

TB programs will apply appropriate administrative, environmental and respiratory measures to prevent exposure to and transmission of *M. tb*.

Activities

- A. Develop a TB infection-prevention plan to include administrative, environmental and a respiratory protection measures.
 1. Administrative measures that reduce the risk of exposure to people with infectious TB may include:
 - a) Assigning responsibility for TB infection prevention to a designated staff member
 - b) Conducting a TB risk assessment (see [DSHS TB-500](#))
 - c) Developing and implementing a written TB infection prevention plan (See [Appendix J: Sample Tuberculosis Infection Prevention Plan](#))
 - d) Ensuring the availability of recommended laboratory processing, testing and reporting of results
 - e) Implementing effective work practices for managing patients with TB disease and infection
 - f) Ensuring proper cleaning, sterilization or disinfection of equipment and surfaces to prevent contamination
 - g) Educating, training and counseling health care workers, patients and visitors about TB infection and disease
 - h) Screening direct care TB personnel for TB (see [E below](#)).
 - i) Applying epidemiology-based prevention principles, including the use of setting-related TB infection-control data
 - j) Using posters and signs to remind patients and staff of proper cough etiquette and respiratory hygiene
 - k) Coordinating efforts with high risk healthcare or congregate settings to reduce and prevent exposure to TB
 2. Environmental measures that prevent the spread and reduce the concentration of infectious droplet nuclei and may include:
 - a) Using local exhaust ventilation (e.g., hoods, tents or booths) to control the source of infection
 - b) Using general ventilation to dilute and remove contaminated air
 - c) Using high-efficiency particulate air (HEPA) filtration and/or ultraviolet germicidal irradiation (UVGI) to clean the air
 - d) Controlling airflow to prevent the contamination of air in areas adjacent to airborne infection isolation (AII) rooms
 3. A respiratory protection program further reduces the risk of exposure to infectious droplet nuclei that have been expelled into the air from a



patient with infectious TB and may include:

- a) Developing protocols and procedures on respiratory protection to include the type and size of respirators available to staff, routine inspection/maintenance and appropriate use
 - b) Providing N-95 fit testing to employees who share the same air space with patients suspected or diagnosed with infectious TB disease. Fit-test employees at risk for exposure to infectious droplet nuclei:
 - 1) upon initial hire and then every 12 months;
 - 2) when physical changes (e.g., weight loss, growth of facial hair) alter the fit of the respirator; and/or
 - 3) whenever a different respirator is used (e.g., size, style, make, model).
 - 4) Maintain documentation of employee fit-testing in accordance with local record retention policies and procedures.
 - c) Using N-95 respirators in situations that pose a high risk of exposure to TB disease
 - d) Training health care workers on personal respiratory protection
 - e) Educating patients on respiratory hygiene and the importance of cough etiquette procedures and providing surgical masks as needed
 - f) Evaluating the effectiveness of the respiratory protection procedures through monitoring employees for conversion of TST or IGRA results.
- B. Ensure all environmental control equipment is properly installed, operated and maintained.
1. Outline the responsibility and procedures for all environmental control equipment maintenance in a written TB infection prevention plan.
 2. Maintain a log of all environmental control equipment maintenance in accordance with local retention policies and procedures.
 3. Document training required for the proper operation of environmental control equipment and retain in accordance with local policies and procedures.
- C. Ensure separation of infectious or potentially infectious patients from other patients in the clinic (e.g., separate clinic spaces or appointment times).
1. Determine degree of infectiousness (see DSHS SDOs).
 2. Review DSHS SDOs to determine when a patient is no longer deemed infectious.
- D. Perform droplet nuclei producing procedures (e.g., bronchoscopy, sputum collection/induction) in an AIIR or booth, if available. For clinics without these capabilities, sputum specimens must be collected outside in a location that protects patient confidentiality.



E. Monitor effectiveness of TB infection prevention measures.

1. Screen direct care TB personnel for TB. Refer to *Tuberculosis Screening, Testing and Treatment of U.S. Health Care Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019*
cdc.gov/tb/publications/guidelines/infectioncontrol.htm
 - a) TB programs should screen all direct care TB staff upon hire and test direct-care TB employees at baseline with an IGRA unless there is documentation of a previous positive IGRA test result, or unless there is documentation of adequate treatment completion for TB infection or TB disease.
 - b) The frequency of subsequent tests may be determined by the medical director. Direct-care TB staff should be tested at least annually.
2. Document results of TB personnel screening and respond to any TB test conversions. TB Programs must:
 - a) Complete the [TB-603](#) Tuberculosis (TB) Screening of TB Personnel form, or equivalent, annually. Maintain records of TB screening in the health department according to local personnel records retention policies.
 - b) Report TB test conversions to the TB Unit within 60 days of the screening date. Document on [TB-604](#) Report of Tuberculosis Test Conversion(s) in TB Personnel form and send to the TB Unit Nurse Administrator.



XVII. Maintain a Competent Workforce

General Requirement

TB programs will provide professional education, training and orientation for new TB program staff and continuing education for current TB program staff.

Activities

- A. Ensure all people providing services under the SDOs or equivalent protocols and procedures have the requisite experience and/or training to deliver appropriate services. See [Appendix K: TB Training and Education Resources](#) for TB training and education resources.
- B. Provide orientation and training to all employees involved in TB activities, including physicians, nurses, contact investigators, outreach workers, case registry staff, receptionists and other support staff.
 1. Initial training includes 40 hours of TB training specific to job duties within 90 days of employment:
 - a) Use the CDC "Self-Study Modules on Tuberculosis" for the initial training (see cdc.gov/tb/education/ssmodules/)
 - b) For registry, surveillance staff and other staff assigned to THISIS data entry, initial training will include CDC "RVCT Self-Study Modules" (see cdc.gov/tb/programs/rvct/)
 2. Core training topics for TB program staff include:
 - a) transmission and pathogenesis of TB;
 - b) epidemiology of TB;
 - c) diagnosis of TB infection and disease;
 - d) treatment for TB infection and disease;
 - e) TB reporting and notifiable conditions;
 - f) cultural awareness; and
 - g) interpreter utilization.
 3. Specialized training topics based on duties and responsibilities include:
 - a) drug interactions and medication toxicity;
 - b) TB CI;
 - c) TB surveillance in hospitals and institutions;
 - d) infectiousness and infection prevention;
 - e) patient adherence;
 - f) interviewing, investigating and influencing techniques;
 - g) directly observed therapy;
 - h) TB nurse case management for TB infection, TB disease and drug resistant TB;
 - i) TB program management; and/or
 - j) CDC TB surveillance and reporting.
 4. TB program managers, nurses, contact investigators and data entry



- staff must participate in the TB Unit Orientation *after* three months of hire.
5. TB program staff must participate in the monthly TB conference calls and other required conference calls or trainings.
 6. TB program staff must complete 16 hours of ongoing education each calendar year relevant to each staff member's position.
 7. Staff responsible for data entry must take THISIS trainings.
 8. Attend TB trainings, including webinars provided by all CDC regional TB medical and consultation centers such as those offered by Heartland National TB Center and other Centers of Excellence (COE) as needed.
 9. Participate in DSHS TB Unit trainings where offered.
- C. Ensure all staff performing TB services are competent in navigating THISIS, as per the [THISIS Training and Implementation Plan \(TIP\)](#). Program managers may choose to require certificates of training completion of each THISIS training course.
- D. Maintain documentation of training for all employees and contracted staff.
1. Retain logs (see [Appendix L: Sample In-Service and Training Roster](#)) for in-house trainings in accordance with local protocols and procedures, including:
 - a) job titles;
 - b) training dates;
 - c) training or course titles; and
 - d) number of hours.
 2. Retain copies of employee training certificates.
 3. Each medical director and/or local health authority must have access to training records to verify that those operating under their medical license have the requisite experience and training.
- E. Notify the TB Unit of newly hired TB program managers, nurses, contact investigators and case registry staff within 30 days of hire. Submit the *Notice of Change of TB Personnel* (dshs.texas.gov/idcu/disease/tb/forms/) to TBProgram@dshs.texas.gov.
- F. Educate external stakeholders.
1. As resources allow, provide TB education and training to:
 - a) schools;
 - b) correctional facilities;
 - c) community health care providers;
 - d) homeless shelters; and
 - e) social service providers who may serve populations at high risk for TB or where the consequences of disease transmission could be severe.
 2. Maintain documentation (see [Appendix M: Sample Stakeholder](#)



Training/Education Roster) of all external stakeholder TB trainings (including hours, topics, dates, group type and number of participants) in accordance with local retention protocols and procedures.

3. Report stakeholder trainings on the DSHS APR.



XVIII. Monitor Budget Expenses

General Requirement

Local health departments will monitor budget expenses and maintain records in accordance with DSHS contract general provisions. Public health regions will monitor budget expenses and maintain records as outlined in DSHS policies.

Activities

- A. LHD TB programs are allowed a 25% maximum deviation from total DSHS funds to shift between direct cost categories (except equipment).
 - 1. If the budget transfer exceeds 25% of the total contract, alone or cumulatively, a formal contract amendment is required.
 - a) Contractors shall provide notification of the budget transfer by submission of a revised Categorical Budget Form to the System Agency Contract Manager, highlighting the areas affected by the budget transfer.
 - b) After review, the System Agency Contract Manager shall provide notification of acceptance to the contractor via email, upon receipt of which the revised budget shall be incorporated into the contract.
 - 2. LHDs must notify the DSHS Contract Management Section (CMS) of any requests greater than 25% of their award, including any equipment and indirect requests. The equipment threshold is currently \$5,000.
- B. Submit requests for reimbursement or payment by the last business day of the month following the month in which expenses were incurred or services provided.
- C. Lapse no more than one percent of federal and state funds. Lapsing above the maximum percentage may impact future allocations.
 - 1. At the beginning of each state fiscal year, maximize the use of federal funds FIRST as lapses may impact future CDC funding.
 - 2. The TB Unit reserves the right to decrease funding amounts as the result of budgetary shortfalls and/or due to lapsing more than one percent of total funds.
- D. Notify CMS if personnel change requires a contract amendment.



XIX. Monitor Surveillance, Reporting and Case Management Activities in Correctional and Detention Facilities

General Requirement

TB programs will monitor and participate in TB prevention and care activities in correctional and detention facilities, except TDCJ. The goals of correctional TB activities are early detection (case-finding), containment, treatment and prevention in correctional and detention facilities.

The TDCJ is responsible for directing TB care-related services within all prison units and community corrections under their purview. The TDCJ Health Services Division oversees medical services provided by contractors in state prisons and has the statutory authority and responsibility to ensure access to care, monitor the quality of care, investigate medical grievances and conduct operational review audits of health care services.

Regardless of size and ownership, all correctional and detention facilities in Texas, including federal prisons, state prisons, local jails and community correction facilities are subject to the provisions of the Communicable Disease Prevention and Control Act (Texas Health and Safety Code, Chapter 81, Rule§ 81.065, 2016) and other applicable federal and state laws.

Activities

- A. Provide technical assistance on TB prevention and care for all correctional and detention facilities, except TDCJ, and monitor compliance with state laws.
- B. Promote TB screening and treatment.
 - 1. Offer guidance to promote appropriate and timely screening practices (e.g., symptom screening, testing with TST or IGRA).
 - 2. Provide medical oversight for TB cases, suspects and contacts.
 - 3. Provide consultation for TB infection treatment among high risk groups.
 - 4. The initiation of treatment for TB infection should include consideration and planning for the likelihood of patient continuing and completing treatment under supervision or being released from the facility before completion of treatment.
- C. Participate in discharge planning and continuity-of-care activities.
 - 1. Facilitate discharge planning for inmates with suspected or confirmed TB who are scheduled to be released or transferred to other correctional facilities or jurisdictions.
 - 2. Follow-up to ensure that TB cases and suspects continue TB treatment at the TB clinic nearest their residence or at the receiving correctional facility.



3. Provide continuity-of-care for employees and any inmates released to the community who are undergoing treatment for TB disease or infection.
 4. Provide technical consultation to ensure adequate precautions are taken while transporting patients between correctional facilities or detention centers.
 5. Refer foreign nationals to CURE-TB or Migrant Clinicians Network for continuity-of-care coordination outside the U.S. See dshs.texas.gov/disease/tb/surv.shtm.
- D. Coordinate, plan and/or actively participate in CIs.
1. Conduct an interview to identify contacts and determine an inmate's infectious period.
 2. Provide TB education and counseling to patient.
 3. Assess TB transmission risk based on the index case's degree of infectiousness, length of exposure to index, environmental factors and contact characteristics (e.g., HIV-positive).
 4. Evaluate identified contacts based on CDC priority classification. (TB testing may be conducted by the TB program or the facility medical staff under the strict guidance of the TB program).
 5. Ensure that contacts start and complete treatment for TB infection or TB disease, as indicated.
- E. Provide oversight for Texas Health and Safety Code Chapter 89 facilities (see statutes.capitol.texas.gov/Docs/HS/htm/HS.89.htm).
1. Review and submit *Monthly Correctional TB Report* (DSHS [Form TB EF-12-11462](#)) and the Positive Reactors/Suspects/Cases Report (DSHS [Form TB EF-12-11461](#)) to DSHS Congregate Settings Program no later than the fifteenth day of each month.
 2. To the extent funds are available, distribute Purified Protein Derivative (PPD) and syringes to correctional facilities that meet Texas Health and Safety Code, Chapter 89 criteria upon their request (see [VII. Inventory Management of Medication and Supplies](#) for ordering and distribution criteria).
 - a) Chapter 89 facilities must submit the *Monthly Correctional TB Report* to the TB program by the fifth working day of the following month.
 - b) Monitor monthly jail reports to ensure the number of TB tests reported justifies the amount of PPD and syringes provided.
 - c) Address suspected misuse of state funded supplies immediately with the correctional facility and report to the TB Unit.
 3. Review correctional TB screening plans for completion and accuracy.
 - a) Chapter 89 facilities must submit the *Correctional Tuberculosis Screening Plan* (DSHS [Form TB 805](#)) to the DSHS Congregate Settings Program for review and approval 90 days before the current Screening Plan expiration date or anniversary date.



- b) Before final approval, the TB Unit will forward the Screening Plan to the PHR or LHD for review. The reviewed Plan with the LHD comments must be returned to the TB Unit within 10 days of receipt.
 - c) Review and submit the *Tuberculosis Screening Plan* (DSHS [Form TB 805](#)) to the DSHS Congregate Settings Program for review and approval 90 days before the current Screening Plan expiration date or plan anniversary date.
- F. Provide training and education to correctional facility staff as resources allow; report on the DSHS APR.



XX. Initiate and Maintain Self-Auditing Practices

General Requirement

TB programs will implement practices that meet clinical and reporting quality standards and assure the appropriate use of state and federal funds.

Activities

- A. Perform self-audits.
 1. Designate staff to review program practices to ensure services are delivered in accordance with DSHS program standards and as outlined in the TB Work Plan.
 2. Ensure medical record documentation to include and follow current *Texas Administrative Code requirements, Title 22, Part 9, Chapter 165, Rule §165.1*.
 3. Develop a checklist to ensure the completeness of medical record documentation.
 4. TB Programs may refer to the TB Unit's *Onsite Review Tool* as a guide. See dshs.texas.gov/IDCU/disease/tb/policies/OnsiteReviewTool.pdf.
- B. Ensure that the most current SDOs are reviewed and signed once a year by authorizing physician.
 1. TB Program staff providing clinical or data services will review and sign SDOs and the protocols and procedures under which SDO activities are performed.
 2. TB program managers will ensure that SDOs and subsequent protocols are reviewed and signed at least once a year by employees delivering TB services.
- C. PHRs must provide technical TB support and guidance to LHDs that provide TB services, as needed.



XXI. Conduct Continuing Quality Improvement Activities to Maintain a Robust Tuberculosis Program Infrastructure

General Requirement

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

Activities

- A. Update protocols and procedures to support TB program performance evaluation and CQI.
- B. Conduct quarterly cohort reviews in accordance with the DSHS *Tuberculosis Cohort Review Process* (see [Appendix N: Cohort Review Process](#)).
 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 Cohort Review Summary and each individual presentation form. Submit summary and presentation forms along with a list of counted cases to the TB Unit via GlobalScape. See [Table 14. Cohort Periods and Submission Schedule](#) for cohort review periods and submission schedule.
 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.
- C. 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.

Table 14. 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
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- D. Use NTIP and Texas Performance Measures to assess progress toward achieving state and national objectives.
1. Identify TB program staff who need access to NTIP. At minimum, this should include the TB Program Manager.
 2. Contact the TB Unit for access to NTIP.
- E. Meet Texas TB Performance Measures (see [Table 15. 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 Title 22, Part 9 Chapter 165, §165.1,* regarding retention of medical records.

Table 15. Texas TB Performance Measures

Performance Measure	Benchmark (%)
Newly-reported TB cases must have an HIV test performed unless there is documented evidence of an HIV-positive result or the patient refuses.	91
All suspected and confirmed TB patients 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 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*.	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



Performance Measure	Benchmark (%)
Newly-diagnosed TB cases that are eligible to complete treatment within 12 months must complete therapy within 365 days or less. Exclude the following TB cases who: - are diagnosed at death; - die during therapy; - are resistant to rifampin; - have meningeal disease; and - are age 14 or younger with either miliary disease or a positive blood culture for TB.	89
Increase the proportion of culture-confirmed TB cases with genotyping result reported.	99
TB cases with initial cultures positive for <i>M. tb</i> complex are tested for drug susceptibility with results documented in the medical record.	84
Newly-reported TB patients 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 TB case are evaluated for TB infection and disease.	80
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.	69
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.	54
For Class-B immigrants and refugees whose overseas CXR results indicate consistent with TB, increase the proportion whose medical evaluation was initiated within 30 days of notification.	62.4
For Class-B immigrants and refugees whose overseas CXR results indicate consistent with TB, increase the proportion whose evaluation was completed within 120 days of notification.	46
For Class-B immigrants and refugees whose overseas CXR results indicate inconsistent with TB and subsequent evaluation in the U.S. reclassifies patient as having TB infection, increase the proportion who start treatment for TB infection.	75



Performance Measure	Benchmark (%)
For Class-B immigrants and refugees whose overseas CXR results indicate inconsistent with TB and subsequent evaluation in the U.S. reclassifies patient as having TB infection, increase the proportion who complete treatment for TB infection.	69

†The 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.



XXII. Court-Ordered Management

General Requirement

TB programs will make efforts to support patients diagnosed with TB disease in adhering to the treatment plan. When those efforts fail, TB programs will seek court-ordered management for patients whose actions pose a public health threat as a last resort. Court-ordered management ensures that:

- non-adherent TB patients complete an adequate course of TB treatment;
- patients receive appropriate evaluation and care when treatment is interrupted due to patient's violation of the terms of the signed control order; and
- the public is protected from infectious TB patients who have refused voluntary isolation when their actions pose a public health threat.

Programs may consider court proceedings on patients who are not infectious but rather, non-adherent with their treatment plan if the Health Authority and/or treating physician determines that without treatment the patient will pose a public health threat.

The process outlined in this chapter should facilitate processes between the TB program and local county/city attorney to establish legal justification for isolation. See *Health and Safety Code, Chapter 1, Communicable Diseases, Subchapter E. Control, 81.081*. "A health authority has supervisory authority and control over the administration of communicable disease control measures in the health authority's jurisdiction unless specifically preempted by the department."
statutes.capitol.texas.gov/Docs/HS/htm/HS.81.htm#81.081

Activities

- A. Ensure the following is done before initiating court-ordered management:
 1. Patient has been issued the *Health Authority Control Order* ([Form TB-410](#)) acknowledging understanding of treatment and compliance expectations.
 - a) This document should be signed by the patient, the local health authority, and a witness.
 - b) Maintain clear documentation if the patient refuses to sign.
 2. Patients with suspected or confirmed TB disease understand their role in receiving treatment and care for TB.
 3. Patients understand services they will receive from the TB program for successful treatment outcomes.
 4. Document any breach of expectations outlined on [Form TB-410](#) (e.g., missed DOT, attempts to reach patient) in the patient's medical record.



- B. Include the following in the patient's medical record:
1. A description of the physical and mental condition of the patient.
 2. The degree of infectiousness.
 3. Proposed threat to public health and supporting documentation of clinician, health authority or DSHS-recognized medical consultant.
 4. A description of non-compliant behaviors and the steps taken to address non-compliance to include all attempts taken to contact the patient.
 5. Documentation from the clinician, health authority or DSHS-recognized medical consultant if the patient has converted to smear negative but is expected to become infectious again.
- C. Begin the court-ordered management process.
1. The TB program will notify the following of an impending application for Court Ordered Managed care and / or Order of Protective Custody.
 - a) Medical Director
 - b) Public Health Region Medical Director
 - c) TB Program Manager
 - d) Nursing Supervisor
 - e) Local Health Authority
 - f) Jurisdiction's District Attorney (DA)
 - g) **DSHS Office of General Counsel:**
Department of State Health Services
1100 W. 49th Street
Austin, Texas 78756
(512) 458-7236
 - h) Texas Center for Infectious Disease:
dshs.texas.gov/tcid/courtmgmt.shtm
 2. The TCID admission process must be followed and transportation⁷ arranged by the managing jurisdiction.
 - a) TCID serves as the designated facility for patients who are court-ordered for extended management in Texas.
 - b) TCID **will not** accept patients with an MPC as they are not a holding facility. For patients with an MPC, the TB program must secure a holding facility before this motion.
- D. Initiate court-ordered management proceedings for Extended Management (MEM). Forms can be found at

⁷ **Texas Health & Safety Code Sec. 81.179. Transportation of Person.** (a) The court shall order the sheriff or constable to transport the person to the designated health care facility. (b) A female shall be accompanied by a female attendant during conveyance to the health care facility. (c) The health authority or department shall instruct the sheriff or constable on procedures that may be necessary in transporting the person to prevent the spread of disease.



dshs.texas.gov/idcu/disease/tb/forms/#CourtOrder

1. Complete the *Health Authority's Affidavit of Medical Evaluation* (DSHS [Form 86749_1](#)) which is Exhibit A of the application. This document should specify reasons an order for commitment is being sought. Indicate these reasons on line seven. This form must be filed in the district court in the county where the person resides, is found or is receiving court ordered health services.
 2. Present the following to the local health authority for signature:
 - a) Exhibit A (DSHS [Form 86749_1](#), which will need to be notarized)
 - b) Exhibit B, *Health Authority Control Order* ([TB-410](#)) and Exhibit 1A, which includes all medical notes, reports, etc.
 - c) Once complete and signed by the LHA, DSHS [Form 86749_1](#), [TB 410](#) and Exhibit 1A information will need to be faxed to the DSHS General Counsel's office at 512-776-7751.
 3. The Office of General Counsel will obtain the Commissioner of Health Concurrence and provide this document to the TB program by fax. The original concurrence will be mailed to the TB program to be placed in the patient's medical record. The TB program must wait for the commissioner's concurrence to move forward with court ordered management proceedings.
 4. Once all forms are completed and the commissioner's concurrence has been received, provide the above forms to the DA and follow local procedures as directed by the local attorney, who will likely file an Original Petition for either an MPC or MEM.
 - a) The health authority or treating physician will be asked to testify when a MEM is petitioned. It is recommended that the nurse case manager also attend this hearing as directed by the local attorney.
 - b) The local attorney will ask the court to appoint a lawyer for the patient and submit the necessary documents to the court.
 - c) Notify TCID that all paperwork has been filed with the court and final commitment approval is pending.
 - d) If approval for commitment has been granted, the signed MEM will need to be fax to the designated facility by the TB program. e.g. TCID.
 - e) Follow internal procedure for transfer of patient.
- E. Initiate court-ordered Motion for Protective Custody (MPC)
- This option is only available if the patient is contagious at the time the order is sought and the patient has the potential of fleeing and the treating physician has determined an MPC is needed. **NOTE:** TCID will not hold a patient with a MPC.
1. Ensure that a facility has been secured prior to submitting an MPC. TCID is not a holding facility and will not accept patients with an MPC.



This holding facility serves as placement for the patient until the judge issues the final order for a MEM.

2. Complete activity #3 and #4 as stated above with the exception of the commissioner's concurrence as this is not needed for an MPC.
3. The attorney will file an MPC and Writ of Commitment to the judge. TB program staff are not asked to testify for this hearing.
4. Once signed, the attorney will forward the signed documents to the TB program.
5. Follow internal procedure for transfer of patient.

F. Additional forms used for Court Ordered Management are located at dshs.texas.gov/disease/tb/forms/#court

Definitions

Application for Extended Management (DSHS Form 86963 1): Also referred to as Motion for Extended Management (MEM). This is the application to the court for the management of a person with a communicable disease. This refers to the full application that is used in the court order process.

Motion for Protective Custody (MPC) (DSHS Form 86964 1): Also referred to as Order of Protective Custody (OPC). An order to have the patient detained in appropriate isolation for a short period of time. This option is only available if the patient is an immediate threat to the public at the time the order is sought.

Non-adherent: Failure to comply with the health authority's written control order (DSHS Form TB-410). Examples include but are not limited to missing medication and failure to follow respiratory isolation which precludes safe and effective TB therapy and presents a potential for public health impact.



XXIII. Confidentiality and Security Standards

General Requirement

TB programs will perform activities outlined in this plan in accordance with applicable state and federal security and confidentiality standards, policies, procedures and guidelines, including but not limited to:

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

Activities

- A. Submit documentation to the DSHS TB/HIV/STD (THS) Section Security Officer to confirm that all staff and subcontractors working on activities outlined in this TB Work Plan receive yearly training on the [DSHS Security and Confidentiality Training](#) with a passing score of 85% or above.
- B. Submit inquiries related to database access and security training to TBHIVSTD.AccountRequest@dshs.texas.gov.
- C. Ensure that newly-hired staff successfully complete the [DSHS Security and Confidentiality Training](#) within 30 days of hire.
- D. Ensure that all staff successfully complete the [DSHS Security and Confidentiality Training](#) yearly, within one year of having taken the previous training.
- E. Submit appropriate documentation of security and confidentiality training to TBHIVSTD.AccountRequest@dshs.texas.gov within ten (10) days of completing course.
- F. Designate and identify a HIPAA Privacy Officer authorized to act on behalf of the TB program in developing and implementing requirements outlined in federal and state privacy laws.
- G. Designate a TB program staff (e.g., TB Program Manager) to serve as the Local Responsible Party (LRP). The LRP will:
 1. Ensure appropriate protocols and procedures are in place for handling



confidential information, releasing confidential TB/HIV/STD data and for rapid response to suspected privacy incidents of protocol and/or confidentiality.

- a) Local protocols and procedures must comply with DSHS policies and procedures.
 - b) TB Programs may choose to adopt DSHS policies and procedures as their own.
2. Approve and validate (provide signature) any program staff requiring access to TB/HIV/STD confidential information.
 - a) The LRP will grant authorization to program staff who have a work-related need to view confidential information.
 - (1) Complete the LRP fields on the Account Request form.
 - (2) Contact TBHIVSTD.AccountRequests@dshs.texas.gov and copy the person requesting access. The email should include:
 - (a) a statement verifying this person is under your authority;
 - (b) person's security training certificate;
 - (c) access request form;
 - (d) confidentiality agreement; and
 - (e) acceptable use agreement form.

DSHS will return access requests that do not include the required documents. Email should only request access for one person. Requests for multiple employees will not be accepted. Maintain email correspondence as part of your records. All current forms and instructions are at dshs.texas.gov/thsvh/account.shtm.
3. Maintain a current list of authorized staff with permission to view and work with confidential information in accordance with the [DSHS TB/HIV/STD Local Responsible Party Handbook](#), Required Documentation Section.
4. Maintain copies of current confidentiality forms and training certifications (e.g., personnel files, staff training records).
5. Ensure staff members including IT personnel, contractors, mailroom and custodial staff with access to identifiable public health data complete the DSHS Security and Confidentiality Training yearly.
6. Consult with the THS Section Security Officer on suspected privacy incidents of protocol and confidentiality in compliance with the [DSHS TB/HIV/STD Breach of Confidentiality Response Policy](#).
 - a) Investigate and complete privacy incident reports.
 - b) Limit or restrict access to confidential information for an involved user until the privacy incident investigation is complete.
 - c) Establish and/or enforce corrective and/or disciplinary actions when needed.
7. Submit required quarterly reports on time. See *Local Responsible Party*



Checklist at dshs.texas.gov/hivstd/policy/security.shtm.

- a) Ensure computers and networks meet DSHS security standards.
 - b) Submit requests for TB/HIV/STD systems user account terminations to TBHIVSTD.AccountRequest@dshs.texas.gov within one business day of identifying the need for account termination.
 - c) Identify local point of contact for changes in user access to secure data, secure network, secure reason and for receipt of notifications once a user account is terminated.
 - d) Transfer secure data electronically via GlobalScape.
 - e) Maintain a visitor's log for people entering secured areas. The LRP must conduct quarterly reviews of this log.
 - f) Verify user password changes occur at least every 90 days.
 - g) Ensure that portable devices used to store confidential data are encrypted and approved by the LRP.
- H. Ensure confidential data are:
- 1. maintained in a secure area when not in use;
 - 2. not left in plain sight; and
 - 3. shredded with a cross-cut feature before disposal.
- I. See [DSHS TB/HIV/STD Local Responsible Party \(LRP\) Handbook](#) for other roles and responsibilities.



Appendix A: Sample Letter for Child Window Prophylaxis

<insert date>

<insert patient name>

<insert patient address>

<insert city, state, zip code>

Dear <insert name of parent/guardian>,

I have recommended that your child, <name of child>, take preventive treatment (medicine) to stop <him/her> from getting tuberculosis. Your child was exposed to someone with tuberculosis. Taking medicine will decrease their chance of becoming sick.

Children aged 4 and younger exposed to tuberculosis are at greatest risk of quickly developing life-threatening disease. To prevent this from happening, your child must take medicine observed by (name of LHD/PHR) for at least the next <number of weeks recommended> weeks.

We will do a second tuberculosis skin test in <number of weeks> weeks. If the test is negative, we will stop the medicine. If the test is positive, we must continue the medicine for <length of treatment> to stop the infection from developing into active disease.

If you do not give your child this important medicine, you will endanger your child's health. This may result in the (name of the LHD/PHR) contacting Child Protective Services. I hope that we can work together to ensure the health of your child.

Please contact <phone number here> with your questions or concerns.

Sincerely,

<insert your name, title, contact information>



Appendix B: Sample Tuberculosis Program and Private Physician Agreement Letter

<insert date>

Dear <insert private provider's name>,

On <date reported to TB Program>, our office was notified that <insert patient's name/DOB> had <insert diagnostic findings, e.g. "an abnormal CXR showing cavitation, AFB sputum was smear positive">. He/she was reported to <insert PHR/LHD> and upon my review, he/she has been diagnosed with <suspected/confirmed> *Mycobacterium tuberculosis*.

We discussed this case on <date> and you have indicated that you will remain the patient's treating physician. You have also agreed to coordinate care with <LHD/PHR> in the following way:

<insert private provider's name> will:

<list below in detailed bulleted form, such as:>

- *Follow the prescribed TB regimen based on TB program recommendations (regimen is based on national guidelines for the treatment of drug-susceptible TB).*
- *Perform monthly laboratory tests as indicated and recommended by the TB program.*
- *Perform routine physical exams.*
- *Refer to radiology when indicated.*
- *List other details as appropriate*

The <LHD/PHR> TB Program staff will:

<list below in detailed bulleted form, such as:>

- *Order medications from the DSHS pharmacy.*
- *Provide directly observed therapy (DOT) on __(days) to this patient.*
- *Provide DOT results monthly for visibility of patient's adherence to treatment.*
- *Contact your office __(frequency) for copies of diagnostics, progress notes and updates in patient status.*
- *Collect__(frequency) sputum samples for AFB smear and culture and send results to your office.*
- *Keep the patient in airborne infection isolation until (criteria here).*
- *Maintain contact with your office __(frequency) until completion of therapy.*
- *Conduct an appropriate contact investigation following DSHS guidelines.*

Thank you for your partnership. Please contact <Insert point of contact, e.g., MD or TB Program Manager/Nurse Case Manager> with concerns or changes in the



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patient's plan of care.

Sincerely,

<insert your name, title, contact information>



Appendix C: Sample Correspondence Letter for Patients Treated by Private or Community Providers

<insert date>

<insert provider address>

Subject: <insert patient name and DOB>

Dear <insert private provider's name>:

The <insert PHR/LHD> TB Program requires a monthly status report on the above-named patient under your care for the treatment of tuberculosis.

Please complete all sections of the attached Medical Update Form and return within seven days to <insert name of recipient, physical address and fax number>. Please include additional radiology and/or laboratory results of acid-fast bacilli testing such as smear, culture or sensitivity results.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) indicates that protected health information (PHI) can be shared for public health, without individual authorization, to a public health authority. See [45 CFR 164.512(b)].

Thank you for your partnership. Please contact our office at <insert number> with questions.

Sincerely,

<Insert Your name, Title, contact information>

Adapted from "Tuberculosis Case Management: A Guide for Nurses", by Rutgers Global TB Institute, 2017.

Appendix D: Sample Medical Update Form for Patients Treated by Private or Community Providers

Medical Update Form⁸

Patient:

Date of Visit:

Date of most recent physical exam:

Weight:

Symptoms:

☐ Cough (if present specify): ☐ Productive ☐ Unproductive	☐ Hemoptysis	☐ Fever
☐ Weight loss	☐ Fatigue	☐ Chest pain
☐ Decreased appetite	☐ Night sweats	☐ Chills

Medications, frequency and dosages:

Bacteriology:

Results of most recent chest X-ray (if abnormal, please indicate whether X-ray is stable, worsening or improving):

TST or IGRA results:

☐ TST	☐ IGRA
Date administered:	Type of IGRA:
Date read:	Date:
Millimeter reading:	Result:

HIV Status:

Date TB treatment initiated:

Number of doses completed:

If completed, date of completion:

Comments:

⁸ Adapted from "Tuberculosis Case Management: A Guide for Nurses", by Rutgers Global TB Institute, 2017.



Appendix E: Additional Patient Services

This is a list of federal, state and county services available to patients who may need help supporting their medical care outside of tuberculosis disease management. The agencies below cover many aspects of medical care, from primary health services to low cost pharmacies to clinics that support patients regardless of their residency. Refer patients to agencies or programs depending on need.

Services for Children

Texas Health Steps

One of the benefits of Texas Health Steps is case management for those who need it. Case management helps families with Medicaid get services their children need—whether the services are for medical or dental needs, medical supplies and equipment, school or education issues or other issues.

hhs.texas.gov/doing-business-hhs/provider-portals/health-services-providers/case-management-providers-children-pregnant-women *Children's Health Insurance Program/Medicaid*

The Children's Health Insurance Program (CHIP) and Medicaid are jointly funded state-federal programs developed to help Texas Families obtain and utilize affordable coverage for uninsured children (ages 0-18). CHIP helps families who earn too much money to qualify for Medicaid but cannot afford to buy private insurance. Programs generally cover regular checkups, immunizations, prescription drugs, lab tests, X-rays and hospital visits. Under CHIP, cost sharing for prescription drugs is based on family income as a percentage of the Federal Poverty Income Level (FPL).

[CHIP/Medicaid](#) 1-877-KIDS-NOW (1-877-543-7669)

Children with Special Health Care Needs

Children with Special Health Care Needs (CSHCN) provides medically necessary care to Texas children with special health care needs. The program is the payer of last resort – all other medical benefits must be used first. Eligibility requirements apply. Participants must re-apply for benefits at six months. CSHCN offers a full range of services, including primary care, specialty care, durable equipment, transportation and medicines.

hhs.texas.gov/services/disability/children-special-health-care-needs-program; csn@dshtexas.gov; Toll-free: 1-800-252-8023

General Primary and Specialty Services

Federally Qualified Health Centers

Federally Qualified Health Centers (FQHCs) provide comprehensive health



care services to underserved communities. Many of the Texans they serve are indigent, uninsured and underserved. Some FQHCs offer additional services, such as dental, mental health or substance abuse treatment. FQHCs are community organizations with defined target populations and service areas. Services are provided to Medicare, Medicaid, CHIP, Insured and Uninsured people. Patients may be eligible for services based on their family income and a sliding fee schedule.

dshs.texas.gov/chpr/fqhcmmain.shtm

County Indigent Health Care Program

The County Indigent Health Care Program (CIHCP) was established by the Indigent Health Care and Treatment Act authorized by the 69th Texas Legislature in 1985. CIHCP provides health care services to eligible residents through counties, hospital districts and public hospitals in Texas. Programs are administered in accordance with [Chapter 61, Health And Safety Code](#) and [Texas Administrative Code, Title 25, Part 1, Chapter 14](#).

Eligibility requirements apply, including household income. CIHCP offers a full range of services, including primary care, specialty care, durable equipment and medicines.

hhs.texas.gov/services/health/county-indigent-health-care-program

Texas Association of Community Health Centers

The Texas Association of Community Health Centers (TACHC) is a private, non-profit membership association that represents safety-net health care providers in Texas. TACHC members include Community and Migrant Health Centers, Health Center Networks and other providers who strive to meet the healthcare needs of the uninsured and underserved.

TACHC serves as the federally designated primary care association for Texas.

tachc.org/find-healthcare-center

Other Benefits and Resources

Medicaid

Medicaid is a jointly funded state-federal healthcare program established in Texas in 1967. The Social Security Act specifies a set of benefits that state Medicaid programs must provide and a set of optional benefits that states may choose to provide. Eligibility requirements apply. The range of services provided include inpatient/outpatient hospital, lab and X-ray, physician services, nursing facility care, home health care and Texas Health Steps medical and dental plan for people aged 20 and younger.

tmhp.com



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Your Texas Benefits

This site allows you to apply online for health and human services, including Medicaid, Children's Medicaid, CHIP and other programs.

tmhp.com

2-1-1 Texas

2-1-1 Texas, a program of the Texas Health and Human Services Commission, is committed to helping Texas citizens connect with the services they need. Call 211 or click on link below to locate services in your community.

211texas.org

Low Cost Pharmacies and Medications

Medication Assistance Programs

Many pharmaceutical companies, non-profit organizations and state/national agencies provide access to low-cost medications prescribed by healthcare providers. Visit the site below for a list of resources for low or no-cost prescription medicines, including eligibility requirements and contact information.

staterxplans.us/texas.html

Transportation Services

LogistiCare

LogistiCare helps state governments and managed-care organizations run transportation and integrated health care programs, affording over 24 million covered plan members better access to care in their communities.

logisticare.com



Appendix F: Medical Consultation Templates

Sample 1: Complex Patient

Date Submitted:		PHR/LHD:	
Case Demographics			
Name:		Date of Birth:	Age:
Treating Provider:			
Sex: ☐ Male ☐ Female		Nurse Case Manager:	
Diagnosis: (e.g., MDR-TB, disseminated TB)			
Co-morbidities/TB risk factors: (e.g., diabetes, HIV, history of incarceration)			
TB History: (e.g., previous TB treatment, regimen, date of treatment completion)			
Resistant to:			
Susceptible to:			
Treatment Start Date:		Initial Treatment Regimen (medications):	
Changes in Treatment Regimen: (e.g., if injectable for how long patient received injectable; please provide drug-o-gram or equivalent)			

Current TB Regimen: (<i>medication/doses list with dates started or provide drug-o-gram</i>)		
Symptoms at Diagnosis:		
☐ Cough ☐ Productive ☐ Non-productive ☐ Hemoptysis ☐ SOB	☐ Fever/Chills ☐ Loss of appetite ☐ Weakness ☐ Night sweats ☐ Weight loss ☐ Chest pain ☐ Other:	
Weight at diagnosis/BMI: /		
Bacteriology: (<i>Include date collected, specimen type, test and results</i>)		
Date Collected	Specimen Type/Test	Results
Converted cultures? ☐ Yes ☐ No Date Converted:		
Isolation status:		
Chest X-ray: (<i>indicate what was noted on report</i>)		
Baseline Date: Read:	☐ Normal ☐ Cavitory ☐ Non Cavitory	
Current Date: Read:	☐ Normal ☐ Cavitory ☐ Non Cavitory	
Current Status		
Current weight/BMI: /		
Current labs: (<i>attach if needed</i>)		
HIV results:	☐ Negative ☐ Positive (if applicable)	
CD4:	Viral load:	
Abnormal labs:		



ECG (BDQ) ☐ **Normal** ☐ **Abnormal** ☐ **Changes**

Visual Acuity: (EMB, LZD or RBT) ☐ **Normal** ☐ **Abnormal** ☐ **Changes**

Ishihara Plates: (EMB, RBT or LZD) ☐ **Normal** ☐ **Abnormal** ☐ **Changes**

Neuropathy Checks (INH, LZD) ☐ **Normal** ☐ **Abnormal** ☐ **Changes**

Hearing Test (Injectable) ☐ **Normal** ☐ **Abnormal** ☐ **Changes**

Psychological Evaluation (CS, CFZ) ☐ **Normal** ☐ **Abnormal** ☐ **Changes**

(Any abnormal results or changes to baseline provide detailed forms showing trends and status)

Current Symptoms: *(Compare with symptoms at diagnosis, e.g., appetite improved, symptoms at diagnosis improved, improved energy?)*

Adherence to treatment:

Reason for consult:



Sample 2: Routine Consult

Patient Name:	Age:
Weight:	Medical history:
TB history:	TB risk factors:
Signs and symptoms upon admission to clinic/hospital:	
Imaging results: <i>(e.g., CXRs, CT scans)</i>	
HIV result <i>(if applicable):</i> CD4: Viral load:	CBC: <i>(baseline and most recent)</i>
CMP: <i>(baseline and most recent):</i>	Results of therapeutic drug monitoring: <i>(if applicable)</i>
Other labs: <i>(as applicable)</i>	
Medications: <i>(list dosages, start/stop dates, dates of interruption in therapy)</i>	
Bacteriology: <i>(list test, specimen type, collection date and result)</i>	
Current status of patient: <i>(provide details of clinical status, DOT, etc.)</i>	
Reason for consult: <i>(clearly state reason for consultation)</i>	



Appendix G: Requesting Molecular Detection of Drug Resistance (MDDR) Testing

The MDDR test is a way to rapidly and accurately detect potential drug resistance in *Mycobacterium tuberculosis* complex (MTBC). MDDR is performed on positive MTBC cultures or on patient specimens that are positive by nucleic acid amplification tests (NAAT) such as the polymerase chain reaction (PCR). MDDR is performed at the Centers for Disease Control (CDC) Reference Laboratory.

Indications for Submitting MDDR

Isolates of MTBC and NAAT positive processed specimens may be submitted by U.S. Public Health Laboratories for MDDR if one or more of the following criteria is met:

- Known multi-drug resistant (MDR) TB (by culture-based drug-susceptibility testing [DST])
- Known Rifampin resistance (by NAAT or by culture-based DST)
- Contact to known MDR TB case
- Previously treated for MTB
- From a country with a high rate of drug resistant TB
- Travel to/lived in a country with a high rate of drug resistant TB
- Patients where the result of drug resistance will predictably have a high public health impact (e.g., daycare workers, nurses)
- Patient is known to have certain adverse reactions to critical anti-TB drug (e.g., unable to tolerate rifampin)
- Other situations considered on a case-by-case basis (*must have a consult from a DSHS-recognized TB medical consultant. Visit dshs.texas.gov/idcu/disease/tb/consultants for contact information*)

DSHS Process for Submitting MDDR

First, ensure patient meets one or more of the above criteria. A consult from a DSHS-recognized medical consultant is highly recommended and is required once DR TB is confirmed.

- A. Contact the DSHS State Lab via phone or email.
 1. Main point of contact:
Denise Dunbar
Email: Denise.Dunbar@dshs.texas.gov
Phone: (512) 776-7342
 2. Secondary point of contact:
Benjamin Alpers
Email: Benjamin.Alpers@dshs.texas.gov
Phone: (512) 776-2699



- B. If indication is "Other situations considered on a case-by-case basis," secure written consult from a DSHS-recognized medical consultant.
- C. Ensure there is a plan in place for medical consultation for any patient with drug resistance.

If the above indications are not met, the state laboratory must notify the requestor to get a written consult from a DSHS-recognized medical consultant before submitting request for MDDR.



Appendix H: DSHS TB Formulary

The following medications and supplies for outpatient TB management are available to TB programs approved by the TB and Hansen's Disease Unit. Place orders via ITEAMS or contact the DSHS Pharmacy at (512) 776-7500.

Drug (Name Brand)	Item Description	Route	Comments
Amikacin	Vial	IM, IV	See VII; Requires consult*
Bedaquiline (Situro)	Tablet (Tab)	PO	See VII; Requires consult*
Clofazimine	Capsule (Cap)	PO	See VII; Requires consult*
Cycloserine (Seromycin)	Cap	PO	See VII; Requires consult*
Ethambutol (Myambutol)	Tab	PO	First Line
Ethionamide (Trecator)	Tab	PO	See VII; Requires consult*
Isoniazid	Solution (Soln)/Tab/Vial	PO, IM	First Line
Levofloxacin (Levaquin)	Soln/Tab/Vial	PO, IV	See VII; Requires consult*
Linezolid (Zyvox)	Suspension (Susp)/Vial	PO, IV	See VII; Requires consult*
Moxifloxacin (Avelox)	Tab/Vial	PO, IV	See VII; Requires consult*
Para-amino salicylic acid (Paser)	Packet	PO	See VII; Requires consult*
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	Each	NA	
Syringes (1/2", 27 gauge)	Syringe	NA	
Tuberculin Skin Test PPD	Vial	SC	
Amber RX bottles	Vial	NA	For self-admin. DOT
Auxiliary Medications			
Azithromycin (Zithromax)	Susp/tab/vial	PO/IV	See VII
Ondansetron	Tab, ODT(orally dissolving tablet)	PO	See VII
Promethazine	Tab	PO	See VII
Prednisone	Tab	PO	See VII
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	Cream	External	See VII
*See DSHS SDOs for medical consultation requirements			



Appendix I: Medication Mailing Processes

Patients with TB Infection Requiring Bulk Bottles

Medications prescribed for the treatment of latent TB infection may be mailed to patients when needed. Before mailing⁹, ensure the patient understands all instructions regarding their prescription. This includes when to stop taking the medicine and when to contact the clinic if they experience any symptoms of medication toxicity. Remind the patient of upcoming follow-up appointments. Finally, instruct the patient to keep medication out of reach of children and in a secure area of the home.

Order bulk bottles of medications and child-resistant amber prescription vials via ITEAMS.

TB programs shall not distribute or supply state-purchased medications to jails and other entities for which the patient receiving the medications are not under the direct care of the TB program.

The following must be included in the mailed package:

1. As required by the Texas State Board of Pharmacy (TSBP Rule Title 22, Texas Administrative Code §291.93), a medication label with the following information must be printed and attached to bottles for self-administered medications:
 1. Name, address and telephone number of clinic
 2. Name and strength of drug - if generic, name of manufacturer or distributor of drug
 3. Quantity
 4. Lot number
 5. Expiration date

The authorized, licensed nurse will complete the labeling directions to contain:

1. Patient name
2. Date medication provided
3. Physician name
4. 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).

⁹ Follow all security standards when mailing information to patients. Verify mailing procedures with local responsible party (LRP). See dshs.texas.gov/hivstd/policy/procedures/2016-01.shtm



Figure 3. Medication Label Example 1

DSHS Pharmacy Near You 123 Pharmacy Lane Pharmacy, TX 1231234 (512)555-5555		Date:
Net.:	Exp:	01/01/19
Dir:	Lot:	111222
RIFAMPIN CAP 300 MG #60 Take ___ caps by mouth each day. Take 1 hour before or 2 hours after meals. May decrease effectiveness of birth control pills.		
VERSAPHARM		
STORE BELOW 86 DEGREES F.		61748001860

2. A medication fact sheet using patient friendly language should be given to patients to reflect current prescription. Contact local pharmacist or the DSHS Pharmacy Branch for details. Sample fact sheets that may be used are:

- **Isoniazid/Rifapentine (3HP)**
[cdc.gov/tb/publications/pdf/3HP_508.pdf](https://www.cdc.gov/tb/publications/pdf/3HP_508.pdf)
- **Rifampin**
[cdc.gov/tb/publications/pdf/RIF_508.pdf](https://www.cdc.gov/tb/publications/pdf/RIF_508.pdf)
- **Isoniazid**
[cdc.gov/tb/publications/pdf/INH_508.pdf](https://www.cdc.gov/tb/publications/pdf/INH_508.pdf)
- **Moxifloxacin (Avelox)**
accessdata.fda.gov/drugsatfda_docs/label/2013/021085s057,021277s054lbl.pdf
- **Levofloxacin (Levaquin)**
accessdata.fda.gov/drugsatfda_docs/label/2018/020634s070lbl.pdf#page=52-
- **Bedaquiline (BDQ):**
[cdc.gov/tb/publications/factsheets/treatment/bedaquiline.htm](https://www.cdc.gov/tb/publications/factsheets/treatment/bedaquiline.htm)

3. A letter in the patient's preferred language explaining how to take the medication, any scheduled toxicity assessments and contact information for the clinic. Sample language is:

Hello (Patient),

As discussed on our phone call of (date), the (TB program's name) will mail your medications for TB infection. This package contains a (one-month/four week) supply of (name of medication here). Please take the medication as prescribed below and as stated on the enclosed (Name of Fact Sheet) drug fact sheet and bottle(s).

- *You have been prescribed: (Name of Medication)*
- *You should take this medicine as follows: (dosage, frequency)*



- *The physician who has prescribed this medication is: (Name here)*
- *Their contact is: (Insert MD direct contact or LHD/PHR contact)*

The TB program must follow up with you at least (weekly/monthly) while you take this medication. Your scheduled phone calls for (enhanced self-administration [ESAT], toxicity assessments, etc.) are:

- *Dates here*
- *Dates here*

Do not take the medication if you have symptoms or reactions as listed on the fact sheet. Contact the nurse right away at (contact numbers[s] here). Please call the (TB program contact here) if you have questions.

Thank you,

(TB Program Staff)

Patients with Known or Suspected TB Disease or Those on Observed Preventative Therapy for TB Infection (Including Window Prophylaxis) Requiring Medication Packets

When mailing¹⁰ or providing directly observed therapy (DOT) or directly observed preventative therapy (DOPT) for self-administration (i.e. weekend/holiday doses) or for video-enabled directly observed therapy (VDOT), TB programs must follow guidance recommended by the Texas State Board of Pharmacy (TSBP).

The TSBP recommendations are to reclassify DOT packets to fall under physician provision of medications per Texas Occupations Code, Title 3, Chapter 158. This states that a physician may provide medications to a patient, free of charge, as part of an indigent pharmaceutical program for adherence to a course of treatment.

Before providing the medication, ensure the patient understands all instructions regarding their prescription. This includes when to stop taking the medicine and when to contact the clinic if they experience any symptoms of medication toxicity. Remind the patient of upcoming follow up appointments. Finally, instruct the patient to keep medication out of reach of children and in a secure area of the home.

When physicians or their designees provide medications in this manner, there are labeling requirements that must be met in accordance with Texas Dangerous Drug Act, Section 483.042(a)(2).

¹⁰ Follow all security standards when mailing information to patients. Verify mailing procedures with local responsible party (LRP). See dshs.texas.gov/hivstd/policy/procedures/2016-01.shtm



The following must occur:

1. Place the allotted number of DOT packets in a light-resistant amber Ziploc bag and place a medication label on the outside of the bag. The label must contain the required information printed or handwritten by the clinician/nurse at the time medication is provided to the patient. The label must include:
 1. Name and address of medical director or physician who prescribed the drug
 2. Date drug is delivered to patient
 3. Patient name
 4. Name, strength and directions for use of drug(s)

Figure 4. Medication Label Example 2

Health Department Name Here 123 Main St. City, TX 77000 Phone 123-456-7891	
Date:	01/01/2018
Physician:	John Watson, MD
Patient:	Jane Doe
Medications:	Rifampin 600mg, Isoniazid 300mg, Pyrazinamide 1000mg, Ethambutol 800mg, Pyridoxine 50mg
Instructions:	Take 2 packets each day

2. Provide patients with a medication fact sheet. Contact the DSHS Pharmacy or TB Unit Nurse Consultant for the *Facts and Comparisons* medication fact sheets.
3. If mailing medications, include a letter in the patient's preferred language explaining how to take the medication, any follow up toxicity assessments needed and information on contacting the clinic. Sample language is:

Hello (Patient),

As discussed on our phone call of (date), the (TB program name) will mail your medications for (enhanced self-administration [ESAT], video DOT [VDOT], etc.).

This package contains a (two-week/one-month, etc.) supply of medications prescribed for the treatment of TB disease. Please take the medication as prescribed below and as stated on the enclosed bag of medication packets.



- *You have been prescribed: (Name of Medication)*
- *You should take this medicine as follows: (dosage, frequency)*
- *The physician who has prescribed this medication is: (Name here)*
- *Their contact is: (Insert either MD direct contact or LHD/PHR contact)*

The TB program must follow up with you at least (daily/monthly) while you take this medication. Your scheduled phone calls for ESAT and toxicity assessments are:

- *Dates here*

Do not take the medication if you have symptoms or reactions as listed on the fact sheet. Contact the nurse right away at (contact numbers[s] here). Please call the (TB program contact here) if you have questions.

Thank you,

(TB Program Staff)

Contact the DSHS Pharmacy at 512-776-7500 with questions regarding labeling or ordering of supplies.



Appendix J: Sample Tuberculosis Infection Prevention Plan

Purpose

According to the Centers for Disease Control and Prevention (CDC), people who work or receive care in high risk congregate settings are among those at higher risk for becoming infected with *Mycobacterium tuberculosis* (*M. tuberculosis*). Therefore, it is necessary to have a tuberculosis (TB) infection prevention plan as part of a general infection control program to ensure:

- prompt detection of TB;
- airborne precautions; and
- treatment of people suspected or confirmed to have TB disease.

To ensure the safety of the work environment, the following TB infection control plan should be implemented.

General Outline

The TB infection prevention plan IPP is based on three (3) levels of prevention, listed by levels of hierarchy:

- Administrative measures that reduce the risk of exposure to people with infectious TB.
- Environmental measures that prevent spread and reduce the concentration of infectious droplet nuclei.
- Respiratory protection or the use of personal protective equipment (PPE) prevent exposure from individuals with suspected or infectious TB.

Responsibility

The person responsible for the implementation and maintenance of the TB infection prevention plan is _____.

Administrative Controls

A written copy of the TB infection prevention plan is located at _____ and is available for inspection during regular business hours.

Ensure that TB prevention education and training is provided to staff, contractors and interns upon hire. Training topics include:

1. Mode of TB transmission;
2. TB sign and symptoms;
3. TB risk factors;
4. TB disease vs. TB infection;
5. Disinfection practices for equipment and exam rooms; and
6. Proper use of environmental and respiratory controls.



- B. The facility provides TB screening or requests proof of TB clearance before or upon employment.
- C. Patients with suspected or confirmed TB disease are separated from other patients. A surgical mask is placed on the patient if an airborne infection isolation (AII) room is not available.
- D. Posters and signs are used throughout the facility to remind patients, visitors and staff of proper cough etiquette.
- E. Initial and ongoing TB education is provided to people receiving TB prevention and care services.
- F. Testing and evaluating clinic personnel at higher risk of becoming infected with TB disease, including:
 - a. Reviewing results of TB screening for employees at least annually
 - i. Document using the TB-603 Tuberculosis (TB) Screening of TB Personnel or equivalent form
 - b. Documenting and investigating TB test conversion in TB personnel
 - i. Document using the TB-604 Report of Tuberculosis Conversion(s) in TB Personnel or equivalent form
- G. Maintaining documentation in accordance with local record retention policies and procedures.

Environmental Prevention

This facility utilizes the following method(s) of environmental measures:

A. General Ventilation

- 1. _____ is responsible for implementing schedule of preventive maintenance in accordance with manufacturer's instructions.
- 2. The current log is located at _____.
- 3. Historic records are filed in _____.

B. Local Exhaust Ventilation

- 1. _____ is responsible for implementing schedule of preventive maintenance in accordance with manufacturer's instructions.
- 2. The current log is located at _____.
- 3. Historic records are filed in _____.

C. AIIR (location):

- 1. AII rooms meet CDC criteria.
- 2. Negative pressure is monitored daily by _____. The method of monitoring is ☐ smoke test, ☐ tissue test or ☐ other visual check.



3. Negative pressure checks are documented using the _____ log.
The current log is located at _____.
4. Historic records are filed in _____.

D. High-Efficiency Particulate Air (HEPA) Filters (location):

1. _____ is responsible for implementing schedule of preventive maintenance in accordance with manufacturer's instructions.
2. The current log is located at _____.
3. Historic records are filed in _____.

E. Ultraviolet Germicidal Irradiation (location):

1. _____ is responsible for implementing schedule of preventive maintenance in accordance with manufacturer's instructions.
2. The current log is located at _____.
3. Historic records are filed in _____.

Respiratory Protection Program

The facility's respirator protection program is in accordance with Occupational Safety and Health Administration (OSHA) Respiratory Protection Standard 29CFR 1910.134.

- A. In this facility, the following brand/model of N-95 respirator(s) are used to protect staff _____.
- B. Respirators are purchased by _____.
- C. Initial fit testing is provided to employees who work in assignments that may require use of an N-95 respirator.
- D. Before fit-testing, a medical evaluation is conducted to determine the employee's ability to wear a respirator.
- E. Fit testing is repeated once a year and whenever a different respirator is used.
- F. A medical re-evaluation is obtained if an employee reports medical signs or symptoms that are related to the ability to use a respirator or if observations during fit testing indicate a need for a medical evaluation.
- G. If a staff person's weight changes significantly, or if facial/dental alterations occur within a year, the staff person will request that a fit test be repeated to ensure adequate respirator fit.
- H. The use of N-95 respirators is prohibited for any staff member who has facial hair that comes between the sealing surface of the face piece and the face of



the wearer, because it is impossible to get a sufficient seal.

- I. In this facility, staff with the following duty assignments require respirator fit testing:
 1. people entering rooms in which patients with suspected or confirmed TB disease are being isolated;
 2. people present during cough-inducing or aerosol-generation procedures with patients with suspected or confirmed TB disease;
 3. people who transport patients with suspected or confirmed TB disease;
 4. people who conduct maintenance on environmental control equipment; and
 5. other people based upon risk for TB exposure.
- J. A current list of staff who have been fit-tested, along with the date of fit-testing, manufacturer, model number and size of the respirator that was fit-tested, is located _____.
- K. A fit test qualifies the staff person to wear only the specific make, model and size respirator for which an acceptable fit test result was achieved.
- L. Staff wearing a respirator do a "seal check" of the respirator each time the respirator is used, in accordance with manufacturer's recommendations.

TB Infection Prevention Plan

Date Created:

Approved by:

Director/Deputy Director

Date

Medial Director

Date

TB Program Manager

Date

Date of Reviewed:

By:_____

Date of Reviewed:

By:_____

Date of Reviewed:

By:_____

Appendix K: TB Training and Education Resources

Designated staff using and signing the DSHS TB Standing Delegation Orders (SDOs) or local equivalent must have training and competency in TB care.

TB Nursing staff must complete 40 hours of initial training and education with 90 days of hire, followed by 16 hours of continuing education and training each calendar year.

Training	Reference
TB 101 for Health Care Workers	cdc.gov/tb/webcourses/tb101/
TB Core Curriculum	cdc.gov/tb/education/corecurr/
CDC TB Self-Study Modules (1-9)	cdc.gov/tb/education/ssmodules/
CDC RVCT Self-Study Modules	cdc.gov/tb/programs/rvct/instructionmanual.pdf cdc.gov/tb/programs/rvct/ParticipantManual_compress.pdf
DSHS TB Orientation (after 90 days of hire)	texas.tb.org
Heartland TB Nurse Case Management	heartlandntbc.org/training.html
Heartland TB Intensive	
Heartland Pediatric TB Intensive	
Heartland TB Contact Investigation	
TST Competency Check-List (TB-905)	dshs.texas.gov/disease/tb/forms/
Curry Center Guidelines for the Treatment of Drug Susceptible TB Webinar	currytbcenter.ucsf.edu/trainings/2016-atscdcidsa-clinical-practice-guidelines-treatment-drug-susceptible-tuberculosis
Vision and Hearing Certification	Local/regional training; contact regional office
THISIS Trainings on Texas Train	dshs.texas.gov/thsvh/thisis/tb.shtm



Training	Reference
Yearly continuing education and training	Education and training as required by CD or TB manager (or designee). May include: • Local yearly training (e.g., blood borne pathogens); may vary • Continuing education required for certification/professional license renewal; may vary • Yearly review of SDOs, TB Work Plan or other guidance documents; maintain training rosters • DSHS webinars (e.g., Research Rounds, TB Brown Bag sessions); maintain training rosters • Skills training (e.g., phlebotomy, TST, sputum collection) • Local case study review • Conference attendance (e.g., National TB Controller's Association [NTCA], Texas Public Health Association)



Appendix L: Sample In-Service and Training Roster

Topic: _____

Trainer/Educator: _____

Date: _____

Location: _____

Number of Hours: _____

Printed Name	Signature



Appendix M: Sample Stakeholder Training/Education Roster

Topic: _____

Trainer/Educator: _____

Date: _____

Location: _____

Group Type: _____

Format: _____

Number of Hours: _____

Printed Name	Signature



Appendix N: 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 of time 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:

1. Examined for the patient’s clinical status
2. Adequacy of patient’s regimen
3. Treatment adherence and completion
4. 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 in order to improve patient care and programmatic performance and to promote efficiency.

Process

In order 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 14: Cohort Period and Submission Schedule

Cohort Period & 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 (July 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

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 the following participants:

1. TB Program Manager
2. Nurse Case Manager
3. Supervisor

If available, the following participants should also be a part of the team:

- Medical reviewer
- Data analyst or epidemiologist
- Contact Investigator
- DOT Worker
- Social Worker
- Clinicians
- Lab Personnel

Reporting Requirements for Cohort Reviews

The **Cohort Presentation Form** shall be used to collect and present patient information during the cohort review meetings.

The **Cohort Review Summary Form** shall provide summarized and quantifiable data from all counted cases and associated contacts presented at each quarterly cohort review.

The **Cohort Review List of Counted Cases** shall be used to list counted cases presented at each quarterly cohort review.



Submit, by the dates identified in Table 1, the above forms using GlobalScape, or as specified by the TB and Hansen's Disease Unit.

Cohort Review Resources

The following links provide information on cohort review models:

- The Centers for Disease Control and Prevention (CDC)
cdc.gov/tb/education/cohort.htm
- Heartland National Tuberculosis Center
heartlandntbc.org/training/archives/tbnucama_20120720_0815.pdf



Appendix O: Resources, References and Timeframes for Reporting to the TB Unit

1. Access Requests (THISIS, EDN, ITEAMs, etc.)

- dshs.texas.gov/thsvh/account.shtm

2. Adverse Drug Reactions Resulting in Hospitalization or Death

- Update THISIS question package only if the reaction caused hospitalization or death and notify DSHS Pharmacy Branch at 512-776-7500.

3. Annual Progress Report

- Submit DSHS Annual Progress Report to TBContractReporting@dshs.texas.gov by April 1 of the current year.

4. Cohort Review

- Submit via GlobalScape and email CQIteam@dshs.texas.gov

5. Correctional Reports

- Chapter 89 facilities must submit the *Monthly Correctional TB Report* (DSHS Form [TB-EF-12-11462](#)) to the TB Program by the 5th working day of the following month.
- Local and regional TB programs must review and submit the *Monthly Correctional TB Report* (DSHS Form TB-EF-12-11462) and *Positive Reactors/Suspects/Cases Report* (DSHS Form [TB EF-12-11461](#)) via GlobalScape no later than the 15th day of each month.
- Chapter 89 facilities must submit the Correctional Tuberculosis Screening Plan (DSHS Form [TB 805](#)) into GlobalScape for review and approval 90 days before the current Screening Plan expiration date or anniversary date.
 - Before final approval, the TB Unit will forward the Screening Plan to the PHR or LHD for review. The reviewed Screening Plan with the PHR or LHD comments must be returned to the TB Unit within ten (10) days of receipt.

6. Deaths Related to TB

- Report when a person with known or suspected TB dies. The report must be sent to the TB Unit within 48 hours while investigating if TB was the cause of death by emailing: TB.feedback@dshs.texas.gov or by uploading details to GlobalScape.

7. Drug Resistant TB (RR, MDR, Pre-XDR, XDR-TB)

- Notify the TB Unit Nurse Consultant within 2 days for any consults submitted for RR-TB, MDR-TB, Pre-XDR TB or XDR-TB.
- Submit changes in case management, drug resistance patterns or residence on DR TB case within 72 hours of notification in THISIS and



notify the DR TB Nurse Consultant.

8. FedEx Accounts and Shipping Guide

- To set up accounts or order more shipping supplies, see:
dshs.texas.gov/IDCU/disease/tb/policies/TBSpecimenShippingGuide.pdf

9. Notice of Change in TB Personnel

- dshs.texas.gov/IDCU/disease/tb/policies/TBPersonnelNotice.pdf
- Send to TBProgram@dshs.texas.gov no later than the 5th of each month when changes in staff occur.

10. Incident Reports

- Report concerning contact investigations and/or mass screenings to the TB Unit Epidemiology team within 48 hours of meeting the criteria for an incident report.
- Submit Form EF12-12104 to GlobalScape and send an email notification to TBEpi@dshs.texas.gov

11. Targeted Testing

- Report outcomes of targeted testing by the 15th day of the following month to the Continuing Quality Improvement CQIteam@dshs.texas.gov using GlobalScape.

12. SDOs attestation

- No longer required to be submitted to TB Unit but must be signed by all staff and kept at the health department; this must be made available to the TB Unit upon request.

13. Requests for Second Line Medications

- No longer required to be submitted to TB Unit, but copies of consultation recommending second line medications from a DSHS recognized TB medical consultant must be made available to the TB Unit upon request, and kept in the medical record.

14. Report of TB Test Conversion of TB Personnel

- Send [the TB 604](#) to the TB Unit within 60 days of initial test at TB.Feedback@dshs.texas.gov

15. DNB/LO alerts

- For patients that are candidates for a Do Not Board and Be on the Look Out alert, contact the Epidemiology team at TBEpi@dshs.texas.gov to review criteria.

Appendix P: Case Detection, Accuracy, Completeness, Timeliness, Security and Confidentiality (DACTS) Audit Tool

DACTS Audit Tool

1.0	Training Requirements	Yes	No	If no, plan for improvement:
1.1	Have all members of TB Case Registry team completed their training? How many members? _____ How many completed? _____ How many did not complete? _____			
1.2	Basic TB Facts			
1.3	Core Curriculum on Tuberculosis, Seventh Edition 2021			
1.4	Diagnostic Standards and Classification of TB in Adults and Children; American Journal of Respiratory Critical Care Medicine 2000; Volume 161			
1.5	Guidelines for the Investigation of Contacts of Persons with Infectious Disease; MMWR 2005, 54 (No RR-15, 1-37)			
1.6	Aggregate Reports for TB Program Evaluation, Training Manual and Users Guide			
1.7	RVCT Instructions Manual			
1.8	A Guide and Toolkit for QA for TB Surveillance Data			
1.9	TB101 for Health Care Workers cdc.gov/tb/webcourses/TB101/intro.html			



1.0	Training Requirements	Yes	No	If no, plan for improvement:
1.10	TB Unit Orientation			
1.11	Annual Workshop			
1.12	Monthly TB Surveillance Conference Calls			
1.13	TBNN Workgroup			

2.0	System Access Requirements	Yes	No	If no, plan for improvement:
2.1	Do all team members have access to the necessary systems to perform their surveillance duties?			
2.2	GlobalScape			
2.3	Access to state and federal training websites			
2.4	THISIS			
2.5	PHLIMS/Labware – Public Health Laboratory Information Management System			
2.6	NTIP – National TB Indicators Project System			
2.7	NTSS – National Telecommunications Surveillance System			
2.8	TB GIMS – TB Genotyping Information Management System			
2.9	EDN – Electronic Disease Notification System			



3.0	Protocol Requirements	Yes	No	If no, plan for improvement:
3.1	Written Protocol for Surveillance QA			
3.1	Case Detection			
3.2	Data Accuracy			
3.3	Data Completeness			
3.4	Data Timeliness			
3.5	Data Security and Confidentiality			
3.6	Plan for Improvement			

4.0	Case Detection Requirements	Yes	No	If no, plan for improvement:
4.1	Maintain a Registry of TB Records: • Cases-contacts • Suspects-contacts • LTBI's referred or targeted testing			
4.1a	Records Inventory			
4.2	Established liaisons with appropriate reporting sources to enhance quality assurance of TB surveillance data			
4.3	Developed and implemented active case detection activities			
4.4	Evaluated the completeness of reporting of TB cases to the surveillance system			



5.0	Data Accuracy Requirements	Yes	No	If no, plan for improvement:
5.1	Evaluated accuracy or validity of RVCT data			
5.2	Assessed knowledge, skills and abilities of staff and provided training if needed			
5.3	Provides training on Data Entry Standards			
5.3a	Adheres to Data Stamping policy			
5.2b	Adheres to complete record search			

6.0	Data Completeness Requirements	Yes	No	If no, plan for improvement:
6.1	Maintains Completeness of all RVCT variables			
6.2	Matches TB and HIV Case Registries			
6.3	Evaluates programmatic performance by using TB surveillance data, at least once a year			

7.0	Data Timeliness Requirements	Yes	No	If no, plan for improvement:
7.1	Reports all newly diagnosed cases of TB to the TB Unit according to schedule			
7.1a	Persons with known TB			
7.1b	Persons with suspected TB			
7.1c	Contacts to persons with infectious TB			



7.0	Data Timeliness Requirements	Yes	No	If no, plan for improvement:
7.1d	IJNs			
7.1e	Persons with TB Infection			
7.2	Submits complete RVCT reports to the TB Unit according to schedule			
7.3	Analyzes TB surveillance data at least quarterly			
7.4	Evaluates programmatic performance by using TB surveillance data at least once a year.			

8.0	Security and Confidentiality Requirements	Yes	No	If no, plan for improvement:
8.1	List of the minimum standards required for data sharing and use of surveillance data for public health action			
8.2	Guidelines on how to initially assess the TB program's data security and confidentiality policies and procedures			
8.3	Checklist for conducting ongoing assessment of TB program compliance with the data security and confidentiality guidelines			
8.4	Questions and Answers to clarify issues regarding the Data Security and Confidentiality Guidelines			
8.4a	Guidelines filed with Surveillance Procedures Manual			
8.4b	Records in locked cabinet, in locked room			
8.4c	Fax machine and copier in locked room			



8.0	Security and Confidentiality Requirements	Yes	No	If no, plan for improvement:
8.4d	Use only iron key flash drives for storing working files containing data			
8.4e	Data files have a back-up system			

9.0	Maintains log for TB employees and other entities and dates of training and presentations.	Yes	No	If no, plan for improvement:
9.a	Log for TB employees			
9.aa	Date, name of employee, jurisdiction or clinic, name of training			
9.b	Log for other entities			
9.bb	Date, employee, entity, name of training, number participated			

10.0	Maintains personal folder of training materials in common or shared drive.	Yes	No	If no, plan for improvement:
10.a	Slide Presentations from conferences and workshops			
10.b	World TB Day Presentations			
10.c	TB Surveillance Brown Bag Presentations			
10.d	What is TB, Questions and Answers Test			
10.e	THISIS Instructions and Updates			
10.f	Other Training Documents			

Appendix Q: List of Acronyms

AFB	Acid-Fast Bacillus
AII	Airborne Infection Isolation
APR	Annual Progress Report
ATS	American Thoracic Society
BCG	Bacillus Calmette-Guerin
BDQ	Bedaquiline
CDC	Centers for Disease Control and Prevention
CFZ	Clofazimine
CI	Contact Investigation
CMS	DSHS Contract Management Section
CPS	Child Protective Services
CQI	Continuous Quality Improvement
DGMQ	CDC Division of Global Migration and Quarantine
DNA	Deoxyribonucleic Acid
DOPT	Directly-Observed Preventative Therapy
DOT	Directly-Observed Therapy
DACTS	Case Detection, Accuracy, Completeness, Timeliness, Security and Confidentiality
DR TB	Drug-Resistant Tuberculosis
DSHS	Texas Department of State Health Services
DST	Drug Susceptibility Test
DTBE	CDC Division for TB Elimination

EDN	Electronic Disease Notification
ELR	Electronic Laboratory Reporting
FDA	U.S. Food and Drug Administration
FEFO	First-Expiring/First-Out
FQHC	Federally Qualified Health Center
FUW	Follow-Up Worksheet
HNTC	Heartland National TB Center
ICE	U.S. Immigration Customs Enforcement Agency
IGRA	Interferon Gamma Release Assay
IJN	Interjurisdictional Notification
ITEAMS	Inventory Tracking Electronic Asset Management System
LHD	Local Health Department
LTFU	Lost to Follow-Up
MAC	<i>Mycobacterium avium</i> complex
M.TB BCG	<i>Mycobacterium bovis-Bacille Calmette-Guerin</i>
MDDR	Molecular Detection of Drug Resistance
MDR-TB	Multi-drug resistance
MMWR	Morbidity and Mortality Weekly Report
MPC	Motion for Protective Custody
MTBC	<i>Mycobacterium tuberculosis</i> Complex
NAAT	Nucleic Acid Amplification Test
NTCA	National TB Controllers Association

NTIP	National TB Indicators Project
PAS	Para-Aminosalicylic Acid
PCR	Polymerase Chain Reaction
PHI	Protected Health Information
PHR	Public Health Region
PPD	Purified Protein Derivative
Pre-XDR TB	Pre-Extensively Drug Resistance
QA	Quality Assurance
RIPE	Rifampin, Isoniazid, Pyrazinamide and Ethambutol
rpoB	RNA-polymerase Beta subunit
RR-TB	Rifampin Mono-Resistance
RVCT	Report of Verified Cases of TB
SAT	Self-Administration Therapy
SDOs	Standing Delegation Orders
SMOs	Standing Medical Orders
SQA	Surveillance Quality Assurance
TB	Tuberculosis
TBNN	TB Network News
TCID	Texas Center for Infectious Disease
TDCJ	Texas Department of Criminal Justice
THISIS	TB/HIV/STD Integrated System
THMP	Texas Medicaid & Healthcare Partnership



TEXAS
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**Texas Department of State
Health Services**

Texas Tuberculosis Work Plan
(Revised 8/30/21)

TNF	Tumor Necrosis Factor
TSBP	Texas State Board of Pharmacy
TST	Tuberculin Skin Testing
UOT	Unit Operations Team
VDOT	Video-Enabled Directly Observed Therapy
XDR-TB	Extensively Drug Resistance