1. **OVERVIEW**
   1. **Collecting Performance Measures**

Performance measures for this evaluation are the NTIP performance targets for 2025 that address laboratory turnaround time for nucleic acid amplification tests (NAATs) and culture results.

* 1. **Responding to Evaluation Questions**

Once evaluation questions are developed, the following will be identified in order to address the evaluation questions: (1) what data sources can be utilized; (2) what reports should be generated; and (3) how evaluation plans and results will be communicated to stakeholders.

* 1. **Using Evaluation Findings for Continuous Program Quality Improvement**

Findings from this program evaluation will be used for program quality improvement by: (1) identifying gaps in communication that could improve data quality; (2) identifying best practices that may result in improved programmatic performance; and (3) improving relationships with TDH state public health lab (SPHL) and non-public health laboratories.

* 1. **Program Partner Involvement**

Stakeholders previously identified will be engaged at various stages of the evaluation. Initial engagement will involve the following stakeholders:

* TTBEP medical director
* TTBEP program manager
* TTBEP epidemiologist

Additional stakeholders will be engaged at various stages of the evaluation. Stakeholders will be involved via in-person meetings (when feasible), webinars, conference calls, and through electronic communication.

* 1. **Data**
     1. Data Sources
        1. Report of Verified Case of Tuberculosis (RVCT)
           1. Item #5: Count Status
           2. Item #16: Site of TB Disease
           3. Item #18: Sputum Culture
           4. Item #20: Culture of Tissue and Other Body Fluids
           5. Item #21: Nucleic Acid Amplification Test Result
        2. National TB Indicators Project (NTIP)
           1. Program Area = Tennessee
           2. Indicator = Laboratory Turnaround Time
           3. Case Year or Quarter = 2018 and 2019
        3. National Electronic Disease Surveillance System (NEDSS)-based System (NBS)
           1. NBS is the surveillance system that the TTBEP utilizes for TB surveillance and reporting
        4. CPRS
           1. State electronic medical records utilized by nine (9) public health regions in Tennessee
        5. Patient medical records
           1. For those regions that do not utilize CPRS, paper records will be accessed to determine lab reporting entity
        6. TDH SPHL
           1. Turnaround time data
           2. Non-public laboratory points of contact
     2. Collecting Appropriate Evaluation and Performance Data

Reports will be generated from both NBS and NTIP. Data quality reviews will be performed on all cases not meeting the culture and NAA test laboratory turnaround time indicator.

* 1. **Success and Improvement**
     1. Identifying Programmatic Areas of Success
        1. Increase the number of culture and NAAT results that are correctly recorded on the RVCT
        2. Increase in knowledge of how to interpret culture and NAA test lab results
        3. Increase in laboratory turnaround time performance toward the 2025 national objectives
        4. Development of education on interpreting laboratory results
     2. Identifying Areas in Need of Improvement
        1. Data quality reviews will identify areas in need of improvement
        2. Communication between public health and non-public health laboratories
  2. **Meeting National TB Program Objectives and Performance Targets for 2025**

The TTBEP will develop benchmarks to measure progress toward the 2025 NTIP performance targets. Quarterly data reviews will be conducted to identify any ongoing data quality issues and laboratories that do not meet the NTIP laboratory TAT targets.

* 1. **Using NTIP Reports**

NTIP reports will be used to compare with state surveillance reports and to identify individual TB cases that do not meet the NTIP indicators.

* 1. **Factors Contributing to Program Performance**

The TTBEP will seek to understand factors contributing to the program’s performance by (1) gathering stakeholder feedback about program performance; (2) soliciting input from stakeholders regarding activities that would improve program performance.

* 1. **Remediation Strategies to Improve Program Performance**

Remediation strategies will largely focus on education of regional TB staff on interpretation of laboratory results to ensure accurate data are entered into NBS. TTBEP will also provide education to non-public health labs about the importance of rapid TATs for NAA tests and cultures, and utilizing the TDH SPHL for initial specimen processing.

* 1. **Evaluating and Updating Data Management Plan**

TTBEP will review the Data Management Plan quarterly to reflect any updated information about policies and procedures for data extraction, data storage, and data dissemination that may be provided by the Tennessee Department of Health.

1. **DATA MANAGEMENT PLAN**
   1. **Data Description**

The following data will be created for use in this evaluation project:

* + 1. Surveillance Case Reports
       1. Format: Excel spreadsheets, Access databases, SAS outputs
       2. Volume: the volume of these reports is not expected to be large given the cohort years that will be used for this evaluation project
    2. Medical Records:
       1. Format: electronic and paper depending on the type of medical records system utilized by each public health region
       2. Volume: the entire medical record will not be utilized; only laboratory reports will be extracted from each medical record for patients that did not meet the NTIP indicator
    3. Cohort Review Summaries
       1. Format: Word document summaries of each patient within the cohort review that did not meet the laboratory TAT
       2. Volume: the volume is not expected to be large given the amount of information needed from cohort reviews and the cohort years that will be used for this project
  1. **Data Standards**
     1. Data Collection

Data will be collected utilizing the following methods: (1) reports from NBS and NTIP; (2) non-public health laboratory point-of-contact information from TDH SPHL and the TDH Healthcare Associated Infection (HAI) program; (3) phone and email communication to non-public health laboratory contacts; and (4) REDCap surveys.

* + 1. Limitations of Data

Limitations of the data include but are not limited to: (1) accuracy of data entered into NBS; (2) timeliness of data entry into NBS; (3) willingness of non-public health laboratories to provide requested information; and (4) accuracy of non-public health laboratory point-of-contact information due to employee attrition

* + 1. Documentation Needed to Interpret Data

Documentation that will be needed to interpret that data include: (1) explanation of the NTIP objectives; (2) description of variables used to calculate NTIP performance; and (3) description of TTBEP organizational structure regarding data collection and data entry into NBS.

* 1. **Data Access**

The Tennessee Strategic Technology Solutions (STS) Department provides either remote servers at a data center or virtual servers that provide secure storage for health data. NBS servers have dedicated resources and disaster recovery plans as well as mechanisms in place for system audit purposes.

At the department level, TDH is revising its health data release policy to minimize potential trace-back of patients with the joining of multiple publically available datasets. The TDH Division of Communicable and Environmental Disease and Emergency Preparedness (CEDEP) plans to release non-identifiable, actionable public health data in the form of public-facing dashboards and reports. This policy, once completed and approved, will advance the department’s mission of transparency.

The state surveillance system, NBS, is a CDC-vendor system that is utilized by several programs within the Tennessee Department of Health (TDH). The TDH Division of Communicable and Environmental Disease and Emergency Preparedness has a dedicated program, Surveillance System and Informatics Program (SSIP), which is responsible for maintenance of the surveillance system. TDH will work will Strategic Technology Solutions (STS) and Community Health Systems (CHS) to ensure data use and release process are upheld by system users. All system users are required to supply signed documentation of the state’s Computer Access Security Agreement and Acceptable Use Agreements in addition to adhering to HIPAA policy and state policy for data containing protected health information. Any additional policies will be utilized as necessary.

* 1. **Archival and Long-Term Data Preservation Plan**

Data will be retained according to TDH data retention policies and will be archived in a secure location. Acts 1971, ch. 210, § 11; 1977. ch. 145, § 6, T.C.A., § 53-1030 states, “The department shall maintain a tuberculosis register system and conduct epidemiologic studies of the conditions existing within the state, regarding the prevalence, prevention, treatment and cure of tuberculosis. It shall compile data from the register system and the studies and keep a record of the data, to the end that the disease may be more effectually combated.”

1. **PROGRAMMATIC EVALUATION AND PERFORMANCE MEASUREMENT**
   1. **Program Evaluation Plan**
      1. Background

Delays in diagnosis and effective treatment for TB (such as inadequate treatment regimens, increased length of treatment, and acquired drug resistance) can have detrimental effects for persons with suspected or confirmed TB. Historically, failure of the TTBEP to meet certain National TB Indicators Program (NTIP) objectives for laboratory turnaround time (TAT) has been a result of the following factors: (1) delays or failures in reporting respiratory specimens positive for acid-fast bacilli (AFB); (2) delays or failures in sending specimens (reference or raw samples) to the TDH SPHL for processing; and (3) errors in interpreting lab reports and subsequent inaccurate documentation on the Report of a Verified Case of Tuberculosis (RVCT).

The TDH SPHL is the primary laboratory utilized by regional TB programs to test samples for *M. tuberculosis* complex (MTBC). **Figure 1** outlines the TDH SPHL testing algorithm.

**Figure 1. TDH SPHL Testing Algorithm**



Non-reference specimens received by the TDH SPHL are set-up for smear and culture. If a smear result is AFB-positive, a GeneXpert® reflex test is performed. The TDH SPHL has validated the GeneXpert® for respiratory and non-respiratory samples. In addition, GeneXpert® test may be performed on AFB smear-negative samples upon request. The experience of the TTBEP is that many hospital laboratories do not perform reflex testing, and separate clinician orders are required for separate tests for Mtbc. Hospital laboratories may perform smear or nucleic acid amplification (NAA) tests. These laboratories may set up a culture if the smear or NAA test is positive, either within the hospital laboratory or by a contracted commercial laboratory. The sum of these factors may increase the TAT for these specimens and result in delayed diagnosis and effective treatment for TB disease

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**Table 1** outlines the NTIP objectives for laboratory TAT for culture and nucleic acid amplification (NAA) testing.

**Table 1. NTIP Objectives for Laboratory TAT, 2025**

|  |  |
| --- | --- |
| **Objective** | **2025 Target** |
| Increase the proportion of TB patients who have the identification of *M. tuberculosis* complex from culture of respiratory specimens reported by the laboratory within 25 days from the date the specimen was collected. | 78.0% |
| Increase the proportion of TB patients who have the identification of *M. tuberculosis* complex by nucleic acid amplification (NAA) testing from respiratory specimens reported by the laboratory within 6 days from the date specimen was collected. | 97.0% |

**Figures 2 and 3** show Tennessee’s performance toward meeting the two (2) NTIP laboratory TAT objectives for 2017-2019.

**Figure 2. Identification of *M. tuberculosis* Complex (MTBC) from Culture of Respiratory Specimens Reported within 25 days of Specimen Collection—Tennessee, 2017-2019**

**Figure 3. Detection of *M. tuberculosis* Complex (MTBC) by NAA Testing from Respiratory Specimens Reported within 6 Days of Specimen Collection—Tennessee, 2017-2019**

* + 1. Evaluation Objectives and Key Evaluation Questions

The following evaluation questions have posed for this evaluation:

* + - 1. For the TDH SPHL, what was the average turnaround time for nucleic acid amplification (NAA) test and culture results for respiratory specimens from Tennessee TB cases positive for *Mycobacterium tuberculosis* complex disease for years 2018-2019?
      2. What non-public health entities (hospitals, private providers, commercial laboratories, etc.) reported respiratory cases of TB to the TTBEP for years 2018-2019?
         1. Which laboratories identified Mtbc for these non-public health entities for years 2018-2019?
      3. Which non-public laboratories tested respiratory specimens obtained from Tennessee TB patients that were positive for Mtbc for years 2018-2019?
      4. What are the testing capabilities for Mtbc for all non-public health laboratories in Tennessee?
      5. What is the testing algorithm for Mtbc for those laboratories that testing respiratory specimens obtained from Tennessee TB patients that were positive for Mtbc for years 2018-2019?
      6. What was the average TAT from specimen collection to result report for those non-public health laboratories that tested respiratory specimens obtained from Tennessee TB patients that were positive for Mtbc for years 2018-2019?
    1. Methods and Timelines for Data Collection and Analysis

This evaluation will be completed within two (2) years. **Table 2** outlines the timeframes for this evaluation:

**Table 2. Evaluation Activities and Target Dates**

|  |  |
| --- | --- |
| **Evaluation Activity** | **Timeline** |
| Identify all TB cases that did not meet the NTIP culture or nucleic acid amplification (NAA) test indicators. | August 15, 2020 |
| Identify any data entry errors for data on patients that did not meet the NTIP indicator. | September 30, 2020 |
| Identify performing laboratories and turnaround times for those specimens that did not meet the NTIP laboratory TATs | October 31, 2020 |
| Identify points-of-contact for those laboratories that tested respiratory specimens obtained from Tennessee TB patients that did not meet the NTIP TATs. | December 31, 2020 |
| Describe the testing algorithms for each of the laboratories that tested respiratory specimens for Tennessee TB patients that did not meet the NTIP TATs | March 1, 2021 |

* + 1. Key Program Partners

Stakeholders for the Tennessee Tuberculosis Elimination Program (TTBEP)’s program evaluation plan can be categorized as:

* Those involved in programmatic operations
  + TTBEP central office staff
  + Regional and local TB program staff
  + Tennessee Department of Health (TDH) Division of Laboratory Services Special Microbiology Department
* Those affected by the program evaluation
  + Tennessee TB patients
* Intended users of the TTBEP program evaluation
  + TTBEP central office staff
  + Regional and local TB program staff
  + Tennessee Department of Health Division of Laboratory leadership
  + Non-public health laboratory leadership
  + Centers for Disease Control and Prevention (CDC), Division of Tuberculosis Elimination (DTBE)
  1. **Logic Model**



* 1. **Cohort Review Plan**

The Tennessee TB Elimination Program conducts bi-annual cohort reviews with two (2) regions that account for the majority of the TB morbidity in the state—Memphis/Shelby County and Nashville/Davidson County. Cohort reviews are conducted either in-person or via phone/webinar. At the conclusion of each cohort review, systems issues are identified for the cohort. A cohort action plan is developed and at the subsequent cohort review, activities conducted to address those previously-identified systems issues are presented.

1. **LABORATORY EVALUATION AND PERFORMANCE MEASUREMENT**
   1. **Laboratory Element 1: Ensure availability of high-quality and prompt core laboratory services for tuberculosis (TB)**

The process for establishing laboratory-specific goals if met from the prior year is a 3% improvement. If the goal is unmet, it remains the same for the following year. Turnaround time (TAT) data is used to develop and evaluate strategies for all performance targets. LIMS queries will be used to identify TATs that are out of range. These data allow the laboratory to track specimens from collection, submission, receipt, identification, and final approval. Queries will also be used to identify the best testing format within the laboratory as well as educational opportunities. These monitors will be conducted by the lab supervisor or manager.

* Improve the TAT of specimens received within one (1) day of collection to 65.0%
* Report drug-susceptibility testing results for 75% of all isolates within 17 days of identification.
* Report NAAT results within 48 hours for 85% of specimens received.
* Report smear within 24 hours of specimen receipt for 85% of specimens received.
* Improve TAT to 65% of MTBC isolates reported within 21 calendar days of specimen receipt.
  1. **Laboratory Element 2: Advancement of efficiency and quality improvement based on lab data**

The goal is to reduce the number of transcription errors by laboratory personnel by 5%. To achieve this, various quality assurance (QA) activities will be performed to verify accuracy of the test request, specimen submission, and test reporting format. Quality assurance monitoring will be conducted by the TB lab supervisor, Natasha Lindahl. In addition, the laboratory informatics team is working to develop in an effort to reduce result transcription.

* 1. **Laboratory Element 3: Collaborate with partners**

An existing goal is to develop a universal cross-contamination standard to be used by TDOH lab services and the TTBEP. This protocol could be used internally and utilized by the TTBEP when cross-contamination is suspected from non-public health laboratories. Following this protocol would simplify investigations and expedite the resolution of contamination issues. This protocol is being developed by TB lab manager, Dorothy Baynham, and the TTBEP with a target implementation date of December 2020.