**PREVENTION AND CONTROL**

**NTIP Summary Report**

*Source*: 2020 data (NTIP data updated 7/28/21)

 2021 Q1 and Q2 data (accessed 7/28/21)

|  |  |  |  |
| --- | --- | --- | --- |
| **National TB Program Objective** | **2025 Target** | **2020 Result** | **2021 Result** |
| **Q1** | **Q2** |
| **Goals for Reducing TB Incidence (incidence per 100,000 population)** |
| TB Incidence | 1.3 | 1.7\* | 0.22§ | 0.40§ |
| U.S.-born Persons | 0.4 | 0.9\* | 0.11§ | 0.20§ |
| Non-U.S.-born Persons | 8.8 | 15.4\* | 2.1§ | 3.7§ |
| U.S.-born, Non-Hispanic Blacks | 1.0 | 3.1\* | 0.54§ | 0.63§ |
| Children Younger than 5 Years of Age | 0.1 | 0.5\* | 0.0§ | 0.00§ |
| **Objectives on Case Management and Treatment (%)** |
| Known HIV Status | 99.0 | 96.4\* | 100§ | 96.0\*§ |
| Treatment Initiation | 96.0 | 96.4 | 100§ | 87.5\*§ |
| Recommended Initial Therapy | 97.0 | 94.5\* | 100§ | 88.0\*§ |
| Sputum Culture Result Reported | 99.0 | 96.8\* | 100§ | 88.2\*§ |
| Sputum Culture Conversion | 83.0 | 91.9 | 71.4\*§ | 20.0\*§ |
| Completion of Treatment | 95.0 | 71.6\*§ | 7.1\*§ | 0.0\*§ |
| **Objectives on Laboratory Reporting (%)** |
| Turnaround Time—Culture | 78.0 | 59.7\* | 37.5\*§ | 30.8\*§ |
| Turnaround Time—NAA | 97.0 | 74.1\* | 100\*§ | 100\*§ |
| Drug-Susceptibility Testing | 100 | 96.5\* | 90.0\*§ | 78.9\*§ |
| Universal Genotyping | 100 | 96.5\* | 90.0\*§ | 89.5\*§ |
| **Objectives on Contact Investigations (preliminary 2020 ARPE data) (%)** |
| Contact Elicitation | 100 | 90.0\*§ | -- | -- |
| Contact Examination | 94.0 | 85.3\*§ | -- | -- |
| LTBI Treatment Initiation | 92.0 | 72.5\*§ | -- | -- |
| LTBI Treatment Completion | 93.0 | 86.5\*§ | -- | -- |
| **Objectives on Examination of Immigrants and Refugees (%)** |
| Examination Initiation | 72.0 | 56.0\* | 78.6\*§ | 43.8\*§ |
| Examination Completion | 78.0 | 56.0\* | 50.0\*§ | 37.5\*§ |
| LTBI Treatment Initiation | 87.0 | 50.0\* | 0.0\*§ | -- |
| LTBI Treatment Completion | 87.0 | 100 | -- | -- |
| **Indicators for Date Reporting (%)** |
| RVCT | 100 | 97.4\*§ | 89.5§ | 81.5\*§ |
| ARPE | 100 | 88.9\*§ | -- | -- |
| EDN | 93.0 | 75.1\*§ | 63.0\*§ | 47.6\*§ |

Case rates for Q1/Q2 calculated using case counts for the quarter and population estimates

\*Indicator not met

§Data are preliminary

**Tennessee TB Elimination Program (TTBEP) and COVID-19 Response**

During the COVID-19 pandemic, TB staff at the state, regional, and local level throughout Tennessee were reassigned from their TB duties to assist with the COVID-19 response. At the state level, six of the seven TB staff members assisted in the response. State, regional, and local TB staff assisted with the following activities during the COVID-19 response:

* COVID-19 call bank
* COVID-19 testing events
* COVID-19 vaccination points of distribution (PODs)
* Contact tracing
* COVID-19 case interviews
* COVID-19 cluster surveillance and reporting
* Administrative support for centralized interview team
* Data visualization
* Epi-X notification processing

TTBEP Interim Recommendations during COVID-19

During 2020, the TTBEP issued interim recommendations for statewide TB program operations on three (3) separate occasions: March, May, and October. Recommendations issued in March 2020 included:

* Temporarily suspending collection of induced sputum in sputum induction booths
* Completing as much of the initial assessment via phone or video, when possible
* Deferment to second round testing for persons exposed to sources cases with ruled out pulmonary disease
* Relaxing the criteria needed for electronic directly observed therapy (DOT)
* Deferment of treatment of TB infection (TBI) for patient except for those high-priority contacts
* Reduction in the number of visits to health department clinics for medication and increase in the number of bottles of medication for TBI provided at a single time
* Temporarily suspending the use of the 12-week isoniazid/rifapentine (“3HP”) regimen for TB infection

Subsequent iterations recommended testing for COVID-19 for all persons with suspected or confirmed TB disease with symptoms of COVID-19. In addition, later recommendations encouraged TB programs to progress toward resuming pre-COVID operations as resources allowed.

TB and COVID-19 Surveillance in Tennessee

In an effort to quantify the number of persons diagnosed with TB in Tennessee who were also co-infected with COVID-19, TTBEP central office staff worked with staff from the Surveillance Systems and Informatics Program (SSIP) to add locally defined fields (LDFs) the TB and TBI pages in the statewide surveillance system. The fields added were: “Date of COVID Test” and “COVID Test Result.” The table below shows TB cases counted and corresponding COVID-19 test results:

|  |  |  |
| --- | --- | --- |
| **Year** | **Case Count** | **COVID-19 Test Result** |
| **Positive(%)** | **Negative****(%)** | **Unknown****(%)** |
| 2020 | 113 | 16§(14.2) | 63(55.8) | 34(30.1) |
| 2021\* | 42 | 6±(14.3) | 30(71.4) | 6(14.3) |
| **TOTAL** | **155** | **22****(14.2)** | **93****(60.0)** | **40****(25.8)** |

\*Includes quarters 1 and 2 (January – June 2021)

§One positive COVID-19 occurred three (3) months prior to the initiation of the TB investigation

±One positive COVID-19 test result occurred 11 months prior to the initiation of the TB investigation, and another COVID-19 test result occurred six (6) months prior to the TB investigation

In addition, for those patients with confirmed TB that are counted in the state’s morbidity with a positive COVID-19 test have “Other” listed as an additional risk factor, and the CDC nCOVID ID is entered in the “Other” text field per CDC Division of TB Elimination guidance.

**Tennessee TB Elimination Program, and Nitrosamine Impurities in Rifamycins, and Drug Shortages**

On August 26, 2020, the Food and Drug Administration (FDA) issued a statement related to mitigating shortages of rifampin and rifapentine and its interim guidance to continue using these drugs in the treatment of TB after nitrosamine-class impurities were detected through recently adopted regulatory standards. In June 2020, shipments of rifapentine were paused after a nitrosamine impurity was found. In addition, Sanofi announced the discontinuation of three (3) oral rifampin-containing products.

The TTBEP works closely with the Tennessee Department of Health Director of Pharmacy to monitor medication inventories and expiration dates of medication at regional pharmacies. Regional TB program staff were made aware of the nitrosamine impurities as well as the possibility of a rifapentine shortage of a statewide program conference call. During 2020, statewide initiation of the 12-week isoniazid/rifapentine (“3HP”) regimen decreased 76.8% compared to 2019 (89 patients initiated 3HP in 2020 compared to 384 in 2019).

Interim guidance issued in March 2020 by the TTBEP recommended further prioritizing contact investigations, temporarily suspending the use of 3HP for all new patients diagnosed with TB infection, notifying non-health department providers that referrals for positive TB tests to the public health department should be temporarily deferred, and deferring treatment for TBI in all patients excepts those high-risk patients (i.e., contacts <13 years of age, contacts to MDR-TB, and contacts with an immunocompromising condition or taking immunosuppressive therapy). In May 2020, the TTBEP issued follow-up interim guidance which lifted the suspension of use of 3HP and instructed that patients could be started on the 3HP regimen after clinical consultation and approval from central office due to the shortage of rifapentine. Finally, a third iteration of recommendations was released in October 2020 that instructed that patients could be started on the 3HP regimen provided that there was enough stock of medication in the regional pharmacy to initiate the patient on therapy and complete therapy. Despite removing restrictions for use of 3HP across the state, some clinicians in regional TB programs were still hesitant to offer this 12-week regimen to patients as an option for treatment of TB infection.

**Tennessee TB Elimination Program and CDC Direct Assistance**

On October 28, 2020, the Tennessee TB Elimination Program (TTBEP) submitted direct assistance request for isoniazid #300 from the CDC Division of Tuberculosis Elimination (DTBE) stockpile. A total of 46 bottle of isoniazid were requested from the CDC to be sent to three (3) regional public health pharmacies in Tennessee. All medication was received by the pharmacies between November 10 – 13, 2020.

**Tennessee TB Elimination Program and Electronic Directly Observed Therapy (eDOT)**

In 2020, the TTBEP piloted the emocha® video DOT platform with two (2) regional TB programs. In 2021, the TTBEP purchased additional licenses for up to five (5) TB staff in each regional TB program. One of the initial pilot regions opted not to use emocha® beginning in 2021. At the time of this report, 15 patients in four (4) counties have utilized emocha® during treatment: 11 active TB patients and four (4) patients with TB infection.

**Strategies/Activities/Accomplishments/Barriers**

|  |
| --- |
| **Strategy/Activity: Diagnosis/treatment of persons with TB disease** |
| **Short-Term Outcome** | **Planned Program Activities** | **Accomplishments** | **Barriers** |
| Increase in cases with HIV and drug susceptibility results | Ensure that HIV testing is offered to all confirmed and suspected cases of TB. For hospitalized patients, health departments should review hospital records for HIV result; if no result, ask hospital to draw HIV or draw HIV at first post-hospital clinic visit. For culture-positive specimens collected by non-public health entities, ensure that (1) a DST is ordered or (2) a specimen is sent to the state public health lab for DST. Encourage health department to collect specimen from hospital for transport to state lab, when feasible. | The Tennessee TB Elimination Program (TTBEP) has identified gaps in laboratory reporting to focus on as the program evaluation plan in hopes of improving NTIP indicators related to turnaround times (TATs), drug-susceptibility testing (DST), and genotyping. | Delayed data entry due to TB staff working on COVID-19 pandemic. Not all hospital and commercial lab sent positive cultures to the Tennessee Department of Health state lab for confirmation and subsequent DST and genotyping testing. |
| Increase in patients on/responding to appropriate treatment | Continue use of therapeutic drug monitoring (TDM) for patients who are slow to convert AFB smears and cultures and for patients with risk factors for malabsorption. Use CDC’S MDDR service when drug resistance is suspected, when appropriate. Expand use of electronic DOT (eDOT). | On February 4, 2021 the Tennessee TB Elimination Program (TTBEP) recommended using TDM for all adult (≥18 years of age) persons with suspected or confirmed TB disease after receiving initial two (2) weeks of TB treatment. In 2020, specimens on 15 patients were sent for MDDR testing and resistance was identified in four (26.7%). In the first six months of 2021, specimens on five (5) patients were sent and resistance was detected on one (20.0%).In 2020, the Tennessee TB Elimination Program purchases licenses for emocha® for synchronous and asynchronous eDOT. Two (2) regional TB programs piloted this platform. In 2021, the TTBEP purchased additional licenses for statewide implementation. | Several logistical issues were encountered during collection and shipment of specimens for TDM to Florida throughout this APR time period. These issues included specimens being lost in transit, delivered to the wrong address, and lab closure due to weather (i.e., tropical storms and hurricanes) |
| **Strategy/Activity: Diagnosis/treatment of persons with latent TB infection (TBI)** |
| **Short-Term Outcome** | **Planned Program Activities** | **Accomplishments** | **Barriers** |
| Increase in the number of contacts elicited/examined (contacts to infectious TB cases) | Reiterate the importance of identification of contacts to smear-positive TB patients and the criteria for expanding a contact investigation. | Contact investigations are reviewed during cohort reviews, annual programmatic assessments, and during data collection for ARPEs. Staff are reminded during these of the importance of contact elicitation. | During the COVID-19 pandemic, the Tennessee TB Elimination Program issued interim recommendations for TB programs that recommended prioritization of contact investigations as well as prioritizing high-risk contacts to limit face-to-face contact with individuals. In addition, due to regional TB being assigned to the COVID-19 response, many regional TB programs reduced the number of scheduled TB clinics held. |
| Increase in treatment initiation for patients with LTBI who are recommended for treatment (contacts to infectious TB cases) | Increase the availability of electronic DOT (eDOT) for use of 12-week isoniazid/rifapentine (“3HP”) regimen.  | Two (2) public health regions piloted emocha® for asynchronous eDOT in 2020. Licenses for emocha® were purchased for staff in each regional TB program in early 2021. |
| Increase in treatment initiation for patients with LTBI/prior pulmonary TB who are recommended for treatment (Class B notifications) | Increase the use of shorter course regimens for TB infection (i.e., 12-week isoniazid/rifapentine and three-month isoniazid/rifampin) for Class B notifications. | The shorter course regimens for TB infection and guidance for using these regimens was included in the 2020/2021 TB Manual revisions. | The number of Class B notifications received by the Tennessee TB Elimination Program in 2020 decreased 77.0% from 2019. Due to regional TB staff being reassigned to the COVID-19 responses and the reduction in the number of scheduled TB clinics, evaluation of Class B notifications was delayed in many regions. |
| Targeted Testing and treatment of TB infection (TBI) in high-risk populations | Re-visit the Community Partnerships to End TB (CPETB) initiative with regional TB programs. | The initiative was re-introduced on statewide TB program call in 2021 with an anticipated relaunch date in early 2022. | The COVID-19 pandemic paused all non-essential TB program activities throughout the state. |
| **Strategy/Activity: Program planning, evaluation, and improvement** |
| **Short-Term Outcome** | **Planned Program Activities** | **Accomplishments** | **Barriers** |
| Increase in identification/dissemination of best practices within and between state/local programs | Participate in TB PEN and TB ETN calls; participate in NTCA Community of Practice (CoP) calls;  | Staff from the state and regional TB program participate on statewide and national educational calls and webinars. | None identified. |
| **Strategy/Activity: Surveillance** |
| **Short-Term Outcome** | **Planned Program Activities** | **Accomplishments** | **Barriers** |
| Increase in national accuracy and completeness of surveillance, genotyping, and whole-genome sequencing data | Perform more frequent data quality assurance (QA).  | Utilization of NTIP line list reports of cases not meeting indicators prompted a thorough review of all cases not meeting each indicator. This review resulted in the identification of 33 cases that did not meet seven (7) single or multiple NTIP indicators due to missing or incorrect data. Data were added or corrected which resulted in these cases meeting the particular indicator(s). | Data QA is performed by state TTBEP epidemiologists. During the COVID-19 pandemic, central office TB staff were assigned to the COVID-19 response and routine data QA was not performed. |
| Increase in cases genotyped and linked to surveillance data | Early identification of culture-positive cases for which a reference isolate was not received by the Tennessee Department of Health, Division of Laboratory Services.  | A database was created that identifies all culture positive cases whose culture was processed and identified as M. tb from a non-public health laboratory. | Due to the COVID-19 pandemic, follow-up with non-public health laboratories regarding the requirements for sending a reference isolate for confirmation, DST, and genotyping was not done.  |
| **Strategy/Activity: Human resources development (HRD) and partnerships** |
| **Short-Term Outcome** | **Planned Program Activities** | **Accomplishments** | **Barriers** |
| Increase in availability/accessibility of competency-based education/training | Continue to identify educational opportunities for state, regional, and local TB staff.  | The TTBEP education focal point is on the list serve for educational opportunities from all Centers of Excellence as well as other national partners. | Due to the COVID-19 pandemic, the availability and participation of state, regional, and local TB staff in educational opportunities decreased throughout 2020 and into 2021. |
| **Strategy/Activity: Laboratory Strengthening** |
| **Short-Term Outcome** | **Planned Program Activities** | **Accomplishments** | **Barriers** |
| Decrease in TATs for specimen receipt, acid-fast bacillus smear, NAA identification, identification of MTBC, and growth-based or molecular drug-susceptibility testing | Identify specimens above the established thresholds for TATs. Identify opportunities for improvement in TATs. | The Tennessee Department of Health, Division of Laboratory services sends a quarterly TAT report to the TTBEP program manager for review. | The COVID-19 pandemic caused delays in specimen collection and receipt at the lab which resulted in an increase in TATs. |

**Collaborations**

|  |  |  |  |
| --- | --- | --- | --- |
| **Outcome**  | **Planned Program Activities** | **Accomplishments** | **Barriers** |
| Collaborate with CDC programs and CDC-funded organizations | Identify opportunities to collaborate with other CDC-funded organizations. | The TTBEP met with the Tennessee Department of Health HIV/STD/Viral Hepatitis medical director and STD director to discuss opportunities to utilize funding for DIS and cross-training of DIS across the state in both programs. | Opportunities to collaborate with other organizations were decreased during the COVID-19 and not identified as core TB functions during the pandemic which were given higher priority. |
| Collaborate with organizations not funded by CDC | Continue to partner with the Tennessee Department of Correction. Explore opportunities to collaborate with other state partners such as the Tennessee Sheriffs Association, Federally Qualified Health Centers (FQHCs), and the Tennessee Academy of Family Physicians (TNAFP). | The TTBEP medical director gave a presentation on TB during the annual meeting of the Tennessee Sheriffs Association. | The COVID-19 pandemic limited the opportunities for collaborations with other partners throughout the state. |

**Target Populations and Health Disparities**

|  |  |  |  |
| --- | --- | --- | --- |
| **Outcome**  | **Planned Program Activities** | **Accomplishments** | **Barriers** |
| Collaborate with partners throughout Tennessee that serve high-risk populations | Facilitate the partnership between the Metro Public Health Department of Nashville and Davidson County and Siloam Family Health Center. Identify other partners throughout the state that serve high-risk populations. | The TTBEP medical director and program manager met with the Tennessee Department of Mental Health and Substance Abuse (TDMHSA) to review and update TB policies. The TTBEP program manager worked with the Tennessee Department of Correction (TDOC) to revise the TDOC TB Prevention and Treatment Guidelines.  | Due to the COVID-19 pandemic, Siloam Family Health Center paused collaborative efforts with the Metro Public Health Department of Nashville and Davidson County, but it expected to resume in fall 2021 and will result in a Metro Public Health Department employee visiting Siloam Family Health Center to assist with evaluation (including a chest X-ray) and initiation of treatment for refugees who visit the clinic. |
| Provide plain language educational materials in 10 most commonly spoken languages of TB and TBI patients | Review current and historic data to identify the 10 most commonly spoken languages of TB and TBI patients in Tennessee.  | None. | Due to the COVID-19 pandemic, this initiative/project was considered a lower priority TB activity. |

**Work Plan**

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| --- |
| **Strategy 1: Diagnosis/Treatment of Persons with TB Disease** |
| **Related Outcome** | **Measure of Success** |
| 1. Earlier patient diagnosis; (2) increase in TB cases with HIV results; (3) cases with drug-susceptibility testing (DST) results; (4) patients on/responding to appropriate treatment
 | National TB Indicator Project (NTIP) objectives for case management and treatment can be accessed at: <https://www.cdc.gov/tb/programs/evaluation/indicators/default.htm>  |
| **Objectives** | **Activities** | **Timeline** | **Success** | **Barriers** |
| For patients with newly diagnosed TB disease for whom ≤12 months of treatment is indicated, increase the proportion who complete treatment within 12 months. | Review all case records; identify opportunities for use of incentives and enablers; cohort review with two (2) public health regions; review NTIP quarterly ensure case management of all TB patients; utilize eDOT; utilize therapeutic drug monitoring (TDM) | 95% by 2025 | 1. Weekly report is

generated to monitor treatment progress at 3-, 6-, 9-, and 12-month intervals; (2) cohort review held with one regional TB program; (3) 2/4/21: recommended use of TDM for all adults with suspected and confirmed TB disease after receiving two weeks of treatment; piloting of emocha® asynchronous eDOT platform with two public health regions in 2020 (4) statewide implementation of emocha®  | Statewide and regional TB staff were involved in the COVID-19 response; one regional TB program was unable to conduct a cohort review due to the COVID-19 pandemic; operational hours of the University of Florida pharmacokinetics lab (e.g., during tropical storms/hurricanes) and transport issues were barriers to collecting TDMs; technological issues with emocha®; utilization of CDC’s MDDR lab services for early detection of resistance to ensure proper treatment regimen |
| For TB patients with positive AFB sputum smear results, increase the proportion who initiated treatment within 7 days of specimen collection | Identify providers/entities that do not start patients on treatment within 7 days of specimen collection; ensure case management of all persons with suspected or confirmed TB; review NTIP quarterly | 96% by 2025 | Upon notification of a person with suspected or confirmed TB disease that is hospitalized, regional TB case managers have increase efficiency in collecting a specimen for testing at the state public health lab and educating providers on the importance of initiating treatment when TB is suspected | Delayed notification of persons with suspected or confirmed TB disease to health departments from non-public health providers; COVID-19 possibly resulted in delayed diagnosis and treatment initiation. |
| Increase the proportion of TB patients who have a positive or negative HIV test reported | Ensure case management for all persons with suspected or confirmed TB disease; ensure opt-out for all patients receiving a TST or QFT; education providers on the importance of collecting HIV when testing for TB infection; quarterly cross match with HIV program database | 99% by 2025 | None. | A review of NTIP data for 2020 and quarters one and two of 2021 showed that two (2) patients refused HIV testing; one (1) patient died in the hospital prior to an HIV testing being drawn; one (1) patient that was one year of age was not offered HIV testing, and one (1) patient was dying and receiving hospice service and subsequently expired prior to an HIV test being drawn. |
| For patients whose diagnosis is likely TB disease, increase the proportion who are started on the recommended initial 4-drug regimen | Create a database of all persons with suspected or confirmed TB disease and regimen initiated; educate providers on the importance of initiating 4-drug regimen for all persons with suspected or confirmed TB disease, ensure access to recommended 4 drugs for all patients | 97% by 2025 | Regional TB clinicians are asked to provide rationale to statewide TB medical director and nurse consultant manager if a non-standard TB regimen is prescribed for any patient  | A review of NTIP data for 2020 and quarters one and two of 2021 showed that one (1) did not take PZA for the initial two (2)-week period due to medication intolerance; EMB was not initiated for two (2) patients due to eye issues (i.e., uveitis eye TB and inability to follow-up with an ophthalmologist); one (1) patient did not initiate PZA due to pregnancy; and INH for one (1) patient was discontinued after nine (9) doses due to INH-resistance. |
| For patients aged ≥12 years with a pleural or respiratory site of disease, increase the proportion who have a sputum culture result reported | Ensure case management for all persons with confirmed TB disease; identify processing lab for hospitals statewide; identify which commercial laboratories do reflex TB testing; ensure providers are aware of reportable conditions and timeframes | 99% by 2025 | Of the 13 cases in 2020 and the first six (6) months of 2021 that did not initially meet this indicator, eight (8) were due to missing or incorrect information that was identified during an NTIP data AQ project. Data updates resulted in these eight (8) cases subsequently meeting the indicator.  | Of the remaining five (5) cases that did not meet this NTIP indicator, a NTIP line list review showed that three (3) patients did not have sputa collected due to the patient expiring or dying; one (1) was unable to produce a sputum specimen; and one (1) patient had a pending culture at the time of the NTIP data extract. |
| For patients with positive sputum culture results, increase the proportion who have documented conversion to negative within 60 days of treatment initiation | Maintain sputum culture conversion log; ensure case management for all persons with confirmed TB disease; maintain laboratory summary log | 83% by 2025 | Statewide sputum culture conversion rate has increased over the past four (4) years; increase use of therapeutic drug monitoring | For 2020 and the first six (6) months of 2021, there were 18 cases that did not initially meet this NTIP indicator. Of those, six (6) were identified to have an incorrect date for sputum culture conversion that, when updated, resulted in these cases meeting the NTIP indicator. These data entry errors highlight the need for additional training of staff on the definition of culture conversion and correct identification of the date of culture conversion. |
| **Strategy 2A: Contact Investigation for Infectious Cases** |
| **Related Outcomes** | **Measures of Success** |
| Increase in (1) contacts elicited/examined and (2) contacts initiating/completing LTBI treatment | National TB Indicator Project (NTIP) objectives for contact investigation can be accessed at: <https://www.cdc.gov/tb/programs/evaluation/indicators/default.htm>  |
| **Objectives** | **Activities** | **Timeline** | **Successes** | **Barriers** |
| For TB patients with positive AFB sputum smear results, increase the proportion who have contacts elicited  | Ensure that all staff conducting contact investigations are adequately trained in contact investigation; assess contact investigation data to determine if re-interviews of index patients are needed.  | 100% by 2025 | None. | A review of cases not meeting this NTIP indicator was completed, and the following results found: one (1) case that was smear-positive/culture-negative did not have any contacts due to the fact that she was a contact to her husband who was a confirmed case and her contacts had previously been identified and tested as part of her husband’s contact investigation. Two patients did not provide contact information even after repeated interviews. |
| For contacts to sputum AFB smear positive TB cases, increase the proportion who are examined for infection and disease | Ensure all regional TB clinicians know the criteria for “fully evaluated”; ensure that contact investigations are prioritized according to Tennessee TB Elimination Program (TTBEP) Manual | 94% by 2025 | Due to the COVID-19 pandemic, the TTBEP issued interim guidance for regional TB programs that included recommendations to perform as much of the focused evaluation as possible either over the phone or via video (i.e., telehealth). This was a successful initiative that has continued. | Due to the COVID-19 pandemic, staff were reassigned to assist with COVID-19 activities which limited the number of scheduled clinics held. In addition, persons identified as contacts were hesitant to visit health departments to complete the evaluation process. |
| For contacts to sputum AFB smear positive TB cases diagnosed with latent TB infection, increase the proportion who start treatment  | Ensure providers provide culturally appropriate education about TB infection and progression to active TB disease; ensure contacts are prioritized for treatment according to TTBEP Manual | 92% by 2025 | None. | Due to the COVID-19 pandemic the TTBEP recommended that regional TB clinics limit clinic hours and face-to-face contact with patients. In addition, patients were hesitant to visit the health department.  |
| For contacts to sputum AFB smear positive TB cases who have started treatment for latent TB infection, increase the proportion who complete treatment | Increase use of 12-week isoniazid/rifapentine regimen; expand use of electronic directly observed therapy (eDOT); ensure case management of persons with confirmed TB infection (TBI) | 93% by 2025 | In 2020, the TTBEP piloted the emocha® electronic directly observed therapy (eDOT) platform for synchronous and asynchronous use and expanded use to 11 of the 12 regional TB programs (one regional TB program opted out of using emocha®). In addition, the criteria to begin using eDOT was modified during COVID-19 to allow for patients to utilize eDOT earlier in their treatment regimen. | The same barriers for initiation of treatment for contacts is applicable for completion of treatment. In addition, for a period of time during the COVID-19 pandemic, the TTBEP recommended that no new patients diagnosed with TB infection (TBI) initiate the 12-week isoniazid/rifapentine (“3HP”) regimen due to a shortage of rifapentine. Once those restrictions were lifted in October 2020, providers remained hesitant to initiate 3HP due to nitrosamine impurities in rifamycins. |
| **Strategy 2B: Examination of Immigrants and Refugees**  |
| **Related Outcomes** | **Measures of Success** |
| Increase in (1) treatment initiation for patients with LTBI/prior pulmonary TB who are recommended for treatment and (2) LTBI diagnoses and high-risk patients who initiate treatment | National TB Indicator Project (NTIP) objectives for examination of immigrants and refugees can be accessed at: <https://www.cdc.gov/tb/programs/evaluation/indicators/default.htm>  |
| **Objectives** | **Activities** | **Timeline** | **Successes** | **Barriers** |
| For immigrants and refugees with abnormal CXRs read overseas as consistent with TB, increase the proportion who initiate a medical examination within 30 days of notification | Identify barriers that increase the amount of time between notification and examination; increase the number of clinic-level users for EDN; provide regional TB programs with 30-day timeframe from date of notification | 72% by 2025 | None. | In 2020, the TTBEP received 31 immigrants and refugees with a B1 TB classification. Of those, 22 initiated an evaluation. The average number of days between notification and initiation of the evaluation was 76.2 days. During the first six (6) months of 2021, the TTBEP received a total of 36 notifications of arrivals of immigrants and refugees with a B1 TB classification. Preliminary data show that 13 (36.1%) initiated an evaluation with an average of 42.8 days between notification and initiation of evaluation. This is likely due to delays resulting from the COVID-19 pandemic.  |
| For immigrants and refugees with abnormal CXRs read overseas as consistent with TB, increase the proportion who complete a medical examination within 120 days of notification | Provide regional TB program managers with 90-day target dates for each B-notification received; follow-up with regional TB program managers as the 90-day deadline approaches | 78% by 2020 | None. |
| For immigrants and refugees with abnormal CXRs read overseas as consistent with TB who are diagnosed with LTBI or have radiographic findings consistent with prior pulmonary TB on the basis of examination in the U.S., for whom treatment was recommended, increase the proportion who start treatment | Ensure culturally sensitive education is provided; partner with agencies providing primary care to immigrants/refugees; ensure providers stress the importance of treatment for TB infection and the possibility of progressing to active TB disease if untreated; ensure educational materials are translated and in plain language | 87% by 2025 | None. | The same barriers for initiation of treatment in this population is applicable for completion of treatment. In addition, for a period of time during the COVID-19 pandemic, the TTBEP recommended that no new patients diagnosed with TB infection (TBI) initiate the 12-week isoniazid/rifapentine (“3HP”) regimen due to a shortage of rifapentine. Once those restrictions were lifted in October 2020, providers remained hesitant to initiate 3HP due to nitrosamine impurities in rifamycins. In addition, a partnership was formed between a family health center that serves as an initial medical home for many refugees in this population and TB staff from the corresponding local health department. This partnership was established to reduce the number of visits to the health departments for these patients to be evaluated for TB infection and to begin treatment and address the TB infection cascade of care. Due to COVID-19, this partnership was paused and will be re-evaluated in late 2021/early 2022. |
| For immigrants and refugees with abnormal CXRs read overseas as consistent with TB who are diagnosed with LTBI or have radiographic findings consistent with prior pulmonary TB on the basis of examination in the U.S., and who have started on treatment, increase the proportion who complete treatment | Ensure case management of patients with TB infection; increase use of 12-week isoniazid/rifapentine regimen; use incentives/enablers when appropriate; partner with agencies providing primary care to immigrants/refugees; ensure information is provided in the patient’s primary language  | 87% by 2025 | In 2020, the TTBEP piloted the emocha® electronic directly observed therapy (eDOT) platform for synchronous and asynchronous use and expanded use to 11 of the 12 regional TB programs (one regional TB program opted out of using emocha®). In addition, the criteria to begin using eDOT was modified during COVID-19 to allow for patients to utilize eDOT earlier in their treatment regimen. |
| **Strategy 2C: Focused Testing and Treatment of TB Infection (Program-Identified)** |
| **Related Outcomes** | **Measures of Success** |
| Increase in: (1) treatment initiation for high-risk patients diagnosed with TB infection; (2) treatment completion for patients diagnosed with TB infection who initiate treatmentDecrease in (1) number of patients diagnosed with TB infection who progress to active TB disease | 1. 100% of regional TB programs will identify at least one high-risk population for prioritized education and TB infection testing activities; (2) regional TB programs will establish regional education and testing benchmarks; (3) regional TB programs will establish regional treatment initiation benchmarks for each high-risk population identified; (4) regional TB programs will identify treatment completion benchmarks for each high-risk population identified **(New measures of success)**
 |
| **Objectives** | **Activities** | **Timeline** | **Successes** | **Barriers** |
| Implement “Community Partnerships to End TB (CPETB)” initiative statewide | Conduct meetings with leadership of each regional TB program | 100% of regional TB program participation by March 31, 2022. | In June 2021, regional TB programs were queried on the feasibility of re-implementing the CEPTB initiative beginning in 2022 as well as identification of barriers to implementing. The initiative was reintroduced during a statewide call in June 2021 with an anticipated start date in early 2022. | Implementation of the CPETB initiative initially was postponed due to the COVID-19 pandemic and staff being reassigned to COVID-19 duties. Anticipated barriers from regional TB programs (from a statewide survey) include community partner participation, barriers to testing and treatment, and the uncertainty of COVID-19. |
| Identify of at least one (1) high-risk population by each regional TB program for focused education and testing for TB infection | Provide county- and regional-level TB and TB infection (TBI) data to each regional TB program manager | At least one (1) high-risk population will be identified by each regional TB program by June 30, 2022.  | Data quality assurance and compilation has begun to provide regional TB programs with demographics and risk factors of TB and TBI patients as well as data on providers in their respective regions that are performing tests for TB infection. |
| Provide education, screening, and testing activities for identified high-risk populations | Assist regional TB programs with the development of plan to screen and test high-risk population that include culturally appropriate and plain language educational materials | Education, screening, and testing activities will be initiated by each regional TB program for their identified high-risk population by December 31, 2022. | None at the time of this report. | Anticipated barriers from regional TB programs (from a statewide survey) include community partner participation, barriers to testing and treatment, and the uncertainty of COVID-19. |
| **Strategy 3: Program Planning, Evaluation, and Improvement** |
| **Related Outcomes** | **Measures of Success** |
| Increase in (1) identification/dissemination of best practices internally and externally; (2) annual progress toward or meeting NTIP objectives; and (3) using findings to inform programmatic changes | 1. Annual increase in programmatic NTIP performance and (2) annual review and update of Tennessee TB Elimination Program Manual
 |
| **Objectives** | **Activities** | **Timeline** | **Successes** | **Barriers** |
| Develop a program evaluation plan | Review NTIP indicators; develop SMART objectives | December 31, 2021 | Evaluation plan has bee written and steps to implement have been outlined. | Due to the COVID-19 pandemic and TTBEP staff being reassigned to assist with core COVID-19 activities, the program’s evaluation plan was not initiated as scheduled. |
| Implement a program evaluation plan | Develop program evaluation committee; execute planned activities; monitor and report findings | Begin implementation steps by June 30, 2022. | None. |
| Develop strategies to implement activities to address finding of program evaluation plan | Solicit input from regional TB programs; review program evaluation plan; update plan as needed | December 31, 2022. | None. |
| **Strategy 4: Epidemiologic Surveillance and Response** |
| **Related Outcomes** | **Measures of Success** |
| Implementation of the 2020 RVCT **(new)**; increase in: (1) accuracy and completeness of surveillance, genotyping, and WGS data; (2) linkage of genotyping and surveillance data; (3) availability | 1. Full integration and implementation of 2020 RVCT into Tennessee surveillance system; (2) 100% of regional TB staff trained on 2020 RVCT and surveillance system pages prior to integration into statewide surveillance system; (3) 100% of genotype results will be provided to regional TB programs within three (3) business days of receiving results.
 |
| **Objectives** | **Activities** | **Timeline** | **Successes** | **Barriers** |
| Implement the 2020 RVCT **(new)** | Work with Surveillance Systems and Informatic Program (SSIP) to ensure implementation of the 2020 RVCT page into the NEDSS-based system | December 31, 2022 | None. | Tennessee is unable to move forward until the vendor develops the page in NBS. Due to COVID-19, this project has been delayed. |
| Provide education and training for regional TB program staff on 2020 RVCT **(new)** | Develop education and training material; ensure use of plain language | December 31, 2022 | The 2020 RVCT and user guide have been combined into one document for training purposes in Tennessee. | None. |
| Ensure the completeness of each core RVCT data item reported to CDC | Provide quality assurance (QA) on TB case data prior to submission to CDC | 100% by 2025 | At the time of this report, the surveillance coordinator for the TTBEP has been relieved of all of his COVID-19 duties and is working 100% in TB. | Due to central office staff being reassigned to COVID-19 duties, data quality for the RVCT, ARPE, and EDN has decreased compared to previous years. |
| Ensure the completeness of each core ARPE data items reported to CDC | Review contact investigation data; provide quality assurance on ARPE data | 100% by 2025 | The TTBEP is exploring options to make the ARPE process easier on regional TB program staff. These options include adding ARPEs to our disease surveillance system TB page and/or a “Contact Investigation Summary” after completion of a contact investigation for each patient. |
| Ensure the completeness of each core TB Follow-Up Worksheet data item reported to CDC via the EDN system | Maintain state EDN database; review EDN data and provide quality assurance prior to final submission in EDN system | 93% by 2025 | None. |
| Report PCRType, GENType, and WGS results and genotype matches to regional TB programs | Provide genotype data and cluster snapshot data to regional TB programs for each genotyped case | 100% of genotype reports and matches sent to regional TB programs within three (3) business days of receipt in TB GIMS. | Upon receipt of notification of new genotype data in TB GIMS, the TTBEP program manager sends genotype information along with any genotype matches in the previous five (5) years to the respective TB program manager. | None. |
| Transmit TB infection (TBI) data to CDC | Ensure state surveillance system contains all recommended LTBI variables; ensure HL7 messaging | December 31, 2023 | Work has begun to ensure that all surveillance variables in NBS align with that of TBLISS. | Due to COVID-19 and routine TB priorities, this has become a lower priority activity.  |

**2021 ACTIVITIES AND PROPOSED 2022 ACTIVITIES**

|  |
| --- |
| **Strategies and Activities Progress** |
| **Strategy** | **2021 Proposed Activities** | **2021 Narrative** | **2022 Proposed Activities** |
| Strategy 1: Diagnosis/Treatment of Persons with TB Disease | Continue use of Cepheid GeneXpert® statewide and increase communication to clinical partners on the benefit of utilizing GeneXpert® for rapid diagnosis and release from isolation. | For the first six (6) months of 2021, the Tennessee Department of Health, Division of Laboratory Services performed 84 GeneXpert® tests for 62 unique patients. Of those 84 tests, 18 (21.4%) were positive. Of the 18 positive results, four (22.2%) were initially smear-negative. | Ensure validation of the new Cepheid GeneXpert® equipment at the Tennessee Department of Health, Division of Laboratory Services. |
| Strategy 2A: Conduct Contact Investigations for Infectious Cases | Provide in-person trainings (if allowed) to new case managers and contact investigation staff. Identify patient education needs and work to meet those needs. | In 2021, one (1) new case manager training was held virtually for one (1) new staff member. | Develop “Conduct Investigation Summary” form to include ARPE variables to be completed for each case of TB upon completion of the contact investigation. Include this activity as a Standard of Public Health Practice in the revised Tennessee TB Elimination Program manual. |
| Strategy 2B: Evaluation of Immigrants and Refugees with TB or TBI | Evaluate the efficacy of adding additional clinic-level users to EDN. Continue to partner with Siloam Family Health Center. Evaluate the feasibility of partnering with other agencies that serve immigrant and refugee populations. | Feasibility of adding a clinic-level user for the region/clinic that receives the largest volume of EDN notifications. Due to technology limitations of the clinic, it was decided that adding a clinic-level user for this region was not feasible. The partnership with Siloam Family Health Center continued in 2021; however, health department staff presence in the facility as well as partnering with other agencies was temporarily held due to COVID-19. | Re-evaluate options for adding clinic-level users for regional TB programs who receive the largest volume of immigrant and refugee B-notifications.  |
| Strategy 2C: Targeted Testing and Treatment of TBI in High-Risk Populations | Re-launch of the “Community Partnerships to End TB (CPETB)” initiative. | In June 2021, regional TB programs were queried on the feasibility of re-implementing the CEPTB initiative beginning in 2022 as well as identification of barriers to implementing. The initiative was reintroduced during a statewide call in June 2021 with an anticipated start date in early 2022. | 1. Provide data to regional TB programs for high-risk populations with confirmed TB infection and TB disease for 2018-2020
2. Provide list of providers to regional TB program managers located within their region who perform QFTs
 |
| Strategy 3: Program Planning, Evaluation, and Improvement | Implement program evaluation plan as outlined in the Tennessee Performance Management Plan submitted on July 20, 2020. | Due to the COVID-19 pandemic and central office staff being reassigned to COVID-19 activities, the program evaluation was not fully implemented and paused until staff were able to return to fully performing their TB duties. | 1. Finalized spreadsheet that will utilized to collect information about non-public laboratories that conduct testing and report results
2. Ensure that all reporting laboratories are aware of the Tennessee reportable conditions and timeframes.
 |
| Strategy 4: Epidemiologic Surveillance and Response | Modify current TBI surveillance variables in statewide NEDSS-based system (NBS) to align with CDC-identified LTBI variables. Evaluate the feasibility of submitting TBI surveillance data to CDC. Implement revised RVCT and provide training.  | Due to the COVID-19 pandemic and the need for creating of surveillance pages for COVID-19, the TBI surveillance variable project was deferred. Implementation of the 2020 RVCT is dependent on creating of the page in NBS by a CDC vendor which has not occurred at the time of this report.  | Implement the 2020 RVCT and provide training to regional TB staff. Re-visit the feasibility of revising statewide TBI variables in NBS to align with CDC-identified variables. Provide refresher surveillance training to regional TB staff. Create a surveillance data “Best Practices” document for regional TB staff. |
| Strategy 5: Human Resources Development (HRD) and Partnerships | Evaluate the feasibility of conducting a TB Clinical Symposium and statewide meeting (canceled in 2020 due to COVID-19). Evaluate additional statewide agencies that serve high-risk populations and develop partnerships. | Due to the COVID-19 pandemic, restrictions on in-person meetings and attendance, and a short planning timeframe, a TB Clinical Symposium and statewide meeting was determined to be not feasible. Work to identify additional partners serving high-risk populations was temporarily postponed due to the COVID-19 pandemic. | Re-evaluate the feasibility of conducting a TB Clinical Symposium and statewide meeting. Collaborate with regional TB programs to identify external agencies statewide that serve high-risk populations. |

**Program Planning, Evaluation, and Improvement**

1. Results and Conclusions of 2020 Program Evaluation Activities
2. Remediation Plan
3. Background for 2021 Program Evaluation Focus Area
4. 2021 Program Evaluation Plan

Due the COVID-19 pandemic, TTBEP central office staff were reassigned to assist with core COVID-19 activities including data visualization and reporting, cluster detection, monitoring, reporting, assisting at points of dispensing (PODs) for testing and vaccination, assisting with the call bank, and serving as a liaison between public health and entities that serve high risk populations such as corrections. More specifically, the program evaluation focal point was a member of the data visualization team that was responsible for ensuring daily data were accurate and posted on the state health department website. In addition, he also served as team lead for the Epi-X notification team responsible for receiving notifications of exposed travelers and ensuring proper follow-up. Because of these staff reassignments, the program evaluation plan was not initiated as scheduled and the program staff will begin implementation in 2022.

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**Cohort Review**

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| --- | --- |
| **Element** | **Progress** |
| Date(s) of cohort review(s) | April 14, 2021 |
| Number of cases discussed (per review/total) | 8 |
| Summary of review process | Due to COVID-19, no cohort reviews were held in 2020.  |
| Key issues identified and resolved | Timeliness of reporting of persons with suspected TB diseased from non-public health providers |
| Recommendations | Continued outreach and partnership with non-public health providers. Provide copy of “2021 Reporting Guidance List for Healthcare Providers” <https://www.tn.gov/content/dam/tn/health/documents/reportable-diseases/Provider-list-2021.pdf> and “How to Report for Healthcare Providers” <https://www.tn.gov/content/dam/tn/health/documents/reportable-diseases/2020_HowtoReport_ForHealthcareProviders.pdf>. This an ongoing health department activity. |
| New tools or trainings | None |

Data Management Plan

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| --- | --- | --- | --- | --- | --- |
| **Dataset Title** | **Study Type/Design** | **Frequency of Data Collection** | **Data Collection Timeframe** | **Where Data Will Be Maintained During Study Period** | **Responsible Person/Contact Information** |
| Reporting Laboratories | Descriptive analysis | At least quarterly | Previous quarter from time of data collection | Secure folder on state network | Ben Katz615-253-1369Ben.Katz@tn.gov  |
| Describe the content (topics, variables) of the data | National TB Indicator Project (NTIP) reports and line lists – * Laboratory Turnaround Time
* Drug-Susceptibility Results
* Sputum Culture Result Reported
* Universal Genotyping

Report of a Verified Case of TB (RVCT) variables –#18 Sputum Culture Reporting Laboratory Type#20 Culture of Tissue and Other Body Fluids Reporting Laboratory Type#21 Nucleic Acid Amplification Test Result Reporting Laboratory TypeLocally Defined Fields (LDFs) created in the Tennessee NEDSS-based system TB Program Area Module (TB PAM)* Reporting Source Type (e.g., hospital, laboratory, etc.)
* Reporting Organization
* Was the patient hospitalized for this illness?
* Hospital Information
 |
| **Description of Standards for Collecting Data** |
| Describe the data collection/generation methods | Reports and line lists will be generated from the NTIP system at least quarterly. A standard report will be created in the NEDSS-based system and run at least quarterly. |
| Describe measures to ensure data quality | Missing or unknown data will be entered/corrected in the state surveillance system. Electronic data will be verified for correctness by utilizing patient medical record reviews (paper and electronic medical records) housed at the TTBEP central office. Queries of the state public health laboratory LIMS system will be done to confirm/refute that the state lab received a reference specimen or isolate for confirmation. |
| **Providing Access to Data** |
| Describe what level of access of data will be provided and when it will be made available | Central office TTBEP staff including program epidemiologists, program manager, public health nurse consultant manager, and medical director will all have access to these data that will be securely housed on the state network. Reports will be generated at least quarterly and saved on the state network for central office staff to review as needed. Reports may be generated more frequently upon request. |
| Describe when, where, and how the data will be available | See above. Raw data will be maintained in an Excel spreadsheet.  |
| If free public access to the data will not be provided, give a justification | There will be no public access. |
| For data that will be released, describe procedures for data security, privacy/confidentiality | Data will be primarily for internal use only. Aggregate may be reported to reporting laboratories regarding the number of tests performed for which an isolate or reference specimen was not sent to the Tennessee Department of Health, Division of Laboratory Services. |
| **Description of Standards Accompanying Release of data** |
| Describe the established standards to be used to ensure usability and interoperability of data | NTIP data are updated based on standard HL7 messaging of TB data to CDC. |
| Describe the documentation that will be available regarding data source | A description of the data sources will be provided. Standard descriptions of RVCT variables will be provided to consumers of the data. |
| Describe the documentation that will be available for analysis | For this descriptive analysis, documentation of methods of data collection and variable descriptions will be provided. |
| **Archival and Long-Term Data Preservation** |
| Describe the planned long-term preservation or the justification for no long-term preservation | Data will be maintained on the state network and the timeframe for data retention has yet to be determined. |
| If applicable, name the planned final location of the data and describe who it can be accessed | Data will be maintained on the state network and will be available to TTBEP central office staff including program epidemiologist, program manager, public health nurse consultant manager, and medical director. |

**HUMAN RESOURCE DEVELOPMENT**

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| --- | --- |
| **Activity** | **Narrative** |
| Description of use of HRD funds | For budget period 2020, planned uses of HRD funding included: annual statewide conference, travel and lodging for National TB conference, travel and lodging for regional staff to attend the Program Managers course, travel and lodging for the TB ETN/PEN conference, and travel for one regional TB program staff to attend the Comprehensive Clinical Course hosted by the Southeastern National TB Center (SNTC). The Tennessee TB program did not hold a statewide annual conference. In addition, the National TB Conference was virtual, therefore no HRD funds were used for travel and lodging to this conference. During 2020, one regional TB clinician attended the SNTC Comprehensive Clinical Course virtually (no funding was needed for travel and lodging). HRD funds for budget period 2020 were used to purchase registration for the virtual National TB Conference ($1,075). In addition, funds during this budget period were used for registration ($750) for the TB program medical director to attend The Union-North America Region (NAR) conference. At the time of this report, no HRD budget period 2021 has been spent. |
| Training courses provided | The Tennessee TB Elimination program held the following trainings:2020:* NEDSS-based system (NBS) training for new TB staff

2021:* New ARPE form training for regional TB staff
* New TB case manager training
* ARPE training for Ohio TB program staff
 |
| Training courses attended | 2020: 30 training events were attended by 91 state and regional TB staff2021: 21 training events were attended by 124 state and regional TB staff |
| Educational resources purchased or leased | Seventh Edition 2021 “Core Curriculum on Tuberculosis: What the Clinician Should Know” manuals were ordered free of charge and provided to each regional TB program and central office staff; “Radiographic Manifestations of Tuberculosis” 2nd edition from Curry International Center (free of charge) were ordered and sent to each regional TB program.  |
| Educational materials developed | 1. Tennessee TB Elimination Program emocha® User Guide
 |
| Description of collaboration with partners, such as those serving high-risk populations |  |
| Attendance at TB ETN conference and focal point meeting | There was no TB ETN conference held during 2020. |
| Salary for training and education personnel | The salary for the Tennessee TB Elimination Program’s Education and Training focal point is supported by state funding |

HRD Work Plan

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| --- |
| **Strategy 5: Human Resource Development (HRD)** |
| **Related Outcomes** | **Measures of Success** |
| Increase in: (1) availability/accessibility of competency-based education; (2) awareness and use of HRD resources; (3) awareness of TB among patients, providers, and community; (4) capacity to diagnose/treat high-risk populations with TB infection (TBI) | 1. Number of training sessions held
2. Number of trainings attended
 |
| **Objectives** | **Activities** | **Timeline** | **Successes** | **Barriers** |
| Designate a staff member to serve as TB education and training focal point | Identify staff member to serve as TB education and training focal point. Include education and training activities in staff’s individual performance plan (IPP) with focused action steps **(new)** | Annually | Trudy Stein-Hart, epidemiologist, has served in the role of TB education and training focal point for the TB program for several years. A work outcome statement has been added to Trudy Stein-Hart’s IPP stating, “Serve as the Education and Training Network (ETN) focal point as required by the Centers for Disease Control and Prevention (CDC) Division of TB Elimination (DTBE) Cooperative Agreement. | Due to COVID-19 and several training and education opportunities that were planned by the TB program and would have involved extensive work for the education and training focal point were cancelled.  |
| Register focal point as a member of TB Education and Training Network (TB ETN) | TB ETN membership form completed and returned to CDC | Annually | Trudy Stein-Hart is currently a member of TB ETN | None identified. |
| Identify Centers of Excellence (CoE) training opportunities and disseminate to state, region, and local TB staff | 1. Sign-up for CoE newsletter and training announcements
2. Monitor CoE website for calendar of education and training opportunities **(new)**
 | Monthly | 1. Both the TB program manager and TB education and training focal point receive the Southeastern National TB Center (regional CoE for Tennessee) newsletter and training announcements
2. In 2020, seven (7) CoE trainings were attended by 21 state and regional TB staff. Between January 1 – June 30, 2021, six (6) CoE trainings were attended by 15 state and regional TB staff
 | None identified. |
| Establish partnerships with organizations that serve high-risk populations | Ensure implementation of Community Partnerships to End TB (CPETB) initiative | December 31, 2022 **(new)** | June 10, 2021: survey sent to all regional TB program managers to assess feasibility of resuming CPETB initiativeJune 17, 2021: statewide TB call held to discuss results of survey and reintroduce initiative; most TB programs indicated initiative implementation was feasible beginning in 2022 | Barriers identified from the 6/10/21 survey of regional case managers include:1. regional TB program staffing and ability to effectively implement initiative
2. COVID-19 uncertainty
3. scheduling
4. cooperation from community partners
 |
| Hold bi-monthly statewide conference calls with 100% regional attendance | 1. Provide conference call calendar
2. Create and send calendar invites
3. Develop agenda and materials for each call
 | Bi-monthly | The conference call held in June 2021 was the first statewide call since the beginning of COVID-19 that all had 100% regional attendance | Statewide conference calls were temporarily suspended for the majority of 2020 due to COVID-19; the conference call scheduled resumed in 2021 |
| Plan and present a clinical symposium | 1. Convene a symposium planning committee to develop agenda/content
2. Identify date(s) and location for the symposium
3. Identify presenters
 | Bi-annually | None. | HRD funds were allocated in 2020 and again in 2021 to conduct a clinical symposium but due to COVID-19, the symposium was postponed  |
| Provide quarterly new case manager training | 1. Review existing case manager training content
2. Update content for case manager training as needed
 | Annually | 2020: no new case manager trainings were held due to the lack of need/demandJan – June 2021: one (1) case manager training was held for one (1) new regional case manager | 1. Coordinating schedules of the central office public health nurse case manager and the new regional TB case manager
2. Navigating technical issues with conducting the training online
 |

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**PUBLIC HEALTH LABORATORY STRENGTHENING**

Organizational Chart



Laboratory Contact

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Laboratory Methods and Testing Algorithm

|  |  |  |
| --- | --- | --- |
| **Test Method** | **Description** | **Testing Frequency** |
| Specimen Processing | All non-sterile specimens must be processed through a digestion and decontamination procedure. This procedure employs N-acetyl-L-cysteine (NALC) as a mucolytic agent (digestion) and sodium hydroxide (NaOH) to decontaminate. The sodium citrate included in this mixture exerts a stabilizing effect on the acetyl-cysteine because of its ability to bind (by chelation) many heavy metal ions that may be present in this specimen. Reflex testing: acid-fast bacilli (AFB) smear, liquid media, and solid media.  | Monday-Friday |
| AFB Smear | Direct and processed samples have slides reviewed for the presence of AFB by fluorochrome smear. New AFB smear-positive specimens reflex to Cepheid GeneXpert® MTB RIF assay. | Monday-Friday |
| AFB Solid Media Culture | All direct and processed samples are inoculated to 7H11 Mitchison bi-plates and possible growth is reviewed weekly after week two (2) of CO2 incubation. Pates are reviewed for up to six (6) weeks in total. All samples suspected of mycobacterium growth are sent to MALDI-TOF for identification following a one (1)-month culture referral policy.Culture referral policy1. Any specimen received on the same patient for one (1) months following the identification will be referred to the identified isolate. Referral would be based on the date of collection of each isolation and morphology must be consistent for referral.
2. If morphology does not match, possible mixed culture, or the timeframe is >1 month from identification, the specimen will be sent for identification testing.
 | Monday-Friday |
| AFB Liquid Media Culture | VersaTREK® Myco System is FDA-cleared for the rapid detection of mycobacteria in clinical specimens. The following sources were used during the clinical evaluation of the VersaTREK® Culture System: respiratory (including sputum, lavage, etc.), body fluids (including CSF, synovial fluid, pleural fluid, etc.), urine, stool, gastric aspirates, tissues, blood, and bone marrow.The system combines a liquid culture medium (VersaTREK® Myco Formula), a growth supplement (VersaTREK® Myco GS Formula), and an antibiotic supplement (VersaTREK® Myco PVNA Formula). The VersaTREK® growth supplement provides substances essential for the growth of mycobacteria. The VersaTREK® Myco PVNA contains a mixture of antimicrobial agents used to suppress the growth of contaminating bacteria. Sponges in the VersaTREK® Myco bottles provide a growth-support matrix and increase the surface area exposed to headspace oxygen. The technology of the VersaTREK® Culture System monitors changes in either gas production or gas consumption due to microbial growth. This information is used to generate a curve for each bottle. An internal algorithm analyzes the information to determine the status of each specimen. When a certain set of conditions are met, a bottle is flagged as positive. There are approximately 106 CFU/ml of mycobacteria at the time of detection. Positive liquid media is sub-cultured, and growth is reviewed weekly for possible mycobacterium growth. Possible growth is sent to MALDI-TOF for identification following a one (1)-month identification referral policy.  | Instrumentation runs seven (7) days/week with positive and negative bottles being addressed Monday-Friday |
| Cepheid GeneXpert® | The GeneXpert® Dx system integrates and automates sample processing, nucleic acid amplification, and detection of the target sequences in simple or complex samples using real-time PCR and reverse transcriptase PCR. It consists of self-contained test cartridge that eliminates cross-contamination between samples. Assay includes reagents for detection of *Mycobacterium tuberculosis* and rifampin (RIF) resistance as well as sample processing control (SPC) to control for adequate processing of the target bacteria and to monitor the presence of inhibitor(s) in the PCR reaction. The Probe Check Control (PCC) verifies reagent rehydration, PCR tube filling in the cartridge, probe integrity, and dye stability. Testing is performed on all new AFB smear-positive samples as well as any smear-negative samples that are requested by the Tennessee TB Elimination Program.  | Dependent on smear-positive results and upon request from TB Elimination Program |
| DNA Probe | The GEN-PROBE® ACCUPROBE® identification test is a rapid DNA probe test that utilizes the technique of nucleic acid hybridization for culture identification of *M. tuberculosis* complex. This testing only performed when a GeneXpert® positive sample occurs for fast tracking of drug-susceptibility testing (DST). Testing is performed on all GeneXpert® positive samples when MGIT tubes flag positive. | Only when liquid is received and soon to be discontinued |
| LiPA | LiPA is based on the reverse hybridization principle. Biotinylated DNA material is hybridized with specific oligonucleotide probes immobilized as parallel lines on membrane-based strips. After hybridization, streptavidin labeled with alkaline phosphatase is added and bound to any biotinylated hybrid previously formed. Incubation with 5-bromo-4-chloro-3-indolyl phosphate and nitroblue tetrazolium (BCIP/NBT) chromogen results in purple/brown precipitate. To perform the LiPA, amplification of the 16S-23S ribosomal rRNA spacer region should be carried out. Amplification products are subsequently hybridized using 1 typing strip onto which 22 parallel DNA probe lines and 2 control lines are fixed. This method is used to identify mixed or contaminated cultures only. Testing is reflexed if a reportable score is not obtained by MALDI-TOF or the isolate appears to be a mixed culture or contaminated. | Bi-monthly |
| MALDI-TOF (Matrix-Assisted Laster Desorption/Ionization) | MALDI-TOF is a mass spectrometry process that transforms the proteins and peptides of a microorganism into positively charged ions. The samples are analyzed from a fresh culture and then transferred to a selected position onto the sample plate. Each sample will have matrix added which absorbs the laser energy and transfers protons to the intact proteins or peptides in the gas phase. These ions become electrostatically accelerated and travel through the flight tube. Each ion’s mass will determine the speed at which it travels through the flight tube to the detector. The system measures the time (nanosecond range) between the pulsed acceleration and the detector signal of ions. The time is then converted into an exact molecular mass. Each organism has a unique “molecular fingerprint” that identifies it. The acquired mass spectra are then transformed to a peak list and compared to the reference library. All suspect mycobacterium samples undergo the Mycobacterial Extract protocol requiring heat inactivation.  | At least twice/week |
| Drug-Susceptibility Testing (DST) | The BACTEC™ MGIT™ 960 SIRE kit and BACTEC™ MGIT™ 960 PZA kit are used as a rapid qualitative procedure for susceptibility testing of *Mycobacterium tuberculosis* complex (MTBC) to streptomycin (STR), isoniazid (INH), rifampin (RIF), ethambutol (EMB), and pyrazinamide (PZA). The BACTEC™ MGIT™ 960 STR 4.0 kit and the BACTEC™ MGIT™ 960 INH 0.4 kit are for testing at higher drug concentrations.The BACTEC™ MGIT™ 960 SIRE kit is a 4–13-day qualitative testing while the BACTEC™ MGIT™ 960 PZA kit is a 4-21-day qualitative test. The test is based on growth of the *M. tuberculosis* isolate in a drug-containing tube compared to a drug-free tube (growth control). The BACTEC™ MGIT™ 960 instrument continuously monitors tubes for increased fluorescence. Analysis of fluorescence in the drug-containing tube compared to the fluorescence of the growth control tube is used by the instrument to determine susceptibility results.DST is performed on all newly identified MTBC patients and any patient that has remained culture positive for *Mycobacterium tuberculosis* complex for three (3) months or longer from the initial isolate identified as MTBC.  | Twice/week |
| Interferon-Gamma Release Assay (IGRA) - QuantiFERON®-TB Gold Plus (QFT Plus) | The QuantiFERON®-TB Gold Plus (QFT Plus) is an *in vitro* diagnostic test using a peptide cocktail simulating ESAT-6, CFP-10 proteins to stimulate cells in heparinized whole blood. Detection of interferon-γ (IFN-γ) by Enzyme-Linked Immunosorbent Assay (ELISA) is used to identify *in vitro* responses to these peptide antigens that are associated with *Mycobacterium tuberculosis* infection. | Monday-Friday |

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| **Activity** | **Description** | **Frequency** |
| Electronic Ordering | Electronic orders are placed in the PTBMIS system by health department staff in 94 of the 95 counties and the files are converted to an extensible markup language (XML) format via an electronic data exchange (EDI). The EDI deposits the transformed file into a shared directory that StarLIMS uses to upload the orders into a database at prescribed times. One county does not utilize the PTBMIS system. All specimens are ordered via a Division of Laboratory Services Clinical Submission Requisition (PH-4182) that must be keyed by state laboratory staff upon specimen receipt. In addition, non-public health department providers who send specimens to the laboratory for testing utilize the PH-4182 requisition. | Monday-Friday |
| Reporting Protocols | Preliminary reports are generated for the AFB smear. Preliminary reports are generated once identification is made on one form of media (liquid or solid). A final report is generated when the six (6)-week incubation period has ended or both the liquid and solid media have corresponding mycobacterium growth.For health departments who order tests electronically, preliminary, and final reports are received both electronically and via fax. Non-health providers receive preliminary and final results via fax and mail. | Monday-Friday |



**Testing Algorithm**

Work Plan

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| **Laboratory Element 1: Ensure availability of high-quality and prompt core laboratory services for tuberculosis (TB)** |
| **What are your laboratory objectives for Element 1 during the five-year Cooperative Agreement period? All laboratories, regardless of volume, should provide objectives related to improving each of the national benchmark turnaround time recommendations.** | **How will your laboratory measure success related to these objectives?** |
| Reduce turnaround time (TAT). | Specimen receipt: improve TAT to 65% of specimens received within one (1) day of collection.1. DST: within 17 days of identification for 75% of isolates
2. NAAT: 85% of NAAT reported within 48 hours of specimen receipt
3. Smears: 85% of all smears reported within 24 hours of specimen receipt
4. ID: improve TAT to 65% of MTBC isolates reported within 21 calendar days of specimen receipt
 |
| **Activities** | **Measure of Success** | **Anticipated Obstacles** | **Responsible Laboratory Staff** | **Target Completion Date/Timeline** | **Progress** |
| NAATPerform QA monitor to determine reasons for testing not being performed within a timely manner. | 85% of NAAT reported within 48 hours of specimen receipt | 1. Weekends and/or holidays
2. NAATs not performed on smear-negative
 | Natasha Lindahl, TB Lab Supervisor | December 2024 | **Ongoing**QA monitor determined that in many specimens received during the weekend or in the afternoon were not performed in a timely manner because the processing had already begun prior to receipt of these specimens or NAAT testing was scheduled to complete after business hours |
| Smear* Monitor batch specimens (two or more specimens received on the same day on the same patient) from all public health departments.
* Perform a QA monitor to determine reasons for delay and address delays as appropriate.
 | 85% of all smears within 24 hours of specimen receipt | 1. Weekends and/or holidays
 | Natasha Lindahl, TB Lab Supervisor | December 2024 | **Ongoing**A QA monitor was not performed to address this issues knowing that TB activities and clinics were recommended by the Tennessee TB Elimination Program (TTBEP) to reduce patient contact and limit face-to-face contact. |
| DSTMaintain current TAT. | Maintain current TAT | 1. Growth rate of the organism
 | Natasha Lindahl, TB Lab Supervisor | December 2024 | **Ongoing**Multiple patient samples failed to grow initially on DST media |
| Organism identificationPerform a QA monitor to identify which step(s) in the workflow result in the majority of delays and address the delays as appropriate. | Improve TAT to 65% of MTBC isolates reported within 21 calendar days of specimen receipt | 1. Mixed or contaminated cultures
 | Natasha Lindahl, TB Lab Supervisor | December 2024 | **Ongoing**Slight improvement made in 2020. In the process of switching liquid media system that will lead to fewer false-positive liquid mediate and solid media plate readings. |
| ReportingCreate a log to track all samples affected by system downtime. Call provider with results when system is down. Document calls in the report when system becomes functional. | 1. Improve TAT to 85% of AFB smear results reported within one (1) days of receipt
2. Improve TAT to 65% of MTBC isolates reported within 21 calendar days of specimen receipt
 | 1. Current LIMS system does not generate reports in real-time
2. Not all providers have the ability to receive reports electronically
3. Weekends and/or holidays
 | Natasha Lindahl, TB Lab Supervisor | December 2024 | **Achieved**One benefit from COVID is that the current LIMS system now generates reports in almost real-time. In addition, the informatics staff currently monitors, documents, and informs laboratory department management staff when samples are affected by system downtime.  |
| Specimen receiptMonitor batch specimens (two or more specimens received on the same day on the same patient) from all public health departments | Receipt within one (1) day of collection for 65% of the specimens | 1. Weekends and/or holidays
 | Natasha Lindahl, TB Lab Supervisor | December 2024 | **Ongoing**This is a scheduled annual QA monitor. All data is shared with the TTBEP. Follow-up is maintained by TTBEP. This monitor was not performed in 2020 due to reduction of in-person clinic visits. QA monitor will resume once recommendation is lifted. |
| **Laboratory Element 2: Promote continual advancement of laboratory efficiency and quality assurance through the use of local data (i.e., your laboratory-specific data)** |
| **What are your laboratory objectives for Element 2 during the five-year Cooperative Agreement period?**  | **How will your laboratory measure success related to these objectives?** |
| Reduce laboratory pre- or post-analytical error rates. | Implementation of cross-contamination protocol to guide lab staff and TTBEP staff on how to investigate; 5% decrease in transcription documentation errors made by lab staff. |
| **Activities** | **Measure of Success** | **Anticipated Obstacles** | **Responsible Laboratory Staff** | **Target Completion Date/Timeline** | **Progress** |
| Develop a universal cross-contamination SOP for lab and TTBEP staff | Completion and implementation of cross-contamination procedure with approval from laboratory director and TTBEP leadership | None | Dorothy Baynham, TB Lab Manager | December 2022 | **In progress**Meeting held between lab and TTBEP staff to discuss procedure. Rough draft of cross-contamination procedure has been written with input of testing personnel.  |
| Reduce transcription and documentation errors | 1. Reduce the number of transcription or data entry errors by lab personnel by 5%
2. Perform various QA monitors throughout the year to verify accuracy of test request, specimen submission, and accuracy in testing formats
 | Equipment interface with LIMS system | Natasha Lindahl, TB Lab Supervisor | December 2024 | **Achieved**Annual QA reports show the laboratory’s current accuracy rate is 99.5% and have been maintained. |
| **Laboratory Element 3: Collaborate with partners (e.g., healthcare providers, TB programs, and other laboratories) to ensure optimal use of laboratory services and timely flow of information.** |
| **What are your laboratory objectives for Element 2 during the five-year Cooperative Agreement period?**  | **How will your laboratory measure success related to these objectives?** |
| Increase collaboration with internal and external partners | 1. Recorded sign-in sheets, agenda, and minutes from meeting with TTBEP leadership
2. Distribution of unsatisfactory logs to TTBEP leadership and regional TB programs
3. Ensuring laboratory module of TTBEP TB Manual is current with up-to-date procedures and tests
 |
| **Activities** | **Measure of Success** | **Anticipated Obstacles** | **Responsible Laboratory Staff** | **Target Completion Date/Timeline** | **Progress** |
| Conduct a minimum of six (6) meetings (in-person or virtual) with TTBEP program | 100% of meetings schedule by mid-year | 1. Availability of staff
2. Coordination of staff schedules
 | Dorothy Baynham, TB Lab Manager | December 2024 | **Ongoing**In-person meetings have been postponed due to COVID-19 concerns. Conference calls with TTBEP leadership have been ongoing throughout this time period. |
| Provide monthly communication logs for unsatisfactory smear and culture submissions and GeneXpert® testing to TTBEP program | Distribution of the document to the TTBEP by the last working day of each month | None | Dorothy Baynham, TB Lab Manager | December 2024 | **Ongoing**Communication logs for unsatisfactory smear and culture submissions and GeneXpert® testing are set on the last day of the month to the TTBEP program |
| Provide a weekly DST log to the TTBEP program for all pending and completed DST results | Distribution of the document to the TTBEP by the last working day of each month | None | Dorothy Baynham, TB Lab Manager | December 2024 | **Ongoing**A weekly DST log sheet is emailed by the last working day of each work week |
| Attend and contribute to the annual TB program statewide meeting | Attendance and/or presentation at the meeting | None | Dorothy Baynham, TB Lab Manager | Annually | **Ongoing**The statewide meeting for 2020 and 2021 was canceled due to COVID-19. Awaiting details for 2022. |
| Review and update lab module of the TTBEP TB Manual | Submission of revisions by TTBEP-specified deadline | None | Dorothy Baynham, TB Lab Manager | Annually or according to TTBEP revision schedule | **Achieved**Annual revisions and input were solicited and completed. |