

Calendar Year 2013 – Final Progress Report

Tuberculosis Control Section



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FLORIDA DEPARTMENT OF HEALTH

Division of Disease Control and Health Protection

Bureau of Communicable Diseases

Tuberculosis Control Section

Calendar Year 2013 Final Progress Report – April 1, 2014

Introduction

This report addresses Centers for Disease Control and Prevention (CDC) cooperative agreement recipient activities that support tuberculosis (TB) prevention and control in Florida. This report also addresses the performance of the Florida Department of Health (FDOH) TB Control Section (TBCS) and its local partners towards national objectives. Florida's System of Tuberculosis Care (FSTBC) provides the framework to continue reducing the number of tuberculosis cases in the state and reach the goal of no more than two TB cases per 100,000 of population by 2020. The FSTBC is comprised of five components essential to the quality of care: surveillance, diagnosis, treatment, case management and education. Full implementation of the FSTBC is expected to reduce the need for hospitalization of TB patients by expanding community-based care options.

The FSTBC is founded upon proven public health practices, standards and evidence-based TB control strategies. This patient-centered, community-focused and population-based system of care provides the accountability and adaptability necessary to reduce the rate of TB in the state. The cornerstone of the system is a holistic assessment of each person's needs combined with intensive case management and effective outreach to ensure every patient with active disease remains under medical supervision until completion of curative therapy.

Under the leadership of the FDOH Office of Performance and Quality Improvement, TBCS incorporates the CDC Standardized Performance Measurement Framework for the National Public Health Improvement Initiative (NPHII): Year Four, Objective Three, the FDOH Agency Strategic Plan (2012-2015) and the Florida State Health Improvement Plan (2012-2015) to determine measures of success for performance management and program evaluation (PE). The

National TB Indicators Project's (NTIP) objectives and 2015 performance targets serve as guidance for program operations to achieve the goal of elimination of TB in Florida.

TB PREVENTION AND CONTROL

Program Narrative

FSTBC consists of three distinct levels of care, all of which are accessible whenever needed to facilitate the effective management and treatment of persons with TB.

Level 1

The first-line providers, the county health departments (CHDs), are designated Level 1 Care. The dedication and effectiveness of Level 1 providers is essential to the success of FSTBC. These Level 1 TB operations are ongoing in the CHDs. See Human Resource Development section of this progress report to learn about Florida's plan to maintain and strengthen the competencies of Level 1 providers, even in low incidence counties.

Level 2

Level 2 Care consists primarily of consultation and patient service contingencies available to any Level 1 provider to improve medical and nurse case management services, to address barriers to care, and facilitate continuity of treatment until cure in the community. Services will also include interventions to identify and address operational issues that may jeopardize the success of Level 1 providers, such as education, training and/or infrastructure deficiencies. A key component of effective Level 2 Care will be program evaluation/quality improvement initiatives undertaken in collaboration with Level 1 providers.

Level 2 Care must be the most flexible and fluid of all levels of care, because this level is designed to identify services specific to the needs of a given patient or group of patients. These are not available through Level 1 providers, but are essential to assisting these providers to manage and treat their patient population in the community. It is certain that the range of services available through Level 2 Care will expand significantly over time. In fact, the development and refinement of Level 2 Care will never end as long as TB persists in Florida. All expected deliverables for Level 2 Care elaborated in the System of TB Care document are

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currently being provided by TBCS or its contractors and are available to Level 1 CHDs statewide.

Level 2 services currently include the provision of:

- Expert physician consultation and clinical coverage,
- Expert nurse case management consultation,
- Specialized medical services,
- Incentives to promote treatment until cure, and enablers to address barriers to care,
- Educational initiatives and experiential opportunities.

Expert Physician Consultation and Clinical Coverage

The following is a summary of key aspects of Florida's approach to providing physician consultation and clinical coverage statewide.

The TB Physicians Network (TBPN) is essential to the success of FSTBC by providing adequate expert physician consultation capacity in Florida. From July 1 through December 31, 2013, TBPN interpreted 988 films submitted for diagnosis and treatment recommendations. These films were submitted to TBPN because no local expertise existed for the diagnosis and treatment of active TB or latent TB infection (LTBI). In that same time period, TBPN provided physician staffing for a total of 24 clinical hours in CHDs statewide. TBPN routinely provides consultations that are not associated with films, but do impact the quality of care favorably, i.e., managing adverse reactions to medications. With this unique resource, Florida enhances its potential to use current and future technologies to ensure a consistent and high quality of care to its residents, regardless the TB case rate or lack of local expertise in the diagnosis and treatment of TB and LTBI.

In May 2014, TBCS will begin building a medical consultation module to provide access to streamlined technology to support statewide clinical consultation. It will provide a user-friendly interface for both CHDs and TBPN. Local imaging providers will be able to send images directly from their offices, eliminating the need for CHD staff to retrieve disks from the imaging provider and upload into CareStream. Information will flow electronically and securely in both directions eliminating faxes or mailing of patient information when seeking consultation. Chest

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radiograph interpretations and treatment recommendations will auto-populate the Health Management System (HMS), eliminating transcription into HMS by CHD nurse case managers (NCMs). Alerts will be incorporated to notify users when consultations are requested and completed, eliminating the need to e-mail or call to notify, as is currently the case. In short, this module is being built to maximize efficiency in the TB medical consultation process. Ease of access to expert physician consultation is essential to the FSTBC going forward.

Expert Nurse Case Management Consultation

This service is currently provided by the Medical Director, TB Controller, Nursing Director and Nurse Consultant at TBCS on one-on-one or conference calls typically initiated by the CHDs. These calls are generally related to congregate setting contact investigations in health care facilities, schools or local jails. Calls have also been for consultation in dealing with difficult populations, i.e., migrant workers. These calls provide the confidence and support local NCMs need to deal with these complicated situations.

TBCS has developed a form for TB Program Managers/Coordinators to make the program aware of contact investigations in congregate settings, such as schools, worksites, nursing homes, etc. It will serve as an early warning system for contact investigations which might provoke press interest and provide TBCS an opportunity to be proactive in consultation.

See Human Resource Development section of this progress report for another way Florida will become proactive in nurse case management consultation and local capacity building in the future.

Specialized Medical Services

TBCS offers access to and payment for specialized medical services, including CT scans, minimum inhibitory concentration (MIC) testing, peripherally inserted central catheter (PICC) lines and infusion therapy for MDR-TB patients.

From July 2013 through March 2014, TBCS has provided \$48,135 in support of specialized medical services for Level 1 CHDs statewide.

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Incentives and Enablers

Incentives are products or services that motivate patients to adhere to treatment, take medications, to attend clinic appointments or to cooperate in other ways to complete treatment. TBCS offers an array of incentives to assist NCMs and Disease Intervention Specialists (DIS) to encourage patient adherence. Incentives stocked at TBCS and available to NCMs upon request are Publix and Winn-Dixie grocery store coupons and McDonalds, Kentucky Fried Chicken, and Popeye's Chicken coupons. Boost nutritional supplement is also available. TBCS will also pay for incentives that will meet a specific need for a single patient. This program is designed to be flexible to meet the needs of a diverse patient population.

An enabler describes anything that helps a patient to complete treatment by eliminating barriers to cooperation. One such enabler is housing assistance. This enabler is available to all Level 1 clients statewide. The assistance provided is targeted towards patients who are currently homeless. Providing housing to homeless TB patients is challenging in Florida, due to the practice of only using stand-alone housing. It has, however, led to many creative solutions to assist this population, such as utilization of a CHD-owned mobile trailer at a campground when needed for housing.

From July 2013 through March 2014, TBCS housed 18 TB cases for a total of 1,213 days. The ability to provide housing to the homeless has saved hospital days for a population that, without housing, is almost impossible to manage and treat until cure in the community.

In calendar year (CY) 2014, TBCS will consider expanding housing assistance to patients at-risk for becoming homeless. Assistance is often needed to ensure that no patient loses existing housing due to a lack of income associated with the diagnosis or treatment of TB or measures taken to protect the public's health.

Educational Initiatives and Experiential Opportunities

See Human Resource Development section of this progress report.

The expectations of Level 2 care within the FSTBC are currently being fulfilled by TBCS. Further discussion regarding the originally envisioned Area Networks is needed to clarify functions and infrastructure required to sustain the network functions.

Level 3

Level 3 Care is primarily managed by the TBCS Medical Director. It involves access to hospitalization, both voluntarily and court-ordered. The two hospitals currently under contract are Shands-Jacksonville (Shands) and Jackson Memorial Hospital (JMH) in Miami. The TBCS Medical Director holds detailed case reviews for each hospitalized patient every week with hospital staff to ensure the quality of care being provided. This is a substantial, but essential investment of time and effort.

Dependence upon hospitalization and the courts has been reduced significantly in Florida, in favor of treatment in the community. Hospitalization is being used when needed to provide care to patients with serious complications and to protect the public health, but only so long as medically needed or to ensure the cure in those that continue to pose a threat to the public health.

In state fiscal year (SFY) 2011, the last year A. G. Holley was in operation, 62 unique TB cases were admitted to the hospital for an average length of stay totaling 144 days each. In SFY 2013, the first year of TBCS's contract with Shands and JMH, 76 unique TB cases were admitted with an average length of stay of 93 days. This documents a 35.4% reduction in length of stay. Total hospital days were reduced by 38.1% from 8,928 in SFY 2012 to 7,068 in SFY 2013. Court-ordered admissions decreased by 38.1% from 21 in SFY 2012 to 13 in SFY 2013. To date in SFY 2014, 15 or 22.7% of 66 hospital admissions have been court-ordered.

The implementation of some aspects of the FSTBC was delayed in an effort to build essential infrastructure. Although TBCS is expanding its offerings in Level 2 Care and will continue to do so, access to Level 2 and Level 3 services to "ensure the cure" are currently available to Level 1 CHDs statewide.

TB Policy Manual

The FDOH created a "Florida TB Control Section Policy Manual" and posted it to the TBCS website in August 2013. The purpose of the manual is to ensure consistency and standardization throughout the state in the implementation of the TB System of Care.

Performance Towards Achievement of Objectives

Data Sources

In calendar year (CY) 2013, TBCS developed a TB registry (see Attachment A) to warehouse its data for analysis. It also developed a performance assessment tool. During this process it worked with surveillance staff at the Centers for Disease Control and Prevention's Division of TB Elimination (CDC-DTBE) to validate that its local analysis of performance indicators associated with TB cases until it arrived at the same numerator and denominator as the analysis in the National TB Indicators Project (NTIP). The analysis of Florida's TB registry data is more accurate and timely than analysis in NTIP for the CY 2012 and CY 2013 cohorts. Submission of data to CDC-DTBE is a five step process in Florida, but data is available for analysis in our TB registry the day after it is placed in HMS at the local level. Most of the reported levels of performance in this report were generated using these new tools.

Generation of contact and targeted testing aggregate reports for program evaluation (ARPEs) will be achieved through analysis of the TB registry beginning with the ARPEs submitted in August 2014 for the contacts to TB cases and targeted testing provided in CY 2012. The generation of these reports was previously achieved through HMS. It was a time-consuming process that is now obsolete.

Florida will utilize population data from Florida CHARTS, rather than the American Community Survey, so there may be a variation between its reported case rates and those in NTIP.

Florida is dependent on NTIP for outcomes of screening and treatment activities surrounding Class B refugees and immigrants, but will attempt to develop the capacity to conduct this analysis locally through its performance assessment tool in the future.

Evaluation of Negative Outcomes

The level of positive performance toward stated objectives can be less important than being able to review the records of patients for whom the objective was not met. This patient-specific review is essential to identify any systemic issues that may be leading to these negative outcomes. Without such investigation, true program evaluation cannot be achieved. TBCS developed a mechanism whereby it can capture "why" a negative outcome occurred. In some

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instances, the information captured through this mechanism provides only partial insights into the reasons for negative outcomes, but it is more information than Florida has captured historically. The completeness of this important information will improve in future reports as TBCS refines its methods for capturing it routinely. TBCS surveillance staff members do not have access to statewide patient-specific information in HMS, but efforts are underway to secure this access, which is essential to effective program evaluation.

Immediate Objectives: These objectives are termed “immediate” because the only delays that exist to having this information are laboratory testing/reporting time and provider reporting time.

In CY 2013, Florida performed at its highest level in the last five years on four of five of these measures of program effectiveness. The only exception was the measure for drug susceptibility test results. Failure on this measure is most commonly associated with the biology of the *M.tb* bacillus.

Year	2009	2010	2011	2012	2013
Objective 1 Treatment Initiated Within 7 Days of Sputum Collection	70.8% (170 of 240)	71.5% (173 of 242)	80.4% (181 of 225)	75.7% (187 of 247)	91.1% (216 of 237)
Objective 2 Started on recommended 4-drug regimen	91.1% (720 of 790)	91.1% (733 of 805)	92.4% (680 of 736)	93.3% (610 of 654)	94.3% (595 of 631)
Objective 3 Known HIV Status	81.9% (651 of 795)	84.8% (688 of 811)	83.9% (618 of 737)	83.1% (547 of 658)	87.7% (555 of 633)
Objective 4 Drug Susceptibility Results	96.1% (615 of 640)	95.3% (604 of 634)	95.7% (578 of 604)	95.6% (518 of 542)	93.6% (479 of 512)
Objective 5 Sputum Culture Reported	88.6% (603 of 681)	85.9% (561 of 653)	86.2% (501 of 581)	93.1% (523 of 562)	94.0% (501 of 533)

Data Source: Florida TB Registry - Performance Assessment Tool

Objective 1: In CY 2013, at least 90.0% of sputum-smear positive TB patients will initiate treatment within 7 days of specimen collection.

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Status: Met

Major Findings: Performance in CY 2013, 91.1%, was the best ever recorded by Florida towards achievement of the national target of 95.2% in CY 2015. It exceeded the national average of 90.1% in this cohort year. The national average in CY 2013 was also the highest recorded over the past five-year period.

The following reasons were identified for 10 of the 21 patients not meeting the objective:

- Five were lost and later found and treatment was initiated by the CHD. Four of these patients left the hospital against medical advice (AMA) and were later found.
- Sputum smear result reporting was delayed for two (12 and 15 days).
- Treatment was delayed in one, awaiting nucleic acid amplification (NAA) test results.
- One patient refused treatment upon diagnosis and died 12 days later.
- Reporting of a TB suspect to CHD was delayed by the primary care provider.

There may be little or nothing that can be done about patients lost to medical supervision, unless they telegraph their intentions. Finding these patients and returning them to care is an indication of dedicated public health work. Delayed sputum smear and NAA test results and delays in reporting are a concern, but not occurring at a level which indicates a systemic issue.

Barriers Encountered: The 15.4 percentage point improvement over the CY 2012 cohort is primarily due to “alerts” (see Attachment A) which improve the accuracy, completeness and timeliness of data for program performance assessment. A common problem leading to depressed performance was documentation of when treatment started in the CHDs, rather than when it actually started in the hospital. This problem has been addressed and corrected.

Action Plan: The Bureau of Public Health Laboratories’ (BPHL) Mycobacteriology and Mycology Laboratory is drafting a guideline to laboratories doing TB work throughout the state. This guideline will provide instructions on submitting specimens to BPHL for NAA testing to identify *Mycobacterium tuberculosis* (MTB) and HAIN testing to identify mutations indicating resistance to isoniazid (INH) and/or rifampin (RIF). This guideline is designed to increase and speed access to these specialized tests. It may also result in earlier initiation of effective treatment.

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Objective 2: In CY 2013, at least 91.4% of TB cases will be started on the recommended initial 4-drug treatment regimen.

Status: Met

Major Findings: Florida has performed above the national average for this measure of program effectiveness four of the past five years. In CY 2013, Florida's 94.3% performance exceeded the national average by 1.9 percentage points. The national objective performance target for CY 2015 is 93.4%. Florida exceeded this performance level for the first time in CY 2013.

The following reasons were identified for the 36 patients not meeting this objective:

- Nine were initially hospitalized on 3-drug regimen for the 14-day window period.
- Eight were children whose hearing could not be tested, no ethambutol (EMB).
- Three were pregnant, no pyrazinamide (PZA).
- Three were on a liver sparing regimen due to initially high liver function tests (LFTs).
- Three were not on PZA and/or EMB due to advanced age with concurrent health issues.
- Two had adverse reactions or liver issues during the 14-day window period, requiring medications to be dropped and not all could be restarted.
- Three had multi-drug resistant (MDR) TB, no INH or RIF.
- One was being treated for suspected BCG-osis, no PZA.
- One was a contact to a pan-sensitive TB case, no EMB.
- One started treatment in India.
- One was a culture negative case treated by a private provider.
- One was a child initially diagnosed as LTBI and later reclassified as a TB case.

Most of the reasons above are medically prudent and reveal no systemic issues. The major exception is 3-drug treatment during hospitalization, but the level at which it is occurring does not indicate a systemic issue.

Barriers Encountered: The Health Management System (HMS) makes no allowance for adding a new drug as part of the initial regimen drug within the 14-day window CDC allows to intervene to change an inadequate treatment regimen. If a new drug is added after treatment starts and indicated as part of the initial treatment, then the dates of initiation of all other drugs

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are changed to the later date. This impacts favorably on this indicator, but may unfavorably impact on the timely initiation of therapy indicator.

Action Plan: A decision will be made, in consultation with the TB Technical Team, on how best to manage this dilemma until HMS can be modified to allow the required flexibility. This strategy will be shared with TB Program Managers/Area TB Coordinators for implementation statewide.

Objective 3: In CY 2013, at least 87.7% of TB cases will have a documented HIV test result.

Status: Met

Major Findings: Florida's performance in CY 2013, 87.7%, is its best historically. It is higher than the national average of 86.7% in the same year. This has been true three of the past 5 years. The national target for CY 2015 is 88.7%. Florida's current performance approaches this target.

Of the 78 TB cases in CY 2013 for which no HIV test results are known, 62 or 79.5% refused testing, 3 or 3.8% were tested, but the results are unknown and 1 or 1.3% was reported as "unknown." The TB case reported as unknown was 81 years old under the care of a private physician.

Sixty-two or 9.8% of the 633 TB cases eligible for inclusion in this objective refused testing. This is a higher than typical refusal rate. That being said, 15 or 24.2% of these TB cases were over the age of 65 and 6 or 9.7% were under the age of 15 years.

Twelve or 15.4% of TB cases without a HIV test result were reported as not offered testing. One or 8.3% of these 12 cases was 2 years old and 7 or 58.3% were over the age of 65 years. One 75 year old case died in the hospital where HIV testing was not done. Another 91 year old case was on a respirator and unresponsive at TB diagnosis and was discharged to hospice care in Alabama.

Barriers Encountered: Florida has an "opt in" strategy for HIV testing. It has not adopted an "opt out" strategy for HIV testing as recommended nationally.

Action Plan: TBCS will stress the importance of offering HIV testing to all TB cases, but the barrier above and the small and decreasing number that are not offered testing may limit the potential impact.

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Objective 4: In CY 2013, at least 95.0% of culture positive TB cases will have a documented drug susceptibility test result.

Status: Ongoing

Major Findings: Performance over the past 5 years has ranged from 96.1% in CY 2009 to 93.6% reported for the CY 2013 cohort. Florida's performance has been consistently above 95% and may improve further for cases reported in CY 2013. This reporting lag is not unique to Florida, the national average is historically above 97%, but is currently reported at 88.7% for CY 2013 cohort and will likely improve.

The most common reason for not having conventional drug susceptibility test (DST) results is the inability to obtain a pure culture for testing. Of the 33 culture positive cases without a DST result, a reason was reported for 16 or 48.5%. Of these 16, the lab could not obtain a pure culture for 14 or 87.5%. The other two cases died before a culture was reported and the DST was cancelled. It may seem prudent to cancel DST, because the TB case does not need therapy. It is not, however, if there are contacts which may have LTBI, because these contacts will need treatment and DST results are essential to prescribing effective preventive therapy.

There are no systemic issues here, conventional DSTs are being ordered, but there may be ways to improve performance nonetheless.

Barriers Encountered: The likelihood of obtaining a pure culture decreases with TB treatment. Therapy kills the bacilli, allowing other organisms to overgrow TB in culture. Ideally, a culture submitted for conventional DST is obtained prior to treatment initiation, but the earlier in treatment the better. Likewise, the ability to obtain a pure culture is enhanced by the number of specimens received. BPHL requests cultures from other laboratories routinely, but often receives specimens obtained after treatment began and usually only one specimen, handicapping its ability to perform conventional DST. The lag in reporting is caused when BPHL persists in its efforts to purify a culture, rather than reporting it cannot.

Florida's advantage over other states is the availability of the HAIN test, which identifies mutations indicative of resistance to INH and/or RIF, the two most effective TB drugs. The HAIN test is a molecular DST and does not require a culture. In the absence of conventional

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DST results, HAIN test results may inform treatment decisions even though it is not the gold standard.

Action Plan: BPHL is now requesting multiple specimens from submitters. It will also market HAIN testing for rapid identification of possible drug resistance. This should lead to the submission of specimens earlier in the course of treatment.

Objective 5: In CY 2013, at least 91.4% of TB cases with pulmonary and/or pleural disease, aged 12 years or older, will have a documented sputum culture result.

Status: Met

Major Findings: Florida's performance in CY 2013 was 94.0%. This is Florida's highest historical performance. It surpassed the national average of 90.5% for the first time in the last five years. The national objective performance target for CY 2015 is 95.7%.

The following are the reasons given for 11 of the 32 cases not meeting this objective:

- Five were unable to produce sputum.
- Two sputum cultures were contaminated with no results.
- One was terminally ill and died in hospice.
- One died after starting therapy, but while still hospitalized.
- One had Downs Syndrome.
- Sputum was not ordered for one due to age and health issues (hemiplegic).

Information on why sputum was not collected for the remaining 21 patients is not available to TBCS at this time.

Barriers Encountered: The barriers to improved performance are not well defined due to the missing reasons for negative outcomes.

Action Plan: TBCS will enable broader capacity for sputum induction statewide, more broadly collect reasons for negative outcomes and intervene as warranted based on this additional information in efforts to improve future performance.

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Intermediate Objectives: These objectives are termed “intermediate” because these activities require time to:

- Identify, locate and facilitate medical evaluation (contacts and immigrants and refugees),
- Ship and process laboratory specimens and report results (genotyping),
- Report a valid annual measure of prevalence (case rates).

Year	2009	2010	2011	2012	2013
Contact Investigation					
Objective 6 Cases with Contacts Elicited*	88.8% (214 of 241)	88.1% (208 of 236)	92.8% (205 of 221)	92.4% (220 of 238)	84.0% (194 of 231)
Objective 7 Contacts Evaluated*	86.0% (2,987 of 3,474)	77.8% (2,042 of 2,624)	81.3% (1,653 of 2,033)	79.1% (1,576 of 1,993)	57.6% (1,540 of 2,674)
Objective 8 Infected Contacts who Start Treatment*	62.7% (379 of 604)	62.2% (375 of 603)	60.4% (262 of 434)	64.6% (257 of 398)	67.4% (250 of 371)
Class A/B1/B2/B3 Immigrants and Refugees					
Objective 9 Initiate Evaluation within 30 Days**	37.0% (193 of 522)	48.5% (249 of 513)	55.0% (249 of 453)	47.1% (280 of 594)	33.6% (191 of 568)
Objective 10 Complete Evaluation within 90 Days**	34.1% (178 of 522)	45.8% (235 of 513)	49.2% (223 of 453)	39.7% (236 of 594)	22.2% (126 of 568)
Objective 11 Starting Treatment for LTBI**	60.3% (82 of 136)	68.7% (103 of 150)	64.0% (64 of 100)	50.0% (61 of 122)	40.0% (30 of 75)
Universal Genotyping					
Objective 12 Universal Genotyping**	61.4% (393 of 640)	90.5% (574 of 634)	98.3% (594 of 604)	99.1% (537 of 541)	99.2% (505 of 509)
TB Case Rates per 100,000 in Specific Populations					
Objective 13 State Case Rate	4.4 (822 cases)	4.4 (835 cases)	4.0 (749 cases)	3.5 (679 cases)	3.4 (652 cases)
Objective 14 U.S.-born Persons	2.8 (410 cases)	2.9 (416 cases)	2.3 (354 cases)	2.2 (337 cases)	1.8 (286 cases)
Objective 15 Foreign-born Persons	12.1 (410 cases)	12.3 (419 cases)	10.8 (395 cases)	9.2 (342 cases)	9.8 (366 cases)
Objective 16 U.S.-born Non-Hispanic Blacks	9.7 (220 cases)	9.4 (171 cases)	7.4 (176 cases)	6.0 (143 cases)	5.9 (140 cases)
Objective 17 Children < 5 years old	1.7 (20 cases)	3.0 (32 cases)	2.0 (21 cases)	1.2 (13 cases)	1.6 (17 cases)
<i>Data Sources: *Florida TB TB Registry – Performance Assessment Tool **CDC SAMS - NTIP Population data from Florida Charts</i>					

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For contact-related objectives, objectives six through eight, the CY 2013 data is **provisional** data for informational purposes only. Performance on the CY 2012 cohort of cases and their associated contacts will be discussed below.

Objective 6: In CY 2012, at least 89.0% of sputum smear-positive TB cases will have one or more contacts elicited.

Status: Met

Major Findings: The reported CY 2012 performance level of 92.4% is from a preliminary report. It is unlikely to change upon submission of the final Aggregate Report for Program Evaluation (ARPE) for this cohort to CDC on August 15, 2014. The national average has exceeded the performance in Florida from CY 2009 through CY 2011. No national data is available for either CY 2012 or CY 2013. The national objective performance target for CY 2015 is 100.0%.

Additional information is only available for 5 or 27.8% of the 18 sputum smear positive TB cases with no contacts reported:

- 1 case was lost and unable to locate.
- 1 case was uncooperative and refused to identify contacts.
- In 3 cases the fact that no contacts were identified was confirmed.

Barriers Encountered: Historically, an aggregate report has been generated by each CHD in HMS and submitted to TBCS where the county reports are used to generate a state aggregate report. TBCS has developed a performance assessment tool that queries data from Florida's TB registry to create aggregate reports associated with contact investigation activities. This tool is capable of creating both county-specific and statewide aggregate reports from a single data source. What previously took a week at TBCS can now be achieved in seconds (see Attachment A for more information). This new method of assessing performance on the Contact ARPE will continue in the future.

Action Plan: TBCS will gather additional information regarding why no contacts are being identified for these, most potentially infectious TB cases. Based on what this information reveals, interventions will be developed and implemented to improve future performance.

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Objective 7: In CY 2012, at least 87.0% of contacts associated with sputum smear positive TB cases will be evaluated for latent TB infection (LTBI) and/or active TB disease.

Status: Unmet

Major Findings: The reported CY 2012 performance of 79.1% is from a preliminary report. It is unlikely it will change upon submission of the final ARPE for this cohort to CDC on August 15, 2014. Florida's performance exceeded the national average in CY 2009 and CY 2011. National data is not yet available for CY 2012 or CY 2013. The national objective performance target for CY 2015 is 93.0%.

Of the 417 contacts that were not evaluated, information on the reason they were not evaluated is available for 182 or 43.6%. The reasons given included:

- 81 contacts could not be located.
- 55 contacts refused evaluation.
- 45 contacts were lost to follow-up before the evaluation was complete.
- 1 contact died before they could be evaluated.

Barriers Encountered: The incompleteness of information regarding negative outcomes.

Action Plan: Documentation of the reason for negative outcomes regarding this indicator has always been available, but not routinely utilized. For the cohort of contacts associated with TB cases reported in CY 2014, this documentation will be monitored to ensure it is completed. This will provide a clear picture of why Florida is not achieving its objective, which will lead to the development and implementation of strategies designed to improve performance.

Objective 8: In CY 2012, at least 81.0% of infected contacts to sputum smear positive TB cases will initiate treatment for LTBI.

Status: Unmet

Major Findings: The reported CY 2012 performance of 64.6% is from a preliminary report. It is unlikely it will change upon submission of the final ARPE for this cohort to CDC on August 15, 2014. Florida's performance was below the national average in CY 2009 through CY 2011.

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National data is not yet available for CY 2012 or CY 2013. The national objective performance target for CY 2015 is 88.0%.

Barriers Encountered: The incompleteness of information regarding negative outcomes.

Action Plan: See Objective 7 above.

Objective 9: In CY 2013, at least 55.0% of immigrants and refugees with radiographs consistent with TB and referred in CY 2012 will have an evaluation for TB initiated within 30 days of arrival in the U.S.

Status: Ongoing

Major Findings: Florida's currently reported performance level in CY 2013 is 33.6%. Performance towards this objective has fluctuated throughout the current 5-year period, hitting a high of 55.0% in CY 2011. Florida has exceeded the national average two of the last five years. There is no national objective performance target for this measure in CY 2015.

Although timely evaluation may be of benefit in this population, it is essential that an evaluation be initiated. Florida's performance ranges from 79.7% in CY 2010 to 66.8% in 2012, when timeliness is not considered.

Barriers Encountered: Before data is transferred for analysis to CDC, patient records must be approved by TBCS. No records have been approved since September 2013 due to staffing shortages and competing priorities. Like TBCS, manpower and competing priorities in the CHDs will always be an issue for short turnaround times for these evaluations.

Action Plan: Responsibility for approval of records in the Electronic Disease Notification (EDN) system will be reassigned. This should result in an accompanying performance improvement as the backlog is cleared. The volume of Class B referrals in Florida is high and any increased emphasis on the **timeliness** of these evaluations may impact higher priority activities, such as case management, directly observed therapy, and contact follow-up.

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Objective 10: In CY 2013, at least 45.0% of immigrants and refugees with radiographs consistent with TB will have an evaluation for TB completed within 90 days of arrival in the U.S.

Status: Ongoing

Major Findings: Florida's currently reported performance level in CY 2013 is 22.2%. Florida has exceeded the 45% objective level of performance twice in the past five years and has exceeded the national average the same two years, CY 2010 and CY 2011. There is no national objective performance target for this measure in CY 2015.

As in objective 9 above, if timeliness is not considered, performance ranges from 71.2% to 57.4% between CY 2009 and CY 2012.

Barriers Encountered: See Objective 9.

Action Plan: See Objective 9.

Objective 11: In CY 2013, at least 70.0% of immigrants and refugees with radiographs consistent with TB and diagnosed with LTBI in the U.S. will initiate treatment.

Status: Ongoing

Major Findings: Florida's currently reported performance level in CY 2013 is 40.0%. Florida outperformed the national average for the first three years of the most recent 5-year period. There is no national objective performance target for this measure in CY 2015.

Barriers Encountered: See Objective 9.

Action Plan: See Objective 9.

Objective 12: At least 90.0% of all culture confirmed TB cases reported in CY 2013 will have a genotyping result.

Status: Met

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Major Findings: Florida's performance has consistently improved over the past 5-years, from 61.4% in CY 2009 to 99.2% in CY 2013. This performance exceeds the national average for the past four years. The national objective performance target for CY 2015 is 94.0%.

Barriers Encountered: Florida submits *M. tuberculosis* cultures for genotyping, with the occasional exception when a pure culture cannot be obtained despite BPHL's best efforts.

Action Plan: No intervention planned as Florida is performing as well as the biology of *M.tb* will allow.

Objective 13: In CY 2013, Florida's TB case rate will be 3.5 per 100,000 of population.

Status: Met

Major Findings: In CY 2013, Florida's TB case rate of 3.4 was its lowest historically, but still higher than the national case rate of 3.0 per 100,000 of population. Florida's case rate has declined steadily for the past 3 years from 4.4 in CY 2010. There is no national target case rate stated for CY 2015.

Barriers Encountered: The ability to successfully evaluate, initiate and complete treatment for contacts to TB cases and Class B immigrants and refugees is building a reservoir of latent TB infection that could result in active TB cases in the future. In the past, Contact ARPEs were only generated from HMS once annually, at a point in time when the opportunity to intervene was long past.

Action Plan: Raise the priority of these important prevention activities by monitoring and providing performance feedback to the CHDs, discerning the reasons for negative outcomes and developing and implementing interventions to improve performance.

Objective 14: In CY 2013, Florida's TB case rate in the U.S. born will be 1.4 per 100,000 of population.

Status: Unmet

Major Findings: Florida's case rate for this population in CY 2013 was its lowest historically at 1.8. This was above its objective and the national case rate of 1.2 for this population. The case

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rate in this population has dropped steadily for the past three years from 2.8 in CY 2010. The national case rate has dropped consistently over the past 5 years. The national target case rate for this population in CY 2015 is 0.7.

Barriers Encountered: See Objective 13.

Action Plan: See Objective 13.

Objective 15: In CY 2013, Florida's TB case rate in the foreign-born will be 11.5 per 100,000 of population.

Status: Met

Major Findings: Florida's CY 2013 case rate for this population was 9.8, achieving the objective and below the national case rate of 15.1 for this population. It is, however, an increase from 8.8 reported for the CY 2012 cohort. Both the percentage of the caseload (56.1%) and the case rate in Florida is increasing in the foreign-born. Florida's case rate is already below the national target case rate of 14.0 for this population in CY 2015. The national case rate for this population has consistently declined over the past 5 years.

Barriers Encountered: See Objective 13.

Action Plan: See Objective 13.

Objective 16: In CY 2013, Florida's TB case rate in U.S. born, non-Hispanic Blacks will be 3.0 per 100,000 of population.

Status: Unmet

Major Findings: There were 5.9 cases per 100,000 of population in Florida in CY 2013. Although not representing an achievement of the stated objective, it is a continuation of a downward trend over the last 5-year period. The national average case rate for this population is 3.5, also declining consistently over the past 5 years. The national target case rate for this population in CY 2015 is 1.3.

Barriers Encountered: See Objective 13.

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Action Plan: See Objective 13.

Objective 17: In CY 2013, Florida’s TB case rate in children under the age of 5 years will be 1.3 per 100,000 of population.

Status: Unmet

Major Findings: There were 17 TB cases reported in this population in CY 2013, resulting in a case rate of 1.6 per 100,000 of population. This was an increase over a case rate of 1.3 in CY 2012. Florida’s case rate was slightly higher than the national rate of 1.5 in this population group in CY 2013. The national target case rate is 0.4 for this population in CY 2015.

TB in this age group is an indication of transmission in the community, but contact investigations surrounding these cases offer opportunities to stop transmission by identifying previously undiagnosed TB, usually in an adult close to the child. This was the case in 9 or 52.9% of the cases in this population group in CY 2012. Risk factors for TB exposure, such as travel to high incidence countries, were discovered in an additional 3 cases in this cohort.

Barriers Encountered: The barrier to achieving this objective is for the adult source case to seek medical evaluation and treatment for themselves, before the children become ill.

Action Plan: Cases in this age group, although increased in number from CY 2012, are not at a level to cause concern and source case finding activities surrounding these cases are successful at identifying the undiagnosed adult source case most of the time.

Lagging Objectives: These objectives “lag” by two years to allow for either the time:

- Required to complete therapy (3 treatment completion objectives),
- To capture data under the current surveillance system (sputum culture conversion),
- For complete data to be available (3 data reporting objectives).

Year	2008	2009	2010	2011	2012
Objective 18 Completion of Treatment in 12 Months*	89.6% (740 of 826)	93.2% (648 of 695)	94.9% (670 of 706)	92.9% (564 of 607)	89.9% (507 of 564)
Objective 19 Completion for Treatment for Infected Contacts*	58.8% (300 of 510)	62.8% (238 of 379)	58.4% (219 of 375)	53.1% (139 of 262)	64.7% (165 of 255)

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	2008	2009	2010	2011	2012
Objective 20 Completion of Treatment for Immigrants and Refugees**	71.8% (51 of 71)	66.1% (121 of 183)	53.6% (119 of 222)	42.2% (95 of 225)	42.6% (26 of 61)
Objective 21 Sputum Culture Conversion in 60 days*	44.9% (226 of 503)	44.2% (187 of 423)	50.9% (202 of 397)	48.9% (177 of 362)	54.9% (195 of 355)
	2008	2009	2010	2011	2012
Data Reporting Completeness					
Objective 22 RVCT**	99.7%	99.5%	98.7%	98.3%	98.7%
Objective 23 ARPE**	100.0%	100.0%	100.0%	100.0%	Due 8/15/2014
Objective 24 EDN**	87.2%	77.9%	81.3%	78.6%	69.9%
<i>Data Sources: *Florida TB Registry – Performance Assessment Tool **CDC SAMS-NTIP</i>					

All CY 2012 performance levels discussed below are **provisional** awaiting additional information, which has not yet been reported.

Objective 18: In CY 2012, at least 90.5% of TB cases for which 12 months or less of treatment is prescribed will complete therapy within 12 months.

Status: Ongoing

Major Findings: Florida’s performance towards this most important of objectives has exceeded 90.0% three of the past five years, the last was in CY 2011 at 92.9%. Florida has surpassed the national average every year over this 5-year period. The national objective performance target for CY 2015 is 93.0%, which was exceeded by Florida in CY 2010.

Analysis indicates that final dispositions for 8 TB cases in the CY 2012 cohort have yet to be reported. Although it may seem unlikely that any more TB cases in this cohort would complete in less than 12 months, it may be a reporting, rather than a treatment issue. The current level of performance for the CY 2012 cohort of cases is 89.9%. This is a floor, not a ceiling.

Of the 49 TB cases for which a negative outcome has been reported:

- 31 or 63.3% completed therapy in greater than 12 months,
- 9 or 18.4% were lost to follow-up,

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- 3 or 6.1% had an adverse reaction serious enough to stop medications,
- 2 or 4.1% were uncooperative,
- 4 or 8.2% were closed for “other” reasons.

The reasons for the 31 cases that completed therapy in greater than 12 months were as follows:

- 18 cases or 58.1%, extended therapy was clinically indicated,
- 4 cases or 12.9%, treatment was extended due to non-adherence,
- 3 cases or 9.7%, treatment was extended due to adverse drug reactions,
- 6 or 19.4%, the general reason “other” was reported and no further information is available.

Barriers Encountered: The analysis above indicates that Florida is quite good in the management of active TB disease once diagnosed, with the exception of the cases that were lost to medical supervision or uncooperative. Fortunately, these cases represented only 2.0% of all cases eligible to be evaluated under this indicator.

Action Plan: Active surveillance to collect final disposition information in a timelier and more complete manner. TBCS will develop a mechanism to capture the reasons for therapy being extended for more than 12 months in a cohort where this should be unnecessary. This information will be utilized to develop and implement interventions to result in improved performance.

Objective 19: In CY 2012, at least 69.0% of infected contacts to sputum smear positive TB cases will complete treatment for LTBI.

Status: Ongoing

Major Findings: Current performance for the CY 2012 cohort of contacts is 64.2%. This represents a floor, not a ceiling for performance as final dispositions are not currently reported for 28 contacts in this cohort year. It is possible that final performance will exceed the objective level when all data is reported. Florida’s performance was below the national average CY 2008 through CY 2011. National data is not available for CY 2012, because ARPEs reporting this

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information to CDC are not due until August 15, 2014. The national objective performance target for CY 2015 is 79.0%.

Of the 62 contacts reporting negative outcomes to date:

- 40 or 64.5% stopped treatment against medical advice,
- 11 or 17.7% were lost to medical follow-up,
- 6 or 9.7% had treatment stopped by their provider,
- 1 or 1.6% had an adverse reaction serious enough to stop therapy,
- 1 or 1.6% moved during treatment with no follow-up information,
- 1 or 1.6% died while on treatment,
- 2 or 3.2% were closed for “other” reasons with no additional information.

Barriers Encountered: Patients stopping medications against medical advice and being lost to medical supervision during treatment accounted for 82.2% of all contacts starting, but not completing treatment for LTBI.

Action Plan: Expanded utilization of short-course therapy, either rifampin for 4 months or isoniazid and rifapentine once a week for 12 weeks, holds the most promise for improved performance towards achievement of this objective in the future. It has been demonstrated that shorter treatment durations increase completion rates. The 12 week regimen requires directly observed therapy, which may limit its practicality. It should be considered for highly mobile populations or in the case of school or local jail populations where access to the patients is time limited. The four month regimen, however, does not require DOT and is 5 months shorter than the traditional isoniazid regimen. This regimen holds the most promise for improved outcomes.

Objective 20: In CY 2012, at least 65.0% of immigrants and refugees with abnormal chest x-rays consistent with TB, diagnosed with LTBI in the U.S. and started on therapy, will complete treatment.

Status: Ongoing

Major Findings: Florida’s performance has steadily declined over the last 5 years from 71.8% in CY 2008 to 42.6% in CY 2012. However, its performance has consistently been superior to

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the national average, until CY 2012. There is no national objective performance target for CY 2015.

Barriers Encountered: There are two identified barriers to improved performance towards achievement of this objective. First, before data is transferred for analysis to CDC, patient records must be approved by TBCS. No records have been approved since September 2013 due to staffing shortages and competing priorities. Second, completeness of data for EDN indicates that passive reporting of final disposition data by CHDs is less than ideal for providing a clear picture of performance.

Action Plan: Responsibility for approval of records in the EDN system will be reassigned. This should result in an accompanying performance improvement as the backlog is cleared. TBCS will secure the names of patients with missing final disposition information reported through EDN and conduct active surveillance to collect the information for the CY 2012 cohort and in the future. Once a true performance level is determined and the reasons for failure assessed, TBCS will provide performance feedback to raise the priority of these TB prevention activities. Armed with this information, TBCS will develop and encourage implementation of interventions designed to improve performance.

Objective 21: In CY 2012, at least 65.0% of sputum culture positive TB cases will convert to sputum culture negative within 60 days of initiating treatment.

Status: Ongoing

Major Findings: Florida's performance towards achievement of this objective in CY 2012 at 54.9% is the highest over the past 5 years. Florida has not exceeded the national average until CY 2012. Final performance may be higher than currently reported, because 11 cases are still pending final disposition (conversion is reported at the same time as final disposition on the follow-up 2 report). The national objective performance target for CY 2015 is 61.5%.

An additional 88 or 24.8% of the cohort had documented sputum culture conversion at greater than 60 days after treatment was initiated for a total sputum culture conversion rate in the CY 2012 cohort of 79.7%. Many of these cases may have converted within 60 days if the NCM was

prompted to collect sputum within the prescribed time frame. The reasons for negative outcomes for the remaining 72 cases are not known.

Barriers Encountered: Inability to spontaneously produce sputum after therapy has been initiated is a common reason for the failure to document sputum conversion. Failure to collect sputum without a doctor's order may be another reason for Florida's current performance level. The Board of Nursing requires no such order, but NCMs may be unaware of this fact. The TB Manual is explicit in elaborating a schedule for sputum collection, but does not assign responsibility for following this schedule to anyone specifically.

Action Plan: TBCS is generating an "alert" or "prompt" to collect sputum 40 days after the initiation of therapy to provide the NCM 20 days to do so. Battery powered portable nebulizers are being purchased and will be distributed to the CHDs to increase the capacity to induce sputum where it does not exist in Florida. The TB Manual will be revised to assign responsibility for sputum collection to the NCMs and they will be educated that they may do so without a doctor's order. Nursing protocols allowing NCMs to collect sputum without a patient-specific doctor's order may also improve performance. Providing battery powered field nebulizers for sputum induction in CHDs where such capacity does not currently exist is another measure which could enhance performance.

Objective 22: For TB cases reported in CY 2011, at least 97.5% of the core data elements in the Report of a Verified Case of Tuberculosis (RVCT) will be complete upon final disposition of cohort cases.

Status: Met

Major Findings: Of the 22 core data elements on the RVCT, 98.7% were completed (13,688 of 13,863 data fields completed). Twenty-one were reported at the 96.0% level or above. The remaining element "sputum culture conversion documented" was reported for 91.2% of TB cases reported in CY 2012. "Reason therapy stopped" and "date therapy stopped" are both reported at 96.0% complete for the CY 2012 cohort, confirming that final disposition data is incomplete for this cohort of TB cases, potentially resulting in artificially depressed performance towards this objective. National performance target for CY 2015 is 99.2%.

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Barriers Encountered: Accuracy, completeness and timeliness of documentation were an issue in CY 2013.

Action Plan: TBCS initiated active surveillance activities in September 2013 which have led to improvement in all three areas.

Objective 23: All of the core data elements of the Aggregate Report of Program Evaluation (ARPE) for contacts to TB cases reported in CY 2012 will be complete upon submission to CDC, August 15, 2014.

Status: Ongoing

Major Findings: All fields in the Contact ARPEs have historically been populated when submitted to CDC by the Florida Department of Health.

Barriers Encountered: Historically, CHDs have submitted aggregate reports generated by an analysis program which is designed to pull the data from HMS. These local aggregate reports are then compiled into a state aggregate report prior to submission to CDC. The issue with this aggregate report was that there was no mechanism to verify its completeness and accuracy/validity.

Action Plan: In CY 2013, TBCS developed a series of contact-related alerts and a program performance assessment tool. The former assures the timeliness, completeness and accuracy/validity of the data in the aggregate report and the latter provides the state performance level. The performance assessment tool was used to generate the performance level in this report and this will continue in the future, replacing the analysis in HMS. This new tool will reduce the time required to produce the statewide aggregate report from one week to seconds.

Objective 24: At least 75.0% of core data elements of the Electronic Disease Notification (EDN) system will be complete upon final disposition of all immigrants and refugees referred to Florida for follow-up in CY 2012.

Status: Ongoing

Major Findings: For the CY 2012 cohort of referrals, 69.9% of core data elements are complete at the time of this writing.

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Barriers Encountered: There are two identified barriers to improved performance towards achievement of this objective. First, before data is transferred for analysis to CDC, patient records must be approved by TBCS. No records have been approved since September 2013 due to staffing shortages and competing priorities. Second, completeness of data for EDN indicates that passive reporting by county health departments is less than ideal for providing a clear picture of performance.

Action Plan: Responsibility for approval of records in the EDN system will be reassigned. This should result in an accompanying performance improvement as the backlog is cleared. TBCS will develop a methodology to identify Class B immigrant and refugee records in the TB registry and create alerts to ensure the accuracy, completeness and timeliness of the information reported in the EDN system via this active surveillance mechanism. The success of this effort could be assured if Florida could download information from the EDN system itself directly into the TB registry for analysis and to generate these alerts.

HUMAN RESOURCE DEVELOPMENT

Program Narrative

The Florida TB Control Section (TBCS) continues to transition and align program priorities to support ongoing implementation of the Florida System of Tuberculosis Care (FSTBC). The program focus is to ensure that resources are uniformly available to support statewide TB control efforts. Although the Health Educator (HE) position has been lost, the Nurse Consultant has acted as the designated focal point for training in collaboration with the Southeastern National TB Center (SNTC). The need for training in case management of medically complex TB cases is greater than ever since the July 2012 closure of A.G. Holley State TB Hospital. Complicated TB cases now receiving care in their communities creates a need for training. In addition, Florida is experiencing continuous TB staff turn-over, as seasoned TB nurses and program staff retire and are replaced by those with little or no experience. The need for training in nurse case management and contact investigation has become critical to program success. The migration to electronic health records (EHR) creates a demand for training TB program staff in the county health departments (CHDs) to navigate through the EHR, and document services appropriately.

Several initiatives have been developed to combat the loss of experience and rebuild expertise among a younger, less experienced group of nurse case managers (NCMs), which will be essential to the success of the FSTBC in the future. Florida is considering a plan to build and maintain expertise in nurse case management in an increasingly low incidence environment which is multi-faceted. It would begin with formal training, followed by its practical application in a real-life situation. This practical experience would be gained working with an experienced NCM in a CHD with sufficient TB incidence to provide a diverse learning opportunity. This experience would need to recur at least every six months for at least a week at a time, if the NCM has not had a TB case in his or her CHD. When the NCM does have a TB case in the local CHD, mentoring would be provided, on-site at first, and later remotely. Participation in a proposed NCM network conference call would be available on a weekly basis for additional support, to promote collegiality, provide an opportunity for sharing experiences and best practices, and drawing on more experienced NCMs for problem solving new or difficult patient management issues.

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Nurse Case Management Course

In 2013, TBCS Nurse Consultants began updating the nurse case management course in appearance, but left the content as-is so that at least one course could be offered in 2013, with the understanding that improvements were needed and participant feedback would be used to help identify and prioritize those improvements.

In August 2013, the course was offered at the Florida Department of Health (FDOH) in Duval County. Thirty-two local health department staff attended. TB NCMs represented the majority of the participants, followed by Disease Intervention Specialists (DIS) and one Advanced Registered Nurse Practitioner (ARNP). Also in attendance was an observer from Office of Performance and Quality Improvement to audit the course and offer feedback/recommendations for improvement.

Members of the training team met shortly after the course offering to review feedback and improve the course. Overall feedback was good, but participants suggested that the program offer more in-depth training using patient scenarios and the clinical pathway, while also addressing appropriate documentation in the Health Management System (HMS) so they could get a more complete picture of the TB case management process along the continuum of care.

A course schedule for 2014 was drafted with plans to offer at least one nurse case management training per quarter in 4 regions:

- North Florida – Leon County
- Central Florida West - Orange County
- Central Florida Southeast – Manatee County
- South Florida – Broward County

In January 2014, new content was piloted when the course was offered at the FDOH-Orange. Over 20 participants attended this course, including some that had not registered to attend and two participants from the August 2013 course attended to audit day two content only. Day two was TB documentation in HMS. The majority of participants were TB NCMs, with a few more DIS than the previous course, and one TB Program Manager from Orange County.

Expanding the training team for the second training, based on feedback from the first training, allowed TBCS to guide participants through the case management process from three different

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perspectives: surveillance, documentation and nursing practice. It provided the participants a more personalized experience as all subject matter experts were available for their consultation in a single training experience.

The TB Nurse Case Management course will be presented April 14th to 16th in Broward County, followed by July 23rd to 25th in Manatee County and October 22nd to 24th in Leon County.

Two other course offerings are expected in 2014, contact investigation and TB in corrections, both in collaboration with the Southeastern National TB Center (SNTC) at the University of Florida.

Proposed TB Nurse Case Manager Networks

The two most important attributes of a TB NCM are being invested in the patient's outcome and being an effective problem solver. Problem solving is a learned behavior. It comes as a result of trial and error, and that only comes from experience. The more TB cases you have managed, the more effective problem solver you become, if you are invested in the patients' outcome. In some low to rare incidence CHDs, the opportunity to gain this valuable experience is not available. It is, however, available through colleagues in TBCS and higher incidence counties with years of experience and many individual patients from which to learn. Conference calls between TBCS and CHD NCMs, at the request of the CHDs, have been an effective tool to facilitate the sharing of potential solutions to identified case management issues. The TBCS is considering a more proactive process. Weekly conference calls would facilitate communication and networking between NCMs. These calls would provide a forum to share experiences and problem solve among colleagues. For NCMs in low incidence CHDs, it would provide an experienced sounding board, not available locally, and another opportunity to learn.

Proposed TB Nurse Case Manager Credentialing

Effective TB nurse case management is a nursing specialty. It requires specific knowledge, skills and abilities (KSAs) that are not required by other public health nurses. These KSAs are acquired only through formal training and experience, with the latter being the more important of the two. TBCS is in the process of creating a TB NCM Credentialing Program. This would ensure that the public health nurses providing nurse case management services in CHDs possess

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the KSAs required to do the job. Prerequisites would include web-based self-study and required reading. Formal training would include four courses; nurse case management, contact investigation, comprehensive TB clinical, and tuberculin skin testing (train the trainer). Practicum would be clinical experience with a preceptor for a minimum of 40 hours. This would be followed by a case presentation. It would be on one of the TB cases followed during the clinical experience by remaining in contact with the preceptor and following the progression of the case to completion, through the preceptor. This would provide the information necessary for the case presentation and continuing guidance from a knowledgeable preceptor. A passing score on a comprehensive test is being considered as a requirement for certification.

“Grandfathering” of experienced NCMs would be granted with the passing of the comprehensive test, 5 or more years TB experience, a letter or recommendation from a supervisor, submission of successful clinical outcomes, and a willingness to serve as a preceptor.

Recertification would occur every 3 years and require completion of a “refresher” course and a case presentation.

Nurse Case Manager Empowerment

TBCS has nursing clinical pathways and a TB Policy Manual which clearly define when activities need to occur to achieve a high quality of care for patients with active TB and latent TB infection. TBCS will promote the empowerment of NCMs to perform tasks related to effective TB prevention and control (tuberculin skin testing or interferon gamma release assays to screen for LTBI and HIV testing) and monitor patient progress or adverse reactions to medications (sputum collection and routine blood work) without a doctor’s order. None of these diagnostic tests specifically require a doctor’s order, according to consultation with the Board of Nursing. NCMs and DIS have consistent access to patients and are likely to adhere to predetermined schedules as defined in the clinical pathways and policy manual.

Performance Towards Achievement of Objectives

Objective 1: By September 30, 2013, a TB health educator will be hired to serve as the TB educational focal point to meet funding and grant requirements.

Status: Met

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Major Findings: TBCS lost its HE position due to prolonged vacancy, but Sherrie Arnwine, RN, Nurse Consultant, has been designated as Florida's TB educational focal point. This employee will join the TB Education and Training Network (ETN) and attend the annual conference as a job-specific duty.

Barriers Encountered: A dual role for a single Nurse Consultant, educational focal point and liaison with the Florida Department of Corrections, is a daunting task.

Action Plan: TBCS will seek approval to hire a second Nurse Consultant in its Tallahassee office to assist with the workload related to the current position and provide additional flexibility in provision of technical and on-site assistance and mentoring services to CHDs statewide.

Objective 2: By October 31, 2013, the TB Nursing Consultants will collaborate with the new HE (educational focal point) to develop an agenda, objectives and course content for advanced case management activities such as therapeutic drug level testing procedures, safe injection of TB medications, and monitoring of TB outpatients requiring intravenous medications.

Status: Met

Major Findings: Therapeutic drug level testing procedures and monitoring of outpatients requiring intravenous medications have been built into the curriculum of the Nurse Case Management Course. Technical assistance with safe injection of TB medications is provided to individual NCMs by TBCS Nurse Consultants on a case-by-case basis, as needed.

Barriers Encountered: None

Corrective Action: None required.

PUBLIC HEALTH LABORATORY

PROGRAM NARRATIVE

The Florida Department of Health, Bureau of Public Health Laboratories (BPHL) consists of four laboratories located in Jacksonville, Miami, Pensacola and Tampa. The Jacksonville laboratory provides mycobacteriology/TB laboratory testing services for all 67 county health departments (CHD) as well as reference services for private and hospital laboratories in Florida. BPHL-Jacksonville evaluates current procedures and implements changes as necessary to meet the CDC recommended reporting turnaround times (TAT) for specimens and reference isolates. It investigates and evaluates new cutting edge technologies and new commercial tests for adaptation in the laboratory and for incorporation into the TB testing algorithm to provide the best laboratory support possible for the providers in Florida. To meet quality assurance objectives, the laboratory adheres to comprehensive Quality Assessment/Quality Control programs (QA/QC) and federal CLIA regulations that apply to the pre-analytical, analytical, and post-analytical components of the laboratory processing paradigm for all clinical specimens.

Activities performed by BPHL-Jacksonville include the processing of various specimen types using CDC protocols. Once processed, all specimens are cultured using both broth and solid media [broth-based MGIT 960 and solid agar Gruft's modification Lowenstein-Jensen (LJ)]. BPHL-Jacksonville processes specimens, performs acid-fast bacilli (AFB) smears, and performs Nucleic Acid Amplification Testing (NAAT) by real-time PCR, directly on specimens 6 days a week, Monday through Saturday. Culture isolates of mycobacteria can be identified on a same day basis (for reference isolates and on first detection of isolates on specimens processed in the laboratory) using the rapid PCR Restriction Analysis (PRA) method. In addition to the PRA, DNA probes are used for confirmatory identification of certain species including *M. tuberculosis* complex and *M. avium* complex.

Drug susceptibility testing of solid culture isolates of *M. tuberculosis* complex is performed on all initial isolates or on isolates for patients that have been on treatment for 60 days that continue to have positive cultures. Isolates shown to have multi-drug resistance (MDR) are sent to CDC for further study and characterization. The BPHL-Jacksonville is utilizing the Sensititre® MYCOTB Susceptibility plates to report Minimal Inhibitory Concentrations (MICs) on twelve first and second-line anti-TB drugs. The laboratory is also utilizing sequencing of the *pncA* gene to detect mutations associated resistance to pyrazinamide (PZA).

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In addition, BPHL-Jacksonville is utilizing the Hain Genotype® MTBDR_{plus} (Hain test) version 2, a molecular method for the detection of common mutations resulting in resistance to rifampin (RIF) and isoniazid (INH). Specimens are automatically reflexed to this test, irrespective of the AFB smear result (positive or negative) if they are positive for *M. tuberculosis* complex (MTBC) DNA. The Hain test can also be performed on liquid or solid cultures identified as MTBC, including referral isolates. The Hain test is available to providers and public health laboratories in other states as well for suspected drug resistant or problematic cases.

BPHL-Jacksonville also has a Cepheid GeneXpert Instrument that was acquired in 2011 with TB Control Section (TBCS) funding. The Xpert MTB/RIF assay detects the presence of *M. tuberculosis* complex DNA and the presence of mutations associated with resistance to RIF. The instrument can test processed or unprocessed specimens, requires a simple 2-step preparation, and has a rapid turn-around time, making this a valuable tool when time and circumstance are critical and a full service mycobacteriology laboratory is not accessible. The portability of the instrument enhances its utility in cases of outbreaks or exposures in shelters, confinement facilities or other congregate living facilities. In July 2013, the Xpert MTB/RIF assay received FDA-approval in the U.S.

In 2013, over 99% of all first time isolates on TB patients received by the BPHL-Jacksonville were submitted to the Michigan public health laboratory for genotyping. The number of clinical specimens submitted for AFB smear and culture ranged between 19,275 and 21,943 per year for the last three years, and TB susceptibilities averaged 664 per year. While the overall number of TB cases is going down, BPHL-Jacksonville receives isolates with requests to perform either identification or drug susceptibility testing or both from private and hospital laboratories. BPHL-Jacksonville and TBCS have collaborated to implement policies and guidelines to limit over-use of testing and duplicate testing on patients.

PERFORMANCE TOWARDS ACHIEVEMENT OF OBJECTIVES

Please see **Benchmarks** in Attachment B for a summary of the TAT data presented in the following section.

Objective 1: For at least 80% of initial diagnostic specimens received by the TB Laboratory for diagnosis the recommended turnaround time will be met.

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Status: Met

Major Findings: BPHL-Jacksonville staff members consistently encourage all providers to submit specimens in a timely manner and emphasize the importance of not batching specimens or holding specimens until the recommended three consecutive specimens have been collected. In 2013, 16.1% of samples were received within one day of collection, 42.5% within two days, and 55.9% within three days. In 2013, a TAT of less than 24 hours was achieved on 97.9% of all acid fast bacilli smear test results.

For specimens received by 12:00 p.m., AFB smear results and NAAT results are sent electronically to submitters within 48 hours. AFB smear and NAAT results are reported and faxed daily to the TBCS in Tallahassee and electronically transmitted daily to the CHD of residence and TBCS.

Barriers Encountered: Time between collection and receipt by BPHL-Jacksonville.

Action Plan: Reduce the time between collection and receipt by BPHL-Jacksonville to reduce the likelihood of contaminated cultures due to the growth of normal flora through more timely solicitation of specimens from providers outside the CHDs.

Objective 2: For at least 80% of initial diagnostic specimens received by the Public Health Laboratory for TB diagnosis, *Mycobacterium tuberculosis* complex will be identified within 21 days of receipt.

Status: Met

Major Findings: In 2013, 100% of the PRA results performed on diagnostic specimens received were identified in less than 14 days of receipt. In samples for which the PRA does not provide identification, the laboratory uses DNA probes to rule-in or rule-out *M. tuberculosis* complex, *M. avium* complex, *M. kansasii*, and/or *M. goodii*.

Barriers Encountered: None

Action Plan: None required.

Objective 3: For at least 80% of isolates of *Mycobacterium* species referred to the laboratory for additional TB diagnostic testing the following turnaround times should be met: The identification of *Mycobacterium tuberculosis* complex within 7 days of isolate receipt.

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Status: Met

Major Findings: BPHL-Jacksonville employs an in-house developed PCR method (PRA) to identify *Mycobacterium tuberculosis* complex as well 38 other common mycobacteria with a turnaround time of less than 24 hours. This is an important test due to the high numbers of non-tuberculous mycobacteria, many with AFB+ smears, cultured from specimens in Florida. Of the isolates referred to the TB laboratories in Florida, over 99% are identified in <7 calendar days, and 100% reported within 14 days. Results are reviewed and faxed/electronically reported to providers daily.

Barriers Encountered: None

Corrective Action: None required.

ATTACHMENT A

PROGRAM EVALUATION

I. Introduction

Two concerns of the System of TB Care Workgroup were the quality and completeness of information in the Health Management System (HMS) and the inability to perform routine performance assessment in most county health departments (CHDs). The first concern must be addressed before the second, because there can be no valid performance assessment without the assurance of the quality and completeness of the information on which it is based. The efforts to date have been focused on dealing with these two important issues. The purpose of this evaluation was to assess the quality, completeness and timeliness of patient information, which directly affects performance levels as monitored and reported by the National TB Indicators Project (NTIP).

II. Description of Data Collection and Analysis

Florida's primary source of TB surveillance data is HMS. The Florida Department of Health (FDOH) currently utilizes HMS to document all TB clinical services provided and the results of these services to Floridians, both inside and outside the CHDs. HMS also stores and messages data related to the Report of a Verified Case of Tuberculosis (RVCT) to the Centers for Disease Control and Prevention (CDC) as a condition of the receipt of grant funding.

HMS cannot be utilized directly as a statewide surveillance system, because each of the 67 CHDs in Florida owns its data and controls access to this information. The TB Control Section (TBCS) utilizes a subset of the minimum data set (MDS), called the TB registry, for statewide TB surveillance and performance assessment. The TB registry contains information on all TB services provided in the CHDs and their outcomes since HMS statewide implementation in CY 2007.

The MDS consists of HMS data tables downloaded daily. The first issue which must be addressed, if using a subset of the MDS as a statewide surveillance system, is to ensure that it is a mirror image of HMS. Duplicates and tables that fail to download are a common problem. TBCS evaluates MDS for these issues daily and has them corrected, when identified.

In September 2013, TBCS began publishing "alerts," based on analysis of the TB registry to address data quality issues in HMS. "Alerts" identify specific patients whose records contain

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errors and/or omissions. Others identify patients for whom reporting is not timely. To date, 21 specific “alerts” have been generated and 2,541 issues with data elements in HMS have been successfully addressed by the single county TB Program Managers/Surveillance Coordinators and multi-county Area TB Coordinators.

Depending on the data the “alert” seeks to monitor, it is auto-generated and e-mailed daily, weekly or monthly. All clinical service data not yet reported or corrected remain in the new “alert” until resolved. If the data reflect a negative outcome and are correct or complete, a report of the reason for the negative outcome is sufficient to remove it from the next “alert.” These reported reasons for negative outcomes provide a method to identify and resolve any systemic issues leading to these outcomes.

“Alerts” are essential tools to ensure timely, complete, and accurate clinical service data are available for performance assessment. Another positive effect has been to reduce the repetition of previously identified errors. In December 2013, single county TB Program Managers/Surveillance Coordinators and multi-county Area TB Coordinators were provided the capacity to run “alerts” locally.

NTIP was utilized to assess the success of efforts to impact indicators by more accurately and completely documenting reality. The documentable positive effect of these “alerts” has been to improve assessed performance as a result of more timely reporting and improved data quality and completeness.

The documentable positive effect of these “alerts” has been to improve assessed performance as a result of more timely reporting and improved data quality and completeness. See table below for results to date.

TB Cases - Performance Pre-Alerts Compared to Post-Alerts

OBJECTIVE	Cohort	NTIP Performance	NTIP Performance	Change
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	Group	August 11, 2013	February 10, 2014	
Treatment initiation within 7 days of sputum smear positive collection date	Jan-Jun 2013	68.6% (71 of 103)	92.0% (103 of 112)	+23.4%
	CY 2012	72.0% (172 of 239)	74.5% (181 of 243)	+2.5%
Started on recommended initial 4-drug treatment regimen	Jan-Jun 2013	91.0% (264 of 290)	93.6% (291 of 311)	+2.6%
	CY 2012	93.0% (609 of 655)	93.8% (610 of 654)	+0.8%
Known HIV status	Jan-Jun 2013	81.8% (254 of 306)	88.7% (276 of 311)	+6.9%
	CY 2012	79.4% (539 of 679)	83.1% (547 of 658)	+3.7%
Known drug susceptibility results	Jan-Jun 2013	76.9% (186 of 242)	94.4% (237 of 251)	+17.5%
	CY 2012	92.6% (500 of 540)	95.2% (515 of 541)	+2.6%
Respiratory or pleural site of disease with a sputum culture result	Jan-Jun 2013	81.7% (200 of 252)	94.2% (245 of 260)	+12.5%
	CY 2012	82.4% (467 of 567)	92.2% (518 of 562)	+9.8%
Sputum culture conversion within 60 days of treatment initiation	CY 2011	40.3% (147 of 365)	45.9% (163 of 355)	+5.6%
Completion of therapy within 12 months of initiation	CY 2011	87.6% (558 of 637)	92.3% (556 of 607)	+4.7%

With accurate and complete information and an on-going automated method to keep it that way, TBCS developed a performance assessment tool for each of the objectives associated with TB cases and their associated contacts. To date, these tools exist for eleven NTIP indicators, including:

- Treatment initiation within 7 days of sputum smear-positive collection date
- Started on recommended 4-drug treatment regimen
- HIV status known
- Drug susceptibility test results for culture positive TB cases
- Sputum culture result available for all respiratory, pleural and laryngeal TB cases
- Sputum culture conversion within 60 days of treatment initiation
- Completion of therapy within 12 months for TB cases that can be adequately treated within that timeframe
- All four indicators associated with contact investigation.

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The validity of the results of these performance assessments has been verified against information in HMS and in conjunction with surveillance staff at CDC's Division of TB Elimination. These assessments of program effectiveness pull information directly from the TB registry and update automatically, whenever opened. The data are presented graphically and in numeric values. Two options for graphic presentation are available; performance over time and comparison of performance. Both graphs offer the choice to analyze the performance of a single county, multiple counties (region) or all counties (state) over single or multiple years, quarters or months. The same choices are available for the page that offers the numbers behind the graphs. For those assessments related to active TB cases, case numbers and/or names and/or any other information in the TB registry can be displayed for positive and/or negative outcomes, facilitating further investigation, as warranted.

III. Conclusion and Discussion of Results

By improving the quality of the data reported to CDC on the RVCT, the "alerts" improved the quality of the assessments reported in NTIP. The quality of the TB data in Florida is much improved and what has not been corrected yet is being monitored routinely until it is corrected.

New "alerts" can be generated anytime, whether or not they are designed to deal with an HMS documentation issue. For example, the most recent "alert" will be used to advise CHD staff proactively of a pending deadline associated with achievement of a performance objective. This type of "alert" will increase the likelihood of achieving the objective, i.e., notifying CHD staff on the 40th day after treatment is initiated, that a sputum specimen needs to be collected within the next 20 days to document conversion within 60 days of treatment initiation.

The performance assessment tool is quick, versatile, always up to date, and provides performance tracking capacity, not previously available in Florida. After a few cosmetic changes this tool will be provided to CHD Directors/Administrators, single county TB Program Managers/Surveillance Coordinators and multi-county Area TB Coordinators to build performance assessment capacity locally.

IV. Recommendations

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TBCS should continue to explore ways in which “alerts” can be used to directly and proactively impact performance, as is currently being done with sputum culture conversion. Another potential example is notification when the ex-window period test for latent TB infection is due for a contact.

TBCS developed its performance assessment tool to look at performance towards achieving national objectives in the NTIP indicators, but should expand the scope of such a powerful tool. It can be used to assess performance towards achievement of locally identified objectives, examine the impact of providing nucleic acid amplification (NAA) testing routinely at BPHL-Jacksonville on the initiation of TB treatment, informing data-driven policy decisions, identification of high performing CHDs leading to the sharing of best practices. Its power and utility is only limited by the information captured in HMS and that power and utility should be utilized to its fullest.

Program Evaluation Focal Point for Florida is Jose Zabala.

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Bureau of Public Health Laboratories

Workload Statistics

Workload			
Year	2011	2012	2013
1 a. Total number of clinical specimens (no isolates)	21,943	21,082	19,275
1 b. Number of individual patients for whom a clinical specimen was processed	5,832	10,695	8,821
1 b. i. Report number of individual patients who had a clinical specimen positive for <i>M. tuberculosis</i>	586	560	554
1 c. Number of individual patients for whom a reference isolate was received for identification	2,496	2,242	2,175
1 c. i. Report the number of individual patients that had a reference isolate with at least one <i>M. tuberculosis</i> positive culture	185	177	157
1 d. Number of individual patients for whom <i>M. tuberculosis</i> drug susceptibility tests were performed	705	639	646
1 e. Number of individual patients from your jurisdiction for whom a clinical specimen was tested directly with a NAAT (includes processed sputa from private and hospital labs submitted for NAAT)	6,450	5,599	5,197
1 e. i. Report number of individual patients for whom NAAT was positive	361	706	382
1 f. number of individual patients for whom the laboratory referred an isolate of <i>M. tuberculosis</i> complex for genotyping	594	537	505
2. e. Number of individual patients for whom laboratory confirmation of tuberculosis was provided within 48 hours of clinical specimen receipt.	361	706	382

Bureau of Public Health Laboratories

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Benchmarks

Benchmarks			
CY2011	CY2012	CY2013	Description of turnaround times (TAT) for initial diagnostic specimens
1. Promote rapid delivery of specimens. (TAT goal: Specimens should be received in the laboratory within 24 hours of specimen collection)			
22.9%	20.0%	16.1%	% of specimens received within 1 calendar day
50.8%	47.0%	42.5%	% of specimens received within 2 calendar days
66.5%	60.0%	55.9%	% of specimens received within 3 calendar days
2. Use fluorescent acid-fast staining and promptly transmit results by phone, FAX, or electronically. (TAT goal: Report acid-fast microscopy results within 24 hrs of specimen receipt.)			
99.9%	99.8%	97.9%	% of specimens reported within 1 calendar day
100.0%	100.0%	98.9%	% of specimens reported within 2 calendar days
100.0%	100.0%	99.0%	% of specimens reported within 3 calendar days
3. % of <i>M. tuberculosis</i> isolates identified within 21 calendar days			
100.0%	100.0%	100.0%	
4. Determine the susceptibilities (DST) of initial <i>M. tuberculosis</i> complex isolates to first-line drugs* in a rapid culture system and report results promptly. (TAT goal: 21-28 calendar days from receipt of specimen)			
Florida no longer performs conventional drug susceptibility testing. Instead it uses molecular testing to identify mutations associated with isoniazid and/or rifampin resistance, using the CDC laboratory for confirmation if rifampin resistance is identified. Otherwise, susceptibilities are reported using Sensitre MYCOTB susceptibility plates to report minimum inhibitory concentrations.			