PS20-2001: Tuberculosis Elimination Cooperative Agreement (CoAg) – Laboratory Component Informational Call

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June 17, 2019

Background

- Support for laboratories began in 1992 focused on upgrade of TB methodologies
- Change in focus for 2015-2019 project period to laboratory strengthening
- Focus for 2020-2024 remains laboratory strengthening

Public Health Laboratory Strengthening

- Laboratory component consists of 3 elements described beginning on page 23 of the NOFO
    1. Ensure availability of high quality and prompt core laboratory services for TB.
    2. Promote continual advancement of laboratory efficiency and quality assurance through the use of local data (your laboratory specific data).
    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.

Definitions

- **Elements** – CDC CoAg goals
- **Objectives** – CoAg awardee goals
- **Activities** – Plans/strategies within the laboratory to achieve objectives
- **Measure of success** – results/outcomes the laboratory wants to achieve
- **Local data** – laboratory specific data
- **Workload indicators** – data to understand volume and complexity of testing
- **Turnaround time indicators** – data to monitor progress in meeting national recommendations

Laboratory Element 1: Availability of High Quality and Prompt Core Laboratory Services

Workload Indictors	Turnaround Time Indicators
▪ Focused on understanding the volume and complexity of testing ▪ Data should be included for testing performed in house or through referral New for 2020-2024 ▪ Indicator added to capture volume of individual patients for whom in-house molecular DST performed by PHL o Clinical specimens/sediments o MTBC isolates	▪ Used for monitoring progress in meeting national recommendations ▪ Facilitates the identification of effective testing practices and algorithms and those possibly needing examination New for 2020-2024 ▪ Indicator added to capture mean and range TAT in days for in-house molecular DST o Clinical specimens/sediments o MTBC isolates ▪ Indicator added to capture mean number of days between specimen collection and test result for IGRA

Volume Considerations for Laboratory Elements 2 and 3

- Different level of required activities based on volume
  - Consideration for differences in level of funding, staff, and capacity to support activities
  - Description of requirements on page 20 of NOFO

New Tiers For Each Element Based on Volume	Work Plan Requirement
1. ≤1,000 clinical specimens/year 2. 1,001 – 5,000 clinical specimens/year 3. ≥ 5,001 clinical specimens/year	Tier 1– Provide at least one measurable objective Tier 2– Provide at least two measurable objectives Tier 3– Provide at least three measurable objectives

Laboratory Element 2: Promote Continual Advancement of Laboratory Efficiency and Quality Assurance through the Use of Local Data (Your Laboratory-Specific Data)

- Different level of required activities based on volume for this element

Potential Areas of Focus
▪ Assessment of testing algorithms and workload trends to identify potential sources of delay ▪ Examine or develop written policies to eliminate redundant testing ▪ Examine business practices for process improvements ▪ Conduct laboratory assessments using standard tool

Laboratory Element 3: Collaborate with Partners to ensure Optimal Use of Laboratory Services and Timely Flow of Information

- Different level of required activities based on volume for this element

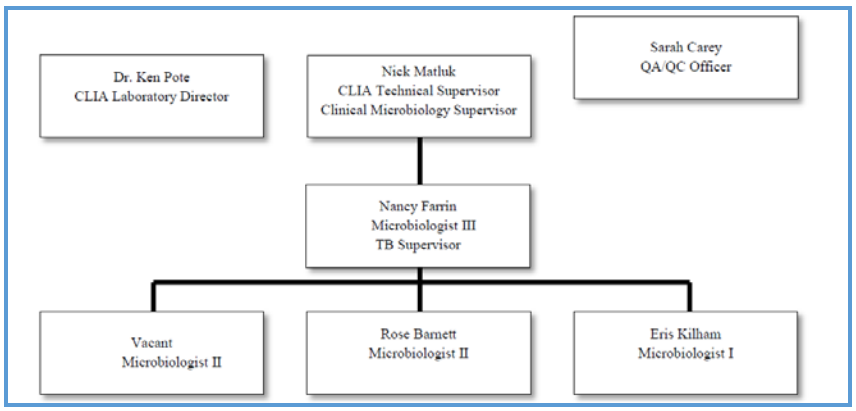
Potential Areas of Focus
▪ Develop and initiate educational opportunity for TB Program or clinical laboratory partners ▪ Collaborative development of specimen collection guidelines ▪ Promotion of laboratory services to improve test ordering ▪ Collaborative development of nuclei acid amplification testing guidelines for jurisdiction ▪ Incorporate more providers into electronic ordering and reporting systems across the jurisdiction

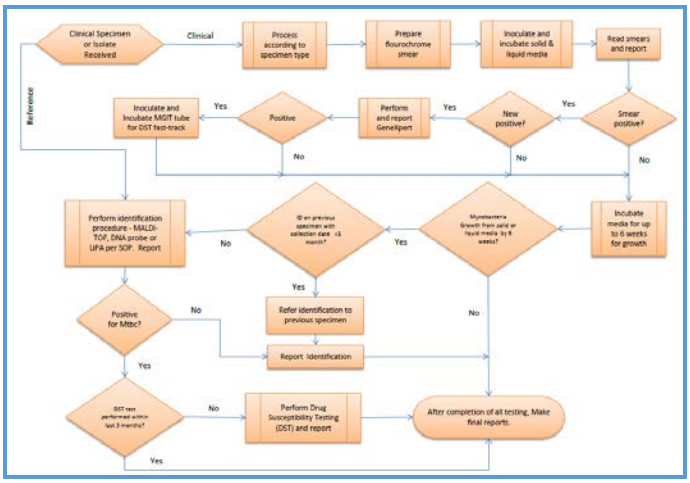
Application Process

- 20 page limit for the entire application, due to CDC 9/5/2019
- To include (page 44):
  - Laboratory CoAg Point of Contact (telephone number & email)
  - Laboratory Organizational Chart
  - Overview of Testing Algorithms and Methods
  - Work Plan Spreadsheet (Year 1 only)
  - Line item budget (true needs not required)
- Will **not** include for Year 1:
  - Workload volume and performance measure TAT data

Contact, Organizational Chart, & Testing Algorithm/Methods

- Laboratory CoAg Point of Contact (telephone number & email)
- Laboratory Organizational Chart
- Overview of Testing Algorithms (visual if possible) and Methods





Work Plan

- **New**
  - Excel document provided on the DTBE NOFO webpage under Sample Work Plans/Laboratory Work Plan
    - https://www.cdc.gov/tb/education/funding-opportunity-notice.htm
  - CDC-RFA-PS20-2001 applicants may use this layout if desired. Alternatively, applicants may choose to format their required work plan in a different manner, as long as it contains all of the required elements for each strategy.
  - Laboratory objectives for Elements 1, 2, and 3 over 5 years (2020-2024) with activities to achieve the objectives listed

Public Health Laboratory Strengthening Work Plan				
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 this 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 times (TAT).			55% of specimens will be received within 1 day of collection, we hope to improve this to 65%. Achieve drug susceptiblity testing (DST) within 17 days of identification (ID) for 75% of isolates.	
List the Activities that Your Laboratory Will Use to Achieve the Above Objectives.	**List What Your Measure of Success Will Be.**	**List any Anticipated Obstacles to Success.**	**Responsible Laboratory Staff**	**Target Completion Date/Timeline**
Pilot use of overnight courier for 3 high volume submitters.	Receipt within one day of collection.	Weekends/holidays.	Chris, TB Laboratorian	Nov 2020
Make changes to DST workflow following data analysis. Monitor for 6 months for improvements.	Increased number of DST results available within recommended TAT.	Staff turnover.	Jay, TB Lab Supervisor	July 2021

https://www.cdc.gov/tb/education/funding-opportunity-notice.htm

Laboratories receiving ≤ 1,000 clinical specimens each year should provide at least one measurable objective for both Elements 2 and 3 as described below. Those laboratories receiving 1,001– 5,000 clinical specimens each year should provide at least two measurable objectives, and those receiving ≥ 5,001 clinical specimens each year should provide at least three measurable objectives for Element 2 and 3.

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 this five-year Cooperative Agreement period?			How will your laboratory measure success related to these objectives?	
Reduce contamination rate.			Reduce contamination rate from 12% to 8% by 2022.	
List the Activities that Your Laboratory Will Use to Achieve the Above Objectives.	**List What Your Measure of Success Will Be.**	**List any Anticipated Obstacles to Success.**	**Responsible Laboratory Staff**	**Target Completion Date/Timeline**
Stratify contaminated cultures by submitter and transport time.	Identification of a target for intervention.	Possible missing data.	John, TB Laboratorian	June 2020
Meet with submitter(s) to discuss possible reasons for contamination and potential interventions.	Interventions identified.	Availability of resourses (e.g., courier, personnel).	Nancy, TB Lab Supervisor	Dec 2020

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 3 during this five-year Cooperative Agreement period?			How will your laboratory measure success related to these objectives?	
Strenthen relationships with other laboratories within the state and state-wide to evaluate optimal use of TB laboratory services.			Improved communication with laboratory partners and development of a document describing the TB laboratory services network within the state.	
List the Activities that Your Laboratory Will Use to Achieve the Above Objectives.	**List What Your Measure of Success Will Be.**	**List any Anticipated Obstacles to Success.**	**Responsible Laboratory Staff**	**Target Completion Date/Timeline**
Perform site-visit(s) to mycobacteriology laboratories throughout the state to assess TB services and to strengthen relationships.	Visit >90% of laboratories.	Availability of staff and coordination of schedules.	Jim, TB Lab Supervisor	Dec 2020
Develop one-pager illustrating the TB laboratory network within the state.	Distribution of the document to state partners.	None.	Lucy, TB Laboratorian	August 2020

Budget

- Line-item budget only (reflects anticipated funding level)
  - **Estimate anticipated using 2019 funding levels + 20% increase**
  - To include:
    - Salaries & Wages (e.g., name or vacant)
    - Fringe Benefits (supply the percentage)
    - Consultant Costs
    - Equipment
    - Supplies (per unit cost for items)
    - Travel (e.g., flights, hotel, per diem)
    - Other (e.g., conference or training registration fees)
    - Total Direct Costs
    - Total Indirect Costs (supply the percentage)
    - Contractual Costs

Laboratory Specific Funding Restrictions

- Laboratories performing first-line drug susceptibility testing for <50 patient isolates/year should refer isolates to National DST Reference Center
- As such, laboratories reporting, as part of this application, DST for <50 patient isolates/year may not request funding support for reagents and supplies associated with growth-based DST.
- Laboratories within this category may request the use of funds for shipping supplies and costs for access to referral services such as those available at the National DST Reference Center for MTB.

Laboratory Funding Formula Remains Unchanged for 2020-2024

		Per patient basis				
	Total # specimens	TB culture inoculated	Isolates received for ID	NAA testing of clinical specimen	DST for first-line drugs	Lab System – Equal Amounts
FY2020	10%	15%	15%	25%*	25%	10%

*Base amount determined by number of patients for whom clinical specimen is received with remaining funds distributed by number of patients positive by direct detection for *M. tuberculosis.*

Workload Volume and Turnaround Time (TAT) Data

- LCT will ask awardees to collect 2018 and the first half of 2019 data separately from the application
  - Using new OMB template documents provided to awardees
  - Sent by Laboratory Consultants
  - Due August 2nd

PERFORMANCE
PROGRESS and
MONITORING REPORT
Table of Activity Results

Form Approved
OMB No: 0920-1132
Exp. Date: 08/31/2019

		Page	of Pages
1.Federal Agency and Organization Element to Which Report is Submitted	2. Federal Grant or Other Identifying Number Assigned by Federal Agency	3a. DUNS 3b. EIN	4. Reporting Period End Date *(Month, Day, Year)*

D. Table of Activities and Results

(1) Activity Number or Label	(2) Activity Description	(3.1) Result Label: CY2018	(3.2) Result Label: CY2019 (to date)			
1	Total number of clinical specimens processed for smear and culture. Do not include isolates referred from another laboratory.					
2	Number of individual patients for whom a clinical specimen was processed for smear and culture.					
2a	Of these, report the number of individual patients for whom at least one culture was positive for MTBC.					
2b	Of these individuals positive for MTBC by culture, report the number initially positive by NAAT from a clinical specimen in your laboratory.					

PERFORMANCE PROGRESS and MONITORING REPORT
Performance Measures

Form Approved
OMB No: 0920-1132
Exp. Date: 08/31/2019

Page

1. Federal Agency and Organization Element to Which Report is Submitted		4. Reporting Period End Date *(Month, Day, Year)*	

(1) Measure Number	(2) Objective/Goal	(3) Measure	(4) National Target (%)	(5) Testing Method	(6) PHL Goal	(7) PHL TAT: FY2018	(8) PHL TAT: FY2019	(9) Obstacles to Meeting Target/Goal
1	Promote rapid delivery of specimens to the laboratory.	Percentage of specimens received within one day of specimen collection.	>67%	NA				
1a		Percentage of specimens received within two days of specimen collection.		NA				
1b		Percentage of specimens received within three days of specimen collection.		NA				
2	Use fluorescent acid-fast staining and promptly transmit results.	Percentage of smear results reported within one day of receipt of specimen.	>92%					
2a		Percentage of smear results reported within two days of receipt of specimen.		NA				
2b		Percentage of smear results reported within three days of receipt of specimen.		NA				

Important Upcoming Dates

- **August 2, 2019:** 2018/First Half of 2019 Workload Volume and TAT Data Due
- **September 5, 2019:** TB CoAg Application Due
- **March 31, 2020:** 2018/2019 Closeout Report Due
- **August 31, 2020:** January 2020 – June 30, 2020 Annual Performance Report Due

Questions?

- After this call, questions concerning the NOFO application must be sent to 2020nofo@cdc.gov