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Availability of a Continuity of Operations Plan Toolkit for Public Health Mycobacteriology Laboratories

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Abstract

Interruption of service events may result in a temporary inability to use equipment or laboratory space, compromise staffing and infrastructure, preclude maintenance or calibration of equipment, and prevent or require extensive disinfection and decontamination. A continuity of operations plan allows a mycobacteriology laboratory to shift efficiently from its regular structure to one that enables timely continuation of testing services. The *Continuity of Operations Plan Toolkit for Public Health Mycobacteriology Laboratories* was developed to aid continuity of operations planning for mycobacteriology laboratories that offer testing services for diagnosing tuberculosis. The toolkit includes processes for creating, modifying, or implementing mycobacteriology continuity of operations plans, including considerations for leveraging partnerships. Available within the toolkit are various templates and checklists which can be adapted to meet specific local needs. While intended for public health laboratories, the toolkit is applicable for clinical, commercial, and other laboratory types that may perform tuberculosis testing.

Keywords

continuity of operations plan (COOP); interruption of service event (ISE); mycobacteriology; tuberculosis (TB) testing

Many state and local public health laboratories (PHLs) have experienced situations that have the potential to disrupt testing services, including pandemics, natural disasters, and laboratory-related facility or maintenance issues. These types of interruption of service events (ISEs) may result in a temporary inability to use equipment or laboratory space, compromise staffing and infrastructure, preclude maintenance or calibration of equipment, and prevent or require extensive laboratory disinfection and decontamination. A continuity of operations plan (COOP) allows for the development of specific processes and

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procedures to minimize interruptions to laboratory testing when an ISE occurs. Resources are available for the development of broad organizational and laboratory COOPs.^{1,2} However, these resources do not include approaches or templates specifically related to the mycobacteriology laboratory, where diagnostic testing for tuberculosis (TB) is performed. TB is a disease caused by members of the *Mycobacterium tuberculosis* complex (MTBC). Many state and local PHLs across the United States serve as reference laboratories to detect and identify MTBC from patient specimens received from submitters such as hospitals, clinics, and health departments as testing for mycobacteria, including MTBC, is not performed in all diagnostic laboratories. Diagnostic testing for MTBC includes complex test methods and requires a biosafety level 3 (BSL-3) laboratory meeting regulated laboratory standards. In addition, MTBC has a long culture incubation period of up to 8 weeks under specific incubation conditions.³ Maintaining core TB testing services to provide prompt test results for public health action is essential to reduce TB morbidity and mortality while complimenting TB prevention and control activities at state and local levels.

A COOP is defined as a documented comprehensive plan that describes the procedures, policies, and critical functions necessary for an organization or laboratory to quickly and effectively respond to a wide variety of possible disruptions or threats and ensures that critical operations can be continued if an event were to affect normal operations.² This plan should be a living document, or set of documents, that is reviewed periodically and updated as needed. In some instances, activation of a COOP may be required for ISEs that impact a PHL for more than a day or two. Advantages of having an effective COOP include continuance of critical functions, delegation of authority, continuity of communications, reduction in operational disruptions, protection of essential assets, timely recovery, as well as minimization of danger, damage, or loss of life.^{1,2}

A COOP should be specific to the needs of the laboratory for which it is being written. Although PHLs may have a general COOP in place, it is important for the mycobacteriology laboratory, to also have a specific plan that describes continuity of mission-critical testing services for the diagnosis of TB for public health and clinical importance. When drafting a COOP, all aspects of the mycobacteriology laboratory should be considered. Infrastructure conditions and the availability of testing personnel are important topics to include. Additionally, the ability to receive and test specimens at different timepoints during an ISE along with biosafety requirements and equipment status must be considered. With the extended incubation times for MTBC, a plan for incubating cultures in process and any additional testing of isolates should be developed. Finally, a referral laboratory to outsource testing for TB specimens should be identified.

A mycobacteriology COOP should align with the larger COOP that may already be in place for a state or local PHL. Persons involved in considering the aspects important for preparing or updating a mycobacteriology laboratory COOP would include the mycobacteriology laboratory supervisor, PHL director, testing personnel, biosafety officer, and quality assurance manager. It is also critical that the jurisdictional TB program is consulted for input and kept aware of events necessitating implementation of a mycobacteriology COOP.

Methods

In 2021, an electronic data collection instrument was designed containing 15 to 56 questions depending on responses to the questions and routing. Questions were created to understand the availability of both general and mycobacteriology-specific laboratory COOPs and the types of ISEs experienced that were greater than 48 hours in duration within PHLs during the years 2019 to 2021. This project was determined by the Centers for Disease Control and Prevention (CDC) to be non-research program evaluation not requiring institutional review board approval (45 CFR 46.102 [I]) and the collection instrument was approved for CDC use by the Office of Management and Budget (OMB Number 0920-0879). Representatives from 58 state, local, and territorial PHLs, funded in part by the CDC Tuberculosis Elimination and Laboratory Cooperative Agreement, were provided a questionnaire link via email. After 4 weeks, the questionnaire was closed, and responses were downloaded and saved in Excel for analysis. Data were organized into ISE categories and availability of a mycobacteriology COOP. For each ISE category, the PHL's annual mycobacteriology testing volume (low-volume ≤ 1000 specimens, mid-volume 1001-5000 specimens, and high-volume ≥ 5001 specimens) was noted. For more granular data collection, focus groups were conducted with questionnaire respondents online via Zoom. To ensure comprehensive PHL representation in each focus group, groups were created based on specific ISEs experienced and annual mycobacteriology testing volume. PHLs could be included in multiple focus groups if affected by more than one ISE. Scripted questions were asked during each focus group to learn how each ISE impacted TB testing services, if referral testing was established, if revisions were made to an existing COOP, best practices identified and lessons learned, as well as suggestions for other mycobacteriology laboratories that may encounter the same ISE in the future. Responses from focus group discussions were recorded and analyzed. Common topics and themes were noted and categorized to guide development of a mycobacteriology-specific COOP resource.

Results

Forty-three of 58 (74%) PHLs responded to the initial questionnaire; all 43 PHLs were affected by an ISE during 2019 through 2021. Twenty-four of 43 (56%) PHLs had at least one ISE affect the ability to perform TB testing in their laboratory for more than 48 hours, while 19 did not. Thirty-eight of 43 (88%) PHLs had a general COOP across different laboratory sections already in place before the ISE; 23 of the 38 (60.5%) PHLs specifically included TB testing services within their PHL's COOP. From information learned, 13 focus groups were created for six combined ISE categories including earthquakes and fires, winter and ice storms, flooding and hurricanes, equipment failure and maintenance, facility issues, COVID-19 pandemic, and an additional category of no COOP in place. On average, each focus group session included four PHLs with various testing volumes. Participants in each focus group detailed their mycobacteriology laboratory ISEs, challenges and lessons learned, and COOP availability. During focus group sessions, many PHLs described the need for PHL infrastructure investments. Equipment maintenance was also discussed as being costly, but the importance of properly functioning equipment and redundancy of equipment was highlighted. Several PHLs stressed the importance of prior preparedness for various ISEs, the value of cross-training staff, and the power of building relationships

with other laboratories. Additionally, maintaining communication with staff, leadership, submitters, and the TB public health program was a top priority. The development of checklists and process documentation were also mentioned as beneficial.

Responses and information received from both the questionnaire and focus groups were aggregated to develop the *Continuity of Operations Plan Toolkit for Public Health Mycobacteriology Laboratories*. The toolkit contains a narrative that highlights the importance of mycobacteriology laboratory preparedness for various types of ISEs and details main topic areas to include in a mycobacteriology COOP.

Also included are seven editable and printable templates: “Mycobacteriology Laboratory COOP” template, “Laboratory Personnel Contact List,” “Laboratory Submitter/Client Contact List,” “Laboratory Vendor Contact List,” “Referral Laboratory Identification Form,” “Referral Specimen Test Requisition Form,” and “After-Action Report.” The toolkit also contains four checklists: “Advanced Preparation of the Mycobacteriology Laboratory for Any Type of ISE,” “Considerations When an ISE is Planned or Forecasted,” “Considerations When a Mycobacteriology COOP is Activated,” and “Considerations After a Mycobacteriology COOP is Inactivated” (see Figure for examples of toolkit content). The *Continuity of Operations Plan Toolkit for Public Health Mycobacteriology Laboratories* can be found on the CDC website at <https://stacks.cdc.gov/view/cdc/131520>.

Discussion and Conclusion

The *Continuity of Operations Plan Toolkit for Public Health Mycobacteriology Laboratories* was developed to prepare mycobacteriology laboratories for future ISEs that could interrupt critical laboratory TB testing services. Mycobacteriology laboratories whether public health, clinical, commercial, or reference laboratories can use the information provided in this resource to develop, revise, and, as applicable, implement a COOP for continuity of testing services for the diagnosis of TB for both public health and clinical importance. The knowledge gained from questionnaire responses and focus group discussions with PHLs who experienced ISEs is included in this toolkit and will prepare other PHLs for future ISEs. This toolkit will also prompt mycobacteriology laboratories to identify referral laboratories prior to an ISE and to collaborate and communicate with internal and external partners. Preparation and organization of this information, compiled in one location for the mycobacteriology laboratory community, is vital to ensuring critical TB testing and results reporting is continually available for patient care and treatment.

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Implications for Policy and Practice

- PHLs should have a COOP in place for ISEs that could affect laboratory testing services.
- Many PHLs have a general COOP, however, a plan specific to the mycobacteriology laboratory and continuation of critical TB testing may not be available.
- A COOP that identifies a referral laboratory for TB testing services is of the utmost importance.
- PHLs with a COOP in place for TB testing are prepared with a plan for mission-critical functions, staffing, specimen receipt and testing, ongoing incubation of cultures, and potential referral testing.
- In the event the PHL must temporarily discontinue testing or close, a mycobacteriology-specific COOP is critical for the diagnosis of TB and for patient care and treatment.

MYCOBACTERIOLOGY LABORATORY COOP

A. Organization and Point(s) of Contact

Laboratory Name	
Department	
Point(s) of Contact and Contact Information	
Date Finalized	
Reviewed	

B. Introduction

Public health laboratories (PHLs) and the core testing services provided are vulnerable to external and internal unforeseen events as well as planned or tracked events. Most laboratory organizations have an overall continuity of operations plan (COOP) to ensure core services within the laboratory can be continued if an interruption of service event (ISE) occurs. ISEs may occur internally (i.e., facility issues such as disruptions in heating, ventilation, and air conditioning [HVAC], negative pressure, or biological safety cabinets [BSCs] and equipment maintenance issues) or due to external sources (i.e., hurricanes, tornadoes, winter/ice storms, wildfires, or pandemics). It is imperative that the mycobacteriology laboratory within the greater laboratory organization be prepared for ISEs by having a written mycobacteriology laboratory COOP. This COOP allows the laboratory to shift efficiently from its regular structure to a structure that enables timely continuation of services. The ability to make this rapid shift without delay is critical specifically for mycobacteriology laboratories regarding timely testing and result reporting.

C. Purpose

The purpose of this COOP is to document processes, procedures, and activities that must be completed within the mycobacteriology laboratory prior to, during, or after an ISE. This plan will allow the mycobacteriology laboratory to consider how best to efficiently resume services or plan for the referral of testing services.

Advanced Preparation of the Mycobacteriology Laboratory for Any Type of ISE

The mycobacteriology laboratory for ISEs by taking the following actions and ensuring the specifics of items are included in their mycobacteriology laboratory COOP:

Topic	Checklist Item	Additional Considerations
Laboratory Preparation		
Prepare facilities, mycobacteriology laboratory space(s), and equipment	Ensure availability of a generator	Install mitigation measures for anticipated ISEs (e.g., flood clearance pallets, bolting bookshelves to walls, secure objects from falling, etc.)
	Have a back-up plan for each piece of equipment in the event of equipment failure or damage	
Personnel Support		
Personnel support	Create/maintain mycobacteriology personnel contact list information	Assess mycobacteriology personnel proximity to laboratory and, if allowable, willingness to travel to the laboratory during and/or after ISE
	Cross-train personnel in all aspects of mycobacteriology (if possible)	Provide COOP refresher training annually when PHL mycobacteriology laboratory typically less impacted by work or prior to seasonally recurring ISEs
	Provide COOP training to new and existing laboratory personnel annually	Hold annual COOP review by management
	Schedule and execute readiness exercises/drills to reinforce training modules	
Testing Status		
Evaluate anticipated ISE and ability to perform mycobacteriology testing	Assess anticipated ISE and determine which specific events may result in temporary testing suspension, laboratory closure, or potential referral of specimens/cultures/isolates	Discuss the threshold of time in which it is acceptable for specimens/cultures/isolates to remain in the laboratory (e.g., in refrigerator, incubator, BACTEC™ MGIT™ 320/960, etc.)
	Determine if pending testing should be completed before a laboratory closure	Determine if a laboratory is willing and/or able to monitor the specimens/cultures/isolates due to their proximity to the laboratory
	Create a plan for cultures already inoculated and incubating	Determine when the mycobacteriology laboratory will begin to consider referral of testing of specimens/cultures/isolates
	Consider a timeline for mycobacteriology testing according to how long the mycobacteriology laboratory may be unable to perform testing	

FIGURE.

Examples of Content Included in the *Continuity of Operations Plan Toolkit for Public Health Mycobacteriology Laboratories*.