

Continuity of Operations Plan Improvement Tool for Public Health Laboratories

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GLOSSARY

AAR After Action Report	HR Human Resources
APHL Association of Public Health Laboratories	ICS Incident Command System
BT Biological Terrorism	IP Improvement Plan
COOP Continuity of Operations Plan	IS Information Systems
CLIA Clinical Laboratory Improvement Amendments	LRN Laboratory Response Network
CT Chemical Terrorism	MEF Mission Essential Function
FEMA Federal Emergency Management Agency	MOA Memorandum of Agreement
	MOU Memorandum of Understanding

EXECUTIVE SUMMARY

Laboratories play an essential role in public health and safety. Laboratory testing generates critical data that is used to make informed decisions about the implementation of preventative measures and development of effective policies to protect the public from unforeseen conditions, hazards, and threats. As such, testing at public health laboratories must be resilient to disruptions caused by natural or man-made disasters. Recent incidents, such as Hurricanes Irma and Maria, have demonstrated the importance of continuity of operations planning for public health laboratories.

In particular, public health laboratories must have in place a continuity of operations plan (COOP). The laboratory COOP is a comprehensive, pre-event plan that describes the procedures, policies, and arrangements necessary for a laboratory to respond quickly and effectively to a wide variety of possible disruptions or threats.

Public health laboratories are in various stages of development of their COOP. While all but three state laboratories have a COOP, the extent to which they have tested their COOP varies. This testing is critical for confirming the accuracy and appropriateness of their continuity of operations planning, and uncovering gaps or incorrect assumptions during an exercise allows the opportunity for correction before an event occurs. The Association of Public Health Laboratories (APHL) contracted with the RAND Corporation to build upon RAND's past work for APHL in 2011 (Olmsted et al., 2012) to update the previously developed tabletop exercise and pilot test it in four laboratories. To inform development of the exercise, RAND also reviewed a convenience sample of voluntarily submitted COOP.

Review of Current COOPs

APHL obtained COOPs from 21 of its 54 member laboratories and provided them to RAND. The received COOPs varied in completeness, and included both lab-specific plans and state- or department-wide plans. RAND evaluated the plans for their coverage of 27 elements in seven areas: pre-event planning, activation, mission essential functions (MEFs), alternative arrangements, communications and information systems (IS), reconstitution, and maintenance.

RAND identified whether, for each of the 27 elements, the plans had detailed, minimal, or no information. Five of the 21 plans lacked information on most of the elements, while the remaining 16 had at least minimal information on an average 24 elements.

Pre-event planning was a strength of the COOPs, with assumptions, scope, and succession generally well-defined. Most plans at least mentioned elements of activation, but differentiated procedures for COOP activation during non-business hours were often not included. Most COOPs indicated some prioritization of their MEFs, though how the MEFs would be prioritized varied by laboratory. Most plans indicated information about alternative arrangements, but less than one-fourth included evidence of an actual Memorandum of Understanding (MOU) or Memorandum of Agreement (MOA). Few plans provided detailed information on elements of communications and IS, with details on redundancy and interoperability of communications systems missing from most plans. More than one-fourth of the plans did not contain any information on elements of reconstitution after an incident. Most plans did contain some description regarding maintenance and exercise of the COOP.

Tabletop Exercise

The tabletop exercise pilot tested with four laboratories provided opportunities to identify strengths and gaps in COOP development and implementation. Each of the four laboratories, which had varying experience with developing and testing COOPs, tested performance against a different scenario, yielding insights on how staff would implement each area of the COOP.

All four pilot site laboratories heavily relied on their laboratory director as a source of information and to make decisions. Succession and delegation of authority in absence of the director was not always defined, and should be clarified. Directors should ensure that their deputies and other relevant staff members have access to information and resources needed to sustain operations in the event that they are unavailable.

Activation of the COOP reflected the scenario under consideration and more than generalized formal triggers. Laboratories also indicated a willingness to activate the COOP partially if only some core activities are impacted. As was evident in the review of plans, the pilot site laboratories had differing means of prioritizing MEFs.

Each of the pilot site laboratories had identified alternative facilities that would be able to take over their sample testing in the event that the laboratory had to cease testing. These plans, however, were not formalized with signed Memorandum of Understanding (MOU) or Memorandum of Agreement (MOA).

Most laboratories reported cross-training staff to be able to work across areas in their own laboratory, which may reduce the impact of staff absences during emergencies. However, Clinical Laboratory Improvement Amendments (CLIA) regulations limit the ability of staff to perform clinical testing of samples at laboratory facilities not under the same license.

Laboratories can use multiple modes of communication for notifying personnel of emergencies, but the amount of redundancy varied. In particular, the pilot site laboratories struggled to identify alternative communication methods that did not rely on cell phones. While the review of the 21 plans submitted by laboratories showed a potential gap in identifying COOP deactivation criteria and describing reopening procedures, the exercises suggested that three of the pilot test sites had a good sense of the quality assurance, quality control, and certification requirements for resuming after an incident and closure.

Across the pilot test sites, the laboratory director was most familiar with the COOP. The degree of familiarity of general staff varied. Laboratories would benefit from increasing staff knowledge of the COOP and conducting incident command system (ICS) training.

Next Steps

Our work indicates that public health laboratories are generally aware of the need for continuity of operations planning, but not all have invested the time and resources to develop comprehensive COOPs and test them. This leads to the following recommendations for APHL and public health laboratories.

APHL

- **Update COOP guidance with more specific information.** APHL last published model COOP guidelines seven years ago following RAND's initial project. Updated guidance should consider the areas reviewed in this report.
- **Collect and share successful MOU documents.** Because executing a MOU is a significant hurdle for many laboratories and typically outside their expertise, providing examples of successful MOU documents as a template would be beneficial.

Public Health Laboratories

- **Conduct regular notification drills, both announced and unannounced during business and non-business hours.** This may motivate laboratories to update their staff contact information and also help in determining additional communication modes.
- **Hold tabletop exercises facilitated by the laboratory director.** Such exercises could also help with succession planning should the director not be available in the case of an actual incident.
- **Designate a week each year for preparedness.** This could be a time to re-stock emergency supplies, ask staff to update their contact information, and ensure plans and training are up-to-date.

1. INTRODUCTION

Laboratories play an essential role in public health and safety. Laboratory testing generates critical data that is used to make informed decisions about the implementation of preventative measures and development of effective policies to protect the public from unforeseen conditions, hazards, and threats. Data provided by public health laboratories include those related to screening newborn babies, detecting infectious outbreaks, responding to terrorism threats and other emergencies, and monitoring significant public health trends. While laboratories in the private sector may also provide analytical services in some of these areas, the core activities of public health laboratories are uniquely focused on both population health and individual health. This dual focus requires public health laboratories to have special analytical expertise, instrumentation, methods, and response capability not available in the private sector.

Recent incidents, such as Hurricanes Irma and Maria, have demonstrated the importance of continuity of operations planning for public health laboratories. Public health laboratories need to be able to continue their core activities when events occur that disrupt their normal operation. To ensure continuation of these essential activities, laboratories must have in place an effective continuity of operations plan (COOP). The laboratory COOP is a comprehensive, pre-event plan that describes the procedures, policies, and arrangements necessary for the laboratory to respond quickly and effectively to a wide variety of possible disruptions or threats. It describes what is in place, what the laboratory does to respond, and what is required to maintain the COOP.

Public health laboratories are in various stages of development of their COOP. While nearly all state public health laboratories have a COOP in the event that a laboratory loses some or all of its operations due to a number of hazards (e.g. fire, power outage, natural weather), the extent to which they have tested the accuracy and completeness of their COOP varies. The Association of Public Health Laboratories (APHL) contracted with the RAND Corporation to build upon RAND's past work for APHL in 2011 (Olmsted et al., 2012) to update the previously developed tool (i.e., tabletop exercise) and pilot it in for four laboratories across the nation in order to help assess their continuity of operations planning.

RAND worked with APHL to recruit the four sites for the tabletop exercises. In order to ensure that the tool is useful to a wide range of laboratories, we selected sites to represent public health laboratories of various sizes, type (i.e., state, county), geographic location, and laboratory structure. The four pilot sites also had varying experience with developing and testing COOPs: two relied on a broader agency COOP, one had a lab-specific COOP, and the fourth was in the process of rewriting its COOP.

Each tabletop exercise used a different scenario based on the laboratory's vulnerability to specific threats. Three of the exercises used a natural disaster (earthquake, hurricane, tornado) scenario and one used a man-made (explosion) scenario. Weather related threats are common and, if severe enough, involve activation of the COOP at some level. Earthquakes, and subsequent fires or flooding, can cause substantial damage to laboratory buildings and activation of COOPs. Explosions (whether terrorist or accidental) can not only impact a laboratory, but also result in the laboratory being treated as a crime scene.

Prior to the exercises, APHL and RAND personnel held a phone meeting with the laboratory director from each site to discuss logistics for conducting the exercise and customizing the exercise to best fit the needs of the particular laboratory. Two RAND staff facilitated the exercises and "hot wash" (immediate post-exercise debrief), and took notes on the discussions. APHL staff also attended and observed the exercises. The exercises lasted 2.5 to 4 hours and averaged about 3 hours to complete. Following the exercises, RAND staff summarized the laboratory's COOP strengths and opportunities for improvement.

This report describes the analysis of COOPs we reviewed (**Chapter 2**) and provides a brief description of the exercise tool (**Chapter 3**). We summarize lessons learned from the pilot testing in **Chapter 4**. The four slide templates to lead the exercises are available as downloadable files.

We read through a few of the more complete plans, along with the *Guidelines for the Public Health Laboratory Continuity of Operations Plan (COOP)* of APHL (2011) and the *Continuity of Operations Plan Template for Federal Departments and Agencies* of the Federal Emergency Management Agency (FEMA, 2013) to identify an initial list of critical COOP elements to look for in the plan review. We refined the list of critical COOP elements with APHL and added elements to account for potential gaps, such as the legal implications of alternative laboratory arrangements, in existing COOPs. While the COOP elements generated are the product of a review of existing COOPs and planning guidance documents, they have not been operationally tested to confirm their necessity for a successful response to an incident. As an organizational principle, we grouped the elements in to broader review areas. **Table 2.1** lists the review areas and their elements.

Table 2.1 Plan Review Elements and Definitions

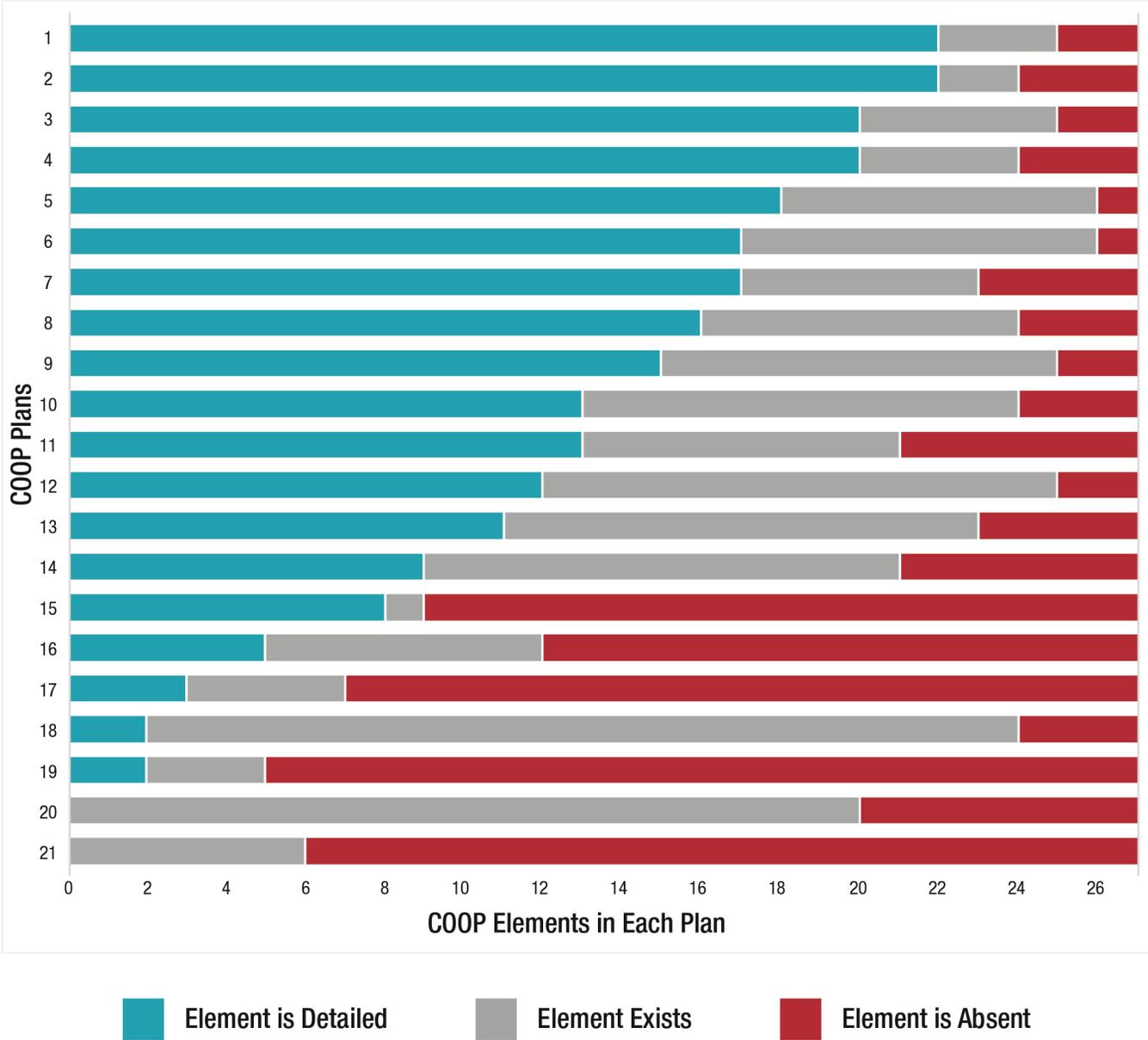
Review Area	Element	Definition
Pre-event planning	Assumptions	Any pre-event assumptions upon which successful execution of the COOP depends.
	Scope	To which organizations and for how long the COOP applies.
	Scenarios	How implementation of the COOP varies in different situations.
	Vulnerability Analysis	Potential threats that may affect laboratory operations, which may also include risk assessments or mitigation measures.
	Succession and Delegation	The order of succession for designating responsibilities and delegating authority, including use of the Incident Command System (ICS).
Activation	Triggers for Activation	Criteria that determine when the COOP is activated and at what level (i.e., partial activation, full activation).
	Activation Procedures	The procedures that are followed to activate the COOP.
	Time-based procedures	The procedures to follow during or after business hours.
	Notification Procedures	The procedures that to alert and notify relevant parties that the COOP has been activated.
	Roles and Responsibilities	The tasks assigned to relevant employees.
	Contact Information	A consolidated list of contact information for relevant employees.
Mission Essential Functions (MEFs)	MEF Prioritization	Description of mission essential functions and explanation, criteria, or methodology for prioritization
	Resource Requirements	The resources required to conduct mission essential functions.
	Staffing Requirements	The staff required to conduct mission essential functions.
Alternative Arrangements	Alternate Facility	The facility or facilities identified for use if the primary site is unavailable.
	Agreement in Place	Any official agreement (e.g., MOU, MOA, contract) that allows use of the alternate facility.
	Legal Barriers	Any legal ramifications or considerations faced in arranging an alternate facility.
	Logistics	Logistics needs (security, transportation, lodging, etc.) for using the alternate facility.
Communications and Information Systems (IS)	Redundancy	Multiple means of communication.
	Interoperability	Use of systems that are compatible with each other.
	Records and Data Protection	Procedures or equipment that allow for the preservation of vital records.
	Back-up Systems	Systems that are available for use if the primary systems are not able to function.
Reconstitution	Deactivation Criteria	Criteria that define when the COOP is to be deactivated and normal operations may resume.
	Reopening Procedures	Procedures that describe what needs to be done to resume normal operations.
	After Action Report	A report that describes the event and any lessons learned.
Maintenance	Tests, Trainings, and Exercises	Activities undertaken to test the COOP and improve emergency response preparedness.
	Updates and Review	The COOP is reviewed and kept up to date.

One team member reviewed the sample of 21 COOPs and assessed their quality and completeness by the degree to which they included a description of the 27 elements in Table 2.1. If the plan did not contain any text about an element, element was rated as “absent.” For instances in which the plan described an element clearly and completely, the element was rated as “detailed.” If the plan included an element, but described it with minimal detail, the element was rated as “exists.” Cases where the plan referenced an element, but the text or documentation was not accessible (e.g., due to redaction, references to another appendix or document not included with plan), were rated as “exists.”

Results

The review of plans indicated significant variation in COOP quality and completeness across public health laboratories, as **Figure 2.2** shows. Five plans lacked over half of the elements. The other 16 plans included at least minimal detail for an average of 24 out of 27 elements, indicating that at least three-quarters of the laboratories included in the sample have an understanding of which elements to include in a COOP. No laboratory COOP covered all 27 elements, although two included something on 26 of the 27 elements.

Figure 2.2 Summary of COOP Elements Covered in Plan Review



Analysis of the elements covered by each COOP generated additional insights and revealed common gaps in plans. Below we summarize the key findings. **Figure 2.3** depicts the summary evaluation of the review areas, and Figures 2.4 through 2.10 show both the summary evaluation of the particular review area as the top bar (the same as depicted in **Figure 2.3**) and the evaluation of the elements within the review area in the faded bars below it. There was a range of how complete the elements were within most review areas covered in the COOPs.

As **Figure 2.3** shows, three-quarters of plans included at least minimal description of pre-event planning, activation, mission essential functions (MEFs), communications and IS, and maintenance elements. Identification of MEFs, which refers to the laboratory testing that must continue even after a disruptive event, was absent in one-quarter of the COOPs. Plans for alternative arrangements and reconstitution were missing in more than one-quarter of the COOPs.

Pre-event planning was a strength of the COOPs, and assumptions, scope, and succession and delegation were all well-defined in the COOPs, as **Figure 2.4** shows. Scenarios, or how implementation of the COOP would vary in different situations, were generally not described in detail. However, the criticality of this element to implementation of the plan is not known. Most of the sample of plans included or referenced a vulnerability analysis specific to the lab, which allow for mitigation of vulnerabilities and enhanced preparedness.

Figure 2.3 Summary Ratings of Plan Review Areas

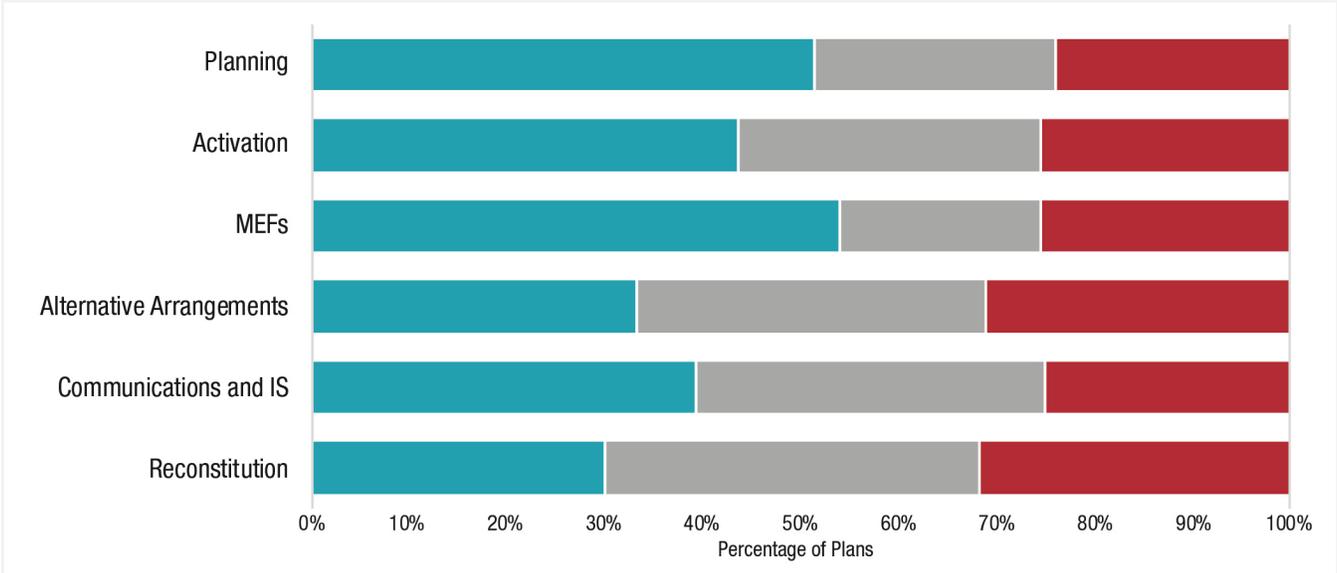
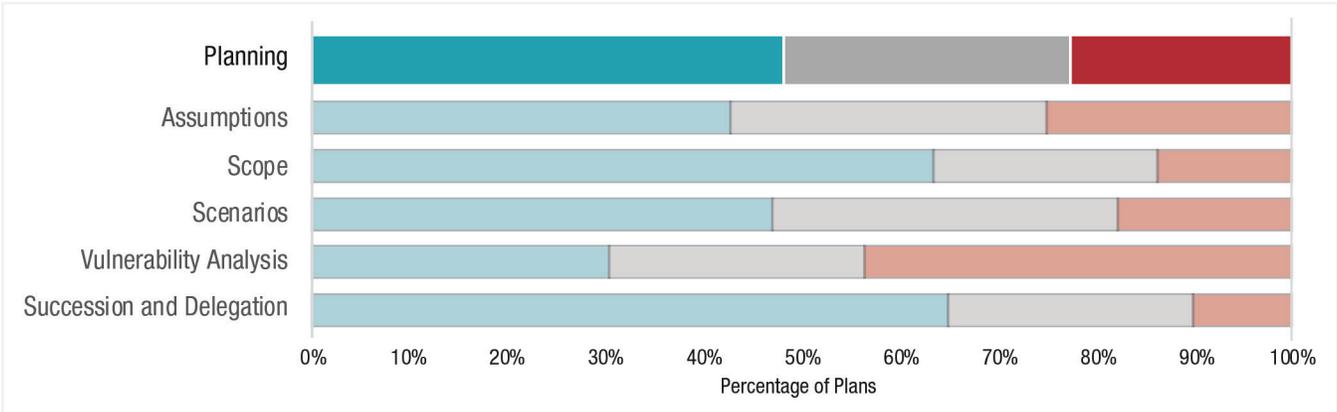


Figure 2.4 Summary Ratings of Pre-event Planning Elements



Element is Detailed
 Element Exists
 Element is Absent

Figure 2.5 shows the summary ratings for the various procedures, responsibilities, and other necessary information required to activate a COOP. Most plans did not include procedures for activating the COOP during non-business hours. During the exercises, we tested if having these time-differentiated procedures was necessary, and also probed the accuracy of the COOP contact information.

Figure 2.6 shows most COOPs indicated some prioritization of their MEFs, although the prioritization schema varied from the discretion of the lab director to detailed, multi-factorial methodology. Additional factors for determining the criticality of an activity were the amount of time the activity could be suspended without adverse impacts and/or legal obligations. More than one-quarter of the COOPs lacked any description of resource requirements or staffing requirements to fulfill essential functions.

Figure 2.7 shows many plans were lacking in detailed information about alternative arrangements for laboratory operations. Nearly all of the plans identified an alternative facility that could take over laboratory operations and over three-quarters at least mentioned having an agreement in place, but less than one-quarter included evidence of an actual MOU or MOA. None of the COOPs described in detail any of the legal considerations of alternative arrangements.

Figure 2.5 Summary Ratings of Activation Elements

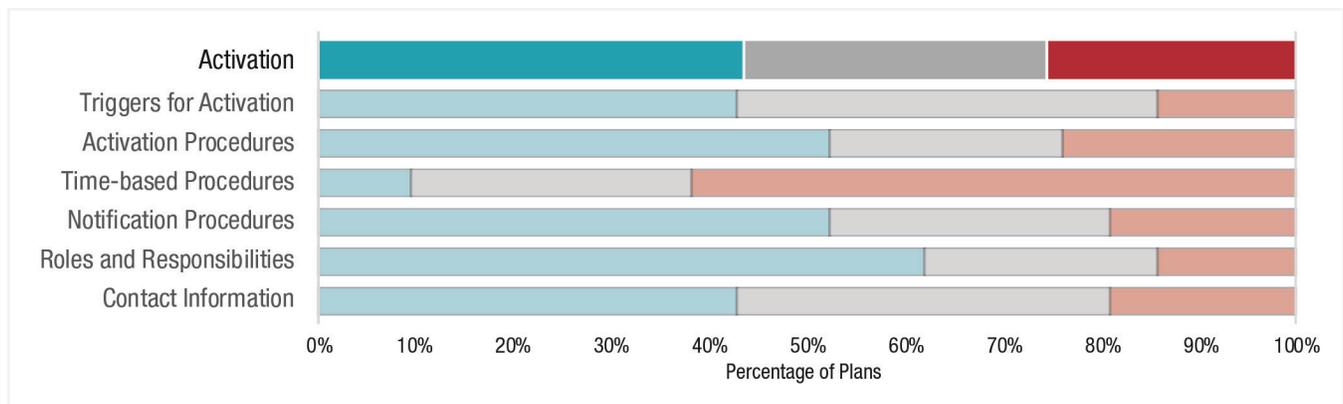


Figure 2.6 Summary Ratings of MEF Elements

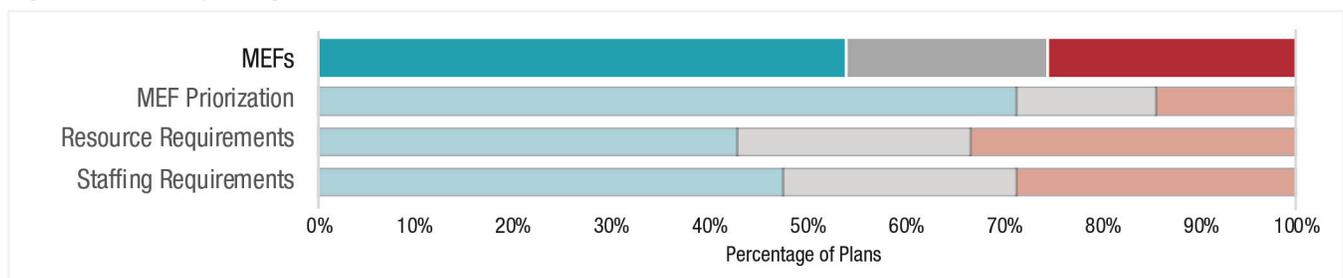
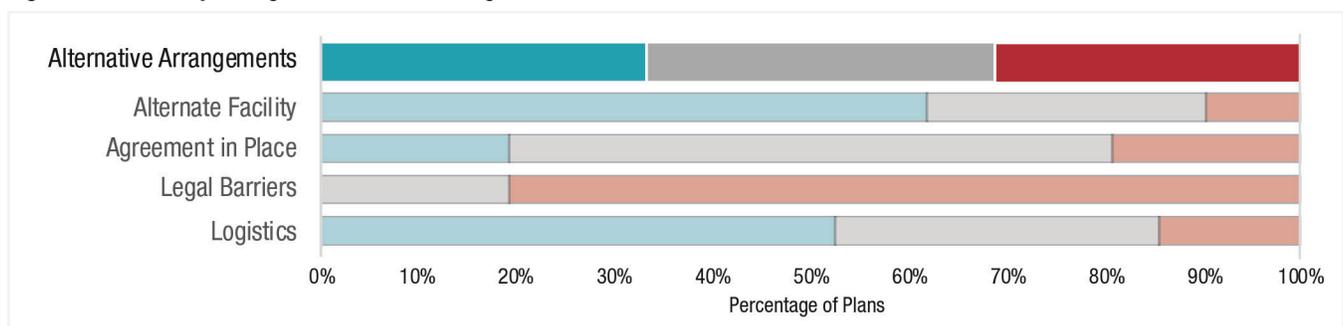


Figure 2.7 Summary Ratings of Alternative Arrangements Elements



Element is Detailed
 Element Exists
 Element is Absent

Figure 2.8 shows few plans provided detailed communications and IS information, although most plans referenced records and data protection policies as well as back-up systems. Details on redundancy and interoperability of communications systems were missing in most plans. We probed whether laboratories might have redundant or interoperable communications without specifically noting them as such, as well as the laboratories' utilization of communications systems, during the tabletop exercises.

Figure 2.9 shows that more than one-quarter of the plans did not contain any information on the elements of reconstitution: COOP deactivation criteria, reopening procedures, or plans for compiling an After Action Report. This may indicate a knowledge gap for what is required to reopen a laboratory after a major event.

Most plans contained some description of policies regarding the maintenance and exercise of the COOP, as **Figure 2.10** shows. Many plans stated that they were to be reviewed at least once per year.

Figure 2.8 Summary Ratings of Communications and IS Elements

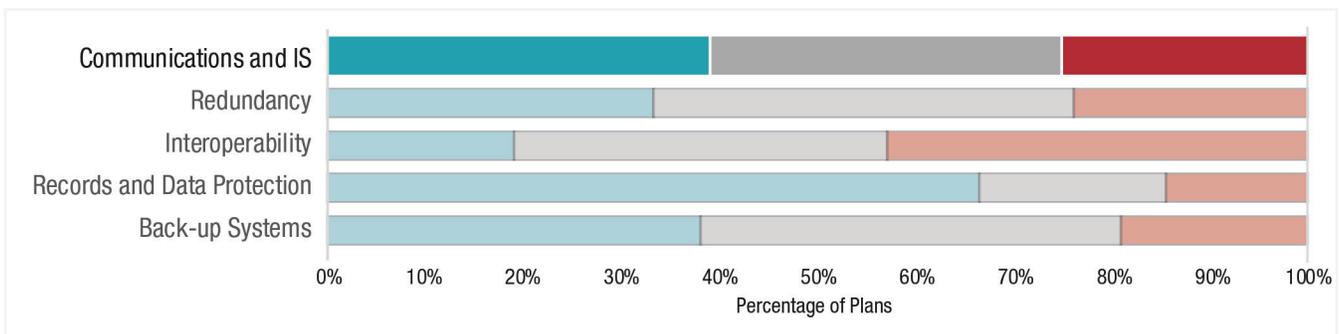


Figure 2.9 Summary Ratings of Reconstitution Elements

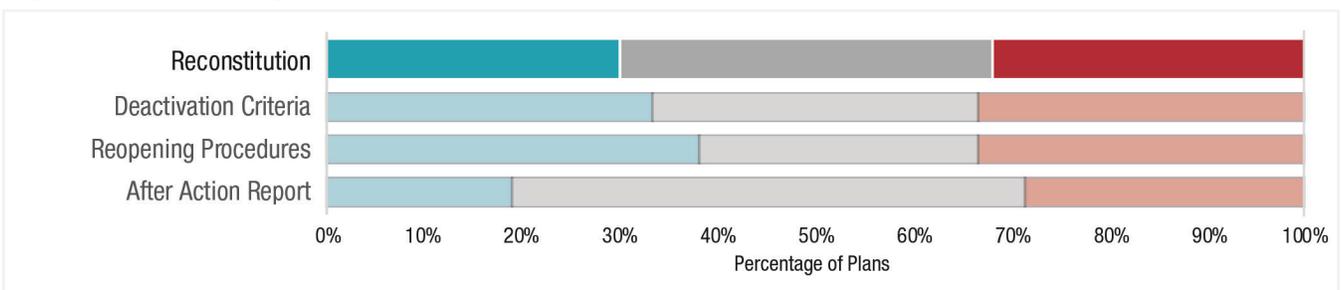
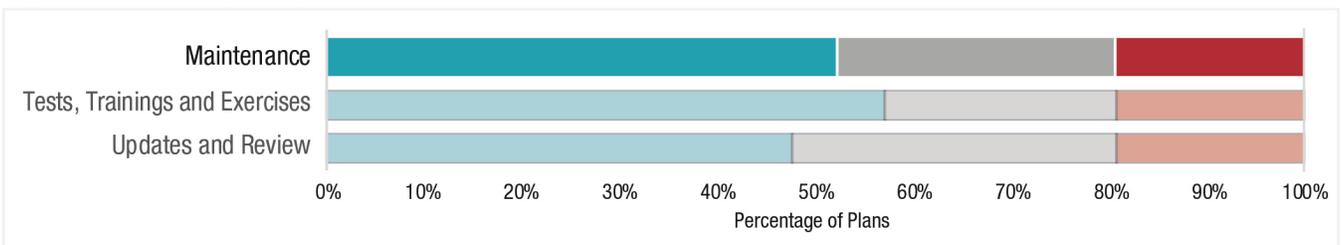


Figure 2.10 Summary Ratings of Maintenance Elements



Element is Detailed
 Element Exists
 Element is Absent

Limitations

There are at least four limitations to the review of plans. First, the review is based on a convenience sample of public health laboratories that voluntarily shared their COOP; as earlier noted, only 21 of the 54 nationwide did so. Our findings may not therefore represent the state of continuity of operations planning among all public health laboratories. Second, a single reviewer assessed the plans after an informal calibration of interrater reliability with another team member; rating results may have differed if all of the plans were reviewed by more than one person. Third, many of the COOPs that we received contained redacted information, were missing specific appendixes, or referenced other documents to which we did not have access. Therefore, we could not assess the COOPs in their entirety. Finally, our review did not evaluate if the content of the plan was valid or up-to-date. As a COOP is not just a reference document but also an operational guide, it must be both accurate and current to be useful.

Conclusions

Both the COOP areas emphasized and the gaps uncovered in the plan review informed the structure and focus of the tabletop exercise, which was pilot tested in four laboratories. In particular, the review confirmed that the COOPs generally did not address legal barriers to procuring and using alternate facilities during an emergency, so we used the exercise to help uncover potential explanations for this gap. The exercises also helped assess the accuracy of COOP contents, such as contact information, and identify COOP areas that may need further development.

3. OVERVIEW OF THE TABLETOP EXERCISE

We developed a discussion-based exercise to provide public health laboratories with an opportunity to evaluate their current continuity of operations plans in a response to a disaster or disruptive event. The tabletop exercise focuses on assessing and improving established policies and procedures to assure continuous performance of critical laboratory testing and support activities; it is not intended to be an operational exercise requiring actual laboratory testing and mobilization of resources. Exercise participants may vary, but at a minimum should include the laboratory director (or deputy), management staff, key leaders within the various divisions of the laboratory including, but not limited to, microbiology, molecular biology, newborn screening, biological terrorism [or BT], chemical terrorism [or CT], BioWatch, environmental, biosafety, a staff member with strong knowledge of information technology systems and structure, and a facilities manager or staff member with strong knowledge of the facilities.

The exercise is designed to be led by a facilitator using one of the customizable templates of PowerPoint briefing slides (Appendixes A through D). The slides lay out a scenario to prompt participants to discuss COOP activation and implementation following a disruptive event that inflicts major physical damage on the laboratory facility. While the pilot tests of the exercise were facilitated by RAND staff, the exercise template is designed so that the exercise can be facilitated by a member of the laboratory staff, such as the laboratory director, or someone from an outside agency with some knowledge of laboratory operations and emergency response.

The initial slides of the exercise template describe the exercise structure, objectives, and guidelines for discussion. The guidelines reinforce that the tabletop exercise is intended to provide a low-stress environment for identifying, discussing, and developing action plans for addressing gaps in the COOP. The exercise objectives are:

- In response to a disruptive incident, assess the laboratory's ability to:
 - Activate the COOP
 - Notify key personnel
 - Identify and implement essential lab activities after the disruption
 - Identify alternative labs and process for relocation
 - Reconstitute normal operations
- Evaluate the adequacy of the COOP, identify gaps in the COOP, and suggest improvements in the COOP.

The exercise template offers four scenario options—hurricane, earthquake, tornado, and bomb—with accompanying slide sets for laboratories to customize based on their known vulnerabilities. Each slide set follows the same general format, with a series of four to five situation reports followed by a list of questions for discussion to cover the COOP elements identified in the plan review. The facilitator presents the situation report and then leads participants through a discussion to review potential impacts on the laboratory and identify actions and decisions that need to be made. The discussion sections include high-level questions soliciting participant response followed by specific prompts for the facilitator to use for encouraging discussion. The questions are intended to be customizable; the facilitator may choose to add questions based on specific laboratory needs or skip the specific questions if they come up in discussing the high-level questions.

The exercise template concludes with a hot wash and an assessment of the exercise design and conduct. The hot wash aims to identify the strengths and gaps of the current COOP, lessons learned from the exercise, and action steps to improve the COOP. Information gathered through the hot wash may be useful for putting together a formal After Action Report (AAR) and Improvement Plan (IP).

4. FINDINGS FROM PILOT TEST AND NEXT STEPS

As described in the first chapter, we pilot tested the exercise in four laboratories with varying experience developing and testing COOPs. Two RAND staff facilitated the exercises and took notes on the discussions. Three of the exercises used a natural disaster (weather-based) scenario and one used a man-made (explosion) scenario. The exercise was well received by laboratory staff and management at the four pilot sites, and seemed to be useful based on the oral and written feedback offered to RAND and APHL. Below we summarize the key findings across pilot sites for each of the COOP review areas.

COOP Review Areas

Pre-event planning

Across all of the pilot sites, there was a large reliance on the laboratory director as both a source of information and decision-maker. In the event that the laboratory director was not available, succession and delegation of authority was not clear, and laboratory staff often did not possess the authority and delegation of power to sustain operations without the director. The degree to which pilot sites discussed implementing ICS also varied. Laboratories would benefit from more detailed training for assistant directors and department back-ups, as well as completing ICS training and practicing implementing ICS.

Activation

Contrary to what we expected from the review of plans, the decision about when to activate the COOP seemed to be more organic and situationally dependent, rather than focused on formalized triggers for activation. In part, this was because of the specific scenario that the laboratory staff were reacting to. For example, in the hurricane scenario, laboratory staff indicated that they would close down the day before the hurricane is expected to hit, but they would likely activate the COOP earlier as their sections prepared for the storm. Activation of the COOP depends on the assessment of the incident and its impact and the extent to which core activities are affected. The COOP is intended to be scalable; if only some core activities are impacted, then the COOP may be activated partially.

Mission Essential Functions

The review of plans indicated prioritization of MEF varied from the discretion of the laboratory director to detailed, multi-factorial methodology. Some laboratories delineate the level of priority for each laboratory activity within their COOP. Other laboratories reported that the essential activities would depend on the circumstances and often be decided by the laboratory director.

The exercise confirmed this variation among the four pilot site laboratories. For example, one laboratory had prioritized all laboratory functions from on a scale of 1 to 5 (with 1 being the highest), with testing for life-threatening diseases, such as rabies, ranking most essential. Similarly, the laboratories that conducted newborn screening tests all identified it as an activity that cannot be delayed significantly. Each of these laboratories had a formal agreement with another newborn screening laboratory to handle their tests during an emergency. Each laboratory that was part of the Laboratory Response Network (LRN) reported that they would rely on other LRN laboratories to handle biological and chemical testing.

One opportunity for improvement that came up in all of the pilot sites is increasing redundancy in staff roles and clarifying which staff members are considered to be essential. All the sites relied on the laboratory director as both the source of information and decisionmaker on COOP. Laboratories would benefit from identifying back-ups to management positions and the laboratory director. One of the pilot site laboratories had identified essential staff (A, B, C lists) and used this information for notification exercises.

Alternative Arrangements

Each of the pilot site laboratories had identified other facilities that would be able to take over their sample testing. These plans, however, were not written down, and most laboratories did not have formal Memorandums of Understanding (MOU) or Memorandums of Agreement (MOA). In one state with a centralized laboratory system, transfer

of testing responsibilities between the public health laboratories would not be difficult as the laboratory could turn to the other laboratories within the state to conduct sample testing. The laboratory also had an MOU with another state laboratory to handle newborn screening. In another site, the laboratory director had a handshake agreement with other state laboratories for handling sample testing in the event of an emergency, but no formal MOU or MOA. A third site had an MOU for LRN testing and identified alternative testing sites for other types of testing, but it had no pre-existing agreements for non-LRN testing. In at least one case, MOUs were held up by legal review, even when the laboratory directors favored the arrangements. With the exception of the laboratory in the state with a centralized system, the pilot site laboratories did not have a clear sense of the testing capacity and protocols of the alternative laboratories, which would impact the alternative laboratories' ability to handle testing for an increase in samples.

Should samples need to be re-routed to another laboratory, the pilot site laboratories reported that they would send out a notification and have customers send the specimens directly to the new laboratory. One issue that came up in multiple exercises was remembering to notify courier services if samples were to be sent elsewhere.

Most laboratories reported cross-training staff to work across areas during emergencies, though there are restrictions due to Clinical Laboratory Improvement Amendments (CLIA) regulations. Because CLIA licenses are linked to the facilities, it is unlikely that staff from one laboratory would be able to relocate and conduct clinical testing in another facility. Testing not covered under CLIA regulations, such as PulseNet, rabies, and environmental testing, could potentially be conducted by relocated staff, but this would also depend on human resources (HR) policies. None of the pilot site laboratories had a good sense of their agency's HR policies for teleworking, paying staff if the laboratory is closed, and relocating staff to other laboratory facilities in the event of an extended closure.

Communications and IS

Laboratories can use multiple modes of communication for notifying personnel (e.g., email, work issued cell phones, landlines, toll-free number/call line, emergency alert systems such as Everbridge), but the amount of redundancy that laboratories incorporate into their communications varied. Part of the exercise scenario included a disruption to the cell phone network. Pilot site laboratories struggled to identify alternative communication methods that did not rely on cell phones. Laboratories should look into alternative methods of distributing and collecting information, such as county/city/local university emergency alert systems, social media, and use of 8MHz radios, and ensure that staff know how to check email remotely. They should also ensure they have procedures to notify partner organizations of alternative arrangements for testing in the event that the laboratory is closed.

All of the pilot site laboratories reported having staff call-down lists, and most COOPs either included the lists in their directly or referred to their existence elsewhere. Three of the laboratories recognized during the exercise that their contact information had not been updated recently, and they did not have a systematic way to ensure that updates happen regularly. At the conclusion of one of the exercises, one laboratory decided to conduct an impromptu call-down drill to test how many staff received the notification.

The pilot site laboratories discussed the location of back-up servers and processes for ordering new IS equipment if needed due to damage from the incident. At least two of the pilot site laboratories had transitioned to the use of Microsoft 365 so that services are cloud-based; however, not all staff had the ability to connect to the virtual private network (VPN) and access services remotely. Another issue that came up was how to retrieve testing results from alternative laboratory facilities if they used different reporting systems.

Reconstitution

While the results of the plan review indicated a potential gap in identifying COOP deactivation criteria and describing reopening procedures, nearly all of the pilot sites had a good sense of the quality assurance, quality control, and certification requirements for resuming operation after an incident and closure. Discussion focused on assessing reagents and supplies for damage, ordering new reagents and supplies as needed, evaluating instrument status, and re-validating testing equipment. The sites also discussed the possibility of a phased move-in process should staff or parts of the laboratory not be available immediately after it was safe to resume operations.

Maintenance

Across the pilot test sites, not surprisingly, the laboratory director was most familiar with the COOP. The degree of familiarity of general staff varied, as did experience with the Incident Command System (ICS). Laboratories would benefit from increasing staff knowledge of the COOP and conducting ICS training. While the tabletop exercise tested the completeness of plans, it did not test operational capability to execute COOP elements. Laboratories with more mature COOP may want to consider conducting an operational exercise focused on specific functions such as notification, shutting down equipment, and evacuation or shelter-in-place.

Next Steps

Based on our review of COOPs and the tabletop exercises conducted, we consider state public health laboratories to be generally aware of the need for COOPs, but not all have invested the time and resources to develop comprehensive COOPs and test them. We recommend the following steps to APHL and public health laboratories.

APHL

- **Update COOP guidance with more specific information.** APHL last published model COOP guidelines in 2012 following RAND's 2011 project. Laboratories are now farther along in their COOP development since then and would benefit from updated guidance, especially in the areas of succession and delegation of authority, MEF identification and prioritization, legal barriers, and reconstitution. Table 2.1 can be used as a template to help ensure laboratory COOPs are comprehensive.
- **Provide laboratories with examples of successful/exemplary sections of COOPs.** Specifically, APHL can share redacted COOP sections in areas that many laboratories have less well developed COOPs, such as MEF, reconstitution, and alternative arrangements.
- **Collect and share successful laboratory MOUs.** Because executing MOUs is a significant hurdle for many laboratories, and is outside the expertise of most laboratory professionals, providing laboratory directors with successful MOUs to use as a template would be beneficial.

Public Health Laboratories

- **Conduct regular notification drills.** Both announced and unannounced notification drills, conducted during business and non-business hours, would compel laboratories to maintain up-to-date staff contact information. Notification drills are also helpful for determining whether communication modes are sufficient and functioning as expected.
- **Hold tabletop exercises facilitated by the laboratory director.** Across the pilot sites, the laboratory director was most knowledgeable about the COOP. A COOP exercise facilitated by the laboratory director would help with succession planning in case the director is not available and also with evaluating staff knowledge of the COOP. While these tabletop exercises were designed to probe the full scope of continuity of operations planning, laboratories may choose to scale back the exercise to a less complex scenario that requires partial COOP activation.
- **Designate a week each year for preparedness.** September is National Preparedness Month and provides an opportunity to remind laboratories to be prepared for disasters. Public health laboratories may wish to designate one week each year to re-stock emergency supplies, ask staff to update their contact information, ensure staff have taken ICS training, update evacuation and shelter-in-place plans, and update their COOPs.

REFERENCES

American Public Health Laboratories (APHL), Guidelines for the Public Health Laboratory Continuity of Operations Plan (COOP), Silver Spring, Md., 2011.

APHL, 2018 APHL All-Hazards Laboratory Preparedness Survey: Summary Data Report, Silver Spring, Md., February 2019. As of July 22, 2019: <https://www.aphl.org/aboutAPHL/publications/Documents/PHPR-May2019-All-Hazards-Summary-Data-Report.pdf>

Federal Emergency Management Agency (FEMA), Continuity of Operations Plan Template for Federal Departments and Agencies, Washington, DC, 2013. As of July 23, 2019: https://www.fema.gov/media-library-data/5c4896dd74fd2b18bc900e60935debe9/COOP_Planning_Template.pdf

Olmsted, Stuart S., Shoshana R. Shelton, Christopher Nelson, and Jeffrey Garnett, Developing and Pilot Testing a Laboratory Specific Continuity of Operations Tabletop Exercise, Silver Spring, Md.: Association of Public Health Laboratories, 2012.

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Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

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