

Identifying Operational Challenges and Solutions During the COVID-19 Response Among US Public Health Laboratories

Christina Potter, MSPH; Natasha Kaushal, MSPH; Kelly Wroblewski, MPH; Scott Becker, MS; Jennifer B. Nuzzo, DrPH, SM

ABSTRACT

Context: The ability to diagnose and screen for infection is an important component of the US COVID-19 response and is facilitated by public health laboratories (PHLs). Anecdotal media reports and limited case studies have described some of the challenges faced by PHLs during the pandemic, particularly initial challenges related to developing and deploying tests to PHLs, but there has not been a systematic evaluation of the experience of PHLs during the pandemic.

Objective: To document challenges and lessons learned experienced by local and state PHLs during the COVID-19 pandemic to support generation of best practices for current and future similar emergencies.

Design, Setting, and Participants: From February to June 2021, researchers conducted 24 interviews with 68 leaders and staff representing 28 local and state PHLs across 27 states. Thematic analysis of interview content documented operational challenges and any identified solutions or preventive measures used or proposed.

Main Outcome Measures: Analysis identified the following themes regarding challenges faced among PHLs: strategic decision making and determining the mandate of the PHL; political interference by jurisdictional leadership; federal mismanagement of the emergency; regulatory challenges; managing partnerships with other laboratories; acquisition of appropriate supplies; insufficient information systems; acquiring and retaining workforce; and difficulty accessing sufficient funding.

Results: Within the identified themes, key informants provided further elaboration regarding how PHLs experienced, evaded, or solved these challenges. In addition, PHLs described how challenges evolved throughout the course of the COVID-19 pandemic and made proposals regarding how challenges could be prevented or further addressed in the future by laboratories or other decision makers and stakeholders.

Conclusions: While fellow laboratories and political leadership may gain inspiration from creative solutions employed by PHLs, recognition of long-standing gaps related to funding, laboratory workforce, and consideration of laboratory needs in preparedness policies must be addressed for future large-scale outbreaks.

KEY WORDS: COVID-19, pandemics, preparedness and response, public health laboratories, public health surveillance

Author Affiliations: Center for Health Security, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland (Mss Potter and Kaushal); Association of Public Health Laboratories, Silver Spring, Maryland (Ms Wroblewski and Mr Becker); and Brown University School of Public Health, Providence, Rhode Island (Dr Nuzzo).

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Correspondence: Christina Potter, MSPH, Center for Health Security, Johns Hopkins Bloomberg School of Public Health, 621 E. Pratt St, Ste 210, Baltimore, MD 21202 (cpotter7@jhu.edu; christina.potter1996@gmail.com).

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The ability to diagnose infection is an important component of the US COVID-19 response. Initially, challenges in developing and deploying tests to laboratories hindered the country's ability to detect and characterize transmission. Since the beginning of the pandemic, more options for testing for SARS-CoV-2, the infectious agent that causes COVID-19, have become available, including at-home and point-of-care testing. As incidence continues, laboratories remain essential in supporting public health surveillance and disease control efforts.

The COVID-19 pandemic strained US public health laboratories (PHLs) in multiple ways. Key among these challenges are the operational difficulties of continuing activities during a multiyear pandemic as well as the sheer scale of COVID-19 testing required.¹ Coupled with the emergence of variants, this burden

has at times overwhelmed existing capacity, resulting in delays in testing or communication of results to stakeholders and public health responders.² While media and federal bodies have reported on select challenges facing laboratories, this coverage has been largely focused on supply chain difficulties or quality assurance issues related to specific test kits.^{3–5} To our knowledge, a few individual PHLs have published peer-reviewed articles describing the difficulties they have faced, but there has been no systematic evaluation of the operational challenges faced and solutions created by PHLs during the pandemic.^{6–8}

This analysis focused on capturing these lessons learned to identify and propose improvements for laboratories, particularly PHLs, regarding the COVID-19 response and preparation for future emergencies. In addition, this analysis can help inform policy makers and government leaders, so they are better prepared to support PHLs during public health emergencies. In future emergencies, PHLs will retain an essential role in detecting infections and supporting ongoing surveillance activities, so understanding how best to support these entities in future response efforts is important for improving preparedness.

Methods

From February 2021 to June 2021, semistructured, qualitative interviews were remotely conducted by Johns Hopkins Center for Health Security (CHS) team members via the Zoom videoconferencing platform with leadership and other technical staff from US state and local PHLs involved in COVID-19 response activities.⁸ PHLs invited to participate were jointly identified and invited by Johns Hopkins CHS and Association of Public Health Laboratories (APHL) partners, with participating laboratories demonstrating variation across geography, urbanicity, COVID-19 burden, and other catchment population features.⁹ In total, 54 PHLs—all 50 state PHLs and 4 local PHLs—were invited to participate. PHLs self-identified relevant personnel for interviews based on involvement in COVID-19 response activities, including laboratory directors, deputy laboratory directors, molecular laboratory supervisors, emergency preparedness and response supervisors, heads of satellite laboratory locations, and quality assurance managers. Recruitment concluded when thematic saturation had been reached.

The interview guide (see Supplemental Digital Content 1, available at <http://links.lww.com/JPHMP/B8>) was codeveloped by CHS and APHL based on experience related to outbreak response and laboratory operations. Interviews were semistructured in nature, allowing interviewees to direct conversation based

on their experience. Interview questions focused on PHL challenges and attempted or proposed solutions to those challenges during progressing stages of the pandemic. Interviewees were also asked whether they recommended any changes in preparedness for or in response to future similar events by PHLs, government officials, or other response actors. Interviews were conducted by CHS authors. Composition and number of interviewees per interview varied, with some interviews including members of different laboratories together while others included a single individual or multiple members of a single laboratory based on scheduling needs of participants. All interviews were conducted on a not-for-attribution basis to promote transparency. Interview notes and recordings were collected for each interview with participants' consent.

Two CHS team members independently conducted an initial thematic analysis of interview notes using an a priori list of themes regarding operational challenges encountered during the COVID-19 pandemic and any identified solutions or preventive measures used or proposed. Additional themes identified in the interview notes were noted and added to create a final list of themes. Interview content was analyzed again with the final list of themes to identify more detailed information for each topic. The proportion of PHLs reporting each theme was also recorded.

Johns Hopkins Bloomberg School of Public Health Institutional Review Board determined that this study did not constitute human subjects research (IRB00015368).

Results

In total, 24 interviews were conducted with 68 participants representing 28 PHLs (25 state PHLs, 3 local PHLs) across 27 states. See Figure 1 for a map of coverage.

Interview content was analyzed with 9 key themes identified (Figure 2). See Supplemental Digital Content 2 (available at <http://links.lww.com/JPHMP/B9>) for full details of findings. The proportion of PHLs reporting each theme was also recorded in the Table.

PHL mandate lacks clarity

PHLs reported challenges related to strategic decision making and determining their role in the response relative to other response actors. PHLs struggled with pivoting from their traditional, surveillance-based testing roles to what ultimately became the need to run a large-scale clinical diagnostic testing operation, which was perceived by interviewees as typically the role of clinical laboratories and not something PHLs

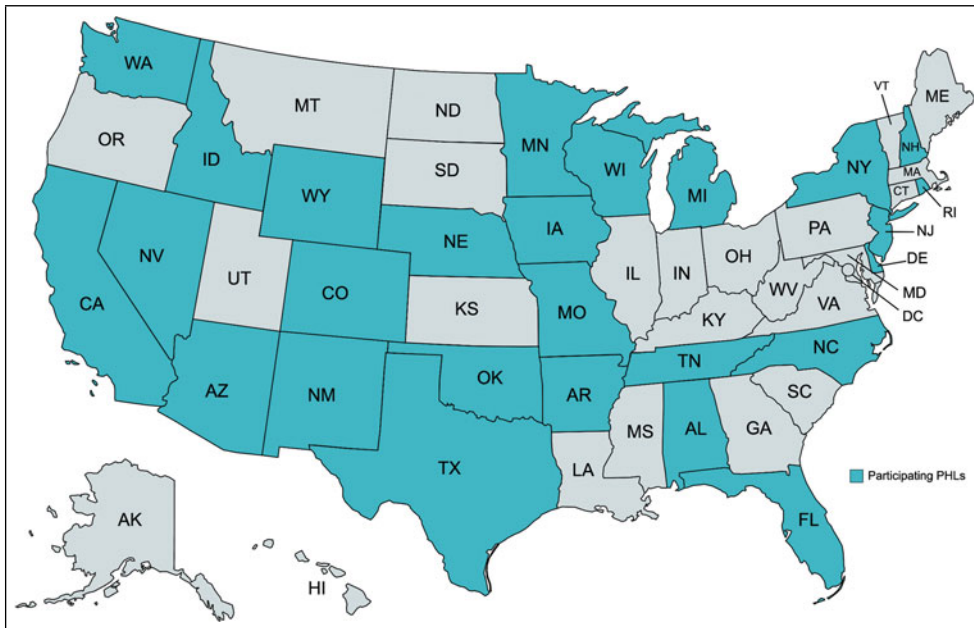


FIGURE 1 Map of Public Health Laboratory Participant Coverage
 This figure is available in color online (www.JPHMP.com).

are typically equipped to do. Some PHLs also found themselves shut out of PHL response planning by non-PHL leaders. They cited examples of external parties making decisions for them about the formation of new partnerships (eg, supply vendors, outside laboratories), testing criteria, and diagnostic strategy (ie, use of specific diagnostics or types of diagnostics). Other PHLs found it difficult to form an effective strategy due to lack of timely, clear guidance from federal leadership, poor initial preparedness or high throughput testing capacity, lack of fiscal or institutional

support from jurisdictional leadership, or a lack of institutional knowledge from staff. To mitigate future challenges, PHLs advocated for creative problem-solving and a clearly defined role during emergencies, including how to balance their emergency responsibilities, such as acting in an advisory capacity and new testing requirements, with nonemergency responsibilities, such as remaining in compliance with Clinical Laboratory Improvement Amendments and continuing routine public health surveillance and other testing programs.

Evolving Challenges Challenges evolved over the course of the pandemic 	PHL MANDATE	JURISDICTIONAL LEADERSHIP	FEDERAL MISMANAGEMENT & REGULATION	OUTSIDE LABORATORIES
	<i>Difficulty making short-term decisions and determining long-term strategy amidst political interference and lack of guidance</i>	<i>Leaders could facilitate creative problem solving and coordinate partnerships or sabotage response efforts with undue interference</i>	<i>Regulatory hurdles exacerbated supply chain issues and there was no national strategy; guidance was limited and often changing</i>	<i>Other laboratories provided technical support and problem solving, but working with new or inexperienced testing partners was challenging</i>
	MATERIAL NEEDS	INFORMATION SYSTEMS	WORKFORCE	FUNDING
	<i>Inability to acquire and maintain supplies in sufficient quality or quantity, exacerbated by suppliers and the federal government; insufficient space to meet distancing and equipment needs</i>	<i>Outdated systems - including paper forms - lead to slower testing and data sharing as well as difficulty producing usable analysis</i>	<i>Difficulty hiring & onboarding qualified staff; burn out; poaching by private sector; danger of COVID-19; fear of political backlash</i>	<i>Not enough funding; too much red tape around funding; slow disbursement or limited access to PHL funding</i>

FIGURE 2 Themes of Findings
 Abbreviation: PHL, public health laboratory. This figure is available in color online (www.JPHMP.com).

TABLE
Proportion of PHLs Reporting Each Theme

Theme	Proportion of PHLs Reporting Theme
PHL mandate	100% (28/28)
Jurisdictional leadership	93% (26/28)
Federal mismanagement and regulation	96% (27/28)
Outside laboratories	96% (27/28)
Material needs	100% (28/28)
Information systems	61% (17/28)
Workforce	100% (28/28)
Funding	79% (22/28)
Evolving challenges	100% (28/28)

Abbreviation: PHL, public health laboratory.

Jurisdictional leadership provides support or political interference

PHLs operate within a wider response system and rely upon the leadership, cooperation, and support of local and state governments. Some PHLs reported successful leadership from governors' offices, emphasizing that it was particularly helpful when leadership allowed PHLs to define their own specific needs that could be aided by government apparatuses or creation of novel industry partnerships. For example, multiple PHLs described instances in which leaders and their staff coordinated with vendors or private corporations to secure needed supplies when PHLs were not able to acquire supplies on their own. Conversely, other PHLs reported frustration with micromanagement from leaders and having to continuously defend their testing strategy compared with misinformation or disinformation heard, strategies proposed in the media, or strategies utilized by other states. Challenges were created for PHLs when governors engaged in major decision making without consent or notice. One PHL noted a governor engaged in a multimillion-dollar testing-related product contract on behalf of the PHL without any opportunity for input. PHLs recommended that leadership consult PHL experts on testing strategy and provide financial, verbal, and logistical assistance as requested. PHLs also recommended that relationship-building efforts between leaders and PHLs during nonemergency times improve.

Federal mismanagement and regulatory challenges undermined efforts

PHLs reported frustration with federal agencies providing confusing or insufficient operational guidance,

such as the US Centers for Disease Control and Prevention (CDC) and the US Food and Drug Administration (FDA). PHLs noted the well-documented failure of the first COVID-19 testing assay deployed by the CDC, causing weeks-long delays in their abilities to initiate testing. In addition, the early requirement to ship presumptive positive samples to the CDC for confirmation delayed test results.

However, the most prevalent, significant challenge reported that created later complications was the FDA's emergency use authorization (EUA) process. PHLs explained that the FDA's EUA requirement allowed only a select few diagnostics early during the pandemic and that these diagnostics often required specific equipment, supplies, and extraction platforms from a select few suppliers. Because of the high demand for COVID-19 testing, there was competition between numerous testing facilities, further exacerbating the supply chain bottleneck. In addition, early diagnostics that used commonly available instrumentation were predominantly manual rather than automated, and therefore low throughput, requiring more staff time, equipment, and space per test, delaying PHLs ability to scale up quickly. Some PHLs felt that had they been able to develop their own in-house diagnostic tools, they likely would have been spared some of these challenges.

Numerous PHLs also noted frustration with the absence of a comprehensive national COVID-19 testing strategy, ever-changing guidance, and early lack of action by the federal government to solve supply chain issues. PHLs recommended that prior to and during future emergencies, the federal government provide timely, consistent guidance, streamline the process for diagnostic development, and better restrict authorization of low-quality diagnostics.

Outside laboratories served as facilitator or obstacle to testing

The COVID-19 response involved numerous hospital laboratories, commercial laboratories, academic laboratories, and new COVID-19 testing ventures involved directly or playing a supportive role in testing. For some PHLs, new or existing partnerships with outside laboratories were a powerful facilitator to rapidly scale up capacity, distribute testing responsibilities, and engage in creative problem-solving. However, some PHLs reported that partnering with other laboratories was challenging. For example, some partnering laboratories, particularly laboratories inexperienced with diagnostic testing for infectious diseases, had insufficient capacity or expertise to conduct diagnostic testing, resulting in lack of standardization and/or quality control issues. On the basis

of these experiences, some PHLs called for creation of programs aimed at building partnerships with established laboratories, as well as the development of a licensure or standardized process to vet laboratories that wish to engage in testing during a public health emergency.

Material needs unmet and unhelpful help creates issues

PHLs reported difficulty acquiring essential supplies in a timely fashion, reducing their capacity to respond or continue normal operations. These difficulties were attributed to a number of factors including supply chain issues, competition between other organizations seeking supplies, miscommunication with vendors and other suppliers, and breakdowns in transportation systems. PHLs noted that the early process of ordering and receiving supplies from the CDC and the International Reagent Resource was insufficient to meet the demands of the response. Even when PHLs were able to receive orders from suppliers, there were other major problems. PHLs provided examples of deliveries of unlabeled, nonsterile, counterfeit, unrequested, or random, incorrect, contaminated, and poor-quality and even dangerous supplies, particularly when supplies were provided through government contracts organized by the Federal Emergency Management Agency (FEMA). One PHL reported receiving hundreds of moldy vials from the federal government. Another PHL reported that a federal shipment provided viral transport media from a noncredible manufacturer that let off cyanide gas when run on a particular instrument. When appropriate supplies were delivered, some PHLs were unprepared to receive, store, and distribute such a large scale of supplies. In addition, some PHLs were required to make space for other activities, such as vaccine storage in refrigerators or the conversion of an area for a press conference. Aging building infrastructure was also an issue for some PHLs.

Partnerships, such as with other laboratories, manufacturers, and government contacts, can be helpful to identify innovative solutions to track down needed space or supplies. In addition, in-house production of certain supplies and diversification of testing platforms, supplies, and suppliers were helpful tactics. Some PHLs also emphasized that federal partners needed to better plan and execute supply chain management during future pandemics with clear communication of these plans to PHLs.

Antiquated information systems limit testing capacity

PHLs reported various challenges related to data entry, management, and sharing that caused unnecessary

delays for reporting of test results and added unnecessary burdens for staff. For example, some PHLs still utilized slow paper request forms, had nonstandardized systems that involved extensive data cleaning needs, or had issues with computers crashing. Relatedly, one PHL reported that meaningful data analysis was impossible with the scale of testing results and an outdated laboratory information system. Other challenges stemmed from timely managing of the flow of data sharing between stakeholders (eg, governors' offices, epidemiologists, clinicians, patients). PHLs found that upgrading information technology (IT) systems and incorporation of automated or semi-automated data entry and data sharing were helpful. One laboratory reported 2 minutes saved per test when switching from paper test request forms to semi-automated data entry. In addition, incorporating IT staff or similar experts early in response planning processes can aid in finding solutions.

Workforce experienced scale-up, burnout, safety issues, and retention challenges

PHLs reported needing to dramatically scale up their staffing for the COVID-19 response. However, acquiring and retaining healthy, capable staff presented various challenges. Attainment of competent new staff was difficult due to bureaucratic red tape during onboarding, government hiring freezes, and lack of sufficient expertise in the geographic hiring pool. New staff then still had to be trained, putting an additional burden on the existing staff. There were also concerns about retention, since pandemic surge hires would lack responsibilities once testing demand reduced. Maintaining the mental and physical health of staff was difficult due to the threat of COVID-19, shortages of personal protective equipment, burnout, working unprecedented extended hours, inability to take time off, external pressures and criticism from the public and media, fear of politically motivated termination or layoffs, and issues retaining work/life balance due to school closures. For some PHLs, these pressures became too much, causing brain drain with early retirements occurring or poaching from private sector employers.

PHLs recommended utilization of alternative staffing sources for menial tasks such as data entry or easily teachable tasks in the laboratory including National Guard members or staff from laboratories who were unable to continue their research due to COVID-19 restrictions or wanted to assist as volunteers. In the future, contract agencies or other formal vetted pools of competent individuals similar to a Medical Reserve Corps could be helpful to streamline onboarding. To better retain and utilize staff

efficiently, automation and high throughput upgrades wherever possible, COVID-19 mitigation measures, utilization of a flexible shift system, cross-training staff on molecular diagnostics, task switching, time off when possible, and additional financial compensation such as overtime pay were found to be helpful solutions. Additional federal training and fellowships were also recommended.

Funding was insufficient or difficult to manage

Limited or inaccessible funding mechanisms hindered the ability of PHLs to successfully implement a sufficient and sustained response. PHLs reported pre-pandemic that they were often underfunded, leading to a lack of initial capacity or preparedness. During the pandemic, some PHLs reported being unable to receive available federal funding due to politicization of COVID-19. Others reported problems with disbursements or management of emergency funds. For example, some funds were slow to arrive or had a short-term allowance to access and spend them. One PHL reported that only one spending card with a spending limit of \$2500 was allowed for only one staff member. Another PHL reported that their state legislature was hesitant to provide additional emergency funding because, in their opinion, the pandemic was over. Other PHLs reported that supply purchases,

overtime pay, and raises for staff would sometimes be denied or difficult to request. In addition, PHLs were concerned that future funding would not cover maintenance of equipment bought during the pandemic. Various PHLs expressed hope that the pandemic could serve as a launching point for consistent funding to laboratory improvements and a greater prioritization of PHLs in routine government funding in addition to emergency funding when needed. PHLs also recommended that emergency funding disbursements were more flexible and streamlined but less bureaucratically hampered during future emergencies.

PHLs faced evolving challenges

As the pandemic progressed, so did the nature of the challenges that PHLs faced. Figure 3 categorizes the different challenges experienced during 3 different stages of the pandemic.

Challenges early in the pandemic revolved around poor and limited diagnostic options including the CDC-developed assay due to the EUA restrictions, the time required to validate new materials and processes, and difficulty initializing scale-up. Later, as testing criteria expanded and increased the volume of samples that PHLs received, scale-up became a major challenge as staff left, political pressures increased, supply chain and competition strained resources, and

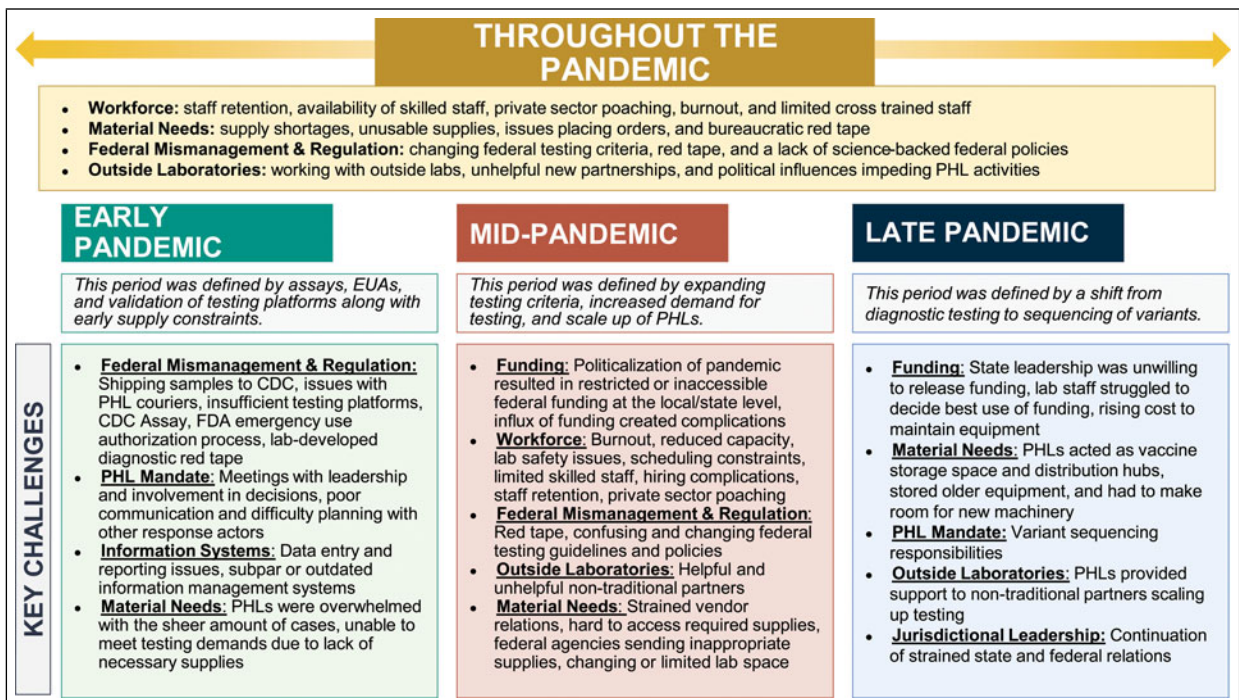


FIGURE 3 Timing of Challenges
 Abbreviations: CDC, Centers for Disease Control and Prevention; FDA, Food and Drug Administration; PHL, public health laboratory. This figure is available in color online (www.JPHMP.com).

guidance was often changing and unclear. As the pandemic progressed, and with the detection of variants of concern, the political nature of the pandemic became more apparent and more unpredictable; state leadership was often unwilling to release federal funding, and PHLs were asked to perform next-generation sequencing on top of resumption of some normal, prepandemic laboratory operations. While there were challenges unique to each phase of the pandemic, there were also challenges present throughout the pandemic, such as staff burnout, aging infrastructure, difficulty meeting staffing or supply needs, and challenges collaborating and coordinating with partners.

Discussion

PHLs reported numerous, evolving, interconnected challenges during the pandemic related to strategic planning, state and federal leadership, partnerships, supplies, space, workforce, information systems, and funding. Sometimes, PHLs were able to rely on lessons learned from past emergencies and the assistance of supportive partnerships to engage in creative problem-solving to meet these challenges. Some of the issues identified may be inherent to pandemic response and unprecedented during nonpandemic times, such as a rise in testing demand outside of a PHL's typical mandate. Those issues may require planning to meet them but should be expected as a stressor. However, many of the challenges that PHLs reported are recurring issues. For example, inconsistent funding, difficulty competing for new hires with private laboratories, and poor IT infrastructure were all issues prior to the pandemic yet allowed to continue. During the pandemic, these issues spiraled into major challenges, impeding PHLs' ability to meet the demand for COVID-19 testing. If the trend of failing to provide consistent resources for PHLs to meet their day-to-day needs and build capacity continues, then PHLs will have the same exacerbated issues during the next response.

Concerningly, many of the issues PHLs reported were not caused by the pandemic but created, maintained, or exacerbated by government leadership. Funding from federal agencies was difficult to utilize or access. Guidelines by federal agencies were unclear and often changing. The initial slow pace of FDA test authorization exacerbated issues with supply chain and delays in testing scale-up when more laboratories could have developed diagnostics in-house using their own equipment and expertise as was allowed later in the response. Supplies delivered by federal agencies were sometimes incorrect to the point of being dangerous if used or unusable due to contamination.

Jurisdictional leaders acted as a response-saving facilitator or an impossible to overcome barrier for PHLs. PHLs with supportive leadership reported a faster and easier time scaling up testing capacity with easy-to-access funding, streamlined hiring mechanisms, higher staff morale, political and staff support acquiring needed supplies, and ease in agile pivoting to adapt to challenges. Other PHLs reported combative relationships with their leadership, including inability to access funding, major operational and spending decisions made without the concurrence of PHL leadership motivated by profit or politics, as well as low staff morale and retainment with these issues, culminating in an inability to respond effectively. For future success, jurisdictional leadership must strengthen relationships with PHLs, establishing lines of communication that allows for consistent support.

Challenges were often interconnected and shifted throughout the pandemic. Information systems and having sufficient physical space to scale testing affected the burden on staff and ability to add new staff or supplies. While ideally all challenges reported in this article should be addressed by PHLs and government leadership, particular attention should be given to addressing interconnected challenges that may have an outsized effect in future public health emergencies. Similarly, while PHLs may be able to solve some problems utilizing recommended solutions alone, many of these challenges will require effort from jurisdictional and federal leadership and other partners.

Implications for Policy & Practice

- Lessons learned by PHLs during the COVID-19 pandemic can inform solutions to current challenges and future preparedness efforts for other similar emergencies for both PHLs and other diagnostic laboratories.
- Key informants described challenges experienced by PHLs and attempted or proposed solutions to those challenges during progressing stages of the COVID-19 pandemic.
- Major challenges encountered by PHLs were related to strategic decision making, government leadership, partnerships, supplies, workforce, space, information systems, and funding, although these challenges evolved throughout the emergency.
- While laboratories may gain inspiration from problem solving utilized by PHLs, larger recognition of long-standing gaps related to funding, laboratory workforce, and consideration of laboratory needs in preparedness policies must be recognized and addressed by federal and jurisdictional leadership prior to and during future large-scale outbreaks.

This study has several limitations. Although our aim was to interview individuals who had broad perspective of laboratory operations, individual staff and PHLs faced unique challenges. Some PHLs participating only had directors attend interviews while others included experts across all levels of hierarchy. Difficulty scheduling interviews and politicization of COVID-19 also hampered recruitment. Although our team utilized a semistructured interview guide as a benchmark for questions to maintain consistency across all interviews, most interviews were guided by the interviewees' experiences. For these reasons, our findings, including frequency of themes reported among PHLs, may not be reflective of the perspectives of all PHL staff members and every PHL. As the pandemic progressed, PHL experiences evolved, so findings may not represent challenges that emerged later during the response.

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