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Building Biosafety Capacity in Our Nation's Laboratories

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Abstract

The 2014 Ebola outbreak revealed biosafety vulnerabilities across the United States. We distributed $24.1 million to health departments to support public health laboratories (PHLs) and sentinel clinical laboratory partners to improve biosafety practices. We used 9 indicators to evaluate PHLs and associated clinical laboratories from March 2015 through April 2018 using descriptive statistics. On average, over 6 reporting periods, 59 awardee PHLs and 4,040 clinical laboratories responded. By April 2018, 92% (57 of 62) of PHLs had conducted at least 1 risk assessment for work with Ebola and another highly infectious disease. The number of PHLs having a policy for risk assessments increased from 32 of 61 (52%) to 49 of 54 (91%). The percentage of awardees meeting the target (80%) for associated clinical laboratories with staff certifications to package/ship rose from 32% (19 of 60) to 46% (25 of 54). The percentage of awardees meeting the target (70%) for associated clinical laboratories with risk assessment policies increased from 18% (8 of 44) to 28% (15 of 54). Awardees reported improvement among Ebola treatment centers/Ebola assessment hospitals with policies to perform risk assessments

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from 48% (20 of 42) to 67% (34 of 51). Public health laboratories and their clinical partners made progress on their abilities to address biosafety concerns and implement consistent biosafety practices, improving their ability to work safely with biological threats. More attention is needed to address gaps in the clinical community. Support for biosafety activities is critical to continuing to achieve progress.

Keywords

Biosafety capacity; Public health laboratories; Clinical laboratories; Ebola; Capacity building

In March 2014, West Africa experienced the largest outbreak of Ebola virus disease (EVD) on record, ultimately leading to domestic cases in the United States. When EVD cases first appeared in US hospitals, public concern heightened, and healthcare workers experienced anxiety about potentially caring for EVD patients. Many healthcare workers, including laboratorians, had training in handling samples and wearing personal protective equipment when testing highly infectious pathogens.[1,2] However, most doubted that their training was adequate for mitigating the risks of contracting EVD.[3]

The EVD outbreak revealed serious biosafety vulnerabilities in public health and clinical laboratories across the United States, including the inability to safely and correctly package and ship specimens, improper use of personal protective equipment, lack of knowledge around conducting proper risk assessments, and lack of connectivity between the healthcare and public health systems.[4,5] It also revealed a lack of or a largely inconsistent and uncoordinated adherence to biosafety practices. Although most public health laboratories (PHLs) had a safety officer or state training coordinator, most did not have a designated full-time person to work on implementing a biosafety program. These vulnerabilities, coupled with laboratories' perceptions that they were ill-equipped to handle, process, and test highly infectious specimens like those from EVD patients, highlighted a need for renewed focus on biosafety.

To support EVD response and recovery activities, the US Congress designated an emergency appropriation of $5.4 billion to US agencies, including $1.77 billion to the Centers for Disease Control and Prevention (CDC).[6] In March 2015, the CDC's Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases awarded $24.1 million to 63 state, local, and territorial health departments to improve biological safety practices in PHLs and among their clinical partners for a project period of 3 years. Named the Enhanced Laboratory Biosafety Capacity Project, this funding supported personnel (biosafety officers), travel, training, and laboratory equipment needed to manage highly infectious pathogens. We also awarded the Association of Public Health Laboratories (APHL) $2.2 million to provide subject matter expertise and develop biosafety tools, resources, and training for the laboratories.

The project aimed to improve public health and sentinel clinical laboratories' (hereafter ''clinical laboratories'') abilities to address biosafety concerns, strengthen biosafety management, promote the continuous assessment of biosafety improvement strategies, and improve coordination between public health and clinical laboratory partners. We developed

indicators to monitor progress toward attaining programmatic milestones and identify needs for assistance. With the APHL staff, we conducted calls with awardees to discuss indicator data and reviewed annual progress reports. This article summarizes findings on the evaluation of the Enhanced Laboratory Biosafety Capacity Project based on data collected from indicators.

Methods

We developed 9 performance indicators through several phases of vetting from program staff, partner organizations, and a subset of awardees (Table 1), and we established awardee-level targets for the 3-year project period for each indicator. The set of 9 indicators focused on the PHL and the associated clinical laboratories in their jurisdiction, with whom PHLs share an important relationship during a response event. Clinical laboratories are usually the first interface between patients and the public health system, and they have the potential to receive samples with hazardous agents. We asked PHLs to define clinical laboratories based on a prior designation by APHL, CDC, and the American Society for Microbiology, as well as those that tested or referred specimens that could contain Ebola virus or other emerging, highly infectious disease pathogens.[7] These included clinical laboratories in frontline healthcare facilities, such as acute care hospitals, critical access hospitals, and urgent care clinics that perform or send out infectious disease testing. We also focused a portion of the analysis on a subset of clinical laboratories contained in Ebola treatment centers/Ebola assessment hospitals, points of care designated to receive, isolate, and/or treat individuals under investigation or confirmed as having EVD.[8] This subset of clinical laboratories played a critical role in caring for people under investigation and/or treatment for EVD and was a primary target in outreach efforts by PHLs.

Indicators

Indicators for Public Health Laboratory Performance—Indicator 1 assessed whether awardees hired and/or designated a biosafety officer in their PHL. Biosafety officers had the main role of conducting risk assessments, developing and updating biosafety processes and procedures, and coordinating outreach activities with clinical labs. Most awardees did not have a designated full-time biosafety officer to work on biosafety activities in their jurisdiction prior to this funding. Monitoring this indicator was important for accountability, as the majority of funding went toward hiring and training biosafety officers.

Indicator 2 asked awardees how many public health laboratorians certified in packaging/shipping of International Air Transport Association (IATA) Division 6.2 infectious substances (Categories A and B) they needed out of the overall number of laboratorians. Public health laboratories receive samples that may contain highly infectious pathogens, such as EVD. Training and certification in proper packaging and shipping of infectious substances protects the packager, courier/shipper, and others from the dangers associated with exposure to these substances. Therefore, it was critical that each awardee had a sufficient number of staff who were certified to package and ship. We recommended that each PHL have a minimum of 2 laboratorians trained and certified to package/ship per

laboratory. By the end of the project period, we expected PHLs to have 100% of the public health laboratorians needed for packaging/shipping infectious substances certified.

Indicator 3 focused on PHLs with a biosafety level 3 (BSL-3) facility; these PHLs needed to show that they had a sufficient number of laboratorians who demonstrated competence to work in a BSL-3 laboratory. Biosafety Level 3 facilities are warranted for work performed with agents that can potentially cause serious or lethal diseases via inhalation; designations for BSL-3 laboratories denote these facilities are safer for working with highly infectious agents. Because of variations such as size and structure across the PHLs, they defined the number of laboratorians they needed to demonstrate competency. We provided a definition for a demonstration of competency and asked PHLs to provide a 1-time open-ended text response to describe their specific method.[9]

Over the project period, we expected PHLs to have conducted at least 1 biosafety risk assessment each for work with EVD and 1 other pathogen, based on the laboratory's priority, and to have addressed gaps found in the risk assessments (indicator 4). Conducting risk assessments is critical for improving laboratory biosafety as it helps laboratories identify potential hazards and associated risks related to infectious agents or materials.[10,11] Typically done before working with a new agent or procedure or after changes in processes, this process provides information about risk that can facilitate the appropriate selection of practices, equipment, and safeguards to eliminate or control the hazard.[12] In each data collection period, we asked awardees if their PHLs had met this requirement within the prior 6 months, documenting the completion of risk assessments and gaps mitigated as a result of any identified unacceptable risks.

Having both a standing biosafety plan and a written policy and/or standard operating procedure for performing risk assessments as part of a comprehensive biosafety program implies that safety is a priority and that PHLs have placed an emphasis on articulating methods to ensure safety in laboratories. We asked awardees if they had a biosafety plan in place for the PHL, how often they reviewed the plan, and whether leaders communicated the plan to staff (indicator 5).[11] Additionally, we asked awardees if PHLs had a written policy and/or standard operating procedure for performing risk assessments (indicator 6).[13] This policy needed to include methods for performing risk assessments, when to perform risk assessments, and what the process should cover.

Indicators for Sentinel Clinical Laboratory Performance—Like indicator 6, indicators 7a and 7b focused on having a standard operating procedure in place for performing risk assessments at the clinical laboratory level. For each PHL, we aimed for a written policy and/or standard operating procedure in place to perform risk assessments in at least 70% of their clinical laboratories and 100% of Ebola treatment centers/Ebola assessment hospitals in their jurisdiction.

Clinical laboratories routinely receive highly infectious substances and could potentially receive one as severe as EVD. As with PHLs, training and certification to properly package and ship infectious substances are imperative for preventing the spread of highly infectious diseases. For PHLs, we established a target for having at least 2 staff members certified to

package/ship IATA 6.2 infectious substances (Categories A and B) (indicator 8a) in 80% or more of associated clinical laboratories. Among Ebola treatment centers/Ebola assessment hospitals, this target was 100% (indicator 8b).

Public health laboratories queried clinical laboratories about the completion of risk assessments for each 6-month data collection period (indicators 9a and 9b) and reported the percentage completing at least 1. By the end of the 3-year project period, we expected at least 80% of clinical laboratories and 100% of Ebola treatment centers/Ebola assessment hospitals in each PHL's jurisdiction to have completed at least 1 risk assessment. At the culmination of the project period, we also asked awardees the number of clinical laboratories in their jurisdiction that had completed at least 1 risk assessment over the 3 years.

Data Collection

We contacted all 63 awardees funded for the project with information on indicators, the importance of submitting data, and our methods for data collection. With the exception of indicator 1, we collected data from the awardees' PHLs via Research Electronic Data Capture (REDCap), a secure, web-based reporting system, every 6 months from March 2015 through April 2018 (the completion of the project period).[14] We solicited information for indicator 1 via conference calls. The PHLs contacted clinical laboratories in their jurisdiction to acquire information about their progress and reported their data directly to us.

Data Analysis

We analyzed data from October 2015, the first data collection time-point including all 9 indicators, through April 2018. At the conclusion of each data collection period, we assessed data quality through direct awardee contact, and we conducted descriptive analyses using Excel and SAS v.9.3. We calculated the median percentage and range among the distribution of percentages reported by PHLs for indicators 2, 3, 7, 8, and 9 (Table 1) to look for positive trends in measures of central tendency (Table 2). We calculated the percentage of awardees meeting targets to show progress over time, where applicable (Figures 1 and 2). Additionally, we analyzed major themes from awardee conference calls conducted during the project period to provide context for challenges and limitations.

Results

On average over 6 data collection periods, 59 of 63 awardees' PHLs (94% response rate) responded to our data request during the 3 years; 62 awardees responded at least once. An average of 4,040 clinical laboratories responded to PHLs; of those, an average of 364 were Ebola treatment centers/Ebola assessment hospitals. Ninety-four percent of awardees (58 of 62) reported having Ebola treatment centers/Ebola assessment hospitals.

Public Health Laboratories

Workforce Competency—In June 2015, 50% (29 of 58) of awardees who responded to calls had hired or designated a biosafety officer (indicator 1) to implement project activities (Figure 1). Awardees reported they had difficulty identifying qualified candidates. In April

2017, 97% (59 of 61) of awardees had hired or designated a biosafety officer. When surveyed in October 2017, 71% (41 of 59) of awardees said they wanted to continue the position after the project period was over. Of those, 53% (31 of 59) planned to continue the biosafety officer position with other federal, state, and local funds. Those who planned to discontinue the position noted they still wanted to sustain some activities using other existing staff, although activities pertaining to outreach with clinical partners would likely discontinue. By 2018, 61% (33 of 54) of awardees reported their biosafety officer was still in place (Figure 1).

Over 3 years, the median percentage among all awardees of PHL staff certified in packaging and shipping highly infectious substances (indicator 2) increased by 77%, from 150% in October 2015 to 227% in April 2018 (Table 2). The recommended number of laboratory staff members certified in packaging/shipping was 2 in each jurisdiction. Values over 100% indicated laboratories that had more than 2 staff certified in packaging/shipping. By April 2018, 76% (41 of 54) of PHLs had more certified staff than expected, while 6% (3 of 54) of PHLs did not meet the target (100%).

Of 62 awardees who responded, 56 (90%) PHLs had a BSL-3 designation. Public health laboratories needed between 2 and 51 laboratorians who demonstrated competency to work in a BSL-3. The median number was 6 in 2015 and 7 in 2018. For both periods, the median number of laboratorians that actually had BSL-3 competency across awardees was 7.5 in 2015 and 11 in 2018. When asked what percentage of laboratory staff passed a BSL-3 competency assessment (indicator 3), the median percentage among the distribution of percentages reported by PHLs met our target of 100% in October 2015 and April 2018 (Table 2). In October 2015, 73% (41 of 56) of awardees met the target (100%); by April 2018, 88% (45 of 51) of awardees met the target (Figure 1). The majority of PHLs said they used training with assessments and direct observations to determine staff competency. To develop these guidelines, many public health laboratories cited standard reference materials and publications, such as *Biosafety in Microbiological and Biomedical Laboratories,* and CDC's Division of Select Agents and Toxins and the Laboratory Response Network.[12]

Risk Assessments—During the 6 months prior to October 2015, 38% (23 of 61) of PHLs conducted at least 1 risk assessment for work with EVD *and* 1 other highly infectious agent, and they mitigated gaps if risks were identified. At the end of 3 years, 92% (57 of 62) of PHLs met these same criteria (Figure 1). Over 3 years, 100% (62 of 62) of PHLs conducted at least 1 risk assessment, 85% (53 of 62) of PHLs conducted at least 4 risk assessments, and 3% (2 of 62) of PHLs completed only 1 risk assessment. Gaps during risk assessments were found in handwashing, personal protective equipment donning and doffing, movement of samples, decontamination and destruction, shower-out procedures, and receipt of Category A and B shipments. Though the push for risk assessments was initially targeted for work with EVD, by the end of the project period, awardees reported PHLs conducted risk assessments for work with infectious agents other than EVD, including Zika (42%, or 19 of 45), *Mycobacterium tuberculosis* (31%, or 14 of 45), and carbapenem-resistant Enterobacteriaceae (18%, or 8 of 45).

Management of Biosafety—The percentage of awardees who had a biosafety plan in place for the PHL, annually reviewed the plan, communicated guidelines to necessary staff, and ensured or provided biosafety training to employees (indicator 5) remained consistent from October 2015 (90%, or 55 of 61) to April 2018 (96%, or 52 of 54) (Figure 1). Additionally, the number of PHLs with a written policy and/or standard operating procedure in place to conduct risk assessments increased from 32 of 61 (52%) in October 2015 to 49 of 54 (91%) in April 2018 (Figure 1).

Sentinel Clinical Laboratories

Workforce Competency—From October 2015 to April 2018, the overall percentage of clinical laboratories who had at least 2 staff members certified to package/ship IATA 6.2 infectious substances (Categories A and B) (indicator 8a) changed from 48% (1,907 of 3,997) to 62% (2,507 of 4,019). Among all Ebola treatment centers/Ebola assessment hospitals, a subset of clinical laboratories, the percentage of laboratories with at least 2 staff members certified to package/ship increased from 71% (244 of 344) in October 2015 to 91% (424 of 465) in April 2018 (indicator 8b). The percentage of awardees meeting the target (80%) for associated clinical laboratories with staff certifications to package/ship IATA 6.2 infectious substances (Categories A and B) changed from 32% (19 of 60) to 46% (25 of 54) (Figure 2). The percentage of awardees who reported at least 2 staff members were certified in Ebola treatment centers/Ebola assessment hospitals, a subset of clinical laboratories (indicator 8b), also increased from October 2015 (82%, or 46 of 56) to April 2018 (90%, or 46 of 51).

Risk Assessments—At the culmination of the project period, 2,144 of 4,019 (53%) clinical laboratories reported to PHLs that they had completed at least 1 risk assessment during the 3 years, compared to only 15% (593 of 3,828) at baseline. The overall number of Ebola treatment centers/Ebola assessment hospitals completing at least 1 risk assessment during the 3-year project period increased from 46% (153 of 331) to 93% (433 of 465). Fifty-two PHLs reported the percentage of clinical labs in their jurisdiction that had completed a risk assessment in the past 6 months (indicator 9a); the median percentage was 17% in October 2015 (Table 2). By April 2018, this median percentage increased to 30% (for 54 PHLs). Public health laboratories also provided the percentages of Ebola treatment centers/Ebola assessment hospitals in their jurisdiction that completed a risk assessment in the prior 6 months (indicator 9b); the median was 73% in October 2015 and 60% in April 2018 (Table 2).

Management of Biosafety—Among all clinical laboratories reporting to PHLs, 15% (607 of 3956) reported they had a written policy and/or standard operating procedure in place to perform risk assessments in October 2015 (38%, or 127 of 344, for associated Ebola treatment centers/Ebola assessment hospitals). By April 2018, that percentage rose to 46% (1,840 of 4,019) for all clinical laboratories and 86% (399 of 465) for associated Ebola treatment centers/Ebola assessment hospitals. From October 2015 to April 2018, the percentage of awardees meeting the target (70%, Indicator 7a) for associated clinical laboratories with risk assessment policies changed from 18% (8 of 44) to 28% (15 of 54) (Figure 2). In the same time span, the percentage of awardees meeting the same target

for associated Ebola treatment centers/Ebola assessment hospitals (100%, indicator 7b) increased by 19%, from 48% (20 of 42) to 67% (34 of 51) (indicator 7b) (Figure 2).

Discussion

As EVD became more of a realized threat to the US public, challenges surrounding logistics and operationalizing laboratory testing of suspected EVD patient specimens revealed gaps in biosafety programs. The Enhanced Laboratory Biosafety Capacity Project aimed to enhance the ability of PHLs and their associated clinical laboratories to address biosafety concerns and implement consistent biosafety practices. Data from indicators collected from October 2015 to April 2018 showed PHLs and associated clinical laboratory partners made progress toward increasing laboratories' ability to work safely with samples containing unknown or highly infectious pathogens, although considerable gaps remain.

Public Health Laboratories

Results suggest that having the resources to designate a biosafety officer was essential for PHLs to make improvements in biosafety and develop a full-time laboratory biosafety program. Munson and colleagues believe that 1 element essential to nurturing a culture of biosafety is identifying a single champion to support this cause.[15] Awardees initially faced challenges in hiring biosafety officers because of shortages in qualified applicants, delaying the start of project activities. The requirements for biosafety officers are a complex set of focused duties and include unique communications, leadership, and laboratory skills.[16] In particular, formal training and applied experience with biosafety was insufficient among many candidates and newly hired staff. Although most awardees were able to hire a biosafety officer in the first year, final project data show that awardees have eliminated almost half of these positions due to lack of sustained funding. Without a dedicated staff member to ensure internal biosafety compliance, biosafety programs in PHLs will likely revert to a set of activities assigned to the workload of existing staff. This will undoubtedly halt the momentum of progress made on improving biosafety in both PHLs and the clinical laboratories.

Over 3 years, most awardees reached their targets for having a written policy and/or standard operating procedure in place to perform and complete risk assessments, making the most progress in these areas. Having formal processes and policies in place to conduct risk assessments suggests laboratories have made safety a priority and have institutionalized processes to sustain these activities. Furthermore, though most PHLs likely already conducted risk assessments, this project facilitated a more formal, documented risk assessment process. At project inception, PHLs focused on conducting risk assessments specifically for EVD work. By April 2018, the focus on risk assessments shifted to work with other infectious agents such as Zika; this suggests these resources were also important for addressing other biological agents beyond EVD.

Public health laboratories were largely meeting milestones for certification in packaging and shipping IATA Division 6.2 infectious substances (Categories A and B) and having a biosafety plan in place, results which remained consistent during the 3-year time span. This indicates these were not gaps in most PHLs and were likely attributable to the existence of

activities already in place prior to the project. Training programs on packaging and shipping highly infectious samples were in place before our funding through the CDC's Public Health Emergency Preparedness Cooperative Agreement and the Hospital Preparedness Program.[17,18] Many awardees said the ability to package and ship, as well as perform risk assessments, was already required by state regulations prior to EVD funding.

Sentinel Clinical Laboratories

In contrast to indicators focused on the PHLs, most awardees were not able to reach targets for clinical laboratories having a standard operating procedure in place to conduct risk assessments and certifications in packaging and shipping IATA Division 6.2 infectious substances. Nevertheless, the number of clinical labs making progress on these indicators did increase. Clinical labs began at a lower baseline compared to PHLs; most reported to PHLs they did not have standard operating procedures in place, nor had they done any risk assessments in the 6 months prior. The improvements demonstrated by the end of the project period suggest that PHLs made a positive difference in improving biosafety through their outreach efforts with clinical labs despite limited time and resources, but gaps remain. Clinical labs are usually responsible for the highest volume of specimen testing and are often the first point of contact with a potentially infectious agent, yet these data show they may still not be prepared to work safely with unknown or highly infectious diseases.

The percentage of awardees where all associated Ebola treatment centers/Ebola assessment hospitals in their jurisdiction had a written policy and/or standard operating procedure in place to perform risk assessments and were certified to package and ship IATA Division 6.2 infectious substances was much higher compared to the larger universe of clinical laboratories. This was not surprising, as there were complementary efforts rolled out by CDC. The Healthcare Infection Control Assessment and Response project aimed to support jurisdictions in defining and applying standards of infection control for transmission prevention through Ebola readiness assessments at Ebola treatment centers/Ebola assessment hospitals as well.[19] Progress on these indicators is important because we consider the Ebola treatment centers/Ebola assessment hospitals priority entities as the initial point of care for individuals under investigation and/or people being treated for EVD. Having a written policy and/or standard operating procedure in place to perform risk assessments and conducting risk assessments in the laboratories of these facilities is critical to ensuring risks are properly and systematically assessed and mitigated. Still, almost a third of awardees had Ebola treatment centers/Ebola assessment hospitals in their jurisdiction that did not have a standard operating procedure in place to perform risk assessments. Conversely, by the end of the project period, almost all the Ebola treatment centers/Ebola assessment hospitals had conducted at least 1 risk assessment. This suggests that Ebola treatment centers/Ebola assessment hospitals may have addressed and mitigated risks in handling specimens from patients who were at risk of having EVD, but perhaps they had not formalized a broader plan to integrate the concepts around risk management into their daily operations.

Awardees suggested several reasons for the difficulty they had in meeting targets associated with their clinical laboratories. It is likely that different types and levels of engagement

with clinical laboratories played a role in hindering or facilitating progress. Public health laboratories said they experienced resistance from some clinical laboratories to engage in laboratory biosafety activities, and since PHLs have no regulatory authority in the realm of biosafety, they could not enforce these activities. Additionally, staffing shortages in the clinical laboratory setting and other competing priorities among clinical laboratory leadership made implementation of activities challenging. Anecdotal evidence suggests that it was often a challenge for clinical laboratory staff to attend biosafety training sessions because laboratories either did not prioritize this type of training or were already short-staffed. Lastly, targets established for the clinical laboratories may have been unrealistic for the scope of the project, timeframe, and amount of funding.

Among those PHLs that were successful in conducting outreach with their clinical partners, some attributed this to their level of on-site assistance. However, site visits are not always feasible, especially in large jurisdictions with many clinical laboratories. Those with relationships with their clinical partners in place prior to funding also appeared to be more effective in conducting biosafety outreach. Others noted that persistence in contacting clinical laboratories despite poor initial receptivity was effective; instead of viewing the biosafety officer as an interference to daily activities, clinical labs began to see the biosafety officer as a resource. Generally, PHLs that were able to get all or nearly all of their clinical laboratories to conduct risk assessments and put a standard operating procedure in place for risk assessments were those that tended to have fewer clinical labs in their jurisdiction, and/or had strong biosafety officers. Offering easy access to resources such as live webinars and online tools and incentives such as credits to maintain licenses also contributed to strengthening rapport between the biosafety officers and their clinical peers.

Moving Forward

Multiple facets of this project made improvements in biosafety among PHLs and clinical laboratories possible. The highly pathogenic nature of the EVD outbreak motivated urgent action to address gaps in safety. This was the impetus for this dedicated source of funding. Having a biosafety officer whose job was to focus solely on developing a full-time laboratory biosafety program was key; they served as a resource for their internal PHL and external clinical partners. Additionally, the resources (eg, tools, training, workshops, templates) and communities of practice (eg, online listservs, peer networks) developed by APHL offered a rich repository of information for biosafety officers to access.[17] Finally, we believe that consistent program monitoring of work plan activities was an important factor; checking in with awardees on a periodic basis helped identify gaps and challenges that were impeding the completion of work plan activities and goals.

Though funding has expired, aspects of the project remain sustainable. The networks and relationships fostered during this project encourage ongoing discussion between PHLs and clinical partners to address biosafety challenges and successes in the future. Additionally, the biosafety tools and resources developed by APHL for public health and clinical laboratories during this project have assisted in establishing a consistent and coordinated approach to biosafety practices.[17]

Assessing biosafety outcomes at the national level is difficult. For example, there are no known mechanisms that capture all exposure events or illnesses acquired from working in laboratories. Without visible surveillance of laboratory-acquired infections, we lack concrete data that would help laboratories better understand causes of exposures, determine if current capacity-building or prevention efforts are effective, and develop more targeted strategies to improve safety. By aiding in estimation of costs associated with laboratory-acquired infections and exposures, a national system capturing exposures and infections would also help gain leadership buy-in, especially in clinical laboratories.

Limitations

This evaluation is subject to several limitations. Awardees self-reported data, and we did not have a secondary data source to validate their responses. In 1 instance, 2 of the indicators (indicators 2 and 3) asked respondents to establish their own targets; as such, they have may defined their target to reach their desired outcome. Additionally, there may be reporting bias among awardees because of the recipient-funder relationship. Although we told awardees that we were not going to use the data they submitted in a punitive way, they may have still worried about a possible funding gain or loss tied to data submitted. The number of awardees responding also decreased over time from 61 in October 2015 to 54 in April 2018. The decrease in response, likely due to survey response fatigue over 6 reporting periods, affects the robustness of the data and may lead to issues with validity and reliability. Public health laboratories also used varied methods (eg, phone calls, surveys, site visits) to contact clinical laboratories for data, which may have affected the completeness and validity of the data pertaining to clinical laboratories, Ebola treatment centers, and Ebola assessment hospitals. We attempted to mitigate these limitations by incorporating frequent data collection periods and conducting calls with awardees to discuss data interpretation and data quality. Despite these limitations, we believe that this evaluation helps provide key insights into the successes and gaps of implementing a large-scale effort to improve biosafety capacity in PHLs and clinical laboratories across the United States.

Conclusion

Public health laboratories and clinical laboratories are better equipped now to implement biosafety practices and address biosafety concerns than before the EVD outbreak. In 3 years, the ELC Enhanced Laboratory Biosafety Capacity Project established an important framework for addressing biosafety and elevated the importance of biosafety in laboratories. Challenges in addressing biosafety still exist; results suggest we need more attention and work to address gaps in the clinical laboratory community. Nevertheless, these results emphasize the importance of preserving the biosafety officer position in PHLs to help promote a culture of biosafety in their laboratories and with their clinical laboratory partners. With continually evolving technologies and emerging/reemerging threats, building a strong biosafety program requires a continuous and iterative process rather than a finite effort. Both PHLs and clinical laboratories should collaborate to strengthen biosafety practices and ensure the United States remains safely prepared for future public health responses.

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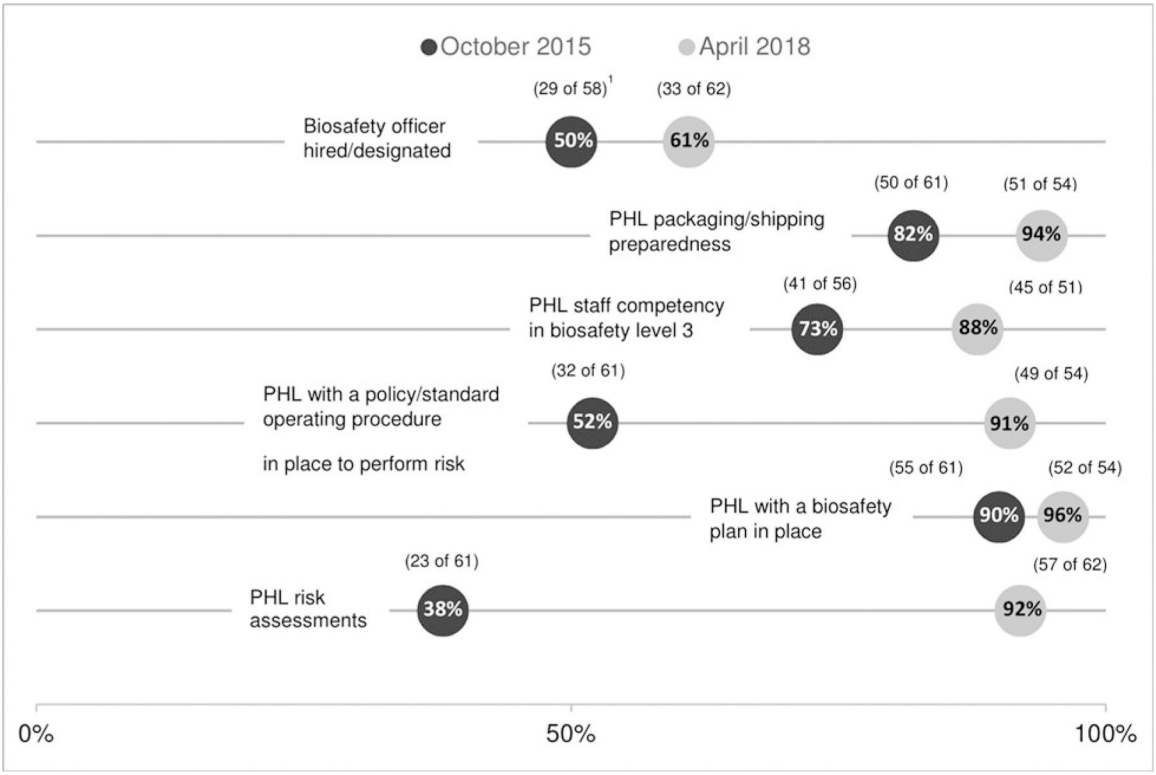

Figure 1.

Percentage of awardees that met indicator targets for their public health laboratory (PHL) for the Enhanced Biosafety Capacity Project, October 2015 and April 2018. Of 62 awardees, only 58 responded during initial phone calls about biosafety officer staffing.

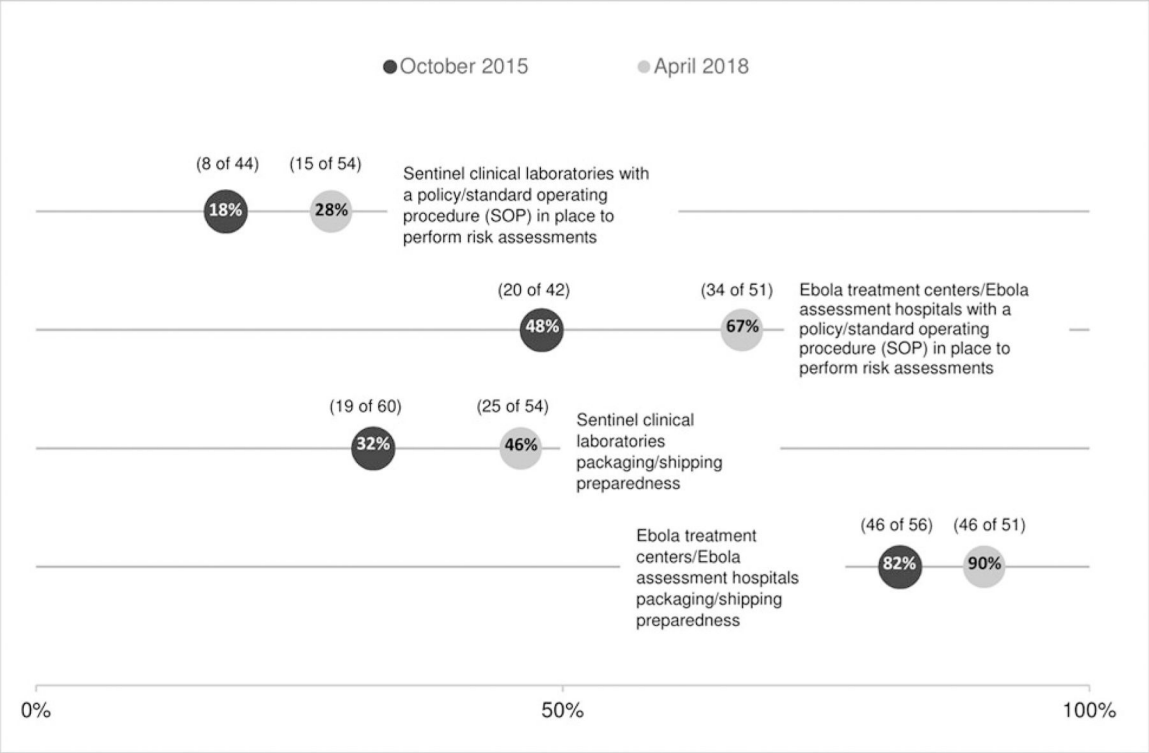

Figure 2.

Percentage of awardees that met targets for the network of sentinel clinical laboratories, Ebola treatment centers, and Ebola assessment hospitals in their jurisdiction for the Enhanced Biosafety Capacity Project, October 2015 and April 2018.

Table 1.

Enhanced Laboratory Biosafety Capacity Project Indicators and Awardee Level 3-Year Targets for Public Health Laboratories and Sentinel Clinical Laboratory Partners, 2015–2018

Indicator Reference No.	Indicators for Public Health Laboratory (PHL) Performance	Targets	Reporting Frequency
1	PHL with biosafety officer	Biosafety officer hired/designated	Twice, at the initiation and conclusion of the study
2	PHL staff certification for packaging and shipping[a]	100% of public health laboratorians needed[b] to be certified to package/ship International Air Transport Association (IATA) Division 6.2 infectious substances (Categories A and B) are currently certified	6 months
3	PHL staff biosafety level 3 competency	100% of public health laboratorians that need to be competent to work in a biosafety level 3 laboratory are competent[c]	6 months
4	PHL laboratory risk assessment	By end of the 3-year project period:	6 months
		• At least 1 PHL biosafety risk assessment conducted for Ebola	
		• At least 1 PHL biosafety risk assessment conducted for another highly infectious disease	
		If unacceptable risks were found:	
		• Improvement plan developed to address unacceptable risks	
		• Mitigation measures implemented for gaps found	
5	PHL biosafety plan	• PHL has biosafety plan in place	12 months
		• Reviewed plan on an annual basis	
		• PHL communicated guidelines to necessary staff	
		• PHL's biosafety plan ensures/provides at least annual access to biosafety training for all employees	
6	PHL has a written policy and/or a standard operating procedure (SOP) in place to perform risk assessments	PHL has a written policy and/or SOP in place to perform risk assessments	6 months
7a, 7b	Sentinel clinical laboratory has a written policy and/or an SOP in place to perform risk assessments	≥70% of sentinel clinical laboratories in awardee's jurisdiction will have a written policy and/or an SOP in place to perform risk assessments	6 months

Indicator Reference No.	Indicators for Public Health Laboratory (PHL) Performance	Targets	Reporting Frequency
		100% of Ebola treatment centers/Ebola assessment hospitals (subset of sentinel clinical laboratories) will have a written policy and/or an SOP in place to perform risk assessments	
8a, 8b	Sentinel clinical laboratory packaging and shipping preparedness	≥80% of sentinel clinical laboratories in awardee's jurisdiction in which at least 2 staff members are certified in packaging/shipping of IATA Division 6.2 infectious substances (Categories A and B)	6 months
		100% of Ebola treatment centers/Ebola assessment hospitals will have at least 2 staff members certified of IATA Division 6.2 infectious substances (Categories A and B)	
9a, 9b	Sentinel clinical laboratory risk assessments	By end of the 3-year project period: ≥80% of sentinel clinical laboratories in each jurisdiction have completed at least 1 risk assessment	6 months
		100% of Ebola treatment centers/Ebola assessment hospitals in each jurisdiction have completed at least 1 risk assessment	

[a]The recommended minimum number of public health laboratorians needed to package/ship IATA Division 6.2 infectious substances (Category A) per laboratory is 2.

[b]Sufficient/needed number deemed by PHL; the recommended minimum number of public health laboratorians needed to package/ship IATA Division 6.2 infectious substances (Categories A and B) per PHL is 2.

[c]A demonstration of competency refers to passing an assessment after training has been conducted. Training could be conducted in-house or through a recognized biosafety training entity. A demonstration of competency could be based on existing standards that the PHL uses to demonstrate competency (eg, observance, performance evaluation, test, etc) for working in a BSL-3 lab. See Guidelines for Biosafety Laboratory Competency: http://www.cdc.gov/mmwr/pdf/other/su6002.pdf.

Table 2.

Median Percentages and Ranges of Distributions for Quantitative Indicators for Public Health Laboratories and Sentinel Clinical Partners Among Awardees (n = 61) in the Enhanced Laboratory Biosafety Capacity Project, October 2015 and April 2018

Indicator Reference No.	Indicator	October 2015		April 2018		Awardee-Level Target
		Median % (Range)		Median % (Range)		
2	Public health laboratories (PHL) packaging and shipping preparedness[a]	150	(33–1,800)	227	(77–12,150)	100
3	PHL staff competency in biosafety level 3 (BSL-3)[b]	100	(25–1,300)	100	(22–7,100)	100
7a	Sentinel clinical laboratories with a policy/standard operating procedure (SOP) in place to perform risk assessments	8	(0–100)	54	(0–100)	70
7b	Sentinel clinical laboratories (Ebola treatment centers/Ebola assessment hospitals only) with a policy/SOP in place to perform risk assessments	69	(0–100)	100	(0–100)	100
8a	Sentinel clinical laboratories packaging and shipping preparedness	66	(0–100)	78	(26–100)	80
8b	Sentinel clinical laboratories (Ebola treatment centers/Ebola assessment hospitals only) packaging and shipping preparedness	100	(0–100)	100	(44–100)	100
9a	Sentinel clinical laboratories risk assessments	17	(0–100)	30	(0–100)	N/A
9b	Sentinel clinical laboratories (Ebola treatment centers/Ebola assessment hospitals only) risk assessments	73	(0–100)	60	(0–100)	N/A

[a] Values are often over 100%, as laboratories may have more staff certified in packaging and shipping and demonstrating competency in BSL-3 than needed.

[b] A demonstration of competency refers to passing an assessment after training has been conducted. Training could be conducted in-house or through a recognized biosafety training entity. A demonstration of competency could be based on existing standards that the PHL uses to demonstrate competency (eg, observance, performance evaluation, test, etc) for working in a BSL-3 lab. See Guidelines for Biosafety Laboratory Competency: http://www.cdc.gov/mmwr/pdf/other/su6002.pdf.