Culture Shift: Strengthening Biosafety and Biosecurity in Laboratories
A Report of the 2017 APHL Biosafety and Biosecurity Survey
ACKNOWLEDGMENTS

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Vietnam Director of Biosafety Thuy Nguyen (left) and APHL staff member Sean Page engage in the Single Overriding Communication Objective (SOCO) exercise—a communication technique used to establish a main message during an interview—at a Biosafety Officer Leadership Workshop

Cover photo: Maureen Sullivan from the Minnesota Department of Health Public Health Laboratory processes specimens in Class II Biological Safety Cabinet
EXECUTIVE SUMMARY

The ability to safely work with high consequence and emerging pathogens is a critical necessity for laboratories. Recent lapses in institutional biosafety and responses to emerging infectious diseases revealed gaps and deficiencies in the biosafety apparatus. Highly publicized laboratory accidents involving biological agents at multiple US government institutions and exposures related to new technologies have placed a spotlight on biosafety and biosecurity practices in laboratories. In order to close these gaps, the Association of Public Health Laboratories (APHL) partnered with the US Centers for Disease Control and Prevention (CDC) in a three-year program to strengthen the culture of safety of US public health and clinical laboratories.

APHL, with the support of CDC funding, conducted an initial survey in spring 2016 of 110 state, local territorial and US Affiliated Pacific Islands (USAPI) public health laboratories to identify biosafety and biosecurity practices and gaps. Subsequently, in the fall of 2017, APHL conducted a follow-up survey to examine progress and remaining gaps. This report focuses on the status of biosafety and biosecurity in the public health laboratories that received funding via the CDC Domestic Ebola Supplement to the Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) Cooperative Agreement.

Key findings from the second survey revealed that public health laboratories:

- continue to utilize CDC funding to strengthen internal biosafety and biosecurity programs. Successes include hiring full time biosafety officers (BSOs) maintaining and enhancing their risk assessment process, attending trainings and building a culture of biosafety within their institutions
- rely on APHL for technical assistance and biosafety training resources including leadership development workshops, peer-to-peer mentoring and discussion forums
- face challenges in implementing external biosafety and biosecurity efforts, specifically outreach to clinical laboratories
- face challenges in gaining buy in for biosafety from clinical and public health laboratory leadership

The threat of federal funding elimination to support biosafety and biosecurity programs has jeopardized the ability of public health laboratories to retain skilled BSOs and outreach staff. Biosafety and biosecurity programs urgently need dedicated sustainable funding to ensure the upkeep of safe and secure practices in facilities across the nation, professional development opportunities for laboratorians beyond technical competency, a strong community of practice to foster learning, networking with other laboratory professionals, and information sharing.
INTRODUCTION

Public health laboratories protect the public’s health by providing services to prepare for and respond to all-hazard threats—biological, chemical and radiological—as well as emerging infectious diseases and natural disasters. The ability of a public health laboratory to effectively respond to threats is rooted in its infrastructure—that is, a highly skilled workforce, modern equipment and advanced technologies, safe and secure facilities and electronic systems to quickly send test results. At the core of this effective response is a robust quality management system (QMS) with biosafety and biosecurity practices vital to every function. US laboratories rely on the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) for guidance on biosafety and biosecurity activities. The *BMBL 5th Edition* defines biosafety and biosecurity as:

“Biosafety programs reduce or eliminate exposure of individuals and the environment to potentially hazardous biological agents. Biosafety is achieved by implementing various degrees of laboratory control and containment, through laboratory design and access restrictions, personnel expertise and training, use of containment equipment, and safe methods of managing infectious materials in a laboratory setting.

*The objective of biosecurity is to prevent loss, theft or misuse of microorganisms, biological materials and research-related information. This is accomplished by limiting access to facilities, research materials and information. While the objectives are different, biosafety and biosecurity measures are usually complementary.*”

The ability to safely work with high consequence and emerging pathogens is a critical necessity for laboratories. Recent lapses in institutional biosafety and responses to emerging infectious diseases revealed gaps and deficiencies in the biosafety apparatus. Moreover, highly publicized laboratory accidents in biosafety involving biological agents at multiple United States government institutions and exposures related to new technologies have placed a spotlight on biosafety and biosecurity practices in laboratories. In order to close these gaps, APHL partnered with CDC in a three-year program to strengthen the culture of safety of the US public health and clinical laboratories. CDC utilized the following funding mechanisms to support strengthening biosafety:

1. **Via the Hospital Preparedness Program (HPP) and Public Health Emergency Preparedness (PHEP) Supplemental for Ebola Preparedness and Response Activities and the Domestic Ebola Supplement to the Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) Cooperative Agreements, Building and Strengthening Epidemiology, Laboratory and Health Information Systems Capacity in State and Local Health Departments,** CDC is collaborating with state and local public health agencies to strengthen healthcare infection control practices, enhance laboratory biosafety and biosecurity practices and enhance surveillance of migrant populations and international travelers. Via the ELC Domestic Ebola Supplement, CDC provided $24.1 million (as part of the $1.77 billion appropriated by Congress to the CDC) to 62 state, local (District of Columbia, Los Angeles County, Houston, New York City and Philadelphia) and territorial health departments with the goal to support public health departments and their clinical partners in assessing, developing and implementing measures to improve laboratory and biological safety practices for dealing with current and emerging infectious diseases. CDC anticipated the following outcomes:
   - more trained staff knowledgeable in working with infectious organisms and other emerging pathogens of public health concern
   - improved biosafety practices for handling/processing Ebola and other highly infectious specimens at public health and clinical labs
   - better coordination of biosafety practices between public health labs and clinical partners
   - labs better equipped to serve jurisdiction in the inactivation and disposal of specimens and other laboratory waste from suspected Ebola or other highly infectious agents
2. In May 2015, CDC via the Domestic Laboratory Biosafety for Ebola and other Highly Infectious Diseases, CDC-Request for Applications (RFA)-OE15-1504, provided $2.2 million over a three year period to APHL to (a) Enhance Public Health Laboratory Biosafety Capacity and (b) Improve Laboratory Coordination and Outreach. Over the three year funding period, APHL has strengthened biosafety across US laboratories by coordinating with CDC, state, local, territorial and USAPI health departments and other partners to review biosafety practices, address identified gaps, create a biosafety community of practice, and develop and promote tools to help laboratorians improve biosafety practices with the overall goal to enhance the culture of biosafety. APHL has also assisted public health laboratories with performing outreach to clinical laboratories.

APHL, with the support of CDC funding, conducted an initial survey in the spring of 2016 of 110 state, local territorial and USAPI public health laboratories to identify biosafety and biosecurity practices and gaps. Subsequently, in the fall of 2017, APHL conducted a follow-up survey to examine progress and remaining gaps. This report focuses on the status of biosafety and biosecurity in the public health laboratories that received funding via the CDC Domestic Ebola Supplement to the ELC Cooperative Agreement.

METHODS

In fall 2017, APHL launched its 2017 Biosafety and Biosecurity Survey to public health laboratories requesting information on biosafety and biosecurity activities. The survey, which covered March 2016 to September 2017, was distributed to 64 public health laboratories via email. A unique survey link, along with a copy of the full survey, was sent to all 50 state public health laboratories and the District of Columbia, Chicago, Houston, Los Angeles County, New York City, Philadelphia, American Samoa, Federated States of Micronesia, Guam, Marshall Islands, Northern Mariana Islands, Palau, Puerto Rico and US Virgin Islands public health laboratories.*

The City of Chicago combined its responses with the state of Illinois, thus for purposes of this report the total sample size is 63. Of the 63 public health laboratories surveyed, 55 responded for an overall response rate of 87.3%. Respondents encompassed 48 state, four territorial and three local public health laboratories. Data was collected using Qualtrics®, a web-based survey tool and data repository.

The 2017 APHL Biosafety and Biosecurity Survey Summary Data Report presents aggregate survey assessment results for all questions. Descriptive statistics were gathered for the following categories:

- Funding
- Workforce
- Biosafety Competencies
- Risk Assessments
- Biosafety/Biosecurity Drills or Exercises
- Clinical Laboratory Outreach
- Training and Related Resource Needs

* In addition to the 62 public health laboratories funded via the CDC Domestic Ebola Supplement to the ELC Cooperative Agreement, APHL included Marshall Islands and Palau in this survey as these jurisdictions received biosafety funding from other CDC sources.
KEY FINDINGS

WORKFORCE

Laboratories are responsible for protecting workers from exposure to infectious and hazardous agents and local communities from accidental or intentional release of such agents. It is essential that laboratory staff at all levels possess the necessary skillset to safely work in the laboratory. Prior to 2015, many public health laboratories had lost or combined the functions of their BSO position, leading to a burdensome amount of responsibility on an already-stressed workforce. Moreover, staff often lacked training in biosafety and biosecurity practices, which some perceived as an impediment to productivity. With the CDC Domestic Ebola Supplement to the ELC Cooperative Agreement funding, public health laboratories were able to hire laboratory staff dedicated to biosafety and biosecurity—a designated BSO and/or Biosafety Outreach Officer (BOO).

These biosafety professionals still face numerous challenges such as buy in from colleagues on the importance of strengthening the biosafety culture. BSOs have many roles in the laboratory including maintaining and enhancing the biosafety and biosecurity programs within their institutions, providing guidance to clinical laboratories to assist with risk assessments and other safety practices as well as developing trainings and resources for public health laboratories and clinical laboratories. In a relatively short time period, many BSOs have made enormous strides to review and improve practices and policies in both their institution and clinical laboratories within their jurisdictions.

Fifty-one public health laboratories (92.7%) have a full time BSO in place. However, more than 80% of these BSOs in public health laboratories have been in their role for less than three years. Given that the majority of BSOs are still relatively new to their role, they are heavily focused on strengthening biosafety within their institutions. Much more remains to be done with external outreach to clinical laboratories. Forty-four public health laboratories (86.3%) dedicated less than half of their time reaching out to clinical laboratories.

Fifty-three public health laboratories (96.4%) indicated that they are aware of the APHL/CDC-developed Competency Guidelines for Public Health Professionals and Guidelines for Biosafety Laboratory Competency. However, only 26 public health laboratories (47.3%) have developed safety specific competencies for their laboratory staff. Public health laboratories which have not developed these competencies noted that they experienced time constraints and were unable to implement these competencies.

APHL Activities to Strengthen the Biosafety Workforce

Under the leadership of its Public Health Preparedness and Response program and Biosafety and Biosecurity Committee, APHL is working with public health laboratories and partners across the globe to develop and share readily accessible biosafety resources such as risk assessment templates, biorisk management frameworks, site visit tools and other resources.
checklists. APHL has also focused on building a stronger biosafety community by providing the following programs:

**Biosafety Peer Network**

Established in 2016, the Biosafety Peer Network aims to strengthen biosafety and biosecurity by connecting state, local, and territorial public health laboratories and laboratories in the USAPI to facilitate mentoring and information sharing among BSOs. The exchange is expected to advance and harmonize biosafety and biosecurity in laboratories while fostering a collaborative community, and ultimately improving public health laboratory biosafety and biosecurity nationwide. Over a two-year period, 24 public health laboratories successfully participated in the Biosafety Peer Network, describing the invaluable experienced gained from observing their colleagues and practices in other comparable institutions.

**Strengthening Biosafety Across the Pacific: Hawaii and Guam**

Due to their rather secluded locations, USAPIs tend to have laboratory issues unique to their geographic region. Therefore, during the application process for the Biosafety Peer Network, APHL endeavored to garner interest from BSOs in USAPI public health laboratories. For the Biosafety Peer Network Year 1 Cohort, the Hawaii (HI) State Laboratory Division was paired with the Guam (GU) Public Health Laboratory to promote mentorship and standardization of biosafety practices across the Pacific Ocean.

For the first half of the exchange, GU BSO Anne Marie Santos traveled to the HI State Laboratory Division. As she arrived at the lab and proceeded to sign into the lab’s Visitor Log Book, Anne was greeted with a warm “Aloha” by HI BSO Paul Fox and Acting Laboratory Director Rebecca Sciulli. As a relatively new BSO, Anne learned from Paul and Rebecca about establishing strong biosecurity measures, effective sentinel clinical laboratory outreach strategies and improving Guam’s competency assessments and biosafety trainings. One of the key lessons Anne took away from this experience was “repetitive training and demonstrated competency ensures proficiency.”

Following the completion of the GU staff visit, HI staff Paul Fox and Rebecca Sciulli traveled to Guam to learn about biosafety practices and lend their expertise where needed. During the site visit, Paul and Rebecca worked with Anne to develop standard operating procedures on building and sustaining a culture of safety within the Guam Public Health Laboratory. By working together, the trio was able to share ideas to strengthen the lab’s Biosafety Manual. On the final day, the HI staff performed a risk assessment using the APHL Biosafety Checklist to
provide constructive feedback. Overall, the Hawaii lab staff felt the visit was “informative and productive and we look forward to Guam sending us their new Biosafety Manual for review in a few months.”

The story of Hawaii-Guam exchange is featured in the Lab Culture podcast What is the Biosafety Peer Network?

**Minnesota Warms Up in Delaware**

As a participant in any new program, it is normal to have a healthy level of skepticism. When the Delaware (DE) Public Health Laboratory was selected as a member of the Biosafety Peer Network Year 2 Cohort, DE BSO Marion Fowler felt concerned that “she didn’t have enough time for another meeting” and worried that since Delaware is a rather small laboratory, it would not be able to offer similar experiences that larger laboratories provided. On the other hand, Eric Lundquist, Minnesota (MN) BOO, expressed excitement to tackle on this new experience.

The first portion of the exchange involved the MN BOO visiting Delaware. While touring the public health laboratory, Eric discovered the laboratory had an excellent Safety Committee. Upon returning to Minnesota, Eric followed Delaware’s example by collaborating with Bonita Bryant and other staff to form a Safety Task Force which meets monthly and includes representatives from each lab section. The Task Force addresses safety topics and proposes solutions which are submitted to leadership for review and approval.

A couple of months later, the DE BSO visited the MN Public Health Laboratory. During her site visit, Marion encountered an unexpected benefit from the exchange: they were invited by the staff of the National Ebola Training and Education Center (NETEC) to visit the University of Minnesota Medical Center and attend their full scale exercise. By participating, Marion was able to witness a site assessment of an Ebola Treatment Center and gather pertinent information for the benefit of Delaware.

By the end of their journey together, Marion expressed that “this was one of the best learning experience in 40+ years of my career. [Due to the very nature of the twinning program], the sharing of BSO experiences, procedures and testing experiences ended up working both ways. In effect, there were six total days of learning experiences!”

**COLLABorate**

In 2015, APHL launched a Listserv® which has now transitioned to the Biosafety and Biosecurity ColLABorate Community for BSOs across public health laboratories. Today, more than 140 biosafety professionals across US public health laboratories participate on this platform where they exchange information with their peers. In fact, it is one the most active discussion forums across APHL with 48 public health laboratories (94.1%) utilizing APHL’s ColLABorate Platform as a biosafety resource for guidance and assistance (See Figure 1).
Given the success of this platform and a request from clinical partners, in 2018, APHL launched a new communication platform community called Laboratory Biosafety and Biosecurity CoLABorate which serves as an online forum for engaging over 160 public health professionals and non-public health members.

There is still much to be accomplished for biosafety professionals in the laboratory workspace. Given the specific scientific background needed for this area, there is no projected path for professional careers in biosafety and biosecurity in current course curricula across the US. As the American Biological Safety Association (ABSA) states in their *Biosafety Curriculum for Undergraduate and Graduate Students*, “Many undergraduates, and even graduate students, lack rigorous instruction in biological safety. They don’t understand the risk present in the laboratory or how to protect themselves from those risks.” There needs to be an effort in developing and including more biosafety curriculum in current programs both at an undergraduate and graduate level to build on the concept of safe and secure practices in all laboratories and establishing a career ladder for those interested in pursuing a career in laboratory biosafety.

Aside from building a specific biosafety curriculum, there needs to be support from laboratory leadership for an effective biosafety system. Lack of leadership support for a robust biosafety program hinders the performance and operation of an entire laboratory. Learning from previous events like Ebola and Zika, there needs to be staff devoted to ensuring safety in the laboratory. These leaders must continue to advocate for dedicated biosafety personnel to remain employed in our nation’s laboratories and ensure these personnel have access to professional trainings to continue to build their biosafety expertise and overall career development in the public health laboratory system.

**TRAINING**

To build and promote the culture of biosafety, training is a critical pillar for all laboratory staff. Traditionally, training is focused on strengthening the technical skills of laboratorians as seen in Table 1.

<table>
<thead>
<tr>
<th>Table 1: Training Courses Completed by BSOs</th>
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<tr>
<td><strong>n</strong></td>
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<tr>
<td>Bloodborne Pathogens</td>
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<tr>
<td>Personal Protective Equipment (PPE)</td>
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<td>Biological Risk Assessment</td>
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With specialized trainings, BSOs used their expertise in real time to mitigate possible hazards in the laboratory when performing a risk assessment. **Fifty-two (94.5%) public health laboratories performed risk assessments between March 2016 and September 2017.** Of these, 34 laboratories identified significant gaps and also took steps to mitigate the gaps.

With the unique role of BSOs—a hybrid of science, policy and practice—there is a need for training beyond technical laboratory procedures. Training must focus on the technical aspects of biosafety as well as leadership skills including change management, communications and storytelling, community outreach and network building, educational advocacy, and public policy. With this foundation, BSOs in public health laboratories can develop into laboratory leaders.

### APHL Activities to Strengthen Biosafety Leadership

BSOs rely heavily on APHL for biosafety training courses. **Forty-six public health laboratories (90.2%) used APHL courses for developing BSOs knowledge, skills and abilities.** With the assistance of the Biosafety and Biosecurity Committee, APHL developed courses, tools and other resources for BSOs across the country.

#### Leadership Workshops

Due to an ever changing and increasingly complex environment, public health laboratories need biosafety leaders who embrace change, manage people and processes efficiently and anticipate future needs. In collaboration with APHL’s Training and Workforce Development and Public Policy Departments, the Public Health Preparedness and Response Department developed a four-day workshop for BSOs which offered skill development sessions on leadership, project management, public policy, communications, training program development and implementation of evaluation measures.

This workshop convened BSOs by region and provided a forum which encouraged personal and professional growth with the overall goal to strengthen leadership skills. Upon completion of the workshop, participants gained an invaluable...
network and a broader skill set that directly benefits the individual, the host laboratory and, ultimately, the greater public health laboratory system.

During the four-day workshop, participants enjoyed participating in several group interactive and didactic exercises, including Exemplary Leadership, Affinity Exercise, and Single Override Communication Objective (SOCO). By the end of the week, attendees expressed they were leaving the workshop with more confidence, new communication and leadership tools to bring back to their lab staff, a fresh understanding of effective communication, persuasion and connecting stakeholders under the mission of upholding biosafety and biosecurity practices.

“I plan to use Responsible-Accountable-Consulted-Informed (RACI) charts in project management areas in the workplace. This will help with defined roles and responsibilities.”

“Helped focus the biggest challenges facing BSOs and provided opportunities to network and build relationships with peers.”

“The SOCO training was very effective in identifying communication strengths and weaknesses.”

BioSafe360® Program
APHL partnered with Sean Kaufman, founder and Chief Executive Officer of Behavioral-Based Improvement Solutions, to offer a unique program to public health laboratories. BioSafe360® is a remote-based program designed to engage BSOs and other biosafety professionals as well as support the implementation of biosafety strategies and programs. In addition, the program is designed to develop their cognitive and applied biosafety skills, with the goal of transforming BSOs and other biosafety professionals into laboratory leaders. Since its introduction in 2016, the APHL-funded program has engaged 160 biosafety professionals in the US and globally.

Following a monthly format, each module is delivered by biosafety and biosecurity leaders from organizations such as the American Society for Microbiology (ASM), CDC, APHL, public health laboratories and other entities. One module that showcased the impact of biosafety culture was Controlling Human Factors. The module discussed the blending of leadership, workforce and safety into the “one safe” culture. The key activity required participants to study cell phone usage in their laboratory by randomly selecting peers and swabbing their phones to test for the presence of microorganisms. Alarmingly, participants discovered that a variety of microorganisms, including *Micrococcus luteus* and *Corynebacterium amylolactis*, grew on agar plates. As a result, some participants decided to address their laboratory’s leadership on changing the cell phone usage policy.

Assistant Director Alana Sterkel of Wisconsin State Laboratory of Hygiene isolated a number of microorganisms from a colleague’s cell phone as part of an assignment for BioSafe360.
Table 2: Training Courses Offered by APHL BioSafe360° Program

<table>
<thead>
<tr>
<th>BioSafe360° Program Year 1 Courses</th>
<th>BioSafe360° Program Year 2 Courses</th>
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<tr>
<td>Four Primary Controls of Biosafety and Biosecurity</td>
<td>Biological Risk Mitigation</td>
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<tr>
<td>Applied Biosafety and Biological Risk Mitigation</td>
<td>CDC Training Support Services and Biorisk Management</td>
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<tr>
<td>Risk Assessment Process</td>
<td>Importance of Occupational Health Programs</td>
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<tr>
<td>Biosafety Guidelines: 5th Edition of BMBL</td>
<td>The Benefits of Select Agent Program Development</td>
</tr>
<tr>
<td>Developing and Sustaining a “One-Safe” Culture</td>
<td>21st Century Challenges for Public Health Laboratories</td>
</tr>
<tr>
<td>Evaluating and Validating Standard Operating Procedures</td>
<td>The Practice of Ethics in Biosafety</td>
</tr>
<tr>
<td>Laboratory Emergency Preparedness</td>
<td>Blending Silos between Healthcare Providers and Clinical Microbiologists</td>
</tr>
<tr>
<td>Biosafety Cabinets</td>
<td>Biosafety Research Needs and Cost Benefit Analysis</td>
</tr>
<tr>
<td>Medical and Incident Surveillance Programs</td>
<td>Controlling Human Risk Factors with a “ONESAFE” Culture</td>
</tr>
<tr>
<td>Biological Waste Management</td>
<td>Effective Training Strategies for Biosafety</td>
</tr>
<tr>
<td>The Philosophy of Leadership and Human Risk Factors</td>
<td>Laboratory Emergency Preparedness and Response</td>
</tr>
</tbody>
</table>

"Without the support of the CDC/APHL biosafety and biosecurity program, I would never have been able to meet so many people in such a short time and so early in my career, nor would I have received the quantity or quality of training made possible by the program." --Drew Fayram, MS, safety officer, State Hygienic Laboratory and the University of Iowa.

National Laboratory Training Conference (NLTC) IV: In 2017, APHL’s Training and Workforce Development program and CDC convened NLTC IV for training coordinators and BSOs from public health laboratories to facilitate outreach and the exchange of training ideas.

Several biosafety training efforts face the limitation of in-person events where they only reach those professionals present. Due to the lack of staff time and funds to attend multiple training courses, it becomes imperative that BSOs use a “train the trainer” approach to colleagues and other biosafety professionals who lack the time and resources to attend them. BSOs also face challenges when trying to find training opportunities outside of the standard scope of biosafety. It is essential that the scope of BSO trainings are expanded beyond the technical aspects of biosafety and biosecurity in order for BSOs to perform effectively in the laboratory as well as when they perform visits and conduct trainings with clinical laboratories.

CLINICAL LABORATORY OUTREACH

“I personally would say...the biggest value [of the CDC/APHL Biosafety and Biosecurity Program] has been keeping biosafety and emerging pathogens on our radar so we don’t just forget about such things until we are faced with SARS, Monkey Pox, MERS, Ebola, etc.” --Raymond P. Podzorski, PhD, D(ABMM), microbiologist, St. Mary’s Hospital Laboratory, Wisconsin Region SSMHealth

A competent biosafety workforce is crucial for the maintenance of the public health laboratory system—that is, safety from the patient level (clinical) to the broader population (public health). As discussed earlier, one of
the key activities funded through the CDC Domestic Ebola Supplement to the ELC Cooperative Agreement was outreach by public health laboratories to sentinel clinical labs. The Centers for Medicare and Medicaid Services (CMS) regulates all laboratory testing performed on humans through the Clinical Laboratory Improvement Amendments (CLIA). In total, CLIA covers approximately 260,000 laboratory entities. Public health laboratories identify a subset of these 260,000 laboratories and engage them to (1) provide guidance on packaging and shipping of samples; (2) provide training and guidance on rule out and/or referral of biothreat and other agents; (3) share resources for performing risk assessments and developing biosafety/biosecurity (biorisk management) plans; and (4) maintain strong relationships to ensure rapid detection and response to all threats.

The [APHL-CDC-ASM](#) defines a laboratory as a “sentinel clinical laboratory” when:

> “The laboratory is certified to perform high complexity testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) by CMS for the applicable Microbiology specialty or the laboratory is a Department of Defense (DoD) Laboratory certified under the DoD Clinical Laboratory Improvement Program or the laboratory is a veterinary medical diagnostic laboratory that is fully accredited by the American Association of Veterinary Laboratory Diagnosticians (AAVLD). Laboratory in-house testing includes Gram stains and at least one of the following: lower respiratory tract, wound or blood cultures.”

The CDC ELC definition of a sentinel clinical laboratory encompasses laboratories which meet the APHL-CDC-ASM definition as well as laboratories that test or refer specimens that may contain Ebola virus or other emerging highly infectious disease pathogens. These laboratories may be located in designated Ebola treatment centers, Ebola assessment hospitals and front line healthcare facilities such as acute care hospitals, critical access hospitals and urgent care clinics that perform or send out infectious disease testing. Across the US, there are thousands of clinical laboratories which perform tests of varying complexities. Fifty-five public health laboratories noted that they have 5,249 clinical labs which meet the definition of a sentinel clinical laboratory or were considered a clinical laboratory for outreach purposes. Public health laboratories utilized various forms of communication to reach these clinical laboratories (Figure 2).

BSOs in public health laboratories are seen as the subject matter experts for the clinical laboratories within their jurisdictions and have been able to provide multiple training courses and workshops; risk assessment templates and onsite risk assessments. Forty-seven public health laboratories (85.4%) reported visiting 730 clinical laboratories.
Strengthening Biosafety Across New Jersey

In fall 2017, the New Jersey Public Health and Environmental Laboratories (NJPHEL) facilitated one-day biosafety workshops at three hospitals which competed for and were awarded as host sites for the workshops. With the assistance of a biosafety committee consisting of NJPHEL biosafety experts and APHL staff, the agenda was designed based on data collected from biannual laboratory preparedness surveys. The workshop highlighted the three Ebola hospitals’ response plans and the use of PPE, donning and doffing drills and the use of Glo Germ™, a tool to demonstrate handwashing, surface cleaning, hygiene and containment techniques. A risk assessment exercise was conducted during the workshop using laboratory work hazards, human risk factors and the perceived awareness of biosafety hazards in clinical laboratories.

Based on pre- and post-test results and participants feedback, the workshops were highly valued by the participants. Unanimously, all 87 participants which included laboratory directors, managers, supervisors and bench technicians agreed that the presentations, drills and the risk assessment exercise provided real-time feedback and information that may be used to improve existing biosafety programs.

Prior to the workshops, in 2016, only 23% of NJ clinical laboratories had performed an internal risk assessment and only 58% had developed a biosafety plan. Following the workshops, in 2018, 64% of clinical laboratories had performed an internal risk assessment while 76% had developed a biosafety plan.

Once the workshops concluded, the Biosafety Outreach team at NJPHEL conducted site visits to the laboratories that were unable to participate in the workshops and provided them with resources from the workshops including templates and support documents on flash drives.

Engaging Clinical Laboratories Across Idaho

Idaho Bureau of Laboratories (IBL) accomplished several sentinel clinical lab outreach activities as a result of CDC Domestic Ebola Supplement to the ELC Cooperative Agreement. One activity executed was a workshop curriculum on lab safety. Topics included biological and chemical safety practices, hazard risk management program and risk assessments, proper use of BSCs, selection and safe use of PPE, and an overview on packaging and shipping infectious substances. During 2017-2018, over 70 sentinel clinical lab staff and epidemiologists participated in seven workshops across northern, central and southern Idaho.

As stated in their evaluations, attendees found the workshop useful in providing implementation steps to improve a culture of safety in their labs.

In 2016-2017, IBL conducted a voluntary Category A packaging and shipping exercise with 16 Idaho hospital labs to evaluate their ability to correctly package and ship infectious substances. This exercise revealed that some sentinel clinical labs lacked adequate training and experience to properly package and ship infectious substances. To address this, IBL has since delivered five workshops on this topic and has trained over 50 individuals to become certified by their employer to correctly package and ship infectious substances. IBL also routinely evaluates packages sent from sentinel clinical sites and provides feedback to submitters to improve compliance with federal shipping regulations.

To date, IBL staff have visited approximately 50 sentinel labs across the state and distributed safety equipment such as Glo Germ™ kits to visualize effective hand washing, Wizard fog generator sticks to visualize BSC airflow.
and OSHA-compliant secondary containers (e.g., bleach squirt bottles). Conversations ranged from brief to in-depth on lab safety practices in each facility.

These federally-funded activities have improved communications and professional relationships with sentinel clinical labs as well as provided workforce development opportunities to improve laboratorian safety. Unfortunately, with the federal funding no-cost extension slated to end in March 30, 2019, IBL will not be able to continue funding a part-time Health and Safety Specialist position to assist the IBL safety officer in continuing these outreach activities. Regardless of current funding levels, IBL intends to continue offering annual workshops across the state on lab safety and packaging and shipping infectious substances, including offering another Category A packaging and shipping drill in the coming year.

As technology evolves and clinical laboratories move away from traditional methods (e.g. biochemical tests for microorganisms), laboratorians are faced with more exposures.9 Some states and cities have reported multiple exposures to Brucella in laboratories.10 Laboratories are faced not only with handling emerging biological pathogens but also a lack of guidance on decontamination of laboratory equipment and outdated practices which link biosafety to the agent rather than the methods used to detect the agent.

Public health laboratory BSOs regularly reach out to clinical laboratories to assist them with biosafety questions. Even though BSOs serve as a readily available resource for these laboratories, some clinical facilities have yet to fully endorse the importance of biosafety and biosecurity. Often, these laboratories have heavy workloads and rapid delivery of test results is seen as the main priority. Aside from workload, frequent turnover at clinical laboratories requires ongoing training to ensure that each laboratory has at least two staff able to package and ship highly infectious agents as well as staff versed in rule-out and referral methods. Another challenge facing BSOs in public health laboratories is the demand to engage with a higher number of clinical labs which may be geographically dispersed.

APHL Activities to Strengthen Public-Private Partnerships
APHL is engaged in several activities to strengthen public-private partnerships. The outreach efforts are far reaching and encompass diverse stakeholders.

Partners Forum
In 2016, APHL formed the Laboratory Biosafety and Biosecurity Partners Forum to facilitate information exchange among various federal partners and other stakeholders engaged in evaluating and improving clinical laboratory biosafety and biosecurity practices in the US. The forum convenes on an annual basis and invites 12 (or more) partners, including representatives from federal agencies as well as associations that represent and/or accredit clinical laboratories:

- APHL
- ASM
- American Association of Bioanalysts
- American Association for Clinical Chemistry
- ABSA
- American Society for Clinical Pathology
- CDC
- CMS
- Clinical Laboratory Management Association
- COLA (formed as the Commission on Office Laboratory Accreditation)
- College of American Pathologists
- US Food and Drug Administration
- The Joint Commission
This forum enabled key stakeholders to discuss policies, practices, gaps and improvements with the overall goal of sharing timely information to improve biosafety and biosecurity in the nation’s clinical laboratories. Since its inception, the efforts of these stakeholders and APHL are to further enhance biosafety and biosecurity in clinical laboratories through public health laboratory outreach and through direct action with the clinical laboratories.

Website and Online Training
APHL maintains all of its biosafety resources on www.aphl.org/biosafety which can be freely accessed by anyone. In collaboration with partners such as ASM and ABSA, APHL convenes webinars on topics such as “Practical Disinfection Guidance for the Clinical Laboratory” intended for both public health and clinical laboratory biosafety professionals. This particular webinar reached over 500 participants from across the country including laboratory directors, BSOs and bench technologists. APHL plans to conduct similar trainings in the future.

Laboratory Preparedness Exercise: APHL, CDC and CAP Partnership
APHL has a long-standing collaboration with the College of American Pathologists (CAP) and CDC to issue the Laboratory Preparedness Exercise (LPX), a semiannual challenge in which laboratories are sent live organisms that may exhibit characteristics of bioterrorism agents and are directed to follow the ASM Sentinel Clinical Laboratory Protocols for Suspected Biological Threat Agents and Emerging Infectious Diseases. APHL’s role in the LPX encompasses reviewing the kit instructions and results form prior to distribution of the exercise; sharing aggregate data and sharing jurisdiction specific results for each state with the public health laboratory directors and key training staff; and contributing to the final critique and participant summary. APHL uses this opportunity to help guide state public health laboratories in identification of training needs and other difficulties encountered by sentinel clinical laboratories in working with potential biothreat agents.

Member Expertise
In addition to the Biosafety and Biosecurity Committee, APHL is comprised of other committees that support work to enhance safety practices within all laboratories. For example, the APHL Sentinel Laboratory Partnerships and Outreach Subcommittee (SLPOS) provides guidance to public health laboratories to enhance and maintain vital relationships with sentinel clinical laboratories. The subcommittee provides direct feedback, data and recommendations to the Public Health Preparedness and Response Committee (PHPR) and, through the committee, informs relevant local, state and federal partner organizations of needs affecting sentinel laboratories.

Recent accomplishments of SLPOS include the release of the sentinel laboratory biothreat agent rule-out bench cards and biothreat identification poster, which are comprehensive preparedness resources that include information on biosafety, biological risk assessments and biothreat agent characterization for sentinel clinical laboratories. Through the committees and subcommittee, APHL is addressing the challenges of establishing a successful outreach program by developing a model that can be distributed to public health laboratories.

Federal Workgroups
APHL assisted CDC’s Division of Laboratory Systems (DLS) to form the Clinical Laboratory Partners Workgroup in June 2017. Meeting semiannually, this workgroup provides CDC and professional laboratory organizations such as APHL the opportunity to identify and address the needs of clinical and public health laboratories. Members of the group work to strengthen relationships and communications for preparedness and response, ensuring laboratory systems across the nation are adequately prepared to handle a challenging situation.

Biosafety Guidance for Clinical Laboratories
On the association level, APHL and ASM have recommended the inclusion of a new chapter on clinical laboratory safety in the BMBL 6th Edition. Due to the recent biosafety lapses that have been widely reported as well as biosafety concerns that have been raised in clinical and public health laboratories dealing with emerging infectious diseases, APHL and ASM requested the revision to better integrate and strengthen the practices of the clinical and public health diagnostic laboratories. The new edition is planned to be released in in early 2019.
Communication Platform for Biosafety Professionals

APHL maintains the Laboratory Biosafety and Biosecurity CoLABorate Community to facilitate information exchange among more than 160 clinical and public health laboratories to continue to foster this culture of biosafety and biosecurity.

Much of the feedback on public-private partnerships is filtered through public health laboratories and a patchwork of national organizations. As such, APHL actively engaged the Partners Forum and other stakeholders to develop a survey which will provide feedback on biosafety practices directly from clinical laboratories. In June 2018, APHL launched the Biosafety Practices and Needs in Clinical Laboratories Survey to thousands of US clinical laboratories to gather information on their institutional biosafety practices; linkages with public health laboratories; and unmet biosafety needs. Once APHL compiles the data, the information gathered will be used by APHL, CDC and other partners to prioritize and address the needs of the clinical laboratories. In a collaborative effort with CDC, APHL also plans to develop focus groups across the country to evaluate the status of outreach efforts to strengthen biosafety in sentinel clinical labs.

CONCLUSION AND FUTURE DIRECTIONS

With federal support, public health laboratories continue to make progress on strengthening biosafety and biosecurity in their institutions while engaging clinical labs. Training and outreach efforts require dedicated funding and skilled personnel. The threat of federal funding elimination further jeopardizes the ability of public health laboratories to retain BSOs and outreach staff.

US laboratory scientists are exposed routinely to hazardous pathogens, and the associated risks must not be ignored. The activities supported by APHL, CDC and other partners are critical to ensuring that the nation’s public health system safeguards the health of laboratory staff and their communities.

If biosafety and biosecurity programs are not continued, the US risks losing its investment in a safer laboratory system with the following consequences:

• Biosafety and biosecurity practices at clinical laboratories will devolve. Without the support of a BSO, clinical laboratories will not be able to keep pace with risks from emerging pathogens, toxic spills, contaminated foods and other evolving threats.

• Highly-skilled BSOs will be hired away by private firms. In the rapidly growing field of biosafety, professionals with this specialization are in high demand. If positions at public health laboratories are no longer available, biosafety officers will leave for positions in universities and research centers, leaving the public health system and its clinical laboratory partners without their expertise.

• Many clinical laboratories will not be able to package and ship infectious agents when the next emerging infectious disease reaches the US. Frequent turnover at clinical laboratories requires ongoing training to ensure that each facility has at least two staff able to package and ship highly infectious agents. Without access to regular training, clinical laboratories will quickly lose this capacity.

• The laboratory workforce will be vulnerable to absences from laboratory-acquired illnesses. The laboratory workforce is being depleted by retirements and a lack of professionals entering the field. Absences from laboratory-acquired illnesses could erode it further.
REFERENCES


7. Behavioral-Based Improvement Solutions, course information available at: http://www.saferbehaviors.com/


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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