Enhancing Biosafety and Biosecurity in the Nation’s Public Health Laboratories

A Report of the APHL 2016 Biosafety and Biosecurity Survey
ACKNOWLEDGMENTS

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Cover photos:

Top: Erin Swaney demonstrates Ebola Zaire virus sample inactivation to Garrick Gillispie at the Texas Department of State Health Services Laboratory Services Section.

Bottom: Specimen load at the State Hygenic Laboratory at the University of Iowa.
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EXECUTIVE SUMMARY

Recent events such as Zika in the US and Ebola Virus Disease (EVD) in Sierra Leone, Guinea and Liberia have called attention to the climate of biosafety and biosecurity in laboratories around the US. During the Ebola response, significant gaps were identified in US laboratory biosafety practices, specifically around the ability of some clinical laboratories to safely and correctly package and ship specimens to public health laboratories (PHLs) and the lack of biosafety programs in most clinical laboratories. Incidents at federal laboratories including the inadvertent shipment of live Bacillus anthracis (anthrax) further highlighted biosafety and biosecurity challenges.

The Association of Public Health Laboratories (APHL) and the US Centers for Disease Control and Prevention (CDC) have stepped up to take on this challenge and transition laboratories to a climate of responsibility and a culture of safety.

- Via the Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) and the Hospital Preparedness Program (HPP) and the Public Health Emergency Preparedness (PHEP) Cooperative Agreements, 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.

- In May 2015, CDC awarded APHL a $2.2 million Domestic Laboratory Biosafety for Ebola and other Highly Infectious Diseases Cooperative Agreement, where over the course of three years, APHL will strengthen biosafety across US laboratories by coordinating with CDC, state, local and territorial 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. APHL will also assist governmental PHLs with performing outreach to public and private clinical laboratories. The anticipated outcomes of this initiative are strengthened PHL biosafety and biosecurity capacity and improved laboratory coordination and outreach for a more robust public health system capable of safely responding to all threats.

APHL, with the support of CDC funding, conducted a survey in the spring of 2016 of 110 state, local, territorial and US Affiliated Pacific Island (USAPI) PHLs to identify current biosafety and biosecurity practices and gaps. This report focuses on the 62 PHLs that received $21 million in March 2015 via the CDC ELC Domestic Ebola Supplemental for Enhanced Laboratory Biosafety and Biosecurity Capacity Cooperative Agreement.
These 62 state, local and territorial PHLs include all 50 states, the District of Columbia, the five largest US metropolitan areas, the US territories and USAPI. The three year funding of $21 million aims to strengthen biosafety and biosecurity programs at PHLs and to assist these labs with outreach to clinical laboratories. Key objectives and priorities for this CDC funding include:

- **Enhancing PHL biosafety capacity**
  - Hire or designate a PHL biosafety official (BSO)
  - Update biosafety guidelines
  - Conduct risk assessments (RA) and implement risk mitigation strategies
  - Develop and provide training and tools

- **Improving laboratory coordination and outreach**
  - Work with clinical laboratory partners to facilitate their risk assessments and development/implementation of measures to address gaps and mitigate risks

Key findings of the first APHL Biosafety and Biosecurity Survey include:

- PHLs are utilizing CDC funding to strengthen internal biosafety and biosecurity programs. Successes include implementing risk assessments, reaching out to sentinel clinical laboratories and delivering training courses to thousands of clinical laboratorians.

- PHLs still face challenges such as inconsistent funding, a diminished workforce pool, limited guidance documents and limited buy-in from clinical laboratories.

Through a newly formed Biosafety and Biosecurity Committee (BBC) which is comprised of representatives from across US PHLs, CDC, the American Society for Microbiology (ASM) and the American Biological Safety Association (ABSA), APHL is addressing these gaps and continues to provide support to PHL directors and biosafety professionals. A long-term, sustainable funding strategy is needed to strengthen PHL and clinical biosafety and biosecurity programs. The funding will assist laboratories with maintaining highly skilled Biosafety Officers or Officials (BSOs), improving outreach to clinical labs, providing training to internal staff and external laboratories and ultimately ensuring a safe and secure work place thus preventing laboratory-acquired infections.
INTRODUCTION

PHLs 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. Over the course of the past year, US PHLs responded to several biological threats, notably Zika and EVD, and chemical threats, such as water contamination. The ability of a PHL to effectively respond to threats is rooted in its infrastructure—that is, its highly skilled workforce, modern equipment, safe and secure facilities and electronic systems to quickly send test results.

Recent events such as Zika in the US and EVD in the West African countries of Sierra Leone, Guinea and Liberia have called attention to the climate of biosafety and biosecurity in the US. During the Ebola response, significant gaps were identified in US laboratory biosafety practices, specifically around the ability of some clinical laboratories to safely and correctly package and ship specimens to PHLs and the lack of biosafety programs in most clinical laboratories. Incidents at federal laboratories including the inadvertent shipment of live Bacillus anthracis (anthrax) further highlighted biosafety and biosecurity challenges.

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METHODS

APHL collected data for the 2016 Biosafety and Biosecurity Survey in spring 2016, requesting information on PHL biosafety and biosecurity activities prior to March 2016.

The survey was distributed via email with a unique survey link and a copy of the survey; it was sent to 110 state, local, territorial and USAPI PHLs. 81 PHLs responded to the Survey for an overall response rate of 74%. APHL received a 92% (57 of 62) response rate from CDC ELC-funded PHLs, which included 48 state, five local and four territorial PHLs.

For the purpose of this report, APHL will focus on 62 PHLs which received funding in March 2015 via the CDC ELC Domestic Ebola Supplemental for Enhanced Laboratory Biosafety and Biosecurity Capacity Cooperative Agreement. The 62 PHLs encompass the 50 state PHLs, the District of Columbia, Chicago, Houston, Los Angeles County, New York City, Philadelphia, American Samoa, Federated States of Micronesia, Guam, Northern Mariana Islands, Puerto Rico and US Virgin Islands Public Health Laboratory.

Data was collected using Qualtrics, a web-based survey tool and data repository. The 2016 APHL Biosafety and Biosecurity Survey Summary Data Report, available at APHL.org, presents aggregate survey assessment results for all questions. Descriptive statistics were gathered for all categories:

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

FUNDING

62 PHLs received $21 million for a three-year term to enhance laboratory biosafety and biosecurity. As described in the metrics and deliverables for this three-year term, the funding will be used for:

- Hiring a full time Biosafety Officer or Official
- Increasing the number and percent of sentinel clinical laboratories in which at least two staff members are currently certified in packaging/shipping of IATA division 6.2 Category A infectious substances
- Increasing the number and percent of public health laboratorians certified in packaging/shipping of IATA division 6.2 Category A infectious substances.
- Increasing the number and percent of public health laboratorians whom can demonstrate competency to work in a BSL-3.
- Increasing the number and percent of sentinel clinical laboratories that have completed at least one laboratory risk assessment for an identified infectious agent.
- Completing biosafety risk assessment(s) and mitigation of risks for Ebola and/or other infectious agents of public health concern at the public health laboratory.
- Ensuring PHL biosafety plans are reviewed and communicated.

During the initial year of the awarded ELC Ebola Supplemental Project B-Enhanced Laboratory Biosafety and Biosecurity Capacity funding, 51% (29) of laboratories experienced funding gaps for their laboratory biosafety and biosecurity programs. Funding gaps included a lack of biosafety personnel and limited training and travel funds for clinical laboratory outreach. While funding was available in March 2015, it took time for PHLs to receive these funds and recruit and hire new personnel.

WORKFORCE

An effective biosafety and biosecurity program hinges on the ability of highly trained public health and clinical laboratory staff to implement specific policies and practices. The cases of Ebola in the US provide an excellent example of a response that required staff to follow specific safety and security practices. During this response, the US government leveraged the infrastructure of the Laboratory Response Network for Biological Threats Preparedness (LRN-B). Although leveraging the LRN-B to respond to Ebola was a success, many gaps were observed in laboratory preparedness and response. These include but are not limited to:

- Ability of some clinical laboratories to safely and correctly package and ship specimens to public health laboratories: There were several inconsistencies and multiple interpretations of the US Department of Transportation regulations, including whether to classify EVD as a Category A or Category B infectious substance.
- Lack of biosafety programs in most clinical laboratories: CDC’s Domestic Ebola Supplement to ELC—Building and Strengthening Epidemiology, Laboratory and Health Information Systems Capacity in State and Local Health Departments stated, “The events surrounding laboratory testing of patient specimens suspected of Ebola virus infection point to a lack of biosafety programs in most US clinical laboratories. For example, biosafety plans may be absent or outdated and staff charged with implementing and training additional staff on biosafety procedures may require additional education and practice to do so effectively and confidently. Some deficiencies illustrated during this event may span across many US laboratories while others may only apply to some laboratories.”
- Lack of timely guidance for clinical laboratories to perform routine diagnostic tests on patients under investigation.
- Connectivity between healthcare and public health systems.
Florida Uses Federal Funds to Strengthen Biosafety and Biosecurity

Prior to the CDC ELC Cooperative Agreement, the Florida Department of Health (DOH) Bureau of Public Health Laboratories did not have a formal biosafety risk assessment standard operating procedure (SOP). While biosafety and biosecurity risk assessments were completed at three branch PHLs in Jacksonville, Tampa and Miami, the two newly created Biosafety Outreach Officer positions allowed the state to create a formalized and standardized biosafety risk assessment SOP, documents, worksheets and resources for all three labs to use going forward. Their model internal risk assessment is featured as one of the six PHL examples in the APHL Risk Assessment Best Practices and Examples document and has been shared across the PHLs in the US.

The resources generated are also being used for outreach with clinical labs and are available on the FL DOH Bureau of Public Health Laboratories website. The website is used to reach a larger clinical laboratory audience. Additionally, the two Biosafety Outreach Officers located in Tampa have completed many site visits to clinical laboratories in their jurisdiction and trained 47 sentinel clinical laboratories in-person. The Biosafety Outreach Officers used a mixture of presentations during regional workshops, hospital system workshops and single-site trainings where other institutions were invited. The presentations encompassed engineering controls, PPE, administrative and work practice controls, including SOPs and risk assessments. The biosafety risk assessment presentation has been given to both public health and clinical laboratories and describes the process of conducting a biosafety risk assessment. The Bureau of Public Health Laboratories staff realized how clinical laboratorians are working in a different laboratory setting and approach risk assessments differently.

Funding via CDC’s ELC Ebola Supplement Cooperative Agreement enabled Florida to hire these Biosafety Outreach Officers and to implement relevant biosafety and biosecurity practices and policies such as how to conduct risk assessments.
Laboratories face a number of workforce challenges in all areas. It is increasingly difficult to recruit and retain a skilled workforce necessary to ensure robust biosafety and biosecurity programs without adequate funding. With CDC funding, many PHLs were able to create and, in some cases, restore the BSO or Biosafety Outreach Officer positions. The role of the Biosafety Outreach Officer is to engage clinical and other laboratory partners in their jurisdiction. Prior to dedicated federal funding for the BSO position, laboratory staff took on this role in addition to their routine duties, leading to a burdensome amount of responsibility on an already-stressed workforce. In 2016, 74% (42) of ELC laboratories indicated they have a full time designated BSO. Of the 26% (15) that do not have a full time BSO, the majority of respondents indicated that this gap was due to the lack of long-term funding for that staff position.

This short-term funding approach has hindered hiring of full time BSOs and, in a few cases, led to PHLs employing temporary contractors. Some respondents indicated that states did not have a comparable position in their state job classification. APHL has addressed this issue and created a competencies-based position description for BSOs (see References).

Of the 42 full-time BSOs hired with CDC ELC Ebola supplemental funding, 81% (34) have been in their role for less than a year (see Figure 1).

To ensure safe practices, all laboratory staff need to be competent in all aspects of biosafety and biosecurity. Typically, the BSO develops safety-specific competencies and provide trainings for laboratory staff. 51% (29) of the labs have developed these competencies. In the coming years, this number is expected to rise significantly due to the BSOs and the laboratory staff familiarity (93%, 53) with the existing resources: Competency Guidelines for Public Health Laboratory Professionals, MMWR 2015 and/or the Guidelines for Biosafety Laboratory Competency, MMWR 2011.

In 2016, BSOs attended trainings and conferences from numerous sources including APHL, CDC, American Biological Safety Association (ABSA) and the Eagleson Institute. Over 52% (22) participated in APHL trainings such as the APHL-sponsored Division 6.2 Infectious Substance Packaging and Shipping training and biosecurity and biosafety webinars.

Along with the BSO, other laboratory staff must be trained in safe work practices in the laboratory setting. The types of trainings laboratory staff and BSOs have completed were high in areas that were mandated by current law. Given the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard and the Federal Select Agent

Figure 1: Landscape of PHL Biosafety Officials in 2016

<table>
<thead>
<tr>
<th>OF THE 42 BIOSAFETY OFFICERS WORKING AT PHLS IN 2016...</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>34</strong> have been a BSO for less than 1 year</td>
</tr>
<tr>
<td><strong>2</strong> have been a BSO for more than 5 years</td>
</tr>
<tr>
<td><strong>22</strong> have experience working in a public health laboratory performing analytical work</td>
</tr>
<tr>
<td><strong>21</strong> have experience working in a clinical laboratory</td>
</tr>
<tr>
<td><strong>19</strong> have experience working in a research or academic laboratory</td>
</tr>
<tr>
<td><strong>2</strong> are Certified Biosafety Professionals</td>
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Program (FSAP), the top four trainings completed were Biosecurity Planning, Select Agent Regulations, Personal Protective Equipment and Bloodborne Pathogens. Only 40.4% (23) of the laboratories stated that 76% or more of their laboratory staff have completed trainings on biological risk assessments and only 59.6% (34) of the laboratory BSOs have completed training on biological risk assessments (see Figure 2).

Figure 2: Biosafety & Biosecurity Courses Completed by Laboratory Staff and BSOs
RISK ASSESSMENTS

Risk assessment is the process that allows the appropriate selection of microbiological practices, safety equipment and facility safeguards that can prevent laboratory acquired infections. Risk assessments are an essential component of maintaining safety within a laboratory and must be performed regularly and when there are changes in agents, procedures, equipment or staff. If risks are identified by the assessment, they should be prioritized and a mitigation plan should be established.

Eighty-eight percent (50) of the ELC-funded PHLs have completed a risk assessment and, of those, 62% (31) have identified certain gaps, including proper PPE usage and engineering controls. To address these concerns, 100% (31) of PHLs stated they have taken the proper steps to mitigate the gaps identified in the risk assessment. The mitigation steps identified by the PHLs included updating their SOPs.

The frequency of completing a risk assessment varies on several factors in the laboratory. When PHLs receive a new agent or there is a change in equipment, change in procedures or an incident occurs, performing a risk assessment is essential to address any potential gaps. In molecular testing and virology, at least 72% (41) of the labs completed a risk assessment when a new agent arrived in the laboratory. Last year with the emergence of the Zika virus and the complicating issues of possible other viral co-infections such as dengue and chikungunya, risk assessment was at the forefront of PHL activities.

Figure 3: Outcomes of Risk Assessments Performed by PHLs

<table>
<thead>
<tr>
<th>Risk Assessments Performed</th>
<th>Gaps Identified</th>
<th>Steps Taken to Mitigate Gaps</th>
</tr>
</thead>
<tbody>
<tr>
<td>50</td>
<td>31</td>
<td>19</td>
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<tr>
<td>7</td>
<td>19</td>
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Figure 4: Frequency of Risk Assessments

<table>
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<th></th>
<th>Annually</th>
<th>Quarterly</th>
<th>Biannually</th>
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<tbody>
<tr>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Molecular Testing</td>
<td>22</td>
<td>38.6</td>
<td>0</td>
</tr>
<tr>
<td>Virology</td>
<td>21</td>
<td>36.9</td>
<td>0</td>
</tr>
</tbody>
</table>

Figure 5: Reasons for Completing Risk Assessments

<table>
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<tr>
<th></th>
<th>New agent</th>
<th>Change in procedure</th>
<th>Change in equipment</th>
<th>Incident</th>
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<tr>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>Molecular Testing</td>
<td>42</td>
<td>73.7</td>
<td>36</td>
<td>63.2</td>
<td>29</td>
<td>50.9</td>
</tr>
<tr>
<td>Virology</td>
<td>41</td>
<td>71.9</td>
<td>33</td>
<td>57.9</td>
<td>26</td>
<td>45.6</td>
</tr>
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</table>
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Figure 3: Outcomes of Risk Assessments Performed by PHLs

Minnesota: Training Sentinel Clinical Laboratories Region By Region

To improve clinical laboratory outreach and overall knowledge of biosafety and biosecurity, Minnesota convened the Minnesota Department of Health (MDH) Regional Laboratory Conferences. These six identical conferences focused on biosafety, biosecurity and risk assessments for clinical laboratories. Utilizing metrics from surveys sent out in the fall of 2016 to Minnesota clinical laboratories regarding their capabilities, MDH proposed the conferences to increase biosafety awareness for laboratory workers. The Biosafety Outreach Coordinator and the Emergency Preparedness and Response Unit Supervisor at MDH served as instructors for these conferences.

The conference locations were spread out across the state including St. Paul, Duluth, Alexandria, Bemidji and Mankato with an overall total of 120 attendees from over 70 different laboratories. The courses were specifically targeted for the clinical laboratorians in Minnesota, but other attendees included infection control personnel, safety specialists not located in the clinical setting and veterinary laboratorians. The topics included in the conference were LRN Overview, Fundamentals of Biosafety and Biosecurity, Packaging and Shipping Training and Risk Assessments. Utilizing didactic presentations and hands-on exercises, attendees were able to get a detailed approach on how to better improve their laboratories biosafety and biosecurity programs. The interactive group exercise sessions included six different packaging and shipping scenarios and used “Glo Germ” to highlight potential routes of exposure in the laboratory. Prior to these conferences, through their challenge set program in 2016, MDH required clinical laboratories to package and send an isolate back to them as a drill.

At the end of the conference, attendees were asked to take a survey on what they have learned and the concepts they plan to translate back into their laboratories. Some takeaways from the attendees included that prior to the conferences, some of the laboratory staff were not trained in PPE procedures and biological safety cabinet operation, in addition to many never having conducted a risk assessment. Using the results from the post conference survey, MDH will work on addressing these issues in future conferences. MDH PHL staff are working on ideas generated from these conferences to reach out and educate laboratory staff in regards to biosafety and biosecurity.
**CLINICAL LABORATORY OUTREACH**

While having a competent workforce for PHLs is essential for biosafety, communicating and collaborating with sentinel clinical laboratories is equally vital for enhancing biosafety and biosecurity in the overall public health system. During the Ebola response, government agencies such as CDC noted a lack of biosafety programs in most clinical laboratories. For instance, biosafety plans may be absent or outdated and staff charged with implementing and training additional staff on biosafety procedures may require additional education and practice to do so effectively and confidently. As noted earlier, one of the key activities funded via the CDC ELC Ebola Supplemental Cooperative Agreement was outreach by PHLs to sentinel clinical labs. PHLs are collaborating with clinical laboratories by engaging these laboratories in training, assessing current biosafety policies and practices and encouraging them to foster a culture of safety in their laboratories through risk assessments and mitigation controls.

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 the Centers for Medicare & Medicaid Services (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 includes all 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. The total number of sentinel clinical laboratories within PHL jurisdictions varies by state. The number of sentinel clinical laboratories that meet the APHL-CDC-ASM definition identified by all 57 respondents was 4,192, with 1,002 additional laboratories described in the CDC ELC Performance Measures (see Figures 6 and 7).

**Figure 6: Clinical Laboratories Within PHL Jurisdictions**

<table>
<thead>
<tr>
<th>Labs Per Jurisdiction (state, local or territorial)</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
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<td>1</td>
<td>1.8</td>
</tr>
<tr>
<td>1-49 labs</td>
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<td>100-199 labs</td>
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<td>200+ labs</td>
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<td>8.8</td>
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<table>
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<th>Labs Per Jurisdiction (state, local or territorial)</th>
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<th>%</th>
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<tbody>
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<td>0 labs</td>
<td>36</td>
<td>63.2</td>
</tr>
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<td>1-49 labs</td>
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<td>5.3</td>
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<tr>
<td>200+ labs</td>
<td>1</td>
<td>1.8</td>
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Georgia: Site Visits Lead to Improvements

The Georgia Public Health Laboratory (GA PHL) has conducted over 20 clinical laboratory site visits since their newly-hired Biosafety Outreach Officer took the position.

To set up the site visits, the Officer will call the laboratory director to ensure approval and buy-in for the visit. The Officer will highlight the purpose of the visit, explaining the initiative along with the CDC ELC Cooperative Agreement funding and what it entails. Once they agree to the visit, the Officer will email the director and other appropriate staff six weeks prior to the date of the visit, highlighting the goals and information on plans to strengthen their biosafety and biosecurity programs. The Officer will also attached relevant resources for the labs such as a site visit informational letter, an agenda and the APHL Clinical Laboratory Biosafety Risk Management Program Assessment Checklist and guidance documents for review prior to the visit.

The Officer will help the designated laboratory team develop an agenda, customizing each visit to the specific facility. The agenda includes a laboratory assessment tour with sections on managing an effective biosafety program, biological risk assessment, fundamental safety practices, engineering controls, laboratory facilities, pre-analytic processes, post-analytic processes, management of regulated waste, lab equipment hazards, management of biological releases, exposures, incidents or accidents, occupational health, biosafety training, competency assessment, compliance with select agent regulations and preparedness of public health emergencies. The Officer will also discuss collaborations available between the clinical laboratory and GA PHL.

The Officer will review all documents thoroughly and answer any questions asked by the staff. After the site visit assessment, the Officer will send a summary report with references and recommendations to improve their program. A month after the visit, the Officer will conduct a follow-up conference call to answer any questions or provide more guidance for the laboratory.

After one site visit, the clinical laboratory staff were observed addressing the recommendations on vaccinations provided in the visit summary report. In the APHL Clinical Laboratory Biosafety Risk Management Program Assessment Checklist there is a question on recommended vaccines and the method for obtaining the advice of a medical professional on the advisability of vaccination. The staff reviewed 10 years of records and found there were eight staff members that had not received a meningococcal vaccination. Thanks to the Officer and the APHL checklist, the lab corrected this and offered it to the staff with seven of the eight microbiologists receiving the meningococcal vaccine.

With CDC funding and the relationships developed with clinical laboratories, the Officer was able to provide assistance and recommendations to a lab on a Brucella exposure. The Officer performed a site visit, assessing the area using the APHL guidance tools and provided recommendations on mitigating the exposure from occurring again in the future. The Officer also conducted a post-exposure assessment that was provided to the lab along with bio-assessment post exposure recommendations. Further, the Officer collaborated with the microbiology supervisor in performing a risk assessment to implement mitigation controls in their facilities; respiratory, wound, blood and sterile body site fluid protocols to include triggers (a combination of laboratory test results) that would have all laboratorians working in a biological safety cabinet when the possibility of a suspect biothreat agent presented. The Officer worked with the clinical lab on implementing other administrative controls such as training, contact protocols and a Neisseria meningitides SOP through emails, conference calls and phone calls.

The Georgia approach to biosafety outreach serves as a model for other locations which are now developing and implementing similar programs.
Nebraska: Inside a BSO Site Visit

In 2016, the Nebraska’s BSO successfully implemented an outreach program, visiting 77 sentinel clinical laboratories during the year. Roxanne Alter, MS, MLS (ASCP), state biosafety coordinator for the Nebraska Public Health Laboratory, which is located in the University of Nebraska Medical Center, shared what a visit may entail.

The main role of the BSO visiting the clinical labs is to advocate and educate for biological safety and best practices. Before the site visit, the BSO sends a template of questions and resources regarding the laboratory biosafety and biosecurity practices and provides the APHL Clinical Laboratory Biosafety Risk Management Program Assessment Checklist as a resource.

For site visits, the BSO routinely travels with the Infection Control Assessment Program. Combining these visits saves resources and prevents major disruptions to the laboratory’s day-to-day activities. Working with the Director of Nursing, Quality Officer, Infection Control Practitioner and the Laboratory Supervisors, the BSO is able to tour the entire facility and observe all laboratory testing. Occasionally, the sentinel clinical laboratories request a site visit but typically, the state BSO is initiating these visits. At the beginning of the visit, the BSO always communicates that the state PHL is not a regulatory body and will not report the findings.

Upon arriving at the laboratory, the BSO provides a hard copy of CDC’s MMWR Supplements, Vol. 61, Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories as a guideline for the lab to follow and keep for their records. The BSO reviews the APHL Clinical Laboratory Biosafety Risk Management Program Assessment Checklist and addresses questions the laboratory may have. Staff are encouraged to show the BSO around the facility to evaluate the entire laboratory and possibly perform equipment risk assessments. During the walk-through, the BSO will focus on looking for possible aerosols, proper PPE, needle stick hazards through phlebotomy demonstration, sharps containers and how they are performing certain testing such as influenza or monospot testing. The BSO may also take pictures of unsafe practices and will later offer suggestions based on them.

After the site visit concludes, the BSO will issue a verbal report which is reviewed with the laboratory Chief Executive Officer (CEO), Infection Control Practitioner or other laboratory staff on how they can improve their laboratory biosafety program. When the BSO leaves the laboratory, the staff receive an evaluation form where they can anonymously provide feedback. The BSO will also follow up with a letter documenting all of the areas where the laboratory needs to improve, providing references, links or articles that support the findings.

The BSO has followed up with some of the laboratories visited last year and is now making repeat rounds in 2017. Using the mitigation steps and recommendations provided, the BSO has observed that the laboratories are already improving their biosafety practices. Improvements include providing laboratory coats to staff, ensuring coats are properly laundered, providing proper PPE and installing splash guards to prevent unintended aerosol exposures.
PHLs use various methods of communication to reach out to sentinel clinical laboratories (see Figure 8). PHLs have created websites and list-servs specifically for these clinical laboratories to develop a community of practice within the state and to make communications more user-friendly.
To foster a strong biosafety and biosecurity community of practice for clinical laboratories, it is essential to visit these laboratories and provide specific recommendations for their biosafety and biosecurity programs (see Figure 9). Of the 57 PHLs which responded to this survey, 54% (31) have traveled to their sentinel clinical laboratories and performed site visits. The site visits included review of standard operating procedures, risk assessments, laboratory workforce competencies and overall biosafety and biosecurity programs in place. In 2016, only 25% (14) PHLs provided risk assessment templates for their clinical laboratories and 23% (13) performed risk assessments with them. Some PHLs noted that they are working to address gaps in internal biosafety practices before reaching out to and engaging sentinel clinical labs. Others noted that they were still recruiting for the BSO position and as such outreach activities were deferred. As seen in Figure 9, 13% (4) PHLs performed more than 20 site visits by February 2016.

Of the survey respondents, 35% (20) of PHLs also conducted drills and exercise with their sentinel clinical laboratories. The examples mentioned were the College of American Pathologists (CAP), CDC and APHL Laboratory Preparedness Exercise, Rule-Out/Refer of biological threat agents and a state-wide Ebola exercise that entailed notification drills to ensure that laboratories can rapidly communicate with the PHL during an emergency response.

**Figure 9: Number of Visits to Clinical Laboratories by Each Respondent**

<table>
<thead>
<tr>
<th>Number of Visits</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-4 labs visited</td>
<td>18</td>
<td>58.1</td>
</tr>
<tr>
<td>5-9 labs visited</td>
<td>4</td>
<td>12.9</td>
</tr>
<tr>
<td>10-19 labs visited</td>
<td>5</td>
<td>16.1</td>
</tr>
<tr>
<td>20+ labs visited</td>
<td>4</td>
<td>12.9</td>
</tr>
</tbody>
</table>

**TRAINING AND RELATED RESOURCE NEEDS**

PHLs are often seen as a resource for other laboratories within their state or local jurisdictions. As such, there is an expectation that PHLs will provide training on key topics to other laboratories including clinical laboratories. From May 2015 to February 2016, PHLs trained thousands of laboratorians across the country (see Figure 10).

**Figure 10: Training Provided to Clinical Laboratories**

<table>
<thead>
<tr>
<th>Training Provided</th>
<th>Provided training</th>
<th>Did not provide training</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Packaging/Shipping of IATA Division 6.2 infectious substances (Category A)</td>
<td>52</td>
<td>91.2</td>
</tr>
<tr>
<td>BSL-2 Safe Practices</td>
<td>30</td>
<td>52.6</td>
</tr>
<tr>
<td>Personal Protective Equipment</td>
<td>29</td>
<td>50.9</td>
</tr>
<tr>
<td>Biosafety Cabinets and Other Engineering Controls</td>
<td>24</td>
<td>42.1</td>
</tr>
<tr>
<td>Biological Risk Assessments</td>
<td>22</td>
<td>38.6</td>
</tr>
<tr>
<td>Emergency Management and Response</td>
<td>21</td>
<td>36.8</td>
</tr>
<tr>
<td>Biosecurity Plan</td>
<td>20</td>
<td>35.1</td>
</tr>
<tr>
<td>Decontamination</td>
<td>19</td>
<td>33.3</td>
</tr>
<tr>
<td>BSL-3 Safe Practices</td>
<td>19</td>
<td>33.3</td>
</tr>
<tr>
<td>Sharps Hazard</td>
<td>18</td>
<td>31.6</td>
</tr>
<tr>
<td>Spill Prevention, Control and Countermeasures</td>
<td>16</td>
<td>28.1</td>
</tr>
<tr>
<td>Bloodborne Pathogens</td>
<td>15</td>
<td>26.3</td>
</tr>
<tr>
<td>Regulated Waste Management</td>
<td>13</td>
<td>22.8</td>
</tr>
<tr>
<td>Chemical Hazards</td>
<td>12</td>
<td>21.1</td>
</tr>
<tr>
<td>Safe Handling and Use of Cryogenic Liquids</td>
<td>6</td>
<td>10.5</td>
</tr>
</tbody>
</table>
North Carolina: Engaging and Educating Sentinel Clinical Laboratories

Through ELC Cooperative Agreement funding, the North Carolina State Laboratory of Public Health (NCSLPH) hired two biosafety laboratory outreach consultants and integrated them into their Bioterrorism Response Unit. Their positions were solely dedicated for sentinel clinical laboratory outreach with the goal to perform over 100 site visits in the state reaching each laboratory at least once in a two year period. Most of the staff time is spent out on these site visits where they review sentinel clinical laboratory guidelines, packaging and shipping certification and provide laboratories training on risk assessments. Using the APHL Risk Assessment Best Practices and Examples Template, they will work with the individual laboratories on developing their own risk assessments.

In October 2017, NCSLPH will convene their 13th Clinical Laboratory Day specifically focused on biosafety. The Laboratory Improvement Unit organizes this educational program each year for clinical laboratorians and other healthcare personnel across the state. The day will include numerous presentations on biosafety topics such as laboratory-acquired infection case studies with discussion on prevention and response, the whys and hows of risk assessment, group exercises and a panel discussion from the individuals that deal with biosafety in the PHL and clinical laboratory. Past events covered topics in the laboratory setting such as sexually transmitted diseases and foodborne diseases. Last year’s Clinical Laboratory Day had over 150 attendees from clinical laboratories throughout the state. Many participants from previous years indicated that the information presented allowed them to better serve and educate others, as well as evaluate and update their testing capabilities.
PHLs which responded to the survey noted that they would like their BSOs, laboratory staff, PHL trainers and sentinel clinical laboratory staff to receive training on areas such as laboratory safety, designing risk assessments, case studies on laboratory accidents and waste management.

Further, PHLs requested specific biosafety and/or biosecurity guidance documents such as standardized risk assessment tools and templates, reference guides for biosafety procedures, guidelines for occupational health programs and reference material for packaging and shipping agents. APHL addressed these comments by providing the following tools:

- APHL Risk Assessment Best Practices and Examples, providing six different risk assessment examples from PHLs
- Clinical Laboratory Biosafety Risk Management Program Assessment Checklist to be used by PHL BSOs to work with their clinical laboratories to further enhance their biosafety programs
- Biorisk Management for Clinical and Public Health Laboratories, a tool used to enhance support to clinical and local health departments to reduce risk in laboratory biosafety and biosecurity areas.
- Packaging and Shipping Division 6.2 Infectious Substances, a seminar that provides a comprehensive overview of regulations applicable to packaging and shipping laboratory specimens.

**CONCLUSION**

Strengthening biosafety and biosecurity across public health and clinical laboratories is imperative to ensure the US is prepared for the next threat. New infectious agents and diseases have emerged and safely working with them in the PHL and clinical settings is a priority. It is essential that PHLs have the capacity to work safely with high consequence and emerging infectious diseases and to provide appropriate guidance to clinical laboratories. In providing training to these PHLs, staff can ensure more of the workforce has the appropriate knowledge in biosafety and biosecurity. PHLs and clinical laboratories need to evaluate their biosafety programs and the competency of their workers, as well as the capability of equipment, facilities and management practices to provide the proper security of microbiological agents.

With funding from the CDC ELC Domestic Supplemental Cooperative Agreement, PHLs have been working diligently to hire biosafety professionals, review and revise biosafety and biosecurity plans, implement new policies and provide appropriate guidance to sentinel clinical laboratories. The work to enhance biosafety and biosecurity programs across laboratories is just beginning and urgently needs dedicated funding to ensure a robust and highly skilled workforce, safe and secure facilities, ongoing training and professional development for laboratorians and a strong community of practice to foster learning and information sharing. An uncertain funding stream threatens both jobs and the safety of laboratorians and the security of the public. A sustainable funding strategy is needed to invest in laboratory biosafety and biosecurity programs.
REFERENCES


APPENDIX: APHL BIOSAFETY AND BIOSECURITY ACTIVITIES

LEADERSHIP
In May 2015, APHL’s Board of Directors approved the formation of a new group, the Biosafety and Biosecurity Committee to provide leadership and guidance on policies and practices which impact biosafety and biosecurity in state and local governmental laboratories. Key activities for the committee include serving as technical experts and assisting member laboratories and federal partners such as CDC with strengthening biosafety and biosecurity programs; collaborating with partners to provide guidance to private clinical laboratories to assist them with implementing biosafety programs; and developing and delivering biosafety and biosecurity training programs. This Committee is comprised of state and local public health laboratorians as well as representatives from the American Society for Microbiology (ASM), College of American Pathologist (CAP) and the American Biological Safety Association (ABSA).

TRAINING AND EDUCATION
APHL convened a pre-conference workshop, “Tools to Enhance Laboratory Biosafety and Biosecurity” at the 2015 APHL Annual Meeting Ninth Government Environmental Laboratory Conference where over 45 participants gathered information on conducting risk assessments, incorporating competencies into their biosafety programs and laboratory practices, training staff and maintaining a culture of biosafety. Since packaging and shipping was a significant gap during the response to Ebola in the US, APHL increased the number of packaging and shipping training courses to ensure a competent workforce.

APHL created the APHL BioSafe360 Program via a contract with Behavioral Based Improvement Solutions. This program is comprised of a monthly webinar session focusing on different topics in biosafety and biosecurity followed by three monthly assignments for improving/maintaining a laboratory’s biosafety program.

From August 2016 to February 2017, APHL convened four biosafety and biosecurity workshops designed to enhance the technical knowledge of BSOs across PHLs. Four APHL member laboratories graciously hosted these regional workshops: Massachusetts State Public Health Laboratory in Jamaica Plain, Hawaii State Laboratories Division in Pearl City, Florida Bureau of Public Health Laboratories in Tampa and Los Angeles County Public Health Laboratory in Downey, CA. These two-day workshops provided BSOs with a forum to ask questions and network with one another. The four regional workshops reached 80% of the ELC biosafety laboratories. Topics included engineering controls, risk assessments, biosafety competencies, biosecurity, decontamination, personal protective equipment and sentinel clinical laboratory outreach.

In addition APHL has held numerous biosafety, biosecurity and clinical laboratory outreach webinars. Other trainings include the pre-conference workshop, “Enhancing Biosafety and Biosecurity in Public Health Laboratories” at the ABSA International 59th Annual Biological Safety Conference and “Resources and Strategies for Successful Clinical Laboratory Outreach” at the 2017 Epidemiology and ELC Annual Awardees Meeting held on April 11-13 2017 in Atlanta, GA.

GUIDANCE TOOLS
APHL issued the Clinical Laboratory Biosafety Risk Management Program Assessment Checklist and Biosafety Checklist: Developing A Culture of Biosafety, which are intended for any laboratory performing testing on infectious agents or clinical specimens that could contain infectious agents in the United States. It is designed to provide laboratories with the broad recommendations for components that should be considered for inclusion in any
laboratory’s biosafety policy. Further, APHL issued a template position description (PD) for a BSO. This PD builds upon the competencies and captures the requirements for a typical Biosafety Officer in a public health laboratory. In addition APHL developed the pathogen-specific Zika Risk Assessment Template and the APHL Risk Assessment Best Practices and Examples document to be used by public health laboratories and their clinical partners as a resource to create their own in-house risk assessment process. Finally, APHL published Biorisk Management for Clinical and Public Health Laboratories, a comprehensive and systematic approach to laboratory biorisk management, including a list of essential elements laboratories can use to assess their operations and better integrate and enhance programs for biosafety and biosecurity.

COMMUNICATIONS

APHL members and staff have presented at several domestic and international conferences to promote biosafety and biosecurity practices. The association will continue to educate laboratorians as well as to share successes and challenges with policy makers and the public.

APHL has also developed a website with tools developed and approved by the Biosafety and Biosecurity Committee along with resources and relevant presentations. An “Ask an Expert” button allows anyone to ask a subject matter expert a question related to biosafety and biosecurity. Upcoming biosafety and biosecurity trainings with organizational partners Eagleson Institute, ABSA and ASM are posted regularly.

Under the guidance of APHL’s Biosafety and Biosecurity Committee, a community-of-practice was created to allow BSOs and biosafety professionals to interact regularly via an APHL-maintained list serv, as well as connect via meetings and webinars. Over 140 US PHL biosafety professionals are currently subscribed to the list serv, and the number continues to grow. Recent discussions have covered questions about disinfectants, spill kits, Ebola and Zika testing, laboratory procedures, laboratory equipment purchases, laboratory acquired infections, packaging and shipping courses, personnel protective equipment, risk assessment templates and sharing of biosafety trainings. To prevent this valuable information from being lost, APHL has also developed a SharePoint site to archive these discussions.

OUTREACH

APHL has engaged CDC, ASM, ABSA and other partners in critical discussions on enhancing biosafety and biosecurity. The organization routinely provides feedback to CDC’s Division of Select Agents and Toxins (DSAT) to promote an open dialogue and facilitate transparency on public health laboratory activities.

In addition APHL convened their Biosafety and Biosecurity Partners Forum comprised of 12 different organizations, associations and government agencies that are stakeholders in improving biosafety and biosecurity in the nation’s clinical laboratories. The purpose was to facilitate information exchange among clinical and public health laboratory partners. Some unique partners are the Centers for Medicare and Medicaid Services (CMS), COLA, the Joint Commission, Clinical Laboratory Management Association (CLMA), the American Society for Clinical Pathology (ASCP), the American Association for Clinical Chemistry (AACC) and the American Association of Bioanalysts (AAB).
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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