



CDC/APHL

BIO SAFETY AND BIOSECURITY PROGRAM

MAKING LABS SAFER FOR SCIENTISTS AND COMMUNITIES

February 2018

During the Ebola virus outbreak in 2014, a four-year-old girl who had recently returned from West Africa arrived in the emergency room of a hospital in the US Northeast suffering from a high fever and severe dehydration. Out of concern that their young patient might be infected with Ebola, the hospital staff sought the advice of the state epidemiologist who informed them that the girl's illness was most likely malaria. But this information did not allay their concerns. Fearing exposure to the virus, they refused to insert an IV or perform other laboratory tests until they had test results from the state public health laboratory.

So for over 10 hours the girl waited, receiving only popsicles, while a specimen was transported to the laboratory and analyses conducted. And the result? The girl was positive for malaria. With this diagnosis, the hospital finally initiated treatment.

The girl was fortunate—she lived—but others were not so lucky; at least two others died in similar cases.¹ Had the US Ebola outbreak been widespread, there would have been more such deaths. Yet staff at these hospitals could have protected themselves against infection while still providing time-sensitive evaluation and treatment if they had been trained in the biosafety risk assessment process.

BIO SAFETY SAVES LIVES.

US laboratories are responsible for protecting lab workers from exposure to infectious and hazardous agents and local communities from accidental or intentional release of such agents. Yet the Ebola outbreak and other recent incidents have demonstrated serious gaps in biosafety and biosecurity practices at US laboratories. Incorrect packaging and shipping of biological agents, discovery of long forgotten smallpox samples in freezers, inappropriate inactivation of anthrax and other incidents indicate unmet needs at both clinical (i.e., laboratories at hospitals and clinics) and public health laboratories (US governmental laboratories working in public health).

To address these needs, the Centers for Disease Control and Prevention (CDC) partnered with the Association of Public Health Laboratories (APHL) and its public health laboratory members and allocated \$21 million over the course of FY16 - FY18 to enhance laboratory biosafety and biosecurity nationwide. Sixty-two state, local and territorial public health laboratories² received supplemental funding under the Epidemiology in Laboratory Capacity for Infectious Diseases cooperative agreement.³ For reasons of brevity, this program is described within as the "CDC/APHL Biosafety and Biosecurity Program."

¹ CDC. (December 12, 2014). Clinical Inquiries Regarding Ebola Virus Disease Received by CDC—United States, July 9–November 15, 2014. *Morbidity and Mortality Weekly Reports*. Retrieved from: <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6349a8.htm>

² All US states, District of Columbia, Chicago, Houston, Los Angeles County, New York City, Philadelphia, American Samoa, Federated States of Micronesia, Guam, Marshall Islands, Northern Mariana Islands, Puerto Rico, the Republic of Palau and US Virgin Islands.

³ The Domestic Ebola Supplement to Epidemiology and Laboratory Capacity for Infectious Diseases - Building and Strengthening Epidemiology, Laboratory and Health Information Systems Capacity in State and Local Health Departments.

“Before the CDC/APHL program, clinical labs were conducting risk assessments seldom—if at all. Biosafety and emerging pathogens were simply not on their radar.”

Erin Bowles, MT(ASCP), clinical laboratory network coordinator and biosafety officer, Wisconsin State Laboratory of Hygiene

BEFORE THE CDC/APHL PROGRAM

Prior to the CDC/APHL Biosafety and Biosecurity Program, workload trumped biosafety at US clinical laboratories where rapid delivery of test results was the priority. Few clinical laboratories conducted assessments to manage the risks posed by pathogens and other hazardous agents. Moreover, staff often lacked training in biosafety and biosecurity practices, which some perceived as an impediment to productivity. At public health laboratories, biosafety and biosecurity procedures had been instituted but resources to support a biosafety and biosecurity program were limited. The position of biosafety officer was most commonly part time and staffed by an individual with little or no formal training in the discipline. There was no established career ladder for those interested in pursuing a career in laboratory biosafety. Public health laboratory outreach to clinical laboratory partners varied by scope and topic among jurisdictions. There were no outreach programs dedicated to strengthening biosafety and biosecurity practices at clinical laboratories.

BIOSAFETY AND BIOSECURITY ISSUES FOUND AT CLINICAL LABS

- Incorrect use and placement of biosafety cabinets
- Microbiologists not vaccinated for key pathogens
- Lack of two certified staff to package and ship Category A and B pathogens
- Contaminated surfaces not impervious to spills thereby creating potential for contamination with infectious agents
- No formalized risk assessment procedures
- No risk management plan
- Overall lack of awareness of biosafety and biosecurity practices

PROGRESS TO DATE

Nearly three years after the launch of the CDC/APHL Biosafety and Biosecurity Program, public health laboratories funded under the program have made significant advances in strengthening biosafety and biosecurity practices. Public health laboratories (state, territorial and selected local institutions) have hired, or are in the process of hiring, a full-time biosafety officer to strengthen internal operations and guide assessment of biosafety and biosecurity practices at clinical laboratories in the region.

These officers help clinical laboratory staff to identify potential risks at their facility and follow up with guidance and training. For example, they may assist with development of a risk management plan or provide training in packaging and shipping of hazardous agents. APHL supports these officers with resources, training, leadership development programs and a community of practice. The goal is a national cadre of professionally trained biosafety officers in public health laboratories.

Multiple clinical laboratories have completed risk assessments, with positive results. Their biosafety officers report a change in attitude following an assessment. Staff now consider biosafety and biosecurity as part of daily operations, and find ways to mitigate risk while still delivering test results quickly. Additionally, they maintain the relationship with their biosafety officer long after the assessment, reaching out with questions as issues arise.

“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 at the University of Iowa

FUTURE DIRECTIONS AND SUPPORT

US laboratory scientists are exposed routinely to hazardous pathogens, but the risks associated with this work must not be ignored. The CDC/APHL program is critical to ensuring the nation's public health system safeguards the health of laboratory staff and their communities. If the program is not continued, the US risks losing its investment in a safer laboratory system, and the effects will be multiple:

- **Biosafety and biosecurity practices at clinical laboratories will devolve.** Without the support of a biosafety officer, clinical laboratories will not be able to keep pace with risks from emerging pathogens, toxic spills, contaminated foods and other evolving threats.
- **Highly skilled biosafety officers will be hired away by private firms.** In the rapidly growing field of biosafety, professionals with this specialized skill set 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 Ebola hits the United States.** 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.

“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

APHL: SUPPORTING LAB BIOSAFETY AND BIOSECURITY

- Developed +20 tools, templates and resources to support development of sound laboratory biosafety and biosecurity practices
- Offered +15 trainings and webinars for biosafety officers
- Established a community of practice for +130 public health biosafety professionals
- Launched a Biosafety and Biosecurity Committee that has created resources and a training curriculum
- Under the auspices of the Global Health Security Agenda (GHS), drafted a Biorisk Management Framework to help Ghanaian laboratories to assess their operations and better integrate biosafety and biosecurity practices across human, veterinary and environmental laboratories.

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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