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Enhancing Biosafety and Biosecurity in the United States

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2018 Canadian Biosafety Symposium

What is APHL?

- Association of Public Health Laboratories
- A non-profit, non-governmental US based organization
- Over 900 members from state and local public health laboratories, state environmental and agricultural labs and others federal agencies and academic institutions.
- Advocates at the national level to shape public health policy and to secure increased support/resources for member labs
- Provides training, model practices, technical assistance domestically and internationally



Public Health Preparedness and Response Program Goals

1. Improve the capability and capacity of member laboratories to **safely** respond to biological, chemical, radiological threats, and other public health emergencies
2. Promote information and technology transfer from the CDC and other agencies to members to support preparedness functions
3. Expand and enhance relationships among member laboratories, clinical laboratories, first responders, CDC, FBI, and other federal agencies and international partners
4. Provide support for the Laboratory Response Network (LRN)
5. Shape legislation, regulations and promote policies that support laboratory preparedness and response



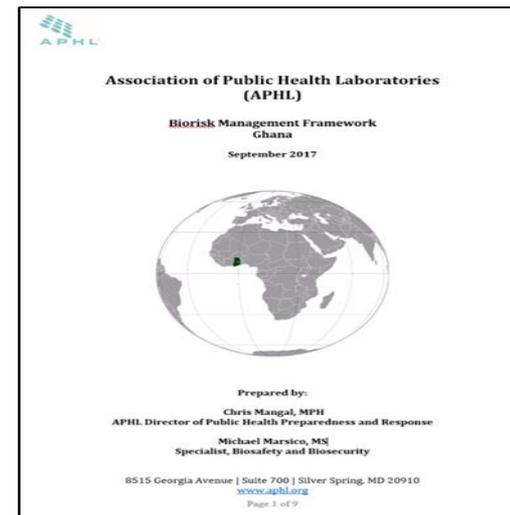
APHL Activities to Strengthen Biosafety

- Serve as Subject Matter Experts for Public Health Labs (PHLs)
- Provide Tools/Resources: **FREE**
- Ensure access to targeted educational and training opportunities
- Coordinate national efforts to improve biosafety in PHLs and support outreach to clinical laboratories



Subject Matter Experts

- Site visits as requested by PHLs
- Member expertise available to support CDC and other PHLs
- Develop Tools/Templates: aphl.org/biosafety
- Support for other programs (e.g. Global Health Security Agenda)
- Established Community of Practice



Provide Tools/Resources

- Online Repository: www.aphl.org/biosafety
 - Competency based position description for Biosafety Officer (BSO)
 - Risk Assessment Templates (e.g. Zika)
 - Biorisk Management Framework
 - Checklists



LAB ID and LABORATORY NAME:	
ASSESSOR NAME:	DATE:

Question	Y	N	NA	Comments
3. ESSENTIAL ELEMENTS FOR MANAGING AN EFFECTIVE BIOSAFETY PROGRAM				
3.1 Responsibility for Managing Biosafety				
Is the laboratory director responsible for ensuring that systems are in place and documented for identifying potential hazards, assessing risks associated with those hazards, and establishing precautions and standard procedures to minimize employee exposure to those risks? Is there a standard operating procedure (SOP) in place to document these?				
Is the laboratory director responsible for providing facilities commensurate with each laboratory's function and the recommended containment level for the agents or materials being handled? Is this written in an SOP?				
Are supervisory staff responsible for the following and are these responsibilities documented? <ul style="list-style-type: none"> • Conducting, reviewing, and approving risk assessment results. • Developing lab-specific safety plans; • Ensuring completion of initial and refresher training of laboratory workers, and for ongoing monitoring and correction of unsafe practices and conditions within the lab. 				
Are employees encouraged to report accidents or incidents and are these reports promoted as nonpunitive and as opportunities for improvement?				
Is compliance with safety policies and completion of safety-related training considered in staff performance evaluations?				



Access to Targeted Training Opportunities

- *Risk Assessment Training – still a need*
- Webinars
- Packaging and Shipping Seminars
- Regional Workshops
- Support for members (e.g. share training information and provide travel stipend when appropriate)
- Presentations at Conferences/National Meetings



Biosafety Community of Practice

- BioSafe 360

- Collaboration between APHL and Behavioral-Based Improvement Solutions (Sean Kaufman)
- 200+ participants, including global community
- Current cohort focused on leadership



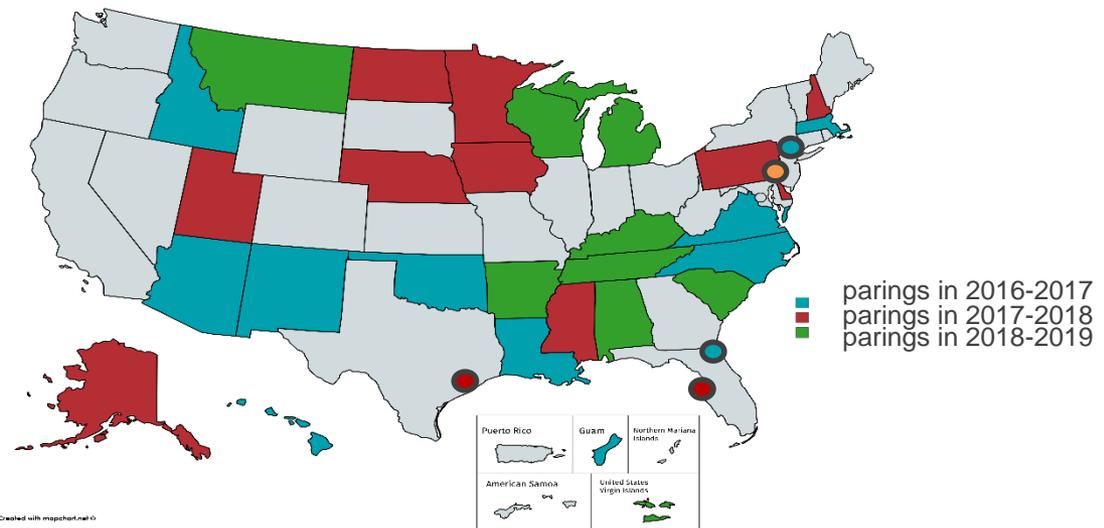
- Biosafety Peer Network

- 36 PHLs have been paired; visits are in progress or have been completed
- Continue to accept applications from PHLs across the US

- Biosafety ColLABorate Communities

Biosafety Peer Network

- The Network utilizes a twinning concept, pairing BSOs from two PHLs who alternately visit the other's institution. Laboratories are paired based on responses to an application.
- To date, thirty-six PHLs have been selected and paired – for a total of eighteen pairs.
- Deliverables: Peer Network Posters, PowerPoints with lessons captured, Trip Reports, and [Lab Culture Podcast](#)



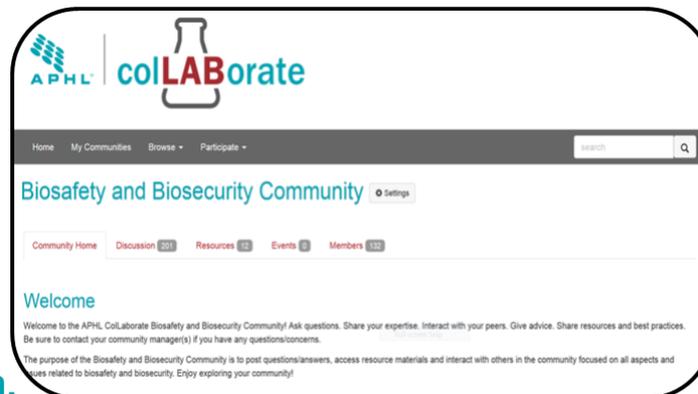
Biosafety and Biosecurity ColLABorate Communities

- **Biosafety and Biosecurity Community**

- Currently includes PHLs BSOs (~140), Biosafety Outreach Officers, and other pertinent Biosafety personnel

- **Laboratory Biosafety and Biosecurity Community**

- Currently includes PHLs BSOs (~180), Biosafety Outreach Officers along with clinical laboratory staff
 - Public Health Lab-59
 - Private Clinical Lab-110
 - National Organization-10
 - Federal Agency- 1



Biosafety Leadership Workshops

- Four-day workshop convenes all BSOs by region.
- Provides a forum which encourages personal and professional growth with the overall goal to strengthen leadership.
- 37 BSOs from 34 PHLs



Leadership Workshops



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



Coordinate National Efforts to Improve Biosafety in PHLs

- Maintain Biosafety and Biosecurity Committee
- Educational Efforts
 - Public Policy, Communications
- Engage broader stakeholders – e.g. Biosafety and Biosecurity Partners Forum
- Conduct PHL Surveys



Educational Efforts



BIOSAFETY & BIOSECURITY

UNMET NEEDS

- Increase funding to the US Centers for Disease Control and Prevention (CDC) for public health laboratories to sustain biosafety and biosecurity programs to protect laboratory workers and the public
- Provide resources to support public health laboratory outreach and training to clinical laboratories
- Provide resources to build and maintain a competent public health laboratory biosafety and biosecurity workforce, ensuring at least one full-time biosafety officer in each public health laboratory
- Bridge the lack of connectivity between healthcare and public health systems



Diseases (ELC) - Building and Strengthening Epidemiology, Laboratory and Health Information Systems Capacity in State and Local Health Departments.



APHL Position Statement Improving Biosafety in Our Nation's Laboratories

A. Statement of Position

Biosafety practices in the nation's laboratories must be enhanced through implementing routine risk assessments and standardized training, identification of true risk, and best practices

leadership to promote a culture of biosafety in their laboratories.

4. APHL will work with public health laboratories to provide outreach and training to other laboratories within their jurisdictions that are biosafety practices and guidelines. public health laboratories public about the principles of



CDC/APHL BIOSAFETY AND BIOSECURITY PROGRAM

February 2018

MAKING LABS SAFER FOR SCIENTISTS AND COMMUNITIES

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. Had the US Ebola outbreak been widespread, there would have been more such deaths. Yet staff



Biosafety and Biosecurity Partners Forum

- Federal partners and other stakeholders engaged in evaluating biosafety and biosecurity practices in the United States
- Successes:
 - Clinical Laboratory Survey
 - Clinical Laboratory Checklist
 - Access to training opportunities



**CDC ASM
CMS
ABSA
CLMA CAP
AACC
COLA
FDA ASCP AAB
The Joint Commission**



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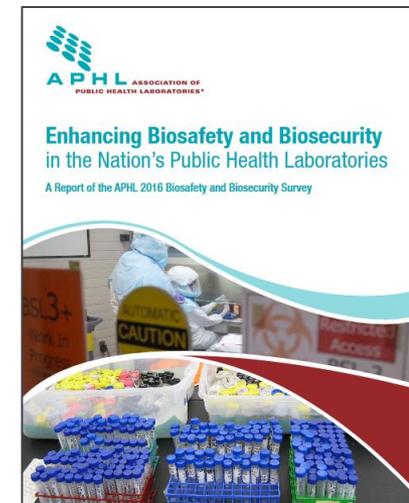
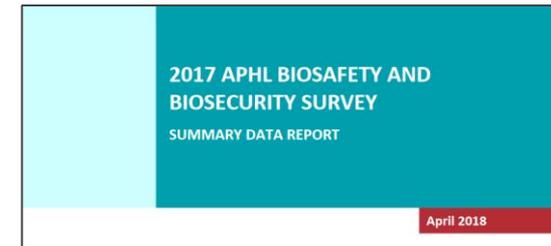
Biosafety and Biosecurity Survey

- APHL conducted the second annual Biosafety and Biosecurity survey in 2017
 - Focused on accomplishments and needs of CDC Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) CoAg Grantees
 - 55/63 PHLs (87%) responded
 - **Aggregate** summary data report provided to participants, CDC and the public
 - Report highlighting successes from the grantees and challenges which remain
 - First report issued in 2017
 - New report: will be published in September 2018



2017 Biosafety and Biosecurity Survey

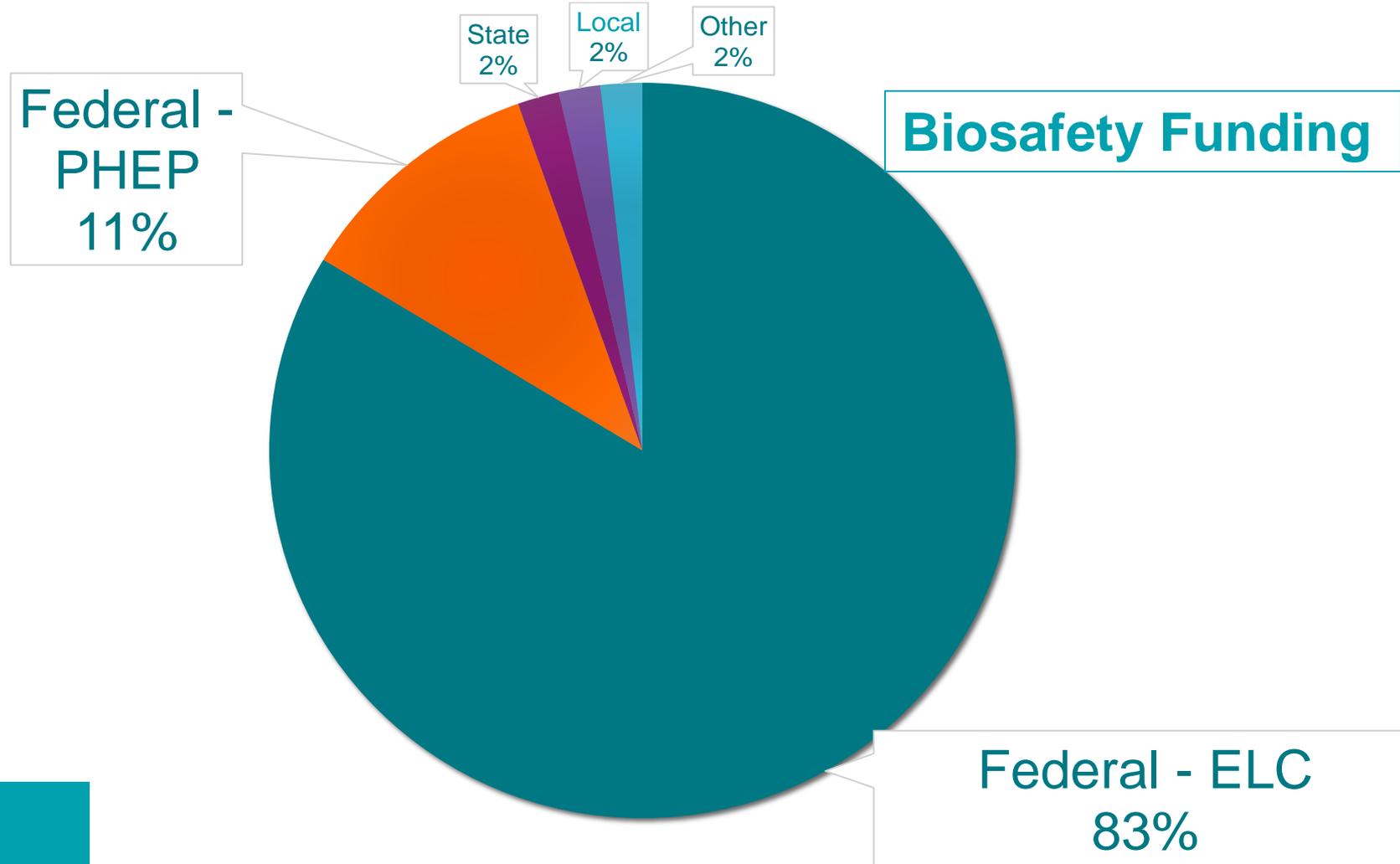
[Survey Instructions](#) [Survey Glossary](#) [Email Support](#)



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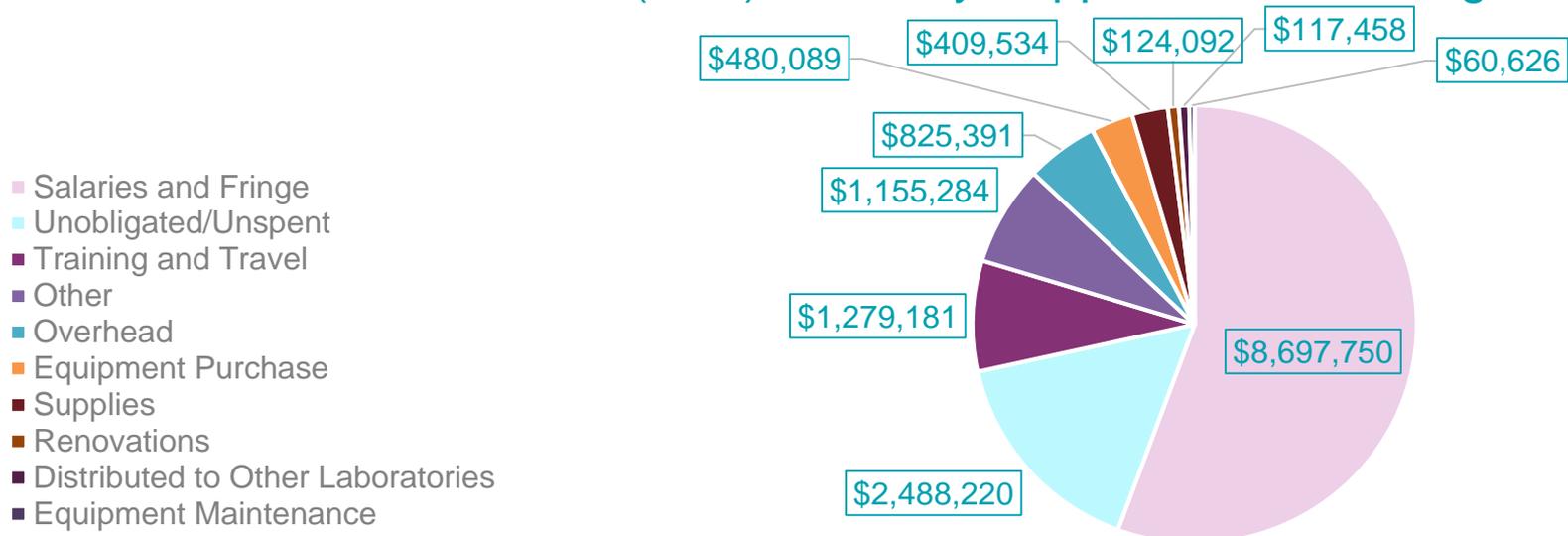
Key Data Points: 2017 APHL Biosafety and Biosecurity Survey



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- 55 PHLs received \$15.6 million from CDC (over a 3 year period)

Allocation of CDC Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) Biosafety Supplemental Funding



Key Data Points: 2017 APHL Biosafety and Biosecurity Survey

If funding ends, will you be able to maintain/enhance biosafety activities?	%	Number of PHLs
Yes, maintain internal biosafety activities	38.9%	28
No - Please describe what will be lost if Biosafety funding is no longer available	29.2%	21
Yes, maintain external outreach activities (e.g. training for clinical labs, site visits, guidance on risk assessments)	20.8%	15
Yes, enhance internal biosafety activities	8.3%	6
Yes, enhance external outreach activities (e.g. training for clinical labs, site visits, guidance on risk assessments)	2.8%	2
Total	100%	72



Key Data Points: 2017 APHL Biosafety and Biosecurity Survey

- More than 80% of BSOs in PHLs have been in their positions less than 3 years
- Most BSOs are focused on internal initiatives (present state)
- 94% of BSOs rely on APHL Listserv/Platform for guidance/assistance
- 90% of BSOs use APHL courses



Key Data Points: 2017 APHL Biosafety and Biosecurity Survey

- 52.7% (29) PHLs have not developed safety specific competencies for their laboratory staff – note 96.4% (53 PHLs) are familiar with CDC published competencies.

BBC: Addressing Adoption of Competencies



Key Data Points: 2017 APHL Biosafety and Biosecurity Survey

5,249 clinical labs: 55 PHLs

47 PHLs performed 730 site visits

54 PHLs communicated with clinical labs

33 PHLs Hosted Meeting with Clinical Labs

Number of Sentinel Clinical Labs	Total # of Labs
Sentinel clinical labs which meet the APHL-CDC-ASM Definition	3,254
Additional clinical labs (as described in the ELC Performance Measures Guidance)	1,995



Key Data Points: 2017 APHL Biosafety and Biosecurity Survey

- Challenges with Outreach
 - Lack of staff time/Lack of staff
 - Lack of buy-in from clinical labs
 - Clinical lab staff turnover
 - Geographic distance
- Training Needs
 - Risk Assessments
 - Hazardous Waste Disposal
 - BSL-3 Training



Outreach to Clinical Laboratories

Stronger public-private linkages; quality management system in all laboratories

- Evaluate PHL Outreach to Sentinel Clinical Labs
 - Facilitate a series of expert consultations with public health and clinical laboratory professionals via workshops
 - Survey: Biosafety Practices and Needs in Clinical Laboratories
 - Collect and share successful models of PHL outreach to sentinel clinical laboratories





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Questions?