Enhancing Biosafety and Biosecurity in the United States

Chris N. Mangal, MPH
Director, Public Health Preparedness and Response

September 11, 2018
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](http://www.aphl.org/biosafety)
  – Competency based position description for Biosafety Officer (BSO)
  – Risk Assessment Templates (e.g. Zika)
  – Biorisk Management Framework
  – Checklists
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 CoLABorate 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.

**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.

**February 2015**

**CDC/APHL BIOSAFETY AND BIOSECURITY PROGRAM**

**MAKING LABS SAFER FOR SCIENTISTS AND COMMUNITIES**

**EDUCATIONAL EFFORTS**

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 even more 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
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
Key Data Points: 2017 APHL Biosafety and Biosecurity Survey

Biosafety Funding

- Federal - ELC: 83%
- Federal - PHEP: 11%
- State: 2%
- Local: 2%
- Other: 2%

Key Data Points: 2017 APHL Biosafety and Biosecurity Survey

• 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

- Salaries and Fringe: $480,089
- Unobligated/Unspent: $409,534
- Training and Travel: $124,092
- Other: $117,458
- Overhead: $60,626
- Equipment Purchase: $825,391
- Supplies: $1,279,181
- Renovations: $1,155,284
- Distributed to Other Laboratories: $2,488,220
- Equipment Maintenance: $8,697,750
### Key Data Points: 2017 APHL Biosafety and Biosecurity Survey

If funding ends, will you be able to maintain/enhance biosafety activities?

<table>
<thead>
<tr>
<th>Options</th>
<th>%</th>
<th>Number of PHLs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes, maintain internal biosafety activities</td>
<td>38.9%</td>
<td>28</td>
</tr>
<tr>
<td>No - Please describe what will be lost if Biosafety funding is no longer available</td>
<td>29.2%</td>
<td>21</td>
</tr>
<tr>
<td>Yes, maintain external outreach activities (e.g. training for clinical labs, site visits, guidance on risk assessments)</td>
<td>20.8%</td>
<td>15</td>
</tr>
<tr>
<td>Yes, enhance internal biosafety activities</td>
<td>8.3%</td>
<td>6</td>
</tr>
<tr>
<td>Yes, enhance external outreach activities (e.g. training for clinical labs, site visits, guidance on risk assessments)</td>
<td>2.8%</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>100%</td>
<td>72</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Number of Sentinel Clinical Labs</th>
<th>Total # of Labs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sentinel clinical labs which meet the APHL-CDC-ASM Definition</td>
<td>3,254</td>
</tr>
<tr>
<td>Additional clinical labs (as described in the ELC Performance Measures Guidance)</td>
<td>1,995</td>
</tr>
</tbody>
</table>
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
Questions?