

Enhancing Domestic Laboratory Biosafety for Ebola and Other Highly Infectious Diseases

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OUTLINE

- ❑ Background information
- ❑ Summary of accomplishments & challenges
- ❑ Next steps

BACKGROUND INFORMATION

Identified Gaps in Laboratory Safety During 2014 US Ebola Event

- ❑ Clinical laboratories' ability to ship specimens for Ebola testing was not uniform
- ❑ Some laboratories declined requests to test specimens for malaria or other more likely diagnoses from persons under investigation (PUI) for Ebola
- ❑ Instrument decontamination procedures were not available
- ❑ Inconsistent laboratory response due to:
 - ❑ The lack of guidance for handling and testing of PUI specimens
 - ❑ Gaps in laboratory biosafety programs

CDC's Epidemiology and Laboratory Capacity (ELC) Program to Enhance Laboratory Biosafety

- ❑ \$110 million Cooperative Agreement with categorical and flexible components
- ❑ For public health departments in 50 states, 6 locals, & 8 territories/affiliates.
- ❑ Strengthens the following areas:
 - identify and monitor occurrence of known infectious diseases,
 - detect new emerging infectious disease threats,
 - identify and respond to disease outbreaks, and
 - develop and evaluate public health interventions.

ELC Supplemental Awards

- ❑ **March 30, 2015 - Funds awarded to 62 grantees - 3 years, \$21 million**
- ❑ **Strategy 1: Enhance public health laboratory (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
- ❑ **Strategy 2: Improve laboratory coordination and outreach**
 - Work with clinical laboratory (CL) partners to facilitate their risk assessments and development/implementation of measures to address gaps and mitigate risks

Role of Association of Public Health Laboratories (APHL)

Awarded a 3-year supplement (\$2.2 million) to:

- ❑ Serve as subject matter expert for ELC biosafety grantees
- ❑ Develop and deliver tools, materials, guidance
- ❑ Ensure access to targeted educational and training opportunities
- ❑ Coordinate national efforts to improve PHL biosafety capacity
- ❑ Conduct outreach with and engage CL partners
- ❑ Facilitate and strengthen communication among biosafety and biosecurity stakeholders

ACCOMPLISHMENTS (YEAR 1)

Progress Report: Activities Focused on Public Health Laboratories

- ❑ 97% (60/62) of grantees have hired or designated a BSO
- ❑ As of Oct 2015, performance measurement reports from grantees indicated that approximately:
 - 90% (53/57) had conducted RA for EVD
 - 82% (50/61) had certified personnel to pack and ship Category A specimens
 - 71% (40/56) had personnel with demonstrated competency to work in a BSL-3 laboratory
 - 55% (34/61) had policies and/or procedures for conducting RAs

Progress Report: Activities Focused on Clinical Laboratories

- ❑ ELC grantees provided performance measurement data for CLs in their jurisdictions in May & Oct 2015
- ❑ Measures addressed CL capacity for packing & shipping specimens to their PHL for Ebola testing and risk assessment capabilities
- ❑ Most grantees will address CL activities in Years 2 and 3
- ❑ A few have started working with CL partners by convening meetings, conducting site visits and providing training and tools

Performance Measurement Results for Clinical Laboratories

As of Oct 2015 –

- ❑ 33% of the grantees (19/57) reported that 80% of CLs in their jurisdiction had at least two staff members certified in packaging & shipping
- ❑ 8% (5/59) reported 80% of CLs in their jurisdiction had completed at least one RA
- ❑ 10% (6/60) reported 70% of CLs had a policy and/or procedure for performing RA

Summary: Laboratory Performance Measures

Public Health Laboratories:

- ❑ PHLs are on track to meet targets
- ❑ Focus area for improvement = risk assessment process and documentation

Clinical Laboratories

- ❑ Staffing for packaging and shipping is improving
- ❑ Outreach is needed for performing RAs

APHL Accomplishments

- ❑ Hired biosafety subject matter experts
- ❑ Convened a Biosafety and Biosecurity Committee (BBC) with PHL and CL representatives
- ❑ Developed and distributed competency-based BSO job description
- ❑ Developed and distributed templates to PHLs for Ebola and Zika Virus risk assessment and mitigation
- ❑ Conducted a needs assessment survey of ELC grantees
- ❑ Offered webinars to ELC grantees on 1) basics of biosafety & biosecurity, 2) PHL biosafety competencies, and 3) PHL outreach to CLs

Challenges

- ❑ The pool of individuals with laboratory biosafety knowledge and experience is insufficient to meet the need, resulting in
 - Delays in hiring BSOs
 - The need for training to bring everyone to a basic level
- ❑ Biosafety risk management appears to be a relatively new concept in CLs that will require extensive outreach efforts to address
- ❑ Uncertainty as to the ability to fund these activities past 2018

NEXT STEPS

ELC Grantees

- ❑ Year 2 continuation guidance published March 14, 2016, applications due May 17, 2016
- ❑ Additional Ebola funds are available for which ELC grantees can apply (e.g. to supplement BSO training)
- ❑ ELC grantees will work to enhance outreach to their CL partners
- ❑ Performance measurement data will be collected in April-May for the period Oct 1, 2015 to Mar 31, 2016

APHL

- ❑ Results from the needs assessment survey will be used to target certain activities
- ❑ A Biosafety & Biosecurity Partners Forum will be convened in 2016 to facilitate information exchange among federal, state, clinical laboratory organizations and other stakeholders
- ❑ Guidance and tools for risk assessments will be developed & distributed
- ❑ Checklists to assist with CL outreach are under development by the BBC
- ❑ Webinars and other training will be provided to the BSOs
- ❑ Regional workshops for BSOs will be convened in 2016

Questions?

