



# Update on CLIAC's Biosafety Recommendations

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Atlanta, GA

# CLIAC Recommendations on Biosafety, April 2016

CLIAC considers the matter of biosafety in clinical laboratories as an urgent unmet national need. We therefore recommend that CDC convene a multidisciplinary task force to develop a biosafety strategy for clinical laboratories that

- Includes stakeholders from all areas of clinical laboratories (including professional societies), diagnostic instrumentation industry, other relevant Federal agencies, and patient / clinician representatives
- Recommends areas requiring further research in clinical laboratory safety

# CLIAC Biosafety Recommendations Continued

- Develops tools, templates, and guidelines for risk assessment in all areas of the clinical laboratories, both for routine operations and for emerging infectious diseases
- Publishes interim materials and progress reports broadly, and specifically to CLIAC, to inform and to solicit input from the clinical laboratory and broader medical communities
- Describes cultural, regulatory, measurement, and evaluation strategies for goal achievement in biosafety
- Develops a framework for implementation of good clinical practices that also addresses transparent evaluation and monitoring of biosafety practices

# Specific Questions to Explore\*

- What is the status of biosafety practices and training in CLIA-certified laboratories?
- To what extent do manufacturers assure safety and provide guidance for decontamination of laboratory instrumentation?
- How are laboratory acquired infections and accidents investigated and reported? How do we capture lessons learned?
- Can guidelines be developed to help clinical laboratories manage biosafety risks when working with any clinical sample?
- How can we persuade clinical laboratories to adopt a culture of risk assessment, particularly for managing biosafety risks when working with unknown clinical samples?
- Could biosafety be incorporated into existing laboratory accreditation process?

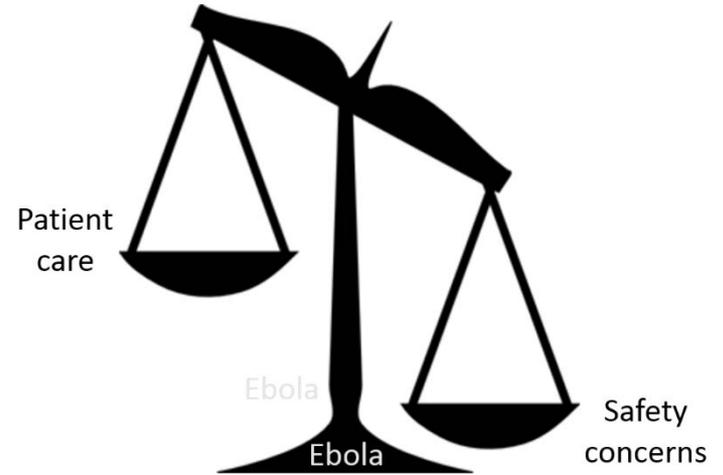
\*Derived from CLIAC discussions, April 2016

# Current Clinical Biosafety Improvement Taskforce

- Sheldon Campbell, MD, PhD, Yale University
- Andrew Bryan, MD, PhD, University of Washington
- James Snyder, PhD, University of Louisville
- Michael Pentella, PhD, State of Massachusetts Public Health Laboratory
- Chris Tormey, MD, Yale University
- Elizabeth Wagar, MD, MD Anderson Cancer Center
- Beverly Dickson, MD, Texas Presbyterian
- Kevin Matthai, Qiagen
- Nancy Burton, PhD, National Institute for Occupational Safety and Health
- Nancy Cornish, MD, Centers for Disease Control and Prevention
- Elizabeth Weirich, MS, Centers for Disease Control and Prevention
- Matt Arduino, DrPH, Centers for Disease Control and Prevention
- Reynolds Salerno, PhD, Centers for Disease Control and Prevention
- Bin Chen, PhD, Centers for Disease Control and Prevention

# Presentation at ASM Microbe, June 2016

- “Emerging Infections, Biosafety, and Clinical Laboratory Professionals”
  - During the Ebola crisis, safety concerns often outweighed patient care
  - Ebola was perceived to be an “absolute risk”
  - For the sake of future patient care and the safety of laboratorians, the clinical laboratory community needs much better biosafety information and tools – especially on risk assessment



# “Clinical Laboratory Biosafety” Paper in Process

- Multidisciplinary team identified
- Outline drafted
- Authors designated for each of the sections
- External SharePoint site created to share documents



# Public Health Ethics Case Study

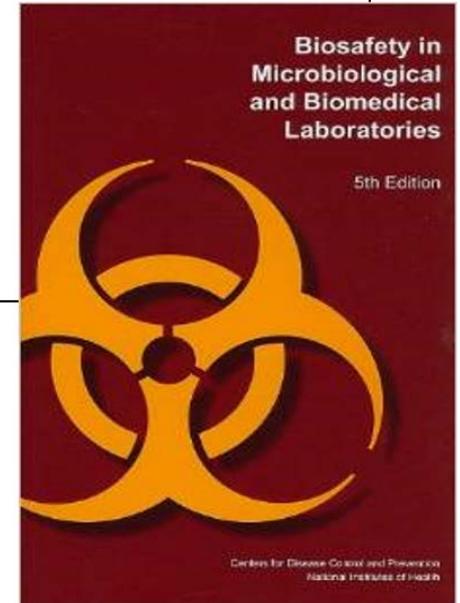
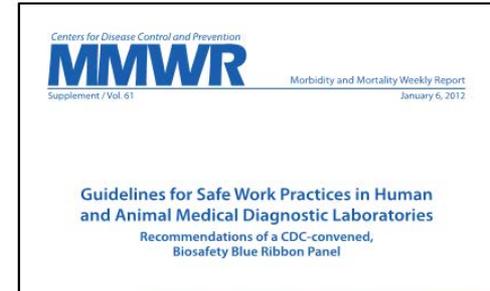
- Presented to the CDC Public Health Ethics Committee meeting in September 2016
- Next steps
  - Develop facilitator guide with ethics analyses
  - Pilot with the Laboratory Leadership Service fellowship program
  - Publish for use as a training tool for the clinical laboratory community
  - Use outcomes of case study training to facilitate guidance development



Alex Dubov, et al., 2016, “Ebola virus preparedness: emerging viruses and ethics in laboratory medicine,” *Archives of Pathology and Laboratory Medicine*, 140

# Supporting Revision of the BMBL

- Helped arrange for a joint letter from ASM and APHL, urging that the 6<sup>th</sup> edition of the BMBL
  - Include an editor from the clinical laboratory community
  - Provide biosafety guidance for clinical laboratories, recognizing that they generally work with unknown samples
  - Emphasize risk assessment rather than agent-based biosafety recommendations



# Laboratory-Associated Incident Reporting System

- CDC-convened Blue Ribbon Panel recommendation (2012)
- National, centralized, voluntary, and non-punitive reporting system to capture data regarding laboratory-associated incidents
  - Incidents defined as accidents, exposures, infections, and near-misses
- CDC multi-disciplinary workgroup developing an implementation and sustainability strategy
  - Developed questionnaire and promotion plan
  - Reviewed challenges and solutions with program managers of existing CDC surveillance systems
  - Exploring logistical and funding mechanisms

Report an Incident

Joint Project of CDC, NIH, and FDA

**Report laboratory-acquired infections here!**

Report-RLAI is a website dedicated to the anonymous reporting of laboratory incidents that may result in a laboratory-acquired infection. As a joint project of the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC), this website's goal is to provide an easy and secure means of collecting data that can be analyzed to help you make your workplace safer.

In addition to being able to enter data about incidents in biological laboratories, site visitors will have the ability to view standardized reports generated from all data entered here.

Report-RLAI is a simple, voluntary and anonymous reporting system. At no time will your identity be made known to anyone by any other means that will identify you.

**UNDER DEVELOPMENT**

**Our Mission**  
Laboratory biosafety is in everyone's best interest. The more we know about accidents, exposures to potentially infectious agents, any resulting laboratory-acquired infections, and patient outcomes, the better prepared we will be to respond to situations appropriately.  
[Click here to read more.](#)

**About the Joint Project**  
During revision of the CDC/NIH publication entitled *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, it was necessary to make decisions about inclusion of pertinent agent summary statements in the 5th Edition.  
[Click here to read more.](#)

**Why You Should Participate**  
Report-RLAI participating individuals or institutions cannot be identified, whether they have submitted an incident report or are viewing standardized reports, alerts, and safety trend analyses.  
[Click here to read more.](#)

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# New CDC Laboratory Biosafety Courses

- Currently going through internal and external review for public release
- Will be freely available and hosted on CDC TRAIN ([www.cdc.train.org](http://www.cdc.train.org))

# Thank you!

For more information, contact CDC  
1-800-CDC-INFO (232-4636)  
TTY: 1-888-232-6348 [www.cdc.gov](http://www.cdc.gov)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

