



# Biosafety in Clinical Laboratories

**Reynolds M Salerno, PhD, Director**

Division of Laboratory Systems/CSELS

Clinical Laboratory Improvement Advisory Committee

April 14, 2016

# Risk of exposure and infection

- In general, safety in health care and the biosciences has focused on health care workers and research laboratories
- Workers in clinical labs have often fallen through the cracks
- We need to refocus attention on risk to workers in clinical labs

# Occupation Safety and Health Act of 1970

- General Duties Clause (section 5)

“Each employer shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees.”

## Early biosafety, 1970s

- First laboratory acquired infection (LAI) studies
  - Recognition that most LAIs were bacterial, and the primary route of transmission was by aerosol
- Subsequent decline in laboratory acquired infections attributed to
  - Development and use of laminar-flow biological safety cabinets
  - Fewer bacterial patient samples in laboratories because of increased availability of antibiotics



Image from CDC Public Health Image Library

# Increased reliance on laboratory testing for patient care

- Led to a rise in exposure of laboratory workers to blood and body fluids
- Increased risk of transmission through contact with blood and other specimens
- Most laboratory acquired infections were now caused by viruses

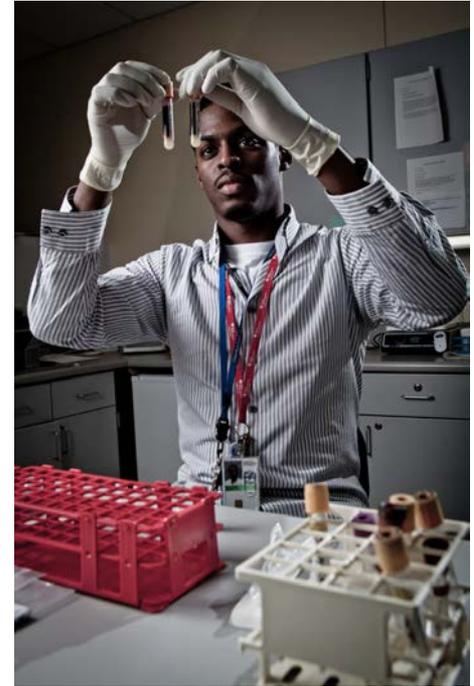


Image from CDC Public Health Image Library



# AIDS epidemic, 1980s

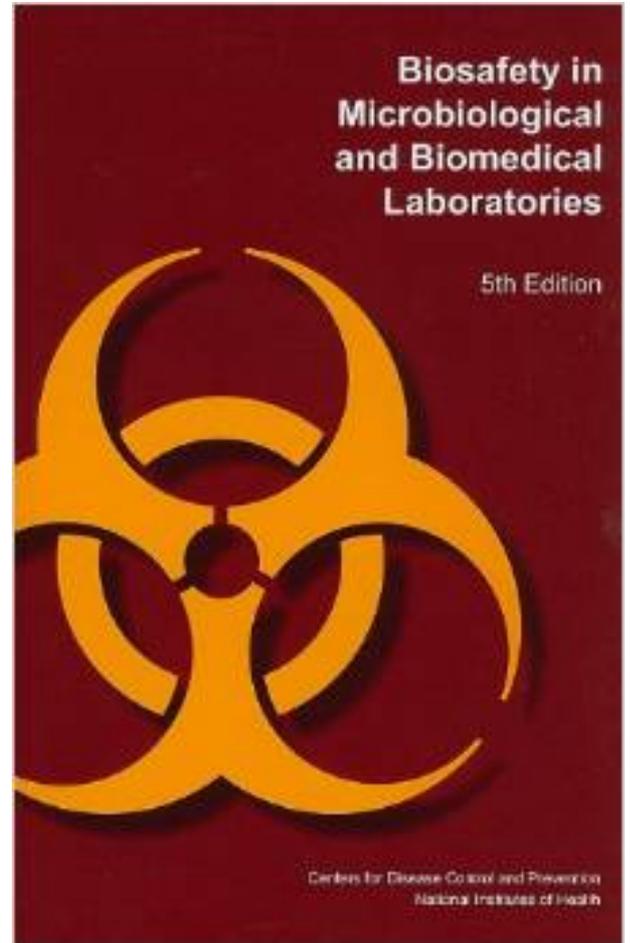
## Healthcare Personnel with Documented and Possible Occupationally Acquired HIV Infection, by Occupation, 1981-2010

Occupation	Documented	Possible
Nurse	24	36
<b>Laboratory worker, clinical</b>	<b>16</b>	<b>17</b>
Physician, nonsurgical	6	13
Laboratory tech, nonclinical	3	-
Housekeeper/maint worker	2	14
Technician, surgical	2	2
Embalmer/morgue technician	1	2
Health aide/attendant	1	15
Respiratory therapist	1	2
Technician, dialysis	1	3
Dental worker, incl dentist	-	6
Emerg med tech/paramedic	-	12
Physician, surgical	-	6
Other tech/therapist	-	9
Other healthcare occ	-	6
<b>Total</b>	<b>57</b>	<b>143</b>

<http://www.cdc.gov/HAI/organisms/hiv/Surveillance-Occupationally-Acquired-HIV-AIDS.html#table>

# BMBL

- First published in 1984, fifth edition 2009
- Set the standard for laboratory biosafety in the US and around the world
- Led to the creation of a new laboratory position title: biosafety officer



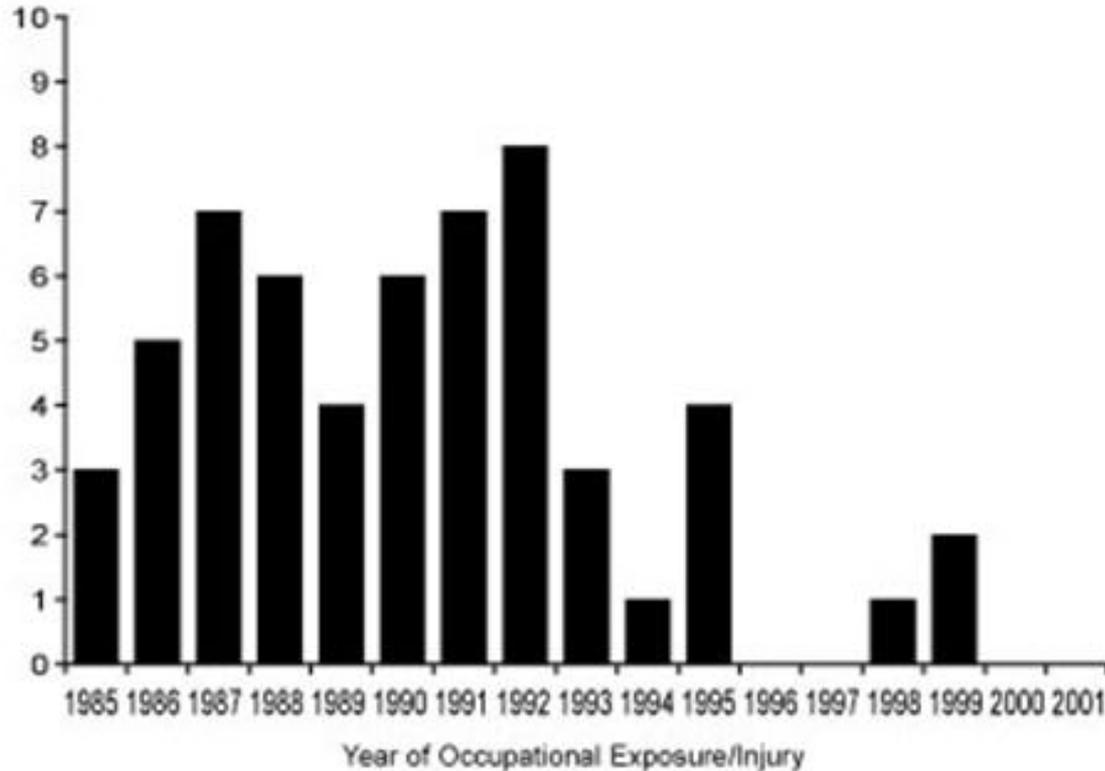


# Standards for working with bloodborne pathogens

- 1987: CDC recommendations to prevent transmission of HIV in health care settings
- 1989-91: OSHA final rule on occupational exposure to bloodborne pathogens
  - Became effective in March 1992



# HIV occupational exposures



<http://www.cdc.gov/HAI/organisms/hiv/Surveillance-Occupationally-Acquired-HIV-AIDS.html#table>

# Laboratory acquired infections continue

- **Laboratory-acquired Meningococcal disease** -- United States, 2000
- **Laboratory-acquired West Nile virus infections** -- United States, 2002
- **Laboratory-acquired Brucellosis** -- Indiana and Minnesota, 2006
- **Laboratory-acquired vaccinia virus infection** -- Virginia, 2008
- **Fatal laboratory-acquired infection with an attenuated Yersinia pestis strain** -- Chicago, Illinois, 2009

# UCLA study on laboratory safety, 2013

- Almost half had experienced injuries in the laboratory
- 30% of respondents had witnessed a major injury
- US respondents:
  - 25% conduct formal risk assessments
  - 50% assessed risk only “informally”

Richard Van Noorden, “Safety Survey Reveals Lab Risks,” *Nature* 493, 9-10 (02 January 2013).

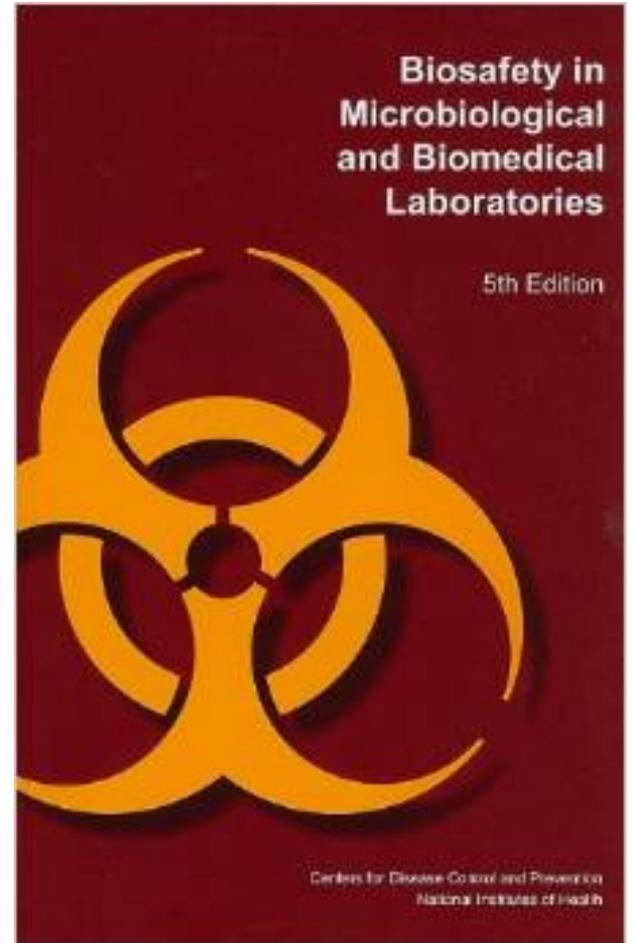


Image in accordance with fair use terms under the federal copyright law, not for distribution.



# BMBL

- Focus on biological research – not work in clinical laboratories
- Associates agents with specific biosafety levels
- Challenges for emerging and reemerging disease agents
  - SARS virus
  - H1N1 avian influenza
  - MERS CoV



# Case of Ebola, 2014

- Prior to 2014, Ebola only used in research laboratories in the US
- Ebola is a “BSL4 select agent”
- Hospitals and clinical laboratories are not BSL4 facilities
- Some health care workers and clinical labs fearful about treating suspect Ebola patients or testing suspect Ebola samples
- Yet certain facilities (Emory, Nebraska, Mount Sinai) successfully treated Ebola patients without using BSL4 facilities



[cbsnews.com](http://cbsnews.com)

Image in accordance with fair use terms under the federal copyright law, not for distribution.

# Case of Zika, 2016

- BMBL recommends biosafety level 2 for Zika virus
- Potential Zika patient may present with symptoms nearly identical to chikungunya or dengue
  - Necessary to assume sample could contain any of those arboviruses
- BMBL recommends BSL3 conditions for chikungunya
- Yet these arboviruses are blood borne infections that are not known to transmit by aerosol (BSL3 designed to reduce aerosol transmission risk)
- Perception that diagnosing Zika might require a BSL3 facility



*Aedes aegypti* mosquito.  
Photo by Jim Gathany, CDC

# CLIA and Biosafety

493.1101 (d)

Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.

493.1407 (e) (2)

The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards.

1445 (e) (2)

The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards.

# CLIA requirements applicable to safety

- Construction and arrangement of the laboratory must ensure necessary space, ventilation, and utilities
- Appropriate and sufficient equipment, instruments, reagents, materials, supplies needed
- Required compliance with Federal, State, and local requirements
- Have policies and procedures to assess employee and consultant competency
- Test requisition must include information needed to ensure accurate and timely testing and reporting of results
- Must perform and document maintenance and function checks
- Have sufficient staff with appropriate education and experience to consult, supervise, accurately perform tests and report results
- Before testing patient specimens, personnel must have appropriate education, experience, and training, and have demonstrated competency
- Have policies and procedures to monitor and assure competency of testing personnel

# Recommendations of a CDC-convened Biosafety Blue Ribbon Panel (2008)

*Centers for Disease Control and Prevention*

Supplement / Vol. 61

Morbidity and Mortality Weekly Report

January 6, 2012

## Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories

Recommendations of a CDC-convened,  
Biosafety Blue Ribbon Panel



**U.S. Department of Health and Human Services**  
Centers for Disease Control and Prevention

# CLIAC on Biosafety, 2015

- Sent a series of general recommendations to HHS May 2015
  - Ensure manufacturers assess safety and decontamination of laboratory instrumentation
  - Ensure all CLIA-certified laboratories require biosafety training
  - Conduct robust studies that evaluate safety of all laboratory practices
  - Develop a process for investigating and reporting laboratory acquired infections
- HHS response (August 2015): “We will carefully consider the CLIAC’s recommendations regarding clinical laboratory biosafety and will welcome any additional comments and suggestions that the CLIAC may have.”

# What perhaps now needs more emphasis

- Adopting an management systems approach to safety that is analogous to a quality management system



# Today's challenge

- Demographic, environmental, economic, and cultural trends have made outbreaks of emerging and reemerging infectious disease more common
- We must assume that health care workers, including the laboratory workforce, will encounter more outbreaks of unknown disease in the future
- We need to provide better biosafety guidance and support, especially in risk assessment, to clinical and diagnostic laboratories

# Discussion questions

- Are clinical laboratories familiar with the CDC Blue Ribbon Panel's Biosafety Guidelines?
- What is the status of biosafety practices and training in CLIA-certified laboratories?
- How are laboratory acquired infections in CLIA-certified laboratories investigated and reported?
- To what extent do manufacturers assure the safety and decontamination of laboratory instrumentation?
- Can guidelines be developed to help clinical laboratories manage biosafety for unknown diseases?
- How can CMS/FDA/CDC persuade clinical laboratories to adopt a culture of risk assessment?
- What studies should CDC/CMS/FDA conduct to answer the questions above?

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.

