



Wisconsin State Laboratory of Hygiene

UNIVERSITY OF WISCONSIN-MADISON

"Improving the Culture of Laboratory Biosafety"

April 30, 2015

Pete Shult, Ph.D., CDD Director and Emergency Laboratory Response, Communicable Disease Division, Wisconsin State Laboratory of Hygiene, Madison, WI, peter.shult@slh.wisc.edu

Erin Bowles, B.S., MT(ASCP), Clinical Laboratory Network Coordinator, Communicable Disease Division, Wisconsin State Laboratory of Hygiene, Madison, WI, erin.bowles@slh.wisc.edu



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2

Objectives

- Explain why there is a focus on improving the culture of laboratory biosafety and biosecurity.
- Discuss the Wisconsin State Laboratory of Hygiene 3 year plan for WCLN laboratories.
- Summarize the outcomes/benchmarks of the 3 year plan.

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3

Why Are We Talking About Biosafety Again?



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4



Headlines!

It's 10 o'clock -- Do You Know Where Your Bubonic Plague Is?

Spilled smallpox, missing SARS, and rogue scientists with mutant H1N1. If you're not scared, you should be.

BY LAURIE GARRETT

Anthrax scare reveals more CDC lab safety problems
By Associated Press
July 11, 2014

**After Lapses, C.D.C. Admits a Lax
Culture at Labs**
By RICHARD FAUSSET and DONALD G. MCNEAL Jr.,
JULY 13, 2014

**Frieden Testifies At Hearing
On CDC Lab Safety Lapses**

CBS Evening News 7/16/14

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5

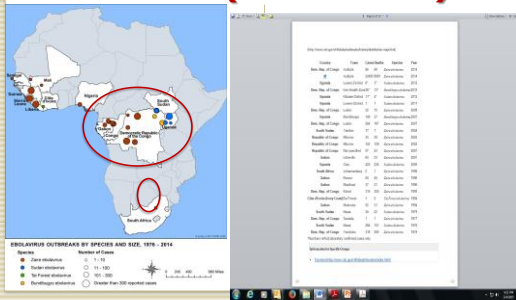
EBOLA!



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6

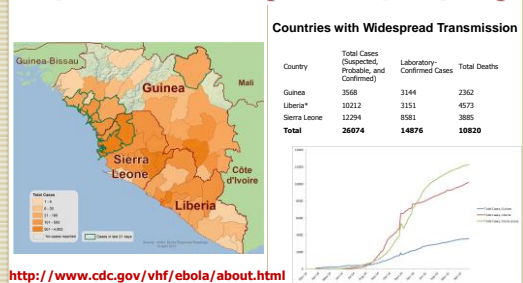
Cases of Ebola Virus Disease in Africa (1976 – 2014)



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7

2014-15 Ebola Outbreak in West Africa (As of 4/23/15)

<http://www.cdc.gov/vhf/ebola/about.html>

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8

Why should we be concerned about emerging diseases occurring abroad?



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9

EVD Cases (United States)

- EVD has been diagnosed in the United States in four people, one (the index patient) who traveled to Dallas, Texas from Liberia, two healthcare workers who cared for the index patient, and one medical aid worker who traveled to New York City from Guinea
- Index patient** – Symptoms developed on September 24, 2014 approximately four days after arrival, sought medical care at Texas Health Presbyterian Hospital of Dallas on September 26, was admitted to hospital on September 28, testing confirmed EVD on September 30, patient died October 8.
- TX Healthcare Worker, Case 2** – Cared for index patient, was self-monitoring and presented to hospital reporting low-grade fever, diagnosed with EVD on October 10, recovered and released from NIH Clinical Center October 24.
- TX Healthcare Worker, Case 3** – Cared for index patient, was self-monitoring and reported low-grade fever, diagnosed with EVD on October 15, recovered and released from Emory University Hospital in Atlanta October 28.
- NY Medical Aid Worker, Case 4** – Worked with Ebola patients in Guinea, was self-monitoring and reported fever, diagnosed with EVD on October 24, recovered and released from Bellevue Hospital in New York City November 11.

Information on U.S. EVD cases available at <http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/united-states-imported-case.html>.

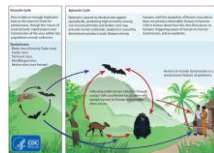
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10

Transmission

In nature

- Fruit bats likely reservoir
- Bush meat



In humans

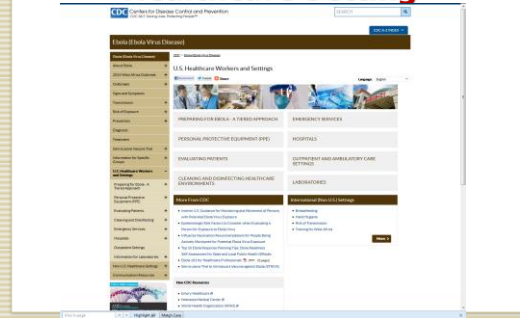
- Direct contact with blood and body fluids
 - Traditional burial preparation and mourner contact with the body
 - Skin of patients highly infected
 - Parenteral inoculation (via sharps)
 - Broken skin and mucous membrane contact
- Contact with environments contaminated with body fluids



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11

Ebola: Impacts in the Healthcare Setting



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12

Ebola Planning Continues...



<http://www.cdc.gov/vhf/ebola/>

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13

WI DHS Key Elements of Planning

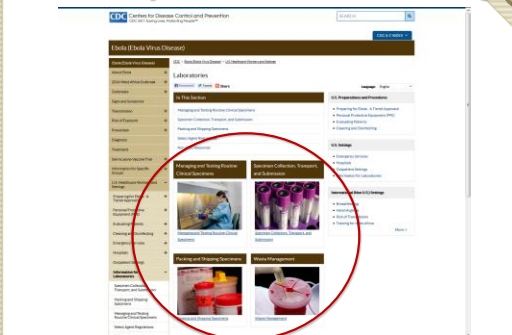


<https://www.dhs.wisconsin.gov/disease/ebola-virus-disease-partnerinfo.htm>

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14

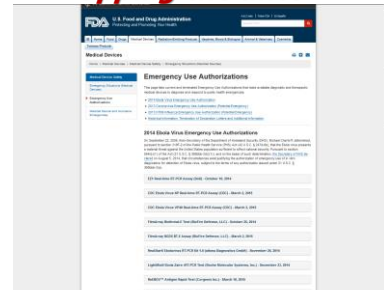
Ebola: Impacts in the Laboratory



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1

Testing for Ebola in the Clinical Lab



<http://www.fda.gov/medicaldevices/safety/emergencysituations/ucm161496.htm>

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16

Emerging Diseases Beyond Ebola...

- Ebola virus
- EV-D68
- MERS CoV
- Dengue fever
- Chikungunya
- ...and let's not forget Influenza
 - H5N1, H7N9, HPAI



<http://www.slh.wisc.edu/clinical/diseases/ebola-virus-information-for-lab-professionals/>

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1

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18

...and don't forget about other more common Lab Acquired

TABLE 1 Comparison of 10 most common symptomatic LAIs over time

Agent ^a	1930-1979 ^b		Agent	1979-2004	
	No. of cases	No. of deaths		No. of cases	No. of deaths
<i>Brucella</i> spp.	426	5	<i>Mycobacterium tuberculosis</i>	199	0
<i>Coccidia hominis</i>	280	1	Arboviruses ^c	192	3
Hepatitis B virus	268	3	<i>Coccidia hominis</i>	177	1
<i>Salmonella typhi</i>	258	20	Hantavirus	155	1
<i>Francisella tularensis</i>	225	2	<i>Brucella</i> spp.	143	4 ^d
<i>Mycobacterium tuberculosis</i>	194	4	Hepatitis B virus	82	1
<i>Rickettsia dermatitidis</i>	162	0	<i>Salmonella</i> spp.	66	0
<i>Yersinia enterocolitica</i>	146	1	<i>Salmonella</i> spp.	64	2 ^e
Chlamydia pneumoniae	136	10	Hepatitis C (formerly non-A, non-B)	32	1
<i>Coccidia hominis</i>	93	2	<i>Neisseria meningitidis</i>	31	11
Totals	2,168	48		1,141	24

^aAdapted from Pfaller, 1978.

^bNot included are 113 cases of hemorrhagic fever contracted from wild rodents in one laboratory in Russia in 1962 (Kladnig, 1962).

^cTypical arboviruses and others, including encephalitis, and arboviruses that are associated with arthropods or have zoonotic cycles (SALZ, 1983).

^dAll deaths were reported from.

^eOne death was associated with a secondary exposure case.

Biological Safety Principles and Practices 4th Edition, ASM 2006

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19

APHL Position Statement: Improving Biosafety in Our Nation's Laboratories

"The Association of Public Health Laboratories (APHL) supports the enhancement of biosafety practices in the nation's laboratories through the development of consensus standards, improved reporting of exposure events, identification of true risk and best practices, and by implementing routine risk assessments and standardized training"

-April 2015-

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20

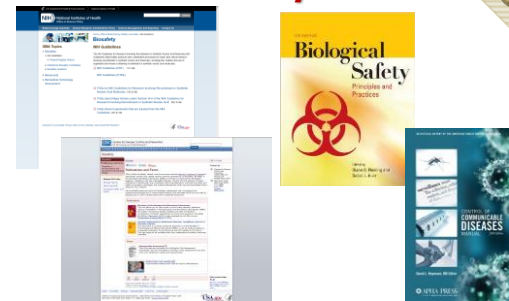
A Culture of Biosafety –Why?

- Reduces injuries and exposures
- Establishes team concept - all laboratory personnel share equal responsibility for maintaining safe workplace
- Ensures management's commitment to safety
- Staff are comfortable reporting incidents or near misses - viewed as opportunities for improvement
- Improves compliance with safety practices and regulations
- Safety is a critical component of a laboratory CQI program

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21

General Biosafety Resources



<http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines>
<http://www.cdc.gov/biosafety/publications/index.htm>

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22

Biosafety Guidelines



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23

Ebola: Laboratory Update

Laboratory testing (Non-Ebola) of specimens from suspect Ebola case

- Strict adherence to **Standard Precautions** is a basic starting point
- Understand the basic **Principles of Biosafety**
- Each laboratory needs to perform a **Risk Assessment** to determine whether they can safely perform routine testing in their diagnostic lab

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24

Laboratory Biosafety Principles of Biosafety

- The primary objective of biosafety is the **containment** of potentially harmful biological agents
- The purpose of **containment** is to reduce/eliminate exposure of lab workers, other persons within the institution, and the outside environment to biohazardous agents
- Key elements of **containment** include:
 - **Laboratory practice and technique**
 - **Safety equipment (primary barriers and PPE)**
 - **Facility design and construction (secondary barriers)**

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25

Step 1: Risk Assessment



Risk can be defined as the probability that a health effect will occur after an individual has been exposed to a specified amount of hazard.



Risk assessment is the process of gathering all available information on a hazardous substance and evaluating it to determine the possible risks associated with exposure. This is followed by determining the mitigation strategies necessary to provide protection. There is no one standard approach to the RA process.

The risk can be mitigated but never zero.
Goal: Predict, Identify and Mitigate Risk

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26

Lab Safety Begins With Risk Assessment

- **Assess biological risks**
 - Identify hazards
 - Consider the agent, the host, and the environment
 - Estimate risk based on likelihood and severity of the occurrence
- **Risk mitigation and exposure avoidance**
 - Identify and implement controls and work practices
- **Monitor effectiveness**
 - Review all accidents, exposures and near misses
 - Review effectiveness of control measures
 - Identify training needs
 - Modify procedures

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27

What should the Risk Assessment Cover?

- **Pre-analytical activities** from the time the specimen is collected, transported, unpackaged, centrifuged, aliquoted, and moves through the lab
- **Analytical activities**
- **Post-analytical activities** – clean up of the lab and destruction of the specimen and lab generated materials

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28

What Are We Going to Do to Improve the Culture of Laboratory Biosafety in Wisconsin?



We want to be #1 in laboratory biosafety

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29

WCLN Ultimate Goal

For all WCLN members to be prepared to respond to any emerging biohazard threat and to be able to do so in a manner where all laboratory employees, all facility coworkers and the surrounding community, are confident that all laboratory testing is being conducted as safely as possible in order to protect not only the health of the laboratory employees but the health of the community they serve.



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30

Epidemiology and Laboratory Capacity (ELC) Funding

- Domestic Ebola supplemental funding opportunity for public health
- Funding objective:
 - To enhance laboratory biosafety and biosecurity capacity at the WSLH.
 - To support public health partners to assess, develop and implement measures to improve laboratory biological safety practices for dealing with current and emerging infectious diseases.
- Funding covers a 3 year project

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31

Support from Partners

- Engage support from LabTAG for commitment to a 3 year project to improve laboratory biosafety and biosecurity.
- APHL will provide subject matter expert guidance.
- Engage State Training Coordinators from other states to develop trainings and tools that are useful to all states.
- Engage all WCLN laboratories and ask for feedback.



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32

It All Begins With Risk Assessment

Year 1 of the Project:

- Explain the project to WCLN members.
- Revise current "Laboratory Biosafety: Performing a Risk Assessment" guidance document.
- Roll-out revised risk assessment tool at 2015 Regional Meetings and ask all WCLN laboratories to perform a risk assessment.
- Develop a tool for collecting risk assessment data from WCLN laboratories to identify common biosafety issues.



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33

Next Steps: Risk Mitigation Strategies

Year 2 of the Project:

- Review the risk assessment data reported by WCLN members and identify common gaps in biosafety/biosecurity.
- WSLH and LabTAG develop risk mitigation strategies/tools/trainings to address the identified common gaps.
- Review the collective results from the 2014 risk assessment at the 2015 Regional Meetings and roll-out mitigation strategies/tools/trainings for the WCLN members to apply in their laboratories.



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34

Evaluate Our Progress

Year 3 of the Project:

- Ask WCLN members to repeat the original risk assessment and report their results.
- Collaborate with LabTAG to review results and to identify any further trainings or tools that may help mitigate any remaining biosafety issues.
- Review our laboratory biosafety progress at the 2016 Regional Meeting and roll-out any further aids to continue improving our culture of laboratory biosafety in WI.
- Expand culture of laboratory biosafety/biosecurity to all areas of the clinical laboratory.



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35

Additional Activities

- **Provide training** on biosafety/biosecurity related topics.
 - Packaging and shipping training
 - Biosafety/biosecurity best practices
- **Maintain a library** of links to biosafety/biosecurity resources on our "WCLN Resources" webpage: <http://www.slh.wisc.edu/wcln-surveillance/wcln/wcln-resources/>
- **Conduct drills/exercises** to determine competency in select areas of biosafety/biosecurity.
 - Packaging and shipping drills

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36

Ebola Hospital Preparedness Site Visits

- CDC and WDPH has visited all Category I facilities that have prepared to care for a known positive Ebola patient.
- WDPH has organized a team to visit all Category II facilities that have planned to care for a suspect Ebola patient for up to ≥ 72 hours while the patient is being assessed for Ebola infection.
 - Infection Prevention
 - Physician
 - WSLH CDD
 - Environmental Health
 - Wiscon
 - Preparedness/EMS Representative

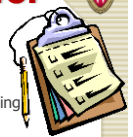


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37

Laboratory Checklist for Ebola Site Visits

- Have you performed a risk assessment?
- How is the specimen handed off for testing?
- Who is performing testing and where is the testing being performed?
- Are competency records for testing while wearing PPE in place and is competency being maintained on a regular basis?
- Are competency records for donning and doffing PPE in place and is competency being maintained on a regular basis?
- Is the test menu adequate to care for the patient?
- Is a spill kit in the room where testing is being performed?
- Where and how do you dispose of waste and how do you decontaminate the work area?
- How are the results being reported?
- Who is packaging and shipping the specimen and where?



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38

Can We Improve the Culture of Biosafety/Biosecurity in Our WI Laboratories?

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39

We Can't Do it Without Your Participation and Help!



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40

What questions do you have for us?

What are your recommendations as we move forward?



- Send your ideas to erin.bowles@slh.wisc.edu

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41