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

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.

Why Are We Talking About Biosafety Again?

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

Smallpox find was among hundreds of other long-lost vials, FDA says

By LAUREN RAAB, July 16, 2014

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

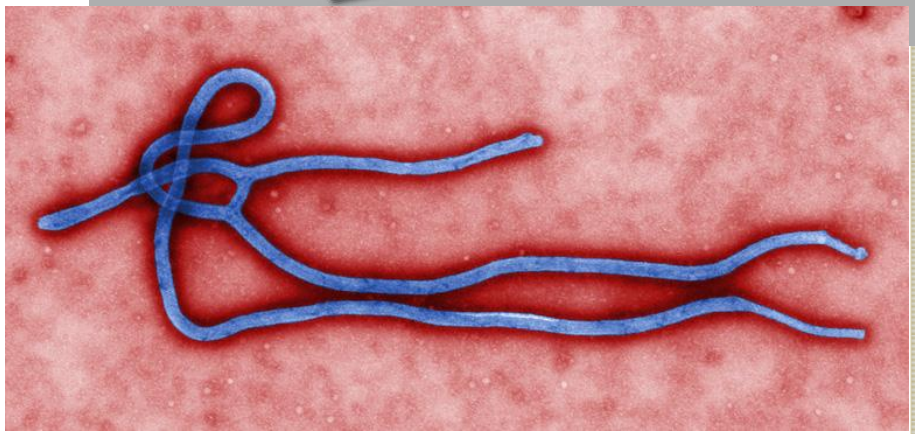
Frieden Testifies At Hearing On CDC Lab Safety Lapses

CBS Evening News 7/16/14

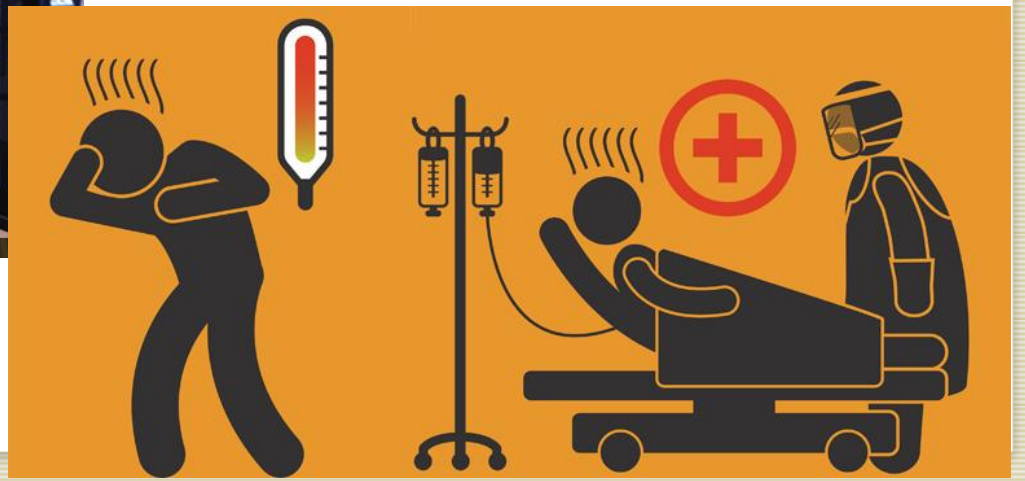
EBOLA!


EBOLA
SIGNS AND SYMPTOMS
IF YOU HAVE FEVER, DIARRHOEA AND VOMITING WITH OR WITHOUT BLEEDING
Go immediately to the Nearest HEALTH FACILITY
For more information Call: 117 (Toll Free)


CARE
Check and Report Ebola Kit
Digital Thermometer
go




What You Need to Know about Ebola
HEALTH ADVISORY: EBOLA OUTBREAK
Going to West Africa?



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

EBOLAVIRUS OUTBREAKS BY SPECIES AND SIZE, 1976 - 2014

Species	Number of Cases
Zaire ebolavirus	1 - 10
Sudan ebolavirus	11 - 100
Tai Forest ebolavirus	101 - 300
Bundibugyo ebolavirus	Greater than 300 reported cases

0 245 490 980 Miles

(http://www.cdc.gov/vhf/ebola/outbreaks/history/distribution-map.html)

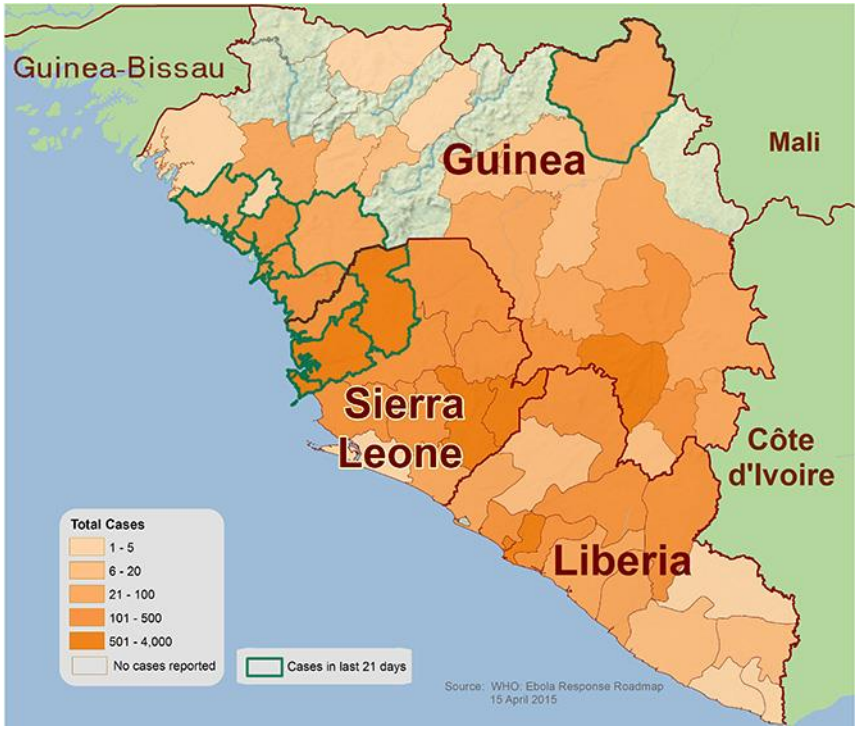
Country	Town	Cases	Deaths	Species	Year
Dem. Rep. of Congo	multiple	66	49	*Zaire ebolavirus*	2014
M	multiple	22495	8981	*Zaire ebolavirus*	2014
Uganda	Luwero District	6*	3*	*Sudan ebolavirus*	2012
Dem. Rep. of Congo	Isiro Health Zone	36*	13*	*Bundibugyo ebolavirus*	2012
Uganda	Kibaale District	11*	4*	*Sudan ebolavirus*	2012
Uganda	Luwero District	1	1	*Sudan ebolavirus*	2011
Dem. Rep. of Congo	Luebo	32	15	*Zaire ebolavirus*	2008
Uganda	Bundibugyo	149	37	*Bundibugyo ebolavirus*	2007
Dem. Rep. of Congo	Luebo	264	187	*Zaire ebolavirus*	2007
South Sudan	Yambio	17	7	*Zaire ebolavirus*	2004
Republic of Congo	Mbomo	35	29	*Zaire ebolavirus*	2003
Republic of Congo	Mbomo	143	128	*Zaire ebolavirus*	2002
Republic of Congo	Not specified	57	43	*Zaire ebolavirus*	2001
Gabon	Libreville	65	53	*Zaire ebolavirus*	2001
Uganda	Gulu	425	224	*Sudan ebolavirus*	2000
South Africa	Johannesburg	2	1	*Zaire ebolavirus*	1996
Gabon	Booue	60	45	*Zaire ebolavirus*	1996
Gabon	Mayibout	37	21	*Zaire ebolavirus*	1996
Dem. Rep. of Congo	Kikwit	315	250	*Zaire ebolavirus*	1995
Côte d'Ivoire (Ivory Coast)	Tai Forest	1	0	*Tai Forest ebolavirus*	1994
Gabon	Mekouka	52	31	*Zaire ebolavirus*	1994
South Sudan	Nzara	34	22	*Sudan ebolavirus*	1979
Dem. Rep. of Congo	Tandala	1	1	*Zaire ebolavirus*	1977
South Sudan	Nzara	284	151	*Sudan ebolavirus*	1976
Dem. Rep. of Congo	Yambuku	318	280	*Zaire ebolavirus*	1976

*Numbers reflect laboratory confirmed cases only.

Information for Specific Groups

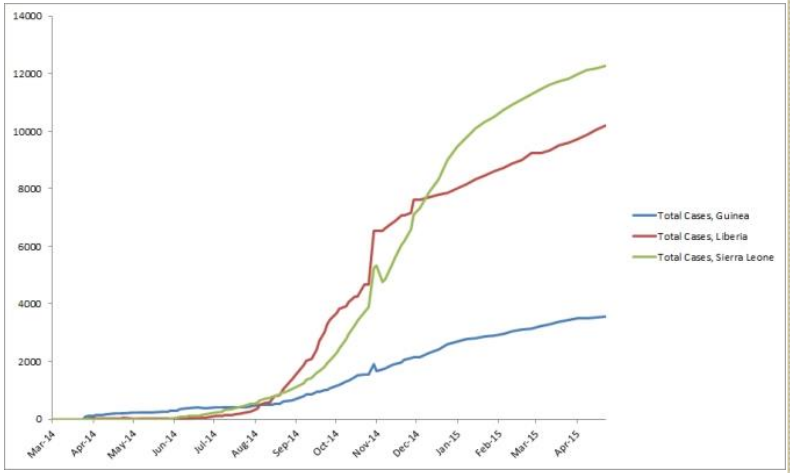
- Travelers(http://www.cdc.gov/vhf/ebola/travelers/index.html)

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



Countries with Widespread Transmission

Country	Total Cases (Suspected, Probable, and Confirmed)	Laboratory-Confirmed Cases	Total Deaths
Guinea	3568	3144	2362
Liberia*	10212	3151	4573
Sierra Leone	12294	8581	3885
Total	**26074**	**14876**	**10820**



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

Why should we be concerned about emerging diseases occurring abroad?

H3N2v

H7N9

Ebola

MERS-Coronavirus

EVD Cases (United States)

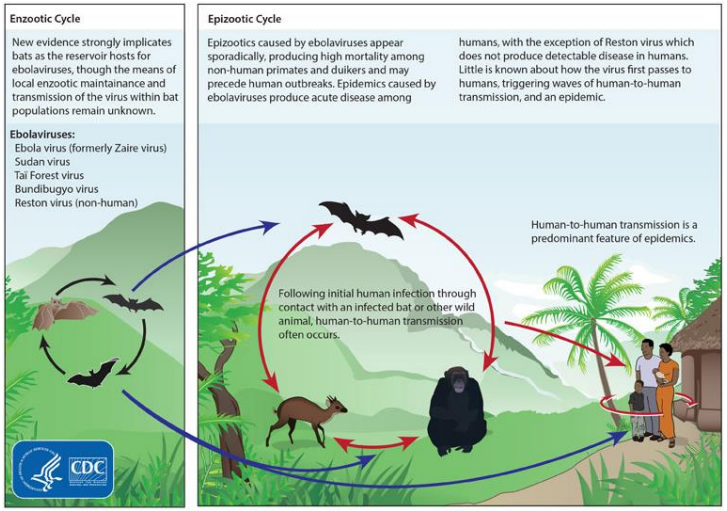
- EVD has been diagnosed in the United States in four people, one (the index patient) who traveled to Dallas, Texas from Liberia, two healthcare workers who cared for the index patient, and one medical aid worker who traveled to New York City from Guinea
  - **Index patient** – Symptoms developed on 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.

Transmission

In nature

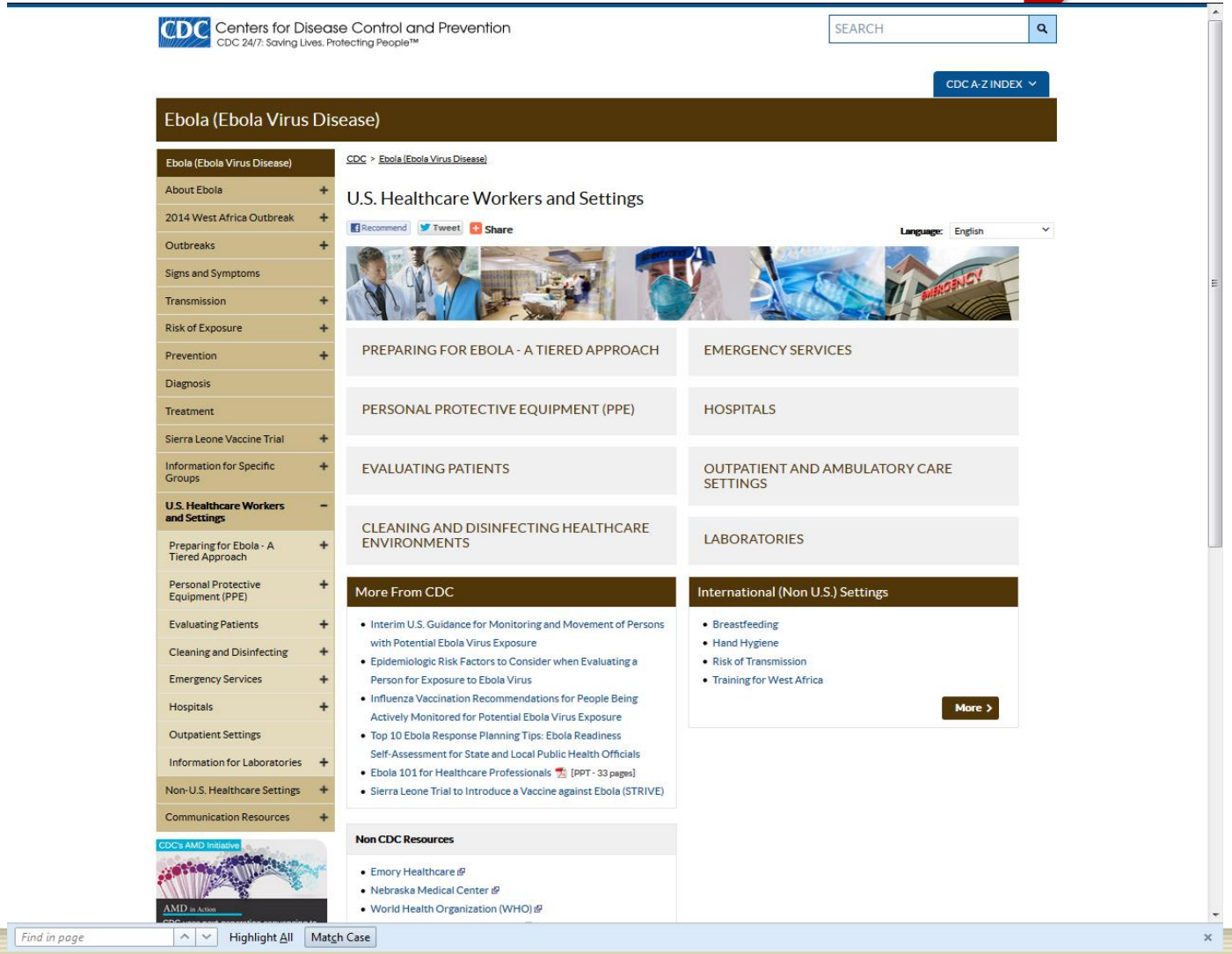
- Fruit bats likely reservoir
- Bush meat



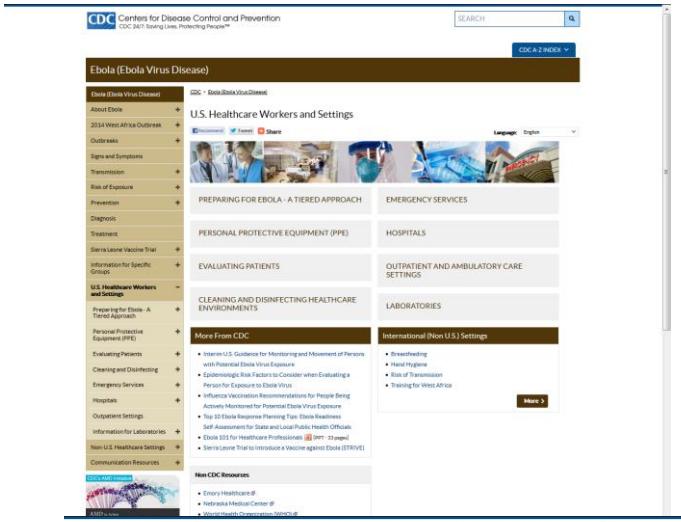
In humans

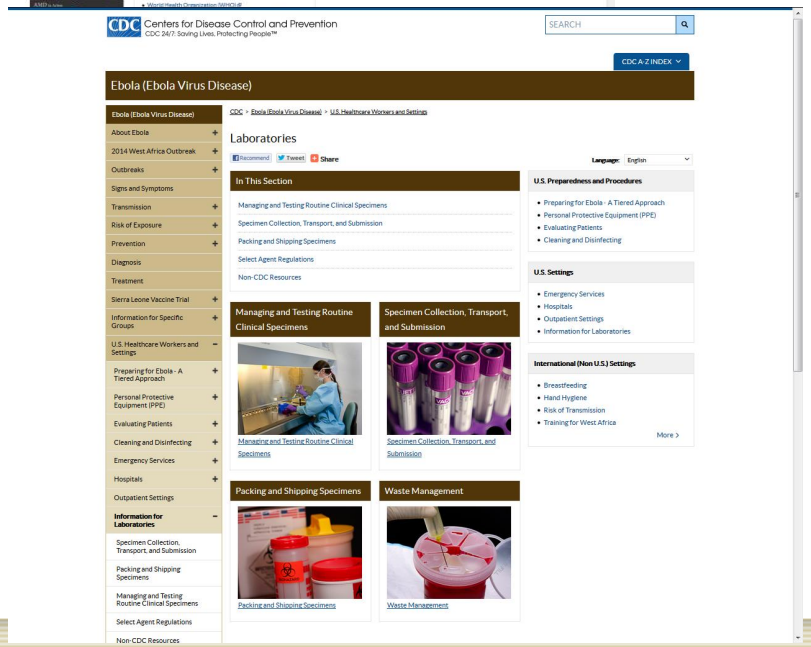
- Direct contact with blood and body fluids
  - Traditional burial preparation and mourner contact with the body
    - Skin of patients highly infected
  - Parenteral inoculation(via sharps)
  - Broken skin and mucous membrane contact
- Contact with environments contaminated with body fluids

Ebola: Impacts in the Healthcare Setting



Ebola Planning Continues…





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

WI DHS
Key Elements of Planning

General Information

Wisconsin DHS is hosting regularly scheduled webcasts for partners to provide information regarding important Ebola preparedness topics, in addition to providing online resources. Archived and upcoming webcasts can be accessed at the provided in the Webcast tab.

- CDC National Calls
- CDC Ebola 101
- CDC Pets and Ebola
- DHS Ebola and Pets Algorithm

- Preparedness
- Screening
- Monitoring
- Transport of Patients
- Hospital Categories
- Personal Protective Equipment
- Collection and Testing of Specimens
- Decontamination
- Waste
- Human Remains
- Ebola Traveler Notification
- DHS Contact Information
- DHS Partner Webcasts
- Wisconsin's Ebola Preparedness Updates

Last Revised: January 7, 2015

Ebola Hospital Categorization

Wisconsin Department of Health Services Division of Public Health

CATEGORY ONE (TREATMENT) HOSPITALS

- *Category One Hospitals* are pre-identified facilities prepared to care for a *confirmed* Ebola patient.
- In Wisconsin, these facilities are the University of Wisconsin Hospital and the American Family Children's Hospital, the Medical College of Wisconsin and Froedtert Hospital, and Children's Hospital of Wisconsin.

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CATEGORY TWO (ASSESSMENT) HOSPITALS

- *Category Two Hospitals* are those facilities that can care for a *potential* Ebola case for up to 96 hours while confirmatory testing takes place or transportation arranged.
- These hospitals should focus on the following areas while preparing:
  - Transportation and isolation: Points of facility entry for ambulances or ambulatory patients, transportation routes within the hospital, and a private room should be pre-identified, along with an area for donning and doffing PPE.
  - Evaluation and Treatment: A patient care team should be pre-selected and infectious disease specialists should be available for immediate consultation (phone consultation is acceptable).
  - Laboratory Testing: Protocols should be in place to safely collect specimens – both for testing at the hospital and for testing at the state public health laboratory and/or CDC. Procedures should be in place to collect and ship specimens for Ebola testing with the assistance of DHS. Facilities should be able to safely collect blood specimens in 4 ml plastic EDTA tubes for Ebola testing. Facilities should have the materials and certified staff to package and ship blood specimens as Suspect Category A Infectious Substances.
  - Healthcare Worker Protection and Environmental Controls: All members of the patient care team should have adequate supplies of PPE until Ebola testing can be performed. Team members should be properly trained in donning and doffing of PPE. Protocols and supplies should be available for the proper cleaning and disinfection of the patient room and medical equipment. Facilities should be prepared to properly package and store and potentially contaminated waste in a secure area in the event the patient tests positive for Ebola.
  - For more complete guidance, please see http://www.cdc.gov/vhf/ebola/hcp/preparing-ebola-assessment-hospitals.html

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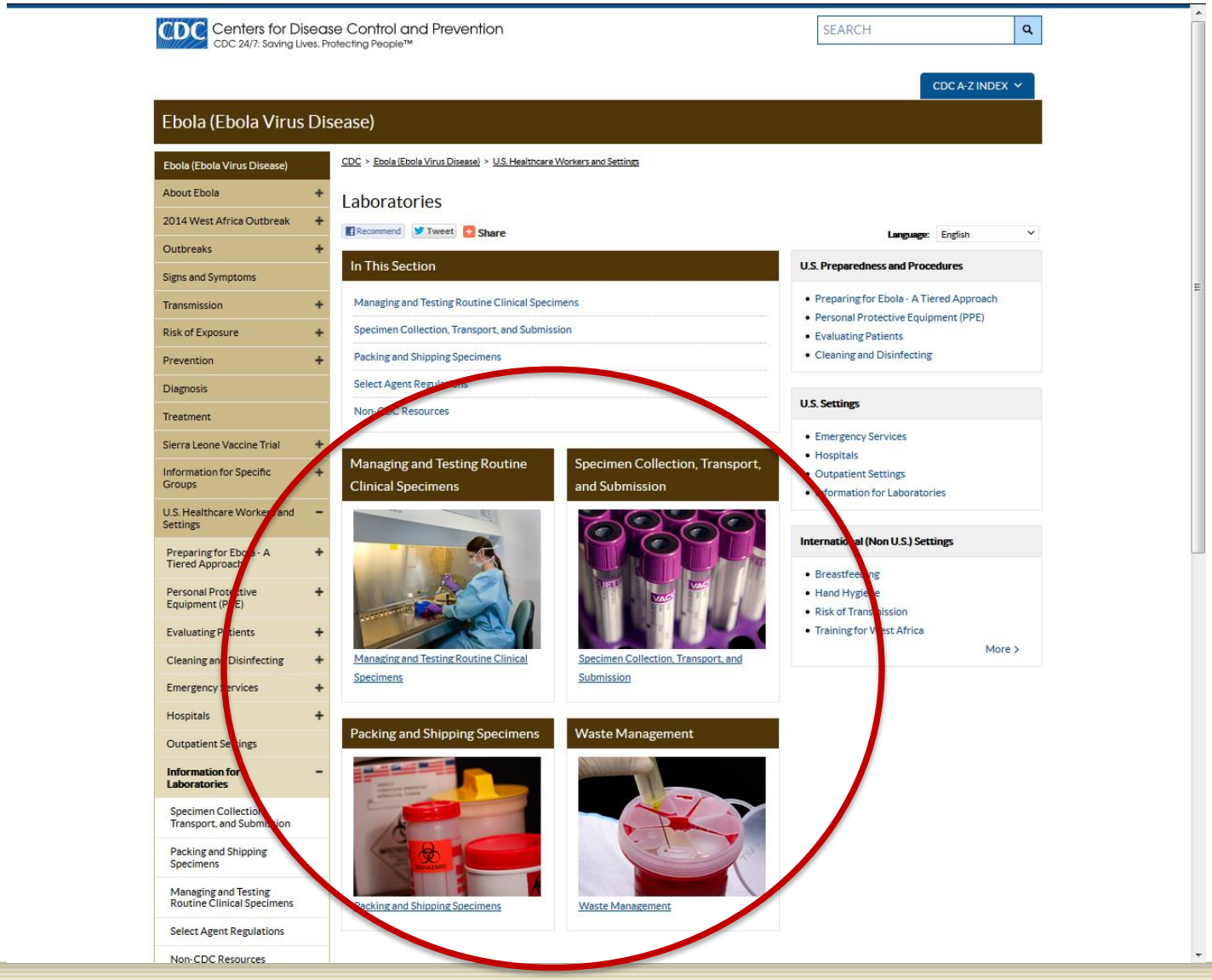
CATEGORY THREE (FRONTLINE) HOSPITALS

- *Category Three Hospitals* can screen, identify, and isolate a patient with risk factors and symptoms of Ebola, but are unable to care for suspect or confirmed Ebola patients.
- These facilities should have a transfer plan in place with a *Category Two facility* in the event that they identify a suspect patient.
- If these facilities identify a suspect case of Ebola, they should immediately call the 24/7 provider hotline at the Wisconsin Department of Health Services.

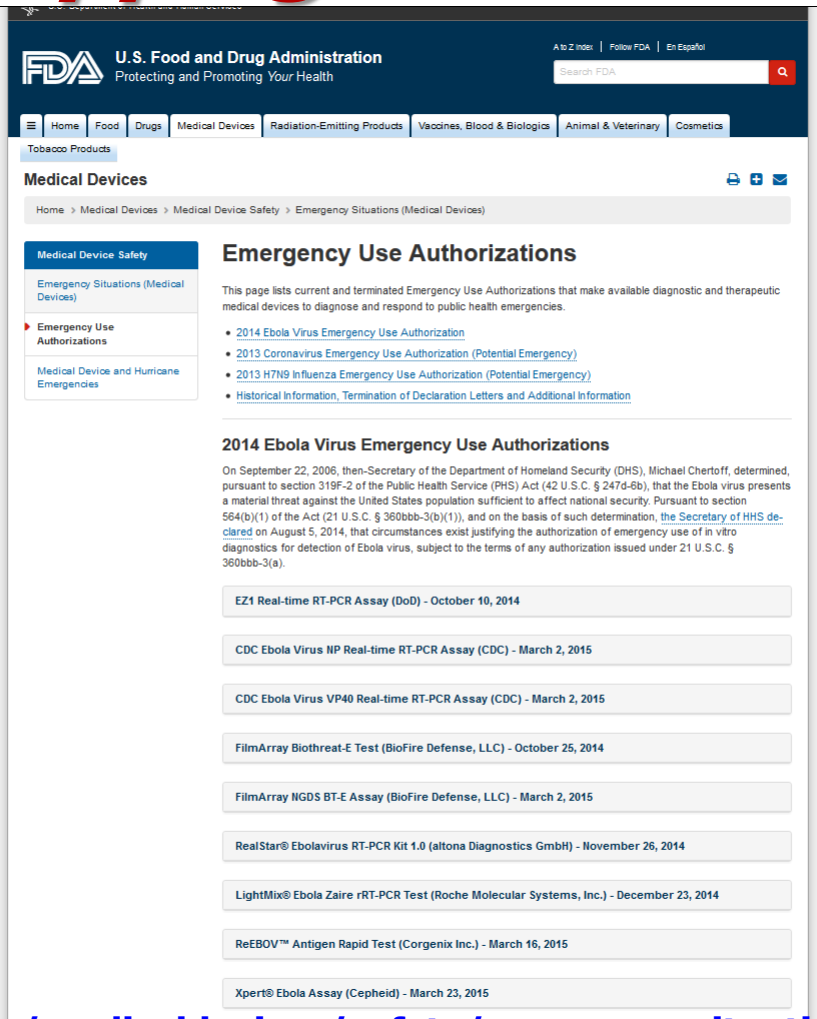
https://www.dhs.wisconsin.gov/disease/ebola-virus-disease-partnerinfo.htm

Ebola: Impacts in the Laboratory



Testing for Ebola in the Clinical Lab

Upping the ante



U.S. Food and Drug Administration
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Medical Devices

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- Medical Device Safety
- Emergency Situations (Medical Devices)
- Emergency Use Authorizations
- Medical Device and Hurricane Emergencies

Emergency Use Authorizations

This page lists current and terminated Emergency Use Authorizations that make available diagnostic and therapeutic medical devices to diagnose and respond to public health emergencies.

- 2014 Ebola Virus Emergency Use Authorization
- 2013 Coronavirus Emergency Use Authorization (Potential Emergency)
- 2013 H7N9 Influenza Emergency Use Authorization (Potential Emergency)
- Historical Information, Termination of Declaration Letters and Additional Information

2014 Ebola Virus Emergency Use Authorizations

On September 22, 2006, then-Secretary of the Department of Homeland Security (DHS), Michael Chertoff, determined, pursuant to section 319F-2 of the Public Health Service (PHS) Act (42 U.S.C. § 247d-6b), that the Ebola virus presents a material threat against the United States population sufficient to affect national security. Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), and on the basis of such determination, the Secretary of HHS declared on August 5, 2014, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection of Ebola virus, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).

- EZ1 Real-time RT-PCR Assay (DoD) - October 10, 2014
- CDC Ebola Virus NP Real-time RT-PCR Assay (CDC) - March 2, 2015
- CDC Ebola Virus VP40 Real-time RT-PCR Assay (CDC) - March 2, 2015
- FilmArray Biothreat-E Test (BioFire Defense, LLC) - October 25, 2014
- FilmArray NGDS BT-E Assay (BioFire Defense, LLC) - March 2, 2015
- RealStar® Ebolavirus RT-PCR Kit 1.0 (altona Diagnostics GmbH) - November 26, 2014
- LightMix® Ebola Zaire rRT-PCR Test (Roche Molecular Systems, Inc.) - December 23, 2014
- ReEBOV™ Antigen Rapid Test (Corgenix Inc.) - March 16, 2015
- Xpert® Ebola Assay (Cepheid) - March 23, 2015

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

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

Emerging Diseases Beyond Ebola…

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

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

TABLE 1 Comparison of 10 most common symptomatic LAIs over time

1930–1978[a]			1979–2004		
Agent[b]	No. of cases	No. of deaths	Agent	No. of cases	No. of deaths
Brucella spp.	426	5	*Mycobacterium tuberculosis*	199	0
Coxiella burnetii	280	1	Arboviruses[c]	192	3
Hepatitis B virus	268	3	*Coxiella burnetii*	177	1
Salmonella typhi	258	20	Hantavirus	155	1
Francisella tularensis	225	2	*Brucella* spp.	143	4[d]
Mycobacterium tuberculosis	194	4	Hepatitis B virus	82	1
Blastomyces dermatitidis	162	0	*Shigella* spp.	66	0
Venezuelan equine encephalitis virus	146	1	*Salmonella* spp.	64	2[e]
Chlamydia psittaci	116	10	Hepatitis C (formerly non-A, non-B)	32	1
Coccidioides immitis	93	2	*Neisseria meningitidis*	31	11
Totals	2,168	48		1,141	24

[a]Adapted from Pike, 1978.
[b]Not included are 113 cases of hemorrhagic fever contracted from wild rodents in one laboratory in Russia in 1962 (Kulagin, 1962).
[c]Typical arboviruses and orbiviruses, rhabdoviruses, and arenaviruses that are associated with arthropods or have zoonotic cycles (SALS, 1980).
[d]All deaths were aborted fetuses.
[e]One death was associated with a secondary exposure case.

Biological Safety *Principles and Practices* 4th Edition, ASM 2006

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

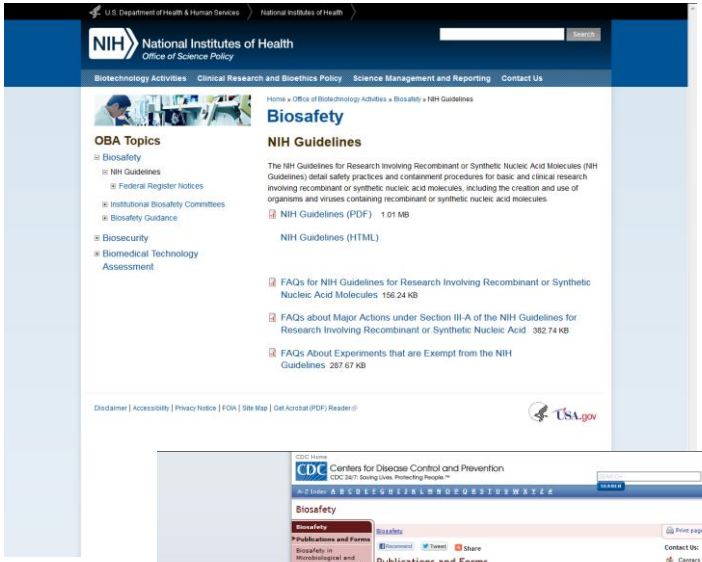
"The Association of Public Health Laboratories (APHL) supports the enhancement of biosafety practices in the nation's laboratories through the development of consensus standards, improved reporting of exposure events, identification of true risk and best practices, and by implementing routine risk assessments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

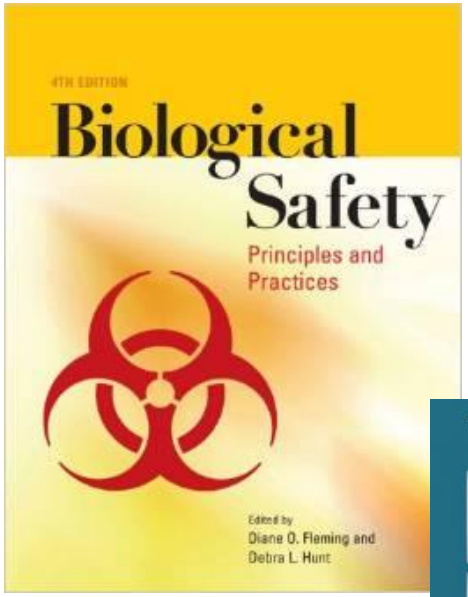
-April 2015-

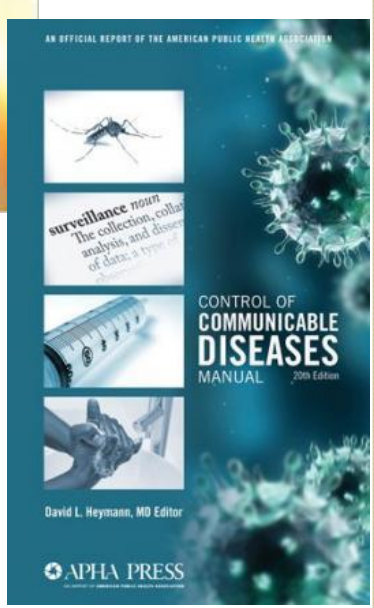
A Culture of Biosafety –Why?

- 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

General Biosafety Resources

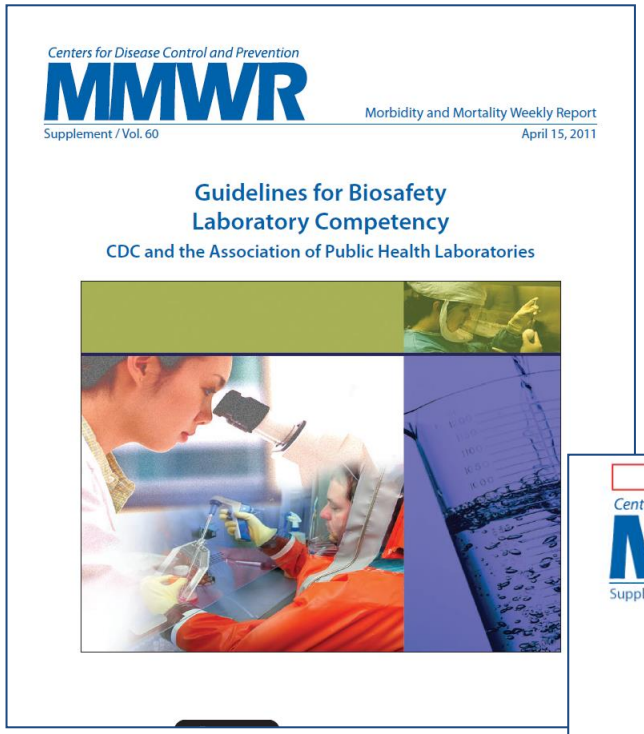


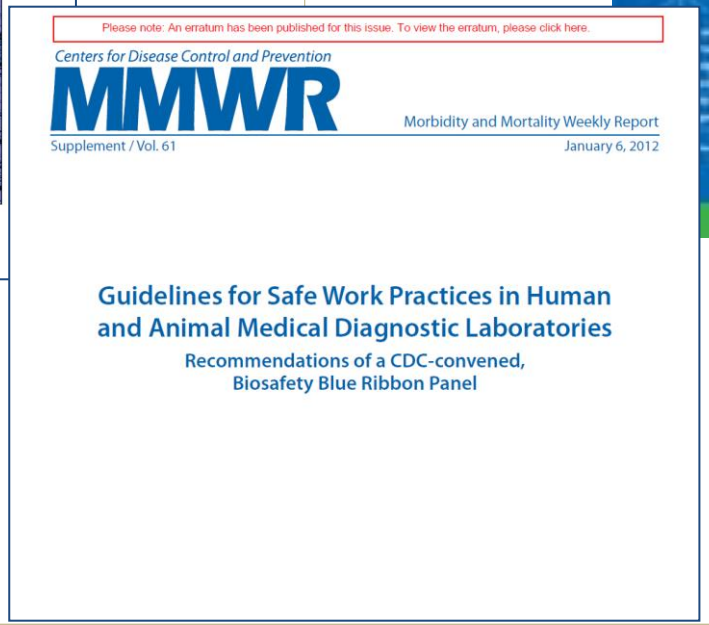




http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines
http://www.cdc.gov/biosafety/publications/index.htm

Biosafety Guidelines





Ebola: Laboratory Update

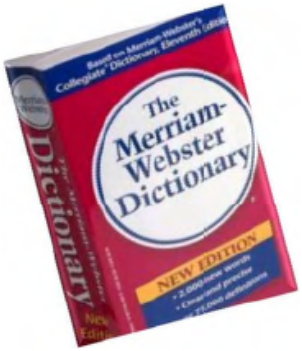
Laboratory testing (Non-Ebola) of specimens from suspect Ebola case

- 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

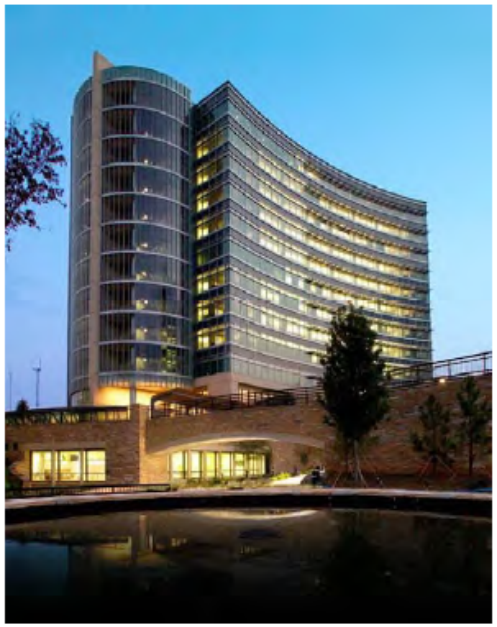
Laboratory Biosafety
Principles of Biosafety

- 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)**

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

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

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

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

We want to be #1 in laboratory biosafety

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.

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

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.

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.

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 2015 risk assessment at the 2016 Regional Meetings and roll-out mitigation strategies/tools/trainings for the WCLN members to apply in their laboratories.

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 2017 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.

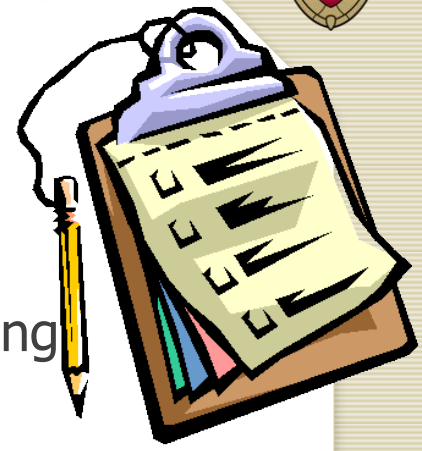
Additional Activities

- **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

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

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?

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

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

What questions do you have for us?

What are your recommendations as we move forward?

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