DLS ECHO Biosafety Session: April 25, 2023

Decontamination of Laboratory Equipment

Shawn G. Gibbs, PhD, MBA, CIH
Dean
Texas A&M University School of Public Health
College Station, TX

Aurora Le, PhD, MPH, CSP, CPH
John G. Searle Assistant Professor
University of Michigan School of Public Health
Ann Arbor, MI

Agenda

- Didactic and Case Presentation
- Discussion
- Summary of Discussion
- Closing Comments and Reminders

DLS ECHO Biosafety Session: April 25, 2023

Decontamination of Laboratory Equipment

Shawn G. Gibbs, PhD, MBA, CIH
Dean
Texas A&M University School of Public Health
College Station, TX

Aurora Le, PhD, MPH, CSP, CPH
John G. Searle Assistant Professor
University of Michigan School of Public Health
Ann Arbor, MI

TEXAS A&M UNIVERSITY

School of Public Health

Decontamination of Laboratory Equipment

Shawn G. Gibbs, PhD, MBA, CIH
Dean of the School of Public Health
Texas A&M University
sgibbs@tamu.edu
https://public-health.tamu.edu/dean/index.html

Aurora B. Le, PhD, MPH, CSP, CPH
John G. Searle Assistant Professor
Department of Environmental Health Sciences
University of Michigan School of Public Health
aurorale@umich.edu

Brought to you by:

- **Prevention, Preparedness and Response (P2R) Consortium** Funded by the NIEHS Worker Training Program (U45ES019360-11)
- **National Emerging Special Pathogens Training and Education Center** (formerly the National Ebola Training and Education Center). Funded by U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response and Centers for Disease Control and Prevention National Center for Emerging and Zoonotic, Infectious Diseases.
- Distinguished Lecturer Program of the **American Industrial Hygiene Association**

SCHOOL OF PUBLIC HEALTH

Special Thanks To:

Peter C. Iwen, MS, PhD, D(ABMM), F(AAM)

Professor, Pathology and Microbiology

Director, NE Public Health Laboratory

Biosafety Program Director

University of Nebraska Medical Center

Scott Patlovich, DrPH, CIH, CBSP, CHMM, CPH

Assistant Vice President of Environmental Health & Safety

UTHealth Houston

SCHOOL OF PUBLIC HEALTH

Learning Objectives

1. Identify effective biosafety practices that strengthen laboratory systems and advance laboratory safety.
2. Examine biosafety concepts that apply to conducting risk management when performing laboratory activities.
3. Apply practices and concepts discussed to highly hazardous communicable disease scenarios.

SCHOOL OF PUBLIC HEALTH

This isn’t how a highly hazardous communicable disease (HHCD) will arrive at most facilities

Photo John Lowe

Photo Omaha World Herald

Laboratory associated infection (LAI):

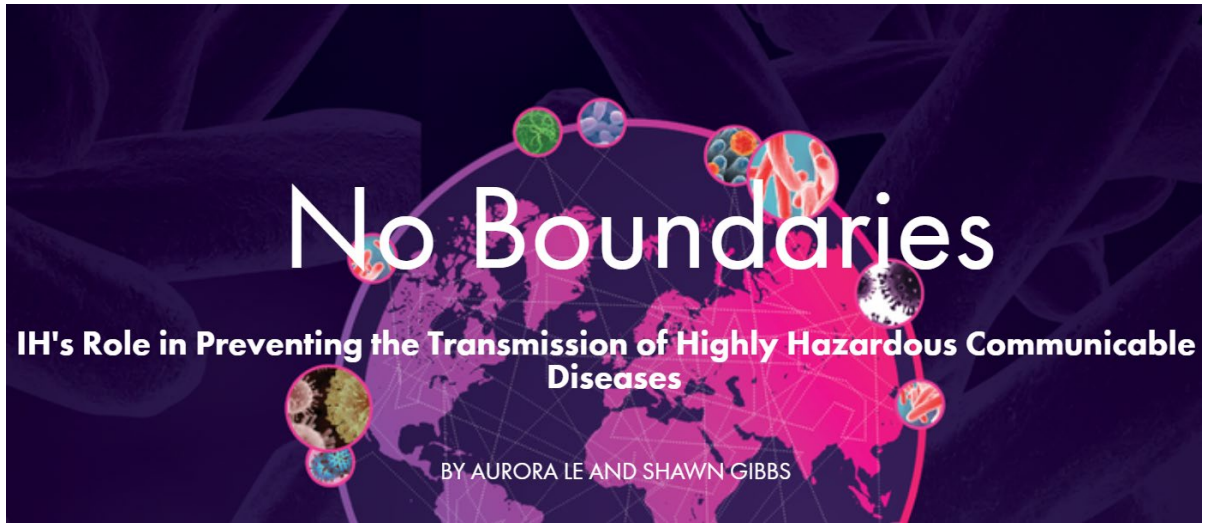
An infection resulting from work with infectious biological agents during the course of laboratory, or laboratory related, activities. May be either symptomatic or asymptomatic.

Synonyms include:

- lab acquired infection
- lab acquired illness
- lab associated illness
- lab acquired infection or intoxication (Canada)

Slide Provided by Scott Patlovich

Published in 2018



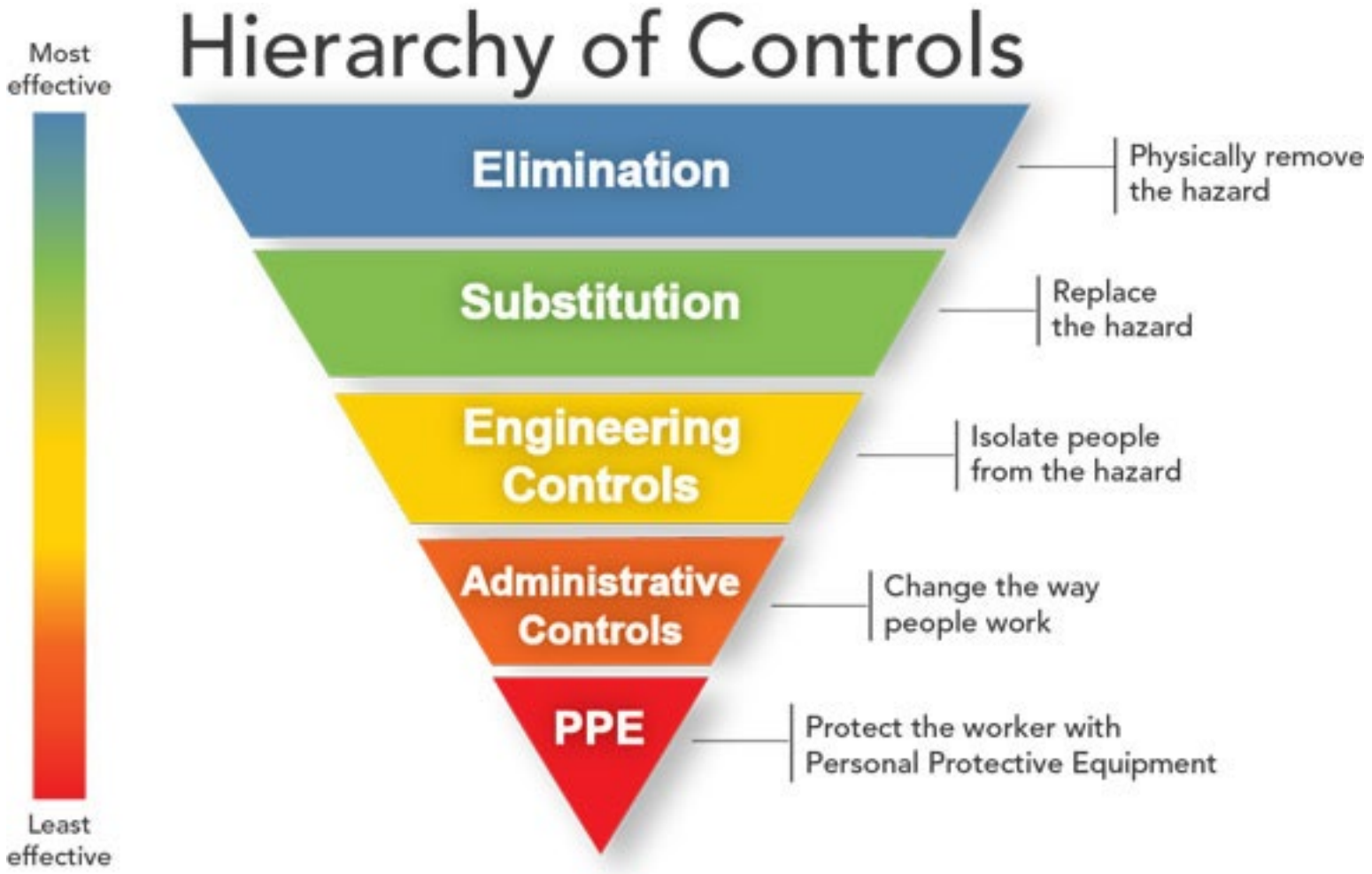
https://synergist.aiha.org/201804-no-boundaries

Published in 2022

https://synergist.aiha.org/20220607-next-pandemic

SCHOOL OF PUBLIC HEALTH

Hierarchy of Controls



https://www.cdc.gov/niosh/topics/hierarchy/default.html

SCHOOL OF PUBLIC HEALTH

Safety

Risk Mitigation

Based on the biological risk assessment

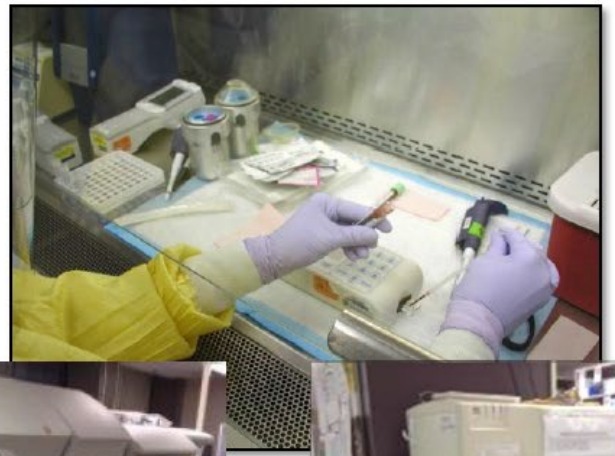
- Engineering Controls
  - Equipment
    - Biosafety cabinet
    - Sealed centrifuge rotors or safety cups
    - Testing instruments
  - Facilities
    - Negative ventilation
    - Dedicated space
- Administrative/work practice controls
  - Staff
    - Training
    - Limited access
  - Written safety policies
  - Medical surveillance
- Appropriate PPE

Slide from Peter Iwen

Safety

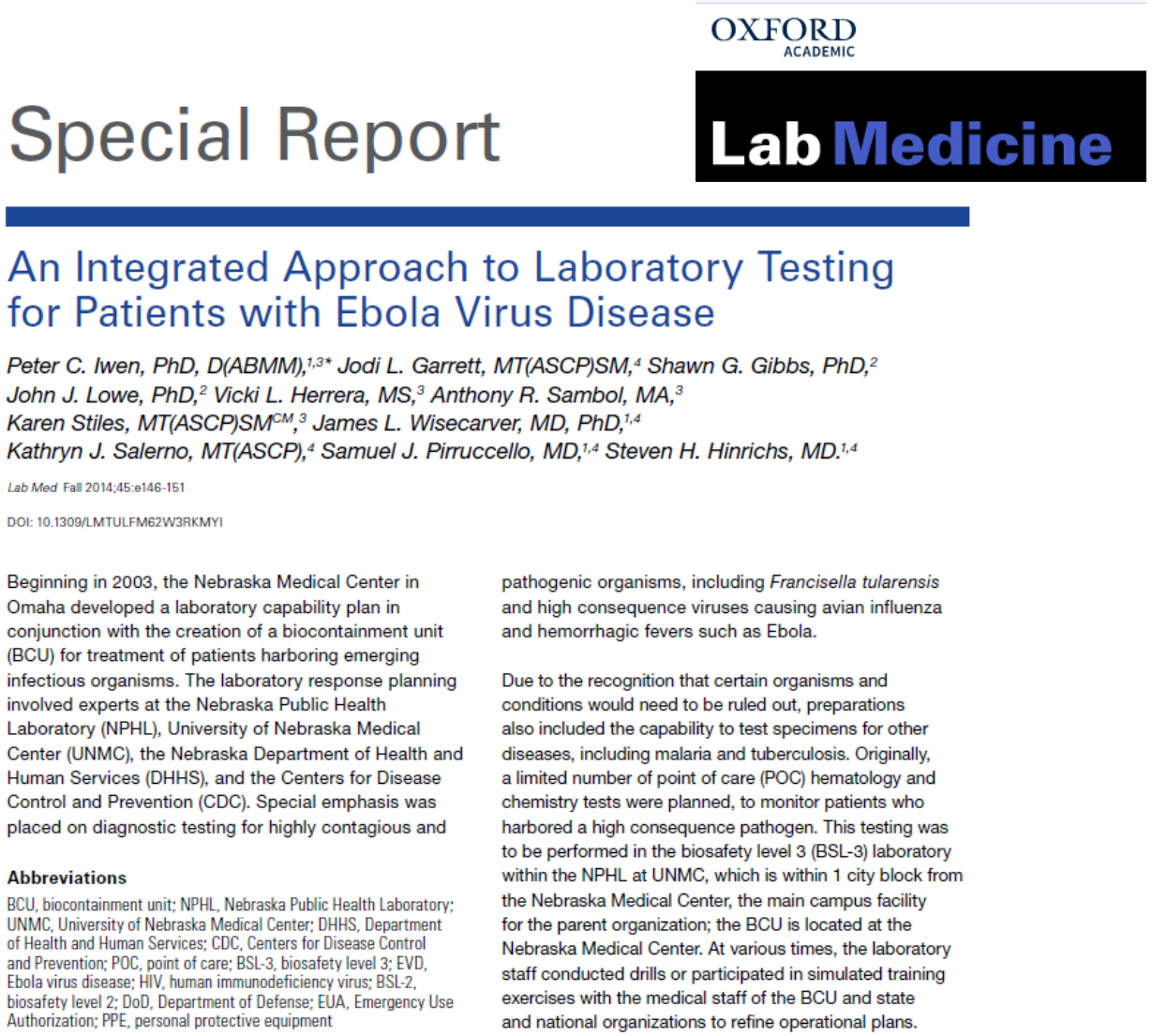
Risk Mitigation

- Equipment
  - Creating aerosols an issue
    - Inability to use automated chemistry analyzer
  - Use point-of-care instruments
  - Biosafety cabinet



Slide from Peter Iwen

Handling Specimens



OXFORD ACADEMIC

Lab Medicine

Special Report

An Integrated Approach to Laboratory Testing for Patients with Ebola Virus Disease

Peter C. Iwen, PhD, D(ABMM),[1,3] Jodi L. Garrett, MT(ASCP)SM,[4] Shawn G. Gibbs, PhD,[2] John J. Lowe, PhD,[2] Vicki L. Herrera, MS,[3] Anthony R. Sambol, MA,[3] Karen Stiles, MT(ASCP)SM[CM],[3] James L. Wisecarver, MD, PhD,[1,4] Kathryn J. Salerno, MT(ASCP),[4] Samuel J. Pirruccello, MD,[1,4] Steven H. Hinrichs, MD.[1,4]*

Lab Med Fall 2014;45:e146-151

DOI: 10.1309/LMTULFM62W3RKMYI

Beginning in 2003, the Nebraska Medical Center in Omaha developed a laboratory capability plan in conjunction with the creation of a biocontainment unit (BCU) for treatment of patients harboring emerging infectious organisms. The laboratory response planning involved experts at the Nebraska Public Health Laboratory (NPHL), University of Nebraska Medical Center (UNMC), the Nebraska Department of Health and Human Services (DHHS), and the Centers for Disease Control and Prevention (CDC). Special emphasis was placed on diagnostic testing for highly contagious and pathogenic organisms, including *Francisella tularensis* and high consequence viruses causing avian influenza and hemorrhagic fevers such as Ebola.

Due to the recognition that certain organisms and conditions would need to be ruled out, preparations also included the capability to test specimens for other diseases, including malaria and tuberculosis. Originally, a limited number of point of care (POC) hematology and chemistry tests were planned, to monitor patients who harbored a high consequence pathogen. This testing was to be performed in the biosafety level 3 (BSL-3) laboratory within the NPHL at UNMC, which is within 1 city block from the Nebraska Medical Center, the main campus facility for the parent organization; the BCU is located at the Nebraska Medical Center. At various times, the laboratory staff conducted drills or participated in simulated training exercises with the medical staff of the BCU and state and national organizations to refine operational plans.

Abbreviations

BCU, biocontainment unit; NPHL, Nebraska Public Health Laboratory; UNMC, University of Nebraska Medical Center; DHHS, Department of Health and Human Services; CDC, Centers for Disease Control and Prevention; POC, point of care; BSL-3, biosafety level 3; EVD, Ebola virus disease; HIV, human immunodeficiency virus; BSL-2, biosafety level 2; DoD, Department of Defense; EUA, Emergency Use Authorization; PPE, personal protective equipment

- Processes and Testing Performed in the POC BSL-3 Laboratory
- Processes and Assays Available in the NPHL BSL-3 Laboratory
- Procedures and tests performed by the core laboratory of the hospital
- Transportation of Specimens Within the Hospital or on Campus
- Transportation of Specimens Outside the Institution (i.e., to the CDC)

SCHOOL OF PUBLIC HEALTH

Handling HHCD Specimens

AJCP / Editorial

AJCP
American Journal of Clinical Pathology

Safety Considerations in the Laboratory Testing of Specimens Suspected or Known to Contain Ebola Virus

Peter C. Iwen, PhD, D(ABMM),[1,2] Philip W. Smith, MD,[3] Angela L. Hewlett, MD,[3] Christopher J. Kratochvil, MD,[4] Steven J. Lisco, MD,[5] James N. Sullivan, MD,[5] Shawn G. Gibbs, PhD, CIH,[6] John J. Lowe, PhD,[6] Paul D. Fey, PhD, D(ABMM),[1] Vicki L. Herrera, MS,[2] Anthony R. Sambol, MA,[2] James L. Wisecarver, MD,[1] and Steven H. Hinrichs, MD[1]

From the [1]Department of Pathology and Microbiology, College of Medicine, University of Nebraska Medical Center, Omaha; [2]Nebraska Public Health Laboratory, Omaha; [3]Department of Internal Medicine, Division of Infectious Diseases, University of Nebraska Medical Center, Omaha; [4]Department of Psychiatry, College of Medicine, University of Nebraska Medical Center, Omaha; [5]Department of Anesthesiology, Division of Critical Care, University of Nebraska Medical Center, Omaha; and [6]Department of Environmental, Agricultural, and Occupational Health, College of Public Health, University of Nebraska Medical Center, Omaha.

Am J Clin Pathol January 2015;143:4-5

DOI: 10.1309/AJCP26MIFUIETBPL

Reference to the Ebola virus causes concern among all individuals, whether from the public or within the medical community. Realization that patients with Ebola virus disease (EVD) have now been recognized in the United States in response to the major outbreak occurring in West Africa has heightened this fear. Recently, the World Health Organization declared the Ebola epidemic to be a Public Health Emergency of International Concern to provide containment of this major international health threat. In response to this threat to public health, the United States has stepped up efforts to provide care for infected patients, which include bringing individuals with EVD into the United States for treatment. These activities, along with the increased possibility of having more individuals recognized with EVD in the United States, have caused hospitals to evaluate how to contain and care for patients suspecting of having EVD. As a part of this response, laboratorians have been asked to be prepared to test specimens patients.[3] In our risk assessment, we determined that the core laboratories where chemistry and hematologic testing takes place do not have facilities that can safely handle specimens suspected of containing or known to contain Ebola virus. For example, the processing of open tubes without the availability of a biosafety cabinet and the centrifugation of specimens without safety cups or sealed rotors are common practices within the core laboratory. In addition, clinical laboratories that do have the facilities to perform biosafety level 3 (BSL-3) practices (to include processing within a biosafety cabinet, centrifugation using safety cups or sealed rotors, and enhanced PPE to include respiratory protection) are generally available only to the clinical microbiology laboratory and specific to the testing of specimens potentially containing the causative agents for tuberculosis or for endemic fungi such as *Coccidioides immitis* and *Histoplasma capsulatum*.

Table 1
Essential and Supplemental Tests Used for the Support of a Patient Infected With Ebola Virus[a]

Test	Laboratory Location[b]	Centrifugation Required[c]
Essential		
CBC count with automated differential	Core	No
Basic metabolic panel	Core	Yes[d]
Magnesium	Core	Yes
Comprehensive metabolic panel	Core	Yes[d]
Ionized calcium[e]	BCU	No
Standard calcium	Core	Yes[d]
Phosphorus	Core	Yes
Cortisol	Core	Yes
Troponin	Core	Yes
Blood gases[e]	BCU	No
Lactate	Core	Yes[d]
Prothrombin time[e]	BCU	No
Partial thromboplastin time[e]	BCU	No
Platelet count	Core	No
Blood typing[f,g]	BCU	No
Culture procedures[h]	NPHL[i]	No
Molecular assay[j]	NPHL[i]	No
Supplemental		
Manual differential	Core	No
Lipase	Core	Yes
Amylase	Core	Yes
Creatine kinase total	Core	Yes
Malaria smear[k]	Core	No
HIV screen	Core	No

BCU, biocontainment unit; HIV, human immunodeficiency virus; NPHL, Nebraska Public Health Laboratory.

[a] All open-tube testing and centrifugation were performed within the biosafety level 3 (BSL-3) laboratory environment. The lists of tests were determined from a risk assessment for safety in consultation with infectious diseases and critical care physicians. This list will not necessarily represent capabilities and needs for all clinical laboratory applications.

[b] Laboratory locations were determined following a risk assessment.

[c] Centrifugation was performed in the BCU laboratory and transferred to the core laboratory as noted.

[d] Testing also available on point-of-care testing instrument.

[e] Utilization of point-of-care testing instrument.

[f] Using slide agglutination method.

[g] Type O, Rh- and Kell-negative blood were recommended where appropriate.

[h] All cultures were performed in the BSL-3 laboratory using culture media contained in plastic containers.

[i] Provides for a BSL-3 containment facility.

[j] Using an emergency use authorization kit assay approved by the Food and Drug Administration.

[k] Smear prepared and fixed in the BCU laboratory.

TAMU SCHOOL OF PUBLIC HEALTH

PUBLIC HEALTH REPORTS

Commentary

Public Health Reports
2019, Vol. 134(4) 332-337

DOI: 10.1177/0033354919856936
journals.sagepub.com/home/phr
SAGE

Clinical Laboratory Equipment Manufacturer Policies on Highly Hazardous Communicable Diseases

Jocelyn J. Herstein, PhD, MPH[1,2]; Sean A. Buehler, BSPH[3]; Aurora B. Le, MPH, CPH[3]; John J. Lowe, PhD[1,2]; Peter C. Iwen, PhD[4]; and Shawn G. Gibbs, PhD, MBA, CIH[3]

Keywords
communicable diseases, disease outbreaks, emerging infectious diseases, laboratory, public health preparedness

The 2014-2016 outbreak of Ebola virus disease (EVD) in West Africa prompted a shift in how US institutions and agencies respond to cases of highly hazardous communicable diseases (HHCDs). Private and public institutions developed novel procedures or amended existing procedures for the identification, isolation, and diagnostic testing of patients

laboratory equipment manufacturers created further uncertainties. For example, manufacturers were unable to guarantee the effectiveness of certain decontamination procedures used for their products. Some equipment manufacturers announced that use of their equipment for Ebola virus testing would void warranties and/or service contracts and might result in a

Table. Methods used to contact clinical laboratory equipment manufacturers and their procedures and policies for using equipment on a patient with a highly hazardous pathogen, United States, December 2017

Company	Contact Method[a,b] (Division)	Response(s)
A	Online (sales)[c]	None of the pathogens would void the warranty.
	Online (marketing)[c]	None of the pathogens would void the warranty or cancel a service contract.
		Decontamination instructions have been developed for company engineers and customers.
	Email (customer care)	Undeliverable
B	Email (representative)[d]	Ebola virus disease policies had been developed, but the representative asked to be unsubscribed from "contact list" with no additional response (ie, representative thought it was a soliciting email).
	Email (communications)	No response
	Online (sales)	Forwarded to marketing and regulatory teams.
		Offers training in lieu of a 1-year warranty and parts supplied for service at no additional cost for this warranty period.
C	Online (sales)	No response
	Online (warranty)	No response
	Email (technical support)	Documentation sent to customers who might handle Ebola virus.[e]
D	Email (sales)	No response
	Email (technical support)	Forwarded to another department.
		Warranty claims are on a case-by-case basis.
		Requires a decontamination label (company supplied) when shipping an instrument for service.
E	Email (technical support)	Undeliverable; no online inquiry available; as such, company was electronically unreachable.
F	Email (technical support)	No response
G	Online (not identified)	No response
	Email (customer service)	Generic response that the "message has been received and will be addressed in a timely manner." No additional response received.
H	Email (customer service)	No response
I	Online (not identified)	Instructed to send email to a different contact and provide contact information. No additional response received.

[a]Email contacts were publicly available or company directed after an inquiry.
[b]Online contacts were publicly available.
[c]Original inquiry was to the diagnostics division, which was forwarded to marketing and sales.
[d]The representative was identified as the company's contact for information on Ebola virus disease policies.
[e]Ebola-specific standard operating procedures for the return of analyzers for repair, recertification, or replacement that were used in facilities that test patients with suspected or confirmed Ebola virus disease.

HHCD Opportunities to address potential issues

- Improve clarity of contact information for inquiries, including who and how to contact.
- Improve clarity of communication to rely less on verbal communications from sales representatives.
- Improve timeliness of responses.
- Improve clarity of digital guidelines.
- Develop protocols beyond those that are organism (i.e., Ebola) dependent.
- Improve clarity decontamination procedures that are compatible.

SCHOOL OF PUBLIC HEALTH

HHCD Manufacturer Decontamination Recommendations Update Study

- Currently working to determine manufacturer decontamination recommendations
- Preliminary Data
  - Over multiple weeks and multiple requests only 2 of 14 responded
  - Responses state that manufacturer does not provide guidance for HHCD
  - It is up to you to determine decontamination processes
  - In an HHCD event you can not count on your manufacturer to provide timely information.

Decontamination Considerations

Impacts from HHCD

- Waste (solid/liquid) is potentially now a Category A waste
- Perception impacts everything
- Be mindful of damage to equipment from decon
- Understand the organism you are dealing with and be prepared to relate that to your strategy.
- With decon, in most cases time is on your side with the organism
- Understand the pros and cons of your approach, including down time of your clinical lab.

Decontamination Options

- Know your basics 1) Cleaning, 2) Disinfection, and 3) Sterilization
- Must remove organic matter
- Work within your organizations processes.
- Surface (hydrogen peroxide, etc.)
- Gaseous/vapor (vaporized hydrogen peroxide, ethylene oxide, etc.)
- UVGI
- Understand concentration and contact time requirements

Decontamination Recommendations

In Advance

- Evaluate your standard processes for decontamination for each piece of equipment, including PPE needs
- Evaluate your personnel's perception of these processes and how they perceive their safety, create a feedback mechanism.
- Make sure you have personnel health monitoring plans that can be implemented
- Loop in your LHD or other regulator on your plans
- Training

During/Post Event

- Communication, communication, communication
- Phone a friend—Check with FDA, CDC, NETEC, and others on an updates
- Remind your LHD or other regulators of your plan
- Execute your plan but be open to adjusting if needed based upon organism
- Personnel monitoring

Didactic Summary

- We can *reduce* likelihood of laboratory acquired infections, we *cannot truly eliminate* that risk, including for highly hazardous communicable diseases (HHCD).
- It is highly likely than an HHCD sample will be in the lab before you are aware/confirmed that there is an HHCD event.
- Identification of potential risks from equipment, procedures, and personnel within your laboratory for laboratory acquired infections should not be done at the last minute.
- Consideration of decontamination processes need to be planned in advance to handle all scenarios (all-hazards approach).

HHCD Case Study for Breakout Groups

Scenario

- Supervisor and LHD inform you that a sample you tested 24 hours ago was from a patient now determined to have Marburg virus disease.
- The patient had the following tests done in your clinical lab.
  - Blood cultures
  - Molecular assay
  - CBC count with automated differential
  - Basic and complex metabolic panels

Questions

1. What are the risks to the lab personnel both those who ran the tests and who worked in the lab?
2. What should the lab personnel be told and what should they do?
3. Should you shut down the entire clinical lab?
4. Should you decontaminate the entire lab or the equipment used?
5. How do you start a decontamination plan?

Some Biosafety Guidelines

- CDC/NIH. Biosafety in Microbiological and Biomedical Laboratories, 6th Edition. (2020) https://www.cdc.gov/labs/BMBL.html

- World Health Organization. Laboratory Biosafety Manual, 4th Edition. (2020) https://www.who.int/publications/i/item/9789240011311

- Nebraska Isolation and Quarantine Manual (2020) https://www.nebraskapress.unl.edu/university-of-nebraska-medical-center/9780989353731/

Slide Provided by Scott Patlovich

SCHOOL OF PUBLIC HEALTH

CLIA items Related to 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

From Reynolds M Salerno, PhD, https://www.cdc.gov/cliac/docs/addenda/cliac0416/8_Salerno_BIOSAFETY_CLIAC_April2016.pdf

SCHOOL OF PUBLIC HEALTH

Thank you for your time!

Aurora B. Le, PhD, MPH, CSP, CPH
John G. Searle Assistant Professor
Department of Environmental Health Sciences
University of Michigan School of Public Health
aurorale@umich.edu

Shawn G. Gibbs, PhD, MBA, CIH
Dean of the School of Public Health
Texas A&M University
sgibbs@tamu.edu
https://public-health.tamu.edu/dean/index.html

SCHOOL OF PUBLIC HEALTH

DLS ECHO Biosafety Session: May 30, 2023

PPE Use (Who, When, What, Why, and How)

Peter C. Iwen, PhD, D(ABMM), F(AAM)

Nebraska Public Health Laboratory University

Nebraska Medical Center