TEXAS A&M UNIVERSITY

School of Public Health

Independent Assessment of Risks and Clinical Laboratory Instrument Design that Impact Highly Hazardous Communicable Disease (HHCD) Response

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Brought to you by:

Prevention, Preparedness and Response (P2R) Consortium

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Learning Objectives

1

Attendees will understand that we can only reduce the likelihood of laboratory acquired infections, we cannot truly eliminate that risk.

2

Attendees will be able to organize stakeholders within their organization toward the goal of reducing the risks of laboratory acquired infections.

3

Attendees will be able to identify potential risks from equipment, procedures, and personnel within their laboratory for laboratory acquired infections.

4

Attendees will be able to analyze laboratory equipment procedures for ways to increase or decrease risks associated with laboratory acquired infections.

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)

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Risk Group vs. Biosafety Level

Risk Group

Describes ***what you are working with*** – *Agents* categorized into 4 groups based on relative risk, accounting for:

- Pathogenicity
- Transmission
- Host range
- Effective preventive measures
- Effective treatment

Biosafety Level

Describes ***how and where you work*** – 4 levels of containment for working with microbes/materials, based on:

- Safety equipment (e.g. biosafety cabinets)
- Facility safeguards
- Procedures/practices
  - *Emphasis on risk assessment, training, SOPs, safe work practices, disinfection, waste management, immunization, post-exposure prophylaxis, biosecurity, and so forth…*

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Potential Routes of Transmission

- Inhalation infectious aerosols, droplets, sniffing samples
- Ingestion mouth pipetting; eating, drinking
- Percutaneous inoculation needle sticks and other contaminated sharps; animal bites; exposure to previously broken or damaged skin
- Mucous membrane exposure infectious materials in contact with eyes, nose, mouth (splashes, contact from contaminated surfaces

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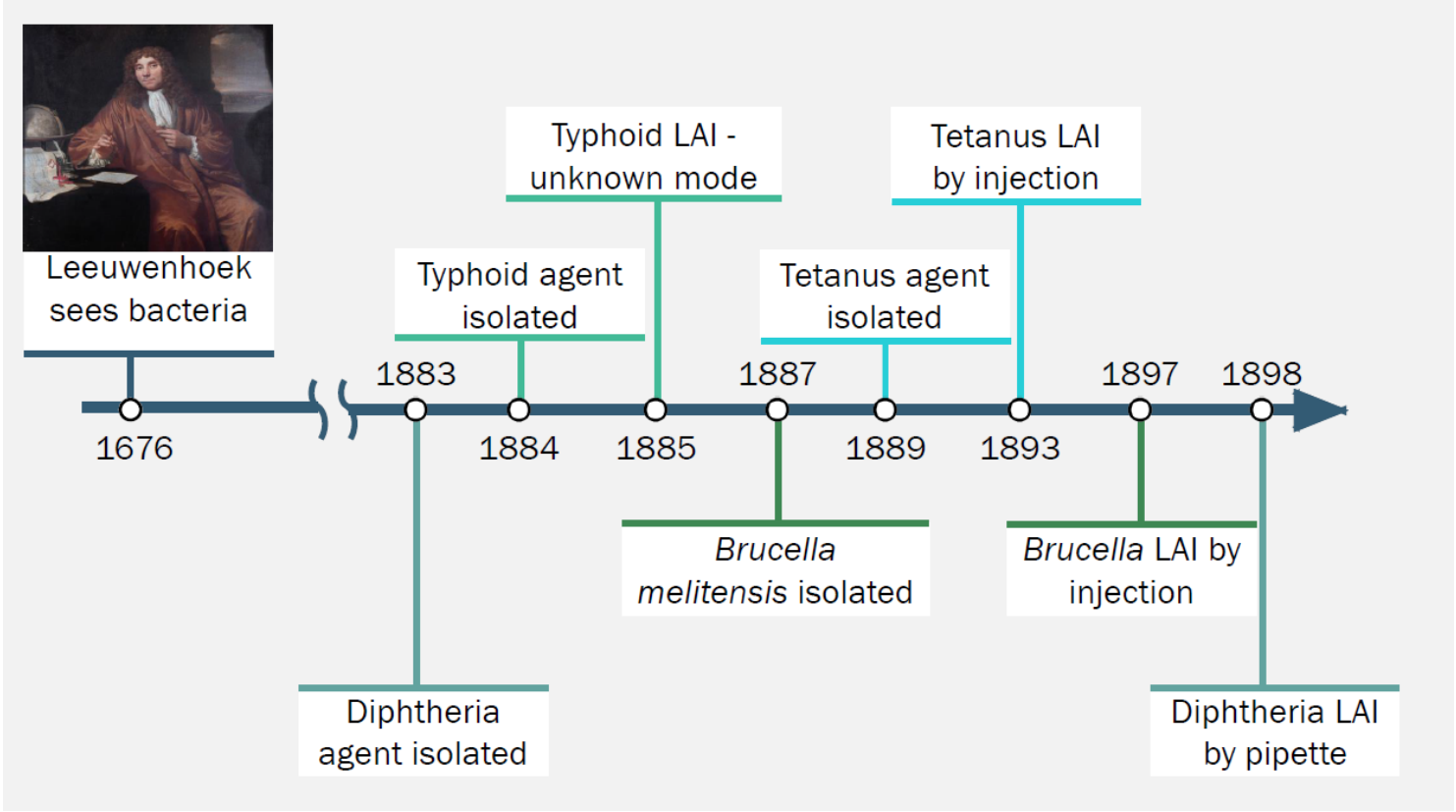
Early History of LAIs



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More Recent History of LAIs

- Four hallmark studies by Pike and Sulkin collectively identified 4,079 LAIs resulting in 168 deaths between 1930 and 1978
- 159 causative agents identified but > 50% of infections were caused by only 10 agents

- Byers and Harding identified 3,230 3,246 primary LAIs and 41 fatalities between 1979 and 2015
  - 854 of these were asymptomatic
- There were also 19 secondary and 8 tertiary infections recorded
- Again, more than half of these infections were caused by only 10 agents

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TABLE 1.

Comparison of 10 most commonly reported LAIs

1930–1978[a]				1979–2015			
Rank	Agent[b]	No. LAIs	No. deaths	Rank	Agent[b]	No. LAIs	No. deaths
1	*Brucella* spp.	426	5	1	*Brucella* spp.	378	4[c]
2	*Coxiella burnetii*	280	1	2	*Mycobacterium tuberculosis*	255	0
3	Hepatitis B	268	3	3	Arboviruses[d]	222	3
4	*Salmonella enterica* serovar Typhi	258	20	4	*Salmonella* spp.	212	2[e]
5	*Francisella tularensis*	225	2	5	*Coxiella burnetii*	205	3
6	*Mycobacterium tuberculosis*	194	4	6	Hantavirus	189	1
7	*Blastomyces dermatitidis*	162	0	7	Hepatitis B virus	113	1
8	Venezuelan equine encephalitis virus	146	1	8	*Shigella* spp.	88	0
9	*Chlamydia psittaci*	116	9	9	Human immunodeficiency virus	48	Not known
10	*Coccicioides immitis*	93	10	10	*Neisseria meningitidis*	43	13
		2,168	48			1,753	24

[a]Adapted from reference 27.
[b]Not included are 113 cases of hemorrhagic fever contracted from wild rodents in one laboratory in Russia in 1962 (486).
[c]All deaths are aborted fetuses.
[d]Typical arboviruses and orbiviruses, rhabdoviruses, and arenaviruses that are associated with arthropods or have zoonotic cycles (233), with additional arboviral reports added.
[e]One death was a secondary exposure case (47).

Slide Provided by Scott Patlovich Source: Byers and Harding, 2017

Munson et al. 2017 Laboratory Focus on Improving the Culture of Biosafety: Statewide Risk Assessment of Clinical Laboratories That Process Specimens for Microbiologic Analysis

- Wisconsin Clinical Laboratory Focused.
- Information important to the assessment of risk were often not available to the laboratory.
- “Over 88% of the respondents complied with more than three-quarters of the mitigation control measures listed in the survey.”
- “Facility assessment revealed that subsets of laboratories that claim biosafety level 1, 2, or 3 status did not possess all of the biosafety elements considered minimally standard for their respective classifications.”
- “Task assessment identified deficiencies in…packaging and shipping, direct microscopic examination, and culture modalities solely involving screens for organism growth.”

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5744218/

Surveillance of laboratory exposures to human pathogens and toxins, Canada 2020

Nicole Atchessi[1], Megan Striha[1], Rojiemiahd Edjoc[1]*, Emily Thompson[1], Maryem El Jaouhari[1], Marianne Heisz[1]

Abstract

Background: The Laboratory Incident Notification Canada surveillance system monitors laboratory incidents reported under the *Human Pathogens and Toxins Act* and the *Human Pathogens and Toxins Regulations*. The objective of this report is to describe laboratory exposures that were reported in Canada in 2020 and the individuals who were affected.

Methods: Laboratory incident exposures occurring in licensed Canadian laboratories in 2020 were analyzed. The exposure incident rate was calculated and the descriptive statistics were performed. Exposure incidents were analyzed by sector, activity type, occurrence type, root cause and pathogen/toxin. Affected persons were analyzed by education, route of exposure sector, role and laboratory experience. The time between the incident and the reporting date was also analyzed.

Results: Forty-two incidents involving 57 individuals were reported to Laboratory Incident Notification Canada in 2020. There were no suspected or confirmed laboratory acquired infections. The annual incident exposure rate was 4.2 incidents per 100 active licenses. Most exposure incidents occurred during microbiology activities (n=22, 52.4%) and/or were reported by the hospital sector (n=19, 45.2%). Procedural issues (n=16, 27.1%) and sharps-related incidents (n=13, 22.0%) were the most common occurrences. Most affected individuals were exposed via inhalation (n=28, 49.1%) and worked as technicians or technologists (n=36, 63.2%). Issues with standard operating procedures was the most common root cause (n=24, 27.0%), followed by human interactions (n=21, 23.6%). The median number of days between the incident and the reporting date was six days.

Conclusion: The rate of laboratory incidents were lower in 2020 than 2019, although the ongoing pandemic may have contributed to this decrease because of the closure of non-essential workplaces, including laboratories, for a portion of the year. The most common occurrence type was procedural while issues with not complying to standard operating procedures and human interactions as the most cited root causes.

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Notification and Reporting Under the HPTA and HPTR

From Public Health Agency of Canada

Overview

This Guideline provides comprehensive guidance on how to complete and submit a notification report and, where exposure or laboratory acquired infections/intoxications (LAIs) is concerned, a subsequent follow-up report to the Public Health Agency of Canada in accordance with requirements in the Human Pathogens and Toxins Act and Regulations and the Canadian Biosafety Standard.

Who this guide is for

1. Pathogen and Toxin Licence holders
2. Biological Safety Officers
3. Alternate Biosafety Contacts

Related Services

- Apply for a Pathogen and Toxin Licence
- Submit a Notification using the secure Biosecurity Portal

Related guides and help

- Canadian Biosafety Standard
- Canadian Biosafety Handbook

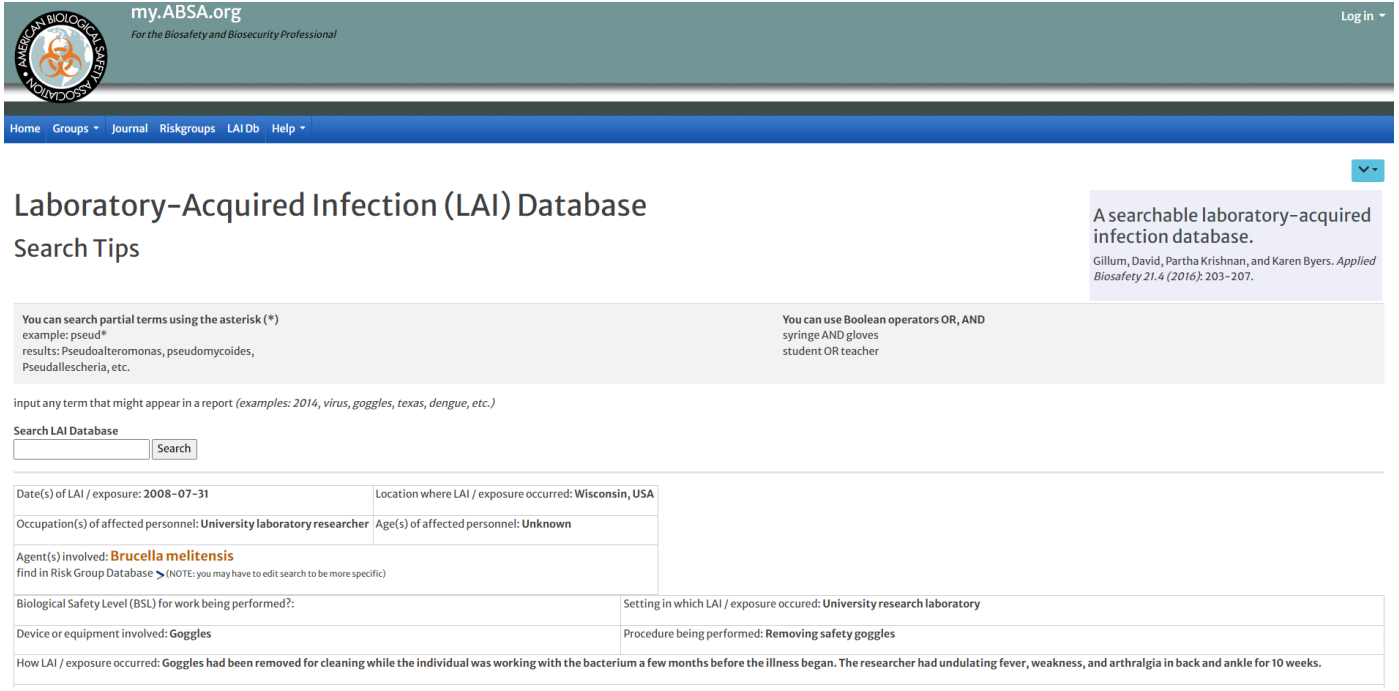
Related acts and regulations

- Human Pathogens and Toxins Ac
- Human Pathogens and Toxins Regulations

Related program

LAIs Database (ABSA)

https://my.absa.org/LAI



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Some Biosafety Guidelines

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

- 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/

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CLIA items Related to Biosafety

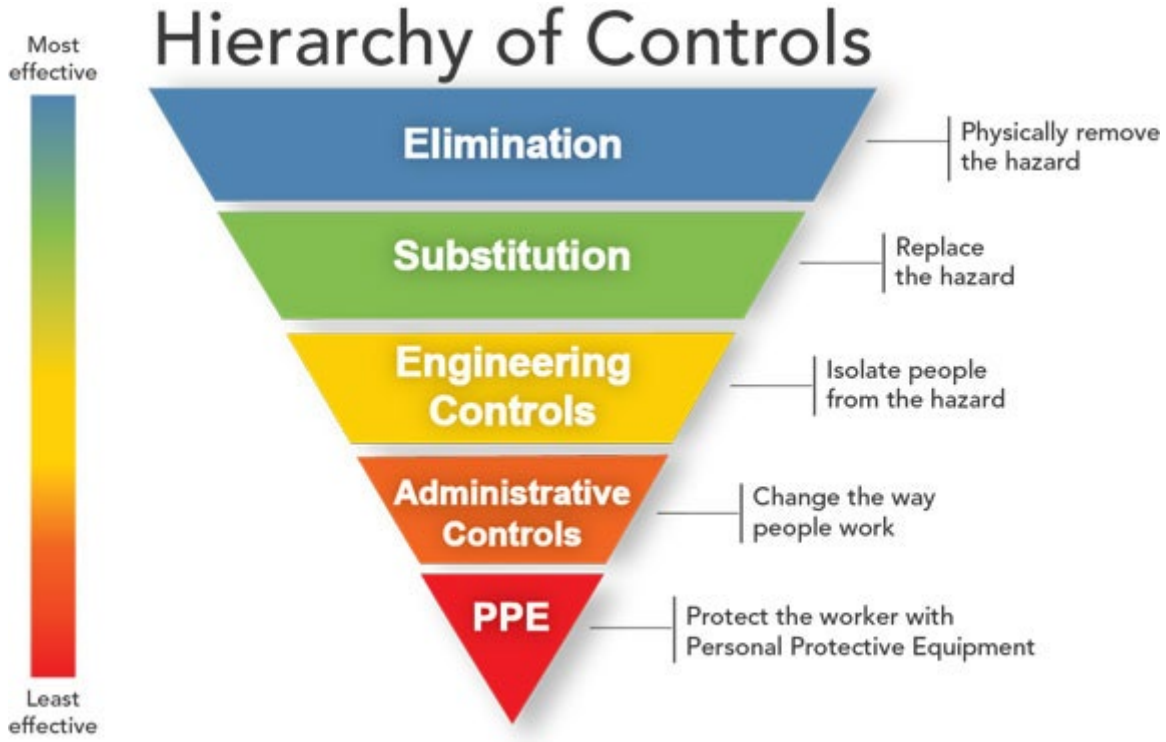
- **493.1101 (d)** Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.
- **493.1407 (e) (2)** The laboratory director must ensure that the physical plant and environmental conditions 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

Hierarchy of Controls

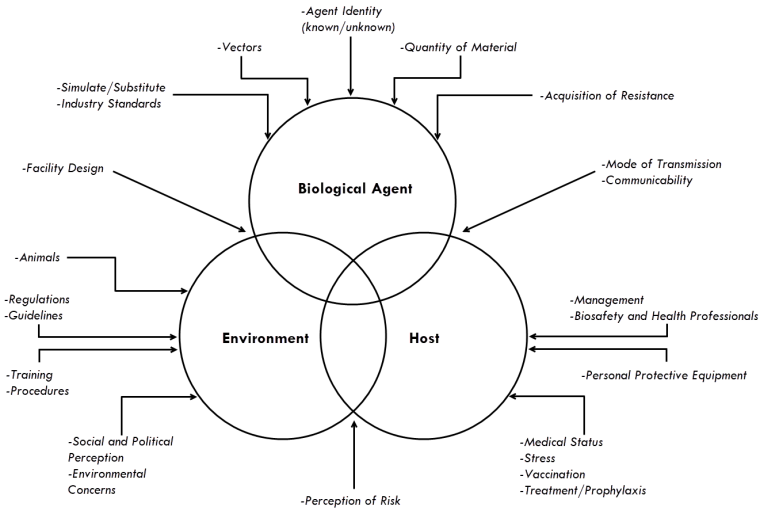


https://www.cdc.gov/niosh/hierarchy-of-controls/about/

LAIs –Lessons Learned

Prevention of LAIs can be achieved through:

- *Risk assessment!*
- *Administrative (SOPs, education, training) and engineering (BSCs) controls appropriate for organisms used*
- *Personal protective equipment (PPE)*
- I*mmunization –when available*
- *Prompt injury/accident/illness reporting –know signs/symptoms*



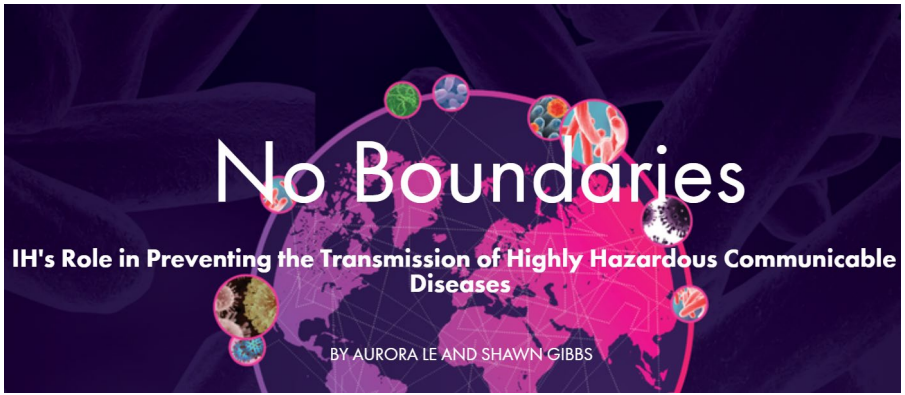
Slide Provided by Scott Patlovich Source: Byers and Harding, 2017

This isn't how an HHCD will arrive at most facilities

Photo John Lowe

Photo Omaha World Herald

Published in 2018



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

Published in 2022

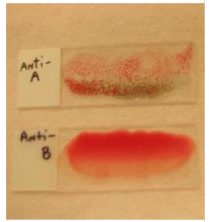
https://synergist.aiha.org/20220607-next-pandemic

If a HHCD is identified

1. Know your limitations
2. Prepare for what you can and can't do safely
3. Look for alternatives

On-Site Risk Assessment Results

- Chemistry automated analyzer
  - Initial centrifugation – no sealed rotors
- Coagulation automated analyzer
  - Required open tube testing
- Blood Bank
  - Cross match required open tube centrifugation
- Biosafety cabinet not available in the core lab



Conclusion: Not all laboratory sections could safely handle specimens from a patient with the potential to have EVD.

Slide from Peter Iwen

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

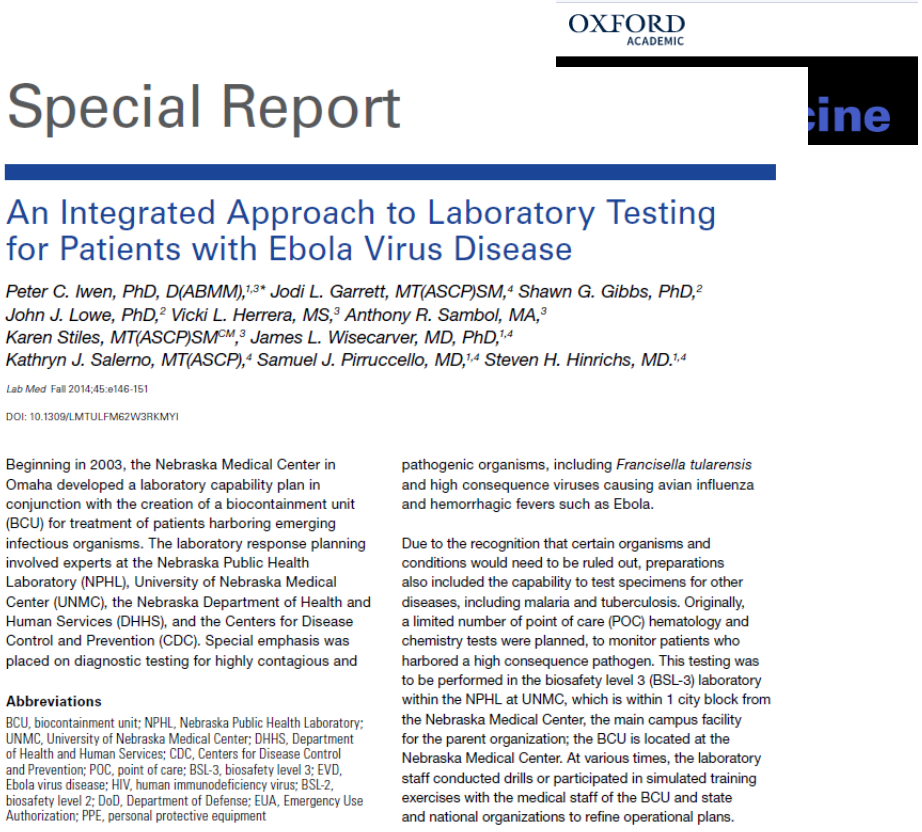
Major Learning Lessons

- Developed an essential list of test
  - To meet CLIA standards
  - Testing instruments to meet safety standards (risk assessment process)
  - Opened lines of communication (important)
    - Medical staff
    - Equipment manufactures
    - CDC
- Not all tests could be performed safely
  - Alternatives
- Lab policies/procedures needed to be fluid

"Be prepared to provide optimal patient management in an environment that was safe for employees, students, and visitors."

Slide from Peter Iwen

Handling Specimens



OXFORD ACADEMIC

Special Report

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

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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)

Handling HHCD Specimens

AJCP

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

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

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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.

Commentary

PUBLIC HEALTH REPORTS

Clinical Laboratory Equipment Manufacturer Policies on Highly Hazardous Communicable Diseases

Public Health Reports
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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.

Evaluation to complete after presentation

This evaluation is of this presentation during the 2022-2023 trainings for Prevention, Preparedness and Response (P2R) Consortium Funded by the NIEHS Worker Training Program (U45ES019360-11)

https://umich.qualtrics.com/jfe/form/SV_5oGkmwJEZolvzJs