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School of Public Health

Independent Assessment of Risks and Instrument Design: Sharing Information for Preparation

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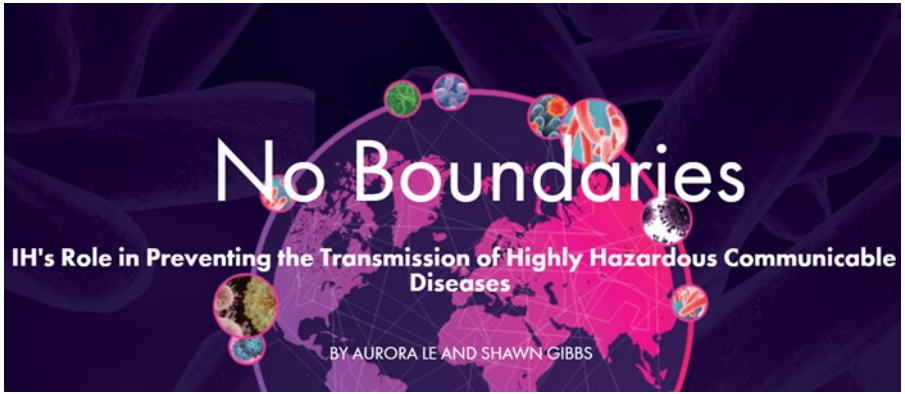

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SCHOOL OF PUBLIC HEALTH

Laboratory Capabilities

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U.S. Ebola Treatment Center Clinical Laboratory Support

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Fifty-five hospitals in the United States have been designated Ebola treatment centers (ETCs) by their state and local health authorities. Designated ETCs must have appropriate plans to manage a patient with confirmed Ebola virus disease (EVD) for the full duration of illness and must have these plans assessed through a CDC site visit conducted by an interdisciplinary team of subject matter experts. This study determined the clinical laboratory capabilities of these ETCs. ETCs were electronically surveyed on clinical laboratory characteristics. Survey responses were returned from 47 ETCs (85%). Forty-one (87%) of the ETCs planned to provide some laboratory support (e.g., point-of-care [POC] testing) within the room of the isolated patient. Forty-four (94%) ETCs indicated that their hospital would also provide clinical laboratory support for patient care. Twenty-two (50%) of these ETC clinical laboratories had biosafety level 3 (BSL-3) containment. Of all respondents, 34 (72%) were supported by their jurisdictional public health laboratory (PHL), all of which had available BSL-3 laboratories. Overall, 40 of 44 (91%) ETCs reported BSL-3 laboratory support via their clinical laboratory and/or PHL. This survey provided a snapshot of the laboratory support for designated U.S. ETCs. ETCs have approached high-level isolation critical care with laboratory support in close proximity to the patient room and by distributing laboratory support among laboratory resources. Experts might review safety considerations for these laboratory testing/diagnostic activities that are novel in the context of biocontainment care.

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VIROLOGY

U.S. High-Level Isolation Unit Clinical Laboratory Capabilities Update

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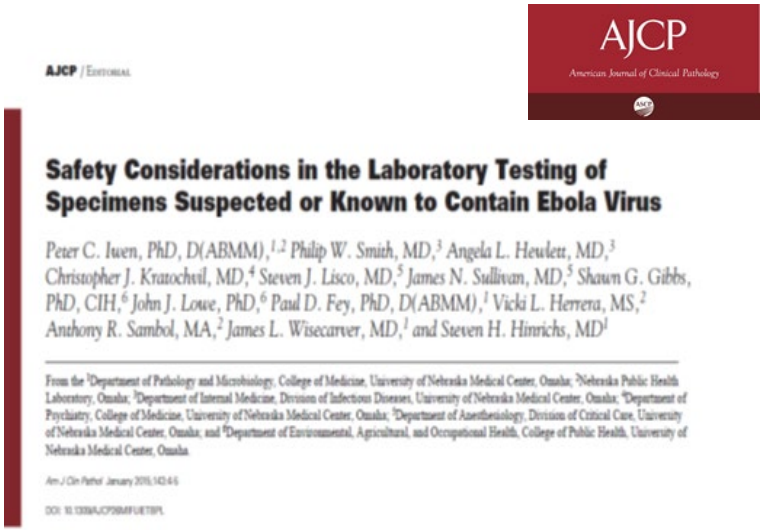
ABSTRACT In late 2014, 56 hospitals in the United States were designated by state and federal public health authorities as specially designed high-level isolation units (HLIUs) equipped with advanced infrastructure, laboratory capabilities, and trained staff to care for patients with highly hazardous communicable diseases (HHCDs), such as Ebola virus disease. This survey describes the clinical laboratory support capabilities of U.S. HLIUs, including the specific test menus that HLIUs have identified to safely manage HHCD patients and the locations where such testing would be

Handling Specimens



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

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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*.

OXFORD ACADEMIC

Lab Medicine

Special Report

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

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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

PUBLIC HEALTH REPORTS

Public Health *Reports*

Clinical Laboratory Equipment Manufacturer Policies on Highly Hazardous Communicable Diseases

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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.

For the following, please select whether use of laboratory equipment or devices manufactured and serviced by your company on a patient confirmed to be infected with the listed agent would void the warranty or result in cancellation of service contracts. Additional space is provided to describe company policy and provide further information.

Disease	Void warranty	Cancel service contracts	Recommendations for Laboratories	Policy Description/Additional Information
Anthrax	☐	☐		
Avian Influenza	☐	☐		
Botulism	☐	☐		
Ebola virus disease (EVD)	☐	☐		
Extensively drug-resistant tuberculosis (XDR-TB)	☐	☐		
Guanarito virus disease	☐	☐		
Junin virus disease	☐	☐		
Lassa fever	☐	☐		
Middle East respiratory syndrome (MERS)	☐	☐		
Monkeypox	☐	☐		
Machupo virus disease	☐	☐		
Pneumonic Plague	☐	☐		
Q fever	☐	☐		
Sabia virus disease	☐	☐		
Severe acute respiratory syndrome (SARS)	☐	☐		
Smallpox	☐	☐		
Staphylococcal enterotoxigenic B (SEB)-caused disease	☐	☐		
Tularemia	☐	☐		
"Unknown" emerging infectious disease	☐	☐		

Figure. Table of pathogens sent to laboratory manufacturers to identify their procedures and policies for using equipment on a patient with the listed highly hazardous pathogens, United States, December 2017.

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.

Thank you for your time!

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https://public-health.tamu.edu/dean/index.html