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An Assessment of Preparations Made in the United States for Highly Hazardous Communicable Diseases Following the 2014-2016 Ebola Virus Disease Epidemic

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**An Assessment of Preparations Made in the United States for Highly Hazardous
Communicable Diseases Following the 2014-2016 Ebola Virus Disease Epidemic**

by

Jocelyn J. Herstein

A DISSERTATION

Presented to the Faculty of the University of Nebraska Graduate College

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Environmental Health, Occupational Health & Toxicology

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University of Nebraska Medical Center

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**An Assessment of Preparations Made in the United States for Highly Hazardous
Communicable Diseases Following the 2014-2016 Ebola Virus Disease Epidemic**

Jocelyn J. Herstein, Ph.D.

University of Nebraska, 2018

Supervisor: John J. Lowe, PhD

The 2014-2016 Ebola virus disease (EVD) epidemic in West Africa was unprecedented in magnitude and scope. The threat of imported cases of EVD in the United States prompted the Centers for Disease Control and Prevention (CDC) to establish a tiered network of hospitals to enhance domestic isolation capacity, including the designation of select hospitals as Ebola treatment centers (ETCs). As of spring 2015, no information existed on the capacity, physical infrastructure, staffing models, or infection control protocols of these newly-established ETCs, nor was there information on other highly hazardous communicable diseases (HHCDs) these units would admit. Moreover, no documentation was available on the varying preparedness activities of state health departments related to HHCD transport and the treatment center network. The purpose of these studies was to assess preparations made in the United States in response to the 2014-16 EVD epidemic; specifically, to determine costs incurred by CDC-designated ETCs in establishing their unit, capabilities developed by ETCs, and guidelines established by state health departments for the management and transportation of patients with EVD or another HHCD. Data were obtained through the distribution of three electronic national assessments; two administered to the 56 CDC-designated ETCs in 2015 and 2016 (85% and 64% response rate, respectively) and one to all state public health departments (73% response rate). On average, responding ETCs incurred \$1.2 million in establishing their facility and are awaiting \$650,000 in reimbursement. Cumulative capacity of reporting ETCs was 121 beds. Although nearly all facilities had written protocols for various infection control domains,

procedures and capabilities varied. ETCs and state health departments differed in reports on diseases that would be treated in high-level isolation. The domestic preparedness efforts described in this dissertation are fundamental to U.S. response to the next HHCD threat; however, questions on the sustainability and scalability of this network and the use of these units for a non-EVD HHCD outbreak remain.

TABLE OF CONTENTS

ACKNOWLEDGEMENTS	ii
ABSTRACT.....	iii
TABLE OF CONTENTS.....	v
LIST OF FIGURES	vii
LIST OF TABLES	viii
LIST OF ABBREVIATIONS	x
CHAPTER 1: INTRODUCTION	1
CHAPTER 2: LITERATURE REVIEW.....	15
CHAPTER 3: INITIAL COSTS INCURRED BY EBOLA TREATMENT CENTERS IN THE UNITED STATES^a	35
CHAPTER 4: CURRENT CAPABILITIES AND CAPACITY OF EBOLA TREATMENT CENTERS IN THE UNITED STATES^b	41
CHAPTER 5: SUSTAINABILITY OF HIGH-LEVEL ISOLATION CAPABILITIES AMONG US EBOLA TREATMENT CENTERS^c	55
CHAPTER 6: HIGH-LEVEL ISOLATION UNIT INFECTION CONTROL PROCEDURES^d	64
CHAPTER 7: US HIGH-LEVEL ISOLATION UNIT CLINICAL LABORATORY CAPABILITIES UPDATE^e	78
CHAPTER 8: PERSONNEL MANAGEMENT AND BIOSECURITY OF U.S. HIGH LEVEL ISOLATION UNITS^f.....	93
CHAPTER 9: US STATE PUBLIC HEALTH DEPARTMENTS SPECIAL PATHOGEN PLANNING^g	110

CHAPTER 10: DISCUSSION	123
REFERENCES	134
APPENDICES	159
Appendix A. First Ebola Treatment Center Survey (2015)	159
Appendix B. A Highly Infectious Disease Care Network in the US Healthcare System^h	164
Appendix C. US Ebola Treatment Center clinical laboratory supportⁱ	175
Appendix D. Follow-up Ebola Treatment Center Survey (2016)	185
Appendix E. State Public Health Department Survey	240
Appendices References.....	246

^aChapter 3 was published in Emerging Infectious Diseases Feb 2016

^bChapter 4 was published in Infection Control and Hospital Epidemiology Mar 2016

^cChapter 5 was published in Emerging Infectious Diseases June 2017

^dChapter 6 was published in Health Security Sep 2017

^eChapter 7 was published in Journal of Clinical Microbiology Jan 2018

^fChapter 8 was published in Journal of Nursing Administration Nov 2018

^gChapter 9 was published in Journal of Public Health Management and Practice Sep 2018

^hAppendix B was published in Health Security May 2017

ⁱAppendix C was published in Journal of Clinical Microbiology Apr 2016

LIST OF FIGURES

Figure 2.1. Communication flow for diagnosing and transferring a PUI for EVD and a patient with EVD after confirmatory testing.	20
Figure 3.1. Average total costs incurred in each of the 10 US Health and Human Services regions.	38
Figure 3.2. Interquartile ranges of the distribution of costs of 45 Ebola treatment centers.....	39
Figure 4.1. U.S. Department of Health and Human Services (HHS) Regions with Centers for Disease Control and Prevention designated Ebola Treatment Centers and Assistant Secretary for Preparedness and Response designated Regional Ebola and Other Special Pathogen Treatment Centers.....	43
Figure 5.1. Diseases that 31 high-level isolation units (HLIUs) reported they would treat, United States, 2016.....	59
Figure 5.2. Challenges to establishing an HLIU and to maintaining HID care reported by survey respondents, United States, 2016.....	60
Figure 6.1. Infection control tasks performed by various staff in responding US high-level isolation units.....	70
Figure 8.1. Number of HLIUs reporting non-clinical services available to the units.....	99
Figure 8.2. Composition of High-Level Isolation Unit (HLIU) Leadership Team and compensation of members.....	100
Figure 9.1. State health department preference for transfer to high-level isolation for treatment	116

LIST OF TABLES

Table 1.1. CDC Guidance on ETC Capabilities	6
Table 3.1. Initial costs in US\$ incurred by 45 Ebola treatment centers in the United States	37
Table 4.1. CDC Guidance on ETC Capabilities	44
Table 4.2. High-Level Isolation Unit (HLIU) Capacity of the 47 Ebola Treatment Centers Participating in the Survey	49
Table 4.3. Comparison of the Ebola Virus Disease Treatment Capacity of the 7 Regional Treatment Centers and 40 Non-Regional Treatment Centers Participating in the Survey ..	50
Table 5.1. Activation of HLIUs and management of PUIs, United States	58
Table 5.2. Operational capabilities HLIUs reported they would add or construct if funding were available, United States.....	61
Table 6.1. Infection Control Protocols and Procedures for US High-Level Isolation Units	68
Table 6.2. Decontamination Procedures for U.S. High-Level Isolation Units	69
Table 6.3. Results of Personal Protective Equipment Use, Decontamination, and Selection for Responding US High-Level Isolation Units.....	72
Table 7.1. Reported tools available for diagnostic testing for patients with HHCDs and tool location closest to the patient room in 32 U.S. HLIUs.....	83
Table 7.2. Reported tests available for HHCD patient clinical care and test locations closest to the patient care room in 32 U.S. HLIUs.....	84
Table 7.3. Analyzers used by various HLIUs for testing of specimens that might contain a high- consequence pathogen	88
Table 8.1. Approximate number of staff currently trained to work in the unit in personal protective equipment (PPE)	97
Table 8.2. Staffing protocols for responding U.S. High-level isolation units.....	101

Table 8.3. Methods of training and hours required for orientation by staff working in U.S. High-	
Level Isolation Units	103

LIST OF ABBREVIATIONS

AAP	American Academy of Pediatrics
ASPR	Assistant Secretary for Preparedness and Response
BSL	biosafety level
CBC	complete blood count
CDC	Centers for Disease Control and Prevention
CSF	cerebrospinal fluid
EAH	Ebola assessment hospital
EIA	enzyme immune assay
EPA	Environmental Protection Agency
ETC	Ebola treatment center
EUNID	European Network of Infectious Diseases
EuroNHID	European Network for Highly Infectious Diseases
EVD	Ebola virus disease
HCW	healthcare worker
HEPA	high-efficiency particulate air
HHCD	highly hazardous communicable disease
HHS	Health and Human Services
HID	highly infectious disease
HIV	human immunodeficiency virus
HLIU	high-level isolation unit
IRB	Institutional Review Board
MERS	Middle East Respiratory Syndrome
NBU	Nebraska Biocontainment Unit

PAPR	powered air purifying respirator
PCR	polymerase chain reaction
PHL	public health laboratory
POC	point-of-care
PPE	personal protective equipment
PUI	patient under investigation
RESPTC	Regional Ebola and Other Special Pathogen Treatment Center
RTC	Regional treatment center
SARS	Severe Acute Respiratory Syndrome
TAT	turnaround time
USHIDCN	United States Highly Infectious Diseases Consensus Network
UV	ultraviolet
VHF	viral hemorrhagic fever
WWTP	wastewater treatment plant

CHAPTER 1: INTRODUCTION

History is steeped in the impact, devastation, and disruption of societal, political, and economic systems by infectious disease epidemics. Outbreaks of smallpox, bubonic plague, and pandemic strains of influenza have been attributed to the collapse of long-standing empires, the decimation of military forces, and catastrophic losses of human life (1, 2). Pathogens have also been used deliberately as weapons. British forces during the French and Indian Wars (1754-1767) distributed blankets from the smallpox hospital to Native Americans to initiate an outbreak, contributing to epidemics that killed more than 50% of affected tribes (3). More recently, the U.S. anthrax attacks in 2001 highlighted that even small numbers of cases can lead to significant economic costs and societal disruption.

Cases of emerging and reemerging infectious diseases have been increasing in recent years; on average, a new HHCD has been identified every year for the past 30 years, while others have reemerged in different regions or populations or have caused a greater number of cases than in the past (4). In part, this rise is due to increasing human populations expanding to previously uninhabited geographic areas and changes in land use (e.g., deforestation, intensive farming practices) (5), both of which contribute to greater exposure and interaction with animals and therefore new opportunities for zoonotic diseases to pass to humans. Moreover, international travel and trade has vastly grown over the last few decades: the movement of humans and goods is happening at a faster and greater volume than ever before, roads have surfaced in parts of the world where infectious diseases have historically been contained by travel challenges, and commercial air travel is becoming cheaper and easier. In this globalized era, a disease that emerges in the most remote parts of the world can appear in any other region of the globe in a matter of hours to days.

Perhaps the most demonstrative case of this was the emergence and global epidemic of Severe Acute Respiratory Syndrome (SARS) in 2002 and 2003, respectively. Likely emerging in live-game trade markets in Guangdong province, China in November 2002, a physician that traveled from Guangdong to Hong Kong on February 21, 2003 transmitted the infection to 16 people staying in the same hotel; these 16 cases then initiated outbreaks in Toronto, Singapore, Vietnam, and Hong Kong (6). Within weeks, the disease spread to over 35 countries on 5 continents and infected 8,096 patients; 774 of them died (7). The impact of the SARS epidemic extended beyond the global public health infrastructure: schools, hospitals, and regional borders closed; travel to affected areas and hotel occupancy in some cities dropped by 50-70% and 60%, respectively; and many businesses were forced to suspend operations due to cases among workers or quarantine orders (8). In all, the estimated short-term global economic impact of the SARS outbreak exceeded \$40 billion (9).

SARS is one of many diseases considered to be “highly hazardous”. Although there is no consensus definition of a “highly hazardous communicable disease” (HHCD), nor is there a consensus list of which diseases warrant this designation, HHCDs are generally considered high mortality diseases that are transmissible from person-to-person, are relatively rare or unfamiliar, have limited treatment options with proven effectiveness, and are preferably treated in a specialized clinical care unit (10). The term HHCD has been used interchangeably with highly infectious disease (HID) and high-consequence infectious disease (HCID); HHCD has become the preferred term, however, as many of the diseases considered highly infectious or of high-consequence are not particularly contagious and would not warrant containment and isolation in a special clinical unit.

These units, high-level isolation units (HLIUs), are designed to protect healthcare workers treating patients with HHCDs through advanced engineering controls analogous to

biosafety level (BSL)-4 laboratories (e.g., directional airflow, autoclave), highly trained staff, biosecurity measures (e.g., restricted access), and well-developed infection control protocols and procedures atypical of a routine clinical setting (10). In past HHCD outbreaks, healthcare workers have significantly higher infection rates than the general population, and therefore assume immense occupational risk; the utilization of HLIUs for dangerous pathogens can minimize nosocomial transmissions.

The first such known unit in the U.S. was established at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) in 1967; informally termed the “Slammer,” the 2-bed unit was dedicated to scientists working with diseases in defensive weapons programs and used to isolate 21 patients during its existence, none of who developed disease (11). The facility was decommissioned in 2012, by which time three other HLIUs had been independently established in the US: Emory University’s Serious Communicable Disease Unit, the Nebraska Biocontainment Unit, and the National Institute of Health (NIH) Clinical Center’s Special Clinical Studies Unit. Around the same time USAMRIID’s facility was established, units in Germany and Italy were built for smallpox eradication. Beginning in 2004, to address the growing threat of HHCDs following the 2001 U.S. anthrax attacks and global SARS epidemic, funds were allocated by the European Commission within the Public Health and Risk Assessment Program to train clinicians, strengthen diagnostic infrastructure, and construct new, additional HLIUs (12, 13).

In the mid-2000s, infectious disease experts conducted two consensus efforts to establish guidelines and best practices for HLIUs (10, 13, 14). The European Consensus effort from 2005-2006, consisting of a multidisciplinary group of experts on HHCDs and HLIU management, ensued as many European countries invested in heightening preparedness following the importation of emerging infectious diseases that included Marburg, Lassa Fever, and SARS into the European Union (10, 13). The 2005 U.S. consensus meeting engaged

representatives from the three existing U.S. biocontainment patient care units, federal and state agency representatives, and others with relevant expertise to establish guidelines and standards for high-level isolation facilities in response to emerging threats posed by bioterrorism and emerging infectious diseases (14). However, only a handful of the existing European and U.S. HLIUs managed sporadic cases of HHCDs over the next decade.

The 2014-2016 Ebola virus disease (EVD) epidemic in West Africa again propelled health security into the global agenda. Unprecedented in scale and scope, over 28,500 suspected and confirmed cases and 11,000 deaths were reported, more than all previous outbreaks of EVD combined (15). A fragile preexisting health system, weak surveillance systems, and a low ratio of healthcare workers to population in the three affected countries (Guinea, Sierra Leone, Liberia) hindered containment of the disease and facilitated its spread within the region, which was further complicated by relatively high rates of infection among available healthcare personnel. In August 2014, the World Health Organization declared the outbreak an international public health emergency, calling for foreign medical workers to deploy to West Africa to assist in the response and prompting officials from the U.S. and Europe to plan for the possibility of a citizen becoming infected while responding. During the course of the outbreak, at least 24 patients were known to be transported from West Africa to higher-resource HLIUs for EVD treatment in the U.S. and Europe; mortality rates were significantly lower (18.5%) than patients treated in West Africa (37-74%) (16). Seven of these patients were evacuated to the three preexisting units in the U.S., with all but one surviving (15).

Despite these evacuations, leaders in public health and hospital management maintained the viewpoint that all hospitals within the U.S. had sufficient isolation capability to safely care for patients with HHCDs. Included in a CDC press release in August 2014 is the statement, "U.S. hospitals can safely manage patients with Ebola disease" (17). This position

radically changed with the first imported case of EVD in the U.S. in September 2014 and the subsequent secondary infections of two healthcare providers caring for the index patient. The patient, a 45-year-old man who had arrived from Liberia 5-days prior, presented at an emergency department in Dallas, Texas and was initially misdiagnosed and sent home. He returned three days later, was isolated and later confirmed to have EVD, and succumbed to the disease two weeks later (18). Two nurses caring for the patient contracted EVD and were transported to and treated in HLIUs. The case garnered immense media attention and criticism for the hospital's insufficient preparedness; independent experts identified inadequate safety protocols, poor communication among the clinical team, and incomplete history taking as factors contributing to the hospital's mishandling (19). The case and the subsequent infection of the two healthcare workers exposed the general lack of U.S. preparedness for HHCD patients and prompted a paradigm shift in how the nation manages and cares for these patients. As the Dallas case illustrated, few hospitals had sufficient engineering controls, administrative controls, personal protective equipment (PPE), robust protocols, and dedicated trained staff for the complex and high-risk care necessitated by EVD patients.

To address the growing threat of imported cases of EVD within the U.S. and develop domestic isolation and care capacity, the U.S. Centers for Disease Control and Prevention (CDC) established a multilevel network of hospitals in late 2014 to respond to cases of EVD in the US. Hospitals were categorized into: 1) frontline facilities, able to identify suspected cases with relevant EVD exposure history (e.g., recent travel to an affected West Africa country) and EVD symptoms, isolate them and inform the local health department; 2) Ebola assessment hospitals (EAHs), capable of receiving, isolating, and caring for suspected patients for up to 96 hours until laboratory-confirmed diagnosis; and 3) Ebola treatment centers (ETCs), specialized units with advanced capabilities in eleven designated areas encompassing engineering controls, trained

and dedicated staff, and well developed infection control protocols (20). State public health officials, the CDC-led Rapid Ebola Preparedness teams, and subject matter experts conducted site visits of potential ETCs to evaluate facility readiness and proficiency in the eleven designated capability areas and provide technical assistance on each capability. These eleven capabilities, described in Table 1.1 (and later in Chapter 4), are related to the extensive infection control, infrastructure, operations, and clinical management necessary to treat patients with EVD and to minimize risks to healthcare workers and supporting roles. By December 2014, the CDC had assessed and designated 55 hospitals in the U.S. as ETCs; state health departments across the U.S. later designated an unknown number of hospitals as state ETCs.

Table 1.1. CDC Guidance on ETC Capabilities*

Capability	Description
(1) Operations Coordination (21)	<ul style="list-style-type: none"> • ETCs utilize an emergency management structure for hospital communication with state and local public health agencies, healthcare coalition partners, employees, patients, and the community to ensure timely response to facility needs and accurate information dissemination.
(2,3) Staffing and Training (21, 22)	<ul style="list-style-type: none"> • ETCs are operated by interdisciplinary teams of clinical and non-clinical personnel able to sustain weeks of clinical care with strategies to minimize the number of staff in direct contact with patients. • Personnel are trained specifically for their ETC role and demonstrate competency in: proper waste management, infection prevention and control, safe processing and transport of laboratory specimens, and proficiency in donning and doffing personal protective equipment (PPE). • ETCs conduct functional core exercises of processes

	and establish continuous training programs and retraining for infection control breaches.
(4) Clinical Competency (10, 21)	<ul style="list-style-type: none"> ETCs have a level of clinical expertise and readily available consultation not often found in routine clinical settings. ETC staff are familiar with clinical protocols for patients with EVD and have ready access to experienced clinical EVD specialists.
(5) Personal Protective Equipment (PPE) (21, 23)	<ul style="list-style-type: none"> ETC staff have drilled and demonstrated proficiency in critical donning and doffing PPE procedures. Each step of the PPE donning and doffing process is supervised by a trained observer to ensure proper protocol compliance.
(6) HCW Safety (21, 23)	<ul style="list-style-type: none"> ETCs have implemented policies and procedures for HCW safety. This includes compliance with all state and federal occupational safety standards, and the assurance of direct active monitoring of HCWs caring for patients with EVD or those in contact with the contaminated environment or waste for signs and symptoms potentially consistent with EVD throughout patient care and for 21 days afterwards. Such monitoring is overseen by public health officials for all healthcare professionals in direct patient care.
(7) Laboratory (14, 21, 24)	<ul style="list-style-type: none"> ETC laboratories have implemented risk assessments of safe work practices, PPE requirements, laboratory equipment, and instrumentation. ETCs have the capability to safely process laboratory specimens on-site. This requires appropriate laboratory procedures and protocols, a dedicated space, possible point-of-care testing, equipment, staffing, reagents, necessary training, and specimen transport.

(8) Infrastructure (21, 23)	<ul style="list-style-type: none"> • ETCs have designated private patient care rooms with dedicated in-room bathrooms or covered bedside commodes, and dedicated patient-care equipment. • ETC patient rooms are equipped with separate designated areas for donning and doffing PPE, allowing sufficient space for trained observers to verify proper fit and technique.
(9) Transportation (21)	<ul style="list-style-type: none"> • In collaboration with state and local public health agencies, and emergency medical services providers, ETCs have established inter-facility transportation plans and logistical details of safe patient transport from the ambulance entrance to the ETC. • Designated EMS providers and the ETC transport team have been adequately trained for their roles and demonstrate proficient donning and doffing of PPE.
(10,11) Waste Management and Environmental Services (21, 25)	<ul style="list-style-type: none"> • ETC personnel are trained in fundamental infection control practices, including the proper handling and storage of Category A infectious waste. • Personnel require direct supervision for the cleaning and disinfecting processes of patient care areas and equipment, using EPA-registered hospital disinfectants. • Waste contaminated with EV is classified as a Category A infectious substance, which requires the proper containers and procedures for safe handling, storage, and a waste management vendor capable of transporting Category A infectious substances, with the exception of waste autoclaved prior to transport which would then classify it as Category B waste.

Note. CDC, Centers for Disease Control and Prevention; EMS, emergency medical services; EPA, Environmental Protection Agency; ETC, Ebola treatment center; EV, Ebola virus; EVD, Ebola virus disease; HCW, healthcare worker; PPE, personal protective equipment.

*Table is found in Chapter 4 and was previously published in: Herstein, J.J., Biddinger, P.D., Kraft, C., Saiman, Lisa, Gibbs, S.G., Le, A.B., Smith, P.W., Hewlett, A., Lowe, J.J. 2016. Current

Capabilities and Capacity of Ebola Treatment Centers in the United States. *Infection Control and Hospital Epidemiology*. 37(3): 313-318. <http://dx.doi.org/10.1017/ice.2015.300>

As the outbreak in West Africa progressed and U.S. HLIUs gained experience treating repatriated patients with EVD, experts and public health officials began to recognize the comprehensive clinical care, advanced engineering controls, and highly trained personnel demanded for the care of a patient with EVD. At the suggestion of Congress and key stakeholder groups, the Department of Health and Human Services' (HHS) Assistant Secretary of Preparedness and Response (ASPR) built upon the newly established ETC framework to develop a fourth tier: ten designated Regional Ebola and Other Special Pathogen Treatment Centers (RESPTCs) (26). Nine of these facilities had previously been CDC-designated ETCs, with the tenth designated a RESPTC several months after the announcement of the nine other regional treatment centers, for a combined total of 56 RESPTCs and ETCs (27). RESPTCs allow for strategically concentrated resources to maximize federal funding while ensuring geographic distribution among regional jurisdictions. Having been screened for even higher competency than ETCs in the required high-level isolation capabilities, RESPTCs can be ready to accept patients within 8-hours of notification and have increased capacity for EVD and other HHCDs.

Funding for the regional network is a subset of \$5.4 billion in Congress appropriations for emergency supplemental funding, of which \$259.7 million was directed to HHS for domestic response activities over a 5-year period ending in FY19 (26). The vast majority of funding was allocated within the first year to heighten preparedness and response capabilities of facilities within the regional treatment network; RESPTCs were granted at least \$2.25 million in the first year, with \$250,000 allocated for the subsequent four years for a total of \$3.25 million over the course of the 5-year period. It is important to note that while the ten RESPTCs are federally

funded, the remaining 46 original CDC-designated ETCs had no guaranteed federal assistance and therefore had to identify other avenues and sources to sustain their capabilities.

In addition to establishing the regional treatment network, funds supported the establishment of the National Ebola Training and Education Center (NETEC), a cooperative agreement between the University of Nebraska Medical Center /Nebraska Medicine, Emory University, and the New York Health and Hospitals Corporations, Bellevue Hospital Center to draw on their safe and successful experiences treating patients with EVD to train and prepare other U.S. facilities for HHCDs. Funds also supported the development of a Training Simulation and Quarantine Center for Ebola and Other Special Pathogens to train federal healthcare personnel on HHCD response and treatment and to construct the largest national center for quarantining persons with high-risk exposure to a HHCD, to be housed at the University of Nebraska Medical Center (26, 28). The development of these preparedness programs in conjunction with the establishment of specialized HLIUs in the U.S. draws on the understanding that although minimizing the risk of HHCD treatment will necessitate specialized infrastructure and highly trained teams, a patient with a HHCD may present to any clinic or hospital (large or small, rural or urban, frontline facility or designated regional treatment center) in the U.S. without warning; therefore, all hospitals within the tiered system must be educated and prepared to identify and isolate such patients.

Purpose of the Study

The framework for domestic EVD response was rapidly established in 2014-2015. Fifty-six hospitals were assessed by the CDC for eleven distinct Ebola-specific capabilities; although ten of these facilities have been granted federal funds to expand capabilities to include increased capacity, rapid activation, and the treatment and management of other HHCDs, the

other 46 treatment centers were developed specifically for EVD care, and capabilities were not evaluated beyond those required for EVD designation. As of spring 2015, no information existed on the national capacity, specific physical infrastructure features, staffing models, or infection control protocols of CDC-designated ETCs or on other HHCDs these units would admit, nor was there documentation of varying preparedness activities of state health departments related to HHCD transport and the treatment center network. The purpose of this study was to assess preparations made in the United States in response to the 2014-2016 EVD outbreak; specifically, to determine capabilities developed by CDC-designated ETCs and guidelines established by state health departments for the management and transportation of patients with EVD or another HHCD. Only the 56 CDC-designated treatment centers were surveyed; these facilities were all assessed by the CDC to be competent in the required capabilities and were all publicly listed (29), whereas many state-designated treatment facilities are not publicly known and have remained unnamed.

Research Objective and Aims

To describe preparations made by ETCs and state health departments from 2014-2016 in response to potential imported cases of EVD and other HHCDs, this study:

1. Determined capabilities ETCs acquired related to laboratory resources, waste sterilization, staffing and training, biosecurity, infrastructure, environmental services, and unit procedures, and the variability of those capabilities among treatment centers.
2. Identified costs incurred by hospitals in establishing their treatment center and strategies to sustain high-level isolation capabilities

3. Determined existing guidelines and perspectives of state health departments related to the management and transportation of patients with suspected or confirmed HHCDs

In spring 2015, shortly following the CDC-designation of the original 55 U.S. ETCs, we distributed a 3-page survey (Appendix A) with the aim to identify costs ETCs incurred in preparing their facilities to manage and treat potential cases of EVD (Chapter 3), to describe ETC location, capacity and physical infrastructure features (Chapter 4), to inquire on facilities' interest in participating in a consensus network comprised of ETCs (Appendix B), and to determine laboratory support of units (Appendix C). The survey was distributed to 55 facilities; as previously noted, one RESPTC was not one of the originally designated ETCs and had not been announced prior to survey distribution. A much longer, more comprehensive survey (Appendix D) was administered to the 56 ETCs 18-months later to identify sustainability strategies of ETCs and adaption of capabilities to other HHCDs (Chapter 5), detail infection control and personal protective equipment (PPE) procedures (Chapter 6), describe additional laboratory support capabilities of treatment centers (Chapter 7), and determine staffing models and biosecurity of units (Chapter 8). In tandem with the follow-up ETC survey, a survey was distributed to state health departments (Appendix E) to gather details on planning activities conducted by states in response to the threat of imported HHCD cases (Chapter 9).

Significance

The data obtained from these surveys made a substantial contribution to the current knowledge of the level of domestic preparedness for HHCDs and to the wider body of literature on operations and design of HLIUs. Indeed, pre-published data from the first ETC survey was

requested by the US National Security Council to inform national policy and planning activities. As few global units had experience managing confirmed EVD or other HHCD cases prior to 2014-16, publicly available information or best practices from experienced units were not widely available and units had to develop or substantially alter existing protocols during the course of patient management (30). Findings from this study added to the body of literature that rapidly grew as units in Europe and the U.S. treated evacuated patients with EVD in 2014-15 and published on their experience.

Although ETCs have shown competency in 11 specified areas to be a designated treatment facility, there is nothing to suggest these units are equally prepared; in fact, this study showed great variability in capabilities and capacity amongst treatment centers. This variability is important to identify; as previously argued, the care and management of patients infected with HHCDs is high-risk and complex. Public health officials, other hospitals, and clinicians should be aware of receiving facilities' capabilities and prepared to provide augmented assistance in the necessary areas (e.g., coordinating transport of category A waste if on-site waste sterilization is unavailable). These capabilities (or lack thereof) represent real national security issues and directly affect the cost burden to hospitals and states. For example, EVD is considered a category A agent (i.e., poses the highest threat to national security), and the transport of waste generated during the care of the patient diagnosed and treated at Bellevue Hospital (which did not initially have availability of waste sterilization onsite) was estimated to exceed \$1 million (31).

In addition, apart from the ten hospitals designated as regional treatment centers, the capabilities developed by ETCs in preparing their unit for potential patients were exclusively tailored to EVD. While those capabilities could likely be adapted for diseases similar to EVD (e.g., Marburg and Lassa fever, both of which are also viral hemorrhagic fevers (VHFs) and have

similar person-to-person transmission characteristics), it was unclear prior to this dissertation how prepared designated ETCs were for other HHCDs. This study was the first of its kind to assess which diseases these designated treatment centers are prepared to admit (Chapter 5). In addition, Chapter 9 determined perspectives of state health departments on which diseases warrant high-level isolation, and which diseases they would allow treated in a conventional hospital within their state, transport to an ETC, or transport to their RESPTC. Obtaining the perspectives from both ETCs and state health departments on which diseases would be treated in a HLIU can lead to a comparison from two major stakeholders in HHCD response.

As previously described, funds allocated to establishing the regional treatment network were targeted to the ten RESPTCs and used to support the development of education and training programs for other hospitals. However, these funds were not directed to the 46 non-RESPTC treatment centers. While it has been acknowledged that select acute care hospitals were initially reluctant to volunteer to be a designated ETC due to concerns related to high costs and lost revenue (26), no information existed on the financial aspect of being a designated treatment center, including how facilities planned to maintain their capabilities and readiness. The U.S. government can use this information to set appropriations for preparedness funding of EVD and other HHCDs in the future. This study not only described the costs these treatment centers incurred, but also the extent of reimbursement from state or federal entities.

CHAPTER 2: LITERATURE REVIEW

Prior to 2014-2016, there is a dearth in the literature on treatment of patients with HHCDs in high-level containment. As previously described, only three preexisting HLIUs existed in the U.S. pre-2014, although the “Slammer” at USAMRIID existed for over 40 years prior to its decommission in 2012; again, having never treated a symptomatic patient. While U.S. preparedness for HHCDs in specialized units lagged behind, included in funding to establish specialized containment patient care units in Europe was the establishment of the European Network for Infectious Diseases (EUNID) in 2004, composed of infectious disease clinicians and public health officers from 16 member countries with expertise in the management and treatment of HHCDs with the objective to share best practices and improve connections between national and regional designated HHCD facilities (32). EUNID (2004-2007) was later continued as the European Network for Highly Infectious Diseases (EuroNHID).

A 2009 survey distributed by EuroNHID was administered to 48 facilities in 16 European countries identified by national representatives as centers for referral and management of HHCDs to determine hospital resources, hospital procedures, and health care worker safety protocols in these specialized facilities (22). The survey consisted of 44 items and 148 questions separated into three developed checklists: 1) hospital resources, 2) hospital procedures, and 3) healthcare worker safety (12, 32). In order to identify sources of misinterpretation and structural gaps, network partners conducted a pilot application in five HLIUs (33). Data from the 48 facilities was collected via on-site visits to all but four centers, performed by the project coordinator in conjunction with a representative from each of the surveyed facilities (34). Survey results were subsequently published into at least 10 separate articles, covering areas

that include transportation capacity, infection control procedures, biosecurity, personal protective equipment ensembles and procedures, and diagnostic capabilities (12, 22, 32-40).

Previously, institutional responses to HHCD events that relied on alterations to existing procedures and resources increased occupational exposure risks and delayed critical laboratory analyses (14). However, in areas or countries with no existing HLIU, hospital rooms had to be adapted for use in the treatment of patients with HHCDs. In response to over 230 imported and locally transmitted cases of SARS in Singapore, the country's stand-alone Communicable Disease Center rapidly underwent renovations and rebuilding to add rooms and update facilities; several months later, a second Communicable Disease Center was built for \$22 million (US dollars) in anticipation of future SARS outbreaks (41). During the SARS outbreak, redistribution of SARS patients to different hospitals within Taiwan and Hong Kong led to high risks of nosocomial infection; as such, Taiwan and Beijing designated specific SARS hospitals. These hospitals were renovated to include engineering controls, facilitate proper triage and patient flow, and ensure staff were aware and adequately prepared for suspected SARS cases (42).

Consensus reports from the European and U.S. consensus efforts identified key elements in the design and operation of HLIUs (10, 13, 14). These collective recommendations, which include the eleven advanced capabilities required for ETCs (20), highlight the key areas of concern in promoting an efficient facility workflow and preventing disease transmission to healthcare workers, other patients, and the wider general public. With the exception of manuscripts published from the EuroNHID surveys, these two consensus documents, and a handful of articles describing the USAMRIID facility, little information was available in published literature on high-level containment until 2014, despite 21 of 48 EU facilities having managed at least one HHCD case; specifically, as of 2012, EU units had treated 15 cases of SARS, 6 cases of Lassa fever, 1 case of EVD, 4 cases of Crimea-Congo hemorrhagic fever, 3 cases of hantavirus,

and 2 cases of poxvirus (22). The EuroNHID survey included findings on operational protocols; however, less than half of these units had ever implemented those procedures in a confirmed case. Post 2014, as units in the U.S. and Europe gained experience treating repatriated patients with EVD, a large influx of articles related to this field was rapidly published to detail successful protocols and procedures and share best practice. This literature review describes current operational and infrastructural features of global high-level isolation units that lay the foundation for the current landscape of HHCD care and management. Of note, this review is specific for care within a high-level isolation environment and does not address the procedures, infrastructure, or needs of low-level isolation and care within a field setting.

HLIU infrastructure and capacity of Global Units

While immediate isolation of a patient with suspected EVD is crucial to the adherence of precautions designed to prevent Ebola virus (EV)-transmission by direct and indirect contact, the majority of hospitals would be insufficiently prepared to dedicate and staff a costly special isolation accommodation on short notice (14, 43). The special infection control infrastructure features recommended by EUNID and the CDC for HHCD patients are prohibitively expensive. Smith et al. and Bannister et al. detail numerous consensus recommendations for facility design (10, 14). Included in both consensus criteria are negative pressure rooms, anterooms, aerosolizing tight doors and windows, High Efficacy Particulate Air (HEPA) filtration of exhausted air, air-handling systems independent from other hospital units, restricted access, adequate storage space for equipment, and seamless surfaces that can withstand disinfection processes (10, 14, 32). The demands of a facility to adopt a HLIU are costly and may be used too infrequently to justify costs of construction and sustained operation; in Europe, many units (75%

from the EuroNHID surveys) operate as training tools for HHCD management or are revertible (e.g., routine use as an infectious disease ward with the ability to rapidly convert to a BSL3 analogous patient isolation room), while others are dedicated to HHCD care (25% of EuroNHID surveyed facilities) (44).

Availability of technical infection control features (in conjunction with staffing demands) impacts the capacity of specialized HHCD rooms but is essential to limit disease transmission within the hospital and to the community. An earlier inventory by EuroNHID of high-level isolation rooms in the EU reported 17 HLIUs in 9 countries, cumulatively offering at least 92 beds (45). A brief report of infectious disease preparedness in Japan indicated that, as of April 2014, the country had 84 beds in 44 different hospitals that are designated for class 1 infectious diseases, which includes EVD according to the Japanese Act Regarding Infectious Disease (46). However, specifications of Japanese units and designation as HLIUs are unknown. In the U.S., ETCs were designated based on the capability to admit and treat one patient with EVD; exact capacities of the treatment centers were not known at the time.

Transportation

Transportation of patients with HHCDs poses increased risk of disease transmission due to its vulnerable and fluid setting; therefore, infection control in the transportation of patients with HHCDs is critical (47). However, infection control and safe patient transport can be accomplished with a dedicated team of trained individuals, appropriate equipment, and the development of proper work practices, environmental controls, and relationships among transport partners (47-49). The CDC has published interim guidance on both ground and aeromedical transport of patients with HHCDs (50-52).

Transportation of patients with HHCDs in aeromedical and ground transportation require unique planning, training, and coordination between and engagement of numerous public health, law enforcement, emergency management, and clinical agencies and institutions (47, 49). The Nebraska Biocontainment Unit (47) and Emory (48, 49) have released best practices from experience transporting patients with EVD in 2014 on PPE use for EMS providers, route selection, and preparing and decontaminating the ambulance. Both units recommend enveloping the patient compartment of the ambulance in impermeable, plastic sheeting to facilitate terminal decontamination. In Germany and Sweden, several HLIUs have adopted the use of a specialized ambulance equipped with HEPA filtration and negative pressure (39).

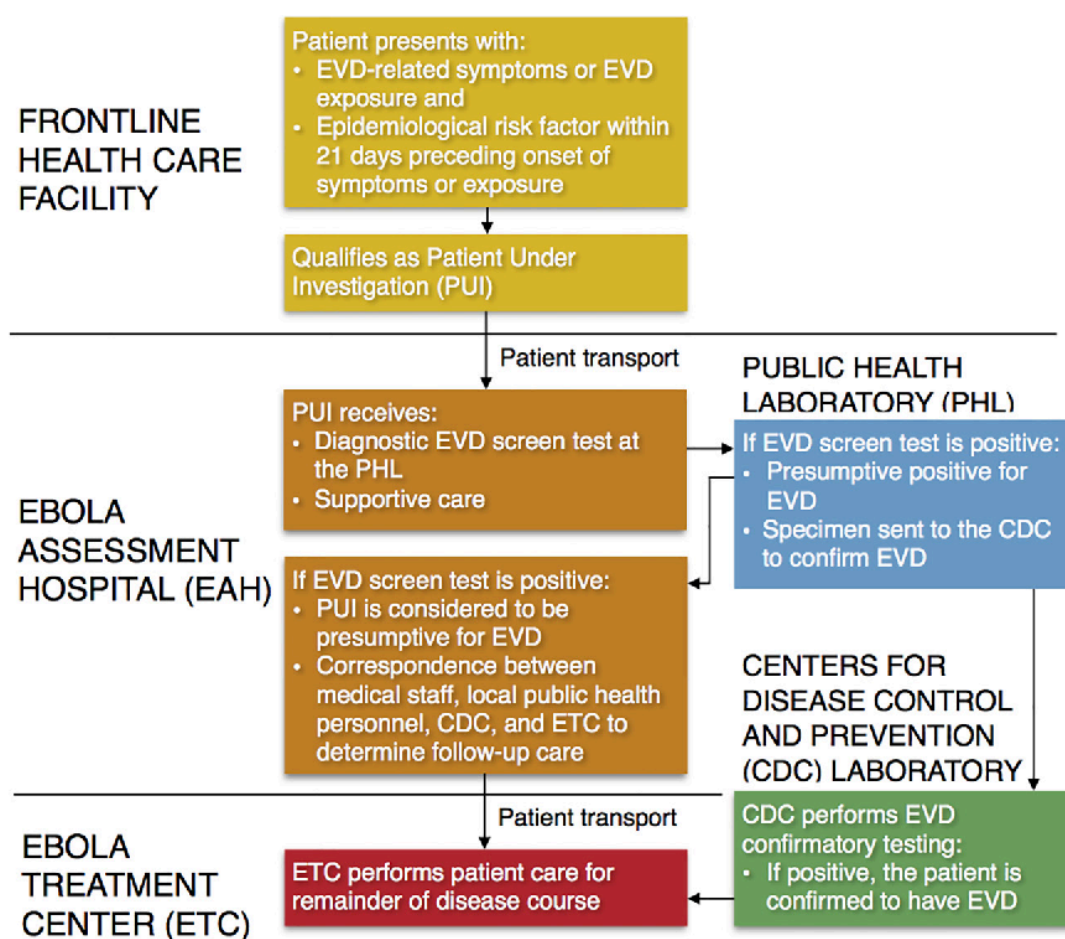
Prior to the 2014 EVD outbreak, there were only a handful of articles in the literature on aeromedical transportation of patients with HHCDs (12, 53-60). Only four articles have been published on best practices since the outbreak. Biselli et al. (61) and Ewington et al. (62) describe the use of the air transport isolator (ATI) system by the Italian military and British Royal Air Force, respectively. Dindart et al. detail the use of a smaller isolator for transport within Guinea (63) and Thoms et al. explain the development by the U.S. military of an evidence-based protocol for long-range transportations of Ebola-exposed patients on a military C-17 cargo aircraft (64).

Considering the relatively small number of HLIUs within the US, it is more likely a suspected HHCD case would present at a standard hospital ill-equipped for the care and strict infection control procedures needed for a patient with a HHCD (as was the case with the first US patient with EVD in Dallas, TX); as such, patients may need to be transferred to a designated high-level containment facility. In Europe, almost all imported cases of SARS and VHF since 2000 were first admitted into a general hospital before being transferred to a HLIU (65). The multi-tiered framework for EVD response in the U.S. established by CDC and ASPR calls for the

transport of patients between Ebola Assessment Hospitals, ETCs, and RESPTCs should a patient be diagnosed in the U.S. and present at a hospital that is not a designated ETC or RESPTC.

Communication flow for the decision to transport patients under investigation (PUIs) and confirmed patients is detailed in Figure 1.1

Figure 2.1. Communication flow for diagnosing and transferring a PUI for EVD and a patient with EVD after confirmatory testing.*



*Figure appears in Appendix C and was previously published in Jelden, K.C., Iwen, P.C., Herstein, J.J., Biddinger, P.D., Kraft, C.S., Saiman, L., Smith, P.W., Hewlett, A.L., Gibbs, S.G., Lowe, J.J. US Ebola Treatment Center clinical laboratory support. *J Clin Microbiol.* 2016 Apr;54(4):1031-1035 doi:10.1128/JCM.02905-15.

In contrast, in Japan patients with a confirmed class 1 disease (e.g., EVD) are placed in isolation and medically treated at the hospital that performed the first medical examination, even if it is not a designated hospital, due to concerns that transportation of the diseased could increase the probability of transmission (46). While this decision reduces the probability of transmitting the infection in a transport situation, there is a need for all hospitals in Japan to be prepared for and capable of managing and treating HHCDs. In Europe, basic recommendations for transporting HHCD patients were agreed upon in the EUNID consensus; however, the absence of EU-wide legally binding regulations resulted in a broad range of individual facility concepts adapted to local prerequisites (32). Indeed, half of the facilities that lacked any local protocols for patient transport were located within the same country as other facilities providing protocols, reflecting variable levels of preparedness within single nations (32).

PPE use and worker safety

ETCs are designed to provide optimal care for patients with EVD while also safeguarding healthcare workers, other patients, and the general public from infection (10). Due to PPE shortages and the potential difficulty procuring in advance the amount of PPE needed for the duration of patient care, ETCs have sufficient PPE for Ebola treatment for at least 7 days (20). Local health authorities and the CDC will facilitate the procurement of additional supplies if the hospitalization is expected to surpass the 7 days. This minimum stockpile ensures facilities have ample PPE for the first week of care while also addressing storage and expiration problems that may arise with the stockpiling of larger amounts of PPE.

The appropriate use of PPE in an HHCD setting is fundamental to healthcare worker safety. Healthcare-associated cases of EVD in Spain and the U.S. revealed the importance of proper healthcare worker training in PPE usage, donning, and doffing, yet a 2015 survey of 236 hospitals (primarily tertiary care facilities) in 38 European and western Asian countries found that only 27% of hospitals indicated they had performed or planned training of healthcare workers in PPE (66). In contrast, in the EU, 46 of the 48 facilities surveyed use PPE during contact with patients infected with a HHCD while two facilities in the UK isolate patients in a completely sealed single-bed unit (35, 67). Known as a Trexlar unit, the isolator provides additional protection to health care workers compared with PPE, but it limits the scalability and ease of medical intervention.

Selection of PPE may vary due to availability, patient acuity, and potential for aerosol-generating procedures (68, 69). Tolerance is also an important consideration in selecting PPE, as PPE can become hot and uncomfortable during HHCD care (68). Forty of the 48 surveyed European units select PPE based on a risk assessment process, while 8 (17%) always use maximum protection in a suspected or confirmed HHCD case (35). Beam et al. detail the Nebraska Biocontainment Unit's selection rationale and donning and doffing procedures for two different types of PPE (69), while Hewlett et al. provide best practice recommendations based off experiences from the Nebraska Biocontainment Unit and Emory University (68). The amount of time spent in PPE differed in facilities that treated EVD patients. Nebraska Biocontainment Unit personnel rotated every 2-4 hours while the maximum time spent in PPE at the Major Incident Hospital in Utrecht, Netherlands, was 45 minutes to minimize the loss of concentration due to discomfort (30).

Staffing and Training

Although patients with HHCDs have been treated in hospitals with normal isolation precautions, transmissions of these diseases in hospital settings is documented and may in part be due to failure to identify the infection or from inadequate training of hospital personnel on PPE and infection control measures, as evidenced in the transmission of EVD to the two Dallas healthcare workers (14). The 2014 experience of HLIUs revealed the comprehensive care necessitated by EVD, much of which involved the vast skillsets, specialties, and large teams of multidisciplinary providers required for EVD care. HHCDs demand highly trained staff that have drilled, exercised, and proven competency in infection control practices (e.g., waste handling, PPE donning and doffing) (68). The Nebraska Biocontainment Unit, Johns Hopkins' Biocontainment Unit, and HLIUs in France and Netherlands have published staff selection process, composition of team members, and shift procedures (23, 70, 71).

Frequency and means of training staff in U.S. HLIUs is unknown and likely varies substantially. The Utrecht, Netherlands HLIU trains staff on PPE donning/doffing and rehearses protocols every 10 weeks for 1.5 hours, while the Nebraska Biocontainment Unit staff drill quarterly (30). Clinicians face unfamiliar responsibilities (e.g., management of category A waste, handling of highly hazardous specimens), have to meticulously adhere to infection control procedures, and should be comfortable wearing PPE for long hours and competent in conducting clinical procedures in PPE, which may affect dexterity and communication. As HHCD cases are rare, HLIU leaders must rely on simulated situations and practice-based exercises to maintain competencies and clinical skills. Such was the case with the Nebraska Biocontainment Unit, which did not receive a single patient for its first nearly ten years of existence until 2014; staff routinely conducted exercises and drills within the space and as a result, procedures, emergency response plans, and relationships with external partners were already established

and practiced (23, 72). Full-scale and tabletop exercises allow for the testing and refining of procedures and protocols.

Laboratory capabilities

In 2015, the CDC released interim guidance for the safe collection, handling, and packaging of EV specimens, and the American Society for Microbiology (ASM) distributed guidelines recommending specimens from EVD patients should only be performed either in the patient room or in a biological safety cabinet (73, 74). Emory University, the Nebraska Biocontainment Unit, and the Frankfurt University Hospital HLIU have also shared best practices on supplementary laboratory equipment and tests for high-risk patients (24, 75-77). The EUNID consensus identified recommended capabilities for routine diagnostic tests in HLIUs including optimal use of bed-side testing inside the isolation unit area, use of the central hospital laboratory after the inactivation of samples, and use of a BSL-3 laboratory (10, 40).

However, the 2009 EU survey found that only 17% and 27% performed microbiological and routine diagnostic tests in the isolation area, respectively (40). In the 2014 survey of 236 hospitals in 38 European and western Asian countries, only 17 (17.2%) had on-site EVD diagnostic capabilities (66). A total of 39 of the 48 (81%) surveyed European units had access to BSL-3 laboratories within the same hospital or city as the unit (40). Proper biosafety regulations and vigilance to developed procedures are critical to personnel safety and the management of outbreaks, as the infection of a single laboratory worker with a highly hazardous pathogen can initiate an outbreak; however, due to robust HLIU laboratory procedures, the risk of contamination for laboratory personnel is low and, as of late 2015, only 4 laboratory accidents

involving EVD exposure have been reported worldwide since the discovery of the disease in the late 1970s (71).

Waste Management

A key concern for ETCs is identifying and addressing environmental exposure risks through infection control procedures, including the logistical capabilities and regulatory requirements for processing EVD medical waste (25, 78). Waste contaminated with EV is classified as a category A infectious substance, which requires specific containers and procedures for safe handling and storage, as well as a vendor to transport the waste; EVD waste that has been treated onsite using an autoclave, however, can be downgraded to category B waste prior to transport (i.e., routine regulated medical waste) (20, 25). In cases where a vendor capable of transporting category A waste has not been arranged, ETCs need to consider segregating EV-contaminated medical waste until EVD test results are known. If diagnosis is confirmed, infection control requirements in waste control must be met and arrangements secured with an appropriate vendor to obtain a DOT category A infectious substance special permit for transportation to an incineration facility. If EVD diagnosis is ruled out, waste can be handled through routine procedures specific to local waste management ordinances (20, 25).

Although considered the optimal solution to handling medical waste by the EUNID, the Nebraska Biocontainment Unit, and Emory, autoclaving was available in only 12 of the 48 surveyed European facilities (38). The absence of an in-unit waste processing capability increases risks of exposure in both the management and transport of HHCD waste. This is particularly important considering the immense amount of waste generated during the care of a patient with EVD (both directly by the patient and indirectly in the high number of staff involved

in care and their disposable PPE use)—more than 1,000 pounds of waste was generated by one patient during a 3-week stay at the Nebraska Biocontainment Unit (79), while two patients generated 3,000 pounds of waste over a 33-day period at Emory (80). The U.S. Environmental Protection Agency (EPA) has estimated that contaminated waste is generated by EVD patients at a rate 30-40 times that of a standard hospital patient (79). Moreover, in the U.S., only a small number of facilities accept and process category A waste, and the logistic challenges and cost of transporting waste to those facilities is significant (81). Of note, due to the particularly excessive amounts of waste generated by EVD, at least one HLIU in Netherlands equipped with an autoclave deemed in-hospital autoclave capacity as insufficient while treating an EVD patient and chose to outsource waste destruction to an external facility (30).

Initial guidance from U.S. EPA and CDC stated liquid waste from EVD patients could be disposed of normally, in toilets and in drains, as there was no evidence at the time to indicate the virus could survive a wastewater treatment plant (WWTP) (82, 83). However, the agencies neglected to consider viral survivability and potential for wastewater transmission in the liquid waste stream prior to the WWTP (a 2017 study later found that EV remains viable in sterilized wastewater for 8 days under laboratory conditions) (84). The Nebraska Biocontainment Unit and Emory University, therefore, selected to pretreat liquid waste prior to discharge to the metropolitan sewer district with a hospital grade disinfectant for over the recommended contact time prior to disposal as added precaution and to both address potential exposure concerns prior to the WWTP and to alleviate concerns of stakeholders and the community (25). A solidifying agent could also be used, as was the case in a UK HLIU, in which case the waste would be disposed of as category A solid waste (10); however, as EVD patients may generate up to 9L of liquid waste a day (25), solidifying contributes to already substantial amounts of solid waste to dispose. Importantly, U.S. regulatory agencies, hospitals, and those in the wastewater

industry differed on their recommendations for liquid waste disposal during the 2014-16 EVD response, and a lack of identified best practices remains. Likewise, the disposal of liquid waste was one of only two facets of HLIU care that EUNID and European experts were unable to reach a consensus on during the 2006 EU consensus effort (10).

Environmental Services

Studies have shown EV is viable on hard hospital surfaces for days (85, 86). As such, well-developed decontamination protocols and strict staff adherence to such procedures is crucial. The EPA, CDC, and Occupational Safety and Health Administration (OSHA) all released guidance for the disinfection of EVD-contaminated surfaces in 2014-2015 (87-89) and the European consensus group offered recommendations on unit and equipment decontamination (10). In 2014, the U.S. EPA had to develop a specific list of disinfectants for EVD use, as no disinfectant carried a label indication for EV due to challenges with such certifications (87).

The 2009 EuroNHID survey found that 90% of facilities used surface cleaning followed by disinfection for terminal decontamination; 35% of units also had formalin fumigation available (38). Of note, gross contamination must be removed prior to surface disinfection for full efficacy. Over one-fourth of surveyed EU units did not have written procedures for routine hygiene, terminal decontamination, or disinfection of reusable equipment (38).

The Nebraska Biocontainment Unit published their protocols for terminal decontamination of the unit, which includes sealing and leaving the unit undisturbed for 48 hours, manual decontamination, and ultraviolet germicidal irradiation (UVGI) (78). At the Royal Free London HLIU, which cared for an EVD case in 2014, patients are treated in a patient isolator. Decontamination was done using hydrogen peroxide vapor (HPV), with biological and

chemical indicators situated throughout the isolator and holding room to validate the process: HPV was used the first day outside of the isolator, the second day inside the isolator, and the third day in the room housing the isolator (67). HPV was also used for the terminal decontamination of a HLIU in Utrecht, Netherlands, although the unit contracted an external company (30).

At the Lazzaro Spallanzani National Institute for Infectious Diseases in Rome, which treated two patients with EVD in 2014, terminal decontamination was conducted through manual scrubbing and wipe downs of all room surfaces and reusable equipment using wipes and mops saturated with 0.5% sodium hypochlorite (90). Puro et al. collected samples from different surfaces in the patient care room following patient discharge both before and after terminal cleaning to assess efficacy of decontamination procedures. PCR-positive samples were found prior to terminal cleaning six days post-patient discharge at the bedside and under a table; both areas had been grossly contaminated with body fluid and had undergone routine daily cleaning (using wipes and mops saturated with 0.5% sodium hypochlorite) during the remaining course of treatment (90). Authors suggested positive samples were due to imperfect cleaning and heavy contamination of areas, highlighting the importance of vigilant routine cleaning procedures. All other swabs tested were negative.

Post-mortem Management

Post-mortem management of a patient that succumbed to a HHCD presents an additional risk for transmission of highly hazardous pathogens if human remains are not properly handled; however, it is not detailed in any of the eleven CDC-designated ETC areas. Remains of patients with VHF, moreover, are extremely infectious and require specialized

infection control measures, with autopsies representing an especially high-risk procedure for transmission (37, 78). This was highlighted in a case in Germany in 2016, when an American healthcare worker was medically evacuated to Germany from Togo and died one day later from unknown causes; Lassa fever was diagnosed during a postmortem examination twelve days later (91). A funeral home worker who handled the patient remains was subsequently infected with the disease, the first person to contract Lassa fever outside of Africa (92). Consensus recommendations on handling HHCD remains include avoiding autopsies on a confirmed patient with a HHCD or, if an autopsy is necessary, performing the autopsy in a BSL-3 or BSL-4 isolation room and performing only limited autopsies or post-mortem collection of percutaneous biopsy material or blood (13, 14).

The 2009 EuroNHID survey evaluated four features considered in safe post-mortem management: (1) availability of written procedures for handling of human remains; (2) availability of safety procedures for the performance of autopsies; (3) location and availability of a BSL-3 autopsy room; and (4) availability of specialized devices for postmortem examination including PPE and devices for reducing aerosol production during the use of certain medical equipment (37). Of the 48 surveyed facilities, 4 (8.3%) reported having all safe post-mortem management features while 5 facilities (10.4%) lacked any of the features (10.4%) (37).

No study has yet reported post-mortem management protocols in U.S. ETCs, but as one of two facilities in the U.S. faced with handling EVD remains (and the only HLIU), the Nebraska Biocontainment Unit has reported their approach, including protocols developed to protect HCWs and eliminate the potential for infectious remains to transfer environmental contamination outside of the unit (78). Although consensus recommendations exist on handling human remains of HHCD patients, the lack of legal mandatory standards for safe post-mortem management underscores the variability in the level of preparedness of facilities designed to

manage HHCD patients (10, 20, 37). Outside of the HLIU environment, Le et al. found that less than one-third of surveyed personnel in the U.S. death care sector (e.g., from funeral homes, crematoriums, burial services) have received training on handling of highly hazardous remains (93).

State Health Department Preparations

State and local public health departments were key players in the response to the 2014-16 outbreak of EVD. Beyond implementing the tiered framework of hospitals within the state, local and state public health authorities monitored travelers returning from affected areas, ensured symptomatic persons were isolated and appropriate agencies and institutions notified, and educated the community and key partners (e.g., law enforcement, EMS teams) on EVD (94). The effort was immense: from October 2014 to October 2015, over 20,000 travelers arrived in the U.S. from affected countries, resulting in over 400,000 cumulative contacts that were monitored by public health officials (95). Moreover, the communication and public health education campaigns to disseminate accurate information were fundamental to quelling the fear and misinformation that rapidly spread nationwide (18, 96). Importantly, this came at a time when federal support for public health preparedness significantly decreased. Federal support for the Public Health Emergency Preparedness Program has declined by 40% from its peak in FY2006, translating to 51,000 jobs lost at local public health departments nationwide (97). Reduced funding renders reduced ability to rapidly and effectively respond to HHCD threats.

Three different states had experience responding to imported cases of EVD in the U.S. and have released best practice and recommendations based on their response (Ohio (98),

Texas (18), and New York (99)). In Texas, following the first case of EVD diagnosed in the US, 179 contacts were identified and actively monitored, with all healthcare workers that provided care to the index patient placed under movement restrictions (18). In Ohio, a confirmed case visited the state prior to disease confirmation; however, as the date of illness onset was unknown, the visit to the state was included in the potentially infectious period. Over 164 contacts were monitored and local health jurisdictions identified seven hospital systems in northern Ohio as capable of isolating a contact who could develop the disease (98). In New York City, where a physician was diagnosed with EVD at Bellevue Hospital upon return home from working in an Ebola Treatment Unit in Guinea, the New York City Department of Health and Mental Hygiene (DOHMH) worked closely with NYC Health + Hospitals to prepare the NYC area for possible EVD-exposed individuals; plans began in April 2014 and by the time the patient was diagnosed in late October 2014, 25 simulated drills had been conducted and Bellevue had been designated by public health officials as the area's isolation facility for PUIs (99).

Apart from the experience of these public health departments and the known role of public health officials during the EVD response, there is little public information on the interplay of public health departments and high-level isolation facilities in the U.S. However, in Chicago, which houses one of the busiest international airports in the world, a network was established between designated ETCs, assessment hospitals, and local public health to "share expertise, risk, and resources" (100). The Chicago Ebola Response Network (CERN) sought to ensure the prompt identification and transfer of a confirmed or suspected patient with EVD to a CERN hospital; the four designated hospitals (all ETCs) rotated to evaluate PUIs (100). Standardized protocols, PPE ensembles, and training competencies align with familiarity among clinical staff, EMS, public health, and communication networks to ensure a city wide coordinated response to a HHCD threat (100).

Schwemm Dwyer et al. (2017) describe an in-progress review to evaluate the domestic public health response to the 2014-16 EVD outbreak, led by the National Association of County and City Health Officials (NACCHO) and the Association of State and Territorial Health Officials (ASTHO), in cooperation with the CDC (94). The review engaged experts at the federal, state, and local levels in public health, hospital care, emergency management, laboratory sciences, communications, and homeland security and details the response's strengths and areas for improvement. Included in the areas of improvement is to further involve state and local health departments in the development of guidance, specifically those that were developed and released by the CDC. Secondly, stakeholders expressed concern that the tiered hospital strategy established in 2014 is "not sustainable in its current capacity" and identified challenges in organizing hospitals into the three categories within the state and encouraging facilities to self-designate as an assessment or treatment hospital due to apprehension of high costs and the stigma of being labeled an "Ebola hospital" (94).

Gaps in literature

The CDC provided guidance for newly designated ETCs in early 2015 (20). However, apart from the capabilities mandated by the CDC to be a designated treatment facility for EVD patients, there is no information on the capabilities of the new domestic preparedness system that was established in 2014-2015. It is unknown what infrastructure, staffing models, training programs, and infection control capabilities these units have acquired apart from those described in this literature review; capabilities required for EVD care and management reach far beyond the eleven designated CDC areas. The experiences of U.S. HLIUs treating patients with EVD in 2014 highlight a number of other areas that are not required by U.S. ETCs nor are

detailed in ETC guidance, including but not limited to post-mortem management, training frequency and programs, and liquid waste management.

Furthermore, it is unknown at this time what, if any, diseases these units are prepared to manage and treat, other than EVD. This gap cannot be understated: facilities have likely expended immense resources into equipping their units with the 11 designated capabilities (and more), yet it is unknown if these facilities can be relied upon for the next emerging infectious disease outbreak. The establishment of NETEC and other state and federal programs that aim to prepare and educate hospitals for the next HHCD event are working to address this question; however, there remains a need to identify current preparedness for other HHCDs and inventory the capacity of these U.S. units. This information is key to determining the current state of readiness of the hospitals designated for treatment of EVD and other HHCDs.

Despite the leading role held by local and state health departments in the response to the EVD outbreak of 2014-16, there is a lack of information in the published literature on preparations state health departments have made in response to this new national framework of hospitals. Identifying these plans, as well as state and jurisdictional policies related to HHCD events, is critical to the U.S. domestic response to HHCDs. For example, although an entire tiered system has been established for HHCD response, state-specific or inter-jurisdictional barriers may exist that could limit or prohibit the transport of a confirmed patient, lab specimen, or infectious waste to a facility in a different state. This was the case in 2014, when waste from the first EVD case in the U.S. was incinerated at a facility in Texas (and no longer infectious or a threat to public safety) was to be transported to a landfill in Louisiana; upon notification, the Louisiana Attorney General filed a restraining order to prohibit the waste from entering and being disposed of within state borders (101).

The primary objectives of this study are to identify current capabilities of hospitals that were designated as Ebola Treatment Centers in the U.S. in 2014 and to determine preparations made and plans developed by U.S. State health departments in response to the establishment of this novel hospital preparedness system. This study will add to the body of literature on high-level isolation protocols, infrastructure, staffing models, capacity, and care. Although much of the data represents areas of HLIU operations that have never been published, some data provides opportunities to directly compare U.S. ETC capabilities with EuroNHID surveyed centers for infectious disease care.

CHAPTER 3: INITIAL COSTS INCURRED BY EBOLA TREATMENT CENTERS IN THE UNITED STATES¹**Initial Costs of Ebola Treatment Centers in the United States**

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Background

The 2014-2015 outbreak of EVD in West Africa was unprecedented in scale and scope. During the outbreak, 11 patients with EVD were cared for in the United States (102). Safely caring for patients with suspected EVD requires specialized protocols and training for hospital staff in the use of PPE and isolation precautions (43, 103). The care of a hospitalized patient with confirmed EVD in high-level isolation units requires large specialized teams of nurses, physicians, laboratory technologists, environmental service workers, and waste management specialists, and inpatient care may continue for weeks (21, 103). The staff-to-patient ratio necessary to care for a patient with EVD in high-level isolation is much higher than that in a typical intensive care unit because of extensive PPE used and the need for partners to assist with PPE donning and doffing.

In response to preparedness challenges in the United States, the Centers for Disease Control and Prevention recommended a multi-tiered framework of hospitals with advanced capabilities for Ebola care: frontline facilities, Ebola assessment hospitals, and ETCs (43). Within this federal framework, 55 hospitals in the United States have been designated by their states as ETCs, which have the advanced capabilities required to provide medical care to patients with confirmed EVD throughout their illness (29). Although the cost of preparing these healthcare facilities to care for EVD patients was believed to be substantial (29, 104, 105), we aimed to directly survey the ETCs to determine the costs incurred to prepare their facilities to manage and treat EVD patients.

In April 2015, we sent a 19-question electronic survey to all 55 ETCs, including the three preexisting biocontainment patient care units (Appendix A). Participation was voluntary, and individual responses were confidential. The survey assessed the ETCs' general organization and the costs incurred to establish the ETC. Of the ETCs, 45 indicated interest in participating in the

establishment of the United States Highly Infectious Diseases Consensus Network (USHIDCN) to establish infection control metrics and competencies for high-level patient isolation centers. The Institutional Review Board of the University of Nebraska Medical Center (UNMC) declared this study exempt.

Of the 55 ETCs, 47 (85%) responded to the survey, 45/47 reported the total costs incurred to establish their ETC, and 43/47 provided a detailed assessment of costs. The 45 ETCs reporting total costs incurred a cumulative total of \$53,909,701 (mean \$1,197,993/ETC) to establish the ETCs (Table 3.1). The most costly activity was facility construction and modifications. Costs incurred to provide initial training for staff averaged \$267,075 (range \$10,000--\$1,624,639). Each ETC spent \$172,581 (mean per facility; range \$3,000 to \$560,000) on other expenses not included in the five specified categories (Table 3.1).

Table 3.1. Initial costs in US\$ incurred by 45 Ebola treatment centers in the United States*

	Total Costs	Construction/ Facility Modifications	PPE Supplies	Staff Training	Unit Planning	Laboratory equipment	Non-PPE and non-laboratory supplies and equipment
Average	1,197,993	420,502	213,347	267,075	176,713	99,106	172,581
Median	1,000,000	202,980	110,000	150,000	82,000	84,000	100,000
High	6,556,457	3,839,000	1,067,573	1,624,639	1,200,000	317,406	560,000
Low	51,500	8,500	10,000	10,000	15,000	0	3,000
Sums	53,909,701	16,820,080	8,747,240	10,950,072	4,947,966	3,865,124	6,385,513

*PPE, personal protective equipment

Summarized data were collected through self-report by individual treatment centers through an electronically administered survey

Examples of additional costs included computer hardware and software, nonmedical equipment, office supplies, and employee apparel. Costs and expenses allocated to specific purchases varied by region (Figures 3.1, 3.2).

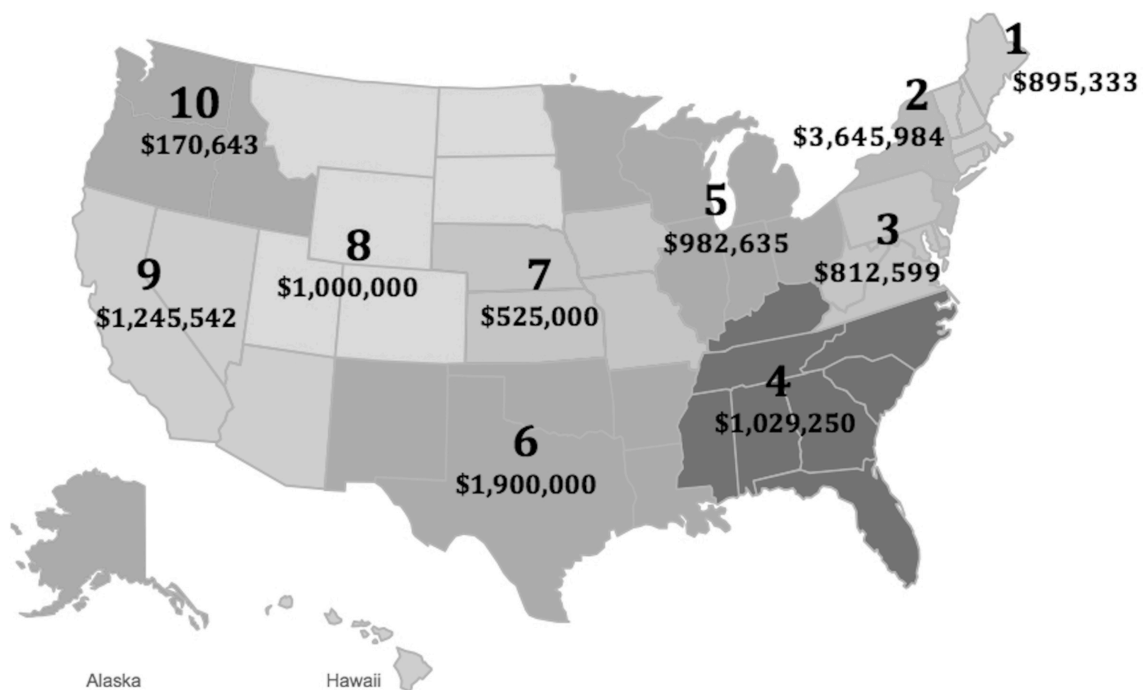


Figure 3.1. Average total costs incurred in each of the 10 US Health and Human Services regions. Summarized data was collected through self-report by individual treatment centers through an electronically administered survey. All Region 8 Ebola treatment centers provided estimates

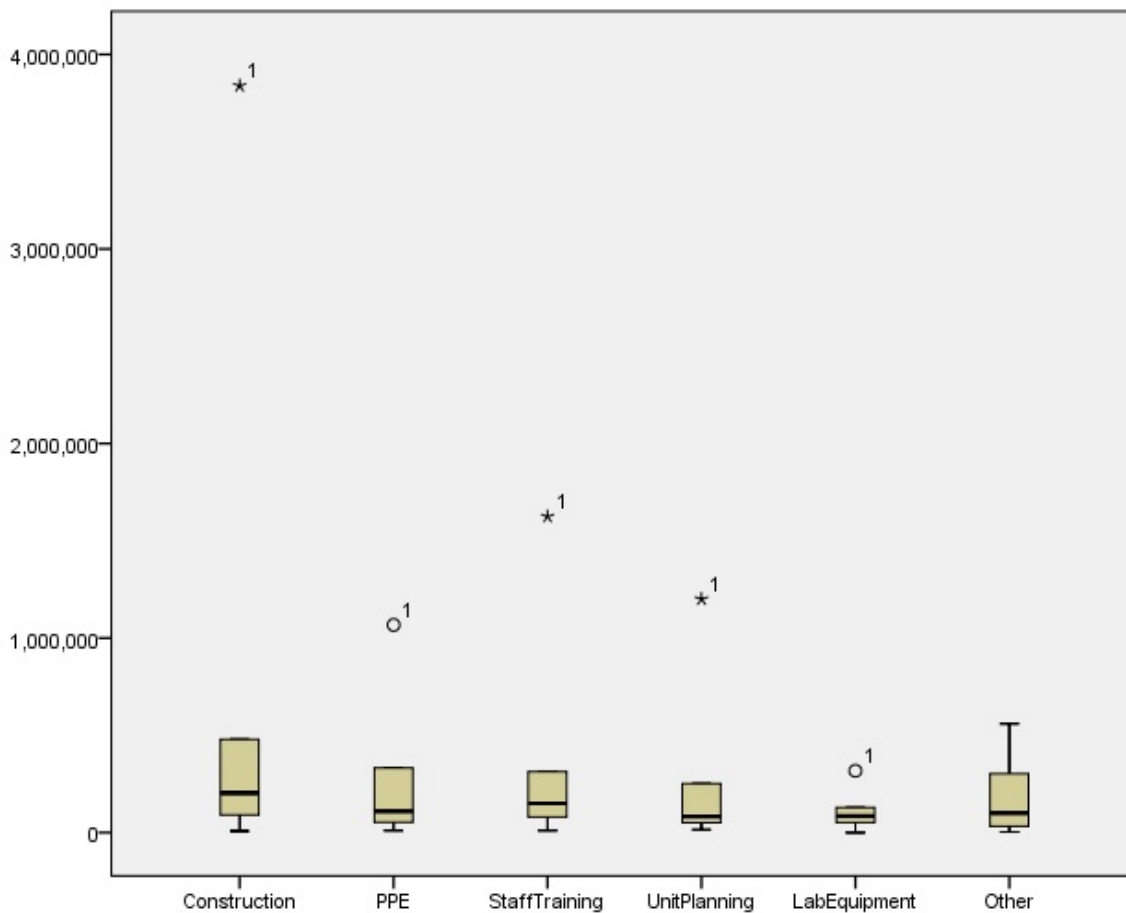


Figure 3.2. Interquartile ranges of the distribution of costs of 45 Ebola treatment centers (US\$). Data were collected through self-report by individual ETCs through an electronically-administered survey.

With the exception of three hospitals with preexisting biocontainment units, 52 hospitals had to undertake novel activities to prepare to care for patients with EVD, including development of plans, recruitment of facility leadership, recruitment and training of a multidisciplinary team of volunteers, and purchase of specialized supplies and equipment. The nearly \$54 million in previously unbudgeted expenses was a significant financial burden on the ETCs. Wide variations for overall expenditures and for specific types of expenditures were noted.

Because 10 ETCs did not report financial data, the overall costs reported here do not fully estimate the expenses incurred by ETCs. Furthermore, these overall costs represent only the initial start-up costs of establishing ETCs and do not include the costs of ongoing maintenance such as resupplying validation reagents for the laboratory, purchasing supplies and equipment, continual training of staff, or testing the units and programs.

This study had limitations. We could not validate self-reported data from the ETCs with information from expense reports. We also acknowledge that many additional hospitals undertook similar efforts to those of the designated ETCs but were not included in this survey (106). The costs incurred by public and private public health organizations also were not included.

In conclusion, we have described the initial preparation costs incurred by designated ETCs in the United States. The substantial start-up costs as well as ongoing maintenance costs of EVD programs underscore the need for specialized facilities to treat EVD (14, 32). A tiered nationwide network of healthcare facilities that can rapidly identify, isolate, and treat patients with EVD has been established to improve the nation's preparedness for EVD and can serve as a valuable resource for future outbreaks of other highly infectious diseases. Ongoing resources will be needed to sustain the readiness of such a network.

CHAPTER 4: CURRENT CAPABILITIES AND CAPACITY OF EBOLA TREATMENT CENTERS IN THE UNITED STATES²

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ORIGINAL ARTICLE

Current Capabilities and Capacity of Ebola Treatment Centers in the United States

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² The material presented in this Chapter was previously published: Herstein, J.J, Biddinger, P.D., Kraft, C., Saiman, Lisa, Gibbs, S.G., Le, A.B., Smith, P.W., Hewlett, A., Lowe, J.J. 2016. Current Capabilities and Capacity of Ebola Treatment Centers in the United States. Infection Control and Hospital Epidemiology. 2016 Mar;37(3): 313-18. <http://dx.doi.org/10.1017/ice.2015.300>

Background

In September 2014, identification of the first case of a patient with EVD to present in the United States was delayed and infection of two healthcare workers (HCWs) occurred (107). This experience exposed the difficulty that hospitals faced in adequately training dedicated staff to care for patients with EVD. Historically, institutional responses to HID events have modified existing policies, procedures, and resources. However, this approach resulted in increased risks of HCW occupational exposure and delayed critical laboratory testing (14). Consensus reports from the European Network of Infectious Diseases and state and federal agencies in the United States, as well as experts from the three initial biocontainment patient care units in the United States, have identified key elements in the design and operation of specialized facilities caring for patients with HIDs (10, 14), including EVD. These units, defined by the European Network of Infectious Diseases as high level isolation units, include recommendations for infection control, clinical competency, physical features, facility workflow, and worker safety protocols to prevent disease transmission to HCWs, other patients, and the general public (10, 14).

To maximize HCW safety and domestic EVD isolation capacity, the CDC established an unprecedented multi-tiered network of hospitals with specialized capabilities for Ebola care, including frontline facilities, Ebola assessment hospitals, and ETCs (43). ETCs have largely been designated in metropolitan areas that receive significant amounts of travelers from West Africa, leaving sparsely populated areas in further proximity from ETCs (Figure 4.1).

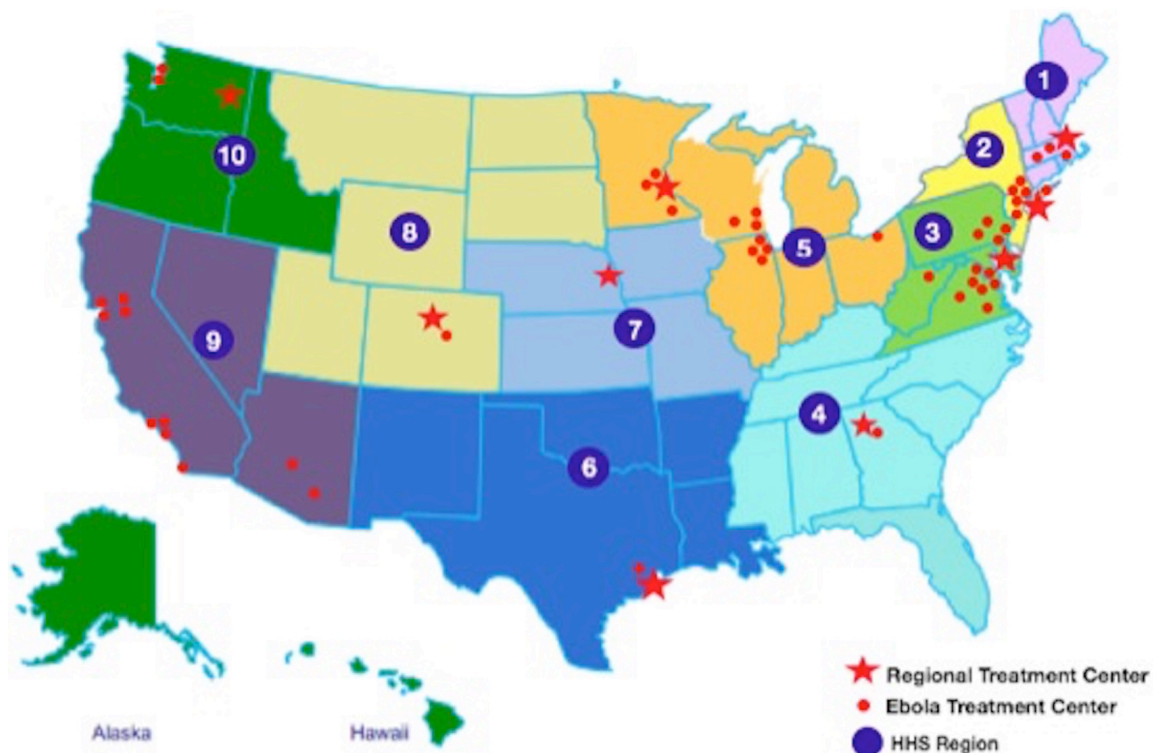


Figure 4.1. U.S. Department of Health and Human Services (HHS) Regions with Centers for Disease Control and Prevention designated Ebola Treatment Centers and Assistant Secretary for Preparedness and Response designated Regional Ebola and Other Special Pathogen Treatment Centers

To ensure rapid readiness to provide Ebola care, local public health officials and the CDC coordinated site visits to potential ETC hospitals, assessed facility readiness in 11 augmented capabilities, and provided technical assistance, as needed. As of August 2015, 55 U.S. hospitals designated as ETCs have acquired the enhanced operational capabilities detailed in Table 4.1.

Table 4.1. CDC Guidance on ETC Capabilities*

Capability	Description
(1) Operations Coordination (21)	<ul style="list-style-type: none"> ETCs utilize an emergency management structure for hospital communication with state and local public health agencies, healthcare coalition partners, employees, patients, and the community to ensure timely response to facility needs and accurate information dissemination.
(2,3) Staffing and Training (21, 22)	<ul style="list-style-type: none"> ETCs are operated by interdisciplinary teams of clinical and non-clinical personnel able to sustain weeks of clinical care with strategies to minimize the number of staff in direct contact with patients. Personnel are trained specifically for their ETC role and demonstrate competency in: proper waste management, infection prevention and control, safe processing and transport of laboratory specimens, and proficiency in donning and doffing personal protective equipment (PPE). ETCs conduct functional core exercises of processes and establish continuous training programs and retraining for infection control breaches.
(4) Clinical Competency (10, 21)	<ul style="list-style-type: none"> ETCs have a level of clinical expertise and readily available consultation not often found in routine clinical settings. ETC staff are familiar with clinical protocols for patients with EVD and have ready access to experienced clinical EVD specialists.
(5) PPE (21, 23)	<ul style="list-style-type: none"> ETC staff have drilled and demonstrated proficiency in critical donning and doffing PPE procedures. Each step of the PPE donning and doffing process is supervised by a trained observer to ensure proper protocol compliance.

(6) HCW Safety (21, 23)	<ul style="list-style-type: none"> ETCs have implemented policies and procedures for HCW safety. This includes compliance with all state and federal occupational safety standards, and the assurance of direct active monitoring of HCWs caring for patients with EVD or those in contact with the contaminated environment or waste for signs and symptoms potentially consistent with EVD throughout patient care and for 21 days afterwards. Such monitoring is overseen by public health officials for all healthcare professionals in direct patient care.
(7) Laboratory (14, 21, 24)	<ul style="list-style-type: none"> ETC laboratories have implemented risk assessments of safe work practices, PPE requirements, laboratory equipment, and instrumentation. ETCs have the capability to safely process laboratory specimens on-site. This requires appropriate laboratory procedures and protocols, a dedicated space, possible point-of-care testing, equipment, staffing, reagents, necessary training, and specimen transport.
(8) Infrastructure (21, 23)	<ul style="list-style-type: none"> ETCs have designated private patient care rooms with dedicated in-room bathrooms or covered bedside commodes, as well as dedicated patient-care equipment. ETC patient rooms are equipped with separate designated areas for donning and doffing PPE, allowing sufficient space for trained observers to verify proper fit and technique.
(9) Transportation (21)	<ul style="list-style-type: none"> In collaboration with state and local public health agencies, and emergency medical services providers, ETCs have established inter-facility transportation plans and logistical details of safe patient transport from the ambulance entrance to the ETC.

	<ul style="list-style-type: none"> • Designated EMS providers and the ETC transport team have been adequately trained for their roles and demonstrate proficient donning and doffing of PPE.
(10,11) Waste Management and Environmental Services (21, 25)	<ul style="list-style-type: none"> • ETC personnel are trained in fundamental infection control practices, including the proper handling and storage of Category A infectious waste. • Personnel require direct supervision for the cleaning and disinfecting processes of patient care areas and equipment, using EPA-registered hospital disinfectants. • Waste contaminated with EV is classified as a Category A infectious substance, which requires the proper containers and procedures for safe handling, storage, and a waste management vendor capable of transporting Category A infectious substances, with the exception of waste autoclaved prior to transport which would then classify it as Category B waste.

Note. CDC, Centers for Disease Control and Prevention; EMS, emergency medical services; EPA, Environmental Protection Agency; ETC, Ebola treatment center; EV, Ebola virus; EVD, Ebola virus disease; HCW, healthcare worker; PPE, personal protective equipment.

To further geographic reach and strengthen capacity to care for patients with HIDs, in June 2015 the U.S. Department of Health and Human Services selected nine ETCs to serve as Regional Ebola and Other Special Pathogen Treatment Centers (RTCs) for patients with Ebola and other HIDs, in conjunction with their respective public health departments (Figure 4.1). The Assistant Secretary for Preparedness and Response funded the RTCs to expand their operational capabilities and capacity to sustain ongoing readiness throughout the United States (108). Among other requirements, ETCs selected as RTCs must have the capacity to treat at least two Ebola patients at one time, have respiratory infectious disease isolation capacity or negative pressure rooms for at least 10 patients, accept patients within eight hours of being notified, be

able to treat both pediatric and adult patients, and must conduct quarterly trainings and exercises for facility staff (109).

The extensive operational requirements and comprehensive treatment protocols required to care for an EVD patient limit an ETC's capacity. The treatment of patients with EVD and other HIDs in ETCs with proper operational capabilities is critical to nationwide preparedness and the safety of the patient, HCWs, and the community. The recent Ebola epidemic was a grave example of the severity of HID threats, exacerbated owing to increasing global fluidity. This report describes current ETC locations, infection control infrastructure, and their capacity to care for EVD patients.

Methods

In April 2015, a 19-question electronic survey (with institutional review board exemption UNMC IRB #165-15-EX) was sent to all 55 ETCs, including the 9 RTCs (Appendix A). The survey was re-sent two weeks later to follow up with facilities that had not responded. The survey inventoried current capabilities and capacity as well as the cost of establishing the ETCs; the latter is the subject of another manuscript, currently under review. This survey, which consisted of discrete responses with the ability to provide qualitative feedback for every question, was adapted from existing assessment questions developed by European Network of Infectious Diseases (110). The survey included questions regarding isolation unit location within the facility, overall capacity for care, and infection control infrastructure. To assess capacity for care, the maximum number of EVD or HID isolation rooms and beds that can be used simultaneously as well as the total capacity for adult and/or pediatric patients were requested. The number of isolation beds per million of population was calculated using the most recent census estimates (111). To assess the features of the infection control infrastructure,

respondents were asked about separate air handling units, physical barriers separating isolation rooms within the same unit, negative pressure, high-efficiency particulate air (HEPA) filtration, details about entrances and exits to the isolation unit, and the processes used for sterilization of medical waste. Data were coded and analyzed using descriptive statistics with an electronic spreadsheet (Excel; Microsoft).

Results

Forty-seven (85%) of the 55 ETCs, including 7 of the 9 RTCs, completed the survey. Thirty-eight ETCs are located in academic teaching institutions, 5 are in referral hospitals providing specialized tertiary care, and 2 designated themselves “other”. Nearly all (44 [94%]) of the high-level isolation units are located within the main hospital building. A portion of ETCs have separate wards (20 [43%]) or separate rooms within another ward (24 [51%]); 3 facilities (6%) are stand-alone. Of the 20 units located on isolated wards, 14 (70%) have separate air-handling systems. Of the 24 units located within other wards, 14 (58%) have independent air-handling systems and 23 (96%) have a physical barrier separating the isolation rooms from the rest of the ward.

Of the 47 responding ETCs, there is a total of 84 adult beds, 35 pediatric beds in children’s hospitals, and 56 pediatric beds in hospitals treating both adults and pediatric patients (Table 4.2). Twenty-four hospitals accept both adult and pediatric patients; the children’s hospitals designated as ETCs have only pediatric beds available. The mean maximum number of beds that can be used simultaneously by individual ETCs is 2.6.

Table 4.2. High-Level Isolation Unit (HLIU) Capacity of the 47 Ebola Treatment Centers Participating in the Survey

Variable	No. of hospitals	Total no. HLIU rooms	Total adult bed capacity	Total pediatric bed capacity	Average no. HLIUs per Ebola treatment center
Overall ^a	47 ^b	121 ^c	84	91	2.6
Children's Hospitals	9	35	0	35	3.9
Hospitals treating only adults	13	23	23	0	1.8
Hospitals treating Adults and Pediatrics	24	61	61	56	2.5

^a Some can be used simultaneously.

^b Of the 47 facilities, 46 provided separate adult and pediatric bed capacity numbers.

^c One facility listed only their maximum isolation bed capacity (2) but did not specify whether the beds could be used for pediatric patients.

The average capacity of the 7 RTCs that completed the study is shown in Table 4.3 and is higher than that of non-RTCs. On the basis of the current U.S. census (111), the number of staffed isolation beds available from the survey respondents is 0.38 beds per million population. Several centers provided additional feedback that capacity varies depending on the HID being treated and that staffing is insufficient for their current bed capacity.

Table 4.3. Comparison of the Ebola Virus Disease Treatment Capacity of the 7 Regional Treatment Centers and 40 Non-Regional Treatment Centers Participating in the Survey

Variable	Non-Regional Treatment Centers ^a			Regional Treatment Centers		
	Overall Bed Capacity	Adult Bed Capacity	Pediatric Bed Capacity	Overall Bed Capacity	Adult Bed Capacity	Pediatric Bed Capacity
Total	97	60	74	24	24	17
Average	2.4	1.5	1.9	3.4	3.4	2.4

^aOne facility listed only their maximum isolation bed capacity (2) but did not specify whether the beds could be used for pediatric patients.

Anterooms and negative pressure (no. of air exchanges per hour: mean, 14.3; median, 12) are available for 45/47 (96%) of high-level isolation units. Consensus guidelines for high-level isolation recommend separate entrances and exits for units, which are available in 23 units surveyed (49%), whereas 24 (51%) use the same pathway for staff to enter and exit (43). Thirty-one facilities (66%) use HEPA filtration in the units, of which 4 (13%) filter only intake air, 13 (42%) filter only exhausted air, and 13 (42%) have HEPA filtration for both intake and exhausted air. One facility did not specify the HEPA filtration direction.

Eleven ETCs (23%) have the capability to sterilize waste on-site, of which 10 have an autoclave and 1 unit is equipped with an incinerator. However, this ETC noted they do not use the incinerator but use a separate certified facility for the disposal of category A infectious waste. Of the 11 ETCs equipped with on-site sterilization capability, 5 (45%) are located within the unit. Six ETCs noted that they were in the process of acquiring and installing an autoclave or intended to do so if they received the funds. All 36 facilities without the capability to sterilize waste on-site have processes for category A waste disposal with certified facilities. Only 10 (21%) of the 47 ETCs have isolation units equipped with negative pressure, an anteroom, on-site

sterilization of waste, and HEPA filtration. Forty-five ETCs indicated their willingness to participate in the U.S. Highly Infectious Disease Consensus Network (USHIDCN) to establish control metrics, competencies, and peer review for high-level isolation units.

Discussion

Before the establishment of ETCs, the great majority of hospitals were inadequately prepared to care for a patient with suspected or confirmed EVD (14, 21). Although the development of 55 ETCs has heightened nationwide preparedness levels, the treatment paradigms necessary for EVD care drastically limits patient capacity in these facilities. Furthermore, because no pediatric EVD patients have been treated in the United States, questions remain on the resources, staffing levels, and care required for pediatric patients. Responses show most ETCs distinguish adult bed capacity from pediatric beds and many ETCs do not plan to care for pediatric patients (Table 4.2), highlighting the need to distinguish between pediatric and adult bed capacity and capability.

Limitations to capacity include both beds available in high-level isolation units and the need for dedicated multidisciplinary staff. Expectations for staff include low turnover rates, regularly scheduled drill exercises for staff to maintain competency in infection control procedures, and a leadership system based on the incident command model (14, 23, 68). Despite efforts to designate specific team roles and minimize the number of staff in direct contact with the patient and/or infectious secretions, large numbers of staff are needed to care for an individual patient. Furthermore, owing to the intensity of treatment for EVD and the extended use of personal protective equipment, Nebraska Biocontainment Unit staff, for example, rotate after every 2-4 hours to prevent physical and mental fatigue (112). Because staff participation in ETCs is voluntary, scheduling and backfill issues may further complicate

staffing (23). An additional challenge is how facilities will sustain a fully trained team when unoccupied.

Another unanticipated concern for ETCs has been the logistical capabilities and regulatory requirements associated with processing and disposing of EVD medical waste (78, 113). The challenges of medical waste may be one of the factors that limit an ETC's ability to manage more than one EVD patient at a time. Although autoclaves and incinerators, which cost approximately US \$100,000 to install (112), can transform Ebola virus category A infectious waste to category B waste, only 11 facilities have on-site autoclaves or incinerators. The other 36 facilities must develop expensive procedures for safe handling and use a vendor capable of off-site transport and disposal of category A waste, which could cost millions of dollars (21, 25, 112). ETCs without the ability to manage waste on-site through autoclaves or incinerators heighten exposure risks during management, packaging, and transporting of contaminated materials (38). Even with autoclaves and incinerators, the immense amount of waste generated by a single EVD-patient requires a temporary waste storage area/site and a nearly constant sterilization process (25).

The establishment of the CDC's national Ebola network has heightened U.S. preparedness for EVD, but questions on the use and efficacy of these isolation units in response to other diseases remain. Several ETCs noted that if patients are admitted into units located within the same ward as other hospital activities, surrounding rooms will be closed, likely resulting in lost revenue. Beyond the physical number of beds available, it is the negative pressure rooms, physical barriers, staffing capability, and other infection control capabilities that determine a facility's capacity to treat a specific disease. HEPA filtration is not required for isolation of patients with EVD but has been recommended for high-level isolation units (10, 14). Further, having negative pressure rooms, on-site waste sterilization, and an anteroom reduces

the risk of disease transmission to HCWs and has been attributed to successfully treating an EVD patient (78, 113).

Although EVD is a highly infectious viral hemorrhagic fever that can be spread to others via infected body fluids, it is not as contagious as some other HIDs spread via the airborne route, such as Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS) coronaviruses, which can be spread through respiratory droplets and fomites (114-117). Furthermore, the number of travelers from affected nations arriving in the United States varies greatly. An average of 130 to 150 people travel from West Africa to the United States each day (118), while between March 16 and April 3, 2003, more than 220,000 passengers traveled to the United States from SARS-affected China, Vietnam, and Singapore (119). Given the more than 121 simultaneous available beds nationwide, it is probable that the ability to control and treat a national outbreak of EVD (albeit unlikely) is adequate, whereas controlling and treating an airborne HID would be challenging.

This study has limitations. Data were self-reported by facility representatives and results were not validated. Many facilities noted their response was Ebola-specific and would change with other diseases. Therefore, results cannot be generalized to the capacity for other HIDs. At the time of survey distribution, RTCs had not yet been designated. The establishment of these centers included requirements on increased capacity. As such, the inclusion of any further capacity development by these facilities is not included here, and therefore the average capacity per RTC is likely greater than as indicated in Table 4.3. Lastly, these figures do not account for the 9 ETCs that did not respond to the survey, nor were non-ETCs that have made similar preparations but are not designated as ETCs counted; hence the complete number of beds available in the United States could not be tabulated.

The 2014-2015 Ebola epidemic was a reminder of the increasing global fluidity of HID threats. Multilevel, interprofessional collaboration to isolate HID cases and reduce disease transmission will be crucial to contain future outbreaks (23, 34). Although the current capacity of ETCs in the United States is adequate to manage and treat the few sporadic cases of EVD that occur or are treated domestically, future HID pandemics or larger domestic outbreaks warrant surge capacity owing to the low number of patients who can be treated simultaneously in the existing facilities. Finally, although ETCs have acquired specialized capabilities and infrastructure to successfully treat and manage EVD, whether or not these units can be adapted for other HIDs is unknown and should be explored.

CHAPTER 5: SUSTAINABILITY OF HIGH-LEVEL ISOLATION CAPABILITIES AMONG US EBOLA
TREATMENT CENTERS³

DISPATCHES

Sustainability of High-Level Isolation Capabilities among US Ebola Treatment Centers

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To identify barriers to maintaining and applying capabilities of US high-level isolation units (HLIUs) used during the Ebola virus disease outbreak, during 2016 we surveyed HLIUs. HLIUs identified sustainability challenges and reported the highly infectious diseases they would treat. HLIUs expended substantial resources in development but must strategize models of sustainability to maintain readiness.

outbreak revealed vulnerabilities within the US healthcare and public health infrastructure to address HIDs. We aimed to identify barriers to maintenance of recently developed isolation and care capabilities, how those capabilities might be applied to outbreaks other than EVD, and further infrastructure and resources HLIUs would add if additional funding were available.

The Study

In early 2016, we sent a 70-question survey to the original 56 designated US HLIUs, including the 10 RESPTCs. The sur-

³ The material presented in this Chapter was previously published: Herstein, J.J., Biddinger, P.D., Gibbs, S.G., Le, A.B., Jelden, K.C., Hewlett, A., Lowe, J.J. 2017. Sustainability of High-Level Isolation Capabilities among U.S. Ebola Treatment Centers. *Emerging Infectious Diseases*. 2017 Jun;23(6): 965-967. DOI: 10.3201/eid2306.170062.

Background

During the 2014-2016 West Africa EVD outbreak, 56 hospitals in the United States were designated by the CDC as ETCs. ETCs added national capacity to care for patients with HIDs; that is, hazardous, easily transmissible, life-threatening illnesses with limited treatment options such as EVD and severe acute respiratory syndrome coronavirus (10). ETCs were equipped with the clinical care resources, specialized infrastructure, and trained staff to safely manage and treat a person suspected or confirmed to have EVD (43). After the initial designation, one ETC in each U.S. Department of Health and Human Services region was selected as a Regional Ebola and Other Special Pathogens Treatment Center (RESPTC) capable of managing HIDs for sustained periods (27).

In 2009, a consensus group of infectious disease experts in Europe defined high-level isolation units (HLIUs) as facilities providing optimal infection containment and procedures specifically designed for HID care and released specifications for such units (10). A 2015 pilot survey of U.S. HLIUs described the actions taken to establish high-level isolation capabilities and identified the costs of those efforts (120-122). The survey revealed that 45 of the U.S. hospitals spent a cumulative total of \$53.9 million (nearly \$1.2 million per facility) to stand up their specialized isolation units (120).

Because of the substantial expenses and operational challenges of maintaining readiness, how HLIUs can continue these efforts has been questioned (123). The EVD outbreak revealed vulnerabilities within the U.S. healthcare and public health infrastructure to address HIDs. We aimed to identify barriers to maintenance of recently developed isolation and care capabilities, how those capabilities might be applied to outbreaks other than EVD, and further infrastructure and resources HLIUs would add if additional funding were available.

The Study

In early 2016, we sent a 70-question survey to the original 56 designated U.S. HLIUs, including the ten RESPTCs (Appendix D). The survey queried challenges and concerns about the maintenance of capabilities. Results were collected via Adobe Pro (<https://acrobat.adobe.com/us/en/acrobat/acrobatpro.html>) and analyzed using descriptive statistics. The University of Nebraska Medical Center Institutional Review Board declared the study exempt (#172-16X).

Thirty-six (64%) hospitals responded. Of the 33 that completed the full survey, 3 reported they no longer maintained their HLIU capabilities. The 2 that provided qualitative information about their decision to close reported needing HLIU resources for other, more pressing areas and cited close proximity to at least one other HLIU as reasons for closing.

Nineteen (58%) hospitals reported using their HLIU for non-HID patients when not activated; the other 14 (42%) use the unit exclusively for patients with HIDs or for training (Table 5.1). When the 19 hospitals with adaptive isolation units (i.e., units otherwise used for normal hospital care) are activated, an average of 6.31 beds (median 6, range 2-12) must be taken offline when caring for one patient with an HID and an average of 6.97 beds (median 7.75, range 2-12) for two patients. Ten (53%) HLIUs with adaptive units stated preference for a unit dedicated to care for patients with HIDs; however, when asked the estimated costs of developing a unit for 2 HID patients, estimates ranged from \$1 million to \$12 million. Perceived benefits of a dedicated unit include minimizing disruption of other patients (4 hospitals), a constant state of readiness (3 hospitals), and an ability to train in the unit (4 hospitals).

Table 5.1. Activation of HLIUs and management of PUIs, United States*

Variable	Facilities, no/N (%)
Activation of HLIU	
HLIU can be activated 24/7 throughout the year†	32/33 (97)
Standing Protocol to contact team members 24/7	31/33 (94)
Involve local/state public health officials in managing public concerns	32/33 (97)
PUIs	
Plan to provide care for PUIs and persons with confirmed cases	32/33 (97)
Staff used to care for PUI	
Use only HLIU staff to care for a PUI	28/32 (88)
Use other staff before disease is confirmed	4/32 (13)
Placement of PUI	
Place PUI exclusively in the HLIU while being assessed	14/32 (44)
Place PUI in either HLIU or hospital Emergency Department	12/32 (38)
Place PUI in emergency department until confirmed diagnosis	4/32 (13)
Other‡	2/32 (6)

*ED, emergency department; HLIU, high-level isolation unit; PUI, patient under investigation.

†Average time necessary to activate HLIU after notification of pending patient transfer is 4.58 h (median 4 h, range 1.24 h).

‡One facility sends a mobile response team to a PUI's home for evaluation, and another plans to use a mobile treatment unit (i.e. tent) for PUI placement.

Our initial 2015 survey reported that hospitals designated as ETCs incurred an average per hospital of \$1,197,993 (120). Since that time, 25 (76%) of those original facilities reported receiving some degree of federal reimbursement, and 8 (24%) have not received any reimbursement to date. A cumulative total of \$28,146,558 in federal funding (average \$1,407,328, range \$33,650-\$6,000,000) was reported by the 20 (60%) reporting HLIUs. After we excluded federally funded RESPTCs and HLIUs that did not report initial investments in the pilot survey, the remaining 14 HLIUs reported a gap in reimbursement of \$9,113,072.50 (mean \$650,933.75 per HLIU).

Although one HLIU reported lacking specific protocols or an ability to care for patients with an HID other than EVD, all other HLIUs (97%) reported being prepared to care for HIDs other than EVD (Figure 5.1).

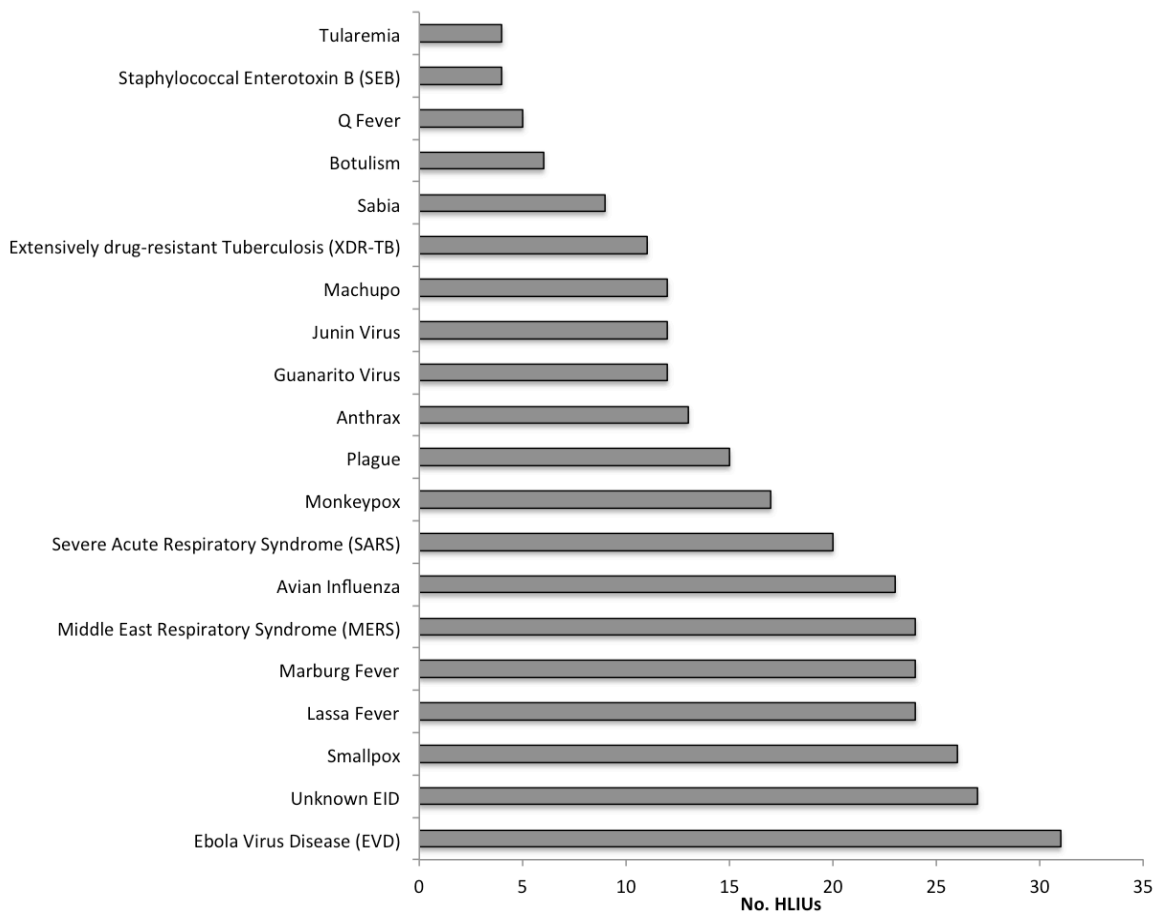


Figure 5.1. Diseases that 31 high-level isolation units (HLIUs) reported they would treat, United States, 2016

Our survey also queried HLIUs about the challenges they experienced and challenges they foresee in maintaining the capabilities and capacity needed for HID care (Figure 5.2).

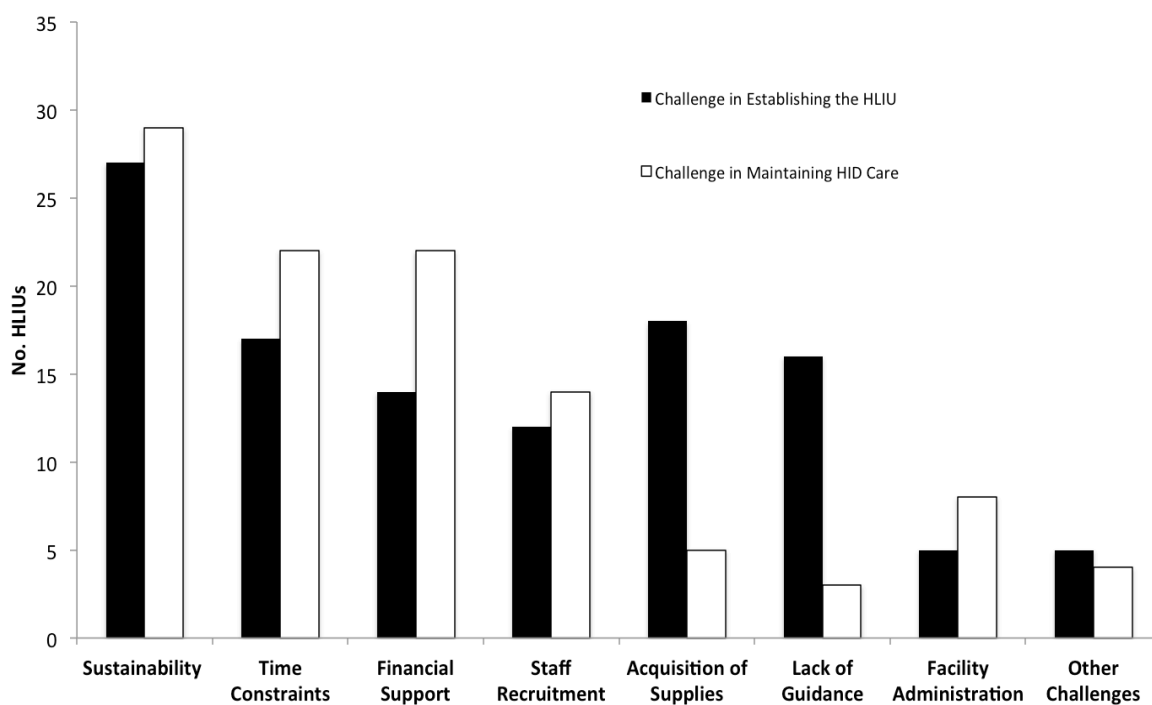


Figure 5.2. Challenges to establishing an HLIU and to maintaining HID care reported by survey respondents, United States, 2016 (n=32 HLIUs). Other challenges include external support, lack of dedicated unit space, competing priorities, staffing needs, and decreasing hospital capacities. HLIU, high-level isolation unit; HID, highly infectious disease.

Sustainability concerns was the most cited challenge in establishing and maintaining a HLIU. HLIUs also detailed facility modifications and/or capabilities they would add if additional hypothetical funding were available (Table 5.2).

Table 5.2. Operational capabilities HLIUs reported they would add or construct if funding were available, United States*

Funding amount	Capability	No. HLIUs
\$100,000	Additional training/drills (e.g., for other diseases, simulation equipment)	6
	Broad supplies/equipment (e.g., beds, family support technology/equipment)	4
	Laboratory capability and capacity (e.g., reduced transport of materials, lab hood in unit, purchase of new decontamination equipment)	4
	On-site waste disposal	4
\$500,000	Expanded and updated patient rooms	3
	Enhanced laboratory capabilities (e.g., additional lab tests, larger lab space)	3
	Expanded isolation unit (e.g., increase capacity of negative-pressure rooms)	2
\$1,00,000	Renovated/expanded isolation unit	4
	Separate, permanent isolation unit	3
	Expanded training (e.g., increased frequency)	2

*Individual HLIUs self-reported data through an electronically administered survey administered in 2016. HLIU, high-level isolation unit

Conclusions

Developed during the height of the West Africa Ebola outbreak, most newly established U.S. HLIUs invested immense resources and effort into preparing for patients with EVD. However, no formal network of HLIUs has been established in the United States, except for the 10 RESPTCs, and at least three former HLIUs no longer maintain HLIU capabilities. Moreover, 14 HLIUs not designated as RESPTCs reported having spent \$9.1 million more than they have been reimbursed to initially develop HLIU capabilities. As a result, these hospitals reported struggling to fund ongoing operations and sustain readiness.

Although many facilities have created adaptable-use HLIUs because they lack the capital funds, space, or both to create a dedicated unit, such units have major disadvantages because healthcare workers are unable to train in the unit, existing patients must be relocated when the unit is activated for an HID patient, and multiple additional rooms must be taken off-line for the care of one patient with an HID (32). Thus, more than half of U.S. HLIUs that routinely care for non-HID patients would build a HID-dedicated unit if funds were available. However, because future funding sources for non-RESPTCs are unclear, lessons on sustainability might be learned from flexible-use HLIUs in Italy and the Netherlands, which offer levels of containment based on a patient's condition and offset costs by routine use (10).

Our study had several limitations. The data were self-reported and not validated by external sources. The current status of HLIUs that did not participate in the follow-up survey is unknown. A decrease in participation from the initial survey to the follow-up could also be due to the longer, more detailed follow-up and could indicate the lack of attention to this area now that the EVD outbreak is over. The study population was based solely on a list published by the CDC (124) and does not include data from other hospitals that similarly tried to strengthen their ability to treat HID patients.

In conclusion, a network of hospitals capable of treating patients with HIDs was rapidly constructed in response to the recent EVD outbreak. However, without the impending threat of EVD or another HID on the immediate horizon, public attention on HID preparedness tends to waver, and governments tend to prioritize and shift funding elsewhere. Additional external funding sources remain generally uncertain for U.S. HLIUs not designated as RESPTCs; therefore, these HLIUs must strategize methods and models of sustainability if they are to maintain capabilities and readiness.

CHAPTER 6: HIGH-LEVEL ISOLATION UNIT INFECTION CONTROL PROCEDURES⁴

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HIGH-LEVEL ISOLATION UNIT INFECTION CONTROL PROCEDURES

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Background

During the 2014-2016 Ebola outbreak in West Africa, the US CDC reviewed the ability of US healthcare facilities to identify, isolate, and care for patients at risk of HIDs (43). While most hospitals had made substantial efforts to review and enhance their protocols for use of PPE and adjust use of their physical facilities in response to infection control concerns raised by the outbreak, hospitals across the United States generally struggled in their attempts to develop comprehensive patient care units with the ability to provide safe isolation and definitive care for a patient with an HID such as EVD, especially through the full course of illness (125).

In late 2014, the CDC announced a new system of categorization of U.S. hospitals' differing abilities to care for patients with EVD or other diseases requiring high-level isolation, classifying hospitals as either frontline hospitals, Ebola assessment hospitals, or ETCs (43). In this new system, 56 hospitals across the United States were designated as ETCs and were deemed capable of providing the highest level of isolation care to patients with HIDs. In addition, one ETC in each of the ten US Department of Health and Human Services (HHS) regions was subsequently designated as a RESPTC and given funding for additional enhancement to their physical units, labs, training, and other activities (27).

Although the CDC did provide guidance on the specific augmented operational and infection control capabilities they believe form the foundation for creation of HLIUs in the 56 ETCs, each facility had to work with its existing physical plant, infrastructure, budget, and safety culture to establish its HLIU. Therefore, although previous consensus reports from both European and US infectious disease experts have identified numerous recommended elements in the design and construction of HLIUs (10, 14), hospitals generally labored to develop their high-level isolation capabilities with consistent adherence to these recommendations, and

notable differences have been previously reported in the choices each hospital has made in developing its unit (120-122).

It is noteworthy that similar isolation units have existed in Europe for more than a decade, with greater agreement among them on the specific details regarding operational commonalities such units should share. European infectious disease experts have defined HLIUs as clinical units specifically designed for HID care, equipped with enhanced engineering controls and stringent infection control protocols to minimize the potential for disease transmission to HCWs, hospital personnel, and the public; they have detailed recommendations and specifications for these units (10).

The newly developed network of HLIUs in the United States has been operational for more than 2 years, but little detail is currently available about the comprehensive protocols developed by US HLIUs to protect the safety of their HCWs and patients. This article details routine and terminal decontamination procedures of HLIUs and medical devices, postmortem management, liquid waste disposal, and PPE selection and protocols of US HLIUs.

Methods

In spring 2016, a survey (with institutional review board exemption University of Nebraska Medical Center IRB #172-16X) was electronically distributed to all 56 original CDC-designated HLIUs, including the 10 RESPTCs (Appendix D). The survey was developed referencing robust checklists used by the European Network for Highly Infectious Diseases (EuroNHID) in a 2009 evaluation of European HLIUs (110) and consisted of 70 questions of varying types: open-ended qualitative questions; discrete, multiple-choice questions, some with the option to provide qualitative information for “other”; and multiple-choice questions allowing for multiple selections. Most questions had additional sub questions that were dependent on the response.

The survey was distributed electronically via email as a fillable Adobe PDF and organized into thematic sections. Sections of the survey, which were further divided into 3 to 4 subsections, were: personnel management, management of personal protective equipment, infection control procedures and promotion, laboratory capabilities, and operational capabilities. We discuss the results of the data related to PPE management and infection control here; other results will be detailed in later publications. If the HLIU had completed the 2015 pilot survey inventorying HLIU capabilities and listed a point of contact, the follow-up survey was delivered to the provided email address. For all other HLIUs, the survey was sent to personnel with publicly accessible email addresses. The survey was completed by site representatives and collected via Adobe Pro. Non-respondents were emailed with follow-up requests two weeks after the initial return deadline. Responses were coded and analyzed using descriptive statistics in an electronic spreadsheet (Microsoft Excel).

Results

Thirty-six (64%) HLIUs responded: 33 completed the survey, and 3 responded by stating their facility was no longer maintaining HLIU capabilities.

Infection Control

Thirty-two (97%) HLIUs reported their strategies to promote hand hygiene and procedures established to monitor staff adherence to correct hand hygiene practices (Table 6.1). HLIUs implemented a variety of strategies for hand hygiene promotion, with the majority using posters ($n=27$, 84%), hand hygiene campaigns ($n=26$, 81%), on-site exercises ($n=20$, 63%) and videos ($n=17$, 53%).

Table 6.1. Infection Control Protocols and Procedures for US High-Level Isolation Units

<i>Variable</i>	<i>Proportion</i>	<i>Percentage</i>
Hand Hygiene		
Strategies for promotion of hand hygiene ^a	32/33	97
Posters	27/32	84
Campaign	26/32	81
On-site Exercises	20/32	63
Videos	17/32	53
Lectures	14/32	44
Leaflets	11/32	34
Other strategy	7/32	22
Procedures for monitoring adherence of staff to correct practices ^{a,b}	32/33	97
Direct observations by trained observers/IC specialists	12/29	41
“Secret shoppers” (i.e. unidentified observers)	7/29	24
Hand hygiene audits	5/29	17
Peer monitoring	2/29	7
Liquid Waste Management^c		
Solidify and dispose as solid waste	10/33	30
Flush the waste down the toilet with no disinfectant	4/33	12
Treat with a disinfectant and flush down toilet	25/33	76
Use bleach compound	20/25	80
Quaternary ammonium	4/25	16
Oxavir	1/25	4
Post-Mortem Management		
Written procedures for safe performance of an autopsy	2/32	6
Plan to use a specially trained pathologist in HIDs	1/2	50
Only needle necropsies are performed	1/2	50
Written procedures for management of human remains	30/32	94
Memorandum of Understanding (MoU) with a funeral home or crematorium for disposition of HID human remains	18/30	60

^aFor each high-level isolation unit, more than 1 selection was allowed.

^b29/32 high-level isolation units described their procedures.

^cSix high-level isolation units plan on either solidifying and/or treating with disinfectant and flushing down toilet.

Written protocols for routine hygiene (i.e., daily cleaning) of the HLIU were available in all 32 facilities that responded to the decontamination section of the survey and were available in 31 (97%) for final decontamination of both the unit and medical devices (Table 6.2).

Table 6.2. Decontamination Procedures for U.S. High-Level Isolation Units

<i>Variable</i>	<i>Proportion</i>	<i>Percentage</i>
Decontamination Procedures		
Written Protocols for routine hygiene (i.e. daily cleaning) of unit ^a	32/32	100
Surface disinfection process (removal of pathogen organisms)	32/32	100
Surface cleaning process (removal of debris e.g. dirt, blood)	32/32	100
Written Protocols for final decontamination of HLIU ^a	31/32	97
Surface disinfection process	31/31	100
Surface cleaning process	31/31	100
UV light exposure process	9/31	29
Hydrogen peroxide gas	8/31	26
Written Protocols for decontamination of medical devices ^a	31/32	97
Surface disinfection and surface cleaning	25/31	81
Destruction/disposal	19/31	61
Final fumigation/UV light exposure	14/31	45
Required training for personnel involved in decontamination ^a	32/32	10%
Orientation training	29/32	91
Just-in-time training	20/32	63
Annual training	3/32	9

^aFor each high-level isolation unit, more than 1 selection was allowed.

Twenty-seven (87%) of the 31 HLIUs with final decontamination procedures designated staff to observe the final decontamination to provide quality assurance of the process. Figure 6.1 displays infection control tasks performed in the HLIU and designated responsible staff members.

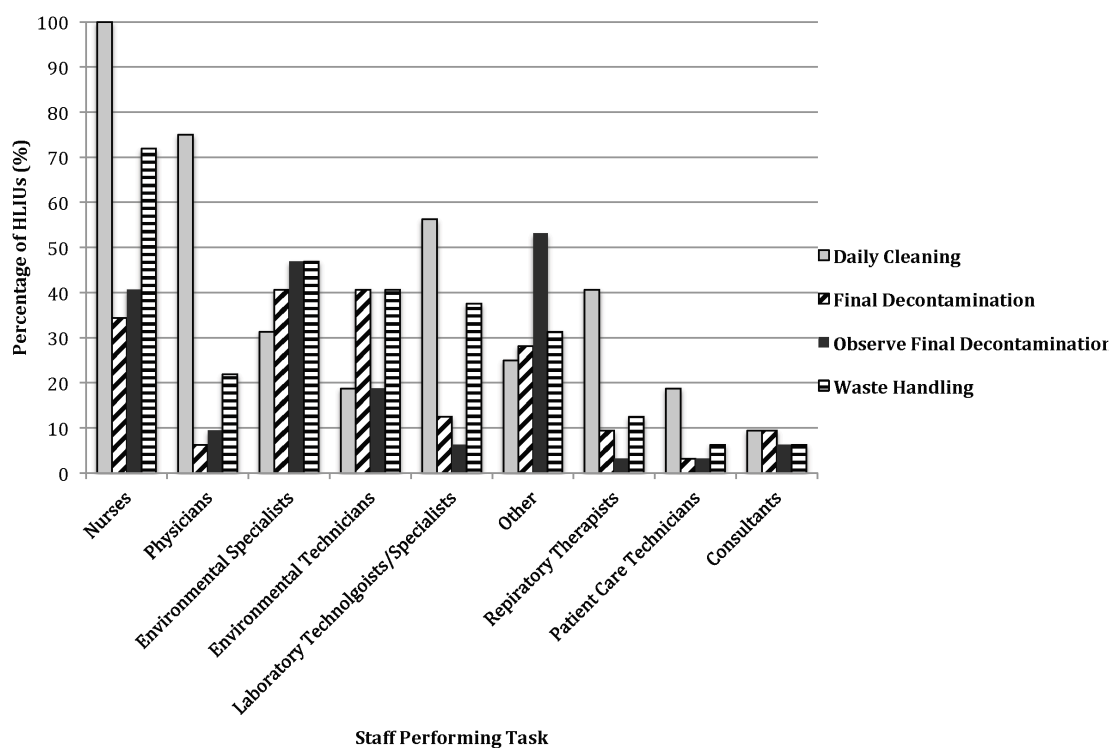


Figure 6.1. Infection control tasks performed by various staff in responding US high-level isolation units

All but three (91%) HLIUs do not intend to transport the patient outside of the isolation unit at any point of care (e.g. operating room, MRI, x-rays). Two reported that patient movement would be performed after case-by-case evaluation while the other HLIU would transport a patient to an operating room or for CT or MRI imaging. All 3 reported having final decontamination procedures for the areas to where the HID patient would be transported.

In all, 32 HLIUs responded to questions on post-mortem management. Thirty of the 32 (94%) had procedures to manage human remains of a patient with a HID, and 2 HLIUs (6%) had specific procedures to perform an autopsy (Table 6.1). In the area provided for additional information, 5 HLIUs reported no autopsies would be performed, while another stated that whether or not an autopsy would be offered would be contingent on the specific HID. Plans for disposal of liquid waste (e.g., urine, vomit, feces) is presented in Table 6.1. Average reported disinfection contact time for the 25 (76%) units that planned to treat liquid waste with a disinfectant prior to disposal was 11.5 minutes (range 3-30 minutes).

PPE Use

Twenty-three (70%) HLIUs had protocols or procedures for the selection of differing kinds of PPE ensembles, depending on the specific patient acuity and also on the types of procedures to be performed during patient care (i.e., routine care vs. aerosol-generating procedures, such as sputum induction). Of the 10 units without variable PPE selection procedures, 9 (90%) plan to use complete suits, including powered air purifying respirators (PAPRs), at all times during patient care. HLIU strategies for monitoring correct use of PPE and ensuring adequate PPE supplies, including procedures for PPE decontamination for re-use, are detailed in Table 6.3. Nearly all ($n=31$, 94%) HLIUs reported protocols restricting maximum time allowed in full PPE, with a mean shift of 3.45 hours (median=4.0; range 1.5 to 4.0).

Almost all ($n=32$, 97%) HLIUs reported having procedures to ensure adequate quantities of PPE if there was a sudden demand. Of these, 31 (97%) used internal stockpiling and 23 (72%) were supplied from an external structure or institution. Thirty-one (94%) HLIUs had protocols for monitoring stockpiled PPE for expiration dates.

Table 6.3. Results of Personal Protective Equipment Use, Decontamination, and Selection for Responding US High-Level Isolation Units

<i>Variable</i>	<i>Proportion</i>	<i>Percentage</i>
PPE Selection		
Presence of procedures for selection of PPE ^a	23/33	70
Developed by infectious disease specialists	23/23	100
Developed by infection control specialists	19/23	83
Developed by occupational medicine specialists	13/23	57
Involved entire staffing team in selection process	3/23	13
PPE Monitoring		
Used strategies for implementing and monitoring correct PPE use ^a	33/33	100
Supervision by a trained observer	33/33	100
Crosschecking between staff (i.e. donning partner)	33/33	100
Inspected PPE for defects prior to donning	32/33	97
Doffing partners	32/33	97
Posted checklist/instructions in donning and doffing areas	29/33	88
Full body mirror for self-assessment	20/33	61
Seal checks for respiratory masks, if applicable	18/33	55
PPE Decontamination		
Protocols for decontamination of reusable PPE for re-use ^a	16/33	49
PAPR motors and belts	13/16	81
PAPR hoses	11/16	69
Outside of PAPR filters	8/16	50
Hoods	3/16	19

^a For each high-level isolation unit, more than 1 selection was allowed.

Discussion

Prior to the establishment of a national network of HLIUs, most regions in the United States lacked access to hospitals with the enhanced isolation capabilities, advanced staff training, and extensive infection control protocols necessary for safe and effective HID care. HLIUs have developed policies, procedures, and operational measures to mitigate infection control challenges posed by HIDs and have used engineering controls to maximize healthcare worker safety. Results indicate that most HLIUs have specified procedures for infection control processes (e.g. decontamination, liquid waste management, hand hygiene practices) and PPE management, but approaches vary. This may reflect the lack of formalized guidance and science-based evidence in these areas, in tandem with the rapid, unprecedented establishment of such units in the United States. Consensus recommendations, however, have been developed by the EuroNHID following their 2009 survey of European HLIUs and include guidance on PPE and infection control practices for HLIUs (35, 37, 38).

The emergence of EVD, MERS, and novel influenza viruses pose occupational risks to HCWs treating patients with these diseases and to the public. As the final barrier, strict vigilance on proper PPE use is critical to preventing disease transmission to HCWs; yet, previous studies show poor compliance to donning and doffing behaviors can lead to self-contamination (126, 127). Every surveyed HLIU reported implementing multiple strategies for monitoring correct PPE use, with all units using trained observers and donning and doffing partners. Fewer units reported having full body mirrors and posted checklists with written instructions on donning and doffing orders (61% and 88%, respectively). While there is not one accepted “correct” sequence for donning and doffing PPE, doing so in a sequence that avoids exposure is critical. Checklists serve as a guide for trained observers and donning/doffing partners to confirm completion of each step recommended by the individual facility, while mirrors can be used for real-time self-

assessment and ensuring the HCW avoids touching the skin while doffing PPE (69). Employing these strategies and requiring staff to frequently demonstrate competence in donning and doffing practice can minimize self-contamination during doffing.

Equally important to PPE behaviors is the selection of appropriate PPE for care of patients with HIDs. While securing the best possible protection, PPE should be comfortable and well tolerated by unit staff, as HLIUs reported staff spend an average of 3.45 hours per shift in full PPE, during which PPE can become cumbersome and warm (68). Physical exhaustion and emotional fatigue due to extensive spells in PPE and intensive HID care may further exasperation. Using a full PAPR suit, regardless of the HID or the acuity of the patient, as 27% of HLIUs do, ensures a high level of protection and can provide temperature cooling for the HCW by increasing airflow in the PPE. However, full suits may decrease HCWs' dexterity and hinder communication, given the excess motor blower noise that powers filtration in a PAPR. Tolerability and comfort of PPE should be assessed during competency demonstrations and through training and exercises (68).

The Environmental Protection Agency (EPA) has asserted that domestic wastewater treatment plants were designed to handle a multitude of microorganisms, including viruses, and the diseases present in waste systems (128). EPA and CDC initially advised that liquid wastes from patients with HIDs could therefore be disposed of safely through normal means (toilets and drains) (82, 83). However, only 4 (12%) HLIUs reported they would flush waste without first treating it with disinfectant prior to disposal. A recent study showed that the Ebola virus could survive in sterilized wastewater for up to 8 days (albeit under laboratory conditions), which contributes to the decision and need to disinfect wastewater prior to discharge (129). A subsequent study by the same group conducted a risk assessment that found the potential exists for the transmission of EVD to sewer workers through contaminated sewage (130).

Although no data exists specifically on the effectiveness of inactivating Ebola virus by treating liquid waste with disinfectant prior to discharge, it is likely the decision to disinfect wastewater eases public concern and provides assurance to municipal workers. Similarly, terminal decontamination best practices offered by the Nebraska Biocontainment Unit following EVD care include meticulous procedures that may go beyond requirements for Ebola virus inactivation but were completed, in part, to appease public concern (78).

Post-mortem handling of HID patient remains is a known transmission route (78), yet US HLIUs report insufficient levels of preparedness in this area. While nearly all reporting units have written procedures for managing human remains, a majority have not established a memorandum of understanding with a funeral home or crematorium, which may pose difficulties in disposing of human remains of patients with a HID. Furthermore, just 6.3% have specific procedures for the safe performance of an autopsy, compared to nearly 60% in a 2009 survey of European HLIUs (37). Both US and European consensus groups considered a lack of written and exercised safety protocols for performing an autopsy to be high risk for workers, given the nature of the procedure and that autopsies may be necessary in HID patients if a diagnosis has not been established (14, 37).

The majority of HLIUs surveyed have written protocols for the selection of PPE based on patient acuity and disease, monitoring and adherence to PPE use, liquid waste disposal, post-mortem management, unit decontamination, and hand hygiene promotion of unit staff. While written procedures are the foundation of HLIU operations and training programs, staff compliance and application of these procedures are the true indicators of the state of HLIU preparedness for a HID patient. For example, HCWs have been shown to be inconsistent when performing hand hygiene and disinfection tasks (11). Despite HLIUs reporting numerous hand hygiene promotion and monitoring strategies, staff that are noncompliant with written

procedures increase exposure risks. Rigorous training of staff on hand hygiene, PPE use, decontamination and other infection control protocols is therefore essential to HCW safety, as is ensuring staff remain alert and vigilant in adhering to infection control practices within this high-risk environment.

This study had several limitations. Data was self-reported and was not validated by our group or by external sources. Furthermore, our study solely surveyed the availability of procedures; as such, we are unable to report on the actual procedural application or staff compliance for those procedures. We also recognize that countless other US hospitals that were not captured in our study took measures to increase their facilities' capability to care for a patient with EVD. This survey and the initial survey were only administered only to a list of hospitals released by the CDC in late 2014 and early 2015 (124). Lastly, the response rate decreased from the initial survey (85%) to this follow-up (64%). While the follow-up was more comprehensive and time-consuming to complete, the decreased response rate could reflect waning interest and current perceived importance of HLIU capabilities. As reflected in the decisions of 3 hospitals to no longer maintain their HLIU capabilities, US HLIUs face challenges in sustaining their preparedness to HIDs. Moreover, it is possible that the 64% of units that completed the survey may have more advanced capabilities and therefore are more willing to disclose their current state of preparedness than the more than one-third of units that did not complete the survey. As such, reported results may not be indicative of all HLIUs. It is also possible that the one-third of HLIUs that did not complete the survey are no longer maintaining their capabilities, which could negatively affect national readiness.

In conclusion, with little doubt that the future holds novel HID threats, the combination of highly trained staff, technical equipment, infection control infrastructure, and updated procedures unique to HLIUs offer biocontainment facilities capable of handling the most

dangerous of pathogens. Despite the existence of advanced technical infrastructure, HCWs in HLIUs are frequently in close contact with HID patients and must rely on correct PPE use, including removal processes, to reduce exposure (14). Protocol recommendations for both infection control processes and PPE management were consistently revised throughout the EVD outbreak as new research and best practices were disseminated, and it can be expected that the same will occur with the next HID outbreak. Having written, practiced protocols and procedures can facilitate adaptation of HLIU operations to diverse diseases and enhance overall domestic preparedness for HIDs.

CHAPTER 7: US HIGH-LEVEL ISOLATION UNIT CLINICAL LABORATORY CAPABILITIES UPDATE⁵

VIROLOGY



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

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Introduction

In late 2014, the CDC recommended that states stratify hospitals into one of three tiers, based on their ability to identify, to isolate, and to care for patients with confirmed or suspected EVD (43). The majority of U.S. hospitals providing emergency care were classified as frontline hospitals and, as such, were asked to identify patients with relevant EVD exposure history and EVD-compatible symptoms, to isolate these patients, and to inform the local health department. Ebola assessment hospitals were tasked with receiving, isolating, and providing supportive care for patients under investigation (PUIs) for up to 5 days, until laboratory results either confirmed or refuted the diagnosis. Upon confirmation of a diagnosis of EVD, states subsequently planned that patients would be transferred to an ETC capable of safely administering sustained medical care through the entire course of the illness.

Fifty-six hospitals in the United States were designated by the CDC as ETCs, having specially designed HLIUs equipped with the advanced infrastructure, laboratory capabilities, and trained staff to minimize transmission risks while caring for patients with HHCDs such as Ebola (10, 14, 120-122, 131). HHCDs have been defined as easily transmissible, life-threatening diseases that pose a threat to both healthcare workers and the public (e.g., VHF, SARS). Because of these infectious and pathogenic features, HHCDs warrant specific control measures, such as stringent infection control procedures and specialized personal protective equipment (10, 14). To expand upon the capabilities of this tiered network of ETCs, 10 hospitals were later designated by the Assistant Secretary for Preparedness and Response as RESPTCs and were granted additional federal funding to enhance their isolation and care capabilities for HHCDs (108).

Analysis of previous institutional actions in response to HHCD events in the United States has revealed delayed critical laboratory analyses for patients suspected of having disease

(14). Because of this history, the CDC included specific recommendations for performance of laboratory testing in its list of augmented areas necessary for EVD care (43). To qualify for designation as an ETC, HLIUs were required to possess the capability of safely processing laboratory specimens on site, utilizing appropriate laboratory procedures and protocols, dedicated space, possible point-of-care testing, appropriate equipment, staffing, and reagents, advanced training, and specialized specimen transport (43). HLIUs were required to utilize highly trained and skilled laboratory personnel and to perform risk analyses of the range of laboratory tests that they might perform, to offer optimal patient support while minimizing occupational risks to laboratory workers.

Although the CDC and U.S. HLIUs that treated EVD patients have released best practice recommendations for clinical laboratory support (24, 75, 76, 132-134), inconsistencies in guidelines and practices remain (135, 136). A 2015 survey of HLIUs conducted by our group found that 91% of HLIUs had biosafety level 3 (BSL-3) laboratory support in their clinical laboratory and/or public health laboratory (PHL) and 87% planned to provide some type of laboratory support (e.g., point-of-care-testing) within the isolated patient's room (published manuscript presented in Appendix C) (122). However, the extent of laboratory support available in the hospital laboratory (as opposed to the PHL) and within the patient's room remained unknown. This study aimed to describe clinical laboratory support capabilities of U.S. HLIUs, including identification of the specific test menus that HLIUs have identified to safely manage HHCD patients and the locations where such testing would be performed.

Materials and Methods

In early 2016, a follow-up survey to the 2015 HLIU survey was emailed to each of the original 56 designated U.S. HLIUs, including the 10 RESPTCs (Appendix D). If the HLIU had

completed the 2015 survey, then the listed point of contact was used; for the remaining HLIUs, the survey was sent to the same contact as used in the 2015 study. When possible, known personnel from the remaining HLIUs were identified and contacted using publicly accessible email addresses. Non-respondents were additionally solicited for responses, by email, twice after the original deadline had passed.

The follow-up survey was administered to expand on findings from the 2015 survey (120-122) and included questions relating to personal protective equipment, staffing models and personnel management, operational capabilities, sustainability concerns, infection control protocols, and laboratory capabilities. The clinical laboratory capabilities section, the results of which are detailed here, assessed diagnostic testing and laboratory tools available to HLIU patients and the location of testing for each instrument, as well as decontamination protocols for laboratory equipment, the results of risk analysis for procedures and equipment, and protocols for the transport of specimens.

The location of tools available for diagnostic testing and the test location closest to the patient's room were defined as within the patient care room, within the isolation unit, within the facility, or outside the facility (excluding the CDC laboratory for confirmation diagnosis). A patient care room was defined as the location within the isolation unit where the patient was contained for care. The isolation unit was defined as a controlled-access patient care area functionally separated from other hospital wards and independently operated.

Surveys were completed by site representatives and were collected via Adobe Pro. Data were coded and analyzed in an electronic spreadsheet, using descriptive statistics. The survey was reviewed by the University of Nebraska Medical Center's Institutional Review Board and determined to be exempt from review.

Results

Thirty-six (64%) hospitals responded to the survey, and 33 completed the clinical laboratory capabilities section. Thirty-one (94%) of the 33 HLIUs with data on laboratory capabilities stated that they had performed risk analyses for all laboratory procedures and equipment. Twenty-nine (88%) had decontamination procedures specified for all laboratory equipment used for patients with suspected or confirmed HHCD, while the four units without procedures planned to dispose of equipment after HHCD use. The equipment considered “disposable” included the Piccolo chemistry analyzer (Abbott Laboratories, Abbott Park, IL), the i-STAT system for blood analysis (Abbott Laboratories), glucometers, the pocHi-100 hematology analyzer (Sysmex, Lincolnshire, IL), the FilmArray PCR system (BioFire Diagnostics, Salt Lake City, UT), and the Clinitek urine dipstick reader (Siemens Medical Solutions USA, Malvern, PA).

On-site laboratories in 27 HLIUs (81%) had the capacity to inventory and securely store HHCD patient specimens for additional testing as needed. For off-site testing, government officials (i.e., local or state health department officials) were trained to transport specimens that might contain a high-consequence pathogen to off-site laboratories for 18 HLIUs (55%), while 12 (36%) would use commercial courier services, and 3 (9%) would utilize hospital staff. Thirty-two HLIUs (97%) had procedures for recording the chain-of-custody, to document specimen handling throughout transport.

HLIUs reported an average distance to the jurisdictional PHL of 46.67 miles (median, 20 miles; range, <1 to 290 miles). Turnaround times (TATs) for initial tests at the PHLs had a median of 6 h (range, 3 to 36 h). Available laboratory tools and their locations are described in Tables 7.1 and 7.2. A total of 10 HLIUs (31%) that reported laboratory testing menus had at least one test they would conduct within the patient care room.

Table 7.1. Reported tools available for diagnostic testing for patients with HHCDs and tool location closest to the patient room in 32 U.S. HLIUs

Tool	No. (%) available					
	For HLIU	Within Patient Room	Within Isolation Unit	Within Facility	Outside facility ^a	Other
Incubator for bacteria culture ^b	30 (94)	0 (0)	8 (27)	19 (63)	2 (7)	1 ^c (3)
Biological Safety Cabinet	31 (97)	0 (0)	17 (55)	14 (45)	0 (0)	0 (0)
PCR assay	28 (88)	0 (0)	9 ^d (32)	11 ^d (39)	8 ^e (29)	0 (0)
EIA reader ^f	19 (59)	1 (5)	4 (21)	11 (58)	2 (11)	1 ^c (5)
Microscope	23 (72)	0 (0)	6 (26)	17 (74)	0 (0)	0 (0)

^aIncluding the jurisdictional Public Health Laboratory (excluding the Centers for Disease Control and Prevention laboratory for confirmation diagnosis).

^bIncluding the availability of a standalone incubator for bacterial culture; although this did not include automated blood culture systems, many facilities preferred to incubate blood culture bottles in a standalone incubator for visual observation, with Gram staining and culture performed when necessary.

^cThe health system's core laboratory.

^dPCR testing within the isolation unit or facility generally included access to Biofire instrumentation (BioFire, Salt Lake City, UT), including the FDA emergency use authorization-approved FilmArray Biothreat E-Test to test for the presumptive presence of Ebola Zaire virus, as well as FDA-approved FilmArray assays including panels for blood culture identification (BCID) and gastrointestinal tract and respiratory tract pathogens.

^eJurisdictional Public Health Laboratories utilized real-time PCR assays developed by the CDC and validated in-house to test for pathogens such as Ebola Zaire virus, Novel Middle Eastern Respiratory Syndrome (MERS) coronavirus, and influenza A/H7 virus.

^fIncluding enzyme immunoassay (EIA) readers for the direct detection of agents such as influenza viruses, group A *Streptococcus*, human immunodeficiency virus, and malaria.

Table 7.2. Reported tests available for HHCD patient clinical care and test locations closest to the patient care room in 32 U.S. HLIUs

Tool	No. (%) available					
	For HLIU	Within Patient Room	Within Isolation Unit	Within Facility	Outside facility ^a	Other
Complete blood count with automated differential	29 ^b (91)	0 (0)	16 (55)	11 (38)	0 (0)	0 (0)
Basic Metabolic panel	29 (91)	4 (13)	17 (59)	8 (28)	0 (0)	0 (0)
Magnesium level	21 (66)	0 (0)	14 (67)	7 (33)	0 (0)	0 (0)
Comprehensive metabolic panel	25 (78)	0 (0)	15 (60)	10 (40)	0 (0)	0 (0)
Ionized calcium level	24 (75)	4 (17)	12 (50)	7 (29)	0 (0)	1 ^c (4)
Standard calcium level	25 (78)	0 (0)	16 (64)	9 (36)	0 (0)	0 (0)
Phosphorous level	21 ^b (66)	0 (0)	10 (48)	9 (43)	0 (0)	0 (0)
Cortisol level	8 (25)	0 (0)	0 (0)	7 (88)	0	1 ^c (12)
Troponin level	12 (38)	0 (0)	3 (25)	8 (67)	0 (0)	1 ^d (8)
Blood gases concentrations	28 (88)	4 (14)	14 (50)	10 (36)	0 (0)	0 (0)
Lactate level	23 (72)	3 (13)	12 (52)	8 (35)	0 (0)	0 (0)
Prothrombin time	25 (78)	3 (12)	13 (52)	9 (36)	0 (0)	0 (0)

Partial thromboplastin time	16 (50)	0 (0)	8 (50)	8 (50)	0 (0)	0 (0)
Platelet count	28 (88)	0 (0)	15 (54)	13 (46)	0 (0)	0 (0)
Blood typing	16 (50)	0 (0)	6 (38)	9 (56)	0 (0)	1 ^e (6)
Blood culture ^f	28 (88)	0 (0)	9 (32)	17 (61)	1 (4)	1 ^c (4)
Urine culture ^f	14 (44)	0 (0)	2 (14)	10 (71)	1 (7)	1 ^c (7)
Other body fluid culture ^f	15 (47)	0 (0)	3 (20)	10 (67)	1 (7)	1 ^c (7)
Molecular assay	17 ^b (53)	0 (0)	2 (12)	8 (47)	4 (24)	1 ^c (6)
Manual differential ^g	15 (47)	0 (0)	3 (20)	12 (80)	0 (0)	0 (0)
Lipase level	13 (41)	0 (0)	3 (23)	10 (77)	0 (0)	0 (0)
Amylase level	16 ^h (50)	0 (0)	6 (38)	9 (56)	0 (0)	0 (0)
Total creatine kinase level	11 (34)	0 (0)	4 (36)	7 (64)	0 (0)	0 (0)
Malaria smear ^g	28 ^h (88)	0 (0)	9 (32)	18 (64)	0 (0)	0 (0)
HIV screen	17 (53)	0 (0)	6 (35)	10 (59)	1 (6)	0 (0)
Urinalysis	24 (75)	4 (17)	12 (50)	8 (33)	0 (0)	0 (0)
Pregnancy test	23 (72)	3 (13)	11 (48)	9 (39)	0 (0)	0 (0)

Cerebrospinal fluid analysis ⁱ	7 (22)	0 (0)	0 (0)	7 (100)	0 (0)	0 (0)
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^a For example, a Public Health Laboratory or Reference Laboratory.

^b Two HLIUs did not report where the test is located.

^c The health system's core lab.

^d Not planned, but could obtain from the I-Stat system if needed.

^e Not planned, but slide interpretation was available.

^f Microbiological assays, including inoculation of culture medium followed by incubation and pathogen identification if necessary.

^g Including staining and microscopic identification.

^h One HLIU did not report where the test was located.

ⁱ Including microbiological analysis (culture and Gram staining), cell counting, and protein/glucose analysis.

Discussion

These results supplement findings from our 2015 HLIU survey on HHCD laboratory support (Appendix C) by specifying the tests available at the various laboratory locations (122). Results indicate that HLIUs in the United States are prepared to provide a range of laboratory tests for patients with HHCDs, both within the unit and in the facility's clinical laboratory. Most HLIUs have conducted risk analyses and developed specimen transport procedures.

Laboratory support is critical for optimal patient care; however, the risk to laboratory workers in handling HHCD specimens should be assessed prior to ordering such tests (135). The Nebraska Biocontainment Unit and the Emory University Serious Communicable Disease Unit, two US HLIUs that cared for repatriated EVD patients in the autumn of 2014, have described their risk evaluation of laboratory processes and instruments generating aerosols and microdroplets and have detailed the equipment and testing offered in their laboratories (24, 75, 76, 134). The units differed in testing locations, as Emory University confined all laboratory testing within the HLIU except for specimens sent to the CDC, while the Nebraska

Biocontainment Unit performed testing at multiple locations within the HLIU, hospital, and campus. Both approaches proved to be safe and successful in managing the laboratory support for patients with EVD. The two units, along with guidance issued by the CDC, have also described procedures for specimen transport both within the hospital and outside of the institution (24, 75, 133).

All responding U.S. HLIUs reported the ability to provide laboratory support within the hospital, if not closer to the patient care room (i.e., within the isolation unit or in the patient care room itself). Although the survey did not specifically ask which instruments or assays were used to perform the various tests, point-of-care assays, compact analyzers, and core analyzers that have been reported to be used for the care of EVD patients are indicated in Table 7.3 (24, 75, 132).

Table 7.3. Analyzers used by various HLIUs for testing of specimens that might contain a high-consequence pathogen

Manufacturer	Device ^a	Clinical area	Analyzer type ^b	Test types ^c
Beckman Coulter	DxC880i	Chemistry	Core	Electrolytes
Abbott Laboratories	i-Stat	Chemistry	POC	Electrolytes and blood gases
Siemens	CliniTek	Chemistry	POC	Urinalysis and pregnancy test
Abaxis	Piccolo Xpress	Chemistry	Compact	Electrolytes and blood gases
Alere	epoc blood analysis	Chemistry	POC	Electrolytes and blood gases
SynDx Medical	SenDx 100	Chemistry	POC	Electrolytes and blood gases
Instrumentation Lab	Gem Premier 4000	Chemistry	Compact	Electrolytes and blood gases
Ciba Corning	Corning 865	Chemistry	Compact	Blood gases
Siemens	Dimension RxL	Chemistry	Core	Electrolytes
ITC	Hemochron Signature	Coagulation	POC	Coagulation analysis
Sysmex	pocH-100i	Hematology	Compact	CBC with differential
Sysmex	XN 9000	Hematology	Core	CBC with differential

^aList of analyzer types (not all inclusive) that have been known to be validated and used by HLIUs for the safe testing of specimens that might contain a high-consequence pathogen.

^bIncluding analyzer types that are point-of-care (POC) testing devices that could be used for testing in the patient care room, compact analyzers with a small footprint for utilization within a biosafety cabinet, or large automated analyzers with closed-tube testing capabilities that could be used in a core testing facility.

^cCBC, complete blood count

Our previous study, conducted in 2015, found that 87% of surveyed HLIUs initially planned to provide some type of laboratory support within the patient care room. Results from this follow-up study, however, indicate that only 31% of HLIUs now plan to conduct the specified tests or to use the listed tools within the patient care room (Tables 7.1 and 7.2). While some HLIUs might have elected to minimize testing capabilities within the unit, it is important to note that this list may not be exhaustive regarding the laboratory support HLIUs plan to provide for HHCD patients within the patient care room. Moreover, the contacts completing the survey might not have been laboratorians and might have chosen not to specify the testing locations if they were unsure.

All specimens collected from persons suspected or confirmed to have EVD require specialized packaging as category A infectious substances and must comply with federally regulated transport procedures if they are transported outside of the facility (137). Specimens that test positive for Ebola virus using a PCR assay are considered presumptive positive and must be transported to the CDC for further evaluation and confirmation, and only personnel trained and certified to package and transport category A substances are allowed to package and to ship Ebola virus-infected specimens (24, 133). All but three HLIUs have identified category A shippers, with one-third identifying a certified courier service. During the EVD outbreak in 2014 to 2016, however, few certified couriers accepted category A risk group 4 pathogens for transport. Moreover, the costs of transporting samples during the EVD outbreak were exorbitant, and the TAT for testing is not acceptable for optimal patient care. The extent of these services if an HHCD outbreak occurs within the United States remains to be seen (24).

Although a majority of HLIUs had procedures for decontaminating laboratory equipment used for HHCD patients, the four units that planned to dispose of devices after use must identify “disposable equipment” specific to each HHCD, as reported equipment is applicable only to EVD.

Planning to dispose of equipment represents a great potential cost to those facilities. However, those that plan to decontaminate laboratory equipment may face challenges in acquiring the necessary services and maintenance for their diagnostic devices. During the EVD outbreak in 2014 to 2016, contrary to CDC recommendations that laboratory equipment used for testing of Ebola virus samples could be disinfected and reused safely, many manufacturers reported that they would restrict maintenance services for laboratory equipment that had been used for patients with EVD, citing exposure risks for their technicians, while other manufacturers advised that devices be incinerated after use for EVD patients (132, 138). Refusal to service and to maintain diagnostic devices may lead laboratories to seek other options, as they are unable to afford the costs of disposing equipment after use for each HHCD patient. Moreover, the same equipment is used, disinfected, and reused after testing specimens from patients with other HHCDs, including extensively drug-resistant tuberculosis (XDR-TB), and diseases that have elicited the same heightened public fears in the past (e.g., HIV).

TATs for testing performed at PHLs ranged from 3 to 36 h. PHLs have only a very limited menu of confirmatory tests (e.g., EVD, Middle East Respiratory Syndrome [MERS], and avian influenza), and any other testing would need to be performed at the CDC, further extending the TAT. Extended TATs could result in a patient being in isolation longer than necessary and, as a result, utilizing limited resources (e.g., facilities, personnel, and equipment) that would then be unavailable to other patients in need of HLIU care. Minimizing processing times is of paramount importance in the care of EVD patients, who require extensive fluid and electrolyte management, as well as dialysis in some cases. The Nebraska Biocontainment Unit reported that TATs for certain routine laboratory tests were initially longer than expected, and it made significant efforts to decrease TAT during the care of their EVD patients (24).

There is wide variation in the laboratory management guidelines for EVD patients that were released by international and domestic public health agencies and private organizations during and in the aftermath of the outbreak in 2014 to 2016 (135). These inconsistencies may generate confusion among HLIU laboratorians regarding the tests and instruments that should be provided for HHCD patients, waste disposal, and occupational safety procedures to minimize exposure risks. Therefore, consistent guidelines among international and national organizations are needed to delineate HLIU laboratory standards and capabilities.

Although this report describes current capabilities of U.S. HLIUs pertaining to laboratory testing, it does not address laboratory needs of assessment hospitals or frontline facilities. Guidelines focused on HHCD treatment facilities are not necessarily adequate for assessment hospitals, as such facilities have been asked to offer their own laboratory testing capabilities for an extensive differential diagnosis list, including malaria and influenza (132). The ability of assessment hospitals to perform basic laboratory testing is critical, as assessment centers are more likely to receive a PUI who is eventually not found to have the disease than an HLIU that receives a patient with confirmed disease. Frontline facilities also may end up performing laboratory testing on a patient who is in critical condition; thus, they require protocols for safely handling specimens that may contain a high consequence pathogen. Future guidance for such hospitals is required so that, when necessary, they may safely test specimens while waiting for results from the jurisdictional PHL for confirmation of the diagnosis.

There were limitations to this study. Survey questions were not validated prior to distribution, and results were self-reported by HLIU site representatives. The survey was distributed to one HLIU contact; in most cases, this was not laboratory personnel. Although respondents were encouraged to split the survey and forward the sections to the appropriate person for each survey section, it is possible that not all responses regarding laboratory

capabilities were completed by a laboratorian; therefore, answers may not be accurate. Additionally, the response rate decreased from the 2015 survey to this follow-up survey (from 85% to 64%). Since the designation of these units by the CDC in 2014, at least three have opted to discontinue high-level isolation operations (131) and the lower response rate may indicate that others have also chosen to no longer maintain high-level isolation capabilities. Similarly, respondents might have more advanced capabilities and thus might have been more willing to complete the survey. Therefore, results may not be entirely indicative of all CDC-designated HLIUs. Lastly, we acknowledge that numerous hospitals across the United States have invested in strengthening their laboratory capabilities to identify, to support, and to manage PUIs until confirmed HHCD diagnosis but were not included in our survey of CDC-designated HLIUs.

Due to the high-risk nature of HHCDs and potential occupational exposures that can occur in clinical laboratories, advanced preparation and risk assessment of work practices, personal protective equipment requirements, laboratory equipment, and instrumentation by HLIU laboratories are critical for providing a safe working environment and adapting to evolving HHCD situations. Although risk analyses that HLIUs have conducted on clinical laboratory testing and equipment have likely focused on those for Ebola virus, HLIUs must be prepared to revise their current procedures for other HHCDs and unknown emerging infectious diseases.

CHAPTER 8: PERSONNEL MANAGEMENT AND BIOSECURITY OF U.S. HIGH LEVEL ISOLATION

UNITS⁶

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Personnel Management and Biosecurity of U.S. High-Level Isolation Units

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Background

In response to recent global cases of HIDs—including SARS, avian influenza, and EVD—U.S. and European HID experts have released consensus recommendations for HLIUs. HLIUs support safe, quality care of HID patients while minimizing transmission risks to HCWs through use of infrastructure and administrative measures atypical of routine clinical settings (10, 14). The surge of EVD cases in West Africa during the 2014-2016 outbreak, coupled with the infection of 2 nurses in Dallas, TX who cared for the 1st diagnosed EVD case in the U.S., prompted the CDC to assess a number of U.S. hospitals in the fall of 2014 on their ability to provide high-level isolation and care for patients with suspected or confirmed EVD (43).

Following CDC review, 56 hospitals were deemed to be equipped with the advanced physical infrastructure and operational procedures to safely care for HID patients (43). The capabilities of this network of U.S. HLIUs (originally described specifically as Ebola Treatment Centers, although these institutions have since augmented their efforts to treat other HIDs) was further expanded with the selection and funding of 10 regional Ebola and other special pathogen treatment centers to maintain heightened and sustained readiness (27).

HIDs pose significant occupational risks for HCWs, as highlighted in recent outbreaks: HCWs accounted for 37-63% of SARS cases in highly affected countries and were 21-32 times more likely to become infected with EVD than the general population in West Africa (11, 139). Therefore, in addition to the appropriate physical features and extensive infection control protocols recommended for HLIUs, the CDC recommended specialized staffing and training capabilities to minimize HID transmission risks to HCWs. This includes, but is not limited to, requiring staff involved in patient care to demonstrate competency in PPE, infection control, and waste handling; minimizing the number of staff in direct contact with the patient; developing staffing plans to manage several weeks of clinical care; and establishing a robust training

program that includes strategies to address infection control breaches through retraining (43).

Furthermore, comprehensive biosecurity measures that are seldom applied in routine clinical settings are an important part of an HLIU's ability to ensure the broader safety of other hospital personnel, patients, and the community. When activated, HLIUs may contain reservoirs of highly infectious and dangerous pathogens in waste, laboratory samples, and bodily fluids that have the potential to be manufactured into biological weapons. Therefore, European experts have recommended several specific biosecurity measures, including restricting access to the unit, tracking movements of specimens and contaminated materials, and incorporating biosecurity issues into staff trainings and exercises (22).

A 2015 survey of U.S. HLIUs identified the infrastructure and capabilities acquired and costs incurred by hospitals in developing their units (120-122). However, little is known on biosecurity of these specialized facilities, staffing models, or how unit personnel are managed before and during activation, apart from best practices identified by the three preexisting biocontainment units (69, 140, 141). This study aimed to identify how these units are secured and to describe the strategies used by U.S. HLIUs to recruit, train, and sustain their full team, ensuring that all staff are competent in all of their appropriate tasks required for unit operations.

Methods

In the spring of 2016, an electronic survey was administered to the 56 CDC-designated U.S. high-level isolation facilities. This survey was a comprehensive follow-up to an initial survey (120-122) of U.S. units in 2015 and consisted of discrete responses with qualitative or discrete multiple-choice subquestions dependent on the response, multiple-choice questions lending for the selection of multiple options, and open-ended qualitative questions. Questions were adapted from robust checklists used to evaluate European HLIUs and infectious disease referral

centers (10) and were organized into the following sections: Personnel Management, Management of PPE, Infection Control Procedures and Promotion, Laboratory Capabilities, and Operational Capabilities. Results of the Personnel Management section are described here; other results have been detailed in earlier publications (131, 142, 143).

Electronic surveys were distributed via email as a fillable Adobe PDF and completed by directors or executive administrators of U.S. HLIUs. Listed contact information for the 47 facilities that had returned the initial survey was used; for the other 9 units, publicly accessible emails were identified. Non-respondents were emailed a follow-up reminder when the original deadline passed; when possible, information for other HLIU contacts were identified and emailed. Data were coded and analyzed in an electronic spreadsheet using descriptive statistics. The University of Nebraska Medical Center institutional review board declared the study exempt (#172-16X).

Results

Thirty-six (64.3%) HLIUs responded to the survey; 33 completed surveys and 3 reported no longer being designated HLIUs.

Staff Selection and Model

Staff was entirely volunteer-based in 23/33 (70%) HLIUs, meaning staff may receive compensation but had to opt-in to participate in the treatment of an HID patient. Of the 10 units that were not volunteer-based, staff in 6 hospitals nonetheless had the ability to opt-out of working in the unit (e.g. if they had substantial discomfort working with HIDs). Twenty-one HLIUs (64%) were composed solely of personnel employed by the sponsoring hospital. Of the 12 HLIUs that used external or contract personnel; environmental services (n=7) and security (n=4) were external contractors, while 2 HLIUs noted HCWs from other hospitals within the same

health system were used. Eleven (33%) HLIUs scheduled staff to work in the unit even when inactivated, with an average of 5.2 weeks (median=6, range 2-8) scheduled in advance.

Table 8.1 lists reported numbers of trained HLIU staff and average number of staff in the unit when activated. Staffing teams primarily consisted of registered nurses (RNs) and critical care physicians, although HLIUs reported a variety of specialist physicians trained for HLIU care.

Table 8.1. Approximate number of staff currently trained to work in the unit in personal protective equipment (PPE)

Position	Mean per Unit	Median	Range
Number of staff currently trained to work in the unit in Personal Protective Equipment (PPE)			
Registered Nurses	56.89	39	13-214
Internal Medicine MD	6.65	5	0-28
Pediatric MD	6.91	5	0-59
Clinicians (e.g. RNs, MDs, nurse practitioners) trained in critical care	11.18	10	0-37
Respiratory Therapists	6.20	3	0-37
Laboratory/Pathology Staff	12.0	9	2-75
Environmental specialists	3.59	3	0-15
Environmental technicians	6.04	4	0-37
Security Staff	10.18	4	0-37
EMS Personnel	8.94	6	0-30
Specialists MDs			
Infectious Disease	3.96	4	1-10
Obstetrics	3.21	2.5	0-10

Surgeons	1.32	0.5	0-4
Anesthesiologists	3.36	2	0-15
Emergency	9.40	5	0-46
Critical Care	6.04	5	0-18
Minimum number of staff present within Isolation unit and minimum number in full PPE at all times when activated			
Nurses			
Number in room/unit	2.97	3	1-6
Number in full PPE	2.06	2	1-4
Physicians			
Number in room/unit	1.11	1	1-2
Number in full PPE	0.94	1	0-2
Respiratory Therapists			
Number in room/unit	0.72	1	0-2
Number in full PPE	0.46	0.5	0-1
Care technicians			
Number in room/unit	0.36	0	0-1
Number in full PPE	0.36	0	0-1

While most units used facility employees for infection prevention teams, pastoral services, and logistic oversight, 39% (n=13) of units employed outside contractors for waste management (Figure 8.1).

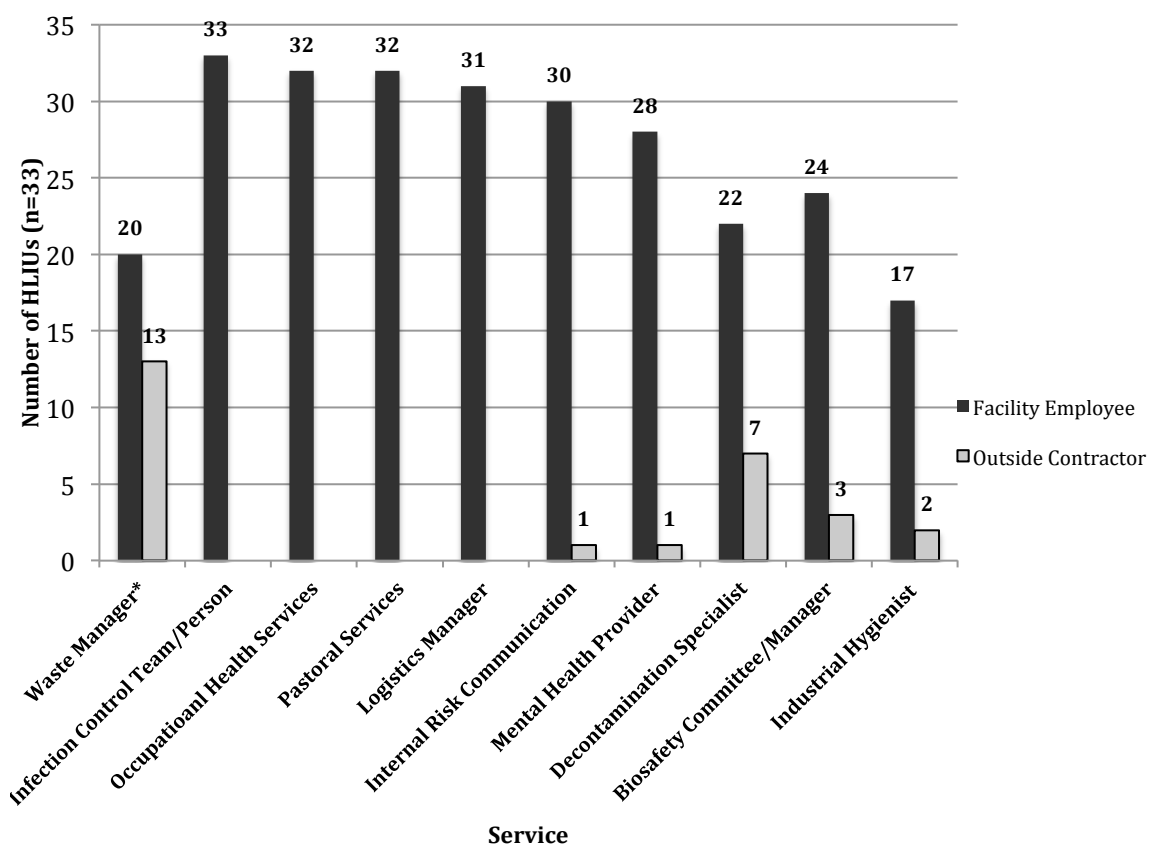


Figure 8.1. Number of HLIUs reporting non-clinical services available to the units
 *Four HLIUs reported they contract waste managers for waste disposal (and were listed as contractors here) but do have a facility employee responsible pre-disposal

Of the 32 hospitals that reported on staff recruitment, 27 (84%) had plans for recruiting nurses for HLIU teams. Seventeen (53%) HLIUs did not have requirements on years of experience for nurses, 14 (43%) required 1-4 years, and 1 required < 1 year. Thirty units listed evaluation factors for nurse selection, including clinical skills (n=28, 93%), attitude (77%, n=23),

and physical skills (n=20, 67%). Positions requiring physical fitness were assessed through lifting (n=8), cardio (n=7), and pulmonary function (n=10), while clinical skills were evaluated through clinical competence (n=26) and procedural skills (n=26).

All responding HLIUs were directed by a leadership team (Figure 8.2). Twenty-seven reported how often the leadership team, which is separate from incident command and responsible for management duties (e.g. finances, education/training coordination, lead medical and nursing care), meets: weekly (n=7; 26%), every 1-2 months (n=12; 44%), quarterly (n=5; 19%), twice a year (n=2; 7%), and at least once a year (n=1; 4%).

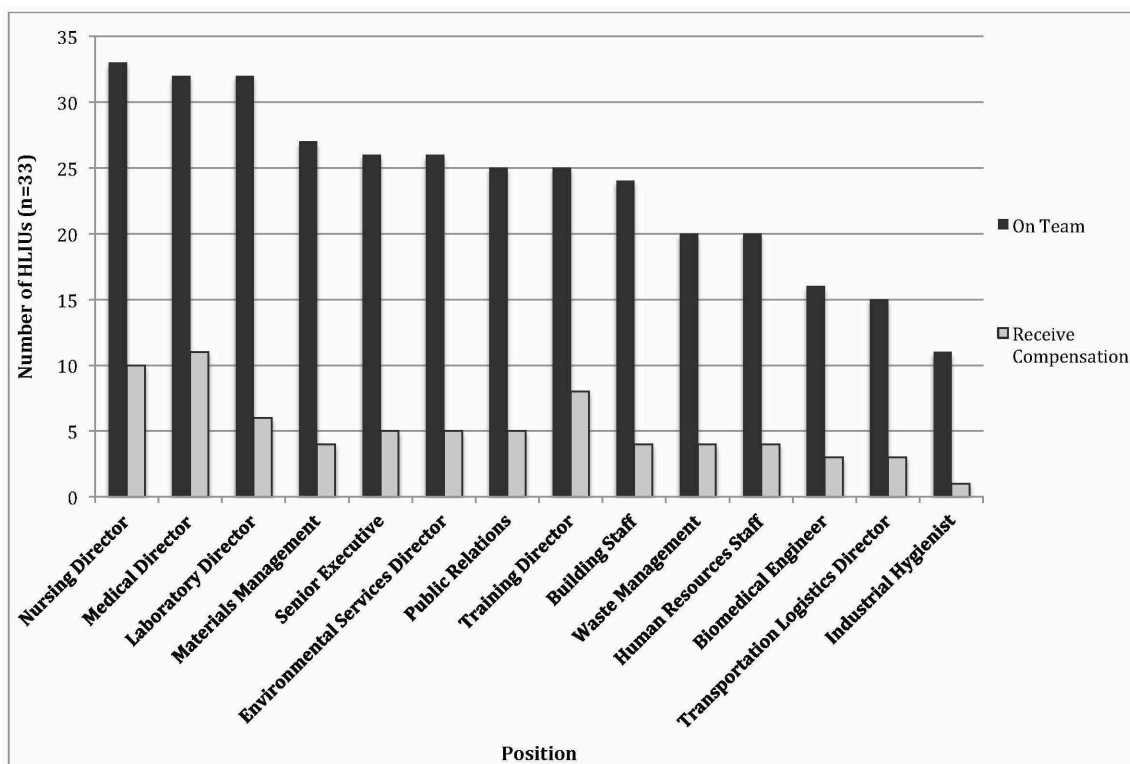


Figure 8.2. Composition of High-Level Isolation Unit (HLIU) Leadership Team and compensation of members.

Care providers were able to see other patients immediately following HID patient discharge in 24 HLIUs (73%). Units that restricted providers from immediately seeing other

patients reported it was due to hospital regulations (n=4) or local public health department restrictions (n=2). Staff from 6 (18%) HLIUs received compensation (e.g. pay differential, bonus) for being HLIU staff, while an additional 10 (30%) units compensated staff when the unit is activated. Other aspects of staff management (e.g. health monitoring, student involvement, and staff dedicated to the HID patient) are detailed in Table 8.2.

Table 8.2. Staffing protocols for responding U.S. High-level isolation units

Variable	Facilities	
	Proportion	Percentage
Staffing Model		
Utilize Incidence Command System (ICS) ^a	31/33	93.9%
At all times	28/31	90.3%
During patient transport operations	18/31	58.1%
During patient care	16/31	51.6%
Other (e.g. depending on needs, upon initial notification)	4/31	12.9%
Some or all staff dedicated to unit/patient when activated	28/33	84.8%
Nurses	28/28	100%
Physicians	16/28	57.1%
Respiratory Therapists	11/28	39.3%
Laboratory Specialists	10/28	35.7%
Environmental Specialists	4/28	14.3%
Environmental Technicians	4/28	14.3%
Patient Care Technicians	2/28	7.1%
Procedures for Health Monitoring of all staff in contact with HID patient or infectious substances (e.g. laboratory specimens) ^a	32/33	97.0%
Performed at home (with check of temperature)	31/32	96.9%
Performed at the hospital (not in isolation unit)	22/32	68.8%
Reported to Local/State Health Department	19/32	59.4%

Performed at the hospital (in isolation unit)	14/32	43.8%
Website/online data entry	14/32	43.8%
Plans to identify and address staffing shortages/concerns ^a	30/33	90.9%
Protocol(s) implemented during activation	29/30	96.7%
Protocol(s) implemented prior to activation	20/30	66.7%
Mandatory for staff to have contact with an Employee Assistance Program (EAP) or some other counseling service ^a	3/33	9.1%
Prior to activation	1/3	33.3%
During activation	2/3	66.7%
Following activation	3/3	100%
Student Involvement		
Incorporate students/residents into HLIU activities inside unit	4/33	12.1%
Fellows	4/4	100%
Residents	4/4	100%
Students	2/4	50.0%
Allowed in patient room	0/4	0.0%
Allowed in warm zone	1/4	25.0%
Allowed in cold zone	4/4	100%
Students/residents/fellows can participate in HLIU activities outside of patient room ^c	9/25	36.0%
Video Link	6/9	66.7%
Direct observation (through window, spotters after JIT)	2/9	22.2%
Logistical coordination/preparation	1/9	11.1%

^a HLIUs were allowed more than one response

^b Description was not multiple choice; HLIUs detailed JIT in additional space

^c Only 25 HLIUs responded to this question

Training

Thirty-one (94%) HLIUs required orientation training prior to allowing staff to work in the isolation unit; the remaining two units reported orientation-training plans were under development (Table 8.3). Trainees had to successfully demonstrate competence (i.e. perform

manual skills and medical care procedures) prior to being part of the HLIU team in 31 (94%) hospitals, including skill demonstrations while wearing HLIU-level PPE. Twenty-seven (82%) facilities required staff to undergo retraining/continuing education, either quarterly or biannually, and the remaining six (18%) HLIUs were developing retraining plans. Methods of retraining conducted or planned included: hands-on demonstration of skills (n=30, 91%), lecture (n=22; 67%), video (n=13, 39%), and reading (n=11; 33%).

Table 8.3. Methods of training and hours required for orientation by staff working in U.S. High-Level Isolation Units

Orientation Training prior to working in the HLIU				
	Number conducted or planned	Average per unit (hours)	Range (hours)	Median (hours)
Hands on demonstration of skills	33 (100%)	6.36	1-40	4
Lecture/Course	26 (78.8%)	3.39	1-8	2.5
Video	19 (57.6%)	2.15	0.5-7	1
Reading	14 (42.4%)	1.5	1-2	1.5
Other methods ^a	9 (27.3%)	--	--	--

^aOther methods include drills (n=3) and simulation (n=4)

Just-in-time (JIT) training was performed in 25 (76%) HLIUs. Reported circumstances under which JIT training would be conducted included upon activation (n=13), when a consultant or external specialist is required (n=5), when a new procedure is established or needed (n=3), and during emergency response situations (n=2). Two HLIUs reported JIT plans were under development.

Healthcare Worker Monitoring

All 33 HLIUs had written emergency management procedures in case of PPE breach, leakage, or other accidents potentially occurring during use in the HLIU, and also had written procedures for post-exposure evaluation and health monitoring of staff. Health monitoring was performed on the basis of a risk-assessment in 32 (97%) HLIUs. Depending on the level of risk (HLIUs were able to select more than one option), 25 (76%) HLIUs allowed for health monitoring at home, with scheduled checks of temperature and observation for symptoms, 18 (55%) would admit an exposed employee to the hospital, but not in the isolation unit, while 12 (36%) would place the exposed employee in the HLIU itself. Of 31 that responded to the frequency of health monitoring post-exposure, 13 (42%) HLIUs plan to perform a medical evaluation daily while 18 (58%) would assess twice daily.

Biosecurity

All 32 hospitals that completed the biosecurity section reported that they restrict access to the HLIU. Security was used in 28 (88%) facilities, followed by key/card access (n=23; 72%) and requiring identification to enter (n=22; 69%). Thirty-one HLIUs (97%) enabled methods of communication for family members of the patient, which include video link (n=30; 97%), phone calls (n=26; 84%), texting (n=19; 61%), and internet chat (n=17; 55%).

Of the 29 non-children's hospitals, 3 (10%) HLIUs allowed family members to visit an adult HID patient within the unit while wearing PPE. One reported access to family is at the discretion of staff while another would allow limited visitations from the cold zone. Four (17%) of 24 hospitals that treat HID pediatric patients would allow family members within the same room as the pediatric patient while wearing PPE. One HLIU reported this would only be allowable throughout the rule-out process, while the other 3 would evaluate on a case-by-case

basis.

Discussion

Due to the potential threats posed by HIDs, optimal care within an HLIU requires significant collaboration among a multidisciplinary team of clinical personnel, public health experts, occupational and environmental specialists, laboratory staff, and administrators. Clinical teams are primarily comprised of registered nurses and experts in infectious diseases and critical care; however, results indicate relationships with specialty clinicians (e.g., respiratory therapists, surgeons, physicians in pediatrics and obstetrics) are also often maintained.

HLIUs reported significant numbers of staff needed to care for an HID patient (Table 8.1); this, coupled with an extensive use of PPE and intensity of HID treatment, is a limiting factor in the capacity of many U.S. HLIUs (121) and likely contributed to at least three previously-designated HLIUs no longer maintaining high-level isolation capabilities. Two of these 3 HLIUs reported the unit required immense resources and costs to sustain readiness that were reallocated to other higher-priority areas within the hospital; indeed, the 2015 survey found HLIUs expended an average \$1.2 million in establishing high-level capabilities (120). Due to the large number of reported multidisciplinary staff used for HID care, costs to support staff salaries and fund training and exercise programs comprise a significant part of ongoing HLIU operational costs. Units must strategize methods to maintain highly trained teams even as staff training programs demand extensive financial support, resources, coordination, and participation.

Despite requiring a large team of multidisciplinary experts, staffing models that minimize the number of personnel with direct patient contact are recommended by European infectious disease experts and U.S. HLIUs that have treated EVD patients (10, 140, 141).

Assigning specific team roles and developing protocols for clinical care staff to perform routine cleaning (e.g. bleach wiping surfaces within the patient room, handling infectious waste), linen changing, and food service minimizes the number of potentially exposed personnel (141). Contradictory to recommendations to limit staff-patient contacts, 3 HLIUs reported they would allow family to visit adult patients in PPE. Devoting large numbers of staff to HID patients also presents challenges to an institution's ability to staff other services (140). Although only 33% of HLIUs reported doing so, scheduling staff in advance during inactivation can help address scheduling and backfill issues that may arise during activation, especially if staff is comprised solely of volunteers.

Leadership teams managed and directed operations in all 33 HLIUs, but there was variation in the frequency of meetings and positions included. Although nearly all teams included nursing and medical directors, non-clinical roles (e.g. training director, transportation logistics, industrial hygienists) were represented on fewer leadership teams. While one leadership position may comprise multiple roles (e.g. industrial hygienist and waste manager), it is important for environmental specialists, trainers, and other non-clinical personnel to have a stake in leadership teams to ensure HLIU protocols adhere to strict infection control principles and promote safety of all HLIU staff. The Nebraska Biocontainment Unit, for example, includes nursing and medical directors as well as an environmental specialist, transportation specialist, and PPE manager/trainer (23).

The training and procedures necessary for the provision of HID care are significant and should be in place well in advance of actual need (144). All 33 HLIUs reported either having or developing retraining programs to maintain a fully trained team, and staff involved in HID patient care have demonstrated competency in areas beyond routine clinical skills, including performing clinical procedures while wearing PPE and properly managing highly infectious

waste. However, results indicated large variations in training requirements for orientation, both in hours required and the type of training (e.g. lectures, readings, videos) conducted (Table 8.3). CDC assessed training capabilities of HLIUs only on the existence of a training program and demonstrated proficiency of staff in their role and in infection control areas; specific indications on staff training are lacking (43). Research is needed to narrow and identify adequate and effective amounts of time HLIU staff spend learning HLIU protocols, infection control policies, and clinical procedures, as well as to identify the best methods for delivering HID care training.

External contractors present important implications in enforceability of trainings and other hospital requisites for HLIU staff. Thirty-nine percent of HLIUs hired external contractors for waste management, and nearly a quarter of decontamination specialists were contracted out. While facility employees must demonstrate competencies and comply with training requirements, external contractors may be exempt from extensive HLIU training programs and may be unaware of HLIU practices outside of their area of expertise. HLIUs will have to work with contractors to identify and address gaps in knowledge and training.

Extensive training instills confidence within the HLIU team as well as in hospital personnel, government officials, and the general public. Studies have shown HCWs can be inconsistent in performing infection control and hand hygiene measures; in an HLIU environment, any lapses in equipment disinfection, doffing PPE, or other infection control practices produces the potential for contamination (11, 69). Due to the hazardous nature of HIDs, minor errors can prove dire for HCWs, highlighting the importance of extensive and well-developed training programs. Donning and doffing of PPE likely provides the greatest risk of exposure if performed improperly, and these processes should be repetitiously trained and carefully observed, with protocols for peer monitoring (144).

The high-risk nature of HID care necessitates restricted access to the unit, including

family members of the patient. Nearly all responding HLIUs reported enabling communication lines between the patient and family; however, as no pediatric patient with a confirmed HID has been treated in a U.S. HLIU to date and multiple HLIUs reported assessing communication with a pediatric HID case on a case-by-case basis, questions remain on the frequency and degree of family contact with a pediatric patient. Since distribution of this survey, the American Academy of Pediatrics (AAP) has released guidance for hospitals and providers on parental presence at the bedside for suspected or confirmed pediatric HID patients (145). The AAP recommends a care team consider multiple factors prior to determining caregiver presence within the HLIU, including development level, age, and acuity of patient; hospital resources available to manage at least two cases, should the caregiver need to be isolated; the risk to healthcare workers, other hospital personnel, and other patients; and the caregiver's ability to comply with PPE protocols (145).

A majority (88%) of HLIUs also restricted students, residents, and fellows from entering the unit and no HLIU allowed them into the patient room, although 36% of responding HLIUs incorporated trainees into HLIU activities through video links, direct observations, or logistical coordination. The care of an HID patient poses a unique and informative opportunity to educate the next generation of HID caregivers; yet, the risk of transmission to trainees and ensuring patients receive optimal clinical care must be weighed (146). Even without entering the unit, trainees can benefit from external observations and participation in team meetings.

This study had some limitations. The data was not externally validated and was submitted by self-reporting of HLIU contacts. There was a decrease in response rate from the 2015 HLIU survey (85% response rate) to this follow-up (120-122). This could be due to the longer, more comprehensive follow-up as well as shifting priorities now that the Ebola outbreak has ended. Moreover, it is possible that some of the hospitals that responded to the first survey

but did not complete this follow-up may no longer serve as designated HLIUs, as three previously designated HLIUs indicated. We also recognize that although this study only surveyed staffing management of designated U.S. HLIUs, hospitals across the U.S. have invested significantly in strengthening their capabilities to care for an HID patient, including recruitment and training of staff.

In conclusion, over a short period of time, HLIUs recruited and trained large numbers of multidisciplinary staff to safely provide HID care with little guidance on training and management of HLIU personnel. Although best practices and recommendations have been released by U.S. HLIUs that treated EVD patients in 2014 and by European and U.S. consensus groups, there is still a clear lack of standardization in biocontainment practices not only on staffing but also on areas related to infection control, PPE use, and laboratory procedures. As reflected in at least 3 units no longer being designated HLIUs, it is unclear how HLIUs will continue ongoing staff trainings with little or no funding to support these activities or provide salary support for the HLIU staff. As new policies and recommendations on HIDs are released by agencies and HLIUs that have treated HID patients, HLIUs must continuously reevaluate protocols to ensure sustained preparedness for the next infectious disease outbreak.

CHAPTER 9: US STATE PUBLIC HEALTH DEPARTMENTS SPECIAL PATHOGEN PLANNING⁷**Research Full Report**

US State Public Health Departments Special Pathogen Planning

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Introduction

State public health departments play a vital role in US preparations for and response to infectious disease outbreaks, which was emphasized during the 2014-2016 EVD outbreak. During this period, states and hospitals invested significant resources to strengthen the nation's capabilities and capacity to address the potential threats posed by EVD and other HHCDs. In the fall of 2014, recognizing the differing abilities of hospitals to deliver appropriate HHCD care, the CDC recommended a 3-tiered framework of hospitals that acknowledged their different roles and levels of preparedness to identify, isolate, and evaluate PUIs for EVD (43). In collaboration with hospital executives, state and local public health officials were encouraged to apply this framework to their state hospitals, designating them in 1 of 3 tiers: frontline healthcare facilities, Ebola assessment hospitals, and ETCs. Frontline facilities needed to be capable of identifying and isolating PUIs and informing their health departments; Ebola assessment hospitals were asked to be prepared to receive and isolate PUIs for up to 96 hours until the EVD diagnosis was either confirmed or ruled out; and ETCs were identified as having specialized facilities, high-level isolation capabilities, and appropriately trained staff to be able to care for EVD patients throughout the entire course of their illness (131).

The CDC determined that at least 56 U.S. hospitals had the enhanced capabilities to safely care for patients with EVD to permit them to be designated as ETCs, and an unknown number of additional hospitals have been designated as ETCs by their respective state health departments (131). Although termed "Ebola" treatment centers, a survey of US ETCs indicated that these 56 units have expanded their capabilities to provide treatment and management for other HHCDs (131). To further expand the capabilities of this network of hospitals specializing in HHCD care, the Assistant Secretary for Preparedness and Response within the Department of Health and Human Services designated a group of 10 geographically dispersed ETCs as RESPTCs

and offered them additional federal funding to further enhance their HHCD capabilities (27). A formal creation of a HHCD care network has been proposed to promote information exchange and further foster connections among these 56 HLIUs, while also facilitating a patient's access to the most geographically proximate hospital for high-level isolation care (147). However, sustainability concerns have been cited as the greatest challenge HLIUs face in maintaining HHCD care capabilities and have resulted in at least 3 previously designated ETCs no longer holding that designation (131).

The importance of maintaining access to such a network, and of the role of state and local health departments in HHCD response, was highlighted with the infection of 2 nurses in Dallas, Texas, after caring for the first diagnosed EVD case in the United States in September 2014. This case resulted in the need for subsequent monitoring by state and local health officials of 179 contacts from the 3 EVD patients' healthcare workers for a total of 40 days. It also led to the implementation of public health control orders (e.g., restricting attendance at crowded public events and use of public transport), albeit only for a small number of "high-risk" contacts (18). Missteps in managing the first patient with EVD exposed gaps in US HHCD preparedness among multiple sectors, as emergency medical services transported the patient without proper PPE, the health department had difficulties obtaining the required permit to transport the highly infectious EVD waste and delayed sending laboratory specimens for diagnostic testing, and 2 nurses caring for the patient were infected with EVD, leading the CDC to reconsider the ability of all hospitals to safely treat patients with HHCDs (96).

Between October 2014 and October 2015, public health departments in all 50 states actively monitored more than 20 000 travelers arriving to the United States from an Ebola-affected country (95). As each traveler reported his or her temperature and any symptoms daily to his or her local health department for 21 days post-departure from a country with the

ongoing EVD outbreak, the effort involved more than 400 000 cumulative contacts with arriving travelers (95). Although only 4 EVD cases were ultimately diagnosed within the United States (7 others treated in the United States were medically evacuated from West Africa after diagnosis), public health departments across the country were required to invest significant effort and resources during the EVD outbreak. However, despite the recent public outcry about the nation's limited readiness for HHCDs, and the immense surge in resources required of health departments to enhance HHCD preparedness capabilities, federal domestic preparedness funding is again declining, complicating the ability of public health agencies to maintain their abilities to monitor travelers and to collaborate with healthcare facilities to improve HHCD preparedness. Specifically, funding for the CDC Public Health Emergency Preparedness program has declined 40% since its peak in 2006, resulting in state and local public health departments losing more than 51 000 jobs (97).

Recent studies have described sustainability concerns and variability of high-level isolation infrastructure among ETC and RESPTC facilities, which have resulted in at least 3 previously designated treatment centers no longer maintaining isolation capabilities (120-122, 131). Although the CDC has continued to advise state and local health officials to maintain and enhance operational plans that include the transfer of HHCD patients to appropriately prepared hospitals, limited information is available on state public health guidelines for managing patients with EVD and other HHCDs. Moreover, an original list of CDC-designated ETCs included hospitals in only 18 states and the District of Columbia, leaving 32 states without a high-level isolation facility within their jurisdiction (124). This study aimed to identify guidelines and perspectives of state health departments as they relate to the management and transport of patients with EVD and other HHCDs.

Methods

In the summer of 2016, an 8-question survey with 5 subquestions (Appendix E) was electronically distributed as a fillable PDF and sent to publicly identifiable emails of public health department employees (e.g., state epidemiologists, emergency preparedness directors, chief medical officers) from each of the 50 states and the District of Columbia. One follow-up email was sent to the original identified contact of each health department to further solicit responses; if no survey was returned, at least 1 more employee was identified by the health department's Website and contacted. The study was reviewed by the UNMC Institutional Review Board and declared exempt.

The survey consisted of multiple-choice questions with the ability to select multiple responses for subquestions. The survey consisted of 2 sections: 1 focusing on patient admission and the other on patient transport. For the patient admission section, public health departments were presented with a list of 20 different infectious diseases, and were asked to state whether they would prefer to keep a patient confirmed to have each of the diseases listed in the hospital of diagnosis (no interfacility patient transfer) or to have the patient transferred to an HLIU (i.e., designated ETC or RESPTC). The patient transport section included questions on state laws and existing protocols as they relate to the transport of HHCDs and also questions on the involvement of the state health department in exercising its capabilities to transport a suspected or confirmed HHCD patient. The survey also requested respondents to list their state assessment hospitals, the designated ETCs within their state, and their RESPTC. Responses were collected via email and coded and analyzed using an electronic spreadsheet.

Results

Thirty-seven (73%) of the surveyed 51 health departments (50 states and the District of Columbia) completed the survey. Aforementioned health departments were asked to list their state's RESPTC, ETCs, and assessment hospitals in the survey. Respondents listed a total of 55 ETCs (including RESPTCs) (mean per state=1.49; range: 0-8, median=1). Forty of these were noted on the publicly accessible list of CDC-designated ETCs (124, 131). The other 15 were state-designated. Five CDC-designated ETCs were no longer reported as ETCs on their state health department's listed facilities. Eighteen states (49%) lacked an ETC. States reported a total of 149 assessment hospitals (mean per state=4.51, range: 1-40, median=3), although 7 states reported that the names of these facilities remain internally held and, therefore, did not share their names.

Twelve of the 37 respondents (32%) reported that the state health department (e.g., state epidemiologist, state public health director) is responsible for the decision of whether the patient is transferred to an ETC or an RESPTC. The remaining 25 states (68%) reported that decision-making is shared between the state health department and the facilities involved (e.g., physician or other leading representative of the receiving facility, primary medical provider at the sending facility). Figure 9.1 details the differing diseases for which state health departments reported that they would prefer to have transferred to an HLIU (i.e., ETC or RESPTC) for the treatment if a patient presented with the disease at a conventional hospital within their state.

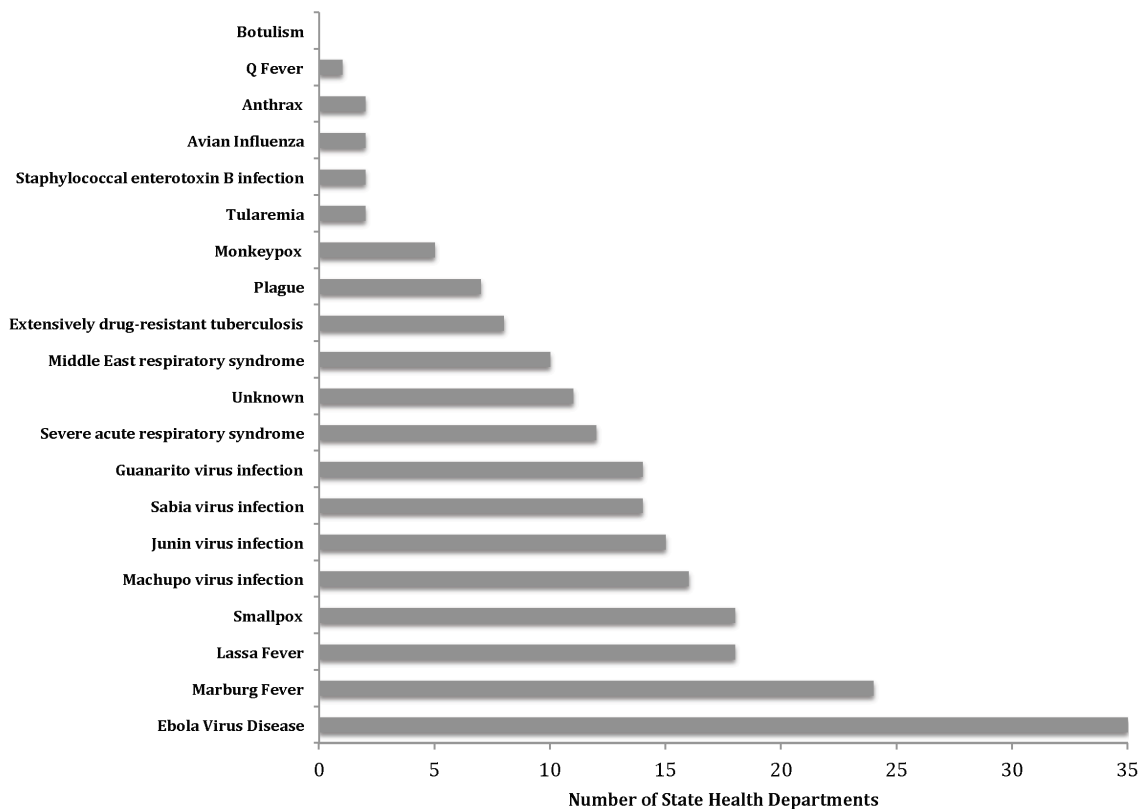


Figure 9.1. State health department* preference for transfer to high-level isolation for treatment *N=30 except for Ebola virus disease (N=35)

Thirty-three states (89%) stated that they had written protocols or official guidelines governing the details of transportation of patients with HHCDs to HLIUs. Of these 33 states, 21 (64%) had protocols/guidelines for transportation within the state to a state HLIU, 21 (64%) had them for transportation from the state to an out-of-state HLIU, and 8 (24%) had guidelines for transportation from out-of-state to an HLIU within the state. All states lacking a treatment facility had protocols for the transportation to an out-of-state ETC and/or RESPTC, while 3 states with ETCs had existing protocols for an out-of-state transfer (i.e., certain diseases states would prefer to have treated in a RESPTC rather than an in-state ETC).

Four (11%) states reported that they have state laws restricting the transport of HHCD patients (e.g., prohibited routes of travel for patient with EVD as dictated by a state's department of transport), while 3 states reported restrictions on distance to be traveled by ground transport teams. All of the distance restrictions were identical in distance (200 miles), but they were not similarly restricted by time (4 hours for 1 state, 4.5 hours for the other). One additional state noted there were no current restrictions on HHCD patient transport, but that there were plans in development to limit ground transport team shifts to 2 hours before switching out staff. Six states (16%) reported having written protocols or official guidelines for the management of accidents or other travel disruptions (e.g., vehicle collision, PPE breaches, inability of provider(s) to continue care) that may occur during transportation of an HHCD patient within the state, while 28 (76%) had no such protocols (3 states left this question blank).

Twenty-two state health departments (59%) stated that they had evaluated their plans with an operational exercise of patient transport involving 1 or more of the state's ETCs. The responding departments reported having participated in the following types of exercises: ground transport (via ambulance) within the state (n=17, 77%); ground transport from a facility within the state to an out-of-state HLIU (n=4, 18%); ground transport from an out-of-state facility to a HLIU within the state (n=2, 9%); air transport from a facility within the state to an out-of-state HLIU (n=3, 14%); and air transport from an out-of-state facility to a HLIU within the state (n=3, 14%). All 6 of the states that had written procedures for the management of accidents during HHCD transport had participated in an operational exercise.

Twenty-two (59%) state health departments reported they had participated in the transfer of an actual HHCD patient (PUI or confirmed patient). For nearly all states (95%, n=21), their experience had been with ground transport (via ambulance) of a patient within the state. Two state health departments participated in the receipt of an HHCD patient by air from

another country, and one state had been involved with air transport from a facility within the state to an out-of-state ETC/ RESPTC. All of these air transports were confirmed cases of EVD.

Discussion

The 2014-2016 Ebola outbreak highlighted the threat HHCDs can pose and reaffirmed that a patient who contracts an HHCD in all but the most remote parts of the globe can present anywhere else in the world within days. During the outbreak, hospitals across the United States invested millions of dollars to strengthen their ability to identify and isolate suspected HHCD patients (120). The state and federal designation of hospitals with augmented capabilities for HHCDs strengthened the nation's ability to provide care to patients with HHCDs through their full course of illness. To best capitalize on these investments of money and planning efforts, effective coordination and collaboration among health departments and hospitals are essential to ensuring safe access to care for patients with potential and confirmed infections with HHCDs and to minimize risk to the public.

The decision to transfer a patient with EVD or other HHCDs from one hospital to another is complex and context-dependent but is generally the product of informed joint discussions between state public health officials and medical personnel at the sending facility and receiving HLIU. The process of transfer to physically move such a patient to an HLIU requires detailed coordination among local and state health departments, the transporting and receiving hospitals, emergency medical services, law enforcement, and other agencies involved in the transportation process, and also relies heavily on the presence of clearly established operational procedures and interagency plans (47). Written protocols or official guidelines for the transportation of patients with HHCDs to HLIUs promote uniformity amongst participating agencies, reduce the need to improvise last-minute logistics in high pressure scenarios, minimize exposure risks to the public, and ensure that the patient receives optimal care during transport

(68). However, more than one-third (38%) of responding state health departments have not yet participated in an operational exercise of the transfer of a patient with an HHCD to an HLIU. In addition, only a few responding state health departments (16%) have written protocols and guidelines for the management of accidents that may occur during the transport of an HHCD patient. Transport of an HHCD patient is a relatively high-risk and uncontrolled environment that demands well-developed and uniform operational procedures to minimize the risk of disease transmission to involved workers, and considerations for worst-case scenarios should be thoroughly discussed between all stakeholders.

Conventional hospitals have the capability to safely care for most patients with infectious diseases that are non-transmissible to healthcare personnel or can be managed in routine negative pressure room (e.g., botulism, tularemia, anthrax, Q Fever). While a previous study of US HLIUs (ETCs and RESPTCs) found that 42% and 19% had reported they would treat anthrax and botulism (131), respectively, the large majority of state health departments would recommend that an anthrax patient be treated in the hospital of diagnosis and no health departments would transfer a botulism patient to high-level isolation. Disagreement between health departments and HLIUs was also found in the isolation of patients with an unknown emerging infectious disease. While nearly all HLIUs have previously reported that they would admit a patient with an unknown emerging infectious disease (131), just more than one-third of health departments in this study indicated they would prefer the said patient be transferred to high-level isolation, although high-level isolation facilities were first designed in the 1990s and 2000s for the purpose of isolating patients with unknown infections (10, 14).

Therefore, there are discrepancies between diseases US HLIUs and health departments believe warrant high-level isolation. To date, there is no guidance available beyond consensus recommendations (10, 14) on which diseases demand high-level isolation. The lack of a

consensus HHCD list endangers a coordinated system of HLIUs and public health departments during a HHCD response, as confusion may be generated upon diagnosis of a particular disease. Moreover, disagreement between the 2 entities poses important financial and reimbursement implications, as care in an HLIU may likely be costlier due to dedicated staff and supplementary resources compared to routine inpatient care.

At least 15 hospitals have been appointed HLIUs specifically by their state health departments and have not been assessed by the CDC. In assessing hospital high-level isolation infrastructure, the CDC identified 12 augmented capabilities US HLIUs must possess; however, capabilities and capacity for these state-designated HLIUs are unknown, and it is unclear how comparable they are to those reviewed and designated by the CDC. Moreover, 49% (n=18) of the responding health departments still lack an HLIU within their state and must, therefore, ensure that plans are in place for the transport of an HHCD patient to an HLIU outside of their jurisdiction.

The network of US HLIUs is complemented by state-designated assessment hospitals prepared to receive and isolate patients for up to 96 hours or until diagnostic tests are complete (43). As with HLIUs, the capabilities of assessment hospitals may differ between states. Reported number of state assessment hospitals ranged from 1-40; therefore, it may be that assessment hospitals in states with fewer similar facilities have received a greater amount of resources and technical assistance than hospitals in the state in which public health officials have assisted 40 different hospitals in establishing their isolation and assessment capabilities.

This study had limitations. The US state public health departments and hospitals/hospital systems widely vary in organization, resources, and laws, and this survey allowed for little flexibility in listing where a state would prefer a HHCD patient to be treated, particularly for states without a designated ETC. Although assessment hospital was not listed as

an option, as the CDC recommended these facilities have capabilities to isolate an EVD PUI until confirmed diagnosis, several states noted the facilities that have been designated as state assessment hospitals have the trained staff and capabilities to treat patients with other infectious diseases throughout the entire course of illness, and they would prefer to transfer patients with certain diseases to these facilities rather than to out-of-state ETCs or their state's designated RESPTC. For this reason, and because a few state health department contacts noted the decision to transfer a patient from the original hospital would be based on a case-by-case assessment of the capabilities of the hospital of diagnosis, 5 states did not complete the section on the disease lists. Moreover, as results were self-reported and not validated, responses may have differed depending on the scope of knowledge of the responding public health official. Lastly, the 73% of states that responded may have a higher state of preparedness than non-respondents and were, therefore, more willing to complete the study. As such, results may not be entirely indicative of the degree to which other state health departments have developed protocols for special pathogens within their state.

The structure of high-level patient isolation care among US hospitals has significantly changed in the past 2 years, as has the role of state health departments. This survey captured only a small portion of the responsibilities state health departments have in supporting the effective care and management of HHCD patients. State public health officials also have a vital role in the transport of waste and laboratory specimens through state jurisdictions, identifying and monitoring potentially exposed persons, coordinating with federal and local efforts, and supporting hospital preparations for HHCDs, including disseminating guidance. Recent budget cuts and uncertainty of future funding threaten the abilities of state health departments to devote the necessary resources and staff to prepare for and respond to HHCD cases.

Implications for Policy and Practice

- To date, no consensus guidance is available on which diseases warrant high-level isolation. Without these specifications, state and local health departments may disagree with the hospital of diagnosis and/or the jurisdictional ETC/RESPTC. Moreover, high-level isolation may be costlier than conventional inpatient treatment, potentially creating financial implications and reimbursement issues for high-level isolation units that treat diseases that otherwise could have been safely managed in routine clinical settings.
- At least 13 new HLIUs have been designated by states, yet 18 responding states still lack a designated high-level isolation unit. These states must, therefore, rely on external hospitals and health departments to accept an HHCD patient diagnosed within the state and should have clear protocols and consistent collaboration with external agencies. The lack of HLIUs in some states may complicate transport to a geographically proximate HLIU, especially considering 4 states have laws restricting ground transport distance.
- Limited federal guidance is available for biocontainment unit practices. The current guidance is purposely vague to allow for hospitals and health departments to adapt to their circumstances (148). However, this has led to variation in HLIU capabilities and challenged local health departments to implement practices complying with both federal and state recommendations (120-122, 148).

CHAPTER 10: DISCUSSION

The EVD outbreak in West Africa exposed weaknesses in U.S. healthcare preparedness for HHCDs and presented a pivotal moment in enhancing U.S. hospital preparations for and response framework to highly hazardous pathogens. The initial approach for containment by national leadership and experts that suggested standard hospital facilities were capable of containing and providing safe and effective care for patients with HHCDs was undermined with the first case of EVD diagnosed in the U.S. and the subsequent hospital-acquired infection of two care providers. This defining moment accelerated plans for a tiered system to optimize the distribution of limited resources, with select specialized units to be designated centers for EVD treatment and care.

With the exception of three hospitals with pre-existing biocontainment units, hospitals across the U.S. rapidly developed plans, recruited and trained a multidisciplinary team of volunteers, and purchased specialized supplies and equipment with the guidance of CDC recommendations (43). National experts evaluated numerous US hospitals and validated the ability of 56 of these to provide safe care. Stringently adhering to these minimum capabilities, these designated centers should be enabled to safely provide care for patients diagnosed with EVD while effectively minimizing the risk of transmission to healthcare providers, other hospital patients, and the general public. However, the CDC guidelines detail the *minimum* requirements for CDC-approved treatment centers; as evidenced in the previous chapters, these facilities vary in physical infrastructure, range in level of development of detailed procedures and protocols, and differ in their ability to adapt capabilities for other HHCDs. Similarly, state health departments reported variability in HHCD transportation plans, experience conducting HHCD exercises, and the number of state-designated ETCs. This dissertation explored the resources

invested and plans and protocols developed by these CDC-assessed treatment centers and state health departments in response to the threat of imported cases of EVD between 2014-16; although independent, the surveys are highly connected and provide insight on the unprecedented planning and preparations made by these entities and the broader advancements in domestic HHCD isolation and care capabilities.

Since the designation of the CDC-approved ETCs, states and jurisdictions have established and designated their own ETCs. The most recent publicly available information on the number of U.S. ETCs is addressed in a report by the ASPR in response to a request by the House Committee on Appropriations for plans for each tier of the ETC response framework (26). The report states that as of June 2017, there are 63 state- and jurisdiction-designated ETCs in the U.S., not including the 10 RESPTCs; however, it is unclear if the former ETCs that we identified in this dissertation that no longer maintain their high-level isolation capabilities are reflected in this updated count.

It is likely that state- and jurisdiction-designated ETCs face similar logistic, sustainability, and staffing challenges as CDC-assessed treatment centers; as such, it is possible that some of these facilities have also chosen to prioritize other hospital needs and have since 'closed' their treatment unit. Therefore, it is unknown how many of the 63 ETCs counted in June 2017 continue to maintain physical space, staff, and high-level isolation capabilities for EVD. As discussed in Chapter 9, it is critical that local, state, and federal public health agencies, hospitals, and healthcare systems are aware of which area hospitals are prepared for HHCD care and the capabilities of such units. As each state may have had different requirements for ETC designation, it is unknown how these facilities compare to CDC-assessed and designated treatment facilities.

In Europe, the EUNID survey established variability in regional capabilities due to an absence of EU-wide legally binding regulations on various HLIU-features (e.g., transport, infection control, biosecurity, post-mortem handling) that has led to a diverse range of individual facility protocols and procedures adapted to local qualifications (32). The EUNID suggested that different implemented solutions are highly dependent on national legislation, the availability of transport vehicles and funds, geography, population density, and public health challenges or threats encountered in the past in different nations (32). Similarly, U.S. states differ in population, public health infrastructure and networks, hospital systems, volume of travel to and within the state, and previous experience responding to suspected or confirmed HHCD cases within state borders. Differing state laws and resources surely impact HHCD preparedness and response frameworks, including state ETC capabilities and capacities, resulting in variances among states' preparedness levels.

Prior to this dissertation, the capacity of U.S. ETCs was unknown. RESPTCs have enhanced requirements that include a capacity of at least two beds for patients with EVD and ten beds for patients with respiratory illnesses (108). Extrapolating the average bed capacity for non-regional ETCs (2.4 beds, n=45) and RESPTCs (3.4 beds, n=10), based on dissertation findings, there are at least 144 beds for EVD care within the U.S. (not including state-designated ETCs, for which there is no known bed capacity requirement or estimation). We previously speculated this capacity exceeds that which is likely necessary for a VHF outbreak primarily contained in a region outside of the U.S.; however, if non-regional treatment centers are unable to sustain capabilities and must discontinue their HLIUs—as we found many have already done—U.S. capacity for VHFs could substantially decrease, possibly to just those within the 10 RESPTCs. These remaining beds could be quickly depleted in situations with other HHCDs, such as high-pathogenic avian influenza. Importantly, as described in Chapter 3, most units distinguish

between adult and pediatric bed capacity and many do not plan to accept pediatric patients; it is therefore critical for public health departments and potential transferring hospitals to identify ETC bed capacity in terms of both pediatric and adult patients.

Historically, HHCDs have not always been treated in HLIUs; while many of these cases led to infection transmission to healthcare providers, as was the case in Dallas in 2014 and hospitals across East Asia and in Toronto during the SARS outbreak in 2003, many were successfully and safely treated in standard hospital rooms, including the two cases of MERS that have been diagnosed and treated in the U.S., as of September 2018. In addition, the first documented imported case of a VHF in the U.S. occurred in 2008, when a woman returned to Colorado from a safari in Uganda and presented to a hospital with nausea, chills, rash, and vomiting (149). Initial testing for VHF was negative. The patient was therefore treated in a standard hospital setting with standard precautions, and was discharged 12 days later (149). It was only after the patient heard about a case of Marburg fever in a Dutch tourist that had visited the same cave as the patient that she requested repeat testing, six months later; serological testing was returned positive for Marburg fever.

Despite a handful of similar cases successfully managed in a conventional hospital, HHCDs pose heightened occupational exposure risks to healthcare workers. In West Africa treatment centers, HCWs were 21-32 times more likely to be infected with EVD than the general public, while HCWs accounted for 21% of all SARS cases during the outbreak in 2003 and up to 57% of cases in areas of Hong Kong, Singapore, and Toronto (150). The high infection rates in previous HHCD outbreaks emphasize the importance of specialized facilities for HHCD care, particularly as the burden of nosocomial infections in the U.S. remains significant, affecting 5-10% of hospital inpatients (151, 152). Studies have shown healthcare workers consistently perform inadequate hand hygiene and exhibit inconsistent compliance to other infection control

measures during routine care; the smallest of infection control breaches can be detrimental when considering the highly infectious nature of many hazardous pathogens. HHCD treatment therefore demands staff that are rigorously and consistently trained. A recent study found that self-contamination during PPE doffing occurs in up to 30% of instances when there were no lapses in technique observed (153), while other studies have shown that unrecognized contamination from suboptimal performance of other infection control facets can occur in a high-level isolation setting, particularly from those who have not worked in a high-risk environment (11, 49). Moreover, HLIUs are equipped with optimal engineering controls to further isolate the patient and disease from HCWs and disrupt and contain transmission to direct care providers, laboratory personnel, and other patients.

High-threat, low probability events—such as a HHCD outbreak within the U.S.—are challenging for hospitals to prepare for as they defer resources away from day-to-day needs (e.g., using rooms if a dedicated unit is unavailable to drill and train) and are a costly venture to construct, operate, and maintain (10). However, the more than 56 U.S. hospitals that have been designated as a place for EVD care have expended at least \$54 million to prepare their units. Again, this is likely a very low estimate as this dissertation’s findings on the costs incurred by these units represent only the initial “start-up” costs of creating ETCs and do not include the costs of on-going maintenance. As costs incurred were surveyed and gathered in 2015, these figures are likely significantly greater three years later as units have had to resupply validation reagents for the laboratory, maintain supplies and equipment, provide continuous and ample training to staff, and conduct exercises and drills. Reimbursement amounts for non-RESPTCs surveyed in 2016 only reinforce the immense burden hospitals invested in establishing their unit: facilities were awaiting reimbursement of nearly \$650,000 per unit in 2016, and it remains to be seen how much of that will be fully returned to the hospitals.

These challenges regarding program sustainability are a major concern. Sustaining and retaining a staff of volunteers and facility capabilities as well as expanding facility capacities for additional patients and for other infectious diseases threats are costly. Surely, it is more cost effective to build on this new framework and strengthen capabilities gained in 2014-2016 than to decommission facilities only to spend significantly more later on response; the education, infrastructure, and expenditures already invested in this network has provided the foundation on which to continue and expand domestic preparedness efforts as well as select groups with developed expertise in HHCD management within the U.S. There is a real risk of wasting the resources already expended and described here if ongoing maintenance and quality improvement efforts are not funded. Moreover, there is a general lack of funding for research related to best practices. Current ASPR and CDC funding for RESPTCs, the tiered network, and programs to train and educate hospitals on EVD preparedness (including the National Ebola Training and Education Center) is set to expire in 2020; plans to continue funding this new regional network and supplemental national preparedness programs remain uncertain. If failed to be renewed, the U.S. would once again be vulnerable to the next HHCD threat. We have further detailed and reviewed sustainability of Ebola emergency supplemental funding in a previous publication (154).

With uncertainties in future funding, the question of whether U.S. treatment facilities will be sustained and managed in a way so as to offset the initial significant financial investment remains unanswered and may well depend on their ability to adapt to diseases beyond their initial EVD-specific capabilities. Many responding ETCs noted their responses were Ebola-specific and reported capabilities and capacity would be different when considering a different HHCD. As noted in Chapter 8, the discussion on which diseases warrant high-level isolation has recently come into greater focus; subject matter experts have provided greater detail on pathogens of

concern and situations that call for the transfer of a patient to high-level containment facilities (13, 155). The ability of these units to accept HHCDs other than EVD is critical to advance U.S. domestic readiness for the next emerging infectious disease threat.

Limitations

As with any research endeavor, this dissertation had limitations. As was previously described in chapter discussions, the survey responses were not independently validated and in most cases, were completed by one representative from the facility. In comparison, the EUNID study consisted of site visits by survey team members to verify and detail European capabilities and infrastructure (32). Moreover, the first U.S. ETC survey was administered prior to the designation of the ten RESPTCs that were later required to obtain more advanced capability and capacity requirements; as such, resources, infrastructure features, and protocols may not be fully representative of those facilities' current capabilities. Neither ETC survey had a 100% response rate and neither surveyed state- or jurisdiction-designated treatment centers; as such, results do not reflect the full extent of high-level isolation capabilities within the U.S.

Units surveyed were only declared a CDC-approved ETC because of their proven competencies in 11 specific capabilities prior to an arbitrary deadline. State- and jurisdiction-designated ETCs or facilities that were federally validated after the deadline were not included in this study but are an important component of the regional treatment network established in 2015; however, requirements to be a state- or jurisdiction-designated ETC are unknown and likely vary between states. Many of these facilities have yet to be named and remain publicly unknown. Although it is expected that most states, if not all, required facilities to demonstrate competency in the same areas as those assessed and required by the CDC, it is very possible that

capabilities vary widely between these centers and from those facilities that were CDC-approved. In addition to these additional units, hospitals across the country modified existing infrastructure, protocols, and trained staff to prepare for possible imported cases of EVDs. This dissertation did not assess the investments and costs incurred by these hospitals in enhancing their facilities, nor did it assess preparations made by other organizations; cumulative expenditure and resource investment by all domestic hospitals and health organizations is undoubtedly substantial.

The surveys were of cross-sectional design and therefore provide a limited snapshot of current capabilities and, in the case of the ETC surveys, did not evaluate for capabilities units were not equipped with but would have constructed or planned for with additional funding or time. These findings would be useful in assessing for further enhancements to be made in U.S. hospitals as well as identifying lapses in preparedness as a result of lack of funding or due to the rapid nature of establishing the centers in 2015.

Future Research Areas

New emerging infectious disease threats are imminent with growing threats of intentional use of bioweapons and an increasingly globalized world; both will encourage high-level isolation facilities to continually adapt for other HHCDs. The recent influx of knowledge related to high-level containment care can further develop global consensus standards as they relate to all HHCDs, and previously debated issues can be readdressed. For example, uncertainties identified in the EU consensus include optimum air exchange rate, optimum mode of patient transport, disposal methods of liquid clinical waste, and management of routine clinical samples (10). There was not enough evidence at the time in the above cases to

determine the safest practice (10), but the EVD epidemic prompted extensive research and debate into these areas, as well as identified best practices by units that treated patients with the disease in 2014-16.

The lack of legal documents and mandated requirements regulating the treatment of HHCD patients in facilities in Europe and the U.S. has resulted in variability in the preparedness levels amongst global HLIUs. Previous European and U.S. consensus efforts identified guidelines and standards for high-level isolation units preparing to treat patients with HHCDs (10, 14), but an outdated European survey and the rapid standing-up of the ETC network calls for more research on whether the current facilities meet the standards set by the two former consensus efforts. An International Consensus Conference was held in April 2018 that brought together 17 global HLIUs with experience treating and managing patients with various HHCDs (e.g., VHF, MERS, SARS) and resulted in the formation of a Global Infectious Disease Network. The Conference was preceded by an electronic survey adapted from the two ETC surveys developed and distributed for this dissertation; as of this writing, results are being analyzed. Survey results, the establishment of a global network, and consensus discussions from the Conference represent a critical step in disseminating best practices and encouraging collaboration among global units.

While this dissertation surveyed U.S. treatment centers on all previously identified uncertainties during the mid-2000 consensus conferences, there remains a lack of documented consensus on the safest, optimum method for various HLIU operations including but not limited to: aeromedical and ground transportation, clinical laboratory testing, staffing models and leadership team composition, frequency of training and optimal training curriculum, and minimum stockpiled PPE, equipment, and supplies. Considerations to each of these factors must be made by units considering receiving patients with HHCDs, by EMS transport teams and

federal agencies responsible for transporting personnel and citizens to higher-resources settings within the US, by local and state public health departments, and by laboratories providing support to designated facilities. Moreover, as new emerging diseases surface around the world, developed protocols, facility design, and personnel management should be evaluated through the purview of airborne diseases.

Conclusions

The 2014-16 EVD outbreak highlighted the historic trend of international prioritization to global health security: sufficient funding available immediately following a HHCD threat is reduced and global health security de-emphasized as the threat fades and attention is shifted to other areas. In 2012, WHO cut funding and staffing for HHCD prevention and preparedness activities as priorities shifted, including to non-communicable diseases (156), only to expend immense resources into responding to the 2014-16 EVD outbreak. In the U.S., much of the influx of funding and preparedness activities in response to the EVD outbreak is set to expire in 2020; it remains to be seen for how long these efforts will be sustained. Since the 2014-16 epidemic, two new EVD outbreaks have occurred in the Democratic Republic of Congo (DRC), including one that is ongoing at the time of this writing and has just been declared the second largest outbreak of EVD in history, behind the 2014-16 West Africa epidemic.

The domestic preparedness efforts described in this dissertation are fundamental to U.S. response to the next HHCD threat and represent important considerations for hospitals around the world looking at constructing and staffing their own HLIUs; however, these enhancements to HHCD preparedness at the local, regional, and national level only address one component of a global issue. As Heyman et al. reflect, the 2014-16 EVD epidemic demonstrated

that “we are only as safe as the most fragile states” (156). Predictions of a global pandemic event on the scale of the 1918 pandemic could kill 19 to 33 million people, with the World Bank estimating economic losses spawning from a such a pandemic could total upwards of \$3 trillion (157, 158). It is thus in the interest of the entire world that all nations have the capacity to prevent, identify, and respond to HHCD epidemics and that these capabilities are sustained for future HHCD threats.

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APPENDICES

Appendix A. First Ebola Treatment Center Survey (2015)

A.1 General Aspects. The facility addressed in this checklist:

A.1.a) Please indicate the name of the EVD/Special Pathogens Care Treatment sponsoring hospital and location:

Hospital: _____ City/State: _____

A.1.b) Is the hospital applying to be the regional center? YES NO

A.1.c) EVD inpatient care facility is located within:

i) Main Hospital Building(s) YES NO

If yes: Located within

Academic/teaching hospital

Referral / regional hospital (but not Academic Medical Center)

Other (Armed Forces/Infectious Disease Center): _____

ii) Independent facility (stand alone facility) YES NO

If yes, is facility located on the same campus as main hospital building(s)?

YES NO

No information / other (please specify): _____

A.2. High level isolation Capacity:

A.2.a) Number of Ebola or Highly Infectious Disease ISOLATION ROOMS AND BEDS

i) Maximum number of high level patient isolation rooms and beds that can be used simultaneously

number of rooms: _____ number of beds (total): _____

ii) Bed capacity for adult patients n = _____

Critical care capable?	YES	NO
iii) Bed capacity for pediatric patients n = _____		
Critical care capable?	YES	NO
No information / other (please specify): _____		

A.3. Location of isolation rooms

A.3.a) Where are the isolation rooms specifically located?

i) In a separate ward, but within same building as other main hospital facilities?

YES	NO
-----	----

If yes, is the air handling for the ward separate from the air handling for the rest of the building?

YES	NO
-----	----

ii) In separate rooms, but in the same ward as other hospital facilities? (e.g. Inf. Diseases Ward, or ICU)

YES	NO
-----	----

If yes, is there a physical barrier (wall or other) separating the isolation rooms from the rest of the ward?

YES	NO
-----	----

If yes, please describe the barrier: _____

If yes, is the air handling for the rooms separate from the air handling for the rest of the ward?

YES	NO
-----	----

iii) No information / other (please specify): _____

B.1 Infrastructure features for infection control available

B.1.a) Use of Ante room/area adjacent to patient *isolation room* for doffing PPE?

YES	NO
-----	----

If yes, please specify:

i) Are the "Clean" entrance and "dirty" exit separated? (2 doors) YES NO

ii) Is the entrance/exit via same pathway (door) YES NO

No information / other (please specify): _____

B.1.b) Isolation unit layout

i) Are the entrance and exits to the unit separated (2 doors/paths)? YES NO

i) Do the staff enter/exit via same pathway/door? YES NO

ii) No information / other (please specify): _____

B.1.c) Are all of the EVD isolation rooms negative pressure patient isolation rooms?

YES NO

If yes, please specify

i) Number of air changes per hour _____ Quantity: _____

No information / other (please specify): _____

B.1.c) HEPA filtration YES NO

If yes, filtration of: intake air exhausted air both

No information / other (please specify): _____

B.1.d) On-site sterilization of medical waste YES NO

If yes, please specify

i) sterilization method: autoclave incinerator other

If yes, please specify:

in the isolation unit itself In the hospital elsewhere

If no, process identified for Category A Infectious Substance disposal?

YES NO

No information / other (please specify): _____

B.2 Laboratory capabilities of isolation facility

B.2.a) Location of laboratory support (Check all that apply)

i) Located within the patient care room YES NO

- | | | |
|---------------------------------------|-----|----|
| ii) Located within the isolation unit | YES | NO |
| iii) Located within the same campus | YES | NO |
| iv) Located within the same city | YES | NO |

No information / other (please specify): _____

B.3.b) Classification of laboratory support (Check all that apply)

- | | | |
|----------------------------------|-----|----|
| i) Bedside Point of Care Testing | YES | NO |
| ii) Clinical laboratory | YES | NO |
| iii) Public Health laboratory | YES | NO |

No information / other (please specify): _____

B.3.c) Biosafety designation of hospital laboratory

- i) BSL-2
- ii) BSL-3
- iii) BSL-4

No information / other (please specify): _____

B.3.c) Biosafety designation of public health laboratory

- i) BSL-2
- ii) BSL-3
- iii) BSL-4

No information / other (please specify): _____

C.1 Cost of establishing high-level isolation capability

C.1.a) Approximate total cost incurred to establish ETC capacity since June, 2014: \$ _____

Construction/facility modifications: \$ _____

PPE purchases: \$ _____

Staff training: \$ _____

Unit planning: \$ _____

Acquisition of lab testing equipment: \$ _____

Other unit equipment purchases (not PPE or lab equipment): \$ _____

D.1. Ebola treatment center consortium participation

D.1.a) Would your facility participate as a member in a consensus network of isolation units to establish infection control metrics, competencies, and peer review for high-level patient

isolation centers?

YES

NO

If yes, please specify

Point of contact for consortium participation:

Name: _____

E-mail: _____

Appendix B. A Highly Infectious Disease Care Network in the US Healthcare System⁸

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EMERGING PATHOGENS AND HEALTH SECURITY

COMMENTARY

A HIGHLY INFECTIOUS DISEASE CARE NETWORK IN THE US HEALTHCARE SYSTEM

Aurora B. Le, Paul D. Biddinger, Philip W. Smith, Jocelyn J. Herstein, Deborah A. Levy,
Shawn G. Gibbs, and John J. Lowe

⁸ Material presented in this appendix is previously published: Le, A.B., Biddinger, P.D., Smith, P.W., Herstein, J.J., Levy, D.A., Gibbs, S.G., Lowe, J.J. A Highly Infectious Disease Care Network within the United States Healthcare System. *Health Secur.* 2017; 15(3): 282-287. doi: 10.1089/hs.2016.0073

Abstract

During the 2014-2015 Ebola outbreak in West Africa, the United States responded by stratifying hospitals into one of three Centers for Disease Control and Prevention (CDC)-designated categories—based on the hospital’s ability to identify, isolate, assess and provide care to patients with suspected or confirmed Ebola virus disease (EVD)—in an attempt to position the U.S. healthcare system to safely isolate and care for potential patients. Now with the Ebola epidemic quelled, this time period is crucial to act on the lessons learned from the EVD response in order to broaden our national perspective on infectious disease mitigation and management, build on our newly enhanced healthcare capabilities to respond to infectious disease threats, develop a more cost-effective sustainable model of infectious disease prevention, and continue to foster training so that the nation is not in a vulnerable position once more.

We are proposing the formal creation of a United States Highly Infectious Disease Care Network (HIDCN) modeled after two previous highly infectious diseases consensus efforts in the United States and European Union, respectively. A U.S. Highly Infectious Disease Care Network can provide a common platform for the exchange of training, protocols, research, knowledge and capability sharing among high-level isolation units. Furthermore, we envision the HIDCN will cultivate relationships among facilities and serve as a means to establish national standards for infectious disease response, which will consequently strengthen domestic preparedness and the nation’s ability to respond to the next highly infectious disease threat.

During the devastating and historically significant 2014-2015 Ebola virus disease (EVD) epidemic, numerous public and academic leaders voiced concerns about the United States' healthcare system's ability to diagnose, safely isolate, and provide high-level care for patients with suspected or confirmed EVD and other highly infectious diseases (HIDs) (1-3). At the height of the outbreak, hospitals across the country responded with emergency purchases of new personal protective equipment (PPE), requiring just-in-time training (JIT) or retraining for large numbers of staff on donning and doffing procedures, and alterations of their protocols to care for persons at risk of EVD infection, commonly incurring substantial costs (4-6). During this same period, the U.S. Centers for Disease Control and Prevention (CDC) stratified U.S. hospitals into one of three different tiers according to their ability to identify, isolate, assess and provide care for patients with suspected or confirmed EVD. Most hospitals were subsequently designated as either: 1) frontline hospitals, 2) assessment hospitals, or 3) Ebola Treatment Centers (ETCs) within their states (3).

Supplementing the hospitals designated as ETCs, the U.S. Department of Health and Human Services (DHHS) also funded the creation of Regional Ebola and other special pathogen treatment centers (RESPTC) network, through 2019, as part of the Hospital Preparedness Program (HPP). Existing hospitals were designated as a RESPTC in each of the ten DHHS regions throughout the United States to add, "regional capability [to increase] our domestic preparedness posture to protect the public's health" (7). These RESPTCs were selected based on their enhanced capabilities to treat a patient with confirmed Ebola or other highly infectious diseases. RESPTCs are intended to be positioned to provide care in future outbreaks of highly infectious diseases and have requirements such as: conduct quarterly trainings and exercises, have the capacity to treat at least two EVD patients at a time and the isolation capacity or negative pressure rooms for at least 10 patients with highly infectious respiratory diseases, and

be able to treat pediatric patients with EVD or other infectious diseases with a partner or neighboring facility (7). However, since the last of the ten RESPTCs was not designated until June 2016, post-Ebola outbreak, they have not had an opportunity to demonstrate successful use of their respective supplemental resources on repatriated or domestically acquired cases of highly infectious diseases, nor have they exercised operational communication and coordination amongst each other (8). In addition to the RESPTCs, the Assistant Secretary for Preparedness and Response (ASPR) and the CDC also funded the creation of a National Ebola Training and Education Center (NETEC) to conduct national training and educational activities based upon the best practices of U.S. institutions (the Nebraska Biocontainment Unit, Emory University, NYC Health + Hospitals/ Bellevue, and National Institutes of Health Clinical Center), which have successfully cared for patients with EVD, in conjunction with CDC guidance (9). The outbreak in West Africa has now been contained (10), and Ebola is no longer prominently featured in the news. However, there is little doubt that future outbreaks of HIDs will continue to occur and that there will be new infectious pathogens emerging and re-emerging on the global stage (11, 12). Following the recent EVD epidemic, there is a critical opportunity to act on the lessons learned from the 2014-2015 response—to broaden our perspective on infectious disease mitigation and management, and to build on our newly enhanced national capabilities to respond to infectious disease threats. Indeed, further investment—including but not limited to financial, infrastructural, and educational resources—into strengthening and maintaining these capabilities will be more cost-effective in the long term rather than spending in response, and will save lives when the next global infectious disease epidemic emerges (12). However, there is also a significant risk that without the impending threat of infectious disease morbidity and mortality, much of the funding that has been spent, the trainings that have been conducted, and

the plans that have been made will deteriorate and diminish in significance again until the next major outbreak occurs, leaving the nation vulnerable once more.

Previous Consensus Efforts

Previously, two consensus efforts have been conducted to try to characterize portions of the capabilities that Western health systems needs to effectively provide care for persons infected with HIDs. In 2004, the European Union established the European Network for Highly Infectious Diseases (EuroNHID) in response to the 2001 SARS outbreak and 2002 H5N1 influenza virus (13). EuroNHID was established with national representatives from 16 countries, “to exchange information, share best practices, and improve the connections between national (or regional) centers designated for the care of patients with highly infectious diseases” (13) and was ground-breaking, representing the world’s first efforts to coordinate consistent national approaches to HIDs. EuroNHID’s consensus effort highlighted the need to provide patients with HIDs safe, secure, and high-quality medical care with high-level infection control in a high-level isolation unit (HLIU). EuroNHID also emphasized the need for specially trained staff and detailed recommendations which covered topics such as: clinical care provision, diagnostic services, transport, health and safety, infrastructure features, support, and planning (13). A previous assessment, in 2009-2010, of EuroNHID’s collective isolation capabilities and capacities in HLIUs demonstrated that they were well-positioned to provide optimal infection containment and infection prevention and control procedures. During the recent EVD outbreak, members of the EuroNHID consortium stated that HLIUs, in nations where they are available, should play a key role in providing safe, secure, high-quality and appropriate care for a single or small number of patients with a highly infectious disease, such as EVD (14, 15).

In 2005, an ad hoc U.S.-based consensus group organized by the medical director of the Nebraska Biocontainment Unit (NBU), at the time, and 30 infectious disease experts from academic institutions, federal and state agencies, and military personnel developed a consensus statement detailing key considerations required for establishing biocontainment patient care units (BCPUs) to standardize the planning, design, construction and operation of HLIUs as one element to manage HIDs and to increase U.S. preparedness efforts (1). Although the 2005 U.S. recommendations for designing BCPUs presented were frequently referenced during the 2014-2015 Ebola outbreak, the U.S. consensus group was a one-time consensus conference that lacked sustained funding and consequently had no plans for continuance beyond this statement.

Suggestions

In this “peacetime” period following the EVD epidemic, governmental, public health, and medical leaders have the opportunity to build on prior pioneering efforts, and to nurture and strengthen our capabilities for identifying, isolating, and caring for patients with HIDs while simultaneously considering how this can be accomplished in a cost-effective and sustainable manner. In order to suggest a path forward to achieve this goal, we propose the formal creation of a United States Highly Infectious Disease Care Network (HIDCN). We envision that the HIDCN would link the U.S. ETCs and RESPTCs, forming a platform for common training, protocols, research, and knowledge- and capability-sharing among HLIUs and could facilitate access for patients needing high-level isolation care to a geographically proximate facility.

Furthermore, the HIDCN would support further development of the additional necessary components for national healthcare and public health preparedness for HIDs, including:

- Establishing a consensus network among key expert individuals from the participating ETCs and RESPTCs in order to have a large body of engaged individuals, which mirrors EuroNHID's consensus efforts.
- Expanding the scope of current plans and systems for EVD to be appropriate for the care of other HIDs of public health significance.
- Proposing standards for key characteristics and capabilities required of HLIUs in the United States based on the best available evidence, practice, and science.
- Maintaining a formal inventory of current capabilities and capacities of HLIUs in the U.S.
- Establishing a formal relationship with EuroNHID and the European HLIUs to facilitate a global exchange and sharing of research, best practices, and lessons learned on organizational structure, operational capacity and HLIU sustainability.
- Assisting the National Ebola Training and Education Center (NETEC) in the peer-review of metrics and other training materials.
- Facilitating front-line clinicians' ability to easily access information 24/7 on current outbreaks of relevant emerging highly infectious diseases via an easily accessible, curated internet portals and applications.
- Providing front-line clinicians', front-line providers, and other first response personnel with resources and information on where to obtain up-to-date highly infectious disease and infectious disease education and training. One such example is the new Ebola Biosafety and Infectious Disease Response Program, part of the National Institute of Environmental Health Sciences (NIEHS) Worker Training Program (WTP), which promotes the development and implementation of occupational safety and health, and infection control training programs and

education for workers at risk of exposure to infectious diseases, in healthcare and non-healthcare settings (16).

- Partnering with federal officials and other key stakeholders to strengthen and formalize the ties among, resources available to, and best practices shared between front-line, assessment, ETCs and RESPTCs facilities.
- Including EMS experts, representing the diversity of EMS system in the U.S., in the design and implementation of interstate and intrastate HID patient transportation capabilities among front-line, assessment, treatment, and regional HID centers to form a cohesive, national network.
- Including other industries impacted by the care of patients within HLIUs, such as Medical Waste, Law Enforcement, Death Care Sector, Environmental Services, etc.

The HIDCN can begin by building on the prior consensus work to improve overall national HID preparedness, and could use similar processes to help to unify and advance the protocols and capabilities of the U.S. ETCs and RESPTCs. To date, four high-level isolation units in the U.S. have demonstrated the ability to receive and treat repatriated EVD patients from Africa (17). Three of the four aforementioned HLIUs were already established as BPCUs following the consensus criteria outlined by Smith et al. (2006). However, no new units were built in the ten years preceding the EVD outbreak and, largely due to their rapid construction, most of the 55 CDC-designated ETCs, as well as many of the ten RESPTCs have not been created to meet the same criteria as the three BPCUs (1, 3). In fact, as the recommended capabilities of ETCs provided by the CDC for EVD care can be found in advanced pre-existing inpatient care units, many ETCs and RESPTCs may not have been created as separate, dedicated isolation facilities (3). These newer units are used for routine patient care, as well as care for patients with EVD and other HIDs only if the situation arises; this creates significant limitations on the design,

training, exercise, and real clinical experience opportunities available to staff operating within these facilities. Additionally, the new national network of ETCs still has significantly varying approaches to the clinical services that may be offered, as well as to hospital preparedness and infection control. Not surprisingly, a high degree of variability has been found in both laboratory support approaches and infection control capabilities among ETCs (4,6). A HIDCN could be of great value in not only better defining the operational and clinical capabilities needed to successfully and safely care for patients with HIDs within an appropriate facility, but also assisting facilities in building capacity to address HIDs in light of new and evolving CDC and governmental guidelines and designations. Building capacity includes the increase and optimization of available adult and pediatric beds, flexible-use units, efficacious staffing models, and regular training and drills (4).

Moreover, a HIDCN can assist to clarify the specific capabilities that are expected of front-line and assessment hospitals across the U.S., and could help to provide toolkits, trainings, and other materials that help to limit the burden of maintaining these capabilities on the hospitals. Currently, the roles of frontline hospitals and assessment hospitals in the U.S. varies by state, and there can be little similarity among state plans that anticipate caring for patients with HIDs (3, 18). A HIDCN could shepherd differing state HID plans towards a common national goal, while still allowing for the preservation of unique state infrastructure elements. This could not only to reduce variation among the plans but also better ensure that the nation's plans are consistent with the best available science, research, practice, and are consistent with ETC and RESPTC protocols and procedures.

Lastly, a HIDCN could play an important role in better unifying the disparate guidance that is currently available to prehospital and front-line clinical staff regarding awareness of the current HID outbreaks of concern as they evolve. There is currently not a clear single, curated

way to inform the millions of EMTs, paramedics, nurses, doctors and others who work on the “front lines” of the ambulances, clinics, offices, and emergency departments of the U.S. healthcare system to easily access case definitions and updated outbreak geographic data from expert governmental sources for the HID in question, while simultaneously linking that information to the appropriate degree of isolation and personal protective equipment (PPE) required. In the current absence of such easily accessible, coordinated and vetted national guidance, front-line staff are often asked to rely on their own personal or organizational vigilance, which has a high potential for failure (19). Based on lessons learned from the EVD response, in order to best protect public health, first responders, and healthcare personnel, the United States now needs to develop new and innovative ways to ensure that all front-line personnel in the U.S. can have current and reliable access to up-to-date outbreak information for existing or emerging HIDs.

Clearly, creating an HIDCN will require new resources to initiate and support the efforts suggested above, and in the current fiscal climate we acknowledge that it will be challenging to secure those resources. However, as demonstrated in the recent national response to EVD, the costs incurred by individual hospitals preparing in an uncoordinated system far exceeded the amount of federal resources that were ultimately dedicated to supporting a more coordinated network of ETCs and RESPTCs (5). We hypothesize that a nationwide, sustained effort to continually improve the United States health system’s ability to detect, isolate, and care for patients with HIDs will potentially be more cost-effective in the long term, and may potentially decrease the magnitude of future supplemental appropriation requests, as have been funded in recent years for Ebola and Zika virus.

Conclusions

In this new and complex arena of providing care for the patients with both known and unexpected HIDs, especially in view of the lessons learned from the nation's response to EVD, the changing landscape necessitates the coordination and development of a cohesive network of experts involved in such care. The current national network of ETCs has been designed based on CDC guidance for EVD. However, varying approaches to infection control and laboratory support among current ETCs emphasize the need for collective nationwide standards, especially in preparing ETCs for other HIDs beyond EVD. In addition, the complex and costly nature of both preparing for and providing HID treatment, as well as the lack of common regulations, currently threatens to degrade the U.S. healthcare system's future ability to safely adapt to manage emerging HID threats (4).

A new United States Highly Infectious Disease Care Network would be positioned to not only facilitate expert communication and information exchange on best practices, but could also foster connections among facilities, establish standards for response capabilities and capacities, use the best available science and evidence to offer recommendations on infection control practices and infrastructure features, and can increase the overall preparedness of the United States for the next highly infectious disease outbreak.

Appendix C. US Ebola Treatment Center clinical laboratory support⁹



U.S. Ebola Treatment Center Clinical Laboratory Support

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⁹ The material presented here was previously published: Jelden, K.C., Iwen, P.C., Herstein, J.J., Biddinger, P.D., Kraft, C.S., Saiman, L., Smith, P.W., Hewlett, A.L., Gibbs, S.G., Lowe, J.J. US Ebola Treatment Center clinical laboratory support. *J Clin Microbiol.* 2016 Apr;54(4):1031-1035 doi:10.1128/JCM.02905-15

Abstract

Fifty-five hospitals in the United States have been designated as 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 ETCs planned to provide some laboratory support (e.g. point-of-care [POC] testing) from within the isolated patient room. Forty-four (94%) indicated that their hospital would also provide clinical laboratory support for patient care. Twenty-two (50%) of these ETC clinical laboratories had biosafety level (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 US ETCs. ETCs have approached high-level isolation critical care with laboratory support in close proximity to the patient room and by distributing laboratory support throughout laboratory resources. Expert consensus might review safety considerations for these laboratory testing/diagnostic activities that are novel in the context of biocontainment care.

Introduction

The ongoing West African Ebola virus disease (EVD) epidemic, and the occurrence of three domestic EVD cases in the United States, has prompted national revision of strategies to combat EVD and other highly infectious diseases (2, 20). The US Department of Health and Human Services (HHS), through the Centers for Disease Control and Prevention (CDC) in coordination with the Office of the Assistant Secretary for Preparedness and Response (ASPR) has created interim guidance for hospitals and health departments intended to assist them in developing preparedness plans for evaluating patients under investigation for EVD and for patients with confirmed EVD (21). HHS also recommends that hospitals work to develop a coordinated, networked approach by designating medical facilities as frontline healthcare facilities, Ebola assessment hospitals (EAHs), or Ebola treatment centers (ETCs) (3). Personnel in frontline facilities (e.g., hospital-based emergency departments, critical access hospitals, urgent care clinics) should be trained to quickly detect and isolate patients and notify local and state public health departments when patients present with EVD-related symptoms in combination with an Ebola virus exposure history (3). Patients who meet the criteria for patients under investigation (PUI) are recommended to be transported to an EAH for supportive care and for diagnostic testing by the jurisdictional public health laboratory (PHL) to evaluate for the presence of EVD (Figure 1.1, Introduction) (22). Patients identified with a presumptive positive test for EVD would subsequently have specimens sent to the CDC for confirmatory testing (22). If EVD is confirmed, patients would then be transferred to an ETC, where the patient with EVD is cared for in an isolated patient room for the remainder of the disease course.

Patients with EVD become critically ill several days into their illness, requiring high levels of supportive care, including aggressive intravenous fluid resuscitation and management of electrolytes due to the high rates of fluid loss in the fulminant stages of the disease (23, 24). The

CDC recommends that hospitals caring for a PUI and/or a patient with confirmed EVD be able to perform a variety of laboratory tests, including a complete blood cell count, measurement of basic electrolyte levels, liver function tests, coagulation studies, blood cultures, urinalysis, as well as tests for the presence of other infectious diseases such as malaria and influenza (25). Hospital planning to provide aggressive intensive care therapies for a patient with fulminant EVD has been complicated. The highly infective nature of the patients' body fluids has prompted many laboratorians to be concerned about their ability to safely provide support for the care of EVD patients using standard hospital laboratory equipment (26). Indeed, perspectives from West African ETCs during the 2014-2015 outbreak emphasized the laboratories' vital role in monitoring pathophysiology in patients with EVD (27).

As of August 2015, 55 US hospitals were designated ETCs by state and local health authorities. To validate EVD care capabilities, these hospitals volunteered for assessments by the Rapid Ebola Preparedness (REP) teams of CDC personnel and subject matter experts (22, 25, 28). As part of this designation, ETC-qualifying medical facilities had arranged to have "laboratory procedures/protocols, dedicated space, [and] is possible, point-of-care testing, equipment, staffing, reagents, training, and specimen transport" capabilities available (28). The CDC has offered additional guidance on personal protective equipment (PPE), risk assessment and mitigation, laboratory instruments, point-of-care (POC) testing, transportation of specimens with Ebola virus, and decontamination and waste management (25). In addition, Emory University and Nebraska Medicine, as part of their treatment protocols, reported lists of essential and supplemental laboratory equipment and tests for high-risk patient care (26, 29, 30).

Although limited standards for laboratory support have been identified for the 55 ETCs, no documentation on their current capabilities has been reported. This report discloses the

laboratory support for participating US ETCs as they prepared to care for patients with EVD in their hospital biocontainment setting.

Materials and methods

Referencing European Network of Infectious Diseases (EUNID) checklists (31), a survey was developed to determine current structural and operational features of US ETCs, including laboratory characteristics, infection control infrastructure, laboratory location, costs of establishment and operation, and patient capacity (Appendix A). These checklists were derived from EUNID consensus agreements on the structural aspects of highly infectious disease patient care units in Europe (<http://www.eunid.edu/>) (31). Survey questions related to laboratories are listed in Table 1.

Table 1. Laboratory capability survey questions distributed to U.S. Ebola treatment centers

Survey question
Location of nearest laboratory support (check all that apply)
Patient care room, yes or no
Isolation unit, yes or no
Same campus, yes or no
Same city, yes or no
No information/other (please specify)
Classification of laboratory support (check all that apply)
Bedside point-of-care testing, yes or no
Clinical laboratory, yes or no
Public health laboratory, yes or no
No information/other (please specify)
Biosafety designation of accessible clinical laboratory
BSL-2
BSL-3
BSL-4
No information/other (please specify)
Biosafety designation of accessible public health laboratory
BSL-2
BSL-3
BSL-4
No information/other (please specify)

The location of ETC laboratory support in relation to the isolation unit was defined as within the patient care room, within the unit, on the same campus as the unit, or within the same city as the unit or as a combination of these locations. A patient care room was defined as the room in which the ETC planned to contain the patient within the isolation unit. The isolation unit was defined as the patient care area separated from other patient care wards, with access restricted to personnel entering under appropriate isolation precautions.

Types of laboratory support available for the ETCs were classified as bedside POC testing, clinical laboratory support, PHL support, or as a combination of these types of support. Laboratory containment was defined as biosafety level (BSL-2), BSL-3, or BSL-4 (32).

Surveys were distributed electronically in April 2015 for self-completion to the directors and/or assistant directors of the 55 US ETCs. Survey responses were collected via email. Any discrepancies were followed-up by email, phone call, or referencing of information available online. Responses were coded and analyzed for the number and percentage of ETCs indicating their specific location of laboratory support, classification of laboratory support, BSL containment of accessible hospital laboratories, and BSL containment of PHLs by using Microsoft Excel (Microsoft Corporation, Redmond, WA).

Results

Survey responses were obtained from 47 of the 55 ETCs (85%). Of these ETCs, 41 (87%) reported that the patient room was the nearest location of some laboratory support relative to the location of the patient (Table 2). Of the six ETCs without laboratory support in the patient room, three each had laboratory support within the unit and on the same campus. Each of the ETCs with laboratory support limited to the same campus as their isolation unit indicated support from a clinical laboratory and/or their jurisdictional PHL.

Table 2. Reported location closest to the patient room and classification of laboratory support in caring for patients with Ebola virus disease from U.S. Ebola treatment centers^a

Location or classification of laboratory support	No. (%) of ETCs
Location^b	
Patient care room	41 (87)
Isolation unit	3 (6)
Same campus	3 (6)
Classification	
Bedside POC testing	41 (87)
Clinical laboratory	44 (94)
Public health laboratory	34 (72)

^aThe number of responders was 47

^bThe laboratory support location is defined as follows: patient care room indicates a location within the patient's room, isolation unit is located in a designated space contained within the isolation unit, and same campus is located within the same medical facility.

All ETCs provided at least one type of laboratory support (i.e., POC testing within the patient room, clinical laboratory, or PHL). In classifying the type of laboratory support, 41 (87%) of the respondents indicated that bedside POC testing was available (Table 2). Forty-four (94%) ETCs indicated that they were supported by a clinical laboratory, and 34 (72%) indicated that they were supported by their jurisdictional PHL. Overall, 30 (64%) of the ETCs offered a combination of bedside POC testing and assistance from a clinical laboratory and their PHLs, with all but 1 of these ETCs having access to BSL-3 laboratory.

Of 42 ETCs responding regarding clinical laboratory containment, 20/42 (43%) reported BSL-2 containment, and 22/42 (52%) reported BSL-3 containment. Thirty-four of 47 (72%) ETCs reported that they had access to their jurisdictional PHL, all of which (34/34) have available BSL-3 containment laboratories.

In total, 40 of the 44 ETCs (91%) reported that they had access to a BSL-3 laboratory facility (a clinical laboratory and/or PHL), while 4 (9%) reported that they had access to BSL-2 laboratory facilities. Of the four latter facilities, three were supported by POC tests in the patient room. The remaining facility was supported by a laboratory within the isolation unit.

Discussion

This survey investigated laboratory support for the 55 CDC-designated ETCs. A majority of these ETCs offered laboratory testing in close proximity to the patient room while simultaneously dispersing support through their clinical laboratory and PHL. Given the critical nature of EVD and the potential need to assess patients for other diagnoses, laboratory support is well recognized as a crucial aspect for the optimum clinical care of patients with or without EVD (24).

The location of the laboratory to support a patient with EVD was defined as the location nearest the patient room. Previously reported laboratory support located within an isolation area was found to reduce specimen processing times, provide personnel improved safety assurance for handling of specimens, and decrease exposure risks (26,30,33). In this study, we noted that many ETCs have adopted at least some portion of a contained laboratory care model in which the location of the laboratory is located in close proximity to the patient care area to allow for rapid laboratory processing and enhanced laboratory safety and patient supportive care.

Conversely, laboratory support within the patient room or isolation unit may be disadvantageous. For instance, laboratory technologists may be required to enter the isolation unit where space may be limited to minimize the risks of occupational exposures (25). Exclusion of laboratory personnel from the isolation unit requires that clinicians with less familiarity with

POC technologies complete testing while simultaneously performing other care activities.

Additionally, the isolation unit may not have a contained area large enough for placement of a biosafety cabinet for the safe processing of specimens.

The Nebraska Biocontainment Unit (NBU) described the safe utilization of multiple laboratories to care for patients with EVD to include an in-unit BSL-3 laboratory, a BSL-3 laboratory at the on-campus PHL, and a core hospital laboratory (26). In contrast, Emory University contained nearly all laboratory testing (excluding specimens sent to the CDC or other government agencies for testing) within the patient care isolation unit (30). Both models have been proven to be safe and effective in providing laboratory care for patients with EVD (26, 30). ETCs have equally approached providing laboratory support from within the patient room and/or isolation unit (44 /47 [94%]) as well as from their hospital clinical laboratory (44/47 [94%]). Of the 47 surveyed ETCs, 30 (64%) have laboratory support including bedside POC testing, a clinical laboratory, and assistance from their PHLs, likely sharing responsibilities among resources. Distributing laboratory tasks among various locations may, however, also introduce exposure risks for additional laboratory personnel in each setting. A laboratory risk assessment at each location can help to reduce these risks (25, 29).

Of the hospitals in the United States that have cared for patients with EVD, both BSL-2 and BSL-3 containment laboratories have been used for clinical laboratory testing, with BSL-3 containment being available in 40/44 (91%) ETCs (25).

In comparison, a survey of European high-level isolation units (HLIUs) showed that only 17 and 27% of these units performed microbiological and routine tests, respectively, within the isolation patient care area (Table 3) (34). Overall, 32/47 (68%) and 15/48 (31%) of these HLIUs sent specimens for microbiological testing and routine clinical testing, respectively, to a reference BSL-3 laboratory, while 24/47 (51%) and 41/48 (85%) HLIUs sent specimens for

microbiological testing and routine testing, respectively, to a central hospital laboratory (with and without closed-type automatized analyzers) (34). A total of 39/48 (81%) European HLIUs had access to BSL-3 containment laboratories for diagnosis within the same city/facility as the unit, and 11/48 (23%) had access to BSL-4 containment laboratories (with overlap in access to BSL-3 and BSL-4 containment laboratories).

Limitations of this study included that the survey did not differentiate which tests, diagnostic or routine, were performed within the isolation unit, clinical laboratory, or PHL. Some ETCs responded to the survey question on the location of laboratory support by making only a single selection rather than checking all that applied, so answers were interpreted as laboratory support in closest proximity to the patient room. Thus, the cross-sectional design of this survey provided a limited snapshot of the current laboratory capabilities of US ETCs. One ETC also indicated simultaneous construction of a BSL-3 laboratory within their isolation unit during completion of the survey.

In general, US ETCs were rapidly created in response to the Ebola epidemic of 2014 to 2015, and the care and laboratory capabilities of these facilities will continue to transform as plans for sustainability and the national role in responses to highly infectious diseases are refined.

Further details need to be considered regarding specific recommendations for the types of tests that need to be available to care for a patient with a highly infectious pathogen, the locations that are optimal for laboratory testing, the types of PPE utilized and training available, and qualified staff to perform laboratory testing. An expanded future survey to demonstrate the evolution of ETC facilities and to gain a more complete picture of national capabilities within this area is planned.

Appendix D. Follow-up Ebola Treatment Center Survey (2016)

Please indicate the name of the Ebola Treatment Center (ETC) sponsoring hospital and location:

Hospital: _____ City/State: _____

Point(s) of contact (Name/Email): _____

Personnel Management

A. Staff Selection (+ denotes definition provided in appendix)

Are staff:+

Allowed to opt out of working in the ETC/RTC?

YES NO

If yes, what are the criteria to opt out (e.g. pregnancy): _____

Entirely volunteer-based (staff opt into working in the ETC/RTC)?

YES NO

Composed of a hybrid of volunteer workers, required supervisors, and other trained staff?

YES NO

Composed solely of personnel who are employed by the sponsoring facility⁺/hospital?

YES NO

If no, please specify which staff are not employed by the sponsoring facility/hospital (e.g. security): _____

Please select whether the ETC/RTC evaluates potential employees based on selection criteria (e.g. screening mental and/or physical health), has a plan to recruit new staff members, and requires staff to have experience⁺ working in their field for each of the following positions.

Position	Evaluation of	Recruitment plan		Years of experience ⁺			
		Yes	No				
Nurses	Attitude	<input type="checkbox"/>	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No requirement	<input type="checkbox"/>
	Physical fitness	<input type="checkbox"/>	<input type="checkbox"/>	No	<input type="checkbox"/>	<1 year	<input type="checkbox"/>
	Clinical skills	<input type="checkbox"/>				1-4 years	<input type="checkbox"/>
	No evaluation plan	<input type="checkbox"/>				5-9 years	<input type="checkbox"/>
	Other (please specify)	<input type="checkbox"/>				≥10 years	<input type="checkbox"/>
<hr/>							
Physicians	Attitude	<input type="checkbox"/>	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No requirement	<input type="checkbox"/>
	Physical fitness	<input type="checkbox"/>	<input type="checkbox"/>	No	<input type="checkbox"/>	<1 year	<input type="checkbox"/>
	Clinical skills	<input type="checkbox"/>				1-4 years	<input type="checkbox"/>
	No evaluation plan	<input type="checkbox"/>				5-9 years	<input type="checkbox"/>
	Other (please specify)	<input type="checkbox"/>				≥10 years	<input type="checkbox"/>
<hr/>							
Respiratory	Attitude	<input type="checkbox"/>	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No requirement	<input type="checkbox"/>
Therapists	Physical fitness	<input type="checkbox"/>	<input type="checkbox"/>	No	<input type="checkbox"/>	<1 year	<input type="checkbox"/>
	Clinical skills	<input type="checkbox"/>				1-4 years	<input type="checkbox"/>
	No evaluation plan	<input type="checkbox"/>				5-9 years	<input type="checkbox"/>
	Other (please specify)	<input type="checkbox"/>				≥10 years	<input type="checkbox"/>
<hr/>							
Patient Care	Attitude	<input type="checkbox"/>	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No requirement	<input type="checkbox"/>
Technicians	Physical fitness	<input type="checkbox"/>	<input type="checkbox"/>	No	<input type="checkbox"/>	<1 year	<input type="checkbox"/>

	Clinical skills	<input type="checkbox"/>			1-4 years	<input type="checkbox"/>
	No evaluation plan	<input type="checkbox"/>			5-9 years	<input type="checkbox"/>
	Other (please specify)	<input type="checkbox"/>			≥10 years	<input type="checkbox"/>
<hr/>						
Laboratory	Attitude	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No requirement	<input type="checkbox"/>
Specialists/ Technologists	Physical fitness	<input type="checkbox"/>	No	<input type="checkbox"/>	<1 year	<input type="checkbox"/>
	Clinical skills	<input type="checkbox"/>			1-4 years	<input type="checkbox"/>
	No evaluation plan	<input type="checkbox"/>			5-9 years	<input type="checkbox"/>
	Other (please specify)	<input type="checkbox"/>			≥10 years	<input type="checkbox"/>
<hr/>						
Environmental Specialists	Attitude	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No requirement	<input type="checkbox"/>
	Physical fitness	<input type="checkbox"/>	No	<input type="checkbox"/>	<1 year	<input type="checkbox"/>
	Clinical skills	<input type="checkbox"/>			1-4 years	<input type="checkbox"/>
	No evaluation plan	<input type="checkbox"/>			5-9 years	<input type="checkbox"/>
	Other (please specify)	<input type="checkbox"/>			≥10 years	<input type="checkbox"/>
<hr/>						
Environmental Technicians	Attitude	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No requirement	<input type="checkbox"/>
	Physical fitness	<input type="checkbox"/>	No	<input type="checkbox"/>	<1 year	<input type="checkbox"/>
	Clinical skills	<input type="checkbox"/>			1-4 years	<input type="checkbox"/>
	No evaluation plan	<input type="checkbox"/>			5-9 years	<input type="checkbox"/>
	Other (please specify)	<input type="checkbox"/>			≥10 years	<input type="checkbox"/>
<hr/>						
Consultants	Attitude	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No requirement	<input type="checkbox"/>
	Physical fitness	<input type="checkbox"/>	No	<input type="checkbox"/>	<1 year	<input type="checkbox"/>

	Clinical skills	<input type="checkbox"/>		1-4 years	<input type="checkbox"/>
	No evaluation plan	<input type="checkbox"/>		5-9 years	<input type="checkbox"/>
	Other (please specify)	<input type="checkbox"/>		≥10 years	<input type="checkbox"/>
<hr/>					
Others	Attitude	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No requirement <input type="checkbox"/>
(please specify)	Physical fitness	<input type="checkbox"/>	No	<input type="checkbox"/>	<1 year <input type="checkbox"/>
	Clinical skills	<input type="checkbox"/>		1-4 years	<input type="checkbox"/>
	No evaluation plan	<input type="checkbox"/>		5-9 years	<input type="checkbox"/>
	Other (please specify)	<input type="checkbox"/>		≥10 years	<input type="checkbox"/>
<hr/>					

If yes to any physical fitness, how is physical fitness assessed (check all that apply)?

Lifting

Cardio

Pulmonary function

Other (please specify) _____

If yes to any clinical skills, how are clinical skills assessed (check all that apply)?

Clinical competence

Procedural skills

Others (please specify) _____

B. Training

Does the ETC/RTC implement orientation training to be completed before staff are allowed to work in the isolation room/unit?

YES NO IN DEVELOPMENT

If yes, please specify the method(s) and duration (hours) of orientation training for staff to work in the isolation room/unit: (check all that apply)

Method	Conducted	Planned	Hours
“Hands on” demonstration of skills	<input type="checkbox"/>	<input type="checkbox"/>	_____
Lecture/course	<input type="checkbox"/>	<input type="checkbox"/>	_____
Video	<input type="checkbox"/>	<input type="checkbox"/>	_____
Reading	<input type="checkbox"/>	<input type="checkbox"/>	_____
Other (please specify) _____	<input type="checkbox"/>	<input type="checkbox"/>	_____

If yes to orientation training, must trainees successfully demonstrate competence (i.e. perform manual skills and medical care procedures) to their instructors before working in the isolation room/unit (i.e. not solely attend a course)?

YES NO

If yes, please detail how (i.e. which manual skills and medical care procedures) trainees demonstrate competence:

If yes to trainee demonstration, are trainees observed to ensure possession of these skills while wearing PPE?

YES NO

If yes, please detail how are trainees observed to possess these skills while wearing PPE:

Must staff undergo re-training/continuing education?

YES NO IN DEVELOPMENT

If yes, please specify the method(s) and duration (hours) of re-training/continuing education:

Method	Conducted	Planned	Hours
"Hands on" demonstration	<input type="checkbox"/>	<input type="checkbox"/>	_____
Lecture/course	<input type="checkbox"/>	<input type="checkbox"/>	_____
Video	<input type="checkbox"/>	<input type="checkbox"/>	_____
Reading	<input type="checkbox"/>	<input type="checkbox"/>	_____
Other (please specify) _____	<input type="checkbox"/>	<input type="checkbox"/>	_____

If answered "yes" to 1 or 2 above, please specify the duration of training (hours), whether staff are required to pass a skills competency check before working in the isolation room/unit, whether staff undergo re-training/continuing education (CE), and if applicable, frequency of re-training/CE (e.g., quarterly), duration (hours) of re-training/CE required for each position listed below:

Position	Hours of Training	Skills check	Re-training/CE	Frequency
Nurses	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
Physicians	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
Respiratory				
Therapists	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
Patient Care				
Technicians	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
Laboratory Specialists/ Technologists	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
Environmental Technicians	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____

Environmental

Specialists _____ _____

Consultants _____ _____

Others _____ _____

(please specify) _____

Does the ETC/RTC perform “just-in-time” (JIT) training before personnel work in the isolation room/unit in PPE?

YES NO

If yes, please specify under what circumstances the ETC/RTC would perform JIT training:

Does the ETC/RTC incorporate students/residents/fellows into activities?

YES NO

If yes, please specify if this measure involves: (check all that apply)

Students

Residents

Fellows

Others (please specify) _____

If students/residents/fellows are integrated into the ETC/RTC workflows, please specify:

Are students/residents/fellows allowed into the:

Patient room

Warm zone

Cold zone

Other (please specify) _____

Would students/residents/fellows participate in ETC/RTC activities *outside of the isolation room/unit* (e.g. through a video link, logistics coordination/preparation, direct observation through window)?

YES NO

If yes, please specify how students/residents/fellows would participate in procedures outside of the isolation room/unit: _____

C. Staffing Model

Approximate total number of staff currently trained to work in the isolation room/unit (or ambulance during patient transportation) in PPE (please indicate "NA" if non-applicable to the ETC/RTC):

Registered nurses _____

Internal medicine MD _____

Pediatric MD _____

Clinicians trained in critical care _____

Respiratory therapists _____

Laboratory/pathology staff _____

(either working in isolation room/unit or in laboratory in PPE depending on unit plan)

Environmental specialists _____

Environmental technicians _____

Security staff _____

EMS personnel _____

Others (please specify)	_____
Specialist MD	
Infectious disease	_____
Obstetrics	_____
Surgeons	_____
Anesthesiologists	_____
Emergency medicine	_____
Critical care	_____
Others (please specify) _____	_____

Are the following services available to the ETC/RTC either as an employee, outside contractor, or other during planning, activation, or both, with specific roles and functions within the unit in case of an event? (check all that apply)

Services	Role	
Infection control team and/or responsible person (prevent/reduce cross-infection)	Available	<input type="checkbox"/>
	During planning	<input type="checkbox"/>
	During activation	<input type="checkbox"/>
	Facility Employee	<input type="checkbox"/>
	Outside contractor	<input type="checkbox"/>
	Other (please specify) _____	<input type="checkbox"/>
	Occupational health service/responsible person (promote/maintain worker mental, physical,	Available
	During planning	<input type="checkbox"/>

and social wellbeing)

During activation

Facility employee

Outside contractor

Other (please specify) _____

Bio-safety committee and/or manager

Available

(ensure regulatory compliance and safety in
handling infectious or biohazardous materials;
qualified as Biosafety Officer, Certified Biological
Safety Professional (CBSP), or Registered
Biosafety Professional (RBP))

During planning

During activation

Facility employee

Outside contractor

Other (please specify) _____

Decontamination specialist

Available

(ensure disinfection of contaminated environmental
surfaces, medical equipment, etc.)

During planning

During activation

Facility employee

Outside contractor

Other (please specify) _____

Waste manager

Available

(ensure safe collection, transport, treatment, and
disposal of infectious waste generated in unit)

During planning

During activation

Facility employee

Outside contractor

Other (please specify) _____

Industrial hygienist

(identify, assess, and reduce occupational health hazards/risks)

Available

During planning

During activation

Facility employee

Outside contractor

Other (please specify) _____

Internal risk communication

(initiates/maintains dialogue with internal team on risk presented by isolation room/unit)

Available

During planning

During activation

Facility employee

Outside contractor

Other (please specify) _____

Logistics manager

(plans/manages flow of materials to complete activities of isolation room/unit)

Available

During planning

During activation

Facility employee

Outside contractor

Other (please specify) _____

Pastoral services

Available

(offers spiritual or religious services to staff, family members, patients, etc.)

During planning

During activation

Facility employee

Outside contractor

Other (please specify) _____

Mental health provider

(offers mental health services to staff, family members, patients, etc.)

Available

During planning

During activation

Facility employee

Outside contractor

Other (please specify) _____

Other services (please specify)

Available

During planning

During activation

Facility employee

Outside contractor

Other (please specify) _____

Is the ETC/RTC directed by a “leadership team,” or group of individuals responsible for management duties (e.g. financial management, education/training coordination, lead medical and nursing care)?

YES NO

If yes, please specify which of the following roles are represented within the “leadership team” and which receive compensation or full-time equivalent (FTE) for their work:

Position	Available	Compensation or FTE
Senior Executive (Executive Director, VP, or higher)	<input type="checkbox"/>	<input type="checkbox"/>
Medical Director	<input type="checkbox"/>	<input type="checkbox"/>
Nursing Director	<input type="checkbox"/>	<input type="checkbox"/>
Laboratory Director	<input type="checkbox"/>	<input type="checkbox"/>
Training Director	<input type="checkbox"/>	<input type="checkbox"/>
Environmental Services Director	<input type="checkbox"/>	<input type="checkbox"/>
Industrial Hygienist	<input type="checkbox"/>	<input type="checkbox"/>
Transportation Logistics Director	<input type="checkbox"/>	<input type="checkbox"/>
Waste Manager	<input type="checkbox"/>	<input type="checkbox"/>
Public Relations	<input type="checkbox"/>	<input type="checkbox"/>
Building Staff	<input type="checkbox"/>	<input type="checkbox"/>
Human Resources Staff	<input type="checkbox"/>	<input type="checkbox"/>
Biomedical Engineer	<input type="checkbox"/>	<input type="checkbox"/>
Materials Management	<input type="checkbox"/>	<input type="checkbox"/>
Others (please specify) _____	<input type="checkbox"/>	<input type="checkbox"/>

If yes, please specify how often the “leadership team” will meet while the isolation room/unit is vacant? _____ (e.g. monthly)

Does the ETC/RTC plan to utilize an incident command system (ICS) at any point during activation?

YES NO

If yes, please specify when the ICS will be activated: (select all that apply)

At all times during unit operations

During patient transportation

During patient care

Other times (please specify) _____

Does the ETC/RTC have a pre-specified plan for working in shifts within the isolation room/unit?

YES NO

If yes, please specify for which position(s) work shifts are applied, the number of shifts per day, and the number of hours per shift for each position:

Position	Shifts	Shifts Per Day	Hours per shift
Nurses	<input type="checkbox"/>	_____	_____
Physicians	<input type="checkbox"/>	_____	_____
Respiratory Therapists	<input type="checkbox"/>	_____	_____
Patient Care Technicians	<input type="checkbox"/>	_____	_____
Laboratory Technologists/Specialists	<input type="checkbox"/>	_____	_____
Environmental Specialists	<input type="checkbox"/>	_____	_____
Environmental Technicians	<input type="checkbox"/>	_____	_____
Consultants	<input type="checkbox"/>	_____	_____
Others (please specify) _____	<input type="checkbox"/>	_____	_____

Does the ETC/RTC incorporate breaks for staff during activation shifts?

YES NO

Please indicate if the ETC/RTC provides the following for unit staff: (check all that apply)

- Dedicated break area
- Hydration
- Food
- Other (please specify) _____

Please specify how many staff at minimum would be present within the isolation room/unit and the minimum number in full PPE *at all times when activated* (for one patient).

Position	Number in isolation room/unit	Number in full PPE
Nurses	_____	_____
Physicians	_____	_____
Respiratory therapists	_____	_____
Care technicians	_____	_____
Others (please specify) _____	_____	_____

When activated, are the ETC/RTC staff “dedicated” to only caring for highly infectious disease (HID)⁺ patients within the isolation room/unit (i.e. staff do *not* provide care for patients in other units)?

YES NO

If yes, please specify if this measure involves:

- Physicians
- Nurses
- Respiratory Therapists
- Patient Care Technicians
- Laboratory Technologists/Specialists

- Environmental Specialists
- Environmental Technicians
- Consultants
- Others (please specify) _____

Can the facility's clinical care providers see other patients immediately after a highly infectious patient has been discharged from the isolation room/unit (i.e. are staff under quarantine from caring for other patients following HID patient care)?

YES NO

If no, please specify if this is a restriction imposed by:

- Hospital regulation
- Local public health regulation
- State regulation
- Other (please specify) _____

Does the ETC/RTC have procedures for health monitoring (twice daily temperature and symptoms) of all staff after working in the isolation room/unit or coming into contact (no exposure) with infectious substances (e.g. laboratory testing)?

YES NO

If yes, is the health surveillance: (check all that apply)

- Reported to the local/state public health department
- Performed at home (with check of temperature)
- Performed at the hospital (not in isolation room/unit)
- Performed at the hospital (in isolation room/unit)

Website/online data entry

Other locations (please specify) _____

Do staff receive a pay differential while working in the *activated* isolation room/unit (e.g. hazards pay)?

YES NO

Do staff receive compensation (e.g., pay differential, bonus) *for being staff members* of the ETC/RTC?

YES NO

As applicable, please specify if compensation involves: **When activated** **As staff**

Physicians

Nurses

Respiratory Therapists

Patient Care Technicians

Laboratory Technologists/Specialists

Environmental Specialists

Environmental Technicians

Consultants

Others (please specify) _____

Is a plan/protocol in place to identify and address staffing shortage concerns?

YES NO

If yes, please specify if the plan/protocol is implemented: (check all that apply)

Prior to activation

During activation

Is it mandatory for staff to have contact with an employee assistance program (EAP) or some other counseling services?

YES NO

If yes, please indicate when the EAP/counseling is required:

Prior to isolation room/unit activation

During isolation room/unit activation

Following isolation room/unit activation

Other (please specify) _____

Are staff scheduled to work in the ETC/RTC in advance, even when not activated (e.g. ghost schedule)?

YES NO

If yes, how far in advance are staff scheduled? _____(weeks)

If no, please explain how staff are scheduled once the ETC/RTC is activated:

Does the ETC/RTC serve as an Ebola Assessment Hospital for patients under investigation (PUIs) for HIDs?

YES NO

If yes, does the facility plan to use only ETC/RTC staff to care for PUI cases?

YES NO

If yes, please indicate where PUIs are placed:

In the ETC/RTC isolation room/unit

In the hospital (e.g. emergency department)

Other (please specify) _____

D. Sustainability Management

Is the ETC/RTC's isolation room/unit used to care for non-HID patients when not activated?

YES NO

If yes, how many beds will be out of commission if the isolation room/unit is activated to care for *one* HID patient? _____ (number of beds)

If yes, how many beds will be out of commission if the isolation room/unit is activated to care for *two* HID patients? _____ (number of beds)

If yes, would you prefer to have an isolation room/unit dedicated to the care of patients with HIDs?

YES NO

If yes to preferring a dedicated HID isolation room/unit, what are the estimated costs of developing an isolation room/unit for the care of 2 patients with HIDs? \$ _____

If yes to preferring a dedicated HID isolation room/unit, what are the perceived benefits of having an isolation room/unit dedicated to the care of patients with HIDs? _____

Is the ETC/RTC willing/able to accept patients from outside the ETC/RTC's legal jurisdiction?

YES NO

If no, please specify if this is a restriction imposed by: (check all that apply)

Hospital policy

Local public health policy/regulation

State policy/regulation

Other (please specify) _____

Can the ETC/RTC isolation room/unit and staff be activated 24/7 throughout the year?

YES NO

No information / other (please specify) _____

Quantify the amount of time necessary from first notification of an incoming patient to activate the ETC/RTC as operational: _____ (hours)

Does a protocol exist for the ETC/RTC to contact team members, consultants, and other involved services 24/7 throughout the year?

YES NO

If yes, does the ETC/RTC use the following methods to notify staff of activation: (check all that apply)

Electronic notification system

Call tree

Other (please specify) _____

If yes, please specify by which method(s) ETC/RTC's team members, consultants, and services are contacted: (check all that apply)

Phone call

Email

Pager

Text

Other (please specify) _____

Is the ETC/RTC able to sustain staffing for *one* patient with Ebola virus disease (EVD) for 28 days?

YES NO

If no, how long can staffing be sustained for *one* patient? _____ (days)

Is the ETC/RTC able to sustain staffing for *two* EVD patients for 28 days?

YES NO

If no, how long can staffing be sustained for *two* EVD patients? _____ (days)

What is the maximum capacity in caring for patients with EVD? _____ (patients)

Is the ETC/RTC able to sustain staffing for *one* Middle East respiratory syndrome (MERS) patient for 28 days?

YES NO

If no, how long can staffing be sustained for *one* MERS patient? _____ (days)

Is the ETC/RTC able to sustain staffing for *two* MERS patients for 28 days?

YES NO

If no, how long can staffing be sustained for *two* MERS patients? _____ (days)

What is the maximum capacity in caring for patients with MERS? _____ (patients)

Is the local/state public health department involved in managing public health concerns outside the ETC/RTC (e.g. question hotlines, follow-up with patient contacts) if activated?

YES NO UNKNOWN

If yes, what are the responsibilities of the local/state public health department during ETC/RTC activation?

If yes, is the local/state public health department available to manage public health concerns outside the ETC/RTC 24/7 throughout the entire year?

YES NO UNKNOWN

Other (please specify) _____

Management of Personal Protective Equipment (PPE)

A. Selection of PPE

Does the ETC/RTC have protocols/procedures for the selection of differing kinds of PPE ensembles depending on patient acuity and the type of procedures required during expected patient care (routine care versus aerosol-generating procedures, such as bronchoscopy and sputum induction)?

YES NO

If yes, please specify if the PPE selection procedures were: (check all that apply)

Developed by infectious diseases (ID) specialists

Developed by infection control (IC) specialists

Developed by occupational medicine specialists

Others (please specify) _____

If no, are complete suits used, including respiratory protection (powered air purifying respirators (PAPRs)), at all times during patient care?

YES NO

B. Use of PPE

Does the ETC/RTC have strategies for implementing and monitoring the correct use of PPE?

YES NO

If yes, please indicate which of the following strategies are applied: (check all that apply)

Checklist on donning and doffing order posted in donning/doffing areas

Cross check between staff (i.e. donning partner)

Supervision by a trained observer (e.g. infection control expert)

Doffing partner

Full body mirror used for self-assessment

PPE inspected for defects (e.g. holes) prior to donning (application)

Seal/fit check of respiratory mask before entering patient room (as applicable)

Other (please specify) _____

Does the ETC/RTC have protocols for a maximum time shift allowed in full PPE (e.g. for patient care) without changing?

YES NO

If yes, what is the ETC/RTC's maximum time allowed in full PPE? _____ (hours)

Answer questions 3-4 only if the ETC/RTC implements PPE other than a complete PAPR suit.

Are fit-tests performed to all staff potentially involved in the care of an HID patient in compliance with the facility's respiratory protection program?

YES NO

Does the facility have protocols for the periodical repetition of fit-test?

YES NO

If yes, when are fit-tests repeated? (check all that apply)

Every year

When there is a change in facial features of the wearer

When a medical condition affecting respiratory function of the wearer emerges

When there is a change in the manufacturer providing PPE

Other (please specify) _____

C. PPE supplying

Does the ETC/RTC have procedures for ensuring adequate PPE quantities in case of sudden increase of demand?

YES NO

If yes, which strategy of the following is used: (check all that apply)

Supplying from an external structure/institution

Internal stockpiling

Other (please specify) _____

Does the ETC/RTC have protocols and/or a responsible person for monitoring stockpiled PPE for the expiration date?

YES NO

Do protocols exist for the decontamination of PPE for re-use, in case of shortage?

YES NO

If yes, for which PPE do decontamination protocols exist? Please list:

If yes, does the ETC/RTC have protocols for the decontamination of complete suits (including powered air purifying respirators (PAPRs)) for reuse?

YES NO

If yes, please specify for which materials:

PAPR motor blower

PAPR hose

PAPR belt

Outside of PAPR filters

Suits

Hoods

Other (please specify) _____

Infection Control Procedures and Promotion

A. Staffing infection control

Does the ETC/RTC have specific emergency procedures in case of PPE damage, leakage, or other accidents during use in the isolation room/unit?

YES NO

If yes, please detail: _____

Does the ETC/RTC have procedures for post-exposure evaluation and health monitoring of staff following an exposure (e.g. needlestick, skin contact with infectious fluid)?

YES NO

If yes, is health monitoring performed: (check all that apply)

On the basis of a risk-assessment

At home (with check of temperature)

At the hospital (not in isolation room/unit)

At the hospital (in isolation room/unit)

Other (please specify) _____

If yes, who medically evaluates an employee after an exposure? _____

If yes, what is the time period until the medical evaluation after an exposure? __ (hours)

If yes, how often after an exposure is the health evaluation/monitoring performed (e.g. daily)?

B. Hand hygiene

Are there any strategies for the promotion of the correct hand hygiene practices among staff?

YES NO

If yes, please clarify type of strategy used: (check all that apply)

- Campaign
- Leaflets
- Posters
- Videos
- On-site exercises
- Lectures
- Other (please specify) _____

Are there any procedures established for monitoring adherence of staff with correct hand hygiene practices?

YES NO

If yes, please describe: _____

C. Routine hygiene during activation and final disinfection

Existence of specific procedures/written protocols for *routine hygiene* of isolation room/unit?

YES NO

If yes, please which method(s) of routine hygiene the isolation room/unit utilizes: (check all that apply)

- Surface disinfection process (removal of pathogen organisms)
- Surface cleaning process (removal of debris such as dirt, blood)
- Other (please specify) _____

Existence of specific procedures/written protocols for *final decontamination* of isolation room/unit (after the patient has been discharged from the room)?

YES NO

If yes, please specify which methods of final decontamination the isolation room/unit utilizes:

(check all that apply)

Final fumigation or UV light exposure process

Surface disinfection process

Surface cleaning process

Other (please specify) _____

If final decontamination involves final fumigation or UV light exposure, please specify the method(s) of decontamination utilized: (check all that apply)

UV light

Vaporized hydrogen peroxide

Gaseous chlorine dioxide

Other (please specify) _____

Does the ETC/RTC designate staff to observe final decontamination to provide quality assurance of the decontamination process?

YES NO

As applicable, please specify which staff perform the following tasks (waste handling defined as transporting, packaging, and/or autoclaving waste): (check all that apply)

Routine

Final

Observe final

Waste

	hygiene	decontamination	decontamination	handling
Physicians	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nurses	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Respiratory Therapists	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patient Care Technicians	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lab Technologists/Specialists	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Environmental Specialists	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Environmental Technicians	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Consultants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Others (please specify)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Does the ETC/RTC plan to transport the highly infectious patient to an area within the facility but outside of the isolation room/unit (e.g. operating room, x-rays, MRI, Cardiac Cath lab, etc.) at any point to provide care?

YES NO

If yes, please specify the areas in the facility to which the patient would be transported for care:

If yes, does the facility have final decontamination procedures for the areas to which the highly infectious patient is transported?

YES NO

Existence of specific procedures for hygiene and/or disinfection of medical devices (e.g. dialysis machine, bronchoscopy, gastroscopy, ultrasound machines) after contact with HID patient?

YES NO

Please specify the ETC/RTC's methods for final decontamination of medical devices: (check all that apply)

Final fumigation or UV light exposure process

Surface disinfection process

Surface cleaning process

Destruction/disposal

Other (please specify) _____

If yes, specify the *location* of hygiene/disinfection of these medical devices: (check all that apply)

Within the isolation room/unit

In a BSL (biosafety level) 2 laboratory

In a BSL 3 laboratory

Central sterilization area of the facility

Other (please specify) _____

Are personnel performing routine hygiene and final decontamination of the ETC/RTC required to complete training (e.g. PPE donning and doffing) before working in the isolation room/unit?

YES NO

If yes, please specify if these personnel complete: (check all that apply)

Orientation training

JIT training

Other (please specify) _____

Existence of specific procedures for the management (i.e. movement to crematorium) of human remains of HID patients?

YES NO

If yes, does the ETC/RTC have a memorandum of understanding (MoU) with funeral home/crematorium for disposition of human remains of HID patients?

YES NO

Existence of specific procedures for the safe performance of an autopsy?

YES NO

If yes, please specify if the autopsy is completed: (check all that apply)

By specially-trained pathologist in HIDs or specific experience working in PPE

By non-specifically trained/experienced pathologist

Under the supervision of an infection control expert

Only needle necropsies are performed

Other (please describe) _____

If yes, does the ETC/RTC have specific medical devices for the safe performance of an autopsy (i.e. high-level PPE, devices to reduce aerosolization)?

YES NO

If yes, please list devices used to safely perform an autopsy:

D. Biosecurity

Is access to the isolation room/unit restricted when activated?

YES NO

If yes, is access to isolation room/unit restricted by: (check all that apply)

Key/card access

Security

Must show identification to enter

Other (please specify) _____

If no, please explain access to the isolation room/unit: _____

Does the ETC/RTC enable methods of communication for the HID patient with family, friends, etc.?

YES NO

If yes, please specify which of the following the ETC/RTC utilizes for patient communication:

(check all that apply)

Video link

Texting

Internet chat

Internet access

Phone calls

Other (please specify) _____

Are family members of the adult HID patient allowed to visit within the isolated patient room in PPE during activation?

YES NO

If yes, are family members of the adult HID patient allowed to enter and exit the isolation room/unit:

At any hour

At specified hours

Please describe: _____

Family members remain in the isolation room/unit throughout activation

Other (please specify) _____

If applicable to the ETC/RTC: In the care of a pediatric HID patient, are family members of the pediatric HID patient allowed within the isolated patient room in PPE during activation?

YES NO

If yes, are parents of the pediatric HID patient allowed to enter and exit the isolation room/unit:

At any hour

At specified hours

Please describe: _____

Parents remain in the isolation room/unit throughout activation

Other (please specify) _____

Laboratory Capabilities

A. Diagnostic Laboratory Capabilities

Please specify tool(s) available to provide diagnostic testing for a patient with a **HID** (excluding the Centers for Disease Control and Prevention laboratory for confirmatory testing) and the tool location if available:

Diagnostic tool	Available	Location of tool
Incubator for bacteria culture	<input type="checkbox"/>	Patient room <input type="checkbox"/>
		Isolation unit (not pt room) <input type="checkbox"/>
		Facility (not in room/unit) <input type="checkbox"/>
		Core hospital lab <input type="checkbox"/>
		Clinical hospital lab <input type="checkbox"/>
		Outside facility <input type="checkbox"/>
		Public health/state lab <input type="checkbox"/>
		Reference/private lab <input type="checkbox"/>
		Other (please specify) <input type="checkbox"/>

Biological safety cabinet	<input type="checkbox"/>	Patient room <input type="checkbox"/>
		Isolation unit (not pt room) <input type="checkbox"/>
		Facility (not in room/unit) <input type="checkbox"/>
		Core hospital lab <input type="checkbox"/>
		Clinical hospital lab <input type="checkbox"/>
		Outside facility <input type="checkbox"/>
		Public health/state lab <input type="checkbox"/>
		Reference/private lab <input type="checkbox"/>
		Other (please specify) <input type="checkbox"/>

Polymerase chain reaction (PCR) assay <input type="checkbox"/>	<input type="checkbox"/>	Patient room <input type="checkbox"/>
		Isolation unit (not pt room) <input type="checkbox"/>
		Facility (not in room/unit) <input type="checkbox"/>

		Core hospital lab	<input type="checkbox"/>
		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>
		Public health/state lab	<input type="checkbox"/>
		Reference/private lab	<input type="checkbox"/>
		Other (please specify)	<input type="checkbox"/>
		<hr/>	
Enzyme immunoassay (EIA) reader	<input type="checkbox"/>	Patient room	<input type="checkbox"/>
		Isolation unit (not pt room)	<input type="checkbox"/>
		Facility (not in room/unit)	<input type="checkbox"/>
		Core hospital lab	<input type="checkbox"/>
		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>
		Public health/state lab	<input type="checkbox"/>
		Reference/private lab	<input type="checkbox"/>
		Other (please specify)	<input type="checkbox"/>
		<hr/>	
Microscope	<input type="checkbox"/>	Patient room	<input type="checkbox"/>
		Isolation unit (not pt room)	<input type="checkbox"/>
		Facility (not in room/unit)	<input type="checkbox"/>
		Core hospital lab	<input type="checkbox"/>
		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>
		Public health/state lab	<input type="checkbox"/>

		Reference/private lab	<input type="checkbox"/>
		Other (please specify)	<input type="checkbox"/>

Screening for HIV pathogen	<input type="checkbox"/>	Patient room	<input type="checkbox"/>
(e.g. Biofire FilmArray, other)		Isolation unit (not pt room)	<input type="checkbox"/>
		Facility (not in room/unit)	<input type="checkbox"/>
		Core hospital lab	<input type="checkbox"/>
		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>
		Public health/state lab	<input type="checkbox"/>
		Reference/private lab	<input type="checkbox"/>
		Other (please specify)	<input type="checkbox"/>

Other (please specify)	<input type="checkbox"/>	Patient room	<input type="checkbox"/>
_____		Isolation unit (not pt room)	<input type="checkbox"/>
		Facility (not in room/unit)	<input type="checkbox"/>
		Core hospital lab	<input type="checkbox"/>
		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>
		Public health/state lab	<input type="checkbox"/>
		Reference/private lab	<input type="checkbox"/>
		Other (please specify)	<input type="checkbox"/>

B. Laboratory Tests/Tools

Please specify test(s)/tool(s) available for **HID patient clinical care** and test location if available:

Laboratory test/tool available	Available	Location of test/tool
CBC count w/ automated differential	<input type="checkbox"/>	Patient room <input type="checkbox"/>
		Isolation unit (not pt room) <input type="checkbox"/>
		Facility (not in room/unit) <input type="checkbox"/>
		Core hospital lab <input type="checkbox"/>
		Clinical hospital lab <input type="checkbox"/>
		Outside facility <input type="checkbox"/>
		Public health/state lab <input type="checkbox"/>
		Reference/private lab <input type="checkbox"/>
		Other (please specify) <input type="checkbox"/>
<hr/>		
Basic metabolic panel	<input type="checkbox"/>	Patient room <input type="checkbox"/>
		Isolation unit (not pt room) <input type="checkbox"/>
		Facility (not in room/unit) <input type="checkbox"/>
		Core hospital lab <input type="checkbox"/>
		Clinical hospital lab <input type="checkbox"/>
		Outside facility <input type="checkbox"/>
		Public health/state lab <input type="checkbox"/>
		Reference/private lab <input type="checkbox"/>
		Other (please specify) <input type="checkbox"/>
<hr/>		

Magnesium	<input type="checkbox"/>	Patient room	<input type="checkbox"/>
		Isolation unit (not pt room)	<input type="checkbox"/>
		Facility (not in room/unit)	<input type="checkbox"/>
		Core hospital lab	<input type="checkbox"/>
		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>
		Public health/state lab	<input type="checkbox"/>
		Reference/private lab	<input type="checkbox"/>
		Other (please specify)	<input type="checkbox"/>
		<hr/>	
Comprehensive metabolic panel	<input type="checkbox"/>	Patient room	<input type="checkbox"/>
		Isolation unit (not pt room)	<input type="checkbox"/>
		Facility (not in room/unit)	<input type="checkbox"/>
		Core hospital lab	<input type="checkbox"/>
		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>
		Public health/state lab	<input type="checkbox"/>
		Reference/private lab	<input type="checkbox"/>
		Other (please specify)	<input type="checkbox"/>
		<hr/>	
Ionized calcium	<input type="checkbox"/>	Patient room	<input type="checkbox"/>
		Isolation unit (not pt room)	<input type="checkbox"/>
		Facility (not in room/unit)	<input type="checkbox"/>
		Core hospital lab	<input type="checkbox"/>

		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>
		Public health/state lab	<input type="checkbox"/>
		Reference/private lab	<input type="checkbox"/>
		Other (please specify)	<input type="checkbox"/>
		<hr/>	
Standard calcium	<input type="checkbox"/>	Patient room	<input type="checkbox"/>
		Isolation unit (not pt room)	<input type="checkbox"/>
		Facility (not in room/unit)	<input type="checkbox"/>
		Core hospital lab	<input type="checkbox"/>
		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>
		Public health/state lab	<input type="checkbox"/>
		Reference/private lab	<input type="checkbox"/>
		Other (please specify)	<input type="checkbox"/>
		<hr/>	
Phosphorous	<input type="checkbox"/>	Patient room	<input type="checkbox"/>
		Isolation unit (not pt room)	<input type="checkbox"/>
		Facility (not in room/unit)	<input type="checkbox"/>
		Core hospital lab	<input type="checkbox"/>
		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>
		Public health/state lab	<input type="checkbox"/>
		Reference/private lab	<input type="checkbox"/>

		Other (please specify)	<input type="checkbox"/>

Cortisol	<input type="checkbox"/>	Patient room	<input type="checkbox"/>
		Isolation unit (not pt room)	<input type="checkbox"/>
		Facility (not in room/unit)	<input type="checkbox"/>
		Core hospital lab	<input type="checkbox"/>
		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>
		Public health/state lab	<input type="checkbox"/>
		Reference/private lab	<input type="checkbox"/>
		Other (please specify)	<input type="checkbox"/>

Troponin	<input type="checkbox"/>	Patient room	<input type="checkbox"/>
		Isolation unit (not pt room)	<input type="checkbox"/>
		Facility (not in room/unit)	<input type="checkbox"/>
		Core hospital lab	<input type="checkbox"/>
		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>
		Public health/state lab	<input type="checkbox"/>
		Reference/private lab	<input type="checkbox"/>
		Other (please specify)	<input type="checkbox"/>

Blood gases	<input type="checkbox"/>	Patient room	<input type="checkbox"/>
		Isolation unit (not pt room)	<input type="checkbox"/>

		Facility (not in room/unit)	<input type="checkbox"/>
		Core hospital lab	<input type="checkbox"/>
		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>
		Public health/state lab	<input type="checkbox"/>
		Reference/private lab	<input type="checkbox"/>
		Other (please specify)	<input type="checkbox"/>

Lactate	<input type="checkbox"/>	Patient room	<input type="checkbox"/>
		Isolation unit (not pt room)	<input type="checkbox"/>
		Facility (not in room/unit)	<input type="checkbox"/>
		Core hospital lab	<input type="checkbox"/>
		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>
		Public health/state lab	<input type="checkbox"/>
		Reference/private lab	<input type="checkbox"/>
		Other (please specify)	<input type="checkbox"/>

Prothrombin time	<input type="checkbox"/>	Patient room	<input type="checkbox"/>
		Isolation unit (not pt room)	<input type="checkbox"/>
		Facility (not in room/unit)	<input type="checkbox"/>
		Core hospital lab	<input type="checkbox"/>
		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>

- Public health/state lab
- Reference/private lab
- Other (please specify)
-
- Partial thromboplastin time
- Patient room
- Isolation unit (not pt room)
- Facility (not in room/unit)
- Core hospital lab
- Clinical hospital lab
- Outside facility
- Public health/state lab
- Reference/private lab
- Other (please specify)
-
- Platelet count
- Patient room
- Isolation unit (not pt room)
- Facility (not in room/unit)
- Core hospital lab
- Clinical hospital lab
- Outside facility
- Public health/state lab
- Reference/private lab
- Other (please specify)
-

Blood typing	<input type="checkbox"/>	Patient room	<input type="checkbox"/>
		Isolation unit (not pt room)	<input type="checkbox"/>
		Facility (not in room/unit)	<input type="checkbox"/>
		Core hospital lab	<input type="checkbox"/>
		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>
		Public health/state lab	<input type="checkbox"/>
		Reference/private lab	<input type="checkbox"/>
		Other (please specify)	<input type="checkbox"/>
Blood Culture	<input type="checkbox"/>	Patient room	<input type="checkbox"/>
		Isolation unit (not pt room)	<input type="checkbox"/>
		Facility (not in room/unit)	<input type="checkbox"/>
		Core hospital lab	<input type="checkbox"/>
		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>
		Public health/state lab	<input type="checkbox"/>
		Reference/private lab	<input type="checkbox"/>
		Other (please specify)	<input type="checkbox"/>
Urine Culture	<input type="checkbox"/>	Patient room	<input type="checkbox"/>
		Isolation unit (not pt room)	<input type="checkbox"/>
		Facility (not in room/unit)	<input type="checkbox"/>
		Core hospital lab	<input type="checkbox"/>

		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>
		Public health/state lab	<input type="checkbox"/>
		Reference/private lab	<input type="checkbox"/>
		Other (please specify)	<input type="checkbox"/>
		<hr/>	
Other Bodily Fluids Culture	<input type="checkbox"/>	Patient room	<input type="checkbox"/>
		Isolation unit (not pt room)	<input type="checkbox"/>
		Facility (not in room/unit)	<input type="checkbox"/>
		Core hospital lab	<input type="checkbox"/>
		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>
		Public health/state lab	<input type="checkbox"/>
		Reference/private lab	<input type="checkbox"/>
		Other (please specify)	<input type="checkbox"/>
		<hr/>	
Molecular assay	<input type="checkbox"/>	Patient room	<input type="checkbox"/>
		Isolation unit (not pt room)	<input type="checkbox"/>
		Facility (not in room/unit)	<input type="checkbox"/>
		Core hospital lab	<input type="checkbox"/>
		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>
		Public health/state lab	<input type="checkbox"/>
		Reference/private lab	<input type="checkbox"/>

		Other (please specify)	<input type="checkbox"/>

Manual differential	<input type="checkbox"/>	Patient room	<input type="checkbox"/>
		Isolation unit (not pt room)	<input type="checkbox"/>
		Facility (not in room/unit)	<input type="checkbox"/>
		Core hospital lab	<input type="checkbox"/>
		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>
		Public health/state lab	<input type="checkbox"/>
		Reference/private lab	<input type="checkbox"/>
		Other (please specify)	<input type="checkbox"/>

Lipase	<input type="checkbox"/>	Patient room	<input type="checkbox"/>
		Isolation unit (not pt room)	<input type="checkbox"/>
		Facility (not in room/unit)	<input type="checkbox"/>
		Core hospital lab	<input type="checkbox"/>
		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>
		Public health/state lab	<input type="checkbox"/>
		Reference/private lab	<input type="checkbox"/>
		Other (please specify)	<input type="checkbox"/>

Amylase	<input type="checkbox"/>	Patient room	<input type="checkbox"/>
		Isolation unit (not pt room)	<input type="checkbox"/>

		Facility (not in room/unit)	<input type="checkbox"/>
		Core hospital lab	<input type="checkbox"/>
		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>
		Public health/state lab	<input type="checkbox"/>
		Reference/private lab	<input type="checkbox"/>
		Other (please specify)	<input type="checkbox"/>

Creatine kinase total	<input type="checkbox"/>	Patient room	<input type="checkbox"/>
		Isolation unit (not pt room)	<input type="checkbox"/>
		Facility (not in room/unit)	<input type="checkbox"/>
		Core hospital lab	<input type="checkbox"/>
		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>
		Public health/state lab	<input type="checkbox"/>
		Reference/private lab	<input type="checkbox"/>
		Other (please specify)	<input type="checkbox"/>

Malaria smear	<input type="checkbox"/>	Patient room	<input type="checkbox"/>
		Isolation unit (not pt room)	<input type="checkbox"/>
		Facility (not in room/unit)	<input type="checkbox"/>
		Core hospital lab	<input type="checkbox"/>
		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>

		Public health/state lab	<input type="checkbox"/>
		Reference/private lab	<input type="checkbox"/>
		Other (please specify)	<input type="checkbox"/>
		<hr/>	
HIV screen	<input type="checkbox"/>	Patient room	<input type="checkbox"/>
		Isolation unit (not pt room)	<input type="checkbox"/>
		Facility (not in room/unit)	<input type="checkbox"/>
		Core hospital lab	<input type="checkbox"/>
		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>
		Public health/state lab	<input type="checkbox"/>
		Reference/private lab	<input type="checkbox"/>
		Other (please specify)	<input type="checkbox"/>
		<hr/>	
Urinalysis	<input type="checkbox"/>	Patient room	<input type="checkbox"/>
		Isolation unit (not pt room)	<input type="checkbox"/>
		Facility (not in room/unit)	<input type="checkbox"/>
		Core hospital lab	<input type="checkbox"/>
		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>
		Public health/state lab	<input type="checkbox"/>
		Reference/private lab	<input type="checkbox"/>
		Other (please specify)	<input type="checkbox"/>
		<hr/>	

Pregnancy Test	<input type="checkbox"/>	Patient room	<input type="checkbox"/>
		Isolation unit (not pt room)	<input type="checkbox"/>
		Facility (not in room/unit)	<input type="checkbox"/>
		Core hospital lab	<input type="checkbox"/>
		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>
		Public health/state lab	<input type="checkbox"/>
		Reference/private lab	<input type="checkbox"/>
		Other (please specify)	<input type="checkbox"/>
CSF analysis	<input type="checkbox"/>	Patient room	<input type="checkbox"/>
		Isolation unit (not pt room)	<input type="checkbox"/>
		Facility (not in room/unit)	<input type="checkbox"/>
		Core hospital lab	<input type="checkbox"/>
		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>
		Public health/state lab	<input type="checkbox"/>
		Reference/private lab	<input type="checkbox"/>
		Other (please specify)	<input type="checkbox"/>
Auto-analysers for clinical chemistry	<input type="checkbox"/>	Patient room	<input type="checkbox"/>
		Isolation unit (not pt room)	<input type="checkbox"/>
		Facility (not in room/unit)	<input type="checkbox"/>
		Core hospital lab	<input type="checkbox"/>

		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>
		Public health/state lab	<input type="checkbox"/>
		Reference/private lab	<input type="checkbox"/>
		Other (please specify)	<input type="checkbox"/>
		<hr/>	
Blood-gas analyser	<input type="checkbox"/>	Patient room	<input type="checkbox"/>
		Isolation unit (not pt room)	<input type="checkbox"/>
		Facility (not in room/unit)	<input type="checkbox"/>
		Core hospital lab	<input type="checkbox"/>
		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>
		Public health/state lab	<input type="checkbox"/>
		Reference/private lab	<input type="checkbox"/>
		Other (please specify)	<input type="checkbox"/>
		<hr/>	
(Semi-)quantitative analyzers	<input type="checkbox"/>	Patient room	<input type="checkbox"/>
		Isolation unit (not pt room)	<input type="checkbox"/>
		Facility (not in room/unit)	<input type="checkbox"/>
		Core hospital lab	<input type="checkbox"/>
		Clinical hospital lab	<input type="checkbox"/>
		Outside facility	<input type="checkbox"/>
		Public health/state lab	<input type="checkbox"/>
		Reference/private lab	<input type="checkbox"/>

	Other (please specify) <input type="checkbox"/>

Hand held bedside machines <input type="checkbox"/>	Patient room <input type="checkbox"/>
(POC testing for chemistries, clotting time, etc.)	Isolation unit (not pt room) <input type="checkbox"/>
	Facility (not in room/unit) <input type="checkbox"/>
	Core hospital lab <input type="checkbox"/>
	Clinical hospital lab <input type="checkbox"/>
	Outside facility <input type="checkbox"/>
	Public health/state lab <input type="checkbox"/>
	Reference/private lab <input type="checkbox"/>
	Other (please specify) <input type="checkbox"/>

Other (please specify) _____ <input type="checkbox"/>	Patient room <input type="checkbox"/>
	Isolation unit (not pt room) <input type="checkbox"/>
	Facility (not in room/unit) <input type="checkbox"/>
	Core hospital lab <input type="checkbox"/>
	Clinical hospital lab <input type="checkbox"/>
	Outside facility <input type="checkbox"/>
	Public health/state lab <input type="checkbox"/>
	Reference/private lab <input type="checkbox"/>
	Other (please specify) <input type="checkbox"/>

As applicable, please indicate approximate distance of the core hospital laboratory from
ETC/RTC patient room: _____(meters)

As applicable, please indicate approximate distance of clinical hospital laboratory from ETC/RTC patient room: _____(meters)

As applicable, please indicate approximate distance of public health/state laboratory from ETC/RTC patient room: _____(miles)

As applicable, please indicate approximate distance of reference/private laboratory from ETC/RTC patient room: _____(miles)

C. Laboratory Management

Have risk analyses been performed for all laboratory procedures and equipment used to test specimens of a patient with or the potential to have an HID?

YES NO

If no, please specify the laboratory procedure(s) and equipment for which a risk analysis has *not* been performed:

Does the ETC/RTC have decontamination procedures specified for all laboratory equipment used to test specimens of a patient with or the potential to have a HID?

YES NO

If no, will laboratory equipment be disposed of after use on specimens of HID patients?

YES NO

If applicable, please specify the laboratory equipment that will be disposed of after use on specimens of HID patients: _____

Please list the ETC/RTC's reference laboratory to screen for a HID (e.g. state public health laboratory): _____

What is the turn-around time for reference laboratory testing? _____(hours)

Does the on-site laboratory have the capacity to safely and securely store specimens of a patient with a HID for additional testing as needed?

YES NO

Transport of samples to laboratories offsite from the facility (e.g. reference laboratory) is carried out by:

Private/commercial courier service (certified)

Governmental organization

Hospital staff

Other (please specify) _____

Does the ETC/RTC have procedure(s) for recording the "chain of custody," or documentation detailing possession/handling of specimens throughout transport?

YES NO

Operational Capabilities

Please specify whether a patient with the diseases listed would be admitted into the ETC/RTC:

Disease	Check if admitted
Anthrax	<input type="checkbox"/>
Avian influenza	<input type="checkbox"/>
Botulism	<input type="checkbox"/>
Ebola virus disease (EVD)	<input type="checkbox"/>
Extensively drug-resistant tuberculosis (XDR-TB)	<input type="checkbox"/>
Lassa fever	<input type="checkbox"/>
Marburg virus disease	<input type="checkbox"/>
Middle East respiratory syndrome (MERS)	<input type="checkbox"/>
Monkeypox	<input type="checkbox"/>
Pneumonic Plague	<input type="checkbox"/>
Q fever	<input type="checkbox"/>
Severe acute respiratory syndrome (SARS)	<input type="checkbox"/>
Smallpox	<input type="checkbox"/>
Staphylococcal enterotoxigenic B (SEB)-caused disease	<input type="checkbox"/>
Tularemia	<input type="checkbox"/>
“Unknown” emerging infectious disease	<input type="checkbox"/>

Is the ETC/RTC prepared to safely care for patients with HIDs other than Ebola virus disease (e.g. MERS, Smallpox)?

YES NO

If no, what capabilities is the ETC/RTC currently lacking to effectively care for other HIDs?

Has the facility received any reimbursement from federal/state government funds in costs incurred in establishing their ETC?

YES NO

If yes, what is the total reimbursement received? _____

If additional funding were available, what operational capabilities would the ETC/RTC add/construct as a part of the isolation room/unit?

By funding amount:

\$100,000: _____

\$500,000: _____

\$1,000,000: _____

By funding period:

1 year: _____

5 years: _____

10 years: _____

What were the most difficult challenges/barriers in establishing the facility as an ETC/RTC (check all that apply)?

Financial support

Facility administrative support

Staff recruitment

Time constraint/commitment

Lack of guidance

Acquisition of supplies (e.g. PPE)

Sustainability concerns

Other (please specify) _____

Please specify: _____

What does the ETC/RTC foresee as the major challenges/barriers to maintaining capabilities in
HID care?

Financial support

Facility administrative support

Staff recruitment

Time constraint/commitment

Lack of guidance

Acquisition of supplies (e.g. PPE)

Sustainability concerns

Other (please specify) _____

Please specify: _____

If previously unanswered, would the ETC/RTC like to join the United States Highly Infectious
Disease Network?

YES NO

Appendix E. State Public Health Department Survey

Please indicate the location of the State Health Department:

State: _____

Point(s) of contact name(s): _____ Email: _____

A. Patient Admission

A.1 If a patient was diagnosed with any of the following diseases in a hospital within the state, under current ETC/RTC capabilities and capacity, would the state's public health department prefer a patient be cared for at the hospital of diagnosis (no inter-facility patient transfer), be transferred and admitted into an Ebola Treatment Center (as applicable) within the state, or transferred directly into a Regional Treatment Center (RTC):

Disease	Original Hospital	ETC	RTC
Anthrax	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Avian influenza	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Botulism	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ebola virus disease (EVD)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Extensively drug-resistant tuberculosis (XDR-TB)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Guanarito virus disease	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Junin virus disease	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lassa fever	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Marburg virus disease	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Middle East respiratory syndrome (MERS)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Monkeypox	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Machupo virus disease	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Pneumonic Plague	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q fever	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sabia virus disease	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Severe acute respiratory syndrome (SARS)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Smallpox	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Staphylococcal enterotoxigenic B (SEB)-caused disease	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Tularemia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
“Unknown” emerging infectious disease	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

A.2 Who is the responsible entity/person responsible for deciding to which facility (an ETC or RTC) a diagnosed patient is to be transported (e.g. Chief Medical Officer of ETC or RTC, state public health director)?

B. Patient Transport

B.1 Are there written protocols / official guidelines for the safe transportation of patients with highly infectious diseases to Ebola Treatment Centers?

YES NO

If yes, please specify (check all that apply):

for transportation within the state to a state ETC

for transportation from the state to an out-of-state ETC and/or RTC

for transportation from out-of-state to an ETC within the state

B.2 Are there state laws restricting transport of highly infectious disease patient transportation (e.g. to determine which route are allowed and which are not)?

YES NO

If yes, please specify how patients are allowed to be transported within the state:

- i) Ground transport by designated and/or contracted ambulance companies only
- ii) Ground transport without designated and/or contracted ambulance companies
- iii) Air transport

If air transport allowable, please specify the air transfer provider:

If air transport is allowable, does your state have a written plan/procedure for:

- Air transport within your state (intrastate)
- Air transport between other states (interstate)
- Air transport from another country

B.3 If ground transport is allowed according to state laws, are there restrictions on distance to be traveled?

YES NO

If yes, please specify the distance: _____ (miles)

If yes, please specify the hours: _____ (hours)

B.4 Are there written protocols / official guidelines for the management of accidents that may occur during transportation of a patient with a highly infectious disease within the state?

YES NO

B.5 Has the state health department been involved with operational exercises of patient transport with one or more of the state's ETCs/RTCs?

YES NO

If yes, select which functional exercises the state health department has been involved:

Ground transport to an in-state ETC/RTC from a facility within the state

Ground transport from a facility within the state to an out-of-state ETC/RTC

Ground transport from an out-of-state facility to an ETC/RTC within the state

Air transport from a facility within the state to an out-of-state ETC/RTC

Air transport from an out-of-state facility to an ETC/RTC within the state

B.6 Has the state health department been involved with the transfer of an actual patient (patient under investigation (PUI) or confirmed patient)?

If yes, select which transport scenarios the state health department been involved:

Ground transport (via ambulance) within the state

Ground transport from an out-of-state facility to an ETC/RTC within the state

Ground transport from a facility within the state to an out-of-state ETC/RTC

Air transport from an out-of-state facility to an ETC/RTC within the state

Air transport from a facility within the state to an out-of-state ETC/RTC

Air transport from another country

Please list the state's designated Regional Ebola Treatment Center (RTC)

Hospital: _____ City/State: _____

Does the state have one or more designated Ebola Treatment Centers (ETCs)?YES NO

If yes, please list the state ETC(s):

Hospital: _____ City: _____

Hospital: _____ City: _____

Hospital: _____ City: _____

Hospital: _____ City: _____

Hospital: _____ City: _____

Hospital: _____ City: _____

Hospital: _____ City: _____

Hospital: _____ City: _____

Hospital: _____ City: _____

Hospital: _____ City: _____

Others: _____

Does the state have one or more designated Assessment Hospitals?YES NO

If yes, please list the state Assessment Hospital(s):

Hospital: _____ City: _____

Hospital: _____ City: _____

Hospital: _____ City: _____

Hospital: _____ City: _____

Hospital: _____ City: _____

Hospital: _____ City: _____

Hospital: _____ City: _____

Hospital: _____ City: _____

Hospital: _____ City: _____

Hospital: _____ City: _____

Hospital: _____ City: _____

Others: _____

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