

Designing Medical Facilities to Care for Patients with Highly Hazardous Communicable Diseases

In: Preparing for Bioemergencies: A Guide for Healthcare Facilities

MARK G KORTEPETER MD, MPH^{1,2}

ELENA H KWON, DO, MPH³

THEODORE J CIESLAK, MD¹

¹Department of Epidemiology
University of Nebraska Medical Center, College of Public Health
Omaha NE 68198

²Department of Preventive Medicine and Biometrics
Uniformed Services University of the Health Sciences
Bethesda, MD 20814

³Division of Medicine
U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)
Fort Detrick, MD 21702

The views expressed herein are those of the authors and do not necessarily reflect the position of the University of Nebraska or its component entities, the US Army Medical Research Institute of Infectious Diseases, the Medical Research and Materiel Command, the US Army Medical Command, the US Army, the Department of Defense, or the US Government.

Correspondence:

Mark Kortepeter
1114 Churchview Place
Potomac, MD 20854
TEL: 202-853-7299

e-mail: mark.kortepeter@unmc.edu or mark.kortepeter@gmail.com

Keywords:

high-level containment care, highly hazardous communicable diseases, biocontainment, viral hemorrhagic fevers, biosafety level

Introduction

The Ebola virus disease (EVD) outbreak in West Africa from 2013-2016 necessitated an international response and required countries around the world to reassess their ability to manage highly hazardous contagious pathogens. Care facilities often serve as epicenters for the spread of such pathogens. Experience in a field setting has historically demonstrated the ability to reduce, but not eliminate nosocomial infections among healthcare providers. Despite four decades of experience managing Ebola in a field setting, an estimated 815 confirmed and suspected infections of caregivers occurred.¹[REF-WHO] The World Health Organization estimated that care providers were 21 to 32 times more likely to become infected than the general population.²[REF-WHO]

Although the establishment of containment care units preceded the EVD outbreak, the outbreak provided impetus for developed countries to make new investments in capabilities to handle patients infected with highly hazardous contagious pathogens. This chapter will focus on the physical features, engineering controls, infection control modalities, and training regimens that hospitals housing containment units have developed and implemented to adapt or design their facilities to minimize the spread of high consequence pathogens to healthcare providers. Other medical facilities need not adapt all such features, but they can utilize some of the principles noted here for improving their own management of the unannounced patient with such an infection. This chapter will not discuss healthcare associated infections, such as ventilator-associated pneumonia or catheter-related infections.

Background

Consideration of the need for containment care of highly hazardous contagious pathogens has undergone significant evolution since the discovery of Ebola virus in 1976.³ [REF-

Kortepeter JID] As we have argued previously, care of patients infected with hemorrhagic fever viruses should not be taken lightly, and can be made safer for healthcare providers utilizing specialized units designed for such care.⁴ [REF-Kortepeter Annals] The concept of containment care in the U.S. began in the late 1960s at the United States Army Medical Research Institute of Infectious Diseases (USAMRIID), Fort Detrick, Maryland.[3] [REF: Kortepeter JID] The facility broke ground in 1967. At that time, Ebola had not yet been discovered, but other hemorrhagic fever viruses were known (Crimean-Congo Hemorrhagic Fever, CCHF (Crimea, 1944; Congo, 1969), Junin (Argentina, 1958), Machupo (Bolivia, 1963). Marburg was first discovered that same year (Germany, Yugoslavia, 1967). Lassa followed (Nigeria, 1969), and Ebola emerged in two separate outbreaks in the former Zaire and Sudan in 1976.^{5,6}[REF-Bull WHO 1978 Zaire; REF Bull WHO 1978 Sudan]

In the 1960s, further impetus for the development of specialized containment care systems occurred at a time when the US program to develop offensive biological weapons was transitioned to a more defensive posture. In 1969, President Nixon officially closed the program, noting biological weapons “have massive, unpredictable, and potentially uncontrollable consequences.”⁷ [REF-Tucker] Along with this came the interest in management of potential casualties to reduce spread.

Other events, such as fear of extraterrestrial pathogens from the Apollo missions, fueled by the popular media,⁸[REF-Andromeda strain] in addition to infections of researchers in the U.S. during discovery of Lassa virus, contributed to the perceived need for containment laboratory safety and biocontainment patient care.⁹[REF-Crawford]

The original concept and design of the care facility at USAMRIID, affectionately known as the “slammer,” was based on the model of the Biosafety Level 4 lab. The slammer consisted

of a two bed state-of-the-art facility and a neighboring surgical room.^{10,11} [REF-Covert] [REF-Hill] The name derived from the ominous sound produced by the closure of its heavy steel containment shower door, and reflected the sense of isolation one might feel after being “locked in” the unit for a lengthy period.

“Hard-wired” features [TABLE 1] that were unique to the Slammer included negative pressure air handling, with HEPA-filtered intake air and double HEPA-filtered exhaust air. Liquid waste drained into the laboratory sewer system that was steam sterilized prior to its release into the general waste stream. The walls were coated with epoxy paint for ease of decontamination. Caregivers could wear the “space suits” that utilized positive pressure in-line air, analogous to those employed in the BSL-4 laboratories. The facility had its own pass-thru autoclave on site, in addition to other measures to pass small objects or specimens in or out of the unit, including an ultraviolet pass box and dunk tank. Patients could also be brought directly into the unit from the outside through an external wall portal, rather than traversing the building. A specially designed shower was utilized at the end of a worker’s shift to decontaminate the reusable positive-pressure suits.

The slammer was decommissioned in 2012 and converted to a training facility for new entrants into the BSL-4 laboratory. During its active period, twenty-one patients were observed or considered for observation after potential exposure to a variety of BSL-4 pathogens,¹² [REF-Cieslak-CID]¹³ [REF-Kortepeter-EID] most of which occurred in the containment laboratories, although two of these exposures occurred in the field. Agents involved in the potential exposures included Ebola, Lassa, Machupo, and Junin viruses. The final patient (Ebola lab exposure) was admitted after a 19-year gap in 2004.[13] [REF – repeat Kortepeter-EID] None of the patients became ill or demonstrated evidence of infection.

Although USAMRIID employed the BSL-4-like slammer for quarantining exposed individuals who were asymptomatic, caregivers in field environments did not have the luxury of such extraordinary infrastructure to isolate ill patients and utilized barrier precautions (gowns, gloves, eye protection, masks, impermeable aprons), which led to significant decreases in spread of virus to care givers.¹⁴ [REF-Pigott] Over the years, the guidelines from CDC have evolved significantly, as new information has surfaced regarding the spread of these infections.[3][REF (repeated) –Kortepeter JID] Unfortunately, the 2013-16 Ebola outbreak and some prior outbreaks,[14]¹⁵ [REF: repeat-Pigott] [REF: Borchert - Sudan Gulu] demonstrated that although better, the methods used in the field did not completely eliminate health care worker infections in those settings.

Although the military began to transition away from the slammer model, academic medical centers around the country began to develop their own specialized capabilities. Emory University opened a two-bed facility (the Serious Communicable Disease Unit-SCDU) in Atlanta in 2004 [FIGURE 1] and the University of Nebraska Medical Center in Omaha opened a 10-bed facility in 2005 (the Nebraska Biocontainment Unit-NBU). The National Institute of Allergy and Infectious Diseases of the NIH opened the Special Clinical Studies Unit (SCSU) in Bethesda, Maryland, in 2010.

Unlike the slammer, these facilities were outfitted inside existing medical centers, but they employed some (but not all) of the engineering features contained within the USAMRIID facility. In 2006, leaders from the three facilities in existence at the time published the first consensus guidelines for the construction, design, and employment of such units, which they dubbed “Biocontainment Patient Care Units (BPCUs).¹⁶ [Smith PW-BPCUs] A European

Network of Infectious Diseases has published their own “framework” recommendations on design and operation of high-level containment care (HLCC) units.¹⁷[REF: Bannister Lancet ID]

Although care facilities don’t operate under the same categorization as laboratories, as espoused in the CDC/NIH handbook on biosafety (e.g. Biosafety Levels 1 through 4), the USAMRIID containment unit operated under conditions that might be considered analogous to those employed in a Biosafety Level 4 lab (BSL-4).¹⁸ [REF: DHHS BMBL] This level of lab safety is reserved for a handful of deadly viral pathogens for which there are no treatments or vaccines and that have the potential to infect laboratorians. In this regard, a conventional hospital room employs methods similar to a BSL-2 laboratory, while a negative pressure isolation room employs BSL-3-like controls. The HLCC units at Emory, the University of Nebraska, and the NIH, which cared for Ebola patients during the 2013-16 outbreak, can be viewed as BSL-3+ entities.¹⁹ [REF-Cieslak-Current Rx options]

Although at one time considered to be on the fringe, some recent outbreaks have led to a re-examination of the importance of containment care facilities. The “Amerithrax” attacks of October 2001, occurring after the World Trade Center assault, and two outbreaks in 2003 added momentum, particularly as they demonstrated the risk to healthcare providers from their patients harboring lethal pathogens. The first was Severe Acute Respiratory Syndrome (SARS), a highly lethal and very contagious disease transmitted via the airborne route. The second was Monkeypox, which arrived in the U.S. carried by imported Gambian giant rats. Some physicians, fearful of becoming infected, balked at treating patients infected with monkeypox.²⁰ [REF: Reynolds] The 2015 outbreak of Middle Eastern Respiratory Syndrome Corona virus (MERS-CoV), in Korea led to 186 cases, and significant nosocomial spread. The outbreak exposed several factors that helped facilitate the outbreak, including “late diagnosis, quarantine failure of

'super spreaders', familial care-giving and visiting, non-disclosure by patients, poor communication by the South Korean Government, inadequate hospital infection management, and 'doctor shopping'."²¹ [REF-Kim-MERS Korea] The concept of biocontainment became more mainstream, though, during the 2013-16 Ebola outbreak in West Africa, as patients were brought back for care to US and European facilities.[3][REF (repeat) Kortepeter – JID] The nosocomial infection of two nurses who cared for a severely ill patient in Dallas, Texas, solidified the role of biocontainment units in medicine in the US.²² [REF-poor planning]

Although there is no consensus on which patients infected with highly hazardous contagious pathogens should be admitted to biocontainment units, a couple have been proposed, which are discussed in another chapter in this text. These include severe illness resulting from laboratory exposures, travel, or bioterrorism events, as well as diseases such as smallpox, monkeypox, SARS, highly pathogenic avian influenza and those viral hemorrhagic fevers known for nosocomial spread (Ebola, Marburg, Lassa, CCHF). [REF:PW Smith] In addition, it makes sense for the US to have an integrated, national network, with strategically located facilities around the country as part of an overall strategy to manage such diseases. Coordination with containment laboratory locations is reasonable, such that occupational exposures, as well as index cases of potential highly hazardous contagious diseases could be managed safely.[4][16]²³[REF: repeat: PW Smith; REF repeat: Kortepeter – AIM] [REF: Jahrling]

Design Features of Containment Units

Before a potentially infected or definitely infected patient reaches a hospital, it is useful to consider the pathway to care. For facilities that serve as a central hub or referral center from remote distances, proximity to an airfield is optimal.²⁴ [REF-Beam – PHN] Even when utilizing air transport, having a method for safe transport of the patient by ground to the care facility is

important.²⁵ [REF-Lowe Prehosp Emerg Care] For suspected patients, use of PPE and separation of the driver component from the passenger compartment was common – this can be as simple as using layers of plastic lining the patient compartment.[25]²⁶ [REF: repeat Lowe] [REF: Hewlett]

Once in the facility, having a space to evaluate suspect or ill patients at potential risk of spread is useful. During the Ebola outbreak of 2013-16, some facilities did this in their intensive care units rather than in the emergency department. Planning in advance is key when considering transport of a patient within a facility. It is important to designate pre-planned entry points, transport routes within the facility (preferably shorter distances or more direct routes to minimize contamination risk en route), including pre-designated elevators and pre-arranged security to cordon off those routes during patient transport.²⁷ [REF: Wadman-ED processes] In some instances, individual patient isolation systems were used during ambulance or intra-facility transport.[24] [REF repeat-Beam PHN]

The biocontainment units at Emory, University of Nebraska, and the NIH cared for 9 Ebola-infected patients during the 2013-16 outbreak without any spread to caregivers, thus confirming the ability to care for these patients safely in a developed setting. One patient was also cared for at the New York University-Bellevue Hospital in New York City, demonstrating that with adequate precautions and infection control measures, other hospitals may be able to do this safely; however, the nosocomial transmission experience of the Dallas Presbyterian hospital also demonstrates that the virus is unforgiving, and that unprepared facilities could have significant challenges.[22], [REF-repeat Dallas AAR] There is no room for error.[4] [REF-(repeat) Kortepeter – AIM]

The Europeans and Americans have come up with recommendations on the types of design features that should be included in biocontainment units.[16][17] [REF-repeat Bannister; Smith

repeat]. These include designation of “cold, warm, and hot” or “clean” and “contaminated” areas in the units, adopted from nomenclature used in containment labs. These demarcations help guide access by individuals with different skill sets and the appropriate personal protective equipment in different locations in the units. Having the appropriate space for storage, donning, and doffing of equipment must also be considered. A consensus group in the U.S., which included representatives from biocontainment units and containment laboratories also put together consensus guidelines on recommended features of facilities that care for accidental exposures in labs to Biosafety Level -3 and -4 agents.[23] [REF: repeat Jahrling]

The three currently designated national facilities have dedicated units that are physically separated from other patient care areas. These facilities are of varying sizes: the Nebraska unit has 10 beds in 5 rooms, the NIH unit has 4 rooms, with 7 beds, and the Emory unit has two rooms, each with single beds.²⁸ [REF-Courage] Numbers of beds do not adequately represent the number of patients that could be cared for. Logistically, more patients with a respiratory disease (SARS, MERS-CoV) might be able to be cared for, than EVD patients, depending on their disease acuity.

The personnel burden to care for a single patient with Ebola in the containment units numbered in the dozens, making caring for more than one or two ill patients extremely challenging. In order to minimize the number of individuals who need to enter the “hot” patient care area, units have set up video monitoring equipment and use of electronic medical record charting. Video monitoring also can be useful for communication with the patient by medical staff or communication between patients and family members, who are not allowed to enter the unit.²⁹ [REF: Johnson]

Air handling and directional airflow with sequential pressure differentials is a major feature, with units' air handling separate from the rest of the medical facility, with HEPA filtration upon exit and negative pressure air flow. Back-up generators are used in case of power outage. Other features include secured access, the ability to control and monitor entry and egress from the facility, and dunk tanks for passing specimens out of the containment unit. Other options that have been used include pass through autoclaves and ultraviolet light boxes. Having an occupational health program to monitor anyone entering the facility is an important adjunct. Units have used sealed floors and walls for ease of decontamination after patient discharge, although the housekeeping is frequently done by those who work on the unit, rather than ancillary personnel, who are kept to a minimum.

Within the care areas, having all the necessary life support equipment for patient care is important to minimize the movement of equipment such as plain film radiology, ultrasound, dialysis, and ventilator equipment in and out of the care area. Other design features include hands free or self-closing doors and ready access to handwashing facilities (hands-free, if possible).

Ready access to laboratory testing is key to minimize sending potentially contaminated patient samples to the main hospital laboratory. Units have used a combination of on-site testing with "point of care" assays for routine labs. In addition, the three units that cared for Ebola patients recently have established their own on-site labs.

Waste handling turned out to be one of the major unexpected challenges during the Ebola outbreak.^{30,31,32} [REFs: Lowe - Am J Infect Control x 2] [REF - Jelden AmJInfectControl] In the old "slammer" model, this was not an issue, since caregivers in fully encapsulated "space" suits passed through a decontamination shower when leaving the unit, and suits were re-used. This

minimized the need for autoclaving. With the use of disposable suits, PAPR hoods, gloves, face shields, aprons, and booties, the amount of PPE waste was enormous. Patient waste was another unexpected challenge, due to the profound volume of emesis, diarrhea, and contamination of clothing and linens. On a given day, up to 40 bags of medical waste could be generated for a sick patient.³³ [REF: Leligdowicz] Units adapted by putting in pass-through autoclaves (usually more than one for redundancy to allow for maintenance of one while remaining operational). Areas need adequate space for storage of solid waste, in case the autoclaves go down. Specific validation of autoclave protocols, along with proper waste packaging, may also be needed, to ensure effective decontamination, depending on the agent in question.³⁴ [REF-Garibaldid]

Handling of waste must take into consideration textiles, (linens, pillows, mattresses, and privacy curtains) in addition to solid waste. Liquid waste handling was also a challenge. [REFS: repeat Lowe x 2, Jelden] Most facilities don't have the luxury of a steam sterilization plant on-site, as the slammer facility did. They used expedient measures such as pouring MicroChem Plus (Emory SCDU) or "Ecolab Neutral Disinfectant Cleaner" (Nebraska NBU) into the toilets, with an appropriate contact time, prior to releasing to the general sewage stream. Placing a cover over the toilet prior to flushing limits potential for droplet spread. Different health departments may have local requirements for such handling.

When a patient is discharged or succumbs to the disease, it is useful to have procedures in place for decontaminating the facility and for proper care and transport of the deceased. At the Nebraska NBU, when one patient succumbed to Ebola infection, visitation by the family was facilitated by a video link. Afterward, the remains were wrapped in bed sheets and placed in a biosafety level 4 containment bag. The bag was then transferred into an 18-mil thick leak-proof laminated vinyl bag, followed by a second one. After a patient discharge, the room is left

undisturbed for 48 hours (this has the effect of allowing most pathogens to succumb to dessication), followed by manual disinfection and ultraviolet germicidal irradiation using four uv light generations. Floors were mopped twice with a hospital disinfectant, and medical equipment was manually disinfected.[32] [REF repeat: Jelden]

Hewlett, and others from the Nebraska NBU provide a description of lessons learned from the 2013-16 Ebola outbreak that might benefit others.[26] [REF: repeat Hewlett] It was useful to have dedicated space for staff changing and storage of PPE. Patient rooms had seamless surfaces for ease of decontamination. The unit was located in a secured area separate from the rest of the hospital. This provides reassurance to the patients elsewhere in the facility, and the public at large. Unit entrances and exits were monitored. Having a well-trained, competent and interdisciplinary team of providers, appropriate protocols for PPE donning and doffing, specimen and waste handling were useful. Including laboratorians on the team, and limiting labs to point of care testing in the patient room or a biosafety cabinet in close proximity to patient is also useful.

In response to the Ebola outbreak and being cognizant of the need for better national preparedness, Europe has developed its own network of isolation facilities within the European Network for Highly Infectious Diseases (EuroNHID) project. In the U.S., the CDC recommended a 3-tiered system for evaluation and management of patients with suspected or confirmed Ebola infection. While the system was initially created in response to the 2013-2016 Ebola outbreak, it is expected that participating facilities will be able to manage patients potentially infected with a number of other high-consequence pathogens, such as those noted in an accompanying chapter in this text.

These three tiers include: “Frontline” facilities, Ebola assessment hospitals, and Ebola treatment centers.³⁵ [REF: CDC online reference] Dovetailed with this recommendation, the U.S.

Department of Health and Human Services has designated one facility in each of 10 Federal Emergency Management Agency (FEMA) regions around the US as regional “Ebola and Other Special Pathogen Treatment Centers.”³⁶[REF-Herstein – Infect Control Hosp Epi] Three of those facilities: Emory University, University of Nebraska, and Bellevue Hospital have been designated as national treatment centers. These three centers have joined in a consortium called the National Ebola Training and Education Center (NETEC), which trains caregivers on PPE and provides education site assessments of hospitals. Other facilities around the country have met certain criteria to serve as Ebola Treatment Centers, which include the following elements: operational coordination, staffing and training, clinical competency, PPE, policies and procedures for healthcare worker safety, laboratory safe work practices, private care rooms with designating donning/doffing spaces, inter-facility transportation plans, and waste management.[36][REF: repeat Herstein] Even among these facilities, design features appear to be vastly different. For example, 94% of them have their isolation unit within the main hospital building, 43% have separate wards, 51% have separate rooms within another ward, 3 (6%) are standalone. 70% have separate air handling systems, and of the 24 units inside other wards, 14 (58%) have independent air handling systems. Twenty-three of those twenty-four (96%) have a physical barrier separating the isolation units. Only 10 of the 47 ETCs that responded to a survey on capabilities had all of the following: negative pressure isolation, an anteroom, on-site sterilization with autoclaves, and HEPA filtration. Some of the major limitations of these units include bed capacity and the need for dedicated, multidisciplinary staff.[36] [REF (repeat)-Herstein]

Adapting Design Features for More General Use

Even with appropriate isolation precautions, nosocomial transmission of infectious diseases, such as tuberculosis, measles, SARS, smallpox, and other diseases may occur, so it is reasonable for all facilities to have some sort of preparation.[16]³⁷[REF: repeat Smith] [REF: Siegel] While we recognize the advantages of caring for certain highly hazardous communicable diseases within biocontainment units, we note that a principle benefit of NETEC efforts will derive from a re-examination and a strengthening of ‘conventional’ infection control practices throughout the healthcare system.

All hospitals need not attempt to build biocontainment units, but hospitals, in general should have some kind of plan to prepare for the highly communicable patient(s) who might arrive at their facility unexpectedly. In this vein, some of the features embraced by biocontainment units might be adopted by other facilities. One key feature is early identification and triage of such patients at the places where they are most likely to show up – in the emergency room or acute care and primary care clinics. Assessments of patient flow within a facility, and potential contact points between patients and caregivers, family members, and other patients is a critical part of risk assessment. Having protocols in place to query patients about recent travel, ill contacts, or respiratory illness may be beneficial in those areas. Preparation for all comers, and ensuring procedures for evaluation are as “idiot proof” as possible is key, because variable adherence is a huge challenge. Therefore, staff members potentially involved require regular reinforcement with practice, testing, and management.

Some simple design features should be achievable for most facilities, such as designating a location separate from other patient care areas, but still readily accessible by staff, as a holding or triage area as well as an appropriate treatment area.[27] [REF-repeat Wadman] This need not be a locked or secured ward, as has been utilized in the containment units – simply a separate

designated area. This would include some neighboring space for staff changing, storage space for PPE, and possibly an on-site shower.[24]³⁸[REF- repeat Beam – PHN], [REF: Beam-Am JInfect Control] Positioning the isolation area a short distance from the entry point into the facility and laboratory assets, thus reducing the length of passage through the facility of a potentially communicable patient or potentially contaminated laboratory samples should reduce potential risk to others.[26] [REF- repeat Hewlett] The patient room should be equipped with surfaces that are easy to wipe down for disinfection, and designated equipment should be selected for easy decontamination. Having a room capable of negative pressure air handling, independent from the hospital's primary air handling system, with HEPA filtered exhaust, is a plus. Other general features include easy access to hand washing stations and PPE.[35] [REF repeat – Beam AmJInfect Control]

Lenaghan and Schwedhelm provide a nice summary of the stages that the Nebraska Biocontainment Unit went through to bring the unit from a concept to fully operational.³⁹ [REF: Lenaghan] This included a design phase with input from multiple sources, where issues such as air handling systems, the sewer system, transport of linens, waste, safety, security, mortuary, and emergency medical systems were discussed. Features planned for included access and egress of patients, materials, and supplies as well as patient transport. The unit went to great lengths to vet the appropriate staff and provide adequate orientation. Ensuring individuals interested in participating embrace the culture of safety and are willing to work in a team environment is very important. In addition, time spent in PPE can be physically demanding and working in such an environment is stressful, so individuals should be screened for a minimum level of fitness – both physical, but also psychological. The second phase included addition of video monitoring capability and text messaging. Unit leadership empowered all team members to be equally

accountable for safety. Unit personnel engaged in regular drills and debriefs, and larger drills brought in organizations outside the hospital facility, such as the regional airport, the local US Air Force base, and the state health department. Unit activation occurred in advance of the first patient arriving in September 2014.

Risi, et al,⁴⁰ [REF-Risi EID 2010] provide a summary of how a facility might be upgraded using existing space. Key aspects emphasized included “redundant engineering of safety features, strict administrative oversight, biosecurity measures, and extensive training.” Upgrades included: access control, three standalone rooms (with bathroom and shower), an anteroom for each, directional air flow, a dedicated exhaust system with HEPA filtration, construction of seamless surfaces for topical disinfection, capability for full range of ICU care, and a separate autoclave. When not needed for high consequence pathogens, the rooms operate as conventional ICU beds.

Although this chapter is focused on facility design, design elements are just one important aspect for reducing the spread of infections in a healthcare setting. It is worth noting that, despite a facility’s layout, or the type of PPE used, limiting the spread of infection relies on people. It starts with having a workplace culture and climate of safety.⁴¹[REF-Moore] Infrastructure is of little utility without appropriate policies and procedures for safety.[35] [REF repeat: Beam AmJInfectC] This comes from the top down. It also includes appropriate redundancies, appropriate levels of staffing, recurrent training and observation of procedures, and having the right, interested caregivers, who are willing to work within a team and follow procedures. Any planning is only as strong as the weakest link. Gershon found six foundational elements for a successful climate of safety.⁴²[REF-Gershon AJIC] These include senior management support, absence of workplace barriers to safe work practices, worksite

cleanliness/orderliness, good staff communication and minimal conflict, frequent training and safety-related feedback by supervisors, and PPE availability and engineering controls.

Multiple potential barriers exist to implementing infection control guidelines in a crisis, including: lack of imperative or precise wording, lack of easily identifiable instructions, and lack of concrete performance targets, and lack of timely and adequate guidance on PPE or other aspects.⁴³ [REF: Timen] As noted by Brett-Major, et al, care must be deliberate, every procedure must be practiced and follow risk/benefit, and anyone on the team can and should call a safety stop if unsafe practices are observed.⁴⁴[REF: Brett-Major] Training, repeatedly reinforced, is at least as important, if not more important than the physical infrastructure and the specific PPE utilized. Finally, significant communication among all aspects of care, early and often, are tantamount to appropriate preparedness and care when needed. [29][REF-repeat Johnson]

In summary, we have discussed different design features that have been incorporated in specialized biocontainment units at strategic locations around the country. Not every hospital can develop such complex infrastructure, but hospitals can decide which aspects they would like to adopt to minimize the risk of spread of hazardous pathogens to their healthcare staff. More importantly, ensuring individuals have adequate training, repeatedly reinforced, in basic infection control practices, can go a long way to reducing healthcare provider risk of spread for routine as well as exotic diseases.

TABLE 1: Built-in facility design features of the USAMRIID isolation unit (the “slammer”)

Two-bed facility with neighboring surgical/laboratory room
 Negative pressure air handling
 Intake HEPA filtration and Exit double HEPA filtration in series
 Decontamination shower
 In-line pressurized air for use of fully encapsulating positive pressure “space” suits
 Steam sterilization of liquid waste
 Pass-through autoclave
 Pass-through ultraviolet light box
 Dunk tank
 Direct patient entry from outside the facility through a wall with hookup to portable isolation unit
 On-site portable laboratory isolator
 Epoxy coated walls
 Telemetry, video monitoring

FIGURE 1: The Emory University Serious Communicable Disease Unit [REF 33-Leligdowicz]

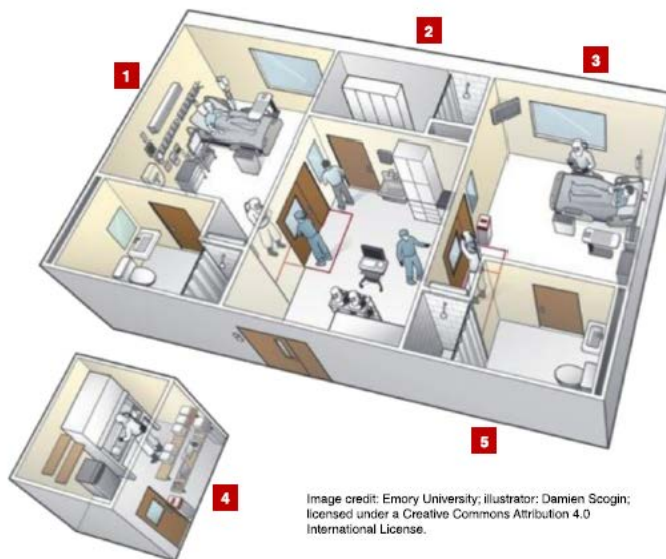


Fig. 4 Emory University Hospital special isolation unit. (1) The private patient rooms resemble intensive care unit rooms, with adjustable beds, intravenous drips, and monitors. Every procedure a patient could need, from mechanical ventilation to hemodialysis, can be performed in the unit. (2) Medical staff who are providing direct patient care use a locker room to change into full-body protective suits and masks, which shield them from blood and bodily fluids. (3) Family members are able to speak with patients through glass windows in the unit; patients have access to phones and laptop computers. (4) A dedicated lab was built specifically for the use with the isolation unit that has the capacity to perform blood counts, routine chemistries, blood gas measurements, urinalysis, and tests for a variety of infectious agents. (5) All liquid waste is disinfected and flushed, and disposable waste is autoclaved and incinerated. At the peak of an Ebola patient's illness, up to 40 bags a day of medical waste were produced

References

- ¹ World Health Organization. Health worker Ebola infections in Guinea, Liberia and Sierra Leone, Preliminary report. Found at <http://www.who.int/csr/resources/publications/ebola/health-worker-infections/en/> 20 January 2017.
- ² World Health Organization. Ebola health worker infections. Found at <http://www.who.int/features/ebola/health-care-worker/en/> 24 April 2017.
- ³ Kortepeter MG, Kwon EH, Hewlett AL, Smith PW, Cieslak TJ. Containment care units for managing patients with highly hazardous infectious diseases: a concept whose time has come. *J Infect Dis* 2016;214:S137-141.
- ⁴ Kortepeter MG, Smith PW, Hewlett AL, Cieslak TJ. Caring for patients with Ebola: a challenge in any care facility. *Ann Int Med* 2015-162:68-9.
- ⁵ World Health Organizations. Ebola haemorrhagic fever in Zaire, 1976. Bull World Health Organ. 1978;56:271-93.
- ⁶ World Health Organization. Ebola haemorrhagic fever in Sudan, 1976. Report of a WHO/International Study Team. *Bull World Health Organ.* 1978;56:247-70.
- ⁷ Tucker JB, Mahan ER. President Nixon's decision to renounce the U.S. offensive biological weapons program. National Defense University Press, Washington DC, 2009.
- ⁸ Crichton M. The Andromeda strain. Centesis Corporation, 1969, New York.
- ⁹ Crawford DH. The invisible enemy: a natural history of viruses. Oxford University Press, 2000.
- ¹⁰ Covert NM. Cutting edge: a history of Fort Detrick, Maryland, 3rd Ed. Public Affairs Office, Headquarters U.S. Army Garrison, 1997, p.79.

- ¹¹ Hill EE, McKee KT. Isolation and biocontainment of patients with highly hazardous infectious diseases. *J Army Medical Dept* 1991;PB8-91-1/2:10-4.
- ¹² Cieslak TJ, Christopher GW, Eitzen EM. The “slammer”: isolation and biocontainment of patients exposed to biosafety level 4 pathogens. *Clin Infect Dis* 1999;29:1083.
- ¹³ Kortepeter MG, Martin JW, Rusnak JM, et al. Managing potential laboratory exposure to Ebola virus by using a patient biocontainment care unit. *Emerg Infect Dis* 2008;14:881-7.
- ¹⁴ Pigott DC. Hemorrhagic fever viruses. *Crit Care Clin* 2005;21:765-83.
- ¹⁵ Borchert M. BMC-ID 2011;11:357.
- ¹⁶ Smith PW, Anderson AO, Christopher GW, et al. Designing a biocontainment unit to care for patients with serious communicable diseases: A consensus statement. *Biosecurity and Bioterrorism* 2006;4:351-65.
- ¹⁷ Banniser B, Puro Vincenzo, Fusco FM, Heptonstall J, Ippolito G, EUNID working Group. *Lancet Infect Dis* 2009;9:45-56.
- ¹⁸ U.S. Department of Health and Human Services. Biosafety in microbiological and biomedical laboratories. 5th Edition, 2009.
- ¹⁹ Cieslak TJ, Kortepeter MG. A brief history of biocontainment. *Current Treatment Options in Infectious Diseases* [in press].
- ²⁰ Reynolds G. Why Were Doctors Afraid to Treat Rebecca McLester? *New York Times*, April 18, 2004.
- ²¹ Kim KH, Tandi TE, Choi JW, Moon JM, Kim MS. Middle East respiratory syndrome coronavirus (MERS-CoV) outbreak in South Korea, 2015: epidemiology, characteristics and public health implications. *J Hosp Infect* 2017;95:207-213.

- ²² Poor planning, communication lead to missteps in care of Ebola patient. *ED Manag* 2015 Nov;27(11):121-6.
- ²³ Jahrling P, Rodak C, Bray M, Davey RT. Triage and management of accidental laboratory exposures to biosafety level-3 and -4 agents. *Biosecur Bioterror: Biodef Strat, Practice, Science* 2009;7:135-43.
- ²⁴ Beam EL, Boulter KC, Freihaut F, Schwedhelm S, Smith PW. The Nebraska experience in biocontainment patient care. *Pub Health Nursing* 2010;140-6.
- ²⁵ Lowe JJ, Jelden KC, Schenarts PJ, Rupp LE, Jr, Hawes KJ, Tysor BN, Swansiger RG, Schwedhelm SS, Smith PW, Gibbs SG. Considerations for safe EMS transport of patients infected with Ebola virus. *Prehosp Emerg Care* 2015;19:179-83.
- ²⁶ Hewlett AL, Varkey JB, Smith PW, Ribner BS. Ebola virus disease: preparedness and infection control lessons learned from two biocontainment units. *Curr Opin-Infect Dis* 2015;28:343-8.
- ²⁷ Wadman MC, Schwedhelm SS, Watson S, Swanhorst J, Gibbs SG, Lowe JJ, Iwen PC, Hayes AK, Needham S, Johnson DW, Kalin DJ, Zeger WG, Muelleman RL. Emergency department processes for the evaluation and management of persons under investigation for Ebola virus disease. *Ann Emerg Med* 2015;66:306-14.
- ²⁸ Courage KH. Inside the 4 U.S. biocontainment hospitals that are stopping Ebola. *Scientific Am* 2014. Found at <https://www.scientificamerican.com/article/inside-the-4-u-s-biocontainment-hospitals-that-are-stopping-ebola-video/>. March 24, 2017.
- ²⁹ Johnson DW, Sullivan JN, Piquette CA, Hewlett AL, Bailey KL, Smith PW, Kalil AC, Lisco SJ. Lessons learned: critical care management of patients with Ebola in the United States. *Crit Care Med* 2015;43:1157-64.

- ³⁰ Lowe JJ, Gibbs SG, Schwedhelm SS, Nguyen J, Smith PW. Nebraska biocontainment unit perspective on disposal of Ebola medical waste. *Am J Infect Control* 2014;42:1256-7.
- ³¹ Lowe JJ, Olinger PL, Gibbs SG, Rengarajan K, Beam EL, Boulter KC, Schwedhelm MM, Hayes AK, Kratochvil CJ, Vanairsdale S, Frislie B, Lewis J, Hewlett AL, Smith PW, Gartland B, Ribner BS. Environmental infection control considerations for Ebola. *Am J Infect Control* 2015;43:47-9.
- ³² Jelden KC, Gibbs SG, Smith PW, Schwedhelm MM, Iwen PC, Beam EL, Hayes AK, Narion N, Kratochvil CJ, Boulter KC, Hewlett AL, Lowe JJ. Nebraska biocontainment unit patient discharge and environmental decontamination after Ebola care. *Am J Infect Control* 2015;43:203-5.
- ³³ Leligdowicz A, Fischer WA, Uyeki TM, Fletcher TE, Adhikari NKJ, Portella G, et al. Ebola virus disease and critical illness. *Crit Care* 2016;20:217-31.
- ³⁴ Garibaldi BT, Reimers M, Ernst N, Bova G, Nowakowski E, Bukowski J, Ellis BC, Smith C, Sauer L, Dionne K, Carroll KC, Maragakis LL, Parrish NM. Validation of autoclave protocols for the successful decontamination of Category A medical waste generated from the care of patients with serious communicable disease. *J Clin Micro* 2016. Epub ahead of print.
- ³⁵ CDC. Interim Guidance for U.S. Hospital Preparedness for Patients Under Investigation (PUIs) or with Confirmed Ebola Virus Disease (EVD): A Framework for a Tiered Approach Found at <https://www.cdc.gov/vhf/ebola/healthcare-us/preparing/hospitals.html> 20 January 2017.
- ³⁶ Herstein JJ, Biddinger PD, Kraft CS, Saiman L, Gibbs SG, Le AB, Smith PW, Hewlett AL, Lowe JJ. Current capabilities and capacity of Ebola treatment centers in the United States. *Infect Cont Hosp Epi* 2016;37:313-8.

³⁷ Siegel JD, Rhinehar E, Jackson M, Chiarrello L, the Healthcare Infection Control Practices Advisory Committee. 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. Found at

<https://www.cdc.gov/hicpac/pdf/isolation/isolation2007.pdf> January 2017.

³⁸ Beam EL, Schwedhelm SS, Boulter K, Kratochvil C, Low J, Hewlett A, Gibbs SG, Smith PW. Personal protective equipment processes and rationale for the Nebraska biocontainment unit during the 2014 activations for Ebola virus disease. *Am J Infect Control* 2016;44:340-2.

³⁹ Lenaghan PA, Schwedhelm M. Nebraska biocontainment unit design and operations. *J Nurse Admin* 2015;45:298-301.

⁴⁰ Risi GF, Bloom ME, Hoe NP, Arminio T, Carlson P, Powers T, Feldmann H, Wilson D. Preparing a community hospital to manage work-related exposures to infectious agents in biosafety level 3 and 4 laboratories. *Emerg Infect Dis* 2010;16:373-8.

⁴¹ Moore D, Gamage B, Bryce E, Copes R, Yassi A. Protecting health care workers from SARS and other respiratory pathogens: organizational and individual factors that affect adherence to infection control guidelines. *Am J Infect Control* 2005;33:88-96.

⁴² Gershon RR, Karkashian CD, Grosch JW, Murphy LR, Escamilla-Cejudo A, Flanagan PA, et al. Hospital safety climate and its relationship with safe work practices and workplace exposure incidents. *Am J Infect Control* 2000;28:211-21

⁴³ Timen A, Hulscher MEJL, Rust L, van Steenberg JE, Akkermans RP, Grol RPTM, van der Meer JWM. Barriers to implementing infection prevention and control guidelines during crises: experiences of health care professionals. *Am J Infect Control* 2010;38:726-33.

⁴⁴ Brett-Major DM, Jacob ST, Jacqueroz FA, Risi GF, Fischer WA 2nd, Kato Y, Houlihan CF, Crozier I, Bosa HK, Lawler JV, Adachi T, Hurley SK, Berry LE, Carlson JC, Button TC,

McLellan SL, Shea BJ, Kuniyoshi GG, Ferri M, Murthy SG, Petrosillo N, Lamontagne F, Porembka DT, Schieffelin JS, Rubinson L, O'Dempsey T, Donovan SM, Bausch DG, Fowler RA, Fletcher TE. Being ready to treat Ebola virus disease patients. *Am J Trop Med Hyg* 2015.92:233-7.