Nebraska Isolation and Quarantine Manual
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High-level containment care (HLCC) refers to the management of patients with highly hazardous communicable diseases (HHCDs) performed in specialized clinical biocontainment units that possess a variety of controls to prevent transmission of infection while facilitating effective patient care. However, the presence of a purpose-built patient care unit does not guarantee safe and effective care of HHCDs, nor is it an indispensable component of such care. The foundation of HLCC is a well-trained team of providers adhering to core principles of operation, such as the hierarchy of controls. This chapter explores the fundamentals of HLCC operations and the application of hierarchy for the care of HHCD patients, along with other key concepts.

Infection control and biocontainment practices in HLCC units are
implemented by interdisciplinary teams with competency in patient care, biosafety, infection control, and the utilization of personal protective equipment (PPE). These practices emphasize pathogen containment in order to reduce and limit health care worker (HCW) exposures while enabling the provision of advanced critical care. HCWs require time and training to develop competencies in their organization’s standard operating procedures (SOPs) and transmission-based infection control practice within the biocontainment unit environment. With education and training comes deeper knowledge of the nuances of HHCD care, mastery of the principles of HLCC, and confidence in the appropriate execution of protocols.

The safe care for patients with HHCDs utilizes a combination of effective biosafety and infection control practices that extends well beyond negative pressure rooms and PPE. Although HLCC units incorporate many of the engineering designs and industrial hygiene standards developed for laboratory biosafety (most closely reflecting laboratory biosafety level 3), they must also provide an environment conducive to patient care and recovery. Human factors associated with HCW comfort, safety, and effectiveness also weigh heavily in the development of protocols and selection of PPE and other equipment. The provision of safe HLCC care requires extensive prior planning, development, and implementation of administrative policies, work practices, and environmental controls.

**Key Concepts: Zones of Risk and Movement within the Biocontainment Unit**

Actions within HLCC settings are predicated on the concept of zones of risk. To create standard frames of reference, risk of pathogen contamination is geographically defined, and protocols and activities are dictated by the zone in which they reside. Spaces in the HLCC unit where confirmed/infected patients reside (e.g., isolation rooms) constitute the area of highest risk. Administrative areas, completely separated from isolation rooms by physical and engineering barriers, are areas of negligible risk. These different areas are often described by a variety of naming systems, such as “dirty” and “clean,” “hot” and “cold,” or “red” and “green.”
Naming schemes can inject gradations of risk as well, such as “warm” or “yellow.”

Facility design and operation should promote unidirectional movement of personnel, equipment, and supplies into and out of the facility whenever possible, ideally moving from zones of lower to higher risk and then egressing through a process of donning and decontamination. On entry to the HLCC unit, staff move into an anteroom that allows them to don the appropriate PPE ensemble for the activities to be performed. All personal items, jewelry, watches, and other nonessential items are left in the anteroom or outside the facility altogether. Entry into the high-level containment patient care area occurs after verification of correct donning of all PPE. Movement within the unit should proceed from zones of lowest to highest risk, or warm to hot. Personnel should avoid backtracking to zones of lower risk, and protocols and procedures should reflect this concept.

Egress from the high-risk area and associated donning of PPE presents one of the most significant opportunities for self-contamination of HCWs. Based on the lessons learned from Dallas in 2014, where two health care workers contracted Ebola virus disease (EVD) during patient care, it is imperative that all personnel are trained and drill frequently on the proper donning process to prevent cross contamination. Suggested procedures for donning and doffing are detailed later in this chapter. The use of a trained observer is also recommended by the Centers for Disease Control and Prevention (CDC) for this process to assist personnel leaving the biocontainment facility.

**The Hierarchy of Controls**

The industrial hygiene concept of the hierarchy of controls (HoC) is instrumental in the management of individuals with a suspected or confirmed HHCD (see figure 8.1). The concept of HoC is used throughout industry to minimize occupational exposures to hazards, and its implementation in HLCC creates the foundation of effective biocontainment. Regardless of whether the pathogen of concern is transmitted via the airborne, droplet, or contact route, each level of the hierarchy—*elimination, substitution, engineering controls, administrative controls, and PPE*—
must be considered with respect to its role in minimizing hazard and optimizing care. One should note that the HoC is indeed a hierarchy, proceeding in order of importance and effectiveness. Elimination of the hazard is always preferred as the most effective intervention, with substitution being the next most effective, although these options obviously are not always possible with respect to pathogens in an HLCC unit. At the bottom of the HoC, PPE is considered the least effective modality. It is a last line of defense, the effectiveness of which depends on proper usage and maintenance, selection of equipment, fit, donning and doffing technique, and operation. Finally, the HoC applies to all hazards in the HLCC environment—such as techniques for pathogen decontamination—and should shape decisions for all protocols and activities occurring within the biocontainment unit.

**ELIMINATION**

Essentially, HLCC units functionally achieve elimination of HHCD pathogens for hospitals and health systems by removing them from the standard health care environment. As noted, however, this means that complete pathogen elimination is not possible within HLCC. Nevertheless, opportunities exist to eliminate unnecessary points of exposure. Elimination efforts also should address hazards other than the HHCD pathogen.

Stepwise processes within HLCC often present opportunities to eliminate pathogen hazards upstream. For example, infectious patient specimens can be inactivated and nucleic acids extracted at the bedside or within the HLCC unit prior to transportation to a clinical laboratory. During the 2014–16 West Africa Ebola outbreak, HLCC units used a variety of procedures to inactivate Ebola virus in clinical specimens. Establishing a satellite clinical laboratory inside the unit, including a biosafety cabinet, centrifuge, and other necessary equipment can eliminate the need to transport some specimens outside of the unit altogether.
Selection of disinfectants and other chemicals present additional opportunity for hazard elimination within HLCC units. For instance, while the US Environmental Protection Agency (EPA) approves both quaternary ammonium and sodium hypochlorite (bleach) disinfectants against various HHCD pathogens, improper use of these agents in combination can generate toxic chloramine gas. Eliminating one of these classes of agents from standard procedures can remove the potential for chloramine exposure within HLCC.

**SUBSTITUTION**

Substitution is the second-most effective means to control hazards and entails replacing a hazard with a comparable process with reduced risk. As with elimination, pathogen substitution is not applicable for HLCC, but substitution is a key method of control related to other hazards in the HLCC unit.

For example, substitution of alternative decontamination procedures, such as vaporized hydrogen peroxide or ultraviolet germicidal irradiation (UVGI), can prevent exposure to more hazardous compounds (e.g., formaldehyde). Instead of chemical dunk tanks or sprayers, such as sodium hypochlorite, substitution of sodium hypochlorite wipes for decontamination of medical equipment could eliminate slip hazards. Physical hazards are often overlooked in HLCC environments, but they are major sources of potential direct injury or breach of PPE. Due to the sensory, movement, and dexterity restrictions associated with PPE, staff within the unit are more vulnerable to such hazards. Liquid disinfectants can create significant slip hazards when applied to flooring, and this hazard can be moderated by substitution of lower volume/more rapidly drying decontamination methods (wipes) or footwear and floor surfaces with higher coefficients of friction. Moreover, sharp edges and pinch points can lead to physical trauma as well as PPE breach and pathogen exposure, and they present important opportunities for hazard substitution. HLCC unit design should consider alternatives to shelves and other wall decor that can serve as bump or cut hazards. Furniture and equipment should be minimized and selected so as to avoid sharp edges that are likely to catch on PPE. Furniture or building materials made of porous
materials (e.g., fabric) should be substituted for nonporous materials to prevent harboring of pathogens.

When drafting supply lists for use in a HLCC unit, teams should look at medical supply options that have the highest safety margin and lowest likelihood of being out of stock during surge periods. Retracting needle systems for syringes and IV catheters can reduce the risk of needle sticks. Needle-less systems of IV infusion kits might reduce risk even further. HLCC protocols should replace any glassware with nonbreakable plastics. Glass ampules, common items in emergency medication kits such as code carts, are particularly hazardous and should be avoided.

ENGINEERING CONTROLS

Engineering controls are design or function features of the physical facility that reduce the odds of HCW exposure to pathogens in the HLCC unit. These features include high-flow negative pressure heating, ventilation, and air-conditioning (HVAC) systems, nonporous finishes on surfaces, physical separation of areas of high risk from low, and others.

Current recommendations for HLCC HVAC systems include a separate air system from the rest of the hospital with a minimum of 12 air exchanges per hour and high-efficiency particle air (HEPA)–filtered exhaust. Exhaust should vent a minimum of 25 feet from any building openings, and dual fans provide redundancy in case of malfunction. Isolation rooms should be negatively pressured at no less than 0.01 inches water gauge (wg) and preferably to 0.03 inches wg compared to noncontainment rooms. HLCC units should have pressure gauges to monitor the pressure continuously in each room, and digital gauges can allow for alarm function and remote monitoring.

Many HLCC units employ a variety of other engineering controls. Floor plans can provide for unidirectional movement of HCWs through the facility from areas of least to greatest contamination, reducing risk of cross contamination. Finish materials with antimicrobial properties can also reduce fomite contamination risk. If UVGI is deployed as part of the decontamination process, UV-reflective paint can be utilized within the HLCC setting to maximize the effect of UVGI. Walls, flooring, and ceiling materials can be engineered and sealed to prevent air and fluids (and pathogens) from exiting the HLCC unit while withstanding surface de-
contamination with chemical disinfectants. Windows should be sealed to prevent aerosol escape. Built-in, pass-through autoclaves can facilitate safe and efficient disposal of solid waste on-site. The liquid waste system can be designed to allow for storage and disinfection prior to discharge to the wastewater stream.

Details of design and engineering features of HLCC units are well beyond the scope of this text, which is not intended to be an exhaustive reference. Readers who are interested in discussion in more depth should consult some of the published overviews of HLCC unit design (see references), which can serve as a useful starting point for further research.

**ADMINISTRATIVE CONTROLS**

When engineering controls cannot provide complete protection from exposure, administrative controls such as staffing protocols, SOPs, and training can be used to reduce risk. HLCC operation requires robust administrative support to manage personnel rosters, unit access, training requirements and currencies, equipment maintenance, supply inventory, and curation of SOPs. The combination of these administrative functions should be used to create a *culture of safety* within the organization, a culture that should infuse every training and operation activity.

*Standard Operating Procedures.* SOPs are key elements in the administrative controls used in a biocontainment unit. The development, practice, and refinement of these protocols form the foundation of the training and exercise program. HLCC team members who participate in training should be encouraged to contribute to the development of the SOPs. Improvement modifications identified during training and exercises should be documented and integrated using a standardized approach. The ability to integrate team members’ feedback in an agile fashion will facilitate a deeper understanding of the SOPs and foster a culture of safety and engagement in which staff feel empowered to participate in all aspects of the unit operations.

*Telemedicine.* The incorporation of telemedicine into HLCC operations is an administrative control that can expand patient access to specialty care and support services while limiting transmission opportunities to other hospital staff and bystanders. Telemedicine, or alternative web-based communication solutions, can be used to
complete patient interviews, conduct intermittent assessments, access spiritual support, allow family communications, and provide ancillary services such as physical therapy, occupational therapy, dietetics, and child life. Telemedicine has been used to allow specialty consultation services (e.g., dermatology) to access the patient without having to enter the isolation room. While high-fidelity secure video systems may offer optimal telemedicine capability (particularly for transmission of images or video for diagnostic purposes), secure internet-based video communication platforms using dedicated tablets can provide a more affordable and easier alternative.

**Access Control.** The HLCC unit should be clearly demarcated and isolated from the rest of the building. A combination of engineering and administrative controls can be used to limit access to high-risk areas and thus reduce chances of accidental exposure of HCWs or bystanders. Entry into the biocontainment unit should be through locked doors, and access should be monitored and limited to only essential, trained, and authorized personnel. Entry controls such as badge-activated access locks and/or biometrics verification with computer-monitored security systems and security officers at the entrance points are typically in place to provide gatekeeping. Signs should be posted to inform nonauthorized personnel of entry restrictions and should include contact information for individuals responsible for and knowledgeable about the facility in case of emergency. Direct access from the exterior of the building is ideal for delivering patients, so that access to the HLCC area does not require comingling with other building operations. If a dual-door system is utilized for entry into the HLCC unit, doors should be interlocked so that the second door will not open until the first is completely closed.

**PERSONAL PROTECTIVE EQUIPMENT**

With engineering and administrative controls in place, PPE provides a final layer of safety by imposing a barrier between the infectious microorganisms and the human operator. While attention frequently gravitates toward PPE in HLCC operations, experienced staff understand that it represents the last resort of protection. The effectiveness of PPE depends on the selection of appropriate PPE posture and equipment, and it most directly relies on adequate training and proficiency of staff in its
use. Generally speaking, a variety of PPE ensembles can be successful in any given situation; however, any poor infection-control behaviors among staff will inevitably result in failure, with potential risks to the individual or others.

Biocontainment units have access to a wide variety of manufacturers and models of PPE approved by appropriate governmental agencies (Food and Drug Administration, National Institute for Occupational Safety and Health, etc.) and manufactured and tested to the proper standards.

In selecting specific PPE products for use in HLCC, leaders should consider the unique needs of their biocontainment unit and a variety of internal and external factors, including:

- Level of protection required for the transmission risk
- Barrier properties of the materials and protection of interfaces
- Durability, fit, and comfort of the equipment
- Ease of use
- Cost and availability

In safety, cost is generally omitted from consideration during PPE selection. However, given the uniqueness of the environment, as well as the high throughput of PPE usage during HLCC care, cost and availability should be a factor.

The US Occupational Safety and Health Administration (OSHA) promulgates standards on blood-borne pathogens, PPE, and respiratory protection (29 CFR 1910.1030; 29 CFR 1910.132; 29 CFR 1910.134) with which employers must comply when preparing employees to care for patients with HHCDs. Leadership should be familiar with these standards and understand the types of PPE available, the training required for reliable protection, and the written procedures necessary. Prior to selecting PPE, HLCC unit leadership should conduct a thorough risk assessment to identify environmental risks to personal safety and health. This assessment should guide selection of individual pieces of equipment that make up the full PPE ensemble. An OSHA PPE selection matrix is provided in figure 8.2.

Selecting Appropriate PPE. Depending on the type and level of pro-
Figure 8.2. OSHA PPE Selection Matrix for Ebola (Figure by OSHA)
tection required, PPE ensembles can include a myriad of equipment options. Because most pathogens require mucus membrane deposit or nonintact skin contact for transmission, equipment to protect the face (especially the mucus membranes) and hands should receive the most attention. Supply orders should account for a variety of sizes. Equipment that does not fit properly creates exposure risks due to physical injuries or unintentional exposure (e.g., tripping on a gown that is too long, tearing a too-tight coverall while squatting, loose-fitting face shield sliding down the face), and ill-fitting equipment is more likely to breach.

Goggles, face shields, respirators, masks, and hoods can be used separately or in combination with other pieces of equipment to protect the face, head, and neck from exposure to pathogens. Eye protection should protect from droplets and splashes at all angles, meaning that common safety glasses are generally inadequate. Although standard surgical masks provide adequate mucous membrane protection for droplet/contact precautions, long-term wear can compromise comfort, particularly if the mask is exposed to sweat or other liquids. Noncollapsible surgical mask products may provide a more comfortable alternative.

Several options exist for respiratory protection in HLCC. Although surgical masks do not protect against airborne or aerosolized particles, placing a surgical mask on an infectious patient, if they can tolerate it, has been shown to reduce the aerosolization of infectious particles into the environment, which protects the HCW. Filtering facepiece respirators (e.g., N95, P100) are disposable respirators that cover the nose and mouth with an air-purifying filter that is tightly fitted and sealed to the face. Half-facepiece and full-facepiece elastomeric respirators (figures 8.3 and 8.4) are reusable respirators with disposable parts. The masks can be cleaned and decontaminated, but the cartridges or canisters used for filtration eventually require replacement. The half- and full-facepiece elastomeric respirators are tightly fitted to the face and sealed around the nose and mouth. Full-facepiece elastomeric respirators have a larger face coverage area and provide eye protection the half-facepiece does not offer, along with a higher assigned protection factor (APF). The filtering facepiece respirator and the half- and full-facepiece elastomeric respirators require fit testing before they are used. Fit testing checks the respirator’s seal to the face of the individual being tested, based on the
respirator model selected, and the stability of the respirator while the individual is moving and talking; workers must only wear respirators for which they have been properly fit tested.

Powered air-purifying respirators (PAPRs) are loose-fitting respirators that use a battery-powered blower to circulate filtered air through the facepiece. PAPRs can be used with a hood or helmet for varying degrees of face, head, and neck protection. The cartridges or canisters attached to the PAPR are disposable but usually last for multiple uses. Batteries for the PAPR blower can be single-use or rechargeable. Loose-fitting PAPRs do not require fit testing and can be used effectively with facial hair, as opposed to most fitted respirators. PAPRs must be assembled and tested to identify safety risks with each use. Respirator use requires attention to many critical aspects, and all HCW and staff wearing them must be part of the organization’s respiratory protection and occupational health programs. These programs manage proper fit testing for nonpowered respirators, suitability assessments such as pulmonary function testing, and other requirements, depending on institutional policy. Some PAPR units are noisy enough to warrant participation in hearing conservation programs as well.

Gloves used for HLCC protect the health care worker’s hands from
Figure 8.4. Full-Facepiece Respirator (Courtesy of Nebraska Medicine)
body fluids and chemicals such as cleaning solutions. Disposable gloves manufactured from nitrile, neoprene, or other nonlatex materials are less likely to cause skin and respiratory reactions than natural rubber latex. Long-cuff nitrile gloves provide extended coverage for the wrist and lower arm and reduce the risk of separation from the sleeve cuff of a gown or suit. Reusable gloves (e.g. thick, chemical-resistant nitrile) are best reserved for nonpatient care duties, as they tend to be less form fitting and more difficult to use when fine motor skills are needed.

Body coverings include scrubs, gowns, aprons, coveralls, footwear, and boot covers. Materials can be fluid resistant or impermeable and single-use or reusable. Reusable items can lose some of their durability and effectiveness during the decontamination and laundering processes. Although some expert panels advocate fluid-impermeable materials for enhanced contact precautions for VHF, fluid-resistant materials are adequate for some applications and can be combined with fluid-impermeable aprons or other equipment when high-volume fluid exposure may be expected. Special attention should be given to gown and suit seams, however, because unsealed stitched seams can provide a direct portal of entry. Scrubs worn as a base layer of PPE should be loose fitting and comfortable and do not necessarily need to be fluid resistant. When selecting gowns, aprons, coveralls, and boot covers, consider products that provide protection based on transmission risk. Coveralls should be worn loosely to allow the suit to easily roll over the shoulders when doffing, and to reduce the likelihood of a seam breach. PPE selection should account for the clinical challenges presented by basic patient care and interaction, close contact with large amounts of body fluids, aerosol generating procedures, and even postmortem care. Procedures outside of patient care areas, such as waste processing and equipment disinfection, may also require special protective equipment relative to the nature of the hazards present and the work to be done.

OSHA published a PPE selection matrix for protection against occupational exposure to Ebola to assist employers in identifying and selecting appropriate PPE. Figure 8.5 shows an excerpt from this matrix for individuals that provide medical and supportive care for patients being screened or treated for EVD.

Approach to Donning and Doffing. While PPE can effectively protect
HCW from exposure and transmission, it only works when used appropriately. Human factors often limit PPE effectiveness, such as forgetting to secure ties on an isolation gown or touching the filter surface of a respirator during removal. Complete compliance with PPE protocols for donning and doffing should not rely on memory alone. Most units use a variety of donning and doffing aids, including posted checklists, picture references, buddy checks, and external observers to confirm proper sequence and actions and thus reduce the likelihood of human errors leading to contamination. Tables 8.1 and 8.2 provide examples of checklists employed in our biocontainment unit. Other interventions to reduce human error include full-length mirrors to allow self-checks of donned PPE and video recording of donning and doffing procedures to

<table>
<thead>
<tr>
<th>Donning Checklist</th>
<th>Doffing Checklist</th>
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<tbody>
<tr>
<td>1. Boot covers</td>
<td>1. Tape</td>
</tr>
<tr>
<td>2. Surgical hood</td>
<td>2. Long-cuff gloves secured with duct tape</td>
</tr>
<tr>
<td>3. Gown</td>
<td>3. Doffing partner change gloves</td>
</tr>
<tr>
<td>4. Disposable respirator (N95 or P100) and seal check</td>
<td>4. Gown</td>
</tr>
<tr>
<td>5. Face shield</td>
<td>5. Inner gloves</td>
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<tr>
<td>6. Hand hygiene</td>
<td>6. Doffing partner and doffer change gloves</td>
</tr>
<tr>
<td>7. Exam gloves</td>
<td>7. Face shield</td>
</tr>
<tr>
<td>8. Long-cuff gloves secured with duct tape</td>
<td>8. Disposable respirator (N95 or P100)</td>
</tr>
<tr>
<td>9. Safety check</td>
<td>9. Surgical hood</td>
</tr>
<tr>
<td>10. Third layer of gloves, aprons for patient care</td>
<td>10. Bleach wipe plastic footwear</td>
</tr>
<tr>
<td></td>
<td>11. Hand hygiene</td>
</tr>
<tr>
<td></td>
<td>12. Antimicrobial wipe personal eyewear</td>
</tr>
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<td></td>
<td>13. Shower</td>
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</tbody>
</table>

Table 8.1. Checklist for Donning and Doffing with a Disposable Respirator. Adapted from Beam et al. (2015). Used with permission.
allow for systematic assessment. As with most critical human activities, simplicity and repeatability are important themes in developing donning and doffing protocols.

*Donning Procedures.* The process of donning PPE occurs in a controlled environment outside of the at-risk zone but requires training with equal vigilance to detail as with doffing. Individuals should remove jewelry and personal items (e.g., watches, earrings, pens, cell phones) before starting the donning process, and the unit should provide safe storage options to incentivize behavior. Donning sequence will vary depending on equipment used in the PPE ensemble, but it should be specified well in advance by organizational leadership and workers trained on
a regular basis. As donning sequence frequently drives doffing sequence, donning protocols should account for core principles and priorities in doffing, namely, removing the most contaminated items first, maintaining protection of the eyes and respiratory tract for as long as possible, and facilitating appropriate hand hygiene.

Gowns are worn with the opening to the back of the body and secured at the neck and waist. Eye and face protection should be secured behind the ears or over the head. Donning order for gloves will depend on the level of protection needed. If more than one layer of gloves is used, the final layer should overlap the cuffs on the gown’s sleeves. Some HLCC unit protocols also use tape at the interface of the glove and sleeve to prevent unintentional skin exposure. This is an institutional preference but when done should use tape that does not tear sleeve material with removal and should incorporate a folded-over tab to enable ease of removal and to prevent tears.

When used, a respirator is placed over the nose, mouth, and chin, then secured to the head with elastic straps and adjusted to fit. A seal check is performed after the respirator is situated firmly against the face; the respirator should collapse in toward the face during inhalation. During exhalation, air should exit through the respirator (or valve) and not escape around the sides. A general principle for tight-fitting respirators is that equipment that is in place before donning the respirator should not impede direct contact of the mask and straps with the wearer’s head. Straps that secure the respirator in place should not be placed over goggles or another eye protection and should be used per design (i.e., no cross-strapping). The PAPR provides a loose-fitting alternative for respiratory protection that also protects the eyes. Before donning a PAPR, complete a safety check of the blower, battery, and air supply hose. PAPRs vary by manufacturer and should be donned according to the manufacturer’s guidelines.

Doffing Procedures. The doffing procedure depends greatly on the layout and design of the specific HLCC unit. Regardless, doffing should consist of a coordinated sequence that removes potential sources of contamination while moving stepwise from areas of higher to lower contamination risk. While zones of risk are best separated by physical barriers (walls and doors), simple distance with tape lines or other demarcation
may suffice. Doffing begins prior to exit from the high-risk zone. Before removing any PPE, the wearer and the doffing partner should inspect PPE for tears or other breaches in the integrity of the material, disinfect any areas of visible or suspected contamination, and identify areas that are considered contaminated and clean. In general, the most contaminated areas are the front of the PPE ensemble, gloves, and sleeves—where there was a likelihood of coming into contact with the patient or the environment. Generally, areas of PPE that are considered cleaner are the back side of the PPE ensemble, where it is less likely that the PPE came in contact with the patient or the environment.

The doffing sequence depends on the equipment used and the order that it was donned. When multiple layers of gloves are used, the outermost that had frequent contact with patients or contaminated environments can be decontaminated and removed prior to leaving the patient care area. A new outer glove may be donned, if necessary, to ensure that at least two pairs of gloves are present to initiate the formal doffing sequence. In addition, some units will also remove an outer apron or gown inside the patient care area in order to contain materials with the highest likelihood and degree of contamination inside the high-risk zone. If conducted in the patient care area, these actions should occur as far away from areas of intense contamination (such as the patient) as possible and close to the exit, to limit opportunities for further contamination prior to leaving the highest-risk zone. The use of chemical sprayers, foot baths, and wipes for decontamination in doffing is a point of debate and remains an institutional decision. Selection of doffing decontamination methods should account for the environment considerations (indoors, outdoors, drains) when selecting an appropriate method. Some experts have expressed concern regarding the opportunity for splash and re-aerosolization associated with decontamination sprayers in enclosed spaces. Since most HLCC units in developed countries operate in fixed indoor facilities with finished flooring, sprayers may create slip and chemical fume hazards for HCWs and patients that may be more consequential. Disinfectant wipe options do exist for decontamination beyond gross soiling (which is universally recommended) and in high-risk scenarios may provide an extra margin of safety.

As doffing proceeds, PPE on the body should be removed prior to
PPE protecting the head and face. This provides mucous membrane protection from any aerosolization that might occur as contaminated PPE on the body is removed. When drafting and training doffing procedures, the mantra “Clean touches clean; dirty touches dirty” can help reinforce principles for avoiding cross contamination. External gloves (considered more dirty) should touch external surfaces of gowns and suits, while inside surfaces of PPE garments and inner-layer gloves (all considered more clean) should touch each other. Assistance from a doffing partner or a chair or stool can reduce the fall risk associated with balance issues and fatigue. When removing gloves, the wearer should use the glove-in-glove technique, creating a bundle of both gloves, with the least contaminated surfaces on the outside, that is gently discarded. After each doffing step in which the wearer touches a component of PPE, hand hygiene with alcohol-based hand rub or handwashing should be performed. When removing a gown, a doffing partner can carefully unfasten ties at the neck and waste, which reduces opportunity for aerosol generation or splatter when these ties are forcibly torn. Doffing partners can also help with zippers on suits. Removal of gowns, suits, and boot or shoe covers while avoiding cross contamination is one of the more challenging aspects of doffing. Specific procedures should account for the style and model of garment being removed and for dexterity challenges associated with staff fatigue. Doffing partners and rolling techniques (to contain outer dirty layers and expose clean inner surfaces) can be employed to reduce risk of self-contamination. Handles, chairs, or stools can help provide balance and support to prevent falls and stumbles.

Core principles of safety during doffing include slow and intentional movements, control of garments to avoid flailing of dragging pieces, diligent attention to hand hygiene, and protection of mucous membranes. The doffing process is significantly aided by visual cues from the observer/doffing partner or marked on floors or walls. Sensible placement of waste receptacles and hand hygiene stations can greatly streamline the process. Trash cans with larger mouth openings make easier targets for disposing doffed garments and may reduce the urge to push down trash, which presents a re-aerosolization hazard.

The last stage of doffing is hand hygiene performed outside the area of risk and removal of scrubs and other clothing that was worn under
PPE in the patient care area. Some units require staff to “shower out” of the unit, taking a personal shower after removing scrubs. While not necessary for most situations, it may be advisable for certain high-risk scenarios and can simply provide peace of mind to the personnel providing HLCC.

Disinfection

Disinfection is the process of destroying, or rendering inactive, biological pathogens by physical or chemical means. Although technically different terms, disinfection and decontamination are often used interchangeably within the HLCC environment. Disinfection should be conducted frequently during HLCC operations. Spot disinfection is used in instances where visible contamination is present, such as body fluid spills. Daily disinfection involves routine cleaning with appropriate disinfectants to reduce pathogen load on surfaces. Terminal decontamination is the final definitive process to remove pathogen contamination after patient care operations cease. Disinfection should be conducted by trained professionals utilizing the proper PPE, taking into account the causal microorganism, disinfectant(s), and the environmental conditions. In HLCC operations, HCWs can be cross-trained to conduct spot and daily disinfection as functions of routine duties. This can be beneficial as it reduces the number of individuals who come into the HLCC unit and are subject to risk.

The causal microorganism will drive the disinfectant selection. In the United States, the EPA has authority on the registering of disinfectants, and only EPA-registered hospital disinfectants with a label claim for the particular pathogen should be utilized. In a case where such a label claim does not exist, seek guidance from both the US EPA and CDC prior to deciding on disinfection technique, as was done during the 2014–16 West Africa EVD outbreak.

When utilizing a disinfectant, it is critical that the manufacturer's instructions be followed for its proper use, particularly around minimum contact times and concentration. Many chemical disinfectants lose potency when exposed to oxygen, high temperatures, and humidity; therefore, staff should monitor the expiration time/date or age of
each compound both before and after they are prepared for use. Because the organic load of gross contamination (e.g., blood, feces, other body fluids, etc.) will drastically reduce the efficacy of any disinfectant, gross contamination must be mechanically removed prior to disinfection. The HLCC environment may present scenarios not covered by the manufacturer’s instructions, and in these cases it is recommended that you consult with the proper professionals, including representatives from the US EPA and CDC. If the causal microorganism is unknown, then often the disinfectant utilized should be a more robust disinfectant with a US EPA–registered hospital disinfectant with a label claim against spores, such as the US EPA List K disinfectants.

An effective daily cleaning/disinfection routine should be established and maintained throughout HLCC operations; however, staff should take advantage of every opportunity to clean and disinfect throughout the day. As with other movement in HLCC units, cleaning should proceed from the least contaminated (cold) zone to the most contaminated (hot) zones, ideally with each zone having its own designated cleaning and disinfecting equipment.

Several options exist for whole room disinfection associated with terminal cleaning and decontamination (e.g., UVGI, gaseous chlorine dioxide, and vaporized hydrogen peroxide). Whole room disinfection should occur after patient discharge and should be performed by personnel specifically trained in how to do so safely, including proper PPE selection and use. Environmental science and industrial hygiene experts should weigh whole room disinfectant options for each facility accounting for specific needs. For example, UVGI is effective at surface disinfection but requires that the UV light reach all surfaces for the proper amount of exposure. This method would be less effective in rooms crowded with equipment or with hidden and shielded areas.

Movement of Waste and Materials Out of Containment

Design and operation of HLCC units should account for movement of waste and other materials (e.g., patient specimens) out of HLCC settings. Waste management constitutes one of the more challenging features of HLCC and is covered extensively in chapter 19. However, principles per-
taining to design and protocol for movement of materials out of containment will be addressed here.

As a general rule, materials exiting the unit are either rendered non-infectious prior to passing out of the unit or are sealed in redundant layers of protective containment. All surfaces—bags and containers—are extensively decontaminated with appropriate disinfectant wipes or sprays. The authors prefer to pass out or receive materials in rigid containers in order to reduce the odds of plastic bag tears or punctures that could result in breach of containment. Air locks or pass-through boxes (with interlocking doors) provide the highest safety margin for passing material out of the isolation space; however, these features are expensive to retrofit and infrequently featured in patient units. Pass-through boxes can be fitted with UV irradicators to provide additional safety. While pass-through dunk tanks also offer a high degree of protection from cross contamination, we do not recommend their use in HLCC due to associated splash and slip hazards. In most instances, materials are passed out of a briefly opened door and to a receiving person outside of isolation who is wearing appropriate PPE, depending on the material and pathogen involved. For most pathogens with limited aerosol transmission potential (e.g., viral hemorrhagic fever viruses) opening a door from a lower risk (warm) area to the cold zone presents negligible risk of pathogen escape, primarily due to the negative pressure gradient that exists. However, for small spaces without antechambers and with airborne pathogens, this risk may be more substantial. Ideally, solid waste materials are decontaminated prior to removal from the containment space, which reduces requirements for further safe handling and hazardous materials shipping and disposal procedures.

Lab specimens to be passed out of isolation can be sealed in at least two layers of leak-proof bags that are surface decontaminated (with contact time necessary to achieve decontamination) and then passed out by one of the above methods to the outside of the HLCC unit for transportation to the laboratory for analysis. Sample seals should be maintained and not opened until they are within the containment of a biological safety cabinet within the laboratory. Passage of all other materials, supplies, and equipment that cannot be autoclaved can be sent out through air locks/fumigation chambers where they are subjected to chemical gas
disinfection, or another approved process (e.g., disinfection and desiccation), prior to removal.

**HLCC Unit Leadership, Staffing, and Training**

*Unit Leadership.* An interprofessional leadership team to provide strategic direction is critical to HLCC readiness and operational success. Such a team should integrate nurse leaders, physicians, biosafety and infection control professionals, laboratorians, and industrial hygienists. The leadership team must embrace a mindset and culture of safety. Additionally, in the complex environment of HLCC, a comprehensive approach to problem-solving and decision-making, pursuit of novel ideas, and adherence to evidence-based protocols can dramatically improve team performance. The leadership team should meet frequently to discuss key components of biocontainment unit operations: research, protocols, emergency response, staff engagement, training and exercise plans, and progress.

*Staff Recruitment and Selection.* Biocontainment unit staffing must take into account the facility’s organizational structure, physical layout, institutional staffing requirements (for noncontainment wards), and organized labor (union) considerations. Currently in the United States, some Ebola treatment centers (ETCs) include HLCC duties as a component of standard hospital job descriptions. For unionized labor, this approach provides the foundation for contractual agreements that include HLCC care. When it is a tenable strategy, volunteer-based staffing allows for a more selective process and more buy-in from staff.

Ultimately, the HLCC staff must possess a solid foundation of clinical skills and sufficient expertise to manage complex patients, often critically ill, in a challenging environment. Because the appropriate care of the patient with an HHCD and the risk of pathogen transmission to staff must constantly drive decisions, infectious disease physician involvement is central. Critical care nurses and physicians form an important core of the health care team in HLCC, but staff from wards, emergency departments, and other backgrounds bring important diversity of perspective and problem-solving. Staff should also include other skilled professions required for care and safe operations such as respiratory therapists, in-
fection prevention specialists, industrial hygienists, environmental scientists, and so on. Other skilled positions such as imaging and dialysis technicians can be fully incorporated into the team or may be able to cross-train and guide unit staff to be able to manage specific applications. Due to the challenges and stress of HLCC operations, staff should have preexisting experience in their care discipline and must possess critical thinking skills, work well on a team, embrace strong attention to detail, and demonstrate psychological stability. These characteristics can be assessed by using a standardized psychological assessment tool.

**Onboarding.** Once selected, team members should undergo a structured onboarding process to include orientation and initial training. Onboarding should focus on skills and equipment unique to the HLCC environment. Key areas to consider include safe entry and exit procedures, modified patient assessment techniques, waste management, decedent management, body fluid management, and donning and doffing procedures for selected PPE. Emergency response plans should also be communicated to new incoming staff. Introductory educational modules should be tailored to include discipline-specific considerations when including physicians, nurses, respiratory therapists, or other support staff. Onboarding should allow for ample time, training, and supervised work prior to certification for independent operations within the HLCC environment.

**Routine Training.** Standardized training should be coordinated by a structured training program that establishes requirements for initial certification of competency in independent biocontainment work and specific tasks designated for general personnel and specific specialty. The training program should track up-to-date relevance and provide training plans to maintain currency and individual certification for HLCC operations. Although no national or international standards exist at this time, we recommend training at least annually for all facilities and at least quarterly in designated regional ETCs by rostered staff members. At a minimum, training should include donning and doffing of PPE, review of protocols that address high-impact, low-frequency events such as “provider down” and decedent management, and performance of basic skills. Units should develop an evaluation process that addresses both individual proficiency and team dynamics. The ability to evaluate and
trend both individual and team progress over time will assist with the progressive enhancement of a training program that meets the needs of the rostered staff. In addition, it is critical that a method be determined to accurately track the attendance and performance of all HLCC team members. This documentation can be used to guide any just-in-time (JIT) training material development and deployment if the biocontainment unit is activated.

In addition to routine training, implementing a progressive multiyear training and exercise plan that adheres to Homeland Security Exercise and Evaluation Program (HSEEP) guidance will serve to continually advance HLCC capabilities. HLCC staff should be encouraged to participate on the exercise planning committee. Inviting team members to participate in exercise planning procedures provides a strategy to foster development of additional expertise, a deeper knowledge of HLCC unit operations and SOPs, and team engagement. Incorporating a variety of discussion-based and operational exercises provides staff members and leadership with a venue to test the SOPs that have been established and make any necessary improvements. At a minimum these exercises should consider activation, transportation, admission, and patient care procedures. When structuring a training and exercise program for HLCC teams, it is advisable to start with basic, plausible scenarios. This allows the leadership team to fine tune protocols and establish a foundation of trust and confidence within the team. As the team progresses, exercises can be expanded to include specialized scenarios such as surgical interventions and multiple patient admissions. Incorporating emergency management experts in constructing exercises can also optimize support and assist with meeting essential exercise requirements.

**Just-in-Time Training.** Health care professionals that are not included among the rostered HLCC staff but whose expertise may be needed should have access to JIT training prior to providing care in the HLCC unit. However, completion of JIT training should not be interpreted as having the HLCC facility knowledge and skills to operate autonomously but should prepare the trainee to enter the environment under direct supervision of HLCC staff. A JIT training curriculum should include essential elements that are critical to safe patient care delivery, identified by a risk assessment of potential tasks to be carried out. Focal areas to
consider include safe entry and exit procedures, PPE donning and doff-ing, role-specific procedures to be performed in PPE, and communication techniques in the hot zone. Delivery methods should be tailored to the needs of the individual and include multiple strategies such as online modules, electronic distribution, and in-person hands-on training.

**Resilience Training.** The incorporation of resilience and mindfulness strategies into routine training for HLCC team members should be considered an essential component of a comprehensive training and exercise plan. HLCC units providing patient care have cited mental health as an important element in a biocontainment unit occupational health program. HCWs who provided care for patients in the Nebraska Biocontainment Unit known to have EVD identified interpersonal stressors to include alterations in their home or social life or feeling isolated during the period of activation. Integrating behavioral health experts into the HLCC team training provides easy access to rostered staff and helps instill healthy coping mechanisms in team members. Having a behavioral health worker available for staff members during training helps foster strong relationships in advance of an actual event. Several HLCC-activated staff identified that having a behavioral health expert available for informal conversations was beneficial during activations. Strategies to enhance the focus on resiliency include team training events, inclusion of presentations and time to practice techniques before or after drills and exercises, and inviting behavioral health experts to observe and participate in scheduled trainings.

**HLCC Team Culture**

Effective HLCC operations require a unique team culture of cohesion, communication, teamwork, problem-solving, and above all safety. Safety must permeate all day-to-day activities, training, and operations. Leadership must embrace this concept and act deliberately toward that goal. Ideally, each team meeting or function should begin and end with a safety message, and safety concerns should be the ultimate point of emphasis before entry into the HLCC unit.

A horizontal hierarchy is one key component of this culture, where each staff member feels empowered to speak up to address safety issues.
Because staffing inside the biocontainment unit is at a premium, custodial tasks and scut work must be performed by all individuals within the unit, from the medical director to the newest technician. The philosophy that nobody is above any job begins to build a culture of shared responsibility. Staff members should be trained to leave rank and title at the door of the HLCC unit, and teams can consider using first names in addressing each other within HLCC.

A team with horizontal hierarchy, where every member feels they have equal value, importance, and responsibility for safe operations, will manage unexpected hazards more effectively. Every HLCC unit should have a code word that informs team members of a safety concern and immediately prompts them to stop all activity and listen. Often this code word is as simple as “STOP!” In a team with appropriate safety culture, every member would feel empowered and obligated to call a time-out as soon as they encounter a major safety concern. On hearing the code word, all team members should cease movement (or proceed to the first safe stopping point), listen to the concern (described in direct and succinct terms) from the member who raised the alarm, and jointly formulate a plan to address the hazard. This concept should be taught and drilled constantly to become second nature.

**Conclusion**

Safe and effective operation in HLCC requires an efficient and high-functioning unit, working in accordance with foundational principles of containment care. HLCC operations rely heavily on implementation of the HoC. Most importantly, they rely on meticulous planning, tested SOPs, and continuous training of staff. A highly functioning HLCC unit and team requires a significant commitment of time and resources.

While no national or international certifying body exists for HLCC, and practice will necessarily vary among different units related to unique features, most aforementioned engineering controls are not only practice- and evidence-based but also validated through analysis. Thus, consensus design and engineering features among high-level isolation units in developed nations should be considered the “gold standard” for engineering controls in HLCC units. In addition, a growing evidence
base supports some consensus practice in administrative controls and PPE. With continued research, best practices can be established across all components of HLCC operations.

Adherence to the infection control and biocontainment practices in HLCC units implemented by interdisciplinary teams with competency in patient care, biosafety, infection control, and utilization of PPE will allow your organization to establish a facility and operations to safely care for these unique patients. While there are many different ways to accomplish these goals, the basic principles of safety continue to apply. Mindfulness toward the mental well-being of all those involved will also contribute toward the success of your HLCC unit.