



# High-Consequence Infectious Disease: 10 Principles for Patient Safety

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The 2014 Ebola outbreak in West Africa—which resulted in patients traveling to the United States and Europe for treatment—raised awareness of the need for renewed efforts to safely care for patients with highly pathogenic infectious diseases. We learned that these diseases pose a significant risk not only to patients, but to healthcare workers as well. From July to October 2014 alone, it's estimated that three to five percent of infections and deaths were of healthcare workers. Over 800 healthcare workers were infected with the virus and over 500 of them died.

During the entire outbreak, over 27,000 were infected and over 11,000 died, according to the World Health Organization. While the risks of working in Africa are different from working in Western countries, a high rate of infection was experienced in Western personnel working with these patients both in Africa and in the U.S. We also learned that modern critical-care medicine can significantly reduce mortality rates. If future outbreaks occur, it is likely that suspect or confirmed patients will be brought to the U.S for care. It's important that we recognize, assess and plan to address the risk rationally and proactively. As we saw, a reactive, after-the-event approach creates problems.

As the leading design firm for both healthcare and science facilities, we assembled a core team of planners, architects and engineers; healthcare and biosafety professionals who have planned patient biocontainment isolation units and over 250 Biosafety Level-3 (BSL-3) and Biosafety Level-4 (BSL-4) containment facilities on six continents, including CDC's laboratories that handle Ebola and other BSL-4 viruses.

Working with the Eagleson Institute, we sponsored a colloquium in April 2015 on patient-care facilities for highly pathogenic infectious diseases. Representatives from CDC, the University of Nebraska, Emory University, UCLA, KSU, and the Association of Infection Control Professionals participated. The group reviewed lessons learned from the first round of Ebola patients cared for in the US, design and operational issues for the facilities supporting their care, and safety for healthcare workers and the general community.

This white paper provides an overview of the issues and ideas discussed during the colloquium. They will assist design teams and healthcare organizations develop appropriate operational and facility responses for both emergency room intake and patient care biocontainment units



## Preparedness Leads to a Safer Environment

While only a limited number of health systems in the US and Europe actually cared for patients in the 2014 Ebola outbreak, the outbreak served to raise awareness of the serious issues we face in preparing for emerging, re-emerging and even purposefully-engineered infectious disease.

Even for institutions that plan to operate patient biocontainment units for highly pathogenic infectious diseases, one size does not fit all from the perspective of design. For example, some institutions may face pressure from unions representing nursing or maintenance staff that may require highly engineered design solutions; others may have staff willing to implement more

protocol-driven solutions. Some patient biocontainment units may be built in new facilities, while others may be located on upper floors of old buildings with piping infrastructure prone to leaks. There are many issues like these. Each institution needs an environment tailored to its specific requirements and circumstances.

Despite these differences, there is a set of planning and design principles based on lessons learned from institutions such as Emory University and the University of Nebraska Medical Center. Experience from biocontainment facilities in healthcare and research can guide the design of these facilities.

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## Principle 1

### Understand the Biocontainment Risks Unique to Healthcare

While there is much to be learned from containment models used in the laboratory, the risk to workers is significantly higher in patient care facilities than in laboratories. Most patient biocontainment units are, at best, equivalent to BSL-3 facilities; in a laboratory environment, BSL-3 applies to specific known agents, while hospitals are often dealing with unknown risks and agents.

In laboratory facilities, primary containment protects both the worker and the environment. In healthcare, by contrast, it has proven extremely difficult to treat patients in primary containment isolators—so, these isolators are not often used. Instead, a healthcare provider is in the room with an infected patient, exposed to infectious materials in the air and on surfaces. This exposure requires complex Personnel Protective Equipment (PPE)—including gowns, gloves and respiratory protection that is difficult to don and doff—to be worn at all times. In a laboratory, PPE other than gloves and sleeves is not normally exposed to infectious agents.

When working with highly pathogenic infectious agents like Ebola in a BSL-4 lab (the highest biosafety level in laboratories), PPE is completely decontaminated with chemicals before removal; a splash would require immediate disinfection. For patient-care workers, PPE is frequently exposed to aerosol-producing procedures, a high volume of infectious waste, and uncontrolled large-scale events such as explosive vomiting and diarrhea. The worker has to remove and decontaminate their PPE without exposing themselves to infection—a difficult and complex procedure.

Understanding the risks inherent to biocontainment in a healthcare setting will help set expectations during planning.

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## Principle 2

### Plan and Prepare for the Unexpected

Healthcare has little control over potential patients. With emerging, re-emerging and evolving diseases, increased drug resistance, and unknown agents that may create higher risks and consequences, a hospital never knows who might walk through the door. Patients may need medical care above normal infectious-disease care, particularly suspect cases. Plan the capability to provide unexpected medical care. A laboratory can choose if, when, and how to handle an infectious agent. A hospital may have no control of the same disease that may present itself in an unexpected manner. Plan facilities to handle unexpected events and have proactive operational plans and contingencies in place.

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## Principle 3

### Provide Flexible Patient Care Space

Four major lessons learned from patient-care activities during the care for Ebola patients in the US in the 2014 outbreak were:

1. Patients have a much higher acuity of disease requiring a level of critical care not previously found with infectious diseases.
2. The acuity varied during a stay from healthy to critically-ill to recovering to a healthy state.
3. Patients were required to stay in the patient biocontainment units much longer than anticipated.
4. The current patient biocontainment units were not designed for all events and potential care required.

Patient-care activities should accommodate diagnostics, procedures, labor and delivery. Suspect patients as well as confirmed cases must be given appropriate medical care. Plan a facility that can accommodate both, concurrently, with maximum safety for both patients and staff. Also, patients are likely to have existing comorbidities or conditions that may require diagnostics and treatments.

Patients may be pregnant and require labor, delivery, and mother-baby care capabilities. Equipment needs will change during the stay. Plan to allow equipment to easily enter and exit the room with decontamination. The rooms should be capable of providing most care without removing patients from containment.

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## Principle 4

### Prioritize Engineering Controls Over Protocols

Many accidents and unplanned events are a result of human error or the inability for staff to consistently follow complex operational protocols. Most containment laboratory incidents are a result of human error. Hospitals, in particular, have had a difficult time reducing error to acceptable levels. Engineering systems can be designed to accommodate failure scenarios. The facts show that humans are much more likely to make a mistake than well engineered systems.

In designing for biocontainment and biosafety, use engineering controls to replace protocols whenever practicable. An example would be to provide a through-wall autoclave to disinfect waste at the point of use, rather than requiring bagging waste, disinfecting it, and moving it out of the facility to an autoclave. As the risk increases, engineering controls should increase, minimizing the need for protocols.

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## Principle 5

### Integrate Facility Design with Operational Protocols

The facility design must be fully integrated with the planned operational models to minimize the potential for adverse events. When facilities and operational protocols are mismatched, shortcuts and workarounds are taken, and the chance of an adverse event occurring significantly increases. Design the facility to match planned operations, not the reverse.

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## Principle 6

### Control Contamination Through Separation

Separating contaminated areas from non-contaminated areas will minimize risk to patients, staff, and the community. First, look at how to reduce the number of spaces that will potentially be contaminated to the absolute minimum required for operation. Where possible, achieve separation through primary containment. Take a particularly close look at eliminating clean and contaminated cross-flows. This includes eliminating the potential for cross contamination between spaces serving confirmed and suspect patients as well as patients with different diseases.

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## Principle 7

### Eliminate Airborne Spread of Infectious Agents

It was generally believed that Ebola had limited potential for transmission through the aerosol route. However, that will not likely be the case for all future diseases. Plan flexibility in the facility to handle what may be required for diseases with higher aerosol risk. These provisions also provide safety for handling patients with diseases such as Ebola, as these provisions also limit airborne spread of viruses to surfaces, where the viruses may be unexpectedly picked up through contact. Anterooms, filtration and directional airflow are important to consider for worker safety as well as preventing airborne and aerosol contamination outside the patient-care space. Consider HEPA filtration of exhaust and vent openings. Provide directional airflow from areas of lower risk to areas of higher risk. Recognize the limitations of directional airflow and provide physical barriers such as ante-rooms, which create a better air boundary as airflow must go through a minimum of two doors in series.

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## Principle 8

### Choose Surfaces and Finishes for Decontamination

In laboratories where the infectious agent is handled in a primary containment device such as a biosafety cabinet, there is rarely a need to decontaminate the room with chemicals that degrade finishes. However, due to the lack of primary containment in healthcare settings, application of surface disinfectants will be required more often in biocontainment patient units than in comparable laboratory facilities. In addition, patient biocontainment units may not be able to be shut down for finish maintenance. This was an important lesson learned from the Emory and Nebraska facilities. Choosing finishes that can withstand these harsh chemicals will decrease maintenance and downtime of these limited facilities.

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## Principle 9

### Minimize the Possibility of HVAC System Failure

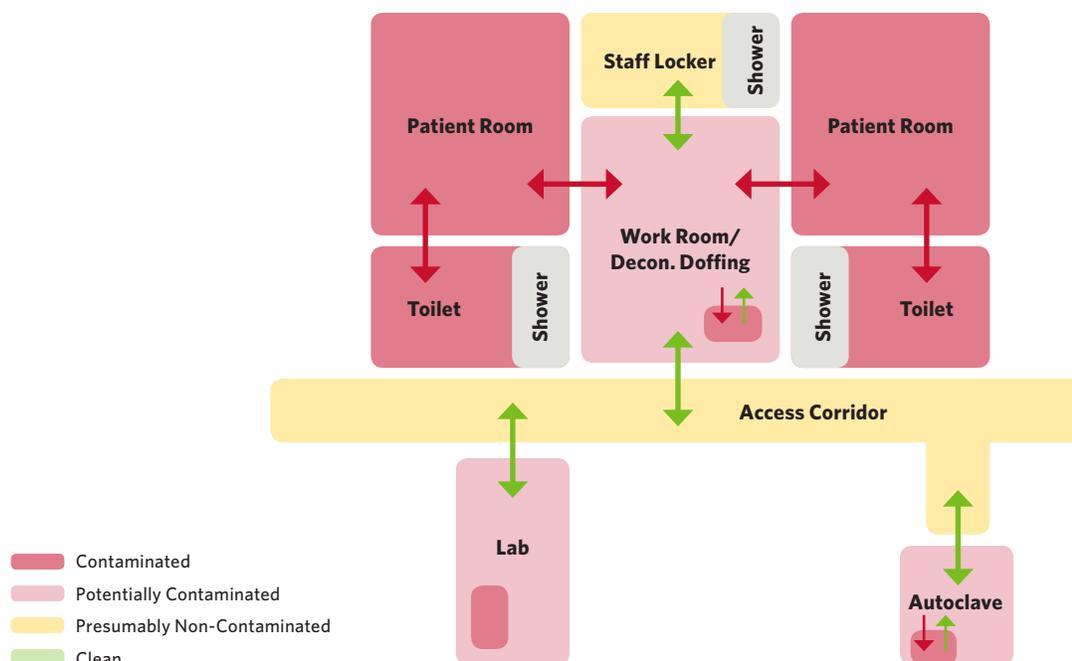
When a laboratory has a system failure and experiences loss of containment airflow, operations shut down immediately. Not so in healthcare: if a supply or exhaust unit for a patient room fails during occupancy, patients still must be cared for. All systems must function properly for safety; a patient room that continues to operate without appropriate airflow increases risk to staff and other patients. The design must minimize the possibility of system failure by incorporating redundancy, reliability, and system isolation. In the event of a system failure, separation of components by filtration will reduce the risk of maintenance personnel being exposed.

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## Principle 10

### Define How to Measure Containment Success

Nothing is more frustrating than completing the design and construction of a biocontainment facility only to find there is disagreement on design or operational parameters. There may also be excess alarm conditions that distract from operating the facility. Define ahead of time what specifically must be achieved for containment, or there will be questions and disagreements from the team and everyone may not get the level of containment that they feel is appropriate.



## Models for Biocontainment Patient Units

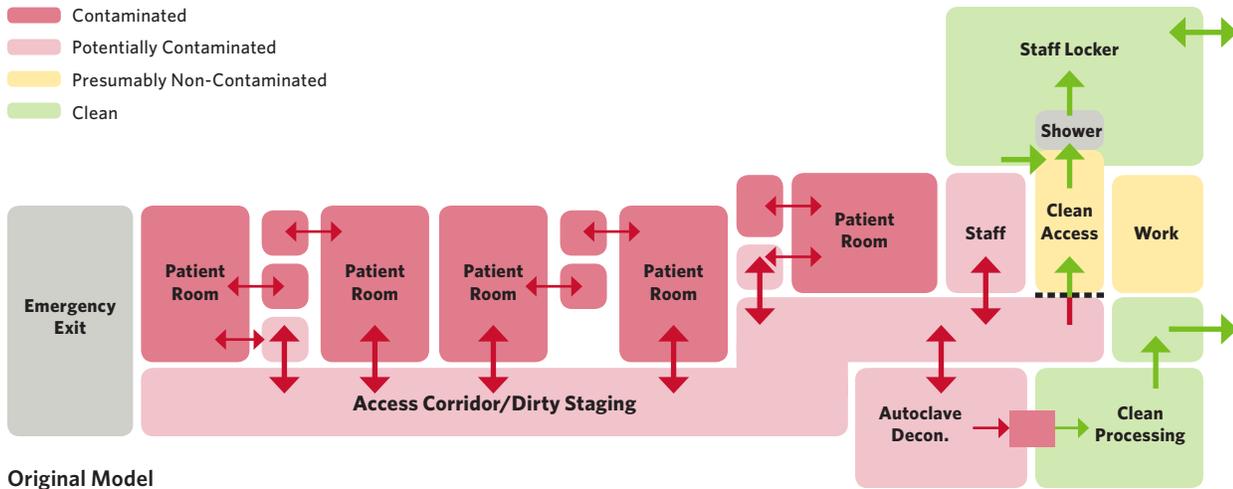
Historically patient biocontainment units at US hospitals have been standard patient rooms with an ante room attached. Little thought was given to complex PPE, the amount of care required, and the high volume of infectious waste generated during care for patients with highly pathogenic infectious diseases such as Ebola. Historic models of these facilities such as the “Slammer” at the US Army Medical Research Institute for Infectious Diseases were not used enough to fully understand of the issues involved.

## The Emory Model

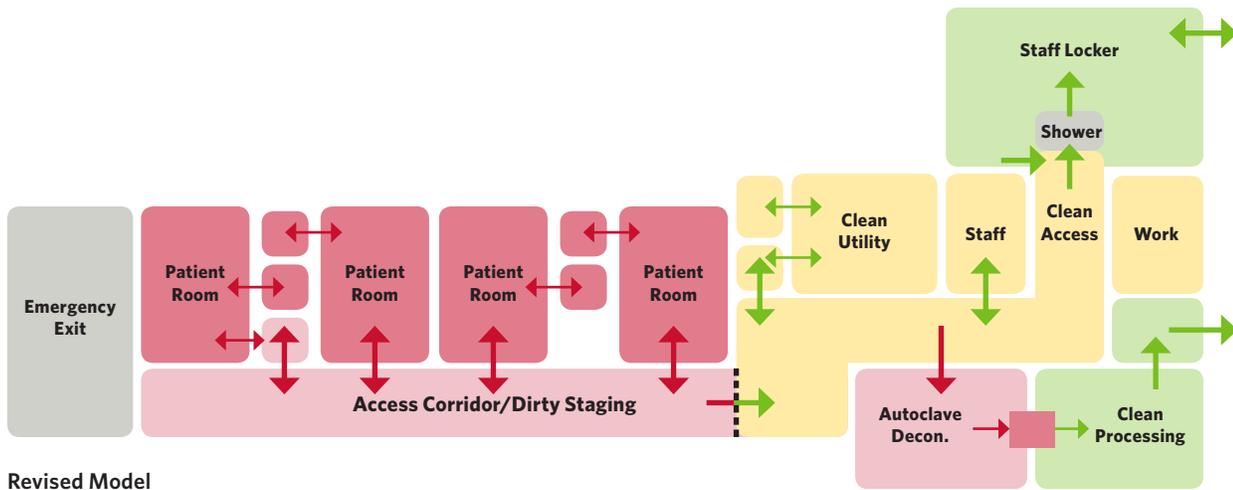
Approximately ten years ago, CDC, in conjunction with Emory University, renovated existing space and installed a patient biocontainment unit at Emory University Hospital. Built a few blocks away from CDC’s maximum containment laboratories, the facility was intended to be able to receive someone from CDC who had been exposed to a pathogen for observation and care. A two-patient-room suite was developed with the patient rooms served by an ante-room that doubled as both entry and exiting area to the patient rooms. Embedded in the rear of the ante-room was a locker and shower area for the staff.

In 2014, Emory University leaders decided they had the capability to care for patients with Ebola and made the decision to treat US healthcare workers who had been exposed in West Africa. They evaluated operations and added an autoclave for decontamination down the hall from the unit. During operation with the infected patients, it was determined that a testing laboratory should be placed near the unit for handling clinical samples. A room with a biosafety cabinet was added. It should be noted that because of the need for rapid response while housing infectious patients, this lab did not have an anteroom and would be considered BSL-2.

This unit is highly protocol-dependent for the safety of both patients and personnel. Strict adherence to protocol is necessary to minimize chances of an infectious material coming into the anteroom (from the patient rooms) and contaminating personnel entering, exiting, or moving into the locker changing area. In addition, infectious material must be contained in bagging or transport areas and either removed from the facility for analysis in the laboratory or decontaminated in the autoclave. This operational pattern, driven by the facility layout, creates a large footprint that must be viewed as potentially contaminated.



Original Model



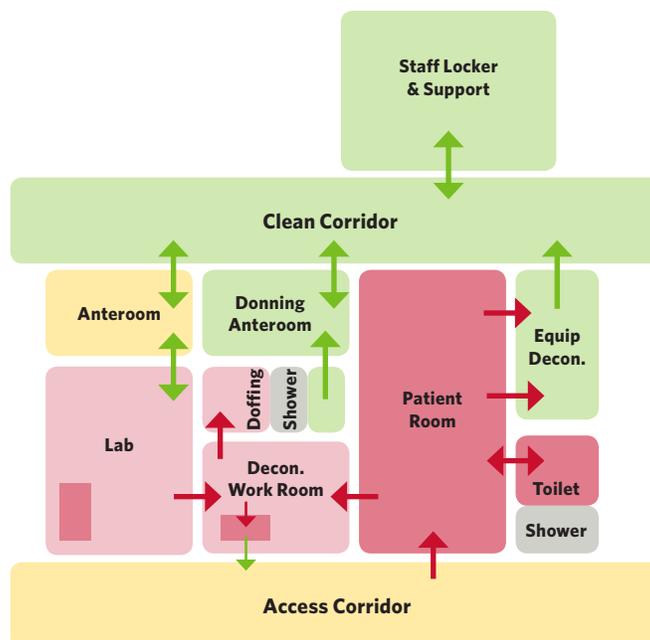
Revised Model

## The Nebraska Model

In 2008, the University of Nebraska Medical Center, in conjunction with a number of agencies, renovated a wing of the hospital at Nebraska Medical Center to create a patient biocontainment unit. They originally planned a seven-room suite. The double-loaded corridor serves as both entry and exit space for the rooms, generating a high potential for cross contamination. In addition, the location of the decontamination autoclave at the entry end of the corridor requires the corridor to be viewed as a potentially contaminated space.

After initial operation, they added a laboratory, storage space and ante-rooms to the unit, reducing the effective size to four rooms. They also relocated the line on the floor that was used to define and separate the contaminated from the non-contaminated areas. During the shutdown for these changes, they also upgraded finishes to create a facility that would better withstand the harsh disinfectants routinely used in patient biocontainment units.

- Contaminated
- Potentially Contaminated
- Presumably Non-Contaminated
- Clean



## The Developing Model

New models have been developed, combining lessons learned from BSL-3 and BSL-4 laboratory design with lessons learned from initial operations of patient biocontainment units. The features of these models include laboratory testing, one-way flow to limit cross contamination and decontamination of waste within the suite. These features help to reduce reliance on protocol and offer patient access to the suite from a restricted access corridor.

In the developing model, care activities use a clean support zone and corridor for patient-care activities on the front side of the patient rooms combined with a potentially, but not routinely, contaminated access zone to the rear of the patient rooms. This area is kept clean by BSL-3 level entry and exit zones from patient care, decontamination of waste within the unit, and patient access from the non-clean side of the patient rooms. Staff enters from the clean corridor and dons PPE in a clean space. They then move into the patient room to provide care. After exiting the patient room, they dispose of waste and then doff their PPE before exiting through a shower into the clean side of the facility. A room is provided for moving equipment into the patient room and for decontaminating the equipment during removal.

The lab is entered and exited through the ante-room from the clean corridor. A biosafety cabinet provides primary containment for protection of the worker and laboratory samples during analysis. The laboratory worker has the option of exiting the laboratory through the doffing and shower area.

This new model allows the ten principles of planning and design for patient biocontainment units to be implemented, improving patient care and increasing safety for patients, staff and the community.

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