Applying Principles and Lessons Learned in Biosafety and Biocontainment Facility Design to the Challenges of Handling Patients with Highly Pathogenic Infectious Diseases

PRESENTORS
Cyndi McCullough
Andrew Yosten
Introduction
"A Rational Basis for Biocontainment"

Can biocontainment facility design be based on reason?
Ebola Healthcare Risk

There is a Significant Risk for Healthcare Workers

- Up through October 2014, In the 2014-2015 Ebola Zaire outbreak in West Africa 3-5% of infections and deaths have been Healthcare workers
- There were 560 Infected and 320 Deaths in healthcare workers out of 14,098 cases in the general population (WHO)
- > 24,800 Infected > 10,000 Deaths (WHO)
Labs and Patient Care are not Equivalent

The Risk is Significantly Higher in Patient Care Facilities than in Laboratory and Animal Facilities.
01
Design Principles
for patient biocontainment
1 Recognize, Assess and Plan to Address the Risk.

The Risk is Significantly Higher in Patient Care Facilities than in Laboratory and Animal Facilities.

- Potentially Unknown Risks and Agents
- Limited Primary Containment
- Complex Personnel Protection Equipment (PPE)
- Limited Disinfection Before PPE Removal
- Aerosol Producing Procedures Outside Primary Containment
- High Volumes of Waste
- Uncontrolled Large Scale Events (Vomiting, Diarrhea)
Emerging, re-emerging and evolving diseases, increasing drug resistance and unknown agents may create higher risks and consequences.

A laboratory can choose if, when and how to handle an infectious agent. A hospital may have no control of a disease that may walk in through the door.

- Plan you facilities to handle unexpected events.
- Have proactive plans in place.

Healthcare has little control over potential patients.
In designing for biocontainment and biosafety, use engineering controls whenever practicable.

As the risk increases, engineering controls should increase minimizing the need for protocols.

Protocols are subject to human error.

Humans are much more likely to make a mistake than an engineered system.
When facilities and operational protocols are mismatched, shortcuts and workarounds must be taken and the potential for an adverse event significantly increases.

Design your facility to match planned operations, not the reverse.

The facility design must be fully integrated with the planned operational models(s) to minimize the potential for adverse events.
Control Contamination through Separation.

Minimize Risk to Patients, Staff and the Community

- Minimize area with potential contamination.
- Utilize primary containment where possible.
- Eliminate clean and contaminated cross-flows.
- Separate confirmed and suspect patients as well as patients with different diseases.
Eliminate Airborne Spread of Infectious Agents.

Anterooms, filtration and directional airflow may be important considerations for worker safety as well as preventing contamination outside the patient care space.

- HEPA filtration of exhaust and vent openings may be important.
- 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.

“It is impossible to traverse any doorway, or to have a single doorway from one space to another, without having substantial interchange of air”

Chatigny & West, 1976
Surfaces and Finishes Must Facilitate Decontamination.

Healthcare facilities will require more surface decontamination than comparable laboratory facilities.

- Due to lack of primary containment, application of surface disinfectants will be required more often than in comparable laboratory facilities.
- Lack of finishes that can withstand these harsh chemicals will increase maintenance and downtime of these limited facilities.
Redundancy, reliability and HVAC system isolation are critical design considerations.

When a lab has a system failure you can shut down operations.

- If a patient room supply or exhaust unit fails and need maintenance during occupancy you still must take care of the patient.
- A laboratory would shut down upon loss of airflow into the contained areas, a patient room that continues to operate will have increased risk for staff and other patients.
- Design to minimize the possibility of system failure.
- In the event of a system failure, separation of components by filtration will reduce the potential for exposure of maintenance personnel.
Define how you will measure containment success.

Or you may not

- Without defining ahead of time what you need to achieve for containment, there will be questions and disagreements from the team.
- You may not get the level of containment that you feel is appropriate.
Keep the Solutions Simple.
Design Models for patient biocontainment
Models of Patient Biocontainment

The Emory Model

- CONTAMINATED
- POTENTIALLY CONTAMINATED
- PRESUMABLY NON-CONTAMINATED
- CLEAN

- PATIENT ROOM
- STAFF LOCKER
- WORK ROOM / DECON. DOFFING
- TOILET
- SHOWER
- AUTOCLAVE
- LAB
- ACCESS CORRIDOR
Models of Patient Biocontainment

The Nebraska Model - Original

- CONTAMINATED
- POTENTIALLY CONTAMINATED
- PRESUMABLY NON-CONTAMINATED
- CLEAN

Diagram:
- EMERGENCY EXIT
- PATIENT ROOM
- PATIENT ROOM
- PATIENT ROOM
- PATIENT ROOM
- PATIENT ROOM
- PATIENT ROOM
- ACCESS CORRIDOR / DIRTY STAGING
- AUTOCLAVE DECON.
- STAFF LOCKER
- SHOWER
- STAFF
- CLEAN ACCESS
- WORK
- CLEAN PROCESSING
Models of Patient Biocontainment

The Developing Model - Goals

- Prioritize engineering controls over protocols.
- Minimize areas with potential contamination.
- Eliminate the crossing of clean and potentially contaminated flows of personnel, equipment and waste.
- Reduce the potential for airborne contamination.
- Provide BSL-3 enhanced laboratory capability.
- Reduce footprint for HVAC and plumbing systems.
Models of Patient Biocontainment

The Developing Model

- CONTAMINATED
- POTENTIALLY CONTAMINATED
- PRESUMABLY NON-CONTAMINATED
- CLEAN

Diagram shows a layout with areas such as Patient Room,anteroom, lab, decon. work room, toilet, and support areas. Arrows indicate movement and containment pathways.
Models of Patient Biocontainment

The Developing Model
Models of Patient Biocontainment

The Developing Model - Example
03
Guidelines
for patient biocontainment
HDR Architectural Guidance

The Containment Barrier

- Provide an anteroom with two doors in series from any space that may be potentially contaminated.

- Provide primary containment devices (biological safety cabinets) for small scale work, laboratory testing that requires sample manipulation and for other procedures where practicable.

- Provide sealed interior windows and cameras to allow viewing of staff and patients without entering space.
HDR Engineering Guidance

The Containment Barrier

- Seal windows and wall penetrations on the containment boundary.
- Provide finishes (floors, walls, ceilings, doors frames, etc.) that are easily cleanable and can withstand routine chemical disinfection.
- Provide a pass-through decontamination autoclave with both solid and liquid waste cycles. Place the autoclave service space outside of containment.
HDR Engineering Guidance

The Containment Barrier

- Provide laboratory testing space (BSL-3 minimum) within the PBU.
- Provide a dunktank or other method for laboratory samples to be removed from the contained patient area.
HDR HVAC System Guidance

Control Areas with Potentially Contaminated Air

- Provide inward directional airflow from areas of lower risk to areas of higher risk.
- Provide a separate air handling and exhaust system for the Patient Biocontainment Unit.
- Provide a decontamination-in-place HEPA filter system on the exhaust system with zero leakage ductwork from room to HEPA filter.
HDR HVAC System Guidance

Control Areas with Potentially Contaminated Air

- Provide redundant exhaust fan capacity with the ability to lose a fan with minimal impact on airflow.
- Provide redundant supply fans.
- Provide a decontaminate-in-place HEPA filter system on the air supply system with zero leakage ductwork from room to HEPA filter.
Provide a liquid effluent decontamination system. Connect, toilet, sinks, patient shower, dialysis diluent disposal, staff shower and sinks, autoclave chamber drain. Provide low leakage piping with leak detection on drainage to effluent decontamination tanks.

Provide backflow prevention or filtration on liquid or gas services entering the room.
HDR Plumbing System Guidance

Minimize Staff Handling of Infectious Waste and Control Areas with Potential Infectious Waste

- Provide HEPA filtration (or equivalent) on plumbing vents.
- If vacuum is provided, use a local dedicated system.
- Provide a system for space decontamination.
HDR Electrical System Guidance

The Risk is Significantly Higher in Patient Care Facilities than in Laboratory and Animal Facilities.

- Provide back-up power.
- Provide UPS for power continuity for system controls.
- Seal conduits passing through the containment barrier.
- Provide a hands free communication system.
  - Consider I-pads and wireless technology
  - Consider Bluetooth headsets for communication
Conclusion
Conclusion:

Three Lessons Learned

It will be more difficult to build, commission and operate a biocontainment facility for high consequence pathogens than team members anticipate.
Conclusion:

Three Lessons Learned

Humans make errors.

Don’t believe people who tell you they won’t.
Conclusion:

Three Lessons Learned

You can work very hard to be rational; however, you will always be challenged by based on “perception” rather than “reality” of risk.
Thank you.