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Designing a Biocontainment Unit to Care for Patients with Serious Communicable Diseases: A Consensus Statement

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In spite of great advances in medicine, serious communicable diseases are a significant threat. Hospitals must be prepared to deal with patients who are infected with pathogens introduced by a bioterrorist act (e.g., smallpox), by a global emerging infectious disease (e.g., avian influenza, viral hemorrhagic fevers), or by a laboratory accident. One approach to hazardous infectious diseases in the hospital setting is a biocontainment patient care unit (BPCU). This article represents the consensus recommendations from a conference of civilian and military professionals involved in the various aspects of BPCUs. The role of these units in overall U.S. preparedness efforts is discussed. Technical issues, including medical care issues (e.g., diagnostic services, unit access); infection control issues (e.g., disinfection, personal protective equipment); facility design, structure, and construction features; and psychosocial and ethical issues, are summarized and addressed in detail in an appendix. The consensus recommendations are presented to standardize the planning, design, construction, and operation of BPCUs as one element of the U.S. preparedness effort.

OVER THE PAST DECADE, most healthcare facilities in the United States have been involved in the national effort to plan for a bioterrorism event, and hospital biopreparedness planning is mandated.[1,2] The global spread of emerging infectious diseases has further highlighted the importance of hospital planning for hazardous infectious diseases. Hospitals are faced with the potential situation of providing care to patients with avian influenza, severe acute respiratory syndrome (SARS), or viral hemorrhagic fever (VHF) while assuring optimal safety for staff. Few hospitals would be prepared to dedicate and staff a ward or a wing for one or a few patients, and creating special isolation accommodations on short notice would be inefficient and potentially very costly.[3] In addition, as the national effort directs more research funding to the study of the agents of bioterrorism, the likelihood of an occupational exposure to one of these illnesses will increase.[4]

When such events have occurred in the past, institutional responses were generally guided by compromises using in-place procedures and resources.[3,5,6] Laboratory tests were deferred or laboratories experienced disruptions of work flow to accommodate laboratory testing for

A complete list of authors and their affiliations can be found at the end of this article (Appendix 1). The views, opinions, and findings contained herein are those of the authors and should not be construed as official U.S. Department of the Army, Department of the Air Force, Department of Defense, Department of Health and Human Services, or U.S. government position, policy, or decision, unless so designated by other documentation.

patients potentially infected with serious communicable diseases. Nosocomial infections with multidrug-resistant (MDR) tuberculosis,[7] SARS,[8] and VHF[9] in hospital workers underscore the importance of immediate availability and appropriate capacity for isolation facilities for infectious patients.

Biocontainment patient care units (BPCUs) are clinical facilities specifically designed to minimize nosocomial transmission of highly contagious and hazardous diseases by incorporating engineering and safety measures used in biosafety level (BSL) 3 and 4 containment laboratories. These include negative air pressure ventilation systems for entire units, disinfectant pass-through boxes, restricted access, and other infrastructure and administrative controls not typically found in routine clinical settings.

The first BPCU constructed in the United States was built at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) in Fort Detrick, Maryland, to support a research mission: to care for a limited number of patients with possible laboratory-acquired infections due to exotic, highly hazardous pathogens.[10] At the present time, only three facilities are known to exist in the U.S. that are specifically designed to safely care for patients with serious communicable illnesses: the abovementioned military unit; a patient care suite contained within Emory University Hospital in Atlanta, Georgia; and a patient care suite contained within the University of Nebraska Medical Center in Omaha.

In an effort to guide other facilities considering implementation of a specialized unit for the care of patients with serious communicable diseases, a group of interested parties convened in Omaha, Nebraska, on November 8 and 9, 2005. Representatives from the three BPCUs were in attendance, together with representatives from federal and state agencies and others with relevant expertise. By the end of the conference, the group had developed consensus statements for the key elements for designing and operating a biocontainment unit. We believe that these statements will offer others a practical approach for planning for the care of patients with serious communicable diseases.

METHODS

A consensus conference of staff from the existing BPCUs, experts from various related fields (e.g., biosafety, laboratory biocontainment, infection control, public health, architecture, health facilities planning), and experts from interested organizations (e.g., USAMRIID, CDC, NIOSH, the VA system, several medical centers) participated in a 2-day consensus conference on November 8–9, 2005, in Omaha, Nebraska.

Participants were polled regarding key issues before the meeting, and responses were used to initiate discussion. Small working groups developed summary statements in one of the five topic clusters (see Figure 1). Small group consensus statements were voted on by the overall group, and those receiving less than 75% agreement were reworked after additional group input; the revised statements were voted on again.

The Group Decision Room (GDR) electronic interactive meeting support software with professional facilitation was employed at the consensus conference. GDR is an electronic meeting system used in group processes to help generate new ideas, define concepts, organize discussion categories, and evaluate ideas by consensus voting techniques. During the proceedings, all conference participants had the opportunity to review concepts and make comments. As statements were developed, the subgroups were engaged to refine the final versions that were presented to the overall group for final consensus vote. The technology allowed each participant to observe the comments and ideas of the others for incorporation into the final statements. The system allowed for anonymity, parallel communication, data storage, and concurrent development of consensus statements.[11,12]

CONSENSUS RECOMMENDATIONS

The Role of Units in Overall Preparedness

- **Definition of BPCUs**

The term *biocontainment patient care unit* (BPCU) is proposed to describe a facility designed and operated to maximize patient care with appropriate infection control practices and procedures. These units are secure, physically separated from other patient care areas, and have special air-handling systems and advanced personal protective measures for staff. The specific measures are listed below in facility design.

- **Diseases that should be handled in BPCUs**

The mission of BCPUs is to provide medical care to patients having, or suspected of having, a disease that poses extraordinary public health risks. These may include, but are not limited to, quarantinable diseases designated by the World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC), and state and local health departments. Definite admission criteria should be based on accepted case definitions, exposure history, and clinical syndrome. Examples of potential admissions include cases of severe illness resulting from laboratory exposure, travel, bioterrorism, and other events (e.g., smallpox, monkeypox, SARS, avian influenza, VHF). Other examples include cases of appar-

FIGURE 1. BIOCONTAINMENT PATIENT CARE UNIT CONSENSUS TOPICS

I. The Role of Units in Overall U.S. Preparedness
   A. Definition of BPCUs
   B. The mission of BPCUs
   C. Integration of units into military and civilian preparedness
   D. National capacity for BPCUs
   E. Plans for capacity for hazardous diseases beyond the units
   F. Federal or local control of regulatory issues
II. Medical Care Issues
   A. Clinical services provided in the unit
   B. Consultants and other personnel
   C. Care issues
   D. Pathology issues
   E. Minimum diagnostic services and regulatory compliance
   F. Housekeeping and security
   G. Emergency evacuation
   H. Additional clinical issues
III. Infection Control Issues
   A. Personal protective equipment
   B. Biosafety program
   C. Occupational health program
   D. Environmental disinfection
   E. Large equipment disinfection
   F. Infectious waste
   G. Transportation of patients to the unit
   H. Visitor infection control issues
IV. Facility Issues
   A. Air-handling system
   B. General facility design criteria
   C. Unit design features
   D. Essential unit construction features
   E. Certification and commissioning
   F. Communication
   G. Additional facility issues
V. Psychosocial and Ethical Issues
   A. Patient psychosocial issues
   B. Staff psychosocial issues
   C. Ethical issues

ently novel infectious diseases, and people exposed to highly hazardous human pathogens who develop prodromic symptoms while under active surveillance.

The first priority for the unit is to care for patients with highly communicable infectious diseases with high morbidity or mortality and limited treatment options. Depending on the capability of the unit, it may have secondary missions such as research into transmission modes, pathogenesis, or therapeutic agents.

- **Integration of units into military and civilian preparedness**

Military and civilian BPCU facilities should function as an integrated network. As per the National Response Plan and other federal plans, military-civilian coordination is to be authorized at the federal agency level (e.g., by Northern Command [NORTHCOM] and the Directorate of Military Support [DOMS]).[13] Memoranda of understanding should be established among academic, military, and industry partners.

- **National capacity for BPCUs**
  - The mission of the units should be directed toward occupational exposures occurring in maximum con-

tainment laboratories and index cases of potentially high-risk infectious diseases (e.g., related to international travel). Therefore, a need is envisioned for broad regional distribution of units, strategically located, such that each unit would have a designated catchment area. In addition, each BSL-4 lab would have a designated referral unit. Ideally, these units would not be freestanding but associated with a major medical center and have day-to-day utility and dual functionality. These units should be readily converted from their standard use to biocontainment function without having an adverse impact on patient care or causing undue logistical concerns. Regional capability for high-level containment transport should be available.

- The units should be considered a national resource. The Department of Health and Human Services (HHS) and CDC, in consultation with state health authorities, should make decisions on the coordination of BPCU resources. Correspondingly, military BPCU use should be coordinated through the Department of Defense (DoD). Financing of hospitalizations in these units should be augmented with federal resources. BPCUs can be used for noncontainment patients with the caveat that units can be made ready for biocontainment function within 3 hours.

- **Plans for capacity for hazardous diseases beyond the unit**

BPCUs are not an asset to increase surge capacity in the community, but rather should be used when there are small numbers of patients or to provide more advanced diagnostics for a limited number of cases. Admission criteria and triage protocols should be clearly defined for BPCUs, and facility security should be in place. Healthcare organizations with BPCUs should develop plans for expanding surge capacity if the BPCU bed capacity is overwhelmed.

- **Federal or local control of regulatory issues**

BPCU facilities should fulfill all existing requirements for healthcare facilities under state health regulations. In addition, the existing state regulatory system for healthcare facilities should be augmented by expert consultation with federal partners. Federal guidelines can be used for construction parameters, commissioning, maintenance, and inspection requirements. However, final regulatory authority rests with the state.

Medical Care Issues

The unit needs to provide the complete spectrum of clinical care from basic medical observation to intensive care unit–level patient care, including minor surgical procedures. The limited access to the BPCUs will affect the availability of consultants, the decision to use paper versus electronic charts, the availability of laboratory and radiology services, and the handling of laboratory specimens. Planning for a BPCU needs to encompass housekeeping and security issues, emergency evacuation, and the use of experimental therapeutics. Consensus findings in these areas are presented under Medical Care Issues in the appendix.

Infection Control Issues

The major purpose of the BPCU is to provide care for contagious patients with the safety of optimal infection control. The appendix under Infection Control Issues presents consensus recommendations from the conference on issues such as selection of personal protective equipment, occupational health for healthcare workers in the unit (e.g., vaccinations, health screenings), environmental and large equipment disinfection, transportation of patients to the unit, and an overarching biosafety program.

Facility Issues

Key points in the design and construction of the unit include the air-handling system (e.g., negative air flow, HEPA filtered exit air), seamless and cleanable surfaces, secured unit access, fire and tornado protection, a pass-through autoclave, and a dunk tank for specimens. Detailed consensus recommendations for these Facility Issues are presented in that section of the appendix. Also discussed are unit commissioning and a communications plan.

Psychosocial and Ethical Issues

Appendix 2 discusses the Psychological and Ethical Issues that arise for both patients and healthcare workers in the course of providing care in a special isolation unit. Psychological support is advisable for both patients and staff in a BPCU.

DISCUSSION

Since 9/11 and the anthrax mailings of 2001, the U.S. has focused planning efforts on various aspects of biopreparedness, including such measures as enhancing laboratory capacity, incident command training, provider education, and pathogen-specific research. One aspect of biopreparedness is special isolation facilities that provide patient care for those infected with hazardous infectious diseases.

The Health Resources and Services Administration (HRSA) guidance specifies that each region should be able to care for 10 patients at a time in a negative pres-

sure environment within 3 hours of an event.[14] Of the agents on the CDC Category A list,[15] smallpox and VHF pose the greatest risk to caregivers[16] and other patients in the hospital. Both of these diseases can have a high mortality rate in infected healthcare personnel and require special isolation measures.[17–19]

Although bioterrorism was the impetus for much preparedness planning, the hospital is more likely to encounter naturally occurring emerging infectious diseases, such as multidrug-resistant tuberculosis, SARS, monkeypox, hemorrhagic fever virus infection, avian influenza, and vancomycin-resistant *Staphylococcus aureus.* These hazardous infectious diseases also require special isolation measures.[20,21] Biopreparedness planning helps to prepare for naturally occurring infections as well.[2]

Laboratory personnel exposed to dangerous pathogens while working under maximum containment laboratory conditions also may require care in a BPCU. A number of articles have been published regarding the military and civilian experiences in dealing with potential occupational exposures that can occur in a laboratory.[4,22–25] Despite appropriate training and containment laboratory facilities, potential exposures in the laboratory can and will continue to occur.[23] The USAMRIID unit had isolated 12 patients for potential exposures to infectious agents who were working under BSL-4 conditions.[10] The death of a Russian lab worker in 2004[26] after an Ebola virus exposure demonstrates that laboratories that work on such agents need to have a plan in place for managing an exposure to a BSL-4 agent.

Patients who are infected with hazardous infectious diseases are routinely and safely treated in hospitals using normal isolation precautions.[15] However, occasional transmission of these infections in the hospital setting is well documented and may be due to failure to recognize a hazardous infection and consequent failure to implement isolation, as happened with SARS.[27] Even after isolation precautions have been implemented, nosocomial transmission of tuberculosis, measles, SARS, smallpox, and other diseases[15] may occur due to technical problems (such as airflow system malfunction) or human error in following isolation procedures.

A related concern is the anxiety of the hospital staff in providing care to a patient with a hazardous infection, which could lead to refusal to report to work or provide care for those patients, as occurred with monkeypox in 2003.[28] A survey of infectious disease physicians found that most had concerns about their facilities' preparation and capacity for managing patients with SARS.[29] More aggressive isolation of patients with a hazardous infectious disease may be indicated early in an outbreak (e.g., the SARS outbreak in Canada was caused by a single case) or if genetically engineered bioterrorism agents have not been ruled out.

Thus, although hospitals generally have the ability to provide airborne isolation and other appropriate infection control, additional measures can improve the capacity to care for patients with the high mortality diseases discussed above. Measures such as powered air purifying respirators (PAPRs) for respiratory protection, negative air pressure isolation rooms with 12 or more air exchanges per hour, HEPA filtration of exit air, secured access pass-through autoclaves (for contaminated linen and clothing), and dunk tanks (for disinfecting the outside of lab specimens) are not routine. Additional features that enhance biosafety include vaccination of employees (e.g., with smallpox and hepatitis A vaccines), special education of staff in infectious diseases, and isolators for transportation of contagious patients outside or within the hospital. These biosafety features may be consolidated in a BPCU. Coordinating special patient biocontainment units with the diagnostic laboratory and with public health facilities is an essential part of planning.

Even though there are no current standards specifically for design and construction of BPCUs, there is applicable information in the medical literature. Some information may be extrapolated from laboratory biosafety practices.[30,31] Other resources discuss isolation of hazardous infectious disease patients,[15,17,19] construction guidelines,[32,33] and hospital biopreparedness documents,[34,35] but they do not specifically address BPCUs.

In spite of the advantages, few BPCUs are currently in use, undoubtedly due to the expense of building and operating the special isolation environments. The USAMRIID unit opened at Fort Detrick, Maryland, in 1971,[36] and in 2005 units opened at Emory University (2 beds) and the University of Nebraska (10 beds). Some of the BPCU infrastructure recommendations (e.g., entire units with a negative pressure, HEPA filtered ventilation system) and special features such as isolation transporter units[37] are prohibitively expensive and cannot be advocated as a national standard of care.

Most community hospitals facing a large epidemic of a contagious disease will have to group patient cohorts in dedicated wards or buildings. Modifying infrastructure to create special isolation facilities on an urgent basis in the face of an infectious disease outbreak is both costly and inefficient.[5,38,39] Additionally, creating a temporary isolation arrangement disrupts normal operations.[5,6] Preplanned BPCUs provide extra protection for the staff and patients in the hospital that will receive patients with contagious diseases whether or not a special biocontainment unit is available and enable optimal care for the afflicted patients.

Although it is very likely that a patient who would ideally be cared for in a BPCU will enter a U.S. hospital in the future, the likelihood that any given hospital would need to care for one is low. Therefore, the consensus

group does not envision the BPCU as the standard of care for a community, but rather sees a potential role for a limited number of regionally distributed BPCUs.

The BPCUs' role will be to care for a limited number of patients with illnesses acquired from laboratory accidents, travel, bioterrorism, or an outbreak of an emerging disease. Since their capacity would be saturated during a large epidemic, BPCUs will not substitute for epidemic preparedness planning by public health officials at the national, regional, and local levels. BPCUs are of greatest utility early in an epidemic, or for small numbers of cases of hazardous infectious disease cases or diseases of unknown risk. The construction of BPCUs is only one component of multifaceted preparedness for bioterrorism and emerging infections.

The guidelines present the opinions of a number of experts in the field, but not every expert could be included in the conference, and there are limited scientific data on which to base recommendations. The consensus recommendations are based on the current experiences of the authors and extrapolations from laboratory experience and infection control guidelines. Further, the efficacy and cost-effectiveness of BPCUs has not yet been systematically studied. Our intent is to have the consensus points inform future standards for planning and building of biocontainment patient care units, as well as overall biopreparedness planning.

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MEDICAL CARE ISSUES

Clinical Services Provided in the Unit

The unit needs to provide a spectrum of care from complete basic care to intensive care unit (ICU) level care, including minor invasive procedures. Specific items will include complete Basic Life Support (BLS), Advanced Cardiac Life Support (ACLS), and Pediatric Advanced Life Support (PALS) capabilities; hemodynamic monitoring; pulse oximetry; mechanical ventilation; and portable digital radiology and ultrasonography. Capabilities to perform basic clinical laboratory tests such as hematology; chemistries including blood gases, urinalysis, and basic metabolic profile (BMP); and light microscopy in the unit may be considered in the planning and design.

Consultants and Other Personnel

- Organizations establishing a BPCU referral center should be fully aware of the need for support from their administrative and medical staffs in terms of initial and ongoing personnel requirements, financial resources, and logistic issues that a facility of this nature entails. Consultation in advance with experts and administrators at existing facilities should be considered.
- Key personnel and consultants (e.g., specialists in infectious disease, hematology, intensive care, cardiology, surgery, and nephrology) who may be involved in the care of patients should be prospectively identified, credentialed, oriented to the unit, and trained on infection control practices within the unit.
- Staffing of these units should preferentially be by individuals who would be expected to have low turnover to minimize ongoing start-up training requirements. Therefore, inclusion of individuals still in training (e.g., students, residents, fellows) would be expected to be limited, but if they were included they would be appropriately supervised.
- When establishing personnel staffing requirements for facilities, redundancy of personnel must be planned for in advance to prepare for foreseeable and unpredictable contingencies (e.g., illness, travel, family issues, refusal to work).
- Ingress and egress should be documented, and all individuals entering the unit should be included in the occupational health program as noted below. Staffing within the unit should comply with relevant human resources and occupational health guidelines.

Care Issues

- Electronic charts with a backup "pen to paper" charting system are strongly recommended.
- Broken equipment should be removed from the patient care area and placed in an area for decontamination within the BPCU before maintenance or repairs are initiated.
- Telemetry monitors and portable digital diagnostic tests (e.g., x-ray), internet and/or intranet medical references, and telephone or e-mail consultations (e.g., lead agencies or subject matter experts) are all applications of technology that are highly recommended.
- Personal protective equipment (PPE) should be selected that accommodates patient assessment needs, including equipment that does not interfere with auscultation.
- Medical staff and nursing staff involved with direct patient care in the BPCU should be fully trained to conduct cardiopulmonary resuscitation while using PPE and without additional ancillary personnel in order to minimize traffic into the unit.

Pathology Issues

Handling of diagnostic services

- Laboratory information management systems should be available in the unit to order and report diagnostic procedures. Every effort should be made to utilize electronic systems for submitting requests and accessing results of diagnostic tests.
- A confidential location in the nursing unit should be equipped to view computerized digital x-rays and laboratory images.
- All invasive and noninvasive diagnostic specimens should be handled according to established protocols. Specific procedures must be established to process and handle specimens collected from patients in the unit.
- Specimens should be placed in unbreakable tubes or sealed containers (preferably plastic), undergo surface decontamination with appropriate disinfectant, and be double-bagged in a sealed transportation device, processed through the chemical dunk tank, and hand-carried to the laboratory (not transported in pneumatic tubes) according to institutional policies based on established Biosafety in Microbiological and Biological Laboratories (BMBL) guidelines.
- The specimens should be documented with clear chain of custody throughout acquisition and delivery. A designated recipient should be identified and the contact name appended to the specimen before transport from the BPCU.

- Specimen containers and lab slips should be uniquely labeled as originating in BPCU and address whether fixed or fresh (e.g., infectious).
- If an inactivating agent such as formalin is used, this should be clearly written on the primary container. Laboratory and transport personnel should presume that specimens are infectious.

Safety and security aspects of outside laboratory studies

- Guidelines should be established describing which specimens should be transported to the facility laboratory as opposed to being transported to a state public health or federal laboratory.
- A memorandum of understanding should be in place for testing referred samples with the state public health laboratory and/or federal laboratories in collaboration with the CDC.

Disposal of physical remains

- BPCU facilities should have standard operating procedures for the disposal of human remains. Mortuary and funeral directors in the community should be engaged when drafting the procedures to ensure that there is adequate capacity for cremation and that the need for prompt disposition of remains without viewing is clearly communicated. Embalming should not be performed, and remains should not be viewed. Sufficient capacity should exist for safe storage of refrigerated bodies at the institution before final disposition. Planning for disposal of human remains should be coordinated with state and local agencies pertaining to emergency plans, mass casualty, and related issues.
- Cadavers should be sealed in leak-proof body bags and appropriate transport containers for cremation. If cremation is not possible, burial without embalming may be an alternative. Unit officials should discuss appropriate handling of infectious remains and communicate with mortuary personnel.

Minimum Diagnostic Services and Regulatory Compliance

- The minimum laboratory testing services that must be available on site should be defined. The expected turnaround time for these tests should be estimated and posted.
- Laboratories should be certified by agencies that monitor quality systems (e.g., College of American Pathologists [CAP], Clinical Laboratory Improvement Act of 1988 [CLIA88], etc.). There should be mechanisms in place for certifying personnel with regard to point-of-care testing in the BPCU and specifying who performs the tests.
- Laboratory procedures performed by supporting laboratories should follow CLIA88 guidelines for non-FDA (Food and Drug Administration) approved diagnostic procedures.

Housekeeping and Security

- Routine hygiene and cleaning of a patient room should be performed by nursing staff when the room is occupied. Trained housekeeping staff may handle appropriately treated or contained material that leaves the BPCU.
- Security may need to enter the patient care area under certain conditions—for example, to restrain a patient. Restraint and sedation procedures and protocols should be followed to limit the need for forceful restraint.
- A medical surveillance program should be in place for ancillary personnel (e.g., housekeeping, security, maintenance staff) who enter the unit while it is in use or who are involved with room decontamination once a patient is discharged. Ancillary personnel who might need to enter the BPCU while it is in use should be involved in a biosafety program that provides initial and refresher training on local procedures to enter and exit the facility. Entrance into the BPCU rooms should be limited for these personnel while the room is occupied and should take place under the direct supervision of trained nursing staff.

Emergency Evacuation

Evacuation plans should be in place and exercised. These evacuations should have the capability to maintain isolation (e.g., isolation pods) and have a plan to transport to another facility with isolation capability, or to set up a temporary shelter or quarantine facility. Evacuation over long distances should be avoided.

Additional Clinical Issues

- Access to the patient room should be limited to trained, essential personnel only.
- Bedside surgical procedures are recommended if needed.
- Aerosol-generating procedures should be limited (e.g., bronchoscopy, orthopedic procedures).
- Closed mechanical ventilation systems and enclosed nebulizer treatments should be used to reduce aerosolization of respiratory secretions from intubated patients.
- Policies and procedures for use of investigational new drugs (IND) or investigational device exemption (IDE) products in BPCUs should be in place.

INFECTION CONTROL ISSUES

Personal Protective Equipment (PPE)

- Infection control practices and procedures should be based on appropriate risk assessments for the agents infecting patients admitted to the facility.
- The use of PPE per federal regulations should be standard for all employees entering the unit when in use.
- There may be a graduated response, ranging from standard and contact precautions for asymptomatic exposures to patients who are undergoing observation, to expanded precautions for symptomatic individuals. Patients with symptoms such as hemorrhage or respiratory symptoms should be presumed to be highly infectious, and full high-level precautions should be used. Higher levels of aerosol protection (e.g., powered air purifying respirators [PAPRs] for all room entry) or isolation garb (e.g., impervious suits or pressurized suits) may be indicated for hazardous diseases for which the transmissibility is not fully described (e.g., avian influenza, SARS, VHF, novel agents) and for any procedures that may create a mechanically generated aerosol. Physicians responsible for care may also decide to adjust the level of protection based on issues such as the specific agent and availability of vaccination or therapy.
- Fit testing for respirators (e.g., N95s) is an occupational health responsibility in conformity with OSHA (Occupational Safety and Health Administration) and federal hospital regulations.
- The facility should have a procedure for cleaning reusable equipment (e.g., PAPRs, impervious suits, and other PPE).

Biosafety Program

- A sound biosafety program should be in place with oversight from the institutional biosafety committee.
- Policies and procedures pertaining to safety should be generated based on institutional, local, state, and national regulations regarding biosafety and biocontainment in consultation with subject matter experts (e.g., facilities, biosafety, infectious disease, and infection control personnel). During use of the BPCU, compliance with the required policies and procedures should be under constant review by the biosafety officer, the medical director, and the manager of the unit. A written protocol that includes a daily or per shift checklist detailing critical activities and issues should be implemented.
- Because responses to incidents involving highly infectious pathogens will be scrutinized, there is an exceptional need for policies and procedures to document key decisions in patient care, breaches in containment, and deviation from standard operating procedures. After individual incidents involving breaches in containment or deviation from standard operating procedures, or upon completion of patient care, an after-action report followed by an improvement plan matrix for corrective action should be generated to address gaps uncovered in medical and nursing care, policies and procedures, and staff and facility preparedness.

Occupational Health Program

- As part of an occupational health program, a system needs to be in place for mandatory, regular, and routine surveillance of individual care providers to ensure that they:
  - receive appropriate training commensurate with their role in the BPCU;
  - maintain recommended vaccinations for providing medical care;
  - can be evaluated for potential occupational exposures; and
  - have ongoing evaluation of fitness for duty and potential disqualifying factors, such as new medical or psychological illnesses, pregnancy, medications, or other circumstances that might impair their ability to provide patient care. The surveillance program should include specific criteria for determining eligibility or exclusion from work based on signs and symptoms of illness.
- All individuals working in the BPCU should receive routine vaccinations per the Advisory Committee on Immunization Practices (ACIP) guidelines for adult vaccinations. In addition, those individuals involved in direct patient care, or those who may sustain exposures to blood and body fluids, should receive routine health-care-specific vaccinations, including hepatitis B, varicella, and influenza. Additional special vaccinations may be considered, depending on the scope of care and the patients who are to be considered for admission to the unit, including vaccinia, meningococcal disease, and hepatitis A. Although other FDA-approved vaccines may be available for infectious diseases that may be treated in the unit (e.g., Japanese B encephalitis, anthrax, yellow fever), these would not generally be indicated for care providers due to the negligible risk of transmission from patients infected with these specific agents.
- Pre-event vaccination against smallpox should not be routinely offered; however, in the presence of a credible threat of smallpox, a known outbreak, or a patient who is known to have or suspected of having smallpox or monkeypox, vaccination with vaccinia for patient care providers should be required. Pre-screening unit

personnel should be performed as part of occupational health surveillance, to determine in advance of an event whether they have any obvious contraindications to vaccinia vaccination. If a patient with smallpox or monkeypox is cared for in the unit, only vaccinia-vaccinated individuals should care for the patient.

- As part of the occupational health program, individuals should have routine and regular surveillance for tuberculosis. In the event that the unit is used for known multidrug-resistant cases of tuberculosis, increased frequency of surveillance should be considered along with postexposure testing within 2 to 3 months of an event.
- When the unit has been activated, a more rigorous program for active surveillance of individuals who work in the unit should be established and will include the following: tracking of employees, screening for signs and symptoms of illness, and screening for indicators of stress-related illness. This more active surveillance program should continue for the duration of the anticipated incubation period of the illness in question. Adequate supplies of postexposure prophylactic medications and vaccinations, when available, should be kept on hand or within reasonable access, so that individuals who sustain potential exposures may be given prophylaxis. In addition, consideration should be given to banking serum on all containment unit workers in advance of work in the unit for the purposes of diagnosis and surveillance for potential exposures and infection (both symptomatic and subclinical).
- Curriculum and competencies regarding infectious diseases need to be standardized based on job description and level of patient care involvement.

Environmental Disinfection

Surface decontamination with standard Environmental Protection Agency (EPA) registered hospital disinfectants with demonstrated efficacy in the hospital setting (specifically inactivation of viruses and mycobacteria) are appropriate for disinfection. Cleaning supplies should be readily available to the patient care area.

Large Equipment Disinfection

- Standard operating procedures should be implemented that incorporate applicable institutional, local, state, and federal regulations for disinfecting specific agents using an approved disinfectant. Generally, routine surface decontamination is appropriate for laboratory equipment in the BPCU and should occur routinely during use and both immediately before and after removal from the BPCU area. Patient care or laboratory equipment containing tubing and internal sampling chambers should be dismantled and decontaminated. Paraformaldehyde decontamination is most often used, especially in cases of highly infectious and dangerous agents, and should be performed in a special decontamination area (e.g., airlock, anteroom, or decontamination tent). Manufacturers should be consulted regarding the equipment being disinfected to ensure that these procedures will not compromise equipment function.
- Confirmatory testing for decontamination efficacy should be performed.
- For equipment that cannot be safely disinfected for reuse, a disposable alternative should be identified.

Infectious Waste

- For solid waste, BPCU facilities should ensure that autoclave capacity is adequate to handle the expected quantity of waste generated by the maximum number of patients admitted. To ensure that confusion and variability are minimized in a high-risk setting, it may be preferable for all solid waste to undergo autoclaving before disposal into the medical waste stream. If specified solid waste is to be discarded as routine regulated medical waste without autoclaving, the criteria for categorizing such waste as routine must be clearly defined and systems put in place to prevent inadvertent release of infectious solid waste.
- Verification testing should be used for autoclaves (e.g., heat indicator or chemical indicator). If biological indicators (e.g., spore strips) are used, they should be incubated and verified before equipment is reused. Real time indicators (e.g., chemical) are preferred.
- Collection of soiled linens in melt-away laundry bags followed by routine laundering is appropriate. In some instances, linens may be autoclaved before removal to hospital laundry facilities.
- For liquid waste, BPCU facilities should engage state and local health authorities and wastewater handling agencies to ensure that municipal wastewater treatment is appropriate before commissioning of the facility. Liquid waste (e.g., blood, body fluids, fecal material, urine) should be disposed of by pouring down a sanitary sewer leading to appropriate municipal wastewater treatment facilities. Waste need not be pretreated (e.g., by addition of bleach to toilets). Care should be taken to avoid any splashing. Splashes and spills should be cleaned immediately with an appropriate EPA-registered hospital disinfectant.

Transportation of Patients to the Unit

- Before any patient with a suspected highly communicable illness is transported, consideration needs to be given to the patient's condition, the risk of additional potential exposures during transfer; and patient stabil-

ity. Ideally, ambulances should be configured with special air-handling equipment, and appropriate isolation should be employed en route. Upon arrival at the receiving hospital, the patient should be transported to the biocontainment unit using mechanisms developed to protect the hospital environment and other patients.
- If a portable isolator is used, a device should be selected that optimizes access to the patient, is at negative rather than positive pressure to the surrounding environment, and has HEPA filtered air outflow. If a model with reusable patient-care surfaces is chosen, the materials should be able to withstand cleaning with EPA-registered hospital disinfectants.

Visitor Infection Control Issues

- In general, patients in isolation should not be allowed physical contact with visitors. Provision should be made to address the psychological needs of patients and family members by providing a means of direct communication and visualization, such as glass windows or closed circuit television with intercoms. Exceptions may be considered for parents visiting children. Visitors should follow the same level of precautions as the healthcare workers who are caring for the patient, including exposure surveillance, wearing PPE under supervision, and symptom screening.
- A log of visitor access to the unit should be maintained.

FACILITY ISSUES

Air-handling System

Number of air exchanges per hour

Air flow in the BPCU should be negative, with 12 or more air changes per hour. Equally important is maintaining good negative pressure of the isolation room, which should be no less than 0.01 inches wg (water gauge) and ideally 0.03 inches wg between containment and noncontainment rooms (e.g., patient room to corridor).

Handling of exhausted air and redundancy

- Supply air should enter the room high with the unobstructed exhaust air grille located 6 inches above the finished floor near the head of the patient's bed. Airflow movement should be from "clean" to "dirty," or less contaminated to more contaminated. Although anterooms are not required, they can be helpful to control air flows when lower pressure differentials are used.
- BPCU air should have a dedicated exhaust separate from the hospital heating, ventilation, and air-conditioning (HVAC) system. Exhaust fans should use high-velocity upblast fans to discharge and dilute exhaust air. Exhaust air needs to be HEPA-filtered and 100% exhausted. Exhaust discharge should be a minimum of 25 feet from any opening to a building (e.g., windows, doors, air intakes, or occupied areas) and at least 10 feet above ground or meet local and state requirements if they are more stringent.
- Dual exhaust fans should be provided for redundancy, with each capable of providing 100% exhaust.
- All HEPA-filtered housings should be installed in such a manner that the filters can be decontaminated, tested for system efficiency, and replaced when necessary.

Testing of air flow

The BPCU should have wall-mounted digital pressure gauges for continuously monitoring the pressure differential in the room. Such pressure should be continuously monitored by an alarmed calibrated airflow sensor with sensitivity down to 0.001 in wg. Validation pressure monitoring should occur quarterly. Supply air should follow American Institute of Architects (AIA) and American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) design criteria for clinical settings. Airflow performance testing is an essential part of ensuring that a BPCU directional airflow is functioning properly. To perform this testing, a handheld pressure manometer, flow hood, and particle counter should be used to verify the pressure and filtration.

General Facility Design Criteria

The BPCU should:

- be separated from normal patient care areas;
- be equipped with physical and information technology (IT) security measures;
- have independent air-handling systems (with HEPA-filtered exhaust and fan system redundancy);
- be operated under negative air pressure;
- be provided with interlocking double-door access and egress;
- have staff entrance area of sufficient size to allow for employee clothing change, storage of PPE, and a staff egress area with shower-out capability; and
- have available means for appropriate decontamination of materials and equipment.

Individual patient care rooms should at a minimum:

- be equipped with all necessary life support equipment;
- be constructed for ease of cleaning and decontamination;
- have self-closing doors;
- have handwashing sinks; and
- be equipped to meet patient isolation standards of care.

Unit Design Features

- The unit should be located in a secured area of the facility. The layout should include space for clean and soiled equipment handling, a storage area for supplies, a decontamination area for large items (wastes, beds, large equipment, and reusable supplies), a staff break area in close proximity to the unit, a pass-through autoclave, and staff changing areas for ingress and egress. The ability to control entrance and egress is important, as is the ability to provide egress during emergencies. This unit should be placed in a building that is fully equipped with sprinklers to minimize the potential for evacuation during fires. Life safety considerations for evacuation must be made in addition to providing protection to the staff and patients in regions prone to tornadoes, hurricanes, and other natural disasters.
- Security measures must include methods to identify and clear those who enter the unit. These measures should include patient and staff entrance areas with interlocking doors to minimize the possibility of "tag-alongs" (shadows) into the unit. The access area should be large enough to allow for the movement of equipment with personnel and beds into an anteroom before gaining access to the unit.
- The control desk needs to have good vision (line-of-sight) of traffic into and out of the unit (employees and outside personnel).
- The unit including the entire HVAC system needs to be on an emergency power system.
- Adequate space needs to be provided to assure storage in compliance with fire codes and to keep exits clear. Storage should include a place to keep PPE in close proximity to the point of use.
- Staff changing and decontamination areas should provide for storing of clothing and valuables that should not be taken into the unit but that should be available upon exit. There should be designated clean and dirty areas for staff personal items and equipment.
- An employee break room should be available to the staff in or near the unit.
- Standard equipment includes a pass-through autoclave, a chemical dunk tank, and a decontamination shower.

Essential Unit Construction Features

- Design needs to include compliance with applicable life safety codes and building codes (local, state, and federal).
- Construction features need to include seamless surfaces for walls and floors. Horizontal surfaces should be solid where possible, and plastic laminate materials should be avoided, especially in wet areas.
- Window and exterior walls should be designed to minimize the need to evacuate in the event of adverse weather (tornadoes, hurricanes, etc.)
- Life safety features should include 1-hour fire separation from other areas, smoke compartments within the unit if possible, and automatic sprinkler protection.
- Airflow system shutdown for smoke should be specific to this unit and not shut down for alarms in other portions of the building.
- Alarms activated in other portions of the building should send an alert to staff in the BPCU so staff can pre-plan and prepare if evacuation becomes necessary.
- Identify unit perimeter walls, designating them as "biocontainment walls," so future construction or maintenance does not penetrate inadvertently. The wall labels should indicate fire rating, if applicable.

Certification and Commissioning

- BPCUs should be commissioned during construction and before operation to assure that all containment systems are functioning according to the design specifications. The commissioning process should include a review of all operation manuals, standard operating procedures, and biosafety manuals. Protocols for commissioning containment laboratories could serve as templates for BPCUs.
- The initial commissioning is typically performed by an external entity or agent who works closely with the design and construction teams from the start of the project.
- Annual audits, which include review of all containment systems, protocols, training records, practices, procedures, and occupational health programs should be performed and can be conducted by in-house personnel. The audit team should include the biosafety officer, the facility engineer, and the laboratory supervisor.

Communication

The parent institution of the BPCU should have a public affairs and communications plan. Any statements within the institution, to the public, or to the press should be coordinated in advance with the administration, the medical director, and the medical care team.

Additional Facility Issues

- Equipment can be cleaned and surface disinfected for reuse during the care of a single patient. Between patients, the unit should be terminally cleaned, and any equipment that cannot be surface decontaminated and cleaned should be gas sterilized. All equipment and its internal components should be evaluated for the ability to withstand gas sterilization followed by gas aeration.
- A preventive maintenance program needs to be in place at all times during unit operation. Key maintenance staff should be trained in advance to address maintenance needs while the unit is operational. Main-

tenance staff should be warned that the unit is in use before entry.

PSYCHOSOCIAL AND ETHICAL ISSUES

Patient Psychosocial Issues

- Psychological issues should be addressed with the patient on a regular basis, and every attempt should be made by the staff to make the patient comfortable. Telephone, internet, television, and videophones should be available. Counseling support, education, and discussion with the patient's family members are important. Patients and their families should understand that personal items brought into the biocontainment area will have to be decontaminated or destroyed.
- Psychiatrists should be available for diagnosis and management of patients with more complicated psychiatric presentations.

Staff Psychosocial Issues

- It is important to acknowledge that BPCU workers may experience high levels of stress. Mental health services should be provided. A separate psychological team and process for determining "fitness for duty" should be established.
- Staff training is crucial to minimize fears and dispel misunderstandings. Regular staff meetings should occur to discuss difficulties and encourage staff communication. Patient issues should be discussed to ensure uniform communication between staff members and patients. Issues such as counseling for staff members as well as patients and their families should be addressed.

Ethical Issues

- BPCUs generate significant ethical challenges. Patient autonomy should be preserved as much as possible. The principal approach will be a risk/benefit analysis for both the patient and the institution (e.g., balance between infection control and the need for advanced diagnostic and treatment modalities). Undue risk to other patients by providing a medical/surgical/nursing service is a legitimate reason for denying an infected patient access to additional services (e.g., surgery, CT scan, interventional cardiology). A service that could save the patient could be withheld if providing the service would severely limit the use of that service for other patients. This recommendation reflects a shift to a more institution-focused ethic rather than a patient-centered ethic (greater good versus individual needs).
- Clear policies should be developed for providers to understand the consequences of not reporting for duty.