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

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Abstract

In spite of great advances in medicine, serious communicable diseases are a significant threat. Hospitals must be prepared to deal with patients infected with pathogens introduced by a bioterrorist act (e.g., smallpox), by a global emerging infectious disease (e.g., avian influenza or 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. Elements addressed include the role of these units in overall US preparedness efforts; medical care issues (such as diagnostic services and unit access); infection control issues (such as disinfection and personal protective equipment); facility design, structure, and construction features; and psychosocial and ethical issues. The consensus recommendations are presented to facilitate the planning, design, construction, and operation of BPCUs as one element of the US preparedness effort.

Introduction

Over the past decade, most health-care facilities in the US have been involved in the national effort to plan for a bioterrorism event. Billions of dollars and countless hours have been devoted to this effort.(1) The global spread of emerging infectious diseases such as avian influenza, Marburg virus infection, severe acute respiratory syndrome (SARS) and monkeypox, has further highlighted the importance of hospital planning for hazardous infectious diseases. The hospital is faced with the potential situation of providing care to a patient with avian influenza, SARS, or viral hemorrhagic fever (VHF) while assuring maximal safety for staff. Few hospitals would be prepared to close a ward or a wing for one or a few patients, and creating special isolation accommodations on short notice is very costly (2). In addition, as the national effort directs more research funding to the study of the agents of bioterrorism, the likelihood of an occupational exposure resulting in a laboratory worker contracting one of these illnesses and requiring medical care continues to increase (3).

When such events occurred in the past, institutional responses were generally guided by compromises using in-place procedures and resources (2, 4, 5). Laboratory tests were deferred or laboratories experienced disruptions of work flow to accommodate laboratory testing for patients potentially infected with serious communicable diseases. Nosocomial cases of multi-drug-resistant (MDR) tuberculosis (6) and the occurrence of SARS(7) and VHF (8) in hospital workers raise concerns about standard isolation facilities for these diseases. Such facilities were designed to care primarily for patients with tuberculosis, chickenpox, and similar illnesses.

Biocontainment patient care units (BPCU) 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 not typically used in routine clinical settings.

The first BPCU constructed in the US was built at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), Fort Detrick, MD to support a research mission - to care for a limited number of patients with possible laboratory-acquired infections due to exotic, highly hazardous pathogens (9). At the present time, only three facilities are known to exist in the US specifically designed to safely care for patients with serious communicable illnesses: the above mentioned military unit, a patient-care suite contained within Emory University Hospital in Atlanta, GA; and a patient-care suite contained within the University of Nebraska Medical Center in Omaha, NE.

In an effort to guide other facilities planning for the appearance of a patient with a possible or definite serious communicable disease, a group of interested parties convened in Omaha, NE, on November 8 and 9, 2005. Representatives from the three BPCUs, together with representatives from federal and state agencies and others with relevant expertise were in attendance***.*** 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 a patient with a serious communicable disease.

Disclaimer:

The views, opinions, and findings contained herein are those of the authors, and should not be construed an 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.

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

Participants were polled regarding key issues before the meeting, and responses were used to initiate discussions. Small working groups developed summary statements in one of the five topic clusters (e.g., facility design and construction features; medical care issues; infection control issues; the role of special units in overall US preparedness; and psychosocial/ethical issues). Small group consensus statements were voted upon by the overall group, and those receiving less than 75% agreement were reworked after additional group input followed by a revote on the revised statements. An outline of the consensus topic areas is shown in Table 1.

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, to define concepts, to organize discussion categories, and to evaluate ideas by consensus voting techniques. During the proceedings, all conference participants had the opportunity to review selected concepts and make comments. As statements were developed, the subgroups were engaged to refine the final versions which 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 (10, 11).

Consensus Recommendations

Role of Units in Overall Preparedness

- **Definition of BPCUs**

  Criteria should be defined for facilities that house patients requiring biocontainment. To differentiate these facilities from the current classification of laboratory biosafety levels, the term “biocontainment patient care unit” (BPCU) is proposed as 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, 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**

  Candidates for admission to the unit will include 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), 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, and VHF). Other examples include cases of apparently novel infectious diseases, and persons 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. Current examples include SARS, VHF, and avian influenza. Depending on the capability of the unit, it may have secondary missions such as research into transmission modes, pathogenesis, or therapeutic agents. There will be a limited role for the unit in regard to patients with chemical or radiation exposures. However, patients exposed to infectious agents in addition to chemical or radiation exposures need to be cared for with the appropriate personal protective equipment (PPE) in recognition of these additional risk factors. Other uses for the unit may be considered at the discretion of the unit director provided they do not interfere with the primary mission of the unit.

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

Military and civilian BPCU facilities should function as an integrated network. Best-practice, incident-command systems and training should be coordinated and exercised with military and civilian response plans. 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 Directorate of Military Support (DOMS)]. Memoranda of understanding should be established among academic, military, and industry partners. Precedents include the response to West Nile virus infection in 1999, anthrax mailings in 2001, and hurricane Katrina in 2005.

- **National capacity for BPCUs**
  - The ideal national capacity for BPCUs depends on their mission. It is not practical or feasible to use these units in response to large-scale outbreaks, terrorism, or mass casualty events. Based upon logistics, economics, and historical precedent, the mission of the units should be directed toward occupational exposures occurring in maximum containment 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, have day-to-day utility, and dual functionality. These units should be readily converted from their standard use to biocontainment function without adversely impacting patient care or causing undue logistical concerns. In the rare event that a patient needs to be evacuated to a regional center, regional capability for high-level containment transport should be available.

  - The units should be considered a national resource. BPCUs can be used for noncontainment patients with the caveat that units can be made ready for biocontainment function within 3 hours. The justification for these units is that they prevent the closing of a wing or floor of a hospital to provide care to a handful of highly infectious patients. Health and Human Services (HHS) and the 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), quarantinable diseases through state governments and international overflights and aircraft landing rights through the State Department. Financing of hospitalizations in these units should be augmented with federal resources.

- **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. Health-care organizations with BPCUs must develop plans for expanding surge capacity if the BPCU bed capacity is overwhelmed. Current Bioterrorism Hospital Preparedness Program training should be coordinated within the region for hazardous diseases beyond the unit capacities. Strategies at the community level may include cohorting, creation of isolation wards, use of temporary facilities, recommissioning of old health-care facilities, or use of ancillary care facilities based on the local assets available and coordinated with local and state health department officials and emergency management agencies.

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

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 cardiopulmonary resuscitation (CPR), complete basic life support (BLS), and advanced cardiac life support (ACLS) capabilities, hemodynamic monitoring, pulse oximetry, mechanical ventilation, and portable conventional radiology and ultrasonography. Capabilities to perform basic clinical laboratory tests such as hematology; chemistries including blood gases, urinalysis, 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 staff 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 at existing facilities should be considered.
  - Key personnel and consultants (e.g., specialists in infectious disease, hematology, intensive care, cardiology, 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, using individuals in training (e.g., students, residents, and fellows) would expect to be limited, but if used, would be appropriately supervised. The skills needed to work in the BPCU should be integrated into certain training programs to ensure institutional memory and professional development.

- 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, or 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 elsewhere. Staffing within the unit will comply with relevant human resources and occupational health guidelines.

- **Care issues**
  - Electronic charts with a backup "pen to paper" charting system is strongly recommended. All paper documents initiated in the BPCU will be transcribed by a person outside of the unit and/or paper documents faxed from the unit to medical records. In addition, progress notes could be dictated by using the telephone dictation system.

  - Electronic medical equipment that fails during BPCU operation will be replaced by a new, clean piece of equipment. Broken equipment will be removed from the patient-care area and placed in an area for decontamination before maintenance or repairs are initiated.

  - Telemetry monitors and portable digital diagnostic tests (e.g., X-ray), internet and/or intranet medical references and telephonic or e-mail consultations (e.g., lead agencies or subject matter experts) are all applications of technology that are highly recommended.

  - PPE should accommodate patient assessment needs with careful attention to auscultation.

  - Medical staff and nursing staff involved with direct patient care in the BPCU should be fully trained to conduct a cardiopulmonary arrest while using PPE and without additional ancillary personnel to minimize traffic into the unit [e.g., BLS,ACLS, pediatric advanced life support (PALS)].

- **Pathology Issues**

  - Handling diagnostic services

- Laboratory information management systems should be available in the unit to order and report diagnostic procedures. Every effort should be made to create a paperless medical record.

- A confidential location in the nursing unit should be equipped to view computerized digital x-rays and laboratory images.

- All invasive and non-invasive 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. All procedures must be in place before commissioning the unit. These procedures should address the specific specimen type, including (a) tissues and cytological preparations not fixed, (b) tissues and cytological preparations that are placed into fixatives, (c) blood and body fluids, and (d) swabs.

- Specimens should be placed in unbreakable tubes or 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.

- An established point of contact or responsible party must 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. Hospitals may not have the diagnostic capability of onsite tests for certain diseases such as SARS and avian influenza.
- 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. For remains that must be buried, local soil conditions and water tables should be assessed and appropriate depth and type of burial should be determined. Sufficient capacity should exist for storage of refrigerated bodies at the institution before final disposition. Planning for disposal of refrigerated 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 is an alternative. Unit officials should discuss appropriate handling of infectious bodies and communicate to mortuary personnel.

- **Minimum diagnostic services and regulatory compliance.**
  - The minimum laboratory testing services that must be available on site should be defined. The expected turn-around 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 the 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 (housekeeping, security, maintenance staff etc.) who enter the unit while in use or are involved with room decontamination once the patient is discharged. Ancillary personnel who have the potential to enter the BPCU while 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.

- **Use of experimental therapies**
  - Policies and procedures for use of investigational new drugs (IND) or investigational durable equipment (IDE) products in BPCUs must be in place before certification and commissioning of unit.
  - Staff and institutional review board (IRB) members must be trained in provisions of Project Bioshield Act of 2004, especially the emergency use authorization and its use in patient care.

- **Additional clinical issues**
  - Access to the patient room is 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 disease-producing microorganisms in intubated patients.

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 practices should also be based on the specific agents, the condition, and the clinical manifestations of the patient.
  - The use of PPE 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 who are undergoing observation,

to droplet precautions for patients who are in the incubation phase, and airborne precautions for patients with respiratory symptoms. Patients with full-blown symptoms (to include 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, and novel agents). 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 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 under 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, medical director, and 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, 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 routine vaccinations for ongoing 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 [measles, mumps, rubella (MMR), tetanus/ diphtheria (Td), polio]. 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, and yellow fever), these would not generally be indicated for care providers due to 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, known outbreak, or known or suspect patient with 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 smallpox or monkeypox patient 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 (i.e., annual) surveillance for tuberculosis. In the event that the unit is utilized for known multi-drug-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 should be kept on hand or within reasonable access, so that individuals who sustain potential exposures may be given prophylaxis. In addition, considerations 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 standard based on job description and level of patient care involvement.

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

  - Room fumigation may be considered but is not mandatory to remove aerosol risk, assuming the high-efficiency particulate air (HEPA) filtration negative pressure system is functional and producing air circulation in adherence with the recommended number of air exchanges per hour.

- **Large equipment disinfection**
  - Standard operating procedures should be implemented that incorporate applicable institutional, local, state, and federal regulations for disinfecting specific agents, depending on the pathogen in question, using an approved virucidal / bactericidal disinfectant. Generally, surface decontamination of laboratory equipment should be acceptable 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 safe and reliable function upon reuse.

  - Confirmatory testing for decontamination efficacy should be performed.

  - For equipment that cannot be safely disinfected for reuse, a disposable alternative should be considered.

- **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. Autoclave function should be verified regularly to ensure appropriate contact time and temperature. Chemical and biological indicators should be used in a real-time manner to confirm effective sterilization. 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. Landfills expected to receive medical waste should comply with state and local standards for controlled medical waste. Solid waste from clinical or pathology specimens should be handled as other solid waste (i.e., autoclaved before entering the medical waste stream).

  - 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. However, should there be any concern regarding handling after collection (e.g., at off-site contractual laundry facilities), linens may be autoclaved before removal to hospital laundry facilities.

  - For liquid waste, BPCU facilities should engage state and local health authorities and waste water-handling agencies to ensure that municipal wastewater treatment is appropriate before commissioning of the facility. Liquid waste (e.g., blood, body fluids, fecal material, and urine) should be disposed 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 transport of any patient with a suspected highly communicable illness, consideration needs to be made whether: 1) the patient can be safely managed at the originating patient care facility without transfer; 2) the risk of additional potential exposures outweighs the benefits of

transferring the patient to higher care; and 3) the patient is stable for transport (i.e., does the benefit of transport to the patient outweigh the risk of medical complications in route?). Most ambulances do not provide airborne isolation precautions, as the air in the driver's compartment is the same as the air in the patient-care compartment. Ideally ambulances should be configured with special air-handling equipment, such as specifically designed high-containment patient isolators with negative air pressure and HEPA filtration of exhaust air. When airborne isolation precautions are required, the patient should wear a surgical mask and all heath-care workers should wear N95- or higher rated respirators. The level of transmission-based precautions will depend on the pathogen to which the patient has been potentially exposed and the degree of illness. Patients who require contact precautions can be placed in a biological protective suit or equivalent, provided it does not interfere with health care. Upon arrival at the receiving hospital, the patient is to be transported to the biocontainment unit by using mechanisms developed to protect the hospital environment and other patients. Protocols need to be in place to decontaminate the ambulance after transport of the infected patient.

- 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 (versus disposable liner-membranes) the materials should be able to withstand cleaning with EPA-registered hospital disinfectants.

- If the patient is already in the emergency department or another area of the hospital, transmission-based precautions already in place in the hospital should be followed.

- **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. Facilities need to address the issue of non-infected parents visiting children who are infected or in observation for potential exposure. In those rare situations, the BPCU director may allow visitors to have physical contact with patients in isolation. In those circumstances, visitors should follow the same level of precautions as the health-care workers caring for the patient to include exposure surveillance.

  - Visitors need to be informed of the risks of entering the unit and be instructed on the proper donning and doffing of PPE and demonstrate the capability of remaining calm in the PPE before entering the unit. They should be instructed on the early signs and symptoms associated with infection by that pathogen and be asked to notify appropriate medical personnel as soon as possible if any symptoms should occur. They also need to be under constant staff supervision while in the unit. A log of visitor access to the unit must be maintained.

- BPCU policies should be developed to provide guidelines on access by family members and selected visitors. Specific elements should include the number of visitors and the age limits for visitors (considerations include the potential visitor's competency in adhering to infection control). If a parent/guardian can demonstrate ability to conform to isolation practices and PAPR protocols, this individual may be considered for direct access to a child or psychologically compromised patient. The physician or charge nurse would make the final decision on visitor access based on risk/benefit analysis. At the discretion of the attending physician or BPCU director, a no visitor policy may be invoked. A policy on barring access of disruptive visitors should be developed.

Facility Issues

- **Air handling system**

  - Number of air exchanges per hour

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

  - Handling of exhausted air and redundancy

    - Supply air should enter the room high with the exhaust air grille located 6 inches above the finished floor near the head of the patient bed. This configuration helps to protect the patient care-givers' breathing zone, as air should flow away from the patient to the floor. 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, with minimum efficiency reporting value (MERV) 16 or greater 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.

- Dual exhaust fans should be provided for redundancy, with each capable of providing 100% exhaust. Interlocking supply fans are recommended such that if exhaust fails, the supply fans will shut down to prevent positive pressure in the containment areas. The unit including the entire HVAC system needs to be on an emergency power system.

- All HEPA-filtered housings should be installed in such a manner that the filters can be decontaminated scanned and replaced when necessary.

- When completely encapsulating environmental suits with supplied breathing are used, the air supply must meet regulations for grade D breathing air and be HEPA-filtered downstream of the hose connection.

– Testing of air flow

Airflow performance testing is an essential part of ensuring that a BPCU directional airflow is functioning properly. To perform this testing, a hand-held pressure manometer, flow hood, and particle counter should be used to verify the pressure and filtration. Pressure differential is related to off-set airflow and room leakage area. Pressure differential between the patient room and the adjoining areas should be a minimum of 0.01 in w.g. and ideally 0.03 in w.g. These higher pressure differentials are designed to ensure consistent airflow into the unit. 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 a calibrated airflow sensor with sensitivity down to 0.001 in w.g. Alarms should be installed with allowances made to prevent nuisance alarms of monitoring devices. Validation pressure monitoring should occur quarterly. The handheld pressure gauge is used to check the wall-mounted pressure gauge. Supply air should follow American Institute of Architects (AIA)(12) and American Society of Heating Refrigeration and Air-Conditioning Engineers (ASHRAE) (13) design criteria for clinical settings (MERV 14 filtration efficiency).

- **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,

  - have available means for appropriate decontamination of materials and equipment, and
  - have a “safe haven” area for employees to take breaks.

- 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 well as 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. A means to visualize personnel requesting access needs to be provided. 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)

  - Emergency power should be provided for lighting, life support equipment, general equipment (computers, monitors, entrance and exit controls, security devices, etc.), and both supply and exhaust fans.

  - 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 have a method for storing clothing and valuables that should not be taken into the unit and yet be available upon exit.

- An employee break room should be available to the staff in or near the unit. There should be designated clean and dirty areas for staff personal items and equipment.

- 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 & 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.

  - HVAC shutdown for smoke should be specific to this unit and not shutdown 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.

  - Consideration should be given for how the specific areas of the unit (e.g., patient rooms) will be decontaminated. If gas/vapor decontamination is used in rooms, the room must be sealed to maintain the concentration of gas for the time period needed. Drywall joints, voids in floors and ceilings will need to be sealed to prevent gas/vapor leakage outside the area.

  - Identify unit perimeter walls designating them as "biocontainment walls" so future construction or maintenance does not penetrate inadvertently. The wall labels should also indicate fire rating.

  - Consideration in the design should be given to sewer and water handling in the event that local or state requirements are more stringent. Waste handling is discussed above under Infection Control Issues.

- **Certification and commissioning**

- BPCUs should be commissioned 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 BCPUs.

- 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, facility engineer, and the laboratory supervisor, etc.

- **Communication**
  - The parent institution of the BPCU needs to have a public affairs 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,
    - follow appropriate HIPAA (Health Insurance Portability and Accountability Act) guidelines to ensure patient confidentiality,
    - be approved by the local IRB chair when they involved research or the use of investigational products or protocols.

  - The medical personnel who interface with the staff, the public, or the press should have training in risk communication. Communication to any other department(s) that may be impacted should be done in advance of public statements. Regular and routine communication between the institution and local or state health departments is also recommended.

- **Additional facility issues**
  - Equipment can be wiped off and reused during the same event unless dirty or visibly contaminated. At the end of an event, the unit should be terminally cleaned and any equipment that cannot be surface decontaminated and cleaned should be gas sterilized. All equipment and their internal components should be evaluated for the ability to withstand gas sterilization followed by gas aeration for effectiveness of this method.

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

- Policies of the unit should incorporate federal and state requirements for facilities and infectious agents. Written communication policies, to include notification of officials, need to be available.

- Current scientific evidence does not support the use of UV (ultraviolet) lights in BPCU ductwork. HEPA filters are designed to capture and contain infectious particles in the exhaust system, and contamination of filters should not affect the rest of the air handling system. However, decontamination of biological safety cabinets with UV irradiation lamps may be warranted.

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. Each patient should have a thorough history which would include prior psychiatric and addictive disorders. Telephone, internet, and television should be available, as well as providing for exercise modalities (per physician's discretion) for patient well-being. Video-conferencing or visits through windows with a limited number of relatives and friends should be encouraged, although the number of visitors should be minimized. Counseling support, education, and discussion with the patients' family members are also important to prevent panic by the family, which will have a negative impact on the patient and could hamper patient cooperation. 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. Specific attention should be provided to patients who have had significant prior psychiatric illness. Patients with severe mental conditions such as delirium, dementia, psychotic disorders, and severe personality disorders require a more significant commitment of psychiatric, psychological, and social work time. Guidelines for seclusion (no roommate) and restraint should be developed before opening the BPCU.

- **Staff psychosocial issues**

  - It is important to acknowledge that BPCU workers may experience high levels of stress. Mental health services should be provided, and counselors and clergy should be available to staff members at all hours. A separate psychological team and process for determining "fitness for duty" should be established.

- Staff training is crucial to minimize fears and dispel misunderstandings. Education and support for family of staff members is also critical. 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. Shorter work shifts and a staff break room near the unit should be available. Issues such as daycare, pets, housekeeping, and counseling for staff members, as well as inpatients, and their families should be addressed before work in the unit. Increased counseling for staff members, as well as inpatients and their families, should be implemented upon diagnosis or death of a patient.

- **Involvement of psychological support teams**
  Each institution should develop guidelines for psychiatric and psychological services. Early involvement with a mental health-care team is an important facet of providing full-spectrum health care. The health-care team should be fully cognizant of stress issues, have specific training in effective measures for intervention, and be available to dedicate the resources to respond quickly to developing situations. A recommended priority for access to services would be patients, BPCU health care workers, and the patients' family members.

- **Ethical issues**
  - BPCUs generate significant ethical challenges. Patient autonomy should be preserved as much as possible with regard to medical procedures but patients should be informed about possible limitations in patient care intrinsic to confinement in the unit. The principle 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 for other patients in 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). Providing 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). Each institution should review with the relevant governmental agencies (state and federal) the legitimate approaches to holding a non-psychiatrically ill patient.

  - The ethical demands for the staff should include an acknowledgement of ongoing patient-care responsibility. The institution should provide relevant support services (childcare, transportation assistance, etc) to enhance providers' availability.

  - Clear policies should be developed for providers to understand the consequences of not reporting for duty.

Discussion

After 9/11 and the anthrax mailings of 2001, the US 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-pressure 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. Smallpox has been the focus of intense planning (17), and has long been a concern in hospitalized patients (18). Smallpox patients require a combination of airborne and contact isolation, vaccination of personnel, and special handling of linen (19, 20), and in a limited outbreak it is recommended that patients be admitted to the hospital with airborne isolation and HEPA filtration. For VHF-infected patients, the suggested infection control approach includes airborne isolation, impermeable gowns, double gloves, and shoe coverings (5, 21, 22). Both of these diseases have a high mortality rate in infected health-care personnel.

Although bioterrorism was the impetus for much preparedness planning, the hospital is more likely to encounter naturally occurring emerging infectious diseases such as multi-drug-resistant tuberculosis, SARS, monkeypox, Marburg virus infection, avian influenza, and vancomycin-resistant *Staphylococcus aureus.* SARS, a well known cause of hospital epidemics (23), spreads primarily by the airborne route, but may also contaminate environmental surfaces (24). Airborne and full barrier precautions were recommended (25), but did not prevent all spread to hospital staff. Avian influenza, the current focus of intense national planning (26), has the potential to combine the high mortality of avian influenza with the contagiousness of pandemic influenza to produce a disease which may be quite hazardous in the hospital setting. A combination of airborne, droplet, and contact isolation is recommended (27), with negative airflow, face shields, and limited staff contact with the patient. Biopreparedness planning helps to prepare for naturally occurring infections as well.(1)

Another source of potential hazardous patients in the health-care setting is laboratory personnel exposed while working under maximum containment laboratory conditions. A number of articles have been published regarding the military and civilian experience in dealing with potential occupational exposures that can occur in a laboratory (3, 28-31). The use of biological safety cabinets has been beneficial in reducing laboratory-acquired illness, but biological safety cabinets alone have been insufficient to eliminate laboratory-acquired disease in the absence of an effective vaccine, especially when dealing with an organism that has a low infective dose (3). Despite appropriate training and containment laboratory facilities, potential exposures in the laboratory can and will continue to occur.(29) The USAMRIID unit had isolated 12 patients for potential exposures to infectious agents who were working under BSL-4 conditions (9). The unit was reactivated in 2004, after a 19-year hiatus, to monitor a lab researcher potentially exposed to a mouse-adapted strain of Ebola virus. Fortunately, that patient and all 12 prior patients did not become ill; however, the death of a Russian lab worker in 2004(32) 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 generally treated in hospitals under traditional 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 (33). 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 for 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 (34). A survey of infectious disease physicians found that most had concerns about their facility's preparation and capacity for managing patients with SARS (35).

Thus, although hospitals generally have the ability to provide airborne isolation, additional measures are needed to care for patients with the high mortality diseases discussed above. Measures such as 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.

Biosafety is by definition the combined application of practices, procedures, facilities, and safety equipment when working with potentially infectious agents. Biosafety is provided by a combination of facility design (e.g., an appropriate airflow and filtration system) and operational practices (e.g., use of personal protective apparel and staff vaccination). The necessary elements to work with these agents within the laboratory (identified as BSL 1 through 4) have been described (36, 37). Although laboratory-directed, the basic principles apply in any situation where a biohazardous agent is encountered, including BPCUs.

Even though there are no current standards specifically for design and construction of patient-care biocontainment units, there is applicable information in the medical literature. General hospital preparedness has been addressed by a number of organizations, including HRSA (14), the Association for Professionals in Infection Control (APIC) in its healthcare facilities planning template(38), Health and Human Services (HHS) in the 2002 Smallpox Preparedness Plan (17), the 2003 guidelines for SARS response (39), and the 2005 Pandemic Influenza Plan (26). Also valuable is the reference literature on isolation guidelines for general hospitals(15), consensus isolation recommendations for specific biohazardous diseases (19, 22, 40), CDC guidelines for environmental control and tuberculosis (41, 42) and other construction guidelines (12, 13).

Access to a special environment in which to care for hazardous infectious disease patients and a specially trained and vaccinated staff is costly. However, modifying infrastructure to create special isolation facilities on an urgent basis in the face of an infectious disease outbreak is both costly and inefficient (4, 43). Additionally, creating a temporary isolation arrangement disrupts normal operations(4, 5). Other advantages to preplanned BPCUs include providing extra protection for the staff and patients in the hospital which will receive the contagious diseases whether or not a special biocontainment unit is available, and enabling optimal care for the afflicted patients. Coordinating special patient biocontainment units with the diagnostic laboratory and with public health facilities is an essential part of planning.

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 For Detrick, MD in 1971(44), and in 2005 units opened at Emory University (two beds) and the University of Nebraska (10 beds). Some of the BCPU infrastructure recommendations (e.g., entire units with a negative pressure, HEPA-filtered ventilation system) and special features such as isolation transporter units (45) 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 cohort patients in dedicated wards or buildings, per current guidelines for smallpox, SARS, and avian influenza. (14, 24, 26)

No published standards for biocontainment units that are used for patient care are currently available. To give guidance to other facilities planning biocontainment strategies, a group of individuals involved in the current biocontainment units, or with expertise in related fields such as laboratory biocontainment units, infection control, bioterrorism preparedness, hospital architecture and construction, staff psychology, engineering, intensive care and biosafety, convened in Omaha, NE November 8-9, 2005 to develop a consensus document of suggestions for planning, building and operating biocontainment patient care units.

We propose the construction of a limited number of regionally distributed BCPUs. Their 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. Because their capacity would be saturated during a large epidemic, BCPUs will not substitute for epidemic preparedness planning by public health at the national, regional, and local levels. BCPUs 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. Furthermore, the efficacy and cost effectiveness of BCPUs has not yet been systematically studied. Our intent is to have the consensus points inform future standards for planning and building biocontainment patient care units, as well as overall biopreparedness planning.

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Table 1: Biocontainment Patient Care Unit Consensus Topics

I) The Role of Units in Overall US Preparedness

A) Definition of BPCUs

B) Diseases that should be handled in BPCUs

C) Integration of units into military and civilian preparedness

D) National capacity for BCPUs

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) Use of experimental therapies

I) 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 patient 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) Involvement of psychological support teams

D) Ethical issues