TECHNICAL COMMENTS
Interim Smallpox Response Plan and Guidelines
Draft 2.0 (11/21/01)

Summary

The overall approach to controlling the spread of smallpox in facilities presented in this plan conveys a perception that the variola major virus is hardier when released into the environment than anthrax spores. While comparative models are not available, investigation by the CDC of the dissemination of anthrax spores in the Brentwood Mail Processing & Distribution Center suggests spores are more resistant and more easily disseminated in the environment than smallpox virus (**1**). Perhaps this can be explored further with scientists familiar with aerobiology of both spores and viruses. The Canadian Department of National Defense also has conducted experiments with environmental dissemination of Bacillus spores and is another potential source of information. The extraordinary history and consequences of smallpox epidemics may also justify the conservative approach taken in the draft plan.

However, some of the recommendations could substantially increase confusion or promote misinformation at a time when implementation of standard procedures would be critical. Therefore, it is essential to plan control measures using the most current and scientifically sound information, particularly in the sections related to air management and disinfection issues. The current version of the plan's recommendations appears to draw heavily from experiences from outbreaks in Europe in the early 1970s. However, review of primary references that described these outbreaks reveals physical facility and ventilation designs that differ dramatically from contemporary U.S. health care facilities. The comments below identify the issues and our recommendations for revision to make the plan relevant to America's hospitals today.

General Comments

Risk associated with mode of virus transmission (Guides A and B)
Although our comments are primarily confined to Guides C, F, and a few items in Guide D, they are based on agreement regarding the most frequent mode of transmission of the smallpox virus with implications for control strategies. However, there are inconsistencies in the plan's description of mode of transmission of smallpox. For instance, in *Guide A, Section 4, (page A-7) Surveillance, Contract Tracing and Epidemiology Investigations,* it is stated that droplet spread is the most common mode of transmission; contaminated materials less common; and airborne spread the least common. On the other hand, *Guide B Section 2 (page B 5) Vaccination Guidelines for State and Local Health Agencies, Indications for Vaccination During a Smallpox Emergency,* states that droplet spread is most common; airborne spread less common; and contaminated materials least common. Review of the primary literature on transmission of smallpox in hospital environments (primarily from European outbreaks) sheds light on the source for some this variation. (**2-14**) A number of these reports involving hospitals reveal basic

agreement on the mode of transmission. That is, "droplet spread" – eg, contact with persons within approximately 6.5 ft or 3 meters **–** is the *most* common mode of transmission. However, current CDC guidelines for isolation precautions define the distance for large droplet transmission as 2-3 feet. **(15)** It may be that a margin of safety was integrated into these recommendations in the past, but the definition of terms should be revised for consistency with the current CDC guidelines. The discrepancy in defining the distance of droplet spread is confusing. CDC should clearly indicate whether an additional buffer zone (i.e., 3 more feet), is considered necessary for control purposes. Any such distinction should be clearly defined.

These reports of past outbreaks also noted that "aerosols," which likely accounted for the airborne spread in a few hospital settings, occurred where more severe cases or cases with a cough were admitted. But important differences in the environment of care, compared to most U.S. health care facilities, are notable. Patients in these past smallpox outbreaks were "isolated;" that is, they were merely separated from other patients and barriers were used. Descriptions of the smallpox outbreak investigations, particularly the numerous reports concerning the outbreak at the Meschede hospital in Germany, reveal that the air supply was shared and ventilation was accomplished by opening windows and doors (**2-6, 9, 21-22)**. Further, ambient meteorological conditions at the time of the outbreak in Meschede, e.g., low relative humidity and low outdoor air temperature, also played a significant role in dissemination of virus to others in this hospital.

By contrast, U.S. hospitals today require the use of more effective procedures, such as airborne infection isolation rooms (AIIRs) that supply negative air pressure at 6-12 air changes/hour. According to current standards, exhaust from AIIRs is either direct to the outside or, if recirculated, passed initially through HEPA (high efficiency particulate air) filters. This design is deemed effective for *M. tuberculosis* and *V. zoster* and therefore also likely effective for the less hardy smallpox virus. (**16)** The *CDC Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Facilities, 1994* define isolation rooms in these terms (**17**). And these guidelines apparently work. Three consecutive CDC/AHA or CDC/Premier hospital surveys conducted between 1992 and 2002 measured increasing compliance of hospitals in design and maintenance of AIIRs and falling incidence of TB transmission in hospitals. (**18-20**)

Recommendation 1:

- The definition of "large droplet spread" should be revised for consistency with the current CDC guidelines of 2-3 feet.

- Given the stated agreement that droplet transmission is the most common mode of spread, the plan should more clearly support control measures based on droplet transmission. This recommendation is reflected in specific comments to follow.

- CDC recommendations related to overall management of known or suspected smallpox cases in hospital facilities as described in Sections C and F should be reexamined in light of current U.S. hospital capacity for AII rooms, based on accepted definitions. Current design, operation, and regulation of U.S. hospitals would not appear to justify a number of extraordinary and not necessarily effective precautions recommended in Guides C and F.

Guide C: Guidelines for Isolation and Quarantine

Ventilation Design

Section 1 A.: (page C-4) Facility types and recommendations related to ventilation designs to control transmission of smallpox virus
Facilities are categorized as types for managing groups of: known/presumed infectious individuals (Type C), febrile contact with rash (Type C or X) and asymptomatic contacts (Type R). Our concerns focus on Type C facilities since these are intended for care of contagious individuals. The buildings that CDC recommends are not structures commonly found in the U.S. Therefore it is unrealistic for CDC to rely on this approach for future planning. The recommendations call for the use of buildings *other than* hospitals for "contagious patients, such as nursing homes and hotels." Yet hospitals are the only buildings *likely* to have negative pressure rooms with 100% exhausted air (or recirculated air through HEPA filters). Further, the complexity of equipment needed to care for critically ill persons is also unlikely to be readily available in a facility that does not provide health care. Nursing homes, hotels, and other types of facilities, as a rule, are designed with recirculated air systems. Even if the intent is to provide care in these settings using vaccinated health care workers, there will necessarily be time lapses before sufficient numbers are immunized and able to staff such facilities. In addition, health care facilities are routinely assessing airflow and exchange within AIIRs as required by accrediting organizations such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Such validation is rare or nonexistent in buildings such as offices and hotels.

The current plan provides for two extremes of potential smallpox transmission. It addresses either small numbers of patients (safely managed in AIIRs) or large numbers (transfer to a Type C facility). It does not address facilities that do not have AIIRs (e.g., nursing homes), facilities with limited numbers of AIIRs, and the intake and holding areas for patients while a Type C facility is activated.

Hospital facilities must have minimum numbers of AII and other negative pressured rooms as required by state and federal regulation. Most facilities may use 100% exhaust; some using recirculated air for that specific room if equipped with HEPA filters for return air. Hospitals are beginning to identify ways to place larger areas (units) under negative pressure as the need for more AIIRs increases or to contain areas caring for persons involved in an episode of suspected bioterrorism. This direction of contingency planning may be more effective for the "middle ground" than immediate transfers to other facilities. Some specific recommendations are listed below in Recommendation 4, but we would encourage further direct discussion with the ASHE regarding possible approaches. The fuller ASHE discussion is appended **(23).**

Hospitals should not only expect but should feel competent in managing initial, possible smallpox cases. Although later cohorting to a single facility for infected cases may be efficient, once sufficient numbers of staff are immunized, facilities should be confident in initial management of patients with potential airborne disease. (See specific comments and recommendation 4, below.)

Recommendation 2: We propose that the plan's initial focus be on utilizing the safe and effective design of AIIRs in hospitals, understanding that AIIRs are defined in terms of negative air pressure, minimum hourly air changes and appropriate means of air exhaust.

Recommendation 3*:* Rather than focusing on locating other buildings (with less effective ventilation systems) to house contagious patients, with related risks of transmission during patient transport, hospitals should be urged to maintain an inventory and records of ongoing effectiveness for their negative pressured AIIRs as required by state and federal regulations or accreditation organizations.

Recommendation 4*:* Planning should begin with the assumption that most hospitals can manage a finite number of patients in negative pressure AIIRs. Additional attention should be placed on the protection and ventilation of intake areas of hospitals, where diagnosis of infection is likely to occur first, such as emergency departments (EDs) and direct admission areas. The 2001 AIA guidelines **(16)** require that new emergency rooms include an AIIR room as well as negative air pressure in the emergency department (ED) waiting and triage rooms. We would further suggest planning to include the following approach:

1. **Immediate response:** Address what health care organizations can do immediately to prepare the environment for the possibility of receiving an influx of smallpox patients (eg, inventory AIIRs, and negative pressured areas throughout the facility eg, ED negative air rooms/areas.) Assess the facility for larger spaces that could be used as triage and treatment areas, remote from patient care areas, and which permit ventilation disruption and utilization of portable HEPA filter units.
2. **Retrofit:** Consider reasonable modifications facilities can make within existing ventilation systems to isolate the additional rooms or areas needed to house the potential of a larger influx of infected patients. Perform due diligence of flexible space and identify zones in which blocks of rooms can maintain negative pressure with respect to adjacent areas (Using qualified personnel, review blueprints, field survey for areas with 100% exhaust; identify areas that can be run in economizer mode; identify smoke control system, understanding limitations of smoke barrier compartments).
3. **Future:** Longer term design planning when considering replacement ventilation systems or designing a new hospital should include identification of criteria and future need for the ventilation system design which anticipates accommodation of several patients requiring airborne precautions. The AIA guidelines already require use of infection control risk assessment (ICRA) during such planning, which could include facility-specific assessment of bioterrorism response and containment. The AHA can help encourage inclusion of this into the ICRA process for its member organizations.

Ventilation Exhaust and Filtration

Section 1 A: (page C-5) Type C facility requirements

The draft plan currently provides for Type C facilities to have dedicated air handlers as part of the building's heating, ventilating, air conditioning (HVAC) system that exhaust 100% of the air to the outside. This aptly describes current AIIR design in U.S. hospitals. However, the plan calls for the facilities to also exhaust air *through* HEPA filters, *or* for the facility exhaust vents to be located 100 yards from any other occupied building or area. We do not agree with the recommendations that exhaust air needs to be HEPA filtered or that exhaust vents should be located this distance from other areas. Filtering exhaust air has not been an element of effective ventilation control for *M. tuberculosis*, a microorganism hardier than the smallpox virus. **(17)** In fact, HEPA filtration on large exhaust systems can lead to greater risks of infection transmission due to imbalances or inappropriate placement.

Part of the rationale for these CDC recommendations may be, as the draft plan states, that the hospital-related outbreak in Europe (Meschede) was likely from airborne transmission. Yet the index case at Meschede was cared for in a hospital that did not have dedicated air handlers for isolation patients. As described in the published reports of this and other European outbreaks (**2-14, 21-22),** ventilation was achieved by opening doors and windows. Henderson noted that "the design of the hospital led to the raising of strong air currents when the building was heated, as it was during the winter, when the episode occurred."(**21**) Again, isolation in these European outbreaks was not defined in terms of negative air with 100% exhaust or use of recirculated air returned through HEPA filters, as is the standard in U.S. hospitals today. This U.S. standard has been in place for several decades and is not comparable to the setting that supported secondary transmission in Meschede.

Regulations that govern hospital design for air intake and exhaust require proper separation to protect air intake and enhance dilution of released "contaminated" air. (**16**) Moreover, the extraordinary description for Type C buildings in the draft plan does not appear consistent with the *most* common mode of transmission of *Variola major* as described within this Response Plan --droplet, not airborne. As noted, current guidelines do support use of recirculated air in negative pressured isolation rooms only if the air is returned through HEPA filters. This is an effective use of HEPA filtration and the proposed recommendations are unnecessary even for the worst-case scenario of airborne droplet nuclei from a highly infectious patient.

Recommendation 5: Consider that current U.S. hospital requirements for airborne disease isolation have continued to improve and have been effective for managing *M. tuberculosis*. More rigorous containment methods such as final filters on exhaust air are unnecessary and could even increase the risk of transmission of smallpox. The U.S. hospital standard for AIIR should be considered an effective method for managing smaller numbers of patients and should not require exhausted air to be HEPA filtered.

Ventilation and Filter Contamination

Section 1 B. (page C-6): Isolation of infectious individuals in hospital facility initially utilized for non-smallpox medical purposes.

The plan requires that filters be disposed of through incineration or autoclaving. We disagree. It is unnecessary to autoclave or incinerate HEPA or pre-filters prior to disposal. **(17)** Work done with *Mycobacterium spp* (a microbe known for its capacity to survive in the environment as droplet nuclei) in filters have shown little risk of re-aerosolization once captured in the filter matrix given waning viability of the filtered organisms (**24)**. Although inactivation studies have not been done directly with *Variola major*, this study by Gwangpyo et al. may provide some applicability to containment of smallpox virus. In the tests, solutions of *M. tuberculosis* (TB) were applied directly to filter material in quantities greatly in excess than that expected in the field and tested at various times afterward for viable organisms. TB was also applied by spray aerosol in a test duct system and cultured similarly. Tests were repeated with a HEPA media treated with a quaternary ammonium compound (QAC) as a biocide. Results indicate that only a small percentage of viable cells survive after 24 hours on the filter media. Virtually all of the organisms were dead after 72 hours. Biocide treatment to HEPA filter material before cell deposition had little effect on the survival of the TB. Airflow across the filter media had little effect on the results. Overall, the data indicate that the potential for exposure to viable cells of TB during changing of filters is minimal (**24).**

Further, current TB guidelines do not require autoclaving prior to disposal, and in fact AIIR filters may be managed as general waste. Therefore, given the effectiveness of the current CDC TB control recommendations, and the hardiness of *M. tuberculosis* compared to smallpox, we believe that standard methods for managing filter changes and disposal are also appropriate for smallpox.

Recommendation 6: AIIR or air handling system filter changes and disposal should be managed in accordance with standard infection control guidelines for waste management and not require autoclaving or incineration prior to disposal.

Gloves/Masks/Particulate Respirators (PRs)

Section 1, I.C.3: (page C-8) Procedures for isolating known/presumed infectious individuals

The draft plan's suggestion to use disposable latex and/or vinyl gloves may signal that vinyl gloves are not effective. In light of ongoing sensitivity regarding latex allergy, we recommend deleting the reference to latex gloves, and instead refer to disposable gloves.

Further, the plan inconsistently refers to N-95 particulate respirators, sometimes referring to these are "masks." We recommend that terminology throughout the document be made consistent when referring to N-95 particulate respirators (N 95 PRs) since they are not masks but are certified by NIOSH as respirators.

Recommendation 7: Use the phrases "disposable gloves, for example, vinyl" and "N-95 particulate respirators" consistently throughout the plan.

Dishes/Utensils

Section 1, I. E.: (pages C 9-C 10) Procedures for isolating known/presumed infectious individuals

Most issues of concern related to cleaning, disinfection, and waste management will be addressed more fully in Guide F**-** *Decontamination* (e.g., references to autoclaving or incineration of linen, bedding and waste). However, as modifications are considered in Guide F, we would expect these would also be reflected in the procedures outlined in Guides A-N, particularly Guide I (*Patient Care Precautions*). For example, Guide J requires utensils to be "sterilized in a standard dishwasher." In fact, utensils are effectively "sanitized" at regulated and appropriate hot water temperatures, not "sterilized."

Recommendation 8**:** Language in the plan should consistently reflect accepted terminology in current guidelines, such as sanitization of utensils rather than sterilization.

Use of N-95 PRs

Section 1 II.C.: (page C 11) Procedures for isolation of an infectious individual in hospital facility utilized for care of non-smallpox patients

The plan describes a protocol for managing a patient being admitted with smallpox infection and notes that caregivers who are vaccinated do not need to don a N-95 PR for patient care and transportation. We are concerned that endorsing a practice that permits vaccinated individuals to avoid the use of N-95PRs may cause administrative confusion. The caregivers' vaccination status is not necessarily known by other caregivers and may transmit the message that the patient is no longer communicable. The decision about whether to use PRs should depend on the patient's communicability status and not on the immune status of the caregiver. Isolation guidelines should be consistent with current CDC isolation precaution guidelines regarding appropriate use of masks (for patients) or particulate respirators (N-95 PRs) for caregivers. **(15)**

Recommendation 9**:** It would be prudent for all staff to follow standard precautions and continue wearing an N-95 until a patient's communicability status is determined, since caregivers and support staff may not know who is or is not vaccinated. Further, the plan should reinforce the fact that transport of a suspected case of smallpox does not require a special containment facility. Instead, a mask and cover gown for the patient and appropriate respiratory protection for health care personnel is sufficient.

Guide F Decontamination

Reusable Medical Equipment –Cleaning and Disinfection

Section A: (page F-2) Guides C and F would benefit by reexamining the entire issue of appropriate selection of cleaners, disinfectants and sterilants. The proposed Guide F recommends the use of 5% phenolic germicidal detergent, followed by decontamination through autoclaving (steam), ethylene oxide or more soaking in phenolic detergent, eg, "industrial strength Lysol." The emphasis on "prolonged soaking in phenolic detergent" is not without risk, since prolonged exposure of phenolic solutions to skin can be damaging. The text does not appear to reference current guidelines addressing the efficacy of other disinfectants, or the scientific basic for such recommendations, and this section could be clarified without the use of brand names.

Although viral inactivation studies have not been done on *Variola major*, there are inferences that can be derived from studies of other members of *Chordopoxvirinae*. Published information merits assessment of alternative methods of disinfection processes and agents that are effective against orthopox viruses. (**2, 25-30**) The literature cited indicates that *Variola major* is classed with other group A (lipophilic) viruses that are readily inactivated by halogens, aldehydes, quaternary ammonium compounds (QACs), phenolics, alcohols, proteases, detergents, and hydrogen peroxide. References to brand names, such as "Lysol" or "industrial strength Lysol." are not helpful, nor are they appropriate in guiding the selection and use of required hospital-grade disinfectants. This approach is supported by a recent review in the *Journal of the American Medical Association (JAMA)* of smallpox as a biological weapon: "Disinfectants that are used for standard hospital infection control such as hypochlorite and QACs are effective for cleaning surfaces possibly contaminated with virus." **(26)**

We agree with the draft plan's statements that manufacturers' guidelines should always be reviewed for recommended disinfection/ sterilization guidance, whether chemical disinfectant/sterilants, steam autoclaves or ethylene oxide is employed. The comments in this section regarding ethylene oxide (time, concentration, and aeration) should again refer to standard guidelines and the manufacturer, since gas mixture type, concentration, exposure time, and aeration time can vary considerably with different equipment. (**30**) These are available as standard operating procedures in any hospital using ethylene oxide, and would not likely found in other Type X or R facilities.

Recommendation 10: The authors of this section should reexamine science-based rationales for selection of disinfectants, and make new recommendations based on CDC and other accepted published guidelines. (**30**) Further, the plan recommendation would be clearer by using the terms "disinfection" and "sterilization" consistently throughout this section, as opposed to "decontamination."

Medical Waste

Section B: (Page F-3) The draft plan currently recommends that medical waste be bagged and then incinerated or autoclaved on-site. In today's environment, hospitals generally do not have the capacity to autoclave or incinerate medical waste within the facility. However, standard infection control practices in hospitals, in compliance with local, state, and federal guidelines, mandate that care should be exercised in the management of medical waste. Therefore, the plan's recommendations should be reconsidered and CDC should examine other strategies, short of on-site autoclaving/incineration. Further, the recommendation to wipe down the outside of medical waste bags should consider the use of other disinfectants than Lysol for clean up of medical waste.

Recommendation 11**:** The plan should not limit recommendations regarding medical waste treatment to incineration and/or autoclaving. Instead, CDC should consider other methods of waste disposal that reflects newer technologies and alternatives to managing medical waste in a manner that is consistent with local, state and federal regulations.

Surfaces

Section C: (page F-4) The draft plan recommends that contaminated horizontal surfaces be decontaminated using a 5% aqueous solution of a phenolic germicidal detergent (e.g. Lysol). It also recommends that solutions stand for 20 minutes on the surface for clean up. The cleaning materials are to be autoclaved or incinerated. Today, infection control practices recommend following the disinfectant labeling from manufacturers.

Recommendation 12*:* The time of contact for cleaning/disinfection depends on the solution used, and manufacturer directions should be adhered to. Laundering of cleaning equipment and cleaning material with hot water and bleach should be acknowledged in the plan as effective, and autoclaving or incineration should not be required. (**26**)

Laundry, Bedding and Linens

Section D: (page F-3) The introduction to this section begins with a reminder of the rare spreading of smallpox via clothing and articles. Although older accounts of smallpox outbreaks indicate that laundry workers became infected, no disease transmission occurred once the textile became wet. (**21**) Henderson and Moss also noted that reports of transmission from other fomites, such as carpets and cotton rags, are suspect because the virus does not survive for long periods at customary ambient temperatures. Despite this historical evidence the current version of the response plan recommends autoclaving or incineration of laundry, bedding and linens.

Water temperature: There is no need to autoclave items that can be washed in hot water. CDC recommends laundering with hot water [71°C (160°F)] and hypochlorite for smallpox-contaminated clothing elsewhere; this is also recommended in the JAMA consensus statements on smallpox. (**26, 31**)

We also recommend that low-temperature laundering be reexamined as an effective alternative. Evidence shows that microbiocidal action is affected by several physical and chemical factors. CDC has supported the addition of chlorine (or other types of oxygen-activated bleach) in current and proposed environmental infection control guidelines (**32,33**). Low-temperature laundry requires appropriate use of detergents and chemical additives affecting pH, resulting in the inactivation of microorganisms. Given the susceptibility of the smallpox virus to chemicals, there is no reason to doubt the effectiveness of low temperature laundering for smallpox.

Whether facilities manage their laundry on-site or contract with off-site commercial laundries, a large percentage of U.S. hospitals rely on lower temperature washing because of their major energy and cost savings. In other documents, CDC cites several studies showing that lower water temperatures of 22°C - 50°C (71°F - 77°F) can satisfactorily reduce microbial contamination when the cycling of the washer, the wash detergent, and the amount of bleach are carefully monitored and controlled. (**32,33**) Low-temperature laundry cycles rely heavily on the presence of chlorine- or oxygen-activated bleach to reduce the levels of microbial contamination.

Regardless of whether hot or cold water is used for washing, the temperatures reached in drying and especially during ironing provide additional significant microbiocidal action.

Mattresses: Pillows and mattresses are usually encased in plastic and require surface cleaning. Use of disinfectants that are compatible with the cover materials will prevent the development of tears, cracks, or holes in the covers. The current CDC guidelines and draft guidelines for Environmental Infection Control are adequate for addressing laundry concerns, even in smallpox outbreaks.

Recommendation 13: The draft plan recommendations for laundering should be revised, with attention to the effectiveness of hot and cold water laundry processes, considering use of chemical additives in modern laundries, whether on site or off-site. These CDC recommendations should be consistent with other current CDC guidelines. (**31-32**) We recommend that use of low temperature (<70°C) laundry cycles be considered an effective alternative, based on current CDC guidelines and manufacturer equipment instructions that describe appropriate chemicals suitable for low-temperature washing, and used in proper concentrations.

Room/Facility; Fogging

Section E: (pages F-3 –F-6) We do not believe fogging the facility with formaldehyde as a means of "disinfecting the facility", as described in the draft plan, is warranted based on the known mode of transmission and evidence demonstrating susceptibility of related orthopox viruses to a broad range of chemical disinfectants applied to surfaces. This approach in U.S. modern hospitals is not only unnecessary but would cause harm to patients and caregivers, given the significant toxicity associated with heating volatile aldehydes. Further, there are no guidelines for determining when re-entry of a room is safe following vaporization of paraformaldehyde. Recent experience of attempting whole-building disinfection following contamination with anthrax spores using vaporized disinfectants such as chlorine dioxide also demonstrates the difficulty in ensuring efficacy and safety for reoccupation.

CDC, APIC and other groups have long discouraged the use of fogging as an effective method for disinfection. **(27-34)** Inclusion of such methods, even for exotic microorganisms such as the smallpox virus, is inconsistent with years of training recommending against fogging and would therefore only serve to confuse infection control professionals. Further, these fogging recommendations are not supported by the discussion from the JAMA consensus statement on smallpox. (**26**) Comment is made in the plan that fogging may be impractical for homes. It is less practical and even less safe for hospitals. CDC, in a recent Webcast, recommended standard terminal cleaning procedures as effective (**31**) and we support the application of those recommendations over those currently contained in the draft plan.

Recommendation 14**:** Delete any reference to fogging. Instead, emphasize the use of a wide range of chemical disinfectants. CDC should also investigate alternatives such other surface-active agents (decontaminating foam) from Sandia laboratories. (**35**)

Guide D - Specimen Collection and Transport Guidelines

Ventilation and Autopsies

Section III: (page D-7) The draft plan states that autopsies should be carried out in a negative air pressure room, with air exhausted to outside. We would note that this recommendation, unlike that in other sections of the draft plan noted above, does not require contaminated air to be discharged through HEPA filters. We believe that this reflects current, effective design requirements from federal and state authorities.

Recommendation 15: We support this recommendation and suggest that other ventilation recommendations in the draft plan be aligned with this one.

Hand washing; Specimen Collection

Section III (page D-8) The hand washing section of the draft plan related to laboratory handling of specimens recommends the use of soap containing Lysol or Hibiclens.

Recommendation 16*:* While CDC's intent is clear, this recommendation should reference current CDC/Hospital Infection Control Practices Advisory Committee Guidelines for Hand washing without citing specific brands. (**36**)

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Reference 23

Report of Ad-Hoc Task Group to Address Health Care HVAC Design for Smallpox

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Purpose: Review CDC Smallpox guidelines – Part C Isolation & Quarantine, and provide comments specific to ventilation requirements for the housing and treatment of smallpox infected patients identified in the document.

Problem: In its present form, the CDC *Guidelines* discuss only the two extremes of a smallpox scenario. The lower limit identifies intake of 1-2 smallpox patients requiring isolation precautions, including negative pressure rooms and 95% filtration of exhaust. The upper extreme designates transfer to a Type C facility for housing smallpox patients to minimize the exposure of susceptible individuals to contagious individuals. The document fails to address the response of health care facilities without Airborne Infection Isolation (AII) areas, facilities with limited AII that may be overwhelmed at the initial intake of more than one or two patients, and the "middle ground" scenario of patient intake and holding while a type C facility is activated.

Discussion: Dissect the issue of ventilation needs to three problem statements.

1. **Immediate Response** - What can a healthcare organization do immediately to prepare the environment for the possibility of receiving an influx of smallpox patients?
2. **Retrofit** - Within reason, how can existing ventilation systems be modified to isolate the additional rooms or areas needed to house the potential of a mass influx of infected patients?
3. **Future Design Criteria** - When designing replacement ventilation systems or designing a new hospital, what criteria should be placed on the ventilation system design anticipating the future need for the isolation of infectious patients?

1) Immediate Response – do the best we can with what we have
   a. Evaluate patient intake and emergency treatment areas
      i. Evaluate ventilation systems serving the emergency department (ED) triage area and waiting area to determine whether 100% exhaust (directly to the outside) or high-efficiency particulate air (HEPA) filters are used to clean the air before recirculation. Identify whether treatment rooms meeting AII requirements are available within the ED.
      ii. If the ED cannot meet these requirements, identify a large space, or multiple smaller spaces remote from traditional patient care area, with ventilation that can be disrupted, to be used as a remote triage and treatment area. Place a portable HEPA filtration unit(s), designed to ensure adequate air mixing, in all areas of the room with greater than or equal to 15 air changes per hour. Adequate security and two-way communication are required to ensure that isolation protocols are maintained.

b. Admit small numbers of patients or hold until Type C facility is prepared.

i. Identify AII rooms throughout facility and the patient transportation route from the ED to each room. Determine proper airborne infection isolation procedures to transport the patient through the hospital (i.e. N-95 PRs for staff and surgical masks for patients).

ii. If no AII rooms have been designed into the facility (e.g. Critical Access Hospital) or if AII rooms are overwhelmed, place patient in other rooms or areas with 100% exhaust where supply air and any return exhaust may be disrupted locally with the use of portable HEPA filtration units. Note – the room or area must be evaluated to determine whether altering the supply air will create a negative pressure relationship for the building.

iii. Ensure that all areas considered for airborne infection isolation have ducted returns. Areas and buildings used for housing or treatment of patients needing AII shall not have plenum returns systems.

2) Retrofit – Perform due diligence of adaptable space and flexible space – how can the existing space be modified to prepare for the influx of patients needing isolation?

a. Establish emergency airborne infection isolation plans with plan evaluation by a qualified group

i. Review blueprints to identify areas with 100% exhaust. Perform field surveys to ensure proper installation and operation, determine condition of fans, and assess the condition of ducts so that, if a system alteration is necessary, the proper airflow will be available.

ii. Review blueprints to identify air-handling systems that can go to economizer mode. Perform field survey to ensure smoke tight return damper and evaluate heating and cooling requirements for space comfort and potential coil freeze damage.

iii. Identify campus-based clinics with independent ventilation (often 70% fresh air with 30% return) that can potentially be run in economizer mode.

b. Determine whether the facility has smoke management systems (i.e., return air goes to 100% exhaust but maintains some supply air to keep pressure relationships) to be used to create a negative pressure area with 100% exhaust. (Note - hospitals being compartmentalized by smoke barriers is not enough to provide unit isolation – active ventilation is needed to ensure proper separation of the isolated area.

Future Design – Future design will be the focus of additional detailed discussion. This general discussion centered on the need for future designs to provide for adaptability of large areas (i.e. the ability to selectively place large areas/multiple rooms under negative pressure and 100% exhaust on an "on demand" basis). It was noted that the HEPA filtration on large exhaust systems, identified in the CDC *Guidelines*, is not realistic for current or future design. Except for AII systems already in place, HEPA filtration of exhaust can lead to a greater chance of infection due to air balance changes, inappropriate placement, or inappropriately trained workers changing the filters. The best approach is to discharge the exhaust to the air and allow sunlight to kill any airborne pathogens. All exhausts potentially used for discharge of pathogens should be in compliance with standards that direct placement of intake and exhaust units.