

*Bioterrorism and Other Public Health Emergencies
Tools and Models for Planning and Preparedness*

Development of Models for Emergency Preparedness

Personal Protective Equipment, Decontamination, Isolation/Quarantine, and Laboratory Capacity

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AHRQ is the lead Federal agency charged with supporting research designed to improve the quality of health care, reduce its cost, address patient safety and medical errors, and broaden information on health care outcomes; quality; and cost, use, and access. The information helps health care decisionmakers—patients and clinicians, health system leaders, and policymakers—make more informed decisions and improve the quality of health care services.

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Development of Models for Emergency Preparedness

Chapter 1. Introduction

This section summarizes the purpose of this project and provides background on the Agency for Healthcare Research and Quality (AHRQ) Bioterrorism Initiative.

The Threat

A biological or other WMD event could result in many casualties presenting themselves in a variety of clinical settings, including emergency rooms, physicians' offices, and walk-in clinics. To reasonably accommodate these casualties, health-care professionals need training and tools to help them recognize and diagnose diseases caused by biological weapons, recognize toxidromes indicative of chemical exposure, inform public health authorities, and treat patients. Health professionals also need access to the most appropriate protection for themselves and to prevent the spread of disease and the ability to address surge capacity issues, including laboratory services, regionally.

AHRQ Bioterrorism Initiative

Under Congressional direction, AHRQ, within the U.S. Department of Health and Human Services (HHS), is providing support for assessing and improving the U.S. health-care system's capacity to respond to possible incidents of bioterrorism. This initiative, which focuses on clinical preparedness of health-care providers and health-care systems, is part of a broad effort by HHS and other Federal agencies directed toward potential instances of bioterrorism. AHRQ's Bioterrorism Initiative is examining the clinical training and ability of front-line medical staff – including primary care providers, emergency departments, and hospitals – to detect and respond to a bioterrorist threat.

The Bioterrorism Initiative is consistent with AHRQ's overall research goals of supporting improvement in health outcomes, strengthening quality measurement and improvement, and identifying strategies to improve health-care access, foster appropriate use of the health-care system, and reduce unnecessary expenditures.

In the first task order of the *Bioterrorism Initiative*, AHRQ supported research on the use of information and decision support systems to enhance clinical preparedness in the event of a bioterrorist threat and to assess and improve links between the health system, local and State public health departments, and emergency preparedness units.

Project Goals

AHRQ's *Bioterrorism Initiative* provides Models for Emergency Preparedness in the subject areas of personal protective equipment, decontamination, isolation/quarantine, and laboratory capacity for the medical, public health, and emergency preparedness systems in an effort to improve detection and response to a bioterrorist event. The primary objective of this task order is to assess and prepare guidelines and models for evidence-based, best-demonstrated practices. Current literature has been assessed to address the subject areas of this task order in the medical and public health emergency preparedness arena, including health-care professional practices, the public health infrastructure, and emergency preparedness. In general, the assessment focused on identifying and measuring evidence-based, best-demonstrated practice models that have been used effectively to improve the guidelines for use of personal protective equipment, decontamination, isolation/quarantine, and laboratory capacity. This assessment will consider strategies to enhance regional preparedness guidelines and a resource approach for a bioterrorism and WMD response. While the initial statement of work addressed only the threat of bioterrorism, authors found it difficult to ignore the overlapping full spectrum threats of chemical and radiological events, and as such, addressed these areas in the decontamination and personal protective equipment sections.

Research Methods

As described in the AHRQ-approved work plan, the Science Applications International Corporation (SAIC) team examined open source publications and interviewed Federal, State and local stakeholders representing a broad spectrum of regulatory, professional, government, and private agencies and organizations. The goal was to summarize current evidence-based, best demonstrated practices relating to preparedness for healthcare professionals in the topics of personal protective equipment, decontamination, isolation/quarantine and laboratory capacity. Gaps and shortfalls would be identified, as well as future research and development needs. A series of questions was posed to frame the best demonstrated practices, and a summary was developed in the form of guidelines and models for use in all-hazards planning.

Technical Approach

SAIC conducted this research referencing professional literature, with a focus on literature published in the last 5 years, with each subject area assigned to subject-matter experts (SMEs) in bioterrorism and infectious diseases, emergency medicine/nursing, hazardous materials, emergency management, environmental engineering, and public health (see Appendix A). Further, SAIC engaged SMEs from a variety of government, military, academia, non-profit, and commercial organizations to broaden the research agenda. SAIC also considered related research activities sponsored by AHRQ and other government agencies as additional sources of

information, maintaining close contact with AHRQ's Task Order Officer (TOO) for the duration of the project.

SAIC assessed current literature in the medical and public health arenas to address the subject areas of personal protective equipment, decontamination, isolation/quarantine, and laboratory capacity. The goal was to prepare guidelines for evidence-based, best-demonstrated practices in an effort to improve detection and response to a bioterrorist or other WMD event. Open-source literature resources included MEDLINE/PubMed, MedJournals, LexisNexis®, MDLinx, MedWorld, MedWeb, Medic8®, Oxford Journals, BioMedNet, and eMedicine®, as well as publications from collegiate and medical libraries.

In assessing the subject areas, SAIC followed the relevant requirements and/or guidelines from the following agencies and organizations: AHRQ, Joint Commission on Accreditation of Healthcare Organizations (JCAHO), Occupational Safety and Health Administration (OSHA), National Fire Protection Association (NFPA), National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC), U.S. Army Soldier and Biological Chemical Command (SBCCOM), Agency for Toxic Substances and Disease Registry (ATSDR), and professional associations, including Emergency Nurses Association (ENA), American College of Emergency Physicians (ACEP), American Hospital Association (AHA), American Medical Association (AMA), American Nurses Association (ANA), Association for Professionals in Infection Control and Epidemiology (APIC), American Biological Safety Association (ABSA), American Society for Healthcare Engineering (ASHE), American Society for Testing and Materials (ASTM), and others.

Findings and Conclusions

Sections are designed to present evidence-based best practices, shortfalls, gaps, research and development recommendations, and guidelines extracted from the research summaries and stakeholder interviews. Each section has appendices with stakeholder rosters, bibliography, and draft recommended models for stakeholder review and refinement. Guidelines and models focus on planning with applications to an operational setting, instead of operational guidelines that would be developed after a site specific concept-of-operations plan. Guidelines and models are meant to synthesize best demonstrated practices and offer practical solutions to overcome currently identified gaps and shortfalls. The targeted end user is a health-care emergency planner, in either a pre-hospital or facility-based setting.

Ch. 1 Appendix A. Subject Matter Interview Questions and Experts

The Science Applications International Corporation team interviewed Federal, State, and local subject-matter experts representing a broad spectrum of regulatory, professional, government, and private agencies and organizations. The goal was to summarize current evidence-based, best demonstrated practices relating to preparedness for health-care professionals in the topics of personal protective equipment, decontamination, isolation/quarantine, and laboratory capacity. The interview questions for each report topic and the subject matter experts interviewed are below.

Personal Protective Equipment

Interview Questions

1. What is the appropriate PPE for a bioterrorism event? What is the appropriate PPE for a chemical event? What is the appropriate PPE for a radiological event? Please answer these questions as they pertain to a medical facility and for EMS in the field, and for infectious events, as well as contamination events necessitating the performance of decontamination?
2. Is there any new or recent research that you know of that would assist healthcare professionals in choosing appropriate PPE for an infectious agent or a contaminant?
3. Would you recommend flexible levels of PPE, for the healthcare professional to choose from, based on patient symptoms, positive pathogen or agent identification and immune status (i.e, past hx of chickenpox), or do you recommend a “prescriptive” approach, such as full standard precautions for an infectious pathogen and Level B or C for a chemical contaminant?
4. What is the financial impact of maintaining flexible levels of PPE available?
5. What are the current barriers for healthcare professionals in utilizing/having the appropriate PPE for a biological, radiological or chemical event, manmade or naturally occurring?
6. What types of research and development needs to be done to enable healthcare professionals to utilize appropriate PPE?
7. Is there anything else you would like to add?

Development of Models for Emergency Preparedness:
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Decontamination

Interview Questions

1. What are some best practices for mass casualty decontamination?
2. How can throughput be maximized?
3. What are the elements of detailed/technical decontamination that healthcare professionals should strive for?
4. What are the cost and regulatory impacts of mass casualty decontamination?
5. What type or level of training should healthcare professionals engaged in patient decontamination have?
6. What research and development is needed for mass casualty decontamination?

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Development of Models for Emergency Preparedness:
Personal Protective Equipment, Decontamination, Isolation/Quarantine, and Laboratory Capacity

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Isolation/Quarantine

Interview Questions

1. What provisions have been enacted in your jurisdiction or in other communities of which you are aware that would assist in the coordination of reporting suspected disease events and contact information to local or state public health departments 24 hours a day, 7 days a week? What technological equipment or advances would you suggest be utilized or created?
2. There have been discussions among the hospital community that during a biological incident, hospitals should be reserved for persons who do not have the virulent agent and such persons should be assessed and treated in off-campus isolation units. However, until technological advances allow for immediate triage and diagnosis of emerging infectious diseases and bioterrorism agents, patients infected with bioterrorism agents or emerging infectious diseases will present to hospitals and health care providers with early forms of transmissible diseases. What principles should be implemented or models would you recommend regarding the use of off-campus isolation units that would minimize contamination of health care facilities both before and during a biological

exposure event?

3. What should be an equitable provision for remediation, decontamination, or clean-up of a public or private facility that has had patients isolated/quarantined in it who have been infected with an agent such as SARS or other communicable diseases after the disease situation has passed? What agencies need to be involved?
4. The monitoring of thousands of infectious disease case contacts that were under quarantines during the Toronto and Hong Kong SARS outbreaks required many hours of telephone and personal contact by a core of public health staff. What pre-emptive, pre-event training capacities can be pursued now to increase the local level surveillance capacity of public health department and/or hospital staff?
5. What legal protections/provisions are you aware of that maintain not only continuity of life operations (income protection, care of family members, etc.) for persons involved in voluntary or mandatory home/work or full-fledged quarantine but for resumption of employment after the quarantine is completed? What regulatory provisions would assist in this process or need to be developed to assist in this process?
6. During the anthrax incidents of October 2001 and the SARS epidemics in 2002/2003 there was an attrition of workers out of and away from the workforces that were exposed to these events. Some workers requested transfers out of the affected facilities to other types of occupations, some left that particular line of work altogether, and some health care workers refused to treat infected patients. What provisions need to be established to a) address the mental and physical protection issues of health care workers for their own health during infectious disease situations and b) to support the maintenance of a viable health care workforce during times of surge needs? Would the provision of "incentive pay" for treating certain types of infected patients create a perception that treating certain illnesses is more financially lucrative than treating others? If so, who should pay for the incentives for the workers?
7. What provisions should be in place to actually enforce community isolation or quarantine, above and beyond after the health officer orders such to occur? How specifically should law enforcement act to carry out the order, including use of force? Should this be state/region-specific or should this be a federal/national act? What specific provisions need to be in place prior to the incident for either of these scenarios to occur?

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Laboratory Capacity

Interview Questions

1. Is there clear direction and formal coordination between emergency responders and laboratories that defines the laboratory's roles and functions?
2. Is the decision-making process based on adequate information (what samples to test, how to test them, procedures for referrals, etc.)?

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3. Is there adequate capacity for environmental testing in addition to clinical samples?
What is the testing capacity/capability for each sample type?
4. Are adequate planning and protocols in place for surge capacity?
5. Are there adequate equipment and training available to safely handle, store, and ship/transfer samples that may contain biological warfare agents? Are facilities maintained and personnel trained to the appropriate biosafety level (BSL2, BSL3, etc.)?
6. Are there adequate security and safety measures in place to protect select agents and samples from theft or misuse and laboratory personnel and emergency responders from exposure?
7. Are training and reagents provided by Centers for Disease Control and Prevention's (CDC) Laboratory Response Network adequate for effective and timely diagnosis and identification of biological weapons agents?
8. Is proposed funding from Health and Human Services/CDC adequate to upgrade laboratory capacity within the Laboratory Response Network (LRN) in preparation of potential bioterrorist attack?
9. What is/are the greatest gap(s) in laboratory capacity preparedness for a bioterrorism attack (appropriate facilities (size, security, and containment level), equipment, appropriately trained personnel (full-time employees or on loan for surge capacity), diagnostic protocols for clinical and environmental samples, reagent availability, cooperation between organizations (LRN, Public Health Laboratory Services, hospitals, Federal Bureau of Investigation, etc.), rapid and accurate communication of tests, results, etc. (high speed internet and email access to secure databases (Health Alert Network, Epi-X, etc.), etc. How do you think we could bridge or fill the gap? Which agency, department, or organization do you think is best suited to handle this?
10. There has been a huge increase in bioterrorism spending. In regard to laboratory capacity, do you generally feel that the money is being well spent? Who do you think should oversee spending efforts? The States? A Federal agency? Where do you see the most/least amount of money being spent?
11. How do you feel the LRN is evolving? Do you see any gaps in responding to a BT event or naturally occurring epidemic that could be filled by the LRN?
12. What do you think are the most important "dual-use" resources that laboratories require (e.g., personnel, training, clinical lab connectivity, or equipment)?
13. Can you identify preparedness steps that laboratories can take that do not require a great deal of funding (e.g., interagency communications, or on-line training)?

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Chapter 2. Personal Protective Equipment

Background

Health care professionals are faced with an ever expanding list of possible contaminants and infectious diseases against which they must protect themselves and their patients. As infection control professionals and scientists strive to remain on the cutting edge of identification, protection, and treatment of the latest emerging infections, they must also respond to the newer wrinkle of terrorism within the United States. A deliberate release of an infectious agent or contaminant, such as the 1995 Tokyo Sarin attack, 2001 U.S. Anthrax attacks, and 2004 Ricin attacks, in addition to rapidly emerging infectious diseases, such as Severe Acute Respiratory Syndrome (SARS), adds a dimension of the unknown when choosing or developing protocols for personal protective equipment (PPE). PPE is protective clothing and equipment that serve as barriers and may range from gloves, gowns, masks, and protective eyewear (Centers for Disease Control and Prevention 1997) to fully encapsulated vapor protective ensembles with self contained breathing apparatus.

Choosing the appropriate level of PPE to respond to a broad spectrum of threats from naturally occurring endemic events to a potentially virulent engineered weapon of mass destruction is a challenge. An additional challenge is posed by the operational issues involved to effectively obtain, maintain, train for, and use personal protective equipment (PPE). While one level, filter, garment, or device does not fit all circumstances, maintaining a broad spectrum of flexibility with PPE has a price tag. The price includes material costs of obtaining and maintaining PPE; initial and ongoing training costs; and the cost of medical monitoring, fit testing, and regular drills and exercises in the context of an all-hazards, community integrated emergency response plan. The price may be more than we have to spend, which may result in a lack of suitable, effective PPE for health care professionals.

Ideally, as with current infection control standards, the choice of appropriate PPE would be flexible and dependent on key symptoms or pathogen identification and the tasks to be performed. Health care professionals could escalate levels of protection based on risks such as degree of pathogen contact and route of exposure. Logistical requirements for flexible PPE availabilities would be accommodated in routine operations, such as daily patient care in a hospital, where clinical staff has the opportunity to select from an array of PPE (gowns, masks, gloves, etc). However, the cost to maintain the large quantities necessary for care of mass casualties or chemical or contaminated patient events is prohibitive. Stakeholders and subject matter experts are divided on this issue. Some believe various levels of PPE should be provided to be used at the discretion of the caregiver. Others suggest a prescriptive approach designed to provide a baseline level of protection against most hazards. This approach may promote a greater degree of safety if the caregiver is unable to determine the pathogen or contaminant or is not knowledgeable enough to make a safe PPE decision. (Marcus 2002) Advocates for a prescriptive approach focus on safety as a primary factor. Not all health-care professionals should be expected to have a working knowledge of hazmat or weapons of mass destruction issues or to retain details about each emerging disease. They

should not be expected to know how to rapidly determine what level of PPE is suitable for each presenting toxidrome. Clinicians should be able to rely on evidence-based, best practice standards that provide guidelines for the safest, most effective PPE to wear in each circumstance.

Determining what baseline level of PPE to provide for staff should be based upon an ongoing hazards vulnerability analysis, which is currently required for health care facilities by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO Standard EC 1.4). The hazards vulnerability assessment should reflect community hazards as well as facility specific hazards. An example of a comprehensive hazards vulnerability assessment could include data already collected by the Local Emergency Planning Committee, which is mandated by the Occupational Safety and Health Administration (OSHA) Superfund Amendments and Reauthorization Act (SARA) Title III Hazardous Waste Operations Standard (HAZ-WOPER) (U.S. Department of Labor, Occupational Safety and Health Administration 1991a) and reflects local industrial hazards. Additional vulnerability and credible threat data can come from sources such as the information collected for the ODP State Homeland Security Assessment Strategy (SHSAS), which has evaluated top credible threats from a terrorist act, in addition to the already evaluated industrial hazards. After credible threats are assessed, health care facilities and agencies should evaluate their own capabilities and resources in addressing these threats. Gaps should be addressed in relation to their impact rating. An example of the PPE component of this hazards vulnerability assessment could be that the facility or agency is at risk for an industrial chemical event involving agent X, in which case it is reasonable to provide PPE appropriate to care for patients exposed to agent X. Health care facilities already follow standard and transmission based precaution infection control guidelines (U.S. Department of Justice, National Institute of Justice 2002), but also should have a logistics plan to respond to a mass casualty event. PPE should be provided in numbers and sizes sufficient to address the predicted casualty numbers and staffing needs. Staff should be trained in a competency based format to be able to operate safely in the ensemble(s) with regular follow-on training and exercises in addition to required medical monitoring and pertinent fit testing (U.S. Department of Labor, OSHA 1996).

There are many differences between a response to a biological agent event and a response to a chemical or radiological event. PPE differs for infectious (caused by a pathogenic microorganism or agent) versus contaminated categories as well. PPE worn for care of an infectious patient should follow standard infection control guidelines developed to manage the transmission of specific diseases, including airborne, droplet, and contact precautions (Association for Professionals in Infection Control and Epidemiology, Inc. Bioterrorism Task Force and Centers for Disease Control and Prevention [CDC] Hospital Infections Program Bioterrorism Working Group 1999).

The charts on the following page are CDC Hospital Infection Control Practices Advisory Committee (HICPAC) recommendations related to standard and transmission-based infection control practices in the clinical setting.

Events predicted by the release of an engineered, weaponized biological agent resulting in infectious pathogens may defeat current standard precautions. It is not impossible that such an event may occur or a new strain of disease may emerge that would require a higher level of PPE than what is used routinely in standard precautions (Alibek 2002). During the SARS outbreak in China and Tokyo, medical personnel were shown providing care to infected patients in air purifying respirators. The training and logistical infrastructure is not

yet in place in the United States to provide safe, sustained patient care with this higher level of PPE. Even so, planning discussions should include exploring options for supporting infectious mass casualty care involving higher levels of PPE, such as air purifying respirators or contained air atmospheres (SLAMMER unit model – United States Army Medical Research Institute of Infectious Disease.) This effort would most certainly necessitate Federal support of personnel and equipment, as the cost to sustain such a capability at the health care facility or community level would be prohibitive.

Health-care professionals care for infectious patients in daily practice and should be adept at choosing and donning routine standard precaution PPE. The Association for Professionals in Infection Control and Epidemiology (APIC) Bioterrorism Working Group identifies standard precautions routinely practiced by health care providers including hand washing, gloves, masks/eye protection or face shields, and gowns. Infection control professionals describe the lack of a sustained fit testing program (for N95 masks, etc.) and the frequent breaches of basic practice standards, such as changing PPE, hand washing, and early initiation of droplet precautions, as contributing to the spread of infection (APIC Bioterrorism Task Force and CDC Hospital Infections Program Bioterrorism Working Group 1999). Systems and procedures should be evaluated and improved to facilitate early recognition of a potentially infectious patient, such as the standard of care for identifying tuberculosis (TB) patients.

CDC Hospital Infection Control Practices Advisory Committee (HICPAC) Recommendations Related to Standard and Transmission-based Infection Control Practices	
Recommendations The recommendations are limited to the topic of isolation precautions. Therefore, they must be supplemented by hospital policies and procedures for other aspects of infection and environmental control, occupational health, administrative and legal issues, and other issues beyond the scope of this guideline. The recommendations presented below are categorized as follows:	
<ul style="list-style-type: none"> • <i>Category IA.</i> Strongly recommended for all hospitals and strongly supported by well-designed experimental or epidemiologic studies. 	<ul style="list-style-type: none"> • <i>Category II.</i> Suggested for implementation in many hospitals. Recommendations may be supported by suggestive clinical or epidemiologic studies, a strong theoretical rationale, or definitive studies applicable to some, but not all, hospitals.
<ul style="list-style-type: none"> • <i>Category IB.</i> Strongly recommended for all hospitals and reviewed as effective by experts in the field and a consensus of HICPAC based on strong rationale and suggestive evidence, even though definitive scientific studies have not been done. 	<ul style="list-style-type: none"> • <i>No recommendation; unresolved issue.</i> Practices for which insufficient evidence or consensus regarding efficacy exists.
Administrative Controls	
<i>Education</i>	Develop a system to ensure that hospital patients, personnel, and visitors are educated about use of precautions and their responsibility for adherence to them. <i>Category IB</i>
<i>Adherence to Precautions</i>	Periodically evaluate adherence to precautions and use findings to direct improvements. <i>Category IB</i>
Standard Precautions	
Use Standard Precautions, or the equivalent, for the care of all patients. <i>Category IB</i>	
<i>Hand Washing</i>	Wash hands after touching blood, body fluids, secretions, excretions, and contaminated items, whether or not gloves are worn. Wash hands immediately after gloves are removed, between patient contacts, and when otherwise indicated to avoid transfer of microorganisms to other patients or environments. It may be necessary to wash hands between tasks and procedures on the same patient to prevent cross-contamination of different body sites. <i>Category IB</i>
	Use a plain (nonantimicrobial) soap for routine hand washing. <i>Category IB</i>
	Use an antimicrobial agent or a waterless antiseptic agent for specific circumstances (e.g., control of outbreaks or hyperendemic infections), as defined by the infection control program. <i>Category IB</i> (See Contact Precautions for additional recommendations on using antimicrobial and antiseptic agents.)

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Gloves	Wear gloves (clean, nonsterile gloves are adequate) when touching blood, body fluids, secretions, excretions, and contaminated items. Put on clean gloves just before touching mucous membranes and nonintact skin. Change gloves between tasks and procedures on the same patient after contact with material that may contain a high concentration of microorganisms. Remove gloves promptly after use, before touching noncontaminated items and environmental surfaces, and before going to another patient, and wash hands immediately to avoid transfer of microorganisms to other patients or environments. <i>Category IB</i>
Mask, Eye Protection, Face Shield	Wear a mask and eye protection or a face shield to protect mucous membranes of the eyes, nose, and mouth during procedures and patient-care activities that are likely to generate splashes or sprays of blood, body fluids, secretions, and excretions. <i>Category IB</i>
Gown	Wear a gown (a clean, nonsterile gown is adequate) to protect skin and to prevent soiling of clothing during procedures and patient-care activities that are likely to generate splashes or sprays of blood, body fluids, secretions, or excretions. Select a gown that is appropriate for the activity and amount of fluid likely to be encountered. Remove a soiled gown as promptly as possible, and wash hands to avoid transfer of microorganisms to other patients or environments. <i>Category IB</i>
Patient-Care Equipment	Handle used patient-care equipment soiled with blood, body fluids, secretions, and excretions in a manner that prevents skin and mucous membrane exposures, contamination of clothing, and transfer of microorganisms to other patients and environments. Ensure that reusable equipment is not used for the care of another patient until it has been cleaned and reprocessed appropriately. Ensure that single-use items are discarded properly. <i>Category IB</i>
Environmental Control	Ensure that the hospital has adequate procedures for the routine care, cleaning, and disinfection of environmental surfaces, beds, bedrails, bedside equipment, and other frequently touched surfaces, and ensure that these procedures are being followed. <i>Category IB</i>
Linen	Handle, transport, and process used linen soiled with blood, body fluids, secretions, and excretions in a manner that prevents skin and mucous membrane exposures and contamination of clothing, and that avoids transfer of microorganisms to other patients and environments. <i>Category IB</i>
Occupational Health and Bloodborne Pathogens	Take care to prevent injuries when using needles, scalpels, and other sharp instruments or devices; when handling sharp instruments after procedures; when cleaning used instruments; and when disposing of used needles. Never recap used needles, or otherwise manipulate them using both hands, or use (any other technique that involves directing the point of a needle toward any part of the body; rather, use either a one-handed "scoop" technique or a mechanical device designed for holding the needle sheath. Do not remove used needles from disposable syringes by hand, and do not bend, break, or otherwise manipulate used needles by hand. Place used disposable syringes and needles, scalpel blades, and other sharp items in appropriate puncture-resistant containers, which are located as close as practical to the area in which the items were used, and place reusable syringes and needles in a puncture-resistant container for transport to the reprocessing area. <i>Category IB</i>
	Use mouthpieces, resuscitation bags, or other ventilation devices as an alternative to mouth-to-mouth resuscitation methods in areas where the need for resuscitation is predictable. <i>Category IB</i>
Patient Placement	Place a patient who contaminates the environment or who does not (or cannot be expected to) assist in maintaining appropriate hygiene or environmental control in a private room. If a private room is not available, consult with infection control professionals regarding patient placement or other alternatives. <i>Category IB</i>
<p>Airborne Precautions In addition to Standard Precautions, use Airborne Precautions, or the equivalent, for patients known or suspected to be infected with microorganisms transmitted by airborne droplet nuclei (small-particle residue [5 µm or smaller in size] of evaporated droplets containing microorganisms that remain suspended in the air and that can be dispersed widely by air currents within a room or over a long distance). <i>Category IB</i></p>	

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<i>Patient Placement</i>	Place the patient in a private room that has 1) monitored negative air pressure in relation to the surrounding areas, 2) 6 to 12 air changes per hour, and 3) appropriate discharge of air outdoors or monitored high-efficiency filtration of room air before the air is circulated to other areas in the hospital.(23) Keep the room door closed and the patient in the room. When a private room is not available, place the patient in a room with a patient who has active infection with the same microorganism, unless otherwise recommended,(23) but with no other infection. When a private room is not available and cohorting is not desirable, consultation with infection control professionals is advised before patient placement. <i>Category IB</i>
<i>Respiratory Protection</i>	Wear respiratory protection (N95 respirator) when entering the room of a patient with known or suspected infectious pulmonary tuberculosis.(23,81) Susceptible persons should not enter the room of patients known or suspected to have measles (rubeola) or varicella (chickenpox) if other immune caregivers are available. If susceptible persons must enter the room of a patient known or suspected to have measles (rubeola) or varicella, they should wear respiratory protection (N95 respirator).(81) Persons immune to measles (rubeola) or varicella need not wear respiratory protection. <i>Category IB</i>
<i>Patient Transport</i>	Limit the movement and transport of the patient from the room to essential purposes only. If transport or movement is necessary, minimize patient dispersal of droplet nuclei by placing a surgical mask on the patient, if possible. <i>Category IB</i>
Droplet Precautions In addition to Standard Precautions, use Droplet Precautions, or the equivalent, for a patient known or suspected to be infected with microorganisms transmitted by droplets (large-particle droplets [larger than 5 µm in size] that can be generated by the patient during coughing, sneezing, talking, or the performance of procedures). <i>Category IB</i>	
<i>Patient Placement</i>	Place the patient in a private room. When a private room is not available, place the patient in a room with a patient(s) who has active infection with the same microorganism but with no other infection (cohorting). When a private room is not available and cohorting is not achievable, maintain spatial separation of at least 3 ft between the infected patient and other patients and visitors. Special air handling and ventilation are not necessary, and the door may remain open. <i>Category IB</i>
<i>Mask</i>	In addition to wearing a mask as outlined under Standard Precautions, wear a mask when working within 3 ft of the patient. (Logistically, some hospitals may want to implement the wearing of a mask to enter the room.) <i>Category IB</i>
<i>Patient Transport</i>	Limit the movement and transport of the patient from the room to essential purposes only. If transport or movement is necessary, minimize patient dispersal of droplets by masking the patient, if possible. <i>Category IB</i>
Contact Precautions In addition to Standard Precautions, use Contact Precautions, or the equivalent, for specified patients known or suspected to be infected or colonized with epidemiologically important microorganisms that can be transmitted by direct contact with the patient (hand or skin-to-skin contact that occurs when performing patient-care activities that require touching the patient's dry skin) or indirect contact (touching) with environmental surfaces or patient-care items in the patient's environment. <i>Category IB</i>	
<i>Patient Placement</i>	Place the patient in a private room. When a private room is not available, place the patient in a room with a patient(s) who has active infection with the same microorganism but with no other infection (cohorting). When a private room is not available and cohorting is not achievable, consider the epidemiology of the microorganism and the patient population when determining patient placement. Consultation with infection control professionals is advised before patient placement. <i>Category IB</i>
<i>Gloves and Hand Washing</i>	In addition to wearing gloves as outlined under Standard Precautions, wear gloves (clean, nonsterile gloves are adequate) when entering the room. During the course of providing care for a patient, change gloves after having contact with infective material that may contain high concentrations of microorganisms (fecal material and wound drainage). Remove gloves before leaving the patient's room and wash hands immediately with an antimicrobial agent or a waterless antiseptic agent.(72,94) After glove removal

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	and hand washing, ensure that hands do not touch potentially contaminated environmental surfaces or items in the patient's room to avoid transfer of microorganisms to other patients or environments. <i>Category IB</i>
<i>Gown</i>	In addition to wearing a gown as outlined under Standard Precautions, wear a gown (a clean, nonsterile gown is adequate) when entering the room if you anticipate that your clothing will have substantial contact with the patient, environmental surfaces, or items in the patient's room, or if the patient is incontinent or has diarrhea, an ileostomy, a colostomy, or wound drainage not contained by a dressing. Remove the gown before leaving the patient's environment. After gown removal, ensure that clothing does not contact potentially contaminated environmental surfaces to avoid transfer of microorganisms to other patients or environments. <i>Category IB</i>
<i>Patient Transport</i>	Limit the movement and transport of the patient from the room to essential purposes only. If the patient is transported out of the room, ensure that precautions are maintained to minimize the risk of transmission of microorganisms to other patients and contamination of environmental surfaces or equipment. <i>Category IB</i>
<i>Patient-Care Equipment</i>	When possible, dedicate the use of non-critical patient-care equipment to a single patient (or cohort of patients infected or colonized with the pathogen requiring precautions) to avoid sharing between patients. If use of common equipment or items is unavoidable, then adequately clean and disinfect them before use for another patient. <i>Category IB</i>

Synopsis of Types of Precautions and Patients Requiring the Precautions*	
Standard Precautions	Use Standard Precautions for the care of all patients
Airborne Precautions	In addition to Standard Precautions, use Airborne Precautions for patients known or suspected to have serious illnesses transmitted by airborne droplet nuclei. Examples of such illnesses include:
	Measles
	Varicella (including disseminated zoster)†
	Tuberculosis‡
Droplet Precautions	In addition to Standard Precautions, use Droplet Precautions for patients known or suspected to have serious illnesses transmitted by large particle droplets. Examples of such illnesses include:
	Invasive <i>Neisseria meningitidis</i> disease, including meningitis, pneumonia, and sepsis
	Other serious bacterial respiratory infections spread by droplet transmission, including:
	Diphtheria (pharyngeal)
	Mycoplasma pneumonia
	Pertussis
	Invasive <i>Haemophilus influenzae</i> type b disease, including meningitis, pneumonia, epiglottitis, and sepsis
	Pneumonic plague
	Streptococcal (group A) pharyngitis, pneumonia, or scarlet fever in infants and young children
	Serious viral infections spread by droplet transmission, including:
	Adenovirus†
	Influenza
	Mumps
	Parvovirus B19
	Rubella

<p>Contact Precautions In addition to Standard Precautions, use Contact Precautions for patients known or suspected to have serious illnesses easily transmitted by direct patient contact or by contact with items in the patient's environment. Examples of such illnesses include:</p>
Gastrointestinal, respiratory, skin, or wound infections or colonization with multidrug-resistant bacteria judged by the infection control program, based on current State, regional, or national recommendations, to be of special clinical and epidemiologic significance
Enteric infections with a low infectious dose or prolonged environmental survival, including:
<i>Clostridium difficile</i>
For diapered or incontinent patients: enterohemorrhagic <i>Escherichia coli</i> O157:H7, <i>Shigella</i> , hepatitis A, or rotavirus
Respiratory syncytial virus, parainfluenza virus, or enteroviral infections in infants and young children
Skin infections that are highly contagious or that may occur on dry skin, including:
Diphtheria (cutaneous)
Herpes simplex virus (neonatal or mucocutaneous)
Impetigo
Major (noncontained) abscesses, cellulitis, or decubiti
Pediculosis
Scabies
Staphylococcal furunculosis in infants and young children
Zoster (disseminated or in the immunocompromised host)†
Viral/hemorrhagic conjunctivitis
Viral hemorrhagic infections (Ebola, Lassa, or Marburg)*

However, this should be on a broader scale and with quicker initiation of effective infection prevention and control, including donning PPE, initiating isolation, and potential quarantine. An example would be a patient presenting to a medical triage area with a productive cough and fever being immediately placed in a barrier mask, the triage professional using protection against droplet transmission, and the need for isolation being considered quickly (Staiti, Katz, and Hoadley 2003). Increased indicators for isolation initiation will result in the demand for cost effective solutions to maximizing and increasing isolation ability in the United States, both with fixed and portable filtration systems.

The challenge of preventing transmission of infectious pathogens is exemplified in the current inability to prevent transmission of the common cold. Infection control standards are proven to reduce transmission rates, but gaps in practices such as hand washing and use of appropriate PPE continue to contribute to the failure to contain infectious diseases. While the answer to containment is most certainly more complicated than basic infection control practices, the inability to be consistent with them must be addressed.

Current guidelines for administering care to a potentially contaminated patient are based on traditional hazardous materials (HAZMAT) models (Bronstein and Currence 1994). Organizations such as the OSHA, National Fire Protection Agency (NFPA), National Institute for Occupational Safety and Health (NIOSH), Soldier and Biological Chemical Command (SBCCOM), and ODP have descriptive categories for PPE that would be suitable for functioning in a hazardous materials environment. PPE ensembles are traditionally geared towards industrial HAZMAT functions, but with the threat of WMD terrorist events, the need for availability and use of chemical protective PPE for health care professionals is apparent.

Following a traditional HAZMAT model, if an event occurs that results in contaminated victims, it is widely taught that field health care providers should wait for arriving HAZMAT technicians to determine the contaminant and level and to separate and decontaminate victims before emergency medical services professionals can treat them. Several factors complicate this scenario.

Emergency Medical Services

The first arriving Emergency Medical Services (EMS) units may not be aware of potential contamination until they are already engaged in care. Portable detection technology small enough to be worn on a service uniform to vehicle mounted systems do exist; however, this technology has a large price tag, not only in the cost of the technology, but also in the training, planning, and maintenance to assure system reliability. Naturally, this is a capability that would enhance the EMS professional's ability to recognize the warning signs of a possible contaminated scene prior to scene entry. This capability is being taught in emergency medical technician curricula (O'Keefe et al. 2001), though the depth of coverage and time allotted is limited.

Additionally, should EMS professionals suddenly find themselves in a contaminated environment, most do not have escape masks or other PPE that would enable them to minimize further contamination while they self-evacuate from the scene. This does not take into consideration that once health care professionals have initiated care and seen patients in need, they may stay on the scene to help (National Personal Protective Technology Laboratory 2003).

Currently, escape masks are not widely provided and, while small enough to be clipped to a utility belt, are not small enough to be a minimal burden yet have some length of effectiveness. Longer effectiveness generally requires a larger size, with potential non-compliance issues in light of all the other items carried on a typical EMS utility belt. To be effective, the EMS professional or other first responder would need to have the mask available at the time of discovery of a possible contaminated area. Some EMS agencies are budgeting for and providing escape masks to EMS professionals as an additional layer of PP. Additionally, some agencies are overpressuring and filtering their vehicle airflow to provide a sheltered environment for personnel and patients while the doors and windows are closed (personal communication with Steve Cantrill, M.D., December 8, 2003).

In the event of an incident resulting in potentially contaminated patients, such as an industrial accident, a deliberate release, a “white powder” incident, or detonation of a radioactive dispersal device (RDD or “dirty bomb”), ambulatory victims are likely to self refer to the nearest medical facility, as occurred after the 1995 Tokyo subway Sarin attacks. Non-ambulatory and deceased casualties may be left at the scene to be cared for by arriving EMS professionals and other first responders. If EMS is on scene early in the event, ambulatory victims may gravitate towards the visible presence of help, the emergency vehicle and professionals in uniform. Plans, processes, equipment, and training designed to protect EMS professionals and other responders are needed, preferably without increasing the mortality rate of the victims. Rapid access to appropriate PPE and the ability to provide a clean shelter, such as by overpressurizing the emergency response vehicle and providing filters around air intake and output, would be ideal. Rapid access to detection equipment to determine presence, type, and level of contaminant is also needed. Technologies such as hand held devices and mounted sensors, supported by training and funding, may one day be the rule rather than the exception.

Currently, most EMS plans focus on traditional response elements in these scenarios, such as identifying a contaminant potential, removing the responder from immediate danger, and calling in trained responders, such as fire department HAZMAT teams. The plan to preserve the critical medical capacity is sound, but may occur at the expense of the victim. Increasingly, EMS professionals are being called on to provide medical care, triage, and treatment in a hot or warm zone. They are donning PPE, with a range from standard precautions to barrier suits such as Tyvek; standard or powered air purifying respirators with concurrent chemical resistant suits, boots, and gloves; and even self-contained breathing apparatus and related suits, including bunker gear. Debate continues as the price of equipment, maintenance, training, and exercising necessary to sustain this response capability is high. Whether EMS should be engaging in warm or hot zone entry at all, whether to triage, treat or decontaminate (Lindsay 1999) are some of the issues. Some agency plans state that this is a role not for EMS, but for fire department HAZMAT. Others argue that fire department HAZMAT personnel are limited in number, and should focus on agent identification, not victim rescue. Properly outfitted and trained EMS professionals may be able to enter some contaminated areas safely and begin to save lives. If trained personnel can determine contaminant type and level and immediate dangers, such as flammable or oxygen deficient atmospheres, specially equipped and trained EMS personnel may enter an area and commence operations. Life saving measures can be instituted with simple airway establishment, effective triage and administration of antidotes. Since there is

a credible threat in the United States of an act of terrorism involving a weapon of mass destruction, should not the treatment paradigm shift to provide EMS professionals the tools and PPE to effectively and rapidly save lives in the face of contamination? The Department of Homeland Security (DHS) National Medical Response Teams: Weapons of Mass Destruction, (NMRT: WMD) have long supported the model of hot or warm zone medical entry, with the express purpose of initiating time weighted life saving measures, such as effective triage, airway establishment, and antidote administration (personal communication with RADM Robert Knouss, Director, Office of Emergency Preparedness, National Disaster Medical System, United States Public Health Service, April 2002).

Ultimately, the PPE choice for field health care personnel will vary by circumstances and agent. In the broader categories of infectious agent versus contaminant, infection control standards guide the choice with standard precautions for the infectious pathogen. For treatment of contaminated patients, the choice of PPE must co-exist with an effective all-hazards response plan that clearly describes the expected roles and responsibilities of EMS personnel. If EMS personnel are expected to provide medical treatment or triage during the decontamination process, then a prescriptive approach to PPE would suggest a minimum of “Level C” for the warm zone, consisting of powered air purifying respirators with a protection factor of at least 1000, hooded to eliminate the need for fit testing, and appropriate filters such as the combination organic vapor/acid gas/HEPA or “WMD” cartridges, or the filter appropriate in response to the identified agent such as radioactive particles, chemicals not filtered by the “WMD” cartridges, as well as chemical resistant gloves, boots, and suits to match or exceed the level of respiratory protection chosen. This level ensemble or higher would require a medical monitoring program, potential fit testing, ongoing competency based training and exercises, a scene safety process, and equipment availability and ongoing maintenance.

In 2005, OSHA published an interpretation of their industrial PPE standards specifically geared towards healthcare professionals engaged in care of potentially contaminated patients. This standard of care outlines the use of Level C PPE, to include a hooded, powered air purifying respirator with an APF of 1000, appropriate filters chosen as the result of a hazards vulnerability analysis, level C chemical resistant suit, gloves, and boots. The original OSHA regulations for medical monitoring, presence of a safety officer, and training standards still apply. With a minimum standard of PPE for contaminated casualty response, agencies must focus on standards compliance, many having chosen to purchase partial face shield APRs instead of the PAPRs required. Agencies must still engage in a hazards vulnerability analysis to determine their operational needs for PPE; some agencies may need to provide a higher level of PPE as a result. Agencies should be aware of the limitations and requirements for functioning in the level(s) of PPE chosen, and include maintenance, training, exercises, safety, and medical monitoring as part of their overall response plan, as it pertains to PPE. (OSHA Best Practices for Hospital-based First Receivers of Victims from Mass Casualty Incidents Involving the Release of Hazardous Substances 2005.).

Health Care Facilities

Since the expectation following an event involving contamination is that many victims will self-refer to known or closest medical facilities, health-care facilities must be prepared to deal

with contaminated casualties without the benefit of prior decontamination. While health care facilities that are JCAHO-compliant have decontamination capabilities, often rudimentary, for one or two patients, they may not have the ability to address a surge of self-referred, contaminated patients, including non-ambulatory patients. Many health care facilities have increased their decontamination ability with such items as portable decontamination tents and/or expanded fixed facility plumbing, but the larger numbers of patients predicted by such credible threat scenarios as those identified in assessments such as ODP SHSAS process cannot be handled by the majority of health care facilities (U.S. Department of Justice, National Institute of Justice 2002). The health care facilities are slowly acquiring the PPE necessary to support sustained and robust mass casualty decontamination with the concurrent resource price tag of operations level or functional competency based training necessary to function safely in PPE. Other costs include equipment maintenance, resupply, fit testing, and medical monitoring prior to and during PPE operations, and effective emergency plan development. The remaining issue to be addressed is sustainability funding once these levels have been achieved. Will health care facilities and health care professionals continue to develop a robust PPE program without another large scale terrorist attack, or will motivation diminish as other health-care system challenges arise.

Choosing appropriate PPE for health care facility personnel is subject to debate with positions from, “We don’t provide that capability; we lock the door and call the fire department” to a variety of Level A, B, or C, as defined later in this document. Available research on specific residual levels of contamination that will result in secondary contamination of health care professionals and facilities is scant. However, existing research and theory suggest that self-referring ambulatory patients will have lower levels of contamination than non-ambulatory patients and that contamination will primarily be present in clothing and exposed areas such as the face, hair, and hands. Non-ambulatory patients presumably will have a greater chance of field decontamination intervention prior to transport to a health-care facility. Additional research needs to be conducted on these theories, starting with designated, credible, high threat agents. Assuming that these theories are correct, PPE choices for health-care professionals can best be described as providing protection against the most credible threats with the least restrictive impact on providing patient care, and the least operational impact with fit testing, medical screening, lengthy training, onerous equipment maintenance, and high costs. Based on the community integrated hazards vulnerability assessment, a baseline example of prescriptive PPE could be a hooded, powered, air purifying respirator, appropriate filter cartridges, and chemical resistant suits, gloves, and boots providing splash and vapor protection. Possibly the hazards vulnerability assessment will reveal the need for a greater level of protection, such as Level B with supplied air or self-contained breathing apparatus (SCBA). Processes must surround the PPE choices, to include methods for identifying potential contamination as soon as possible, initial and sustained competency based training, medical screening and monitoring suitable for the PPE level chosen, an ongoing safety program that allows changes in personnel in PPE during an incident, and the ability to recognize the need for rehabilitation and rehydration. Providing and maintaining these levels of PPE are the new reality for U.S. health care professionals. Advances must strive to allow the most flexible and cost effective, safest, least restrictive ensembles that will allow ease of operations and achieve the bottom line -- life saving patient care without sacrificing the caregiver. Ultimately, a best practice for health care professionals to

choose appropriate PPE will hinge on an agency's or facility's detection capability, which should be a combination of passive, fixed sensors, and portable monitors.

Currently a plethora of anecdotal theories give recommendations and suggestions for personal protection during a WMD incident, although the health care industry lacks not only an absolute standard of pertinent PPE but also best practices for utilizing PPE in the context of a chemical or radiological event. Much of this problem stems from the premise that health care facilities lack the financing or personnel necessary to meet or exceed recommendations. A solid best practice guideline would give health-care facilities the opportunity to strive toward meeting a nationally identified standard and would bring health-care facilities into compliance with the best practice methods supported by quantitative research. 2005 OSHA standards address a baseline of Level C PPE consisting of a hooded PAPR with an APF of 1000, chemical resistant gloves, boots and suits, in the context of the current OSHA training and safety standards.

In addition to the need for best practice PPE guidelines, an increase in public education regarding infection control standards and hazardous materials response expectations is needed in the context of an all-hazards response plan. Educating the public, such as with the current CDC public messages for SARS and West Nile Virus, will assist health care professionals in managing public expectations of how treatment would be provided in a WMD event. A barrier to quickly taking respiratory precautions such as placing a mask on a symptomatic patient when the patient enters the medical system has been the perception that such action is customer unfriendly. Certainly, a robust public education and risk communication program would help diminish the spread of disease and contamination.

Several elements need to be considered by health-care professionals when it comes to choices of PPE. PPE is widely thought of in ensembles and rated in levels that reflect its ability to protect from biohazards or industrial hazards. NFPA and OSHA have descriptions of the widely used fire/HAZMAT/industrial protective ensembles, (Levels A, B, C, and D), and DHS has an adapted description that attempts to make the descriptions applicable to first responders/health care professionals (Levels 1, 2, 3, and 4).

Understanding the various levels of PPE and what they will protect against is important in assessing the needs of health-care facility preparedness. Most health-care facilities lack sufficient PPE for health care providers. This situation drastically reduces the facilities' capabilities in handling a mass casualty incident involving a biological agent, offers an increased risk of secondary exposure, and creates the potential of rendering a facility useless if contaminated. Although PPE preparedness and planning levels are increasing due to community and Federal planning efforts, according to several U.S. General Accounting Office (GAO) reports, most U.S. hospitals are not prepared for biological or WMD incidents. Hospitals lack planning, training, and PPE. In fact, most hospitals surveyed by the GAO had no more than 3 PPE suits per 100 staffed beds. Often, they had only one PPE suit per 100 staffed beds. As a benchmark, the GAO recommends that each hospital have a 3-day supply of PPE, including gloves, gowns, and shoe coverings (U.S. General Accounting Office, April 2003, and U.S. General Accounting Office, August 2003.)

PPE classifications

PPE for hazardous materials response are traditionally classified as Level A (highest), B, C, and D (lowest). While **Level A** precautions provide the maximum protection available, the incorporation of Level A use in incident response by hospital and EMS staff is not conducive to sustained medical operations; requires the highest level of ongoing training, suit acclimation, and medical monitoring; and provides the shortest length of time in a protective garment. Additionally, Level A protection for health-care workers may exceed the protection level necessary to accomplish the health-care facility mission. The complete encapsulation condition of Level A diminishes the health care worker's movement, ability to access patients, and ability to render care.

Level B protections offer less vapor protection than Level A, but still have similar training, medical monitoring, and sustainability issues. Some facilities have opted to provide Level B protection to their decontamination staff, usually on a supplied air line to extend the length of time possible in the suit. Level B ensembles generally restrict motor skills less than Level A, yet the addition of an air line hose may limit the health care professional's range of motion and create a potential trip hazard.

Level C PPE is defined as a liquid splash-resistant suit with the same level of skin protection as Level B, along with a full-faced positive or negative pressure respirator (a filter-type mask) rather than an SCBA or air line, used when the concentration(s) and type(s) of airborne substances(s) are known and the criteria for using air-purifying respirators are met (National Fire Protection Agency 2001b). Level C is increasingly supported as the ensemble of choice for health-care professionals engaged in warm zone care of potentially contaminated patients.

Level D is equivalent to everyday uniforms worn by health-care professionals and provides no additional protection against an infectious pathogen or a contaminant. Level D PPE consists of a work uniform affording minimal protection used for nuisance contamination only (U.S. Department of Labor, OSHA 1991a). Level D PPE is, by definition, acceptable in a cold zone environment.

Military-specific PPE levels, such as mission-oriented protective postures (MOPP) gear, are not generally discussed in this document, as battlefield conditions should rate different standards and guidelines than those applicable in a civilian setting.

Elements for consideration include:

- the contaminant or infectious agent personnel may be exposed to during patient care and scene operations;
- the level or amount of contamination or method of transmission;
- the minimal ensemble of PPE that will protect personnel against the agent;

- the training necessary to allow personnel to safely choose, don, doff, and operate in that level of PPE;
- the requirements of safe operation in that PPE, including medical screening programs, fit testing, the ability to have facial hair, glasses, or changes in size or shape of personnel between fit testing; safety monitoring and rehabilitation during operation in the PPE; availability of enough PPE to sustain safe operations, the ability to maintain enough personnel competent and eligible to operate in that PPE, and the ability to maintain enough PPE in safe working order for a mass casualty situation.

The OSHA 29 CFR standards of required PPE in effect at the time of this writing refer to donning the highest level of PPE if workers are entering a contaminated zone with an unknown level of contamination or an unknown agent. This is a sound principle meant for protection of workers primarily in an industrial setting. Field or hospital based health-care professionals would find maintaining the training, medical screening program, equipment, and operational skills set for Level A prohibitive. Much discussion and some research has taken place, including by OSHA, to determine the safest, most reasonable, and most achievable level of PPE guideline specifically for health-care professionals or first responders. In 2005, OSHA published first responder standards, with first responder standards for hot zone entry remaining aligned with 29 CFR industrial standards.

Figure 2.1 OSHA 29 CFR 1910.120 excerpt

Based on the results of the preliminary site evaluation, an ensemble of PPE shall be selected and used during initial site entry, which will provide protection to a level of exposure below permissible exposure limits and published exposure levels for known or suspected hazardous substances and health hazards and which will provide protection against other known and suspected hazards identified during the preliminary site evaluation. If there is no permissible exposure limit or published exposure level, the employer may use other published studies and information as a guide to appropriate PPE (U.S. Department of Labor, OSHA, 1991b).

According to the OSHA HAZ-WOPER standard (specified by 1910.120(a)(1)(i-v), these standards apply to employees who are exposed or potentially exposed to hazardous substances, including “emergency response operations for releases of, or substantial threats of release of, hazardous substances, regardless of the location of the hazard.”

HAZ-WOPER requires that hospital workers be trained to perform their anticipated job duties without endangering themselves or others. To determine the level and type of training that workers need, the community’s hazards must be considered, as well as the capabilities personnel need to respond to those hazards. A determination should be made based on worst-case scenarios. If personnel are expected to provide limited decon services in order to attend to medical problems, they must be trained to the first responder operations level, with emphasis on the use of PPE and decon procedures. This level of emergency response training is described in 29 CFR 1910.120(q)(6)(ii), OSHA First Responder Guidelines. Hospitals may develop in-house training or they may send personnel to a

standard first responder operations level course, and then provide additional training in decon and PPE, as needed. HAZWOPER requires the employer to certify that workers have the training and competencies listed in (q)(6)(ii). The standard also requires annual refresher training or demonstration of competency, as described in (q)(8).





“The approach in selecting PPE must encompass an “ensemble” of clothing and equipment items which are easily integrated to provide both an appropriate level of protection and still allow one to carry out activities involving chemicals. In many cases, simple protective clothing by itself may be sufficient to prevent chemical exposure, such as wearing gloves in combination with a splash apron and face shield or safety goggles. The following is a list of components that may form the chemical protective ensemble:

- Protective clothing (suit, coveralls, hoods, gloves, boots)
- Respiratory equipment (SCBA, combination SCBA/SAR, Powered Air Purifying Respirator (PAPR) Air Purifying Respirator (APR)
- Cooling system (ice vest, air circulation, water circulation)
- Communications device
- Head protection
- Eye protection
- Ear protection
- Inner garment
- Out protection (overgloves, overboots, flashcover)

Factors that affect the selection of ensemble components include:

- How each item accommodates the integration of other ensemble components. Some ensemble components may be incompatible because of how they are worn (e.g., some SCBAs may not fit within a particular suit)
- The ease of interfacing ensemble components without sacrificing required performance (e.g., a poorly fitting overglove that reduces wearer dexterity)
- Limiting the number of equipment items to reduce donning time (e.g., some communications devices are built into SCBAs, which as a unit are NIOSH certified).

Figure 2.2: Comparison of Personal Protective Equipment Levels by OSHA, NFPA, ODP, and NIOSH

Comparison Table of Personal Protective Equipment Levels by OSHA, NFPA, ODP, and NIOSH				
Occupational Safety and Health Administration (OSHA) Regulation 1910.120 App B and 1926.65 App B				
PPE Level	Level A	Level B	Level C	Level D
				
Definition/Indicators	<ul style="list-style-type: none"> <input type="checkbox"/> The hazardous substance has been identified or is an unknown, and requires the highest level of protection for skin, eyes, and the respiratory system based on either the measured (or potential for) high concentration of atmospheric vapors, gases, or particulates; or the site operations and work functions involve a high potential for splash, immersion, or exposure to unexpected vapors, gases, or particulates of materials that are harmful to skin or capable of being absorbed through the skin, <input type="checkbox"/> Substances with a high degree of hazard to the skin are known or suspected to be present, and skin contact is possible; or <input type="checkbox"/> Operations must be conducted in confined, poorly ventilated areas, and the absence of conditions requiring Level A have not yet been determined. <input type="checkbox"/> When an event is uncontrolled or 	<ul style="list-style-type: none"> <input type="checkbox"/> The type and atmospheric concentration of substances have been identified and require a high level of respiratory protection, but less skin protection. <input type="checkbox"/> The atmosphere contains less than 19.5 percent oxygen; <li style="text-align: center;">or <input type="checkbox"/> The presence of incompletely identified vapors or gases is indicated by a direct-reading organic vapor detection instrument, but vapors and gases are not suspected of containing high levels of chemicals harmful to skin or capable of being absorbed through the skin. <input type="checkbox"/> A liquid-splash-resistant ensemble used with the highest level of respiratory protection 	<ul style="list-style-type: none"> <input type="checkbox"/> The atmospheric contaminants, liquid splashes, or other direct contact may adversely affect or be absorbed through any exposed skin; <input type="checkbox"/> The types of air contaminants have been identified, concentrations measured, and an air-purifying respirator is available that can remove the contaminants; and <input type="checkbox"/> All criteria for the use of air-purifying respirators are met. 	<ul style="list-style-type: none"> <input type="checkbox"/> Selected when the atmosphere contains no known hazards <input type="checkbox"/> Work functions preclude splashes, immersion, or the potential for unexpected inhalation of or contact with hazardous levels of any chemicals

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	information is unknown about: the type of airborne agent, the dissemination method, if dissemination is still occurring or it has stopped.	<input type="checkbox"/> The suspected aerosol is not longer being generated, but other conditions may present a splash hazard		
Ensemble/ Component	<input type="checkbox"/> A fully encapsulated, liquid and vapor protective ensemble selected when the highest level of skin, respiratory and eye protection is required <input type="checkbox"/> Positive pressure, full face-piece self-contained breathing apparatus (SCBA), or positive pressure supplied air respirator with escape SCBA, approved by the National Institute for Occupational Safety and Health (NIOSH). Closed-circuit Rebreather/ open circuit SCBA. <input type="checkbox"/> Totally-encapsulating chemical-protective suit. <input type="checkbox"/> Gloves, outer, chemical-resistant. <input type="checkbox"/> Gloves, inner, chemical-resistant.	<input type="checkbox"/> A liquid-splash-resistant ensemble used with the highest level of respiratory protection <input type="checkbox"/> Positive pressure, full-face piece self-contained breathing apparatus (SCBA), or positive pressure supplied air respirator with escape SCBA (NIOSH approved). <input type="checkbox"/> Hooded chemical-resistant clothing (overalls and long-sleeved jacket; coveralls; one or two-piece chemical-splash suit; disposable chemical-resistant overalls). <input type="checkbox"/> Gloves, outer, chemical-resistant. <input type="checkbox"/> Gloves, inner, chemical-resistant. <input type="checkbox"/> Boots, outer, chemical-resistant steel toe and shank. <input type="checkbox"/> Boot-covers, outer, chemical-resistant <input type="checkbox"/> Hard hat, personal cooling system, chemical resistant tape* <input type="checkbox"/> Coveralls* <input type="checkbox"/> Face shield*	<input type="checkbox"/> A liquid-splash-resistant ensemble, with the same level of skin protection as Level B, used when the concentration(s) and type(s) of airborne substances(s) are known and the criteria for using air-purifying respirators are met. <input type="checkbox"/> Full-face or half-mask, air purifying respirators (NIOSH approved). <input type="checkbox"/> Hooded chemical-resistant clothing (overalls; two-piece chemical-splash suit; disposable chemical-resistant overalls). <input type="checkbox"/> Gloves, outer, chemical-resistant. <input type="checkbox"/> Gloves, inner, chemical-resistant. <input type="checkbox"/> Boots (outer), chemical-resistant steel toe and shank <input type="checkbox"/> Boot-covers, outer, chemical-resistant <input type="checkbox"/> Coveralls* <input type="checkbox"/> Hard hat, face shield, personal cooling system* <input type="checkbox"/> Escape mask* <input type="checkbox"/> Face shield*	<input type="checkbox"/> A work uniform affording minimal protection: used for nuisance contamination only <input type="checkbox"/> Coveralls. <input type="checkbox"/> Boots/shoes, chemical-resistant steel toe and shank. <input type="checkbox"/> Boots, outer, chemical-resistant (disposable)* <input type="checkbox"/> Gloves* <input type="checkbox"/> Safety glasses or chemical splash goggles* <input type="checkbox"/> Hard hat* <input type="checkbox"/> Escape mask* <input type="checkbox"/> Face shield*
	<input type="checkbox"/> Boots, chemical-resistant, steel toe and shank, outer booties. <input type="checkbox"/> Disposable protective suit, gloves and boots (depending on suit construction, may be worn over totally-encapsulating suit). <input type="checkbox"/> Coveralls* <input type="checkbox"/> Long underwear* <input type="checkbox"/> Hard hat (under suit), personal cooling system, chemical resistant tape* * optional/as needed	* optional/as needed	* optional/as needed	* optional/as needed
National Fire Protection Association (NFPA)				
PPE Level	Level 1	Level 2	Level 3	Level 4
Definition/ Indicators	<input type="checkbox"/> The hazardous substance has been identified or is unknown, and requires the highest level of protection for skin, eyes, and the respiratory system based on either the measured (or potential for) high concentration of atmospheric vapors, gases, or particulates; or the site operations and	<input type="checkbox"/> The type and atmospheric concentration of substances have been identified and require a high level of respiratory protection, but less skin protection. <input type="checkbox"/> The atmosphere contains less than 19.5 percent oxygen;	<input type="checkbox"/> The atmospheric contaminants, liquid splashes, or other direct contact may adversely affect or be absorbed through any exposed skin; <input type="checkbox"/> The types of air contaminants have been identified, concentrations measured, and an	<input type="checkbox"/> Selected when the atmosphere contains no known hazards <input type="checkbox"/> Work functions preclude splashes, immersion, or the potential for unexpected inhalation of or contact with hazardous levels of any chemicals

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	<p>work functions involve a high potential for splash, immersion, or exposure to unexpected vapors, gases, or particulates of materials that are harmful to skin or capable of being absorbed through the skin,</p> <p><input type="checkbox"/> Substances with a high degree of hazard to the skin are known or suspected to be present, and skin contact is possible; or</p> <p><input type="checkbox"/> Operations must be conducted in confined, poorly ventilated areas, and the absence of conditions requiring Level A have not yet been determined.</p> <p><input type="checkbox"/> When an event is uncontrolled or information is unknown about: the type of airborne agent, the dissemination method, if dissemination is still occurring or it has stopped.</p>	<p>or</p> <p><input type="checkbox"/> The presence of incompletely identified vapors or gases is indicated by a direct-reading organic vapor detection instrument, but vapors and gases are not suspected of containing high levels of chemicals harmful to skin or capable of being absorbed through the skin.</p> <p><input type="checkbox"/> Necessary to provide sufficient vapor protection for the intended operation, where direct contact of liquid droplets is probable, and where victims are not ambulatory but symptomatic</p> <p><input type="checkbox"/> The agent or threat has generally been identified and where the actual release has subsided. Exposure include possible contact with residual vapor or gas and highly contaminated surfaces</p>	<p>air-purifying respirator is available that can remove the contaminants; and</p> <p><input type="checkbox"/> All criteria for the use of air-purifying respirators are met.</p> <p><input type="checkbox"/> Use well after the release has occurred or in the peripheral zone of the release scene. Or when there is no potential for vapor or gas exposure and exposure to liquids is expected to be incidental through contact with contaminated surfaces</p> <p><input type="checkbox"/> Necessary to provide sufficient liquid protection for the intended operation, where direct contact of liquid droplets is possible, and where victims are impaired but ambulatory</p>	
<p>Ensemble/ Component</p>	<p><input type="checkbox"/> A fully encapsulated, liquid and vapor protective ensemble selected when the highest level of skin, reparatory and eye protection is required</p> <p><input type="checkbox"/> Positive pressure, full face-piece self-contained breathing apparatus (SCBA), or positive pressure supplied air respirator with escape SCBA, approved by the National Institute for Occupational Safety and Health (NIOSH). Gas tight.</p> <p><input type="checkbox"/> Totally-encapsulating chemical-protective suit. Highest levels of permeation resistance. Highest level of physical hazard resistance.</p> <p><input type="checkbox"/> Disposable protective suit, gloves and boots (depending on suit construction, may be worn over totally-encapsulating suit).</p> <p><input type="checkbox"/> Gloves, outer, chemical-resistant.</p> <p><input type="checkbox"/> Gloves, inner, chemical-resistant.</p> <p><input type="checkbox"/> Boots, chemical-resistant, steel toe and shank.</p> <p><input type="checkbox"/> Coveralls*</p>	<p><input type="checkbox"/> A liquid-splash-resistant ensemble used with the highest level of reparatory protection</p> <p><input type="checkbox"/> Positive pressure, full-facepiece self-contained breathing apparatus (SCBA), or positive pressure supplied air respirator with escape SCBA (NIOSH approved). Not gas tight, but still low levels of leakage (< 2%)</p> <p><input type="checkbox"/> Hooded chemical-resistant clothing (overalls and long-sleeved jacket; coveralls; one or two-piece chemical-splash suit; disposable chemical-resistant overalls). Permeation resistance and shower test to show no penetration of liquid.</p> <p><input type="checkbox"/> Gloves, outer, chemical-resistant. Lower levels of physical hazard resistance.</p> <p><input type="checkbox"/> Gloves, inner, chemical-resistant.</p> <p><input type="checkbox"/> Boots, outer, chemical-resistant steel toe and shank.</p> <p><input type="checkbox"/> Boot-covers, outer, chemical-resistant *</p> <p><input type="checkbox"/> Coveralls*</p> <p><input type="checkbox"/> Hard hat*</p>	<p><input type="checkbox"/> A liquid-splash-resistant ensemble, with the same level of skin protection as Level B, used when the concentration(s) and type(s) of airborne substances(s) are known and the criteria for using air-purifying respirators are met.</p> <p><input type="checkbox"/> Full-face or half-mask, air purifying respirators (NIOSH approved). Not gas tight.</p> <p><input type="checkbox"/> Hooded chemical-resistant clothing (overalls; two-piece chemical-splash suit; disposable chemical-resistant overalls). Must be liquid tight, not tested on gases.</p> <p><input type="checkbox"/> Gloves, outer, chemical-resistant.</p> <p><input type="checkbox"/> Gloves, inner, chemical-resistant.</p> <p><input type="checkbox"/> Coveralls*7</p> <p><input type="checkbox"/> Boots (outer), chemical-resistant steel toe and shank*</p> <p><input type="checkbox"/> Boot-covers, outer, chemical-resistant (disposable)*</p> <p><input type="checkbox"/> Hard hat*</p>	<p><input type="checkbox"/> A work uniform affording minimal protection: used for nuisance contamination only</p> <p><input type="checkbox"/> Coveralls.</p> <p><input type="checkbox"/> Boots/shoes, chemical-resistant steel toe and shank.</p> <p><input type="checkbox"/> Boots, outer, chemical-resistant (disposable)*</p> <p><input type="checkbox"/> Gloves*</p> <p><input type="checkbox"/> Safety glasses or chemical splash goggles*</p> <p><input type="checkbox"/> Hard hat*</p> <p><input type="checkbox"/> Escape mask*</p> <p><input type="checkbox"/> Face shield*</p> <p>* optional/non-mandatory</p>

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	<input type="checkbox"/> Long underwear* <input type="checkbox"/> Hard hat (under suit)* * optional/as needed	<input type="checkbox"/> Face shield* * optional/as needed	<input type="checkbox"/> Escape mask* <input type="checkbox"/> Face shield* * optional/as needed	
Office for Domestic Preparedness (ODP) Selected Equipment List				
PPE Level	Level A	Level B	Level C	Level D
Definition/ Indicators	<input type="checkbox"/> The hazardous substance has been identified or is unknown, and requires the highest level of protection for skin, eyes, and the respiratory system based on either the measured (or potential for) high concentration of atmospheric vapors, gases, or particulates; or the site operations and work functions involve a high potential for splash, immersion, or exposure to unexpected vapors, gases, or particulates of materials that are harmful to skin or capable of being absorbed through the skin, <input type="checkbox"/> Substances with a high degree of hazard to the skin are known or suspected to be present, and skin contact is possible; or <input type="checkbox"/> Operations must be conducted in confined, poorly ventilated areas, and the absence of conditions requiring Level A have not yet been determined. <input type="checkbox"/> When an event is uncontrolled or information is unknown about: the type of airborne agent, the dissemination method, if dissemination is still occurring or it has stopped.	<input type="checkbox"/> The type and atmospheric concentration of substances have been identified and require a high level of respiratory protection, but less skin protection. <input type="checkbox"/> The atmosphere contains less than 19.5 percent oxygen; or <input type="checkbox"/> The presence of incompletely identified vapors or gases is indicated by a direct-reading organic vapor detection instrument, but vapors and gases are not suspected of containing high levels of chemicals harmful to skin or capable of being absorbed through the skin.	<input type="checkbox"/> The atmospheric contaminants, liquid splashes, or other direct contact may adversely affect or be absorbed through any exposed skin; <input type="checkbox"/> The types of air contaminants have been identified, concentrations measured, and an air-purifying respirator is available that can remove the contaminants; and <input type="checkbox"/> All criteria for the use of air-purifying respirators are met.	<input type="checkbox"/> Selected when the atmosphere contains no known hazards <input type="checkbox"/> Work functions preclude splashes, immersion, or the potential for unexpected inhalation of or contact with hazardous levels of any chemicals
Ensemble/ Component	<input type="checkbox"/> A fully encapsulated, liquid and vapor protective ensemble selected when the highest level of skin, respiratory and eye protection is required (level A) <input type="checkbox"/> Closed circuit rebreather or open circuit Self-Contained Breathing Apparatus (SCBA) or, when appropriate, Supplied Air Breathing Apparatus (SABA) (level A) <input type="checkbox"/> Reusable or limited-use fully	<input type="checkbox"/> A liquid-splash-resistant ensemble used with the highest level of respiratory protection (level B) <input type="checkbox"/> Closed circuit rebreather or open circuit SCBA or, when appropriate, SABA (level B) <input type="checkbox"/> Hooded chemical-resistant clothing (overalls and long-sleeved jacket; coveralls; one or two-piece chemical-splash suit; disposable chemical-resistant overalls).	<input type="checkbox"/> A liquid-splash-resistant ensemble, with the same level of skin protection as Level B, used when the concentration(s) and type(s) of airborne substances(s) are known and the criteria for using air-purifying respirators are met (level C). <input type="checkbox"/> Full-Face Air Purifying Respirators with appropriate cartridges or positive pressure units (Powered Air Purifying--PAPR)	<input type="checkbox"/> A work uniform affording minimal protection: used for nuisance contamination only (level D) <input type="checkbox"/> Escape mask for self-rescue <input type="checkbox"/> Decontamination Equipment used to clean, remediate, remove, or mitigate chemical or biological contamination of first responders.

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		<p>encapsulated chemical resistant suit ensemble (level A)</p> <ul style="list-style-type: none"> <input type="checkbox"/> Chemical Resistant Gloves, including thermal as appropriate to hazard (level A) <input type="checkbox"/> Chemical resistant boots, steel or fiberglass toe and shank (level A) <input type="checkbox"/> Chemical Resistant Outer Booties (level A) <input type="checkbox"/> Disposable protective suit, gloves and boots (depending on suit construction, may be worn over totally-encapsulating suit). <input type="checkbox"/> Two-Way Local In-suit Communications <input type="checkbox"/> Personnel Accountability System to alert for downed personnel (specific to SCBA use only) 	<ul style="list-style-type: none"> <input type="checkbox"/> Liquid Chemical Splash Resistant Hood (permeable or non-permeable) (level B) <input type="checkbox"/> Chemical Resistant Gloves, including thermal as appropriate to hazard (level B) <input type="checkbox"/> Chemical resistant boots, steel or fiberglass toe and shank (level B) <input type="checkbox"/> Chemical Resistant Outer Booties (level B) <input type="checkbox"/> Spare cylinders for rebreathers, SCBA or SABA, and service/repair kits <input type="checkbox"/> HAZMAT gear bag 	<p>(level C)</p> <ul style="list-style-type: none"> <input type="checkbox"/> Liquid Chemical Splash Resistant Hood (permeable or non-permeable) (level C) <input type="checkbox"/> Hooded chemical-resistant clothing (overalls; two-piece chemical-splash suit; disposable chemical-resistant overalls) (level C). <input type="checkbox"/> Chemical Resistant Gloves, including thermal as appropriate to hazard (level C) <input type="checkbox"/> Chemical resistant boots, steel or fiberglass toe and shank (level C) <input type="checkbox"/> Chemical Resistant Outer Booties (level C) <input type="checkbox"/> HAZMAT gear bag <input type="checkbox"/> Emergency Escape Breathing Apparatus (EEBA) 10 minutes or longer 	
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National Institute for Occupational Safety and Health (NIOSH)







PPE	Level A	Level B	Level C	Level D
Definition/ Indicators	<ul style="list-style-type: none"> <input type="checkbox"/> The hazardous substance has been identified or is unknown, and requires the highest level of protection for skin, eyes, and the respiratory system based on either the measured (or potential for) high concentration of atmospheric vapors, gases, or particulates; or the site operations and work functions involve a high potential for splash, immersion, or exposure to unexpected vapors, gases, or particulates of materials that are harmful to skin or capable of being absorbed through the skin, <input type="checkbox"/> Substances with a high degree of hazard to the skin are known or suspected to be present, and skin contact is possible; or <input type="checkbox"/> Operations must be conducted in confined, poorly ventilated areas, and the absence of conditions requiring Level A have not yet been determined. 	<ul style="list-style-type: none"> <input type="checkbox"/> The type and atmospheric concentration of substances have been identified and require a high level of respiratory protection, but less skin protection. <input type="checkbox"/> The atmosphere contains less than 19.5 percent oxygen; <li style="text-align: center;">or <input type="checkbox"/> The presence of incompletely identified vapors or gases is indicated by a direct-reading organic vapor detection instrument, but vapors and gases are not suspected of containing high levels of chemicals harmful to skin or capable of being absorbed through the skin. <input type="checkbox"/> Full respiratory protection is required but danger to the skin from vapor is less. It differs from Level A that is incorporates a 	<ul style="list-style-type: none"> <input type="checkbox"/> The atmospheric contaminants, liquid splashes, or other direct contact may adversely affect or be absorbed through any exposed skin; <input type="checkbox"/> The types of air contaminants have been identified, concentrations measured, and an air-purifying respirator is available that can remove the contaminants; and <input type="checkbox"/> All criteria for the use of air-purifying respirators are met. <input type="checkbox"/> Utilizes a splash suit along with a full-faced positive – negative pressure respirator (a filter-type gas mask) rather than a SCBA or air line 	<ul style="list-style-type: none"> <input type="checkbox"/> Selected when the atmosphere contains no known hazards <input type="checkbox"/> Work functions preclude splashes, immersion, or the potential for unexpected inhalation of or contact with hazardous levels of any chemicals

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	<p><input type="checkbox"/> When an event is uncontrolled or information is unknown about: the type of airborne agent, the dissemination method, if dissemination is still occurring or it has stopped.</p>	<p>non-encapsulating, splash-protective, chemical-resistant suit (splash suit) that provides Level A protection against liquids, but is not airtight</p>		
<p>Ensemble/ Component</p>	<p><input type="checkbox"/> A fully encapsulated, liquid and vapor protective ensemble selected when the highest level of skin, respiratory and eye protection is required</p> <p><input type="checkbox"/> Positive pressure, full face-piece self-contained breathing apparatus (SCBA), or positive pressure supplied air respirator with escape SCBA, approved by the National Institute for Occupational Safety and Health (NIOSH). Pressure-demand, self-contained breathing apparatus (SCBA) or pressure-demand supplied respirator (air hose) and escape SCBA</p> <p><input type="checkbox"/> Totally-encapsulating chemical-protective suit.</p> <p><input type="checkbox"/> Gloves, outer, chemical-resistant.</p> <p><input type="checkbox"/> Gloves, inner, chemical-resistant.</p> <p><input type="checkbox"/> Boots, chemical-resistant, steel toe and shank.</p>	<p><input type="checkbox"/> A liquid-splash-resistant ensemble used with the highest level of respiratory protection</p> <p><input type="checkbox"/> Positive pressure, full-facepiece self-contained breathing apparatus (SCBA), or positive pressure supplied air respirator with escape SCBA (NIOSH approved).</p> <p><input type="checkbox"/> Hooded chemical-resistant clothing (overalls and long-sleeved jacket; coveralls; one or two-piece chemical-splash suit; disposable chemical-resistant overalls).</p> <p><input type="checkbox"/> Gloves, outer, chemical-resistant.</p> <p><input type="checkbox"/> Gloves, inner, chemical-resistant.</p> <p><input type="checkbox"/> Boots, outer, chemical-resistant steel toe and shank.</p> <p><input type="checkbox"/> Boot-covers, outer, chemical-resistant (disposable)</p>	<p><input type="checkbox"/> A liquid-splash-resistant ensemble, with the same level of skin protection as Level B, used when the concentration(s) and type(s) of airborne substances(s) are known and the criteria for using air-purifying respirators are met.</p> <p><input type="checkbox"/> Full-face or half-mask, air purifying respirators (NIOSH approved).</p> <p><input type="checkbox"/> Hooded chemical-resistant clothing (overalls; two-piece chemical-splash suit; disposable chemical-resistant overalls).</p> <p><input type="checkbox"/> Gloves, outer, chemical-resistant.</p> <p><input type="checkbox"/> Gloves, inner, chemical-resistant.</p> <p><input type="checkbox"/> Boots (outer), chemical-resistant steel toe and shank</p> <p><input type="checkbox"/> Boot-covers, outer, chemical-resistant (disposable)</p>	<p><input type="checkbox"/> A work uniform affording minimal protection: used for nuisance contamination only</p> <p><input type="checkbox"/> Coveralls.</p> <p><input type="checkbox"/> Gloves</p> <p><input type="checkbox"/> Boots/shoes, chemical-resistant steel toe and shank.</p> <p><input type="checkbox"/> Safety glasses or chemical splash goggles</p> <p><input type="checkbox"/> Hard hat</p> <p><input type="checkbox"/> Escape mask</p>

Figure 2.3: DoD Personal Protective Equipment Levels (AM 32-4012, February 1998)

MISSION-ORIENTED PROTECTIVE POSTURES (MOPP)

					
MOPP LEVEL 0	MOPP LEVEL 1	MOPP LEVEL 2	MOPP LEVEL 3	MOPP LEVEL 4	MOPP LEVEL ALPHA
WORN¹	WORN	WORN	WORN	WORN	WORN
♦ MASK CARRIER ♦ FIELD GEAR ^{2,3}	♦ OVERGARMENT ♦ FIELD GEAR ² ♦ MASK CARRIER	♦ OVERGARMENT ♦ FIELD GEAR ² ♦ MASK CARRIER ♦ FOOTWEAR COVERS	♦ OVERGARMENT ♦ FIELD GEAR ² ♦ MASK/HOOD ♦ FOOTWEAR COVERS	♦ OVERGARMENT ♦ FOOTWEAR COVERS ♦ MASK/HOOD ♦ GLOVES ♦ FIELD GEAR ²	♦ MASK/HOOD ♦ GLOVES ♦ FIELD GEAR ²
AVAILABLE	CARRIED³	CARRIED³	CARRIED³	CARRIED³	CARRIED³
IPE ISSUED, PREPARED, AND AVAILABLE WITHIN 5 MINUTES	FOOTWEAR COVERS MASK/HOOD GLOVES	MASK/HOOD GLOVES	GLOVES		OVERGARMENT FOOTWEAR COVERS
PRIMARY USE	PRIMARY USE	PRIMARY USE	PRIMARY USE	PRIMARY USE	LIKELY USE
CB THREAT PRE-ATTACK	CB THREAT PRE-ATTACK	CB THREAT PRE-ATTACK	CB THREAT TRANS/POST ATTACK	CB THREAT TRANS/POST ATTACK	CB THREAT TRANS/POST ATTACK
- DURING PERIODS OF INCREASED ALERT WHEN ENEMY HAS CHEMICAL BIOLOGICAL EMPLOYMENT CAPABILITY BUT THERE IS NO INDICATION OF USE IN THE IMMEDIATE FUTURE.	- CHEMICAL BIOLOGICAL ATTACK IN THEATER IS POSSIBLE	- CHEMICAL BIOLOGICAL ATTACK IN THEATER IS PROBABLE	- IN AREAS WITH NEGLIGIBLE CONTACT HAZARD	- WHEN THE HIGHEST DEGREE OF CB PROTECTION IS REQUIRED - WHEN PERSISTENT CHEMICAL AGENTS ARE PRESENT - WHEN CB AGENTS ARE PRESENT; THE ACTUAL HAZARD HAS NOT BEEN DETERMINED	- UPWIND FROM A NEGLIGIBLE CHEMICAL VAPOR HAZARD AGENT. - BIOLOGICAL WARFARE AGENTS ARE BEING EMPLOYED - INSIDE VEHICLES, BUILDINGS OR AIRCRAFT - UNDER NUCLEAR FALL OUT CONDITIONS
VARIATIONS⁴: Authorized variations include: Ventilation, No BDUs, and Mask-Only.		Ventilation - Open Overgarment: In some cases, personnel may, with little risk, open the overgarment jacket to aid ventilation and reduce thermal build-up. This variation is automatically revoked with each MOPP level increase, unless specifically reauthorized by the commander. No BDUs: Individuals, when directed, wear the overgarment over underwear when heat stress is expected to be a significant factor			
NOTES:			Mask-Only: The mask, hood, and long sleeve duty uniform (for limited skin protection) may be worn.		
1. Field Gear consists of helmet, web belt, canteen, and, if issued, body armor (WORN OVER THE OVERGARMENT).		3. If "All Clear, MOPP 0" is announced, web belt and canteen may be worn if desired.		4. Only the installation commander directs the MOPP levels and variations listed above. Modifications to MOPPs and variations must be approved by MAJCOM or Theater commander.	
2. Carry or keep at hand protective equipment such as M8/M9 paper, Nerve agent antidotes, and decontamination kits.		4. Only the installation commander directs the MOPP levels and variations listed above. Modifications to MOPPs and variations must be approved by MAJCOM or Theater commander.			

Since health care professionals in their traditional settings of either a health care facility or EMS in the field, generally lack detection and testing equipment to rapidly screen and confirm the presence of specific agents, health care professionals would likely determine the presence of contaminant or infectious agents by the presenting symptomatology of their patients or by physiologic sensory indicators. While suggestions and policies exist to protect health care professionals and health care facilities by separating potentially contaminated or infected patients, either on the scene away from the health care professionals or outside the health care facilities in a lock down setting, the reality of daily scene operations limits the effectiveness of these strategies. Contamination may not be readily apparent by symptomatology; health care professionals can not easily apply force or erect barriers to separate themselves from potentially contaminated patients; and self-referred patients can be within the health care facility before health care professionals realize the potential for contamination. To effectively reduce the risk of contamination and to insure that a system can accommodate such an event, a procedure for early recognition of potential contamination requires:

- relevant sustained training for health care professionals;
- early access to appropriate PPE;
- early access to effective detection equipment;
- the ability to isolate areas of contamination;
- the ability to provide swift decontamination of patients, personnel, equipment and facilities;
- access to and the ability to rapidly administer pertinent antidotes;
- realistic answers to a force continuum with law enforcement professionals, involvement for patient containment;
- and a public education and crisis communications program empowering the public to take appropriate action to avoid and reduce contamination.

Many gaps currently are being addressed by Federal, State, and local agencies to help the Nation effectively respond to a mass casualty event involving patient contamination or infection. Health care facilities and health care professionals do not have the luxury of waiting for a final, overarching consensus of best practices, and have had to make choices as to how best to prepare for such an event despite the many unanswered planning and preparedness questions. The lack of overarching, clear, evidence-based guidelines has resulted in a wide spectrum of planning and preparedness choices by health care professionals who do not have the option of not responding to an event. As further evidence-based guidelines and regulations emerge, there should be a period for health care

professionals and health care facilities to conform to the newest standards, as the time and financial impact of additional safety programs and supplies will be onerous.

A pattern of PPE ensemble choices is emerging as health care professionals and health care facilities examine the research and regulations related to contamination and infectious event response. The ability to diminish the in-depth HAZMAT physical and fit testing programs traditionally required with higher levels of PPE (level A or B) is a trend based on practicality and resources. Theory and some tentative research (SBCCOM, etc.) have suggested that most victims of a chemical or radiological event will rapidly self refer to health care facilities, vastly reducing the ability of public safety professionals to mobilize a rapid, effective, mass casualty decontamination and detection effort to treat patients and protect health care facilities from contamination. Theory also supposes that self-referred patients will generally be healthier than patients at the scene unable to self evacuate. Self-referred patients will, therefore, have less contamination, reducing the risk of secondary contamination in health care facilities and to health care professionals. This theory would suggest the ability to use lower levels of PPE for health care professional protection, such as level C, in providing care to these patients. Traditional level C protection consists of:

- Full-face or half-mask air purifying respirators (NIOSH approved);
- Hooded chemical-resistant clothing (overalls, two-piece chemical-splash suit, disposable chemical-resistant overalls);
- Coveralls (as needed);
- Gloves, outer, chemical-resistant;
- Gloves, inner, chemical-resistant;
- Boots, outer, chemical-resistant, steel toe and shank (as needed);
- Boot-covers, outer, chemical-resistant (disposable) (as needed);
- Hardhat (as needed);
- Escape mask (as needed);
- Face shield (as needed); (U.S. Department of Labor, OSHA 1991b)

Level C PPE ensembles provide protection from liquids and are designed to protect personnel at chemical/biological terrorism incidents in which a risk analysis indicates victims are ambulatory and symptomatic and/or there is a potential for direct liquid droplet or aerosol contact (National Fire Protection Agency 2001a).

A current best practice to address the issues of sustained operations and fit testing is use of hooded powered air purifying respirators, a chemical resistant laminate suit such as Tyvek F

or CPF 3 fabric, chemical resistant boots, and a set of surgical gloves under a set of chemical resistant gloves. The hooded Powered Air-Purifying Respirator (PAPR) eliminates the fit testing required of a fitted face mask used in the APR and affords a higher level of protection than the APR. A PAPR is more comfortable and easier to use for a sustained operation. In the absence of detection equipment to determine the exact contaminant present, a combination filter may serve as the best initial choice, such as a combined organic vapor (OV), acid gas (AG), and HEPA filter, or one that is designed as a "WMD" cartridge. Health care facilities and health care professionals must be aware that this cartridge, while multi-purpose, does not protect against all industrial hazards that may be present in the community. Regulatory agencies, including JCAHO, require a regular hazards vulnerability analysis by health care facilities that integrate with the community required hazards vulnerability assessment, to determine if additional or alternative levels of PPE and/or different ensemble versions, such as additional filter cartridges, are necessary. Health care facilities must be able to demonstrate an integrated community hazards vulnerability assessment that results in pertinent plans and procedures, training, and equipment and supplies to include PPE.

What is appropriate PPE for EMS professionals is not clear, as EMS professionals straddle the line between facility-based health care professionals and HAZMAT teams. Many think EMS personnel should not be executing hot zone entry, extraction, or decontamination, and as such should require a lower level of PPE, such as Level C, since they would remain in the warm or cold zone of a contaminated scene. Newer response standards advocate EMS hot zone entry in appropriate PPE for rapid victim triage, time sensitive antidote administration and decontamination triage and decision with ALS intervention, this would likely require SCBA and on scene time dependent, minimally bunker gear for the first hour of rescue or the OSHA industrial standard of Level B or A. With on scene agent detection confirmation, EMS hot zone PPE can be appropriately adjusted. NFPA 1994 standard (National Fire Protection Agency, 2001b) provides the following requirement for the following environments:

Level A

- Identity or concentration of the vapor or liquid is unknown.
- If liquid contact is expected and no direct skin contact can be permitted, as exposure of personnel at these levels will result in the substantial possibility of immediate death or immediate serious injury or illness, or the ability to escape with be severely impaired.

Level B

- Victims are not ambulatory and are symptomatic
- Potential for direct liquid droplet or aerosol contact is probable.

Level C

- Victims are ambulatory and symptomatic
- Potential for direct liquid droplet or aerosol is possible.

Current EMT curriculum supports the process of scene safety as a paramount consideration and initial assessment by EMS professionals. The possibility of contamination should result in EMS professionals maintaining distance from the scene, while appropriate HAZMAT personnel are deployed to identify the agent and level. The reality is that it may not be readily apparent to first responders that contamination or infection is present, and they will likely be engaged in patient care before such a determination is made. A gap exists in the readily available, lightweight detection equipment that EMS professionals can wear or attach to a response vehicle that will warn them of contamination, other than newer efforts in radiological detection. Likewise, limited small, lightweight, field applicable PPE, such as wearable filters or barrier cream, is available or approved for civilian use to decrease or eliminate the risk of secondary contamination and infection. It is widely recognized and accepted that initially responding units to an event where contamination or infection risks have not been identified may become casualties themselves.

Figure 2.4 Best Practices at time of publication
Medical facilities should conduct an annual and ongoing hazards vulnerability analysis to determine credible threats, in conjunction with local, regional and State assessments. After determining what the facility is at risk for, such as industrial hazards, and potential WMD risks, planning and research can be implemented for appropriate PPE.
Standard precautions must be fully and regularly used for the highest, defensive impact against an infectious agent. The national standards exist. Routine masking of coughing patients and staff is one example of a standard precaution that is often not initiated at point of entry into the medical system.
Expansion of isolation capacity is critical to a large-scale infectious event. Some efforts have been made to plan for the grouping and containment of infectious patients, and expansion of isolation capability.
For an infectious biological agent, the current model of screening, recognition and PPE for TB is a best practice example. The recognition should be expanded to non-specific droplet risks, such as cough and fever.
The best practices to be used for bioterrorism incidents may vary from region to region; however, compliance with standard precautions should serve as a baseline and the best practice method should include either Level B or Level C protection depending on the health care facilities' assessed threat, environment, location, and operating condition and feasibility.
A best practice for Level C protection currently is hooded powered air purifying respirators, a chemical resistant laminate suit such as Tyvek F or CPF 3 fabric, chemical resistant boots, a set of surgical gloves under a set of chemical resistant gloves. The hooded PAPR eliminates the fit testing required of a fitted face mask used in the APR and affords a higher level of protection than the APR, with an additional comfort level and ease of use that will enable a sustained operation.

Guidelines for Building the Model

The following areas specify items that should be explored when developing a best practices methodology for dealing with biological terrorism preparedness planning:

Adaptability -- Is the best practice suitable for use in any region?

PPE choices should be guided by the results of a facility-specific hazards vulnerability assessment that is integrated with a regional threat analysis. If one health care facility is deemed at risk from casualties contaminated from a local industrial site accident, other local facilities may also be at risk and, as such, should consider similar levels of protection. Regional models have been proposed in which certain facilities become the designated “contaminated” or “infectious” receiving facility, and greater funding and preparedness efforts are concentrated there. The danger is that this does not address the highly likely circumstance where patients self-refer to the closest or known facility. It would be difficult to ensure that all patients self-refer to the designated receiving facility. Even with a robust public education plan that is designed to inform the public about where to report for appropriate treatment, other health care facilities will most likely be receiving self-referred contaminated or infectious patients. While health care facilities are viewed as private industry, whether they are for-profit or non-profit, a mass casualty event or a WMD event is a community problem (personal communication with Zachary Goldfarb, BS, CHSP, CEM, EMT-P, Consultant, Incident Management Solutions, Inc., December 2003). As such, best practices should be reflected on a community and regional planning level.

Additional regional environmental concerns, such as heat or cold stressors, will affect length of time and type of appropriate PPE. In hot environments, rotations of health care providers must be provided so that all have appropriate rehabilitation time to avoid heat related injuries. In cold environments, health care providers need appropriate layers of clothing to protect against cold related injuries without compromising their protection levels.

Throughput -- How many victims of a WMD attack will the best practice aid?

The ability to sustain the par levels of available PPE to care for infectious or contaminated patients will affect the number of victims who can be safely treated. Standard on-hand numbers would not be enough for the ensemble changes necessary to care for a large number of infectious patients requiring quarantine or isolation. For a chemical event, having enough trained staff to rotate in and out of higher PPE levels, such as Levels B and C, would be key in providing sustained medical services for contaminated patients prior to definitive decontamination. The number of health care providers and the amount and availability of protective equipment at their disposal would determine how many victims could be treated quickly and efficiently.

Cost -- How much will it cost regions to implement the best practice?

Depending upon the extent of the program adopted by particular regions, the cost for purchasing, maintaining, and storing PPE can be significant. Costs also will be incurred for initial and ongoing training for health care providers designated to use higher levels of PPE. Also, cost consideration must be given to how many staff members a health care facility will need to be suited for what function at what level. Will standards allow the suit to be re-used after

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decontamination, or will the facility need to have additional stock? Some Federal funding exists to support the initial purchase of PPE. While current funding levels from such sources as ODP, CDC and Health Resources and Services Administration (HRSA), are not enough to cover all purchasing costs to achieve necessary par levels, accessing these sources through State and regional planning committees can help mitigate the initial cost for some organizations. Funding has not fully addressed equipment maintenance and replacement, sustained training, staffing and backfill (personal communication with Fran Santagata, MS, Domestic Preparedness Officer, ODP, DHS, February 26, 2004).

An additional item for cost and planning consideration is the provision of PPE for the general public, especially during times of elevated threat, or at high threat locations or events. As with the Israeli model (Marcus 2002), the general public becomes an active participant in mitigating the negative health effects of a WMD event. Public education addresses such public health strategies as sheltering in place, public facility decontamination and appropriate use of PPE for all ages.

Figure 2.5 Sample cost chart for PPE equipment purchase (Denver Health Medical Center, 2002)

PPE Sample Price List – (1 person)	
<i>Adult PPE</i>	
PAPR Butyl Rubber Hood System, Lithium Battery, Breathing Tube, Butyl Hood, Turbo Unit 3 FR-57Filters, Belt, Flow Meter, Duffel Bag	\$587
Cordura Vest for PAPR	\$147
Extra FR-57 cartridges 6 pack	\$141
CPF3 Suit Hood, Sock Boots, elastic wrist- taped seam, zipper, 6 count, 3xxl (for 6)	\$213
Chemical Tape 2"x60'	\$13
Nitrile Powder free gloves , 1 box, xxl	\$10
Latex nuke boot, 1 pair L-4x	\$3
APR with drinking straw (adult) (fitted face mask option)	\$40
Tyvek coverall redress suits M-XL	\$16
M8 and M9 chemical detection paper	\$20/roll
<i>Est Level C PAPR Adult cost</i>	\$837

Operational Impact -- What are the operational considerations of implementing best practice?

The operational impact for using Level B or C PPE may be significant. Since specialized training is needed to participate and function properly in a WMD incident, the initial and sustained training burden is significant. Performing medical care and screening in elevated levels of PPE is difficult, and prolonged activity in these PPE ensembles is not sustainable. During an incident, providers selected to operate in elevated PPE levels will be excused from their regular functions to mitigate the incident, which will impact the personnel requirements for other standard operations. Using Level C or B protective ensembles will restrict the health care provider's movement, range, and function in the decontamination and patient treatment areas.

PPE must be used in the framework of an effective all-hazards emergency response plan, with logistics, maintenance, re-supply, training, fit testing, medical monitoring, safety, and exercise components. An effective all-hazards emergency response plan would best be developed with a dedicated, experienced emergency planner with the ability to provide dedicated expertise to all the planning and maintenance components that will allow a sustained, safe, effective PPE choice and capability.

Training -- What level of training does this best practice require?

OSHA has current guidelines for health care professionals related to PPE and expected function. Awareness level is recommended for all employees, and a competency based Operations level of 8-16 hours is recommended for all employees engaged in decontamination processes or patient care utilizing PPE. ODP SHSAS recommends several levels of training, such as performance defensive and performance offensive, for health care personnel engaged in the treatment of WMD casualties.

Training should be ongoing and competency based to be compliant with JCAHO standards. The training provided to health care providers needs to be comprehensive in addressing the indicators, application, limitations, and proper use of the protective equipment. Training should incorporate both didactic and functional components, which are compliant with regulatory, equipment manufacturer and current safety recommendations. Additionally, repetitive and ongoing training is crucial to maximizing the health care provider's safety and proficiency in Level B and C protection.

Resources -- Does the practice build on existing practices/infrastructure? Are there available resources to implement the practices?

In a radiological, biological or infectious agent incident, current infection control standards provide the appropriate response framework. Gaps in this model may exist in addressing the number of patients that can be expected in a large scale incident, with concurrent staffing and supply deficits, and the potential emergency of infectious diseases that can defeat commonly available standard precaution PPE, such as a fitted, N-95

respirator. Current health care practices are already in place reflecting daily use of standard precautions; the deficits are slowly being addressed by various Federal funding sources and plans, such as CDC, HRSA, ODP and the National Disaster Medical System (NDMS). Health care facilities and communities should plan to be self sufficient for up to 72 hours before significant Federal supplies and personnel are efficiently functioning (personal communication with Fran Santagata MS, February 26, 2004).

In a chemical event, the fire-based hazardous material response standard is the most applicable. The gap exists in number of personnel trained and equipped, and the lack of definition in the medical role, both EMS and health care facility based. The fact is that contaminated casualties will need care, both at health care facilities and at the scene, and health care professionals are best qualified to render that care. Accordingly, health care professionals must be able to access the contaminated patients as soon as safely possible to institute life saving measures. Resources for expanding the health care professional's capacity to function in PPE are becoming slowly available via Federal funding sources, such as those mentioned previously. However, the main fiscal burden of health care preparedness has fallen on the already beleaguered medical system. As such, preparedness efforts have been slow, incomplete and inconsistent.

Training sources include ODP funded courses found in their training catalog. The courses are subsidized, and can be accessed through each State's training officer. Metropolitan Medical Response System (MMRS) cities have received some training, and are targeted for additional support, primarily in the exercise arena. The ODP Homeland Security Exercise and Evaluation Program (HSEEP) is also providing exercise support to States and encourages a medical component. The Federal Emergency Management Agency (FEMA) Emergency Management Institute (EMI) is embarking on health care leadership courses at the Noble Training Center in Anniston, Alabama; the Radiation Emergency Assistance Center/Training Site (REAC/TS), out of Oak Ridge Institute for Science and Education has radiological training opportunities, and a plethora of other courses exist in the United States. Generally, a person interested in this training and education must be aggressive about pursuing available time and traveling to the out-of-State course location. Continuing education units are often provided, and funding subsidies may be available. Overall, there is no centralized, large-scale, funded effort to provide up-to-date clinical and planning information to health care professionals, on a larger scale than the past domestic preparedness series. Currently, health care professionals must seek resources, such as local infection control and HAZMAT experts, university-based classes, out-of-State courses, Web-based training classes from a variety of sources, or consultants/contractors. There is a continued need to embed appropriate all-hazards education in health care professional education and training programs, and the provision of an accredited, expert endorsed, cadre of clinical and didactic education in a variety of formats (American College of Emergency Physicians, Terrorism Response Task Force 2002).

Morbidity and Mortality -- What impact will this practice have on saving lives?

Providing victims of a WMD event rapid access to appropriately protected health care professionals who can institute early life saving measures will positively impact morbidity

and mortality. Health care professionals in appropriate PPE, in conjunction with proactive public education, can facilitate access to antidotes, educated triage personnel, and basic and advanced life support capabilities. . PPE will reduce the danger of infection or contamination to critical health care services and infrastructure, providing the sustained capability to impact morbidity and mortality. This can only occur with an effective all-hazards response plan that is integrated on a facility, local community and regional level, with State and Federal support. PPE is one component of an effective plan, albeit a critical piece. PPE will prevent transmission of infection and eliminate secondary contamination.

Following the National Medical Response Team (NMRT) model (Staiti, Katz, and Hoadley 2003; personal communication with Robert Knouss, April 2002), if health care professionals can function effectively in PPE with appropriate supplies and can have rapid access to WMD victims, lives can be saved. PPE must work in conjunction with emerging detection and decontamination technologies, such as hand held devices, on site sensors and on-the-spot decontamination solutions (personal communication with Duane Caneva, CDR, MC, U.S. Naval Reserve, Medical Corps, December 8, 2003).

Evidence-based Practice versus Theory -- Is there a body of professional research supporting this practice or is it theoretical?

While unclassified research addresses various WMD agents and effective PPE, there is a lack of definitive scientific research specific to choosing PPE for health care professionals engaged in scene or health care facility triage, care and decontamination of WMD victims. Anecdotal evidence is derived from the mélange of available studies, in combination with available regulations and guidelines. Best demonstrated practice favors the stringent adherence to standard precautions in the face of an infectious agent, and a minimum of Level C components, defined as a hooded, powered air purifying respirator with appropriate filters, laminate chemical resistant gloves, boots and suits, all deployed within the parameters of an effective, regionally integrated, all-hazards emergency response plan.

Regulatory Compliance -- Does the practice comply with existing regulations or does it require a regulatory change?

While current OSHA industrial-based hazardous materials response guidelines indicate Level A PPE for response to an unknown agent of unknown concentration, the newly developed OSHA guidelines for health care professional PPE are pending, as such, there is no current regulation specifically mandating health care professional PPE in a WMD event. OSHA guidelines suggest Level C, as a minimum, with the possibility of higher levels based on an accurate hazards vulnerability assessment, while JCAHO necessitates OSHA compliance, and compliance with infection control standards of care (U.S. Department of Labor, OSHA 1996).

Federal, State, local, and agencies have regulations that mandate the use of specific protection levels for certain health care facilities such as laboratories with virulent agents, but these depend on the nature and work of the facility, exposure probability, and other factors related to the risk of infection. Essentially, health care facilities may implement a system that mandates the use of a certain PPE level after conducting a hazards vulnerability

analysis to justify that decision and when firmer guidelines and standards of care exist for PPE selection regarding infection control.

The Bottom Line -- Guidelines for Selecting PPE

Facilities and agencies must:

- Conduct a hazards vulnerability analysis, integrated with the community, that details relative threats, including industrial and terrorist, pertinent credible threat scenarios with a casualty impact.
- Based on the hazards vulnerability analysis, decide which contaminants and infectious pathogens for which they are most credibly at risk.
- Based on the credible threat data, evaluate their resources and existing plans.
- Based on their resources and plans evaluation, identify the areas with opportunities for improvement.
- Based on contaminant and pathogen credible threats, such as nearest industrial facilities, proximity to areas with documented infectious disease outbreaks, borders, ports, rail or highway shipping routes, etc, choose the best practice PPE.
- Choose a baseline level of PPE for an unknown contaminant that is operationally feasible to obtain and sustain, such as hooded, powered, air purifying respirators with chemical resistant laminate suits such as Tyvek F or CPF 3 fabric, chemical resistant gloves and boots and combination organic vapor/acid gas/HEPA filters, with access to additional filters that are appropriate for other identified industrial hazards.
- Understand that the baseline level of PPE for an infectious pathogen are standard and transmission based precautions, such as barrier gown, gloves, mask, eye protection and respirator are appropriate for infection control standards.
- Be aware that higher levels of PPE may be necessary if the community hazards vulnerability analysis reveals a greater threat to that agency's or facility's response.
- Provide awareness level training to *all* staff, with the required competencies in recognizing a Hazardous Materials situation, initiating immediate safety, isolation, and notification activities, and being aware of their role in an emergency.
- Provide operations level/ functional training to staff engaged in care of contaminated or infectious patients, decontamination or triage procedures, and/or mass casualty response, including staffing secondary treatment facilities.

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- Use competency based training with a focus on staff safety. Staff should be able to demonstrate safe operations in all PPE, and perform expected tasks, such as mass casualty triage and decontamination.
- Conduct regular and sustained training that allows for staff turnover and includes regularly scheduled hands-on exercises to promote skill competencies.
- Involve staff expected to function in PPE, such as a PAPR, in a medical screening and monitoring program, and monitor staff safety during incidents where PPE is utilized, with plans for rehabilitation and rotation of personnel that is activity and weather dependent.

Ch. 2 Appendix A. References and Bibliography

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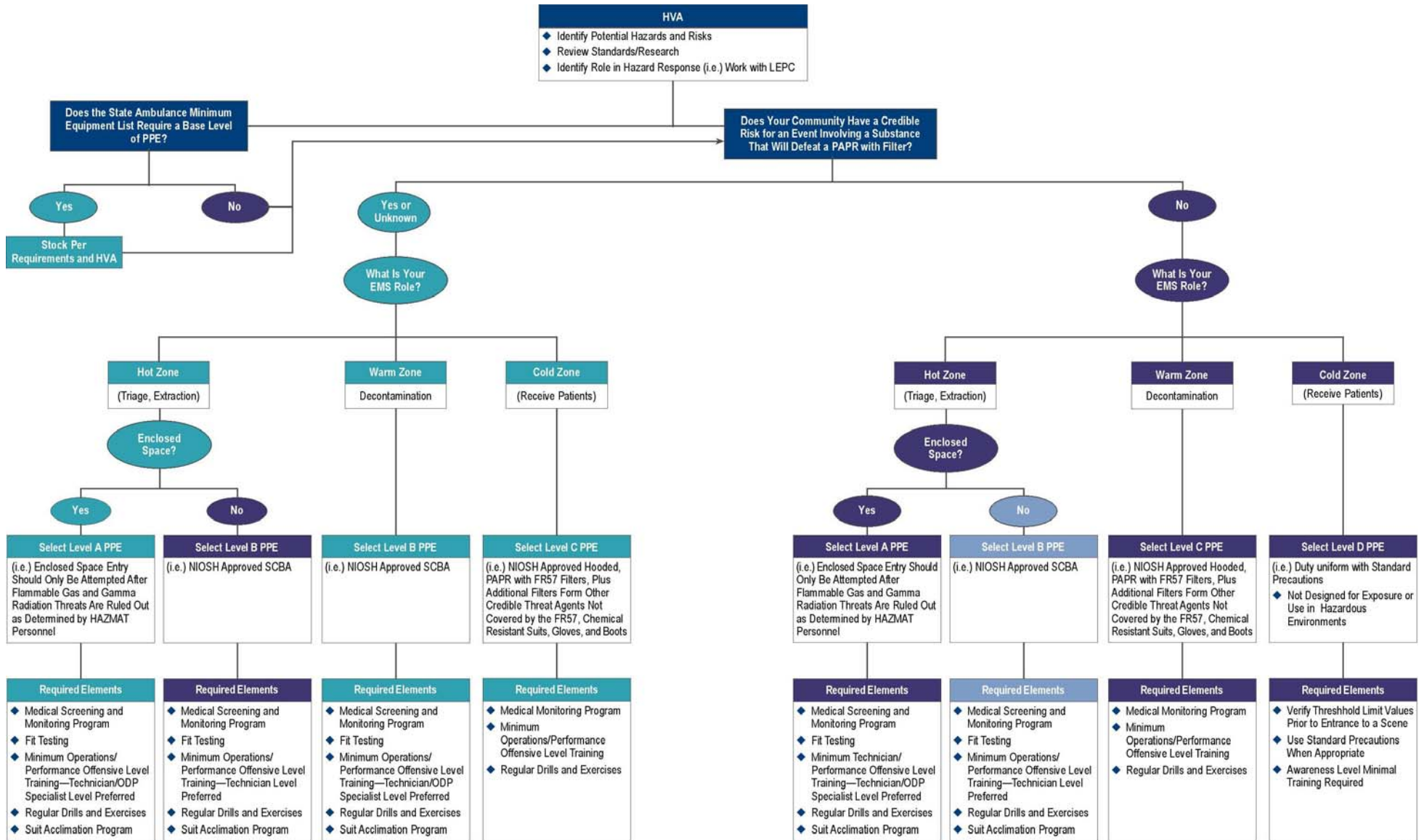
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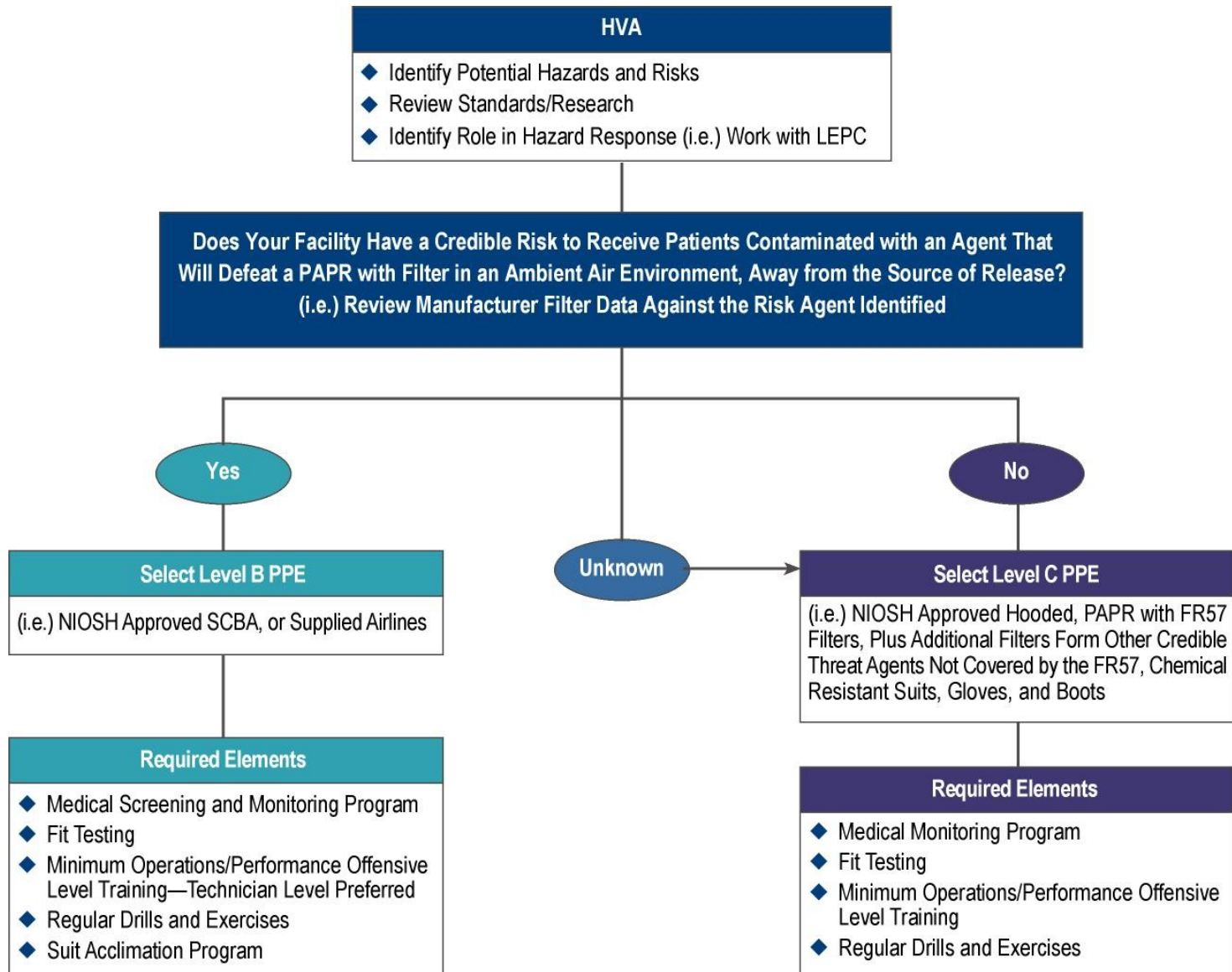
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Ch. 2 Appendix B. Emergency Medical Services PPE Model



Ch. 2 Appendix C. Healthcare Facility PPE Model



J2593-F2-01

Chapter 3. Decontamination

Background

The presentation of contaminated patients seeking treatment at local health care facilities is not a new concept. Every day, health care facilities are presented with patients who are exposed to chemicals from industrial accidents and agricultural chemical incidents. Additionally, acute and chronically ill patients frequently present to health care facilities with possible contagious pathogens requiring that appropriate control procedures, such as personal protection and isolation by health care workers, be initiated. While a contaminated patient will likely require decontamination, an infectious patient will not. Care of the infectious patient should follow infection control standards, such as standard, droplet, or airborne precautions. While contaminated patient incidents can be relatively common in many health care facilities and communities, they frequently affect only a small number of patients and rarely pose a serious threat of toxic exposure to the health care staff, patients, bystanders, equipment, and infrastructure.

The attention and perceived threat of a terrorist incident directed against civilians involving chemical, radiological, or biological weapons of mass destruction (WMD) has reinforced the need for health care facilities to re-examine their level of preparedness in the management of contaminated casualties. This threat has forced health care facilities and first responders to scrutinize current methodologies and design rapid responses to the emerging threat of a WMD event resulting in mass contaminated casualties. Health care facilities and providers must implement a “best practice” approach in the management of contaminated casualties requiring decontamination specific to their facility policies, protocols, infrastructure, training and education, and situation.

The catastrophic nature of a terrorist attack involving WMD demands that the medical community be prepared. Unless such an attack is announced (overt), hospitals, clinics, and urgent care centers will become front line “emergency responders” or “first receivers” (personal communication with Dennis L. Jones, RN, BSN, State Hospital Community Preparedness Coordinator, Georgia Division of Public Health, November 19, 2003). The assumption can be made that many of the contaminated patients will present directly to the health care facility. Thus, health care facilities will need to activate a plan for initiating contaminated patient recognition, care, triage, and decontamination, and institute hospital emergency management decisions.

These decontamination best practices and guidelines will identify technical and operational submissions and recommendations for the health care provider and facility following a terrorist attack involving WMD. These best practices will identify the most efficient and effective techniques and procedures to best manage a large-scale mass casualty incident requiring decontamination.

This document offers evidence-based strategies and methodologies for giving health care providers and facilities options and direction for implementing a workable decontamination system. The information provided in this document is based on the collection and analysis of

data from open source literature, government/industry regulations, public and private organizations and agencies, academic institutions, and subject matter experts.

To provide a “best practices” methodology, it is important for the health care facility and provider to understand the logic behind decontamination. The purpose of decontamination is to: 1) remove the agent from the victim’s skin and clothing, thereby reducing further possible agent exposure and further effects among victims. This practice is the single most important action associated with an effective decontamination process; 2) protect emergency responders and medical personnel from secondary transfer exposures, which is the primary rationale for ensuring detailed decontamination at the health care facility, thereby preserving critical medical services and infrastructure; and 3) provide victims with psychological comfort at or near the incident site to mitigate negative long-term psychological impact (Tan 2003).

The health care facility staff should conduct a hazard vulnerability analysis and review its operational capabilities and concept of operations in the framework of practice standards. This review should be community driven, based on perceived and substantiated data and intelligence, and the likely impact credible threats would have on the facility and community. The health care facility staff need to: 1) be conversant with the credible threat, presenting symptoms, available treatments and resources regarding potential chemical/biological/radiological/nuclear/explosive (CBRNE) agents; 2) possess a heightened index of suspicion; 3) have the ability to identify possible unusual disease patterns, toxidromes or clinical findings; 4) have a process for early notification of a potential threat or incident in the community; 5) possess established relationships with neighboring public health and healthcare organizations, pharmacies, labs, emergency responders and medical suppliers, usually via their local emergency management agency; 6) develop, train, and exercise decontamination procedures and facility treatment area re-organizations; and 7) be vigilant.

Regulatory

The regulatory authority for accredited health care facilities is the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). JCAHO has identified specific requirements under the emergency management standards EC 1.4 and 1.6.

This Federal government regulation requires the health care facility to be prepared to decontaminate patients and have regularly scheduled drills and exercises in order to test emergency preparedness (Hoover, A 2001), although JCAHO does not specifically require the hospital to have its own onsite mass casualty decontamination capabilities. In addition, JCAHO requires that:

- Health care facilities must implement and utilize an internal incident management system.
- Health care facilities must mitigate effects from possible contaminated patients presenting to facilities by conducting a hazard vulnerability analysis. This should identify potential credible hazards and threats to life, safety, property, and environment. (This analysis, when incorporated with the local and regional emergency management plans,

offers the health care facility and providers estimated values of potential patient impact statistics following a CBRNE incident.)

- Health care facilities must be prepared to address contaminated casualty issues by developing decontamination plans. These plans must address the health care facility's normal approach to individual patient decontamination methods. In addition, these plans will require evaluation and validation by regular drills and exercises formatted to test the plans' efficiency and effectiveness.
- In addition to JCAHO requirements, the following organizations have provided additional guidance:
 - The Agency for Toxic Substances and Disease Registry (ATSDR) released a series of guidelines to help local emergency departments, communities, and other policymakers develop their own response plan for hazardous materials incidents (US HHS, 1994a).
 - The Centers for Disease Control and Prevention's (CDC's) Planning Guidance for the Chemical Stockpile Emergency Preparedness Program (CSEPP) provides recommendations for civilian communities near chemical weapons depots (US HHS, 1995b). Although helpful, the outlines are generic, and do not address how to actually perform mass decontamination or contain information on many of the agents that are likely to be seen in a terrorist incident (Macintyre, 2000).
 - The US Army's Soldier and Biological Chemical Command (SBCCOM), now Research, Development, and Engineering Command (RDECOM), has published several documents addressing mass casualty decontamination.
 - Regulations affecting decontamination team training are primarily those of Occupational Safety and Health Administration's (OSHA) Hazardous Waste Operations and Emergency Response regulations (29 CFR 1910.120). Though the emergency response provisions were written for operations at the scene of a release, OSHA requires health care facility personnel providing decontamination services to be trained to the "Operations" level. Annual refresher training or demonstration of competency is also required (O'Keefe, 2000).

Assumptions

To perform mass casualty patient decontamination safely and correctly requires a response plan, proper equipment, and trained personnel. Accepted military procedures and their adaptation for use in the civilian sector provide generic guidance for some highly specific situations, but to date there is no detailed national guideline on how to set up and conduct a mass casualty decontamination process in the civilian setting (personal communication with Steve Cantrill,

MD, Associate Director of Emergency Medical Services, Denver Health Medical Center, December 8, 2003).

When developing a mass casualty plan, the three primary objectives of a disaster response are: 1) do the greatest good for the greatest number of victims; 2) effectively utilize personnel, equipment, and health facilities; and 3) do not relocate the disaster from one location to another by poor command, control, or communication practices. Additionally, an assumption can be made that self-referred contaminated patients will not have been decontaminated in the field and that the hospital will be responsible for providing the detailed or technical decontamination that results from removing all clothing and washing the entire body. Gross field decontamination practices do not address this level of care. Gross or hasty decontamination practices designed to rapidly “put water” on potentially contaminated mass casualties may result in the inadequate washing of the contaminant from the victim, and may cause complications such as hypothermia, even in warm weather.

Practice and preparation will mitigate casualties to staff, patients, bystanders, and equipment. Without planning, education, supplies, equipment, and training, the casualty count may rapidly mount when the number of persons exposed escalates, particularly as the event is likely to be unprecedented in a community. Health care facilities have voiced concern with the development of decontamination systems. Limited funding, no direct regulatory authority, and the lack of approved/tested systems have created significant gaps in health care facility implementation. Local and State government agencies receiving Federal funding generally view hospitals as private industry and responsible for their own preparedness. In recent years, limited HRSA funding has been made available to hospitals, much of which has been spent on PPE and decontamination equipment, with little assurance of sustained funding or funding for training or backfill. Mass casualty decontamination is a community problem and should be addressed as such. Additionally, local governments and health care facility fiscal management are reluctant to spend large amounts of money and time preparing for what they judge to be low-probability events (Tan, 2003).

Best Practices

- Health care facilities and emergency management must coordinate an annual hazard vulnerability analysis and assessments to determine credible threats in conjunction with local, regional, and State assessments. Data collected can determine potential community risks and threats, such as neighboring industrial, transportation, chemical, biological, and nuclear hazards. Based on the hazards identified and the potential risk to the population, a health care facility can estimate a mass casualty patient flow factor. Health care facilities can expect at least a 20:1 ratio of unaffected to affected casualties (mentally impacted), although this ratio was well exceeded following the 1995 Tokyo subway Sarin release (Tan, 2003). Planning can be developed for appropriate decontamination needs, medications, antidotes, and equipment.
- Participation in community emergency planning, public health, local government, and inter-facility healthcare committees is critical in efforts to mitigate health and medical

issues, as well as disseminate capabilities and limitations. Community involvement includes participation in the local emergency management planning committee (LEPC), local office of emergency management planning, and with public safety agencies and 911 dispatchers as applicable.

- Health care facilities need to have the ability to rapidly deploy a decontamination system (either internal-environmentally controlled yet not within the facility, or external) capable of capturing mass numbers of potentially contaminated, self-referred, ambulatory patients. In addition, the health care facility should develop decontamination system plans to accommodate non-ambulatory contaminated patients. The system of choice must provide the security, privacy, environmental control (heat and warm water), and size to allow for rapid progression through disrobing, decontamination, triage, gowning, and medical treatment. Some health care facilities are researching the possibility of sharing decontamination responsibilities based on the type of event. Some discussion has indicated a possible concentration of services with facilities designated as expert resources for certain event types. (Hospital A = Chemical Decontamination facility, Hospital B = Biological /Infectious Disease facility.). Designating hospitals in the same region with equivalent threat levels and different resources leaves the non-designated facilities at risk for the self-referred contaminated patients. Especially without an in-depth, ongoing public education program, victims will not know to go only to certain hospitals.
- A “best practice” system would have the decontamination infrastructure or system fixed to the external structure of the hospital. The idea behind this is to provide an area separate from the main health care facility, preventing facility contamination. The decontamination system would provide gender-segregated areas for undress, washing and redress, environmentally controlled conditions, warm water and soap for detailed decontamination, and all necessary supportive equipment. Ideally, the mass casualty decontamination capability would be immediately accessible and rapidly activated, such as by flipping a switch. When the detailed decontamination capability takes time to set up and deploy, the facility should be prepared with immediately accessible, gender-segregated, environmentally sheltered areas for undress. This would allow patients to remove gross contamination by removing clothing. Clothing and contaminated belongings should be secured, such as by sealing them in a vapor-resistant bag. This will assist healthcare facilities in limiting areas of contamination as victims self refer and give the victims treatment options while detailed decontamination capabilities are being deployed. Health care facilities should not wait for response assets to arrive to begin the contaminated patient treatment process, but develop a plan that can immediately protect the health care facility and health care professionals while providing appropriate lifesaving patient care. Health care facilities should not just rely on facility lock-down to keep potentially contaminated patients out while waiting for rescue. It is highly likely that the contaminated patients will already be within the health care facility at the time of discovery of contamination, rendering a complete lock-down as a barrier ineffective. Lock-down is a useful security measure that provides controlled ingress and egress, but not an absolute protection against secondary contamination. Rather, health care facilities

should consider minimally providing an undress area as previously mentioned, compartmentalizing egress points for containment purposes, and strive to develop a “flip-switch” mass casualty definitive decontamination capability.

- While resource designations may assist with the fiscal constraints, it will not prevent self-referring contaminated patients from walking into a health care facility seeking treatment. Health care facilities must assume that their facility will receive mass numbers of contaminated casualties (walk-ins). A system must be in place to control this type of situation.
- As identified in the Personal Protective Equipment (PPE) Section, health care facilities providing decontamination services must fully and regularly provide the standard precautions for the highest, defensive impact against the contaminant. Personal protective equipment deficits for infectious pathogens currently exist with the number of on-hand supplies available for mass casualties. Newly published OSHA guidelines (2004) indicate that personal protective equipment should be based on a hazards vulnerability analysis and assessment, with a minimum of a National Institute for Occupational Safety and Health-approved, hooded, fit-tested, powered air purifying respirator with an assigned protection factor of 1000, in addition to Level C chemical resistant garments, gloves and boots.
- Health care facilities need to identify ancillary staff capable of assisting in the deployment and execution of the facilities’ decontamination system. Non-patient care/ancillary personnel (i.e., housekeeping, maintenance, engineering, security) should ideally be trained to assist in the rapid execution of decontamination system set-up. In addition, HCFs must incorporate standardized all-hazards awareness training as part of the initial employee orientation education. Staff expected to participate in decontamination procedures or provide care to potentially contaminated patients should have an operations-level or performance offensive-level training that is competency based. (OSHA, JCAHO, Office for Domestic Preparedness [ODP 2003]) Non-patient care providers need to understand and be trained in the threats, hazards, and facility response. The health care facility needs to assure annual training, education, and participation in community “live-water” full scale exercises. Additional education and training must be available for staff from all shifts to assure total facility preparedness 24 hours a day/7 days a week.

When identifying decontamination locations and the type of system that best suits the facility, keep in mind the body’s response to ambient temperatures. The health care facility may need to establish multiple decontamination locations in the event that external temperatures prohibit a safe environment for decontamination.

Decontamination Methods

Patient decontamination is to be performed when the contaminant poses a further risk to the patient or a secondary risk to response personnel. Fire and Emergency Medical Services (EMS) publications frequently describe how patient decontamination can be accomplished, but few of the recommendations are based on empirical research. Because little scientific documentation and regulation exist on patient decontamination, health care facilities and providers must make a “best guess,” “most cost effective” approach until more conclusive research is reported. Decontamination studies provided by the military are available, though there are numerous issues not addressed by these reports that are crucial in the development of a workable system in the civilian community. These issues fail to address key planning initiatives with regard to health care facilities and providers and the public, private, and local government sectors.

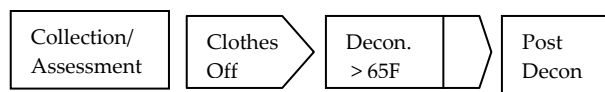
It can be expected that following a large scale mass casualty incident involving an agent of contamination, a large number of the patients seeking emergency medical care will self-refer to the nearest emergency health care facility. Facilities must have the capability to activate decontamination protocols, policies, and procedures while limiting further patient, bystander, staff, and equipment infrastructure exposure. The decontamination equipment or structure should be pre-constructed or capable of simple assembly and rapid utilization. Decontamination locations should be pre-established, offering environmental protection from the elements, privacy, security, and initial triage care. Additionally, a critical gap in the healthcare system is the fact that the vast majority of health care facilities do not have onsite detection equipment or sensors to allow the rapid identification of a contaminated patient event. Health care facilities and EMS rely on presenting signs and symptoms alone.

Unless a health care facility has implemented structural modifications for a fixed decontamination facility, best practices would suggest the identification of an external location. The definition of an external location is an area within close proximity to the health care facility that will eliminate the risk of secondary contamination to health care facility patient treatment areas. This external location should incorporate a dedicated ventilation capability, the ability to keep runoff from entering the health care facility, and allow patients to access the location without entering the health care facility. The external location is typically more suitable for an influx of mass casualties. In addition, it lends itself to allowing the facility to lock down, preventing untrained or unprepared staff, bystanders, and equipment from becoming contaminated or exposed. The external decontamination facility should provide environmental protection, lighting, and privacy, with the ability to become active at all hours. The health care facility should also provide a means of decontamination for non-ambulatory patients, in addition to those who are ambulatory. The decontamination facility should never allow contaminated patients to penetrate the patient care facility.

It can be assumed that due to the significant costs for developing a fixed decontamination facility, most health care facilities will be forced to create external or temporary locations and facilities. When a decontamination incident occurs, the health care facility needs to be aware of the environmental conditions to assure that additional harm or risk is not presented to those who have been contaminated. The health care facility needs to consider the four-method approach described below (United States Army Soldier and Biological Chemical Command, January 2000).

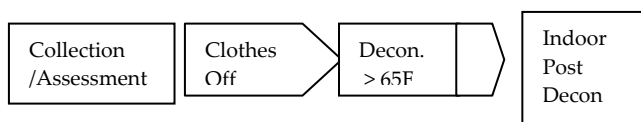
Method I.

The first method is a general baseline external decontamination system. All decontamination tasks may be conducted externally. If decontamination is conducted outdoors, regardless of the temperature, hypothermia primarily due to convection will be a medical issue to be monitored. Accordingly, decontamination facilities should still be sheltered, offer environmental control, gender segregation to increase compliance, and the ability to funnel run-off away from the victims. This method provides the health care facility with the quickest way to execute and maximize throughput. Recommendations for Method I decontamination suggest environmental conditions and ambient temperatures of greater than 65 degrees Fahrenheit (Tan, 2003).



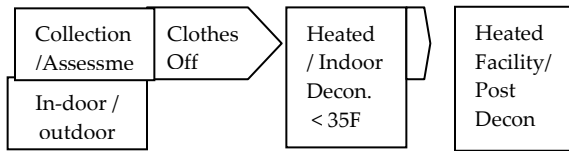
Method II.

The baseline for Method II is identical to Method I. The primary difference is the evacuation of patients to a warm indoor facility for post-decontamination redress and medical screening. A pre-designated corridor or heated entranceway large enough to handle the number of casualties would be sufficient. Method II is recommended when the ambient temperature is colder than 35 and warmer than 65 degrees Fahrenheit (Tan, 2003).



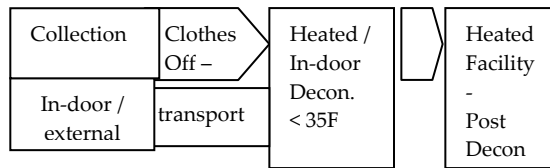
Method III.

Method III, disrobing/collection/assessment, can be conducted indoors or outdoors, yet the ambient temperatures may dictate indoor decontamination to avoid inducing additional cold weather related injuries to the patient. Method III challenges the facility as to the location of casualty collection and assessment. The actual decontamination will need to be accomplished indoors. Buildings that have indoor shower or pool facilities will best serve as mass decontamination locations. If the health care facility does not have access agreements with these types of locations, then a facility or building with indoor sprinkler-like capabilities may also provide an all-weather solution (Tan, 2003).



Method IV.

Method IV should be the method of choice when the environmental conditions prohibit the health care facility from activating an open-air, outdoor decontamination set-up; when ambient temperatures are generally less than 35 degrees Fahrenheit; or when conditions exist that prevent equipment deployment (73). Method IV incorporates dry decontamination options (use of blotting with absorbent materials) with indoor wet decontamination. These systems pose significant challenges to the health care facility. Method IV would require the movement of contaminated casualties to a location for complete indoor decontamination. The health care facility would need to assign a casualty collection point and decide on disrobing prior to transportation to the decontamination site. Failure to disrobe prior to transportation may lead to significant “off-gassing” in an enclosed vehicle, while disrobing may lead to cold-weather shock or hypothermia (Tan, 2003).



Generally, the decontamination process involves three stages: gross, secondary, and definitive (detailed or technical) decontamination.

Gross Decontamination

1. Evacuate the patient(s) from the high-risk area.
2. Remove the patient's clothing.
3. Perform a one-minute quick head-to-toe rinse with water.
4. Field emergency decontamination often involves cold water from a fire hose, no clothing removal, and is targeted to ambulatory patients.

Secondary Decontamination

1. Perform a quick full-body rinse with water.
2. Wash rapidly with cleaning solution from head to toe.

3. Rinse with water from head to toe.

Definitive (detailed or technical) Decontamination

1. Perform thorough head-to-toe wash until "clean."
2. Rinse with water thoroughly.
3. Towel off and put on clean clothes.

It should be noted that in the absence of a rapidly accessible warm water decontamination capability, a best practice would be to provide a sheltered area for patients to undress and remove potentially contaminated clothing. This may also be a good solution to the initial timeframe when presenting victims are recognized to be potentially contaminated and the first contacted health care professionals are waiting for the decontamination capability to be deployed.

It is difficult to determine when a patient is "clean," especially when mass numbers require decontamination. Few chemical or biological agents can be readily seen on the skin or quickly assayed to determine whether any residual product remains after washing. The lack of detection equipment at health care facilities is a major gap in current capabilities. Existing technology does exist, though it is either too expensive or does not provide the needed reliability, ease, and versatility to be used in the civilian environment. In the absence of knowing "when clean is clean or safe enough," health care facilities and providers are left to use their best clinical judgment as to when the decontamination process is complete. This practice can be inefficient and potentially unsafe. Unfortunately, there are no approved standards that provide the health care facility with speed, reliability, and cost-benefit. Health care facilities must pre-designate large areas such as cafeterias or auditoriums for the observation of large numbers of patients with minor or no apparent injuries or illnesses following decontamination and an initial evaluation by the healthcare staff. This area must provide adequate ventilation in an effort to ensure that potential "off-gassing" consequences are minimized. Particularly in the case of potential radioactive contamination, the current standard of care is not to deny or withhold lifesaving treatment while waiting for or performing decontamination. Patient decontamination is a medical procedure, and maintaining lifesaving "ABC's" (airway, breathing, circulation) can be accomplished with proper personal protective equipment both before and during decontamination.

The ability to control and reduce anxiety, confusion, and panic among patients and staff will be key in managing this type of mass casualty incident. The health care facility must initiate a risk and crisis communication plan, providing up-to-date information on the exposure, potential short- and long- term effects, recommended treatments, and other relevant information. Ideally, local and State emergency management agencies recognize that a mass casualty decontamination event is a community problem, and work with health care professionals and health care facilities to provide ongoing, proactive public education before any mass casualty event to allow citizens to become part of their own care and response planning. An example of such public education is describing what citizens could do and expect to have happen during a mass casualty event that would require decontamination, including clothing removal and mass showering.

Procedures

The most important aspect of decontamination is the timely and effective removal of the agent. The precise methods used to remove the agent are not nearly as important as the speed by which the agent is removed. The first steps in the decontamination process are the removal and disposal of clothing. Cox (1994) estimates that 70 - 80 percent of contaminants, and 90-100 percent of trapped vapors, will be removed with the patient's clothes. However, little scientific data exist to support this assertion. More scientific research is needed for the identification of an ideal skin decontaminant capable of removing and neutralizing a wide range of hazardous chemicals, that is inexpensive, readily available, quick-acting, and safe (personal communication with Steve Cantrill, MD, December 8, 2003). Although the FDA has just approved the use of a decontamination lotion (Reactive Skin Decontamination Lotion [RSDL]) for the US military, it is not available for civilian use. Additionally, there are some systemic absorption issues to be addressed. Further research and more products are needed for the civilian health care setting. Although hospitals are required by JCAHO to be prepared to respond to disasters including hazardous material accidents, few have undertaken realistic planning and preparation. Many hospitals defer HAZMAT issues to the local fire department; however, in a mass casualty event, realistically the fire department assets may be otherwise engaged at the incident scene.

Some hospitals have decontamination facilities; however, very few have external facilities or an easy way of expanding their decontamination operations in a mass casualty event (Cox, 1994; Levitin and Siegelson, 1996). Often their initial response to an incident will be to contact the local fire department or HAZMAT team for assistance. This may not be a viable solution if the incident results in the rapid arrival of self-referred contaminated patients. The issue remains of what to do with a large number of contaminated patients who are actively seeking medical treatment, while waiting for external response to set up decontamination. Ideally, the receiving facility can set up a capability that provides immediate containment of contaminated patients, climate controlled shelter, gender-segregated areas in which to remove contaminated clothing, the ability to secure belongings, and the ability to provide immediate medical screening and life-saving intervention. Unannounced, contaminated ambulatory patients or those brought in by ambulance may contaminate the facility before "outside" help arrives to address the situation and before internal resources can be organized to respond. If assistance from the local public safety agency is not available, the hospital is left to fend for itself and, if unprepared, the response is likely to place the patient, staff, and facility at great risk.

Recent reports on the Tokyo subway incident of 1995, which involved the non-persistent nerve agent Sarin, provide some support for this position (Okumura et al., 1998). No field decontamination was performed onsite, and emergency medical technicians (EMT) transported 688 victims to hospitals by ambulance. Ten percent of 1,364 EMTs showed symptoms and had to receive treatment at the hospital themselves. Once the hospitals learned that nerve agent was suspected, the most seriously ill patients were directed to a shower upon arrival. Their clothes were placed in plastic bags and sealed up. Despite these precautions and the use of surgical masks and gloves, 110 hospital staff (23 percent) complained of acute poisoning symptoms on a follow-up questionnaire.

There is little financial incentive for a hospital to be prepared for a "once in a lifetime" event, and proper equipment and training may be perceived as too expensive under the circumstances.

Generally, hospitals that are prepared are usually capable of handling only a few patients an hour. What happens when a large number of patients begin to arrive? Currently, evidence-based, best practice research findings to assist hospitals with cost-effective HAZMAT or terrorist response planning are scarce.

Best practices should include addressing the needs of jurisdictional special populations; for example, translating directions and signage into languages other than English, providing accommodations for wheelchairs and seeing-eye dogs, being culturally sensitive, and providing guidance for the visually and hearing impaired.

ATSDR released a series of guidelines to help local emergency departments, communities, and other policymakers develop their own response plans or HAZMAT incidents (ATSDR, 1994a). The CDC's Planning Guidance for the Chemical Stockpile Emergency Preparedness Program provides recommendations for civilian communities near chemical weapons depots (CDC, 1995b). Since planning is left to the local jurisdictions, the success of any national initiative depends on cooperation at the local level.

Decontamination Shelter

Health care facilities and emergency medical service agencies may choose to integrate resources with public safety organizations by making available specially designed trailers to decontaminate multiple patients simultaneously (e.g., New York City and Salt Lake City Metropolitan Medical Response Systems units). These units can provide protection from the environment, as well as privacy from onlookers, in addition to decontaminating multiple patients at a time. However, these trailers are expensive and cannot always be placed in desirable locations within the parameters of a health care facility's or a scene's needs.

Easily erected tents are used as decontamination shelters. They provide some of the benefits of trailers and are less expensive, but generally take some time to assemble and require planning and coordination to handle large numbers of patients at a time. Inflatable shelters may be affected by environmental conditions such as snow, wind, and decreased temperatures, as well as come with a logistical burden of using powered air units or air tanks to inflate. Some facilities initially designed portable mass casualty decontamination capabilities with inflatable tents, only to switch to "exoskeleton" framed, lightweight pop-up tents when those became commercially available (58). The exoskeleton tents have their own trip hazards, but are generally lightweight and rapidly deployable. Tents come in a variety of sizes to accommodate different amounts of throughput. Some tents have different decontamination "tracks" or corridors to cover both ambulatory and non-ambulatory functions. Local communities will need a primary decontamination plan that the first personnel on the scene can rapidly implement, and a secondary plan to implement when additional personnel and equipment become available. The ultimate goal is rapid, definitive decontamination. While the portable units are often the cost effective answer to mass casualty decontamination, the ultimate best practice is an instantly operational, large capacity, fixed, warm water facility, such as that built at the Noble Training Center in Anniston, AL, and adapted at such facilities as George Washington University Medical Center in Washington DC, Vanderbilt University Medical Center in Nashville, TN, Good

Samaritan Hospital in Islip, NY, Denver Health Medical Center in Denver, CO, and others, augmented by portable units for surge capacity and continuity of operations.

While hospitals and other health care facilities are often viewed as private industry, a mass casualty WMD event is a community problem (personal communication with Zachary Goldfarb, BS, CEM, EMT-P, Deputy Chief, FDNY-EMS (Ret.), Consultant, Incident Management Solutions, Inc., December 2, 2003.) Protecting the critical medical services offered within a health care facility should be a primary goal within the community, region, and State. While some services can be relocated to secondary treatment facilities assembled in non-medical buildings such as gymnasiums, most medical equipment would be difficult to relocate, diminishing the level of care available. A primary goal of community emergency planning must be to minimize or eliminate the threat of contamination of health care facilities, thereby preserving the critical life-saving services.

Critical to managing the decontamination of large numbers of patients is gaining control of the crowd. Repeatedly giving definitive instructions on what to do over loudspeakers in various languages and signage can be useful, along with having an adequate number of properly protected personnel directing the victims through the decontamination process. Providing verbal instructions may be all that is needed to care for the ambulatory populations, but non-ambulatory victims will require more assistance and equipment (e.g., back-boards). The military model of how to organize and manage such a decontamination effort primarily addresses how to handle young healthy soldiers already wearing protective clothing and respiratory protection. This model is not directly applicable to a heterogeneous, unprotected, and undisciplined population that has not had the benefit of a program to familiarize the public with their expected role in an event requiring decontamination. Ideally, what is needed is a program to educate the public about mass casualty decontamination before such an event occurs. The United States Public Health Service, now Department of Homeland Security (DHS) National Medical Response Teams: WMD (NMRT:WMD), has focused on building a methodology and capacity for civilian mass casualty decontamination and has achieved maximum, reported rates of ambulatory hourly decontamination of up to 1700 patients per hour. This capability is achieved with more personnel (36-50) and physical gear than any health care facility or agency is likely to have. Lessons learned from their response capabilities include frequent practice, immediate deployment of life-saving interventions pre-decontamination, not withholding life-saving medical stabilization during the decontamination process, and immediate access to WMD-specific antidotes. The United States Marine Corps (USMC) Chemical Biological Incident Response Force (CBIRF) uses a similar rapid response methodology from which applicable lessons have been learned for the civilian community. In addition, CBIRF is exploring emerging technologies such as decontamination and protective solutions that will allow symptom mitigation and protection in the hot zone, geared toward eliminating the labor-intensive “roller system” (assembly line methodology using a track of rollers for smooth patient transfer and reduction of potential worker injuries) of victim decontamination.

Health care organizational planning must also consider space limitations and geographic and demographic complications. Organizing a large decontamination corridor to handle inordinate numbers of patients is another vital concern. Research is needed to determine the optimal responder/patient ratio, how large an area is needed to decontaminate 50, 500, or 5,000 people, what level of medical training is required for the personnel performing decontamination, and how much medical care should be given in the warm zone as opposed to the cold zone or at the

hospital. Delaying or improperly conducting decontamination increases the danger to the patient as well as the health care provider (personal communication with Steve Cantrill, MD, December 8, 2003).

Estimating the number of potential casualties that must be decontaminated is a process that begins with an integrated hazards vulnerability analysis and assessment. The DHS Office of Domestic Preparedness State Homeland Security Assessment Strategy conducted by each U.S. State and territory in 2003 and early 2004 required local, regional, and State governments to identify credible threats along with their associated projections for mass casualties. Health care organizations and facilities should coordinate estimates for expected numbers of casualties with these data, in addition to reviewing baseline planning recommendations from such Federal funding sources as Health Resources and Services Administration, CDC, and Metropolitan Medical Response System contracts. In the absence of specific threat data, an initial planning effort of effectively decontaminating 100 patients is a reasonable default for the size of most communities (personal communication with John Sinclair, Deputy Chief (ret.) Chair, Emergency Medical Services Section, International Association of Fire Chiefs, February 20, 2004.). Often, if health care facilities that usually have the capability to decontaminate one or two patients are confronted with the need to prepare for staggering numbers such as 1,000 or 10,000, they feel overwhelmed, do not know where to start, and default to a plan of lock-down while waiting for the fire department. There are reasonable steps the health care facilities can take annually that comply with regulations, are fiscally responsible, and offer a spiral development of capabilities that are not overwhelming.

Spiral development of mass casualty decontamination capabilities may start with sustained training of staff to recognize toxidromes that may require decontamination, and providing external, sheltered areas for patients to change clothing, thereby eliminating the greater percentage of contamination. Utilizing commercial, off the shelf products such as tarps, space heaters, curtains with tracks to provide rapidly deployable, environmentally protected, gender-segregated undress areas--with boxes of inexpensive Tyvek-style suits for redress and baggies to seal personal belongings--may increase crowd compliance. It may also reduce the immediate impact of contamination to the health care facility and provide an intermediary step to wet decontamination, with its inherent problems of potential hypothermia.

Aside from the issues related to effective decontamination procedures, training of emergency department personnel must also be considered. There are few courses emergency department personnel may attend to improve their level of preparation for the decontamination of large numbers of people. Many rely on training with traditional fire department-based HAZMAT teams which, while an excellent resource, may not always address the differences in health care facility resources, regulations, or capabilities.

Disrobing

Decontamination by removing clothing and flushing or showering with water is the most effective method for definitive decontamination. Applying this to a rapidly evolving mass casualty event may be logistically difficult. Ideally, gender segregated, environmentally controlled disrobing areas would be rapidly provided while a warm water definitive

decontamination capability is being deployed. A controversial school of thought persists that if people feel they are in danger due to potential contamination, they will willingly, publicly disrobe and submit to cold water “hasty” decontamination. Agencies subscribing to this theory are less likely to develop a definitive decontamination capability, since they believe that hasty, cold water decontamination is sufficient. In actual practice, there have been lawsuits resulting from forced public disrobing for hasty decontamination. Since cost effective methods exist to mitigate this, a best practice is to provide gender-segregated, sheltered, environmentally controlled areas to disrobe. This can be achieved in a rapidly deployable, inexpensive manner and serves the dual purpose of increasing crowd compliance and mitigating long-term psychological effects of loss of privacy. It is recommended that victims be encouraged to remove clothing at least down to their undergarments prior to showering. Issues of crowd control and compliance should be discussed with onsite security and local law enforcement personnel. Since onsite security forces are generally not available in large numbers and local law enforcement personnel are likely to be engaged at the incident scene at the time of an event requiring mass decontamination, the health care facility should promote crowd cooperation through an effective crisis communication plan. There should be a clear message that not participating in the decontamination process may impact a person’s access to health care. Patients who are unwilling to disrobe or fully comply with the decontamination process should be separated from those who do comply to avoid causing a chokepoint in the decontamination process. In addition, the health care facility should promote directed patient self-decontamination. This will significantly decrease the required number of health care workers in the decontamination area with appropriate personal protective equipment. It is critical to have assigned health care staff monitoring the ambulatory decontamination area. If a patient’s condition deteriorates, the progress of others may be impeded without health care provider intervention.

Belongings and Evidence Collection

Within the vicinity of the disrobing area, health care facilities need to ensure that a system is in place for the collection of personal belongings. For complete decontamination, personal items will need to be collected and either decontaminated or discarded. All items collected could be placed in a sealable bag and assigned a unique identifying number that corresponds with the triage tag or chosen patient tracking system. This system will ensure that the patient is either repatriated with the items relinquished, or notified that the item was discarded as a hazardous item or turned over to a law enforcement agency as evidence (English, 1999). Belongings made with any type of animal hide, cotton, or other natural materials have a high potential for absorbing toxins and contaminants. These items may need to be identified as hazardous, discardable items and destroyed if they are unable to be decontaminated. Items collected as evidence will be processed by the law enforcement agency having jurisdiction. While health care facilities may insist on patients relinquishing their personal items, the reality is that victims may not be willing to part with sentimental or valuable items. A decision will need to be made addressing the level of force used to ensure compliance; however, there may be alternatives, such as allowing certain items, such as rings, through decontamination; allowing patients to bring a

sealed bag of valuables through decontamination; or disallowing through decontamination those who are unwilling to part with belongings. Security officials will need to be on hand in appropriate personal protective equipment to assist in collecting items from patients unwilling to turn over those items to staff, or to facilitate crowd control and support the scripted procedures. Policies and procedures for the reimbursement or replacement of items discarded during decontamination should be included in a health care facility. For example, if a patient is unwilling to relinquish personal belongings, a health care facility might consider allowing the patient to self-decontaminate non-porous items during their shower and/or to double-bag the items and allow them to carry them through the decontamination process. The goal of separating the patient from their belongings is strictly medical: to remove contamination. Removing contaminated items can be accomplished by sealing them to avoid secondary contamination of the health care personnel or health care facility. Decisions about how to handle contaminated items can be made with law enforcement and HAZMAT agencies; for the detection of actual contamination, forensic evidence collection and remediation recommendations are needed.

Water Pressure / Temperature

It is recommended that high volume, low pressure water be delivered at a minimum of 60 pounds per square inch (psi) to ensure the showering process physically removes the agent. (A standard household shower pressure is typically between 60 and 90 psi.) Shower time will be incident-specific, based on the suspected amount of exposure and the number of patients requiring decontamination. OSHA standards for a chemical accident suggest a high volume-low pressure wash for contaminated patients. Incapacitated or non-ambulatory patients will require healthcare staff to assist with the decontamination procedures. To reduce the possibility of patients presenting with hypothermia, warm or temperate water should be used. Excessively hot water should be avoided, as this may promote peripheral vasodilatation and toxin absorption. Best practices would suggest using sponges and disposable towels in place of brushes to ensure that additional dermal damage does not occur.

As a caveat, direct observation of fit, young, military personnel processing through rapid, sheltered decontamination with warm water while partially clothed in hot ambient temperatures (summer in the Nevada desert) still resulted in visible hypothermia secondary to convection (Stopford, Nov 2001).

Decontamination Solutions

Soap and Water

Limited data suggest that the most reliable solution for the rapid decontamination of mass casualty patients is soap and water. Soap will aid in emulsifying oily substances like vesicants/blister agents, e.g. mustard agents. Liquid soaps are quicker to use than solids and reduce the need for mechanical scrubbing. The biggest disadvantage of the use of soap is the

large amount that will be necessary. The health care facility or responding agency will need to plan for the amount required in a mass casualty event. Ultimately, the damage to the patient will likely be done in the first few minutes of contamination. The goal of rapid, definitive decontamination of patients is to prevent secondary contamination to rescuers and receivers, in addition to potentially mitigating continued patient contamination.

Bleach and Water

Sodium hypochlorite (bleach) and water solutions remove hydrolyze and neutralize most chemical and biological agents. However, this approach is less favored in a mass casualty decontamination situation than soap and water, where speed is the paramount consideration, for the following reasons:

- Commercial bleach must be diluted and applied with equipment that may not be readily available.
- Skin contact time is excessive. Laboratory studies indicate that that 15 to 20 minutes of contact time is necessary for hydrolysis or oxidation and, thus, for the inactivation of a chemical agent.
- Laboratory studies suggest that bleach solutions at the 0.5 percent level may not be better than flushing with water alone, although some of these data are limited in sample size.
- Bleach solutions are not recommended for use near eyes or mucous membranes, or for those with traumatic wounds.
- The lack of clear safety and efficacy data for bleach decontamination suggest that it should be avoided, especially if soap and water are available.
- Hypochlorite tends to exacerbate the effects of some riot control/irritant agents, causing vesiculation.
- Chemical neutralizers are exothermic reactors and may cause additional harm.

A recent review of the literature suggests that under certain conditions bleach, even at the 0.5 percent level, may actually increase the toxicity of some nerve agents and abrade the skin, potentially causing additional damage in cases involving radiological contaminants (personal communication with Steve Cantrill, MD, December 8, 2003).

Non-Aqueous Methods

The use of dry, gelled, or powdered decontamination materials that absorb the chemical agent are appropriate if their use is expedient and no water is available. Commonly available

absorbents include dirt, flour, Fuller's earth, baking powder, sawdust, and charcoal. The military M291 and M295 Skin Decontamination Kits employ a charcoal based resin as an absorbent, are used in the military, and may be purchased commercially. However, while these kits are effective in removing spots of liquid chemical agent contamination, they may not be suitable for treating mass casualties due to the potentially limited availability, relatively high labor requirements, and the need to use these kits quickly after the patient has been exposed.

Additional mass casualty decontamination solutions that have been proposed include facilitating rapid clothing removal of potentially contaminated victims without exposing them to water, or a gross decontamination "drench drill." commercial off-the-shelf products (COTS) products have been developed that allow a patient to disrobe in public under bag-like overgarments for modesty and some environmental protection (Marcus, 2002). A possible deficiency of this solution is the potential to transfer contamination located on the exterior clothing to the interior of the overgarment, thereby placing contamination against the skin.

Continued evidence-based research is needed while these products are adapted from environmental site or equipment remediation to patient use, including the need for lengthy dwell times, potential absorption issues, and the logistics for managing the large quantities necessary. Other COTS products are emerging for decontamination purposes, such as decontamination foams and skin solutions as a barrier or a cleaner.

Other models to consider for mass casualty decontamination include providing a basic large-scale sheltered area for victims to change clothing and the Israeli model of public fixed decontamination sites such as parking garages. Israel has successfully utilized public venues, such as parking garages, as mass casualty decontamination facilities and has educated the public to their use and location. Coupled with a sustained, effective public education program, the general public may report to local fixed mass casualty decontamination structures for self-treatment, similarly to the general public reporting to their closest tornado shelter. This may be an option to test in a recognized high threat location, such as the National Capital Region, or in high threat venues, such as large arenas or convention centers. A security concern with publicizing a decontamination facility is the risk of the facility itself becoming a primary or secondary target, which is ultimately no different from the current threat against hospitals and other icons of life-saving, such as ambulances or fire apparatus.

Summary of Solutions

The problems associated with the use of soap and bleach solutions include time delay, dilution and application, medical contraindications, and their efficacy compared with water alone. These limitations make the use of soap and bleach less desirable than using water alone for speed, but substances will often not rinse off with water alone, requiring a non-toxic solution to disrupt the surfactant layer allowing cleansing to occur. Limited studies exist of decontamination solution efficacies, particularly in a mass casualty situation with limited resources and dwell time.

Water Containment and Runoff

As health care facilities and providers begin to develop and evaluate mass decontamination systems, it is important to also consider the capabilities for managing the contaminated water run-off. Following a mass casualty event, environmental liability resulting from critical lifesaving actions may seem unlikely but could be a serious concern for many first responders and facilities. There currently is no legislation or regulatory mandate describing the details for the containment procedures and capacities of a decontamination system (Berino), although the Environmental Protection Agency (EPA) provides guidance for decontamination planning. An EPA letter is widely circulated limiting liability for agencies engaged in mass casualty emergency decontamination. However, since mass casualty decontamination should be a part of community's emergency planning, the appropriate containment of contaminated run-off should be addressed. Cost effective solutions exist to contain run off, including berms, pumps and containers. Each health care facility must establish water containment capacity based on the facility's hazards vulnerability analysis and assessment. In addition, health care facilities should consider the risks to the community of exposure to hazardous material exposure based on the potential number of victims that may present to the facility. Health care facilities should develop specific contaminated water containment plans in conjunction with the proper local regulatory authorities (Environmental Protection) and Municipal Separate Storm Sewer systems.

Contaminated run-off should be avoided whenever possible but should not impede or interfere with necessary lifesaving actions. The key to managing the problem of water run-off is planning. Health care facilities need to coordinate with the local emergency planning committee to obtain community support and technical guidance and direction in minimizing the environmental impact of decontamination water run-off (personal communication with Kathy Dolan, Risk Manager, Safety and Disaster Coordinator, Mercy Medical Center, Nov 19 2003).

While health care facilities with fixed or designated portable decontamination capabilities should address the issues of run-off to comply with EPA regulations, the EPA has also furnished a letter regarding run-off from a mass casualty event that suggests there will be leniency in dealing with a lack of proper containment. The health care facility or agency depending upon this in their decontamination plan should verify their risks with local government agencies, internal risk management, and legal counsel (personal communication with Kathy Dolan, Nov 19 2003).

Triage

The three primary objectives of a disaster response are: 1) to do the greatest good for the greatest number of victims; 2) to effectively use personnel, equipment, and health care facilities; and 3) to not relocate the disaster from one location to another by poor command, control, or communication practices.

The triage process is the initial step taken to meet the primary objectives of a disaster response. The purpose of triage is to sort the injured by priority and determine the best use of available resources (e.g., personnel, equipment, medications, ambulances, and hospital beds). Many first responder agencies and health care facilities have a triage plan in place to implement in the event of an airplane crash, train derailment, or school bus accident. Traditional triage uses

diagnosis-based criteria or involves the evaluation of each patient's respiration, perfusion, and mental status to determine whether they should be classified as immediate (urgent), delayed, low priority, or deceased. Both triage approaches require the examiner to see the patient and obtain certain clinical data by verbal communication and tactile examination. In a terrorist incident involving chemical or biological WMD, the victim(s) may suffer from the effects of toxins, trauma, or both. In a more conventional disaster, unless they are in danger, patients can usually remain in place until directed to relocate. Their evacuation and treatment priority is indicated on a triage tag or colored ribbon, with an emphasis on saving as many persons as possible (personal communication with Steve Cantrill, MD, December 8, 2003).

There are several differences between the triage done for the traditional disaster scenario and that conducted for a HAZMAT incident or a chemical/biological terrorist event. Time demands, patient volume, and the personal protective equipment being worn by response personnel in the hot and warm zones may preclude normal life-saving measures from being rendered quickly, if at all. For example, verbal communication may not be possible because of the responder's personal protective equipment. A tactile examination may not be possible for the same reason. In a New York City model for mass casualty triage, responders in personal protective equipment may utilize a noxious stimulus, such as a forceful nudge, to elicit a victim response. The patients who react to the stimulus will become the highest priority for intervention, which includes scene extraction, antidote administration, and further medical care.

In addition, the whole concept of traditional triage (treating the most seriously injured first) may not be applicable in a chemical or biological incident. Ambulatory victims may need to be among the first to be decontaminated and evacuated because they may have the best chance of survival. It is not desirable that victims remain in place in the hot zone until examined. Rather, immediate evacuation efforts should be undertaken and the victims directed toward the decontamination process established in the warm zone. Further theory proposes initiating decontamination in the hot zone. For example, non-ambulatory patients who were victims of a non-persistent vapor causing life-threatening effects may be saved in the hot zone by immediate administration of antidote, neutralizing solution, and basic airway management. Also, there will be little if any time to indicate a patient's priority on a triage tag in the hot or warm zones. In addition, the patient data recorded on a triage tag is at risk of being defaced when the tag becomes wet during decontamination (17). The U.S. Marine Corps (USMC) Chemical Biological Incident Response Force (CBIRF) has designed waterproof, mass casualty decontamination tags that other agencies have adapted to address this issue. Additional COTS products exist with a similar purpose.

Psychological Impact

The psychological impact of being exposed to a WMD is not well studied. Whether crowds will listen to instructions or panic, what they need to be told and how that message should be given, whether they will take off their clothes in the absence of an obvious immediate danger, whether they will shower with persons they have never met before, and how best to control or avoid hysteria are among the issues that need to be addressed.

Actions that can be taken that may mitigate the long-term psychological consequences that will accompany a mass casualty WMD event include a robust crisis and risk communications plan, pre-prescribed actions that the public can take for self-protection, and providing sheltered,

gender segregated undress, decontamination, and redress areas. One purpose of shelter is to protect against intrusion, such as by bystanders or the media. Ultimately, in a situation characterized by loss of control, allowing victims to retain or obtain as much control over their environment and themselves as possible is desirable. Methods for achieving this do not need to be complicated or expensive, but cannot be ignored in favor of “if they are really sick, they will just strip naked in the parking lot” mentality. Citizens of the United States are aware of both the credible terrorist threat and the concurrent funding and planning efforts occurring. They may not be so forgiving of a lack of planning that strips them of their usual civil rights (Stopford, 2001).

Needs, Shortfalls, and Gaps

Research and development efforts in decontamination and mass triage must concentrate on operations research and research on procedures and techniques for the effective decontamination of large numbers of people. Such research should include:

- Physical layout, equipment, and supply requirements for performing mass decontamination for ambulatory and non-ambulatory patients of all ages, in all kinds of health, in the field and at the hospital.
- Standardized patient assessment and triage process for evaluating contaminated patients of all ages, both in the hot zone and pre/post decontamination.
- Optimal solution(s) for performing patient decontamination, including decontamination of mucous membranes and open wounds.
- Benefit versus risk of removing patient clothing, including the need to remove undergarments.
- Effectiveness of removing agent from clothing by a showering process.
- How much contact time for showering is necessary to remove a chemical agent?
- Whether high pressure/low volume or low pressure/high volume spray is more effective for patient decontamination.
- Alternatives to the fire hose “drench drill” gross decontamination method.
- Best way to determine whether a patient is "clean."
- Psychological impact of undergoing decontamination on all age groups.
- The ideal avenues through which health care facilities can disseminate information during an event of this magnitude.

- Equipment and training requirements. How can health care facilities realistically provide support for mass casualty decontamination? And what is the funding source?
- Need for decontamination preparedness capabilities at all health care facilities.
- Cost-effective retrofitting for fixed decontamination at health care facilities and high-threat locations and venues.
- Educational and training materials specifically developed for the general public and mental health professionals.
- Enlist mental health professionals in mass casualty planning and emergency management to develop appropriate guides and standards.
- Psychological screening methods to differentiate the public reaction to terrorist attacks from other psychological illnesses.
- Evaluation of techniques for preventing or controlling adverse effects in health care and emergency workers, victims, and the “worried well.”
- Debriefing methodologies on pediatric psychological issues following suspected or actual terrorist attacks (personal communication with Steve Cantrill, MD, December 8, 2003).

Guidelines for Building the Model

The following areas specify items that should be explored when developing a best practices methodology for dealing with WMD terrorism preparedness planning:

Adaptability -- Is the best practice suitable for use in any region?

Decontamination capabilities are based on the hazards vulnerability analysis and assessment within the geographic boundaries of the health care facility and agency’s service. In addition, the chosen decontamination system will be developed and prepared as the demographics of the community dictate.

A baseline of standardized preparedness must occur throughout the United States and territories, to be augmented based on credible threats discovered during a systematic hazards vulnerability analysis and assessment (Mann, S, 2003).

With the theory that a mass casualty decontamination event is a community problem, not just a health care facility or private industry problem, communities using a regional approach have provided mobile decontamination assets, such as those already in place in select Metropolitan Medical Response System cities (United States Environmental Protection Agency, 2000).

Additional efforts should be made to ensure that all health care facilities have some expanded capacity to cope with contaminated casualties, even if they start with an undress area and small

shower set up. A mobile regional approach alone will not be effective in the face of rapidly self-referring casualties to health care facilities if they have no containment or initial treatment capability while waiting for assets to arrive.

Progression through the Decontamination System -- How many victims of a WMD attack will the best practice aid?

The best practices to maintain rapid progression through the decontamination system will require two systems (Stopford, B. 2001). First, an ambulatory system; this system will allow for rapid progression of contaminated or suspected contaminated casualties experiencing minimal or no signs or symptoms of exposure. The ambulatory system will require self-decontamination by the individual, limiting the staffing requirements. Second, a non-ambulatory system; this system is specifically designed for contaminated casualties who are unable to walk or who are producing significant signs and symptoms of contamination, including unconsciousness and unresponsiveness. This system will require qualified and trained staff to actively assist and possibly provide life-saving care during patient decontamination.

Depending upon the extent of the program adopted by particular regions--the cost for purchasing, maintaining, and storing decontamination equipment, in addition to the possible structural modifications to the facility--costs may be significant. Additional costs may be incurred for initial and in-service training. Although the costs may be considerable, failing to provide a system for decontamination may prove even more costly.

One approach to progression through the decontamination system is that of spiral development. Based on a regional hazards vulnerability analysis and capabilities assessment, a plan can be developed with progressive capabilities. For example, first year funding can provide portable, regional mass casualty units such as tents or trailers to augment scene and facility needs, while initial augmentation of current health care facility capabilities ensues. A high end approach is ensuring each health care facility can accommodate an equal percentage of predicated casualty numbers, with both fixed and portable capabilities, in conjunction with a community public education plan and public and home-based decontamination options.

Operational Impact -- What are the operational considerations of using the best practices?

The operational impact in decontamination system development may be significant. As with personal protective equipment, specialized training is required and regulated by OSHA. Competency-based, Operations level training will be required for all staff members responsible for ambulatory and non-ambulatory casualty decontamination. In addition, staff members assigned to non-ambulatory decontamination will need back-fill coverage to ensure their normally assigned duties are being completed. Thus, there will be a significant impact on manpower and staffing availabilities for other required duties. Health care facilities and agencies should address the rotational needs of maintaining staff at elevated levels of personal protective equipment as needed to conduct decontamination. In addition, an increase in the security of the facility must be managed. A large-scale incident involving mass casualties to a facility could maximize and surpass the capabilities of the institution. Health care facilities will need to mitigate this possibility by identifying surge capacity sites for patient overflow, as well as

identifying or developing a hospital shared services call down. This call down system will provide contact information for agencies, organizations, and facilities able to provide medical staff as reserve or relief personnel in an emergency. A community planning consideration should be given to directing ambulatory, potentially contaminated but asymptomatic patients, to go home to shower during a mass casualty event, then to be able to report to a secondary treatment site for further screening.

Training -- What level of training does this best practice require?

OSHA regulations affecting decontamination team training, including health care facility personnel providing decontamination services, require “operations” level training with an annual refresher or competency requirement. The Office for Domestic Preparedness describes this competency-based training as “performance offensive”. Health care facilities will need to provide staff the appropriate level of training based on the responsibility involved in the assignment. (Office for Domestic Preparedness, August 2001).

- Hazard Communications – all employees; orientation to HAZMAT in the workplace.
- First Responder/Receiver Awareness – employees likely to discover a HAZMAT situation or come in contact with a potentially contaminated casualty.
- First Responder/Receiver Operations – all members of a decontamination team.
- Skilled Support Personnel – personnel that are not part of the decontamination team or response team but have special skills that are immediately required in the contaminated area.
- On-Scene Incident Commander – oversight of the decontamination operation.

Once again, these OSHA-regulated levels of training require annual review and competency testing.

Resources -- Does the practice build on existing practices/infrastructure? Are there available resources to implement the practices?

Very few health care facilities have decontamination capabilities able to handle a large number of contaminated casualties. In fact, those facilities that do have current decontamination systems are typically designed for the (individual) ambulatory patient. Failure to recognize the need and the potential for a mass casualty event may put the health care facility, its staff, and patients at great risk. While Federal funding supporting domestic preparedness is prevalent, the impact has not been greatly felt at the health care facility level. Decontamination is a medical procedure and must be supported as such by empowering health care professionals with training, equipment, and procedures to provide lifesaving care (Mann, 2003).

Morbidity and Mortality -- What impact will this practice have on saving lives?

Health care facilities and health care agencies, including pre-hospital professionals with well-developed plans based on their hazards vulnerability analysis and assessment, will have a dramatically positive effect on saving lives. No one can prevent unannounced contaminated casualties from walking into a health care facility. But with staff vigilance and awareness of potential hazards and toxidromes, health care facilities can contain additional facility contamination and initiate decontamination policies and procedures. Pre-hospital medical personnel who can provide oversight, initiation, or conduct decontamination have the ability to save lives (Mann, 2003).

Evidence-Based Practice verses Theory -- Is there a body of professional research supporting this practice or is it theoretical?

Research has been conducted in the area of decontamination specifically for on-scene response by emergency medical service, fire department, and law enforcement personnel. The need for standards for health care facilities is not a new concept. As mentioned earlier in this document, health care facilities are presented with patients possessing chemical exposures from industrial accidents and agricultural chemical exposure incidents. Only recently have government, military, academic, and public and private entities begun looking at mass casualties presenting to civilian health care facilities with chemical and/or biological contaminants. Logical hypotheses can be developed regarding the negative outcomes from failing to prepare appropriately, yet evidence-based scientific data are not available for the official support of a particular direction. The information is largely anecdotal and based on traditional HAZMAT response.

Regulatory Compliance -- Does the practice comply with existing regulations or does it require a regulatory change?

JCAHO and OSHA provide the bulk of the regulations that impact health care facilities regarding decontamination. As the numbers of patients for which a facility must be prepared will vary by community, the focus has been on establishing an effective plan, to include role definition and training needs. Numerous periodicals and professional organizations offer suggestions, recommendations, and practices, yet there is no government authority regulating standards. It is important to note that with government regulation comes a price tag. To fully prepare a health care facility with decontamination design, facility modifications, equipment, training, and exercise, a significant cost will be incurred.

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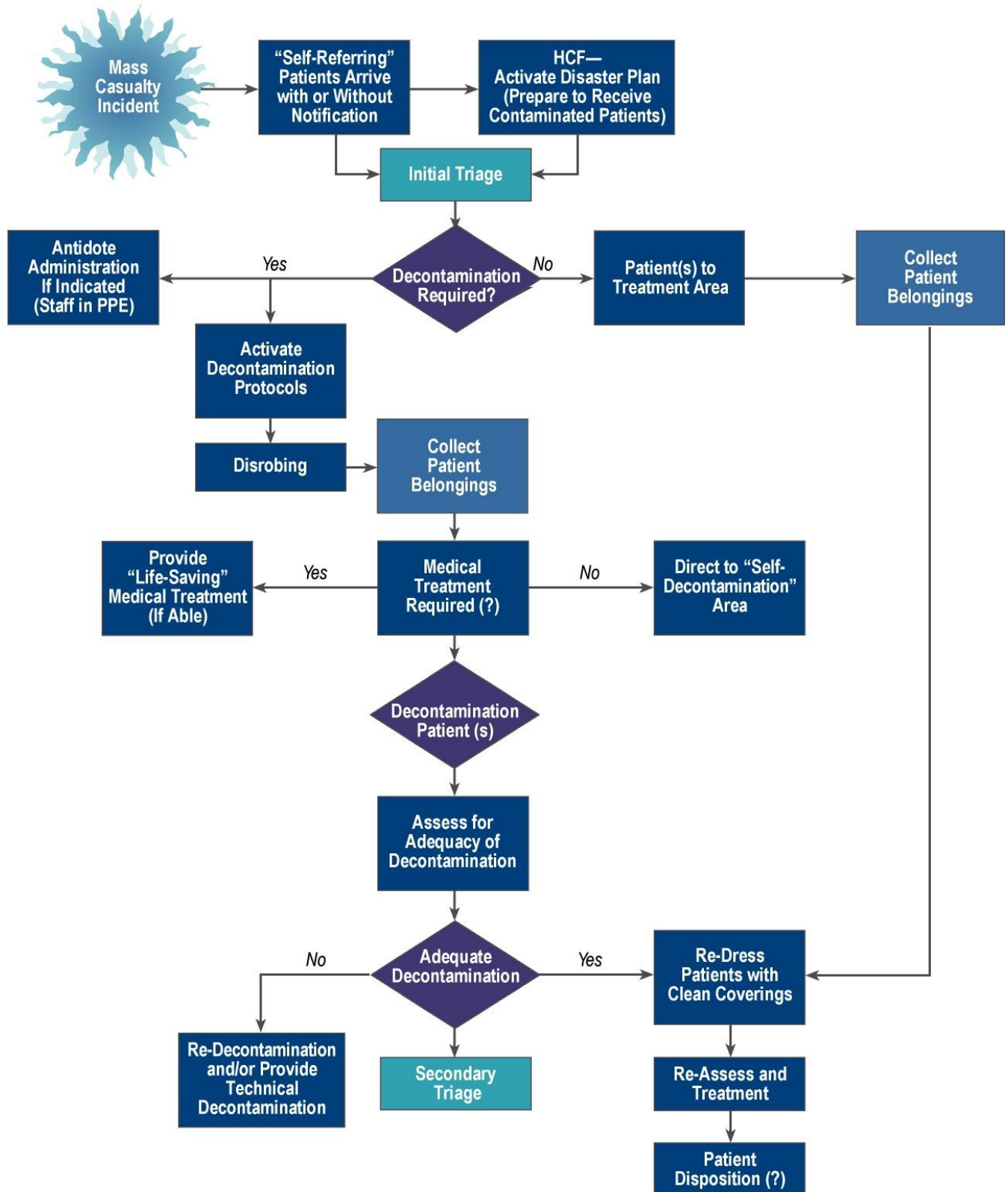
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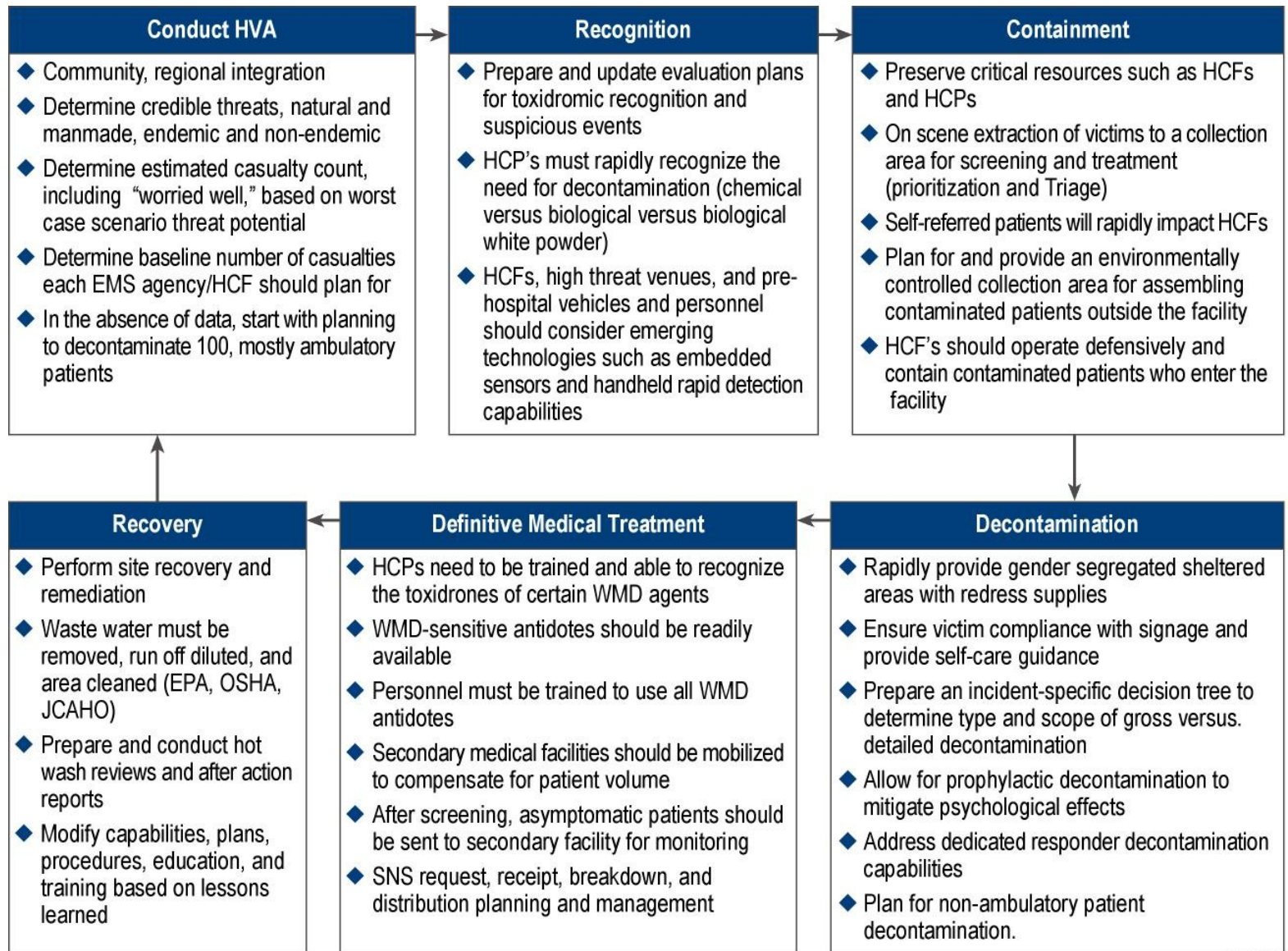
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Ch. 3 Appendix B. Mass Casualty Patient Decontamination



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Ch. 3 Appendix C. Model for Mass Casualty Decontamination Planning



Chapter 4. Isolation/Quarantine

Background

Isolation and quarantine are public health measures that historically have been used to control the spread of contagious diseases. Isolation restricts the movement of persons known to have a contagious disease and is currently used by hospitals on patient floors and in emergency departments. Quarantine, used by medical providers and public health authorities, separates persons who have been exposed to but who have not actually developed a contagious disease (Canadian Society for Medical Laboratory Science 2003). Health professionals who need to successfully implement isolation and quarantine practices must address gaps and shortfalls in current systems and embrace emerging best practices in the field as improvement models.

Gaps

There are challenges to implementing isolation and quarantine at both the hospital and community levels. Isolation practices in hospital settings are contingent upon the activities of hospital infection prevention and control programs. In addition, there has been debate about the importance of inanimate environmental contamination/decontamination, prevention of airborne agent transmission, and prevention of disease when in contact with moist body substances or body fluids (Jackson and Lynch 1985). Hospital plans are constantly challenged to find adequate operational space, staffing to support the needs of persons in isolation settings, and the environmental barriers to have the capacity to handle a surge of patients with communicable diseases who could overwhelm such a facility.

The arrival of Severe Acute Respiratory Syndrome (SARS) in 2003 in Asia and Toronto, Canada, introduced the concept of “respiratory etiquette,” where health care facilities directed patients with respiratory symptoms to wear surgical masks or cover their nose and mouth with a tissue. There was also increasing attention given to hand washing, the urging of hospitals to separate patients with respiratory illnesses, and posting notices at health care facility entrances requiring persons with respiratory symptoms to inform health officials of their arrival. However, the responses to these recommendations were varied, even after guidance documents were sent from the U.S. Centers for Disease Control and Prevention (CDC). This added another variable into the matrix of debate, discussion, and practice that exists with health care providers and facilities, and is causing gaps in disease outbreak hospital isolation plans. The absence of rapid and accurate diagnostic testing for SARS and other bioterrorism agents, which could give indication of a need to isolate or quarantine, is another challenge that health care facilities face. They must cast a broad net to include all people at risk in order to protect the public’s health.

The increasing threat of rapidly emerging infectious disease and bioterrorism agents that could cause mass casualties has brought renewed attention to the practice of quarantine as a public health measure that could involve large-scale geographic or regional quarantine. Large-

scale quarantine was implemented during the 2003 SARS outbreak in Beijing, China, where approximately 30,000 Beijing residents were quarantined in their homes or at sites of known SARS patients. The human resources to manage, implement, and enforce this quarantine process were monumental. To guide future quarantine policy, the Chinese Field Epidemiology Training Program of the Chinese Center for Disease Control and Prevention recommended, as a component of a comprehensive SARS-control program, that quarantine be limited to persons who had contact with an actively ill SARS patient in the home or hospital, allowing for better focus of resources (Centers for Disease Control and Prevention [CDC] July 2003).

The implementation of individual or community-level sustained quarantine in both China and Toronto during the SARS outbreaks brought forth logistical concerns such as income and job protection, disability status, family and dependent care, relief staffing at health care facilities, and the psychological effects of quarantine on patients and health care providers. Uncertainty and stigmatization were prominent, particularly when the presence of law enforcement was added to the quarantine (Maunder et al. 2003). Hospitals and health care facilities that isolated SARS patients or were used for home or work quarantine faced significant financial challenges and social stigma after the resolution of the outbreak and the remediation and decontamination of the facilities.

SARS was an emerging infectious disease, and the technology and science for decontamination was also emerging. The social understanding and acceptance of health care facilities as safe, non-infectious buildings to inhabit was in conflict. The cost of remediation and decontamination of the buildings to public and regulatory agency satisfaction was significant. In Asia and Toronto, the government was largely responsible for costs, with lesser, but still significant costs to the facilities themselves. The U.S.'s experience with the decontamination of Congressional office buildings, U.S. postal facilities, and the American Media Building in Florida after the anthrax incidents of 2001 indicated that significant financial burdens would have to be negotiated between the public and private sectors. Many U.S. hospitals, health care facilities and providers, as well as local, State, and Federal governments, do not have clearly defined mechanisms to address which parties are responsible for incurring costs as a result of a facility being isolated or quarantined during an infectious disease outbreak.

In the United States, States and local jurisdictions have primary responsibility for isolation and quarantine within their borders. The Federal government has residual authority under the Constitution's Commerce Clause to prevent the interstate spread of disease. Also, the Federal government has primary responsibility for preventing the introduction of communicable diseases from foreign countries into the United States.

Because isolation and quarantine are "police power" functions, public health officials at the Federal, State, and local levels may occasionally seek the assistance of their respective law enforcement counterparts to enforce a public health order (CDC January 20, 2004). State and local law enforcement entities will look to State and local health departments for operational guidance in terms of personal protection and the criteria for urgency of action and, in turn, State and local health departments need the proper legal backing to operationally handle a public health emergency such as SARS. However, this delegation of responsibility at the State level creates a patchwork of more than 50 potentially different quarantine laws. Furthermore, as legal entities and judiciaries are beginning to explore the topics of isolation, quarantine, and civil liberties, the appellate process and operational definitions of the law enforcement process and Federal, State, and local statutes are not being taken into consideration. Legal entities and

judiciaries have varying levels of interest and expertise on this topic, and their protocols need to be clearly defined in advance of the first case of a disease requiring isolation.

During the SARS outbreaks in Asia and Toronto, police powers were activated as part of the quarantine process. However, many of the people within these communities did not require intervention by police or law enforcement to enforce the public health quarantine order. In both localities, the “social norm” was to be compliant with the legal order to stay home, partly because of aggressive public education campaigns that emphasized the need to comply with the quarantine order, and partly because many of the affected people had occupations that permitted them to work from home or in the quarantined facility. In the United States, many of the isolation and quarantine laws that have been and are being written allow for varying levels of the appellate process. This may or may not allow for additional time to elapse before a person is forcibly quarantined, which could expose additional people to the contagious agent. If an infectious disease situation occurs that requires the quarantine of thousands of U.S. citizens, many of the affected persons will not have occupations permitting them to work from home. Therefore, there is the potential for thousands of people to violate the quarantine to maintain continuity of life activities (i.e., earned income or food) and to exercise the appellate process. Many of the isolation and quarantine laws do not address mechanisms to resolve continuity of life activities, which poses a threat within the U.S. if a significant communicable disease outbreak requiring community-wide isolation and quarantine were to occur.

Shortfalls

In the public health sector, successful disease containment depends on the public and private health care systems’ ability to rapidly detect, recognize, and treat disease while implementing barriers to limit the spread of the disease in question. Private health care providers and hospitals depend on public health departments to provide treatment recommendations and to assist in identifying persons at risk or those actively infected with the disease. Public health departments have a history of conducting contact tracing for diseases; there are reporting mechanisms in place to identify the first case of a potential disease once a case definition is determined. However, the appropriate mechanisms and funding streams to implement staff, procedures, and detection technology for monitoring illnesses with broad communicable spread, in the short and long-term, are not yet in place.

Many challenges are involved in monitoring communicable diseases. State public health departments request and sometimes mandate that private providers and hospitals report suspected diseases. However, health care providers often do not comply. Often, there is a gap in public health departments’ capacity to provide real-time or rapid feedback to health care providers due to lack of around-the-clock public health staffing and real-time notification technology. While it is the appearance of a patient at a hospital or other health care facility that begins the process of surveillance and notification, the patient is also the last “responder,” since monitoring for long-term effects of a communicable disease continues long after hospital discharge. The lack of funding and technology for the surveillance of long-term health effects may create a system with gaps in disease understanding, treatment, and prevention.

A hallmark of the SARS experience in Toronto was the creation of a SARS Command Center to include a public health department representative, who was in contact with hospitals at

all times. The purpose of this constant contact was to provide ongoing communication between the hospitals and local health departments. The capacity of local and State public health departments to maintain this level of epidemiological or disease investigational representation 24 hours a day during an outbreak currently is often only minimally present, even in the largest U.S. cities. In all localities there is a need to train people from within the public health system to provide advice to hospitals, help assess patients, and communicate surveillance data on isolated and quarantined patients to the local health department.

During the SARS outbreaks, thousands of people were quarantined. It was incumbent upon the public health system to conduct twice-daily telephone contact and assess people in quarantine (for 10 or more days at a time) who were at risk for developing the infectious disease. This did not account for people who required quarantine but did have telephones or other communication devices at their disposal. In Asia and Toronto, the public health systems had to monitor those who were quarantined in more regulated government facilities; yet, monitoring was still a labor-intensive enterprise, involving numerous telephone calls, continual monitoring of fever, and the like. It is likely that if a disease outbreak occurred in the U.S. requiring community-wide quarantine, there would be people who would not have telephone access. This would lead to challenges in the public health system to protect the public's health while maintaining personal liberties currently being outlined in State and local isolation and quarantine laws.

A key link to supporting isolation and quarantine at any level, but particularly if it becomes a community-wide need, is to have a well integrated electronic network where public health staff can conduct real-time contact tracing. During the Hong Kong SARS experience, the local public health department placed information on their Web site as to how they integrated their surveillance and contact tracing of isolated and quarantined patients into all aspects of emergency response. The Hong Kong SARS emergency response units included police and fire departments and emergency medical systems. In the U.S., private and public health system surveillance and contact tracing could be improved by using several means of electronic communication (Web-based, wireless, etc.) for rapid communication. U.S. hospitals need to be able to communicate with the CDC, local and State public health departments, and other responding agencies. The implementation of video conferencing could enhance communications and sharing of important information between hospitals and public health authorities (e.g., transmitting pictures for diagnostic purposes in order to communicate with, and safely monitor, the health of larger numbers of people).

There have been discussions that during a biological incident, hospitals should be reserved for persons who have not been exposed to the virulent agent, and those who have been exposed should be assessed and treated at off-site isolation units. However, until technological advances allow for immediate triage and diagnosis of emerging infectious diseases and bioterrorism agents, people will present to hospitals and health care providers with early forms of transmissible diseases.

Authorities in Asia designated "SARS hospitals" to treat SARS patients; non-SARS infected patients were moved to unaffected facilities. This practice is advocated by some who recommend changes in the U.S. inter-hospital transfer regulations, such as the Emergency Medical Treatment and Active Labor Act (EMTALA). Proposed changes would allow larger communities with multiple hospitals or health care facilities to rapidly identify receiving hospitals and promote community self-triage to those hospitals. However, if this practice were to occur, plans would be needed to consolidate existing hospital patients who were not infected with the particular disease and to direct them to alternate locations, since hospitals are at or near

full-bed capacity at all times. On a federal level, the National Disaster Medical System and its patient movement system could be activated; however, regions and jurisdictions need similar, operationally feasible, autonomous planning as well.

Currently, U.S. hospitals are generally overwhelmed with patients but understaffed with providers. Hospitals may have only vague, untested intra-jurisdictional or regional mutual aid agreements and/or alternate patient transfer plans for sending less critically ill patients to non-affected facilities after an infectious disease outbreak. In small communities with one hospital, triage and alternate care facilities (e.g., mobile hospitals) would need to be created to keep the disease out of the hospital.

It should be noted that an alternate scenario would likely appear in the U.S. since many U.S. hospitals are privately owned. If there were a designated hospital for infectious disease treatment during an outbreak in the U.S., this hospital could become bankrupt, since the community's fear of becoming infected would drive the hospital to end all surgeries and other business. The dialogue between public governments that implement a forced isolation or quarantine on a private sector entity would then have to lead to a resolution as to how to deal with economic disruption. U.S. hospitals, other health care facilities, and providers--as well as the U.S. local, State, and Federal governments--do not appear to have clearly defined mechanisms to determine which parties are responsible for incurred costs as a result of a forced isolation or quarantine due to an infectious disease outbreak.

Personal protective equipment (PPE) is available for health care staff if there is the chance that they could be exposed to an infectious disease (i.e., N-95 masks, gowns, gloves, and face and eye protection). While all U.S. healthcare facilities will have at least basic PPE for infectious control needs, the amount of supplies necessary to care for many infected patients for a sustained period of time is not usually on hand. Additionally, some of this equipment is cumbersome, unfamiliar, and untested except for use in case of a disease outbreak. For example, full protective Level C PPE was difficult and stressful for health care workers to use in past SARS outbreaks. Staffs were constantly rotated because they were unable to work 8-hour shifts. This resulted in the need for additional staff. Health and safety surrounding the work force are important issues, particularly among the currently understaffed public and private health care workforce. It will be difficult to expect and depend upon the workforce to increase the numbers needed to treat large-scale disease outbreaks or outbreaks of unknown diseases, and to treat unknown persons, if there is a lack of institutional support for their physical and mental well-being. Attention to this topic is critical for the maintenance of the workforce, but even more so when diseases such as SARS or hospital-based gastroenteritis outbreaks adversely affect health care workers.

The proper and consistent use of PPE is critical not only to the protection of staff tending to isolated or quarantined patients, but also to prevent further spread of the disease within the facility. Poor adherence to PPE standards and poor compliance to well-known infectious disease contact or universal precautions by health care staff has been shown to prolong outbreaks of norovirus and other pathogens. Furthermore, health care workers may be reluctant to report to duty during a disease outbreak, despite being provided with PPE or even incentive pay; the ethical and legal ramifications of workers subsequently failing to care for infected patients or using financial incentives to mitigate this type of situation have not been clearly defined. Staff might be less afraid to report to work to assist in the treatment of isolated or quarantined persons if they were trained in using PPE. It is essential to educate the public health care workforce so

they will feel reassured about their own health and that of their families. Health care workers tend to have the same “it can’t happen to me” mentality as the general public.

Finally, appropriate mental health specialists need to be trained to respond to fear and crisis in the health care workforce, both during and after crisis situations. Fears of being socially marginalized by being placed in isolation or quarantine, loss of income, and social stigma as a result of potentially being victims of a disease outbreak, may cause many people--particularly the public health or private health care workforce--to ignore early symptoms of disease that may contribute to their failure to seek timely medical care. Too often, the mental health support for health care workers, public or private, is offered after, not during, the event. Therefore, the stressful emotional effects of isolation and quarantine on the health care workforce--whether they are caring for patients and/or colleagues in these situations or they themselves are in isolation or quarantine--are delayed and more difficult to resolve when they do surface (Arlington County 2002).

Most State public health laws, including those recently rewritten to provide emergency powers, seem to be a patchwork and of debatable flexibility when it comes to responding to infectious diseases requiring isolation and quarantine. There are minimum standards outlined in the Model State Emergency Health Powers Act, such as the requirement of the government to provide for people in isolation and quarantine a respect for dignity, necessary facilities, and comfort (21). For example, a quarantine measure for the government at the local level requires people to remain at home for a certain number of days and not interact with other people. However, the fact that there are potentially 50 State public health laws, all addressing various issues, could produce a level of inconsistency that could result in illegal restrictions, improper releases, the lack of development of clear plans for protecting public health and personal liberties, and a lack of clear mechanisms for the actual enforcement of the necessary isolation or quarantine.

If the Beijing SARS experience--in which several thousand people needed to be quarantined--were to occur today in the U.S., it would be a significant challenge to supply enough lawyers, judges, and health care officials to put people in mandatory quarantine, and enough law enforcement officials to monitor homes and communities to enforce it. These segments of the workforce need to be involved in concrete operational planning for public health requests for isolation and quarantine measures. Large-scale community quarantine may involve neighborhoods and entire zip codes. It would be a challenge to erect a “traditional” barricade around all the streets and buildings in an entire neighborhood or town needing to be quarantined. Unless the public were to heed the warning to stay home if they are infected or potentially infected, there would be an excessive number of people who would break quarantine by leaving their homes. It would be incumbent on the public health community to implement effective and dynamic risk communication plans to meet this challenge. The community would have to create a climate that supports people staying in their homes for the public’s welfare. In terms of technology, monitoring bracelets could be a resource to ensure that people stay in their homes, but the community would need to be well educated by health and law enforcement personnel on the importance of quarantines.

Communities need to develop specific, operational-level quarantine plans and implement them in advance of an event to include the needs of special populations such as persons with addictions, the homeless, and those with special health needs or disabilities. In short, specific operating procedures and protocols of law enforcement and legal procedures would need to be put in place prior to an event, and they would have to be practiced. This would have to involve

educating the judiciary and city attorneys and any associated regulatory bodies. All logistical support would need to be in place so that food, medications, repair services, shelter, and maintenance of basic life services could be provided. The number of services that would need to be provided is extraordinary and must be provided for in advance of an outbreak or epidemic, not at the time an event takes place. Regional approaches to this problem should also be considered to minimize the fragmentation that is present with multiple State plans.

In the area of law enforcement of isolation and quarantine, a potentially serious problem to address would be that most law enforcement personnel may not be trained to deal with public health issues, and so would worry about contracting an infectious disease during a quarantine enforcement. To complement their work, they need to have contact training in a public health role (forensic epidemiology). Using law enforcement as the basis for a successful quarantine is rarely effective on a large scale, as seen in Canada and China. Rather, public health officials need to encourage residents to stay home voluntarily. Encouraging compliance with public education and providing support for resilient communities will be more effective than relying on potentially overtaxed law enforcement agencies. Bringing in the Federal government to enforce isolation and quarantine should only be necessary to back up military activity if riots were to take place.

A challenge in terms of legal provisions to successfully implement isolation and quarantine would be to provide for income protection. Some people believe that the Americans with Disabilities Act (ADA) would be an applicable vehicle for anyone under quarantine (personal communication with James G. Hodge, Jr., J.D., L.L.M., Deputy Director, Center for Law and the Public's Health, January 7, 2004). These opinions state that people who might be contagious or exposed can be considered to have a disability. In such situations, employers may have to meet their own needs and employ or reassign other workers; the ADA may not apply.

In the Canadian system, there are possibilities for worker compensation. However, in the U.S., the employer or government does not have to pay for lost salaries if the disability is not job related. However, in the case of a bioterrorism attack, this area could be hotly debated. This problem would require rethinking of our social welfare system because recent Federal catastrophes have demonstrated that there have been problems with providing coherent models for compensation. Current models include the Federal Emergency Management Agency (FEMA) or the September 11 Compensation Funds, but these are last resorts and may (as in the case of the September 11 Compensation Funds) require the recipient not to file any legal action against the government. However, in order to compensate victims and their families in a timely manner, there would need to be a large pool of funds available and set aside for the Nation in preparation for a declared state of emergency.

Best Practices

Isolation

Rapid and sustained implementation of stringent infection control procedures by health care workers in hospitals have been effective in combating the spread of new, infectious diseases for which there is no vaccine; implementation of such procedures also has been effective in combating known threats and pathogens, and are relatively inexpensive and easy to implement

(Association for Professionals in Infection Control and Epidemiology, Inc. (APIC) Bioterrorism Task Force and CDC Hospital Infections Program Bioterrorism Working Group 1999).

The establishment of “outside-the-facility” triage, medical assessment, mobile medical units, and diversion protocols are options to prevent infectious diseases from entering health care facilities (Farquharson and Baguley 2003). After the Canadian SARS experience, Canadian authorities retrofitted two long-term care facilities with additional negative pressure rooms to be used for SARS patients. In Taiwan, authorities are building 1,000 new negative pressure rooms, routinely used for patients with tuberculosis, to prevent infectious particles from spreading. They also are converting campsites and military facilities into makeshift SARS isolation areas (“U.S. Anti-SARS Efforts Based on the Nation’s Fight Against TB” 2003).

Public Health Reporting

Worldwide lessons learned about suspected disease reporting and contact tracing have helped to stem disease outbreaks and to generate preparedness efforts in the U.S. In addition, cross-training of multiple types of public health staff to assist in the management of large-scale disease tracing was used to combat recent SARS epidemics and is a model to be implemented for training people in other occupations (social workers, teachers, etc.) in advance of an event (personal communication with Daniel Lucey, M.D., Washington Hospital Center, December 23, 2003).

Legal

The CDC and national health law centers are developing educational programs for judges on public health law, which cover a varied range of public health issues. The University of Louisville School of Medicine Institute of Bioethics, Health Policy, and Law is developing a program that involves 30 national organizations reaching agreement so they can run their own health law programs to include issues related to isolation and quarantine. The States that are piloting the program include Arizona, Texas, Wisconsin, New York, Mississippi, Michigan, and Indiana (personal communication with Mark Rothstein, J.D., University of Louisville School of Medicine, Institute of Bioethics, Health Policy and Law, January 7, 2004).

Future Research Needs

1. Develop real-time disease reporting technology to be used at and between health care facilities. This would allow providers to alert public health authorities of suspicious patient symptoms or actual disease detection at the time of the event. This technology must be easy to use and must have redundant communication outlets (Web, video, wireless). This will enhance communications and sharing of important diagnostic information related to persons involved in isolation and quarantine situations.
2. Create and preserve additional funding streams to support an increased number of public health personnel whose role it would be to discern early warning signs of illness.

Development of Models for Emergency Preparedness:
Personal Protective Equipment, Decontamination, Isolation/Quarantine, and Laboratory Capacity

3. Fund and develop technology for the short- and long-term surveillance of persons required to be isolated or quarantined. Systems need to allow public health practitioners to conduct surveillance and monitoring of persons who do not have telephone access, who have language or cultural differences, or who do not have a permanent residence (homeless).
4. Develop model templates for health care facilities so they, in turn, can develop intra-jurisdictional and regional mutual aid agreements and alternate patient transfer plans. These plans would allow health care facilities needing to isolate and quarantine patients to transfer less critically ill patients to non-affected facilities. Such plans would also allow for review of existing Emergency Medical Treatment and Active Labor Act (EMTALA) regulations to permit such patient transfers.
5. Develop clearly defined regulatory or legal mechanisms to address which parties are responsible for incurred costs of a private facility being isolated or quarantined by local, State, or the Federal government as part of an infectious disease or bioterror outbreak. This should also include recommendations and provisions to resolve financial issues of the private facility.
6. Develop PPE and in-house facility barrier protections (room dividers, negative pressure rooms, and the like) that will protect health care personnel and other first responders working in an infectious disease situation while permitting ease of work for the entire normal work shift. Develop PPE such as masks for patients and staff when respiratory or other communicable diseases are suspected. During disease outbreaks, staff shortages are a significant concern; having a diminished staff pool using PPE that makes it difficult for them to perform their tasks is likely to cause gaps in the disease containment process.
7. Develop models and practices to address the apprehension and anxiety of the health care workforce in working during an infectious disease or bioterror outbreak situation, including concerns about the use of PPE or other protective measures. These models need to include templates and models for localities, public health, and health care facilities so they will be able to respond to the fears of the health care workforce both during and after crisis situations.
8. Review State laws and statutes on isolation and quarantine frequently to address and minimize, where possible, variations in the ability of local and State jurisdictions to declare and enforce isolation and quarantine.
9. Develop additional models, templates, and practices from centers of public health law and other ethics institutes to educate and involve the judiciary and law enforcement personnel in concrete operational planning, standard operating procedures, and legal protocols when public health requests for isolation and quarantine measures occur.
10. Develop specific, realistic, operational-level quarantine model templates and plans for community level isolation and quarantine that reflect real U.S. resident culture. These models must include the use of home and work quarantine and not assume that

telecommuting or “snow days” are a viable option. These plans should be drilled and exercised in advance of an event and include the needs of special populations such as persons with language differences, addictions, special health needs or disabilities, and those who are homeless. These plans must include provisions to maintain continuity of life operations (income protections, job protections, food, shelter, and care for other family members who are not required to be placed in isolation and/or quarantine).

Model Components

As outlined in the discussion of best practices and further research needs, a best practice model for isolation and quarantine would be built upon the foundation of real-time suspected and actual disease reporting and information sharing between all public health departments and hospitals. Disease reporting frequently depends on having a laboratory-confirmed diagnosis of a particular illness and then having the health care facility report that disease to local or State public health departments. In the absence of rapid confirmatory technology to detect and diagnose infectious diseases such as SARS, or bioterrorist agents such as anthrax or plague, the practice of isolating patients will have to depend on the absolute compliance and adherence to precautions on the parts of both health care providers and patients. Syndromic surveillance models that identify certain symptom complexes and then refer trends detected at the health care provider level back to public health department show promise. However, until these systems can be adapted to gather data, disseminated to public health departments in real-time, and consistently have public health staff receive, analyze, and respond to this type of information, disease reporting systems will continue to have to depend on astute medical providers to make initial contact with public health departments. Funding for public health departments will have to include cross-training of additional staff to ensure 24 hour a day, seven days a week reporting coverage back to the health care providers.

Once a situation occurs that may require isolation of infected patients or quarantine of persons at risk for infection, facilities should have the capacity to adhere to standards such as those from the Association for Professionals in Infection Control and Epidemiology. Patients should be placed in isolation rooms, cohorted wings or wards of health care facilities, or rooms that have dedicated ventilation systems. The Canadian and Taiwanese models of creating additional surge capacity by building additional negative pressure rooms in their hospitals is a model that could be adapted in U.S. hospitals. Public sector financial supplements would be needed to accomplish this in the U.S. Current Office for Domestic Preparedness (ODP) and other public sector funding grants containing restrictions that do not readily allow for construction of isolation facilities should be revised to allow for increased physical surge capacity for health care facilities.

Models and practical steps for the operational legal aspects of public health departments to isolate and quarantine persons connected to disease situations have been collected at the CDC Public Health Law Program. State and local laws vary and therefore the procedural models to implement them could best be adapted if they followed the guidance steps outlined in the CDC’s SARS Legal Planning Fact Sheets of September 2003. The actual standard operating procedures for law enforcement personnel, however, have not been as detailed and should include early notification of potential isolation and quarantine situations. Identification of command center

locations and electronic monitoring (e.g. video conferencing, Web site sharing) between public health and law enforcement personnel should be outlined to ensure compliance with isolation and quarantine laws when voluntary compliance is not achieved.

A first-step model for community containment measures, including non-hospital isolation and quarantine, has been outlined in the CDC's Public Health Guidance for Community Level Preparedness and Response to Severe Acute Respiratory Syndrome, Version 2. Supplement D contains five appendices that detail suggested interventions, community containment, frequently asked questions about the use of community containment measures, guidelines for evaluating homes and facilities for isolation and quarantine, threshold determinants for the use of community containment measures, and a preparedness checklist for community containment measures. It is based on "lessons learned" from the community isolation and quarantine situations in the SARS outbreaks in Asia and Canada. In the absence of having access to the 50 U.S. State laws, the checklist is a productive first step for the operational aspects of implementing community-wide isolation and/or quarantine for hospital and public health staff. However, the checklist does not fully address the gaps identified in this document in terms of U.S. residents' attitudes toward voluntary or mandatory quarantine, particularly if the real-life mental health, income protections, continuity of life, and PPE concerns mentioned in this document are not addressed.

Guidelines for Building the Model

The following areas specify items that should be explored when developing a best practices methodology for dealing with biological terrorism preparedness planning:

Adaptability – Is the best practice suitable for use in any region?

Real-time disease detection, reporting, and surveillance between public health personnel, health care providers, and law enforcement personnel are suitable for use in any region. This type of communication permits rapid identification of the need for isolation and quarantine, and accurate assessment of the process to be used to contain the outbreak. The Hong Kong experience of placing public health disease surveillance information on SARS cases on their Web site and integrating this information into other aspects of the responder community brought critical responders to the disease containment effort and could be replicated in the U.S. Identifying additional physical surge capacity for negative pressure rooms is possible but would require further analysis for funding streams and mechanisms to provide the least disruption of currently used facilities while this revision occurs. It is possible to establish a common legal standard that protects the community and the health care workforce, as well as one that allows for individual due process. However, there would need to be agreement that protection of the public's health may have to temporarily supersede individual liberties; the person under isolation and quarantine would have the right to contest the order after the period of infectivity has passed.

Throughput – How many victims of a biological attack will the best practice aid?

Providing real-time disease detection and surveillance technology would diminish the transmission of infectious agents by allowing public health personnel and health care providers to quickly and realistically share critical data that would be used to implement isolation or quarantine control measures. Linking and integrating such technology with other responders, such as emergency medicine, law enforcement, and legal partners would further reduce the number of potential victims because additional responders would be able to assist in information dissemination to the public. Providing additional isolation and quarantine facilities would provide capacity to monitor and contain disease outbreak for significant numbers of the U.S. population who would not be able to remain under isolation and quarantine at home.

Cost – How much will it cost regions to implement the best practice?

Depending on the extent of the program adopted by particular regions, the cost for purchasing, maintaining, and staffing real-time disease diagnosis and surveillance technology could be significant. In addition, costs will be incurred for initial and in-service training for health care providers and public health staff using this technology. Although development of such systems is reportedly underway at the Federal level, it is important that creation of real-time reporting systems between local and State public health departments and health care providers occur in the immediate future. Funds should be allocated for this process immediately and its completion designated on a fast track so as not to jeopardize disease containment efforts. Funds must also be utilized to continually train and hire public health disease detectives and to maintain a strong infrastructure to not only quickly identify disease outbreaks, but to mitigate spread by increasing the distance between well and ill persons identified by real-time technologies. Each jurisdiction that receives Department of Health and Human Services (DHS) or CDC funding should also be able to access and be required to demonstrate access to multiple redundant communication technologies (Web, video conferencing, wireless) for this effort as a condition of funding. There should be sufficient staff to maintain these technologies and all staff must achieve competency in its use, or detection and containment will fail.

Operational Impact – What are the operational considerations of using this best practice?

The operational impact will initially be significant for creating such real-time disease detection and reporting technology. The ability to provide funding to support staff and responders to use it, to retrofit or create surge capacity for additional isolation rooms in health care facilities, and to have operational legal provisions that clearly declare isolation orders, rights of appeal/due process, and standard operating procedures for monitoring community level quarantine will also be significant. Specialized training is needed in order to participate and function properly in the event of a biological incident. However, by identifying systems, responders, and protocols in advance of a biological incident, training and cross-training multiple types of responders in advance of an outbreak or bioterror attack provides for less attrition of staff during an actual event. Recognition of and attention to various cultural challenges of implementing community quarantine and soliciting community involvement will promote

compliance with a public health quarantine order. The government will have to demonstrate the capacity to protect the workforce with sufficient PPE and other job-related supports and protect and support the community.

Training – What level of training does this best practice require?

When real-time disease diagnosis and surveillance technology between health care facilities and public health departments is created, staff will need to be trained in use of the various redundant communication technologies involved in the process (Web, wireless, and video). Training in the importance of information sharing between legal staff, law enforcement, emergency management, public health, and hospital staff is a relatively simple process and inexpensive models for forensic epidemiology currently exist. Forensic epidemiology training programs involve awareness of common practices by each of the provider communities and allow essential team building that will be useful in responding to a potential need for isolation and quarantine. Creation of additional physical locations for isolation or quarantine should require only minimal training of staff. Community education and training about the concepts of isolation and quarantine and how government and health care facilities can support the community during an outbreak situation or bioterror attack will be a challenge, but utilizing community input to develop risk communication messages in advance will greatly support community acceptance and maximize disease containment efforts. Training should include real-world operational aspects of “how this applies to the public” and should be practiced among all involved parties, public and private.

Resources – Does the practice build on existing practices/infrastructure? Are there available resources to implement the practices?

The practice of using real-time disease detection and reporting practices builds upon current relationships between health care facilities and public health departments. Priority funding from DHS appropriations in this area would foster and strengthen this relationship. Redundant communication devices have already been targeted by other “first responders” as a priority area for funding and training to protect public safety. The challenge is to move the end-point of development of such technology to a “fast track” status so public health personnel, hospital staff, and any other medical responders can act quickly to share information. Guidelines for community isolation and quarantine build upon recent experiences with disease outbreaks but need to be reviewed with respect to recent disasters as well.

The use of distance learning technologies, e.g. video conferencing for supporting large-scale community isolation and quarantine, builds upon distance learning technologies that have been successfully utilized in military field medicine and in disease treatment between urban and rural areas. It is known that most regions do not have an existing procedure for dealing with this issue and if one does exist, minimal equipment and personnel are available to perform necessary functions. This may result in additional challenges in assessing the community’s need for isolation and quarantine. Health care facilities should aggressively pursue this type of training and should capitalize on the opportunity to participate in inter-agency training, especially with agencies that offer subject matter expertise in this area.

Morbidity and Mortality – What impact will this practice have on saving lives?

Earlier disease detection results in earlier identification of persons needing treatment and earlier recognition of those at risk for disease. Community education about culturally sensitive plans for isolation and quarantine will promote disease containment practices by both health care providers and the public. In turn, this may result in the least possible restrictive isolation and quarantine procedures and the maximum containment of disease.

Evidence-based Practice versus Theory – Is there a body of professional research supporting this practice or is it theoretical?

A great deal of research has been identified with lessons learned from recent SARS outbreaks and bioterror attacks in the areas of isolation and quarantine. Current research and guidelines use community isolation and quarantine modeling based on cultures and populations that are less likely to challenge government authority than U.S. populations and on success stories from populations that are far less diverse and have less socioeconomic, language, racial, and cultural differences than the U.S.

Regulatory Compliance – Does the practice comply with existing regulations or does it require a regulatory change?

Currently there are no regulations to mandate the use of real-time disease diagnosis and reporting technology; of having a required level of staff capacity to conduct surveillance and monitor isolated or quarantined persons; or of specific legal/law enforcement training to address common statutes in the areas of isolation and quarantine. Health officials at the State and local levels generally have the authority to order isolation or quarantine when health conditions indicate. However, addressing gaps and shortfalls identified in this document's future research section may require regulatory change in the areas of patient transfer and in funding streams such as at the Office of Domestic Preparedness (ODP), Health Resources and Services Administration grants to allow for hospital/health care facility isolation and quarantine protection.

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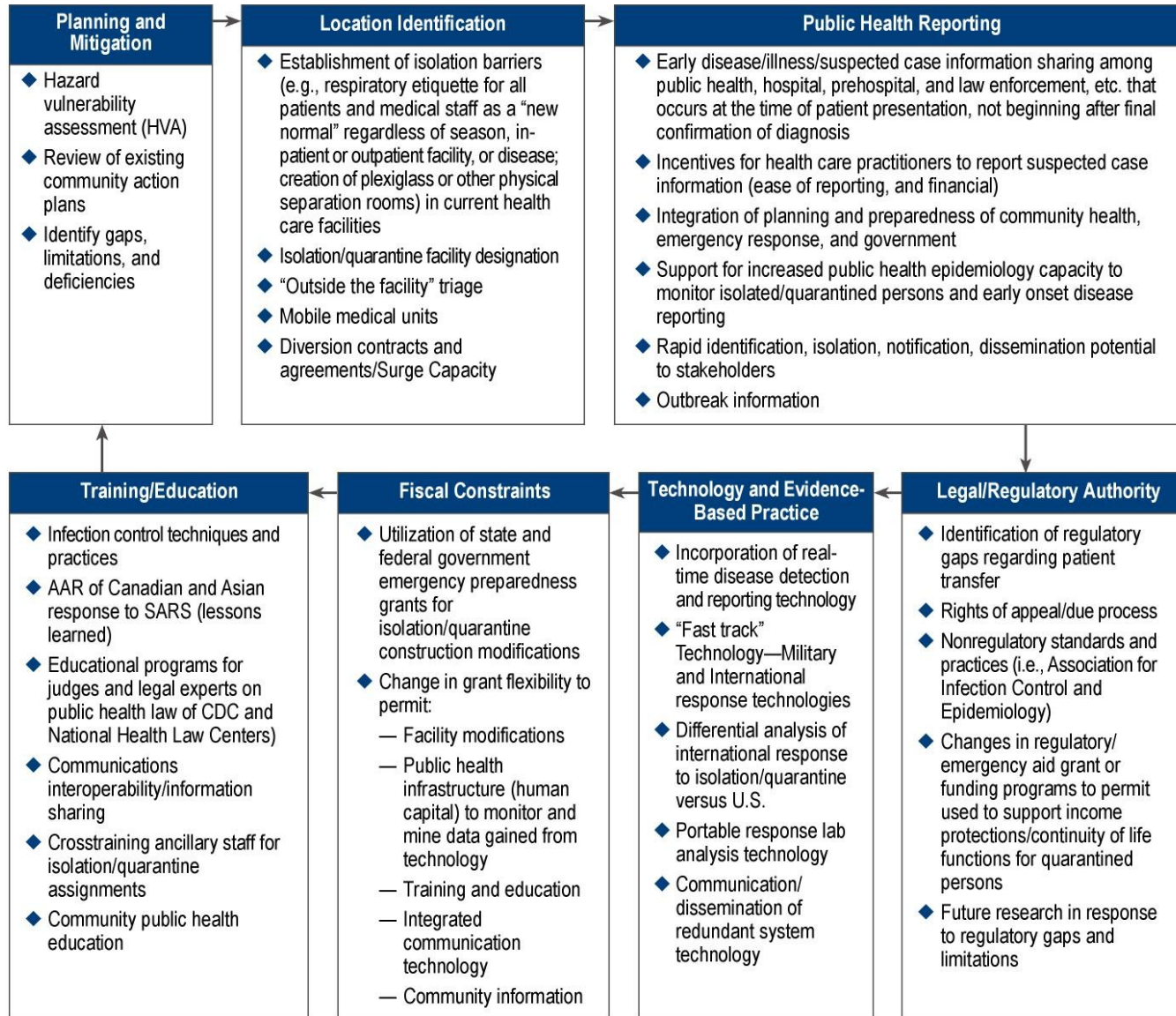
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Ch. 4 Appendix B. Isolation and Quarantine Best Practices Model for Plan Development



Chapter 5. Laboratory Capacity

Background

A biological attack could rapidly overburden State and local public health systems. Initial detection of an event would likely take place at the local level in clinical settings, such as emergency rooms, physicians' offices, and walk-in clinics, and in the field through the intervention of hazardous materials (HAZMAT) groups, National Guard Weapons of Mass Destruction Civil Support Teams (WMD-CSTs), and local first responders. To reasonably contain these casualties and reduce the time from a bioterrorism (BT) event to its detection, health professionals need the most applicable training, facilities, personal protective equipment, and tools to enhance their ability to diagnose diseases caused by BT agents, rapidly inform public health authorities of such events, and treat individual patients.

Laboratories play a critical role in the response to any bioterrorist (BT) event, as the timeliness, accuracy, and security of lab diagnostics will have a direct impact on the containment and mitigation of an incident and on the clinical treatment of victims. Surge capacity at the local, State, and Federal levels, however, remains alarmingly insufficient. There also is a profound dichotomy between the likely local nature of an initial response to the discovery of a suspect agent and the quality of the training, facilities, connectivity, and equipment in local "sentinel" labs. In addition, coordination of preparedness activities between Federal agencies, public health departments, and local labs still presents numerous challenges. Laboratory surge capacity issues urgently need to be addressed at the local, State, and national levels.

This section on laboratory capacity was reviewed at a meeting of subject matter experts (SMEs) at an Agency for Healthcare Research and Quality-sponsored stakeholder forum held in the Washington, D.C., area in April 2004. The section was revised based on comments at that meeting. Many of the experts also had further input, as noted throughout the section.

The primary audience for this set of guidelines and best practices is intended to be healthcare emergency planners at the Federal, State, and local levels. However, the analysis of gaps and shortfalls, as well as the recommendations and suggested best practices, include information pertinent to first responders, microbiologists, laboratory technicians, clinicians, laboratory directors, law enforcement, and State, local, and Federal agencies involved in either emergency response or allocation of BT funds.

These guidelines are provided in support of the Agency for Healthcare Research and Quality's (AHRQ) Bioterrorism Initiative at the U.S. Department of Health and Human Services (HHS). In light of the specific focus on agents of biological terrorism, an examination of emergency response protocols and laboratory standard operating procedures for terrorism involving chemical, radiological, nuclear, or explosive agents falls beyond the scope of this analysis and is recommended as an area for future research at the conclusion of our chapter. Whereas there is considerable overlap among guidelines in areas such as personal protective equipment, the procedures and equipment vary significantly in a laboratory context. Nonetheless, certain elements of our analysis – such as procedures for handling and triaging unknown environmental samples; connectivity and laboratory IT and communication

capabilities; and interagency communication – do have some relevance to preparedness and response targeted at other (non-biological) forms of terrorism, and may be useful to emergency planners in a broader context.

Lastly, defining the term "capacity" appropriately in the context of laboratory BT response poses significant challenges. This chapter includes a discussion of the lack of a current model for measuring and evaluating an individual laboratory's capacity to triage, handle, process, and refer environmental samples (as opposed to clinical samples), and provides a list of variables that would factor into the development of such a model. The guidelines and best practices provided below are thus better articulated as "Laboratory Capabilities", as this term encompasses all of the factors that influence and determine capacity, as well as other critical issues that govern emergency preparedness and response.

Biosafety in Laboratories

The primary purpose of biosafety in the laboratory is containment – to reduce or prevent exposure of laboratorians, others in the immediate area, and the surrounding environment to potentially hazardous agents. There are four biosafety levels (BSL): BSL-1 (lowest), BSL-2, BSL-3, and BSL-4 (highest): (*U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health 1999*)

BSL-1, the lowest biosafety level, is only suitable for work with non-pathogenic organisms and is used in undergraduate and secondary education laboratories. It therefore will not be included in this report.

BSL-2 practices, safety equipment, and facility design support work with clinical and diagnostic agents of moderate risk that are present in the community and are associated with varying levels of disease severity. Using good microbiological techniques, these agents can be handled safely for activities conducted on the open bench, provided the potential for producing splashes and aerosols is low. Even though organisms routinely manipulated at BSL-2 conditions are not known to be transmissible by the aerosol route, procedures that have potential for producing splashes or aerosols should be performed under a biosafety cabinet, and appropriate personal protective equipment – e.g., face cover, gloves, gown – should be utilized. BSL-2 conditions are appropriate when the presence of an agent may be unknown.

BSL-3 practices are employed in clinical, diagnostic, research, or production facilities in which indigenous or exotic agents with potential for respiratory transmission are handled that may cause serious or potentially lethal disease. This level is also appropriate for procedures that may produce aerosols or require high concentrations of agents normally manipulated under BSL-2 conditions. At this level, more emphasis is placed upon using primary barriers (e.g., personal protective equipment, biosafety cabinet [BSC]) and secondary barriers (e.g., controlled access, special air ventilation systems) to prevent contamination of personnel and the surrounding environment.

BSL-4 practices are appropriate when working with dangerous and exotic agents that pose a significant individual risk of life-threatening disease that may be transmitted by the aerosol route

and for which no known treatment or vaccine exists. There are currently only four operational BSL-4 laboratory suites in the United States: at the Centers for Disease Control and Prevention (CDC) in Atlanta; at the United States Army Medical Research Institute for Infectious Diseases (USAMRIID) at Fort Detrick in Frederick, MD; at the Southwest Foundation for Biomedical Research in San Antonio; and at the University of Texas at Galveston. A small BSL-4 facility exists on the National Institutes of Health (NIH) campus in Bethesda, MD, but it is currently being operated only at a BSL-3 level for research on important emerging infectious diseases (National Institute of Allergy and Infectious Diseases 2004). Therefore, BSL-4 facilities will not be covered in depth in this report.

An exception to these defined levels can be found in the 4th edition of *Biosafety in Microbiological and Biomedical Laboratories*, which allows that some existing facilities may not have all the features that are recommended for BSL-3. Under these circumstances, BSL-2 laboratories may achieve an acceptable level of safety to conduct routine BSL-3 procedures provided that the exhaust air is discharged to the outdoors, the ventilation is balanced to provide directional airflow into the room (negative pressure), access to the laboratory is restricted while work is in progress, and the standard microbiological practices, special practices, and safety equipment for BSL-3 are rigorously followed. This practice may be prohibitive, however, as an existing BSL-2 facility must be dedicated exclusively to BSL-3 until work is completed and the facility has been appropriately decontaminated.

In general, three elements of containment determine which biosafety level is recommended for specific agents: laboratory practices and techniques, safety equipment, and facility design. Laboratory practices and techniques comprise the standard microbiological practices used to manipulate microorganisms. Safety equipment, which acts as the primary barrier against select agents, includes BSCs, enclosed containers for transporting agents, personal protective equipment, and safety centrifuges. Facility design is considered a secondary barrier and includes controlled access, interior surfaces designed for easy cleaning and decontamination, and special air ventilation systems.

Most agents can be manipulated at more than one biosafety level, depending on the specific procedure being performed. For instance, procedures for isolating and identifying *Yersinia pestis* can be performed safely at BSL-2; however, manipulations that may produce aerosols, such as those required for antimicrobial susceptibility testing, should be performed at BSL-3.

The Laboratory Response Network

The Laboratory Response Network (LRN) was established in 1999 through the primary collaborative efforts of the CDC, the Association of Public Health Laboratories (APHL), and the Federal Bureau of Investigation (FBI). The LRN was established following a mandate from Congress aimed at protecting the United States from biological and chemical terrorism events, both by standardizing laboratory procedures across States and by formalizing a network of labs to respond to both overt and covert events. One of the primary goals of the LRN is to develop validated, national standard operating procedures for testing and referring potential BT agents, in order to accelerate the identification of these organisms in the event of a BT attack. Other functions of the LRN include providing reagents to confirmatory labs; disseminating information and communications (both routine and crisis) through broadcast emails; standardizing training;

administering proficiency testing for reference labs; compiling a directory of reference labs, including emergency contact information; and more.

Prior to the establishment of the LRN, standard operating procedures varied from facility to facility among the nation's public health, hospital, physician's office, and private laboratories, rendering a coordinated response virtually impossible, and increasing the risk of improper handling of high-risk samples.

Within the LRN, there are now three hierarchical laboratory levels. Laboratories occupy a level based upon training, facilities, equipment, and availability of secure Internet access. Most hospital and small city/county health department laboratories are classified as sentinel laboratories (formerly known as "Level A" laboratories). At this lowest level of the hierarchy, these laboratories have the ability to access widely available testing protocols to *rule out* BT agents. The American Society for Microbiology (ASM) originally developed and wrote the Sentinel Level Laboratory Protocols, which were reviewed by CDC representatives and are posted on several Web sites, including the ASM Web site and CDC Web site. If the laboratory is unable to rule out a specimen, it is referred to the next higher level, a reference laboratory (also known as a confirmatory laboratory, and formerly known as a "Level B" or "Level C" laboratory), for further testing to either rule out or *rule in* the specimen. Reference laboratories represent larger metropolitan city/county health departments, State Public Health Department Laboratories, and some military laboratories. Unlike sentinel laboratories, reference laboratories have access to secure LRN Web site information that provides advanced testing protocols and also allows laboratories to order special standardized reagents – which are necessary to perform these procedures – directly from the LRN. National laboratories (formerly known as "Level D" laboratories) are comprised of the CDC and USAMRIID laboratories. National laboratories operate at the most sophisticated level of engineering and safety measures and can perform high-level characterization of BT agents, provide confirmatory testing, and archive agents (Centers for Disease Control and Prevention 2005; Heatherley 2002; personal communication with Richard Kellogg, LRN Coordinator, Centers for Disease Control and Prevention).

All U.S. laboratories that perform microbiology testing are part of the LRN, since laboratories are required to report and refer select agents to State public health departments as a matter of routine practice. However, sentinel laboratories are not officially registered with the LRN as they only access basic protocols that are widely available for ruling out specimens. Reference laboratories are required to meet certain facility requirements in order to be registered with the LRN and to obtain secure Internet access to advanced protocols and standardized reagents. Reference and national laboratories must also be in compliance with the Select Agent Regulation, 42 Code of Federal Regulations (CFR) 73.0. This regulation establishes requirements for the possession, use, and transfer of select agents and toxins as listed in § 73.4 and § 73.5. Requirements address registration of select agents, security risk assessments, safety plans, security plans, emergency response plans, training, transfers, recordkeeping, inspections, and notifications. The Select Agent Regulation also provides specific criminal and civil penalties for violation of the regulations set forth (U.S. Department of Health & Human Services 2002). Compliance with this regulation also requires compliance with the U.S. Department of Agriculture (USDA) regulation (9 CFR 121) for those overlapping select agents that not only infect humans, but also are known animal pathogens (e.g., *Francisella tularensis*), and therefore fall under the auspices of both USDA and HHS.

While the LRN provides periodic training sessions and updates via secure Internet access, distributes funding to States, and implements proficiency testing with reference laboratories, it has no regulatory powers. As such, laboratories are not held accountable to the LRN for allocation of funds or time-bounded performance measures, such as results of proficiency testing challenges (personal communication with Richard Kellogg, LRN Coordinator, Centers for Disease Control and Prevention).

Gaps in Emergency Preparedness and Laboratory Capacity

In order to assess the gaps and shortfalls in laboratory capacity and identify best practices, Science Applications International Corporation engaged in an extensive review of laboratory materials and conducted research through open sources. We also interviewed a number of SMEs to cull specific stories and experiences from those "on the front lines" of laboratory management and defense. We asked a number of SMEs from different communities in the emergency response and laboratory spectrum to review an early draft of this chapter (March 2004). Finally, we organized a meeting of "stakeholders" from these communities (April 2004) to discuss the gaps, shortfalls, best practices, and recommendations contained herein and to provide further guidelines for discussion and analysis. A summary list of SMEs is provided in Chapter 1, Appendix A.

The criteria used to assess hospital, private, military, public health, and State laboratories are as follows (Association of Public Health Laboratories 2003):

- Personnel
- Funding
- Facilities/biosecurity
- Clinical laboratory connectivity
- Equipment/supplies
- Transportation/courier services
- Training
- Interagency communications.

It is nearly universally acknowledged that covert biological events will be detected initially at the local level. In that context, it is particularly important to assess the preparedness of sentinel laboratories (formerly Level A), which carry the responsibility of recognizing, ruling out, or referring potential BT agents. Sentinel labs are comprised of hospital, physician's office, and walk-in clinical laboratories, as well as private laboratories, and are equipped and trained only to

handle clinical samples. They are not equipped to triage unknown or mixed samples and have little or no surge capacity in the case of an unusually large influx of clinical specimens from hospitals or clinics. In this context, their understanding of when and how to rapidly and properly isolate and refer suspect samples to confirmatory labs will be critical. Many sentinel labs also require improvements in their connectivity and emergency communications capabilities and in their staff's clear understanding of courier constraints and chain-of-custody requirements.

Reference and national laboratories face the challenge of having to rely largely on their own resources in the immediate aftermath of a biological incident. There are external surge capacity resources at the national level – primarily of a military nature – including deployable public health laboratories, Mobile Analytical Labs (MALs), Dismounted Analytical Labs, Biological Integrated Detection Systems, and Analytical Lab Systems. However, these external resources would require time to deploy; therefore laboratories cannot expect additional resources to arrive for at least 36-48 hours. Additionally, mobile field laboratories such as WMD-CST MALs are focused on rapid field identification. Although they could provide a first evaluation, they are not suitable for confirmatory purposes. Thus the overall surge capacity they provide in support of reference and national labs remains modest at best.

In the event of a BT attack, no State or even national lab will have the surge capacity to meet the requirements of a sharp increase in incoming samples. Some experts have suggested that a solution might be to admit more private labs to the LRN as reference labs. According to one researcher, allowing just one or two private labs per State to act as reference labs (under the "control" of the LRN) would be sufficient to provide adequate surge capacity to respond to a local BT incident. This expansion of reference laboratory capabilities currently would be at the discretion of each individual State (personal communication with James Snyder, Ph.D., Department of Pathology, Division of Laboratory Medicine, University of Louisville School of Medicine). Most stakeholders and experts, however, caution against admitting private or clinical laboratories to reference lab status, because of concerns over the potential misuse (for private gain) of reagents and protocols designated specifically and uniquely for reference testing. Specific regulations exist prohibiting the private use of detection assays not approved by the U.S. Food and Drug Administration (FDA) for *in vitro* diagnostic use of clinical samples (personal communication with Richard Kellogg, LRN Coordinator, Centers for Disease Control and Prevention).

Before a sample arrives at a reference laboratory, it will frequently be handled and possibly tested by a HAZMAT group or WMD-CST. If a suspicious substance such as a white powder is discovered by a private citizen or if an accident triggers the spill of a noxious substance, 911 will be called and, generally, both the local Fire Department and a HAZMAT team will be deployed to the scene. Hazardous Materials Technicians are certified to handle equipment to contain, transport, and conduct basic field testing on biological materials. If there is any suspicion that the agent is of a terrorist nature, the State's Incident Command System (ICS) will go into effect and the Incident Commander will call in an initial response team from the State WMD-CST, who have a mobile field lab as well as capabilities for decontamination, emergency communications, operations, reach-back, and preliminary medical care. WMD-CSTs are trained to handle WMD and related materials; they are authorized by Congress, certified by the Department of Defense (DoD), and fall under the authority of the State's Governor (California National Guard 2000; U.S. Northern Command, Joint Task Force Civil Support, n.d.).

Like the military mobile labs, neither the HAZMAT teams nor the WMD-CSTs have the equipment or training to conclusively determine the precise nature of an agent or conduct definitive rule-out or rule-in testing. They would not serve as definitive laboratories to provide final confirmation of pathogens. A discussion of the current gaps and shortfalls in field testing (and specifically, the current uses of handheld devices) appears in the “Funding” section below. Any sample that is processed initially by a team in the field must be sent to the closest LRN lab for confirmatory testing and potential referral to a national lab or to law enforcement.

With this background, the following gaps and shortfalls cause great concern in the public health community and among laboratorians and should form the core of an urgent remediation strategy.

Handling an Unknown Sample

Many experts feel that the most salient gap in laboratory emergency preparedness is the inability of many laboratories to handle an unknown sample. Environmental samples are of particular concern, for several reasons. Locally, sentinel and private laboratories simply are not equipped to handle them and should not handle them (see discussion below). At the State level, many public health laboratories have equipment and space constraints, which curtail their ability to accept certain environmental samples. One illustrative example is that of a State public health lab that received an entire phone booth for testing, in the aftermath of the October 2001 anthrax mailings. Another example from the same timeframe is USAMRIID, which received rugs as well as numerous pieces of furniture, as well as thousands of smaller, more manageable samples. All in all, USAMRIID received close to 30,000 samples in less than nine months, and conducted more than 260,000 assays, growing from a 7-person to an 80-person lab.

Sometimes the problem is more complex. A major concern for State public health laboratories is the unknown status of environmental samples delivered to their doorstep. One expert recalls that he once received a stainless steel tube from first responders who had x-rayed it to ensure that no explosives were present, and were requesting that the tube be opened and sampled for potential BT agents. When laboratorians opened the container, a noxious green gas escaped – and even though the tube had been opened in a biosafety cabinet, the building had to be evacuated and emergency management personnel had to respond to the scene. There are numerous other examples of labs receiving samples from the field with requests for biological testing when they potentially contain chemical, radiological, or explosive materials as well or when the biological nature of the sample (animal, clinical, environmental, food-borne, water-borne, etc.) is undetermined. Field screening will not always flag these complexities. Receiving an unknown sample directly into a laboratory area from the field is simply not advisable.

Some experts have proposed a concrete solution to this gap for reference and national labs, which is to have a triage area in a separate building from the lab through which all samples must pass before entering the laboratory. Ideally, in addition to essential HAZMAT and biological agent triage capabilities, this area would provide a dedicated facility to handle chemical, radiological, and explosive samples – including, if possible, an explosive containment room and chemical hoods to handle nefarious gasses. It is clear that the latter facilities will be unrealistic for many reference labs, particularly in smaller States. As a further alternative, experts have suggested the implementation of equivalent mobile units, to be used for testing in the field. A central challenge would be securing funding for such facilities, a topic that merits further and

urgent exploration. The Department of Homeland Security has indicated its willingness to fund three or four prototypes of triage areas, potentially under the auspices of the Environmental Protection Agency (EPA), but concrete action has not yet been taken on this front. The FBI and FDA have some prototypes of mobile units, but their effectiveness is still insufficiently tested or proven.

In addition, some State public health laboratories, as well as national labs spanning the CBRNE spectrum – e.g., the U.S. Army Edgewood Chemical Biological Center, Lawrence Livermore National Laboratory, and USAMRIID – are beginning to develop protocols for unknown samples. The emerging guidelines focus first on the field screening process (for which current gaps and shortfalls are discussed below) and then on how to handle the sample safely once it arrives at the lab, without contaminating or killing lab staff.

In general, sentinel labs should never receive or test environmental samples. While currently no Federal regulation governs environmental sampling in a hospital/clinic/private laboratory, both SMEs and groups such as APHL and the LRN all strongly discourage it. Sentinel labs should not accept or handle such samples for several reasons. First, the exclusive focus of patient care centers (physicians' offices, hospitals, or clinics) should be to treat their patient population. Second, there is a strong possibility of contamination that would extend to the healthcare facility and endanger the lives of hospitalized patients, who already are at high risk of infection due to compromised immune systems. At the time of the anthrax crisis, there were many examples of State public health labs – all of which were allegedly prepared to handle "white powders" – that contaminated their facilities, and in some cases took several months to fully decontaminate. Sentinel lab staff are not trained nor are the labs equipped to handle environmental samples, including "white powders", and in some States (e.g. New York) are prohibited from doing so (personal communication with Ann Willey, J.D., Ph.D., Director of Policy and Planning, Wadsworth Center, February 27, 2004). Third, environmental samples are "unknown" and may contain a mixture of biological, chemical, radiological, or explosive agents. Such samples simply cannot be processed and tested in a healthcare facility with a patient population. Finally, sentinel labs do not have Select Agent status, and therefore cannot process a sample suspected of containing a select agent.

Environmental samples usually will be collected (and sometimes triaged and field-tested) by HAZMAT teams, WMD-CSTs, or local first responders. Following this initial handling, and assuming the sample is not determined to be chemical, explosive, or radiological, it should be taken by these teams (or transported via an authorized courier) to the closest reference lab. EPA labs, veterinary labs, and FDA labs currently play a smaller role in this general emergency response, although they are proactive in the case of zoonotics, food-borne illnesses, and infectious diseases. Many experts feel strongly that these labs should be integrated into the response plans of sentinel and reference labs and included in training exercises for BT events (personal communication with Mary Gilchrist, Ph.D., Vice President for Research, Hygienic Laboratory, University of Iowa); this area is recommended for further research below. For a flowchart of the pathway for handling both environmental and clinical samples in both routine and crisis scenarios, please see Model 1, *Model for Laboratory Capacity and BT Response Planning*.

A problem that plagued many first responders and sentinel labs during the 2001 anthrax attacks was not knowing where to send a suspect sample or how to handle a non-clinical sample. Many State laboratories had insufficient funding to be "open and on-call" 24 hours a day, 7 days

a week. The reaction of first responders who found a suspicious substance was to contact private labs for testing after hours, because State labs were not open (personal communication with James Snyder, Ph.D.). Fortunately, this situation has changed fairly significantly over the several years. All State public health labs now have 24/7 "call", so that a sample can be brought in at any time. Sentinel labs also now know who to call if they are "first receivers" of an unknown sample, and to what number they must redirect first responders who report a suspicious substance or specimen. More inclusive State-level training programs, meetings, and exercises will help States further increase awareness of emergency protocols and contact numbers among first responders, sentinel labs, and LRN reference labs.

Personnel

Shortage of personnel is one of the most significant gaps in laboratory preparedness at all levels. Clinical microbiologists certified by the American College of Microbiology (ACM) and other classically trained microbiologists have the necessary knowledge, skills, and abilities to use standardized protocols to rule out, identify, and perform further testing of BT agents. However, the United States is currently experiencing a shortfall in the number of ACM-certified and/or classically trained personnel working in clinical laboratories (personal communication with James Snyder, Ph.D.).

Perhaps of even greater concern for future requirements is that fewer and fewer qualified personnel are entering the field of microbiology or taking the coursework at the undergraduate university level. Neither universities nor the Federal government have addressed this issue. An interest in science needs to be inculcated in students beginning in grade school (personal communications with Scott Becker, Executive Director, Association of Public Health Laboratories; Rosemary Humes, MS, MT (ASCP) SM, Director, Infectious Disease Programs, Association of Public Health Laboratories; Chris Mangal, Program Manager, Emergency Preparedness and Response, Association of Public Health Laboratories; Jim Pearson, M.D., Association of Public Health Laboratories, Virginia State Laboratory. While a discussion of the specific incentives and academic curricula lies beyond the scope of this chapter, a recommendation for future research is made in "Future Research Needs" on page 153.

Compounding this shortfall, State public health laboratories are currently experiencing a significant retention problem, due largely to their low pay rates. State labs are able to recruit quality entry-level employees to whom they provide extensive and generally high-quality training. However, many of these entry-level employees move on after only two or three years with a State lab to more lucrative careers in private labs or with contractors (personal communication with James Snyder, Ph.D.). State labs thus experience tremendous turnover, because they cannot meet their salary requirements. They lose the staff they have spent time and money training before they are able to get a return on their investment in the form of staff productivity (personal communications with Scott Becker; Rosemary Humes; Chris Mangal; Jim Pearson, M.D.). State labs become a "training ground" for entry-level microbiologists and laboratory technicians. This revolving door phenomenon is costly to the labs. In addition, lower salaries mean that they have difficulty attracting "career" mid-level employees and quality senior staff.

Short-term BT funding also creates a significant challenge for those in charge of hiring personnel for public health laboratories at the State and local levels. In most States, allocations are made annually or for the duration of a specific grant. Appropriately trained and skilled microbiologists seeking permanent career opportunities will be unlikely to accept a position at these labs if they know that their job may be eliminated a year or even a few months later. This, in addition to the deficit in the number of classically trained microbiologists and medical technicians entering the field, makes it increasingly difficult for public health laboratories to attract personnel. Other personnel such as laboratory technicians, chemists, security guards, and IT specialists are also difficult to hire and retain because of these funding constraints (personal communications with Scott Becker; Mary Gilchrist, Ph.D.; Rosemary Humes, MS, MT (ASCP) SM,; Chris Mangal; Jim Pearson, M.D.; Ann Willey, J.D., Ph.D., February 27, 2004).

A final hiring and retention issue that primarily afflicts sentinel labs but can be an issue for some reference and State public health labs is geography. The pool of specialists is already small. If he/she can choose, a qualified microbiologist, lab tech, security guard, or IT specialist is more likely to go to an urban area with an agreeable climate than to a remote or unpleasantly cold location (personal communication with Ann Willey, J.D., Ph.D., February 27, 2004).

Another personnel issue that has a direct impact on laboratory capacity to respond to a BT event is the issue of vaccines for laboratory staff. The CDC has a program in place to recommend vaccinations, and States can access this information through the CDC, although not all States do. Some States also use Investigational New Drugs (IND) vaccines, which require special training to administer. Currently the only two Select Agent vaccines that are available are for smallpox and anthrax. USAMRIID does not have the funds to develop other INDs, a process that is very expensive – e.g., a single assay simply to test a vaccine for potency every two years costs \$70,000. In terms of obtaining and administering vaccines, it is often difficult for sentinel labs to convince State public health labs that they need to vaccinate their staff, even though the latter are included in emergency response plans and require protection. Healthcare, first responder, and laboratory personnel are vaccinated selectively, based on criteria determined by each State. In Iowa, for example, physicians, nurses, and smallpox response teams are vaccinated, but emergency management technicians and laboratorians are not. This is a serious potential impediment to lab capacity in a BT event and is an issue that State health emergency planners must address urgently as part of their general preparedness strategy; each State should execute a plan articulating who is to be vaccinated prior to an event. In addition to the microbiologists and technicians working in the labs, ancillary personnel such as maintenance staff should be considered for vaccination, as they are responsible for maintaining BSCs and other potentially tainted equipment.

A discussion of vaccines for the general U.S. population is beyond the scope of this chapter. Experts do note, however, that such a program is unlikely in the short term due to serious liability issues for the DoD. It is an issue that is being (and will need to be) handled at the White House level.

Other gaps and shortfalls related to personnel issues are discussed in the “Training” section below.

Funding

The primary concerns with BT funding are that it is short-term, often too generalized, and frequently thrown at projects or technologies that are neither validated nor effective. Short-term funding has serious implications for personnel recruitment and retention, as discussed above. It also has an impact on a laboratory's ability to conduct proper maintenance of its specialized facilities, a critical component of biosafety. While most BT funding is allocated to general preparedness activities, oversight of such funding is still focus-area-specific. Federal funding also is allocated primarily to human services and does not factor in important related activities, such as environmental laboratory concerns or veterinary issues related to zoonotic agents. As a result, for example, States that have smaller human populations but larger animal populations are not receiving commensurate funding for their biosecurity activities (personal communication with Mary Gilchrist, Ph.D.).

Funding problems also exist with private labs that currently compete for State monies or, if they are for profit, must abide by strict Federal Acquisition Regulations (FAR) and restrictions concerning private use of public funds. Even though private labs are not public health entities, their role is sufficiently significant that they are unquestionably part of the overall public health response mechanism. A funding model to be considered might be Federal funding earmarked for smaller or not-for-profit labs, a recommendation that also applies to veterinary labs and food labs, most of which do not currently receive specially-allocated Federal funds (personal communication with James Snyder, Ph.D.).

Another salient problem is that funding has been thrown at technologies or equipment that can aggravate a crisis situation rather than remediate it. An excellent example is field testing, where – from the confirmatory laboratory perspective – current approaches generate additional costs in both time and equipment. Specifically, the handheld devices that are in widespread use to test environmental samples are notorious for giving false positive results and are considered inadequate and unreliable by laboratorians. Although HHS has never endorsed these devices as a reliable way of providing definitive agent identification, other agencies that do not fall under HHS, as well as many first responders, still support their use.

Facilities/Biosecurity

There is significant consensus among experts that, in spite of improvements over the past few years, the laboratory surge capacity in the United States in the event of multiple BT events – or even a single but widespread event – is almost nonexistent. This is one of the central challenges that the LRN is specifically designed to address, and it has made significant progress.

A primary constraint for responding to a BT event is laboratory space. This is due not only to the equipment required to evaluate, test, and handle suspect samples, but also to the huge diversity of samples brought in during a crisis – ranging from compact swipes to entire pieces of furniture. A significant related concern is that, during an event, dedication of laboratory space for BT testing will severely inhibit the ability of a laboratory to perform its normal operations. Surge capacity must be sufficient not only to respond to a crisis, but to incorporate a laboratory's routine daily load. The notion of a triage area, discussed above, should be considered for future funding for all reference and national laboratories.

Space constraint is an important factor when calculating laboratory capacity and is the greatest limiting factor to throughput for both, not just for sentinel labs and, but also for reference labs. Capacity calculations, however, may be inadequate, particularly for environmental testing. They may not take into consideration "outlying" worst-case scenarios. For example, the capacity (personnel, equipment, and time) during the anthrax crisis to handle the receipt of the phone booth for testing at the Hygienic Laboratory at the University of Iowa cannot be compared to the capacity to test a clinical sample or an environmental swipe (personal communication with Mary Gilchrist, Ph.D.).

Capacity calculations for such a diversity of environmental samples are quite complex. Relevant variables include whether the potential agent is known; types of materials being sampled; laboratorian experience testing different types of samples; reliability of assays; whether new assays are being developed or are currently available; availability of equipment; options for secure transport; etc. In this context, using models that build on laboratory capacity for clinical samples – which has been attempted by some States – is not recommended, since environmental sampling and testing is vastly different from testing clinical specimens.

The issue of environmental testing in and of itself has not been adequately resolved in most States. Who should do the testing both at the time of a suspect incident and post-cleanup to verify that proper remediation has been effected? Should reference labs be using CDC-provided reagents for this purpose? These are examples of important questions that remain unanswered. In New York City, following the anthrax attacks, a whole cottage industry sprang up of groups who claimed to have the ability to conduct environmental assessments. Currently in New York, only five to seven labs are permitted to do environmental anthrax testing, and only two (the New York City and New York State public health laboratories) can handle "white powders." Other labs may only do swipes (personal communication with Ann Willey, J.D., Ph.D., February 27, 2004).

Some experts have argued that a solution might be to allow more laboratories to become proficient at testing environmental samples. However, validated protocols and procedures do not currently exist, and more research is needed to create standardized methods for processing environmental samples. As discussed above, first responders, sentinel labs, and State public health labs must have a clear understanding of the LRN's "rule-out or refer" concept of operations and of current chain-of-custody mandates and requirements. BSL-3 operations require moderate to high security, which is normally unavailable in sentinel laboratories (HHS 2002). Reference laboratories, on the other hand, are registered with the LRN and, as such, are required to possess select agent certification, have moderate to high security, and have a dedicated BSL-3 suite or BSL-2/3 suite (CDC 2005).

At the level of national and DoD labs, facilities are also insufficient. DoD labs are contracting out, rather than increasing the capacity of their own laboratories, even for routine testing missions. This means that in the event of a national crisis, such as what followed 9/11 and the anthrax mailings – when, for security reasons, contractors cannot be utilized for certain functions and all testing for DoD purposes has to be carried out by USAMRIID (and, to some extent, the Naval Medical Research Center)—these labs would be overwhelmed. In addition, the national labs are the only ones with equipment and trained staff for high levels of Select Agent and environmental testing, and they will be for the foreseeable future. Therefore, expanding the capacity of the DoD labs is essential. Even at the routine research and development level, more space is required in both DoD and national labs. Lastly, the amount of BSL-3 and BSL-4 space

for carrying out the research that is required for diagnostics, therapeutics, and vaccines is lacking, a fact that is recognized throughout the Federal government (personal communications with George Ludwig, Ph.D., Chief, Diagnostic Systems Division, U.S. Army Medical Research Institute of Infectious Diseases; Mark Wolcott, Ph.D., Chief, Special Pathogens and Field Operations and Training Branches, U.S. Army Medical Research Institute of Infectious Diseases.)

A final biosecurity concern, discussed below, is waste disposal for sentinel labs. Alternative medical waste disposals are available specifically for BT agents. Since it is unlikely that sentinel labs will deliberately propagate unusual pathogens – rather, they will only encounter them under extraordinary circumstances – most specimens would go through the standard waste stream. This is a serious issue that most States have not addressed either separately or as part of a holistic biosecurity strategy (personal communication with Ann Willey, J.D., Ph.D., February 27, 2004). Simply installing specialized autoclaves in sentinel labs is a suboptimal solution, since such autoclaves would be difficult for these labs to maintain.

Clinical Laboratory Connectivity

The electronic reporting mechanisms for moving information quickly and effectively between sentinel labs and public health labs are not well established. Many public health labs have connectivity neither within the lab itself or nor with external partners. While integrated information system solutions have been discussed, few have been developed or implemented. Most reference labs do not have robust enough lab information management systems to be able to capture or cross-reference data from multiple streams and matrices. This is especially problematic when the labs are dealing with different sample types in different carriers – air, water, waste, tabletops, dirt, etc. At the same time, raw data cannot be simply transferred to CDC, because of the risk of duplication, misinterpretation, and acceptance without validation. Transferring data to CDC also bypasses the State public health personnel who have primary responsibility for dealing with those data and the LRN procedures for reporting data (personal communications with Scott Becker; Rosemary Humes; Chris Mangal; Jim Pearson, M.D.). The CDC has provided funds for data systems that provide interconnectivity among State labs, but many of these systems are not yet implemented.

As a result, Web-based reporting systems usually have been created on the fly during crisis situations – as happened during events surrounding both West Nile Virus and Severe Acute Respiratory Syndrome (SARS) – and these systems are both limited and stovepiped. As data cannot be transferred electronically in real-time, it is frequently provided by telephone, which often leads to mistakes in transcription or interpretation. Even outside of a crisis, this lack of integrated connectivity is problematic. For example, most State labs are not aware of important and relevant research going on in the private sector (personal communications with Scott Becker; Rosemary Humes; Chris Mangal; Jim Pearson, M.D.).

Several issues arise from a dearth of information technology resources at many sentinel labs. For example, New York State has 270 sentinel labs outside of New York City, but only one third of these (roughly 80 labs) have Internet connectivity. This means that 66 percent of sentinel labs are not connected to the State Public Health Department electronically. A Health Resources and Services Administration (HRSA) grant has allowed the State to provide hospitals with electronic capabilities -- namely, hardware, software, and staff training – but not all private labs

have benefited. According to public health officials, however, the lack of Internet connectivity is not a funding issue, but rather a problem of both management and organizational culture (personal communication with Ann Willey, J.D., Ph.D., February 27, 2004).

The lack of Internet connectivity creates serious information management problems on many levels. These are particularly critical in crisis situations, as was illustrated during the evolution of the West Nile Virus outbreaks (personal communications with George Ludwig, Ph.D.; Mark Wolcott, Ph.D.). On a more basic and routine level, being "offline" prevents sentinel labs from enrolling in Statewide healthcare provider networks, so State public health facilities do not have current information on critical laboratory capabilities or deficits (e.g. assay or containment capabilities) for many of their laboratories. Labs that do have Internet connectivity can update their data regularly via a secure Web-based profile instrument (personal communication with Ann Willey, J.D., Ph.D., February 27, 2004). Even labs with connectivity experience information management problems with respect to resources such as the CDC's National Electronic Disease Surveillance System and Health Alert Network, because they are unaware of the timelines and steps being performed to implement these systems (personal communication with Mary Gilchrist, Ph.D.).

Connectivity becomes an even greater issue when you include not only the sentinel labs that are doing the rule-out testing, but also the physician's office labs that are handling routine clinical specimens. For example, there are 70,000 physicians licensed in New York State alone (personal communication with Ann Willey, J.D., Ph.D., February 27, 2004). Layered upon these concerns are HHS regulations that address the requirements of the Federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) and govern patient privacy. HIPAA regulations stipulate that any sensitive patient information – specifically, individually identifiable health information transferred via the Internet be sent only through a secure connection, and regulations also exist that govern the types of information that can be transferred. Therefore, sentinel lab Internet connectivity is not sufficient in and of itself to ensure full functionality, particularly in a sensitive crisis situation. Investment in information protection software and secure servers or encryption tools is also necessary. It should be noted that these HIPAA regulations also govern the appropriate uses of fax and voice communications for the transmission of individually identifiable patient health information (HHS 2005).

Several organizations are taking active steps to combat laboratory connectivity gaps. With funds from The Robert Wood Johnson Foundation, the Public Health Informatics Institute has launched several successful initiatives, including a new collaboration with State and local public health laboratories to develop a "comprehensive requirements document for public health laboratory information management systems" (LIMS). This project also received funding from APHL based on their 2002-2005 strategic plan. The project began in November 2003 and completion is anticipated for June 2004. So far, 26 State and local public health laboratories are participating. This project also builds on ongoing national standards efforts, including the Public Health Information Network and the National Health Information Infrastructure (NHII) (Public Health Informatics Institute 2003).

Equipment/Supplies

While the equipment used both for routine activities and for select agent testing is increasingly sophisticated and effective, many steps still remain to improve laboratory capacity

to respond to a BT event. Concerns range from equipment used by first responders to procedures in sentinel labs to a universal shortage of reagents used in reference and national labs. These issues require a variety of remedial approaches, and are discussed in greater detail below.

Most experts concur that a primary requirement for laboratory equipment (and BT emergency response equipment) is that it must, wherever possible, have dual-use applications. When equipment is purchased and dedicated solely to BT use rather than to dual-use or all-hazards purposes, the likelihood increases that laboratorians will be unfamiliar with it during an event. If personnel do not gain practical experience, time will be lost during an event while laboratorians familiarize themselves with the equipment (personal communications with Scott Becker; Rosemary Humes; Mary Gilchrist, PhD.; Richard Kellogg, LRN Coordinator, Centers for Disease Control and Prevention; Chris Mangal; Jim Pearson, M.D.; Ann Willey, J.D., Ph.D., February 27, 2004). Equipment not used in everyday practice also takes up valuable space in laboratories that already suffer spatial limitations.

Biosafety concerns, reviewed above, are also important when evaluating laboratory equipment and supplies. Specific equipment requirements for different BSL levels are discussed above. An additional biosafety constraint that tends to be specific to clinical laboratories is that while many of them have autoclaves on site, they do not use them for viable organisms and instead send these offsite for disposal. This is an important security and safety issue when working with potential BT agents and is discussed further in the Transportation section below (personal communication with James Snyder, Ph.D.).

Laboratorians have a number of concerns about the devices employed for field testing. Experts feel that these technologies should address the differing needs of first responders, laboratorians, and clinicians and the need to carry out both clinical and environmental testing (personal communication with Mary Gilchrist, Ph.D.). A more focused evaluation of the current research and development is urgently needed along with an acknowledgement of the importance of evaluating long-term investments concurrently with short-term solutions. Rapid pathogen or agent identification tools for first responders and first receivers will enable them to implement lifesaving medical actions and make rapid treatment decisions based on more than just presenting signs and symptoms, which may be vague and cause delays in patient care and responder protection. Many experts also recommend the establishment of Federal guidelines and regulations for these devices, including baseline tests for each type of instrument.

A final concern in this area is that laboratorians require a pristine sample that is also large enough to meet testing demands. Samples frequently are "used up" in the field, leaving none for the definitive, gold-standard tests performed in the confirmatory laboratory. Many experts have suggested that first responders need more guidance on the appropriate use and limitations of handheld devices, as well as clearer direction for proper collection and processing of samples. This training will vary depend on the nature of the field equipment developed, vetted, and utilized in the future; protocols for the correct handling of samples will be universal.

Finally, in terms of supplies, a significant problem cited by many experts is the current shortage of lab reagents for confirmatory labs. These reagents generally are provided by the LRN to participating laboratories, but supply is not sufficient. During the ricin scare in the summer of 2003, many labs could not obtain the reagents they requested from the CDC. One expert noted that the LRN is currently unable to meet even daily (routine) reagent requests. Some experts suggested the need to establish a national stockpile of lab reagents, similar to the current stockpiles of prophylactics and vaccines.

Transportation/Courier Services

A major gap in preparedness relates to the challenge of distinguishing a routine clinical specimen from a select agent or engineered pathogen before testing is completed. Public health providers send a clinical specimen on a patient suspected of having an infectious disease to a sentinel lab. If that specimen is found to be unusual, it is immediately sent to a public health reference lab. Most such samples are generally sent via the United States Postal Service (USPS) or via overnight courier (e.g., FedEx), depending on what is being sent. Delivery time thus ranges from roughly 24 hours to 2-3 days (personal communication with Ann Willey, J.D., Ph.D., February 27, 2004).

In the case of a BT agent, law enforcement agents may be responsible for taking over transport of the sample. There is currently significant confusion at the level of sentinel labs as to which transportation system they should use if a specimen is ambiguous. At a minimum, such a specimen should be labeled as an infectious substance and packaged accordingly. To remedy this shortfall, certain States (e.g., New York) are implementing State-wide training programs for sentinel labs, public health departments, and local hospitals concerning the packaging and shipping of ambiguous specimens (personal communication with Ann Willey, J.D., Ph.D., February 27, 2004). This training is critical to ensure that sentinel laboratories (as well as first responders) use appropriate, authorized, trained couriers in the event of a potential BT attack or when encountering infectious disease agents.

At the State level, bonded couriers whose services are not available to the public are specifically trained in the handling of potentially infectious substances. Sentinel labs must be aware of who these couriers are, so they do not give a suspect sample to the local entrepreneurial courier service who does not have adequate proficiency in handling such materials. There also are inconsistencies in the ways in which couriers interpret Federal regulations. For example, Virginia's State Public Health Lab has stopped using FedEx because of concerns about this issue.

Many States, have no mechanism for regular and timely delivery of isolate samples, even just from a hospital to a lab. If delivery is reliant solely on air travel, it will be paralyzed in the case of a broader terrorism emergency – and yet very few States have thought through alternative delivery vehicles for crisis response (personal communications with Mary Gilchrist, Ph.D.; Barbara Johnson, Director, Center for Biosecurity, STRA, Science Applications International Corporation; Ann Willey, J.D., Ph.D., February 27, 2004). Information to guide such thinking can be downloaded from the ASM and CDC Web sites, and specific packaging and air transport guidelines have been developed by the International Air Transport Association and appear on their Web site as well (<http://www.iata.org>).

Training

A fundamental training issue is the ability to detect BT agents and to distinguish them from routine clinical samples. Most laboratories, especially hospital and physician office laboratories, are unlikely to recognize BT agents without prompting from clinicians. Currently, most sentinel laboratories have not introduced algorithms into everyday practice that would aid in detecting potential BT agents. Guidelines for such algorithms are available on both the ASM and the CDC Web sites. State public health departments frequently offer training by providing periodic

updates on emerging diseases such as SARS, the avian flu, monkeypox, or West Nile Virus, as well as more general training materials (written by their staff) that are intended to supplement materials available from other sources, such as the CDC or LRN (personal communication with Ann Willey, J.D., Ph.D., February 27, 2004).

Training in the correct use of specialized laboratory equipment currently falls short of what would be necessary during a BT event. It should be noted that some select agents can be worked up at BSL-2, depending on the procedure being performed, and most clinical samples also can initially be handled under BSL-2 conditions. Though actual testing practices for BT agents are widely used for less potentially lethal agents, BT agents require use of a BSC hood and special personal protective equipment to prevent both self-contamination and environmental contamination.

Other special precautions, such as preventing aerosols and appropriately disposing of biological waste materials, must also be considered. All sentinel labs and most reference labs are equipped and funded, and their staff trained, for clinical diagnostics, not for environmental testing. Staff at many reference laboratories lack full understanding of how to carry out environmental testing – both at the pre-analytical level (what information to collect) and at the collection level (what collection method to employ – wet swabs or high efficiency particulate air socks, for example) (personal communications with Scott Becker; Rosemary Humes; Richard Kellogg; Chris Mangal; Jim Pearson, M.D.). During the 2001 anthrax attacks, many labs were unexpectedly thrust into that environmental role. Staff at many labs inadvertently contaminated their environment with anthrax spores, making them seem incompetent – which, ultimately, led to overall under-utilization of the reference laboratories during the crisis, the over-utilization of national laboratories, and to a shortfall in the U.S. capacity to respond (personal communications with George Ludwig, Ph.D.; Mark Wolcott, Ph.D.). A salient problem is that clinical laboratories simply do not have the necessary protocols to follow for processing environmental samples – and should not do so under any circumstances.

The challenges present in training State public health staff to handle unknown environmental samples in unusual contingencies can have deleterious consequences in any biological agent crisis, however small and localized. If a State identifies a suspect agent and the Governor says "test it," but the State labs don't have the methods, reagents, people, or training to carry out the testing, the consequences can be grave for both containment and decontamination. If a new pandemic (such as SARS) hits, and staff know what personal protective equipment to wear but not how to remove it afterwards, they can inadvertently contribute to the transmission of the disease (personal communications with Scott Becker; Rosemary Humes; Chris Mangal; Jim Pearson, M.D.; James Snyder, Ph.D.).

Many States have statewide proficiency testing requirements. The LRN also regularly performs proficiency training with reference labs, and their overall training support to States is excellent. Kentucky, for example, has taken strong advantage of LRN training sessions, which have included training for packaging and shipping isolates, similar to what has been provided in the State of New York by its Public Health Department (personal communications with James Snyder, Ph.D.; Ann Willey, J.D., Ph.D., February 27, 2004).

Overall, many experts point to the need for sustained, Statewide education and training for potential BT events as part of a regular, inclusive routine. If laboratorians are not used to working with certain types of equipment and following specific protocols in the course of their daily work, they will not be able to perform competently in a time of crisis. An outbreak or

emergency is *not* the time to train. Training sessions and educational programs for a BT event should include representatives not only from State and local labs, but also HAZMAT teams, first responders, and environmental labs. (New CDC chemical terrorism funding for all 50 States should help bring first responder communities together with laboratorians as well.) These sessions also should include an overview of the Incident Command System for that State, as many sentinel and reference laboratory staff members do not have a clear understanding of ICS. The more inclusive the Statewide programs, the more likely different stakeholders will be to perform better individually, work better collectively and understand each other's roles in a crisis. An expert from Iowa's State public health lab has noted that monthly meetings are held in her State that promote training and contribute to building trust between the different constituents (personal communication with Mary Gilchrist, Ph.D.). Such training will have the ancillary benefit of lessening the burden on public health laboratories – many of which are already underfunded and carry a large load of day-to-day activities – in the event of a crisis, as other receivers and responders will have a better understanding of when to refer a sample.

A related challenge, which is as much cultural as it is technical, is to train personnel to operate in a "law enforcement" context – rather than in a clinical context – in the case of a BT event. Public health personnel, and in particular laboratory personnel, are not accustomed to dealing routinely with matters involving criminal investigations, although they are trained to handle samples requiring chain-of-custody (with potential criminal charges), and they also are occasionally called upon to testify (personal communication with Barbara Johnson). The core challenge is providing laboratorians with an understanding of the law enforcement investigative process (to include ICS and the hierarchy of relationships, e.g., HAZMAT to WMD-CST to State Criminal Investigation to local police to FBI). Similarly, law enforcement organizations are sometimes uninformed about the realities of dealing with specific agents and organisms, and about the related routine requirements for laboratorians (personal communication with Barbara Johnson).

Though most investigative matters would not directly affect laboratorians, matters such as chain-of-custody and the proper shipment of isolates need to be addressed in the laboratory through continued – and possibly increased – training. A better mutual understanding of protocol could help resolve the tension between the laboratory's ability to carry out collaborative research and its need to lock down evidentiary material in the case of ambiguous agents. Several experts have suggested that regular joint exercises, which already take place in several States (e.g. Iowa), are one of the best ways to deepen the mutual understanding between laboratorians and law enforcement (personal communication with Barbara Johnson). This is particularly important since there are no set national procedures for chain of custody, which varies widely from State to State, and even between jurisdictions within States.

Finally, addressing their training and retention issues, several State public health officials have pointed to a dearth in information technology experience among their personnel. Many microbiologists and laboratory technicians have little or no experience working with complex information systems. At the same time, recruiting IT staff is challenging for State public health labs for the funding and salary reasons discussed above. An APHL expert has suggested that a basic understanding of laboratory IT issues, requirements, and procedures should be integrated into any instruction that laboratory personnel receive both academically and in the laboratory.

Interagency Communications

Although communication mechanisms and plans among State, local, Federal, defense, and LRN laboratories in the event of a crisis exist, details are sensitive and not public. The resilience of these mechanisms and plans remains largely untested and, in the opinion of many experts, questionable. This is one of the most significant and potentially detrimental gaps in laboratory emergency preparedness (personal communications with George Ludwig, Ph.D.; Mark Wolcott, Ph.D.).

Agency-specific parochialism is at least partially responsible and is difficult to overcome, because everyone wants to maintain their funding and status (personal communications with George Ludwig, Ph.D.; Mark Wolcott, Ph.D.). In that context, the environment for open and complete sharing needs to evolve. Changes need to be made at the State level in the area of oversight, which has a direct impact on both communications and funding. Food programs, agricultural diagnostic programs, and public health lab programs are all administered very differently at the State level, and yet they compete for funds (personal communications with Scott Becker; Rosemary Humes; Chris Mangal; Jim Pearson, M.D.). An interagency communication matrix that gives one agency more political muscle than another can be damaging to the public health infrastructure.

Even at the Federal level, emergency communication protocols are lacking. During the anthrax episodes of 2001, there was no formal Incident Command process between the U. S. Department of Justice (DOJ) and USAMRIID because USAMRIID's usual mandate is research and development, not emergency response (personal communications with George Ludwig, Ph.D.; Mark Wolcott, Ph.D.). Progress has been made in this area but most experts concur that much work remains. In addition, and somewhat surprisingly, the EPA has no current funding for BT activities. This issue is causing significant debate in laboratory circles, particularly due to the concerns over the handling of environmental samples. One expert also noted that some attempts at the State level to be included in Federal working groups were ignored, even though the State public health laboratories are expected to be major players in the event of a BT attack.

The LRN and the national and defense labs share routine information frequently. Many LRN assays were evolved from DoD models, although LRN assays were developed specifically to ensure that standardized testing methods would be followed. The LRN and DoD labs at the national level may use different protocols for assays, because the level of testing may differ between DoD and the CDC (personal communications with George Ludwig, Ph.D.; Mark Wolcott, Ph.D.). In addition, there is no Federal guidance on environmental samples. The CDC, EPA, DoD, and Congress have yet to agree on procedural or funding issues, aside from the very limited Biowatch environmental surveillance project, which is focused exclusively on the passive monitoring of select urban areas (personal communications with Scott Becker; Rosemary Humes; Chris Mangal; Jim Pearson, M.D.).

In the context of interagency collaboration on surveillance, experts also point to the controversial USPS Biohazard Detection System (BDS), set up in the aftermath of the anthrax mailings and aimed at providing a "scientifically valid approach" to detecting threats in the mail. The automated system is designed to shut down all operations if a biological agent is detected. However, following testing in 15 pilot sites, the USPS halted further deployment of the machines in April 2004 after several sorting lines yielded "non-determinant" (inconclusive) test results (U.S. Postal Service 2004). As with Biowatch, experts are concerned about the high incidence of

false positives, particularly if the program spans all 283 main USPS mail processing and distribution plants.

Lastly, HRSA has had little involvement with States to assist with sentinel lab connectivity or other sentinel lab capacity issues. As a result, the guidance and support of the State Cooperative Agreement are not reaching sentinel labs (personal communications with Scott Becker; Rosemary Humes; Chris Mangal; Jim Pearson, M.D.).

“ Worst Practices ”

Before presenting guidelines and “best practices,” it is necessary to emphasize the danger of laboratories ignoring or not knowing protocols and procedures. Every expert who was interviewed for this chapter or who attended the Stakeholder Meeting in April 2004, pointed to “worst practices” he or she had encountered in his or her experience with sentinel, reference, and national laboratories, or as a public health official. This ignorance or lack of information on the part of a public or private laboratory or first responder group – particularly in a time of crisis – could result in casualties.

Examples of “worst practices” that have been encountered by experts include:

- Laboratories purchasing reagents not approved by the CDC from private companies instead of obtaining them from the LRN;
- Private (for-profit) laboratories claiming that they had the ability to carry out environmental assessments and/or to test “white powders”;
- HAZMAT teams or first responders bringing environmental samples to sentinel laboratories or bringing untested materials through reference laboratory doors;
- Labs growing a known select agent or pathogen *in vitro* but not reporting it to the CDC for days or weeks. In one case, a strain of monkeypox was not reported for 12 days because the laboratory, which was well-equipped and had highly trained staff, assumed it could handle it “on its own”

Best Practices, Recommendations, and Guidance for Reference and National Laboratories

Based on the gaps and shortfalls identified above, and on the input from SMEs and our independent research, we propose the following set of best practices to form the basis of a preliminary guideline for laboratory emergency preparedness. As the needs, requirements, and functions of sentinel labs differ from those of reference and national labs, we have separated our recommendations into two sections.

Best practices for reference and national laboratory capacity include:

Personnel

1. Staff practiced and proficient in the use of LRN protocols, use of LRN reagents, and BSL-3 practices and procedures (personal communications with Scott Becker; Rosemary Humes; Chris Mangal; Jim Pearson, M.D.).
2. As an ideal target, at least two doctoral-level scientists on staff with laboratory medicine experience, although this is not necessarily realistic and will vary from State to State, depending on size and population (personal communications with Scott Becker; Rosemary Humes; Chris Mangal; Jim Pearson, M.D.).
3. At least one full-time information technology specialist to manage laboratory information systems (personal communications with Scott Becker; Rosemary Humes; Chris Mangal; Jim Pearson, M.D.).
4. At least three laboratorians able to perform Real-time PCR, Time-Resolved Fluorescence, and confirmatory testing of bacterial Category A select agents.
5. Consultants from other confirmatory labs. Written agreements should be made by State labs to address surge capacity needs (not just for BT, but also for epidemics), to allow the samples to move out of State, and to ensure sufficient numbers of qualified microbiologists trained to perform BSL-3 procedures should an emergency occur (personal communications with Barbara Johnson; James Snyder, Ph.D.).
6. Mutual aid agreements between neighboring States should be implemented (personal communication with Barbara Johnson). The CDC has Memoranda of Agreement (MOA) with States, which could potentially be used to provide an appropriate legal framework for such documents.
7. The CDC can detail out laboratorians on a short-term basis to fill critical needs (personal communication with Barbara Johnson).
8. A Statewide vaccination program should be considered for all first responders and laboratory staff potentially coming into contact with select agents, including maintenance staff.

Funding

1. Long-term funding for personnel should be provided in order to attract qualified candidates (personal communications with Scott Becker; Mary Gilchrist, Ph.D.; Rosemary Humes; Chris Mangal; Jim Pearson, M.D.).

2. Long-term funding for BSL-3 and BSL-4 research and development also should be provided in order to ensure the availability of appropriate laboratory space for surge capacity during a BT event (personal communications with George Ludwig, Ph.D.; Mark Wolcott, Ph.D.).
3. States should contribute a minimum of 40% of laboratory budgets to ensure proper capacity (Trust for America's Health 2003).
4. Funding must go both into upgrading labs to the BSL-3 level and into sustaining labs that have upgraded to BSL-3 standards so that they do not go unused at that level simply because they cannot afford the maintenance (personal communications with George Ludwig, Ph.D.; Mark Wolcott, Ph.D.). The LRN should work with States to tie its funding to satisfactory proficiency testing results (personal communication with Richard Kellogg).
5. Zoonotic agents should factor into Federal funding considerations for smaller, more agricultural States (e.g., Iowa) (personal communication with Mary Gilchrist, Ph.D.).
6. Federal oversight – or at a minimum, clear guidance – should be required for State funds to ensure that public health monies are allocated judiciously to State public health labs, veterinary labs, agricultural labs, and forensics labs based upon need (personal communications with Scott Becker; Rosemary Humes; Chris Mangal; Jim Pearson, M.D.).

Facilities/Biosecurity

Ideally, each State should have at least two reference laboratories with dedicated BSL-3 or BSL-2/3 facilities (Campbell 2002) that meet standards consistent with those published in the 4th edition of *Biosafety in Microbiological and Biomedical Laboratories* (personal communications with Barbara Johnson; Richard Kellogg; James Snyder, Ph.D.). One reference laboratory may be sufficient for some States.

1. All reference laboratories should meet Select Agent requirements. Implementation of the Select Agent requirements should be focused on improved personnel identification measures and sophisticated control measures that extend beyond locks (personal communication with Barbara Johnson).
2. Laboratories must have autoclaves on-site for waste disposal.
3. In order to cooperate effectively with law-enforcement, national labs and select reference labs must have the appropriate security, tamper-proof materials, and tight login entry abilities. Reagents should be computer-based, including order, receipt, lot, quantity, date opened, and amount used, so that when a laboratorian mixes a reagent, he/she knows exactly where it came from and how to troubleshoot any problems (personal communication with Barbara Johnson). A Clinical Laboratory Improvement Amendment

(CLIA) requirement already exists for labs to maintain a record of reagents as part of their quality control documentation, but this requirement would be enhanced if its implementation could be computer-based.

4. To aid in the processing of unusual or excessive environmental samples, a triage area should be set up in a separate building from the lab, to prevent non-biological or unknown samples from crossing the laboratory threshold. If funding permits, this area would provide a dedicated facility to handle chemical and radiological samples, and possibly explosive samples, in addition to diverse biological samples.

Clinical Laboratory Connectivity

1. Each State should have a complete list of all clinical and diagnostic laboratories located in the State (personal communications with Scott Becker; Rosemary Humes; Chris Mangal; Jim Pearson, M.D.).
2. Each State should distribute contact lists and algorithms to each hospital laboratory and private laboratory (including physicians' offices and commercial laboratories) within the State. These lists should include locations of State and Federal laboratories with 24-hour/7-day contact information.
3. State and local public health laboratories should consider participation in the Public Health Informatics Institute's collaborative program to establish requirements for a public health LIMS.
4. Laboratories should ensure that their uses of information technology are HIPAA-compliant.

Equipment/Supplies

Equipment should be for dual-use for personnel to achieve proficiency with procedures and to maximize use of limited space (personal communications with Scott Becker; Mary Gilchrist, Ph.D.; Rosemary Humes; Richard Kellogg; Chris Mangal; Jim Pearson, M.D.; Ann Willey, J.D., Ph.D., February 27, 2004).

1. Laboratories should, at a minimum, have the following equipment: BSC Type IIB (full or partial exhaust), Phase Contrast microscope, Fluorescence Microscope, Real-time PCR unit, centrifuge, incubator, -70°C freezer, and water bath (Florida Department of Health 2002). HAZMAT team, WMD-CSTs, and military rapid response units can play a support role to the LRN with their mobile RT-PCR units. They can rapidly deploy to the site of an event and provide preliminary field testing in the case of a BT event (personal communication with James Snyder, Ph.D.). However, the field equipment currently used by such teams and mobile labs – in particular, handheld devices for testing environmental samples – has a high yield of false positives, and all samples tested in the field will need to be retested by confirmatory labs for definitive rule-out or rule-in results.

2. A more comprehensive stockpile of reagents should be made available from the LRN for select agent testing.

Transportation/Courier Services

1. Arrangements and agreements should be made with State courier systems to ensure sustained and timely delivery of isolates to reference laboratories. Efforts should be made to ensure delivery from a sentinel laboratory to a reference laboratory within a few hours of notification that a potential BT agent has been isolated.
2. If existing courier and transportation services are unable to provide quick and reliable delivery of potential agents, alternate delivery methods should be put in place in advance to be deployed only in the event of an emergency. One possibility is an agreement with National Guard forces (Mothershead, Tonat, and Koenig 2002).
3. Only bonded or authorized Statewide and national couriers with the appropriate training should be employed for the transport of ambiguous samples or select agents. Law enforcement may also be brought in as a courier (and custodian) if a sample is confirmed as being of a BT nature or is otherwise associated with criminal intent.

Training

1. At least one full-time State laboratory training coordinator should be present in each State (Campbell 2002).
2. At least one full-time BT State training coordinator should be present in each State (APHL 2003).
3. At least one simulation exercise that involves at a minimum one Category A surrogate agent should be conducted each year. Exercise assessments should be based on laboratory readiness and capability from intake prioritization, identification and confirmatory tests results, and the reporting of results via the LRN Web site.
4. Regular training courses and tabletop exercises involving laboratories and using surrogate agents should supplement the simulation described above (personal communication with Richard Kellogg)..
5. More BSL-3 training should be implemented. Labs also need to identify trained staff who can act as instructors in select facilities (personal communications with Scott Becker; Rosemary Humes; Chris Mangal; Jim Pearson, M.D.).
6. CDC-sanctioned BT training should be exempt from SAP and USDA restrictions.
7. The CDC should develop a basic laminated reference manual for specific tests for suspect agents that can be distributed to all LRN reference labs and possibly another version

made available to sentinel labs. (The information for such a manual is already available on the LRN Web site, but sentinel laboratories do not have online access to this restricted, private site.) An online version of this manual that can be downloaded to a personal digital assistant should be developed concurrently with the laminated reference guide (personal communication with Barbara Johnson). Funding is not currently allocated for this activity; however, the process is relatively inexpensive and a combination of LRN and Federal funds potentially could be used.

8. Reference labs should participate in Statewide training programs with other first responders as well as law enforcement agencies, to address joint emergency response protocols, State and local chain-of-custody requirements, and State and local ICS, and to build mutual trust and personal relationships between the different emergency response communities.

Interagency Communications

1. Reference laboratories should identify and communicate with other relevant local, State, and Federal groups, including other public health organizations, civil support teams, HAZMAT teams, law enforcement agencies, and other local first responders; State emergency management agencies, environmental agencies, and State National Guard Bureaus; and the Department of Defense, FBI, and the Federal Emergency Management Agency (FEMA).
2. State public health departments should also establish their own independent networks. Iowa has taken steps to set up a regional support system for testing isolates with other North-Central States (North Dakota, South Dakota, Nebraska, Kansas, Minnesota, Missouri, Wisconsin, Illinois, Indiana, and Michigan). Their goal is to be prepared to act alone if necessary, but to be able to act in concert if possible. They are creating lists of what each health department specializes in according to testing capabilities, facilities, and personnel (personal communication with Mary Gilchrist, Ph.D.).
3. Notification algorithms should be available to all reference laboratories and should be activated and verified on a quarterly basis.
4. The LRN should integrate veterinary laboratory testing into its matrix (personal communication with Mary Gilchrist, Ph.D.).
5. Interagency integration of data should be attempted between the LRN, the FDA's Food Emergency Response Network, and the Veterinary Diagnostics Laboratory's new network, as well as other parallel emergent networks (personal communications with Scott Becker; Rosemary Humes; Chris Mangal; Jim Pearson, M.D.).
6. The national labs should work with the LRN to establish general acceptance of multiple assay protocols and procedures that meet specific performance criteria (personal communications with George Ludwig, Ph.D.; Mark Wolcott, Ph.D.).

7. All reference labs should be familiar with the Incident Command System and with their local chain-of-custody requirements.

Best Practices, Recommendations, and Guidance for Sentinel Laboratories

A core best practice for sentinel labs is to ensure that they only handle clinical samples and under no circumstances accept environmental samples or mixed samples for testing. Such samples should be referred immediately to the closest confirmatory reference lab. Similarly, if a clinical sample cannot be conclusively ruled out, it should also be referred to the appropriate State public health laboratory for further testing. The core reasons for this critical best practice are discussed on page 127; the greatest concern is that a clinical facility might become contaminated and not only put a patient population at risk, but also require lengthy decontamination procedures.

Other best practices for sentinel laboratories are recognizing potential BT agents for referral; identifying the closest reference laboratory prior to an event; retaining the chain-of-custody and becoming familiar with law enforcement requirements and protocols; understanding both routine and crisis shipping procedures and having a list of authorized couriers in a format that is readily accessible; participating in State-run exercises; and enrolling in the new College of American Pathologists (CAP) Lab Preparedness Survey proficiency testing program, if feasible, or in training programs developed by the National Laboratory Training Network (NLTN). Specific details on sentinel lab best practices are discussed below.

Personnel

In the event of a BT attack, personnel who are certified in routine testing should be available to assist with shift work to provide surge capacity to reference laboratories for routine tests such as TB or HIV, which the confirmatory labs will not be able to handle in addition to their rule-in BT testing (personal communications with Scott Becker; Rosemary Humes; Chris Mangal; Jim Pearson, M.D.).

When they encounter a suspicious agent, clinical laboratorians should be freed of the restraints of requiring a physician order to initiate investigatory testing. Federal funding should support this enhancement to BT preparedness, to avoid insurance conundrums. Such funding would have the ancillary benefit of contributing to an active surveillance program of random high threat agent screening on suspicious diagnoses – for example, a certain small percentage of patients presenting with "fever of unknown origin" and respiratory symptoms would be automatically screened, with the cost deferred to a Federal surveillance budget, and patient information protected by HIPAA (personal communication with Bettina Stopford, R.N., Director, Public Health and Medical Emergency Preparedness, Science Applications International Corporation, Justice and Security Solutions Group, March 2004). This is akin to other syndromic surveillance programs currently in effect across the United States and specifically in cities such as New York, where sentinel lab personnel play a significant role.

Funding

Many private laboratories are for-profit entities that do not – and, some experts argue, should not – receive State (or Federal) funds. Other hospital labs and small local public health labs require State funds, particularly for investments such as supplemental training, information technology upgrades, and specialized equipment. Such laboratory funding could be contingent on specific qualification criteria and appropriate time-bound performance measures or on proficiency testing performance. "Public" annual report cards submitted to the Governor could allow problems to be addressed at the State level with labs being held accountable for the funding they request (personal communication with Richard Kellogg, LRN Coordinator, Centers for Disease Control and Prevention).

Several experts suggest that alternative funding mechanisms should be considered for BT funds. As discussed previously, the short-term nature of most BT funding has caused significant human resources issues for labs seeking to attract quality personnel. One notable exception is New York State, which has managed to circumvent some of the short-term funding issues by channeling all funds through a not-for-profit corporation, founded 20 years ago, that receives funds on behalf of the New York State Public Health Department. BT funds are awarded to the nonprofit corporation and segregated from other State funds. New York is in its fourth year of such BT funds, and is not constrained by a short-term focus. The employment of quality personnel is contingent only on the life of the grant to the not-for-profit corporation (personal communication with Ann Willey, J.D., Ph.D., February 27, 2004).

Facilities/Biosecurity

As most sentinel labs do not have BSL-3 capabilities and do not have the necessary waste disposal and containment equipment in place, their best biosecurity practice will be to clearly understand and apply the LRN "rule-out or refer" concept of operations. Sentinel labs with access to funding should not spend monies building BSL-3 facilities or acquiring specialized autoclaves or other containment and disposal equipment; as they only perform rule-out testing, they do not require such investments. Sentinel labs must have contingency plans for maintaining control of and protecting evidence in the event they encounter a select agent and must establish a clear and documentable procedure for chain-of-custody that meets law enforcement standards (personal communication with Barbara Johnson).

Sentinel labs are exempt from the Select Agent requirements (42 CFR 73) (personal communication with Barbara Johnson). Per these requirements, however, they will only remain exempt if they transfer or destroy any select agent they encounter within seven calendar days after identification has been confirmed unless otherwise directed by the FBI or by another law enforcement agency and following consultation with the HHS Secretary (HHS 2002).

Clinical Laboratory Connectivity

Internet connectivity should be a significant priority for sentinel labs, to allow better training, better communication with both State public health departments and Federal agencies, better reporting during a crisis or for syndromic surveillance purposes, and better tracking of patients.

Sentinel labs should establish Internet connectivity and ensure that they comply with HIPAA regulations concerning patient confidentiality and the secure transmission of any individually identifiable health data.

"Online" labs should enroll in Statewide healthcare provider networks so that State public health labs have current and accurate data on their capabilities and needs (personal communication with Ann Willey, J.D., Ph.D., February 27, 2004).

Equipment/Supplies

The routine testing carried out by sentinel labs is not equipment-intensive, and therefore, as noted above, additional equipment should not be a primary concern for those labs, particularly those dependent on State funds for their daily operations (personal communication with Ann Willey, J.D., Ph.D., February 27, 2004).

As frequently as possible, equipment should be for dual-use purposes to maximize use of limited space and ensure that personnel achieve sufficient proficiency with procedures to avoid attempting to master new equipment during a crisis (personal communications with Scott Becker; Mary Gilchrist, Ph.D.; Rosemary Humes; Richard Kellogg, LRN Coordinator, Centers for Disease Control and Prevention; Chris Mangal; Jim Pearson, M.D.; Ann Willey, J.D., Ph.D., February 27, 2004). The only caveat would be that sentinel labs must remain mindful of FAR clauses governing the private use of public funds, as discussed previously.

Transportation/Courier Services

Sentinel lab personnel must know about packaging and shipping of suspect samples and about alternative transportation methods in a crisis. Each lab should have a reference document or manual on these topics. This information can be downloaded from the CDC or ASM Web sites, and also can be provided via mail or fax by State Public Health Labs (personal communication with Barbara Johnson).

Sentinel and private labs should also ensure that they use only authorized couriers for the transfer of suspect clinical samples to reference labs. An authorized courier is either a HAZMAT or first responder unit with the appropriate experience or a bonded courier who is trained to handle potentially infectious substances. Certain national couriers, such as FedEx, also are specifically equipped to handle select agent samples. If there is any suspicion that a sample might be a BT agent, law enforcement agents may be called in to act as both the custodian and the courier for the sample, depending on chain-of-custody requirements. Sentinel labs should never entrust a sample to a local, unproven courier.

Training

To be able to provide routine testing surge capacity in support of State public health laboratories during an emergency, sentinel lab staff should receive training to perform non-BT testing that falls outside their regular routine. They should be trained in standard testing protocols, since Select Agent regulations prohibit them from engaging in BSL-3 work at their regular (sentinel) lab, and certification is laboratory-specific (U.S. General Accounting Office 2001; personal communication with James Snyder, Ph.D.).

Representatives from sentinel labs can and should participate in meetings and exercises organized by State public health labs, and should also be familiar with their local law enforcement, HAZMAT, and WMD-CST points of contact. In addition, "Adopt-a-Lab" programs can allow local and regional meetings of representatives from sentinel labs to discuss new concepts and requirements, testing procedures, and general emergency preparedness challenges. These meetings can include reference labs as well. Louisville, KY, has implemented this program very successfully for labs within a 50-mile radius (personal communication with James Snyder, Ph.D.).

Where funds allow, sentinel laboratory staff should be provided with basic IT training and education about online emergency communication protocols, as well as related HIPAA regulations.

Interagency Communications

On a related issue, sentinel labs must have the capability of receiving both routine and emergency guidance either through e-mail or, if the lab is not online, through broadcast fax (personal communication with Ann Willey, J.D., Ph.D., February 27, 2004).

Both sentinel and reference labs should establish communication lines with veterinary resources, environmental organizations, and food laboratories within their State, in order to maximize their ability to troubleshoot in a crisis and to share general laboratory best practices and lessons learned (e.g., with respect to zoonotics or food-borne illnesses) (personal communication with Mary Gilchrist, Ph.D.).

Guideline for Building the Model: Applicability of Best Practices

The best practices discussed above serve as a gold standard for sentinel, reference, and national laboratories and should be used as guidelines, rather than as a mandate, to ensure laboratory preparedness and ensure sufficient capacity should a BT event occur. Below, we answer several outstanding questions about our recommended best practices.

Adaptability. Are these best practices suitable for use in any region?

The best practices outlined above are suitable for use in any region.

Throughput. How many victims of a biological attack will these best practices aid?

It is difficult to quantify how many victims would be aided by instituting the recommended best practices; however, it is certain that these practices would reduce the time from occurrence of a BT event to detection, significantly decreasing morbidity and mortality.

Capacity calculations are realistic for clinical samples. For example, approximately 60 clinical samples per BSC can be tested and reported within a 12-hour period assuming a high index of suspicion for a particular agent and dependent on the experience of the laboratorian performing the testing. (Florida Department of Health 2002) However, measuring the capacity of laboratories to handle environmental samples is quite difficult and no model currently exists to accurately assess environmental testing capacity. Suggestions that environmental samples take twice as long to process as clinical samples can be misleading, as environmental samples can differ dramatically (e.g., a swipe vs. a phone booth). Building a model to assist with these calculations would be challenging, but worth exploring.

Cost. How much will it cost regions to implement the best practices?

Based on government grade scales (GS) 13-15, the starting salary for a Ph.D.-level scientist ranges from \$65,000 to \$90,000 per year depending upon experience. The starting salary for an Information Technology Specialist is approximately \$35,000 to \$55,000 per year.

Conversion of BSL-2 suites into BSL-3 suites and construction of new BSL-3 suites can be very costly. Remodeling of existing facilities may cost in excess of \$500,000 and construction of new facilities may cost a minimum of \$1.5 million.

Costs to meet minimum equipment requirements:

Phase Contrast Microscope	\$2,000 +
Fluorescence Microscope	\$2,000 +
RT-PCR unit (e.g., Smart Cycler II)	\$30,000 +
Centrifuge	
* (benchtop or microcentrifuge)	\$2,000 +
* (floor model)	\$7,000 +
Incubator (0.6 cu. ft. benchtop)	\$800 +
70°C freezer (7 cu. ft.)	\$7,000 +
Water bath (10L capacity)	\$800 +

Costs for transportation and courier services are difficult to enumerate as special agreements may need to be made. These services are not federally funded and many States must cut budgets for these services because of financial constraints.

The salary for a full-time laboratory coordinator or a full-time BT State training coordinator is approximately \$35,000 - \$70,000, depending on location and experience.

While the LRN currently funds proficiency testing for reference labs, the sources of funding for annual exercises and for proficiency testing for sentinel labs will vary and merit further consideration.

Institution of the best practices would cost more than most labs can afford.

Operational Impact. What are the operational considerations of using these best practices?

The operational impact would be significant. During the anthrax crisis in October, 2001, laboratories reported a major negative impact for testing both BT and routine non-BT isolates.

Enacting the recommended best practices would help reduce the capacity burden placed on already overwhelmed laboratories. Institution of mutual aid agreements, prior arrangements for transportation and courier services, and training recommendations would also positively affect operational impact.

Training. What level of training do these best practices require?

Several levels of training are required if best practices are instituted. For sentinel laboratories, training should be coordinated by the State laboratory training coordinator and should be offered regionally within the State. Training for sentinel laboratories should include recognition of select agents, procedures used to rule out potential BT agents, activation of a notification algorithm, appropriate waste disposal, and shipping regulations. Proficiency testing also should be addressed. Training must be offered on a regular basis to ensure that newly hired laboratorians are trained properly. Annual refresher courses are recommended.

The NLTN is a good resource for sentinel laboratories. The network was created jointly by APHL and CDC and provides continuing education for laboratorians performing clinical, public health, and environmental laboratory testing. Training resources developed for BT by the NLTN include: Webcasts, sentinel laboratory protocols, a calendar of NLTN training seminars, and other useful links. NLTN training seminars are held frequently and in different locations. The seminars are offered gratis or for a nominal fee (e.g., \$10.00).

For reference and national laboratories, training is handled primarily through the LRN and includes instruction-based training as well as practical exercises and proficiency testing. A State-based laboratory training coordinator is necessary, however, to provide supplemental training and refresher courses.

Resources. Do the practices build on existing practices/infrastructure? Are there available resources to implement the practices?

Most of these recommended practices build on existing practices and infrastructures, including those recommendations for personnel, clinical laboratory connectivity, and training. However, existing infrastructure is not apparent for transportation/courier services and is lacking in the areas of facilities/biosecurity and equipment/supplies.

Morbidity and Mortality. What impact will these practices have on saving lives?

These practices will significantly decrease morbidity and mortality, as the time from occurrence of an event to its detection will be greatly reduced. The best practices protect laboratorians and their immediate environment from contamination and rapid identification of the responsible BT agent will ensure that antimicrobial therapy and other treatment measures can be optimized, which will benefit the general public. Rapid identification will allow epidemiologists and other emergency management personnel to make quick decisions and

optimize their response based upon the mode of transmission, incubation period, and treatment options for the identified agent.

As an additional benefit, dual-use technologies and overall improvements that would be made to public health facilities should result in decreased morbidity and mortality from other infectious diseases.

Evidence-based Practice versus Theory. Is there a body of professional research supporting these practices or are they theoretical?

These practices are supported by decades of research with BT agents and facility requirements for handling these agents. Notification call-lists, or algorithms, are used and activated on a regular basis by many emergency responder groups. This practice should transfer well to public health agencies. Proficiency testing has been widely used for years as a measure of laboratory performance, although BT agents were not incorporated into testing programs until recently.

The LRN has been in existence since 1999 and there has been a significant amount of research aimed at establishing such a network. The decentralized nature of the LRN is similar to the PulseNet project established to identify food-borne illness outbreaks. Regional, rather than State-based, projects have been less successful in their ability to respond in a timely fashion and State boundaries are a natural catchment for funding, training and transportation/courier services. In addition, the LRN has added practical experience, due to its involvement during the anthrax crisis in October 2001.

Regulatory Compliance. Do the practices comply with existing regulations or do they require a regulatory change?

At this time, the main existing regulation for reference and national laboratories in regard to testing BT agents is the Select Agent Regulation, 42 CFR 73.0. All clinical and diagnostic laboratories do, however, undergo general annual inspections and must be in compliance with regulations established by agencies such as CLIA or CAP. FAR and HIPAA regulations also apply to specific laboratory activities, as does the Patriot Act.

The LRN has no regulatory powers and cannot penalize reference laboratories that perform poorly. There is currently no accountability for funding allocation or time-bounded performance measures. These practices do require a regulatory change in order to promote responsibility and accountability.

Lastly, experts recommend the establishment of Federal guidelines and regulations for handheld devices used for environmental testing in the field, similar to the guidelines and regulations currently in existence for devices to test clinical samples (which must receive Federal certification).

Future Research Needs

We identified several research areas that lie beyond the scope of this chapter but warrant urgent and in-depth exploration:

A better definition of environmental capacity. What are the relevant variables? Measuring the capacity of different laboratories to handle environmental (vs. clinical) samples is not simple. No model currently exists to accurately assess environmental testing capacity. The calculations of time and quantity are complex. Variables include whether the potential agent is known or suspected, the types of materials being sampled, laboratorian experience testing reliability of assays, whether new assays are being developed or are available, availability of equipment, options for secure transport, etc. Building a model to assist with these calculations would be challenging, but certainly worth pursuing.

A guideline for handheld devices. What types of devices should first responders use and *not* use, and when should they use them? Handheld devices for clinical specimens currently must be nationally certified, but there is no Federal certification program or regulation for environmental devices. This research should include an exploration of the current state-of-the-art in handheld devices, and a delineation of core criteria for development, testing, and selection by both Federal agencies and State and local governments.

A guideline for staffing the workforce at confirmatory labs. What is the appropriate mix of skills, experience, and academic requirements that will allow a confirmatory lab to adequately support response and development? What variations exist (or should exist) from State to State?

An analysis of laboratory capacity to handle chemical, radiological, or explosive samples. How do the capabilities and requirements differ from BT, and where do they overlap?

An analysis of how better to integrate EPA labs, FDA labs, and veterinary labs into the emergency preparedness and response discussions and plans of both reference labs and sentinel labs.

A national guideline for chain-of-custody issues. Current chain-of-custody protocols differ from State to State and even from jurisdiction to jurisdiction within States, causing tremendous confusion as to how to handle unknown or suspect samples.

A proposal to build a primary and secondary educational curriculum focused on laboratory disciplines. Fewer and fewer students are showing an interest in pursuing careers as microbiologists or medical technicians, which is causing a shortage of classically trained staff at public health laboratories nationwide. By contrast, careers in forensics and nursing have become popular due to television shows and sustained public relations campaigns. How can careers in biological and laboratory sciences be similarly popularized? What is the best approach to inculcate an interest in these disciplines at a young age?

Ch. 5 Appendix A. References and Bibliography

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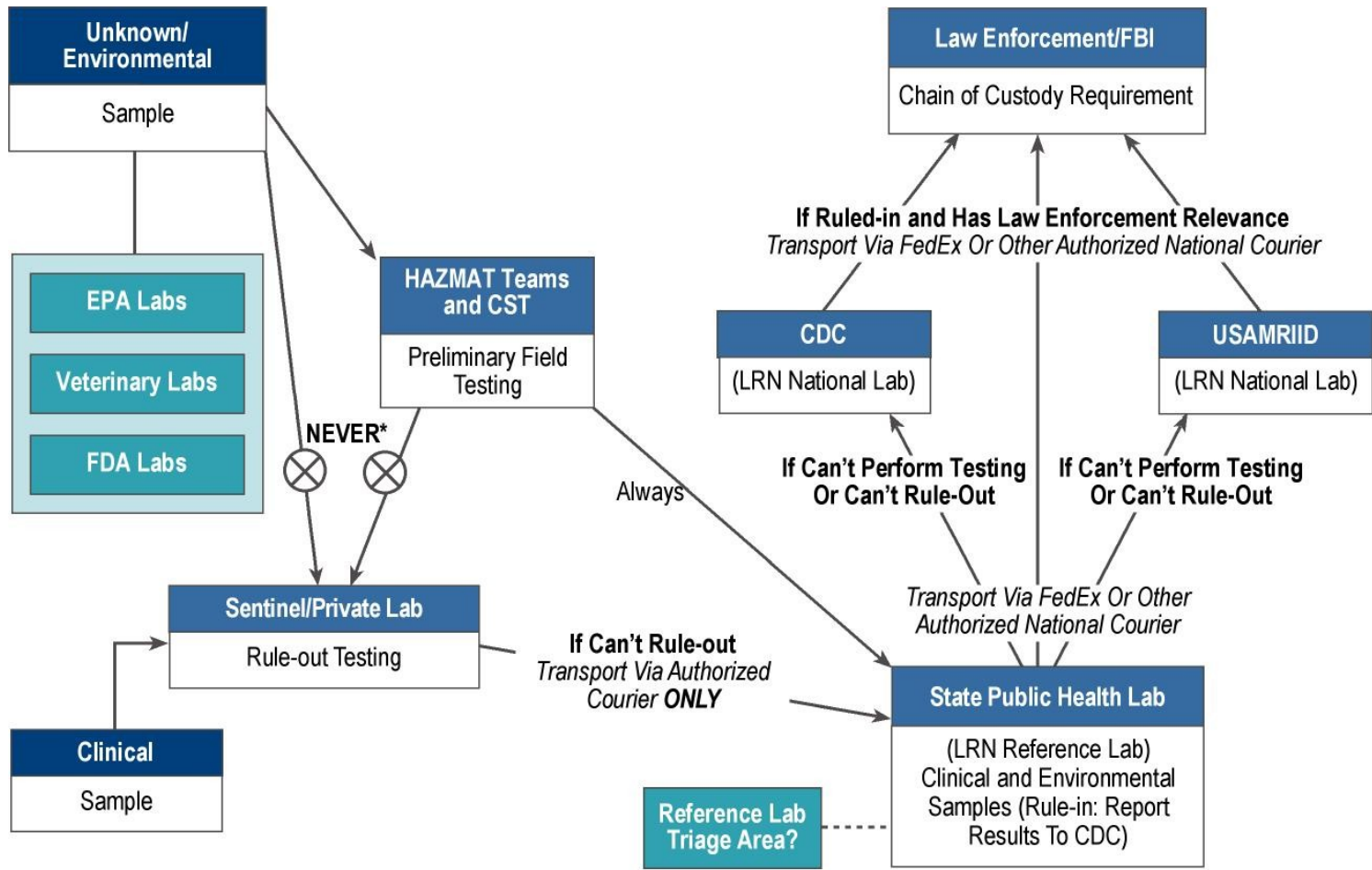
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Ch. 5 Appendix B. Model for Laboratory Capacity and Bioterrorism Response Planning

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Current BT Response Algorithm **Outcomes of Sample Testing**
 Proposed Additions to Algorithm *Transportation of Sample*
 * Not prohibited by law, but is strongly discouraged by both the LRN and subject matter experts.

Roles and Definitions

Unknown/Environmental Sample: A sample obtained in the field that may be biological, chemical, or radiological in nature; a combination of at least two types of unknown samples (e.g. biological and chemical); or a benign sample.

Clinical Sample: A sample collected from a patient and processed by a hospital, physician's office, or walk-in clinic laboratory.

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Sentinel Laboratory
<ul style="list-style-type: none"> ◆ Comprised of hospital, physician's office, and walk-in clinic laboratories, as well as all private laboratories. ◆ Handles clinical samples only; NOT unknown samples. ◆ Refers isolates to reference labs if unable to rule-out. ◆ Provides surge capacity for routine testing functions (e.g., TB testing).

Reference Laboratory
<ul style="list-style-type: none"> ◆ Generally a state public health lab. ◆ Rules-in clinical samples sent from sentinel labs. ◆ Receives and processes environmental samples from the field. ◆ Uses LRN protocols for testing and LRN procedures for reporting. ◆ Participates in LRN proficiency testing program.

LRN
<ul style="list-style-type: none"> ◆ Includes reference labs, APHL, ASM, national labs (including CDC, USAMRIID, and LLNL), EPA. ◆ Responsible for posting testing protocols used by reference labs, providing standardized test reagents, compiling a facility referral directory, and administering proficiency testing programs. ◆ Provides "rule out or refer" concept of operations and structure for agent testing and clinical specimen flow.

National Laboratory
<ul style="list-style-type: none"> ◆ Currently refers only to the CDC and USAMRIID, which are two of the only four labs that can perform rule-in testing that requires BSL-4 facilities. (The other two labs with BSL-4 practices are at the Southwest Foundation for Biomedical Research in San Antonio, Texas, and at the University of Texas at Galveston). ◆ Includes FBI Lab, a required custodian if a law enforcement or terrorism concern is associated with the sample; will carry out testing if sample has been inconclusively tested by reference lab or if required by a court. ◆ Includes other national-level federal labs with BT concerns, including FDA, EPA, and National Veterinary Service Lab (USDA). ◆ May provide on-site surge capacity to state public health labs. ◆ Performs advanced procedures not done in reference labs ◆ Archives BT agents.

HAZMAT Team/CST
<ul style="list-style-type: none"> ◆ Responds at the scene in the field. ◆ Performs preliminary field screening. ◆ Collects environmental samples to be sent to reference labs. ◆ May be involved in transportation of samples to reference labs.

Authorized Courier
<ul style="list-style-type: none"> ◆ At state level, either a trained HAZMAT or first responder unit, or a statewide courier specifically approved for potential BT sample transport, e.g., a bonded courier (whose services are not available to the public), or FedEx. ◆ At national level, FedEx or other similarly trained/approved courier. ◆ Law enforcement may be called upon to act as courier (and possibly also as custodian) if a sample is linked to a potential BT event or other criminal activity. ◆ A sample should NEVER be given to a random, untrained individual or company!

Best Practices

Sentinel Laboratory

- ◆ Is able to recognize potential BT agents.
- ◆ Is able to perform rule-out testing procedures that are readily available to all sentinel labs.
- ◆ Identifies the closest reference lab prior to an event.
- ◆ Has plans in place to provide surge capacity for routine tests (e.g., TB, HIV) to that reference lab in an emergency.
- ◆ Understands packaging/shipping procedures and has a current list of authorized couriers for both routine and suspect samples.
- ◆ Is familiar with the Incident Command System (ICS) ; local chain-of-custody requirements; local first responder points-of-contact (e.g., HAZMAT); and local law enforcement requirements.
- ◆ Allocates funds to establishing at least basic (and HIPAA-compliant) Internet connectivity.
- ◆ Participates in state-run BT preparedness exercises; has a working relationship with other local first responders; and actively engages in training such as CAP or NLTN.
- ◆ Never accepts, handles, or tests environmental samples.

HAZMAT Team/CST

- ◆ Conducts preliminary field-testing of all samples.
- ◆ Coordinates response with local law enforcement and emergency planners.
- ◆ Refers all biological samples to the closest reference lab for confirmatory testing.
- ◆ Ensures that at least one sample from every set sent to the reference lab is **pristine**.
- ◆ Never brings untested (i.e., potentially mixed, chemical, radiological, or explosive) environmental samples to reference labs.
- ◆ Never brings an environmental sample to a sentinel lab.

Reference Laboratory

- ◆ Is able to perform rule-in testing using LRN protocols and test reagents. Reagents should be obtained only from the LRN
- ◆ Is able to implement all Select Agent Regulation requirements (42 CFR 73.0).
- ◆ Promptly reports the presence of select agents or pathogens to the CDC.
- ◆ Emphasizes the acquisition of equipment that has dual-use potential.
- ◆ Maintains a current list of all sentinel labs located within state boundaries, including contact information.
- ◆ Uses only approved couriers and has crisis contingency plans for transport.
- ◆ Is familiar with the Incident Command System (ICS) and both state and local chain-of-custody requirements.
- ◆ Participates in state- and LRN-run proficiency testing and training programs.
- ◆ Participates in regular joint exercises and develops working relationships with state and local groups that would also be involved in responding to a BT event, including HAZMAT, CST, local first responders, and law enforcement.
- ◆ Develops mutual aid agreements with reference labs in neighboring states for surge capacity during a crisis.
- ◆ In coordination with state public health authorities, develops and implements a vaccination plan for all relevant staff.

National Laboratory

In addition to reference lab best practices:

- ◆ Performs high-level procedures.
- ◆ Performs all BSL-4 work.
- ◆ Archives agents.
- ◆ Provides limited on-site personnel for surge capacity.
- ◆ Has the ability to triage and process unknown, mixed, or odd-shaped environmental samples (e.g., furniture).
- ◆ Works with the LRN to establish general acceptance of multiple assay protocols that meet specific performance criteria.

Ch. 5 Appendix C. Checklist for the Preliminary Triage of Unknown Environmental Samples

GENERAL INFORMATION

Person Receiving Call/Page:	Date:	Time:
Initial Caller:	Agency:	Phone No.:
Incident Commander:	Agency:	Phone No.:
Incident Location: Site closed? YES NO	Collection Site:	
Event Description: (may include responders present and site actions taken)		

Risk Assessment by Incident Commander:
HUMAN EXPOSURE INFORMATION

Number Exposed:	Type of Exposure: <input type="checkbox"/> Dermal <input type="checkbox"/> Inhalation <input type="checkbox"/> Ingestion	Number of Fatalities:
Victim Status: <input type="checkbox"/> Not applicable <input type="checkbox"/> Released <input type="checkbox"/> Medical Evacuation to: <input type="checkbox"/> Decontaminated <input type="checkbox"/> Isolated <input type="checkbox"/> Medical Examiner at:		
Exposure Symptoms: <input type="checkbox"/> None <input type="checkbox"/> Blistering <input type="checkbox"/> Disorientation <input type="checkbox"/> Difficulty Breathing <input type="checkbox"/> Convulsions <input type="checkbox"/> Nausea/Vomiting <input type="checkbox"/> Other, describe:		Reaction Time:

RESPONSE INFORMATION

Reason for Sampling: (overt threat, suspicious circumstances, specific request from partnering agency)

Has Chemical Field Testing Been Performed?	YES: SIGNIFICANT / NORMAL	NO	Unknown
Describe test(s) used and results:			

Has Biological Field Testing Been Performed?	YES: POSITIVE / NEGATIVE	NO	Unknown
Describe test(s) used and results : <input type="checkbox"/> Hand held device <input type="checkbox"/> RAPID			

Sample Checked for Radioactivity? YES NO Unknown	If yes, are levels above background? YES NO
---	---

Unopened Package / Container Checked and found NEGATIVE for: Explosives Incendiaries Pressurized Devices

Is Sample Collection/Packaging Information Needed?	
NO Is Sample: <input type="checkbox"/> Double bagged <input type="checkbox"/> Decontaminated, describe method:	Has COC been initiated? YES
YES:	NO (http://forms.dgs.virginia.gov/)

Number of Samples Collected:	Is Public/Media Aware of Incident: YES NO
-------------------------------------	--

Transportation: <input type="checkbox"/> DCLS Courier <input type="checkbox"/> Walk-in <input type="checkbox"/> Mail <input type="checkbox"/> Other	ETA:
--	-------------

Expectations for Sample(s) IDENTIFY RULE OUT :

SAMPLE DISTRIBUTION AND PHYSICAL PROPERTIES

Sample Distribution: <input type="checkbox"/> DCLS <input type="checkbox"/> Other LRN lab:	<input type="checkbox"/> Other:
---	---------------------------------

Sample Type: Envelope Package Swab Swipe Air Collection Container Other:

Physical State of Material: Solid Liquid Gas	If Liquid – Viscosity: Water Oil Honey Paste Other NA
---	--

Acronyms and Abbreviations

ABSA	American Biological Safety Association
ACEP	Advisory Committee on Export Policy
ADA	Americans with Disabilities Act
AHA	American Hospital Association
AHRQ	Agency for Healthcare Research and Quality
ALS	advanced life support
AMA	American Medical Association
ANA	American Nurses Association
APHL	Association of Public Health Laboratories
APIC	Association of Professionals in Infection Control and Epidemiology
ASM	American Society for Microbiology
BDS	biohazard detection system
BIDS	biological integrated detection system
BMBL	biosafety in microbiological and biomedical laboratories
BSC	biological safety cabinets
BSC	biosafety containment
BSI	body substance isolation
BSL	biosafety level (lab)
BT	bioterrorism
BW	biological weapons
CAP	College of American Pathologists
CBIRF	Chemical Biological Incident Response Force (US Marines)
CBRNE	chemical/biological/radiological/nuclear/explosive
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CLIA	Clinical Laboratory Improvement Amendments
CSEPP	Chemical Stockpile Emergency Preparedness Program
CSIS	Center for Strategic and International Studies
CST-WMD	Civil Support Team--Weapons of Mass Destruction
DECON	decontamination
DHS	U.S. Department of Homeland Security
DoD	U.S. Department of Defense
DOJ	U.S. Department of Justice
ECBC	United States Army Edgewood Chemical Biological Center
EIPs	emerging infectious programs
EMI	Emergency Management Institute (FEMA)
EMS	emergency medical service
EMT	emergency medical technicians
EMTALA	Emergency Medical Treatment and Active Labor Act
ENA	Emergency Nurses Association
EPA	U.S. Environmental Protection Agency
FBI	U.S. Federal Bureau of Investigations
FDA	U.S. Food and Drug Administration
FEMA	Federal Emergency Management Agency
FERN	Food Emergency Response Network
GAO	General Accounting Office

Development of Models for Emergency Preparedness:
 Personal Protective Equipment, Decontamination, Isolation/Quarantine, and Laboratory Capacity

HAN	Health Alert Network
HAZMAT	hazardous materials
HAZWOPER	Hazardous Waste Operations and Emergency Response
HCF	health care facilities
HCP	health care professional
HEPA	high efficiency particle arrestor (mask)
HICPAC	Hospital Infection Control Practices Advisory Committee
HHS	U.S. Department of Health and Human Services
HRSA	Health Resources and Services Administration
HSEEP	Homeland Security Exercise and Evaluation Program
HVA	hazards vulnerability assessment
IATA	International Air Transport Association
ICS	Incident Command System
JCAHO	Joint Commission for the Accreditation of Healthcare Organizations
LEPC	Local Emergency Planning Committee
LLNL	Lawrence Livermore National Lab
LRN	Laboratory Response Network
MALS	mobile analytical laboratory system
MMRS	Metropolitan Medical Response System
NACCHO	National Association for City and County Health Officials
NDMS	National Disaster Medical System
NEDSS	National Electronic Disease Surveillance System
NFPA	National Fire Protection Agency
NIIMS	National Interagency Incident Management System
NIOSH	National Institute for Occupational Safety and Health
NMRT	National Medical Response Team
ODP	Office of Domestic Preparedness
OSHA	Occupational Safety and Health Administration
PAPR	powered purifying air respirator
PCR	polymerase chain reaction
PDA	personal digital assistant
PHLS	Public Health Laboratory Service
PPE	personal protective equipment
RDD	radiological dispersal device
REAC/TS	Radiation Emergency Assistance Center/Training Site
RSDL	reverse spiral dual layer
SARS	severe acute respiratory syndrome
SAIC	Science Applications International Corporation
SBCCOM	U.S. Army Soldier Biological Chemical Command
SHSAS	State Homeland Security Assessment Strategy
SME	subject matter expert
SOP	standard operator procedure
TOO	task order officer
USAMRID	U.S. Army Medical Research Institute of Infectious Diseases
USAR	Urban Search and Rescue
USPHS	U.S. Public Health Service

Development of Models for Emergency Preparedness:
Personal Protective Equipment, Decontamination, Isolation/Quarantine, and Laboratory Capacity

USPS
WMD

U.S. Post Office
weapons of mass destruction

U.S. Department of Health and Human Services

Mike Leavitt, *Secretary*

Office of Public Health and Science

Richard H. Carmona, M.D., M.P.H., F.A.C.S., *Surgeon General of the United States*

Agency for Healthcare Research and Quality

Carolyn M. Clancy, M.D., *Director*