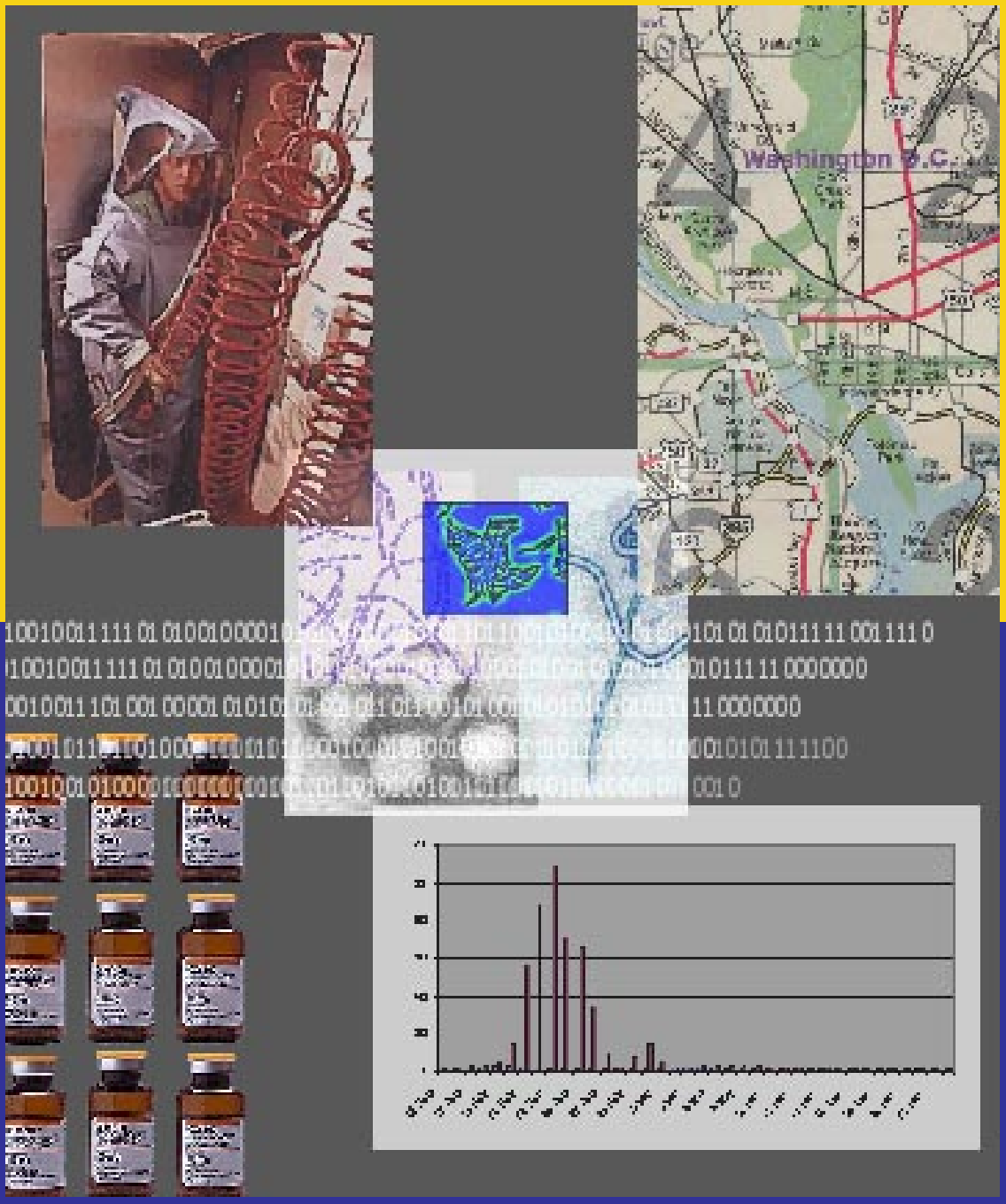
BIOTERRORISM IN THE UNITED STATES: THREAT, PREPAREDNESS, AND RESPONSE



Chemical and Biological Arms Control Institute

BIOLOGICAL TERRORISM IN THE UNITED STATES: THREAT, PREPAREDNESS, AND RESPONSE

FINAL REPORT

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EXECUTIVE SUMMARY

Over the last several years, a confluence of events – the World Trade Center bombing, the Tokyo subway sarin gas attack by the Aum Shinrikyo, and the bombing of the Murrah Federal Building in Oklahoma City – focused attention on the growing threat of terrorist use of chemical, biological, radiological, or nuclear (CBRN) weapons in the United States. These developments gave rise to a set of perceptions – among policy makers and the public alike – that the United States is vulnerable to terrorist attack; that such attacks could entail the use of CBRN weapons; and that the United States has not been well prepared to deal effectively with such a challenge.

Biological terrorism differs from other types of CBRN terrorism in that it would impose particularly heavy demands on the nation's public health and health care systems. Although a chemical attack would also tax these systems, bioterrorism would impose especially stressful burdens. Yet, that same public health system is *the* crucial factor in an effective response. A highly effective public health system should make an important contribution to deterring the threat by demonstrably diminishing the gains of a potential attack. It also constitutes the "first line of defense" in the event deterrence or prevention fails. Ultimately, it will be the public health system that will be called on to mitigate and ameliorate the consequences of a terrorist attack using biological weapons.

A number of programs are underway to improve the health and medical dimensions of the national response to the threat of bioterrorism. Uncertainty exists, however, as to whether current programs are those that are most needed or whether they are being implemented in the most effective way possible. This uncertainty exists because to date there have been insufficient means to judge the efficacy of existing programs. This lack of criteria is the product of not having an analytic framework that establishes national requirements for an effective response derived from a comprehensive threat assessment. The development and application of a strategic framework is urgently needed. Making a contribution to the development of that framework is the purpose of this project.

PART I: THE CHALLENGE OF BIOLOGICAL TERRORISM

An analytical framework for assessing the threat of biological terrorism is needed to reduce the uncertainty that currently permeates the national debate over an issue that has forced its way on to the national agenda. A good threat assessment creates a "threat envelope" that describes the most plausible contingencies and identifies those possibilities that fall within it and those that lie outside. Defining a plausible threat envelope also provides a means to identify those contingencies that require hedging, in that, due to the severity or enormity of their consequences, some preparation for them should be undertaken, even if they are relatively unlikely. The combination of the threat envelope and the hedging contingencies should give policy makers some measure for making decisions regarding policy priorities and resource allocations.

An analytical framework for thinking about the biological terrorism threat will also highlight the fact that the threat is not unidimensional; it does not come from only one factor. Rather, it is composed of several elements. Each of these elements, in turn, entails a significant array of possibilities. The key to a successful bioterrorism threat assessment is disaggregating the threat into its component elements and assessing the relationships among them. Only by doing so can one examine comparative likelihood of various contingencies. It is the introduction of likelihood into the analysis that distinguishes a threat assessment from a vulnerability assessment. For purposes of this study, the key elements of the bioterrorism threat have been identified as the *who* (the actor), the *what* (the agent), the *where* (the target), and the *how* (the mode of attack).

The key components of the threat assessment – who, what, how, and where – were integrated into a "matrix-pathways" approach to develop a representation of the complex nature of the bioterrorism threat. Given the importance of the actor in shaping the threat, the team decided to break the question of "who?" into two distinct but related elements suggested by the questions: "what are the motivations for a group to use a biological weapon?" and "what capabilities must an actor possess to develop and use a

Motivation		Capabilities			Agents			Dissemination		Target	
Number of Casualties	Level of Panic	Group Size	Technical Proficiency	Financial Resources (x $1000)	Agent Availability	Ease of Growth	Morbidity and Mortality	Ease of Dissemination	Efficacy of Dissemination Technique	Number Exposed at Target (x 1000)	Target Vulnerability
50000	High	1000	Expert	1000	High	High	High	High	High	1000	High
5000	Med.	100	Good	100	Med.	Med.	Med.	Med.	Med.	100	Med
500	Low	10	Low	10	Low	Low	Low	Low	Low	10	Low
50		Loner	None	1	None		None			1	None

Figure 1. Biological Terrorism Threat Pathways Matrix

biological weapon?" These five components provided the starting point for constructing the matrix, shown graphically in Figure 1 above.

Bioterrorism pathways were produced by systematically identifying plausible relationships between factors and outcomes. Combining the pathways with judgments regarding the comparative likelihood of each pathway produced the "plausible threat envelope" for biological terrorism.

The project team also examined the historical record to inform its pathways analysis. It did so in two ways. First, it examined cases of bioterrorism to determine the pathway that was exploited. Second, the project team turned the question around and asked whether the historical record could offer analogs to some of the pathways deemed more probable than others by the project team because of the logical relationship between factors and outcomes. Given the paucity of historical data, however, this step in the analysis had limited utility.

THE THREAT OF BIOLOGICAL TERRORISM: KEY FINDINGS

The application of the "pathways" methodology yielded several important findings that should inform efforts to develop an effective health and medical dimension to the nation's overall capabilities to respond to bioterrorism.

1. **A key relationship exists between the degree of risk and the level of casualties desired in an attack. That relationship, however, is *not* the straightforward one that higher risk is associated with catastrophic casualty scenarios. Indeed, the degree of risk declines as the level of desired casualties increases, insofar as *it becomes less likely*.**

   - Few terrorists have the necessary combination of size, resources, skills, facilitative ethos, or appropriate organizational structure to achieve mass casualty capabilities.
   - Traditional agents capable of inflicting mass casualties are difficult to acquire, cultivate, and produce, or disseminate effectively.
   - Likely targets for attacks do not necessarily facilitate mass casualty outcomes.

2. **Despite the low probability of catastrophic bioterrorism, there is still ample cause for concern. We do not know how "massive" a mass attack has to be; worst-case scenarios may not need to happen.**

   - We do not know, for example, at what point the response system will become overburdened and stressed to the point of collapse.
   - The danger and harm inherent in the bioterrorism threat is not limited to physical fatalities and casualties. Psychological impact and social disruption could also be severe if effective preparations are not made and useful responses are not developed.
   - Use of unconventional terrorism for other than massively destructive purposes is consistent with the historical record.

3. **Although many terrorists will not be interested in using biological weapons or not able to do so, two categories of non-state actors – those with relationships with national governments and those outside the traditional scope of governmental scrutiny – warrant particular attention.**

Terrorism analysis tends to exclude violent acts by non-state actors allied with foreign governments in times of conflict because such actions are considered acts of war. In terms of national bioterrorism response planning, this is short-sighted for three reasons:

- The consequences of such an attack would be no different than if it occurred as an isolated incident and the response needs would be the same.
- State-sponsored terrorists are among the few actors who could assemble the requisite resources, skills, and materials to conduct a successful attack that produces significant levels of casualties.
- Countries who see themselves potentially in a conflict with the United States are demonstrating an increasing interest in "asymmetric strategies" to obviate the overwhelming U.S. advantage in conventional military power. When combined with a perception of the United States as a country that insists on "casualty-free" conflicts, enjoys only limited credibility in terms of its commitments to friends and allies overseas, and retains little consensus on when and how to use its military power, the appeal of asymmetric strategies that include terrorism with unconventional weapons could increase.

The second category of actor that bears particular attention includes those who may not have been a regular focus of scrutiny either because they are new to the scene or they have not been considered part of the terrorism universe. Among the actors who now define contemporary terrorism – which itself is a combination of old and new dimensions – recent analysis suggests that those who might be most attracted to the use of biological agents include:

- non-state actors inspired by religious ideals;
- groups from the Right of the political spectrum;
- actors with millennial world views that combine with notions of the "cleansing" value of violence;
- transnational networks that are less constrained by central authority; and

- radical single-issue groups.

Few of these actors will have the requisite skills to perpetrate bioterrorist attacks that produce catastrophic casualties. These groups must continue to be of concern regarding future bioterrorism, however, if only because smaller-scale events in terms of casualties could still produce significant negative impacts.

4. The environment of uncertainty surrounding bioterrorism will remain.

The threat is not static and will continue to evolve. Changing actors and evolving technology – especially in biology-related areas – will be major drivers of such change but not the only ones. Globalization and the Information Revolution will shape the terrorism environment just as they will most other forms of social organization and interaction. Specific events outside the bioterrorism realm will intrude to influence terrorists' goals, perceptions, and modes of operation. The impact of individual personalities should not be discounted.

Two final points in relation to the uncertainty about the bioterrorism threat by ongoing change are important for those who must respond to the challenge. First, the assumption is usually made that such change will make the threat more severe. Such an assumption is not necessarily warranted. Change should also benefit those who must respond to the threat, not only in the tools they could have available, but in terms of the broader social, political, and psychological context.

Second, uncertainty is created by the constant adjustment in the dynamic between terrorists and those who fight them. Like the offense-defense relationship in military affairs, the relationship between terrorists and responders is constantly in flux, and uncertainty arises because it is not possible to state precisely at any given point in time how the balance stands between them. The important point, however, is that both elements are necessary to create that dynamic relationship. In the case of responding to the threat of bioterrorism, certainty will only be achieved if we take ourselves out of the game and do nothing.

PART II: PUBLIC HEALTH AND MEDICAL RESPONSES

This Part of the report evaluates the public health and medical response to bioterrorism in the United States in the context of the threat described in Part I. The discussion is in two sections. Section I identifies the major components or functions of the public health and medical response system, including:

- Surveillance
- Epidemiology
- Laboratory Capability
- Medical Management
- Training and Education
- Information and Communication

The discussion of each of these functions identifies the requirements that must be met if each it is to be performed effectively, describes the current situation in the United States with respect to meeting those requirements, discusses the key issues associated with each component, and provides recommendations.

Section II discusses the major issues associated with organizing and coordinating national efforts among responsible entities at the federal, state, and local levels to prepare and execute the public health and medical system in the event of a bioterrorism attack. This Part discusses three main questions: the nature and success of preparedness efforts of federal, state, and local entities, the need to develop a strong partnership between the private and public sectors, and the structure and organization of CDC's bioterrorism preparedness and response program.

SECTION I: SYSTEM REQUIREMENTS

SURVEILLANCE

Health surveillance systems are required to provide the initial detection capability for bioterrorism incidents. The earlier detection occurs, the earlier epidemiologists and laboratory personnel can determine the nature of an incident, which in turn enables a more effective and efficient response. To serve this early warning function, surveillance systems must: detect minor changes in the health status of the monitored population; develop data baselines to establish the monitored population's "normal" health situation; monitor the health of the population in continuous, near real-time fashion; and integrate local systems to provide coverage over larger areas.

Four main elements comprise most surveillance system models: 1) information indicating the health status of the population; 2) providers of that information; 3) recipients of that data who will also perform the monitoring function; and 4) a system of systems to exchange the appropriate data between providers and users.

Surveillance systems should monitor as many data types as possible, establish systems of exchanging this information on an on-going basis, and then analyze that information. The table below provides a general typology correlating data types with possible providers. In addition to their roles in analyzing incoming data, "recipient entities" such as local public health agencies should plan, organize, and establish surveillance networks at the county or municipal level.

Although some limited, experimental surveillance systems have been established with support from CDC, few robust systems have been created, established, and maintained on a permanent basis. Thus, only a small number of surveillance systems are monitoring a small segment of the country. Moreover, there is no national strategy encouraging and supporting local efforts to organize health surveillance systems.

Data Types	Possible Providers
Unusual cases of illness	Hospitals, clinics, physician offices, EMS system
# of hospital admissions	Hospitals
# of emergency department, clinic, and physician office visits	Hospitals, clinics, physician offices
Patient complaints/syndromes information	Hospitals, clinics, physician offices, EMS system
EMS runs	EMS Dispatch – Fire department, Private ambulance services
Purchase of medications	Drug stores, pharmacies, clinics, hospitals, warehouses
Animal illness incidents	Local zoos, veterinary offices
Access to self-medication information	Hotlines, medical information websites
Sick calls	Local schools and employers
Unusual deaths – infectious disease related	Office of the local coroner or medical examiner

Possible Surveillance Data Providers

CDC should develop and implement such a strategy for a national health surveillance capability for bioterrorism and other infectious disease emergencies.

Developing such a strategy requires:

- creating a joint surveillance task force comprised of representatives from federal, state, and local public health agencies to put such a strategy in place and guide its implementation;

- establishing a separate category in CDC's grant program to support local efforts to develop surveillance systems and better track resources devoted to this area;

- providing adequate funding for a multi-year program for local public health agencies both to organize and provide the infrastructure for local surveillance networks;

- increasing the number of epidemiologists and other public health professionals at state and local health departments working on bioterrorism issues or programs;

- continuing information infrastructure improvements in state and local public health departments through the Health Alert Network program;

- developing a national electronic information system for exchanging disease reporting data between state health departments and the CDC; supporting local surveillance projects designed to test new concepts and improve the technical state of the art; and

- supporting an on-going research and development program designed to push technology related to health surveillance systems.

EPIDEMIOLOGY

While health surveillance systems provide the *detection tool*, epidemiology is an *assessment tool* used to ascertain the exact nature of a bioterrorist event. Epidemiologists interpret raw data gathered through surveillance and investigations to determine the source of an outbreak, mode of transmission, extent of exposure, and pattern of progress. Based on this information, they make recommendations for the appropriate public health and treatment measures needed to contain the outbreak. To perform this function, epidemiologists must have the capability to: interpret surveillance data; conduct investigations; build case definitions; and continuously monitor surveillance data.

Because epidemiologists interpret surveillance data, they will have a central role in determining:

- The approximate point of exposure and the population most likely to have been exposed so that prophylaxis and treatment can be focused here first;
- Measures for containing the outbreak;
- Whether a single attack or multiple attacks occurred;
- Whether follow-on attacks have been carried out that may result in additional waves of patients;
- How the outbreak will unfold over time; and
- Clues that may aid a law enforcement investigation.

Once an attack is suspected, epidemiologists must create a case definition to alert public health and medical personnel. A case definition will include known symptoms, the geographic location of patient clusters, and a time window of exposure (if known). It will also provide physicians with treatment protocols and advanced clinical symptoms.

Once an outbreak is underway, epidemiologists need continued access to information on patient load and symptoms, as well as laboratory results, and must have a means of providing information back to public health and medical officials who can use it to make critical decisions about treatment of patients. At present, very few localities have established electronic systems for epidemiologists and other public health and medical entities to receive or exchange surveillance data.

Requirements for a robust epidemiological investigation capability include:

- Adequate personnel to analyze surveillance data and investigate unusual outbreaks;
- Real-time access to surveillance data, including archived historical disease data for comparison;
- Electronic systems to compile and analyze patient data gathered manually during epidemiological interviews;
- Easy communication and shared information with laboratories, hospitals, physicians, and federal level entities; and
- Broad understanding of a variety of disease patterns – endemic, non-endemic, food and waterborne – produced by both traditional bioterrorism agents, as well as unexpected or non-traditional agents.

At present, there is insufficient local capacity for conducting rapid and wide-reaching epidemiology during suspected bioterrorist attacks. Given the small number of epidemiologists at even the largest local public health departments, much of their time and effort is already consumed by investigating natural disease outbreaks or engaging in public health campaigns.

A number of initiatives should be undertaken to improve the nation's epidemiological capabilities in preparation for bioterrorism incidents, including:

- Improving disease surveillance systems;

- Increasing funding to state and local public health departments for hiring and maintaining epidemiological staff. This should be a priority focus area for building assessment tools that can make the response more focused and efficient.

- Identifying epidemiological thresholds for triggering particular medical responses to avoid unnecessary "hair trigger" responses. This would include triggers for a phased response that could progress through *initial response, localized disease emergency*, and *large-scale mobilization* stages.

LABORATORY CAPACITY

Like epidemiology, the laboratory component of the public health and medical response to bioterrorism is largely an assessment tool. Physicians will depend on laboratories to distinguish the agents used in a bioterrorism attack, several of which initially could present similar symptoms. Laboratories must also be able to test for anti-microbial sensitivity and determine whether a particular antibiotic or vaccine will be effective against the given agent. Laboratories will also be important in determining how many agents are involved and must support law enforcement efforts through microbial forensics to determine where the agent may have originated.

Having the ability to refer culture samples within a network of laboratories with varying capabilities provides the necessary technologies and surge capacity to prevent backlogged culture requests during an event. The Laboratory Response Network (LRN) is a series of laboratories of varying capabilities that assist one another in the event of a bioterrorism attack through cooperative arrangements. Each laboratory is assessed according to its level of capability, from Level A laboratories – the least capable but the most numerous type of laboratory common in hospitals and clinics – to Level D laboratories at the Centers for Disease Control and US Army Medical Research Institute for Infectious Disease (USAMRIID). This network alleviates the need for costly upgrades of laboratory capacity at the local level. All states now have some laboratory capacity to respond to a bioterrorism event, if not locally, then through LRN resources.

A number of initiatives should be undertaken to improve the nation's laboratory response capabilities in preparation for bioterrorism incidents and other infectious disease emergencies:

- Given that many bioterrorism agents result in flu-like symptoms, physicians must be encouraged to take cultures and request laboratory analyses on a more routine basis to ensure that something unusual is not underway, especially if patients are presenting with flu-like symptoms out of flu season.

- Because rapid diagnostics will be critical for early intervention, Level B and C laboratories need to continue to upgrade their capabilities, including increasing the range of potential bioterrorism agents that they are capable of positively identifying.

- Training for laboratory technicians is needed to expand their awareness of the full range of potential bioterrorism agents.

- The LRN must expand its network of clinical laboratories and better integrate food, water, and veterinarian laboratories to ensure that diagnostic capabilities for the full range of bioterrorism agents are available.

- The CDC should continue to provide funding through the federal grants process to build advanced laboratory capacity at the state level, which will reduce dependence on CDC and bolster bioterrorism assessment tools at the state level.

MEDICAL MANAGEMENT

Medical responses to bioterrorism incidents involve four key functional areas: prophylaxis, treatment, triage, and logistics. *Prophylaxis* is the provision of medicines or vaccines necessary to prevent the onset of symptoms and the further transmission of the disease to potential bioterrorism victims. Providing prophylaxis to a large population entails overcoming significant challenges, including: quickly determining the agent used and the segment of the population most likely to have been exposed; finding adequate supplies of the appropriate medicine or vaccine; and rapidly mobilizing distribution systems to disseminate the medicine or vaccine either by bringing them to the people or asking people to come to the supplies.

Providing *treatment* to victims is also challenging. While the extent of the task ultimately depends on the number of people affected, three elements are essential to effective treatment: meeting resource needs – including both material needs (equipment, medicines, and space) and staff – developing a care standard for those affected, and implementing appropriate treatment measures. Care providers must also establish appropriate procedures to provide adequate levels of care while preventing transmission (if the agent is contagious).

Providing prophylaxis and treatment hinges upon effective *triage* mechanisms. Effective triage can reduce system stress by separating the worried well, the potentially exposed, and the sick, and sending them to the appropriate care facility, which may include self-medication in the home.

All of these activities depend on the establishment and exploitation of adequate *logistical arrangements* for materials, equipment, and personnel. Bioterrorism-related logistics systems begin with the creation of tracking systems at the local, state, and federal levels to track the availability and expenditure of medicines, equipment, and medical supplies, in addition to the establishment of local and federal supply stockpiles of these materials. The recent establishment of the National Pharmaceutical Stockpile represents an excellent first step.

Considerable progress has been made in developing a national response capacity built upon local, state, and federal capabilities. Among the notable elements are:

- The National Disaster Medical System, including the Disaster Medical Assistance Teams and cooperative hospital agreements.
- A series of 70 Metropolitan Medical Response Systems (MMRS) whose purpose is to support the organization and development of a local medical response system for CBRN terrorism incidents in designated urban areas.
- National stockpiles of pharmaceuticals and medical supplies, including CDC's National Pharmaceutical Stockpile Program, started last year.

There are a number of areas, however, in which capability remains insufficient or uncertainty remains. An important area of uncertainty is the degree to which hospitals and treatment facilities are preparing for bioterrorism. While hospitals have been involved in some planning efforts, for example, they remain unwilling and unable to bolster their bioterrorism response capacity. Few hospitals maintain more than a few weeks supply of medicines and other materials and generally maintain less than 100 available beds at any one time. In addition, localities are developing plans for triage, mass prophylaxis, and treatment, but there is a lack of means to thoroughly test these plans. Most of these plans, for example, fail to identify additional sources of manpower for contingencies that would be needed when the size and scale of the response quickly absorbs local resources. A related problem is the relatively narrowly defined urban areas covered by the MMRS approach, which leaves many suburban areas uncovered.

Successful preparation and execution of medical management activities requires addressing a number of **key issues**:

- Triage plans should be in place before an incident and include public information measures to promote order at triage points, and measures to resolve legal ambiguities associated with denial of treatment.
- Further consideration should be given to providing pre-event prophylaxis to key response personnel to ensure their availability during a crisis.
- Medical management plans should be developed and tested to ensure they have sufficient flexibility and scalability to the size of the incident.
- To ensure maximum flexibility, scalability, and efficiency, the eight “push packages” of the National Pharmaceutical Stockpile should be broken into smaller packages, with each mini-package containing a single type of material or equipment.
- Municipalities and counties should develop local medical supply bubbles, with state and federal support, both to improve local response capabilities for smaller scale incidents and to address the time delay associated with the arrival of state and federal assets in response to large-scale incidents.
- Bioterrorism response plans must include detailed procedures for identifying and mobilizing additional manpower reserves for large-scale incidents.

TRAINING AND EDUCATION

Early recognition of a biological attack depends on two critical resources: epidemiological warning networks and the individual clinical expertise of medical personnel. Training for medical personnel, lab technicians, public health officials, and hospital administrators will play a key role in helping to ensure that hospitals and communities are prepared to detect and respond to bioterrorism incidents.

Training requirements fall into two distinct but connected categories: content and organization. Content addresses what trainees need to know; organization provides the medium through which training can be carried out most effectively.

Education and training for physicians and nurses on bioterrorism should encompass several important elements:

- Agent and outbreak recognition;
- Treatment of casualties;
- Protection of personnel and hospital staff;
- Resource acquisition; and
- Response plan implementation.

Some key organizational mediums for conveying this information include classroom-style seminars, web-based teleconferencing, continuing medical education programs, and tabletop exercises. Each of these methods, however, has strengths and weaknesses, and an effective training program over time will likely require all of them, integrated into a multi-faceted, coherent program.

Training to date has been conducted largely through programs that take a “train-the-trainer” approach. The Nunn-Lugar-Domenici Domestic Preparedness Program (DPP), established in 1996, has played the largest role in training. DPP has provided training to over 90 cities since its inception, and many of the cities have institutionalized various adaptations of its weapons of mass destruction training, primarily in their fire and law enforcement training academies.

While DPP has resulted in substantial improvements in the "first responder" community's preparedness for chemical terrorism incidents, problems specific to the organization and content of the courses have contributed less to bioterrorism preparedness. The program has focused heavily on traditional agent recognition and treatment. Training has not fully addressed some issues related to the public health and medical response, such as implementing a community-based surveillance system, expanding the current capacity of the health care system, creating more bed space, accessing additional supplies and equipment, and providing adequate staff. In addition, DPP has frequently scheduled training events without keeping the nature of hospital staff schedules in mind. This fact, in combination with inadequate publicity for scheduled events, has resulted in lower attendance by medical professionals in several cities than should be the case.

A number of initiatives should be undertaken to improve training and education efforts, including:

- National bioterrorism training programs should place a greater emphasis on health and medical response issues and focus more closely on procedures for dealing specifically with biological incidents, including agent and outbreak recognition and treatment measures.

- Training should focus on "big picture" response issues, such as implementing a community-based surveillance system, expanding the capacity of the health care system, creating more bed space, and acquiring additional medical equipment.

- Greater efforts must be made to attract medical personnel to training sessions. A greater focus should be placed on flexible sessions that can accommodate the schedules of health care practitioners. Training activities must be scheduled to fit better into a typical medical calendar.

- Medical personnel should be more involved with the planning of local, state, and federal government response efforts. Public health and medical organizations must play a greater role in shaping training guidelines, class content, and program structure.

INFORMATION AND COMMUNICATIONS

Building an integrated detection, assessment, and response system depends on providing the right people with the right information, at the right time. Information strategies must be developed both to guide capacity building in the areas outlined above and to ensure that necessary information requirements are met in a timely fashion – before, during, and after an event.

The requirements for information and communication fall into two distinct but related categories. The first category relates to requirements derived from preparedness and planning activities, including:

- Mechanisms for planners at the local and state levels to exchange ideas and concepts produced by their activities with counterparts across the country;
- Training systems that provide instruction and information in an effective, efficient, and low-cost manner;
- Links between health surveillance data providers and the agency or department charged with performing the monitoring and assessment function;
- Links between laboratories at all levels of capability into a national laboratory network;
- Warning and alert systems that raise awareness and suspicion of a potential bioterrorism incident;
- Mechanisms for public safety and public health officials to interact and share ideas and perspectives about their roles and responsibilities during a bioterrorism incident; and
- Appropriate feedback mechanisms to government officials at all levels of government.

The second category of information requirements relates to those during an actual bioterrorism incident, when information and communication requirements shift in terms of content, the types of media utilized, and timeframes. Much of the emphasis in the medical arena must focus on providing public safety personnel, health care providers,

logisticians, safety and security personnel, and the general public with information on the nature of the incident and how it is progressing, the actions they should take, and the current status of response activities. Coordinating this activity requires meeting a number of requirements:

- Effective communication systems should link public health officials, medical care providers, and the incident commander to provide real-time, two-way voice and data communications;
- The respective communication systems of federal, state, and local organizations must be interoperable;
- Information systems should be able to track available resources and how those resources are being utilized throughout a response scenario;
- Epidemiologists and laboratory personnel should remain in coordination with the incident coordinator throughout the event; and
- Communication systems should be tested on a regular basis to ensure continuous system availability.

Increasingly, the central role of information and communication in counterterrorism activities is being recognized by those involved with capacity building programs. Because of this, a number of initiatives have been designed and are being implemented to improve the ability of information infrastructures to meet this objective. Foremost is the Health Alert Network (HAN) program, which is designed to improve the basic information technology infrastructure of state and local public health departments.

The HAN Program represents an excellent first step in substantially improving the public health information infrastructure. **A number of next steps must still be taken, however, to develop a more robust national information infrastructure for bioterrorism preparedness and response, including:**

- Identification of the full set of communication systems and initiatives and work to ensure they are integrated and interoperable;
- Creation of organizations and processes to involve local, state, and federal response stakeholders in coordinating communication requirements, needs assessments,

standards development, and program implementation – a coordination process that must begin with federal agencies; and

- Establishment of a section within CDC's Bioterrorism Preparedness and Response Program office dedicated to information sharing and outreach activities.

SECTION II: ORGANIZATION AND COORDINATION ISSUES

FEDERAL, STATE, AND LOCAL PREPAREDNESS & RESPONSE ISSUES

Many federal departments and agencies have been mandated to work with local entities to bolster the nation's preparedness to respond to a WMD terrorist attack. As federal, state, and local interaction has evolved, it has become apparent that the initial approach to building preparedness needed mid-course adjustment. This is largely due to how programs were initially designed, differing federal, state, and local perspectives, and differences in culture between the public health and public safety communities. Central to these adjustments has been the increased integration of the public health and medical communities into preparedness activities, largely because of the growing realization that a response to bioterrorism will depend on their expertise with disease outbreaks, as well as greater emphasis on building awareness and assessment strategies. While progress has been made on all fronts, some problems in building preparedness and integrating the various communities into the response system remain.

The initial approach to building preparedness was based primarily on building response capacity. A myriad of local, state, and federal entities are now involved. According to current counterterrorism policy, the Federal Bureau of Investigation (FBI) has the "lead agency" responsibility for crisis management, while the Federal Emergency Management Agency (FEMA) will be responsible for the consequence management phase of the response. This bifurcation complicates unity of command, as half of the response will be dominated by the federal government, while the other half, although

overseen by FEMA, will rest mainly in the hands of state and local authorities. Moreover, there is no definitive point at which response to a terrorist incident moves from the crisis to consequence management stage; in some cases, these phases may occur simultaneously, or consequence management may precede crisis management.

Many local responders have also expressed concern that federal agents will try to assume command following an attack without any knowledge of or attention to local dynamics, and they point out that local response agencies have a better grasp of the synergies of their city or region, know where excess supplies exist, how to get around, and whom to contact if something is needed. As a result, confusion exists over which agencies will take the lead if federal assistance is requested and how they will interact with local authorities.

Many other federal entities now have a stake in bioterrorism response and preparedness. Some states' National Guard units have WMD Civil Support Teams (CST). The role of the Civil Support Team is to "assist local entities in determining the nature of a bioterrorism attack, provide medical and technical advice, and help identify what federal military response assets may be necessary." However, while CST teams may prove useful in responding to a chemical attack, it is unclear how much they could contribute in responding to a covert biological attack.

The Department of Defense's official role is to support FEMA. The Secretary of the Army directs DoD's efforts to provide a wide variety of support services, ranging from laboratory assessments to specialized teams trained and equipped to detect, neutralize, and respond to incidents involving biological agents. For biological incidents, response teams and laboratories at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) and the U.S. Naval Medical Research Institute can help identify biological agents and administer appropriate antidotes and vaccines. The Marine Corps also established the Chemical Biological Incident Response Force (CBIRF) as a consequence management tool capable of responding to chemical and biological

attacks and the Army's Technical Escort Units (TEU) and the Navy's Defense Technical Response Group (DTRG) could also be used in these scenarios.

Furthermore, the Department of Health and Human Services (HHS) has developed specialized National Medical Response Teams for Weapons of Mass Destruction (NMRTWMD) which are designed to provide medical services and assist federal or local agencies in the event of an incident involving biological or chemical agent release. HHS also coordinates the federal health and medical response and recovery activities in the event of catastrophe, natural or man-made. The initial approach of HHS was to develop the Metropolitan Medical Strike Teams (MMST) to rapidly respond to disasters. Today, however, its strategic plan takes a system-wide approach that focuses on developing partnerships with local jurisdictions to develop enhanced Metropolitan Medical Response Systems (MMRS) as the primary local resource for dealing with both man-made and natural disasters, including CBRN terrorist incidents. Given that these and a number of their federal entities will have to interact with many local entities – private physicians, hospital staff, public health officials, laboratory technicians, the military, fire, police, and other emergency responders – reducing confusion and ensuring that efforts are not working at cross purposes is a significant challenge to be overcome.

Initial federal efforts at building bioterrorism preparedness were focused on response and done through DoD's Domestic Preparedness (DPP) training program. While the DP program incorporated information on biological incident response, it was largely designed around a HAZMAT template. This is due in part to the similarities between chemical weapons attacks and HAZMAT incidents which led the DP program to target public safety entities – in particular, fire departments – already responsible for HAZMAT incidents.

Coordination of response activities after an act of domestic terrorism have also been organized under the Incident Command System (ICS), the most widely accepted command and control model for emergency response. ICS is a management system that

promotes coordination and communication between responding agencies and attempts to minimize duplication of effort. In essence, ICS creates a unified command to oversee the action and interactions of the various organizations involved in response, and sets forth standardized procedures for managing personnel, communications, facilities, and resources. But the public health community, which is a central part of bioterrorism preparedness and response, is not trained in this system. Although developed through HHS, the MMRS program is also heavily public safety oriented and is focused largely on building response capacity at the local level. HHS has left the building of awareness and assessment tools – surveillance, detection, epidemiology, and laboratory capacity – to the CDC, which works with state and local health departments in these areas.

A public safety-heavy approach initially left the public health and medical communities largely out of the mix. Today, the public health community is more integrated into the bioterrorism preparedness and response system, although some resistance is apparent on the part of those in the public safety sector who feel that they must defend their stake in the issue, sustain funding levels, and maintain their importance as a player in bioterrorism-related activities. This "friction" resulting from competition over limited resources has been exacerbated by a "clash of cultures" between the public health and public safety communities. Even when significant efforts are made at the local level to integrate elements of the health and medical systems with more traditional emergency response communities, the result is sometimes less than satisfactory. Probably the most glaring example is the lack of involvement of hospitals, both public and private, and primary care physicians in bioterrorism response planning and coordinating processes. While lower-level hospital representatives often participate in bioterrorism response planning meetings, senior hospitals administrators and staff generally do not give bioterrorism issues high priority.

A number of next steps could improve on many of these concerns:

- Roles of the federal government and the state and local government must be examined and clarified to prevent confusion. Responders at all levels must continue

to resolve intergovernmental issues, including minimizing redundancy among federal, state, and local efforts and eliminating confusion at the recipient level.

- The creation of an integrating body at the level of the Executive Office of the President that possesses executive and budgetary authority could greatly benefit the nation's overall counterterrorism initiative and may also be a catalyst for integrating the public health and medical communities more thoroughly into bioterrorism preparedness activities.

- Current and future WMD preparedness initiatives should make a conscientious effort to distinguish more clearly between chemical, biological, radiological, and nuclear terrorism, with particular attention to how the response requirements for bioterrorism differ from the others.

- Senior leadership at HHS needs to clearly delineate preparedness roles and responsibilities for CDC and OEP respectively and conduct regular program reviews to prevent "mission creep."

- Planning and coordination activities at all levels need to pay special attention to the challenge of integrating hospitals into the bioterrorism response system. A federal Task Force or Working Group should be established to identify the challenges that hospitals face in becoming integrated in the bioterrorism response system, and to devise some realistic solutions for overcoming those challenges. Federal grants for building public health and medical capacity for responding to bioterrorism should be extended to a sixth focus area aimed at hospitals.

- Few bioterrorism response plans have incorporated public health and medical personnel into command roles, despite their frequent designation as the "first line of defense." Public health must be more fully integrated into the command and control infrastructure at the local level.

PUBLIC-PRIVATE PARTNERSHIPS

Bioterrorism preparedness and response is a *national* security challenge, with the federal government playing a central role. But the federal government cannot respond to this challenge alone. It requires the support and cooperation of a number of both public, non-federal institutions and private organizations. Developing a strong partnership between the public and private sectors, however, has its own set of challenges and complications.

Developing a strong public-private partnership requires the government to undertake several initiatives to garner interest, address the private sector's concerns, and develop a lasting partnership. These include:

- Developing a public and private dialogue on issues of common concern
- Understanding differing motivations and perspectives
- Cooperatively defining roles and responsibilities
- Addressing burden sharing issues

Several industry sectors play important roles in bioterrorism preparedness.

- Hospitals and other medical care providers serve as a central data source for health surveillance systems while also providing the core capability for providing medical care to the victims.

- The print and electronic media serve as the main interface between the government and the general public – before, during, and after bioterrorism incidents.

- Companies manufacturing medical supplies and pharmaceuticals support preparedness through their involvement in building the national stockpiles and supporting local capabilities.

- The information technology sector's role in building the information infrastructure underpinning both preparedness and response capability means this sector also plays an increasingly central role.

Integrating these sectors into the bioterrorism preparedness effort has been a difficult process, perhaps for the health care industry most especially. The desire for increased cost efficiency and increased competition within this sector has reduced the resources and time expended on bioterrorism planning and preparedness to very low levels. Moreover, this drive for efficiency is rapidly shrinking excess capability available for responding to emergency situations. These difficulties have been compounded by a common belief among hospital administrators that bioterrorism incidents are highly unlikely, especially in comparison with the emergencies to which their facilities have to respond on a daily basis. **As a first step towards an improved partnership between the government and the health care industry, a national summit on the public health and medical dimensions of bioterrorism preparedness and response should be held.**

CENTERS FOR DISEASE CONTROL AND PREVENTION

The Bioterrorism Preparedness and Response Program (BPRP) Office is the nexus of CDC's bioterrorism preparedness and response activities. Because it has been charged with the mission of building capacity within state and local public health agencies, it also serves as an interface between federal, state, and local entities on issues pertaining to public health and medical preparedness. Since its creation, BPRP has produced numerous improvements in bioterrorism detection, assessment, and response capabilities in these communities. Specifically, BPRP has:

- Significantly raised the level of awareness, both with other federal departments and agencies and with the local and state public health agencies themselves, regarding the role of public health in bioterrorism preparedness and response;
- Organized and improved CDC's bioterrorism response capacity by improving laboratory response within the CDC, developing the National Pharmaceutical Stockpile, and developing a 24-hour emergency response system;
- Coordinated a significant grant program to support bioterrorism planning and preparedness programs of state and local public health agencies; and
- Worked to improve the integration of public health and medical organizations into counterterrorism programs at the federal, state, and local level.

While these successes are significant, no one believes the nation's public health and medical system is fully prepared to respond to bioterrorism incidents. BPRP should build upon its successes, exploit the strengths of its approach, specifically its focus on building public health capacity at the state and local level, and make adjustments where necessary.

During the initial two years of its bioterrorism preparedness and response program, CDC has based programs on a number of planning assumptions, fostering a specific approach to both planning and preparedness. To date, for example, CDC has used worst-case, low-probability hypothetical incidents as the prime scenario against which planning has occurred. Furthermore, CDC has not adequately defined in sufficient

detail the capability requirements of the detection, assessment, and response system. Without such a specification of requirements, it is difficult to gauge the effectiveness of current levels of preparedness, develop realistic program timelines, and estimate the resources needed to improve capacity to an acceptable level.

Additionally, CDC officials must consider shifting the strategic focus from all functions to developing a special emphasis on detection and assessment capabilities. Robust "front end" capabilities – early and accurate detection and assessment – reduces the demand placed on "back end" capabilities, especially medial measures.

To this end, BPRP must have the leverage necessary to manage and integrate CDC's bioterrorism initiative. Such leverage could be created if BPRP was placed within the Office of the Director and given budgetary authority over the overall initiative.

Providing BPRP with leverage and influence will allow it to improve its coordination not only within CDC but also with other government agencies and departments and with private sector entities. CDC should continue to work closely with private organizations – for example, the Association of Public Health Laboratories, the Association of State and Territorial Health Officials, and the National Association of City and County Health Officers – as well as federal partners, including the Office of Emergency Preparedness at HHS and the Office of Justice Programs at DOJ, and their partners at the state and local public health departments.

To this end, **BPRP should serve as an information clearinghouse for bioterrorism preparedness and response for the public health and medical community. Central to such a function is a concerted outreach and education program aimed at critical constituencies for improving bioterrorism preparedness.** This includes both lawmakers on Capitol Hill, senior executives within the health care industry, and the public at large.

PART III: GENERAL CONCLUSIONS AND RECOMMENDATIONS

HHS and CDC bioterrorism planning and preparedness seem to be based on defining the driving factor as the potential of some agents to create catastrophic casualty situations without looking at the probability of these types of incidents. For a number of reasons, including technical difficulties and motivational issues, however, a catastrophic bioterrorism event is not the most likely contingency. Among the various technical bioterrorism pathways, only the release of a very contagious or very high quality agent using a highly efficient dissemination technique could produce casualty figures in the thousands or higher. In essence, the number of pathways open to terrorists to produce catastrophic levels of casualties are few, and those that do exist are technically difficult.

The number of technical pathways for producing a low to mid-range bioterrorism incident are more numerous, less technically challenging, and fit better within the motivations and constraints of more traditional concepts of terrorism. A graphical representation of the bioterrorism "threat envelope" is shown in figure three.

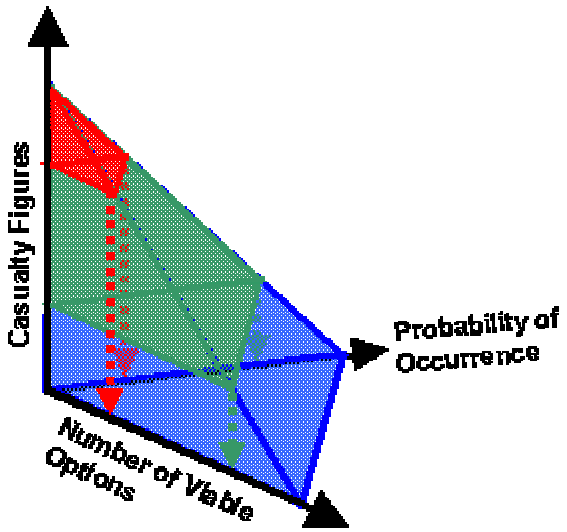

Figure 3 – Graphic Representation of the Bioterrorism Threat

It is sometimes assumed that preparing for the high-end attacks provides a capability to respond to the middle and low range attacks. But in certain areas, this assumption does not necessarily hold true. Examples include:

- Providing doctors and nurses with training only on the handful of agents with the highest potential for massive casualties rather than a more complete set of agents, including incapacitating agents;

- Providing laboratories with training, testing protocols, and reagents for the same restricted set of threat agents rather then ensuring that the laboratories can rapidly diagnose a more complete set of agents;

- Compiling and structuring the National Pharmaceutical Stockpile to provide a "one-size fits all" response capability based on the treatment and prophylaxis requirements for a large-scale attack rather than ensuring that scalability and flexibility is built into the stockpile to ensure the response can be tailored to the size and scope of the incident; and

- Drafting local-area response plans with a focus on massive response capability rather than using an integrative planning approach that accounts for a range of attack scenarios, ranging from a few hundred casualties to tens of thousands.

While focusing planning and preparedness on the set of high-end attack scenarios simplifies planning and preparedness by narrowing the range of contingencies for which preparations are necessary, it introduces a substantial degree of risk that the public health and medical system will be unprepared for the more likely, but less drastic contingencies or will inappropriately respond to a low or middle range incident as though it were a catastrophic situation. Such a response could produce the severe social disruption and psychological impact many terrorists look to achieve.

Keeping this risk in mind, this reports emphasizes several key themes that must shape CDC initiatives to improve the nation's capacity to detect, assess, and respond to bioterrorism incidents. These include:

- ***The Need for Flexibility***

This analysis suggests the need to shift HHS and CDC planning assumptions and operational focus from an emphasis on preparedness for a narrow set of "catastrophic" bioterrorism incidents to preparedness for a wider, more likely set of low and mid-range attacks while hedging against the possibility of a high-end attack.

Emphasizing flexibility imposes the need to alter planning and programmatic activities in a number of areas. Greater emphasis, for example, should be placed on developing response systems that are flexible and scaleable according to the nature of the agent utilized and the number of people affected. Local and federal response plans should take a tiered approach that links a range of casualty figures with certain actions.

Increasing flexibility raises the demand for effective detection and assessment tools. Such robust tools facilitate early and effective intervention. Early detection, for example, decreases the burden placed on medical management. Robust assessment tools provide the ability to tailor the response to the incident by identifying the agent utilized and the group of people who are likely to have been affected by the incident. In situations in which detection and assessment capabilities are weak, all bioterrorism incidents are likely to be treated as high consequence incidents – if they are detected at all – to eliminate the possibility of some potential victims having not been provided with appropriate care.

- ***The Importance of Information and Communication***

Flexibility depends in large measure upon providing the right people with the right information at the right time. A robust information infrastructure underpins all of the components of an integrated detection, assessment, and

response system. Surveillance, epidemiology, and laboratory capacity depends on information infrastructure for capacity building – training, networking, sharing ideas and lessons learned, and development and exchange of procedural guidelines – and executing their respective functions on a day-to-day basis. Coordinating the providers, materials, and recipients during the response requires robust information and communication infrastructure. Integrating detection, assessment, and response components into a system depends on developing the necessary social and technological information infrastructure to provide accurate information in a timely manner.

- ***The Value of Public-Private Partnerships***

Accomplishing many of the objectives defined in this study will require cooperation between the public and private sector. There are key preparedness activities in which the private sector should play a role, but others should not burden the private sector, especially those that are only relevant to a massive response to a large-scale attack. At present, the threat of a large-scale attack is low, and asking the private sector to assist in preparing massive distribution plans for medications or to maintain unnecessary surge capacities for this contingency is unreasonable.

On the other hand, there are key preparedness activities from which the participation of the private sector would greatly benefit. Surveillance is one example. Health Maintenance Organizations should be encouraged to permit physicians to request laboratory culture analyses on a more routine basis, but HMO's cannot be expected to pay for hospitals to maintain surge capacities to absorb casualties from a large-scale bioterrorist attack. Likewise, private laboratories and hospitals, work places, pharmacies, etc. have a wealth of data to provide a surveillance system, and the more data sources that are integrated into the surveillance system, the better public health awareness will be. Given that surveillance is critical for providing the overarching response system with

awareness, private sector participation in surveillance should be encouraged over participation in response measures that will only apply in a mass casualty attack.

It is these types of measures, the kinds that are flexible and relevant for dealing with the full range of bioterrorism contingencies as well as natural outbreaks, that need to be emphasized when building preparedness, at least in the current situation. Not everything can be done immediately. The key question is what should be given priority today and, as improvements in key sectors are made, what future shifts in priorities can be contemplated. This report recommends placing initial emphasis on building and connecting the "front-end" of the bioterrorism response system. As those capabilities are enhanced, efforts can then begin to focus more intensively on other capabilities, including treatment requirements.

RECOMMENDATIONS

Surveillance:

- CDC must devise a program for developing a national health surveillance system to provide early warning of bioterrorism incidents. A national system would integrate federal, state, and local public health departments, health care providers, and non-traditional surveillance partners such as local pharmacies, emergency medical services, and the veterinary community.

- The first step toward the creation of a national system would be the development of a national strategy for building such a system. The strategy would examine the feasibility, determine the requirements, and design a multi-year program for creating the system.

- Surveillance systems should establish and integrate automated disease reporting systems, syndromic surveillance systems, and automated data reporting systems from non-traditional partners.

- Developing a national health surveillance system to detect bioterrorism incidents requires the establishment of electronic data networks between local public health departments and local area health care providers.

- CDC should establish a separate surveillance grant program and work with Congress to ensure adequate funds are available to build the necessary information infrastructure.

- Local providers of surveillance information, including health care providers, should not be expected to use their own resources to develop the required communication infrastructure.

- Mechanisms should be established to provide the necessary surveillance information without compromising proprietary or confidential patient information. An important element of the solution is enforcement of federal regulations for patient data confidentiality. Another is development of technological solutions for parsing data to compile general and statistical information without association with specific patients, customers, or businesses.

- A national research and development program focused on improving surveillance technologies should be initiated.

Epidemiology:

- Developing better disease surveillance systems bolstering epidemiological staff in state health departments to manage surveillance functions are critical.

- The labor-intensive nature of epidemiology requires that more funding be provided to state departments of health to hire additional epidemiological staff. This should be a priority focus area for building assessment tools that can make the response more focused and efficient. In rural states, this capacity should be built at the state level. In mixed urban and rural states, urban centers should maintain a robust epidemiological capacity to deal with incidents in that city, but efforts must be balanced with state efforts to develop a state-wide capability.

- The CDC should emphasize a wider range of bioterrorism agents than those that currently receive most of the attention. Greater awareness of the range of bioterrorism agents should be better conveyed to epidemiologists.

- Thresholds for triggering particular responses should be defined to avoid unnecessary "hair trigger" responses. The first inclination of a suspicious outbreak should trigger an *initial response phase* -- alert hospitals and physicians, require doctors to take culture samples, seek laboratory diagnosis, and notify the appropriate federal, state, and local authorities. *Large-scale mobilization* of the response system should require that a second threshold be crossed, for example, laboratory identification of the etiologic agent representing an imminent public health threat or the accumulation of surveillance data that indicates such measures are necessary.

- Local departments of health need funds to make use of, and integrate, information technologies that can be used to collect, deposit, analyze, and share surveillance and epidemiological data from a central location in the department of health.

Laboratory Requirements:

- Physicians must be encouraged to take cultures and request laboratory analyses on a more routine basis to ensure that something unusual is not underway, especially if patients are presenting in large numbers or with flu-like symptoms out of flu season.

- The LRN must expand its network of Level A laboratories and better integrate food, water, and veterinary laboratories to ensure that diagnostic capabilities for the range of bioterrorism agents are available.

- The CDC should continue to provide funding through the federal grants process to build advanced laboratory capacity at the state level.

- Level B and C laboratories need to continue to upgrade their capabilities, including increasing the range of potential bioterrorism agents that they are capable of positively identifying, so as to reduce their dependence on the CDC laboratories.

- State laboratories should also bolster their ability to test for microbial sensitivity and determine whether a particular medication will be effective against the given agent.

- The CDC's Rapid Response and Advanced Technology laboratory (RRAT) should continue to expand its technical capacity for rapidly diagnosing critical agents as well as a broad range of potential bioterrorism agents that may be used in an attack.

- Technology-based training is continuously needed.

- Training for laboratory technicians is needed to expand their awareness of the range of potential bioterrorism agents.

- Laboratory technicians at all levels, particularly in Level A laboratories, should receive awareness training and proficiency screening for issues related to bioterrorism.

- Laboratory communication and information infrastructure should be bolstered.

- Funding is needed to renovate or redesign laboratory floor plans to ensure the best use of space and to accommodate additional equipment and personnel.

Medical Management:

- Localities should develop prophylaxis and treatment plans that are phased or broken into escalatory segments.

- A pre-incident plan for where triage will take place needs to be in place before an event. A public information strategy should be devised in advance of an attack that will provide clear and accurate information about when treatment is required and where it should be received.

- Localities should be provided with the resources needed to develop an independent first-tier prophylaxis capacity within local medical care providers, either through mutual aid agreements or regional buy-ins, to

allow for a comprehensive response in the 48 hours before federal aid arrives.

- Arrangements for counseling patients should be made to reduce panic and confusion at triage points and to ensure order.

- Agreement must be reached in advance about who can make triage decisions in the event of a bioterrorist attack, and the medical and legal ramifications of these decisions need to be considered.

- Some thought might be given to providing certain segments of the population with pre-event prophylaxis.

- To ensure efficient use of local resources, a tracking system should be set up to track the movement and use of medical supplies during a bioterrorism response.

- As a hedge against a possible smallpox incident, the current supplies of vaccine should be readied for a rapid, mass prophylaxis program and a surge vaccine production capability should be established.

- Additional planning is needed to determine how the state and federal government can provide additional manpower in support of prophylaxis and treatment as a hedge against large-scale bioterrorism incidents. Given the size of its available manpower base and its logistical capabilities, the Department of Defense should lead this effort.

- Improved evaluation methods, including the development of computer simulations, must be developed to assess the adequacy of local prophylaxis and treatment plans.

- Local plans for prophylaxis should recognize and account for additional state and federal assets that will be made available by planning for how these assets will be utilized.

Training and Education:

- Properly training medical, public health, and emergency personnel is essential to a comprehensive detection, assessment, and response framework.

- The Domestic Preparedness Program should place a greater focus on health and medical response issues, and training should be adapted from HAZMAT criteria to focus more closely on procedures dealing specifically with biological weapons response, including agent and outbreak recognition and treatment measures. Training should focus on

"big picture" response, incorporating integrated response issues, communication, surveillance, and reporting.

- Efforts must be made to attract medical personnel to training sessions. Greater emphasis should be placed on flexible training sessions and the exploitation of electronic and multimedia training techniques to accommodate the schedules of health care practitioners. A good first step is making DP training materials available through the internet.

- Medical personnel should be involved with the planning of local, state, and federal government response efforts.

Information and Communication:

- CDC and other federal agencies should further emphasize the need for improved information infrastructure and actively work to provide state and local partners with both the necessary financial resources and the consultative expertise to build a truly national public health information network that includes traditional local public health agencies, as well as other key bioterrorism preparedness and response partners like federal and local law enforcement entities.

- The keys to developing a national BT preparedness and response information infrastructure are making sure the individual components and initiatives already in train are able to meet key requirements, defining and implementing new initiatives where gaps exist, and then working to integrate the various technical communication systems into an effective network.

- In order to ensure interoperability of their communication systems, health departments, hospitals and other primary care givers, and public safety agencies need to be contacted and consulted throughout the process of developing such standards.

- Federal departments and agencies must coordinate their various information infrastructure-building initiatives to ensure the communication systems they are supporting are integrated and interoperable.

- During the initial years of CDC's bioterrorism preparedness effort, special emphasis should be provided to the HAN program to include increased funding allocations for building upon information infrastructure.

- The Bioterrorism Preparedness and Response Program Office should establish an information sharing and outreach branch within the office.

Federal, State and Local Preparedness & Response:

- Current and future WMD preparedness initiatives should make a conscientious effort to distinguish more clearly between chemical, biological, radiological, and nuclear terrorism, with particular attention to how the response requirements for bioterrorism differ from the others.

- Given their familiarity with the local geography, resources, and personnel, local authorities should play a significant role in response management. Command and control of a bioterrorism incident should be shared between federal and local entities, and capabilities should be built by recognizing the differing strengths of the two levels.

- Bioterrorism planning related activities should be administered at the state level to ensure that not only "metropolitan proper", but the surrounding municipalities and suburbs are included in planning activities. The Bioterorism Preparedness Plan contracts currently included as an annex to the MMRS emergency response plans should be developed at the outset. Some level of federal follow-on funding is required to sustain bioterrorism planning activities to ensure that the current level of communication and interaction between the local health and medical and public safety communities continues.

- Planning and coordination activities at all levels need to pay special attention to the challenge of integrating hospitals into the bioterrorism response system. A federal Task Force or Working Group should be established to identify the challenges that hospitals face in becoming integrated in the bioterrorism response system, and to devise some realistic solutions for overcoming those challenges. Federal grants for building public health and medical capacity for responding to bioterrorism should be extended to a sixth focus area aimed at hospitals.

- Public health must be more fully integrated into the command and control infrastructure at the local level.

- Roles of the federal government versus the state and local government need to be examined and clarified to prevent confusion. Responders at all levels must continue to resolve intergovernmental issues, including minimizing redundancy among federal, state and local efforts and eliminating confusion at the recipient level.

Public-Private Partnership:

- Government must work with the private sector to ensure they become a full partner in the bioterrorism preparedness activities. The sectors of greatest importance are the health care industry, the print and electronic

media, the pharmaceutical industry, and the information technology sector.

- The health care industry is an especially important private sector partner in bioterrorism preparedness. As such, federal government officials need to focus on integrating the health care sector into bioterrorism efforts. One idea for a first step, both as a means of demonstrating political commitment and fostering an improved dialogue, is a national summit on the medical dimensions of bioterrorism preparedness.

- Because the media will serve as the main interface between the government and the public before, during, and after bioterrorism incidents, a media strategy for bioterrorism and other disasters must be integrated into counterterrorism efforts.

- HHS and CDC should strive to become the recognized governmental "authority" regarding medical and health issues associated with BT, preparedness, and response. They must take a more active role in developing strong relationships with the media to better inform them on the technical aspects of public health practice and biological terrorism.

- Through the Health Alert Network Program, CDC should work more closely with the information technology sector to build public health information infrastructure and exploit information technology to improve bioterrorism preparedness and the practice of public health more broadly.

Centers for Disease Control and Prevention:

- CDC planning assumptions should shift from the narrow set of low probability, high consequence events to the array of more likely middle and low consequence incidents while maintaining a hedge against high-consequence incidents.

- For each component of the bioterrorism detection, assessment and response system, CDC must clearly define the operational capability requirements the respective component should be able to meet.

- In its programs, BPRP must place greater emphasis on developing the "front-end" of the system – surveillance, epidemiology, and laboratory response – to ensure the creation of a robust ability to both detect and assess suspected bioterrorism incidents.

- CDC must develop an "urban strategy" for supporting the organization of local-level partners - public health departments, public safety organizations, medical care providers, and non-traditional partners - into

county and municipal systems for bioterrorism detection, assessment, and response.

- The Bioterrorism Preparedness and Response program Office should be elevated to the level of the Office of the Director at CDC and be provided with budgetary authority over CDC's bioterrorism preparedness initiative. This move will provide BPRP with the necessary leverage to manage the direction, integrate, and, when necessary, adjust public health and medical bioterrorism programs at the CDC.

- Senior leadership at Health and Human Services needs to better coordinate CDC's Bioterrorism Preparedness and Response Initiative with the Office of Emergency Preparedness' disaster preparedness initiatives.

- BPRP should be serving an information "clearinghouse" function and embark on a concerted outreach and education program that is aimed at building critical constituencies for BT preparedness.

- BPRP should develop and implement a strategic plan to educate lawmakers about the importance of both BT issues and public health more broadly to ensure that efforts that are currently underway will be sustained financially into the future.

PART I

THE CHALLENGE OF BIOLOGICAL TERRORISM

INTRODUCTION

Over the last several years, a confluence of events – the World Trade Center bombing, the Tokyo subway sarin gas attack by the Aum Shinrikyo, and the bombing of the Murrah Federal Building in Oklahoma City – focused attention on the growing threat of terrorist use of chemical, biological, radiological, or nuclear (CBRN) weapons in the United States. These developments gave rise to a set of perceptions – among policy makers and the public alike – that the United States is vulnerable to terrorist attack; that such attacks could entail the use of CBRN weapons; and that the United States has not been well prepared to deal effectively with such a challenge.

This set of perceptions promoted a sense of urgency among lawmakers and other policy makers that the United States must act. Over the last five years, the U.S. Congress has provided substantial financial support to many government agencies that have initiated programs to address the CBRN terrorism problem.

The rapid emergence of the perceived threat and the urgency of the U.S. government's response did not provide an opportunity for full development of a systematic analysis of the CBRN terrorism problem. In particular, programs were begun without a strategic framework to guide program definition and resource allocation. Such a framework can serve several critical functions: defining objectives and relating means to ends; identifying key functions of an effective response; creating awareness of tradeoffs among those key components; determining their priorities; and establishing the basis for sustained support of the most critical components over time.

The need for a strategic framework to address the threat of terrorist use of biological weapons (BW) is especially critical. Biological weapons unique instruments of violence, and many of their characteristics could make them particularly attractive for terrorists contemplating the use of mass casualty weapons. As a result, biological weapons could become the mass casualty weapon of choice among terrorists in the years ahead.

Terrorist use of biological weapons could produce widespread, devastating, and tragic consequences. According to the Office of Technology Assessment, if used under optimal conditions, biological weapons could have an impact similar to that of a small nuclear device. A single attack using a sophisticated biological weapons in a major metropolitan area such as Washington, DC could kill as many as 3 million people. Even if casualty levels from a biological attack do not achieve their theoretical maximum, *any* terrorist use of biological weapons in the United States could have profound effects.

Bioterrorism differs from other types of CBRN terrorism in that it would impose particularly heavy demands on the nation's public health and health care systems. Although a chemical attack would also tax these systems, bioterrorism would impose especially stressful burdens. Yet, that same public health system is *the* crucial factor in an effective response. A highly effective public health system should make an important contribution to deterring the threat by demonstrably diminishing the gains of a potential attack. It also constitutes the "first line of defense" in the event deterrence or prevention fails. Ultimately, it will be the public health system that will be called on to mitigate and ameliorate the consequences of a bioterrorist attack.

A number of programs are underway to improve the health and medical dimensions of the national response to the threat of bioterrorism. Uncertainty exists, however, as to whether current programs are those that are most needed or whether they are being implemented in the most effective way possible. This uncertainty exists because to date there have been insufficient means to judge the efficacy of existing programs. This lack of criteria is the product of not having an analytic framework that establishes national requirements for an effective response derived from a comprehensive threat assessment. The development and application of a strategic framework is urgently needed. Making a contribution to the development of that framework is the purpose of this project.

This report analyzes the requirements for an effective health and medical component of the overall bioterrorism response system and assesses where the United

States stands today in meeting those requirements. It does so in the context of an evaluation of the current bioterrorism threat. What is the link between the two? It is simple: a better and more sophisticated understanding of the threat – which emerges from this analysis as a complex, multidimensional phenomenon – better informs decisions about needed response capabilities, helps establish priorities, and more effectively guides resource allocations. The report also includes a series of recommendations, both general and specific, that could strengthen current and future health and medical response capabilities.

Shortcomings of Vulnerability Assessments

One might ask why there is a need for such a study, given that several analyses of terrorism with biological weapons have already been conducted. The reason is that most of the studies done in relation to health and medical requirements of a response to bioterrorism have focused on what biological weapons *could* do, not on what they are most likely to do. They are vulnerability assessments, which, as suggested by terrorism expert Brian Jenkins, suffer from a number of drawbacks in guiding policy and establishing resource priorities.

First, the vulnerabilities of the United States to a bioterrorism attack are virtually infinite. As a result, no definitive catalogue of problems can be developed against which to plan and allocate resources. Defining the bioterrorism problem as virtually limitless can also instill policy paralysis. Confronted with an enormous range of potential disasters, it is hard for policy makers and those who lead response efforts to know where to begin.

Second, vulnerability assessments lead to worst-case analysis. Emphasizing vulnerabilities promotes a focus on catastrophic events, regardless of their likelihood. Indeed, as terrorism expert Brian Jenkins argues, “focusing on only the most horrendous events overwhelms any estimates of their likelihood. The possibility of occurrence becomes irrelevant unless the threat can be dismissed with a high degree of confidence –

of course, it cannot." In fact, the possibility of occurrence, the likelihood, of an event is a critically important factor in planning efforts. It does little good to engage in elaborate preparations for an event that is not likely to happen to the exclusion of addressing those contingencies that are. Moreover, as the Gilmore Commission and others have argued, the assumption that lower consequence/higher probability events can be treated as "lesser included cases" of more catastrophic contingencies is not necessarily warranted.

Worst-case analysis, therefore, can skew resource allocation. It can shift limited resources – money, manpower, and time – toward high consequence, low probability events and away from those events that are lower consequence, but higher probability. The danger, of course, is that without proper preparation, even so-called "lower consequence events" could produce results with significant impact both locally and nationally.

Third, vulnerability assessments create a mentality that tends to reify "what ifs" into imminent risks. In the way that high consequence scenarios are discussed and approached, theoretical possibilities are too often transformed into real contingencies. The result is to give such possibilities more credence than they deserve.

Vulnerability assessments, therefore, while identifying the potential scope of the challenge, provide no sense of whether or not those vulnerabilities can and will be exploited by a terrorist. As a result, they can produce a misdirected planning process, inadequately defined policy choices, and distorted resource allocations.

Vulnerability assessments, however, are not without value. It is natural for policy makers and lead responders to focus on vulnerabilities and the high, indeed catastrophic consequences that could ensue if theoretical possibilities did become reality. No policy maker could accept ignoring the possibility of such consequences even if they were highly unlikely. To do so is politically unacceptable. Vulnerability assessments, therefore, identify contingencies that, while perhaps not central to the planning process,

nevertheless constitute possibilities against which some "hedging" is necessary so that, if the unlikely happens, the system is not totally unprepared.

An effective response to the bioterrorism threat, then, includes both threat and vulnerability assessments – the former to determine the most plausible threat against which the majority of planning and resources should be directed, and the latter to identify those outcomes whose consequences are so severe that they demand some preparatory action and some resources. Of course, what the balance will be between core planning and hedging and how resources will be divided among them is often hard to determine.

The Need for a Strategic Approach

Successfully meeting the challenge of bioterrorism requires a multifaceted response. No single approach will, in and of itself, be successful. It must also be a response that is *strategic* in nature. Clausewitz defined strategy at the military level as "the combination of individual engagements to attain the goal of the campaign…[It is] the employment of battles as a means to gain the object of war." At the level of national policy, a strategy is the intellectual construct that marshals all appropriate resources and guides them toward the achievement of the objective. For the response to bioterrorism to be genuinely strategic, it must integrate all critical policy tools in an approach in which those elements of policy are mutually reinforcing, support the same objectives, do not work at cross purposes, and provide a flexibility that is responsive to changing circumstances and different conditions.

A strategic response to the BW terrorism challenge, therefore, is one in which:

- Each element of policy is as strong as possible.
- Those elements of policy are brought together in a framework marked by
  - Clearly defined objectives;

- ❑ Awareness of pitfalls and potential contradictions; and

- ❑ Emphasis on reinforcing strengths of individual policy tools and compensating for shortcomings.

- The U.S. government is organized to facilitate strategic thinking and action, including

  - ❑ Mechanisms for the effective exchange of information and interaction of key players; and

  - ❑ Flexibility and responsiveness to change.

The Need for Flexible Response

This report emphasizes the need for a strategic approach to the development of public health and medical response capabilities. It places particular emphasis on the need for flexibility. To be successful, any strategy must be agile; it must be flexible enough to adapt to the full range of potential contingencies that can cause harm.

Strategic flexibility derives, most importantly, from having more than a single response option that allows for tailoring responses to the specifics of the event and the severity of the crisis. It diminishes the prospect of wasting resources by not incorporating elements that are marginal or irrelevant to the challenge at hand. Furthermore, it improves the chances of avoiding unintended consequences.

In the military realm, an analogy that provides important insights is the evolution of NATO strategy. In the late 1960s, NATO shifted from a strategy of massive retaliation to a strategy of flexible response. It did so because the alliance did not want to depend on the threat of a major nuclear retaliation as its only response to a wide range of potential contingencies, from a limited "land grab" by Warsaw Pact forces to their full-scale invasion of Western Europe using conventional forces alone. The catastrophic scenario, a strategic nuclear attack by the Soviet Union against the United States or Western Europe – the "bolt out of the blue" – was one for which the threat of massive

retaliation was deemed appropriate. But it was also considered highly unlikely. For those events considered more likely but of lesser consequence, the implications of only having the ability to respond with a major nuclear attack were not acceptable to alliance political leaders. As a consequence they improved NATO's "front-end" capabilities, particularly allied conventional forces. If those capabilities proved insufficient, then NATO would move to ever more dramatic options to deal with an escalating crisis. In essence, NATO strategy came to depend on having a range of effective potential options that could be applied in ways appropriate to the crisis at hand.

The NATO experience suggests a number of lessons for developing a strategic response to the threat of bioterrorism. First, a single, massive response option has serious drawbacks with respect to both resource allocations and unintended consequences. If the only response available to a bioterrorism incident – particularly those that are most likely but of consequences below catastrophic levels – is mobilization of a massive federal apparatus, resources may be unnecessarily expended because more limited capabilities, perhaps local resources augmented in selected areas, are all that are needed to deal with the problem. Moreover, such a massive mobilization could create unnecessary public panic, media scrutiny, and political repercussions. A strategic response should be viewed as drawing on a spectrum of capabilities that can be tailored to the event, organized to be implemented in a phased or tiered manner in increasingly demanding circumstances.

Second, along this spectrum, enhancing "front end" capabilities – surveillance, detection, and assessment – is likely to yield disproportionate dividends. The better the deployed initial capabilities are to meet the crisis, the less likely the crisis will escalate. In the bioterrorism context, this "lesson" suggests paying special attention to improving surveillance and epidemiological capabilities as much as possible. Robust surveillance, epidemiology, and laboratory capacity could lead to fewer demands on medical treatment – and all of the tasks that entails – by limiting the number of victims.

Third, creating flexible response options is neither easy nor cheap. An effective flexible response capability creates more demanding planning requirements in that it

entails the coordination of more policy areas and more actors, requires extensive and ongoing training and exercising, and can involve complex communication requirements. It depends on organizational adaptability, which is not always a hallmark of government bureaucracies. A flexible response strategy also relies on high levels of cooperation among a range of independent actors, which is not always easy to promote. Moreover, it absorbs significant resources in an effort that must be sustained over time. Shifting to Flexible Response was expensive for NATO because developing effective conventional forces was costlier than relying on a limited arsenal of nuclear weapons. Similarly, implementing an effective flexible response strategy to deal with bioterrorism could entail significant expenditures over time. The alternative is to rely on a limited number of response options that may or may not be appropriate to the specifics of a crisis and that may or may not provide the right kinds of hedges against the less likely but potentially catastrophic contingencies.

This report addresses these issues and provides recommendations on means by which the U.S. government can enhance its strategic approach to improving the health and medical dimensions of the response to the challenge of bioterrorism. The recommendations are offered as a contribution to promoting effective national responses to a challenge that deserves sustained attention, adequate resources, and unflinching political will.

THE BIOLOGICAL TERRORISM THREAT: A MULTI-FACTOR ASSESSMENT

Introduction

Biological agents are living organisms, or the byproducts of living organisms, that cause diseases that lead to incapacitation or death. The most pervasive characteristic of the threat of terrorist use of such biological agents is its uncertainty. An enormous range of possibilities exists in terms of the character and impact of a bioterrorism attack; the variety of scenarios that could be elaborated is virtually unlimited. Anything can happen. Popular culture is suggestive in this regard. It has produced movies and books using bioterrorism as their major plot device, describing situations from a lone scientist genetically modifying diseases to strike against major urban populations to fanatic ethno-separatist or religious groups exploiting agents that have been researched for biological warfare to hold cities or governments hostage.

These fictional accounts, however, may be divorced from reality, and they may have contributed to fostering an impression of biological terrorism as easy and effective that does not square with the facts. With respect to biological terrorism, the formulation that "it is not a matter of if, but when," also is not helpful. Something may never happen. The historical incidence of successful biological terrorism is very, very small, and, while the past is not always prologue, history should not be ignored. With respect to the threat, therefore, we just do not know with any certainty.

A threat assessment is needed precisely to reduce the uncertainty that currently permeates the debate over bioterrorism. Undertaking a threat assessment is particularly important in the current environment in which government investments in programs to combat terrorism with chemical, biological, radiological, and nuclear (CBRN) weapons are increasing significantly. We will be able to ensure that society is prepared in the event of a bioterrorism incident – and to do so in a way that ensures that taxpayers' money is wisely spent – only only if the nature of the threat is systematically addressed, and its complexity is understood and appreciated.

A good threat assessment will create a “threat envelope” that describes the most plausible contingencies and identifies those possibilities that fall within it and those that lie outside. Defining a plausible threat envelope also provides a means to identify those contingencies that require hedging, in that, due to the severity or enormity of their consequences, some preparation for them should be undertaken, even if they are relatively unlikely. The combination of the threat envelope and the hedging contingencies should give policy makers some measure for making decisions regarding policy priorities and resource allocations.

A framework is needed for thinking about the bioterrorism threat. That framework should cast the threat more in the nature of a forecast than a prediction; that is, it should identify the ranges of probability of something happening, while recognizing that those ranges can sometimes be quite wide. Expecting certainty creates a standard that will never be achieved, and it implies a greater precision in the analysis than, in fact, can be achieved given the complexity of the subject matter.

An analytical framework for thinking about the biological terrorism threat will also highlight the fact that the threat is not unidimensional; it does not come from only one factor. Rather, it is composed of several elements. For purposes of this study, the key elements of the bioterrorism threat have been identified as the *who* (the actor), the *what* (the agent), the *where* (the target), and the *how* (the mode of attack). Each of these elements, in turn, entails a significant array of possibilities. The different kinds of actors who might try to exploit biological weapons, the large number of potential agents, and the variety of possible dissemination methods are some examples of the complexity of each element of the threat. The endless scenarios and contingencies that have been described as potential bioterrorism events represent the plausible or fanciful combination of the many facets of these factors into particular configurations.

The key to a successful bioterrorism threat assessment, therefore, is disaggregating the threat into its component elements and assessing the relationships among them. Only by doing so can one examine comparative likelihood of various

contingencies. With the ability to make those comparisons, policy makers will have a better means by which to determine those contingencies that are more important. It is the introduction of likelihood into the analysis that distinguishes a threat assessment from a vulnerability assessment, a distinction of critical importance, as already discussed.

The goal of this assessment, then, is not to provide a detailed examination of every possible bioterrorism scenario or contingency, but to suggest an analytical framework about the biological terrorism threat that facilitates making judgments about effective responses – especially in the public health and medical arena.

In the last several years, the analytical community has given considerable attention to the bioterrorism threat. This assessment is not intended to "reinvent the wheel" by replicating these existing studies, but to take the best of that work and integrate it into a coherent, holistic framework. The bibliography on which the project team drew and the experts interviewed for this phase of the project are presented in the appendix.

Integrating the Components

The key components of the threat assessment – who, what, how, and where – must be pulled together into an integrated assessment that provides the basis for formulating policy and program requirements for an effective national response. The analysis that constitutes such an integration, however, must be informed by several important considerations.

The Impact of Change

In looking to the future of the threat of biological terrorism, three sets of changes are especially important to note: technological change, the changing socio-political context, and the changing face of terrorism.

Changing technology will have an impact on future terrorist options. People have described the next hundred years as the "century of biology," and incredibly rapid and profound changes in biotechnology in particular are likely to have a major influence on the prospects for bioterrorism. Genetic modification, biomolecular engineering, and enhanced bioproduction technologies, for example, may make it easier for terrorists to overcome the barriers that inhibited acquisition of biological weapons in the past. Technological change, however, should not be considered only for what it might do to make the threat more severe, but such change must also be evaluated for what it can do to facilitate responses to the threat. Advances in biotechnology and materials sciences, for example, may underpin the development of rapid and effective detection and identification devices. Breakthroughs in understanding of human physiology may provide new approaches to improving the immune response to pathogens. Evaluating the future terrorism threat demands that we pay attention to both positive and negative aspects. It requires a balanced appreciation of the impact of technology, not just a focus on what may capture the headlines.

Technological change is only one aspect of the evolving context within which the new terrorism will have to be confronted. That context involves the interplay of political, economic, social, ethnic, and religious factors, not just in one country but around the world. The terrorism of the future will be in response to broad trends such as globalization, accelerating interconnectedness, and population dynamics, but it is also likely to entail narrow psychological elements from marginalization to techno-rage to revenge for real or imagined wrongs. As motivations move away from the traditionally political, the more important the special mindsets of potential terrorists become. Refining understanding of the threat of bioterrorism demands special attention to these distinctive mental topographies. Equally important is the requirement to understand how these unique psychologies interact with circumstances, capabilities, and opportunities, to take potential terrorists down particular paths, including one path (among many) at the end of which may be the use of biological weapons.

A third aspect of the evolving environment is the changing face of terrorism itself. In part, it is a question of the change in the actors. Of the current watch list maintained by the U.S. Department of State of terrorist groups of concern to the United States, more than half were not on the list at the end of the Cold War. The structure of terrorist actors, however, is also changing, as more transnational, network-based entities join traditional organizational hierarchies, a development exemplified by Osama bin Laden's al-Queda. Terrorist tactics also appear to be evolving, with more indiscriminate attacks and less acceptance of responsibility for those attacks that do occur.

"Lessons" of History?

Finally, much of the skepticism about the severity of the bioterrorism threat derives from the fact that, historically, not only have few terrorist attacks with biological weapon been attempted, but those few that can be identified have either been unsuccessful or have produced only limited results with respect to casualties. Looking to history for answers to the bioterrorism threat, however, provides mixed results. This is the case for several reasons. First, the historical record in fact identifies relatively few data points, especially with respect to BW use. Second, while developments in the years ahead must be expected to combine continuity and change, which one will dominate? It is not necessarily the case that, in all things, the future will resemble the past. History provides few precedents, clear indicators, or discernable trends to instill confidence that looking at history will alert us in advance to what will happen in the future, particularly given the nature of the changes mentioned above and the variety of factors involved in shaping the bioterrorism threat.

Evaluating Bioterrorism "Pathways"

The project team used a "matrix-pathways" approach to integrate the components – actor, agent, method of attack, and target – into a representation of the complex nature of the bioterrorism threat. Given the importance of the actor in shaping the threat, the team decided to break the question of "who?" into two distinct but related elements

suggested by the questions: “what are the motivations for a group to use a biological weapon?” and “what capabilities must an actor possess to develop and use a biological weapon?” These five components provided the starting point for constructing the matrix. This matrix is represented graphically in Figure 1.

A bioterrorism pathway is produced by systematically identifying plausible relationships between factors and outcomes. For example, a group seeking to produce over 500 casualties will need certain connections between its internal group dynamics, technical expertise, dissemination technique, and target to reach its desired goal. Working

Motivation		Capabilities			Agents			Dissemination		Target	
Number of Casualties	Level of Panic	Group Size	Technical Proficiency	Financial Resources (x $1000)	Agent Availability	Ease of Growth	Morbidity and Mortality	Ease of Dissemination	Efficacy of Dissemination Technique	Number Exposed at Target (x 1000)	Target Vulnerability
50000	High	1000	Expert	1000	High	High	High	High	High	1000	High
5000	Med.	100	Good	100	Med.	Med.	Med.	Med.	Med.	100	Med
500	Low	10	Low	10	Low	Low	Low	Low	Low	10	Low
50		Loner	None	1	None		None			1	None

Figure 1 – Bioterrorism Pathways Matrix

through the complete set of factors generates a bioterrorism pathway. In many cases, a pathway cannot be completed because logical connections between factors and desired outcomes cannot be made. For example, a group seeking to create disruption or illness without actually killing anyone is not likely to follow the path of an aerosolized anthrax attack. Using the threat matrix in this way produced the set of possible bioterrorism pathways. Combining these pathways with judgments regarding the comparative likelihood of each pathway produced the “plausible threat envelope” for bioterrorism.

Some examples of pathways are represented graphically in Figures 2 and 3. The first example represents a pathway that successfully produces a middle range attack using anthrax that infects a total of 500 people. The second example has two variants in which an attempt to produce a mass casualty anthrax attack (over 5000 people infected) ultimately fails. In the red variant, the group plans to carry out numerous small aerosol releases of anthrax slurry in a large metropolitan city. The attack fails due to a lack of microbiological expertise within the group. The group possesses the resources to illicitly acquire a sample of anthrax, a large fermenter (500 L), and sufficient quantities of growth media. However, the type of growth media obtained is not ideal for growing anthrax and the particular strain of anthrax does not grow rapidly. The group is consequently not able

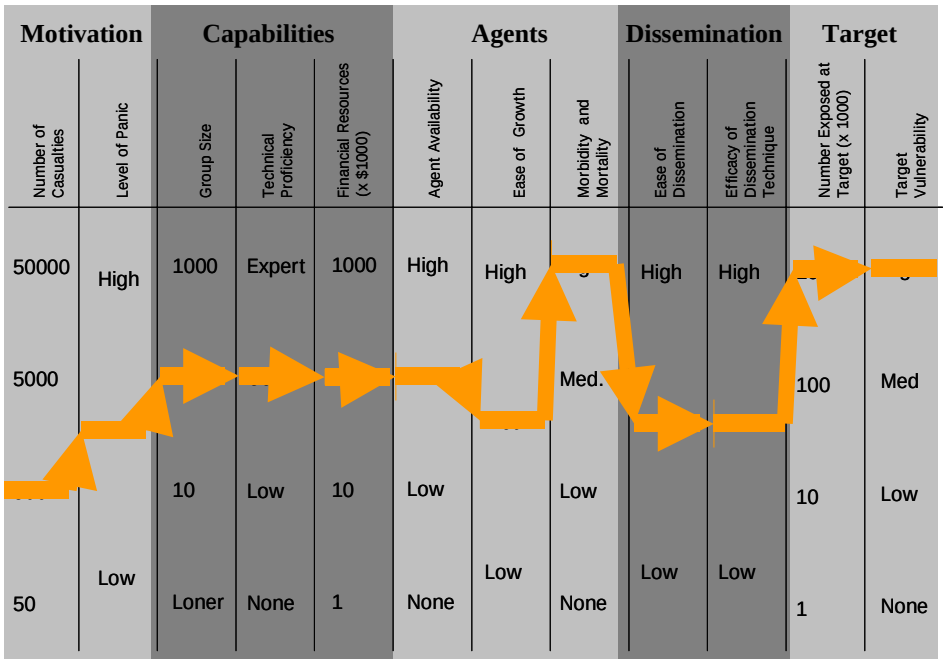

Figure 2 – Successful Mid-Range Attack
(500 Casualties)

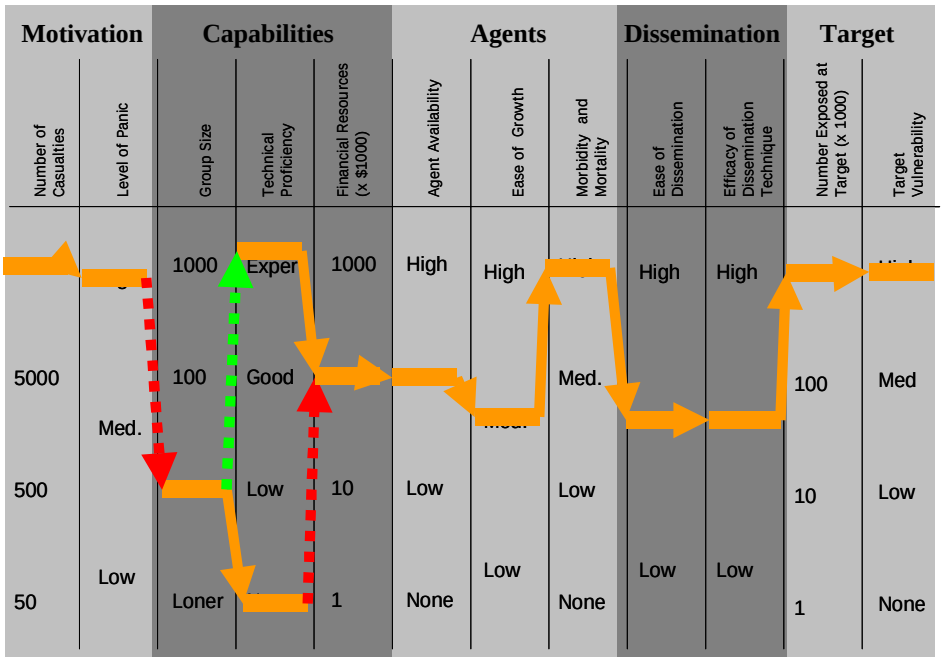

Figure 3 – Failed Attempt at Mass Casualty Attack

to produce sufficient quantities of viable anthrax slurry to execute a successful attack. The green variant of this example shows that the group, while possessing many of the technical requirements, is not large enough to enjoy the full set of skills necessary to conduct a successful attack.

These two examples are hypothetical. The project team also examined the historical record to inform its pathways analysis. It did so in two ways. First, it examined cases of bioterrorism to determine the pathway that was exploited. Figure 4 represents the case of Aum Shinrikyo which, despite having a large manpower pool, scientific expertise, major financial resources, technical equipment and so on, was nevertheless unsuccessful in conducting several biological attacks aimed at producing large casualties because it did not have the appropriate agent. Figure 5 represents the case of the Rajneeshee cult in which the motivation to achieve a limited impact through

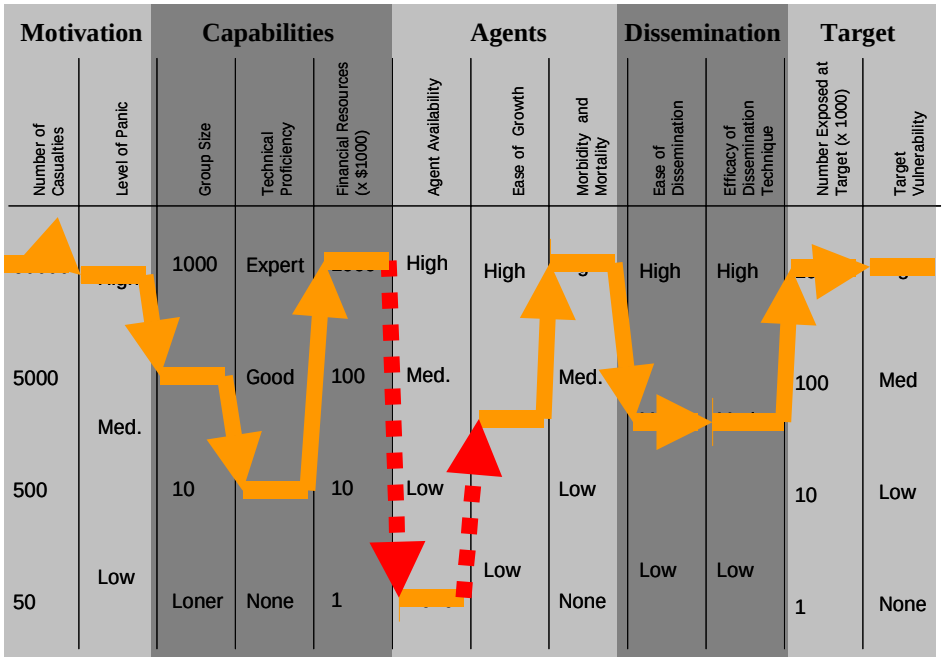

Figure 4 – Aum Shinrikyo's Failed Catastrophic Attack

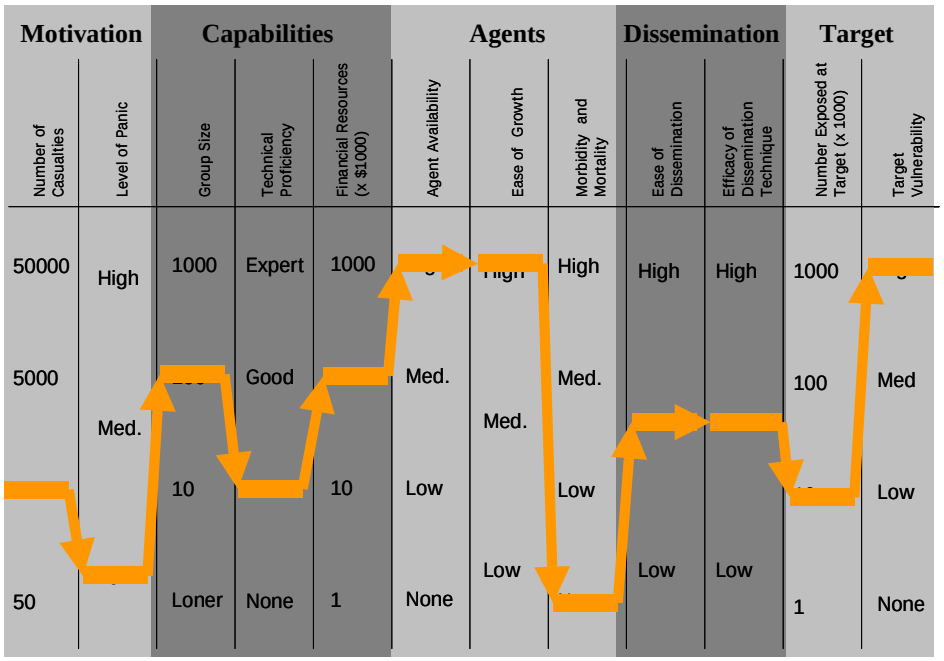

Figure 5 – Rajneeshees Attack in Oregon

the use of biological materials produced a less sophisticated, but ultimately successful pathway.

Second, the project team turned the question around and asked whether the historical record could offer analogs to some of the pathways deemed more probable than others by the project team because of the logical relationship between factors and outcomes. Given the paucity of historical data, however, this step in the analysis had limited utility.

The Threat of Biological Terrorism: Key Findings

The application of the "pathways" methodology yielded several important findings that should inform efforts to develop an effective health and medical dimension to the nation's overall capabilities to respond to bioterrorism.

A key relationship exists between the degree of risk and the level of casualties desired in an attack. That relationship, however, is *not* the straightforward one that higher risk is associated with catastrophic casualty scenarios. Indeed, the degree of risk declines as the level of desired casualties increases, insofar as *it becomes less likely*.

In essence, *as a terrorist seeks higher casualties, fewer pathways are available to achieve that objective, and those that remain are more difficult.* There are several reasons:

- Few terrorist actors have the necessary combination of size, resources, skills, facilitative ethos (e.g., willingness to experiment and accept failure), or appropriate organizational structure to achieve mass casualty capabilities.

- Traditional agents capable of inflicting mass casualties are either difficult to acquire, cultivate and produce, or disseminate effectively. The relationship between agent and dissemination technique is especially important in that if the dissemination process is less than optimal (due to the device, the method, or the

environment), the terrorist must compensate through meeting more demanding technical requirements such as producing greater volumes or better quality agent to achieve the same effect. Producing and disseminating more agent also increases the possibility of detection and capture.

- Likely targets for bioterrorism attacks do not necessarily facilitate mass casualty outcomes given the other requirements for conducting an effective attack against such targets, including technical knowledge (of air flows in large arenas, for example) or operational skills (surveillance, planning, finance, etc.).

Despite the low probability of catastrophic bioterrorism, there is still ample cause for concern. We do not know how "massive" a mass attack has to be; worst-case scenarios may not need to happen.

Bioterrorism attacks that produce levels of casualties below those considered catastrophic constitute a significant problem for two key reasons:

- We do not know at what point the response system will become overburdened and stressed to the point of collapse. Some officials involved in response preparation, particularly at the local level, suggest that the threshold is not very high.

- Use of unconventional terrorism for other than massively destructive purposes is consistent with the historical record, which suggests that such events have often been designed to achieve more discriminate goals, including assassination and financial gain.

The danger and harm inherent in the bioterrorism threat is not limited to physical fatalities and casualties. Psychological impact and social disruption could also be severe if effective preparations are not made and useful responses are not developed.

Terrorism expert Brian Jenkins has argued that "Frightening millions may exceed the desire to kill thousands." Terrorists might seek leverage and advantage from provoking a number of psychological reactions to even limited use of bioterrorism: panic that would magnify the attack; hysteria that would stimulate untoward behavior among the population; futility that could create momentum for responding to terrorist demands; depression that could make it more difficult to shape an effective strategic reaction; lack of confidence in government that would be seen as incapable of meeting its fundamental purpose of safeguarding its citizenry. One could argue that the Aum Shinrikyo attack, while a failure in terms of achieving mass casualties, nevertheless had a profound impact on the way we look at the world and the problems society now confronts. Targets may be selected, therefore, more for their symbolic value than for the number of people that can be killed.

Beyond the psychological impact, even a lower scale bioterrorist attack could disrupt civil society on a significant scale, both in the locale of the attack and more broadly. Experience with natural disasters or conventional terrorist attacks suggests that it could take a community considerable time for its life to return to some kind of "normalcy."

Although many terrorists either will not be interested in using biological weapons or not able to do so, two categories of non-state actors – those with relationships with national governments and those outside the traditional scope of governmental scrutiny – warrant particular attention.

Terrorism analysis tends to exclude violent acts by non-state actors allied with foreign governments in times of conflict because such actions are considered acts of war. In terms of national bioterrorism response planning, this is short-sighted for three reasons:

- The consequences of such an attack would be no different than if it occurred as an isolated incident and the response needs would be the same.

- State-sponsored terrorists are among the few actors who could assemble the requisite resources, skills, and materials to conduct a successful attack that produces significant levels of casualties.

- Countries who see themselves potentially in a conflict with the United States are demonstrating an increasing interest in "asymmetric strategies" to obviate the overwhelming U.S. advantage in conventional military power. When combined with a perception of the United States as a country that insists on "casualty-free" conflicts, enjoys only limited credibility in terms of its commitments to friends and allies overseas, and retains little consensus on when and how to use its military power, the appeal of asymmetric strategies that include terrorism with unconventional weapons could increase.

This is not to argue that an adversary of the United States would share biological weapons technology with a non-state actor or allow such an entity to "set off" a biological weapon in isolation from a major confrontation. The potential costs will generally prevent those countries from giving the United States "a poke in the eye with a sharp stick" just for the sake of doing so. But the United States should not expect that its future will be free of conflict with adversaries in other parts of the world, and if that conflict entails interests great enough for the other party – for example, regime survival – they may be willing to "bring the conflict home" to the United States through domestic attacks by non-state actors using unconventional means.

The second category of actor that bears particular attention includes those who may not have been a regular focus of scrutiny either because they are new to the scene or they have not been considered part of the terrorism universe. Among the actors who now define contemporary terrorism – which itself is a combination of old and new dimensions – recent analysis suggests that those who might be most attracted to the use of biological agents include

- non-state actors inspired by religious ideals;
- groups from the Right of the political spectrum;
- actors with millennial world views that combine with notions of the "cleansing" value of violence;
- transnational networks that are less constrained by central authority; and
- radical single-issue groups.

Few of these actors will have the requisite skills to perpetrate bioterrorist attacks that produce catastrophic casualties. Cults, for example, tend to be insular, paranoid, smaller groups that lack the full range of skills necessary to carry out a mass attack. The diffusion of transnational networks could make it hard for them to assemble all of the necessary requirements. The concept of "leaderless resistance" that is a value of the right-wing in the United States may leave it without the organizational discipline to conduct successful attacks. Despite all of these shortcomings, however, these groups must continue to be of concern regarding future bioterrorism, if only because smaller-scale events in terms of casualties could still produce significant negative impacts.

The environment of uncertainty surrounding bioterrorism will remain.

The threat is not static and will continue to evolve. Changing actors and evolving technology – especially in biology-related areas – will be major drivers of such change but not the only ones. Globalization and the Information Revolution will shape the terrorism environment just as they will most other forms of social organization and interaction. Specific events outside the bioterrorism realm will intrude to influence terrorists' goals, perceptions, and modes of operation. The impact of individual personalities should not be discounted.

Two points in relation to the uncertainty about the bioterrorism threat by ongoing change are important for those who must respond to the challenge. First, the assumption is usually made that such change will make the threat more severe. Such an assumption is not necessarily warranted. Change should also benefit those who must respond to the threat, not only in the tools they could have available, but in terms of the broader social, political, and psychological context. Whether terrorism waxes or wanes at any particular

time depends on a confluence of factors that is not always in the terrorist's favor. Part of the overall objective of those responsible for dealing with terrorism must be to promote an environment in which the elements that support or facilitate terrorism find expression difficult.

Second, uncertainty is created by the constant adjustment in the dynamic between terrorists and those who fight them. Like the offense-defense relationship in military affairs, the relationship between terrorists and responders is constantly in flux, and uncertainty arises because it is not possible to state precisely at any given point in time how the balance stands between them. The important point, however, is that both elements are necessary to create that dynamic relationship. In the case of responding to the threat of bioterrorism, certainty will only be achieved if we take ourselves out of the game and do nothing. In that case, we can be confident that the terrorists will prevail. Otherwise, a measure of threat and a degree of risk must be accepted. The challenge is to reduce that risk to manageable, and acceptable, levels. In the case of bioterrorism, the health and medical dimension of the overall response system will play an important role in achieving that objective.

PART II

PUBLIC HEALTH AND MEDICAL RESPONSE

INTRODUCTION

This Part of the report evaluates the public health and medical response to bioterrorism in the United States in the context of the threat described in Part II. The discussion is in two sections. Section I identifies the major components or functions of the public health and medical response system, including:

- Surveillance
- Epidemiology
- Laboratory Capability
- Medical Management
- Training and Education
- Information and Communication

In discussing each of these six functions, Section I identifies the requirements that must be met if each of these functions is to be performed effectively in responding to a bioterrorism threat, describes the current situation in the United States with respect to meeting those requirements, discusses the key issues associated with each component, and provides recommendations.

Section II discusses the major issues associated with organizing and coordinating a national effort among a disparate group of responsible entities at the federal, state, and local levels to prepare and execute the public health and medical system in the event of a bioterrorism attack. This Part discusses three main questions: the nature and success of preparedness efforts of federal, state, and local entities, the need to develop a strong partnership between the private and public sectors, and the structure and organization of CDC's bioterrorism preparedness and response program.

Section I – System Requirements

I. Surveillance
II. Epidemiology
III. Laboratory Requirements
IV. Medical Management
V. Training and Education
VI. Information and Communication

I. SURVEILLANCE

What Are the Requirements?

Before an effective response to a bioterrorism incident can be mounted, even before an investigation of an unusual outbreak of an infectious disease can be initiated, mechanisms must be in place to monitor the health status of the relevant population. In order to intervene successfully to treat existing infections and prevent the onset of new ones, health surveillance systems should provide a continuous, real-time (or as near real-time as possible), and accurate overview of a population's health. The goal, of course, is to provide the earliest possible indication of a bioterrorism incident.

Mechanisms for gathering health data of a number of types from a variety of sources and sending it in real time to the appropriate monitoring entity are the basic foundation of surveillance. Reliance on a single source of data cannot provide a complete representation of the monitored population's health status. Therefore, information from multiple sources must be integrated and synthesized. While improved, rapid, and, where possible, automated infectious disease reporting networks provide the core component of a health surveillance system for bioterrorism, current networks depend on official diagnosis before reports are made. For many diseases, waiting for confirmed diagnoses may squander narrow windows for effective intervention. Changes in the system will be required to exploit other information sources – EMS runs, numbers of visits to hospital emergency departments and clinics, sales of over-the-counter medications, unusual infectious disease-related deaths, and others – as early warning indicators.

In order to function effectively as the nation's bioterrorism early warning system, health surveillance systems must be able to meet four key requirements. First, health surveillance systems must be capable of detecting minor changes in the normal health status of the monitored population. This includes detecting any cases of diseases unexpected in that area or time of year and detecting minor changes in the frequency of expected diseases. Increased sensitivity will increase the likelihood of early detection of bioterrorism incidents.

Early detection is important for two reasons. One, it facilitates early initiation of epidemiological investigations and laboratory assays. Given the higher probability of low and middle range attacks (up to 500 casualties), these assessment tools are important for determining the actual type and scope of an incident rather than basing the response on a presumption that the incident is high consequence, but time is required to complete these assessments. Two, early detection and assessment facilitates early and appropriate intervention. Early intervention increases effectiveness by providing prophylaxis early enough to prevent new cases and dispensing treatment rapidly enough to reduce severity of illness.

Second, baselines of health information are needed over extended periods of time to establish definitions for "normal" and "abnormal" patterns of infectious disease. Improved health monitoring systems are likely to generate large amounts of information regarding patterns of infectious disease that can and should be combined with information previously gathered through traditional disease reporting systems to develop this baseline. Such a baseline can be utilized to evaluate the health status of the population at any given point in time by comparing the current health status with baseline data. A baseline data set for infectious disease should establish the frequency of certain types of infectious disease, the normal distribution of cases during seasonal and calendar cycles, and the normal geographical spread of certain diseases. Developing accurate baseline data is essential for detecting low and middle range attacks that more closely resemble natural disease patterns in terms of frequency of cases, geographical distribution, and type of disease. Baseline data sets are essential for early detection of bioterrorism events – while their patterns still closely resemble the normal pattern of disease.

Third, surveillance systems should monitor the health of the population in near-real time and on a continuous basis. Many biological warfare agents offer only a brief window between exposure and the onset of symptoms. Many agents, like anthrax, cannot be successfully treated once symptoms appear. Thus the window of time during which effective intervention is possible can be very narrow. In order to facilitate rapid responses, surveillance systems must be capable of monitoring information on an ongoing basis. Moreover, they should gather and synthesize information in as close to near real time as possible, thus allowing for early and rapid

investigation and intervention. This requires systems that can provide the monitoring entity with a continuous stream of information on the full range of health indicators.

In part, the promise of near real-time surveillance is being fulfilled by improvements in information technologies and telecommunications. Improvements in both computer power and data storage systems, with corresponding decreases in the cost of these systems, allow for quicker and more efficient storage, maintenance, and transmission of surveillance information. Exploiting advances in telecommunications and information technology -- such as improved data networks -- provides the potential for information stored on computer systems to be retrieved and transmitted almost instantaneously.

Finally, surveillance systems must be capable of coping with the potential of a bioterrorism attack over a wide area. Certain disease-causing organisms are contagious, most notably plague, smallpox, and certain strains of influenza. In addition, there is a high degree of mobility associated with American lifestyles. This includes daily travel between urban centers and surrounding suburban communities. Frequent travel between various parts of the country is also common.

Consequently, surveillance systems must be integrated over wide areas to detect an attack that produces a wide geographical distribution of victims. This requires that surveillance systems monitor the health status of the population at the local, state, and national levels in an integrative fashion. Establishing a single national or international surveillance system, however, would be extremely difficult. Therefore, a wide area surveillance system should be derived through the operational integration of local health surveillance systems. Such an integrated system should build upon existing city and county surveillance systems and integrate them into state and territorial systems. Integrating state and territorial systems into a national system - probably with CDC acting as national integrator – is more problematic, but the requirements for doing so should be identified and evaluated.

Given the increasing pace of international travel and commerce and the possibility of transnational attacks, integrating national systems into an international health surveillance

system must also be considered. With additional resources and manpower, the well-established World Health Organization might serve as the central hub of an international surveillance system. Some public health experts have also suggested the CDC should be the international center, given its expertise in infectious disease prevention and control.

Key System Elements

Any surveillance system is based on four basic elements: 1) information regarding the health of a monitored population; 2) providers of that information; 3) recipients of that data who will perform the monitoring function; and 4) a "system of systems" for sharing data between the various providers and recipients.

1. Information

Given that no single data set is likely to provide definitive warning, monitoring a variety of data sets that could indicate a bioterrorism attack or another infectious disease outbreak is necessary. Some of the types of data that are either currently being monitored or should be monitored to detect possible incidents of bioterrorism include:

- Reports of unusual disease cases;
- Patients appearing in hospital emergency departments, clinics, and primary care facilities;
- Hospital admissions and bed capacity;
- Unusual deaths that might be caused by infectious disease;
- Number of reported sick calls from employers and schools;
- Sales of over-the-counter medications;
- Numbers of emergency medical services and ambulance runs in combination with general types of cases seen on these runs;
- Calls to health care hotlines; and
- Information from veterinary disease reporting networks.

While there are a number of indicators for the current status of a population's health, no single data set provides a totally accurate picture. Although it is easy to focus surveillance efforts on a single information source or a small subset of information types, surveillance systems must increasingly incorporate and analyze as many information sources as possible.

Some of these individual data sets possess inherent weaknesses in their ability to provide an accurate representation of the health situation of the population at large. For example, sharp increases in the number of over-the-counter cold remedies and the number of sick calls at area schools and employers might indicate a flu outbreak, perhaps unusual in the high number affected and the time of year. That information in combination with a sharp increase in the number of Emergency Room consultations for respiratory distress and a few unusual infectious disease-related deaths might indicate an etiological agent different from influenza. Other data types are complementary or require comparison with other information in order to provide an accurate snapshot. Adequate health surveillance systems must acquire as many indicators as possible, establish systems for obtaining this information on an ongoing basis, and then analyze that data continually to determine the health status of the monitored population.

2. Data Providers

A number of organizations can be potential sources for surveillance data. Exact organizations, their titles, their situation, and the ease with which they are or can be incorporated into the system will depend on the individual locality. Table 1, however, provides a general typology that correlates the range of surveillance system data with the types of organizations that could provide that information.

Because of the central role of case reporting and syndromic networks in detecting outbreaks of infectious disease, organizations and individuals that will most likely encounter and treat infected patients first must provide data on both the numbers and types of diseases and syndromes they are seeing. This means hospital emergency departments and immediate care centers, public clinics, and primary care physicians play important surveillance roles as the initial sentinels for infectious disease outbreaks. Due to the need for continuous real time surveillance, doctors, nurses, and other staff members must be able to diagnose diseases caused by potential bioterrorism agents and have a means to provide that information to the entity responsible for conducting health surveillance. There must be a system for efficiently collecting syndromic information from incoming patients and making it available to the monitoring entity. Hospital and clinic administrators must support efforts to plug their establishment into surveillance

Data Types	Possible Providers
Unusual cases of illness	Hospitals, clinics, physician offices, EMS system
# of hospital admissions	Hospitals
# of emergency department, clinic, and physician office visits	Hospitals, clinics, physician offices
Patient complaints/syndromes information	Hospitals, clinics, physician offices, EMS system
EMS runs	EMS Dispatch – Fire department, private ambulance services
Purchase of medications	Drug stores, pharmacies, clinics, hospitals, warehouses
Animal illness incidents	Local zoos, veterinary offices
Access to self-medication information	Hotlines, medical information websites
Sick calls	Local schools and employers
Unusual deaths – infectious disease related	Office of the local coroner or medical examiner

Table 1- Possible Surveillance Data Providers

systems. This requires providing critical staff with opportunities to participate in bioterrorism training, making information infrastructure investments to support communication between their establishment and the local public health department for disease reporting and syndromic surveillance, and establishing procedures and confidentiality safeguards to enable sharing of certain types of patient information. It is important to note, however, that most hospitals are strapped financially; for example, 71% of hospitals in Alabama are currently in debt.

Consequently, new equipment or techniques should be as dual-use as possible. In addition to medical care providers, those entities that could generate other types of data - drug stores and pharmacies, veterinary offices, medical advice hotlines, local schools and major employers, etc. – also need to be connected to the monitoring entity. For information that is gathered and stored digitally, monitoring entities need to contact owners and producers of this data and establish systems for providing all or some of it to the monitoring agency on an ongoing basis. This includes automated systems for transmitting digitally gathered and stored information to the monitor and procedures for installing and maintaining these systems. Information that cannot be gathered and exchanged automatically using electronic systems requires human intervention. One example is tallying illness at schools and employers. For

these data sets, procedures and protocols need to be developed and implemented to gather that data and manually provide it to the monitoring agency.

3. *Data Recipients*

Surveillance systems must give a local agency or department the assignment of organizing, installing, and monitoring the system. How that decision is made and its outcome depends upon the individual dynamics and organization of the locality. For most localities, that function is best served by the public health department. One noteworthy exception is New York City, where the Mayor's Office of Emergency Management (OEM) has been given the responsibility and resources to organize and maintain a robust surveillance system with the cooperation of the public health department.

Regardless of whether the public health department or an office like OEM has primary responsibility, only local level entities will be able to identify specific data providers locally, work with those providers to develop the telecommunications infrastructure and procedures to deliver their information on an ongoing basis, work with the local telecommunications providers to develop the necessary infrastructure, and understand the unique political and bureaucratic dynamics that could either complicate or enable assembly of a local surveillance system. With the financial and technical support of the federal government, the local public health department should hire the required staff and begin designing and organizing local surveillance systems. Some basic steps in the process include identifying the data that will be monitored and determining the sources of that data, working with the providers of the health data to design the technical and organizational components of systems to provide data to the department on a regular basis, installing the technical infrastructure, maintaining the system, and finally monitoring the data provided by the system. As of today, only the very largest U.S. cities have been constructing these types of systems, with New York City being the best example. But even this handful of cities need to address significant gaps in their systems, including incorporating more hospitals and improving the speed of data transfers.

Assuming the city or county public health department has responsibility for establishing the local system, the public safety community must remain involved with the monitoring

function. Public safety, specifically law enforcement, needs to have some access to surveillance information. According to current reporting protocols, possible bioterrorism events should be reported to local law enforcement, including the local FBI field office, and local political leaders to trigger appropriate response activities. Because most public safety organizations do not possess the background and experience needed to analyze and interpret available surveillance data, public health will be asked to provide political leaders and law enforcement with surveillance data and analyses to assist with decision-making in most cases.

4. Systems

Existing formal disease reporting obligations require public health departments to collect, compile, and assess case information related to patients diagnosed with specific infectious diseases as reported by doctors, nurses, and other primary care providers. Once a patient is either confirmed or strongly suspected of having a reportable infectious disease, the care provider sends that information to the public health department. Public Health then compiles an ongoing case list for the jurisdiction for which they have responsibility, determines the frequency of that disease, plots the appearance of cases geographically, and then reports cases to the next highest public health department when appropriate.

Relying on these passive reporting systems to detect bioterrorism incidents requires two criteria be met. First, the biological agent used must present symptoms specific enough to allow for symptomatic diagnosis, or a high enough level of suspicion for the physician to send samples for laboratory assessment. Second, the doctors, infectious disease nurses, and other primary care providers who are likely to be the first to see bioterrorism victims must be able to recognize the disease and rapidly report cases to the appropriate public health officers. As discussed below, it is difficult to meet these objectives if certain agents are used.

Active disease reporting systems would help to alleviate the need for physicians or nurses to report cases manually by having computer systems automatically search for and retrieve electronic patient information and then electronically transmit that information, by e-mail or through a wireless system, to the local public health databases. But even automated reporting

systems rely upon a specific diagnosis being entered into a patient's record as a flag for the system to record and transmit that report to the local public health office.

Establishing and maintaining syndromic surveillance systems could provide a solution to the inherent problems of formal disease reporting networks. Syndromic systems acquire and then centrally compile syndromic information from incoming patients at their point of entry into the health care system. Such systems do not wait for specific disease diagnoses before reporting to the local public health department. This allows for ascertaining in a general sense the types of complaints from incoming patients and their frequency. When plotted geographically, these systems can also provide a distribution indication. Such a system relies upon caregivers obtaining information from the patient, which can be manually entered after the consultation has been concluded or automatically transmitted to the monitoring organization. Because syndromic surveillance requires all incoming patients to be assessed and information gathered, it does not require that doctors or nurses have the ability to associate specific symptoms with specific diseases and does not require diagnostic confirmation before symptoms are reported.

In addition to infectious disease reporting and syndromic surveillance, rapid spikes in either the degree to which the medical system is being stressed or attempts at self-medication could indicate an emerging health crisis. The number of EMS runs, types of patients received by EMS, and the number of patients at area hospitals are useful indicators of system stress. Because of the types of non-specific and relatively mild initial symptoms of many biological warfare agents, infected individuals might also attempt to self-treat or self-medicate before symptoms become severe enough to require visits to primary care physicians, care centers, and hospital emergency departments. Monitoring sales of over-the-counter medications, calls to medical care hotlines, hits on medical care Internet sites, and sick calls to area employers and schools can indicate the prevalence of an unusual pattern of illness within the population.

Because many potential biological warfare agents are zoonotic, it is also important to integrate veterinary disease reporting networks into surveillance systems. Aerosol releases could affect both humans and animals. Contagious zoonotic diseases could also move between animals and humans. Plague is such an agent. Certain strains of influenza could also move between

animals and humans. For this reason, sudden increases in the prevalence of infectious disease within an animal population could indicate unusual infectious disease outbreaks. In conjunction with formal disease reporting systems, monitoring these types of information also provides indications of unusual infectious disease outbreaks.

Where Are We?

Until recently, the core of infectious disease surveillance was a set of specified infectious diseases for which reporting from doctors was mandatory. Because individual state public health departments developed their own lists, they vary from state to state. Doctors are required to declare cases of reportable diseases to their local or state level public health department. This usually consists of a phone call by a doctor or nurse to the appropriate public health department. Staff epidemiologists and infectious disease specialists at the department compile reported information and then pass that information on to the next highest public health agency or department, at either the state or national level. Primary federal recipients of this data include the CDC for inclusion in the Morbidity and Mortality Weekly Report (MMWR). As was previously mentioned, this type of disease reporting system is not ideal for detecting incidents of bioterrorism, primarily because of its lack of speed.

Some progress is being made. A number of programs have been initiated to help public health departments establish improved monitoring capabilities. The centerpiece of these efforts has been grants from CDC to state and local health departments to support surveillance and epidemiological capacity, bolster local organization and planning efforts, improve information technology infrastructure through the Health Alert Network (HAN) program, and support a small number of special surveillance projects.

A number of problems, however, have emerged in relation to these programs. First, grant money provided by CDC stops at the local level public health department. Much of it is absorbed by departmental operating expenditures related to bioterrorism preparedness – specifically personnel costs. Second, surveillance and epidemiology is combined into a single grant category, with emphasis on the latter rather than the former. Third, except for the special

surveillance projects section, the amount of funding available to support local surveillance efforts has been minimal. Finally, there has been little financial support for the task of organizing local surveillance systems. Identifying and working with all the various data providers is a labor-intensive process for local public health officers. CDC grants for the purpose of planning have focused on a limited number of states.

Some cities have been working to establish real-time surveillance systems using a combination of CDC grants, other federal support, and local resources. Some of these have only been limited duration experiments supported by the Bioterrorism Preparedness and Response Program Office. Among the more well known examples are the surveillance system in Denver, the syndromic surveillance experiment in Seattle during the recent meeting of the World Trade Organization, the nascent systems being established in New Mexico, and a small experimental hospital monitoring network currently being established in New York City. These systems have focused on developing electronic networks of hospitals and other medical care providers to track numbers of incoming patients, record and compile the numbers and types of syndromes reported by incoming patients, and in some systems plotting those cases geographically.

These early surveillance systems have helped define the cutting edge of surveillance technologies. They have also served to identify many of the challenges associated with establishing and maintaining integrated health surveillance systems. These include the difficulties associated with permanently integrating hospitals and care providers into a surveillance system – lack of attention from hospital administrators, the associated lack of resources, increased work loads placed on doctors and nurses by the need to enter patient data manually, and the challenges in maintaining computers and telecommunications linkages. Most of these systems have been experimental due to a lack of funding to establish such systems permanently. A few localities have established permanent surveillance systems, but have done so with resources available at the local level. For this reason, such systems may be difficult to repeat in small to mid-sized cities and localities, unless federal resources are made available. Perhaps the most important lesson has been that such systems can be established using today's information technology, while remaining challenges are largely related to human factors.

To expedite the national disease reporting system, the CDC has taken a number of important first steps in creating an electronic system for exchanging disease information between local, state, and federal public health departments. In cooperation with the Council for State and Territorial Epidemiologists, the CDC has begun a program called the National Electronic Disease Surveillance System for (NEDSS). NEDSS is focused on developing a set of standards for collecting, managing, transmitting, analyzing, and accessing electronic disease data. To meet this goal, the NEDSS program is developing standard data formats, software guidelines, including database management tools, data transmission protocols, and data analysis tools and methodologies. In addition, state and local public health departments are receiving grants through the Bioterrorism Preparedness and Response Program to improve their surveillance capabilities. This includes money for bolstering the staff available to organize local surveillance systems and conduct ongoing monitoring. Through the Health Alert Network program, CDC has provided grants to improve the computer and telecommunication infrastructure of state and local public health departments. This has improved development of a national public health system linking national, state, and local public health departments.

A central challenge in developing surveillance systems remains organization at the local level. An integrated national health surveillance system for dealing with bioterrorism and other infectious disease emergencies begins with health surveillance of local populations that integrates traditional public health and non-traditional partners. These local systems should be integrated into statewide systems with the state systems integrated into a national system. *There is no national strategy or program supporting local efforts to organize health surveillance systems that integrate not just public health agencies and local health care providers, but also non-traditional partners like EMS dispatch centers, drugstores and pharmacies, local schools and employers, and the veterinary community.* Little guidance or funding has been provided to local public health or other local entities to organize, develop, and maintain surveillance systems. This includes providing guidance on organizational constructs, like identification of the local monitoring entity, or the funding necessary to install the telecommunication equipment necessary to network local health data providers to the monitoring entity.

Key Issues and Recommendations

A number of key issues continue to shape progress with respect to developing health surveillance systems for detecting bioterrorism incidents. CDC and HHS need to focus on these issues as they identify their next steps in bioterrorism preparedness.

Limits of Formal Reporting Networks

Even assuming the existence of instantaneous, robust communication capabilities between all area medical care providers and the local public health department, complete reliance upon even active disease reporting systems to detect incidents of bioterrorism is problematic for a number of reasons. First, several biological agents, like anthrax, present with flu-like symptoms early in their progression. With time, the discomfort experienced by patients increases. For many of the more commonly available agents, like certain strains of e-coli or salmonella, patients' symptoms remain relatively mild. Waiting until the symptoms become more severe means that victims will fail to seek medical care until the later stages of disease progression. This is an important consideration for bioterrorism surveillance because formal disease reporting systems depend on medical care providers to assess patients and provide the reporting information.

Second, current infectious disease reporting systems wait until diagnosis of a specific disease before the care provider reports to the public health department. Many possible bioterrorism agents do not present with specific symptoms in the early stages of the disease. This means care providers have to wait until the disease has progressed to advanced stages before they report to the local health department.

The lack of expertise and familiarity among physicians, nurses, and other care providers in recognizing the symptoms of the diseases associated with biological warfare decreases the probability of symptomatic diagnoses. Because diseases like anthrax, plague, and tularemia are rare and are given little if any attention in medical school and public health school curricula, most doctors would have difficulty recognizing cases appearing in their hospitals and offices. In

fact, it is more likely that doctors and public health officials will recognize a quantitative increase in the number of patients presenting at an emergency room or clinic rather than a qualitative change in the type of patient complaint or disease. This decreases the probability that primary care providers will recognize the symptoms of a specific disease and then report a case. In combination, these three factors increase the amount of time that elapses between infection and the entry of information into the surveillance system. With certain agents, that elapsed time might erase the window of opportunity for effective medical intervention.

Integrating Health Care Providers

Hospitals and other medical care providers should play an important role in surveillance because they provide so much of the information. Except for the experimental systems listed above, however, hospitals remain a key challenge to the establishment of real-time surveillance systems. Hospitals have expressed concerns regarding the financial costs of installing and maintaining these systems. No program exists to create electronic linkages between hospitals and local monitoring agencies. The Chicago Fire Department is looking to overcome this gap creatively by proposing to utilize Department of Justice (DOJ) equipment grants to establish a wireless data network connecting the public health department to hospitals within the Chicago city boundaries.

Another factor mentioned frequently by hospitals as restricting their involvement in surveillance systems is the operational burden such systems impose. The problem is getting personnel at the hospitals, clinics, and offices to enter the necessary information into the system. All of the experimental syndromic surveillance systems tested thus far have created secondary processes for entering patient information into the system after the patient has been seen, assessed, and a record created. This has created additional layers of work. Increased workloads have translated into short-term syndromic surveillance experiments that are finite in length and have complicated the development and maintenance of permanent syndromic surveillance systems. As care providers become more reliant upon computerized patient record management systems, their potential for providing health surveillance data will increase. To paraphrase a representative from a major metropolitan hospital association, “My members will work with

public health to develop systems where existing data and records can be exploited. What they cannot support are systems where they are asked to generate new data sources or have to take on additional workloads."

Integrating Non-Health Care Providers

As mentioned earlier, other types of health-related information should also be monitored as part of an integrated surveillance system. With the exception of a few localities, these additional information sources are not monitored. Localities must do a better job of identifying the types of data to be monitored and then working with the providers of that data to establish systems to provide it.

One important disconnect is the absence of strong links with the veterinary and zoological communities. Because illness within the animal population could provide a strong indication of an unusual disease outbreak also affecting humans, information from these communities must be incorporated. Many public health departments fail to interact with their colleagues in the veterinary and zoological communities on a regular basis. Information exchanges between these organizations remain infrequent and must be improved.

Confidentiality

Because many surveillance data providers are private institutions (including many hospitals), improved public-private discussions are necessary at both the local and national levels. Private institutions and companies can provide a great deal of surveillance data, but concerns regarding difficult issues like consumer/client/patient confidentiality must addressed.

The issue of confidentiality could emerge as a major barrier to improving surveillance because maintaining confidentiality of data provided by private sector players is an important obstacle to integrating those data providers into surveillance systems. Some providers, like hospitals and clinics, operate within a very competitive environment. Providing certain types of information as part of a surveillance system is seen by many private sector entities as harming

their competitive advantage. Some may fear a loss of trust from their customers if confidential patient information is shared. Others may fear providing information that might be useful to both potential customers and competitors to evaluate their performance. This includes hospitals, clinics, and private physicians but also other for-profit entities like pharmacies, medical care information providers, and hotline providers. **Mechanisms must be established for providing the necessary surveillance information without compromising confidential information. An important element of the solution is the enforcement of federal regulations for patient data confidentiality. Another is the development of technological solutions for parsing data to compile general and statistical information without association with specific patients or other customers**.

Social and Technical Solutions

Developing good health surveillance systems is a function of both technology and social organization. It is a technical problem because resources and expertise are needed to establish the information technology and telecommunication infrastructure required to link sources of information using hardware solutions -- for example, fiber-optics links, cellular and microwave systems, or simple telephone connections – and software solutions – for example, automated search agents to access electronic medical and health records from hospitals and primary care providers. As both information technology and the exploitation of that technology increases over time, opportunities should expand to improve the speed, accuracy, and coverage of national surveillance systems by shifting from passive systems to increasingly active ones.

Good surveillance, however, is also a question of social organization. Regardless of whether the surveillance system relies on people manually to provide surveillance data or to organize and install automated, computerized surveillance systems, people continue to play the pivotal role not only in gathering and distributing that information, but in the critical task of analyzing it.

A number of specific steps should be taken to improve the current capabilities in the area of health surveillance.

1. Special emphasis must be placed on organizing and developing local level surveillance capacity. **CDC should establish a national strategy for developing surveillance systems capabilities at the level of counties and the municipalities**. First, while it is closely related to epidemiology, surveillance requires special consideration within CDC and HHS programs. **Surveillance programs should be separated from grants and programs related to improving epidemiological capabilities.**

Second, **CDC must actively support local initiatives to organize and monitor local-level health surveillance systems while simultaneously developing the national infrastructure necessary to integrate local systems into statewide and ultimately national systems.** CDC must work with local public health departments to provide financial support to fund both the personnel necessary to organize local data providers, develop the electronic infrastructure needed to link data providers with the local public health agency, and then perform monitoring on an on-going basis.

2. **Local public health agencies should have the responsibility and the necessary resources to develop communication infrastructure with data providers. Through local public health agencies, CDC must focus on providing the guidance and resources to establish local surveillance systems.** This includes providing the resources to fund needed personnel at the monitoring entity, providing guidance on the types of health information to be monitored, and assisting with the establishment of working groups and meetings to build strong partnerships between the local monitoring agency and data providers. Special emphasis must be directed toward getting hospitals and medical care providers involved in this process. CDC should also provide the resources and technology necessary to establish real-time telecommunication linkages with local health data providers. *Local providers of surveillance information should not be expected to use their own resources to develop fully the required communication infrastructure.* This is especially true for hospitals and other medical care providers.

3. In addition to supporting local surveillance initiatives, **CDC must serve as the lead national surveillance system integrator.** Given the work of the Bioterrorism Preparedness and Response Office and the CDC's position as the nation's center of excellence in the area of infectious disease prevention and control, CDC, through BPRP, should play this role. BPRP, working in close conjunction with the Association of State and Territorial Health Officials and the Council of State and Territorial Epidemiologists, should work with state departments of public health to integrate local systems into statewide systems. It should also work with state departments to integrate state systems into a national system. This national electronic network between the CDC, state public health departments, and local public health departments must provide not only the communication infrastructure necessary for an integrated national health surveillance system, but also the infrastructure needed for communication, training, and warning. **The first step toward a national system would be the creation of a national strategy for building such a system that would examine the feasibility, determine the requirements, and design a multi-year program for creating the system.**

4. Although the NEDDS programs represent a step in the right direction, **with the support of Congress, the Department of Health and Human Services (DHHS) and CDC should do more to organize and manage a national research and development program focused on improving surveillance technologies.** One candidate project should be development of software systems to exploit the vast information resources available within the electronic record of hospitals, clinics, HMOs, and other computerized medical records systems. Automated software programs that independently gather certain health information and bioterrorism indicators such as the number of patients seeking care, the types of symptoms and complaints described by incoming patients, results from certain types of tests including x-rays and laboratory tests, and consumption of medicines and equipment can automatically be gathered and transmitted from the care provider's system to the local monitoring entity. As hospitals and other care providers increasingly use electronic systems, much of the necessary health surveillance data will be obtained and processed by the hospitals during the course of normal business. Improved systems and software applications are required to mine this potentially rich source of data. A closely related area requiring focused R&D is development of advanced automated search agents to "scrub" information systems for key indicators of bioterrorism

incidents. Such agents could be used to search for and distribute health related information from a number of sources including the Internet, local public safety communication systems, EMS systems, and databases of hospital patient records.

II. EPIDEMIOLOGY

What Are the Requirements?

Whereas surveillance is an *awareness tool* used to monitor and accumulate data about disease outbreaks, epidemiology is an *assessment tool* used to interpret the raw data gathered through various surveillance sources. While some assessing takes place during the course of surveillance – a physician recognizes and reports an unusual case or a medical examiner reports an unexplained death – it is largely left up to the epidemiologists to interpret surveillance data and recognize the significance of unusual occurrences. In determining the exact nature of an outbreak or bioterrorist event, the epidemiologist will conduct an investigation by working with a variety of data to determine the source of an outbreak, mode of transmission, extent of exposure, and how the outbreak is likely to spread. He will also predict future patterns, and calibrate the necessary response. Based on this information, epidemiologists make recommendations for the appropriate public health measures needed to contain the outbreak. The epidemiologist also informs the medical community of the nature of the problem they confront so that they can devise the appropriate treatment. In order to achieve these objectives, epidemiologists perform the following activities: 1) interpreting surveillance data; 2) conducting investigations; 3) building case definitions; and 4) ongoing monitoring.

Interpreting Surveillance Data

While epidemiologists will be able to draw some preliminary conclusions about an outbreak from even the most basic surveillance data, the sophistication of what epidemiologists will be able to deduce from the surveillance data will depend on the quality of that data as well as how quickly it is received. Data gathered from surveillance will largely inform the epidemiological investigation at the onset, and the more thorough this data is, the closer it will bring the epidemiologist to the source and nature of the outbreak. For example, data that indicates a sharp increase in hospital admissions, while a sign that something unusual may be occurring, will be far less useful to epidemiologists than data that indicates syndromic information distributed geographically over time. The former set of data indicates little more

than the presence of an emerging epidemic, while analysis of the latter set of data can tell an epidemiologist something about the characteristics of the disease of concern, and roughly when and where the exposure occurred.

If surveillance data is insufficient (i.e. single source -- unusual clinical reports from physicians), then epidemiologists will have to go through the painstaking, time-consuming, and labor-intensive process of interviewing patients to collect data that can reveal necessary clues about the outbreak. Local departments of epidemiology, however, rarely, if ever, have the personnel to conduct large numbers of interviews of this type within the short timeline of a bioterrorist event. Therefore, should it become necessary to conduct case interviews, it is likely that local and state officials will call on the CDC's Epidemic Intelligence Service (EIS) to support their efforts. If a request is made, the EIS, as it has in the past, will need to mobilize rapidly in support of a local investigation.

Interpretation of raw data compiled through various forms of surveillance is a critical part of detecting and appropriately responding to a bioterrorist attack. Although hospital personnel and physicians are given guidance on reportable disease outbreaks and are required to report unusual patient cases, and laboratories are required to report unusual cultures to the local department of health, the current system is largely manually based. If an unusual case presents itself at a hospital, the department of health is likely to be notified by phone. Even in instances in which locales have made arrangements with hospitals or laboratories for regular reporting of admissions or culture characteristics, this data must first be manually entered into a system and then forwarded to the department of health for analysis. There are no automated surveillance systems that gather surveillance data and forward it to the department of health hourly, after each shift, or at the end of each day.

In the event of a bioterrorist attack, epidemiologists will need access to real-time surveillance data to monitor how an attack is progressing and unfolding. This is a major challenge to utilizing epidemiology effectively in a bioterrorism attack. Even if real-time surveillance data is available and forwarded to a department of health, someone must continually monitor that data to ensure prompt analysis and response. Certain data are signals of a

suspicious outbreak that should prompt epidemiologists to involve the larger public health and medical communities and request rapid laboratory identification of the etiologic agent. Some of these signals are:

- Identification of rare or unusual cases of disease;
- A surge in the number of people with similar syndromes;
- A surge in the number of unexplained deaths;
- Higher than normal morbidity or mortality associated with a syndrome;
- Multiple diseases existing in a single patient;
- Higher than normal or unseasonable occurrence of a disease;
- Unusual geographic distribution;
- Atypical presentation of disease;
- Endemic disease with an unexplained increase in incidence;
- A genetically altered or atypical strain;
- Atypical aerosol, food, or water borne transmission; and
- Concurrent animal outbreak.

If signals of a suspicious outbreak are present, epidemiologists should alert public health and medical personnel as well as law enforcement to the emergence of a suspicious outbreak of disease so that a response can be initiated. Once the larger public health and medical communities have been alerted and advised to report unusual illnesses, identification of the etiologic agent by a laboratory must be initiated immediately to determine if criminal activity has occurred and to initiate the appropriate measures for containing and treating an outbreak (see section on Laboratory Capacity, pp. 34-46).

Epidemiologists are unlikely to be able to make a positive confirmation until surveillance and patient data begins to accumulate several days into the event. Many bioterrorism agents, however, have very short incubation periods – 3 to 5 days from time of exposure to becoming symptomatic – and treatment is often not effective after patients become symptomatic. Because these symptoms are non-specific and flu-like, physicians and epidemiologists may not recognize that something unusual is occurring until an unusual number of patients begin to present (unless there are obvious indications of bioterrorism or if the attack is announced). These time constraints could limit the initial role that epidemiology will play to that of analyzing data and determining the extent of the exposure and how the outbreak is likely to progress over time. If epidemiologists are to play a central role in detecting a bioterrorist attack in its earliest stages, they must be provided with quality, real time surveillance data, preferably distributed

geographically so that epidemiologists can not only detect, but characterize the event and guide the necessary response.

Outbreak Investigation

Traditionally, epidemiology is a slow, labor-intensive process of investigating disease outbreaks. Epidemiology usually begins after patients have presented at hospitals or physicians offices with unusual symptoms. If background or baseline disease data suggests that patients are presenting at unusual rates or in unusually high numbers epidemiologists must initiate an investigation. This involves interviewing patients to determine life-style patterns and identify commonalities between patients that may indicate the source of the outbreak and mode of transmission so that public health measures can be taken to contain the outbreak. If the source of the outbreak cannot be determined from patient interviews, epidemiologists will collect and test environmental samples – food or water samples, insect and animal vectors, or soil samples – to identify the source of the outbreak and mode of transmission.

While traditional epidemiology is useful for understanding and containing slow moving disease outbreaks, an epidemiological investigation will need to move much more rapidly if a bioterrorist attack is suspected. Although the ability of epidemiology to guide the bioterrorism response system in the early hours and days of a bioterrorist attack will be limited because of the pace at which events will unfold, epidemiology will be important as a bioterrorist attack plays out over time, especially if non-traditional BW agents are utilized.

The crucial moments of recognizing a bioterrorist attack are likely to unfold over a period of days, but the effects are likely to continue over a period of weeks. For instance, after the Sverdlovsk anthrax release, approximately one-third of the patients presented with symptoms in the first week, another one-third presented in the second week, and the final one-third presented sporadically over the next 3 to 6 weeks. The Sverdlovsk experience is telling given that a bioterrorist attack is likely to involve less than optimal (from the attacker's viewpoint) environmental conditions, agent quality, and dissemination techniques, and thus produce less than optimal results. As a bioterrorism scenario plays out over several days to weeks, and as

patient data begins to accumulate, epidemiologists will have a central role in analyzing that data to determine:

- The approximate point of exposure and the population most likely to have been exposed so that prophylaxis and treatment can be focused there first;
- Measures for containing the outbreak;
- Whether a single attack or multiple attacks occurred;
- Whether follow-on attacks have been carried out that may result in additional waves of patients;
- How the outbreak will unfold over time; and
- Clues that may aid a law enforcement investigation.

Environmental samples are important in identifying the source and nature of an outbreak. If an approximate release location can be determined from patient interviews, then analyses of soil samples may indicate the presence of a non-endemic microbe or a higher than normal presence of a particular microbe. The presence of an unusual number of dead animals or the presence of abnormal symptoms in animals treated by veterinarians may prove to be a key to understanding an outbreak. The West Nile outbreak in New York City is a good example; dead crows became central to discovering that the outbreak was caused by West Nile virus and not St. Louis encephalitis. Epidemiologists will collect environmental samples such as rodents, insects or other animal vectors for laboratory analysis to determine the reservoir of the outbreak. Good surveillance data accumulated by veterinarians will prove very helpful to epidemiologists, especially when zoonotic diseases are involved.

Epidemiologists will assess the type of outbreak as well as advise on the type of measures that should be taken to contain the outbreak. Containment of a contagious disease will require extremely effective disease control and quarantine measures. Epidemiology will be important for monitoring patient data and animal illnesses to determine the approximate point of exposure so that prophylaxis or antibiotic treatments can be focused on people who can be placed in that particular geographic area at the time of the attack. Epidemiology will also be important for monitoring and securing a contaminated water or food supply, and infection control measures will depend largely on the information gathered during an epidemiological investigation.

Epidemiology will also play an important role in bioterrorism events that do not involve agents of highest concern. Because inhalation anthrax or plague is almost non-existent, a single

case is enough to suspect bioterrorism. But in many other deliberately induced disease outbreaks, linking the disease to bioterrorism may not be obvious. A bioterrorism attack may not necessarily have a steep epidemic curve. In the case of a food-borne attack in which the source of the outbreak is a food product that is purchased and consumed gradually over the period of days to weeks, the contaminated products would result in a slow rise in an epidemic curve that may resemble natural phenomena. Small-scale food and waterborne attacks are easier to conduct than those using aerosols, and it is difficult to distinguish a natural outbreak from a bioterrorism event. It was thought that the Rajneeshee salmonella poisoning in The Dalles, Oregon was caused by poor sanitary conditions at restaurant salad bars and was only discovered to be the result of bioterrorism over a year later, and only then after a cult member confessed to the deliberate contamination. In food and waterborne incidents, epidemiologists will have an important role in determining the source of the outbreak so that access to and distribution of the materials are halted.

Constructing Case Definitions

Even with relatively little surveillance data, epidemiologists can create a case definition from the beginning of an outbreak in order to alert public health and medical personnel of the need to report cases that are similar to the case definition and request laboratory cultures to confirm that a patient has been afflicted. A case definition will initially describe known symptoms: fever, chills, nausea, headache, vomiting, etc., the geographic location of patient clusters, and a time window of exposure (if known). It will also provide physicians with treatment protocols and advanced clinical symptoms. A case definition is an important tool for aiding physicians and public health officials in identifying, reporting, monitoring, and tracking both old and new cases related to the attack. Construction of a case definition will be essential to medical personnel tasked with triage responsibilities as guidance for distinguishing between potential attack victims and the “worried well,” and directing these individuals to the appropriate treatment regimen.

The starting point for constructing a case definition will be surveillance data. Epidemiologists will then begin to fill in gaps in that data by compiling additional information.

Epidemiological investigations will include interviews with patients to uncover common linkages and identify additional people who may have been exposed. If a common facility is linked to a high percentage of case patients, the administrative records of that facility -- work schedules or time cards, visitor sign-in sheets, personal contact information on employees – may be reviewed to identify potential victims. Press releases, news stories, advertisements, or other communications means may be used to encourage individuals that have information pertaining to the outbreak to come forward or to direct individuals with symptoms similar to those described by the case definition to the appropriate treatment center where additional information can be gathered during the course of treatment.

Monitoring a Bioterrorism Event

Simple case accumulation will allow epidemiologists to calculate an epidemic curve and give a rough estimation of when the initial exposure occurred based on the average incubation period for the particular disease. But this calculation will depend on positive laboratory confirmation of the etiologic agent. The pattern of the epidemic curve will also be important for determining the nature of an outbreak, and may, but will not always, signal that an outbreak is intentionally induced. A rapid spike in the epidemic curve may indicate that a bioterrorist attack has occurred if exposed victims become ill at approximately the same time after exposure. Most natural outbreaks gradually accumulate as people come into contact with the source of the outbreak over time, although sharp spikes are sometimes seen in natural point source exposures. Eventually all of those people who are likely to come into contact with the source of a natural outbreak will have done so and the curve begins to tail off, but in the early stages, a natural and intentional outbreak spike may be indistinguishable. This is especially true if the outbreak presents itself over a longer period of time. Epidemiologists will continue to gather information from the Office of the Medical Examiner, local coroners, veterinarians, toxicologists, medical providers, and hospitals, and analyze this information to make judgments and projections about the nature and course of the outbreak.

Once an outbreak is underway, epidemiologists need continued access to information on patient load and symptoms, as well as laboratory results, and they must have a means of

providing information back to public health and medical officials who can use it to make critical decisions about treatment of patients. A distilled version of the epidemiological data will need to be disseminated to the response entities to keep them abreast of developments, and some information must be provided to the public about the nature of the outbreak and practices and procedures for containing it. At present there is no mechanism for epidemiologists and other public health and medical entities to receive or exchange surveillance data or add to that data via a central information and communications system.

In summary, while the practice of epidemiology is very similar in natural outbreaks and bioterrorist attacks, there is a basic set of requirements that are helpful in conducting any epidemiological investigation, and other requirements that can greatly benefit epidemiology during a bioterrorism event. These requirements include:

- Baseline disease data;
- Real-time access to surveillance data;
- Adequate personnel to continuously analyze surveillance data and investigate unusual outbreaks;
- Personnel and equipment to gather environmental samples;
- Robust laboratory capacity to test environmental samples, confirm epidemiological findings, and provide additional information about the demographics of patients;
- IT systems that can compile and analyze patient data gathered manually during epidemiological interviews;
- Ability to communicate easily and share information with laboratories, hospitals and physicians and federal level entities;
- Broad understanding of a variety of disease patterns -- endemic, non-endemic, food and waterborne, traditional bioterrorism agents, as well as unexpected or non-traditional bioterrorism agents.

In essence, epidemiology engages in the process of collecting disease data using a variety of tools, analyzing that data, and making recommendations for controlling the outbreak and maintaining public health. Many of these requirements are labor-intensive and require staff to meet them, yet building epidemiological capacity at the local level is a daunting challenge.

Building Epidemiological Capacity

Because surveillance begins at the local level, and because detection and response to a bioterrorism attack – at least initially – will most likely occur on the local level, epidemiological capacity must begin with local public health departments. In states with largely rural counties that do not have the resources to maintain a staff of epidemiologists or even a single dedicated epidemiologist in some cases, this capacity should be built primarily at the state level. However, it should be responsive enough that the capability can be mobilized to support an investigation at the county level in the event of a bioterrorist attack or disease outbreak. To build this capacity from the ground up in rural states is a daunting task that would require enormous sums of money; anything short of significant sums would result in uneven and sporadic epidemiological coverage throughout the state. Such expenditures must be balanced by the reality that bioterrorism attacks in rural areas are in and of themselves of lower probability than attacks in urban areas and far less likely to cause overwhelming casualties because of lower population densities.

Capacity must also be built at the city level in larger urban areas where disease outbreaks are more likely to be significant and bioterrorism attacks are more probable. States and regions with several large cities in fairly close proximity should build a robust epidemiological capacity at both the state and local levels. Large urban centers already supply epidemiologists with numerous challenges in containing disease outbreaks and improving public health.

Bioterrorism is one more challenge that epidemiologists in urban centers must face. While epidemiologists in a particular city may be able to monitor the health of that city, urban populations tend to move significantly on a daily basis. In the event of a bioterrorist attack, a city epidemiologist will not be able to track potentially exposed victims who have left the city for the suburbs or another city in that state or elsewhere. For this reason, it is essential that epidemiological capacity exists on the state level in regions with multiple large urban centers. For example, victims from a bioterrorist attack in New York City are likely to present in the city, but also in New Jersey, Connecticut, upstate New York, and possibly even Boston, Philadelphia, or Washington. Therefore, epidemiological capacity will be required on the state level to

investigate the relationship between what is occurring as the result of a bioterrorism attack in New York City and syndromic trends in a broader geographic area.

Where Are We?

Epidemiological capacity at the local level is currently lacking. Many state and most county health departments lack the funds to add staff to address bioterrorism issues. Instead, responsibilities for building epidemiological capacity for responding to bioterrorism are being handled by current staff members whose time is already consumed by investigations of natural disease outbreaks – influenza, food-borne illnesses, sexually transmitted diseases – or by public health campaigns aimed at generally improving the health of local populations. This approach leaves only a small percentage of time, if any, for bioterrorism-related planning. Public health officials in New York City trying to cope with West Nile virus, for example, have little if any time to deal with normal problems, let alone bioterrorism preparedness efforts. While some health departments have received federal grant money for bioterrorism planning activities, and have been able to use these grants to supplement their administrative staff or bring on an additional epidemiologist, most health departments have not received planning grants for these purposes. The result is added workloads for current staff members.

Even when health departments are engaged in planning and preparedness activities, because epidemiological investigations are labor-intensive, there is still insufficient local capacity for conducting rapid and wide-reaching investigations in the event of a bioterrorist attack. In many cases, then, epidemiological support will have to come from state health departments where available, or rely on the CDC's epidemiological assets. Although CDC's epidemiological assets are exceptional, a major bioterrorist attack would seriously tax these resources, leaving little excess capacity to deal with multiple attacks in different locales or other health concerns.

Local health departments also do not have the capacity to dedicate a staff member to developing relationships with potential providers of surveillance data – hospitals, primary care physicians, laboratories, pharmacies, school and employment personnel offices, etc. – or

devising ways to implement and installing data gathering or communications mechanism with these entities. This is partly due to a lack of staffing but derives from the lack in local health departments of information technology (IT) to gather surveillance data in real time, share that information, or communicate with response entities during an event through a common IT system. This is partly due to a lack of funding for putting IT infrastructure into place (see section on Information and Communication, pp. 115-130).

Key Issues and Recommendations

Surveillance and Monitoring

Without adequate surveillance and monitoring, it is unlikely that epidemiologists will detect a bioterrorist attack early on. Rather, it is more likely that an attack will be detected after the event when a surge of symptomatic patients begins to present at emergency rooms and doctors offices. At this point it may be too late to effectively treat the first wave of victims (see section on Surveillance, pp. 18-36). Without adequate surveillance and monitoring, it will also be extremely difficult for epidemiologists to determine the nature of the event. Because epidemiologists require quality data to do their job**, it is critical to develop better disease surveillance systems and bolster epidemiological staff in state health departments.**

Epidemiological Capacity

Current epidemiological capacity in local or state health departments is lacking and would be overwhelmed by a bioterrorist attack. This is largely because epidemiology at the local level has been neglected over the past two decades. Rebuilding this capacity is an enormous task. Epidemiology is labor intensive and staff is required to establish agreements with the providers of surveillance data, monitor, and analyze this data in real time, conduct patient interviews, and collect environmental samples. Local health departments do not have the staff to perform all of these functions under normal operating conditions, let alone under crisis conditions characteristic of a bioterrorist attack.

The labor-intensive nature of epidemiology requires that more funding be provided to state departments of health to hire additional epidemiological staff. This should be a priority focus area. The objective, however, should not be only to build assessment tools that make the response to bioterrorism more focused and efficient. It should also have practical benefits for responding to natural outbreaks of disease or for mitigating public health threats generally. In rural states like New Mexico or Montana, building epidemiological capacity at the local level is prohibitively expensive and largely unnecessary. This capacity should be built at the state level. In mixed urban and rural states such as New York or Illinois, urban centers should maintain a robust epidemiological capacity to deal with the myriad of public problems in that city, including bioterrorism, but efforts must be balanced with state efforts to develop statewide epidemiological capabilities.

Response Triggers

A tension exists between the need to initiate treatment and prophylaxis as quickly as possible and the need to know the nature and extent of a bioterrorist attack before initiating a massive response. **Thresholds for triggering particular responses should be defined to avoid unnecessary "hair trigger" responses. The first inclination of a suspicious outbreak should trigger an *initial response phase* -- alert hospitals and physicians, require doctors to take culture samples, seek laboratory diagnosis, and notify the appropriate federal, state, and local authorities. *Large-scale mobilization* of the response system should require that a second threshold be crossed, for example, laboratory identification of the etiologic agent representing an imminent public health threat or the accumulation of surveillance data that indicates such measures are necessary.**

Diverse Knowledge of Potential Bioterrorism Agents

A range of possible agents may be used in a bioterrorist attack to varying degrees of effectiveness. CDC's bioterrorism agents list encompasses a broad spectrum of possible agents, and considerable work is being done on many of them. Much of the focus has been on high impact agents such as smallpox, anthrax, plague, and tularemia, which are usually associated

with mass casualties. This has created an assumption that if bioterrorism occurs it will involve one of these agents. Epidemiologists need to be made more aware of the full range of potential bioterrorism agents, not just those few that have been the focal point of most discussions to date. **CDC should develop a mechanism, therefore, that conveys new developments to epidemiologists as its work generates new information regarding the full range of agents. Although primary attention must continue to be paid to agents that are most likely to be used or have the greatest potential impact in terms of casualties, periodic seminars or other awareness-raising mechanisms should be developed to inform state and local epidemiologists about those agents that are not at the top of the CDC list.**

Information Technology

Local departments of health need funds to make use of, and integrate, information technologies that can be used to collect, deposit, analyze, and share surveillance and epidemiological data from a central location in the department of health. Because the HAN network underpins many of the bioterrorism assessment and response tools, including epidemiology, it is essential that this infrastructure be expanded in ways that facilitate other tools.

III. LABORATORY REQUIREMENTS

Like epidemiology, the laboratory component of the public health and medical response to bioterrorism is largely an assessment rather than an awareness tool. Laboratories work closely with epidemiologists to determine the nature of a disease outbreak, whether natural or deliberate. Laboratories will be critical in identifying the etiologic agent, cueing public health officials about the most effective response, and ensuring that physicians administer appropriate treatment regimens.

What Are the Requirements?

Sampling

For laboratories to be an effective assessment tool for responding to bioterrorism, laboratory technicicans must be more aware of the bioterrorism issue and more capable than they are today of identifying potential bioterrorism agents. Unfortunately, physicians are generally reluctant to order more cultures given pressures from insurance companies and by Health Maintenance Organizations (HMO) to reduce the number of non-essential procedures. In this environment, physicians are unlikely to refer a culture sample to a clinical laboratory unless something unusual is suspected, thus placing a heavier burden on surveillance to detect an outbreak. Given that HMOs operate in a for-profit culture, it will be difficult to convince them to pay for additional laboratory analyses as a mechanism for detecting bioterrorism. Bringing HMOs into public-private partnerships to address the threat of bioterrorism is an important requirement (see section on Public-Private Partnerships, pp. 155-170).

Surveillance

Clinical laboratories, or laboratories that receive routine culture samples from physicians for confirmation of syndromic diagnoses, represent part of the front line in a bioterrorism event and are essential for effective utilization of laboratories for surveillance and early detection of an unusual outbreak of disease (see section on Surveillance, pp. 18-36). A drastic increase in

culture requests, the appearance of an unusual sample, or a cluster of samples with the same characteristics may indicate a bioterrorism event. Because physicians may not associate clinical flu-like symptoms with a bioterrorist attack, clinical laboratories receiving patient samples may be the first to detect a bioterrorist attack if they are aware of what they should be looking for and what to do if they suspect something unusual is occurring.

Diagnostics

Assuming that physicians take cultures from patients exhibiting flu-like or unusual symptoms, and assuming that laboratory technicians detect and report an unusual culture sample, forwarding a sample to a laboratory that can rapidly diagnose the etiologic agent is critical to initiating proper medical treatment and response procedures. The sample also will be an essential source of information for epidemiological investigations of the location of an attack and the people potentially exposed. Given the short time period between exposure to many bioterrorism agents and sickness and death, rapid diagnosis and treatment are absolutely essential to minimizing fatalities. Physicians will depend on laboratories to determine the agent used in a bioterrorist attack in order to treat patients effectively. Laboratories must be able to test for anti-microbial sensitivity and determine whether a particular antibiotic will be effective against the given agent. Likewise, public health officials will need to know the nature of an outbreak in order to institute the appropriate public health measures to protect uninfected people. These measures will be drastically different for anthrax than for smallpox. Laboratories will also be important in determining whether more than one attack has occurred and how many agents are involved. Laboratories must also support law enforcement efforts not only by identifying the agent used in an attack, but by conducting microbial forensics to determine where the agent may have originated.

There is also a need to enhance laboratory capabilities to identify a wide-range of potential bioterrorism agents. While the CDC recognizes that the bioterrorism threat is broader than the five bioterrorism agents it has identified as having the greatest potential for causing mass casualties, it has only recently added 14 more bioterrorism agent protocols to the list of

laboratory procedures. These protocols, however, have not been fully disseminated or integrated into most laboratory operating procedures.

Ultimately, more attention must be paid in the laboratory context to the potential for a bioterrorist attack with agents that have not traditionally been weaponized by militaries, particularly those that have been the source of recent disease outbreaks. Salmonella, E. coli, and cryptosporidium are examples of agents that may be used by terrorists, yet are unlikely to raise suspicion among laboratory technicians that a biological attack has occurred. They could assume, for example, that an outbreak caused by these agents is the result of unsanitary food service or handling conditions. As the Rajneeshee salmonella attack demonstrated, a link to bioterrorism may only be discovered later. Conducting advanced microbial analyses on agents like salmonella or E. coli could determine that rare or multiple strains are involved in an outbreak indicating the possibility that the outbreak was intentionally introduced. Building the laboratory capacity to routinely conduct advanced microbial analyses on common agents is not feasible, yet an unusual surge in culture requests for one of these agents should prompt laboratories to forward samples for more advanced analyses. A balance must be drawn between building laboratory capacity for identifying the most likely bioterrorism agents and less likely, but still possible, contingencies.

Surge Capacity

State and local laboratories possess a range of capabilities and perform different functions, from simple culturing to genetic sequencing. Some of these facilities are public and others are private; some are housed in hospitals and public health departments, and others are independent entities; some handle an enormous volume of cultures and others far fewer. For these reasons it is difficult to place the onus of building laboratory capacity on a single type of laboratory. Like other functions in the bioterrorism response system, providing a surge capacity is critical. Such a surge capacity requires laboratories to cooperate during a bioterrorist event. Having the ability to refer culture samples within a network of laboratories with varying capabilities provides the necessary technologies and surge capacity that will prevent backlogged culture requests during an event.

Personnel and Equipment

Conducting rapid diagnostics and producing surge capacity cannot be done without equipment and trained personnel. The number of personnel available and trained to conduct culture analyses of potential bioterrorism agents during an event will be critical, as will the amount of technical equipment to conduct identification analyses. For each positive confirmation of a clinical diagnosis that laboratories make during a bioterrorist event, epidemiologists will have another patient profile that can be used to characterize the nature and scope of the attack. This information will prove useful for guiding medical management decisions. Eventually technological tools may provide rapid diagnostic capabilities in accurate hand-held assays that can be used during a bioterrorism event to triage patients and quickly decipher the "worried well" from the truly ill. Other technological tools that will aid laboratories include shared access to databases housing molecular sequencing of pathogen strains, microbial sensitivities, and areas of origin for use in defining both appropriate public health measures and law enforcement actions.

Training

Educating state and county laboratory personnel in using new techniques and equipment is also an important component of building laboratory capacity, especially given advances in molecular biology and biotechnology. Technology-based training is needed to familiarize employees with new technologies that will enable state and county laboratories to perform more advanced tests during a bioterrorism event. Using a set of "unknowns" may also be a helpful training method. Personnel must also be trained in agent-specific protocols for sampling, conducting laboratory procedures, transferring samples to better equipped laboratories, and chain of custody issues so as to get accurate results and maintain evidence for law enforcement. As training continues for laboratory personnel, bioterrorism issues should be included in training proficiency testing to gauge how well laboratory personnel understand the procedures that will be involved and roles that laboratories generally will play in responding to a bioterrorism event.

Communication and Information Sharing

The ability of laboratories to communicate and share information with other laboratories, as well as with public health departments, hospital staff and physicians, and other response entities so that all those involved in responding to a bioterrorism attack are well informed and acting on the same information will aid a more efficient response. The CDC is the principal hub of communications among laboratories. The Public Health Laboratory Information System (PHILS) is the information sharing system that is currently used by the majority of laboratories that communicate and send information to the CDC. The CDC should work with laboratories to standardize software and IT systems to facilitate the exchange of information and allow laboratories to communicate more effectively. This would allow for better integration and cooperation between laboratories and other public health and medical entities in monitoring infectious diseases and responding to bioterrorist attacks.

Where Are We?

The CDC and the Association of Public Health Laboratories (APHL) have organized and are expanding the Laboratory Response Network (LRN), a series of laboratories that assist one another in the event of a bioterrorist attack. The LRN establishes cooperative arrangements between network laboratories with varying degrees of capabilities to provide the necessary diagnostic and support services. The LRN provides laboratories with a surge capacity to handle increases in specimen analysis requests that could result from a bioterrorism attack by allowing local laboratories to distribute the load among many laboratories in the network as well as by providing the necessary personnel, technical equipment, and diagnostic services that may not be available at lower level laboratories. The LRN also utilizes the existing capabilities of laboratories to ensure that a wide-range of procedures and capabilities are available to perform diagnostics in the event of a bioterrorist attack.

The LRN extends from clinical laboratories through state public health laboratories with more advanced capabilities to the most advanced laboratories at the federal level. Any suspicious samples identified by lower level laboratories will immediately be forwarded up the

chain. In the case in which a specimen is thought to be related bioterrorism, arrangements have been made for immediately forwarding the sample to federal laboratories at the CDC with Biosafety Level 3 and 4 capabilities for working with the most dangerous pathogens like smallpox, or viral hemorrhagic fevers. The CDC Rapid Response and Advanced Technology (RRAT) laboratory will initially receive an unusual sample and either identify the sample quickly or refer it to a divisional laboratory with agent-specific capabilities. These laboratories will confirm the results of lower laboratories, perform advanced microbial forensics, check the specimen against agents and strains formerly encountered, and bank the specimens for future reference. The specimen may also be referred from the CDC for evaluation by the laboratories at the U.S. Army Medical Research Institute for Infectious Diseases (USAMRIID) or FBI laboratories, but that decision is made at the federal level and coordinated between DoD/USAMRIID, DHHS/CDC, and/or DoJ/FBI.

Once results are confirmed on the federal level they are reported back to state and local departments of health and laboratories so that appropriate public health measures can be taken. Essentially, the LRN provides a surge capacity and gives local level laboratories access to advanced capabilities, alleviating the need for costly upgrades to ensure laboratory capacity at the local level. All states now have some laboratory capacity to respond to a bioterrorism event, if not locally, then through the resources of the LRN.

All laboratories that are registered as part of the LRN are designated Level A, B, C, or D based on their capacity to support the diagnostic requirements of a bioterrorist attack. Level A laboratories include hospitals and other clinical laboratories, which receive culture requests from physicians to confirm clinical diagnoses. These laboratories are the front-line of laboratory capacity in the sense that they process the highest volume of culture requests and are the first to receive cultures from physicians. While Level A laboratories can confirm some specimens and rule out others, they cannot positively identify bioterrorism priority agents.

Although Level A laboratories will likely be the first laboratories to receive a sample from a potential bioterrorism victim with flu-like symptoms, most have not been integrated into the LRN and have little understanding of how the network operates. By definition, they have the

least trained technicians and lowest technical capacity. In many cases Level A laboratory personnel are unaware of bioterrorism issues or potential bioterrorism agents. Technicians, for example, will dispose of culture samples containing *bacillus*, which is a common laboratory contaminant, without referring the sample to another laboratory for additional testing to rule out *bacillus anthracis*, the causative agent of anthrax. Level A personnel must be better informed about potential bioterrorism agents, how to report unusual cultures to the local public health department, and how to forward the culture to a higher level laboratory for additional testing. They also need to be sensitive to their role in surveillance, given that in the event of a bioterrorist attack, Level A laboratories will receive more culture requests of a particular type. Such surges must first be reported, and then be processed in a timely fashion to determine if something unusual is occurring.

Level A laboratories must recognize the importance of these issues and have mechanisms in place for monitoring, reporting, and transferring samples in the event of a surge. If Level A laboratories do not recognize unusual agents or an initial surge in atypical cultures and refer these samples to Level B or C laboratories for further analysis, it may take several days for enough sick people to present before a public health official or physician recognizes that something unusual is happening. By this point, many people will be exhibiting symptoms and will be much more difficult to treat if treatment is possible at all. Laboratory technicians, who fail to recognize the importance of, or dismiss unusual culture results, will delay detection of an outbreak and treatment of potential victims.

Level B and C laboratories, are critical in detecting and shaping the response to unannounced bioterrorist attacks; their analyses of samples that may indicate suspect bioterrorism activities will serve as the basis for mobilizing law enforcement as well as federal assets. Because there are fewer Level B and C laboratories than Level A laboratories, they are well integrated into the LRN. Laboratory personnel in Level B and C laboratories have a relatively high awareness of how the LRN operates in the event of a bioterrorist attack and they are trained in new procedures using more advanced equipment. Level B and C laboratories are usually county and state public health laboratories (SPHL) that have more highly trained personnel and better technical capabilities. They can identify etiologic agents, confirm clinical

diagnoses, and conduct anti-microbial susceptibility testing so that the best possible medical treatment can be administered.

The LRN has also established procedures and protocols for analyzing and transferring specimens, and communicating and sharing information among network laboratories. These protocols standardize the laboratory procedures in dealing with bioterrorism agents to ensure accurate results and preserve evidence for law enforcement. For example, in an announced bioterrorism event, mid-level laboratories will analyze the sample for law enforcement entities to determine if it is a biological agent. If it determines it is not, the FBI takes custody of the evidence and the sample goes no further. Prior to establishing this as standard procedure, there was confusion over who should analyze the sample. Likewise, laboratory technicians were unfamiliar with priority bioterrorism agents or how to culture. The CDC and APHL have now established these protocols so that technicians have guidance during a bioterrorism event. The CDC and APHL have also held a series of training and education programs aimed at raising awareness of LRN laboratory personnel about bioterrorism issues and how laboratories fit into the public health and medical response to such an event.

Considerable progress has been made on the laboratory front over the past year. The CDC has aided laboratories through its grants process, providing funds to state and county laboratories to procure needed equipment and personnel for handling a bioterrorist event. Generally, bioterrorism grantee laboratories can handle initial response and surveillance requirements and conduct molecular analyses, but state and county laboratories that have not been recipients of grant money have little or no response capacity and no molecular methods capacity. Even without this capacity, all states have access to other laboratories in the LRN with sufficient response capacity, and molecular methods technologies.

Even with funds from CDC, however, state and local public health departments and laboratories are still constrained financially. Many laboratories are old and utilize outdated equipment. Some laboratories are also limited by their physical size and layout, which inhibits them from expanding to accommodate additional equipment and personnel. Some laboratories have rearranged parts of their facilities to make additions, but many others do not have this

ability and cannot afford to expand. Molecular technologies are being increasingly used on the state and local level but state and local laboratories do not have a large staff that can exploit these techniques in the event of a surge in demand during a bioterrorism event. Therefore, such laboratories will largely rely on support from CDC in a crisis.

Communication and Information Sharing

Individual laboratories interface with LRN largely through a website. This simple arrangement is sufficient for obtaining bioterrorism training protocols and ordering and transmitting reagents, but it does not allow for substantial information sharing or actual interaction between individual laboratories. Laboratories lack the basic equipment necessary to communicate and share information with their partners in the LRN as well as with the local department of health and other public and private health institutions like hospitals, clinics, and primary care physicians (see section on Information and Communication, pp. 115-130).

This lack of basic information technology requires that personnel do potentially automated tasks by hand, which drains a laboratory's staffing resources. For example, laboratories and state public health offices keep databases on pathogen strains and their prevalence in local communities. Various databases, IT systems, and software applications are largely uncoordinated and result in duplication of infectious disease tracking by multiple organizations and institutions and inhibit the sharing of information across entities with different IT systems. This problem is probably most pronounced between private laboratories and public institutions and hinders the ability of Level A laboratories to communicate or provide surveillance data to the local department of health regarding disease outbreaks. Laboratory directors are concerned that these systems may drain staff resources by forcing staff members to constantly report information to different databases at the CDC, which often overlap.

Awareness and Training

The CDC has recognized a lack of knowledge about technological developments and how they can help in the laboratory setting. Therefore, CDC is providing trainers to work with staff in state health departments and laboratories to provide training in technologies like pulsed field gel electrophoresis (PFGE) and other molecular techniques. It provides training on technological advances dealing with food microbiology, fungal and viral infections, rabies, tuberculosis, and new and emerging pathogens. To conduct this training, the CDC has sponsored workshops around the country at which laboratory staff gain hands-on experience with the latest technologies. The CDC has also arranged 8 awareness-raising courses directed at Level A laboratory technicians and is funding state and county laboratory personnel to travel to the CDC to study advanced laboratory techniques.

The APHL has continued this training for members of the LRN and has developed web-based informational materials that can raise awareness of the bioterrorism issue. APHL has also developed the official protocols for analyzing the five bioterrorism priority agents: smallpox, plague, anthrax, tularemia, and botulinum toxin. Although these provide initial guidance for laboratory technicians, the CDC has recognized that these protocols need to be expanded to include additional agents and are in the process of doing so. In the near future laboratory technicians will have web-based access to an additional fourteen bioterrorism agent protocols.

Key Issues and Recommendations

Sampling

Shrinking health care budgets and HMO regulations have resulted in a reluctance by physicians to request unnecessary procedures, including requesting laboratory culture analyses. **Given that many bioterrorism agents result in flu-like symptoms, physicians must be encouraged to take cultures and request laboratory analyses on a more routine basis to ensure that something unusual is not underway, especially if patients are presenting in unusual numbers or are exhibiting flu-like symptoms out of flu season.**

Diagnostics

Laboratories are important for determining what agents are involved in a bioterrorism attack so that patients are treated appropriately. Given the short time period between exposure to many bioterrorism agents and sickness and death, rapid diagnosis will enable treatment to minimize fatalities. A number of steps should be considered

1. **Level B and C laboratories should continue to upgrade their capabilities, including increasing the range of potential bioterrorism agents that they are capable of positively identifying, so as to reduce their dependence on the CDC laboratories.**

2. **State laboratories should also bolster their ability to test for microbial sensitivity and determine whether a particular medication will be effective against the given agent.**

3. **Technology-based training is needed** to familiarize employees with new technologies that will enable state and county laboratories to perform more advanced tests and use these capabilities to support lower level laboratories if needed in a bioterrorism event**.**

4. **The CDC's Rapid Response and Advanced Technology laboratory (RRAT) should continue to expand its technical capacity for rapidly diagnosing both critical agents as well as a broad range of potential bioterrorism agents that may be used in an attack.** Because rapid diagnostics will be critical for early intervention, the RRAT should also expand its personnel to ensure that it will be able to support the State Public Health Laboratory during a bioterrorism event. Research and development needs to continue in the area of diagnostics tools that can relieve the burden placed on laboratories. In particular, hand held assays capable of giving a quick and accurate confirmation of patients at triage and point of delivery stations.

Awareness of a Wide-range of Bioterrorism Agents

Although the CDC has acknowledged a range of potential bioterrorism agents, the emphasis on a narrow set of bioterrorism agents has created a perception that a bioterrorist attack is most likely to involve agents that have traditionally been weaponized by militaries. This threat analysis has found otherwise, therefore, **training for laboratory technicians is needed to expand their awareness of the range of potential bioterrorism agents.**

Laboratory Surveillance

Laboratories have a critical role to play in bioterrorism surveillance. Level A laboratories could be the first to notice a surge in culture requests, unusually high disease prevalence, or the appearance of an unusual etiologic agent. Recognizing the implications of these indicators of a bioterrorist attack and communicating this data to the local department of health is critical to mobilizing a prompt public health and medical response. The LRN has been successful at creating a network of laboratories in each state with a range of capacities to bring to bear during a bioterrorist event, but it has been less successful at integrating clinical Level A laboratories that will be the first to receive culture samples in most cases. This is a weakness of the LRN, especially given that Level A laboratories have a role to play in surveillance and could be the first to notice a surge in culture requests or an unusual agent. Level A technicians as a result are largely unaware of bioterrorism issues. Integration into the LRN will help to raise the awareness of bioterrorism in Level A laboratories and what role they will play.

The LRN must expand its network of Level A laboratories and better integrate food, water, and veterinary laboratories to ensure that diagnostic capabilities for the range of bioterrorism agents are available. Laboratory technicians at all levels, particularly in Level A laboratories, should receive awareness training and proficiency screening for issues related to bioterrorism.

Surge Capacity

Laboratories must be prepared to handle an influx of culture requests in the event of a bioterrorist attack. While the LRN has done a good job of providing surge capacity for less-advanced diagnostic capabilities as well as access to a full-range of diagnostic capabilities through the network, the current surge capacity for meeting advanced microbial diagnostics requirements during a bioterrorist attack is questionable. **The CDC should continue to provide funding through its grants process to build advanced laboratory capacity at the state level,** which will reduce dependence on CDC for the provision of these services and will bolster bioterrorism assessment tools at the state level.

Communication and Information Sharing

Individual laboratories interface with LRN largely through a website, but lack the basic equipment necessary to provide automated surveillance data to the local department of health or communicate and share information with their partners in the LRN, hospitals, clinics, or primary care physicians. **Laboratory communication and information infrastructure should be bolstered, particularly through greater automation.**

Funding

Adequate funding for laboratories is central to building capacity and raising awareness of the bioterrorism issue. The equipment and techniques used in many laboratories are outdated and the facilities are limited on space. **Funding is needed to renovate or redesign laboratory floor plans to ensure the best use of space and to accommodate additional equipment and personnel.**

IV. MEDICAL MANAGEMENT

What Are the Requirements?

Prophylaxis

Prophylaxis in response to a bioterrorism incident means providing potential victims with the medicines necessary to prevent the onset of symptoms or the vaccine needed to prevent the spread of the disease through the population. In order for a mass prophylaxis program to be effective, it must provide the appropriate medicine to all individuals who are possibly infected rapidly enough to prevent disease onset and provide that medication over the extended period of time necessary to eliminate symptomatic individuals. Vaccines should be provided to the group of people likely to have come into contact with the agent. For contagious diseases, when available, vaccines must be distributed to certain segments of the population to prevent further transmission of the disease within an exposed population.

Planning for and executing a major rapid prophylaxis campaign is a challenge requiring development of pre-event plans based on possible contingencies. Included among the key decisions are:

- Medicines or vaccines to be provided;
- The segment of the population to be provided with prophylaxis;
- The amount of medicine or vaccine needed to provide prophylaxis;
- The distribution system most appropriate for the speed requirement and the decisions listed above; and
- Any adjustments to these decisions as the event changes over time.

Prophylaxis should begin with identifying the agent used in the attack. Accurate identification will ensure that the most appropriate available medicine or vaccine is provided. In the case of chemoprophylaxis, there is a high degree of commonality between the ideal treatment options for many biological agents. Some examples are listed in Table 2. Some degree of uncertainty in the type of agent used will not make prophylaxis impossible, but it does increase the risk that the prophylactic treatment used until the point of agent identification will be

inappropriate or not ideal. This is especially true of vaccinations, given that vaccines are usually specific to agents or close families of agents.

Identifying the amount of medicine required to apply prophylaxis successfully in response to a bioterrorist attack is a function of:

- The amount of medicine needed per person per day to prevent onset; by
- The estimated number of people who may have been infected or
- The length of treatment regime to eliminate presentations of symptoms.

Table 2: Treatment Options for Biological Weapons

Agent	*Agent Treatment*
Q-Fever	Doxycycline
Tularemia	Doxy or Gentomycin
Prodromal Anthrax	Doxy or Ciprofloxacin
Prodromal Plague	Doxy or Gent
Brucellosis	Doxycycline
VEE	None

Source: "Biological Casualties: The Ten Commandments of Medical Treatment," Presentation by LTC Ted Cieslak, USA Chief, Operational Medicine Division, USAMRIID at the DOD Medical Initiatives Conference for WMD Casualties, April 3, 2000

In the case of providing vaccinations, the amount necessary is determined by the number of people that must be vaccinated to prevent the further spread of the disease times the number of doses needed to achieve full immunity.

The need to estimate the number of people infected reflects an important relationship between prophylaxis and epidemiology. Providing effective and efficient prophylaxis requires good epidemiological information – ideally to include an approximation of how an attack occurred operationally, the time frame for the attack, the method of agent dissemination, and the location of the release – to determine which people might have been infected. Without this information, everyone in the metropolitan area could be assumed to be potentially infected and should be prophylaxed. For attacks in large urban centers, the blanket approach to prophylaxis might require millions of doses per day for periods as long as two months. With good

information, however, epidemiologists can develop a profile of those individuals most at risk. These profiles provide a useful tool for sorting out those people who should receive prophylactic treatment and those who are either not infected or at low risk.

Once the type and amount of medicines and vaccines have been identified and sources specified for providing the supplies, the final requirement for prophylaxis is a distribution system. Given the complexities associated with distributing medicines or vaccines to many people, it is also the requirement most likely not to be met.

Planning for and managing mass prophylaxis should be done at the local level. Local officials will know in detail the layout of their city, including the population distribution, road configuration and traffic patterns, an approximation of available local level resources, and available labor pools upon which they can draw. Local officials can also anticipate the types of problems that might be encountered during a mass prophylaxis distribution effort before they occur, thus facilitating development of plans that mitigate those problems. In order to calibrate and adjust their prophylaxis plans, local officials should also have information on what resources will be available externally, including medicines and people, and how they will be deployed.

Plans for prophylaxis distribution vary from city to city, but most candidate systems are derived from a few basic options. The first option is to canvass the population being provided prophylaxis to provide them directly with the medicine or vaccine. Basically, a large team would move door-to-door to residences and employers to provide people directly with the appropriate prophylaxis. Some localities have even studied the potential applicability of the U.S. Postal Service in providing this canvassing capability. Even if the Postal Service is used, the central problem with this type of system is the number of people necessary for distributing supplies. There is an inverse relationship between the size of the canvassing team and the speed of distribution. Fewer people could be utilized to cover the same area and number of people, but would take more time. When there is an urgent need to provide prophylaxis, time is not an available resource.

Another option is to establish points of distribution (PODs) throughout the area where the individuals targeted for prophylaxis reside. Of course, having thousands if not tens of thousands of people converging on several distribution points introduces serious traffic difficulties that must be addressed or else risk having large segments of the infected population not have the ability to reach the PODs in a timely manner. One solution to this problem is to increase the number of PODs. Higher numbers of PODs decreases the number of people served by each individual POD. Like the canvass approach, manpower requirements increase as the number of distribution points increases. Moreover, more PODs make the distribution system more complex, increasing the risk of a breakdown.

Some cities have taken a novel approach to the concept of increasing the number of distribution points by using existing distribution points for pharmaceuticals. This plan envisions providing existing pharmaceutical distribution points - drug stores, pharmacies, clinics, hospitals – with the appropriate medicine or vaccines and then directing people to their regular pharmaceutical provider for prophylaxis. This system allows people to go to the place with which they are most familiar, increases the number of distribution points to decrease traffic and confusion, and utilizes the labor pool available within the existing system.

Treatment

Medical treatment will be key in mitigating the effects of a biological attack. Although treatment requirements will differ according to the circumstances of the attack – large versus small numbers of casualties or the period of time over which patients present at care facilities – several elements will be essential to an effective treatment regime, regardless of the context: assessing resource needs, developing a standard of care, and determining appropriate treatment measures.

1. Resources Needs

Resource needs fall into two broad categories: material needs, such as medicine, equipment, and treatment facilities, and human needs, such as medical staff and volunteers.

a. Material Needs

Material needs will surface in three main areas: equipment, medicine, and space. To some extent, the amount of resources needed will be determined by the size and scope of an attack. In the case of a limited attack – for example, one resulting in 10 or 20 casualties – hospitals or care facilities will probably have adequate equipment and antibiotics to treat any incoming victims. However, if an attack overwhelms local health care capabilities, local authorities will have to call on state or federal resources to provide the additional resources needed for treatment.

Necessary equipment can range from personal protective supplies, such as latex gloves, to negative air-flow rooms, respirators, and separate ventilation and waste collection systems. Blood, ventilators, and special treatment units are especially critical for effective treatment. As most hospitals have limited amounts of this equipment on-hand, if needed it will have to be procured from other local or regional hospitals and clinics. The amount of equipment needed must be assessed in terms of the projected number of casualties; logically, a greater number of expected casualties will require a larger volume of equipment. Because certain types of equipment will be stockpiled within the national stockpile, hospitals and primary care facilities will have to establish agreements with other medical centers, city response agencies, or private companies to provide excess supplies. Partnerships should be considered based on an organization's proximity to the primary care facility, the type of equipment it can provide, and the sophistication of its distribution methods.

Antibiotics are another critical treatment element whose availability must be assessed. Medication will be needed for treating those who are already ill in addition to preventing disease in those who may have been exposed. Because hospitals keep no more than a few weeks of medication on-hand, casualties mounting into the hundreds will quickly deplete available supplies. Several efforts have been considered to address the problem of sufficient medicines for treatment. The immediate supply problem could be resolved in part through mutual aid agreements between health care facilities; for example, an agreement established among several hospitals and clinics in the Washington, D.C., region provides for the pooling of medication in the event of an attack. Contingency plans of this type may be vital to saving lives, since time

constraints limit support from state and federal agencies during the initial critical period of an outbreak. However, as with equipment procurement, partnerships should be established based on proximity and distribution concerns.

Finally, adequate space for treatment is an issue. How a region will assess available space will depend in large part on how it structures its local response plan; some areas have designated several hospitals as primary treatment centers, while others have placed one hospital or clinic at the forefront of a response. Whether the agent is contagious or not will also have an important affect on the community's space assessment; a non-contagious agent will allow patients to be treated in more than one facility, while a contagious agent will require centralization of casualties.

In the event of an attack resulting in a large number of victims, local care facilities may be confronted with more victims than they have bed space. Consequently, alternative treatment facilities may need to be established. Local response plans should contain specific contingencies anticipating such an outcome. Potential care facilities may range from older, non-operational hospitals, to community centers or elementary schools. If a non-medical setting, such as a gymnasium, is chosen as an alternative care site, it is important to determine during the planning stages whether the facility has the necessary infrastructure to sustain a full medical response. For example, during the recent TOPOFF exercises in Denver, patient treatment was moved to an abandoned factory when hospitals became overwhelmed. However, once there, workers discovered that the factory lacked both electricity and running water, making treatment impossible. Adequate planning must include requirements for the provision of resources found in hospitals or other care settings, from beds and ventilators to linen, food, and waste management services.

b. Human Needs

Staffing will be a major concern for health facilities attempting to treat victims. In the event of a bioterrorist incident, staffing shortages may be severe, for many staff may fear transmission of the disease to themselves and their families, resulting in a high degree of absenteeism. Consequently, hospitals or primary care facilities must consider alternative

personnel sources. As with medication and equipment, mutual aid agreements between local and regional health facilities may allow for doctors and nurses to be dispatched quickly to treatment sites. Similarly, local hospitals or primary care clinics may call upon EMS providers to participate in treatment activities, from administering care to discharging patients.

If local partnerships do not provide enough staffing resources, a variety of specialized teams have been established to improve the ability of the medical community to respond to incidents involving biological weapons release. However, for the most part, state and federal assistance teams have been developed independently of existing local emergency management structures. Consequently, the majority of the teams are unfamiliar with the response mechanisms of any given locality. Without a clear understanding of how these teams will be integrated with local resources, their utility is diminished.

Personnel requirements are exacerbated by the need to incorporate appropriate rest periods and stress management activities into a response plan. In fact, proper rest will be critical in successfully containing an outbreak. According to several officials involved in bioterrorism planning in Seattle, a major cause of the law enforcement failure during the WTO talks was a lack of rest periods for on-duty policeman. While health management of a bioterrorist event will require different skills and activities of doctors and nurses than of the public safety community, taking care to avoid staff fatigue and stress will be important to the ability of doctors and nurses to do their job.

2. Developing Standard Care Procedures

Developing a standardized approach to patient management is needed both to avoid transmission of a contagious agent and to protect hospital staff from secondary infection. Because health professionals will be key caregivers in the event of an attack, the priorities of the health care facility or facilities responding to a biological weapons attack could be ranked as protection of the current staff and patients and then provision of the best possible medical care for infected patients presenting to the facility. Current hospital infection control procedures are appropriate for the level of risk involved with aerosolized biological agents. These procedures include both standard and transmission-based precautions. Standard precautions are designed for

use during the treatment of pre-hospital and hospital patients regardless of their diagnosis or presumed infection status, and are intended to reduce the risk of transmission of microorganisms from both recognized and unrecognized sources of infection.[1] Transmission-based procedures, which are disease-specific, are designed only for the care of those patients known or suspected to be infected with transmissible pathogens. However, as most diseases associated with bioterrorism are not easily transmitted from person to person, these procedures will not be as critical, although certain contingencies require awareness of them. Those entities involved in treating casualties will need a working knowledge of isolation and infection control measures, and these measures should be standardized within any treatment facility.

3. Determining Appropriate Treatment Measures

After the onset of illness, only general supportive care and specific medical treatment are left to health care providers. Appropriate medical care may involve life support measures, such as mechanical ventilation, as well as administration of antidotes. Supportive therapy may include attention to skin lesions, supplementary oxygen, pulmonary toilet, and treatment of complicating infections. Treatment will depend in large part on the characteristics of the disease, as well as on whether the agent is contagious or non-contagious. For a contagious agent, treatment will have to include the establishment of isolation wards and negative air-flow rooms, and doctors and nurses will have to be outfitted in full Personal Protection Equipment. However, these requirements will not be necessary for a non-contagious agent. Throughout the treatment process, attention must be given to symptoms that indicate early life-threatening deterioration.

Medical personnel involved in treatment must also consider methods to discharge patients once they have improved, as well as methods to dispatch those who have died to mortuary facilities. While most hospitals and clinics implement standard discharge procedures during regular operation, the ratio of victims to staff during a bioterrorism event will largely determine discharge thresholds. If the ratio of medical personnel to patients is high, victims may be monitored until symptoms disappear entirely, and long hospital or clinic stays may be instituted. However, if the ratio is low, doctors and nurses may not be able to provide care to

[1] Mark Keim and Arnold Kaufmann, "Principles for Emergency Response to Bioterrorism," *Annals of Emergency Medicine*, Vol. 34, No. 2, August 1999, p. 181.

those who are not desperately ill, and a simple improvement in symptoms, or passing of a crisis point, may be enough for doctors to decide that the patient can continue with home-based care. It is important to note that if the agent is contagious, patients will have to be kept isolated until transmission is no longer possible. Depending on the size of the treatment facility and the number of resources available, patients who are no longer critically ill may be transferred to a second facility to await final discharge. Because most doctors and nurses will be busy administering to the sick, medical students, residents, or EMS providers may need to be charged with collecting patient information and prescribing long-term prophylactic care or therapy to those being discharged. Similarly, students or EMS providers will need to coordinate the transfer of any fatalities to mortuaries or funeral homes. Fatalities will have to be carefully tagged and tracked.

Triage

It is estimated that when the Aum Shinrykyo attacked the Tokyo subway with sarin in 1995, three out of four people who sought medical care did not require treatment. Since that attack, those psychosomatic patients who seek unneeded care during a WMD terrorist attack have been termed the "worried well".[2] In a bioterrorism event, in which symptoms take days to weeks to appear, the phenomenon of the worried well threatens to overwhelm the medical system with people seeking treatment. Given that medical resources are limited, triage will act as a critical part of the medical management system by sorting patients who truly need treatment from those who do not. If triage is performed effectively, it can substantially reduce the stress placed on the medical system.

In the early stages of a bioterrorism event when a handful of patients begin presenting, hospital staff, alternative care providers, and primary care physicians who receive patients will largely perform triage. In the very early stages of an outbreak of an unusual disease, some suspicion may exist that exposure to a bioterrorism agent has occurred, but there will be little certainty. As a result, officials will be reluctant to initiate mass prophylaxis. But as larger numbers of people begin to present for treatment and it is determined that many people were

[2] Danzig, Richard J. "It Can Happen Here", *Hoover Digest*, No. 2, 1999.

potentially exposed, or if the extent of the exposure is unknown, a decision will have to be made to begin mass prophylaxis to prevent more people from becoming ill. Effective triage of potential victims is essential in reducing the stress on care providers as it will direct victims in need of treatment to facilities that can provide such services and will direct all other potential victims to points where they can receive prophylactic or self-treatment regimens.

In such situations it may be necessary to distribute prophylaxis to large numbers of people in a short period of time to prevent them from becoming symptomatic. The local medical resources for treating and prophylaxing victims are limited. Triaging patients therefore is essential to efficient use and management of these resources. Once a decision to begin massive prophylaxis has been made, a large-scale mobilization of local, state, and federal resources will be needed.

The task of deciding which patients should receive initial treatment at hospitals and which patients should receive initial prophylactic resources could be complicated. Limits in prophylactic supplies may raise ethical issues about who receives priority consideration. Many response plans call for administering pre-incident prophylaxis to key personnel and decision makers, including medical and public safety personnel, to ensure that they remain in good health to treat potential victims as well as to political leaders who will ultimately be in charge of maintaining command and control of the situation. Large numbers of "worried well", however, are also likely to present themselves for treatment despite having no need for it, raising difficult decisions. This challenge could arise especially in the early stages of an event when local supplies of medicine, vaccines, and so on are sparse.

Although triage is wrought with operational and ethical dilemmas and will differ according to the circumstances of the attack (e.g., large versus small numbers of casualties, or the period of time over which patients present themselves) as well as local resources and organization, the following activities will have to take place regardless:

- Establishing triage points;
- Providing information to the public about triage alternatives;
- Information collection and patient evaluation at triage points;
- Supplying triage points with prophylaxis medication and staff;

- Sorting of patients on the basis of
    - Direction to self-treatment regimens;
    - Direction to treatment area;
    - Determine that treatment is unnecessary;
- Follow-on mechanisms to monitor patient progress.

1. Triage Points

Establishing triage points for the appropriate treatment regime will reduce the number of potentially exposed victims who go to already stressed hospitals, alternative care providers, or physicians offices. Directing potentially exposed persons to triage points where they will be evaluated and treated accordingly is a key part of the necessary public information strategy. There should be many, geographically dispersed triage points to prevent a large convergence of people and vehicles on one or a few areas. In planning the location of triage points, consideration should be given to how well these locations will be able to receive large numbers of people as well as how population movements may complicate the delivery of supplies. Good locations for triage points might include areas that are easily accessible by major roads or highways or rail transportation to reduce vehicle congestion in the area.

Triage points might serve not only as places where potential victims are sorted by their treatment requirements, but also as Points of Distribution (POD) areas for delivering prophylactic medication to exposed persons who are not yet symptomatic. Once a determination has been made that a patient needs prophylactic treatment they should be provided with that treatment as well as directions for self-administering the medication and monitoring their health status. The best way to provide these services is to set up a station that is separate from the "evaluation station" whereby large numbers of exposed people can receive instructions on how to administer their prophylactic treatment and where questions can be answered and fears allayed. Triage points will also have to be equipped with transportation services for people in need of more elaborate medical treatment

In many cases, especially for a large-scale attack, local hospitals, alternative care providers, and physicians offices may be flooded with potential victims who do not follow public information guidelines but rather present at the place where they normally receive care. Under these circumstances each facility will need to establish triage points someplace on the grounds of

the facility to sort out which patients should be admitted into the facility for medium to long-term treatment and monitoring, and which patients can be administered self-treatment regimens without entering and overwhelming the facility where physical space is scarce.

2. Providing Information to the Public

A good public information strategy can help reduce the stress on the medical management system by providing the public with details on the time and location of the attack and advising them on where to receive appropriate treatment. Much of the challenge of triage will be getting potential victims to the right treatment area. In the case of a non-contagious release, the public will need to know that prophylactic measures can treat potentially exposed persons and where they can receive this treatment. Providing the public with information on time and place of the attack, and informing people that only those who can place themselves in the exposed area during a short time window need to seek treatment, can act as a self-selection triage tool. Public communications must also provide information on what symptoms may indicate exposure, where symptomatic patients should seek treatment, and where potentially exposed victims who are not symptomatic should go for evaluation and receipt of prophylactic medication. This information will be important for keeping hospitals from being overwhelmed. Meanwhile, in a contagious event, information messages should seek to convince potentially exposed persons to impose a self-quarantine by staying in their homes as the best way to contain the spread of the disease.

3. Information Collection and Patient Evaluation

Triage points will need to be staffed by personnel who can ask a potential victim a series of demographic and symptomatic questions to collect additional data that may prove useful to epidemiologists and law enforcement agents. Whenever possible, these interviews should be conducted by trained medical personnel who can make a decision about the appropriate treatment regimen. But in a bioterrorism scenario, numbers of real or potential victims seeking prophylaxis may appear, and there may not be enough trained medical professionals to staff both triage points and care facilities. Under these circumstances, a doctor cannot see every patient, but only those who, after initial evaluation, are determined to be at high risk of exposure. Initial evaluations will have to be conducted by public safety personnel, medical residents, or other

available emergency response personnel. This determination will be made on how closely a patient profile fits the case definition constructed by epidemiologists and medical personnel, and on answers to a standardized series of questions that collect information on where the patient was at the day and time of the attack (if the approximate day and time of the attack is known) and what symptoms they are exhibiting. Based on this information, an initial determination can be made as to whether or not a patient was at a high risk of exposure and symptomatic, and therefore should be referred to medical personnel for further evaluation. In essence, if medical personnel are completely overwhelmed in a bioterrorism event, the collection of patient information acts as an initial filter so that only patients who truly need to see medical personnel actually do. The liberties that might be taken with this initial filtering decision will largely depend on the number of patients and the available medical resources and staff.

4. Staffing Triage Areas

Hospital staff, alternative care providers, and primary care physicians who may begin to receive the first victims of a bioterrorism attack will need to be notified that patients fitting the epidemiological case definition should be referred to a designated care facility where specialists can provide a more conclusive diagnosis. This initial triaging of patients by referral will allow epidemiologists to gather information on the location and time of the attack, which will be critical to making the decision about beginning large-scale prophylaxis.

Triage will take place at different places and the number of people who need to be triaged will not necessarily depend on the scale of a bioterrorism incident as many “worried well” will seek treatment. The triage for small numbers of exposed people requires little more than notifying care providers that they should refer patients fitting the case definition to a designated facility. As the number of potentially exposed individuals grows, triage requirements will increase and could necessitate massive numbers of personnel to interview, diagnose, and sort patients by treatment needs. Hospitals will have to set up a triage station on the hospital grounds to separate patients in need of immediate admittance from asymptomatic patients who require prophylaxis. Much of the sorting of patients must be done outside of the hospital facility to ensure that its interior can maintain normal operations in the face of increased treatment demands. Points of distribution may also be set up to relieve the triage and prophylaxis burden

placed on hospitals. When appropriate, POD stations can give symptomatic patients a certified referral for admittance to treatment facilities for treatment and monitoring.

Once a decision to begin mass prophylaxis has been made, doctors, nurses, or other health technicians who are, by nature of their profession, more familiar with clinical recognition and treatment of disease, should make triage decisions whenever possible. However, in the case of an extremely large number of potentially exposed people requiring prophylaxis, some initial filtering of patients may need to be done by medical residents, pre-med students, veterinarians, dentists, or by the fire department or other representatives of the public safety community to weed out patients who were either not at the time and place of the attack if it is known, or who do not fit the case definition. As the number of people requiring prophylaxis or extended treatment increases, non-medical personnel are likely to take over much of the triage responsibilities as medical personnel are needed at treatment facilities.

Logistics and Distribution

A significant challenge in treating or providing prophylaxis to victims of a bioterrorist attack will be ensuring that response entities have the necessary equipment, medical supplies, and personnel. Achieving continuity of supplies in a crisis environment will be a daunting task. Putting into place a plan for distributing supplies before an incident occurs will be necessary for equipping response personnel to do their job in a time of crisis.

The starting point for any distribution system is a needs assessment to determine what resources -- antibiotics, occupied and available hospital beds, ventilators, personnel, etc. -- are currently available at the local and state levels. Such information can then be collated into a baseline of medical resource data. In the event of a bioterrorist attack, knowledge of where these resources are housed will be important for making decisions about re-supply efforts. As resources outside of the immediate area of the attack – nearby locales, state, or federal -- are brought to bear, officials will need to rely on baseline resource data to determine the best distribution of these resources. The availability of this information prior to a bioterrorism incident will give local planners an indication of how state and federal medical assets can be

integrated with local assets to have the maximum impact. This data will also be important for identifying and transferring resources from facilities with normal patient admissions to a facility that is stressed by an influx of patients as well as for informing response personnel about which facilities have resources available.

Some mechanism to track locally available resources must be developed. Facilities in the immediate area of attack will bear the brunt of treatment and prophylaxis activities and thus require much of the available medical resources. For this reason, initial decisions about where medical supplies should be distributed will be straightforward. But as medical supplies begin to dwindle and more potentially exposed victims present for prophylaxis and treatment, additional resources will have to be identified to meet the demand. Some of this demand can be met by transferring resources from care facilities that are not receiving large numbers of patients. But to do so requires knowledge of where available resources are housed and the ability to transfer those resources to care facilities that need them most.

While facilities receiving the bulk of the patient load will need a constant supply of medical resources throughout the crisis, as the medical treatment challenge grows with time, many care facilities outside of the immediate area surrounding the release site will also be receiving victims and PODs may need to be set up to triage and prophylax. Understanding the rate at which supplies are being utilized, as well as the re-supply needs of secondary facilities and PODs, requires some means for tracking what resources are being used to ensure that some areas are not oversupplied while others are undersupplied. It will also be necessary to track supply levels at central distribution points that are receiving state resources or CDC push packages to determine what additional outside resources may still be necessary.

Having identified the amount needed to provide treatment or conduct prophylaxis, the next key question is identifying sources of medications and vaccines. A number of potential sources of medicines and vaccines exist at the local level including supplies already distributed to area medical care providers. Hospitals, clinics, and doctors' offices immediately surrounding the area of the attack may possess some excess capacity not needed to treat both normal patients and bioterrorism victims. Extended reliance on local supplies is problematic, however, for a

number of reasons. Some vaccines and antibiotics, like ciprofloxacin or anthrax vaccine, are infrequently or never stocked by hospitals, perhaps because they are not useful in regular practice or because of high cost. Even for those medicines frequently used, it is unlikely that local care facilities will be able to provide anything but minimal amounts due to just-in-time medical supply systems, the use of hospitals' and clinics' supplies to treat symptomatic individuals, and the sheer amount of medicines that might be necessary to prophylax very large numbers of people.

One strategy for dealing with this problem is to establish mutual aid networks with care facilities in surrounding counties and cities. Excess resources within the network could be gathered and brought to the area of the attack. Such a network would have to include an extremely large number of hospitals and care providers given the general lack of excess supplies at most hospitals and the amount of medicines that may be needed. In addition, the process of gathering and moving resources within the network will be complex and time-consuming. Another local asset that could be available is pharmaceutical warehouses or production facilities, but the number of facilities producing the exact antibiotic or vaccine necessary is likely to be small, and the chance of having those facilities located near the area of attack is very slim.

An additional option is to develop dedicated stockpiles of medicines and vaccines most likely to be needed for prophylaxis in response to bioterrorism events. Determining which medicines and vaccines and how much should be stockpiled is a challenge due to the variety of potential attacks.

Working with state and local partners, the federal government must develop national stockpiles of appropriate pharmaceuticals for use in both prophylaxis and treatment. These stockpiles should be based on rough estimations of the amounts of antibiotics and vaccines necessary to meet the needs identified by answering the previous questions – which medicines might be necessary based on the agent used, how many might require prophylactic treatment, and how many doses would be needed per person to complete the recommended treatment regime. The types of medicines and vaccines stockpiled should be based upon a sound threat assessment

that identifies the most likely agents to be utilized and should capitalize upon the degree of commonalty among ideal treatment modalities.

This challenge is especially daunting given the high degree of specificity associated with vaccines. Developing, stockpiling, and maintaining a standing supply of a specific vaccine like smallpox vaccine will be expensive and is useful only if smallpox is deployed in an attack. Given the difficulties associated with acquisition, manipulation, and dissemination, the use of smallpox by a non-state actor must be deemed unlikely. But it is possible, and it would be an event of potentially enormous consequences. Given these consequences, it may make sense to develop some smallpox vaccine as a hedge against this possibility. The amount produced will depend on the amount necessary to stop the spread of a smallpox outbreak, the costs associated with production and maintenance, and how that cost compares with the resources necessary to meet other requirements.

Having established baseline resource data at the local level, planning should take into account how state and federal assets can be integrated into the local environment. Statewide medical resources could be mobilized in an emergency, and some states like Illinois have pharmaceutical caches that can be utilized in emergency situations. The CDC's National Pharmaceutical Stockpile "push packages" need to be factored into local planning based on local needs assessments. The challenge to fully utilizing the CDC's pharmaceutical stockpile is logistical. These resources will be delivered to local airports and handed off to local officials for distribution. In order to distribute this amount of prophylaxis, mechanisms for distributing medical supplies should be identified well in advance of a bioterrorist attack. Otherwise, the push packages will not be used to their fullest capacity.

Once a local airport receives supplemental medical supplies from the CDC Pharmaceutical Stockpile (state caches should be shipped directly to PODs via rail or truck), they must be effectively distributed to the appropriate facilities and/or treatment areas via local transportation mechanisms. In order to establish a reliable distribution system, cooperative arrangements need to be set up to use all available distribution systems, public and private, to

distribute supplies in the event of a bioterrorist attack. Possible medical supply distribution mechanisms that could be used in the event of a bioterrorist attack include:

- Pharmaceutical supply houses;
- Commercial shipping companies (Federal Express, UPS, or trucking companies);
- U.S. Postal Service;
- National Guard assets;
- Department of Defense local assets;
- Public transportation;
- Private transportation companies (Greyhound or Shortline);
- Rental companies (Uhaul or Ryder).

At the local level, pharmaceutical supply houses ship medical supplies to care providers and pharmacies on a daily basis, maintain warehouses for storing supplies, have employees and equipment for loading and moving them, as well as established supply routes and trucks for distribution. In some areas local response planners are talking with pharmaceutical supply houses about creating cooperative arrangements to support distribution requirements during a bioterrorism event. This would include using their loading docks, personnel, and transportation vehicles to distribute warehoused medical supplies as well as supplies contributed by states or federal entities. Commercial shipping companies or the U.S. Postal Service also maintain crews and trucks for distributing goods that may be utilized during an event. Public safety and public works or local volunteers may also be employed to drive rental trucks or public and private transportation vehicles such as buses or taxi cabs that can be loaded with medical supplies. State level transportation vehicles or assets operated by the National Guard, or even local DoD transportation vehicles, could also be utilized to ship additional medical supplies to care facilities if local distribution mechanisms become overwhelmed. In any case, identifying the available distribution mechanism, putting into place cooperative agreements to utilize them during a bioterrorism event, and having a pre-incident distribution plan in place can help to ensure a smooth transition of outside medical supplies to local officials.

Regardless of the type of system, large labor pools could be needed to provide treatment and distribute prophylaxis to the population. Where might local officials obtain the manpower needed to execute their plans? Increasing the number of people providing prophylaxis at the POD will increase the rate of service, but other people must track individuals who have received medicine or vaccine. Additional staff will be necessary to support those directly providing the

prophylaxis. People are going to be needed to provide medical information and advice. Others will be required for the simple but critical task of opening supplies from their packing and moving them to the front line providers. People will be needed to track receipt and distribution of medicines at the individual POD. This is necessary to determine the rate of distribution and the point at which a call for additional supplies must be made.

Public safety personnel will also be needed to provide security for medical supplies located at the PODs. Motivated by profit or fear of not being able to reach supplies quickly enough, people may attempt to steal materials from distribution points. A small number of conglomerated distribution points could be guarded by smaller numbers of people, but only with a reduction in the speed of distribution. With less supply located at the PODs, a large number of small distribution points reduces the impact of having the supply at a distribution point stolen. The more extensive the distribution system, the more people will be necessary to serve security functions.

At the local level, the public safety community represents one potential resource for this task. Police, however, would probably be heavily involved with security and maintaining public order. Likewise, paramedics and emergency medical service personnel will have their hands full responding to 911 calls and transporting sick individuals. One potentially untapped source could be the fire department, although firefighters may also be involved with security and responding to acts of vandalism and malfeasance. State and federal assets might also be useful in support of local prophylaxis efforts. National Guardsmen en masse could be trained and deployed to support prophylaxis efforts. Regular Department of Defense personnel, especially medically trained personnel like nurses and medical technicians, could also be useful. Like the national stockpiles, time will be required to move and then integrate available federal assets into prophylaxis systems. In fact, it may take days longer for a sufficient number of federal personnel to arrive than the push packages.

Another option is to organize a corps of reserve medical personnel from retired or former doctors, nurses, physician's assistants, veterinarians, and dentists. Such a corps could be created by asking people to join voluntarily and have their names included within a national database.

During a bioterrorism crisis, members of this corps could be called up from within the area affected by the attack.

Where Are We?

The Office of Emergency Preparedness, Department of Health and Human Services (OEP/HHS) maintains the National Disaster Medical System (NDMS). The NDMS is comprised of two main elements. The first involves voluntary agreements between the NDMS and hospitals in major metropolitan areas. Member hospitals agree to commit a number of their acute care beds, subject to availability, to patients received through NDMS. The federal government pays the costs of care provided to NDMS patients received by the participating hospitals. Because this is a voluntary program, member hospitals can provide more or fewer beds than committed in the agreement. The second element of the NDMS is comprised of a number of Disaster Medical Assistance Teams that could provide both additional personnel and supplies for treatment and prophylaxis. Currently, the combined total membership in DMAT teams is over 5,000 individuals.

According to existing plans, the Office of Emergency Preparedness of the Public Health Service (OEP/HHS) would coordinate federal assistance in the area of medical treatment. Other agencies, specifically the Department of Defense and the CDC, would also provide information and services. CDC, for example, is to provide its push packages within 12 hours of their release by the Director, although in a best case situation, an additional 24 hours would be needed to breakdown, catalogue, and package the contents and then transport them to area points of distribution. CDC could also establish an epidemiology command center within 24 hours. With these timelines in mind, it is imperative for local health facilities to have their own contingency plans.

In that regard, the OEP is also responsible for coordinating the creation of Metropolitan Medical Response Systems (MMRS), a process in which over 70 cities have been asked to organize local medical capabilities into a response system for incidents of CBRN terrorism. Recognizing that health and medical responses to bioterrorism are different than for chemical or

radiological incidents, within the last year, OEP has asked those cities that completed their original MMRS response plans to develop further response plans specifically geared for bioterrorism incidents. In order to fulfill their contracts, localities must develop detailed plans for how they would conduct a rapid and massive prophylaxis program. While the bioterrorism track is relatively recent, approximately 10 of the largest MMRS cities have been able to complete their plans and have them certified.

Cities and regions involved in bioterrorism preparedness, therefore, are beginning to think through medical management issues as they develop their local response plans. Most locales have included procedures for acquiring additional resources and equipment, either through mutual aid agreements or from federal stockpiles. However, very few have considered planning for additional medical staff. Aside from resource acquisition, the primary challenge will be treating patients in a timely manner while maintaining a high level of care. Decisions will have to be made about who can be discharged, when they will be discharged, and what types of long-term care they will receive.

Hospitals also remain unable to cope with even a limited bioterrorism event. Few hospitals have more than 100 beds available at any given time. Similarly, hospitals keep no more than a few weeks of medication on hand, which would be inadequate to meet the needs of a large number of casualties.

Most locales have triage plans and have identified schools, churches, arenas, conference spaces, and other sites where large numbers of people can be accommodated and processed or prophylaxed. Many locales have also considered setting up triage functions outside of hospitals, but most hospitals are reluctant to expend planning resources to coordinate triage activities given other health care priorities. Staffing and supplying triage points will be a significant challenge, especially as the numbers of exposed persons rises. Aside from staffing and supplying triage points, the primary challenge of triaging large numbers of people will be processing them in a timely manner.

In addition to the NDMS and the MMRS Contracts, OEP began stockpiling vaccines and drugs for use against biological agents in 1998. The stockpile program, managed by the Department of Veterans' Affairs, initially targeted smallpox, anthrax, tularemia, and plague, with other diseases to come later. While this program allowed for a greater potential availability of needed vaccines and antibiotics, a recent General Accounting Office (GAO) report indicates that the efficacy of the these stockpiles is compromised by poor management controls and a lack of required items.[3] A physical inventory of OEP's stockpiles indicated a discrepancy of more than 12 percent, and also revealed an alarming number of expired items that sometimes included the entire supply of a specific drug.[4] According to the GAO, the principal cause of these problems was a failure to implement basic internal controls that could reasonably assure that all medical supplies and pharmaceuticals are current, accounted for, and available for use. In fact, the inventory systems lacked basic information required for good record keeping, such as documentation and back orders, replacements, and shipment and receipt of all pharmaceutical and medical supplies.[5] Furthermore, the OEP did not conduct periodic inventories, maintain program policies and procedures, or provide adequate security of the stockpiles.[6] As a result, GAO concluded that the system cannot be relied on to provide complete medical support in the case of a bioterrorism incident.

In response to the perceived need for a more efficient, centralized supply of drugs and vaccines, the Centers for Disease Control received $51 million in FY 1999 to establish the National Pharmaceutical Stockpile (NPS) Program.[7] The "stockpile" will consist of two distinct elements:

1. A series of eight pre-positioned stockpiles of medicines, equipment, and medical supplies configured into push packages.

Full packages will be kept at Louisville and Memphis, the major hubs for Federal Express and other parcel carriers. One package each will be also kept in Dallas, Sacramento, and

[3] General Accounting Office, "Combating Terrorism: Chemical and Biological Medical Supplies are Poorly Managed," Report GAO/HEHS/AIMD-00-36 to Congressional Committees, October 1999, p.2.
[4] GAO, p. 2.
[5] GAO, p. 2.
[6] GAO, p. 3.
[7] GAO, p.9.

Philadelphia, while a half package will be kept in Hawaii and another in Puerto Rico. Currently, the stockpile is focused on compiling antibiotics, mainly oral and intravenous ciprofloxacin and doxycycline, and medical supplies like ventilators, tubing, needles, and so on. As of today, the push packages do not contain vaccines. Each push packages is identical in size and contents and designed to provide a rapid response capability. The combined push packages will contain sufficient quantities of antibiotics to provide prophylaxis to 7.3 million people for three days. Each package is located and maintained to reach any part of the country within 12 hours after their release by the Director of the CDC. Under the program, CDC will assemble the push packages with the Department of Veterans' Affairs assigned with management responsibilities. To address concerns regarding tracking and inventory controls, CDC and the VA are installing a computerized inventory management system that will track contents, shelf life, and movement of materials into and out of the packages.

2.Vendor-managed inventories (VMI)

VMI are designed to support the maintenance of excess capacity by the pharmaceutical industry. As opposed to the prepositioned supplies provided by the eight NPS push packages, the VMI are designed to provide follow-on supplies from the nation's pharmaceutical supply system as push package supplies are exhausted. Through contracts with HHS, certain drug manufactures will agree to maintain excess production and supplies and make them available to the government in an emergency. This reserve provides a source of additional antibiotics and materials necessary for long-term treatment and prophylaxis.

While the NPS ensures that certain drugs and vaccines are on hand in the case of a biological or chemical emergency, it does not ensure that these drugs will be available to local and state hospitals when they are needed. In fact, most officials estimate that drugs received from a regional stockpile will not be available at the local points of distribution for 36 to 48 hours after an incident has been detected. As a result, local health authorities recognize that they must prepare for an unexpected situation that requires large amounts of antibiotics or rare vaccines. Those physicians and emergency responders involved in bioterrorism preparation for the 1996 Atlanta Olympic Games stated that placement of necessary pretreatment drugs in local

medical facilities was an important lesson.[8] Despite the availability of CDC's regional antibiotic stockpile, hospitals and local public health departments need to identify and augment supplies.[9] During the May, 2000, TOPOFF exercises in Denver, participants underlined major problems with prophylaxis. During their notional deployment in the Topoff scenario, the push packages were delivered nearly 48 hours after they were requested. Moreover, no system was in place to deliver the antibiotics from the airport to the city, and no clear method of distribution to the populace was available. Similarly, because the distribution of antibiotics was delayed, few serious cases of disease were actually prevented. While all of these TOPOFF findings are notional given the artificial nature of some of the exercise play, these findings nevertheless highlight key issues that need attention.

Although the options discussed above could potentially be effective for distributing medical supplies during a bioterrorism crisis, the details of the necessary public-private partnerships have yet to be worked out. Even in the public sphere, drivers and the most optimal supply routes for distributing massive amounts of medication have not been fully identified. Nor have local DoD assets and National Guard assets (other than the Civil Support Teams which have little distribution ability) been integrated into planning for distribution purposes.

Although the CDC has put a lot of effort into ensuring that logistically the NPS push packages can be loaded on C-130s air transports and shipped anywhere in the contiguous United States within 12 hours (ideally the push packages could be delivered in under 8 hours – forty minutes for loading time, one hour and thirty minutes for flight preparations, and 4-6 hours maximum flight time), once the push packages are delivered to a local airport, control is taken by local authorities. Federal planning fails to plan for the integration of federal and local assets by operating under the assumption that once the push packages are delivered, local distribution mechanisms have the capacity to distribute them. In reality, the medical distribution plans of most locales are rather vague and do not detail how current medical supply mechanisms or supplemental mechanisms would actually operate in the event of a bioterrorist attack. Rather,

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[8] Sharp, Trueman,and Richard J. Brennan, Mark Keim, Joel Williams, Edward Eitzen, and Scott Lillibridge, "Medical Preparedness for a Terrorist Incident Involving Chemical or Biological Agents During the 1996 Atlanta Olympic Games," *Annals of Emergency Medicine*, Vol. 32, No. 2, August 1998, p. 218.

they simply identify potential partners in achieving this task. Likewise, while Emergency Medical Disaster Plans note that emergency medical service personnel and health care facilities should provide mutual assistance in situations in which local resources are overwhelmed, few formal partnerships have actually been put into place. Procedurally, these plans form the basis of cooperative agreements that could be applied during a bioterrorism event, but operationally they lack mechanisms for identifying where resources are housed or ways of transporting resources between facilities.

While cities are developing plans for prophylaxis distribution systems, overcoming the local manpower shortages produced by the response to a bioterrorism incident may require state and federal assistance. OEP has done a good job of organizing specialized national medical response teams that could be deployed to support the medical response to a bioterrorism incident. These teams, however, are oriented toward providing additional treatment capacity and are relatively small in size; thus, their role in supporting mass prophylaxis programs is likely to be minor. As was mentioned previously, the Department of Defense has also focused on developing and maintaining relatively small WMD response teams like the Marine Corps' Chemical and Biological Incident Response Force (CBIRF) and the National Guard's WMD Civil Support Teams. CBIRF consists of approximately 300 personnel skilled in the provision of security isolation, agent identification, and medical support. As with the MMSTs, CBIRF teams may represent a useful resource in the event of a significant number of casualties. However, most WMD Civil Support Teams are trained and equipped for agent recognition and environmental clean up, not for providing medical care. As such, their contribution to patient treatment is questionable. Given their small complement, these specialized teams are not likely to provide significant assistance in supporting prophylaxis. Neither OEP nor the various civil support planning elements at the Department of Defense have focused adequate attention on planning how their available manpower resources might be used to support large-scale prophylaxis programs. DOD, both within regular and National Guard units, has the potential for providing large numbers of personnel to support prophylaxis programs.

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[9] Richards, Christopher F., and Jonathan L. Burstein, Joseph F. Waeckerle, H. Range Hutson, "Emergency Physicians and Biological Terrorism," *Annals of Emergency Medicine*, August 1999, p. 189.

Key Issues and Recommendations

Triage

A pre-incident plan for the location of triage stations needs to be in place before an event. This plan should include multiple points to reduce congestion, by both vehicles and people, in a single area and keep management of the area to a realistic size. Arrangements should also be made for triaging patients outside of hospital facilities and identifying both medical and non-medical triage personnel.

Providing public information will be an important tool for encouraging "self-selection triage" as well as for directing the public to appropriate triage points. **A public information strategy should be devised in advance of an attack that will provide clear and accurate information about when treatment is required and where it should be received.** An effective public information campaign can inform people whether treatment is necessary or not given their particular situation and direct them to the appropriate treatment center. Such a campaign can greatly reduce the stress that hospitals and other treatment facilities and triage points will feel.

Arrangements for counseling patients should be made to reduce panic and confusion at triage points and to ensure order. A follow-on mechanism should also be put into place to monitor patients' mental and physical conditions and perform secondary triage accordingly. It is unlikely that patients at triage or other prophylaxis and treatment points will accept whatever treatment is offered to them without asking any questions. Rather, patients will be concerned given the novel and frightening nature of bioterrorism. Patient-counseling services can calm and reassure victims, help maintain order, and reduce confusion over how and why treatment regimens are being administered, especially self-treatment regimens.

Legal constraints forbid non-medical personnel to diagnose, treat, or refer medical patients. But in the event of a bioterrorist attack, allowing non-medical personnel to perform some of these functions on a limited basis may be essential if there are large numbers of people

presenting for treatment. At present, no agreement has been reached on which non-medical personnel could make what medical decisions should it become necessary. **Agreement must be reached in advance about who can make triage decisions in the event of a bioterrorist attack, and the medical and legal ramifications of these decisions need to be considered.** Giving the authorities the option to suspend legal action for non-medical referrals during times of crisis may give triage personnel more security in the decisions they make.

Pre-Event vs. Post-Event Prophylaxis

Given the manpower requirements of prophylaxis systems, emergency medical services, medical care, security, and public safety, some thought might be given to providing certain segments of the population with pre-event prophylaxis. This might be most appropriate with anthrax vaccine. Pre-event prophylaxis will ensure the availability of key segments of the population - fire and police services, emergency medical services, and medical care professionals - by protecting them from certain agents, thus eliminating any psychological impact that may prevent their involvement with response activities.

A number of issues need to be addressed before undertaking such pre-event prophylaxis programs. The first issue is the cost of such a program. The Department of Defense has provided over 1.7 million doses of anthrax vaccine to over 440,000 U.S. service members at a combined cost of over $150 million. According to some estimates there are approximately 2.8 million fire, police, and EMS personnel who could be involved in bioterrorism response.[10] This figure does not include public health personnel, pharmacists, laboratory technicians, and emergency room doctors and nurses. Providing anthrax vaccinations to fire, EMS, and emergency room doctors and nurses in just the 50 largest U.S. cities would be exorbitant.

The second, and related, issue is the safety of these vaccines. As the Department of Defense's experience with anthrax vaccine demonstrates, there is a need for reliable production entities with stringent quality control systems in place. In addition, there is the need for research

[10] Paul M. Maniscalco and James P. Denney, "Public Safety Agencies: Trying to Define Readiness While Surviving the Rhetoric," in Hype or Reality: The "New Terrorism" and Mass Casualty Attacks, ed. Brad Roberts, Chemical and Biological Arms Control Institute, p. 260

to ensure no adverse side affects are associated with the specific vaccine. Meeting these two requirements, while providing education about the vaccine to those receiving it, should reduce the number of people refusing to participate in the program due to safety concerns. This is a key consideration when participation in this inoculation program will necessarily be of a more voluntary nature than the military's anthrax vaccination program.

The final issue is the likely response from the general public when a pre-event prophylaxis program begins. Some members of the public are sure to feel anxiety regarding their continued vulnerability to an attack and could begin calling for a program to provide prophylaxis to the general public, substantially increasing the cost of such a program. Calls to increase the availability of vaccines might come from those individuals who have already been prophylaxed, but who fear their family members remain vulnerable. With justification, they may call for vaccines to be provided to their families or else they may remain with their family members after an attack.

Scalable Prophylaxis and Treatment Capability

A catastrophic attack producing thousands of casualties is not the highest likelihood contingency. This suggests **localities should develop prophylaxis and treatment plans that are phased or broken into escalatory segments**. For situations in which small amounts of agent is released, moving from the normal situation to executing a plan to provide millions of doses or prophylaxis or treat 5000 casualties is not appropriate. The possibility of high-end attacks must not be ignored, but they are not the only contingencies against which planning should occur. A "scalable" plan is required to rapidly begin providing treatment and prophylaxis and then scaling the system upward if required. This flexible approach provides the capability to treat and prophylax in an effective and efficient method.

Such a system may require a combination of distribution methods. For example, a limited canvassing system to deal with lower impact, higher likelihood events, a local PODs capability for dealing with large events, and finally a "full-up capability", including state and national resources in the event of a catastrophic event. It may also entail a scalable, phased

approach to providing medical treatment – with hospitals treating the first 100 to 200 casualties, locally established and maintained alternative care facilities treating up to 500 casualties, and then state and federal assets providing medical care to casualties above 500. Building flexibility and scalability into response plans makes the process more difficult with plans becoming more complicated, but it will serve to maximize resources.

Reliance on Federal Stockpiles

Another important issue is the almost total reliance on federal stockpiles to provide medical supplies. Such reliance could diminish the timeliness of the response given the rough estimations for the time between the release of national stockpiles and the arrival of those supplies at local points of distribution. Push packages are slated to arrive locally within 12 hours after they are released. Once they have arrived, additional time will be needed to break down the package, a task that, according to one jurisdiction's bioterrorism plans will require an additional 12 hours if 32 person crews are utilized in 2-3 hour rotations. Once broken down, more time is required to move supplies from their arrival point to points of distribution, determined by the distance between the arrival point and the distribution points, availability of transportation, and any obstacles like traffic.

Local assets will have to provide the necessary supplies until this external assistance arrives. But few hospitals or primary care clinics possess a sufficient amount of drugs and supportive medical equipment on-hand for treating or providing prophylaxis to an unusually high number of patients. In the event of a biological attack, health facilities could be overwhelmed, lacking bed space, medicine, protective gear, and even staff. According to an administrator at a major urban hospital, "as it is, emergency rooms are limited in what they can do for many casualties, especially if it is a mass casualty situation. If we had 100 casualties, it would severely stress the hospital system."

Addressing this problem is a difficult challenge. One option that has been suggested is that localities should be provided with the resources to develop an independent first-tier prophylaxis capacity with local medical care providers, either through mutual aid agreements or

regional buy-ins, to allow for a comprehensive response in the 48 hours before federal aid arrives. One way for smaller communities to combat the logistical difficulties of acquiring and stockpiling both vaccines and antibiotics is to create, in essence, a "supply bubble" within the current hospital pharmacy system. Implemented in New York City, this method involves purchasing more drugs than the usual one-week on-hand supply, but fewer drugs than would be used by the end of their shelf life.[11] Such an approach, however, is questioned, both for its feasibility and cost-effectivness, particularly for smaller metropolitan areas that are not likely to have the necessary financial resources. Another approach may be to build on the OEP stockpiles, assuming that the problems associated with that program identified by the GAO are aggressively resolved.

To ensure efficient use of local resources, a system should be established to track the movement and use of medical supplies during a bioterrorism response. A tracking system will give public health officials some awareness of how medical resources are being used so they can plan accordingly for procuring the necessary supplies as they are depleted. A tracking system will also ensure that patients are directed to facilities where supplies are still available. Without some type of tracking system in place, officials will quickly lose control over the flow of medical supplies.

Contents of the National Pharmaceutical Stockpile

Clearly, it will be necessary for the federal government to provide most of the antibiotics, vaccines, and associated supplies necessary for prophylaxis and treatment in response to a bioterrorism incident. This is the reason for the NPS Program. Keeping in mind the likely size of groups requiring treatment or prophylaxis, the variety of agents for which the stockpile should be prepared, and the corresponding variety of materials, what types of and how much medicine should the stockpiles contain? It is impossible to develop a stockpile large enough to prophylax the entire population of the United States against the entire range of threat agents. The size and the contents must balance the competing interests of cost, efficacy, and comparative likelihood

[11] Jerome Hauer, Testimony before the Senate Health, Education, Labor and Pensions Committee, March 25, 1999, p. 3.

of certain events, while recognizing the degree of risk associated with choosing not to produce a certain medicine or vaccine or produce it in limited quantities.

As mentioned previously, the combined push packages will contain sufficient quantities of antibiotics to provide post-exposure prophylaxis to approximately 7.3 million people for three days. The types of antibiotics being stockpiled are appropriate given the high degree of commonality between treatment modalities for agents. The amount being stockpiled, however, might not be sufficient. Prophylaxing the population of a city the size of New York would exhaust the antibiotics supplies of all eight push packages within three days. This does not account for antibiotics necessary for treatment and does not provide additional antibiotics for attacks in other parts of the country. Of course, New York is one of the largest U.S. cities, and most terrorists are not likely to disseminate sufficient quantities of anthrax, plague, or tularemia to infect the entire population of that size. But without good epidemiological data indicating the scope of an attack, there is a risk that a substantial portion of a city may be exposed; prudence will dictate applying prophylaxis to more people rather than fewer. The size of the antibiotics portion of the push packages appears to be appropriate given the low probability of a catastrophic attack, but only if adequate detection and assessment capabilities are in place. Early detection and accurate assessments will ensure the size of the prophylaxis effort is calibrated according to the size of the attack. While the current amount of antibiotics provides a hedge against a catastrophic event, the antibiotics portion of the packages might be reduced as confidence in the nation's detection and assessment capabilities increases.

The other issue is the lack of vaccines in the stockpile. Other than possibly reducing the course of antibiotic treatment necessary to prophylax successfully, anthrax vaccine does not provide effective post exposure prophylaxis. This fact, in combination with its lack of person-to-person transmissibility and its 20-30% mortality rate even after treatment, makes stockpiling anthrax vaccine unnecessary.

Because it is contagious, some quantities of smallpox vaccine will be necessary as a hedge against possible future outbreaks, relatively unlikely as they may be. The issue is how much. Re-immunizing the entire country against smallpox would prevent all future infections,

but the cost of such a program would be prohibitive, especially when the chance of a smallpox attack is minimal. Stopping short of providing smallpox vaccine to everyone in the country, the current strategy is to stockpile sufficient quantities of vaccine to immunize the entire population surrounding the affected area to prevent new infection and prevent its spread outside that immediate area. Roughly 9 million doses of vaccine are currently available, but only by diluting current stocks. In FY 2000, CDC is spending over $16 million on the special, bifurcated needles required for immunization, dilutant, and additional immune globulin. Because the effectiveness of the current vaccine is in doubt, CDC is spending an addition $22.5 million for research and production of a new vaccine.

There is considerable risk associated with this approach. The effectiveness of providing vaccine to only a limited segment of the population depends on detecting the smallpox outbreak before it spreads outside a confined geographic region, like a metropolitan area. Providing vaccine to the population of that area can prevent further transmission between members of that area's population. As the disease spreads within an increasingly larger area, the number of people needing vaccine increases. Given the mobility associated with urban lifestyles and current gaps in the nation's surveillance capabilities, a smallpox outbreak could spread outside a limited geographic area before it is detected. Such a situation makes a major smallpox outbreak a complicated event in which vaccine delivery will become only one aspect of the fight to stem it. Looking at such a scenario also highlights how difficult it is to determine just how much smallpox vaccine should be on hand across the United States.

As a hedge against a possible smallpox incident, the current supplies of vaccine should be readied for a rapid, mass prophylaxis program and a surge vaccine production capability should be established. One or more vaccine producers would be compensated for maintaining a reserve surge capacity for future response and for the cost of production and any associated disruption if a smallpox incident occurs. This surge capability should be able to manufacture additional vaccine if current reserves are insufficient for response to an incident. **At the same time, efforts should be made to develop measures of merit to help determine the levels at which the national smallpox stockpile should be maintained.** Those measures should make it clear to policy makers and others why a particular level of stocks is optimal.

Finding Manpower

Staffing is a challenge that for the most part must be met at the local level, yet to date few localities have incorporated staffing issues into their planning. As previously discussed, several options exist for acquiring additional staff, including establishing mutual aid agreements with local hospitals, developing strike teams made up of local or regional medical personnel, or calling in national response teams. The efficacy of each of these options has already been detailed, but it is clear that a great deal of coordination will be necessary to integrate any one option into the local response framework. As such, additional staffing must be considered when creating response plans if public health and medical personnel are to effectively treat patients and provide prophylaxis.

More planning is needed to determine how the state and federal government can provide additional manpower in support of prophylaxis and treatment as a hedge against large scale bioterrorism incidents. As was previously discussed, canvass-type distribution systems require massive numbers of people. Manning specially designed points of distribution also requires large numbers of individuals. This challenge is less daunting for those plans utilizing existing pharmaceutical distribution systems. Pharmacists and pharmacy technicians already in place at existing pharmacies, drug stores, and clinics would form the core of the prophylaxis workforce. But even they are going to require additional resources to handle the much higher than normal demand at their stores. They will also need security personnel to protect their persons and supplies.

Given the sheer numbers that may be involved, finding people is a challenge to meet with local resources. New York has developed two models for rapidly prophylaxing a large exposed population in the event of an attack. The first model, based on the canvass approach, calls for bringing medications directly to the home; with an exposed nighttime population of 7.5 million people, delivering a five-day supply of ciprofloxacin would require 41,652 personnel.[12] The second model, based on the points of distribution approach, would require 45,344 personnel to

[12] Hauer, p. 3.

dispense 75 million tablets in 48 hours.[13] This type of distribution system might be required in situations in which people should remain quarantined, the disease is contagious, or the rate of infection is so high that there is no alternative to self-treatment. However, while New York's stockpile program could serve as a model for local entities, it is extremely expensive and labor-intensive, and would require an enormous level of logistical support. Furthermore, as TOPOFF demonstrated, personnel charged with delivering medication cannot work as quickly as the prophylaxis models indicate, resulting in a longer, slower distribution process.[14]

Improvements in Prophylaxis Plans

Identifying where POD sites will be located, the best transportation routes for distributing medical supplies, and available personnel should be done before an incident to ensure that the distribution system is operational. **Improved evaluation methods must be developed to assess the adequacy of local prophylaxis plans developed through the bioterrorism track.** Most of the plans have not been operationally tested due to the cost and disruption that would be imposed by a large-scale exercise. Smaller exercises could be done, but their ability to evaluate the entire plan is limited. One tool that might help to evaluate these plans is a computer simulation to model how a locality's prophylaxis plan would be implemented and how well it would work. New York City's models could be adapted by other cities to more accurately determine their own personnel and material requirements before a formal plan is drafted. Such computer simulations might be provided by some of the bioterrorism response system architectures being developed at the national laboratories and the Defense Threat Reduction Agency.

A key challenge is the time needed to move personnel to the affected area. **Local plans for prophylaxis should recognize and account for additional state and federal assets that will be made available by planning for how these assets will be utilized.** Likewise, state and federal assistance plans should account for the local prophylaxis plan by accounting for the type of system in place, the work already accomplished by the time of their arrival, and how they can be integrated into the local system. OEP, although it does not possess an organic manpower

[13] Hauer, p. 3.
[14] Discussions with officials attending the Denver portion of the exercise.

resource pool, has the potential for organizing systems by which additional state and national medical manpower resources could be exploited to support prophylaxis response programs. This could include asking local and state officials to develop mutual aid agreements to provide additional personnel to support prophylaxis. It should also include systems for national mutual aid protocols. While the CDC has worked out the logistics behind delivering the NPS to localities, once there, the CDC turns over responsibility for distributing the NPS to local care facilities. Few arrangements have been made locally for doing this.

V. TRAINING AND EDUCATION

Early recognition of a biological attack depends on two critical resources: warning networks, such as those within hospitals and public health agencies, and individual clinical expertise of medical personnel. A central defense against bioterrorism will be the astute emergency clinician or laboratory technician who spots a suggestive epidemiological pattern early and sounds the alarm.

Medical personnel, lab technicians, public health officials, and hospital administrators can clearly play a key role in helping to ensure that hospitals and communities are prepared to respond to bioterrorism. However, in order to do so, they must receive adequate training and education on a variety of issues related to bioterrorism response, including agent and outbreak recognition, treatment of casualties, protection of personnel and hospital staff, resource acquisition, and response plan implementation.

What Are the Requirements?

Training requirements can be broken into two distinct but connected categories: content and organization. Content addresses what trainees need to know; organization provides the medium through which training can be carried out most effectively.

Content

Education and training for physicians and nurses on bioterrorism should encompass several important elements essential to a comprehensive medical response. These elements include recognition of an unusual outbreak or uncommon syndrome, treatment of casualties, protection of hospital staff, resource acquisition, and the implementation of an integrated, community-based plan.

1. Outbreak and Disease Recognition

Because diseases like anthrax, plague, and tularemia are given scant attention in medical school and daily practice, most doctors would have difficulty recognizing cases appearing in their hospitals and offices. Furthermore, many of these diseases have non-specific, flu-like

symptoms until their advanced stages. An effective training program should incorporate not only extensive clinical analysis of agent presentation, but should also highlight basic surveillance and epidemiological warning signs and signals. Moreover, training should encompass both traditional biological agents and non-traditional, more common agents. Dr. Paula Krapf, writing in *Illinois Medicine*, recommends specific education to teach the medical community how to distinguish between common disease outbreaks and those resulting from intentional poisoning. Some warning signs that should be stressed include a strongly suspected case of a disease in a patient with no risk history, a cluster of patients who present with a similar syndrome, an unusual disease or a disease uncommon to a particular geographic area, and an unexplained increase in a common syndrome, such as influenza.[15] Recognition of the signs of a bioterrorist attack by physicians will be critical to early treatment and saving lives.

2. Treatment of Casualties

Medical personnel must also be educated about treatment guidelines in the event of a biological attack. Many doctors, nurses and technicians who have previously received HAZMAT training assume that the triage and decontamination procedures that accompany chemical weapons exposure also apply to biological weapons; however, biological agents require specific forms of treatment and mitigation.

Training programs to date have emphasized decontamination procedures as part of a comprehensive response to bioterrorism. The emerging consensus, as explained by Nicki Pesik and Mark Keim in "Do U.S. Emergency Medicine Residency Programs Provide Adequate Training for Bioterrorism," and Christopher Richards in "Emergency Physicians and Biological Terrorism," is that decontamination of persons exposed to a biological agent is unnecessary; at most, clothing removal and a soap and water shower are adequate to prevent secondary exposure. Similarly, reaerosolization of an agent from clothing or skin is not a major issue and does not pose a risk to health care providers.

[15] Paula Krapf, "Bioterrorism Alert: How Physicians Can Detect the Signs," *Illinois Medicine*, July 30, 1999. See also Julie Pavlin, "Epidemiology of Bioterrorism," *Emerging Infectious Diseases*, Vol. 5, No. 4, July-August 1999, p. 3.

Another important component of treatment training should be basic prophylactic guidelines. Most physicians or nurses have neither sufficient clinical knowledge of many of the agents commonly associated with bioterrorism, such as smallpox or anthrax, nor familiarity with the antibiotics or special forms of treatment necessary in the event of a biological attack. For example, during an informal anthrax scenario conducted by John Bartlett, Chief of Infectious Diseases at the Johns Hopkins University School of Medicine, several physicians did not know the size of Baltimore's standing supply of ciprofloxicin, a common antibiotic used against anthrax. Many physicians and nurses also do not know the prophylactic schedule for antibiotics associated with biological agents. Medical training should couple clinical analysis of agent manifestations with their appropriate prophylactic and treatment strategies.

3. Protection of Hospital Staff and Patients

A bioterrorist event will unfold in an environment populated with primary care workers and immuno-suppressed patients. As doctors and nurses are key caregivers in the event of an attack, they must take care to ensure their own health. Consequently, while treating victims of an attack will be important, training should also be geared toward the protection of the hospital staff, patients, health facility and its environment, and the victims, in that order.

While full NBC protective suits are not necessary, it is important that hospital personnel implement standard infection control measures until definitive laboratory confirmation is received that the agent is non-contagious. These measures include the use of surgical masks, eye protection, gloves, and barrier gowns, as well as the thorough disinfection of medical instruments. Previous use of these protective measures during large disease outbreaks has proven effective at diminishing disease transmission; notably, emergency department staff in New Mexico pointed to protective gear as an important tool in the confinement of the Hantavirus outbreak of 1994.

If the agent is determined to be contagious, a more comprehensive set of infection control measures are necessary, including separate isolation wards, negative air-flow rooms, and respirators. In this case, training medical personnel to take proper precautions in evaluating and

treating victims will stem the transmission of a biological agent while protecting the "front line" defenders – hospital staff.

4.Resource Acquisition

A bioterrorist attack will strain the infrastructure of an already strapped hospital and public health system. Needed resources can range from personal protective supplies, such as latex gloves and air masks, to negative air-flow rooms, respirators, and separate ventilation and waste collection systems. Further response requirements may include additional staff, direct communication tools, or vaccines.

It is critical for public health officers involved in consequence management to understand where and how to acquire resources quickly. Most medical personnel, however, do not know whom to contact at their local public health department for support or to request additional equipment or antibiotics. For example, during a 1998 test of Maryland's response system, John Bartlett discovered that no one knew the phone number to set into motion the state's bioterrorism response network, and the number itself was not in the hospital directory or 911 listings.[16] Teaching medical personnel about reporting structure and resource acquisition is key to a comprehensive and rapid response.

5. Coordinated Action and Communication Between Response Entities

Perhaps the most important, and often overlooked, element of a strong training program is relaying the intricacies of a complicated response system to medical personnel and instilling the need for clear and consistent communication among public health and medical workers and other response entities. In the past, training has addressed nuclear, chemical, and biological weapons response simultaneously, and has specifically stressed responding to chemical terrorism with HAZMAT-like procedures. As a result, the public safety community took the early lead role in shaping the WMD terrorism response. Training programs have provided little room for awareness of the role of public health departments or medical personnel.

[16] John G. Bartlett, "Applying Lessons Learned From Anthrax Case History to Other Scenarios," *Emerging Infectious Diseases*, Vol. 5, No. 4, July-August 1999, p.2.

A greater understanding is emerging that bioterrorism is largely a public health and medical issue and that hospitals and public health agencies will bear the brunt of the response, although local and state emergency management agencies, EMS services, fire and law enforcement agencies, and federal organizations will all play a role. Many of these entities are nontraditional partners for the public health and medical sectors, and as such, do not have previously established communication networks. The complex hierarchy of agencies and departments involved with a potential bioterrorist incident has often resulted in a lack of knowledge of who is in charge, what roles various entities play, or how they relate to each other, further complicating the response system.

For the public health officer attempting to respond to a suspicious outbreak of disease, being able to communicate early with these entities is critical because their resources and legal authority will be vital in containing the effects of an attack. In fact, getting the public safety and public health communities to understand their respective roles is a key factor in an effective response. Organizations like the Federal Bureau of Investigation will be important in evidence collection and preservation, while local and state public health agencies, the Centers for Disease Control, and the U.S. Army Medical Research Institute of Infectious Diseases may provide epidemiologic and laboratory diagnostics expertise. Because hospital and community response plans should indicate when these agencies should be involved and which agencies will be in charge, training should include an analysis of the federal, state, and local response structure. Similarly, encouraging tabletop exercises that integrate members of the public safety and medical community will allow both entities to better understand their distinct roles and how they will support each other in the event of an attack.

6. Implementing a Bioterrorism Response Plan

As the first to recognize a potential attack, medical personnel must be familiar with the hospital plan and chain of command to be able to set into motion the local, state and federal response. Knowing when and how to begin an overall strategic response, which hospital departments to contact, and who is in charge is a critical aspect of medical preparedness. Training doctors, nurses and technicians to take an active role in creating and implementing their facility's response plan will allow for a stronger, more rapid, more integrated local response.

Organization

Training can be carried out through a number of different mediums, from classroom-style seminars to web-based teleconferences to tabletop scenarios. The choice of medium can have important effects on both the quality and quantity of information relayed, as well as on the ability of trainers to reach their target audience.

1. Classroom-style Seminars

To date, classroom-style seminars have been the standard form of bioterrorism training available to medical personnel. Whether sponsored by national organizations such as the Department of Defense or the American Medical Association (AMA), or by state and local health departments, conferences usually unfold as intensive sessions that run from one day to one week addressing critical topics related to bioterrorism preparedness.

Seminars offer the opportunity to hear directly from issue experts, ask questions related to information presented, and interact with colleagues interested or involved in bioterrorism response. They further allow for a compact, generalized overview of the most salient response elements. However, because of their length, seminars often cannot address in detail large response issues, such as how a bioterrorism plan should be implemented. Moreover, because conferences are often off-site, multiple-day sessions, many doctors and nurses, who balance hectic schedules and work in chronically understaffed environments, do not make time to attend. Consequently, additional training is needed.

2. Web-based Teleconferencing

Web-based teleconferencing combines the style and content of conferences and seminars with a more flexible, off-site approach. Teleconferencing allows doctors, nurses, and other medical personnel to attend pre-planned discussions or educational presentations by logging on to the Internet from their home or office computer. By eliminating the need for physical attendance, medical personnel can fit appropriate sessions into their schedule.

As previously discussed, one of the problems of classroom-style teaching is the inability of trainers to hold the attention of participants for a long period of time. Thus, in theory, the

shorter, more frequent sessions associated with teleconferencing should result in greater focus, and thus better information retention. Because of the flexibility of the format, training managers can use an increased number of short sessions to provide more in-depth education on a larger variety of subjects. However, the pick-and-choose format of teleconferencing means that many medical personnel may not receive training in areas essential to their ability to mount an effective response simply because they do not recognize that the topic is important. Similarly, because only a few of a series of sessions may be attended by a doctor, nurse, or infection control professional, those trained may fail to understand the larger response picture.

3. Continuing Medical Education Materials

Continuing medical education (CME) offers great flexibility and potential breadth of information. CME materials can be provided in a variety of forms, from self-tests attached to published articles in medical journals, to full courses offered by professional organizations, newsletters, and web-based information. To some extent, medical personnel are expected to initiate educational efforts on their own; however, attaching increased knowledge about bioterrorism to additional educational credit has proven to be an incentive for many medical personnel who may not otherwise participate in training sessions. By using CME credit, an almost endless number of topics or response issues can be discussed, allowing trainers to access a large audience.

Because some form of test accompanies most CME materials, CME works to reinforce educational principles while providing a level of accountability for information learned. However, CME contains many of the same problems associated with web-based distance learning; by allowing medical personnel to pick and choose their topics, many participants will not receive training on important response issues simply because the issues are considered uninteresting or inapplicable. Moreover, because CME training is an individual exercise, participants will not benefit from the discussions or opinions of other colleagues involved in bioterrorism response.

4. Tabletop Exercises

Tabletop exercises and scenarios aim to educate through hands-on experience. While a few important principles or response elements may be reviewed during the course of a tabletop exercise, training takes place largely by working through a scenario focused on a hypothetical attack. Participants learn through interaction and group discussion, and minimal written materials are provided. Tabletop exercises are most effective when participants have some prior knowledge of the subject being tested, and can put that knowledge to use in a problem-solving setting.

Tabletop exercises allow for new information to be rapidly incorporated into practical experience, as well as for reinforcement of important principles relayed in the course of training. In many ways, tabletop exercises promote an understanding of different entities' response roles, as well as an appreciation for the high-level coordination needed for a successful response. However, because of the fast-paced and immediate-problem-solving nature of tabletop exercises, longer-term problems or solutions are rarely addressed. Similarly, because exercises focus on scenarios rather than concrete information dissemination, important educational aspects may not be addressed. For example, in an exercise during which participants focus primarily on triage and prophylaxis, agent or outbreak recognition may not be effectively stressed.

Where Are We?

Training for Medical Personnel

Training to date has been conducted largely through the Domestic Preparedness Program (DPP) run by the Department of Defense that takes a "train-the-trainer" approach. According to this approach, a "training hierarchy" is established; those first trained are expected to train other emergency responders through follow-on courses. Training begins with national-level professionals and responders, and is then replicated at the state and local levels. While the training programs have reached countless emergency responders across the country, the number of medical personnel participating has been disappointing. Attendance by doctors, nurses and technicians has been consistently low, and the sessions themselves have concentrated heavily on agent recognition and treatment rather than on larger response issues.

The Nunn-Lugar-Domenici Domestic Preparedness Program was established in 1996. The Department of Defense was designated the lead agency but the program was also designed to stress DoD collaboration with the Federal Bureau of Investigation, the Federal Emergency Management Agency, the Department of Energy, the Environmental Protection Agency, and the Public Health Service. Designed as a "train-the-trainer" program to build on the existing knowledge and capabilities of local first responders, those trained are expected to train other emergency responders through follow-on courses. Training is to occur in over 120 cities, and, to date, the DPP has reached over 90 cities. Many of the cities that have received training have institutionalized various adaptations of that training program, primarily in their fire and law enforcement training academies.

The DPP's efforts to educate the medical community have been concentrated in its Hospital Provider course, a program emphasizing overall disaster planning skills and hospital-based decontamination. Specifically, the Hospital Provider course provides instruction to trainers of emergency department physicians and nurses. The course has focused primarily on those agents with the greatest morbidity and mortality rates, including anthrax, smallpox, and plague, and has also stressed the use of personal protective equipment and on-site triage. Most courses run as 8-hour, single-day workshops with NBC-unique demonstrations and individual case studies. As with other DPP efforts, the Hospital Provider course allows participants, upon completion, to instruct the technical aspects of bioterrorism and the defensive actions required for responders to protect themselves and their community to other first responders.

The General Accounting Office (GAO) has criticized the Domestic Preparedness Program for failing to take advantage of existing state emergency management structures, mutual aid agreements among local jurisdictions, or other collaborative arrangements for emergency response. By delivering the program to cities based on population size, GAO argues that a program conducted in one place often replicates training sessions in nearby cities that also qualified for the DPP and may be part of the same response system. According to the GAO, increasing mutual aid agreements, unified emergency service districts, councils of government, hazardous materials response regions, and traditional state roles in fire and emergency

management training would allow the DPP to consolidate training and result in less training repetition.

Moreover, because the program is limited to 120 cities, training will not be provided to smaller cities that may, for reasons other than population size, face a higher threat index. Follow-on training is insufficient to address trainer turnover, and the program is perceived to have a strong chemical bias. Despite its one-day Hospital Provider course, the program is also geared towards the public safety community, resulting in limited involvement from public health or medical organizations.

Several problems specific to the organization and content of the DPP Hospital Provider course have also limited its effectiveness. Howard Levitin of Disaster Planning International, an organization that runs the course for the Department of Defense, has underlined that specific requirements for response have not been well defined, and no training currently exists on how to implement a bioterrorism response plan. Furthermore, training has not touched on many issues that will be essential to a comprehensive medical response, including implementing a community-based surveillance system, expanding the current capacity of the health care system, creating more bed space, accessing additional supplies and equipment, and providing an adequate number of staff. The program has focused heavily on traditional agent recognition and treatment, and as such, often fails to give the medical provider a complete response picture. Most practicing physicians and nurses possess a low level of awareness about the program, as well as about other training opportunities at the local and state level, resulting in diminished interest and low attendance. According to the Emergency Management Coordinator of a large metropolitan area, "participation by hospital and medical personnel has been minimal at best."

Education of Medical Students

There is currently no standardized curriculum for training emergency medical students and physicians about the health hazards related to biological weapons. Furthermore, opportunities for teaching this material remain limited. Indeed, the current emergency medicine core content and most popular training textbooks do not contain specific reference to the

recognition, reporting, detection, or management of biological weapons disasters. In a survey distributed to 118 emergency medicine residency program directors participating in the 1997 National Resident Matching Program, the majority of respondents indicated that they felt inadequately prepared to manage casualties of a biological attack.[17] While more than 50 percent had participated in a residency program that included formal training in bioterrorism, the most common form of training was through lectures, with only 6 percent incorporating training courses into their operational program. In contrast, over 85 percent had received formal training in HAZMAT.[18]

Respondents to the survey also revealed a limited knowledge of how to access information regarding biological warfare agents; most listed toxicologists, poison control centers, and local health departments as reference sources, all of which would likely be unable to provide the appropriate information on biological weapons. Only 8 percent of respondents could claim access to more than three sources, and of all references available, the most prevalent were military manuals.[19] Similarly, only slightly more than half of the respondents were aware of the appropriate protective equipment in their emergency departments.[20] A lack of access to vital information represents a weak link in physician and health care training.

A multi-specialty Weapons of Mass Destruction Education Task Force organized by the American College of Emergency Physicians (ACEP) is currently developing curricula for emergency health care providers that should form the basis of ongoing educational efforts. To date, the Task Force has identified several key content learning objectives that will serve as the basis of an improved medical school and training curricula. The first category -- awareness objectives -- aims to increase general knowledge of terrorism, event types, index suspicion and event recognition, response systems and communications, and personal protection and safety. The second category -- performance objectives -- encompasses such themes as response support, decontamination, isolation and containment, evidence preservation, psychological effects, communication and agency interaction, triage, and fatality management. Once developed, these

[17] Nicki Pesik and Mark Keim, "Do U.S. Emergency Medicine Residency Programs Provide Adequate Training for Bioterrorism?", *Annals of Emergency* Medicine, Vol. 24, No. 2, August 1999, p. 174.
[18] Pesik and Keim, 175.
[19] Pesik and Keim, 175.

curricula should be incorporated into medical school coursework, residency training programs, disaster medicine and toxicology fellowships, and continuing education meetings and symposia.

Key Issues and Recommendations

Lack of Preparedness within the Medical Community

Most medical personnel are unprepared to respond to a bioterrorist threat. The experience of physicians who dealt with anthrax hoaxes over the last three years demonstrates that most medical personnel are unprepared to respond to a bioterrorist incident and generally rely on HAZMAT principles to guide their response. As Keim and Arnold Kaufmann chronicle, case management of anthrax hoaxes has varied from incident to incident. In some cases, patients were provided with no intervention and were sent home from a threat scene without accompanying documentation of care; in other incidents, people were removed from the workplace, disrobed, scrubbed down in portable decontamination units, and referred for clinical evaluation and prophylaxis.[21] In a bioterrorism scenario carried out by John Bartlett at Johns Hopkins University Hospital, the chief emergency room physician, despite having completed an 8-hour training course on bioterrorism, confessed that an early case of inhalation anthrax would have been diagnosed as the flu. As a result, the patient would have been sent home without additional laboratory tests or treatment.[22] Moreover, during planning for a possible CBRN terrorist incident during the 1996 Atlanta Olympics, it was discovered that only the FBI specialized assessment team had clinicians who were experienced in identifying the signs and symptoms of exposure to chemical and biological agents.[23] The inconsistent response of public health and EMS organizations indicates that the proper training of medical, public health, and emergency personnel is essential to a comprehensive response framework.

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[20] Pesik and Keim, 174.
[21] Keim and Kaufmann, p. 177.
[22] Bartlett, p. 1.
[23] Trueman Sharp et al, "Medical Preparedness for a Terrorist Incident Involving Chemical or Biological Agents During the 1996 Atlanta Olympic Games," *Annals of Emergency Medicine*, Vol. 32, No. 2, August 1998, p. 220.

Bias Toward Chemical/HAZMAT Training

As with most response plans, the programs currently in place to train medical personnel in weapons of mass destruction response have been built on the existing infrastructures of EMS and fire services' plans for hazardous materials response. While some of these procedures, including isolation and infection control, yield positive results when treating BW patients, the majority of HAZMAT responses are not optimized for biological agents and do not underline the distinct responses required for a biological event. Specifically, HAZMAT responses rely on a sentinel event, the expectation of rapid agent detection and identification, and on-site decontamination, all of which may not be needed or helpful in a biological attack.[24] As Christopher Richards points, the HAZMAT model does not address some essential components inherent to bioterrorism planning, including delayed emergence of disease and evolvement in a hospital setting.[25]

DoD's training program, which today represents the most widely available training forums for personnel involved with bioterrorism response, in particular retain a chemical focus. This is in part because the target audience of the DPP was initially the public safety community. Fire departments in particular were dubbed "first responders" because they go to the scene of an emergency and take control of the situation. The DP training initiatives built on the operational experience fire departments had in responding to HAZMAT incidents. As a result of their HAZMAT bias, training programs often leave the health care worker unprepared to respond to an event involving a biological agent release.

Even those training programs that have focused more specifically on the health response to bioterrorism, such as the DPP's Hospital Provider course, continue to emphasize procedures more in line with HAZMAT response. Moreover, these programs have not touched on a myriad of issues that are unique to responding to a biological event, including implementing a community-based surveillance system, expanding the capacity of the health care system, creating more bed space, and acquiring additional medical equipment. Consequently, even those

[24] Richards et al, p. 184.
[25] Richards et al, p. 186.

physicians who have received training in bioterrorism response under existing programs may not have addressed the correct issues or treatment plans. **The Domestic Preparedness Program should place a greater focus on health and medical response issues, and training should be adapted from HAZMAT criteria to focus more closely on procedures dealing specifically with biological weapons response, including agent and outbreak recognition and treatment measures. Training should focus on "big picture" response, incorporating integrated response issues, communication, surveillance, and reporting.**

Poor Attendance by Medical Personnel at Training Sessions

The DPP courses have not been organized in a way to attract medical personnel. During a recent "train-the-trainer" session in Baltimore, only 5 emergency physicians attended, with no other medical representatives present. According to Levitin, interest in bioterrorism among medical personnel falls into four main categories, each representing a different level of commitment to the issue. Those in the "immediate" category possess a profound interest in the topic, and will thus attend training sessions regardless of location, cost, or availability. The second, or "delayed", category encompasses medical personnel who are casually interested in the issue and may attend training sessions, but will not get involved in planning unless they are convinced it is necessary. Medical personnel in this category are more likely to attend training sessions if they are convenient and continuing education credit is offered. Those nurses, doctors and technicians in the "self-care" category are not interested at all in learning about bioterrorism and will not willingly attend any training sessions offered. Consequently, they must be convinced that bioterrorism is truly a health priority. Finally, the "dead" category includes personnel who believe that if a bioterrorist incident does occur, there is no way to adequately prepare for it. As a result, medical personnel in this category will not attend a training session no matter how hard they are lobbied.

The difficulty in getting doctors and nurses to attend educational sessions related to bioterrorism highlights that training must be both marketed and flexible. Many doctors and nurses balance hectic schedules and multiple training priorities. Similarly, most hospitals and public health centers are chronically understaffed and unwilling to pay for additional training

sessions. Consequently, attending a day-long session focused on a low-probability event is deemed neither feasible nor practical by most medical personnel. In order to attract doctors and nurses to bioterrorism training modules, sessions must be scheduled to better fit into a typical medical calendar. One option would be scheduling sessions in two four-hour periods on different days, which would allow doctors and nurses greater flexibility. Distance learning also provides a potential educational alternative. The satellite distance learning program established by USAMRIID and the Centers for Disease Control has had wider participation among physicians than the DPP, although there is a need to reach an even greater number of medical personnel. It is also important to make bioterrorism training a priority among medical personnel. Instead of focusing exclusively on clinical manifestations of certain agents, training programs should focus on medical surveillance, reporting requirements, identifying rare events, interaction with public health agencies, local hospitals, and infection control, and the applicability of training to daily practice. **Efforts must be made to attract medical personnel to training sessions. A greater focus should be placed on flexible sessions that can accommodate the schedules of health care practitioners.** A good first step is making DP training materials available through the Internet.

Lack of Involvement by Health Organizations

Health organizations have not been involved with creating or implementing training programs. Public health and medical organizations must play a greater role in shaping training guidelines and class content. The Nunn-Lugar-Domenici Domestic Preparedness Program courses, for example, were developed with insufficient input from national, state, or local medical organizations. As such, they have lacked guidelines for several critical components of medical response, including coordination and command issues, and have had trouble attracting medical and public health personnel.

Involvement by the Centers for Disease Control and the Department of Health and Human Services could improve the content of educational initiatives by incorporating a more concentrated medical approach into current training programs and placing a larger priority on bioterrorism preparedness among medical providers. Both the CDC and HHS have emphasized

a more holistic method of medical training, one that involves a variety of organizations and extensive partnership development. According to this method, training must be applicable to a number of different medical response entities, from doctors and nurses to infection control professionals, public health officials, epidemiologists, and laboratory technicians. Training programs would thus focus not only on agent and outbreak recognition but also on the roles played by the different medical response entities, how these entities coordinate their actions in the event of an attack, and how the medical community should interact with other response entities, including the public safety community. Similarly, both CDC and HHS, by increasing opportunities for continuing education credit and distance learning, could make training available to a larger percentage of the medical population. The involvement of national medical organizations such as the American Public Health Association (APHA), the National Association of City and County Health Officials (NACCHO), the American Red Cross, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and the Association of State and Territorial Health Officials (ASTHO) would give training activities an even greater reach; in fact, many of these organizations are currently campaigning to educate their membership on bioterrorism-related issues.

Local and state public health departments should also carry out training. Local health departments can do this internally, by educating health department personnel on bioterrorism recognition and informatics, as well as externally, by going directly to medical clinics and hospitals to promote awareness and access to available resources. In many ways, local and state training programs may have more success at reaching a greater number of medical personnel because they already have partnerships in place with local and regional hospitals and clinics, and will be able to use real examples based on local data. For example, the Chicago Department of Health has established a “training through partnerships” program that reaches local medical responders through a technical advisory group, a monthly newsletter covering timely local public health issues, conferences, grand rounds presentations at local hospitals, and on-site surveillance rounds. One of the most effective aspects of the program has been site-visits, which allow doctors and nurses to undergo training without spending time away from their hospitals or clinics. While Chicago’s program serves as a potential model, training can also be carried out by more personnel-strapped health departments through distance learning classes and tabletop

exercises, as well as by creating a clearinghouse of available information and resources that can be tapped by medical personnel involved with the issue. **Medical personnel should be involved with the planning of local, state, and federal government response efforts.**

VI. INFORMATION AND COMMUNICATION

What Are the Requirements?

An effective response system depends in large measure upon providing the right people with the right information at the right time. Preparedness and response capabilities, therefore, will rely heavily on effective information dissemination and communication. As a result, information strategies underpin efforts to bolster the public health and medical response to bioterrorism and help to integrate various components into a genuine system. Effective communication "mechanisms" are comprised of human organizations using technology to share information. Both the technological and human dimensions must be addressed if requirements of communication and information dissemination are to be met.

Requirements for information and communication can be broken into two distinct, but closely connected categories. The first set of requirements is shaped by communication needs of the various government and non-governmental entities involved in bioterrorism preparedness efforts. The second set of requirements is defined by the communication and information needs during the course of responding to a bioterrorism incident itself.

Preparedness

1. Planning

The response planning function should be supported by two communication capabilities. The first is a communication capability among all the participants involved in local efforts. Different locales have organized their planning processes differently. Each, however, involves many players, and a shared frustration appears to be insuring that all those involved receive necessary information in a timely and effective manner. Local planning officials must have a mechanism for sharing their concepts for detecting and responding to bioterrorism incidents, assessing local response capabilities, and developing response capabilities.

The second key communication capability is a means through which plans and concepts can be shared among state and local jurisdictions across the nation. Few formal mechanisms or processes currently exist for local and state jurisdictions to exchange information and ideas on local preparedness and planning. The jurisdictions completing their Metropolitan Medical Response System and bioterrorism response plans, for example, need better methods of communicating and sharing ideas and concepts with colleagues in other jurisdictions. Most sharing has occurred through informal networking and previously established contacts, but the efficiencies of this system can be improved by more systematic information sharing.

2. Training

Bioterrorism training efforts will be best served by an effective, efficient, and low cost system for providing training materials to different communities of users. The most effective and efficient method of accomplishing this task is to exploit telecommunications and the Internet to provide tailored training. Among the more frequently mentioned communication capabilities to support training are distance-learning capabilities, satellite broadcasting systems, and web-based learning courses. Distance learning requires the audience to have the technical capacities for participating. This means public health officers, doctors, and other care providers should have rapid and reliable Internet access in order to exploit web-based training opportunities. It also requires that satellite downlink and teleconferencing capabilities be available for satellite broadcast opportunities.

In order to exploit available training opportunities, either through distance learning technologies or by the traditional classroom techniques, information on how and when training is taking place must be made available early enough for the audience to schedule their participation. A central location or clearinghouse for providing bioterrorism training information would be an important step in identifying future training opportunities and distributing that information to relevant audiences.

Surveillance and Detection

As previously discussed, good information and effective communication are vital to successful surveillance. Various information suppliers and recipients must be connected to ensure effective monitoring of the health status of a population.

In order to develop a national system for health surveillance, information linkages should be installed between providers of basic information and entities with the mandate and expertise to analyze that data. At the local level, this requires information infrastructure improvements to link the local public health agency or other monitoring entity with the various data providers, especially health care providers. It also requires improvements to connect other data providers – pharmacies, EMS systems, schools and employers, and so on – to the local public health department.

As already discussed, an improved national surveillance information infrastructure to integrate local systems into state systems and, ultimately, a national system should be a long-term goal. Possible methods of establishing these links are numerous. The type of link utilized would depend on the number, size, and type of care providers within a jurisdiction and should exploit previously established communications systems. Whatever type is chosen, it should balance cost-effectiveness with the need for sufficient capacity to allow continuous exchanges of surveillance information, disease reporting, and periodic communications and consultations between the health department and care providers. While it is possible to transmit this data between providers and users using other, less sophisticated systems, the slow operation times of such systems make them virtually useless in detecting bioterrorism incidents fast enough for effective intervention.

Laboratory Systems

The information and communication needs to support an effective laboratory response to bioterrorism are significant. They include extensive databases of agent characteristics, testing protocols for a range of organisms, and information on anti-microbial sensitivities of agent strains to evaluate the efficacy of treatment options. A number of laboratories exist across the

country, each with a unique set of skills and capabilities - that together provide the expertise and knowledge necessary to provide sufficient support.

In order to effectively exploit available laboratory response capacity, however, a communications network is required to link public health and other clinical laboratories. Such a network would serve a number of important functions. First, it would provide a useful platform for training materials, laboratory protocols, and other forms of information from experts to clinicians. While a great deal of expertise and information resides with experts at federal institutions like the CDC and USAMRIID, an information network would allow for systematic information exchange between laboratories and laboratory clinicians, and also provide information back to the federal institutions. Second, this network would serve as a mechanism for disseminating standardized laboratory protocols and procedures. It could also provide a standard process for public health laboratories to order reagents.

Warning and Alert Systems

An important communication requirement in the bioterrorism response architecture is the ability to communicate warnings and alerts between the federal, state, and local levels and across functional areas. During a suspected or confirmed bioterrorism incident, a system is needed to provide broadcast alerts that raise awareness among those responsible for detecting additional cases and treating existing cases. Such a system should also provide information to the broader public on what types of precautions should be taken and points of contact to obtain further information or ask questions.

Possible mechanisms include broadcast fax capabilities, *listservs*, secure web pages, e-mail distribution lists, or pager gateways. To be successful, each of these systems requires contact information for all key agencies and their critical people. This contact information requires continuous updating for accuracy and relevance.

Cooperation with Law Enforcement

During suspected incidents of bioterrorism, both epidemiologists and law enforcement personnel will be conducting investigations. They will need some channel or mechanism for communicating – not just during an incident but on an ongoing basis. Such a channel can produce a better understanding of respective investigatory responsibilities and requirements between the law enforcement and epidemiological communities. From such an improved understanding can come agreed procedures for sharing information during bioterrorism investigations, a reduction in the chance of the two investigations working at cross-purposes, exchanges of best practices and new approaches to conducting investigations, as well as sharing information more generally.

Feedback Loops

Formal and informal communication channels should be available to local and state level public health and medical communities to provide federal entities with information, ideas, and critiques regarding ongoing preparedness efforts and programs. While federal entities like the DoD, DOJ, HHS, and CDC have considerable expertise and experience pertaining to CBRN weapons, counterterrorism, infectious disease control and prevention, public health practice, and other important issues, considerable expertise exists at lower levels as well. Moreover, it is at the local level that things must be made to work, and what looks good at the federal level may be seen quite differently by others. Because the HHS counterterrorism program has focused on bolstering the ability of the state and local public health and medical systems to respond to bioterrorism, feedback on how those programs are being implemented is extremely important for making the best decisions about future programmatic planning and execution. Local level input is an important evaluation tool for federal officials, both during preparation activities as well as during actual incidents.

In looking at candidate processes for this kind of needed feedback, a number of areas require particular focus. Public health officials at the local, state, and federal levels should interact and communicate as often as possible. In part, the national organizations of public health officials, like the National Association of City and County Health Officials (NACCHO) and the Association of State and Territorial Health Officials (ASTHO), fulfill this function by

representing their constituencies in interactions with colleagues at CDC, HHS, and even Congress. State and local public health officials should also have opportunities to provide information, ideas, and critiques in a more direct fashion through telephone calls, e-mail, presentations at conferences and workshops, and by publishing articles and books. Importantly, CDC and HHS need to recognize and engage in these processes and exploit them as they make policy and programmatic decisions.

Response

Communication and information needs during an incident are quite different than those associated with on-going preparedness efforts.

1. Mass Prophylaxis and Medical Treatment

The information and communication requirements to support the organization and implementation of a program to provide prophylaxis and therapeutics to a very large number of people are considerable and will demand effective coordination among many organizations and entities. The general public will need detailed information on the nature of the outbreak, procedures for acquiring medicines or vaccinations, time frames in which they must be obtained for maximum effectiveness, and procedures for acquiring treatment if they are sick. People directly participating in the distribution system will require information on their roles in receiving and distributing medicines and other material supplies – from the people responsible for receipt of the national pharmaceutical stockpile to those driving the delivery trucks and manning points of distribution. In addition, primary care providers need information on their responsibilities while they must provide incident coordinators with regular updates on their capabilities and requirements.

Coordinating this massive medical response requires effective communication, from the incident coordinator down to individual responders and back up. Pre-defined frequencies, equipment, and communication protocols shared among all local-level response entities – public health, fire, EMS, hospitals, etc – are clearly essential. In the end, each of these elements should be planned, tested, and constantly updated.

A number of communication requirements are defined by the need to coordinate the logistical dimension of the medical response effort. First, responding to a bioterrorism incident requires clearly defined roles and relationships and effective communication systems for the local and on-scene public health officials, medical care providers, and the incident "coordinator." Importantly, all require access to and training on the use of emergency radio systems used by the public safety and emergency management agencies. The coordinator in particular requires a two-way exchange of information to assess the degree of effectiveness of certain response initiatives and make changes in the response activities.

Second, while the initial response will be a local activity, federal and national assets will arrive – some quickly, some more slowly – to support the response. Integrated communication systems will be one means to integrate federal resources into local efforts. This requires some level of standardization of communication equipment to insure interoperability between local and federal authorities. This is an important issue because those entities with the mandate to manage the response must have two-way communication with both local and federal response assets.

Third, improved inventory tracking systems are required both during an event, but also before. These systems are especially important for improving the transparency of medicine, material, and equipment stockpiles at the federal, state, and local level. Greater transparency allows supply managers to determine how much medicine and equipment is available on a regular basis before an incident. This information creates an ability to assess what is available at the local, state, and federal level, and to determine what the local responders require from national stockpiles.

In addition to tracking medicines and supplies, improved tracking systems would also be useful in managing the distribution of prophylaxis and medicines by recording who has received medicines, which medicines they have received, and when they received them. This type of system could be constructed using paper and pen. The size and arrival time of shipments to distribution points or care providers would be recorded on paper and then called or faxed into the

central distribution point. Points of distribution could also use paper-based systems to record the name, address, social security number, and time of prophylaxis of people receiving medicines. But these systems would be slow and prone to inaccurate records. Electronic systems similar to the scanning systems used by parcel companies like UPS and FedEx could be applied to track movement of supplies and their distribution.

Fourth, it is extremely important for epidemiologists and laboratory personnel, typically assumed to be part of the detection and assessment but not response function, to remain in communication with response coordinators to provide information on how the event is progressing and how the response may have to be modified. Detecting changes in the numbers affected, their location, perhaps even in the symptoms presented by patients is a necessary aspect of assessing how well the response is meeting the event. As the event changes, the response may have to change as well. Another issue is the possibility of additional attacks. This requires the involvement and consultation of both epidemiologists and laboratories throughout the event.

Finally, these systems of communication, both people and technologies, must be used on a regular basis, either through simulations and testing or by incorporating key systems into normal operations. Regular use ensures that systems are both available and effective and also helps to ensure that the necessary people are part of the communication system, have access to the various communication technologies, and know how to use them. Without regular use, the social communication constructs will wither and become ineffective, and the technical systems may fail.

Where Are We?

Through various bioterrorism related initiatives, a number of successes have been achieved in meeting the requirements discussed above. In spite of these successes, however, more work is still required in a number of areas.

Through the Health Alert Network (HAN) Program, the CDC is providing grants to state and local public health departments to bolster their information technology infrastructure. This

program has provided the resources necessary for localities to improve computer capabilities, establish telecommunication networks between public health departments, bolster distance learning and teleconferencing capabilities, and improve alert and warning capabilities through improved e-mail, broadcast fax, and pager systems. In addition to the grants to develop the physical infrastructure, HAN is also developing bioterrorism-related training materials and other information packages to be made available to state and local public departments.

HAN has provided an excellent first step in developing a national public health information network. But this effort needs to be followed with important next steps. First, funding should be extended to all 50 states and territories. To date, HAN funding has been provided to 37 states and the three largest U.S. cities. Second, HAN needs to be integrated with other public health bioterrorism networks, most notably the Laboratory Response Network (LRN). To date, little funding has been provided to the public health laboratories to improve their information infrastructure. Improved communication capabilities between laboratories and public health departments will bolster coordination of surveillance, epidemiology, laboratory assessment, and response. This requires linkages and integration between information provided through the HAN and the LRN. Third, HAN focuses on interconnecting national, state, and local public health departments through information technologies. Both the network and funding for the network stops at the local public health department. No funding is provided to link local public health departments with other local entities.

A second issue that must be addressed is the uncertain capacity of emergency response communication capabilities in many cities. Importantly, the extent to which state and local public health departments have been integrated into state and local emergency communications systems is uncertain. As mentioned previously, public health authorities must help shape disaster management plans and preparations, including effective, robust emergency communication capabilities. It is one thing to agree on a communication plan for bioterrorism response. It is another thing to make sure sufficient radios and telephones are available before an event, test the adequacy of communication procedures and hardware, and test the system to see if it can withstand increased loads and deliberate disruption attempts.

There are several opportunities for improvement. Fire departments and public safety agencies often lead the bioterrorism response planning process at the local level. While many local public safety personnel recognize the centrality of public health and medical capabilities in detecting, assessing, and responding to bioterrorism incidents, this understanding is not universal. Localities should ensure local public health officials are fully integrated into emergency communication systems by ensuring their involvement in local planning efforts and by working with them to ensure they have communication hardware compatible with public safety systems.

The necessary "feedback loops" do not appear to exist, at least in any systematic sense. One salient example is a consistent complaint by local officials that the federal government entities responsible for response planning do not provide them with citywide emergency response plan templates, press release templates, and hospital emergency plans, etc., that have been written in other locales. On a number of occasions local officials have said, "It's not a good use of our time and funds to reinvent the wheel when many cities before us have already written templates." While it is understandable that some locales are concerned about providing these templates to other cities for fear they may get criticized for shortcomings in their preparedness plans, it is clear that some mechanism should be put in place to facilitate communication flows from locales back to federal entities as well as between states and locales directly.

With respect to information systems to support detection and assessment, a major gap in local communication capabilities remains the link between the local public health agency and area medical care providers. Such connections are vital not only for establishing real-time surveillance and disease reporting networks, but also for developing distance learning capabilities and communications between the public health agency and care providers during an event. Even in major municipalities the physical communication infrastructure between area medical care providers and the local public health department is inadequate. Too often, the telephone remains the only method of communication between public health officials and care providers. According to many local officials and representatives interviewed during the project, many doctors and nurses still do not know how to contact their local public health agency.

Lastly, federal activities related to building communication infrastructure preparedness and response have been marked by a lack of coordination and frequent disconnects. This lack of connectivity is not specific to the communication issue, but is indicative of the broader lack of coordination among various counterterrorism programs, most notably between public safety programs administered by DoD and DoJ and the public health and medically oriented programs administered by HHS and CDC. If Justice is going to manage state and local public safety preparedness programs and Health and Human Services in partnership with CDC is going to manage state and local public health and medical preparedness, then these entities must coordinate their efforts better to build communication and information infrastructure. Integrating federal programs to build the necessary infrastructure will determine how well local entities will be able to integrate their communication systems. Without this federal coordination, it is possible for DoJ to provide local fire and EMS systems with communication systems incompatible with systems provided to local health departments through CDC grants. To date, insufficient coordination has taken place at the federal level.

Key Issues and Recommendations

CDC and other federal agencies should further emphasize the need for improved infrastructure and actively work to provide state and local partners with both the necessary financial resources and the consultative expertise to build a truly national public health information network that includes traditional local public health agencies, as well as other key bioterrorism preparedness and response partners like federal and local law enforcement entities. The Bioterrorism Preparedness and Response Program Office, with the advice of the Public Health Practice Program Office, needs to have increased responsibility for making program allocation decisions for building public health information infrastructure at the state and local level. States should also be provided with consultative information and advice on the types of hardware and telecommunication systems they should acquire with grant funds and the types of software and protocols they should utilize.

Developing a new national information infrastructure for bioterrorism preparedness and response would be neither cost-effective nor efficient, given the number of communication and

networking initiatives already underway. **The keys to developing a national BT preparedness and response information infrastructure are making sure the individual components and initiatives already in train are able to meet key requirements, defining and implementing new initiatives where gaps exist, and then working to integrate the various technical communication systems into an effective network.**

Based on the requirements listed above, this network can be divided into three layers. The first layer should provide a platform for the bioterrorism preparedness effort. Federal, state, and local agencies require communication technologies to move expertise from those who have it to those who need it and exchange ideas on where programs might need adjustments or changes. A single infrastructure should improve local level efforts at developing detection and response capabilities by facilitating communication between local level entities, easing regular consultation between local and national organizations, and providing a mechanism for coordinating and sharing ideas between different cities and states. It should also provide the infrastructure for efficiently and effectively delivering training materials tailored to specific audiences using distance-learning technologies. This layer should exploit the internet as much as possible to support planning, training, and information exchanges. Current internet technologies can support these activities in a way that adequately balances cost efficiency and security.

The second layer of the system would focus on supporting detection and assessment capabilities in the areas of surveillance, epidemiology, and laboratory response. Such an infrastructure could provide the capability for real-time data exchange between surveillance data sources and local health monitoring entities as well as between those local health monitoring entities and state and federal public health agencies. The infrastructure should also provide national, state, and local microbial laboratories with real-time communication and data exchange capabilities. This includes information exchanges, consultations, and training before an attack as well as communication between laboratories in response to an attack. This infrastructure must serve to facilitate and coordinate information exchanges and warning between surveillance entities, epidemiologists, and laboratories. Because of the lack of highly robust security and power outages, this layer requires development of a dedicated, secure infrastructure. One locality is planning on establishing an area network between hospitals and the local public health

department using a dedicated secure, microwave transmission system. Another locality is considering the use of virtual private networks, a relatively new technology combining the wiring of the Internet with vastly improved software to create highly secure wide area networks.

The final layer of the infrastructure must provide reliable and robust emergency communications in order to coordinate and implement responses to incidents of bioterrorism. This means providing various local response entities with a single integrated emergency communication system that will reliably continue to operate despite the surge created during an actual incident and deliberate attempts to disable all or part of the communication infrastructure.

Due to the size of certain types of responses, the demand placed on radio bandwidth and the telephone system, and the possibility that a bioterrorism incident may be coordinated with cyber attacks on the communication infrastructure, it is vitally important that both the national and local emergency communication infrastructure is secure and highly redundant. Thus, this layer also requires a secure, dedicated communication system. Normal wireless communication such as radio pagers, radios, and cell phones could be overwhelmed and prove inadequate for use in a large-scale disaster. This could be overcome by having independent local reserve communication capacity in place before an event occurs. An emergency cellular system or reserve radio system could provide such redundancy. Satellite communication systems could also provide a useful reserve function because they are independent from the local communication infrastructure. Satellite systems also provide a means of long distance medical communication and consultation. Emergency response procedures could be developed with communication providers like AT&T to rapidly provide dedicated communication capabilities when normal systems are not available.

Consultations between infrastructure providers and the public health community should also focus on the development of standards for infrastructure, to include hardware and software standards and standards for information protocols. **In order to ensure interoperability of their communication systems, health departments, hospitals and other primary care givers, and public safety agencies need to be contacted and consulted throughout the process of developing such standards.** Consultations between government and the private sector might

also prove useful in developing these standards. Achieving common standards can serve to remove barriers to information movement between communities and enable public health to mine and exploit information gathered by hospitals, clinics, and other care providers. Logical Observations Identifiers Names and Codes (LOINC) and Systemized Nomenclature of Medicine (SNOMED) are two types of code standards. LOINC is an extensive database of synonyms and cross-mappings covering a wide range of laboratory and clinical subject areas (i.e. blood bank, microbiology, vital signs, etc). Private industry could help government understand the current state of information technology and the design systems necessary to meet requirements and work with government to put these systems into place.

Finally, federal departments and agencies must coordinate their various information infrastructure-building initiatives. Such coordination should involve the Office of Justice Programs at the Department of Justice, the National Domestic Preparedness Office at the FBI, the Bioterrorism Preparedness and Response Office and the Public Health Practice Program Office at CDC, the Office of Emergency Preparedness at the Department of Health and Human Services, the National Laboratories, and the Advanced Systems and Concepts Office at the Defense Threat Reduction Agency.

Building and sustaining capacity for communication and information sharing requires an active partnership between the federal government and its partners at the state and local level. The federal agencies, specifically Health and Human Services and the Centers for Disease Control, can provide leadership in a number of key areas.

The first important area is to ensure sustained funding and assistance to their state and local partners for the explicit purpose of bolstering information infrastructures. **During the initial years of CDC's bioterrorism preparedness effort, special emphasis should be given to the HAN program to include increased funding allocations for building upon information infrastructure.** During discussions with Congress, federal level public health agencies like HHS and the CDC should stress the key role played by communication and information in enabling and integrating an effective public health and medical response to

bioterrorism, as well as and the current lack of information infrastructure within the nation's public health system.

CDC, in partnership with HHS, DoJ, and DoD should develop a strategy for identifying the various organizations involved with bioterrorism preparedness and response, determining their communication and information requirements, developing social constructs to facilitate communication between them, and then using various instruments of leverage to implement these structures. With such a strategy, a national communication infrastructure can be developed that supports both preparedness and response to bioterrorism. This national infrastructure should serve as the communication hardware backbone for communication and information dissemination in support of a number of areas. This strategy should be based on the current infrastructure needs of the public health and medical system. The federal government should work with state and local entities to assess their information infrastructure requirements.

CDC's urban strategy for bioterrorism preparedness must include coordination and building of communication and information processes and capabilities at the local level. Local municipalities working on bioterrorism response plans should be asked to answer the following questions in the affirmative:

- Is the local public health agency a primary author of the bioterrorism response plan?
- Are local public health officials trained in the incident command system?
- Can local public health officials and representatives of local medical care givers communicate in real time with local public safety agencies, including fire, police, and emergency management? Has that capability been exercised?
- Can the local public health department and area primary care provider communicate in a bi-directional fashion during a bioterrorism event?

CDC's Bioterrorism Preparedness and Response Office should also take the lead role in ensuring that local public health agencies and medical care providers are able to communicate and exchange information in the period preceding an event. Through the CDC's bioterrorism grant process, local level health departments need to be provided with the resources to establish real-time electronic linkages with area hospitals and other care providers. Such linkages would be established for a number of purposes including surveillance, epidemiology, training, response coordination, asset and materials tracking, and consultation. BPRP should also leverage the

grants to ensure local level response entities are not only developing response plans, but also have adequate communication capabilities.

Finally, the Bioterrorism Preparedness and Response Program Office should continue to strengthen the office's information sharing and outreach activities. BPRP has undertaken several improvements to enhance the office's information sharing and outreach capabilities. These include hiring a full-time Congressional and Executive liaison, hiring a full-time constituencies liaison, and improving the amount and quality of information provided through the CDC's Bioterrorism website. While these actions represent significant improvements, the creation of a small office focused on information dissemination and outreach (including liaison personnel and the Bioterrorism webmaster) would relieve the burden placed on the staff by focusing on developing and maintaining mechanisms for answering commonly asked questions and facilitating information exchanges between BPRP and the various partners.

The purpose of this office would be two fold. First, it would provide a day-to-day point of contact within BPRP for government officials and representatives from non-governmental partners involved in bioterrorism preparedness. Second, this office would exploit telecommunications technologies - specifically the world wide web, *listservs*, newsgroups, and internet chat groups. In serving these functions, this office would facilitate BPRP's role as a information clearinghouse for bioterrorism preparedness within the nation's public health system. This would include improving and maintaining the CDC bioterrorism website to provide information on bioterrorism preparedness events – including training opportunities, workshops, and conferences – exchange ideas on developing local response systems, and even provide regular updates on the nation's health status based on incoming data from various surveillance systems.

Section II – Organization and Coordination Issues

I. Federal, State, and Local Preparedness and Response Issues
II. Public-Private Partnerships
III. Centers for Disease Control and Prevention

I. FEDERAL, STATE, AND LOCAL PREPAREDNESS & RESPONSE ISSUES

Many federal departments and agencies have been mandated to work with local entities to bolster the nation's preparedness to respond to a WMD terrorist attack.[1] As federal, state, and local interaction has evolved over time, it has become apparent that the initial approach to building WMD preparedness needed mid-course adjustment. Central to these adjustments has been the increased integration of the public health and medical communities into preparedness activities, largely because of the growing realization that a response to bioterrorism will largely depend on their expertise with disease outbreaks. While progress has been made, some problems in the process of building public health and medical capacity to respond to bioterrorism, as well as integrating these communities into the response system, have occurred. This is partly due to differing federal, state, and local perspectives on the issue, but is also a function of how programs were initially designed. Momentum was created at the start of this process, but it is possible to slow this momentum down and redirect it.

The Top Down Approach of Federal Planning

The way the counterterrorism agenda has evolved has resulted in perceptions of a "top down" approach that in some cases causes friction among federal, state, and local entities. With respect to the health and medical dimensions of bioterrorism preparedness, the perception exists at the state and local level that federal authorities often dictate rather than facilitate bioterrorism preparedness planning. Such a view may be a function of how the CDC grants process is structured for building public health capacity. When a state health department applies for a federal bioterrorism grant throught the CDC, for example, it can apply in any or all of five focus[2] areas established by the Bioterrorism Preparedness and Response Program, the CDC office that administers the grants. In most cases, however, states have not received funding for projects in all five focus areas. State health departments have complained, therefore, that federal authorities do not always have a good understanding of the best way to allocate this money within a

[1] Several federal initiatives in recent years -- the Nunn-Lugar-Domenici Domestic Preparedness Program (DPP), Presidential Decision Directive (PDD) 39 and PDD 62 – catalyzed federal activities to build preparedness to respond to WMD terrorist attacks.

particular locale. For example, often a locality will receive money for one or more focus areas, such as laboratories or improved detection and surveillance, but will not receive any money for planning. This means that they have to find their own planning money because some planning is essential to utilize the federal grant. One local health official complained that, "Effectively utilizing federal grant money for improving surveillance and IT infrastructure is impossible without planning staff who can implement these initiatives. How are we supposed to implement a surveillance system if someone from the Department of Health doesn't go out into the community and establish reporting agreements with hospital staff, doctors, pharmacies, and other providers of surveillance data?"

Although funds can sometimes be shifted from one focus area to another after the money has been awarded, this process is difficult and time consuming at both the federal and the local levels. In many cases funding specified for a single focus area would be better utilized if some flexibility existed to spread the money across multiple focus areas, should the need or opportunity arise. Some locales have suggested that increased flexibility be provided to local officials. Rather than have federal authorities decide how local entities should use grant money, local officials argue that these grants should be given in block sums and used in ways that best suit their particular situation.

Issues of Coordination

A biological agent release presents potential coordination challenges that will be difficult to address according to current planning guidelines. A major problem with response planning as it is being implemented is the bifurcation of overall command into two phases. According to current counterterrorism policy, the FBI has the "lead agency" responsibility for crisis management, while FEMA will be responsible for the consequence management phase of the response. Clearly, this bifurcation complicates unity of command, as half of the response will be dominated by the federal government, while the other half, although overseen by FEMA, will rest mainly in the hands of state and local authorities. Moreover, there is no definitive point at

[2] The five focus areas for building public health and medical capacity for responding to bioterrorism are preparedness planning, detection and surveillance, laboratory capacity, information and communications capacity (Health Alert Network), and training.

which the response to a terrorist incident moves from the crisis to consequence management stage; in some cases, these phases may occur simultaneously, or consequence management may precede crisis management. As a result, confusion exists over which agencies will take the lead if federal assistance is requested. This determination will likely have to be made on a case-by-case basis, taking into consideration the nature of the incident, the source, the actual or potential consequences, and the capabilities available. The main concern will be to coordinate crisis management and consequence management activities in such a manner that command issues do not compromise patient care.

Local responders also harbor fears of having their authority assumed by federal officials. Many local responders have expressed concern that federal agents will try to assume command following an attack without any knowledge of or attention to local dynamics. They point out that local response agencies have a better grasp of the synergies of their city or region, know where excess supplies exist, how to get around, and whom to contact if something is needed. As the Emergency Management Coordinator of a major metropolitan area commented, "this is a local problem that will be dealt with by locals under local organization." Consequently, most responders see the proper role of federal agencies as one of assistance to and augmentation of local resources. The Federal Response Plan insists that final authority to make decisions regarding consequence management rests with the local Incident Commander. However, this view of command and control has not been clearly conveyed to local authorities, and does not address the problems inherent in the coordination of responsibilities among local responders and a federally mandated "lead" agency. Fear of a federal "takeover" may lead those in charge at the state and local levels to delay seeking federal help.

Federal agencies are currently working to clarify command and control issues through interactive exercises that test and validate policies and procedures, probe the effectiveness of response capabilities, and increase the skill level of the personnel involved.[3] Most important, exercises allow various agencies' personnel to become familiar with each other and learn to coordinate their operating procedures. Through these exercises, response organizations have

attempted to establish the mechanisms needed for coordination before federal assets arrive, as well as to educate local responders about how to use federal assets properly to augment the existing response structure. However, a GAO report underlined that domestic crisis response exercises led by federal law enforcement agencies did not include many of the state and local authorities that would be needed to respond.[4] From the perspective of this study, there has been minimal inclusion of public health or medical personnel in many command exercises. The continued focus by federal agencies on the public safety community has only enhanced the confusion that many health personnel feel about coordination between local and federal responders.

The FBI has begun taking steps to include local and state agencies in federal drills, although staffing and budget considerations sometimes hinder their participation.[5] Most programs have not practiced crisis and consequence management simultaneously. For a true improvement in overall response coordination, training programs and interactive exercises must be reorganized to include a broader range of responders, including public health and medical officials, and scenarios that to do not depend on a separation of crisis and consequence management.

Office of Emergency Preparedness

Through the U.S. Public Health Service (PHS), the Department of Health and Human Services has developed four specialized National Medical Response Teams for Weapons of Mass Destruction (NMRTWMD), three of which are deployable in the event of a biological terrorist attack. The deployable teams are based in North Carolina, Colorado, and California, and are designed to provide medical services and assist federal or local agencies in the event of an incident involving biological or chemical agent release. Each team consists of 50 members, the majority of whom are physicians, nurses, paramedics, or other allied health care professionals. The NMRTs supplement the 24 deployable Disaster Medical Assistance Teams (DMAT)

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[3] GAO Report NSIAD-00-145, "Combating Terrorism: Issues in Managing Counterterrorist Programs," Testimony of Norman J. Rabkin before the Subcommittee on Oversight, Investigations, and Emergency Management, Committee on Transportation and Infrastructure, House of Representatives, April 6, 2000, p. 11.
[4] GAO Report NSIAD-00-145, p. 11.
[5] GAO Report NSIAD-00-145, p. 11.

composed of professional and paraprofessional medical personnel that can provide medical support in any type of disaster. DMATs can deploy with at least 35 team members to disaster sites for a period of 72 hours to triage and provide medical care to patients. Any of these teams may help augment local public health and medical resources in the event of a bioterrorist incident, although they cannot provide the manpower that will be required in larger attacks.

The Office of Emergency Preparedness (OEP), located in the PHS, coordinates the federal medical management response and recovery activities for HHS in the event of catastrophe, natural or man-made. Initially, OEP developed the Metropolitan Medical Strike Teams (MMST) because of the rapid response times required for responding to terrorist acts. MMSTs were designed to be highly trained, readily deployable, and fully equipped local response teams organized to address the effects of biological and chemical weapons on humans and to aid hospitals and other health centers with medical response issues. Each MMST would operate within a system that provides an initial, on-site response, safe patient transport to hospital emergency rooms, definitive medical and mental health care, and movement of patients to other regions, should local health care resources be insufficient to meet demand.

Today OEP's strategic plan takes a system-wide approach by developing partnerships with local jurisdictions to develop enhanced Metropolitan Medical Response Systems (MMRS) as the primary local resource for dealing with the medical consequences of a CBRN terrorist incident. The MMRS plan serves to coordinate the response of public safety, public health, and the health services sector to a CBRN terrorist incident by enhancing local capabilities, particularly in the public safety community, and by developing medical management plans that utilize the unique characteristics of each city's existing system. The goal is to develop MMRS for the 120 most populous metropolitan areas in the United States within five years.

OEP has made significant strides toward these goals since expanding the Metropolitan Medical Strike Teams (MMST) to a systems level approach in late 1995 and pilot testing the MMRS programs in Washington, D.C. and Atlanta the following year. In fiscal year 1997 the MMRS program expanded to include an additional 25 cities which began systems level planning and coordination activities, and to date MMRS programs have been initiated in over 90 cities. In

addition, cities that develop certified MMRS plans are then awarded a contract to develop a bioterrorism Response Plan (see section, p. 6). A number of cities have completed their MMRS plans and begun their Bioterrorism Response Plan contracts.

One of the most important achievements of the MMRS program has been its ability to bring together response entities that in many cases had formerly been unfamiliar with one another. For example, in most cities the public health community was not accustomed to working closely with the public safety, law enforcement, or national security communities. As a local public health official put it, "Had they told me a year ago when I was interviewed for a staff epidemiologist position at the local department of health, that I'd soon be sitting in a room with a chief from the local fire department, an FBI agent, and a member of the Army National Guard talking about bioterrorism, I probably would have thought I had gone to the wrong interview."

Although today many of these gaps have been bridged as a result of the MMRS program, significant challenges still remain. The structure of the MMRS program has some inherent shortfalls that have raised concerns among local responders. First, the MMRS targets the same 120 cities as DoD's Domestic Preparedness Program, an approach that builds response capacities in these cities but leaves many of the next largest urban centers unprepared (although DoD's Center for Domestic Preparedness has trained some smaller city and rural responders in residence). Furthermore, the MMRS program is specifically focused on activities in areas deemed "metropolitan proper." For example, metropolitan Chicago, as it is officially defined, is a relatively small geographic area compared to the sprawling suburbia that is usually associated with "Chicago." The MMRS system for Chicago only integrates this small area into the system, and excludes response entities located in the surrounding suburbs. This approach is problematic, especially in a bioterrorism attack when people do not present for treatment for several days or even weeks after a release. Because of the delayed onset of symptoms, many of these victims will have returned to suburbs and municipalities outside of the immediate metropolitan area, which will require some coordinated response across city boundaries.

Second, funding for the development of a Bioterrorism Response Plan normally takes the form of an appendix to the general MMRS plan and is contingent on completion of MMRS

planning. By not including the Bioterrorism Response Plan as part of the MMRS planning process from the beginning, some of the health and medical requirements for bioterrorism response preparedness are not taken into consideration. As a result, locales run the risk of developing response plans and procedures that do not adequately meet the requirements of responding to a bioterrorism event. This approach has an inherent bias toward emergency response with a public safety framework and assumes that even in a bioterrorism event there is a "crisis scene" to which responders go. It has become increasingly apparent that there is no crisis scene in a covert bioterrorism event, and that the "incident" will emerge at hospital and care facilities in the area and depend on public health and medical entities as "first responders."

Third, the MMRS program is largely focused on organizing medical management response capacity at the local level, but not surveillance, detection, and assessment (epidemiology and laboratory capacity) preparedness. These tasks are the responsibility of CDC's Bioterrorism Preparedness and Response Program (BPRP) Office. This may be an understandable division of responsibilities, but it does create some problems. Each office, for example, worries about the "mission creep" of the other into its defined domain, a worry that is somewhat justified. One example is OEP's inclusion of guidance for the MMRS Bioterrorism Annex regarding surveillance and monitoring, tasks that CDC's BPRP rightly considers its responsibility. Clearly, it is critical that the medical management response system being promoted by OEP is compatible with the awareness and assessment functions being built by BPRP. It is also important that OEP and BPRP support one another and ensure that their efforts do not work at cross purposes. Currently, there is considerable interaction between the two offices, but the working relationship does not always appear to be an easy one. It is critical that their roles and responsibilities be clearly defined and understood and that their activities remain within the boundaries of those defined functions. Senior HHS officials should ensure the integrity of each set of activities if necessary.

Finally, officials in many locales are concerned that state and local budgets will not be able to sustain planning and coordination that have been initiated by the MMRS program once the contract period is over. Questions have arisen about funding for training of new members of the response community in local MMRS plans as well as maintaining the relationships and level

of cooperation that have developed between response entities. Some people fear that the results of years of hard work will begin to degrade if federal funds are not made available to sustain what has been achieved to date.

In sum, the MMRS program has made significant strides in better preparing local communities to respond to bioterrorism attacks as well as a range of medical emergencies, yet concerns remain that many gaps still exist in that system which will begin to widen if progress is not sustained.

Clash of Cultures

Bringing together response entities who previously had little interaction has improved relationships among them, but tension continues to be generated by culture clashes between communities, as well as turf wars and differing perspectives on the importance of the issues at hand. This may be most evident between the public safety and public health communities. Public safety officials often see themselves as "action oriented" while describing public health personnel as "analytically oriented". Public health sees the public safety community as performing largely a support role -- security, transport, and possibly staffing -- in a bioterrorism event, given that their expertise is not dealing with disease outbreaks or medical management. In some instances public health resents that the fire department has been given the lead for bioterrorism response planning. Meanwhile, fire departments see bioterrorism responsibilities as a logical extension of their HAZMAT responsibilities.

In addition to the cultural disconnect, part of the clash is a momentum problem. DoD's Domestic Preparedness Program, while incorporating biological aspects, has been largely designed around a HAZMAT template. This is in part because chemical weapons attacks resembled HAZMAT incidents, in part because the target audience of the DPP was initially the public safety community, in particular, fire departments. The DP training initiatives built on the fire departments' operational experience in responding to HAZMAT incidents. As a result, especially in the early years, some training seminars had a heavy bias toward chemical attacks, and bioterrorism tended to be underplayed. The comment of one trainer during a program that,

“If you can do radiological, you can do bio” is an example of the kind of mindset to which the public health community points in arguing that biological events have not been given enough attention in light of their differences from chemical or radiological incidents.

As policy makers became increasingly concerned about bioterrorism, it became apparent that bioterrorism events – especially covert attacks – would not have scenes to which public safety personnel would rush off. The realization also grew that a public safety response to bioterrorism would not be sufficient and that the public health and medical communities had to play a key part in medical management of casualties, surveillance, detection, assessment, and response.

Today it is more widely -- although not universally -- understood that the public health and medical communities will have a central role to play in responding to bioterrorism. Although relationships between the public health and public safety communities continue to improve as they become more familiar with each other, some competition still exists between the two over resources and incident command and control. In many locales, the public health community feels that they were overlooked as key players in early planning efforts despite the central role they would obviously play. They resented the lion’s share of federal funding going to build response capacity in fire departments and other “first responders” whose role in a bioterrorism event would likely be limited. Today, the public health community receives more money to build capacity, and some resistance is apparent on the part of fire departments who feel that they have to defend their stake in the issue, sustain funding levels, and maintain their importance as a player.

In other cases, certain entities that are logically part of the bioterrorism response system, particularly hospitals and private practitioners, do not see the bioterrorism issue as a significant problem. As one hospital administrator put it, “The probability of a catastrophic bioterrorist attack occurring that overwhelms the medical system is extremely low, but the probability of such an attack in this state, in this city, that overwhelms my hospital, is rapidly approaching zero. Given this probability, what am I going to concern myself with, heart disease, cancer, gunshot wounds, common infectious disease outbreaks that we see all the time, or bioterrorism which I

will probably never witness?" This attitude stems partly from the constraints under which hospital administrators must operate. Both public and private hospitals are struggling to adapt to a managed care system and declining budgets which have forced them to reduce operating costs. Under these circumstances, hospital administrators have few resources to dedicate to bioterrorism issues. Furthermore, resistance stems from the for-profit oriented culture of private hospitals who see little profit incentive in the bioterrorism business. (see section on Public Private Partnership, pp. 155-170).

Incident Command System

Coordination of response activities after an act of domestic terrorism is organized under the Incident Command System (ICS), the most widely accepted command and control model for emergency response. ICS is a management system that promotes coordination and communication between responding agencies and attempts to minimize duplication of effort. In essence, ICS creates a unified command to oversee the actions and interactions of the various organizations involved in response, and sets forth standardized procedures for managing personnel, communications, facilities, and resources. The Incident Commander is usually the senior responder of the organization with the preponderance of responsibility for the event (i.e., the police chief, fire chief, emergency medical coordinator) at the local level. However, if local assets are insufficient to respond effectively to an attack, state or federal organizations may assume the overall command role.

To date, the ICS system has served as the primary response model for weapons of mass destruction attacks; developing a unified command structure has been essential because of the number of local, state, and federal agencies involved. Responding to a bioterrorism incident requires clearly defined roles and relationships, as well as effective operating procedures for local, state, and federal public safety and public health officials and medical care providers. Most of the current programmatic efforts to build a response capacity at the local and state levels have focused on the public safety community and have been based on military or HAZMAT models. Consequently, fire, police, and emergency management agencies have taken the lead

responsibility for implementing response plans. Depending on the region or city, a top official from one of these organizations has usually been designated as Incident Commander.

Because a bioterrorist event may occur covertly and unfold over an extended period of time in numerous locations, the applicability of the ICS to biological attacks is potentially problematic. A covert bioterrorist attack rarely has a "scene." By the time a covert attack is recognized, it is possible that victims may be dispersed throughout a city or region. With no one "incident" to oversee, it is unclear what role the Incident Commander would serve. To deal with this kind of BT event, it may be more appropriate to create response "managers" or "coordinators" who can assess and adjust response activities on a continuous basis, rather than asserting command of a specific, ambiguous "scene." The coordinator would require an exchange of information among local, state, and federal agencies involved to assess the degree of effectiveness of certain response initiatives and would make changes in the response activities as needed.

Few bioterrorism response plans have incorporated public health and medical personnel into command roles, despite their frequent description as the "first line of defense." To some extent, this is a result of funding decisions – because response funding was initially channeled through the public safety community, police and fire departments developed systems based on existing approaches with which they were familiar and in which they would play a lead role. According to the Chief of Communicable Disease Control at an urban public health department, "public health was really an afterthought."

While creating a command and control infrastructure will depend in large part on the individual dynamics of each community, it is important that public health and medical personnel be more fully included in the command structure. Medical personnel will play a key role in determining what resources are needed, where they will come from, and how they will be disseminated. Given that most medical personnel will be heavily involved with treatment and triage, it is unlikely they will be able to play a large role in overall coordination. Public health officials could serve as incident coordinators, at least until federal assistance arrives on scene, but only a few public health entities have been trained in the system.

Public health personnel need greater experience in working with disaster management systems, and specifically with the incident command system. This experience can be generated in two ways: first, through active education and participation in training exercises, and second, through stronger partnerships and communication with other agencies involved in bioterrorism response. Those organizations involved with disaster management, however, must seek out health personnel as partners and work to foster greater communication between the two communities. Many cities are beginning to incorporate public health officers and hospital administrators into the ICS response system, with varied levels of success. In one major metropolitan area visited during this study, a comprehensive effort was underway to include public health in developing response protocols and to brief them in the particulars of command and control. The effort centered on monthly planning meetings attended by representatives of the public health community, hospital emergency management coordinators, fire department leaders, public safety personnel, and the head of the local emergency management agency. At the meetings, members of these different communities took part in developing the city response plan while negotiating the roles each would play in the overall response structure. As a result of the meetings, a strong dialogue was fostered between the public health community and other response entitites, and both the public health and public safety communities felt more comfortable with each other and with their respective response roles.

However, a complaint of those overseeing incident command, namely the public safety community, has been that public health and medical personnel have trouble understanding how the system works once they are brought in. In many ways, this is a result of the clash of cultures discussed previously. Most public safety communities use the ICS system on a day-to-day basis; it serves as the key response model for both fire and police departments. Public health and medical personnel, on the other hand, work in more collaborative environments where strict hierarchies and task designations are not as pervasive.

Although relationships between public health and public safety continue to improve, some competition and confusion between the two communities over incident command and control still exists. In many regions and cities, the public health community still chafes at the supporting roles it has been handed in the command structure. One official at a metropolitan

public health department complained that the public safety entity charged with overseeing BT response had unwisely used funds "to buy new trucks" instead of shoring up medical capabilities, a comment that underlines the public health sector's frustration at its lack of authority within the response system. In most locales, the two communities are working together to resolve these issues. However, before an ICS can be truly effective, public health and medical personnel must both understand the system and be incorporated into it in a meaningful way.

Integration of the Public Health and Medical Communities

Even when significant efforts are made at the local level to integrate elements of the health and medical communities into the response system, the result is sometimes less than satisfactory. The most glaring example is the lack of involvement of the hospitals, both public and private, and primary care physicians in the bioterrorism response planning and coordinating processes. While hospital representatives often participate in planning meetings, hospital administrators and staff generally are largely ignorant of bioterrorism response issues, and administrators have been less than cooperative about considering serious engagement or integration of hospitals into the MMRS plan. For them, bioterrorism response planning is at the bottom of a long list of priorities.

A lack of consideration of the public health and medical community's roles in responding to bioterrorism is also evident at the federal level. A glaring example occurred last year when the original construction of the DoJ needs assessment survey was solely aimed at the public safety and law enforcement communities and did not contain any questions related to public health infrastructure. It was only after the public health community exerted pressure on DoJ that the survey was appended to include a section on public health and medical assets. Today, bureaucratic biases still inhibit a full integration of the public health community. Many federal departments and agencies, however, have begun to understand that the health and medical communities are partners in fighting bioterrorism. This acceptance is probably most strongly indicated by the growth of the DHHS counterterrorism budget which has made the department a significant counterterrorism player.

An often noted problem plaguing federal counterterrorism activities is the large number of departments and agencies involved. The bureaucratic maze is dizzying, and in many cases significant overlaps exist. A number of GAO reports have raised this concern, as did the Gilmore Commission Report to the President and Congress.[6] The creation of an integrating body at the level of the Executive Office of the President that possesses executive and budgetary authority is being called for more often in recent months. An Executive Office could be extremely useful for

- Devising a national strategy;
- Ensuring that the various departments and agencies work together towards a strategic objective;
- Conducting a comprehensive review of all current federal counterterrorism programs; and
- Determining where unnecessary overlap exists and beginning the process of streamlining the bureaucracy, especially if they are granted budgetary authority.

While a national coordinator in the Executive Office of the President would greatly benefit the nation's overall counterterrorism initiative, it could also be a catalyst for integrating the public health and medical communities more thoroughly into bioterrorism response activities. The political atmosphere surrounding counterterrorism activities has traditionally been driven by the national security community, a community that is, generally speaking, not sensitive to the role that public health and medical personnel would play in responding to bioterrorism attacks. An executive body that is sensitive to the nontraditional entities that contribute to WMD preparedness could ensure the integration of the public health and medical communities in counterterrorism planning, both at the federal and local levels. Such an entity could also more clearly define the public health and medical requirements for responding to bioterrorism and more clearly distinguish between chemical, biological, radiological, nuclear, and conventional terrorism and the tools needed to address each.

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[6] *First Annual Report to The President and Congress of the Advisory Panel to Assess Domestic Preparedness Capabilities for Terrorism Involving Weapons of Mass Destruction*, December 15, 1999; GAO, *Combating Terrorism: Opportunities to Improve Domestic Program Focus and Efficiency*, November 1998; GAO, *Combating Terrorism: Observations on Federal Spending to Combat Terrorism*, March 11, 1999; Combating Terrorism: Issues in Managing Counterterrorism Programs, April 6, 2000; GAO, *Combating Terrorism: Need to Eliminate Duplicate Federal Weapons of Mass Destruction Training*, March 2000.

Integration of State and Federal Assets

State-level Response Teams

To date, most state level response assistance has been organized through the National Guard and coordinated through the state Office of Emergency Services. In the event of a bioterrorist attack, National Guard units may be called upon by governors or federalized by the president to assist states in need. The Guard's rapid response capabilities, manpower, and ability to provide security assets may prove to be an asset in managing the response to a biological incident. Guard units are to be capable of mobilizing at their armories within 12 hours of being activated, and deployed within 24 hours of activation.[7]

Some states' National Guard units have WMD Civil Support Teams (CST), formerly known as Rapid Assistance and Initial Detection (RAID) teams. The role of the Civil Support Team is to "assist local first responders in determining the precise nature of an attack, provide medical and technical advice, and to help pave the way for the identification of and arrival of follow-on federal military response assets."[8] The teams are supposed to be able to deploy anywhere in their region of responsibility within four hours of notification. Each team is staffed with 22 full-time National Guard members organized into 6 functions: command, operations, administration and logistics, communication, medical, and survey. The medical unit primarily provides medical support to other CST personnel, not to victims of an attack, but can "provide guidance" to the incident commander on the medical implications of a WMD event and coordinate with health care facilities for follow-on support requirements. Originally, 10 teams were created -- one for each of FEMA's designated geographical regions of the United States. In January 2000, Secretary of Defense William Cohen announced the creation of an additional 17 teams.[9] DoD aims eventually to raise the number to 54, one for each state and territory, and the District of Columbia.

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[7] Department of Defense, Report to Congress, Volume I, Domestic Preparedness Program in the Defense Against Weapons of Mass Destruction, <http://www.defenselink.mil/pubs/domestic/5.html>.
[8] Berkowsky, Pamela B., and Charles Cragin, Joint Statement before the Senate Committee on Armed Services, March 24, 2000.
[9] For a greater description of the roles and capabilities of RAID teams, see: General Accounting Office, Combating Terrorism: Use of National Guard Response Teams is Unclear, (GAO/NSIAD-99-184 June 23, 1999).

In designing the CST teams, Army officials stated that they tried to create a capability that would detect and identify WMD, an element missing from most local and state response units.[10] According to these same officials, having a CST team in the National Guard gives a state governor "an asset that can be rapidly deployed in the event of an attack".[11] However, while CST teams may prove useful in responding to a chemical attack, it is unclear whether they would be so effective in responding to a covert biological attack. One of the most useful elements the National Guard has to offer -- a triage component -- would take 72 hours to deploy to a site.[12] If reacting to the clandestine release of a fast acting agent such as tularemia, the triage element of the team will be of little use, as most of the patients will already have presented themselves to hospitals or other facilities. The teams themselves have limited medical capabilities, and those they do possess are advisory, not operational. In fact, the majority of the Civil Support Team's functions are based on on-site agent identification and decontamination, both of which have little applicability to a covert BW event.

Officials from both the FBI and FEMA have expressed concern about how the teams would fit into the federal response structure, and have further underlined the potential for conflicts between CSTs and other federal assets.[13] Given their HAZMAT focus, it is questionable whether Civil Support Teams will provide resources different from those already available through local HAZMAT teams or other federal teams like the Chemical Biological Incident Response Force.

This does not mean that these teams do not have a role to play in consequence management. Because of their rapid mobilization abilities, National Guard units and Civil Support Teams will prove effective in a tiered response structure, working to aid first responders between the initial call for federal help and the arrival of that help. While it is unlikely that the teams will be qualified to participate in direct patient treatment or dispense medical advice, they may be critical in enforcing security or transporting supplies and equipment, and may serve as

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[10] Report GAO/T-NSIAD-99-184, p. 5.
[11] Ibid.
[12] Department of Defense, DoD Plan for Integrating National Guard and Reserve Component Support for Response to Attacks Using Weapons of Mass Destruction, January 1998. <http://www.defenselink.mil/pubs/wmdresponse/chapter_5.html>.
[13] Report GAO/T-NSIAD-99-184, p. 5.

liaisons between local authorities and the Department of Defense. According to the DoD *Plan for Integrating National Guard and Reserve Component Support for Response to Attacks Using Weapons of Mass Destruction*, published in January, 1998, officials are working with partners in both the public and private sector to develop a more detailed medical response mission and task base. However, in order for these teams to truly provide the assistance they were designed to offer, they must be incorporated early on into a local community's response plan. Issues of coordination and integration must be worked out ahead of time, and exercises must be held to determine how these teams will interact with additional response entities.

Federal Response Teams

The Department of Defense's official role in consequence management is to support FEMA, the lead federal agency. The Secretary of the Army directs DoD efforts to provide a wide variety of support services, ranging from laboratory assessments to specialized teams trained and equipped to detect, neutralize, and respond to incidents involving biological agents. These specialized teams include the Army's Technical Escort Units (TEU) and the Navy's Defense Technical Response Group (DTRG). For biological incidents, response teams and laboratories at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) and the U.S. Naval Medical Research Institute can help identify biological agents and administer appropriate antidotes and vaccines. USAMRIID can also deploy Aeromedical Isolation Teams consisting of physicians, nurses, medical assistants, and laboratory technicians who are specially trained to provide care for and transport of patients with diseases caused either by biological agents or infectious diseases requiring high containment.[14] The Mobile Analytical Response System, a part of the Edgewood Research Development and Engineering Center, is further capable of providing assessments of biological contamination at incident sites.

The Marine Corps also established the Chemical Biological Incident Response Force (CBIRF) in July 1996 as a consequence management tool capable of rapid response to chemical

[14] The teams are capable of providing transportation and care to a very limited (two teams exist, each capable of caring for 1 victim at a time) numbers of victims of a bioterrorist attack, and are meant to be able to transport patients at biosafety level 4 (BSL-4). Patients could be safely transported to USAMRIID's BSL-4 facility for care and diagnosis. Christopher, George W., and Edward M. Eitzen, Jr., "Air Evacuation Under High-Level Biosafety Containment: the Aeromedical Isolation Team," <http://www.cdc.gov/ncidod/eid/vol5no2/christopher.html>.

and biological attacks. CBIRF consists of a 350-man self-sustaining force that can assemble within four hours to respond to an incident involving biological or chemical weapons. CBIRF's response elements include reconnaissance, detection, decontamination, medical, security, and service support. Specifically, CBIRF has the ability to provide command and control support to a civilian incident site commander, conduct detection in a contaminated environment, and insert Navy doctors into an infected zone for triage and decontamination. The force is supported by an "electronic reachback" group of scientific and medical consultants. With these myriad assets contained in one deployable unit, CBIRF may have the extended support structure capable of helping local communities respond to a crisis situation.

However, CBIRF has a number of inherent problems that will diminish its ability to aid local responders effectively during the critical period before federal resources arrive. Like the Civil Support teams, CBIRF has focused its activities on "incident" response. In fact, a majority of its capabilities, including environmental detection and decontamination, depend on an overt agent release. CBIRF has also relied primarily on HAZMAT training, and has emphasized response to a chemical or radiological disaster over a biological one. Of its 350 members, only 23 are slated for medical management, including 17 corpsmen, three physicians, one Environmental Health Officer, one physician's assistant, and one nurse.[15] Furthermore, CBIRF does not currently have its own stock of prophylaxis for biological agents. Consequently, it is doubtful that it will be able to play a large role in aiding a community response to a biological outbreak during a period when treatment and triage will be paramount.

As with the Civil Support Teams, it is possible that CBIRF can contribute in other ways to local and federal response efforts. Because it can be mobilized fairly rapidly and is independently equipped, CBIRF may be useful in enforcing security or transporting supplies and equipment. CBIRF may further serve as a communication pathway between local authorities and the Department of Defense. Although still limited, CBIRF's medical capability is more extensive than that of the Civil Support Teams, and in the event of an attack with a particularly high number of casualties, it is possible that CBIRF could be called upon to aid in patient triage and treatment.

[15] "Chemical/Biological Incident Response Force," <http://www.au.af.mil/au/awc/awcgate/CBIRF/cbirf.html>.

Without careful coordination and pre-planning, the numerous state and federal teams that may arrive to respond to an event will exacerbate the confusion and friction of an already complicated response network. For the most part, federal agencies developed their assistance teams without first coordinating them with existing state and local emergency management structures. While HHS has built its response teams into already-existing local networks, DoD has built its teams at the federal level. Consequently, the majority of the teams are unfamiliar with the response mechanisms of any given locality. Moreover, many of these teams have been trained independently of other response organizations and do not know how they will coordinate or communicate their actions with these disparate agencies and groups. For example, FBI officials have expressed concerns about conflicts between Department of Defense response teams and their own units.[16] Without a clear understanding of how these teams will operate within a multi-tiered response system, their utility is greatly diminished.

It is also important to assess the applicability of these teams in the event of a simultaneous attack on multiple cities, or the dispersion of casualties over a wide geographic area. While such scenarios admittedly are of low probability, they are nevertheless a contingency for which some planning must be done. Both CBIRF and the National Guard teams operate as small, self-contained response cells; Civil Support Teams have only 22 members, while CBIRF's medical unit is made up of just 23 marines. Because of their size, it is unlikely that they will have the manpower to respond to attacks that occur in more than one region or city. Similarly, if casualties are dispersed over a wide region, particularly across state boundaries, it is unclear how these teams would distribute their resources while remaining operational. Members of the National Guard and CBIRF have been trained to work interdependently with other members of their teams; as a result, breaking down the teams into smaller operational groups is not feasible. In the event of a two-state outbreak, it is possible that more than one Civil Support Team could respond, especially if both states have indigenous teams. However, integrating two separate teams raises difficult coordination challenges given the already confusing nature of a geographically dispersed attack. Finally, as previously underlined, both CBIRF and the Civil Support Teams have at most three or four physicians and nurses –not enough to make a large

[16] GAO Report NSIAD-00-145, "Combating Terrorism: Issues in Managing Counterterrorist Programs," Testimony of Norman J. Rabkin before the Subcommittee on Oversight, Investigations, and Emergency Management,

difference in triage or treatment capabilities if they are dispersed among several different sites. It is thus doubtful that either team will be able to play a large role in aiding a community response to such an outbreak.

Key Issues and Recommendations

The initial WMD preparedness programs largely targeted the public safety community and the capabilities and experience that they acquired from responding to HAZMAT incidents. While the HAZMAT template applies in many ways to chemical and radiological incidents, bioterrorism has unique response requirements. **Current and future WMD preparedness initiatives should make a conscientious effort to distinguish more clearly between biological, chemical, radiological, and nuclear terrorism, with particular attention to how the response requirements for bioterrorism differ from the others.**

Federal agencies are often perceived by local officials as taking a "top down" approach to bioterrorism preparedness planning. The most salient examples include a lack of flexibility in how federal grants are distributed on the local level, and current federal response plans that call for command and control of a bioterrorism incident to be passed from local authorities to the FBI, and FEMA's consequence management mandate. **Given their familiarity with the local geography, resources, and personnel, local authorities should play a significant role in response management. Command and control of a bioterrorism incident should be shared between federal and local entities, and capabilities should be built by recognizing the differing but complementary strengths of the two levels.**

The MMRS program has targeted the most populous cities of the United States but has largely neglected additional cities that may be targets as well as suburban areas which will likely be involved in bioterrorism response. Bioterrorism Response Plan contracts are awarded after a city is certified as having a MMRS plan. This approach does not allow for sufficient input of bioterrorism-related response entities from the outset. Sustaining MMRS and bioterrorism response planning after the federal contracts expire will be difficult for locales operating with

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Committee on Transportation and Infrastructure, House of Representatives, April 6, 2000.

small budgets. **While the MMRS program is a good first step, these activities should be administered at the state level to ensure that not only "metropolitan proper", but the surrounding municipalities and suburbs are included in planning activities**. **The Bioterrorism Preparedness Plan contracts currently included as an annex to the MMRS emergency response plans should be developed at the outset. Some level of federal follow-on funding is required to sustain bioterrorism planning activities** to ensure that the current level of communication and interaction between the local health and medical and public safety communities continues.

The OEP and CDC's federal preparedness initiatives operate simultaneously, but target different aspects of bioterrorism preparedness. OEP concentrates on medical management response planning and coordination; the CDC builds incident awareness and assessment tools in the public health and medical communities. Although distinct streams, they need to be integrated to ensure an effective system. **HHS must develop an overall strategy at the department level that integrates these functions and ensures that they work together rather than dilute each office's respective effort through bureaucratic competition.**

To date hospitals represent a significant challenge in creating a robust bioterrorism public health and medical response system, largely because of tight budgets and other health care priorities. **Planning and coordination activities at all levels need to pay special attention to the challenge of integrating hospitals into the bioterrorism response system. A Task Force or Working Group should be established at both federal and state levels to identify the challenges that hospitals face in becoming integrated in the bioterrorism response system, and to devise some realistic solutions for overcoming those challenges. Federal grants for building public health and medical capacity for responding to bioterrorism should be extended to a sixth focus area aimed at hospitals.**

Few bioterrorism response plans have incorporated public health and medical personnel into command roles, despite their frequent designation as the "first line of defense." Moreover, some competition and confusion still exists between the public safety and public health communities over incident command and control. Before an ICS can be truly effective, public

health and medical personnel must both understand the system and be incorporated into it in a meaningful way. **Public health representatives must be more fully integrated into the command and control infrastructure at the local level.**

Finally, a major problem with response planning is the bifurcation of overall command into crisis management and consequence management phases, which both complicates unity of command and causes confusion over which agencies will take the lead if federal assistance is requested. This confusion has been exacerbated by the number of agencies and teams with potential roles in a response effort. **Roles of the federal government versus the state and local government need to be examined and clarified to prevent confusion. Responders at all levels must continue to resolve intergovernmental issues, including minimizing redundancy among federal, state and local efforts and eliminating confusion at the recipient level.**

II. PUBLIC-PRIVATE PARTNERSHIP

Building a strong partnership between the government and the private sector will be a vitally important element of the national bioterrorism preparedness and response effort. The private sector holds a number of unique resources and capabilities directly pertinent to bioterrorism preparedness and response. Private entities play key roles in detecting, assessing, and responding to incidents of bioterrorism, including medical treatment, provision of medicines, supplies, and vaccines, public outreach, and information technologies. The importance of the private sector in any biological terrorism response system requires the U.S. government to complete two key tasks: First, the government itself must recognize the need for a partnership with the private sector in bioterrorism preparedness. Without private sector involvement, the nation's ability to respond will be less than adequate. Second, the government should work actively to encourage and facilitate the private sector's involvement in the national preparedness effort. This begins by demonstrating to the private sector that bioterrorism is a national priority and requires its participation.

General Issues

Effectively building the relationship between the private and public sector in bioterrorism health and medical response efforts has several dimensions. In particular, the government must do more in the following areas to incorporate the private sector as a full partner:

Developing a Public and Private Dialogue on Issues of Common Concern

A public-private sector dialogue could take place with the private sector as a whole or on a sector-by-sector basis. Through such a dialogue, both sides can exchange ideas and recommendations, criticisms, and concerns regarding their perceived roles and responsibilities, differences in perspectives and respective motivations, and issues related to burden sharing.

To date, most discussions have been lower-level exchanges between private sector and government officials relating to implementation of specific preparedness programs. In a way,

these discussions have been premature because they did not have the context of previous senior level exchanges among government and private business leaders. In one example provided by the health care industry, hospital representatives indicated they are being asked by government officials at both the federal and local levels to develop certain biological response capabilities when administrators and industry officials remain dismissive of the need for such preparedness. Today's challenge is working to develop mechanisms at which senior-level discussions can occur to foster the interest and cooperation among senior industry officials needed to facilitate progress in preparedness implementation.

Understanding Differing Motivations and Perspectives

A natural tension is created by differences in motivations between the private and public sector. For most private sector entities, the driving motivation is increasing revenues. Even for non-profit entities like certain health care facilities or public radio and television, their motivation is not profit but a desire to seek new sources of financial support and secure those sources already in place. On the other hand, the government's driving motivation in bioterrorism preparedness is its mandate to promote national security.

The government, however, must also accomplish its goal in the context of increased fiscal responsibility, balanced budgets, cuts in Medicaid and Medicare and other entitlement programs, and cuts in discretionary spending. The trend has been toward shaping the government to be smaller, less intrusive, and less burdensome. This makes developing and implementing solutions based on direct government support or leveraging the government's regulatory authority especially difficult.

Cooperatively Defining Roles and Responsibilities

An important feature of public-private dialogue must be development of a cooperative process to define respective roles and responsibilities clearly. The government's most challenging step in opening a dialogue with the private sector is the first one: convincing them that they play an important role in preparedness. Government and industry can develop sound

approaches to overcoming some of the current obstacles, but before that can occur, both sides must begin using available communication mechanisms to begin an active dialogue.

Addressing Burden Sharing Issues

Cost has served as the main deterrent preventing greater involvement of the private sector in preparedness activities, especially the health care industry. This cost question and the resulting reticence have fostered tension between government and industry. At one level, government entities perceive the private sector as not willing to forgo revenues for the sake of national security. On the other hand, private sector entities perceive parts of the government as lacking understanding of the economic and market realities of their industry. They fear, in particular, a series of cascading costs that result in the loss of competitive advantage and of their ability to shape market perceptions of their particular goods or services.

Government and the private sector must develop cooperative approaches for equitably distributing the cost of preparedness and response. Some approaches that have been suggested include shifting the burden of bioterrorism preparedness and response to government, having the government subsidize the private sector's activity, and encouraging dual-use programs and identifying secondary benefits for bioterrorism preparedness. For example, working with the media on current bioterrorism programs provides them with information in which the general public is becoming increasing interested; selling more papers or increasing viewers could be the result.

Key Industry Sectors

A number of specific private industries play key roles in bioterrorism preparedness and response. Hospitals and other medical care providers must serve as the central data source for health surveillance systems and provide the core element of the national capability to provide care to victims. The print and electronic media will serve as the main interface between the government and the general public before, during, and after bioterrorism incidents. Pharmaceutical and medical supply companies will support both preparedness and response by

providing the necessary medicines, vaccines, medical supplies, and technologies to provide prophylaxis and medical care. The information technology sector will provide the hardware, software, and expertise needed for a national information and communication infrastructure. If these sectors are to become full partners in the bioterrorism effort, however, government and private industry require an improved understanding of the major difficulties of increasing their involvement and new, cooperative approaches to overcoming these challenges must be identified.

Hospitals and Medical Care Providers

As has been mentioned on several occasions in this report, hospitals, clinics, physician offices, and even individual physicians have a two-part role in bioterrorism preparedness and response. First, they provide a sentinel in the nation's bioterrorism surveillance systems. Since they are likely to be the first professionals to examine bioterrorism victims, they are a key source of information that must be integrated into infectious disease reporting and syndromic surveillance systems. Second, hospitals, clinics, and private practices form the core of the nation's medical treatment capacity.

On a nation-wide basis, hospitals have been only partially involved in bioterrorism planning and preparedness and must be better integrated into the national bioterrorism preparedness effort. To date their involvement can best be described as marginal but improving. Some cities have developed bioterrorism response plans with little or no input from hospital representatives. When hospitals have been involved with planning at the local level, they usually have been represented by less-than-senior officials from the hospital or the local hospital industry association. With some exceptions, few senior executives from local hospitals or the local hospital association have engaged in bioterrorism planning. In general, they have paid little attention to bioterrorism issues.

Some hospitals have begun to develop CBRN, and more specifically bioterrorism annexes to their individual disaster response plans. Some localities have also been able to integrate hospitals successfully into local response planning efforts, mainly through the

municipality's individual bioterrorism planning contracts with the Office of Emergency Preparedness at HHS. The degree of integration has depended on local dynamics and personalities.

Little if any progress has been made in building hospital capacity to detect, assess, or provide treatment related to bioterrorism events. Training provided through the Nunn-Lugar-Domenici program was designed to improve the ability of physicians to recognize and treat the victims of biological attack. The program, however, has been plagued by poor hospital and physician participation, mainly due to a combination of tight schedules and the absence of marketing by the training providers. A small number of hospitals have been involved with some of the various syndromic surveillance projects currently underway. But even those systems have ceased operations once external financial support was removed. For example, the syndromic surveillance system installed for last year's meeting of the World Trade Organization in Seattle was completely dismantled when CDC discontinued support following conclusion of the meeting. Many of the hospitals who have participated in these experiments, such as the University of New Mexico Medical Center, are either university medical centers or large not-for-profit institutions. Not surprisingly, these institutions emphasize research and the public good. Finally, there has been no progress in improving hospital capacity to treat high numbers of bioterrorism victims. In fact, that capacity continues to shrink as the number of available hospital beds and the associated staffing and infrastructure declines in most major U.S. cities.

Why has integrating hospitals and care providers been so difficult? The answer is cost. Most of what the hospitals have accomplished in bioterrorism preparedness, namely, the development of hospital-specific and local area response plans, have cost hospitals little in the way of financial resources or time. To make meaningful progress from this point forward, serious differences between the hospital industry and the government on respective roles and responsibilities and the financial burdens related to them will have to be addressed.

Hospital representatives argue that hospitals and medical systems operate within a completely different economic structure than existed as little as 5 or 10 years ago. This new situation has been produced by such factors as growth in managed care and health maintenance

organizations created by the desire among consumers for reduced health care costs. This reduced economic margin has been further squeezed by the political drive for balanced budgets, which has been achieved in part through cuts in Medicaid and Medicare payments to hospitals and private physicians. In response to these shifts, hospitals have sought improved efficiencies. They have reduced the frequency of hospital stays and increased outpatient care. Within urban centers, smaller hospitals have either closed or joined with bigger hospitals to create large hospital networks. In addition, HMOs and managed care organizations have encouraged hospitals and doctors to reduce the frequency of expensive tests and procedures, including laboratory tests.

This desire for improved economic efficiencies has worked synergistically with an increase in the level of competitiveness between HMOs and insurance companies, between hospitals and care providers, and between physicians. In part, cost saving measures foster competitive advantages that are used to attract new patients. This includes not only reducing costs incurred by patients, but also reinvesting savings derived through cost reduction measures to provide for improvements in the facility's quality of care. In this way, a hospital can invest in a new piece of state-of-the-art technology or build a new treatment center and then use it to attract new patients.

How does this dual dynamic of increased efficiencies within the health care industry and increased competition affect hospital preparedness for bioterrorism? Quite simply, eliminating excess capacity within the health care system directly counters the perceived need to maintain some "surge" capacity within the health care system in the event of a bioterrorism incident. The basic objective for which most health systems are striving is to create as closely as possible a one-to-one relationship between the available health care services and the normal demand for those services. The closer the industry comes to achieving that objective, both the excess treatment capacity existing within the nation's health care system and any surplus financial resources available for bioterrorism preparedness diminish.

Increased competition between medical care providers further reduces the involvement in bioterrorism preparedness. In some cases, increased competition between care providers makes

it more difficult for them to work cooperatively. In one major metropolitan area, for example, the two major hospital networks have waged an intense, often bitter, and personal competition that has not only spilled over into the city's media but has been pursued in the corridors of political power in the state capital. While these barriers might be lowered during the response to an actual incident of bioterrorism, cooperation in planning, capacity building, training, and surveillance activities is hampered.

Hospitals have also expressed some trepidation regarding bioterrorism-related systems that will provide increased information about hospital operations, for example improved surveillance systems. They argue that competitors might use information from these systems to critique their operations. It might also reduce the appeal of their institution to potential customers. In addition, any excess resources are probably going to be used to improve their standard of care rather than to prepare for an event that is unlikely, has little bearing on their daily business, and generates few revenues. Finally, competition makes it difficult for government officials, at either the federal or local level, to approach hospitals as a single entity with which they could deal more effectively than with many smaller ones.

How can this impasse between government, hospitals, and medical care providers be resolved? First, the government must do much better in communicating to the hospital industry that bioterrorism preparedness is a national priority and that hospitals play a central role. This is not simply a matter of providing the hospitals with additional information. Some senior leaders within the hospital industry already know bioterrorism is a priority. What is needed is an expenditure of political capital to help gain increased cooperation from these and other leaders of the medical care industry**. One idea for a first step, both as a means of demonstrating political commitment and fostering an improved dialogue, is a national summit on the medical dimensions of bioterrorism preparedness.** In order to demonstrate the importance of this issue, such a summit should include senior representatives from the executive branch, including the Secretary of Health and Human Services and the Attorney General, representatives from Congress, and senior representatives from the health care industry. This last group of participants should include the President of the American Hospital Association, CEOs from local hospital associations and major medical centers, and CEOs of the leading national medical

insurance companies. Such a meeting would be an opportunity for senior leaders from both the executive and legislative branches and senior representatives from the hospital and medical care industries to discuss their objectives, exchange their perspectives and concerns, and begin developing agreed approaches.

One of the key objectives of such a meeting must be agreement on what is expected of hospitals and other local medical care providers in both detecting and responding to a bioterrorism event. Agreeing to their appropriate role and responsibilities is an important step in defining necessary capabilities and developing programs to achieve objectives.

At a minimum hospitals and local care providers should provide a level and amount of care agreed with government authorities responsible for bioterrorism response. A tiered approach to medical treatment might be best. Such an approach would require local hospitals and treatment facilities to treat a certain level of casualties, above which state or federal assistance will be necessary. Reflecting previous sections of the paper, the hospital systems of most major metropolitan areas are capable of quickly absorbing approximately 100-200 additional patients at any single time. A bioterrorism attack producing 300 to 500 casualties is quite possible. Based on these two figures, a key question that must be addressed by the government and the hospitals is to what degree *can* and *should* the figure specifying the number of patients to be treated be increased. Clearly additional state and federal resources will be needed to treat casualty numbers higher than 500. But how should the range between 200 and 500 be handled, especially given the time required for additional resources to arrive on scene?

A number of solutions have been suggested to bolster the current shortcomings in hospital response capabilities. One is for the federal government to subsidize, perhaps through some type of grant program, bioterrorism preparedness activities of hospitals and care facilities. But such a program would be very expensive and could quickly “break the bank”. A closely related solution is for the government to support bioterrorism preparedness in a more indirect fashion. One suggestion is linking Medicaid and Medicare payments to progress in building detection and response capacity. Such a program might provide an incentive to hospitals if the

additional payments associated with preparedness are above current levels. If not, hospitals are likely to see such a strategy as another unfunded mandate.

Another approach is to exploit the government's regulatory and oversight responsibilities to "encourage" preparedness for bioterrorism. A frequently mentioned possibility is to change the hospital accreditation process to include requirements for developing certain capabilities or conducting certain preparedness activities before accreditation is approved. This approach might force hospitals and care providers to undertake preparedness activities or develop certain capabilities, but they would do so in a very reluctant and resentful fashion if there is no funding to support these requirements. Because the costs of meeting these additional requirements are likely to be passed on to the consumer, this approach is unlikely to receive support either from the general public or from Congress, let alone from the hospitals themselves.

A third approach is for the government to reduce as much of the cost incurred by hospitals as possible. This means the government spends its available resources to provide hospitals with preparedness tools without directly providing the hospitals with additional financial resources. For example, hospitals would be given the equipment and software to incorporate their hospital into a local surveillance system. Hospitals could also be provided with additional beds, medicines, and equipment that could be kept in reserve for bioterrorism or other disasters. This approach is a two-edged sword. A key argument in favor is that it relies upon the hospital as little as possible to undertake certain actions. On the other hand, some argue that directly providing hospitals with the additional resources needed for these activities, like installing the telecommunications equipment or purchasing additional medicines and equipment, allows them to do so more efficiently and with better results than if they were executed by government agencies.

The last solution, paraphrasing a senior representative from the national hospital industry association, is doing nothing, especially in attempting to bolster hospitals' capacity to respond to mass casualty situations. Their argument is that because current economic forces are strongly allied against preparedness, any increase in excess treatment capacity would be expensive and provide only marginal improvements. Hospitals have dealt with disaster situations and have

protocols and procedures already in place. They will do their best to creatively utilize available resources until assistance arrives.

In the end, no single approach will provide an adequate solution to developing a true partnership between the government and the medical care industry. It must be some combination of all of them. But, it must be a combination that is cost effective, agreeable to both sides, and based upon a common vision.

Print and Electronic Media

A second key sector with which the government should build a partnership is the print and electronic media. Communication with the public has been a cornerstone of the practice of public health. It must also be a cornerstone of bioterrorism preparedness and response.

Media outlets are likely to play an important role by acting as the main interlocutor between the government and the general public. Both during and before an incident, these outlets serve as the main channel by which the general public receives most of its information regarding terrorism.

During a bioterrorism event, the public will be clamoring for information. The media will fulfill that demand, regardless of the quality or the accuracy of the information provided. The government, therefore, must work *with* the media to provide critical information to the public. This material should be designed to provide timely and accurate information regarding the nature of the incident and the response. Public communication can also serve not only to calm the public's fears and concerns, but to enable incident response by providing information on which measures should be taken by people to protect themselves, where they can find prophylaxis or medical treatment, etc. Government officials have recognized communication's role in response and have made considerable progress in developing media relations strategies, creating protocols and formal procedures detailing who has responsibility for public information during a bioterrorism incident, and formulating the types of messages and information that should be provided.

In addition to crisis communications, the media provides the main source of information for the public on two issues. First, how much of a problem does the U.S. government perceive bioterrorism to be and how concerned should I be? Second, if this is such a problem or threat, what is the government doing to prevent it and prepare for such an attack? These are important questions because the general public's reaction to a bioterrorism incident will be determined as much by information and perceptions formed before the event as by the information provided to them during an event. The government must develop strategies for working with the media to help shape pre-incident public perceptions.

Creating a partnership with the media is challenging for a number of reasons. One is the sheer number and variety of media entities. There are a number of different media outlets, each with different perspectives, designed for different types of audiences, and possessing a different degree of proficiency and professionalism. Attempting to predict how information might be reported to the public in an environment of such diversity is virtually impossible.

Also, the media is motivated by profit. But unlike the other sectors, the supply and demand relationship between the media and the government is reversed. The government is not a consumer. Buying more of the media's services does not fulfill the government's objective. On the contrary, the media relies on the government as a source of much of its information, especially on defense and national security issues. It is because government is such an important source of information that government can find means of leveraging the media.

Another difficulty, but one in which the government can make some headway through a stronger partnership, is the general lack of understanding of bioterrorism issues within the journalism community. Most journalists are not well versed in matters pertaining to biological weapons. Few are knowledgeable in the areas of public health or medical care. If journalists are not well informed about these issues, it will be harder for them to ask the right questions; the more difficult it will be to evaluate the quality and sources of information; the risk of omitting key dimensions of issues that provide needed balance will be created; and the possibility of fostering panic in the event of a bioterrorism crisis will be higher. Journalists do not just need

information they can report to the public, they also need a firm grounding in the more technical aspects of both the problem and the response.

What are some of the next steps government entities should take to bolster this partnership? First, both the content and the process of crisis communications in the event of a bioterrorism attack must be refined. While there has been progress in preparing the communication dimension of the response to bioterrorism, further work needs to be completed in a few areas. First, **public health officers should be better incorporated into procedures for conducting public information activities during an incident.** While the FBI and FEMA have been designated to lead the formation of joint information centers at the local scene and in Washington, representatives from the local public health department, the CDC, and HHS must be active participants within these centers. Second, these **procedures need to be exercised on a regular basis to ensure their effectiveness.** These exercises or simulations should include actual members of the press when possible. Third, **the national media strategy for CBRN terrorism incidents and other disasters needs to be better integrated into the federal response plan.** This will ensure effective dissemination of the media strategy and allow state and local officials to develop their own approaches for media relations.

An additional step is improving cooperation with the media for pre-incident communications. Recognizing the bureaucratic and political hurdles that will have to be overcome, **HHS and CDC should strive to become the recognized governmental "authority" regarding medical and health issues associated with bioterrorism preparedness and response. They must take a more active role in developing strong relationships with the media to better inform them on the technical aspects of public health practice and biological terrorism.** This begins with recognition of the media's role in communicating with the public before incidents. It entails providing reliable streams of information to the media on both the nature of the bioterrorism problem and the work to prevent, prepare, and respond. It means establishing reliable mechanisms for communicating with the media. Some examples include:

- Providing improved information on the HHS and CDC webpages to both the media, but also the general public, keeping in mind the role of the internet in communicating directly with the public;

- Making senior HHS and CDC officials available for interviews and news programs; and
- Establishing programs to educate journalists and other media on issues relating to bioterrorism, public health practice, current preparedness programs. This might be accomplished through more formal mechanisms like seminars or workshops. This also might be accomplished through special sections of webpages.

Pharmaceutical and Medical Supply Industry

Another key private sector partner is the pharmaceutical and medical supply industry. These companies are being asked to provide pharmaceuticals, vaccines, medical supplies, and medical technologies.

Both pharmaceutical and medical supply companies will be involved with supplying the standing stockpiles and in establishing the vendor managed inventories. Given the number and size of the push packages, it will take time to produce sufficient quantities to compile the packages while also meeting regular demand for these drugs and materials. In certain cases, the CDC has purchased the entire available quantity of certain drugs in order to compile the first packages as rapidly as possible.

CDC and HHS will have to work closely with industry to develop a sound, efficient, and economical approach to developing the vendor managed inventories. One approach is to have a company, either the pharmaceutical company supplying the specific material or a third party, rotate a certain amount of excess medicines or equipment into a cache of supplies available for bioterrorism and then rotate it back into regular circulation after a certain period of time. The other approach is to pay the producing company to produce excess goods to ensure they are available for bioterrorism response.

The relationship between the government and the drug and supply companies appears to be reasonably cooperative. Pharmaceutical manufacturers are actively working with the government to develop both the standing stockpiles and the vendor managed inventories because it is in their interest – they are being compensated for the goods and services. Pharmaceutical manufacturers and medical supply companies are not being asked to donate their materials to

supply the standing stockpiles. They are not being mandated to produce excess capacity even though there is no demand for that additional material. The government is directly paying those companies for their goods and services. Because of this, the government's relationship with these companies will remain more cooperative than its relationship with the medical care industry.

As has been discussed elsewhere in the paper, consideration is being given to the use of normal pharmaceutical distribution systems to provide medicines and prophylaxis in response to a bioterrorism event. This includes national drug stores chains, for example CVS and Walgreens, and increasingly discount department store chains like Wal-Mart. It is not clear that the stores themselves, their parent companies, or the pharmacists and technicians manning them have been consulted about the concept. Their input and reaction to these plans could prove useful in providing some evaluation and means of refinement.

Another area in which improvements are needed in the relationship between government and the pharmaceutical and medical supply industry is in research and development. One specific piece of this problem is a need for greater cooperation in working through the regulatory and approval process, for both new and existing drugs and equipment. Many existing antibiotics have not been approved for use in treating many of the diseases produced by biological weapons. One example was Bayer's recent application with the Food and Drug Administration (FDA) to add treating inhalational anthrax to the list of indicated uses for an antibiotic it produces. That application was the first time a company had applied for FDA approval for a medicine to be specifically approved for treating biological casualties.

Another specific area for improvement is working with and supporting industry research and development projects in improved laboratory diagnostic technologies. Government needs to actively scan the environment to identify promising technologies being developed in the private sector and then nurture those most promising technologies.

A dual challenge is the number of governmental and private sector entities involved in this area, both directly and in a supporting capacity. The list includes the Department of Energy

through the national laboratories, the DoD, including the Defense Threat Reduction Agency, HHS, and DoJ. While it would be impossible to provide a single department or agency with the oversight authority for diagnostic research and development, it is possible and important to develop methods for government agencies to share information and ideas.

Information Technology and Telecommunication

This report has argued strongly that building improved information and communication infrastructure is a key to a number of functional capabilities including detection, assessment, and response. The private sector's role should not only be providing the hardware and software necessary to build the national public health information infrastructure, but also sharing their expertise and advice. This includes information on what technologies are available and advice on how to meet the requirements and challenges of assembling this national infrastructure.

Currently, there is no formal mechanism or process for developing a strong partnership between government officials charged with building bioterrorism preparedness and response capacity and representatives from the IT and telecommunications industries. Interaction between these entities has taken place on an ad hoc basis. Most of what has occurred at both the federal and local levels is a process in which the government actor develops a set of IT or telecommunication requirements, identifies a range of companies who could help meet that need, and then chooses a company to provide that good or service. This includes a local public health department using grant money to purchase a set of desktop computers from Dell or leasing high-speed internet access from AT&T. It also includes CDC grants to support the work of various university research centers in surveillance technologies and improved information security projects.

A good example of the ad hoc nature of the relationship between information technologists and public health officials is the recent conference sponsored by the CDC and others on the public health informatics and improvements in the practice of public health. Almost every one of the scheduled panelists and keynote speakers were members of the public health community. It is surprising that a national conference whose objective was a discussion

of how information technology can be used to improve the practice of public health did not include input from the information technology sector. While one must not draw conclusions or generalizations from a single conference agenda, it does provide a demonstration of the need for a better partnership between these two communities.

There are a number of factors contributing to this disconnect. One is a lack of mutual understanding among members of the two communities. Given the lack of support and resources available to the public health community until the bioterrorism grant program began, most public health practitioners have little professional exposure to recent improvements in computers, software applications, and telecommunications. On the other side, because the nation's public health system spent so little on information infrastructure improvements, it did not provide the industry with a potential market and the industry paid it little attention.

This situation is changing with the bioterrorism grants, but the need to strengthen dialogue between these communities remains. Government is fearful of directly approaching industry for fear of appearing biased toward a small subset of companies or segments of the industry. This is complicated by the many government entities and offices involved with bioterrorism preparedness and the myriad of companies and subsectors within the IT/telecommunication industry.

One way to circumvent this problem is to **establish a single point of contact within HHS and CDC to work with industry to build the necessary infrastructure**. The best office to serve this liaison function is the Public Health Practice Program Office at CDC given its program management responsibilities for the Health Alert Network (HAN) program. Once provided with this authority, this office should work with the various national IT and telecom industry organizations on a regular basis. Through these organizations, this office can obtain information on the latest technology development, advice on its strategy for information infrastructure building, and solutions for unforeseen challenges.

III. CENTERS FOR DISEASE CONTROL AND PREVENTION

The Bioterrorism Preparedness and Response Program (BPRP) office at CDC has a unique vantage point from which to improve the nation's bioterrorism preparedness. It serves as the main interface between federal, state, and local entities on issues of public health and medical preparedness for meeting the bioterrorism challenge. It is charged not only with coordinating the bioterrorism preparedness activities of various entities at the CDC, but also with leveraging federal resources to improve bioterrorism readiness in state and local public health systems. To these ends, dramatic improvements have been made over the past two years. The BPRP has begun the process of raising awareness about the role that the public health and medical communities play in preparing and responding to bioterrorism and has helped integrate them into the emergency response systems at the federal and local levels.

The following section delineates issues pertaining to BPRP and the CDC's current strategy for building bioterrorism preparedness, their internal organization and structure, and how each of these has affected the current state of preparedness. It also provides recommendations and potential next steps.

Planning Assumptions

CDC's planning assumptions have been based on single-factor, worst-case, lower-probability scenarios. CDC defines the bioterrorism threat by identifying the agents that have the greatest potential for producing the highest number of casualties and fatalities, not on the comparative likelihood of such a scenario occurring. CDC measures an agent's potential for producing high numbers of casualties and fatalities through a combination of ease of dissemination and transmissibility, high mortality, potential for panic, and impact on the public health and medical system. CDC's initial threat assessment, while recognizing a fairly broad range of bioagents, gave priority to a relatively small set of threats without accounting for other factors in their assessments such as difficulties associated with acquisition, production requirements needed for producing mass casualties, or dissemination considerations. By focusing on a narrow range of outcomes, CDC assumptions do not account for the relationships

between the components involved in achieving a mass casualty attack or the difficulties that terrorists may face, and the capabilities they will need to bring these components together effectively. They also do not account for the range of terrorist motivations or the relationship between motivations and mass casualty scenarios. This report emphasizes the need to examine the threat as a complex set of factors, including the relationships between terrorists' motivations and the number of casualties desired, and the technically feasible approaches needed to produce mass casualties.

Recognizing that it is vastly more difficult to mount an actual response to worst-case scenarios, focusing on only a relatively small set of contingencies – admittedly lower-probability, higher consequence – simplifies bioterrorism planning and preparedness requirements by narrowing the range of contingencies. But it can also drive sub-optimal and possibly very costly response options.

Preparing the nation's public health and medical system to detect and respond to the full range of more likely medium and low-end scenarios is more difficult. CDC seems to have assumed that preparing the nation's medical and public health system to respond to worst-case scenarios will provide a capability to respond to the full-range of scenarios. It is unclear to the authors of this study as well as other recent studies[17] that this assumption is valid across all functional areas. For example, expending large amounts of financial resources on research, development, production, and stockpiling of smallpox vaccine improves response capacity for a single agent capable of yielding massive casualties, but it does not promote further enhancement of tools for improving the response capacity for a wide array of agents that might be useful in contingencies of lesser consequence but greater probability. What is the proper balance in this case between the need to be adequately prepared for more likely contingencies and the need to hedge against high-consequence ones? Another example is providing reagents to laboratories for a narrow set of agents that does little to ensure preparedness for the full-range of potential agents that may be used.

[17] See the Gilmore Commission report

Finally, the emphasis that has been placed on agents with the greatest potential for producing mass casualties has resulted in distorted perceptions within the response community, policy community, and general public of what a bioterrorist attack is most likely to look like. Such a perception remains problematic, partly because the response communities tend to see the response to bioterrorism as "all or nothing", partly because policy makers have an inaccurate conception of the best use of resources, and partly because the general public may overreact to a bioterrorist attack that in reality was localized and ineffective.

The National Pharmaceutical Stockpile, a central activity in building public health and medical preparedness for bioterrorism, provides an example of the kinds of questions that can be raised when planning is based on "worst case scenarios." While everyone agrees that a bioterrorist attack with smallpox is a potentially devastating event, a number of factors mitigate the probability of such an attack being conducted. Issues of terrorist access to smallpox, for example, or the danger to a terrorist in trying to use it are factors that diminish the likelihood of a smallpox attack. This raises serious planning questions regarding initiatives underway for producing and storing smallpox vaccine. Is the production and stockpiling of vast amounts of smallpox vaccine a wise use of resources given the low probability of such an attack? Although some hedging against a smallpox attack is necessary – for example, preparing current vaccine stocks for deployment, purchasing needles and globulin – are research and development efforts for smallpox vaccines currently underway a cost-effective priority of preparedness building?

Some people would argue that it is, contending that some vaccine is necessary, and, if a little is made, it is not significantly more expensive to make considerably more. Particularly since the smallpox vaccine, as one expert put it, is "essentially out of the tech base already," money spent in this area as a hedge against the kind of truly catastrophic event that a smallpox outbreak would represent is not an unwise resource allocation.

The question, of course, is not whether or not smallpox vaccine should be produced. Rather, the issue is how much and at what opportunity costs. HHS recently entered into a 10-year contractual agreement to spend approximately $40 million dollars per year to research and produce additional quantities of smallpox vaccine. Money spent on smallpox vaccine cannot be

spent on other areas of bioterrorism preparedness. Without robust detection and assessment capabilities, for example, early quarantine and treatment measures that might contain an outbreak are not likely to occur. Moreover, surveillance, epidemiology, and laboratory capacity are crucial to responding to all varieties of bioterrorism scenarios. A stockpile of smallpox vaccine is useful for only one type of scenario. Unofficial figures place the costs of preparing existing doses of smallpox at $17 million, probably a good hedge. But the $27 million that is already committed for research and development into better production techniques for smallpox vaccines might be better spent stockpiling pharmaceuticals able to treat victims for a wider array of bioterrorism attacks or to build epidemiological and microbial forensics capabilities to assess the nature of an attack and aid law enforcement. If such an effort could lead to cheaper and more cost effective vaccine production, however, the investment might be worth it, but the cost savings would have to be substantial.

Similar questions arise about research and development for activities for anthrax vaccines. Post-exposure vaccination for anthrax is not an effective treatment, and pre-incident vaccination of critical response personnel is prohibitively expensive (see section on Medical Management, pp. 63-98).

Given the complexity involved with using anthrax, botulinum toxin, plague, and tularemia effectively as weapons for inflicting mass casualties, what is the appropriate size of a pharmaceutical stockpile for prophylaxis and treatment of exposure to these agents? The push packages currently provide the capacity to prophylax just under eight million people. They are largely comprised of cyprofloxicin and doxycycline, two antibiotics with the widest applicability to bioterrorist agents. This capability, combined with vendor managed inventory and state and local supplies or caches, is sufficient to prophylax and treat victims of the higher probability bioterrorism attacks that are localized and limited exposure attacks. Some additional consideration should be given to identifying antidotes for other bioterrorism agents and stockpiling some level of reserve stocks to be shipped to an attacked area, even if these reserves are as simple as anti-diarrheal medications for countering the effects of salmonella or E. coli.

While medications are an important part of preparedness, the key to using these medical resources effectively will be the quality of the tools that are available for assessing the scope of an attack. Good assessment tools can reduce the amount of medication that needs to be stockpiled by ensuring that those resources are properly directed and used efficiently. Therefore, given current pharmaceutical supplies, the best use of resources appears to be: 1) capacities that are applicable to a wide variety of bioterrorist attacks; 2) assessment tools that can appropriately guide the response; and 3) capacities that have spin-off for responding to naturally occurring infectious disease outbreaks.

It is unclear whether the CDC has sufficiently outlined the bioterrorism detection/assessment and response requirements the public health and medical system should be able to meet. The recently released recommendations of the CDC's Strategic Planning Workgroup are a good first step toward a better definition of the core capacities for pubic health and medical bioterrorism response capabilities. The grant programs and the strategic plan do a good job of identifying the functional areas within the practice of public health that are necessary components of bioterrorism detection, assessment, and response. They also identify the types of activities that must be taken to develop these functional capabilities. What they fail to establish adequately are well-defined operational requirements that together constitute measures of merit for an effective response. Such measures of merit are needed for each of the key functional areas. Such measures are important because they provide a metric for evaluating the progress of preparedness programs. Also needed is a measure for the success of integrating these components into a system. Once these measures have been established, current programs should be linked to specific operational requirements and time frames for meeting them. Without clear requirements and related measures to evaluate progress, assessing preparedness programs over time and making adjustments when necessary is difficult.

The BPRP Office should be given the necessary leverage to manage the direction of, and integrate, public health and medical bioterrorism programs at the CDC. When the BPRP was established nearly two years ago, it was placed in the National Center for Infectious Diseases (NCID), a natural choice in that bioterrorism is a problem of infectious diseases, but also an odd choice given that BPRP's mandate was to coordinate bioterrorism planning and

preparedness activities across CDC's various centers. This choice has made the BPRP essentially one program of many within the NCID, making it difficult to coordinate the activities of programs with similar status in other centers. For example, the National Center for Environmental Health's national pharmaceutical stockpile program, the Public Health Practices Program Office's Health Alert Network (HAN), and the Epidemiology Program Office's detection and surveillance activities are first and foremost responsible to the directors of the respective centers or program offices that house them and not to BPRP, which is tasked with coordinating them. Given BPRP's status within the NCID, it is difficult for it to exert leverage over other program offices in other centers.

This challenge is exacerbated by the fact that individual centers directly receive funds for their bioterrorism-related programs. While NCID receives some congressional funding to support BPRP, much of its budget is generated out of the bioterrorism budgets of the other centers (i.e. the HAN or National Stockpile). This essentially makes BPRP beholden to the programs they are expected to coordinate. In order for BPRP to manage public health and medical bioterrorism preparedness activities more effectively, it must be given more leverage as well as some control over budgetary decisions. One way to do this is to **elevate the BPRP to the level of the Office of the Director at CDC and give BPRP budgetary authority over the BT preparedness programs at CDC.**

Through BPRP's grant program, CDC has taken an even, uniform approach to improve response capacity within the public health system. To a great extent, the CDC's approach to building capacity is the result of a sense of urgency that a bioterrorist event that produces catastrophic levels of casualties is "not an if, but when" scenario. In order to address this imminent and overwhelming threat, funding was freed through emergency appropriations to improve functional areas that are weakest in the public health departments across the country. The "fix the weak link" approach was adopted over an integrated system approach because many felt that the "bioterrorism buzz" and corresponding flow of financial support for preparedness programs could wane in subsequent years. Therefore, attempting to develop a systems approach to the problem and implement a multi-year, phased preparedness strategy was futile. Given these

concerns, limited resources, and time constraints, distributing available resources to as many states as possible to support as many functional areas as possible made sense.

In allocating its grants, BPRP has simultaneously improved all five major components of the public health systems' response capability. The grants program has divided the funding fairly evenly between detection/assessment tools – surveillance, epidemiology, laboratory – or the "front-end" of the system, and response tools – establishing the pharmaceutical stockpile or research and development into vaccines – or the "back-end" of the system. Furthermore, substantial funding has been allocated to other agencies within HHS for building response capacities – the MMRS and Bioterrorism Response Plans. But this approach suggests that both detection/assessment tools and response tools should be of the same importance at this stage of preparedness efforts and that each makes a comparable contribution to an effective bioterrorism response in the current circumstances.

Is that assumption warranted? Probably not, given that many of the front-end tools are essential for detecting an attack, characterizing its nature, guiding the response, and ensuring that response resources are efficiently utilized. Therefore, to a large degree the effectiveness of response tools will largely depend on the quality of the detection and assessment tools. For this reason, **the "front-end" of the system should be given priority consideration given that it can enable the response system.**

Planning Coordination

Senior HHS leadership must better coordinate CDC's Bioterrorism Preparedness and Response Initiative with the Office of Emergency Preparedness's disaster preparedness initiatives. Both BPRP and OEP provide local agencies and departments with federal funding through grant programs as well as guidance on grant implementation, but each organization focuses on different aspects of bioterrorism preparedness. CDC concentrates on strengthening the public health system at the state and local levels to improve *detection and assessment capabilities.* OEP's all-hazards approach, which includes chemical or biological terrorism incidents, is oriented toward improving the *medical management system* of localities.

As these programs have progressed, it appears that certain aspects of the CDC and OEP programs have begun to overlap and are proceeding toward the same goal without the benefit of coordination between them.

Cleanly dividing responsibility for the public health system from the medical system is problematic in both theory and practice. While the nation's medical system plays an important role in providing treatment, it is also key in both surveillance and initial assessments. The CDC Strategic Plan for Biological and Chemical Terrorism Preparedness and Response includes medical treatment and prophylaxis in a comprehensive public health response to biological or chemical terrorism. CDC is also compiling the National Pharmaceutical Stockpile and is planning to provide on-site consultations for both medical treatment and prophylaxis. At the same time, OEP has asked local terrorism planners to develop bioterrorism preparedness and response plans through the MMRS grant process. Although these bioterrorism plans are focused on development of local response systems, OEP is also asking planners to include surveillance, epidemiology, and laboratory response components in their plans.

Although some overlap of efforts is inevitable, senior HHS management must ensure that the delineation of bioterrorism preparedness roles and responsibilities for BPRP and OEP is done in such a way that it maximizes the contribution of both entities. Solving this issue could require organizational changes, including changes in budgetary and management responsibilities at HHS, as well as shifts in program responsibilities and structure. One option could be to specify that one office – BPRP, for example – has the overall leadership role and that OEP's role is clearly one of support. Changing the current status of responsibilities will be difficult, but it may be the best way to facilitate the programmatic decision making that will be key to the success of the effort over the long term.

Development of a bioterrorism preparedness "urban strategy"gives HHS leadership an opportunity to address these concerns while providing local planners with a set of guidelines and suggestions that encourage and facilitate local planning and capacity building. CDC should develop and disseminate such an "urban strategy" bioterrorism planning and organization template designed for use by local public health departments

and other local entities. Absent such a template, local planners lack a reference for defining overall preparedness tasks and activities, identifying system requirements, listing potential partners and measuring progress, while CDC lacks an important tool for ensuring that local agencies effectively leverage bioterrorism support into improved capabilities. Because effectively designing, organizing, and implementing a local detection, assessment, and response system involves a wide array of other organizations and entities, both public and private, the template should include sections on:

- Organizing local health surveillance systems, including the integration of non-traditional partners;
- Developing bioterrorism response plans based on the previously discussed tiered approach;
- Ensuring effective and integrated emergency communication capabilities;
- Developing and managing local training programs;
- Coordinating with the public safety and law enforcement communities;
- Developing linkages with other localities and the state public health department.

In addition to developing an "urban strategy" and related template, CDC should provide local public health departments with financial support to design a local bioterrorism system based on the template, develop a plan for creating their system, and then execute it. BPRP's plan to create a bioterrorism coordinator for each of the 50 states represents a good first step. Using the state coordinators to link BPRP with local health departments, planning grant recipients should be required to specify objectives related to each of the items listed above and develop operations concepts to achieve them. While planning and organization provide the foundation, CDC must also allocate sufficient resources to build local capacity for detection, assessment, and response. Grant recipients should begin with city and county public health agencies but also include hospitals, clinics, and other local partners.

While CDC is working closely with national public health organizations, many members of the public health community at the state and local level have expressed apprehension regarding CDC's proclivity to provide operational guidelines and information without being sufficiently receptive to suggestions or concerns from state or local public health officials. One example that has been mentioned frequently is CDC's reluctance to allow laboratory technicians to alter laboratory testing protocol text because of the requirement for a standard protocol to facilitate criminal prosecution. In addition, some states have asked for greater flexibility in

grant execution, specifically the ability to move funds between different focus areas which would facilitate grant execution in the context of state or local procedures for hiring new employees or obligating funds.

Many localities feel that their suggestions have received a lack of attention and perceive a top down approach to preparedness building. But given the large number of entities with whom CDC must deal, it is easier for an organization of CDC's size to disseminate information to a large number of people and organizations than it is to receive and assimilate information from the same number of recipients. This tendency is only reinforced by a lack of personnel within the Bioterrorism Preparedness and Response Program Office, given the scope and importance of the work it does.

In administering the federal grants process, BPRP has played an integral role in coordinating and providing guidance to local public health entities and coordinating national organizations and associations with expertise on the BT challenge, but more could be done. Much of the time BPRP's small staff is consumed with providing guidance to local entities on the grants process, making BPRP largely an administrative office for federal grants rather than a central focal point of all bioterrorism-related public health and medical activities. Instead, BPRP relies heavily on national organizations to provide guidance on more technical issues related to preparedness, a reliance that results in the dilution of BPRP's overall coordinating function and often sends mixed signals to local entities about where their first point of reference should be.

BPRP has done an excellent job in coordinating with national organizations that represent the public health community. This includes work done cooperatively with national organizations like the Association of Public Health Laboratories (APHL), the Association of State and Territorial Health Officials (ASTHO), the National Association of City and County Health Officers (NACCHO), and the American Public Health Association (APHA). These organizations are an important part of BPRP's strategy for building preparedness for a number of reasons:

- They provide CDC with a large pool of expertise and knowledge about the practice of public health at the state and local level;

- They provide CDC with a feedback channel on the process of grant implementation and on the types of improvements taking place because of the grants;
- They have been a source of information regarding the current status of the system and provide the institutional memory of how pre-BPRP efforts to improve public health have fared.

Early in the execution of the bioterrorism preparedness program CDC recognized the value of these organizations and worked to develop strong partnerships with them. CDC and APHL have developed a good relationship in developing the Laboratory Response Network, and both ASTHO and NACCHO have worked in closely in developing and administering the public health portion of the Department of Justice's vulnerability and needs assessment. In addition, CDC, through the Public Health Practice Program Office, has supported an exemplars program in which three local public health departments are working closely with NACCHO to continually assess the execution of their CDC bioterrorism grants and the progress in their functional improvements. Continued partnership with these organizations will only benefit preparedness efforts.

Many local public health officials have expressed a need for a "national clearinghouse" for bioterrorism-related issues, a focal point to receive questions and comments, and provide information and guidance, or a hub through which local entities can communicate across jurisdictions about preparedness-building experiences. As one local public health official put it, "On a number of occasions when I have had questions about surveillance initiatives or prophylaxis issues I called Annie Fein in the New York City Department of Health. She has been dealing with these issues for years and has been very helpful by sharing her wealth of knowledge, but she is also very busy and cannot be expected to answer my questions every time they arise."

BPRP should perform this "clearinghouse" function for information on activities of the states and localities dealing with the public health and medical dimension of bioterrorism preparedness and response. At the present time, however, it has little time for providing this service. With a larger staff, BPRP could act as a clearinghouse for bioterrorism public health and medical related issues. This would make them more responsive to local needs.

First, it would facilitate communication not only in the direction of BPRP to local entities, but provide a mechanism for BPRP to listen and respond to the concerns of local entities. Second, BPRP could provide an extremely valuable service by assembling information – MMRS plans, Bioterrorism Response Plans, laboratory protocols, and general lessons learned – from all those entities involved in bioterrorism-related public health and medical activities. Depositing this information a single place for distribution among many jurisdictions is a much more efficient and less confusing pathway for information flows than forcing local entities to connect to many, many different informational sources.

One mechanism for providing this function is through an expanded BPRP web page. At present, the BPRP web page provides very little substantive information for local public health and medical officials. Providing materials such as hospital BT facility templates, BT Response Plan templates, educational materials for primary care physicians, and general lessons learned from experiences in other locales when preparing for bioterrorism would be useful to officials currently in the midst of BT planning activities.

The BPRP web page should also be used as a central depository for all public health and medical informational materials. Protocols for laboratory technicians who analyze BT samples are currently provided on the APHL website, while pharmaceutical and epidemiological information is difficult to find anywhere. The BPRP website should become the definitive website on public health and medical related BT activities. This will reduce confusion about where to find BT materials and will ensure quality control of the materials that are being provided.

BPRP is embarking on a concerted outreach and education program that is aimed at critical constituencies for building BT preparedness. These efforts should be strongly supported, as should its plan to raise awareness of public health and medical dimensions of the bioterrorism issue on Capitol Hill. While many senators and representatives are increasingly aware that bioterrorism could represent a serious national security threat, few know the intricacies of this threat or of the response to it, especially the public health and medical responses. While Congress has many members who are well schooled in national security

affairs, only a single member is a medical doctor and only a handful are well versed in public health issues. Some concern exists that bioterrorism is the "policy issue of the month" in Washington and funding for building bioterrorism preparedness will quickly dry up when some other "hot" issue appears. **BPRP should develop and implement a strategic plan to educate lawmakers about the importance of both BT issues and public health more broadly to ensure that efforts that are currently underway will be sustained financially into the future.**

Aside from lawmakers on Capitol Hill, **BPRP could target educational efforts at hospital administrators and training centers, such as the Noble PHA Training Hospital,** who have largely escaped involvement in BT preparedness activities, the media, and international entities because BT may be a foreign threat or a domestic one.

PART III

General Conclusions and Recommendations

This Part offers conclusions and recommendations based on the assessment of the bioterrorism threat and its relationship to the function and organization of preparedness and response efforts. In addition to the specific recommendations related to each of the functional areas discussed in Section I of Part III, this discussion formulates a series of general recommendations on the HHS's and CDC's bioterrorism preparedness program based on how the nature of the threat shapes each function in an integrated bioterrorism detection, assessment, and response system.

For a number of reasons, including technical difficulties and motivational issues, a catastrophic bioterrorism event is not the most likely contingency U.S. officials and the American people will confront. The number of technical pathways available for achieving a catastrophic bioterrorism incident is limited.

The technical pathways for producing a low to mid-range bioterrorism incident, however, are more numerous, less technically challenging, and fit better within the motivations and constraints of more traditional concepts of terrorism. Figure 3 shows a graphic representation. At the top of the pyramid rests the narrow set of high-consequence, low-probability bioterrorism attacks. Moving down the pyramid, the likelihood of attack increases, the severity of consequences decreases, and the number of technical pathways increases.

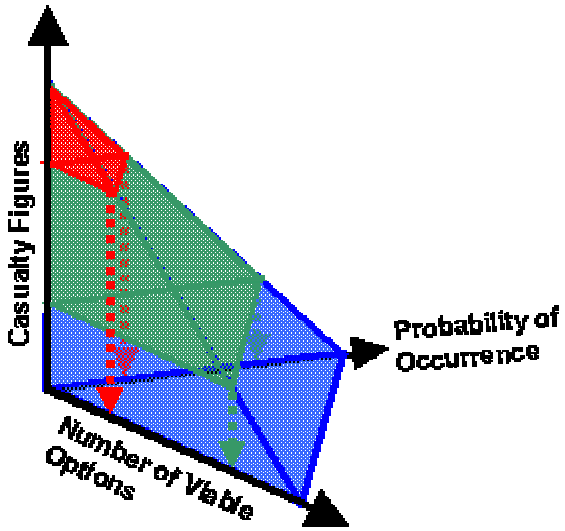

Figure 3 – Graphic Representation of the Bioterrorism Threat

This threat analysis shapes the nature of the public health and medical response at a number of key points. The first issue is which segment of the pyramid is the basis for HHS and CDC planning and preparedness. Today, the answer seems to be the top section in which the driving factor is the potential of some agents to create catastrophic casualties even though such scenarios are less probable than other types of incidents. It is assumed that preparing for the high-end attacks provides a capability to respond to the middle and low range attacks. But in certain areas, this assumption does not necessarily hold true. Examples include:

- Providing doctors and nurses with only the training to recognize and treat the list of top three or four agents defined by their casualty potential;
- Conducting training, and providing protocols and reagents for a limited set of threat agents to laboratories;
- Developing the National Pharmaceutical Stockpile based on the treatment and prophylaxis requirements for a large-scale attack using the most lethal agents, including large expenditures of resources on stockpiling large quantities of smallpox vaccine; and
- Drafting local-area response plans with a focus on massive response capability with little attention provided to responding to low or middle range attacks.

Focusing planning and preparedness on the set of high-end attack scenarios may simplify planning and preparedness efforts by narrowing the range of types of scenarios against which a capability should be developing. But, as the examples listed above begin to demonstrate, preparing for the high-end attacks provides some level of preparedness against a narrow set of contingencies at the risk of being unprepared for the most likely scenarios, or inappropriately responding to a low or middle range incident in a massive fashion. Such a response could produce the severe social disruption and psychological impact many terrorists look to achieve.

The low probability of “catastrophic” bioterrorist events, however, is no reason for complacency. Events that produce lower levels of casualties, which are far more likely, will also stress response systems severely, particularly at the local level. Moreover, the psychological impact of any attack is hard to estimate, and it could be profound.

The Need for Flexibility

This analysis suggests that HHS and CDC must shift their planning assumptions from an emphasis on preparedness for the narrow set of high-end bioterrorism incidents to preparedness for the wider array of low and middle-range attacks while hedging against the possibility of a high-end attack. This shift in emphasis entails improving the nation's public health and medical system in such a way as to promote robust awareness and assessment tools as well as flexibility within the response system. Robust awareness capabilities will increase the likelihood of early detection; effective assessment tools allow for proper characterization of the event; and flexibility gives the system the ability to react to incidents according to their actual nature.

Emphasizing flexibility imposes the need to alter planning and programmatic activities in a number of areas. Greater emphasis, for example, should be placed on developing response systems that are flexible and scalable according to the nature of the agent utilized and the number of people affected. Scalable response capability provides the ability to tailor the type and size of response to the type and size of attack. Importantly, increased flexibility and scalability allows the response to change over time as the event unfolds.

Improving flexibility and scalability requires execution of a number of specific planning and preparedness initiatives. Local and federal response plans should take a tiered approach that links a range of casualty figures with certain actions. Specific response capabilities should also be constructed along the basis of this tiered approach. Local response capabilities should be bolstered to be capable of responding to a certain level of casualties with a combination of regular treatment capabilities and the establishment of secondary treatment mechanisms when regular capabilities become overwhelmed. Flexibility and scalability should also be built into state and federal assistance capabilities for those incidents that overwhelm local capacity require additional assistance.

Increasing flexibility increases the demand for effective detection and assessment tools. Such robust tools facilitate early and effective intervention. Early detection and intervention decreases the burden placed on response capabilities by increasing the effectiveness of

prophylaxis while simultaneously decreasing treatment requirements. Robust assessment tools provide the ability to tailor the response to the incident by identifying the agent utilized and the group of people who are likely to have been affected by the incident. Without these tools, it is impossible to assess the nature of a bioterrorism incident and impossible to calibrate the response to the attack. In situations in which detection and assessment capabilities are weak, all bioterrorism incidents are likely to be treated as high consequence incidents if they are detected at all to eliminate the possibility of some potential victims having not been provided with appropriate care.

Promoting flexibility and scalability will enhance the ability to deal with tensions inherent in the current system between the need to initiate treatment and prophylaxis as quickly as possible and the need to know the nature and extent of an attack before mobilizing a massive response. Thresholds need to be built into the bioterrorism response system to avoid a massive response to a limited, localized incident, especially given that the most likely bioterrorist contingencies are likely to produce casualty levels that do not require mass prophylaxis or treatment. Because a smaller-scale bioterrorism attack may be indistinguishable from a large-scale attack early on, however, giving priority to assessment tools is essential to determining the scope of a bioterrorism attack to guide a response that is proportional. Without these tools, officials will be prone in an atmosphere of uncertainty to initiate mass prophylaxis just to be on safe side.

A three-part response system might be contemplated to achieve flexibility and scalability. The first inclination of a suspicious outbreak should trigger an *initial response phase* and should alert hospitals and physicians and other response personnel, require doctors to take culture samples, seek laboratory diagnosis, and notify the appropriate federal, state, and local authorities. It should also mobilize all available assessment tools, including federal assessment assets, to characterize the nature of the attack and identify available medical resources. A *mobilization response* may be needed when larger numbers (approaching 100 or more) of patients present, or when awareness and assessment tools indicate that an attack was fairly substantial. At this point, medical resources may need to be transported to care facilities that are receiving the bulk of patients and limited prophylaxis and treatment options may be exercised in

localized areas where the attack is suspected. A *large-scale response* should be initiated when it becomes apparent that the attack is widespread. Considering the current nature of the bioterrorism threat, staggered response thresholds are necessary to ensure that the system does not overreact to what is most likely to be a lower-impact attack.

Another example of improving flexibility and scalability is the design of the National Pharmaceutical Stockpile. The eight push packages are uniform in size, contents, and design. In lower-consequence, higher-probability incidents, the whole push package will be deployed, but it is unlikely that everything, or even most things in it will be needed. The resulting waste is not only expensive but could leave the country open to additional attacks. One approach would be to make the individual packages more modular, allowing them to be tailored to the type of incident, but this may increase deployment times to unacceptable levels. The other approach is to maintain uniformity among the packages, but further subdivide them into a larger number of smaller packages. This approach could increase the scalability of the amount of medicines and equipment deployed to an incident while decreasing transit time.

The Importance of Information and Communication

Flexibility depends in large measure upon providing the right people with the right information at the right time. A robust information infrastructure underpins all of the components of an effective response system. Surveillance, epidemiology, and laboratory capacity depend on information infrastructure both in terms of capacity building -- training, networking, sharing ideas and lessons learned, and development and exchange of procedural guidelines -- and day-to-day execution. Coordinating the providers, materials, and recipients during the response to a bioterrorism incident requires robust information and communication infrastructure. Importantly, integrating detection, assessment, and response components into a system depends on developing the necessary social and technological information infrastructure to provide accurate information in a timely manner. Tightening the integration between the detection, assessment, and response will increase the system's capability to detect and assess bioterrorism incidents and then calibrate the response according the assessment.

The Value of Public-Private Partnerships

Accomplishing many of these objectives will require cooperation between the public and private sectors. There are key preparedness activities in which the private sector should play a role, but other preparedness activities should not burden the private sector, especially those that are only relevant in the event of a massive response to a large-scale attack. At present, the threat of a large-scale attack is low, and asking the private sector to assist in preparing massive distribution plans for medications or to maintain unnecessary surge capacities for this contingency is unreasonable.

On the other hand, there are key preparedness activities from which the participation of the private sector would greatly benefit. Surveillance is one area in which the private sector should become more involved. Health Maintenance Organizations should be encouraged to permit physicians to request laboratory culture analyses on a more routine basis, but HMO's cannot be expected to pay for hospitals to maintain surge capacities to absorb casualties from a large-scale bioterrorist attack. Likewise, private laboratories and hospitals, work places, pharmacies, etc. have a wealth of data to provide a surveillance system, and the more data sources that are integrated into the surveillance system, the better public health awareness will be. Given that surveillance is critical for providing the overarching response system with awareness, private sector participation in surveilling should be encouraged over participation in response measures that will only apply in a mass casualty attack.

It is these types of measures, the kinds that are flexible and relevant for dealing with the range of bioterrorist contingencies as well as natural outbreaks, that must be emphasized when building preparedness, at least initially. Having a massive capability to respond to a bioterrorist attack is not as useful at the present time as having a less robust response capability but good awareness and assessment tools that can detect an outbreak early, characterize it, and guide the response system effectively.

The time frame over which preparedness efforts are made is important to keep in mind. Not everything can be done immediately. The key question is what is given priority today and,

as improvements in key sectors are made, what shifts in priorities can be contemplated. In essence, emphasis must be placed at the outset on building the "front-end" of the bioterrorism response system. As those capabilities are enhanced, efforts can then begin to focus more intensively on other capabilities, such as treatment requirements.

Achieving a robust health and medical response capability will require the successful exploitation of all available information and tools. One item in this regard is the DoJ needs assessment.[1] The data provided by the assessment is extremely comprehensive and could be very valuable as a tool for state public health departments to identify gaps in public health and medical preparedness and direct resources to their most efficient possible use. In addition, the data should be used as the basis for establishing more concrete cooperative agreements between public and private sector entities to aid one another in responding to a bioterrorist attack.

At the federal level, data from the assessments should be a used not only as a tool for determining the best allocation of resources to build bioterrorism preparedness, but also to raise awareness about the degree to which the nation's public health system has been degraded. Given a growing interest in public health on Capitol Hill, in particular the Frist-Kennedy sponsored Public Health Threats and Emergencies Act of 2000, the DoJ survey may give lawmakers some ammunition to reinvigorate public health capacity across the board. Therefore, it is important that the public health community, primarily HHS or CDC, have a central role in analyzing the public health and medical data compiled by the survey to ensure its accurate and credible interpretation.

Having identified the public health and medical requirements for responding to bioterrorism, HHS and CDC must elaborate a viable strategy – especially an "urban strategy" – for building public health and medical capacities for meeting the bioterrorism challenge. Given the nature of today's threat, a bioterrorist attack is likely to be a limited event for which local authorities will have primary operational responsibilities. Therefore, a strategy should take a "bottom up" approach that recognizes that the federal role in responding to a bioterrorist attack

[1] The DoJ needs assessment is a questionnaire provided to public safety and state public health departments to compile baseline data on local capacity for responding to bioterrorism.

will depend on the severity of the attack, and for this reason the delineation between local, state, and federal responsibilities should be clear. The strategy should, above all, articulate how priorities and programs will be integrated into a holistic system in support of public health and tie capacity building to a timeline for achieving these objectives.

RECOMMENDATIONS

Surveillance:

- CDC must devise a program for developing a national health surveillance system to provide early warning of bioterrorism incidents. A national system would integrate federal, state, and local public health departments, health care providers, and non-traditional surveillance partners such as local pharmacies, emergency medical services, and the veterinary community.

- The first step toward the creation of a national system would be the development of a national strategy for building such a system. The strategy would examine the feasibility, determine the requirements, and design a multi-year program for creating the system.

- Surveillance systems should establish and integrate automated disease reporting systems, syndromic surveillance systems, and automated data reporting systems from non-traditional partners.

- Developing a national health surveillance system to detect bioterrorism incidents requires the establishment of electronic data networks between local public health departments and local area health care providers.

- CDC should establish a separate surveillance grant program and work with Congress to ensure adequate funds are available to build the necessary information infrastructure.

- Local providers of surveillance information, including health care providers, should not be expected to use their own resources to develop the required communication infrastructure.

- Mechanisms should be established to provide the necessary surveillance information without compromising proprietary or confidential patient information. An important element of the solution is enforcement of federal regulations for patient data confidentiality. Another is development of technological solutions for parsing data to compile general and statistical information without association with specific patients, customers, or businesses.

- A national research and development program focused on improving surveillance technologies should be initiated.

Epidemiology:

- Developing better disease surveillance systems bolstering epidemiological staff in state health departments to manage surveillance functions are critical.

- The labor-intensive nature of epidemiology requires that more funding be provided to state departments of health to hire additional epidemiological staff. This should be a priority focus area for building assessment tools that can make the response more focused and efficient. In rural states, this capacity should be built at the state level. In mixed urban and rural states, urban centers should maintain a robust epidemiological capacity to deal with incidents in that city, but efforts must be balanced with state efforts to develop a state-wide capability.

- The CDC should emphasize a wider range of bioterrorism agents than those that currently receive most of the attention. Greater awareness of the range of bioterrorism agents should be better conveyed to epidemiologists.

- Thresholds for triggering particular responses should be defined to avoid unnecessary "hair trigger" responses. The first inclination of a suspicious outbreak should trigger an *initial response phase* -- alert hospitals and physicians, require doctors to take culture samples, seek laboratory diagnosis, and notify the appropriate federal, state, and local authorities. *Large-scale mobilization* of the response system should require that a second threshold be crossed, for example, laboratory identification of the etiologic agent representing an imminent public health threat or the accumulation of surveillance data that indicates such measures are necessary.

- Local departments of health need funds to make use of, and integrate, information technologies that can be used to collect, deposit, analyze, and share surveillance and epidemiological data from a central location in the department of health.

Laboratory Requirements:

- Physicians must be encouraged to take cultures and request laboratory analyses on a more routine basis to ensure that something unusual is not underway, especially if patients are presenting in large numbers or with flu-like symptoms out of flu season.

- The LRN must expand its network of Level A laboratories and better integrate food, water, and veterinary laboratories to ensure that diagnostic capabilities for the range of bioterrorism agents are available.

- The CDC should continue to provide funding through the federal grants process to build advanced laboratory capacity at the state level.

- Level B and C laboratories need to continue to upgrade their capabilities, including increasing the range of potential bioterrorism agents that they are capable of positively identifying, so as to reduce their dependence on the CDC laboratories.

- State laboratories should also bolster their ability to test for microbial sensitivity and determine whether a particular medication will be effective against the given agent.

- The CDC's Rapid Response and Advanced Technology laboratory (RRAT) should continue to expand its technical capacity for rapidly diagnosing critical agents as well as a broad range of potential bioterrorism agents that may be used in an attack.

- Technology-based training is continuously needed.

- Training for laboratory technicians is needed to expand their awareness of the range of potential bioterrorism agents.

- Laboratory technicians at all levels, particularly in Level A laboratories, should receive awareness training and proficiency screening for issues related to bioterrorism.

- Laboratory communication and information infrastructure should be bolstered.

- Funding is needed to renovate or redesign laboratory floor plans to ensure the best use of space and to accommodate additional equipment and personnel.

Medical Management:

- Localities should develop prophylaxis and treatment plans that are phased or broken into escalatory segments.

- A pre-incident plan for where triage will take place needs to be in place before an event. A public information strategy should be devised in advance of an attack that will provide clear and accurate information about when treatment is required and where it should be received.

- Localities should be provided with the resources needed to develop an independent first-tier prophylaxis capacity within local medical care providers, either through mutual aid agreements or regional buy-ins, to allow for a comprehensive response in the 48 hours before federal aid arrives.

- Arrangements for counseling patients should be made to reduce panic and confusion at triage points and to ensure order.

- Agreement must be reached in advance about who can make triage decisions in the event of a bioterrorist attack, and the medical and legal ramifications of these decisions need to be considered.

- Some thought might be given to providing certain segments of the population with pre-event prophylaxis.

- To ensure efficient use of local resources, a tracking system should be set up to track the movement and use of medical supplies during a bioterrorism response.

- As a hedge against a possible smallpox incident, the current supplies of vaccine should be readied for a rapid, mass prophylaxis program and a surge vaccine production capability should be established.

- Additional planning is needed to determine how the state and federal government can provide additional manpower in support of prophylaxis and treatment as a hedge against large-scale bioterrorism incidents. Given the size of its available manpower base and its logistical capabilities, the Department of Defense should lead this effort.

- Improved evaluation methods, including the development of computer simulations, must be developed to assess the adequacy of local prophylaxis and treatment plans.

- Local plans for prophylaxis should recognize and account for additional state and federal assets that will be made available by planning for how these assets will be utilized.

Training and Education:

- Properly training medical, public health, and emergency personnel is essential to a comprehensive detection, assessment, and response framework.

- The Domestic Preparedness Program should place a greater focus on health and medical response issues, and training should be adapted from HAZMAT criteria to focus more closely on procedures dealing specifically with biological weapons response, including agent and outbreak recognition and treatment measures. Training should focus on “big picture” response, incorporating integrated response issues, communication, surveillance, and reporting.

- Efforts must be made to attract medical personnel to training sessions. Greater emphasis should be placed on flexible training sessions and the exploitation of electronic and multimedia training techniques to accommodate the schedules of

health care practitioners. A good first step is making DP training materials available through the internet.

- Medical personnel should be involved with the planning of local, state, and federal government response efforts.

Information and Communication:

- CDC and other federal agencies should further emphasize the need for improved information infrastructure and actively work to provide state and local partners with both the necessary financial resources and the consultative expertise to build a truly national public health information network that includes traditional local public health agencies, as well as other key bioterrorism preparedness and response partners like federal and local law enforcement entities.

- The keys to developing a national BT preparedness and response information infrastructure are making sure the individual components and initiatives already in train are able to meet key requirements, defining and implementing new initiatives where gaps exist, and then working to integrate the various technical communication systems into an effective network.

- In order to ensure interoperability of their communication systems, health departments, hospitals and other primary care givers, and public safety agencies need to be contacted and consulted throughout the process of developing such standards.

- Federal departments and agencies must coordinate their various information infrastructure-building initiatives to ensure the communication systems they are supporting are integrated and interoperable.

- During the initial years of CDC's bioterrorism preparedness effort, special emphasis should be provided to the HAN program to include increased funding allocations for building upon information infrastructure.

- The Bioterrorism Preparedness and Response Program Office should establish an information sharing and outreach branch within the office.

Federal, State and Local Preparedness & Response:

- Current and future WMD preparedness initiatives should make a conscientious effort to distinguish more clearly between chemical, biological, radiological, and nuclear terrorism, with particular attention to how the response requirements for bioterrorism differ from the others.

- Given their familiarity with the local geography, resources, and personnel, local authorities should play a significant role in response management. Command and

control of a bioterrorism incident should be shared between federal and local entities, and capabilities should be built by recognizing the differing strengths of the two levels.

- Bioterrorism planning related activities should be administered at the state level to ensure that not only "metropolitan proper", but the surrounding municipalities and suburbs are included in planning activities. The Bioterorism Preparedness Plan contracts currently included as an annex to the MMRS emergency response plans should be developed at the outset. Some level of federal follow-on funding is required to sustain bioterrorism planning activities to ensure that the current level of communication and interaction between the local health and medical and public safety communities continues.

- Planning and coordination activities at all levels need to pay special attention to the challenge of integrating hospitals into the bioterrorism response system. A federal Task Force or Working Group should be established to identify the challenges that hospitals face in becoming integrated in the bioterrorism response system, and to devise some realistic solutions for overcoming those challenges. Federal grants for building public health and medical capacity for responding to bioterrorism should be extended to a sixth focus area aimed at hospitals.

- Public health must be more fully integrated into the command and control infrastructure at the local level.

- Roles of the federal government versus the state and local government need to be examined and clarified to prevent confusion. Responders at all levels must continue to resolve intergovernmental issues, including minimizing redundancy among federal, state and local efforts and eliminating confusion at the recipient level.

Public-Private Partnership:

- Government must work with the private sector to ensure they become a full partner in the bioterrorism preparedness activities. The sectors of greatest importance are the health care industry, the print and electronic media, the pharmaceutical industry, and the information technology sector.

- The health care industry is an especially important private sector partner in bioterrorism preparedness. As such, federal government officials need to focus on integrating the health care sector into bioterrorism efforts. One idea for a first step, both as a means of demonstrating political commitment and fostering an improved dialogue, is a national summit on the medical dimensions of bioterrorism preparedness.

- Because the media will serve as the main interface between the government and the public before, during, and after bioterrorism incidents, a media strategy for bioterrorism and other disasters must be integrated into counterterrorism efforts.

- HHS and CDC should strive to become the recognized governmental "authority" regarding medical and health issues associated with BT, preparedness, and response. They must take a more active role in developing strong relationships with the media to better inform them on the technical aspects of public health practice and biological terrorism.

- Through the Health Alert Network Program, CDC should work more closely with the information technology sector to build public health information infrastructure and exploit information technology to improve bioterrorism preparedness and the practice of public health more broadly.

Centers for Disease Control and Prevention:

- CDC planning assumptions should shift from the narrow set of low probability, high consequence events to the array of more likely middle and low consequence incidents while maintaining a hedge against high-consequence incidents.

- For each component of the bioterrorism detection, assessment and response system, CDC must clearly define the operational capability requirements the respective component should be able to meet.

- In its programs, BPRP must place greater emphasis on developing the "front-end" of the system – surveillance, epidemiology, and laboratory response – to ensure the creation of a robust ability to both detect and assess suspected bioterrorism incidents.

- CDC must develop an "urban strategy" for supporting the organization of local-level partners - public health departments, public safety organizations, medical care providers, and non-traditional partners - into county and municipal systems for bioterrorism detection, assessment, and response.

- The Bioterrorism Preparedness and Response program Office should be elevated to the level of the Office of the Director at CDC and be provided with budgetary authority over CDC's bioterrorism preparedness initiative. This move will provide BPRP with the necessary leverage to manage the direction, integrate, and, when necessary, adjust public health and medical bioterrorism programs at the CDC.

- Senior leadership at Health and Human Services needs to better coordinate CDC's Bioterrorism Preparedness and Response Initiative with the Office of Emergency Preparedness' disaster preparedness initiatives.

- BPRP should be serving an information “clearinghouse” function and embark on a concerted outreach and education program that is aimed at building critical constituencies for BT preparedness.

- BPRP should develop and implement a strategic plan to educate lawmakers about the importance of both BT issues and public health more broadly to ensure that efforts that are currently underway will be sustained financially into the future.

APPENDICES

Bibliography

Site Visits and Interviews

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