NATIONAL HEALTH POLICY FORUM

Will the Nation Be Ready for the Next Bioterrorism Attack? Mending Gaps in the Public Health Infrastructure

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OVERVIEW – *This paper provides an overview of critical weaknesses in existing public health preparedness capabilities and discusses current policy initiatives to address these shortcomings. It examines developmental needs related to communication and coordination, information systems, laboratories, the development and distribution of vaccines and other countermeasures, emergency medical preparedness and response, and the public health workforce. The paper summarizes the current status of federal and state plans to respond to these developmental needs and touches on the future challenges likely to emerge as these plans are implemented.*

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The events of September 11 and the subsequent anthrax attacks revealed numerous weaknesses in the existing public health infrastructure. In recent years, many experts have made cautionary pronouncements regarding the condition of our nation's public health system and have voiced serious concerns regarding its ability to respond to threats such as emerging infections, bioterrorism attacks, and the increasing prevalence of antimicrobial-resistant strains of microbes. Despite these warnings, the general public and many policymakers did not fully appreciate these threats and the nation's state of unreadiness until the recent terrorist attacks. These events triggered an unprecedented infusion of federal funding for public health preparedness and stimulated policymakers to craft new authorities and funding mechanisms to support the nation's biodefense capacity.

In response to this sudden infusion of funds and heightened attention, public health officials at federal, state, and local levels are scrambling to assess preparedness and response capabilities, identify priority improvement needs, and implement program and personnel upgrades. The needs confronting public health are great, the timelines required for making critical investment decisions are short, and the stakes are high.

The extraordinary complexity of the public health system, which relies on a diverse web of federal, state, and local activities, further complicates efforts to bolster public health capacities. Not only will the opportunities for improvement vary across jurisdictions, but a variety of different strategies may be required to address perceived deficiencies. Therefore, achieving meaningful improvements will require a tremendous degree of sustained effort and coordination across all levels of government and among a variety of public- and private-sector partners.

While the recent press of legislative and planning activity offers the promise of improved public health preparedness, it remains to be seen if real progress will be achieved. Although good intentions and reasonable seed funding are now in place, a host of complex and seemingly intractable problems still need to be resolved:

■ Will funding go where it is most urgently needed, or will politics and existing power structures prevail and distribute resources regardless of real need and assessed risk?

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■ Can organizations break out of their traditional silos, overcome turf battles, and resist "business as usual" to develop new relationships, or will insularity prevent the true transformation of working relationships?

■ Can an appropriate balance be struck between responding to the threat of bioterrorism and ensuring an effective public health response to the health problems facing the nation on a daily basis, such as HIV/ AIDS and heart disease?

Although many of the gaps in the public health infrastructure may be fairly clear, resolving these and other fundamental questions regarding realistic priorities will determine whether the nation is able to address deficiencies and ensure an adequate state of readiness for the next bioterrorism event or other public health emergency. This paper seeks to summarize some of the critical weaknesses in existing preparedness capabilities, provide an overview of current policy initiatives to address these deficiencies, and explore the implementation challenges that lie ahead.

OVERVIEW OF CRITICAL GAPS IN THE PUBLIC HEALTH INFRASTRUCTURE

Although specific needs and priorities for infrastructure improvement are just beginning to be clarified and will likely differ across jurisdictions and levels of government, public health officials and other experts have identified a number of general deficiencies that must be addressed for the nation to improve its readiness capabilities.

Improving Coordination and Communication

Preparing for and responding to a public health emergency involves many stakeholders. The complex interactions that must occur across multiple agencies at the federal, state, and local levels, as well as interactions across levels of government, across jurisdictions, and with private-sector providers and businesses, create an almost overwhelming coordination and communication challenge. The most challenging dimension of these relationships is that they require collaboration among parties who, under normal circumstances, have limited—if any—interaction. Therefore, purposeful planning, established protocols, regular drills, and robust support infrastructure (for example, telecommunications) become critical.

The recent terrorist attacks brought to light significant concerns about communication capabilities at the local level; fire and rescue personnel, law enforcement officers, and public health officials soon found that their communications systems and operating protocols did not function well across organizational disciplines and jurisdictions. The recent crisis also revealed some level of uncertainty regarding which organizations should assume responsibility for which activities. The ambiguity of organizational roles is particularly pronounced during a

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bioterrorism event because, historically, public health has not been well-integrated into law enforcement or emergency planning and preparedness activities.

The need for improved coordination is evident at all levels of government. A recent study by the U.S. General Accounting Office documents the fragmentation of federal agencies and raises serious concerns about lines of authority and operating protocols.[1] Questions have also been raised regarding how well Department of Health and Human Services (DHHS) officials have been integrated into national security briefings and intelligence gathering efforts. Timely information related to threat assessments will clearly influence DHHS research and capacity-building priorities. Also, many experts and congressional leaders have suggested that the Centers for Disease Control and Prevention (CDC) and the Federal Bureau of Investigation (FBI) need to improve protocols for melding forensic and epidemiological investigations and should gain a better understanding of each other's methods and requirements. Resolving tensions and improving working relationships across federal agencies represent major challenges facing federal policymakers.

Less well-documented are concerns related to the coordination of federal and state authorities and responsibilities. The Dark Winter exercise held in June 2001 by the Johns Hopkins Center for Civilian Biodefense Strategies simulated a smallpox outbreak in the United States. A key finding of this exercise was that federal and state priorities may be unclear, differ, or conflict; and that relative authorities are uncertain. In the Dark Winter simulations, tensions rapidly developed between state and federal authorities. State officials wanted authority over decisions related to quarantine and vaccination, as well as control over state borders and transportation hubs. Federal officials argued that these decisions should be made on a national basis. Disagreements were recorded on whether or not to federalize a state's National Guard. As one participant noted, "We're going to have absolute chaos if we start having war between the federal government and the state government."[2]

Questions regarding the appropriate degree of federalism in preparing for and responding to a public health emergency are still unresolved. The Model State Emergency Health Powers Act, developed by the Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities, was funded by the CDC. Written as a model state statute, the act is largely silent on the federal role in responding to a public health emergency. It does include provisions that charge a state public health emergency planning commission with centralizing coordination of local, state, and federal resources and operations. But with its focus on the state level, the model act does not clearly establish the nature and scope of federal assistance. A comprehensive federal review of emergency powers has not yet been disclosed publicly, and a policy debate regarding the role of the federal government in responding to a public health emergency is just beginning to emerge.

> Questions regarding the appropriate degree of federalism in preparing for and responding to a public health emergency are still unresolved.

The challenges inherent in assuring state-to-state collaboration are also formidable. Nearly 25 percent of the U.S. population resides in a metropolitan area that straddles state boundaries.[3] An even greater proportion of the population relies on cross-state resources for health care and other service needs. Ensuring appropriate regional planning, coordination of investment and response decisions, and consistent approaches to information technologies will require a tremendous degree of interaction among states and may necessitate stronger federal leadership. Collaborating with tribal governments presents a different set of challenges and opportunities and necessitates extensive government-to-government consultations. These issues are likely to vary across states and among tribes, which may prefer to interact directly with federal authorities. Moreover, international coordination for border states will necessitate federal involvement.

Collaboration between states and local jurisdictions is also problematic. In some states, there is a serious tension at this interface, with poor working relationships between local and state officials. These tensions are sometimes most prominent between states and large municipalities that have fairly well-developed public health and emergency response infrastructures and that are accustomed to working with little support from state resources. Because each state has organized its public health system differently and has developed different types of relationships with local jurisdictions, the flow of federal funds, through states, and ultimately to local capacity building is likely to vary greatly.

Enhancing coordination with private-sector health care providers and philanthropic organizations is also a major concern. During the recent anthrax outbreaks, public health officials confirmed what they had already believed to be serious limitations in their ability to communicate quickly and effectively with private-sector physicians. Concerns have been raised that some public health officials are not able to send broadcast messages, either electronically or via fax, to alert local physicians about health emergencies. In turn, physicians complained that the information they received was not timely and was incomplete and sometimes conflicting. Communication with and among hospitals and other health care facilities is also believed to be inadequate.

Recognizing the importance of effective communication with the public is also essential. Experts have noted that public health does not have adequate plans, resources, or trained personnel to properly communicate the risks of a bioterrorism attack or other public health emergency.[4] Minimizing panic and, at the same time, providing substantive information to the public requires both tremendous knowledge and skill. Such capabilities are just as crucial to an effective public health response as the ability to identify the source of contamination or distribute appropriate countermeasures.

Enhancing Information Systems

Improved information technologies have been heralded as promising tools for meeting many of the coordination and communication challenges discussed above. Inadequate information and telecommunications capacities have been cited as a major weakness in the existing public health infrastructure. A 1999 National Association of County and City Health Officials (NACCHO) survey of local public health departments found that 80 percent of local public health agencies had e-mail capabilities. However, only 65 percent of jurisdictions serving less than 25,000 persons had e-mail capabilities. The same survey revealed that only 70 percent of local health agencies serving populations under 25,000 had access to the World Wide Web, and only 28 percent of those agencies had continuous, high-speed Internet access, a capability required for real-time alerts and instant messaging. Only 44 percent of all respondents had broadcast fax capabilities, a mechanism considered important for reaching physician offices.[5]

The CDC has established the Health Alert Network (HAN) program to enhance the telecommunications capacity of state and local health departments. The program provides state and local governments with both financial support to make information technology investments and technical assistance to guide state and local officials in implementing these investments. Although the national plan for HAN and other CDC information efforts includes an Internet backbone, hardware, secure Web sites, curriculum, distance learning, and media programs, some contend that the original needs were so great that much of the initial investment went simply to putting computers on health officers' desks.[6] Others have stressed the need for redundant capacities to ensure that back-up communications mechanisms exist in the event of a disaster that incapacitates primary systems.

Experts have also looked to emerging information technologies to significantly enhance public health response capabilities. Innovative new technologies currently being developed and evaluated include "syndromic" surveillance (that is, technology that allows the rapid identification of patients presenting with symptoms associated with bioterrorism or other public health emergencies, without first relying on the identification of a particular pathogen) and wireless information-management technology that can be used in the field to better manage the collection and processing of environmental and clinical samples. Also in the works are the development of widely accepted data standards and the expanded use of electronic, Web-based disease reporting from physicians and laboratories to improve reporting compliance and timeliness.

Expanding Laboratory Capacity

Better and expanded laboratory capacity has been cited as a critical need in improving the public health system's emergency response capabilities.

The Laboratory Response Network (LRN) was developed by CDC, the Association of Public Health Laboratories (APHL), and the FBI for the express purpose of improving bioterrorism response capabilities, but the capabilities developed by the LRN have broader applications. The LRN is composed of county, city, state, and federal public health labs, and the network can accept samples from hospitals, clinics, the FBI, and others.

The LRN is divided into four levels: (*a*) Level A labs are primarily hospital-based laboratories that can rule out specific agents from clinical specimens and forward organisms or specimens to higher-level public health laboratories; (*b*) Level B labs represent the core public health lab capacity maintained by state and large local health departments and are able to rule in specific pathogens and perform environmental sampling; (*c*) Level C labs have more advanced capacity and can perform rapid-detection molecular typing for comparison; (*d*) Level D labs can detect genetic recombinations, can "bank" the isolates identified, and possess high-level biocontainment facilities. Level D labs represent highly specialized federal laboratories with unique capabilities.

Despite these efforts to better organize and systematize lab resources, the recent anthrax attacks revealed serious deficiencies in the nation's lab capacity. In addition to testing a high volume of environmental samples that represented credible anthrax threats, labs were inundated with hoaxes and other "white powder" samples. At the peak of the anthrax event, public health laboratories in the LRN were testing over 1,200 powders a day.[7] The lab at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), a Level D laboratory, processed over 8,200 samples between September 11 and late November. As Edward M. Eitzen, commander of USAMRIID indicated: "It is my perception that the nation needs considerably more diagnostic capacity, and the LRN needs to work better. The A, B, and C laboratories should be able to handle most samples, and the D laboratories should be used for confirmation and difficult or high priority analyses."[8]

Some experts have suggested that improved partnerships with private-sector labs, such as hospital labs and laboratories maintained by pharmaceutical companies, are needed to create the "surge" capacity required during a public health emergency. The National Laboratory System (NLS), a cooperative initiative of the CDC and APHL, seeks to strengthen relationships between independent clinical labs and public health labs, both to develop surge capacity and to improve compliance with disease reporting requirements.

In addition to needs related to expanding the sheer capacity of the nation's laboratories, concerns have also been raised about laboratories' technological capabilities. Experts have called for the accelerated development and dissemination of rapid diagnostic and detection tests to identify the presence of specific pathogens in clinical specimens or environmental samples. As Mary Gilchrist, director of the Iowa public

"The nation needs considerably more diagnostic capacity."

health laboratory and president of APHL, points out, "The testing of samples during the fall bioterrorism outbreak was primarily conducted using conventional methods, culture and staining. These tests are relatively accurate, but speed [of diagnosis] is often important and the culture requires 2–3 days to produce a final result."[9]

Some have argued the need for a dedicated high-throughput laboratory focused on bioweapons agents, which would enable exhaustive molecular fingerprinting for a broad spectrum of known threats. Such a lab could be configured to provide full chain-of-custody support in a criminal investigation and could operate both a "closed" compartment, available to homeland security agencies, and a separate "open" compartment, available to the scientific community.

Concerns have also been raised regarding the adequacy of security at laboratory facilities that store and process hazardous microbes and chemicals. Traditional laboratory biosafety guidelines have emphasized good work practices and containment to minimize the risks of *accidental* infection, injury, or environmental contamination. As early as 1999, however, the CDC issued guidelines to focus attention on the security issues associated with the *intentional* removal of select agents from laboratories.[10] While these guidelines have been in place for several years, there is widespread recognition that additional measures will be needed to ensure appropriate levels of laboratory security, including better monitoring of labs and personnel with access to dangerous agents and improved tracking of microbial stock transfers between laboratories.

Improving the Development and Distribution of Countermeasures

Prophylactic and therapeutic countermeasures, such as vaccines, antibiotics, antivirals, and antitoxins, are an important component of public health emergency preparedness and response. Research to improve existing countermeasures and develop new vaccines, therapeutics, and diagnostics is a high priority, with particular emphasis on the Category A bioterrorism agents[11] considered to be the greatest threat. Although the Department of Defense (DOD) has a large role to play in research related to bioweapons agents, significant differences between civilian and military populations call for a collaborative partnership with the National Institutes of Health (NIH). Because the civilian population is more diverse than the combat personnel upon which DOD research is focused—and includes children, the aged, pregnant women, and persons with compromised health status—attention must be given to the development of safer countermeasures with fewer adverse side effects. The NIH bioterrorism research budget has risen dramatically in recent years, increasing from $17 million in 1998 to an estimated $92.7 million in 2002.

While the development of new and improved countermeasures is clearly desirable and acknowledged as an important tool to counter bioterrorism,

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numerous challenges exist to meeting this goal. As Gail Cassell, Ph.D., vice president for infectious diseases drug discovery research and clinical investigation at Eli Lilly and Company, noted at a recent Institute of Medicine (IOM) workshop on biological threats and terrorism:

> It would be mistaken to be sanguine about current antibiotic therapies to counter bioterrorism. Nor can one be optimistic about near-term prospects. Eli Lilly recently conducted a competitive analysis revealing that most of the large pharmaceutical companies, with the possible exception of Pfizer, are reducing their investment in antibiotic development....There is a 90 percent failure rate from the discovery of a target to the launch of a new antibiotic. This lack of success has likely dampened further spending in this area.[12]

In addition to the high cost of research and development associated with antibiotic and vaccine development, the market for these products and other countermeasures is considered modest. Further impeding industry interest and investment in countermeasures have been concerns regarding product liability, as well as a recent Food and Drug Administration (FDA) decision that requires pharmaceutical manufacturers to use more patients in their clinical trials for most antibacterial products. Additionally, few organizations possess the biocontainment facilities required to safely perform efficacy studies of likely bioterrorism agents. Taken together, these factors add to the required investment and perceived risks associated with developing countermeasure products, resulting in a small number of manufacturers willing to participate in the vaccine and antibiotic markets.

The FDA has taken several steps to accelerate countermeasure availability and licensing. These steps include allowing emergency use of a product under investigational new drug (IND) status; "fast tracking" products to speed the approval process; and granting approval under the "Animal Rule," which will eliminate the need for human efficacy trials in situations where such trials would be infeasible or unethical. Conducting human efficacy studies on most types of diseases associated with bioterrorism would raise ethical concerns, as large populations of persons already suffering from these diseases are not likely to be available to participate in clinical trials. The Animal Rule would allow the use of data derived from animal studies to demonstrate product efficacy. Human clinical studies would still be needed to establish product safety and pharmacokinetics (that is, how drugs are processed by the body, as affected by uptake, distribution, elimination, and biotransformation.

While the development of new and improved countermeasures has received considerable attention in the scientific community, policymakers have also focused on ensuring the availability of existing countermeasures and the adequacy of distribution capacity to disseminate these products in the event of an emergency. A recent IOM study on civilian medical response to bioterrorism found that, with a few exceptions,

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drugs, antitoxins, and supportive medical equipment are available in very small quantities and that few locales will have adequate supplies for a true mass casualty event. The fiscal year (FY) 2002 appropriation included $593 million for expanding the National Pharmaceutical Stockpile. Some have raised questions regarding the need for a more direct federal role in the manufacture and distribution of some high-priority countermeasures to assure their availability. Others have voiced concerns about the capacity of the local public health and health care delivery system infrastructures to distribute countermeasures to large populations during an emergency.

Bolstering Emergency Medical Preparedness and Response

The medical response to a bioterrorism event or naturally occurring public health emergency obviously involves more than distribution of appropriate countermeasures. The recent terrorist events served to stimulate serious reflection among health care providers as they assessed their capabilities to respond to mass casualty events. However, thoughtful consideration had been given to these capacity needs well in advance of the recent tragedies. A 1999 IOM report, which focused on identifying a research agenda to improve civilian medical response to bioterrorism, identified a number of areas ripe for improvement, including: pre-event planning and communication, decontamination protocols and processes, mass casualty triage, availability of drugs and other therapies, and surge capacity for emergency treatments.

This study noted that, "Although hospitals are required by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to be prepared to respond to disasters, including hazardous material [HAZMAT] accidents, few have undertaken realistic planning and preparation. Some hospitals have decontamination facilities; however, very few have outdoor facilities or an easy way of expanding their decontamination operations in a mass-casualty event."[13] The communicable nature of many biological agents adds additional challenges to traditional HAZMAT approaches, requiring special attention to minimizing further disease exposures.

The resources required by health care facilities to respond to bioterrorism or other mass casualty events are likely to be significant. The American Hospital Association (AHA) estimates that over $11 billion will be needed to ensure that each of the nation's 4,900 acute-care hospitals are prepared for a nuclear, biological, or chemical attack. AHA identified eight key areas that must be addressed to increase hospital readiness: (*a*) communications and notification systems; (*b*) disease surveillance, disease reporting, and laboratory identification; (*c*) personal protective equipment; (*d*) facility requirements related to security, patient isolation, storage capacity, auxiliary power, and water purification; (*e*) dedicated decontamination facilities; (*f*) medical/surgical and pharmaceutical supplies; (*g*) train-

Over $11 billion will be needed to ensure all hospitals are prepared for a nuclear, biological, or chemical attack.

ing and drills; and (*h*) mental health resources.[14] The AHA has also called for improved regional planning, the identification of best practices, and a comprehensive review of existing regulations that could impede emergency response. Some critics have questioned the need to build significant capacities in *all* of the nation's hospitals and have advocated for much stronger regional planning and strategic investment to maximize the effective use of resources.

The readiness of physicians and other health care professionals to respond to a public health emergency is also widely believed to be inadequate. In May 2001, the American Medical Association's Council on Scientific Affairs updated its report on Medical Preparedness for Terrorism and Other Diseases. The report concluded that significant needs remain to prepare the civilian medical community for terrorism and other mass casualty events.[15] Priority needs emphasized in the report included the following:

■ Preparing physicians to identify the clinical signs of likely bioterrorist agents.

■ Improving disease reporting and health alert mechanisms.

■ Enhancing information dissemination related to risk assessment, triage techniques, treatment, and prophylactic protocols.

■ Expanding physician training on the mental health responses to traumatic stress in patients, caregivers, first responders, and other community members.

The council recommended that steps be taken to develop model medical education curricula, improve the timeliness and reliability of disease reporting, and increase the involvement of the medical community in preparedness planning efforts related to disaster and bioterrorism.

These recommendations provide important guidance, but a great deal of work remains to be done to meet providers' preparedness needs. The most effective ways to communicate information to practicing providers and to caregivers in training are still being explored. Furthermore, differences in needs across disciplines and professions are not fully known. Beyond training needs, significant policy issues related to provider malpractice liability in responding to public health emergencies and cross-state reciprocal licensing provisions in the event of emergencies are just starting to be confronted. Also, concerns related to the personal health and mental health needs of emergency responders are only beginning to be tackled.

Developing the Public Health Workforce

Although much of the current discussion on strengthening the public health infrastructure has focused on the development and deployment of improved technologies and countermeasures, the need for an adequate number of well-trained professionals prepared to respond to a public health

emergency is clearly critical. Human capital requirements are considerable. In addition to ensuring an adequate surge capacity for medical response and improving health professionals' ability to provide appropriate diagnosis, treatment and prophylaxis, maintaining epidemiological staff capacity to investigate disease outbreaks and assuring a sufficient number of trained laboratory personnel to conduct diagnostic testing are also essential.

While federal personnel resources clearly represent a safeguard for state and local governments, the adequacy of such federal assistance could be stretched quite thin in the event of a multi-site bioterrorism attack. Current disaster assistance models assume that the disaster will be limited geographically. However, a bioterrorism attack could result in multiple outbreaks throughout the country. In the three months following September 11, CDC made 213 individual field deployments of Epidemic Intelligence Service (EIS) officers to assist with state and local epidemiological investigations associated with the World Trade Center and anthrax attacks. Eighty-eight percent of EIS officers have been in the field at least once, and many have been deployed multiple times. If a larger-scale epidemic involving more geographic loci were to occur, existing federal support capacity would quickly be overwhelmed.[16]

Both "pipeline" education and ongoing training needs of public health practitioners have been identified as major weaknesses in existing preparedness capacity. Training needs range from basic instruction in epidemiological techniques to the development of better skills in communicating with the media. Public health officials also cite the need to practice their response capabilities through drills and "real world" exercises. Such simulations, practiced on a frequent basis, are viewed as critically important for building relationships with other disciplines and fields, such as emergency medical services (EMS), fire and rescue, and law enforcement, as well as clarifying organizational roles and responsibilities.

Concerns have also been raised regarding the most appropriate ways to leverage volunteer assistance in the event of an emergency. While proposals to better manage volunteer resources have largely focused on health care service providers (physicians and nurses, for example), some consideration has also been given to developing a "reserve corps" of epidemiologists who could be mobilized if a large-scale epidemic were to occur. Other training issues have focused on how to better incorporate other disciplines, such as veterinary medicine and environmental science, into surveillance activities.

STATUS OF INITIATIVES TARGETED AT BOLSTERING PUBLIC HEALTH PREPAREDNESS

While many of the weaknesses in public health and medical preparedness cited above have been recognized for some time, the recent terrorist threats have heightened the visibility and perceived urgency of

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addressing these deficiencies. These renewed concerns have triggered a variety of policy responses at all levels of government.

Federal Policy Efforts

Federal policy priorities for improvements in public health emergency preparedness are currently expressed through four major vehicles: (*a*) the bioterrorism preparedness authorizing legislation; (*b*) FY 2002 appropriations; (*c*) the president's FY 2003 budget; and (*d*) the planning guidance issued by CDC and the Health Resources and Services Administration (HRSA) to advise states as they prepare plans to secure FY 2002 funding. While other funding sources, such as grants from the Department of Justice (DOJ) and the Federal Emergency Management Agency (FEMA), also are likely to influence state and local planning, the four policy mechanisms listed above will be dominant in shaping efforts to improve public health and hospital preparedness. These policies offer slightly different, yet generally consistent, directions for upgrading public health capacities.

In May 2002, Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act to improve the nation's public health infrastructure. The act builds on the programs and authorities established in Title III of the Public Health Service Act as amended by the Public Health Threats and Emergencies Act of 2000. The act creates authorizing legislation for and expands the National Disaster Medical System (NDMS), the National Pharmaceutical Stockpile (NPS), and the federal smallpox vaccine purchase program, activities that had been carried out previously under DHHS general authorities.

The act calls for upgrading the CDC's facilities and capacities, establishes funding mechanisms to support state and local public health capacity, authorizes grants to support a coordinated network of public health labs, calls for research and development on vaccines and other countermeasures, and provides for fast-track FDA approval of countermeasures. The act also provides FDA with enhanced authorities related to food safety, including provisions related to prior notice for food importation shipments, prohibitions against port shopping (tht is, seeking admission at an alternative U.S. port after having been denied admission at the initial port of entry), and detainment authorities. The act gives the U.S. Department of Agriculture new authority to safeguard the nation's agricultural industry and includes provisions to protect community drinking water.

In FY 2002, Congress appropriated $3 billion to improve bioterrorism preparedness at the federal, state, and local levels, through both the FY 2002 Labor-HHS-Education appropriations bill and the emergency supplemental appropriations included in the FY 2002 Department of Defense appropriations bill. Taken together, these appropriations allocate funding under several broad categories, including $645 million for the NPS,

$512 million to purchase smallpox vaccine, $183 for NIH research, $116 million for CDC capacity building, $98 million for food safety, $47 million to support vaccine and drug approval, $940 for state and local public health preparedness, and $135 for hospital preparedness. The president's FY 2003 budget generally continues these funding levels for state and local preparedness, significantly decreases funding for the NPS and vaccine procurement (given these are not recurring expenses), and significantly increases funding for hospital preparedness and NIH research. The impact of the newly announced Cabinet-level Department of Homeland Security on public health and hospital preparedness efforts is currently unclear.

Both the FY 2002 Appropriations Acts and the Public Health Security and Bioterrorism Preparedness and Response Act establish broad legislative parameters for building state and local capacity, with an emphasis on flexibility to respond to local needs. Consistent with congressional intent, DHHS began making initial disbursements of FY 2002 funds to states in February 2002. Approximately 20 percent of total funding was made available for immediate use; the remaining 80 percent is being restricted until state work plans are submitted to and approved by DHHS. On February 15, the CDC and HRSA issued guidance to assist states in preparing their public health and hospital preparedness work plans.

The CDC guidance for the public health preparedness plans identified focus areas under which states could request support. These focus areas include preparedness planning and readiness assessment, surveillance and epidemiology capacity, laboratory capacity for biological agents, Health Alert Network/communications and information technology, health risk communication and health information dissemination, and education and training. The CDC has identified critical capacities for each focus area. For each of these critical capacities, the guidance instructs states to provide a brief description of existing capacity, an assessment of whether this capacity is adequate, and a proposal for effecting improvements during this budget period. The guidance requires states to work collaboratively with their local public health departments and encourages appropriate interstate and international cooperation.

The HRSA guidance for hospital preparedness requires states to submit applications in two phases. Phase 1 applications (due to HRSA on February 25, 2002) include information on how the planning effort will be staffed and governed, discussions of how the hospital preparedness plan will be coordinated with the public health preparedness plan, and a description of the approach to be taken in developing a needs assessment and implementation plan. At least 50 percent of Phase 1 funds must be allocated to hospitals and other health care entities. Phase 2 applications call for a needs assessment related to hospital and EMS bioterrorism response, an implementation plan that addresses (*a*) the first-priority issues of medication and vaccines, personal protection, quarantine, decontamination, communications systems, and biological

Current law establishes broad legislative parameters for building state and local capacity, with an emphasis on flexibility to respond to local needs.

disaster drills; and (*b*) second-priority issues of personnel, training, and patient transfer protocols. At least 80 percent of the funds awarded for Phase 2 must be allocated to hospitals through written contractual agreements. To ensure public health and medical response activities are well-integrated, the public health and hospital preparedness plans must be reviewed and approved by the governor of each state before they are submitted to DHHS.

State and Local Policy Efforts

Based on the guidance documents issued by the CDC and HRSA, state governments were charged with quickly assessing their needs and establishing a work plan for utilizing FY 2002 funds and anticipating further developmental needs for FY 2003 and beyond. In preparing these plans, states were asked to elicit the involvement and input of a wide variety of stakeholders, including local public health departments, hospitals and other health care facilities, and physicians and other medical professionals, as well as a host of sister government agencies, including fire and rescue, law enforcement, transportation, and agriculture. Intra- and interstate coordination were also concerns. The need to solicit the perspectives of so many organizations and individuals and to foster some level of consensus in such a short timeframe was clearly a challenge to state planners.

Many states previously had initiated planning efforts utilizing federal bioterrorism funding from FY 1999 through FY 2001 and, thus, had some organizational foundation upon which to build their preparedness plans. However, the magnitude of FY 2002 funding created a new set of expectations and challenges. State planners faced pressures from a variety of fronts, as multiple organizations, both private and public, looked to the preparedness funding to enhance their own capabilities. A number of contentious decisions on how to invest the new resources needed to be made. Some of the key questions facing states included:

■ How should funding be allocated across the focus areas identified in the federal guidance?

■ How much funding should be distributed directly to local areas, and how should resources be allocated across localities? How much latitude should local governments be given in investment decisions? To what extent should some investments, such as information technology upgrades, be made at the state level and shared with local jurisdictions?

■ How should funding decisions be integrated between the CDC and HRSA funding streams and with other funding sources (for example, FEMA, DOJ, state appropriated funds)?

■ How should traditional essential public health functions, such as sexually transmitted disease control, health education activities, and restaurant inspections be preserved as resources and staff are diverted to emergency preparedness activities?

A number of contentious decisions on how to invest the new resources needed to be made.

■ What practical steps need to occur to operationalize investment decisions?

It is not yet clear how states will establish priorities in their preparedness efforts or the extent to which priorities and strategies will vary across states. States are likely to receive some additional direction from DHHS before their plans are approved. Once approvals are granted and summaries of state proposals are made public, priorities for infrastructure improvement at state and local levels will be clarified. Even then, plans are likely to be nascent and will no doubt evolve significantly in subsequent years.

At the same time that governors and state health departments are formulating their plans for upgrading public health and hospital preparedness, state legislatures are considering legislation to expand public health authorities. While the federal bioterrorism legislation currently being considered does little to alter the fundamental scope and reach of public health authorities (with the exception of some significant food-safety provisions), state lawmakers are debating legislation that would significantly expand the powers of public health officials in the event of an emergency. At least 27 states have recently enacted or have pending legislation to grant new public health powers during an emergency. Many of these acts draw from the Model State Emergency Health Powers Act developed for the CDC. These emergency powers include provisions related to planning, disease surveillance, declaration of a public health emergency, quarantine, control of facilities and property, mandatory treatment, and the controlled disposal of infectious waste and human remains.

WHERE TO GO FROM HERE? IMPLEMENTATION OF PREPAREDNESS POLICIES

In the wake of this recent flurry of policy activity, the real work of upgrading public health readiness capabilities must now begin. The implementation challenges facing federal, state, and local public health officials and health care providers are significant. While the full range of challenges cannot be identified until implementation begins to unfold, some early concerns are already surfacing. These concerns include shortages of trained personnel to fill the hiring needs generated by capacity-building efforts, erosions in support and consensus as the perceived risk of a bioterrorism attack begins to ebb, and bureaucratic hurdles and turf battles that could slow infrastructure change.

With unprecedented levels of federal funding to support the public health infrastructure, questions have been raised about how best to ensure that these investments yield significant improvements in public health preparedness and response capacity. As states face looming budget deficits, some experts worry that federal funding directed at improving

bioterrorism readiness will merely supplant existing state contributions to the public health infrastructure. Others question whether states have the guidance they need to make wise investment decisions and, also, if states are motivated to work together to leverage their funding and better coordinate activities.

The Public Health Threats and Emergencies Act mandates the establishment of reasonable capacities for national, state, and local public health systems; ties grant funding to an assessment of these capacities; and requires that funds supplement, not supplant, existing federal, state, and local funding. The CDC is currently developing performance and capacity standards for public health. The National Public Health Performance Standards Program seeks to develop performance standards for public health for each of the ten essential services, collect data on compliance with these standards, and improve systemwide performance. Working collaboratively with the Department of Justice, the CDC has developed an instrument for public health performance assessment that focuses specifically on emergency preparedness. The Public Health Security and Bioterrorism Preparedness and Response Act requires states to develop response plans that detail the initiatives and programs that will be implemented to improve core capacities. While these efforts provide important first steps in measuring the performance of public health agencies, additional efforts will likely be needed to ensure appropriate accountability.

Fortifying the public health infrastructure will clearly be a long-term endeavor. Although policymakers and public health officials wisely emphasized immediate action without a protracted planning phase, there is widespread recognition that meaningful improvements will not happen overnight. The potential for a real reform of public health preparedness capabilities will depend on the sustained involvement and commitment of policymakers at all levels of government. Close scrutiny must be paid to determine what is working, what is not, and what additional measures need to be pursued.

As George Poste, a bioterrorism adviser to the Department of Defense, noted in a recent *Health Affairs* "Web Exclusive" interview with Jeff Goldsmith:

> A comfortable, complacent society that is cocooned from risk is a great target for our enemies. Too many people in Washington feel that by dispensing billions in the wake of September's horrors, they've done their bit and all is now well. They believe this in no small measure because the people who are the beneficiaries of the funding have told them that it will indeed be so. Let us hope that they are right.[17]

The steps that must be taken to ensure that these people and organizations *are* ultimately proved right will not be easy.

Fortifying the public health infrastructure will clearly be a long-term endeavor.

ENDNOTES

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2.   Tara O'Toole, Michael Mair, and Thomas V. Inglesby, "Shining Light on 'Dark Winter,'" Johns Hopkins Center for Civilian Biodefense Strategies, February 2002; accessed June 6, 2002, at http://www.hopkins-biodefense.org/lessons.html.

3.   National Health Policy Forum analysis of 1990 Census data, derived from U.S. Census Bureau, "Land Area, Population, and Density for Metropolitan Areas: 1990"; Census data accessed June 6, 2002, at http://www.census.gov/population/censusdata/90den_ma.txt.

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5.   National Association of County and City Health Officials, "Information Technology Capacity and Local Public Health Agencies," *Research Brief,* no. 4 (July 1999); accessed June 6, 2002, at http://www.naccho.org/files/documents/Research_Brief_4.pdf.

6.   Michael S. Ascher, "State and Local Needs for Responding to Bioterrorism," in *Biological Threats and Terrorism: Assessing the Science and Response Capabilities: Workshop Summary (2002),* ed. Stacey L. Knobler, Adel A. F. Mahmoud, and Leslie A. Pray, based on a workshop of the Forum on Emerging Infections, Board on Global Health, Institute of Medicine (Washington, D.C.: National Academy Press, 2002), 170–172; accessed June 6, 2002, at http://books.nap.edu/books/0309082536/html/170.html.

7.   Mary J. R. Gilchrist, "The Progress, Priorities, and Concerns of Public Health Laboratories," in *Biological Threats and Terrorism: Assessing the Science and Response Capabilities: Workshop Summary (2002),* ed. Stacey L. Knobler, Adel A. F. Mahmoud, and Leslie A. Pray, based on a workshop of the Forum on Emerging Infections, Board on Global Health, Institute of Medicine (Washington, D.C.: National Academy Press, 2002), 160–165; accessed June 6, 2002, at http://books.nap.edu/books/0309082536/html/160.html.

8.   Edward M. Eitzen, Jr., "Framing the Issues," in *Biological Threats and Terrorism: Assessing the Science and Response Capabilities: Workshop Summary (2002),* ed. Stacey L. Knobler, Adel A. F. Mahmoud, and Leslie A. Pray, based on a workshop of the Forum on Emerging Infections, Board on Global Health, Institute of Medicine (Washington, D.C.: National Academy Press, 2002), 32; accessed June 6, 2002, at http://books.nap.edu/books/0309082536/html/32.html.

9.   Gilchrist, "Progress," 161.

10. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health, "Appendix F: Laboratory Security and Emergency Response for Microbiological and Biomedical Laboratories," in *Biosafety in Microbiological and Biomedical Laboratories (BMBL),* 4th ed. (Washington, D.C.: U.S. Government Printing Office, 1999); accessed June 6, 2002, at http://www.cdc.gov/od/ohs/biosfty/bmbl4/b4af.htm.

11. The CDC has identified the following biological disease/agents as Category A threats: anthrax (*Bacillus anthracis*), botulism (*Clostridium botulinum* toxin), plague (*Yersinia pestis*), smallpox (variola major), tularemia (*Francisella tularensis*), and viral hemorrhagic fevers, including filoviruses (such as Ebola and Marburg) and areanaviruses (such as Lassa and Machupo). See Centers for Disease Control and Prevention, "Biological Diseases/Agents Listing"; accessed June 12, 2002, at http://www.bt.cdc.gov/Agent/Agentlist.asp.

12. Gail H. Cassell, "Countermeasures to Biological Threats: The Challenge of Drug Development," in *Biological Threats and Terrorism: Assessing the Science and Response Capabilities: Workshop Summary (2002),* ed. Stacey L. Knobler, Adel A. F. Mahmoud, and Leslie A. Pray, based on a workshop of the Forum on Emerging Infections, Board on Global Health, Institute of Medicine (Washington, D.C.: National Academy Press, 2002), 115–116; accessed June 6, 2002, at http://books.nap.edu/books/0309082536/html/115.html.

13. Institute of Medicine, *Chemical and Biological Terrorism: Research and Development to Improve Civilian Medical Response* (Washington, D.C.: National Academy Press, 1999), 101.

14. American Hospital Association, "Hospital Resources for Disaster Readiness"; accessed June 6, 2002, at http://www.aha.org/Emergency/Readiness/ReadyAssessmentB1101.asp.

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16. Centers for Disease Control and Prevention, "Bioterrorism and Emergency Operations," in *Centers for Disease Control and Prevention Budget Request Summary Fiscal Year 2003* (Washington, D.C.: Department of Health and Human Services, February 2002), 19; accessed June 6, 2002, at http://www.cdc.gov/fmo/BudgetReqSummaryFY2003.pdf.

17. Goldsmith, "Facing Reality," W228.