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Issue Brief

Assessing the Threat of Bioterrorism: Are We Ready?

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Biological Threats and Weapons of Mass Destruction

Health officials have long considered the possibility of bioterrorism, but since September 11 preparation for the possibility has gained greater urgency. Efforts to avert or cope with this threat have raised a number of concerns about the need to coordinate governmental activities, strengthen federal, state, and local programs, supplement the pharmaceutical stockpile, and examine regulatory and legal policies.

Bioterrorism is the release—or simply the threat of releasing—biological agents, such as viruses or bacteria, in order to influence government or intimidate civilians.[1] Biological terrorism is one within a class of so-called weapons of mass destruction (WMD) that also includes nuclear and chemical agents. Weapons of mass destruction are defined as those able to harm or kill a large number of people at one time.[2] Until the recent anthrax attacks, the one known instance of bioterrorism in the United States occurred in 1984, when a religious cult in Oregon poisoned salad bars with Salmonella.[3] The sarin attack in 1995, by a religious cult in the Tokyo subway system, is the one known chemical attack.[4]

Biological weapons may be transmitted by people or animals, food or water, or in the air (aerosol). Aerosol transmission has the greatest potential for harm.[5] The Centers for Disease Control and Prevention (CDC) has classified as "Category A" those biological agents that pose a great threat because they cause easily transmitted diseases, result in many deaths, and may produce social panic. Anthrax and smallpox are two such diseases, as are plague, tularemia, and viral hemorrhagic fever. The CDC's Categories B and C diseases pose progressively lesser threats. Chemical threats include those classified as nerve (such as sarin), blister (such as mustard gas), and blood (hydrogen cyanide).

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Acute responses to either chemical or biological threats involve similar emergency and health infrastructures. Biological weapons are most able to produce damage from a small quantity of agent, unlike nuclear or chemical weapons.[6] Bioterrorism also differs from chemical or nuclear threats in that release of a biological agent may go undetected for days while it spreads to people who were not originally exposed. Thus, bioterrorism poses the additional challenge of disease tracking as compared to responding to an emergency health situation in a localized area.

Federal Preparedness

The recent anthrax attacks dramatically illustrated the need for greater coordination across federal agencies that hold responsibilities for bioterrorism preparedness and response, a point terrorism experts have made for several years.[7,8] Efforts to assess preparedness through simulated exercises also have revealed shortcomings in response readiness, including public health infrastructure, coordination of federal and state responses, civil liberties, and media information management.[9,10,11]

Anthrax Overview

As of December 5, 2001, the CDC had identified 22 cases of anthrax. Of the 11 cases of inhalational anthrax, nine were likely due to exposure to a letter containing anthrax.[12] Five individuals exposed to inhalational anthrax died. Based on analysis of the contaminant contained in the letters, investigators suspect that the terrorist is not a member of an international group, but rather may be from the United States, possibly with ties to the U.S. military. Early responses to the attacks indicate the challenge of responding to threats that health authorities do not fully understand. The first cases of cutaneous anthrax in New York were not reported immediately to the CDC disease surveillance system. Furthermore, a lack of understanding that anthrax could be transmitted through sealed envelopes resulted in delayed treatment for postal workers in the Washington, D.C., Brentwood facility. Since September 11 and in light of experience with the anthrax attacks, efforts are under way to build up preparedness and response systems quickly.

Federal Disaster and Emergency Response Infrastructure

Federal preparedness efforts are fragmented across many agencies with limited responsibilities. GAO studies of bioterrorism preparedness efforts found that over 20 federal departments and agencies are involved in preparation or responses to health-related aspects of a bioterrorist attack, and over 40 agencies have responsibility for responses to terrorism more broadly.[13] Agencies include the departments of Agriculture, Commerce, Defense, Energy, Health and Human Services, Justice, Transportation, Treasury, and Veterans Affairs, and the Environmental Protection Agency and Federal Emergency Management Agency.

Bioterrorism preparedness and response activities fit within a larger framework for responding to presidentially declared disasters or emergencies. The Robert T. Stafford Disaster Relief and Emergency Assistance Act (P.L. 93-288, as amended) as further clarified by Presidential Decision Directives 39 and 62, establishes two key roles for federal agencies:

- *Crisis management,* which involves law enforcement activities. The lead federal agency is the Department of Justice, through the Federal Bureau of Investigation; and
- *Consequence management,* which involves functions related to public health, restoration of government services, and emergency relief. The Federal Emergency Management Agency (FEMA) holds responsibility for preparedness and consequence management. FEMA's actions are governed by the Federal Response Plan, which identifies lead agencies for responding to subcategories of emergency support functions. HHS is the lead federal agency for the *health and medical services* support function and coordinates the efforts of at least 10 additional supporting agencies.[14]

Agencies bring differing philosophies to bioterrorism preparations and responses. The FBI's responsibility for law enforcement may dictate caution in sharing information during an ongoing investigation. In contrast, the CDC, with a role in containing the spread of disease (consequence management), gives priority to sharing as much information as possible with health-care providers and the public.

Department of Health and Human Services Responsibilities

In November 2001, the Administration created the Office of Public Health Preparedness within the Department of Health and Human Services. The purpose of this office is to coordinate federal agencies' responses to public health emergencies. It also will serve as a liaison to the Office of Homeland Security, created by the Bush Administration to oversee all federal terrorist prevention and protection activities. Key HHS activities include emergency response, the pharmaceutical stockpile, and pharmaceutical research.

- *Emergency Response.* HHS operates several programs to develop state and local response infrastructure. Since 1995, the Office of Emergency Preparedness in HHS has entered into contracts with localities to develop Metropolitan Medical Response Systems (also known as the Nunn-Lugar-Domenici, or "120 Cities," program).[15] These systems integrate local emergency response, medical, and legal, and fire departments to allow a coordinated approach to respond to an emergency health situation. As of September 30, 2001, HHS held contracts with 97 municipalities to create MMRSs.[16] The Office of Emergency Preparedness also runs the National Disaster Medical System (NDMS), which consists of 7,000 volunteer health and support professionals who travel anywhere in the country to assist local response systems.[17] The NDMS is further organized into 44 Disaster Medical Assistance Teams capable of providing on-site medical care and transportation to medical facilities; and four National Medical Response Teams, which travel with pharmaceuticals and can detect harmful agents, decontaminate victims, provide medical care, and remove victims. In addition, the CDC operates programs for preparedness planning, epidemiology and surveillance, laboratory capacity, and electronic communications for local areas.
- *The National Pharmaceutical Stockpile.* The pharmaceutical stockpile stores treatments necessary in the event of an emergency health event. It includes treatments for a host of diseases or emergency situations, such as antibiotics, antidotes, vaccines and medical materials.[18] CDC, in collaboration with the Veterans Administration, maintains the stockpile.
- *Vaccine and Drug Research and Development.* The NIH, particularly the National Institute of Allergy and Infectious Diseases (NIAID), funds and conducts research on diagnostics, therapies, and vaccines against potential bioterrorist agents. Some research is done in collaboration with the Defense Department's Defense Advanced Research Projects Agency (DARPA).[19] In addition, the FDA is responsible for ensuring safety of vaccines and drugs. Those developed for bioterrorism defense go through the same review process as other drugs.

State and Local Infrastructure

State Public Health Agencies and Local Health Departments

State public health agencies and local health departments identify and monitor disease outbreaks. The public health infrastructure is not well equipped to respond to a large-scale emergency health event.[20] Public health agencies require greater capacity for rapid communication with hospitals and other health agencies.[21] Not all agencies have e-mail, and those that do often do not have capacity to send confidential information. Staffing does not typically include a person on call for emergencies 24 hours per day.[22] The CDC has identified seven key areas in which to improve the public health infrastructure: public health workforce, laboratory capacity, epidemiology and surveillance; secure and accessible information systems, communications, effective policy and evaluation, and preparedness and response capacity. The Association for State and Territorial Health Officials (ASTHO) has affirmed these priority areas and stressed the need for a strong national strategy and availability of federal funds to support local capacity.[23]

The CDC has developed two systems, both in early stages of development, to address shortcomings in information exchange. One is the Health Alert Network, an electronic communication system with high-speed Internet connections that share disease outbreak information nationally.[24] The other, the Epidemic Information Exchange System (Epi-X), is a secure electronic network that will facilitate sharing of sensitive information. Experts cite both systems as solid approaches to improving such capacity.[25]

PHYSICIANS, HOSPITALS, AND LABORATORIES

Physician training is essential for early detection and effective responses to bioterrorist attacks. The American Medical Association has issued recommendations for medical preparedness. Key recommendations include developing curriculum, information, coordinated response plans, and disease-reporting protocols to respond to a terrorist threat.[26] The federally created Advisory Panel to Assess Domestic Response Capabilities for Terrorism Involving Weapons of Mass Destruction (also known as the Gilmore Commission) recommended that the AMA guidelines be implemented in full.

Hospitals require further readiness preparation to respond to a large-scale emergency. The American Hospital Association estimated that, on average, metropolitan hospitals would need to spend $3 million, and nonmetropolitan and rural hospitals $1.4 million, to adequately prepare.[27] Costs reflect service areas such as communications, disease surveillance, protective equipment, and supplies for an attack resulting in 1,000 people seeking services at a metropolitan hospital, and 200 at a rural hospital. The Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), clarifying its standards on preparation for emergency health events, said it will place "special emphasis" on such factors in future reviews.[28]

Laboratories perform tests to diagnose potential disease outbreaks. Currently, laboratories lack sufficient staffing, equipment, and communications tools to respond to a large-scale attack.[29] The Laboratory Response Network is a recent model effort designed to improve preparedness. This partnership among public health agencies, laboratories, and federal agencies, including the CDC, FBI, and Department of Defense, would require additional funding for broader implementation.[30]

Congressional Actions to Improve Preparedness

The 107th Congress has passed a number of bills to increase federal funding and strengthen bioterrorism preparedness activities. The estimated total for HHS bioterrorism efforts is $2.9 billion. Of this amount, an estimated $2.6 billion is for HHS bioterrorism efforts under an emergency supplemental appropriation that was included in the Defense appropriations legislation, H.R. 3338. The President signed the Defense appropriations legislation on January 10, 2002. As of January 10, 2002, no public law had been assigned.[31] The legislation provides appropriations for multiple bioterrorism preparedness activities allocated mainly through the Public Health and Social Services Emergency Fund. Funds will be used to:

- Supplement the pharmaceutical stockpile,
- Purchase smallpox vaccine,
- Improve hospital capacity to respond to bioterrorism,
- Upgrade CDC capacity, including research,
- Support bioterrorism-related research and development,
- Improve federal laboratory security,
- Support CDC environmental hazard control activities,
- Support mental health programs, and,
- Fund preparedness and response activities in the Office of the Secretary.

In addition, approximately $342 million was provided for bioterrorism preparedness activities in two appropriations bills that responded to the President's FY 2002 budget request.[32] One bill (H.R. 3061, the Labor-Education-HHS appropriation) was presented to the President on January 4, 2002. The other (P.L. 107-76, Agriculture, Rural Development, Food and Drug Administration, and Related Agencies) was signed into law on November 28, 2001.

On December 12, 2001, the House passed H.R. 3448, the Public Health Security and Bioterrorism Response Act of 2001. The bill would provide $2.7 billion for such bioterrorism preparedness activities as improving the pharmaceutical stockpile, strengthening state and local preparedness efforts, and protecting food and water safety. On December 20, 2001, the Senate passed H.R. 3448, as amended, the Bioterrorism Preparedness Act of 2001. The bill authorizes $3.2 billion for bioterrorism preparedness activities similar to the House-passed bill. The legislation is expected to go conference early in the 107th Congress, 2nd session.

Supplementing the Pharmaceutical Stockpile

Since September 11, HHS has taken steps to supplement the pharmaceutical stockpile by negotiating agreements to purchase large quantities of pharmaceuticals at discounted prices. In agreements reached with pharmaceutical manufacturers, HHS will receive additional pharmaceuticals effective against anthrax and smallpox, including 100 million Cipro tablets, 54 million doses of smallpox vaccine, and 155 million doses of smallpox vaccine.

The stockpile includes two components. First, the stockpile currently maintains eight five-ton rapid response "Push Packs," which contain antibiotics and medical supplies such as bandages that can be transported anywhere within 12 hours. The system was tested following the September 11 attacks, when one Push Pack was delivered to New York City within seven hours of the order.[33] Second, the stockpile contains a larger supply of pharmaceuticals than are stored by drug manufacturers, referred to as Vendor Managed Inventory (VMI). The VMI supplements the rapid response Push Pack inventory, arriving within 24 to 36 hours, and can be tailored to respond to a specific chemical or biological attack.[34,35]

The CDC began efforts to create the stockpile in November 1999. CDC directs its purchases based on an inventory list created by HHS and external experts. GAO estimated that CDC had filled about 47 percent of its rapid response inventory requirement, and had completed the first of five or more contracts for vendor-managed inventory, by the end of 2000.[36] The inventory list puts in priority responses to smallpox, anthrax, pneumonic plague, tularemia, botulinum toxin, and viral hemorrhagic fevers, with the purchase of antibiotics (effective against anthrax, plague, and tularemia) as the first priority.[37]

While the pharmaceutical stockpile is a tremendous national resource, a GAO report completed prior to September 11 found that it could be further improved in several respects. In particular, security, rotation of stock, inventory, and response readiness merit further attention.[38] For example, facilities may not be adequately guarded, and inventory may be expired and yet remain in the stockpile.

Regulatory and Legal Policies

Pharmaceuticals

Supplementing the pharmaceutical stockpile also raises new issues in regulatory policy regarding the pharmaceutical industry.

- *Patent protections.* The HHS agreement with the Bayer Corporation to manufacture Cipro and sell it at nearly a 50 percent discount represents a departure from past government policy that supported patent protections for pharmaceuticals. Bayer and HHS settled on the reduced price only after HHS Secretary Tommy Thompson threatened to break Bayer's patent. The U.S. has consistently supported patent protections of pharmaceutical companies in the context of challenges made by governments of developing countries that seek to purchase generic versions of HIV/AIDS treatments for prices dramatically lower than those charged by the patent-holding companies.
- *Pharmaceutical development and review.* Pharmaceutical companies have pressed for expedited review processes, permission to collaborate with other companies (a loosening of antitrust restrictions), greater ability to work directly with federal researchers, and exemptions from liability lawsuits for drugs and vaccines produced to respond to potential agents of bioterrorism.
- *Vaccines.* The Institute of Medicine and the Gilmore Commission recommended that the government undertake vaccine production directly rather than purchasing from private companies.[39] Private investors, concerned that the demand for vaccines will diminish over time, are less willing to support production.

Civil Liberties

To contain disease in a large-scale attack, federal, state, and local governments, particularly public health authorities, may need to take actions that restrict civil liberties. Many states are expected to consider legislation on state authority in emergency health situations in upcoming legislative sessions.

The CDC recently released a Model State Emergency Health Powers Act, developed by the Center for Law and Public Health at Georgetown University and Johns Hopkins

University.[40] The model legislation is intended to serve as a potential framework for states to use in updating statutes. Existing state laws, many written before the 1930s, tend to contain little detail on the scope of health department authority in emergency situations.[41] The model legislation provides broad authority to health officials in the event that a Governor declares a state of public health emergency. In particular, provisions authorize public health authorities to undertake mandatory medical examinations, isolation of infected people and, quarantine of exposed people "with respect to individual liberties consistent with due process," mandatory vaccinations, collection of laboratory tests, and limited disclosure of patient records.[42] Such provisions have prompted debate regarding the proper level of power to accord health officials in an emergency.

Preventing Panic and Ensuring Appropriate Treatment

An additional key role for the government is to protect people from making choices based on fear or misinformation. For example, after the anthrax attacks, the government warned consumers not to purchase Cipro over the Internet, since the drugs may not be medically recommended and government regulated.[43] The FDA issued "cyber" letters in October and November 2001 to 11 foreign Internet sites that sold Cipro, indicating that they may be engaging in illegal practices.[44,45]

Conclusion

Bioterrorism poses threats not only for its ability to produce physical harm but also for its ability to create fear at a level greater than the actual physical threat.[46] In a large-scale attack, appropriate government information and a coordinated plan would be essential to an effective response.

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