

# **The Center for Disease Control's Public Health Response to the Threat of Bioterrorism**

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## **Introduction**

Good afternoon, Mr. Chairman and Members of the Subcommittee. I am Dr. James M. Hughes, Director, National Center for Infectious Diseases (NCID), Centers for Disease Control and Prevention (CDC). I am accompanied by Dr. James W. LeDuc, Acting Director of NCID's Division of Viral and Rickettsial Diseases. Thank you for the invitation to update you on CDC's public health response to the threat of bioterrorism. I will discuss the overall goals of our bioterrorism preparedness program, and I will briefly address specific activities aimed at preparedness for a deliberate release of variola virus, the pathogen responsible for smallpox.

## **Vulnerability of the Civilian Population**

In the past, an attack with a biological agent was considered very unlikely; however, now it seems entirely possible. Many experts believe that it is no longer a matter of "if" but "when" such an attack will occur. Unlike an explosion or a tornado, in a biological event, it is unlikely that a single localized place or cluster of people will be identified for traditional first responder activity. The initial responders to such a biological attack will include emergency department and hospital staff, members of the outpatient medical community, and a wide range of response personnel in the public health system, in conjunction with county and city health officers. Increased vigilance and preparedness for unexplained illnesses and injuries are an essential part of the public health effort to protect the American people against bioterrorism.

## **Public Health Leadership**

The Department of Health and Human Services (DHHS) anti-bioterrorism efforts are focused on improving the nation's public health surveillance network to quickly detect and identify the biological agent that has been released; strengthening the capacities for medical response, especially at the local level; expanding the stockpile of pharmaceuticals for use if needed; expanding research on disease agents that might be released, rapid methods for identifying biological agents, and improved treatments and vaccines; and preventing bioterrorism by regulation of the shipment of hazardous biological agents or toxins. On July 10, 2001, Secretary Thompson named CDC's Dr. Scott Lillibridge as his special advisor to lead the Department's coordinated bioterrorism initiative.

As the Nation's disease prevention and control agency, it is CDC's responsibility on behalf of DHHS to provide national leadership in the public health and medical communities in a concerted effort to detect, diagnose, respond to, and prevent illnesses, including those that occur as a result of a deliberate release of biological agents. This task is an integral part of CDC's overall mission to monitor and protect the health of the U.S. population.

In 1998, CDC issued Preventing Emerging Infectious Diseases: A Strategy for the 21st

Century, which describes CDC's plan for combating today's emerging diseases and preventing those of tomorrow. It focuses on four goals, each of which has direct relevance to preparedness for bioterrorism: disease surveillance and outbreak response; applied research to develop diagnostic tests, drugs, vaccines, and surveillance tools; infrastructure and training; and disease prevention and control. This plan emphasizes the need to be prepared for the unexpected — whether it is a naturally occurring influenza pandemic or the deliberate release of smallpox by a terrorist. It is within the context of these overall goals that CDC has begun to address preparing our Nation's public health infrastructure to respond to acts of biological terrorism. Copies of this CDC plan have been provided previously to the Subcommittee. In addition, CDC presented in March a report to the Senate entitled "Public Health's Infrastructure: A Status Report." Recommendations in this report complement the strategies outlined for emerging infectious diseases and preparedness and response to bioterrorism. These recommendations include training of the public health workforce, strengthening of data and communications systems, and improving the public health systems at the state and local level.

### **CDC's Strategic Plan for Bioterrorism**

On April 21, 2000, CDC issued a Morbidity and Mortality Weekly Report (MMWR), Biological and Chemical Terrorism: Strategic Plan for Preparedness and Response — Recommendations of the CDC Strategic Planning Workgroup, which outlines steps for strengthening public health and healthcare capacity to protect the nation against these threats. This report reinforces the work CDC has been contributing to this effort since 1998 and lays a framework from which to enhance public health infrastructure. In keeping with the message of this report, five key focus areas have been identified which provide the foundation for local, state, and federal planning efforts: Preparedness and Prevention, Detection and Surveillance, Diagnosis and Characterization of Biological and Chemical Agents, Response, and Communication. These areas capture the goals of CDC's Bioterrorism Preparedness and Response Program for general bioterrorism preparedness, as well as the more specific goals targeted towards preparing for the potential intentional reintroduction of smallpox. As was highlighted in the recent Dark Winter exercise, smallpox virus is of particular concern.

#### **• Preparedness and Prevention**

CDC is working to ensure that all levels of the public health community — federal, state, and local — are prepared to work in coordination with the medical and emergency response communities to address the public health consequences of biological and chemical terrorism.

CDC is creating diagnostic and epidemiological performance standards for state and local health departments and will help states conduct drills and exercises to assess local readiness for bioterrorism. In addition, CDC, the National Institutes of Health (NIH), the Department of Defense (DOD), and other agencies are supporting and encouraging research to address scientific issues related to bioterrorism. In some cases, new vaccines, antitoxins, or innovative drug treatments need to be developed or stocked. Moreover, we need to learn more about the pathogenesis and epidemiology of the infectious diseases which do not affect the U.S. population currently. We have only limited knowledge about how artificial methods of dispersion may affect the infection rate, virulence, or impact of these biological agents.

In 1999, the Institute of Medicine released its Assessment of Future Scientific Needs for Live Variola Virus, which formed the basis for a phased research agenda to address several scientific issues related to smallpox. This research agenda is a collaboration between CDC, NIH, and DOD and is being undertaken in the high-containment laboratory at CDC with the concurrence of WHO. The research addresses: 1) the use of modern serologic and molecular diagnostic techniques to improve diagnostic capabilities for smallpox, 2) the evaluation of antiviral compounds for activity against the smallpox virus, and 3) further study of the pathogenesis of smallpox by the development of an animal model that mimics human smallpox infection. To date,

genetic material from 45 different strains of smallpox virus has been extracted and is being evaluated to determine the genetic diversity of different strains of the virus. The NIH, with CDC and DOD collaborators, has funded a Poxvirus Bioinformatics Resource Center ([www.poxvirus.org](http://www.poxvirus.org)) to facilitate the analysis of sequence data to aid the development of rapid and specific diagnostic assays, antiviral medicines and vaccines. A dedicated sequencing and bioinformatics laboratory also is being developed at CDC to help further these efforts. This laboratory will also be used to help characterize other potential bioterrorism pathogens. In addition, a team of collaborating scientists has screened over 270 antiviral compounds for activity against smallpox virus and other related poxviruses and have found several compounds which merit further evaluation in animal models. These compounds were evaluated initially in cell cultures, and 27 promising candidates are being further evaluated for efficacy. The identification of one currently licensed compound with in vitro and in vivo efficacy against the smallpox virus has led to the development of an Investigational New Drug (IND) application by NIH and CDC to the FDA for use of this drug, cidofovir, in an emergency situation for treating persons who are diagnosed with smallpox. Researchers also have been funded by NIH to design new anti-smallpox medicines and to create human monoclonal antibodies to replace the limited supply of vaccinia immune globulin that is needed to treat vaccine complications that arise during immunization campaigns.

The Advisory Committee for Immunization Practices (ACIP) worked with CDC to develop updated guidelines for the use of smallpox vaccine. These guidelines were published in the MMWR in June 2001 and serve to educate the medical and public health community regarding the recommended routine and emergency uses and medical aspects of the vaccine as well as, the medical aspects of smallpox itself. Several infection control and worker safety issues were also addressed by the ACIP within the updated guidelines.

While we are pursuing the development of additional smallpox vaccine to improve our readiness to respond to a smallpox outbreak, we are also working to ensure that the stores of vaccine that we have in the United States currently are ready for use, including protocols for emergency release and transportation of the vaccine.

#### • **Detection and Surveillance**

Because the initial detection of a biological terrorist attack will most likely occur at the local level, it is essential to educate and train members of the medical community, both public and private, who may be the first to examine and treat the victims. It is also necessary to upgrade the surveillance systems of state and local health departments, as well as within healthcare facilities such as hospitals, which will be relied upon to spot unusual patterns of disease occurrence and to identify any additional cases of illness. CDC will provide terrorism-related training to epidemiologists and laboratorians, emergency responders, emergency department personnel and other front-line health-care providers, and health and safety personnel. CDC is working to provide educational materials regarding potential bioterrorism agents to the medical and public health communities on its bioterrorism website at [www.bt.cdc.gov](http://www.bt.cdc.gov). For example, we are preparing a video on smallpox vaccination techniques for public health personnel and healthcare providers who may administer vaccine in an emergency situation. CDC is planning to work with partners such as the Johns Hopkins Center for Civilian Biodefense Studies and the Infectious Diseases Society of America to develop training and educational materials for incorporation into medical and public health graduate and post-graduate curricula. With public health partners, CDC is spearheading the development of the National Electronic Disease Surveillance System, which will facilitate automated, timely electronic capture of data from the healthcare system. CDC has also worked with organizations such as the Council of State and Territorial Epidemiologists to ensure that suspected cases of smallpox are immediately reportable in their jurisdictions and that clear lines of communication are in place.

## • **Diagnosis and Characterization of Biological and Chemical Agents**

To ensure that prevention and treatment measures can be implemented quickly in the event of a biological or chemical terrorist attack, rapid diagnosis will be critical. CDC is developing guidelines and quality assurance standards for the safe and secure collection, storage, transport, and processing of biologic and environmental samples. In collaboration with other federal and non-federal partners, CDC is co-sponsoring a series of training exercises for state public health laboratory personnel on requirements for the safe use, containment, and transport of dangerous biological agents and toxins. CDC is also enhancing its efforts to foster the safe design and operation of Biosafety Level 3 laboratories, which are required for handling many highly dangerous pathogens. In addition, CDC is helping to limit access to potential terrorist agents by continuing to administer the Select Agent Rule, Additional Requirements for Facilities Transferring or Receiving Select Agents (42 CFR Section 72.6), which regulates shipments of certain hazardous biological organisms and toxins. Furthermore, CDC is developing a Rapid Toxic Screen to detect people's exposure to 150 chemical agents using blood or urine samples.

## • **Response**

A decisive and timely response to a biological terrorist event involves a fully documented and well rehearsed plan of detection, epidemiologic investigation, and medical treatment for affected persons, and the initiation of disease prevention measures to minimize illness, injury and death. CDC is addressing this by (1) assisting state and local health agencies in developing their plans for investigating and responding to unusual events and unexplained illnesses and (2) bolstering CDC's capacities within the overall federal bioterrorism response effort. CDC is working to formalize current draft plans for the notification and mobilization of personnel and laboratory resources in response to a bioterrorism emergency, as well as overall strategies for vaccination, and development and implementation of other potential outbreak control measures such as quarantine measures. In addition, CDC is working to develop national standards to ensure that respirators used by first responders to terrorist acts provide adequate protection against weapons of terrorism.

## • **Communication Systems**

In the event of an intentional release of a biological agent, rapid and secure communications will be especially crucial to ensure a prompt and coordinated response. Thus, strengthening communication among clinicians, emergency rooms, infection control practitioners, hospitals, pharmaceutical companies, and public health personnel is of paramount importance. To this end, CDC is making a significant investment in building the nation's public health communications infrastructure through the Health Alert Network, a nationwide program designed to ensure communications capacity at all local and state health departments (full Internet connectivity and training), ensure capacity to receive distance learning offerings from CDC and others, and ensure capacity to broadcast and receive health alerts at every level. CDC has also established the Epidemic Information Exchange (EPI-X), a secure, Web-based communications system to enhance bioterrorism preparedness efforts by facilitating the sharing of preliminary information about disease outbreaks and other health events among public health officials across jurisdictions and provide experience in the use of secure communications.

An act of terrorism is likely to cause widespread panic, and on-going communication of accurate and up-to-date information will help calm public fears and limit collateral effects of the attack. To assure the most effective response to an attack, CDC is working closely with other federal agencies, including the Food and Drug Administration, NIH, DOD, Department of Justice (DOJ), and the Federal Emergency Management Agency (FEMA).

## **The National Pharmaceutical Stockpile**

As CDC recently reported to this Subcommittee, another integral component of public health preparedness at CDC has been the development of a National Pharmaceutical Stockpile (NPS), which can be mobilized in response to an episode caused by a biological or chemical agent. The role of the CDC's NPS program is to maintain a national repository of life-saving pharmaceuticals and medical material that can be delivered to the site or sites of a biological or chemical terrorism event in order to reduce morbidity and mortality in a civilian population. The NPS is a backup and means of support to state and local first responders, healthcare providers, and public health officials. The NPS program consists of a two-tier response: (1) 12-hour push packages, which are pre-assembled arrays of pharmaceuticals and medical supplies that can be delivered to the scene of a terrorism event within 12 hours of the federal decision to deploy the assets and that will make possible the treatment or prophylaxis of disease caused by a variety of threat agents; and (2) a Vendor-Managed Inventory (VMI) that can be tailored to a specific threat agent. Components of the VMI will arrive at the scene 24 to 36 hours after activation. CDC has developed this program in collaboration with federal and private sector partners and with input from the states.

## **Challenges Highlighted in Dark Winter Exercise**

CDC has been addressing issues of detection, epidemiologic investigation, diagnostics, and enhanced infrastructure and communications as part of its overall bioterrorism preparedness strategies. The issues that emerged from the recent Dark Winter exercise reflected similar themes that need to be addressed.

- The importance of rapid diagnosis — Rapid and accurate diagnosis of biological agents will require strong linkages between clinical and public health laboratories. In addition, diagnostic specimens will need to be delivered promptly to CDC, where laboratorians will provide diagnostic confirmatory and reference support.
- The importance of working through the governors' offices as part of our planning and response efforts — During the exercise this was demonstrated by Governor Keating. During state-wide emergencies the federal government will need to work with a partner in the state who can galvanize the multiple response communities and government sectors that will be needed, such as the National Guard, the state health department, and the state law enforcement communities. These in turn will need to coordinate with their local counterparts. CDC is refining its planning efforts through grants, policy forums such as the National Governors Association and the National Emergency Management Association, and training activities. CDC also participates with partners such as DOJ and FEMA in planning and implementing national drills such as the recent TOPOFF exercise.
- Better targeting of limited smallpox vaccine stocks to ensure strategic use of vaccine in persons at highest risk of infection — It was clear that pre-existing guidance regarding strategic use would have been beneficial and would have accelerated the response at Dark Winter. As I mentioned earlier, CDC is working on this issue and is developing guidance for vaccination programs and planning activities.
- Federal control of the smallpox vaccine at the inception of a national crisis — Currently, the smallpox vaccine is held by the manufacturer. CDC has worked with the U.S. Marshals Service to conduct an initial security assessment related to a future emergency deployment of vaccine to states. CDC is currently addressing the results of this assessment, along with other issues related to security, movement, and initial distribution of smallpox vaccine.
- The importance of early technical information on the progress of such an epidemic for consideration by decision makers — In Dark Winter, this required the implementation of various

steps at the local, state, and federal levels to control the spread of disease. This is a complex endeavor and may involve measures ranging from directly observed therapy to quarantine, along with consideration as to who would enforce such measures. Because wide-scale federal quarantine measures have not been implemented in the United States in over 50 years, operational protocols to implement a quarantine of significant scope are needed. CDC hosted a forum on state emergency public health legal authorities to encourage state and local public health officers and their attorneys to examine what legal authorities would be needed in a bioterrorism event. In addition, CDC is reviewing foreign and interstate quarantine regulations to update them in light of modern infectious disease and bioterrorism concerns. CDC will continue this preparation to ensure that such measures will be implemented early in the response to an event.

- Maintaining effective communications with the media and press during such an emergency. The need for accurate and timely information during a crisis is paramount to maintaining the trust of the community. Those responsible for leadership in such emergencies will need to enhance their capabilities to deal with the media and get their message to the public. It was clear from Dark Winter that large-scale epidemics will generate intense media interest and information needs. CDC has refined its media plan and expanded its communications staff. These personnel will continue to be intimately involved in our planning and response efforts to epidemics.

- Expanded local clinical services for victims — DHHS's Office of Emergency Preparedness is working with the other members of the National Disaster Medical System to expand and refine the delivery of medical services for epidemic stricken populations.

CDC will continue to work with partners to address challenges in public health preparedness, such as those raised at Dark Winter. For example, work done by CDC staff to model the effects of control measures such as quarantine and vaccination in a smallpox outbreak have highlighted the importance of both public health measures in controlling such an outbreak. The importance of both quarantine and vaccination as outbreak control measures is also supported by historical experience with smallpox epidemics during the eradication era. These issues, as well as overall preparedness planning at the federal level, are currently being addressed and require additional action to ensure that the nation is fully prepared to respond to all acts of biological terrorism, including those involving smallpox.

## **Conclusion**

In conclusion, CDC has made substantial progress to date in enhancing the nation's capability to prepare for and, if need be, respond to a bioterrorist event. The best public health strategy to protect the health of civilians against biological terrorism is the development, organization, and enhancement of public health prevention systems and tools. Priorities include strengthened public health laboratory capacity, increased surveillance and outbreak investigation capacity, and health communications, education, and training at the federal, state, and local levels. Not only will this approach ensure that we are prepared for deliberate bioterrorist threats, but it will also ensure that we will be able to recognize and control naturally occurring new or re-emerging infectious diseases. A strong and flexible public health infrastructure is the best defense against any disease outbreak.

Thank you very much for your attention. I will be happy to answer any questions you may have.