

BIOTERRORISM AND PUBLIC HEALTH PREPAREDNESS

CDC has been responding to public health emergencies for decades and has been preparing for bioterrorism in particular since 1998. CDC's bioterrorism plans were put into action in fall 2001, with the first biological attack in the United States.

Outbreaks of anthrax proved that the first line of defense is rapid identification—essential for ensuring a prompt response to a biological or chemical attack so that exposure can be limited and those affected can be treated. To accomplish this, regional and state laboratories have strengthened their capacity to detect different biological and chemical agents and to communicate the results to CDC and others. Along the same lines, CDC's Health Alert Network has upgraded the capacity of state and local health agencies to detect and communicate different health threats—including bioterrorism, emerging infectious diseases, chronic diseases, and environmental hazards. This means that we reap the benefits of these investments every day, not just in the event of a bioterrorist attack.

Finally, to help treat victims of a bioterrorist attack, CDC has worked with pharmaceutical companies and other partners to create regional stockpiles of the drugs that would be needed quickly to treat man-made outbreaks of anthrax, plague, tularemia, or other diseases. This resource was essential in responding to the terrorist attacks of September 11, 2001, as well as to the ensuing anthrax outbreak.

Collectively, these measures strengthen the existing public health system while preparing for bioterrorism, infectious disease outbreaks, and other public health threats and emergencies.

LABORATORY RESPONSE TO BIOLOGICAL TERRORISM

WHAT IS THE PUBLIC HEALTH ISSUE?

- Because most bioterrorist agents rarely cause naturally occurring disease, the enhancement of national capacity to rapidly identify these agents remains critical, both at CDC and at state and local public health laboratories.
- Early detection and identification of disease agents is essential in making decisions regarding patient management, guiding epidemiologic investigations, assisting law enforcement, and deploying healthcare resources.

WHAT HAS CDC ACCOMPLISHED?

CDC's laboratory system delivers accurate and timely identification of any agent causing a public health threat, including both naturally occurring diseases and organisms that could be used in a biologic terrorism attack.

CDC, in collaboration with the Association of Public Health Laboratories and the Federal Bureau of Investigation, established the Laboratory Response Network in 1999 to develop federal, state, and local public health laboratory capacity to respond to bioterrorism events. This network is a strategic domestic and international partnership designed to link front-line clinical microbiology laboratories in hospitals and other institutions to state and local public health laboratories. It also supports advanced capacities of public health, military, veterinary, agricultural, water, chemical, and food-testing laboratories at the federal level.

Depending on a laboratory's ability to handle dangerous pathogens, the laboratory is designated either as a reference laboratory or a sentinel laboratory. Reference laboratories are the core, advanced technology public health laboratories that can provide confirmatory testing for agents in biosafety levels 3 and 4. This includes the centralized, state-of-the-art national reference laboratory located at CDC to rapidly and accurately identify any agent used in a biological terrorism attack (the Rapid Response and Advanced Technology Laboratory). Reference laboratories have access to a secure website which allows for timely reporting and monitoring. These reference laboratories (about 120 laboratories) can access online agent protocols, share information, and order reagents. Sentinel laboratories are the basic diagnostic facilities, such as hospital clinical laboratories, that initially identify likely bioterrorism agents and submit specimens to reference laboratories for confirmatory testing. The estimated 25,000 sentinel laboratories are geographically dispersed and play an important role in detecting and reporting possible outbreaks.

CDC, in collaboration with federal, state, and local partners, has identified the biological agents likely to be involved in a terrorist attack and is developing scientifically validated rapid assays to help detect these agents.

WHAT ARE THE NEXT STEPS?

- Continue to enhance capacity of laboratories to rapidly detect and identify agents likely to be used in a terrorist attack and provide crucial information to health professionals.
- Expand training and technical assistance to state and local public health laboratories to ensure they will be better prepared to respond in the event of a terrorist attack.
Increase the number of laboratory members in appropriate sentinel and reference laboratory capacities for human, animal, food, chemical, and environmental testing.
- Increase the number of available validated rapid assays and environmental sampling procedures for biological and chemical agents.
- Optimize communication methods and linkages to facilitate rapid, accurate, secure, data transfer.

NEW PARTNERSHIPS FOR TERRORISM PREPAREDNESS

WHAT IS THE PUBLIC HEALTH ISSUE?

The critical importance of links between business and public health was observed in the aftermath of the fall 2001 terrorism acts. Several problems were revealed in the wake of those events, including the following:

- Almost all the incidents occurred in the workplace, highlighting the workplace risks for the approximately 48% of Americans who are employed.
- The businesses directly affected by these incidents expressed a clear need for information and assistance to take appropriate action.
- The majority of businesses are not linked to their appropriate public health systems.
- The business sector has a wide array of valuable resources that can be shared with the public health system during urgent-need emergency responses.

Therefore, the real and functional links between employers and public health are being developed and strengthened as part of our nation's overall terrorism-preparedness planning.

WHAT HAS CDC ACCOMPLISHED?

To ensure sufficient collaboration between private sector entities within the business community and state and local public health systems, CDC is implementing a cooperative agreement with the National Business Group on Health (NBGH) on two related projects: first, to identify and make recommendations regarding gaps in planning and coordination between the business and public health communities, and second, to collect information and advice from business and public health leaders about steps businesses can take to prepare for, and respond to, a terrorism event. This information will be summarized in a terrorism-preparedness checklist for businesses.

To date, NBGH has worked with CDC, the Association of State and Territorial Health Officers, and the National Association of City and County Health Officials to identify and complete interviews with representatives from the business and public health sector, including organizations that were directly involved with the response to the terrorism events of September 11, 2001, and the subsequent anthrax attacks. These interviews have identified gaps in coordination between the business and public health sectors, and each group has made recommendations to address these gaps. Additionally, a business workgroup has been formed and is providing guidance regarding project activities.

WHAT ARE THE NEXT STEPS?

CDC and NBGH, along with the business workgroup, will be pilot-testing the preparedness checklist during project activities in 2004 and will subsequently disseminate their findings. These efforts will strengthen community-level coordination for terrorism preparedness, emergency response, and other urgent health events.

SELECT AGENT PROGRAM

WHAT IS THE PUBLIC HEALTH ISSUE?

CDC regulates the possession, use, and transfer of select biological agents and toxins that have the potential to pose a severe threat to public health and safety. CDC's Select Agent Program oversees these activities and registers all laboratories and other entities in the United States that possess, use, or transfer a select biological agent or toxin. *The Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (the *Act*) requires entities to register with the U.S. Departments of Health and Human Services (HHS) or Agriculture (USDA) if they possess, use, or transfer select biological agents or toxins that could pose a severe threat to public health and safety; to animal or plant health; or animal or plant products. In addition to ensuring that laboratories safely handle these select biological agents and toxins, the *Act* also requires increased safeguards and security measures of these agents, including controlling access, screening entities and personnel (i.e., security risk assessments), and establishing a comprehensive and detailed national database of registered entities. The *Act* also imposes criminal and civil penalties for the inappropriate use of select biological agents and toxins.

WHAT HAS CDC ACCOMPLISHED?

The Select Agent Program enhances the government's ability to prevent, prepare, and respond to bioterrorism and other public health emergencies. Prior to 2002, these agents were not systematically tracked. The *Act* provides a framework for monitoring threat agents that travel along the highways, railways, waterways, and airways of states.

The *Act* required that HHS promulgate an interim final rule in 180 days, published in the *Federal Register* on December 13, 2002. The December 2002 interim final rule established a phase-in period for certain requirements to allow for compliance without causing disruption or termination of research or educational projects. As a result of delays in completing security risk assessments for individuals and entities, an amendment to the interim final rule authorized provisional approvals to continue critical biodefense research. The December 2002 interim final rule regulated academic institutions and biomedical centers; commercial manufacturing (e.g., the pharmaceutical industry) or distribution facilities; federal, state, and local laboratories (including clinical and diagnostic laboratories); and research facilities.

The Select Agent Program helps to implement the *Act* through

- Evaluation and/or approval of requests to possess, use, and store threat agents.
- Approval of transfer of agents among registered laboratories.
- Registration of laboratories that possess threat agents (including specific viruses, bacteria, rickettsia, fungi, toxins, and recombinant organisms/molecules).
- Inspection of laboratories to ensure appropriate safety and security.
- A new regulation, effective February 7, 2003, which facilitated the registration of 332 entities as of November 12, 2003, and inspection of 211 entities.

WHAT ARE THE NEXT STEPS?

CDC expects to publish a final rule regarding select agents and toxins in late 2004 to address public comments and concerns that have emerged during implementation of the interim final rule. A new information management system, with a Web-based interface to improve customer service, timeliness and data reliability, is being developed.

For additional information on this or other CDC programs, visit www.cdc.gov/program

January 2004

SMALLPOX VACCINATION AND RESPONSE

WHAT IS THE PUBLIC HEALTH ISSUE?

Smallpox is an extremely contagious and dangerous disease where 30% of all cases result in death. The last reported case in the United States occurred in 1949. The ring vaccination method was used to contain and eliminate the disease. Overall, the smallpox vaccinations proved very successful. In 1972, the vaccine was no longer administered, and in 1980 it was announced that smallpox was eradicated from the world. The risks of being infected are minimal, but the United States must still be prepared to respond quickly in the event of a terrorist attack using the smallpox virus. The smallpox vaccine can often prevent or substantially lessen the severity of infection when administered within a few days of exposure. CDC is taking action to protect the public from the dangers of smallpox by establishing response plans, developing vaccination policy and procedures, and providing training to professionals. CDC is committed to helping public health and healthcare communities improve smallpox preparedness and response.

WHAT HAS CDC ACCOMPLISHED?

The list below highlights several of CDC's accomplishments regarding smallpox vaccination and demonstrates the growing success of its terrorism preparedness and response program.

- Supported the development of a federal plan to better protect people from the threat of smallpox.
- Collaborated with the Department of Health and Human Services's (HHS) Health Resources Services Administration to establish the Smallpox Vaccination Injury Compensation Program, authorized through the *Smallpox Emergency Personnel Protection Act of 2003* (Public Law 108-20, 117 Stat. 638). This program appropriated \$42 million to provide medical, lost employment income, and death benefits to eligible individuals.
- Provided all 62 state, local, and territorial State and Local Preparedness Cooperative Agreement grantees a summary of the smallpox "recipient activities" that are found in each of the Cooperative Agreement Focus Areas. This annex provided a framework for how grantees should include smallpox recipient activities in work plans for relevant Focus Areas.
- Requested and helped states develop pre-event and post-event response plans.
- Worked with state and local governments to form volunteer Smallpox Response Teams.
- Helped enhance the nation's supplies of smallpox vaccine and vaccinia immune globulin (VIG), a serum that is used to treat the most severe reactions to smallpox vaccine. The United States currently has sufficient quantities of the vaccine to vaccinate every person in the country in an emergency; there are sufficient quantities of VIG to treat all anticipated adverse events from the current vaccination program.
- Held 19 training and education sessions on smallpox that reached an estimated 800,000 clinicians, public health workers, and the general population.

WHAT ARE THE NEXT STEPS?

- While the federal government is not recommending that the general public be vaccinated at this time, HHS is developing a process for making unlicensed vaccine available to those adult members of the general public without medical contraindications who want to be vaccinated either in 2003 with unlicensed vaccine, or in 2004, with licensed vaccine.
- Post-vaccination surveillance will be conducted for people receiving the smallpox vaccine. CDC is providing vaccination training for laboratorians and information on their role in diagnosing adverse events associated with smallpox vaccination.
- Training and education for Smallpox Response Teams will be critical; and, therefore, these teams will be provided information and instructions about pre- and post- vaccination. CDC will continue to educate clinicians about smallpox in conjunction with medical professional organizations.

For additional information on this or other CDC programs, visit www.cdc.gov/program

January 2004

STATE AND LOCAL READINESS

WHAT IS THE PUBLIC HEALTH ISSUE?

The prospect of terrorists unleashing biological, chemical, radiological, or conventional weapons is a terrifying one. To protect the health of Americans, a fully prepared public health system must be in place at the state and local levels—where public health begins and ends. As the lead federal agency for public health, CDC assists state and local health departments in preparations to respond to terrorism, infectious disease outbreaks, and other public health emergencies. A well-planned, rapid, and effective response is critical to saving lives.

Across the country, state and local health officials are reconsidering the capabilities of their health departments to respond to a biological, chemical, radiological, or conventional weapons terrorism incident. Traditionally, the responsibilities of the state health departments have been disease surveillance and management. Health departments now are expanding their roles to include responding effectively to an intentional release of a terrorist agent into an unsuspecting population.

WHAT HAS CDC ACCOMPLISHED?

Since 1999, CDC has provided funding and support for the State and Local Preparedness Cooperative Agreement Program. The purpose of this program is to upgrade state and local public health jurisdictions' preparedness for and response to terrorism, infectious disease outbreaks, and other public health threats and emergencies. These cooperative agreements comprise the largest public health program outside of Medicare.

Examples of Program in Action

Since its inception, planning activities for the State and Local Preparedness Program have spread from 5 states or localities to the current 50 states, 4 localities, and 8 U.S. territories. Specific accomplishments achieved by the state and local jurisdictions include

- 100% of participants have identified a state-wide Director of Bioterrorism.
- 98% have established a Bioterrorism Advisory Committee.
- 91% can initiate a field investigation within 6 hours of an urgent disease report from all parts of a jurisdiction on a 24/7 basis.
- 100% established a timeline for a state-wide plan.
- 95% indicate a 24/7 system is in place to activate the response plans.
- 82% have systems established to rapidly detect a terrorist event through mandatory disease reporting.

CDC also initiated the current Public Health Preparedness Project. Working with subject matter experts within CDC and across public health, this project will define public health preparedness indicators. These indicators will improve strategic planning and management of CDC's cooperative agreements. By providing an evaluation framework, the indicators will also link preparedness levels to measurement of progress toward the long-term goals and measures of CDC's terrorism program.

WHAT ARE THE NEXT STEPS?

Because a chemical, biological, radiological or nuclear (CBRN) attack will most likely occur locally, disease-tracking systems at state and local health agencies must be ready to detect unusual patterns of disease and injury, and epidemiologists at these agencies must have expertise and resources for responding to reports of rare, unusual, or unexplained illnesses. CDC is also developing new methods to rapidly detect, evaluate, and report suspicious health events that might indicate natural or intentional CBRN releases for all state health departments and selected major metropolitan cities and territories.

STRATEGIC NATIONAL STOCKPILE

WHAT IS THE PUBLIC HEALTH ISSUE?

- An act of terrorism (or large-scale natural disaster) targeting the U.S. civilian population will require rapid access to large quantities of pharmaceuticals and medical supplies.
- Such quantities of pharmaceuticals and medical supplies may not be readily available unless special stockpiles are created.
- Few state or local governments have the resources to create stockpiles on their own. In addition, this would be inefficient due to the shelf life of medical supplies, requiring ongoing logistics management.
- No one can anticipate exactly when, where, or how a terrorist will strike.

WHAT HAS CDC ACCOMPLISHED?

In 1999, Congress charged the Department of Health and Human Services (HHS) and CDC with establishing the National Pharmaceutical Stockpile (NPS). In March 2003, NPS became the Strategic National Stockpile (SNS), managed jointly by the Department of Homeland Security (DHS) and HHS. The SNS is a national repository of antibiotics, chemical antidotes, antitoxins, life-support medications, IV administration supplies, airway maintenance supplies, and medical/surgical items. The SNS supplements and re-supplies state and local public health agencies within 12 hours of federal deployment. The SNS program works with governmental and nongovernmental partners to upgrade the nation's public health capacity for responding to a national emergency and manages and distributes SNS assets.

Example of Program in Action

The SNS program delivers 12-hour push packages to locations in the United States or its territories within 12 hours of federal deployment. Concurrent with the transportation of SNS assets, the SNS program will deploy its Technical Advisory Response Unit (TARU). The TARU staff will coordinate with state and local officials to ensure SNS assets are efficiently managed and used upon delivery. If additional pharmaceuticals and/or medical supplies are required, follow-on vendor managed inventory (VMI) supplies are shipped to arrive within 24 to 36 hours. If well-defined, VMI can be tailored to provide pharmaceuticals, supplies, and/or products specific to the suspected or confirmed agent(s).

WHAT ARE THE NEXT STEPS?

The CHEMPACK Project is an initiative to augment the nation's ability to respond to a chemical or nerve agent terrorist attack. While many states have been preparing for such an attack, CHEMPACK places federally owned antidote and symptomatic treatments in cities across the nation. It will remain federal property and remain in secure, monitored, and environmentally-controlled storage, unless locally needed for use in a chemical or nerve agent incident. As long as CHEMPACK material remains federal property, the material may be included in the Shelf-Life Extension Program (SLEP) of the Food and Drug Administration. Provided SLEP testing continues to certify its effectiveness, CHEMPACK provides readiness capability for a fraction of its replacement cost.

What Does This Mean For States?

The emergency response concept enhances state and local first response activities in an emergency. The SNS team arrives within 12 hours of federal deployment, with pharmaceuticals and other medical material and equipment. The state receives, per established priorities, support for as long as required. The SNS Logistics team will constantly update what is kept in stock to ensure it supports the needs of states. Additionally, the SNS program purchases items not stocked and provides training and technical assistance to states, major cities, and U.S. territories.

For additional information on this or other CDC programs, visit www.cdc.gov/program

January 2004

TERRORISM PREPAREDNESS AND EMERGENCY RESPONSE

WHAT IS THE PUBLIC HEALTH ISSUE?

New and emerging health risks associated with mass trauma events and chemical, biological, radiological, and nuclear (CBRN) agents are increasing matters of concern. Consequently, the role of our public health system is changing to include new areas of concern, such as public health law, forensic epidemiology, and national security.

This expansion has reshaped public health practice, and requires public health preparation for and response to emergencies in a more effective, efficient, and coordinated way. While embracing this new role, public health's cardinal responsibility remains the same—to protect people's health. CDC is committed to enhancing preparedness and emergency response expertise. Core competencies, such as detection; investigation and response; control, containment and recovery; laboratory science; and research have driven past successes and will now provide the foundation for renewed efforts to protect the public from ever changing health threats.

WHAT HAS CDC ACCOMPLISHED?

The list below highlights several of CDC's accomplishments in this emerging area and demonstrates the growing success of its terrorism preparedness and response program.

- Enrolled 25 new laboratories into the national Laboratory Response Network, bringing the total to 121.
- Continued to manage the State and Local Preparedness Cooperative Agreement and provided updated guidance to all 62 grantees.
- Successfully maintained the Strategic National Stockpile (SNS) with 12-hour push packages, ensuring onsite delivery within 12 hours.
- Administered the Select Agent Program, resulting in 332 entities being registered, 211 inspections completed, 131 select agent transfers tracked, and the publication of an interim Final Rule, amending the applicability requirements to allow provisional registration certificates.
- Established an agency-wide public health strategy for terrorism preparedness and response.
- Increased the availability of respirators certified against CBRN agents for first responders based on rigorous laboratory tests, evaluation of product specifications, and assessment of the manufacturer's quality control procedures.
- Issued criteria for testing/certifying CBRN Escape Respirators intended to reduce toxic exposures in the workplace.
- Participated in exercises such as TopOff2, Global Mercury, and Unified Defense 2003 to improve coordinated emergency response.
- Supported state and local public health departments' preparedness capabilities such that 95% of grantees indicate that round the clock systems are in place to activate response plans; 100% identified a state-wide Director of Bioterrorism; and 87% developed plans to receive and manage the SNS.
- Posted over 1,200 notifications on reports of outbreaks on the *Epidemic Information Exchange (Epi-X)*, CDC's nationwide secure communications system. *Epi-X* connects more than 1,800 public health officials, fills requests for epidemiologic assistance, and announces terrorist threats or acts.

WHAT ARE THE NEXT STEPS?

CDC is committed to strengthening the nation's public health system. CDC will continue providing technical assistance to states, improving laboratory capacity to detect biological and chemical agents, detecting emerging threats through a local/national data collection system, developing personal protective equipment technologies, and ensuring health information reaches all clinicians through a comprehensive network of satellite and other communication capacities.