CDC's Strategic Plan for Bioterrorism Preparedness and Response

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The Department of Health and Human Services (DHHS) has played a critical lead role over the past two years in fostering activities associated with the medical and public health response to bioterrorism. Based on a charge from Secretary Donna Shalala in 1998, the Centers for Disease Control and Prevention (CDC) is leading public health efforts to strengthen the nation's capacity to detect and respond to a bioterrorist event.

As a result of our efforts, federal, state, and local communities are improving their public health capacities to respond to these types of emergencies. For many of us in public health, developing plans and capacities to respond to acts of bioterrorism is an extension of our long-standing roles and responsibilities. These are stated in the CDC Mission Statement: to promote health and quality of life by preventing and controlling disease, injury, and disability, and the Bioterrorism Mission: to lead the public health effort in enhancing readiness to detect and respond to bioterrorism.

CDC's infectious diseases control efforts are summarized below:

- Initially formed to address malaria control in 1946;
- Established the Epidemic Intelligence Service in 1951;
- Participated in global smallpox eradication and other immunization programs;
- Estimated 800–1,000+ field investigations/year since late 1990s;
- New diseases: Legionnaire's Disease, toxic shock syndrome, Lyme disease, HIV, hantavirus pulmonary syndrome, West Nile, etc.
- Today: focus on emerging infections and bioterrorism.

Over the past 50 years, CDC has seen a decline in the incidence of some infectious diseases and an increase in some, whereas others continue to present on a more unpredictable basis (i.e., hantavirus). Outbreak identification, investigation, and control have been an integral part of what we do for more than 50 years. We estimate that 800 to 1,000 field investigations have occurred every year since the late 1990s. Today, however, we have a new focus on emerging infectious diseases and bioterrorism.

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CDC PLANS TO ADDRESS THE CHALLENGE

So what are we doing at CDC to address this challenge? We have developed a strategic plan, reflecting broad-based input, for implementing complementary and coordinated improvements in bioterrorism-related preparedness at the federal, state, and local levels. This strategy reflects input received through consultations with many private and public organizations, including the Association of State and Territorial Health Officials, National Association of County and City Health Officials, Association of Public Health Laboratories, Council of State and Territorial Epidemiologists, American Society for Microbiology, Association of Professionals in Infection Control and Epidemiology (APIC), Infectious Diseases Society of America (IDSA), Center for Civilian Biodefense Studies at Johns Hopkins University, Society of Healthcare Epidemiologists of America (SHEA), National Association of Public Health Veterinarians (NAPHV), National Association of Medical Examiners (NAME), Association of State Veterinary Laboratory Directors (ASVLD), American Hospital Association (AHA), American College of Emergency Physicians (ACEP), American Public Health Association (APHA), as well as a number of others. The strategic plan for bioterrorism preparedness and response includes:

- Enhanced capacity for detection, diagnosis, and management of disease outbreaks;
- Improved characterization and identification of causative pathogens, toxins, or selected chemical exposures;
- Strengthened public health response capacities to control and contain such emergencies;
- Information technology infrastructure to rapidly transfer data and information needed to prepare for and respond to these events.

The priority is to ensure that we have the appropriate level of preparedness and response capacities at the local and state levels of the public and private health care system. Because this is where the first signs of a bioterrorist event will be observed, it only makes sense that this is where we place our first lines of defense. However, preparing communities to address the dangers of bioterrorism is a major challenge to public and private health care systems. A critical step in meeting these challenges is to reexamine the core public health infrastructure in the United States (e.g., disease surveillance, training, health communications, and laboratory capacity). Enhancing core public health infrastructure will enable public health agencies and primary health care providers, who are on the front lines of response, to detect and respond rapidly when an incident occurs. Additionally, enhancing the core public health infrastructure will provide the added benefit of strengthening the overall capacity for identifying and controlling emerging infectious diseases, injuries, and other emergencies as they occur.

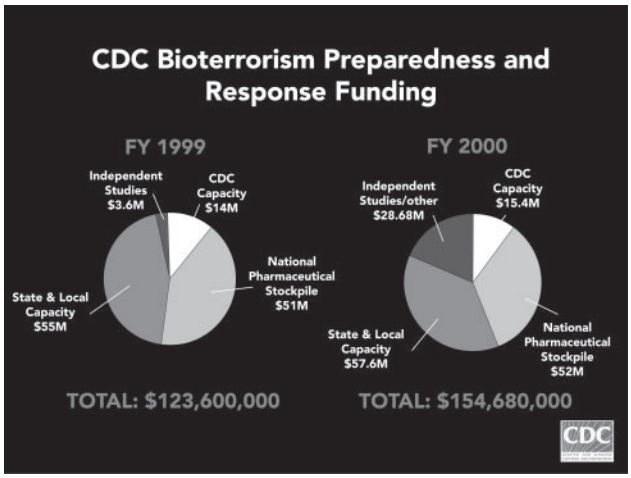

Figure 1.

Combined for Fiscal Years 1999 and 2000, more than $275 million has been appropriated to CDC to help ensure efforts associated with bioterrorism preparedness and response. Apart from the stockpile and other congressional earmarks, more than half of these monies were awarded extramurally to support state and local bioterrorism preparedness and response efforts. With these funds, public health agencies have begun to develop capacities and enhance the existing public health infrastructure in ways not possible without the infusion of the bioterrorism monies.

Specific activities include the development and implementation of information systems used to monitor disease trends, detect outbreaks, and improve public health decisions, such as the National Electronic Disease Surveillance System (NEDSS) and the Health Alert Network, which is used to alert public health officials about emerging disease outbreaks or potential threats; improving hospital-based disease detection systems; enhancing staff competencies to respond to terrorist acts; and improving public health laboratory capacities to rapidly detect and diagnose specific bioterrorism threat agents.

ASSESSING LOCAL CAPACITY

CDC is also working with the Department of Justice to implement an assessment tool for local public health agencies. This effort will help local agencies under-

stand their current emergency response capabilities and needs. Information already obtained from this assessment is helping local health officials identify strengths and weaknesses of their response capacities, an important first step in developing comprehensive plans associated with bioterrorism preparedness and response. We find this effort to be extremely important and look forward to seeing the results.

ACHIEVEMENTS

Since the inception of the bioterrorism initiative, CDC has overcome a number of challenges, resulting in some major improvements in our ability to respond to bioterrorism. I acknowledge Dr. Scott Lillibridge and his colleagues in CDC's Bioterrorism and Preparedness Program for providing leadership and spearheading these efforts.

Laboratory

Before the inception of the bioterrorism initiative, CDC had limitations in its in-house ability to test for five of the six pathogens listed on its Critical Biological Agent Category A List (plague, tularemia, botulinum toxins, smallpox, and viral hemorrhagic fevers). In addition, CDC now has the ability to test for anthrax. These six critical agents represent diseases that can be easily transmitted between individuals, cause high mortality with potential for major public health impact, possibly cause public panic and social disruption, and require special action for public health preparedness. Rapid identification, triage strategies, new labs, and staff provide national capacity to respond to such events. We continue to work with state and local partners to ensure that we develop capacities to test for other critical agents such as Q fever, glanders, brucellosis, alphaviruses, epsilon toxin of *Clostridium perfringens,* staphylococcal enterotoxin B, Nipah virus, tickborne hemorrhagic fever viruses, and tickborne encephalitis viruses.

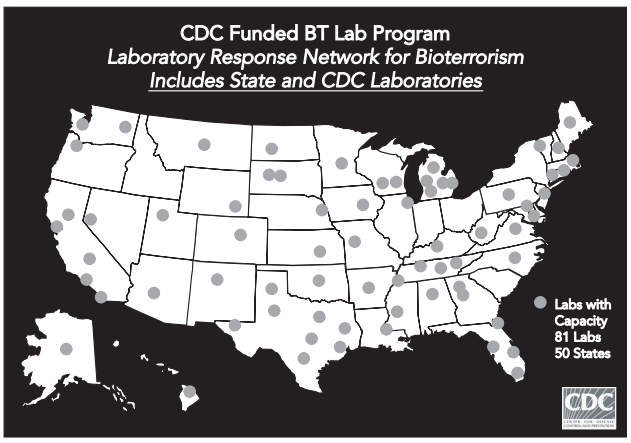

Figure 2.

At the state and local public health laboratory levels, some level of capacity now exists in 72 public health laboratories in 50 states to test for plague, tularemia, and anthrax. Previously, this existed only in a few western states, and no state had the ability to test for anthrax. Now 22 states—up from 19—have the capability to test for botulinum toxins. Having this level of laboratory capability at the state and local level in 81 laboratories in 50 states clearly provides an unprecedented level of surveillance capacity. We will continue to build on this effort in the coming year.

CDC has also established a rapid response and advanced technology laboratory for bioterrorism that triages and initially processes samples from suspect cases, provides 24-hour diagnostic support to bioterrorism response teams, maintains chain of custody, and assesses new rapid diagnostic assays that could be transferred to the national public health laboratory network. To date, more than 600 specimens have been logged into the rapid response and advanced technology laboratory. Each of these specimens tells a story of a public health mobilization at the federal, state, and local levels. Activities associated with this level of threat assessment involve public health and law enforcement partners evaluating threats ranging from smallpox to the anthrax hoax.

Approximately two years ago, CDC recognized the need to ensure appropriate laboratory testing capacities for critical biological agents in state public health laboratories. In response to this need, CDC, in collaboration with the Association for Public Health Laboratories, Department of Justice/Federal Bureau of Investigation, and the Department of Defense, developed the National Laboratory Response Network (NLRN). This secure network provides standardized diagnostic protocols and reagents needed by state public health labs to test for plague, tularemia, anthrax, and botulinum toxins. The NLRN also offers assistance in locating other laboratories that have the capability to test for specific agents on the Critical Biological Agent List. This function helps to share information and communicate best practices. Currently, more than 100 individuals, mostly state public health laboratory staff, are registered as members of the network. In 2001, CDC expects the number of users to grow.

Besides the work being done to improve the capabilities of the public health labs, CDC is also working with the American Society for Microbiology (ASM) to

ensure the capacity of the thousands of clinical laboratories across the country is included in the bioterrorism laboratory effort. Specific laboratory protocols developed by ASM will be promoted by CDC to ensure standard methodologies are used in the clinical lab setting to rule out potential bioterrorism agents. With the clinical labs making up such a large part of our front-line defenses against bioterrorism, we continue to focus on this important work in the months ahead.

In 1999, more than 700 individuals received clinical laboratory training associated with the critical biological agents. During this year, CDC staff provided "train-the-trainer" training to 75% of the state public health laboratory personnel who are members of the NLRN. This training focused on specialized testing methods to determine presumptive and confirmatory diagnoses of five critical biological agents associated with bioterrorism. These efforts will continue into 2001 as we strive to improve the competencies of laboratory personnel to rule out and identify bioterrorism threat agents.

Surveillance and Epidemiology

Critical to CDC's bioterrorism preparedness effort is early detection of an event coupled with effective and timely response. Because the initial response to a biological or chemical event is likely to be made at the local level, epidemiologists at state and local health agencies need to acquire, develop, and maintain the resources and expertise necessary for responding to reports of rare, unusual, or unexplained illnesses.

All 50 states, the District of Columbia, Guam, New York City, Chicago, and Los Angeles are supported by funds for activities to support enhancing epidemiology and surveillance capacities. These funds are being used to hire surveillance coordinators and epidemiologists, support rapid reporting of bioterrorism-specific diseases and unusual epidemiological events, identify and train rapid response teams, and improve overall emergency notification procedures.

In keeping with lessons learned from the West Nile virus outbreak in the Northeast, some states are also developing reporting mechanisms with medical examiners, poison control centers, hospitals, emergency medical system units, animal health care providers, and other nontraditional partners to enable early detection. Working with state and local partners, CDC has also developed disease-specific information for health care providers, emergency first-responders, and the public that will instruct them on what to do during an actual bioterrorism event. Working with the US Army Medical Research Institute of Infectious Diseases (USAMRIID), CDC has trained, via satellite, more than 15,000 health care providers, including emergency room physicians and infectious disease practitioners. In addition, CDC is beginning work with IDSA, APIC, and SHEA to develop training materials targeted at these medical specialties to help them to detect, recognize, and respond to bioterrorism. These efforts as well as many others demonstrate the value of bioterrorism preparedness and response activities in improving public health response infrastructure. The West Nile encephalitis outbreak typifies how an improved public health infrastructure is vitally needed to deal with ongoing outbreaks of naturally occurring infectious diseases as well as bioterrorism. These response efforts can be greatly improved by upgrading laboratory and surveillance capacities along with added surge capacity at CDC. Each of the surveillance activities mentioned supports the broad theme of preparedness, enhanced response, and integration of surveillance activities.

Research and Development

CDC, along with the National Institutes of Health (NIH), continues to make investments in research and development associated with vaccines related to the diseases on our Critical Biological Agent list. To better prepare the United States against the possible use of smallpox virus, CDC has awarded a contract with Oravax, Inc. (Cambridge, MA) to produce smallpox vaccine. Approximately 40 million doses of vaccine will be produced initially, with anticipated delivery of the first full-scale production lots in 2004. The contract allows for increased production of the vaccine should the need arise.

To address overall vaccine issues associated with bioterrorism, a working group of representatives from DHHS (Office of Emergency Preparedness, CDC, NIH, Food and Drug Administration), Department of Defense/Joint Vaccine Acquisition Program, USAMRIID, and US Department of Agriculture was formed to evaluate vaccines currently available or in development for the following biological threat agents: *Variola major, Bacillus anthracis, Yersinia pestis, Clostridium botulinum* toxins, *Francisella tularensis,* filoviruses and arenaviruses, *Coxiella burnetii, Brucella* species, and alphaviruses. This is a work in progress and continues to be a major priority for us as we assess the role of vaccines in bioterrorism preparedness.

A number of academic institutions have also been funded to support bioterrorism preparedness and response. These institutions (Johns Hopkins University Center for Civilian Biodefense Studies, Carnegie-Mellon Research Institute, St. Louis University School of Public Health, University of Texas at Galveston, and

UCLA School of Public Health) are performing work associated with:

- Developing national medical and public health policies and structures to protect civilian populations from bioterrorism
- Assessing the capability of computer-based surveillance systems to detect naturally occurring disease outbreaks and acts of bioterrorism
- Establishing a center for research and education focused on bioterrorism
- Conducting studies of viral hemorrhagic fevers as well as other critical bioterrorism diseases considered to be the greatest threat to the American people

Each of these research activities will offer insights into how best to prepare the nation to counter bioterrorism.

National Pharmaceutical Stockpile

Our strategy in addressing bioterrorist threats involves both preparedness and response efforts. This being the case, we must not only build effective disease surveillance and detection systems but also have a response strategy that is clearly understood by both public health and other emergency first-responders.

A key component of this response capacity is CDC's national pharmaceutical stockpile (NPS). The NPS is organized into two components. The first includes eight identical "push packages," which CDC has strategically placed at distribution centers throughout the United States. Each 12-hour push package, which is made up of 109 palletized air cargo containers and takes two airplanes to deliver, is composed of pharmaceuticals, intravenous and airway supplies, emergency medications, bandages, and dressings. These items are necessary to enhance state and local capacities to provide therapeutic treatment and prophylaxis of a population affected by a biological or chemical terrorism incident.

In addition to the 12-hour push packages, CDC will use vendor-managed inventory to provide specific quantities of antibiotics and other medical materials to the requesting agency within 24 to 36 hours after the federal decision to deploy. CDC, through a partnership with the Department of Veterans Affairs, has contracted with vendors and manufacturers to stock these additional pharmaceuticals and supplies.

State and local health agencies in collaboration with CDC are working on strategies to address methods of receiving and managing the medical materials that would be deployed from the national stockpile. This is important work because providing the medicines to the individual in the most expeditious and effective manner possible will improve our chances of rapidly controlling and containing the consequences of a bioterrorist incident.

CDC Staff Support

For many years, CDC has provided assistance in the form of trained epidemiologists and public health advisors to complement existing local expertise to respond to naturally occurring infectious disease outbreaks or to deal with chemical exposures. In the event of a bioterrorist incident, CDC will, when requested, provide staff to support state and local efforts.

However, the magnitude of the response and the fact that we may need to deploy larger numbers of staff to varying locations around the country require us to change our institutional model for response.

During the Top Off exercise (see below), we quickly realized that we could exhaust our resources. The need to develop plans for training a greater number of staff to respond to large disease outbreaks, similar to the simulated plague outbreak in Denver, became readily apparent.

In conjunction with improving our internal response efforts, we are also working with state and local public health agencies and other first-responders to develop training programs focused on appropriate response to bioterrorism. We believe that enhancing the response competencies of the key responders at the federal, state, and local levels improves our overall chances of combatting the consequences of a real bioterrorist event.

Information Technology

With new and ever-changing technologies, CDC is positioning itself to ensure accurate and timely data collection and analysis, which will improve overall public health decision-making capabilities.

CDC, working with the Defense Advanced Research Projects Agency, used cutting-edge technology to conduct real-time syndrome surveillance at the World Trade Organization meeting in Seattle in late 1999 as well as the Republican and Democratic National Conventions in the summer of 2000. These experiences confirmed the importance of rapid and accurate data-reporting systems.

Another example of CDC's use of information technology is in the development of the NEDSS project, which will provide guidance and funding to state and local health agencies to further the development of sophisticated information systems for enhanced reporting of diseases and allow greater use of disease data in detecting potential acts of bioterrorism. To support this effort, $9.8 million was awarded to 49

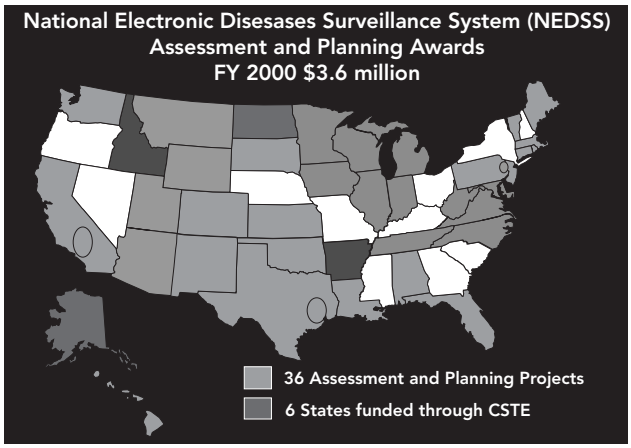

Figure 3.

state and local health agencies in September 2000. These monies have been awarded to states to support information technology assessment and planning activities needed to help prepare them for future project growth and expansion. In addition, 12 states have been selected to focus on the development of specific technologies (e.g., web browser data entry, HL7 messaging). These projects are called element development sites. Finally, two states—New York and Oregon—have been selected as charter sites. These two states will be supporting the development of demonstration projects to provide models and best practices in support of NEDSS standards and specifications. Once these systems begin to develop, the nation will see a significant improvement in how public health agencies collect and analyze infectious disease data.

Based on concerns from state epidemiologists that a system for rapidly sharing information pertaining to outbreaks of infectious diseases nationally did not exist, CDC has developed the Epidemic Information Exchange Program, or Epi-X. This system provides real-time information about ongoing disease outbreak activities (both bioterrorism and naturally occurring), provides a link to related outbreaks and other health events, helps health officials respond to emerging public health incidents, and ensures notification of health officials. Epi-X is in the process of being rolled out, and we expect a significant increase in users in 2001.

CDC will continue to promote, develop, and support various technologies that will enhance and enable disease detection strategies associated with bioterrorism preparedness and response as we move into the future.

Top Off Exercise

CDC, as well as our partners at the state and local levels, continues to learn valuable lessons as we move further into the emergency response arena. In May 2000, CDC staff participated in a national exercise,

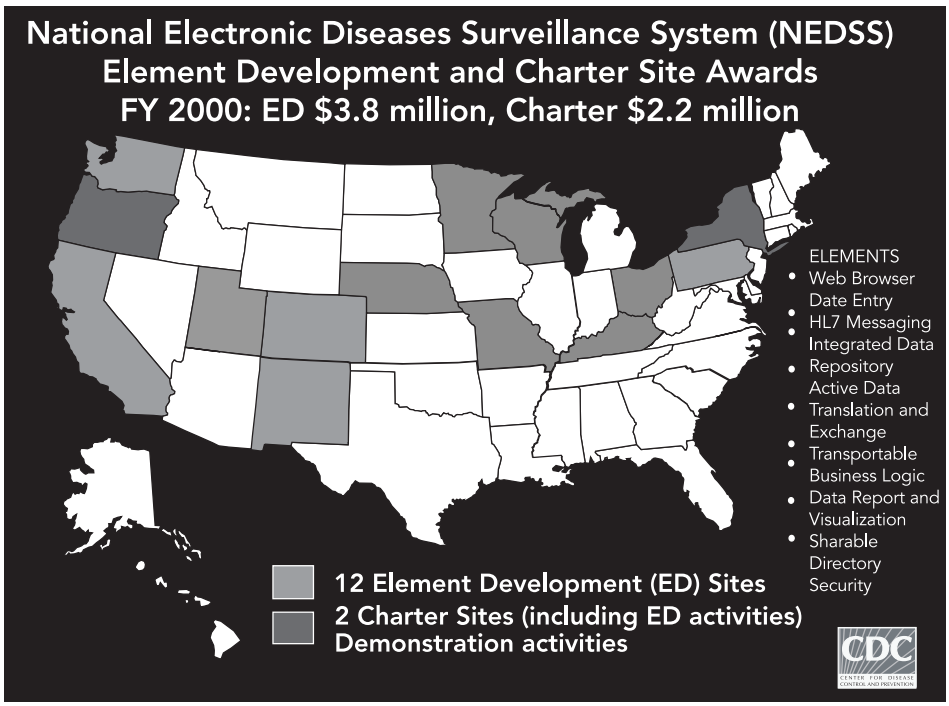

Figure 4.

Top Off. Our involvement in the exercise was significantly focused on a simulated pneumonic plague outbreak in the Denver metropolitan area, but we were also involved in a simulated mustard gas release in Portsmouth, New Hampshire, and a simulated radiological incident in the Washington, DC, area. Staff from CDC were assigned to a number of response components. I was in Washington, DC, to brief the secretary and consult with Surgeon General David Satcher. A command post was set up in Atlanta, headed by Dr. Jim Hughes, director of the National Center for Infectious Diseases. An operational component was staffed by the National Center for Environmental Health's Emergency Preparedness and Response Branch as well as a number of on-site field staff deployed to two of the three exercise venues.

The exercise in Denver taught us many valuable lessons on how to plan for and respond to outbreaks of infectious diseases of this magnitude. Several challenges were presented during the Top Off exercise in Denver to include difficulties in implementing and exercising federal, state, and local quarantine authorities, complications in the distribution of the national pharmaceutical stockpile from the state receiving site to local points of distribution, the complexity of providing support for expanded health care delivery, and long-term outbreak control strategies.

To address these challenges, CDC developed and implemented an action plan from June to October 2000 to strengthen CDC's internal response capacities. As a result, CDC drafted a national bioterrorism training plan focusing on the public health work force, addressed the critical issues associated with distribution of the stockpile once deployed to a state location, developed a better understanding of its role in response to an outbreak of this magnitude, and developed capacities to use geographical information systems that did not previously exist.

CDC continues to work on issues associated with federal, state, and local quarantine authorities, finalizing and implementing training plans and working with other DHHS components that address the clinical needs in health care facilities.

CDC has also committed to develop a centrally located emergency operations center to deal with public health emergencies and enhance communications with key response components of the US government.

Exercises such as Top Off provide invaluable experiences for CDC that help improve our capacity to respond to events from the federal perspective and help us understand how best to support state and local efforts.

SUMMARY

Although much has been accomplished in the past 2 years, there is still much to do to prepare the nation to

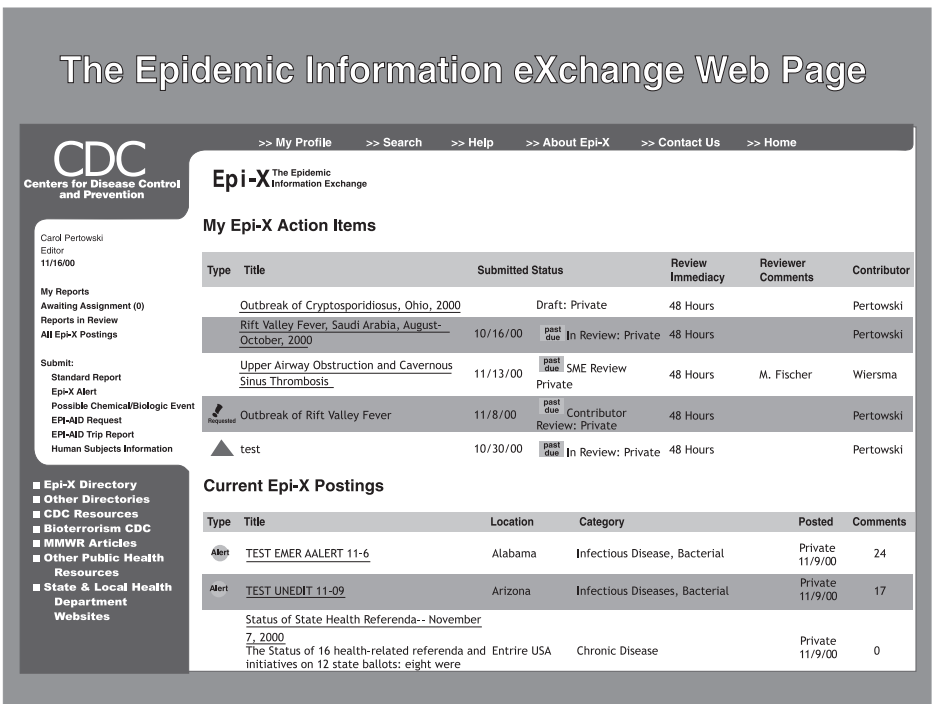

Figure 5.

Figure 6.

effectively counter acts of biological terrorism and acts of chemical terrorism. We need to strengthen capabilities of CDC, state and local health departments, key health care providers, academic institutions, federal partners, as well as traditional first-responders. This can only be accomplished through provision of adequate resources, development of mutually beneficial partnerships, enhancement of effective public health systems, research, training, and technical support. Plans for the future will continue to support the development of needed public health capabilities at the state and local levels and linkages with clinical and infection control professionals and veterinary communities, enhance emergency response coordination within DHHS, as well as address infrastructure improvements at CDC.

Specifically, these plans include defining core capacities needed at the federal, state, and local levels to prepare for, detect, and respond to acts of bioterrorism; strengthening state and local surveillance; developing new algorithms and statistical methods for searching medical databases on a real-time basis for evidence of suspicious events impacting public health; and establishing criteria for investigating and evaluating suspicious clusters of human or animal disease or injury.

CDC will continue to foster linkages between public health and emergency management agencies. To support this effort, CDC is working to partner with the National Governors Association and the National Emergency Management Association to recognize the unique role public health of in emergency response.

To widen the global bioterrorism preparedness and response network, CDC will continue to strengthen collaborations with our international partners, such as the World Health Organization and various ministries of health. The work we do now to detect and respond to bioterrorist acts and the partnerships that we develop will improve our ability to minimize the consequences of such an event as well as the nation's public health infrastructure to combat many of the day-to-day public health issues to ensure we are all safer—healthier—people.