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Preparing for Bioterrorism

When an emergency room doctor sees a patient who presents with the symptoms of a common cold or flu, in the absence of other indicators or tests, the doctor will conclude that it *is* a cold or the flu – not the first case in a bioterror attack. This is consistent with the training doctors receive in medical school– to look first to the most common ailments in forming their diagnoses. This is prudent medical practice, but such a practice could present problems if one day that apparent cold instead *actually is* a bioterror attack – that is a deliberate attack on the lives of innocent people through the use of a lethal biological agent. If that event occurs, a rapid and correct diagnosis and response will mean saving hundreds or thousands of lives.

When and where a bioterror attack might happen and what specific biological weapons would be employed are open questions, but few experts question that terrorists intend for this inevitability. How can U.S. citizens have confidence that the nation’s front-line healthcare practitioners will have the ability to quickly detect and properly respond to a biological attack? And what can the federal government do to help assure that the correct diagnoses and responses are made so Americans’ lives are protected?

Given the range of potential agents that terrorist groups may employ, the U.S. response must be broad. Preparedness efforts on federal, state, and local levels are crucial, and Congress has the critical role of fostering the coordination among the three levels.

Responding to a Bioterror Attack: Project BioShield

Once the medical community has been able to detect that a bioterror attack has occurred, it must be able to quickly initiate a full-scale response. One key aspect to assuring a proper response is Project BioShield, which was proposed by President Bush during his State of the Union Address in 2003. This is a comprehensive effort to develop and make available modern effective drugs and vaccines to protect against and treat attacks from biological and chemical weapons or other dangerous pathogens. The President demonstrated his commitment to the effort in saying, “The budget I send you will propose almost \$6 billion to quickly make available effective vaccines and treatments against agents like anthrax, botulinum toxin, Ebola, and plague. We must assume that our enemies would use these diseases as weapons, and we must act before the dangers are upon us.”

Many potential biological terrorism agents lack available treatments and countermeasures. As a result, the President's initiative includes: (1) expedited procedures for bioterrorism-related procurement and peer review; (2) a guarantee of a government market for new countermeasures; and (3) authorization for the emergency use of unapproved countermeasures.¹

A CDC assessment issued in February of 2002 determined that smallpox, anthrax, plague, botulism, tularemia, and Ebola present the greatest "potential for adverse public health impact with mass casualties, and require broad-based public health preparedness efforts (e.g., improved surveillance, laboratory diagnosis, and stockpiling of specific medications)." Yet today, the need for reliable countermeasures exceeds current vaccination capability. As medical science advances, it is clear that, in addition to vaccines, other countermeasures, such as devices, drugs, and antitoxins, need to be made available. This task is complicated by the fact that only a limited number of vendors actually manufacture such treatments. Given the highly specialized process that requires an extensive infrastructure, it is critical to support those vendors currently involved in this market and to create incentives for new vendors to enter this field.

The Senate could consider S. 15, the Project BioShield Act, this week. The House passed its version, H.R. 2122, in July of last year. Meanwhile, the Department of Homeland Security (DHS) Appropriations Act, 2004 [P.L. 108-90] appropriated \$5.593 billion for FY2004-FY2013 for "necessary expenses for securing medical countermeasures against biological terror attacks."

Detecting a Bioterror Attack

As previously noted, the nation's success in adequately responding to a bioterror attack hinges on its ability to rapidly detect it. Important federal initiatives are underway at the federal, state, and local levels to implement systems to improve detection and response. Since FY03, the federal government already has appropriated \$8.79 billion for biodefense efforts at the Department of Homeland Security and the Department of Health and Human Services. President Bush's budget request for FY05 includes \$6.59 billion for biodefense efforts at DHS and HHS.²

Public-Sector Initiatives

The Centers for Disease Control (CDC) is at the forefront of efforts to detect bioterror agents. Its Public Health Information Network (PHIN) helps coordinate existing and new public health information systems to increase the efficiency of information technology across the public health spectrum.³ Several programs contained within PHIN include:

- Epidemic Information Exchange (Epi-X) – Epi-X links the HHS and CDC command centers with state terrorism surveillance and response programs and provides 24-hour-a-day, seven-day-a-week ("24x7") emergency alerts. It also creates a protected forum to

¹ Congressional Research Service, "Project Bioshield," May 10, 2004.

² See: Department of Health and Human Services, "DHHS Budget in Brief - FY05," available at: <http://www.hhs.gov/budget/docbudget.htm>; and Department of Homeland Security, "DHS Budget in Brief - FY05," available at: http://www.dhs.gov/interweb/assetlibrary/FY_2005_BIB_4.pdf.

³ Information on the listed programs from CDC, "National Public Health Strategy for Terrorism Preparedness and Response," March 2004.

share important disease information nationwide, positioning public health officials to detect and respond accordingly to suspected terrorism emergencies.

- National Electronic Disease Surveillance System (NEDSS) – CDC’s NEDSS sets standards to facilitate data collection, management, transmission, analyses, access and dissemination that can be used to track a potential bioterror attack from the moment of its detection.
- PulseNet – PulseNet, a program in the National Center for Infectious Diseases’ (NCID) Foodborne and Diarrheal Branch, is an early-warning system for outbreaks of foodborne disease, consisting of a national network of public health laboratories that perform DNA “fingerprinting” on bacteria that may be foodborne.
- BioWatch – Under BioWatch, air samples are tested in cities for the presence of biological pathogens to generate early warnings of possible attacks.

CDC currently is reviewing how to better make use of syndromic surveillance for bioterrorism preparedness. Syndromic surveillance uses data that precedes the diagnosis, such as laboratory test requests, ambulance run sheets, prescription and over-the-counter drug use, and school or work absenteeism. Such a surveillance system would also take into account clusters of medical signs and symptoms that may signal a sufficient probability of an outbreak that then would undergo a further public health response.

CDC continues to collaborate with the Council of State and Territorial Epidemiologists (CSTE) to update, publish, and distribute standard case definitions to each state and jurisdiction so that health officials and workers may more accurately diagnose and report conditions related to identified threat agents. Without standard case definitions and data, unusual occurrences of diseases might not be detected. This system also will help accurately monitor trends and evaluate the effectiveness of intervention activities.

These and numerous other efforts aimed at detection – and efforts aimed at response and treatment such as Project BioShield – must continue to receive the attention of Congress to ensure our defense evolves ahead of the threat.

Yet, CDC officials and others in government recognize that the front line of this battle is not in government office buildings but in America’s hospital emergency departments and urgent care clinics. It is imperative that all these facilities and the laboratories that serve them have the diagnostic tools necessary to recognize a biological attack as rapidly as is technologically possible. Time saved between the start of a deliberate attack and its identification by public health officials translates into lives saved.

Private-Sector Initiatives

Recognizing that rapid detection and response are the keys to weakening the blow of a bioterror attack, the Senate Judiciary Subcommittee on Terrorism, Technology and Homeland Security hosted a hearing last week that featured a panel of scientists who have been exploring the means to provide rapid detection of a bioterror attack.

Like most experts, the scientists who testified before the subcommittee believe the threat posed by bioterrorism is real, and recognize that Al Qaeda has demonstrated its intention to use

biological agents as weapons of mass destruction.⁴ As such, they are eager to lend their expertise to the creation of the best possible disease-detection system.

One of many private-sector initiatives to aid in the biopreparedness effort is “Project Zebra” – a collaborative, scientific research effort dedicated to giving the nation’s front-line health infrastructure a critical diagnostic tool to determine if an attack has occurred. Specifically, the project entails creating a genetic-profile database of infectious agents, along with a new diagnostic test that, together, will quickly determine the source of infection in patients.⁵

The name of the project comes from the saying “When you hear hoofbeats, think of horses; don’t think of zebras.” This adage, likely recognizable to anyone who has attended medical school, suggests that usually it is better to start solving a problem by considering the most likely scenarios first before moving on to more exotic possibilities. As earlier noted, doctors are trained to anticipate that the most common diseases are what occur most often. Yet, that training must now be broadened to allow for the less likely possibilities of bioterror attacks; that is, sometimes doctors should consider the presence of a “zebra.”

Project Zebra may be able to build on the work of the Human Genome Project⁶ to develop its diagnostic test. By analyzing how individual pathogens influence DNA once introduced into an individual, scientists hope to use this “gene expression” to establish a set of profile data. Researchers hope that the creation of the data set may allow for the development of a test that can determine if an individual has been infected by a biological weapon even before the onset of significant signs and symptoms. Additionally, the test results might contain specific information about the likely future clinical course for the individual, and so aid in his treatment.

What is critical to the nation’s public health infrastructure is being able to “distinguish the many-fold greater numbers of ‘worried-well’ from the otherwise indistinguishable people with incipient serious infectious disease,” as one of the scientists noted in his testimony.⁷ Determining who has been infected early on can help divert scarce resources to those who have been attacked while relieving the worry of those with similar, but unrelated, symptoms.

The success of Project Zebra and other projects like it will not only benefit public health in the event of a bioterror attack, but in dealing with the spread of infectious diseases that will occur naturally.

⁴ See: George Tenet, “DCI’s Worldwide Threat Briefing: (As Prepared for Delivery) - The Worldwide Threat in 2003: Evolving Dangers in a Complex World,” February 11, 2003; CIA, “The Darker Bioweapons Future,” November 3, 2003; James B. Petro and David A. Relman, “Understanding Threats to Scientific Openness,” *Science*, December 12, 2003.

⁵ Panelists included: Dr. Paul Keim, Regents Professor of Biology at Northern Arizona University and director of Pathogen Genomics, Translational Genomics Research Institute; Dr. Harvey W. Meislin, MD FACEP, Professor and Chair of the Department of Emergency Medicine at the University of Arizona Health Science Center; Dr. David A. Relman, Associate Professor, Stanford University; Dr. Jeffrey Trent, President and Scientific Director of the Translational Genomics Research Institute.

⁶ An international research effort to sequence and map all of the genes - together known as the genome - of members of our species, *Homo sapiens*, the Human Genome Project was completed in April 2003. Now we can, for the first time, read nature’s complete genetic blueprint for building a human being. For more info: <http://www.nhgri.nih.gov/>

⁷ Dr. David A. Relman, Associate Professor, Stanford University, before a hearing of the Senate Judiciary Subcommittee on Terrorism, Technology and Homeland Security on May 11, 2004.

Conclusion

Congress must continue to foster coordinated biopreparedness efforts. The threat is real and growing – requiring federal, state, and local officials to work together to establish the most effective means to detect and then communicate detection of an outbreak, followed by effective treatment and response. Congress has and must continue to foster and fund public-private initiatives that build on the strengths of the public health infrastructure to make further improvements in our preparedness efforts. A broad detection-and-response plan that stays ahead of the evolving threat is surely a fundamental service this government should provide.