

A Crossroads in Biosecurity: Steps to Strengthen U.S. Preparedness



Published by the Center for Biosecurity of UPMC, September 2011 Copyright © UPMC 2011 It is important to recall what we are seeking to achieve in biosecurity the prevention of sudden, large-scale, deliberate, or natural disease threats—and failing prevention, the capacity to save large numbers of lives and diminish the consequences of such events.

Editorial and Design Team

Editor: Mary Beth Hansen, Chief Information Officer

Graphic Design and Typesetting: Davia Lilly, Director of Design and Production

Copyediting and Proofreading: Molly D'Esopo, Senior Communications Specialist Jackie Fox, Senior Science Writer

Table of Contents

A Crossroads in Biosecurity	5
Tom Inglesby and Anita Cicero	
Post-9/11 Challenges of a Crisis	9
D. A. Henderson	
Managing the Insider Threat in	
High-Containment Laboratories	13
Gigi Kwik Gronvall	
Connecting the Dots: Creating a	
National Biosurveillance Capability	17
Jennifer Nuzzo	
Delivering Medical Care in a Catastrophe:	
Time for Crisis Standards	23
Dan Hanfling	
Preparing Hospitals for Large-Scale	
Infectious Disease Emergencies	29
Eric Toner and Amesh A. Adalja	
Four Ways to Reduce the Time and	
Cost of Anthrax Cleanup	33
Crystal Franco	
Community Resilience: Beyond Wishful Thinking	37
Monica Schoch-Spana	



Tom Inglesby, MD, is Chief Executive Officer and Director of the Center for Biosecurity. Dr. Inglesby has published extensively in the field, including a 2010 article in the *Harvard Law and Policy Review* that he co-authored with former Senator Tom Daschle titled, "Necessary Progress in Biosecurity." He was recently named Chair of the Board of Scientific Counselors to CDC's Office of Public Health Preparedness and Response. From 2009 to 2011, Dr. Inglesby served on the National Academy of Sciences expert committee that reviewed the scientific approaches employed in the investigation of the 2001 anthrax letters.



Anita Cicero, JD, joined the Center in 2010 as Chief Operating Officer and Deputy Director after nearly 2 decades as a practicing attorney in both the federal government and private practice. In addition to serving as managing partner of the Washington, DC, office of Drinker Biddle, Ms. Cicero formed and managed a range of biopharmaceutical consortia focused on scientific, regulatory, and policy issues, including issues pertaining to biodefense and countermeasure development. Her most recent publications include the commentary "Early Learning from the Events in Japan," which she co-authored with Tom Inglesby in March 2011.





A U.S. Capitol police officer walks through a part of the Russell Senate office building after the anthrax attacks, Washington, DC (October 17, 2001).

A Crossroads in Biosecurity

Tom Inglesby and Anita Cicero

This fall marks the tenth anniversary of the anthrax attacks and the U.S. biosecurity community born in response. The shocking anthrax attacks in 2001 galvanized government and private sector action and put us on a determined path to reduce the dangers posed by biological threats. This is an appropriate moment for the community to consider the impressive distance that we've traveled since 2001, to understand the options ahead for biosecurity policy, and to map out priorities for future action at this 10-year point.

Before the anthrax attacks, few had seriously planned for such a biological threat, and there was certainly no tangible, multidisciplinary community devoted to improving biosecurity. There were no major government or nongovernment programs on biodefense beyond the DoD biodefense research programs and the anthrax vaccination program. There was no hospital preparedness effort and no CDC program to prepare states and local health departments. There was no NIH biodefense research initiative or FDA countermeasures initiative. There was no Pandemic and All-Hazards Preparedness Act, no ASPR, no BARDA, no BioShield fund. No DHS. Little sustained White House or Congressional attention to bioweapons or pandemic threats.

We Have Already Come Far

We have all those government initiatives now, and more. During the past 10 years, the U.S. government has established many efforts with missions related to improving biosecurity. As a result, substantial gains have been made in public health and hospital preparedness. Scientists have been provided billions of dollars to undertake fundamental research to improve biosecurity. A new FDA initiative is expressly focused on speeding up the regulatory process for necessary medicines and vaccines. There is major U.S. government interest in improving both domestic and international biosurveillance programs. Along the way, SARS, the concerns about avian influenza, and the 2009 H1N1 pandemic reinforced the importance of these programs.

The stakes related to the country's biosecurity have been emphasized from the very top. In 2009, President Obama's National Security Council said, "The effective dissemination of a lethal biological agent within an unprotected population could place at risk the lives of hundreds of thousands of people. The unmitigated consequences of such an event could overwhelm our public health capabilities, potentially causing an untold number of deaths. The economic cost could exceed \$1 trillion for each such incident."¹

But We Still Have a Distance To Go

Despite this warning and despite the steady progress made since 2001, we have a long way to go. We do not have a public health workforce sufficient for recognizing or managing lethal infectious disease outbreaks: the U.S. public health workforce has been thinned substantially in the past few years as state and local budgets have been cut. Our burdensome laboratory security

regimen is inadvertently creating barriers to progress in basic scientific research. We still have far too few of the medicines and vaccines we may need because the advanced development process has been slow and underfunded. Even if we had sufficient medical countermeasures, we do not have plans and reliable means to distribute them to people in the time needed to make a difference. Our hospitals do not yet have all the tools or plans they would need to take care of patients in a large infectious disease emergency. If there were not enough of a medicine or vaccine to go around, we do not yet have a plan for deciding who gets prioritized for treatment. In the event of a wide-area bioterror attack, there is uncertainty regarding how to conduct major decontamination efforts and whether mass evacuation should occur.

Renewed and Steady Determination

The reality now is that biosecurity is no longer benefiting from the collective, intense interest of political leaders or the funding commitments that followed the 2001 anthrax attacks. With the passage of time, the initial sense of urgency in efforts to shore up the nation's biosecurity has waned, even as it is increasingly understood that advances in the biosciences over the past decade make biological weapons ever more accessible and technically feasible, and even with evidence that terrorist groups are interested in acquiring and using them.^{2,3}

Immediate priorities of government have crowded out concern about biothreats over time. It is always a challenge in a democracy to plan for high-consequence, uncommon crises, and biosecurity is the archetype of this phenomenon. But there is no use in bemoaning this situation. At this crossroads of biosecurity on the tenth anniversary of the 2001 anthrax attacks, the biosecurity community (including both government and nongovernment leaders) should not accept the road of diminishing capacity, benign neglect, or gradually lowered expectations about the level of biosecurity that is achievable. We need to commit to tackling the nation's biosecurity challenges in real and tangible ways during the decade ahead.

Suggestions for the Road Ahead

This compendium offers a series of pragmatic suggestions and goals that, if achieved, will move the nation forward on the road to biosecurity. The commentaries that follow offer specific recommendations regarding healthcare preparedness, community resilience, biosurveillance, laboratory security, and post-event remediation. To start, there are a number of proposed changes set forth below that, if made, would position the U.S. government to achieve more steady and efficient progress in the years ahead.

Stabilize and Prioritize Preparedness Investments

Proposed cuts this year include a reduction of more than \$100 million or 15% to CDC preparedness grant funding, more than \$40 million or 10% in cuts to hospital preparedness funding, and reductions of 35% to already limited EPA budgets for decontamination—cuts that will reduce funding for these 3 programs to their lowest levels since 2002.⁴ There has been little political penalty for cutting public health, hospital, and emergency preparedness investments. Leaders and the public should recognize that the great majority of the federal resources in these programs are used to protect people at home in states and cities. It is profoundly unwise to drop preparedness programs that have been built with federal investment and have been successful, but which will degrade without such support.

Increase Clarity and Transparency

We need greater clarity about the government's medical countermeasure needs and decision-making processes. What diagnostics, medicines, and vaccines does the U.S. government now seek for the nation's pharmaceutical stockpile? It has been more than 4 years since HHS, in its PHEMCE Implementation Plan for Chemical, Biological, Radiological and Nuclear Threats, provided a list of its near-term (FY07-08), mid-term (FY09-13), and long-term (FY14-23) goals for research, development, and acquisition of medical countermeasures. It is unclear whether the April 2007 list reflects current HHS priority requirements. Increased clarity in this area would improve the interaction between the government and private industry and allow assessment of overall progress. In addition, when decisions are made to purchase one or another vaccine or medicine, a detailed public rationale should be provided that explains the choice of medicine purchased, justifies the quantities, and explains how that countermeasure will be used operationally in time of crisis. This added level of transparency will help shield the process from undue political influence and will help the broader biosecurity community understand the tools at hand and how best to use them in the event of a crisis.

Build Congressional Expertise

In the words of the White House National Security Council, bioterrorism could place at risk the lives of hundreds of thousands of people. We believe there should be more energy directed toward biosecurity on the Hill. Just as there have been a number of Congressional members and staff who were nuclear specialists and were valued by the rest of the government for this expertise, there should be informed and committed staff members with specialized knowledge of biological threats. Right now, there are a few serious, expert, and effective Congressional leaders, but far too few for an issue of this potential consequence. Without attention to and deep knowledge about biosecurity programs, oversight has devolved too often into parochial interests.

Restore Responsible Budgeting

The recent changes in the way the federal budgeting process works has undermined important programs. Within the federal agencies, long-term program planning is nearly impossible when every year is funded via a continuing resolution. New priorities cannot be established, and course corrections are difficult to make. Exacerbating the effects of continuing resolutions is the recent mid-year slashing of agency funding. How are agency leaders supposed to manage programs with the constraints of such a system? And how is the private sector supposed to interact with a government that runs like this? The U.S. government should reestablish a clear, sensible, and predictable budget process.

Continue to Engage Civil Society

In the aftermath of an attack with a biological agent, or in the midst of a pandemic response, nongovernmental institutions and organizations will be crucial in determining the ultimate outcomes of those events. Government preparedness efforts have been far more inclusive of civil society over the years, with greater emphasis on resilience and involving the whole of the community. Both CDC and FEMA are providing communities with detailed guidelines for building broad coalitions for epidemic and disaster management, and this advice is welcome. What we need now is for leaders to step up and commit the personnel and resources needed to create and sustain these partnerships.

Stay Focused on the End Goals

Sometimes the details of building a government program obscure its larger purpose and the broader context. It is important to recall what we are seeking to achieve in biosecurity: the prevention of sudden large-scale deliberate or natural disease threats and, failing prevention, the capacity to save large numbers of lives and diminish the consequences of such events. This is honorable and critical work of government and its private sector partners. It is work to improve our country's public health system and our national security. So when the barriers seem too high to overcome, and the easier path would be to stall out or avoid the challenges ahead, we need to remember why we are doing this work and press ahead.

Steps to Strengthen U.S. Preparedness

It is useful to recall the very real and urgent problems that our nation faced in the days and weeks following the 2001 attacks. In his commentary that follows, D. A. Henderson reflects on the anthrax crisis, recounts his experiences at HHS during that time and the programs that were launched in response, and identifies several important goals not yet achieved. In their commentaries, our other Center for Biosecurity colleagues provide a number of concrete recommendations to improve the country's ability to prepare for, respond to, and recover from major biological events. Their suggestions embrace a wide range of imperatives that stress the need for sustained efforts to build hospital and healthcare system preparedness, create strong U.S. biosurveillance capacity, plan for wide-area decontamination, work through practical and legal issues related to crisis standards of care, implement prudent laboratory security, and build community resilience.

Many of the suggestions offered would cost relatively little but would result in substantial improvements in biosecurity. All of the goals are conceivably within reach in the years ahead. At this crossroad, they would help us move in the right direction toward biosecurity.

References

- 1. National Security Council. National Strategy for Countering Biological Threats. November 2009; p. 1. http://www.whitehouse.gov/sites/ default/files/National_Strategy_for_Countering_BioThreats.pdf. Accessed August 24, 2011.
- Statement for the Record on the Worldwide Threat Assessment of the U.S. Intelligence Community for the House Permanent Select Committee on Intelligence. Office of the Director of National Intelligence. February 10, 2011. http://dni.gov/testimonies/20110210_ testimony_clapper.pdf. Accessed August 10, 2011.
- 3. Norway killer wrote of anthrax attacks. Global Security Newswire July 27, 2011. http://www.globalsecuritynewswire.org/gsn/ nw_20110727_8719.php. Accessed August 10, 2011.
- 4. Franco C, Sell TK. Federal agency biodefense funding, FY2011-FY2012. Biosecur Bioterror 2011;9(2):117-137.



D. A. Henderson, MD, MPH, is Distinguished Scholar and Coeditor-in-Chief of Biosecurity and Bioterrorism. Having founded the Center in 1999, Dr. Henderson is best known for his tenure as director of the World Health Organization's global smallpox eradication campaign in the 1960s and 1970s. He later served as Dean of Faculty at the Johns Hopkins School of Public Health, as Associate Director of the Office of Science and Technology Policy under George H. W. Bush, and as Director of the Office of Public Health Emergency Preparedness. He was a Principal Science Advisor in the Office of the Secretary of the Department of Health and Human Services in the George W. Bush Administration. Dr. Henderson is a recipient of the Presidential Medal of Freedom, the nation's highest civilian honor, and of the National Medal of Science, the National Academy of Sciences' Public Welfare Medal, and the Japan Prize, which he shares with 2 colleagues.



AN



Banner headlines outside the Times Square studios of ABC's "Good Morning America" announce news in the anthrax scare, while show host Diane Sawyer interviews New York Mayor Rudolph Giuliani (October 16, 2001).

Post-9/11 Challenges of a Crisis

D. A. Henderson

The attacks on the U.S. on September 11, 2001, startled the country with a brutal demonstration that the nation was a fully susceptible target for terrorism. Two oceans and permeable borders provided little protection. A newly inaugurated administration began a confused scramble to mobilize the limited available emergency resources and to comprehend the anatomy of the disaster. But there was more to come. Intelligence intercepts suggested that there would be a second event—a biological attack. Until then, national planning, let alone preparations, for an attack by terrorists had been negligible.

Before 2001

Few will recall that little more than a decade ago, the possibility of biological terrorism was neither anticipated nor understood by professionals or the civilian community. The effects of a nuclear attack were documented and tangible, and chemical accidents were not uncommon, but the potential catastrophe of an epidemic following the deliberate release of a biological pathogen was difficult to comprehend. A surprising number dismissed the prospect out of hand.

At that time, there were remarkably few in public health or medicine who were concerned about biological weapons or the challenges for preparedness and response. Until the late 1990s, the medical community regarded the subject of biological weapons as morally repugnant. Only a handful of laboratories were engaged in research pertaining to the organisms of greatest concern. One of the very few groups struggling with issues of preparedness and response was our Center for Civilian Biodefense Studies (later called the Center for Biosecurity). The Center began its work in 1998 and subsequently received generous support from the Alfred P. Sloan Foundation. Its primary concerns were the national and community-wide planning and response necessary for dealing with biological agents that were the most likely candidates for use. The government's concerns at that time were principally nuclear threats and the special problems they posed. The lack of interest in biological terrorism was not surprising as the leadership in counterterrorism was provided primarily by physicists. Few had a background in biology and even fewer in public health or medicine.

It was widely acknowledged at that time that smallpox and anthrax were the 2 most likely and potentially catastrophic agents that could be used. They were known to have been the preferred organisms of a previously secret Soviet bioweapons program. However, it was impossible to rule out the possibility that other governments or terrorist groups might have obtained relevant expertise and specimens.

Smallpox was the primary concern. It could readily spread from person to person, there was no treatment, and the death rate was 30%. It could be contained only by preventive vaccination. At least three-fourths of the world's population was without protective immunity. Subsequent to smallpox eradication, vaccination had been stopped in the U.S. and in other parts of the world; vaccine production laboratories had been dismantled. Only a few countries retained stores of vaccine. The U.S. itself had only 15 million doses of freeze-dried vaccine that had been produced

in 1978. Discussions with vaccine manufacturers in 1999 revealed that the earliest possible delivery time for additional supplies was 5 years.

The situation with regard to anthrax was not much better. Substantial quantities of antibiotics had recently been procured and stockpiled for emergency use subsequent to an outbreak. The only available vaccine was a crude, whole-cell preparation that had been developed and licensed 40 years earlier and required 6 doses to be given for protection. A new recombinant vaccine developed by the Army was promising but had not yet reached production.

Community preparedness was sadly deficient. Beginning in 1995, modest federal support had been provided to 120 major cities to develop emergency response teams—police, fire, and emergency rescue personnel. The Department of Defense developed strategy and provided training. The need for health personnel was not foreseen; the Department of Health and Human Services was not included in the planning, nor was it given support. Compounding the problem was the fact that academic medical centers then regarded biological weapons as morally repugnant and disdained both relevant teaching and research. There were few staff at CDC or NIH who were engaged in coping with the threat of biological weapons.

The threat only began to be appreciated little more than 3 years before the September 11, 2001, attack. Modest federal resources were made available to begin to build an emergency stockpile, to develop federal response capabilities, to alert hospitals and medical personnel to the threat and needs for response, and to offer encouragement to understaffed health departments to develop plans.

By the end of September 2001, the country was only beginning to appreciate that bioterrorism posed a threat and to appreciate how desperately unprepared it was, when, on October 4, a case of anthrax was reported.

The 2001 Anthrax Attacks

On October 4, 2001, Florida health officials reported an anthrax case—a 63-year-old photo editor from Fort Lauderdale. The patient was desperately ill with pneumonia and meningitis and had been hospitalized. He died a week later. Where he might have acquired the infection was a puzzle. Anthrax pneumonia could result only from inhaling anthrax spores, but no such spores had ever been detected anywhere east of the Mississippi River. State and federal officials sought in vain to find a source for infection.

Little thought was given to the possibility that this could be the result of a terrorist attack.

But then, a week later, on October 12, a case of cutaneous anthrax in an NBC network employee was diagnosed in New York and reported. Her illness actually had begun on September 25. She recalled having opened a threatening letter that had been sent to the network and that it had powder in it. The letter was retrieved; anthrax spores were present. It was the first recognition that a bioterrorist attack had taken place. The eventual outcome was 22 cases of anthrax, including 5 who died. All had been exposed to 1 of at least 5 envelopes bearing anthrax powder.

Coast-to-Coast Chaos

Chaos soon prevailed and extended from coast to coast. There were countless reports of suspicious white powder that ranged from powdered sugar on donuts to talcum powder. Specimens flooded the few laboratories capable of identifying anthrax. A diverse array of professionals and technicians became involved, including public health and medical personnel, emergency response and management teams, the FBI, environmental experts, civilians and military staff, and public and private laboratories. The media cast a wide net and gathered fragments of information wherever they could be found-from knowledgeable sources and self-anointed experts alike. Handheld diagnostic instruments were peddled aggressively by entrepreneurs. They proved to be little more accurate than tossing a coin. However, every positive reading heightened the alarm. The discovery of a suspect white powder in an office or school often led to a mass evacuation of the inhabitants to be "decontaminated" by having everyone pass through a shower-a procedure taught to first responders for dealing with a chemical release, but meaningless for coping with a biological attack.

Compounding the chaos was the fact that there was, at the time, no designated authority with responsibility for overseeing and coordinating the diverse activities, no agreed-upon strategic plan for responding to a bioweapons attack, no established communication network for informing the press and public. Events moved far too quickly to ensure the full and knowledgeable involvement of states and local communities and to ensure the execution of an agreed-upon and coordinated action plan that aligned federal assets and actions with those of states and local communities. Fortunately, the attack was a limited one and extended over a very short span of time.

And Then?

The anthrax outbreak dramatized the potential for chaos and meaningless expenditures of time and money when leadership is lacking, seriously divided, or simply confused. Congress responded quickly to strengthen capabilities. By January 2002, it had passed an emergency appropriation of \$3 billion to be used by the Department of Health and Human Services (HHS) for preparedness planning, education, response, and research. Additional resources were made available to other agencies as well- including the Federal Emergency Management Agency and the Departments of Defense and Justice. Of the \$3 billion HHS appropriation, \$1 billion was provided to state and local health departments for community planning and organization. Emergency communications equipment and special operations centers facilitated new response plans. Funds were made available to hospitals to help in developing emergency responses to cope with large numbers of casualties. Vaccines, drugs, and equipment for a national stockpile were purchased, and a targeted program of relevant laboratory research was funded.

The flurry of activity was impressive, but, as the initiatives grew and more agencies were funded, the overall program became increasingly fragmented with problematic overlaps of activities and perceived responsibilities in some areas and serious omissions in others. Eventually, however, interest and concern gradually ebbed, and funds and energy began to be diverted to other activities. It was a reaction similar to that following other catastrophes. Without an identified strong base of authoritative and articulate leadership, erosion of the national effort was pronounced.

Where to Go from Here

The National Biodefense Science Board in its 2010 review of the effort to acquire medical countermeasures offered a succinct criticism that is broadly applicable to preparedness as a whole: "The [initiative] to date can be characterized as a good effort conducted by talented people, but currently lacks centralized leadership with authority, is poorly synchronized by agencies within HHS (as well as across Departments), and is underresourced."¹

After the attacks of September 2001, the dark cloud of probable additional attacks hovered over those of us with responsibilities for national preparedness. The perpetrator was unknown, but it seemed likely that he might possess additional quantities of anthrax powder. It could be distributed in many different ways and in different places. There was a need for strategic plans ready to be implemented immediately as soon as an attack was identified, plans that were known to and shared by all, including state and local authorities. These plans would have to be developed within the context of a national strategic policy that identified the probable range of threats and the resources the nation could afford to expend in support of supplies and infrastructure. Ten years later those plans have yet to materialize.

For the different threats, it would be necessary to decide what was best suited to deal with each. For smallpox, patient isolation and protective vaccines are essential; antiviral drug research might provide a useful therapy. For anthrax, antibiotics and specialized, intensive clinical care resources are vital, but patient isolation is not required. An inexpensive and safe anthrax vaccine might be useful for protecting groups at special risk, but research would be required to develop one suitable for widespread use. And what other agents deserve special attention?

Practical problems in implementing preventive and control measures need to be worked out. However, few have been enthusiastic about wrestling with the difficult practical problems of execution, let alone have the experience to do so. For example, when cases of smallpox are discovered, how extensive should the vaccination program be? Should all hospital personnel be vaccinated? What about first responders? Perhaps all essential personnel? Schoolchildren? Commuters on trains or buses? All who visit the city? All people in the state? The quandaries with anthrax are even more difficult-on discovery of an attack in a city, should the population in the entire affected area be advised to evacuate or to shelter in place? If a large block of office buildings is considered to have been contaminated, should workers be allowed to reenter? Should they be given antibiotics until after the building is cleaned? How should the buildings be cleaned? State and local health personnel need answers to these questions in order to finalize plans that are ready for immediate implementation.

As we remind ourselves of the terrible events of just a decade ago and the fear and anxiety they provoked, we must take stock of what has been accomplished and what has not. To be adequately prepared to cope is no less urgent today than it was then. There is still a lot to be done.

Reference

 National Biodefense Science Board. Where are the Countermeasures? Protecting America's Health from CBRN Threats. March 2010. Available at: http://www.phe.gov/Preparedness/legal/ boards/nbsb/meetings/Documents/nbsb-mcmreport.pdf. Accessed August 24, 2011.





Gigi Kwik Gronvall, PhD, Senior Associate, is an immunologist. She recently participated in the European Union Visitors Programme for 2011, and she serves on the American Association for the Advancement of Science (AAAS) Committee on Scientific Freedom and Responsibility. Since joining the Center, Dr. Gronvall has published and testified before Congress on the role of scientists in biodefense. Currently, she is working on a book on the history of the Alfred P. Sloan Foundation's work in the field of biosecurity and biodefense.



Biohazard suits hang inside a newly renovated Biosafety Level 4 laboratory suite at the U.S. Army Medical Research Institute of Infectious Diseases in Fort Detrick, Maryland (August 10, 2011).

Managing the Insider Threat in High-Containment Laboratories

Gigi Kwik Gronvall

When the FBI declared in 2008 that Bruce Ivins, a senior scientist for the U.S. Army, was solely responsible for the 2001 anthrax attacks, the insider threat to U.S. laboratories came into sharp focus. Many security measures had already been put into place since 2001 to address the concern that someone could misuse legitimate access to pathogens and laboratory equipment, but the Ivins allegation provoked additional questions about whether enough was being done.

External security threats to a laboratory would be apparent and straightforward to counter. Unauthorized people can be easily prevented from gaining access to anthrax in a laboratory by key-card access, a refrigerator lock, and/or a security guard who checks personnel badges. At the other extreme, a paramilitary attack on a university laboratory might allow the perpetrators to steal frozen tubes of pathogens, but not without drawing considerable attention to their crime. Discovering and countering an insider threat is a challenge that requires other forms of attention and calibrated action.

"Security" Has Its Costs

In the 10 years since the anthrax attacks, there have been no insider (or externally led) thefts or deliberate misuse of regulated pathogens. Laboratory security has been greatly enhanced, so there are now more checks on laboratory personnel and facilities than before. But additional security procedures come at a cost to both science and the research facilities. It is now considerably more expensive to conduct research on regulated pathogens¹—the Biological Select Agents and Toxins (BSATs)—and it is much more difficult for U.S. scientists to form international research collaborations on BSATs, which cause disease everywhere in the world.²

If we are going to impose increased costs for lab security, then we should have great confidence that additional spending is sensible and actually buys enhanced security. Unfortunately, some measures, particularly personnel behavioral assessments and inventory control, incur costs without a security benefit, while other measures that could yield substantial benefits, such as management training for laboratory directors, are left relatively neglected. We should redirect our efforts accordingly.

Behavioral Assessment Is Not the Right Answer

Many of the laboratory security measures that are in effect now are intended to weed out a potential security risk during the hiring process, with the goal of avoiding hiring a high-risk scientist altogether. To that end, a clearance process has been in place since 2003 for scientists who work with regulated pathogens. The clearance process is administered by the U.S. Department of Justice, and it applies to all personnel who have access to BSATs.

Most research institutions actually go beyond the federal requirements and have their own procedures for checking personnel background, credentials, references, and credit. And personnel reliability checks do not cease once a person has been cleared for access; BSAT workers are continually monitored through laboratory inspections and record checks. Some facilities conduct video surveillance of all laboratory activities, while others enforce a 2-person rule, which stipulates

that a BSAT researcher is not permitted to work alone in a laboratory—the security effectiveness of which has been called into question.³

The monitoring of BSAT workers extends to behavior as well, and a federal panel is currently examining whether psychological assessments of BSAT workers should be a national requirement.⁴ All BSAT researchers who work in maximum containment labs (BSL-4) in the National Institutes of Health (NIH) are required to undergo annual behavioral health screens "designed to help assess the worker's psychological resilience and individual attitudes toward laboratory safety and personal responsibility."⁵ While the Federal Experts Security Advisory Panel (FESAP), which has been tasked with evaluating the BSAT program, "will further explore the utility of behavioral assessments to identify indicators of potential for violent behaviors, criminal behaviors, or other behaviors that pose a national security risk," some research institutions may try to anticipate FESAP's recommendations and establish behavioral monitoring systems preemptively.

Will behavioral assessments of thousands of laboratory personnel catch an insider threat? A National Academies of Science (NAS) committee charged with examining personnel reliability measures thought that it would not. They also wrote of experts' concern that, if a screening procedure is thought to be unfair or too intrusive, it could "ironically contribute to someone becoming disgruntled and potentially susceptible to the very behavior screening is intended to prevent."⁶ At some point, considering their extensive, years-long training, security clearances, and continual monitoring, those professionals who research deadly diseases need to be trusted to perform their work.

Federally required behavioral assessments could also give research institutions a false sense of security. Experts on the psychology of terrorism "have been nearly unanimous in [the] conclusion that mental illness and abnormality are typically not critical factors in terrorist behavior," and that what is characteristic is a terrorist's normality, in spite of performing heinous acts.⁷ People who exhibit behaviors that are evidence of research misconduct, including fraud, certainly make for terrible laboratory personnel and would justify investigation and dismissal, but there is no evidence that those behaviors are linked to terrorism.

The Right Answer? Enlightened Leadership, Trust, and Openness

What then should research institution officials and the FESAP do about the insider threat? First, requirements already in place

should be assessed and changed (or eliminated) if they are not effective. As an example, one of the duties of a BSAT laboratory is inventory control of pathogens. The intent of this security requirement seems logical. But tube-counting, quantity estimates, and regulatory inventorying make no sense in the context of a biology laboratory, as microorganisms multiply. The NAS committee on BSAT research recommended this procedure be changed because the practice is "both unreliable and counterproductive, yielding a false sense of security."⁶

Unfortunately, this security requirement is not a harmless nuisance. Many hours are wasted cataloging laboratory inventory, and an empty tube could lead to an FBI investigation. But in addition to the time and expense incurred for this work and the prospect of misguided investigations of scientists who are guilty of nothing, these measures undermine the credibility of the security officials. Scientists who are being regulated need to understand the purpose and value of the measures with which they must comply. Otherwise, scientists may come to think they are being treated unfairly, that the regulations are just for show, and that they are not trusted. Such conditions are not conducive to scientific productivity.

To enhance protection against the insider threat, considerably more attention should be paid to promoting active laboratory management—to making sure that laboratory leaders have the time, responsibility, and training to be able to observe and evaluate what is happening in their laboratories day to day. After all, personnel screening tests are not perfect, and people change over time: Bruce Ivins was apparently able to function as a productive scientist for several decades before he is alleged to have mailed the anthrax letters.

Research on insider threats suggests that "in many cases there will be signs or signals that something is wrong prior to an event. Those cases in which an individual's action is genuinely spontaneous are rare."⁶ To recognize potential security risks as they emerge, there has to be at least 1 person in a lab who is close to personnel and who can detect changes and potential problems and intervene if needed. Ideally, this person is an aware, trained manager who has the tools to detect and act on a potential problem.

Educating and training laboratory leaders and giving them the time they need to be actively engaged with their staff so they can detect troublesome behavior may be the most important security investment for deterring the insider threat. This point has been highlighted by many—most recently David Franz and James LeDuc, who stated that, "Official biosecurity policy must include means of fostering enlightened leaders . . . troubled scientists have and will come to an engaged and enlightened leader for help, where openness has been built and trust is the currency."⁸

Do Not Discourage BSAT Research

Finally, it is important that we do not eliminate the insider threat by eliminating BSAT research altogether because it has been made too onerous to perform. Even if all biological laboratories had in place every conceivable security measure, the U.S. would not be secure against the threat of biological weapons. As the Defense Science Board put it, "A determined adversary cannot be prevented from obtaining very dangerous biological materials intended for nefarious purposes. . . . We need to recognize this reality and be prepared to mitigate the effects of a biological attack. We, as a nation, are not prepared."³ And we do not have time or money to waste in chasing a false sense of security by imposing ineffective measures on laboratories and scientists.

References

- Dias MB, Reyes-Gonzalez L, Veloso FM, Casman EA. Effects of the USA PATRIOT Act and the 2002 Bioterrorism Preparedness Act on select agent research in the United States. *Proc Natl Acad Sci USA YEAR* May 25;107(21):9556-9561.
- 2. Rambhia KJ, Ribner AS, Gronvall GK. Everywhere you look: select agent pathogens. *Biosecur Bioterror* 2011;9(1):69-71.
- Report of the Defense Science Board Task Force on Department of Defense Biological Safety and Security Program. Washington, DC: Office of the Under Secretary of Defense for Acquisition, Technology, and Logistics; 2009. http://purl.access.gpo.gov/ GPO/LPS113763. Accessed August 24, 2011.
- Federal Experts Security Advisory Panel. Recommendations Concerning the Select Agent Program. 2010; revised 2011. http://www.phe.gov/Preparedness/legal/boards/fesap/ Documents/fesap-recommendations-101102.pdf. Accessed August 24, 2011.

- 5. Skvorc C, Wilson DE. Developing a behavioral health screening program for BSL-4 laboratory workers at the National Institutes of Health. *Biosecur Bioterror* 2011;9(1):23-29.
- National Research Council. Committee on Laboratory Security and Personnel Reliability Assurance Systems for Laboratories Conducting Research on Biological Select Agents and Toxins. Responsible Research with Biological Select Agents and Toxins. Washington, DC: National Academies Press; 2009.
- 7. Borum R. *Psychology of Terrorism*. Tampa, FL: University of South Florida; 2004.
- 8. Franz DR, LeDuc JW. Commentary: Balancing our approach to the insider threat. *Biosecur Bioterror* 2011;9(3).





Jennifer Nuzzo, SM, Senior Associate, is an epidemiologist. Most recently, she led DTRAsponsored Center projects that convened expert panels to evaluate U.S. government programs and investments in international disease surveillance and diagnostics. Ms. Nuzzo's recent publication, "Global Health Security: Closing the Gaps in Responding to Infectious Disease Emergencies," was published in the spring 2011 edition of the journal *Global Health Governance*.



An employee of Werder Frucht vegetable company throws away tomatoes in Werder, East Germany (June 7, 2011).

Connecting the Dots: Creating a National Biosurveillance Capability

Jennifer Nuzzo

In May 2011, Germany announced that a toxin-producing strain of *Escherichia coli* had infected thousands of people and killed dozens.¹ Health officials launched an investigation to identify the outbreak's cause in hopes of preventing additional illnesses and deaths. Initially, they suspected that cucumbers from Spain might be to blame and cautioned the public not to consume raw produce.² But soon thereafter, authorities retracted that conclusion and began scrutinizing other possible sources.³ Weeks later, after most of the German cases seemed to be on the decline, health officials announced with greater confidence that they had identified the source of the outbreak: raw sprouts produced at an organic farm.⁴ By late June, though, hopes that the outbreak had been contained were dashed when a cluster of people in France fell ill with the same strain that was involved in the German outbreak.⁵ Although the investigation is ongoing, genetic analysis of the clinical isolates, shoe-leather epidemiology, and an analysis of import and supply-chain information from the private sector now suggest that the outbreaks in France and Germany may have a common cause: fenugreek seeds imported to Europe in 2010.⁶

At the time of this writing, in early August, as many as 5,000 human *E. coli* cases have been reported from this outbreak, and European officials are predicting that it may be the most expensive one the EU has witnessed. Shortly after German officials spoke publicly about the outbreak, many countries around the world announced bans on produce from Germany and Spain.⁷ Some countries, like Russia and Lebanon, opted to ban all produce from the EU, citing ongoing uncertainty about the true cause of the outbreak.⁸ German retail sales in May fell by 2.8%, the fastest decline in 4 years.⁹ To compensate those farmers whose crops were destroyed, EU officials are proposing an aid package of close to \$300 million, which many experts fear falls far short of actual losses incurred.¹⁰

"A Wake-up Call"

In the words of U.S. Agriculture Secretary Tom Vilsack, "What's happened in Europe is a wakeup call" for the United States.¹¹ Although the U.S. has worked hard since 2001 to improve biosurveillance capabilities across the nation, there are reasons to be concerned about how we would fare in a large-scale epidemic, in a foodborne outbreak, or worse, in a bioterrorist attack. Like Europe, the United States has also suffered losses as a result of a foodborne outbreak: in 2008, an outbreak of *Salmonella* Saintpaul sickened close to 1,500 people in 43 U.S. states and territories.¹² Although U.S. health officials eventually settled on the correct culprit (imported jalapenos), this pronouncement was made long after fingers initially pointed at tomatoes and the outbreak had peaked. The U.S. tomato industry suffered hundreds of millions of dollars in losses.

Achievable Improvements Within Reach

While an outbreak is unfolding, it is indeed a challenge to gather and assess the correct data quickly so that officials can accurately identify the source and contain an outbreak before additional people are affected. Recent experience suggests we might do better in the future if we start making some achievable improvements now. Specifically, U.S. biosurveillance systems could benefit greatly from adoption of new and better tools, greater and sustained support for existing

programs, and improved integration of biosurveillance data across multiple agencies. These improvements should be prioritized given the nation's reliance on its biosurveillance systems to minimize the spread of disease, prevent unnecessary sickness and death, and reduce the economic and social harm caused by outbreaks, epidemics, pandemics, and bioterrorist attacks.

Develop Better Surveillance Tools

When an outbreak occurs, whether from an infectious disease or foodborne pathogen, public health officials rely on patient data acquired from the doctors' offices, hospitals, and laboratories where diagnosis occurs. Health authorities rely on these data to detect outbreaks, track down the source, identify how many people are infected, determine the severity of the disease, and make key decisions about which public health control measures are likely to work and how many resources are needed for responding. Those data also inform critical decisions regarding how to control the outbreak and allocate the resources needed for response. Even small delays in diagnosis and access to surveillance data can have significant consequences for the public's health.

For all the communication technologies available in this digital age, our biosurveillance approaches are, in many respects, still quite rudimentary. In many places, biosurveillance systems still rely on clinicians and laboratories to phone, fax, or mail in reports of important diseases.¹³ If, upon receiving these reports, public health officials want to obtain additional information, they often must contact hospitals and clinicians one by one. Each of these time-consuming steps is subject to delay, and it can be difficult to keep up in the midst of a large-scale outbreak.

A major boost for biosurveillance could come from improving public health officials' access to data from healthcare providers. As the nation builds a national framework for electronic health records (EHRs), we should seize the opportunity to develop critical connections between health care and public health. But current efforts to promote the use of EHRs across the nation do not adequately address the importance of these data for biosurveillance. For example, the current federal guidelines have not made it mandatory for providers to successfully report laboratory data-a critical biosurveillance information need-to public health agencies in order to receive incentive payments for using EHRs. Moreover, there has been little to no support for already cash- and personnel-strapped health departments to help them develop data systems to receive incoming EHR data. More than \$18 billion in federal funds has been allocated for incentive payments for healthcare providers to promote adoption of EHRs. At least a modest portion of these funds should be used to support health departments to enable them to build and maintain strong and flexible digital connections with healthcare entities that adopt EHRs.¹³

We should also use our best efforts to design EHR systems that will significantly improve not just the quantity of data received by public health, but its quality and value for disease detection and response purposes. Specifically, HHS should expand future iterations of the guidelines for the use of EHRs by clinicians—the so-called Meaningful Use Criteria—to promote the development and adoption of EHRs that have the ability to evolve over time and allow for the addition of new features not currently envisioned, such as enabling public health departments to have remote, query-based access to patient records during outbreaks.

Another pressing need in surveillance is the development of technologies to improve the accuracy and speed with which we diagnose sick people, which is our best hope for detecting outbreaks early. Although 10 years have elapsed since the anthrax attacks, the diagnosis of this deadly disease is still dependent on assessing a patient's symptoms (which can be imprecise) and/or by growing clinical specimens in the laboratory (which is timeconsuming). Rapid, reliable, and cheap diagnostic tests for a range of diseases are within reach, but development is slow, and commercialization is difficult due to high costs, market failures, and other factors. Although U.S. agencies such as the Biomedical Research and Development Authority are authorized to develop and purchase the diagnostic tools that will be necessary to manage public health emergencies, progress in this area has been limited.¹⁴ The USG should address this critical gap in our biosurveillance capabilities by making the development and acquisition of diagnostic tools a top national priority.

Preserve U.S. Biosurveillance Gains

Since 2001, federal support for state and local health departments has produced measurable improvements in national biosurveillance. Prior to the post-9/11 infusion of preparedness funds, most health departments lacked even the most basic surveillance infrastructure. For example, in 1999, more than 50% of public health departments did not have continuous access to high-speed internet or the ability to send broadcast faxes to alert clinicians about important outbreaks.¹⁵ Bolstered by support from federal public health preparedness funds, most health departments now have those capacities along with more laboratories that can test for important diseases and more epidemiologists to review, investigate, and interpret disease reports. In fact, most public health departments now maintain 24/7 monitoring capabilities, something almost unheard of prior to 9/11. These are substantial gains.

However, recent declines in both federal preparedness funding and state and local financial resources are threatening those hard-won biosurveillance gains. For instance, federal funding for state and local public health preparedness programs has declined by 27% since 2005. That loss, combined with state budget cuts due to the economic downturn, has made it difficult for health departments to maintain newly developed information systems and analytical staff, which has threatened the viability of nascent biosurveillance programs. Worsening matters, local health departments have lost 15% of their workforce since 2008.¹⁶ Significant personnel losses result in declines in capacity, as evidenced by reduced programs and services, including emergency preparedness efforts, in 40% of public health departments nationwide.¹⁶

To prevent the further erosion of the gains we have made since 2001, the U.S. should restore funding for these programs to at least their 2005 levels. Though money is scarce across all levels of government, this is a small but important investment relative to the substantial health and economic losses that can occur when outbreaks are not detected and contained in a timely manner because biosurveillance systems have been cut.

Improve Data Integration

The next important goal is integration of data across multiple sectors, a goal that may be more difficult to achieve but that is worth attempting. The more we can integrate healthcare and public health data with data from intelligence, law enforcement, and private sector sources, the better off we will be. Data integration could shave precious time from the weeks or even months that it can take now to identify the source of an outbreak, develop a successful control strategy, and prevent unnecessary illness and death.

During the 2011 *E. coli* outbreak in Europe and the 2008 Salmonella outbreak in the U.S., it was private sector supply chain and shipping data that proved most useful in identifying the contaminated sources responsible for those foodborne outbreaks.¹⁷ In a biological attack, information from law enforcement and intelligence will be critical, as was the case in 1984, following an outbreak of salmonellosis in Oregon. It was a law enforcement investigation that traced the source of that outbreak to a cult seeking to influence the outcome of an election by perpetrating a biological attack.¹⁸ Before the source was definitively identified, a public health investigation had concluded that the outbreak was likely caused by poor hygiene among food handlers at local salad bars.¹⁹

Unfortunately, in many places communication between public health agencies and other entities that might play an important role in biosurveillance happens largely on an ad hoc, relationshipdriven basis. Congress tried to address this problem in 2007 with passage of the "Implementing the Recommendations of the 9/11 Commission" bill, which calls on the Department of Homeland Security to develop a National Biosurveillance Integration Center (NBIC) to coordinate biosurveillance across the federal government.²⁰ Whether NBIC will continue to have this mission remains to be seen, but the USG should work to integrate the information that exists across federal agencies.

What would be worth exploring now is creation of a dedicated interagency process for conducting joint analyses of biosurveillance information on a routine basis and during national emergencies. Any such process would have to be clearly defined, have a clear governance structure, and include provisions for sharing analyses with state and local partners that contribute data to federal biosurveillance programs.

Preparing for the Next One

Although the number of new human cases in Europe appears to be on the decline, the fallout from the outbreak is just beginning. Many of those who survived their *E. coli* infection will likely require expensive, life-altering, long-term treatments, such as dialysis. This is expected to place additional strain on hospitals, which are already struggling from budget cuts following Europe's economic troubles.

U.S. outbreaks and Europe's recent experience are reminders of the significant consequences of not being able to connect the dots in order to efficiently contain outbreaks. While we may not be able to prevent future outbreaks, we can mitigate their effects by developing better biosurveillance tools, shoring up state and local surveillance programs, and improving integration of biosurveillance data.

References

- Frank C, Faber MS, Askar M, et al; HUS investigation team. Large and ongoing outbreak of haemolytic uraemic syndrome, Germany. *Eurosurveillance* 2011;16(21):1-3.
- Kupferschmidt K. Cucumbers may be culprit in massive E. coli outbreak in Germany. Science Insider May 26, 2011. http:// news.sciencemag.org/scienceinsider/2011/05/cucumbers-maybe-culprit-in-mass.html. Accessed July 28, 2011.
- Tremlett G, Pidd H. Germany admits Spanish cucumbers are not to blame for *E coli* outbreak. guardian.co.uk May 31, 2011. http://www.guardian.co.uk/uk/2011/may/31/e-coli-deaths-16germany-sweden. Accessed July 28, 2011.
- Cowell A. Germany says bean sprouts are likely *E. coli* source. New York Times June 20, 2011. http://www.nytimes. com/2011/06/11/world/europe/11ecoli.html. Accessed July 28, 2011.
- Kanter J. French E. coli episode seems isolated, officials say. New York Times June 26, 2011. http://www.nytimes. com/2011/06/27/world/europe/27ecoli.html. Accessed July 28, 2011.
- European Food Safety Authority. Tracing seeds, in particular fenugreek (*Trigonella foenum-graecum*) seeds, in relation to the Shiga toxin-producing *E. coli* (STEC) 0104:H4 2011 outbreaks in Germany and France. EFSA/ECDC Joint Rapid Risk Assessment June 29, 2011. http://ecdc.europa.eu/en/publications/ Publications/2011June29_RA_JOINT_EFSA_STEC_France.pdf. Accessed July 28, 2011.
- Goodman A. Warning lifted against Spanish cucumbers suspected in *E. coli* outbreak. CNN June 1, 2011. http://www. cnn.com/2011/WORLD/europe/06/01/spain.germany.e.coli/ index.html. Accessed July 28, 2011.
- Norman L. E.coli row could overshadow EU-Russia summit. Wall Street Journal June 9, 2011. http://online.wsj.com/article/ SB10001424052702304392704576373720030940058. html?mod=googlenews_wsj. Accessed July 28, 2011.
- E. coli outbreak hits German retail sales in May. Reuters June 30, 2011. http://in.reuters.com/article/2011/06/30/ idlNlndia-58006420110630. Accessed July 28, 2011.
- Willis A. EU agrees compensation deal for bacteria-hit farmers. EUObserver June 15, 2011. http://euobserver.com/9/32490. Accessed July 28, 2011.

- Peterson M, Bjerga A. FDA seeks \$1.4 billion for food-safety law as budget faces cuts. Bloomberg July 6, 2011. http://www. bloomberg.com/news/2011-07-06/fda-seeks-1-4-billion-for-foodsafety-law-as-budget-faces-cuts.html. Accessed July 28, 2011.
- U.S. Centers for Disease Control and Prevention. Investigation of outbreak of infections caused by Salmonella Saintpaul. August 28, 2008. http://www.cdc.gov/Salmonella/saintpaul/jalapeno/. Accessed July 28, 2011.
- 13. Toner E, Nuzzo J, Watson M, et al. Biosurveillance where it happens: state and local capabilities and needs. *Biosecur Bioterror* 2011;9(4).
- 14. National Biosurveillance Advisory Subcommitee. Improving the Nation's Ability to Detect and Respond to 21st Century Urgent Health Threats: First Report of the National Biosurveillance Advisory Subcommittee. April 2009. http://www.avma.org/ atwork/NBASreport072209.pdf. Accessed July 24, 2011.
- U.S. Centers for Disease Control and Prevention. Public Health Preparedness: Mobilizing State by State. February 2008. http:// www.bt.cdc.gov/publications/feb08phprep/pdf/feb08phprep. pdf. Accessed August 8, 2011.
- National Association of County and City Health Officials. Local health department job losses and program cuts: findings from January/February 2010 survey. Research Brief. May 2010. http://www.naccho.org/topics/infrastructure/Ihdbudget/upload/ Job-Losses-and-Program-Cuts-5-10.pdf. Accessed August 8, 2011.
- Pew Charitable Trusts' Produce Safety Project. Lessons to Be Learned from the 2008 Salmonella Saintpaul Outbreak. November 17, 2008. http://www.pewtrusts.org/uploadedFiles/ wwwpewtrustsorg/Reports/Produce_Safety_Project/produce_ safety_Salmonella.pdf. Accessed July 24, 2011.
- Carus S. Working Paper: Bioterrorism and biocrimes: the illicit use of biological agents since 1900. February 2001. http:// www.dtic.mil/dtic/tr/fulltext/u2/a402108.pdf. Accessed July 24, 2011.
- III handlers suspected in Oregon food poisonings. New York Times October 21, 1984. http://www.nytimes. com/1984/10/21/us/ill-handlers-suspected-in-oregon-foodpoisonings.html. Accessed July 24, 2011.
- Implementing Recommendations of the 9/11 Commission Act of 2007 (9/11 Commission Act). Pub. L. 110-53.



A medical technical assistant in the microbiology lab of the University Hospital Eppendorf (Hamburg, Germany) holds an enterohemorrhagic *E. coli* bacteria culture (May 24, 2011).





Dan Hanfling, MD, is a Contributing Scholar at the Center and special advisor to the Inova Health System for emergency preparedness and response. He is a practicing emergency physician at northern Virginia's Level I trauma center, medical director for flight services, and a veteran of Fairfax County's elite urban search and rescue team. He is Vice Chair of the IOM Committee on Establishing Standards of Care in Disaster Situations, and he recently contributed as a co-author to "Radiation Injury After a Nuclear Detonation: Medical Consequences and the Need for Scarce Resources Allocation" and "Health Care System Planning for and Response to a Nuclear Detonation," both published earlier this year in Disaster Medicine and Public Health Preparedness.



An airboat pulls up to help evacuate patients and staff at Memorial Medical Center in New Orleans (August 31, 2005).

Delivering Medical Care in a Catastrophe: Time for Crisis Standards

Dan Hanfling

New Orleans after Hurricane Katrina was a city underwater. Tulane Medical Center, Charity Hospital, and Memorial Medical Center were flooded. Power and water supplies were quickly exhausted, sewage backed up, a sickening stench filled the air, and there was no food. Medical resources and staff were in short supply. There were a lot of very sick patients. At greatest peril were those maintained on mechanical ventilators to breathe. Without electrical power, they were ventilated by hand with a bag that pushed air into their lungs for hours, even days at a time.

In the immediate aftermath of the storm, when it became evident that the entire city had to be evacuated, doctors and nurses worked in the dark, in extreme heat and humidity, to do what they thought best for their patients. But there was no coordinated, overarching plan, so hospital patients were prioritized for evacuation in an ad hoc manner. This meant, for instance, that at Memorial hospital, it was not necessarily the sickest patients who were prioritized last for evacuation; it was those patients who had "do not resuscitate" orders on their medical charts. Many were given anti-anxiety and pain medications to ease their suffering—desperate actions taken in a desperate situation. Despite all best efforts, a horrifying outcome ensued. Dozens died, their bodies left behind when the last doctors and nurses were rescued from the flooded Memorial hospital.

Establishing Standards of Care

Whether it follows a catastrophic earthquake, another massive hurricane, a large-scale attack with anthrax, or the detonation of an improvised nuclear device, a time may come in the United States when our healthcare system will be forced to adjust the ways in which medical care is delivered to victims and survivors. This will be a profoundly difficult adjustment, because in the U.S., care delivery tends to focus on trying to achieve the best outcomes for every individual, regardless of resources, age, diagnosis, or prognosis. It is highly likely that our normal standards will be impossible to maintain during a catastrophic event when, predictably, resources will be scarce.

"Standard of care" is both a medical and a legal concept. In medicine, a standard of care is a diagnostic and treatment process that all clinicians should follow in a specific clinical circumstance or when treating a specific type of illness or patient.¹ Medical standards are reached through evidence-based professional consensus, with the understanding that the ability to meet those standards is predicated on the availability of necessary equipment, supplies, therapeutics, and staff who are trained and licensed to deliver that care. From a legal perspective, standard of care refers to the level at which the average, prudent provider in a given community would practice. It describes how similarly qualified practitioners would manage a patient's care under the same or similar circumstances.¹

Any attempt to define crisis standards of care (CSC) must take into account the interests of individual patients, healthcare providers, care delivery settings, the needs of the community, and the demands of both medicine and the law. Consequently, the questions and issues that attend any discussion of establishing standards of care for use in disaster situations are numerous and complex. For instance, the 2003 SARS epidemic (followed by the efforts to plan for pandemic

influenza) made clear that most, if not all, hospitals, cities, and regions in the U.S. did not have available the number of mechanical ventilators and other critical care resources that would likely be needed in a worst-case respiratory illness scenario. If mechanical ventilators and IV pumps, along with commonly used antibiotics and other key medications, and trained professionals are in short supply, then who will be prioritized to receive critical care? Will it be those most likely to survive or those who are already receiving inpatient care when crisis strikes? When care cannot be provided to all, will it be clear who should and should not get care? Who will make those decisions, and what criteria will they apply? When the delivery of medical care as we know it is not possible, the healthcare system as a whole or in affected parts will have to shift to crisis standards of care.

In health care, the concept has come to describe a framework for medical care delivery in a catastrophic situation. It suggests a neat and tidy transition, with clear indicators for when it will be time to make that transition, who should make the call, and what it will look like. In reality, there is not much clarity around this issue, at least not now. There are, however, important steps that can be taken to begin to impose some order on this complicated area of medical and legal practice.

A Framework for Medical Care in a Catastrophe

To forge a path toward establishing crisis standards of care, it is necessary to understand the evolution of this policy issue. In medicine, the focus in this area was initially on developing *altered* standards of care, discussions of which centered on the potential rationing choices that would have to be made when it could be predicted that the need for resources would outstrip supply.²⁻⁴ With the emergence of the 2009 H1N1 influenza pandemic, the issue gained an immediacy that shifted the perspective and emphasis from the probable to the practical in catastrophic response planning and formulation of guidance. Toward that end, in 2009, the IOM issued a letter report⁵ delineating a medical surge response framework in which care and services may be delivered along a spectrum, with conventional response at one end and contingency and crisis response at the other. It also highlighted the importance of ethical transparency in decision making under such dire circumstances and proposed a number of recommendations that would further engage local and state partners in planning for such a dreaded, but possible, response scenario.

In simplest terms, conventional response is the same as usual care, or standard of care, whereas contingency and crisis response refer to a shift in focus from what is best for individuals to what is best for the greatest number of people. In a contingency response, maximal efforts are made to conserve, adapt, and substitute resources whenever possible. In a worst-case crisis response, selected patients may receive limited care, staff may have to practice outside of their usual professional boundaries, and medical supplies and equipment may have to be reused, or in a worst-case scenario, reallocated to those who may have a better chance of survival. This IOM framework emphasizes making decisions based on sound ethical principles that dictate allocating resources to save the greatest number of lives, accounting for the needs of at-risk populations, and maintaining the public's trust.

Planning Across All Health Response Entities

More recently, this issue gained some traction with the 2011 release of the CDC's Public Health Emergency Preparedness (PHEP) grant, which includes language that specifically promotes planning for the implementation of crisis standards of care amongst public health departments and their emergency planning partners.⁶ CDC prioritizes the development of written plans that "clearly define the processes and indicators as to when the jurisdiction's healthcare organizations and healthcare coalitions transition into and out of conventional, contingency, and crisis standards of care." With this grant, state and local health departments will be expected to begin to address these difficult issues. This means that focused effort to plan for crisis response will be given added priority in state and local public health and medical planning for response to catastrophic disaster.

The important next step in health care is for the ASPR Hospital Preparedness Program (HPP) to prioritize development of crisis standards in its next set of guidance for grantees. After all, it will be hospitals, healthcare facilities, and their healthcare providers who will bear the overwhelming burden of delivering care under catastrophic conditions, and they must be compelled and funded to prepare in advance. No one should have to make the types of decisions that will arise in a catastrophe without benefit of advance planning, guidance, and support. With adequate funding and guidance, medical surge response plans should be developed, and they should emphasize a proactive rather than reactive approach to triage, and should promote the stewardship of equipment and supplies over reuse and reallocation whenever possible.

If the HPP emphasizes planning for crisis response efforts and development of crisis standards of care, then healthcare system stakeholders will receive the "green light" they need to tackle these very thorny issues. The requirements of the HPP and PHEP grant programs should be aligned to ensure that planning for a catastrophic healthcare response is occurring across the entire spectrum of health response entities—hospitals, public health agencies, and the medical community.

Clearing Legal Impediments to Response

Without question, there are numerous complex issues related to delivery of medical care during a catastrophic disaster and significant implications for patients. But there are equally important legal concerns for healthcare providers and the component parts of the healthcare system. Therefore, any discussion of crisis standards of care must address liability protections for healthcare providers, hospitals, and other acute care delivery settings within states and across the federalized U.S. system. The aftermath of Hurricane Katrina made clear that legal protections must be in place for medical practitioners who may be forced to make life or death decisions in a disaster. Without such protections, fear of professional and/or financial devastation may inhibit or even prohibit delivery of care when it is needed most.

Progress in this area has been slow and complicated by language and terminology. There has been a slowly evolving discourse from one corner of the academic legal community that counters the need for a distinct standard of care for use in disasters. The argument is that care delivered in a disaster setting will be judged based on the circumstances of the disaster event, including resources available to medical practitioners who choose to respond to the disaster. This line of reasoning discounts the fact that the entire system of healthcare delivery will be fundamentally affected, not just those volunteers who attend to patients in a disaster event. There have even been some attempts to conflate discussion of disaster standards of care with tort reform, which is disingenuous at best and dangerous at worst, because it discourages honest discussion and planning.

It must be made explicitly clear that responding under catastrophic conditions is not something that simply involves "disaster volunteers," nor does response under catastrophic conditions condone poor medical decision making or delivery of "negligent" care. Conditions such as those created during the aftermath of Hurricane Katrina will necessitate involvement of all available healthcare personnel responsible for doing whatever they can under extraordinarily trying circumstances. They must know that their decisions and the care they delivered will not be subject to legal scrutiny in a retrospective assessment, provided those decisions and actions were taken in the context of a declared disaster and within the accepted framework of local, regional, and state catastrophic disaster response efforts.

All attempts at distortion of the issue aside, though, a handful of states and regions have taken important steps to prepare for such eventualities by establishing legal protections for healthcare providers. Virginia is one of the states at the vanguard. In 2008, its government adopted one of the most comprehensive statewide legal approaches, with legislative language that explicitly offers protection to healthcare providers who respond to disasters:

> ... in the absence of gross negligence or willful misconduct, healthcare providers who respond to a disaster are immune from civil liability. .. if the emergency and subsequent conditions caused a lack of resources, attributable to the disaster, rendering the healthcare provider unable to provide the same level or manner of care that would have been required in the absence of the emergency.⁷

Legal protections similar to those approved by the state of Virginia ought to be introduced in and adopted by every state legislature. Local and regional healthcare planners and responders need to know that state authorities are supportive and protective of their efforts to deliver health care during catastrophes. Moreover, as recommended in the 2009 IOM report, achieving state- to-state consistency is of utmost importance. This will not be easy in a federalized system, but it is not impossible, and it is an important goal.

Amending the Stafford Act for Catastrophic Response

When disaster strikes, the statutory authority for federal response to a disaster, including mobilization of resources and funding of the response and recovery efforts, is derived from the Stafford Act. This law is intended to provide federal support to state and local governments in their response to a crisis. There are policy discussions under way regarding the relevance and adequacy of Stafford Act declarations in truly catastrophic situations.⁸ Serious consideration should be given to amending the Stafford Act for catastrophic response. However, current discussions are incomplete without the inclusion of language that both specifically recognizes the implementation of crisis standards of care under catastrophic response conditions and clarifies liability protections for healthcare providers and facilities that are compelled to respond under such conditions. Indeed, the recent settlement out of court by Tenet Healthcare for \$25 million as a result of a class action lawsuit brought against it by patients of and visitors to Memorial Medical Center in New Orleans demonstrates that "a nearly impossible legal standard"⁹ of preparedness has been established for hospitals and healthcare facilities in their response to catastrophic disaster conditions. Consideration for passage of an amendment to the Stafford Act cannot be based solely on damage estimate costs. It must reflect the reality that in the worst-case scenarios, it will not be possible to deliver medical care as we know it. Healthcare providers will do the very best with what they have available to them, but hard decisions will have to be made regarding who gets care and what kind of care can be delivered. It must be understood that, despite all best efforts and noble intentions, patients may not receive and should not expect to receive the care they get under normal, dayto-day circumstances. And healthcare providers must be supported in their efforts to do the best possible for the most number of patients, given the resources available to them. In short, there will be desperate actions taken in desperate circumstances, and the nation must face that reality now and start addressing the issues at hand.

- MedicineNet.com website. Definition of standard of care. http://www. medterms.com/script/main/art.asp?articlekey=33263. Accessed August 24, 2011.
- Agency for Healthcare Research and Quality. Altered Standards of Care in Mass Casualty Events. AHRQ publication no. 05-0043. Rockville, MD: Agency for Healthcare Research and Quality; April 2005.
- 3. Hick JL, O'Laughlin DT. Concept of operations for triage of mechanical ventilation in an epidemic. *Acad Emerg Med* 2006;13:223-229.
- Christian MD, Hawryluck L, Wax RS, et al. Development of a triage protocol for critical care during an influenza pandemic. *CMAJ* 2006;175(11):1377-1381.
- Altevogt BM, Stroud C, Hanson SL, Hanfling D, Gostin LO; Committee on Guidance for Establishing Standards of Care for Use in Disaster Situations; Institute of Medicine. Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations: A Letter Report. Washington, DC: National Academies Press; 2009.
- Centers for Disease Control and Prevention. Public Health Preparedness Capabilities: National Standards for State and Local

Planning. March 2011. http://www.cdc.gov/phpr/capabilities/ Capabilities_March_2011.pdf Accessed August 24, 2011.

- Virginia Acts of Assembly, House Bill 403. Approved March 2, 2008. http://leg1.state.va.us/cgi-bin/legp504.exe?081+sum+HB403. Accessed August 24, 2011.
- Lindsay BR, McCarthy FX. Considerations for a Catastrophic Declaration: Issues and Analysis. Washington, DC: Congressional Research Service; July 6, 2011. http://www.fas.org/sgp/crs/ homesec/R41884.pdf. Accessed August 24, 2011.
- Hodge JG, Brown EF. Assessing liability for health care entities that insufficiently prepare for catastrophic emergencies. *JAMA* 2011;306(3):308-309.



Hallway of Memorial Medical Center (New Orleans, LA) in the days following Hurricane Katrina (September 12, 2005).



Eric Toner, MD, Senior Associate, is an internist and emergency medicine physician who has been involved in hospital disaster planning since the mid-1980s. He has published widely in the field and was principal investigator for the Center's commissioned evaluation of the HHS Hospital Preparedness Program. Dr. Toner's most recent article, "Acting on the Lessons of SARS: What Remains To Be Done," was published in the June 2011 issue of the journal *Biosecurity and Bioterrorism*.



Amesh A. Adalja, MD, an Associate at the Center, is board certified in critical care, emergency, infectious disease, and internal medicine. A contributing author for the *Handbook of Bioterrorism and Disaster Medicine* and primary author of the biweekly *Clinicians' Biosecurity News*, Dr. Adalja's recent publications include "Response to the Sudden Closure of St. Vincent's Hospital: Learning from a Real, No-notice, Prolonged Surge Event," which was published in the June 2011 issue of the journal *Biosecurity and Bioterrorism*.





Survivors of Hurricane Katrina arrive at New Orleans Airport (LA) where FEMA's D-MAT teams set up a medical hospital and where people were flown to shelters in other states (September 1, 2005).

Preparing Hospitals for Large-Scale Infectious Disease Emergencies

Eric Toner and Amesh A. Adalja

Anyone who has been to a hospital emergency department during peak flu season has probably witnessed firsthand the strain that even a modest increase in patient volume can put on a hospital. A much larger and more prolonged surge of patients might be expected in the event of other significant infectious disease (ID) outbreaks, whether they are naturally occurring or the result of a terrorist attack with a biological agent. On the tenth anniversary of the anthrax attacks of 2001, it is appropriate to consider whether our healthcare system would be able to respond to a major ID emergency and, if not, to ask what new actions or resources are needed to prepare for large-scale epidemics.

The goal of healthcare preparedness is to save as many lives as possible by enabling a more effective medical response to a significant disaster. Over the past decade we have witnessed several notable examples of non-ID disaster response that clearly benefited from healthcare preparedness efforts— among them, the Virginia Tech mass shooting, the Minnesota bridge collapse, and the Rhode Island nightclub fire. An ID emergency, however, adds layers of complexity and uncertainty to the response, because the route of disease transmission may not be fully understood, effective vaccines and antimicrobials may or may not be available, and extensive patient isolation may be needed to prevent spread of a contagious disease.

Had the 2001 attacks involved a wide-area release of *Bacillus anthracis*, thousands of patients might have needed hospital care. Managing an event of this scale requires the involvement of all parts of our healthcare system, ideally working in coordination and collaboration. However, efforts to create a system in which the provision of health care can be well coordinated across a region have been hindered by cost, competition among hospitals, and a lack of government authority.¹

Progress Achieved in Hospital Preparedness Since 2001

There has been notable progress. Following the terrorist attacks of 2001, the federal government created the Hospital Preparedness Program (HPP) in the Department of Health and Human Services (HHS). That program has made a significant difference in national hospital preparedness, which the Center for Biosecurity documented in 2009 when we evaluated the program.²

We found significant improvement in preparedness of individual hospitals. Perhaps more important, we found substantial improvement in collaboration among hospitals and between hospitals and government agencies (local and state). We identified these relationships as hospital coalitions, and consider their emergence to be the most significant advance in healthcare preparedness in the past decade. Their value has been demonstrated in a number of recent events—most recently, the 2009 H1N1 influenza pandemic, during which hospitals collaborated with each other and with public health departments to share information and resources.

Necessary Steps Forward

Although hospital preparedness has come a long way in the past decade, preparedness levels have plateaued in recent years. Many communities have created—or are creating—coalitions to improve resilience to common disasters, such as tornados and hurricanes, which is important.

However, there is little evidence of improvement in preparedness for ID emergencies of the magnitude that would follow largescale bioterrorism or severe pandemic flu. This is an area in need of focused attention and additional improvement, and there are several specific actions that should be taken in the near term to build national capacity to respond to large-scale ID emergencies. If achieved, the 4 goals that we set forth below would make a substantial contribution to advancing healthcare system preparedness.

Preserve, Expand Upon, and Make Best Use of HPP and NDMS

This first goal entails building and expanding upon investments we have already made, starting with the Hospital Preparedness Program. The HPP has been demonstrably effective in bolstering hospital preparedness. We cannot emphasize enough the value of healthcare coalitions in emergency response. Because the HPP can directly instigate the development and proliferation of coalitions that can, in turn, support constituent hospitals during a crisis, we strongly support continued USG support for the HPP. With continued support, this important program will be able to continue to foster the development and proliferation of the coalitions that enable healthcare entities within a community to plan, train, share information and resources, and respond as a cohesive unit in a disaster that could otherwise overwhelm.

There is another existing asset that should be maintained and expanded as well: the federal National Disaster Medical System (NDMS). It is clearly of great potential value in a national disaster. But its total deployable capabilities and capacity are limited and would be insufficient for responding to a large-scale ID emergency.

To accommodate the expected numbers of patients in an ID emergency, the healthcare surge capacity of the entire country, both public and private, may have to be tapped. Doing so would require transporting large numbers of patients to private hospitals around the country. NDMS has contracts with thousands of hospitals for this purpose, but the system depends primarily on the U.S. Air Force for long-distance transport, and the military's capacity to move patients is quite limited and takes a long time to ramp up. Even if we had a feasible plan for moving large numbers of patients around the country, it is not clear that private hospitals would voluntarily accept large numbers of patients who were transported in for care.^{1,3}

But this problem is solvable if the role, capabilities, and capacities of the NDMS—its deployable teams, transportation, and definitive care (hospital) components—were expanded to align with the challenges posed by anticipated threats. With input from subject matter experts and stakeholders from outside the federal government, this expansion should involve greater collaboration with and harnessing of assets in the private sector.

Improve Hospital Infection Control

During the 2009 H1N1 influenza pandemic, much debate centered on the types of infection control needed to curb the spread of the disease. For example, the relative importance of hand-washing and contact precautions were compared with the value of wearing some sort of respiratory protection. There also was considerable debate over whether respiratory protection should be a simple surgical mask or a more scarce, costly, and cumbersome N-95 respirator. The resolution of those debates depended on understanding whether influenza virus is transmitted primarily by large respiratory droplets or by fine aerosols. (This same debate occurred during the 2003 SARS epidemic.)

The available scientific data was and remains limited and inconclusive. But out of concern for the safety of healthcare workers, the Centers for Diseases Control and Prevention (CDC), following the advice of the National Academy of Sciences, recommended use of N-95 masks. However, many healthcare facilities found this to be infeasible because of cost and scarcity of masks; scarcity and shortages then led many hospitals to consider cleaning and reusing the masks. Again, due to a lack of clear scientific data, there was no guidance available on mask reuse. Complicating matters, once the CDC guidance was issued, hospitals expressed concern that they would be cited by the Occupational Safety and Health Agency (OSHA) for not following that guidance.⁴

This experience reinforces the need to ramp up scientific research that will elucidate the transmission characteristics of novel pathogens, inform infection control practices, and deter punitive actions against hospitals that are acting in good faith but are unable to comply with recommendations.⁵

Toward this end, the USG should prioritize research into the nosocomial transmission of respiratory pathogens and the efficacy of various infection control measures via the National Institutes of Health (NIH), the National Institute for Occupational Safety and Health (NIOSH), and other entities within the CDC.

Prioritize Development of Rapid Diagnostic Tests

During a large-scale ID emergency, the patients most likely to benefit from medical care and from receipt of what is sure to be limited resources must be identified rapidly. This will not be easy when there will be multitudes of people seeking medical evaluation and care. For illnesses caused by most of the biological threat agents, initial assessment based on clinical features alone can be highly inaccurate and unreliable. What is needed for effective patient triage on this scale are rapid and inexpensive diagnostic tests. To date, there are *no* approved rapid diagnostics for any of the major biological threat agents (ie, the pathogens that cause anthrax, smallpox, plague, tularemia, botulism, and the viral hemorrhagic fevers).

Tests to rapidly characterize unknown agents are essential to an effective ID emergency response as well. With a novel pathogen, such as the 2009 H1N1 influenza or the SARS coronavirus, the faster it is identified, the faster control measures can be implemented to stop disease spread and limit illness and death. These tests will be needed most in reference laboratories, but they may also be needed at the point-of-care (ie, in emergency departments), because transporting pathogens to labs may be difficult in some settings.⁵

To speed development and licensing of rapid diagnostic tests, therefore, the USG should also prioritize research on, and development and approval of, rapid and portable diagnostic tests and devices for the most serious biological agents and for characterization of novel pathogens.

Establish Capacity for Real-Time Clinical Trials and Information Sharing

Our experience with the 2001 anthrax attacks and with ID epidemics of the past 10 years—SARS, H1N1 influenza, and H5N1 (avian) influenza in humans—made clear the need for immediate sharing of the best available clinical information. This is crucial during a widespread and/or fast-moving ID outbreak caused by an unknown or unfamiliar pathogen. During such events, up-to-date treatment guidelines are not likely to exist. As new cases emerge in disparate locations, treating clinicians must have access to the knowledge of global experts and the ability to learn from the experiences of other clinicians who have treated patients with the same illness. Furthermore, to answer immediately critical questions, structured clinical trials must be conducted, and they may have to be developed rapidly and spontaneously. Currently, it can take weeks or months for clinical trials to be approved, and once a trial is complete, the results may not be available or shared for months or even years pending the review and publication of academic papers.

If we had a national (or international) network or consortium of academic medical centers, clinicians, and experts organized in advance to collect and distribute real-time clinical information rapidly during an ongoing health emergency, we would be much better positioned for response to an ID emergency. The USG should facilitate and support development of such a network.

Challenges to Meet

While the healthcare system is unquestionably better prepared today than it was in fall 2001 when the anthrax attacks occurred, significant challenges remain. Fortunately, we are fairly well positioned to meet them if we make use of and expand national resources that we have already invested heavily in, if we set and support rigorous research and development agendas, and if we work toward developing a system to support real-time testing and exchange of clinical data. All of these goals are attainable with focused effort and USG support.

References

- Toner E, Waldhorn R, Franco C, et al. The Next Challenge in Healthcare Preparedness: Catastrophic Health Events. January 2010. http://www.upmc-biosecurity.org/website/resources/ publications/2010/pdf/2010-01-29-prepreport.pdf. Accessed August 1, 2011.
- Toner E, Waldhorn R, Franco C, et al. Hospitals Rising to the Challenge: The First Five Years of the U.S. Hospital Preparedness Program and Priorities Going Forward. March 2009. http://www. upmc-biosecurity.org/website/resources/publications/2009/ pdf/2009-04-16-hppreport.pdf. Accessed August 1, 2011.
- Franco C, Toner E, Waldhorn R, Inglesby TV, O'Toole T. The National Disaster Medical System: past, present, and suggestions for the future. *Biosecur Bioterror* 2007;5(4):319-325.
- Zoler M. Is N-95 respirator really best in H1N1? ACEP News December 2009. http://www.acep.org/content.aspx?id=47239. Accessed August 1, 2011.
- Center for Biosecurity. Diagnostics for Gobal Surveillance: Turning Promising Science into Tools Needed for the Field. In press.





Crystal Franco, MPH, is an Associate at the Center for Biosecurity. In 2009-10, she was asked by the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism to lead a study of U.S. government progress and gaps in environmental decontamination following a large-scale bioterrorism attack, the results of which were published in the June 2010 edition of the journal *Biosecurity and Bioterrorism*. Ms. Franco also conducts the Center's annual analysis of federal biodefense funding.



With the U.S. Capitol in the background, members of the U.S. Marine Corps' Chemical-Biological Incident Response Force, known as CBIRF, were demonstrating anthrax clean-up techniques during a news conference in Washington, DC. These men had been searching for anthrax in different buildings on Capitol Hill. (October 30, 2001)

Four Ways to Reduce the Time and Cost of Anthrax Cleanup

Crystal Franco

Given that cleanup of the 2001 anthrax attacks required 2 years of effort and cost hundreds of millions of dollars to remediate only a few buildings, it is hard to imagine what it might take to remediate a city contaminated in a large-scale anthrax attack. Federal, state, and local preparedness experts have estimated that a wide-area release of anthrax would render a city, such as Seattle, WA, contaminated, uninhabitable, and unusable for an extended period of time—up to 5 years by some estimates, given the limitations of current plans and technologies.¹

An anthrax attack, then, would be not just a public health and medical catastrophe, but an economic catastrophe as well. Five years might as well be an eternity for the businesses and residents of a contaminated city, which means that residents and business owners would likely cut their losses and relocate well before acceptable levels of contamination could be achieved.

How might we change this equation and avoid long-term devastation? If the nation is firmly committed to decreasing the impact of an anthrax attack like the one articulated in the National Planning Scenarios (#2, Biological Attack—Aerosol Anthrax), then we must identify the knowledge gaps and political stumbling blocks that are keeping us from being truly prepared. With continued sound planning and additional research, the time and resources needed to clean up after an attack could be dramatically reduced.

Most immediately, the USG can achieve progress in this area by taking the 4 steps outlined below.

Determine How Clean Is Sufficient

It is time to confront this difficult question, the answer to which has important public health, financial, and political ramifications. In 2001, government buildings and media offices contaminated by anthrax spores were remediated to the highest possible standard—to the point at which no (zero) viable anthrax spores could be detected. The process was thorough but costly and would be impossible to replicate following a wide-area attack within a reasonable period and for a manageable cost in human and financial resources.²

Central to answering this question is understanding and being able to characterize with reasonable certainty the public health risk posed by contamination. *Bacillus anthracis* is a hardy bacterium that can live for many years in its spore form. Unlike most other bacteria and viruses, which attenuate naturally with time, anthrax can survive and be resuspended in the air (reaerosolized) long after an initial aerosolized release of the spores.

Because there are few historical examples of aerosolized releases, there is limited insight into the infectious nature and aerosol dynamics of anthrax spores. To date, scientific study has not been able to elucidate the true public health risks associated with anthrax reaerosolization. We don't know, for example, very much about the infectivity of reaerosolized *B. anthracis*—whether it is capable of causing disease in humans—or about reaerosolization dynamics, which can differ depending on surface (ie, concrete, carpet, vegetation, etc) and climate. Health risk is especially uncertain when it comes to outdoor environments.

Without additional research, it will be impossible to characterize the public health risks and the levels of remediation necessary to keep people safe without causing terrible economic impact. While some research has been done, there has been no definitive study that answers fundamental questions: Under what conditions do anthrax spores pose a reaerosolization risk? Under what conditions do we actually need to decontaminate? Are there some environments (outdoor, in particular) where normal environmental degradation will sufficiently diminish the risk without other intervention? Is the 2001 standard of zero viable spores necessary? Is there a less rigid standard that would be reasonable and acceptable? In other words, we need to know how clean is sufficient and under what conditions.

Given our risk-averse society and the precedent set by the 2001 anthrax remediation process, policy discussions regarding how clean is safe are stuck on the zero viable spores standard.³ Should an anthrax attack occur, decisions about remediation would depend on the best political judgment and the scientific expertise available at the time. But it would be a mistake to fail to confront these issues now by funding the science and preparing ahead to the degree possible. This is not something we should have to tackle for the first time during an emergency. Policymakers ought to define, in advance of an attack, a scientifically sound approach to determining appropriate clearance levels for decontamination. This can be accomplished with a focused research and policy analysis agenda and forthright examination and debate of the issues at hand.

Ensure Sufficient Laboratory Resources

Remediation after an anthrax attack will begin and end in the laboratory. Therefore, labs must have the resources and capabilities to process the thousands of environmental samples needed to characterize the amount and extent of contamination and to verify success in decontamination.

A number of federal agencies have a limited number of laboratories with environmental testing capabilities. They would be quickly overwhelmed in a large-scale attack. To build greater capacity, the Environmental Protection Agency (EPA) has established the Environmental Response Laboratory Network the only network dedicated solely to testing environmental samples.⁴ The USG should support EPA efforts to further develop and strengthen this network in order to ensure rapid processing of samples after a biological attack.

Involve the Private Sector

Private sector businesses and building owners and managers will be severely affected by an anthrax attack on a U.S. city. Representatives from the private sector have made clear that longterm abandonment of a city due to anthrax contamination would be devastating. Most businesses would not be able to sustain a shutdown of months, let alone years, waiting for remediation to be completed.

And they should not have to. Remediation of a bioterrorism attack is often thought of as a function of the USG, but the job will be too large to be handled by the public sector alone. There are not enough government personnel or resources to manage remediation on a city-sized scale. The private sector's help will be essential. Private sector representatives, including property owners and managers, will need to be educated about the threat, involved in the planning process, and provided with the necessary resources and authorities to carry out decontamination and remediation of their own assets.

Current planning for anthrax remediation is largely a governmentcentric function, despite the fact that most of the country's assets reside in the private sector. If there is any potential for bringing the time and cost of remediation within the realm of the manageable, it will be achieved through engagement of the private sector as a partner in both preparedness and response.

Plan for Vaccination

The need for anthrax remediation could be greatly lessened through strategic use of anthrax vaccine. If inhabitants of an anthrax-contaminated city could be vaccinated post-attack, it would offer protection from residual anthrax spores. While vaccination would not supplant the need for a remediation response, it would decrease economic damages and reduce the public health risk. Moreover, vaccination would allow remediation to be completed without the pressures of an unvaccinated population.

To date, an anthrax vaccine strategy has not been well incorporated into remediation plans. The U.S. has stockpiled anthrax vaccine, but we do not have a concrete plan for its use after an attack. Policymakers at the state and federal levels should consider the use of vaccine as part of the broader strategy for anthrax remediation.

Achievable Goals Within Reach

Ten years later, we certainly know more about anthrax remediation than we did in 2001, but we still have critical knowledge gaps that are limiting our preparedness. Now, we need to cross the finish line by actively seeking the answers to those questions and using that scientific knowledge to inform sensible policy and planning. The collective result of implementing the 4 measures detailed above would be a substantial reduction in the time and resources needed to remediate a city after a wide-scale anthrax attack. But that result depends on all 4: we need the science to develop attainable, safe, and sufficient standards; we need laboratory capacity to ascertain the effects of an attack and cleanup; we need the involvement of private sector partners to make remediation feasible; and we need vaccination plans to protect the public and buy the time needed to decontaminate to a safe level. All of these goals are achievable and within our reach.

References

- Regional Recovery Framework for a Biological Attack in the Seattle Urban Area. September 2010. Prepared for the Interagency Biological Restoration Demonstration Program. http://nwrtc.pnnl.gov/PDFs/ RegionalRecoveryBioAttack201009.pdf. Accessed July 26, 2011.
- 2. Crockett K. IBRD: a collaborative approach to biological incident recovery. *Biosecur Bioterror* 2011;9(3).
- Interim Consequence Management Guidance for a Wide-Area Biological Attack. Lawrence Livermore National Laboratory. LLNL-TR-484706. May 24, 2011.
- 4. Environmental Protection Agency website. Environmental Response Laboratory Network. http://www.epa.gov/ oemerln1/biological.html#add. Accessed July 26, 2011.







Monica Schoch-Spana, PhD, Senior Associate, is a medical anthropologist whose work centers on research, education, and focused efforts to encourage community engagement in health emergency planning and to encourage enlightened leadership by government officials who plan for and respond to catastrophic emergencies of all types and sources. Most recently, Dr. Schoch-Spana led the Center's development of a framework for planning and preparing for nuclear terrorism. "Rad Resilient City: A Preparedness Checklist for Cities to Diminish Lives Lost from Radiation after a Nuclear Terrorist Attack," has a release date of September 27, 2011.



Volunteers hand out food to fire evacuees at Qualcomm Stadium during Southern California wildfires (October 24, 2007).

Community Resilience: Beyond Wishful Thinking

Monica Schoch-Spana

Community resilience, a concept frequently embedded in today's U.S. government statements about disasters and public health emergencies, has upended previous notions of the public as hapless victims or hysteria driven mobs. The National Health Security Strategy (2009) and its Draft Biennial Implementation Plan (2010) single out an informed and empowered citizenry as fundamental to the nation's ability to confront catastrophic health events.^{1,2} Only a decade ago, however, the thinking was quite different, as I recall. Then, senior decision makers and emergency professionals contemplated worst-case bioterrorism scenarios in which the public was seen as a problem to manage, along with the pathogen and the perpetrator. During the anthrax letter attacks in 2001, the media zeroed in on so-called panic buying of antibiotics (a behavior displayed by very few people) and failed to remark on the order and patience exhibited when at-risk groups waited hours in line for their medication. Now, citizens are embraced as critical partners in managing public health emergencies; victims have become survivors.

Citizens' Role in Public Health Emergency Preparedness

Trust in the ability of average people to cope with disastrous events and to play a key role in response and recovery is not misplaced, as the example of a severe pandemic influenza demonstrates. Thankfully, we escaped such a situation with the 2009 H1N1 influenza outbreaks. Citizen contributions—from personal preparedness at home to public deliberations in the town hall—can help mitigate both the health effects and the social discord possible with a large-scale public health emergency.³

The public's role in health emergency management encompasses an individual's (and household's) ability to weather the crisis period. This includes acting on authorities' guidance about community mitigation measures; being attuned to instructions on when and where to obtain vaccine and medications; and setting aside reserves of food, water, and medicines to weather shortages if they occur.

Volunteer networks, like the Medical Reserve Corps (MRC), enhance a locality's preparedness and response capabilities. Neighborhood associations, faith communities, trade groups, and social service nonprofits can also rally constituents to convey event-related news, especially to hard-toreach groups; fill key support positions at overburdened hospitals and health agencies; and stand up systems to aid the homebound sick and their families.

As part of pre-incident planning, policymakers can solicit the input of community residents on some of the tough choices posed by a pandemic flu. What guidelines, for instance, should hospitals follow if they have to turn patients away for lack of staffed beds? Actively involving residents in public health and safety policymaking can foster greater trust among officials and their constituents and generate new ideas that improve plans and enhance the social legitimacy of a final course of action. ⁴⁻⁶

The Duty of Government to Leverage the Public's Contributions

During the past 10 years, the U.S. government has increasingly asserted the need to integrate citizens into public health emergency preparedness (PHEP), and it has carried out initiatives on each of the fronts discussed above—from providing preparedness guidance at ready.gov and pandemic.gov, to expanding volunteer opportunities through Citizen Corps programs, to piloting public deliberations on the feasibility and social acceptance of pandemic flu containment measures (see Figure 1). Recognition of a citizen role in PHEP has also framed federal grants to state and local health departments for preparing their agencies and communities to respond to disasters with significant health impacts.

In March 2011, the Centers for Disease Control and Prevention (CDC) issued "Public Health Preparedness Capabilities: National Standards for State and Local Planning" to aid state and local health departments in forming strategic plans, setting priorities, and measuring progress.7 At least 4 of the 15 capabilities bear on citizens and civil society contributions, with "community preparedness" presenting the most robust agenda. To strengthen this capability, state and local planners are advised to take key steps including: (1) convene coalitions that include business as well as community- and faith-based partners; (2) incorporate community input into emergency operations plans and into problem-solving sessions; (3) provide occasions for volunteers to participate in safety efforts year round and to help maintain health services during an incident; and (4) identify community leaders who can serve as trusted spokespersons to deliver public health messages.

The federal government is not alone, however, in singling out community engagement as critical to public health emergency preparedness. In 2008, the Institute of Medicine argued that citizens, communities, and businesses were part of the public health preparedness system and that the governmental public health infrastructure was the "final accountable entity" for integrating them.⁸ More generally, current principles of practice call on public health professionals to work alongside community members in tackling top health concerns. Two of the CDC's 10 "essential public health services" codify the importance of partnering with the public.⁹ One is to "inform, educate, and empower people about health issues"; the other is to "mobilize community partnerships and action to identify and solve health problems."

Local Health Departments' Capacity for Community Engagement

Community engagement is enshrined in federal PHEP grant guidance, national consensus statements on preparedness, and current principles of public health practice. But does its popularity signify its common practice? Are health departments well equipped to achieve the national vision of broad-based PHEP coalitions and a ready and aware citizenry? With these questions in mind, the Center for Biosecurity has investigated the capacity of local health departments (LHDs) to engage the community in public health preparedness efforts. We first relied on national survey data on LHDs from 2005 and 2008 collected by the National Association of County and City Health Officials.¹⁰ We then began to interview LHD leadership and staff about organizational elements that enable greater community engagement in PHEP.

Community Engagement Workforce

Our statistical analysis revealed that 3 LHD staff positionsemergency preparedness coordinator, public information specialist, and health educator-were strong predictors of whether an LHD involves the public in PHEP (controlling for other variables, including annual expenditure, size of population served, and whether the LHD is located in an urban, suburban, or rural setting). Like any other critical public health function, community engagement depends on proper staffing. LHDs with an emergency preparedness coordinator were 13% more likely to organize PHEP coalitions, 17.9% more likely to conduct PHEP public education, and 7.8% more likely to develop a local MRC unit. However, the data also showed that the presence of LHD personnel critical to community engagement in PHEP was highly variable across the country. Less than half of the LHDs surveyed had a public information specialist, and 1 of every 4 LHDs queried did not employ a health educator or preparedness coordinator.

Leadership and Political Backing

Although interviews are at an initial stage, some dominant themes have emerged during our conversations with practitioners. Skilled personnel, with fewer priorities competing for their time, are necessary if an LHD is going to engage the community in PHEP successfully. Dedicated people are needed to develop an engagement strategy, cultivate relationships with community- and faith-based groups, conduct broad public outreach and education, and mobilize volunteers. An influential, top LHD leader who explicitly endorses community engagement in PHEP as a strategic priority is seen as a prerequisite for the work to go forward. Helping to trigger that endorsement is clear communication by the federal government that community engagement in PHEP is a genuine priority and a grant deliverable. The backing of local political leadership advances the goal of public involvement as well.

The Earnest Path to Greater Community Resilience

In thinking about the next 10 years in biosecurity, 3 key recommendations quickly come to mind in relation to community resilience.

Make It Happen

We need to stop talking about resilience in longing terms and start taking concrete steps known to enhance a community's ability to anticipate and to mitigate the consequences of epidemics and disasters. These steps are well outlined in CDC's new PHEP guidance to state and local health agencies on the community preparedness capability. No other public health preparedness capability—whether biosurveillance, medical countermeasure dispensing, or medical surge—is treated as if it were an organic process that will somehow happen on its own.

A little more than 10 years ago, a national assessment confirmed that U.S. public health laboratories were on the decline.¹¹ In response, investments in modern equipment were made, practice standards and protocols were developed, training sessions were offered, and more laboratorians were hired. As a result, the laboratory infrastructure was revitalized, and health agencies are now in a better position to detect, characterize, and communicate about confirmed threat agents. Resilience to disasters similarly depends on a robust community engagement infrastructure: sufficient staffing, practice standards, and training opportunities.

Admit the Costs

One of the appeals of community engagement models of disaster resilience is that business partners and community- and faithbased organizations can bring assets to the emergency planning table, thus extending scarce public sector resources. Like any other enterprise, however, there are upfront costs in garnering support from external partners. In the case of preparedness coalition building, the principal cost is stable support for skilled and dedicated personnel who can nurture trusting relationships over time, as suggested by our research. Nevertheless, at the 2011 Public Health Preparedness Summit in Atlanta, I heard a resilience panelist promote community engagement on the premise that it was inexpensive—virtually free. During a period of economic austerity, it is sensible to package ideas for new government initiatives in terms of the "cheap factor." But I would argue that this is disingenuous and ultimately undercuts the value of community engagement. The bottom line is that soliciting partnerships, volunteers, and citizen input requires resources once and forever. And doing so has the potential to multiply preparedness resources, improve the quality of emergency planning, better protect vulnerable populations, and save lives.

Commit the Personnel

Our research suggests that LHDs that retain a community engagement workforce and that give them a clear mandate are more likely to integrate citizens and community-based groups into the larger system for public health preparedness and response. Studies of community partnerships to advance population health, in general, indicate that dedicated staff and an institutional champion are among the key ingredients for successful collaborations.^{12,13} The same was found when FEMA evaluated Project Impact, a program in the 1990s to build private-public linkages aimed at enhancing local disaster resistance.¹⁴ Successful Project Impact communities had a full-time coordinator who could actively facilitate partnerships and champion program goals among diverse audiences. If, as the National Health Security Strategy sets forth, community resilience is one of the country's top health security goals, then we need to put a greater priority on adequate staffing for community engagement work in public health departments.

Recommit to Strengthening the Public Health Infrastructure

During the past 10 years, it is has been gratifying to see a reversal in ideas about the role of average people in a public health emergency—from being a foil to the official response to serving as a critical ally. To seize the full potential of this vision, however, we must recommit to strengthening the public health infrastructure, this time with an emphasis on hiring, training, and assigning sufficient staff to engage the larger community in PHEP. Greater community resilience will not come through wistfully written federal doctrine, but through more and better inclusion of the public in local preparedness, response, and recovery systems.

Federal Policy Milestones Acknowledging Citizens and Community Groups as Essential Partners in Public Health Emergency Preparedness

Public Health Security and Bioterrorism Preparedness and Response Act, 2002¹⁵

Authorizes federal preparedness grants to state/local health departments that include priority on risk communication and health information dissemination

Citizen Corps launched, 2002^{16,17}

Broadens opportunities to volunteer in disasters, including Medical Reserve Corps units composed of volunteer health professionals and non-medically trained personnel.

Ready.gov launched, 2003¹⁸

Provides citizens with advice on threat awareness, personal preparedness, and protective actions for bioterrorism and other scenarios

Homeland Security Presidential Directive 10: Biodefense for the 21st Century, 2004¹⁹

Asserts that "[t]imely communications with the general public...can significantly influence the success of response efforts, including health- and life-sustaining interventions"

Pandemic Flu Planning, 2005–06²⁰

Releases preparedness checklists for individuals, businesses, and faith-based and community organizations • Pilots public deliberations about best early use of limited vaccine and about community-wide controls

Pandemic and All-Hazards Preparedness Act, 2006²¹

Names risk communication and public preparedness as "essential public health security capabilities" • Makes federal preparedness grants to state and local health agencies contingent on a mechanism "to obtain public comment and input" on preparedness and response plans

Homeland Security Presidential Directive 21: Public Health and Medical Preparedness, 2007²²

Identifies community resilience as 1 of the 4 "most critical components of public health and medical preparedness" • Promotes education initiatives to "enhance private citizen opportunities for contributions to local, regional, and national preparedness and response" • Asserts that resilient communities are made of empowered residents who are familiar with their local public health and medical systems and who are poised to provide neighbor-to-neighbor support

National Health Security Strategy (NHSS), 2009

Sets forth community resilience as 1 of 2 top national health security goals

NHSS Draft Biennial Implementation Plan, 2010²

Singles out "informed, empowered individuals and communities" as essential to U.S. readiness and resilience; measures citizen empowerment in terms of: (1) community members, including at-risk groups, who are knowledgeable about health threats, what to do, and where to seek out help; (2) faith-based organizations, private business, and NGOs with community ties that are integrated into emergency planning; and (3) social networks that are adept at disseminating risk information and aiding community members in response and recovery

Public Health Preparedness Capabilities: National Standards for State & Local Planning, 2011⁷

Provides capability definitions and functions for community preparedness, community recovery, emergency public information and warning, and volunteer mobilization

40

References

- U.S. Department of Health and Human Services. National Health Security Strategy. 2009. http://www.phe.gov/Preparedness/planning/ authority/nhss/strategy/Documents/nhss-final.pdf. Accessed August 9, 2010.
- U.S. Department of Health and Human Services. Biennial Implementation Plan for the National Health Security Strategy of the United States of America—Draft. July 2010. http://www.phe.gov/ Preparedness/planning/authority/nhss/comments/Documents/ nhssbip-draft-100719.pdf. Accessed August 9, 2010.
- Schoch-Spana M, Franco C, Nuzzo JB, Usenza C, on behalf of the Working Group on Community Engagement in Health Emergency Planning. Community engagement: leadership tool for catastrophic health events. *Biosecur Bioterror* 2007;5(1):8-25.
- 4. Beierle TC. The quality of stakeholder-based decisions. *Risk Anal* 2002;22(4):739-749.
- Godschalk DR, Brody S, Burby R. Public participation in natural hazard mitigation policy formation: challenges for comprehensive planning. J Environ Planning Manage 2003;46(5):733-754.
- 6. Lasker RD. Redefining Readiness: Terrorism Planning Through the Eyes of the Public. New York: New York Academy of Medicine; 2004.
- U.S. Centers for Disease Control and Prevention. Office of Public Health Preparedness and Response. Public Health Preparedness Capabilities: National Standards for State and Local Planning. March 2011. http:// www.cdc.gov/phpr/capabilities/. Accessed August 1, 2011.
- Altevogt BM, Pope AM, Hill, Shine KI. Research Priorities in Emergency Preparedness and Response for Public Health Systems: Letter Report. Washington, DC: National Academies Press; 2008.
- U.S. Centers for Disease Control and Prevention. 10 Essential Public Health Services. http://www.cdc.gov/od/ocphp/nphpsp/ EssentialPHServices.htm. Accessed August 11, 2010.
- Schoch-Spana M, Selck F, Sell TK, Morhard R. Health departments and the evolving role of the public in U.S. national health security. [Unpublished manuscript.]
- 11. U.S. Centers for Disease Control and Prevention. Improving the Public Health Laboratory Infrastructure. http://www.bt.cdc.gov/Irn/ infrastructure.asp. Accessed August 1, 2011.

- 12. Roussos ST, Fawcett SB. A review of collaborative partnerships as a strategy for improving community health. *Annu Rev Public Health* 2000;21:369-402.
- Orians C, Rose S, Hubbard B, et al. Strengthening the capacity of local health agencies through community-based assessment and planning. *Public Health Rep* 2009;124:875-882.
- Tierney KJ. Executive Summary: Disaster Resistant Communities Initiative: Evaluation of the Pilot Phase, Year 2. Submitted to the Federal Emergency Management Agency. University of Delaware Disaster Research Center. June 2000. http://www.udel.edu/DRC/archives/ Documents/Project%20Impact/projectreport42.pdf. Accessed August 1, 2011.
- Public Health Security and Bioterrorism Preparedness and Response Act of 2002. PL 107-188; 107th Congress. June 12, 2002. http:// frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_cong_ public_laws&docid=f:publ188.107. Accessed November 5, 2010.
- Middleton G. Medical Reserve Corps: engaging volunteers in public health preparedness and response. *Biosecur Bioterror* 2008;6(4):359-360.
- 17. Simpson DM. Community Emergency Response Training (CERTs): a recent history and review. Natural Hazards Rev 2001;2(2)54-63.
- Department of Homeland Security launches Citizen Preparedness Campaign [news release]. Washington, DC: Department of Homeland Security, Ready.gov website; February 19, 2003. http://www.ready.gov/ america/about/pressreleases/release_030218.html. Accessed August 6, 2010.
- Homeland Security Presidential Directive 10: Biodefense for the 21st Century. April 28, 2004. http://www.dhs.gov/xabout/laws/ gc_1217605824325.shtm#1. Accessed August 6, 2010.
- U.S. Department of Health and Human Services. H1N1 flu: a guide for community and faith-based organizations. http://www.pandemicflu.gov/ professional/community/cfboguidance.html. Accessed August 6, 2010.
- 21. Pandemic and All-Hazards Preparedness Act. PL 109-417; 109th Congress, 2d sess. December 19, 2006. http://frwebgate. access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_public_ laws&docid=f:publ417.109.pdf. Accessed August 6, 2010.
- 22. Homeland Security Presidential Directive 21: Public Health and Medical Preparedness. October 18, 2007. http://www.fas.org/irp/offdocs/nspd/ hspd-21.htm. Accessed October 13, 2010.

Printer Mosaic, Cheverly, MD Portrait Photos Kaveh Sadari

Center for Biosecurity of UPMC

621 E. Pratt Street Suite 210 Baltimore, MD 21202 www.upmc-biosecurity.org Tel: 443.573.3304 | Fax: 443.573.3305