



BIODEFENSE

The Threat, the Cost & the Priority

Survey and Report

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The Threat, the Cost & the Priority

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Foreword by Stephen Reeves

June 2013

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ACKNOWLEDGEMENTS

Working with professionals who can see through the fog of complexity, develop an action plan, and skillfully execute that plan is always a pleasure. This report was developed through a collaborative effort that spanned the nation – from the general public to subject-matter experts. Many professional sources came together either physically or virtually to provide useful perspectives. I am very grateful to the hard work and determination of many people who brought that thought leadership together.

First and foremost, DomPrep’s staff Susan Collins, Catherine Feinman, and Derek Sharp did a remarkable job in coordinating and facilitating the briefing, as well as designing, compiling, editing, and producing this report. A special thank you goes to all of them.

A warm thank you also goes to DomPrep40 Advisor Major General Stephen Reeves, USA (Ret.), former joint program executive officer for chemical and biological defense for the Department of Defense, who played a key role in the planning process, provided thought leadership and insight, and led an engaging discussion that was used to create this report. The following key presenters provided content and increased the report’s importance, credibility, and relevance to planners and policy professionals alike: Nathaniel Hupert of Weill Cornell Medical College, Peter Emanuel of the U.S. Army’s Edgewood Chemical and Biological Center, Keith H. Wells of Biologics Consulting Group, Maureen Sullivan of Minnesota Department of Health Public Health Laboratories, Steven P. Bucci of The Heritage Foundation, and Matthew Kozey of NORC at the University of Chicago.

A special thank you goes to DomPrep40 Advisor Dr. Jeffrey Runge who began this discussion at a briefing held in September 2012 at Harvard University’s Faculty Club.

This report, of course, would not be possible without the support of its underwriters: Emergent Biosolutions and Luminex. It is important to note that these underwriters are experts in the field of preparedness and response and have a vested interest in America remaining vibrant and strong.

Last, but certainly not least, thank you to the many DomPrep readers and members of the general public, who each provided valuable feedback that led to the discovery of important insights. Because of the new realities of funding, the entire homeland preparedness enterprise is experiencing significant change. By facilitating dialogue, perhaps together we can forge a new paradigm of decision-making. It is gratifying that DomPrep can serve as a catalyst for this type of interaction.

Martin D. Masiuk
Publisher of DomPrep

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FOREWORD

There has been an explosive growth in biotechnology, and a greater knowledge of genetic engineering is spreading throughout the world. The tools used and experience required for bioengineering organisms that were once the province of experienced researchers and scientists are now routinely used in undergraduate and even high school biology classes.

What makes the biothreat significant is the fact that it is multidimensional, it transcends domestic and foreign policy, and it presents an element of surprise. Although there is little evidence of state or non-state actors developing biological weapons, there certainly are a lot of general biotechnology developments. Many competent scientists now have the ability to create bioweapons relatively easily. Even a small-scale biological attack would likely overshadow other domestic and international incidents, and promote social, economic, and political upheavals.

The United States faces several challenges, including a lack of reliable international public health efforts, perceived threats, and vulnerabilities as a nation. It is not possible to terror-proof the nation and those who wish to do harm are willing to adapt and will attempt to overcome any countermeasures that are implemented. Health resources, surveillance systems, epidemiological expertise, and laboratory networks must be integrated with healthcare, emergency management, law enforcement, national security systems, and others to be able to rapidly share information and communicate across sectors, both nationally and internationally.

Although difficult and expensive, consequence management and a new infusion of energy and support must be pushed to the forefront. DomPrep has taken steps in that direction by: (a) using a survey to solicit feedback from emergency planners, responders, and receivers, as well as the general public; and (b) bringing together subject-matter experts to discuss the survey results and address concerns related to biothreats.

Of the surveys that were sent out, 572 members of the general public and 577 DomPrep readers, who represent professionals within the emergency community, replied by completing the survey. As Matthew Kozey, principal research analyst in the Security, Energy, and Environment Department of NORC at the University of Chicago, pointed out during the briefing, “the data are unweighted, but nevertheless instructive.”

The biothreat topic is important not only for the actual risk of attack, but also the perceived risk. To be sufficiently prepared, a balance must be reached – for security, technology, and situational awareness.

Major General Stephen Reeves, USA (Ret.)
*Former Joint Program Executive Officer
Chemical and Biological Defense for the Department of Defense*

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SUMMARY

In recent months, nonbiological threats dominated the public media – al-Qaida, lone wolves, bombings, hurricanes, tornadoes, school shootings, and the list goes on. After 9/11, many security gaps were closed because of investments and changes – for example, Operation Noble Eagle.¹ Other events, like the bombings at the Boston Marathon, exposed vulnerabilities that make the nation more susceptible to attack because some gaps cannot be closed; special events like the marathon will continue to take place.

Biothreats are unique in that they can be intentional, natural, and/or perceived. Because the validity of any particular attack is based on the last attack using the same method, many people may consider the likelihood of a biological attack lower since no recent biological attacks, such as the ricin letters, have been successful in inflicting harm on their desired targets. There are two main views about what such threats will become in the not too distant future: (a) biotechnology is becoming more powerful, available, familiar, and decentralized, so the threat is expected to grow; (b) there is a lot of uncertainty about the future development of biotechnology due to complex social, economic, scientific, and technological factors that shape the biotech innovations and their applications.

Participants at the DomPrep Executive Briefing agree that biological agents pose a huge threat to the nation. From the ricin letters to the new strain of influenza in China, the threat is great, but the information about, and publicity of, such events is minimal. Major General Stephen Reeves, USA (Ret.), former joint program executive officer for chemical and biological defense for the Department of Defense, described the imminent threat by saying that, “We are one microbiologist away from a biological attack.”

Input from participants at the briefing as well as the survey results suggest a real and present threat that could occur at any time and in any place. This report discusses the threat, efforts to address the threat, environmental surveillance and detection, costs, and priorities; and summarizes results from the nationwide survey on biodefense awareness.

From those results, DomPrep has derived five key findings that must be brought to the attention of policymakers at all levels of government:

- I. Advances in technology have enabled persons with relatively little scientific knowledge to develop bioweapons easily and inexpensively by changing the route, state, or size of the particles.
- II. Public health laboratories are ready, willing, and equipped to work with responders and other agencies to rapidly detect and identify potential biothreats before they spread to other populations.
- III. A single perfect tool does not exist for detecting biothreats, but there are current tools that can be enabled or reallocated now to provide better protection than what is currently being used.
- IV. Although the lifecycle cost of a biological attack is unquantifiable, there is sufficient evidence that such an attack would overwhelm a city, thus requiring an effective business model with careful supply chain management.
- V. Three key priorities should be considered when preparing for a biological incident: the readiness of the responders and receivers, the role of the private sector, and the need for effective and informed leadership.

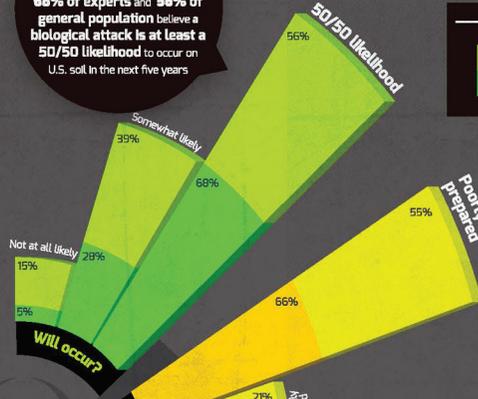


Biodefense in the USA

ARE WE PREPARED?

A real & urgent threat

68% of experts and 56% of general population believe a biological attack is at least a 50/50 likelihood to occur on U.S. soil in the next five years



Legend

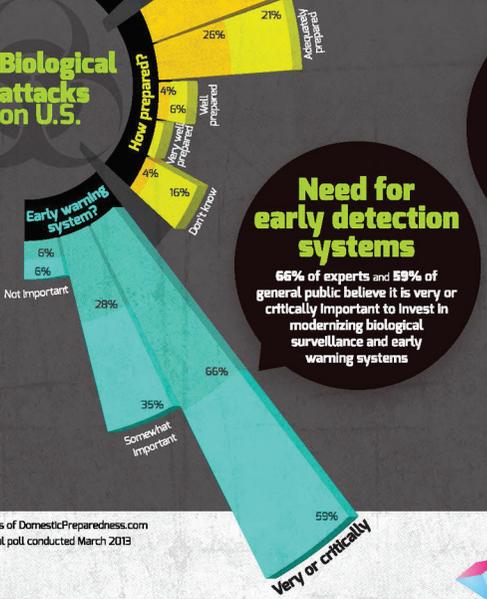
- General Public
- Experts*

NORC poll on the state of domestic preparedness related to bioterrorism

We're unprepared

66% of experts and 55% of general public believe that the U.S. is poorly or not at all prepared to deal with a biological attack

Biological attacks on U.S.



Why it's so important?

Biological weapons are a silent and invisible threat, and have the potential to inflict mass casualties



The effects are delayed and potentially catastrophic if not identified early

Need for early detection systems

66% of experts and 59% of general public believe it is very or critically important to invest in modernizing biological surveillance and early warning systems

*Readers of DomesticPreparedness.com National poll conducted March 2013



I. BIOTHRREATS – PAST, PRESENT & FUTURE

Biological warfare has existed for centuries and can be found in the deliberate contamination of water and food supplies, the use of plagued bodies (both human and animal) to spread disease, and more recently the sophisticated use of specific pathogens. The exact number of casualties from many biological attacks, though, remains uncertain because the attacks themselves often coincide with natural outbreaks and spread of disease; and/or the evidence is lacking that a deliberate attack actually occurred.

One of the deadliest naturally occurring biological events in world history was the 1918 Spanish flu virus, which had a global death toll estimated at up to 100 million people. The Centers for Disease Control and Prevention (CDC) estimate that as many as 575,400 people may have died as a result of the 2009 H1N1 swine flu.² When the severe acute respiratory syndrome (SARS) began in 2003, more than 8,000 people were infected in more than 30 countries – leading to the deaths of nearly 800.³

“The Poor Man’s Atomic Bomb”

Deliberate biological attacks have not proven to be as successful at mass killings as the examples of naturally occurring events mentioned above, but the threat is real and the potential death toll is significant. Described in 1988 by the speaker of the Iranian parliament, Hashemi Rafsanjani, as “the poor man’s atomic bomb,” chemical and biological weapons are easier to fabricate and the materials are more readily available than their nuclear counterparts.⁴

Although the 1993 anthrax attack in Tokyo by the Japanese Aum Shinrikyo terrorist organization resulted in no deaths, the 2001 anthrax letters mailed in the United States shortly after the 9/11 attacks raised great concern. Although only five people died from inhaling anthrax during that incident, the federal government spent billions of dollars to address and combat similar attacks that potentially could be planned in the future.

Sociological, Psychological & Financial Impacts

When a team of virologists in Germany and France successfully constructed the Ebola virus in 2001,⁵ it became apparent that preventing the use and misuse of dangerous pathogens would take more than simply securing stockpiles of viruses such as smallpox.⁶ In addition to

the infections caused by biological incidents, there is also a concern for the sociological, psychological, and financial well-being of the affected communities.

In early 2013, two new threats were detected – one seemingly natural in occurrence and the other deliberately distributed. First, a new strain of the H7N9 bird flu was found to have infected its first human host in China. As of 29 April 2013, the CDC reported 126 cases and 24 deaths – a significant percentage of fatalities compared to other influenza outbreaks – as a direct result of the H7N9 outbreak in Shanghai, China.⁷ Since that date, more cases have been reported. To help prevent the spread of disease, poultry markets were temporarily closed and citizens used personal safety prevention methods such as wearing surgical masks to avoid contamination.

Soon after the discovery of the new strain of H7N9, in an unrelated incident, letters laced with ricin – a poison that is found in low quantities in castor beans – were mailed to President Barack Obama, Mississippi Senator Roger Wicker, and a Mississippi judicial official. In another case, more ricin letters were intercepted at a Spokane, Washington post office in May. All of the letters were detected before reaching their final destination through routine postal screening procedures that were implemented following the 2001 anthrax letters. No one was injured in those attacks.

The Science Behind the Threat

During the 22 April briefing, Keith H. Wells, senior consultant and head of the New England Office of Biologics Consulting Group, Inc., discussed scientific research and pointed out two of the many lessons learned from the U.S. Offensive Biological Weapons Program (1943-1969), in particular Project 112 (1961-1969): (a) all agents are not created equal; and (b) particles are the key. During the timeframe of Project 112, scientists researched, stockpiled, and/or weaponized a variety of biological agents, including: *Francisella tularensis* (tularemia), Staphylococcal enterotoxin B, *Bacillus anthracis* (anthrax), *Brucella* sp. (brucellosis), *Coxiella burnetii* (Q fever), the Venezuelan equine encephalitis virus (VEE), and *Clostridium botulinum* toxin (botulism).

That research showed how biological weapons could be used as a viable alternative to chemical, or even nuclear, weapons because of the ability to transform naturally occurring disease agents into non-naturally occurring weapons. The program placed great emphasis on

the properties of particles, namely the route, state, and size. By altering the natural route of a toxin (e.g., from contact to inhalation), researchers were able to produce a non-natural disease. By altering the state of the material (e.g., from wet to dry), researchers were able to create a much more effective disease.

By choosing an optimal size of the particles, researchers were able to target a specific region of the airway (e.g., a particle that is 2-5 microns would target the bronchia and alveoli) and significantly increase both the infectivity and lethality of an attack. Wells pointed out that the smaller size also can affect incubation by compressing “normal” incubation periods for infectious agents from four days to only 24 hours and for toxins from up to 18 hours to as little as 1 hour depending on the dose. To produce a lethal result, however, the required dose decreases as the size of the particles decrease.

Technological Advances – Bigger, Better Weapons

Wells concluded by discussing the effect of quantity, combinations, and advances since 1969. During an intentional attack, the particles are distributed in doses that are much greater in quantity than the dose from a naturally occurring event (1000s, 100,000s, or millions of organisms vs. 10s). Such overwhelming doses then can further compress incubation periods and prevent the effectiveness of antibiotics and vaccines. Toward the end of Project 112 program, toxins and infectious agents were combined in ways that would never be found in nature, thus taking it, as Wells stated, “completely out of the realm of natural disease and planting it squarely in the realm of biological weapons.”

Since 1969, revolutions in biotechnology, bioprocessing, and biopharmaceuticals have driven advances in innovations and understanding of bacterial physiology, bacterial virulence factors, fermentation, purification, aerosol formulation, aerosol delivery, and stabilization. Perhaps the most surprising change, though, that Wells discussed is the fact that, “Technical advances that earned Nobel Prizes 20 years ago are now routinely performed by high school and middle school students.”

Survey Results

A terrorist threat using biological weapons obviously is not new, especially at the federal level, but the threat perceived by the U.S. population does not seem to reflect that fact. When asked about

the likelihood of a biological attack on U.S. soil within the next five years, less than 13 percent of the respondents from the general public reported that such an attack is very likely or almost certain, compared to 26 percent of their emergency preparer, responder, and receiver counterparts. Likewise, more than 54 percent of the public perceives the threat to be not at all likely or only somewhat unlikely, compared to only 33 percent of DomPrep readers who responded (Figure 1).

The perceived threat of attack among DomPrep respondents is greater than that of the general public for all modes – biological, chemical, conventional bombing, or cyber/computer – with one key exception being nuclear (Table 1). Further research and discussion is needed to determine the reason for such discrepancy, which could be attributed to the quantity and quality of information sharing, the level of situational awareness, and general preparedness efforts at the local, state, and federal levels.

Figure 1:

How likely do you believe a biological attack that causes casualties or disruptions in government or civil activities is to occur on U.S. soil in the next five years?

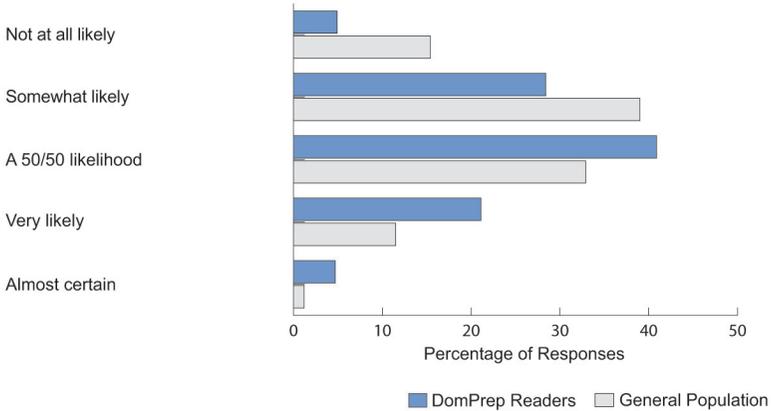


Table 1:

In the next five years, how likely do you believe the following attacks on U.S. soil are to occur?

		Not at all likely	Somewhat likely	A 50/50 likelihood	Very likely	Almost certain
Nuclear Attack	DomPrep Readers	20.7%	48.6%	22.3%	7.5%	0.9%
	General Population	28.2%	38.5%	25.0%	7.4%	0.9%
Chemical Attack	DomPrep Readers	4.0%	27.7%	41.6%	23.5%	3.3%
	General Population	13.8%	39.7%	35.0%	10.1%	1.4%
Conventional Bombing	DomPrep Readers	6.3%	16.6%	23.8%	33.7%	19.6%
	General Population	23.3%	25.9%	29.1%	18.0%	3.7%
Cyber or Computer Attack	DomPrep Readers	0.0%	2.3%	6.8%	31.2%	59.8%
	General Population	3.0%	10.0%	20.8%	36.9%	29.4%

II. LEGISLATION & MITIGATION EFFORTS

Unlike chemical and nuclear threats, biological agents are a legitimate health concern that cannot be precisely quantified and measured. There are numerous presidential directives, national strategies and executive orders, and cabinet-level strategies specifically addressing the biological threat, but also many uncertainties.⁸

Although the 1972 Biological Weapons Convention⁹ prohibited the development, production, and stockpiling of biological and toxin weapons, many nations have been able to continue expanding their biological weapons programs because they are not required to declare: (a) every biological agent or toxin that is used in nonprohibited activities; and (b) every laboratory that is engaged in research and development of substances that possibly could be used as biological warfare agents. Two ways to help mitigate the current threat are by using effective environmental surveillance and working closely with public health laboratories.

Environmental Surveillance

Peter Emanuel, bioscience division chief at the U.S. Army's Edgewood Chemical Biological Center (ECBC),¹⁰ pointed out that all-hazards environmental surveillance, public health management, and data-fused situational awareness are key components of biosurveillance. He defined a “multi-tiered, complementary, layered defense strategy” as “many devices working in concert as a system of systems to provide an informed, data-fusion operating picture” – not simply “point detectors that sit in a field and collect air.”

Over the past 10 years, many key documents have been published that have led to advances in biosurveillance as it pertains to systems, humans, and animals. Emanuel directed special attention to one particular report published in 2009 by the CDC's National Biosurveillance Advisory Subcommittee.¹¹ That federal advisory committee made two recommendations concerning investments in technology: (a) “electronic health records and electronic laboratory data should be leveraged to improve how they serve biosurveillance and public health missions”; and (b) “strategic investments in new technologies (e.g., genomics, supply chain management, visualizations, display dashboards) to strengthen U.S. biosurveillance capabilities.”

Public Health Laboratories

The term “public health” in general refers to community health, prevention of disease, and promotion of health, whereas in the laboratory setting it refers more to disease detection. “Healthcare is important and vital to us some of the time, but public health is critical to all of us, all of the time,” said Maureen Sullivan, supervisor of the Emergency Preparedness and Response Laboratory Unit at the Minnesota Department of Health Public Health Laboratory.

Under the National Public Health Performance Standards Program (NPHPSP)¹² of the CDC, there are 10 essential public health services:¹³

1. Monitor health status;
2. Diagnose and investigate health problems and hazards;
3. Inform, educate, and empower the people;
4. Mobilize community partnerships and action;
5. Develop policies and plans that support health efforts;
6. Enforce laws and regulations;
7. Link people to needed personal health services;
8. Assure a competent healthcare workforce;
9. Evaluate personal and population-based health services; and
10. Research insights and solutions to health problems.

However, there are 11 essential services of public health laboratories, which focus not just on the person and the disease, but also the community and population as a whole:¹⁴

1. Disease prevention, control, and surveillance;
2. Integrated data management;
3. Reference and specialized testing;
4. Environmental health and protection;
5. Food safety;
6. Laboratory improvement and regulation;
7. Policy development;
8. Emergency response;
9. Public health-related research;
10. Training and education; and
11. Partnerships and communication.

Laboratories, which have the resources and ability to respond to both natural and manmade events, collect surveillance data from human, animal, and environmental samples. Even small rural laboratories can

be very effective – responding possibly even more rapidly than larger laboratories – in detecting potential threats, but success depends on laboratory networks, partnerships, and communication.

The Laboratory Response Network – established by the CDC, the Federal Bureau of Investigation, and the Association of Public Health Laboratories – offers both chemical and biological capabilities. To address biosafety and biosecurity concerns, federal regulations that all public health laboratories must follow require that: (a) facilities collecting, analyzing, and/or storing biological agents are very secure; and (b) comprehensive documentation is kept to identify the location of the organisms and the persons who have access to them. Laboratory capabilities are just one of the tools in the toolbox. In addition to the integrated Public Health Laboratory Systems and partner relationships/collaborations, other detection capabilities such as Biowatch are also needed.

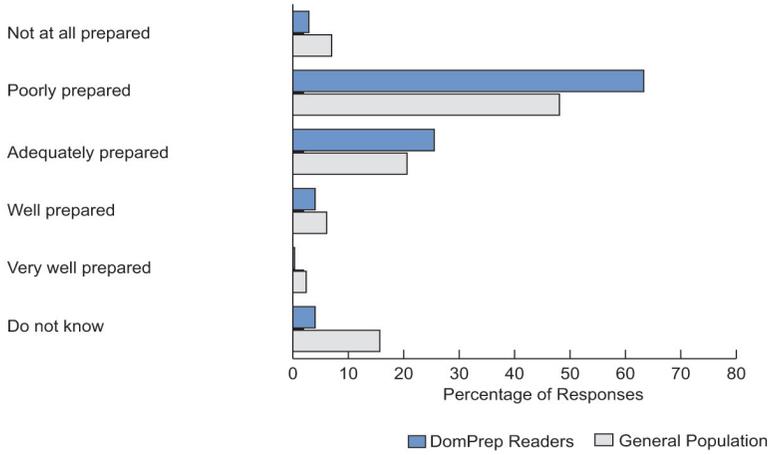
Survey Results

Despite legislative efforts, environmental surveillance, and public health laboratory detection, the threat of a biological attack within the United States remains. If efforts to prevent or mitigate an attack fail, then the nation must be prepared to rapidly respond. However, when asked if the nation is prepared to deal with the consequences of such attacks on a major U.S. population center, respondents overwhelmingly agreed that the United States is “poorly prepared” (Figure 2).

If respondents are correct and a biological incident would overwhelm a city, then mitigation efforts are that much more important. Even nontraditional partners (e.g., the Association of Emergency Room Physicians, National Pharmaceutical Association, dentists, faith-based organizations, private citizens, and veterinarians) are building greater disaster networking capabilities.

Figure 2:

How prepared is the United States to deal with the consequences of a biological attack on a major U.S. population center?



III. SURVEILLANCE TECHNOLOGY

Better technology means better data. Peter Emanuel of the U.S. Army's Edgewood Chemical and Biological Center described a detector as, "a piece of machinery that provides data and then feeds into a common operating picture."¹⁵ Currently, the U.S. Army and U.S. Department of Defense are developing the JUPITR (Joint USFK Portal Integrated Threat Recognition) Advanced Technology Demonstration, which will support the U.S. forces in Korea (USFK). The four key components of JUPITR are: data fusion, fielding environment sensors, early warning, and laboratory response.

The U.S. Department of Agriculture's National Animal Health Surveillance System gathers and analyzes animal health data from a network of partners to rapidly detect new or emerging threats. Biowatch is another federal program in the United States that was launched in 2003 to detect airborne pathogens. Maureen Sullivan of the Minnesota Department of Health Public Health Laboratories described Biowatch as a collaborative tool that stretches across disciplines. Steven Bucci, director of the Allison Center for Foreign Policy Studies at the Heritage Foundation stated that, although "Biowatch is not a perfect system, it's the best we have right now."

Interoperability & Collaboration

Respondents reported that the threat of a cyber attack is much greater than a biological attack (Table 1), but the consequences of a simultaneous attack could reach a whole new level. Most modern hospital and emergency response systems are electronic and some are dependent on seamless electronic communication. An acute event raises long-term questions about funding for flexibility and interoperability: security and resilience of medical records; better collaborative communication between emergency medical services, hospitals, fire, public officials, etc.; and more chemical, biological, radiological, and nuclear training for emergency room doctors and other medical and nonmedical responders and receivers.

First responders must be informed about what to do with suspicious powders and other potentially dangerous agents. Building relationships with and sending samples to public health laboratories as soon as possible will provide better diagnostics and improve mitigation efforts. Ongoing relationships with public health laboratories and other

jurisdictions and agencies also will help identify investments that may be unnecessarily duplicated.

The effectiveness of detection efforts suffers when jurisdictions do not share information and technologies to determine deliberate versus natural occurrences. It is critical to overcome interagency differences and properly prepare cities and their residents.

Detection: Finding the Perfect Tool

There is no perfect device, technology, or tool when preparing for a biological event. Rather than relying heavily on one single tool, jurisdictions must take a multifaceted approach. The quantity and placement of data sources also must be taken into consideration. Because technology may perform differently under different conditions, it is important to thoroughly test equipment and train users for various potential scenarios and locales.

Even without developing new technology, jurisdictions still can take a step toward better technology by simply closing the gap between what they currently possess and how they are using it. Implementing the detection methods that currently exist puts the nation at less risk than it faces while waiting for a perfect system. “If there is a threat and it’s the only tool, it still needs to be deployed and the real world will be the laboratory,” said Bucci.

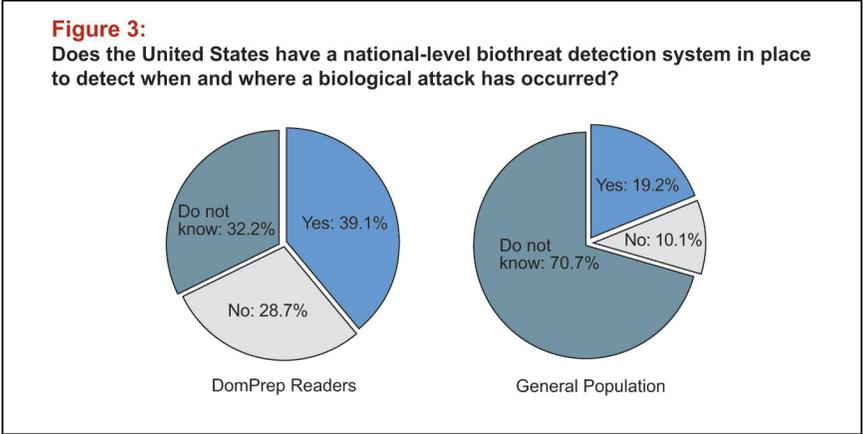
It is also important to consider that the needs of various stakeholders may not significantly differ from one another. A cohesive strategy for using and analyzing data, investing dollars, and reinforcing risk mitigation offers stakeholders a more sustainable, affordable, and interoperable system now. As Emanuel stated, “The reality is that the pieces are there, but they are not being put together well.”

Survey Results

Ideally, every jurisdiction would have the perfect tool in the right location to detect a biological incident before anyone gets injured or killed. Unfortunately, no perfect system exists – now or in the near future – but the current system could be made much better by evaluating and combining resources that are already in the toolbox.

Based on the discussions at the briefing, it is no surprise that more than 70 percent of the respondents from the general population do not know whether the United States has a national-level biothreat detection system in place to detect when and where a biological

attack has occurred. When systems exist but are not being deployed or are not being used efficiently, the end result suffers. If the U.S. Postal Service had waited for a perfect system, the recent ricin attacks would most certainly have had a different outcome. Even technology that is less than perfect is still better than no technology at all.



IV. COSTS

Determining the real cost of biosurveillance is difficult because the biothreat is an unquantifiable risk. Without a specific dollar amount, it can be a challenge to get the governmental backing required to move biosurveillance programs and technology forward. When the bombings at the Boston Marathon effectively shut down the city, it cost upwards of \$1 billion in lost revenue for a single day.¹⁶ Although significant, it pales in comparison to the estimated cost of \$1.5 trillion for a small anthrax attack at the same location.

Overwhelming a Major Metropolitan Area

Nathaniel Hupert, Associate Professor of Public Health and of Medicine as well as Associate Attending Physician at Weill Cornell Medical College, and his colleagues have contemplated what would happen if an anthrax attack were to occur in New York City. Because there has not been much research published about the health impact of such attacks in a modern urban setting, they have been using quantitative models to break down the costs:

- *The event itself* – the length of time to exhibit symptoms and report to a medical facility;
- *The preparedness cost* – the reasons for investing in biodefense, the risks, and the daily operating costs; and
- *The human cost* – the potential for loss of life and ongoing medical care for survivors.

Even with extremely rapid detection and mass prophylaxis distribution operations, Hupert and his colleagues have calculated that up to 15 percent of people exposed in a large-scale anthrax attack could become symptomatic – potentially resulting in a large hospital surge. To counteract such consequences, in addition to other preparedness efforts, hospitals must improve efficiencies and increase surge capacity. He stated that, “in the ambulatory operating rooms alone, if we just increase communication and integrate people’s activities in a better way, we could probably save about an hour a day per operating room of overtime or lost time. And that can translate to millions of dollars just for [a single] hospital and hundreds of millions of dollars across the country.”

The good news, he pointed out, is the fact that a biological attack is not like a conventional bomb being detonated. Patients will exhibit symptoms over time, which means that hospitals and caregivers will have a greater time span over which to treat and release those affected by an attack. Primary care doctors also can play a critical role during a large-scale event by treating patients who are in less critical conditions, thus reducing the risk of an overwhelming surge on hospital resources. This, of course, would raise concern by some doctors about their practices' liability and malpractice insurance. Addressing that concern should be addressed within the preplanning process.

Business Model & Supply Chain Management

The bottom line is that specific costs and benefits are impossible to conclusively determine for a biological incident. Cost-benefit analyses for such events often delay jurisdictions in launching preparedness initiatives and investing in biosecurity. A good business model is to purchase from the bottom up, rather than the top down, to ensure that the people using the tools are included in the acquisition process. When taking into consideration the total lifecycle cost of those tools, stakeholders also should engage new partners and find nontraditional funding because traditional federal funding is declining.

Public health laboratories set a good example for other sectors by funding operations proactively before an incident occurs, rather than reactively in response to an actual threat. A proactive approach for mitigating a biothreat would include routine surveillance plus good technologies (even ones that are less than perfect).

Supply chain management is also a major consideration. Although a three-day emergency supply is a common guideline to follow, many agencies and organizations have much less than that on hand. At many facilities, the three days of supplies are at various stages – some on hand, some currently being used, and some in transit or in storage at another location. Hupert understands that, “if you want a better supply chain, you have to pay for it,” but he also acknowledged that it is unlikely that most hospitals would willingly pay more without being convinced of its importance.

One example that demonstrates a potential impact on most if not all responders and receivers in North America is that much of the supply of gear, masks, and raw materials that are critical during a biological event are produced in China and elsewhere. If an epidemic were to occur

that lasts a few months, it would be very difficult to keep supplies on hand. In addition, if the epidemic affects other nations as well, the entire supply chain could shut down. The vulnerabilities within the whole system, therefore, are unknown.

In addition to protecting the supply chain, cost-effective/low-cost/no-cost solutions must be explored (e.g., pro-bono federal services and nonfederal funding). Working with other agencies and jurisdictions to combine resources and purchase products using economies of scale can potentially decrease spending by more than half. Communication and collaboration are the key.

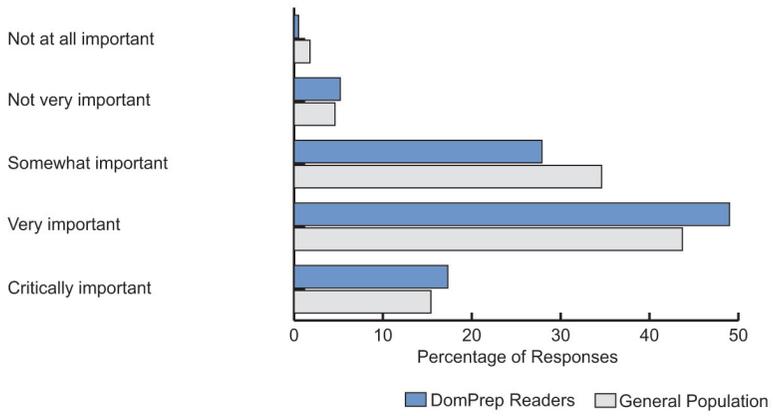
Survey Results

Determining the true overall cost of a biological incident involves considering the many separate costs related to the event – the costs incurred from patient zero to the ongoing long-term treatment of patients exhibiting real and perceived symptoms. If one hour per day equates to millions of dollars for a single operating room, the cost of a long-term pandemic or biological event could easily overwhelm the healthcare system.

Although the threat itself cannot be quantified, there is a general consensus from the majority of respondents from both the DomPrep readership and the general population that it is very important for the United States to invest in modernizing its biological threat surveillance and early warning system. Despite the high cost of investing in better technology and improving the detection process, the cost of responding to a biological attack would be much greater.

Figure 4:

How important is it for the United States to invest in modernizing its biological threat surveillance and early warning system?



V. PRIORITIES

Readiness of Responders & Receivers

One briefing participant, Erik Gaull of the Metropolitan Police Department in Washington, D.C., expressed a genuine concern about the healthcare system's willingness and ability to respond to a biological event. Nathaniel Hupert of Weill Cornell Medical College responded that he believes the dedicated workforce and the maturing understanding of risk associated with specific diseases would prevent most emergency responders and receivers from "fleeing from the battle." The key is to treat those people as critical infrastructure and make every effort to protect them. To do that, some modeling needs to be done and responders and receivers must be prepared to handle unlikely events.

When hospitals operate on no margin, it can be a challenge to find places to put patients. A large-scale biological incident has a time component, which could aid with surge capacity because cases will present over time rather than all at once. Things to consider are: regional efforts; mass transport of people; protecting civilians; balancing heroism and saving oneself; shift rotations to promote rest; and training for terrorist events.

Private Sector's Role

Interdependencies between the public and private sectors are another priority for any natural or manmade event. Jeffrey Runge, DomPrep40 Advisor and principal at The Chertoff Group LLC, pointed out the dependence on private sector resources, but the lack of planning and guidance provided by the public sector. Representatives from the Department of Defense, for example, typically do not attend private sector meetings and do not invite private organizations to attend their planning sessions. However, if an avian flu or other pandemic outbreak occurred, most people would rely on the Department of Defense as their backup plan.

Situational awareness is another way that the public sector can educate and work with private sector stakeholders. Elin Gursky, Analytic Services Inc.'s Senior Advisor for the Office of the Assistant Secretary for Preparedness and Response at the Department of Health and Human Services, pointed out how untrained civilians or undertrained responders in Boston rushed to the aid of bombing victims. In such instances, they placed themselves at greater risk

by following their natural inclinations. She suggested to the panel of military and civilian representatives that the private sector could learn much from military expertise. Major General Stephen Reeves, USA (Ret.), offered one relevant example that, in Iraq and Afghanistan, when the first bomb explodes, the next step is to wait to see if a second bomb goes off.

Leadership

There is little or no resistance from the public or private sectors to using every asset available to aid survivors in the aftermath of a major disaster. Before the event occurs, however, the allocation and investment of assets is not unified. Leadership must be able to break down the barriers by sharing information and assets. The survey results of the general public illustrate that many people do not understand the implications of biothreats and/or do not perceive that bioweapons pose a significant threat. As one participant pointed out, information about the ricin letters was not on the front page, but should have been.

Leadership's role should be to: identify the threat in an interactive, multifaceted environment; determine how to mitigate the threat; provide more data sources; find redundancies; and collaborate with public and private sector partners. It is certainly easier to respond to disasters when agencies know their partners, so it is important to keep both the public and private sectors involved in every step of the process.

KEY FINDINGS & ACTION PLAN

Since the early 1960s, biological weapons have proven to be easier and less expensive to create than their chemical counterparts. As recent events like the Boston bombings and the ricin letters have shown, the United States must constantly maintain its guard for a variety of potential threats. Although the damages from such events are often mitigated through investments in technology, resources, surveillance, training, and situational awareness, a lot of planning still must be done in the area of biodefense.

There has not been a major intentional biothreat on U.S. soil in recent history, which makes it more difficult for some agencies and organizations to understand the need to invest more. When outlining the risks, threats, and priorities, consider the following key points:

- The history of intentional biological attacks, as well as naturally occurring pandemics;
- The sociological, psychological, and financial impacts of an incident, including event, preparedness, and human costs;
- The ways in which a biological agent can be transferred;
- Advances in technology that make it easier to reproduce deadly agents;
- Legislation and key documents that address the biothreat;
- The public health laboratory's role in detecting and identifying emerging threats;
- Current resources and capabilities, and potential new combinations;
- Compounded threats to the supply chain and electronic data;
- The private sector's growing role in preparedness and response efforts; and
- Leadership responsibilities to protect the health, life, and safety of the nation's population.

The U.S. vulnerability to biothreats may not be catastrophic, but there is much room for improvement. Those improvements do not necessarily need to be in the form of new technologies but, more importantly, the current resources and technologies can be repurposed to provide new solutions. The nation needs to prepare and take every step possible to mitigate this real and potentially imminent threat.

NOTES

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- ² Centers for Disease Control and Prevention (CDC), 25 June 2012, *First Global Estimates of 2009 H1N1 Pandemic Mortality Released by CDC-Led Collaboration*. Retrieved from <http://www.cdc.gov/flu/spotlights/pandemic-global-estimates.htm>
- ³ CDC, 23 May 2013, *SARS 10 Years Later*. Retrieved from <http://wwwnc.cdc.gov/eid/pages/sars-10th-anniversary.htm>
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APPENDIX A

Examples of Biological Agents

Bacillus anthracis (anthrax)

<http://www.bt.cdc.gov/agent/anthrax/>

Brucella sp. (brucellosis)

<http://www.bt.cdc.gov/agent/brucellosis/>

Clostridium botulinum toxin (botulism)

<http://www.bt.cdc.gov/agent/botulism/>

Coxiella burnetii (Q fever)

<http://www.cdc.gov/qfever/>

Francisella tularensis (tularemia)

<http://www.bt.cdc.gov/agent/tularemia/>

Staphylococcal enterotoxin B

http://www.cdc.gov/ncidod/dbmd/diseaseinfo/staphylococcus_food_g.htm

Venezuelan equine encephalitis virus (VEE)

<http://www.cdc.gov/ncidod/dvbid/arbor/arbdet.htm>

APPENDIX B

Legislation

2012 (July) U.S. President's *National Strategy for Biosurveillance*, http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Biosurveillance_July_2012.pdf

2011 (October) U.S. Department of Health and Human Services' *BARDA Strategic Plan 2011-2016*, <http://www.phe.gov/about/barda/Documents/barda-strategic-plan.pdf>

2011 (June) U.S. President's *National Strategy for Combating Terrorism*, http://www.whitehouse.gov/sites/default/files/counterterrorism_strategy.pdf

2011 (May) U.S. National Science and Technology Council Committee on Homeland and National Security, Subcommittee on Standards' *A National Strategy for CBRNE Standards: National Science and Technology Council Committee on Homeland and National Security*, http://www.whitehouse.gov/sites/default/files/microsites/ostp/chns_cbrne_standards_final_24_aug_11.pdf

2011 (March) Presidential Policy Directive 8: National Preparedness, <http://www.fas.org/irp/offdocs/ppd/ppd-8.pdf>

2010 (February) U.S. Department of Health and Human Services' *National Biosurveillance Strategy for Human Health*, http://www.cdc.gov/osels/pdf/NBSHH_v2.pdf

2009 (December) *Executive Order 13527: Establishing Federal Capability for the Timely Provision of Medical Countermeasures Following a Biological Attack*, <http://www.whitehouse.gov/the-press-office/executive-order-medical-countermeasures-following-a-biological-attack>

2009 (December) U.S. Department of Health and Human Services' *National Health Security Strategy*, <http://www.phe.gov/Preparedness/planning/authority/nhss/strategy/Documents/nhss-final.pdf>

2009 (November) Presidential Policy Directive 2: Implementation of the National Strategy for Countering Biological Threats, <http://www.fas.org/irp/offdocs/ppd/ppd-2.pdf>

2009 (November) U.S. President's *National Strategy for Countering Biological Threats*, http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf

2009 (January) *Executive Order 13486: Strengthening Laboratory Biosecurity in the United States*, <http://www.gpo.gov/fdsys/pkg/FR-2009-01-14/pdf/E9-818.pdf>

2008 (September) U.S. Department of Defense's *Chemical Biological Defense Program Strategic Plan*, http://www.acq.osd.mil/cp/cbdreports/cbdp-strategic-plan_9-30-08.pdf

2007 (October) Homeland Security Presidential Directive 21: Public Health and Medical Preparedness, <http://www.fas.org/irp/offdocs/nspd/hspd-21.htm>

2007 (February) Homeland Security Presidential Directive 18: Medical Countermeasures against Weapons of Mass Destruction, <http://www.fas.org/irp/offdocs/nspd/hspd-18.html>

2006 (September) U.S. President's *National Strategy for Combating Terrorism*, <http://www.cbsnews.com/htdocs/pdf/NSCT0906.pdf>

2005 (March) U.S. Department of Defense's *National Defense Strategy of the United States of America*, <http://www.defense.gov/news/mar2005/d20050318nds1.pdf>

2004 (June) National Security Presidential Directive 33: Biodefense for the 21st Century, <http://www.fas.org/irp/offdocs/nspd/biodef.html>

2004 (April) Homeland Security Presidential Directive 10: Biodefense for the 21st Century, <http://www.fas.org/irp/offdocs/nspd/hspd-10.html>

2004 (January) Homeland Security Presidential Directive 9: Defense of United States Agriculture and Food, <http://www.fas.org/irp/offdocs/nspd/hspd-9.html>

2003 (February) U.S. Central Intelligence Agency's *National Strategy for Combating Terrorism*, https://www.cia.gov/news-information/cia-the-war-on-terrorism/Counter_Terrorism_Strategy.pdf

2003 (February) Homeland Security Presidential Directive 5: Management of Domestic Incidents, <http://www.fas.org/irp/offdocs/nspd/hspd-5.html>

2002 (December) Homeland Security Presidential Directive 4/National Security Presidential Directive 17: National Strategy to Combat Weapons of Mass Destruction, <http://www.fas.org/irp/offdocs/nspd/nspd-17.html>

1995 (June) Presidential Decision Directive-39, <http://www.fas.org/irp/offdocs/pdd/pdd-39.pdf>

APPENDIX C

Additional Resources

Biowatch, <http://www.dhs.gov/health-threats-resilience-division>

CDC online biosecurity course, http://www.cdc.gov/od/ohs/biosecurity_training/index.html

Center for Arms Control and Non-Proliferation, <http://www.armscontrolcenter.org/issues/biochem>

Federation of American Scientists' *Biosecurity and Biodefense Resource*, <http://www.fas.org/programs/ssp/bio/resource/index.html>

Federation of American Scientists' Case Studies in Dual Use Biological Research, <http://www.fas.org/biosecurity/education/dualuse/index.html>

Institute for Biosecurity at St. Louis University School of Public Health (Project EQUIPP), <http://biosecurity.slu.edu>

National Animal Health Surveillance System, <http://www.aphis.usda.gov/vs/nahss/nahss.htm>

National Select Agency Registry's *Guidance on the Applicability of the Select Agent Regulations to Issues of Synthetic Genomics*, <http://www.selectagents.gov/resources/Applicability%20of%20the%20Select%20Agents%20Regulations%20to%20Issues%20of%20Synthetic%20Genomics.pdf>

National Institutes of Health's online biosafety/biosecurity training module, <http://apbtn.com/apbtn/index.html>

Politics and The Life Sciences online biosecurity course, http://politicsandthelifesciences.org/Biosecurity_course.html

Southeast Regional Center of Excellence for Emerging Infection and Biodefense's (SERCEB) online course on Dual Use Dilemma, <http://www.serceb.org/dualuse.htm>

The Laboratory Response Network, <http://www.bt.cdc.gov/lrn/>

U.S. Department of Health and Human Services' *Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight*, <http://www.phe.gov/Preparedness/legal/boards/biosafetytaskforce/Pages/default.aspx>

University of Bradford, Bradford Disarmament Research Center, <http://www.brad.ac.uk/acad/sbtwc/>

University of Pittsburgh Medical Center – Center for Biosecurity, <http://www.upmchealthsecurity.org/>

APPENDIX D

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State Medical Assistance Team
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North Carolina State Medical Response
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And others who asked to not have their names and affiliations disclosed.

**Table 2:
In what sector are you employed?**

	DomPrep Readers	General Population
Fire Service	7.0%	0.2%
Law Enforcement	6.3%	1.1%
EMS	3.1%	0.4%
Emergency Management	10.4%	0.0%
Public Health	16.7%	3.5%
Hospital (including VA)	8.2%	5.2%
Federal Government	8.3%	1.4%
Military	3.3%	0.9%
State/Local Government	10.6%	5.1%
Non-Government Organizations	3.1%	2.8%
Privately Owned Company	7.5%	16.7%
Publicly Traded Company	3.3%	7.6%
Self-Employed	2.8%	9.7%
Not Employed	1.2%	13.7%
Academic Institution	5.4%	10.0%
Student	0.2%	6.2%
Other	2.6%	15.5%

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“No mission could be timelier. The simple reality is that the risks that confront us today are evolving faster than our multilayered responses. Many thousands of dedicated people across all agencies of our government are working hard to protect this country, and their efforts have had a positive impact. But the terrorists have been active, too – and in our judgment America’s margin of safety is shrinking, not growing.”

“World at Risk: The Report of the Commission on the Prevention of WMD Proliferation and Terrorism” (December 2008, <http://bit.ly/WorldAtRisk>)

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