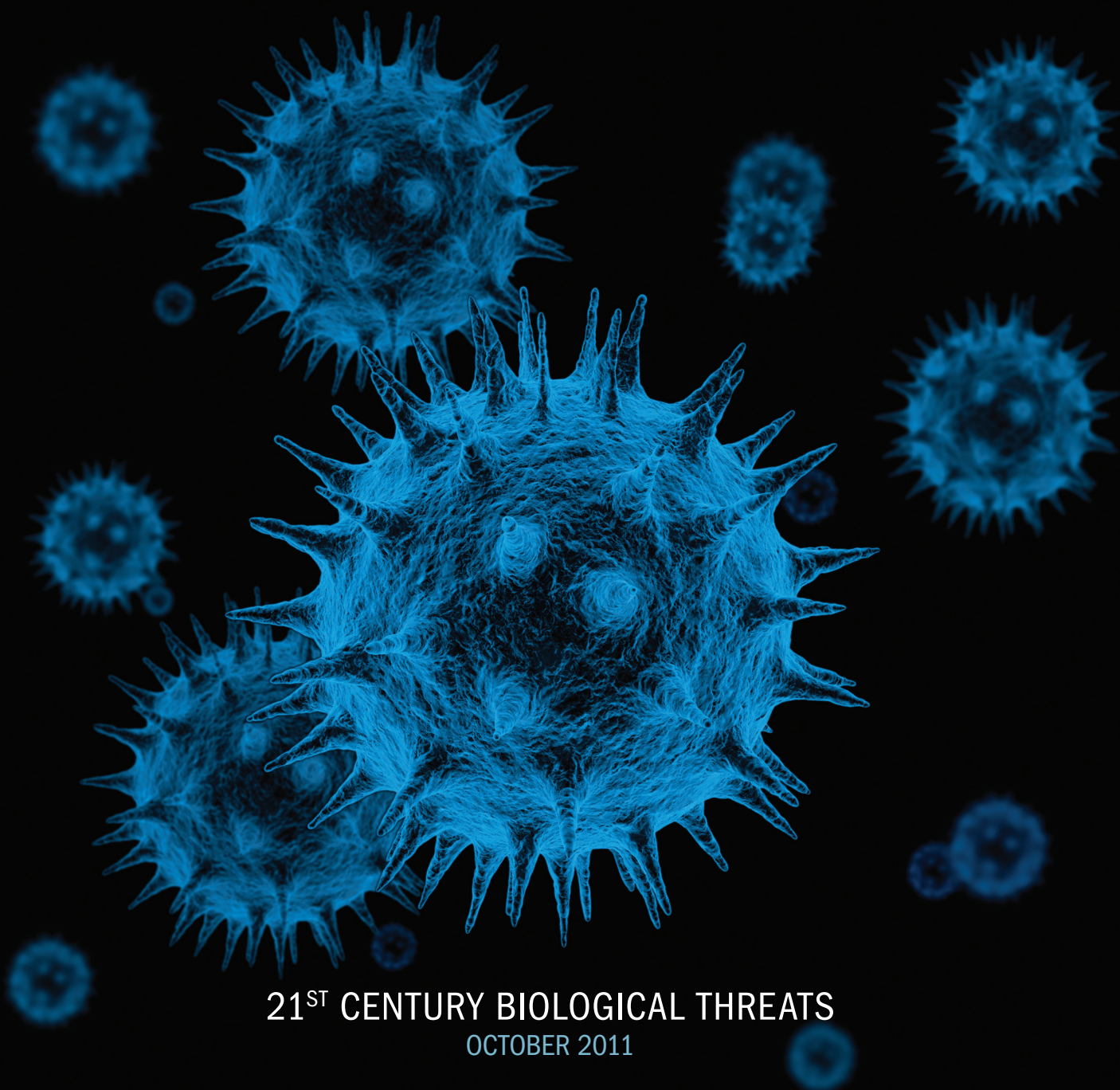


THE BIPARTISAN WMD TERRORISM RESEARCH CENTER'S

# BIO-RESPONSE REPORT CARD



21<sup>ST</sup> CENTURY BIOLOGICAL THREATS

OCTOBER 2011



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21ST CENTURY BIOLOGICAL THREATS  
**OCTOBER 2011**

Senator Bob Graham, Chairman  
Senator Jim Talent, Vice Chairman  
Randy Larsen, CEO  
Lynne Kidder, President

WMD|CENTER

1747 Pennsylvania Ave NW | Suite 700 | Washington, DC 20006 | [wmdcenter.org](http://wmdcenter.org)

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## ABOUT THE WMD CENTER

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The Bipartisan WMD Terrorism Research Center (the WMD Center) is a not-for-profit 501(c)(3) research and education organization dedicated to helping government and private sector leaders better understand the unique threats and challenges of bioterrorism. Founded in early 2010, at the conclusion of the Congressional Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, the WMD Center serves as an honest broker between government and the American public to strengthen individual, community, and national bio-preparedness and bio-response capabilities. ▸

### LEADERSHIP TEAM

#### **Chairman-Senator Bob Graham**

Senator Bob Graham is the former Chairman of the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism. He served two terms as Governor of Florida and three terms as a U.S. Senator, chairing the Senate Select Committee on Intelligence. Senator Graham was also the Co-chair of the Congressional Joint Inquiry into the Terrorist Attacks of September 11, 2001.

#### **Co-Chairman-Senator Jim Talent**

Senator Jim Talent was the Vice Chairman of the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism. He served four terms in the U.S. House of Representatives and one term as a U.S. Senator. He was a member of both the House and Senate Armed Services Committees. Previously, he was elected to four terms in the Missouri House of Representatives and in 1988, was unanimously selected by his colleagues as the Minority Leader.

#### **Chief Executive Officer-Randy Larsen**

Colonel Randy Larsen, USAF (Ret.) formerly served as executive director of the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism. Colonel Larsen also served as the chairman of the Department of Military Strategy and Operations at the National War College, as the National Security Advisor at the Center for Biosecurity—UPMC, and was the founding director of the ANSER Institute for Homeland Security.

#### **President-Lynne Kidder**

Lynne Kidder is the former senior vice president for public-private partnerships at Business Executives for National Security (BENS). She currently co-chairs the Institute of Medicine's Forum on Medical and Public Health Preparedness for Catastrophic Events and is a senior advisor to the Center for Excellence in Disaster Management & Humanitarian Assistance.

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## PREFACE

### A BIO-RESPONSE REPORT CARD

The idea for this report card project began late last year, when we asked ourselves the question, “If the nation is unprepared for a biological attack, what more can we do?” Since 2001, the United States government has spent more than \$65 billion on biodefense, and yet it has done so without an end-to-end, strategic assessment of the nation’s bio-response capabilities. This report seeks to fill that gap.

By design, this review provides a high-level analysis of a complex enterprise. Our hope is that this report will result in a better-prepared nation. We know America’s leaders want to address what everyone agrees is a task of the highest priority: ensuring the safety and security of our citizens.

Eleven of the nation’s leading biodefense experts have guided our project, and many more have informed this report. Its purpose is to provide America’s leadership both a strategic assessment and concrete advice, in a user-friendly form, so that policymakers better understand what can and should be done.

This report offers:

- An overview of current and emerging bioterrorism threats,
- Fundamental expectations and evaluations for each of seven bio-response categories,
- An overview of challenges that affect the entire bio-response enterprise, and
- Recommended priorities that will strengthen the nation’s bio-preparedness and response capabilities.

Our nation will always face the threat of biological disasters. The more robust our nation’s preparedness, however, the more we reduce the consequences and the likelihood of being attacked. Most important, strong biodefense capabilities will bring us closer to the day when biological threats, whether natural or man-made, are no longer potential weapons of mass destruction.



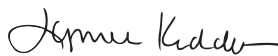
Bob Graham



Jim Talent



Randy Larsen



Lynne Kidder

## ACKNOWLEDGMENTS

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The WMD Center is indebted to the Skoll Global Threats Fund and the Smith Richardson Foundation for providing their vision and financial support to this project.

We also thank the Alfred P. Sloan Foundation for its early support of the WMD Center, as well as the leadership and staff of NTI, for their contributions and encouragement.

The tireless efforts and talents of Ms. Sara E. Rubin, MPH, the Assistant Director of Research at the WMD Center, and Dr. Dave McIntyre, Senior Fellow at the WMD Center, have made this report more thorough and readable. They have each offered invaluable support throughout this project.

And finally, the authors offer their deepest gratitude and respect to this project's Board of Advisors (Appendix I), and to the many biodefense, public health, medical, and national security professionals—both inside and outside of government—who generously shared their expertise and candor. ▽



## EXECUTIVE SUMMARY

### THE PURPOSE OF THIS REPORT CARD IS TO PROVIDE A STRATEGIC, END-TO-END ASSESSMENT OF AMERICA'S BIO-RESPONSE CAPABILITIES.

Although naturally occurring disease remains a serious threat, a thinking enemy armed with these same pathogens, or with multi-drug-resistant or synthetically engineered pathogens could produce catastrophic consequences.

These threats are not new. Naturally occurring diseases have devastated societies throughout history. Sophisticated biological weapons, however, did not become a threat until the early days of the Cold War, and a combination of the Biological Weapons Convention (BWC) and the threat of nuclear retaliation provided credible prevention and deterrence.

Unfortunately, the biotech revolution now affords non-state actors the capability to produce sophisticated biological weapons. Although traditional deterrence may not be effective against non-state actors, a strong bio-response capability may provide a deterrent effect. Therefore, the primary means of defending the American homeland against bioterrorism is the capability to effectively respond after an attack has occurred.

The purpose of this report card is to provide a strategic, end-to-end assessment of America's bio-response capabilities. It is intended to complement other recent reports that have offered detailed assessments of various components of bio-response, such as public health, medical countermeasures, and hospital prepared-

ness. Our strategic overview of national bio-response capabilities is designed to provide broad context to policymakers and government leaders for setting priorities.

Many of the nation's top biodefense, public health, and medical experts guided this project. A Board of Advisors (Appendix 1) informed project methodology, the seven categories of bio-response, the scale of potential bio-events, and the proposed metrics by which to assess capabilities in each category. A separate group of diverse subject-matter experts helped with subsequent research and early analysis. Other biodefense stakeholders—both inside and outside of government—provided numerous briefings and recommendations that also informed this report. The conclusions and content are the sole responsibility of its authors—the directors and officers of the WMD Center.

Findings are summarized in the chart on page 9. It includes letter grades in each bio-response category as assessed for each level of biological event. Trend lines project likely future progress, or lack thereof, assuming baseline funding.

The primary means of defending the **American homeland** against bioterrorism is the capability to effectively respond **after an attack has occurred.**

The nation does not yet have **adequate bio-response capability** to meet fundamental expectations during a **large-scale biological event**.

**The chart was produced as a quick reference guide. It should not, however, be interpreted by calculating a grade point average (GPA).**

No one in the fields of biodefense, public health, or medicine will be surprised by the report's finding that the United States is unprepared to respond to a global outbreak of a deadly virus for which we have no medical countermeasures. Likewise, by definition, a response to bioweapons that have been made resistant to our current medical countermeasures would fail to meet fundamental expectations. If Congress and the Administration focused primarily on addressing these most extreme, less common scenarios, it could easily expend most available biodefense resources, without a measurable return on investment.

The WMD Center recommends that future preparedness programs focus on the center two columns in the chart—large-scale events. It is possible to improve these grades in the relative near-term, and doing so would significantly improve readiness for small-scale events as well.

This report suggests that moving from Orange to Yellow (Ds to Cs) will provide the best return on investment. To do so, the nation should focus its efforts on three strategic priorities:

- Leadership that sets clear priorities and engenders commitment and unity of effort,
- Mobilizing “whole of nation” response planning, and
- Sustained investment in purpose-driven science.

Throughout the past year, the leadership of the WMD Center has met with many senior-level officials throughout government and the bio-response enterprise. They are incredibly hard working and dedicated and they represent the very best America has to offer in the fields of biodefense, public health, medicine, and the biological sciences. Although their efforts have yielded considerable progress over the past decade, the nation does not yet have adequate bio-response capability to meet fundamental expectations during a large-scale biological event.

The nation's leaders need to ensure that those responsible for defending America against bioterrorism are provided the resources, organizational framework, policies, and leadership to meet this growing national security challenge. ▽

## BIO-RESPONSE REPORT CARD

	TREND	SMALL-SCALE NON- CONTAGIOUS	SMALL-SCALE CONTAGIOUS	LARGE-SCALE NON- CONTAGIOUS	LARGE-SCALE CONTAGIOUS	LARGE-SCALE DRUG RESISTANT	GLOBAL CRISIS CONTAGIOUS	
DETECTION & DIAGNOSIS	↗	C	C	D	D	F	F	
ATTRIBUTION	→	D*	F	F	F	F	F	
COMMUNICATION	↗	B	B	C	C	C	C	
MEDICAL COUNTERMEASURE AVAILABILITY	↗	B	B	D	D**	F	F	
MEDICAL COUNTERMEASURE DEVELOPMENT & APPROVAL PROCESS	→	D						
MEDICAL COUNTERMEASURE DISPENSING	→	B	B	D	D	F	F	
MEDICAL MANAGEMENT	→	B	C	D	D	F	F	
ENVIRONMENTAL CLEANUP	→	B	NOT APPLICABLE	F	NOT APPLICABLE	F	NOT APPLICABLE	

\* D FOR ANTHRAX, FOR ALL OTHER PATHOGENS AND TOXINS F  
 \*\* B FOR SMALLPOX



ARROWS INDICATE CURRENT TRAJECTORY TOWARD MEETING  
 FUNDAMENTAL EXPECTATIONS (ASSUMES BASELINE FUNDING)

A	MEETS MOST EXPECTATIONS
B	MEETS MANY EXPECTATIONS
C	MEETS MINIMAL EXPECTATIONS
D	MEETS FEW EXPECTATIONS
F	FAILS TO MEET EXPECTATIONS

↗	IMPROVING TREND
→	STATUS QUO
↘	DECLINING TREND



## 21ST CENTURY BIOLOGICAL THREATS

**TODAY WE FACE THE VERY REAL POSSIBILITY THAT OUTBREAKS OF DISEASE, NATURALLY OCCURRING OR MAN-MADE, CAN CHANGE THE VERY NATURE OF AMERICA—OUR ECONOMY, OUR GOVERNMENT, AND OUR SOCIAL STRUCTURE.**

- Naturally occurring disease remains a serious biological threat; however, a thinking enemy armed with these same pathogens—or with multi-drug-resistant or synthetically engineered pathogens—could produce catastrophic consequences.
- A small team of individuals with graduate training in several key disciplines, using equipment readily available for purchase on the Internet could produce the type of bioweapons created by nation-states in the 1960s.
- Even more troubling, the rapid advances in biotechnology, such as synthetic biology, will allow non-state actors to produce increasingly powerful bioweapons in the future.
- Prevention alone will never be enough to secure America against these 21st century threats.

There is no question America is vulnerable to infectious and contagious diseases. The influenza pandemic of 1918–1919 killed more than 20 million people—more than 600,000 in the United States. That winter, more U.S. soldiers died from influenza than had died on World War I battlefields.<sup>1</sup>

According to Centers for Disease Control and Prevention (CDC), nearly 40,000 Americans die annually from seasonal flu. And most experts agree that the human race is long overdue for an influenza pandemic far more deadly than the H1N1 pandemic of 2009–2010. However, the threat from Mother Nature goes far beyond the flu.

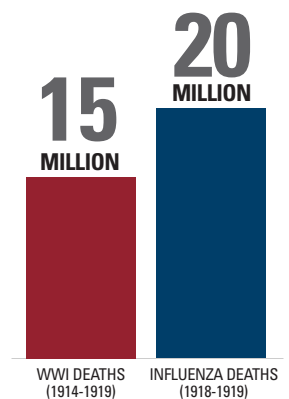
An average of 15–20 previously unknown diseases have been discovered in each of the past few decades—including incurable diseases like HIV/AIDS, Ebola, hepatitis C, Lyme disease, hantavirus pulmonary syndrome, and Severe Acute Respiratory

Syndrome (SARS). Studies indicate that new strains of influenza and other newly emerging diseases are likely to spread even more broadly and quickly due to the mobility of the world's population. Additionally, many of the diseases once managed with medical countermeasures are now re-emerging in strains resistant to drug therapies.<sup>2</sup> And modern technology threatens to speed the development of such novel diseases and enhance the threat they pose to the population at large.

The emergence of such a deadly pandemic, for which the nation was unprepared to respond, could change America forever.

Naturally occurring disease remains a serious biological threat; however, a thinking enemy armed with these same pathogens—or with multi-drug-resistant or synthetically engineered pathogens—could produce catastrophic consequences.

**INFLUENZA  
KILLED MORE  
PEOPLE IN TWO  
YEARS (1918-1919)  
THAN DIED IN ALL  
OF WWI.**



A better way to forecast the **threat of bioterrorism** is by careful examination of **three critical questions...**

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## A NATIONAL SECURITY PERSPECTIVE

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The relative threat of bioterrorism has been intensely debated within the national security community for more than a decade, with a focus on the biotech revolution and which capabilities fall within the reach of non-state actors.

In many respects, this debate is reminiscent of previous national security arguments. Shortly after World War I, two junior Army officers began writing articles in military journals about high-speed tanks and how they could revolutionize land warfare. Their ingenuity was severely chastised by the Commander of the Infantry in the War Department. He threatened the young officers with charges of insubordination if they continued to advocate high-speed tanks. The senior officer stated, “There is no reason for a tank to ever exceed three miles per hour, because that is the fastest an infantry unit can move on a battlefield.”<sup>3</sup>

Thankfully, Major George S. Patton and Captain Dwight D. Eisenhower were undeterred by the warnings from the War Department. They continued their research and advocacy because they were convinced we could not predict the future by looking to the past.

During World War I, the technology was not available to produce high-speed tanks, so few really considered the possibility of massive armored juggernauts moving at high speed out in front of the infantry. However, on September 1, 1939,

2,400 German tanks raced across the Polish border, far in advance of German infantry units. The armored columns were supported by another rapidly emerging technology—airpower—and a new concept of warfare was introduced: Blitzkrieg (lightening war).

Some national security technologies require decades to mature, such as tanks and airplanes; others require far less time. In June 1941, the U.S. Navy concluded that Pearl Harbor was too shallow for the effective use of air-dropped torpedoes. This was a correct assessment for June 1941. But in September 1941, the Japanese Navy discovered that simple wooden boxes attached to the rear of torpedoes would allow them to operate in shallow water. On December 7, 1941, 27 of these newly modified torpedoes struck U.S. warships in Pearl Harbor.

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## ASSESSING THE THREAT

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Today, some scholars would look to the past to predict the future of bioterrorism. They argue it has proven too difficult for terrorist groups to successfully develop and use sophisticated bioweapons—that the threat is overstated.

A better way to forecast the threat of bioterrorism is by careful examination of three critical questions:

- Can non-state actors produce and deliver biological weapons? (Capability)
- Is there a desire by terrorists to use biological weapons? (Intent)

- Would using biological weapons produce the intended effects? (Vulnerability and Consequences)

## CAPABILITY

When the Biological Weapons Convention (BWC) was ratified in 1972, the ability of nation-states to produce sophisticated bioweapons was unquestioned. These weapons were capable of killing on the scale of nuclear weapons, but compared to the cost of a nuclear weapons program, they were far less expensive—hence the term, “poor-man’s atom bomb.”<sup>4</sup>

There was little or no consideration of non-state actors producing such weapons in the 1970s. That changed, however, by the end of the century. Dr. George Poste, then chairman of the Defense Science Board, predicted, “In terms of national security, the 20th century will be remembered as the century of physics, but the 21st century will be remembered as the century of biology.”<sup>5</sup>

The first piece of hard evidence regarding the capability of non-state actors to produce sophisticated biological weapons came in 1999 from a Defense Threat Reduction Agency study called Biotechnology Activity Characterization by Unconventional Signature (BACUS).<sup>6</sup> The initial purpose of the study was to determine if a small-scale bioweapons production facility would produce an observable “intelligence signature.”

The answer was no. The study concluded that even when using “national technical means,” it would be extremely difficult, if not impossible, for the intelligence community to detect a clandestine production

facility. This conclusion was somewhat expected. The surprise, however, came from an experiment conducted as part of the study. Individuals, with no background in the development and production of bioweapons and no access to the classified information from the former U.S. bioweapons program, were able to produce a significant quantity of high-quality weaponized *Bacillus globigii*—a close cousin to the well-known threat, Anthrax.

In spring 2001, the Defense Science Board (DSB) released a report, co-authored by Nobel Laureate Dr. Joshua Lederberg and the former chair of the chemistry department at Harvard Dr. George Whitesides, entitled Biological Defense. The report stated:

...major impediments to the development of biological weapons—strain availability, weaponization technology, and delivery technology—have been largely eliminated in the last decade by the rapid global spread of biotechnology.<sup>7</sup>

Unbeknownst to the authors of the DSB report, al Qaeda had already begun its bioweapons programs in Afghanistan and Malaysia in late 1999 under the supervision of Ayman Zawahiri.<sup>8</sup> (Zawahiri is now the leader of al Qaeda.)

Although many initially assumed the anthrax letters of October 2001 came from al Qaeda, the Federal Bureau of Investigation (FBI) is now convinced the anthrax letters came from a U.S. Army civilian employee at Ft. Detrick, Maryland.

This conclusion remains controversial. If the FBI is correct, however, then a single individual with no work experience in the

“In terms of national security, the 20th century will be remembered as **the century of physics**, but the 21st century will be remembered as **the century of biology**.”

-Dr. George Poste

Most **pathogens** likely to be used as weapons **exist widely in nature.**

weaponization of pathogens (a vaccine specialist), using equipment that could readily be purchased over the Internet, was able to produce very high-quality, dry-powdered anthrax.

Fortunately, the casualties were limited (22 infected and five died) because the small quantity of material was delivered with warning notes inside the envelopes. But according to Dr. Peggy Hamburg, the current FDA Administrator, an attack releasing the same quantity of dry-powdered anthrax into the ventilation system of the World Trade Center in late August 2001, could have killed far more people than the airplane attacks did on 9/11.<sup>9</sup>

The FBI theory of the attacks is that a single individual, working alone late at night, produced enough dry-powder anthrax to mount the attacks through the mail. A small team could have used the same approach to create enough product to attack a city.

Despite advances in biotechnology, some skeptics continue to ask where terrorists could obtain such pathogens. Unfortunately, most pathogens likely to be used as weapons exist widely in nature.<sup>10</sup> Anyone seeking to develop these pathogens as weapons would not have to look far for sources.

Clearly then, small, disaffected, but technically competent groups could develop credible biotreats to the United States. The next question is whether they could deliver it.

There are three primary means of delivering a bioweapon:

- Putting it in food or water,
- Using vectors (such as fleas, ticks, or infected humans), or
- Pumping it into the air (aerosolization).

All of these approaches are possible, but the most effective method is aerosol release.

The aerosolization of pathogens was perfected during the Cold War by U.S. and Soviet military scientists. Releasing pathogens in 3–5 micron size allows them to enter the lungs and flow immediately into the blood stream. In the 1960s, achieving this effect required sophisticated technology available only to major nation-states. Today, pulmonary drug delivery is used worldwide by the medical and pharmaceutical industries.

In summary, modern biotechnology provides small groups the capabilities for a game-changing bio-attack previously reserved to nation-states. Even more troubling, rapid advances in biotechnology, such as synthetic biology, will allow small teams of individuals to produce increasingly powerful bioweapons in the future.



## INTENT

Critics who question whether terrorists intend to develop and use bioweapons should consider the following:

- The Aum Shinrikyo cult in Japan attempted to produce both anthrax and botulinum toxin weapons. In 1995 they released large quantities of non-pathogenic *Bacillus anthracis* in Tokyo.
- A January 2010 Belfer Center Study on Terrorism and WMD by Rolf Mowat-Larssen observed:<sup>11</sup>

*Another 9/11-scale operational plot managed by the al Qaeda core leadership was the development of anthrax for use in a mass casualty attack in the United States. The sophisticated anthrax project was run personally by al Qaeda deputy chief Ayman Zawahiri, in parallel to the group's efforts to acquire a nuclear capability; anthrax was probably meant to serve as another means to achieve the same effect as using a nuclear bomb, given doubts that a nuclear option could be successfully procured. Notably, al Qaeda's efforts to acquire nuclear and biological weapons capability were concentrated in the years preceding September 11, 2001. Based on the timing and nature of their WMD-related activity in the 1990's, al Qaeda presumably anticipated using these means of mass destruction against targets in the U.S. homeland in the intensified campaign they knew would follow the 9/11 attack. There is*

*no indication that the fundamental objectives that lie behind their WMD intent have changed over time.*

- A video played worldwide on al Jazeera TV in February 2009 featured a Kuwaiti professor talking about bringing four pounds of dry-powdered anthrax to Washington, D.C., and killing several hundred thousand Americans.<sup>12</sup> It has been viewed more than 100,000 times on various web sites.
- The web site of Anders Behring Breivik, the perpetrator of the 2011 terrorist attacks in Norway, talked of using anthrax weapons. There is serious doubt that he had the technical capability to produce any type of bioweapon, but little question he would have used one if available. Clearly, one should not assume that international terrorists are the sole threat for bioterrorism. Had Ted Kaczynski (the Unibomber) been a microbiologist rather than a mathematician, he might have selected a far more deadly form of weapon.<sup>13</sup>

Had the Unibomber been a **microbiologist** rather than a mathematician, he might have selected a far more **deadly form of weapon.**

Deterrence is largely **ineffective** against non-state actors because they are **hard to find** and hold accountable.”

## VULNERABILITY & CONSEQUENCES

Despite major improvements in public health and medical science, the human race remains vulnerable to infectious diseases. A global economy and highly mobile population make the likelihood and consequences of a disease outbreak even greater. In 2003, a single individual infected with the SARS virus spread the disease to 24 people—who in three days, had traveled to six countries on four continents.<sup>14</sup>

With respect to man-made threats, this vulnerability is also clear. The offensive bioweapons programs of the United States and the former Soviet Union demonstrated, without question, the potential lethality of sophisticated bioweapons.

But 40 years of advancement in biotechnology may now enable development of bioweapons by small nation-states and non-state actors. This growing threat creates significant new vulnerabilities for our nation and the world, as described by President Obama in a foreword to the National Security Council’s Strategy for Countering Biological Threats.

“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 one trillion dollars for each such incident. In addition, there could be significant societal and political consequences that would derive from the incident’s direct impact on our way of life and the public’s trust in government.”<sup>15</sup>

Consider, for example, smallpox, a disease that killed more than 300 million people in the 20th century. Although it was eradicated in its natural form 30 years ago, concerns remain that someone might still hold stores that could have a devastating effect on unvaccinated populations today. Even worse, the causative agent, variola virus, can be synthetically produced in high-tech laboratories. Should the government prove unprepared for either a natural outbreak or an attack, the consequences might shake the very foundations of America.

As technology spreads, the growing challenge of attribution may also make us even more vulnerable than in the past.

Until now, the combination of the Biological Weapons Convention and traditional deterrence has prevented nation-state use of bioweapons. But, deterrence is largely ineffective against non-state actors because they are hard to find and hold accountable. Should rogue nation-states provide sophisticated bioweapons to non-state actors, while remaining “a silent partner” to bioterrorism, the problem would be compounded.

The threat of biological disaster is real and growing. There are people in this world with the capability and the intent to use biological weapons. Americans are vulnerable to such an attack, as we are to a naturally occurring disease pandemic. The consequences of either could harm the fabric of the nation itself. ▽

## Notes

- <sup>1</sup> John Barry, *The Great Influenza: The Epic Story of the Deadliest Plague in History* (Viking Adult, September 2004).
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- <sup>3</sup> Dwight D. Eisenhower, *At Ease: Stories I Tell My Friends* (Eastern Acorn Press, 1981).
- <sup>4</sup> Committees of the North Atlantic Assembly, *Chemical and Biological Weapons: The Poor Man's Bomb*, (United Kingdom: North Atlantic Assembly, 1996), p.1 <http://www.fas.org/irp/threat/an253stc.htm>.
- <sup>5</sup> George Poste, "The Impact of Life Sciences on National Security" (speech presented at Preserving National Security: The Growing Role of the Life Sciences, Center for Biosecurity meeting, Washington, D. C., March 3, 2011).
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- <sup>8</sup> Rolf-Mowatt Larrsen, *Al Qaeda Weapons of Mass Destruction Threat: Hype or Reality?* (Cambridge, MA: Harvard Kennedy School, Belfer Center for Science and International Affairs, 2010) <http://belfercenter.ksg.harvard.edu/files/al-qaeda-wmd-threat.pdf>.
- <sup>9</sup> Peggy Hamburg (presentation at NORTHCOM Homeland Security Conference, Colorado Springs, CO, October 25, 2005).
- <sup>10</sup> Kunal J. Rambhia, Abigail S. Ribner, and Gigi Kwik Gronvall, *Everywhere You Look, Select Agent Pathogens*, [www.upmc-biosecurity.org/website/resources/publications/2011/2011-03-03-select\\_agent\\_pathogens.html](http://www.upmc-biosecurity.org/website/resources/publications/2011/2011-03-03-select_agent_pathogens.html).
- <sup>11</sup> Rolf-Mowatt Larrsen, *Al Qaeda Weapons of Mass Destruction Threat: Hype or Reality?*
- <sup>12</sup> Kuwaiti Professor Anthrax, YouTube video 9:05, Kuwaiti Professor Abdallah Nafisi Dreams about a Biological Attack at the White House and Prays for the Bombing of a Nuclear Plant on Lake Michigan, uploaded by "opposed1" on February 18, 2009, <http://www.youtube.com/watch?v=M3z2M-2B2mz8>.
- <sup>13</sup> Former National Security Advisor Anthony Lake's book, *Six Nightmares: Real Threats in a Dangerous World and How America Can Meet Them* (New York: Little, Brown & Company, 2000), devoted a chapter to domestic bioterrorism.
- <sup>14</sup> World Health Organization. *SARS: How a Global Epidemic Was Stopped*. Geneva, Switzerland: World Health Organization, 2006.
- <sup>15</sup> 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](http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf).



# BIO-RESPONSE REPORT CARD

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## METHODOLOGY

**More than two dozen** of the nation's top biodefense, public health, and medical experts guided this project.

The WMD Center's Bio-Response Report Card project was designed to provide an objective, strategic assessment of the nation's preparedness to respond to a biological attack. The report includes an update on 21st century biological threats, provides metrics and an evaluation of current capabilities in seven categories of bio-response, highlights cross-cutting issues, and identifies priorities that will strengthen the nation's collective response capabilities.

More than two dozen of the nation's top biodefense, public health, and medical experts guided this project. Its Board of Advisors (see Appendix 1) informed project methodology, the categories of bio-response, and then proposed metrics by which to assess capabilities in each category.

The WMD Center enlisted a separate group of diverse subject-matter experts to perform much of the research and analysis required to answer these questions. Additionally, numerous other biodefense stakeholders—both inside and outside of government—provided the WMD Center briefings, contributions, and recommendations for the report card.

Definitions were developed for each of the seven categories.

Our research found a general lack of standards for various capabilities within the seven categories—i.e., How much is enough? How quickly do we need it? How clean is safe? Therefore, we identified fundamental expectations in each category—requirements to ensure effective response to a biological event.

The metrics developed by the Board of Advisors are presented in the form of questions. We believe these questions (and answers) will remain useful in the months and years ahead, as a means to gauge improvement in each of the categories and across the bio-response enterprise.

The WMD Center created a scale of biological events and used it to evaluate U.S. response capabilities in each category.

Upon review, project staff identified several crosscutting issues that affected multiple categories and the enterprise as a whole.

Finally, having examined more than 130 recommendations from reports spanning the past five years, the WMD Center elected to offer its recommendations in the form of strategic priorities for action.

The conclusions and content of the report are the sole responsibility of its authors—the directors and officers of the WMD Center. ▽

# SCALE OF BIOLOGICAL EVENTS

Although there is an unlimited number of potential biological scenarios (man-made and naturally occurring), this model is useful in identifying the range of challenges we may face. The Small-Scale Non-Contagious category would be similar to what was experienced during the anthrax letters of 2001—a man-made event that caused considerable social, psychological, and economic disruption, but limited cases of illness and death. A Global Crisis scenario was realistically depicted in the 2011 movie, Contagion. In between these extremes are scenarios that could occur naturally or by deliberate or accidental release. ▸

“Essentially, **all models** are wrong, but some are **useful.**”

-George E. P. Box

LEVEL	BIOLOGICAL EVENT
<b>SMALL-SCALE NON-CONTAGIOUS</b>	<ul style="list-style-type: none"> <li>LIMITED EXPOSURE TO PATHOGEN</li> <li>NO ADDITIONAL EXPOSURES</li> <li>SMALL NUMBERS OF ILLNESSES AND/OR DEATHS</li> <li>POTENTIAL FOR MEASURABLE PSYCHOLOGICAL AND SOCIO-ECONOMIC IMPACT</li> </ul>
<b>SMALL-SCALE CONTAGIOUS</b>	<ul style="list-style-type: none"> <li>LIMITED INITIAL EXPOSURE TO PATHOGEN</li> <li>SMALL NUMBERS OF ILLNESSES AND/OR DEATHS</li> <li>PERSON-TO-PERSON TRANSMISSION WITH CONTAGION POTENTIAL</li> <li>POTENTIAL FOR MEASURABLE PSYCHOLOGICAL AND SOCIO-ECONOMIC IMPACT</li> </ul>
<b>LARGE-SCALE NON-CONTAGIOUS</b>	<ul style="list-style-type: none"> <li>EXPOSURE IN ONE OR MORE CITIES</li> <li>ADDITIONAL EXPOSURES POSSIBLE OVER TIME</li> <li>EPIDEMIC NUMBERS OF ILLNESSES AND/OR DEATHS</li> <li>SIGNIFICANT PSYCHOLOGICAL AND SOCIO-ECONOMIC IMPACT: CIVIL UNREST</li> </ul>
<b>LARGE-SCALE CONTAGIOUS</b>	<ul style="list-style-type: none"> <li>EXPOSURE IN ONE OR MORE CITIES</li> <li>ADDITIONAL EXPOSURES OVER TIME</li> <li>EPIDEMIC NUMBERS OF ILLNESSES AND/OR DEATHS WITH CONTAGION POTENTIAL</li> <li>SIGNIFICANT PSYCHOLOGICAL AND SOCIO-ECONOMIC IMPACT: CIVIL UNREST</li> </ul>
<b>LARGE-SCALE DRUG RESISTANT</b>	<ul style="list-style-type: none"> <li>EXPOSURE IN ONE OR MORE CITIES</li> <li>ADDITIONAL EXPOSURES OVER TIME</li> <li>POTENTIALLY UNCONTROLLABLE NUMBER OF ILLNESSES AND/OR DEATHS</li> <li>MEDICAL COUNTERMEASURES UNAVAILABLE OR INEFFECTIVE</li> <li>CIVIL AND POLITICAL UNREST IN THE AFFECTED REGION; GLOBAL ECONOMIC IMPACT</li> </ul>
<b>GLOBAL CRISIS CONTAGIOUS</b>	<ul style="list-style-type: none"> <li>NUMEROUS EXPOSURES IN MULTIPLE LOCATIONS OF HIGHLY CONTAGIOUS, NOVEL PATHOGEN(S)</li> <li>MEDICAL COUNTERMEASURES UNAVAILABLE</li> <li>GLOBAL OUTBREAK WITH POTENTIAL FOR MILLIONS OF ILLNESSES AND/OR DEATHS</li> <li>BREAKDOWN OF POLITICAL INSTITUTIONS; GLOBAL ECONOMIC DISRUPTION</li> </ul>





# DETECTION & DIAGNOSIS

## DEFINITION

Detection is the recognition of a biological event. Diagnosis is the identification of a specific biological agent in humans, animals and other wildlife, or the environment.



## FUNDAMENTAL EXPECTATIONS

- Capability to rapidly detect and diagnose a potentially catastrophic health event, in order to provide accurate and timely information to decision makers and the public
- A fully functional and integrated national biosurveillance system
- Ability to continuously monitor and assess both population-related and environmental indicators of a biological event
- Nationwide laboratory capacity to rapidly identify, provide timely diagnoses, and share continually updated information

## EVALUATION

SMALL-SCALE NON-CONTAGIOUS	SMALL-SCALE CONTAGIOUS	LARGE-SCALE NON-CONTAGIOUS	LARGE-SCALE CONTAGIOUS	LARGE-SCALE DRUG RESISTANT	GLOBAL CRISIS CONTAGIOUS
<b>C</b>	<b>C</b>	<b>D</b>	<b>D</b>	<b>F</b>	<b>F</b>
MEETS MINIMAL EXPECTATIONS	MEETS MINIMAL EXPECTATIONS	MEETS FEW EXPECTATIONS	MEETS FEW EXPECTATIONS	FAILS TO MEET EXPECTATIONS	FAILS TO MEET EXPECTATIONS

## SUMMARY OF ASSESSMENT

The United States does not yet have a nation-wide multisource disease surveillance system, as mandated by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (BioSense). Notable improvements in disease surveillance at the state/local level are now threatened by funding shortfalls. The United States has made progress in strengthening detection and diagnostic capabilities since 2001, including environmental and population-based biosurveillance and advances in promising technologies. The larger the event, however, the higher the demand for detection and diagnosis. Large-scale events would overwhelm existing capabilities.

There are not yet FDA-approved diagnostic tools for most Class A select agents.

## DETECTION & DIAGNOSIS METRICS

### Question 1:

*Is an effective multisource disease surveillance system in place, as mandated by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002?*

### Answer:

Not yet. Since 2001, the United States has made progress in strengthening its biosurveillance capabilities, with significant gains at the state/local level. There are, however, two factors that cause concern:

1. Current biosurveillance approaches do not adequately involve or integrate data from entities outside of public health (i.e., clinical sector, private sector, animal, food, water, etc.), slowing governments' ability to detect and respond to large-scale, multisector outbreaks, such as food-borne illness.<sup>1</sup>
2. Declining federal support for preparedness activities is translating to shuttering of programs and staff layoffs at state/local health departments and threatens to erode progress made in bolstering surveillance.<sup>2</sup>

### Question 2:

*Are there surveillance systems capable of providing adequate early detection and rapid assessment of highly dangerous diseases, including potential bioterrorism-related illnesses, related Class A select agents, and zoonotic disease?*

### Answer:

Unclear, but probably not. Although there have been seasonal tests of the biosurveillance systems' abilities to detect and monitor influenza outbreaks, it remains unclear the extent to which this can be generalized to outbreaks of other diseases, especially rare or novel diseases. Although laboratory and diagnostic data are considered the most valued and actionable biosurveillance data, there are not yet FDA-approved diagnostic tools for most Class A select agents.

### Question 3:

*Does the Department of Homeland Security (DHS) have a fully functional and effective National Biosurveillance Integration System and Center (NBIS and NBIC) to integrate streams of surveillance information from different agencies, as mandated by legislation and Presidential directive?*

### Answer:

No, but there are promising signs. To date, efforts to develop NBIC have been hindered by lack of a strategic plan to clearly define the role, function, and governance of NBIC, and by a resistance of federal agencies to share information with DHS.<sup>3</sup>

New leadership at NBIS has fostered a more open and responsive relationship with other agencies. This is a very encouraging development. If given more time and stable funding, DHS could potentially build an operational and useful NBIS/NBIC.

**Question 4:**

*Do front-line clinicians have the linkages and decision support tools to help them identify, report, and swiftly contain index cases of illness that may indicate the first signs of a bioterror attack?*

**Answer:**

Not yet. Robust, digital connections between clinical sector and public health are critical for detecting and managing the consequences of a biological attack, but those connections are seriously lacking. Current efforts to expand the use of electronic health records (EHRs) and to define what constitutes meaningful use of EHRs represent an important step in improving information exchange between clinical and public health.

Current guidelines (Meaningful Use Criteria) for the use of EHRs do not adequately address the nation's biosurveillance needs, because they will not enable public health departments to have robust and flexible access to EHRs. For EHRs to be most useful for biosurveillance, public health must be able to query records during outbreaks and there must be improved two-way communication between public health departments and clinicians.<sup>4</sup>

**Question 5:**

*Are there readily available diagnostic tools that can be used by clinicians to rapidly diagnose or rule out diseases like anthrax?*

**Answer:**

No. These capabilities are critically important, but have not been developed and/or approved by the Food & Drug Administration (FDA). Following a confirmed biological release, it will be important to rapidly assess patients to determine who may be infected or sick and to separate them from the well, so as to limit transmission (in case of a contagious pathogen). Diagnosis of Class A agents in humans, however, still requires in-depth assessment using laboratory tests or other clinical means (such as x-rays)—both of which are time-consuming approaches.

Although there has been an effort to grant emergency use authorization (EUA) to laboratory tests for diseases like anthrax, EUAs pose some operational challenges. Namely, an EUA does not permit a device to be pre-deployed prior to an emergency, which prevents laboratories from training staff on their use and performing validation tests to ensure their accuracy.

**Question 6:**

*Is there an integrated plan and sufficient support to manage the national Laboratory Response Network (LRN)?*

**Answer:**

No. The LRN is being hit especially hard by federal funding cuts and the economic downturn, and there is neither an integrated management plan for the LRN, nor sufficient funds to support it. States have been forced to furlough employees, cut training programs, and leave positions vacant due to hiring freezes. Labs also report a reduced ability to test and hone response capacity through exercises, due to reduced funding.<sup>5</sup>

Diagnosis of **Class A agents**...still requires in-depth assessment using **laboratory tests or other clinical means**—both of which are time consuming.

In any **bioterrorism scenario** involving an aerosol release, **rapid detection will be key** to a successful response.

**Question 7:**

*Does the BioWatch program provide capabilities that justify the long-term financial investment required?*

**Answer:**

Unclear at this time. In any bioterrorism scenario involving an aerosol release, rapid detection will be key to a successful response. BioWatch is a system that was rapidly deployed in 2003 in response to a specific threat. BioWatch Generations I & II have suffered from early growing pains and system limitations. However, if Generation III works as advertised, it would reduce detection time from 12–36 hours (Generation I & II) to 4–6 hours and provide indoor detection capabilities. Initial testing was completed in Chicago in 2011. Further testing is scheduled for 2012 in four other cities. DHS has indicated it will delay full deployment until operational testing validates capability.<sup>6</sup>

**Question 8:**

*Are there accurate on-site rapid biologic test kits for event screening in the field by first responders, local law enforcement, and public health personnel?*

**Answer:**

No. Current approaches to detecting biological agents still rely on lab-based methods, which are resource intensive and slow. Although there have been a profusion of hand held detectors developed since 2001, an early review of these devices prompted the Office of Science and Technology Policy (OSTP) to discourage their use in the field by first responders.<sup>7</sup>

There is some evidence of progress. The Environmental Protection Agency (EPA) recently announced the development of a faster (although still lab-based) anthrax detection method. Also, OSTP is currently evaluating ways to improve the availability and quality of environmental detectors, including those to be used by first responders.<sup>8</sup>

**Question 9:**

*Are first responders, local public health, and medical personnel coordinated in a manner that improves the timely, accurate identification of a bioterrorist event?*

**Answer:**

This occurs better in some places than in others, because it largely depends on local and state efforts. Since 2001, there have been significant efforts to encourage coordination among public health, healthcare, emergency management, law enforcement, and other relevant personnel at the local, regional, and federal levels.<sup>9</sup>

In some cities, there has been significant progress. In 30 U.S. cities, interdisciplinary BioWatch Action Committees meet and jointly confer when BioWatch Actionable Results (BARs) are detected. This process has been credited with strengthening coordination/communication among different disciplines. In other places, regional coalitions of medical providers, public health, emergency management, and other public and private sector stakeholders have organized for the purposes of improving regional disaster preparedness and response.

**Question 10:**

*Does the United States have sufficient partnerships and access to global health surveillance information necessary to rapidly detect and characterize threats occurring abroad that have the potential to affect U.S. interests?*

**Answer:**

Sometimes. Although the United States has made progress in working with other countries to strengthen global health surveillance, the availability of critical health information during global outbreaks has been mixed. Recently, delays in detecting the source of the E. coli outbreaks in Germany and France led to thousands of cases and severe economic disruption. The cause of the outbreak now appears to have been seeds imported from Egypt, underscoring the need for better data sharing and monitoring globally.

Although global health surveillance has been bolstered by the 2005 revisions to the International Health Regulations (IHRs), which now permit the World Health Organization (WHO) to question data pertaining to outbreaks, several shortcomings remain. For example, the WHO does not publicly question a country's assessment of an outbreak unless there is compelling public evidence that a country is not being forthright. This means that suspicious outbreaks may be delayed until hard evidence becomes available.<sup>10</sup>

In 30 US cities,  
interdisciplinary  
BioWatch Action  
Committees meet  
and jointly confer  
when **BioWatch  
Actionable  
Results (BARs)**  
are detected.

**Notes**

- <sup>1</sup> U.S. Government Accountability Office, Biosurveillance: Developing a Collaboration Strategy Is Essential to Fostering Interagency Data and Resource Sharing, (December 18, 2009), <http://www.gao.gov/products/GAO-10-171>.
- <sup>2</sup> U.S. Government Accountability Office, Biosurveillance: Efforts to Develop a National Biosurveillance Capability Need a National Strategy and a Designated Leader, (June 2010), <http://www.gao.gov/new.items/d10645.pdf>.
- <sup>3</sup> U.S. Government Accountability Office, Biosurveillance: Developing a Collaboration Strategy Is Essential to Fostering Interagency Data and Resource Sharing, (December 18, 2009), <http://www.gao.gov/products/GAO-10-171>.
- <sup>4</sup> Eric Toner, et al. "Biosurveillance Where it Happens: State and Local Capabilities and Needs," Biosecurity and Bioterrorism, (September 9, 2011)
- <sup>5</sup> Association of Public Health Laboratories, Response by the Numbers: the Nation's Public Health Laboratories Protect the Country: 2011 APHL All-Hazards Laboratory Preparedness Report, (June 2011), [http://www.aphl.org/aphlprograms/phpr/ahr/Documents/PHPR\\_2011\\_AllHazardsReport.pdf](http://www.aphl.org/aphlprograms/phpr/ahr/Documents/PHPR_2011_AllHazardsReport.pdf).
- <sup>6</sup> Interview with Department of Homeland Security Senior Official, August 25, 2011.
- <sup>7</sup> U.S. Government Accountability Office, Homeland Security: First Responders' Ability to Detect and Model Hazardous Releases in Urban Areas Is Significantly Limited, (June 2008), <http://www.gao.gov/new.items/d08180.pdf>.
- <sup>8</sup> U.S. Environmental Protection Agency, Development and Verification of Rapid Viability Polymerase Chain Reaction (RV-PCR) Protocols for Bacillus Anthracis—For Application to Air Filters, Water and Surface Samples, (January 2011), [http://oaspub.epa.gov/eims/eimscomm.getfile?p\\_download\\_id=500924](http://oaspub.epa.gov/eims/eimscomm.getfile?p_download_id=500924).
- <sup>9</sup> Congressional Research Service, Public Health and Medical Emergency Management: Issues in the 112th Congress, (February 2011), <http://www.fas.org/sgp/crs/misc/R41646.pdf>.
- <sup>10</sup> Center for Biosecurity of UPMC, International Disease Surveillance: United States Government Goals and Paths Forward, (June 2010), <http://www.dtic.mil/cgi-bin/GetTRDoc?AD=ADA528990&Location=U2&doc=GetTRDoc.pdf>.



# ATTRIBUTION

## DEFINITION

Attribution identifies the source of a biological event. Ideally, it uses dispositive information to assign responsibility to a person, group, geographic or biologic source. The attribution process serves two purposes: (1) to determine who was, and was not, responsible for the attack (to permit arrest, prosecution, or other appropriate action); (2) to halt any continuing or follow-on attacks. The first purpose is law enforcement and counterterrorism focused; the second has significant public health/resilience implications.



## FUNDAMENTAL EXPECTATIONS

- Capability for rapid, accurate, and reliable identification, with full characterization of the distinct nature of a pathogen through technical forensics
- Sciences of microbial and supporting forensics recognized by U.S. courts of law and useable and defensible to support policy decisions
- Adequate and timely collaboration between public health responders and law enforcement during an investigation of a suspected bioterrorism event
- National and global repositories and databases adequate and accessible to meet the needs of bioforensics research and investigative uses
- Local, national, and international collaborations that effectively coordinate research, intelligence, and law enforcement efforts

## EVALUATION

SMALL-SCALE NON-CONTAGIOUS	SMALL-SCALE CONTAGIOUS	LARGE-SCALE NON-CONTAGIOUS	LARGE-SCALE CONTAGIOUS	LARGE-SCALE DRUG RESISTANT	GLOBAL CRISIS CONTAGIOUS
D*	F	F	F	F	F
MEETS FEW EXPECTATIONS	FAILS TO MEET EXPECTATIONS	FAILS TO MEET EXPECTATIONS	FAILS TO MEET EXPECTATIONS	FAILS TO MEET EXPECTATIONS	FAILS TO MEET EXPECTATIONS

\*FOR ANTHRAX, ALL OTHER PATHOGENS F

## SUMMARY OF ASSESSMENT

Despite extensive research, a scientifically and legally validated attribution capability does not yet exist for anthrax or virtually any other pathogen or toxin. There is not yet a networked system of national and international repositories to support microbial forensics, and existing mechanisms to facilitate collaboration among stakeholders worldwide are insufficient. However, the Centers for Disease Control and Prevention (CDC) and the Federal Bureau of Investigation (FBI) have made considerable progress in building partnerships between public health and law enforcement organizations at the federal, state, and local levels that will significantly improve cooperation during an investigation.

A scientifically and legally validated **attribution capability** does not yet exist for anthrax or virtually any other **pathogen or toxin**.

## ATTRIBUTION METRICS

### Question 1:

*Does the capability to attribute a Bacillus anthracis (anthrax) attack using microbial forensics currently exist? Is the same true for other bacterial pathogens, toxins, and viruses?*

#### Answer:

No. A scientifically and legally validated attribution capability does not yet exist for anthrax or virtually any other pathogen or toxin.<sup>1</sup>

There has been extensive research into the methods and processes of microbial forensics related to Bacillus anthracis since 2001. There were several improvements in the development, testing, and validation methods applied to anthrax, and microbes in general, following the attacks of October 2001. However, the science required for forensic analysis is complex. This was apparent in the FBI investigation of the anthrax letters, where some of the very best minds on the subject disagreed with interpreting test results.<sup>2</sup>

In 2009, the National Science and Technology Council published a national research and development (R&D) strategy for microbial forensics that lays out a framework to advance the ability to identify, characterize, and compare strains of different pathogens for attribution purposes. Although there is significant research underway, it has not been resourced, directed, or prioritized adequately.

### Question 2:

*Are current methods of attribution adequate to serve as a basis for U.S. national security decisions and to convince allies and the court of world opinion?*

#### Answer:

Probably not. If the United States cannot attribute an attack to the point of legal sufficiency, then its related actions in response to an attack are more likely to be challenged or blocked by the international community—even if that action is in self-defense, or in pursuit of those the United States suspects of waging criminal war. Our limited capability for attribution invites enemies to conduct “false flag” attacks, in which they pretend to be someone else. Without solid attribution capability, the United States risks the possibility of never knowing who launched an attack, or worse, taking action against the wrong party.

### Question 3:

*Do U.S. capabilities in microbial forensics currently meet the standards required in the justice system for the Daubert test? (Note: The Daubert test established legal precedence, in a 1993 U.S. Supreme Court case, for a judge to assess the reliability and validity of a scientific technique used as evidence in a trial. The Daubert guidelines are forensic techniques based on well-established scientific principles and techniques, sound methodology, rigorous analysis, and peer-reviewed published works.)*

#### Answer:

Unknown. The U.S. capability has not yet been put to the test in U.S. courts. Although microbial forensic experts are keenly aware of Daubert legal issues and have tried to address them, current operational capabilities have not produced results and interpretations capable of withstanding significant legal challenges in U.S. courts. This could be problematic in high profile, contentious cases—particularly those in which a pathogen other than anthrax was used.



Daubert does not set a universal, binding standard, but serves as a guide for individual judges to consider when scientific evidence is submitted in court. Some forensic capabilities valid for policy purposes will probably never be admissible in a court under Daubert. For example, the radiocarbon dating and stable isotope analysis techniques used during the anthrax letters investigation might have been adequate for policy purposes, but might not been reliable enough to win a conviction.

The determination of whether specific microbial forensic capabilities meet the standards of the Daubert test will be made by individual judges during trial proceedings. Additionally, the ability of the government to introduce forensic evidence into a trial will not depend on any one or a collection of scientific techniques alone, but also how it was applied in the context of each particular case. For example, a phylogenetic analysis of HIV was admitted as evidence in a 1998 case, but that does not mean that phylogenetic analysis of a different pathogen would be admissible in another legal proceeding at a different place or different time.<sup>3</sup>

Although Daubert provides a legal framework for testing the admissibility of forensic evidence to U.S. courts, there is no commensurate U.S. policy framework to direct microbial forensic scientists in the development and validation of their capabilities.

Furthermore, should the United States become engaged with the international community in an event that depends upon microbial forensic evidence for decision making (whether legal or policy), there is no generally accepted international framework by which to proceed.

The relationship between **CDC** and the **FBI** continues to be strong, ongoing and **productive**.

#### **Question 4:**

*Have public health and law enforcement reconciled their competing requirements during an investigation? (i.e., Can public health responders protect human lives and mitigate disease while law enforcement maintains chain-of-evidence and other evidentiary requirements?)*

#### **Answer:**

Yes, there has been progress. Beginning before the 1996 Olympic games in Atlanta, the FBI and CDC created a partnership to join the law enforcement and public health communities to forge stronger cooperation during investigations of suspected outbreaks. This collaboration supported the creation of the CDC's Laboratory Response Network (LRN), which uses FBI laboratory-approved methods. There has also been better coordination of local capabilities and resources between FBI field offices and local first responders, with extensive joint training programs between the FBI and state/local public health agencies. The relationship between CDC and the FBI continues to be strong and productive.

There is **no comprehensive system** of agreements to support the entire continuum of priority activities associated with **microbial forensics**.

**Question 5:**

*Are national and global databanks adequate to meet the needs of bioforensic research?*

**Answer:**

To some extent. At present, numerous organizations focused on genetic data have built valuable individual collections that would be of use for bio-attribution. Examples include the National Bioforensics Analysis Center, key academic collaborators, national laboratories, and other federal agencies. Additional collections and databases exist in the private sector. There is no centralized repository or networked system, however, to support microbial forensic research and casework applications.

**Question 6:**

*Are national law enforcement and public health authorities in effective cooperative agreements with foreign counterparts to share data and rapidly assess the source of biological attacks?*

**Answer:**

Not really. There are numerous informal bilateral or limited multilateral relationships between U.S. law enforcement, public health, and homeland security agencies and their specific international counterparts in the field of microbial forensics. The United States has also provided limited preparedness training and equipment to international partners.

Agreements of this sort, however, have been primarily case-specific and generated on an as-needed basis (e.g., acquiring *Bacillus anthracis* Ames isolates to support the U.S. investigation). There is no comprehensive system of agreements to support the entire continuum of priority activities associated with microbial forensics investigation, or preparedness for investigative support.<sup>4</sup>

Consequently, response to an attack today would be unnecessarily delayed while agreements and standards were hammered out “on the fly.”

**Notes**

- <sup>1</sup> Multiple interviews with former senior government official who has extensive experience in microbial forensics, July/August 2011.
- <sup>2</sup> Interview with senior government official, July 2011.
- <sup>3</sup> Jonathan Tucker and Gregory Koblentz, “The Four Faces of Microbial Forensics,” *Biosecurity and Bioterrorism* 7(4, December 2009): 389–97, <http://www.ncbi.nlm.nih.gov/pubmed/20028247>.
- <sup>4</sup> Interview with Gregory Koblentz, July 2011

# COMMUNICATION

## DEFINITION

Communication is discerning and sharing credible, actionable information among all stakeholders (federal agencies, state and local officials, the private sector, and the general public), before, during, and after a biological event. Effective communication improves a wide range of preparedness and disaster-response functions, including inter-agency/inter-governmental coordination; maintaining situational awareness; assessing and communicating risk; and mobilizing communities, families, and individuals to strengthen their preparedness and capacity for self-care.



## FUNDAMENTAL EXPECTATIONS

- Credible threat and risk assessments of bioterrorism and naturally occurring disease outbreaks, suitable to engage and educate the public
- Federal, state, and local public health agencies coordinate on risk communication messages (fact sheets, web sites, checklists, etc.), and have pre-scripted messaging in place for biothreats
- Government guidance provides actionable information to enable all stakeholders to prepare for and respond to biological threats
- Clearly defined protocols to assure coordinated inter-agency emergency communications and information sharing during a biological/public health disaster
- Effective use of innovative technology and social networking tools to gather, translate, and share relevant information
- Tested, proven protocols for communicating to diverse and special needs populations

## EVALUATION

SMALL-SCALE NON-CONTAGIOUS	SMALL-SCALE CONTAGIOUS	LARGE-SCALE NON-CONTAGIOUS	LARGE-SCALE CONTAGIOUS	LARGE-SCALE DRUG RESISTANT	GLOBAL CRISIS CONTAGIOUS
<b>B</b>	<b>B</b>	<b>C</b>	<b>C</b>	<b>C</b>	<b>C</b>
MEETS MANY EXPECTATIONS	MEETS MANY EXPECTATIONS	MEETS MINIMAL EXPECTATIONS	MEETS MINIMAL EXPECTATIONS	MEETS MINIMAL EXPECTATIONS	MEETS MINIMAL EXPECTATIONS

## SUMMARY OF ASSESSMENT

The Centers for Disease Control and Prevention (CDC) and the Department of Health and Human Services (HHS) have made good efforts to coordinate risk communication strategies with state/local partners, and have also provided pre-scripted messages for Category A biological agents and pandemic influenza. The recent development of the Biological Assessment and Threat Response (BATR) Protocol is a significant step forward in federal interagency coordination for large-scale biological events. The federal government has improved engagement of state/local agencies to address communication challenges, but has not enlisted private and non-government entities with the same effectiveness. Despite significant progress, risk communication does not always reach diverse/special needs populations. No suitable threat and risk assessment for bioterrorism is available for engaging and educating the public.

An assessment suitable for convincing the American people of the **threat** and **risk** of bioterrorism is **not readily available**.

## COMMUNICATION METRICS

### Question 1:

*Has the federal government prepared threat and risk assessments suitable for educating and engaging the public about the consequences of biological threats?*

### Answer:

For bioterrorism, no. For pandemic flu, yes.

Presidential Policy Directive 8 (National Preparedness, dated March 30, 2011) requires that a national risk and threat assessment be completed before September 30, 2011.<sup>1</sup> The draft version, posted for public comment at this writing, breaks from the methodology of past risk assessments to focus on capabilities required to meet a single, extremely challenging meta-scenario. Although this approach may meet the needs of DHS in establishing national preparedness goals, it does not capture the biological threat in a way likely to engage the public.

Thus, the short answer is that although considerable effort has been expended in this direction, an assessment suitable for convincing the American people of the threat and risk of bioterrorism is not readily available.

A model for effectively communicating a threat assessment and its practical application does exist in the federal planning and communications for pandemic flu. HHS effectively communicates the “characteristics and challenges of a flu pandemic,” and distinguishes pandemic flu from seasonal flu through its flu.gov web site. Used heavily during the 2009 H1N1 pandemic, this site continues to provide excellent guidance, checklists, and other resources to engage every sector of society in preparing for pandemic or seasonal flu.<sup>2</sup>

### Question 2:

*Do formal decision-making structures clearly define leadership roles and coordination of inter-agency emergency communications during a biological/public health disaster?*

### Answer:

Yes. The Public Affairs Support Annex to the National Response Framework (NRF) describes “the interagency policies and procedures used to rapidly mobilize Federal Assets to prepare and deliver coordinated and sustained messages to the public in response to incidents requiring a coordinated Federal response.”<sup>3</sup>

For example, the U.S. Government Pandemic Influenza Public Health Communications Plan was finalized in November 2006. Some core elements of the plan include planning assumptions that will frame the U.S. government communications response, the current agreed-upon federal messages on pandemic influenza preparedness and response, along with a comprehensive listing of target audiences, credible federal expert spokespersons, and roles and responsibilities of the relevant federal agencies.<sup>4</sup>

Planning seems to have paid off, based on the federal communications executed during the 2009 H1N1 influenza pandemic. GAO reports that “Public surveys generally found CDC’s communication efforts to be successful in reaching a range of audiences; however, these messages fell short in meeting the needs of some non-English-speaking populations.”<sup>5</sup>

**Question 3:**

*Are federal, state, and local public health agencies coordinated on risk communication messages (fact sheets, web sites, checklists, other)?*

**Answer:**

Yes, particularly between CDC and state/local public health agencies. Many local agencies that have limited ability to develop their own materials rely heavily upon CDC products and CDC capabilities, such as language translation. Even well resourced health departments frequently reference and use CDC materials.

**Question 4:**

*Do HHS, DHS, and other relevant federal agencies have pre-scripted messaging in place for the most likely bioterrorism scenarios?*

**Answer:**

Yes. As part of the “Communicating in the First Hours” initiative, CDC and the HHS Office of Public Affairs have developed pre-scripted messages and other resources (e.g., slates, B-roll, sound bites, short- and long-format radio live-read scripts) for federal, state, local, and tribal public health officials to use during response to an emergency. Messages apply to all Category A biological agents, to chemical and radiological events, and to suicide bombing. HHS has also developed pre-event message maps for pandemic influenza.<sup>6</sup>

**Question 5:**

*Do multi-agency agreements or protocols exist regarding how information is shared, guarded, or publicly released during a disease outbreak or possible bio-attack?*

**Answer:**

Yes. The Public Affairs Support Annex to the National Response Framework describes “the interagency policies and procedures used to rapidly mobilize federal assets to prepare and deliver coordinated and sustained messages to the public in response to incidents requiring a coordinated federal response.” The degree to which this is followed during unique events, however, has varied.

The recent development of the BATR Protocol represents a significant step forward in national level, interagency consultation during large-scale bioterrorism and biosecurity events.

**Question 6:**

*Does the federal government effectively engage state, local, private sector, military, civilian, tribal governments, faith-based community, and other non-federal partners on emergency communication challenges?*

**Answer:**

Somewhat. There has been marked improvement in the past several years. The federal government has various institutional mechanisms through which it engages its governmental partners (tribal, state, local) to address emergency communication challenges. It does not, however, always enlist private and non-government entities with the same effectiveness.

CDC and the HHS Office of Public Affairs developed **pre-scripted messages** and other resources for federal, state, local, and tribal public health officials to use during **response to an emergency.**

There has been progress on strategies to include **multi-lingual, multi-cultural, and multi-channel media** to reach diverse and special needs populations.

**Question 7:**

*Does the disaster response enterprise effectively use innovative mobile technology and social networking to gather, analyze, and share relevant information?*

**Answer:**

Increasingly so. In the past few years, social media and new technologies have demonstrated significant potential to improve communication during disasters. Various social media sites (i.e., Facebook, Twitter, LinkedIn, YouTube) are already in widespread use by citizens and rank fourth as the most popular means to receive emergency information.<sup>7</sup> Emergency management organizations (including the Federal Emergency Management Agency, or FEMA) have begun to use these tools to disseminate information to targeted populations.

Organizations like FEMA use social media to passively disseminate information and enlist user feedback. Social media can also be applied as an emergency management tool that issues warnings, receives requests for assistance, or monitors online activity to generate situational awareness. Many emergency management organizations have embraced the passive use of social media, but have yet to expand to systemic two-way use.<sup>8</sup>

One example that shows the power of social media is the May 16, 2011, blog post by CDC. “Preparedness 101: The Zombie Apocalypse” spread rapidly, with more than 2.5 million page views from May 16–25, 2011. The message cleverly reminds the reader that the steps taken by individuals and the CDC in preparation for a zombie apocalypse would be very similar to those needed for all hazards.<sup>9</sup>

In addition to government-driven use of social media, the public is turning to community web sites, social networking sites, personal blogs, public texting systems, and photo and mapping sites to gather and disperse helpful information and to coordinate a broader response to disaster.<sup>10</sup> The public increasingly relies on Internet-based applications as a source of useful, credible information, as well as a medium for sharing information. There is ongoing research to further study the benefits and implications of these tools.

**2.5 MILLION**  
PAGE VIEWS FROM MAY 16–25, 2011  
ON CDC.COM OF “**PREPAREDNESS**  
**101: THE ZOMBIE APOCALYPSE**”

[HTTP://EMERGENCY.CDC.GOV/SOCIALMEDIA/ZOMBIES.ASP](http://EMERGENCY.CDC.GOV/SOCIALMEDIA/ZOMBIES.ASP)



## Question 8:

*Are tested and proven communication strategies in place to address the unique needs of diverse populations?*

### Answer:

There has been progress toward this goal on many levels, with an emphasis on strategies to include multi-lingual, multi-cultural, and multi-channel media to reach diverse and special needs populations.

Several federal agencies have used their web sites to communicate information on biological threats to non-English speakers. The whole of flu.gov—an exceptional web site (see Question 1)—is available in Spanish, as are many of its print materials about seasonal flu. The core of Ready.gov materials, including information on bio-attacks, is available in 12 languages other than English.

The National Library of Medicine has compiled materials from health departments and other sources, which provide general information on biological emergencies and individual biological agents in multiple languages. These clearinghouses of information are valuable, although in an actual emergency, it will be important for the federal government (as well as state and local agencies) to identify credible and knowledgeable spokespersons who are trusted by specific subpopulations.<sup>11</sup>

Despite this effort, risk communication does not always reach diverse populations. For example, during the Deepwater Horizon oil spill, outreach efforts to one ethnic community were in a dialect the community found politically offensive.<sup>12</sup>

### Notes

- <sup>1</sup> U.S. Department of Homeland Security, Presidential Policy Directive 8: National Preparedness, (March 30, 2011), [http://www.dhs.gov/xabout/laws/gc\\_1215444247124.shtm](http://www.dhs.gov/xabout/laws/gc_1215444247124.shtm).
- <sup>2</sup> GAO, Influenza Pandemic: Lessons from the H1N1 Pandemic Should Be Incorporated into Future Planning (June 2011), <http://www.gao.gov/new.items/d11632.pdf>.
- <sup>3</sup> DHS, Overview: ESF and Support Annexes Coordinating Federal Assistance in Support of the National Response Framework, January 2008, <http://www.fema.gov/pdf/emergency/nrf/nrf-overview.pdf>.
- <sup>4</sup> Summary of Progress on National Strategy for Pandemic Influenza Implementation Plan (July 2007), <http://www.flu.gov/professional/federal/summaryprogress2007.html#Introduction>.
- <sup>5</sup> GAO, Influenza Pandemic: Lessons from the H1N1 Pandemic Should Be Incorporated into Future Planning.
- <sup>6</sup> U.S. Centers for Disease Control, Communicating in the First Hours, (June 2011), <http://www.bt.cdc.gov/firsthours/intro.asp>; U.S. Department of Health and Human Services, Pandemic Influenza Pre-Messaging Maps, (January/February 2006), [http://www.pandemicflu.gov/news/pre\\_event\\_maps.pdf](http://www.pandemicflu.gov/news/pre_event_maps.pdf).
- <sup>7</sup> Bruce Lindsay, Social Media and Disasters: Current Users, Future Options, and Policy Considerations, (Congressional Research Service, September 6, 2011), <http://www.fas.org/sgp/crs/homesecc/R41987.pdf>.
- <sup>8</sup> Bruce Lindsay, Social Media and Disasters: Current Users, Future Options, and Policy Considerations.
- <sup>9</sup> CDC, Social Media: Preparedness 101: Zombie Apocalypse, <http://emergency.cdc.gov/socialmedia/zombies.asp>.
- <sup>10</sup> Raina Merchant, et al., "Integrating Social Media into Emergency-Preparedness Efforts," *New England Journal of Medicine* 365: 4 (July 27, 2011), <http://healthpolicyandreform.nejm.org/?p=14975>.
- <sup>11</sup> Caring for Special Needs during Disasters: What's Being Done for Vulnerable Populations?, Before the House Committee on Homeland Security, Subcommittee on Emergency Communications, Preparedness, and Response, U.S. House of Representatives, 111th Cong. (June 15, 2010), Testimony of Jonathan M. Young, Ph.D., J.D., Chairman, National Council on Disability, and Marcie Roth, Director, Office of Disability Integration and Coordination, FEMA/DHS.
- <sup>12</sup> National Commission on the BP Deepwater Horizon Oil Spill, *Deep Water: The Gulf Oil Disaster and the Future of Offshore Drilling* (January 11, 2011), <http://www.oilspillcommission.gov/final-report>.





# MEDICAL COUNTERMEASURE DEVELOPMENT & PRODUCTION

## DEFINITION

Medical countermeasures (MCM) include vaccines, therapeutics, medical devices, and diagnostic tools. This study assesses the nation's capability to identify, develop, produce, and acquire medical countermeasures for response to a biological event.



## FUNDAMENTAL EXPECTATIONS

- Adequate supplies of medical countermeasures currently available for use against the top priority biothreats (as identified by the Department of Health and Human Services (HHS) in 2007)
- Integrated system to establish requirements and set priorities for the MCM enterprise
- An enterprise that optimizes the resources and capabilities of government and private industry to meet these requirements and priorities
- Efficient process from requirements to basic/applied research, through advanced development, approval, acquisition, and utilization policies

## EVALUATION

### MEDICAL COUNTERMEASURE AVAILABILITY

SMALL-SCALE NON-CONTAGIOUS	SMALL-SCALE CONTAGIOUS	LARGE-SCALE NON-CONTAGIOUS	LARGE-SCALE CONTAGIOUS	LARGE-SCALE DRUG RESISTANT	GLOBAL CRISIS CONTAGIOUS
<b>B</b>	<b>B</b>	<b>D</b>	<b>D*</b>	<b>F</b>	<b>F</b>
MEETS MANY EXPECTATIONS	MEETS MANY EXPECTATIONS	MEETS FEW EXPECTATIONS	MEETS FEW EXPECTATIONS	FAILS TO MEET EXPECTATIONS	FAILS TO MEET EXPECTATIONS

\*FOR SMALLPOX—B

### MEDICAL COUNTERMEASURE DEVELOPMENT & PRODUCTION PROCESS

<b>D</b>
MEETS FEW EXPECTATIONS

## SUMMARY OF ASSESSMENT

Current stockpiles of medical countermeasures could limit the impact of small-scale attacks using anthrax and several other likely pathogens, but may not be adequate for large-scale attacks. Medical countermeasures are not currently available for resistant or novel pathogens. Adequate supplies of medical countermeasures have removed smallpox as a large-scale threat. The process for developing and producing medical countermeasures still lacks clearly defined requirements, a common set of prioritized research and development goals, coordinated budget requests, and sufficient, sustained funding.

Depending on the **scale of an attack** and pathogen used, there could be insufficient quantities of MCMs, or in the case of resistant or novel pathogens, **no medical countermeasures available.**

## MEDICAL COUNTERMEASURE DEVELOPMENT METRICS

(Questions 1 and 2 address availability issues; questions 3 through 10 address the process of medical countermeasure development, production, and approval.)

### Question 1:

*Does the United States have adequate quantities of medical countermeasures available for the most likely biological terrorism scenarios?*

### Answer:

Significant progress has been made for defense against smallpox and anthrax attacks, (the only two human biothreats identified in the 2006 National Planning Scenarios); however, depending on the scale of an attack and pathogen used, there could be insufficient quantities of medical countermeasures—or in the case of resistant or novel pathogens, no medical countermeasure available.<sup>1</sup>

In 2001, America had only 14 million doses of smallpox vaccine available. In 2002, there was a decision to acquire smallpox vaccine for the entire U.S. population. The Strategic National Stockpile (SNS) now has 300+ million doses of Food and Drug Administration (FDA)-approved smallpox vaccine. Additionally, an attenuated vaccine, use for immune compromised individuals and immediate contacts, and a recently developed smallpox antiviral drug are being added to the SNS for emergency use.<sup>2</sup>

The response to the threat of smallpox is one of the top success stories for biodefense during the past decade. A coordinated attack on America’s population with this deadly contagious disease could have been an existential threat to our way of life. Today, smallpox has been removed from the category of weapons of mass destruction. (This is assuming the nation has a system to rapidly dispense the vaccine—see assessment of Medical Countermeasures Distribution and Dispensing.)

Although not contagious, inhalation anthrax is actually more deadly than smallpox—untreated, up to 90 percent infected will die. Although there are little data available, oral antibiotic treatment of humans for inhalation anthrax is generally believed to provide protection if given within 48 hours of exposure. Currently, the SNS maintains a sufficient supply of oral antibiotics to provide approximately 60 million individuals with a 60-day course of treatment. An FDA-approved vaccine (AVA) exists and is used widely for military personnel. The SNS currently has sufficient AVA vaccine for 4.4 million adults, with another 6.3 million courses on order. Studies are underway to determine means to further increase the supply of AVA in the SNS through dilution.

The oral antibiotics in the SNS could also be used for response to attacks with likely bacterial agents such as *Yersinia pestis* (plague) and *Francisella tularensis* (tularemia). There are sufficient quantities of antitoxin to respond to more than 100,000 cases of botulium poisoning, but there are no medical countermeasures for the wide range of viral diseases commonly referred to as hemorrhagic fevers.

“One drug per bug” is not a viable, sustainable defense strategy. With more than 40 widely available pathogens that have potential for use as bioweapons, it will not be possible to develop separate medical countermeasures for each. The current strategy calls for developing broad-spectrum antibiotics and antiviral drugs.

The long-term strategy identified in a 2001 Defense Science Board study co-authored by Dr. Joshua Lederberg and Dr. George Whiteside called for “bug to drug in 24 hours.” At that time, this was purely science fiction, but there have been dramatic advances in the past decade.

In spring 2009, the H1N1 virus was first identified in a Department of Defense test program in Southern California. It was genetically mapped, and a candidate antiviral drug was designed and produced within two weeks.<sup>3</sup> This was a demonstration of the technologies that will be required for developing and producing medical countermeasures in the years ahead; however, rapid development and production will be of little value without the capability to also test the safety and efficacy of these new medical countermeasures.

Success will require a nimble, flexible, highly integrated medical countermeasure enterprise. These are not the adjectives normally associated with government contracts, but this type of system, one that includes both the public and private sectors, will be an absolute requirement for national security in the 21st century.

### Question 2:

*Are there adequate provisions for using medical countermeasures with children and pregnant women?*

#### Answer:

No. There are serious deficiencies regarding dosing for infants, children, and pregnant women (10 percent of all women of child-bearing age are pregnant at any given time).<sup>4</sup> Although children may require smaller doses, they may also have greater or different side effects than adults. Children may also require specially sized equipment (needles and tubes), and medical countermeasures may need to be specially formulated (liquid instead of pills). There are no data for vaccinating children against anthrax: the CDC and FDA are currently developing a strategy for vaccinating children (if required during a crisis), and then collecting additional data during such an event.

### Question 3:

*Is there a system within the federal government for identifying requirements for medical countermeasures?*

#### Answer:

Yes, there is a clearly defined system; however, there is no consensus on prioritized research goals and product requirements across various organizations.<sup>5</sup> Top priority bioterrorism agents are identified by the Department of Homeland Security (DHS) in Material Threat Determinations and Population Threat Assessments. HHS is responsible for assessing the medical and public health consequences of these agents, establishing medical countermeasure requirements, and establishing priorities for near-, mid-, and long-term acquisitions.<sup>6</sup>

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development  
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countermeasures.**

## Drug development

in the non-biodefense sector generally takes 8-10 years from basic science to FDA approval, and the vast majority of these initiatives (up to 90 percent) fail.

### Question 4:

*Does this system within HHS effectively manage the medical countermeasure enterprise? Are clearly defined priorities established for basic and applied science, advanced development, and procurement?*

### Answer:

No. The National Biodefense Science Board (appointed by the HHS Secretary) reviewed the enterprise in 2010 and found that the individual agencies of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) have “generally been working well within their individual sets of responsibility, but that these multiple organizational entities, each with unique missions, do not have an overarching authority to whom they are held responsible.”<sup>7</sup> Thus, some good work has been accomplished, but at multiple purposes—work needs to stem from a common set of priorities, which is not the case now.

### Question 5:

*Does an integrated system exist to seamlessly transition from requirements identification to National Institutes of Health (NIH) basic and applied research to Biomedical Advanced Research and Development Authority (BARDA) for advanced development and acquisition?*

### Answer:

Yes; however, there are too few examples of success. The development of smallpox vaccine suitable for immune compromised individuals is a textbook example of how the system should work. NIH funded both the basic and applied science and then transitioned the program to BARDA, which funded advanced development and procurement. This generation III smallpox vaccine is now in the SNS and available for use during an emergency.

It is important to understand that drug development in the non-biodefense sector generally takes 8–10 years from basic science to FDA approval, and that most initiatives (up to 90 percent) fail. This system must improve.

### Question 6:

*What is being done to improve the access to not-yet-approved medical countermeasures during a crisis?*

### Answer:

The FDA cannot issue an Emergency Use Authorization (EUA) for any medical countermeasures prior to an emergency declaration, which hinders planning and preparation for a biological attack.<sup>8</sup> It is up to Congress to authorize the FDA to issue EUAs in advance of an emergency, as well to streamline other FDA planning activities.

### Question 7:

*How many medical countermeasures have been approved using the Animal Efficacy Rule?*

### Answer:

None. In July 2002, the Animal Efficacy Rule<sup>9</sup> was created to allow testing of medical countermeasures that cannot be safely tested on humans. This includes most of the likely bioterrorism pathogens (such as smallpox, anthrax, plague, Ebola, and Marburg). Despite nine years of research in this area, the science is immature, and no new medical countermeasures have been approved using the Animal Rule.<sup>10</sup>

In 2009, the FDA issued draft guidance for industry on developing animal models, and in November 2010, FDA held a public meeting on Animal Rule challenges, which will lead to additional guidance. The FDA also signed a memorandum of understanding (MOU) with the Defense Advanced Research Projects Agency (DARPA) to develop new tools for developing safety and effectiveness data that may be used when limited human data are available.

No **new medical countermeasures** have been approved using the **Animal Rule**.

### Question 8:

*What is the status of efforts to build an advanced development and manufacturing facility (public-private partnership) for medical countermeasures to biological and toxin agents?*

### Answer:

Ongoing. On March 30, 2011, BARDA issued a Request for Proposal (RFP) for the Centers for Innovation in Advanced Development and Manufacturing (CIADM). This project is intended to increase the national capacity for rapid manufacturing of pandemic influenza vaccines and “provide a readiness posture to produce other products in an emergency to known and unknown threats” including for a biological attack. It will be established as a public-private partnership. The Department of Defense has issued an RFP for a similar MCM manufacturing center.

### Question 9:

*One of the top five recommendations in the March 2010 National Biodefense Science Board report on medical countermeasures was that the Secretary of HHS should task “senior HHS leaders to develop a common set of prioritized research goals, prioritized product requirements, and prioritized dispensing goals for civilian populations; and coordinate these priorities with DoD.” Has this been accomplished?*

### Answer:

As of this writing, no.

### Question 10:

*Has there been sufficient, sustained funding for the medical countermeasure enterprise?*

### Answer:

No. Initial Project BioShield funding (\$5.593 billion for FY2004 to FY2013)<sup>11</sup> was a good start, but there have been constant raids and attempted raids on the fund. BARDA is currently funded at about 10 percent of its actual requirements and FDA lacks sustained, balanced funding for work on medical countermeasures.<sup>12</sup> Without sufficient, sustained funding there will be little chance of success. Medical countermeasures are the most important arrow in the biodefense quiver.

Notes

- <sup>1</sup> Interviews and briefings with numerous current and former government officials, spring/summer 2011.
- <sup>2</sup> National Institute of Allergy and Infectious Disease, Smallpox (March 6, 2009), <http://www.niaid.nih.gov/topics/smallpox/Pages/research.aspx>.
- <sup>3</sup> U.S. Department of Defense briefing to the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, December 2009.
- <sup>4</sup> National Biodefense Science Board, Where Are the Countermeasures? Protecting America's Health from CBRNE Threats: A Report of the National Biodefense Science Board, (March 2010), <http://www.phe.gov/Preparedness/legal/boards/nbsb/meetings/Documents/nbsb-mcmreport.pdf>.
- <sup>5</sup> National Biodefense Science Board, Where Are the Countermeasures?
- <sup>6</sup> Developing and Acquiring Medical Countermeasures against Chemical, Biological, Radiological, and Nuclear Agents, Testimony Before the Subcommittee on Emergency Preparedness, Response, and Communications, Committee on Homeland Security, U.S. House of Representatives, 112th Cong. (April 13, 2011), Statement of Cynthia A. Bascetta Managing Director, Health Care, <http://www.gao.gov/new.items/d11567t.pdf>.
- <sup>7</sup> National Biodefense Science Board, Where Are the Countermeasures?
- <sup>8</sup> Interview with senior government official, August 4, 2011.
- <sup>9</sup> The likelihood that a terrorist attack using Chemical, Biological, Radiological, or Nuclear (CBRN) substances might occur in the United States led FDA to promulgate regulations on May 31, 2002—intended to expedite the development and approval of new drug and biological products. The final rule, titled “New Drug and Biological Products; Evidence Needed to Demonstrate Effectiveness of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible” (commonly referred to as the Animal Efficacy Rule), amended FDA’s drug and biologic regulations to “allow appropriate studies in animals in certain cases to provide substantial evidence of effectiveness of new drug and biological products used to reduce or prevent the toxicity of [CBRN] substances.” See [http://www.fdalawblog.net/fda\\_law\\_blog\\_hyman\\_phelps/2008/09/fda-issues-anim.html](http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2008/09/fda-issues-anim.html).
- <sup>10</sup> Interview with former senior U.S. Federal Drug Administration official, August 4, 2011.
- <sup>11</sup> Frank Gottron, Project BioShield: Purpose and Authorities, Congressional Research Service (July 6, 2009), <http://www.fas.org/sgp/crs/terror/RS21507.pdf>.
- <sup>12</sup> “The estimated cost of developing medical countermeasures required to meet the threats identified by the Department of Homeland Security is \$3.4 billion a year for the next five years.” Prevention of WMD Proliferation and Terrorism Report Card (Washington, D.C.: Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, January 2010), p. 6. Additionally, the Center for Biosecurity of UPMC estimated BARDA requirements of \$3.7 billion per year. See [http://www.upmc-biosecurity.org/website/resources/To%20USG/USG-correspondence/2009-07-07-barda\\_fy10.html](http://www.upmc-biosecurity.org/website/resources/To%20USG/USG-correspondence/2009-07-07-barda_fy10.html).

# MEDICAL COUNTERMEASURE DISTRIBUTION & DISPENSING

## DEFINITION

Distribution refers to the mechanism for bulk transporting medical countermeasures from the Strategic National Stockpile (SNS) to the affected area—a federal responsibility. Dispensing refers to providing medical countermeasures to the identified population—a state and local responsibility, augmented by federal support.



## FUNDAMENTAL EXPECTATIONS

- Appropriate quantities and types of medical countermeasure stockpiles, strategically located, subject to rigorous security and environmental controls, with schedules of resupply, rotation, and shelf-life extension
- Distribution and dispensing mechanisms that are timely, efficient, and deliver medical countermeasures to the point of need
- Redundant and exercised community-based dispensing strategies developed to address specific population needs (age distribution, at risk populations, logistics, etc.)
- Supporting communication strategies that are multi-lingual, multi-cultural, and multi-channel
- A trained and knowledgeable workforce (professional and/or volunteer) with the skill set, willingness, and necessary preparation to participate in mass dispensing activities

## EVALUATION

SMALL-SCALE NON-CONTAGIOUS	SMALL-SCALE CONTAGIOUS	LARGE-SCALE NON-CONTAGIOUS	LARGE-SCALE CONTAGIOUS	LARGE-SCALE DRUG RESISTANT	GLOBAL CRISIS CONTAGIOUS
<b>B</b>	<b>B</b>	<b>D</b>	<b>D</b>	<b>F</b>	<b>F</b>
MEETS MANY EXPECTATIONS	MEETS MANY EXPECTATIONS	MEETS FEW EXPECTATIONS	MEETS FEW EXPECTATIONS	FAILS TO MEET EXPECTATIONS	FAILS TO MEET EXPECTATIONS

## SUMMARY OF ASSESSMENT

The inability to dispense potentially lifesaving medical countermeasures in the event of a large-scale bio-attack presents a serious risk of needless deaths, social disorder, and loss of confidence in government. It is highly unlikely that antibiotics could be dispensed to a large population within 48 hours. The federal role in assisting local authorities to achieve this critical mission is growing, but has been slow and uneven. No local jurisdiction has demonstrated the ability to rapidly dispense medical countermeasures on a large scale under realistic conditions. Meeting the 48 hour standard will not be possible without multiple and redundant dispensing strategies.

Few jurisdictions have conducted full scale exercises to evaluate adequacy of planned staffing and security.

## DISTRIBUTION & DISPENSING METRICS

### Question 1:

*Can medical countermeasures in the SNS be dispensed to affected populations within 48 hours (as specified in HSPD-21)?*

### Answer:

No. There is little evidence of capability to dispense medical countermeasures to large populations in the initial life-saving phase after a bioterrorism event. The challenge is three-fold:

- Early detection and/or clinical diagnosis and rapid decision making to dispense,
- Determination of who is at risk and who is not, and
- Logistics of rapidly dispensing to large populations.

Some local authorities have done extensive planning for a large scale anthrax attack. However, all local dispensing plans depend on a large number of volunteers. Few jurisdictions have conducted full-scale exercises to evaluate adequacy of planned staffing and security. It remains doubtful whether points of distribution alone could handle the public demand following a large-scale attack, and many local jurisdictions are exploring alternative dispensing modalities.

### Question 2:

*Do current dispensing plans include use of retail pharmacies and “big box” stores? If not, why?*

### Answer:

Some jurisdictions such as New York City are exploring options with commercial pharmacies to augment the existing point of distribution (PODs) system.<sup>1</sup> Because retail pharmacies and other commercial stores are widely distributed within population centers, using commercial retail outlets could potentially increase the throughput and speed of dispensing in an emergency.

From a business perspective, however, the potential for legal liability remains a barrier, despite partial indemnification provided by the Public Readiness and Emergency Preparedness Act of 2005 (PREP Act).<sup>2</sup>

### Question 3:

*What is the potential role for the federal government in assisting state and local authorities in rapidly dispensing antibiotics in the event of a bioterrorism attack?*

### Answer:

The role of the federal government in dispensing has been limited, but is expanding.<sup>3</sup> The Cities Readiness Initiative (CRI) is a federally funded program managed by the Centers for Disease Control and Prevention (CDC), focused on improving the efficacy of mass dispensing in major metropolitan areas following a biological attack. CRI cities have developed dispensing mechanisms tailored to local jurisdictions. In the event of a large-scale attack, however, local capabilities could easily be overwhelmed, necessitating federal support.



President Obama signed an Executive Order in December 2009 calling for the establishment of (1) U.S. Postal Service (USPS) dispensing model for residential delivery of medical countermeasures; (2) a federal rapid response capability; and (3) creation of mechanisms to ensure mission essential federal government personnel have immediate access to medical countermeasures.<sup>4</sup>

Adapting the USPS mail distribution system is one approach that has demonstrated the potential capability to rapidly dispense oral antibiotics. During drills, volunteer postal workers in Seattle, Boston, Philadelphia, and Minneapolis delivered facsimile of antibiotics to all residences in specified zip codes within 12 hours.<sup>5</sup> An essential enabling requirement for this capability, however, is providing the volunteer postal workers security escorts as they make their deliveries. To date, only Minneapolis has actually implemented the “postal option” as part of their bioterrorism response plan.

The federal government is also exploring alternative dispensing strategies, including repositioning caches of antibiotics, using federal employees to support dispensing, and providing additional security to assist local authorities.

#### **Question 4:**

*If the “postal option” is a viable solution, why haven’t more cities adopted it?*

#### **Answer:**

Several cities have expressed interest and have indicated a desire to incorporate the “postal option” in their dispensing plans. USPS, however, is neither resourced nor staffed to provide this service. Further, an essential enabling requirement is providing the volunteer postal workers security escorts. In some jurisdictions, local law enforcement is incapable or unwilling to do so.

#### **Question 5:**

*Is there a plan to provide home medical kits containing antibiotics for use following a biological attack?*

#### **Answer:**

Currently there is no FDA-approved home medical kit containing antibiotics. In 2006, HHS sponsored a pilot project in St. Louis, which dispensed medkits to several thousand homes. The intent of the study was to determine if individuals would reliably maintain medkits without misplacing or misusing the antibiotics. The vast majority (97 percent) of the kits were returned unopened at the end of the study.<sup>6</sup>

Despite these findings, there are still concerns within the public health community that home medkits would be misused, contributing to the problem of antibiotic resistance. Additional issues include cost, shelf life, storage conditions, and resupply. A September 2011 report by the Institute of Medicine reviews potential benefits and concerns related to medkits and a variety of other pre-positioning strategies.

## Question 6:

*Are there alternative countermeasures available for anthrax that would reduce the need to distribute antibiotics?*

### Answer:

Yes. An FDA approved anthrax vaccine is available for pre-exposure protection from inhalation anthrax. To date its use has been limited to U.S. military deploying to threat areas overseas. In October 2008 and February 2009, the Advisory Committee on Immunization Practices (ACIP) re-examined its recommendations for pre-event anthrax vaccination for civilian first responders, including National Guard personnel likely to be involved in an anthrax post-attack response.<sup>7</sup> The committee determined that first responder organizations may offer their workers voluntary pre-event vaccination. Pre-event vaccination also offers the additional advantage of providing protection against antibiotic resistant anthrax.

To date, the federal government has purchased tens of millions of doses of anthrax vaccine, with a shelf life of four years. Each year millions of doses expire, costing taxpayers in excess of \$100 million annually.<sup>8</sup> And yet, the federal government has been reluctant to provide this vaccine to non-military first responders. It would be relatively easy and improve local preparedness by vaccinating this group.

### Notes

- <sup>1</sup> Dispensing Medical Countermeasures for Public Health Disasters, Institute of Medicine: Forum on Medical and Public Health Preparedness for Catastrophic Events, (2008), <http://www.ncbi.nlm.nih.gov/books/NBK4100/>.
- <sup>2</sup> Multiple interviews with senior corporate executives.
- <sup>3</sup> Interview with senior Administration official, August 11, 2011.
- <sup>4</sup> Exec. Order No. 13527: Medical Countermeasures Following a Biological Attack, <http://www.gpo.gov/fdsys/pkg/DCPD-200901027/html/DCPD-200901027.htm> (December 30, 2009).
- <sup>5</sup> Dispensing Medical Countermeasures for Public Health Disasters, Institute of Medicine: Forum on Medical and Public Health Preparedness for Catastrophic Events, (2008), <http://www.ncbi.nlm.nih.gov/books/NBK4100/>
- <sup>6</sup> Trust for America's Health, Ready or Not? Protecting the Public's Health from Diseases, Disasters, and Bioterrorism, (December 2008), p. 22, <http://www.rwjf.org/files/research/3613.1208.readyornot.tfahrpt.pdf>
- <sup>7</sup> Centers for Disease Control and Prevention, Use of Anthrax Vaccine in the United States: Morbidity and Mortality Weekly Report (July 23, 2010), <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5906a1.htm>.
- <sup>8</sup> Biosecurity Blog, Vaccines to Burn (October 20, 2010), <http://biosecurityblog.com/2010/10/20/209/>.

# MEDICAL MANAGEMENT & RESPONSE

## DEFINITION

This report defines medical management and response as the practical, ethical, and transparent alignment of available medical resources from across the spectrum of government, health response entities, and community stakeholders, with the objective of saving as many lives as possible. The primary focus of this assessment is the unique challenges of medical response to the intentional release of a deadly pathogen.



## FUNDAMENTAL EXPECTATIONS

- Swift and efficient identification, coordination, and use of available medical capabilities to save as many lives as possible
- Citizens equipped with the tools and timely information for better self-protection and self-care
- Aligned federal guidance and adequate legal protections for public health agencies, hospitals, healthcare facilities, and individual providers to plan for crisis standards of care—and the processes and indicators for their application
- Full engagement of private sector and non-governmental organizations (NGOs) to marshal and provide needed medical supplies, resources, and capabilities, aligned with the emergency response plans of government agencies
- Health care providers and facilities organized into regional coalitions that are prepared and willing to augment the disaster-response capabilities of their members

## EVALUATION

SMALL-SCALE NON-CONTAGIOUS	SMALL-SCALE CONTAGIOUS	LARGE-SCALE NON-CONTAGIOUS	LARGE-SCALE CONTAGIOUS	LARGE-SCALE DRUG RESISTANT	GLOBAL CRISIS CONTAGIOUS
<b>B</b>	<b>C</b>	<b>D</b>	<b>D</b>	<b>F</b>	<b>F</b>
MEETS MANY EXPECTATIONS	MEETS MINIMAL EXPECTATIONS	MEETS FEW EXPECTATIONS	MEETS FEW EXPECTATIONS	FAILS TO MEET EXPECTATIONS	FAILS TO MEET EXPECTATIONS

## SUMMARY OF ASSESSMENT

A catastrophic biological event in the United States would quickly overwhelm the capacity of an already-stressed health care system. Although there has been progress over the past decade, there is not yet a comprehensive approach to emergency medical response—from the individual citizen, through the first responder emergency medical system (EMS), to emergency departments, hospitals, and alternate sites of medical care. Although evidence suggests that a better-prepared, informed citizenry can reduce demand on hospital-based services during a crisis, currently there is minimal public investment in demand-reduction strategies. There has been incremental, but to date, insufficient progress in developing crisis standards of care. Federal medical resources and capabilities, including those residing in the Veteran’s Administration (VA), Department of Defense (DoD), and Department of Health and Human Services (HHS), have not been fully coordinated and exercised to support response to a large-scale biological disaster.

## A catastrophic

biological event would quickly overwhelm the capacity of the traditional **health care system...**

## MEDICAL MANAGEMENT & RESPONSE METRICS

### Question 1:

*Is the nation's health system prepared to handle the surge of patients that would result in the event of a potentially catastrophic bioterror attack or infectious disease outbreak?*

#### Answer:

No. A number of previous reports have concluded that a catastrophic biological event would quickly overwhelm the capacity of America's health care system. Although hospital surge capacity might reach 20 percent, some experts suggest that a large-scale bioterror attack could require 1,000 percent of present capacity. A large-scale attack in an American city could infect tens of thousands who would require medical care—and generate up to 10 times that number of “worried well” seeking care. Unique aspects of bioterrorism, including associated psychological trauma and a potential for “reload” attacks, could amplify work force shortages and other challenges associated with medical response during disasters.<sup>1</sup>

### Question 2:

*Is there a lead federal agency for emergency care preparedness and response, including medical and public health response to acts of bioterrorism?*

#### Answer:

Yes. Under Emergency Support Function 8 (ESF-8), as described in the National Response Framework (NRF), HHS is the lead for all medical and public health preparedness and response—including bioterrorism. The HHS Assistant Secretary for Preparedness and Response (ASPR) is the lead office for medical preparedness and response, and the CDC Office of Public Health Preparedness and Response is the lead for public health preparedness and response. The ASPR has administrative and operational control of the National Disaster Medical System (NDMS), which is composed of deployable medical and related support teams. The ASPR also oversees the Hospital Preparedness Program that provides grants to private and public hospitals for improving their disaster preparedness and potential surge capacity.

Federal roles and responsibilities supporting medical preparedness and response are less clear when considering the pre-hospital emergency medical care provided by local EMS. EMS is under the aegis of the Department of Transportation (DOT), which maintains a small office in its National Highway Traffic Safety Administration. Although one-third of the nation's first responders are EMS professionals, EMS receives scant federal grant support from DOT, HHS, or DHS. In addition, the Federal Emergency Management Agency (FEMA) (within DHS) manages a contract to secure contingency ambulance support in the event of a declared Stafford Act disaster or public health emergency.<sup>2</sup>

### Question 3:

*Is the federal government's approach to emergency care sufficiently broad—does it extend beyond hospital and public health preparedness to leverage the full range of medical and community resources?*

#### Answer:

No. Federal efforts and associated grants have focused largely on building hospital and state/local public health surge capacity. Despite this federal support, however, urban and rural emergency medical care systems are barely managing day-to-day demand. Medicare does not adequately reimburse the costs of EMS, particularly in rural areas.

Worsening access to primary care is driving over-utilization of emergency departments (EDs); crowded EDs lead to frequent ambulance diversions, and lack of on-call hospital staff hinders rapid expansion of bed capacity. Hospital acquired infections are a significant challenge, and hospitals have extremely limited isolation capacity. Efforts to foster regional health care coalitions to coordinate emergency care and share resources during disasters are promising, but under-developed.<sup>3</sup>

State and local public health agencies have significantly improved their emergency preparedness training, with support from the Public Health Emergency Preparedness grant program and pandemic influenza preparedness grants. Unfortunately, these preparedness gains are now threatened by public health budget cuts, furloughs, and layoffs—and an aging public health workforce. The combination of these factors is rapidly undermining the gains of the past decade, and represents a serious threat to public health emergency preparedness and response capabilities at the state and local level.<sup>4</sup>

The medical community has demonstrated the ability to manage small-scale bioterrorism, like the 2001 anthrax letters. But in a large scale or catastrophic scenario, it is likely that medical assistance would be required from a broad array of professional and lay responders, many of whom will be drawn from outside the traditional hospital and medical community. Currently there are limited efforts to optimize the role of EMS pre-hospital emergency services or the capabilities of health-related service organizations, faith-based groups, or other private sector entities that could augment an overwhelmed medical system. Currently, members of such organizations are not optimally trained, organized, or equipped to serve.<sup>5</sup>

## Preparedness

gains are now  
**threatened** by  
public health budget  
cuts, furloughs and  
layoffs—and an  
aging public health  
workforce.

### Question 4:

*Have the medical response capabilities resident in the federal government been effectively resourced, mobilized, and managed?*

#### Answer:

No. Although there has been progress, more is needed to effectively mobilize and integrate the full range of federal medical resources (ASPR/NDMS, CDC, Public Health Service (PHS), DoD, VA) to ensure both timely and effective deployment of assets in a large-scale bio-emergency. For example, the VA is the largest health provider in the United States, but has yet to act on the authorities specified by the Pandemic and All Hazards Preparedness Act of 2006 to organize, train, and equip the VA to support HHS and NDMS in the event of declared national disasters and public health emergencies.<sup>6</sup>

### Question 5:

*Are there mechanisms to coordinate federal, state, and local engagement in a biodefense response? Have there been exercises to test the adequacy of this plan?*

#### Answer:

Yes, mechanisms do exist, but testing has been inadequate. The NRF is the formal mechanism to guide intergovernmental coordination and response to all types of large-scale disasters, including a biological attack. Below that level, there are several organizations, grants, and programs to promote intergovernmental and interagency coordination. Ten regional HHS/ASPR coordinators have facilitated greater involvement and coordination of federal state and local agencies. There have been few exercises, however, to rigorously test the ability of federal, state, and local, medical and public health and non-government providers to coordinate their efforts in response to a bioterrorist attack.

**Health Alert Network** has been used many times over the past several years and has **proven quite effective** in delivering official information to the right people within public health—but to a lesser extent, health care providers.

**Question 6:**

*Is there an interagency process in place to draft and rapidly disseminate “just in time” guidance to public health, clinical, and health system officials following a bio-attack?*

**Answer:**

Somewhat. CDC has a process through its Health Alert Network (HAN) to rapidly deliver clinical and public health information to health departments, hospitals, and to some extent, clinicians. This system has been used many times over the past several years and has proven quite effective in delivering official information to the right people within public health—but to a lesser extent, health care providers. One limitation is the challenge of reaching busy clinicians with fast-breaking information. Conventional communication channels like mail, faxes, and even e-mail don’t work well, given the volume of messages directed at doctors each day. Another limitation is that the health care information clinicians will need shortly after a bio-attack may not exist. Because there is very limited clinical experience with diseases normally associated with bioterrorism, clinical guidance may boil down to the best judgments of “experts.” Even then, there may not be consensus.

During the 2009 H1N1 pandemic, CDC put together a “Team B” panel of experts to advise the CDC on care recommendations. That process could be refined and used to pre-designate panels of non-government experts to help the federal government develop practical guidance where no clear-cut answer exists.<sup>7</sup>

**Question 7:**

*Do citizens possess the basic knowledge and competencies to take appropriate early actions in the event of a bioterror attack? Do they know where to get reliable information about a developing public health threat and when and where to seek appropriate care?*

**Answer:**

No. Most citizens do not have basic knowledge about bioterror threats and response. CDC has developed a web page with information available in multiple languages about seven likely bioterror agents. These fact sheets address the most common questions about the nature of the disease, its infectivity, and possible treatments. It isn’t clear, however, how citizens, particularly those with limited health literacy, would use this information in a large-scale emergency.

There is limited information about self-care or family protection from the threat of bioterrorism. One useful source is Ready.gov. There are no clear-cut recommendations, however, about the advisability of staying indoors, whether or when to evacuate, or what physical protective measures citizens should take for respiratory protection.<sup>8</sup>

**Question 8:**

*Are there core competencies, standards of care, and standards for disaster health education and training related to bioterrorism for doctors, nurses, allied health professionals, emergency medical service providers, and support staff? Does this training address specialty care needs of at-risk populations, such as children?*

**Answer:**

Yes. In 2007, the American Medical Association (AMA) convened a cross-disciplinary expert working group that reviewed the competencies health care professionals at various levels of training need to respond to disasters and health emergencies, including bioterrorism. The group published a consensus framework and

competency set in 2008, which educators have used to devise learning objectives and curricula for various health professionals.

Using these tools, the National Disaster Life Support Education Consortium (NDLS) has developed courses stressing a comprehensive, “all-hazards” approach, to help health professionals responding during catastrophic emergencies. This training recognizes the specialty care needs of all ages and populations, including children. The goal is to teach a common lexicon, vocabulary, and standardized curriculum that is practical and relevant for health professionals at all levels.

Currently, the AMA is working with a multi-disciplinary stakeholder group to further refine core competencies in disaster medicine and public health. The final results of this effort will be presented to the Federal Education and Training Interagency Group (FETIG) in fall 2011.<sup>9</sup>

### Question 9:

*Are there adequate clinical guidelines and legal protections to help health systems adopt crisis standards of care when necessary?*

#### Answer:

Not yet. The Institute of Medicine (IOM) of the National Academies offered some useful guidance in its 2009 report, and is expected to publish updated guidelines in early 2012. The consensus study will include metrics and templates for states, EMS, hospitals, and individuals to guide decision making when implementing crisis standards of care. In addition, the Agency for Healthcare Research and Quality (AHRQ) is sponsoring a comprehensive review to identify the best available evidence on effective strategies for allocating scarce resources during mass casualty events.

### Question 10:

*Is there legal liability protection for individuals, private entities, businesses, and non-profit stakeholders that volunteer resources or personnel during disasters? Do liability protections cover pre-event planning and training activities?*

#### Answer:

There are some protections, but legal liability remains a significant barrier to engaging and using business and non-government entities to their full potential.<sup>10</sup>

The Public Readiness and Emergency Preparedness Act (PREP Act) provides tort liability protection to individuals and entities “involved in the development, manufacture, testing, distribution, administration, and use of countermeasures”—when the Secretary of HHS declares that a disease, threat, or conditions constitute a present, or credible risk of a future public health emergency.<sup>11</sup> The PREP Act does not extend liability protection to other aspects of medical response.

Currently, there is no federal Good Samaritan law to protect individuals, businesses, and non-profit entities that respond to a public health disaster or biological attack. Some, but not all states have Good Samaritan laws that broadly apply to life threatening emergencies. Although the lack of federal liability protection and the lack of uniformity across states probably would not deter many healthcare workers and organizations from volunteering during a disaster, there is widespread concern that it discourages many businesses, NGOs, and individual healthcare workers from volunteering and practicing in advance, perceiving that doing so will increase their liability in any subsequent event.<sup>12</sup>

## Legal liability

remains a significant barrier to engaging and utilizing business and non-government entities to their **full potential.**



## Question 11:

*Are adequate financial mechanisms in place to sustain key organizations and institutions during a large-scale incident?*

### Answer:

No. Without adequate and timely allocation of disaster funding, important elements of a biodefense response will be hampered and/or delayed. The existing processes for approving and allocating funding in large-scale emergencies could be streamlined without sacrificing accountability. Because the majority of the response to any incident takes place at the state and local level, it is critical that the federal government be able to disburse funds quickly to supplement state and local resources and support local response activities. The mechanism for obtaining and distributing funds to states during the response to H1N1 took far too long, was burdensome to states, and lacked flexibility. New mechanisms are needed to strike an appropriate balance between accountability and speed to support rapid and decisive action at the state and local level.<sup>13</sup>

### Notes

- <sup>1</sup> Richard J. Danzig, Rachel Kleinfeld, and Philipp C. Bleek, *After an Attack: Preparing Citizens for Bioterrorism* (Washington, D.C.: Center for New American Security, June 2007), [http://www.cnas.org/files/documents/publications/DanzigBleekKleinfeld\\_Bioterror\\_June07.pdf](http://www.cnas.org/files/documents/publications/DanzigBleekKleinfeld_Bioterror_June07.pdf).
- <sup>2</sup> *Emergency Medical Services: The Forgotten First Responder* (New York: New York University, Center for Catastrophe Preparedness and Response, December 2004), <http://www.nyu.edu/ccpr/NYUEMSreport.pdf>.
- <sup>3</sup> Eric Toner and Amesh Adalja, "Preparing Hospitals for Large-Scale Infectious Disease Emergencies," *Crossroads in Biosecurity: Steps to Strengthening U.S. Preparedness*. (Baltimore, MD: Center for Biosecurity UPMC, September 20, 2011), <http://www.upmc-biosecurity.org/website/resources/publications/2011/pdf/2011-09-08-Crossroads-in-Biosecurity.pdf>.
- <sup>4</sup> *Local Health Department Job Losses and Program Cuts: Findings from January 2011 Survey and 2010 National Profile Study*, Research Brief (Washington, D.C.: National Association of County and City Health Officials (NACCHO), June 2011), <http://www.naccho.org/topics/infrastructure/lhdbudget/loader.cfm?csModule=security/getfile&PageID=198106>.
- <sup>5</sup> *Hospital-based Emergency Care: At the Breaking Point*, Institute of Medicine: Consensus Report, (June 13, 2006), <http://www.iom.edu/Reports/2006/Hospital-Based-Emergency-Care-At-the-Breaking-Point.aspx>.
- <sup>6</sup> Interviews with former senior Administration official and Senate professional staff, July 20-21, 2011.
- <sup>7</sup> Interview with former "Team B" member, July 2011.
- <sup>8</sup> D.A. Henderson, "Post 9/11 Challenges of a Crisis," *A Crossroads in Biosecurity: Steps to Strengthen U.S. Preparedness* (Baltimore, MD: Center for Biosecurity UPMC, September 20, 2011), <http://www.upmc-biosecurity.org/website/resources/publications/2011/pdf/2011-09-08-Crossroads-in-Biosecurity.pdf>.
- <sup>9</sup> The Center for Public Health Preparedness and Disaster Response, American Medical Association, <http://www.ama-assn.org/ama/pub/physician-resources/public-health/center-public-health-preparedness-disaster-response.page>.
- <sup>10</sup> Interviews with numerous senior corporate executives.
- <sup>11</sup> *Public Readiness and Emergency Preparedness Act Declarations* (February 8, 2011), <http://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx>.
- <sup>12</sup> *Ready or Not? Protecting the Public's Health from Diseases, Disasters and Bioterrorism*, (Washington, D.C.: Trust for America's Health, December 2009), p. 34-6, <http://healthyamericans.org/reports/bioterror09/pdf/TFAHReadyorNot200906.pdf>.
- <sup>13</sup> *Ready or Not? Protecting the Public's Health from Diseases, Disasters, and Bioterrorism*, (Washington, D.C.: Trust for America's Health, December 2010), p. 36-37, <http://healthyamericans.org/assets/files/TFAH2010ReadyorNot%20FINAL.pdf>.



# ENVIRONMENTAL CLEANUP

## DEFINITION

Environmental cleanup is the remediation of a contaminated area after a biological event, as required to protect public health and welfare. Because anthrax is the only persistent biological agent likely to be used in an attack, this report assesses capability to respond to a small-scale event (like the anthrax letters of 2001) and a large-scale event (2006 National Planning Scenario—Anthrax).



## FUNDAMENTAL EXPECTATIONS

- Capability to manage environmental consequences of a large-scale release of aerosolized anthrax
- An integrated, tested plan for environmental remediation
- Environmental cleanup standards defined, transparent, and feasible
- Provisions for long-term environmental and public health monitoring to assure the continued safety of the population
- Responsibility clearly defined for the costs of cleaning up privately owned property

## EVALUATION

SMALL-SCALE NON-CONTAGIOUS	SMALL-SCALE CONTAGIOUS	LARGE-SCALE NON-CONTAGIOUS	LARGE-SCALE CONTAGIOUS	LARGE-SCALE DRUG RESISTANT	GLOBAL CRISIS CONTAGIOUS
<b>B</b>	NOT APPLICABLE	<b>F</b>	NOT APPLICABLE	<b>F</b>	NOT APPLICABLE
MEETS MANY EXPECTATIONS		FAILS TO MEET EXPECTATIONS		FAILS TO MEET EXPECTATIONS	

## SUMMARY OF ASSESSMENT

An integrated, tested environmental remediation plan for wide-area anthrax cleanup does not currently exist. The federal government has recently released interim guidance addressing federal, state, and local roles in environmental remediation following a wide-area anthrax attack, but the document does not address all outstanding questions—such as evacuation and long-term health issues. No remediation plans have yet been tested in a national level exercise. There is currently no consensus-based outdoor or indoor clearance policy to establish safety standards. There is no policy defining responsibility for the cleanup costs of privately owned facilities. Without the ability to clean up after an anthrax event, even an unsophisticated attack could produce an effective area-denial weapon with enormous economic consequences.

Remediation plans for anthrax have never been tested in a national level exercise.

## ENVIRONMENTAL CLEANUP METRICS

### Question 1:

*Does the federal government have an integrated, tested plan for wide-area environmental remediation following a biological attack? Is the plan clear, directive, and transparent?*

### Answer:

An integrated, tested plan does not exist. In May, 2009, under the auspices of the White House Office of Science and Technology Policy, the Department of Homeland Security (DHS) and the Environmental Protection Agency (EPA) published “Draft Planning Guidance for Recovery Following Biological Incidents.”<sup>1</sup> Subsequently, on May 17, 2011, nearly 10 years after the anthrax cleanup at the U.S. Capitol and Brentwood postal facility, DHS published the Interim Consequence Management Guidance for a Wide-Area Biological Attack. The guidance was developed through the Interagency Biological Restoration Demonstration (IBRD) program, a collaborative effort of DHS and other federal agencies and laboratories, with involvement from some Seattle area and Washington State agencies. From this guidance, federal, state, and local partners have developed a regional plan that has been tested in Seattle, and another to be tested in Denver.

The guidance document does not address all outstanding questions on remediation, but provides a roadmap for continued work in this area. For indoor and outdoor decontamination, it recognizes current technological and lab capacity limitations and specifically points out sampling and analytical limitations.<sup>2</sup>

### Question 2:

*Are the roles and responsibilities of the federal agencies clearly defined and understood within the interagency community for cleanup operations following a biological attack?*

### Answer:

Yes. Federal agency roles and responsibilities are clear, but only at the strategic level. The National Response Framework (NRF) provides guidance to federal agencies about their potential involvement in remediation response; however, roles of specific offices or individuals are not identified.

### Question 3:

*Have the cleanup operational procedures been tested during national level exercises?*

### Answer:

No. Remediation plans for anthrax have never been tested in a national level exercise.<sup>3</sup>

### Question 4:

*Has the research and development program identified and certified the operational procedures and products required for an anthrax cleanup?*

### Answer:

Not yet. The Interim Consequence Management Guidance from IBRD provides a set of procedures and a list of potential technologies that may be used to decontaminate various environments. In 2010 the Bio-Response Operational Testing and Evaluation Project began work to determine the best methods to cleanup outdoor environments, water resources, and water-distribution systems. No certified operational procedures and products exist.<sup>4</sup> Without the ability to clean up after an anthrax event, even an unsophisticated attack could produce an effective area-denial weapon with enormous economic consequences.

**Question 5:**

*Is responsibility clearly defined for the costs associated with the cleanup of privately owned facilities?*

**Answer:**

No. Responsibility for the cleanup of privately owned facilities has not been defined. In a large-scale biological attack, the President would likely declare a Major Disaster under the Stafford Act. This could provide some federal funding to cover losses. It is unclear, however, how much money would be provided to private-entities. Federal assistance is typically limited to \$5 million per disaster under the Stafford Act, although this limit can be raised at the President's discretion.<sup>5</sup>

Some businesses may have insurance that covers terrorism and other catastrophic events. Many insurance policies, however, will not provide such coverage. The cost of remediation may also be so high that insurance will not be able to reimburse losses. The roles, responsibilities, and needs of the private sector have not been adequately addressed.

**Question 6:**

*Are there standards for environmental remediation clearance levels, and if so, are they sufficient? (How clean is safe?)*

**Answer:**

There is currently no consensus-based outdoor or indoor clearance policy for a wide-area attack. In 2001, the policy for anthrax clearance was zero viable anthrax spores, and no new policy has been adopted since. This clearance policy would be impossible to meet in a wide-area attack. Therefore, alternative clearance policies must be established.

There are key gaps in knowledge of the risks associated with long-term indoor exposure to anthrax contamination, and limited understanding about the dynamics of outdoor contamination. The consensus is that clearance decisions will be site-specific and might be based on recommendations made at the time of an incident by local, state or federal Environmental Clearance Committees (ECC) convened in an emergency.

The Interim Guidance provides a list of recommendations for clearance in the event that an attack happens tomorrow. There must be additional research, however, into anthrax infectivity and re-aerosolization dynamics to inform the public health risk assessment and clearance process.

**Question 7:**

*What are the metrics for consideration of economic impacts to determine if and how to recover large-scale contaminated areas?*

**Answer:**

The WMD Center is unaware of any comprehensive evaluation of the potential economic effects of an anthrax attack and the costs associated with remediation. The primary drivers of remediation have been based on public health rather than economic considerations. Some IBRD tools in the Interim Consequence Management Guidance, however, do take cost into consideration when it recommends decontamination approaches.

Without the ability to clean up after an **anthrax event**, even an unsophisticated attack could produce an effective area-denial weapon with enormous **economic consequences**.

There is currently no consensus-based outdoor or indoor clearance policy for a **wide-area attack**.

**Question 8:**

*Do plans provide guidance on the issue of evacuation following an anthrax attack?*

**Answer:**

No. The Interim Consequence Management Guidance document mentions evacuation as a “key decision with important implications,” but it leaves the decision-making about evacuation up to state and local officials. No guidance is provided on this issue.

**Question 9:**

*Are there plans in place for use of anthrax vaccine in addition to, or as an alternative to anthrax remediation?*

**Answer:**

The WMD Center was unable to determine if any such plan exists. The use of vaccine has been considered, particularly for scenarios involving anthrax releases in subway systems where cleanup could take months or even years. Operational considerations make this alternative problematic considering the current anthrax vaccine requires five doses over an 18-month period as a pre-exposure prophylactic.

**Question 10:**

*Have capabilities for small-scale, indoor cleanup of anthrax improved during the past decade?*

**Answer:**

Yes, considerably. Significant research and testing using an anthrax simulant have repeatedly demonstrated the capability for environmental restoration of small buildings. A small-scale attack using limited quantities of dry-powdered anthrax (amounts equal to that released in October 2001) would likely be cleaned up at far less cost and in far less time than experienced during the response to the anthrax letters. This capability requires placing a tent over the building, and therefore, would be of no value to large-scale, outdoor releases.<sup>6</sup>

**Notes**

- <sup>1</sup> Biological Decontamination Standards Working Group, The White House National Science and Technology Council (May 2009), p. 80–3, <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-ORD-2009-0331-0002>.
- <sup>2</sup> Multiple interviews with current and former senior U.S. government officials, May–August 2011.
- <sup>3</sup> Ibid.
- <sup>4</sup> Ibid.
- <sup>5</sup> Elizabeth B. Bazan, Robert T. Stafford Disaster Relief and Emergency Assistance Act: Legal Requirements for Federal and State Roles in Declarations of an Emergency or a Major Disaster (Washington, D.C.: Congressional Research Service, September 16, 2005), <http://fpc.state.gov/documents/organization/53688.pdf>.
- <sup>6</sup> Multiple interviews with current and former senior U.S. government officials, May–August 2011.

# STRATEGIC PRIORITIES

## CLEARLY, AMERICA'S PREPAREDNESS TO RESPOND TO SMALL-SCALE BIO-EVENTS HAS IMPROVED IN MANY OF THE CATEGORIES ASSESSED FOR THIS REPORT.

This is true even in some categories that still fail to meet fundamental expectations. There are generally higher marks (Bs and Cs) for small-scale events, in part because resource coordination, communication, and collaboration are easier to accomplish on a local or regional basis—especially when encouraged with federal support. Response capabilities for large-scale bio-events, however, remain largely inadequate to meet fundamental expectations.

Conventional wisdom might suggest that leaders focus public resources on those bio-response categories receiving failing

(red) grades—especially those relative to large-scale drug resistant and global crisis scenarios (mostly Fs). The very nature of these two worst-case scenarios is distinct from other large-scale contagious or non-contagious events—primarily due to lack of medical countermeasures. By definition, they largely preclude an effective response with current capabilities. Improving these grades, even marginally, would require dedicating most available resources to the most daunting, but least common contingencies.

## RECOMMENDED AREAS FOR IMPROVEMENT

CONCENTRATING EFFORTS ON LARGE SCALE EVENTS RATHER THAN WORST-CASE SCENARIOS WILL GENERATE THE BEST RETURN ON INVESTMENT IN THE NEAR TERM.

	LARGE-SCALE		TREND	SMALL-SCALE	SMALL-SCALE	LARGE-SCALE	LARGE-SCALE	LARGE-SCALE	GLOBAL CRISIS
	NON-CONTAGIOUS	CONTAGIOUS		NON-CONTAGIOUS	CONTAGIOUS	NON-CONTAGIOUS	CONTAGIOUS	DRUG RESISTANT	CONTAGIOUS
DETECTION & DIAGNOSIS	D	D	↗	C	C	D	D	F	F
ATTRIBUTION	F	F	→	D*	F	F	F	F	F
COMMUNICATION	C	C	↗	B	B	C	C	C	C
MEDICAL COUNTERMEASURE AVAILABILITY	D	D**	↗	B	B	D	D**	F	F
MEDICAL COUNTERMEASURE DEVELOPMENT & APPROVAL PROCESS	D		→	D		D		D	
MEDICAL COUNTERMEASURE DISPENSING	D	D	→	B	B	D	D	F	F
MEDICAL MANAGEMENT	D	D	→	B	C	D	D	F	F
ENVIRONMENTAL CLEANUP	F	NOT APPLICABLE	→	B	NOT ASSESSED	F	NOT APPLICABLE	F	NOT ASSESSED

The **best return on investment**, in terms of cost, feasibility, national security, and saving lives is to change the Ds to Cs on the **next report card**.

Alternatively, the WMD Center recommends that policymakers concentrate their efforts and resources on strengthening response capabilities required for large-scale contagious and large-scale non-contagious events (mostly Ds). These scenarios are more likely, but moreover, it is possible to improve these grades in the relative near-term. Strengthening the nation's preparedness and response capabilities for large-scale events will significantly improve the grades (response capabilities) for small-scale biological events, as well. The best return on investment, in terms of cost, feasibility, national security, and saving lives is to change the Ds to Cs on the next report card.

Based on the deficiencies identified in this assessment, the WMD Center recommends concentrating our bio-response efforts on the following three strategic priorities:

- Leadership that inspires confidence, commitment, and unity of effort;
- Mobilizing a “whole of nation” bio-response capability; and
- Sustained investment in purpose-driven science.

## LEADERSHIP

“Leaders matter. Leaders prioritize, set goals, and define the mission.”

—National Biodefense Science Board Report March 2010

Developing the nation's capabilities to respond to a large-scale bio-event requires capable and informed leadership at all levels of government. The biotech revo-

lution, its global diffusion, and its potential for misuse can radically change the global security equation. America needs leaders who understand the 21st century threat of bioterrorism and how it is fundamentally different from other threats. America needs leaders who will set clear priorities within the bio-response enterprise; assign authority; demand accountability; and inspire the confidence, commitment, and unity of effort necessary to strengthen bio-preparedness and response capabilities nationwide.

Some have argued that biodefense requires more centralized federal leadership. In May 2009, the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism (WMD Commission) recommended the Vice President serve as the leader for all WMD defense programs, including biodefense. Others have recommended reinstating a Special Assistant to the President for Biodefense, as existed during the Administrations of Presidents Bill Clinton and George W. Bush; or that the President designate a cabinet secretary to serve as the lead for all biodefense-related programs. And the most common recommendation—that Congress consolidate oversight responsibility to fewer committees—continues to be ignored.

One or more of these actions might help answer the question, “Who's in charge?” but none would necessarily resolve the underlying problem: Too few leaders in government or the private sector fully understand the growing threat of bioterrorism—and its potential consequences. The nation's ability to prepare for and respond to a large-scale biological event requires in-

formed leadership at every level of government. This deficiency is more fundamental than a wiring diagram.

Convincing any government official or corporate executive to focus on a relatively unknown threat, or one they consider highly improbable, is challenging—especially when so many immediate demands are competing for their attention. Bio-response is a complex enterprise. Small, inexpensive steps, however, could help. For example, if the Office of Management and Budget were to illustrate an integrated bio-defense budget—in much the same way it does for cyber-security and nuclear security—it could enable members of Congress to make better-informed decisions about biodefense spending and priorities.

Leaders can be educated and trained in this regard. Government and professional associations that provide orientation and issue briefs to newly elected public officials should include biodefense as a component of public health, homeland security, and emergency management. Programs like the Meta-Leadership initiative, co-sponsored by the Center for Disease Control and Prevention (CDC) Foundation and the Harvard School of Public Health, prepare business, government and non-profit leaders to work effectively together during a public health or safety crisis.

Leadership is also about setting clear priorities. Interagency rivalries, silos, and competition for funding are legendary, but can be effectively contained by the clear direction of a President, a governor, or a mayor willing to demand accountability for results.

Effective leadership is the great enabler that can take the nation from being marginally prepared today, to effectively prepared tomorrow. Leadership before, during, and following a large-scale biological event may well be the difference between national catastrophic loss and the strengthening of a resilient nation. No single element is more necessary to confront this threat.

### MOBILIZING “WHOLE OF NATION” BIO-RESPONSE CAPABILITY

Some might interpret the seven different bio-response categories identified by our experts as independent needs. That would be a mistake. The complexity of the biodefense enterprise demands that they all be regarded as essential parts in a single enterprise. The WMD Commission used the analogy of links in a chain—if one link is broken, the chain fails (see page 62).

Each of the defined response categories is integral to ensuring the nation’s resilience to biological threats. And each category requires the orchestration of a varied set of stakeholders, providers, and resources to achieve its objectives and meet fundamental expectations.

The nation’s ability to manage disasters has demonstrated significant improvement over the past decade. It follows a growing emphasis on local and regional capacity building by engaging all sectors of society. Across the nation, many communities have self-organized to become more resilient to disasters and other disruptions that threaten their economic vitality, public safety, and quality of life. In

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recent years, FEMA has actively engaged a broader range of interagency and non-federal partners across jurisdictions, disciplines, industry sectors, and non-profit service providers, to strengthen all-hazards resilience. This whole community approach to national emergency management is sound and should be sustained.

There are, however, unique aspects of a bioterrorism attack or a deadly disease pandemic that are not addressed by an all-hazards approach. Unlike other threats and hazards, biothreats could affect all parts of the nation and all of society, simultaneously. And, by their very nature, they could render some of the tenets of emergency management, such as regional mutual aid, either impractical or impossible.

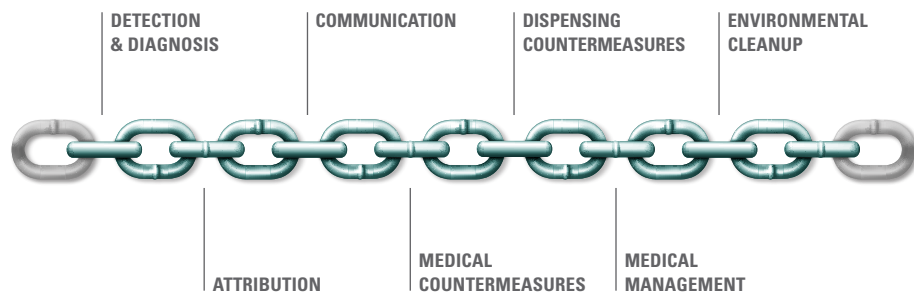
The fear of contagion, or in the case of terrorism, multiple attacks, would exacerbate the challenges associated with responding to any disaster scenario. Transportation and logistics, resource sharing, workforce shortages, medical care, critical infrastructure assurance—these and other aspects of response would be uniquely difficult in

a biological event. Additionally, biological event response may require unique medical countermeasures and mechanisms to dispense medications to large populations within a matter of hours. Consequently, bio-response requires a more unified whole of nation approach than any other national level threat or hazard.

In an era of economic instability and budget constraints, it has never been more important to identify and mobilize the nation’s collective capabilities and resources to greatest effect. A response to a large-scale biological event must bring to bear private sector resources, capabilities and expertise that complement those of government.

For example, hospitals are increasingly organizing self-governed, regional coalitions that better coordinate hospital resources and requirements during disasters. In several states, public-private partnerships have created resource registries of business-owned equipment, facilities, and skilled personnel that can be requested by government officials during disasters. Many states now have a private-sector seat in their

## RESILIENCE CHAIN





emergency operations centers to ensure better communication and resource coordination with the private sector.

Partnerships between FEMA and “big box” retailers have been significantly expanded. By rapidly confirming which stores in disaster-affected communities are operational and able to provide access to basic necessities, FEMA can direct its limited resources to areas where the need is greatest.

Should there be the need to dispense medical countermeasures to large populations, local public health would have only a small fraction of the personnel required to staff points of dispensing (POD). By agreeing to set up a closed POD (limited to a specific population) on a corporate campus or in a federal office building, large employers can simultaneously provide the countermeasures to employees and their families, while reducing the demand on public PODs.

Unity of effort and public-private collaboration are force-multipliers across the entire range of bio-response activities. But they require leadership and modest strategic investment.

To effectively enlist a whole of nation effort toward meeting this challenge, the federal government must address some of the remaining legal and regulatory barriers that impede inter-governmental/interagency coordination and discourage the private sector from partnering with government.

For example, many states have adopted credible entity liability protection during

emergencies—extending Good Samaritan protection to business and non-profit organizations that provide critical support during disaster response. A patchwork of such laws across the country, however, makes it much more difficult for regional or national organizations to develop a single voluntary emergency assistance policy. Enacting a uniform federal approach to this issue makes sense.

It is also important to provide legal protections and guidelines for institutions and providers to plan for modified standards of care in a crisis, should mass casualties overwhelm available medical resources.

Although government will surely play a critical role in responding to a large-scale biological disaster, a well-informed, prepared citizenry is a critical component of the bio-response enterprise. The federal government has neither the means, nor the authority to supplant the responsibility of individual citizens and local communities.

It is most often untrained family members, colleagues, or bystanders who are the first responders in any emergency, and even basic first aid training and preparedness can significantly reduce demand on critical government response services. Government should provide citizens the information and tools to prepare for biological threats.

This report has already identified the fact that new PPD-8 and draft National Preparedness Goals identify a single mega-disaster scenario as a start point for setting national preparedness goals and for measuring preparedness. The

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A **bio-response enterprise** without adequate medical countermeasures is like an **Army without bullets**—it may look good on a parade ground, but **has minimal value** for national security.

scenario identified, however, does not share all the critical aspects of a major biological event, such as nationwide attacks, multiple attacks, threat of attacks over time, and contagion. Any or all of these factors could cause the workforce to stay home, threaten the mobility of people and resources, and interrupt every element of critical infrastructure.

The great power of “whole of nation” is the recognition that the collective resources and capabilities resident in communities nationwide far exceed what can be mobilized by the federal government alone.

America’s response and resilience to a large-scale biological disaster must be built from the ground-up. The federal government must be more inclusive in its efforts to improve national preparedness and response—trusting citizens in local communities with more information, and ensuring that federal policy is informed by ground truth.

Federal hospital and public health preparedness programs should guide local efforts; local officials, however, need greater funding flexibility to address local/regional priorities during disasters. There is no top-down, one-size-fits-all solution.

In an era of funding constraints, Congress needs to make informed funding decisions, as opposed to across-the-board reductions. The Poison Control Centers are a case in point. There are 57 Poison Control Centers that cover 100% of the population, with a single toll-free telephone number, staffed 24-hours a day, seven

days a week. More than 70 percent of the calls received each year by the centers are resolved without referring the subject to a hospital or outside health care provider. The Institute of Medicine has estimated that every dollar spent on U.S. poison centers saves up to \$10 in avoided health-care costs each year. They offer the potential to play a significant triage role during a large-scale biological disaster, reducing demand on overwhelmed healthcare systems. And yet, the modest federal portion of their funding was reduced by 25% in FY 2011 and remains at risk of further cuts.

## SUSTAINED INVESTMENT IN PURPOSE-DRIVEN SCIENCE

“Advances within the life sciences hold extraordinary potential for beneficial progress, but they can also empower those who would use biological agents for ill purposes.”

—President Barack Obama, November 23, 2009

The WMD Center agrees with President Obama’s assessment—the biotech revolution is a double-edged sword. Life sciences hold great promise for the future, but we now live in a world where bioterrorism has the technical advantage over biodefense, thereby creating an incentive for developing and using bioweapons.

It would be optimal to increase funding in many areas of science related to bio-response. But when resources are limited, there must be priorities. Consistent with this report’s observation that our best return on investment is to

concentrate on shifting orange to yellow and Ds to Cs in our evaluation, adequate and sustainable funding should be focused first in the following areas of purpose driven science:

- Medical countermeasures, especially for advanced development and regulatory science;
- Environmental remediation; and
- Bioforensics research.

## MEDICAL COUNTERMEASURE DEVELOPMENT

Based on years of experience with advanced development of drugs and vaccines for naturally occurring diseases, the WMD Commission concluded in January 2010 that the Biomedical Advanced Research and Development Authority (BARDA) had been significantly underfunded since its creation in 2006. Further analysis by the WMD Center confirms this earlier assessment. Congress and the Administration should not expect major success from an organization that is grossly underfunded for its mission. A bio-response enterprise without adequate medical countermeasures is like an Army without bullets—it may look good on a parade ground, but has minimal value for national security.

Another neglected area of medical countermeasure development is regulatory science—the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products. Regulatory science is particularly important

for medical countermeasures because clinical testing for efficacy often cannot be conducted in humans. New scientific processes are required, such as the animal model and perhaps supercomputing, to test the safety and efficacy of medical countermeasures for pathogens like smallpox, plague, and tularemia. Without a timely and effective approval process, all is for naught.

Not only has Food and Drug Administration (FDA) been underfunded for its biodefense mission, funding has varied widely from year to year. FDA cannot build a successful medical countermeasure program with one-year funding. Priority must be placed on creating mechanisms for long-term funding of FDA research, the same way the Department of Defense provides long-term funding for weapons development.

Likewise, BARDA has great difficulty recruiting large pharmaceutical companies into the medical countermeasure enterprise. The BioShield Strategic Reserve Fund was created by Congress in 2004 to address this problem by ensuring availability of funding to purchase medical countermeasures. This fund, however, has been raided and threatened with diversions for unrelated spending. Without a firm commitment from government to protect the “BioShield promise,” there is little chance of winning major commitments from large pharmaceutical companies.

Congress should ensure that additional BioShield funding is available and used only as intended, and provide new appro-

The nation does not yet have adequate **bio-response capability** to meet fundamental expectations during a **large-scale biological event**.

priations for FY 2014 and beyond. Equally important, the Administration should provide Congress a fully integrated and prioritized budget for the entire medical countermeasure enterprise (as recommended in the March 2010 report of the National Biodefense Science Board). Although it may be deemed too sensitive for public release, this integrated budget should clearly define priorities and timelines for specific diagnostic tools, vaccines and therapeutics. The many unknowns and scientific challenges of medical countermeasure development do not negate the requirement for clearly defined priorities, goals, and timelines to adequately measure progress.

### ENVIRONMENTAL CLEANUP

As described in the leadership and unity of effort sections above, significant progress is possible in many areas of bio-response that do not primarily depend on appropriations—of particular importance given current fiscal realities. Improving environmental remediation capabilities, however, depends on research and development (R&D), and that is directly linked to appropriations.

The good news is that a significant increase in appropriations for R&D in environmental remediation is not a big-ticket item. If current EPA funding for bio-remediation R&D programs were tripled, it would still be less than \$40 million per year.

The November 2009 National Security Council document quoted in the threat section of this report looked at the area-denial consequences of an anthrax attack and the current lack of capability for environmental remediation. It concluded that the economic cost could exceed one trillion

dollars for each such incident. A research program of \$40 million would provide extraordinarily good return on investment if America were to experience the type of bio-attack considered most likely in the 2006 National Planning Scenarios.

### ATTRIBUTION

Despite significant research over the past decade, attribution remains the weakest link in our response chain. Without attribution capability, there is little chance for deterrence; In fact, some argue it encourages using bioterrorism, even by nation-states. It also invites “false flag” operations where an attacker pretends to be someone else. This lack of capability also leaves America vulnerable to the reload scenario, where multiple attacks occur over an extended period of time because the attackers cannot be identified and apprehended.

Successful attribution requires three elements working in unison: law enforcement, intelligence, and microbial and technical forensics.

- The FBI has made great progress in the past decade working with CDC to improve the field investigation aspects of attribution; however, there is still the need for considerable improvements in information sharing, and it is important to develop nationally and internationally recognized standards;
- This is an unclassified report, therefore the WMD Center was not able to assess the intelligence community’s capabilities for the attribution mission; however, a Congressionally commissioned classified study was completed in 2011.

- The science of microbial forensics is immature and requires major improvements.

The WMD Center recommends that biological attribution be further examined by an independent organization, such as the National Academy of Sciences, to recommend where and how improvements can be made to this critical link in the bio-response chain.

## CONCLUDING THOUGHTS

Throughout the course of this study, the leadership of the WMD Center met with many senior-level officials throughout government and the bio-response enterprise. They are incredibly hard working and dedicated and they represent the very best America has to offer in the fields of biodefense, public health, medicine, and the biological sciences. Although their efforts have yielded considerable progress over the past decade, the nation does not yet have adequate bio-response capability to meet fundamental expectations during a large-scale biological event. ▾

## APPENDIX I

### BOARD OF ADVISORS TO THE WMD CENTER'S BIO-RESPONSE REPORT CARD

**RADM Kenneth Bernard, MD, (USPHS—Ret.),** has served in a series of senior policy positions in the United States government, including Special Assistant to the President for Biodefense and Special Advisor for Health and Security on the National Security Council Staff during both the Clinton and Bush (43) presidencies.

**Louise Gresham, PhD, MPH,** is the former Senior Epidemiologist for San Diego County's Health and Human Services Agency, and has extensive experience in managing infectious disease surveillance and response activities. She is currently the Senior Director of the Global Health and Security Initiative at NTI.

**Elin Gursky, MSc, ScD,** is the former Deputy State Health Commissioner for Public Health Prevention and Protection at the New Jersey Department of Health and Senior Services. Dr. Gursky is currently a Fellow and Principal Deputy for Biodefense at ANSER/Analytic Services, Inc., where she heads the Health Security Strategy and Systems portfolio.

**Dan Hanfling, MD,** is Special Advisor to the Inova Health System in Falls Church, Virginia. He also serves as an Operational Medical Director for air medical services and has responsibilities as a Medical Team Manager for Virginia Task Force One, a FEMA/USAID-sanctioned international urban search and rescue team.

**James J. James, MD, DrPH, MHA,** is the Director of the American Medical Association's Center for Disaster Medicine and Emergency Response. Dr. James previously served as Director of the Miami-Dade County Health Department. He retired from the U.S. Army as a Major General.

**Arthur Kellermann, MD,** is Vice President and Director of RAND Health. Dr. Kellermann was a professor of emergency medicine and public health and served as Associate Dean for Health Policy at the Emory School of Medicine in Atlanta. He founded Emory's Department of Emergency Medicine and served as its first chair from 1999 to 2007.

**Gene W. Matthews, JD,** served as Chief Legal Advisor to the Centers for Disease Control and Prevention from 1979 to 2004. He currently serves as the Director of the Southeastern Regional Center of the Public Health Law Network. Mr. Matthews has led a national public-private initiative to expand entity liability protection during disasters.

**Paula J. Olsiewski, PhD,** directs the Indoor Environment and Biosecurity programs and the Synthetic Biology Initiative at the Alfred P. Sloan Foundation. Prior to joining the Foundation, Dr. Olsiewski worked in the biotech and bio-medical industries.

**Mary Pendergast, JD, LLM,** was the Deputy Commissioner and Senior Advisor to the Commissioner at the U.S. Food and Drug Administration (FDA) from 1990 to 1998. She also served as Associate Chief Counsel for enforcement at the FDA and in the Office of the General Counsel, Department of Health and Human Services.

**MG Philip K. Russell, MD, (USA—Ret.),** is the Founding President of the Albert B. Sabin Vaccine Institute. During his military career, Dr. Russell conducted research on various infectious diseases and managed vaccine development programs. After the 9/11 attacks, Dr. Russell returned to government work at the U.S. Department of Health and Human Services.

**Thomas C. Voltaggio,** has served as U.S. Environmental Protection Agency Deputy Regional Administrator for Region III and previously as Director of the Region III Hazardous Waste program. Mr. Voltaggio has 36 years of federal service in environmental management. ▽

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## APPENDIX II

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### BACKGROUND

#### History of the WMD Commission

A legacy of the 9/11 Commission, the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism (the WMD Commission) was chartered by the U.S. Congress in 2007 to assess the nation's efforts to prevent the use of weapons of mass destruction. To fulfill its mandate, the WMD Commission released *World at Risk* in December 2008. The report provided a roadmap with specific recommendations to address WMD threats.

#### Among its findings:

- Unless the world community acts decisively and with great urgency, it is more likely than not that a weapon of mass destruction will be used in a terrorist attack somewhere in the world by then end of 2013.
- Terrorists are more likely to use a biological weapon than a nuclear weapon, and the U.S. government needs to move more aggressively reduce the prospect of a bioterror attack.

After Congress extended its authorization for a second year, the WMD Commission published a Report Card in January 2010, assessing America's progress implementing the World at Risk recommendations. Although the Report Card reviewed implementation progress on all the Commission's previous recommendations, the primary failure was "the nation's capabilities for rapid response to prevent biological attacks from inflicting mass casualties."

#### The Bipartisan WMD Terrorism Research Center

Although the Commission concluded in February 2010, the commitment of its leadership to reduce the threat of biological terrorism did not. In March 2010, Senators Graham and Talent and Colonel Larsen (Chair, Vice-Chair, and Executive Director, respectively) founded the Bipartisan WMD Terrorism Research Center (The WMD Center)—a not-for-profit 501(c)(3) research and education organization.

Since the publication of *World at Risk*, there has been significant progress in implementing several of its recommendations related to biosecurity (lab security, Biological Weapons Convention (BWC), etc). The deficiencies in bio-response capability, however, remain. The WMD Center chose to focus its efforts on that subject, in greater depth and across the bio-response enterprise, to provide strategic perspective and recommend priorities to policymakers.

This report is strategic, and therefore concentrates more on the federal role in biodefense. Its authors fully recognize that execution of bio-response capabilities falls heavily to non-federal partners. The WMD Center looks forward to further examining community requirements and challenges in a future project. ▸





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