

# Ethical Challenges in Biodefense and Bioterrorism

# John D. Loike\* and Ruth L. Fischbach

Center for Bioethics, Columbia University College of Physicians and Surgeons, New York, NY 10032, USA

#### Abstract

The threat of a bioterrorist attack is very real and could occur in any country at any time. Today, various governmental agencies in the United States are engaged in biodefense preparedness and response. There is a great need, however, to address ethical challenges in biodefense. In this article, we present diverse bioethical issues associated with bioterrorism and propose various recommendations regarding how to address these challenges.

## Introduction

**Research Article** 

On Tuesday, September 18, 2001, one week after the 9/11 attack on the World Trade Center towers in New York City, letters containing anthrax bacteria were mailed to several news media offices and two U.S. Senators, ultimately killing five people and infecting 17 others. Bob Stevens was the first documented victim in the US killed by this bioterrorist attack. While a great deal of anxiety was generated as well as sadness for the five people who died from this anthrax attack, it appeared that various governmental agencies responded appropriately to limit collateral injury by implementing effective decontamination and sterilization procedures. Unfortunately, despite intense efforts, the perpetrator was never found and brought to justice [1].

According to the Centers for Disease Control, a bioterrorism attack is "the deliberate release of viruses, bacteria, toxins, or other harmful agents used to cause illness or death in people, animals, or plants. Biological agents spread through the air, water, or food [2]. Like a nuclear bomb, a biological weapon has the potential to cause massive loss of human lives and evoke fear and panic across any country. Bioweapons are extremely difficult to detect as they usually do not cause immediate recognizable symptoms of illness for several days.

# History of biological weapons

Biological weapons are as old as war itself. The ancient Hittites marched victims of plague into the cities of their enemies; Herodotus described archers firing arrows tipped with manure. By the 20th century, nearly every major nation developed, produced, and even used in battle a panoply of biological weapons including anthrax, plague, and typhoid [3].

It is difficult to predict when, or even if the United States will be attacked by a bioweapon. In 2010, Congress established the Commission on the Prevention of Weapons of Mass Destruction, Proliferation, and Terrorism, that predicted that the chances were better than 50-50 that a weapon of mass destruction would be used in a terrorist attack somewhere in the world by 2013 [4]. Moreover, according to the members of this commission, the weapon of mass destruction is more likely to be biological than nuclear.

In order to prepare for a bioweapon attack, various simulations have been conducted. The "Dark Winter Exercise", for example, was coordinated by the Center for Strategic and International Studies and the Johns Hopkins Center for Civilian Biodefense Studies to simulate a bioterror attack using smallpox as the biological agent [5]. Based on the results of this simulation, the organizers predicted that as many as a million people in the United States would be killed if such an attack actually occurred. Some experts, such as Milton Leitenberg<sup>1</sup> disagreed with the results of the "Dark Winter Exercise" and argued that this simulation relied on faulty premises designed to increase the death toll and assure a disastrous outcome. Based on Dr. Leitenberg's perspective, the death toll from the exercise would be in the tens of thousands, smaller than one million but astounding nonetheless [6].

It is no surprise that governments around the globe are preparing for a potential bioterrorist event. Determining how a biological attack might unfold depends on a number of variables including which biological agent is used, the extent of its weaponization, the quantity and infectivity of the agent released, and the method of delivery. Some biological agents like the smallpox virus, are rapidly contagious and could spread widely from person to person with just a small number of particles released. Others, like the plague and tularemia bacteria, are not typically contagious but are relatively easy to make and disperse through water contamination.

#### Protecting the United States from bioterrorism

The 9/11 attack triggered tremendous efforts to prepare bioterrorism countermeasures [7,8]. Even before 9/11, the White House and Congress had created a new division of the Centers for Disease Control, known as the National Pharmaceutical Stockpile that was designed to store medicines and vaccines for times of crisis. Since 2001, the federal government has invested more than \$60 billion both to protect our country from a bioterrorist attack and to have in place a strategic response to a bioterrorist event. The government has invested in (1) the development and distribution of air sensors, (2) in educating healthcare providers about the symptoms of bioterrorism pathogens, and (3) in distributing medical supplies for biodefense to selected hospitals around the country. These responses have been based on government assessment of specific biological agents known as "material threats". Material threats are the most virulent pathogens to defend against and include smallpox, anthrax, ebola, plague, and a handful of lesser-known organisms.

<sup>1</sup>Dr. Leitenberg is currently a Senior Research Scholar at the Center for International and Security Studies at the University of Maryland.

\*Corresponding author: John D. Loike, Center for Bioethics, Columbia University College of Physicians and Surgeons, New York, NY 10032, USA, E-mail: jdl5@columbia.edu

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In addition, Project BioShield was initiated in 2004 by the Department of Health and Human Services (DHHS) to oversee a program to develop and stockpile vaccines and treatments that are known collectively as "medical countermeasures" [9,10]. These countermeasures are designed to address the fact that bioterrorists can infect a variety of targets including human beings, water, food, environment, crops, or animals. In fact, argoterrorism is considered by some experts as the easiest bioweapon to deploy.

As a countermeasure to bioterrorism attacks, the Bioterrorism Act of 2002 and the Food Safety Modernization Act of 2010 focused on pathogens that affect the food supply [11]. Under this act, the U.S. Department of Health and Human Services (DHHS) has been authorized to ensure that all food facilities that manufacture, process, pack, distribute, receive, or hold food for consumption by humans or animals in the U.S should be registered with the Food and Drug Administration (FDA). The FDA has the authority to administratively detain food if the agency has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals [12,13].

## Considerations in biodefense

Much has been published on the potential threats and methods by which society can protect itself as well as respond to the health crisis associated with a bioterrorist attack. There are several important questions, beyond the scope of this paper, which should be fully addressed and resolved by government agencies in their preparations for a bioweapon attack.

- 1. Can our government successfully predict the risks and extent of a bioterrorist attack?
- 2. What are our government's strategic plans to avoid panic and organize a response in the event of bioterrorist attack and will our governmental countermeasures work efficiently and effectively to either thwart an attack or to respond appropriately?
- 3. Has our government learned the vital lessons from our (incomplete) responses to natural disasters such as Katrina, oil spills in the Gulf of Mexico, or Sandy, the perfect storm of 2012?
- 4. What are the best political and communication channels for countries to promote international cooperation to counter and to respond to bioterrorism?
- 5. Do we need to develop specialized ethical guidelines for biodefense?

#### Ethical challenges in biodefense

There is a panoply of diverse ethical considerations and challenges that must be discussed or debated that relate to biodefense<sup>2</sup>. In this paper, we review eight vital ethical issues related to bioterrorism and at the end propose specific recommendations to be incorporated into policies that relate to bioterrorism. These eight considerations are:

- 1. Allocation of resources and personnel and cost benefit analysis.
- 2. Triage assessment.
- 3. Clinical testing of potential therapies or vaccines in young children and older adults.

- 4. Preventing unauthorized individuals from entering research laboratories.
- 5. Dual-use: publication of papers containing useful information that also could be used to create bioweapons.
- 6. Dual-use: curtailing the development of harmful technologies while promoting beneficial applications by scientists of these technologies.
- 7. Restriction of personal freedoms.
- 8. Allocation of educational resources.

Allocation of resources and personnel: One critical ethical issue related to allocation of personnel is what risks must healthcare providers take to save other lives? There are several views concerning this issue. Some ethicists espouse the autonomous rights of healthcare providers to balance their health risks with their right of self-preservation in entering and remaining at bioterrorist response sites. Other bioethicists follow the recommendation of the American Medical Association's Council on Ethical and Judicial Affairs. This Council issued a "Declaration of Responsibility" requiring physicians to apply their time, knowledge, and skills when needed, even though doing so may put them at risk [2]. Their recommendations parallel the ethics of mandating that all members of the National Guard or Armed Services risk their lives to save others. On a practical note, we believe that there should be more discussion on ways to encourage healthcare providers to engage and respond to a bioterrorist event. Specifically:

- 1. Nursing staff and other non-MD support staff can play key roles in providing healthcare in these emergency situations but many of them are not educationally prepared to recognize a bioterrorism event or know how to best respond.
- 2. Many healthcare providers are parents who do not have child care resources to cover the continuous and prolonged time that a response requires.
- Healthcare providers may want to place their family safety ahead of their duties to respond to the victims of the bioterrorist attack.
- 4. Healthcare providers have been known to avoid or leave their duties because of fear for their own safety.

Several suggestions have been proposed to ameliorate the problems just mentioned [14]. First, the government should institute educational programs and training drills for all healthcare providers who will be first and second responders to a bioterrorism attack. Second, the government should offer child care programs for all healthcare providers (nurses, physicians, etc.) during these emergencies<sup>3</sup>. With respect to issues 3 and 4, there is a need to openly explore and resolve the dilemma of whether to put self and family safety issues before the obligations to care for bioterrorism victims. One controversial suggestion is that the government should ensure that in a time of emergency, certain groups such as government officials, healthcare professionals and their families, and even undertakers as described by Camus in his classic work, The Plague, receive priority access to limited healthcare resources and treatments [15]. Whatever policies are recommended and implemented, they must be clearly outlined, transparent, publicized, and acceptable to the public.

<sup>2</sup> As of January 2013, a PubMed search revealed that there were 5178 articles (including 972 reviews) on "bioterrorism", 842 articles (including 170 reviews) on "healthcare and bioterrorism", 2558 articles (including 480 reviews) on "health and bioterrorism" and only 192 articles (including 18 reviews) on "ethics and bioterrorism". <sup>3</sup>Where to set up these child care centers is another debatable issue.

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With respect to allocation of equipment and medications, there are many unanswered practical questions such as how much money

should be allocated to provide the necessary equipment and medication in times of crisis? While the US government has millions of vials of smallpox vaccine stockpiled, there are not enough ventilators to meet the demand of an anthrax attack. Many published articles on distributive justice related to the areas of natural and man-made disasters are available that can serve as background lessons for proper allocation of resources in bioterrorism [13,16,17]. Among the many states that have disaster plans, New York State's plan for allocating ventilators during a pandemic offers a viable model for just guidelines [18].

002

In instituting any government policy, it is appropriate to assess the cost of a potential risk of harm versus the cost of strategies to prevent, eliminate, mitigate, or respond to the risk. In practice, while it should be necessary to engage in this cost-benefit analysis, it is often difficult to assess a priori whether the cost of bioterrorist prevention or response is or will be fiscally justified [19,20]. After the 9/11 terrorist attack on New York City, billions of dollars have been spent on preventive activities. In the twelve years since the attack, New York City has never experienced another successful terrorist event even thought scientists have claimed there is a 50/50 chance of another catastrophic 9/11-style attack in the next ten years, and an even greater chance if the world become less stable [21]. Assuming we place the value of a human life between six and nine million dollars [22], these efforts would have to save several thousand lives to be cost effective. How does one ethically assess the cost-benefit analysis since we do not know whether these preventive measures have, in fact, curtailed other terrorist attacks? While we will never be able to establish actual costs of these measures, society has ethically endorsed efforts to spend whatever it takes to protect itself.

Triage assessment: Publications are available that discuss the ethical virtues of treating patients either on a "first come, first treat basis" or triage in order to save "the greatest number of lives" [23,24]. Related to this sentinel issue is the ethical challenge of how healthcare providers should be instructed to triage those individuals who will receive comfort care rather than aggressive care because they are not expected to survive. In other words, should treating those most likely to survive trump treating those who require more extensive care because of their critical condition? This issue arose in Katrina and has been debated in the literature and in the courts without any clear consensus [16,23,25]. Likewise, there is no consensus on other ethical issues such as whether healthcare providers should administer high doses of opiates that may shorten lives but minimize the suffering of those whose chances of survival are slim [26]. This point also raises the ethical issue of whether to free up scarce hospital beds by discharging patients earlier than necessary to make room for new sicker arrivals.

The World Medical Association (WMA) offers several ethical recommendations related to triage in the event of a natural disaster [27]. The WMA recommends that "the physician must act according to the needs of patients and the resources available. He/she should attempt to set an order of priorities for treatment that will save the greatest number of lives and restrict morbidity to a minimum". This is one ethical view that has guided medical response to natural disasters and may be applicable to bioterrorism. Priority should be given to treat patients with life-threatening conditions in the best possible manner to ensure that resources and healthcare personnel are used wisely so they are available to treat the maximum number of victims in need.

Additionally, there are divergent approaches regarding how and where to establish healthcare facilities at the onset of a disaster [28]. Several European countries favor the use of specific non-hospital

facilities as healthcare centers to avoid the bio-contamination of patients or healthcare providers already in the hospital. Obviously, when a disaster strikes, setting up separate centers of response will be more costly and require great thought and planning on how to rapidly populate those centers with the necessary equipment and personnel.

From an ethical or philosophical perspective, issues of allocation and triage can be viewed from at least two alternate theoretical perspectives [23,29-31]. Some bioethicists consider applying a utilitarian approach where the medical needs and resources should be provided to ensure the greatest number of survivors. These bioethicists view an "extended moral horizon" [32] to examine not just the policy effects on individual human victims, but also to apply their policies on humanity as a whole. In contrast, other bioethicists consider a Kantian or non-consequentialist model that focuses on imperatives, such as "first come, first. Whatever model is adopted for bioterrorism situations, it is important to educate triage officers to properly and ethically manage these disasters in a consistent and just manner [33]. These officers should have the capacity to manage and control both victims and healthcare providers under situations where panic could cause absolute disruption of an appropriate and well-coordinated bioterrorism response.

Clinical testing of potential therapies or vaccines in young children and older adults: Good empirical evidence is available which documents that clinical testing of potential medications on adults or military personnel may not be valid predictors in assessing the therapeutic responses of infants and children [34,35]. Hence, the ethical question is whether there should be clinical trials of these untried medications with potentially harmful side effects in young children in preparation for a terrorist attack? The model of the Biomedical Advanced Research and Development Authority (BARDA) used for adults is that non-approved FDA medications can be stockpiled and used in a crisis situation provided that there are good data for phase 2 trials [13,36]. We propose that small clinical trials be conducted involving children to assess the efficacy of life-saving procedures and medications because it is well known that children should not be treated as small adults and their responses cannot always be extrapolated from adult responses [34]. Similarly, an age-related decline in immune responses can occur in the elderly that results in greater susceptibility to infection and reduced responses to vaccination [37]. Thus, one could predict that older adults may also benefit from small clinical trials.

Preventing unauthorized individuals from entering our research laboratories: There are in place multiple measures to ensure biosafety within most US research institutions [38,39]. Yet, there is still concern that unauthorized individuals could gain access to secure laboratories. Even more frightening is the possibility that individuals employed by a biosafety laboratory could use their access to pathogens to set up bioterrorist activities. While it is difficult to completely protect a facility, it is helpful when all members of the facility remain vigilant and ready to provide information to the head of the laboratory if they observe questionable activities. Serving as a whistleblower is not always an easy activity as there may be retaliation or legal and other repercussions if their information is not accurate; yet, without their vigilance, a threat may not be averted.

Raising awareness of those involved in research can be extended to the entire population at large. New York City commuters constantly hear on their subways and bridges that everyone should keep an eye out for potential dangers such as suspicious packages. The public should be instructed on the proper way to inform authorities of questionable activities that may suggest a potential bioterrorist attack.

Dual-use publication of manuscripts containing information that could be used to create bioterrorism weapons: Our scientific enterprise is characterized by a commitment to information sharing as a means to accumulate and disseminate knowledge through a collaborative and collective effort. The chief justification of openness is that it contributes to both generation and acquisition of scientific knowledge. Dual-use in biology relates to the knowledge and skills developed for legitimate scientific and commercial purposes that also have the potential to be misused by those with hostile intent. How can society preserve the openness of scientific research while still preventing information from research papers to be used for terror by non-state organizations or individuals? This is a major ethical concern for ethicists. A second ethical concern is whether publishing in professional journals creates a real danger in dissemination of biodefense information to terrorists.

During the end of 2011 and through June of 2012, the potential publication of genetic modifications of the H5N1 influenza flu virus triggered a significant series of bioethical debates on the issues of dual-use that alerted the press to the importance of bioethics [40,41]. The National Science Advisory Board for Biosecurity's (NSABB) recommendation on 20th December, 2011 which was related to the two H5N1 papers in full detail was unprecedented and delayed their publication [42,43]. This delay in publishing methods for genetically bioengineered H5N1 avian influenza highlights the current status of the dual-use issue and has brought ethical considerations related to bioterrorism into the forefront. With respect to dual-use, one underlying bioethical challenge is how best to balance scientific openness (autonomy to publish and freedom of the press) with censorship and homeland security issues. This dilemma of dual-use is not unique to bioweapons but has historical origins in nuclear physics and bacterial genetics.

As a case in point, it remains unclear whether deliberately publishing false methodologies in nuclear physics during the 1940s and 1950s delayed the Russians and Chinese from developing their own nuclear bombs [44]. In contrast, it appears that scientist-based self-regulation adopted at the Asilomar Conferences in the 1970s successfully prevented the release of genetically modified bacteria containing human oncogenes into the environment [45]. The dual-use issue at the Asilomar Conferences involved transfecting a recombinant DNA molecule made in the laboratory with genes from the tumor virus, SV40, into a strain of the human commensal bacterium, *Escherichia coli*. It is interesting that during the Asilomar Conferences, the question of publishing or refraining from publishing the methodology was not a major issue.

There are several outcomes that have emerged from our debates and experience regarding the issue of whether to publish critical methods for genetically modifying the H5N1 virus. First, was vital information revealed to terrorists in these H5N1 debates? These debates, for example, established that setting up a highly sophisticated laboratory to genetically modify this strain of influenza virus is time-consuming and costly. Second, terrorists may realize from these debates that our capacity to develop effective vaccines against influenza virus renders this pathogen a less desirable candidate for a bioweapon than anthrax. Finally, any global outbreak of H5N1 would more likely have a higher mortality rate in an underdeveloped country where terrorists reside than in western countries. There are certainly many scientists who believe that the open debates may be more informative to the terrorists than simply publishing the methodologies. In the end, the decision to publish was based on the assessment that disseminating these methods would be more beneficial in creating better vaccines and therapies than using them to create more potent bioweapons. One should keep in mind that there is little evidence to suggest that human beings are better equipped to create a lethal pathogen using genetic engineering than 'nature' is in using natural selection.

Even if a society accepts the concept that certain biotechnological methods should be restricted for publication, who should make those decisions? Should regulations be promulgated by a standing governmental panel, such as NSABB's, that is composed of scientists, journal editors, and government officials? Perhaps, an *ad hoc* committee should be created only when an issue arises such as H5N1.

Dual-use curtailing the development of harmful technologies while promoting beneficial applications of these technologies by scientists: History has revealed that it is quite difficult to limit or restrict technological development and the dissemination of scientific information that may be harmful [46]. Yet, scientist-based selfregulations have been shown to be an effective measure to regulate technological development and progress.

The Asilomar Conferences first planned in the 1970s will go down in history as a unique example of scientist-based self-regulation [47,48]. As mentioned earlier, the basic issue that generated these conferences was whether it was safe to clone certain eukaryotic genes, such as insulin or oncogenes, into the common bacteria, *E. coli*. These conferences concluded with a scientist-based self-imposed moratorium which stated that only bacteria that could not survive outside of a laboratory could be used for these types of experiments.

Other lessons emerged from these conferences. First, the people who sounded the alarm about genetically engineering bacteria with oncogenes were not politicians, religious groups, or journalists: they were scientists. Second, participants assigned a risk estimate to different types of experiments they envisioned and they implored that everyone should join in choosing in what facilities the experiments would be conducted. Third, and most important, we believe that these conferences demonstrated that scientists can effectively self-regulate scientific research. While it is difficult to assess the success of this scientistbased moratorium, since its inception there has been no documented accidental release of harmful genetically engineered bacteria outside of any laboratory. Finally, the inclusion of nonscientists in forming these policy decisions strengthened and legitimized the efforts and led to an increased public awareness of this research and a more general willingness to accept biological research using DNA technologies. The entire process was open to reporters and journalists to keep the public updated with the decisions that would potentially guide both the creation of new organisms and the protection of the environment.

The H5N1 debate triggered passionate dialog among biomedical scientists, publishers, and ethicists about biosafety, biosecurity, and bioterrorism, not to mention the vital social responsibility of scientists to ethical challenges of biodefense. These debates concerning the publication of ways to genetically alter virus transmissibility is an essential focus of contemporary research, not just for H5N1, but for all infectious agents. Hopefully, the publication of the H5N1 papers will serve as the scientific foundation for effective new vaccines and the development of other preventive measures and therapies.

**Restriction on personal freedoms:** Although many personal freedoms are included in the United States Constitution (e.g., the Second Amendment guaranteeing "the right of the people to keep and bear Arms, shall not be infringed"), Constitutional rights have been trumped under certain conditions or threats that jeopardize security.

Page 4 of 6

security. Airport security measures and mandatory quarantine are two specific situations (of many) where personal freedoms are restricted. To reduce terrorist threats to airline safety, restrictions are placed on what passengers can bring through the security scanners (e.g., no water bottles even if sealed). After the December 14, 2012 massacre in Newtown, Connecticut that left 27 people dead (20 of them being elementary school children), elected government officials responding to the public outcry have been galvanized to propose restricted ownership of assault weapons. Thus, it is reasonable to assume that both government and society will accept restrictions on personal freedoms if they have the potential to reduce societal harms.

Allocation of educational resources: Educating researchers and healthcare providers regarding the principles and practices of the responsible conduct of research may be another means to protect society from bioterrorist threats. First, it is critical to convey the concept that scientists can serve on the front line of discovery and should accept the ethical responsibility to avoid contributing to the advancement of biowarfare and bioterrorism [49,50]. Once we educate a generation of young scientists in what constitutes research that may have unintended social consequences, it will become part of the research culture, as did the Asilomar recombinant DNA guidelines. Second, society functions much better when there is cooperation, communication, and concern for others. Individuals should feel comfortable revealing to authorities information about potential health and bioterrorist threats.

How should this educational process be put into place? We believe that middle school and high school is a good place to begin to inculcate these principles into ascending sophisticated courses on the responsible conduct of research [51].

## Conclusion

In this article, we have briefly touched on several ethical challenges regarding biodefense. While there is scant consensus on how to resolve many of these issues, we propose the following recommendations to assist in developing sound policies and just guidelines:

- It is crucial to prepare in advance of a bioterrorist attack a set of ethical guidelines gleaned from lessons learned from effective or ineffective responses to natural and man-made disasters.
- In science, as in other professions, financial gain can be an incentive to recruit individuals who might engage in unethical practices. Society may not be able to prevent this type of recruitment but we are able to educate our youth about responsible conduct as it relates to science and thus to infuse them with the bioethical mantra that it is not what can be done but rather what should be done.
- We should educate not only our primary physicians, but nurses and other healthcare providers about the ethical responses to bioterrorism as well as the medical aspects of bioterrorism detection, surveillance, and management. Likewise, we should educate a cadre of triage managers who will be called upon to supervise disaster responses in an ethical and just manner.
- We should educate the public about the threats of bioterrorism and how government agencies are prepared to respond to a bioterrorist attack. The public must understand the principles of triage and their ethical obligations in times of disaster [52]. We doubt that the public or many scientists have been informed about the diverse roles which the governmental agencies play in dealing with bioterrorism.

In conclusion, we believe that a set of ethical guidelines are needed to be drafted, reviewed and publicized by a commission composed of bioethicists, scientists, government officials, and the public regarding responsible and ethical conduct in preparing and responding to times of crisis. The resolution that led to the publication of the H5N1 papers demonstrates that we have the capacity to resolve complex ethical issues.

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Page 6 of 6