Minimization of the Risks Posed by Dual-Use Research: A Structured Literature Review

Margarita Dolgitser

Columbia University, New York, New York

Abstract

Introduction: In a post-9/11 world, the potential risks associated with biodefense research are great. The dual-use dilemma concerns the ability of legitimate biomedical research intended to be used for societal good, to instead be subverted for the development of biological weapons causing a threat to the population. The objective of this study was to review the current life sciences literature in order to identify options to minimize the risks associated with dual-use research.

Methods: The MEDLINE database was searched for studies concerning the ethics of biodefense, or the dual-use dilemma. Ten articles met all inclusion criteria and were thoroughly reviewed and analyzed.

Results: The most commonly suggested strategy for minimizing the potential harm caused by scientific research was self-regulation within the scientific community followed by increased security within the scientific community, international cooperation, and finally, increased biodefense education for professionals. One article suggested that decreases in forced security would minimize the risk of the dual-use of bioterrorism through increased open scientific scrutiny and self-regulation within the community. Another article argued for more clarity in guidelines to define the type of research that would require increased security. Strategies were not mutually exclusive with many articles offering combination approaches to minimize dual-use risks.

Conclusions: To offer the best protection against terrorist use of dual-use research from a biological sciences perspective, many of the proposed measures need to be undertaken simultaneously.

Introduction

On September 11, 2001, the United States experienced the largest domestic terrorist attack in its history. A few weeks later, *B. anthracis* spores were disseminated through the postal system. Since then, the United States government has reevaluated the threats posed by terrorism, determined that bioterrorism is a substantial threat to its people (Federal Bureau of Investigation Strategic Plan, 2004-2009), and spent substantial resources to prepare the nation against a future biological terrorist attack. In 2006, the U.S. government spent approximately $5.1 billion on civilian biodefense (Schuler, 2005), a dramatic increase even from 2001, when funding for biodefense was only $295 million (Lam, Franco, & Schuler, 2006). The budgeted U.S. government funding for civilian biodefense in the fiscal year 2007 is $5.2 billion, an increase of more than 1,700% over biodefense spending in 2001 (Lam, Franco, & Schuler, 2006) Despite such a clear increase in biodefense spending by the government, many scientists and ethicists have suggested that such research may be unethical for a variety of reasons (King, 2005; Atlas, 2005).

Many ethical issues have been raised regarding biodefense, including the use of scarce public health resources for defense against an unlikely threat, the threat classified scientific research poses to national security, safety and ethicality of actual experiments, and how to determine the best approach when responding to an act of bioterrorism (King, 2005; Atlas, 2005). The ethical issue that seems most prominent at the moment is that of the "dual-use dilemma." Traditionally, the term "dual-use" has referred to research that has both civilian and military applications, but recent developments in the life sciences have expanded the dimensions of the "dual-use" term to include possible offensive or hostile purposes (Atlas & Dando, 2006). In the life sciences literature today, the dual-use dilemma concerns the ability of legitimate biomedical research intended to be used for societal good to be used for the development of biological weapons causing a threat to the population (King, 2005; Kelley, 2006). Such a threat may involve researchers inadvertently creating a more virulent strain of an organism while searching for a mechanism to disarm it or trying to create less virulent strains. It is also possible for researchers to make a nonpathogenic organism virulent. Additionally, research that creates a strain of organism that is resistant to antibiotics or antivirals, or to develop a strain that evades diagnosis is seen as having dual-use potential (Atlas & Dando, 2006). Similarly, research in aerosol technology, commonly conducted when developing therapeutic drug delivery systems, could be utilized to weaponize pathogens.

In one controversial study resulting in potential dual-use implications, researchers published the complete methodology and results for synthesizing an artificial poliovirus with the biochemical and pathogenic characteristics of the actual poliovirus. This publication raised serious concerns that these scientists were offering potential blueprints to terrorists for creating similar viruses (Cello & Wimmer, 2002). In 2005, two controversial studies published the full genome sequence of the 1918 flu virus,

which killed an estimated 50 million people worldwide (Tumpey et al., 2005; Taubenberger et al., 2005; Sharp, 2005). Although the public availability of the full genome sequence can lead to the development of new therapies and vaccine, it could also be used by terrorists to start another pandemic. In the week prior to publication of this groundbreaking work, the U.S. National Science Advisory Board for Biosecurity (NSABB) called an emergency meeting to consider the risks, but came to the conclusion that the benefits outweighed the risks and the publication went forward as scheduled (Von Bubnoff, 2005).

The purpose of this paper is to review the current life science literature on the ethics of biodefense with the goal of identifying salient issues in the ethics of the dual-use dilemma and methods for minimizing the harm that could potentially be caused by biological research. As the purpose of this paper was to focus on the relevant issues from the perspective of the life sciences, policy publications were not considered during the review process.

Methods

In order to identify relevant articles, a search of the MEDLINE database was conducted for key words including: "biodefense," "biowarfare," "biosecurity," "biotechnology," "biological weapons," "bioethics," "bioterrorism," and "dual-use," both alone and in combinations. Studies were selected if their title concerned the ethics of biodefense, or the dual-use dilemma. Bibliographies of all selected papers were searched to identify further papers, which were included if they met the same title-relevance criteria.

Twelve articles were identified using the search criteria described above. Of these, two were excluded because they focused on nursing within the realm of biodefense ethics. The 10 remaining relevant articles were thoroughly reviewed and analyzed.

Of the final 10 articles, seven specifically addressed the dual-use dilemma. The remaining three addressed various aspects of the dual-use dilemma without specifying it by name (e.g., instead referring to it as a "double-edged sword") (Sutton, 2005).

Results

Within the peer-reviewed life-science literature, the most commonly suggested strategy for minimizing the potential harm that could be caused by scientific research was self-regulation within the scientific community, followed by increased security within the scientific community, international cooperation, and finally, increased biodefense education for professionals (Atlas, 2005; Atlas & Dando, 2006; Kelley, 2006; Sutton, 2005; Wright, 2004; Atlas & Reppy, 2005; Revill & Dando, 2006; Somerville, 2005). One article suggested that decreases in security would minimize the risk of dual-use by bioterrorists through increased open scientific scrutiny and self-regulation within the community (Saha & Saha, 2004). Another article argued for the need for more clarity in guidelines to define what type of research poses a need for increased security (Anonymous, 2005). Figure 1 shows a distribution of suggestions for minimizing risks posed by dual-use research from reviewed articles.

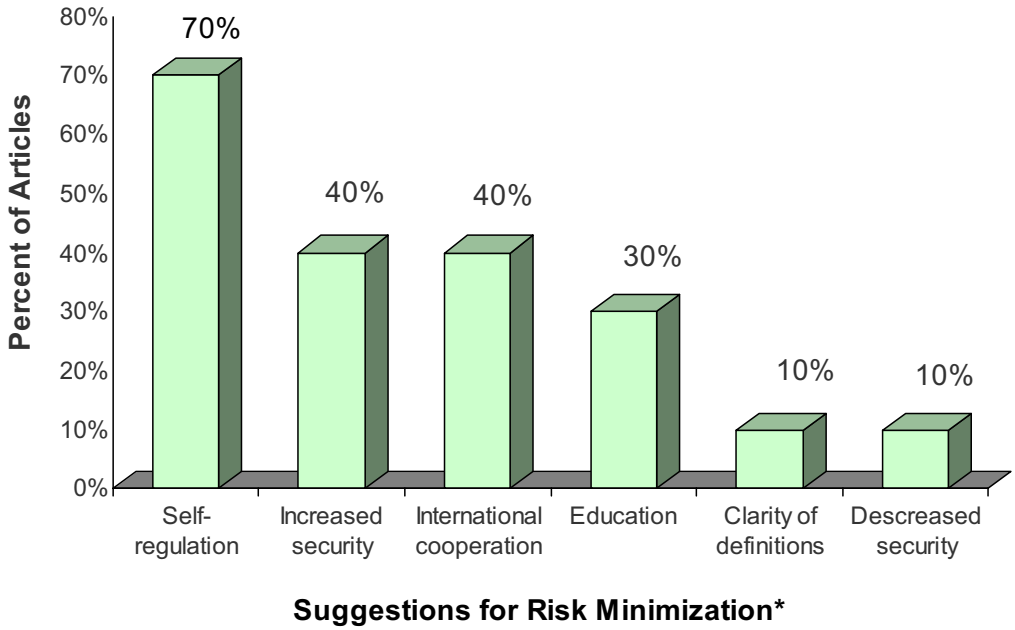
Among the articles that suggest self-regulation, a bottom-up approach, ideas for how this regulation needs to occur, vary substantially (Atlas, 2005; Atlas & Dando, 2006; Kelley, 2006; Atlas & Reppy, 2005; Revill & Dando, 2006; Somerville & Atlas, 2005; Saha & Saha, 2004). One article suggested that life scientists take a Hippocratic Oath similar to the one physicians take to become more aware of the issues surrounding dual-use research and their ethical responsibilities (Revill & Dando, 2006). Another suggested even stricter peer-review guidelines stipulating that work should be reviewed not only for quality but also for its dual-use potential (Kelley, 2006). Most articles agreed that the main responsibility for biosecurity needs to be placed directly in the hands of researchers: "Scientists must be encouraged through their own culture of responsibility to work for our security and the public good" (Saha & Saha, 2004).

Many articles also recommended increased security, or a top-down approach (Atlas, 2005; Atlas & Dando, 2006; Kelley, 2006; Atlas & Reppy, 2005). Suggested increases in security ranged from physical security measures such as tighter security for laboratories, stored samples, and research data, to rigorous background checks for staff, graduate students and faculty, and limitations on access to information and knowledge on a strict need-to-know basis (Atlas, 2005; Kelley, 2006). Others suggested that security measures should involve federal oversight through laws designed to prevent publication of certain types of studies or data that could be useful to terrorists, or through enhanced law enforcement activities such as inspections or data confiscation (Atlas, 2005; Atlas & Dando, 2006).

There are currently many international ethics guidelines such as those pertaining to human rights and principles of war. Following increased self-regulation and security, the next most common suggestion for increased biodefense was international cooperation (Atlas & Dando, 2006; Sutton, 2005; Wright, 2004; Saha & Saha, 2004. The focus of this option is a search for collective security, suggesting a "strength in numbers" approach. Proposals for this type of cooperation focus first and foremost on establishing a clear international consensus on bioethical approaches to protection from bioterrorism; one article stated specifically that an international code of conduct should be created to define ethical behavior for all life scientists (Sutton, 2005). Other articles suggested the necessity of international treaties and frameworks limiting the development of dual-use research (Sutton, 2005; Wright 2004). Interweaving the ideas of self-regulation

Figure 1

Distribution of Suggestions for Minimizing Risk Posed by Dual-Use Research from Reviewed Articles (N=10)



* Not mutually exclusive

and applying them to international cooperation, another article suggested that information should be openly accessible to the global scientific community, but the community should be responsible for protecting itself against hostile misuse of the knowledge (Atlas & Dando, 2006).

Education is another important component of protection against dual-use research (Atlas, 2005; Kelley, 2006; Revill & Dando, 2006). One article suggested the development of an ethics module and implementation of the ethical element in all life-science-related curricula (Revill & Dando, 2006). Such ethics modules already exist for some undergraduate bioscience programs, but are limited in scope and rarely detail the possible misuse of research programs by terrorists. Other than education within the formal setting, it would also be useful to offer on-the-job training and guidance to professionals who currently conduct biological research (Atlas, 2005).

In contrast to all other studies, one article recommended decreases in security in order to minimize the risks of dual-use (Saha & Saha, 2004). This article argued that curtailing a terrorist's access to scientific research also restricts access by the general public and other scientists, a barrier to scientific progress. Furthermore, it argued that hostility caused by increased security could limit researchers' desires to conduct vital research. It argued instead for the ideas presented above: education, self-regulation, and free flow of information.

Conclusions

In a post-9/11 world, the dual-use dilemma poses difficult questions for ethicists and researchers alike. A thorough review of the current life-science literature (MEDLINE only) on dual-use and biodefense ethics yielded self-regulation within the scientific community as the most commonly suggested strategy to minimize the risks posed by dual-use research. Increased security was the second most commonly suggested measure, followed by international cooperation, education, clarity of definitions, and decreased security. Many articles mentioned more than one of the preceding measures, often grouping them together. It is easy to see that one commonly follows from the next, such as increased education, leading to both increased international cooperation and increased security measures. Many of the measures were suggested to be used in tandem to offer increased protections against terrorist use of dual-use research.

This study had several limitations. Ten articles were identified for the study, thus limiting sample size and the ability to detect significant differences, or to make generalizable conclusions. Another limitation is the use of only peer-reviewed literature, which represents a small portion of studies carried out throughout the world. Finally, only one database (MEDLINE) was searched for inclusion into this study and it is possible that the search failed to identify all relevant articles.

Despite these limitations, this study provides important suggestions for methods that can be used to minimize the risks of dual-use research. Further research is necessary to confirm these findings and to provide a detailed plan of action, which incorporates the suggestions described in this study.

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Biosafety "Behavioral-Based" Training for High Biocontainment Laboratories: Bringing Theory into Practice for Biosafety Training

Sean G. Kaufman and Ruth Berkelman

Emory University, Atlanta, Georgia

Abstract

As the number of individuals working in high biocontainment laboratories (BSL-3 and -4) increases over time, human error remains one of the most important factors in the origin of hazardous incidents in laboratories. With support from the National Institutes of Allergy and Infectious Diseases (NIAID), the Southeast Regional Center of Excellence for Emerging Infections and Biodefense (SERCEB) supported construction of a mock BSL-4 laboratory for training on the Emory Campus, and development of a curriculum for BSL-3 and -4 training. In close collaboration with the Centers for Disease Control and Prevention (CDC) and other scientists and safety professionals, the Rollins School of Public Health has developed one-week, intensive behaviorally-based ("hands-on") training courses for those working in BSL-3 and BSL-4 laboratories. Since January 2005, over 200 scientists, graduate students and staff have successfully participated in these courses, and the evaluations have been excellent. Long-term evaluation of participants' knowledge retention