Online Ethics Center
FOR ENGINEERING AND SCIENCE

Topics: Biosecurity

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Description

A guide that provides information and resources on teaching responsible conduct of research that focuses on the topic of biosecurity. Part of the Resources for Research Ethics Education collection.

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Summary

Biosecurity and the concept of dual-use research have important implications for the responsible conduct of research in the life sciences. A good illustration of this point is the statement on responsible publication issued in 2003 by editors and authors of some premier scientific journals. Their statement affirmed a collective responsibility to review papers submitted to their journals for dual-use concerns and to avoid publishing those which pose a significant threat to public health or national security (PNAS 2003). In addition, some scientific societies like the American Society for Microbiology have also made statements or amended their codes of conduct to reflect biosecurity concerns (ASM 2019).

Familiarize yourself with biosecurity and dual-use research.
Whether you are a practicing life scientist, a biosafety professional, a student in the life sciences, or a policy-maker, it is important to understand what biosecurity and dual-use research are. In the life sciences, biosecurity refers to the efforts designed to minimize the likelihood that biological research will be misused for malicious purposes like bioweapons. Dual-use research is any type of legitimate life sciences research which has the potential to be misused for nefarious purposes.

Understand the political atmosphere around biosecurity and dual-use research.
As part of the research community, it is important to make sure that you know what laws and rules are applicable to you and your research. It is also prudent to remain aware of what your local, state, and federal governments may be discussing in regards to additional research oversight or regulation. Staying abreast of the discourse between scientific leaders and the government is important, as the decisions they make may affect your research in the future.

Help create a culture of responsibility.
Once you are familiar with biosecurity and the concept of dual-use research, spread

the word. As more researchers and students in the life sciences become aware of biosecurity and the dual-use concept, the importance of the responsible conduct of research will grow.

Background

Biosecurity is a term that has a variety of definitions, but in the context of life sciences research in the U.S., biosecurity typically refers to processes and procedures that are designed to minimize the likelihood that biological research will be misused for the production and enhancement of biological weapons.

Biosecurity became an important issue following the U.S. anthrax attacks in 2001. The anthrax letters which were sent through the U.S. Postal Service to news media offices in New York City and Boca Raton, Florida, as well as to Senators' offices in Washington, D.C. illustrated the serious threat associated with the misuse of dangerous pathogens. This incidence of bioterrorism resulted in 22 known infections, five deaths, and millions of dollars worth of decontamination efforts (Centers for Disease Control and Prevention 2002). The perpetrator of these events has still not been identified, a fact which demonstrates that acts of bioterrorism can be very hard to trace.

In an effort to prevent bioterror events like the anthrax attacks from occurring again, the U.S. government has taken a number of steps to strengthen biosecurity.

Regulations and Guidelines

Following the 9/11 attacks and the anthrax letters of 2001, the U.S. Government passed the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT) Act of 2001. The PATRIOT Act includes a number of provisions aimed at strengthening biosecurity. The Act:

- Makes it a felony to possess a type or quantity of a biological agent that cannot be justified for prophylactic, protective, or peaceful purposes;
- Makes it a federal offense for convicted felons, illegal aliens or fugitives to possess or transport biological agents or toxins, in any quantity or for any reason; and

- Defines biological agents as "microorganisms, or any recombinant or synthesized component thereof, capable of causing death, disease, or other biological malfunction in a human, animal, plant or other living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment" (US Public Law 2001).

The following year, the U.S. Government also passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. This Act requires that the United States improve its ability to prevent, prepare for, and respond to acts of bioterrorism and other public health emergencies that could threaten either public health and safety or agriculture. More commonly referred to as the Bioterrorism Preparedness Act, it requires that:

- Certain federal agencies must be informed of research, possession, and transport of select agents;
- FBI background checks must be performed for anyone accessing, transporting, or receiving these agents;
- Defined security procedures must be followed for facilities within which these agents are contained.
- The heads of the US Dept of Agriculture (USDA) and the Department of Health and Human Services (DHHS) have new responsibilities to consider when determining what should be listed as a select agent (US Public Law 2002).

Acting in accordance with this Act, both the Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA) passed rules governing the possession, use, and transfer of "select agents," or those agents which are deemed to be the most dangerous to human, plant, or animal health. The two Acts passed were the HHS Select Agent Final Rule (HHS Select Agent Rule 2005) and the USDA Select Agent Final Rule (USDA Select Agent Rule 2005).

Since these laws were passed, there have been a few instances of researchers being prosecuted for not adhering to the select agent regulations. One such example was the Thomas Butler case in 2003. Dr. Thomas Butler was an infectious disease scientist at Texas Tech University, and in January 2003, he reported 30 vials of Yersinia pestis, the causative agent of plague, missing from his laboratory. This report triggered an FBI investigation, and later the same year, Dr. Butler was convicted on a number of charges, including three associated with the improper shipment of a select agent (Science 2005). Dr. Butler was sentenced to two years in

prison; his term ended in January 2006. This case remains controversial because many felt that Dr. Butler was unjustly persecuted, but it does illustrate the importance of becoming familiar with the rules and laws that govern certain types of scientific research.

Discussion

Case Study 1

Dalshi Beng finished her Ph.D. in a microbiology program three years ago and has joined a group of microbiologists at the Polytechnic Institute of Technology (PIT). Her expertise is in the development of antibiotics that will help prevent the spread of infectious diseases, with a particular focus on the bacterium that causes anthrax, Bacillus anthracis. To develop effective treatments, she and her colleagues have to anticipate genetic variations in the bacterium that will alter its virulence and transmissibility from one person to another. Dr. Lim Bagoda, one of her colleagues at PIT, is widely known for his abilities to identify and induce relevant mutations in bacteria and has created a wide repertoire of candidates for screening. Based on preliminary tests, Dr. Beng and Dr. Bagoda realize that one variant is relatively easy to create, and it is of a size and potency that it could effectively be transmitted as an aerosol and induce severe disease. Dr. Beng is excited by the remarkable finding and argues for publication as soon as possible. In her view, it is important for the scientific community to know about the variant so that others can work on the agent and develop effective countermeasures. Dr. Bagoda is horrified by the suggestion and points out that once this method is in the literature it is plausible that anyone with the inclination and expertise could readily produce large quantities of the enhanced bacterium and cause widespread illness and death. Drs. Bagoda and Beng have come to an impasse.

The Federation of American Scientists (FAS) created a series of case studies to help define issues associated with dual-use research. These case studies include interviews with actual scientists who have embarked on legitimate scientific experiments that have turned out to have considerable dual-use implications.

The Policy, Ethics, and Law Core of the Southeastern Regional Center of Excellence For Emerging Infections and Biodefense (SERCEB) created a Dual-use Education Module in 2005 to familiarize practicing life scientists, students, biosafety professionals and administrators with the dual-use issue. By walking users through a scenario in which a Ph.D. candidate comes across dual-use concerns in her dissertation research, the module provides a realistic scenario to teach users how to handle unexpected dual-use results responsibly. A discussion guide is also provided in order to engage users in a discussion with colleagues after taking the module.

1. Can you explain what biosecurity in the life sciences is? Can you explain the concept of dual-use research?
2. What is the connection between dual-use concerns and the responsible conduct of research?
3. How do you feel about pre-publication review of papers that involve one of the seven experiments of concern as defined by the NSABB dual-use criteria?
4. What if it was one of your papers that was being reviewed?
5. Do you feel that decisions regarding dual-use oversight should be made by the scientific community or by the government?

Most of the provisions passed by the U.S. Government in 2001 and 2002 dealt with the possession and transfer of select agents. At the same time that the government passed laws to regulate the security of world's most dangerous pathogens, it infused a significant amount of money into basic research to help understand the nature of these organisms and to create countermeasures against them. With billions of dollars dedicated to biodefense research and many scientists entering the field of emerging infectious disease, the both the scientific community and the government started taking steps to prevent the misuse of scientific knowledge that would inevitably be gained from increased research with these pathogens.

- In 2002, the National Academies of Science convened an expert committee to specifically consider ways to protect public health and national security from the misuse of biological science. The committee, called the Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology published a report in 2004 called *Biotechnology Research in an Age of Terrorism* (often referred to as the "Fink Report") which examined modern life sciences research in the context of national security and called for the creation of a Federal Advisory Committee dedicated to advising the

government on how to handle experiments which could me misused to cause harm.
- In 2005, the federal government created the National Science Advisory Board for Biosecurity (NSABB). This Board was tasked with defining "dual-use research," or research that could be misused for malicious purposes. The board was also charged with making recommendations to the federal government on ways to identify, monitor, and communicate results stemming from dual-use research.

So what is considered dual-use research in the life sciences? Dual-use research is legitimate scientific research that may be misused to pose a biologic threat to public health, the environment, and/or national security. According to the NSABB, there are seven specific types of experiments which are considered to be of dual-use concern. These are:

- Any experiment which would enhance the harmful consequences of a biological agent or toxin.
- Any experiment which would disrupt immunity or the effectiveness of an immunization without clinical and/or agricultural justification.
- Any experiment that would confer resistance to prophylactic or therapeutic interventions, or facilitate the ability of an agent or toxin to evade detection methodologies.
- Any experiment that would increase the stability, transmissibility, or the ability to disseminate a biological agent or toxin.
- Any experiment that would alter the host range or tropism of a biological agent or toxin.
- Any experiment that would enhance the susceptibility of a host population
- Any experiment that would generate a novel pathogenic agent or toxin or reconstitute an eradicated or extinct biological agent.

These draft criteria were included in a June 2007 report to the Secretary of Health and Human Services. Also included in this report were principles for the responsible communication of dual-use research of concern and considerations for the development of a code of conduct for life scientists (NSABB Proposed Framework 2007).

One final consideration important to any discussion about biosecurity is its relationship to biosafety. Biosafety has to do with the protection of people, animals,

and the environment from exposure to infectious agents or other biohazards. Without appropriate biosafety training and precautions, biosecurity efforts are not likely to be effective. Biosafety is a critical component to biosecurity as well as to the responsible conduct of research in the laboratory.

Resources

OEC Resources

- OEC Activities and Resources on Biosecurity from Academies and Scientific Unions

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Notes

The Resources for Research Ethics Education site was originally developed and maintained by Dr. Michael Kalichman, Director of the Research Ethics Program at the University of California San Diego. The site was transferred to the Online Ethics Center in 2021 with the permission of the author.

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Resource Type

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Resources for Research Ethics Education

Topics

Security

Discipline(s)

Research Ethics
Teaching Ethics in STEM