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Fostering an International Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences

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Introduction: Culture of Responsibility in the International Context

There is no internationally agreed upon definition of an organizational culture that emphasizes biosafety, biosecurity, and responsible conduct in the life sciences, and no concerted international approach to identify, collect, analyze, and disseminate lessons and best practices in strengthening the organizational culture of life sciences research laboratories worldwide. Here, we describe how these concepts are covered by relevant international treaties, international organizations, and professional organizations. While there are some efforts under way, opportunities exist to evaluate and strengthen the culture of biosafety, biosecurity, and responsible conduct in the life sciences in order to prevent the loss, theft, misuse, and diversion of biological agents, related materials, technology, or equipment, and the unintentional or intentional exposure to (or release of) biological agents. We propose that (1) international regimes and organizations partner with international professional organizations to enhance efforts to share best practices and lessons learned in strengthening a culture of biosafety, biosecurity, and responsible conduct, (2) the international community strive to create an organizational culture within the life sciences that is modeled and assessed in part similarly to

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the well-established nuclear safety and security culture, and (3) the international community enhance efforts to recognize "champions of culture" at the state level both for their biosafety and biosecurity efforts as well as their potential to model these efforts for the international community.

International Treaties, Agreements, and Partnerships

The logical place to begin assessing a culture of biosafety, biosecurity, and responsible conduct in the international context is with international treaties and partnerships that help establish international norms. The Biological and Toxin Weapons Convention (BWC), the Global Health Security Agenda (GHSA), the G7 (formerly G8) Global Partnership against the Spread of Weapons and Materials of Mass Destruction (G7 GP), United Nations Security Council Resolution 1540 (UNSCR 1540), the International Health Regulations (IHR; 2005), and the Global Health Security Initiative (GHSI) are instruments with the potential to strengthen an international culture of biosafety, biosecurity, and responsible conduct in the life sciences. Of these treaties and partnerships, only the BWC (largely through its Meeting of Experts), GHSA, and G7 GP explicitly address culture; UNSCR 1540, the IHR, and the GHSI do not directly address culture but do participate in activities that are complementary or supportive of putative strengthening initiatives. However, none of these agreements offers a detailed discussion of what defines a culture of responsibility and how culture change initiatives can be measured and evaluated.

The BWC provides a foundation for the current debate pertaining to dual-use research; much of what is allowed under the treaty as biodefense research for "prophylactic, protective, or other peaceful purposes" could be used for malicious intent. The uncertainty in judging research for offensive versus defensive purposes makes this a complicated matter. The BWC implicitly requires a sense of responsibility among those conducting dual-use research, and fostering a culture of responsibility is deeply relevant to the BWC's objectives.[1]

The Final Declarations of recent BWC review conferences offer brief references to codes of conduct.[2] In 2006, the Sixth Review Conference Final Declaration specifically references the "importance of codes of conduct and self-regulatory mechanisms" and "encourages their development, promulgation, and adoption." While the mention of codes of conduct is encouraging and indicates an international awareness of their significance among researchers, there is no detailed description of mechanisms by which to accomplish such self-regulation or normalization of responsible conduct. The Final Declarations of the Seventh and Eighth Review Conferences (in 2011 and 2016, respectively) both "encourage the promotion of a culture of responsibility amongst relevant national professionals" as well as the

"voluntary development, adoption, and promulgation of codes of conduct." While encouraging a culture of responsibility is a positive addition in the two most recent Review Conferences, there is still little in the way of specific prescriptions, and the emphasis remains solely on voluntary adoption of codes of conduct.

The annual Meeting of Experts also provided an important venue for discussions relevant to the BWC, and heavily influenced international nonproliferation and counterproliferation efforts. In 2015, the delegation from Argentina stated that "the continuous and accelerating rate of progress in knowledge imply the necessity of deepening a culture of responsible use of this knowledge."[3,4] Other delegations have expressed bounded support, or even outright criticism, citing restrictions on innovation, concerns over a "one size fits all" code of conduct, and uncertainty regarding the actual utility of codes of conduct.[5] To date, the Meeting of Experts has advised states parties to pursue voluntary codes of conduct. Overall, while the ongoing discussion has been valuable and may influence states to pursue such voluntary codes of conduct independently, no tangible changes have resulted at the BWC level.

An international culture of responsibility also is addressed by the Global Health Security Agenda which was launched in February 2014. The most recent of these treaties and partnerships, the GHSA is aimed largely at capacity building, working in a collaborative fashion to achieve the core capacities of both the IHR (2005) and the World Organisation for Animal Health's Performance of Veterinary Services Pathway. The GHSA objectives are divided into a number of action packages. Of these, Action Package Prevent 3: Biosafety and Biosecurity aims specifically to "promote a shared culture of responsibility." The vision of the GHSA also describes global health security as a "shared responsibility" of the international community.

In addition to the BWC and GHSA, the G7 Global Partnership against the Spread of Weapons and Materials of Mass Destruction, in its 2016 Statement on Non-Proliferation and Disarmament, included a call to "establish a culture of responsibility" among industry and other stakeholders. The G7 GP also continuously pledges support for a number of international treaties and nonproliferation regimes, including the BWC and UNSCR 1540.[6]

Unlike the BWC, GHSA, and G7 GP, other international treaties and partnerships address the culture of responsibility only indirectly. UNSCR 1540 is designed to support all international nuclear, chemical, and biological weapons (NCB) nonproliferation but does not explicitly consider a safety and security culture. However, such a culture would be one that is intrinsic to the "implementation of appropriate controls over related materials" and complementary to the required "appropriate effective laws prohibiting activities involving the proliferation of NCB

weapons and their means of delivery to non-state actors, in particular for terrorist purposes," mandated by the UNSCR 1540. While the resolution text itself makes no specific mention of responsible conduct or codes of conduct, it is difficult to see how the goals of UNSCR 1540 could be achieved without consideration of a safety and security culture and responsible conduct in science.

While the IHR (2005) has a broad scope, the actual treaty text makes no reference to culture or responsible conduct. In fact, there is no mention of the words culture, biosafety, biosecurity, code of conduct, responsible conduct, or responsible practices in the entire document. The focus of the IHR text largely revolves around outbreak protocol, surveillance, reporting, and capacity building; however, there is surprisingly little mention of laboratory safety concerns. The IHR Joint External Evaluation Tool includes an assessment of IHR capacities as well as biosafety and biosecurity but does not mention either topic in relation to organizational culture.

Lastly, the GHSI also makes no specific reference to a culture of biosafety, biosecurity, or responsible conduct. Although designed to fill gaps in addressing international health issues, the focus of the GHSI does not appear to have expanded to include responsible conduct in the life sciences, perhaps avoiding duplication of efforts with the GHSA.

International Organizations

International organizations (IOs), while not possessing the authority of treaties, typically focus on intergovernmental cooperation in specific subject areas. IOs that engage with the life sciences are a natural partner for the promotion of a culture of biosafety, biosecurity, and responsible conduct. The World Health Organization (WHO), the World Organisation for Animal Health (OIE), and the Food and Agriculture Organization (FAO) are also players in strengthening an international culture of biosafety, biosecurity, and responsible conduct in the life sciences.

The WHO, as the leading global health IO, does provide guidance on this matter in the form of a document titled Responsible Life Sciences Research for Global Health Security (a guidance document), published in 2010. This guidance document specifically identifies a "culture of scientific integrity and excellence" as the "best protection against the possibility of accidents and deliberate misuse, and the best guarantee of scientific progress and development." This document's thorough exploration of responsible research is a valuable tool that can be relied upon in fostering an organizational culture at the international level.

The OIE also has its own Biological Threat Reduction Strategy. In this document, the objective of Key Area 2: Good Governance, Capacity Building, and

Implementation of the One Health Concept is to "maintain the OIE Laboratory Twinning Programme to improve compliance with OIE Intergovernmental Standards, including for biosecurity and biosafety, to create a culture of responsible science and good laboratory practice, and to develop scientific expertise in developing countries." As with the WHO, the OIE provides veterinarians, animal science researchers, and those researchers who work with laboratory animals a wealth of guidance. While not focused explicitly on culture, this document acknowledges culture as vital to threat reduction.

Lastly, the FAO discusses a "regulatory culture" in relation to the development of national biosecurity strategies.[7] While more limited in scope than the WHO guidance document, the encouragement of national biosecurity strategies and related shifts in regulatory culture is positive.

International Professional Organizations

International professional organizations are another important and influential group to consider when discussing professional culture and the creation of norms. Such organizations create standardized training, certification requirements, codes of conduct, professional oaths, and shared values. A number of international professional organizations play a role in creating and strengthening an international culture of biosafety, biosecurity, and responsible conduct in the life sciences. While the use of codes of conduct has been debated at many BWC review conferences and BWC Meetings of Experts, professional organizations have plentiful practical experience in using codes of conduct and could serve as a model for the international community.

The International Federation of Biosafety Associations (IFBA) is one such prominent professional organization. In the IFBA's own words, its "mission is safe, secure and responsible work with biological materials," and with regard to biosecurity and biological nonproliferation, it references encouraging a "culture of responsibility and accountability."[8] The IFBA uses innovative methods to foster such a culture. The association's Biosafety Heroes program, for example, recognizes specific individuals nominated by their peers "who make significant contributions to help others in the field of biosafety and biosecurity" and who "serve as role models, showing others that each individual is important and can contribute to the global fight against infectious diseases."[9] Creating a system of recognition for outstanding work in biosafety and biosecurity not only incentivizes such efforts, it also highlights individuals whose actions ought to be emulated, offering an unconventional way in which to foster a culture of responsible research. The IFBA also has a mentoring program that works in a similar community-driven manner to establish an international culture of biosafety and biosecurity. In this program,

the IFBA offers to connect young scientists with mentor volunteers as well as to connect new biosafety and biosecurity associations with nearby established associations in their respective global regions. By acting as a facilitator, the IFBA helps encourage a culture of responsible conduct through voluntary, open, and consistent communication among scientists and regional science groups.[10]

The InterAcademy Panel (IAP), or IAP for Science, also has been active in arguing for and supporting the idea of a professional code of conduct or code of ethics for scientists. The panel has published a number of documents proposing possible content for such a code, including a 2005 Statement on Biosecurity. In subsequent years, the panel has supported the inclusion of a code of conduct in the BWC; while this topic has been discussed at multiple BWC Review Conferences, states parties have yet to reach a consensus regarding the necessity, utility, or possible content of such a code. In 2012, the panel published a policy report titled Responsible Conduct in the Global Research Enterprise, continuing to encourage international consensus. The American Biosafety Association International (ABSA International) also has undertaken efforts to share best practices with international partners; however, for the utmost benefit, the international community should seek to share best practices multilaterally, with participation from a variety of professional organizations worldwide.[11]

Lastly, while strictly not a "professional" organization, DIYbio provides a similar community and services to amateur and "do it yourself" scientists. The last decade has seen increased amateur engagement in the life sciences, and the growing number of groups for amateur scientists (DIYbio chief among them) ought not to be ignored when discussing the creation and strengthening of a culture of responsibility, particularly in the context of biosafety. DIYbio is an organizing body for amateur and novice scientists with the mission of "establishing a vibrant, productive, and safe community of DIY biologists." DIYbio, in line with its mission statement, has both a European and a North American Code of Ethics.

Professional organizations offer the international community a wealth of best practices and lessons learned in creating and influencing an organizational culture and can be valuable partners in future international efforts.

The Nuclear Safety and Security Model

Finally, in efforts to foster a safety and security culture, nuclear safety and security culture often is held up as an example of success. One possible method for fostering an international culture of responsibility in the life sciences is to model efforts, in part, after the well-established international nuclear safety and security culture. The nuclear industry maintains a robust and relatively standardized safety

and security culture. In 2008, the International Atomic Energy Agency (IAEA) published an Implementing Guide for Nuclear Security Culture that indicates the importance of a security culture, identifies the roles and responsibilities of key stakeholders, and describes the characteristics of security culture, including beliefs and attitudes, principles, management systems, and behavior. There is also a Code of Conduct on the Safety and Security of Radioactive Sources and self-assessment guidance for IAEA member states, as well as a biennial Nuclear Security Summit. The nuclear model should not be replicated exactly because the safety and security needs of nuclear materials are vastly different from those of living pathogens. However, the spirit of such a safety and security culture provides a myriad of possible strategies to pursue for the life sciences. The life sciences can learn from and adapt many of the practices rather than "reinvent the wheel."[12]

U.S. Efforts to Strengthen the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences

Although the federal biological select agent and toxin (BSAT) regulations—which govern agents specifically identified by the U.S. Department of Health and Human Services/Centers for Disease Control and Prevention and the U.S. Department of Agriculture (USDA)/Animal and Plant Health Inspection Service (APHIS) as having the potential to pose a severe threat to human, animal, or plant health, or to animal and plant products—have been strengthened over the past decade, the unique security challenges posed by BSAT demand continuous vigilance and complementary nonregulatory measures. Such nonregulatory measures should be appropriate for the life sciences research environment, which is driven by data and material sharing, national and international collaboration, and a history of openness. In this context, the National Science Advisory Board for Biosecurity set a proposed goal that at every institution conducting BSAT research "personnel approved for access to select agents and toxins are behaving in a responsible and trustworthy manner that upholds public health and safety, national security, and the integrity of the scientific enterprise."[13, 14, 15]

Similarly, the 2009 edition of the National Academies of Sciences, Engineering, and Medicine "On Being a Scientist" emphasizes that research must be based on the same ethical values that apply in everyday life, including honesty, fairness, objectivity, openness, trustworthiness, and respect for others; it also notes that a researcher is more likely to make responsible choices when considering his or her obligations toward other researchers, toward oneself, and toward the public. Other professional organizations such as ABSA International, the American Society for Microbiology (ASM), and the Association of Public Health Laboratories each have developed tools and conducted workshops and webinars supporting a culture of responsibility. Within academia, a number of universities, particularly those

housing National Biocontainment Laboratories, have led the way in fostering a culture of responsibility. Various academic and professional organizations also have adopted codes of ethics and professional conduct to raise awareness, reinforce the central norm that biological weapons are unacceptable, discourage any misuse of life sciences, and seek a balance between the pursuit of scientific knowledge and the ethical responsibilities toward society.

Following a number of reports of lapses in biosafety and biosecurity at federal laboratories, the Federal Experts Security Advisory Panel (FESAP) was directed by the White House National Security Council in September 2014 to undertake a comprehensive review and to identify specific recommendations to strengthen biosafety and biosecurity practices and oversight of federally funded activities involving (but not limited to) BSAT. While directed at the federal research system, FESAP recommendations have broad applications and also have the potential to inform biological risk management practices in nonfederal life sciences research. Of note, most FESAP recommendations are directly relevant to operative paragraphs of UNSCR 1540 on accounting for, securing, and physically protecting biological weapons–related materials.[16]

First among the FESAP recommendations is that the U.S. government strive to "create and strengthen a culture that emphasizes biosafety, laboratory biosecurity, and responsible conduct in the life sciences." This recommendation is currently being implemented by an interagency working group co-chaired by the U.S. Department of Health and Human Services/Office of the Assistant Secretary for Preparedness and Response and the USDA/APHIS with engagement by several members of academic and professional organizations.

The FESAP working group envisions a culture of biosafety, biosecurity, and responsible conduct in the life sciences to be characterized by compliance with laboratory biosafety and biosecurity regulations, guidelines, standards, policies, and procedures, and enhanced by effective training in biorisk management. A culture of responsibility also encompasses the willingness of personnel to report problems, respond to incidents, and communicate possible risks in a nonpunitive environment. This type of organizational culture depends on effective risk communication based on a desire and responsibility to protect the health and safety of people and the environment while also maintaining the public trust in the biomedical enterprise. A strong culture of responsibility can be an effective tool in mitigating many of the risks of life sciences research without adding stringent or overbearing regulations.

The FESAP interagency working group based its definition of a culture of biosafety, biosecurity, and responsible conduct on Edgar Schein's seminal work

on organizational culture,[17] the IAEA's guidance on nuclear safety and security culture,[18] and the specific attributes of the life sciences domain. As such, the group defined a culture of biosafety, biosecurity, and responsible conduct in the life sciences as "an assembly of beliefs, attitudes, and patterns of behavior of individuals and organizations that can support, complement or enhance operating procedures, rules, and practices as well as professional standards and ethics designed to prevent the loss, theft, misuse, diversion of biological agents, related materials, technology or equipment, and the unintentional or intentional exposure to (or release of) biological agents."

The culture of biosafety, biosecurity, and responsible conduct, as just defined, has several elements that could be targeted to effect culture change or shifts in organizations, as follows: (1) management systems that prioritize biosafety, biosecurity, and responsible conduct; (2) behavior by leadership and personnel that fosters more effective biorisk management; (3) principles for guiding decisions and behavior as they relate to biorisk management; and (4) beliefs and attitudes on biosafety, biosecurity, and responsible conduct. Each of these elements could be defined further by a series of characteristics and indicators to serve as an assessment tool for the culture of biosafety, biosecurity, and responsible conduct at the organizational level, similar to the tools developed by the IAEA in the nuclear domain.

In order to share widely and promote increased attention to organizational culture, the working group has developed a number of educational materials, including a fact sheet, a slide template for training and outreach, a crossword puzzle, and a set of guiding principles to promote a culture of biosafety, biosecurity, and responsible conduct in the life sciences. These materials will assist trainers and educators with integrating culture concepts into existing bioethics and laboratory quality management curricula. The group also developed a case study titled "In Hindsight: Scenarios That Illustrate the Importance of a Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences Research.[19] Working group members have conducted outreach through participating in conferences, publishing articles, and encouraging federal and nonfederal stakeholders to promote culture concepts and working-group-developed materials on their websites and to incorporate them into their training or educational activities.

Other States Championing a Culture of Biosafety, Biosecurity, and Responsible Conduct

There are other sources of best practices and lessons learned about enhancing the culture of biosafety, biosecurity, and responsible conduct in the international community as well. While it is beyond the scope of this undertaking to assess the activities of all states pertaining to a culture of biosafety, biosecurity, and responsible conduct in the life sciences, a number have made notable strides.

The Pakistan Biological Safety Association (PBSA), launched in 2008, is a nongovernmental professional organization that has undertaken "biosafety as a scientific discipline" and seeks to serve as a resource to Pakistan's growing scientific community. The PBSA has joined with a number of national and international partners as well, including the IFBA, National Institutes of Health's Fogarty International Center, International Council for the Life Sciences, Fogarty International Center (Belgium), and ASM. PBSA stands as an excellent example of professional organizations' ability to prioritize a culture of biosafety, biosecurity, and responsible conduct, and its engagement with the concept can be used as a model for other professional organizations, state initiatives, and international partnerships to replicate.

The Netherlands, too, has made notable strides toward creating and strengthening a culture of biosafety, biosecurity, and responsible conduct in the life sciences. In 2008, a Biosecurity Working Group published a Dutch Code of Conduct for Biosecurity, citing both the BWC and the IAP Statement on Biosecurity as influences. This document is a prime example of a comprehensive national code and the pursuit of a voluntary code of conduct that the BWC encourages. The Code of Conduct for Biosecurity could be used as a model for other states seeking to establish voluntary national codes and, eventually, could also serve as a model for an international code. The Danish Centre for Biosecurity and Biopreparedness has also published a book, titled An Efficient and Practical Approach to Biosecurity, that extensively discusses biosecurity culture, including a call for an international culture.

Conclusion

Challenges remain on how best to address the issue of operationalizing the concept of a culture of biosafety, biosecurity, and responsible conduct in order to address goals such as: (1) reducing the occurrence of laboratory-acquired infections (LAIs), incidents, and near misses, (2) ensuring that biosafety, biosecurity, and responsible conduct receive adequate attention, (3) ensuring that organizational members share the same beliefs and attitudes about risks, LAIs, and near misses,

(4) increasing commitments to biosafety and biosecurity, and (5) assessing the breadth and strength of a biosafety and biosecurity program. Because research in the life sciences is characterized by numerous international collaborations and widespread sharing of knowledge and technologies, the achievement of these goals will have significant benefits at both the national and international levels.

The United States has undertaken efforts to implement the recommendations made by FESAP following its 2014 review of federal laboratory practices and federally funded research with the goal of enhancing national biosafety and biosecurity. Similar efforts at the international level could be considered to enhance biosafety and biosecurity as an international research community rather than in limited state-level efforts alone. While it may not be necessary for every international agreement or organization to address this issue, opportunities exist to evaluate and strengthen the culture of biosafety, biosecurity, and responsible conduct in the life sciences. Considerations include:

1. International regimes and organizations could partner with international professional organizations to enhance efforts to share best practices and lessons learned in strengthening a culture of biosafety, biosecurity, and responsible conduct.
2. The international community could strive to create an organizational culture within the life sciences that is modeled and assessed in part similarly to the well-established nuclear security culture.
3. The international community could enhance efforts to recognize champions of culture at the state level both for their biosafety and biosecurity efforts as well as their potential to model these efforts for the international community.

Of the bodies discussed here, professional organizations are leading the way in creating tangible programs and incentives for establishing and strengthening a culture of responsibility in the life sciences. They are often better suited to directly influence organizational culture,[20] and are able to make changes more efficiently, than international regimes or organizations; professional organizations are able to provide trainings and workshops directly to professionals and students and are generally far less weighted down by international politics. International regimes and organizations should partner with these professional organizations and acknowledge their contribution to the establishment and strengthening of a culture of responsibility. The international community may have difficulty agreeing on codes of conduct or standardizing an organizational culture at the international level, as seen in the debates at multiple BWC Meetings of Experts; yet many professional organizations already have standing codes of conduct or ethics and mechanisms for fostering a culture of responsibility. Increased membership in these organizations and increased exposure likely would spur other professional

organizations to follow suit and could move the international research community gradually in the direction of a set of standards.

Additionally, in modeling efforts after those from nuclear safety and security culture, the international community could benefit from lessons previously learned and avoid the need to "reinvent the wheel."[21] Aspects of nuclear safety and security culture, such as self-assessment methodology, the biennial Nuclear Security Summit, and its Code of Conduct on the Safety and Security of Radioactive Sources, could be replicated within the life sciences. There is a long history of calls for an international life sciences code of conduct and a regularly held summit, which would be separate from and more frequent than the BWC Review Conferences. An international effort to "translate" the IAEA's Self-Assessment of Nuclear Security Culture in Facilities and Activities That Use Nuclear and/or Radioactive Material into guidance for life sciences organizations could lead to a useful tool to determine the baseline strength of an organizational culture and to measure outcomes of culture change initiatives. While the nuclear model should not be replicated exactly, the spirit of such a safety and security culture provides a wealth of possible strategies to pursue for the life sciences.

States that have pursued culture change initiatives or voluntary codes of conduct, or that have domestic professional organizations active in this space, can serve as models and champions in the international community. While these states' experiences may contain challenges, issues, and successes specific to their regions, they nevertheless are a valuable source of information and inspiration for the international community. **SD**

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