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LIFE SCIENCES PROFESSIONAL RESPONSIBILITY IN AN AGE OF DUAL-USE RESEARCH

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INTRODUCTION

Biotechnology is progressing at an unprecedented pace promising to bring tremendous benefits by responding to health, socio-economic, and environmental challenges. At the same time, cutting-edge life sciences advances raise multifaceted social, legal, ethical, and security concerns, including the risk of accidental or deliberate misuse. Reconciling the expected benefits with potential risks requires effective governance of dual-use life science research. The US National Science Advisory Board for Biosecurity (NSABB), a consultative committee to the US Government defines 'dual-use research' as "the development of new technologies and the generation of information with the potential for benevolent and malevolent purposes" noting that "virtually all life sciences research has dual use potential" (1). To facilitate policy-making in this area at national as well as institutional level, the NSABB has developed a criterion for identifying dual-use research of concern (DURC): "life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security" (2, 3).

Dual-use risk management needs to be multi-layered and flexible; regulation *per se* is not sufficient to capture the wide-ranging security implications of cutting-edge life science advances. Fostering a shared understanding within the life science community of the risk that the life sciences could be misused in ways that cause harm to humans, animals, or plants is key. Life sciences stakeholders have a duty to be aware of the potential for misuse of scientific findings and of their obligation to help inform and shape critical policy decisions about biological security in the life sciences (1). On the other hand, policymakers should also seek to strike an appropriate balance between national security and unhindered scientific research when considering DURC gover-nance options.

DUAL-USE LIFE SCIENCE RESEARCH

The international norm against deliberate disease and the hostile misuse of life sciences is enshrined in the 1975 Biological and Toxin Weapons Convention (BTWC). Under Article I of the Convention:

> "Each State Party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain: (1) microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes" (4).

A fundamental element of the BTWC is the 'ge-neral purpose criterion' which seeks to gua-rantee a comprehensive international ban on biological and toxin weapons, on the one hand, and ensure the legitimate use of biological agents and toxins for peaceful, prophylactic, and protective purposes, on the other (5). BTWC is of relevance to the governance of dual-use life sciences research, insofar as the latter entails benignly intended (legitimate) work, which could be misused for hostile purposes. Hence, it is of utmost importance that dual-use life sciences research is considered through a broad lens, which takes into account the interdisciplinary character of such activities.

The 2006 National Research Council's report *Globalisation, Biosecurity and the Future of Life Sciences* examined trends and objectives of research in the life sciences and converging fields such as materials science and nanotechnology that may enable the development of a new generation of biological threats (6). The report noted that:

> "The growing concern regarding novel types of threat agents does not diminish the importance of naturally occurring threat agents […] or "conventionally" genetically engineered pathogenic organisms. However, it does mandate the need to adopt a **broader perspective** in assessing the threat, focusing **not** on a **narrow list** of pathogens, but on a **much wider spectrum** that includes biolo-gically active chemical agents. The potential **threat spectrum** is **thus exceptionally broad** and **continuously evolving** – in some ways predictably, in other ways unexpec-tedly. The viruses, microbes, and toxins listed as "select agents" […] are just one aspect of this changing landscape of threats. Although some of them may be the most accessible or apparent threat agents to a potential attacker, particularly one lacking a high degree of technical expertise, this **situation is likely to change** as a result of the **increasing globalization** and **international dispersion** of the most cutting-edge aspects of life sciences research" (6). [emphases added]

A broad-based, intertwined network of mutually reinforcing actions implemented in a manner that engages a wide variety of communities are required to successfully reduce the likelihood that novel technologies may be used for malevolent purposes (6). Those in the life sciences – whether in academia, industry, or government – have an important role to play in shaping the governance ecosystem of dual-use research to ensure that biological security risks are managed in a timely and effective manner (7).

THE VALUE OF LIFE SCIENCES ENGAGEMENT

Promoting awareness of the norm against biological weapons among those in the life sciences has been recognised by BTWC States Parties as a way of ensuring the effective and comprehensive implementation of all elements of the Convention. The Eighth Review Conference of the BTWC in 2016, when considering Article IV on the national implementation of the Convention noted the value of national implementation measures to:

> "(a) implement voluntary management **standards** on **biosafety** and **biosecurity**;
> (b) encourage the consideration of development of appropriate **arrangements to promote awareness** among relevant professionals in the **private** and **public sectors** and throughout relevant scientific and administrative activities;
> (c) promote amongst those working in the biological sciences **awareness** of the **obligations** of States Parties **under the Convention**, as well as relevant **national** legislation and guidelines;
> (d) promote the development of **training and education programmes** for those granted access to biological agents and toxins relevant to the Convention and for those with the knowledge or capacity to modify such agents and toxins;
> (e) encourage the promotion of a **culture of responsibility** amongst relevant national professionals and the voluntary development, adoption and promulgation of **codes of conduct**" (8). [emphases added]

Life scientists need to be aware of the dual-use potential of their work and contribute to the identification, assessment, and mitigation of biological security risks. The Inter-Academy Partnership (IAP)'s guiding document *Doing Global Science: A Guide to Responsible Conduct in the Global Research Enterprise* contains a designated chapter on "Preventing the Misuse of Research and Technology" which elucidates the responsibility incumbent upon those in the life sciences with regard to dual-use research:

> "The difficulty of predicting the future course and applications of research does not absolve researchers of the responsibility for participating in venues to explore these issues. **Researchers need to participate in discussions about the possible consequences of their work, including harmful consequences, in planning research projects**. As the ones who design and carry out research, researchers can provide information on the nature and purpose of research that is not available in any other way" (9). [emphases as original].

In its *Responsible life sciences research for global health security: a guidance document* published in 2010, the World Health Organisation (WHO) has underscored that the consideration of issues related to possibility of accidents or misuse of the life sciences constitutes an essential element of an effective biorisk management framework for responsible life science research (10). Researchers and institutions need to develop "a better understanding of the potential risks associated with accidents and the deliberate misuse of life sciences research" and "learn about practical measures that will enable them to manage some of the risks posed by life sciences research" (10).

Shortly after the publication of this guidance document, the gain-of-function research on the genetic transmissibility of H5N1 influenza virus conducted by two groups (one in the Netherlands and the other a joint Japan/US group) prompted WHO to convene technical consultations with international experts from science, ethics, safety, and security fields to address go-vernance issues on these DURC experiments (11, 12, 13). Participants noted that:

- "DURC is an issue for **all** countries. Scientific research is conducted in virtually all countries and is critical to strengthening global response to **all health threats and hazards**, including those posed by naturally occurring and by accidentally or intentionally released biological agents.
- The management of DURC-related risks should take into account **all stages** of the research cycle, from initial conceptualization and development of a proposal, to provision of funding, to conduct of the research, analysis of results, storage and potential use of material results, including modified biological agents, and dissemination of findings.
- Some countries and institutions have developed **oversight mechanisms** to manage DURC-related risks. Many, however, have not done so, owing to competing demands on resources and capacity, limited awareness of the issue, or a perception that it is not relevant to their particular context or priorities. Nonetheless, oversight mechanisms which take into account **both the benefits** of undertaking such research as well as **the risks are important**.
- The development of guiding principles, toolkits, best practices and other forms of technical assistance would help countries formulate their own policies and procedures for managing DURC. Although establishment of a **legally** binding global agreement or re-gulation is **theoretically possible**, such an approach would be **expensive**, **slow**, likely **impractical** and would **not** necessarily **yield** the desired benefits.
- **Communication** and continuing **dialogue** across a broad range of sectors and stakeholders are **essential** to create a **culture of responsibility**, **cooperation** and **trust**. In particular, improving **mutual** understanding of the various approaches to **risk identification** and **assessment** among stakeholders will be critical to establishing that dialogue.
- **Awareness-raising**, **education** and **training** on biosafety, biosecurity and DURC are **essential** not only for researchers but also for **all sectors and stakeholders**" (11). [emphases added]

The current Intersessional Programme (2018-2020) of the BTWC seeks to advance common understanding and effective action on many of these issues, including the review of science and technology developments and identification of potential benefits and risks relevant to the Convention; biological risk assessment and management; and opportunities for life sciences engagement such as the development of codes of conduct and biosecurity education (14). Nevertheless, it is worth noting that the perceptions of risk differ among States, something evident in the fact that fewer than 5% of the 195 WHO Member States provide oversight for dual-use research with especially dangerous pathogens (15).

As a recent attempt to promote standardised guidance in this domain, in January 2019, the World Organisation for Animal Health (OIE) published *Guidelines for Responsible Conduct in Veterinary Research: Identifying, Assessing, and Managing Dual Use* which seek to raise awareness of the dual-use potential of research in ve-terinary settings and support veterinary professionals, researchers and other stakeholders to effectively identify, assess and manage dual-use implications (16). This guidance document notes that:

"researchers and institutions should integrate **dual-use risk assessment** into their existing

> standard risk assessment procedures. They should exercise their **professional responsibility**, performing a continued, detailed and well-informed risk analysis for **all stages** of the propose research, from project initiation to data publication" (16) [emphases added].

The document further stresses that "the responsibility for the identification, assessment and management of dual-use implications rests to differing degrees across many stakeholders throughout the research life cycle" including researchers and their host institutions, grant and contract funders, companies, educators, scientific publishers and other communicators of research, and regulatory authorities.

TOWARD A BIOLOGICAL SECURITY CULTURE IN THE LIFE SCIENCES

The COVID-19 pandemic has shown how vulnerable the world is to natural and man-made biological threats and there is concern that COVID-19 may lead to a resurgence in interest among terrorists for biological attacks (17). Promoting a shared understanding of dual-use risks in the life sciences is a vital prerequisite for developing effective governance mechanisms and strengthening biological security now and in a post-COVID-19 world (18). Education, awareness-raising, and training are essential instruments in this process and need to be widely utilised by life sciences stakeholders for fostering biological security competence and practical skills for the identification, assessment, management, and mitigation of dual-use risks. Biological security education can serve as a means of facilitating constructive dialogue and cooperation among different disciplines and stakeholders. The *Resource Repository* set up on the BTWC website contains a range of biosafety and biosecurity resources that may assist stakeholders with the national implementation of the Convention (19). The 2019 *Guide to Training and Information Resources on the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences* offers an overview of existing educational content and training opportunities of which life sciences professionals can make use as they develop and implement biological security programmes within their institutions (20). In addition, the International Experts Group of Biosafety and Biosecurity Regulators (IEGBBR), an ad-hoc international initiative that brings together biosafety and/or biosecurity regulatory authorities from eleven countries, is currently developing a "Review of Oversight of Dual-Use in Life Sciences". This resource describing regulatory and non-regulatory oversight approaches for dual-use issues in the IEGBBR countries is intended to serve a useful reference tool for biosecurity capacity building. It takes the form of a mobile application to be launched at the end of 2021 (21).

To maximise the effectiveness of biological security education, training material needs to be paired with an appropriate delivery strategy that meets the needs of the respective training audience. This is particularly important, as "humans are not adept at making connections between disparate fields or types of knowledge, unless they are specifically helped to do so through education" (22). Active learning approaches can help individuals take control of their own learning by enhancing sense-making, self-assessment and reflection:

> "**Motivation** to learn is fostered for learners of all ages when they perceive the school or learning environment is a place where they "belong" and when the environment promotes their **sense of agency** and **purpose**" (23). [emphases added]

An example of an effective teaching and training strategy in the area of biological security is a team-based learning (TBL) (24, 25, 26). TBL is a special form of active learning, which uses a specific sequence of individual work, group work and immediate feedback to create a motivational framework in which the focus is shifted from conveying course concepts by the instructor to the application of course concepts by learners' teams (27). The TBL format is easy to use and replicate but above all, it enables learners to draw links between abstract knowledge and professional practice by learning through experience.

The value of biological security education notwithstanding, relevant additional arrangements need to be in place to ensure sustained engagement within the life sciences community with biological security. To maximise efficacy, such arrangements should be the result of implementing a flexible combination of top-down and bottom-up governance approaches, whereby top-down approaches entail international and national regulations and governmentled initiatives and bottom-up approaches entail civil society-led activities and initiatives (28).

National policies, legal acts, and government strategies and action plans are examples of top-down approaches. Mentorship and professional certification programmes administered by trade associations, biological security codes of conduct implemented by national science academies, and dual-use risk assessment methodologies and frameworks adopted at institutional level are examples of grassroots-level activities. Both sets of approaches are essential for enhancing the governance of dual-use life sciences research and strengthening the international norm of biological prohibition.

Ensuring the effective and sustainable implementation of top-down and bottom-up biosecurity governance approaches that cut across differrent professional communities requires bringing together multiple different voices, including those of women, ethnic minorities, and young people (29). To this end, greater attention needs to be given to the development of equitable and inclusive institutional, national, and international policies, procedures, and practices that encourage and support the active participation of diverse groups of people. For instance, the United Nations has urged Governments to put women's leadership and contributions at the centre of their efforts to recover from COVID-19 and to build a "better future for everyone" (30). Whilst promoting effective gender-responsive approaches to COVID-19 response and recovery is certainly commendable, women also have an important role to play in prevention and preparedness. However, they are often not equitably represented in national or global decision-making on these areas. This is problematic, for a growing body of evidence indicates that fostering diversity and inclusion (D&I) within organisations enhances their capacity for innovation and makes them more adaptive to change, which in turn can bolster their resilience in times of crisis (31). Given the multifaceted challenges posed by the ongoing advancement of the life sciences and the increasing need for biosecurity governance innovation, promoting diversity, and equity-based inclusion within the global life sciences enterprise, including enhancing the participation of women in decision-making constitutes a key element of fostering a sustainable biological security culture.

DISCLAIMER

The views expressed here are those of the authors alone. They may not represent the views of their affiliated organisation and should not be taken as an official statement or position of the affiliated organisation.

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