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Biosafety, biosecurity and internationally mandated regulatory regimes: compliance mechanisms for education and global health security

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Abstract

This paper highlights the biosafety and biosecurity training obligations that three international regulatory regimes place upon states parties. The duty to report upon the existence of such provisions as evidence of compliance is discussed in relation to each regime. We argue that such mechanisms can be regarded as building blocks for the development and delivery of complementary biosafety and biosecurity teaching and training materials. We show that such building blocks represent foundations upon which life and associated scientists – through greater awareness of biosecurity concerns – can better fulfil their responsibilities to guard their work from misuse in the future.

Keywords

awareness-raising; biosafety; biosecurity; education; global health; governance; security; science

Globalization, global governance and the life sciences

The concept of global governance has been described by Held and McGrew as the development of a ‘thickening web of multilateral agreements, global and regional institutions and regimes, transgovernmental policy networks and summits’ that comprise a ‘global governance complex’ (Held and McGrew 2002, preface). While there remains considerable debate as to the nature, scope and limitations of global governance as a concept (Whitman 2005), the intimately related concept of globalization appears to be accepted and embraced by many international organizations and sub-national groups as a means to enhance progress in economic and social well-being. This could be in part due to diverse

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understandings of the term ‘globalization’, which may be understood in terms of trends in acculturation in the form of shared cultural ideals, behaviours and expressions of language, or, for example, at a more political, economic and strategic level in terms of a reduction of national barriers to shared trade and social governance, while also enhancing the division of labour and supply among states based on efficiency motives. For the purposes of this paper, we view globalization as the trend towards interdependence between states, human communities and the environment, arguing that it is now exerting influence over science and security policy just as much as over politics, economics and geostrategic relationships.

We suggest that the effects of globalization on science and security policy are not as well recognized as they could be. In this paper, we set out an argument that illustrates how to make effective responses to emerging scientific and security biorisks in a globalizing world through a number of educational responses undertaken by and for stakeholders in global health security. We propose that these responses can enhance compliance with three internationally mandated regimes relating to global health security, while also maximizing global engagement with the emerging governance of health and political relationships.

Global health governance

Within the twin concepts of globalization and of global governance, it is clear that ‘global health governance’ has emerged over the past 10–15 years as a major concept on the international stage. Work done by, or under the auspices of the World Health Organization (see, e.g. WHO 2001; WHO/WTO 2002; Drager and Fidler 2004; Blouin, Drager, and Smith 2006), the United Nations (see, e.g. UN Global Issues: Health; UNAIDS; UNFPA; UNICEF; UN Economic and Social Council), among others, has highlighted the need for global cooperation and a shared approach to the oversight and monitoring of global health issues. Such an aspiration naturally has implications for the practice of the life sciences, and the WHO recognized this in the opening of its recent document on responsible research:

Advances in life sciences research are inextricably linked to improvements in human, plant and animal health. Promotion of excellent, high-quality life sciences research that is conducted responsibly, safely and securely can foster global health security and contribute to economic development, evidence-informed policy making, public trust and confidence in science. Yet opportunities may also be accompanied by risks that need to be acknowledged and addressed. The risks under consideration in this guidance are those associated with accidents, with research that may pose unexpected risks and with the potential deliberate misuse of life sciences research. The opportunities offered by the life sciences are too important for governments and the scientific community (including individual researchers, laboratory managers, research institutions, professional associations, etc.) to leave the attendant risks unaddressed. (WHO 2010, 1)

Bearing this warning in mind, we suggest that states do not need to deprioritize their own biosafety and biosecurity needs in the process of enhancing a global response to health threats; rather, we argue that it is possible for states to achieve a global role and successful partnerships in health governance while addressing their own local needs effectively and

that this can be achieved by engaging with biorisk education among the life science and security policy communities.

Definition of terms

It is worth spending a few moments at this point in defining our terms, as linguistic and translation-related confusion has often been a source of frustration and misconception to date in the biorisk world. For the purposes of this paper, we define the terms *biosafety* and *biosecurity* in these ways, in line with the definitions offered by the *Laboratory Biorisk Management* (CWA 15793) guidelines (European Committee for Standardization 2011):

Biosafety is defined in CWA 15793 as follows:

laboratory biosafety describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to biological agents and toxins, or their accidental release (European Committee for Standardization 2011,10).

Biosecurity is defined in CWA 15793 as follows:

laboratory biosecurity describes the protection, control and accountability for biological agents and toxins within laboratories, in order to prevent their loss, theft, misuse, diversion of, unauthorized access or intentional unauthorized release. (European Committee for Standardization 2011, 10)

We would strongly argue that this latter definition of biosecurity is incomplete, as it only refers to the potential loss, theft, misuse and so on of biological materials. We believe that equal attention must be paid to all relevant information, knowledge, processes, practices and equipment associated with potentially or actually hazardous biological materials as well. It is possible to construct or promote the construction of biological (and chemical) weapons without having access to laboratory-based biological (or chemical) materials. An individual or group intent on causing harm could make use of information, knowledge, processes, practices and equipment and apply these to biological or chemical materials obtained or developed elsewhere and still produce a viable biological or chemical weapon without having accessed any actual biological or chemical materials in the same laboratory. Further, we believe that consideration must also be given to what goes on 'beyond the laboratory door' so that all personnel and associated workers (for example, administrators, cleaners, delivery drivers and waste disposal technicians) and others (including families and friends of personnel) should be considered as potential security threats (even indirectly). We are not advocating that security checks be implemented per se on all individuals even indirectly associated with laboratory personnel, but we are suggesting that their role in the maintenance of security should be recognized as a potential source of risk.

Accordingly, we suggest that this addition be made to the existing definition of biosecurity as it stands in the CWA 15793 guidelines:

laboratory biosecurity describes the protection, control and accountability for biological agents and toxins, plus the protection, control and accountability for information, knowledge, processes, practices and equipment associated with these

within or associated with laboratories, in order to prevent their loss, theft, misuse, diversion of, unauthorized access or intentional unauthorized release.

An integrated approach

By taking an integrated approach to the management, monitoring and reporting of three major internationally mandated regimes, we argue that states and non-state actors across national boundaries can engage in effective activities that will enhance compliance with these, and other, international agreements on health and security. We describe these activities as an integrated approach that includes, as a key foundation and element of management, programmes of appropriate training for life scientists and other biorisk stakeholders, in the form of hybrid biosafety and biosecurity education courses. When followed up with relevant national and international monitoring and reporting, we argue that these activities constitute a framework of compliance and development on which further initiatives can be built in due course. We strongly believe that scientists should engage with this process as soon as possible, in order to maintain their authority over the nature and scope of their work. In the absence of effective engagement with this approach by the scientific community, we argue that policy decisions are likely to be taken at national and international levels without the knowledge and understanding that scientists will bring to the debate; this may, in turn, impact in a potentially negative manner on the conduct of science.

Education and training in biorisk management as a means of global health governance

Effective implementation of biosafety and biosecurity measures can contribute not only to minimizing the risks posed by natural, accidental and deliberate disease but also to minimizing the potential for the misuse of life science research. States' obligations in regard to biosafety and biosecurity – including provision for education and training – derive, in part, from internationally mandated regulatory regimes including the International Health Regulations (WHO 2005); United Nations Security Council Resolution 1540 (United Nations Security Council 2004); and the Biological Weapons Convention (Biological and Toxin Weapons Convention 1975).

The objectives of this paper are threefold. Firstly, we highlight areas of overlap in the ways in which biosafety and biosecurity are addressed in the three international regulatory regimes introduced above. We note that each of these regimes places States Parties under an obligation to establish provision in biosafety and biosecurity education and training, and to report upon the existence of such provision as evidence of compliance.

Secondly, we argue that in order to meet the biosafety and biosecurity challenges of the twenty-first century, relevant compliance mechanisms can be employed as building blocks for the development and delivery of complementary biosafety and biosecurity teaching and training materials that are designed to address a broad range of 'in-laboratory' and 'beyond the laboratory door' concerns around biological risk management.

Thirdly, we show that by engaging with a globalization approach to hybrid biosafety and biosecurity education and the monitoring and reporting of life science research, stakeholders

can not only meet their international responsibilities under the three regimes we discuss, but also build, at the same time, their national capabilities to effectively address their own biorisk threats.

Towards an expanded concept of biosecurity

Many stakeholders associate the terms ‘biosafety’ and ‘biosecurity’ only with the laboratory setting. We argue that both of these concepts have a far wider application, particularly in the area of biosecurity. Both terms are set out in the World Health Organization’s (WHO) *Laboratory Biosafety Manual* (WHO 2004) which includes a section on biosecurity guidelines; the WHO’s *Biorisk Management: Laboratory Biosecurity Guidance* (WHO 2006) also provides more detailed guidance on laboratory biosecurity and addresses its basic principles and best practices. Similarly, the 5th edition of the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) (Centres for Disease Control and Prevention 2009), while primarily addressing laboratory biosafety, also includes expanded guidance on laboratory biosecurity principles.

These documents describe *biosafety* in terms of the laboratory setting, that is, as the measures and precautions to be taken to reduce or eliminate exposure of individuals and the environment to potentially hazardous biological agents. Such measures include various degrees of laboratory control and containment, including, for example, laboratory design and access restrictions, personnel expertise and training, use of containment equipment and good laboratory practices. *Biosecurity*, however, refers to the measures to be taken to prevent loss, theft or misuse of microorganisms, biological materials, and research-related information. This is accomplished by limiting access to facilities, research materials and information. BMBL notes that ‘While the objectives are different, biosafety and biosecurity measures are usually complementary’ and that biosafety and biosecurity programmes ‘share common components’ including training and assessment of personnel qualifications. Both biosafety and biosecurity in the laboratory can be said to rely on laboratorians’ understanding and acceptance of the rationale for their implementation and the corresponding management oversight.

The WMD Commission report *A World At Risk* (Commission on the Prevention of WMD Proliferation and Terrorism 2008) shared a similar view and recommended the combining of currently separate biosafety and biosecurity concepts ‘into a unified conceptual framework of laboratory risk management’. We would prefer to advocate the unification of these two concepts into a conceptual framework of ‘bioscience-in-society risk management’, as this incorporates both in-laboratory work and ‘beyond the laboratory door’ activities and outcomes. This is an unwieldy title but we offer it as an illustration of our aims; we believe that these can be achieved in the same way by expanding the existing concept of ‘responsible conduct of research’ into the ‘responsible conduct of science’ – thereby including all scientific work, not just that which could be referred to as ‘research’. Work in this field (e.g. Shamoo and Resnick 2009) does address many of our concerns, but not all of these are adequately recognized and responded to even in the most frontline of contexts. Only by taking a social responsibility approach can we ensure that the wider environment

and populations are protected from a range of biorisks that are currently viewed as laboratory-based risks only.

The WMD Commission also recommended that such a framework should be integrated into a 'programme of mandatory education and training for scientists and technicians in the life sciences field, whether they are working in the academy or in industry. Such training should begin with advanced college and graduate students and extend to career scientists'. This is a crucial point that we strongly support. We provide, below, suggestions as to how this may be achieved.

Both BMBL and the U.S. National Research Council (NRC 2011) acknowledge the challenges of biosecurity which seeks to '... move the life sciences forward for legitimate purposes while reducing the risks that some material, knowledge, tools, and technologies, could also be used to do harm.' However, we are faced with a situation in which the life sciences and associated technologies are widely dispersed, easily accessible, increasingly global, and advancing at a rapid pace. They are likely, by their very nature as scientific and commercial enterprises, to provide opportunities to those who seek to misuse them to cause harm. We argue that because of this, any biosecurity measures employed to prevent loss, theft or misuse of microorganisms, biological materials, and research-related information, are not solely the responsibility of laboratory workers or facilities but are in fact a national and global responsibility.

The *Bradford Review Conference Paper No. 26, 'Effective Implementation of the BTWC: The Key Role of Awareness Raising and Education'* (Whitby and Dando 2010), advanced a change to 'broadly-inclusive' definition of the concept of biosecurity, linking it to the language set out in the Biological Weapons Convention which ties the 165 States Parties into compliance with this legally binding agreement through the enactment of 'necessary' national implementation measures. The Bradford definition argues that biosecurity:

relates to the safety and security of materials [including laboratory biosafety and laboratory biosecurity] and concerns minimizing the risk that dangerous materials might be used with malign intent. The term biosecurity relates to a much wider meaning [however] which includes the concept of a web of preventative policies that centre around the legally binding international prohibition that is embodied in the General Purpose Criterion of the Biological and Toxin Weapons Convention (BTWC).

Thus biosecurity, it argues, is:

the objective of a broad but related range of policies and mechanisms that are designed to minimize the risk that the life sciences can be used for hostile purposes and thus as well as laboratory biosafety and laboratory biosecurity, includes a broad range of related measures including biodefence, export controls, and a range of national implementation measures, not least, those that relate to the national implementation of the BTWC.

Further to this, the Bradford definition argues that within the range of biosecurity policies there is:

... an important role for education in the training of young life scientists and in the ongoing training and professional development of practicing life scientists in being aware that the materials, technologies and knowledge they produce may be misused; and, for contributing their expertise to the development and maintenance of preventive policies.

According to the *World At Risk* report:

The choice is stark. The life sciences community can wait until a catastrophic biological attack occurs before it steps up to its security responsibilities. Or it can act proactively in its own enlightened self-interest, aware that the reaction of the political system to a major bioterrorist event would likely be extreme and even draconian, resulting in significant harm to the scientific enterprise.

Bearing this in mind, we argue that the inter-disciplinary nature of life sciences research, the evolving nature of the amateur biology community, and the convergence of biotechnologies with other technologies (for example, *inter alia*, nanotechnology and informatics) requires a diverse and multipronged approach to awareness raising, education and outreach of a variety of stakeholders from life sciences-related disciplines as well as the general public, press and policymakers, all with critical roles in devising the 'web of preventative policies' and best practices to ensure global biosecurity.

Biosafety, biosecurity and internationally mandated regulation

By considering national biosafety and biosecurity implementation obligations in the context of the International Health Regulations (WHO 2005), United Nations Security Council Resolution (UNSCR) 1540 (UNSC 2004), and, the Biological Weapons Convention (BTWC 1975), it is possible for States Parties to find a framework in which biosafety and biosecurity obligations overlap. The process of combining responses to all three regimes by addressing biosafety and biosecurity together in a cross-regime response will be especially helpful in defining a States Party's needs for education and training both now and in the future. Such a cross-regime response will also enhance compliance with all three regimes, and, importantly, ease the management of reporting expectations under each of these instruments. Further, it will facilitate and support a necessary inter-ministerial collaboration; with each of these areas falling under the purview of different national authorities, such interministerial collaboration will maximize the use of limited resources in economically constrained countries and enhance collaboration in more economically sound countries. At the same time, complying States Parties will be engaging in global governance activities involving more than just governmental bodies, supporting the exchange of ideas and progress beyond the constraints of the political arena.

International Health Regulations (IHRs): Core Capacities

The purpose of the WHO International Health Regulations (WHO 2005) is to 'prevent, protect against, control and provide a public health response to the international spread of disease'. New obligations of State Parties under these regulations apply both inside and beyond their borders and cover a wide variety of public-health emergencies that are not solely confined to infectious threats. The International Health Regulations 2005 (WHO

2005), as an international legal agreement, is binding on 194 States Parties across the globe, including all Member States of the WHO.

The 2005 revised version of the IHRs entered into force on 15 June 2007 and they call for:

- Strengthened national capacity for disease surveillance and control, including during travel and transport;
- In country prevention capacity, the provision of effective outbreak and epidemic alert-and-response systems to international public health emergencies;
- Global partnership and international collaboration;
- Rights, obligations and procedures and progress monitoring.

In this connection, States Parties accept an obligation to develop ‘core capacities’ relating to public health and to complete their obligations for plans and infrastructure as early as June 2012 (with the possibility of two, two-year extensions). To monitor compliance, the WHO published the ‘*IHR Monitoring Framework: Checklist and Indicators for Monitoring Progress in the Implementation of IHR Core Capacities in States Parties*’ (WHO 2007) which establishes a framework that provides:

A set of 20 global indicators for monitoring the development of IHR core capacities for reporting annually to the World Health Assembly (WHA) by all States Parties (mandatory for all)

[and]

An additional 10 indicators for monitoring the comprehensive development, strengthening, and maintenance of States Parties’ IHR core capacities (optional).

The WHO questionnaire sent to States Parties in 2011 to assess the status of national implementation of the IHRs consists of 13 sections, covering the eight core capacities required of States Parties (coordination, legislation policy, surveillance, response, preparedness, laboratory, human resource capacity), four hazards (zoonotic events, chemical events, food safety, radiation emergencies) and finally, points of entry. It also includes the following questions:

- Are biosafety guidelines accessible to individual laboratories?
- Do regulations, policies or strategies exist for laboratory biosafety?
- Has a responsible entity been designated for laboratory biosafety and biosecurity?
- Have biosafety guidelines, manuals or SOPs been disseminated to laboratories?
- Are relevant staff trained on biosafety guidelines?
- Has national classification of microorganisms by risk group been completed?
- Is there an institution or person responsible for inspection (could include certification of biosafety equipment) of laboratories for compliance with biosafety requirements?
- Are biosafety procedures implemented, and regularly monitored?

- Has a biorisk assessment been conducted in laboratories to guide and update biosafety regulations, procedures and practice, including for decontamination and management of infectious waste?
- Are diagnostic laboratories designated and authorized or certified BSL 2 or above for relevant levels of the health care system?
- Have country experience and findings related to biosafety been evaluated and reports shared with the global community?

Among the eight Core Capacities required by the IHRs, as Bakanidze, Imnadze and Perkins (2010) point out, the 'Laboratory' capacity, as defined under 'Core Capacity 8', relates to:

those laboratory quality services relying on communication, specimen collection and transport, financial resources, biosafety and biosecurity best practices, trained personnel, suitable infrastructure, appropriate equipment and reagents, and the delivery of reliable results

Bearing this in mind, Bakanidze, Imnadze and Perkins argue that:

[b]uilding laboratory capacity to support a public health system cannot be done effectively without a strong focus on biosafety Laboratory-based surveillance and outbreak detection are essential to the prevention and mitigation of biological threats, and quality laboratory services are dependent on the implementation of biosafety and biosecurity best practices supported by an appropriate legal framework

They argue that biosafety and biosecurity are 'pillars' that underpin a concept which they refer to as 'global health security'. This concept addresses a number of distinct but related international mechanisms that have overlapping and shared international health and non-proliferation objectives. By combining these under a cross-regime concept such as global health security, they argue that unique national concerns can be transcended. We would argue further, in this paper, that biosafety and biosecurity can also act together to both underpin and facilitate responses to these various regimes.

While the WHO offers significant training and educational resources for strengthening those agencies engaged in setting-up and managing systems for securing global public health under the IHR implementation framework (see, e.g. its web pages at <http://www.who.int/ihr/training/material/en/index.html>) and has, to this end, published its *Biorisk Management: Laboratory Biosecurity Guidance*, we contend here that neither these online educational resources or the WHO questionnaire on IHR implementation are effectively addressing the biosecurity component. This significant gap underlines the need for the updating of WHO training materials and/or the development of additional educational and training resources emphasizing the contribution of biosafety and biosecurity measures towards the international health and non-proliferation objectives.

As Dr Nicoletta Previsani, head of WHO's Biosafety and Laboratory Biosecurity Programme stated:

The spectrum of biological risk runs from naturally occurring diseases at the one end, through unintended consequences, accidents, lack of awareness and negligence, to deliberate misuse at the other. Given same, it is evident that it is futile to attempt to tackle these risks individually, as isolated threats. It is therefore imperative that we meet this challenge collectively. We need to coordinate and harmonise our efforts. (Previsani 2011)

A step forward in the area of shared responsibility is represented by the development of the *Laboratory Biorisk Management Standard CWA 15793:2011*, developed by the European Committee on Standardization (CEN) (European Committee for Standardization 2011), superseding the original version of 2008. Further, in 2012, CEN has produced a set of guidelines for the implementation of CWA 15793 (European Committee for Standardization 2012). Among other provisions, the 2011 document provides a framework that can be used as the basis for training, raising awareness of laboratory biosafety and laboratory biosecurity guidelines and best practices within the scientific community. It emphasizes that the document may be useful in the development of new programmes as well as courses integrated into existing certified trainings, and this approach is to be highly recommended. It includes some specific training recommendations, with sections on planning, risk recognition, management, personnel training and competencies, communications, operations, emergency responses, performance monitoring and oversight.

In a significant step towards its practical implementation, the CEN *Laboratory Biorisk Management Standard* has been used by the WHO in the inspection of the maximum containment facilities at the SRC VB VECTOR and CDC repositories for Variola virus (WHO 2009).

The WHO has also taken steps forward by its release of a guidance document entitled '*Responsible life science research for global health security*' (WHO 2010) which identifies biosafety and laboratory biosecurity as one of the pillars supporting public health. It states:

By emphasizing the public health perspective.... this guidance can achieve a broad acceptance of the need to raise awareness in this area and thus be better able to implement the objectives of promoting responsible life sciences research in general on a global level. (WHO 2010, 3)

And:

Research is essential for public health. Communication, international collaboration and openness, which are central to a public health perspective, are indispensable for global health security, scientific discovery and evidence-based measures. (WHO 2010, 4)

The self-assessment questionnaire that is part of this guidance is meant to identify strengths, weaknesses, and gaps and corrective actions to be taken. Of note, the document also emphasizes that:

Good laboratory biosafety practices will mitigate the risks posed by laboratory accidents while laboratory biosecurity procedures will strengthen the accountability and responsibility of laboratory workers and their managers and thereby enhance

public confidence in the responsible conduct of scientific experiments. (WHO 2010, 31)

While this document and its focus on biosecurity alongside biosafety is to be welcomed, we would argue strongly that its definition of laboratory biosecurity is limited and incomplete. It is our argument that by focusing on biosecurity only in terms of the security of 'pathogens', 'infections' and 'biological materials', the WHO guidance is missing the security value of access to records and materials that provide or enhance knowledge and understanding of relevant scientific processes and data; the guidance shows no recognition of the security hazards inherent in access to these. We argue strongly that access to knowledge, data and scientific processes is a security threat equal to recognized biosafety threats, and as such, needs to be addressed in all consideration of biosecurity, both within and beyond the laboratory. This kind of material includes all paper, electronic and digital records that relate to research or other scientific work that has recognized or potential public health implications. BMBL goes some way towards addressing this definition by referring to the need to protect 'relevant sensitive information' (Centres for Disease Control and Prevention 2009, 105) but the notion of protecting knowledge, data and scientific processes is not widely addressed when discussing biosafety and biosecurity. Sture has, however, provided some practical guidance in this area through the use of an applied research ethics framework (Sture 2010) in which she challenges stakeholders to consider their working relationships and practices in terms of biosecurity and ethics. We would urge this 'beyond the laboratory door' approach to be considered in future revisions of this WHO document and in others.

United Nations Security Council Resolution (UNSCR) 1540: strategies for prevention and deterrence

United Nations Security Council Resolution (UNSCR) 1540 was unanimously adopted on 28 April 2004. Acting under Chapter VII of the United Nations (UN) Charter, in accordance with UNSCR 1540, States Parties accept an obligation to refrain from:

1. ... providing any form of support to non-State actors that attempt to develop, acquire, manufacture, possess, transport, transfer or use nuclear, chemical or biological weapons and their means of delivery; (UNSC 2004)
And that:
2. all States, in accordance with their national procedures, shall adopt and enforce appropriate effective laws which prohibit any non-State actor to manufacture, acquire, possess, develop, transport, transfer or use nuclear, chemical or biological weapons and their means of delivery, in particular for terrorist purposes, as well as attempts to engage in any of the foregoing activities, participate in them as an accomplice, assist or finance them;
3. all States shall take and enforce effective measures to establish domestic controls to prevent the proliferation of nuclear, chemical, or biological weapons and their means of delivery, including by establishing appropriate controls over related materials and to this end shall:

- (a) Develop and maintain appropriate effective measures to account for and secure such items in production, use, storage or transport; and
- (b) Develop and maintain appropriate effective physical protection measures; (UNSC 2004).

All States are also called upon to include in their national reports, as appropriate, information relating to the implementation of Operative Paragraphs 6–9 and 10 of UNSCR 1540, which address national control lists, possible provision of assistance to States Parties in need of it, to adopt national measures to enable the meeting of their obligations under, and to strengthen their engagement with, internationally agreed non-proliferation regimes, to involve industry and the public in these areas and to take cooperative action to uphold the aims of non-proliferation regimes.

Under UNSCR 1540, according to Bakanidze, Imnadze, and Perkins (2010, 5), biosafety and biosecurity capacities are implicit in the requirement that the agreement places upon States Parties, since they oblige states to establish a system – and by implication, relevant education and training capacities – within a national legal framework ‘to account for and secure items in production, use, storage or transport’ and to create provision for ‘effective physical protection measures’. Thus as argued by Bakanidze, Imnadze and Perkins, UNSCR 1540 is seen as a framework that facilitates a ‘strategy of prevention based on each individual state accepting responsibility for implementing measures against the proliferation of materials and weapons’. Again, we would argue that compliance with UNSCR 1540 involves not only biosafety and biosecurity measures being implemented in relation to hazardous biological, chemical or nuclear materials per se, but also to all data, records, paper materials and other communications relating to the knowledge and understanding of processes involved in handling these. Any measures implemented nationally under Operative Paragraph 3 (above) will be incomplete without the inclusion of materials under this definition as well as those materials already recognised. Further, unless measures are implemented to educate, train and support the relevant individuals, communities and organizations involved in working with materials as defined by UNSCR 1540, and with materials as we define them here, we argue that States Parties’ capacity to meet their obligations will be seriously compromised, if not fatally flawed.

Compliance with the UNSCR 1540 requires that States implement such measures ‘without delay’ after entry-into-force and report them to the 1540 Committee (established under UNSCR 1540). UNSCR 1810 (UNSC 2008a) further calls upon all States that have not yet presented a first report on steps they have taken or intend to take to implement UNSCR 1540 to submit such a report to the 1540 Committee without delay. Also, States are to provide, at any time or upon request of the 1540 Committee, additional information on their UNSCR 1540 implementation. States are encouraged to prepare, on a voluntary basis, summary action plans mapping out their priorities and plans for implementing UNSCR 1540.

Concerning biological weapons, related materials and means of delivery, the 1540 Committee identified the following areas where domestic controls should be implemented and enforced:

- Measures to account for/secure production
- Measures to account for/secure use
- Measures to account for/secure storage
- Measures to account for/secure transport
- Regulations for physical protection of facilities/materials/transport
- Licensing/registration of facilities/persons handling biological materials
- Reliability check of personnel
- Measures to account for/secure/physically protect means of delivery
- Regulations for genetic engineering work
- Other legislation/ regulations related to safety and security of biological materials

The 1540 Matrix (see: <http://www.un.org/en/sc/1540/national-implementation/matrix.shtml>), adopted in 2005, is the primary method used by the 1540 Committee to organize information about implementation of UNSCR 1540 by Member States. A matrix for each UN Member State is regularly updated and approved by the Committee. The 1540 Committee uses these matrices to examine the status of implementation of UNSCR 1540 and as a tool to identify gaps existing at national level in its dialogue with States; this then facilitates the provision of technical assistance where necessary. We argue that the 1540 Matrix should be updated to provide States the opportunity to incorporate evidence of effective biorisk management education and training.

Of note, the 10th Programme of Work of the 1540 Committee for the period from 1 June 2011 to 31 May 2012 focused its attention on, *inter alia*, five main areas of work:

- (i) monitoring and national implementation;
- (ii) assistance;
- (iii) cooperation with international organizations, including the Security Council Committees established pursuant to resolutions 1267 (1999) and 1373 (2001);
- (iv) transparency and media outreach; and
- (v) administration and resources (see: http://www.un.org/ga/search/view_doc.asp?symbol=S/2011/380).

The 1540 Committee aims to:

... Continue to raise awareness about the relevant multilateral treaties or conventions that aim to prevent the proliferation of, or eliminate, weapons of mass destruction so as to contribute to their universality

and:

... Encourage and, where appropriate, assist States to integrate their implementation of resolution 1540 (2004) obligations into their pursuit of broader national objectives convergent with the resolution ...

Moreover, the 10th Programme of Work states that the 1540 Committee will:

... continue to organize and participate in outreach activity at the international, regional and subregional levels and, where appropriate, with States, to facilitate coordination of assistance programmes, promote the sharing of experience, lessons learned and effective practices, collect information on requests for, offers of or interest in assistance, and liaise on the availability of programmes that might facilitate the implementation of resolution 1540 (2004).

While the 1540 Committee itself does not provide assistance, it has a clearinghouse role to facilitate assistance by others in the implementation of the resolution. This constitutes a significant opportunity for countries to provide and receive assistance in the areas of biosafety and biosecurity which span the areas of focus of UNSCR 1540 on biological weapons, related materials and means of delivery.

Since the Programme of Work also calls for:

encouraging States to promote dialogue and cooperation, including with civil society, academia and industry, to address the threat posed by illicit trafficking in nuclear, chemical or biological weapons and their means of delivery, and related materials.

and also to:

increase efforts to raise awareness among parliamentarians and other high-level decision makers ...

additional opportunities can be seen within these aims for engaging civil society, academia and industry in developing resources on awareness-raising, education and training with regard to UNSCR 1540 implementation, customized for a broad range of training audiences.

Despite these aims, the inherent opportunities offered by the 1540 Committee's role as a clearinghouse, and the transparency shown by Member States agreeing to publicly post online both requests and offers for assistance on UNSCR 1540 implementation, there are still multiple requests for assistance on biosafety and biosecurity education and training still unanswered on the 1540 Committee website. Obviously, by tackling this gap in provision of assistance, we argue that it will be possible to address the weak implementation of the UNSCR 1540 in the area of biorisk.

Examples of weaknesses in national responses were highlighted in the 2008 report on implementation of the 1540 Committee to the UN Security Council on UNSCR 1540 (UNSC 2008b). This report showed that, from the data available for all States, while only 66 States have adopted legislation and regulations for licensing the use, production and possession of biological weapon-related materials as permitted activities for commercial, industrial and public health purposes, only 37 States regulated genetic engineering activities relating to biological weapon-related materials in separate laws. Further, only 38 States reported having measures in place to account for biological weapon-related materials, and only 25 States reported having measures in place to undertake reliability checks of personnel working with sensitive materials. These figures clearly gave cause for concern, but a degree

of cause is likely to be related to the lack of awareness and understanding of exactly what is required in practical terms by States Parties, including in the key area of education and training for scientists, policymakers and other relevant stakeholders across a multiplicity of institutions and political structures.

Encouragingly, however, the subsequent report in 2011 (UNSC 2011) reveals that:

47. From the data of 2011, the Committee notes that **112 States** have a national legal framework prohibiting the manufacture or production of biological weapons, compared to 86 in 2008. By 1 April 2011, **95 States** had adopted enforcement measures related to the manufacture or production of biological weapons, compared to 83 in 2008.

48. The Committee notes that additional efforts remain necessary to enforce prohibitions in the area of biological weapons with respect to non-State actors. By 1 April 2011, **133 States** had adopted enforcement measures related to the manufacture, acquisition, possession, stockpiling, development, transfer, transport or use of such weapons, compared to 76 in the 2008 report. (UNSC 2011, 11). [Emphasis ours].

Despite these ongoing limitations and what some may call slow progress, we argue that the new Programmes of work of the 1540 Committee raise hopes that there will be more synergy in these areas between the 1540 Committee's activities and those undertaken under the auspices of the IHRs and BWC.

The Biological Weapons Convention (BWC): legally binding obligations

Article I of the Biological Weapons Convention outlines a series of measures that are underpinned by a catch-all obligation to do no harm that is referred to as the 'General Purpose Criterion'. Under Article I of the BWC, States Parties agree that:

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;
- (2) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict. (BTWC 1975).

The General Purpose Criterion is referred to by Perry Robinson (1998) as a '*device*' that gives the treaty adequate scope by enabling it to keep up with scientific and technological change. It protects the beneficent, peaceful application of science and technology for prophylactic, protective or other peaceful purposes while establishing broad prohibitions. Other Articles of the Convention relate to a range of measures that demonstrate State Parties' compliance with their legally binding obligations under the Convention and give effect to the General Purpose Criterion.

At the Seventh Review Conference of the BTWC in December 2011, States Parties reaffirmed the importance of Article I of the Convention confirming that:

1. ... the Convention is comprehensive in its scope and that all naturally or artificially created or altered microbial and other biological agents and toxins, as well as their components, regardless of their origin and method of production and whether they affect humans, animals or plants, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes, are unequivocally covered by Article I.
2. The Conference reaffirms that Article I applies to all scientific and technological developments in the life sciences and in other fields of science relevant to the Convention....
3. The Conference reaffirms that the use by the States Parties, in any way and under any circumstances of microbial or other biological agents or toxins, that is not consistent with prophylactic, protective or other peaceful purposes, is effectively a violation of Article I. The Conference reaffirms the undertaking in Article I never in any circumstances to develop, produce, stockpile or otherwise acquire or retain weapons, equipment, or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict in order to exclude completely and forever the possibility of their use ... (BTWC 2011a).

Article IV of the Biological Weapons Convention places States Parties to the Convention under an obligation to put national implementation measures in place to enhance domestic compliance with the Convention. Article IV thus reads as follows:

Each State Party to this Convention shall, in accordance with its constitutional processes, take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention, within the territory of such State, under its jurisdiction or under its control anywhere.

Also at the Seventh Review Conference in 2011, States Parties reaffirmed the importance of Article IV of the BWC thus:

11. The Conference reaffirms the commitment of States Parties to take the necessary national measures under this Article. The Conference also reaffirms that the enactment and implementation of necessary national measures under this Article, in accordance with their constitutional processes, would strengthen the effectiveness of the Convention. In this context, the Conference calls upon States Parties to adopt, in accordance with their constitutional processes, legislative, administrative, judicial and other measures, including penal legislation, designed to:

(a) enhance domestic implementation of the Convention and ensure the prohibition and prevention of the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipment and means of delivery as specified in Article I of the Convention;

- (b) apply within their territory, under their jurisdiction or under their control anywhere and apply, if constitutionally possible and in conformity with international law, to actions taken anywhere by natural or legal persons possessing their nationality; ... (BTWC 2011a)

With respect to biosafety and biosecurity, the Final Declaration of the Seventh Review Conference called upon States Parties to:

- (c) ensure the safety and security of microbial or other biological agents or toxins in laboratories, facilities, and during transportation, to prevent unauthorized access to and removal of such agents or toxins. (BTWC 2011a)

Although 'legislation' is not specifically referred to in the wording of Article IV of the BWC, it has become common to associate the obligation placed upon State Parties to put in place 'necessary measures' with the enactment of national implementation legislation. The latter gives what Sims (1996) refers to as 'domestic legal effect' to the scope of the prohibition as outlined in the Convention. In terms of the function of this Article of the Convention, Sims points out that national implementation legislation:

.... ties the Convention into national legal systems in the clearest possible way. It contributes to the strengthening of compliance by expanding the constituency with an institutional interest in the success of the Convention. It also builds the treaty regime flowing from the Convention into normative structures at the national level, in the form of rules and expectations and procedures for upholding them. These rules, expectations and procedures in turn uphold their counterparts at the international level. (Sims 1996, paragraph 7)

However, as Sims also acknowledges, national implementation measures are not restricted to the implementation of national legislation, which he argues also extend to the following: 'government decrees, regulations and administrative advice ...' Thus, through a combination of mechanisms, the BWC assigns the task of overseeing domestic implementation and treaty compliance to States Parties through the enactment of 'necessary measures' that can be legislative, regulatory, and administrative.

At the Seventh Review Conference, States Parties agreed to extend the programme of intersessional meetings that had been established at the resumed session of the Fifth Review Conference in 2002 and then again at the Sixth Review Conference in 2006. Further, they agreed to hold a further series of Meetings of Experts and Meetings of States Parties in the run up to the Eighth Review Conference in 2016, to address the following topics as Standing Agenda Items in each year from 2012 to 2015:

- (a) Cooperation and assistance, with a particular focus on strengthening cooperation & assistance under Article X;
- (b) Review of developments in the field of science and technology related to the Convention;
- (c) Strengthening national implementation.

The Conference also decided that the following topics will also be discussed during the intersessional programme in the years indicated:

- (a) How to enable fuller participation in the Confidence Building Measures (in 2012 and 2013);
- (b) How to strengthen implementation of Article VII, including consideration of detailed procedures and mechanisms for the provision of assistance and cooperation by States Parties (in 2014 and 2015).

Notably, the Seventh Review Conference identified the following sub-topics to be addressed under the Standing Agenda Item on strengthening national implementation:

- (a) a range of specific measures for the full and comprehensive implementation of the Convention, especially Articles III and IV;
- (b) ways and means to enhance national implementation, sharing best practices and experiences, including the voluntary exchange of information among States Parties on their national implementation, enforcement of national legislation, strengthening of national institutions and coordination among national law enforcement institutions;
- (c) regional and sub-regional cooperation that can assist national implementation of the Convention;
- (d) *national, regional and international measures to improve laboratory biosafety and security of pathogens and toxins*; [our emphasis]
- (e) any potential further measures, as appropriate, relevant for implementation of the Convention. (BTWC 2011a, 24).

Further, the BTWC Implementation Support Unit (ISU) provided guidance, as a background document to the Preparatory Committee meeting of 13–15 April 2011, in the form of ‘*Information provided to past review conferences on compliance by States Parties with their obligations under the Convention*’ (BTWC 2011b). The ISU compilation notes that States Parties reported on their compliance with the BWC under four general themes: national activities; international activities; assistance; and participation. Historically, aspects of national activities covered in compliance reports submitted by States Parties have included:

- ... (e) The presence of biosafety and biosecurity regimes, or efforts to strengthen such capacity, as well as a summary of measures, arrangements and activities or a link to additional information;
- (f) The presence of education and outreach activities with the life sciences (including codes of conduct), as well as a summary of activities or a link to additional information;
- (g) Interactions with industry and the private sector, as well as a summary of activities or a link to additional information. (BTWC 2011b, 3).

Moreover, as part of their compliance-reporting, some States Parties provided details of how they work in other international forums, for example, describing reports provided to the

United Nations Security Council Resolution 1540 Committee, as well as a summary of the information provided, or a link to additional information.

However, as the ISU noted, no State Party has reported on efforts in all four thematic areas and participation in compliance-reporting at the previous Review Conferences has been rather weak and steadily declining: a total of 52 States Parties have provided compliance information to at least one review conference, but by the Sixth Review Conference, only 13% of States Parties participated in compliance-reporting. That percentage rose significantly at the 7th Review Conference to 22 per cent, most likely due to the record attendance to, and States Parties' interest and engagement in the topics addressed by the 2007–2010 intersessional work programme.

Awareness Raising and Education in the BWC forum

Specific reference to the importance of awareness-raising and education of life scientists was included by BTWC States Parties in the Final Declaration of the Second Review Conference of the BTWC in 1986 where:

The Conference notes the importance of inclusion in textbooks and in medical, scientific and military educational programmes of information dealing with the prohibition of microbial or other biological agents or toxins and the provisions of the Geneva Protocol. (BTWC 1986)

As noted in Bradford Review Conference Paper (RCP) No. 19, agreement on the inclusion in the Final Declaration of the Sixth Review Conference (2006) of a new sentence highlighted the importance of awareness raising and education thus:

The Conference urges States Parties to 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, in order to raise awareness of the risks, as well as of the obligations of States Parties under the Convention. (BTWC 2006, 11)

Indeed, as is noted in *Education and Ethics in the Life Sciences* (Rappert 2010), the emergence of a consensus about awareness-raising and education had developed at the 2008 Meeting of the States Parties which considered:

26. ...the importance of ensuring that those working in the biological sciences are aware of their obligations under the Convention and relevant national legislation and guidelines, have a clear understanding of the content, purpose and foreseeable social, environmental, health and security consequences of their activities, and are encouraged to take an active role in addressing the threats posed by potential misuse of biological agents and toxins as weapons, including bioterrorism. (BTWC 2008, 6)

Paragraph 26 of the 2008 BWC Meeting of States Parties includes an acknowledgement that awareness-raising and education could assist in strengthening the Convention:

States Parties noted that formal requirements for seminars, modules or courses, including possible mandatory components, in relevant scientific and engineering

training programmes and continuing professional education could assist in raising awareness and in implementing the Convention. (BTWC 2008, 7)

Moreover, Paragraph 27 went on to confirm that States Parties agreed on the value of education and awareness programmes that would address the following:

- (i) Explaining the risks associated with the potential misuse of the biological sciences and biotechnology;
- (ii) Covering the moral and ethical obligations incumbent on those using the biological sciences;
- (iii) Providing guidance on the types of activities which could be contrary to the aims of the Convention and relevant national laws and regulations and international law;
- (iv) Being supported by accessible teaching materials, train-the-trainer programmes, seminars, workshop, publications, and audio-visual materials;
- (v) Addressing leading scientists and those with responsibility for oversight of research or for evaluation of projects or publications at a senior level, as well as future generations of scientists, with the aim of building a culture of responsibility;
- (vi) Being integrated into existing efforts at the international, regional and national levels (BTWC 2008, 7).

Indeed, calls for awareness-raising and education for life scientists on dual-use and biosecurity issues have become a focus of attention and action for important States Parties including Canada (through the Global Partnership) and the US (through its Bioengagement Programme). One significant contribution in this connection came in the form of United States Ambassador Christine Rocca's Statement prepared for delivery to the Annual Meeting of States Parties to the Biological Weapons Convention on 1 December, 2008, which added further impetus to the drive for raising awareness on dual-use and biosecurity by underlining the US's commitment to seek to build a culture of responsibility in biosecurity across the life sciences. As set out by Rocca:

... individuals involved in any stage of life sciences research have an ethical obligation to avoid or minimize the risks and harms that could result from malevolent use of research outcomes. Given the current state of technology, we are promoting the training of life scientists – both trainees and researchers – on this critical issue. To this end, we plan to develop, in conjunction with other countries, an educational training module for university and other research institutions, as well as funders of research, to help insure all those in the life sciences are as well prepared as possible to carry out responsible science as the field explodes with new cutting-edge developments. (Rocca 2008)

Notably, under the Standing Agenda Item on review of developments in the field of science and technology related to the Convention, the Seventh Review Conference identified the following relevant sub-topics to be discussed in the 2012–2015 intersessional programme:

... (c) possible measures for strengthening national biological risk management, as appropriate, in research and development involving new science and technology developments of relevance to the Convention;

(d) voluntary codes of conduct and other measures to encourage responsible conduct by scientists, academia and industry;

(e) education and awareness-raising about risks and benefits of life sciences and Biotechnology. (BTWC 2011a, 23).

Biosafety and biosecurity in confidence building measures

As set out in Bradford Review Conference Paper No. 24 (Lentzos 2010), Confidence Building Measures (CBMs) under the BWC were first agreed in 1986. States Parties agreed in the Final Declaration of the Second Review Conference that they would exchange information in regard to a number of specific areas:

in order to prevent or reduce the occurrence of ambiguities, doubts and suspicions, and in order to improve international co-operation in the field of peaceful bacteriological (biological) activities ... (Lentzos 2010, 4)

CBMs were elaborated in 1987 and then significantly expanded in 1991 at the Third Review Conference of the BWC. As argued by Lentzos and Hamilton (2010), CBMs serve the important function of strengthening the regime of compliance within the Convention. According to Lentzos and Hamilton:

... over the last twenty-odd years, the annual number of CBM submissions has been somewhere between 30 at its lowest (in 1987) and 65 at its highest (in 2007). Annual CBM submissions are thus made by substantially less than half, and often less than a third, of States Parties to the BWC. (Lentzos and Hamilton 2010)

The Sixth Review Conference (BTWC 2006) also emphasized the importance of the exchange of information among States Parties through the confidence-building measures (CBMs) agreed at the Second and Third Review Conferences. The Conference welcomed the exchange of information carried out under these measures, and noted that this had contributed to enhancing transparency and building confidence.

However, CBMs could also be useful in other areas such as providing information on best practices in biosafety and biosecurity – a fact recognized by the Seventh Review Conference which decided to revise CBM Form E to include biosafety and biosecurity reporting on legislation, regulations and other measures (including guidelines). This revision of CBM Form E offers a key opportunity to highlight educational and training resources and activities to benefit other States Parties so that they will not need to invest heavily in devising their own programmes; rather, they can access full or partial programmes according to their own needs, and work alongside existing educational resource-providers to adapt materials for their own use.

The offering or receiving of assistance in biosafety, biosecurity education and awareness-raising were facilitated by the Seventh Review Conference's decision to:

... 17. ... establish a database system to facilitate requests for and offers of exchange of assistance and cooperation among States Parties ... (BTWC 2011a, 22)

Under this initiative,

... 18. States Parties are invited, individually or together with other states or international organizations, to submit on a voluntary basis to the Implementation Support Unit any requirements, needs or offers for assistance, including in terms of equipment, materials and scientific and technological information regarding the use of biological and toxin agents for peaceful purposes ... (BTWC 2011a, 22)

The Implementation Support Unit (ISU) was given a clearinghouse role, similar to that described above for the 1540 Committee and will now submit annual reports on the operation of the database detailing the offers made, requests sought and matches made during a calendar year. The operation of the database will be reviewed at the Eighth Review Conference based on the reports and/or any recommendations by the meetings of States Parties.

Summarising obligations under the three regimes

Understanding the specific obligations and reporting requirements on biosafety/biosecurity under the IHRs, UNSCR 1540 and BWC as well as how they translate international obligations into national action is necessary, as Bakanidze, Imnadze and Perkins (2010) argued, 'in order to improve the understanding of practitioners and policymakers and maximize the use of national resources employed to comply with internationally mandated requirements'.

This paper has highlighted overlapping biosafety and biosecurity obligations on States Parties in so far as they relate to these internationally mandated regulatory regimes. Whilst all three regimes share related objectives in regard to core capacity obligations and mandated reporting, a number of differences and similarities arise.

Since entry-into-force of the International Health Regulations (IHR) in 2007, compliance with IHR standards requires that States implement the *eight core capacities*, including biosafety and biosecurity measures under Core Capacity 8 (Laboratory), with implementation being required by June 2012 (with the possibility of two, two-year extensions). On the other hand, biosafety and biosecurity obligations under UNSCR 1540 derive from the focus on *strategies of prevention and deterrence* required of UN Member States and are legally binding on all UN Member States regardless of their affiliation with a particular treaty or convention. In contrast, compliance with the BWC in regard to the implementation of national measures to 'prohibit and prevent the development, production, stockpiling, acquisition, retention, transfer or use of biological weapons', derives its core biosafety and biosecurity capacity obligations from legally binding obligations embodied in its tenets and affirmations and agreements contained in the Final Declarations of Review Conferences.

Obligations and reporting requirements stated in UNSCR 1540 do not call per se for implementation of biosafety and biosecurity measures, but these are the underlying red thread in all areas identified by the 1540 Committee in which domestic controls should be implemented and enforced with regard to biological weapons, related materials and means of delivery, in order to deny access of non-authorized individuals to such materials and to prevent the proliferation of biological weapons and their means of delivery. As such, the UNSCR 1540 requirements for biosecurity extend beyond the 'laboratory door' and comprise a framework for ensuring biosecurity at the national and international levels.

In the case of the BTWC, core capacity obligations derive from two distinct sources: firstly, the legally binding agreements embodied in the Final Declaration of the Review Conferences and secondly, those politically binding agreements reached during the Intersessional Processes. Agreements during the Intersessional Meetings of States Parties of the BWC on national implementation, biosafety, biosecurity and awareness-raising and education reflect a concern to develop responses to new security challenges that incorporate a broader concept of biosecurity. According to Bakanidze et al., politically binding agreements such as those set out in Paragraph 27 of the 2008 Meeting of States Parties above, are 'highly relevant', since they represent 'common understandings' that have been agreed by States Parties (BTWC 2008).

We may conclude therefore that compliance with such agreements places obligations on member states to best utilize their national provision for improving awareness-raising and education for life scientists through initiatives that address both laboratory biosafety *and* laboratory biosecurity. Moreover, the growing recognition that biological security extends beyond the laboratory door highlights the need for awareness-raising and education in biological non-proliferation, the responsible conduct of research, dual-use bioethics/ biosecurity and the need for improving the ethical, social and legal awareness and education of those who work in the life and associated sciences. It is also vital that other relevant stakeholders (including the general public, the amateur biology community, policy makers, the media and industry, for example) are also educated in appropriate ways. We argue that the compliance mechanisms attached to the regulatory and prohibition regimes set out above can act as building blocks for the development and delivery of complementary 'hybrid' biosafety and biosecurity teaching and training materials that can be designed to address the broad-based biosecurity challenges we face in the twenty-first century. Moreover, we suggest that such activities need not be burdensome or expensive if shared expertise is exploited and implemented effectively using all possible means, including online tuition where appropriate.

Practical responses

Obviously, there are a number of possible ways in which to respond to the points we have made in this paper. Responses will vary according to the needs of countries, institutions, professional bodies and even individuals; further, responses will be dependent on the possibilities of funding, political will and opportunities for engagement. However, as a starting point, we will briefly outline in this section some attempts at practical responses with which we have been involved. We do not claim that the educational resources

described here will solve all problems, or that they even cover all the ground or meet all needs – we simply present them as examples of work to date that attempts to provide educational materials to support a global recognition of the issues, with some initial steps in implementing practical activities to reduce biorisk, which does, of course, include public health risks.

In recognition of growing requirements for qualifications and training, and in specifically order to meet emerging global biosafety and biosecurity challenges, Bradford Disarmament Research Centre, in collaboration with Public Health Agency (PHAC) Canada, have been working to develop applied hybrid biosafety and biosecurity training materials. By building upon an existing, innovative online distance learning programme, Bradford's *Applied Dual-Use Biosecurity Education* (a Masters-level 30 UK Credit Module) that is available through the University of Bradford (see: <http://www.brad.ac.uk/bioethics/trainthetrainer/>), the BRDC and PHAC course' bridges both laboratory biosafety and biorisk management, while also covering 'beyond the laboratory door' dual-use biosecurity through the development of complementary training materials. All of the content in these courses has public health implications as well as addressing standard biorisk management issues.

With the aim of enhancing biosafety and biosecurity awareness and practice nationally and internationally, the first phase of this collaboration is a significant step in the development of joint curricula that aim to embed biosafety and biosecurity training in Canadian institutions, thus bringing the issues to a broad-based national stakeholder community. A second phase in the development of this initiative aims for the dissemination of this awareness-raising and training material to a wider international audience.

The general aims of the BDRC/PHAC course include:

- Development of awareness and understanding of the concepts of biosafety and its relevance to biosecurity;
- Development of knowledge of approaches to the conduct of pathogen risk assessments, and of strategies to appropriately manage these risks;
- Development of awareness and understanding of a range of dual-use dilemmas that arise due to the impact of science and technology on society;
- Development of awareness and understanding of the ethical, legal and social relevance of biosecurity and dual-use issues;
- Development of knowledge of approaches to the responsible conduct of research and related work and of the justification for decisions or recommendations regarding dual-use technologies;
- The facilitation of further research into biosecurity and dual-use issues as well as the development of policies and practices that will enhance the responsible conduct of research and other work to prevent the misuse of knowledge and products generated by life and associated sciences;
- Development of competency and capacity in training others in the responsible conduct of research and other work of relevance to biosecurity.

While it will be subsequently developed for an international audience, the course outline necessarily reflects the specific Canadian national context; topics, therefore, include the Canadian biosafety regulatory regime and international oversight. Further, the Canadian perspective is also taken on the following issues as part of the course:

- Biosafety principles, practices and biosafety programme management;
- The dual-use dilemma and the ethical, legal and social responsibility of scientists;
- Biowar, bioterror and the International Prohibition Regimes such as the IHR, UNSCR 1540, and the BWC;
- National implementation of the BWC; and
- The Web of Prevention.

Such nationally relevant perspectives can be incorporated into any national version of this course, suiting it perfectly to the needs of diverse State and socio-political contexts. This type of course can be delivered in person to classes in one location, or via online learning to students in multiple global locations, as has been shown by previous work implemented by BDRC. Online access does, of course, reduce costs and alleviates the necessity for experts to travel extensively in their development of new experts.

It is important to note that all of the above content can be tailored to suit a range of regional, national and local needs in a variety of global settings. Thus, those who access courses such as the ones described here will be in a position to develop their own materials and deliveries in such a way as to meet the specific needs that they find themselves facing.

In order to facilitate local and national uptake of the issues along these lines, BDRC has developed a programme of country-specific educational packages, the *National Series* (see: <http://www.brad.ac.uk/bioethics/nationalseries/>) that provides a ready-made set of lectures for specific countries, addressing the status of each country in relation to a range of international regimes, including the BTWC and the Chemical Weapons Convention. These materials include relevant information for science professionals, educators, policymakers and other biosecurity/biosafety stakeholders in these countries, allowing quick access to a range of relevant information to save time and effort in producing their own resources. Each edition of the *National Series* consists of 5 lectures, with accompanying notes, references, lesson plans and an introductory set of Key Notes, allowing delivery by non-experts. The themes of the programme include Threats and Prohibition Regimes, The Web of Prevention, National Measures taken to address threats and to engage with international regimes, and the Responsibilities of Scientists. As well as the possibility of class delivery, these materials can be downloaded freely and used by individuals as well. To date, countries included in the *National Series* portfolio include Algeria, Armenia, Azerbaijan, Egypt, Georgia, Iraq, Iran, Jordan, Kazakhstan, Kyrgyz Republic, Libya, Morocco, Pakistan, Saudi Arabia, Tajikistan, Tunisia and Ukraine. Other editions are planned. The key point with this programme is that in-country users of the materials can adapt and change them to suit their needs – the five lectures are a starting point for stakeholders in each country.

Given that we have placed significant priority in this paper on the need to secure data, information and knowledge, it is also necessary that we mention here some options for achieving this in practice. To take on the ‘securitization’ of all information associated with biological and other forms of life science is a huge and one might argue, impossible task. We are not advocating the wholesale securitization of data, knowledge and understanding of work associated with life sciences that could, potentially be misused. Rather, we are suggesting that scientists and managers need to be aware of the potential for misuse of intellectual property as a security threat and simply take preventive action as a norm of practice. The academic and commercial worlds already place a very high priority on the protection of intellectual property for the sake of academic advancement and/or to protect commercial advantage. What we are saying here is, can we afford to place less importance on intellectual property in order to protect the health and safety of our communities and wider populations from the risk of biological weapons? The *Laboratory Biorisk Management* guidelines (European Committee for Standardization 2011) define biosafety and biosecurity, but as we showed earlier, their definitions fell short of including intellectual property and equipment. This is, we argue, a crucial flaw in the concept of biorisk management as laid out in this otherwise helpful document. It is our view that in order to bolster the strength and application of effective biorisk management, all involved in scientific endeavours in the life sciences should develop and assume *a norm of biosecurity* that incorporates an awareness of the potential risks of the loss of intellectual property and equipment associated with those life sciences and take averting actions accordingly. This is asking only that scientists at all levels think about where they keep their notes, in what format, at home, at work, on public transport and so on, and consider who might have access to them, with what consequences. A simple example of this is the storage of student dissertations in academic offices; many academics have shelves full of recipes for potential biological weapons that could be prepared on kitchen tables by educated individuals, yet these dissertations are open and frequently un-logged, so that theft would not be noticed. We are proposing, in effect, that scientists adopt the biosecurity norm in the same way that they have adopted the biosafety norm. An informed, biosafety-aware scientist would not think of taking home samples to leave around the house or on the bus – so why would he consider it appropriate to do the same with potentially dangerous or compromising notes, data, or other forms of intellectual property – as well as portable pieces of equipment?

Conclusions

We have shown here how awareness-raising activities around the tenets of the IHRs, UNSCR 1540 and the BTWC can both highlight and harmonize educational and training resources and opportunities around the biosecurity requirements they share. By informing and coordinating responses to these regimes, such activities are likely to have a significant impact in expanding the nexus of public health and security for the benefit of humankind through its contribution to global health security.

In order to meet national and international obligations to manage growing biorisk challenges, we have argued here that compliance with internationally mandated core capacity requirements (IHRs), strategic prevention and deterrence activities (UNSCR 1540) and legally binding biosafety and biosecurity obligations (BTWC) can be achieved through

the implementation of improved biosafety and biosecurity awareness-raising, education and training. By taking a broad-based, tri-regime, but combined approach to these activities, states can address both in-laboratory and 'beyond the laboratory door' security requirements in merged-response activities. Work between BDRC and the Canadian public health body shows how this is easily achievable and need not be costly. Further, educational materials can be delivered in a range of ways that can suit a variety of needs and settings.

Whatever the outcomes of future debate and agreement under the BTWC, we argue that there is an urgent need to formulate programmes and maximize opportunities to engage in biosafety/biosecurity awareness-raising, education and training globally. By including these as a regular element of national implementation, with subsequent reporting through national compliance reports to the Eighth Review Conference of the BTWC and through annual CBMs, States Parties will implicitly promote education and training as a topic for the next intersessional process. Such initiatives will enhance global health security through promoting cultural and normative transformations in both the life sciences and associated industry, resulting in improved policy and practice in the areas of professional and corporate social responsibility. Crucially, states will, at the same time, be able to address and meet their own local safety and security needs in these areas.

We also urge stakeholders to engage in the development of appropriate evaluation and monitoring tools and processes with which to support and further expand their educational activities under these three regimes. It is only through such practice-and-review activities that we can be certain of meeting our global responsibilities for a secure world.

Finally, if any readers are still in doubt as to the necessity of the activities that we have sought to promote in this paper, we urge them to consider the current global perspective as seen by Held and McGrew (2007). They identified a number of 'deep drivers' of globalization that operate today, including expansion in global communications via information technologies, the rapidly growing market in global goods and services, the global division of labour driven by multi-national corporations, the spread of consumer values, mass migration and environmental degradation. It is in our global responses to these activities that we can see emerging opportunities for biosecurity risks to be magnified. Can we afford to ignore them? Should we not be striving to put in place effective, easily manageable and coordinated responses to these threats? If so, then it seems most logical to employ frameworks that we are already engaged in, as described above. As the WHO stated:

.... opportunities may also be accompanied by risks that need to be acknowledged and addressed. The risks under consideration in this guidance are those associated with accidents, with research that may pose unexpected risks and with the potential deliberate misuse of life sciences research. The opportunities offered by the life sciences are too important for governments and the scientific community (including individual researchers, laboratory managers, research institutions, professional associations, etc.) to leave the attendant risks unaddressed (WHO 2010, 1)

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