

# Improving Oversight: Development of an Educational Module on Dual-use Research in the West

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## Introduction

The 'dual-use' potential of life science research has been a topic of increasing attention in recent years as part of the growing concern about the inadvertent or deliberate spread of disease. While 'dual-use' functions as an umbrella phrase, one sense of it refers to the possibility that 'the generation and dissemination of scientific knowledge [...] could be misapplied for biological weapons development and production.'<sup>1</sup> Major studies of this sense of the term include the US National Research Council (NRC) and Institute of Medicine's (IOM) report *Biotechnology Research in an Age of Terrorism*, the NRC's *Globalization, Biosecurity, and the Future of the Life Sciences*, and the British Royal Society's *Scientific and Technological Developments Relevant to the Biological & Toxin Weapons Convention*.<sup>2</sup> Echoing sentiments elsewhere, these analyses have underscored the breadth and scale of challenges in preventing the destructive application of the life sciences.

## Education and Awareness Raising

The call for greater education of those associated with the life sciences has been prominent in policy proposals in the West and elsewhere.<sup>3</sup> Over the past several years, international bodies such as the UN Policy Working Group on the United Nations and Terrorism,<sup>4</sup> national organizations such as British Medical Association,<sup>5</sup> and international agencies such as the International Committee of the Red Cross<sup>6</sup> have made calls for the enhanced education of scientists, administrators, physicians, and others about the potential for destructive application of bio- and medical sciences.

Many of the calls have been couched in terms of promoting ethical decision making. For instance, the 2002 World Medical Association's *Declaration of Washington on Biological Weapons* contends that as part of fostering the necessary ethos in biomedical research, those associated with it have "a moral and ethical obligation to consider the implications of possible malicious use of their findings."<sup>7</sup>

A report from a 2006 Royal Society, InterAcademy Panel (IAP), and International Council for Science (ICSU) workshop proposed that researchers and students should be educated by "perhaps by undertaking courses in ethics and responsible research practice, and should be taught about relevant international law obligations of their governments, especially relating to the BTWC (Biological and Toxin Weapons Convention). Bioethics curricula should build on local values and ethical norms".<sup>8</sup>

This reference to legal obligations signals the compliance function that can be sought from education. A 2004 Royal Society and the Wellcome Trust meeting concluded that “education and awareness-raising training are needed to ensure that scientists at all levels are aware of their legal and ethical responsibilities,” and that such training was rare in the UK.<sup>9</sup> The 2005 IAP *Statement on Biosecurity* maintains that scientists “should be aware of, disseminate information about and teach national and international laws and regulations, as well as policies and principles aimed at preventing the misuse of biological research.”<sup>10</sup>

However, many concerns about dual-use research knowledge and techniques extend beyond legal and regulatory compliance. Education has been identified as a vital component in achieving enhanced systems of research governance that address dual-use knowledge and techniques.

In *Globalization, Biosecurity, and the Future of the Life Sciences*, the NRC and IOM Committee on Advances in Technology and the Prevention of Their Application to Next Generation Biowarfare Threats argued that it was prudent to establish a “decentralized, globally distributed, network of informed and concerned scientists who have the capacity to recognize when knowledge or technology is being used inappropriately or with the intent to cause harm.”<sup>11</sup>

In 2005 the UK Biotechnology and Biological Sciences Research Council, Medical Research Council and Wellcome Trust released *Managing Risks of Misuse Associated with Grant Funding Activities*.<sup>12</sup> Later that year the Wellcome Trust released *Guidelines on Good Research Practice* which stated that “institutions should have in place mechanisms to ensure that risks of misuse associated with ongoing research programmes are identified and managed, and to provide advice to the researchers that they employ on these issues.”<sup>13</sup> How and what advice institutions should supply, though, was left unspecified. It is unclear that any activities have been undertaken on a UK-wide basis, let alone an international one, that could adequately underpin this recommendation.

The first recommendation of *Biotechnology Research in an Age of Terrorism* was that “national and international professional societies and related organizations and institutions create programs to educate scientists about the nature of dual-use dilemma in biotechnology and their responsibilities to mitigate its risks.”<sup>14</sup> In 2005 the National Science Advisory Board for Biosecurity (NSABB) was charged with developing recommendations on “mandatory programs for education and training in biosecurity issues for all scientists and laboratory workers at federally-funded institutions.”<sup>15</sup> While critical of certain possibilities that might stem from the mandate of NSABB, an editorial in *New Scientist* argued that “the most important thing...is to educate students and young researchers about the dangers of dual-use research.”<sup>16</sup>

The 2007 *Report of the NSABB Working Group on Oversight Framework Development* repeatedly identified education and raising awareness as crucial prerequisites for proper oversight. The importance of education derived from the emphasis placed on investigators to assess the dual-use dimensions of their own work. Although the strategies outlined by NSABB left many of the exact details of the oversight systems to be worked out by institutions, the overall call is primarily for lead scientists to determine whether their work falls into the category of ‘dual-use research of concern,’ assess its risks and benefits, propose communication strategies, and undertake other responsive efforts for minimizing identified risks. As a result of this devolved approach, NSABB contended “[a]n enhanced culture of awareness is essential to an effective system of oversight and is a critical step in scientists taking responsibility for the dual-use potential of their work.”<sup>17</sup> Related to this point, a 2007 National Research Council report titled *Science and Security in a Post 9/11 World* recommended that “To strengthen and harmonize the institutional review of life sciences research, the Department of Health and Human Service, in conjunction with other agencies that conduct and

fund life sciences research, should develop an education program on the basic principles of risk-based biosafety and biosecurity review.”<sup>18</sup>

Education is not just seen as a prerequisite for an effective system of oversight, but also an end goal of some initiatives. For instance, NSABB was also tasked with developing “guidelines for the oversight of dual-use research, including guidelines for the risk/benefit analysis of dual-use biological research and research results.”<sup>19</sup> Yet, many on the Board have stated they do not expect such oversight mechanisms will identify publications as ‘of concern’ (let alone then subject to some form of restriction).<sup>20</sup> The value of NSABB’s *Points to Consider in Assessing the Risks and Benefits of Communicating Research with Dual-use Potential* then is not just its evaluative-review role, but its educational one.<sup>21</sup> As well, much of the discussion about the utility of codes of conduct has centered on their educational value, rather than their role in compelling certain behavior.<sup>22</sup>

While education has been prominent in the past, this is likely to continue. At the 2006 BTWC 6<sup>th</sup> Review Conference it was agreed that 2008 States Parties will discuss and promote common understanding and effective action on “oversight, education, awareness raising, and adoption and/or development of codes of conduct with the aim to prevent misuse in the context of advances in bio-science and bio-technology research with the potential of use for purposes prohibited by the Convention.”<sup>23</sup>

## **Education Options**

Moving from general calls to practical educational instruction requires addressing many questions. For one, who needs to be educated? Principle Investigators (PIs), any senior scientists and staff, administrators, graduate students, and/or undergraduates? Does it matter in what order awareness raising takes place, i.e. what specific subfields of science or roles in the laboratory should be first? What sort of expertise is required to instruct about dual-use issues? What should dual-use education consist of? Is it important to include instruction about general research ethics issues, information on the history of bioweapons programs, or laboratory security requirements?

Some practical efforts have been undertaken in recent years in the West and elsewhere to enhance the awareness of scientists and others regarding dual-use research.<sup>24</sup> Three of these are mentioned in this paper to map the diversity of responses of possible responses.

### *“The Life Sciences, Biosecurity & Dual-use Research”*

Rappert and Dando have conducted more than 80 seminars titled “The Life Sciences, Biosecurity & Dual-use Research” with practicing scientists and students in 11 countries with a breadth of diversity, including the UK, Kenya, Japan, Argentina, and Israel.<sup>25</sup> In part to secure an audience and in part to promote ethical deliberation, these have been held through existing institute research seminar series. While seeking to inform participants about current life science and security policy debates, the seminars also aim to generate deliberation about how research findings should be communicated, experiments subject to institutional oversight, and funding for projects determined. Central to the latter aim is promoting interaction *between* colleagues and students. The presenters provide minimal background information prior to the seminars, in order to determine which issues each unique group of attendees deem relevant. Based on past experience with seminars, cases and questions are then introduced into the unfolding discussion to test the limits of and basis for participants’ initial statements. That testing is done by finding points of disagreement between participants and then moderating subsequent debate.<sup>26</sup> Two on-line teaching aids have been produced that set to further ethical deliberation.<sup>27</sup>

### *“Case Studies in Dual-use Biological Research”*

The Federation of American Scientists has produced an online educational resource designed to increase awareness of biosecurity and promote enhanced self-regulation by scientists, titled “Case Studies in Dual-use Biological Research.”<sup>28</sup> It examines real life instances of research intended for civilian applications that generated findings queried for their dual-use implications. Cases include videos with scientists involved with these experiments, in which the scientists elaborate on dual-use aspects of their work and their reasoning for handling them as they did. The module primarily employs these testimonies as the basis for underlining the importance of dual-use issues and encouraging ethical reflection by viewers. General information on dual-use issues and extensive information about the cases are provided through hyperlinks. Throughout, additional written questions are proposed for consideration.

#### *“Dual-Use Dilemma in Biological Research”*

In 2004-5, the Policy, Ethics and Law (PEL) Core of Southeast Regional Center of Excellence for Emerging Infections and Biodefense (SERCEB) developed an online module to assist those involved with the biological sciences to better understand the dual-use aspects of their research. SERCEB is one of 10 Regional Centers of Excellence funded by the NIH National Institute of Allergy and Infectious Disease to conduct research on bioweapon agents and emerging infectious diseases.

The module consists of five “chapters” of slides followed by a brief assessment. These chapters include:

1. An introduction to dual-use issues, mainly told through a hypothetical case of a manuscript submission to a journal for publication;
2. A brief account of historical and more contemporary attention to biological weapons with particular emphasis on the implications for contemporary life science research;
3. An overview of the national and international laws governing research that are pertinent to biosecurity;
4. An analysis of the ethical issues associated with dual-use research explored through a more in-depth treatment of the hypothetical journal case; and
5. Consideration of next steps in terms of policy-making (with particular attention to the conclusions of the NRC’s report *Biotechnology Research in an Age of Terrorism*) and the hypothetical case study.

By mid-2007, more than four hundred researchers and staff from institutions across the United States and abroad had taken the module. In spring 2007, 40 semi-structured interviewees were undertaken by the authors of this paper to gather feedback on users’ experiences, assess general awareness of dual-use issues amongst bioscientists and others at SERCEB institutions, and determine what, if any, outstanding issues related to dual-use concerns may be attended to by revising the module.<sup>29</sup> The interviewees ranged from SERCEB funded Principal Investigators, members of Principal Investigators laboratories, members of Institutional Biosafety Committees, and biosafety staff. Although a self-selecting and non-representative (relatively) small sample of interviewees that cannot be taken as statistically representative of SERCEB as a whole, the interviews indicated reasons for concern about the extent of prior knowledge about the destructive application of research. For instance:

\* Ten (25%) interviewees claimed to be entirely unfamiliar with dual-use issues prior to taking the module. In many cases, interviewees expressed familiarity with certain “select agent” physical security concerns, but not with the term or of the issues posed by the “dual-use” risk. Perhaps most striking was the number of SERCEB PIs (4) that claimed hitherto to have never thought about the nefarious purposes that could be served by their work.

\* In terms of module use, of the 40 interviewees, four (4) reported having taken the module prior to being contacted for the assessment project. All four of these individuals were biosafety staff or IBC members. Several of the individuals who had not previously taken the module were PIs or laboratory members of PIs who had previously been recommended to

take the module and discuss dual-use issues with laboratory members. However, as indicated by the number of individuals that eventually took it, being personally solicited and asked participate in an evaluation did motivate most.

\* In four laboratories, lab members interviewed disagreed as to whether or not dual-use issues were relevant to their projects. In one of these laboratories a junior faculty member did not believe dual-use issues were relevant to his laboratory's work, while the lab's primary PI believed they were. In another instance two co-investigators on the same project had directly opposing judgments as to whether or not dual-use issues were relevant to their work.<sup>30</sup>

These findings would suggest that further and more extensive research is needed to provide an understanding of the knowledge of scientists about the destructive application of their research.

## Closing Remarks

This paper has outlined the place and purpose given to education in policy discussions about dual use issues to date as well as some of the educational initiatives undertaken to date. These initiatives provide resources and lessons for those wishing to develop educational modules more suitable to their particular situations. Other initiatives of a more preliminary quality might also prove of use. As a mandated part of the introduction of its 2007 legislation on the physical security of bioagents, the Australian government is currently contemplating exactly what sort of education about biosecurity-related issues it should offer its scientists, research administrators and others. The National Defense Medical College of Japan is now considering extending and revising its postgraduate provisions regarding the matter of dual use. Another paper presented as part of this 'Promoting Biosafety and Biosecurity within the Life Sciences' workshop will talk about another initiative in South Africa highly relevant for East Africa.

## Notes & References

<sup>1</sup> Atlas R, Dando M. The dual-use dilemma for the life sciences. *Biosecur Bioterror* 2006; 4(3): 276.

<sup>2</sup> For information of the effects of biosecurity policies, see, for instance, McLeish C., Nightingale P. *Effective Action to Strengthen the BTWC Regime: The Impact of Dual Use Controls on UK Science* Bradford Briefing Paper May 2005 Available at [http://www.brad.ac.uk/acad/sbtwc/briefing/BP\\_17\\_2ndseries.pdf](http://www.brad.ac.uk/acad/sbtwc/briefing/BP_17_2ndseries.pdf).

<sup>3</sup> For an overview of the possible place of education in response strategies see *Ethical and Philosophical Consideration of the Dual-Use Dilemma in the Biological Sciences* Canberra: Centre for Applied Philosophy and Public Ethics; 2006.

<sup>4</sup> United Nations. *Annex Report of the Policy Working Group on the United Nations and Terrorism*, A/57/273-S/2002/875, 6 August 2002. Available at [http://www.un.org/doc/A.57.0273\\_S.2002.875.pdf](http://www.un.org/doc/A.57.0273_S.2002.875.pdf)

<sup>5</sup> British Medical Association. *Biotechnology, Weapons and Humanity*. London, Harwood Academic Publishers; 1999.

<sup>6</sup> International Committee of the Red Cross. *Responsibilities of Actors in the Life Sciences to Prevent Hostile Use*. Geneva, ICRC; 2004.

<sup>7</sup> World Medical Association. *Declaration of Washington on Biological Weapons*. Washington, DC: WMA; 2002.

<sup>8</sup> Royal Society. *Report of the RS-IAP-ICSU International Workshop on Science and Technology Developments Relevant to the Biological and Toxin Weapons Convention*. RS Policy Document 38(06), London: Royal Society; 2006: 14.

<sup>9</sup> Report of Royal Society and Wellcome Trust Meeting 'Do No Harm – Reducing the Potential for the Misuse of Life Science Research' 7 October 2004: 1.

<sup>10</sup> InterAcademy Panel. *IAP Statement on Biosecurity* 7 November Trieste: IAP; 2005 <http://www.interacademies.net/Object.File/Master/5/399/Biosecurity%20St..pdf>

<sup>11</sup> Committee on Advances in Technology and the Prevention of Their Application to Next Generation Biowarfare Threats. *Globalization, Biosecurity, and the Future of the Life Sciences* Washington, DC: National Research Council; 2006: 193.

<sup>12</sup> See [http://www.wellcome.ac.uk/doc\\_wtx026594.html](http://www.wellcome.ac.uk/doc_wtx026594.html).

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<sup>13</sup> See [http://www.wellcome.ac.uk/doc\\_WTD002753.html](http://www.wellcome.ac.uk/doc_WTD002753.html).

<sup>14</sup> National Research Council. *Biotechnology Research in and Age of Terrorism*. Washington, DC: National Academies Press; 2003.

<sup>15</sup> *Charter – National Science Advisory Board for Biosecurity*. 16 March 2006: 1. See <http://www.biosecurityboard.gov/revise%20NSABB%20charter%20signed%20031606.pdf>

<sup>16</sup> New Scientist. 'Dual-use' Biotech - Proceed with Caution *New Scientist* 14 October 2006.

<sup>17</sup> NSABB. *Report of the NSABB Working Group on Oversight Framework Development*. Bethesda, MD: NSABB; 2007: 10.

<sup>18</sup> Committee on a New Government-University Partnership for Science and Security and Committee on Science, Technology and Law. *Science and Security in a Post 9/11 World* Washington, DC: National Research Council; 2007: 12-3.

<sup>19</sup> *Charter – National Science Advisory Board for Biosecurity*. 16 March 2006: 1. See <http://www.biosecurityboard.gov/revise%20NSABB%20charter%20signed%20031606.pdf>

<sup>20</sup> Comments made by Paul Kiem as Chair of Communications Work of the National Science Advisory Board for Biosecurity 30 March 2006 See [http://www.biosecurityboard.gov/meetings\\_archive\\_033006.asp](http://www.biosecurityboard.gov/meetings_archive_033006.asp), at times 4:17:5, 4:20:20, and 4:27-4:28, 4:57.

<sup>21</sup> Comments made by Paul Kiem as Chair of Communications Work of the National Science Advisory Board for Biosecurity 30 March 2006 See [http://www.biosecurityboard.gov/meetings\\_archive\\_033006.asp](http://www.biosecurityboard.gov/meetings_archive_033006.asp), at 4:17:30

<sup>22</sup> See Rappert B. Codes of conduct and biological weapons: an in-process assessment. *Bio Secur Bioterrorism* 2007; 5(2): 145-154.

<sup>23</sup> United Nations. *Sixth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*. BWC/CONF.VI/6 UN: Geneva, 2006: 21.

<sup>24</sup> See Rappert B. Education for the life sciences. In *A Web of Prevention* B. Rappert & C. McLeish eds. London: Earthscan; 2007.

<sup>25</sup> Rappert B, Chevrier M, Dando M. In-Depth Implementation of the BTWC. *Bradford Review Conference Paper No. 18*. 2006 <http://www.brad.ac.uk/acad/sbtwc/> Rappert, B *Biotechnology, Security and the Search for Limits*. London: Palgrave; 2007.

<sup>26</sup> <http://www.projects.ex.ac.uk/codesofconduct/BiosecuritySeminar/index.htm>

<sup>27</sup> See <http://www.projects.ex.ac.uk/codesofconduct/BiosecuritySeminar/Education/index.htm>

<sup>28</sup> <http://www.fas.org/biosecurity/education/dualuse/>.

<sup>29</sup> Target interviewees were selected from a list of all SERCEB project and program investigators. Investigators with known awareness of dual-use issues (particularly through interaction with the PEL Core) were excluded, as were all SERCEB Steering Committee members. Potential interviewees were then solicited by email seeking their participation, and/or referral to their laboratory members and colleagues. PIs were asked to identify other laboratory members whom they could recommend. As such, the sample population was initially delimited and then self-selected. In addition to practicing scientists, biosafety staff at several main SERCEB institutions were also solicited. Participating interviewees hailed from five main and three affiliate SERCEB institutions. Scientists and technicians interviewed worked in a breadth of disciplines, including bacteriology, virology, vaccine development, immunology, and bioengineering.

<sup>30</sup> An elaborated and more comprehensive treatment of these interviews is currently under submission.