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Towards the responsible conduct of scientific research: is ethics education enough?

Tatyana Novossiolova and Judi Sture*

Bradford Disarmament Research Centre, University of Bradford, Bradford, UK

Abstract

Much of the discourse on ‘beyond the laboratory door’ biosecurity to date has focused on the need to raise awareness among the scientific community of the risks posed by the rapid advancement of biotechnology in recent decades. While education is undoubtedly important, a growing body of evidence suggests that ethics education does not necessarily translate into ethical behaviour. This trend has already been reported in clinical settings, where research has highlighted doctors’ own reports of ethically dubious practices and challenges when confronted with moral dilemmas in their everyday work. The purpose of this paper is to critically evaluate the practical value of ethics education and show why it is an essential, although insufficient, measure for promoting a culture of responsible conduct of research. We conclude by highlighting the importance of continuing professional development as a way of maintaining life scientists’ engagement with biosecurity issues and supporting them in active roles in the effective implementation of the Biological and Toxin Weapons Convention (BWC).

Keywords

biosecurity; biosafety; life science; Biological Weapons Convention; bioethics; whistle-blowing; morals

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*Corresponding author: j.f.sture@bradford.ac.uk.

Notes on contributors:

Tatyana Novossiolova is a Wellcome Trust-funded PhD candidate in the Division of Peace Studies, University of Bradford and a part-time research associate at Bradford Disarmament Research Centre. Her main research interests are international law and disarmament, with a focus on biosecurity. Tatyana has been involved in curriculum development for several programmes, including arms control and disarmament (BA level), critical perspectives on arms control and disarmament and applies dual-use biosecurity (both MA level). She is currently working on a research project entitled ‘Dual-use science and bioethics: improving the governance of biotechnology in post-Communist Russia’.

Judi Sture is a member of the Bradford Disarmament Research Centre at the University of Bradford, UK. She is also Head of the University Graduate School and a senior lecturer in research ethics and research methods. Her PhD in biological anthropology (University of Durham, UK) focused on environmental associations with human birth defects, reflecting her interest in the role of infectious agents in human health and disease. Her current research interests focus on ethics in society, especially taking an anthropological approach to promote a social responsibility perspective to biosecurity norms among life scientists. She is also part of a team delivering online distance learning and short-courses in applied dual-use bioethics and biosecurity education. She has published on dual-use issues, applied ethics and cultural behaviours.

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Ethics education in an era of dual-use science

The rapid advancement of biotechnology over recent decades has raised serious concerns. While such progress promises considerable benefits to humankind by responding to human, societal and environmental challenges, it could also facilitate the development of sophisticated biological weapons and facilitate bioterrorism. This phenomenon has been conceptualized as a 'dual-use dilemma', arising in the context of life sciences when benign scientific knowledge has the potential to be misused for malevolent ends by state or non-state actors (Selgelid 2009). Following the 9/11 terrorist attacks and the anthrax letters in the US in 2001, the subsequent securitization of global public health highlighted a number of 'experiments of concern'. These included the creation of a highly virulent strain of the mousepox virus, the artificial synthesis of the polio virus and the reconstruction of the Spanish influenza virus. These became paradigm cases in a new discourse characterized by a convergence between security, bioethics and life science practice. A central theme of this discourse is the promotion of a culture of responsibility in life sciences to accommodate novel biosecurity concerns. Here, biosecurity is understood not just as laboratory biosafety but as the objective of a whole range of policies, mechanisms, regulations and initiatives. These may include, for example, export controls, bio-defence activities, and national implementation of the Biological and Toxin Weapons Convention (BWC). The biosecurity discourse has been promoted by several important developments. These include two high-level reviews: *Biotechnology research in an age of terrorism* (The Fink Report – National Research Council 2004) and *Globalisation, biosecurity and the future of life sciences* (The Lemon–Relman Report – National Research Council 2006); various outputs from the National Science Advisory Board on Biosecurity (NSABB); the Statement on Scientific Publication and Security (Atlas *et al.* 2003) made by leading publishers and journal editors in 2003 and the changing policy of funding bodies in which applicants are now required to consider possible biosecurity concerns arising from their work.

In order to ensure that life sciences continue to generate benefits and are not deliberately misused, it is essential that life scientists engage with the security community and contribute to the implementation and maintenance of strong ethical frameworks to complement legal and regulatory measures that are being developed by states. Such engagement has been limited to date, not least because of the predominantly low level of awareness among scientists of the current debates on dual-use, the BWC, bioterrorism and emerging threats (Dando and Rappert 2005). Since biosecurity teaching is lacking in the university curriculum of most science students (Revill 2009, Minehata 2010), teaching dual-use bioethics has been suggested as a necessary step in order to enable scientists to develop an understanding of the ethical and security dimensions of their work (Johnson 2010). In 2008 the State Parties to the BWC formally highlighted the 'value of education and awareness raising programmes covering the moral and ethical obligations incumbent on those using the biological sciences' and agreed to 'inform the Seventh Review Conference of, inter alia, any actions, measures or other steps that they may have taken on the basis of the discussions ... in order to facilitate any further action' (BWC 2008, pp. 7–8).

Given the challenges that science students may encounter when confronted with the discipline of philosophy, some commentators have argued in favour of shifting the focus from the philosophical nature of ethics to a practical applied identification of ethical principles to everyday practice in scientific research (Sture 2010a). In other words, instead of being taught ethics theory per se, science students should be introduced to the concept of the responsible conduct of research through an applied ethics approach to their practice, which in turn allows them to reflect, through the lens of 'social responsibility ethics', upon how their work may have a negative impact on those who come into direct or indirect contact with their work beyond the immediate research environment (Sture 2010a).

Two practical examples for pedagogy are worth noting. Firstly, the third edition of *On being a scientist*, a guiding document published by the US National Academies in 2009, 'provides an overview of professional standards in research', as well as aiming 'to highlight a number of particular challenges the science community faces in the early twenty-first century' (NAS 2009, p. ix). The guide avoids stating definite conclusions about what should or should not be done, but rather explores the reasons for specific actions, thus encouraging individual reflection and collective deliberation on issues around ethical practice in scientific research (NAS 2009, p. xv). Its final chapter, 'The researcher in society', presents readers with the history of the development of Agent Orange and its use during the war in Vietnam in the 1960s and 1970s and seeks to reinforce the obligation of scientists to reflect on how their research might be used in the broader context of various social domains. However, the chapter fails to explain how such aims may be met in practice.

Secondly therefore, in order to show how to achieve a practical response, Bradford Disarmament Research Centre (BDRC) has developed a train-the-trainer online distance-learning programme in applied dual-use biosecurity, as part of a five-year Wellcome Trust-funded project on building sustainable capacity in dual-use bioethics. The programme, consisting of 20 lectures and seminars, raises awareness of a range of dual-use conundrums, develops knowledge of various approaches to the responsible conduct of research and builds capacity in training others in dual-use biosecurity skills. To maximize its global dissemination amongst science communities, the Train-the-Trainer module utilizes interactive web-based e-learning platforms such as Black-board, Elluminate and Ning. In a fully supported online learning community, participants can interact with peers, developing their practice through sustained reflection and involvement in various activities and scenarios (Novossiolova and Whitby 2011). Participants bring their own ideas and experiences to the course and reflect upon what practices may be helpful in their future work as trainers.

Though significant improvements are apparent in understanding how scientists can be engaged in ethical deliberation, questions remain about assessment of the practical value of ethics education. As highlighted by a US National Academy:

Attempts to evaluate and improve ethics education for scientific and engineering research and practice are just beginning. However, they do show that even though the immediate results of some programmes are positive, circumstances and pressures can overwhelm graduate students, postdoctoral fellows, and junior faculty and researchers and undermine those results. (NAE 2008, p. 40)

This observation merits further scrutiny, not least because it raises the fundamental issue of whether ethics education can have a transformative effect and contribute to changing the culture of scientific research in ways that facilitate the governance of biotechnology and minimize the risks created by the rapid proliferation of dual-use technologies. To critically examine this question, the next section reviews a number of ethical dilemmas in science outlined in the academic literature between 2002 and 2011, and discusses the challenges that healthcare practitioners, engineers and other scientists encounter when confronted with ethical issues in their everyday work.

The challenge of ethical practice

While the idea of teaching dual-use bioethics to life scientists has been gathering momentum over recent years, it is and even dangerous to treat such teaching as a one-off intervention which will automatically produce ethically-minded and ethically-motivated professionals. A substantial body of evidence suggests that other professionals who are also required to take ethics classes as part of their academic degree often experience serious difficulties in

responding to ethical problems arising in their work (see Sture 2010b). It is far from uncommon even for senior professionals in such fields to fail to comply with ethical stances and worse, to get involved in questionable practices and instances of professional misconduct. These reports reveal how the skills and knowledge that students acquire through ethics education en route to their professional qualifications struggle to find practical application once practice begins.

Ethical breaches in stem cell research

In 2004, Woo Suk Hwang and his team from Seoul University reported in *Science* that they had made a major breakthrough in therapeutic cloning by successfully deriving embryonic stem cells from cloned embryos (Vogel 2005). A year later, in 2005, Hwang published another paper announcing the first derivations of human embryonic stem cells carrying the genome of patients with disease or injury (ibid.). Questions first emerged in 2004 when *Nature* published allegations that two junior researchers at the laboratory had donated oocytes (female egg cells) as part of the trials (Cyranoski 2004). There were also claims that the oocytes used in the experiments preceding both the 2004 and 2005 paper were obtained not by means of volunteer donations but were paid for, even though it is illegal to buy oocytes in South Korea. The gravity of the fraud only became clear in late 2005 when, after a series of reports and an institutional investigation, it was revealed that the data in both the 2004 and 2005 papers was fabricated and that authorship had been granted for helping to procure oocytes (Resnik *et al.* 2006, p. 102). Hwang lost his position at Seoul University and criminal charges were brought against him, resulting in a suspended prison sentence.

Scientific misconduct in microbiology

Thomas Butler, an American microbiologist famous for his work in the area of infectious diseases and biodefence, reported as missing 30 vials of bubonic plague obtained during experimental trials in Tanzania in early 2003. Even though he later admitted destroying the vials himself, the case raised enormous controversy and public opprobrium, not least because the resulting FBI investigation exposed serious breaches of established regulations coupled with illicit activity and failure to comply with federal laws. In a detailed report published in *Science* in December 2003, Enserink and Malakoff gave an extensive overview of how Butler managed to transport plague cultures and send them overseas on regular passenger aircraft without obtaining essential regulatory permissions for the purpose; how he circumvented international and federal import and export controls, tax obligations and institutional regulations; and how ethical considerations and principles of confidentiality were downplayed during data collection. It was further disclosed that the clinical trials conducted in Tanzania had not passed through the Institutional Review Board at Texas Tech, nor did Butler obtain an approval from the Food and Drug Administration (FDA) for the antibiotic he was testing. Along with the allegations that he had mishandled the cultures, prosecutors also accused Butler of defrauding the university administration of clinical trial fees. He was convicted on 47 out of 69 accounts facing up to 240 years in prison and millions of dollars in fines. After a series of appeals, he was sentenced to two years in jail and a fine of more than US \$50,000 (Enserink and Malakoff 2003, p. 2063).

Ethics in bioengineering?

Given the growing demand for novel discoveries and the rapid proliferation of modern technologies, biological engineers often found themselves confronted with ethical dilemmas, including the conflict between the cost and performance of medical equipment, the failure rate of reconditioned devices and the manufacture of low-cost alternative medical instruments designed to be used in poverty-stricken regions of the world (Monzon and Monzon-Wynngaard 2009, p. 2013). The case of the Bjork-Shiley Convexo – Concave (BSCC) mechanical heart valve illustrates this. During clinical trials, the valve showed

material fatigue, resulting in more than 600 reported fatalities. Nevertheless, the valve still reached the market after the manufacturer modified the quality control procedure. Patients were not notified about the possible risks and 86,000 valves were implanted between 1979 and 1986. The US Food and Drug Agency failed not only to carry out a thorough investigation of the manufacturer but also to enforce patient notification (*ibid.*).

The case of the Therac-25, a medical linear accelerator developed to treat cancer patients (*ibid.*), is also relevant here. Instead of exposing patients to low-energy radiation treatment, the machine massively overdosed them, causing the death of six people. The device failure primarily occurred due to errors in the software, resulting from the manufacturer's failure to follow proper software engineering practices.

Ethical practice in healthcare

While clinicians are required to undergo extensive ethics training, they still experience serious difficulties in dealing with real-life day-to-day situations in their practice and sometimes even deliberately choose to circumvent the rules. Nyika (2009) and Sture (2010b) have presented overviews of professional ethics breaches committed by health researchers and practitioners, including falsification, fabrication and plagiarism; publication of the same data multiple times; lack of publication of research findings and inadequate supervision of juniors and students; prioritizing the values of senior doctors over students' own inherent values of care for others and an 'erosion' of personal ethical values because professional life requires adherence to group values in order to 'get on' professionally. These problems were further exacerbated by the unwillingness of medical staff to report unprofessional behaviour. Whistleblowing – the act of exposing negligence and abuse such as incompetence or professional misconduct within an organization – is seen as particularly stressful and risky, because of the limited protections offered to the whistleblower and the resulting negative implications upon their professional, emotional and personal life, which few individuals are ready to bear (Martin 2007, Jackson *et al.* 2010, p. 2196). Hence, clinicians frequently find themselves under pressure to suppress ethical disquiet and remain silent for the sake of maintaining the organizational status quo.

Ethical reasoning and decision-making conflicts constitute another major, daily challenge for healthcare personnel. It has been reported that nurses, for example, encounter considerable difficulties in implementing the ethical dimensions of care, often because they find it impossible to fulfil their duties in line with their own values. As a result, they may tend to prioritize technical interventions at the expense of establishing caring relationships with patients and even make decisions regarded as morally wrong (Goethals *et al.* 2010, p. 636). Disheartened because they cannot substantially influence the outcomes of ethical dilemmas, nurses are reported as preferring to adopt a conformist approach and to go along with established practices and 'group ethics' rather than searching for the best caring response (de Casterle *et al.* 2008, p. 547).

Ethical challenges for scientists

In work focussing on the cultural aspects of ethical behaviour in professional scientific contexts, Crandall and Schaller (2004) highlighted a number of value clashes between scientists' personal and professional ethical stances. According to their research, many scientists held a publicly-stated set of values including a commitment to sharing universal truths, to sharing data with colleagues, to being disinterested in the sense of being non-judgmental and open to whatever the evidence suggests, and to a sceptical outlook that distrusts anything not supported by empirical data and observation. The researchers also found, however, that in order to survive in the competitive professional world, scientists actually employed a hidden set of values, including resistance to new ideas that challenge

the status quo, the selective forgetting of data that contradict personal views, the favouring of work supporting their own views and a generally conservative approach to their practice (Crandall and Schaller 2004).

Challenges to ethical practice

These examples drawn from the literature clearly show that it is difficult to promote ethical practice solely through education. This may be partially due to inappropriate content in ethics courses (problems presented or used as exemplars that exceed the experience or learning level at which students are currently 'located') and the limited practical value of assignments that comprise formal assessment. While the ethics principles and concepts that medical and engineering students are taught at university may help them resolve abstract ethical dilemmas, in real-life situations these principles are often in conflict, making it difficult for professionals to decide which principle to prioritize in particular cases (Arries 2005). This is hardly surprising given that, in the words of Daniel Chambliss (1996, p. 19):

... the hospital is like a war zone, in which common niceties and rules of decorum are discarded in the pursuit of some more immediate, desperate objective. There is an excitement, and a pressure, that frees hospital workers in the 'combat zone' from an array of normal constraints on what they say and do.

Chambliss also doubts the usefulness of case studies and imaginary scenarios, arguing that such exercises are usually framed by hypothetical questions rather than by real situations, aiming not to replicate crucial features of reality but to generate the toughest test of a philosopher's logic (ibid., p. 6). Hence, instead of thinking along the lines of the practical question 'What can be done?', students are obliged to seek the 'right' answer or 'What should be done?' (ibid.). Fully equipped with academic decision-making techniques and solid theoretical foundation in ethics, new science graduates experience a culture shock when they realize that much of their ethics knowledge is virtually inapplicable in their daily work contexts, because ethical reasoning and professional conduct are driven not by textbook rules but by the routines of life in professional bureaucracies (ibid. and Sture 2010b). Further, these routines can be quite tough. A stressful work environment, insufficient resources, tight institutional budgets and workload pressure are just some of the factors impeding ethical decision-making among healthcare practitioners. Difficult circumstances typically make clinicians reluctant to implement their own decisions and force them to seek advice from colleagues and superiors. As a result, they do not feel responsible for their decisions and become disinclined to take action to resolve ethical dilemmas in future.

Conclusion: professional development after education

Ethics courses at university-level constitute an essential element of the education of life scientists. However, as the examples above reveal, the theories and principles taught through such courses do not automatically translate into ethical practice and many of them seem to be viewed as professionally 'inconvenient'. Conflicts between academic problem-solving techniques and daily routines guiding work in hospitals and research facilities appear to be sources of frustration, anger and ethical distress. It is not uncommon, according to research such as that cited above, for scientists to feel 'forced to break the rules', as complying with them may severely disadvantage them with their colleagues and competitors. Ethics education, therefore, regardless of how extensive and practically-oriented, is of limited value in shaping individuals' behaviour, due to the significant influence of circumstantial factors, bureaucratic constraints and institutional cultures.

An adequate practical-ethics response to the challenges posed by dual-use research therefore requires a twofold approach. Firstly, there is a need to build sustainable capacity in the area of dual-use bioethics, promoting a culture of responsibility and self-regulation among life scientists – a norm of biosecurity-aware practice at grassroots level. Secondly, as science is an enterprise involving numerous actors and stakeholders, national commitments to the development of policies and mechanisms in line with national implementation of the BWC is a vital step for building an effective ‘web of prevention’. This holistic approach not only enables scientists to contribute their expertise to the security of their research, but also engages other stakeholders such as institutional boards, funding bodies and professional associations (Dando and Whitby 2011, p. 5).

A central component of this two-fold approach is the introduction of programmes for the continuing professional development (CPD) of life scientists in dual-use bioethics. The rationale behind this derives from evidence such as that presented above. It is naïve to assume that once trained in dual-use bioethics, life scientists will be able to deal with virtually any challenge they encounter in their everyday work. As noted by one professional association:

... ethics is not a vaccine that can be administered in one dose and have long-lasting effects no matter how often, or in what conditions, the subject is exposed the disease agent. Teaching individual students and postdoctoral fellows good professional practices cannot be highly and widely efficacious until academic culture and society also model and reward ethical behaviour. (NAE 2008, p. 36)

Programmes in dual-use bioethics should be updated annually in order to accommodate the latest policy developments and scientific advances. What we propose is a short one- or two-day intensive course comprising four main parts providing updates on: instances of scientific misconduct; the evolving dual-use discourse and latest academic contributions; negotiations within the BWC; and international and national regulations in the area of science and technology. Such a course will be primarily informative, expanding the knowledge of life science practitioners in the field of dual-use biosecurity and giving them insights into how they can play an active role in the ‘web of prevention’. Attendance itself should increase scientists’ capacity to think critically and make ethical decisions, as well as encouraging them to reflect upon how the biosecurity risks of their work can be mitigated. A specific emphasis should be laid on the development of appropriate modes of assessment for determining the annual progress of researchers in CPD. One of the main expected outcomes of the proposed CPD course therefore will be increased ‘ethical mindfulness’ among science practitioners characterized by a number of key features, including an increased ability to recognize ethical dilemmas in their own and in others’ work, being sensitized to and engaged with the ethically important moments that arise in everyday work; being reflexive and able to articulate what is ethically at stake in a given situation; and being courageous, in the sense of opening one’s beliefs and practice to critique (Guillemin *et al.* 2009, p. 199, Sture 2010a, 2010b).

To conclude, we propose that changing the cultural norms of scientific research by promoting applied ethical practice among life scientists will support them in a more cautious and engaged approach to public fears and concerns. An example of such behaviour is the decision by David Edwards to acknowledge the dual-use potential of a new type of inhalation aerosol that his team devised in 1997 (Edwards *et al.* 1997). While the discovery promised tremendous advantages as an effective drug delivery method in the treatment of severe pulmonary diseases, its characteristics in penetrating deeply into the lungs potentially rendered it as a useful means of spreading pathogens or highly toxic substances among human populations. Following the ‘anthrax letters’ attack in October 2001 in which aerosolized anthrax resulted in the deaths of five out of the 22 infected victims, Edwards

(2002, p. 4) revisited his scientific achievement and published another article, giving insights into what could be done to manage biosecurity risks:

Countering efforts to achieve terrorist ends through inhaled pathogens might therefore be thought of, in a sense, as the reverse engineering of an effective drug delivery system. Lessons learned and drawn from the development of inhaled drug delivery systems then prove useful to increasing our understanding as to what might hamper attempts to deliver pathogens through inhalation in future.

David Edwards's example illustrates the invaluable contribution that scientists can make to the development of policies and mechanisms aimed at preventing the malevolent misuse of life sciences while highlighting the benefits that scientific research brings to public welfare. Dual-use bioethics education coupled with appropriate CPD training programmes can tremendously empower science practitioners, equipping them with practical skills and knowledge and enabling them to actively participate in the national implementation of the BWC, which in turn will be a significant step toward fostering a culture of responsible conduct of life science research.

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