

TAKING DUE CARE: MORAL OBLIGATIONS IN DUAL USE RESEARCH

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ABSTRACT

In the past decade, the perception of a bioterrorist threat has increased and created a demand on life scientists to consider the potential security implications of dual use research. This article examines a selection of proposed moral obligations for life scientists that have emerged to meet these concerns and the extent to which they can be considered reasonable. It also describes the underlying reasons for the concerns, how they are managed, and their implications for scientific values.

Five criteria for what constitutes preventable harm are suggested and a number of proposed obligations for life scientists are considered against these criteria, namely, the obligations to prevent bioterrorism; to engage in response activities; to consider negative implications of research; not to publish or share sensitive information; to oversee and limit access to dangerous material; and to report activities of concern.

Although bioterrorism might be perceived as an imminent threat, the analysis illustrates that this is beyond the responsibility of life scientists either to prevent or to respond to. Among the more reasonable obligations are duties to consider potential negative implications of one's research, protect access to sensitive material, technology and knowledge, and report activities of concern. Responsibility, therefore, includes obligations concerned with preventing foreseeable and highly probable harm. A central conclusion is that several of the proposed obligations are reasonable, although not unconditionally.

INTRODUCTION

The perception of a bioterrorist threat has increased in the past decade and created a demand on life scientists to consider the potential security implications of dual use research. Traditionally the term 'dual use' refers to technologies that can have both civil and military applications. However, the term has multiple

dimensions.¹ In this article we focus mainly on those that involve equipment and biological material that could be misused for biological weapons purposes and the generation or dissemination of scientific knowledge that could be misapplied for such purposes.

¹ R.M. Atlas & M.R. Dando. The Dual-use Dilemma for the Life Sciences: Perspectives, Conundrums, and Global Solutions. *Biosecurity & Bioterror* 2006; 4: 276–286: 276.

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Within both the scientific and policy communities, dual use concerns have led to attempts to formulate ethical codes or guidelines for life scientists, on professional and policy levels.² Proposed guidelines and codes reinforce that life scientists have certain obligations to engage with the security sector in preventing the use of disease as a weapon.³ These obligations highlight a tension between, on the one hand, a public desire to control dual use research of concern and, on the other, the principle of research freedom.⁴

Development and practical implementation of codes of conduct are central in the current policy and scientific debate on how to prevent life sciences from being misused for hostile purposes. However, the bioethical reasoning behind the obligations proposed in the codes has not been thoroughly investigated. The purpose of this article is therefore to identify ethical dilemmas that might occur in dual use research and to analyse proposed moral obligations for life scientists. To this end, five criteria for what constitutes preventable harm are suggested. Thereafter, obligations for life scientists are considered against these criteria to determine their reasonableness. The analysis suggests what responsibility life scientists have in preventing misuses of science for biological weapon purposes.

BACKGROUND – THE BIOTERRORIST THREAT

In recent years concern has been expressed over a perceived growing bioterrorist threat. In 2004 a report by the US National Intelligence Council claimed:

² According to Brian Rappert, professional codes can be classified according to aim. Often, codes of ethics are aspiring, codes of conduct advisory or educational, and codes of practice are enforceable. Available at: <http://www.projects.ex.ac.uk/codesofconduct/Examples/index.htm> [Accessed 27 Apr 2008]. Examples of practical guidelines can be found at the US National Science Advisory Board for Biosecurity (NSABB), which lists research areas of concern. The Royal Netherlands Academy of Arts and Sciences (KNAW) recently published a code of conduct for biosecurity requesting practical implementation of the code. Several other professional organizations have formulated codes of ethics and conduct such as the World Medical Association (WMA) and the InterAcademy Panel (IAP).

³ See for example, M.A. Somerville & M.R. Atlas. Ethics: A Weapon to Counter Bioterrorism. *Science* 2005; 307: 1881–1882; D.B. Resnik & A.E. Shamoo. Bioterrorism and the Responsible Conduct of Biomedical Research. *Drug Dev Res* 2005; 63: 121–133; D. Cressey. Not so Secure After All – How Safe are Our Microbiology Labs? *Nature* 2007; 448: 732–733.

⁴ This is acknowledged as the first general principle in the European Charter for Researchers. Commission of the European Communities. 2005. *Commission Recommendation on the European Charter for Researchers and a Code of Conduct for the Recruitment of Researchers*. Brussels: Commission: 11. Available at: http://ec.europa.eu/eracareers/pdf/am509774CEE_EN_E4.pdf [Accessed 8 May 2008].

The most worrisome trend has been an intensified search by some terrorist groups to obtain weapons of mass destruction. Our greatest concern is that these groups might acquire biological agents [. . .] Terrorist use of biological agents is therefore likely, and the range of options will grow.⁵

In the summer of 2007 the European Commission issued a Green Paper stating: ‘Europeans regard terrorism as one of the key challenges [to] the European Union [. . .] Terrorists may resort to non-conventional means such as biological weapons or materials’.⁶

Recent terrorist⁷ attacks around the world have contributed to a heightened perceived threat from international terrorism, including bioterrorism.⁸ Concern has been expressed that the rapid advancements within the life sciences will enable the development of novel pathogens and more effective or easily accessible dissemination methods and techniques. Similar concern applies to potential misuses of neurosciences for military application to enhance soldier performance and to develop new generations of weapons.⁹

Assessments of the probability and magnitude of an attack with biological weapons have been widely debated and some have argued the threat to be greatly exaggerated.¹⁰ Due to the scarce availability of historical cases, records provide limited guidance on how to predict or

⁵ National Intelligence Council (NIC). 2004. *Mapping the Global Future – Report of the National Intelligence Council’s 2010 Project*. Washington, DC: NIC: 95. Available at: http://www.biossecurityboard.gov/Framework%20for%20transmittal%200807_Sept07.pdf [Accessed 23 Oct 2007]. See also National Intelligence Council website. Available at: http://www.dni.gov/nic/NIC_home.html [Accessed 6 Dec 2007].

⁶ Commission of the European Communities. 2007. *Green Paper on Biopreparedness*. Brussels: Commission: 2. Available at: http://eur-lex.europa.eu/LexUriServ/site/en/com/2007/com2007_0399en01.pdf [Accessed 27 Nov 2007].

⁷ It is beyond the scope of this article to present a definition of the multifaceted concept of terrorism. Bioterrorism can be defined as ‘[t]he intentional release of biological agents or toxins for the purpose of harming and killing humans, animals and plants with the intent to intimidate or coerce a government or civilian population to further political or social objectives’. Interpol. 2007. *Bioterrorism Incident Pre-Planning & Response Guide*. Lyon: ICPO-Interpol: 7. Available at: <http://www.interpol.int/Public/BioTerrorism/default.asp> [Accessed 16 Nov 2007].

⁸ F. Kuhlau. 2006. Disease Outbreaks: Managing Threats to Health and Security. In *Health and Conflict Prevention*. Anders Mellbourn, ed. Hedemora: Gidlunds förlag: 63–79.

⁹ M. Wheelis & M. Dando. Neurobiology: A Case Study of the Imminent Militarization of Biology. *International Review of the Red Cross* 2005; 87: 553–571.

¹⁰ M. Leitenberg. 2004. *The Problem of Biological Weapons*. Stockholm, Sweden: Swedish National Defence College; M. Leitenberg. 2007. Evolution of the Current Threat. In *Bioterrorism: Confronting a*

estimate the probability of such an attack.¹¹ This risk can therefore be considered statistically low. Nevertheless, the consequences in case of an attack may be severely disruptive or catastrophic in terms of human suffering and economic and political disruption. Analysis of the terrorist threat is equally difficult due to the elusive context in which new organizations unexpectedly emerge and strikes can come without warning. States' perceived vulnerabilities combined with limited understanding of the ramifications of an attack largely determine how threats are conceived.¹²

Uncertainty about the threat complicates the establishment of proportional measures to prevent biological warfare as well as how to understand the motivation for biomedical researchers to engage and acknowledge their role in the carrying out of preventive measures. Nevertheless, the perceived threat constitutes a primary driving force behind increasing demands for improved security consciousness among life scientists, and for collaboration between multiple relevant actors in society to identify and marginalize perceived vulnerabilities. This perceived threat is also a driving force behind demands for defences (in terms of improved preparedness and response) to an attack with biological material, which may encourage more research on the most dangerous pathogens.

The international and national focus on bioterrorism has led to efforts to prevent and protect dangerous biological agents, technologies and knowledge from reaching actors with harmful intents. Two important and interdependent preventive mechanisms are *biosafety* and *biosecurity*. Most researchers working in laboratories are familiar with required safety procedures such as protective clothing and safe handling of biological materials. This is to protect personnel from exposure to pathogens as well as to prevent accidental releases. These containment efforts are part of an international biosafety sys-

tem.¹³ The threat from deliberate releases has turned the focus also to biosecurity measures to prevent unauthorized access, loss or theft.¹⁴

The role of *bioethics* as a complementary approach to biosafety and biosecurity has relatively recently entered the health and security agendas.¹⁵ Bioethical issues are particularly discussed in terms of the development and implementation of codes to increase scientists' awareness and responsibility for potential misuses of their work. In 2005, state parties of the 1972 Biological and Toxin Weapons Convention (BTWC) discussed the content, promulgation and adoption of codes of conduct; a topic revisited in 2008.¹⁶ Also, in 2007, the EU Commission distributed a consultation paper on bio-preparedness among other things proposing mandatory courses for life scientists on dual use and research ethics at universities.¹⁷

The responsibility for life scientists not to contribute to the development and production of biological weapons, whether intentionally or unintentionally, has seemingly become a central part of the security debate. In 2005 discussions emerged due to the publication of the reconstruction of the 1918 Spanish influenza virus.¹⁸ From a security perspective, this information was considered a potential risk; would it be resurrected for harmful purposes, particularly with respect to the high contagiousness and mortality of the virus?¹⁹ Today's population moreover lacks immunity against the influenza that killed an estimated 50 million people.²⁰ From a scientific point of view, scientists and publicists were defending their

Complex Threat. A. Wenger & R. Wollenmann, eds. London: Lynne Rienner Publishers: 39–76; J. Tucker & A. Sands. *An Unlikely Threat*. *Bul At Sci* 1999; 55, 4: 46–52.

¹¹ The most cited cases of successful and attempted events include the Rajneesh using salmonella on food in Dalles, Oregon in 1984, the Japanese group Aum Shinrikyo, which unsuccessfully attempted to procure, produce, and disseminate anthrax and botulinum toxin in 1990–94, the unsuccessful efforts by al-Qaida to obtain anthrax and prepare a facility in which to do microbiological work in 1999 and 2001, and the successful distribution of high-quality dry powder anthrax spores in 2001. (Ibid. 2004: 22).

¹² J.P. Zanders. Assessing the Risk of Chemical and Biological Weapons Proliferation to Terrorists. *The Non-Proliferation Review* 1999; 6(4): 17–34.

¹³ See for example World Health Organization (WHO). 2004. *Laboratory Biosafety Manual (3rd edition)*. Geneva: WHO.

¹⁴ WHO. 2006. *Biorisk Management: Laboratory Biosecurity Guidance*. Geneva, Switzerland: WHO.

¹⁵ For example in 2006 the World Health Organization (WHO) published a report on bio-risk management and laboratory bio-security guidance where the assistance of bioethics as one of three strategic approaches to prevent bioterrorism is suggested. In 2008, the EU Council adopted an Joint Action which supports the WHO approach and requires the EU to promote bio-risk reduction practices through, among other things, bioethics.

¹⁶ The Biological and Toxin Weapons Convention (BTWC) 1972. Documents from the meetings in 2005 are available at: <http://www.opbw.org> [Accessed 27 Apr 2008]. Information about the meetings in 2008 are available at: [http://www.unog.ch/80256EE600585943/\(httpPages\)/F1CD974A1FDE4794C125731A0037D96D?](http://www.unog.ch/80256EE600585943/(httpPages)/F1CD974A1FDE4794C125731A0037D96D?OpenDocument) [Accessed 27 Apr 2008].

¹⁷ Commission of the European Communities, *op. cit.* note 6.

¹⁸ J.K. Taubenberger et al. Characterization of the 1918 Influenza Virus Polymerase Genes. *Nature* 2005; 437: 889–893.

¹⁹ J. van Aken. When Risk Outweighs Benefit: Dual-use Research Needs a Scientifically Sound Risk-Benefit Analysis and Legally Binding Biosecurity Measures. *EMBO rep* 2006; 7: 10–13.

²⁰ Some estimate the figure to be as high as 100 million. N.P. Johnson & J. Mueller. Updating the Accounts: Global Mortality of the 1918–1920 'Spanish' Influenza Pandemic. *Bull Hist Med* 2002; 76: 105–115.

right to publish. This example illustrates how fundamental scientific values are at stake, which urges the scientific community to engage in finding a balance between meeting public concerns about increased security risks and protecting the scientific freedom of intellectual inquiry and the right to publish.

EXTERNAL AND INTERNAL NORMS

Professional obligations with respect to (state military or terrorist) misuse of research findings have not been extensively developed within the life science community.²¹ The same holds for contemporary literature in biomedical research ethics where dual use security implications are relatively rarely discussed. Obligations emerging for life scientists are based on the ethical principle to prevent harm. Scientists therefore have a basic responsibility to consider potentially harmful implications of their work. To take due care implies that sufficient and appropriate care to avoid causing harm is taken, as the circumstances demand of a reasonable party.²² Appropriate care includes components of knowledge and diligence in circumstances demanding a certain standard of behaviour and failure to make the effort can be considered negligence.

In practice, it would be difficult to consider responsibility for potential misuses of science merely as an individual choice. The merits of a collective and professionally ascribed responsibility cannot be overlooked. Although it would be optimal if all life science researchers voluntarily assumed responsibility, it is crucial for them to be aware of the security issues that they are supposed to be responsible for. The ability and ambition to take responsibility will increase in correspondence with higher degrees of awareness and acceptance. A distinction can be made between internalized and externalized obligations. From a moral philosophical point of view, the more general obligations appear to have a stronger ethos. The obligation to 'do no harm' is a general ethical principle that frames our conduct while to 'screen manuscripts for security sensitive information' is a more specific and practical requirement. The first could be described as an 'internal' moral principle, to which most biomedical researchers would strive to adhere in general, while the latter is considered an obligation externally demanded which therefore spurs less moral incentive (although motivated and justified by the moral reasoning of the first principle). Specific obligations that

are not based on general moral judgements and have no clear 'internal' resonance might be difficult to implement.

Duties are binding in different ways and measures. In national or international legislations a breach of duty results in punishment, whereas in advisory codes and guidelines duties are a matter of responsible self-regulation, based on individual, voluntary norms and guidelines. Formulating obligations for biomedical researchers does not have to be embedded in the legal system (top down) but could take the shape of a system of ethical guidelines that develop from within the research community (bottom up). Top-down legislation runs the risk of hampering research and not being properly adhered to, particularly if decisions are made without proper consultation with the scientific community on what is practically (and ethically) feasible.

THE MORAL DUTY TO PREVENT HARM

A well established ethical principle within research ethics is the principle to prevent harm. However, the meaning of the concept 'harm' and consequently, what to prevent, is not always apparent. An important distinction can be made between *intentional* and *unintentional* harm. The connection between intentional (and direct) participation in developing and using biological weapons and harm is evident. This connection, however, is less obvious in the case of legitimate and peaceful research subjected to unintended misuse and its potential to cause harm. According to one definition of the principle of nonmaleficence, the obligation not to do harm covers not only intentional actions but also imposing *risks* of harm. Individuals can therefore harm or place another person at risk without harmful intent.²³

Additionally, even if harm is unintended, the component of *awareness* reinforces an indirect responsibility beyond the initial purpose of one's actions. To be aware is an active process where you reflect upon your work and its potential consequences. Being aware implies knowing about potential risks and acting accordingly, regardless if the research has nothing but well intended purposes. Awareness includes reflection on for example risks associated with biological material and the ease of which it can be shared. It also includes considering your role as a scientist in a national crisis or war situation and your relation to existing regulations. Lack of awareness of regulations may, for instance, have severe effects on the society and scientific trust due to increased public concern and fear. In 2005, Thomas Butler, a physician

²¹ S.K. Green et al. Guidelines to Prevent Malevolent Use of Biomedical Research. *Camb Q Health Ethics* 2006; 15: 432–439; 435.

²² T.L. Beauchamp & J.F. Childress. 2001. *Principles of Biomedical Ethics* (5th edition). Oxford: Oxford University Press.

²³ T.L. Beauchamp & J.F. Childress, *op. cit.* note 22.

and microbiologist was sentenced to prison for, among other things, illegally shipping bacteria. On one occasion specimens from more than 60 Tanzanian bubonic plague victims was transferred to the US in a way considered potentially dangerous and against regulations.²⁴ Regardless of intent, his professional role would prescribe him awareness of relevant regulations and potential dangers, which ascribes him responsibility. An intention can for this purpose be described as static, isolated and initial whereas awareness entails a continuous process of reviewing one's work in a wider context.

Distinctions of harm are important to avoid implying that scientists have an obligation to prevent *all* harm, intentional as well as unintentional. Neglecting these distinctions lead to the *reductio ad absurdum* result that researchers are unable to conduct any research whatsoever, because everything risks inflicting harm. Thus, criteria are needed for the obligation to prevent harm.

CRITERIA FOR THE OBLIGATION TO PREVENT HARM

Below we suggest five criteria for identifying 'harm' that may reasonably be within researchers' moral responsibility to prevent. The criteria are closely related and therefore somewhat overlapping. In order to take social responsibility and due care, life scientists should strive to prevent harm that is:

Within their professional responsibility

'Scientists have a special responsibility when it comes to problems of "dual use" and the misuse of science and technology'.²⁵ In what Nordgren calls 'social models',²⁶ social practices of blame and praise can be the ground for moral responsibility which in this sense is not separated from socially ascribed responsibility. This model holds individuals responsible for a state of affairs that they did not cause directly or even indirectly by an act or an act of omission because social practices of blame and praise are linked to social roles. Responsibility is determined by

²⁴ M. Enserink & D. Malakoff. Scientific Community: The Trials of Thomas Butler. *Science* 2003; 302: 2054–2063; M. Enserink. Thomas Butler Loses Appeal, Vows to Fight on. *Science* 2005; 310: 758.

²⁵ The Inter Academy Panel on International Issues (IAP). 2005. *IAP Statement on Biosecurity*. Trieste: IAP: 1. Available at: <http://www.royalsoc.ac.uk/displaypagedoc.asp?id=17463> [Accessed 23 Sep 2007].

²⁶ A. Nordgren. 2001. *Responsible Genetics: The Moral Responsibility of Geneticists for the Consequences of Human Genetics Research*. Dordrecht: Kluwer Academic Publishers: 4.

what the social role or position demands.²⁷ The life science research profession, according to this line of reasoning, has a collective responsibility for the potential harm caused by their research. More specific ethical practices could also be ascribed to different fields of expertise, depending on the type of research and the likelihood of it being misused.

Within their professional capacity and ability

Obligations to prevent harm need to be within an individual's professional and personal capacity to perform, which means that they need to be possible to enact. This possibility is determined by available abilities, which are facilitated by awareness raising, training and sufficient structural mechanisms at the work place. Increased ability gives individuals the capacity, for example, to call the attention of relevant authorities in cases of suspicious activities.

Reasonably foreseeable

Researchers should be responsible not only for not engaging in harmfully intended activities but also for research with harmful implications that they can reasonably foresee. This criterion overlaps with the criterion on capacity and the ability to recognize probable harm. It basically states that you are responsible for consequences that you have a reasonable possibility of foreseeing, while consequences that are far-fetched or surprising to the professional are less blameworthy. Such a criterion, however, might open up to claims of ignorance and thereby evasions of responsibility, which should be avoided. Here, 'reasonable' implies active engagement from scientists to seek knowledge and consider potential misuses of research. It can be argued that certain researchers are also responsible for preventing 'unforeseeable' harm in terms of their particular knowledge and insight into how their research might be misused. Special knowledge gives extraordinary capacity to anticipate and to be prepared to respond, in order to minimize harm, should biological weapons or material be used. In a basic sense, researchers know their work best and are therefore in the best position to anticipate the types of knowledge, products, or technologies that might be generated.²⁸ They

²⁷ Ibid.

²⁸ National Science Advisory Board for Biosecurity (NSABB). 2007. *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information*. Bethesda, MD: NSABB: 11. Available at: http://www.biosecurityboard.gov/Framework%20for%20transmittal%200807_Sept07.pdf [Accessed 26 Nov 2007].

can also sometimes give a reasonable estimation of the potential for misuse and the level of immediacy. This closeness to one's research may, on the other hand, be the very reason why a researcher is blinded to ethical implications associated with the work.

Proportionally greater than the benefits

This criterion is central in the dual use dilemma and concerns how risks and benefits from research are balanced. One important factor to consider is the context in which researchers are to analyse the benefits, risks and costs. To make an assessment requires an understanding of society and its processes as well as sensitivity towards the reliability of the interpretation of the same society. Bioterrorism is a phenomenon that has been hyped since the September 11 attacks. The 'evidence' of a growing threat is based on complex qualitative and quantitative assessments and the threat perception therefore varies greatly between states.

In a more narrow sense, researchers can be asked to assess, within reasonable limits, potential misuses of their work and weigh them against the benefits. This assessment would be based on the same reasoning as when medical treatments are selected; if the negative side effects (risks) are greater than the anticipated positive result (benefit), an obligation exists for researchers to prevent or abstain from such work.

Not more easily achieved by other means

This criterion states that there cannot be any special obligation concerning the dissemination of knowledge and materials if that knowledge or material is of less concern than, or equal concern to, similar knowledge and materials more readily available elsewhere. A greater responsibility falls upon the person first making public potentially dangerous knowledge; once the knowledge is disseminated, the moral question changes from 'should this information be made public?' to 'should I disseminate this further?' If doing so facilitates obtaining the information, researchers should take due care; if not, particular action is not needed. Of course, the mere availability of information need not *justify* its further diffusion. The same would be true for the potential misuse of naturally occurring biological material, where this line of reasoning clearly does not exempt researchers from responsibility for protecting themselves and others from any material escaping or being stolen from their workplace.

The obligation to take particular action presents itself when a life scientist rarefies a dangerous material or has

privileged access to potent information. There is a significant difference between naturally occurring anthrax and the powdered anthrax spores distributed in the US in 2001. Society is more vulnerable to biological material that has been manipulated (although not necessarily for weapon purposes).

ANALYSIS OF PROPOSED OBLIGATIONS

A fundamental legal obligation to prevent harm is stipulated in the BTWC, where states undertake never to develop, produce or stockpile biological materials that 'have no justification for prophylactic, protective or other peaceful purposes'.²⁹ Harm is prevented by individuals abstaining from engaging in or contributing to prohibited activities intended to facilitate biological warfare. Another legally binding obligation is the United Nations Security Council Resolution 1540. This resolution obliges states to establish domestic controls to prevent proliferation of nuclear, chemical and biological weapons and their delivery systems.³⁰ The requirement of adequate controls over biological weapons is also found in the BTWC, however, obligations stipulated in resolution 1540 go beyond this and include operative paragraphs on the national legislation of UN member states. Among other things, states must adopt and enforce effective domestic legislation to prevent proliferation of weapons, in particular for terrorist purposes, and to develop effective law enforcement. The resolution requires sanctions for those who violate the obligations.³¹

Engagement from the scientific community in security issues has generally been poor. This is, for instance, reflected in low levels of awareness about the BTWC prohibitions and the understanding of possible misuse of dual use research.³² However, engagement can be noted

²⁹ BTWC, *op. cit.* note 16.

³⁰ United Nations Security Council Resolution (UNSC) 1540. 2004. Available at: <http://daccessdds.un.org/doc/UNDOC/GEN/N04/328/43/PDF/N0432843.pdf?OpenElement> [Accessed 28 Apr 2008]. This resolution is adopted under Chapter VII of the United Nations Charter, meaning that it is legally binding and that a breach constitutes a threat to international peace and security. The resolution obliges states to refrain from supporting by any means non-state actors that attempt to develop, acquire, manufacture, possess, transport, transfer or use nuclear, chemical and biological weapons and their delivery systems. Adopting the resolution under Chapter VII sends a clear message that the risk of non-state actors developing these weapons is taken seriously.

³¹ *Ibid.* Paras. 2 & 3.

³² This lack of awareness has been revealed in studies among life scientists for example in the UK. See for example M. Dando & B. Rappert. Codes of Conduct for the Life Sciences: Some Insights from UK Academia. *Bradford Briefing Paper No. 16 (2nd Series)* 2005. Available at:

on a national level through the work of national academies and their participation in the BTWC meetings.³³

Apart from these legal requirements, more specific ethical obligations for life scientists have been proposed in different scientific and policy forum. To illustrate central bioethical and security dilemmas we will discuss some of these obligations in relation to our criteria for harm, namely; to prevent bioterrorism, to engage in response activities, to consider negative implications of research, not to publish or share sensitive information, to oversee and limit access to dangerous material and to report activities of concern.

The duty to prevent bioterrorism

One proposed duty is that scientists have an obligation to help prevent bioterrorism. 'Since all scientists have an obligation to prevent harm to society, and acts of terrorism can cause substantial harm to society, all scientists have an obligation to help prevent terrorism'.³⁴ Although few would agree with this obligation, scientists are often encouraged to engage in preventing *misuse* of life science research. This obligation therefore illustrates how the bioterrorism threat sometimes complicates and confuses the debate when attempts are being made to define scientific responsibility.

Scientists can help the overall prevention of bioterrorism through ethical research conduct and protecting dangerous biological material and information, thereby marginalizing access. However, they cannot be obliged actively to *prevent* the misuse of such material and information. Having said that, some scientists involved in discovering atomic energy, which gave birth to nuclear weapons, did consider the possibility that they were morally responsible in part for the harmful applications of their findings.³⁵ Misapplication of peacefully intended research may cause moral distress among scientists; however, it is difficult to argue that researchers should be held morally accountable for harm caused by unforeseen acts of misuse. It is equally difficult to argue that they are responsible for preventing these acts. It is therefore important that proposed obligations for scientists that include risk-assessments do not include elements of estimating probability and magnitude of misuse as this is

http://www.brad.ac.uk/acad/sbtwc/briefing/BP_16_2ndseries.pdf [Accessed 26 Nov 2007]; M. Dando & J. Revill. A Hippocratic-Style Oath in the Life Sciences Could Help Educate Researchers About the Dangers of Dual-Use Research. *EMBO Rep* 2006; 7: 55–60.

³³ See lists of participants attending the BTWC meetings. Available at: <http://www.opbw.org/>

³⁴ D.B. Resnik & A.E. Shamoo, *op. cit.* note 3, p. 125.

³⁵ S.K. Green et al. *op. cit.* note 21.

beyond a researcher's capacity to assess. Focus should be on how to conduct ethical research for the purpose of marginalizing unwanted consequences, rather than threats of misuse such as bioterrorism.

The point being made is that care must be taken with how this obligation is framed. Preventing misuse is a moral reason for why scientists should be engaged rather than an obligation in and of itself.

The duty to engage in response activities

Another proposal concerns a duty to advocate for research to respond to bioterrorism.³⁶ This obligation highlights both the dilemma associated with preparedness and response, in particular the growing area of biodefence research, and the importance of clarifying the distinction between obligations to *prevent* harm and obligations to *respond* to it. Responses to bioterrorism intend to limit ramifications of harm but do not aspire to prevent harm from occurring in the first place. Certain researchers may have particular responsibilities to prevent harm through preparedness and response activities, based on their special competence and knowledge, and they are therefore required to 'foresee' (or anticipate) such harm.

Requiring that researchers in general not only take due care to prevent and marginalize risks of unintended misuse of their research but also actively to engage in bioterrorism response research is, in our view, beyond the boundaries of reasonable moral duties. A number of ethical concerns make such an obligation questionable.

- (i) The obligation is too precise and asks all researchers to participate actively in a specific type of research to prevent generally unforeseeable harm (this can hardly be considered a moral obligation but at most an encouragement).
- (ii) The obligation may also have unwarranted dual effects in terms of rapidly increasing numbers of facilities and laboratories handling the most dangerous infectious disease agents³⁷ and consequently, of individuals with access to and specialized knowledge of these agents. This could lead to increased risks of proliferation of sensitive material, technology and knowledge as well as accidental releases and thefts.
- (iii) The biodefence facilities dedicated to bioterrorism preparedness and response measures encourage

³⁶ D.B. Resnik & A.E. Shamoo, *op. cit.* note 3.

³⁷ United States Government Accountability Office (GAO). 2007. *High-Containment Biosafety Laboratories: Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States*. Washington, DC: GAO.

secret research which decreases transparency and spurs distrust about the true purpose of these activities.³⁸ Lack of transparency also has effects on democracy due to limited public insight.

- (iv) Secret research without peer review could lead to a poorer research quality.
- (v) Both the fact that secret research exists and that it has quality concerns may result in lesser public trust in science.
- (vi) Increased funding of bioterrorism-related research may take resources away from other important research, e.g. promoting public health.³⁹

Some preparedness and response research is not secretive and will be undertaken and published without restrictions. Nevertheless, we also find the arguments compelling with respect to such research. The last objection (vi) is recognized by Resnik and Shamoo who nevertheless argue that the potential variety of adverse social and economic effects of bioterrorism on society are much greater, although they may pose less of a public health threat, and so outweighs other arguments.⁴⁰ This implies that they argue that some harm may be acceptable in order to limit a greater harm caused by a bioterrorist attack. This utilitarian approach states that if harm is ultimately prevented, means to further that goal are justifiable. But should bioterrorism really be considered such harm that it outweighs all other potential harms? And even if one agrees, is it reasonable to request life scientists to perform these risk-assessments? In our view, the social and economic effects of bioterrorism on society are beyond the responsibility and capacity of life scientists to judge but rather a task for other authorities in society. Also, this judgement is complicated by the many remaining uncertainties and insufficient evidence to support a real bioterrorist threat. In this case it is particularly difficult to argue for a moral obligation to engage in research permeated with so many ethical dilemmas.

The duty to consider negative implications of research

One obligation expressed by the World Medical Association (WMA) on biological weapons states that 'all who participate in biomedical research have a moral and

³⁸ I. Hunger. 2007. More Transparency for a Secure Biodefense. In *Bioterrorism: Confronting a Complex Threat*. A. Wenger & R. Wollmann, eds. London: Lynne Rienner Publishers: 179–196.

³⁹ H.W. Cohen, et al. The Pitfalls of Bioterrorism Preparedness: the Anthrax and Smallpox Experiences. *Am J Public Health* 2004; 94: 1667–1671.

⁴⁰ D.B Resnik & A.E. Shamoo, *op. cit.* note 3.

ethical obligation to consider the implications of possible malicious use of their findings.⁴¹ Similarly, the IAP issued a statement in 2005 asking scientists to foresee and prevent the harmful consequences of their research.⁴² This is a reasonable duty that arguably applies to all criteria suggested above as well as to ethical research conduct in general. The duty also applies to funding bodies. Their role in deciding which research to finance also gives them the responsibility to deny funding should they suspect potential dangerous consequences. In particular the obligation asks researchers to assess potential risks of harm, which does fall under their professional remit. It is important, however, that capacity should be developed through clearly defined procedures for risk assessments, including guidelines on how to analyse risks and benefits. Implementation may be difficult and would require careful consideration in order to avoid instilling unnecessary fear, which could result in extensive risk averse behaviour that might hamper research.

Many obstacles remain with respect to clarifying what is foreseeable and how to foresee potential misuses. There have been attempts to identify classes of research of particular concern. In the high-risk category are, for example, micro-organisms that are modified to enhance pathogenic properties and resistance of agents to current therapeutics.⁴³ These discoveries aim to enhance public health and combat infectious diseases. It is feared, however, that the same research could be misused for biological weapons purposes. The duty to consider the potential negative implications of research, according to this reasoning, must be balanced by the criterion of preventing harm that is not more easily achieved by other means.

The duty not to publish or share sensitive information

This obligation states that life scientists must seek to restrict dissemination of dual-use information and knowledge to those who need to know, in cases where there are reasonable grounds to believe that the information or knowledge could be readily misused through bioterrorism or biowarfare.⁴⁴ However, we need to recognize such values as publishers' freedom of press and scientists' legal

⁴¹ World Medical Association (WMA). 2002. *The WMA Declaration of Washington Biological Weapons*. (Initiated in 2001 and adopted in 2002 by the General Assembly). Washington: WMA. Available at: <http://www.wma.net/e/policy/b1.htm> [Accessed 15 Oct 2007].

⁴² IAP, *op. cit.* note 25.

⁴³ K. Nixdorff & W. Bender. Ethics of University Research, Biotechnology and Potential Military Spin-Off. *Minerva* 2002; 40, 1: 15–35; NSABB, *op. cit.* note 28.

⁴⁴ M.A. Somerville & M.R. Atlas, *op. cit.* note 3.

right to publish. It is therefore controversial to propose an obligation inflicting too many restrictions. Restrictions on publications have several implications, for example for scientists' need to be able to replicate results in order to conduct further research, build upon the results of others, and develop and maintain a scientific record and reputation. On the other hand, there are concerns that certain sensitive research findings run the risk of causing harm should they be publicly available. How to proceed in this area is therefore frequently debated.⁴⁵

This duty also raises important issues concerning who is responsible and for what. Who determines who needs to know? Another issue concerns the grounds for believing that the information could be readily misused. Sufficient mechanisms are needed to determine what constitutes reasonable grounds and what could easily be misused. This would be extremely difficult for scientists and publishers to judge, which points to a need for assistance in assessments. The criterion for professional responsibility, however, would be fulfilled based on the responsibility of the scientist, publisher or editor for their conduct and for what is published. Some systems already exist that advise on the detection and management of suspected misconduct among scientists and publishers.⁴⁶ It is therefore feasible to enlarge these systems to include suspected misconduct with respect to dual-use research, to be considered by both scientists and publishers. Journal editors and authors in 2003 formulated a statement acknowledging that they would consider how to review effectively, and, on occasion, modify or reject articles when they concluded that potential harm outweighed potential societal benefits.⁴⁷ We believe this to be an important step. Further clarification is required, however, as to where to draw the line, who judges, and by which measures.

One controversial example is the publication of a study involving the mousepox virus.⁴⁸ On the beneficial side, the study advances our understanding of the immune response; however, it also evoked the spectre of genetic engineering of a strain of the eradicated smallpox virus,

which makes this information highly sensitive.⁴⁹ The criterion for proportionality and weighing risks and benefits is central to the obligation to share information responsibly and requires, of both scientists and publishers, great competence in making reasonable judgements. Another important aspect is public concern. Although risks are deemed lower than the benefits, if public concern exists this needs to be taken into consideration and somehow met. A final applicable criterion is to prevent harm not more easily achieved by other means, where information already publicly available should be considered of less concern. Critics claim that the amount of existing dangerous biological information already in the public domain is enough to cause devastation, which would render censorship pointless.⁵⁰ Even if this is true, however, the criterion should not be considered a waiver for publishing sensitive information or used to justify reluctance to acknowledge present and future concerns.

In general, all the suggested criteria can be met and the obligation is therefore potentially reasonable, although phrased too much in the negative. The conditions under which the duty is practically feasible are far from simple to fulfil and, as they stand, run the risk of leading to an altogether too restrictive policy. This duty can perhaps better be formulated as a duty to *consider* whether to refrain from publishing or sharing sensitive information when the information is of such a character that it could invite misuse. The balancing act that the researcher has to think through *together* with editors (and possibly institutional security boards or the like) is a difficult one; what is important is that these scientific values are considered and that outside forces are not given the mandate to restrict publication – except in very clear and grave circumstances, where the right to life must take precedence over the freedom of research. We therefore advocate self-governance as a primary instrument regarding publication issues while also acknowledging the right of governments to restrict various freedoms and rights in cases where national security or the lives of its citizens truly are at stake.⁵¹

The duty to oversee and limit access to dangerous material

'Life scientists must seek to allow access to biological agents that could be used for biological weapon purposes

⁴⁵ See for example a proposal currently discussed within the European Union. D. Cressey. Europe Ponders Restrictions on Life Sciences – Plan for Two-Tier Publications Gets Cool Reception. *Nature* 2007; 449: 646–647.

⁴⁶ Committee on Publication Ethics (COPE) official website. Available at <http://www.publicationethics.org.uk/cases> [Accessed 15 Nov 2007].

⁴⁷ Journal Editors and Authors Group. Statement on the Consideration of Biodefence and Biosecurity. *Nature* 2003; 421.

⁴⁸ R.J. Jackson, et al. Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox. *J Virol* 2001; 75: 1205–1210.

⁴⁹ R.M. Atlas. National Security and the Biological Research Community. *Science* 2002; 298: 753–754.

⁵⁰ S. Miller & M.J. Selgelid. Ethical and Philosophical Consideration of the Dual-use Dilemma in the Biological Sciences. *Sci Eng Ethics* 2007; 13: 523–580.

⁵¹ *Ibid.*

only to individuals for whom there are reasonable grounds to believe that they will not misuse them.⁵² Some national legal obligations already exist in the US; those for example that require research institutions to make accounts and inventories of select agents, check the background of individuals seeking to possess, use, and transfer these agents, and maintain registers to keep track of people with access.⁵³ The question is whether researchers can be responsible for deciding what constitutes 'reasonable grounds' for mistrust or whether this will lead in effect to a default situation where individuals looking for access have to prove their innocence against a general and all-pervading distrust. Such a situation would go strongly against the ethos of science as a pluralistic and communalistic endeavour, built on trust and co-operation. In our view, always evaluating recipients' liability and potential harmful intentions to misuse material before sharing it *cannot* be performed by individual researchers and *should not* be promoted as a tool for assuming scientific responsibility. The duty above is therefore only realistic when accompanied by available expertise and information to assist researchers in making a reasonable analysis, and if rewritten as a duty not to share sensitive material with individuals or organizations where reasonable grounds exist to suspect that sharing might lead to harm. This modification of the duty would not deprive the researcher of a responsibility to assist in preventing access to the materials that terrorists or armies could use to further their means. The ability to fulfil this obligation, however, depends equally on the availability of external resources providing security information and advice, as well as initiatives by researchers to make use of these resources.

This obligation is reasonable in its modified form. Not to share biological material unconditionally with individuals or organizations where harm can be foreseen is within one's professional responsibility and capacity, provided sufficient expertise and information are made available. It also poses similar difficulties to the previous duty on how to determine risks and benefits, which requires an understanding of which biological material causes the most extensive harm, should it be misused. It is a question of assessing the danger of biological material and hence also meets the criteria for preventing harm that is not more easily achieved by other means.

⁵² M.A. Somerville & R.M. Atlas, *op. cit.* note 3, p. 1882.

⁵³ One Hundred Seventh Congress of the United States of America. 2002. Public Health Security and Bioterrorism Preparedness and Response Act. H.R. 3448: 44–52. For more information on US biosecurity measures see for example J.E. Fischer. 2006. *Stewardship or Censorship: Balancing Biosecurity, the Public's Health, and the Benefits of Scientific Openness*. Washington, DC: The Henry L. Stimson Center.

The duty to report activities of concern

The American Society for Microbiology (AMS) requires its members to 'call to the attention of the public or the appropriate authorities misuses of microbiology [. . .]'.⁵⁴ An equivalent obligation exists widely in scientific research communities with respect to reporting research misconduct such as fabrication, plagiarism, and violations of other ethical (or regulated) conduct.

As the moral duty to raise concerns about misconduct is already integrated in the scientific community, the moral duty to prevent harm through reporting suspected misconduct should be fairly easy to argue for. Its existence, however, does not necessarily reflect the actual implementation. Individuals are generally not comfortable with 'telling' on colleagues regardless of existing duties to report suspicions of cheating. Therefore, although misconduct is witnessed, the obligation to report the observation *de facto* is not universally accepted by everyone. Those whose conscience prompts them to act will act and others will not. The obligation may be considered to demand moral heroism in one sense and treachery in another.

There is an ethical ambivalence about techniques such as whistle-blowing including concerns of self-preservation due to the risk of being treated as a traitor.⁵⁵ Even if the duty to report is only part of a solution to general misconduct it may nevertheless have greater effect if implemented in dual-use research. Pending the seriousness of misconduct implications, concerns regarding potential misuses of science could lead the obligation to be taken more seriously. Not to mention the fact that reporting misconduct that constitutes a potential or actual criminal offence (breaches of national and international law concerning dual use material) is a civil duty.

This obligation fulfils the criteria we have suggested, including the prevention of harm within one's responsibility and capacity. For this obligation to be effective, however, awareness needs to be raised about the dual use issue in general and existing prohibitions in particular. Capacity also needs to be built to enable the identification of violations as well as the ability effectively to report concerns to appropriate authorities.

⁵⁴ American Society for Microbiology (AMS). 2005. *Code of Ethics*: 2. Available at: <http://www.asm.org/ASM/files/ccLibraryFiles/FILENAME/000000001596/ASMCodeofEthics05.pdf> [Accessed 27 Nov 2007]. See also M.A. Somerville & R.M. Atlas, *op. cit.* note 3, p. 1882.

⁵⁵ B.E. Rollin. 2006. *Science and Ethics*. New York: Cambridge University Press: 268–270.

CONCLUSION

Ethical dilemmas permeate the debate on life scientists' responsibilities in dual use research. This article has described some elements behind the call for enhanced responsibility in research as well as some of the scientific values at stake.

The five criteria for preventable harm help us to demarcate and better understand what constitutes reasonable obligations for life scientists in preventing misuses of science. These criteria are also essential in stimulating awareness and periodic reflection upon one's role and social responsibility as a scientist. Duties considered in isolation run the risk of becoming static and simplified, which complicate their acceptance.

A number of proposed obligations have been analysed against the criteria. We found that although bioterrorism is perceived by many as an imminent threat, it is not a reasonable obligation for life scientists either to prevent or respond to it. Among the more feasible obligations are duties to consider the potential negative implications of one's research, to protect access to sensitive material, technology and knowledge and to report activities of concern. Responsibility, therefore, does not involve preventing the *act* of misuse but rather involves obligations concerned with preventing foreseeable and highly probable harm.

One main conclusion from the analysis is that many proposed obligations are reasonable, although not unconditionally. This is a reflection of inherent ethical dilemmas and does *not* imply that obligations in this area are useless or unfounded. It is by acknowledging these conditions that creative solutions can be found to how to make progress while keeping the balance of various concerns and values. This would assist the formulation of reasonable obligations and facilitate the implementation of effective codes enabling scientists to take appropriate due care.

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